No. T-2030-13

FEDERAL COURT

BETWEEN:

NEIL ALLARD
TANYA BEAMISH
DAVID HEBERT
SHAWN DAVEY

PLAINTIFFS

AND:

HER MAJESTY THE QUEEN
IN RIGHT OF CANADA

DEFENDANT

AFFIDAVIT OF JEANNINE RITCHOT

I, Jeannine Ritchot, of the City of Ottawa, in the Province of Ontario, MAKE OATH AND SAY:

1. I am an employee of the Public Health Agency of Canada, currently working as the Senior Director of the Surveillance and Analysis Division in the Centre for Chronic Disease Prevention. At the time relevant to this affidavit, however, I was working as the Director, Medical Marihuana Regulatory Reform (2011-2013) and as Director, Bureau of Medical Cannabis (2010-2011), Office of Controlled Substances, Controlled Substances and Tobacco Directorate (CSTD), Health Canada. The CSTD is part of the Healthy Environments and Consumer Safety (HECS) Branch of Health Canada. Prior to this

position, I was Executive Advisor to the Deputy Secretary to Cabinet (Operations) at the Privy Council Office.

2. As Director of the Bureau of Medical Cannabis, my responsibilities included oversight activities related to the administration of the *Marihuana Medical Access Regulations* (MMAR). This included oversight of employees, resources and operational activities related to operations carried out pursuant to the MMAR.

3. As Director of Medical Marihuana Regulatory Reform, my responsibilities included policy development related to the reform of the MMAR and development of the *Marihuana for Medical Purposes Regulations* (MMPR). As such I am able to speak to the relevant facts set out herein. Where any of the following information is based on information and belief, I state the source of the information and that I believe the information to be true.

DRUGS IN CANADA: THE LEGISLATIVE AND REGULATORY FRAMEWORK

4. In Canada, medicines are regulated through the *Food and Drugs Act* (FDA) and the *Controlled Drugs and Substances Act* (CDSA). The FDA and its regulations provide a framework to regulate the safety, efficacy, and quality of drugs. The *Food and Drug Regulations* (FDR) set out a framework for the authorization of drugs for sale in Canada. Drug manufacturers submit evidence on the efficacy, dosage, route of administration, contraindications, side effects, and quality of a drug. Health Canada drug reviewers must conclude that the overall benefits of the drug outweighs its risks, before the product is authorized for sale in Canada.

5. The overall objective of the FDA is to protect the health and safety of Canadians by regulating drugs, medical devices, foods and cosmetics through a series of prohibitions and requirements, including establishing standards for manufacturing, labelling, licensing and advertising. Current regulations ensure that drugs will not be approved for sale in Canada if they are found to cause more harm than good or if their risk benefit ratio is not adequately known. The FDA establishes rigorous processes to ensure that drugs made available for

therapeutic use meet appropriate safety, efficacy and quality standards. The FDA contains offences and penalties for contraventions of any provisions of the FDA or FDR.

6. The overall objectives of the CDSA are the maintenance and promotion of public health and public safety. The CDSA provides the legislative framework for the control of substances that can alter mental processes and that, though they may have therapeutic benefits, also may produce harm to health and to society when diverted or misused. These controls include regulation of the prescription of, the production of, the storage of and records and reporting in relation to, controlled substances.

7. The CDSA imposes strict controls on access to substances that are liable to misuse and or diversion by prohibiting possession, production, and distribution of controlled substances, except as authorized by regulations. The CDSA also contains offences and penalties for possession, trafficking and production of scheduled drugs.

8. The CDSA is the means by which Canada fulfills its international obligations under the three UN international drug control conventions: the Single Convention on Narcotic Drugs, 1961 (as amended by the 1972 Protocol); the Convention on Psychotropic Substances, 1971; and, the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (the "Conventions").

9. The FDA and the CDSA and their respective regulations are important pillars of the legislative and regulatory framework that serves to protect the health and safety of Canadians by preventing misuses of drugs, both recreationally and therapeutically. Their objectives are interrelated and consistent. Together they are intended to support both the maintenance and promotion of public health and the safety of Canadians.

10. Both the CDSA and the FDA and the relevant regulations apply to marihuana. Marihuana is considered a drug under the FDA and a controlled substance under the CDSA. Health Canada is the federal government department with lead responsibility for the FDA and the CDSA as well as their respective regulations.

11. Drugs containing cannabis, other than dried marihuana, have been authorized for sale under the FDR and are available by prescription in Canada. These include:

i) Sativex®, a buccal spray containing extracts of cannabis with standardized concentrations of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). It is authorized to treat certain symptoms associated with multiple sclerosis. It is also conditionally authorized for pain relief in adults with advanced cancer; and,

ii) Cesamet®, a capsule containing nabilone, a synthetic cannabinoid. It is authorized for the management of nausea and vomiting associated with cancer therapy.

12. To sell these products in Canada, their manufacturers were required to meet the rigorous FDA and FDR requirements. Accordingly, these products are of consistent content and chemical composition, they have been manufactured using good manufacturing processes, and there is adverse event reporting and recall capacity should these drugs have unexpected negative impacts. There are also prohibitions on the labelling, packaging or selling of drugs or food in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its character, value, merit or safety.

13. Science-based drug regulatory processes are safeguards. Current regulations ensure that drugs will not be released if the product cannot demonstrate three fundamental characteristics. First, they must have a benefit as demonstrated in clinical studies in diseased patients. Second, the drug's safety issues also demonstrated through the clinical studies can be mitigated through labelling and appropriate access for patients through a prescription if needed. Third, the drugs are manufactured under a Good Manufacturing Practices to ensure a consistent product is sold year to year. The regulatory processes also allow regulators to remove drugs from the market should new information on unacceptable safety concerns be identified. In these ways, regulatory oversight increases the probability that drugs on the market will be safe, efficacious and of the highest quality when used as recommended.

14. There has been no application to Health Canada to approve dried marihuana as a drug for sale under the FDA. Dried marihuana has never been approved as a therapeutic drug in Canada. Marihuana (Marijuana) is the common name for *Cannabis sativa* (i.e. cannabis). Information about Cannabis is available in the publication "Information for Health Care Professionals" attached as **Exhibit "A"** (see page 8), and is also available online at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf

15. One of the aims of MMPR is to treat medical marijuana like any other drug, to the extent possible. HC plays a role in licensing manufacturers of drugs to reduce the risk of consumers receiving a drug which is poorly manufactured or adulterated. The MMPR intend to provide the same type of system to producers of marijuana, in order to protect consumers from adulterated or unsafe products.

DEVELOPMENT OF THE MARIHUANA FOR MEDICAL PURPOSES REGIME

16. Under Health Canada's Marihuana Medical Access Program (MMAP), Canadians have been able to access dried marihuana for medical purposes since 1999, at which time individuals could be authorized to possess dried marihuana or to produce a limited number of marihuana plants for medical purposes via s.56 of the CDSA. Section 56 allows the Minister to exempt any person or class of persons from the application of the CDSA or its regulations if necessary for a medical or scientific purpose or if it is otherwise in the public interest.

17. The Ontario Court of Appeal's July 31, 2000 decision in *R. v. Parker* changed that approach. In response to that decision, the Government promulgated the MMAR in 2001. The MMAR were created to provide access to dried marihuana for medical purposes in a more regulated environment, rather than via a discretionary decision to exempt an individual or class of persons from the application of the CDSA under s. 56.

18. When they were promulgated, the MMAR offered two supply options: an authorized individual could produce dried marihuana for personal use or an authorized individual could designate another person to produce it for them.

19. Over the years, the Regulations have been amended on numerous occasions. The complete regulatory history of the MMAR is appended to this my affidavit at **Exhibit "B"**, with the explanatory Regulatory Impact Assessment Statements that accompanied each set of amended regulations.

EXPANSION OF THE MARIHUANA MEDICAL ACCESS PROGRAM UNDER THE MMAR

20. From their inception in 2001, the MMAR attempted to achieve three goals:

a) to strike a balance between providing legal access to dried marihuana for medical purposes, while controlling access to a controlled substance and unapproved drug with limited available benefit and risk information;

b) to respect existing federal legislation, including the FDA and CDSA, as well as Canada's international obligations under the United Nations Drug Conventions; and,

c) to protect the individual and public health, safety, and security of all Canadians.

21. As is explained in more detail in the next section of my affidavit, these goals have been seriously compromised by the rapid expansion of the number of individuals authorized to possess and produce medical marihuana. What was originally intended to provide legal access to dried marihuana for a relatively small number of seriously ill Canadians has grown exponentially since the 2001 promulgation of the MMAR, leading to unintended consequences with respect to the administration of the MMAR, as well as to the public health, safety and security of Canadians.

22. In 2002, 477 individuals were authorized to possess marihuana for medical purposes. As of April 16, 2013, this had grown to 29, 888 individuals and I am advised by Angela Rea, Senior Policy Analyst at Health Canada, and believe that by January 8, 2014 this number had increased to 37,884. At this rate of growth, it was estimated that by the end of 2014, over 50, 000 individuals will be authorized to possess marihuana for medical purposes.

23. Of the 37,884 Program participants on January 8, 2014, I am advised by Angela Rea and believe that approximately 22% indicate they will access Health Canada's supply of dried marihuana, 66% produce their own marihuana for medical purposes under a personal use production license, and 12% designate another person to produce their marihuana for medical purposes. Many of the authorized users who indicate in their applications to Health Canada that they will buy from Health Canada, ultimately do not. Health Canada does not have access to information regarding where these authorized individuals obtain their supply of marihuana for medical purposes.

24. The charts below illustrate the escalation in participation under the Marihuana Medical Access Regulations over the years.

Chart 1: Number of Authorizations to Possess (ATP's) Issued Under the MMAR

Year	Number of ATP issued for new and renewal applications under the MMAR
2001	88
2002	453
2003	621
2004	740
2005	1,234
2005	1,674
2007	2,405
2008	3,311
2009	4,876
2010	7,858

2011	12, 829
2012	27,788
2013 up to December 11	36,797

Note these numbers do not include ATPs issued to accommodate amendments such as changes to address, dosage etc.

25. I am informed by Angela Rea, Senior Policy Analyst, Health Canada, and believe that on January 30, 2014, she conducted a thorough and diligent search of the data held by the Marihuana Medical Access Program, which yielded the following information about production licenses issued under the MMAR.

Chart 2: Number of Valid Personal and Designated Person Production Licenses as of December of Each Year Under the MMAR

Year	# Production Licenses Nationally
2001	85
2002	324
2003	483
2004	539
2005	930
2006	1218
2007	1735
2008	2472
2009	3603
2010	5749
2011	9737
2012	22,832
2013	29,719

Chart 3: Estimated Total Number of Plants Authorized For Production (Based on Authorized Daily Amounts) Under the MMAR

2012	291,571 daily grams	This daily amount translates into 1,418,980 plants authorized for indoor production
2013	675, 855 daily grams	This daily amount translates into 3,289,162 plants authorized for indoor production

26. I am also advised by Angela Rea, and believe, that her diligent search of data related to the administration of the MMAR indicated that on December 3, 2013, the average number of plants licensed for indoor growth was 101, while the average number of plants licensed for outdoor growth was 11.

Chart 4: Total Number of Plants Authorized For Indoor/Outdoor Production as of December 3, 2013 Under the MMAR

	Indoor Production	**Outdoor Production**
Newfoundland	2, 185	55
Nova Scotia	38, 663	2,127
New Brunswick	16, 535	1, 246
PEI	662	79
Quebec	77,723	1,103
Ontario	510,582	15, 660
Manitoba	81, 594	465
Saskatchewan	19,938	311
Alberta	150, 679	767
British Columbia	2, 073,285	17, 458
Yukon	769	19
NT/NU	159	3

27. I am advised by Angela Rea, and believe, that the average daily amount (i.e. "dosage") has increased to a level of almost 17.7 g per day, as of December 12, 2013. A person authorized to use 18 grams of dried marihuana per day would, under a personal production license and the formula set out in the MMAR, be licensed to grow 88 plants.

28. According to 'Information for Health Care Professionals" at page 24 "Various surveys published in peer reviewed literature have suggested that the majority of people using smoked or orally ingested cannabis for medical reasons reported using between 10-20 g of cannabis per week or approximately 1-3 g of cannabis per day". As noted above, the document "Information for Health Care Professionals" is attached at **Exhibit "A"**.

29. Individuals who purchase their dried marihuana from Health Canada have on average purchased between 1-3 grams per day, which is in line with daily dosages set out in the most current scientific literature referenced "Information for Health Care Professionals" (as noted above, at Exhibit "A").

30. The RCMP Analysis of National Cases produced for the Canadian Association of Chiefs of Police states at p. 14 that "on average, 1 gram of marihuana produces 3-5 joints". A daily average of almost 18 grams translates into 54-90 joints or marihuana cigarettes each and every day. The RCMP Analysis is attached at **Exhibit "C"**.

31. Program participants who either produce their own dried marihuana or have designated producers produce for them generally have the highest daily amounts. Approximately 70% of those licensed under the MMAR to produce marihuana for medical purposes, are authorized to cultivate 25 plants or more.

32. Court decisions have resulted in the MMAR being amended to allow authorization of up to four production licenses to operate in the same location. Using the example above, of average numbers this could result in an average of 352 plants being grown in a single dwelling.

UNANTICIPATED CONSEQUENCES OF THE MMAR

33. The rapid expansion of uptake under the MMAR has had significant unintended consequences. Exponential growth in the number of persons seeking to possess and to produce marihuana for medical purposes, the increase in amounts produced and possessed, and the increase in number of people who could grow in one location, when combined with the fact that the production of marihuana was taking place in private dwellings, has resulted in difficulties and risks not only for the administration of the MMAR, but more importantly, for the health, safety and security of individuals licensed to produce marihuana for medical purposes and for the public in general.

34. The significant increase in the number of licenses issued, combined with the co-location of up to four licenses to grow marihuana on one site and the authority to possess and to produce increasingly high amounts of marihuana for medical purposes, has resulted in large quantities of marihuana being produced in private dwellings, that are not constructed for large-scale horticultural production, and are often in locations unknown by local authorities.

35. The MMAR were never intended to permit such widespread, large-scale marihuana production and, as a result they do not adequately address the public health, safety and security concerns that accompany such production.

36. In addition, rapid expansion under the MMAR has given rise to serious practical difficulties with respect to imposing stringent quality and safety standards on production by personal producers of marihuana for medical purposes.

37. The rapid expansion has also meant that Health Canada does not have the resources necessary to conduct compliance and enforcement activities in respect of personal production in residential homes. Additionally, in the absence of a warrant, and without the

homeowner's consent, Health Canada may not enter a residence to ascertain compliance with the terms of the personal production licenses issued for that location.

38. Program participants have expressed a general dislike for the application process, and also for the fact that only a single strain of marihuana was available for purchase from Health Canada.

39. Under the MMAR, Health Canada has also experienced increases in the cost of producing and distributing dried marihuana. The existing supply contract has a value of $16.8 million (excluding GST) for a three-year period, ending on March 31, 2013. An additional option year was built into the contract and has been exercised. It is estimated that this additional year will cost Health Canada $9.7 million. These high contract costs exist despite that only a minority of Program participants under the MMAR choose to obtain their supply from Health Canada.

40. Finally, as the number of personal production licenses and designated grower licenses expanded under the MMAR, Health Canada became increasingly aware of the significant health and safety risks associated with residential growing operations. As I outline in the next two sections of my affidavit, Health Canada has received extensive unsolicited and solicited feedback on the MMAR. This feedback has resulted in the identification of numerous unanticipated problems with the MMAR's personal production regime, including, but not limited to:

a) violence, including home invasion, theft and homicide;
b) the presence of firearms;
c) diversion to the illicit market;
d) producing over the limit authorized by Health Canada;
e) mould associated with the presence of excess moisture in the homes;
f) fire and electrical hazards;
g) the presence of toxic chemicals, like pesticides and fertilizers;
h) the emission of noxious odours and; and

i) various risks to children living in or near the residential growing operations.

41. As outlined in the next section of my affidavit these problems have effects not only on individual producers, but also on others living at the same address, in adjacent residential units, and/or in the surrounding community, whose residents may be unaware of the existence of these risks.

ONGOING PUBLIC CONCERNS RELATED TO PERSONAL PRODUCTION UNDER THE MMAR

42. Over the years, a variety of stakeholders have expressed to Health Canada concerns about the Marihuana Medical Access Program as it operates under the MMAR. While it is not possible to reproduce salient comments from all of the thousands of pieces of correspondence that have been received over the years, I have attempted to capture the primary concerns expressed to Health Canada by municipalities and first responders, homeowners, and program participants. Each of the excerpts are representative of the concerns expressed by these stakeholders and have been chosen because they encapsulate the issues raised by these stakeholders. All correspondence from which excerpts have been cited is appended collectively at **Exhibit "D"** with personal information redacted for *Privacy Act* purposes.

Municipalities & First Responders

43. Municipalities have raised serious public health and safety concerns regarding production of marihuana in private dwellings. Under the MMAR, applicants are not required to disclose their intent to produce to local authorities. Most often, these production sites are in private dwellings that are not constructed for large-scale horticultural production.

44. One municipality in BC stated to Health Canada that: "research has shown that the incidence of fire in a "Grow Op" is 24 times more likely than a normal home.... From a

public safety perspective, the potential risks in a licenced "Grow Op" are similar to that of an unlicenced one."

45. An Ontario municipal fire authority wrote Health Canada to express public safety concerns "that have been identified with the approval and issuance of licences to produce marihuana through the Marihuana Medical Access Division of Health Canada." The fire authority commented that when called upon to inspect one home occupied by a family with two young children, they found: "A number of violations of the Ontario Fire Code, Electrical Safety Code and Ontario Building Code...The inspection also revealed evidence of the incipient stages of a fire with the discolouration and charring of the floor where the ballasts used in the production of the marihuana plants were placed. The combination of Fire Code violations and the manner in which the grow operation was constructed resulted in a situation where the health and safety of the family as well as emergency responders, were placed at unnecessary risk of injury or even death".

46. Another letter from an administrative officer in a BC district requested "help with what is becoming a growing issue in one of my neighbourhoods. The residence in question is at ----- and is rented by Mr. ----- who contends he has a legal permit to grow marihuana. This home is right in the middle of a young neighbourhood and the smell is unbearable for two of the neighbours. One of the neighbours operates a licenced day care facility...we are unsure of the [grow op's] electrical status under the code... The neighbours have approached Mr. ----- in regard to the smell and the number of cars going in and out at all hours but he is pretty defiant and always says he has a permit. Anything you could do to help the District alleviate this problem would be helpful".

47. A larger BC community wrote stating "While the City of ------ understands the intention behind the adoption of the MMAR, this legislation has regrettably resulted in some adverse consequences for municipalities in Canada. More specifically, we believe that our community is now at greater risk of fires from medical marihuana production sites. Further it is clear that both illegal and legal marihuana production facilities have the potential to attract crime, including violent crime...We certainly support the Federal Government's

plan to revise the program to limit the potential for abuse and to mitigate the negative ancillary consequences associated with same."

48. And this letter from another BC District not only indicates that "the demands for electricity from exceedingly large marihuana grow operations, some licenced and some not, have caused power outages that have left these legitimate businesses without the ability to function and meet their customers' orders." , but goes on to comment that "The extensive lack of regard and abuse of the [Marihuana Medical Access] Regulations makes a mockery of the federal government's process but more importantly presents a safety risk to neighbouring residents and businesses as well as emergency response officials and is causing untold frustration and harm to our communities."

49. Municipalities writing to Health Canada express frustration around the information sharing constraints that apply to licensed marihuana production locations. One letter stated "... having law enforcement fully apprised of the location of the medical marihuana production facilities would assist in crime prevention and promote community safety, including the safety of those individuals who have been granted licences under the MMAR". The MMAR provide for certain information sharing with police in the course of an active investigation.

50. Law enforcement has also raised concerns that residential production activities leave the Program vulnerable to abuse, including criminal involvement and diversion to the illicit market, particularly given the attractive street value of marihuana ($10–$15/gram for dried marihuana) and that production in homes may leave residents and their neighbours vulnerable to violent home invasion by criminals who become aware that valuable marihuana plants are being produced and stored in the home (see RIAS at **Exhibit** "G").

51. One Ontario police service wrote: "We have found that some of the permit holders have drug trafficking convictions on their records or some of the growing activity has been outsourced to people who have been involved previously in illegal drug activities. Although permit holders are supposed to protect the security of their plants, some plants

can and do disappear to trafficking activities and the theft cannot be proven or disproven. Some of the quantities legal growers are allowed to possess in storage strikes us as particularly large numbers... [which] allows for many ways of drug trafficking under the veil of a legal operation... Although the regulations cause us concern the issue for the ----- Police Services Board is that Law enforcement cannot determine on a pro forma basis whether a "grow operation" is legal or not and we would like a list of "legal" producers and "legal users" in our county from your Ministry on an ongoing basis. We have reasonable grounds to believe that some legal producers are growing for illicit drug trade."

52. Firefighters have raised similar concerns around the inability to identify locations of licensed marihuana grow locations, which negatively impacts "...safety for the fire fighters and fire prevention and being aware of a potentially dangerous or health hazardous situation."

53. Another Ontario fire service wrote that, "recently a fire occurred in a building that had obtained a licence pursuant to section 29 of the Marihuana Medical Access Regulations in the City of -----. The location that was damaged by fire had been licenced by your office and signed by Stéphane Lessard." The ---- Fire and Emergency Services Department was not aware of the legal grow op. We have significant concerns with not knowing the locations and risks that emergency responders and other occupants have form (sic) the growing and cultivation of the product."

Homeowners

54. Homeowners comprise another group of stakeholders who have expressed health, safety, and security concerns relating to the production of marihuana by individuals in homes and communities. A review of correspondence received by Health Canada from concerned stakeholders between 2011 and 2013 reveals that in general, community members are concerned about negative impacts related to the presence of licensed personal production of marihuana in their neighbourhoods and communities.

55. Excerpts from samples of this correspondence, set out below, express frustration, fear and anger about health, safety, and security concerns related to production of marihuana for medical purposes by individuals in their neighborhoods and communities. Typically, these letters echo the following writer's comments: "May I stress that my concern is not with Health Canada's issuing of licences but with the blatant oversight that such issuing has on the well-being of Canadians living in my ---- residential community. Residents who are not medical marihuana users are being seriously affected, by overly obnoxious smells, extensive increase in traffic and the grievous eye sore the outdoor growing activities presents".

56. Persons living in Multi-Unit–Dwellings, such as condo owners and semi-detached houses, express concerns about strong and unpleasant odors seeping through common walls and windows. One Ontario Condominium Board Director wrote Health Canada to inform them about concerns raised in relation to an individual license to produce marihuana for medical purposes in their condominium building. The director advised that the board had received, "numerous complaints, some of which I have attached for your reference in regards to multiple problems which have been created and resulted in negative impact to the 209 other unit owners in this building, visitors, employees. As well, the ability of the Board of Directors to maintain Mr. [the license holder's] unit as well as the safety and enjoyment of this property for all owners has been compromised... There are far too many negative impacts to the building relating to the overall safety and health of all residents, visitors and employees of this building for the grow op to be permitted in this unit. Although we recognize the legal rights provided by health Canada for Mr. ----- to be a licenced user ... an alternative method of supplying the marihuana for use must be arranged... Due to the severity of the complaints we have received regarding the pungent odor of the grow op at this location; many residents and guests becoming ill as well as employees of the contracted Security company losing work and claiming WSIB due to diminished health from the effect of the grow op; it must be removed immediately. We ask that you revoke the licence for growing Marihuana in this location and supply Mr. ----- with his legal amount for personal use either through assigning him a licenced grower elsewhere or directly through Health Canada's supply system."

57. Another letter related to that same condominium indicates the condominium has had to involve law enforcement to deal with suspicion of trafficking and marihuana use in the public areas of the condominium; the letter states "there is clearly improper ventilation, poor air quality, moisture control, and low security related to his unit grow op. This building is adjacent to a school which facilitates kindergarten to grade 8. The smell is quite strong in our parking lot … all age groups vising/residing in this building are assaulted with the smell of these plants… owners are questioning their health risk, full impact related to their property value and legal responsibility to declare what they know when they sell their unit. Real estate agents and prospective buyers have experienced the odour on entering the building and are questioning what is going on and in some cases refusing to list or bring buyers to this location."

58. The letter also includes attachments which refer to issues associated with the licensed grow in the condo unit such as "acts of vandalism to the building, different charges laid by police over the years, assaults on security guards, intimidation of Property Managers, and persons jumping over their balcony for access." The letter further notes that, "A very hostile relationship exists between the units… Their attitude is that it is their legal right and they do not care about the impact on all who work/reside/visit the building… An employee of the security company lost 3 months off work last summer 2011 due to health issues and claimed through WSIB as a result of working with the almost continuous smell from smoking and growing of Marihuana. The board has lost its capacity to maintain the property with regards to that unit; not only to ensure the safety and health of all unit owners, but also their investments and right to a comfortable home environment."

59. Another townhome owner complains about a licensed grow op in his townhome development saying: "We have been told by local police in ----- that they will do nothing about this situation… Not only have adjoining homes lost the value…they are subject to possible mold, fire hazards, chemicals and fertilizers and the unbearable odors. We can't even sell our homes to get away… since we have been told by a real estate lawyer that our houses are worth nothing".

60. Another homeowner states: "We live in a beautiful townhouse complex in -----. Our neighbour attached to us is growing marihuana in his basement with a license. A couple of weeks ago the Fire Dept. and police came to check his house. At that time the police did take out a large garbage bag ----- we only assume it was plants. The smell from this growth has been more than unbearable for us and the neighbour on the other side. We are suffering headaches and nauseated most of the time. This neighbour assumed one of us called the police to report him. In response to this he verbally assaulted myself and 2 year old granddaughter (yelled and called us very bad names) and started coming over the fence at us – I ran into the house with my granddaughter and was terrified. My husband arrived home very soon afterwards and was physically assaulted by him – he was punched in the head 5 times and had to go to the doctor. He then went after the single woman next door and threated her. The police arrived and he was taken to jail and now has a probation order to stay away from us... Marihuana should never be allowed to be grown in a townhouse complex where it interferes with adjoining neighbours. It consequently has brought our home value down – our home is our biggest investment and this does not really seem fair."

61. In another letter, a couple with a toddler living in a semi-detached home where the resident in the other half is licensed to grow marihuana for medical purposes stated: "we are so tired of walking into our home and having to smell this. We have a 16 month old son with asthma, and his been breathing this since we moved in 13 months ago. We have to air out out (sic) home every single day and have tried many things to get rid of the smell since we moved in here. Please we just want it gone and don't know who to turn too...WHY SHOULD WE HAVE TO RUN AWAY FROM OUR HOUSE AND THINK THAT (THAT IS THE ONLY ANSWER)." [as written]

62. A woman living in a duplex where the adjoining owner has a license to produce marihuana for medical purposes writes: "His electrical system in (sic) endangering our home with my paraplegic husband, -----. Their electrical system is 60 amps and below code. The risk of fire is a huge concern and the risk to a paraplegic trying to escape a fire and being trapped. Their grow is right next door to our registered part wall and compromising it with molds. I

have asthma and my trigger is mold. My asthma has been dormant for 25 years and now it is back the same time as their grow op."

63. Another homeowner's letter begins: "We dearly love our little neighbourhood in ------. But we have a big problem. We have been struggling to find a solution for this situation". The writer indicates that when a new family bought into the neighbourhood, they "started an indoor marihuana grow op. This is no small operation. They are known cocaine and ecstasy dealers also. The RCMP busted them for a large quantity of marijuana and cash two years ago. They have never quit growing it because they got a doctor's prescription for medical marijuana and started growing twice as much while they were waiting to go to court. Then they were busted again for too many medical marihuana plants in their grow op last year... We have this drug factory in a normally great neighbourhood with kids and families. One of these young families is considering moving because of the gangster activity associated with this drug house... they have young children living in the house."

64. Another homeowner complained that, "our next door neighbour has a legal grow-op... This is a young couple with two children... now I have found out from our local police that they actually have a Health Canada certificate for 'medical reasons'... This is ruining our quiet neighbourhood. We have all been here for over 20 years and have never had to deal with such things and the smell is just disgusting. We cannot even open our kitchen door without that smell filling our house." Another homeowner complained that "the medical marihuana operation next door to me at ----- continues to keep me awake throughout the night and the smell from it disgusts me when I am in my driveway or backyard."

65. One homeowner states that, "local real estate agents... have confirmed that the market value of my home could be impacted by the existence of the marihuana grow op next door, making it difficult to sell for full value".

66. In another instance, a homeowner states that her neighbour "hides behind his [medical] licence to smoke marihuana and because of that licence, the local police as well as the RCMP cannot arrest him for his illegal activities... [despite that he] brags about his drug

exploits…" This writer states the medical marihuana grower about whom she is writing and from whose nuisance she seeks relief "has become an aggressive neighbour… we live in constant fear of what he might do to us and our properties. There have been several incidents of sabotage to people's homes and yards in the past two years and Mr. ----- admitted to my husband that he had hired teenagers to perform one of these deeds to our elderly neighbour's house. Some of the neighbours had to install surveillance cameras on their houses because they are afraid of what Mr. ----- and his 'friends' will do. We live in a very stressful environment."

67. This home owner goes on to say that the RCMP have indicated that this medical grower's house has become "the biggest grow op in the City of ----- "and their neighbourhood is now "polluted with the nauseating smell of skunk grass on a daily basis, not to mention the increase in traffic on our street and criminal in our area…. His illegal business has depreciated the value of every home and every honest citizen in this area. Some neighbours have tried to sell, but to no avail. Would you want to live next door to a marihuana grow op?... If you lived next door to him you would easily be able to answer that question after seeing the numerous people go quickly in and out of his dwelling during all hours of the day and night… Ever since ----- has moved into our neighbourhood, his presence has put an incredible strain on everyone. We want him to leave… We live in fear and we shouldn't have to."

68. Another homeowner complains about the smell from her neighbour's home, where medical marihuana is being grown, stating: "A few weeks ago I had been in the yard with my eight year old daughter decorating our house for Christmas but had to send her inside because of the smell. The odor had gotten to the point where it can be smelled more than a block away. I can smell it from my car as I approach my house... Frankly, it is so unpleasant living next to this operation that we have considered moving. However, this is completely impractical as I cannot reasonably expect to sell my home while it is so apparent that we are neighbouring a considerable (based on odor) grow op. Nor could I, in good conscience, attempt to conceal this from prospective buyers."

69. Still another notes, "We are homeowners in ----- and we have a 'legal medical grow op' in our neighbourhood." The writer cites the challenges they have experienced as a result and asks "Who is protecting us, the respectable, honest homeowners?"

70. Another homeowner, who has lived in his home for 31 years notes he has "enjoyed my life here until Health Canada decided to allow legal marihuana grow operations. I have a neighbour who has 2 such licences, one for her and one for her son. Since the operation started I can no longer enjoy so much as sitting on my stoop or opening my windows to get some fresh air as there is no longer any such thing, As you probably know, the stench from this plants is very rank and is filtering over to my property... not only do I have to put up with the stench, we are on bad terms now and I have to suffer her foul mouth... as she says, 'I have a licence!!". "This grow op's within a school zone... I have a 4 year old grandson who loves to come over and ride his bike and I don't want him subjected to all this ...".

71. Another homeowner writes: "the individual who lives behind me was involved in harvesting of marihuana plans (sic) in his backyard. This process was being conducted by no less that 6 people. The smell was very strong and I was forced to keep my grandchildren in the house for most of the day... When I advised the local police, they did their investigation and I was advised that this individual had a licence to grow 99 marihuana plants."

72. And some homeowners complain of safety and security concerns, such as the writer who stated that: "The residents in our neighbourhood feel threatened by the medicinal grow op operating here. There has been extensive vandalism, attempted break – ins and we feel the threat of fire due to the size of the grow op is likely".

73. Another homeowner wrote to tell Health Canada that "My family and I are going on our third year of having to endure the safety issues and foul emissions from a medical marihuana grow op located 25 feet from our home...because we have raised concerns on these issues, Mr. ----- has become very abusive and we have tried to get the RCMP

involved... he has yelled at us, put up numerous expletive signs and yelled profanities at us, has damaged our property and told people that I am a child molester. There are numerous reports of Mr. ----- offering to trade drugs for goods and services, selling to teenagers... They are using the system under the guise of producing medicine. Some of their customers may be medicinal users but we and others in our neighbourhood see on a daily basis indications that Mr. ----- is selling his marihuana to anybody including high school students... I feel I am gambling with my family's safety and we must move. We would not be able to sell our home for anywhere near market value with this commercial grow op next door. I estimate it will cost us approximately $100,000 to relocate our home and business. We have offered to purchase their property for well over market value, but they have refused. To go rent and leave our home empty will cause our insurance rates to nearly double. We are out of options. This is out home we have raised our teenage children in. None of us want to leave."

74. Another homeowner speaks of the disruption caused by the "number of fans, extractors, CO2 generators and possibly other equipment that is running 24 hours a day and producing vibration and resonance inside my house and whirring and whining noises outside." This personal writes that he lives in "a very quiet area, and this constant noise has grealy (sic) detracted from my enjoyment of my property, while the droning and vibration inside my house can produce some very disturbing effects that include resonance in my head, sleeplessness and mental fuzziness." The writer indicates that the licensed grower neighbour "assured me this would be dealt with, but after almost a year the problem persists".

75. These unsolicited letters from homeowners are illustrative of concerns routinely raised to Health Canada about the unintended consequences of the marihuana medical access program. The concerns raised in these letters are consistent: reduced enjoyment of their own homes, both inside and out; negative impacts on the quality of life in their homes and neighborhoods; concerns about health and safety; and a general sense of frustration and powerless in the face of personal production of marihuana for medical purposes in their neighbourhoods.

Program Participants

76. Program participants and their families have also written to Health Canada regarding the medical marihuana access program's impact on health and safety. One person wrote to Health Canada to express concern with respect to the grow operation in his home: "I am the father of 4 children aged 2-9 who lives with my estranged wife in our previous matrimonial home on Vancouver Island, BC; she has a licence to grow marijuana since last February at least. I feel my children are at risk due to this situation; dangers to children are well-documented." The writer indicates that his wife has "converted the basement of our 2 year old home, where she resided with our 4 children aged 2, 5, 7 & 9 to grow the marihuana plants, which I only accidentally discovered...Obviously, I was concerned about the growing of this controlled substance within the house where 4 young children reside, but also because I noted that the ventilation systems for the plants emptied into the basement space within the house and not to the outside atmosphere, which would obviously be depositing mold-laden moist air into the house living space and ductwork. Additionally, I found out that the electrical system was altered without a permit...My wife removed the marijuana plants within a few months of my discovering them. Dr -----, a local pediatrician assessed the 4 children and concluded they did have 'some respiratory inflammation'. The Bank of Montreal, who holds the house mortgage, tested the air quality and concluded that the house needed a thorough professional cleaning due to mold content, and that if we failed to do so, they would have no alternative but to involve legal counsel..."

77. Another woman writes that her husband, who is licensed to grow marihuana for medical purposes, "was and still is selling marihuana among his close friends... The destruction to the property has devalued it... He can't even smoke all that he is legally allowed to grow himself in one month. He sells the rest."

78. A couple licensed to grow marihuana for medical purposes wrote to Health Canada and stated that: "we are the owners of a designated production facility... and we are writing to

inform Health Canada of a theft of Medical Marihuana from... Plants and dried product were taken from our production facility... (approximately 35 pounds) out of the locked safe...he has now indicated he will not be returning the product... he has also indicated he has no intention of returning all of our paperwork... He has abandoned the rental house on the property... he has left no forwarding address..."

79. Another person licensed to produce his own marihuana for medical purposes advised Health Canada that: "My production and storage site... was forcibly broken into... This resulted in vandalism and theft".

THE NEW MARIHUANA FOR MEDICAL PURPOSES REGIME

80. The RIAS that accompanied the 2009 MMAR amendments weighed the option of establishing a new licensing regime at that time. This option was determined to be impractical then, however, given the policy development work and consultation that would have been required. This RIAS is attached at **Exhibit "B".**

81. In 2011, the Government of Canada proposed changes to the regulatory framework based on concerns that had been expressed, and on June 17, 2011, the Government of Canada announced the proposed reform of the MMAR and the beginning of a public consultation period, during which stakeholder input and opinion was solicited. A copy of her announcement is attached to this my affidavit at **Exhibit "E"**.

82. One of the principles underlying this initiative was that even though it remained an unapproved drug, dried marihuana should be treated as much as possible like other drugs used for medical purposes.

83. A consultation document was posted on the Health Canada website, and stakeholders and the general public were invited to submit comments on or before July 31, 2011. In addition, between August and October, 2011 Health Canada held meetings with a broad array of stakeholders, including law enforcement, fire officials, parties potentially

interested in becoming licensed producers, physicians and their professional regulating bodies, and their associations/regulators, and municipalities, provinces and territories.

84. I attended at these consultations. Notes were taken and summarized. Summaries of consultations with representatives from firefighter organizations, law enforcement, provinces, medical associations, and municipalities are attached, along with the consultation document summarizing stakeholder input are appended to this my affidavit at **Exhibit "F"**.

85. During these consultations, law enforcement officials told Health Canada that: "elimination of personal and designated-person production in residential areas is seen to greatly increase safety in communities". The feedback summary from the law enforcement consultation indicates that: "Unanimously, participants agreed that personal production should not be continued". Reasons voiced in support of this view included the lack of ability to inspect, the vulnerability of production to organized crime, and numerous public safety concerns related to inadequate electrical systems, explosions or fires, smell and exhaust from production sites in residential areas.

86. During a consultation with the Canadian Association of Fire Chiefs, held September 27, 2011, all participants voiced support for phasing out "personal production of marihuana in private dwellings due to serious public safety and public health concerns." As noted above, the Consultation Report summarizing stakeholder input is attached to affidavit at Exhibit "F".

MARIHUANA FOR MEDICAL PURPOSES REGULATIONS (MMPR)

87. The MMPR came into force in June, 2013 and created a framework to replace the MMAR, which will be repealed on March 31. 2014. During the period between June, 2013 and March 31, 2013, both regulatory regimes are operating concurrently, creating a transition period to the new supply and distribution system for dried marihuana, which relies on commercial production of marihuana for medical purposes provided for in the MMPR. A

copy of the MMPR and the Regulatory Impact Analysis Statement (RIAS) is attached to this my affidavit at **Exhibit "G"**.

88. The RIAS published with the MMPR states that one of the objectives of the MMPR is "to reduce the risks to public health, security and safety of Canadians, while significantly improving the way in which individuals access marihuana for medical purposes."

89. Under the MMAR, there were practical difficulties in imposing quality and safety standards on production by personal producers of marihuana for medical purposes, who may lack the capacity, knowledge or motivation to implement them. This situation poses individual health and safety risks for those seriously ill persons who consume cannabis, not knowing what kind or level of microbial or chemical contaminants it may contain, or what standards should be or have been used for products such as fertilizers or pesticides.

90. The MMPR approach to providing access to dried marihuana for medical purposes is intended to address many, if not all, of the significant negative consequences that resulted from the MMAR. At the same time, the MMPR are intended to improve access to quality dried marihuana for medical purposes, which is produced in regulated, sanitary, and secure premises. Accordingly, the new MMPR intends to:

- Increase individual and public health and safety and security; cultivation of marihuana in individual residences under the MMAR ran contrary to these objectives;
- Treat marihuana, to the extent possible, as much as possible like other drugs for medical use; the MMAR did not provide for good production practices, in sanitary secure premises, or require that marihuana products were labelled to show levels of THC and CBD. Under the MMAR there was no capacity to limit microbial and chemical contaminants to generally accepted tolerance limits for human consumption;
- Facilitate access to multiple strains;
- Eliminate government involvement in authorizing possession of marihuana for medical purposes; persons using marihuana for medical purposes will no longer need to seek Heath Canada approval;

- Expand the scope of persons who may sign a medical document to include nurse practitioners, where their licensing bodies permit; under the MMAR doctors only could support an individual's use of marihuana for medical purposes;
- Streamline the medical document and eliminate categories of medical conditions; no specialist is required; under the MMPR one doctor or nurse practitioner can determine together with a patient if marihuana should be used;
- Return Health Canada to its traditional role of regulator HC will no longer be involved in selling marihuana for medical purposes or servicing individual users;
- Create a legitimate, regulated business environment in which:
    a. dried marihuana for medical purposes will be produced and distributed under safe, secure, sanitary conditions;
    b. production site and key personnel of the Licensed Producer must meet security standards;
    c. standards for packaging, transportation and record keeping are required;
    d. inspections of licensed producers can be conducted, during which compliance and enforcement activities can be carried out to the benefit individual users and the general public; and
    e. A better balance can be achieved between providing access to dried marihuana for medical purposes and minimizing negative impacts resulting from its production in dwelling houses.

91. The MMPR authorizes the following key activities:

- possession of dried marihuana by individuals who have the support of a licensed health care practitioner to use marihuana for medical purposes;
- production of dried marihuana by licensed producers only; and
- sale and distribution of dried marihuana by licensed producers and hospitals to individuals who can possess it.

92. The MMPR also allows individuals who hold an authorization to possess under the MMAR to transition to the new framework using their authorization for up to one year after its date

of issue (unless a period of usage of less than 12 months has been indicated in the medical declaration). Individuals can also transition to obtaining their legal supply of dried marihuana for medical purposes under the MMPR by using a medical declaration issued under the MMAR to register with a licensed producer, which can then provide them with dried marihuana for medical purposes.

93. Under the MMPR, personal and designated licenses to produce dried marihuana for medical purposes issued under the MMAR will be phased out, until March 31, 2014 when the MMAR will be repealed and all personal and designated production licenses will become invalid.

94. Health Canada's website provides detailed information for persons who are interested in transitioning to the new MMPR, in using marihuana for medical purposes, or in applying to be a Licensed Producer under the new scheme: http://www.hc-sc.gc.ca/dhp-mps/marihuana/transition-eng.php. These materials are attached at **Exhibit "H"**.

95. The Health Canada guidelines for Licensed Producers, also available at the Health Canada website http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/guide-eng.php . These materials elaborate, for example, Licensed Producer physical security measures and good production practices as required under the MMPR; these materials are attached at **Exhibit "I"**.

96. Health Canada has continued to accept applications for renewal of personal and designated production licenses, however, September 30, 2013 marked the deadline for submission to Health Canada of applications for new licenses to produce marihuana for medical purposes, as well as for increases to personal or designated production licenses and for changes to production sites. The rationale underlying this deadline is that applications submitted beyond the October 1, 2013 would have left inadequate time for new producers to cultivate, harvest and dry a marihuana crop prior to the repeal of the MMAR on March 31, 2014.

97. On repeal of the MMAR, Health Canada will no longer receive, process, or issue applications for authorizations to possess and licenses for personal or designated

production, or continue to produce and supply marihuana for medical purposes. The new MMPR return Health Canada to its traditional role of regulator, as with other drugs, rather than producer and service provider.

THE ADMINISTRATIVE IMPLICATIONS

98. The upcoming repeal of the MMAR on March 31, 2014 has meant that Health Canada has already substantially dismantled the infrastructure put in place to support them. The winding down of the operational support of services provided under the MMAR is well underway and will be completed by March 31, 2014. Examples of these steps include workforce adjustment, employee relocation, and resource reallocation to other programs.

99. To continue to provide services under the MMAR would require recreating that infrastructure, which would be costly and disruptive to government operations, and would have implications for the other programs Health Canada provides to the Canadian public.

100. I am advised by Stéphane Lessard, the Acting Director of the Bureau of Medical Cannabis and Associate Director General, Health Canada and believe that at the peak of operations under the Marihuana Medical Access Regulations between 2012 and 2013, the Bureau of Medical Cannabis employed 142 persons. Since October 2013, staff reductions have taken place. As of January 30, 2014, 86 employees remain.

101. I am also advised by Stéphane Lessard, and believe, that during 2012 and 2013 the Authorizations and Licensing Division was managing upwards of 4,000 pieces of mail per week. At the same time Client Services Division was responding to 250 written requests, 1000 police inquiries, and 7,000 calls per month. The Production Division was processing over 1,000 orders for dried marihuana and seeds per month.

102. I am further advised by Stéphane Lessard and believe that by October 2013, after which new personal and designated production licenses could no longer be issued, demand began

to taper off. By January 2014, each division had reduced its staff, with the Authorizations and Licensing Division reducing its staffing by almost 50%.

103. Hiring temporary help from an agency takes approximately one month and hiring *via* the normal government processes could take between 1 and six months.

104. New employees must undergo an intensive training program before they are capable of performing their duties. Employees must be trained on Standard Operating Procedures, which consist of several volume of information about database operation, the regulatory regime, privacy issues, and other operational details. I am advised by Stéphane Lessard and believe that it takes 10 weeks to bring a new employee to the level of competence required to perform Marihuana Medical Access Regulations related work.

105. Annual maintenance and necessary improvements required to support the existing database's continued functionality, normally planned for in September of the fiscal year, have not been undertaken this year. I am advised by, Stéphane Lessard, and believe, that the SAMMII database is experiencing operational challenges caused by high usage and reduced storage and processing capacity that cause freezing, and other technical problems. Work is ongoing to improve this system for completion of the program and the continued availability of information after the March 31, 2014 repeal of the MMAR.

106. I am advised by Stéphane Lessard, and believe, that providing services under the Marihuana Medical Access Regulations required office space in 4 locations. Due to reduced staffing, work is in progress to consolidate all Bureau of Medical Cannabis offices in one location.

107. I am advised by Stéphane Lessard, and believe, that Health Canada has budgeted for wind-down tasks related to the MMAR, but has not budgeted for continued operations in support of the MMAR.

108. The MMPR are intended to address the significant health and individual and public safety concerns that arose under the old MMAR, while improving streamlined access to quality controlled marihuana for medical purposes. Health Canada is concerned that if personal production continues beyond the March 31, 2014 repeal date of the MMAR, these concerns will unabated and the unintended consequences of the old MMAR will be left unaddressed.

109. Health Canada is also concerned that continued personal production will undermine the establishment and viability of the fledgling licensed producer industry, which has been created to facilitate enhanced access to quality controlled dried marihuana for medical purposes, produced in a safe and secure environment. This industry may be undermined by reversion back to the personal production that was permitted under the MMAR.

AFFIRMED BEFORE ME at the City of Ottawa, Province of Ontario, this 7th day of February, 2014.

Jeannine Ritchot

A Notary Public in and for the Province of Ontario

This is **Exhibit " A "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

Information for Health Care Professionals

Cannabis (marihuana, marijuana) and the cannabinoids

Information for Health Care Professionals

Cannabis (marihuana, marijuana) and the cannabinoids
Dried plant for administration by ingestion or other means
Psychoactive agent

This document has been prepared by the Controlled Substances and Tobacco Directorate at Health Canada to provide information on the use of cannabis and cannabinoids for medical purposes. **Cannabis is not an approved therapeutic product and the provision of this information should not be interpreted as an endorsement of the use of this product, or cannabis generally, by Health Canada**.

Despite the similarity of format, it is not a Drug Product Monograph, which is a document which would be required if the product were to receive a Notice of Compliance authorizing its sale in Canada. This document is a summary of peer-reviewed literature and international reviews concerning potential therapeutic uses and harmful effects of cannabis (marihuana) and cannabinoids. It is not meant to be comprehensive and should be used as a complement to other reliable sources of information.

This document should not be construed as expressing conclusions from Health Canada about the appropriate use of cannabis (marihuana) or cannabinoids for medical purposes.

Cannabis (marijuana, marihuana) is not an approved therapeutic substance in Canada and has not been issued a notice of compliance by Health Canada authorizing sale in Canada.

Prepared by Health Canada

Date of latest version: February 2013

(May 2013) Addendum to the *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013 version)

Following the most recent update to this document (February 2013), a study was published in the Netherlands tracking data obtained from the Dutch medical cannabis program over the years 2003-2010. The study reported that in a population of over 5,000 Dutch patients using cannabis for medical purposes, the average daily dose of dried cannabis (various potencies) used was 0.68 grams per day (range: 0.65 - 0.82 grams per day) (Hazekamp and Heerdink 2013). In addition, information from Israel's medical marihuana program suggests that the average daily amount used by patients was approximately 1.5 grams of dried cannabis per day in 2011-2012 (Health Canada personal communication).

Hazekamp, A., and E.R. Heerdink (2013). The prevalence and incidence of medicinal cannabis on prescription in The Netherlands. Eur. J. Clin. Pharmacol. Published online April 16, 2013.

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List of Abbreviations

2-AG: 2-arachidonoylglycerol
5-HT: 5-hydroxytryptamine
ACEA: arachidonyl-2-chloroethylamide
ACTH: adrenocorticotropic hormone
AD: Alzheimer's disease
AEA: arachidonoylethanolamide (i.e. "anandamide")
AIDS: acquired immune deficiency syndrome
ALS: amyotrophic lateral sclerosis
ApoE: apolipoprotein E
AUC: area-under-the-curve
B.I.D.: *bis in die* (i.e. twice per day)
CAMS: Cannabis in Multiple Sclerosis
CB: cannabinoid
CBC: cannabichromene
CBD: cannabidiol
CBG: cannabigerol
CBN: cannabinol
CNS: central nervous system
CINV: chemotherapy-induced nausea and vomiting
CNR1: cannabinoid receptor gene 1
CNR2: cannabinoid receptor gene 2
CI: confidence interval
CRPS: complex regional pain syndrome
CSF: cerebrospinal fluid
CUPID: Cannabinoid Use in Progressive Inflammatory Brain Disease
CYP: cytochrome P450
Δ^9-THC: delta-9-tetrahydrocannabinol
DAG: diacylglycerol
DEA: N-docosatetraenoylethanolamine
DNBSA: dinitrobenzene sulfonic acid
DSM-IV-TR: diagnostic and statistical manual of mental disorders
ECS: endocannabinoid system
FAAH: fatty acid amide hydrolase
FEV_1: forced expiratory volume in one second
FVC: forced vital capacity
HD: Huntington's disease
HEA: N-homo-γ-linolenoylethanolamine
HIV: human immunodeficiency virus
HMO: health maintenance organization
HSV: herpes simplex virus
IBD: inflammatory bowel disease
IBS: irritable bowel syndrome
IOP: intra-ocular pressure
I.P.: intraperitoneal
I.V.: intravenous
KSHV: Kaposi's sarcoma-associated herpes virus
LDL: low density lipoprotein
MAGL: monoacylglycerol lipase
MDS: macroscopic damage score
MMAR: marihuana medical access regulations
mRNA: messenger ribonucleic acid
MS: multiple sclerosis
MUSEC: MUltiple Sclerosis and Extract of Cannabis trial
NADA: N-arachidonoyl-dopamine
NAFLD: non-alcoholic fatty liver disease
NAPE: N-arachidonoylphosphatidylethanolamine

NAT: N-acyl transferase
NIDA: National Institute on Drug Abuse
nM: nanomolar
NNT: number needed to treat
OA: osteoarthritis
OEA: oleoylethanolamide
OR: odds ratio
PAH: polycyclic aromatic hydrocarbon
PASAT: paced serial addition test
PD: Parkinson's disease
PEA: palmitoylethanolamide
PET: positron emission tomography
PPAR: peroxisome proliferator- activated receptor
PTSD: post-traumatic stress disorder
Q.I.D.: *quattuor in die* (i.e. four times per day)
QOL: quality of life
RA: rheumatoid arthritis
RCT: randomized controlled trial
REM: rapid eye movement
RGC: retinal ganglion cells
S.C.: subcutaneous
SCI: spinal cord injury
SNP: single nucleotide polymorphism
SPECT: single-photon emission computed tomography
THC: delta-9-tetrahydrocannabinol
THCA: tetrahydrocannabinolic acid
THCV: tetrahydrocannabivarin
T.I.D.: *ter in die* (i.e. three times per day)
TNBSA: trinitrobenzene sulfonic acid
TRPV1: transient receptor potential vanilloid channel 1
TS: Tourette's syndrome
µM: micromolar
VSV: vesicular stomatitis virus
WHO: World Health Organization

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IMPORTANT NOTE: For the sake of completeness and for contextual purposes, the content in the following document includes information on dried cannabis as well as selected cannabinoids. However, cannabis and cannabinoids should not be considered equivalent even though the information on both is presented together within the text. Cannabis is a highly complex material with hundreds of chemical constituents whereas cannabinoids are single molecules. Drawing direct comparisons between cannabis and cannabinoids must necessarily take into account differences in the route of administration, dosage, and the different pharmacokinetic and pharmacodynamic properties of these different substances.

1.0 The Endocannabinoid System

The endocannabinoid system **(Figure 1)** is an ancient, evolutionarily conserved, and ubiquitous lipid signaling system found in all vertebrates, and which appears to have important regulatory functions throughout the human body (1). The endocannabinoid system has been implicated in a very broad number of physiological as well as pathophysiological processes including neural development, immune function, inflammation, appetite, metabolism and energy homeostasis, cardiovascular function, digestion, bone development and bone density, synaptic plasticity and learning, pain, reproduction, psychiatric disease, psychomotor behaviour, memory, wake/sleep cycles, and the regulation of stress and emotional state (2,3,4).

Components of the endocannabinoid system

The system consists of the cannabinoid 1 and 2 (CB_1 and CB_2) receptors, the CB receptor ligands N-arachidonoylethanolamine (i.e. "anandamide" or AEA) and 2-arachidonoylglycerol (2-AG) as well as the endocannabinoid-synthesizing and degrading enzymes fatty acid amide hydrolase (FAAH) and monoacylglycerol lipase (MAGL) **(Figure 1)** (2). Anandamide and 2-AG are considered the primary endogenous mediators of cannabinoid signaling, but other endogenous molecules which exert "cannabinoid-like" effects have also been described. These other molecules include 2-arachidonoylglycerol ether (noladin ether), N-arachidonoyl dopamine (NADA), virodhamine, N-homo-γ-linolenoylethanolamine (HEA) and N-docosatetraenoylethanolamine (DEA) (2,5,6,7,8). Molecules such as palmitoylethanolamide (PEA) and oleoylethanolamide (OEA) do not appear to bind to cannabinoid receptors but rather to a specific isozyme belonging to a class of nuclear receptors/transcription factors known as peroxisome proliferator-activated receptors (PPARs) (8). These endocannabinoids may, however, potentiate the effect of anandamide by competitive inhibition of FAAH, and/or through direct allosteric effects on other receptors such as the transient receptor potential vanilloid (TRPV1) channel (9). These types of effects have been generally referred to as the so-called "entourage effect" (9,10).

Endocannabinoid synthesis

Endocannabinoids are arachidonic acid derivatives which are synthesized "on demand" from membrane phospholipid precursors in response to cellular requirements (2,11,12,13). Anandamide is principally produced by the transfer of arachidonic acid from phosphatidylcholine to phosphatidylethanolamine by N-acyltransferase (NAT) to yield N-arachidonoylphosphatidylethanolamine (NAPE). NAPE is then hydrolyzed to form anandamide by a NAPE-specific phospholipase D (2,14). In contrast, 2-AG is principally synthesized through phospholipase C-β-mediated hydrolysis of phosphatidylinositol-4,5-bisphosphate, with arachidonic acid on the *sn-2* position, to yield diacylglycerol (DAG). DAG is then hydrolyzed to 2-AG by a DAG-lipase (2,14). While anandamide and 2-AG are both derivatives of arachidonic acid, they are synthesized by pathways distinct from those used to synthesize eicosanoids (15). Nevertheless, it appears that there may be a certain amount of cross-talk between the eicosanoid and endocannabinoid pathways (15).

Genetics and signaling through the cannabinoid receptors

Endocannabinoids such as anandamide and 2-AG, as well as the phytocannabinoids Δ^9-tetrahydrocannabinol (Δ^9-THC), Δ^8-THC, cannabinol and others, bind to and activate (with differing affinities and efficacies) the CB_1 and CB_2 receptors which are G-protein coupled receptors that activate G_i/G_o-dependent signaling cascades (16,17). The receptors are encoded by separate genes located on separate chromosomes; in humans, the CB_1 receptor gene (*CNR1*) locus is found on chromosome 5q15 whereas the CB_2 receptor gene (*CNR2*) locus is located on chromosome 1p36 (18). The *CNR1* coding sequence consists of one exon encoding a protein of 472 amino acids (19). The CB_1 receptor protein shares 97-99% amino acid sequence identity across species (human, rat, mouse) (19). As with the *CNR1* coding sequence, the *CNR2* coding sequence consists of only one exon, but it encodes a shorter protein 360 amino-acids in length (19). The human CB_2 receptor shares 48% amino acid identity with the human CB_1 receptor; the mouse CB_2 receptor shares 82% amino acid sequence identity with the human CB_2 receptor (19).

Activation of the CB_1 or CB_2 $G_{i/o}$-protein coupled receptors results in inhibition of adenylyl cyclase activity, decreased formation of cyclic AMP with a corresponding decrease in protein kinase A activity, and inhibition of Ca^{2+} influx through various Ca^{2+} channels; it also results in stimulation of inwardly rectifying potassium (K^+) channels and the mitogen-activated protein kinase signaling cascades (3,12). Anandamide is a partial agonist at CB receptors, and binds with slightly higher affinity at CB_1 compared to CB_2 receptors (2,20). 2-AG appears to bind equally well to both CB receptors (with slightly higher affinity to CB_1), but has greater potency and efficacy than anandamide at CB receptors (2,20).

In the central nervous system (CNS), the overall effect of CB_1 receptor activation is suppression of neurotransmitter release (5-hydroxytryptamine, glutamate, acetylcholine, GABA, noradrenaline, dopamine, D-aspartate, cholecystokinin) at both excitatory and inhibitory synapses with both short and long-term effects (2,16,21). Inhibition of neurotransmitter release occurs through a retrograde signaling mechanism whereby endocannabinoids synthesized and released from the post-synaptic neurons diffuse backwards across the synaptic cleft and bind to CB_1 receptors located on the pre-synaptic terminals (3). This retrograde signaling mechanism permits the regulation of neurotransmission in a precise spatio-temporal manner (3). In immune cells, activation of CB_2 receptors inhibits cytokine/chemokine release and neutrophil and macrophage migration, giving rise to complex modulatory effects on immune system function (17).

Cannabinoid receptor expression and receptor distribution

Most tissues contain a functional endocannabinoid system with the CB_1 and CB_2 receptors having distinct patterns of tissue expression. The CB_1 receptor is one of the most abundant G-protein coupled receptors in the central and peripheral nervous systems (17). It has been detected in the cerebral cortex, hippocampus, amygdala, basal ganglia, substantia nigra pars reticulata, internal and external segments of the globus pallidus and cerebellum (molecular layer), and at central and peripheral levels of the pain pathways including the periaqueductal gray matter, rostral ventrolateral medulla, the dorsal primary afferent spinal cord regions including the peripheral nociceptors, and the spinal interneurons (4,21,22). The CB_1 receptor is also expressed in many other organs and tissues including adipocytes, leukocytes, spleen, heart, lung, the gastrointestinal tract (liver, pancreas, stomach, and the small and large intestine), kidney, bladder, reproductive organs, skeletal muscle, bone, joints, and skin (23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41). CB_1 receptor expression appears to be relatively sparse in the brainstem region (4). CB_2 receptors are most highly concentrated in the tissues and cells of the immune system such as the leukocytes and the spleen, but can also be found in bone and to a lesser degree in liver and in nerve cells including astrocytes, oligodendrocytes and microglia, and even some neuronal sub-populations (reviewed in (42,43)).

Other molecular targets of cannabinoids

Besides the well-known CB_1 and CB_2 receptors, a number of different cannabinoids are believed to bind to a number of other molecular targets. Such targets include the third putative cannabinoid receptor GPR55, the transient receptor potential (TRP) cation channel family, and a class of nuclear receptors/transcription factors known as the peroxisome proliferator-activated receptors (PPARs). For additional details on this subject please consult the following resources (7,8,20,44). Modulation of these other cannabinoid targets adds additional layers of complexity to the known myriad effects of cannabinoids.

Signal termination

Endocannabinoid signaling is rapidly terminated by the action of two hydrolytic enzymes: fatty acid amide hydrolase (FAAH) and monoacylglycerol lipase (MAGL) (3). FAAH is primarily localized post-synaptically (45,46) and preferentially degrades anandamide (13); MAGL is primarily localized pre-synaptically (45,46) and favors the catabolism of 2-AG (13).

Dysregulation of the endocannabinoid system and general therapeutic challenges of using cannabinoids

Dysregulation of the endocannabinoid system appears to be connected to a number of pathological conditions, with the changes in the functioning of the system being either protective or maladaptive (47). Modulation of the endocannabinoid system either through the targeted inhibition of specific metabolic pathways, and/or directed agonism or antagonism of its receptors may hold therapeutic promise (12). However, a major and consistent therapeutic challenge confronting the routine use of psychoactive cannabinoids (e.g. THC) in the clinic has remained that of achieving selective targeting of the site of disease and the sparing of other bodily regions such as the mood and cognitive centres of the brain (21,47,48,49,50).

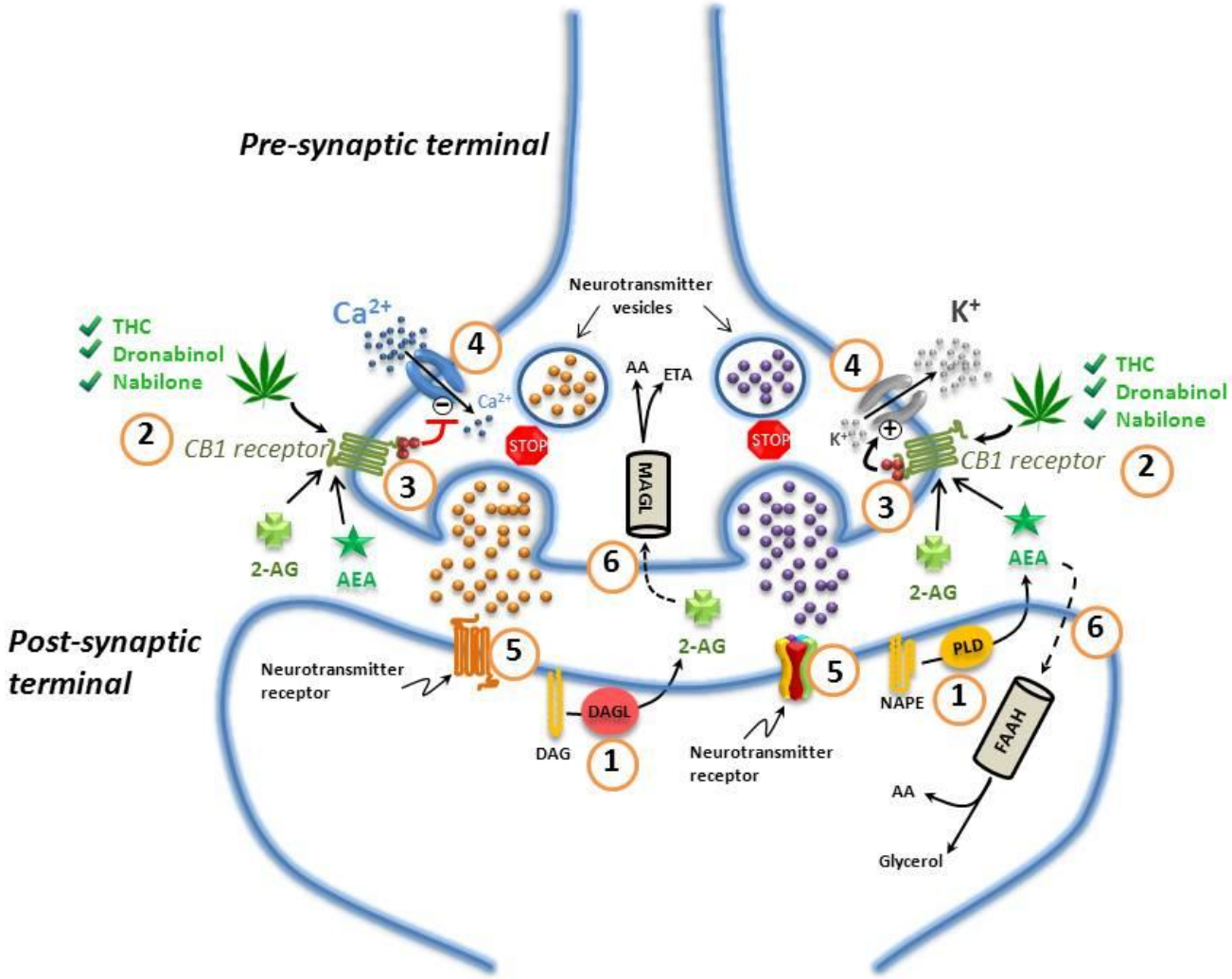

Figure 1. The Endocannabinoid System in the Nervous System

(1) Endocannabinoids are manufactured "on-demand" in the post-synaptic terminals: anandamide (AEA) is generated from phospholipase-D (PLD)-mediated hydrolysis of the membrane lipid N-arachidonoylphosphatidylethanolamine (NAPE); 2-AG from the diacylglycerol lipase (DAGL)-mediated hydrolysis of the membrane lipid diacylglycerol (DAG); **(2)** These endocannabinoids (AEA and 2-AG) diffuse retrogradely towards the pre-synaptic terminals and like exogenous cannabinoids such as THC (from cannabis), dronabinol, and nabilone, they bind and activate the pre-synaptic G-protein-coupled CB_1 receptors; **(3)** Binding of phytocannabinoids and endocannabinoids to the CB_1 receptors triggers the activation and release of the G_i/G_o proteins from the CB receptors and inhibits adenylyl cyclase, thus decreasing the formation of cyclic AMP and the activity of protein kinase A; **(4)** Release of the G_i/G_o proteins also results in the opening of inwardly-rectifying K^+ channels (depicted with a "+") causing a hyperpolarization of the pre-synaptic terminals, and the closing of Ca^{2+} channels (depicted with a "-"), arresting the release of stored excitatory and inhibitory neurotransmitters (e.g. glutamate, GABA, 5-hydroxytryptamine (5-HT), acetylcholine, noradrenaline, dopamine, D-aspartate and cholecystokinin) which **(5)** once released, diffuse and bind to post-synaptic receptors; **(6)** Anandamide and 2-AG re-enter the post- or pre-synaptic nerve terminals (possibly through the actions of a specialized transporter depicted by a "dashed" line) where they are respectively catabolized by fatty acid amide hydrolase (FAAH) or monoacylglycerol lipase (MAGL) to yield either arachidonic acid (AA) and ethanolamine (ETA), or arachidonic acid and glycerol. See text for additional details. Figure adapted from (51,52,53).

1.1 Cannabis

1.1.1 Chemistry and composition

Marihuana (Marijuana) is the common name for *Cannabis sativa* (i.e. cannabis), a hemp plant that grows throughout temperate and tropical climates (54). The leaves and flowering tops of *Cannabis* plants contain at least 489 distinct compounds distributed among 18 different chemical classes, and harbor more than 70 different phytocannabinoids (55). The principal cannabinoids appear to be delta-9-tetrahydrocannabinol (i.e. Δ^9-THC, THC), cannabinol (CBN), and cannabidiol (CBD) (56,57,58), although the relative abundance of these and other cannabinoids can vary depending on a number of factors such as the *Cannabis* strain, the soil and climate conditions, and the cultivation techniques (59,60). Other cannabinoids found in cannabis include cannabigerol (CBG), cannabichromene (CBC), tetrahydrocannabivarin (THCV) and many others (55). In the living plant, these phytocannabinoids exist as both inactive monocarboxylic acids (e.g. THCA) and as active decarboxylated forms (e.g. THC); however, heating (at temperatures above 120 °C) promotes decarboxylation (e.g. THCA to THC) and results in biological activation (61,62,63). Furthermore, pyrolysis transforms each of the hundreds of compounds in cannabis into a number of other compounds, many of which remain to be characterized both chemically and pharmacologically. Therefore, marihuana (cannabis) can be considered a very crude drug containing a very large number of chemical and pharmacological constituents, the properties of which are only slowly being understood.

Among all the chemical constituents of cannabis, and particularly among the cannabinoids, Δ^9-THC is by far the best studied and is responsible for many, if not most, of the physical and psychotropic effects of cannabis (64). Other cannabinoids (such as CBD, CBC, CBG) are present in lesser amounts in the plant and have little, if any, psychotropic properties (64). It is reasonable to consider about 10% (range 1 - 30%) as an average for Δ^9-THC content in cannabis found on the illicit market in Canada (internal communication). The dried marihuana currently provided by Health Canada is composed of the mature flowering heads of female plants and contains 12.5 ±2% total THC (Δ^9-THC and Δ^9-THCA), and less than 0.5% CBD, CBG, CBN, and CBC (65). The MS-17/338 production line has THC concentrations typically higher than 10%, with the mature flowering heads containing the highest concentration of THC (65). The plant is cultivated and harvested in compliance with Good Manufacturing Practices, by Prairie Plant Systems Inc. under contract to Health Canada (66). Furthermore, the product is irradiated to ensure that users whose immune systems may be compromised are not exposed to toxic spores which may contaminate the plant material, and the finished product lot release is based on the results of bacterial, fungal, and moisture testing (65). Irradiated pouches containing the dried cannabis are kept sterile over long-term cold storage, with measures of viable microbes being below detection (Health Canada internal communication).

1.1.2 Other constituents

The large number of compounds found in cannabis span many chemical classes including cannabinoids, nitrogenous compounds, amino acids, proteins, enzymes, glycoproteins, hydrocarbons, simple alcohols, aldehydes, ketones and acids, fatty acids, simple esters and lactones, steroids, terpenes, non-cannabinoid phenols, flavonoids, vitamins, and pigments (55). Furthermore, differences in the presence and the relative abundance of some of these various components have been investigated, and differences have been noted between cannabis extract, vapour, and smoke, and also between cannabis varieties (67). Of note, cannabis smoke contains many compounds not observed in either extracts or vapour, including a number which are known or suspected carcinogens or mutagens (67,68,69). Moreover, comparisons between cannabis smoke and tobacco smoke have shown that the former contains many of the same carcinogenic chemicals found in tobacco smoke (68,70).

Relatively little is known about the pharmacological actions of the various other compounds found within cannabis (e.g. terpenes, flavonoids). However, it is believed that some of these compounds (e.g. terpenes) may have a broad spectrum of action (e.g. anti-oxidant, anti-anxiety, anti-inflammatory, anti-bacterial, anti-neoplastic, anti-malarial), but this information comes from a few *in vitro* and *in vivo* studies and no clinical trials exist to support these claims. Terpenes vary widely among cannabis varieties and are thought to be primarily responsible for differences in fragrance among the different *Cannabis* strains (59). Furthermore, it is thought that terpenes may contribute to the distinctive smoking qualities and possibly to the character of the "high" associated with smoking cannabis (59), but again, this has not been studied in any detail. The concept that terpenes may somehow modify or enhance the physiological effects of the cannabinoids (71,72) is, for the moment, hypothetical as there is little, if any, pre-clinical evidence to support this hypothesis and no clinical trials on this subject have been carried out to date.

1.1.3 Stability and storage

Most of the information on the stability of marihuana/cannabis does not distinguish between Δ^9-THC and its carboxylic acid (Δ^9-THCA). The latter is transformed to Δ^9-THC by heating during vapourization or cooking, or by pyrolysis during smoking or in the inlet of gas chromatographs used in forensic analysis (73). Heat, light, humidity, acidity and oxidation all affect the stability of cannabis and cannabinoids (74,75). The National Institute on Drug Abuse (NIDA) reports that retention samples of their carefully prepared and standardized cigarettes are stable for months, particularly when stored below 0 ^{o}C (-18 ^{o}C) in the dark, in tightly-closed containers (76). Even when stored at +18 ^{o}C, only a third of the THC content is lost over a five-year period with some increase in the concentration of CBN. Lower-potency cigarettes (1.15% THC) appear to lose more THC compared to higher potency cigarettes (2.87% THC) (76). Stability data for cannabis distributed by Health Canada indicate that, when stored in the refrigerator (4 °C ±1 °C) or freezer (-17 °C to -20 °C ±1°C), the finished product is stable for over 2 years without significant conversion of Δ^9-THCA to Δ^9-THC or any alterations in colour or aroma (Health Canada internal communication). The moisture content of the sealed, finished product is constant at 11 - 12% over a period of 12 months. When stored at room temperature (20 °C ± 2 °C), alterations in colour and aroma are detected in the finished product at 9 months, and conversion of Δ^9-THCA to Δ^9-THC is detected as early as 1.5 months, and increases to nearly 25% at 18 months (Health Canada internal communication). The ideal storage temperature for the finished dried cannabis product is 2 °C to 6 °C with a shelf-life of 12 months (Health Canada internal communication).

2.0 Clinical Pharmacology

2.1 Pharmacodynamics

Much of the pharmacodynamic information on cannabis refers to the effects of the major constituent Δ^9-THC which acts as a partial agonist at both CB receptors (77), has activity at non-CB receptors and other targets (78), and is responsible for the psychoactive effects of cannabis through its actions at the CB_1 receptor (79). Δ^8-THC (an isomer of Δ^9-THC) is found in smaller amounts in the plant (64), but like Δ^9-THC, it is a partial agonist at both CB receptors and shares relatively similar efficacy and potency with Δ^9-THC in *in vitro* assays (77). An *in vivo* animal study and one clinical study suggest Δ^8-THC to be a more potent anti-emetic than Δ^9-THC (80,81).

Cannabinol (CBN) is a product of Δ^9-THC oxidation and has 10% of the activity of Δ^9-THC (82). Its effects are not well studied but it appeared to have some possible immunosuppressive properties in a small number of *in vitro* studies (83). Cannabigerol (CBG) is a partial $CB_{1/2}$ receptor agonist and a small number of *in vitro* studies suggest it may have some anti-inflammatory and analgesic properties (44,82,84,85). It may also block 5-HT_{1A} receptors and act as an α_2-adrenoceptor agonist (86).

Cannabidiol (CBD) lacks detectable psychoactivity and does not appear to bind to either CB_1 or CB_2 receptors at physiologically meaningful concentrations, but it affects the activity of a significant number of other targets including ion channels, receptors, and enzymes (reviewed in (16,82,87)). Results from pre-clinical studies suggest CBD has anti-inflammatory, analgesic, anti-nausea, anti-emetic, anti-psychotic, anti-ischemic, anxiolytic, and anti-epileptiform effects (reviewed in (82,88)).

Tetrahydrocannabivarin (THCV) acts as a CB_1 receptor antagonist and CB_2 receptor partial agonist *in vitro* and *in vivo* (89,90), and pre-clinical studies suggest it may have anti-epileptiform/anti-convulsant properties (91).

Much of what is known about the beneficial properties of the non-psychotropic cannabinoids (e.g. CBD, THCV) is derived from *in vitro* and animal studies and few, if any, clinical studies of these substances exist. However, the results from these *in vitro* and animal studies point to potential therapeutic indications such as psychosis, epilepsy, anxiety, sleep disturbances, neurodegeneration, cerebral and myocardial ischemia, inflammation, pain and immune responses, emesis, food intake, type-1 diabetes, liver disease, osteogenesis, and cancer (reviewed in (16,82,92)). For more in-depth information on the pharmacology of cannabinoids, the reader is invited to consult the following resources (20,82,93).

Phytocannabinoid-Phytocannabinoid Interaction and Phytocannabinoid Differences among Cannabis Strains

Despite anecdotal claims, there is limited reliable information regarding real or potential interactions, of biological or physiological significance, among phytocannabinoids, especially Δ^9-THC and CBD. The limited information that exists is complex and requires further clarification through additional investigation. The following paragraphs summarize the available information on this subject.

Factors affecting the nature of the potential phytocannabinoid-phytocannabinoid interactions

Various studies have reported either potentiating, opposing, or neutral interactions between Δ^9-THC and CBD (94,95,96,97,98,99,100,101,102,103,104,105,106,107,108,109). The discrepancies in the nature of the interactions between Δ^9-THC and CBD reported in the literature may be explained by differences in the doses and ratios of THC and CBD used in the different studies, differences in the routes of administration, dose ordering effects (CBD pre-treatment vs. simultaneous co-administration), differences in the duration or chronicity of treatment (acute vs. chronic), differences in the animal species used, as well as the particular biological or physiological end-points being measured (110).

Pharmacokinetic vs. pharmacodynamic interactions

In general, there appear to be two types of mechanisms which could govern possible interactions between CBD and Δ^9-THC: those of a *pharmacokinetic* origin (102,110), and those of a *pharmacodynamic* origin (95,97). Despite the limited and complex nature of the available information, it generally appears that pre-administration of CBD may potentiate some of the effects of THC (through a pharmacokinetic mechanism), whereas simultaneous co-administration of CBD and THC may result in the attenuation of some of the effects of THC (through a pharmacodynamic mechanism). Furthermore, the ratio between the two phytocannabinoids also appears to play a role in determining whether the overall effect will be of a potentiating or antagonistic nature. CBD-mediated attenuation of THC-induced effects may be observed when the ratio of CBD to THC is at least 8 : 1 (±11.1) (96,109), whereas CBD appears to potentiate some of the effects associated with THC when the CBD to THC ratio is around 2 : 1 (±1.4) (109). Potentiation of THC effects by CBD may be caused by inhibition of THC metabolism in the liver, resulting in higher plasma levels of THC (102,110). There is virtually no information in the peer-reviewed scientific or medical literature concerning the effects of varying CBD to THC ratios in the treatment of different medical disorders.

Psychological and physiological effects associated with varying phytocannabinoid concentrations

There are only a handful of studies examining the neurophysiological, cognitive, subjective, or behavioural effects of varying the concentrations of Δ^9-THC, CBD, or other cannabinoids such as cannabichromene (CBC) in smoked cannabis (101,111). In one study, 24 healthy men and women who had reported using cannabis at least 10 times in their lifetime were subjected to a double-blind, placebo-controlled, mixed between- and within-subject clinical trial that showed that deliberate systematic variations in the levels of either CBD or CBC in smoked cannabis were not associated with any significant differences in any of the measured subjective, physiological, or performance tests (101). In another study, the subjective effects associated with the smoked or oral administration of cannabis plant material were directly compared to those associated with smoked or oral administration of Δ^9-THC (using matched doses of Δ^9-THC) to normal, healthy subjects (111). This double-blind, placebo-controlled, within-subject, crossover clinical study reported few reliable differences between the THC-only and whole-plant cannabis conditions (111). The authors further concluded that other cannabinoids present in the cannabis plant material did not alter the subjective effects of cannabis, but they speculated that cannabis samples with higher levels of cannabinoids or different ratios of the individual cannabinoids could conceivably produce different results, although no evidence to support this claim was provided in the study. They also hypothesized that whole-plant cannabis and THC alone could differ on other outcome measures more relevant to clinical entities (e.g. spasticity or neuropathic pain). With the possible exception of one study (112), (see section 4.6.2.3. Cancer Pain), which suggested differences between a whole-plant cannabis extract (i.e. nabiximols, marketed as Sativex®) and THC alone on cancer pain analgesia, no other clinical studies have examined this possibility. One study compared the subjective and physiological effects of oral THC to those of nabiximols in normal, healthy subjects (107). The authors reported the absence of any modulatory effect of CBD (or other components of cannabis) at low therapeutic cannabinoid doses, with the potential exception of the subjective "high" (107). An internet-based, cross-sectional study of 1 877 individuals with a consistent history of cannabis use reported that those individuals who had indicated using cannabis with a higher CBD to THC ratio had also reported experiencing fewer psychotic experiences (an effect typically associated with exposure to higher doses of THC) (113). However, the authors noted that the effects were subtle. The study was also hampered by a number of important methodological issues suggesting that the conclusions should be interpreted with caution. In summary, further careful study is required to elucidate the influence of CBD, and other phytocannabinoids or terpenoids, on the physiological or psychological effects associated with the use of Δ^9-THC, as well as on any medical disorders. There is presently insufficient scientific and clinical evidence to lend support to the anecdotal claims that one strain of cannabis may be more beneficial than another one for a particular medical condition.

Table 1 (next page), adapted from a review (114), notes some of the pharmacological effects of cannabis in the therapeutic dosage range. Many of the effects are biphasic, with increased activity with acute or smaller doses, and decreased activity with larger doses or chronic use (115,116,117). Effects differ greatly among individuals and may be greater in those who are severely ill, elderly, or those taking other drugs.

Most of the available information regarding the acute effects of smoking cannabis comes from studies conducted on recreational users, with much less information available from clinical studies of patients using cannabis for medical purposes. The acute effects of smoking or eating cannabis include euphoria (the marihuana "high") as well as cardiovascular, bronchopulmonary, ocular, psychological and psychomotor effects. Maximum euphoria typically occurs within 15 min after smoking and generally takes longer with oral administration (64). However, some people can experience dysphoria and anxiety (118). The effects on the cardiovascular system (tachycardia, etc.) decline much faster as THC is distributed out of the circulatory system. Tachycardia is the most consistent of the acute physiological effects associated with the consumption of cannabis (117,119,120,121) .

The short-term psychoactive effects associated with cannabis smoking in recreational users include the above-mentioned euphoria but also relaxation, time-distortion, intensification of ordinary sensory experiences (such as eating, watching films, and listening to music), and loss of inhibitions that may result in laughter (122). This is followed by a depressant period (123). While there is some inconsistency in reports regarding the acute effects of cannabis on memory and motor skills (124,125,126), most reviews note that cannabis use is associated with impaired function on a variety of cognitive and short-term memory tasks (83,123,127,128,129,130). The levels of Δ^9-THC in the plasma after smoking appear to have a dose, time, and concentration-dependent effect on cognitive function (131,132,133). Driving and operation of intricate machinery, including aircraft, may be significantly impaired (134,135,136,137).

Table 1: Pharmacologic Actions of Cannabis (adapted from (114) with additional references)

Body System/Effect	Detail of Effects
Central Nervous System (CNS)	
Psychological	Euphoria ("high"), dysphoria, anxiety, depersonalization, precipitation or aggravation of psychosis (64,117,118,138,139,140,141,142,143,144,145,146,147,148,149,150,151,152,153,154,155,156,157,158).
Perception	Heightened sensory perception, distortion of space and time sense, hallucinations, misperceptions (151,156,159,160,161,162,163).
Sedative	Generalised CNS depression, drowsiness, somnolence; additive with other CNS depressants (opioids/alcohol) (117,142,157,158,164,165,166,167,168,169,170,171,172,173,174) .
Cognition, psychomotor performance	Fragmentation of thoughts, mental clouding, memory impairment, global impairment of performance especially in complex and demanding tasks (101,129,134,135,136,137,157,174,175,176,177,178,179,180,181).
Motor function	Incoordination, ataxia, dysarthria, weakness (117,162,168,174,182,183) .
Analgesic	Modest effect for chronic non-cancer pain (142,157,158,164,165,168,172,173,184,185,186,187,188,189).
Anti-nausea/anti-emetic; hyper-emetic	Observed with acute doses (88,190,191,192)-- Tolerance may occur with chronic use (193). Hyperemesis may be observed with larger doses or chronic use (194,195,196,197,198,199,200,201,202,203,204).
Appetite	Increased in normal, healthy subjects, but also in patients suffering from HIV/AIDS-associated anorexia/cachexia (166,167,174,205,206,207,208,209).
Tolerance	To most behavioural and somatic effects, including the "high" (with chronic use) (210,211,212,213,214,215,216,217,218) and (see section 2.4).
Dependence, withdrawal syndrome	Dependence has been produced experimentally, and observed clinically, following prolonged intoxication ((122,156,210,219,220,221) and see section 2.4). Abstinence leads to withdrawal symptoms which can include anger, anxiety, restlessness, irritability, depressed mood, disturbed sleep, strange dreams, decreased appetite, and weight loss ((156,210,222) and also see section 2.4).
Cardiovascular and Cerebrovascular System	
Heart rate/rhythm	Tachycardia with acute dosage; tolerance developing with chronic exposure (117,119,120,121,157,158,223,224,225,226). Premature ventricular contractions, atrial fibrillation, ventricular arrhythmia also seen with acute doses (121,174,227,228,229,230,231).
Peripheral circulation	Vasodilatation, conjunctival redness, supine hypertension, postural hypotension (170,174,225,227,232,233,234).
Cardiac output	Increased cardiac output (227) and myocardial oxygen demand (232).
Cerebral blood flow	Increased with acute dose, decreased with chronic use, region-dependent variations (225,235).
Myocardial infarction	Increased risk of acute myocardial infarction within 1 h after smoking cannabis especially in individuals with existing cardiovascular disease (121,232).
Stroke	Increased risk of experiencing stroke after an acute episode of smoking cannabis (227,236,237).
Respiratory System	
Carcinogenesis/mutagenesis	Cannabis smoke contains many of the same chemicals as tobacco smoke, and cannabis smoke condensates are more cytotoxic and mutagenic than condensates from tobacco smoke (68,70). Conflicting evidence linking cannabis smoking and cancer (238,239,240,241).
Histopathologic changes/ inflammation	Chronic cannabis smoking associated with histopathologic changes in the lung (basal cell hyperplasia, stratification, goblet cell hyperplasia, cell disorganization, inflammation, basement membrane thickening, and squamous cell metaplasia) (242). Long-term smoking associated with

Body System/Effect	Detail of Effects
	cough, increased production of phlegm, and wheeze (243).
Bronchodilatation	Acute exposure causes dilatation; possibly reversed with chronic exposure (by smoking) (243).
Pulmonary function (FEV_1; FVC)	Acute, low-level exposure possibly stimulatory; long-term, heavy smoking possibly associated with increased obstruction and decreased lung function (243,244,245,246,247).
Gastrointestinal System	
General pharmacologic actions	Decreased gastrointestinal motility, decreased secretion, decreased gastric/colonic emptying, anti-inflammatory actions (31,157,189,248).
Liver	Increased risk of hepatic steatosis/fibrosis, especially in patients with Hepatitis C (33,249,250,251). Increased Hepatitis C treatment adherence resulting in a potential sustained absence of detectable levels of Hepatitis C virus (252).
Pancreas	Acute risk of pancreatitis with chronic, heavy, daily use (253,254,255,256).
Musculoskeletal system	
General pharmacologic actions	Possible beneficial effect in chronic pain from rheumatoid arthritis (257,258,259) and fibromyalgia (158,260,261). May attenuate spasticity from multiple sclerosis (164,165,188,262). May negatively impact bone healing (263).
Eye	
General pharmacologic actions	Decreased intra-ocular pressure (264,265).
Immune System	
General pharmacologic actions	Complex immunomodulatory effects with suppressive and/or stimulatory effects (acute and chronic dosing) (24,266).
Reproductive System	
Males	With chronic administration: anti-androgenic, decreased sperm count and sperm motility, altered sperm morphology in animals (and possibly in humans) (267,268). Tolerance to these effects may develop. Possible inhibitory effects on sexual behaviour in men (269).
Females	Effects inconclusive in women (possibly due to tolerance) but changes in menstrual cycle, suppression of ovulation, and complex effects on prolactin secretion observed in female animals (268,270,271). Dose-dependent stimulatory or inhibitory effects on sexual behaviour in women (269).

2.2 Pharmacokinetics

This section is restricted to human pharmacokinetics of smoked and vapourized cannabis, oral preparations including prescription cannabinoid medicines such as dronabinol (Marinol®) and nabiximols (Sativex®), and other routes of administration (e.g. rectal, topical).

2.2.1 Absorption

2.2.1.1 Smoked cannabis

Smoking cannabis results in more rapid onset of action (within minutes), higher blood levels of cannabinoids, and a shorter duration of pharmacodynamic effects compared to oral administration (62). The amount of Δ^9-THC delivered from cannabis cigarettes is not uniform and is a major variable in the assessment of absorption (62). Uncontrolled factors include the source of the plant material and the composition of the cigarette, together with the efficiency and method of smoking used by the subject (62,272). While it has been reported that smokers can titrate their Δ^9-THC intake by adapting their smoking behaviour to obtain desired levels of Δ^9-THC (273), other reasons may also explain the observed variation in smoking topography (274). Δ^9-THC absorption by inhalation is extremely rapid but quite variable, with a bioavailability of 2 - 56% through the smoking route depending on depth of inhalation, puff duration, and breathhold (275,276). In practice, a maximum of 25 - 27% of the THC content in a cannabis cigarette is absorbed or delivered to the systemic circulation from the total available amount (117,277).

Standardized cannabis cigarettes have been developed by the National Institute on Drug Abuse (NIDA), and the relationships among cannabis Δ^9-THC content, dose administered, and resultant plasma levels have been investigated. Mean plasma Δ^9-THC concentrations were 7.0 ±8.1 ng/mL and 18.1 ±12.0 ng/mL upon a single inhalation of either a 1.75% "low-dose" Δ^9-THC cannabis cigarette (total available dose ~16 mg Δ^9-THC), or a 3.55% Δ^9-THC "high-dose" cannabis cigarette (total available dose ~34 mg Δ^9-THC) (62). Smoking cannabis containing 1.64% Δ^9-THC (mean available dose 13.0 mg Δ^9-THC) resulted in mean peak THC plasma levels of 77 ng/mL (278). Similarly, smoking cannabis joints containing 1.8% Δ^9-THC (total available dose ~14 mg Δ^9-THC) resulted in mean peak plasma THC levels of approximately 75 ng/mL, whereas with 3.6% Δ^9-THC (total available dose ~28.8 mg Δ^9-THC), mean peak plasma Δ^9-THC levels of 100 ng/mL were attained (279). Smoking a 25 mg dose of cannabis containing 2.5, 6, or 9.4% Δ^9-THC (total available doses of ~0.6, 1.5, or 2.4 mg Δ^9-THC) was associated with mean peak plasma Δ^9-THC concentrations of 10, 25, or 45 ng/mL Δ^9-THC, respectively (172). Smoking one cannabis cigarette (mean weight 0.79 ±0.16 g) containing 6.8% ±0.2 THC, 0.25% ±0.08 CBD, and 0.21% ±0.02 CBN (w/w) yielding a total THC, CBD, and CBN content of 54, 2.0, and 1.7 mg of these cannabinoids per cigarette, respectively, was associated with a median whole blood THC concentration of approximately 60 ng/mL Δ^9-THC (range 13 - 63 ng/mL) (280).

2.2.1.2 Vapourized cannabis

Vapourization of cannabis has been explored as an alternative to smoking. The potential advantages of vapourization include the formation of a smaller quantity of toxic by-products such as carbon monoxide, polycyclic aromatic hydrocarbons (PAHs), and tar, as well as a more efficient extraction of Δ^9-THC from the cannabis material (273,281,282,283,284). The subjective effects and plasma concentrations of Δ^9-THC obtained by vapourization of cannabis are comparable to those obtained by smoking cannabis, with absorption being somewhat faster with the vapourizer compared to smoking, according to one study (273). In addition, the study reported that the vapourizer was well tolerated with no reported adverse effects, and was preferred over smoking by the test subjects (273). While vapourization has been reported to be amenable to self-titration (as has been claimed for smoking) (273,283), the proper use of the vapourizer for optimal administration of cannabis for therapeutic purposes needs to be established in more detail (284). The amount and type of cannabis placed in the vapourizer, the vapourizing temperature and duration of vapourization, and the balloon volume are some of the parameters that can affect the delivery of Δ^9-THC (283). Bioequivalence of vapourization compared to smoking has not been thoroughly established. Inhalation of vapourized cannabis (0.9 g of 3.56% Δ^9-THC; total available dose of 32 mg of Δ^9-THC) in a group of patients taking stable doses of sustained-release morphine or oxycodone resulted in mean plasma Δ^9-THC levels of 126.1 ng/mL within 3 min after starting cannabis inhalation, rapidly declining to 33.7 ng/mL Δ^9-THC at 10 min, and reaching 6.4 ng/mL Δ^9-THC at 60 min (187). Peak Δ^9-THC concentration was achieved at 3 min in all study participants (187). Maximal subjective "high" ratings occurred at 60 min following beginning of

inhalation, with a stronger and more sustained subjective "high" score for individuals taking oxycodone compared to those taking morphine (187). No statistically significant changes were reported for the AUC_{12} for either morphine or oxycodone, but there appeared to be a statistically significant decrease in the maximum concentration (C_{max}) of morphine sulfate, and a delay in the time needed to reach C_{max} for morphine during cannabis exposure (187).

2.2.1.3 Oral

Whereas the central nervous system and physiological effects occur within minutes by the smoking route or by vapourization (129,285), these effects proceed on a time scale of hours in the case of oral ingestion (285,286). Oral administration results in a slower onset of action, lower peak blood levels of cannabinoids, and a longer duration of pharmacodynamic effects compared to smoking (62). The psychotropic effect or "high" occurs much more quickly by the smoking than by the oral route, which is the reason why smoking appears to be the preferred route of administration by many, especially recreational users (287).

For orally administered prescription cannabinoid medicines such as synthetic Δ^9-THC (dronabinol, marketed as Marinol®), only 10 - 20% of the administered dose enters the systemic circulation indicating extensive first-pass metabolism (174). Administration of a single 2.5 mg dose of dronabinol in healthy volunteers was associated with a mean plasma Δ^9-THC C_{max} of 0.7 ng/mL (range: 0.3 - 1 ng/mL), and a mean time to peak plasma Δ^9-THC concentration of 2 h (range: 30 min - 4 h) (174). A single 5 mg dose of dronabinol gave a reported mean plasma Δ^9-THC C_{max} of 1.8 ng/mL (range: 0.4 - 3.3 ng/mL), whereas a single 10 mg dose yielded a mean plasma Δ^9-THC C_{max} of 6.2 ng/mL (range: 3.5 - 9 ng/mL) (174). Again, the mean time to peak plasma Δ^9-THC concentration ranged from 30 min - 3 h. Twice daily dosing of dronabinol (individual doses of 2.5 mg, 5 mg, 10 mg, b.i.d.) in healthy volunteers yielded plasma Δ^9-THC C_{max} values of 1.3 ng/mL (range: 0.7 - 1.9 ng/mL), 2.9 ng/mL (range: 1.2 - 4.7 ng/mL), and 7.9 ng/mL (range: 3.3 - 12.4 ng/mL), respectively, with a time to peak plasma Δ^9-THC concentration ranging between 30 min and 4 h after oral administration (174). Continuous dosing for seven days with 20 mg doses of dronabinol (total daily doses of 40 -120 mg dronabinol) gave mean plasma Δ^9-THC concentrations of ~20 ng/mL (288).

Δ^9-THC can also be absorbed orally by ingestion of foods containing cannabis (e.g. butters, oils, brownies, cookies), and teas prepared from leaves and flowering tops. Absorption from an oral dose of 20 mg Δ^9-THC in a chocolate cookie was described as slow and unreliable (272), with a systemic availability of only 4 - 12% (278). While most subjects displayed peak plasma Δ^9-THC concentrations (6 ng/mL) between 1 - 2 h after ingestion, some of the 11 subjects in the study only peaked at 6 h, and many had more than one peak (62). Consumption of cannabis-laced brownies containing 2.8% Δ^9-THC (44.8 mg total Δ^9-THC) was associated with changes in behaviour, although the effects were slow to appear and variable (286). Peak effects occurred 2.5 - 3.5 h after dosing. Modest changes in pulse and blood pressure were also noted. Plasma concentrations of Δ^9-THC were not measured in this study. In another study, ingestion of brownies containing a low dose of Δ^9-THC (9 mg THC/brownie) was associated with mean peak plasma Δ^9-THC levels of 5 ng/mL Δ^9-THC (111). Ingestion of brownies containing a high dose of Δ^9-THC (~13 mg Δ^9-THC/brownie) was associated with mean peak plasma Δ^9-THC levels of 6 or 9 ng/mL Δ^9-THC depending on whether the THC in the brownie came from plant material or was added as pure THC (111). Using equivalent amounts of Δ^9-THC, inhalation by smoking cannabis yielded peak plasma levels of Δ^9-THC several-fold (five to six times or more) higher than when Δ^9-THC was absorbed through the oral route (111). Tea made from dried cannabis flowering tops (19.1% Δ^9-THCA (tetrahydrocannabinolic acid), 0.6% Δ^9-THC) has been documented, but the bioavailability of Δ^9-THC from such teas is likely to be smaller than that achieved by smoking because of the poor water solubility of Δ^9-THC and the hepatic first-pass effect (289).

2.2.1.4 Oro-mucosal

Following a single oro-mucosal administration of nabiximols (Sativex®) (four sprays totalling 10.8 mg Δ^9-THC and 10 mg CBD), mean peak plasma concentrations of both THC (~5.5 ng/mL) and CBD (~3 ng/mL) typically occur within 2 - 4 h, although there is wide inter-individual variation in the peak cannabinoid plasma concentrations and in the time to onset and peak of effects (290). When administered oro-mucosally, blood levels of Δ^9-THC and other cannabinoids are lower than those achieved by inhalation of the same dose of smoked cannabis, but Δ^9-THC blood levels were comparable to those seen with oral administration of dronabinol (108,290). Oro-mucosal administration of nabiximols is amenable to self-titration (107,259,291,292).

2.2.1.5 Rectal

While Δ^9-THC itself is not absorbed through the rectal route, the pro-drug Δ^9-THC-hemisuccinate is absorbed; this fact, combined with decreased first-pass metabolism through the rectal route, results in a higher bioavailability of Δ^9-THC by the rectal route (52 - 61%) than by the oral route (293,294,295,296,297). Plasma concentrations of Δ^9-THC are dose and vehicle-dependent, and also vary according to the chemical structure of the THC ester (296). In humans, rectal doses of 2.5 - 5.0 mg of the hemisuccinate ester of Δ^9-THC were associated with peak plasma levels of Δ^9-THC ranging between 1.1 and 4.1 ng/mL within 2 - 8 h, and peak plasma levels of carboxy-Δ^9-THC ranging between 6.1 - 42.0 ng/mL within 1 - 8 h after administration (293).

2.2.1.6 Topical

Cannabinoids are highly hydrophobic, making transport across the aqueous layer of the skin the rate-limiting step in the diffusion process (62). No clinical studies exist regarding the percutaneous absorption of cannabis-containing ointments, creams, or lotions. However, some research has been carried out on transdermal delivery of synthetic and natural cannabinoids using a dermal patch (298,299). A patch containing 8 mg of Δ^8-THC yielded a mean steady-state plasma concentration of 4.4 ng/mL Δ^8-THC within 1.4 h in a guinea pig model, and this concentration was maintained for at least 48 h (298). Permeation of cannabidiol (CBD) and cannabinol (CBN) was found to be 10-fold higher than for Δ^8-THC (300).

2.2.2 Distribution

Distribution of Δ^9-THC is time-dependent and begins immediately after absorption. It is taken up primarily by fatty tissues and highly perfused organs such as the brain, heart, lung, and liver (62). Δ^9-THC has a large apparent volume of distribution, approximately 10 L/kg, because of its high lipid solubility (301). The plasma protein binding of Δ^9-THC and its metabolites is approximately 97% (302,303). Δ^9-THC is mainly bound to low-density lipoproteins, with up to 10% present in red blood cells (304), while the metabolite, 11-hydroxy THC is strongly bound to albumin with only 1% found in the free-fraction (305).

The highest concentrations of Δ^9-THC are found in the heart and in adipose tissue, with levels reaching 10 and 1000 times that of plasma, respectively (306). Despite the high perfusion level of the brain, the blood-brain barrier (BBB) appears to limit the access and accumulation of Δ^9-THC in this organ (62,307,308), and the delay in correlating peak plasma concentration to psychoactive effects may be attributed to the time required for Δ^9-THC to traverse this barrier (272).

Δ^9-THC accumulates and is retained in fatty tissue, and its release from this storage site into the blood is slow (307). It is not certain if Δ^9-THC persists in the brain in the long-term; however, the presence of residual cognitive deficits in abstinent heavy cannabis users raises the possibility that Δ^9-THC may be retained in the brain at least in the short-term (179,309). One animal study suggested food deprivation or adrenocorticotropic hormone (ACTH) administration in rats accelerates lipolysis and the release of Δ^9-THC from fat stores, however further research is needed to determine if these effects are associated with intoxication or behavioural/cognitive changes (310).

2.2.3 Metabolism

Most cannabinoid metabolism occurs in the liver, and different metabolites predominate depending on the route of administration (62,272). The complex metabolism of Δ^9-THC involves allylic oxidation, epoxidation, decarboxylation, and conjugation (272). Δ^9-THC is oxidized by the xenobiotic-metabolizing cytochrome P450 (CYP) mixed-function oxidases 2C9, 2C19, and 3A4 (62). The major initial metabolites of Δ^9-THC are the active 11-hydroxy Δ^9-THC, and the non-active 11-nor-9-carboxy Δ^9-THC (62). 11-hydroxy Δ^9-THC is rapidly formed by the action of the above-mentioned hepatic microsomal oxidases, and plasma levels of this metabolite parallel the duration of observable drug action (311,312).

As would be expected, oral administration of Δ^9-THC results in a greater metabolism of Δ^9-THC to the 11-hydroxy metabolite compared to administration by smoking (or vapourization), resulting in similar plasma concentrations of Δ^9-THC and 11-hydroxy Δ^9-THC through the oral route vs. inhalation (276). Information from the dronabinol (Marinol®) product monograph suggests that single doses of 2.5 mg, 5 mg, and 10 mg of Δ^9-THC in healthy volunteers result in mean plasma C_{max} values of 11-hydroxy Δ^9-THC of 1.19 ng/mL (range: 0.4 - 1.9 ng/mL), 2.23 ng/mL (range: 0.7 - 3.7 ng/mL), and 7.51 ng/mL (range: 2.25 - 12.8 ng/mL), respectively (174).

Twice daily dosing of dronabinol (individual doses of 2.5 mg, 5 mg, 10 mg, b.i.d.) in healthy volunteers resulted in mean plasma C_{max} values of 1.65 ng/mL (range: 0.9 - 2.4 ng/mL), 3.84 ng/mL (range: 1.5 - 6.1 ng/mL), and 7.95 ng/mL (range: 4.8 - 11.1 ng/mL) of 11-hydroxy Δ^9-THC, respectively (174). Time to reach C_{max} for 11-hydroxy Δ^9-THC ranged from 30 min - 4 h, with a mean of approximately 2.5 h (174). Importantly, 11-hydroxy Δ^9-THC has psychotomimetic properties equal to those of Δ^9-THC (276,313,314). The psycho-inactive 11-nor-9-carboxy Δ^9-THC is the primary acid metabolite of Δ^9-THC excreted in urine (315), and it is the cannabinoid often screened for in forensic analysis of body fluids (316,317).

CYP isozyme polymorphisms may also affect the pharmacokinetics of THC (and 11-nor-9-carboxy Δ^9-THC). For example, subjects homozygous for the *CYP2C9*3* allelic variant displayed significantly higher maximum plasma concentrations of Δ^9-THC, significantly higher area under the curve (AUC), and significantly decreased clearance among other measures compared to the *CYP2C9*1* homozygote or the **1/*3* heterozygote (318).

Xenobiotics are not only metabolized by CYPs but they also modulate the expression level and activity of these enzymes; CYPs are therefore a focal point in drug-drug interactions and adverse drug reactions (319). Polyaromatic hydrocarbons found in tobacco and cannabis smoke induce the expression of CYP1A2 (320), while Δ^9-THC, cannabidiol (CBD), and cannabinol (CBN) inhibit the activity of the CYP1A1, 1A2, and 1B1 enzymes (58). CBD has also been shown to inhibit the formation of Δ^9-THC metabolites catalyzed by CYP3A4, with less effect on CYP2C9 (301), albeit sufficiently to decrease the formation of 11-hydroxy THC (102,321).

Results from *in vitro* experiments also suggest that Δ^9-THC inhibits CYP3A4, CYP3A5, CYP2C9, and CYP2C19, while CBD inhibits CYP2C19, CYP3A4, and CYP3A5; however, higher concentrations than those seen clinically appear to be required for inhibition (58,290). While few clinical studies have specifically sought to evaluate cannabis-drug interactions *per se*, many, if not most, studies investigating the therapeutic effects of cannabis (e.g. smoked, vapourized, or orally ingested) and cannabinoid-based medicines (e.g. dronabinol, nabilone, nabiximols) have used patients that were concomitantly taking other medications (e.g. non-steroidal anti-inflammatory agents, opioids, anti-depressants, anti-convulsants, protease inhibitors) and, in general, did not report significantly increased incidences of severe adverse effects associated with the *combination* of cannabis or cannabinoids and these other medications. Nevertheless, clinicians should carefully monitor patients who are concomitantly consuming cannabis/cannabinoids and other medications that are metabolized by the above-mentioned enzymes.

The Sativex® product monograph cautions against combining Sativex® with amitriptyline or fentanyl (or related opioids) which are metabolized by CYP3A4 and 2C19 (290). Cannabis smoking, as well as orally administered dronabinol, may also affect the pharmacokinetics of anti-retroviral medications (322). In addition, and as seen with tobacco smoke, cannabis smoke has the potential to induce CYP1A2 thereby increasing the metabolism of xenobiotics biotransformed by this isozyme such as theophylline (323) or the anti-psychotic medicationsclozapine or olanzapine (324). **Further information on drug-drug interactions can be found in section 6.2.**

2.2.3.1 Inhalation

Plasma values of 11-hydroxy THC appear rapidly and peak shortly after Δ^9-THC, at about 15 min after the start of smoking (325). Peak plasma concentrations of 11-hydroxy THC are approximately 5% - 10% of parent THC, and the area under the curve (AUC) profile of this metabolite averages 10 - 20% of the parent THC (312). Similar results were obtained with intravenous THC administration (326).

Peak plasma values of 11-nor-9-carboxy THC occur 1.5 - 2.5 h after smoking, and are about one third the concentration of parent THC (325). Following oxidation, the phase II metabolites of the free drug or hydroxy-THC appear to be glucuronide conjugates (272).

2.2.3.2 Oral

After oral doses of Δ^9-THC, parent THC and its active metabolite 11-hydroxy- Δ^9-THC (which is similar to or possibly greater in potency than Δ^9-THC) are present in approximately equal concentrations in plasma (276,286,327). The plasma levels of active 11-hydroxy metabolite, achieved through oral administration, are about three times higher than those seen with smoking (312). Concentrations of both parent drug and metabolite peak between approximately 2 - 4 h after oral dosing, and decline over several days. Whole-body clearance of Δ^9-THC and its hydroxy metabolite averages about 0.2 L/kg-h, but is highly variable due to the complexity of cannabinoid distribution (174).

2.2.4 Excretion

Δ^9-THC levels in plasma decrease rapidly after cessation of smoking. Mean THC plasma concentrations are approximately 60% and 20% of peak plasma THC concentrations 15 and 30 min post-smoking (328), respectively, and are below 5 ng/mL THC 2 h after smoking (276). Elimination of THC and its metabolites occurs via the feces (65%) and the urine (20%) (62). After five days, 80% to 90% of the total dose is excreted (312). Nevertheless, THC from a single dose can be detected in plasma up to 13 days in chronic smokers probably due to extensive storage and release from body fat (329).

Following oral administration, THC and its metabolites are also excreted in both the feces and the urine (312,62). Biliary excretion is the major route of elimination, with about half of a radiolabelled THC oral dose being recovered from the feces within 72 h in contrast to the 10 to 15% recovered from urine (312).

The decline of Δ^9-THC levels in plasma is multi-phasic, and the estimates of the terminal half-life of Δ^9-THC in humans have progressively increased as analytical methods have become more sensitive (301). While figures for the terminal elimination half-life of Δ^9-THC appear to vary, it is probably safe to say that it averages at least four days and could be considerably longer (62). The variability in terminal half-life measurements are related to the dependence of this measure on assay sensitivity, as well as on the duration and timing of blood measurements (330). Low levels of THC metabolites have been detected for more than five weeks in the urine and feces of cannabis users (301). The degree of Δ^9-THC consumption does not appear to influence the plasma half-life of Δ^9-THC (272,331).

2.3 Pharmacokinetic-pharmacodynamic relationships

Much of the information on cannabinoid pharmacokinetic-pharmacodynamic relationships (mostly on Δ^9-THC) is derived from studies of recreational cannabis use rather than from studies looking at therapeutic use, but in either case, this relationship depends to some extent on the point in time at which observations are made following the administration of the cannabinoid. Furthermore, the temporal relationship between plasma concentrations of Δ^9-THC and the associated clinical/therapeutic, psychotropic, cognitive and motor effects is not well established. These effects often lag behind the plasma concentrations of Δ^9-THC, and tolerance is known to develop to some of the effects but not to others ((101,151,330) and also see (187) and section 2.4 (Tolerance and Dependence)).

As mentioned above, the relationship between dose (and plasma concentration) versus response for possible therapeutic applications are ill-defined, except for some information obtained for oral dosing with dronabinol (synthetic Δ^9-THC, marketed as Marinol®), nabiximols (a botanical cannabis extract containing approximately equal concentrations of Δ^9-THC and CBD as well as other cannabinoids, terpenoids and flavonoids, marketed as Sativex®), or nabilone (synthetic Δ^9-THC, analog marketed as Cesamet®) for their limited indications (174,290,332). Interpretations of the pharmacokinetics of Δ^9-THC are also complicated by the presence of active metabolites, particularly the psychoactive 11-hydroxy THC, which are found in higher concentrations after oral administration than after inhalation (286,327).

Target Δ^9-THC plasma concentrations have been derived based on the subjective "high" response that may or may not be related to the potential therapeutic applications. Various pharmacodynamic models provide blood plasma concentration estimates in the range of 7 - 29 ng/mL Δ^9-THC necessary for the production of a 50% maximal subjective "high" effect (330). Other studies suggest that Δ^9-THC plasma concentrations associated with 50% of the maximum "high" effect range between 2 and 250 ng/mL Δ^9-THC (median of 19 ng/mL; mean of 43 ng/mL Δ^9-THC) for the smoked or i.v. routes, while for the oral route the values range between 1 and 8 ng/mL Δ^9-THC (median and mean of 5 ng/mL Δ^9-THC) (111,333). Serum concentrations between 7 and 10 ng/mL (whole blood, approximately 3 - 5 ng/mL) have been compared to a blood-alcohol concentration of 0.05% which is associated with driver impairment (133).

Smoked cannabis

Simulation of multiple dosing with a 1% THC cigarette containing 9 mg Δ^9-THC yielded a maximal "high" lasting approximately 45 min after initial dosing, declining to 50% of peak at about 100 min following smoking (151). A dosing interval of 1 h with this dose would give a "continuous high", and the recovery time after the last dose would be 150 min (i.e. 2.5 h). The peak Δ^9-THC plasma concentration during this dosage is estimated at about 70 ng/mL.

One clinical study reported a peak increase in heart rate and perceived "good drug effect" within 7 min after test subjects smoked a 1 g cannabis cigarette containing either 1.8% or 3.9% THC (mean doses of Δ^9-THC being 18 mg or

39 mg, respectively) (129). Compared to the placebo, both doses yielded statistically significant differences in subjective and physiological measures; the higher dose was also significantly different from the lower dose for subjective effects, but not physiological effects such as heart rate. Pharmacokinetic-pharmacodynamic modelling of concentration-effect relationship of Δ^9-THC on CNS parameters and heart rate suggests that THC-evoked effects typically lag behind THC plasma concentration, with the effects lasting significantly longer than Δ^9-THC plasma concentrations (334). The equilibration half-life estimate for heart rate was approximately 7 min, but varied between 39 and 85 min for various CNS parameters (334). According to this model, the effects on the CNS developed more slowly and lasted longer than the effect on heart rate.

The psychomotor performance, subjective, and physiological effects associated with whole-blood Δ^9-THC concentrations in heavy, chronic, cannabis smokers following an acute episode of cannabis smoking has been studied (280). Subjects reported smoking a mean of one joint per day in the previous 14 days prior to the initiation of the study (range 0.7 - 12 joints per day) (280). During the study, subjects smoked one cannabis cigarette (mean weight 0.79 ±0.16 g) containing 6.8 ±0.2% THC, 0.25 ±0.08% CBD, and 0.21 ±0.02% CBN (w/w) yielding a total THC, CBD, and CBN content of 54, 2.0, and 1.7 mg of these cannabinoids per cigarette (280). Mean peak THC blood concentrations and peak visual analog scale scores for different subjective measures occurred 15 min after starting smoking (280). According to the authors of the study, the pharmacodynamic-pharmacokinetic relationship described a counter-clockwise hysteresis (i.e. where for the same plasma concentration of a drug (e.g. THC), the pharmacological effect is greater at a later time point than at an earlier one) for all measured subjective effects (e.g. "good drug effect", "high", "stoned", "stimulated", "sedated", "anxious", and "restless"). This particular kind of relationship demonstrates a lack of correlation between blood concentrations of THC and observed effects, beginning immediately after the end of smoking and continuing during the initial distribution and elimination phases (280). All participants reported a peak subjective "high" between 66 and 85 on the visual analog scale, with peak whole blood THC concentrations at the time of these responses ranging from 13 - 63 ng/mL (280). Following the start of cannabis smoking, heart rate increased significantly at the 30 min time point, diastolic blood pressure decreased significantly only from the 30 min to 1 h time point, and systolic blood pressure and respiratory rate were unaffected at any time (280).

Oral and oro-mucosal cannabinoids

The subjective and physiological effects after controlled administration of nabiximols (Sativex®) or oral THC have also been compared (107). Increases in systolic blood pressure occurred with low (5 mg) and high (15 mg) oral doses of THC, as well as low (5.4 mg Δ^9-THC and 5 mg CBD) and high (16.2 mg Δ^9-THC and 15 mg CBD) dose nabiximols, with the effect peaking at around 3 h after administration (107). In contrast, diastolic blood pressure decreased between 4 and 8 h after dosing. Heart rate increased after all active treatments. A statistically significant increase in heart rate relative to placebo was observed after high-dose oral THC (15 mg Δ^9-THC) and high-dose nabiximols (16.2 mg Δ^9-THC and 15 mg CBD), but the authors indicated that the increases appeared to be less clinically significant than those typically seen with smoked cannabis (107). High-dose oral THC (15 mg Δ^9-THC) and high-dose nabiximols (16.2 mg Δ^9-THC and 15 mg CBD) were associated with significantly greater "good drug effects" compared to placebo, whereas low-dose nabiximols (5.4 mg Δ^9-THC and 5 mg CBD) was associated with significantly higher "good drug effects" compared to 5 mg THC (107). A subjective feeling of a "high" was reported to be significantly greater after 15 mg oral THC compared to placebo and to 5 mg oral THC. In contrast, neither the high nor the low doses of nabiximols were reported to produce a statistically significant subjective "high" feeling. Study subjects reported being most "anxious" approximately 4 h after administration of 5 mg oral THC, 3 h after 15 mg oral THC, 5.5 h after low-dose nabiximols, and 4.5 h after high-dose nabiximols (107). All active drug treatments induced significantly more anxiety compared to placebo. After 15 mg oral THC, the concentration of THC in plasma was observed to have a weak, but statistically significant, positive correlation with systolic and diastolic blood pressure, "good drug effect", and "high" (107). After high-dose nabiximols, positive correlations were also observed between plasma THC concentrations and "anxious", "good drug effect", "high", "stimulated", and M-scale (marihuana-scale) scores (107). Consistent with other studies, the authors of this study reported that linear correlations between plasma THC concentrations and physiological or subjective effects were weak. Lastly, although cannabidiol did not appear to significantly modulate the effects of THC, the authors suggested it may have attenuated the degree of the subjective "high" (107).

2.4. Tolerance, dependence, and withdrawal symptoms

Tolerance

Tolerance, as defined by the Liaison Committee on Pain and Addiction (a joint committee with representatives from the American Pain Society, the American Academy of Pain Medicine, and the American Society of Addiction Medicine) is a state of adaptation in which exposure to the drug causes changes that result in a diminution of one or more of the drug's effects over time (335).

Tolerance to the effects of cannabis or cannabinoids appears to result mostly from pharmacodynamic rather than pharmacokinetic mechanisms (211). Pre-clinical studies indicate that *pharmacodynamic* tolerance is mainly linked to changes in the availability of the cannabinoid receptors, principally the CB_1 receptor, to signal. There are two independent but interrelated molecular mechanisms producing these changes: receptor desensitization (or uncoupling of the receptor from intra-cellular downstream signal transduction events), and receptor downregulation (resulting from the internalization and/or degradation of the receptor) (336). Furthermore, within the brain, tolerance appears to vary across different regions suggesting cellular and tissue-specific mechanisms regulating desensitization/downregulation (see review by Gonzalez et al. (211)). This may also hold true for other tissues or organs, explaining why tolerance develops to some of the effects of cannabis and cannabinoids but not to other effects. In animal models, the degree and time-course of tolerance appear to depend on the species used, the type of cannabinoid ligand, the dosage and duration of the treatment, and the measures employed to determine tolerance (211). *Pharmacokinetic* tolerance (including changes in absorption, distribution, biotransformation and excretion) has also been documented, but apparently occurs to a lesser degree than pharmacodynamic tolerance (337). In the clinical setting, tolerance to the effects of cannabis or cannabinoids can potentially be minimized by combining lower doses of cannabis or cannabinoids along with one or more additional therapeutic drugs (338).

Tolerance to most of the effects of cannabis and cannabinoids can develop after a few doses, and it also disappears rapidly following cessation of administration (118). In normal subjects, tolerance develops to the effects of cannabis on mood, intra-ocular pressure, EEG, psychomotor performance, nausea, as well as on the cardiovascular system (212,213). There is also some evidence to suggest that tolerance can develop to the effects of cannabis on sleep (reviewed in (161)). As mentioned above, the dynamics of tolerance vary with respect to the different effects; tolerance to some of the effects develops more readily and rapidly than to others (214,215). A positron emission tomography imaging study of chronic daily cannabis smokers reported reversible and regionally selective downregulation of brain cannabinoid CB_1 receptors (339). This finding could help explain the results obtained from a previously published double-blind, randomized, placebo-controlled study which showed that subjects who reported frequently using cannabis (*frequently* being defined in this study as a positive toxicological test result for cannabis at screening, at least 10 exposures to cannabis immediately prior to study initiation, and meeting DSM-IV criteria for cannabis use disorder) displayed blunted responses to the psychotomimetic, perceptual altering, cognitive impairing, anxiogenic, and cortisol-increasing effects of THC compared to controls, but notably not to its euphoric effects (216). Another study reported that tolerance to some of the effects of cannabis, including tolerance to the "high", developed both when THC was administered orally (30 mg; four times per day; total daily dose 120 mg) (207) and when a roughly equivalent dose was given by smoking (3.1% THC cigarette; four times per day) (340). Interestingly, there was no diminution of the appetite-stimulating effect from either route of administration.

An uncontrolled, open-label extension study of an initial five-week randomized trial of nabiximols in patients with multiple sclerosis and central neuropathic pain reported the *absence* of pharmacological tolerance (measured by a change in the mean daily dosage of nabiximols), even after an almost two-year treatment period in a group of select patients (217). Another long-term, open-label extension study of nabiximols in patients with spasticity caused by multiple sclerosis echoed these findings, also reporting the *absence* of pharmacological tolerance (measured by a change in the mean daily dosage of nabiximols) after almost one year of treatment (218).

Dependence and withdrawal

Dependence can be divided into two independent, but in certain situations interrelated concepts: physical dependence and psychological dependence (i.e. addiction) (335). Physical dependence, as defined by the Liaison Committee on Pain and Addiction, is a state of adaptation manifested by a drug-class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (190). Psychological dependence (i.e. addiction) is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations, and is characterized by behaviours that include one or more of the following: impaired control over drug use, compulsive use, continued use

despite harm, and craving (335). In the DSM-IV-TR, the term 'dependence' is closely related to the concept of addiction which may or may not include physical dependence, and is characterized by use despite harm, and loss of control over use (341).

There is evidence that cannabis dependence (physical and psychological) occurs especially with chronic, heavy use (122,156,210). The endocannabinoid system has been implicated in the acquisition and maintenance of drug taking behaviour, and in various physiological and behavioural processes associated with psychological dependence or addiction (2). Physical dependence is most often manifested in the appearance of withdrawal symptoms when use is abruptly halted or discontinued. Withdrawal symptoms associated with cessation of cannabis use (oral or smoked) appear within the first one to two days following discontinuation; peak effects typically occur between days 2 and 6 and most symptoms resolve within 1 - 2 weeks (342). The most common symptoms include anger or aggression, irritability, anxiety, nightmares/strange dreams, insomnia/sleep difficulties, craving, headache, restlessness, and decreased appetite or weight loss (156,210,222). Other symptoms appear to include depressed mood, chills, stomach pain, shakiness and sweating (156,210,222).

3.0 Dosing

General remarks

Cannabis has many variables that do not fit well with the typical medical model for drug prescribing (277). The complex pharmacology of cannabinoids, interindividual (genetic) differences in cannabinoid receptor structure and function, interindividual (genetic) differences in cannabinoid metabolism affecting cannabinoid bioavailability, prior exposure to and experience with cannabis/cannabinoids, pharmacological tolerance to cannabinoids, changes to cannabinoid receptor distribution/density and/or function as a consequence of a medical disorder, the variable potency of the cannabis plant material, and the different dosing regimens and routes of administration used in different research studies all contribute to the difficulty in reporting precise doses or establishing uniform dosing schedules for cannabis (and/or cannabinoids) (277,328).

While precise dosages have not been established, some "rough" dosing guidelines for smoked or vapourized cannabis have been published (see below). Besides smoking and vapourization, cannabis is known to be consumed in baked goods such as cookies or brownies, or drunk as teas or infusions. However, absorption of these products by the oral route is slow and erratic, and the onset of effects is delayed with the effects lasting much longer compared to smoking (see section 2.2); furthermore, dosages for orally administered products are even less well established than for smoking/vapourization (111,286,289,343). Other forms of preparation reported in the lay literature include cannabis-based butters, oils, compresses, creams, ointments, and tinctures (64,344,345,346,347) but again, no dosing information exists here and much of the information is anecdotal in nature.

Dosing remains highly individualized and relies to a great extent on titration (277). Patients with no prior experience with cannabis and initiating cannabis therapy for the first time are cautioned to begin at a very low dose and to stop therapy if unacceptable or undesirable side effects occur. Consumption of smoked/inhaled or oral cannabis should proceed slowly, waiting between puffs for a few minutes and waiting 30 - 60 min between bites of cannabis-based oral products (e.g. cookies, baked goods) to gauge for strength of effects or for possible overdosing.

Minimal therapeutic dose and dosing ranges

Information obtained from the monograph for Marinol® (dronabinol) indicates that **a daily oral dose as low as 2.5 mg Δ^9-THC is associated with a therapeutic effect (e.g. treatment of AIDS-related anorexia/cachexia)**. Naturally, dosing will vary according to the underlying disorder and the many other variables mentioned above. Dosing ranges for Marinol® (dronabinol) vary from 2.5 mg - 40 mg Δ^9-THC/day (174). Dosing ranges for Cesamet® (nabilone) vary from 0.2 mg - 6 mg/day (332,348). Dosing ranges for Sativex® (nabiximols) vary from one spray (2.7 mg Δ^9-THC and 2.5 mg CBD) to 16 sprays (43.2 mg Δ^9-THC to 40 mg CBD) per day (290,349).

Various surveys published in the peer-reviewed literature have suggested that the majority of people using smoked or orally ingested cannabis for medical purposes reported using between 10 - 20 g of cannabis per week or approximately 1 - 3 g of cannabis per day (165,277,350).

Monitoring

Currently, there are no clinical guidelines on monitoring patients who are taking cannabis for medical purposes.

3.1 Smoking

According to the World Health Organization (WHO) (351), a typical joint contains between 0.5 and 1.0 g of cannabis plant matter (average weight = 750 mg) which may vary in Δ^9-THC content between 7.5 and 225 mg (i.e. typically between 1 and 30%; see **Table 2**). The amount of other cannabinoids present, mainly cannabinol (CBN) and cannabidiol (CBD), is usually much lower. The actual amount of Δ^9-THC delivered in the smoke varies widely and has been estimated at 20 - 70%, the remainder being lost through combustion or side-stream smoke (277). Furthermore, the bioavailability of Δ^9-THC (the fraction of Δ^9-THC in the cigarette which reaches the bloodstream) from the smoking route is variable (2 - 56%) and influenced by the smoking topography (the number, duration, and spacing of puffs, hold time and inhalation volume) (276). In addition, expectation of drug reward can also influence smoking dynamics (352). Thus, the actual dose of Δ^9-THC absorbed systemically when smoked is not easily quantified but has been approximated to be around 25% of the total available amount of Δ^9-THC in a cigarette (117,277).

Relationship between a smoked dose and an oral dose

Little information exists regarding conversion of a "smoked dose" of THC to an equivalent oral dose, however multiplication of a "smoked dose" of Δ^9-THC by a conversion factor of 2.5 (to correct for differences between the bioavailability of Δ^9-THC through the smoked route (~25%) vs. the oral route (~10%)) can yield an approximately equivalent oral dose of Δ^9-THC (117). The "smoked dose" can be defined as the dose, in mg, of Δ^9-THC that is available in the *cigarette*. As an example, smoking a cigarette containing 75 mg Δ^9-THC by weight (see **Row 4** in **Table 2** [10% Δ^9-THC, 750 mg dried plant material]) would yield an estimated oral dose of 187.5 mg Δ^9-THC (75 mg Δ^9-THC X 2.5 = 187.5 mg Δ^9-THC). Please consult **Tables 3, 4 and 5** for further information regarding converting between smoked and oral doses of Δ^9-THC.

Table 2: Relationship between THC Percent in Plant Material and the Available Dose (in mg THC) in an Average Joint

% THC	**mg THC per 750 mg dried plant material* ("average joint")**
1	7.5
2.5	18.75
5	37.5
10†	75†
15	112.5
20	150
30	225

** WHO average weight*

† see text in section 3.1 for additional details

Table 3: Approximate Conversion Factors Smoked/Oral Δ^9-THC

	To Smoked Dose†	To Oral Dose‡
From Smoked Dose†		**Multiply** the dose of Δ^9-THC (in mg) in the dried plant material to be smoked by a factor of 2.5 to obtain the estimated dose of Δ^9-THC (in mg) to be ingested orally. (Smoked dose in mg X 2.5 = Oral dose in mg)
From Oral Dose‡	**Divide** the dose of Δ^9-THC (in mg) to be ingested orally by a factor of 2.5 to obtain the estimated dose of Δ^9-THC (in mg) to be smoked. (Oral dose in mg ÷ 2.5 = Smoked dose in mg)	

† A "smoked dose" can be defined as the total available amount of Δ^9-THC in a cannabis cigarette (calculated by multiplying the percentage of Δ^9-THC by the total gram amount of cannabis in the cigarette).
‡ An oral dose is defined as the total amount of Δ^9-THC that is ingested orally.

Table 4: Quick Reference of Smoked to Estimated Oral Doses of Δ^9-THC

"Smoked Dose"† % THC in a 750 mg cannabis cigarette (Total available mg Δ^9-THC)	**Estimated Oral Dose (mg Δ^9-THC)‡**
1 % THC (7.5 mg)	18.8 mg
2 % THC (15 mg)	37.5 mg
2.5 % THC (18.8 mg)	46.8 mg
3 % THC (22.5 mg)	56.3 mg
5 % THC (37.5 mg)	93.8 mg
7.5 % THC (56.3 mg)	140.6 mg
10 % THC (75 mg)	187.5 mg
12.5% THC (93.8 mg)	234.4 mg
15 % THC (112.5 mg)	281.3 mg
20 % THC (150 mg)	375 mg

† A "smoked dose" is defined as the total available amount (in mg) of Δ^9-THC in a standard cannabis cigarette (750 mg joint)
‡ An oral dose is defined as the total amount (in mg) of orally ingested Δ^9-THC

Numbers in the table are rounded to the nearest decimal place

Table 5: Quick Reference of Oral to Estimated Smoked Doses of Δ^9-THC

Oral Dose† (mg Δ^9-THC)	Estimated "Smoked Dose" ‡ (Total available mg Δ^9-THC in the dried plant material in the cigarette)
0.25	0.1
0.5	0.2
0.75	0.3
1	0.4
1.25	0.5
1.5	0.6
1.75	0.7
2	0.8
2.25	0.9
2.5	**1**
2.75	1.1
3	1.2
3.25	1.3
3.5	1.4
3.75	1.5
4	1.6
4.25	1.7
4.5	1.8
4.75	1.9
5	**2**
6	2.4
7	2.8
8	3.2
9	3.6
10	**4**
15	**6**
20	**8**
25	**10**
30	**12**
40	**16**
50	**20**
75	**30**
100	**40**

† An oral dose is defined as the total amount (in mg) of orally ingested Δ^9-THC
‡ A "smoked dose" is defined as the total available amount (in mg) of Δ^9-THC in a standard cannabis cigarette (750 mg joint)

Numbers in the table are rounded to the nearest decimal place

Table 6: Comparison between Cannabis and Prescription Cannabinoid Medications

Rx cannabinoids	Cannabinoid (Generic name)	Registered name	Principal constituents/ Source	Official status in Canada	Approved indications	Onset (O)/ Duration of action (D)	Route of admin.	Availability on provincial/ territorial formulary
	Dronabinol†	Marinol®†	Synthetic Δ^9-THC	Approved†	AIDS-related anorexia associated with weight loss; Severe nausea and vomiting associated with cancer chemotherapy	O: 30 - 60 min D: 4 - 6 h	Oral	MB†; NB†; NS†; ON†; PE†; QC†; YT†
	Nabilone	Cesamet®	Synthetic Δ^9-THC analogue	Approved	Severe nausea and vomiting associated with cancer chemotherapy	O: 60 - 90 min D: 8 - 12 h	Oral	AB; BC; MB; NB; NL; NS; NT; NU; ON; PE; QC; SK; YT.
	Nabiximols (THC+CBD and other minor cannabinoids, terpenoids, and flavonoids)	Sativex®	Botanical extract from established and well-characterized *C. sativa* strains	Approved *	*	O: 15 - 40 min D: 2 - 4 h	Oro-mucosal spray	NS.
Plant product	Cannabis (smoked)	N/A	*C. sativa (various)*	Not an approved product	N/A	O: 5 min D: 2 - 4 h	Smoking	N/A
	Cannabis (vapourized)	N/A	*C. sativa (various)*	Not an approved product	N/A	O: 5 min D: 2 - 4 h	Inhalation by vapourizer	N/A
	Cannabis (oral edible)	N/A	*C. sativa (various)*	Not an approved product	N/A	O: 30 - 60 min D: 8 - 12 h	Oral	N/A
	Cannabis (topical)	N/A	*C. sativa (various)*	Not an approved product	N/A	N/A	Topical	N/A

† Product has been discontinued by the manufacturer (post-market; as of February 2012; not for safety reasons)

*** For Sativex®, the following marketing authorizations apply:**

Standard marketing authorization: Adjunctive treatment for symptomatic relief of spasticity in adult patients with multiple sclerosis who have not responded adequately to other therapy and who demonstrate meaningful improvement during an initial trial of therapy.

Marketing authorization with conditions: Adjunctive treatment for symptomatic relief of neuropathic pain in adult patients with multiple sclerosis; and adjunctive analgesic treatment in adult patients with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain.

Plasma concentrations of Δ^9-THC following smoking

Using a paced smoking protocol, the mean plasma concentration of Δ^9-THC after a first inhalation of a cannabis cigarette containing 3.55% Δ^9-THC has been reported to be 18.1 ng/mL (range: 1.8 - 37.0 ng/mL), with the mean peak plasma concentration of Δ^9-THC reaching 162 ng/mL (range: 76 - 267 ng/mL) after seven puffs or almost complete smoking of the cigarette (276,328). Peak plasma concentrations of Δ^9-THC in the range of 50 - 100 ng/mL are associated with a subjective "high" ((279) and section 2.3) and can be easily attained by smoking a single 3.55% Δ^9-THC cannabis cigarette (900 mg plant material, 32 mg total available Δ^9-THC) (328). If the current average "street" marihuana contains 10% THC, joints from such a source might have an available 75 mg dose of Δ^9-THC and could result in rapid attainment of elevated plasma Δ^9-THC concentrations (> 100 ng/mL Δ^9-THC). More potent strains of cannabis could yield even higher plasma concentrations of THC.

Plasma concentrations of Δ^9-THC following smoking, and therapeutic efficacy

There are a small number of efficacy studies on the amounts of cannabis required for therapeutic effects (see **Table 7** for a quick overview, and information throughout this document for more detailed information). A Canadian dose-ranging study showed that a single inhalation of a 25 mg dose of smoked cannabis (Δ^9-THC content 9.4%; total available dose of Δ^9-THC = 2.35 mg) yielded a mean plasma Δ^9-THC concentration of 45 ng/mL within 2 min after initiating smoking (172). The study reported improvements in sleep and pain relief in patients suffering from chronic neuropathic pain (172). Using the above-mentioned conversion formula to translate smoked to estimated oral doses of Δ^9-THC, 2.35 mg Δ^9-THC in the dried plant material would correspond to an estimated oral dose of 5.9 mg Δ^9-THC.

Please consult **Tables 3, 4 and 5** for further information regarding converting between smoked and oral doses of Δ^9-THC. Please consult **Table 7** for a list of clinical trials of smoked cannabis and general details regarding those trials.

3.2 Oral

The pharmacokinetic information described in section 2.2.1.3 reports the erratic and slow absorption of Δ^9-THC from the oral route, and oral doses are estimated from the information in the monograph for Marinol® (dronabinol). A 10 mg b.i.d. dose of Marinol® (20 mg total Δ^9-THC per day) yielded a mean peak plasma Δ^9-THC concentration of 7.88 ng/mL (range: 3.33 - 12.42 ng/mL), with a bioavailability ranging between 10 and 20% (174). By comparison, consumption of a chocolate cookie containing 20 mg Δ^9-THC resulted in a mean peak plasma Δ^9-THC concentration of 7.5 ng/mL (range: 4.4 - 11 ng/mL), with a bioavailability of 6% (278). Tea prepared from *Cannabis* flowering tops and leaves has been documented, but no data are available regarding efficacy (289). To convert an oral dose to an estimated "smoked dose", the oral dose is divided by a conversion factor of 2.5 (117). Thus, an oral dose of 20 mg Δ^9-THC would be approximately equivalent to a "smoked dose" of 8 mg of Δ^9-THC. Please consult **Tables 3, 4 and 5** for further information regarding converting oral to smoked doses of Δ^9-THC.

Marinol

The Marinol® (dronabinol) product monograph suggests a mean of 5 mg Δ^9-THC/day (range: 2.5 - 20 mg Δ^9-THC/day) for AIDS-related anorexia associated with weight loss (174). A 2.5 mg dose may be administered before lunch, followed by a second 2.5 mg dose before supper. On the other hand, to reduce or prevent cancer chemotherapy-induced nausea or vomiting, a dosage of 5 mg t.i.d. or q.i.d. is suggested (174). In either case, the dose should be carefully titrated to avoid the manifestation of adverse effects. Please consult the drug product monograph for more detailed instructions.

Cesamet

The Cesamet® (nabilone) product monograph suggests administration of 1 - 2 mg of the drug, twice a day, with the first dose given the night before administration of the chemotherapeutic medication (332). A 2 mg dose of nabilone gave a mean plasma concentration of 10 ng/mL nabilone, 1 - 2 h after administration (332). The second dose is usually administered 1 - 3 h before chemotherapy. If required, the administration of nabilone can be continued up to 24 h after the chemotherapeutic agent is given. The maximum recommended daily dose is 6 mg in divided doses. Dose adjustment (titration) may be required in order to attain the desired response, or to improve tolerability. More recent clinical trials report starting doses of nabilone of 0.5 mg at night for pain or insomnia in fibromyalgia, and for insomnia in post-traumatic stress disorder (348,353,354). Please consult the drug product monograph for more detailed instructions.

3.3 Oro-mucosal

Dosing with nabiximols (Sativex®) is described in the product monograph along with a titration method for proper treatment initiation (290). Briefly, dosing indications in the drug product monograph suggest that on the first day of treatment patients take one spray during the morning (anytime between waking and noon), and another in the afternoon/evening (anytime between 4 pm and bedtime). On subsequent days, the number of sprays can be increased by one spray per day, as needed and tolerated. A fifteen minute time gap should be allowed between sprays. During the initial titration, sprays should be evenly spread out over the day. If at any time unacceptable adverse reactions such as dizziness or other CNS-type reactions develop, dosing should be suspended or reduced or the dosing schedule changed to increase the time intervals between doses. According to the product monograph, the average dose of nabiximols is five sprays per day (i.e. 13 mg Δ^9-THC and 12.5 mg CBD) for patients with multiple sclerosis, whereas those patients with cancer pain tend to use an average of eight sprays per day (i.e. 21.6 mg Δ^9-THC and 20 mg CBD) (290). The majority of patients appear to require 12 sprays or less; dosage should be adjusted as needed and tolerated (290). Administration of four sprays to healthy volunteers (total 10.8 mg Δ^9-THC and 10 mg CBD) was associated with a mean maximum plasma concentration varying between 4.90 - 6.14 ng/mL Δ^9-THC and 2.50 - 3.02 ng/mL CBD depending whether the drug was administered under the tongue or inside the cheek. Please consult the product monograph for more detailed information.

3.4 Vapourization

The Dutch Office of Medicinal Cannabis has published "rough" guidelines on the use of vapourizers (289). Although the amount of cannabis used per day needs to be determined on an individual basis, the initial dosage should be low and may be increased slowly as symptoms indicate. The amount of cannabis to be placed in the vapourizer may vary depending on the type of vapourizer used. Studies using the Volcano® vapourizer have reported using up to 1 g of dried cannabis in the chamber, but 50 to 500 mg of plant material is typically used (284); Δ^9-THC concentrations up to 6.8% have been tested (273,284). Subjects appeared to self-titrate their intake in accordance with the Δ^9-THC content of the cannabis (273). Peak plasma Δ^9-THC levels varied between 70 - 190 ng/mL depending on the strength of Δ^9-THC. The levels of cannabinoids released into the vapour phase increased with the temperature of vapourization (284). Vapourization temperature is typically between 180 - 195°C (289); higher temperatures (e.g. 230°C) greatly increase the amounts of cannabinoids released, but also increase the amounts of by-products (284).

4.0 Potential Therapeutic Uses

While there are many anecdotal reports concerning the therapeutic value of cannabis, clinical studies supporting the safety and efficacy of smoked cannabis for therapeutic purposes in a variety of disorders are limited, but slowly increasing in number. There are no clinical studies on the use of cannabis edibles (e.g. cookies, baked goods) or topicals for therapeutic purposes. It has been repeatedly noted that the psychotropic side effects associated with the use of cannabinoids have been found to limit their therapeutic utility (21,48,50,185,355). **Table 7** summarizes the information on published clinical trials that have been carried out thus far using smoked/vapourized cannabis.

Dronabinol is the generic name for the oral form of synthetic Δ^9-THC and is marketed in the U.S. and Canada as Marinol®. It is sold in capsules containing 2.5, 5, or 10 mg of the drug dissolved in sesame oil. It is indicated for the treatment of severe nausea and vomiting associated with cancer chemotherapy, and for AIDS-related anorexia associated with weight loss (174). The drug appears to no longer be sold in Canada (post-market discontinuation of the drug product as of February 2012; not for safety reasons).

Nabilone is the generic name for an orally administered synthetic structural analogue of Δ^9-THC which is marketed in Canada as Cesamet®. It is sold as capsules (0.25, 0.5, 1 mg) and is indicated for severe nausea and vomiting associated with cancer chemotherapy (332).

Nabiximols is the generic name for a whole-plant extract of two different, but standardized, strains of *Cannabis sativa* giving an oro-mucosal spray product containing approximately equivalent amounts of Δ^9-THC (27 mg/mL) and CBD (25 mg/mL), and other cannabinoids, terpenoids, and flavonoids per 100 µl of dispensed spray. Nabiximols is marketed as Sativex® in Canada and has received a notice of compliance for use as an adjunctive treatment for the symptomatic relief of spasticity in adult patients with multiple sclerosis who have not responded adequately to other therapy, and who demonstrate meaningful improvement during an initial trial of therapy. It is also marketed (with conditions) as an adjunctive treatment for the symptomatic relief of neuropathic pain in adults with multiple sclerosis and (with conditions) as an adjunctive analgesic in adult patients with advanced

cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain (290).

The existing scientific and clinical evidence for cannabis and certain cannabinoids in treating various symptoms associated with various medical conditions is summarized in the following sections beginning on the next page.

Table 7: Published Clinical Trials on Smoked/Vapourized Cannabis and Associated Therapeutic Benefits

Primary medical conditions and associated secondary end-points (if any) for which <u>benefits</u> were observed	**Percent and dose of Δ^9-THC (if known)**	**Trial duration; and number of patients/participants**	**Reference**
HIV/AIDS-associated weight loss	1 cannabis cigarette (~800 mg) containing 1.8% or 3.9% THC by weight, smoked once daily (i.e. one dose per day) (~14-31 mg Δ^9-THC /day)	8 sessions total (3 sessions per week); 30 participants	(166)
HIV/AIDS-associated weight loss; disease-associated mood and insomnia	1 cannabis cigarette (~800 mg) containing 2.0% or 3.9% THC by weight, smoked four times per day (i.e. 4 doses per day) (~64-125 mg of Δ^9-THC /day)	4 days total; 10 participants	(167)
Multiple sclerosis-associated pain and spasticity	1 cannabis cigarette (~800 mg) containing 4% THC by weight, smoked once per day (i.e. one dose per day) (~32 mg Δ^9-THC /day)	3 days total; 30 patients	(188)
Central and peripheral chronic neuropathic pain (various etiologies)	1 cannabis cigarette (~800 mg) containing either 3.5% or 7% THC by weight, smoked in bouts over a 3 h period (i.e. one dose per day)	1 day total; 38 patients	(168)
Chronic neuropathic pain from HIV-associated sensory neuropathy	1 cannabis cigarette (~900 mg) containing 3.56% THC by weight, smoked three times daily (i.e. 3 doses per day) (~96 mg Δ^9-THC /day)	5 days total; 25 patients	(142)
HIV-associated chronic neuropathic pain refractory to other medications	1 cannabis cigarette (~800 mg) containing between 1 and 8% THC by weight, smoked four times daily (i.e. 4 doses per day)	5 days total; 28 patients	(186)
Chronic post-traumatic or post-surgical neuropathic pain refractory to other medications and associated insomnia	One 25 mg dose of cannabis containing 9.4% THC by weight, smoked three times daily (i.e. three doses per day) (~7 mg Δ^9-THC /day)	5 days total; 21 patients	(172)
Chronic pain of various etiologies (musculoskeletal, post-traumatic, arthritic, peripheral neuropathy, cancer, fibromyalgia, migraine, multiple sclerosis, sickle cell disease, thoracic outlet syndrome)	One 0.9 g dose of vapourized cannabis containing 3.56% THC by weight administered three times per day (one dose the first day, three doses per day for next three days, one dose the last day) (~96 mg Δ^9-THC /day)	5 days total; 21 patients	(187)

4.1 Palliative Care

Among the goals of palliative care described by the World Health Organization (WHO) are relief from pain and other distressing symptoms, and the enhancement of quality of life (356). While integration of cannabis into mainstream medical use can be characterized as extremely cautious, its use appears to be gaining some ground in palliative care settings where the focus is on individual choice, patient autonomy, empowerment, comfort and especially quality of life (357). Nevertheless, establishing the effectiveness of cannabis as a viable treatment option in a palliative care context requires a careful assessment of its effects in a wide range of conditions; such evidence is not yet abundant and further research is needed (358). Furthermore, while prescription cannabinoids demonstrate an acceptable safety profile according to some studies for certain medical conditions, the use of cannabis and cannabinoids in the clinic is known to be limited by their psychotropic effects (21,209,359). Certain patient populations (e.g. the elderly or those suffering from pre-existing psychiatric disease) may be also be more sensitive or susceptible to experiencing adverse psychotropic, cognitive, psychiatric or other effects (359,360).

The evidence thus far suggests that cannabis and prescription cannabinoids (e.g. dronabinol, nabilone, or nabiximols) may be useful in alleviating a wide variety of single or co-occurring symptoms often encountered in the palliative care setting; these symptoms include intractable nausea and vomiting associated with chemotherapy or radiotherapy, anorexia/cachexia, severe intractable pain, severe depressed mood, and insomnia (208,209). The use of cannabinoids for palliative care may also result in a decrease in the number of medications used by this patient population (208).

For information on the use of cannabis/cannabinoids for the **control of nausea and vomiting** please consult section 4.2 of this document. For additional information on the use of cannabis/cannabinoids for **anorexia/cachexia associated with HIV/AIDS infection or cancer** please consult sections 4.3.1 and 4.3.2, respectively. For further information on the use of cannabis/cannabinoids for **chronic pain syndromes** (including cancer pain) please consult sections 4.6.2.2 and 4.6.2.3. For further information on the use of cannabis/cannabinoids in the treatment of **sleep disorders associated with chronic diseases** please see section 4.8.5.2, and please consult section 4.8.9 for information on the use of cannabis/cannabinoids in **oncology**.

Quality of Life

A handful of clinical studies have used standardized quality-of-life (QoL) instruments to measure whether the use of cannabis or prescription cannabinoids (e.g. nabilone, dronabinol, or nabiximols) is associated with improvements in QoL. The available studies report mixed effects of cannabis and cannabinoids on measures of QoL for a variety of different disorders. The evidence from these studies is summarized below.

Clinical studies with dronabinol

A randomized, double-blind, placebo-controlled, crossover trial of dronabinol (maximum dose of 10 mg Δ^9-THC per day, for a total of three weeks) for the treatment of central neuropathic pain in patients suffering from multiple sclerosis reported statistically significant improvements in measures of QoL (SF-36 quality of life questionnaire; measures for bodily pain and mental health) (361).

A two-centre, phase II, randomized, double-blind, placebo-controlled 22-day pilot study carried out in adult patients suffering from chemosensory alterations (i.e. changes in olfaction and gustation) and poor appetite associated with advanced cancer of various etiologies reported improved and enhanced chemosensory perception among patients treated with dronabinol (2.5 mg b.i.d.) compared to those receiving placebo (362). The majority (73%) of dronabinol-treated patients self-reported an increased overall appreciation of food compared to those receiving placebo (30%). While global scores on the Functional Assessment of Anorexia-Cachexia Therapy (FAACT) QoL instrument improved to a similar extent for dronabinol and placebo-treated groups, the FAACT sub-domain for anorexia-cachexia-related nutritional well-being improved with dronabinol compared to placebo (362). Statistically significant improvements were also noted for quality of sleep and relaxation with dronabinol treatment compared to placebo (362). According to the study authors, negative psychoactive effects were minimized by starting patients at a low dose (2.5 mg once a day for three days) followed by gradual dose escalation (up to a maximum of 7.5 mg dronabinol per day) (362).

Clinical studies with cannabis extract

A multi-centre, phase III, randomized, double-blind, placebo-controlled, three-arm, parallel study in adult patients with advanced incurable cancer and suffering from cancer-related anorexia-cachexia syndrome concluded that neither cannabis extract (2.5 mg Δ^9-THC, 1 mg CBD, for six weeks) nor THC (2.5 mg Δ^9-THC b.i.d., for six weeks) provided any statistically significant benefit compared to placebo on measures of QoL (EORTC QLQ- C30) (363).

Clinical studies with nabilone
A randomized, double-blind, placebo-controlled trial of nabilone in patients suffering from fibromyalgia reported that adjuvant nabilone therapy (four weeks; maximum dose in the final week of treatment: 1 mg b.i.d.) was associated with a significant improvement in measures of QoL (Visual Analogue Scale for pain, and the Fibromyalgia Impact Questionnaire) (353). An enriched-enrolment, randomized withdrawal, flexible-dose, double-blind, placebo-controlled, parallel-assignment efficacy study of nabilone as an adjuvant in the treatment of long-standing diabetic peripheral neuropathic pain reported statistically significant improvements in measures of QoL (Composite EQ-5D Index Score) and overall patient status compared to placebo (364). Doses of nabilone ranged from 1 - 4 mg/day; treatment duration was five weeks (364).

Clinical studies with nabiximols
A ten-week, prospective, randomized, double-blind, placebo-controlled trial assessing the safety and efficacy of nabiximols (Sativex®) as an adjunctive medication in the treatment of intractable diabetic peripheral neuropathy concluded that nabiximols failed to show statistically significant improvements in measures of QoL (EuroQOL, SF-36, and the McGill Pain and QOL Questionnaire) (365). A twelve-week, double-blind, randomized, placebo-controlled, parallel-group, enriched enrolment study of nabiximols as add-on therapy for patients with refractory spasticity concluded that there was no significant difference between active treatment and placebo on measures of QoL (EQ-5D Health State Index, EQ-5D Health Status VAS, SF-36) (366). A five-week, multi-centre, randomized, double-blind, placebo-controlled, parallel-group, graded-dose study evaluated the analgesic efficacy and safety of nabiximols in three dose ranges in opioid-treated cancer patients with poorly-controlled chronic pain (349). The study reported the lack of any positive treatment effects on overall QoL in this study population even at the highest doses of nabiximols (11 - 16 sprays per day) (349).

Clinical studies with smoked cannabis
A randomized, double-blind, placebo-controlled, four-period, cross-over trial of smoked cannabis in the treatment of chronic neuropathic pain (chronic post-traumatic or post-surgical etiology) concluded that inhalation of smoked cannabis (25 mg of cannabis containing 2.5, 6.0, or 9.4% Δ^9-THC, t.i.d. for five days) was not associated with a statistically significant difference compared to placebo on measures of QoL (EQ-5D Health Outcomes Quality of Life instrument) (172). In contrast, a cross-sectional survey examining the benefits associated with cannabis use in patients with fibromyalgia reported a statistically significant benefit in the mental health component summary score of the SF-36 Quality of Life questionnaire in patients who used cannabis compared to non-users (158). However, no significant differences between cannabis and non-cannabis users were found in the other SF-36 domains, in the Fibromyalgia Impact Questionnaire, or the Pittsburgh Sleep Quality Index (158).

A preliminary observational, open-label, prospective, single-arm trial in a group of 13 patients suffering from Crohn's disease or ulcerative colitis reported that treatment with inhaled cannabis over a three-month period improved subjects' quality of life, caused a statistically significant increase in subjects' weight, and improved the clinical disease activity index in patients with Crohn's disease (189). Patients reported a statistically significant improvement in their perception of their general health status, their ability to perform daily activities, and their ability to maintain a social life (189). Patients also reported a statistically significant reduction in physical pain as well as improvement in mental distress (189).

4.2 Nausea and vomiting
Chemotherapy-induced nausea and vomiting (CINV) is one of the most distressing and common adverse events associated with cancer treatment (367). While chemotherapy-induced vomiting generally appears to be well-controlled with current first-line therapies, the associated acute, delayed, or anticipatory nausea remain more poorly controlled and the use of cannabis/cannabinoids may provide some measure of benefit in certain cases (88,192). It is important to note that excessive use of cannabis has been reported to paradoxically trigger a chronic cyclic vomiting syndrome (i.e. hyperemesis) (see section 7.6.1 for further details on this syndrome).

Pre-clinical studies
Patient claims that smoked cannabis relieves CINV are widely recognized, and increasing evidence suggests a role for the endocannabinoid system in the regulation of nausea and vomiting (88). Cannabinoid CB_1 and CB_2 receptors have been found in areas of the brainstem associated with emetogenic control (368,369), and results from animal studies suggest the anti-nausea and anti-emetic properties of cannabinoids (e.g. Δ^9-THC, dronabinol, nabilone) are most likely related to their agonistic actions at CB_1 receptors (80,88,370). An *in vivo* animal study and one small clinical study

have also suggested Δ^8-THC to be a more potent anti-emetic than Δ^9-THC (80,81). In addition to its actions at CB_1 receptors, an *in vitro* study has also shown that Δ^9-THC antagonizes the 5-HT_3 receptor (371), a target of standard anti-emetic drugs, raising the possibility that cannabinoids may exert their anti-emetic action through more than one mechanism. More recently, studies carried out in animal models of nausea and vomiting have shown that cannabidiol (5 mg/kg, s.c.) suppressed nicotine, lithium chloride, and cisplatin-induced vomiting in the shrew; lithium chloride-induced conditioned gaping was suppressed in rats through a yet-to-be identified, but probably indirect, activation of somatodendritic 5-HT_{1A} autoreceptors located in the dorsal raphe nucleus (372). Another study showed that the anti-nausea/vomiting effects of cannabidiol could be reversed by pre-treatment with cannabigerol (5 mg/kg, i.p.) (373).

Clinical studies

The evidence for cannabinoids such as nabilone (Cesamet®), dronabinol (Marinol®), and levonantradol in treating CINV has been reviewed (159,374). While cannabinoids present clear advantages over placebo in the control of CINV, the evidence from randomized clinical trials shows cannabinoids to be clinically only slightly better than conventional dopamine D2-receptor antagonist anti-emetics (159,374). In some cases, patients appeared to prefer the cannabinoids over these conventional therapies despite the increased incidence of adverse effects such as drowsiness, dizziness, dysphoria, depression, hallucinations, paranoia, and arterial hypotension. This may be explained in part by the notion that for certain patients a degree of sedation and euphoria may be perceived as beneficial during chemotherapy.

While no peer-reviewed clinical trials of smoked cannabis for the treatment of CINV exist, Musty and Rossi have published a review of U.S. state clinical trials on the subject (191). Patients who smoked cannabis showed a 70 - 100% relief from nausea and vomiting, while those who used a Δ^9-THC capsule experienced 76 - 88% relief (191). Plasma levels of > 10 ng/mL Δ^9-THC were associated with the greatest suppression of nausea and vomiting, although levels ranging between 5 and 10 ng/mL were also effective (191). In all cases, patients were admitted only after they failed treatment with standard phenothiazine anti-emetics. A small clinical trial comparing smoked cannabis (2.11% Δ^9-THC, in doses of 8.4 mg or 16.9 mg Δ^9-THC; 0.30% cannabinol; 0.05% cannabidiol) to ondansetron (8 mg) in ipecac-induced nausea and vomiting in healthy volunteers showed that both doses of Δ^9-THC reduced subjective ratings of queasiness and objective measures of vomiting; however, the effects were very modest compared to ondansetron (192). Furthermore, only cannabis produced changes in mood and subjective state.

Few, if any, clinical trials directly comparing cannabinoids to newer anti-emetics such as 5-HT_3 (Ondansetron, Granisetron) or NK-1 receptor antagonists have been reported to date (367,374). In one clinical study with a small sample size, ondansetron and dronabinol (2.5 mg Δ^9-THC first day, 10 mg second day, 10 - 20 mg thereafter) provided equal relief of delayed CINV, and the combination of dronabinol and ondansetron did not provide added benefit beyond that observed with either agent alone (375). However, two animal studies showed that low doses of Δ^9-THC, when combined with low doses of the 5-HT_3 receptor antagonists ondansetron or tropisetron, were more efficacious in reducing nausea and emesis frequency than when administered individually (376,377). More research is required to determine if combination therapy provides added benefits above those observed with newer standard treatments.

The use of cannabinoids (whether administered orally or by smoking cannabis) is currently considered a fourth-line adjunctive therapy in CINV when conventional anti-emetic therapies have failed (285,378,379,380,381,382). Nabilone (Cesamet®) and dronabinol (Marinol®) are indicated for the management of severe nausea and vomiting associated with cancer chemotherapy (174,332). Nabilone may be administered orally every 12 h at dosages ranging from 1 - 2 mg, whereas dronabinol may be administered every 6 - 8 h orally, rectally, or sub-lingually at doses ranging from 5 - 10 mg (208,383).

The current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana in the context of cancer chemotherapy-associated nausea and vomiting as well as nausea and vomiting associated with HIV/AIDS infection in patients who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

4.3 Wasting syndrome (cachexia, e.g., from tissue injury by infection or tumour) and loss of appetite (anorexia) in AIDS and cancer patients, and anorexia nervosa

The ability of cannabis to increase appetite has been recognized anecdotally for many years (206). In addition, results from epidemiological studies suggest that people actively using cannabis have higher intakes of energy and nutrients than non-users (385). Controlled laboratory studies with healthy subjects suggest exposure to cannabis, whether by inhalation or oral ingestion of Δ^9-THC-containing capsules, correlates positively with an increase in food consumption, caloric intake, and body weight (205,206). Studies showing a high concentration of CB_1 receptors in brain areas associated with control of food intake and satiety lend further support to the link between cannabis consumption and appetite regulation (386,387,388). Furthermore, increasing evidence suggests a role for the endocannabinoid system not only in modulating appetite, food palatability, and intake, but also in energy metabolism and the modulation of both lipid and glucose metabolism (reviewed in (17,387,388,389)).

4.3.1 To stimulate appetite and produce weight gain in AIDS patients

The ability of cannabis to stimulate appetite and food intake has been applied to clinical situations where weight gain is deemed beneficial such as in HIV-associated muscle wasting and weight loss. One study (166) showed that experienced HIV+ cannabis smokers with clinically significant muscle mass loss benefited from both dronabinol (four to eight times the standard 2.5 mg Δ^9-THC b.i.d dose, or 10 - 20 mg Δ^9-THC daily, three times per week for a total of eight sessions) and smoked cannabis (three puffs at 40 sec intervals; ~800 mg cigarettes containing 1.8 - 3.9% THC giving an estimated total daily amount of 14.4 mg - 31.2 mg THC *in the cigarette*, three times per week, for a total of eight study sessions). A subsequent study employed even higher doses of dronabinol (20 - 40 mg total Δ^9-THC daily, for a total of four days) and smoked cannabis (~800 mg cannabis cigarettes containing 2 and 3.0% THC, administered four times per day, giving an estimated 64 - 125 mg total Δ^9-THC daily *in the cigarette*, for a total of four days) (167). Both drugs produced substantial and comparable increases in food intake and body weight, as well as improvements in mood and sleep (166,167). The cannabis-associated increase in body weight appeared to result from an increase in body fat rather than lean muscle mass (390,391). On the other hand, a randomized, open-label, multi-center study to assess the safety and pharmacokinetics of dronabinol and megestrol acetate (an orexigenic), alone or in combination, found that only the high-dose megestrol acetate treatment alone (750 mg/day), but not dronabinol (2.5 mg b.i.d, 5 mg total Δ^9-THC/day) alone or the combination of low-dose megestrol acetate (250 mg/day) and dronabinol (2.5 mg b.i.d, 5 mg total Δ^9-THC/day), produced a significant increase in mean weight over 12 weeks of treatment in patients diagnosed with HIV-associated wasting syndrome (392). The lack of an observed clinical effect in this study could have been caused by too low a dose of dronabinol.

AIDS-related anorexia associated with weight loss is an approved indication in Canada for dronabinol (Marinol®). The Marinol® product monograph summarizes a six-week, randomized, double-blind, placebo controlled-trial in 139 patients, with the 72 patients in the treatment group initially receiving 2.5 mg dronabinol twice a day, then reducing the dose to 2.5 mg at bedtime due to side effects (feeling high, dizziness, confusion and somnolence) (393). Over the treatment period, dronabinol significantly increased appetite, with a trend towards improved body-weight and mood and a decrease in nausea. At the end of the six-week period, patients were allowed to continue receiving dronabinol, during which appetite continued to improve (394). This secondary, open-label, 12 month follow-up study suggested that dronabinol was safe and effective for long-term use for the treatment of anorexia associated with weight loss in patients with AIDS (394). The use of higher doses of dronabinol (20 mg - 40 mg per day) has been reported both in the Marinol® product monograph (174) as well as in the literature (166,167). However, caution should be exercised in escalating dosage because of the increased frequency of dose-related adverse effects.

The current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana in the context of HIV/AIDS-associated anorexia, cachexia, and weight loss in patients who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

4.3.2 To stimulate appetite and produce weight gain in cancer patients

Anorexia is ranked as one of the more troublesome symptoms associated with cancer, with more than half of patients with advanced cancer experiencing a lack of appetite and/or weight loss (395,396). While it is anecdotally known that smoking cannabis can stimulate appetite, the effects of smoking cannabis on appetite and weight gain in patients with cancer cachexia have not been studied. The results from trials with oral Δ^9-THC (dronabinol) or

oral cannabis extract are mixed and the effects, if any, appear to be modest. In two early studies, oral THC (dronabinol) improved appetite and food intake in some patients undergoing cancer chemotherapy (397,398). An open-label study of dronabinol (2.5 mg Δ^9-THC, two to three times daily, four to six weeks) in patients with unresectable or advanced cancer reported increases in appetite and food intake, but weight gain was only achieved in a few patients (399,400). Modest weight gain was obtained with a larger dosing regimen of dronabinol (5 mg t.i.d.), but the CNS side effects including dizziness and somnolence were limiting factors (401). In contrast, a randomized, double-blind, placebo-controlled study involving cancer patients with related anorexia-cachexia syndrome failed to demonstrate any differences in patients' appetite across treatment categories (oral cannabis extract, Δ^9-THC, or placebo) (363). Furthermore, when compared to megestrol acetate, an orexigenic medication, dronabinol was significantly less efficacious in reported appetite improvement and weight gain (402). According to a recent review of the medical management of cancer cachexia, the current level of evidence for cannabinoids (e.g. dronabinol) in the treatment of this condition is low (403).

A two-centre, phase II, randomized, double-blind, placebo-controlled, 22-day pilot study carried out in adult patients suffering from advanced cancer reported improved and enhanced chemosensory perception among patients treated with dronabinol (2.5 mg Δ^9-THC b.i.d.) compared to those receiving placebo (362). The majority (73%) of dronabinol-treated patients self-reported an increased overall appreciation of food compared to those receiving placebo (30%). Similarly, the majority of dronabinol-treated patients (64%) reported increased appetite, whereas the majority of patients receiving placebo reported either decreased appetite (50%) or no change (20%). Total caloric intake per kilogram body weight did not differ significantly between treatment groups but did increase in both groups compared to baseline. Furthermore, compared to placebo, dronabinol-treated patients reported an increase in their protein intake as a proportion of total energy. According to the study authors, negative psychoactive effects were minimized by starting patients at a low dose (2.5 mg Δ^9-THC once a day, for three days) followed by gradual dose escalation (up to a maximum of 7.5 mg dronabinol per day) (362).

Cancer cachexia is not an approved indication for dronabinol either in Canada or the U.S. The current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana in the context of anorexia, cachexia and weight loss associated with cancer in patients who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

4.3.3 Anorexia nervosa

The endocannabinoid system has been implicated in appetite regulation and is suspected to play a role in eating disorders such as anorexia nervosa (387,404). However, genetic studies have thus far failed to agree on an association between genes coding for endocannabinoid system proteins and the manifestation of anorexia nervosa, in spite of epidemiological and familial studies which suggest a genetic basis for this disorder (405,406).

Little information exists on the use of cannabinoids to treat anorexia nervosa. Inter- and intra-species differences in animals with respect to anorexia nervosa-like behaviour have to some extent hampered research on the effects of Δ^9-THC in this disorder. One study in a mouse model of anorexia nervosa reported conflicting results (407), while another study in a rat model reported a significant attenuation in weight loss only at high doses of Δ^9-THC (2.0 mg/kg/day Δ^9-THC) (408). A small, randomized, crossover trial of oral THC in female anorexic patients suggested that Δ^9-THC produced a weight gain equivalent to the active placebo (diazepam) (409). Δ^9-THC was administered in daily doses increasing from 7.5 mg (2.5 mg, t.i.d.) to a maximum of 30 mg (10 mg, t.i.d.), 90 min before meals, for a period of two weeks. Three of the eleven patients administered Δ^9-THC also reported severe dysphoric reactions, withdrawing from the study. Another small clinical study of 15 patients with dementia of the Alzheimer-type reported increases in body weight, but no change in caloric intake with dronabinol (2.5 mg Δ^9-THC, b.i.d.) compared to placebo (410). However, the study suffered from a number of limitations and the results should be interpreted with caution. No studies have examined the effects of smoking cannabis on anorexia nervosa. Both the British Medical Association (115) and the Institute of Medicine (378) concluded that cannabis was unlikely to be effective in patients with anorexia nervosa; however, further research may be warranted.

4.4 Multiple sclerosis, amyotrophic lateral sclerosis, spinal cord injury

Anecdotal reports suggest cannabis can ameliorate spasticity in patients suffering from multiple sclerosis or spinal cord injury when other drugs fail or produce unacceptable side effects (115,378,411,412,413).

4.4.1 Multiple sclerosis

A number of studies, both in patients suffering from multiple sclerosis (MS) and in animal models of the disease, suggest the disorder is associated with changes in endocannabinoid levels, although the findings are conflicting (414,415,416,417).

Pre-clinical studies

Pre-clinical studies across different animal species suggest cannabinoids improve the signs of motor dysfunction in experimental models of MS (reviewed in (418)). Lyman was one of the first to report the effects of Δ^9-THC in one such model (419). In that study, affected animals treated with Δ^9-THC either had no clinical signs of the disorder or showed mild clinical signs with delayed onset (419). The treated animals also typically had a marked reduction in central nervous system tissue inflammation compared to untreated animals (419). Subsequent studies in murine models of MS have supported and extended these findings demonstrating that Δ^9-THC, but not cannabidiol, ameliorated both tremor and spasticity and reduced the overall clinical severity of the disease (414,420). Further work highlighted the importance of the CB_1 receptor in controlling tremor, spasticity, and the neuroinflammatory response. In contrast, the exact function of the CB_2 receptor in MS remains somewhat unclear, although it is believed to play a role in regulating the neuroinflammatory response (420,421,422). Although a large body of evidence suggests cannabinoids exert immunosuppressive effects, which could be beneficial in diseases such as MS, much of this information comes from pre-clinical studies where the levels of exogenous cannabinoids given to animals would likely exceed those typically administered to patients (422). Therefore it is believed that the beneficial effects of cannabinoids are more likely to come from their neuroprotective properties rather than their immunosuppressive characteristics (422,423,424).

Historical and survey data

In humans, published reports spanning 100 years suggest that people with spasticity (one of the symptoms associated with MS) may experience relief with cannabis (425). In the UK, 43% of patients with MS reported having experimented with cannabis at some point, and 68% of this population used it to alleviate the symptoms of MS (426). In Canada, the prevalence of medicinal use of cannabis among patients seeking treatment for MS, in the year 2000, was reported to be 16% in Alberta, with 43% of study respondents stating they had used cannabis at some point in their lives (164). Fourteen percent of people with MS surveyed in the year 2002 in Nova Scotia reported using cannabis for medical purposes, with 36% reporting ever having used cannabis for any purpose (165). MS patients reported using cannabis to manage symptoms such as spasticity and chronic pain as well as anxiety and/or depression (164,165). MS patients also reported improvements in sleep. Reputed dosages of smoked cannabis by these patients varied from a few puffs to 1 g or more at a time (165).

Clinical studies with orally administered cannabinoid medications (cannabis extract, oral THC, nabiximols)

The results of randomized, placebo-controlled trials with orally administered cannabinoids for the treatment of muscle spasticity in MS are encouraging, but modest.

The large, multi-centre, randomized, placebo-controlled CAMS (CAnnabis in Multiple Sclerosis) study researching the effect of cannabinoids for the treatment of spasticity and other symptoms related to MS enrolled over 600 patients (262). The primary outcome was change in overall spasticity scores measured using the Ashworth scale. The study did not show any statistically significant improvement in the Ashworth score in patients taking either an oral cannabis extract (("Cannador") containing 2.5 mg Δ^9-THC, 1.25 mg CBD, and < 5% other cannabinoids), or oral Δ^9-THC, for 15 weeks. However, there was evidence of a significant treatment effect on *subjective*, *patient-reported* spasticity and pain, with improvement in spasticity using either orally administered cannabis extract (61%) (Dosing: 5 - 25 mg Δ^9-THC; 5 - 15 mg CBD/day; and < 5% other cannabinoids, adjusted to body weight and titrated according to side effects) or oral Δ^9-THC (60%) (Dosing: 10 - 25 mg Δ^9-THC/day, adjusted to body weight and titrated according to side effects) compared to placebo (46%). Patients were concomitantly taking other medications to manage MS-associated symptoms. In contrast, a long-term (12 months), double-blind, follow-up to the CAMS study showed evidence of a small treatment effect of oral Δ^9-THC (Dosing: 5 - 25 mg Δ^9-THC/day, adjusted to body weight and titrated according to side effects) on

muscle spasticity measured by *objective* methods, whereas a *subjective* treatment effect on muscle spasticity was observed for both oral Δ^9-THC and oral cannabis extract ("Cannador") (427).

Other randomized clinical trials using standardized cannabis extract capsules (containing 2.5 mg Δ^9-THC and 0.9 mg CBD per capsule) (428) or nabiximols (Sativex®) (291,429,430) reported similar results, in that improvements were only seen in patient *self-reports* of symptoms but not with *objective* measures (e.g. Ashworth scale). The reasons behind the apparent discrepancies between subjective and objective measures are not clear; however, a number of possible explanations may be found to account for the differences. For example, it is known that spasticity is a complex phenomenon (431) and is affected by patient symptoms, physical functioning, and psychological disposition (427). Spasticity is also inherently difficult to measure, and has no single defining feature (430). In addition, the reliability and sensitivity of the Ashworth scale (for objectively measuring spasticity) has been called into question (262,430).

The efficacy, safety, and tolerability of a whole-plant cannabis extract administered in capsules (2.5 mg THC and 0.9 mg CBD/capsule) were studied in a fourteen-day, prospective, randomized, double-blind, placebo-controlled crossover trial in patients with clinically stable MS-associated spasticity and an Ashworth score greater than 2 (428). Slightly more than half of the study subjects had a maintenance dose of 20 mg/day of THC or more (maximum of 30 mg THC/day). Patients were concomitantly taking anti-spasticity medications. Many study subjects had had previous experience with cannabis; a significant number of those who withdrew from the study upon starting treatment with the cannabis extract did not have previous experience with cannabis. While there were no statistically significant differences between active treatment with the cannabis extract and placebo, trends in favour of active treatment were observed for mobility, *self-reported* spasm frequency, and ability in getting to sleep (428). The cannabis extract was generally well tolerated with no serious adverse events during the study period. However, adverse events were slightly more frequent and more severe during the active treatment period.

A six-week, multi-centre, randomized, double-blind, placebo-controlled, parallel-group study of nabiximols (Sativex®) for the treatment of five primary symptoms associated with MS (spasticity, spasm frequency, bladder problems, tremor, and pain) reported mixed results (291). Patients had clinically confirmed, stable MS of any type, and were on a stable medication regimen. Approximately half of the study subjects in either the active or placebo groups had previous experience with cannabis, either recreationally or for medical purposes. While the global primary symptom score (PSS), which combined the scores for all five symptoms, was not significantly different between the active treatment group and the placebo group, patients taking cannabis extract showed statistically significant differences compared to placebo in *subjective*, but not objective measures of spasticity (i.e. Ashworth Score), in Guy's Neurological Disability Score (GNDS), and in quality of sleep, but not in spasm frequency, pain, tremor, or bladder problems among other outcome measures (291). Patients self-titrated to an average daily maintenance dose of nabiximols of 40.5 mg THC and 37.5 mg CBD (i.e. ~15 sprays/day). Adverse effects associated with active treatment included dizziness, disturbance in attention, fatigue, disorientation, feeling drunk, and vertigo (291).

A long-term, open-label, follow-up study of nabiximols (Sativex®) concluded that the beneficial effect observed in the study by Wade et al. 2004 (291) was maintained in patients who had initially benefited from the drug (429). The mean duration of study participation in subjects who entered the follow-up study was 434 days (range: 21 - 814 days). The average number of daily doses taken by the subjects remained constant or was slightly reduced over time. The average number of daily doses of nabiximols was 11, corresponding to a dose of 30 mg THC and 28 mg CBD/day (429). Long-term use of nabiximols in this patient population was associated with reductions in *subjective* measures of spasticity, spasm frequency, pain, and bladder problems (429). Dizziness, diarrhea, nausea, fatigue, headache, and somnolence were among the most frequently reported adverse effects associated with chronic nabiximols use in this study. A two-week withdrawal study, incorporated into the long-term follow-up study, suggested that cessation of nabiximols use was not associated with a consistent withdrawal syndrome but it was associated with withdrawal-type symptoms (e.g. interrupted sleep, hot/cold flushes, fatigue, low mood, decreased appetite, emotional lability, vivid dreams, intoxication) as well as re-emergence/worsening of some MS symptoms (429).

The efficacy, safety and tolerability of nabiximols in MS were investigated in a six-week, multi-centre, phase III, double-blind, randomized, parallel-group clinical study in patients with stable MS who had failed to gain adequate relief using standard therapeutic approaches (430). Patients had to have significant spasticity in at least two muscle groups, and an Ashworth score of 2 or more. A significant number of patients had previous experience with cannabis. Forty percent of subjects assigned treatment with nabiximols showed a $\geq$ 30% reduction in self-

reported spasticity using an 11-point *subjective* numerical rating spasticity scale (NRS) compared to subjects assigned to placebo (21.9%) (difference in favour of nabiximols = 18%; 95% Confidence Interval = 4.73, 31.52; p = 0.014). Mean number of sprays per day was 9.4 ±6.4 (~25 mg THC and ~24 mg CBD) (430). Subjects on placebo or nabiximols exhibited similar incidences of adverse effects, but adverse CNS effects were more common with the nabiximols group (430). The majority of adverse events were of mild or moderate severity (e.g. dizziness, fatigue, depressed mood, disorientation, dysgeusia, disturbance in attention, blurred vision).

Nabiximols (Sativex®), an oro-mucosal spray containing 27 mg/mL of Δ^9-THC and 25 mg/mL CBD, is currently marketed in Canada as an adjunctive treatment for the symptomatic relief of spasticity in adult patients with MS who have not responded adequately to other therapy and who demonstrate meaningful improvement during an initial trial of therapy. It is also marketed (with conditions) as an adjunctive treatment for the symptomatic relief of neuropathic pain in adults with MS.

CUPID and MUSEC clinical studies

The CUPID (**C**annabinoid **U**se in **P**rogressive **I**nflammatory **B**rain **D**isease) study was a randomized, double-blind, clinical investigation designed to measure whether orally administered Δ^9-THC was able to slow the progression of MS (http://sites.pcmd.ac.uk/cnrg/cupid.php). This three-year publicly-funded trial took place at the Peninsula Medical School in the U.K. and followed the earlier, one-year long, CAMS study. A total of 493 subjects with primary or secondary progressive, but not relapse-remitting, MS had been recruited from across the U.K. in 2006 and preliminary results were recently made public (http://sites.pcmd.ac.uk/cnrg/files/cupid/CUPID_results_press_release_web.pdf). The CUPID trial found no evidence to support an effect of Δ^9-THC on MS progression, as measured by using either the Expanded Disability Status Scale or the Multiple Sclerosis Impact Scale 29 (MSIS-29). However, the authors concluded that there was some evidence to suggest a beneficial effect in participants who were at the *lower end* of the disability scale at the time of patient enrolment. Since the observed benefit only occurred in a small sub-group of patients, further studies would be required to more closely examine the reasons for this selective effect.

A double-blind, placebo-controlled, phase III study (the **MU**ltiple **S**clerosis and **E**xtract of **C**annabis trial—i.e. "MUSEC") published by the same group of researchers that conducted the CUPID trial, reported that a twelve-week treatment with an oral cannabis extract ("Cannador") (2.5 mg Δ^9–THC and 0.9 mg CBD/capsule) was associated with a statistically significant relief in *patient-reported* muscle stiffness, muscle spasms, and body pain as well as a statistically significant improvement in sleep compared to placebo, in patients with stable MS (432). There were no statistically significant differences between cannabis extract and placebo on functional measures such as those examining the effect of spasticity on activities of daily living, ability to walk, or on social functioning (432). The majority of the patients using cannabis extract used total daily doses of 10, 15, or 25 mg of Δ^9–THC with corresponding doses of 3.6, 5.4, and 9 mg of CBD. The majority of the study subjects were concomitantly using analgesics and anti-spasticity medications, but were excluded if they were using immunomodulatory medications (e.g. interferons). Active treatment with the extract was associated with an increase in the number of adverse events, but the majority of these were considered to be mild to moderate and did not persist beyond the study period (432). The highest number of adverse events were observed during the initial two-week titration period and appeared to decrease progressively over the course of the remaining treatment sessions (432). The most commonly observed adverse events were those associated with disturbances in CNS function (e.g. dizziness, disturbance in attention, balance disorder, somnolence, feeling abnormal, disorientation, confusion, and falls). Disturbances in gastrointestinal function were the second most commonly occurring adverse events (e.g. nausea, dry mouth).

Clinical studies with smoked cannabis

There has only been one clinical study so far using smoked cannabis for symptoms associated with MS (188). The study, a double-blind, placebo-controlled, crossover trial reported a statistically significant reduction in patient scores on the modified Ashworth scale for measuring spasticity after patients smoked cannabis once daily for three days (each cigarette contained 800 mg of 4% Δ^9-THC; total available Δ^9-THC dose of 32 mg per cigarette) (188). Smoking cannabis was also associated with a statistically significant reduction in patient scores on the visual analog scale for pain, although patients reportedly had low levels of pain to begin with (188). No differences between placebo and cannabis were observed in the timed-walk task, a measure of physical performance (188). Cognitive function, as assessed by the Paced Auditory Serial Addition Test (PASAT), appeared to be significantly decreased immediately following administration of cannabis; however, the long-term clinical significance of this finding was not examined in this study (188). The majority of patients (70%) were on disease-modifying therapy (e.g. interferon β-1a, interferon β-1b, or glatiramer), and 60% were taking anti-

spasticity agents (e.g. baclofen or tizanidine). Cannabis treatment was associated with a number of different, but commonly observed adverse effects including dizziness, headache, fatigue, nausea, feeling "too high", and throat irritation (188). Study limitations included the fact that the majority of patients had prior experience with cannabis, and that the study was unblinded since most of the patients were able to tell apart the placebo from the active treatment with cannabis (188).

The current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana in the context of severe pain and persistent muscle spasms associated with MS in patients who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

Generally speaking, orally administered prescription cannabinoids (e.g. dronabinol, nabilone, nabiximols) are reported to be well tolerated in patients with MS (428,433,434). Clinical trials to date do not indicate serious adverse effects associated with the use of these prescription cannabinoid medications. However, there appears to be an increase in the number of non-serious adverse effects associated with the short-term use of cannabinoids (4). The most commonly reported short-term physical adverse effects are dizziness, drowsiness, and dry mouth (262,434). Prolonged use of ingested or inhaled cannabis was associated with poorer performance on various cognitive domains (information processing speed, working memory, executive function, and visuospatial perception) in patients with MS according to one cross-sectional study (178). In contrast, another study concluded that nabiximols (Sativex®) treatment, in cannabis-naïve MS patients, was not associated with cognitive impairment (434). However, the study did raise the possibility that higher dosages could precipitate changes in psychological disposition, especially in those patients with a prior history of psychosis. In any case, important information is generally lacking regarding the long-term adverse effects of chronic cannabinoid use for therapeutic purposes.

Bladder dysfunction associated with multiple sclerosis or spinal cord injury

Bladder dysfunction occurs in most patients suffering from multiple sclerosis (MS) or spinal cord injury (435). The most common complaints are increased urinary frequency, urgency, urge, and reflex incontinence (436). Cannabinoid receptors are expressed in human bladder detrusor and urothelium (35,36), and may help regulate detrusor tone and bladder contraction as well as affecting bladder nociceptive response pathways (reviewed in (36)).

A survey of MS patients regularly using cannabis for symptomatic relief of urinary problems reported that over half of these patients claimed improvement in urinary urgency (437). A sixteen-week, open-label, pilot study of cannabis-based extracts (a course of Sativex® treatment followed by maintenance with 2.5 mg Δ^9-THC only) for bladder dysfunction, in 15 patients with advanced MS, reported significant decreases in urinary urgency, number and volume of incontinence episodes, frequency, and nocturia (438). Improvements were also noted in patient self-assessments of pain and quality of sleep. A subsequent randomized controlled trial of 250 MS patients suggested a clinical effect of orally administered cannabinoids (2.5 mg Δ^9-THC or 1.25 mg cannabidiol (CBD) with < 5% other cannabinoids per capsule, up to a maximum 25 mg/day) on incontinence episodes (435).

4.4.2 Amyotrophic lateral sclerosis

There is some pre-clinical evidence implicating the endocannabinoid system in the progression of an amyotrophic lateral sclerosis (ALS)-like disease in mouse models of the disorder, and under certain conditions cannabinoids have been reported to modestly delay disease progression and prolong survival in these animal models (reviewed in (439) and in (440)). Anecdotal reports suggest decreased muscle cramps and fasciculations in ALS patients who smoked herbal cannabis or drank cannabis tea, with up to 10% of these patients using cannabis for symptom control (441,442). Only two clinical trials of cannabis for the treatment of symptoms associated with ALS exist, and the results of the studies are mixed. In one four-week, randomized, double-blind, crossover pilot study of 19 ALS patients, doses of 2.5 - 10 mg per day of dronabinol (Δ^9-THC) were associated with improvements in sleep and appetite, but not cramps or fasciculations (443). In contrast, a shorter two-week study reported no improvement in these measures in ALS patients taking 10 mg of dronabinol per day (442). In either case, dronabinol was well tolerated with few reported side effects in this patient population at the tested dosages.

4.4.3 Spinal cord injury (or spinal cord disease)

Pre-clinical animal studies suggest that spinal cord injury triggers changes in the activity of the endocannabinoid system, and that cannabinoid receptor agonists may alleviate neuropathic pain associated with spinal cord injury (444,445,446). However, limited clinical information exists regarding the use of cannabinoids to treat symptoms associated with spinal cord injury such as pain, spasticity, muscle spasms, urinary incontinence, and difficulties

sleeping. No clinical trials of smoked cannabis for the treatment of these symptoms have been documented, but subjective improvements have been anecdotally reported by patients smoking cannabis (378,447). Double-blind, crossover, placebo-controlled studies of oral Δ^9-THC and/or Δ^9-THC : CBD extract (Sativex®) suggested modest improvements in pain, spasticity, muscle spasms, and sleep quality in patients with spinal cord injury (378,448,449). A randomized, double-blind, placebo-controlled parallel study using a minimum of 15 - 20 mg Δ^9-THC/day (mean daily doses of 31 mg Δ^9-THC orally, or 43 mg Δ^9-THC-hemisuccinate rectally) showed a statistically significant improvement in spasticity scores in patients with spinal cord injury (450). A more recent double-blind, placebo-controlled, crossover study using nabilone (0.5 mg b.i.d.) also showed an improvement in spasticity compared to placebo in patients with spinal cord injury (451).

The current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana in the context of severe pain and persistent muscle spasms associated with spinal cord injury or spinal cord disease in patients who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

4.5 Epilepsy

Increasing evidence points to a role for the endocannabinoid system in the modulation of neuronal tone and excitability, and possibly in epilepsy. Human and animal studies suggest epileptic activity is associated with changes in the levels and distribution of CB_1 receptors in the hippocampus (452,453,454). Reduced levels of the endocannabinoid anandamide have been detected in the cerebrospinal fluid of patients with untreated, newly diagnosed, temporal lobe epilepsy (455).

Pre-clinical studies

In vitro studies, as well as those carried out in animals, generally suggest an anti-convulsant role for cannabinoids (91,456,457,458,459). However, a pro-convulsant role has also been described (91,460). CB_1 receptors are located mainly pre-synaptically where they typically inhibit the release of classical neurotransmitters (461). The purported anti-epileptic effect of cannabinoids is thought to be mediated by CB_1-receptor dependent pre-synaptic inhibition of glutamate release (453,462); on the other hand, epileptogenic effects may be triggered by pre-synaptic inhibition of GABA release (456,457,459,463,464). CB_1 receptor agonists therefore have the potential to trigger or suppress epileptiform activity depending upon which cannabinoid-sensitive pre-synaptic terminals are preferentially affected (i.e. glutamatergic or GABAergic) (91,462).

Clinical studies

A review of the literature describing the effects of cannabis on epileptic symptoms in humans concluded that although cannabis use can reduce seizure frequency in some cases and provoke seizures in others, in the majority of cases it probably has no effect (465). This may be caused by the rather unspecific actions of exogenously administered cannabinoids, such as Δ^9-THC, which would target both excitatory and inhibitory neurons (91). Cannabidiol (CBD) has also been examined as a potential anti-epileptic in humans (see (466) for full review) but these early studies have not been followed up with larger and more convincing clinical trials. A recent Cochrane Collaboration review aimed at assessing the efficacy and safety of cannabinoids as monotherapy or add-on treatment for patients with epilepsy concluded that the available evidence is not sufficient to be able to draw reliable conclusions regarding the efficacy of cannabinoids as a treatment for epilepsy (467). While a dose of 200 - 300 mg of CBD could be safely administered to a small number of patients for a short period of time, the safety of long-term cannabidiol treatment could not be reliably assessed (467).

The current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana in the context of epilepsy in patients who experience seizures and who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

4.6 Pain

It is now well established that the endocannabinoid system plays an important role in the modulation of pain states and that elements of the endocannabinoid system can be found at supraspinal, spinal, and peripheral levels of pain pathways (22,468). The particular distribution of cannabinoid receptors provides an anatomical basis to explain some of the analgesic effects of cannabinoids, and a number of pre-clinical studies suggest a functional role for endocannabinoids (such as anandamide and 2-arachidonoylglycerol (i.e. 2-AG)) in suppressing pain under physiological conditions (22).

Considerations and caveats

Animal vs. human studies

Pre-clinical studies in animals predict that cannabinoids should relieve both acute and chronic pain. However, results from both experimental models of pain in human volunteers and from clinical trials of patients suffering from pain instead suggest cannabinoids may be more effective for chronic rather than acute pain (469,470,471). A number of possible explanations can exist to account for discrepancies between animal studies and human clinical trials. Such explanations include interspecies differences, differences in experimental stimuli and protocols used in the studies, and differences in the outcomes measured in the studies. Data from animal pain models are mostly based on observations of behavioural changes and cannabinoid doses sufficient to produce relevant anti-nociception in rodents are similar to those which cause other behavioural effects such as hypomotility and catatonia (21,472). This pharmacological overlap can make it difficult to distinguish between cannabinoid-associated anti-nociceptive effects and behavioural effects (21,472).

Experimental models of pain vs. chronic pain

Translation of research findings from human experimental models of pain (i.e. acute pain) to clinical pain is also complex and not straightforward (185). In contrast to acute pain, chronic pain is a complex condition which involves interaction between sensory, affective, and cognitive components (185). Unlike acute pain, chronic pain is considered a disease and generally originates from prolonged acute pain which is not managed in a timely or effective manner (473). Chronic pain also appears to involve distinct spatiotemporal neuronal mechanisms which differ from those recruited during acute, experimental pain (474). Chronic pain involves altered neural transmission and long-term plasticity changes in the peripheral and central nervous systems which generate and maintain the chronic pain state (473,474). As such, it is difficult to compare studies of interventions for chronic pain with studies of experimentally-induced pain because of fundamental differences in the physiological state of the subjects, differences in the stimulus conditions and experimental protocols employed in the studies, and differences in the outcomes which are measured (185).

Placebo effect

The placebo effect is another consideration to keep in mind when considering studies of cannabis/cannabinoids for the treatment of pain. The placebo effect, a psychobiological phenomenon, is perhaps more salient in disorders which have a more significant subjective or psychological component (e.g. pain, anxiety/depression), and may be somewhat less salient in diseases which have a more objective pathophysiological component (e.g. infectious diseases, cancer) (475,476).

Patient/study subject population

Many, if not most, of the clinical trials of cannabinoids for the treatment of pain (and even other disorders such as multiple sclerosis) have recruited patients or volunteers who have had prior exposure or experience with cannabis or cannabinoids. This has raised the issue of unblinding because any study subjects having prior experience with cannabis or cannabinoids would be more likely to be able to distinguish active treatment with these drugs from the placebo control (364). Furthermore, a number of clinical trials of cannabis/cannabinoids for the treatment of pain (or other disorders) have also used an "open-phase" period which eliminated subjects who would have either responded poorly to cannabinoids or who would have had greater chances of experiencing adverse effects (48). The use of individuals with prior experience with cannabis or cannabinoids or the use of an "open-phase" period would increase the proportion of patients yielding results tending to overestimate some of the potential therapeutic benefits of cannabis/cannabinoids, while also tending to underestimate the extent or degree of adverse effects among the general patient population (48,364).

Other considerations

It is also perhaps worth mentioning that a number of clinical studies suggest the presence of a relatively narrow therapeutic window for cannabis and prescription cannabinoids in the treatment of pain (21,48,50,472). The well-known psychotropic and somatic side effects effects associated with the use of cannabis and cannabinoids (e.g.

dronabinol, nabilone, nabiximols) are known to limit the general therapeutic utility of these drugs; it has therefore been suggested that it may be preferable to pursue therapies which focus on manipulation of the endocannabinoid system (e.g. by inhibiting the endocannabinoid-degrading enzymes FAAH or MAGL), or to combine low doses of cannabinoids with low doses of other analgesics in order to achieve the desired therapeutic effects while minimizing the incidence, frequency, and severity of the adverse effects (21,50).

With the above considerations and caveats in mind, the sections below summarize the results of studies examining the analgesic potential of cannabis or cannabinoids in pre-clinical and clinical models of experimentally-induced acute pain, as well as in clinical studies of chronic pain.

4.6.1. Acute Pain

4.6.1.1 Experimentally-induced acute pain

Pre-clinical studies

A number of pre-clinical studies suggest that anandamide, THC, and certain synthetic cannabinoids block pain responses in different animal models of acute pain (reviewed in (21,472)). Cannabinergic modulation of neuronal circuits in the brain and spinal cord can inhibit nociceptive processing (477,478,479,480). However, despite the results obtained in pre-clinical studies, the results of studies using cannabis or cannabinoids (e.g. nabilone) to alleviate experimentally-induced acute pain in humans are mixed.

Clinical studies with smoked cannabis

An early study by Hill of 26 healthy male cannabis smokers failed to demonstrate an analgesic effect of smoked cannabis (1.4% Δ^9-THC, 12 mg available Δ^9-THC) in response to transcutaneous electrical stimulation (481). The study did, however, report an *increase* in sensory and pain sensitivity to the applied stimulus. In contrast, Milstein showed that smoked cannabis (1.3% Δ^9-THC, 7.5 mg total available Δ^9-THC) increased pain tolerance to a pressure stimulus in both healthy cannabis-naïve and cannabis-experienced subjects compared to placebo (482). Another study employing healthy cannabis smokers reported that smoking cannabis cigarettes (containing 3.55% Δ^9-THC, or approximately 62 mg available Δ^9-THC) was associated with a mild, dose-dependent, anti-nociceptive effect to a thermal heat stimulus (184). A more recent randomized, double-blind, placebo-controlled, crossover trial examined the effects of three different doses of smoked cannabis on intra-dermal capsaicin-induced pain and hyperalgesia in 15 healthy volunteers (185). Capsaicin was administered either 5 min or 45 min after smoking cannabis. Effects appeared to be dose and time dependent. No effect was observed 5 min after smoking, but analgesia was observed 45 min after smoking, and only with the medium dose of smoked cannabis (4% Δ^9-THC by weight). A low dose (2% Δ^9-THC by weight) had no effect. In contrast, a high dose (8% Δ^9-THC by weight) was associated with significant *hyperalgesia*. This study identified a so-called "narrow therapeutic window"; a medium dose provided analgesic benefit, a high dose worsened the pain and was associated with additional adverse effects, and a low dose had no effect.

Clinical studies with oral THC and cannabis extract

A randomized, placebo-controlled, double-blind, crossover study of 12 healthy cannabis-naïve volunteers administered a single oral dose of 20 mg Δ^9-THC reported a lack of a significant analgesic effect following exposure to a multi-model pain test battery (pressure, heat, cold, and transcutaneous electrical stimulation) (483). In addition, significant hyperalgesia was observed in the heat pain test. Psychotropic and somatic side effects were common and included anxiety, perceptual changes, hallucinations, strange thoughts, ideas and mood, confusion and disorientation, euphoria, nausea, headache, and dizziness. Another randomized, double-blind, active placebo-controlled, crossover study in 18 healthy female volunteers reported a lack of analgesia or anti-hyperalgesia with an oral cannabis extract containing 20 mg THC and 10 mg CBD (other plant cannabinoids were less than 5%) in two different experimental pain models (intra-dermal capsaicin or sunburn) (484). Side effects (sedation, nausea, and dizziness) were frequently observed. Hyperalgesia was also observed at the highest dose as in the study conducted by Wallace (above) (185).

Clinical studies with nabilone

A randomized, double-blind, placebo-controlled, crossover study of single oral doses of nabilone (0.5 mg or 1 mg) failed to show any analgesic effects during a tonic heat pain stimulus (485). However, an anti-hyperalgesic effect was observed at the highest administered dose, but only in female subjects. The authors noted a significant placebo effect and also suggested that the lack of an analgesic effect could have been

attributed to the single-dose administration of the cannabinoid; a gradual dose escalation could have potentially revealed an effect (485). Similarly, a randomized, double-blind, placebo-controlled, crossover study in subjects receiving single oral doses of nabilone (1, 2, or 3 mg) failed to show any analgesic, or primary or secondary anti-hyperalgesic effects in response to capsaicin-induced pain in healthy male volunteers (355). Adverse effects of mild to moderate intensity were noted in the majority of subjects. Severe adverse reactions (e.g. dizziness, sedation, anxiety, agitation, euphoria, and perceptual and cognitive disturbances) were reported only at the highest administered dose (3 mg) in four subjects leading to their withdrawal from the study. Dose-dependent CNS effects were observed 1.5 - 6 h after dosing, reaching a maximum between 4 and 6 h after administration. A recent review suggests that there is little convincing evidence of a significant reduction in acute pain in human experimental or clinical studies of cannabinoids (21).

4.6.1.2 Post-operative pain

Despite the introduction of new standards, guidelines, and educational efforts, data indicate that post-operative pain continues to be under or poorly managed and many of the drugs commonly used in this setting either lack sufficient efficacy or cause unacceptable side effects (486,487). To date, there are only four published reports on the use of cannabinoids in post-operative pain (486,488,489,490). The conclusions from these studies were that cannabinoids (THC, nabilone, or an oral cannabis extract containing a 2 : 1 ratio of THC to CBD) are not ideally suited to manage post-operative pain, being either moderately effective (486,488), not different from placebo (489), or even anti-analgesic at high doses (490). However, a definitive conclusion on the role of these cannabinoids in the post-operative setting cannot yet be made because of the different drugs, dosages, routes of administration, and protocols that were used in these studies (491).

4.6.2 Chronic Pain

Acute pain that is poorly managed can lead to chronic pain (492,493). In contrast to acute pain, chronic pain is typically considered a far more complex condition which involves physical, psychological, and psychosocial factors, and which contributes to a reduced quality of life (494). The information below summarizes pre-clinical studies carried out in animal models of chronic pain, clinical studies in human subjects suffering from chronic pain of various etiologies, as well as some studies of experimentally-induced pain performed on patients.

4.6.2.1 Experimentally-induced pain

The anti-nociceptive efficacy of cannabinoids has been unequivocally demonstrated in several different animal models of inflammatory and neuropathic pain (reviewed in (495) and in (496)). In addition, the findings from these studies suggest that modulation of the endocannabinoid system through administration of specific cannabinoid receptor agonists, or by elevation of endocannabinoid levels, suppresses hyperalgesia and allodynia induced by diverse neuropathic states (reviewed in (496)). As such, similar to the situation with acute pain, pre-clinical studies of chronic pain in animal models suggest that endocannabinoids (anandamide and 2-AG), THC, and several synthetic cannabinoids have beneficial effects (reviewed in (21,472,496)).

With respect to cannabidiol (CBD), while chronic oral administration of cannabidiol effectively decreased hyperalgesia in a rat model of inflammatory pain (497), no such parallels have been found to date in humans. A more recent study suggested that a medium or a high dose of CBD attenuates tactile allodynia and thermal hypersensitivity in a mouse model of diabetic neuropathy, when administered early in the course of the disease; on the other hand there is little, if any, restorative effect if CBD is administered at a later time point (498). In contrast, nabilone was not as efficacious as CBD if administered early on, but appeared to have a small beneficial effect when administered later in the course of the disease (498). CBD also appeared to attenuate microgliosis in the ventral lumbar spinal cord, but only if administered early in the course of the disease, whereas nabilone had no effect (498).

There are no studies of experimentally-induced chronic pain in humans. However, in contrast to the mixed findings in human subjects exposed to acute painful stimuli, cannabinoids appear to have a more consistent beneficial profile for patients already suffering from chronic pain.

4.6.2.2 Neuropathic pain or chronic non-cancer pain

Short-term clinical studies suggest prescription cannabinoid medications (e.g. nabiximols, dronabinol, nabilone) are moderately effective in reducing intractable central or peripheral neuropathic pain of various etiologies in individuals already receiving analgesic drugs (499). Side effects appear to be comparable to

existing treatments and typically include dizziness/lightheadedness, sedation, confusion, ataxia, a feeling of intoxication, euphoria ("high"), xerostomia, dysgeusia, and hunger (499,500). These effects may be minimized by employing low doses of cannabinoids that are gradually escalated, as required. The following summarizes the existing clinical information on the use of cannabis and cannabinoids (THC, nabilone, dronabinol and nabiximols) to treat neuropathic and chronic non-cancer pain.

Clinical studies with smoked or vapourized cannabis

A randomized, double-blind, placebo-controlled, cross-over study of cannabis-experienced patients suffering from chronic neuropathic pain of various etiologies (complex regional pain syndrome, central neuropathic pain from spinal cord injury or multiple sclerosis, or peripheral neuropathic pain from diabetes or nerve injury) reported that administration of either a low dose or a high dose of smoked cannabis (3.5% Δ^9-THC, 19 mg total available Δ^9-THC; or 7% Δ^9-THC, 34 mg total available Δ^9-THC) was associated with significant equianalgesic decreases in central and peripheral neuropathic pain (168). No analgesic effect was observed in tests of experimentally-induced pain (tactile or heat stimuli). Patients were taking other pain control medications during the trial such as opioids, anti-depressants, non-steroidal anti-inflammatory drugs, or anti-convulsants. Adverse effects associated with the use of cannabis appeared to be dose-dependent and included feeling "high", sedation, confusion, and neurocognitive impairment. Cognitive changes appeared to be more pronounced with higher doses of Δ^9-THC (168).

In another randomized, placebo-controlled study a greater than 30% decrease in HIV-associated sensory neuropathic pain was reported in 52% of cannabis-experienced patients smoking cannabis cigarettes containing 3.56% Δ^9-THC (32 mg total available Δ^9-THC per cigarette), three times per day (96 mg total daily amount of Δ^9-THC) for five days, compared to a 24% decrease in pain in the placebo group (142). The number of patients that needed to be treated (NNT) to observe a 30% reduction in pain compared to controls was 3.6 and was comparable to that reported for other analgesics in the treatment of chronic neuropathic pain. In the "experimentally-induced pain" portion of the study, smoked cannabis was not associated with a statistically significant difference in acute heat pain threshold compared to placebo. However, it did appear to reduce the area of heat and capsaicin-induced acute secondary hyperalgesia (142). Patients were taking other pain control medications during the trial such as opioids, gabapentin or other drugs. Adverse effects of smoked cannabis in this study included sedation, dizziness, confusion, anxiety, and disorientation.

A phase II, double-blind, placebo-controlled, crossover clinical trial of smoked cannabis for HIV-associated refractory neuropathic pain reported a 30% decrease in HIV-associated, distal sensory predominant, polyneuropathic pain in 46% of patients smoking cannabis for five days (1 - 8% Δ^9-THC, four times daily), compared to a decrease of 18% in the placebo group (186). The NNT in this study was 3.5. Almost all of the subjects had prior experience with cannabis and were concomitantly taking other analgesics such as opioids, non-steroidal anti-inflammatory drugs, anti-depressants or anti-convulsants. Adverse effects associated with the use of cannabis were reported to be frequent, with a trend for moderate or severe adverse effects during the active treatment phase compared to the placebo phase.

A randomized, double-blind, placebo-controlled, four period, crossover clinical study of smoked cannabis for chronic neuropathic pain caused by trauma or surgery and refractory to conventional therapies reported that compared to placebo, a single smoked inhalation of 25 mg of cannabis containing 9.4% Δ^9-THC (2.35 mg total available Δ^9-THC per cigarette), three times per day (7.05 mg total Δ^9-THC per day) for five days, was associated with a modest but statistically significant decrease in average daily pain intensity (172). In addition, there were statistically significant improvements in measures of sleep quality and anxiety with cannabis. The majority of subjects had previous experience with cannabis and most were concomitantly taking other analgesics such as opioids, anti-depressants, anti-convulsants, or non-steroidal anti-inflammatory drugs. Adverse effects associated with the use of cannabis included headache, dry eyes, burning sensation in the upper airways (throat), dizziness, numbness, and cough.

A clinical study of patients suffering from chronic pain (musculoskeletal, post-traumatic, arthritic, peripheral neuropathy, cancer, fibromyalgia, multiple sclerosis, sickle cell disease, and thoracic outlet syndrome) reported that inhalation of vapourized cannabis (0.9 g, 3.56% Δ^9-THC), three times per day for five days, was associated with a statistically significant decrease in pain (-27%, Confidence Interval = 9 - 46) (187). Subjects were on stable doses of sustained-release morphine sulfate or oxycodone, and had prior experience with smoking cannabis (187). There was a statistically significant decrease in the maximum concentration (C_{max}) of morphine sulfate, but not oxycodone, during cannabis exposure. No clinically significant adverse

effects were noted, but all subjects reported experiencing a "high". The study design carried a number of important limitations including small sample size, short duration, a non-randomized subject population, and the lack of a placebo.

A double-blind, placebo-controlled, crossover study of patients suffering from neuropathic pain of various etiologies (spinal cord injury, CRPS type I, causalgia-CRPS type II, diabetic neuropathy, multiple sclerosis, post-herpetic neuralgia, idiopathic peripheral neuropathy, brachial plexopathy, lumbosacral radiculopathy, and post-stroke neuropathy) reported that inhalation of vapourized cannabis (0.8 g containing either a low dose of Δ^9-THC (1.29% Δ^9-THC; total available amount of Δ^9-THC 10.3 mg) or a medium dose of Δ^9-THC (3.53% Δ^9-THC; total available amount of Δ^9-THC 28.2 mg)) during three separate 6 h sessions was associated with a statistically significant reduction in pain intensity (501). Inhalation proceeded using a standardized protocol (i.e. the "Foltin procedure"): participants were verbally signaled to hold the vapourizer bag with one hand, put the vapourizer mouthpiece in their mouth, get ready, inhale (5 s), hold vapour in their lungs (10 s), and finally exhale and wait before repeating the inhalation cycle (40 s) (501). Non-significant differences were observed between placebo and active treatments with respect to pain ratings at the 60 min time point following study session initiation. Following four cued inhalations of either dose of THC at the 60 min time point, a significant treatment effect was recorded 60 min later (i.e. at the 120 min time point following trial initiation). A second cued inhalation of vapourized cannabis, at the 180 min time point following trial initiation (4 - 8 puffs, flexible dosing, 2 h after first inhalation), was associated with continued analgesia lasting another 2 h (501). Both the 1.29% and 3.53% Δ^9-THC doses were equianalgesic and significantly better in achieving analgesia than placebo. The NNT to achieve a 30% pain reduction was 3.2 for the placebo vs. the low-dose, 2.9 for the placebo vs. the medium-dose, and 29 for the medium- vs. the low-dose (501). The authors suggested that the NNT for active vs. placebo conditions is in the range of two commonly used anti-convulsants used to treat neuropathic pain (pregabalin, 3.9; gabapentin, 3.8). Using a Global Impression of Change rating scale, pain relief appeared to be maximal after the second dosing at 180 min, and dropped off between 1 and 2 h later. Both active doses had equal effects on ratings of pain "sharpness", while the low-dose was more effective than either the placebo or medium-dose for pain described as "burning" or "aching". All patients had prior experience with cannabis and were concomitantly taking other medications (opioids, anti-convulsants, anti-depressants, and non-steroidal anti-inflammatory drugs) (501). Cannabis treatment was associated with a small impairment of certain cognitive functions, with the greatest effects seen in domains of learning and memory (501). The study suffered from a number of drawbacks including a relatively small number of patients, a short study period, and the possibility of treatment unblinding.

Clinical studies with orally administered prescription cannabinoids

Nabilone

An off-label, retrospective, descriptive study of 20 adult patients suffering from chronic non-cancer pain of various etiologies (post-operative or traumatic pain, reflex sympathetic dystrophy, arthritis, Crohn's disease, neuropathic pain, interstitial cystitis, HIV-associated myopathy, post-polio syndrome, idiopathic inguinal pain, and chronic headaches) reported subjective overall improvement and reduced pain intensity with nabilone as an adjunctive pain-relief therapy (494). Furthermore, beneficial effects on sleep and nausea were the main reasons for continuing use. Patients used between 1 and 2 mg of nabilone per day. Higher doses (3 - 4 mg/day) were associated with an increased incidence of adverse effects. These included dry mouth, headaches, nausea and vomiting, fatigue, cognitive impairment, dizziness, and drowsiness. Many patients were concomitantly taking other drugs such as non-steroidal anti-inflammatory drugs, opioids, and various types of anti-depressants. Many of the subjects also reported having used cannabis in the past to manage symptoms. Limitations in study design included the lack of an appropriate control group and the small number of patients.

An enriched-enrolment, randomized-withdrawal, flexible-dose, double-blind, placebo-controlled, parallel-assignment efficacy study of nabilone as an adjuvant in the treatment of diabetic peripheral neuropathic pain reported a statistically significant decrease in pain compared to placebo, with 85% of the subjects in the nabilone group reporting a $\geq$ 30% reduction in pain from baseline to end point, and 31% of subjects in the nabilone group reporting a $\geq$ 50% reduction in pain from baseline to end point (364). Subjects taking nabilone also reported statistically significant improvements in anxiety, sleep, quality of life, and overall patient status (364). Doses of nabilone ranged from 1 - 4 mg/day (364). Most subjects were concomitantly taking a variety

of pain medications including non-steroidal anti-inflammatory drugs, opioids, anti-depressants, and anxiolytics. Adverse events associated with the nabilone intervention included dizziness, dry mouth, drowsiness, confusion, impaired memory, lethargy, euphoria, headache, and increased appetite although weight gain was not observed (364).

Dronabinol

A randomized, double-blind, placebo-controlled, crossover trial of patients suffering from multiple sclerosis-associated central neuropathic pain reported a decrease in central pain with 10 mg maximum daily doses of dronabinol (361). Dosing started with 2.5 mg dronabinol/day and employed gradual dose-escalation every other day; total trial duration was three weeks (range: 18 - 21 days). Pain medications, other than paracetamol, were not permitted during the trial. The NNT for 50% pain reduction was 3.5 (95% Confidence Interval = 1.9 to 24.8). Fifty-four percent of patients had a $\geq$ 33% reduction in pain during dronabinol treatment compared with 21% of patients during placebo. The degree of pain reduction in this study was comparable to that seen with other drugs commonly used in the treatment of neuropathic pain conditions (361). There were no significant differences reported between the treatment group and placebo in thermal sensibility, tactile and pain detection, vibration sense, temporal summation, or mechanical or cold allodynia (361). However, there was a statistically significant increase in the pain pressure threshold in dronabinol-treated subjects. Self-reported adverse effects were common, especially during the first week of active treatment. These included lightheadedness, dizziness, drowsiness, headache, myalgia, muscle weakness, dry mouth, palpitations, and euphoria (361).

A phase I, randomized, single-dose, double-blind, placebo-controlled, crossover trial of 30 patients taking short- or long-acting opioids (68 mg oral morphine equivalents/day; range 7.5 - 228 mg) for intractable, chronic non-cancer pain (of various etiologies) reported that both a 10 mg and 20 mg dose of dronabinol was associated with significant pain relief compared to placebo, although no difference in pain relief was observed between the two active treatments (502). Pain intensity and evoked pain were also significantly reduced in subjects who received the active treatments compared to placebo. Significant pain relief compared to baseline was also reported in an open-label, phase II extension to the initial phase I trial. Subjects were instructed in a stepwise dosage schedule beginning with a 5 mg/day dose, and titrating upwards to a maximum of 20 mg t.i.d. Significant side effects were observed in the majority of patients in the single-dose trial, were consistent with those observed in other clinical trials, and occurred more frequently in subjects receiving the highest dosage of the study medication (502). The authors reported that compared to the single-dose phase I trial, the frequency of self-reported side effects in the phase II open-label study decreased with continued use of dronabinol. Limitations in the design of the study included the small number of study subjects, the large number of subjects with a history of cannabis use, the lack of appropriate comparison groups, and the lack of an active placebo. Other limitations specific to the open-label phase-II trial included the lack of a control group or crossover arm (502).

Nabiximols

A number of randomized, placebo-controlled, double-blind crossover and parallel studies have shown a significant reduction in central or peripheral neuropathic pain of various etiologies (e.g. brachial plexus avulsion, multiple sclerosis-related) following treatment with nabiximols (Sativex®) (292,503,504). In all three studies, patients were concomitantly using other drugs to manage their pain (anti-epileptics, tricyclic anti-depressants, opioids, non-steroidal anti-inflammatory drugs, selective serotonin reuptake inhibitors, benzodiazepines, skeletal muscle relaxants). The NNT for 30% pain reduction (deemed clinically significant) varied between 8 and 9, whereas the NNT for 50% pain reduction for central neuropathic pain was 3.7, and 8.5 for peripheral pain. In two of the three studies, the majority of subjects had prior experience with cannabis for therapeutic or recreational purposes (503,504). Furthermore, the majority of subjects allocated to the active treatment experienced minor to moderate adverse effects compared to the placebo group. These included nausea, vomiting, constipation, dizziness, intoxication, fatigue, and dry mouth among other effects.

According to the consensus statement and clinical guidelines on the pharmacological management of chronic neuropathic pain published by the Canadian Pain Society in 2007, the Society considered cannabinoid-based therapies (e.g. dronabinol and nabiximols) to be fourth-line treatments for neuropathic pain, mostly as adjuvant analgesics for pain conditions refractory to standard drugs (505) (but also see section 4.7.3 and reference (506) for updated clinical guidelines on the use of cannabinoids for the treatment of symptoms associated with fibromyalgia). Health Canada has approved Sativex® (with conditions) as an adjunct treatment for the symptomatic relief of neuropathic pain in multiple sclerosis (290).

A Canadian systematic review of randomized clinical trials of cannabinoids (cannabis, nabilone, dronabinol and nabiximols) for the treatment of chronic non-cancer pain (neuropathic pain, mixed chronic pain, rheumatoid arthritis, fibromyalgia) concluded that cannabinoids are modestly effective for neuropathic pain, with preliminary evidence of efficacy in rheumatoid arthritis (see section 4.7.2) and fibromyalgia (see section 4.7.3) (173). Major limitations identified in the review were short trial duration, small sample sizes, and modest effect sizes, with a need for larger trials of longer duration to better establish efficacy and safety as well as potential for abuse.

4.6.2.3 Cancer pain

Clinical studies with dronabinol

Two randomized, double-blind, placebo-controlled studies suggested oral Δ^9-THC (dronabinol) provided an analgesic benefit in patients suffering from moderate to severe continuous pain due to advanced cancer. The first study was a dose-ranging study of 5, 10, 15, and 20 mg Δ^9-THC, given in successive days, to 10 cancer patients (507). Significant pain relief was found at the 15 and 20 mg dose levels, but at these higher doses patients were heavily sedated and mental clouding was common. A second, placebo-controlled study compared 10 and 20 mg oral Δ^9-THC with 60 and 120 mg codeine in 36 patients with cancer pain (508). While the lower and higher doses of THC were equianalgesic to the lower and higher doses of codeine, respectively, statistically significant differences in analgesia were only obtained between placebo and 20 mg Δ^9-THC, and between placebo and 120 mg codeine. The 10 mg Δ^9-THC dose was well tolerated, and despite its sedative effect appeared to have mild analgesic potential. The 20 mg Δ^9-THC dose induced somnolence, dizziness, ataxia, and blurred vision. Extreme anxiety was also observed at the 20 mg dose in a number of patients.

Clinical studies with nabiximols

A more recent randomized, double-blind, placebo-controlled, parallel-group trial of patients suffering from intractable cancer-related pain (mixed, bone, neuropathic, visceral, somatic/incident) suggested that an orally administered THC : CBD extract (nabiximols), containing 2.7 mg of Δ^9-THC and 2.5 mg CBD per dose, is an efficacious adjunctive treatment for such cancer-related pain which is not fully relieved by strong opioids (112). Baseline median morphine equivalents/day ranged from 80 - 120 mg. Forty-three percent of patients (n = 60) taking the extract achieved a $\geq$ 30% improvement in their pain score, which was twice the number of patients who achieved this response in the THC (n = 58) and placebo (n = 59) groups. Both the nabiximols and the THC medications were reported to be well tolerated in this patient population, and adverse events were reported to be similar to those seen in other clinical trials of nabiximols (e.g. somnolence, dizziness, and nausea). This study was followed-up by an open-label extension study which evaluated the long-term safety and tolerability of nabiximols (as well as oro-mucosal THC spray) as an adjuvant pain treatment in patients with terminal cancer-related pain refractory to strong opioid analgesics (509). Patients who had taken part in, fully complied with the study requirements of, had not experienced an unacceptable adverse event in the initial parent study (112), and that were expected to receive clinical benefit from nabiximols (with acceptable tolerability) were enrolled in the extension study. The most commonly reported (50%) pain type was mixed pain (nociceptive and neuropathic), followed by neuropathic pain (37%), and bone pain (28%) (509). The median duration of treatment with nabiximols (n = 39 patients) was 25 days (range: 2 - 579 days) while the mean duration of treatment with oro-mucosal THC spray (n = 4 patients) was 151.5 days (range: 4 - 657 days). The average number of sprays/day for nabiximols during the last seven days of dosing was 5.4 ±3.28 vs. 14.5 ±16.84 for THC only. No dose escalation was noted in patients taking nabiximols beyond six months and up to one year following treatment initiation (509). Although the study was a non-comparative, open-label study with no formal hypothesis testing and mostly used descriptive statistics, a decrease from baseline in mean score on the BPI-SF (Brief Pain Inventory Short-Form) was observed for both “pain severity” and “worst pain” over the five weeks of treatment (509). However, the authors noted that the clinical investigators considered that their patients’ pain control was sub-optimal. A negative change from baseline (i.e. indicating a worsening) was also reported in the physical functioning score on the EORTC QLQ-30 (an assessment tool to measure the quality of life of patients with cancer), although some improvements in scores for sleep and pain, between baseline and week 5 of treatment, were reported (509). Eight percent of the patients on nabiximols developed a serious nabiximols-associated adverse event. The most commonly reported adverse events for nabiximols were nausea/vomiting, dry mouth, dizziness, somnolence, and confusion (509).

In contrast to the above-mentioned studies using nabiximols, a randomized, double-blind, placebo-controlled, parallel group clinical trial of opioid-treated cancer patients with intractable chronic cancer pain (e.g. bone, mixed, neuropathic, somatic, visceral) reported no statistically significant difference between placebo and the nabiximols treatment group in the primary endpoint of 30% relief from baseline pain at study end (349). However, when using a continuous responder rate analysis as a secondary endpoint (i.e. comparing the proportion of active drug vs. placebo responders across the full spectrum of response from 0 to 100%), the study was able to report a statistically significant treatment effect in favour of nabiximols. Patients were taking median opioid equivalent doses ranging between 120 and 180 mg/day. Adverse events were dose-related, with only the highest dose group comparing unfavourably to placebo. The authors noted that the trial was a dose-ranging study, and that confirmatory studies are strongly warranted. The study design also did not permit the evaluation of a therapeutic index.

In Canada, nabiximols (Sativex®) is approved (with conditions) as an adjunctive analgesic in adults with advanced cancer who experience moderate to severe pain during the highest tolerated dose of strong opioid therapy for persistent background pain (290). Current dosing recommendations for nabiximols suggest a maximum daily dose of 12 sprays (32.4 mg THC and 30 mg CBD) over a 24 h period (107,112,290), although higher numbers of sprays/day have been used or documented in clinical studies (290,349). It should be noted that increases in the number of sprays/day were accompanied by increases in the incidence of adverse effects.

While there are no clinical trials of smoked marihuana for the treatment of cancer pain, the current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana in cancer patients who experience severe pain and who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

"Opioid-sparing" effects and cannabinoid-opioid synergy

The "opioid-sparing" effect refers to the ability of a non-opioid medication to confer adjunctive analgesia with the use of a lower dose of the opioid thereby decreasing opioid-associated side effects. While there are some pre-clinical data supporting such an effect for cannabinoids, this is less well-established in published clinical studies. The following information summarizes the results from pre-clinical and clinical studies investigating cannabinoid-opioid interactions and the potential "opioid-sparing effect" of cannabinoids.

Pre-clinical data

There is a fair amount of evidence to suggest a functional interaction between the cannabinoid and the opioid systems, although much additional research is needed to understand precisely how the two systems communicate with one another. The evidence supporting a putative interaction between the cannabinoid and opioid systems comes from a number of observations. First, it is known that cannabinoids and opioids produce similar biological effects such as hypothermia, sedation, hypotension, inhibition of gastrointestinal motility, inhibition of locomotor activity, and anti-nociception (510,511,512). Furthermore, neuroanatomical studies in animals have demonstrated overlapping tissue distribution of the cannabinoid and opioid receptors, with both receptor types found in nervous system tissues associated with the processing of painful stimuli, namely the periaqueductal gray, raphe nuclei, and central-medial thalamic nuclei (510,511,512). There is also some evidence that the CB_1 and mu-opioid receptors can co-localize in some of the same neuronal sub-populations such as those located in the superficial dorsal horn of the spinal cord (510). This co-localization may play an important role in spinal-level modulation of peripheral nociceptive inputs (510). Both receptors also share similar signal transduction molecules and pathways, the activation of which generally results in the inhibition of neurotransmitter release (510,512). The role of these receptors in inhibiting neurotransmitter release is further supported by their strategic localization on pre-synaptic membranes (510). Evidence from some pre-clinical studies also suggests that acute administration of cannabinoid receptor agonists can lead to endogenous opioid peptide release, and that chronic THC administration increases endogenous opioid precursor gene expression (e.g. preproenkephalin, prodynorphin, and proopiomelanocortin) in different spinal and supraspinal structures involved in the perception of pain (510). A few studies have even demonstrated the existence of cannabinoid-opioid receptor heteromers, although the exact biological significance of such receptor heteromerization remains to be fully elucidated (513,514). Taken together, these findings suggest the existence of cross-talk between the cannabinoid and opioid systems. Furthermore, pre-clinical studies using a combination of different opioids (morphine, codeine) and cannabinoids (THC), at acute or sub-effective doses, have reported additive and even synergistic analgesic effects (515,516,517,518,519,520).

Clinical data

A limited number of clinical trials have been carried out to date with mixed results. One double-blind, placebo-controlled, crossover study of healthy human volunteers given low doses of THC, morphine, or a combination of the two drugs failed to find any differences between subjects' ratings of *sensory* responses to a painful thermal stimulus (521). However, the study did report that the combination of morphine and THC was associated with a decrease in the subjects' *affective* response to the painful thermal stimulus (521). The authors suggested that morphine and THC could combine to yield a synergistic analgesic response to the *affective* aspect of an experimentally-evoked pain stimulus. One clinical study (502) reported that patients suffering from chronic non-cancer pain and not responding to opioids experienced increased analgesia, decreased pain intensity, and decreased evoked pain when given either 10 or 20 mg dronabinol (for additional details see section 4.6.2.2, under "Clinical Studies With Orally Administered Prescription Cannabinoids"). More recently it was reported that patients suffering from chronic pain of various etiologies, unrelieved by stable doses of opioids (extended release morphine or oxycodone), experienced a statistically significant improvement in pain relief (27%, Confidence Interval = 9 - 46) following inhalation of vapourized cannabis (0.9 g, 3.56% THC, three times per day for five days) (187) (for additional details see section 4.6.2.2, under "Clinical Studies With Smoked or Vapourized Cannabis"). The findings from this study suggest that addition of cannabinoids (in this case inhaled vapourized cannabis) to existing opioid therapy for pain may serve to enhance opioid-associated analgesia (187).

In contrast, another study did not note a statistically significant decrease in the amounts of background or breakthrough opioid medications consumed by the majority of patients suffering from intractable cancer-related pain and taking either nabiximols or THC (112). Similarly, no statistically significant changes were observed in the amounts of background or breakthrough opioid doses taken by patients suffering from intractable cancer-related pain who were administered nabiximols (349). However, the design of the latter study did not allow proper assessment of an "opioid-sparing effect" of nabiximols.

In summary, while "cannabinoid-opioid synergy" has been proposed as a way to significantly increase the analgesic effects of opioids while avoiding, or minimizing, tolerance to the effects of opioid analgesics and circumventing, or attenuating, the well-known undesirable side effects associated with the use of either cannabinoids or opioids, the clinical results are mixed and further study is required on this topic (510,512).

4.6.2.4 Headache and Migraine

While historical and anecdotal evidence suggest a role for cannabis in the treatment of headache and migraine (522), no controlled clinical studies of cannabis or prescription cannabinoids to treat headache or migraine have been carried out to date (523,524).

With regard to migraine, an endocannabinoid deficiency has been postulated to underlie the pathophysiology of this disorder (525); however, the evidence supporting this hypothesis is limited. Clinical studies suggest that the concentrations of anandamide are decreased in the cerebrospinal fluid of migraineurs, while the levels of calcitonin-gene-related-peptide and nitric oxide (normally inhibited by anandamide and implicated in triggering migraine) are increased (526,527). In addition, the activity of the anandamide-degrading enzyme FAAH is significantly decreased in chronic migraineurs compared to controls (528).

In one case-report, a patient suffering from pseudotumour cerebri and chronic headache reported significant pain relief after smoking cannabis (529). In another case-report, a patient complaining of cluster headaches refractory to multiple acute and preventive medications reported improvement with smoked cannabis or dronabinol (5 mg) (530). However, these single-patient case-studies should be interpreted with caution. A recent report indicated that cannabis use was very frequent among a population of French patients with episodic or chronic cluster headache, and of those patients who used cannabis to treat their headache, the majority reported variable, uncertain, or even negative effects of cannabis smoking on cluster headache (531). It should also be noted that cannabis use has been associated with reversible cerebral vasoconstriction syndrome and severe headache (532). In addition, headache is an observed adverse effect associated with the use of cannabis or prescription cannabinoid medications (172,174,290,332,430,449), and headache is also one of the most frequently reported physical symptoms associated with cannabis withdrawal (533). It is therefore possible that using cannabis simply relieves headache caused by cannabis withdrawal.

4.7. Arthritides and Musculoskeletal Disorders

The arthritides include a broad spectrum of different disorders (e.g. osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, gout, and many others) all of which have in common the fact that they target or involve the joints. Among these, osteoarthritis is by far the most common type of arthritis and is the leading cause of disability in those over the age of 65 years in developed countries (534). Rheumatoid arthritis is a destructive, auto-immune disease that affects a smaller, but not insignificant, proportion of the adult population (534). Also covered in this section are musculoskeletal disorders such as fibromyalgia and osteoporosis.

While scientific studies have demonstrated that joints, bone, and muscle all contain a working endocannabinoid system (38,39,40), there is relatively little scientific or medical information on the use of cannabis or cannabinoids to treat either the arthritides or musculoskeletal disorders. The available information is summarized below.

4.7.1 Osteoarthritis

Pre-clinical studies

Very little information is available regarding the use of cannabis or cannabinoids to treat osteoarthritis. One study reported elevated levels of the endocannabinoids anandamide and 2-arachidonoylglycerol (i.e. 2-AG), and the "entourage" compounds PEA and OEA in the spinal cords of rats with experimentally-induced knee joint osteoarthritis (535). While no changes were observed in the levels or the activities of the endocannabinoid catabolic enzymes FAAH or MAGL in the spinal cords of the affected rats, protein levels of the major enzymes responsible for endocannabinoid synthesis were reported to be significantly elevated in these animals (535). Another study in rats reported that intra-articular injection of the CB_1 receptor agonist arachidonyl-2-chloroethylamide (ACEA) in control animals was associated with a reduction in firing rate and suppression of nociceptive activity from pain fibers innervating the joints when the joints were subjected to either normal or noxious joint rotation (536). Similar results were obtained in animals with osteoarthritic joints. The anti-nociceptive effect was blocked by co-administration of a CB_1 receptor antagonist in osteoarthritic joints, but not control joints (536). Lastly, local administration of URB597 (a FAAH inhibitor) by intra-arterial injection proximal to an osteoarthritic joint was associated with decreased mechanosensitivity of joint afferent fibers in two different rodent models of osteoarthritis (537). Behavioural experiments carried out in these rats suggested that treatment with the inhibitor also decreased joint pain measured by a decrease in hindlimb incapacitance (537).

Clinical studies

To date there have been no clinical studies of cannabis or cannabinoids to treat osteoarthritis. Nevertheless, the current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana for those patients experiencing severe pain associated with severe arthritis who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

4.7.2 Rheumatoid Arthritis

Rheumatoid arthritis is a systemic, auto-immune, inflammatory arthritis characterized by progressive synovitis with resultant joint destruction, functional disability, significant pain, and systemic complications (e.g. cardiovascular, pulmonary, psychological, and skeletal disorders such as osteoporosis) (538,539).

Pre-clinical studies

A pre-clinical study in a rat model of rheumatoid arthritis reported that treatment with either THC or anandamide was associated with significant anti-nociception in the paw-pressure test (258). Another study using the same animal model demonstrated a synergistic anti-nociceptive interaction between THC and morphine in both arthritic and non-arthritic rats in the paw-pressure test (257).

Clinical studies

In humans, one study found that the levels of the endocannabinoids anandamide (AEA) and 2-arachidonoylglycerol (2-AG) in the synovial fluid of patients with osteoarthritis and rheumatoid arthritis were increased compared to non-inflamed normal controls, although the significance of these findings remains unclear (40).

A preliminary clinical study assessing the effectiveness of nabiximols (Sativex®) for pain caused by rheumatoid arthritis reported a modest but statistically significant analgesic effect on movement and at rest, as well as

improvement in quality of sleep (259). Administration of nabiximols was well tolerated and no significant toxicity was observed. The mean daily dose in the final treatment week was 5.4 pump actuations (equivalent to 14.6 mg THC and 13.5 mg CBD/day, treatment duration was three weeks) (259). The differences observed were small and variable across the participants.

A recent Cochrane Collaboration review concluded that the evidence in support of the use of oro-mucosal cannabis (e.g. nabiximols) for the treatment of pain associated with rheumatoid arthritis is weak and given the significant side effect profile typically associated with the use of cannabinoids, the potential harms seem to outweigh any modest benefit achieved (538).

Nevertheless, the current Marihuana Medical Access Regulations (MMAR) allow the use of dried marihuana for those patients experiencing severe pain associated with severe arthritis who have either not benefited from, or would not be considered to benefit from, conventional treatments (384).

4.7.3 Fibromyalgia

Fibromyalgia is a disorder characterized by widespread pain (allodynia and hyperalgesia) and a constellation of other symptoms including sleep disorders, fatigue, and emotional or cognitive disturbances (540). While the underlying pathophysiology of fibromyalgia remains unclear, disturbances in the recruitment or functioning of peripheral and central pain processing pathways and in the levels of several important neurotransmitters (serotonin, noradrenaline, dopamine, opioids, glutamate and substance P) have been noted in patients suffering from fibromyalgia (541,542,543,544). Co-morbid depressive symptoms have also been associated with a more pronounced deficit in pain inhibition, as well as increased pain in fibromyalgia patients (545).

Clinical studies with smoked or orally ingested cannabis

There are no clinical trials of smoked or ingested cannabis for the treatment of fibromyalgia. However, a cross-sectional survey of patients suffering from fibromyalgia found that the patients reported using cannabis (by smoking and/or eating) to alleviate pain, sleep disturbance, stiffness, mood disorders, anxiety, headaches, tiredness, morning tiredness, and digestive disturbances associated with fibromyalgia (158). Subjects (mostly middle-aged women who did not respond to current treatment) reported statistically significant decreases in pain and stiffness, and statistically significant increases in relaxation, somnolence, and well-being 2 h after cannabis self-administration (158). Side effects included somnolence, dry mouth, sedation, dizziness, high, tachycardia, conjunctival irritation, and hypotension (158). The study suffered from a number of limitations including the study design, small sample size, variability in frequency and duration of cannabis use, and a biased subject population.

Clinical studies with prescription cannabinoid medications

There are relatively few properly controlled clinical studies examining the role of cannabinoids in the treatment of fibromyalgia. The available evidence is summarized below.

Dronabinol

A non-placebo controlled pilot study examining the effect of dronabinol monotherapy (2.5 - 15 mg Δ^9-THC/day; with weekly increases of 2.5 mg Δ^9-THC, up to a maximum of 15 mg THC/day) on experimentally-induced pain, axon reflex flare, and pain relief in patients suffering from fibromyalgia reported that a sub-population of such patients experienced significant pain relief (reduced pain perception) with 10 and 15 mg/day Δ^9-THC, but no changes were observed in axon reflex flare (260). Touch-evoked allodynia and pinprick-induced hyperalgesia were also not significantly affected by Δ^9-THC. Subjects who completed a three-month course of therapy (15 mg/day Δ^9-THC) reported a > 50% decrease in pain (260). The study, however suffered from low power due to the high rate of patient drop-out caused by intolerable side effects of the treatment. A multi-center, retrospective study of patients suffering from fibromyalgia who were prescribed an average daily dose of 7.5 mg Δ^9-THC, over an average treatment period of seven months, reported a significant decrease in pain score, a significant decrease in depression, and a reduction in the intake of concomitant pain-relief medications such as opioids, anti-depressants, anti-convulsants, and non-steroidal anti-inflammatory drugs following treatment with Δ^9-THC (261). It is important to note that the study had a number of considerable limitations (method of data collection, heterogeneous patient selection criteria, and high subject drop-out rate) and as such, the results should be interpreted with caution.

Nabilone

A randomized, double-blind, placebo-controlled trial of nabilone (1 mg b.i.d.) for the treatment of fibromyalgia showed statistically significant improvements in a subjective measure of pain relief and anxiety, as well as on scores on the fibromyalgia impact questionnaire, after four weeks of treatment (353). However, no significant changes in the number of tender points or tender point pain thresholds were observed (note: the use of the "tender point" as a diagnostic criterion for fibromyalgia is no longer an absolute requirement) (546). Patients were taking concomitant pain medications such as non-steroidal anti-inflammatory drugs, opioids, anti-depressants, and muscle relaxants. Nabilone did not have any lasting benefit in subjects when treatment was discontinued. A two-week randomized, double-blind, active-control, crossover study of 29 patients suffering from fibromyalgia reported that nabilone (0.5 - 1.0 mg before bedtime) improved sleep in this patient population (354).

The recently published Canadian Clinical Guidelines for the Diagnosis and Management of Fibromyalgia Syndrome (endorsed by the Canadian Pain Society and the Canadian Rheumatology Association) indicate that with regards to possible treatments, a trial of a prescribed pharmacologic cannabinoid may be considered in a patient with fibromyalgia, particularly in the setting of important sleep disturbance (this recommendation was based on Level 3, Grade C evidence) (506). For additional information regarding the use of cannabis/cannabinoids to alleviate sleep disorders or disturbances, please consult section 4.8.5.2.

4.7.4 Osteoporosis

Osteoporosis is a disease characterized by reduced bone mineral density and an increased risk of fragility fractures (547). It occurs when the normal cycle of bone remodelling is perturbed, leading to a net decrease in bone deposition and a net increase in bone resorption (548). While increasing evidence suggests a role for the endocannabinoid system in bone homeostasis, the role of cannabinoids in the treatment of osteoporosis has only been studied pre-clinically and the information remains unclear due to the complex and conflicting results among the various pre-clinical studies.

Pre-clinical studies

CB_1 and CB_2 receptors have been detected in mouse osteoblasts and osteoclasts, although CB_1 is expressed at very low levels compared to CB_2 (18,549,550). In fact, it appears that CB_1 receptors are expressed more abundantly in skeletal sympathetic nerve terminals in close proximity to osteoblasts (551). Besides the receptors, the endocannabinoids 2-arachidonoylglycerol (2-AG) and anandamide have been detected in mouse trabecular bone and in cultures of mouse osteoblasts and human osteoclasts (550,552,553). Taken together, these findings suggest the existence of a functional endocannabinoid system in bone.

The role of the endocannabinoid system in bone physiology has been investigated using mice carrying genetic deletions of either the CB_1 (*CNR1*) or CB_2 (*CNR2*) receptor genes. The skeletal phenotypes of CB_1 receptor knockout mice appear to vary depending on the gene targeting strategy used, the mouse strain, gender, time points at which the phenotypes were assessed, and the different experimental methodologies used to measure bone density (18). In one CB_1-deficient mouse strain, young female mice had normal trabecular bone with slight cortical expansion whereas young male mice had high bone mass (549,551). Loss of CB_1 receptor function was associated with protection from ovariectomy-induced bone loss (549). In addition, antagonism of CB_1 and CB_2 receptors prevented ovariectomy-induced bone loss *in vivo* (549). A subsequent study by the same group reported that CB_1 knockout mice had increased peak bone mass but eventually developed age-related osteoporosis (547). The increased peak bone mass was attributed to a reduction in osteoclast formation and activity, with preservation of normal osteoblast activity. In contrast, age-related bone loss in the knockout mice appeared to be caused by preferential formation and accumulation of adipocytes at the expense of osteoblasts within the bone-marrow space as well as decreased bone formation (547). In contrast to these studies, another study using a different gene targeting strategy and mouse strain reported that both male and female CB_1 knockout mice exhibited low bone mass, increased numbers of osteoclasts, and a decrease in the rate of bone formation (551). The effects of ovariectomy in this mouse line were not examined, most likely because the baseline bone mass was too small to properly measure differences between mice subjected to ovariectomy and controls.

The skeletal phenotypes of CB_2 receptor knockout mice have also been investigated. Ofek reported that CB_2-deficient mice display a low bone mass phenotype as well as age-related trabecular bone loss (554). These deficits were associated with increased numbers of osteoclasts and decreased numbers of osteoblast precursors (554). Furthermore, a selective CB_2 receptor agonist was reported to increase osteoblast proliferation and activity and to decrease the formation of osteoclast-like cells *in vitro*, and administration of this agonist attenuated ovariectomy-induced bone loss *in vivo* (554). While a more recent study supported the finding of age-related bone

loss, it failed to find any significant differences in peak bone mass between wild-type and knockout mice (555). Furthermore, and in contrast to the study by Ofek (554), selective stimulation of the CB_2 receptor was associated with an increase in osteoblast differentiation and function rather than proliferation. Another study reported no differences in peak bone mass between CB_2 receptor knockout mice and wild-type mice under normal conditions (556). Age-related bone loss was not measured in this study. Genetic ablation of the CB_2 receptor appeared to protect against ovariectomy-induced bone loss, an effect mimicked by administration of a CB_2-selective antagonist (556). Conversely, results from *in vitro* studies suggested that CB_2-selective agonists significantly increased osteoclast formation and osteoclast size (556). It may be relevant to note here that single nucleotide polymorphisms (SNPs) and SNP haplotypes located in the coding region of the CB_2 receptor gene have also been associated with osteoporosis in humans (557,558,559).

A pre-clinical study in rats measuring the impact of cannabis smoke on bone healing around titanium implants reported that chronic exposure to cannabis smoke reduced cancellous bone healing around the implants by reducing bone filling and bone-to-implant contact inside the implant threads (263). No such effect was observed for cortical bone (263).

4.8 Other diseases and symptoms

4.8.1 Movement disorders

The individual components of the endocannabinoid system are particularly abundant in areas of the brain which control movement, such as the basal ganglia (560). Motor effects generally arise as a consequence of changes in endocannabinoid system activity, with activation of the CB_1 receptor typically resulting in inhibition of movement (560). A number of studies have reported changes in CB_1 receptor levels and CB_1 receptor activity in motor diseases such as Parkinson's and Huntington's disease (561,562,563,564), and the findings from such studies suggest a role for the endocannabinoid system in the pathophysiology of these and other neurological diseases.

4.8.1.1 Dystonia

Pre-clinical data

A pre-clinical study in a hamster model of primary generalized dystonia reported a dose-dependent decrease in disease severity with administration of the synthetic CB_1 and CB_2 cannabinoid receptor agonist WIN 55,212-2 (565). However, anti-dystonic doses of the agonist were associated with severe side effects including depression of spontaneous locomotor activity and catalepsy. In addition, this CB receptor agonist increased the anti-dystonic effect of diazepam (565). A follow-up study by the same group confirmed the anti-dystonic efficacy of WIN 55,212-2 and also showed that cannabidiol delayed the progression of dystonia, but only at a very high dose (566). A pre-clinical study of anti-psychotic-induced acute dystonia and tardive dyskinesia in monkeys showed that oral dyskinesia, but not dystonia, was dose-dependently reduced by the synthetic CB_1 receptor agonist CP 55,940 (567).

Clinical data

While anecdotal reports suggest cannabis may alleviate symptoms associated with dystonia in humans (568), no properly controlled clinical studies of cannabis to treat dystonia have been published. A placebo-controlled, single-dose trial with 5 mg of Δ^9-THC administered to a musician with focal dystonia ("Musician's Dystonia") reported an improvement in motor control in the subject's affected hand, with tiredness and poor concentration cited as side effects associated with the use of Δ^9-THC (569). The therapeutic effect persisted until 2 h after intake, with a progressive return to baseline values after 5 h (569). A six-week, open-label, pilot trial of five patients taking 100 - 600 mg/day of cannabidiol reported modest dose-related improvements in all study subjects, but a worsening of tremor and hypokinesia in two patients with co-existing Parkinson's disease (570). Results of a double-blind, randomized, placebo-controlled study of 15 patients taking a single 0.03 mg/kg dose of nabilone and not taking any other anti-dystonia medication showed no significant reduction in dystonia (571).

4.8.1.2 Huntington's disease

Pre-clinical and human experimental data

Results from studies carried out in animal models of Huntington's disease (HD) as well as post-mortem studies carried out in HD patients suggest that brain CB_1 receptors, especially those found in the basal ganglia, are downregulated and/or desensitized as a result of the expression of the mutant Huntingtin protein, and that this occurs early in the course of the disease and prior to the appearance of overt clinical symptoms (561,572,573,574,575,576,577,578,579,580,581). A recent *in vivo* PET study of HD patients supports these findings, demonstrating profound decreases in CB_1 receptor availability throughout the gray matter of the cerebrum, cerebellum, and brainstem of HD patients even in early stages of the disease (582). Additional pre-clinical and post-mortem studies in HD patients indicate that the decrease in CB_1 receptor levels appears to be accompanied by an increase in CB_2 receptor levels in glial elements, astrocytes, and in reactive microglial cells (577,583). Thus, a significant amount of pre-clinical evidence and some limited clinical evidence suggests that changes in the endocannabinoid system are tightly linked to the pathophysiology of HD (577,580,581,582).

One pre-clinical study in a mouse model of HD reported no beneficial effects of Δ^9-THC (10 mg/kg/day) (584), while another study reported that Δ^9-THC (2 mg/kg/day) was associated with decreased pathology and delayed onset of HD-like symptoms compared to untreated HD mice (579).

Clinical data

With regard to clinical studies, one double-blind, placebo-controlled, 15-week, crossover trial of 15 patients with HD taking 10 mg/kg/day of oral cannabidiol did not report improvement in symptoms associated with HD (585). A randomized, double-blind, placebo-controlled, crossover pilot study found little or no beneficial effect of nabilone over placebo in patients with HD (586). However, nabilone was well tolerated in this patient population and did not appear to exacerbate chorea or HD-associated psychosis, although some adverse effects such as drowsiness and forgetfulness were noted. Patients were concomitantly taking other HD medications. The results from single-patient case studies are mixed. In one study, daily doses of 1.5 mg nabilone increased choreatic movements (587), while in another case improved mood and decreased chorea were noted in a patient who had smoked cannabis and who then continued on 1 mg nabilone b.i.d. (588).

4.8.1.3 Parkinson's disease

Endocannabinoid ligands, their synthesizing and degrading enzymes, and cannabinoid-activated receptors are highly abundant in the basal ganglia, the brain structures primarily affected in Parkinson's disease (PD) (560). Newly diagnosed PD patients and those undergoing PD medication washout were reported to have more than double the level of anandamide in their cerebrospinal fluid compared to controls, and these results parallel those seen in animal models of PD where dopamine cell loss is accompanied by elevations in anandamide levels (589). In animal models of PD the levels of CB_1 receptors appear to be downregulated during the early, pre-symptomatic stages of the disease, but during the intermediate and advanced phases of the disease there is an increase in CB_1 receptor density and function and an increase in endocannabinoid levels (590,591). Together, these studies suggest a complex link between the pathophysiology of PD and changes in the endocannabinoid system.

Results from animal studies suggest cannabinoid receptor agonists induce hypokinesia and thus are reported to be unlikely as suitable first-line treatments for PD (560,592). On the other hand, cannabinoid-induced hypokinesia could be useful in attenuating the dyskinesia observed in PD patients on long-term levodopa treatment (592). Cannabinoids having mixed CB_1 antagonist/CB_2 agonist properties as well as anti-oxidant effects (such as THCV) may possibly hold some therapeutic potential, but much further research is required to determine whether the beneficial effects of THCV observed in animal models of PD can find applicability in humans (593).

Clinical data

The results of clinical trials examining the role of cannabinoids (cannabis, nabilone and a standardized oral cannabis extract) in the treatment of PD are mixed. One study involving five patients suffering from idiopathic PD found no improvement in tremor after a single episode of smoking cannabis (1 g cigarette containing 2.9% Δ^9-THC, 29 mg total available Δ^9-THC), whereas all subjects benefited from the

administration of levodopa and apomorphine (594). A small randomized clinical trial of the synthetic cannabinoid nabilone (0.03 mg/kg) in seven patients with PD found that the treatment reduced levodopa-induced dyskinesia (595). In contrast, a four-week, randomized double-blind, crossover study demonstrated that an oral cannabis extract (2.5 mg Δ^9-THC and 1.25 mg cannabidiol per capsule, b.i.d.; maximum daily dose 0.25 mg/kg Δ^9-THC) did not produce any pro- or anti-parkinsonian action (596).

4.8.1.4 Tourette's syndrome

Anecdotal and case-reports have suggested amelioration of symptoms associated with Tourette's syndrome when smoking cannabis (597,598). A two-day, randomized, double-blind, placebo-controlled, crossover trial of single oral doses of Δ^9-THC (5, 7.5, or 10 mg) in 12 adult patients with Tourette's syndrome showed plasma concentration-related improvements in control of motor and vocal tics and obsessive-compulsive behaviour, with no serious side effects; although transient, mild side effects (e.g. headache, nausea, ataxia, fatigue, anxiety) were noted in five patients (599). In contrast to healthy cannabis users, neither a 5 mg nor a 10 mg dose of Δ^9-THC caused cognitive impairment in patients with Tourette's syndrome (599). This study was followed up by a six-week, randomized, double-blind, placebo-controlled trial by the same research group. The authors reported a significant difference in tic reduction compared to placebo in some patients, and no detrimental effects on neuropsychological performance during or after treatment with 10 mg doses of Δ^9-THC (600). The major limitations of all three clinical studies were their small sample size and their relatively short duration.

A Cochrane Collaboration Review examining the efficacy and safety of cannabinoids in treating tics, premonitory urges, and obsessive compulsive symptoms in patients with Tourette's syndrome concluded that there was insufficient evidence to support the use of cannabinoids in treating tics and obsessive compulsive behaviour in persons suffering from Tourette's syndrome (601).

4.8.2 Glaucoma

Glaucoma is a multi-factorial disease characterized by the progressive degeneration of the optic nerve and the death of retinal ganglion cells (RGC) ultimately leading to irreversible blindness (602). Increased intra-ocular pressure (IOP) has been implicated in the pathophysiology of glaucoma; however, inadequate blood supply to the optic nerve, oxidative damage, and apoptosis of RGCs are also contributing factors (265,602,603,604). An endocannabinoid system exists in a number of ocular tissues, and post-mortem studies have detected decreased levels of endocannabinoids in such tissues taken from glaucoma patients (605).

Ocular (as well as systemic) administration of cannabinoids typically lowers IOP by up to 30% (see (265) for a full reference list). How cannabinoids reduce IOP is unclear, but several possible mechanisms have been proposed including reduction of capillary pressure, decreased aqueous humour production, and improved aqueous humour uveoscleral outflow and outflow facility (606,607,608,609,610).

A well-controlled pilot study of six patients with ocular hypertension or early primary open-angle glaucoma reported that single sub-lingual doses of 5 mg Δ^9-THC (applied by means of an oro-mucosal spray) significantly but temporarily reduced IOP 2 h after administration (264). A single sub-lingual dose of 20 mg cannabidiol (CBD) (containing ~ 1 mg Δ^9-THC) had no effect, while a single sub-lingual dose 40 mg of CBD (containing ~ 2 mg Δ^9-THC) caused a significant transient increase in IOP 4 h after administration (264). A non-randomized, unmasked, uncontrolled clinical study reported some improvement in IOP after oral ingestion of Δ^9-THC (2.5 or 5 mg q.i.d., up to a maximum of 20 mg/day; treatment duration range 3 - 36 weeks) in patients with end-stage, open-angle glaucoma not responsive to medications or surgery (611). Some patients appeared to develop tolerance to the intra-ocular pressure-lowering effects of Δ^9-THC, and almost half discontinued treatment due to Δ^9-THC-associated toxicity (e.g. dizziness, dry mouth, sleepiness, depression, confusion) (611). Aside from lowering IOP, cannabinoids such as Δ^9-THC and CBD may also have neuroprotective effects which could also be useful in the management of glaucoma (265,612,613,614,615,616,617,618,619,620,621). Results from a survey carried out among 1 516 glaucoma patients at tertiary glaucoma clinics in Toronto and Montreal suggested that approximately 13% of these patients claimed they used complementary and alternative medicines to treat glaucoma, and from among these patients 2.3% reported using cannabis to treat their glaucoma (622).

In conclusion, while smoking or eating cannabis has been shown to reduce IOP (623,624,625), cannabinoid-based therapy appears to be limited by the short duration of cannabinoid action (3 - 4 h) and unwanted physical and psychotropic effects.

4.8.3 Asthma

There is some historical and anecdotal evidence for cannabis as a treatment for asthma (626). In terms of pre-clinical data, there is some evidence suggesting a role for the endocannabinoid system in regulating bronchial smooth muscle tone (627) and studies in animals with classical and synthetic cannabinoids suggest a possible role for cannabinoid-based compounds in the treatment of asthma (628,629,630).

Early clinical studies demonstrated significant decreases in airway resistance and increases in specific airway conductance in healthy, habitual cannabis smokers shortly after smoking cannabis (631,632). This effect has been largely attributed to the bronchodilatory properties of Δ^9-THC (633). However, for asthmatics, the benefits of smoking cannabis are likely to be minimal. While smoking cannabis appears to decrease bronchospasm, increase bronchodilatation, and modestly improve respiratory function in some asthmatics in the short-term (634,635,636), cannabis smoke contains noxious gases and particulates that irritate and damage the respiratory system (633); hence, it is not a viable long-term therapy for asthma. Nevertheless, alternate methods of Δ^9-THC delivery by aerosol or oral administration have been studied. Doses of 100 and 200 µg of aerosolized Δ^9-THC significantly improved ventilatory function in asthmatics and were generally well tolerated (637,638). In another study, 5 - 20 mg of aerosolized Δ^9-THC rapidly and effectively increased airway conductance in healthy subjects, but caused either bronchodilatation or bronchoconstriction in asthmatics (639). Oral administration of 10 mg Δ^9-THC or 2 mg nabilone did not produce clinically significant bronchodilatation in patients with reversible airways obstruction (626,640,641).

4.8.4 Hypertension

CB_1 receptors are expressed on various peripheral tissues including the heart and vasculature, and cannabinoid agonists and endocannabinoids decrease arterial blood pressure and cardiac contractility (reviewed in (642)).
There are very few studies on the effects of cannabis or cannabinoids on hypertension. In one early study, inhalation of cannabis smoke from cigarettes containing 2.8% Δ^9-THC caused a greater and longer-lasting decrease of arterial blood pressure in hypertensive subjects compared to normotensives (643). In one case-report, a woman with longstanding idiopathic intra-cranial hypertension reported improvement in her symptoms after smoking cannabis or after treatment with dronabinol (10 mg b.i.d initially, then 5 mg b.i.d.).

There are no reports on the use of low-dose cannabinoids as supplementary therapy in hypertension.

4.8.5 Psychiatric disorders

There are anecdotal and, in some cases, historical claims regarding the beneficial effects of cannabis and cannabinoids in the treatment of a variety of psychiatric disorders including anxiety, depression, sleep disorders, post-traumatic stress disorder, and withdrawal symptoms associated with drug abuse/addiction. The following sections provide information gathered from the scientific and medical literature regarding the use of cannabis and cannabinoids in the treatment of such disorders.

4.8.5.1 Anxiety and depression

Long-term cannabis users report reductions in anxiety, increased relaxation, and relief from tension (147). One survey conducted among over 4 400 respondents suggested that those who consumed cannabis daily or weekly reported a decrease in depressed mood, and an increase in positive affect, compared to respondents who claimed they never consumed cannabis (644). However, the study suffered from a number of serious drawbacks and should be interpreted with this in mind.

Pre-clinical and clinical evidence indicates important roles for the endocannabinoid system in both anxiety and depression. Results from animal studies suggest low doses of CB_1 receptor agonists reduce anxiety-like behaviour and increase anti-depressant-like responses (645,646). CB_1 receptor agonists appear to enhance central serotonergic and noradrenergic neurotransmission similar to the actions of anti-depressant medications (647,648). On the other hand, high-level stimulation of the CB_1 receptor, or administration of CB_1 receptor antagonists, reverse this response and can also trigger depression (155,647,649,650).

Suppression of endocannabinoid signalling is sufficient to induce a depressive-like state both in animals and in humans (reviewed in (651)). Furthermore, basal serum concentrations of both anandamide and 2-arachidonoylglycerol (2-AG) have been found to be significantly reduced in women with major depression (652). These findings suggest proper endocannabinoid tone plays an important role in regulating mood.

Clinical data for cannabis and THC

While the routine use of cannabis or prescription cannabinoid medications to treat primary anxiety or depression should be viewed with caution, and especially discouraged in patients with a history of psychotic disorders (see section 7.7.3.3), limited clinical evidence indicates that these drugs may present alternative therapeutic avenues in patients suffering from anxiety or depression secondary to certain chronic diseases. For example, in a study of HIV+ patients who reported using cannabis to manage their symptoms, 93% cited an improvement in anxiety and 86% cited an improvement in depression (653). It is important to note that 47% of those surveyed reported deterioration in memory. In another study of HIV+ cannabis smokers, high-dose dronabinol (5 mg q.i.d., for a total daily dose of 20 mg, for two days, followed by 10 mg q.i.d., for a total daily dose of 40 mg, for 14 days) was associated with an increase in self-reported "positive affect" (feeling "content"), but no change was observed in measures of anxiety or "negative affect") (193). The dosage employed in this study was eight times the recommended starting dose for appetite stimulation (i.e. 2.5 mg b.i.d), and double the maximal daily recommended dose. Improved mood was also reported as a beneficial effect of cannabis consumption in patients suffering from multiple sclerosis (654). Improvements in anxiety or depression were equally noted in a study of patients suffering from chronic neuropathic pain who smoked cannabis (172). It may be interesting to note here that rimonabant, a CB_1 receptor antagonist initially marketed as an anti-obesity medication, was withdrawn from the market because its use was associated with a significant incidence of anxiety, depression, and suicide, underscoring the role of the CB_1 receptor in regulating mood (650,655).

Cannabidiol

Increasing evidence suggests a role for cannabidiol (CBD) in decreasing anxiety, although the extent to which CBD (at the concentrations commonly found in cannabis) is able to achieve this effect remains uncertain (181,656). Pre-clinical studies have shown that CBD and CBD-derivatives decreased anxiety-like behaviour in a rat model of anxiety (657). An early clinical study showed that CBD (1 mg/kg) attenuated, but did not completely block, the anxiogenic effects of THC (0.5 mg/kg) in eight healthy volunteers with a history of marihuana use (97). A double-blind, crossover clinical study showed that a single dose of CBD (400 mg) significantly decreased anticipatory anxiety but increased mental sedation, although the findings were deemed to be preliminary and follow-up studies were suggested (658). Single-photon emission computed tomography (SPECT) brain imaging studies showed that in contrast to placebo, CBD decreased regional cerebral blood flow in the limbic and paralimbic cortical areas, regions implicated in the pathophysiology of anxiety (658). Furthermore, a randomized, double-blind, placebo-controlled study showed that 600 mg of CBD attenuated brain activity (blood oxygenation level-dependent response) in these cortical regions in response to anxiogenic stimuli (104). In contrast, 10 mg Δ^9-THC increased anxiety at baseline or in response to anxiogenic stimuli, but the brain regions affected by Δ^9-THC differed from those affected by CBD (104). A more recent double-blind, randomized, placebo-controlled clinical study showed that 600 mg of orally-administered CBD was associated with a significant reduction in anxiety, cognitive impairment, and discomfort in patients suffering from generalized social anxiety disorder subjected to a simulated public-speaking test (659). The authors caution that the study was preliminary in nature, with additional larger and well-controlled studies required to substantiate this effect. Although the precise mechanism by which CBD exerts its anxiolytic effects is not well established, it may act either by decreasing blood flow to brain regions associated with the processing of anxiety or fear-based stimuli (as mentioned above), or possibly through the modulation of serotonergic neurotransmission (660,661).

4.8.5.2 Sleep disorders

Pre-clinical data

There is some evidence to suggest a role for the endocannabinoid system in sleep. Subjects deprived of sleep for a 24 h period had increased levels of oleoylethanolamide (OEA), a natural analog of anandamide, in their cerebrospinal fluid but not in serum, whereas levels of anandamide were unchanged (662). In rats, both acute and sub-chronic administration of anandamide induces sleep (663). Cannabis and Δ^9-THC are known to have a number of effects on sleep. In general, it appears that these substances decrease sleep latency and are associated with greater ease in getting to sleep, but they consistently reduce total rapid-eye movement (REM) sleep and REM density (reviewed in (161)). Furthermore, due to the long half-life of THC, sedative effects typically persist into the day following cannabinoid administration (161).

Clinical data

A number of clinical studies point to a potential beneficial role for smoked cannabis or prescription cannabinoids (dronabinol, nabilone, nabiximols) in the treatment of sleep difficulties or disturbances associated with chronic pain (cancer pain, chronic non-cancer pain, diabetic peripheral neuropathy), HIV-associated anorexia-cachexia, multiple sclerosis, amyotrophic lateral sclerosis, spinal cord injury, rheumatoid arthritis, fibromyalgia, inflammatory bowel disease, multiple sclerosis-associated bladder dysfunction, post-traumatic stress disorder, and chemosensory alterations and anorexia-cachexia associated with advanced cancer (157,158,165,166,167,172,193,259,348,354,362,364,378,432,438,443,448,449,494,506). In most of these studies, the effect on sleep was measured as a secondary outcome. Although presented elsewhere throughout the text in the relevant sections, brief summaries of these studies are presented below.

Dronabinol

A four-week, randomized, double-blind, crossover pilot study of 19 patients suffering from amyotrophic lateral sclerosis (ALS) taking 2.5 - 10 mg per day of dronabinol reported improvements in sleep (443). Two studies reported that dronabinol (20 - 40 mg total Δ^9-THC/day) and smoked cannabis (~800 mg cigarettes containing 2 or 3.9% THC, administered four times per day for four days, corresponding to an estimated daily amount of 64 - 125 mg of Δ^9-THC) produced improvements in mood and sleep in patients with HIV/AIDS-associated anorexia-cachexia (166,167). A study of HIV+ cannabis smokers treated with dronabinol for 14 days (10 mg q.i.d., 40 mg daily) reported improvements in both objective and subjective measures of sleep, but only during the first eight days of the treatment regimen (193). A two-centre, phase II, randomized, double-blind, placebo-controlled 22-day pilot study carried out in adult patients suffering from chemosensory alterations and poor-appetite associated with advanced cancer of various etiologies reported statistically significant improvements in measures of quality of sleep and relaxation with dronabinol treatment (2.5 mg b.i.d.) compared to placebo (362).

Nabilone

An off-label, retrospective, descriptive study of 20 adult patients suffering from chronic non-cancer pain of various etiologies (post-operative or traumatic pain, reflex sympathetic dystrophy, arthritis, Crohn's disease, neuropathic pain, interstitial cystitis, HIV-associated myopathy, post-polio syndrome, idiopathic inguinal pain, chronic headaches) reported beneficial effects of nabilone (1 - 2 mg/day) on sleep (494). An enriched-enrolment, randomized-withdrawal, flexible-dose, double-blind, placebo-controlled, parallel assignment efficacy study of nabilone (1 - 4 mg/day), as an adjuvant in the treatment of diabetic peripheral neuropathic pain, reported statistically significant improvements in sleep and overall patient status (364). An open-label, non-placebo-controlled trial of nabilone for post-traumatic stress disorder reported that nabilone treatment was associated with an improvement in sleep time, cessation or lessening of nightmare severity, and cessation of night sweats (348). Dosing of nabilone was 0.5 mg, 1 h prior to bedtime; effective dose range was 0.2 mg - 4 mg nightly with all doses kept below 6 mg daily. A two-week, randomized, double-blind, active-control, crossover study of 29 patients suffering from fibromyalgia reported that nabilone (0.5 - 1.0 mg before bedtime) improved sleep in this patient population (354).

Smoked cannabis

Surveys carried out among patients suffering from multiple sclerosis reported cannabis-associated improvements in sleep in this patient population (164,165). Reported dosages of smoked cannabis varied from a few puffs, to 1 g or more, at a time (165). A cross-sectional survey of patients suffering from fibromyalgia reported that subjects claimed using cannabis (by smoking and/or eating) for a variety of symptoms associated with fibromyalgia, including sleep disturbance (158). A cross-sectional survey of 291

patients with inflammatory bowel disease (Crohn's disease or ulcerative colitis) reported that one of the reasons patients used cannabis was to improve sleep (157). A two-week, randomized, double-blind, placebo-controlled, cross-over study of patients suffering from chronic neuropathic pain reported that those who smoked 25 mg of cannabis containing 9.4% Δ^9-THC, three times per day for five days (2.35 mg total available Δ^9-THC per cigarette, or 7.05 mg total Δ^9-THC per day), fell asleep more easily and more quickly, and experienced fewer periods of wakefulness (172).

Orally administered prescription cannabinoid medications (Cannador and nabiximols)
A double-blind, placebo-controlled, phase III study, involving patients with stable multiple sclerosis (the **MU**ltiple **S**clerosis and **E**xtract of **C**annabis trial—i.e. "MUSEC") reported that a 12-week treatment with an oral cannabis extract ("Cannador") (2.5 mg Δ^9 –THC and 0.9 mg cannabidiol/dose) was associated with a statistically significant improvement in sleep compared to placebo (432). The majority of the patients using cannabis extract used total daily doses of 10, 15, or 25 mg of Δ^9–THC with corresponding doses of 3.6, 5.4, and 9 mg of CBD. Results from double-blind, crossover, placebo-controlled studies of oral Δ^9-THC and/or Δ^9-THC : CBD extract (nabiximols, marketed as Sativex®) suggested modest improvements in pain, spasticity, muscle spasms, and sleep quality in patients with spinal cord injury (378,448,449). A preliminary clinical study assessing the effectiveness of nabiximols (Sativex®) in pain caused by rheumatoid arthritis reported a modest, but statistically significant, analgesic effect and consequent improvement in quality of sleep (259). The mean daily dose in the final treatment week was 5.4 pump actuations (equivalent to 14.6 mg Δ^9-THC and 13.5 mg CBD). A sixteen-week, open-label pilot study of cannabis-based extracts (a course of Sativex® treatment followed by maintenance with 2.5 mg Δ^9-THC only) for bladder dysfunction in 15 patients with advanced multiple sclerosis reported significant decreases in nocturia and improvement in patient self-assessment of sleep quality (438).

The recently published Canadian Guidelines for the Diagnosis and Management of Fibromyalgia Syndrome (endorsed by the Canadian Pain Society and the Canadian Rheumatology Association) recommend that with regards to possible treatments, a trial of a prescribed pharmacologic cannabinoid may be considered in a patient with fibromyalgia, particularly in the setting of important sleep disturbance (this recommendation was based on Level 3, Grade C evidence) (506).

Data from withdrawal studies
Heavy cannabis users (mean number of joints smoked per week = 100) who abruptly discontinue cannabis use have been shown to exhibit changes in polysomnographic sleep measures, including lower total sleep times, less slow wave sleep, longer sleep onset, shorter REM latency, and worse sleep efficiency and continuity parameters compared to controls (664). Trouble getting to sleep, nightmares and/or strange dreams, and night sweats were frequently cited items associated with cannabis withdrawal (222). These sleep disturbances progress over the first two weeks of abstinence (665). Furthermore, sleep disturbances resulting from abrupt discontinuation of cannabis use may trigger users to relapse (274,665). The symptoms observed during abstinence from cannabis may alternatively reveal a pre-existing sleep disorder masked by the drug.

4.8.5.3 Post-traumatic stress disorder (PTSD)
Post-traumatic stress disorder (PTSD) refers to the development of a cluster of characteristic symptoms that follow exposure to an extreme traumatic stressor and which appears to involve aberrant memory processing and impaired adaptation to changed environmental conditions (666). Characteristic symptoms include persistent, intrusive recollections, or a re-experiencing of the original traumatic event (through dreams, nightmares, and dissociative flashbacks), numbing and avoidance, and increased arousal (348).

Role of the endocannabinoid system in PTSD
Increasing evidence suggests an important role for the endocannabinoid system in PTSD. The endocannabinoid system has been associated with the regulation of emotional states and cognitive processes, and neuroanatomical studies have detected the presence of endocannabinoid system elements in a number of brain structures involved in learning and memory, and in structures which also play central roles in fear conditioning and response (reviewed in (666)). Furthermore, similarities exist between the expression of fear and anxiety in humans suffering from phobias, PTSD, or other anxiety disorders, and the expression of conditioned fear in animals. Therefore, the use of certain animal behavioural models to study PTSD is feasible and relevant (666,667).

Pre-clinical data

A number of pre-clinical studies demonstrate that deletion of the CB_1 receptor or its inhibition by pharmacological antagonists prevent the extinction of aversive memories (i.e. learned inhibition of fear), a naturally adaptive process (667,668,669,670). Conversely, in some cases, CB_1 receptor agonism or increased endocannabinoid-mediated neurotransmission appear to enhance extinction to some degree (667,670), but further research is required to clarify and substantiate this effect. However, no studies have yet investigated the effects of Δ^9-THC *per se* on the extinction of aversive memories. Taken together, the evidence from pre-clinical studies suggests a role for the endocannabinoid system in the extinction of aversive memories, and raises the possibility that the endocannabinoid system may be a valid therapeutic target for the treatment of diseases associated with inappropriate retention of aversive memories or inadequate responses to aversive situations, such as PTSD or phobias (668).

Clinical data

Although anecdotal evidence suggests a role for cannabis in the management of PTSD symptoms, no properly controlled clinical trials on this topic exist. In fact the only clinical trial reported to date examining the effect of cannabinoids in PTSD is an open-label, non-placebo-controlled trial of nabilone for PTSD (348). Forty-seven patients diagnosed with PTSD (according to DSM-IV-TR criteria), having at least a two-year history of PTSD-related nightmares refractory to conventional therapies, a minimum of once weekly nightmares, and with no prior history of sensitivity to cannabinoids or evidence of psychotic reactions, were admitted into the study. Patients did not discontinue any concomitant psychotropic medications, and were started on 0.5 mg nabilone, 1 h prior to bedtime. All doses were kept below 6 mg daily. The effective dose range varied between 0.2 mg and 4 mg nightly. Seventy-two percent of patients self-reported total cessation or lessening of severity of nightmares (treatment duration 4 - 12 months or longer). Other self-reported benefits included an improvement in sleep time, a reduction in daytime flashbacks, and cessation of night sweats. Reported side effects included light-headedness, amnesia, dizziness, and headache. No tolerance to nabilone was observed in this clinical trial.

4.8.5.4 Alcohol and opioid withdrawal symptoms (drug withdrawal symptoms)

Alcohol

There is evidence to suggest complex functional interactions between ethanol and the endocannabinoid system (reviewed in (671)). Acute administration of ethanol in animals is associated with brain region-specific changes in endocannabinoid levels and in the expression of endocannabinoid system components (e.g. CB_1 receptor, FAAH) (671). Furthermore, modulation of endocannabinoid system components through genetic ablation of CB_1 receptor or FAAH expression, or by pharmacological inhibition of CB_1 receptor or FAAH activity, generally results in decreased ethanol consumption in animal models (although a few exceptions have been noted) (671). In contrast, activation of the CB_1 receptor appears to mediate the reinforcing properties of ethanol, facilitates ethanol consumption, and enhances re-instatement of ethanol self-administration in animal models (671). In the case of chronic ethanol consumption, the available evidence suggests long-term exposure to ethanol is in some cases associated with brain region-specific decreases in CB_1 receptor mRNA/protein expression and CB_1 receptor activity, as well as a decrease in FAAH expression and function (671). There is also some limited evidence gathered from animal studies that suggests the endocannabinoid system may be involved in the modulation of alcohol withdrawal symptoms, with CB_1 receptor agonism exacerbating withdrawal severity (671).

Opioids

Anecdotal information and findings from some animal studies suggest that cannabinoids might be useful in treating the symptoms associated with opioid withdrawal (512,672,673,674,675), but there are no supporting clinical studies in this regard. The overlapping neuroanatomical distribution, convergent neurochemical mechanisms, and comparable functional neurobiological properties of the cannabinoid and opioid systems may help explain why cannabinoids could substitute for opioids to potentially alleviate withdrawal symptoms associated with opioid abstinence (511). However, further research is required on this subject.

4.8.5.5 Schizophrenia and psychosis

The endocannabinoid system and psychotic disorders

There is increasing evidence implicating the endocannabinoid system in schizophrenia and psychosis (676). For example, levels of anandamide were reported to be significantly elevated in the cerebrospinal fluid and serum of patients with initial prodromal states of psychosis (677). In addition, anandamide levels were also elevated in the cerebrospinal fluid and serum of anti-psychotic-naïve patients with active schizophrenia (678,679). Post-mortem studies investigating CB_1 receptor densities in the brains of schizophrenic patients have also noted an upregulation of CB_1 receptor levels in the frontal and cingulate brain regions, areas of the brain typically afflicted in schizophrenia (676). While the precise role of the endocannabinoid system in psychosis and schizophrenia remains to be fully elucidated, it appears that such psychiatric disorders are accompanied by changes in the levels of endocannabinoids such as anandamide, as well as changes in CB_1 receptor expression level. Although it remains to be confirmed, one hypothesis holds that the endocannabinoid system may function as a feedback mechanism, negatively regulating dopamine release and dampening the hyperdopaminergic activity observed in the brains of schizophrenic subjects (676,680).

Substance use disorders and psychotic disorders

Interestingly, patients with severe mental illnesses such as schizophrenia are known to have high rates of substance use disorders, with cannabis being one of the substances most often used or misused by this population (681,682). Two competing hypotheses have tried to explain why patients with severe mental illnesses such as schizophrenia also have co-morbid substance abuse. The "self-medication" hypothesis, in the context of psychiatric disorders, posits that those who suffer from such disorders (e.g. schizophrenics) consume cannabis in order to alleviate specific psychopathological symptoms or alternatively to diminish the side effects resulting from the use of medications (682,683). While the "self-medication" hypothesis presents a compassionate, interesting, and attractive explanation to understand why schizophrenics have co-morbid substance abuse disorders, the hypothesis appears to have fallen out of favour (684). On the other hand, the "addiction-vulnerability" hypothesis claims that substance abuse vulnerability and schizophrenic symptoms share a common neuropathology (685). In other words, this hypothesis rests on the idea that certain pathological alterations in brain structure and function will predispose certain individuals to developing both schizophrenia and substance abuse disorders.

Cannabis/THC and psychosis

Regardless of which hypothesis is correct, there is much scientific evidence to suggest a positive association between cannabis use and the development of psychosis, especially in people susceptible to psychotic disorders but also in adolescents (138,139,141,143,144). Furthermore, controlled clinical studies carried out in those with no history of psychotic disorders reported the manifestation of transient schizophrenia-like symptoms induced by the intravenous administration of Δ^9-THC (140). Likewise, intravenous administration of Δ^9-THC in schizophrenics was associated with transient exacerbation of core psychotic symptoms (139).

Genetic factors

A number of studies have investigated the influence of potential genetic factors in the development of psychosis and schizophrenia, and more specifically as a function of interaction with cannabis use. Some studies have focused on the role of genetic polymorphisms at the catechol-O-methyltransferase gene (*COMT*) (686,687,688,689,690), and others have focused on polymorphisms at the *AKT1* gene (691,692,693). Taken together, the data from these studies strongly suggest that single-nucleotide polymorphisms at either the *COMT* or *AKT1* genes interact with cannabis use to predict the age at onset, as well as the likelihood of developing psychosis or schizophrenia in vulnerable individuals. Please consult section 7.7.3 for additional information on the adverse psychiatric effects associated with the use of cannabis and psychoactive cannabinoids (such as THC), and the role of genetic predisposition on the risk of developing a psychotic disorder. **The findings presented above and in section 7.7.3 suggest that cannabis use, as well as exposure to Δ^9-THC alone, would not be beneficial, and in fact would actually be harmful to those who may be suffering from psychotic disorders, or who may have a genetic predisposition or family history of psychosis or schizophrenia.**

Cannabidiol

A number of pre-clinical and clinical studies have suggested that, in contrast to THC, other cannabinoids such as cannabidiol (CBD) may in fact have anti-psychotic properties and may benefit psychotic patients (694,695). For example, studies in certain rat and mouse models of psychosis suggest that CBD (at doses of

15 - 60 mg/kg) reduces psychotic-like behavioural effects in a manner comparable to that observed with atypical anti-psychotic drugs (696,697). Furthermore, one clinical study showed that pre-treatment of a small number of human subjects with CBD (5 mg i.v.), but not placebo, diminished the emergence of psychotic symptoms 30 min after i.v. administration of Δ^9-THC (105). In contrast, a naturalistic study of cannabis users failed to show any differences in the prevalence of psychotic-like symptoms between subjects who reported smoking cannabis containing "low" or "high" levels of CBD; however the authors mention a number of confounding factors, including the lack of adjustment for alcohol consumption that could help explain this apparent inconsistency (656). An internet-based, cross-sectional study of 1 877 individuals who had a consistent history of cannabis use reported that individuals who had consumed cannabis with a higher CBD to THC ratio reported experiencing fewer psychotic episodes; however, the authors noted that the observed effects were subtle (113). Furthermore, the study was hampered by a number of important methodological issues suggesting the conclusions should be interpreted with caution. More recently, a four-week, double-blind, parallel-group, randomized, active-controlled clinical trial comparing CBD (200 mg, q.i.d., up to a total daily amount of 800 mg) to amilsupride (a dopamine D_2/D_3 receptor antagonist used in the treatment of schizophrenia) reported that both drugs were associated with a significant clinical improvement in symptoms with no significant difference between the two treatments (698). Treatment with CBD was well tolerated with significantly fewer side effects compared to those associated with anti-psychotic treatment (e.g. the presence of extra-pyramidal symptoms and lower prolactin release). In addition, CBD did not appear to significantly affect either hepatic or cardiac functions (698). Cannabidiol treatment, but not amilsupride, was also associated with an increase in serum levels of anandamide (698).

While there is some indication for a potential therapeutic role for CBD itself in the treatment of patients with pre-existing schizophrenia or psychosis or those who develop psychotic symptoms as a result of cannabis use, the extent to which CBD (at the levels typically found in cannabis) is able to ameliorate psychotic symptoms has not been firmly established and in fact, much of the cannabis consumed typically contains relatively low levels of CBD (60). For example, the CBD content of cannabis typically varies between 0.1 and 0.5%, although CBD levels of up to 8.8% (in hashish) have been noted (113). Therefore, a 1 g joint could contain between 1 mg (0.1%) and 88 mg (8.8%) of CBD—levels which are much lower than those usually administered in clinical trials (600 - 1500 mg/day) (699).

In conclusion, consumption of cannabis or other psychoactive cannabinoids (e.g. dronabinol, nabilone) should be treated with considerable caution in this patient population as these substances are believed to trigger psychotic episodes, lower the age of onset of symptoms, and contribute to a negative long-term prognosis in vulnerable individuals. Additionally, the therapeutic potential of CBD alone in the treatment of schizophrenia/psychosis, while promising, requires further study.

4.8.6 Alzheimer's disease and dementia

While still controversial, a widely accepted theory underlying the pathophysiology of Alzheimer's disease (AD) is the deposition of amyloid-β (Aβ) protein in specific brain regions leading to localized neuroinflammatory responses and accumulation of intra-cellular neurofibrillary tangles (composed of hyperphosphorylated tau protein); these events result in neuronal cell death with accompanying loss of functional synapses and changes in neurotransmitter levels (700). These pathological processes are thought to give rise to disease-associated symptoms such as memory deficits, and cognitive and motor impairments (700).

The endocannabinoid system and Alzheimer's disease

There is some evidence to suggest a role for the endocannabinoid system in the pathophysiology of AD (700,701). One *in vivo* study reported elevation in the levels of the endocannabinoid 2-arachidonoylglycerol (2-AG) in response to intra-cerebral administration of $A\beta_{1-42}$ peptide in animals (702). Another study using post-mortem brain samples from AD patients showed decreased anandamide levels with increasing $A\beta_{1-42}$ levels, but no association with $A\beta_{40}$ levels, amyloid plaque load, or tau protein phosphorylation (703).

Pre-clinical data

Pre-clinical studies suggest the endocannabinoid system protects against excitotoxicity, oxidative stress, and inflammation—all key pathological events associated with the development of AD (704). However, limited information exists regarding the use of cannabis or cannabinoids in the treatment of AD. Results from *in silico* and *in vitro* experiments suggest Δ^9-THC could bind and competitively inhibit acetylcholinesterase (AChE), which in the context of AD functions as a molecular chaperone accelerating the formation of amyloid fibrils and

forming stable complexes with Aβ (705). Δ^9-THC blocked the amyloidogenic effect of AChE, thereby diminishing Aβ aggregation (705). Other *in vitro* studies suggest that cannabidiol may have neuroprotective, anti-oxidant, and anti-apoptotic effects, as well as preventing tau protein hyperphosphorylation in cellular models of AD (706,707,708). Endocannabinoids have also been shown to prevent Aβ-induced lysosomal permeabilization and subsequent neuronal apoptosis *in vitro* (704). In pre-clinical animal models of AD, cannabidiol dose-dependently and significantly inhibited reactive gliosis and subsequent neuroinflammatory responses in Aβ-injected mice, at doses of 2.5 mg/kg/day and 10 mg/kg/day i.p., during a seven-day course of treatment (709). Another study using both *in vitro* and *in vivo* models of AD reported opposing roles for the CB_1 and CB_2 receptors in this context: CB_1 receptor agonism and CB_2 receptor antagonism were both associated with blunted Aβ-induced reactive astrogliosis and attenuation of neuroinflammatory marker expression (710).

Clinical data

There are very few clinical studies of cannabis or cannabinoids for the treatment of AD. One double-blind, placebo-controlled, six-week, crossover study of 12 patients suffering from Alzheimer-type dementia reported that 5 mg of dronabinol (Δ^9-THC) daily was associated with a decrease in disturbed behaviour (410). However, adverse reactions such as fatigue, somnolence, and euphoria (presumably unwanted) were reported in dronabinol-treated patients. One open-label pilot study of six patients suggested an evening dose of 2.5 mg dronabinol (Δ^9-THC) reduced nocturnal motor activity and agitation in those who were severely demented (711). In one case-report, a patient suffering from dementia of the Alzheimer-type who had been treated unsuccessfully with donepezil, memantine, gabapentin, trazodone, and citalopram was given nabilone (initially 0.5 mg at bedtime, and then twice per day) with immediate reduction in the severity of agitation and resistiveness and eventual improvement in various behavioural symptoms following six weeks of continuous treatment (712). It is unclear if the beneficial effects observed in these three studies are related to the non-specific sedative effects of Δ^9-THC or nabilone, or to a specific cannabinoid-dependent therapeutic mechanism of action. It is also worth noting that one cross-sectional study reported that prolonged use of ingested or inhaled cannabis was associated with poorer performance on various cognitive domains (e.g. information processing speed, working memory, executive function, and visuospatial perception) in patients with multiple sclerosis (178). Similar adverse effects of cannabis/cannabinoids on cognition could potentially apply in the context of Alzheimer-type dementia.

A Cochrane database systematic review of cannabinoids for the treatment of dementia concluded that there was insufficient clinical evidence to suggest cannabinoids as being effective in the improvement of disturbed behavior in dementia or in the treatment of other symptoms of dementia (713).

4.8.7 Inflammation

The role of the endocannabinoid system in inflammation is complex as the endocannabinoid system has been implicated in both pro- and anti-inflammatory processes (701). Endocannabinoids, such as anandamide and 2-arachidonoylglycerol (2-AG), are known to be produced and released by activated immune cells and to act as immune cell chemoattractants promoting or directing the inflammatory response (714). On the other hand, cannabinoids can also suppress the production of pro-inflammatory cytokines and chemokines and thus may have therapeutic applications in diseases with an underlying inflammatory component (714,715). For information on other diseases with an inflammatory component such as the arthritides or inflammatory bowel disease, please consult sections 4.7 and 4.8.8.2, respectively, of this document.

4.8.7.1 Inflammatory skin diseases (dermatitis, psoriasis, pruritus)

The skin possesses an endocannabinoid system (41). CB_1 and CB_2 receptors are expressed in a number of skin cells including epidermal keratinocytes, cutaneous nerves and nerve fibres, sebaceous cells, myoepithelial cells of eccrine sweat glands, sweat gland ducts, mast cells, and macrophages (716). The endocannabinoid system and certain associated signaling pathways (e.g. PPARγ, TRPV1) appear to regulate the balance between keratinocyte proliferation, differentiation, and apoptosis; together, these systems may play a role in cutaneous homeostasis but also in diseases such as psoriasis, which is characterized by keratinocyte proliferation and inflammation (41,717,718,719).

Pre-clinical and clinical studies

The results from pre-clinical studies on the role of cannabinoids in the modulation of cutaneous allergic reactions are mixed. Some studies suggest a protective role for certain cannabinoids, while others suggest an antagonistic role (reviewed in (41)). In clinical studies, experimentally-induced histamine-triggered pruritus was reduced by peripheral administration of the potent synthetic CB_1/CB_2 cannabinoid receptor agonist HU-

210, and the accompanying increases in skin blood flow and neurogenic mediated flare responses were attenuated (720). In another study, topically applied HU-210 significantly reduced the perception of localized pain in human subjects following locally restricted application of capsaicin to the skin, and reduced subsequent heat hyperalgesia and touch-evoked allodynia without any psychomimetic effects (721). On the other hand, there have also been some case-reports of contact urticaria following exposure to cannabis flowers, and extreme sensitization to Δ^9-THC and cannabinol has also been documented in an animal model of contact dermatitis (722,723). Therefore, while it is possible that some cannabinoids (e.g. HU-210) may have therapeutic value in the treatment of certain inflammatory skin conditions (such as psoriasis, pruritus, and dermatitis), it is also possible for some cannabinoids to trigger adverse skin reactions. Much further research is required in this area.

4.8.8 Gastrointestinal system disorders (irritable bowel syndrome, inflammatory bowel disease, hepatitis, pancreatitis, metabolic syndrome/obesity)

Historical and anecdotal reports suggest that cannabis has been used to treat a variety of gastrointestinal disorders (e.g. diarrhea, inflammation, and pain of gastrointestinal origin) (724,725,726).

The endocannabinoid system and gastrointestinal disorders

The expression of both the CB_1 and CB_2 receptors has been detected in the enteric nervous system (enteric sensory neurons, nerve fibers and terminals), whereas the human colonic epithelium, colonic epithelial cells lines, and stomach parietal cells appear to only express the CB_1 receptor (28,29). CB_2 receptor expression appears to be upregulated in sections of the colon in patients with inflammatory bowel disease (31). In contrast, the expression and localization of endocannabinoid synthesizing enzymes have not been well determined (31). However, studies in animals indicate that the endocannabinoid degradative enzymes FAAH and MAGL can be found in the gastrointestinal tract (31). For example, FAAH is expressed in the stomach and in the large and small intestines, and has also been localized to the cell bodies of the myenteric plexus (31). MAGL expression has been detected in the muscle and mucosal layers of the duodenum and the ileum, as well as in the proximal and distal colon, and in the nerve cell bodies and nerve fibers of the enteric nervous system (727). There also appears to be some regional variation in the levels of endocannabinoids in the gut; 2-arachidonoylglycerol (2-AG) appears to be more abundant in the ileum than the colon, whereas the opposite is true of anandamide (31). CB_1 and CB_2 receptors appear to be expressed in the pancreas (30), whereas the CB_1, but not the CB_2 receptor, is expressed in the liver under normal conditions (32,33).

Cannabinoids appear to have many functions in the digestive system including the inhibition of gastric acid production, gastrointestinal motility, and secretion and ion transport, and the attenuation of visceral sensation and inflammation (reviewed in (31)). Perturbations in the levels of various components of the endocannabinoid system have been noted in experimental models of gastrointestinal disorders, as well as in clinical studies (reviewed in (31). The sections below summarize the information regarding the uses of cannabis and cannabinoids in the treatment of various disorders of the gastrointestinal system.

4.8.8.1 Irritable bowel syndrome

Irritable bowel syndrome (IBS) is the most common functional gastrointestinal disorder encountered in clinical medicine (728). It is a spectrum of disorders characterized by the presence of chronic abdominal pain and/or discomfort and alterations in bowel habits (728,729). Symptom patterns can be divided into diarrhea predominant (D-IBS), constipation predominant (C-IBS), and a mixed pattern (M-IBS) (729,730). While the pathophysiology of IBS remains unclear, the disorder is thought to be caused by dysregulation of the 'brain-gut axis' in response to psychological or environmental stressors or to physical stressors such as infection or inflammation, and is characterized by altered gut motility and visceral hypersensitivity (728,729). There is also some emerging evidence that suggests an association between genetic alterations in genes coding for certain endocannabinoid system proteins (e.g. *FAAH* and *CNR1*) and the pathophysiology of IBS (731,732,733).

Pre-clinical data

A few pre-clinical studies in animal models of IBS have been carried out to date. Two studies have employed mechanically-induced colorectal distension to trigger an acute visceral pain response in rodents as a model of IBS-associated visceral hypersensitivity. One study in rats showed that intra-peritoneal injection of different synthetic cannabinoid receptor agonists inhibited pain-related responses to experimentally-induced colorectal distension when administered *prior* to the experimental stimulus (734). Intravenous administration of

different synthetic cannabinoid receptor agonists also appeared to inhibit the overall pain-related responses to experimentally-induced colorectal distension in rats, as well as in mice, when administered *after* the experimental stimulus (735). In another study, subcutaneous administration of CB_1 or CB_2-selective agonists was reported to reduce the enhanced small intestinal transit observed in a mouse model of post-inflammatory IBS (736).

Clinical data with dronabinol

There are only a handful of clinical studies examining the effects of cannabinoids in human experimental models of IBS and in patients with IBS.

One double-blind, randomized, placebo-controlled, parallel-group study examined the effects of dronabinol on gastrointestinal transit, gastric volume, satiation, and post-prandial symptoms in a group of healthy volunteers (737). A 5 mg dose of dronabinol was associated with a significant delay in gastric emptying in female subjects, but not male subjects (737). No significant differences in either small bowel or colonic transit were observed between subjects administered dronabinol or placebo in any gender group (737). The 5 mg dose of dronabinol was used because a 7.5 mg dose caused intolerable side effects in more than half of the subjects (737). Adverse effects associated with the consumption of a 5 mg dose of dronabinol included dizziness/light-headedness, dry mouth, disturbed mental concentration, and nausea (737).

A subsequent double-blind, randomized, placebo-controlled, parallel-group study carried out by the same group investigated the effects of dronabinol on colonic sensory and motor functions of healthy human volunteers (738). Administration of a 7.5 mg dose of dronabinol significantly increased colonic compliance, especially in females, and reduced pre- and post-prandial phasic colonic motility and pressure (738). Colonic compliance is defined as the change in distensibility of the colon in response to a change in applied intracolonic pressure and it is used as a measure of colonic viscoelastic properties and as an indicator of colonic motor/contractile activity (738,739,740). Decreased compliance is typically associated with urgency and diarrhea, while increased compliance is typically associated with constipation (739,741). An increase in colonic compliance in this setting could indicate a return towards proper colonic function. In contrast to the results seen in the pre-clinical rodent studies, dronabinol increased the sensory rating of pain but did not affect the sensory rating of gas, or the thresholds for first sensation of either gas or pain during experimentally-induced random phasic distensions (738).

A double-blind, randomized, parallel-group study investigated the effects of escalating doses of dronabinol on colonic sensory and motor functions in a population of mostly female patients diagnosed with IBS according to Rome III criteria (IBS-C, IBS-D, or IBS-A (i.e. *alternating* between diarrhea and constipation)) (742). Only the highest dose of dronabinol tested (5 mg) was associated with a small, but statistically significant, increase in colonic compliance (742). Furthermore, the effect on colonic compliance appeared to be more pronounced in the IBS-D/A sub-group compared to IBS-C. No significant differences were observed on fasting or post-prandial colonic tone in response to dronabinol at any dose. However, the highest dose of dronabinol (5 mg) was associated with a significant reduction in the proximal left colon motility index, with a trend towards decreased colon motility indices (742). Treatment effects were significant on the proximal colon motility index in patients with IBS-D/A, but not in IBS-C, and only for the highest dose (742). Sensation thresholds and sensation scores for gas and pain during experimentally-induced ramp distensions did not differ significantly among the different treatment groups (742). The effects of genotype and dronabinol dose interaction on gas and pain sensation ratings, as well as on proximal fasting and distal fasting motility indices were also investigated. The results from these preliminary pharmacogenetic studies raise the possibility that the effects of dronabinol on colonic compliance and proximal colonic motility may be influenced by genetic variations in the *FAAH* and *CNR1* genes, but further studies are required to substantiate this hypothesis (742).

A subsequent double-blind, randomized, placebo-controlled, parallel-group study in a population of mostly female patients with IBS-D (Rome III criteria) further investigated gene-treatment interactions on colonic motility in this sub-set of IBS patients (743). Neither the 2.5 mg b.i.d. nor the 5 mg b.i.d. doses of dronabinol had any statistically significant effects on gastric, small bowel, or colonic transit (743). The effects on colonic transit were also examined as a function of genotype-by-treatment dose interaction. While treatment with dronabinol appeared to decrease colonic transit in subjects carrying the *CNR1* rs806378 CT/TT polymorphism, these effects were not statistically significant. Adverse effects were reported not to differ significantly between treatment groups.

4.8.8.2 Inflammatory bowel diseases (Crohn's disease, ulcerative colitis)

Inflammatory bowel diseases (IBD) include Crohn's disease and ulcerative colitis (744). Crohn's disease is characterized by patchy, intra-mural inflammation which may affect any part of the gastrointestinal tract (745). Symptoms include abdominal pain, diarrhea and weight loss as well as systemic symptoms of malaise, anorexia, and/or fever (745). Crohn's disease may cause intestinal obstruction due to strictures, fistulae, or abscesses (745). Ulcerative colitis is characterized by diffuse mucosal inflammation limited to the colon (745). Symptoms commonly include bloody diarrhea, colicky abdominal pain, urgency, or tenesmus (745). Both diseases are associated with an equivalent increased risk of colonic carcinoma (745).

The endocannabinoid system and IBD

Endocannabinoid system changes have been observed in the gastrointestinal tracts of experimental animal models of IBD, as well as in those of IBD patients (31,744). These changes include changes in the levels of endocannabinoids, cannabinoid receptors, and endocannabinoid synthesizing and degrading enzymes (28,31,744,746,747,748).

Pre-clinical data

Pre-clinical experiments in animal models of IBD suggest cannabinoids and endocannabinoids may limit intestinal inflammation and disease severity via activation of CB receptors (749,750,751,752,753,754).

Acute colitis

Mice bearing a genetic deletion of the CB_1 receptor had a stronger colonic inflammatory response (749) following rectal administration of dinitrobenzene sulfonic acid (DNBSA), an established method of inducing an acute colitis-like phenotype in mice (755). In contrast to wild-type mice, histological examination of the colons of CB_1 knockout mice treated with DNBSA revealed disruption of epithelial structure, with extensive hemorrhagic necrosis and neutrophil infiltration into the mucosa, and with acute inflammation extending into the sub-mucosa and muscle layer (749). Pharmacological blockade of the CB_1 receptor in wild-type mice produced similar effects accompanied by thickening of the bowel wall, inflammatory infiltrates, and an increase in lymphoid-follicle size associated with adherence to surrounding tissues (749). Furthermore, in contrast to CB_1 knockout mice, wild-type mice retained a significantly greater body weight following DNBSA treatment (749). Treatment of wild-type mice with the potent synthetic CB_1 and CB_2 receptor agonist HU-210, prior to and after DNBSA insult, significantly reduced the macroscopic colonic inflammatory response (749). Mice bearing a genetic deletion of the FAAH enzyme also displayed an attenuated inflammatory response to DNBSA compared to wild-type littermates (749).

An analogous study found that CB_1 and CB_2 receptor knockout mice and CB_1/CB_2 receptor double knockout mice showed increased extent of colonic inflammation, increased loss of crypt architecture, increased hyperemia/edema, and an increased degree of infiltration of inflammatory cells compared to wild-type mice following trinitrobenzene sulfonic acid (TNBSA)-induced acute colitis (753). All three knockout strains exhibited severe transmural colitis, with severe loss of epithelium, thickening of the bowel wall, and inflammatory infiltrates compared to wild-type mice (753). Genetic deletion of either or both CB receptors was also associated with significantly increased mRNA levels of various pro-inflammatory cytokines compared to wild-type mice in mice treated with TNBSA (753).

TNBSA-induced acute colitis in mice was associated with a significant upregulation of CB_2 receptor mRNA levels in the proximal and distal colons of treated mice (756). Intra-peritoneal administration of CB_2 receptor agonists, prior to and following TNBSA-induced colitis, was associated with a reduction in the macroscopic damage (e.g. reduced ulceration, reduction in colonic adhesions, and reduced colonic shortening) (756). Conversely, administration of a CB_2 receptor antagonist aggravated TNBSA-induced colitis (756).

Acute colitis and cannabidiol

Intra-peritoneal injection of cannabidiol (5 - 10 mg/kg) prior to DNBSA-induced acute colitis was associated with a significant attenuation of body weight loss caused by DNBSA (757). Cannabidiol (CBD) also reduced the wet weight/colon length ratio of inflamed colonic tissue, a marker of the severity and extent of the inflammatory response (757). Furthermore, CBD (5 - 10 mg/kg) significantly reduced macroscopic damage associated with DNBSA administration (mild edema, hyperemia, and small bowel adhesions) as well as microscopic damage (epithelium erosion, and mucosal and sub-mucosal infiltration of inflammatory cells

with edema) (757). Lastly, treatment with CBD significantly attenuated the observed increases in some biological markers associated with inflammation and oxidative stress, as well as attenuating the observed increases in the colonic levels of anandamide and 2-AG (757).

Another study reported that intra-peritoneal (10 mg/kg) or intra-rectal (20 mg/kg) pre-treatment with CBD, again administered *prior* to induction of colitis by TNBSA, caused a significant improvement of the colitis score and a decrease in the myeloperoxidase activity (a measure of neutrophil accumulation in colonic tissue) (758). No such differences were observed for orally administered CBD. Histological examination of colonic tissue further revealed decreased destruction of the epithelial lining, a reduction in colon thickness, and less infiltration of immunocytes compared to vehicle-treated mice (758). In contrast to the study by Borrelli (757), no differences in body weight were observed between vehicle-treated and CBD-treated mice that had developed colitis (758).

The effects of intra-peritoneal injections of THC, CBD, and a combination of THC and CBD on TNBSA-induced acute colitis in rats have been investigated (754). In one experiment, treatment with 10 mg/kg of THC alone, a combination of 5 mg/kg THC and 10 mg/kg CBD, a combination of 10 mg/kg THC and 10 mg/kg CBD, or sulfasalazine alone was associated with a statistically significant decrease in the macroscopic damage score (MDS) (754). The MDS is a linear scale measuring the extent of macroscopic damage to the colon and includes markers such as the presence or absence of hyperemia, ulceration, inflammation, adhesions, damage length, and diarrhea (754). Furthermore, treatment of rats (with experimentally-induced colitis) with CBD alone did not affect body weight. However, treatment with 5 or 20 mg/kg THC alone, or a combination of 10 mg/kg THC and 10 mg/kg CBD, resulted in a significant reduction of body weight gain in rats with experimentally-induced colitis in comparison with the vehicle group (754). Myeloperoxidase activity, a measure of inflammation, was significantly decreased in CBD-treated rats and in rats treated with 10 or 20 mg/kg THC, or 5 mg/kg THC and 10 mg/kg CBD (754). Treatment with 10 mg/kg CBD, 10 mg/kg THC, 10 mg/kg THC and 10 mg/kg CBD, or sulfasalazine alone was also associated with decreased disturbances in colonic motility resulting from TNBSA-induced colitis (754).

In a different experimental mouse model of acute colitis, the CB_1 receptor-selective agonist ACEA and the synthetic CB_2 receptor-selective agonist JWH-133, when injected intra-peritoneally prior to and after colonic insult, significantly reduced colon weight gain, colon shrinkage, colon inflammatory damage score, and diarrhea (751).

Inhibition of the 2-AG degrading enzyme monoacylglycerol lipase (MAGL) in mice by intra-peritoneal administration of a MAGL inhibitor *prior* to induction of acute colitis by TNBSA was associated with decreased macroscopic and histological colon alterations, as well as decreased colonic expression of pro-inflammatory cytokines (759). Inhibition of MAGL was also associated with a reduction in colitis-related systemic and central inflammation in the liver and the CNS (759). Co-administration of either CB_1 or CB_2 receptor-selective antagonists completely abolished the protective effect in the colon afforded by MAGL inhibition, and partially reversed the protective anti-inflammatory effects associated with MAGL inhibition in the liver (759).

Chronic colitis

Intra-peritoneal administration of the synthetic CB_2 receptor-specific agonist JWH-133 significantly attenuated colitis-associated body weight loss, inflammation, leukocyte infiltration, and tissue damage in a mouse model of spontaneous chronic colitis (760). This CB_2 receptor specific agonist also reduced T-cell proliferation, increased T-cell apoptosis, and increased the numbers of mucosal and systemic mast cells (760).

Ileitis

The effect of cannabichromene on inflammation-induced hypermotility in a mouse model of intestinal ileitis has been studied (761). Ileitis is characterized by disruption of the mucosa, infiltration of lymphocytes into the sub-mucosa, increased myeloperoxidase activity, and vascular permeability (761). Administration of cannabichromene (15 mg/kg i.p.) following croton oil-induced intestinal inflammation was associated with a decrease in the expression of CB_1 and CB_2 receptor mRNA in the jejunum, but not in the ileum (761). Cannabichromene did not affect upper gastrointestinal transit, colonic propulsion, or whole gut transit in untreated mice, but did reduce intestinal motility in croton oil-treated mice at 10 and 20 mg/kg i.p. (761). Cannabichromene also dose-dependently and significantly inhibited contractions induced by acetylcholine, as

well as electrical field stimulation, *in vitro* in ilea isolated from control mice and croton oil-treated mice (761). The inhibitory effect of cannabichromene appeared to be cannabinoid receptor-independent (761).

Clinical studies with THC

A double-blind, randomized, placebo-controlled, crossover study examining the effects of 5 and 10 mg Δ^9-THC in visceral sensitivity reported that Δ^9-THC did not alter baseline rectal perception to experimentally-induced distension or sensory thresholds of discomfort after sigmoid stimulation compared to placebo, in either healthy controls or IBD patients (762). However, the authors did note a bias in the patient selection criteria which could have explained the apparent lack of effect.

Surveys and clinical studies with cannabis

Findings from a cross-sectional survey of 291 patients with IBD (Crohn's disease or ulcerative colitis) suggested that the vast majority of those patients reported using cannabis to relieve abdominal pain and to improve appetite (157). In contrast to patients with Crohn's disease, a greater proportion of patients with ulcerative colitis reported using cannabis to improve diarrheal symptoms (157). In general, patients reported being more likely to use cannabis for symptom relief if they had a history of abdominal surgery, chronic analgesic use, alternative/complementary medicine use, and a lower SIBDQ (short inflammatory bowel disease questionnaire) score (157). Both ulcerative colitis and Crohn's disease patients reported using cannabis to improve stress levels and sleep (157). The mean duration of cannabis use (current or previous) was seven years. The majority of cannabis users reported using once per month or less, but 16% reported using cannabis daily or several times per day (157). The vast majority (77%) of users reported smoking the cannabis as a joint without tobacco, 18% of users smoked it with tobacco, 3% used a water pipe, and 1% reported oral ingestion (157). Approximately one-third of patients in this study reported significant side effects associated with the use of cannabis such as paranoia, anxiety, and palpitations. Other commonly reported side effects included feeling "high", dry mouth, drowsiness, memory loss, hallucinations, and depression (157).

A retrospective, observational study of 30 patients with Crohn's disease examined disease activity, use of medication, need for surgery, and hospitalization before and after cannabis use (248). The average duration of disease was 11 years (range: 1 - 41 years). Twenty patients suffered from inflammation of the terminal ileum, five had inflammation of the proximal ileum, and eight had Crohn's disease of the colon. The indication for cannabis was lack of response to conventional treatment in the majority of the patients, and chronic intractable pain in most of the other patients (248). Most patients smoked cannabis as joints (0.5 g cannabis/joint), a few inhaled the smoke through water, and one patient consumed cannabis orally (248). Of those who smoked cannabis, most smoked between one and three joints per day. One patient smoked seven joints per day. The average duration of cannabis use was two years (range: 2 months - 9 years). All patients reported that consuming cannabis had a positive effect on their disease activity (248). The scores on the Harvey-Bradshaw index (an index of Crohn's disease activity) were significantly decreased following cannabis use, and the use of other medications (e.g. 5-ASA, corticosteroids, thiopurine, methotrexate, and TNF antagonist) also appeared to be significantly reduced following use of cannabis (248). The study was limited by design and small size.

A preliminary, observational, open-label, prospective, single-arm trial in a group of 13 patients suffering from Crohn's disease or ulcerative colitis reported that treatment with inhaled cannabis over a three-month period improved subjects' quality of life, caused a statistically significant increase in subjects' weight, and improved the clinical disease activity index in patients with Crohn's disease (189). Patients reported a statistically significant improvement in their perception of their general health status, their ability to perform daily activities, and their ability to maintain a social life (189). Patients also reported a statistically significant reduction in physical pain, as well as improvement in mental distress (189). No serious adverse events were noted. Study limitations included study design, subject selection bias, the lack of a proper control group and placebo, small number of subjects, and the inability to establish a dose-response effect (189).

Note: for sections 4.8.8.3, 4.8.8.4, and 4.8.8.5 below, no clinical studies examining the role of cannabis in the treatment of these disorders have been carried out to date.

4.8.8.3 Diseases of the liver (hepatitis, fibrosis, steatosis, ischemia-reperfusion injury, hepatic encephalopathy)

CB_1 receptors are expressed at low levels in the whole liver, hepatocytes, stellate cells, and hepatic vascular endothelial cells, but increased CB_1 receptor expression has been detected in the context of diseases such as hepatocellular carcinoma and primary biliary cirrhosis (reviewed in (763)). CB_2 receptors are undetectable in normal liver but, like the CB_1 receptors, they are upregulated in pathological conditions; these include non-alcoholic fatty liver disease (NAFLD), liver fibrosis, regenerating liver, and hepatocellular carcinoma (reviewed in (763)). Increases in the concentrations of the endocannabinoids anandamide and 2-AG in the liver appear to vary depending on the pathophysiological condition in question (33).

Steatosis and fibrosis

Mounting evidence suggests an important role for the endocannabinoid system in the pathophysiology of a multitude of diseases affecting the liver (33). In general, the CB_1 and CB_2 receptors appear to play *opposing* roles in the liver: activation of the CB_1 receptors is implicated in the progression and worsening of alcoholic and metabolic steatosis, liver fibrogenesis, and circulatory failure associated with cirrhosis; stimulation of the CB_2 receptors, in general, appears to confer beneficial effects in alcoholic fatty liver, hepatic inflammation, liver injury, liver regeneration, and fibrosis (reviewed in (33) and see also (249,250,251,764)). Conversely, antagonism of the CB_1 receptor appears to attenuate liver fibrosis in animal models by interfering with the production of several pro-fibrotic, pro-inflammatory, as well as anti-inflammatory mediators secreted in the liver during chronic liver injury and the wound healing process (249,765).

In vitro studies indicate that CBD may also play a protective role in attenuating liver fibrosis induced by acute liver injury or by chronic alcohol exposure (766). CBD dose-dependently triggered the apoptosis of cultured, activated hepatic stellate cells isolated from the livers of rats chronically exposed to an ethanol diet (766). The activation of hepatic stellate cells in response to liver injury is considered a key cellular event underlying hepatic fibrogenesis (766). Furthermore, CBD dose-dependently promoted the selective apoptosis of activated hepatic stellate cells, but not control hepatic stellate cells or primary hepatocytes, by triggering an endoplasmic reticulum-associated cellular stress response leading to apoptosis; this effect was independent of CB receptor activation (766).

Ischemia-reperfusion injury and hepatic encephalopathy

Pre-clinical studies also indicate a protective role for CBD in hepatic ischemia/reperfusion injury, and hepatic encephalopathy, in mice and rats (767,768,769). Pre-treatment of mice with 3 or 10 mg/kg body weight CBD (i.p.), 2 h before induction of ischemia-reperfusion in liver, dose-dependently attenuated serum transaminase elevations at 2 and 6 h of reperfusion compared to vehicle (767). CBD administered immediately following the induction of ischemia, or at 90 min of reperfusion, still attenuated hepatic injury measured at 6 h of reperfusion, though to a lesser extent than when administered prior to the induction of the ischemia-reperfusion injury (767). Pre-treatment with CBD also significantly reduced the signs of coagulation necrosis observed 24 h after ischemia-reperfusion, significantly attenuated hepatic cell apoptosis, significantly decreased the expression of pro-inflammatory chemokines and cytokines, attenuated neutrophil infiltration into the injury site, and decreased the expression of markers of tissue and cellular injury (767). Similar beneficial findings in a rat model of ischemia-reperfusion injury were reported in a different study; however, CBD (5 mg/kg, i.v.) was administered *after* ischemia-reperfusion injury (768). CBD treatment resulted in significant reductions in serum transaminase levels, hepatic lipid peroxidation, and the attenuation of various markers of tissue or cellular injury associated with ischemia-reperfusion (768). Administration of Δ^8-tetrahydrocannabivarin (3 or 10 mg/kg, i.p.) 2 h *before* induction of hepatic ischemia-reperfusion injury dose-dependently attenuated serum transaminase elevations at 2 and 6 h of reperfusion compared to vehicle (770). Administration of Δ^8-tetrahydrocannabivarin *post-ischemia* attenuated, although to a lesser degree, the hepatic injury measured at 6 h of reperfusion (770). Pre-treatment with Δ^8-tetrahydrocannabivarin also significantly reduced the extent of coagulation necrosis in the liver, attenuated neutrophil infiltration, decreased the expression of hepatic pro-inflammatory chemokines and cytokines, reduced the hepatic levels of markers of oxidative stress, and decreased the extent of hepatocyte cell death following ischemia-reperfusion injury (770).

Intra-peritoneal administration of CBD (5 mg/kg, i.p.) improved neurological, locomotor, and cognitive functions in a mouse model of fulminant hepatic encephalopathy (769). CBD also attenuated the degree of astrogliosis, but did not affect the extent and severity of necrotic lesions in the liver (769). CBD partially restored whole brain 5-HT levels, as well as the levels of markers of liver function (ammonia, bilirubin, AST, ALT) in affected mice (769).

4.8.8.4 Metabolic syndrome, obesity, diabetes

The endocannabinoid system and energy metabolism

Increasing evidence suggests an important role for the endocannabinoid system in the regulation of energy balance; dysregulation of the system is associated with the development of metabolic syndrome and obesity, and may also increase the risk of developing atherosclerosis and type-2 diabetes (11,17,771). Pre-clinical studies carried out in animal models of obesity and clinical studies performed in obese humans report increased endocannabinoid tone in adipose tissue, liver, pancreas, and in the hypothalamus compared to controls (772).

The regulation of energy balance by the endocannabinoid system appears to occur both centrally (in the CNS, particularly in the hypothalamus) and peripherally in multiple organs such as the white adipose tissue, skeletal muscle, pancreas, liver, and small intestine (11,17,771,773). In general, overactivity of the endocannabinoid system is associated with increased nutrient intake, enhanced energy storage, and reduced energy expenditure (17). Endocannabinoid tone appears to be modulated by hormones and peptides including leptin, insulin, ghrelin, and corticosteroids (17). Endocannabinoids, in turn, appear to modulate the release of neurotransmitters and neuropeptides such as opioids, serotonin, and GABA, which are known to play a role in regulating appetite mainly through central mechanisms (774).

Pre-clinical data

THC and the role of the CB_1 receptor

In pre-clinical *in vitro* studies, THC significantly inhibited basal and catecholamine-triggered lipolysis in a differentiated mouse adipocyte cell line in a concentration-dependent manner and caused dose-dependent accumulation of lipid droplets in these cells (23). In mice, activation of the CB_1 receptor resulted in increased *de novo* fatty acid synthesis in the liver and increased formation and storage of triglycerides in the adipose tissue (11,775,776,777). In rats, central stimulation of the CB_1 receptor was associated with the development of hepatic and adipose tissue insulin resistance (772). Mice lacking overall CB_1 receptor gene expression were hypophagic and were leaner than wild-type mice regardless of diet, had lower plasma insulin levels, did not develop diet-induced insulin resistance or obesity, and had enhanced leptin sensitivity (391,775,778). In mice, targeted deletion of the CB_1 receptor in the forebrain-projecting neurons in the hypothalamus and in the nucleus of the solitary tract, and partial deletion in sympathetic neurons were associated with a lean phenotype and resistance to diet-induced obesity and increases in plasma levels of leptin, insulin, glucose, free fatty acids, and triglycerides; these effects resulted from an increase in lipid oxidation and thermogenesis as a consequence of enhanced sympathetic tone and a decrease in energy absorption (779). Similarly, partial targeted deletion of the CB_1 receptor gene in the adult mouse hypothalamus lead to a significant decrease in body weight gain triggered by an increase in energy expenditure, rather than a decrease in food intake (777).

Targeted deletion of the CB_1 receptor gene in mouse liver is associated with the development of diet-induced obesity, but retention of glucose, insulin and leptin sensitivity and lipid indices; targeted hepatic re-expression of the CB_1 receptor gene in CB_1 receptor gene knockout mice was associated with glucose intolerance and insulin resistance in response to a high-fat diet, but maintenance of proper body weight (780,781). Studies with CB_1 antagonists/inverse agonists strongly suggest that antagonism/inverse agonism at the CB_1 receptor is associated with reduced caloric intake, weight loss, improvement or reversal of hepatic steatosis, and restoration of insulin and glucose sensitivity and normal lipid indices in various animal models of diet-induced obesity (391,782,783,784,785,786,787,788). Clinical studies with the CB_1 antagonist rimonabant have strongly supported the data gathered from animal studies (789,790,791,792,793,794,795).

Taken together, the above findings suggest an important role for the CB_1 receptor, both centrally and

peripherally, in regulating energy balance; stimulation of the CB_1 receptor promotes energy storage and lipogenesis, whereas CB_1 receptor antagonism has the opposite effects. Consistent with these findings, cannabis and prescription cannabinoids (dronabinol, nabilone) are known to increase appetite and body weight and have been used clinically to treat HIV/AIDS-associated anorexia-cachexia, and possibly also cancer-associated cachexia (see sections 4.3.1 and 4.3.2, respectively). Yet curiously, despite these beneficial effects on body weight in clinical disorders, a number of studies have so far failed to find an association between overweight/obesity and consumption of cannabis in the general population (796,797). In fact, the prevalence of obesity appeared to be significantly lower in cannabis users than in non-users, and the proportion of obese individuals also appeared to decrease with frequency of cannabis use according to a cross-sectional analysis of two U.S. epidemiological studies (797).

Role of the CB_2 receptor

The CB_2 receptor also appears to also play an important role in energy balance (798). Pre-clinical studies in mice indicate that the CB_2 receptor is expressed in epididymal adipose tissue in lean mice, and the levels of this receptor appear to increase in the non-parenchymal cell fractions of adipose tissue and liver in genetically obese mice or in wild-type mice fed a high-fat diet (798). Furthermore, systemic administration of a CB_2 receptor-selective agonist to lean or obese mice, or exposure of cultured fat pads to the same agonist, was associated with upregulation of a subset of genes linked to inflammation in the adipose tissue but not the liver (798). Conversely, administration of a CB_2-selective antagonist reduced inflammation both in adipose tissue and liver of obese animals (798). Under a high-fat diet, mice lacking the CB_2 receptor displayed a slower body weight progression and were more insulin sensitive than wild-type mice (798). CB_2 knockout mice on a high-fat diet also exhibited minimal hepatic steatosis compared to wild-type mice (798). Mice deficient in CB_2 receptor expression also exhibited increased food intake and body weight with age compared to wild-type mice (799). The CB_2 receptor knockout mice did not develop insulin resistance and showed enhanced insulin-stimulated glucose uptake in skeletal muscle (799). Taken together, these results suggest an important and complex role for the CB_2 receptor in energy balance and obesity, although further studies are needed to better understand its role.

Other cannabinoids

Pure Δ^9-tetrahydrocannabivarin (THCV) administered i.p. (3 mg/kg, 10 mg/kg, or 30 mg/kg) in mice suppressed feeding and significantly reduced body weight gain, but this effect appeared to be blocked when a botanical extract containing both Δ^9-THCV and Δ^9-THC was used (92). Inclusion of cannabidiol into the botanical extract, as a way of attenuating the proposed hyperphagic effects of THC in this study, resulted in a trend towards decreased food intake in treated mice, but the effect did not reach statistical significance (92). Lean and obese rats injected with a cannabis extract (on alternate days, for 28 days) containing a THC : CBN : CBD ratio of 1.0 : 1.2 : 0.4 (5 mg/kg Δ^9-THC) exhibited a significant reduction in weight gain during the study period, but the cannabis extract treatment was not associated with any changes in either insulin or glucose levels (800).

4.8.8.5 Diseases of the pancreas (diabetes, pancreatitis)

Although there appears to be a general lack of consensus as well as insufficient information regarding the exact expression, distribution, and function of the various endocannabinoid system components in the pancreas among different species, the pancreas does appear to have at least some, and in certain cases many, of the individual elements of the endocannabinoid system (774,801,802).

Function of the endocannabinoid system in the pancreas

Two studies using primary human islet cells suggest that the CB_1 and CB_2 receptors are expressed in these cells, and that stimulation of the CB_1 receptor is associated with secretion of insulin and glucagon while stimulation of the CB_2 receptor is associated with either increased or decreased insulin secretion (801,803) (and also reviewed in (774)). More recently, the endocannabinoid 2-arachidonoylglycerol (2-AG) has been implicated in the regulation of both insulin and glucagon secretion in human pancreas (802).

Intra-muscular administration of cannabis resin (containing 6.3% Δ^9-THC, 3.2% cannabidiol, and 1.9% cannabinol) at increasing doses (Δ^9-THC at 2.5, 5.0, and 10 mg/kg) to dogs was associated with a progressive increase in plasma glucose levels which reached maximum values 90 min after administration, with a return to baseline values 180 min after administration (804). Injection of anandamide or a CB_1 receptor-selective agonist in rats was associated with acute glucose intolerance, whereas administration of a CB_1 receptor

inverse agonist attenuated this effect (805). In humans, intravenous injection of 6 mg of Δ^9-THC to healthy, non-obese male volunteers was associated with acute impairment of glucose tolerance in response to glucose challenge with no change in plasma insulin levels (806).

Survey data

A cross-sectional study of 10 896 adults, ages 20 - 59, who were participants in the National Health and Nutrition Examination Survey III (NHANES), a nationally representative sample of the U.S. population, reported that cannabis use was independently associated with a decreased prevalence of diabetes mellitus, and that cannabis users had lower odds of developing diabetes mellitus compared to non-users (807). The lowest prevalence of diabetes mellitus was seen in current, light cannabis users, but current heavy users and past users also had a lower prevalence of diabetes mellitus than non-cannabis users (807). Due to limitations in study methodology (e.g. cross-sectional nature of the study, self-report bias, and inconsistent sampling methodology) as well as the possibility of additional and uncontrolled confounding factors, the authors indicate that it is not yet possible to conclude that cannabis use does not lead to diabetes mellitus, nor that cannabis should be considered a treatment for this disorder (807).

Cannabis, the endocannabinoid system, and acute and chronic pancreatitis

Acute, heavy cannabis use has been linked to the development of acute pancreatitis (253,254,255,256). Acute pancreatitis is a potentially lethal disorder involving inflammation, cell death, and complex neuroimmune interactions; the management of chronic pancreatitis remains clinically challenging with no definite cure and supportive measures are the only treatment available (808,809). Pancreatic tissue isolated from patients with *acute* pancreatitis has been reported to have a marked upregulation of CB_1 and CB_2 receptors in the acini and ducts as well as elevated levels of the endocannabinoid anandamide but not 2-AG (808). In a subsequent study, an increase in the expression levels of CB_1 and CB_2 receptors, and a decrease in the levels of endocannabinoids (anandamide and 2-AG) were noted in tissue samples isolated from patients suffering from *chronic* pancreatitis compared to pancreatic tissues isolated from healthy subjects (809). In addition, in contrast to the findings obtained for acute pancreatitis (808), tissues isolated from patients with chronic pancreatitis appeared to have decreased levels of anandamide and 2-AG (809). Activation of CB_1 and CB_2 receptors in chronic pancreatitis-derived pancreatic stellate cells was also associated with the induction of a quiescent-cell phenotype as well as the downregulation of extracellular matrix protein production and inflammatory cytokine production (809).

Pre-clinical data and acute or chronic pancreatitis

There are only a handful of reports on the effects of cannabinoids in experimental animal models of acute or chronic pancreatitis, and the findings from these reports are conflicting. Thus, the use of cannabinoids in the treatment of acute or chronic pancreatitis remains unclear. Information gathered from pre-clinical animal studies is summarized below.

Elevations in the plasma levels of anandamide have been noted in a rat model of severe acute pancreatitis (810), and administration of the CB_1 receptor antagonist AM251 after induction of pancreatitis appeared to improve the course of the disease (810). In another study, administration of anandamide *prior* to induction of pancreatic damage further aggravated the usual course of the disease, whereas pre-treatment with the CB_1 receptor antagonist AM251 prevented the development of cerulein-induced pancreatitis and when administered *after* injury also appeared to reverse cerulein-induced pancreatic damage (811). Similarly, mice treated with the CB_1 receptor antagonist rimonabant *prior* to cerulein-induced pancreatitis exhibited significantly decreased pancreatic damage as well as decreased production of inflammatory cytokines (812). Subcutaneous administration of a synthetic CB_1/CB_2 receptor agonist, both prior to as well as after induction of acute pancreatitis in mice, attenuated the abdominal pain, inflammation, and tissue pathology associated with pancreatitis (808). In contrast, a different study reported that pre-treatment of rats with a synthetic CB_1/CB_2 receptor agonist *before* induction of experimentally-induced pancreatitis attenuated the extent of tissue damage and the release of inflammatory cytokines, whereas administration of the same agonist *after* the induction of pancreatitis had the opposite effects and appeared to aggravate the course of the disease (813). These contradictory findings may be due to differences in experimental methods, differences in timing of drug administration, differences in the types of agonists and antagonists that were used, differences in the route of administration, and differences in animal species.

4.8.9 Anti-neoplastic properties

A number of studies have implicated the endocannabinoid system in the pathophysiology of cancer. In general, endocannabinoids seem to have a protective effect against carcinogenesis, and proper regulation of local endocannabinoid tone is likely an important factor in controlling the malignancy of different cancers (814). When compared with healthy tissues, the levels of endocannabinoids appear to be elevated in glioblastomas, meningiomas, pituitary adenomas, prostate and colon carcinomas, and endometrial sarcomas (746,815,816,817,818,819). The expression levels of cannabinoid receptors are also differentially regulated in normal versus malignant cells, with increased or decreased levels of these receptors varying with cancer type (reviewed in (814)). Such differences in the levels of endocannabinoids and in the patterns of expression levels of cannabinoid receptors across different cancer types reflect the complex role of the endocannabinoid system in cancer and are likely to pose challenges to potential therapeutic approaches. Nonetheless, a number of pre-clinical studies have shown that endocannabinoids, certain synthetic cannabinoid agonists, and some phytocannabinoids can inhibit tumour growth and progression of numerous types of cancers through various mechanisms including promotion of apoptosis, cell-cycle arrest/growth inhibition, and prevention of metastasis through inhibition of tumour invasion, migration, and neo-angiogenesis (reviewed in (814,820)).

In general, the anti-neoplastic effects of Δ^9-THC appear to be biphasic: lower doses (under 100 nM), comparable to those typically seen in clinical or therapeutic settings, are considered pro-proliferative; higher doses (above 100 nM) are thought to be anti-proliferative (821), although exceptions have been noted. Furthermore, cannabinoid concentrations above 100 nM, that is two orders of magnitude above the average affinity of these receptors for cannabinoids, are likely to produce off-target, CB receptor-independent effects (822). As a point of reference, single oral doses of dronabinol (Δ^9-THC) of 2.5, 5, and 10 mg have been associated with mean peak Δ^9-THC plasma concentrations of 0.65, 1.83, and 6.22 ng/mL, respectively (174). These concentrations correspond to concentrations of 0.002, 0.006, and 0.02 μM (or 2, 6, and 20 nM) Δ^9-THC. Doubling of these daily oral doses is associated with mean peak Δ^9-THC plasma concentrations of 1.3, 2.9, and 7.9 ng/mL Δ^9-THC (174), respectively, corresponding to 0.004, 0.009, and 0.03 μM (or 4, 9, and 30 nM) Δ^9-THC. Continuous dosing for seven days with 20 mg doses of dronabinol (total daily doses of 40 - 120 mg dronabinol) gave mean plasma Δ^9-THC concentrations of ~20 ng/mL or ~0.06 μM (60 nM) Δ^9-THC (288). Smoking a 1 g joint containing 12.5% Δ^9-THC can be assumed, based on the literature, to yield peak plasma Δ^9-THC concentrations between 50 and 100 ng/mL or more (see section 3.1 "Smoking", subsection "Plasma concentrations of Δ^9-THC following smoking"). Such Δ^9-THC plasma concentrations correspond to 0.16 and 0.32 μM (or 160 and 320 nM) Δ^9-THC, respectively. Plasma concentrations of Δ^9-THC are known to vary widely across individuals, and diminish more rapidly by the smoking route than by oral administration. With respect to doses expressed in mg/kg of body weight, a daily oral dose of 2.5 mg of dronabinol (Δ^9-THC) can be estimated to correspond to a dose of approximately 0.04 mg/kg (assuming a body weight of 70 kg), whereas a daily oral dose of 40 mg of dronabinol would correspond to a dose of approximately 0.6 mg/kg of dronabinol. Smoking a 1 g joint containing 12.5% Δ^9-THC would correspond to a hypothetical dose of 1.8 mg/kg Δ^9-THC.

The following paragraphs summarize the main findings from a number of pre-clinical *in vitro* and *in vivo* studies of cannabinoids in neoplastic diseases. Clinical data are presented at the end of this section.

Pre-clinical data

In vitro studies suggest that Δ^9-THC decreases cell proliferation and increases cell death in human glioblastoma multiforme cell lines, with CB receptor activation accounting for only part of the observed effects (823). In the case of astrocytomas, higher concentrations were deemed to be clinically preferable because this would bypass CB receptor activation and induce apoptosis in all astrocytoma cell sub-populations (824). In the case of breast cancer, Δ^9-THC reduced human breast cancer cell proliferation at concentrations of 4 - 10 μM (i.e. 4 000 – 10 000 nM), with more aggressive estrogen receptor-negative tumour cells being more sensitive to the effects of THC (825). In contradistinction, another study showed that Δ^9-THC (50 μM (i.e. 50 000 nM) *in vitro* or 50 mg/kg *in vivo*) enhanced breast cancer growth and metastasis (826). Furthermore, Δ^9-THC, CBD, and CBN all stimulated breast cancer cell proliferation at concentrations ranging from 5 - 20 μM (i.e. 5 000 – 20 000 nM) (827), but this effect appeared to depend to some extent on the hormonal milieu (with lower estrogen levels promoting, and higher estrogen levels inhibiting growth). On the other hand, cannabinoids such as cannabigerol, cannabichromene, cannabidiolic acid, and THC acid as well as cannabinoid-based extracts enriched in either Δ^9-THC or CBD inhibited cell proliferation (in the micromolar range) in a number of different breast cancer cell lines (828). In *in vitro* studies examining the role of cannabinoids in lung cancer, Δ^9-THC (10 - 15 μM) (i.e. 10 000 – 15 000 nM) attenuated growth factor-induced migration and invasion of non-small cell lung cancer cell lines (829). In the case of colorectal cancer, Δ^9-THC at concentrations of 2.5 μM (i.e. 2 500 nM) and above (range: 7.5

- 12.5 μM) (i.e. 7 500 – 12 500 nM) were associated with a decrease in colorectal cancer cell survival, whereas lower concentrations (100 nM - 1 μM) had no effect (830). Taken together, these and other *in vitro* studies suggest cannabinoids can have complex biological effects in the context of malignancies. Differences in experimental conditions, cancer cell type, CB-receptor expression, hormonal levels, and the existence of CB-receptor dependent and independent regulatory mechanisms all appear to affect the control of growth, proliferation, and invasion of cancer cells in response to cannabinoids. Furthermore, these findings also suggest that the effective inhibitory concentrations of Δ^9-THC seen *in vitro* are between ~ 10 and 7 500 times higher than the concentrations of Δ^9-THC seen clinically, depending on the route of administration.

A pre-clinical *in vivo* study in rats showed that intra-tumoural administration of Δ^9-THC caused significant regression of intra-cranial malignant gliomas, and an accompanying increase in animal survival time without any neurotoxicity to healthy tissues (831). Furthermore, no substantial change was observed in certain behavioural measures suggesting that the effect of Δ^9-THC was limited to diseased neural tissues (831). Other studies showed that peritumoural administration of 0.5 mg Δ^9-THC /day, twice per week, for 90 days, significantly slowed focal breast tumour growth, blocked tumour generation, decreased total tumour burden, delayed the appearance of subsequent tumours, and impaired tumour vascularization in the ErbB2-positive metastatic breast cancer mouse model (832). Δ^9-THC, at doses of 5 mg/kg/day, administered intra-peritoneally or intra-tumourally also dramatically decreased the growth and metastasis as well as the vascularization of xenografted non-small cell lung cancer cell lines in immunodeficient mice (829). CBD (5 mg/kg) or CBD-rich extract (6.5 mg/kg) administered intra-tumourally or intra-peritoneally, twice per week, to breast-cancer-cell-xenografted athymic mice significantly decreased both tumour volume and the number of metastatic nodules (828). Other investigators showed that intra-peritoneal administration of CBD at 1 or 5 mg/kg/day significantly reduced the growth and metastasis of an aggressive breast cancer cell line in immune-competent mice (833). Importantly, the primary tumour acquired resistance to the inhibitory properties of CBD by day 25 of treatment (833). Taken together, these studies suggest that cannabinoids such as Δ^9-THC and CBD can, under a specific set of circumstances, have anti-neoplastic effects in various animal models of cancer at certain doses or concentration ranges.

Combining cannabinoids with other chemotherapeutic agents

Pre-clinical *in vitro* and *in vivo* studies investigating the effects of combining cannabinoids with frequently used chemotherapeutic agents have also been performed. One *in vitro* study showed that combining sub-maximal doses of Δ^9-THC (0.75 μM) with cisplatin or doxorubicin reduced the viability of an astrocytoma cell line in a synergistic manner (834). Likewise, combining sub-maximal doses of Δ^9-THC with temozolomide reduced the viability of several human glioma cell lines and primary cultures of glioma cells derived from human glioblastoma multiforme biopsies *in vitro* (835). Complementing these findings, an *in vivo* study showed that combined treatment with Δ^9-THC (15 mg/kg/day) and temozolomide (5 mg/kg/day) reduced the growth of glioma tumour xenografts in mice in a synergistic manner (835).

Clinical data

There is only one report of a clinical study of Δ^9-THC to treat cancer (836). In this non-placebo controlled pilot study, nine patients with glioblastoma multiforme who had failed standard surgical and radiation therapy, had clear evidence of tumour progression, and had a minimum Karnofsky score of 60 were treated with 20 - 40 μg Δ^9-THC intra-tumourally per day (with doses of up to 80 - 180 μg Δ^9-THC per day). Median treatment duration was 15 days (836). While intra-tumoural administration of Δ^9-THC appeared to be well tolerated, the effect of Δ^9-THC on patient survival was not significantly different from that observed in other studies using chemotherapeutic agents such as temozolomide or carmustine (837,838). Nevertheless, *in vitro*, Δ^9-THC inhibited the proliferation and decreased the viability of tumour cells isolated from glioblastoma biopsies, most likely through a combination of cell-cycle arrest and apoptosis (836,839). In addition, results from a separate *in vitro* study suggest that CBD enhanced the inhibitory effects of Δ^9-THC on human glioblastoma cell proliferation and survival (839).

Despite the evidence presented in these and other studies, there is a general consensus that Δ^9-THC would not be considered the most appropriate CB agonist in anti-tumoural strategies, especially if administered systemically, because of its high hydrophobicity, relatively low agonist potency, and its well-known psychoactive properties (814,840,841). Much remains to be known regarding factors such as the expression levels of the cannabinoid receptors in different cancers, the effects of different cannabinoids on different cancer cell types, the identification of factors that confer resistance to cannabinoid treatment, as well as the most efficient approaches for enhancing cannabinoid anti-tumoural activity whether alone or in combination with other therapies (828,840). Furthermore, the apparent biphasic effect of cannabinoids further highlights the need for more comprehensive dose-response studies (842).

4.8.10 Emerging Potential Therapeutic Uses

There are a few pre-clinical reports which suggest that administration of a low dose of THC, a CB_1 receptor antagonist, or a CB_2 receptor agonist may reduce the progression of atherosclerosis in mouse models of the disease (843,844,845). Oral administration of THC (1 mg/kg/day) has been associated with significant inhibition of disease progression in the apolipoprotein E (ApoE) knockout mouse, a mouse model of atherosclerosis (843). The beneficial effect of THC in this study was mediated by the CB_2 receptor, likely through its inhibitory effects on immune system cells (macrophages and T-cells) located in or near atherosclerotic lesions (843). These findings were supported by another study which showed that intra-peritoneal administration of a synthetic CB_1/CB_2 receptor agonist significantly reduced aortic plaque area in the ApoE knockout mouse (845). Administration of the CB receptor agonist reduced macrophage infiltration into the atherosclerotic plaque, and reduced the expression of vascular cellular adhesion molecule-1 (VCAM-1), intercellular adhesion molecule-1 (ICAM-1), and P-selectin in the aorta, as well as reducing macrophage adhesion (845). Again, the observed beneficial effects appeared to be mediated by activation of the CB_2 receptor (845). A separate study confirmed the atheroprotective effects of selective CB_2 receptor activation by demonstrating increased vascular leukocyte infiltration in atherosclerotic plaques in mice lacking both the ApoE and CB_2 receptors compared to ApoE knockout mice, and decreased atherosclerotic plaque formation and reduced vascular superoxide release in ApoE knockout mice treated with a CB_2 receptor selective agonist (846). In contrast to these findings, a different study showed that activation or deletion of the CB_2 receptor did not modulate atherogenesis in the LDL receptor knockout mouse model of atherosclerosis (847). Another study suggested that the CB_2 receptor, while not affecting the size of atherosclerotic lesions in LDL receptor knockout mice, did increase lesional macrophage accumulation and smooth muscle cell infiltration, as well as reduce lesional apoptosis and alter the extra-cellular matrix of lesions (848). The findings from this study suggested that while the CB_2 receptor did not play a significant role in the initial formation of atherosclerotic lesions, it did play a role in modulating the progression of the disease (848). On the other hand, activation of the CB_1 receptor is associated with the release of reactive oxygen species and endothelial cell death (849), and CB_1 receptor blockade by rimonabant in ApoE knockout mice was associated with a significant reduction in the relative size of aortic atherosclerotic lesions (844). In conclusion, it appears that in the case of atherosclerosis, the CB_1 and CB_2 receptors play opposing roles—the CB_1 receptor appears to be atherogenic, whereas the CB_2 receptor appears to be anti-atherogenic (844,846,849,850,851) although some controversy still remains regarding the exact role played by the CB_2 receptor (852). Cannabidiol has also been shown to potently inhibit the activity of the enzyme 15-lipoxygenase, which has been implicated in the pathophysiology of atherogenesis (850,853). Further studies are needed in this area.

5.0 Precautions

The contraindications that apply to those considering using prescription cannabinoid-based therapies (such as nabilone (Cesamet®), nabiximols (Sativex®) or dronabinol (Marinol®)) also apply to those considering using cannabis. Currently, no clinical guidelines exist with respect to monitoring patients who are taking cannabis for therapeutic purposes.

The risk/benefit ratio of using cannabis should be carefully evaluated in patients with the following medical conditions because of individual variation in response and tolerance to its effects, as well as the difficulty in dosing noted in section 3.0:

- Cannabis should not be used in any person under the age of 18, or in any patient who has a history of hypersensitivity to any cannabinoid or to smoke. The adverse effects of cannabis use on mental health are greater during development, particularly during adolescence, than in adulthood (146,686,690) (see also section 7.7.3).
- Cannabis should not be used in patients with severe cardio-pulmonary disease because of occasional hypotension, possible hypertension, syncope, or tachycardia (117,233,234).
- Smoked cannabis is not recommended in patients with respiratory insufficiency such as asthma or chronic obstructive pulmonary disease (243).
- Cannabis should not be used in patients with severe liver or renal disease. Patients with ongoing chronic hepatitis C should be strongly advised to abstain from daily cannabis use, as this has been shown to be a predictor of steatosis severity in these individuals (32,854).
- Cannabis should not be used in patients with a personal history of psychiatric disorders (especially schizophrenia), or a familial history of schizophrenia.
- Cannabis should be used with caution in patients with a history of substance abuse, including alcohol abuse, because such individuals may be more prone to abuse cannabis, which itself, is a frequently abused substance (675,855,856).
- Patients with mania or depression and using cannabis or a cannabinoid should be under careful psychiatric monitoring (139,143,857).
- Cannabis should be used with caution in patients receiving concomitant therapy with sedative-hypnotics or other psychoactive drugs because of the potential for additive or synergistic CNS depressant or psychoactive effects (169,170,171) (also see section 7.7). Cannabis may also exacerbate the CNS depressant effects of alcohol and increase the incidence of adverse effects (see section 7.7). Patients should be advised of the negative effects of cannabis/cannabinoids on memory and to report any mental or behavioural changes that occur after using cannabis (178,181).
- Cannabis is not recommended in women of childbearing age not on a reliable contraceptive, as well as those planning pregnancy, those who are pregnant, or women who are breastfeeding (see sections 6.0 and 7.4).

6.0 Warnings

Cannabis is one of the most widely abused illicit drugs, and can produce physical and psychological dependence (122,156,210,858,859). The drug has complex effects in the CNS and can cause cognitive and memory impairment, changes in mood, altered perception, and decreased impulse control (152,180,860,861). Patients should be supervised when administration is initiated.

Dosing: In the case of smoked/vapourized cannabis, the dose required to achieve therapeutic effects and avoid adverse effects is difficult to estimate and is affected by the source of the plant material, its processing, and by different smoking techniques. These techniques include depth of inhalation, duration of breath-holding and the number and frequency of puffs, as well as how much of the cigarette is smoked or how much plant material is vapourized. Smoking or vapourization should proceed slowly and cautiously in a gradual fashion and should cease if the patient begins to experience the following effects: disorientation, dizziness, ataxia, agitation, anxiety, tachycardia and orthostatic hypotension, depression, hallucinations, or psychosis. There is also insufficient information regarding oral dosing, but the patient should be made aware that the effects following oral administration only begin to be felt 30 min to 1 h or more after ingestion, and that consumption of cannabis-based products (e.g. cookies, baked goods) should proceed slowly, and that edibles should be consumed only in small amounts at a time in order to gauge the effects and to prevent overdosing.

Psychosis: Anyone experiencing an acute psychotic reaction to cannabis or cannabinoids should promptly stop taking the drug and seek immediate medical attention. A psychotic reaction is defined as a loss of contact with reality characterized by one or more of the following: changes in thinking patterns (difficulty concentrating, memory loss, and/or disconnected thoughts), delusions (fixed false beliefs not anchored in reality), hallucinations (seeing, hearing, tasting, smelling or feeling something that does not exist in reality), changes in mood (intense bursts of emotion, absence of, or blunted emotions), very disorganized behaviour or speech, and thoughts of death and suicide (341).

Occupational hazards: Patients using cannabis should be warned not to drive or to perform hazardous tasks, such as operating heavy machinery, because impairment of mental alertness and physical coordination resulting from the use of cannabis or cannabinoids may decrease their ability to perform such tasks (182). Depending on the dose, impairment can last for over 24 h after last use because of the long half-life of Δ^9-THC (62,131,290,862,863). Furthermore, impairment may be exacerbated with co-consumption of other CNS depressants (e.g. benzodiazepines, barbiturates, opioids, anti-histamines, muscle relaxants, or ethanol) (114,170,174,864,865,866).

Pregnancy: Pre-clinical studies suggest that endocannabinoid tone plays a critical role in fertilization, oviductal transport, implantation, and fetal/placental development (reviewed in (867)). One pilot clinical study suggested that high circulating levels of anandamide were associated with an increased incidence of miscarriage (868). Thus, there is a risk that maternal exposure to cannabis or cannabinoids could potentially adversely affect conception and/or maintenance of pregnancy. In addition, the use of cannabis during pregnancy should be avoided as there is some evidence of long-term developmental problems in children exposed to cannabis *in utero* (869,870). Men, especially those on the borderline of infertility and intending to start a family, are cautioned against using cannabis since exposure to cannabis or THC could potentially reduce the success rates of intended pregnancies (see section 7.4).

Lactation: Cannabinoids are excreted in human milk and may be absorbed by the nursing baby (871,872). Because of potential risks to the child, nursing mothers should not use cannabis.

6.1 Tolerance, dependence, and withdrawal symptoms

Tolerance, psychological, and physical dependence can occur with prolonged use of cannabis (118,210). Tolerance to cardiovascular effects occurs quickly, but dependence is slower to develop and appears more likely with higher, more frequent dosing (219,220). See section 2.4 for further information on tolerance, dependence, and withdrawal symptoms.

6.2 Drug interactions

The most clinically significant interactions may occur when cannabis is taken with other CNS depressant drugs such as sedative-hypnotics or alcohol (114,169,170,171,864,865,866,873,874). An overdose can occur if a patient is smoking/vapourizing cannabis and consuming orally administered cannabinoids, whether from prescription cannabinoid medications (e.g. dronabinol, nabilone), or from consumption of teas, baked goods or other products (174,290).

Xenobiotic-mediated inhibition or potentiation of cannabinoid metabolism

Δ^9-THC is oxidized by the xenobiotic-metabolizing cytochrome P450 (CYP) mixed-function oxidases 2C9, 2C19, and 3A4 (62). Therefore substances that inhibit these CYP isoenzymes such as certain anti-depressants (e.g. fluoxetine, fluvoxamine, and nefazodone), proton pump inhibitors (e.g. cimetidine and omeprazole), macrolides (e.g. clarithromycin and erythromycin), anti-mycotics (e.g. itraconazole, fluconazole, ketoconazole, miconazole), calcium antagonists (e.g. diltiazem, verapamil), HIV protease inhibitors (e.g. ritonavir), amiodarone, and isoniazid can potentially increase the bioavailability of Δ^9-THC as well as the chance of experiencing THC-related side effects (289,875,876). On the other hand, drugs that accelerate Δ^9-THC metabolism via 2C9 and 3A4 isozymes such as rifampicin, carbamazepine, phenobarbital, phenytoin, primidone, rifabutin, troglitazone, and Saint John's Wort may conversely decrease the bioavailability of THC and hence its effectiveness if used in a therapeutic context (289,876).

Cannabinoid–mediated regulation of drug metabolism and drug transport

THC, CBD, and CBN are known to inhibit CYP isozymes such as CYP1A1, 1A2, and 1B1 (58). Cannabis may therefore increase the bioavailability of drugs metabolized by these enzymes. Such drugs include amitryptiline, phenacetin, theophylline, granisetron, dacarbazine, and flutamide (58). THC, carboxy- Δ^9-THC, CBD, and CBN all stimulate, and in some cases even inhibit, the activity of the drug transporter P-glycoprotein *in vitro* (56). This suggests a potential additional role for these cannabinoids in affecting the therapeutic drug efficacy and toxicity of co-

administered drugs (56). Clinicians should therefore be aware other medications that the patient is taking and carefully monitor patients using other drugs along with cannabis or cannabinoids.

Cannabinoid-opioid interaction

Patients taking fentanyl (or related opioids) and anti-psychotic medications (clozapine or olanzapine) may also be at risk of experiencing adverse effects if co-consuming cannabis/cannabinoids (322,323,324,503,877). In one study, subjects reported an increase in the intensity and duration of the "high" when oxycodone was combined with inhalation of vapourized cannabis; this effect was not observed when morphine was combined with inhalation of vapourized cannabis (187). In that study, inhalation of vapourized cannabis was associated with a statistically significant decrease in the maximum concentration (C_{max}) of sustained-release morphine sulfate, and the time to C_{max} for morphine was also delayed, although the delay was not statistically significant (187). There were no changes in the AUC for morphine metabolites, or in the ratio of morphine metabolites to parent morphine (187). In contrast to the effects seen with morphine sulfate, inhalation of vapourized cannabis was not associated with any changes in oxycodone pharmacokinetics (187).

Evidence from pharmacogenetic studies

Pharmacogenetic studies have suggested that patients homozygous for the *CYP2C9*3* allele appear to have impaired THC metabolism and may show greater intoxication than **1/*3* heterozygotes or **1/*1* homozygotes (318).

Data from clinical studies

A significant proportion of published clinical studies of cannabis or prescription cannabinoid medications have used patient populations that were taking concomitant medications for a variety of disorders such as neuropathic pain of various etiologies (142,168,172,186,187,261,292,364,494,501,502,503), cancer-related pain (112,349,509), fibromyalgia (158,261,353,354), pain and spasticity associated with multiple sclerosis (188,262,291,361,428,504), and symptoms associated with Huntington's or Parkinson's disease (586,595). Examples of commonly-used medications seen in clinical trials of cannabis or prescription cannabinoid medications (e.g. dronabinol, nabilone and nabiximols) include non-steroidal anti-inflammatory drugs (e.g. acetaminophen, COX-2 inhibitors), metamizol, topical steroids, muscle relaxants, short- and long-acting opioids (e.g. codeine, morphine, hydromorphone, oxycodone, oxycontin, tramadol, fentanyl, methadone), ketamine, anti-convulsants (e.g. gabapentin, pregabalin), anti-depressants (e.g. tricyclics, selective-serotonin re-uptake inhibitors, serotonin-norepinephrine re-uptake inhibitors, serotonin-antagonist re-uptake inhibitors), and anxiolytics. According to the cited clinical studies, concomitant use of cannabis or prescription cannabinoid medications with other medications was reported to be well tolerated, and many of the observed adverse effects were those typically associated with the psychotropic effects of cannabis and cannabinoids (e.g. transient impairment of sensory and perceptual functions, abnormal thinking, disturbance in attention, dizziness, confusion, sedation, fatigue, euphoria, dysphoria, depression, paranoia, hallucinations, dry mouth, anxiety, hypotension, tachycardia, headache, throat irritation).

6.3 Drug screening tests

Because of the long half-life of elimination of cannabinoids and their metabolites, drug tests screening for cannabinoids can be positive for weeks after last cannabis/cannabinoid use (878,879) depending on the sensitivities of the tests used.

7.0 Adverse Effects

There is generally far more information available in the medical literature on the adverse effects associated with recreational cannabis use than there is with therapeutic cannabis use. Accordingly, much of the information presented below regarding the adverse effects of cannabis use comes from studies carried out among recreational users. Much less information on the adverse effects associated with the use of cannabis for therapeutic purposes comes from clinical studies, mainly because of the small number of such studies that have been carried out to date. Furthermore, while there is some information on the short-term adverse effects associated with the use of cannabis for therapeutic purposes, much less information exists on the long-term consequences of cannabis use for therapeutic purposes because all of the available clinical studies were short-term. A Canadian systematic review of the adverse effects of prescription cannabinoid medications concluded that the rate of non-serious adverse events was almost two-fold higher among those patients using prescription cannabinoid medications compared to controls (880). The most frequently cited adverse events associated with the use of prescription cannabinoid medications were nervous system disorders, psychiatric disorders, gastrointestinal disorders, and vascular and cardiac disorders (880). An additional consideration in the evaluation of adverse effects associated with cannabis use is the concomitant use of tobacco and alcohol as well as other drugs, whether they are non-prescription, prescription, or illicit drugs (122,881,882,883,884) (and also see section 6.2).

7.1 Carcinogenesis and mutagenesis

Qualitatively, cannabis smoke condensates have been shown to contain many of the same chemicals as tobacco smoke (70). Furthermore, a number of *in vitro* studies have provided strong evidence that smoke from burning cannabis is carcinogenic (reviewed in (118)). More recently, the cytotoxic and mutagenic potential of cannabis smoke condensates were compared to their tobacco counterparts (68). In contrast to tobacco smoke condensates, those derived from cannabis smoke appeared to be more cytotoxic and mutagenic, while the opposite was true with respect to cytogenetic damage (68). In addition, for either cannabis or tobacco smoke, the particulate phase was substantially more cytotoxic than the gas phase. Together, these studies suggest that cannabis smoke cannot be deemed "safer" than tobacco smoke.

Despite some persuasive *in vitro* data, the epidemiological evidence for a link between cannabis smoking and cancer remains inconclusive because of conflicting results from a limited number of studies. One epidemiological study in relatively young clients of a health maintenance organization (HMO) found an increased incidence of prostate cancer in those men who smoked cannabis and other non-tobacco materials (238). No other associations were found between cannabis use and other cancers; however, the study was limited by the demographics of the HMO clientele and the very low cannabis exposure threshold employed in the study to define "users". A case-control study suggested that cannabis smoking may increase the risk of head and neck cancer (Odds Ratio = 2.6; Confidence Interval = 1.1 - 6.6), with a strong dose-response pattern compared to non-smoking controls (239). However, the authors note a number of limitations with their study such as underreporting, inaccurate cannabis dose reporting, assay sensitivity, and low power. A large population-based case-control study, carried out in the year 2006, of 1 212 incident cancer cases and 1 040 cancer-free matched controls did not find a significant relationship between long-term cannabis smoking and cancers of the lung and upper aerodigestive tract (240). However, a smaller case-control study carried out in 2008 in young adults (≤ 55 years of age), examined 79 cases of lung cancer and 324 controls and reported that the risk of lung cancer increased by 8% (95% Confidence Interval = 2 - 15%) for each "joint-year" (defined as the smoking of one joint per day for one year) after adjusting for cigarette smoking (241). Despite the conflicting evidence surrounding the carcinogenic potential of cannabis smoke in humans, it is advisable to limit the degree to which cannabis is smoked. Further well-controlled epidemiological studies are required to better establish whether there is causality between cannabis smoking and carcinogenesis in human populations. Lastly, in the case of cancer patients, the potential risks of carcinogenesis and mutagenesis associated with smoking cannabis must be weighed against any potential therapeutic benefits for this patient population; routes of administration other than smoking (e.g. vapourization, oral administration) may warrant consideration. Because vapourization is a lower-temperature process compared with pyrolysis (i.e. smoking), vapourization appears to be associated with the formation of a smaller quantity of toxic by-products such as carbon monoxide, polycyclic aromatic hydrocarbons (PAHs), and tar, as well as a more efficient extraction of Δ^9-THC from the cannabis material (273,281,282,283,284).

7.2 Respiratory tract

Differences in the smoking techniques used by cannabis vs. tobacco smokers are reported to result in three-fold higher levels of tar, and five-fold higher levels of carbon monoxide being retained in the lungs during cannabis smoking compared to tobacco smoking (885). A systematic comparison of the mainstream smoke composition from cannabis (Health Canada product) and tobacco cigarettes (prepared in the same way and consumed in an identical manner),

under two different sets of smoking conditions ("standard" and "extreme") has been reported (70). The "standard" condition reflects typical tobacco cigarette smoking conditions, whereas the "extreme" condition approaches that typically seen in cannabis smoking (70). Ammonia in mainstream cannabis smoke was 20-fold greater than that found in tobacco smoke, and oxides of nitrogen and hydrogen cyanide were three to five times higher in cannabis smoke vs. tobacco smoke. Carbon monoxide was significantly lower in mainstream cannabis smoke, under both smoking conditions. Tar was statistically significantly higher in mainstream cannabis smoke but only under the "extreme" smoking condition.

Mucosal biopsy specimens taken from chronic cannabis smokers, who reported smoking only cannabis, showed a number of histopathologic changes including basal cell hyperplasia, stratification, goblet cell hyperplasia, cell disorganization, inflammation, basement membrane thickening, and squamous cell metaplasia (242). However, the study employed a small number of subjects and relied on the accuracy and integrity of the subjects' recall to establish smoking status as well as frequency and duration of smoking. Epidemiological studies have found mild changes in pulmonary function in heavy cannabis smokers, including reduction of the forced expiratory volume in 1 second (FEV_1), an increase in airway resistance, and a decrease in airway conductance (244,245,246). Heavy chronic cannabis smokers presented with symptoms of bronchitis, including wheezing, production of phlegm and chronic cough, and long-term cannabis smoking may be a risk factor for chronic obstructive pulmonary disease in later life (122,886). All changes were most evident in heavy chronic users, defined as those who smoked more than three joints per day for 25 years (238,887), although evidence of measurable respiratory symptoms (e.g. decreased FEV_1/FVC ratio) was also observed in young, cannabis-dependent individuals whose smoking behaviour was comparable to tobacco smokers consuming 1 - 10 cigarettes/day (888). The potential risk of developing chronic obstructive respiratory disease, with long-term use and/or dependence, has been claimed to be potentially as great as among tobacco users (888). However, a recently published longitudinal study collecting repeated measurements of pulmonary function and smoking over a period of 20 years, in a cohort of 5 115 men and women in four U.S. cities (the CARDIA study), suggested a more complex picture. The study found a non-linear association between marihuana smoking and pulmonary function (247). By comparison, tobacco smoking (current and lifetime) was linearly associated with lower FEV_1 and FVC (247). Low levels of cumulative marihuana smoking were not associated with adverse effects on pulmonary function. Instead, at this level, marihuana smoking was associated with an increase in the FEV_1 and FVC values (247). At up to seven "joint-years" (a "joint-year" defined as smoking one joint/day, 365 days/year) of *lifetime* exposure there was no evidence of decreased pulmonary function. However, heavy chronic marihuana smoking (> ~30 joint-years or > ~25 smoking episodes per month) was associated with an accelerated decline in pulmonary function (FEV_1 but not FVC) (247).

Further research is needed to clarify the complex changes in lung function found in cannabis smokers, and to determine if there is a cause and effect relationship between cannabis smoking and the development of lung disease. Smoking cannabis may also increase the risk of developing respiratory infections in chronic users (889) through exposure to infectious organisms such as fungi and molds which can be found in the plant material (890), or alternatively by decreasing natural host defenses (891). However, further epidemiological research is also required to establish a causal relationship between cannabis smoking and respiratory infections. Vapourization of cannabis may be considered an alternative to smoking, although research is required to determine if there are any adverse effects of vapourization on lung health/function. For additional information on vapourization please consult sections 1.1.1, 1.1.2, 2.2.1.2, 3.4, 4.6.2.3, and **Table 6**.

7.3 Immune system

Pre-clinical studies

Evidence from *in vivo* and *in vitro* studies suggests complex and apparently dichotomous roles for the endocannabinoid system on immune system function (24). First, CB_1 and CB_2 receptors are known to be expressed in various immunocytes (B cells, monocytes, neutrophils, T lymphocytes, macrophages, mast cells), with CB_2 receptor expression generally being more abundant than CB_1 receptor expression; the ratio of CB_2 to CB_1 receptor expression ranges between 10 - 100 : 1 respectively, depending on the immune cell type in question (24,25). Second, immune cells also have the ability to synthesize, secrete, transport and catabolize endocannabinoids (24). Third, while stimulation of the CB_2 receptor appears to be generally associated with immunosuppressive effects, activation of the CB_1 receptor appears to be associated with an opposing immunostimulatory effect (24). Fourth, whereas certain cannabinoids have been shown to modulate the release of pro- or anti-inflammatory cytokines, pro-inflammatory cytokines (such as TNF-α) have, in turn, been reported to affect the functioning of the endocannabinoid system by upregulating the expression of both CB_1 and CB_2 receptor mRNA and protein levels (25). Thus, there appears to be some level of cross-talk between

the endocannabinoid and immune systems. Fifth, as is the case in other situations, Δ^9-THC appears to have a biphasic effect on immune system function. Low doses of Δ^9-THC seem to have stimulatory or pro-inflammatory effects, while higher doses appear to have inhibitory or immunosuppressive effects (266). Both Δ^9-THC and CBD have been reported to modulate cell-mediated and humoural immunity, through CB receptor-dependent and CB receptor-independent mechanisms (266,892,893). Cannabinoids target various cellular signaling and transcriptional pathways resulting in the inhibition of pro-inflammatory cytokine release (e.g. IL-1β, IL-6, IFN-β), and/or stimulation of anti-inflammatory cytokine release (e.g. IL-4, IL-5, Il-10, IL-13) (25,266). CBD also appears to induce a shift in Th1/Th2 immunobalance (892). While under certain circumstances, cannabinoids may appear to have broad anti-inflammatory and immunosuppressive functions which could be of benefit in pathological conditions having inflammatory characteristics, such beneficial functions may become problematic in the context of essential defensive responses to infections (24). For example, *in vitro* as well as *in vivo* experiments suggest cannabinoids have an impact on virus-host cell interactions (894): cannabinoid treatment was associated with increased viral replication of HSV-2, HIV-1, KSHV, influenza, and VSV viruses, or was associated with increases in surrogate measures of infection in these experimental models (895,896,897,898,899,900).

Taken together, the available information suggests that differences in the observed effects of cannabinoids on immune system function (i.e. immunosuppressive vs. immunostimulatory) may be explained by differences in the routes/methods of administration (smoked, oral, or other route), the length of exposure to the cannabinoid(s), the dose and type of cannabinoid used and which receptors are preferentially targeted, but also by differences between species, the experimental protocols and outcome measures that were used, and for clinical studies the health status/medical condition of the human subjects (266).

Clinical studies

The effects of cannabis smoking on the human immune system have been studied, but to a very limited degree. A major concern with HIV-positive cannabis smokers, or patients undergoing cancer chemotherapy, is that they might be more vulnerable than other cannabis smokers to the immunosuppressive effects of cannabis or that they risk exposure to infectious organisms associated with cannabis plant material (378). A group of studies has partially addressed the former concern. In one study, HIV-positive patients on stable anti-retroviral therapy were randomized to smoked cannabis or oral dronabinol and showed no changes in CD4+ and CD8+ T-cell, B cell, or NK cell counts and a number of other parameters compared with placebo, over a 21-day study period (901). A longitudinal study of 481 HIV-infected men who used cannabis and who were followed over an average five-year period found that while cannabis use was generally associated with a higher CD4+ cell count in infected men and controls, no clinically meaningful associations, adverse or otherwise, between cannabis use and T-cell counts and percentages could be established (902). Cannabis use was also not associated with an increased rate of progression to AIDS in HIV-infected individuals (903). In another study, smoking cannabis was associated with lower plasma concentrations of the protease inhibitors indinavir and nelfinavir; dronabinol or placebo had no effect (322). However, the decreased protease inhibitor levels were not associated with an elevated viral load, or changes in CD4+ or CD8+ cell counts (390).

In humans, smoking cannabis was also associated with poorer outcome in patients with chronic hepatitis C (882,904). Although pre-clinical studies strongly suggest that cannabinoids have broad immunomodulatory effects, and raise the possibility that cannabinoids may affect the ability of immunosuppressed patients to successfully resist or combat infections, it is unclear at this time if the immunomodulatory effects seen both pre-clinically and clinically translate into any clinically significant adverse outcomes.

Clear predictions concerning the effects of cannabinoids in those individuals who suffer from a dysregulated immune system are difficult to make because of the relative lack of available, comprehensive information on the subject. The clinician must therefore weigh the potential benefits of using cannabis and/or cannabinoids against the possible risks of using these substances on a case-by-case basis.

A recent cross-sectional study examined the association between cannabis use status and adherence to anti-retroviral therapy as well as the association between cannabis use status, HIV symptoms, and side effects associated with anti-retroviral therapy among a sample of HIV-positive individuals (905). The study reported that those subjects who had a cannabis use disorder (according to DSM-IV criteria and a Marijuana Smoking History Questionnaire score indicating daily cannabis or use more than once per day) had a significantly lower adherence to treatment than those who reported using cannabis once per week or more, but less than daily or not at all (905). Those who had a cannabis use disorder also had a higher viral load than those who used cannabis less than daily but at least once per week, as well as those who did not use at all; absolute CD4 count was not significantly different between groups (905). Furthermore, those

subjects with a cannabis use disorder reported significantly more frequent and severe HIV symptoms and/or medication side effects than those who used cannabis less than daily (but at least once per week), or those who reported not using cannabis at all (905). One limitation to this study was its cross-sectional nature, precluding the ability to establish a cause-and-effect relationship.

7.4 Reproductive and endocrine systems

Role of the endocannabinoid system in sexual physiology

The CB_1 receptor is widely expressed in various brain structures such as the striatum, hippocampus, and the cerebellum, as well as the amygdala, the midbrain, and the cerebral cortex—all structures that play various roles in regulating different aspects of sexual behaviour and function (269). For example, CB_1 receptors within the striatum and cerebellum may regulate motor activity and function; CB_1 receptors located within corticolimbic structures (e.g. pre-frontal cortex, amygdala and hippocampus) may regulate stress responsivity and emotional behaviour; CB_1 receptors located within the dorsal raphe and ventral tegmental area may regulate genital reflexes, sexual motivation and inhibition; and lastly, CB_1 receptors expressed within the hypothalamus and the pituitary gland may modulate the functioning of the hypothalamic-pituitary-gonadal axis either directly through modulation of gonadotropin-releasing hormone or indirectly through other modulators (269,270).

CB_1 receptor-mediated modulation of the hypothalamic-pituitary axis results in the suppression of luteinizing hormone, thyroid stimulating hormone, growth hormone, and prolactin release from the pituitary gland, while the effects on follicle stimulating hormone are seemingly unclear but point to a probable suppression of release (268,906). In animals, these effects are accompanied by changes in reproductive function and behaviour including decreases in plasma testosterone levels, degenerative changes in spermatocytes and spermatids, anovulation, and potential reduction in copulatory behaviour (268,270). Aside from the roles of the cannabinoid receptors in the brain, the male and female reproductive systems also contain an endocannabinoid system, and increasing experimental evidence suggests important roles for the endocannabinoid system in regulating various reproductive functions such as folliculogenesis, spermatogenesis, ovulation, fertilization, oviductal transport, implantation, embryo development, pregnancy, and labour (reviewed in (37)).

Effects of cannabis on human sexual behaviour

There is a relative paucity of data with regards to the effects of cannabis or cannabinoids on human sexual behaviour. One review article has summarized the few available studies on the subject (269). It concluded that in general, the effects of cannabis on sexual functioning and behaviour appear to be dose-dependent. For women, the available information suggests beneficial effects on sexual behaviour and functioning (e.g. reported increases in sensitivity to touch and relaxation and a corresponding increase in sexual responsiveness) at low to moderate doses, and potentially opposite responses at higher doses (269). For men, the available information suggests that cannabis intake at low to moderate doses may facilitate sexual desire and activity, but that at higher doses or with more frequent or chronic use it may inhibit sexual motivation as well as erectile function (269). Results obtained from animal studies appear to mirror some of these findings, although exceptions have also been noted (269). Although the effects of cannabis on human sexual behaviour are still not well understood, some of its reported beneficial effects have been speculatively linked to its psychoactive properties (e.g. increase in tactile sensitivity/perception or slowing of temporal perception) or alternatively, to a loss of inhibitions and an increased state of relaxation (269).

Studies investigating the effects of cannabis consumption on testosterone levels in men have yielded conflicting results (269). While some investigators have found that acute or chronic cannabis consumption significantly lowered plasma testosterone levels in a dose-dependent manner, others have apparently failed to find similar effects (269). Differences in the reported effects of cannabis on testosterone levels among the various studies have been, in part, attributed to differences in the experimental protocols employed (269).

Effects on sperm and testicular health

The effects of cannabis and Δ^9-THC on human sperm have been investigated both *in vivo* and *in vitro* (907,908,909). A significant decline in sperm count, concentration and motility, and an increase in abnormal sperm morphology were observed in men who smoked cannabis (8 - 20 cigarettes/day) for four weeks (907). In an *in vitro* study, sperm motility and acrosome reactions were decreased in both the 90% and 45% sperm fractions, the 90% fraction being the one with the best fertilizing potential and the 45% fraction being a poorer sub-population (909). Decreased sperm motility was observed in both fractions at Δ^9-THC concentrations mimicking those attained recreationally (0.32 and 4.8 μM), and in the 45% fraction at Δ^9-THC concentrations typically seen therapeutically (0.032 μM). Inhibition of the acrosome

reaction was only observed at the highest Δ^9-THC concentration tested (4.8 µM) in the 90% fraction, while the 45% fraction displayed decreased acrosome reactions at all three Δ^9-THC concentrations tested. Such effects carry the possibility of impairing crucial sperm functions and male fertility, especially in those males already on the borderline of infertility (909).

A recently published, population-based, case-control study reported that compared with men who never used cannabis, those who had reported ever-using had a nearly two-fold increased risk of developing testicular germ-cell tumours of any histologic type (Odds Ratio = 1.94, 95% Confidence Interval: 1.02 - 3.68) and a greater than two-fold increased risk of non-seminoma or mixed germ-cell tumours (Odds Ratio = 2.42, 95% Confidence Interval: 1.08 - 5.42) (910). Men who reported using cannabis less than once per week appeared to have an elevated risk of developing testicular germ-cell tumours compared to those men who reported using cannabis more frequently. Men who reported using cannabis for a period under 10 years were also more than twice as likely to develop such tumours as those reporting $\geq$ 10 years of use (910).

Effects on foetal development and child development

Results from human epidemiological studies examining short-term neonatal outcomes among women who smoked cannabis during pregnancy are equivocal; some report reduced neonatal birth weight and length (911,912,913,914) or a slightly increased risk of sudden infant death (915), while others report no effect (916,917,918). On the other hand, there appear to be some long-term effects on the development of children born to mothers who used cannabis during pregnancy. Two longitudinal investigations carried out over a time span of 20 years (reviewed in (869)) suggest that such *in utero* exposure impacts negatively on attentional behaviour and visual analysis and hypothesis testing, but not on standardized derived IQ scores. These findings were confirmed by a third study (870). These behavioural effects also appeared to have an adverse influence on aspects of executive function in later years.

Evidence suggests that cannabinoids accumulate in the breast milk of mothers who smoke cannabis and are transferred to newborns through breastfeeding (871,919). In a case-control study (920), exposure to cannabis from the mother's milk during the first month post-partum appeared to be associated with a decrease in infant motor development at one year of age.

7.5 Cardiovascular system

The most consistent acute physiological effect of smoking cannabis is dose-related tachycardia (121,226,232). While this is not usually considered dangerous for healthy young users, it may be dangerous to those already suffering from cardiac disorders or angina (118,921). Inhalation of cannabis smoke reduces the amount of exercise required to cause an angina attack by 50% (922), and has been associated with a five-fold increased risk of myocardial infarction in the first hour following smoking (232). This may be caused by a Δ^9-THC-related increase in cardiac output, myocardial oxygen demand, catecholamine levels, and carboxyhemoglobin as well as postural hypotension (226,227,923). While tachycardia is observed in both occasional and chronic users, tolerance develops relatively quickly with the degree of tachycardia diminishing with use. After about 8 to 10 days of constant dosing with 10 mg of Δ^9-THC per day (equivalent to 80 - 100 mg of cannabis containing 10% Δ^9-THC), bradycardia (924) with a decrease in supine blood pressure was observed (925).

Cannabis is also known to cause peripheral vasodilatation, postural hypotension, and characteristic conjunctival reddening after smoking (926).

AIDS patients may be at an increased risk of experiencing adverse cardiovascular outcomes caused by interactions between cannabis and anti-retroviral drugs, such as ritonavir, which has been associated with adverse cardiovascular events (927).

There have been a number of case-reports of arteritis associated with long-standing, chronic, daily cannabis smoking (928,929,930,931). Case-reports have also suggested an association between chronic, daily cannabis smoking and multi-focal intracranial stenosis (932) and stroke (236,237).

7.6 Gastrointestinal system and Liver

7.6.1 Hyperemesis

There are an increasing number of case-reports being published regarding the "cannabis hyperemesis syndrome" (CHS). CHS is a condition observed in people chronically using cannabis on a daily basis, often for years, and is characterized by severe, intractable episodes of nausea and cyclic vomiting accompanied by abdominal pain (typically epigastric or periumbilical); these symptoms are relieved by compulsive hot water bathing or showering (194,195,196,197,198,199,200,201,202,203,204). The pathophysiology of CHS is not well understood (202). Treatment of patients presenting with this syndrome has been reported to include: recommending cessation of cannabis use, rehydration, and psychological counselling (200,202). The efficacy of anti-emetics such as metoclopramide, ondansetron, prochlorperazine, and promethazine in relieving the symptoms of nausea and vomiting in patients with CHS appears to be debatable (198,200,201,204). A recent case-report suggests that lorazepam (1 mg i.v., followed by 1 mg tablets b.i.d.) may provide some benefit in alleviating the symptoms of CHS, at least in the short-term (933).

7.6.2 Liver

A number of studies have strongly implicated the endocannabinoid system in chronic liver disease (934,935,936,937,938). Studies in patients with chronic hepatitis C have found a significant association between daily cannabis smoking and moderate to severe fibrosis (904), as well as cannabis smoking being a predictor of fibrosis progression (882). Another study showed that daily cannabis use was a predictor of steatosis severity in these individuals (854). Steatosis is an independent predictor of fibrosis progression and an established factor of poor response to anti-viral therapy (939). The authors recommend that patients with ongoing chronic hepatitis C be strongly advised to abstain from daily cannabis use.

In contrast, another study showed that modest cannabis use (defined as anything less than daily use in this study) was associated with an increase in the duration of time that patients remained on anti-retroviral treatment (252). This effect was postulated to contribute, at least in part, to an increase in the percentage of patients demonstrating a sustained virological response (i.e. the absence of detectable levels of hepatitis C virus RNA six months after completion of therapy) (252).

7.7 Central nervous system

The most frequently reported adverse events encountered with cannabinoids involve the central nervous system (CNS). Commonly reported CNS events in controlled clinical trials with dronabinol (Marinol®) and nabiximols (Sativex®) are intoxication-like reactions including drowsiness, dizziness, and transient impairment of sensory and perceptual functions (174,290). A "high" (easy laughing, elation, heightened awareness), which could be unwanted or unpleasant for patients, was reported in 24% of the patients receiving Marinol® as an anti-emetic, and in 8% of patients receiving it as an appetite stimulant (174). Other adverse events occurring at a rate of > 1% for Marinol® include anxiety/nervousness, confusion, and depersonalization (174). Dizziness, euphoria, paranoia, somnolence, abnormal thinking ranged from 3 - 10% (174). The rates of amnesia, ataxia, and hallucinations were > 10% when used as an anti-emetic at higher doses (174). Dizziness is the most common intoxication effect with Sativex®, reported initially in 35% of patients titrating their dose; the reported incidence of this effect in long-term use is approximately 25% (940). All other intoxication-like effects are reported by less than 5% of users (with the exception of somnolence, 7%) (940). Other events reported for Sativex® include disorientation and dissociation. **Many, if not all, of the above-noted CNS effects also occur with cannabis.**

7.7.1 Cognition

The acute effects of cannabis use on cognition have been reviewed by Lundqvist (235). Cannabis impairs cognition involving faculties such as short-term memory, attention, concentration, executive functioning and visuoperception (180,941,942). The digit span task has been used to estimate the effects of cannabis on recent memory, but results have been inconsistent. Differences may be due to the dosage used, the smoking procedure, or whether the digit span task assesses forward or backward recall (943). Cannabis intoxication significantly impairs the ability to learn and recall word lists or short stories (944).

The long-term effects of cannabis on cognition remain controversial. Some studies report a positive association between cannabis consumption and cognitive deficits (945,946,947), or suggest that cognitive deficits persist after abstinence (180,941,948,949). Other studies did not find an association between cannabis use and long-term cognitive decline (948,949). Methodological limitations and the absence of powerful

effects have contributed to difficulties in assessing the effects of chronic use, and may help explain the discrepancies among studies (950,951). Nonetheless, studies generally suggest that chronic cannabis users suffer varying degrees of cognitive impairment that have the potential to be long-lasting (127). Prolonged use of ingested or inhaled cannabis in patients with multiple sclerosis was associated with poorer performance on various cognitive domains (e.g. information processing speed, working memory, executive function, and visuospatial perception), according to a cross-sectional study (178). A recently published, prospective, longitudinal study investigating the association between persistent cannabis use and neuropsychological functioning in a birth cohort of 1 037 individuals followed over a period of 20 years found that persistent cannabis use beginning in adolescence was associated with statistically significant global neuropsychological decline across a number of domains of functioning (952). Furthermore, cessation of cannabis use, for a period of one year or more, did not appear to fully restore neuropsychological functioning among adolescent-onset persistent cannabis users (952).

7.7.2 Psychomotor performance

Although no studies have been carried out to date examining the effects of cannabis or psychoactive cannabinoid exposure on psychomotor performance in individuals using these substances solely for medical purposes, it is well known that exposure to such substances impairs psychomotor performance (118) and patients must be warned not to drive or operate complex machinery after smoking or eating cannabis or consuming psychoactive cannabinoid medications (e.g. dronabinol, nabilone, nabiximols).

A double-blind, placebo-controlled, crossover study comparing the effects of a medium dose of dronabinol (20 mg) and of two hemp milk decoctions, containing medium (16.5 mg) or high doses (45.7 mg) of THC, reported severe impairment on several performance skills required for safe driving (953). A "moderate" dose (21 mg of THC) was associated with impairments in motor and perceptual skills necessary for safe driving (954). In one study, performance impairment appeared to be less significant among heavy cannabis users compared to occasional users, potentially because of the development of tolerance or compensatory behaviour (169). It has been suggested that, unlike alcohol, cannabis users are aware of their level of intoxication and compensate by becoming hyper-cautious; in tasks such as driving, this kind of behaviour results in decreased speed, decreased frequency of overtaking, and an increase in following distance (955,956). Others disagree with this assertion ((957) and also see (176)).

A recent double-blind, placebo-controlled, randomized, three-way, crossover design study suggested that administration of dronabinol dose-dependently impaired driving performance in both occasional (defined as using a cannabinoid between 5 and 36 times per year) and heavy cannabis users (defined as using 1 - 3 joints per day, > 160 times per year) (958). However, the magnitude of the impairment appeared to be less in heavy users, possibly due to tolerance (958). The authors indicate that driving impairments after dronabinol were of clinical relevance and comparable to drivers operating their vehicles at a blood-alcohol concentration of greater than 0.8 mg/mL (0.08 g%) (958). Approximately 25% of the "heavy users" demonstrated impairment equivalent to, or worse than, that reported for drivers with a blood-alcohol concentration of 0.5 mg/mL (0.05 g%). Driving impairments after dronabinol use were evident even though THC plasma concentrations were relatively low (varying between 2 and 10 ng/mL) (175,958).

A recent case-control study estimating accident risk for a variety of substances including alcohol, medicines, and illegal drugs found that the odds ratio for accident risk for all the THC concentrations measured (1 to > 5 ng/mL) was statistically significant (959). At whole-blood concentrations of ≥ 2 ng/mL THC, the risk of having an accident was significantly increased (959). One study found that the risk of responsibility for fatal traffic crashes, while driving under the influence of cannabis, increased with increasing blood concentrations of THC such that there was a significant dose-effect relationship between risk of responsibility for fatal traffic crashes and blood concentrations of THC. The study showed that the odds ratio of having a fatal crash increased from 2.18 if blood concentrations ranged between 0 and 1 ng/mL of THC, to 4.72 if blood THC concentrations were ≥ 5 ng/mL (960). The findings from this study further support the notion of a causal relationship between cannabis use and crashes (960). Another study suggested that drivers who were judged (by a police physician) as being impaired had higher blood THC concentrations than drivers judged not to be impaired (median: 2.5 ng/mL vs. 1.9 ng/mL) (961). Using a binary logistic regression model, the odds ratio for being judged impaired appeared to increase with increasing drug concentrations from 2.9 ng/mL onwards (961). Serum THC concentrations between 2 and 5 ng/mL have been identified as a threshold above which THC-induced impairment of skills related to driving become apparent (133,959). Performance impairment

after cannabis intake was reported to be highest during the first hour after smoking, and between 1 - 2 h after oral intake, and declining after 3 - 4 h (or longer in the case of oral ingestion) (862,961).

A recent meta-analysis of observational studies examining acute cannabis consumption and motor vehicle collision risk reported that driving under the influence of cannabis was associated with a significantly increased risk of motor vehicle collisions compared with unimpaired driving, with an odds ratio of 1.92 (95% Confidence Interval = 1.35 - 2.73; p = 0.0003) (175). Collision risk estimates were higher in case-control studies and studies of fatal collisions, than in culpability studies and studies of non-fatal collisions (175). It has been reported that individuals who drive within 1 h of using cannabis are nearly twice as likely to be involved in motor vehicle accidents as those who do not consume cannabis (954). For this meta-analysis, only observational studies with a control or comparison group, including cohort (historical prospective), case-control, and culpability designs were included, and experimental laboratory or simulator studies were excluded (175). Furthermore, only studies that assessed acute or recent cannabis use were examined. This meta-analysis supports the findings of other studies which suggest that cannabis use impairs the performance of the cognitive and motor tasks that are required for safe driving, thereby increasing the risk of collision (175). Although driving simulator studies have reported a dose-response effect, in which elevated concentrations of THC were associated with increased crash risk, dose-response effects could not be established in this study (175).

A double-blind, counter-balanced, placebo-controlled driving simulator study reported that driving performance was more impaired in subjects who co-consumed alcohol and low or high doses of THC by smoking cannabis cigarettes (176). The level of THC detected in the blood was higher when cannabis was consumed along with alcohol than when consumed alone (176). It also appeared that regular cannabis users displayed more driving errors than non-regular cannabis users (176).

A recent systematic review and meta-analysis concluded that, after adjusting for study quality, cannabis use was associated with a seven-fold estimated risk of being involved in a fatal accident, benzodiazepine use was associated with a two-fold estimated risk of a fatal accident, and opiate use with a three-fold estimated risk of a fatal accident (177). In contrast, cannabis use was associated with a 1.5-fold estimated risk of having an accident that only caused injury, benzodiazepine use was associated with a 0.71-fold estimated risk, whereas opiates were associated with a 21-fold estimated risk of having an accident that only caused injury (177).

7.7.3 Psychiatric effects

7.7.3.1 Acute psychotic reactions

Cannabis and cannabinoid use has been linked to episodes of acute psychosis in both regular and drug-naïve users (122,145,962). In one report, two healthy patients who had participated in a randomized controlled trial (RCT) measuring the effects of orally administered cannabinoids (including dronabinol or cannabis decoctions) on psychomotor performance displayed acute psychotic reactions following exposure to cannabis (145). The subjects had no psychiatric history or concomitant drug use, but were "occasional" regular cannabis users. In another RCT, 22 healthy subjects, also with a history of occasional cannabis use, no concomitant drug use, and with no psychiatric disorders received intravenous doses of Δ^9-THC paralleling peak plasma THC levels achieved by smoking cannabis cigarettes containing 1 - 3.5% Δ^9-THC (140). Drug administration was associated with a range of acute, transient, behavioural, and cognitive effects including suspiciousness, paranoid and grandiose delusions, conceptual disorganization, and illusions. Depersonalization, derealization, distorted sensory perceptions, altered bodily perceptions, feelings of unreality, and extreme slowing of time were also reported. Furthermore, blunted affect, reduced rapport, lack of spontaneity, psychomotor retardation, and emotional withdrawal were observed. Another study reported similar results (963).

7.7.3.2 Anxiety, Depression and Bipolar Disorder

Anxiety and depression

Cannabis is known to cause an acute and short-lasting episode of anxiety, often resembling a panic attack; this is more often encountered in naïve cannabis users and those who consume higher doses of cannabis or THC (> 5 mg oral Δ^9-THC), and also when cannabis is consumed in novel or stressful environments (147,155). While clinical trials of cannabis, or oral Δ^9-THC, to treat anxiety or depression show either a lack of improvement or worsening of these conditions (964,965,966,967) there is some evidence that cannabis or cannabinoids may be useful in treating anxiety or depression secondary to other disorders (e.g. chronic pain, post-traumatic stress disorder). For more information on potential therapeutic uses of cannabis or cannabinoids to treat anxiety and depression, please consult section 4.8.5.1.

Research on the topic of cannabis and depression is relatively scarce and conflicting. A 2003 review reported that the co-morbidity level between heavy or problematic cannabis use and depression, in surveys of the general population, exceeds what would be expected by chance (968). The authors also identify a modest association between early-onset regular or problematic use and later depression. However, limitations in the available research on cannabis and depression, including limitations in study design, as well as limitations in the ability to measure cannabis use, and limitations in the ability to measure depression were also highlighted. A U.S. study of adults using longitudinal national survey data (n = 8 759) found that the odds of developing depression in past-year cannabis users was 1.4 times higher than the odds of non-users developing depression (969). However, after adjusting for group differences, the association was no longer significant. In a 2008 study, the same group looked at the relationship between cannabis use and depression among youth using a longitudinal cohort of 1 494 adolescents. Similar to the adult study, the results did not support the causal relationship between adolescent-onset cannabis use problems and early adult depression (970). In contrast, another U.S. study based on the results of the National Epidemiological Survey on Alcohol and Related Conditions (n = 43 093) found that major depression was significantly associated with lifetime cannabis disorders and dependence (971). A 2007 study using data from the Netherlands Mental Health Survey and Incidence Study found a modest increased risk of a first depressive episode (Odds Ratio = 1.62; 1.06 - 2.48), after controlling for strong confounding factors (972). Of greater significance in this study was the strong increased risk of bipolar disorder (Odds Ratio = 4.98; 1.80 - 13.81) with cannabis use (see below for further information on cannabis and bipolar disorder). There was a dose-response relationship associated with the risk of 'any mood disorder' for almost daily and weekly users, but not for less frequent users. A survey of 248 French high school students found that cannabis users had significantly higher rates of suicidal behaviours and depressive and anxious symptoms compared to non-users (973). Another study suggested a putative positive association between exposure to cannabis and protracted suicidal thoughts or attempts in young people, although the study suffered from a number of limitations (974).

Bipolar disorder

Cannabis is one of the most frequently abused drugs in people diagnosed with bipolar disorder (148,975,976,977,978). A number of studies have examined the relationship between cannabis use and bipolar disorder, its effect on disease course, and its effect on treatment compliance.

One three-year, prospective study involving 4 815 subjects attempted to determine if baseline cannabis use increased the risk for development of manic symptoms, if the association between cannabis use and mania was independent of the emergence of psychotic symptoms, and if baseline mania predicted cannabis use at follow-up (975). The authors found that cannabis use at baseline was associated with follow-up mania (Odds Ratio = 5.32, 95% Confidence Interval: 3.59, 7.89). After adjusting for confounding factors, the association persisted although it was reduced (Odds Ratio = 2.70, 95% Confidence Interval: 1.54, 4.75). The risk of developing manic symptoms appeared to increase with increased baseline frequency of cannabis use (975). The effect size was largest for those who used cannabis 3 - 4 days/week, followed by those who used daily and 1 - 2 days/week, and lastly for those who used 1 - 3 days/month (975). The authors reported that manic

symptoms at baseline did not predict cannabis use during follow-up. The results suggested that use of cannabis increased the risk of developing subsequent manic symptoms and that this effect was dose-dependent (975).

Another group of investigators conducted a five-year, prospective, cohort study examining three groups of patients: one where a cannabis use disorder preceded the onset of bipolar disorder, another where bipolar disorder preceded a cannabis use disorder, and one group with bipolar disorder only (976). The authors found that cannabis use was associated with more time in affective (manic or mixed) episodes and with rapid cycling, but a causal relationship between cannabis use and bipolar disorder could not be established (976).

A separate prospective study which followed a group of type I bipolar patients over a 10-year period, beginning from the onset of illness, concluded that there was a strong association between cannabis use and manic/hypomanic episodes or symptoms, and that substance abuse preceded or coincided with, but did not follow, exacerbations of affective illness (979).

A two-year, prospective, observational study on the outcome of pharmacological treatment of mania (the **E**uropean **M**ania in **B**ipolar **L**ongitudinal **E**valuation of **M**edication (EMBLEM) study) followed 3 459 eligible in- and out-patients who were being treated for acute mania in bipolar disorder, assessing patients' current cannabis use as well as the influence of cannabis exposure on clinical and social treatment outcome measures (148). The study concluded that during a one-year treatment period, cannabis users exhibited less treatment compliance and higher levels of overall illness severity, mania, and psychosis compared to non-users (148). Cannabis users also reported experiencing less satisfaction with life (148).

A preliminary study found that patients diagnosed with bipolar disorder with psychotic features were significantly more likely to carry a functional polymorphism in the promoter region of the *5-HT* transporter gene and also have a diagnosis of cannabis abuse/dependence, compared to bipolar patients who did not exhibit psychotic symptoms (978). Genetic studies have also raised the possibility of a link between allelic variants of the cannabinoid receptor gene (*CNR1*) and susceptibility to mood disorders (980,981).

The influence of cannabis use on age at onset in both schizophrenia and bipolar disorder (with psychotic symptoms) has been studied using regression analysis (150). The authors of this study found that although cannabis and other substance use was more frequent in patients with schizophrenia than those diagnosed with bipolar disorder, cannabis use was nonetheless associated with a decrease in age at onset in both disorders (150). Cannabis use also preceded first hospitalization in the vast majority of cases (95.4%). Furthermore, the period of most intensive use ("several times per day") preceded first admission in 87.1% of the cases (150). In bipolar patients, cannabis use reduced age at onset by an average of nine years (150). In contrast, in schizophrenic patients, cannabis use reduced age at onset by an average of 1.5 years (150). No significant difference was noted in age at onset between male and female patients in either of the diagnostic groups (150).

Another study investigated which factors were associated with age at onset in bipolar disorder, and also examined the sequence of the onsets of excessive substance use and bipolar disorder (982). A total of 151 patients with bipolar disorder (type I and II) receiving psychiatric treatment participated in the study. The authors found that when compared with alcohol use, excessive cannabis use (defined as either meeting DSM-IV criteria for substance use disorder, or weekly use of cannabis over a period of at least four years) was associated with an earlier age at onset in both primary and secondary bipolar disorder, even after adjusting for possible confounders (982). In addition, the mean age at onset of excessive cannabis use preceded the age at onset of bipolar disease; this was reversed in the alcohol group (982).

One study reported that when compared with controls, patients with bipolar disorder were almost seven times (95% Confidence Interval: 5.41 - 8.52) more likely to report a lifetime history of cannabis use (977). Furthermore, this association appeared to be gender-independent. Those patients who used cannabis after, or in tandem with, their onset of bipolar symptoms had a lower

age at onset of the disorder (17.5 vs. 21.5 yrs) (977). Furthermore, those who used cannabis prior to the onset of a bipolar disease episode were 1.75 times (95% Confidence Interval: 1.05 - 2.91) more likely to report disability attributable to bipolar disorder (977).

Lastly, a retrospective analysis of a large cohort of bipolar I subjects, with or without a history of a cannabis use disorder, reported that bipolar patients with a cannabis use disorder had similar age at onset as patients without such a substance use disorder (983). However, patients with a cannabis use disorder were more likely to have experienced psychosis at some time during the course of their illness compared to patients who never met the criteria for the disorder (983).

7.7.3.3 Schizophrenia and psychosis

The endocannabinoid system has been implicated in the pathogenesis of schizophrenia and psychosis (please see section 4.8.5.5 for more information). Individuals with schizophrenia, or with a family history of this disorder, are likely to be at greater risk of suffering adverse psychiatric effects as a result of using cannabis or psychoactive cannabinoids such as Δ^9-THC (152). Heavy cannabis use can aggravate psychotic symptoms and cause more relapses, and those individuals who use cannabis are at an increased risk of a poor prognosis (118,138,984,985). Self-reported use of cannabis in adolescence has been associated with an increased risk of developing schizophrenia, and this risk was related to frequency of cannabis exposure (986). A cohort study of over 1 000 children followed from birth to age 26 reported a three-fold increased risk of psychotic disorders in those who used cannabis, and suggested that cannabis exposure among psychologically vulnerable adolescents should be strongly discouraged (987). The relationship between cannabis use and psychotic symptoms was also studied in a cohort of 2 437 young people (ages 14 - 24 yrs) who had greater than average pre-disposition for psychosis, and who had first used cannabis during adolescence (146). The authors found a dose-response relationship between frequency of cannabis use and the risk of psychosis. The effect of cannabis use was also much stronger in those individuals with a pre-disposition for psychosis. A systematic review of evidence pertaining to cannabis use and the occurrence of psychotic or affective mental health outcomes reported an increased risk of any psychotic outcome in individuals who had ever used cannabis compared with non-users (Odds Ratio = 1.41) (141). Furthermore, the findings appeared to show a dose-related effect, with greater risk to individuals who used cannabis most frequently (Odds Ratio = 2.09) (149,150).

In one study, the relationship between age at onset of psychosis and other clinical characteristics in a sample of well-characterized patients diagnosed with bipolar disorder with psychosis, schizoaffective disorder, or schizophrenia, has been investigated (149). The study concluded that lifetime cannabis abuse/dependence was associated with a significantly earlier age at onset of psychosis (3.1 years, 95% Confidence Interval: 1.4 - 4.8) (149). Furthermore, among those patients with lifetime cannabis abuse/dependence, the age at onset of cannabis abuse/dependence preceded the onset of psychotic illness by almost another three years (149). However, patients who had a lifetime cannabis abuse/dependence diagnosis and a lifetime alcohol abuse/dependence diagnosis had a significantly later age at onset of psychosis (149).

Another study looked at the influence of cannabis use on age at onset in both schizophrenia and bipolar disorder (with psychotic symptoms) using regression analysis (150). The authors of this study found that although cannabis and other substance use was more frequent in patients with schizophrenia than those diagnosed with bipolar disorder, cannabis use was nonetheless associated with a decrease in age at onset in both disorders (150). Cannabis use also preceded first hospitalization in the vast majority of cases (95.4%) and furthermore, the period of most intensive use ("several times per day") preceded first admission in 87.1% of the cases (150). In bipolar patients, cannabis use reduced age at onset by an average of nine years (150). In contrast, in schizophrenic patients, cannabis use reduced age at onset by an average of 1.5 years (150). No significant difference was noted in age at onset between male and female patients in either of the diagnostic groups (150).

Although cannabis use increases the risk of psychosis, it is only one factor in a larger constellation of contributing factors (988).

Genetic factors

A number of studies have investigated the influence of potential genetic factors in the development of psychosis and schizophrenia, and more specifically as a function of interaction with cannabis use. Some studies have focused on the role of genetic polymorphisms at the catechol-O-methyltransferase gene (*COMT*) (686,687,688,689,690), while others have focused on polymorphisms at the *AKT1* gene (691,692,693), or the brain-derived neurotrophic factor (*BDNF*) gene (989).

Schizophrenia and the Catechol-O-Methyltransferase gene

Catechol-O-methyltransferase (COMT) regulates the breakdown of catecholamines, including neurotransmitters such as dopamine, epinephrine, and norepinephrine (690). A missense mutation at codon 158 in the *COMT* gene, causing a substitution to the methionine (Met) at the positional valine (Val) (Val158Met), results in an enzyme with decreased activity and correspondingly slower dopamine catabolism (990,991). Changes in dopaminergic tone and signaling are known to affect neurophysiological function, and these changes have been implicated in the pathophysiology of schizophrenia (992). Although a large-scale association study and meta-analysis has failed to find a strong association between the Val158Met *COMT* polymorphism and vulnerability to schizophrenia (993), evidence gathered from convergent functional genomic data nevertheless implicates the *COMT* gene (as well as the *CNR1* and *2* genes) in the pathophysiology of schizophrenia (994). Caspi et al. (686) followed an epidemiological birth cohort of 1 037 children longitudinally across the first three decades of life. They concluded that the *COMT* Val/Val homozygous genotype interacted with adolescent-onset cannabis use, but not adult-onset use, to predict the emergence of adult psychosis (686). Subsequent studies confirmed and extended these findings (687,688,689,690,693). Carriers of the Val allele were most sensitive to Δ^9-THC-induced psychotic experiences (especially if they scored highly on a psychosis liability assessment), and were also more sensitive to the Δ^9-THC-induced memory and attention impairments compared to carriers of the Met allele (687). Homozygous carriers of the Val allele, but not subjects with the homozygous Met genotype, showed an increase in the incidence of hallucinations after cannabis exposure, but this was conditional on prior psychometric evidence of psychosis liability (688). Those patients who were Val/Met heterozygous also appeared to be more sensitive to the effects of cannabis than Met homozygotes, but less sensitive than Val homozygotes (688). Another study suggested that cannabis use could reduce the (protective) delay effect of the *COMT* Met allele in influencing the age of onset of psychosis (689). These findings were supported, and extended, by a subsequent study which showed that those who started using cannabis earlier had an earlier age at onset of psychiatric disorders, and that carriers of the Val homozygous genotype had an earlier age of onset of psychosis compared to Met carriers (690). The authors of this study concluded that gene-environment interaction (i.e. the combination of the *COMT* Val to Met polymorphism and cannabis use) may modulate the emergence of psychosis in adolescents (690). Taken together, these studies also suggest the presence of a gene-dosage effect, with increasing disease risk among Val/Val homozygotes, moderate risk in Val/Met heterozygotes, and less risk among Met/Met homozygotes.

Schizophrenia and the AKT1 gene

Other studies have focused on the role of *AKT1*, a gene that encodes a protein kinase involved in the dopamine and cannabinoid receptor signaling cascades, and which is involved in regulating cellular metabolism, cell stress, cell-cycle regulation, and apoptosis as well as regulating neuronal cell size and survival (691). In one study, the authors found evidence of a gene-environment interaction between a single nucleotide polymorphism in the *AKT1* gene (rs2494732, C/C homozygous polymorphism) and cannabis use (692). Individuals with the C/C homozygous polymorphism had an approximately two-fold increased risk of being diagnosed with a psychotic disorder after having used cannabis either daily or weekly (692). In contrast, C/T heterozygous individuals had only a slightly increased risk of developing cannabis-related psychosis compared to T/T homozygotes, which served as the controls (692). In another study by the same group, individuals with the rs2494732 C/C homozygous polymorphism exhibited a deficit in sustained attention, but not in verbal memory, even in the absence of current cannabis use (691).

Schizophrenia and the Brain-Derived Neurotrophic Factor gene

One study found that cannabis use, before diagnosis of schizophrenia, was associated with a decrease in the age at onset of a psychotic disorder, decreasing the age at first admission by almost three years (989). Furthermore, a dose-dependent association between cannabis use and age at onset of psychotic symptoms was found, with an earlier onset of psychotic disorder in heavier users (989). A significant association between a younger age of first cannabis use and an earlier onset of psychotic disorder was also found, even after controlling for possible confounders (989). In that study, cannabis use independently predicted age at onset of a psychotic disorder in male patients, whereas in female patients cannabis use was only associated with age at onset of psychotic disorder in those who carried a Met allele mutation in the gene for brain-derived neurotrophic factor (*BDNF*). Female carriers of the mutant Met allele presented with psychotic symptoms seven years earlier than female patients who did not use cannabis and who had a *BDNF* Val/Val genotype (989).

In conclusion, given the evidence suggesting a strong genetic component in the modulation of psychosis, and especially psychosis or schizophrenia precipitated by cannabis use, the taking of a thorough patient medical history, especially one which includes a psychiatric history/evaluation, would be very valuable in determining whether cannabis/cannabinoids represent a sensible and viable therapeutic option.

7.7.3.4 Amotivational syndrome

The term "amotivational syndrome" is generally used to qualify people who exhibit apathy, lack of motivation, social withdrawal, narrowing of interests, lethargy, impaired memory, impaired concentration, disturbed judgement, and impaired occupational achievement (995).

Some investigators suggest that heavy, chronic use of cannabis is linked to the development of such a syndrome (995); de-intoxication results in resolution of symptoms (152,996). Other investigators have not found such a causal relationship (995,997).

8.0 Overdose/Toxicity

LD_{50} values for rats administered single oral doses of THC, or crude cannabis extract, are approximately 1000 mg/kg (998). Dogs and monkeys are able to tolerate significantly higher oral doses of THC, or cannabis extract, of 3000 mg/kg (or greater in certain cases) (998). The estimated human lethal dose of intravenous THC is 30 mg/kg (2100 mg/70 kg) (174), although there has been no documented evidence of death exclusively attributable to cannabis overdose to date. Significant CNS symptoms are observed with oral doses of 0.4 mg/kg dronabinol (Marinol®) (174). Cannabis and THC often produce unwanted physical effects, typically dizziness, sedation, intoxication, transient impairment of sensory and perceptual functions, clumsiness, dry mouth, lowered blood pressure, or increased heart rate (174,999). These adverse effects are generally tolerable and not unlike those seen with other medications (118). The rare acute complications (e.g. panic attacks, psychosis, convulsions, etc.) that present to hospital Emergency Departments can be managed with conservative measures, such as reassurance in a quiet environment, and administration of benzodiazepines, if required (1000). As is stated in the case of overdose with Marinol® (174), the signs and symptoms observed with smoked or ingested cannabis are an extension of the psychotomimetic and physiologic effects of THC. Individuals experiencing psychotic reactions should stop using cannabis or cannabinoids immediately and seek prompt medical/psychiatric attention.

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This is **Exhibit " B "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

Registration
SOR/2001-227 14 June, 2001

CONTROLLED DRUGS AND SUBSTANCES ACT

Marihuana Medical Access Regulations

P.C. 2001-1146 14 June, 2001

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], hereby makes the annexed *Marihuana Medical Access Regulations*.

MARIHUANA MEDICAL ACCESS REGULATIONS

INTERPRETATION

1. (1) The following definitions apply in these Regulations.

"Act" means the *Controlled Drugs and Substances Act*. (*Loi*)

"adverse drug reaction" means a noxious and unintended response to a drug that occurs at doses normally used or tested for the diagnosis, treatment or prevention of a medical condition or the modification of an organic function. (*réaction indésirable à une drogue*)

"authorization to possess" means an authorization to possess dried marihuana issued under section 11. (*autorisation de possession*)

"category 1 symptom" means a symptom that is associated with a terminal illness or its medical treatment. (*symptôme de catégorie 1*)

"category 2 symptom" means a symptom, other than a category 1 symptom, that is set out in column 2 of the schedule and that is associated with a medical condition set out in column 1 or its medical treatment. (*symptôme de catégorie 2*)

"category 3 symptom" means a symptom, other than a category 1 or 2 symptom, that is associated with a medical condition or its medical treatment. (*symptôme de catégorie 3*)

"conventional treatment" means, in respect of a symptom, a medical or surgical treatment that is generally accepted by the Canadian medical community as a treatment for the symptom. (*traitement conventionnel*)

"designated drug offence" means

(*a*) an offence against section 39, 44.2, 44.3, 48, 50.2 or 50.3 of the *Food and Drugs Act*, as those provisions read immediately before May 14, 1997;

(*b*) an offence against section 4, 5, 6, 19.1 or 19.2 of the *Narcotic Control Act*, as those provisions read immediately before May 14, 1997;

(*c*) an offence under Part I of the Act, except subsection 4(1); or

(*d*) a conspiracy or an attempt to commit, being an accessory after the fact in relation to or any counselling in relation to an offence referred to in any of paragraphs (*a*) to (*c*). (*infraction désignée en matière de drogue*)

[a] S.C. 1996, c. 19

Enregistrement
DORS/2001-227 14 juin 2001

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Règlement sur l'accès à la marihuana à des fins médicales

C.P. 2001-1146 14 juin 2001

Sur recommandation du ministre de la Santé et en vertu du paragraphe 55(1) de la *Loi réglementant certaines drogues et autres substances*[a], Son Excellence la Gouverneure générale en conseil prend le *Règlement sur l'accès à la marihuana à des fins médicales*, ci-après.

RÈGLEMENT SUR L'ACCÈS À LA MARIHUANA À DES FINS MÉDICALES

DÉFINITIONS ET INTERPRÉTATION

1. (1) Les définitions qui suivent s'appliquent au présent règlement.

« aire de production » Endroit où la marihuana est produite, à savoir :

a) soit entièrement à l'intérieur;

b) soit entièrement à l'extérieur;

c) soit en partie à l'intérieur et en partie à l'extérieur, mais sans période de chevauchement entre les deux. (*production area*)

« autorisation de possession » Autorisation de possession de marihuana séchée, délivrée au titre de l'article 11. (*authorization to possess*)

« fins médicales » Fins visant l'atténuation chez une personne d'un symptôme de catégorie 1, 2 ou 3 mentionné dans la demande d'autorisation de possession. (*medical purpose*)

« infraction désignée en matière de drogue » Selon le cas :

a) toute infraction prévue aux articles 39, 44.2, 44.3, 48, 50.2 ou 50.3 de la *Loi sur les aliments et drogues*, dans leur version antérieure au 14 mai 1997;

b) toute infraction prévue aux articles 4, 5, 6, 19.1 ou 19.2 de la *Loi sur les stupéfiants*, dans leur version antérieure au 14 mai 1997;

c) toute infraction prévue à la partie I de la Loi, à l'exception du paragraphe 4(1);

d) le complot ou la tentative de commettre toute infraction visée aux alinéas *a*) à *c*), la complicité après le fait à son égard ou le fait de conseiller de la commettre. (*designated drug offence*)

« infraction désignée relativement à la marihuana » Selon le cas :

a) toute infraction, relativement à la marihuana, prévue aux articles 5 ou 6 de la Loi, à l'exclusion dans ce dernier cas de l'importation;

b) le complot ou la tentative de commettre toute infraction visée à l'alinéa *a*), la complicité après le fait à son égard ou le fait de conseiller de la commettre. (*designated marihuana offence*)

[a] L.C. 1996, ch. 19

"designated marihuana offence" means

(*a*) an offence, in respect of marihuana, against section 5 of the Act, or against section 6 of the Act except with respect to importation; or

(*b*) a conspiracy or an attempt to commit or being an accessory after the fact in relation to or any counselling in relation to an offence referred to in paragraph (*a*). (*infraction désignée relativement à la marihuana*)

"designated person" means the person designated, in an application made under section 37, to produce marihuana for the applicant. (*personne désignée*)

"designated-person production licence" means a licence issued under section 40. (*licence de production à titre de personne désignée*)

"dried marihuana" means harvested marihuana that has been subjected to any drying process. (*marihuana séchée*)

"licence to produce" means either a personal-use production licence or a designated-person production licence. (*licence de production*)

"marihuana" means the substance referred to as "Cannabis (marihuana)" in subitem 1(2) of Schedule II to the Act. (*marihuana*)

"medical practitioner" means a person who is authorized under the laws of a province to practise medicine in that province and who is not named in a notice given under section 58 or 59 of the *Narcotic Control Regulations*. (*médecin*)

"medical purpose" means the purpose of mitigating a person's category 1, 2 or 3 symptom identified in an application for an authorization to possess. (*fins médicales*)

"personal-use production licence" means a licence issued under section 29. (*licence de production à des fins personnelles*)

"production area" means the place where the production of marihuana is conducted, that is

(*a*) entirely indoors;

(*b*) entirely outdoors; or

(*c*) partly indoors and partly outdoors but without any overlapping period between the two types of production. (*aire de production*)

"specialist" means a medical practitioner who is recognized as a specialist by the medical licensing authority of the province in which the practitioner is authorized to practise medicine. (*spécialiste*)

"terminal illness" means a medical condition for which the prognosis is death within 12 months. (*maladie en phase terminale*)

(2) For the purpose of sections 28 and 53, a site for the production of marihuana is considered to be adjacent to a place if the boundary of the land on which the site is located has at least one point in common with the boundary of the land on which the place is located.

« licence de production » Licence de production à des fins personnelles ou licence de production à titre de personne désignée. (*licence to produce*)

« licence de production à des fins personnelles » Licence délivrée au titre de l'article 29. (*personal-use production licence*)

« licence de production à titre de personne désignée » Licence délivrée au titre de l'article 40. (*designated-person production licence*)

« Loi » La *Loi réglementant certaines drogues et autres substances*. (*Act*)

« maladie en phase terminale » État pathologique pour lequel est établi un pronostic de décès du patient dans les douze mois. (*terminal illness*)

« marihuana » La substance appelée Cannabis (marihuana), inscrite au paragraphe 1(2) de l'annexe II de la Loi. (*marihuana*)

« marihuana séchée » Marihuana qui a été récoltée et soumise à un processus de séchage. (*dried marihuana*)

« médecin » Personne qui, en vertu des lois d'une province, est autorisée à exercer la médecine dans cette province et qui n'est pas désignée dans une communication prévue aux articles 58 ou 59 du *Règlement sur les stupéfiants*. (*medical practitioner*)

« personne désignée » Personne désignée, dans une demande présentée au titre de l'article 37, pour produire de la marihuana pour le compte du demandeur. (*designated person*)

« réaction indésirable à une drogue » Réaction nocive et non voulue à une drogue qui survient lorsque la drogue est utilisée selon les doses normales ou selon des doses expérimentales, aux fins de diagnostic, de traitement ou de prévention d'une maladie ou de modification d'une fonction organique. (*adverse drug reaction*)

« spécialiste » Médecin reconnu comme spécialiste par les autorités médicales chargées de délivrer les licences dans la province où il est autorisé à exercer la médecine. (*specialist*)

« symptôme de catégorie 1 » Symptôme associé à une maladie en phase terminale ou à son traitement médical. (*category 1 symptom*)

« symptôme de catégorie 2 » Symptôme visé à la colonne 2 de l'annexe qui est associé à l'état pathologique mentionné à la colonne 1 ou à son traitement médical, à l'exclusion d'un symptôme de catégorie 1. (*category 2 symptom*)

« symptôme de catégorie 3 » Symptôme associé à un état pathologique ou à son traitement médical, à l'exclusion d'un symptôme de catégorie 1 ou 2. (*category 3 symptom*)

« traitement conventionnel » Traitement médical ou chirurgical qui est généralement reconnu dans la communauté médicale canadienne pour le traitement d'un symptôme. (*conventional treatment*)

(2) Pour l'application des articles 28 et 53, est réputé adjacent à un autre terrain le terrain dont l'une des limites touche au moins en un point à l'une des limites de cet autre terrain. (*adjacent*)

PART 1

AUTHORIZATION TO POSSESS

Authorized Activity

2. The holder of an authorization to possess is authorized to possess dried marihuana, in accordance with the authorization, for the medical purpose of the holder.

Eligibility for Authorization to Possess

3. A person is eligible to be issued an authorization to possess only if the person is an individual ordinarily resident in Canada.

Application for Authorization to Possess

4. (1) A person seeking an authorization to possess dried marihuana for a medical purpose shall submit an application to the Minister.

(2) An application under subsection (1) shall contain

(*a*) a declaration of the applicant;

(*b*) a medical declaration that is made

(i) in the case of an application based on a category 1 symptom, by the medical practitioner of the applicant, or

(ii) in the case of an application based on a category 2 or 3 symptom, by a specialist;

(*c*) if the application is based on a category 3 symptom, a second medical declaration made by another specialist, that supports the medical declaration made under subparagraph (*b*)(ii); and

(*d*) two copies of a current photograph of the applicant.

Applicant's Declaration

5. (1) The declaration of the applicant under paragraph 4(2)(*a*) must indicate

(*a*) the applicant's name, date of birth and gender;

(*b*) the full address of the place where the applicant ordinarily resides as well as the applicant's telephone number and, if applicable, facsimile transmission number and e-mail address;

(*c*) the mailing address of the place referred to in paragraph (*b*), if different;

(*d*) if the place referred to in paragraph (*b*) is an establishment that is not a private residence, the type and name of the establishment;

(*e*) that the authorization is sought in respect of marihuana either

(i) to be produced by the applicant or a designated person, in which case the designated person must be named, or

(ii) to be obtained under the *Narcotic Control Regulations*, in which case the licensed dealer who produces or imports the marihuana must be named;

(*f*) that the applicant is aware that no notice of compliance has been issued under the *Food and Drugs Act* concerning the safety and effectiveness of marihuana as a drug and that the applicant understands the significance of that fact; and

(*g*) that the applicant has discussed the risks of using marihuana with the medical practitioner providing the medical declaration under paragraph 4(2)(*b*), and consents to using it for the recommended medical purpose.

PARTIE 1

AUTORISATION DE POSSESSION

Opération autorisée

2. Le titulaire d'une autorisation de possession peut avoir en sa possession, conformément à l'autorisation, de la marihuana séchée à ses propres fins médicales.

Admissibilité à l'autorisation

3. Est admissible à l'autorisation de possession la personne physique qui réside habituellement au Canada.

Demande d'autorisation

4. (1) Quiconque souhaite obtenir une autorisation de possession de marihuana séchée, à des fins médicales, présente au ministre une demande à cet effet.

(2) La demande comporte les éléments suivants :

a) une déclaration du demandeur;

b) une déclaration médicale qui :

(i) si la demande est fondée sur un symptôme de catégorie 1, provient du médecin du demandeur,

(ii) si la demande est fondée sur un symptôme de catégorie 2 ou de catégorie 3, provient d'un spécialiste;

c) si la demande est fondée sur un symptôme de catégorie 3, une seconde déclaration médicale d'un autre spécialiste corroborant la déclaration médicale visée au sous-alinéa *b*)(ii);

d) deux copies d'une photographie récente du demandeur.

Déclaration du demandeur

5. (1) La déclaration du demandeur visée à l'alinéa 4(2)*a*) comporte les renseignements suivants :

a) les nom, date de naissance et sexe du demandeur;

b) l'adresse complète de son lieu de résidence habituelle, ainsi que son numéro de téléphone et, le cas échéant, son numéro de télécopieur et son adresse électronique;

c) l'adresse postale de son lieu de résidence habituelle, si elle diffère de l'adresse mentionnée à l'alinéa *b*);

d) lorsque le lieu visé à l'alinéa *b*) n'est pas une habitation privée, le type d'établissement dont il s'agit et son nom;

e) la mention qu'il entend, selon le cas :

(i) produire la marihuana lui-même ou la faire produire par une personne désignée, auquel cas le nom de la personne désignée doit être mentionné,

(ii) obtenir la marihuana en vertu du *Règlement sur les stupéfiants*, auquel cas le nom du distributeur autorisé qui l'importe ou la produit doit être mentionné;

f) la mention qu'il sait qu'aucun avis de conformité n'a été délivré en vertu du *Règlement sur les aliments et drogues* quant à l'innocuité ou l'efficacité de la marihuana comme drogue, et comprend les implications de ce fait;

g) la mention qu'il a discuté avec le médecin qui a fourni la déclaration médicale visée à l'alinéa 4(2)*b*) des risques associés à l'usage de la marihuana, et consent à l'usage de celle-ci aux fins médicales recommandées.

(2) The declaration must be dated and signed by the applicant attesting that the information contained in it is correct and complete.

Medical Declarations

6. (1) The medical declaration under paragraph 4(2)(*b*) must indicate, in all cases

(*a*) the medical practitioner's or specialist's name, business address and telephone number, provincial medical licence number and, if applicable, facsimile transmission number and e-mail address;

(*b*) the applicant's medical condition, the symptom that is associated with that condition or its treatment and that is the basis for the application and whether the symptom is a category 1, 2 or 3 symptom;

(*c*) the daily dosage of dried marihuana, in grams, and the form and route of administration, recommended for the applicant; and

(*d*) the period for which the use of marihuana is recommended, if less than 12 months.

(2) In the case of a category 1 symptom, the medical declaration must also indicate that

(*a*) the applicant suffers from a terminal illness;

(*b*) all conventional treatments for the symptom have been tried, or have at least been considered;

(*c*) the recommended use of marihuana would mitigate the symptom;

(*d*) the benefits from the applicant's recommended use of marihuana would outweigh any risks associated with that use; and

(*e*) the medical practitioner is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug.

(3) In the case of a category 2 symptom, the medical declaration must also indicate that

(*a*) the specialist practices in an area of medicine, to be named by the specialist in the declaration, that is relevant to the treatment of the applicant's medical condition;

(*b*) all conventional treatments for the symptom have been tried, or have at least been considered, and that each of them is medically inappropriate because

(i) the treatment was ineffective,

(ii) the applicant has experienced an allergic reaction to the drug used as a treatment, or there is a risk that the applicant would experience cross-sensitivity to a drug of that class,

(iii) the applicant has experienced an adverse drug reaction to the drug used as a treatment, or there is a risk that the applicant would experience an adverse drug reaction based on a previous adverse drug reaction to a drug of the same class,

(iv) the drug used as a treatment has resulted in an undesirable interaction with another medication being used by the applicant, or there is a risk that this would occur,

(v) the drug used as a treatment is contra-indicated, or

(vi) the drug under consideration as a treatment has a similar chemical structure and pharmacological activity to a drug that has been ineffective for the applicant;

(*c*) the recommended use of marihuana would mitigate the symptom;

(2) La déclaration est datée et signée par le demandeur et atteste que les renseignements qui y sont fournis sont exacts et complets.

Déclarations médicales

6. (1) La déclaration médicale visée à l'alinéa 4(2)*b*) mentionne dans tous les cas :

a) le nom du médecin ou du spécialiste, les adresse et numéro de téléphone de son lieu de travail, son numéro de licence provinciale de pratique de la médecine, et, le cas échéant, son numéro de télécopieur et son adresse électronique;

b) l'état pathologique du demandeur, ainsi que le symptôme qui est associé à cet état ou à son traitement et sur lequel la demande d'autorisation est fondée, ainsi qu'une mention indiquant s'il s'agit d'un symptôme de catégorie 1, 2 ou 3;

c) la posologie journalière de marihuana séchée, en grammes, ainsi que la forme posologique et le mode d'administration recommandés pour le demandeur;

d) la période pour laquelle l'usage de la marihuana est recommandé, si cette période est inférieure à douze mois.

(2) Dans le cas d'un symptôme de catégorie 1, la déclaration médicale mentionne en outre :

a) que le demandeur souffre d'une maladie en phase terminale;

b) que tous les traitements conventionnels du symptôme ont été administrés au demandeur ou, à tout le moins, envisagés;

c) que l'usage recommandé de la marihuana aurait pour effet d'atténuer le symptôme;

d) que les avantages que le demandeur retirerait de l'usage recommandé de la marihuana l'emportent sur les risques;

e) que le médecin sait qu'aucun avis de conformité n'a été délivré en vertu du *Règlement sur les aliments et drogues* quant à l'innocuité ou l'efficacité de la marihuana comme drogue.

(3) Dans le cas d'un symptôme de catégorie 2, la déclaration médicale mentionne en outre :

a) que le spécialiste pratique la médecine dans un domaine – qui doit être précisé dans la déclaration – pertinent au regard de l'état pathologique du demandeur;

b) que tous les traitements conventionnels du symptôme ont été administrés au demandeur ou à tout le moins envisagés, mais que chacun d'eux est médicalement inapproprié pour l'une ou l'autre des raisons suivantes :

(i) le traitement s'est révélé inefficace,

(ii) le demandeur a eu une réaction allergique à la drogue administrée comme traitement ou il existe, pour lui, un risque de sensibilisation croisée à une drogue de même type,

(iii) le demandeur a eu une réaction indésirable à la drogue administrée comme traitement ou il existe, pour lui, un risque de réaction indésirable à la drogue du fait de réactions antérieures similaires observées chez lui lors de l'administration d'une drogue de même type,

(iv) la drogue administrée comme traitement a provoqué, chez le demandeur, une interaction médicamenteuse néfaste ou il existe, pour lui, un risque d'une telle interaction,

(v) la drogue administrée comme traitement est contre-indiquée,

(vi) la drogue envisagée comme traitement possède une structure chimique et une activité pharmacologique similaires à celles d'une autre drogue qui s'est révélée inefficace pour le demandeur;

(*d*) the benefits from the applicant's recommended use of marihuana would outweigh any risks associated with that use, including risks associated with the long-term use of marihuana; and

(*e*) the specialist is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug.

(4) In the case of a category 3 symptom, the medical declaration must also indicate

(*a*) the matters referred to in subsection (3); and

(*b*) all conventional treatments that have been tried or considered for the symptom and the reasons, from among those mentioned in paragraph (3)(*b*), why the specialist considers that those treatments are medically inappropriate.

7. In the case of a category 3 symptom, the second medical declaration under paragraph 4(2)(*c*) must indicate

(*a*) the specialist's name, business address and telephone number, provincial medical licence number and, if applicable, facsimile transmission number and e-mail address;

(*b*) that the specialist practices in an area of medicine, to be named by the specialist in the declaration, that is relevant to the treatment of the applicant's medical condition;

(*c*) that the specialist is aware that the application is in relation to the mitigation of the symptom identified under paragraph 6(1)(*b*) and that the symptom is associated with the medical condition identified under that paragraph or its treatment;

(*d*) that the specialist has reviewed the applicant's medical file and the information provided under paragraph 6(4)(*b*) and has discussed the applicant's case with the specialist providing that information and agrees with the statements referred to in paragraphs 6(3)(*c*) and (*d*); and

(*e*) that the specialist is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug.

8. A medical declaration under section 6 or 7 must be dated and signed by the medical practitioner or specialist making it and must attest that the information contained in the declaration is correct and complete.

Dosage In Excess of 5 Grams

9. If the daily dosage recommended under paragraph 6(1)(*c*) is more than five grams, the medical practitioner or specialist providing the medical declaration under paragraph 4(2)(*b*) must also indicate that

(*a*) the risks associated with an elevated daily dosage of marihuana have been considered, including risks with respect to the effect on the applicant's cardio-vascular, pulmonary and immune systems and psychomotor performance, as well as potential drug dependency; and

(*b*) the benefits from the applicant's use of marihuana according to the recommended daily dosage would outweigh the risks associated with that dosage, including risks associated with the long-term use of marihuana.

c) que l'usage recommandé de la marihuana atténuerait le symptôme;

d) que les avantages que le demandeur retirerait de l'usage recommandé de la marihuana l'emportent sur les risques, y compris ceux associés à l'usage à long terme de la marihuana;

e) que le spécialiste sait qu'aucun avis de conformité n'a été délivré en vertu du *Règlement sur les aliments et drogues* quant à l'innocuité ou l'efficacité de la marihuana comme drogue.

(4) Dans le cas d'un symptôme de catégorie 3, la déclaration médicale mentionne en outre :

a) les renseignements visés au paragraphe (3);

b) tous les traitements conventionnels du symptôme qui ont été administrés au demandeur ou envisagés ainsi que celles des raisons, mentionnées à l'alinéa (3)*b*), pour lesquelles le spécialiste considère ces traitements comme médicalement inappropriés.

7. Dans le cas d'un symptôme de catégorie 3, la seconde déclaration médicale visée à l'alinéa 4(2)*c*) comporte les renseignements suivants :

a) le nom du spécialiste, les adresse et numéro de téléphone de son lieu de travail, son numéro de licence provinciale de pratique de la médecine, et, le cas échéant, son numéro de télécopieur et son adresse électronique;

b) la mention que le spécialiste pratique la médecine dans un domaine – qui doit être précisé dans la déclaration – pertinent au regard de l'état pathologique du demandeur;

c) la mention qu'il sait que la demande vise à atténuer, chez le demandeur, le symptôme visé à l'alinéa 6(1)*b*) et que le symptôme est associé à l'état pathologique visé à cet alinéa ou à son traitement;

d) la mention qu'il a examiné le dossier médical du demandeur ainsi que les renseignements visés à l'alinéa 6(4)*b*), en a discuté avec le spécialiste qui les a fournis et est d'accord avec les affirmations visées aux alinéas 6(3)*c*) et *d*);

e) la mention qu'il sait qu'aucun avis de conformité n'a été délivré en vertu du *Règlement sur les aliments et drogues* quant à l'innocuité ou l'efficacité de la marihuana comme drogue.

8. Toute déclaration médicale visée aux articles 6 ou 7 est datée et signée par le médecin ou le spécialiste qui la produit et atteste que les renseignements qui y sont fournis sont exacts et complets.

Posologie en excès de cinq grammes

9. Lorsque la posologie journalière recommandée visée à l'alinéa 6(1)*c*) est supérieure à cinq grammes, le médecin ou le spécialiste qui produit la déclaration médicale visée à l'alinéa 4(2)*b*) mentionne en outre dans celle-ci :

a) qu'une évaluation a été faite des risques que présenterait l'administration de cette posologie élevée pour les systèmes cardiovasculaire, pulmonaire et immunitaire du demandeur et quant à la dépendance et aux aptitudes psychomotrices de celui-ci;

b) que les avantages que le demandeur retirerait de l'usage de la marihuana, selon la posologie recommandée, l'emportent sur les risques que présenterait l'administration de cette posologie, y compris ceux associés à son usage à long terme.

Photograph

10. The photograph required under paragraph 4(2)(*d*) must clearly identify the applicant and must

(*a*) show a full front-view of the applicant's head and shoulders against a plain contrasting background;

(*b*) have dimensions of at least 43 mm x 54 mm (1 11/16 inches x 2 1/8 inches) and not more than 50 mm x 70 mm (2 inches x 2 3/4 inches), and has a view of the applicant's head that is at least 30 mm (1.375 inches) in length;

(*c*) show the applicant's face unobscured by sunglasses or any other object; and

(*d*) be certified, on the reverse side, by a medical practitioner treating the applicant, to be an accurate representation of the applicant.

Issuance of Authorization to Possess

11. (1) Subject to section 12, if the requirements of sections 4 to 10 are met, the Minister shall issue to the applicant an authorization to possess for the medical purpose mentioned in the application, and shall provide notice of the authorization to the medical practitioner or specialist who made the medical declaration under paragraph 4(2)(*b*).

(2) The authorization shall indicate

(*a*) the name, date of birth and gender of the holder of the authorization;

(*b*) the full address of the place where the holder ordinarily resides;

(*c*) the authorization number;

(*d*) the name and category of the symptom;

(*e*) the medical condition, or its treatment, with which the symptom is associated;

(*f*) the maximum quantity of dried marihuana, in grams, that the holder may possess at any time;

(*g*) the date of issue; and

(*h*) the date of expiry.

(3) The maximum quantity of dried marihuana referred to in paragraph (2)(*f*) or resulting from an amendment under subsection 20(1) or 22(3) is the amount determined according to the following formula:

A x 30

where A is the daily dosage of dried marihuana, in grams, recommended for the holder under paragraph 6(1)(*c*), 19(1)(*c*) or 22(2)(*b*), whichever applies.

Grounds for Refusal

12. (1) The Minister shall refuse to issue an authorization to possess if

(*a*) the applicant is not eligible under section 3;

(*b*) any information, statement or other item included in the application is false or misleading;

(*c*) the application involves a category 3 symptom and either all conventional treatments have not been tried or considered or they are considered to be medically inappropriate for any reason not mentioned in paragraph 6(3)(*b*); or

(*d*) the person mentioned in the authorization application as a licensed dealer under the *Narcotic Control Regulations* does

Photographie

10. La photographie exigée à l'alinéa 4(2)*d*) doit permettre d'identifier le demandeur de façon précise et doit respecter les exigences suivantes :

a) elle montre sa tête et ses épaules, vues de face, sur un fond contrastant uni;

b) sa tête occupe un espace d'au moins 30 mm (1,375 po) de long sur la photographie, dont les dimensions minimales sont de 43 mm x 54 mm (1 11/16 po x 2 1/8 po) et les dimensions maximales, de 50 mm x 70 mm (2 po x 2 3/4 po);

c) son visage n'est pas caché par des lunettes de soleil ou d'autres objets;

d) elle comporte au verso une déclaration signée par un médecin qui traite le demandeur et attestant que la photographie représente bien le demandeur.

Délivrance de l'autorisation

11. (1) Sous réserve de l'article 12, le ministre délivre au demandeur l'autorisation de possession aux fins médicales précisées dans la demande si les exigences des articles 4 à 10 sont remplies; il en avise le médecin ou le spécialiste qui a produit la déclaration médicale visée à l'alinéa 4(2)*b*).

(2) L'autorisation comporte les renseignements suivants :

a) les nom, date de naissance et sexe du titulaire de l'autorisation;

b) l'adresse complète de son lieu de résidence habituelle;

c) le numéro de l'autorisation;

d) les nom et catégorie du symptôme;

e) l'état pathologique auquel est associé le symptôme, ou le traitement de cet état;

f) la quantité maximale de marihuana séchée, en grammes, que peut posséder à la fois le titulaire de l'autorisation;

g) la date de délivrance;

h) la date d'expiration.

(3) La quantité maximale de marihuana séchée visée à l'alinéa (2)*f*) ou résultant d'une modification aux termes des paragraphes 20(1) ou 22(3) se calcule selon la formule suivante :

A x 30

où A représente la posologie journalière de marihuana séchée, en grammes, qui est recommandée aux termes des alinéas 6(1)*c*), 19(1)*c*) ou 22(2)*b*), selon le cas.

Motifs de refus

12. (1) Le ministre refuse de délivrer l'autorisation de possession dans les cas suivants :

a) le demandeur n'est pas admissible selon l'article 3;

b) la demande comporte des renseignements, déclarations ou autres éléments faux ou trompeurs;

c) la demande vise un symptôme de catégorie 3 à l'égard duquel les traitements conventionnels n'ont pas tous été administrés ou envisagés ou sont jugés médicalement inappropriés pour des raisons autres que celles visées à l'alinéa 6(3)*b*);

d) la personne mentionnée dans la demande comme distributeur autorisé en vertu du *Règlement sur les stupéfiants* ne

not have a valid licence to distribute marihuana under those Regulations.

(2) If the Minister proposes to refuse to issue an authorization to possess, the Minister shall

(*a*) notify the applicant in writing of the reason for the proposed refusal; and

(*b*) give the applicant an opportunity to be heard.

Expiry of Authorization

13. An authorization to possess expires 12 months after its date of issue or, if a shorter period is specified in the application for the authorization under paragraph 6(1)(*d*), at the end of that period.

Renewal of Authorization to Possess

14. (1) An application to renew an authorization to possess shall be made to the Minister by the holder of the authorization and must include

(*a*) the authorization number; and

(*b*) the material required under sections 4 to 10, excluding, in the case of a category 3 symptom, the second medical declaration mentioned in paragraph 4(2)(*c*).

(2) For the purpose of paragraph (1)(*b*), a photograph referred to in paragraph 4(2)(*d*) is required only with every second renewal application.

15. If an authorization to possess for a category 1 symptom has expired and, within 12 months after the expiry, a new application with respect to the category 1 symptom is made by the person who was the holder of the expired authorization, the new application is considered to be an application to renew the expired authorization.

16. An authorization to possess for a category 1 symptom may be renewed only once for that symptom; however, an application for an authorization to possess may be made for that symptom as a category 2 or 3 symptom, whichever applies.

17. Subject to section 18, if an application complies with section 14, the Minister shall renew the authorization to possess for the medical purpose mentioned in the application.

18. The Minister shall refuse to renew an authorization to possess

(*a*) for any reason referred to in section 12; or

(*b*) in the case of an authorization to possess for a category 1 symptom, if the authorization has already been renewed for that symptom.

Amendment of Authorization to Possess

19. (1) An application to amend an authorization to possess shall be made to the Minister by the holder of the authorization when a change occurs with respect to

(*a*) the symptom mentioned in the authorization;

(*b*) the medical condition, or its treatment, with which the symptom is associated; or

(*c*) the recommended daily dosage of dried marihuana, if the new dosage is in excess of five grams.

détient pas de licence valide pour distribuer de la marihuana en vertu de ce règlement.

(2) Lorsqu'il envisage de refuser de délivrer l'autorisation de possession, le ministre :

a) en avise le demandeur par écrit, motifs à l'appui;

b) lui donne la possibilité de se faire entendre.

Expiration de l'autorisation

13. L'autorisation de possession expire douze mois après la date de sa délivrance ou à la fin de toute période plus courte qui est indiquée dans la demande d'autorisation aux termes de l'alinéa 6(1)*d*).

Renouvellement de l'autorisation

14. (1) La demande de renouvellement d'une autorisation de possession est présentée au ministre par le titulaire de l'autorisation et comporte les éléments suivants :

a) le numéro de l'autorisation visée;

b) les éléments exigés aux articles 4 à 10, à l'exception, dans le cas d'un symptôme de catégorie 3, de la déclaration médicale visée à l'alinéa 4(2)*c*).

(2) Pour l'application de l'alinéa (1)*b*), il n'est nécessaire de fournir la photographie visée à l'alinéa 4(2)*d*) qu'à toutes les deux demandes de renouvellement.

15. Toute nouvelle demande d'autorisation de possession présentée à l'égard d'un symptôme de catégorie 1 par la personne dont l'autorisation à ce titre a expiré dans les douze mois précédant la demande est réputée être une demande de renouvellement.

16. Dans le cas d'un symptôme de catégorie 1, l'autorisation de possession ne peut être renouvelée qu'une seule fois à ce titre. Toutefois, une demande d'autorisation peut être présentée pour le symptôme sous une catégorie 2 ou 3, selon le cas.

17. Sous réserve de l'article 18, le ministre renouvelle l'autorisation de possession aux fins médicales précisées dans la demande si celle-ci est conforme aux exigences de l'article 14.

18. Le ministre refuse de renouveler l'autorisation de possession :

a) dans les cas visés à l'article 12;

b) dans le cas où la demande de renouvellement vise un symptôme de catégorie 1 à l'égard duquel l'autorisation a déjà été renouvelée à ce titre.

Modification de l'autorisation

19. (1) L'autorisation de possession fait l'objet d'une demande de modification présentée au ministre par le titulaire de l'autorisation lorsqu'un changement survient à l'égard des éléments suivants :

a) le symptôme visé par l'autorisation;

b) l'état pathologique auquel est associé le symptôme, ou son traitement;

c) la posologie journalière recommandée de marihuana séchée, si la nouvelle posologie excède cinq grammes.

(2) The application must include

(*a*) the authorization number;

(*b*) the requested amendment and supporting reasons; and

(*c*) the material required under sections 4 to 10.

20. (1) Subject to section 21, if an application complies with section 19, the Minister shall allow the amendment.

(2) If the authorization to possess is amended under subsection (1) with respect to the recommended dosage of dried marihuana, the Minister shall, if applicable, amend the licence to produce that was issued on the basis of the authorization to reflect the change in the maximum number of marihuana plants that the holder may produce and the maximum quantity of dried marihuana that the holder may keep.

21. The Minister shall refuse to amend an authorization to possess for any reason referred to in section 12.

Notice of Change of Information

22. (1) The holder of an authorization to possess shall, within 10 days after the occurrence, notify the Minister in writing of a change in

(*a*) the holder's name;

(*b*) the holder's address of ordinary residence and mailing address, if different; or

(*c*) the daily dosage of dried marihuana recommended under paragraph 6(1)(*c*), if the new dosage is not in excess of five grams.

(2) The notice of change must be accompanied

(*a*) in the case of a change under paragraph (1)(*a*), by proof of the change;

(*b*) in the case of a change under paragraph (1)(*c*), by a statement, dated and signed by the medical practitioner or specialist of the holder of the authorization, certifying the new daily dosage recommended for the holder; and

(*c*) if a designated-person production licence has been issued on the basis of the authorization, by a statement indicating the name of the designated person who is the holder of the licence.

(3) On receiving a notice that complies with subsection (2), the Minister shall amend the authorization to reflect the change stated in the notice.

(4) If the authorization to possess is amended under subsection (3) with respect to the name or address of the holder of the authorization, the Minister shall, if applicable, amend accordingly the licence to produce that was issued on the basis of the authorization.

(5) If the authorization to possess is amended under subsection (3) with respect to the recommended dosage of dried marihuana, the Minister shall, if applicable, amend the licence to produce that was issued on the basis of the authorization to reflect the change in the maximum number of marihuana plants that the holder may produce and the maximum quantity of dried marihuana that the holder may keep.

(2) La demande de modification comporte les éléments suivants :

a) le numéro de l'autorisation visée;

b) la modification demandée, motifs à l'appui;

c) les éléments exigés aux articles 4 à 10.

20. (1) Sous réserve de l'article 21, le ministre autorise la modification si la demande est conforme aux exigences de l'article 19.

(2) Lorsque, en application du paragraphe (1), l'autorisation est modifiée quant à la posologie recommandée, le ministre modifie la licence de production délivrée, le cas échéant, sur le fondement de cette autorisation quant au nombre maximum de plants de marihuana que peut produire le titulaire de la licence et à la quantité maximale de marihuana séchée que celui-ci peut garder.

21. Le ministre refuse de modifier l'autorisation de possession dans les cas visés à l'article 12.

Avis de modification des renseignements

22. (1) Le titulaire d'une autorisation de possession avise par écrit le ministre des changements suivants dans les dix jours de leur survenance :

a) toute modification à son nom;

b) tout changement de l'adresse de son lieu de résidence habituelle ainsi que de son adresse postale, si elle diffère de la première;

c) tout changement à la posologie journalière de marihuana séchée recommandée aux termes de l'alinéa 6(1)*c*), dans le cas où la nouvelle posologie n'excède pas cinq grammes.

(2) Le titulaire de l'autorisation joint à l'avis :

a) dans le cas d'un changement visé à l'alinéa (1)*a*), la preuve de ce changement;

b) dans le cas d'un changement visé à l'alinéa (1)*c*), une déclaration, datée et signée par le médecin ou le spécialiste du titulaire de l'autorisation, attestant la nouvelle posologie recommandée;

c) lorsqu'une licence de production à titre de personne désignée a été délivrée sur le fondement de l'autorisation, une mention indiquant le nom de la personne désignée qui est titulaire de la licence.

(3) Sur réception de l'avis conforme au paragraphe (2), le ministre apporte la modification appropriée à l'autorisation.

(4) Lorsque, en application du paragraphe (3), l'autorisation est modifiée quant au nom ou à l'adresse de son titulaire, le ministre modifie en conséquence la licence de production délivrée, le cas échéant, sur le fondement de cette autorisation.

(5) Lorsque, en application du paragraphe (3), l'autorisation est modifiée quant à la posologie recommandée, le ministre modifie la licence de production délivrée, le cas échéant, sur le fondement de cette autorisation quant au nombre maximum de plants de marihuana que peut produire le titulaire de la licence et à la quantité maximale de marihuana séchée que celui-ci peut garder.

Providing Assistance to Holder

23. While in the presence of the holder of an authorization to possess and providing assistance in the administration of the daily dosage of marihuana to the holder, the person providing the assistance may, for the purpose of providing the assistance, possess a quantity of dried marihuana not exceeding the recommended daily dosage for the holder.

Aide à un titulaire de l'autorisation

23. La personne qui aide le titulaire d'une autorisation de possession à prendre de la marihuana séchée peut, en sa présence, pendant qu'elle lui apporte son aide, avoir en sa possession, à cette fin, une quantité de marihuana qui n'excède pas la posologie journalière recommandée pour le titulaire.

PART 2

LICENCE TO PRODUCE

Personal-use Production Licence

Authorized Activities

24. The holder of a personal-use production licence is authorized to produce and keep marihuana, in accordance with the licence, for the medical purpose of the holder.

Eligibility for Licence

25. Subject to subsection (2), a person is eligible to be issued a personal-use production licence only if the person is an individual ordinarily resident in Canada who has reached 18 years of age.

(2) If a personal-use production licence is revoked under paragraph 63(2)(*b*), the person who was the holder of the licence is ineligible to be issued another personal-use production licence during the period of 10 years after the revocation.

Priority of Application for Authorization

26. (1) An application for a personal-use production licence shall be considered only if it is made by a person who

(*a*) is the holder of an authorization to possess on the basis of which the licence is applied for; or

(*b*) is not the holder of an authorization to possess but either has applied for an authorization to possess, or is applying for an authorization to possess concurrently with the licence application.

(2) If paragraph (1)(*b*) applies, the Minister must grant or refuse the application for an authorization before considering the licence application.

Application for Licence

27. (1) A person mentioned in subsection 26(1) who is seeking a personal-use production licence shall submit an application to the Minister.

(2) The application must include

(*a*) a declaration of the applicant; and

(*b*) if the proposed production site is not the ordinary place of residence of the applicant and is not owned by the applicant, a declaration made by the owner of the site consenting to the production of marihuana at the site.

(3) The application may not be made jointly with another person.

Applicant's Declaration

28. (1) The declaration of the applicant under paragraph 27(2)(*a*) must indicate

PARTIE 2

LICENCE DE PRODUCTION

Licence de production à des fins personnelles

Opérations autorisées

24. Le titulaire d'une licence de production à des fins personnelles est autorisé à produire et garder, conformément à la licence, de la marihuana à ses propres fins médicales.

Admissibilité à la licence

25. (1) Sous réserve du paragraphe (2), est admissible à la licence de production à des fins personnelles la personne physique qui réside habituellement au Canada et qui a atteint l'âge de dix-huit ans.

(2) Toute personne dont la licence de production à des fins personnelles est révoquée aux termes de l'alinéa 63(2)*b*) est inadmissible, pour une période de dix ans suivant la révocation, à une nouvelle licence de production à des fins personnelles.

Priorité de la demande d'autorisation

26. (1) La demande de licence de production à des fins personnelles n'est examinée que si elle est présentée par une personne :

a) soit qui est titulaire d'une autorisation de possession sur le fondement de laquelle la licence est demandée;

b) soit qui n'est pas titulaire d'une autorisation de possession mais qui a présenté une demande d'autorisation, ou la présente en même temps que la demande de licence.

(2) En cas d'application de l'alinéa (1)*b*), le ministre statue sur la demande d'autorisation de possession avant d'examiner la demande de licence.

Demande de licence

27. (1) La personne visée au paragraphe 26(1) qui souhaite obtenir une licence de production à des fins personnelles présente au ministre une demande à cet effet.

(2) La demande comporte les documents suivants :

a) une déclaration du demandeur;

b) dans le cas où le lieu de production proposé n'est pas le lieu de résidence habituelle du demandeur ni la propriété de celui-ci, une déclaration, datée et signée par le propriétaire du lieu, portant qu'il consent à la production de marihuana dans ce lieu.

(3) La demande de licence ne peut être présentée conjointement avec une autre personne.

Déclaration du demandeur

28. (1) La déclaration du demandeur visée au paragraphe 27(2)*a*) comporte les renseignements suivants :

(*a*) the applicant's name, date of birth and gender;

(*b*) the full address of the place where the applicant ordinarily resides as well as the applicant's telephone number and, if applicable, facsimile transmission number and e-mail address;

(*c*) the mailing address of the place referred to in paragraph (*b*), if different;

(*d*) if the applicant is the holder of an authorization to possess, the number of the authorization;

(*e*) the full address of the site where the proposed production of marihuana is to be conducted;

(*f*) the proposed production area;

(*g*) if the proposed production area involves outdoor production entirely or partly indoor and partly outdoor production, that the production site is not adjacent to a school, public playground, day care facility or other public place frequented mainly by persons under 18 years of age;

(*h*) that the dried marihuana will be kept indoors and indicating whether it is proposed to keep it at

(i) the proposed production site, or

(ii) the ordinary place of residence of the applicant, if different; and

(*i*) a description of the security measures that will be implemented at the proposed production site and the proposed site where dried marihuana will be kept.

(2) The declaration must be dated and signed by the applicant and attest that the information contained in it is correct and complete.

Issuance of Licence

29. (1) Subject to section 32, if the requirements of sections 27 and 28 are met, the Minister shall issue a personal-use production licence to the applicant.

(2) The licence shall indicate

(*a*) the name, date of birth and gender of the holder of the licence;

(*b*) the full address of the place where the holder ordinarily resides;

(*c*) the licence number;

(*d*) the full address of the site where the production of marihuana is authorized;

(*e*) the authorized production area;

(*f*) the maximum number of marihuana plants that may be under production at the production site at any time;

(*g*) the full address of the site where the dried marihuana may be kept;

(*h*) the maximum quantity of dried marihuana, in grams, that may be kept at the site referred to in paragraph (*g*) at any time;

(*i*) the date of issue; and

(*j*) the date of expiry.

Maximum Number of Plants

30. (1) In the formulas in subsection (2),

(*a*) "A" is the daily dosage of dried marihuana, in grams, recommended for the applicant under paragraph 6(1)(*c*), 19(1)(*c*) or 22(2)(*b*), whichever applies;

a) les nom, date de naissance et sexe du demandeur;

b) l'adresse complète de son lieu de résidence habituelle, ainsi que son numéro de téléphone et, le cas échéant, son numéro de télécopieur et son adresse électronique;

c) l'adresse postale de son lieu de résidence habituelle, si elle diffère de l'adresse mentionnée à l'alinéa *b*);

d) dans le cas où le demandeur est titulaire d'une autorisation de possession, le numéro de cette autorisation;

e) l'adresse complète du lieu proposé pour la production de marihuana;

f) une mention indiquant l'aire de production proposée;

g) dans le cas où l'aire de production proposée est soit entièrement à l'extérieur, soit en partie à l'intérieur et en partie à l'extérieur, une mention indiquant que le lieu de production n'est pas adjacent à une école, un terrain de jeu public, une garderie ou tout autre lieu public principalement fréquenté par des personnes de moins de dix-huit ans;

h) une mention selon laquelle la marihuana séchée sera gardée à l'intérieur et indiquant dans lequel des lieux suivants il est proposé de la garder :

(i) le lieu de production proposé,

(ii) le lieu de résidence habituelle du demandeur, si ce lieu diffère du lieu de production;

i) la description des mesures de sécurité qui seront prises dans le lieu de production proposé et dans le lieu proposé pour garder la marihuana séchée.

(2) La déclaration est datée et signée par le demandeur et atteste que les renseignements qui y sont fournis sont exacts et complets.

Délivrance de la licence

29. (1) Sous réserve de l'article 32, le ministre délivre une licence de production à des fins personnelles au demandeur si les exigences visées aux articles 27 et 28 sont remplies.

(2) La licence comporte les renseignements suivants :

a) les nom, date de naissance et sexe du titulaire de la licence;

b) l'adresse complète de son lieu de résidence habituelle;

c) le numéro de la licence;

d) l'adresse complète du lieu où la production de marihuana est autorisée;

e) l'aire de production autorisée;

f) le nombre maximum de plants de marihuana qui peuvent être produits à la fois dans le lieu de production;

g) l'adresse complète du lieu où peut être gardée la marihuana séchée;

h) la quantité maximale de marihuana séchée, en grammes, qui peut être gardée à la fois dans le lieu autorisé aux termes de l'alinéa *g*);

i) la date de délivrance;

j) la date d'expiration.

Nombre de plants en production

30. (1) Dans les formules figurant au paragraphe (2) :

a) « A » représente la posologie journalière de marihuana séchée, en grammes, recommandée pour le demandeur aux termes des alinéas 6(1)*c*), 19(1)*c*) ou 22(2)*b*), selon le cas;

(*b*) "C" is a constant equal to 1, representing the growth cycle of a marihuana plant from seeding to harvesting; and

(*c*) "D" is the maximum number of marihuana plants referred to in subsections 20(2) and 22(5) and paragraphs 29(2)(*f*) and 40(2)(*g*).

(2) The maximum number of marihuana plants referred to in paragraph (1)(*c*) is determined according to whichever of the following formulas applies:

(*a*) if the production area is entirely indoors,

$$D = [(A \times 365) \div (B \times 3C)] \times 1.2$$

where B is 30 grams, being the expected yield of dried marihuana per plant,

(*b*) if the production area is entirely outdoors,

$$D = [(A \times 365) \div (B \times C)] \times 1.3$$

where B is 250 grams, being the expected yield of dried marihuana per plant; and

(*c*) if the production area is partly indoors and partly outdoors,

(i) for the indoor period

$$D = [(A \times 182.5) \div (B \times 2C)] \times 1.2$$

where B is 30 grams, being the expected yield of dried marihuana per plant, and

(ii) for the outdoor period

$$D = [(A \times 182.5) \div (B \times C)] \times 1.3$$

where B is 250 grams, being the expected yield of dried marihuana per plant.

(3) If paragraph (2)(*c*) applies, the maximum number of marihuana plants for both periods of production shall be mentioned in the licence to produce.

(4) If the number determined for D is not a whole number, it shall be rounded to the next-highest whole number.

Maximum Quantity of Dried Marihuana in Storage

31. (1) In the formula in this subsection (2),

(*a*) "D" is,

(i) if the production area is entirely indoors or outdoors, the maximum number of marihuana plants that the holder of the licence to produce is authorized to produce, calculated under paragraphs 30(2)(*a*) or (*b*), whichever applies,

(ii) if the production area is partly indoors and partly outdoors, the maximum number of marihuana plants that the holder of the licence to produce is authorized to produce, calculated under subparagraph 30(2)(*c*)(ii); and

(*b*) "E" is the maximum quantity of dried marihuana mentioned in paragraphs 20(2) and 22(5) and in paragraphs 29(2)(*h*) and 40(2)(*i*).

(2) The maximum quantity of dried marihuana referred to in paragraph (1)(*b*) is determined according to whichever of the following formulas applies:

b) « C » représente une constante de un, correspondant au cycle de croissance d'un plant de marihuana depuis l'ensemencement jusqu'à la récolte;

c) « D » représente le nombre maximum de plants de marihuana visé aux paragraphes 20(2) et 22(5) et aux alinéas 29(2)*f*) et 40(2)*g*).

(2) Le nombre maximum de plants de marihuana visé à l'alinéa (1)*c*) se calcule selon les formules suivantes :

a) dans le cas où l'aire de production est entièrement à l'intérieur :

$$D = [(A \times 365) \div (B \times 3C)] \times 1,2$$

où B représente le rendement prévu de marihuana séchée par plant, soit 30 grammes;

b) dans le cas où l'aire de production est entièrement à l'extérieur :

$$D = [(A \times 365) \div (B \times C)] \times 1,3$$

où B représente le rendement prévu de marihuana séchée par plant, soit 250 grammes;

c) dans le cas où l'aire de production est en partie à l'intérieur et en partie à l'extérieur :

(i) pour la période de production intérieure :

$$D = [(A \times 182,5) \div (B \times 2C)] \times 1,2$$

où B représente le rendement prévu de marihuana séchée par plant, soit 30 grammes;

(ii) pour la période de production extérieure :

$$D = [(A \times 182,5) \div (B \times C)] \times 1,3$$

où B représente le rendement prévu de marihuana séchée par plant, soit 250 grammes;

(3) Dans le cas visé à l'alinéa (2)*c*), le nombre maximum de plants de marihuana est indiqué, sur la licence de production, pour chacune des périodes de production intérieure et extérieure.

(4) Dans le cas où le résultat du calcul visé au présent article n'est pas un nombre entier, il est arrondi au nombre entier supérieur.

Quantité de marihuana séchée entreposée

31. (1) Dans les formules figurant au paragraphe (2) :

a) « D » représente :

(i) dans le cas où l'aire de production est soit entièrement à l'intérieur, soit entièrement à l'extérieur, le nombre maximum de plants de marihuana, visé aux alinéas 30(2)*a*) ou *b*), selon le cas, que le titulaire de la licence est autorisé à produire,

(ii) dans le cas où l'aire de production est en partie à l'intérieur et en partie à l'extérieur, le nombre maximum de plants de marihuana, visé au sous-alinéa 30(2)*c*)(ii), que le titulaire de la licence est autorisé à produire.

b) « E » représente la quantité maximale de marihuana séchée visée aux paragraphes 20(2) et 22(5) et aux alinéas 29(2)*h*) et 40(2)*i*).

(2) La quantité maximale de marihuana séchée visée à l'alinéa (1)*b*) se calcule selon les formules suivantes :

a) dans le cas où l'aire de production est entièrement à l'intérieur :

(*a*) if the production area is entirely indoors,

E = D x B x 1.5

where B is 30 grams, being the expected yield of dried marihuana per plant,

(*b*) if the production area is entirely outdoors,

E = D x B x 1.5

where B is 250 grams, being the expected yield of dried marihuana per plant, and

(*c*) if the production area is partly indoors and partly outdoors,

E = D x B x 1.5

where B is 250 grams, being the expected yield of dried marihuana per plant.

Grounds for Refusal

32. The Minister shall refuse to issue a personal-use production licence if

(*a*) the applicant is not a holder of an authorization to possess;

(*b*) the applicant is not eligible under section 25;

(*c*) any information or statement included in the application is false or misleading;

(*d*) the proposed production site would be a site for the production of marihuana under more than three licences to produce; or

(*e*) the applicant would be the holder of more than one licence to produce.

Expiry of Licence

33. A personal-use production licence expires on the earlier of

(*a*) 12 months after its date of issue, and

(*b*) the date of expiry of the authorization to possess held by the licence holder.

Designated-person Production Licence

Authorized Activities

34. (1) The holder of a designated-person production licence is authorized, in accordance with the licence,

(*a*) to produce marihuana for the medical purpose of the person who applied for the licence;

(*b*) to possess and keep, for the purpose mentioned in paragraph (*a*), a quantity of dried marihuana not exceeding the maximum quantity specified in the licence;

(*c*) if the production site specified in the licence is different from the site where dried marihuana may be kept, to transport directly from the first to the second site a quantity of marihuana not exceeding the maximum quantity that may be kept under the licence;

(*d*) if the site specified in the licence where dried marihuana may be kept is different from the place where the person who applied for the licence ordinarily resides, to transport directly from that site to the place of residence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued; and

E = D x B x 1,5

où B représente le rendement prévu de marihuana séchée par plant, soit 30 grammes;

b) dans le cas où l'aire de production est entièrement à l'extérieur :

E = D x B x 1,5

où B représente le rendement prévu de marihuana séchée par plant, soit 250 grammes;

c) dans le cas où l'aire de production est en partie à l'intérieur et en partie à l'extérieur :

E = D x B x 1,5

où B représente le rendement prévu de marihuana séchée par plant, soit 250 grammes;

Motifs de refus

32. Le ministre refuse de délivrer la licence de production à des fins personnelles dans les cas suivants :

a) le demandeur n'est pas titulaire d'une autorisation de possession;

b) le demandeur n'est pas admissible selon l'article 25;

c) la demande comporte des déclarations ou renseignements faux ou trompeurs;

d) le lieu proposé pour la production de marihuana serait visé par plus de trois licences de production si la licence était délivrée;

e) le demandeur deviendrait titulaire de plus d'une licence de production si la licence était délivrée.

Expiration de la licence

33. La licence de production à des fins personnelles expire à la première des éventualités suivantes à survenir :

a) l'expiration d'une période de douze mois suivant la date de sa délivrance;

b) l'expiration de l'autorisation de possession du titulaire de la licence.

Licence de production à titre de personne désignée

Opérations autorisées

34. (1) Le titulaire d'une licence de production à titre de personne désignée est autorisé à mener, conformément à la licence, les opérations suivantes :

a) produire de la marihuana aux fins médicales du demandeur de la licence;

b) avoir en sa possession et garder, aux fins visées à l'alinéa *a*), une quantité de marihuana séchée ne dépassant pas la quantité maximale mentionnée dans la licence;

c) si le lieu de production mentionné dans la licence diffère du lieu où la marihuana séchée peut être gardée, transporter directement du premier lieu jusqu'au second une quantité de marihuana séchée ne dépassant pas la quantité maximale qui peut être gardée en vertu de la licence;

d) si le lieu – mentionné dans la licence – où la marihuana séchée peut être gardée diffère du lieu de résidence habituelle du demandeur de la licence, transporter directement du premier lieu jusqu'au second une quantité de marihuana séchée ne dépassant pas la quantité maximale mentionnée dans l'autorisation de possession sur le fondement de laquelle la licence a été délivrée;

(*e*) to transfer, give or deliver directly to the person who applied for the licence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued.

(2) No consideration may be obtained for any activity authorized under subsection (1).

Eligibility for Licence

35. A person is eligible to be issued a designated-person production licence only if the person is an individual ordinarily resident in Canada who

(*a*) has reached 18 years of age; and

(*b*) has not been found guilty, within the 10 years preceding the application, of

(i) a designated drug offence, or

(ii) an offence committed outside Canada that, if committed in Canada, would have constituted a designated drug offence.

Priority of Application for Authorization

36. (1) An application for a designated-person production licence shall be considered only if it is made by a person who

(*a*) is the holder of an authorization to possess on the basis of which the licence is applied for; or

(*b*) is not the holder of an authorization to possess, but either has applied for an authorization to possess or is applying for an authorization to possess concurrently with the licence application.

(2) If paragraph (1)(*b*) applies, the Minister must grant or refuse the application for an authorization before considering the licence application.

Application for Licence

37. (1) A person mentioned in subsection 36(1) who is seeking to have a designated-person production licence issued to a designated person shall submit an application to the Minister.

(2) The application must include

(*a*) a declaration by the applicant;

(*b*) a declaration by the designated person;

(*c*) if the proposed production site is not the ordinary place of residence of the applicant and is not owned by the applicant, a declaration made by the owner of the site consenting to the production of marihuana at the site;

(*d*) a document issued by a Canadian police force establishing that, in respect of the 10 years preceding the application, the designated person does not have a criminal record as an adult for a designated drug offence; and

(*e*) two copies of a current photograph of the designated person that complies with the standards in paragraphs 10(*a*) to (*c*) and is certified by the applicant, on the reverse side, to be an accurate representation of the designated person.

(3) The application may not be made jointly with another person.

e) transférer, donner ou livrer directement au demandeur de la licence une quantité de marihuana séchée ne dépassant pas la quantité maximale mentionnée dans l'autorisation de possession sur le fondement de laquelle la licence a été délivrée.

(2) Aucune contrepartie ne peut être obtenue pour les opérations autorisées par le paragraphe (1).

Admissibilité à la licence

35. Est admissible à la licence de production à titre de personne désignée la personne physique qui réside habituellement au Canada et qui :

a) a atteint l'âge de dix-huit ans;

b) n'a pas été reconnue coupable, au cours des dix années précédant la demande, d'une des infractions suivantes :

(i) une infraction désignée en matière de drogue,

(ii) une infraction commise à l'étranger qui, si elle avait été commise au Canada, aurait constitué une infraction désignée en matière de drogue.

Priorité de la demande d'autorisation

36. (1) La demande de licence de production à titre de personne désignée n'est examinée que si elle est présentée par une personne :

a) soit qui est titulaire d'une autorisation de possession sur le fondement de laquelle la licence est demandée;

b) soit qui n'est pas titulaire d'une autorisation de possession sur le fondement de laquelle la licence est demandée, mais qui a présenté une demande d'autorisation, ou la présente en même temps que la demande de licence.

(2) En cas d'application de l'alinéa (1)*b*), le ministre statue sur la demande d'autorisation de possession avant d'examiner la demande de licence.

Demande de licence

37. (1) La personne visée au paragraphe 36(1) qui souhaite qu'une licence de production à titre de personne désignée soit délivrée à une personne désignée présente une demande à cet effet au ministre.

(2) La demande comporte les éléments suivants :

a) une déclaration du demandeur;

b) une déclaration de la personne désignée;

c) dans le cas où le lieu de production proposé n'est pas le lieu de résidence habituelle du demandeur ou de la personne désignée ni la propriété de l'un d'eux, une déclaration, datée et signée par le propriétaire du lieu, portant qu'il consent à la production de marihuana dans ce lieu;

d) un document émanant d'un service de police canadien établissant que la personne désignée n'a pas de casier judiciaire, en tant qu'adulte, indiquant la perpétration, au cours des dix années précédant la demande, d'une infraction désignée en matière de drogue;

e) deux copies d'une photographie récente de la personne désignée satisfaisant aux exigences des alinéas 10*a*) à *c*), chacune comportant au verso une déclaration signée par le demandeur attestant que la photographie représente bien la personne désignée.

(3) La demande de licence ne peut être présentée conjointement avec une autre personne.

Applicant's Declaration

38. (1) The declaration of the applicant under paragraph 37(2)(*a*) must

(*a*) include the information referred to in paragraphs 28(1)(*a*) to (*d*);

(*b*) indicate the name, date of birth and gender of the designated person;

(*c*) indicate the full address of the place where the designated person ordinarily resides as well as the designated person's telephone number and, if applicable, facsimile transmission number and e-mail address; and

(*d*) indicate the mailing address of the place referred to in paragraph (*c*), if different.

(2) The declaration must be dated and signed by the applicant and attest that the information contained in the declaration is complete and correct.

Designated Person's Declaration

39. (1) The declaration of the designated person under paragraph 37(2)(*b*) must

(*a*) include the information referred to in paragraphs 28(1)(*e*) to (*g*) and (*i*);

(*b*) indicate that the dried marihuana will be kept indoors and whether it is proposed to keep it at:

(i) the proposed production site, or

(ii) the ordinary place of residence of the designated person, if the proposed production site is not the ordinary place of residence of the applicant; and

(*c*) indicate that, within the 10 years preceding the application, the designated person has not been convicted of

(i) a designated drug offence, or

(ii) an offence that, if committed in Canada, would have constituted a designated drug offence.

(2) The declaration must be dated and signed by the designated person and attest that the information contained in it is correct and complete.

Issuance of Licence

40. (1) Subject to section 41, if the requirements of sections 37 to 39 are met, the Minister shall issue a designated-person production licence to the designated person.

(2) The licence shall indicate

(*a*) the name, date of birth and gender of the holder of the licence;

(*b*) the name, date of birth and gender of the person for whom the holder of the licence is authorized to produce marihuana and the full address of that person's place of ordinary residence;

(*c*) the full address of the place where the holder of the licence ordinarily resides;

(*d*) the licence number;

(*e*) the full address of the site where the production of marihuana is authorized;

(*f*) the authorized production area;

Déclaration du demandeur

38. (1) La déclaration du demandeur visée à l'alinéa 37(2)*a*) comporte les renseignements suivants :

a) les renseignements visés aux alinéas 28(1)*a*) à *d*);

b) les nom, date de naissance et sexe de la personne désignée;

c) l'adresse complète du lieu de résidence habituelle de la personne désignée, ainsi que son numéro de téléphone et, le cas échéant, son numéro de télécopieur et son adresse électronique;

d) l'adresse postale du lieu de résidence habituelle de la personne désignée, si elle diffère de l'adresse mentionnée à l'alinéa *c*).

(2) La déclaration est datée et signée par le demandeur et atteste que les renseignements qui y sont fournis sont exacts et complets.

Déclaration de la personne désignée

39. (1) La déclaration de la personne désignée visée à l'alinéa 37(2)*b*) comprend les renseignements suivants :

a) les renseignements visés aux alinéas 28(1)*e*) à *g*) et *i*);

b) une mention selon laquelle la marihuana séchée sera gardée à l'intérieur et indiquant dans lequel des lieux suivants il est proposé de la garder :

(i) le lieu de production proposé,

(ii) le lieu de résidence habituelle de la personne désignée, dans le cas où le lieu de production proposé diffère du lieu de résidence habituelle du demandeur;

c) la mention que la personne désignée n'a pas de casier judiciaire, en tant qu'adulte, indiquant la perpétration, au cours des dix années précédant la demande, d'une des infractions suivantes :

(i) une infraction désignée en matière de drogue,

(ii) une infraction commise à l'étranger qui, si elle avait été commise au Canada, aurait constitué une infraction désignée en matière de drogue.

(2) La déclaration est datée et signée par la personne désignée et atteste que les renseignements qui y sont fournis sont exacts et complets.

Délivrance de la licence

40. (1) Sous réserve de l'article 41, le ministre délivre à la personne désignée une licence de production à titre de personne désignée si les exigences visées aux articles 37 à 39 sont remplies.

(2) La licence comporte les renseignements suivants :

a) les nom, date de naissance et sexe du titulaire de la licence;

b) les nom, date de naissance et sexe de la personne pour le compte de laquelle le titulaire de la licence est autorisé à produire de la marihuana, ainsi que l'adresse complète du lieu de résidence habituelle de cette personne;

c) l'adresse complète du lieu de résidence habituelle du titulaire de la licence;

d) le numéro de la licence;

e) l'adresse complète du lieu où la production de marihuana est autorisée;

f) l'aire de production autorisée;

g) le nombre maximum de plants de marihuana qui peuvent être produits à la fois dans le lieu de production;

(*g*) the maximum number of marihuana plants that may be under production at the production site at any time;

(*h*) the full address of the site where the dried marihuana may be kept;

(*i*) the maximum quantity of dried marihuana that may be kept at the site authorized under paragraph (*h*) at any time;

(*j*) the date of issue; and

(*k*) the date of expiry.

Grounds for Refusal

41. The Minister shall refuse to issue a designated-person production licence

(*a*) if the designated person is not eligible under section 35;

(*b*) the designated person would be the holder of more than one licence to produce; or

(*c*) for any reason referred to in paragraphs 32(*a*) to (*d*).

Expiry of Licence

42. A designated-person production licence expires on the earlier of

(*a*) 12 months after its date of issue, and

(*b*) the date of expiry of the authorization to possess on the basis of which the licence was issued.

General Provisions

Renewal of Licence to Produce

43. An application to renew a licence to produce shall be made to the Minister by the person who applied for the licence and shall include

(*a*) the licence number; and

(*b*) the material required under sections 27 and 28 or under sections 37 to 39, whichever apply.

44. Subject to section 45, if an application complies with section 43, the Minister shall renew the licence to produce.

45. The Minister shall refuse an application to renew a licence to produce for any reason referred to in section 32 or 41, whichever applies.

Change of Production Site or Production Area

46. (1) A person who applied for a licence to produce shall submit an application to the Minister to amend the licence if the person proposes to change the location of the production site or the production area.

(2) The application under subsection (1) shall include

(*a*) the licence number;

(*b*) in the case of a proposed change of production site, the full address of the proposed new site and supporting reasons for the proposed change;

(*c*) in the case of a proposed change of production area, the proposed new production area and supporting reasons for the proposed change; and

(*d*) the material required under sections 27 and 28 or sections 37 to 39, whichever apply.

h) l'adresse complète du lieu où peut être gardée la marihuana séchée;

i) la quantité maximale de marihuana séchée qui peut être gardée à la fois dans le lieu autorisé aux termes de l'alinéa *h*);

j) la date de délivrance;

k) la date d'expiration.

Motifs de refus

41. Le ministre refuse de délivrer la licence de production à titre de personne désignée :

a) dans le cas où la personne désignée n'est pas admissible selon l'article 35;

b) dans le cas où la personne désignée deviendrait titulaire de plus d'une licence de production si la licence était délivrée;

c) dans les cas visés aux alinéas 32*a*) à *d*).

Expiration de la licence

42. La licence de production à titre de personne désignée expire à la première des éventualités suivantes à survenir :

a) l'expiration d'une période de douze mois suivant la date de la délivrance;

b) l'expiration de l'autorisation de possession sur le fondement de laquelle la licence a été délivrée.

Dispositions générales

Renouvellement de la licence de production

43. La demande de renouvellement d'une licence de production est présentée au ministre par le demandeur de la licence et comporte les renseignements suivants :

a) le numéro de la licence visée;

b) les éléments exigés aux articles 27 et 28 ou aux articles 37 à 39, selon le cas.

44. Sous réserve de l'article 45, le ministre renouvelle la licence de production si la demande est conforme aux exigences de l'article 43.

45. Le ministre refuse de renouveler la licence de production dans les cas visés aux articles 32 ou 41, selon le cas.

Modification du lieu ou de l'aire de production

46. (1) Le demandeur de la licence de production présente au ministre une demande de modification de la licence lorsqu'un changement est envisagé quant au lieu de production ou à l'aire de production.

(2) La demande de modification comporte les éléments suivants :

a) le numéro de la licence;

b) si un changement est envisagé quant au lieu de production, l'adresse complète du lieu de production proposé et les motifs à l'appui de ce changement;

c) si un changement est envisagé quant à l'aire de production, une mention de l'aire de production proposée et les motifs à l'appui de ce changement;

d) les éléments exigés aux articles 27 et 28 ou aux articles 37 à 39, selon le cas.

47. Subject to section 48, if an application complies with subsection 46(2), the Minister shall amend the licence to produce.

48. The Minister shall refuse to amend a licence to produce for any reason referred to in section 32 or 41, whichever applies.

Change of Site Where Dried Marihuana Is Kept

49. (1) If the holder of a licence to produce proposes to change the location of the site where dried marihuana is kept, the holder shall apply to the Minister in writing, not less than 15 days before the intended effective date of the change.

(2) The application shall indicate

(*a*) the new site, selected from among those permitted under paragraph 28(1)(*h*) or 39(1)(*b*), whichever applies; and

(*b*) the intended effective date of the change.

(3) On receipt of an application that complies with subsection (2), the Minister shall amend the licence to reflect the change stated in the application.

Notice of Change of Information

50. (1) The holder of a licence to produce shall, within 10 days after the occurrence, notify the Minister in writing of

(*a*) a change in the holder's name; or

(*b*) subject to subsection (2), a change in the holder's address of ordinary residence.

(2) If the holder's address of ordinary residence is also the address of the site for the production of marihuana under the licence, the holder shall make an application under section 46.

(3) A notice under paragraph (1)(*a*) must be accompanied by proof of the change.

(4) On receiving a notice that complies with subsection (3), the Minister shall amend the licence to produce to reflect the change stated in the notice.

Marihuana Seed

51. (1) The Minister, and any person designated by the Minister under section 57 of the Act, is authorized to import and possess marihuana seed for the purpose of selling, providing, transporting, sending or delivering the seed in accordance with this section.

(2) The persons referred to in subsection (1) may sell, provide, transport, send or deliver marihuana seeds only to

(*a*) the holder of a licence to produce; or

(*b*) a licensed dealer under the *Narcotic Control Regulations*.

Restrictions

52. The holder of a licence to produce may produce marihuana only at the production site authorized in the licence and only in accordance with the authorized production area.

53. If the production area for a licence to produce permits the production of marihuana entirely outdoors or partly indoors and partly outdoors, the holder shall not produce marihuana outdoors if the production site is adjacent to a school, public playground,

47. Sous réserve de l'article 48, le ministre modifie la licence de production si la demande est conforme aux exigences du paragraphe 46(2).

48. Le ministre refuse de modifier la licence de production dans les cas visés aux articles 32 ou 41, selon le cas.

Modification du lieu où est gardée la marihuana séchée

49. (1) Le titulaire d'une licence de production qui envisage un changement quant au lieu où est gardée la marihuana séchée présente une demande de modification écrite au ministre au plus tard dans les quinze jours précédant la date du changement proposé.

(2) La demande de modification comporte les éléments suivants :

a) le nouveau lieu choisi parmi ceux visés aux alinéas 28(1)*h*) ou 39(1)*b*) selon le cas;

b) la date proposée du changement.

(3) Sur réception de la demande conforme au paragraphe (2), le ministre modifie la licence en conséquence.

Avis de modification de renseignements

50. (1) Le titulaire d'une licence de production avise par écrit le ministre des changements suivants, dans les dix jours suivant leur survenance :

a) toute modification à son nom;

b) sous réserve du paragraphe (2), tout changement de son adresse de résidence habituelle.

(2) Si l'adresse de résidence habituelle du titulaire de la licence de production est aussi l'adresse du lieu où la production de marihuana est autorisée, le titulaire doit présenter une demande de modification aux termes de l'article 46.

(3) Le titulaire de la licence de production joint à l'avis fourni en application de l'alinéa (1)*a*) une preuve du changement.

(4) Sur réception de l'avis conforme au paragraphe (3), le ministre modifie la licence en conséquence.

Graines de marihuana

51. (1) Le ministre, ainsi que toute personne qu'il désigne en vertu de l'article 57 de la Loi, est autorisé à importer ou posséder des graines de marihuana en vue de les vendre, fournir, transporter, expédier ou livrer conformément au présent article.

(2) Les personnes visées au paragraphe (1) ne peuvent vendre, fournir, transporter, expédier ou livrer des graines de marihuana qu'aux personnes suivantes :

a) le titulaire d'une licence de production;

b) un distributeur autorisé en vertu du *Règlement sur les stupéfiants*.

Restrictions

52. Le titulaire d'une licence de production peut produire de la marihuana uniquement dans le lieu de production et suivant l'aire de production autorisés dans la licence.

53. Dans le cas où le titulaire d'une licence de production est autorisé à produire des plants de marihuana dans une aire qui est soit entièrement à l'extérieur, soit en partie à l'intérieur et en partie à l'extérieur, il ne peut les produire à l'extérieur dans un lieu

day care facility or other public place frequented mainly by persons under 18 years of age.

54. The holder of a licence to produce shall not produce marihuana in common with more than two other holders of licences to produce.

55. The holder of a licence to produce may keep dried marihuana only indoors at the site authorized in the licence for that purpose.

Records

56. (1) The holder of a designated-person production licence must, at either the production site or the site where dried marihuana may be kept, maintain records of the following information in respect of the licence:

(*a*) the number of plants grown;

(*b*) the date each plant was planted from seed or by transplant;

(*c*) the date each plant was harvested; and

(*d*) for each plant harvested, the weight in grams of dried marihuana obtained.

(2) The information referred to in subsection (1) shall be retained for at least two years after it is recorded.

(3) On request, the holder of a designated-person production licence must provide the Minister with a copy of any record referred to in subsection (1).

Inspection

57. (1) To verify that the production of marihuana is in conformity with these Regulations and a licence to produce, an inspector may, at any reasonable time, enter any place where the inspector believes on reasonable grounds that marihuana is being produced or kept by the holder of the licence to produce, and may, for that purpose,

(*a*) open and examine any container found there that could contain marihuana;

(*b*) examine anything found there that is used or is capable of being used to produce or keep marihuana;

(*c*) examine any records, electronic data or other documents found there dealing with marihuana, other than records dealing with the medical condition of a person, and make copies or take extracts;

(*d*) use, or cause to be used, any computer system found there to examine electronic data referred to in paragraph (*c*);

(*e*) reproduce, or cause to be reproduced, any document from electronic data referred to in paragraph (*c*) in the form of a printout or other output;

(*f*) take any document or output referred to in paragraph (*c*) or (*e*) for examination or copying;

(*g*) examine any substance found there and, for the purpose of analysis, take samples, as reasonably required; and

(*h*) seize and retain any substance found there, if the inspector believes, on reasonable grounds, that it is necessary.

(2) Despite subsection (1), an inspector may not enter a dwelling-place without the consent of an occupant.

de production qui est adjacent à une école, un terrain de jeu public, une garderie ou tout autre lieu public principalement fréquenté par des personnes de moins de dix-huit ans.

54. Le titulaire d'une licence de production ne peut produire de la marihuana en commun avec plus de deux autres titulaires de licence de production.

55. Le titulaire d'une licence de production ne peut garder la marihuana séchée qu'à l'intérieur, dans le lieu autorisé à cette fin dans la licence.

Tenue de dossiers

56. (1) Le titulaire d'une licence de production à titre de personne désignée tient, dans le lieu de production ou dans le lieu où la marihuana séchée peut être gardée, des dossiers dans lesquels il consigne les données suivantes relatives à sa licence :

a) le nombre de plants cultivés;

b) la date de chaque semis ou plantation;

c) la date de récolte de chaque plant;

d) le poids, en grammes, de marihuana séchée obtenue à partir de chaque plant récolté.

(2) Les renseignements visés au paragraphe (1) sont conservés pendant une période d'au moins deux ans après leur inscription.

(3) Le titulaire d'une licence de production à titre de personne désignée fournit au ministre, à sa demande, une copie des dossiers visés au paragraphe (1).

Inspection

57. (1) L'inspecteur peut, pour s'assurer que le titulaire d'une licence de production se conforme au présent règlement et à sa licence, procéder à toute heure convenable à la visite de tout lieu où il a des motifs raisonnables de croire que le titulaire produit ou garde de la marihuana. Il peut alors à cette fin :

a) ouvrir et examiner tout contenant trouvé sur les lieux et pouvant contenir de la marihuana;

b) examiner toute chose trouvée sur les lieux et servant — ou susceptible de servir — à produire ou à garder la marihuana;

c) examiner les dossiers, les données électroniques et tous autres documents trouvés sur les lieux et se rapportant à la marihuana, à l'exception des dossiers sur l'état pathologique de personnes, et les reproduire en tout ou en partie;

d) utiliser ou voir à ce que soit utilisé, pour examen des données électroniques visées à l'alinéa *c*), tout système informatique se trouvant sur les lieux;

e) reproduire ou faire reproduire, notamment sous forme d'imprimé, tout document contenu dans ces dossiers;

f) emporter, pour examen ou reproduction, tout document visé à l'alinéa *c*), de même que tout document tiré des données électroniques conformément à l'alinéa *e*);

g) examiner toute substance trouvée sur les lieux et en prélever, en tant que de besoin, des échantillons pour analyse;

f) saisir et retenir toute substance dont il juge, pour des motifs raisonnables, la saisie et la rétention nécessaires.

(2) Dans le cas d'un local d'habitation, l'inspecteur ne peut toutefois procéder à la visite sans le consentement de l'un de ses occupants.

PART 3

OBLIGATIONS CONCERNING DOCUMENTS AND REVOCATION

Showing Documents

58. (1) On demand, the holder of an authorization to possess must show proof of their authority to possess dry marihuana to a police officer.

(2) On demand, the holder of a licence to produce must show the licence to a police officer.

Unauthorized Changes

59. No one may add to, delete or obliterate from, or alter in any other way, an authorization to possess or a licence to produce.

Return of Documents

60. (1) If an authorization to possess or licence to produce is renewed or amended, the holder of the authorization or licence shall, within 30 days after receiving the new document, return the replaced document to the Minister.

(2) If an authorization to possess or licence to produce expires without being renewed or is revoked, the holder of the authorization or licence shall, within 30 days after the occurrence, return the expired or revoked document to the Minister.

Security and Reporting Loss or Theft

61. (1) The holder of an authorization to possess or a licence to produce shall maintain measures necessary to ensure the security of the marihuana in their possession as well as the authorization or licence, or both, issued to them.

(2) In the case of the loss or theft of marihuana or of the holder's authorization or licence, the holder of the authorization or licence shall, on becoming aware of the occurrence,

(*a*) within the next 24 hours, notify a member of a police force; and

(*b*) within the next 72 hours, notify the Minister, in writing, and include confirmation that the notice required under paragraph (*a*) has been given.

Revocation

62. (1) The Minister shall revoke the authorization to possess and any licence to produce issued on the basis of the authorization, if the holder of an authorization requests that the authorization be revoked.

(2) Subject to section 64, the Minister shall revoke an authorization to possess and any licence to produce issued on the basis of the authorization if

(*a*) the holder of the authorization is not eligible under section 3;

(*b*) a medical practitioner for the holder of the authorization advises the Minister in writing that the use of marihuana by the holder is no longer recommended;

(*c*) the authorization was issued on the basis of false or misleading information; or

PARTIE 3

OBLIGATIONS RELATIVES AUX DOCUMENTS ET RÉVOCATION

Présentation de documents

58. (1) Le titulaire d'une autorisation de possession présente à tout agent de police qui lui en fait la demande la preuve qu'il est autorisé à posséder de la marihuana séchée.

(2) Le titulaire d'une licence de production montre celle-ci à tout agent de police qui lui en fait la demande.

Interdiction de modifier les documents

59. Il est interdit de modifier de quelque façon que ce soit, notamment par adjonction ou suppression, une autorisation de possession ou une licence de production.

Document à remettre

60. (1) Dans le cas du renouvellement ou de la modification d'une autorisation de possession ou d'une licence de production, le titulaire doit, dans les trente jours suivant la date de réception du document de remplacement, remettre au ministre le document remplacé.

(2) Dans le cas de l'expiration sans renouvellement ou de la révocation d'une autorisation de possession ou d'une licence de production, le titulaire doit, dans les trente jours de l'expiration ou de la révocation, remettre le document au ministre.

Sécurité et rapport de perte ou vol

61. (1) Le titulaire d'une autorisation de possession ou d'une licence de production prend les mesures de sécurité nécessaires à l'égard de la marihuana qu'il a en sa possession et à l'égard de son autorisation ou de sa licence.

(2) En cas de perte ou de vol de marihuana, de son autorisation ou de sa licence, le titulaire de l'autorisation ou de la licence :

a) en avise un membre d'un corps policier dans les vingt-quatre heures suivant la découverte;

b) en avise le ministre par écrit, dans les soixante-douze heures suivant la découverte, et lui confirme que l'avis prévu à l'alinéa *a*) a été donné.

Révocation

62. (1) Le ministre révoque l'autorisation de possession et, le cas échéant, la licence de production délivrée sur le fondement de cette autorisation si le titulaire de l'autorisation demande que son autorisation soit révoquée.

(2) Sous réserve de l'article 64, le ministre révoque l'autorisation de possession et, le cas échéant, la licence de production délivrée sur le fondement de cette autorisation dans les cas suivants :

a) le titulaire de l'autorisation n'est pas admissible selon l'article 3;

b) le médecin du titulaire de l'autorisation avise le ministre par écrit que l'usage de la marihuana n'est plus indiqué;

c) l'autorisation a été délivrée sur la foi de renseignements faux ou trompeurs;

(*d*) the photograph submitted under paragraph 4(2)(*d*) or section 14 as part of the application for the authorization or renewal is not an accurate representation of the holder of the authorization.

63. (1) On request by the holder of a licence to produce, the Minister shall revoke the licence.

(2) Subject to section 64, the Minister shall revoke a licence to produce if

(*a*) the holder is not eligible under section 25 or 35, whichever applies;

(*b*) the holder of a personal-use production licence is found guilty of a designated marihuana offence committed after the date of issue of the licence;

(*c*) the holder of a designated-person production licence is found guilty of a designated drug offence committed after the date of issue of the licence;

(*d*) the holder of a licence to produce marihuana outdoors produces marihuana in contravention of section 53;

(*e*) the photograph submitted under paragraph 37(2)(*e*) or section 43 as part of the application for a designated-person production licence or renewal is not an accurate representation of the designated person; or

(*f*) the licence to produce was issued on the basis of false or misleading information.

64. The Minister shall not revoke an authorization to possess or a licence to produce under section 62 or 63 unless

(*a*) the Minister has given the holder of the authorization or licence written notice of the reasons for the proposed revocation; and

(*b*) the holder has been given an opportunity to be heard.

Destruction of Marihuana

65. (1) If an authorization to possess expires without being renewed or is revoked, the holder shall destroy all marihuana in their possession.

(2) If a licence to produce expires without being renewed or is revoked, the holder of the licence shall discontinue production of marihuana and, subject to section 66, destroy all marihuana in their possession.

(3) Within 10 days after destroying the marihuana, the holder of the authorization or the licence shall notify the Minister, in writing, of the amount of marihuana destroyed.

66. (1) If a personal-use production licence expires without being renewed but the holder remains the holder of a valid authorization to possess, the holder is not required to destroy dried marihuana that is not in excess of the maximum quantity permitted under the authorization.

(2) If a designated-person production licence expires without being renewed but the authorization to possess on the basis of which the licence was issued remains valid, the holder of the licence, before destroying marihuana, may immediately transport, transfer, give or deliver directly to the holder of the authorization not more than a quantity of dried marihuana that results in the holder of the authorization being in possession of the maximum quantity permitted under the authorization.

67. (1) If a licence to produce is amended under section 47 or at the time of the renewal to reflect an change in the production

d) la photographie fournie, en application du paragraphe 4(2)*d*) ou de l'article 14, avec la demande d'autorisation ou de renouvellement ne représente pas bien le titulaire de l'autorisation.

63. (1) Le ministre révoque la licence de production si le titulaire en fait la demande.

(2) Sous réserve de l'article 64, le ministre révoque la licence de production dans les cas suivants :

a) le titulaire de la licence n'est pas admissible selon les articles 25 ou 35, selon le cas;

b) le titulaire de la licence de production à des fins personnelles est reconnu coupable d'une infraction désignée relativement à la marihuana commise après la délivrance de la licence;

c) le titulaire de la licence de production à titre de personne désignée est reconnu coupable d'une infraction désignée en matière de drogue commise après la délivrance de la licence;

d) le titulaire de la licence de production produit de la marihuana à l'extérieur en contravention de l'article 53;

e) la photographie fournie, en application du paragraphe 37(2)*e*) ou de l'article 43, avec la demande de licence de production à titre de personne désignée ou de son renouvellement ne représente pas bien la personne désignée;

f) la licence de production a été délivrée sur la foi de renseignements faux ou trompeurs.

64. Le ministre ne peut révoquer l'autorisation de possession ou la licence de production aux termes des articles 62 ou 63 que si les conditions suivantes sont réunies :

a) il a envoyé au titulaire de l'autorisation ou de la licence un avis écrit exposant les motifs de la révocation;

b) le titulaire a eu la possibilité de se faire entendre quant à la révocation.

Destruction de marihuana

65. (1) Si l'autorisation de possession expire sans être renouvelée ou est révoquée, son titulaire doit détruire la marihuana qui se trouve en sa possession.

(2) Si la licence de production expire sans être renouvelée ou est révoquée, son titulaire doit cesser toute production de marihuana et, sous réserve de l'article 66, détruire la marihuana qui se trouve en sa possession.

(3) Le titulaire de l'autorisation ou de la licence avise le ministre par écrit de la quantité de marihuana détruite dans les dix jours suivant la destruction.

66. (1) Si la licence de production à des fins personnelles expire sans être renouvelée, son titulaire, s'il détient toujours une autorisation de possession valide, n'est pas tenu de détruire la marihuana séchée qui n'excède pas la quantité maximale prévue par l'autorisation.

(2) Si la licence de production à titre de personne désignée expire sans être renouvelée alors que l'autorisation de possession sur le fondement de laquelle la licence a été délivrée est toujours valide, le titulaire de la licence peut, avant de détruire la marihuana, transporter, transférer, donner ou livrer sans délai, directement au titulaire de l'autorisation, au plus la quantité de marihuana séchée qui lui manque pour atteindre la quantité maximale prévue par l'autorisation.

67. (1) Si la licence de production est modifiée en vertu de l'article 47 ou au moment de son renouvellement, quant à l'aire

area, the holder of the licence must destroy any marihuana plants in production under the licence that are in excess of the maximum number of plants that may be produced under the licence, as changed.

(2) If a licence to produce is amended under section 47 or at the time of the renewal to reflect an change in the production area, the holder of the licence must destroy any dried marihuana kept under the licence that is in excess of the maximum quantity of marihuana that may be kept under the licence, as changed.

Complaints and Disclosure of Information

68. (1) An inspector shall receive and make a written record of any complaint from the public concerning a person who is a holder of an authorization to possess or licence to produce with respect to their possession or production of marihuana.

(2) The inspector shall report to the Minister any complaint recorded under subsection (1).

(3) The Minister may communicate to any police force in Canada or any member of a police force in Canada, any information contained in the report of the inspector, subject to that information being used only for the proper enforcement or administration of the Act or these Regulations.

69. The Minister may provide, in writing, any factual information that has been obtained about a medical practitioner under the Act or these Regulations to the licensing authority responsible for the registration or authorization of the person to practise medicine

(*a*) in the province in which the medical practitioner is authorized to practise if

(i) the authority submits to the Minister a written request that sets out the name and address of the medical practitioner, a description of the information being sought and a statement that the information is required for the purpose of assisting a lawful investigation by the authority, or

(ii) the Minister has reasonable grounds to believe that the medical practitioner has

(A) contravened a rule of conduct established by the authority,

(B) been found guilty in a court of law of a designated drug offence, or

(C) made a false statement under these Regulations; or

(*b*) in a province where the medical practitioner is not authorized to practise, if the authority submits to the Minister

(i) a written request for information that sets out

(A) the name and address of the medical practitioner, and

(B) a description of the information being sought, and

(ii) documentation that shows that the medical practitioner has applied to that authority to practise in that province.

PART 4

SUPPLY BY A MEDICAL PRACTITIONER

70. A medical practitioner who has obtained marihuana from a licensed dealer under subsection 24(2) of the *Narcotic Control Regulations* may sell or furnish the marihuana to the holder of an authorization to possess under the practitioner's care.

de production autorisée, le titulaire de la licence doit détruire les plants de marihuana en production qui excèdent, le cas échéant, la quantité maximale prévue par la licence, telle que modifiée ou renouvelée.

(2) Si la licence de production est modifiée en vertu de l'article 47 ou au moment de son renouvellement, quant à l'aire de production autorisée, le titulaire de la licence doit détruire la marihuana séchée qu'il garde en excès, le cas échéant, de la quantité maximale prévue par la licence, telle que modifiée ou renouvelée.

Plaintes et communication des renseignements

68. (1) L'inspecteur consigne toute plainte reçue du public à l'égard du titulaire d'une autorisation de possession ou d'une licence de production quant à ses opérations de possession ou de production de marihuana.

(2) L'inspecteur fait rapport au ministre de toute plainte consignée aux termes du paragraphe (1).

(3) Le ministre peut communiquer à tout corps policier au Canada, ou membre d'un tel corps policier, tout renseignement contenu dans le rapport de l'inspecteur, sous réserve que ces renseignements ne soient utilisés que pour l'application ou l'exécution de la Loi ou du présent règlement.

69. Le ministre peut communiquer par écrit des renseignements factuels, obtenus en vertu de la Loi ou du présent règlement au sujet d'un médecin, à l'autorité attributive de permis ou chargée d'autoriser l'exercice de la profession :

a) dans la province où le médecin en cause est autorisé à exercer, dans les cas suivants :

(i) il reçoit de cette autorité une demande écrite mentionnant les nom et adresse du médecin et la nature des renseignements demandés et précisant que les renseignements visent à aider l'autorité à mener une enquête officielle,

(ii) il a des motifs raisonnables de croire que le médecin :

(A) soit a enfreint une règle de conduite établie par cette autorité,

(B) soit a été reconnu coupable par un tribunal d'une infraction désignée en matière de drogue,

(C) soit a fait de fausses déclarations dans le cadre du présent règlement;

b) dans une province où le médecin n'est pas autorisé à exercer, s'il reçoit de cette autorité :

(i) une demande écrite précisant :

(A) les nom et adresse du médecin,

(B) la nature des renseignements demandés,

(ii) des documents démontrant que le médecin lui a présenté une demande pour obtenir l'autorisation d'exercer dans cette province.

PARTIE 4

FOURNITURE PAR UN MÉDECIN

70. Un médecin peut vendre ou fournir de la marihuana à la personne qu'il traite à titre professionnel et qui est titulaire d'une autorisation de possession s'il l'a obtenue d'un distributeur autorisé en vertu du paragraphe 24(2) du *Règlement sur les stupéfiants*.

NARCOTIC CONTROL REGULATIONS

71. Paragraph 53(1) of the *Narcotic Control Regulations*[1] is replaced by the following:

53. (1) No practitioner shall administer, prescribe, give, sell or furnish a narcotic to any person or animal except as authorized under this section or the *Marihuana Medical Access Regulations*.

TRANSITIONAL PROVISION

72. If, on the coming into force of these Regulations, a person is, for a medical purpose, exempt under section 56 of the Act from the application of subsection 4(1) and, if applicable, section 7 of the Act in respect of marihuana, the person is, by virtue of this section, exempt from those provisions for a period of six months after the date of expiry for the section 56 exemption, on the same terms and conditions as those contained in the section 56 exemption except for any term or condition pertaining to the expiry date of the exemption.

COMING INTO FORCE

73. These Regulations come into force on July 30, 2001.

SCHEDULE
(Section 1)

CATEGORY 2 SYMPTOMS

Column 1 Medical Condition	Column 2 Symptom
Cancer, AIDS, HIV infection	Severe nausea
Cancer, AIDS, HIV infection	Cachexia, anorexia, weight loss
Multiple sclerosis, spinal cord injury or disease	Persistent muscle spasms
Epilepsy	Seizures
Cancer, AIDS, HIV infection, multiple sclerosis, spinal cord injury or disease, severe form of arthritis	Severe pain

RÈGLEMENT SUR LES STUPÉFIANTS

71. Le paragraphe 53(1) du *Règlement sur les stupéfiants*[1] est remplacé par ce qui suit :

53. (1) Il est interdit à un praticien d'administrer, de prescrire, de donner, de vendre ou de fournir un stupéfiant à une personne ou à un animal sauf dans les cas prévus au présent article ou au *Règlement sur l'accès à la marihuana à des fins médicales*.

DISPOSITION TRANSITOIRE

72. La personne qui, à la date d'entrée en vigueur du présent règlement, est exemptée en vertu de l'article 56 de la Loi, pour des raisons médicales, de l'application du paragraphe 4(1) et, le cas échéant, de l'article 7 de la Loi en ce qui concerne la marihuana, est, en vertu du présent article, soustraite, pour une période de six mois suivant la date d'échéance de l'exemption, à l'application de ces dispositions aux mêmes conditions que celles prévues par l'exemption qui lui a été accordée en vertu de l'article 56 de la Loi, exception faite de la date d'expiration de l'exemption.

ENTRÉE EN VIGUEUR

73. Le présent règlement entre en vigueur le 30 juillet 2001.

ANNEXE
(article 1)

SYMPTÔMES DE CATÉGORIE 2

Colonne 1 État pathologique	Colonne 2 Symptôme
Cancer, SIDA, infection au VIH	Violente nausée
Cancer, SIDA, infection au VIH	Cachexie, anorexie, perte de poids
Sclérose en plaques, lésion ou maladie de la moelle épinière	Spasmes musculaires persistants
Épilepsie	Convulsions
Cancer, SIDA, infection au VIH, sclérose en plaques, lésion ou maladie de la moelle épinière, forme grave d'arthrite	Douleur aiguë

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations*.)

Description

The *Marihuana Medical Access Regulations* (Regulations) provide seriously ill Canadian patients with access to marihuana while it is being researched as a possible medicine. These Regulations have been developed in recognition of a need for a more defined process than the one currently used under section 56 of the *Controlled Drugs and Substances Act* (CDSA) for these Canadian patients.

On July 31, 2000, the Court of Appeal for Ontario rendered its decision in the case of Terrance Parker who uses marihuana to help control his epilepsy. The Court dealt exclusively with the

[1] C.R.C., c. 1041

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(*Ce résumé ne fait pas partie du règlement*.)

Description

Le *Règlement sur l'accès à la marihuana à des fins médicales* (le règlement) donne aux patients canadiens atteints de maladies graves accès à la marihuana à des fins médicales. D'autre part, la marihuana est actuellement évaluée en recherche pour ses applications en tant que médicament possible. Ce règlement a été élaboré parce qu'on a reconnu le besoin de mettre en place un processus mieux défini que celui actuellement utilisé par ces patients, c'est-à-dire celui en vertu de l'article 56 de la *Loi réglementant certaines drogues et autres substances* (LRCDAS).

Le 31 juillet 2000, la Cour d'appel de l'Ontario a rendu sa décision dans la cause de Terrance Parker, qui consomme de la marihuana pour atténuer les symptômes de son épilepsie. La Cour

[1] C.R.C., ch. 1041

issue of medical use of marihuana. The Court upheld a 1997 lower court decision to stay the charges against Mr. Parker on constitutional grounds and raised issues related to the section 56 exemption process of the CDSA, such as the broad discretion given by the law to the Minister of Health to grant exemptions, transparency of the process, and what constitutes medical necessity.

As a result, the Court declared the prohibition of marihuana in the CDSA to be unconstitutional and of no force and effect. The declaration of invalidity was suspended for a year, however, to avoid leaving a gap in the regulatory scheme.

Subsequent to this Court decision, Health Canada announced on September 14, 2000, its intention to develop a new regulatory approach for Canadians to access marihuana. This new approach would bring greater clarity to the process for those Canadians who may request the use of marihuana to alleviate symptoms.

The new Regulations clearly define the circumstances and the manner in which access to marihuana for medical purposes will be permitted. These Regulations appropriately and efficiently address concerns raised in the Parker decision concerning the process currently used under section 56 of the CDSA. These Regulations apply only to marihuana.

Legislative Framework

International

The United Nations (UN) has developed a system for the global control of narcotic drugs and psychotropic substances through a series of drug control Conventions. The UN *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs* (1961 Convention), the UN *Convention on Psychotropic Substances, 1971* (1971 Convention) and the UN *Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988* (1988 Convention) set out a system of controls relating to the international production and distribution of narcotic drugs and psychotropic substances.

Under the 1961 Convention, parties have agreed to enact legislation that strictly controls the cultivation and distribution of opium poppy, coca and marihuana plants, and the production and distribution of other narcotics. All production, distribution and use of any substance listed under this convention must be limited to scientific or medical purposes.

Under the 1971 Convention, psychoactive substances are to be subjected to controls similar to those that apply under the 1961 Convention. THC (delta-9-tetrahydrocannabinol) and other isolated marihuana derivatives, known as cannabinoids, are listed under this Convention.

Under the 1988 Convention, parties must cooperatively take action to control illicit cultivation, production and distribution of drugs of abuse. This includes the cultivation of marihuana.

d'appel a abordé ce cas exclusivement sous l'angle de la consommation de marihuana à des fins médicales. La Cour a confirmé la décision d'un tribunal d'une instance inférieure rendue en 1997, qui suspendait les accusations portées contre M. Parker pour des motifs constitutionnels, et a soulevé certaines questions concernant le processus d'exemption prévu à l'article 56 de la LRCDAS, telles que le pouvoir discrétionnaire conféré par la Loi au ministre de la Santé pour accorder des exemptions, la transparence du processus et la définition de l'expression « nécessité médicale ».

Par conséquent, la Cour a déclaré inconstitutionnelle, nulle et sans effet l'interdiction relative à la marihuana de la LRCDAS. Cette déclaration d'invalidité a toutefois été suspendue pour une durée d'un an afin d'éviter de créer un vide réglementaire.

À la suite de cette décision de la Cour, Santé Canada a annoncé, le 14 septembre 2000, son intention d'élaborer une nouvelle approche réglementaire en ce qui concerne l'accès à la marihuana. Cette nouvelle approche clarifierait nettement le processus que doivent utiliser les Canadiens et les Canadiennes qui désirent avoir recours à la marihuana pour soulager des symptômes.

Le nouveau règlement définit de façon claire les circonstances et les modalités selon lesquelles l'accès à la marihuana à des fins médicales sera accordé. Ce règlement apporte une solution appropriée et efficace aux préoccupations soulevées dans l'exposé de décision de l'affaire Parker en ce qui a trait au processus utilisé actuellement, soit le processus prévu à l'article 56 de la LRCDAS. Le règlement s'applique uniquement à la marihuana.

Cadre législatif

International

L'Organisation des Nations Unies (ONU) a instauré un système mondial de contrôle des stupéfiants et des substances psychotropes en élaborant une série de conventions sur le contrôle des drogues. La *Convention unique sur les stupéfiants de 1961*, modifiée par le *Protocole portant amendement de la Convention unique sur les stupéfiants de 1961* (Convention de 1961), la *Convention sur les substances psychotropes de 1971* (Convention de 1971) et la *Convention de 1988 contre le trafic illicite des stupéfiants et des substances psychotropes* (Convention de 1988) ont établi un système de contrôle de la production et de la distribution internationales des stupéfiants et des substances psychotropes.

En vertu de la Convention de 1961, les parties ont convenu d'adopter des lois contrôlant rigoureusement la culture et la distribution du pavot, de la coca et des plants de marihuana, de même que la production et la distribution d'autres stupéfiants. Toute production, distribution et utilisation des substances visées par cette Convention doit être limitée à des fins scientifiques ou médicales.

En vertu de la Convention de 1971, les substances psychoactives doivent être assujetties à des mécanismes de contrôle semblables à ceux prévus par la Convention de 1961. Le THC (delta-9-tétrahydrocannabinol) et d'autres dérivés isolés de la marihuana, connus sous le nom de cannabinoïdes, sont énumérés dans cette Convention.

En vertu de la Convention de 1988, les parties doivent se concerter pour effectuer le contrôle de la culture, la production et la distribution illicites de drogues pouvant faire l'objet d'abus. La culture de la marihuana est notamment visée.

Canada

Controlled Drugs and Substances Act

The *Controlled Drugs and Substances Act* (CDSA) prohibits possession, double doctoring, trafficking, possession for the purpose of trafficking, importation, exportation and possession for the purpose of exporting and production of substances included in schedules to the CDSA. These activities are illegal unless authorized in Regulations made under the CDSA.

The Regulations currently in force under the CDSA:

- govern the activities of producers, distributors, importers, exporters, researchers and health care professionals relating to controlled drugs and substances used for scientific or medical purposes and, in the case of hemp, for industrial purposes;
- require all dealers to be licensed to produce, distribute, import and export controlled drugs and substances;
- regulate the distribution of controlled drugs and substances by pharmacists, practitioners and hospitals and outline the records that must be kept to account for the distribution of these drugs.

One set of these Regulations, the *Narcotic Control Regulations*, regulates the legal distribution of "narcotic" drugs such as opium, codeine, morphine, heroin, cocaine and *Cannabis* (marihuana).

Food and Drugs Act and Regulations

Drugs are approved for sale in Canada under the *Food and Drugs Act* and Regulations. The *Food and Drug Regulations* provide controls respecting the safety, efficacy and quality of products offered for sale in Canada as well as the importation, distribution and sale of approved drugs.

Marihuana has not been reviewed for safety or effectiveness and has therefore not been approved for sale as a drug in Canada or any other country. Most scientific experts assert that marihuana's future as a drug lies primarily in its pharmacologically active components, the cannabinoids. These chemicals can be isolated, subjected to scientific scrutiny and potentially developed as standardized pharmaceutical drug products.

Within the full set of approved pharmaceutical treatments available to patients there are two commercially available drugs related to marihuana: MARINOL®, which contains chemically synthesized THC; and CESAMET®, a synthetic cannabinoid. In Canada, both drugs are approved for the treatment or management of severe nausea and vomiting associated with cancer chemotherapy and may be prescribed by physicians. MARINOL® has also been approved for the treatment of anorexia associated with weight loss in patients with AIDS. Both drugs are taken orally and must be prescribed by a physician.

Canadien

Loi réglementant certaines drogues et autres substances

La *Loi réglementant certaines drogues et autres substances* (LRCDAS) interdit la possession, le cumul d'ordonnances médicales, le trafic, la possession en vue de faire le trafic, l'importation, l'exportation, la possession en vue de l'exportation ainsi que la production des substances énumérées dans les annexes de la loi. Toutes ces activités sont illégales à moins d'être autorisées par le règlement pris en vertu de ladite loi.

Les règlements actuellement en vigueur :

- régissent les activités des producteurs, des distributeurs, des importateurs, des exportateurs, des chercheurs et des professionnels de la santé en ce qui concerne les drogues et autres substances contrôlées utilisées à des fins scientifiques ou médicales, ainsi que les applications industrielles du chanvre;
- obligent tous les vendeurs de ces substances à détenir une licence pour produire, distribuer, importer et exporter les drogues et substances contrôlées;
- réglementent la distribution des drogues et substances contrôlées par les pharmaciens, les praticiens et les hôpitaux, et indiquent quels dossiers doivent être conservés pour rendre compte de la distribution de ces drogues.

L'un de ces règlements, le *Règlement sur les stupéfiants*, régit la distribution légale de « stupéfiants » comme l'opium, la codéine, la morphine, l'héroïne, la cocaïne et inclut aussi le cannabis (marihuana).

Loi et Règlement sur les aliments et drogues

Au Canada, les médicaments sont homologués en vertu de la Loi et du *Règlement sur les aliments et drogues*. Le *Règlement sur les aliments et drogues* établit des mécanismes de contrôle d'une part garantissant l'innocuité, l'efficacité et la qualité des produits vendus au Canada et d'autre part, concernant l'importation, la distribution et la vente de médicaments homologués.

L'innocuité et l'efficacité de la marihuana n'ayant jamais été étudiées, la vente de marihuana en tant que médicament n'est pas approuvée au Canada ni dans aucun autre pays du monde. Selon la plupart des experts scientifiques, l'avenir de la marihuana en tant que médicament tient principalement à ses composés actifs du point de vue pharmacologique, les cannabinoïdes. Ces substances chimiques peuvent être isolées, soumises à un examen scientifique et éventuellement transformées en produits pharmaceutiques normalisés.

Dans l'éventail des produits pharmaceutiques homologués, deux médicaments vendus au Canada sont associés à la marihuana : MARINOL®, produit qui contient du THC synthétique, et CESAMET®, un cannabinoïde de synthèse. Au Canada, ces deux médicaments sont homologués pour le traitement ou le soulagement des nausées et vomissements sévères provoqués par la chimiothérapie anticancéreuse et ils peuvent être prescrits par un médecin. Le produit MARINOL® a également été approuvé pour le traitement de l'anorexie associée à une perte pondérale chez les patients atteints du sida. Les deux médicaments sont pris par voie orale et doivent être prescrits par un médecin.

Marihuana for Medical Purposes

Therapeutic Claims and Uses

Claims of potential therapeutic benefit of marihuana are usually for symptomatic relief rather than for curative relief. The main claimed therapeutic uses are:

- **Nausea and vomiting:** For the relief of nausea and vomiting associated with cancer and AIDS therapies.
- **Wasting syndrome:** To stimulate appetite and produce weight gain in AIDS and cancer patients.
- **Multiple sclerosis:** For the relief of muscle pain and spasms.
- **Epilepsy:** To help reduce the frequency of epileptic seizures.

Much of the evidence of the potential therapeutic effects of smoked marihuana is heavily anecdotal. Scientific studies supporting the safety and efficacy of marihuana for therapeutic use are often inconclusive.

Adverse Health Effects

The potential health risks associated with the use of marihuana for medical purposes have not been adequately examined. The main known adverse health effects for smoked marihuana include:

- **Dependance:** There is clinical and epidemiological evidence that some heavy marihuana users experience problems in controlling marihuana use. A distinctive marihuana withdrawal syndrome has been identified, although it is mild and short-lived.
- **Psychomotor skills:** Marihuana reduces the ability to perform tasks requiring concentration and coordination such as driving a car.
- **Respiratory:** Marihuana causes lung damage similar to that caused by tobacco smoke. These long-term risks must be considered in long term use by patients with chronic diseases. They may be of lesser concern where short-term use of marihuana is being proposed.
- **Cardiovascular:** Marihuana increases heart rate and blood pressure.
- **Immune system:** Though the complete effects of marihuana on immune function remain unknown, it is suspected that marihuana may have an adverse effect on the immune system.

Research into the use of marihuana for medical purposes may eventually bring new pharmaceutical products to market that contain marihuana components. Until that time however, patients, particularly those with serious medical conditions where conventional treatments may offer little hope of relief, are demanding access to marihuana for personal medical use.

International Perspective

Currently, marihuana is not approved as a drug in any country in the world. Some countries and U.S. States are actively reviewing their policies and laws concerning the medical use of

Usage de la marihuana à des fins médicales

Vertus thérapeutiques alléguées et utilisations de la marihuana

Les allégations des bénéfices possibles thérapeutiques de la marihuana portent sur le soulagement des symptômes plutôt que sur des propriétés curatives. Voici les principales vertus thérapeutiques prêtées à la marihuana :

- **Nausées et vomissements :** Pour le soulagement des nausées et vomissements associés aux traitements contre le cancer et le sida.
- **Syndrome cachectique :** Pour stimuler l'appétit et favoriser la prise de poids chez les patients atteints de sida et de cancer.
- **Sclérose en plaques :** Pour le soulagement des douleurs et des spasmes musculaires.
- **Épilepsie :** Pour aider à réduire la fréquence des crises.

Beaucoup des données citées à l'appui des vertus thérapeutiques de la marihuana fumée sont liées à des cas isolés. De plus, les études scientifiques sur l'innocuité et l'efficacité de la marihuana consommée à des fins thérapeutiques sont rarement concluantes.

Effets défavorables sur la santé

Les risques possibles reliés à la consommation de marihuana à des fins thérapeutiques n'ont pas encore été suffisamment évalués. Les effets nocifs mieux connus de la marihuana fumée incluent :

- **Dépendance :** Selon des données cliniques et épidémiologiques, certains gros consommateurs de marihuana éprouvent de la difficulté à limiter leur usage de cette drogue. Un syndrome de sevrage caractéristique de la marihuana a été découvert, mais il est bénin et de courte durée.
- **Aptitudes psychomotrices :** La marihuana réduit l'aptitude à accomplir des tâches qui nécessitent de la concentration et de la coordination, par exemple conduire une voiture.
- **Appareil respiratoire :** La marihuana cause des lésions aux poumons semblables à celles qu'entraîne la fumée de tabac. S'il faut bien sûr tenir compte des effets de la consommation à long terme chez les patients atteints de maladies chroniques, les risques associés au fait de fumer de la marihuana sont peut-être moins importants dans le cas d'un usage de courte durée.
- **Appareil cardio-vasculaire :** La marihuana entraîne une élévation de la fréquence cardiaque et de la tension artérielle.
- **Système immunitaire :** Bien que l'on ne connaisse pas tous les effets de la marihuana sur la fonction immunitaire, on soupçonne qu'elle peut avoir un effet défavorable sur le système immunitaire.

Les projets de recherche concernant la marihuana à des fins thérapeutiques pourraient éventuellement permettre de mettre au point de nouveaux produits pharmaceutiques contenant des composantes de la marihuana. Entre-temps, des malades demandent d'avoir accès à la marihuana pour leurs propres fins médicales, particulièrement les malades atteints de maladies graves pour qui les traitements conventionnels offrent peu de soulagement.

Perspective internationale

À l'heure actuelle, la marihuana n'a été homologuée nulle part au monde. Plusieurs pays et certains États américains sont en voie de réexaminer leurs politiques et lois relatives à l'utilisation de

marihuana. Several have already allowed or are considering allowing some form of access to marihuana for medical purposes.

What follows are examples of initiatives currently under way relating to permitting certain medical uses of marihuana and the production and distribution of marihuana for medical purposes, as well as research projects attempting to validate the various medical claims being made for marihuana.

United States

In the United States, several individual states have enacted legislation whereby patients who suffer from certain serious or debilitating medical conditions may be granted authorization to possess marihuana for personal medical use. Patients may also be permitted to grow marihuana for this purpose, since there would otherwise be no legitimate supply.

To date, eight states, including Oregon, Hawaii and Alaska, have enacted laws which authorize the legal possession and medical use of marihuana, even though these laws may conflict with current federal laws.

In January 1997, the White House Office of National Drug Control Policy (ONDCP) asked the Institute of Medicine (IOM) to conduct a review of the scientific evidence to assess the potential health benefits and risks of marihuana and its constituent cannabinoids. That review began in August 1997 and culminated with a report issued in 1999, *Marijuana and Medicine — Assessing the Science Base*. This report provided a summary of current scientific knowledge on the potential medical use of marihuana and is being used to guide medical research not only in the U.S. but around the world.

More recently, on April 18, 2001, the U.S. Drug Enforcement Agency published its denial of a petition to reschedule marihuana. The notice includes a lengthy review of the research; it states that since marihuana has no established medical use, and its harmful and addictive effects are well documented, it will remain a Schedule 1 drug, illegal to manufacture, distribute or dispense in the U.S.

On May 14, 2001, the U.S. Supreme Court ruled that marihuana's classification as an illegal drug is valid in an unanimous (8-0) decision *(United States v. Oakland Buyers Co-operative)*. The judges wrote that, "the statute reflects a determination that marijuana has no medical benefits worthy of an exemption (outside the confines of a government-approved research project)," and noted that Congress has decided that marihuana "has no currently accepted medical use."

While this ruling means that the manufacture and distribution of marihuana continues to be illegal in the U.S., which includes the activities of buyers clubs, co-operatives, compassion clubs and so called "pot pharmacies," it does not directly address or quash state laws or initiatives which permit patients to grow, possess and use marihuana for medical purposes.

Australia

The medical use of marihuana is currently prohibited in all states and territories of Australia. However, the government of New South Wales (NSW) commissioned a report, which was

marihuana à des fins médicales. Certains ont déjà permis ou songent à permettre l'accès à la marihuana à des fins médicales.

Voici quelques exemples d'initiatives actuellement mises en place en ce qui concerne certains usages permis de la marihuana à des fins médicales; la production et la distribution de marihuana à des fins médicales; ainsi que des projets de recherche ayant pour but de valider les diverses allégations médicales relatives à la marihuana.

États-Unis

Aux États-Unis, plusieurs États ont adopté des lois autorisant les patients atteints de certaines maladies graves ou débilitantes à posséder de la marihuana pour leur usage médical personnel. Ces patients peuvent aussi être autorisés à cultiver la marihuana à cette fin, puisqu'il n'y a pas de source d'approvisionnement légitime.

Jusqu'à maintenant, huit États, dont l'Oregon, Hawaï et l'Alaska, ont adopté des lois autorisant la possession et l'utilisation de la marihuana à des fins médicales, même si ces lois vont à l'encontre de certaines lois fédérales en vigueur.

En janvier 1997, le White House Office of National Drug Control Policy (ONDCP) a demandé à l'Institute of Medicine (IOM) d'effectuer un examen des preuves scientifiques afin d'évaluer les effets bénéfiques et les risques possibles liés à la consommation de marihuana et de cannabinoïdes. Cet examen a commencé en août 1997 et a mené à un rapport, *Marihuana and Medicine — Assessing the Science Base*, qui a été publié en 1999. Ce rapport contient une synthèse des connaissances scientifiques actuelles sur les applications médicales possibles de la marihuana et sert aussi à orienter la recherche médicale tant aux États-Unis qu'ailleurs dans le monde.

Plus récemment, le 18 avril 2001, la Drug Enforcement Agency des États-Unis a publié son rejet de la pétition visant à réaffecter la marihuana à une autre annexe de loi. L'avis comprend un examen exhaustif des travaux de recherche; il stipule qu'étant donné l'absence d'usage médical reconnu de la marihuana et les nombreuses études démontrant les effets nocifs et toxicomanogènes de la drogue, celle-ci demeurera inscrite à l'annexe 1 et elle ne pourra pas être fabriquée, distribuée ou délivrée légalement aux États-Unis.

Le 14 mai 2001, la Cour suprême des États-Unis a communiqué sa décision unanime (8-0) dans l'affaire *United States v. Oakland Buyers Co-operative*. Elle a conclu que la classification de la marihuana en tant que drogue illégale est toujours valide. Le juge a écrit que cette décision reflète l'avis que la marihuana ne comporte aucun bienfait médical qui justifie une telle exemption (sinon dans le cadre d'un projet de recherche approuvé par le gouvernement) et que le Congrès américain n'avait reconnu aucun usage médical accepté de la marihuana.

Bien que cette décision signifie que la fabrication et la distribution de la marihuana demeureront illégales aux États-Unis, rendant criminels les clubs d'acheteurs, les coopératives, les clubs de compassion et les soi-disant « pharmacies de marihuana », elle n'intéresse ni ne casse les lois et les initiatives des États qui permettent à des patients de cultiver, de posséder et d'utiliser de la marihuana à des fins médicales.

Australie

L'utilisation de marihuana à des fins médicales est actuellement interdite dans tous les États et territoires de l'Australie. Cependant, le gouvernement de la Nouvelle-Galles du Sud (NGS) a

completed in August 2000, to advise the NSW government on whether to allow patients with certain medical conditions to use *Cannabis* (marihuana). The government of NSW also sought input on how best to allow the medical use of marihuana without promoting the recreational use of the drug. The Working Party on the Use of Cannabis for Medical Purposes made specific recommendations for consideration by the government. These recommendations are now under consideration by the NSW government as it assesses the feasibility of using marihuana for medical purposes.

Netherlands

In December 2000, the Ministry of Health, Welfare and Sport of the Netherlands announced its intention to establish an Office of Medicinal Cannabis on January 1, 2001. The goals of this office are to determine whether marihuana may be useful as a medicine. The office will also be the regulator for the production of *Cannabis* for medical research purposes.

Canada

In June 1999, Health Canada published a document entitled *Research Plan for Marihuana for Medicinal Purposes: A Status Report*. This document set out a research plan for determining the risks and benefits of the use of marihuana for medical purposes. It included the following elements:

- a research agenda composed of projects to address the issues of the safety and efficacy of smoked marihuana and of cannabinoids;
- a mechanism (i.e., section 56 of the CDSA) for medical access to marihuana outside of the research projects; and
- activities to develop a Canadian source of research-grade marihuana.

Since the publication of that document, Health Canada has made significant progress on each element of the research plan. Research projects are being developed, a contract has been awarded for the establishment of a domestic source of research-grade marihuana and approximately 250 exemptions allowing patients to possess and produce marihuana for their personal medical purposes have been granted. These Regulations replace the current exemption process with a formal and more transparent process.

Proposed Regulatory Approach

Due to the health risks associated with the smoked form in particular, and due to the lack of evidence supporting the claimed health benefits, access to marihuana will be granted under these Regulations in special medical circumstances only: serious medical conditions, including terminal diseases, where conventional treatments may not provide adequate symptomatic relief.

The necessity to employ marihuana in any specific patient's case is deemed to be best determined by the medical practitioner as it is for the majority of drugs that are used therapeutically.

These Regulations contain two main components: "authorizations to possess" and "licences to produce".

commandé un rapport (qui lui a été remis en août 2000) dont les auteurs devaient le conseiller quant à l'opportunité d'autoriser ou non les personnes atteintes de certaines maladies à utiliser du cannabis (marihuana). Le gouvernement de NGS a aussi demandé l'avis des auteurs du rapport sur les moyens à prendre pour autoriser l'utilisation de marihuana à des fins médicales sans pour autant en promouvoir la consommation ludique. Le Groupe de travail sur l'utilisation du cannabis à des fins médicales a formulé des recommandations précises. Ces recommandations sont actuellement prises en compte par le gouvernement de NGS étant donné qu'elles évaluent la validité d'utiliser la marihuana à des fins médicales.

Pays-Bas

En décembre 2000, le ministère de la Santé, du Bien-être et du Sport des Pays-Bas a annoncé son intention d'établir un Bureau de l'utilisation du cannabis à des fins médicinales le 1er janvier 2001. Ce bureau aura pour but de déterminer si la marihuana peut être utile comme médicament. Il sera également chargé de réglementer la production de cannabis aux fins de recherches médicales.

Canada

En juin 1999, Santé Canada a publié un document intitulé *Plan de recherche concernant l'usage de la marihuana à des fins médicinales — État de la question*. Ce document présente un plan de recherche visant à déterminer les risques et les effets bénéfiques de l'usage de la marihuana à des fins médicales. Ce plan comprenait les éléments suivants :

- un programme de recherche composé de projets visant à étudier les questions d'innocuité et d'efficacité de la marihuana sous forme de fumée et des cannabinoïdes;
- un mécanisme (c'est-à-dire, article 56 de la *Loi réglementant certaines drogues et autres substances*) d'accès à la marihuana en dehors du cadre de projets de recherche;
- des activités visant à établir une source canadienne de marihuana de qualité contrôlée destinée à la recherche.

Depuis la publication de ce document, Santé Canada a réalisé des progrès importants en ce qui concerne chaque élément du plan de recherche. Des projets de recherche sont élaborés, un contrat a été accordé pour l'établissement d'une source canadienne de marihuana de qualité contrôlée destinée à la recherche, et environ 250 exemptions permettant à des patients de posséder et de cultiver de la marihuana, pour leurs propres fins médicales, ont été accordées. Le règlement remplacera le processus d'exemption actuel par un processus officiel et plus transparent.

Cadre réglementaire proposé

Étant donné les risques pour la santé que comporte la marihuana, surtout pour la forme fumée, et l'absence de données scientifiques confirmant ses vertus thérapeutiques, l'accès à la marihuana ne sera accordé en vertu de ce règlement que dans des circonstances médicales particulières : pour les troubles médicaux graves, y compris les maladies en phase terminale, lorsque les traitements conventionnels sont susceptibles de ne pas offrir un soulagement adéquat des symptômes.

Le médecin praticien est le plus en mesure d'effectuer une détermination de la nécessité d'utiliser la marihuana dans le cas particulier d'un patient tout comme il le fait pour la plupart des médicaments dans le traitement des patients.

Le règlement contient deux composantes principales : « l'autorisation de posséder » et la « licence de production ».

Authorization to Possess

- An authorization to possess marihuana for medical purposes will be issued by Health Canada. The application requirements to obtain an authorization to possess will depend on the category under which the request is made. The requirements will range from minimal, in the case of terminal illness situations, to more substantive for non-terminal illness cases where little or no conclusive scientific evidence exists.
- All applications will be submitted by the patient, but must include a declaration from the patient's medical practitioner. Depending on the category under which the application is being made, support from a medical specialist may be required. These Regulations set out three categories.
- Category 1 is for patients who have terminal illnesses with a prognosis of death within 12 months. In this situation, the Regulations provide a less demanding process to obtain the authorization to possess because the risks associated with long-term use are not a major consideration. The Regulations will allow for one renewal under this category should the prognosis be inaccurate. Any subsequent renewals would have to be made under another category.
- Category 2 is for patients who suffer from specific symptoms associated with some serious medical conditions (examples include weight loss in patients with AIDS/HIV in a non-terminal situation; persistent muscle spasms in multiple sclerosis). These symptoms are listed in a schedule to the Regulations. Symptoms associated with serious medical conditions in this category have been selected based on the outcome or conclusions of scientific and medical reports from medical organizations that have performed a review of available scientific literature (for example the IOM report previously mentioned). These reports confirm the existence of a certain amount of inconclusive scientific evidence to indicate a potential benefit but raise caution on the known risks of using a smoked form, particularly with respect to long term use. Seizures associated with epilepsy has been added to the list of symptoms in the schedule to the Regulations in view of the findings in the Parker case. Though the application under this category is to be submitted by the patient, specific statements from a medical specialist are required in support of the application. These statements include, among other things, that conventional treatments have been tried or at least considered and found not medically appropriate for the reasons outlined in the Regulations.
- Category 3 is for patients who have symptoms associated with medical conditions other than those in the other two categories. For this category, although the application will be submitted by the patient, specific statements from two medical specialists are required in support of the application. This is necessary since less conclusive scientific evidence exists supporting the use of marihuana in the treatment of symptoms associated with medical conditions not included in Category 2. All conventional therapies should have been tried or at least considered and found not medically appropriate for the reasons outlined in the Regulations. The list of therapies tried or

Autorisation de posséder

- Une autorisation de posséder de la marihuana à des fins médicales sera accordée par Santé Canada. Les exigences relatives à la demande d'autorisation de posséder dépendront de la catégorie dans laquelle la demande est présentée. Les exigences seront minimales dans le cas de maladies en phase terminale et seront plus importantes dans les cas de maladies non mortelles, pour lesquelles peu de données concluantes sur le plan scientifique sont disponibles, voire aucune.
- Toutes les demandes seront soumises par le patient, mais elles devront comprendre une déclaration en bonne et due forme du médecin praticien. Selon la catégorie dans laquelle la demande est présentée, l'appui d'un médecin spécialiste pourra être nécessaire. Le règlement expose les trois catégories.
- La catégorie 1 est destinée aux patients atteints d'une maladie en phase terminale et dont le pronostic évalue la mort dans un délai de douze mois. Dans une telle situation, le processus prévu par le Règlement pour l'obtention d'une autorisation de posséder est moins exigeant que dans les autres catégories puisque le risque de dangers associés à l'utilisation à long terme pour le patient n'existe pas. Le règlement permettra un renouvellement dans cette même catégorie, dans les cas où le pronostic s'est avéré inexact. Tout autre renouvellement devra être présenté dans une autre catégorie.
- La catégorie 2 est destinée aux patients qui souffrent de symptômes particuliers associés à certains troubles médicaux graves (p. ex., la perte de poids chez les patients atteints du VIH/sida, dont la vie n'est pas menacée à court terme; et les spasmes musculaires constants chez les patients atteints de sclérose en plaques). Ces symptômes sont énumérés dans une annexe au règlement. Les symptômes associés aux troubles médicaux graves de cette catégorie ont été choisis en fonction des résultats ou des conclusions de rapports scientifiques et médicaux effectués par des organismes médicaux ayant procédé à un examen de la documentation scientifique disponible, par exemple le rapport de l'IOM dont on a parlé plus tôt. Ces rapports confirment l'existence d'un certain nombre de données peu concluantes sur le plan scientifique et indiquant un effet bénéfique possible, mais ils invitent à la prudence en raison des risques connus de la consommation sous forme de fumée, en particulier dans les cas d'usage à long terme. Les crises associées à l'épilepsie ont été ajoutées à la liste de symptômes figurant en annexe du règlement compte tenu des conclusions de l'affaire Parker. Bien que la demande dans cette catégorie doive être soumise par le patient, des déclarations précises provenant d'un médecin spécialiste sont nécessaires pour appuyer la demande. Ce spécialiste doit, entre autres, déclarer que les traitements conventionnels ont été essayés ou du moins envisagés et qu'ils ont été jugés inappropriés du point de vue médical pour les raisons exposées dans le règlement.
- La catégorie 3 est destinée aux patients ayant des symptômes associés à des troubles médicaux autres que ceux des deux premières catégories. Pour cette catégorie, bien que la demande doive être soumise par le patient, des déclarations précises de deux médecins spécialistes sont nécessaires pour appuyer la demande. Ceci est nécessaire puisqu'il y a encore moins de données concluantes sur le plan scientifique qui supportent la consommation de la marihuana pour le traitement des symptômes associés à des conditions médicales ne faisant pas partie de la catégorie 2. Tous les traitements conventionnels doivent avoir été essayés ou du moins envisagés

considered will have to be submitted with the reasons as to why they were found medically inappropriate.

- For all three categories, the authorization to possess marihuana for a medical purpose will specify a maximum quantity of marihuana equal to a 30-day treatment supply at any given time. Quantity of supply will be continuously refurbished by quantities produced under the licence to produce. The daily dosage that determines the 30-day treatment supply is provided by the physician and will be subject to additional requirements when proposed dosage exceeds a quantity of 5 grams per day.

Licence to Produce

- A licence to produce marihuana will be issued to either the patient or a representative that the patient designates in the application. A representative cannot be designated by more than one patient. One site may, however, be used for the production of marihuana under a maximum of three separate licences. The licence will authorize and specify the production of a maximum number of plants, and whether they will be grown outdoors or indoors. This will allow flexibility when choosing a growing location and will accommodate the different yields produced by indoor and outdoor growing methods. The number of plants will be dependent upon the patient's daily dosage identified by the physician.
- The licence will also allow for storage and, in the case of a designated person, transportation of marihuana to the patient if the production is conducted at a site other than the patient's residence.
- The licence holder, whether the patient or his/her designated person, must take reasonable precautions to protect his/her plants and the dried marihuana in storage from loss or theft. The type of precautions to be taken are not specified in the Regulations, but will be left to the reasonable discretion of the licence holder.
- A criminal record check will be requested from the person designated by a patient to produce marihuana on his/her behalf. The designated person will not be eligible if he/she has been found guilty of a designated drug offence in the previous ten years. This requirement is not imposed on the patient.

Other Provisions

- The disclosure to police of information concerning the holder of an authorization to possess and the holder of a licence to produce will require the voluntary consent of the holder of the authorization or licence to produce. The Regulations allow for referral to police of complaints received by Health Canada inspectors. Furthermore, provisions also exist to disclose information on medical practitioners to provincial licensing authorities of medicine when requested for a lawful investigation by these authorities.
- Transitional provisions will extend the section 56 exemptions in effect at the time the Regulations come into force for an extra (6 months). As well, the coming into force date for these Regulations will be changed from July 15, to July 30, 2001, to

et avoir été jugés inappropriés du point de vue médical pour les raisons exposées dans le règlement. La liste de traitements essayés ou envisagés devra être soumise ainsi que les raisons pour lesquelles ils ont été jugés inappropriés du point de vue médical.

- Pour les trois catégories, l'autorisation de posséder de la marihuana pour une raison médicale précisera une quantité maximale de marihuana, équivalente à l'approvisionnement nécessaire pour trente jours de traitement, qui devra être respectée en tout temps. L'approvisionnement sera continuellement renouvelé à même les quantités produites en vertu de la licence de produire. La posologie quotidienne permettant de déterminer l'approvisionnement nécessaire pour trente jours de traitement est fixée par le médecin et sera soumise à des exigences additionnelles si la posologie proposée dépasse cinq grammes par jour.

Licence de production

- Une licence de production de marihuana sera délivrée au patient ou à la personne que le patient aura désignée dans sa demande pour le remplacer. Cependant, une personne qui aura été désignée, ne peut l'être pour plus d'un patient. Un site de production pourra cependant être utilisé pour la production de marihuana pour un nombre maximum de trois licences individuelles. La licence autorisera et décrira la production d'un nombre de plants maximal précis, et elle expliquera si les plants seront cultivés à l'extérieur ou à l'intérieur. Cela assurera une plus grande flexibilité au moment de choisir le lieu de culture et permettra de tenir compte du rendement des différentes méthodes de culture à l'intérieur et à l'extérieur. Le nombre de plants sera en fonction de la posologie quotidienne du patient inscrite par le médecin. La licence autorisera également l'entreposage et, dans le cas où une personne aurait été désignée, le transport de la marihuana jusqu'au domicile du patient si le lieu de production est autre que ce domicile.
- Le titulaire de la licence, qu'il s'agisse du patient ou d'une personne désignée, devra prendre des précautions raisonnables pour protéger de la perte ou du vol les plants et la marihuana séchée entreposée. Le type de précautions à prendre n'est pas précisé dans le règlement, qui laisse ainsi au titulaire de la licence le soin d'en décider.
- La personne que le patient aura désignée pour produire la marihuana en son nom devra se soumettre à une vérification de casier judiciaire. Cette personne ne sera pas acceptée si l'on constate qu'elle a été reconnue coupable d'une infraction désignée en matière de drogue au cours des dix dernières années. Cette exigence ne s'applique pas au patient.

Autres dispositions

- La divulgation à la police de renseignements concernant le titulaire d'une autorisation de possession ou d'une licence de production ne pourra être effectuée qu'avec le consentement du détenteur d'une autorisation ou d'une licence de production. Le règlement autorise également le renvoi à la police de plaintes reçues par les inspecteurs de Santé Canada. De plus, certaines dispositions prévoient la divulgation de renseignements sur les médecins aux autorités provinciales chargées d'accorder le permis d'exercer la médecine lorsque celles-ci en font la demande afin de mener une enquête conforme à la loi.
- Les dispositions transitoires feront que les exemptions existant au moment de l'entrée en vigueur du règlement

allow the maximum amount of time for patients and physicians to become familiar with the new requirements.

- Instead of making the related regulatory amendments to the *Narcotic Control Regulations* (NCR) as described in the Regulations which were pre-published in the *Canada Gazette*, Part I, upon further consideration, it is deemed more appropriate to include the necessary provisions within the *Marihuana Medical Access Regulations* (MMAR) and make minimal changes to the NCR. These provisions allow for the potential supply of marihuana to an authorized person where the marihuana is obtained legally under the NCR or MMAR.

Alternatives

The options outlined below provide an overview of the regulatory alternatives that were considered prior to the selection of Option 1 as detailed in this Regulatory Impact Analysis Statement (RIAS).

***Option 1*:** Develop new Regulations under the CDSA, distinct from the *Narcotic Control Regulations*, providing a system of special authorizations and licences permitting individual patients to possess and produce marihuana for the relief of symptoms associated with serious medical conditions or the treatment of these conditions.

Pros: Easier for the public to consult and understand as stand-alone Regulations; control measures of the new regulatory scheme will deal exclusively with the issues relating to access to marihuana for medical purposes; the resulting Regulations will be less complicated than attempting to incorporate these measures in existing Regulations; the regulatory regime could be established within the time available.

Cons: Creates two sets of Regulations under the CDSA that apply to marihuana; linkages required between Regulations create slight risk of confusion on some aspects.

***Option 2*:** Amend existing *Narcotic Control Regulations* (NCR) to provide a system of special authorizations and licences to permit individual patients to possess and produce marihuana for the relief of symptoms associated with serious medical conditions or the treatment of these conditions.

Pros: All Regulations relating to marihuana would be within one set of Regulations.

Cons: Necessary modifications to address marihuana for medical use would require extensive consultation to modernise the whole regulatory framework to accommodate the new provisions; time required to accomplish all this exceeds time available to implement new approach; the structure of the NCR does not easily lend itself to the addition of the proposed scheme; the amended NCR could become too complicated.

***Option 3*:** Amend the CDSA to include a part dealing with access to marihuana for medical purposes.

Pros: Provides greater flexibility in the design and drafting of the regulatory scheme.

Cons: Cannot be completed within the time available; Regulatory schemes are not usually included in the Act itself; more difficult to amend when necessary to adapt to new information.

seront appliquées pendant 6 mois supplémentaires. En outre, ce règlement entrera en vigueur le 30 juillet plutôt que le 15 juillet 2001 pour permettre aux patients et aux médecins d'avoir le plus de temps possible pour se familiariser avec les nouvelles exigences.

- Au lieu de faire certaines modifications corrélatives mineures à l'actuel *Règlement sur les stupéfiants* tel que suggéré au moment de la publication préalable dans la *Gazette du Canada* Partie I, il a été jugé préférable d'apporter certaines modifications au sein du *Règlement sur l'accès à la marihuana* à des fins médicales. Ceci en vue de permettre la distribution légale de marihuana aux personnes qui détiennent une autorisation de possession de marihuana soi sous le *Règlement sur les stupéfiants* ou le *Règlement sur l'accès* à *la marihuana* à *des fins médicales*.

Options envisagées

Les options décrites ci-dessous donnent un aperçu des autres approches réglementaires qui ont été étudiées avant que l'option 1 détaillée dans le présent Résumé de l'étude d'impact de la réglementation (RÉIR) ne soit retenue.

Option 1 : Élaborer de nouveaux règlements en vertu de la LRCDAS, différents du *Règlement sur les stupéfiants*, qui établiraient un système d'autorisations et de licences spéciales permettant à certains patients, à titre personnel, de posséder et de cultiver de la marihuana pour le soulagement des symptômes associés à certaines maladies graves ou à leur traitement.

Le pour : Nouveau régime réglementaire plus facile à consulter et à comprendre pour le public s'il ne porte uniquement que sur les mesures de contrôle visant la question de l'accès à la marihuana à des fins médicales; le règlement sera moins complexe, contrairement à une inclusion des mesures dans des règlements déjà en place. Les mesures pourront être mises en place dans le délai prévu.

Le contre : On crée une autre série de règlements en vertu de la LRCDAS; l'harmonisation des différents règlements risque d'engendrer un peu de confusion sur certains aspects.

Option 2 : Modifier le *Règlement sur les stupéfiants* actuel en y incorporant un système d'autorisations et de licences spéciales qui permettrait aux patients de posséder et de produire de la marihuana à titre personnel pour le soulagement des symptômes associés à certaines maladies graves ou à leur traitement.

Le pour : Tous les règlements relatifs à la marihuana figureraient dans la même série de règlements.

Le contre : Les modifications requises concernant l'utilisation de marihuana à des fins médicales nécessiteraient la tenue de vastes consultations pour moderniser l'ensemble de la réglementation de manière à tenir compte de nouvelles dispositions; le temps qu'il faudrait pour les mener à terme dépasserait le délai accordé pour la mise en place d'une nouvelle approche; la structure du *Règlement sur les stupéfiants* ne se prête pas facilement à l'inclusion des mesures proposées et celui-ci deviendrait trop compliqué une fois modifié.

***Option 3* :** Modifier la *Loi réglementant certaines drogues et autres substances* en ajoutant une partie sur l'accès à la marihuana pour raisons médicales.

Le pour : Offre plus de latitude pour la conception et l'élaboration du plan de réglementation.

Le contre : Ne peut être fait dans les délais impartis; il n'est pas d'usage d'inclure le plan de réglementation dans la loi

Each option was assessed against the following screening criteria. These criteria or considerations represent required outcomes or characteristics of the new regulatory approach for marihuana for medical purposes. The regulatory approach must:

- meet the mandatory requirements of all international drug control Conventions, to the extent possible, in consideration of the *Canadian Charter of Rights and Freedoms*;
- be developed and implemented by July 31, 2001;
- be clear and easy to implement, administer and enforce;
- not unduly restrict the availability of marihuana to patients who may receive health benefits from its use; and
- minimize any increase in regulatory burden on patients, medical practitioners, medical licensing authorities, and enforcement agencies.

Option 1 was determined to be the preferred option as it is the only option that meets all of the screening criteria for selection. It will create the most comprehensive and transparent process.

Benefits and Costs

Health Canada's exemption process operating under section 56 of the CDSA has been in place since May 1999. The new regulatory approach has been developed based on experience gained over the past two years. Under the new regulatory scheme, patients and medical practitioners who are already familiar with the requirements under the current system are offered a more transparent and less discretionary regulatory mechanism under which legitimate patients may obtain permission to possess and grow marihuana for their own medical purposes.

A Business Impact Test was not conducted on this proposal. The activities allowing possession and production of marihuana for medical purposes are already being performed by Health Canada. Accordingly, the added cost and delay to conduct a Business Impact Test is deemed not to be warranted.

The cost of administering the current section 56 exemption process is borne by Health Canada, as the regulator. Similarly, the costs of the new authorization and licensing program will, at least initially, be borne by Health Canada. The costs of administering the new regulatory system will be reassessed following its implementation. No cost-recovery initiative would be contemplated without further consultation with stakeholders.

These Regulations are expected to impact on the following sectors:

Public

Canadian patients, who suffer from serious medical conditions including terminal illnesses, whose symptoms may be relieved through the use of marihuana may qualify for authorization to possess marihuana and may also be granted a licence to produce marihuana for their own medical use. In addition, if a patient is

elle-même; modifications plus difficiles s'il est nécessaire de tenir compte de nouveaux renseignements.

Chacune de ces options a été évaluée en fonction des critères obligatoires suivants. Ces critères ou considérations reposent sur les résultats ou les caractéristiques nécessaires de la nouvelle approche réglementaire relative à l'utilisation de marihuana à des fins médicales. Les mécanismes de contrôle doivent :

- satisfaire dans la mesure du possible aux exigences obligatoires de toutes les conventions internationales sur le contrôle des drogues, en tenant compte des facteurs liés à la *Charte des droits et libertés*;
- être définis et mis en place au plus tard le 31 juillet 2001;
- être clairs et faciles à mettre en place, à administrer et à faire respecter;
- ne pas limiter indûment l'accès à la marihuana pour les patients chez qui son utilisation peut être bénéfique;
- réduire au minimum l'augmentation du fardeau réglementaire pour les patients, les médecins praticiens, les organismes chargés d'octroyer les permis d'exercice de la médecine et les forces de l'ordre.

L'option 1 a été retenue parce que c'est la seule qui satisfait à tous les critères obligatoires de sélection. Elle permettra la mise en place de la procédure la plus globale et la plus transparente.

Avantages et coûts

Le programme d'exemption de Santé Canada en vertu de l'article 56 de la LRCDAS est en place depuis mai 1999. La nouvelle approche réglementaire repose également sur l'expérience acquise au cours des deux dernières années. Les patients et les médecins praticiens qui connaissent déjà bien les exigences imposées en vertu du système actuel se voient offrir un mécanisme de réglementation plus transparent et plus officialisé dans le cadre duquel les patients ayant des besoins légitimes pourront obtenir la permission de posséder et de cultiver de la marihuana à des fins médicales.

Aucun test de l'impact sur les entreprises n'a été effectué au sujet de cette proposition principalement parce qu'il existe déjà des activités autorisant la possession et la culture de marihuana à des fins médicales coordonnées par Santé Canada. Par conséquent, il ne serait pas justifié d'effectuer un test de l'impact sur les entreprises, vu son coût et le temps qu'il faudrait pour le réaliser.

Les coûts d'administration du programme d'exemption en vertu de l'article 56 sont maintenant assumés par l'organisme de réglementation, c'est-à-dire Santé Canada. Il en sera de même des coûts associés au nouveau programme d'autorisation et de délivrance des licences, du moins au début. On réévaluera le coût de l'administration du nouveau système de réglementation après sa mise en place. Aucune initiative en matière de récupération des coûts ne sera envisagée sans avoir préalablement consulté les parties intéressées.

Le règlement devrait avoir un impact sur les secteurs suivants :

Public

Les patients canadiens atteints de maladies en phase terminale ou d'autres affections médicales graves et dont les symptômes peuvent être soulagés par l'utilisation de la marihuana pourront se voir autoriser à posséder de la marihuana et pourront se voir accorder une licence pour produire de la marihuana à des fins

not able to produce the marihuana, an alternate may be designated to perform this function on his/her behalf, again under licence. The regulatory framework defines what activities are permitted. Since patients will be permitted to possess and produce marihuana it may occur that these activities will be performed where they may conflict with the rights of others. Patients may need to be cautioned to avoid, for example, smoking marihuana in public places, near children or any place where others might be exposed to the second-hand smoke without prior consent.

Licensed Dealers

These Regulations will not impact on licensed dealers of controlled substances.

Pharmaceutical Industry

These Regulations will not impact the Canadian pharmaceutical industry in general, since only personal possession and production are addressed.

Practitioners

Activities of practitioners will be affected by these Regulations. There will be some increase in administrative activity for medical practitioners resulting from the necessity to provide a supporting medical declaration as part of the application.

In certain cases, additional statements or evidence may need to be submitted to support the application. This is due in part to the fact that the medical benefits of using marihuana in the treatment of symptoms associated with certain medical conditions have not been scientifically proven. The other reason is that the health risks associated with the use of marihuana, particularly in smoked form, make it essential for a medical practitioner to be involved in making this medical decision. In certain cases, the statements must be supplied by a medical specialist.

Pharmacists

Activities of pharmacists will not be affected by these Regulations. The potential involvement of pharmacists, either at the retail or hospital level, in the distribution of marihuana to patients who hold authorizations to possess marihuana will be contemplated in the future. Pharmacists could eventually play a key role in the distribution of marihuana products as they do today for pharmaceutical drugs.

Hospitals

Activities of hospitals should not be significantly affected by these Regulations.

A patient holding an authorization to possess and/or licence to produce marihuana may reside in a hospital or other health care institution. The decision to allow a patient to possess and/or grow marihuana within the institution remains the decision of that institution.

médicales. De plus, si un patient n'est pas en mesure de produire de la marihuana, un remplaçant qui assumera cette fonction en son nom pourra être désigné, encore une fois en vertu d'une licence. Le cadre de réglementation définit les activités qui sont permises. Puisque les patients seront autorisés à posséder ainsi qu'à cultiver de la marihuana, on peut prévoir la possibilité que ces activités entreront en contradiction avec les droits d'autres personnes. Il faudra mettre en garde les patients afin qu'ils évitent, par exemple, de consommer de la marihuana dans des endroits publics, à proximité d'enfants ou dans n'importe quel lieu où d'autres personnes pourraient être exposées à la fumée découlant de la consommation de marihuana sans avoir donné leur consentement au préalable.

Distributeurs autorisés

Les présentes dispositions réglementaires n'auront pas d'impact sur les distributeurs autorisés de substances contrôlées.

Industrie pharmaceutique

Les présentes dispositions réglementaires n'auront aucun impact sur l'industrie pharmaceutique canadienne en général, puisqu'elles ne visent que la possession et la production personnelles de marihuana.

Praticiens

Les présentes dispositions réglementaires auront un impact sur les activités des praticiens. Les médecins praticiens devront faire face à une augmentation des activités administratives étant donné que toutes les demandes d'autorisation devront être appuyées par une déclaration médicale.

Dans certains cas, le praticien pourrait avoir à soumettre des déclarations ou des preuves supplémentaires à l'appui de la demande. L'une des raisons à cela est le fait que les bienfaits de l'usage de la marihuana à des fins médicales pour le traitement des symptômes associés à certaines affections n'ont pas été scientifiquement prouvés. L'autre raison est que cette décision médicale qui doit être prise par un médecin praticien doit tenir compte des risques pour la santé associés à l'utilisation de la marihuana, particulièrement lorsqu'elle est fumée. Parfois, cette information devra être fournie par un spécialiste.

Pharmaciens

Les présentes dispositions réglementaires n'auront aucun impact sur les activités des pharmaciens. On se penchera dans l'avenir sur le rôle que pourraient avoir à jouer les pharmaciens, au niveau des pharmacies ou des hôpitaux, dans la distribution de la marihuana aux patients qui détiennent une autorisation d'en posséder. Les pharmaciens pourraient jouer un rôle clé dans la distribution des produits de la marihuana, tout comme il le font actuellement pour les produits pharmaceutiques.

Hôpitaux

Les dispositions réglementaires devraient avoir peu d'impact sur les hôpitaux.

Le patient titulaire d'une autorisation de posséder de la marihuana et/ou d'une licence pour en produire pourrait, à un moment donné, être admis dans un hôpital ou dans un autre établissement de santé. Il n'en tiendra qu'à cet hôpital ou établissement de décider s'il permettra à un patient de consommer et/ou de cultiver de la marihuana à l'intérieur de ses murs.

Correctional Institutions

As is the case for hospitals, the decision to allow an inmate to possess and/or grow marihuana within the penitentiaries, jails and other correctional institutions remains the decision of each institution.

Researchers

These Regulations do not affect the activities of researchers.

Canada Customs and Revenue Agency

These Regulations do not permit a patient to import or export marihuana for medical or any other purpose. Existing provisions under the CDSA continue to apply as before, prohibiting any person from importing or exporting marihuana. Although patients who hold authorizations to possess marihuana may attempt to take marihuana out of the country, this activity remains illegal. Customs officials may experience some increase in incidents involving marihuana. Clear guidelines to patients will be necessary to avoid such problems.

Law Enforcement Agencies

Police forces recognize that a regulatory system of authorizations and, at this time, licences to produce for personal medical purposes is required so that legitimate patients may have access to marihuana from a legal source. While Health Canada will manage the activities of authorizations and licences, the police will continue to investigate and enforce the provisions of the CDSA where activities are not permitted under an authorization or licence.

Health Canada

The regulatory scheme will ensure that authorizations are granted for legitimate medical reasons and that any production is done under licence. There will be increased costs to Health Canada associated with implementation of the Regulations, the processing of applications for authorizations and licences and the establishment and maintenance of relevant files and databases. Costs will also be incurred to develop guidelines and forms to support these Regulations as well as to establish a process for providing on-going information to patients, medical practitioners and the general public. There will also be costs associated with administration, investigation, inspection and reporting.

Ongoing impact on Health Canada is difficult to predict since the numbers of potential applicants is unknown at this time. Approximately 250 exemptions for medical purposes have been granted under the existing section 56 exemption process. Due to anticipated increased visibility and efficiency of the new regulatory scheme and increased awareness of the potential uses or medical benefits of marihuana, it can reasonably be expected that the numbers of applicants will increase significantly. As is the case with marihuana access programs operating in several of the States in the U.S., registration fees could eventually be imposed to recover some of the costs of administering these new Regulations in Canada. User fees, however, would not be instituted without a complete analysis of both the costs of delivering the program and the impact of fees on stakeholders.

Établissements de correction

À l'instar des hôpitaux, il n'en tiendra qu'aux prisons et autre établissement de correction de décider de permettre à un détenu de consommer et/ou de cultiver de la marihuana à l'intérieur de ses murs.

Chercheurs

Les présentes dispositions réglementaires n'auront aucun impact sur les activités des chercheurs.

Agence des douanes et du revenu du Canada

Les présentes dispositions réglementaires ne permettront pas à un patient d'importer ou d'exporter de la marihuana pour des raisons médicales ou pour toute autre raison. Les dispositions actuelles de la LRCDAS continuent de s'appliquer comme avant, interdisant à quiconque d'importer ou d'exporter de la marihuana. Bien que les patients qui détiennent une autorisation de posséder de la marihuana puissent tenter de se procurer le produit à l'extérieur du pays, cette activité est illégale. Les fonctionnaires des douanes pourraient faire face à une augmentation des incidents mettant en cause de la marihuana. Il faudra donc donner des directives claires aux patients afin d'éviter ce genre de problème.

Organismes d'application de la loi

Les forces policières reconnaissent qu'on a besoin d'un système de réglementation des autorisations et, à ce stade, des licences pour la production de marihuana à des fins médicales personnelles, de sorte que les patients ayant des besoins légitimes aient accès à la marihuana de source licite. Bien que Santé Canada fera l'administration du programme d'autorisations et de licences, la police continuera de procéder à des enquêtes et d'appliquer les dispositions de la LRCDAS lorsque certaines activités ne feront pas l'objet d'une autorisation ou d'une licence.

Santé Canada

Le système de réglementation fera également en sorte que les autorisations soient accordées pour des raisons médicales légitimes et que toute production se fasse en vertu d'une licence. On prévoit, pour Santé Canada, une augmentation des coûts associés au traitement des demandes d'autorisation et de licence ainsi qu'à l'établissement et à la tenue de dossiers et de bases de données connexes. Le ministère devra aussi assumer les coûts de l'élaboration de lignes directrices et de formulaires à l'appui de ces dispositions réglementaires et de l'établissement d'une procédure pour fournir des renseignements de manière continue aux patients, médecins praticiens et au public en général. Par ailleurs, l'administration, les enquêtes, les inspections et l'établissement de rapports engendreront aussi des coûts.

Il est difficile de prévoir l'impact de la réglementation sur Santé Canada, à la longue, puisque le nombre de demandeurs potentiels est encore inconnu. À l'heure actuelle, environ 250 exemptions à des fins médicales ont été accordées en vertu de l'article 56. Vu que le nouveau système de réglementation attirera une plus grande attention et qu'il sera plus efficace, et vu que la population sera plus sensibilisée aux applications et bienfaits possibles de la marihuana sur le plan médical, on peut raisonnablement s'attendre à une augmentation considérable du nombre de demandeurs. Comme c'est le cas avec les programmes d'accès à la marihuana dans plusieurs États américains, on pourrait éventuellement imposer des frais d'inscription afin de recouvrer une partie des coûts liés à l'administration de ce nouveau

règlement au Canada. Cependant, on ne mettrait pas en place des tickets modérateurs sans avoir préalablement analysé en profondeur les coûts de l'exécution du programme et l'impact des tickets modérateurs sur les parties intéressées.

Consultation

This regulatory framework was developed on the basis of consultation with stakeholders.

In response to requests from individual patients who requested access to marihuana for medical purposes, Health Canada, in consultation with health professionals and legal advisors, developed a process for exemptions for medical purposes under the authority provided in section 56 of the CDSA. The first exemption was issued in June 1999.

On October 6, 1999, Health Canada issued a *News Release*, *Update on Health Canada's initiatives on marijuana for medical and research purposes*. A specific commitment to public consultation was made in relation to the section 56 exemption program.

On February 28, 2000, a multi-stakeholder consultation workshop was held by Health Canada to:

- inform stakeholders of the current status of the section 56 exemption process, Health Canada's research plan for the medical use of marihuana, and activities undertaken related to the supply issue of research-grade marihuana;
- seek feedback from stakeholders on issues related to use of marihuana for medical purposes; and
- provide stakeholders with an opportunity to exchange views on issues related to the use of marihuana for medical purposes.

The following priority issues were identified by the workshop participants:

- Obtaining a legal source of marihuana for section 56 exemptees;
- Exemptions for caregivers;
- Addressing the need for more information on the use of marihuana for medical purposes;
- Addressing concerns of law enforcement agencies;
- Improvement of the process and tools for section 56 applications;
- Communications regarding section 56 process and Health Canada's activities regarding marihuana for medical purposes.

Input resulting from the February 2000 workshop has not only been used to refine the existing section 56 exemption process, it has also provided an important basis for the development of the new regulatory approach. The workshop is therefore considered to have been very useful in terms of early consultation for the new framework.

While not a consultative process, the direction provided in the decision of the Court of Appeal for Ontario in the case of *R. v. Parker*, rendered on July 31, 2000, also provided valuable guidance for the development of a formal regulatory structure.

Consultations

Le présent cadre réglementaire a été élaboré à partir des consultations menées auprès des intéressés.

En réponse aux demandes de patients qui souhaitaient avoir accès à la marihuana à des fins médicales, Santé Canada, en consultation avec des professionnels de la santé et des conseillers juridiques, a élaboré un processus d'exemptions accordées en vertu de l'article 56 de la LRCDAS. La première exemption a été accordée en juin 1999.

Le 6 octobre 1999, Santé Canada a diffusé un Communiqué intitulé *Initiatives de Santé Canada quant à l'utilisation de la marihuana à des fins médicales et à des fins de recherche*. Dans ce communiqué, le ministère s'engageait à consulter le public au sujet du programme d'exemption prévu par l'article 56.

Le 28 février 2000, un atelier de consultation multilatérale a été organisé par Santé Canada dans le but :

- d'informer les intéressés de l'état actuel d'avancement du processus d'exemption en vertu de l'article 56, du plan de recherche de Santé Canada concernant l'utilisation de la marihuana à des fins médicales et des activités entreprises en ce qui concerne l'approvisionnement en marihuana de qualité contrôlée, propre à la recherche;
- d'obtenir les commentaires des intéressés au sujet des questions liées à l'utilisation de la marihuana à des fins médicales, et
- de donner aux intéressés l'occasion d'échanger leurs points de vue sur les questions se rattachant à l'utilisation de la marihuana à des fins médicales.

Les participants à l'atelier ont relevé les questions prioritaires suivantes :

- obtention d'une source de marihuana légale pour les personnes exemptées en vertu de l'article 56;
- exemptions aux dispensateurs de soins;
- réponse au besoin d'information accrue sur l'utilisation de la marihuana à des fins médicales;
- réponse aux préoccupations des organismes d'exécution de la loi;
- amélioration du processus et des outils de traitement des demandes présentées en vertu de l'article 56;
- communications relatives au processus de l'article 56 et aux activités de Santé Canada concernant l'accès à la marihuana à des fins médicales.

Les commentaires exprimés lors de l'atelier de février 2000 ont non seulement servi à apporter des améliorations au programme d'exemption en vertu de l'article 56, mais ont aussi constitué une importante base à partir de laquelle la nouvelle approche réglementaire a été élaborée. L'atelier s'est donc révélé fort utile à titre de consultation préliminaire pour le nouveau cadre de réglementation.

Bien qu'elle n'ait rien à voir avec le processus de consultation, la décision rendue le 31 juillet 2000 par la Cour d'appel de l'Ontario, dans l'affaire *R. c. Parker*, a aussi permis de dégager des orientations intéressantes pour l'élaboration de la nouvelle structure de réglementation officielle.

A Notice of Intent was published in the *Canada Gazette*, Part I, on January 6, 2001, announcing Health Canada's intention to develop a regulatory approach for Canadians to access marihuana for medical purposes. Some comments were received as a result, which were considered in developing these Regulations.

Meetings were held with key stakeholders regarding the proposed regulatory scheme as part of the policy development process. These included meetings with representatives from the Canadian Medical Association, the Canadian Pharmacists Association, the Canadian AIDS Society, the RCMP, Solicitor General Canada, Department of Justice Canada, Correctional Service Canada, and the Canadian Association of Chiefs of Police.

The proposed Regulations were pre-published in the *Canada Gazette*, Part I, on April 7, 2001, followed by a 30-day comment period. Comments were received from 139 individuals and organizations. An analysis of the responses received indicates: 4% were fully supportive of the proposal; 42% were generally supportive and provided detailed constructive comments; 41% opposed the proposal and offered no constructive comments; and 14% were non-committal. It should be noted that 75% of those opposed to the regulatory proposal were supporters of the BC Marijuana Party. They faxed in form letters advocating the general legalization of marihuana for recreational and medical use, "without prior consent of any governing body". General legalization is, of course, outside the scope of this regulatory initiative.

Comments were received from two physicians, two medical associations and two provincial medical licensing authorities. Although a number of constructive comments were provided by these stakeholders, the medical associations and licensing authorities oppose the use of smoked marihuana for medical purposes. Their reasons included: the lack of scientific evidence supporting its use; the fact that marihuana is not an approved drug product; the use of smoked marihuana is not an acceptable form of drug administration; and the responsibility on doctors to support the use of marihuana for medical purposes may place them in conflict with professional conduct rules relating to the use of unapproved or "alternative" medicines. The last point was also a concern expressed by many individuals.

Previous consultations and comments received from enforcement agencies have indicated that they seek clarity and recognize the need for the regulatory framework. Their ongoing concerns relate primarily to the ability of police officers to determine with

Le 6 janvier 2001, un Avis aux intéressés a été publié dans la *Gazette du Canada* Partie I. Cet avis annonçait l'intention de Santé Canada d'élaborer une nouvelle approche réglementaire pour que les Canadiens aient accès à la marihuana à des fins médicales. Les commentaires reçus à la suite de cet avis seront pris en considération dans l'élaboration du présent règlement.

Dans le cadre du processus courant d'élaboration de politiques, des réunions ont eu lieu avec des intéressés clés au sujet du nouveau projet de réglementation. Ces réunions ont été tenues avec des représentants des organisations suivantes : l'Association médicale canadienne, l'Association des pharmaciens du Canada, la Société canadienne du sida, la GRC, Solliciteur général Canada, Justice Canada, Service correctionnel Canada et l'Association canadienne des chefs de police.

La publication préalable du projet de règlement dans la *Gazette du Canada* Partie I, sera suivie d'une période de consultation de 30 jours. À ce moment-là, les intéressés seront avisés par les voies de communication habituelles en plus d'une annonce publique. Les commentaires reçus seront pris en compte lors de la rédaction de la version finale du règlement.

Santé Canada mettra à la disposition des médecins praticiens, des patients et des forces de l'ordre des documents d'orientation et de l'information concernant l'utilisation de la marihuana à des fins médicales. On tiendra compte des observations formulées de façon continue par les intéressés pour améliorer le système de réglementation.

La publication préalable du projet de règlement dans la *Gazette du Canada* Partie I qui a eu lieu le 7 avril 2001, a été suivie d'une période de consultation de 30 jours. On a recueilli les commentaires de 139 personnes et organisations. L'analyse des réponses reçues révèle que : 4 % des répondants appuyaient sans réserve le projet de règlement; 42 % appuyaient la majorité du projet de règlement et ont fourni des commentaires constructifs détaillés; 41 % étaient opposés au projet de règlement et n'ont pas formulé de commentaire constructif; et 14 % se sont montrés réservés. Il importe de noter que 75 % des intéressés opposés au projet de règlement étaient des partisans du Marijuana Party de la Colombie-Britannique. Ils ont envoyé par télécopieur des lettres en faveur de la légalisation générale de la marihuana à des fins récréatives et médicales sans l'autorisation préalable de quelque organe directeur que ce soit. La légalisation générale sort évidemment du cadre de la présente initiative réglementaire.

Deux médecins, deux associations médicales et deux organismes provinciaux responsables de l'octroi de permis d'exercer la médecine ont fait part de leurs commentaires. Si certaines observations étaient favorables, les associations médicales et les organismes chargés de l'octroi de permis aux médecins désapprouvent l'utilisation de la marihuana à des fins médicales. Parmi les raisons invoquées par ceux-ci figuraient : l'absence de preuves scientifiques à l'appui de son utilisation; le fait que la marihuana n'est pas un produit pharmaceutique approuvé; le fait que l'utilisation de la marihuana sous forme de fumée n'est pas un mode d'administration acceptable et que le fait de faire reposer sur les médecins la responsabilité d'appuyer l'emploi de la marihuana à des fins médicales pourrait les placer en situation de conflit par rapport aux règles de conduite de leur profession. Beaucoup de personnes ont aussi fait valoir ce dernier argument.

Il ressort de consultations antérieures et d'observations reçues des forces de l'ordre que ces dernières veulent que les choses soient clarifiées et reconnaissent l'importance d'adopter un cadre de réglementation. Les questions qu'elles se posent concernent

certainty who does or does not possess the necessary authorization or licence, to avoid inappropriate and unnecessary enforcement activity.

Many comments were received from individual patients and patient-advocacy organizations. While a number of patients view these proposed Regulations as too restrictive, others complimented the Department on seriously addressing patient concerns. Their comments have been most useful in identifying areas where these proposed Regulations can be improved and identified other areas where ongoing consultations and refinements may be required. It is greatly appreciated that many seriously ill and disabled Canadians made the effort to participate in the development of the Regulations.

The following is a summary of the major issues identified from this consultation process, and Health Canada's response to the concerns expressed.

Issue #1: Categories of Medical Conditions or Symptoms

Concerns: Many patients felt that other medical conditions should be included in the Schedule of Category 2 illnesses. On the other hand, concerns were expressed by the medical community that there is insufficient scientific evidence to support the use of smoked marihuana in the treatment of any medical condition included in Category 2 and further suggested that Category 3 is much too broad.

Response: The decision as to which medical conditions would be included in Category 2 was made primarily on the basis of available scientific research. The broad wording of Category 3 recognizes that there may be other conditions for which marihuana may provide medical benefit. Health Canada plans to review the list of Category 2 medical conditions on a regular basis, and will amend the Schedule as new information becomes available.

These Regulations are intended to provide access to marihuana for medical purposes, on compassionate grounds; this means that the use of marihuana, an unapproved drug in smoked form, should be considered for use in exceptional medical circumstances only. Category 1 includes terminal illnesses, which obviously meets this criterion and is supported by virtually all stakeholders. Category 2 includes a number of severe symptoms associated with specified serious medical conditions, where there is a reasonable amount of scientific evidence indicating that marihuana may provide symptomatic relief. Category 3, while difficult to precisely define within these Regulations, is intended to apply to severe symptoms. They include those in Category 2, but can be associated with other serious or life-threatening, chronic and severely debilitating, or complex and difficult to manage medical conditions for which compassionate access to marihuana may be justified. Providing access to marihuana for medical conditions that are outside the scope of the above-described categories is not the intended purpose of these Regulations.

essentiellement l'aptitude des agents de police à déterminer avec certitude qui possède ou non l'autorisation ou la licence voulue, pour éviter toute application indue ou inutile de la loi.

De nombreux commentaires ont été reçus de patients et d'organismes de défense de patients. Si un certain nombre de patients considèrent que ce projet de règlement est trop restrictif, d'autres ont félicité le ministère d'avoir pris au sérieux les problèmes des patients. Leurs observations ont été extrêmement utiles en ce sens qu'elles ont permis de déterminer les aspects du projet de règlement qui sont perfectibles et d'autres aspects qui pourraient justifier la poursuite de consultations et des rajustements continus. De nombreux Canadiens gravement malades et handicapés se sont donné la peine de participer à l'élaboration du règlement, et leur effort est très apprécié.

Voici un résumé des principales réserves exprimées lors de cette consultation et des réponses données par Santé Canada.

Point 1 : Catégories d'affections ou de symptômes

Réserves : De l'avis de nombreux patients, d'autres troubles médicaux devraient figurer en annexe, dans la liste des maladies de catégorie 2. Par ailleurs, le milieu médical a fait valoir qu'il n'existe pas suffisamment de données scientifiques à l'appui du recours à la marihuana fumée pour le traitement de toute affection incluse dans la catégorie 2. Il a aussi laissé entendre que la catégorie 3 est beaucoup trop vaste.

Réponse : La décision concernant les troubles médicaux qui seraient inclus dans la catégorie 2 a été prise à la lumière des résultats de recherches scientifiques. Si la formulation choisie pour la catégorie 3 est très générale, c'est parce qu'il existe sans doute d'autres troubles médicaux sur lesquels la marihuana pourrait avoir un effet bénéfique sur le plan médical. Santé Canada prévoit revoir régulièrement la liste des affections de la catégorie 2, et modifiera l'annexe à mesure que de nouvelles données seront disponibles.

Ce règlement vise à assurer l'accès à la marihuana à des fins médicales, pour des raisons humanitaires. C'est dire que la consommation de la marihuana, un médicament non approuvé sous sa forme fumée, ne doit être envisagée que dans des circonstances médicales exceptionnelles. La catégorie 1, qui englobe les maladies en phase terminale, répond évidemment à ce critère, et reçoit l'appui de presque tous les intéressés. La catégorie 2 comprend un certain nombre de symptômes sévères associés à certains troubles médicaux graves, pour lesquels il existe un nombre raisonnable de données scientifiques indiquant un possible effet de soulagement de la marihuana. La catégorie 3, bien qu'étant difficile à définir de manière précise dans le cadre de ce règlement, ne vise que les symptômes sévères, notamment ceux de la catégorie 2, mais peut être associée à d'autres affections graves ou pouvant menacer la vie, à des troubles chroniques et extrêmement débilitants, ou complexes et difficiles à prendre en charge, pour lesquels l'accès à la marihuana pour des raisons humanitaires pourrait être justifié. Le règlement ne vise pas à permettre l'accès à la marihuana pour des troubles médicaux qui ne font pas partie des catégories décrites ci-dessus.

Issue #2: Access to a Legal High-Quality Source of Marihuana

Concerns: Many individuals and organizations were concerned about patients' ability to grow marihuana on their own or, alternatively, to find someone with experience willing to help them by becoming a designated grower. In general, patients, advocacy groups, and some of the medical community strongly recommended that a safe, high-quality, controlled supply of marihuana be made available to patients to avoid the problems associated with growing by the patient, designated person, or unregulated distribution networks which are currently operating outside the law. Some problems that stakeholders mentioned associated with an unregulated supply include: a lack of experience in growing marihuana, leading to crop failures; product of unknown quality or potency; personal health, safety and security risks related to growing marihuana in one's home; and no access to safer alternatives to smoked marihuana.

Response: Health Canada acknowledges this problem and is attempting to deal with the issue. The Regulations address only personal possession and production because these are the most pressing issues. Options for the future production and distribution of a high-quality research or pharmaceutical grade marihuana are currently under consideration. This analysis must take into account a number of factors including Canada's commitments under international drug control conventions, as well as the *Food and Drug Regulations* that regulate the availability of drugs distributed in Canada.

Point 2 : Accès à une source licite de marihuana de qualité

Réserves : De nombreuses personnes et organisations ont exprimé des doutes quant à l'aptitude des patients à cultiver eux-mêmes leur marihuana, ou encore, à trouver une personne compétente qui soit disposée à les aider à devenir des cultivateurs désignés. De manière générale, les patients, les groupes de défense et certains membres du milieu médical étaient très favorables à l'idée que les patients aient accès à un approvisionnement sûr en marihuana de qualité contrôlée pour éviter tous les problèmes associés à la culture par le patient, une personne désignée ou d'autres réseaux de distribution non réglementés qui fonctionnent actuellement en marge de la loi. Certains des problèmes signalés par les intéressés concernaient le caractère non réglementé de l'approvisionnement, notamment le manque d'expérience dans la culture de la marihuana, d'où les récoltes déficitaires; le manque de certitude concernant la qualité ou la puissance du produit; les risques pour la santé et la sécurité des individus et les problèmes d'innocuité associés à la culture de la marihuana à domicile, et le manque d'accès à des solutions de rechange plus sûres à la marihuana fumée.

Réponse : Santé Canada reconnaît qu'il s'agit là d'un problème et s'emploie à y trouver des solutions. Le règlement ne tient compte que de la possession et de la production personnelles de la marihuana, étant donné que ce sont des questions qui doivent être réglées dans l'immédiat. Les possibilités offertes en matière de production et de distribution ultérieures de marihuana de qualité, utilisable dans les recherches ou à des fins pharmaceutiques, sont envisagées actuellement. Cette analyse doit prendre en considération un certain nombre de facteurs, notamment les engagements pris par le Canada dans le cadre de conventions internationales de lutte contre les stupéfiants, ainsi que le *Règlement sur les aliments et drogues* qui régit l'accès aux médicaments distribués au Canada.

Issue #3: Need for Further Research

Concerns: The medical community had serious concerns about the lack of evidence-based medical research on which to base their decisions. In particular, they were worried by the lack of information available to doctors about the dosage, strain, and potency levels best suited to their patients needs, as well as efficacy, possible drug interactions and long-term health effects. They were also concerned by current research which shows the harmful effects of smoking, in general, and smoking marihuana, in particular.

Response: Health Canada openly encourages research into new pharmaceutical uses of marihuana and is particularly interested in safer delivery systems. Until these products are available, along with more conclusive research on its positive and negative health effects, access to marihuana in crude smoked form is being granted only on compassionate grounds.

Point 3 : Nécessité d'approfondir la recherche

Réserves : Le milieu médical avait de sérieuses réserves concernant l'absence de recherches médicales solides sur lesquelles s'appuyer pour prendre des décisions. Ses sujets de préoccupation concernaient surtout le manque d'accès des médecins à de l'information concernant la posologie, la souche et la puissance les mieux adaptées aux besoins de leurs patients, ni sur l'efficacité, les possibles interactions médicamenteuses et effets sur la santé à long terme de la marihuana. Une autre réserve exprimée avait trait aux recherches actuelles qui montrent les effets nocifs de la fumée, en général, et de la marihuana fumée, en particulier.

Réponse : Santé Canada encourage ouvertement la recherche sur les nouvelles utilisations pharmaceutiques de la marihuana, et s'intéresse surtout à des mécanismes d'administration plus sûrs. L'accès à la marihuana sous sa forme fumée est accordé pour des raisons humanitaires jusqu'à ce que ces produits soient disponibles et que des recherches plus concluantes sur les effets bénéfiques et néfastes de la marihuana sur la santé soient réalisées.

Issue #4: Patient vs. Practitioner Application

Concerns: Physicians, medical associations, medical licensing authorities, and other stakeholders felt that designating practitioners as responsible for completing and submitting the application on behalf of the patient created an

Point 4 : Présentation des demandes par le patient ou le médecin

Réserves : De l'avis des médecins, des associations médicales, des organismes responsables de l'octroi de permis d'exercice et d'autres intéressés, le fait de charger les

unreasonable workload and would discourage them from participating. Further, individuals indicated they preferred to take charge of the application process themselves.

Response: The Regulations have been revised so that the application process for the authorization to possess and the licence to produce will be managed by the individual (patient) instead of the medical practitioner. The application must still include signed statements from the practitioner(s), but the responsibility for the application will now lie with the individual. This revision will reduce the burden on physicians and enable patients to manage their own application process.

médecins de remplir et de présenter la demande au nom du patient comporte une charge de travail indue pour ces derniers et découragerait leur participation. De plus, les individus ont fait savoir qu'ils préféreraient s'occuper eux-mêmes de la présentation de la demande.

Réponse : Le règlement a été révisé de manière à ce que ce soit l'individu (le patient), et non le médecin, qui s'occupe de la présentation de la demande d'autorisation de posséder ou de licence de production. La demande doit comprendre malgré tout une attestation signée par le(s) médecin(s), mais c'est au patient qu'incombe la responsabilité de la présenter. Cette modification au règlement allégera le fardeau des médecins et permettra aux patients de prendre en charge leur demande.

Issue #5: Restrictions on Growing Near Schools

Concerns: Individuals indicated that the one kilometre restriction on growing outdoors near schools and other places frequented by children was not feasible, necessary or reasonable.

Response: Health Canada agrees; it is unreasonable to expect either the individual to certify or for Health Canada to confirm the restriction. Also, the one kilometre restriction would likely prevent anyone from growing outdoors within an urban setting. The provision has been revised to be less restrictive and easier for all parties to assess. The revised provision prohibits growing marihuana outdoors immediately next to a school or similar public place a situation that would be unacceptable to the general public. Growers will also be encouraged to provide reasonable and meaningful security for outdoor plants, and to ensure that they are not visible to the public. It is in the best interests of the growers to prevent their plants from being lost or stolen to ensure the supply for medical use.

Point 5 : Restrictions concernant la culture à proximité des écoles

Réserves : De l'avis des individus, il était impossible, inutile ou déraisonnable d'imposer la restriction d'un kilomètre applicable à la culture de la marihuana à proximité des écoles et d'autres lieux fréquentés par des enfants.

Réponse : Santé Canada abonde dans ce sens; il n'est pas raisonnable de s'attendre à ce que la personne ou Santé Canada confirment le respect de la restriction. De plus, cette restriction empêcherait sans doute toute personne de cultiver la marihuana à l'extérieur, en zone urbaine. La version révisée de la disposition est moins restrictive et plus facile à appliquer par toutes les parties intéressées. Elle interdit de cultiver de la marihuana dans le voisinage immédiat d'une école ou d'un lieu public analogue, situation qui serait inacceptable pour l'ensemble de la population. De plus, les personnes qui font la culture de la marihuana seront encouragées à prendre des mesures de sécurité raisonnables et efficaces pour protéger les plantes cultivées à l'extérieur et à faire en sorte qu'elles ne soient pas visibles à la population. Elles ont en effet tout intérêt à protéger leurs plants de la perte ou du vol.

Issue #6: **Number of Plants that may be Produced**

Concerns: Individuals and organizations claiming experience in growing marihuana point out that the formula used to calculate the number of plants that may be grown is inappropriate. These parties cite the following variables as having an impact: different growing methods and conditions and the significant difference in yields between growing marihuana indoors and growing it outdoors. They claim such variables made it impractical to use the proposed formula to determine the number of plants, or the amount of marihuana that can be stored, under indoor and outdoor growing conditions. Some comments suggest that there is confusion about the amount of marihuana a person may possess under an authorization, versus the amount, stipulated in a personal production licence, that may be stored.

Response: Concerns about the differences between indoor and outdoor yields are supported by a review of independent sources of information. As a result, the number of plants permitted under a personal licence to produce has been amended to reflect the different potential yields from indoor vs. outdoor cultivation. The formulas have been revised based on estimated yields per plant of 30 grams per plant grown indoors and 250 grams per plant grown outdoors. The maximum amount of dried usable marihuana that a licensed person may possess will continue to be calculated on the

Point 6 : Nombre maximal de plants

Réserves : Les personnes et les organismes qui allèguent avoir de l'expérience dans la culture de la marihuana jugent inappropriée la formule utilisée pour le calcul du nombre de plants qui peut être cultivé. Ils font valoir les facteurs suivants qui doivent être pris en considération : les diverses méthodes et conditions de culture et la différence importante entre les cultures à l'intérieur et à l'extérieur. De telles variables expliquent que la formule proposée pour calculer le nombre de plants pouvant être produits, ou la quantité de marihuana pouvant être entreposée, qu'il s'agisse de cultures à l'intérieur ou à l'extérieur, n'est pas adéquate. De l'avis de certains, il existe une certaine confusion concernant la quantité de marihuana qu'une personne est autorisée à posséder, et la quantité, précisée dans une licence de production personnelle, qui peut être entreposée.

Réponse : Un examen de sources d'information indépendantes confirme le bien-fondé des réserves émises quant aux différences entre la production à l'intérieur et à l'extérieur. C'est pourquoi le nombre de plants autorisés en vertu d'une licence de production personnelle a été modifié pour tenir compte des possibles différences de rendement entre les cultures à l'intérieur et à l'extérieur. Les formules ont été révisées à la lumière des rendements estimatifs de 30 grammes par plant cultivé à l'intérieur et de 250 grammes par plant

basis of 150% of amount produced, allowing for a reasonable amount of inventory to be on hand at the time newly harvested material is added to the inventory. It will be clearly explained in the guidance documentation being developed that the quantity of dried marihuana that an authorized person may possess (maximum 30 days supply) applies only where that person does not also hold a licence to produce (in which case the higher storage amount would apply) or when that authorized person is away from his/her usual place of residence, i.e. travelling. The 30-day supply for the authorized person should not be confused with the quantity that may be stored as stipulated in a personal production licence.

cultivé à l'extérieur. La quantité maximale de marihuana séchée utilisable que peut posséder une personne détenant une licence demeurera inchangée, soit 150 % de la quantité produite, ce qui permet d'avoir accès à des réserves suffisantes au moment où le matériel nouvellement récolté est ajouté au stock. Il sera bien précisé, dans la documentation d'orientation qui est en cours de réalisation, que la quantité qu'une personne autorisée peut posséder (approvisionnement de 30 jours au plus) ne s'applique qu'aux cas où la personne ne détient pas de licence de production (auquel cas la quantité plus élevée pouvant être entreposée serait applicable), ou lorsque cette personne ne se trouve pas dans son lieu de résidence habituel, par exemple, lorsqu'elle est en voyage. Il faut éviter de confondre l'accès à un approvisionnement de 30 jours, donné à la personne autorisée, avec la quantité qui peut être entreposée, qui est précisée dans la licence de production personnelle.

Issue #7: Transitional Provisions

Concerns: A number of individuals who have been granted exemptions under section 56 of the CDSA expressed concern about the absence of transitional provisions in the Regulations which would ensure they will be given a reasonable amount of time to comply with the new requirements. Many mentioned the possibility of a "grandfather clause" being implemented.

Response: Transitional provisions have been added to the Regulations that will effectively extend by an additional 180 days (6 months), all exemptions in effect at the time the Regulations come into force. Prior to the new expiry date, individuals will need to apply under other parts of the Regulations if they wish to continue to legally possess or produce marihuana for medical purposes. No new exemptions issued under section 56 of the CDSA providing access to marihuana for medical purposes will be granted once these Regulations come into force. Individuals and Health Canada will therefore have an additional 6 months to deal with this transition in a gradual and equitable manner. Extending existing exemptions by 6 months also brings them in line with the authorizations that will be issued under the regulatory scheme, which will be valid for one year. Section 56 exemptees could, of course, apply under the new Regulations at any time before their exemption expires.

The coming into force date for these Regulations has been revised from July 15 to July 30, 2001, to allow the maximum amount of time for patients and physicians to become familiar with the new requirements following their final approval.

Point 7 : Dispositions transitoires

Réserves : Dans leurs commentaires, un certain nombre de personnes qui ont obtenu une exemption en vertu de l'article 56 de la LRCDAS ont déploré l'absence, dans le règlement, de dispositions transitoires qui leur permettraient de disposer d'un délai raisonnable pour se conformer aux nouvelles exigences. Nombre d'entre elles ont mentionné l'application possible d'une clause de maintien des droits acquis.

Réponse : Des dispositions transitoires ont été incluses dans le règlement et auront pour effet d'allonger de 6 mois toutes les exemptions déjà accordées au moment de l'entrée en vigueur du règlement. Il n'est donc pas nécessaire que les personnes qui veulent continuer de posséder ou de cultiver légalement de la marihuana à des fins médicales présentent une demande conformément au nouveau règlement avant la nouvelle date d'expiration. Aucune nouvelle exemption en vertu de l'article 56 de la LRCDAS donnant accès à la marihuana à des fins médicales ne sera accordée une fois que ce règlement entrera en vigueur. Pour que la transition soit graduelle et équitable, les particuliers et Santé Canada bénéficieront ainsi d'un délai supplémentaire de six mois. Le prolongement de six mois des exemptions existantes permettra également de les faire coïncider avec les autorisations qui seront délivrées dans le cadre du nouveau régime réglementaire et qui seront valides pour un an. Les personnes bénéficiant d'une exemption en vertu de l'article 56 pourraient, bien sûr, présenter une demande en vertu du nouveau règlement en tout temps avant que leur période d'exemption ne se termine.

Ce règlement entrera en vigueur le 30 juillet plutôt que le 15 juillet 2001 pour permettre aux patients et aux médecins d'avoir le plus de temps possible pour se familiariser avec les nouvelles exigences après leur approbation finale.

Issue #8: Criminal Record — Designated Person

Concerns: Both law-enforcement agencies and some individuals indicated that the requirement for a document proving that the proposed designated grower does not have a criminal record in another country was unreasonable and practically impossible to provide.

Response: The applicant for a designated-person production licence will not be required to submit a document proving that no foreign drug conviction exists, as it would place unreasonable demands on the applicant and the police. Instead, a statement from the proposed designated grower will be

Point 8 : Casier judiciaire — personne désignée

Réserves : Les organismes chargés de l'application de la loi de même que certains particuliers ont indiqué que l'exigence de produire un document démontrant que le producteur désigné proposé ne possède pas de casier judiciaire dans un autre pays était déraisonnable et impossible à satisfaire sur le plan pratique.

Réponse : La personne qui sollicite une licence de production pour une personne désignée ne sera pas tenue de fournir un document prouvant qu'elle n'a été reconnue coupable d'aucune infraction en matière de drogue à l'étranger, car

required. This statement does not need to include convictions relating to possession.

Issue #9: Inspection Provisions

Concerns: Individuals stated that the proposed provisions, providing for the potential inspection of marihuana-growing premises and records were too broad. In particular, the fact that marihuana is usually grown in private residences combined with the wide powers to search and seize contained in the Regulations was interpreted by many as an unwarranted invasion of privacy.

Response: Under the Regulations, inspectors will be able to conduct an inspection at a licensed production site only if consent is given by the occupant. Inspection provisions are generally deemed to be a necessary requirement for most regulatory schemes, particularly those involving licensing the production of a controlled substance. Furthermore, inspections are typically conducted to assess regulatory compliance. Health Canada appreciates the concerns of potential licence holders who will be growing within their own homes, and regular unannounced inspections are not contemplated. The inspection provisions provide an inspector with the authority to assess compliance with the Regulations. In addition, patients who hold personal-use production licences will not be required to maintain records, in consideration of their medical condition. They are, however, encouraged to voluntarily maintain such records to the extent that they can.

Issue #10: Costs

Concerns: A large number of patients and health advocacy groups were concerned about the possibility that costs of administering this program might be passed on to the users. They pointed out that most of the patients are on fixed incomes because of their medical conditions and are already burdened with the costs of growing or purchasing marihuana. Also, some parties thought that marihuana costs should be covered by health insurance.

Response: Health Canada is sensitive to the financial situation of many patients who have serious illnesses. The related costs of delivering the authorization and licensing program will not, at least initially, be subject to user fees. As with any similar program, the costs will be reviewed in accordance with established government cost-recovery policies which ensure that the client's ability to pay is taken into consideration. The new regulatory scheme is anticipated to be less resource intensive than the existing exemption process with its high level of professional evaluation but the demand for service is expected to be greater in the future. In any case, no fees would be implemented without a thorough review and extensive consultation with affected parties. It should be noted that drug coverage by insurance plans is, in most instances, a provincial responsibility.

cela imposerait un fardeau déraisonnable au demandeur et aux forces de police. On exigera plutôt une déclaration du producteur désigné proposé.

Point 9 : Dispositions relatives à l'inspection

Réserves : Des personnes ont indiqué que les dispositions proposées prévoyant l'inspection possible des locaux des producteurs de marihuana et des dossiers étaient trop générales et portaient donc atteinte à la vie privée. À cause des vastes pouvoirs de perquisition et de saisie prévus et du fait que la marihuana est habituellement cultivée dans des résidences privées, les inspections proposées n'étaient pas très populaires.

Réponse : En vertu du règlement, les inspecteurs ne pourraient pénétrer dans les locaux autorisés que s'ils ont obtenu le consentement d'un occupant. Des dispositions relatives à l'inspection sont habituellement jugées nécessaires dans la plupart des régimes réglementaires, en particulier ceux qui comportent la délivrance de licences pour la production d'une substance contrôlée. De plus, les inspections visent normalement à évaluer la conformité aux règlements. Santé Canada reconnaît le bien-fondé des craintes des titulaires éventuels de licences qui cultiveront de la marihuana à domicile, et des inspections régulières non annoncées ne sont pas envisagées. Les dispositions relatives à l'inspection confèrent cependant, au besoin, à un inspecteur le pouvoir d'évaluer la conformité au règlement. Certaines exigences mineures, considérées comme peut-être excessives et inutiles, ont été éliminées, mais le pouvoir d'effectuer une inspection est maintenu. En outre, les patients qui sont titulaires d'une licence de production à des fins personnelles ne seront pas obligés de tenir des dossiers, compte tenu de leur état de santé; on les encourage toutefois à en tenir volontairement dans la mesure où ils le peuvent.

Point 10 : Coûts

Réserves : Un grand nombre de patients et de groupes de militants dans le domaine de la santé étaient grandement préoccupés par la possibilité que les coûts associés à l'administration de ce programme soient transférés à l'usager. Ils ont indiqué que la plupart des patients ont un revenu fixe à cause de leurs problèmes de santé et doivent déjà supporter le coût de la production ou de l'achat de la marihuana. Certaines parties pensaient également que le coût de la marihuana devait être pris en charge par le régime d'assurance-maladie.

Réponse : Santé Canada est bien conscient de la situation financière dans laquelle se trouvent de nombreux patients atteints de maladies graves. Le coût relatif du programme d'autorisation et de délivrance de licences ne fera pas l'objet, à tout le moins dans un premier temps, d'un recouvrement de coûts. Comme tout programme similaire, les coûts seront étudiés conformément aux politiques en matière de recouvrement des coûts du gouvernement. Ces politiques prévoient également que la capacité de payer du client sera prise en considération. Le nouveau régime réglementaire ne devrait pas exiger autant de ressources que le processus d'exemption existant, qui nécessite de nombreuses évaluations professionnelles; on aura donc besoin dans l'avenir de moins de ressources. En tout cas, aucun frais ne serait exigé sans qu'une étude approfondie et qu'une vaste consultation auprès des parties touchées ne soient entreprises.

Issue #11: Legalization or Decriminalization

Concerns: There were several comments suggesting legalization or decriminalization, instead of limiting access to marihuana for medical purposes.

Response: The Regulations deal exclusively with the medical use of marihuana; therefore they do not address the issue of legalizing marihuana. Legalization and decriminalization arguments will be publicly debated by parliamentary committees over the next several months.

Issue #12: Compassion Clubs, Buyers Clubs and Cooperatives

Concerns: These organizations and some patients suggested the Regulations be revised to increase the number of patients per grower, and to consider licencing "clubs" as an officially recognized distribution method. Reasons cited were "clubs'" expertise, prices charged, and the fact that they are already in the business of providing marihuana, although operating outside of the law.

Response: Health Canada is not prepared at this time to consider licensing other organizations or companies to produce and distribute marihuana. In December 2000, Health Canada issued a contract to a Canadian company to produce research-grade marihuana. Health Canada will be evaluating various options to ensure patients have access to a safe high-quality supply of marihuana for medical purposes.

Issue #13: Use of Photos — ID Cards

Concerns: Law-enforcement agencies suggested that photo identification cards be provided to all authorized individuals and all holders of production licences, including designated-person production licences. Several individuals questioned the provision that requires photos to be submitted along with the application as they saw it as a potential invasion of privacy and, in some cases, a question of personal dignity.

Response: Health Canada intends to provide secure photo identification cards to each individual who holds an authorization to possess or a licence to produce. It will be issued together with the authorization or licence documents containing the detailed information laid out in the Regulations. The identification cards will carry only the basic information required to identify the individual as a holder of an authorization and/or licence to produce and to show possession and production limits. No personal medical information will be indicated on the card. The detailed authorization and licence documents are to be stored at the location indicated on the form. The identification cards would be carried by individuals transporting marihuana either for personal use, in the case of the authorized person, or by the holder of a designated-person production licence, when transporting marihuana from the production site to the authorized person's residence. The card can be shown to a police officer as evidence that the person is permitted to possess marihuana. In cases where police suspect a card has been tampered with, or is a false document, they can contact Health Canada to confirm the card's authenticity. Card holders must take suitable precautions to protect their cards from loss, since they could be misused by unauthorized persons.

Point 11 : Légalisation ou décriminalisation

Réserves : Plusieurs des commentaires reçus prônaient une légalisation ou une décriminalisation, au lieu d'une restriction de l'accès à la marihuana pour fins médicales seulement.

Réponse : Le règlement porte exclusivement sur l'usage de la marihuana à des fins médicales; il ne traite pas de la question de la légalisation de la marihuana. Les arguments pour ou contre la légalisation et la décriminalisation seront débattus publiquement par des comités parlementaires au cours des prochains mois.

Point 12 : Clubs de compassion, clubs d'acheteurs et coopératives

Réserves : Ces organisations et certains patients ont suggéré que le règlement soit révisé pour qu'on augmente le nombre de patients par producteur et qu'on envisage la délivrance de licences à des « clubs » comme méthode de distribution officielle. On citait comme raisons l'expertise des « clubs », les prix demandés et le fait qu'ils offrent déjà de la marihuana, bien qu'ils le fassent en marge de la loi.

Réponse : Santé Canada n'est pas prêt pour le moment à envisager l'octroi de licences à d'autres organisations ou entreprises pour la production et la distribution de la marihuana. En décembre 2000, Santé Canada a signé un contrat avec une entreprise canadienne pour la production de marihuana de qualité propre à la recherche. Santé Canada évaluera les diverses options afin de s'assurer que les patients ont accès à un approvisionnement sûr de marihuana de grande qualité à des fins médicales.

Point 13 : Utilisation de photos — cartes d'identité

Réserves : Les organismes chargés de l'application de la loi ont suggéré que des cartes d'identité avec photo soient fournies à toutes les personnes autorisées et à tous les titulaires de licences de production, y compris les licences de production pour personnes désignées. Plusieurs personnes ont contesté l'obligation d'avoir à fournir des photos en même temps que la demande; ils y voyaient une atteinte possible à leur vie privée et, dans certains cas, une affaire de dignité personnelle.

Réponse : Santé Canada compte offrir des cartes d'identité protégées avec photo à chaque personne qui bénéficie d'une autorisation de possession ou d'une licence de production. La carte sera remise en même temps que les documents d'autorisation ou de licence contenant les renseignements détaillés énoncés dans le règlement. Les cartes d'identité ne porteront que l'information de base requise pour identifier la personne ayant reçu une autorisation ou une licence de production et pour indiquer les quantités limites qu'elle peut posséder et produire. Aucun renseignement médical personnel ne figurera sur la carte. Les documents détaillés d'autorisation et de licence doivent être conservés à l'endroit indiqué sur le formulaire. Les personnes qui transportent de la marihuana soit à des fins personnelles, dans le cas de la personne autorisée, ou en vertu d'une licence de production pour une personne désignée, devront porter sur elles leur carte d'identité lorsqu'elles transportent de la marihuana du lieu de production à la résidence du patient bénéficiant d'une exemption. La carte peut être montrée à un agent de police comme preuve que la personne a le droit de posséder de la marihuana. Dans les cas où la police soupçonne qu'il y a eu falsification d'une carte ou fraude, elle peut communiquer

avec Santé Canada pour confirmer l'authenticité de la carte. Les détenteurs d'une carte doivent prendre les précautions qui s'imposent pour ne pas perdre leur carte, car celle-ci pourrait être utilisée à mauvais escient par des personnes non autorisées.

Issue #14: Restrictions on Smoking or Use of Marihuana in General

Concerns: There were concerns expressed about where and when patients would be permitted to smoke marihuana for medical purposes. Specific concerns included: smoking in public places; second-hand smoke and drug exposure; driving while under the influence of marihuana; and the discretion left to institutions on whether they will allow the medical use of marihuana on their property.

Response: In general, how and where a patient may use a drug for medical use is not subject to federal regulation, but may be subject to the laws and policies of other levels of government. Smoking marihuana for medical purposes in a public setting, thereby potentially exposing others to the drug's effects, is unacceptable. Patients are therefore expected to use common sense when using this drug. The authorization simply allows possession, but does not give patients permission to use marihuana wherever or whenever he/she chooses; the rights of others must also be considered. Hospitals and correctional institutions have their own regulations and policies governing the use of or access to drugs for medical use; these will determine whether marihuana may be used and under what conditions.

Similarly, while it is known that using marihuana influences a person's judgement and performance, and might impair his/her ability to drive, it is not clear how much a patient would need to use within a certain period to be impaired. Typically, approved drug products carry warnings or precautions related to driving or operating heavy machinery after using the drug. Since marihuana is not an approved drug in Canada, this warning will be provided by Health Canada to patients and health professionals in the guidance documents being prepared.

Since the Regulations do not regulate the actual use of the product, Health Canada does not propose to include mandatory restrictions relating to where or when marihuana may be used. These issues will, however, be monitored by Health Canada. Guidance documents provided to patients and practitioners will also include warnings about smoking in public places.

Point 14 : Restrictions visant la consommation ou l'usage de la marihuana en général

Réserves : Des réserves ont été exprimées quant aux endroits et aux moments où les patients seraient autorisés à fumer de la marihuana à des fins médicales. Les réserves particulières portaient sur les points suivants : le fait de fumer dans les lieux publics; l'exposition à la fumée secondaire et à la drogue; la conduite sous l'emprise de la marihuana; et le fait de laisser à la discrétion des établissements la décision d'autoriser ou non la consommation de marihuana dans leurs locaux ou sur leur terrain.

Réponse : En général, la façon dont un patient peut faire usage d'une drogue à des fins médicales et l'endroit qu'il peut choisir ne sont pas des questions qui relèvent de la réglementation fédérale; par contre, elles peuvent faire l'objet de lois et politiques élaborées par d'autres niveaux de gouvernement. Le fait de fumer de la marihuana à des fins médicales dans un établissement public et d'exposer ainsi potentiellement d'autres personnes aux effets de la drogue est en soi inacceptable. On s'attend donc à ce que les patients fassent preuve de bon sens lorsqu'ils consomment cette drogue. L'autorisation porte simplement sur la possession; elle ne permet pas aux patients de faire usage de marihuana au moment et à l'endroit qu'ils choisissent — les droits des autres doivent aussi être pris en considération. Les hôpitaux et les établissements correctionnels appliquent leurs propres règlements et politiques régissant l'usage des drogues ou l'accès à des drogues à des fins médicales. Ce sont ces règlements et politiques qui détermineront si la marihuana peut être consommée et dans quelles conditions elle peut l'être.

Par ailleurs, bien qu'il soit un fait connu que la marihuana a un effet sur le jugement et le fonctionnement d'une personne, et peut affaiblir les facultés d'une personne qui conduit, on ne connaît pas avec précision la quantité qu'une personne doit consommer pendant une période donnée pour que ses facultés soient affaiblies. Habituellement, les médicaments approuvés s'accompagnent d'une mise en garde ou de précautions s'adressant aux personnes qui doivent conduire ou faire fonctionner du matériel lourd après en avoir consommés. Puisque la marihuana n'est pas un médicament approuvé au Canada, Santé Canada inclura dans les documents d'orientation en cours de rédaction une mise en garde à cet effet à l'intention des patients et des professionnels de la santé.

Étant donné que le règlement ne vise pas l'usage réel du produit, Santé Canada ne propose pas d'inclure des restrictions obligatoires concernant les endroits et les moments où la marihuana peut être consommée. Ces questions feront cependant l'objet d'une surveillance de la part du ministère. Les documents d'orientation qui seront distribués aux patients et aux praticiens renfermeront aussi des mises en garde quant à l'usage de la marihuana sous forme de fumée dans les lieux publics.

Issue #15: Reporting Professional Misconduct

Concerns: The Canadian Medical Association was concerned by the broad discretion given to the Minister to report inconsistencies to professional licensing bodies. This concern relates to a lack of criteria by which the practitioner might be judged. Similarly, individuals expressed concern that physicians may fear censure by their colleges and be unnecessarily reluctant to support a patient's application for an authorization to possess marihuana.

Response: The provision in these Regulations is similar to that which exists in other controlled substances regulations. The provision allows Health Canada to share information with medical professional licensing authorities in rare circumstances. Health Canada recognizes the need to establish, in participation with the medical licensing authorities, reasonable standards or criteria for making this decision. This information will be communicated to patients and physicians.

Point 15 : Signalement d'une faute professionnelle

Réserves : L'Association médicale canadienne a émis des réserves quant au large pouvoir discrétionnaire accordé au ministre en ce qui concerne le signalement des incohérences aux organismes chargés de la délivrance des permis d'exercice de la médecine. Ces réserves portent sur l'absence de critères en fonction desquels le praticien pourrait être jugé. Dans le même ordre d'idée, selon certaines personnes, les médecins pourraient craindre que leurs collègues leur fassent des reproches et pourraient hésiter à appuyer la demande d'un patient à l'égard de l'autorisation de posséder de la marihuana.

Réponse : La disposition de ce règlement est similaire à d'autres dispositions réglementaires sur les substances contrôlées. Elle autorise Santé Canada à partager des renseignements avec les organismes chargées de la délivrance des permis d'exercice de la médecine dans de rares circonstances. Santé Canada reconnaît la nécessité d'établir, de concert avec ces organismes, des normes ou des critères raisonnables pour la prise d'une telle décision. Ces renseignements seront communiqués aux patients et aux médecins.

Issue #16: Requirements of Specialists

Concerns: Many individuals and organizations expressed concern that Category 2's requirement that a medical specialist provide specific statements to support an application, and Category 3's requirement for statements from two specialists, make the process more restrictive than the current section 56 process. As well, many were concerned that people with legitimate medical needs would be denied, or at least have their applications delayed for months, because they did not have access to the required specialists. In particular, AIDS groups were concerned since there is no such thing as an AIDS specialist. Others were worried that the long wait to see a specialist could lead to discrimination against those in rural areas.

Response: Specialists play an important part in the diagnosis and treatment of any serious illness. As such, they have a role to play in supplying statements as part of the application process. The decision to support the use of marihuana to treat symptoms of a serious medical condition is not trivial. The fact that marihuana is an unapproved drug and is mainly ingested by smoking, makes the decision even more challenging.

Statements from one or more specialists required to support an application do not necessarily require the patient to visit the specialist in every instance. The primary physician may choose to consult with a specialist for this purpose, providing background on the file. Health Canada also recognizes that there may not be a specialty associated with every medical condition, and would therefore only expect that the specialty relate to some aspect of the condition being treated. The role and involvement of the specialist will be reviewed over time and clarified as necessary.

Point 16 : Exigences concernant l'appui de spécialistes

Réserves : De nombreuses personnes et organisations ont exprimé des réserves quant au fait qu'à l'appui des demandes présentées dans la catégorie 2, on exige qu'un médecin spécialiste fournisse une déclaration précise, et qu'à l'appui des demandes présentées dans la catégorie 3, on exige que deux spécialistes fournissent des déclarations. Selon ces personnes et organisations, ces exigences rendent le processus plus restrictif que le processus actuellement prévu à l'article 56. De même, beaucoup craignent que les demandes des personnes ayant des besoins médicaux légitimes soient rejetées, ou du moins que leur traitement soit retardé pendant plusieurs mois, parce qu'elles n'ont pas eu accès aux spécialistes voulus. Les groupes oeuvrant dans le domaine du sida sont particulièrement inquiets puisqu'il n'existe pas à proprement parler de spécialiste du sida. D'autres craignent que la longue attente imposée aux patients qui veulent consulter un spécialiste donne lieu à de la discrimination contre les personnes vivant dans des régions rurales.

Réponse : Les spécialistes jouent un rôle important dans le diagnostic et le traitement de toute maladie grave. À ce titre, ils doivent intervenir en fournissant des déclarations dans le cadre du processus de présentation des demandes. La décision d'appuyer l'usage de la marihuana pour le traitement de symptômes d'une affection grave ne doit pas être prise à la légère. Le fait que la marihuana ne soit pas un médicament approuvé et soit ingérée principalement sous forme de fumée rend la décision encore plus complexe.

Même si l'on exige les déclarations d'un ou plusieurs spécialistes à l'appui d'une demande, les patients ne sont pas nécessairement obligés d'aller consulter un spécialiste à chaque fois. Le médecin traitant peut décider de consulter un spécialiste à cette fin et inscrire l'information voulue dans le dossier. Santé Canada reconnaît aussi qu'il n'existe pas nécessairement une spécialité pour chaque affection; il s'attend donc uniquement à ce que la spécialité ne se rattache qu'à un aspect quelconque de l'affection traitée. Le rôle et l'intervention du spécialiste seront examinés au fil du temps et seront clarifiés au besoin.

Issue #17: Information

Concerns: Individuals and health professionals had many questions about the proposed Regulations and expressed a strong interest in obtaining current reliable information, not only on the potential health benefits of marihuana, but on the health risks associated with using marihuana in smoked or other forms.

Response: Health Canada recognizes the need for a reliable and comprehensive source of information concerning marihuana so that patients, with the support of their physicians, can make informed health decisions. It is expected that Health Canada will play a lead role in facilitating the development of an information source whereby patients and health professionals can tap into the growing body of knowledge related to marihuana.

Comprehensive guidance documents are being developed to help patients and physicians understand the Regulations, and to guide them through the application process. It should be noted that "marihuana" is spelled with an "h" in the CDSA and its Regulations, as well as in the *Marihuana Medical Access Regulations*. "Marijuana" is the other common spelling both words mean "*cannabis*". Either spelling is acceptable when used informally, however, in Canadian legislation and when referring to this legislation marihuana is spelled with an "h".

As with all Regulations, analysis and consultation on a variety of issues will continue following implementation; as appropriate, any required regulatory amendments will be made in a timely manner. It is therefore Health Canada's intention, upon final approval of the Regulations, to communicate to stakeholders the results of the consultation process and to invite their ongoing participation in improving this regulatory scheme.

Finally, an informal electronic survey was conducted through Health Canada's electronic magazine beginning in August 2000. The following question was asked: "Let us know what you think about making marijuana available for medical purposes." Of the 146 comments received between September 2000 and May 2001, 104 agreed that marihuana should be available for medical purposes. Of this number, 40 respondents suggested the government should go further and consider legalizing marihuana. This forum will continue to be used to seek feedback on the Regulations and related topics.

Compliance and Enforcement

The Regulations include general provisions to conduct inspections relating to the production of marihuana. Health Canada inspectors will be authorized to examine inventories, records and security to ensure that marihuana production conforms with the Regulations. Inspections will take place only at the site where marihuana is produced under a licence, and only with the permission of the occupant. It is not anticipated that inspections would be frequent, regular or unannounced. Rather, they would be an infrequently used tool; for example, there could be inspections where unusually large quantities were being produced, where two

Point 17 : Information

Réserves : Les personnes et professionnels de la santé consultés ont posé de nombreuses questions au sujet du projet de règlement et se sont dits vivement intéressés à obtenir des renseignements fiables et à jour en ce qui concerne non seulement les avantages potentiels de la marihuana pour la santé, mais aussi les risques pour la santé associés à l'usage de la marihuana sous forme de fumée ou sous d'autres formes.

Réponse : Santé Canada reconnaît la nécessité de disposer d'une source d'information fiable et détaillée à partir de laquelle les patients, avec l'appui de leurs médecins, pourront prendre des décisions éclairées concernant leur santé. On s'attend à ce que Santé Canada joue un rôle prépondérant pour ce qui est de faciliter l'élaboration d'une source d'information dans laquelle les patients et les professionnels de la santé pourront puiser des renseignements au fur et à mesure que s'élargira le corpus de connaissances sur la marihuana.

Par ailleurs, on élabore actuellement des documents d'orientation dans le but d'aider les patients et les médecins à comprendre le règlement et de les guider dans le processus de présentation des demandes. Il convient de souligner que le mot « marihuana » est écrit avec un « h » dans la LRCDAS et dans son règlement d'application, ainsi que dans le *Règlement sur l'accès à la marihuana à des fins médicales*. Toutefois, ce terme s'écrit aussi souvent de la façon suivante : « marijuana » — les deux termes s'utilisent pour parler du « cannabis ». Les deux graphies sont acceptables dans les textes courants; cependant, le terme juridique à utiliser en vertu de la législation canadienne est celui qui s'écrit avec un « h ».

Comme pour tous les règlements, après la mise en oeuvre, on poursuivra l'analyse et la consultation au sujet de diverses questions. On apportera rapidement toute modification qui s'impose. Dès l'approbation finale du règlement, Santé Canada a l'intention de communiquer aux intéressés les résultats du processus de consultation et de les inviter à apporter leur concours à l'amélioration de ce cadre réglementaire.

Enfin, à partir d'août 2000, un sondage électronique informel a été mené par le biais de la revue électronique Santé Canada. La question suivante a été posée : « Donnez-nous votre avis sur l'usage de la marihuana à des fins médicales. » Sur les 146 répondants qui ont envoyé des commentaires entre septembre 2000 et mai 2001, 104 étaient d'accord pour que l'usage de la marihuana soit autorisé à des fins médicales. Parmi eux, 40 ont suggéré que le gouvernement aille de l'avant avec le projet et envisage de légaliser la marihuana. On continuera d'utiliser ce forum en vue d'obtenir des commentaires sur le règlement et sur des questions connexes.

Respect et exécution

Le présent règlement renferme des dispositions générales visant les inspections effectuées par les inspecteurs de Santé Canada. Les inspecteurs seront autorisés à effectuer des inspections concernant les inventaires, les dossiers ainsi que la sécurité afin de faire en sorte que la production de marihuana soit conforme au règlement. Les inspections ne se feront que sur le site de production sous licence de la marihuana et uniquement sur autorisation d'un occupant. Il n'est pas prévu que les inspections seront fréquentes, régulières ou non annoncées. Au contraire, les inspections seront assez rares; par exemple, on pourra procéder à des

or three licence holders were growing at a common site, or when there were complaints from members of the public.

Minimal record-keeping provisions exist relating to the production of marihuana by a licence holder. These records are to be shown to an inspector or submitted to the Minister upon request. Information contained in these records will be used to track production and consumption statistics as may be required to prepare reports to the UN.

Any activity that is not permitted under an authorization to possess or a licence to produce marihuana is potentially subject to police enforcement action. Complaints received concerning potential illegal activity may be shared with police agencies for enforcement purposes. For example, the production or storage of marihuana at premises or locations other than those authorized would be subject to enforcement action. Trafficking, which includes, among other things, selling, giving, sending or delivering marihuana to any person not named in the authorization or licence, would also be subject to enforcement action.

Health Canada may also share information concerning any medical practitioner with the responsible provincial medical licensing authority on matters of professional conduct and medical practice or when required in the context of a lawful investigation conducted by the medical licensing authority.

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inspections lorsque des quantités exceptionnellement importantes de marihuana seront produites, lorsque deux ou trois titulaires de licence cultiveront de la marihuana sur un même site ou lorsque des membres du public feront des plaintes.

Le règlement renferme des dispositions minimales sur la tenue de dossiers concernant la production de marihuana par un titulaire de licence. Ces dossiers devront être présentés à un inspecteur ou soumis au ministre, sur demande. Les renseignements qu'ils contiendront serviront à établir des statistiques sur la production et la consommation de marihuana, statistiques qui pourront être utiles pour la préparation de rapports à l'intention de l'ONU.

Toute activité qui n'est pas visée par une autorisation de possession ou une licence de production de marihuana peut faire l'objet d'une mesure d'exécution policière. Les renseignements concernant les activités illicites potentielles peuvent être communiqués aux services de police qui se chargeront d'exécuter la loi. Par exemple, la production et l'entreposage dans des locaux ou des lieux autres que ceux qui sont autorisés feront l'objet de mesures d'exécution. Il en sera de même du trafic qui inclut, entre autres, la vente, le don, l'envoi ou la livraison de marihuana à toute personne dont le nom ne figure pas sur l'autorisation ou la licence.

Santé Canada peut aussi communiquer des renseignements concernant tout médecin praticien à l'organisme provincial chargé de la délivrance des permis d'exercice de la médecine au sujet de questions ayant trait à l'éthique professionnelle et à l'exercice de la profession, ou encore selon les besoins dans le contexte d'une enquête conforme à la loi menée par cet organisme.

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Registration
SOR/2003-387 3 December, 2003

CONTROLLED DRUGS AND SUBSTANCES ACT

Regulations Amending the Marihuana Medical Access Regulations

P.C. 2003-1908 3 December, 2003

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], hereby makes the annexed *Regulations Amending the Marihuana Medical Access Regulations*.

REGULATIONS AMENDING THE MARIHUANA MEDICAL ACCESS REGULATIONS

AMENDMENTS

1. Subsection 4(2) of the *Marihuana Medical Access Regulations*[1] is replaced by the following:

(2) An application under subsection (1) shall contain

(*a*) a declaration of the applicant;

(*b*) a medical declaration that is made

(i) in the case of an application based on a category 1 symptom, by the medical practitioner of the applicant, or

(ii) in the case of an application based on a category 2 or 3 symptom, by a specialist; and

(*c*) two copies of a current photograph of the applicant.

2. (1) Paragraph 5(1)(*e*) of the Regulations is replaced by the following:

(*e*) that the authorization is sought in respect of marihuana to be

(i) produced by the applicant or a designated person, in which case the designated person must be named, or

(ii) obtained from a medical practitioner under section 70 or obtained under section 70.1 from a licensed dealer producing marihuana under contract with Her Majesty in right of Canada;

(2) Paragraph 5(1)(*f*) of the English version of the Regulations is replaced by the following:

(*f*) that the applicant is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug and that the applicant understands the significance of that fact; and

3. Section 7 of the Regulations is repealed.

4. Section 8 of the Regulations is replaced by the following:

8. A medical declaration under section 6 must be dated and signed by the medical practitioner or specialist making it and must attest that the information contained in the declaration is correct and complete.

[a] S.C. 1996, c. 19
[1] SOR/2001-227

Enregistrement
DORS/2003-387 3 décembre 2003

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales

C.P. 2003-1908 3 décembre 2003

Sur recommandation de la ministre de la Santé et en vertu du paragraphe 55(1) de la *Loi réglementant certaines drogues et autres substances*[a], Son Excellence la Gouverneure générale en conseil prend le *Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales*, ci-après.

RÈGLEMENT MODIFIANT LE RÈGLEMENT SUR L'ACCÈS À LA MARIHUANA À DES FINS MÉDICALES

MODIFICATIONS

1. Le paragraphe 4(2) du *Règlement sur l'accès à la marihuana à des fins médicales*[1] est remplacé par ce qui suit :

(2) La demande comporte les éléments suivants :

a) une déclaration du demandeur;

b) une déclaration médicale qui :

(i) si la demande est fondée sur un symptôme de catégorie 1, provient du médecin du demandeur,

(ii) si la demande est fondée sur un symptôme de catégorie 2 ou de catégorie 3, provient d'un spécialiste;

c) deux copies d'une photographie récente du demandeur.

2. (1) L'alinéa 5(1)*e*) du même règlement est remplacé par ce qui suit :

e) la mention qu'il entend, selon le cas :

(i) produire la marihuana lui-même ou la faire produire par une personne désignée, auquel cas le nom de la personne désignée doit être mentionné,

(ii) obtenir la marihuana d'un médecin en vertu de l'article 70 ou l'obtenir, en vertu de l'article 70.1, d'un distributeur autorisé qui la produit au titre d'un contrat avec Sa Majesté du chef du Canada;

(2) L'alinéa 5(1)*f*) de la version anglaise du même règlement est remplacé par ce qui suit :

f) that the applicant is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug and that the applicant understands the significance of that fact; and

3. L'article 7 du même règlement est abrogé.

4. L'article 8 du même règlement est remplacé par ce qui suit :

8. La déclaration médicale visée à l'article 6 est datée et signée par le médecin ou le spécialiste qui la produit et atteste que les renseignements qui y sont fournis sont exacts et complets.

[a] L.C. 1996, ch. 19
[1] DORS/2001-227

5. The portion of section 10 of the Regulations before paragraph (*a*) is replaced by the following:

10. The photograph required under paragraph 4(2)(*c*) must clearly identify the applicant and must

6. (1) Subsection 12(1) of the English version of the Regulations is amended by adding the word "or" at the end of paragraph (*b*) and by striking out the word "or" at the end of paragraph (*c*).

(2) Paragraph 12(1)(*d*) is repealed.

7. (1) Paragraph 14(1)(*b*) of the Regulations is replaced by the following:

(*b*) the material required under sections 4 to 10.

(2) Subsection 14(2) of the Regulations is replaced by the following:

(2) For the purpose of paragraph (1)(*b*), a photograph referred to in paragraph 4(2)(*c*) is required only with every second renewal application.

8. (1) Paragraphs 34(1)(*d*) and (*e*) of the Regulations are replaced by the following:

(*d*) subject to subsection (1.1), if the site specified in the licence where dried marihuana may be kept is different from the place where the person who applied for the licence ordinarily resides, to send or transport directly from that site to the place of residence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued; and

(*e*) to provide or deliver to the person who applied for the licence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued.

(2) Section 34 of the Regulations is amended by adding the following after subsection (1):

(1.1) A holder of a designated-person production licence sending dried marihuana under paragraph 34(1)(*d*) shall

(*a*) securely pack the marihuana in a package that

(i) prevents the contents from being identified without the package being opened, and

(ii) is sealed so that the package cannot be opened without the seal being broken; and

(*b*) use a method of sending that involves

(i) a means of tracking the package during transit,

(ii) obtaining a signed acknowledgment of receipt by the holder of the authorization to possess, and

(iii) safekeeping of the package during transit.

(3) Subsection 34(2) of the Regulations is repealed.

9. (1) Paragraph 41(*b*) of the Regulations is repealed.

(2) Section 41 of the Regulations is amended by adding the following before paragraph (*c*):

(*b*.1) if the designated person would be the holder of more than one licence to produce; or

10. Section 54 of the Regulations is repealed.

5. Le passage de l'article 10 du même règlement précédant l'alinéa *a*) est remplacé par ce qui suit :

10. La photographie exigée à l'alinéa 4(2)*c*) doit permettre d'identifier le demandeur de façon précise et doit respecter les exigences suivantes :

6. L'alinéa 12(1)*d*) du même règlement est abrogé.

7. (1) L'alinéa 14(1)*b*) du même règlement est remplacé par ce qui suit :

b) les éléments exigés aux articles 4 à 10.

(2) Le paragraphe 14(2) du même règlement est remplacé par ce qui suit :

(2) Pour l'application de l'alinéa (1)*b*), il n'est nécessaire de fournir la photographie visée à l'alinéa 4(2)*c*) qu'à toutes les deux demandes de renouvellement.

8. (1) Les alinéas 34(1)*d*) et *e*) du même règlement sont remplacés par ce qui suit :

d) sous réserve du paragraphe (1.1), si le lieu mentionné dans la licence où la marihuana séchée peut être gardée diffère du lieu de résidence habituelle du demandeur de la licence, expédier ou transporter du premier lieu directement jusqu'au second une quantité de marihuana séchée ne dépassant pas la quantité maximale mentionnée dans l'autorisation de possession sur le fondement de laquelle la licence a été délivrée;

e) fournir ou livrer au demandeur de la licence une quantité de marihuana séchée ne dépassant pas la quantité maximale mentionnée dans l'autorisation de possession sur le fondement de laquelle la licence a été délivrée.

(2) L'article 34 du même règlement est modifié par adjonction, après le paragraphe (1), de ce qui suit :

(1.1) Le titulaire d'une licence de production à titre de personne désignée qui expédie, en vertu de l'alinéa (1)*d*), de la marihuana séchée doit prendre les mesures ci-après :

a) préparer son colis de façon sécuritaire conformément aux exigences suivantes :

(i) le contenu du colis est impossible à identifier à moins d'ouvrir celui-ci,

(ii) le colis est scellé de manière qu'il soit impossible de l'ouvrir sans briser le sceau;

b) employer le moyen d'expédition qui assurera les fins suivantes :

(i) le repérage du colis pendant le transport,

(ii) l'obtention d'un accusé de réception portant la signature du titulaire de l'autorisation de possession;

(iii) la garde diligente du colis durant le transport.

(3) Le paragraphe 34(2) du même règlement est abrogé.

9. (1) L'alinéa 41*b*) du même règlement est abrogé.

(2) L'article 41 du même règlement est modifié par adjonction, avant l'alinéa *c*), de ce qui suit :

b.1) dans le cas où la personne désignée deviendrait titulaire de plus d'une licence de production si la licence était délivrée;

10. L'article 54 du même règlement est abrogé.

11. The Regulations are amended by adding the following before section 55:

54.1 The holder of a licence to produce shall not produce marihuana in common with more than two other holders of licences to produce.

12. Section 56 of the Regulations and the heading before it are repealed.

13. Paragraph 62(2)(*d*) of the Regulations is replaced by the following:

(*d*) the photograph submitted under paragraph 4(2)(*c*) or section 14 as part of the application for the authorization or renewal is not an accurate representation of the holder of the authorization.

14. Section 70 of the Regulations and the heading before it are replaced by the following:

SUPPLY OF DRIED MARIHUANA

70. A medical practitioner who has obtained dried marihuana from a licensed dealer under subsection 24(2) of the *Narcotic Control Regulations* may provide the marihuana to the holder of an authorization to possess under the practitioner's care.

70.1 A licensed dealer, as defined in section 2 of the *Narcotic Control Regulations*, producing dried marihuana under contract with Her Majesty in right of Canada may provide or send that marihuana to the holder of an authorization to possess.

COMING INTO FORCE

15. These Regulations come into force on the day on which they are registered.

11. Le même règlement est modifié par adjonction, avant l'article 55, de ce qui suit :

54.1 Le titulaire d'une licence de production ne peut produire de la marihuana en commun avec plus de deux autres titulaires de licence de production.

12. L'article 56 du même règlement et l'intertitre le précédant sont abrogés.

13. L'alinéa 62(2)*d*) du même règlement est remplacé par ce qui suit :

d) la photographie fournie, en application de l'alinéa 4(2)*c*) ou de l'article 14, avec la demande d'autorisation ou de renouvellement ne représente pas bien le titulaire de l'autorisation.

14. L'article 70 du même règlement et l'intertitre le précédant sont remplacés par ce qui suit :

FOURNITURE DE MARIHUANA SÉCHÉE

70. Un médecin peut fournir, à la personne qu'il traite à titre professionnel et qui est titulaire d'une autorisation de possession, de la marihuana séchée s'il l'a obtenue d'un distributeur autorisé en vertu du paragraphe 24(2) du *Règlement sur les stupéfiants*.

70.1 Le distributeur autorisé, au sens de l'article 2 du *Règlement sur les stupéfiants*, qui produit de la marihuana séchée au titre d'un contrat avec Sa Majesté du chef du Canada peut en fournir ou expédier au titulaire d'une autorisation de possession.

ENTRÉE EN VIGUEUR

15. Le présent règlement entre en vigueur à la date de son enregistrement.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Description

On October 7, 2003, the Ontario Court of Appeal issued its decision in the case of *Hitzig et al. v. Her Majesty the Queen*. The Court declared five provisions of the *Marihuana Medical Access Regulations* (MMAR) invalid in order to render the MMAR constitutionally acceptable.

The objective of this regulatory initiative is to give national effect to elements of the remedy imposed by the Ontario Court of Appeal by repealing certain provisions of the MMAR and to implement an alternative mechanism to provide for reasonable access to a legal supply of marihuana for medical purposes.

The Legislative Framework

The MMAR, which were promulgated on July 30, 2001, provide seriously ill persons residing in Canada with a process by which they can obtain an authorization to possess and a licence to produce marihuana for medical purposes, when conventional therapies have been unsuccessful. There are two main components to the MMAR: "authorization to possess" and "licence to produce".

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(*Ce résumé ne fait pas partie du règlement.*)

Description

Le 7 octobre 2003, la Cour d'appel de l'Ontario a rendu sa décision dans l'affaire *Hitzig et al. c. Sa Majesté la Reine*. La Cour a déclaré cinq dispositions du *Règlement sur l'accès à la marihuana à des fins médicales* (RAMM) non valides afin de rendre le RAMM acceptable au plan constitutionnel.

L'objectif de cette initiative de réglementation est de donner un effet national à cetains éléments du recours imposé par la Cour d'appel de l'Ontario en révoquant certaines dispositions du RAMM et de mettre en oeuvre un autre mécanisme pour offrir un accès raisonnable à un approvisionnement légal de marihuana à des fins médicales.

Le cadre législatif

Le RAMM, qui a été promulgué le 30 juillet 2001, offre aux personnes gravement malades résidant au Canada un processus par lequel elles peuvent obtenir une autorisation de possession et une licence de production de la marihuana à des fins médicales lorsque les thérapies conventionnelles ont échoué. Le RAMM comprend deux éléments principaux: « autorisation de possession » et « licence de production ».

An Authorization to Possess (ATP) marihuana for medical purposes is issued on compassionate grounds to patients based on the advice and support of their medical practitioner(s).

A licence to produce limited quantities of marihuana is issued to either the authorized person or a person who has been designated by the holder of an ATP to produce marihuana on that person's behalf. The maximum quantity permitted to be produced is based on the ATP holder's daily dosage.

As of November 7, 2003, 602 persons in Canada hold ATPs. In 384 of those cases, the ATP holders also hold a *Personal-use Production Licence* (PPL) which allows them to produce marihuana for their own medical needs. In 64 cases, a Designated-person Production Licence (DPL) has been issued allowing a designated person to produce marihuana for the authorized person who applied for the licence.

Decisions by the Courts

On January 9, 2003, Justice Sidney N. Lederman of the Ontario Superior Court, in the case of *Hitzig et al. v. Her Majesty the Queen*, declared that the MMAR were constitutionally invalid and of no force and effect on the basis that they failed to provide a legal supply of marihuana for persons authorized to possess it for medical purposes. All parties appealed the decision.

In response to the Lederman decision, and while awaiting the outcome of the appeal, in July 2003, Health Canada implemented the "*Interim Policy for the Provision of Marihuana Seeds and Dried Marihuana Product for Medical Purposes in Canada*" (the Interim Policy). The Interim Policy provides a framework for the legal supply and distribution of marihuana seeds and dried marihuana for medical purposes in Canada. In order to allow for a supply of dried marihuana under Health Canada's Interim Policy, a regulation to exempt marihuana produced under contract with Her Majesty in Right of Canada from the requirements of the *Food and Drugs Act* (FDA) and its regulations was necessary. The *Marihuana Exemption (Food and Drugs Act) Regulations* (MER) came into force on July 8, 2003.

The Ontario Court of Appeal (the court) heard the appeal of the Lederman judgment on July 29-31, 2003. The Government did not ask the court to pass judgment on the constitutionality of the MMAR as modified by the Interim Policy nor did it suggest that the Interim Policy should have any effect on the outcome of the appeal. The Interim Policy was put before the court only so that it would be aware of the current state of affairs.

The court issued its decision on October 7, 2003. It found that the MMAR did not provide for reasonable access to a legal supply of marihuana for medical purposes because some persons granted authorizations to possess marihuana under the MMAR were dependent on the illicit market as a source of supply for their medical needs. The court held that this made the MMAR constitutionally defective. In addition, it found that the requirement in the MMAR that some applicants have the support of a second specialist physician to establish medical need is unconstitutional. The court rectified the constitutional deficiencies it had identified by declaring invalid the following five provisions of the MMAR:

Une autorisation de possession de la marihuana à des fins médicales est accordée pour des motifs de compassion aux patients d'après les conseils et l'appui de leur médecin.

Une licence de production permettant de produire des quantités limitées de marihuana est accordé à la personne autorisée ou à une personne qui est désignée par le détenteur d'une autorisation de possession pour produire de la marihuana pour le compte de cette personne. La quantité maximale pouvant être produite est basée sur la posologie quotidienne du détenteur d'une autorisation de possession.

Le 7 novembre 2003, 602 personnes au Canada avaient une licence de possession. Dans 384 de ces cas, les détenteurs d'une autorisation de possession avaient également une licence de production à des fins personnelles qui leur permet de produire de la marihuana pour répondre à leurs besoins médicaux. Dans 64 cas, une licence de production par une personne désignée a été accordée, permettant à une personne désignée de produire de la marihuana pour la personne autorisée qui a demandé la licence.

Décisions des tribunaux

Le 9 janvier 2003, le juge Sidney N. Lederman, de la Cour supérieure de l'Ontario, dans l'affaire *Hitzig et al. c. Sa Majesté la Reine*, a déclaré que le RAMM était invalide au plan constitutionnel et sans force exécutoire parce qu'il n'offrait pas un approvisionnement légal de marihuana aux personnes autorisées d'en posséder à des fins médicales. Toutes les parties ont interjeté appel de la décision.

En réponse à la décision Lederman, et en attendant le résultat de l'appel, en juillet 2003, Santé Canada a mis en oeuvre la *Politique provisoire pour l'approvisionnement de graines de marihuana et de marihuana séchée à des fins médicales au Canada* (la politique provisoire). La politique provisoire offre un cadre pour l'approvisionnement légal et la distribution de graines de marihuana et de marihuana séchée à des fins médicales au Canada. Afin de permettre un approvisionnement de marihuana séchée en vertu de la politique provisoire de Santé Canada, un règlement visant à exempter la marihuana produite à contrat avec Sa Majesté du chef du Canada des exigences de la *Loi sur les aliments et drogues* (LAD) et de son règlement était nécessaire. Le *Règlement d'exemption de la marihuana (Loi sur les aliments et drogues)* (REM) est entré en vigueur le 8 juillet 2003.

La Cour d'appel de l'Ontario (la cour) a entendu l'appel de la décision du juge Lederman du 29 au 31 juillet 2003. Le gouvernement n'a pas demandé à la cour de rendre un jugement sur la constitutionnalité du RAMM tel que modifié par la politique provisoire et n'a pas suggéré que la politique provisoire devrait avoir quelque effet que ce soit sur le résultat de l'appel. La politique provisoire a été présentée à la cour seulement pour qu'elle soit consciente de la situation actuelle.

La cour a rendu sa décision le 7 octobre 2003. Elle a conclu que le RAMM n'offre pas un accès raisonable à une source d'approvisionnement légale de marihuana à des fins médicales parce que certaines personnes ayant obtenu l'autorisation de posséder de la marihuana en vertu du RAMM dépendent du marché illicite comme source d'approvisionnement pour répondre à leurs besoins médicaux. La cour a soutenu que cela rend le RAMM invalide au plan constitutionnel. De plus, elle a conclu que l'exigence que certains demandeurs aient l'appui d'un deuxième médecin spécialiste pour établir le besoin médical est inconstitutionnelle. La cour a rectifié les lacunes constitutionnelles qu'elle a déterminées en déclarant non valides les cinq dispositions suivantes du RAMM :

- the prohibition against compensating a holder of a DPL for growing marihuana and supplying it to the holder of an ATP (s. 34(2));
- the provision preventing a DPL holder from growing marihuana for more than one ATP holder (par. 41(*b*));
- the prohibition against a DPL holder producing marihuana in common with more than two other DPL holders (s. 54); and
- the two provisions requiring a declaration by a second specialist (par. 4 (2)(*c*)) and s. 7).

In its decision, the court made clear that the Government need not accept the remedy crafted by the court and could address the constitutional shortcomings identified in the MMAR with an alternative regulatory framework. The Government has therefore decided not to appeal the decision, but instead, to respond to the court decision by amending the MMAR and continuing to provide access to the government source of supply under the Interim Policy.

Amendments to the MMAR

In order to improve its marihuana for medical purposes program, in 2003, Health Canada initiated consultations with stakeholders, including patients, physicians, pharmacists and law enforcement agencies, to discuss the need for potential changes to the MMAR. A Stakeholder Advisory Committee on Medical Marihuana (SAC),which is comprised of persons authorized to possess marihuana for medical purposes, physicians, nurses, pharmacists, and law enforcement officials, was established. The consultation activities will continue into 2004.

To respond to the decision of the court issued in early October 2003 in a timely manner, amendments to the MMAR will now be carried out in two phases. The first phase focuses on the response to the court decision, giving national effect to certain elements of the remedy granted by the court, while providing an alternative approach that will afford reasonable access to a legal supply of marihuana for authorized persons. The second phase will involve a broader review of the MMAR to address issues expressed by stakeholders and will incorporate a comprehensive consultative process.

This first phase of amendments to the MMAR includes the following provisions:

(1) To give national effect to the elements of the court remedy with respect to the MMAR requirements for a second specialist declaration under Category 3:

- Repeal the requirement for a second specialist declaration in the case of persons who are seeking an authorization to possess under Category 3 found in paragraph 4(2)(*c*) and section 7.

This amendment is also consistent with input received from stakeholders during the consultation processes undertaken by Health Canada.

(2) To give national effect to the aspect of the court remedy related to allowing DPL holders to obtain consideration:

- l'interdiction contre la compensation d'un détenteur de licence de production à titre de personne désignée pour cultiver de la marihuana et la fournir au détenteur d'une autorisation de posséder (paragraphe 34(2));
- la disposition empêchant un détenteur d'une licence de production par une personne désignée de cultiver de la marihuana pour plus d'un détenteur d'une autorisation de possession (alinéa 41*b*));
- l'interdiction contre un détenteur d'une licence de production à titre de personne désignée de produire de la marihuana en commun avec plus de deux autres détenteurs de licence de production (article 54); et
- les deux dispositions exigeant une déclaration d'un deuxième spécialiste (alinéa 4(2)*c*) et article 7).

Dans sa décision, la cour a indiqué clairement que le gouvernement n'a pas à accepter le recours présenté par la cour et pourrait corriger les lacunes constitutionnelles constatées dans le RAMM par un autre cadre de réglementation. Le gouvernement a par conséquent décidé de ne pas en appeler de la décision mais plutôt de répondre à la décision de la cour en modifiant le RAMM et en continuant de pourvoir à l'accès de la source d'approvisionnement du gouvernement en vertu de la politique provisoire.

Modifications au RAMM

Afin d'améliorer son programme de marihuana à des fins médicales, Santé Canada a entrepris en 2003, des consultations avec les intéressés, y compris les patients, les médecins, les pharmaciens et les organismes d'application des lois, afin de discuter de la nécessité de changements éventuels au RAMM. Un Comité consultatif des intervenants sur la marihuana à des fins médicales (CCIMFM), composé de personnes autorisées à posséder de la marihuana à des fins médicales, de médecins, d'infirmières et infirmiers, de pharmaciens et d'agents d'applications des lois a été établi. Les activités de consultation se poursuivront en 2004.

Afin de répondre à la décision de la cour rendue au début d'octobre 2003 sans retard, les modifications d'une manière opportune au RAMM seront apportées en deux phases. La première phase porte sur la réponse à la décision de la cour, en donnant un effet national à certains éléments du recours accordé par la cour tout en offrant une autre approche visant un accès raisonnable à un approvisionnement légal de marihuana aux personnes autorisées. La deuxième phase consistera en un examen élargi du RAMM concernant les préoccupations exprimées par les intéressés et comprendra un processus consultatif complet.

Cette première phase des modifications au RAMM comprend les dispositions suivantes :

(1) Donner un effet national aux éléments du recours judiciaire concernant l'exigence du RAMM d'une déclaration d'un deuxième spécialiste pour la catégorie 3 :

- Abrogation de l'exigence d'une déclaration d'un deuxième spécialiste dans le cas des personnes qui demandent une autorisation de posséder pour la catégorie 3 se trouvant à l'alinéa 4(2)*c*) et à l'article 7.

Cette modification est aussi compatible avec les commentaires des intéressés au cours du processus de consultation entrepris par Santé Canada.

(2) Donner un effet national à l'aspect du recours judiciaire lié aux détenteurs d'un permis de production par une personne désignée voulant obtenir une contrepartie :

- Repeal of subsection 34(2) to remove the prohibition against obtaining consideration for any activities related to the production of marihuana for persons authorized to possess;
- Amendment of paragraph 34(1)(*e*) to add authority to "provide" marihuana to authorized persons, whether or not for consideration; and
- Amendment of the MER to add an exemption for marihuana produced by DPL holders.

Based on evidence before them, the court found that, having regards to the time and effort involved in the production of marihuana, authorized persons were unlikely to find volunteers to produce marihuana on their behalf.

In addition to repealing the existing prohibition in the MMAR against the DPL holder obtaining consideration, the MMAR must be amended to expressly permit the DPL holder to provide marihuana to the authorized person for consideration in order to prevent the DPL holder from falling within the prohibition against trafficking of marihuana in section 5 of the *Controlled Drugs and Substances Act* (CDSA).

Because marihuana for medical purposes meets the definition of a drug under the FDA, it is also necessary to exempt the marihuana produced by DPL holders from the requirements of the FDA and its regulations, which regulate the sale and distribution of drugs in Canada, in order to permit DPL holders to be remunerated for their production activities.

(3) To provide for reasonable access to a legal source of supply, inclusion in the Regulations of the option of obtaining dried marihuana from a licensed dealer under contract with Her Majesty in right of Canada, as set out in Health Canada's Interim Policy.

- Amendment of paragraph 5(1)(*e*) of the Regulations to reflect the availability of a Government supply of dried marihuana; and
- Addition of a provision in Part IV of the MMAR to enable the Government's supply of dried marihuana to be shipped directly to persons who hold an ATP marihuana for medical purposes.

The Government is committed to continuing to supply dried marihuana to persons authorized to possess marihuana for medical purposes, and marihuana seeds to persons authorized to produce marihuana, until such time as an alternate supply that satisfies the requirements of the FDA, the CDSA and their respective regulations is available.

Some medical practitioners have expressed concerns about receiving marihuana on behalf of their patients who are ATP holders, since there may be increased risks to the safety and security of medical offices. To address such concerns, the MMAR are amended to include authority for a licensed dealer who is producing marihuana on contract to the Government to supply the ATP holder directly. ATP holders will continue to have the option to access their supply of dried marihuana through their practitioner, if the latter is supportive of this arrangement.

- Abrogation du paragraphe 34(2) pour supprimer l'interdiction contre l'obtention d'une contrepartie pour les activités associées à la production de marihuana pour les personnes autorisées à posséder;
- Modification de l'alinéa 34(1)*e*) pour ajouter l'autorisation de « fournir » de la marihuana aux personnes autorisées, que ce soit ou non pour contrepartie; et
- Modification au REM pour ajouter une exemption pour la marihuana produite par les détenteurs d'une licence de production à titre de personne désignée.

D'après la preuve dont elle disposait, la cour a conclu que, ayant égard au temps et à l'effort nécessaires pour produire de la marihuana, il est peu probable que les personnes autorisées trouvent des bénévoles pour produire de la marihuana à des fins médicales pour leur compte.

En plus d'abroger l'interdiction existante dans le RAMM contre le détenteur d'une licence de production à titre de personne désignée obtenant une contrepartie, le RAMM doit être modifié pour permettre expressément au détenteur d'une licence de production à titre de personne désignée de fournir de la marihuana à la personne autorisée pour une contrepartie afin de prévenir que le détenteur d'une licence de production à titre de personne désignée tombe sous le coup de l'interdiction de trafic de marihuana de l'article 5 de la *Loi réglementant certaines drogues et autres substances* (LRCDAS).

Parce que la marihuana à des fins médicales satisfait à la définition d'un médicament en vertu de la LAD, il est également nécessaire d'exempter la marihuana produite par les détenteurs de licences de production à titre de personne désignée des exigences de la LAD et de son règlement, qui réglementent la vente et la distribution de drogues au Canada afin de permettre à ces personnes d'être rémunérées pour leurs activités de production.

(3) Afin d'offrir un accès raisonnable à une source d'approvisionnement légale, l'inclusion dans le règlement de l'option d'obtenir de la marihuana séchée d'un distributeur autorisé à contrat avec Sa Majesté du chef du Canada, tel qu'établi dans la politique provisoire de Santé Canada.

- Modification de l'alinéa 5(1)*e*) du règlement pour refléter la disponibilité d'un approvisionnement gouvernemental de marihuana séchée; et
- Ajout d'une disposition dans la Partie IV du RAMM pour permettre que l'approvisionnement gouvernemental de marihuana séchée soit expédié directement aux personnes qui détiennent une autorisation de possession de la marihuana à des fins médicales.

Le gouvernement s'est engagé à continuer de fournir de la marihuana séchée aux personnes autorisées à en posséder à des fins médicales et des graines de marihuana aux personnes autorisées à en produire jusqu'à ce qu'il existe un autre approvisionnement qui satisfait aux exigences de la LAD, de la LRCDAS et à leurs règlements respectifs.

Certains médecins ont exprimé des préoccupations concernant le fait de recevoir de la marihuana au nom de leur patients qui sont détenteurs d'une autorisation de possession, puisqu'il peut y avoir des risques accrus pour la sécurité de leur cabinet médical. Pour alléger les préoccupations, le RAMM est modifié pour inclure l'autorisation qu'un distributeur autorisé qui produit de la marihuana à contrat avec le gouvernement fournisse directement la marihuana au détenteur d'une autorisation de possession. Les détenteurs d'une autorisation de possession continueront d'avoir

Health Canada will continue discussions with pharmacists and provincial/territorial regulators of pharmacy practice regarding the possibility of establishing a mechanism whereby marihuana for medical purposes would be provided through pharmacies in due course.

The amendment of paragraph 5(1)(*e*), combined with amendments to Part IV of the MMAR, will clearly define the currently available legal sources of supply of marihuana for medical purposes. The Interim Policy, released on July 9, 2003, will be amended to reflect the Government's commitment to provide ongoing access to the Government's supply of dried marihuana.

(4) To maintain control over the production and distribution of marihuana in keeping with the principles of the CDSA and the FDA, and to maintain compliance with Canada's international obligations, the limits on the production of marihuana for medical purposes by DPL holders will be maintained:

- Paragraph 41(*b*) will be re-enacted to reinstate on a national basis, the limit on the number of persons for whom one designated person can produce marihuana; under the MMAR, one DPL holder can cultivate for only one ATP holder; and
- Section 54 will be re-enacted to reinstate on a national basis, the limit on the number of DPL holders who can produce marihuana in common; under the MMAR, a DPL holder is not permitted to produce marihuana in common with more than two other DPL holders.

These limits on the production of marihuana are necessary to:

- maintain control over distribution of an unapproved drug product, which has not yet been demonstrated to comply with the requirements of the FDA/FDR;
- minimize the risk of diversion of marihuana for non-medical use;
- be consistent with the obligations imposed on Canada as a signatory to the United Nations' *Single Convention on Narcotic Drugs*, 1961 as amended in 1972 (the 1961 Convention), in respect of cultivation and distribution of cannabis; and
- maintain an approach that is consistent with movement toward a supply model whereby marihuana for medical purposes would be: subject to product standards; produced under regulated conditions; and distributed through pharmacies, on the advice of physicians, to patients with serious illnesses, when conventional therapies are unsuccessful. Such a model would also include a program of education and market surveillance.

(5) To ease certain other restrictions on DPL holders in order to enhance access to marihuana produced by DPL holders

- Repeal of section 56 which requires DPL holders to keep records of their production activities; and
- Amendment of section 34 to allow shipment of dried marihuana by a DPL holder to an ATP holder under secure conditions. This will allow an ATP holder to designate a person

l'option d'accéder à leur approvisionnement de marihuana séchée par l'intermédiaire de leur médecin si ce dernier soutient cet arrangement.

Santé Canada poursuivra les discussions avec les pharmaciens et les législateurs provinciaux et territoriaux de pharmacie concernant la possibilité d'établir un mécanisme par lequel la marihuana à des fins médicales serait fournie par les pharmacies au moment opportun.

La modification de l'alinéa 5(1)*e*), combinée aux modifications à la Partie IV du RAMM, définira clairement les sources d'approvisionnement légales de marihuana à des fins médicales disponibles actuellement. La politique provisoire publiée le 9 juillet 2003 sera modifiée pour refléter l'engagement du gouvernement de fournir un accès continu à l'approvisionnement gouvernemental de marihuana séchée.

(4) Afin de maintenir un contrôle sur la production et la distribution de marihuana selon les principes de la LRCDAS et de la LAD, et pour maintenir la conformité aux obligations internationales du Canada, les limites pour la production de marihuana à des fins médicales par les détenteurs d'une licence de production à titre de personne désignée seront maintenues :

- L'alinéa 41*b*) sera remis en vigueur pour réintégrer au plan national la limite du nombre de personnes pour lesquelles une personne désignée peut produire; en vertu du RAMM, une seule personne désignée peut produire pour un seul détenteur d'une autorisation de possession; et
- L'article 54 sera remis en vigueur pour réintégrer au plan national la limite du nombre de personnes désignées qui peuvent produire de la marihuana en commun; en vertu du RAMM, un détenteur de licence de production à titre de personne désignée n'est pas autorisé à produire de la marihuana en commun avec plus de deux autres détenteurs.

Ces limites sur la production de marihuana sont nécessaires pour :

- maintenir le contrôle sur la distribution d'une drogue non approuvée, dont la conformité aux exigences de la LAD et du RAD n'a pas encore été démontrée;
- minimiser le risque de détournement de la marihuana à des fins non médicales;
- être compatible avec les obligations du Canada comme signataire de la Convention unique sur les stupéfiants des Nations Unies de 1961, telle que modifiée en 1972 (la convention de 1961), concernant la culture et la distribution de cannabis; et
- maintenir une approche qui est compatible avec le mouvement vers un modèle d'approvisionnement selon lequel la marihuana à des fins médicales serait assujettie à des normes du produit, serait produite sous des conditions réglementées et serait distribuée par les pharmacies, sur avis des médecins, aux patients gravement malades lorsque les thérapies conventionnelles échouent. Un tel modèle comprend également un programme d'éducation et la surveillance du marché.

(5) Alléger certaines autres restrictions imposées afin d'améliorer l'accès à la marihuana produite par les détenteurs d'une licence de production à titre de personne désignée.

- Abrogation de l'article 56 qui exige que les personnes désignées tiennent des dossiers de leur production; et

who is known to the ATP holder but who lives outside the immediate community to grow on the ATP holder's behalf, when the latter is unable to find a designated person who lives close by.

These amendments will provide additional alternatives for ATP holders to obtain a legal supply of marihuana when they are unable to produce marihuana for themselves and choose not to access the dried marihuana produced on contract to the Government.

In addition to the foregoing, a number of technical, consequential amendments are effected to realign the remaining provisions in the MMAR with these changes.

The Government believes that these regulatory amendments, combined with the availability of the Government source of supply under the Interim Policy, satisfy the principles set out in the decision of the Ontario Court of Appeal in that they will provide for reasonable access to a legal source of supply and thus, ensure the constitutionality of the MMAR. At the same time, these amendments provide a framework that is consistent with the principles of the FDA and its regulations regarding limitations on the sale and distribution of a drug product until its safety, efficacy and quality have been demonstrated. Further, these amendments respect the principles underlying the CDSA and its regulations in respect of control over the distribution of controlled substances to ensure that they are used only for legitimate scientific and medical purposes to protect public health and safety.

Alternatives

The options outlined below provide an overview of the regulatory alternatives that were considered prior to the selection of Option 3.

Option 1: Give national effect to the Ontario Court of Appeal remedy in its entirety by repealing all the sections declared invalid.

The Government has no issue with repeal of the provisions of the MMAR with respect to the requirement for a declaration from a second medical specialist or the provision which restricts the ability of the holder of a DPL to obtain consideration. The removal of the limitations on production of marihuana are, however, viewed as being sufficiently problematic to be considered untenable.

Removing the limits on the number of holders of an ATP for whom a DPL holder can produce, and permitting the pooling of multiple DPLs, have the effect of expanding the production and distribution of marihuana to an extent which, when combined with the declaration of invalidity of the restriction on DPL holders from obtaining consideration, facilitates the development of commercial activity that would move Canada away from compliance with its international obligations under the United Nations 1961 Convention. Articles 23 and 28 of the convention require signatory countries who permit the cultivation of marihuana, to create a national government agency that has exclusive right on import, export, wholesale trade and maintenance of

- Modification de l'article 34 pour permettre l'expédition de la marihuana séchée d'une personne désignée productrice à un détenteur d'une autorisation de possession selon des conditions de sécurité. Cela permettra à un détenteur d'une autorisation de possession de désigner une personne qu'il connaît mais qui vit à l'extérieur de la collectivité immédiate pour cultiver en son nom lorsque le détenteur de l'autorisation de possession ne peut trouver une personne désignée qui vit à proximité.

Ces modifications offriront d'autres solutions aux détenteurs d'une autorisation de possession pour se procurer un approvisionnement de marihuana légal lorsqu'ils sont incapables de produire la marihuana eux-mêmes et qu'ils choisissent de ne pas se procurer la marihuana séchée produite à contrat pour le gouvernement.

En plus de ce qui précède, plusieurs modifications techniques conséquentes sont apportées pour réaligner les autres dispositions du RAMM sur ces changements.

Le gouvernement croit que ces modifications à la réglementation, combinées à la disponibilité de la source d'approvisionnement gouvernementale en vertu de la politique provisoire, respectent les principes établis dans la décision de la Cour d'appel de l'Ontario en ce qu'elles offriront un accès raisonnable à une source d'approvisionnement légale et, ainsi, assureront la constitutionnalité du RAMM. En même temps, ces modifications offrent un cadre qui est compatible avec les principes de la LAD et de son règlement concernant les limitations de la vente et de la distribution d'un produit pharmaceutique jusqu'à ce que son innocuité, son efficacité et sa qualité aient été démontrées.

De plus, ces modifications respectent les principes sous-tendant la LRCDAS et son règlement concernant le contrôle de la distribution de substances contrôlées pour s'assurer qu'elles sont utilisées uniquement à des fins scientifiques et médicales légitimes pour protéger la santé et la sécurité publiques.

Solutions envisagées

Les options présentées ci-après offrent un aperçu des solutions de réglementation qui ont été considérées avant de choisir l'option 3.

Option 1 : Donner un effet national au recours de la Cour d'appel de l'Ontario dans son entier en abrogeant tous les articles déclarés non valides.

Le gouvernement n'a aucun problème à abroger les dispositions du RAMM concernant l'exigence d'une déclaration d'un deuxième médecin spécialiste ou la disposition qui restreint la capacité du détenteur d'une licence de production à titre de personne désignée d'obtenir une contrepartie. La suppression des limitations de production de marihuana est toutefois considérée suffisamment problématique pour être considérée insoutenable.

Si l'on supprime les limites quant au nombre de détenteurs d'une autorisation de possession, pour lesquels un détenteur de licence de production à titre de personne désignée peut produire et si l'on permet le regroupement de multiples producteurs, cela aurait pour effet d'étendre la production et la distribution de marihuana à un degré auquel, combiné à la déclaration de l'invalidité de la restriction des détenteurs de licence de production à titre de personne désignée d'obtenir une contrepartie, faciliterait le développement d'une activité commerciale qui éloignerait le Canada de la conformité à ses obligations internationales en vertu de la Convention de 1961 des Nations Unies. Les articles 23 et 28 de la convention exigent que les pays signataires qui permettent la

stocks of marihuana. Provisions within Article 23, as they apply to cannabis [marihuana], include obligations such as the requirement for all cultivators of marihuana to deliver their total crops of marihuana to the agency for distribution. The Government of Canada has been compelled by the courts to develop a system to provide for a legal supply of marihuana for medical purposes. In doing so, the Government has made every effort to implement a system that will meet its international obligations to the fullest extent possible. By permitting only limited production of marihuana by persons authorized to possess for medical purposes, or limited production of marihuana by a designated person on their behalf, that is carried out within the terms and conditions of their licences to produce, the supply of marihuana for medical purposes in Canada is not inconsistent with the intention of the Convention to prevent illicit trade in marihuana. To expand the number of ATP holders that a DPL holder can produce for beyond the current 1:1 ratio, would obligate the Government to implement a system to collect all marihuana produced in order to comply with the 1961 Convention.

The expanded production and distribution of marihuana that would result from removal of the existing limits in the MMAR also runs contrary to the intent of the FDA/FDR to restrict the sale and distribution of an unapproved, non-standardized drug product outside of the manufacturing processes and distribution channels authorized by the FDR. Further, larger marihuana grow operations, in the absence of more stringent requirements for security measures to protect plants and the harvested dried marihuana, would increase the risk of diversion of marihuana thereby posing greater challenges for law enforcement and greater risk to the public health and safety of Canadians. The Government would need to establish a significant administrative infrastructure to maintain regulatory surveillance over such grow operations in order to minimize the risk of diversion. In addition to the domestic concerns, it is anticipated that other countries would view this as a further relaxation of Canada's controls over marihuana and that they would express grave concerns with respect to the increased potential for cross-border diversion and resulting exacerbation of their own domestic drug abuse problems.

Option 2: Reinstate all provisions struck down by the Ontario Court of Appeal and appeal the court's decision.

The court decision left untouched the basic exemption scheme under the MMAR (i.e., authorizations to possess and licences to produce for medical purposes) and afforded the Government large discretion in implementing an alternate remedy to address the issue of reasonable access to a legal supply. The Government is addressing those aspects of the remedy it finds problematic by means of regulatory amendment and provision of marihuana from the Government source of supply under the Interim Policy, rather than by an appeal of the decision. The court decision provides useful guidance on how to strike the proper balance between the need to preserve and promote public health and safety of Canadians through controlled substances legislation, while respecting individuals' rights to access medical marihuana. For instance, removing the requirement for a second specialist declaration for persons seeking to be authorized within Category 3 and allowing

culture de la marihuana établissent un organisme gouvernemental national qui a le droit exclusif d'importer, exporter, vendre en gros et maintenir des stocks de marihuana. Les dispositions de l'article 23, appliquées au cannabis (marihuana) comprennent des obligations, par exemple l'exigence que tous les producteurs de marihuana livrent toute leur production de marihuana à l'organisme pour distribution. Le gouvernement du Canada a été contraint par les tribunaux à développer un système pour fournir un approvisionnement légal de marihuana à des fins médicales. Ce faisant, le gouvernement a fait tous les efforts pour mettre en oeuvre un système qui lui permettra de s'acquitter de ses obligations internationales le mieux possible. En permettant seulement une production limitée de marihuana par les personnes autorisées à posséder à des fins médicales ou une production limitée de marihuana par une personne désignée pour leur compte, produite selon les conditions de leur permis de produire, l'approvisionnement de marihuana à des fins médicales au Canada n'est pas incompatible avec l'intention de la convention de prévenir le commerce illicite de la marihuana. Augmenter le nombre de détenteurs d'une autorisation de possession pour lesquels une personne désignée peut produire au-delà du ratio 1:1 actuel obligerait le gouvernement à mettre en oeuvre un système pour collecter toute la marihuana produite afin de se conformer à la convention de 1961.

La production et la distribution élargies de marihuana qui découleraient de la suppression des limites actuelles du RAMM vont également à l'encontre de l'intention de la LAD et du RAD de restreindre la vente et la distribution d'un produit pharmaceutique non approuvé et non standardisé à l'extérieur des procédés de fabrication et des canaux de distribution autorisés par le RAD. En outre, en l'absence d'exigences plus strictes de mesures de sécurité pour protéger les plants et la marihuana récoltée séchée, des exploitations de culture de marihuana plus importantes accroîtraient le risque de détournement de la marihuana, présentant ainsi de plus grands défis pour l'application des lois et un risque accru pour la santé et la sécurité des Canadiens. Le gouvernement devrait établir aussi une infrastructure administrative considérable pour maintenir la surveillance réglementaire de ces exploitations de culture afin de minimiser le risque de détournement. En plus de ces préoccupations au pays, on prévoit que d'autres pays considéreraient cela comme un autre relâchement des contrôles du Canada sur la marihuana, et qu'ils exprimeraient de graves préoccupations concernant le potentiel accru de détournement transfrontalier et l'aggravation conséquente de leurs problèmes d'abus de drogues nationaux.

Option 2 : Rétablir toutes les dispositions invalidées par la Cour d'appel de l'Ontario et en appeler de la décision.

La décision de la cour laisse inchangé le plan d'exemption de base en vertu du RAMM (c'est-à-dire les autorisations de possession et les licences de production à des fins médicales et permet au gouvernement un vaste pouvoir discrétionnaire quant à la mise en oeuvre d'une autre solution pour régler le problème de l'accès raisonnable à un approvisionnement légal. Le gouvernement aborde ces aspects du recours qu'il trouve problématiques au moyen d'une modification du règlement et de l'approvisionnement d'une source gourvernementale de marihuana en vertu de la politique provisoire plutôt que d'un appel de la décision. La décision de la cour offre une orientation utile sur la façon de trouver le bon équilibre entre la nécessité de préserver et de promouvoir la santé et la sécurité par la législation sur les substances contrôlées et le respect des droits des personnes à l'accès à la marihuana à des fins médicales. Par exemple, le fait de supprimer

consideration to be received by DPL holders, improve the MMAR framework and are consistent with input received to date from stakeholders.

Option 3: Implement regulatory changes as outlined in phase I of "Amendments to the MMAR".

This option gives national effect to the court-imposed remedy with respect to the two provisions that require a second specialist declaration in the case of applications under Category 3 and the provision prohibiting a DPL holder from obtaining consideration. It also respects the intent of the court decision by providing reasonable access to a legal supply of marihuana for medical purposes by entrenching the Government's Interim Policy and commitment to continue to provide marihuana for medical purposes into the Regulations. The amendments further help to facilitate access to marihuana for medical purposes by easing some of the restrictions on DPL holders, pending transition to a new supply model.

Option 3 was determined to be the preferred option. This option incorporates certain aspects of the court's remedy into the MMAR, while providing for reasonable access to a legal source of marihuana. In rendering its decision the court expressly left it open to the Government to develop an alternative mechanism to address the issue of legal supply of marihuana for medical purposes.

The identified regulatory amendments, combined with continued provision of marihuana seeds and dried marihuana by the Government, establish a legal means by which authorized persons can have reasonable access to marihuana for medical purposes in Canada, thereby addressing the constitutionality issues raised by the court. This revised framework offers a balance between facilitating access to a legal supply of marihuana for medical purposes and providing a level of protection against diversion and misuse of marihuana which is comparable to what currently exists under the MMAR. Further, it allows Canada to continue to meet its international obligations under the United Nations drug control conventions to the fullest extent possible.

Benefits and Costs

These regulatory amendments are expected to have an impact on the following sectors:

Public

Persons authorized or wishing to obtain an ATP marihuana for medical purposes will benefit from enhanced clarity around, and access to, the different options for a legal supply of marihuana. DPL holders will benefit from the easing of some of the requirements currently imposed on them.

Some persons may view the maintenance of restrictions on production by DPL holders as depriving them of the opportunity

l'exigence d'une déclaration d'un deuxième spécialiste pour les personnes demandant l'autorisation de la catégorie 3 et de permettre la contrepartie aux détenteurs de licence de production à titre de personne désignée améliore le cadre du RAMM et est compatible avec les commentaires exprimés à ce jour par les intéressés.

Option 3 : Mettre en oeuvre les changements à la réglementation, tel que souligné dans la phase I des « modifications au RAMM ».

Cette option donne un effet national au recours judiciaire concernant les deux dispositions qui exigent une déclaration d'un deuxième spécialiste dans le cas des demandes de la catégorie 3 et la disposition interdisant à un détenteur de licence de production à titre de personne désignée d'obtenir une contrepartie. Elle respecte également l'intention de la décision de la cour en offrant un accès raisonnable à un approvisionnement légal de marihuana à des fins médicales par l'enchâssement de la politique provisoire du gouvernement et l'engagement à continuer de fournir la marihuana à des fins médicales dans le règlement.

Les modifications aident en outre à faciliter l'accès à la marihuana à des fins médicales en allégeant certaines des restrictions imposées aux détendeurs de licence de production à titre de personne désignée pendant la transition vers un nouveau modèle d'approvisionnement.

L'option 3 a été déterminée comme option préférée. Cette option intègre certains aspects du recours de la cour au RAMM en offrant un accès raisonnable à une source légale de marihuana. En rendant sa décision, la cour a laissé expressément le gouvernement libre de mettre au point un autre mécanisme pour régler le problème de l'approvisionnement légal de marihuana à des fins médicales.

Les modifications réglementaires indiquées, combinées à l'approvisionnement continu de graines de marihuana et de marihuana séchée par le gouvernement, établissent un moyen légal permettant aux personnes autorisées d'avoir un accès raisonnable à la marihuana à des fins médicales au Canada, réglant ainsi les problèmes constitutionnels soulevés par la cour. Ce cadre révisé offre également un équilibre entre un accès plus facile à un approvisionnement légal de marihuana à des fins médicales et un niveau de protection contre le détournement et le mauvais usage de la marihuana, protection comparable à celle qui existe actuellement en vertu du RAMM. En outre, il permet au Canada de continuer de s'acquitter de ses obligations internationales en vertu des conventions de contrôle des drogues des Nations Unies dans la plus grande mesure du possible.

Avantages et coûts

On prévoit que ces modifications à la réglementation auront une incidence sur les secteurs suivants :

Public

Les personnes autorisées ou désirant obtenir une autorisation de possession de la marihuana à des fins médicales bénéficieront d'une meilleure clarté et d'un meilleur accès aux différentes options d'approvisionnement légal de marihuana. Les détenteurs de licence de production à titre de personne désignée bénéficieront d'un allégement de certaines des exigences qui leur sont actuellement imposées.

Certaines personnes peuvent considérer le maintien des restrictions de la production par les détenteurs de permis de production

to develop a business or not-for-profit service to supply marihuana to persons authorized to possess. It was never the intent of the MMAR, which permits, on a compassionate basis, seriously ill persons to obtain an authorization to possess marihuana for medical purposes when conventional therapies have been unsuccessful, to give rise to any form of commercial supply network. The amendments will serve to maintain an appropriate level of control over the production and distribution of marihuana, as an unapproved drug, to minimize the risk of diversion and misuse and thereby protect the health and safety of the Canadian public.

Medical Practitioners

Medical practitioners have expressed concern about the risk to their personal and office security if they are the sole avenue for access to the Government supply of dried marihuana. These amendments will benefit medical practitioners by allowing a licensed dealer who produces marihuana on contract to the Government to supply authorized persons directly, thereby alleviating some of the pressures on the practitioners. Similarly, the removal of the requirement for the second specialist declaration for applicants in Category 3 takes into account the concerns expressed by the medical community and relieves some of the burden on the health care system.

Pharmacists

These amendments have no direct effect on pharmacists. They may, however, cause pharmacists to receive more questions from patients concerning the use of marihuana for medical purposes in light of Health Canada's communication of its intent to pursue the possibility of making marihuana for medical purposes available through pharmacies.

Law Enforcement Agencies

Law enforcement agencies will benefit from maintenance of the limits on the production of marihuana as a means to manage the risk of diversion and misuse of marihuana. No increase in enforcement costs associated with these amendments is expected although the number of persons licensed to produce marihuana under a DPL could increase.

Health Canada

Health Canada anticipates that it will be able to manage any additional workload within existing resources and is of the view that the benefits derived from these regulatory amendments in terms of ongoing protection of public health and safety, and compliance with international drug control conventions, outweigh the any additional costs that will be incurred. This initiative is expected to increase costs related to administration of the marihuana medical access program due to an anticipated increase in the number of applications for designated-person production licences, and requests for Government supplied dried marihuana.

Consultation

An exemption from pre-publication was requested in order for these Regulations amending the MMAR to be registered and

par une personne désignée comme les privant de la possibilité de développer une affaire ou un service à but non lucratif pour fournir de la marihuana aux personnes autorisées à en posséder. Ce ne fut jamais l'intention du RAMM qui permet, pour des motifs de compassion, à des personnes gravement malades d'obtenir une autorisation de posséder de la marihuana à des fins médicales lorsque les thérapies conventionnelles ont échoué, de donner naissance à quelque forme que ce soit de réseau d'approvisionnement commercial. Les modifications serviront à maintenir un niveau approprié de contrôle de la production et de la distribution de marihuana, en tant que drogue non approuvée, pour minimiser le risque de détournement et de mauvais usage et à protéger ainsi la santé et la sécurité du public canadien.

Médecins

Les médecins ont exprimé une préoccupation concernant le risque pour leur sécurité personnelle et de leur cabinet s'ils sont la seule voie d'accès à l'approvisionnement de marihuana séchée du gouvernement. Ces modifications bénéficieront aux médecins en permettant au distributeur autorisé qui produit de la marihuana à contrat pour le gouvernement de la fournir directement aux personnes autorisées, allégeant ainsi les pressions sur les médecins. De même, la suppression de l'exigence de la déclaration d'un deuxième spécialiste pour les demandeurs de la catégorie 3 tient compte des préoccupations exprimées par la communauté médicale et soulage une partie du fardeau imposé au système de soins de santé.

Pharmaciens

Ces modifications n'ont aucun effet direct sur les pharmaciens. Toutefois, elles peuvent faire en sorte que les pharmaciens reçoivent plus de questions des patients concernant l'usage de la marihuana à des fins médicales à la lumière de la communication de Santé Canada de son intention de poursuivre la possibilité de rendre la marihuana à des fins médicales disponible dans les pharmacies.

Organismes d'application des lois

Les organismes d'application des lois bénéficieront du maintien des limites de la production de marihuana comme moyen de gérer le risque de détournement et de mauvais usage de la marihuana. On ne prévoit aucune augmentation des coûts d'application associés à ces modifications, bien que le nombre de personnes autorisées à produire de la marihuana grâce à un permis de production par une personne désignée pourrait augmenter.

Santé Canada

Santé Canada prévoit pouvoir gérer la charge de travail supplémentaire à même les ressources existantes et est d'avis que les avantages découlant de ces modifications à la réglementation en termes de protection de la santé et de la sécurité publiques ainsi que de conformité aux conventions internationales de contrôle des drogues dépassent les coûts additionnels qui seront encourus. On prévoit que cette initiative augmentera les coûts associés à l'administration du programme d'accès médical à la marihuana en raison de l'augmentation prévue du nombre de demandes de licences de production à titre de personne désignée et des demandes de marihuana séchée fournie par le gouvernement.

Consultations

Une exemption de publication préalable a été demandée afin que ce règlement modifiant le RAMM soit enregistré et publié

published in the *Canada Gazette*, Part II (CGII) as soon as possible following the Ontario Court of Appeal decision (October 7, 2003) in the Hitzig case. Early registration was requested to:

- give national effect in a timely manner to certain elements of the remedy imposed by the Ontario Court of Appeal;
- protect public health and safety by ensuring that the production and distribution of marihuana for medical purposes occur within a regulatory framework aimed at minimizing the risk of diversion and misuse of marihuana as an unapproved drug; and
- continue to meet Canada's international commitments, particularly in respect of the United Nations' drug control conventions.

Early in 2003, Health Canada commenced consultations with various stakeholder groups regarding changes to the MMAR. These groups included:

- SAC as part of regular, ongoing consultations with this group;
- the Canadian Medical Association (CMA);
- representatives of Canadian pharmacists and their regulatory authorities; and
- law enforcement agencies and associations.

Following release of the Ontario Court of Appeal decision in *Hitzig et al.*, Health Canada has undertaken further, more focused, discussions with stakeholder groups concerning the Department's plans for proceeding with changes to the MMAR using a two-phased approach, and concerning this regulatory initiative, in particular. Groups contacted included:

- the SAC;
- a working group of the SAC, convened specifically for the purpose of timely consideration of proposed regulatory change;
- the CMA; and
- representatives of law enforcement agencies.

Input received from the above-referenced discussions was considered by Health Canada when drafting these Regulations to go directly to CGII. When registration and CGII publication takes place, the stakeholder community and the public will be notified by mail, e-mail, and Web announcement.

Consultations for Phase II amendments to the MMAR are scheduled to continue early in 2004, and will involve all stakeholder groups mentioned above, plus broader consultation with representatives of authorized persons, licensed persons, and other Canadians likely to be affected by further changes to the MMAR.

Compliance and Enforcement

These regulatory amendments have no impact on existing compliance and enforcement mechanisms under the provisions of the CDSA and the MMAR as identified in the Regulatory Impact Analysis Statement published in the *Canada Gazette*, Part II, on July 4, 2001. Maintenance of the limits on the production of marihuana will avoid an increase in existing compliance and enforcement challenges and further strain on law enforcement and regulatory inspection programs.

dans la *Gazette du Canada*, Partie II (CGII) aussitôt que possible après la décision de la Cour d'appel de l'Ontario (7 octobre 2003) dans l'affaire Hitzig. L'enregistrement hâtif a été demandé pour :

- donner un effet national en temps opportun à certains éléments du recours imposé par la Cour d'appel de l'Ontario;
- protéger la santé et la sécurité publiques en s'assurant que la production et la distribution de marihuana à des fins médicales se font dans un cadre réglementaire visant à minimiser le risque de détournement et de mauvais usage d'une drogue non approuvée; et
- continuer de s'acquitter des engagements internationaux du Canada, particulièrement en ce qui concerne les conventions de contrôle des drogues des Nations Unies.

Au début de 2003, Santé Canada a entamé des consultations avec divers groupes intéressés concernant les changements au RAMM, notamment :

- le CCIMFM dans le cadre de consultations régulières avec ce groupe;
- l'Association médicale canadienne (AMC);
- des représentants des pharmaciens canadiens et de leurs organismes de réglementation; et
- les organismes et associations d'application des lois.

Après la publication de la décision de la Cour d'appel de l'Ontario dans l'affaire Hitzig, Santé Canada a entamé des discussions plus centrées avec les groupes intéressés concernant les plans du ministère pour procéder avec les changements au RAMM selon une approche en deux phases et concernant cette initiative réglementaire en particulier. Voici les groupes consultés :

- le CCIMFM;
- un groupe de travail de ce comité, convoqué spécialement dans le but de la considération en temps opportun des changements réglementaires proposés;
- l'AMC; et
- des représentants des organismes d'application des lois.

Les commentaires découlant de ces discussions ont été considérés par Santé Canada pour rédiger ce règlement devant aller directement à la CGII. Lorsque l'enregistrement et la publication dans la CGII auront lieu, les intéressés et le public en seront avisés par courrier, courriel et une annonce sur le Web.

Les consultations pour les modifications de la phase II du RAMM se poursuivront au début de 2004 et y participeront les groupes susmentionnés. Il y aura en outre une consultation élargie avec des représentants des personnes autorisées, des détenteurs de licences et d'autres Canadiens susceptibles d'être touchés par d'autres changements au RAMM.

Respect et exécution

Ces modifications à la réglementation n'ont aucune incidence sur les mécanismes actuels de conformité et d'application en vertu des dispositions de la LRCDAS et du RAMM, tel qu'indiqué dans le Résumé de l'étude d'impact de la réglementation publié dans la *Gazette du Canada* Partie II le 4 juillet 2001. Le maintien des limites de la production de marihuana permettra d'éviter une augmentation des défis relatifs à la conformité et à l'application et de la pression sur les programmes d'applications des lois et d'inspection réglementaire.

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Published by the Queen's Printer for Canada, 2003

Publié par l'Imprimeur de la Reine pour le Canada, 2003

Registration
SOR/2005-177 June 7, 2005

CONTROLLED DRUGS AND SUBSTANCES ACT

Regulations Amending the Marihuana Medical Access Regulations

P.C. 2005-1124 June 7, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], hereby makes the annexed *Regulations Amending the Marihuana Medical Access Regulations*.

REGULATIONS AMENDING THE MARIHUANA MEDICAL ACCESS REGULATIONS

AMENDMENTS

1. (1) The definitions "adverse drug reaction", "category 3 symptom" and "terminal illness" in subsection 1(1) of the *Marihuana Medical Access Regulations*[1] are repealed.

(2) The definitions "category 1 symptom", "category 2 symptom" and "medical purpose" in subsection 1(1) of the Regulations are replaced by the following:

"category 1 symptom" means any symptom treated within the context of compassionate end-of-life care or a symptom set out in column 1 of the schedule that is associated with a medical condition set out in column 2 or with the medical treatment of that condition. (*symptôme de catégorie 1*)

"category 2 symptom" means a debilitating symptom that is associated with a medical condition or with the medical treatment of that condition and that is not a category 1 symptom. (*symptôme de catégorie 2*)

"medical purpose" means the purpose of mitigating a person's category 1 or 2 symptom identified in an application for an authorization to possess. (*fins médicales*)

(3) Subsection 1(1) of the Regulations is amended by adding the following in alphabetical order:

"licensed dealer" has the same meaning as in section 2 of the *Narcotic Control Regulations*. (*distributeur autorisé*)

2. Paragraph 4(2)(*b*) of the Regulations is replaced by the following:

(*b*) a medical declaration made by the medical practitioner treating the applicant; and

3. Paragraphs 5(1)(*e*) to (*g*) of the Regulations are replaced by the following:

(*e*) that the authorization is sought in respect of marihuana to be

(i) produced by the applicant or a designated person, in which case the designated person must be named, or

[a] S.C. 1996, c. 19
[1] SOR/2001-227

Enregistrement
DORS/2005-177 Le 7 juin 2005

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales

C.P. 2005-1124 Le 7 juin 2005

Sur recommandation du ministre de la Santé et en vertu du paragraphe 55(1) de la *Loi réglementant certaines drogues et autres substances*[a], Son Excellence la Gouverneure générale en conseil prend le *Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales*, ci-après.

RÈGLEMENT MODIFIANT LE RÈGLEMENT SUR L'ACCÈS À LA MARIHUANA À DES FINS MÉDICALES

MODIFICATIONS

1. (1) Les définitions de « maladie en phase terminale », « réaction indésirable à une drogue » et « symptôme de catégorie 3 », au paragraphe 1(1) du *Règlement sur l'accès à la marihuana à des fins médicales*[1], sont abrogées.

(2) Les définitions de « fins médicales », « symptôme de catégorie 1 » et « symptôme de catégorie 2 », au paragraphe 1(1) du même règlement, sont respectivement remplacées par ce qui suit :

« fins médicales » Fins visant l'atténuation chez une personne d'un symptôme de catégorie 1 ou 2 mentionné dans la demande d'autorisation de possession. (*medical purpose*)

« symptôme de catégorie 1 » Tout symptôme dont le traitement est effectué au moyen de soins palliatifs ou l'un des symptômes figurant à la colonne 1 de l'annexe et associé à l'état pathologique mentionné à la colonne 2 ou à son traitement médical. (*category 1 symptom*)

« symptôme de catégorie 2 » Symptôme débilitant associé à un état pathologique ou à son traitement médical, à l'exclusion d'un symptôme de catégorie 1. (*category 2 symptom*)

(3) Le paragraphe 1(1) du même règlement est modifié par adjonction, selon l'ordre alphabétique, de ce qui suit :

« distributeur autorisé » S'entend au sens de l'article 2 du *Règlement sur les stupéfiants*. (*licensed dealer*)

2. L'alinéa 4(2)*b*) du même règlement est remplacé par ce qui suit :

b) une déclaration médicale fournie par le médecin traitant du demandeur;

3. Les alinéas 5(1)*e*) à *g*) du même règlement sont remplacés par ce qui suit :

e) la mention qu'il entend, selon le cas :

(i) produire la marihuana lui-même ou la faire produire par une personne désignée, auquel cas le nom de la personne désignée doit être mentionné,

[a] L.C. 1996, ch. 19
[1] DORS/2001-227

(ii) obtained under section 70.2 from a licensed dealer producing marihuana under contract with Her Majesty in right of Canada or obtained from a medical practitioner under section 70.4;

(*f*) that the applicant is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug;

(*g*) that the applicant has discussed the potential benefits and risks of using marihuana with the medical practitioner providing the medical declaration under paragraph 4(2)(*b*);

(*h*) that the applicant

(i) is aware that the benefits and risks associated with the use of marihuana are not fully understood and that the use of marihuana may involve risks that have not yet been identified, and

(ii) accepts the risks associated with using marihuana;

(*i*) if the daily amount stated under paragraph 6(1)(*c*) is more than five grams, that the applicant

(i) has discussed the potential risks associated with an elevated daily consumption of dried marihuana with the medical practitioner providing the medical declaration, including risks with respect to the effect on the applicant's cardiovascular and pulmonary systems and psychomotor performance, risks associated with the long-term use of marihuana as well as potential drug dependency, and

(ii) accepts those risks; and

(*j*) that marihuana will be used only for the treatment of the symptom stated for the applicant under paragraph 6(1)(*b*).

4. Section 6 of the Regulations is replaced by the following:

6. (1) The medical declaration under paragraph 4(2)(*b*) must indicate

(*a*) the medical practitioner's name, business address and telephone number, facsimile transmission number and e-mail address if applicable, the province in which the practitioner is authorized to practise medicine and the number assigned by the province to that authorization;

(*b*) the name of the applicant, the applicant's medical condition, the symptom that is associated with that condition or its treatment and that is the basis for the application and whether the symptom is a category 1 or 2 symptom;

(*c*) for the purpose of determining, under subsection 11(3), the maximum quantity of dried marihuana to be authorized, the daily amount of dried marihuana, in grams, and the form and route of administration that the applicant intends to use;

(*d*) the anticipated period of usage, if less than 12 months;

(*e*) that conventional treatments for the symptom have been tried or considered and have been found to be ineffective or medically inappropriate for the treatment of the applicant; and

(*f*) that the medical practitioner is aware that no notice of compliance has been issued under the *Food and Drug Regulations* concerning the safety and effectiveness of marihuana as a drug.

(2) In the case of a category 2 symptom, the medical declaration must also indicate

(ii) obtenir la marihuana, en vertu de l'article 70.2, d'un distributeur autorisé qui la produit au titre d'un contrat avec Sa Majesté du chef du Canada ou l'obtenir, en vertu de l'article 70.4, d'un médecin;

f) la mention qu'il sait qu'aucun avis de conformité n'a été délivré en vertu du *Règlement sur les aliments et drogues* quant à l'innocuité ou à l'efficacité de la marihuana comme drogue;

g) la mention qu'il a discuté avec le médecin qui a fourni la déclaration médicale visée à l'alinéa 4(2)*b*) des avantages éventuels et des risques associés à l'usage de la marihuana;

h) la mention :

(i) d'une part, qu'il sait que les avantages et les risques associés à l'usage de la marihuana ne sont pas parfaitement compris et que son usage pourrait présenter des risques non prévus,

(ii) d'autre part, qu'il accepte les risques associés à l'usage de celle-ci;

i) si la quantité quotidienne mentionnée à l'alinéa 6(1)*c*) excède cinq grammes, la mention :

(i) d'une part, qu'il a discuté avec le médecin qui a fourni la déclaration médicale des risques que présenterait la consommation quotidienne d'une quantité élevée de marihuana séchée, notamment des risques associés à l'usage à long terme de la marihuana, du risque d'accoutumance à celle-ci et des effets qu'elle peut avoir sur les systèmes cardiovasculaire et pulmonaire du demandeur ainsi que sur ses aptitudes psychomotrices,

(ii) d'autre part, qu'il accepte ces risques;

j) la mention qu'il n'utilisera la marihuana que pour le traitement du symptôme mentionné à l'alinéa 6(1)*b*).

4. L'article 6 du même règlement est remplacé par ce qui suit :

6. (1) La déclaration médicale visée à l'alinéa 4(2)*b*) comporte les renseignements suivants :

a) le nom du médecin, les adresse et numéro de téléphone de son lieu de travail, la province où il est autorisé à exercer la médecine, le numéro d'autorisation attribué par la province et, le cas échéant, son numéro de télécopieur et son adresse électronique;

b) le nom du demandeur, son état pathologique, le symptôme associé à cet état ou à son traitement et sur lequel la demande d'autorisation est fondée, avec mention de la catégorie 1 ou 2 du symptôme;

c) la quantité quotidienne de marihuana séchée, en grammes, ainsi que la forme posologique et le mode d'administration que le demandeur entend utiliser afin que soit déterminée, selon le calcul prévu au paragraphe 11(3), la quantité maximale de marihuana séchée à autoriser;

d) la période d'usage prévue, si elle est inférieure à douze mois;

e) la mention que des traitements conventionnels du symptôme ont été essayés ou envisagés mais se sont révélés inefficaces ou ne conviennent pas dans le cas du demandeur;

f) la mention que le médecin sait qu'aucun avis de conformité n'a été délivré en vertu du *Règlement sur les aliments et drogues* quant à l'innocuité ou à l'efficacité de la marihuana comme drogue.

(2) Dans le cas d'un symptôme de catégorie 2, la déclaration médicale comporte en outre les renseignements suivants :

(*a*) if the medical practitioner making the medical declaration is a specialist, the practitioner's area of specialization and that the area of specialization is relevant to the treatment of the applicant's medical condition; and

(*b*) if the medical practitioner making the medical declaration is not a specialist,

(i) that the applicant's case has been assessed by a specialist,

(ii) the name of the specialist,

(iii) the specialist's area of specialization and that the area of specialization is relevant to the treatment of the applicant's medical condition,

(iv) the date of the specialist's assessment of the applicant's case,

(v) that the specialist concurs that conventional treatments for the symptom are ineffective or medically inappropriate for the treatment of the applicant, and

(vi) that the specialist is aware that marihuana is being considered as an alternative treatment for the applicant.

5. Section 8 of the Regulations is replaced by the following:

8. A medical declaration under paragraph 4(2)(*b*) must be dated and signed by the medical practitioner making it and must attest that the information contained in the declaration is correct and complete.

6. Section 9 of the Regulations and the heading before it are repealed.

7. Paragraph 10(*d*) of the Regulations is replaced by the following:

(*d*) be certified, on the reverse side, by the medical practitioner making the medical declaration under paragraph 4(2)(*b*) to be an accurate representation of the applicant.

8. Section 11 of the Regulations is replaced by the following:

11. (1) Subject to section 12, if the requirements of sections 4 to 10 are met, the Minister shall issue to the applicant an authorization to possess for the medical purpose mentioned in the application, and shall provide notice of the authorization to the medical practitioner who made the medical declaration under paragraph 4(2)(*b*).

(2) The authorization shall indicate

(*a*) the name, date of birth and gender of the holder of the authorization;

(*b*) the full address of the place where the holder ordinarily resides;

(*c*) the authorization number;

(*d*) the name of the medical practitioner who made the medical declaration under paragraph 4(2)(*b*);

(*e*) the maximum quantity of dried marihuana, in grams, that the holder may possess at any time;

(*f*) the date of issue; and

(*g*) the date of expiry.

(3) The maximum quantity of dried marihuana referred to in paragraph (2)(*e*) or resulting from an amendment under subsection 20(1) is the amount determined according to the following formula:

$$A \times 30$$

where A is the daily amount of dried marihuana, in grams, stated under paragraph 6(1)(*c*) or subparagraph 19(2)(*d*)(i), whichever applies.

a) si le médecin qui fournit la déclaration est un spécialiste, son domaine de spécialisation et la mention que celui-ci est lié au traitement de l'état pathologique du demandeur;

b) si le médecin qui fournit la déclaration n'est pas un spécialiste :

(i) la mention qu'un spécialiste a procédé à une évaluation médicale du dossier du demandeur,

(ii) le nom du spécialiste,

(iii) son domaine de spécialisation et la mention que celui-ci est lié au traitement de l'état pathologique du demandeur,

(iv) la date de l'évaluation médicale du dossier du demandeur,

(v) la mention que le spécialiste est d'accord que les traitements conventionnels du symptôme sont inefficaces ou ne conviennent pas dans le cas du demandeur,

(vi) la mention que le spécialiste sait que la marihuana est une méthode subsidiaire de traitement pour le demandeur.

5. L'article 8 du même règlement est remplacé par ce qui suit :

8. La déclaration médicale visée à l'alinéa 4(2)*b*) est datée et signée par le médecin qui la fournit et atteste que les renseignements qui y figurent sont exacts et complets.

6. L'article 9 du même règlement et l'intertitre le précédant sont abrogés.

7. L'alinéa 10*d*) du même règlement est remplacé par ce qui suit :

d) elle comporte au verso une déclaration signée par le médecin qui a fourni la déclaration médicale visée à l'alinéa 4(2)*b*) et attestant que la photographie représente bien le demandeur.

8. L'article 11 du même règlement est remplacé par ce qui suit :

11. (1) Sous réserve de l'article 12, le ministre délivre au demandeur l'autorisation de possession aux fins médicales précisées dans la demande si les exigences des articles 4 à 10 sont remplies; il en avise le médecin qui a fourni la déclaration médicale visée à l'alinéa 4(2)*b*).

(2) L'autorisation comporte les renseignements suivants :

a) les nom, date de naissance et sexe du titulaire de l'autorisation;

b) l'adresse complète de son lieu de résidence habituelle;

c) le numéro d'autorisation;

d) le nom du médecin qui a fourni la déclaration médicale visée à l'alinéa 4(2)*b*);

e) la quantité maximale de marihuana séchée, en grammes, que peut posséder le titulaire de l'autorisation;

f) la date de délivrance;

g) la date d'expiration.

(3) La quantité maximale de marihuana séchée visée à l'alinéa (2)*e*) ou résultant d'une modification aux termes du paragraphe 20(1) se calcule selon la formule suivante :

$$A \times 30$$

où A représente la quantité quotidienne de marihuana séchée, en grammes, déterminée aux termes de l'alinéa 6(1)*c*) ou du sous-alinéa 19(2)*d*)(i), selon le cas.

9. Subsection 12(1) of the Regulations is amended by adding the word "or" at the end of paragraph (*a*), by striking out the word "or" at the end of paragraph (*b*) and by repealing paragraph (*c*).

10. Subsection 14(2) of the Regulations is replaced by the following:

(2) For the purpose of paragraph (1)(*b*), a photograph referred to in paragraph 4(2)(*c*) is required only with every fifth renewal application.

11. Sections 15 and 16 of the Regulations are repealed.

12. Section 18 of the Regulations is replaced by the following:

18. The Minister shall refuse to renew an authorization to possess for any reason referred to in section 12.

13. Sections 19 to 22 of the Regulations are replaced by the following:

19. (1) An application to amend an authorization to possess shall be made to the Minister by the holder of the authorization when a change occurs with respect to

(*a*) the holder's name;

(*b*) the holder's address of ordinary residence or mailing address; or

(*c*) the daily amount of dried marihuana if the new amount requires an increase in the maximum quantity of dried marihuana, in grams, that the holder may possess at any time.

(2) The application must include

(*a*) the authorization number and, if applicable, the licence number of the licence to produce that has been issued on the basis of the authorization;

(*b*) the requested amendment;

(*c*) in the case of a change under paragraph (1)(*a*), proof of the change; and

(*d*) in the case of a change under paragraph (1)(*c*),

(i) a statement containing the information required under paragraph 6(1)(*c*), signed and dated by the medical practitioner who made the medical declaration under paragraph 4(2)(*b*), and

(ii) if the new daily amount is more than five grams, the statement required under paragraph 5(1)(*i*), signed and dated by the applicant.

20. (1) Subject to subsection (2), if an application complies with section 19, the Minister shall amend the authorization to possess.

(2) The Minister shall refuse to amend an authorization to possess for any reason referred to in section 12.

21. (1) If an authorization to possess is amended with respect to the name or address of the holder of the authorization, the Minister shall, if applicable, amend the licence to produce that was issued on the basis of the authorization.

(2) If an authorization to possess is amended with respect to the daily amount of dried marihuana, the Minister shall, if applicable, amend the licence to produce that was issued on the basis of the authorization to reflect the change in the maximum number of marihuana plants that the holder of the licence may produce and the maximum quantity of dried marihuana that the holder of the licence may keep.

9. L'alinéa 12(1)*c*) du même règlement est abrogé.

10. Le paragraphe 14(2) du même règlement est remplacé par ce qui suit :

(2) Pour l'application de l'alinéa (1)*b*), il n'est nécessaire de fournir la photographie visée à l'alinéa 4(2)*c*) qu'à toutes les cinq demandes de renouvellement.

11. Les articles 15 et 16 du même règlement sont abrogés.

12. L'article 18 du même règlement est remplacé par ce qui suit :

18. Le ministre refuse de renouveler l'autorisation de possession dans les cas prévus à l'article 12.

13. Les articles 19 à 22 du même règlement sont remplacés par ce qui suit :

19. (1) L'autorisation de possession fait l'objet d'une demande de modification à présenter au ministre par le titulaire de l'autorisation dans le cas où un changement survient à l'égard de l'un des éléments suivants :

a) le nom du titulaire;

b) l'adresse de son lieu de résidence habituelle ou son adresse postale;

c) la quantité quotidienne de marihuana séchée, s'il en résulte une augmentation de la quantité maximale de marihuana séchée, en grammes, que le titulaire est autorisé à posséder.

(2) La demande de modification comporte les éléments suivants :

a) le numéro d'autorisation et, le cas échéant, le numéro de la licence de production délivrée sur le fondement de l'autorisation;

b) la modification demandée;

c) dans le cas d'un changement visé à l'alinéa (1)*a*), une preuve à cet effet;

d) dans le cas d'un changement visé à l'alinéa (1)*c*) :

(i) une déclaration contenant les renseignements mentionnés à l'alinéa 6(1)*c*) que signe et date le médecin qui fournit la déclaration médicale visée à l'alinéa 4(2)*b*),

(ii) si la nouvelle quantité quotidienne de marihuana séchée excède cinq grammes, une déclaration comportant la mention prévue à l'alinéa 5(1)*i*) que signe et date le demandeur.

20. (1) Sous réserve du paragraphe (2), le ministre apporte la modification à l'autorisation de possession si la demande de modification est conforme aux exigences de l'article 19.

(2) Le ministre refuse de modifier l'autorisation de possession dans les cas visés à l'article 12.

21. (1) Le ministre, s'il modifie le nom ou l'adresse du titulaire de l'autorisation de possession apporte, le cas échéant, les modifications voulues à la licence de production délivrée sur le fondement de l'autorisation.

(2) Le ministre, s'il modifie la quantité quotidienne de marihuana séchée mentionnée dans l'autorisation de possession apporte, le cas échéant, les modifications voulues à la licence de production délivrée sur le fondement de l'autorisation concernant le nombre maximum de plants de marihuana que peut produire le titulaire de la licence de production et la quantité maximale de marihuana séchée qu'il peut garder.

14. Section 23 of the Regulations is replaced by the following:

23. While in the presence of the holder of an authorization to possess and providing assistance in the administration of marihuana to the holder, the person providing the assistance may, for the purpose of providing the assistance, possess a quantity of dried marihuana not exceeding an amount equal to the maximum quantity of dried marihuana the holder is authorized to possess as set out in the authorization to possess, divided by 30.

15. The heading before section 26 of the Regulations is replaced by the following:

Application for Licence

16. The heading before section 27 of the Regulations is repealed.

17. (1) Paragraph 30(1)(*a*) of the Regulations is replaced by the following:

(*a*) "A" is the daily amount of dried marihuana, in grams, stated under paragraph 6(1)(*c*) or subparagraph 19(2)(*d*)(i), whichever applies;

(2) Paragraph 30(1)(*c*) of the Regulations is replaced by the following:

(*c*) "D" is the maximum number of marihuana plants referred to in subsection 21(2) and paragraphs 29(2)(*f*) and 40(2)(*g*).

18. (1) The portion of subsection 31(1) of the English version of the Regulations before paragraph (*a*) is replaced by the following:

31. (1) In the formulas in subsection (2),

(2) Paragraph 31(1)(*b*) of the Regulations is replaced by the following:

(*b*) "E" is the maximum quantity of dried marihuana mentioned in subsection 21(2) and in paragraphs 29(2)(*h*) and 40(2)(*i*).

19. Subsection 34(1.1) of the Regulations is replaced by the following:

(1.1) A holder of a designated-person production licence sending dried marihuana under paragraph (1)(*d*) shall

(*a*) securely pack the marihuana in a package that

(i) will not open or permit the escape of its contents during handling and transportation,

(ii) is sealed so that the package cannot be opened without the seal being broken,

(iii) prevents the escape of odour associated with the marihuana, and

(iv) prevents the contents from being identified without the package being opened; and

(*b*) use a method of sending that involves

(i) a means of tracking the package during transit,

(ii) obtaining a signed acknowledgment of receipt, and

(iii) safekeeping of the package during transit.

20. The heading before section 36 of the Regulations is replaced by the following:

14. L'article 23 du même règlement est remplacé par ce qui suit :

23. La personne qui aide le titulaire d'une autorisation de possession à prendre de la marihuana séchée peut, en sa présence, pendant qu'elle lui apporte son aide, avoir en sa possession, à cette fin, une quantité de marihuana séchée qui n'excède pas le résultat obtenu par la division de la quantité maximale de marihuana séchée que le titulaire de l'autorisation est autorisé à avoir en sa possession aux termes de l'autorisation par 30.

15. L'intertitre précédant l'article 26 du même règlement est remplacé par ce qui suit :

Demande de licence

16. L'intertitre précédant l'article 27 du même règlement est abrogé.

17. (1) L'alinéa 30(1)*a*) du même règlement est remplacé par ce qui suit :

a) « A » représente la quantité quotidienne de marihuana séchée, en grammes, déterminée aux termes de l'alinéa 6(1)*c*) ou du sous-alinéa 19(2)*d*)(i), selon le cas;

(2) L'alinéa 30(1)*c*) du même règlement est remplacé par ce qui suit :

c) « D » représente le nombre maximum de plants de marihuana visé au paragraphe 21(2) et aux alinéas 29(2)*f*) et 40(2)*g*).

18. (1) Le passage du paragraphe 31(1) de la version anglaise du même règlement précédant l'alinéa *a*) est remplacé par ce qui suit :

31. (1) In the formulas in subsection (2),

(2) L'alinéa 31(1)*b*) du même règlement est remplacé par ce qui suit :

b) « E » représente la quantité maximale de marihuana séchée visée au paragraphe 21(2) et aux alinéas 29(2)*h*) et 40(2)*i*).

19. Le paragraphe 34(1.1) du même règlement est remplacé par ce qui suit :

(1.1) Le titulaire d'une licence de production à titre de personne désignée qui expédie, en vertu de l'alinéa (1)*d*), de la marihuana séchée doit prendre les mesures ci-après :

a) préparer son colis de façon à assurer la sécurité du contenu et conformément aux exigences suivantes :

(i) le colis ne peut s'ouvrir ou laisser son contenu s'échapper pendant la manutention ou le transport,

(ii) il est scellé de sorte qu'il soit impossible de l'ouvrir sans en briser le sceau,

(iii) son étanchéité est telle qu'aucune odeur de marihuana ne peut s'en échapper,

(iv) il est impossible d'en connaître le contenu à moins de l'ouvrir;

b) employer le moyen d'expédition qui assurera les fins suivantes :

(i) le repérage du colis pendant le transport,

(ii) l'obtention d'un accusé de réception signé,

(iii) la garde diligente du colis durant le transport.

20. L'intertitre précédant l'article 36 du même règlement est remplacé par ce qui suit :

Application for Licence

21. The heading before section 37 of the Regulations is repealed.

22. Section 51 of the Regulations and the heading before it are repealed.

23. The headings before section 58 of the Regulations are replaced by the following:

PART 3

GENERAL OBLIGATIONS

Documents

24. Subsection 58(1) of the English version of the Regulations is replaced by the following:

58. (1) On demand, the holder of an authorization to possess must show proof of their authority to possess dried marihuana to a police officer.

25. The heading before section 59 and sections 59 and 60 of the Regulations are replaced by the following:

59. No one may add to, delete or obliterate from, or alter in any other way, an authorization to possess, a licence to produce or any other document provided to the holder of an authorization to possess or a licence to produce as proof of their authorization or licence.

60. (1) If an authorization to possess, licence to produce or any other document provided to the holder of an authorization to possess or a licence to produce as proof of their authorization or licence is amended, the holder of the authorization or licence shall, within 30 days after receiving the amended document, return the replaced document to the Minister.

(2) If an authorization to possess or licence to produce is revoked, the holder of the authorization or licence shall, within 30 days after the revocation, return to the Minister the revoked document and any other document provided to the holder of the authorization or the licence as proof of their authorization or licence.

26. Paragraph 62(2)(*b*) of the Regulations is replaced by the following:

(*b*) the medical practitioner who made the medical declaration under paragraph 4(2)(*b*) for the holder of the authorization advises the Minister in writing that the continued use of marihuana by the holder is contraindicated.

27. The heading before section 68 of the English version of the Regulations is replaced by the following:

Complaints and Communication of Information

28. Subsection 68(3) of the Regulations is replaced by the following:

(3) The Minister is authorized to communicate to any Canadian police force or any member of a Canadian police force, any information contained in the report of the inspector, subject to that information being used only for the proper administration or enforcement of the Act or these Regulations.

29. The Regulations are amended by adding the following after section 68:

Demande de licence

21. L'intertitre précédant l'article 37 du même règlement est abrogé.

22. L'article 51 du même règlement et l'intertitre le précédant sont abrogés.

23. Les intertitres précédant l'article 58 du même règlement sont remplacés par ce qui suit :

PARTIE 3

OBLIGATIONS GÉNÉRALES

Documents

24. Le paragraphe 58(1) de la version anglaise du même règlement est remplacé par ce qui suit :

58. (1) On demand, the holder of an authorization to possess must show proof of their authority to possess dried marihuana to a police officer.

25. L'intertitre précédant l'article 59 et les articles 59 et 60 du même règlement sont remplacés par ce qui suit :

59. Il est interdit de modifier de quelque façon que ce soit, notamment par adjonction ou suppression, une autorisation de possession, une licence de production ou tout autre document prouvant que le titulaire est autorisé à posséder de la marihuana séchée ou à en produire.

60. (1) Dans le cas où l'autorisation de possession, la licence de production ou tout autre document prouvant l'autorisation de posséder de la marihuana séchée ou d'en produire est modifié, le titulaire doit, dans les trente jours suivant la date de réception du document de remplacement, remettre au ministre le document remplacé.

(2) Dans le cas où l'autorisation de possession ou la licence de production est révoquée, le titulaire doit, dans les trente jours suivant la révocation, remettre au ministre le document révoqué au ministre ainsi que tout autre document prouvant son autorisation de posséder de la marihuana séchée ou d'en produire.

26. L'alinéa 62(2)*b*) du même règlement est remplacé par ce qui suit :

b) le médecin qui a fourni la déclaration médicale visée à l'alinéa 4(2)*b*) avise le ministre par écrit que l'usage continu de la marihuana est contre-indiqué pour le titulaire;

27. L'intertitre précédant l'article 68 de la version anglaise du même règlement est remplacé par ce qui suit :

Complaints and Communication of Information

28. Le paragraphe 68(3) du même règlement est remplacé par ce qui suit :

(3) Le ministre est autorisé à communiquer, à tout corps policier canadien ou à tout membre d'un tel corps policier, tout renseignement contenu dans le rapport de l'inspecteur, sous réserve que son utilisation soit limitée à l'application ou l'exécution de la Loi ou du présent règlement.

29. Le même règlement est modifié par adjonction, après l'article 68, de ce qui suit :

68.1 In response to a request from a Canadian police force or a member of a Canadian police force engaged in an investigation under the Act or these Regulations, the Minister is authorized, for the purpose of that investigation and the proper administration or enforcement of the Act or these Regulations, to communicate

(*a*) in respect of a named individual, whether the individual is the holder of an authorization to possess or a licence to produce;

(*b*) in respect of a specified address, whether the address is

(i) the place where the holder of an authorization to possess ordinarily resides and, if so, the name of the holder of the authorization and the applicable authorization number,

(ii) the site where the production of marihuana is authorized under a licence to produce and, if so, the name of the holder of the licence and the applicable licence number, or

(iii) the site where dried marihuana may be kept under a licence to produce and, if so, the name of the holder of the licence and the applicable licence number;

(*c*) in respect of an authorization to possess,

(i) the name, date of birth and gender of the holder of the authorization,

(ii) the full address of the place where the holder ordinarily resides,

(iii) the authorization number,

(iv) the maximum quantity of dried marihuana that the holder is authorized to possess,

(v) the dates of issue and expiry, and

(vi) if the authorization has expired, whether an application to renew the authorization has been made prior to the date of expiry and the status of the application; and

(*d*) in respect of a licence to produce,

(i) the name, date of birth and gender of the holder of the licence,

(ii) the full address of the place where the holder ordinarily resides,

(iii) the licence number,

(iv) the full address of the site where the production of marihuana is authorized,

(v) the authorized production area,

(vi) the maximum number of marihuana plants that may be under production at the production site at any time,

(vii) the full address of the site where dried marihuana may be kept,

(viii) the maximum quantity of dried marihuana that may be kept at the site referred to in subparagraph (vii) at any time,

(ix) the dates of issue and expiry, and

(x) if the licence has expired, whether an application has been made to renew the licence prior to the date of expiry and the status of the application.

30. Part 4 of the Regulations is replaced by the following:

68.1 Le ministre est autorisé à communiquer les renseignements ci-après à tout corps policier canadien ou à tout membre d'un tel corps policier qui en fait la demande dans le cadre d'une enquête en application de la Loi ou du présent règlement, sous réserve que leur utilisation soit limitée à l'enquête en cause ou à l'application ou l'exécution de la Loi et du présent règlement :

a) dans le cas d'une personne identifiée, l'existence d'une autorisation de possession ou d'une licence de production;

b) dans le cas d'une adresse donnée, s'il s'agit :

(i) du lieu de résidence habituelle d'un titulaire d'une autorisation de possession et, dans l'affirmative, le nom de celui-ci ainsi que le numéro de l'autorisation,

(ii) d'un lieu de production de marihuana autorisé aux termes d'une licence de production et, dans l'affirmative, le nom du titulaire de la licence ainsi que le numéro de celle-ci,

(iii) d'un lieu où peut être gardée de la marihuana séchée aux termes d'une licence de production et, dans l'affirmative, le nom du titulaire de la licence ainsi que le numéro de celle-ci;

c) dans le cas d'une autorisation de possession :

(i) les nom, date de naissance et sexe du titulaire de l'autorisation,

(ii) l'adresse complète du lieu de résidence habituelle du titulaire,

(iii) son numéro,

(iv) la quantité maximale de marihuana séchée que le titulaire est autorisé à avoir en sa possession,

(v) ses dates de délivrance et d'expiration,

(vi) dans le cas où elle est expirée, l'existence d'une demande de renouvellement présentée avant l'expiration et l'état de cette demande;

d) dans le cas d'une licence de production :

(i) les nom, date de naissance et sexe du titulaire de la licence,

(ii) l'adresse complète du lieu de résidence habituelle du titulaire,

(iii) son numéro,

(iv) l'adresse complète du lieu où la production de la marihuana est autorisée,

(v) l'aire de production autorisée,

(vi) le nombre maximum de plants de marihuana que le titulaire est autorisé à produire au lieu de production,

(vii) l'adresse complète du lieu où peut être gardée la marihuana séchée,

(viii) la quantité maximale de marihuana séchée que le titulaire est autorisé à garder au lieu mentionné au sous-alinéa (vii),

(ix) ses dates de délivrance et d'expiration,

(x) dans le cas où elle est expirée, l'existence d'une demande de renouvellement présentée avant l'expiration et l'état de cette demande.

30. La partie 4 du même règlement est remplacée par ce qui suit :

PART 4

SUPPLY OF MARIHUANA SEED AND DRIED MARIHUANA

Marihuana Seed

70. The Minister is authorized to import and possess viable cannabis seed for the purpose of selling, providing, transporting, sending or delivering the seed to

(*a*) the holder of a licence to produce; or

(*b*) a licensed dealer.

70.1 A licensed dealer producing viable cannabis seed under contract with Her Majesty in right of Canada may provide or send that seed to the holder of a licence to produce.

Dried Marihuana

70.2 A licensed dealer producing dried marihuana under contract with Her Majesty in right of Canada may provide or send that marihuana to the holder of an authorization to possess.

70.3 A pharmacist, as defined in section 2 of the *Narcotic Control Regulations*, may provide dried marihuana produced by a licensed dealer under contract with Her Majesty in right of Canada to the holder of an authorization to possess.

70.4 A medical practitioner who has obtained dried marihuana from a licensed dealer under subsection 24(2) of the *Narcotic Control Regulations* may provide the marihuana to the holder of an authorization to possess under the practitioner's care.

70.5 The Minister may sell or provide dried marihuana produced in accordance with section 70.2 to the holder of an authorization to possess.

31. The schedule to the Regulations is replaced by the following:

SCHEDULE
(Section 1)

CATEGORY 1 SYMPTOMS

Item	Column 1 Symptom	Column 2 Associated Medical Conditions
1.	Severe nausea	Cancer, AIDS/HIV infection
2.	Cachexia, anorexia, weight loss	Cancer, AIDS/HIV infection
3.	Persistent muscle spasms	Multiple sclerosis, spinal cord injury or disease
4.	Seizures	Epilepsy
5.	Severe pain	Cancer, AIDS/HIV infection, multiple sclerosis, spinal cord injury or disease, severe form of arthritis

COMING INTO FORCE

32. These Regulations come into force on the day on which they are registered.

PARTIE 4

FOURNITURE DE GRAINES DE MARIHUANA ET DE MARIHUANA SÉCHÉE

Graines de marihuana

70. Le ministre est autorisé à importer ou posséder des graines de marihuana viables en vue de les vendre, fournir, transporter, expédier ou livrer aux personnes suivantes :

a) le titulaire d'une licence de production;

b) le distributeur autorisé.

70.1 Le distributeur autorisé qui produit des graines de marihuana viables au titre d'un contrat avec Sa Majesté du chef du Canada peut en fournir ou en expédier au titulaire d'une licence de production.

Marihuana séchée

70.2 Le distributeur autorisé qui produit de la marihuana séchée au titre d'un contrat avec Sa Majesté du chef du Canada peut en fournir ou en expédier au titulaire d'une autorisation de possession.

70.3 Le pharmacien, au sens de l'article 2 du *Règlement sur les stupéfiants*, peut fournir au titulaire d'une autorisation de possession de la marihuana séchée produite par un distributeur autorisé au titre d'un contrat avec Sa Majesté du chef du Canada.

70.4 Le médecin peut fournir, à la personne qui est soumise à ses soins professionnels et qui est titulaire d'une autorisation de possession, de la marihuana séchée s'il l'a obtenue d'un distributeur autorisé en vertu du paragraphe 24(2) du *Règlement sur les stupéfiants*.

70.5 Le ministre peut vendre ou fournir au titulaire d'une autorisation de possession de la marihuana séchée produite conformément à l'article 70.2.

31. L'annexe du même règlement est remplacée par ce qui suit :

ANNEXE
(article 1)

SYMPTÔMES DE CATÉGORIE 1

Article	Colonne 1 Symptôme	Colonne 2 État pathologique
1.	Violente nausée	Cancer, SIDA/infection au VIH
2.	Cachexie, anorexie, perte de poids	Cancer, SIDA/infection au VIH
3.	Spasmes musculaires persistants	Sclérose en plaques, lésion ou maladie de la moelle épinière
4.	Convulsions	Épilepsie
5.	Douleur aiguë	Cancer, SIDA/infection au VIH, sclérose en plaques, lésion ou maladie de la moelle épinière, forme grave d'arthrite

ENTRÉE EN VIGUEUR

32. Le présent règlement entre en vigueur à la date de son enregistrement.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

The primary objective of these amendments to the *Marihuana Medical Access Regulations* (MMAR) is to streamline the regulatory requirements and processes associated with applying for an authorization to possess marihuana for medical purposes under the MMAR. In addition, the amendments provide explicit authority for Health Canada to communicate limited information concerning authorizations to possess and licences to produce marihuana for medical purposes to police under prescribed circumstances. The amendments also provide limited authority for pharmacists to supply marihuana to authorized persons to allow for the conduct of a pilot project to assess the feasibility of distributing marihuana for medical purposes through the conventional pharmacy-based drug distribution system.

These amendments are based on input Health Canada has received concerning the MMAR since the Regulations came into force in July 2001 as well as a comprehensive review and consultation process conducted over 2003 and 2004.

In presentations made to Health Canada, patients often characterized the MMAR requirements and processes for obtaining an authorization to possess marihuana, as onerous, and therefore, an impediment to access.

Physicians have expressed concern that the role they are asked to play under the MMAR is difficult to fulfil due to the unapproved status of the drug and the lack of adequate scientific and clinical evidence concerning the use of marihuana for specific medical purposes. Such information, physicians point out, is necessary if they are required under the Regulations to assess the benefits and risks and to recommend a dosage, and form and route of administration for a particular patient. Physicians have also noted that the MMAR in general may have created an expectation that all physicians should support the use of marihuana for medical purposes. Although the decision to support an application and to sign a medical declaration is clearly within the professional purview of the physician, they are concerned that this expectation has the potential to strain the physician-patient relationship should a physician opt not to support a patient's application under the MMAR.

Police have emphasized that they must be able to confirm with Health Canada whether named individuals are authorized to possess or produce marihuana, and whether specified locations are the sites of licensed marihuana production activities. Police point out that authorized and licensed persons, police and others in the community may be exposed to unnecessary risks, if police are not able to distinguish between persons who are acting within the law and those engaged in illegal activities related to marihuana prior to enforcement action being initiated.

These amendments maintain an appropriate balance between providing seriously ill persons with compassionate access to marihuana, on the one hand, and the need to regulate marihuana — a controlled substance and an unapproved drug product — on the other. They also serve to assist Health Canada in moving the

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(Ce résumé ne fait pas partie du règlement.)

Description

Les présentes modifications au *Règlement sur l'accès à la marihuana à des fins médicales* (RAMM) visent essentiellement à rationaliser les exigences et les processus réglementaires liés à la demande d'une autorisation de possession de marihuana à des fins médicales en vertu du RAMM. En outre, ces modifications fournissent une autorité explicite à Santé Canada pour communiquer à la police les renseignements concernant les autorisations de possession de marihuana et les licences de production de marihuana à des fins médicales dans des circonstances prescrites. De plus, les modifications fournissent une autorité limitée aux pharmaciens de fournir de la marihuana aux personnes autorisées afin que puisse être mené un projet pilote d'évaluation du caractère faisable de la fourniture de marihuana à des fins médicales dans le cadre du régime habituel de distribution des médicaments par l'entremise des pharmacies.

Ces modifications sont fondées sur les commentaires transmis à Santé Canada concernant le RAMM depuis l'entrée en vigueur du règlement en juillet 2001 et sur un examen et une consultation approfondis menés en 2003 et en 2004.

Dans des exposés faits à Santé Canada, des patients ont qualifié de pénibles les exigences et les processus du RAMM pour l'obtention d'une autorisation de possession de marihuana et, par conséquent, ils y voyaient un obstacle à l'accès.

Des médecins se sont inquiétés du fait que le rôle qu'ils doivent jouer en vertu du RAMM est difficile en raison du caractère non approuvé de la drogue et du manque de renseignements scientifiques disponibles sur l'usage de la marihuana à des fins médicales précises. Ces renseignements, aux dires des médecins, leur sont nécessaires pour appuyer une demande d'autorisation de possession de marihuana faite par un patient, en particulier, s'ils doivent donner les renseignements actuellement requis sur les avantages, les risques, la posologie, la forme posologique et le mode d'administration. Les médecins ont aussi fait valoir que le RAMM pouvait avoir conduit à penser que tous les médecins devraient appuyer l'usage de la marihuana à des fins médicales. Bien qu'il continue d'être dans les compétences professionnelles du médecin de recommander qu'un patient n'utilise pas une certaine pharmacothérapie, une telle attente peut créer des tensions entre le médecin et son patient si le médecin décide de ne pas appuyer la demande d'un patient en vertu du RAMM.

La police a insisté sur le fait qu'elle doit pouvoir confirmer auprès de Santé Canada si la personne désignée était autorisée ou non à avoir en sa possession ou à produire de la marihuana, et si des lieux particuliers étaient ou non le lieu d'activités de production de marihuana autorisées par une licence. La police fait valoir que des personnes autorisées et détenteurs de licence, ainsi que la police et d'autres personnes dans la communauté, peuvent courir des risques inutiles si la police même n'est pas capable de faire une distinction entre les personnes qui observent la loi et celles qui participent à des activités illégales liées à la marihuana.

Les modifications conservent un équilibre approprié entre fournir aux personnes atteintes d'une grave maladie un accès à la marihuana pour des motifs de compassion d'une part, et le besoin de réglementer la marihuana, de l'autre, à savoir une substance contrôlée et une drogue non approuvée. Elles permettent en outre

provision of marihuana for medical purposes in Canada toward a more traditional health care model.

The Policy and Legislative Framework: Medical Marihuana Program

Health Canada's medical marihuana program provides compassionate access to marihuana for Canadians who suffer from serious medical conditions while further research is conducted concerning the safety, efficacy and therapeutic usefulness of this presently unapproved drug product. The program does not deal with the use of marihuana for non-medical purposes.

The medical marihuana program is built on three pillars:

1. defining the regulatory framework to permit persons to possess and produce marihuana for medical purposes without the risk of criminal sanctions;
2. fostering research into the safety and efficacy of marihuana when used for specific medical purposes and into alternative dosage forms and delivery mechanisms; and
3. establishing a safe, reliable, and legal source of marihuana for medical purposes in Canada.

The MMAR provide the regulatory framework under which seriously ill persons can obtain an *authorization to possess* marihuana for their own medical purposes. An authorization to possess is issued to an applicant only once the applicant has consulted with a physician, who has confirmed both the applicant's medical condition, and that conventional treatments have been determined to be ineffective or inappropriate in the treatment of their symptoms. As of April 1, 2005, 821 persons are authorized to possess marihuana for medical purposes.

Strategic Direction for the Medical Marihuana Program

To enhance protection of the health and safety of Canadians, Health Canada's strategic direction for the medical marihuana program envisions the program taking on, to the extent possible, the features of the traditional health care model employed for other medicinal agents available in Canada. Such a model would include:

- continued support for research and enrolment of patients in clinical or open label trials as the first consideration of patients and physicians;
- centralized source(s) of marihuana that comply with product standards applied under the *Food and Drugs Act* and its Regulations to ensure the safety and quality of drug products marketed in Canada, accompanied in the longer-term, by a phase-out of personal cultivation;
- distribution of marihuana for medical purposes to authorized persons through pharmacies;
- updated information stemming from research into the risks and benefits of marihuana when used for medical purposes, and education of patients and physicians; and
- improved surveillance of the use to monitor safety and efficacy of marihuana when used for medical purposes.

This strategic direction guided the development of the December 2003 amendments to the MMAR, as well as the current amendments.

à Santé Canada de faire passer la fourniture de marihuana à des fins médicales au Canada à un modèle de soins de santé plus traditionnel.

Le cadre stratégique et législatif : Programme de marihuana à des fins médicales

Le programme de marihuana de Santé Canada offre une approche de compassion et permet l'accès à la marihuana pour les Canadiens atteints d'une grave maladie en même temps que des recherches sont menées sur l'innocuité, l'efficacité et l'utilité thérapeutique de ce produit médicamenteux non approuvé à l'heure actuelle. Le programme ne traite pas de l'usage de la marihuana à des fins non médicales.

Le programme de marihuana à des fins médicales repose sur trois éléments fondamentaux :

1. la définition du cadre réglementaire pour permettre aux personnes d'avoir en leur possession et de produire de la marihuana à des fins médicales sans courir le risque de sanctions pénales;
2. la promotion de la recherche sur l'innocuité et l'efficacité de la marihuana lorsque utilisée à des fins médicales précises;
3. l'établissement d'une source sûre, fiable et légale de marihuana à des fins médicales au Canada.

Le RAMM offre aux personnes gravement malades un cadre réglementaire en vertu duquel elles peuvent obtenir une *autorisation de possession* de marihuana pour leurs propres fins médicales. L'autorisation de possession n'est délivrée au demandeur qu'une fois qu'il a consulté un médecin qui a confirmé à la fois l'état pathologique du demandeur et le fait que les traitements traditionnels sont inefficaces ou ne conviennent pas pour soulager leurs symptômes. En date du 1er avril 2005, 821 personnes étaient autorisées à posséder de la marihuana à des fins médicales.

Orientation stratégique du programme de marihuana à des fins médicales

Afin d'améliorer la santé et la sécurité des Canadiens, l'orientation stratégique de Santé Canada pour le programme de marihuana à des fins médicales envisage que le programme prenne, dans la mesure du possible, les caractéristiques du modèle de soins de santé traditionnel employé par les autres agents médicinaux disponibles au Canada. D'après ce modèle, il y aurait :

- un appui continu qui serait donné à la recherche et à l'inscription des patients à des essais cliniques ou des essais ouverts comme première considération pour les patients et les médecins;
- une source centralisée de marihuana qui serait en conformité avec des normes de produits accompagnée à plus long terme par une diminution de la culture à des fins personnelles;
- une distribution de la marihuana à des fins médicales à des personnes autorisées, par l'entremise de pharmacies;
- des renseignements mis à jour qui découlent de la recherche sur les risques et les avantages de la marihuana quand elle sert à des fins médicales, et une éducation des patients et des médecins;
- une meilleure surveillance de la consommation afin de contrôler l'innocuité et l'efficacité de la marihuana utilisée à des fins médicales.

Cette orientation stratégique a guidé l'élaboration des modifications au RAMM en décembre 2003 ainsi que les modifications actuelles.

Amendments to the MMAR

The first phase of amendments to the MMAR was completed in December 2003. It focussed largely on issues related to source and supply of marihuana for medical purposes, and responded to the October 7, 2003, Ontario Court of Appeal decision in *Hitzig et al. v. Her Majesty the Queen.*

This second phase of the amendments is based on a broader review of the MMAR to address issues expressed by Health Canada's stakeholders in the medical marihuana program and involved a comprehensive consultative process. The following provides a description of the Phase 2 amendments to the MMAR:

Application for an Authorization to Possess Marihuana for Medical Purposes:

The number of categories of symptoms under which a person may apply for authorization to possess marihuana for medical purposes is reduced from three to two. The previous categories 1 and 2 are merged into one category (Category 1). The need for a specialist to sign the medical declaration for the symptoms set out in the Schedule to the Regulations (previous Category 2) has been eliminated. While assessment of the applicant's case by a specialist is still a requirement under the new Category 2, the treating physician, whether or not a specialist, can sign the medical declaration.

Both the Applicant's Declaration and the Medical Declaration required as part of an application for an authorization to possess, are revised. Applicants are now asked to acknowledge and declare their acceptance of the risks associated with the use of marihuana for medical purposes in their declaration.

Physicians are no longer required, in their declarations, to make definitive statements regarding benefits outweighing risks, or to make specific recommendations regarding the daily dosage of marihuana to be used by the applicant. In addition, the information that the physician is required to provide in the medical declaration has been reduced to only those elements essential to confirm that the applicant suffers from a serious medical condition and that conventional treatments are inappropriate or ineffective. For example, physicians are no longer required to list conventional therapies that have been tried or considered, or to provide their reasons for finding those therapies to be ineffective or inappropriate.

Streamlining the Application, Renewal and Amendment Processes for an Authorization to Possess:

The above-cited amendments serve to streamline MMAR application and renewal processes. In addition, the requirement for authorized persons to submit a new photograph for identification purposes with every second renewal, has been changed to every fifth renewal. MMAR requirements related to notifying Health Canada of changes, and to applying for amendments to an authorization have also been streamlined.

Requirements for expired authorization and licence documents to be returned to Health Canada have been eliminated. Authorization and licence documents must still be returned, however, if amended documents are issued, or if the authorization or licence is revoked.

Modifications au RAMM

La première phase des modifications au RAMM s'est achevée en décembre 2003. Elle était centrée en grande partie sur des questions liées à la source et à la fourniture de marihuana à des fins médicales et répondait à un arrêt de la Cour d'appel de l'Ontario, en date du 7 octobre 2003, dans l'affaire Hitzig *et al.* c. Sa Majesté la reine.

Cette deuxième phase des modifications découle d'un examen plus vaste du RAMM pour traiter des questions exprimées par les intervenants de Santé Canada dans le programme de marihuana à des fins médicales et elle fait intervenir un processus complet de consultation. Voici une description des modifications à la phase 2 du RAMM :

Demande d'autorisation de possession de marihuana à des fins médicales

Le nombre de catégories de symptômes pour lesquels une personne peut demander une autorisation de possession de marihuana à des fins médicales passe de trois à deux. Les deux anciennes catégories 1 et 2 sont combinées en une seule (catégorie 1). La nécessité de faire signer la déclaration médicale par un spécialiste pour les symptômes énoncés à l'annexe du règlement (antérieurement la catégorie 2) a été éliminée. Bien qu'il faille toujours faire évaluer le cas du demandeur par un spécialiste en vertu de la nouvelle catégorie 2, le médecin traitant, qu'il soit spécialiste ou non, peut signer la déclaration médicale.

Tant la déclaration du demandeur que la déclaration médicale exigées dans le cadre d'une demande d'autorisation de possession sont révisées. Les demandeurs se voient maintenant priés de reconnaître et de déclarer qu'ils acceptent les risques associés à l'usage de la marihuana à des fins médicales dans leur déclaration.

Les médecins ne sont plus tenus dans leurs déclarations d'expliquer de façon définitive que les avantages dépassent les risques ni de faire des recommandations particulières en ce qui concerne la posologie quotidienne de marihuana devant être utilisée par le demandeur. De plus, les renseignements que le médecin est tenu de fournir dans la déclaration médicale ont été réduits aux éléments essentiels pour confirmer que le demandeur souffre d'une grave maladie et que les traitements traditionnels ne lui conviennent pas ou sont inefficaces. Par exemple, les médecins ne sont plus tenus d'énumérer les thérapies traditionnelles qui ont été essayées ou prises en considération ni de fournir les motifs qu'il y a de conclure que ces thérapies sont inefficaces ou ne conviennent pas au demandeur.

Rationalisation des processus de demande, de renouvellement et de modification pour l'autorisation de possession

Les modifications susmentionnées visent à simplifier les processus de demande et de renouvellement du RAMM. De plus, l'exigence de voir les personnes autorisées fournir une nouvelle photographie à des fins d'identification avec chaque deuxième renouvellement est maintenant changée pour chaque cinquième renouvellement. Les exigences du RAMM en ce qui concerne l'avis de changements à Santé Canada ou la demande de modification d'une autorisation ont aussi été simplifiées.

Les exigences de retour de documents d'autorisation et de licence expirée à Santé Canada ont été éliminées. Toutefois, les documents d'autorisation et de licence doivent toujours être retournés, si des documents modifiés sont délivrés ou si l'autorisation ou la licence est révoquée.

Designated persons sending dried marihuana:

The provisions of the MMAR governing the method by which a designated person can send dried marihuana to the authorized person for whom they are licensed to produce are amended to remove a potential impediment to access for authorized persons.

Authority to Communicate Information to Canadian Police:

These amendments provide Health Canada with explicit authority to communicate limited authorization and licence information to Canadian police in response to a request received from Canadian police in the context of an investigation under the *Controlled Drugs and Substances Act* or the MMAR.

Authority for Provision of Marihuana through Pharmacies:

These amendments provide limited authority for a pharmacy-based distribution system for dried marihuana that is produced by a licensed dealer on contract with Her Majesty in right of Canada, to authorized persons without a prescription from a physician. This will allow the conduct of a pilot project to assess the feasibility of distributing marihuana for medical purposes through the conventional pharmacy-based drug distribution system.

Information Included on an Authorization to Possess:

Information regarding an authorized person's medical condition will no longer appear on authorization documents issued under MMAR section 11. This will provide added privacy protection should authorized persons be required to show their authorization documents as proof of their authority.

The name of the physician who signed the medical declaration will be added to the information that will be included on the authorization. This information will, however, not be included on the photo identification card issued to authorized persons as proof of their authority. An authorization to possess will now contain essentially the same information as found on a prescription from a physician authorizing a pharmacist to dispense a controlled substance. Accordingly, the holder of an authorization to possess may, at some time in the future, be able to present their authorization to a pharmacist in order to obtain dried marihuana, without first obtaining a prescription from their physician.

Clarification of Existing Provisions

Paragraph 10(*d*) of the MMAR has been amended to make clear that the photograph of the applicant required as part of an application for authorization to possess is to be certified by the same physician who signs the medical declaration.

Section 23 of the MMAR has been amended to clarify the maximum quantity of dried marihuana that a care giver may possess while in the presence of, and providing assistance to an authorized person.

Paragraph 34(1.1)(*a*) of the MMAR has been amended to clarify the interpretation of "securely pack" for purposes of shipment of marihuana from the holder of a designated-person production licence to the person authorized to possess.

Expédition de marihuana séchée par les personnes désignées

Les dispositions du RAMM relatives à la méthode d'expédition de la marihuana séchée par la personne désignée à la personne autorisée visée par sa licence de production sont modifiées pour lever un obstacle possible à l'accès pour les personnes autorisées.

Autorisation de communiquer les renseignements à la police canadienne

Les modifications donnent un pouvoir explicite à Santé Canada de communiquer des renseignements limités sur l'autorisation et la licence à la police canadienne, en réponse à toute demande reçue de la police canadienne dans le contexte d'une enquête en vertu de la *Loi réglementant certaines drogues et autres substances* ou du RAMM.

Autorisation de fourniture de marihuana par l'entremise de pharmacies

Les modifications prévoient un pouvoir limité pour un système de distribution en pharmacie de la marihuana séchée produite par un distributeur autorisé sous contrat avec Sa Majesté du Chef du Canada à des personnes autorisées, sans ordonnance de la part d'un médecin. De cette manière, un projet pilote pourra être mené pour évaluer le caractère faisable d'une distribution de marihuana à des fins médicales en recourant au système traditionnel de distribution de médicaments par l'entremise de pharmacies.

Renseignements inclus dans une autorisation de possession

Les renseignements en ce qui concerne l'état pathologique d'une personne autorisée ne figureront plus sur les documents d'autorisation délivrés en vertu de l'article 11 du RAMM. De cette façon une meilleure protection de la vie privée sera garantie si les personnes autorisées sont priées de montrer leurs documents d'autorisation pour prouver qu'elles sont habilitées.

Le nom du médecin qui a signé la déclaration médicale sera ajouté aux renseignements inclus dans la lettre d'autorisation. Ces renseignements ne seront cependant pas inclus dans la carte d'identité avec photo délivrée aux personnes autorisées pour prouver qu'elles sont habilitées. La lettre d'autorisation de possession contiendra maintenant essentiellement les mêmes renseignements que ceux qui se trouvent dans l'ordonnance d'un médecin autorisant un pharmacien à distribuer une substance designée. En conséquence, le détenteur d'une autorisation de possession pourra, à un certain moment, à l'avenir, présenter cette autorisation à un pharmacien pour obtenir de la marihuana séchée, sans devoir au préalable se procurer une ordonnance de son médecin.

Clarification des dispositions actuelles

L'alinéa 10*d*) du RAMM a été modifié pour énoncer clairement que la photographie du demandeur exigée dans le cas d'une demande d'autorisation de possession doit être certifiée par le même médecin que celui qui signe la déclaration médicale.

L'article 23 du RAMM a été modifié pour clarifier la quantité maximale de marihuana séchée qu'un fournisseur de soins peut avoir en sa possession quand il est en la présence d'une personne autorisée à qui il donne de l'aide.

L'alinéa 34(1.1)*a*) du RAMM a été modifié pour clarifier l'interprétation de « préparer son colis de façon sécuritaire » aux fins de l'expédition de marihuana en provenance du détenteur d'une licence de production pour personne désignée à une personne autorisée à avoir en sa possession de la marihuana.

Subparagraph 34(1.1)(*b*)(ii) of the MMAR has been amended to clarify the original intent of the provision: to improve access to marihuana for medical purposes for persons authorized to possess under the MMAR; and to provide for a safe, secure "method of sending".

Section 59 of the MMAR has been amended to make clear that the prohibition on altering an authorization to possess or licence to produce applies to any documents issued to the holder as proof of their authorization or licence, including the photo identification card.

Consequential and Technical Amendments

A number of other MMAR provisions have been amended to ensure consistent use of terminology throughout the Regulations, and to update cross-references between provisions required as a result of renumbering of new or amended provisions. In addition, all provisions related to authorities to supply marihuana seeds or dried marihuana have been re-organized into Part IV of the Regulations.

Alternatives

The challenge in amending the MMAR is to maintain an appropriate balance between the often divergent concerns of different stakeholders and adequate regulatory control. A number of alternatives were considered for each substantive amendment. However, in order for an alternative to be considered viable, it was necessary that it fit within the following parameters, as set out by the Department:

- Marihuana will be accessible on compassionate grounds and its use will be regulated.
- The Government of Canada will continue to respect the international drug control conventions to which Canada is a Party. These conventions include the requirement for a government agency to have exclusive rights over importing, exporting, selling, and maintaining stocks of marihuana. This means that Health Canada will limit and maintain tight control on marihuana production.
- Marihuana is a drug as defined by the *Food and Drugs Act* and is not a natural health product as defined by the *Natural Health Products Regulations*.
- Health Canada will continue to require the opinion and support of a physician, since physicians are the professionals best positioned to assess medical need. Decisions by the Courts have lent support to the continued involvement of physicians, including specialists.
- Authorized persons will have access to a legal, standardized, quality-controlled source of marihuana.

Amendments have been made to other provisions of the MMAR in the interests of consistency, clarifying regulatory requirements, and streamlining the application and renewal processes, wherever possible.

Application for an Authorization to Possess Marihuana for Medical Purposes:

1. Status Quo:

Patients and physicians find the MMAR requirements and processes for obtaining an authorization to possess onerous. Physicians have indicated that it is difficult to provide all of the

Le sous-alinéa 34(1.1)*b*)(ii) du RAMM a été modifié pour clarifier l'intention initiale de la disposition d'améliorer l'accès à la marihuana à des fins médicales par les personnes autorisées d'en posséder en vertu du RAMM et de fournir une méthode d'expédition sûre et sécuritaire.

L'article 59 du RAMM a été modifié pour dire clairement que l'interdiction de modification de l'autorisation de possession ou de la licence de production s'applique à tous les documents délivrés au détenteur comme preuve de l'autorisation ou de la licence, y compris la carte d'identité avec photo.

Modifications en conséquence et techniques

Un certain nombre d'autres dispositions du RAMM ont été modifiées pour garantir une cohérence dans la terminologie de l'ensemble du règlement et pour modifier les renvois entre les dispositions exigées du fait de la renumérotation des dispositions nouvelles ou modifiées. De plus, toutes les dispositions qui concernent les autorisations de fournir des graines de marihuana ou de la marihuana séchée ont été réorganisées dans la partie IV du règlement.

Solutions envisagées

Le défi dans la modification du RAMM consiste à maintenir un équilibre approprié entre les préoccupations souvent divergentes des différents intervenants et un contrôle réglementaire adéquat. Un certain nombre de solutions de rechange ont été envisagées pour chaque modification de fond. Toutefois, pour qu'une solution de rechange soit considérée comme viable, il fallait la faire entrer dans les paramètres suivants qui ont été déterminés par le ministère :

- La marihuana sera accessible pour des motifs de compassion, et son utilisation sera réglementée.
- Le gouvernement du Canada continuera à respecter les conventions internationales de contrôle des drogues auxquelles le Canada est Partie. Ces conventions incluent l'exigence pour un organisme gouvernemental d'avoir des droits exclusifs sur l'exportation, l'importation, la vente et le maintien des stocks de marihuana, ce qui signifie que Santé Canada limitera et maintiendra un contrôle strict sur la production de marihuana.
- La marihuana est une drogue au sens de la *Loi sur les aliments et drogues*, et elle n'est pas un produit de santé naturel au sens du *Règlement sur les produits de santé naturels*.
- Santé Canada continuera à exiger l'avis et le soutien d'un médecin, vu que les médecins sont les professionnels les mieux placés pour évaluer le besoin médical. Les décisions des tribunaux ont fourni un appui à la participation constante des médecins, y compris des spécialistes.
- Les personnes autorisées auront le droit d'accès à une source de marihuana qui soit légale, normalisée et dont la qualité soit contrôlée.

Des modifications ont été apportées aux autres dispositions du RAMM à des fins de cohérence, pour clarifier les exigences réglementaires et simplifier les processus de demande ou de renouvellement dans la mesure du possible.

Demande d'autorisation de possession de marihuana à des fins médicales

1. Situation actuelle

Les patients et les médecins estiment pénibles les exigences et les processus prévus au RAMM pour l'obtention d'une autorisation de possession. Les médecins ont fait savoir qu'il était

information required on the medical declaration (e.g., to document all other treatments that have been tried or considered) and to make definitive statements regarding the risks, benefits, dosage, and form and route of administration associated with the use of marihuana, particularly given the lack of adequate scientific information about the use of marihuana for specific medical purposes. As a result, physicians are generally uncomfortable with signing the medical declarations, and some are reluctant to support a patient's application.

Patients have raised concerns about the need to obtain a signed medical declaration from a specialist for Categories 2 and 3 and the difficulty encountered in accessing specialists, particularly for those patients who live outside of large metropolitan areas. In regards to the specialist requirement, physicians have commented that this requirement may not give due recognition to the level of knowledge and expertise that may be possessed by physicians who have chosen not to pursue accreditation as a specialist.

In light of the general level of dissatisfaction with the current framework, the status quo is unacceptable.

2. One Category, No Specialists Required:

In this alternative, there is only one category of symptoms under which a person may apply for an authorization to possess marihuana for medical purposes. The same level of medical scrutiny is applied to all applications for authorization to possess. The requirements for specialist involvement are eliminated.

Some stakeholders indicated that naturopaths or herbalists should also be permitted to sign the medical declaration in support of an application. However, marihuana is a controlled substance under the *Controlled Drugs and Substances Act*. With the exception of over-the-counter codeine preparations, controlled substances can only be sold or provided to a patient by a physician, dentist or veterinarian or pursuant to a prescription issued by one of these practitioners.

It is clear that there is more scientific information available concerning the use of marihuana to treat some symptoms, than there is for others. A scheme that accepts the same level of medical assessment for all symptoms would not be reflective of the existing state of scientific knowledge concerning the use of marihuana for medical purposes and the different combinations of benefits and risks associated with that use.

This alternative is rejected on the basis that it fails to provide adequate regulatory control over an unapproved, controlled substance, and fails to provide a balanced response to the concerns of stakeholders.

3. Two Categories, Amended Declarations [the recommended alternative]:

This alternative reduces the number of categories of symptoms under which a person may apply for an authorization to possess marihuana for medical purposes from three to two. The distinction between the two categories is based largely on the scientific information available regarding the use of marihuana for specific medical purposes, and accordingly on the level of medical scrutiny required in support of an application.

difficile de fournir tous les renseignements requis sur la déclaration médicale (p. ex., documenter tous les autres traitements qui ont été essayés ou envisagés) et de faire des déclarations définitives sur les risques, les avantages, la posologie, la forme posologique et le mode d'administration associés à l'usage de la marihuana, en particulier vu le manque de renseignements scientifiques adéquats sur l'usage de la marihuana à des fins médicales précises. En conséquence, les médecins ont en général de la réticence à signer les déclarations médicales, et certains hésitent à appuyer une demande de patient.

Les patients se sont inquiétés de la nécessité d'obtenir une déclaration médicale signée auprès d'un spécialiste pour les catégories 2 et 3 et ont signalé la difficulté qu'ils rencontrent pour avoir accès à des spécialistes, en particulier pour les patients qui vivent en dehors des grandes régions métropolitaines. En ce qui concerne l'exigence relative aux spécialistes, les médecins ont déclaré que cette exigence pouvait ne pas tenir compte du niveau de connaissances et d'expertise que peuvent avoir les médecins qui ont choisi de ne pas demander à être agréés à titre de spécialiste.

Compte tenu du niveau généralement constaté d'insatisfaction en ce qui concerne le régime existant, le maintien de la situation actuelle est inacceptable.

2. Une catégorie : pas de spécialiste exigé

Si l'on choisit cette solution, il n'existe qu'une seule catégorie de symptômes pour lesquels une personne peut demander l'autorisation de possession de marihuana à des fins médicales. Le même niveau d'examen médical minutieux est appliqué à toutes les demandes d'autorisation de possession. Les exigences concernant la participation d'un spécialiste sont éliminées.

Certains intervenants ont déclaré que les naturopathes et les herboristes devraient aussi être autorisés à signer la déclaration médicale à l'appui d'une demande. Toutefois, la marihuana est une substance désignée en vertu de la *Loi réglementant certaines drogues et autres substances*. À l'exception des produits à base de codéine en vente libre, les substances désignées peuvent être vendues ou fournies à un patient seulement par un médecin, un dentiste ou un vétérinaire ou sous la supervision de celui-ci.

Il est clair qu'il existe parfois plus de renseignements scientifiques qui sont disponibles sur l'usage de la marihuana pour traiter certains symptômes que pour d'autres. Un régime qui accepte le même niveau d'évaluation médicale pour tous les symptômes ne tient pas compte du contexte de la connaissance scientifique sur l'usage de la marihuana à des fins médicales ni des différentes combinaisons d'avantages et de risques qui sont associés à cet usage.

Cette possibilité est rejetée du fait qu'elle omet de fournir un contrôle réglementaire adéquat sur une substance désignée et non approuvée et de répondre de façon équilibrée aux inquiétudes des intervenants.

3. *Deux catégories : déclarations modifiées* [la solution de rechange recommandée]

Cette solution réduit de trois à deux le nombre de catégories de symptômes pour lesquels une personne peut demander une autorisation de possession de marihuana à des fins médicales. La distinction entre les deux catégories est fondée en grande partie sur les renseignements scientifiques qui sont disponibles sur l'usage de la marihuana à des fins médicales précises et, en conséquence, sur le niveau d'un examen médical minutieux exigé à l'appui d'une demande.

The new Category 1 merges the previous Category 1 and Category 2 symptoms and is comprised of:

- any symptom treated within the context of providing compassionate end-of-life care (previously defined as a symptom associated with a terminal illness for which the prognosis was death within 12 months); or
- the symptoms associated with the specified medical conditions listed in the Schedule to the Regulations. (The Schedule is to be updated periodically, based on a review of emerging scientific evidence and the recommendations of a panel of experts.)

In Category 1, either an applicant's medical condition, or the available scientific information on the applicant's medical symptom(s) and condition(s), make the requirement for a specialist to support the application, unnecessary. It is recognized, however, that in many Category 1 cases, a specialist will have been consulted.

Category 2 now includes any debilitating symptom of a medical condition other than those in Category 1. Under Category 2, persons with debilitating symptoms can apply to obtain an authorization to possess marihuana for medical purposes, if a specialist confirms the diagnosis and that conventional therapies are inappropriate or ineffective for the treatment of that patient's symptom(s).

While an assessment of the applicant's case by a specialist is required, the treating physician, whether or not a specialist, can sign the medical declaration, thereby eliminating the need for an applicant to see a specialist for the sole purpose of having the medical declaration signed.

Under this alternative, the applicant's declaration and the medical declaration are amended to respond to the concerns raised by patients and physicians and better reflect the information currently available with respect to the benefits and risks of marihuana when used for medical purposes. Statements regarding the amount of dried marihuana to be used by an authorized person, if in excess of 5 grams per day, have been moved from the medical declaration to the applicant's declaration. The declarations required for both categories are essentially the same.

In the revised medical declaration, the treating physician is required to provide:

- information about the applicant's medical condition;
- summary statements regarding other therapies that have been tried or considered for the applicant; and
- the amount, and form and route of administration of marihuana that the applicant intends to use.

The physician is no longer required to transcribe information from the patient's medical record into the medical declaration in order to demonstrate that all conventional treatments that have been tried or considered are inappropriate or ineffective.

These amendments more closely align the statements made in the medical declaration with the level of scientific evidence available concerning the use of marihuana for medical purposes and reduce the time required for physicians to complete the medical declaration.

La nouvelle catégorie 1, fusionne les catégories précédentes, catégorie 1 et catégorie 2, et comprend actuellement :

- tout symptôme dont le traitement est effectué au moyen de soins palliatifs (antérieurement défini comme un symptôme associé à une maladie en phase terminale pour laquelle le pronostic était le décès dans les 12 mois); ou
- les symptômes associés à des maladies spécifiques énumérées à l'annexe du règlement. (L'annexe doit être mise à jour périodiquement d'après un examen de la nouvelle preuve scientifique qui est produite et les recommandations d'un groupe d'experts.).

Dans la catégorie 1, soit l'état pathologique du demandeur, soit les renseignements scientifiques disponibles sur le ou les symptômes ou états pathologiques du demandeur rendent inutile l'intervention d'un spécialiste pour appuyer la demande. Il est toutefois reconnu que dans bon nombre de cas de la catégorie 1, le spécialiste aura été consulté.

La catégorie 2 inclut maintenant des symptômes débilitants d'un état pathologique autres que ceux de la catégorie 1. Dans la catégorie 2, les personnes qui ont des symptômes débilitants peuvent demander une autorisation de possession de la marihuana à des fins médicales si un spécialiste confirme le diagnostic et que les thérapies traditionnelles se sont révélées inefficaces ou ne conviennent pas pour le traitement du ou des symptômes de ce patient.

Bien qu'une évaluation du cas du demandeur par un spécialiste soit nécessaire, le médecin traitant, qu'il soit ou non spécialiste, peut signer la déclaration médicale, ce qui élimine la nécessité pour le demandeur de voir un spécialiste à la seule fin de faire signer sa déclaration médicale.

Dans ce cas-là, la déclaration du demandeur et la déclaration du médecin sont modifiées pour répondre aux préoccupations soulevées par les patients et les médecins et mieux refléter les renseignements qui sont disponibles actuellement sur les avantages et les risques présentés par la marihuana lorsqu'elle est utilisée à des fins médicales. Les déclarations sur la quantité de marihuana séchée que peut utiliser la personne autorisée, si cette quantité excède les cinq grammes par jour, ont été déplacées de la déclaration médicale pour se retrouver maintenant dans la déclaration du demandeur. Les déclarations requises pour les deux catégories sont essentiellement les mêmes.

Dans la déclaration médicale révisée, le médecin traitant est tenu de fournir :

- les renseignements sur l'état pathologique du demandeur;
- des déclarations sommaires concernant les autres thérapies qui ont été essayées ou envisagées pour le demandeur;
- la quantité, la forme posologique et le mode d'administration de la marihuana que le demandeur a l'intention d'utiliser.

Le médecin n'est plus tenu de transcrire de renseignements à partir du dossier médical du patient pour les reporter dans la déclaration médicale afin de démontrer que tous les traitements traditionnels qui ont été essayés ou envisagés se sont révélés inefficaces ou ne conviennent pas pour le traitement de ce patient.

Les modifications harmonisent de manière plus étroite le contenu de la déclaration médicale avec le niveau de preuve scientifique qui est disponible sur l'usage de la marihuana à des fins médicales et réduisent le temps nécessaire pour que le médecin remplisse la déclaration médicale.

The new applicant declaration requires the applicant to confirm that potential risks and benefits associated with the use of marihuana have been discussed with the physician making the medical declaration. The applicant must also acknowledge and accept those risks in the declaration to demonstrate that the risks were considered in the applicant's decision regarding the use of marihuana for medical purposes.

These amendments establish between the applicant and the physician, a more appropriate sharing of responsibility for the decision to use marihuana as an alternative treatment.

An authorization to possess will continue to be valid for up to one year, which is consistent with the maximum period a prescription is generally valid before an authorized person is required to re-visit a physician.

In addition to the above, an administrative change will be implemented to allow for an abbreviated application for renewal. When applying to renew an authorization to possess, if there is no change to the information provided in the previous application or request for amendment, the applicant and physician will no longer be required to resubmit all of the information in the application form. A signed declaration from the applicant and physician stating that there has been no change to the information previously provided, will be sufficient.

Designated persons sending dried marihuana:

1. Status Quo:

The MMAR require designated persons, when sending dried marihuana to the authorized person for whom they are licensed to produce, to use a method of sending that involves "obtaining a signed acknowledgment of receipt from the holder of the authorization to possess". Although national couriers and common carriers offer product lines and services that involve signature confirmation of delivery, there are no delivery services typically offered to the general public that restrict confirmation of delivery to a single, named individual. It is, therefore, not reasonably practicable for a designated person to comply with the regulatory requirement to use a method of sending that involves "obtaining a signed acknowledgment of receipt by the holder of the authorization to possess".

When this particular provision of the MMAR came into force in December 2003, it was part of a package of amendments intended to improve access to marihuana for medical purposes for persons authorized to possess under the MMAR, allowing designated persons to send, rather than hand deliver, dried marihuana to the authorized person for whom they are licensed to produce. The current wording of subparagraph 34(1.1)(*b*)(ii) is not consistent with this original intent.

Accordingly, the status quo is rejected.

2. Allow persons other than the authorized person to sign acknowledging receipt of the package sent by the designated person [the recommended alternative]:

In this alternative, the MMAR is amended to remove the stipulation that signed acknowledgment of receipt of the package of dried marihuana sent by the designated person must be obtained from *the holder of the authorization to possess*. This change allows designated persons to choose a method of sending that

La nouvelle déclaration du demandeur exige qu'il confirme que les risques et les avantages potentiels liés à l'usage de la marihuana ont fait l'objet d'une discussion avec le médecin ayant rempli la déclaration médicale. Le demandeur doit aussi reconnaître et accepter ces risques dans la déclaration pour démontrer qu'ils ont été pris en considération dans la décision du demandeur en ce qui concerne la marihuana utilisée à des fins médicales.

Ces modifications établissent entre le médecin et le demandeur un meilleur partage des responsabilités pour la décision d'utiliser la marihuana comme traitement alternatif.

Une autorisation de possession demeurera valide jusqu'à un an, ce qui est conforme à la période maximale de validité d'une ordonnance avant qu'une personne autorisée ne soit tenue de retourner voir le médecin.

En plus de ce qui précède, cette solution est accompagnée d'un changement administratif permettant une demande abrégée de renouvellement. Quand ils cherchent à faire renouveler la demande de possession, s'il n'y a pas de changement dans les renseignements fournis dans la précédente demande ou demande de modification, le demandeur et le médecin n'auront plus à soumettre à nouveau tous les renseignements dans la formule de demande. Une déclaration signée du demandeur et du médecin indiquant qu'il n'y a pas eu de changement dans les renseignements fournis antérieurement sera suffisante.

Expédition de la marihuana séchée par la personne désignée

1. Situation actuelle

En vertu du RAMM, les personnes désignées qui expédient de la marihuana séchée à la personne autorisée visée par leur licence de production doivent le faire d'une manière garantissant « l'obtention d'un accusé de réception portant la signature du titulaire de l'autorisation de possession ». Si les entreprises de messagerie et les transporteurs publics offrent des produits et services dont la livraison doit être attestée par une signature, il n'y a pas de service de livraison destiné au grand public qui accepte uniquement l'attestation d'une personne nommément identifiée. Il n'est donc pas raisonnablement commode pour la personne désignée de respecter l'obligation réglementaire d'expédier le produit d'une manière garantissant « l'obtention d'un accusé de réception portant la signature du titulaire de l'autorisation de possession ».

Quand cette disposition du RAMM est entrée en vigueur en décembre 2003, elle faisait partie d'un ensemble de modifications visant à améliorer l'accès à la marihuana à des fins médicales pour les titulaires d'une autorisation de possession aux termes du RAMM, permettant aux personnes désignées d'envoyer plutôt que de livrer en mains propres, la marihuana séchée à la personne titulaire d'une autorisation de possession pour laquelle ils possèdent une licence de production. Il appert toutefois que le texte actuel du sous alinéa 34(1.1)*b*)(ii) ne correspond pas à cette intention.

La situation actuelle n'est donc pas acceptée.

2. Permettre à d'autres personnes que la personne autorisée de signer l'accusé de réception du colis expédié par la personne désignée [la solution de rechange recommandée]

Cette solution de rechange modifierait le RAMM par le retrait de la disposition exigeant l'obtention d'un accusé de réception portant la signature du *titulaire de l'autorisation de possession* à la livraison du colis de marihuana séchée envoyé par la personne désignée. Ce changement permet aux personnes désignées de

involves a courier company or a common carrier (e.g., Canada Post), while retaining the requirement for obtaining a signed acknowledgment of receipt at the destination.

With this amendment, a potential impediment to access is removed.

Authority to Communicate Information to Canadian Police:

1. Status Quo:

Under the present system, Health Canada does not normally communicate authorization or licence information to police, unless the holder of the authorization or licence has consented to the disclosure. Exceptions to this practice would include situations wherein Health Canada is served with a search warrant requiring disclosure of specific information.

Although authorized and licensed persons are currently required under the Regulations to show proof of their authority to the police on demand, the police have cited examples where unnecessary investigation and enforcement actions could have been avoided by access to authorization and licence information *prior to* action being taken.

As of January 2005, approximately 15% of persons authorized or licensed under the Regulations have not given their consent for Health Canada to communicate information about their authorizations or licences when requested by Canadian police. Police point out that this is problematic and of significant concern to them across Canada as they strive to cope with increasing numbers of illegal marihuana grow operations.

Police would like to be able to focus their limited resources on illegal activities involving marihuana, rather than on the activities of authorized and licensed persons who are operating within the law. Of particular concern to police and Health Canada is that *unnecessary* police entry into a dwelling could put the safety of authorized and licensed persons, police, and others in the community at risk.

Given the negative impact on law enforcement and the risks to public safety, the status quo is rejected.

2. Provide Regulatory Authority for the Minister to Communicate Limited Information to Canadian Police [the recommended alternative]:

In this alternative, Health Canada does not ask for the consent of authorized and licensed persons before communicating limited information, as defined in the Regulations, to Canadian police. The information to be communicated is provided only in response to a request made by Canadian police engaged in an investigation under the *Controlled Drugs and Substances Act* or the MMAR.

The police are not given access to Health Canada's complete database of information regarding authorized and licensed persons. Rather, the information that is subject to disclosure is limited to what the police require to confirm whether the activities of a named individual or at a specified address are associated with an authorization or licence issued under the MMAR.

choisir une méthode d'expédition faisant appel aux services d'une entreprise de messagerie ou d'un transporteur commun (p.ex., Poste Canada), tout en maintenant l'obligation d'obtenir un accusé de réception signé au moment de l'arrivée du colis à destination.

Cette modification lève un obstacle possible à l'accès.

Autorisation de communiquer les renseignements à la police canadienne

1. Situation actuelle

Dans le régime actuel, Santé Canada normalement ne communique pas de renseignements sur l'autorisation ou la licence à la police, sauf si le détenteur de l'autorisation ou de la licence a consenti à la divulgation. Des exceptions à cette pratique pourraient inclure des situations où Santé Canada est signifié par un mandat de perquisition réclamant la divulgation de renseignements spécifiques.

Bien que les personnes autorisées et les détenteurs de licences soient actuellement tenus en vertu du règlement de montrer la preuve de leur autorisation à la police si celle-ci le demande, la police a cité des exemples dans lesquels des mesures non nécessaires d'enquête et d'exécution auraient pu être évitées de par un accès aux renseignements provenant de l'autorisation et de la licence *avant* que la mesure ne soit prise.

En date de janvier 2005, environ 15 % des personnes autorisées ou détenteurs de licences en vertu du règlement n'avaient pas donné leur consentement à Santé Canada pour communiquer leurs renseignements à la police canadienne. La police fait valoir que cette situation pose des problèmes et cause beaucoup d'inquiétudes, vu que, dans l'ensemble du Canada, elle doit faire face au nombre croissant d'opérations illégales de culture de marihuana.

La police voudrait pouvoir concentrer ses ressources limitées sur les activités illégales impliquant la marihuana, plutôt que sur les activités des personnes autorisées et licenciées qui mènent une exploitation conforme à la Loi. La police et Santé Canada s'inquiètent particulièrement lorsque la police pénètre *sans que ce soit nécessaire* dans une habitation, car cela pourrait menacer la sécurité des personnes autorisées et détenteurs de licences, de la police et d'autres personnes de la communauté.

Vu l'incidence négative pour les forces policières et le risque pour la santé publique, la situation actuelle n'est pas acceptée.

2. Fournir une autorisation réglementaire pour que le ministre puisse communiquer des renseignements limités à la police canadienne [la solution recommandée]

Si l'on choisit cette solution, Santé Canada ne demandera pas le consentement de personnes autorisées et détenteurs de licences avant de communiquer des renseignements limités au sens du règlement à la police canadienne. Les renseignements devant être communiqués ne sont donnés qu'en réponse à une demande faite par la police canadienne qui se livre à une enquête en vertu de la *Loi réglementant certaines drogues et autres substances* ou du RAMM.

La police ne se verra pas donner accès à la base de données complète de renseignements de Santé Canada en ce qui concerne les personnes autorisées et détenteurs de licences. Les renseignements qui font l'objet éventuel d'une divulgation sont plutôt limités à ce que la police a besoin de savoir pour confirmer si les activités d'une personne nommée ou à une adresse particulière sont

Information to be provided to Canadian police is that which is included on the authorized or licensed person's photo identification card. An authorized person's medical information is not, under any circumstances, included in what can be disclosed.

This alternative, the recommended alternative, responds to some of the concerns of Canadian police with respect to the MMAR, while also addressing the privacy concerns of other stakeholders regarding communication of information to the police.

Provision of Marihuana through Pharmacies:

1. Status Quo:

Medical organizations are generally discouraging their members from prescribing marihuana until a Notice of Compliance is issued under the *Food and Drug Regulations* regarding the safety, efficacy and quality of marihuana when used for medical purposes. There is currently no authority under the *Narcotic Control Regulations* or the MMAR that would allow an authorized person to obtain marihuana from a pharmacist without first receiving a written prescription from a physician. Without the appropriate authority in legislation, Health Canada cannot take steps to explore the feasibility of distributing marihuana for medical purposes through pharmacies — a key element in Health Canada's vision for moving the program toward a traditional health care model.

The status quo is therefore rejected.

2. Provide Authority for Distribution of Marihuana through Pharmacies [the recommended alternative]:

Using a pharmacy-based distribution system for drugs is an important element of the Canadian health care model. Pharmacists complement the role of physicians by providing additional information to both the authorized person and the physician, and facilitating closer monitoring of a patient's drug therapy between visits to the physician.

While physicians are already involved in the authorization process, involving pharmacists in the distribution system could enhance the identification and mitigation of risks to the authorized person, particularly when marihuana is combined with other drug therapies the authorized person may be using. A pharmacy-based distribution system for marihuana for medical purposes has been in place in the Netherlands since September 2003.

Stakeholders have expressed strong support for the conduct of a pilot project to assess the feasibility of distributing marihuana for medical purposes through a pharmacy-based system. This alternative provides the authority to enable such a pilot project to take place.

Health Canada intends to work with pharmacists and their associations and regulatory authorities to develop a protocol for the conduct of a pilot project. If the feasibility of a pharmacy-based distribution system is confirmed, the regulatory framework will be enhanced to include provisions comparable to those found in the *Narcotic Control Regulations* governing the distribution of other controlled drugs through pharmacies. The Netherlands'

associées à une autorisation ou à une licence émise en vertu du RAMM.

Les renseignements qui seront fournis à la police canadienne sont ceux qui sont inclus sur la carte d'identité avec photo de la personne autorisée ou du détenteur de licence. Les renseignements concernant l'état pathologique de la personne autorisée ne sont pas, dans quelque circonstance que ce soit, inclus dans ce qui peut être divulgué.

Cette solution, qui est la solution recommandée, répond à certaines des préoccupations de la police canadienne concernant le RAMM, tout en calmant les appréhensions liées à la protection de la vie privé d'autres intervenants en ce qui a trait à la communication des renseignements à la police.

Fourniture de marihuana par le biais des pharmacies

1. Situation actuelle

Les organismes médicaux découragent généralement leurs membres de prescrire de la marihuana jusqu'à ce qu'un avis de conformité soit émis concernant l'innocuité, l'efficacité et la qualité de la marihuana utilisée à des fins médicales. Il n'existe actuellement aucune autorité sous le *Règlement sur les stupéfiants* ou le RAMM pour qu'une personne qui détient une autorisation puisse se procurer de la marihuana auprès d'un pharmacien sans avoir une ordonnance écrite d'un médecin. Sans un pouvoir approprié prévu dans une loi, Santé Canada ne peut pas prendre de mesures pour voir le caractère faisable d'une distribution de marihuana par l'entremise de pharmacies, ce qui est un élément clé dans la vision de Santé Canada qui vise à voir le programme avancer vers le modèle de soins de santé traditionnel.

La situation actuelle n'est donc pas acceptée.

2. Fournir une autorisation de distribution de marihuana pour l'entremise des pharmacies [la solution recommandée]

Le recours à un système de distribution par l'entremise de pharmacies constitue un élément important du modèle de soins de santé canadien. Les pharmaciens complètent le rôle des médecins en fournissant des renseignements supplémentaires, tant à la personne autorisée qu'au médecin et par un suivi plus étroit de la thérapie pharmaceutique du patient entre les visites chez le médecin.

Bien que les médecins participent déjà au processus d'autorisation, l'intervention de pharmaciens dans le système de distribution pourrait améliorer la détection et la réduction des risques pour la personne autorisée, en particulier lorsque la marihuana est combinée avec d'autres pharmacothérapies que la personne autorisée pourrait utiliser. Un système de distribution par l'entremise des pharmacies pour la marihuana à des fins médicales existe aux Pays-Bas depuis septembre 2003.

Les intervenants se sont dit très en faveur d'un projet pilote pour établir la faisabilité de la distribution de la marihuana à des fins médicales par l'entremise des pharmacies. Cette solution fournit l'autorité nécessaire pour permettre la tenue d'un projet pilote.

Santé Canada a l'intention de travailler avec les pharmaciens et leurs associations, ainsi qu'avec les autorités réglementaires, pour élaborer un protocole en vue de mener un projet pilote. Si la faisabilité d'un système de distribution par l'entremise de pharmacies se confirme, le cadre réglementaire sera amélioré pour inclure des dispositions comparables à celles qui se trouvent dans le *Règlement sur les stupéfiants*, lequel régit la distribution des

experience with their pharmacy-based distribution system will be taken into consideration when assessing the feasibility of distribution of marihuana through pharmacies in Canada.

Amendment of provincial regulations related to pharmacy distribution may also be required to allow for the distribution of marihuana pursuant to an Authorization to Possess rather than a physician's prescription.

Benefits and Costs

These regulatory amendments are expected to impact the following sectors:

Holders of Authorizations to Possess and Licences to Produce

New applicants and those already authorized to possess marihuana for medical purposes will benefit from facilitated access to marihuana for medical purposes as a consequence of the streamlined application and renewal processes. While an appropriate level of medical scrutiny is maintained to protect the health and safety of authorized persons, the requirements for specialist involvement in the application process are reduced. The indirect cost to applicants associated with the time and travel to see specialists will be reduced accordingly.

The new provisions allowing Health Canada to communicate limited authorization or licence information to Canadian police will benefit authorized and licensed persons insofar as their exposure to risks associated with unnecessary law enforcement action will be reduced. Communication of information to police without explicit consent from authorized and licensed persons may be perceived as a loss of privacy. However, the potential loss of privacy is offset by the greater social good that will be derived from confirming necessary information for police.

The amendment allowing for the signed acknowledgment of receipt of a package of dried marihuana to be obtained from a person at the destination who may or may not be the authorized person, removes a potential and unintended impediment to access for authorized persons, and enables the designated person to fully comply with the prescribed conditions for sending, without having to take exceptional steps to do so. Not only does this change facilitate sending by the designated person, it also facilitates delivery to the authorized person, for example when the authorized person is unavailable or unable to sign for delivery of the package.

This amendment is seen as risk neutral insofar as other MMAR provisions governing sending remain unchanged, and a signature acknowledging receipt of the package at the destination will still be required. Since no new conditions of sending are imposed on designated or authorized persons, and no new services are demanded of courier companies or common carriers, the amendment is also viewed as cost-neutral.

Physicians

Physicians, if they choose to support a patient's application, will benefit from the streamlining of the application and renewal processes. Completion of the required forms should be less time

autres substances désignées par l'entremise des pharmacies au Canada. L'expérience des Pays-Bas avec leur système de distribution de la marihuana par l'entremise de pharmacies sera prise en considération lorsque la faisabilité d'un tel système au Canada sera étudié.

Il faudra peut-être aussi modifier les règlements provinciaux qui concernent la distribution par l'entremise de pharmacies pour permettre la distribution de la marihuana conformément à une autorisation de possession plutôt qu'une ordonnance médicale.

Avantages et coûts

On prévoit que ces modifications à la réglementation auront une incidence sur les secteurs suivants :

Détenteurs d'autorisations de possession et de licences de production

Les nouveaux demandeurs et ceux qui sont déjà autorisés à posséder de la marihuana à des fins médicales bénéficieront d'un accès plus facile à la marihuana à des fins médicales du fait de la simplification des processus de demande et de renouvellement. Bien qu'un niveau approprié d'examen médical minutieux soit maintenu pour protéger la santé et la sécurité des personnes autorisées, les exigences d'intervention de spécialistes dans le processus de demande sont réduites. Le coût indirect pour les demandeurs, qui est associé au temps et aux déplacements afin de rencontrer des spécialistes, sera réduit en conséquence.

Les nouvelles dispositions qui autorisent Santé Canada à divulguer des renseignements limités figurant sur l'autorisation ou la licence, à la police canadienne, profiteront aux personnes autorisées et aux détenteurs de licences, dans la mesure où les risques subis par eux et liés à des mesures d'exécution inutiles seront réduits. La communication des renseignements à la police sans le consentement explicite des personnes autorisées et détenteurs de licences peut être perçue comme une atteinte à la vie privée. Toutefois, le risque potentiel d'atteinte à la protection de la vie privée est compensé par un plus grand bien public qui découlera de la confirmation de renseignements nécessaires pour la police.

La modification permettant à une personne, autre que la personne autorisée, de signer l'accusé de réception du colis de marihuana séchée expédié par la personne désignée, lève un obstacle possible et non intentionnel à l'accès pour les personnes autorisées. Elle permet également aux personnes désignées de respecter intégralement les conditions d'expédition prescrites sans devoir prendre de mesures exceptionnelles. Cette modification facilite non seulement l'expédition par la personne désignée, mais aussi la livraison à la personne autorisée, comme dans le cas, par exemple, où celle-ci n'est pas disponible ou est incapable de signer l'accusé de réception du colis.

Cette modification ne devrait pas avoir d'incidence sur les risques, pour autant que les autres prescriptions relatives à l'expédition restent inchangées et que l'obligation d'obtenir la signature d'un accusé de réception soit maintenue. Comme aucune autre condition d'expédition n'est imposée aux personnes désignées ni aux personnes autorisées, et qu'aucun nouveau service n'est requis des entreprises de messagerie ou des transporteurs communs, cette modification ne devrait pas avoir d'incidence sur les coûts.

Médecins

Les médecins, s'ils choisissent d'appuyer une demande d'un patient, bénéficieront d'une rationalisation des processus de demande et de renouvellement. Le temps nécessaire pour remplir les

consuming. Also, the medical declarations physicians are required to complete in support of an application for authorization to possess are more reflective of the scientific information currently available, and more sensitive to the unique role that physicians have been asked to play under the MMAR.

In addition, amendments to the physician and applicant declarations establish between the applicant and the physician, a more appropriate sharing of responsibility for the decision to use marihuana as an alternative treatment.

The streamlined application process, including the reduced requirements for specialist involvement, could lead to an increase in the number of people seeking to use marihuana for medical purposes, which could in turn result in increased pressure on physicians to support patient applications. It must be noted, however, that while over three hundred Canadian physicians have supported applications for authorization to possess marihuana for medical purposes, some physicians have chosen not to do so. The decision to support an application and to sign or not to sign a medical declaration is clearly within the professional purview of the physician. A physician whose clinical assessment and judgement prevents him or her from signing a medical declaration must be able to state that and be free of the risk of negative consequences for doing so.

Canadian Police Agencies

Canadian police agencies will benefit from the inclusion of provisions in the Regulations that enable them to confirm whether any named individual or specified address is associated with an authority issued under the Regulations. With this information, unnecessary enforcement action can be avoided thereby reducing safety risks for authorized and licensed persons, police and others in the community. Accessibility to this information may also reduce law enforcement costs for police agencies.

Health Canada

Streamlining of the application and renewal processes will reduce Health Canada's costs associated with reviewing and approving applications submitted under the MMAR. These cost savings, however, may be offset by the anticipated increase in the number of applications received by the Department as a result of the removal of some requirements, previously perceived as impediments to access.

Health Canada will incur additional costs to maintain a system for providing Canadian police with access to authorization and licence information 24 hours-per-day, 7 days-per-week. The indirect benefits of such a system, in terms of safeguarding the privacy of authorized and licensed persons, should offset the incremental system costs.

Health Canada plans to manage any additional costs within existing resource allocations. The Department believes that the benefits from these regulatory amendments, in terms of improving patient access to the medical marihuana program, and providing appropriate protections for public health and safety, outweigh the additional costs that may be incurred.

formulaires requis sera moindre. De la même manière, les déclarations médicales que doivent remplir les médecins à l'appui d'une demande d'autorisation de possession reflètent davantage les renseignements scientifiques qui sont actuellement disponibles et sont plus sensibles au rôle unique que les médecins ont été appelés à jouer en vertu du RAMM.

De plus, les modifications aux déclarations du médecin et du demandeur établissent entre le demandeur et le médecin un partage des responsabilités en ce qui concerne la décision d'utiliser la marihuana à titre de traitement de deuxième solution.

Le processus de demande rationalisé, y compris les exigences réduites de participation de spécialistes, pourrait conduire à une augmentation du nombre de personnes qui cherchent à utiliser de la marihuana à des fins médicales, ce qui pourrait entraîner à ce moment-là une pression accrue pour les médecins afin qu'ils appuient les demandes des patients. À noter toutefois que, bien que plus de 300 médecins canadiens aient appuyé des demandes d'autorisation de possession de marihuana à des fins médicales, certains médecins ont choisi de ne pas le faire. La décision d'appuyer une demande d'autorisation et de signer ou de ne pas signer une déclaration médicale entre tout à fait dans la compétence professionnelle du médecin. Un médecin qui décide, en se fondant sur un examen clinique et son opinion, de ne pas signer une déclaration médicale doit pouvoir l'indiquer et n'a pas à subir de conséquences négatives de ce fait.

Corps de police canadiens

Les corps de police canadiens bénéficieront de l'inclusion de dispositions dans le règlement leur permettant de confirmer si une personne nommée ou une adresse particulière est associée à une autorisation délivrée en vertu du règlement. Avec ces renseignements, il sera facile d'éviter des mesures d'exécution inutiles, ce qui réduira les risques pour la sécurité des personnes autorisées et des détenteurs de licences, de la police et des autres membres de la collectivité. L'accessibilité à ces renseignements peut aussi réduire les coûts d'application de la loi pour les corps de police.

Santé Canada

La rationalisation des processus de demande et de renouvellement réduira les coûts pour Santé Canada qui sont liés à l'examen et à l'approbation des demandes soumises en vertu du RAMM. Ces économies pourront cependant être compensées par une augmentation prévue dans le nombre de demandes reçues par le ministère, du fait de l'abolition de certaines exigences qui étaient antérieurement perçues comme des obstacles à l'accès.

Santé Canada engagera des frais supplémentaires pour tenir un système qui permettra de donner à la police canadienne l'accès aux renseignements figurant sur l'autorisation et la licence 24 heures sur 24, sept jours sur sept. Les avantages indirects d'un tel système en termes de respect des renseignements personnels des personnes autorisées et des détenteurs de licences devraient compenser les coûts incrémentiels du système.

Santé Canada a l'intention de gérer les coûts supplémentaires dans les limites actuelles des affectations de ressources. Le ministère estime que les avantages qui découlent de ces modifications réglementaires en termes d'amélioration de l'accès du patient au programme de marihuana à des fins médicales et de fourniture de garanties appropriées pour la santé et la sécurité publiques, dépassent les coûts additionnels qui pouvaient être engagés.

Consultation

Since the Regulations came into force in July 2001, Health Canada has received input concerning the MMAR via a variety of mechanisms, including a "1-800" number, a programme e-mail address, and letters from patients, physicians and others. The Department commenced structured consultations with various stakeholder groups regarding plans to improve the MMAR early in 2003. A series of consultation sessions regarding the medical marihuana program was initiated in the fall of 2003 and sessions which focussed on the current Phase 2 amendments to the MMAR were conducted in January and February 2004. The groups engaged included:

- the *Stakeholder Advisory Committee on Medical Marihuana* (SAC), a multi-disciplinary standing committee established in the fall of 2002 which includes among its members patients, physicians, nurses, pharmacists, law enforcement officers and individuals with experience in different health care associations;
- the *Canadian Medical Association*, the *Federation of Medical Regulatory Authorities of Canada*, and other representatives of Canadian physicians, in particular regarding the role of physicians in the MMAR process;
- the *Canadian Pharmacists Association*, *Canadian Society of Hospital Pharmacists*, the *National Association of Pharmacy Regulatory Authorities* and other representatives of Canadian pharmacists and pharmacies, in particular regarding the feasibility of establishing a pharmacy-based system for the distribution of marihuana for medical purposes;
- representatives of Canadian Police Agencies, in particular regarding issues related to communication of authorization and licence information to police; and
- organizations that represent authorized persons, licensed persons, and other Canadians likely to be affected by amendments to the MMAR.

On February 18, 2004, Health Canada held a multi-stakeholder consultation session in Ottawa involving approximately 45 interested parties external to the Department. The objective of this session was to bring the representatives of the key groups mentioned above together in a single forum to consider the proposed amendments to the MMAR, to discuss their different perspectives, and to provide the Department with their feedback.

By way of a notice posted on its website, Health Canada also invited Canadians to provide written input to the consultation process up until March 5, 2004.

Health Canada heard the following during the consultative process:

Consultations

Depuis que le règlement a été promulgué en juillet 2001, Santé Canada a reçu des commentaires sur le RAMM par le biais de différents mécanismes, notamment par un numéro « 1 800 », une adresse de courriel pour le programme et des lettres de patients, de médecins et d'autres personnes. Le ministère a commencé des consultations auprès de groupes variés d'intervenants au sujet des plans d'amélioration du RAMM au début de 2003. Une série de séances de consultations concernant le programme de marihuana à des fins médicales ont commencé à l'automne 2003 et celles qui étaient centrées sur les modifications de la phase 2 qui sont proposées actuellement au RAMM, ont eu lieu en janvier et février 2004. Les groupes qui ont participé étaient, entre autres :

- le *Comité consultatif des intervenants sur la marihuana à des fins médicales* (CCI), comité permanent pluridisciplinaire établi à l'automne 2002 qui inclut des représentants de groupes de patients, de médecins, d'infirmiers et d'infirmières, de pharmaciens et de pharmaciennes, d'agents d'application de la loi et de personnes ayant acquis de l'expérience dans diverses associations de soins de santé;
- l'*Association médicale canadienne*, la *Fédération des ordres des médecins du Canada* et les autres représentants des médecins canadiens, en particulier en ce qui concerne le rôle des médecins dans le processus du RAMM;
- l'*Association des pharmaciens du Canada*, la *Société canadienne des pharmaciens d'hôpitaux*, l'*Association nationale des organismes de réglementation de la pharmacie* et les autres représentants des pharmaciens et des pharmacies canadiennes, en particulier en ce qui concerne la faisabilité de l'établissement d'un système de distribution par l'entremise de pharmacies pour la distribution de la marihuana à des fins médicales;
- les représentants des organismes canadiens d'application des lois, en particulier en ce qui concerne les questions liées à la communication des renseignements figurant dans l'autorisation et la licence à la police;
- les organismes qui représentent les personnes autorisées, les détenteurs de licences et les autres Canadiens susceptibles d'être touchés par les modifications apportées au RAMM.

Le 18 février 2004, Santé Canada a tenu une séance de consultation avec de multiples intervenants à Ottawa, ce qui a permis la rencontre de quelque 45 parties intéressées externes au ministère. Cette rencontre visait à rassembler les représentants des groupes clés mentionnés ci-dessus dans une seule et même tribune pour examiner les modifications proposées au RAMM, pour discuter de leurs perspectives différentes et pour fournir une rétroaction au ministère.

Grâce à un avis affiché sur son site Web, Santé Canada a aussi invité les Canadiens à fournir leurs commentaires écrits dans les processus de consultation jusqu'au 5 mars 2004.

Santé Canada a recueilli les commentaires suivants pendant le processus de consultation :

Patients expressed support for amendments to the MMAR that would streamline application and renewal processes and improve access to the medical marihuana program. They advocated for more research into the safety, efficacy and quality of the product and alternative forms and routes of administration and expressed willingness to assume, from the physician, a greater share of the responsibility for the decision to use marihuana for medical purposes. Patients generally acknowledged the need for Canadian police to have access to information that would allow them to identify legal marihuana-related activities associated with an authorization or licence issued under the MMAR. At the same time, they expressed concern about adequate safeguards to protect their privacy and prevent potential misuse of their personal information.

Physicians' opinions ranged from very supportive of providing compassionate access to marihuana for medical purposes, to strongly opposed to the program. Those who were opposed, expressed concerns that marihuana is not a medical product in a conventional sense, and that there is a relative lack of scientific information available to support informed recommendations about its use. Physicians generally expressed concerns that marihuana is most often ingested by smoking and encouraged development of alternative forms and routes of administration. They encouraged more clinical research into the safety, efficacy and quality of marihuana, as well as the provision of educational material to physicians, patients and the public on the current body of scientific knowledge available regarding the use of marihuana for specific medical purposes.

Police were emphatic that timely confirmation of authorization and licence information is necessary to mitigate the risk of harm to authorized and licensed persons, police, and others in the community as a consequence of unnecessary law enforcement action. They indicated their support for any proposal that would allow Canadian police to confirm authorization and licence information with Health Canada. On the other hand, police expressed concerns regarding continued personal cultivation of marihuana for medical purposes and the challenges this poses in the context of their efforts to eliminate illegal marihuana grow operations in Canada.

Pharmacists welcomed the prospect of a role for pharmacy in the medical marihuana program, particularly given the availability of a legal, standardized source and supply of the drug product. Pharmacists endorsed the proposal for a pilot project that would be based on a pharmaceutical care model and would potentially involve the dispensing of dried marihuana without a prescription. However, they expressed their continuing reservations regarding the smoked route of administration and encouraged further research into alternative forms and routes of administration, as well as into safety and efficacy of marihuana when used for specific medical purposes.

Les patients ont exprimé leur appui à des modifications au RAMM qui rationaliseraient le processus de demande et de renouvellement et amélioreraient l'accès au programme de marihuana à des fins médicales. Ils se sont déclarés en faveur d'une recherche accrue sur l'innocuité, l'efficacité et la qualité des produits et les formes posologiques et les modes d'administration de rechange, ainsi que d'une volonté d'assumer une part plus grande des responsabilités, de la part du médecin, dans la décision de recourir à la marihuana à des fins médicales. En général, les patients ont reconnu la nécessité pour la police canadienne d'avoir accès aux renseignements qui leur permettront d'identifier les activités liées à la marihuana exercées en vertu d'une autorisation ou d'une licence délivrées en vertu du RAMM. En même temps, ils ont exprimé leurs craintes en ce qui concerne l'institution de mesures de protection adéquates pour protéger leur vie privée et empêcher une utilisation potentiellement néfaste des renseignements personnels.

Les médecins ont exprimé des avis divers, qui allaient d'un très grand soutien à l'accès à la marihuana à des fins médicales pour des motifs de compassion jusqu'à une opposition très vive au programme. Selon les adversaires du programme, la marihuana n'est pas un produit médical au sens traditionnel, et il n'existe pratiquement pas de renseignements de nature scientifique pour appuyer des recommandations éclairées au sujet de son utilisation. Les médecins ont exprimé leurs inquiétudes en général, de voir que la marihuana est fumée la plupart du temps et ils ont encouragé le développement de formes posologiques et des modes d'administration différents. Ils ont encouragé des recherches cliniques plus poussées sur l'innocuité, l'efficacité et la qualité de la marihuana, ainsi que la fourniture aux médecins, aux patients et au public de matériel didactique sur la quantité de connaissances scientifiques disponibles actuellement en ce qui concerne l'usage de la marihuana à des fins médicales précises.

La police a insisté pour dire que la confirmation des renseignements dans l'autorisation et dans la licence en temps opportun était nécessaire afin de réduire le risque de dommages causés à des personnes autorisées et à des détenteurs de licences, à la police et à d'autres membres de la communauté, à cause de mesures d'application de la loi prises inutilement. Les policiers se disent en faveur de toute proposition visant à permettre à la police canadienne de confirmer les renseignements figurant dans l'autorisation et dans la licence avec Santé Canada. Par ailleurs, la police s'est dite inquiète en ce qui concerne la culture personnelle de la marihuana à des fins médicales, et des difficultés qui sont ainsi posées dans le contexte de ses efforts pour éliminer les opérations illégales de culture de marihuana au Canada.

Les pharmaciens ont accueilli favorablement la possibilité d'un rôle pour les pharmaciens dans le programme de marihuana à des fins médicales, en particulier s'il existe une source et un approvisionnement légal et standardisé de ce produit pharmaceutique. Les pharmaciens ont appuyé la proposition en vue d'un projet pilote qui serait fondé sur un modèle de soins pharmaceutiques et pourrait inclure potentiellement la distribution de marihuana séchée sans ordonnance. Toutefois, ils sont toujours réservés au sujet du mode d'administration qui consiste à fumer et encouragent une recherche plus approfondie sur des formes posologiques et des modes d'administration différents, ainsi que sur l'innocuité et l'efficacité de la marihuana quand elle est utilisée à des fins médicales précises.

Pre-publication in the Canada Gazette, Part I

The proposed Phase 2 amendments to the MMAR were pre-published in *Canada Gazette*, Part I, on October 23, 2004. Pre-publication was followed by a 30-day period during which all Canadians had the opportunity to provide Health Canada with their comments on the proposed amendments. To promote stakeholder awareness of this opportunity, Health Canada undertook outreach efforts that included:

- direct mailing of letters of notification to over 1,000 authorized or licensed persons and physicians who have supported authorizations to date;
- e-mail notification to all practitioner and pharmacist licensing authorities and associations and all parties that had participated in earlier stakeholder consultations; and
- notification on the Health Canada website.

Comments were received from 32 respondents including individuals who identified themselves as authorized or licensed persons, or as members of groups representing these persons (over 50% of the respondents); respondents who identified themselves as health professionals (e.g. physicians, pharmacists) or representatives of health professionals' organizations; and others who identified themselves as representing compassion clubs or other interested parties.

The comments provided in the submissions received were not limited to the proposed amendments to the MMAR; rather, they offered comments on the medical marihuana program in general including non-regulatory issues such as research into the safety and efficacy of marihuana when used for medical purposes and the quality, cost and affordability of the dried marihuana product available through Health Canada.

While all comments provided will be taken into consideration and will inform future discussions and decisions concerning the medical marihuana program, this section will focus on the comments pertaining to the proposed amendments to the MMAR as published in *Canada Gazette*, Part I, in October 2004.

Comments ranged from clearly supportive of the proposed amendments to very critical of certain aspects of the proposal. The key issues raised with respect to the MMAR and Health Canada's response are summarized below. None of the comments submitted led to changes to the regulatory proposal published in the *Canada Gazette*, Part I.

Issues specific to the proposed regulatory amendments published in the Canada Gazette, Part I

Issue 1: Authority to communicate limited information to Canadian police

This was by far the most frequently referenced issue with approximately 45% of the 32 respondents referring either directly or indirectly to the new MMAR provision that provides the Minister of Health with explicit authority to communicate limited authorization and licence information to Canadian police subject to the prescribed conditions. A few respondents expressed understanding of

Publication au préalable du règlement dans la Gazette du Canada Partie I

Les modifications proposées au RAMM en vertu de la deuxième phase ont été publiées au préalable dans la *Gazette du Canada* Partie I le 23 octobre 2004. Après la publication au préalable, les Canadiens ont eu, pendant trente jours, la possibilité de communiquer leurs observations à Santé Canada concernant les modifications proposées. Afin de faire connaître cette possibilité aux intervenants, Santé Canada a pris certaines mesures de sensibilisation, dont des avis :

- envoyés par la poste à plus de 1 000 personnes détentrices d'une autorisation ou d'une licence et aux médecins qui ont appuyé les demandes d'autorisation jusqu'à présent;
- envoyés par courriel à toutes les organisations ou associations chargées de délivrer aux médecins ou pharmaciens leurs permis d'exercice et à toutes les parties qui ont pris part à des consultations antérieures;
- affichés sur le site Web de Santé Canada.

Trente-deux répondants ont fait parvenir des commentaires, dont des personnes qui ont déclaré qu'elles possédaient une autorisation ou une licence ou qu'elles faisaient partie de groupes représentant ces personnes (plus de 50 % des répondants); des répondants qui ont déclaré qu'ils étaient des professionnels de la santé (p. ex. des médecins ou des pharmaciens) ou des représentants d'organismes de professionnels de la santé; et d'autres personnes qui ont déclaré qu'elles représentaient des clubs de compassion ou d'autres parties intéressées.

Les commentaires transmis ne visaient pas seulement les modifications proposées au RAMM; ils portaient sur le programme de marihuana à des fins médicales en général, y compris des questions non réglementaires comme la recherche sur l'innocuité et l'efficacité de la marihuana utilisée à des fins médicales et la qualité, le coût et le prix abordable de la marihuana séchée distribuée par Santé Canada.

Même si tous les commentaires seront étudiés et pris en considération dans les discussions et décisions ultérieures concernant le programme de marihuana à des fins médicales, la présente section porte sur les commentaires pertinents du point de vue des modifications apportées au RAMM, telles que publiées dans la *Gazette du Canada* Partie I en octobre 2004.

Les commentaires transmis variaient, depuis ceux faits par des personnes qui étaient tout à fait d'accord avec les modifications proposées jusqu'à ceux formulés par des personnes qui critiquaient vivement certains aspects du projet. Les principales questions soulevées eu égard au RAMM et à la réponse de Santé Canada sont récapitulées ci-dessous. Aucun des commentaires soumis n'a entraîné de modifications à la proposition réglementaire publiée dans la *Gazette du Canada* Partie I.

Questions relatives aux modifications réglementaires proposées publiées dans la Gazette du Canada Partie I

Question 1 : autorisation de communiquer des renseignements limités à la police canadienne

Cette question est, et de loin, celle qui a été le plus souvent abordée car presque 45 % des 32 répondants ont fait, directement ou non, allusion à la nouvelle disposition du RAMM qui accorde au ministre de la Santé l'autorité explicite pour communiquer aux policiers canadiens des renseignements limités concernant les autorisations de possession et les licences de production dans les

the need for this provision and their support; others expressed concern that this provision of the MMAR could result in violations of their rights to privacy and personal security. Most who commented on this provision stipulated that this change must be accompanied by measures to protect the privacy of authorized and licensed persons, and to limit how police can use the information once it is released to them. It was also suggested that Health Canada should notify authorized and licensed persons if information about their authorizations or licences is accessed by police under this provision of the MMAR.

Response: No changes to the proposed provision (section 68.1 of the MMAR) have been made. Police officers must be able to easily distinguish between persons who are acting within the law and those engaged in illicit activities with respect to marihuana. This is required to prevent unnecessary law enforcement action from being taken and to minimize the associated risks for all authorized or licensed persons, their neighbours, communities, and the police themselves.

To protect the privacy of the individuals concerned, the provision imposes strict limitations on what information can be communicated to police, and under what conditions. The database of information on persons authorized under the MMAR remains in the custody of Health Canada. Beyond the specific regulatory requirements included in the MMAR, Health Canada is required to protect personal information obtained under the medical marihuana program, in a manner consistent with the requirements of Canada's *Privacy Act* and Regulations. Health Canada developed and implemented procedures to safeguard client information when the MMAR first came into force. The existing procedures are detailed in Health Canada's document titled, *Communication of Information to Canadian Police Agencies*, which was made available at the time the proposed amendments were pre-published in the *Canada Gazette*, Part I. The document is available online at: www.hc-sc.gc.ca/hecs-sesc/ocma/consultations/comm_info_cdn_police_agencies.htm.

Health Canada will continue to work with representatives of the Canadian law enforcement community to develop and improve measures to ensure maximum protection of client privacy and confidentiality whenever it becomes necessary to communicate information regarding authorizations to possess or licences to produce to the police.

conditions prévues. Quelques répondants ont dit comprendre la nécessité de cette disposition et être d'accord; d'autres s'inquiètent du fait que cette disposition du RAMM pourrait enfreindre leurs droits à la protection de la vie privée et de la sécurité personnelle. La plupart des personnes ayant fait des commentaires au sujet de cette disposition ont déclaré que cette modification devrait être doublée de mesures visant à protéger la vie privée des personnes détentrices d'une autorisation ou d'une licence et à restreindre l'utilisation de ces renseignements par la police une fois qu'ils lui auront été communiqués. On suggère en outre que Santé Canada avise les détenteurs d'une autorisation ou d'une licence du fait que les renseignements concernant l'autorisation et la licence en question ont été communiqués aux policiers en vertu de cette disposition du RAMM.

Réponse : Aucune modification n'a été apportée à la disposition proposée (article 68.1 du RAMM). Les policiers doivent être en mesure de faire facilement la distinction entre des personnes qui agissent conformément à la loi et celles qui commettent des actes illégaux ayant trait à la marihuana. Cela est nécessaire afin d'éviter que des mesures d'application de la loi inutiles ne soient prises et pour réduire au minimum les risques connexes pour toutes les personnes ayant une autorisation ou une licence, leurs voisins, leurs collectivités et les agents de police eux-même.

Afin de protéger la vie privée des personnes en cause, la disposition impose de sévères restrictions relativement aux renseignements pouvant être communiqués aux policiers et aux conditions dans lesquelles ces renseignements peuvent être communiqués. Santé Canada assume toujours la garde de la base de données sur les détenteurs d'une autorisation en vertu du RAMM. Outre les exigences réglementaires dont il est fait état dans le RAMM, Santé Canada doit protéger les renseignements personnels obtenus en vertu du programme sur la marihuana à des fins médicales, d'une manière conforme aux exigences de la *Loi sur la protection des renseignements personnels* et du règlement y afférent. Au moment ou le RAMM est entré en vigueur, Santé Canada a élaboré et mis en application des mécanismes de sauvegarde des renseignements des clients. Les mécanismes existants sont exposés dans le document de Santé Canada intitulé : *Communication de renseignements aux organismes de police canadiens*, diffusé au moment de la publication préalable des modifications proposées dans la *Gazette du Canada* Partie I. Ce document peut être consulté en direct, à l'adresse : http://www.hc-sc.gc.ca/hecs-sesc/bamc/consultation/comm_rens_org_police_cdn.htm.

Santé Canada continuera de travailler avec des représentants du secteur canadien de l'application des lois afin d'élaborer et d'améliorer des mesures visant à protéger le mieux possible les renseignements personnels et la confidentialité lorsqu'il est nécessaire de communiquer à la police de l'information sur les autorisations de possession ou les licences de production.

Issue 2: Authority for provision of marihuana through pharmacies

Approximately 15% of the respondents commented on this provision. Some expressed their support for a pharmacy-based distribution system; a few indicated that pharmacy distribution alone would be insufficient to supply the needs of all authorized persons.

Response: The limited authority afforded in section 70.3 of the MMAR is necessary to enable the conduct of a pharmacy pilot project. The pilot project will allow Health Canada and its pharmacy and provincial/territorial partners to assess the feasibility of implementing a pharmacy-based distribution of marihuana for medical purposes. Health Canada will consult further with stakeholders following the evaluation of the pharmacy pilot project and before any decision is taken to implement a national pharmacy-based system. Completion of the pilot project and its evaluation is not expected to occur before 2007.

Issue 3: Categories of symptoms and requirement for specialist consultation

Some respondents questioned the maintenance of two separate categories of symptoms and the requirement for assessment by a specialist in relation to Category 2 applications. It was stated that the new, two-category scheme creates a disparity and discriminates between the level of medical assessment warranted for different symptoms based on the existing state of scientific knowledge.

Response: No changes to the proposed amendments have been made. Marihuana is not presently an approved drug product in any country; consequently, the safety and efficacy of this drug when used in the treatment of particular medical conditions has not yet been established in accordance with recognized standards of scientific and clinical evidence. While clinical research continues, Health Canada must fulfil its mandate to safeguard the health and safety of Canadians, including patients who apply for authorizations to use marihuana for medical purposes. Category 1 includes symptoms for which there is some scientific evidence to support the use of marihuana. Category 2, on the other hand, allows for applications to be considered on an compassionate and individual basis for patients suffering from symptoms and conditions not captured in Category 1, despite there being significantly less, if any, scientific and clinical evidence available to support the use of marihuana for this "other" category.

In light of the paucity of supporting scientific and clinical evidence concerning the use of marihuana for medical purposes, the requirement for a specialist assessment in the case of Category 2 applications better assures that proven therapeutic approaches have been exhausted before this untested product is added to a patient's treatment protocol. The Courts have concluded that "the specialist requirement does not constitute an undue constraint on the individual's ability to get a medical exemption and represents a fair balance between the interests of the individual and the state".

Question 2 : autorisation de fourniture de marihuana par l'entremise des pharmacies

Environ 15 % des répondants ont fait des commentaires au sujet de cette disposition. Certains se sont déclarés d'accord avec le système de distribution par l'entremise des pharmacies et quelques-uns ont fait savoir qu'à elle seule, la distribution par l'entremise des pharmacies ne permettrait pas de répondre aux besoins de toutes les personnes autorisées.

Réponse : l'autorisation limitée accordée par l'article 70.3 du RAMM est nécessaire si l'on veut mener le projet pilote des pharmacies. Grâce à ce projet pilote, Santé Canada ainsi que les pharmacies participantes et les partenaires provinciaux-territoriaux pourront évaluer s'il est faisable de distribuer la marihuana à des fins médicales par l'entremise des pharmacies. Santé Canada mènera d'autres consultations auprès des intervenants après l'évaluation du projet pilote des pharmacies et avant la prise de toute décision de mettre en place un système axé sur les pharmacies. On ne prévoit pas mener à terme le projet pilote et l'évaluation s'y rapportant avant 2007.

Question 3 : catégories de symptômes et nécessité de consulter un spécialiste

Certains répondants ont mis en doute la pertinence d'avoir deux catégories distinctes de symptômes et d'exiger un examen par un spécialiste pour les demandes de la catégorie 2. On a fait remarquer que le nouveau régime à deux catégories crée une inégalité et établit une distinction entre le niveau d'évaluation médicale requis pour divers symptômes sur la base des connaissances scientifiques actuelles.

Réponse : Les modifications ont été acceptées telles que proposées. À l'heure actuelle, étant donné qu'aucun pays n'a approuvé l'utilisation de la marihuana en tant que produit pharmaceutique, l'innocuité et l'efficacité de cette drogue dans le traitement de problèmes médicaux particuliers n'ont pas encore été établies conformément aux normes éprouvées de la preuve scientifique et clinique. Tandis que les recherches cliniques se poursuivent, Santé Canada doit remplir son mandat de protéger la santé et la sécurité des Canadiens, dont les patients qui présentent une demande d'autorisation de possession de marihuana à des fins médicales. Font partie de la catégorie 1, des symptômes que l'utilisation de la marihuana pourrait soulager selon certaines données scientifiques. Par contre, les demandes présentées en vertu de la catégorie 2, par des personnes souffrant de symptômes ou de troubles non visés par la catégorie 1, peuvent être étudiées sur une base individuelle et pour des motifs de compassion, en dépit du fait que les preuves scientifiques et cliniques à l'appui de l'utilisation de la marihuana pour cette « autre » catégorie sont moins nombreuses, sinon inexistantes.

À la lumière de la pénurie de preuves scientifiques et cliniques à l'appui de l'utilisation de la marihuana à des fins médicales, la nécessité d'un examen par un spécialiste dans le cas d'une demande relevant de la catégorie 2 garantit que les approches thérapeutiques éprouvées ont été épuisées avant que ce produit non vérifié ne s'ajoute au protocole thérapeutique d'un patient. Les tribunaux ont conclu que l'exigence d'avoir recours à un spécialiste ne brime pas de

While a specialist must be consulted in the case of a Category 2 application, the treating physician can sign the Medical Declaration supporting the patient's application.

Issue 4: Schedule to the MMAR: Category 1 Symptoms

A few respondents commented that the Schedule of symptoms should be expanded; symptoms mentioned included chronic pain, fibromyalgia and cyclic vomiting syndrome (CVS).

Response: Health Canada has established an *Expert Advisory Committee on Marihuana for Medical Purposes* to provide the Drug Strategy and Controlled Substances Programme (DSCSP) with timely, expert medical/scientific advice on, among other things, the content of the Schedule to the MMAR. The mandate of the Committee is to explore options and provide recommendations on issue(s)/question(s) that are posed by the Director General, DSCSP. The Terms of Reference for this Committee are available on the Health Canada website at: http://www.hc-sc.gc.ca/hecs-sesc/ocma/consultations/eac_mmp_tor.htm.

Proposals for changes to the Schedule to the MMAR will be submitted to the Committee for review and advice. A periodic review of the Schedule will also be conducted which will take into consideration the evolving state of the scientific and clinical evidence available concerning the use of marihuana for medical purposes.

Issue 5: Medical Declarations and the Role of the Medical Practitioner

Approximately 25% of the respondents commented on the role of the physician in the application process and the amendments to the medical declarations. Many stated that physicians should not be required to prescribe marihuana given the lack of clinical evidence of safety and efficacy. It was proposed that the role of the physician be limited to confirming the diagnosis and that requirements to make statements with respect to conventional therapies having been tried or considered and the daily amount of marihuana, the form and route of administration to be used should be removed from the Medical Declaration.

Response: No changes have been made to the amendments to the Medical Declaration (section 6 of the MMAR) which were pre-published in the *Canada Gazette*, Part I. These amendments are based on extensive consultation with both patient and physician stakeholders. In effect, the amended declaration requires only that the physician state: (1) what the symptom or condition is that is the basis for the patient's application, (2) whether this is a category 1 or 2 symptom, and, (3) that conventional therapies have been found to be ineffective or medically inappropriate for the treatment of the applicant. The second

façon déraisonnable la capacité d'une personne d'obtenir une exemption médicale et représente un juste milieu entre les intérêts des particuliers et ceux de l'État.

Alors qu'un spécialiste doit être consulté dans le cas d'une demande relevant de la catégorie 2, le médecin traitant peut signer la déclaration médicale à l'appui de la demande du patient.

Question 4 : annexe du RAMM : symptômes relevant de la catégorie 1

Quelques-uns des répondants ont fait remarquer que la liste des symptômes figurant en annexe devrait être élargie. Parmi les symptômes mentionnés, signalons les douleurs chroniques, la fibromyalgie et le syndrome de vomissement chronique.

Réponse : Santé Canada a formé un Comité consultatif d'experts sur la marihuana utilisée pour des fins médicales afin de fournir au Programme de la stratégie antidrogue et des substances contrôlées (PSASC) des avis d'experts médicaux et scientifiques, en temps opportun, notamment sur le contenu de l'annexe du RAMM. Le comité a pour mission d'étudier les options et de faire des recommandations sur les enjeux ou questions soumis par le directeur général du PSASC. Le mandat de ce comité est affiché sur le site Web de Santé Canada, à l'adresse suivante : http://www.hc-sc.gc.ca/hecs-sesc/bamc/consultation/cce-mfm_attr.htm.

Les propositions en vue d'apporter des modifications à l'annexe du RAMM seront soumises aux membres du comité pour qu'ils les examinent et fassent des recommandations à ce sujet. L'annexe fera également l'objet d'une révision périodique afin de tenir compte de l'évolution des données scientifiques et cliniques disponibles concernant l'utilisation de la marihuana à des fins médicales.

Question 5 : déclarations médicales et rôle du praticien

Environ 25 % des répondants ont fait part de leurs observations quant au rôle du médecin dans le mécanisme d'application et aux modifications apportées aux déclarations médicales. Bon nombre d'entre eux ont affirmé que les médecins ne devraient pas être tenus de prescrire de la marihuana compte tenu du manque de preuves cliniques relativement à son innocuité et à son efficacité. On a proposé de restreindre le rôle du médecin à la confirmation du diagnostic et d'éliminer de la déclaration médicale les exigences relatives aux déclarations concernant les thérapies traditionnelles essayées ou envisagées, la quantité, la forme posologique et le mode d'administration de la marihuana.

Réponse : Aucun changement n'a été apporté aux modifications à la déclaration médicale (article 6 du RAMM) qui ont été publiées au préalable dans la *Gazette du Canada* Partie I. Ces modifications sont fondées sur des consultations exhaustives menées à la fois auprès des patients et des médecins intéressés. En fait, sur la déclaration modifiée le médecin n'a qu'à indiquer : (1) le symptôme ou l'état motivant la demande du patient; (2) s'il s'agit d'un symptôme de catégorie 1 ou 2; (3) que les thérapies traditionnelles sont inefficaces ou ne conviennent aux fins du traitement du patient. La deuxième exigence vise à

requirement is to enable the physician to more easily distinguish when a specialist consultation is required before signing the declaration. The third requirement is entirely consistent with the fundamental objective of the medical marihuana program which is to provide compassionate access to marihuana for Canadians who suffer from serious medical conditions while balancing the public health and safety risks associated with the use of marihuana. Until further scientific and clinical evidence is available concerning its safety, efficacy and therapeutic usefulness, the use of marihuana is appropriately limited to situations where patients have not been effectively treated with proven conventional therapies.

The requirements in the MMAR for a physician to assess and to recommend treatment with a particular dose of marihuana have been removed. The statement concerning the daily amount of marihuana, the form and route of administration that the applicant intends to use have been kept in the Medical Declaration to ensure that the physician is fully aware of the course of treatment that the patient has chosen to follow.

Issue 6: Applicant Declarations

A few respondents commented on the revision to the Applicant Declaration in regards to statements concerning the benefits and risks of the use of marihuana for medical purposes indicating that there is inadequate information available to inform a discussion, assessment and acceptance of the risks and benefits.

Response: No changes have been made to the amendments to the Applicant Declaration (paragraphs 5(1)(*e*) to (*g*) of the MMAR) which were pre-published in the *Canada Gazette*, Part I. In the consultations leading to the amendments, both patient and physician representatives advocated for changes to the declarations that would: (1) ensure that applicants are aware of the lack of information about the potential risks associated with the use of marihuana for medical purposes and, (2) more clearly convey the personal responsibility the applicant is accepting in making the decision to proceed with an unproven treatment.

Health Canada will continue to update and make publicly available information concerning the use of marihuana for medical purposes to better inform both patients and physicians when making decisions about the treatment of the patient's medical condition.

Issue 7: Period of validity for authorization to possess

A few respondents suggested that the maximum period of validity for an authorization to possess should be extended to at least two years.

Response: The maximum period of validity for an authorization to possess marihuana for medical purposes is maintained at one year to be consistent with standard

permettre au médecin de cerner avec plus de précision les cas où un spécialiste doit être consulté avant que la déclaration ne soit signée. La troisième exigence est parfaitement conforme avec l'objectif fondamental du programme de la marihuana qui est de permettre aux Canadiens qui souffrent de problèmes médicaux graves d'avoir accès à la marihuana pour des raisons de compassion tout en tenant compte des risques pour la santé et la sécurité de la population associés à l'utilisation de la marihuana. Jusqu'à ce que d'autres données scientifiques et cliniques soient disponibles concernant l'innocuité, l'efficacité et l'utilité thérapeutique de la marihuana, l'utilisation de cette substance est restreinte, comme il se doit, aux patients ayant été traités en vain par des thérapies traditionnelles éprouvées.

Les exigences dont il est fait état dans le RAMM voulant qu'un médecin procède à un examen et recommande un traitement à l'aide d'une dose particulière de marihuana ont été éliminées. La quantité, la forme posologique et le mode d'administration de la marihuana que le demandeur a l'intention d'utiliser doivent toujours figurer dans la déclaration médicale afin de s'assurer que le médecin est parfaitement au courant de la série de traitements que le patient a choisi de suivre.

Question 6 : déclarations du demandeur

Un petit nombre de répondants ont fait des commentaires sur la révision de la déclaration du demandeur eu égard aux déclarations concernant les avantages et les risques découlant de l'utilisation de la marihuana à des fins médicales. Ils ont souligné l'insuffisance de renseignements disponibles pour éclairer une discussion, une évaluation ou l'acceptation des risques et des avantages.

Réponse : Aucun changement n'a été apporté aux modifications à la déclaration du demandeur (alinéas 5(1)*e*) à 5(1)*g*) du RAMM), qui ont été publiées au préalable dans la *Gazette du Canada* Partie I. Dans les consultations qui ont mené aux modifications, tant les représentants des patients que ceux des médecins ont recommandé d'apporter des modifications qui d'abord garantiraient que les demandeurs soient conscients du manque de renseignements sur les risques potentiels associés à l'utilisation de la marihuana pour des fins médicales, et ensuite indiqueraient plus clairement la responsabilité personnelle du demandeur qui accepte de prendre la décision d'opter pour un traitement non approuvé.

Santé Canada continuera de tenir à jour les renseignements sur l'utilisation de la marihuana à des fins médicales et de les mettre à la disposition de la population, afin de mieux informer tant les patients que les médecins lorsqu'ils prennent des décisions au sujet du traitement des troubles médicaux du patient.

Question 7 : période de validité de l'autorisation de possession

Quelques répondants ont suggéré que la période maximale de validité de l'autorisation de possession devrait être élargie et que sa durée devrait être d'au moins deux ans.

Réponse : La période maximale de validité d'une autorisation de possession de marihuana à des fins médicales continuera d'être d'un an, ce qui est conforme aux

medical practice that generally requires a patient to see his or her treating physician at least once a year to obtain prescription renewals. This ensures that the patient and physician have an opportunity to discuss the treatment of the patient's symptoms and conditions at regular intervals.

Compliance and Enforcement

These regulatory amendments have little or no impact on the compliance and enforcement mechanisms currently employed by Health Canada in relation to the *Controlled Drugs and Substances Act* and the MMAR. Inspections of licensed production and storage sites may be conducted on a random and complaints-driven basis.

The new provisions, which allow police officers to confirm authorization and licence information with Health Canada, will enhance the ability of Canadian police to investigate and take appropriate enforcement action in regards to any unauthorized marihuana-related activity including, for example, the production or storage of marihuana at locations other than those authorized; or trafficking in marihuana, which includes selling, giving, sending, delivering, or administering marihuana to any person not named in the authorization or licence issued by Health Canada.

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normes régissant l'exercice de la médecine en vertu desquelles un patient doit d'ordinaire rencontrer le médecin traitant au moins une fois par année pour faire renouveler ses prescriptions. De la sorte, le patient et le médecin ont la chance de discuter périodiquement du traitement des symptômes et des troubles du patient.

Respect et exécution

Les modifications apportées au règlement ont eu très peu, voire pas du tout, d'incidence sur les mécanismes actuels de conformité et d'application employés par Santé Canada en ce qui concerne la *Loi réglementant certaines drogues et autres substances* et le RAMM. Les inspections de sites de production et de stockage munis de licences ont lieu de façon aléatoire et pour répondre à des plaintes.

Les nouvelles dispositions qui autorisent les officiers de police à confirmer les renseignements figurant sur l'autorisation et la licence auprès de Santé Canada amélioreront la capacité de la police canadienne de faire des enquêtes et de prendre des mesures d'exécution appropriées en ce qui concerne toute activité non autorisée liée à la marihuana, y compris, par exemple, la production ou le stockage de marihuana dans des lieux non autorisés, ou le trafic de la marihuana, ce qui veut dire le fait de vendre, de donner, d'expédier, de livrer ou d'administrer de la marihuana à toute personne qui n'est pas nommée dans l'autorisation ou la licence délivrée par Santé Canada.

Personne-ressource

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Registration
SOR/2007-207 September 18, 2007

CONTROLLED DRUGS AND SUBSTANCES ACT

Regulations Amending the Marihuana Medical Access Regulations

P.C. 2007-1356 September 18, 2007

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], hereby makes the annexed *Regulations Amending the Marihuana Medical Access Regulations*.

REGULATIONS AMENDING THE MARIHUANA MEDICAL ACCESS REGULATIONS

AMENDMENTS

1. (1) The definition "symptôme de catégorie 1" in subsection 1(1) of the French version of the *Marihuana Medical Access Regulations*[1] is replaced by the following:

« symptôme de catégorie 1 » Tout symptôme dont le traitement est effectué au moyen de soins palliatifs en fin de vie ou l'un des symptômes figurant à la colonne 1 de l'annexe et associé à l'état pathologique mentionné à la colonne 2 ou au traitement médical de cet état. (*category 1 symptom*)

(2) Paragraph (*c*) of the definition "production area" in subsection 1(1) of the Regulations is replaced by the following:

(*c*) partly indoors and partly outdoors. (*aire de production*)

2. Section 3 of the English version of the Regulations is replaced by the following:

3. A person is eligible to be issued an authorization to possess only if the person is an individual who ordinarily resides in Canada.

3. Paragraph 10*(b)* of the Regulations is replaced by the following:

(*b*) have dimensions of at least 43 mm × 54 mm (1 11/16 inches × 2 1/8 inches) and not more than 50 mm × 70 mm (2 inches × 2 3/4 inches), and have a view of the applicant's head that is at least 30 mm (1 3/8 inches) in length;

4. The portion of section 25 of the English version of the Regulations before subsection (2) is replaced by the following:

25. (1) Subject to subsection (2), a person is eligible to be issued a personal-use production licence only if the person is an individual who ordinarily resides in Canada and who has reached 18 years of age.

[a] S.C. 1996, c. 19
[1] SOR/2001-227

Enregistrement
DORS/2007-207 Le 18 septembre 2007

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales

C.P. 2007-1356 Le 18 septembre 2007

Sur recommandation du ministre de la Santé et en vertu du paragraphe 55(1) de la *Loi réglementant certaines drogues et autres substances*[a], Son Excellence la Gouverneure générale en conseil prend le *Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales*, ci-après.

RÈGLEMENT MODIFIANT LE RÈGLEMENT SUR L'ACCÈS À LA MARIHUANA À DES FINS MÉDICALES

MODIFICATIONS

1. (1) La définition de « symptôme de catégorie 1 », au paragraphe 1(1) de la version française du *Règlement sur l'accès à la marihuana à des fins médicales*[1], est remplacée par ce qui suit :

« symptôme de catégorie 1 » Tout symptôme dont le traitement est effectué au moyen de soins palliatifs en fin de vie ou l'un des symptômes figurant à la colonne 1 de l'annexe et associé à l'état pathologique mentionné à la colonne 2 ou au traitement médical de cet état. (*category 1 symptom*)

(2) L'alinéa *c*) de la définition de « aire de production », au paragraphe 1(1) du même règlement, est remplacé par ce qui suit :

c) soit en partie à l'intérieur et en partie à l'extérieur. (*production area*)

2. L'article 3 de la version anglaise du même règlement est remplacé par ce qui suit :

3. A person is eligible to be issued an authorization to possess only if the person is an individual who ordinarily resides in Canada.

3. L'alinéa 10*b*) du même règlement est remplacé par ce qui suit :

b) sa tête occupe un espace d'au moins 30 mm (1 3/8 po) de long sur la photographie, dont les dimensions minimales sont de 43 mm x 54 mm (1 11/16 po x 2 1/8 po) et les dimensions maximales, de 50 mm x 70 mm (2 po x 2 3/4 po);

4. Le passage de l'article 25 de la version anglaise du même règlement précédant le paragraphe (2) est remplacé par ce qui suit :

25. (1) Subject to subsection (2), a person is eligible to be issued a personal-use production licence only if the person is an individual who ordinarily resides in Canada and who has reached 18 years of age.

[a] L.C., 1996, ch. 19
[1] DORS/2001-227

5. Paragraph 26(1)*(b)* of the English version of the Regulations is replaced by the following:

(*b*) is not the holder of an authorization to possess, but either has applied for an authorization to possess or is applying for an authorization to possess concurrently with the licence application.

6. Subsection 27(2) of the English version of the Regulations is replaced by the following:

(2) The application must include

(*a*) a declaration by the applicant; and

(*b*) if the proposed production site is not the applicant's ordinary place of residence and is not owned by the applicant, a declaration dated and signed by the owner of the site consenting to the production of marihuana at the site.

7. (1) Paragraph 29(2)(*b*) of the English version of the Regulations is replaced by the following:

(*b*) the full address of the place where the holder of the licence ordinarily resides;

(2) Paragraph 29(2)(*h*) of the English version of the Regulations is replaced by the following:

(*h*) the maximum quantity of dried marihuana, in grams, that may be kept at the site authorized under paragraph (*g*) at any time;

8. Paragraph 34(1)(*c*) of the English version of the Regulations is replaced by the following:

(*c*) if the production site specified in the licence is different from the site where dried marihuana may be kept, to transport directly from the first to the second site a quantity of dried marihuana not exceeding the maximum quantity that may be kept under the licence;

9. (1) The portion of section 35 of the English version of the Regulations before paragraph (*a*) is replaced by the following:

35. A person is eligible to be issued a designated-person production licence only if the person is an individual who ordinarily resides in Canada and who

(2) The portion of paragraph 35(*b*) of the Regulations before subparagraph (i) is replaced by the following:

(*b*) has not been found guilty, as an adult, within the 10 years preceding the application, of

10. (1) Paragraph 37(2)(*c*) of the English version of the Regulations is replaced by the following:

(*c*) if the proposed production site is not the applicant's ordinary place of residence or of the designated person and is not owned by the applicant or the designated person, a declaration dated and signed by the owner of the site consenting to the production of marihuana at the site;

(2) Paragraph 37(2)(*d*) of the Regulations is replaced by the following:

(*d*) a document issued by a Canadian police force establishing that, within the 10 years preceding the application, the designated person has not been convicted, as an adult, of a designated drug offence; and

(3) Paragraph 37(2)(*e*) of the English version of the Regulations is replaced by the following:

(*e*) two copies of a current photograph of the designated person that complies with the standards specified in paragraphs 10(*a*)

5. L'alinéa 26(1)*b*) de la version anglaise du même règlement est remplacé par ce qui suit :

(*b*) is not the holder of an authorization to possess, but either has applied for an authorization to possess or is applying for an authorization to possess concurrently with the licence application.

6. Le paragraphe 27(2) de la version anglaise du même règlement est remplacé par ce qui suit :

(2) The application must include

(*a*) a declaration by the applicant; and

(*b*) if the proposed production site is not the applicant's ordinary place of residence and is not owned by the applicant, a declaration dated and signed by the owner of the site consenting to the production of marihuana at the site.

7. (1) L'alinéa 29(2)*b*) de la version anglaise du même règlement est remplacé par ce qui suit :

(*b*) the full address of the place where the holder of the licence ordinarily resides;

(2) L'alinéa 29(2)*h*) de la version anglaise du même règlement est remplacé par ce qui suit :

(*h*) the maximum quantity of dried marihuana, in grams, that may be kept at the site authorized under paragraph (*g*) at any time;

8. L'alinéa 34(1)*c*) de la version anglaise du même règlement est remplacé par ce qui suit :

(*c*) if the production site specified in the licence is different from the site where dried marihuana may be kept, to transport directly from the first to the second site a quantity of dried marihuana not exceeding the maximum quantity that may be kept under the licence;

9. (1) Le passage de l'article 35 de la version anglaise du même règlement précédant l'alinéa *a*) est remplacé par ce qui suit :

35. A person is eligible to be issued a designated-person production licence only if the person is an individual who ordinarily resides in Canada and who

(2) Le passage de l'alinéa 35*b*) du même règlement précédant le sous-alinéa (i) est remplacé par ce qui suit :

b) n'a pas été reconnue coupable, en tant qu'adulte, au cours des dix années précédant la demande, de la perpétration d'une des infractions suivantes :

10. (1) L'alinéa 37(2)*c*) de la version anglaise du même règlement est remplacé par ce qui suit :

(*c*) if the proposed production site is not the applicant's ordinary place of residence or of the designated person and is not owned by the applicant or the designated person, a declaration dated and signed by the owner of the site consenting to the production of marihuana at the site;

(2) L'alinéa 37(2)*d*) du même règlement est remplacé par ce qui suit :

d) un document émanant d'un service de police canadien établissant que la personne désignée n'a pas été reconnue coupable, en tant qu'adulte, au cours des dix années précédant la demande, de la perpétration d'une infraction désignée en matière de drogue;

(3) L'alinéa 37(2)*e*) de la version anglaise du même règlement est remplacé par ce qui suit :

(*e*) two copies of a current photograph of the designated person that complies with the standards specified in paragraphs 10(*a*)

to (*c*), each of which is certified by the applicant, on the reverse side, to be an accurate representation of the designated person.

11. The portion of paragraph 39(1)(*c*) of the Regulations before subparagraph (i) is replaced by the following:

(*c*) indicate that, within the 10 years preceding the application, the designated person has not been convicted, as an adult, of

12. Paragraph 40(2)(*i*) of the Regulations is replaced by the following:

(*i*) the maximum quantity of dried marihuana, in grams, that may be kept at the site authorized under paragraph (*h*) at any time;

13. The heading before section 46 of the French version of the Regulations is replaced by the following:

Changement de lieu de production ou d'aire de production

14. (1) Subsection 46(1) of the French version of the Regulations is replaced by the following:

46. (1) Le demandeur de la licence de production présente au ministre une demande de modification de la licence s'il envisage de changer de lieu de production ou d'aire de production.

(2) Paragraph 46(2)(*b*) of the Regulations is replaced by the following:

(*b*) in the case of a proposed change in the location of the production site, the full address of the proposed new site and supporting reasons for the proposed change;

(3) Paragraph 46(2)(*c*) of the Regulations is replaced by the following:

(*b*) in the case of a proposed change in the production area, the proposed new production area and supporting reasons for the proposed change; and

15. The heading before section 49 of the French version of the Regulations is replaced by the following:

Changement de lieu de garde de la marihuana séchée

16. Subsection 49(1) of the French version of the Regulations is replaced by the following:

49. (1) Le titulaire d'une licence de production qui envisage un changement quant au lieu où est gardée la marihuana séchée présente une demande de modification écrite au ministre au moins quinze jours avant la date du changement proposé.

17. Subsection 50(4) of the Regulations is replaced by the following:

(4) On receiving a notice under subsection (1), the Minister shall amend the licence accordingly.

18. Section 52 of the Regulations is replaced by the following:

52. The holder of a licence to produce may produce marihuana only at the production site and production area authorized in the licence.

52.1 The holder of a licence to produce shall not simultaneously produce marihuana partly indoors and partly outdoors.

to (*c*), each of which is certified by the applicant, on the reverse side, to be an accurate representation of the designated person.

11. Le passage de l'alinéa 39(1)*c*) du même règlement précédant le sous-alinéa (i) est remplacé par ce qui suit :

c) la mention que la personne désignée n'a pas été reconnue coupable, en tant qu'adulte, au cours des dix années précédant la demande, de la perpétration d'une des infractions suivantes :

12. L'alinéa 40(2)*i*) du même règlement est remplacé par ce qui suit :

i) la quantité maximale de marihuana séchée, en grammes, qui peut être gardée à la fois dans le lieu autorisé aux termes de l'alinéa *h*);

13. L'intertitre précédant l'article 46 de la version française du même règlement est remplacé par ce qui suit :

Changement de lieu de production ou d'aire de production

14. (1) Le paragraphe 46(1) de la version française du même règlement est remplacé par ce qui suit :

46. (1) Le demandeur de la licence de production présente au ministre une demande de modification de la licence s'il envisage de changer de lieu de production ou d'aire de production.

(2) L'alinéa 46(2)*b*) du même règlement est remplacé par ce qui suit :

b) si un changement de lieu de production est envisagé, l'adresse complète du lieu de production proposé et les motifs à l'appui du changement;

(3) L'alinéa 46(2)*c*) du même règlement est remplacé par ce qui suit :

c) si un changement d'aire de production est envisagé, une mention de l'aire de production proposée et les motifs à l'appui du changement;

15. L'intertitre précédant l'article 49 de la version française du même règlement est remplacé par ce qui suit :

Changement de lieu de garde de la marihuana séchée

16. Le paragraphe 49(1) de la version française du même règlement est remplacé par ce qui suit :

49. (1) Le titulaire d'une licence de production qui envisage un changement quant au lieu où est gardée la marihuana séchée présente une demande de modification écrite au ministre au moins quinze jours avant la date du changement proposé.

17. Le paragraphe 50(4) du même règlement est remplacé par ce qui suit :

(4) Sur réception de l'avis prévu au paragraphe (1), le ministre modifie la licence en conséquence.

18. L'article 52 du même règlement est remplacé par ce qui suit :

52. Le titulaire d'une licence de production ne peut produire de la marihuana que dans le lieu de production et l'aire de production autorisés dans la licence.

52.1 Le titulaire d'une licence de production ne peut pas produire de la marihuana à la fois en partie à l'intérieur et en partie à l'extérieur.

19. (1) Paragraphs 57(1)(*a*) and (*b*) of the English version of the Regulations are replaced by the following:

(*a*) open and examine any receptacle or package found there that could contain marihuana;

(*b*) examine anything found there that is used or may be capable of being used to produce or keep marihuana;

(2) Paragraph 57(1)(*c*) of the French version of the Regulations is replaced by the following:

c) examiner les registres, les données électroniques et tous autres documents trouvés sur les lieux et se rapportant à la marihuana, à l'exception des dossiers sur l'état de santé de personnes, et les reproduire en tout ou en partie;

(3) Paragraph 57(1)(*e*) of the French version of the Regulations is replaced by the following:

e) reproduire ou faire reproduire, notamment sous forme d'imprimé, tout document provenant des données électroniques;

(4) Paragraph 57(1)(*f*) of the French version of the Regulations after paragraph (*g*) is relettered as paragraph 57(1)(*h*).

(5) Paragraph 57(1)(*h*) of the Regulations is replaced by the following:

(*h*) seize and detain, in accordance with Part IV of the Act, any substance found there, if the inspector believes, on reasonable grounds, that it is necessary.

(6) Subsection 57(2) of the Regulations is replaced by the following:

(2) An inspector may not enter a dwelling-place without the consent of an occupant of the dwelling-place.

(3) An inspector who seizes marihuana shall take such measures as are reasonable in the circumstances to give to the owner or other person in charge of the place where the seizure occurred notice of the seizure and of the location where the seized marihuana is being kept or stored.

(4) If an inspector determines that the detention of marihuana seized under paragraph (1)(*h*) is no longer necessary to ensure compliance with these Regulations, the inspector shall notify in writing the owner or other person in charge of the place where the seizure occurred of that determination and, on being issued a receipt for the marihuana, shall return it to that person.

20. Subsection 60(2) of the French version of the Regulations is replaced by the following:

(2) Dans le cas où l'autorisation de possession ou la licence de production est révoquée, le titulaire doit, dans les trente jours suivant la révocation, remettre au ministre le document révoqué ainsi que tout autre document prouvant son autorisation de posséder de la marihuana séchée ou d'en produire.

21. Section 67 of the Regulations is replaced by the following:

67. (1) If a licence to produce is amended under section 47 or at the time of the renewal to reflect a change in the production area, the holder of the licence must destroy any marihuana plants in production under the licence that are in excess of the maximum number of plants that may be produced under the licence, as amended.

(2) If a licence to produce is amended under section 47 or at the time of the renewal to reflect a change in the production area, the holder of the licence must destroy any dried marihuana kept under the licence that is in excess of the maximum quantity of marihuana that may be kept under the licence, as amended.

19. (1) Les alinéas 57(1)*a*) et *b*) de la version anglaise du même règlement sont remplacés par ce qui suit :

(*a*) open and examine any receptacle or package found there that could contain marihuana;

(*b*) examine anything found there that is used or may be capable of being used to produce or keep marihuana;

(2) L'alinéa 57(1)*c*) de la version française du même règlement est remplacé par ce qui suit :

c) examiner les registres, les données électroniques et tous autres documents trouvés sur les lieux et se rapportant à la marihuana, à l'exception des dossiers sur l'état de santé de personnes, et les reproduire en tout ou en partie;

(3) L'alinéa 57(1)*e*) de la version française du même règlement est remplacé par ce qui suit :

e) reproduire ou faire reproduire, notamment sous forme d'imprimé, tout document provenant des données électroniques;

(4) L'alinéa 57(1)*f*) de la version française du même règlement suivant l'alinéa *g*) devient l'alinéa 57(1)*h*).

(5) L'alinéa 57(1)*h*) du même règlement est remplacé par ce qui suit :

h) saisir et retenir, conformément à la partie IV de la Loi, toute substance dont il juge, pour des motifs raisonnables, la saisie et la rétention nécessaires.

(6) Le paragraphe 57(2) du même règlement est remplacé par ce qui suit :

(2) Dans le cas d'un local d'habitation, l'inspecteur ne peut procéder à la visite sans le consentement de l'un de ses occupants.

(3) L'inspecteur qui procède à la saisie de marihuana lors d'une visite prend les mesures justifiées dans les circonstances pour en aviser le propriétaire ou le responsable du lieu visité, en précisant l'endroit où se trouvent les biens saisis.

(4) L'inspecteur qui juge que la rétention de la marihuana saisie aux termes de l'alinéa (1) *h*) n'est plus nécessaire pour assurer l'application du présent règlement en avise par écrit le propriétaire ou le responsable du lieu visité lors de la saisie et, sur réception d'un reçu à cet effet, lui restitue les biens.

20. Le paragraphe 60(2) de la version française du même règlement est remplacé par ce qui suit :

(2) Dans le cas où l'autorisation de possession ou la licence de production est révoquée, le titulaire doit, dans les trente jours suivant la révocation, remettre au ministre le document révoqué ainsi que tout autre document prouvant son autorisation de posséder de la marihuana séchée ou d'en produire.

21. L'article 67 du même règlement est remplacé par ce qui suit :

67. (1) Si la licence de production est modifiée en application de l'article 47 ou au moment de son renouvellement, en raison d'un changement d'aire de production, le titulaire de la licence doit détruire les plants de marihuana en production qui excèdent, le cas échéant, la quantité maximale prévue par la licence modifiée.

(2) Si la licence de production est modifiée en application de l'article 47 ou au moment de son renouvellement, en raison d'un changement d'aire de production, le titulaire de la licence doit détruire la marihuana séchée qu'il garde en excès, le cas échéant, de la quantité maximale prévue par la licence modifiée.

22. The portion of section 68.1 of the English version of the Regulations before paragraph (*a*) is replaced by the following:

68.1 The Minister is authorized to communicate any of the following information to a Canadian police force or a member of a Canadian police force who requests the information in the course of an investigation under the Act or these Regulations, subject to that information being used only for the purpose of that investigation and the proper administration or enforcement of the Act or these Regulations:

23. Subparagraph 69(*a*)(i) of the English version of the Regulations is replaced by the following:

(i) the authority submits to the Minister a written request that sets out the medical practitioner's name and address, a description of the information being sought and a statement that the information is required for the purpose of assisting an official investigation by the authority, or

COMING INTO FORCE

24. These Regulations come into force on the day on which they are registered.

22. Le passage de l'article 68.1 de la version anglaise du même règlement précédant l'alinéa *a*) est remplacé par ce qui suit :

68.1 The Minister is authorized to communicate any of the following information to a Canadian police force or a member of a Canadian police force who requests the information in the course of an investigation under the Act or these Regulations, subject to that information being used only for the purpose of that investigation and the proper administration or enforcement of the Act or these Regulations:

23. Le sous-alinéa 69*a*)(i) de la version anglaise du même règlement est remplacé par ce qui suit :

(i) the authority submits to the Minister a written request that sets out the medical practitioner's name and address, a description of the information being sought and a statement that the information is required for the purpose of assisting an official investigation by the authority, or

ENTRÉE EN VIGUEUR

24. Le présent règlement entre en vigueur à la date de son enregistrement.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Description

This regulatory initiative responds to concerns raised by the Standing Joint Committee for the Scrutiny of Regulations (SJCSR) in relation to the *Marihuana Medical Access Regulations* (MMAR). The MMAR provide the regulatory framework under which Canadians who suffer from serious medical conditions can obtain an authorization to possess and a licence to produce marihuana for medical purposes.

The SJCSR has reviewed the aforementioned Regulations and has identified grammatical and linguistic inconsistencies between the English and French versions, and certain other provisions that require non-substantive clarification.

The purpose of the Miscellaneous Amendments Regulations process is to streamline the regulatory process by shortening the total time taken to make minor and technical amendments to existing regulations. These amendments do not impose new restrictions or burdens on individuals or industry.

These Regulations will address all but one of the concerns raised by the SJCSR. Health Canada has determined that the remaining concern, which relates to the requirement of the holder of a licence to produce to provide a notice of change of information, is substantive in nature and it will be addressed in subsequent amendments to the MMAR.

Inconsistencies Between the English and French Versions

The following paragraphs detail some of the amendments that have been made in order to address the inconsistencies between the English and French versions of the Regulations.

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(*Ce résumé ne fait pas partie du Règlement.*)

Description

Cette initiative réglementaire répond aux préoccupations soulevées par le Comité mixte permanent d'examen de la réglementation (CMPER) relativement au *Règlement sur l'accès à la marihuana à des fins médicales* (RAMM). Le RAMM définit le cadre réglementaire en vertu duquel les Canadiens aux prises avec des maladies graves peuvent obtenir une autorisation pour avoir en leur possession de la marihuana et une licence pour en produire à des fins médicales.

Le CMPER a examiné le RAMM et a relevé des incohérences sur le plan grammatical et linguistique entre les versions anglaise et française, et certaines autres dispositions qui requièrent des clarifications qui ne sont pas substantielles.

Le but du processus de règlement correctif est de simplifier le processus réglementaire en réduisant le temps total nécessaire pour apporter des modifications mineures et techniques au règlement existant. Ces modifications n'imposent pas de nouvelles restrictions ou de nouveaux fardeaux aux personnes ou à l'industrie.

Le règlement modifié répondra à l'ensemble, sauf à une, des préoccupations soulevées par le CMPER. Santé Canada a déterminé que l'autre préoccupation, qui a trait à l'obligation pour le titulaire d'une licence de production de fournir un avis de modification des renseignements, est une question de fond qui fera l'objet de modifications ultérieures du RAMM.

Incohérences entre les versions anglaise et française

Les paragraphes suivants détaillent certaines des modifications qui ont été apportées afin de corriger les incohérences entre les versions anglaise et française du RAMM.

In subsection 1(1) of the French version of the MMAR, the expression "soins palliatifs" in the definition of "category 1 symptom" does not appear to have the same meaning as the expression "compassionate end-of-life care" in the English version. Accordingly, the French version of the definition has been amended to include "soins palliatifs en fin de vie", in order to be more specific to end-of-life situations.

With respect to the issuance of a designated-person production licence, one of the eligibility requirements is that the designated person has not been found guilty, as an adult, within the 10 years preceding the application, of a designated drug offence. Paragraphs 35(*b*), 37(2)(*d*), and 39(1)(*c*) of the English and French versions of the MMAR were inconsistent with respect to the adult qualification and whether conviction or commission of a designated drug offence was the relevant event. Accordingly, the two versions of these paragraphs have been harmonized to require conviction of a designated drug offence, as an adult, as the relevant event.

The SJCSR has indicated that the English and French versions of subsection 46(1) of the MMAR were not consistent with respect to the person to whom the provision applied and the type of changes intended. The English version applied to changes proposed by the applicant for a licence to produce; however, the French version was not specific with regard to the proponent. In addition, the English version applied specifically to a change in the location of a production site or a change of production area, while the French version appeared to apply to any changes affecting a production site or production area. Accordingly, the French version of subsection 46(1) has been harmonized with the English version.

Subsection 49(1) of the French version of the MMAR was not consistent with the English version. It required the holder of a production licence to apply to amend their licence to reflect a change of site where dried marihuana is kept "au plus tard dans les quinze jours" ("at the latest within the 15 days") before the proposed date of the change. In other words, the application was to be made at any time before the date of the proposed change. The English version, which reflects the actual intent, requires the holder to apply "not less than 15 days before". Accordingly, the French version has been harmonized with the English version and amended to "au moins quinze jours avant" ("at least 15 days before").

Non-Substantive Clarifications of Certain Provisions

The following paragraphs detail some of the amendments that have been made in order to clarify certain provisions of the Regulations.

The SJCSR has advised that a definition is not the appropriate place to set out a substantive rule. Consequently, paragraph (*c*) of the definition of "production area" in subsection 1(1) of the MMAR, has been amended by removing the words "but without any overlapping period between the two types of production". Accordingly, the prohibition regarding the simultaneous indoor and outdoor production of marihuana has been moved to a new section 52.1.

The SJCSR has indicated that an inconsistency exists in the requirements of the Minister to amend a licence in response to a notice of change of information in section 50 of the MMAR. Section 50 of the MMAR requires the holder of a licence to produce to notify the Minister in writing, within 10 days after the occurrence,

Au paragraphe 1(1) de la version française du RAMM, l'expression « soins palliatifs » dans la définition de « symptôme de catégorie 1 » ne semble pas avoir le même sens que l'expression « compassionate end-of-life care » dans la version anglaise. Par conséquent, la version française de la définition a été changée pour inclure « soins palliatifs en fin de vie », afin de mieux préciser qu'il s'agit de situations de fin de vie.

En ce qui concerne la délivrance d'une licence de production à titre de personne désignée, une des conditions d'admissibilité est que la personne désignée n'ait pas été reconnue coupable, en tant qu'adulte, au cours des dix années précédant la demande, de la perpétration d'une infraction désignée en matière de drogue. Les alinéas 35*b*), 37(2)*d*) et 39(1)*c*) des versions anglaise et française du RAMM n'étaient pas uniformes pour ce qui est de la qualité d'adulte et à savoir si la condamnation ou la commission d'une infraction désignée en matière de drogue était ce qui comptait. Par conséquent, les deux versions de ces alinéas ont été harmonisées pour exiger que la condamnation d'une infraction en matière de drogue, en tant qu'adulte, soit ce qui compte.

Le CMPER a indiqué que les versions anglaise et française du paragraphe 46(1) du RAMM n'étaient pas uniformes pour ce qui est des personnes et du type de changements visés par cette disposition. La version anglaise s'appliquait aux changements proposés par le demandeur d'une licence de production, alors que l'initiateur du changement n'était pas précisé dans la version française. De plus, la version anglaise s'appliquait expressément aux changements de lieu de production, ou d'aire de production. Par contre, la version française semblait s'appliquer à tout changement touchant le lieu de production ou l'aire de production. Par conséquent, la version française du paragraphe 46(1) a été harmonisée avec la version anglaise.

Le paragraphe 49(1) de la version française du RAMM ne concordait pas avec la version anglaise. Il exigeait que le titulaire d'une licence de production demande la modification de sa licence en cas de changement quant au lieu où est gardée la marihuana séchée « au plus tard dans les quinze jours » précédant la date du changement proposé. Autrement dit, la demande devait être présentée n'importe quand avant la date du changement proposé. La version anglaise, qui reflète l'intention réelle, exige que le titulaire présente une demande « au moins quinze jours avant ». Par conséquent, la version française a été harmonisée avec la version anglaise et changée pour « au moins quinze jours avant ».

Clarifications mineures de certaines dispositions

Les paragraphes suivants détaillent quelques-unes des modifications apportées afin de clarifier certaines dispositions du RAMM.

Le CMPER a fait savoir qu'une définition n'est pas l'outil approprié pour énoncer une règle de droit substantiel. Par conséquent, l'alinéa *c*) de la définition d'« aire de production » au paragraphe 1(1) du RAMM a été modifié par la suppression des mots « mais sans période de chevauchement entre les deux ». Par conséquent, l'interdiction relative à la production simultanée à l'intérieur et à l'extérieur fait maintenant l'objet du nouvel article 52.1.

Le CMPER a relevé une incohérence dans les obligations du ministre de modifier une licence à la suite d'un avis de modification des renseignements à l'article 50 du RAMM. L'article 50 du RAMM exige qu'un titulaire de licence de production avise par écrit le ministre, dans les dix jours suivant leur survenance, de

of a change in the holder's name or of a change in the holder's address of ordinary residence provided that this address is not also the address of the site for the production of marihuana. However, subsection 50(4) of the MMAR required the Minister to amend a licence to produce only if there was a change in a holder's name. Accordingly, subsection 50(4) has been amended to also require the Minister to amend the licence when there is a change to the holder's address of ordinary residence.

The SJCSR has indicated that as a matter of logic and syntax, it makes no sense to state in section 52 of the MMAR that production must occur "in accordance with" an area. Accordingly, section 52 which read: "The holder of a licence to produce may produce marihuana only at the production site authorized in the licence and only in accordance with the authorized production area" has been modified to read: "The holder of a licence to produce may produce marihuana only at the production site and production area authorized in the licence".

The SJCSR has advised that there are a number of inconsistencies between the provisions for inspection set out in subsection 57(1) of the MMAR and those set out in subsection 31(1) of the *Controlled Drugs and Substances Act* (CDSA) in both the English and French versions. For example, the power to seize and retain conferred by paragraph 57(1)(*h*) of the MMAR was not subject to the requirement, found in paragraph 31(1)(*i*) of the CDSA, that the seizure or detention occur "in accordance with" Part IV of the Act. Part IV of the CDSA provides that an inspector who seizes a controlled substance shall take such measures as are reasonable in the circumstances to give to the owner or other person in charge of the place where the seizure occurred notice of the seizure and of the location where the substance is being kept, as outlined in subsection 31(7) of the CDSA. Part IV also provides that an inspector shall, in certain circumstances, have the substance returned to the owner or person in charge of the place where the seizure occurred, as outlined in subsection 31(8) of the CDSA. Accordingly, the regulatory provisions in paragraphs 57(1)(*a*), 57(1)(*b*), 57(1)(*c*), 57(1)(*e*), 57(1)(*h*), and subsection 57(2) have been amended and subsections 57(3) and 57(4) have been added, in order to be consistent with the wording in the Act.

Finally, several of the SJCSR's concerns have resulted in additional non-substantive amendments including the replacement and renumbering of certain sections in the Regulations.

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tout changement à son nom ou à son adresse de résidence habituelle, à condition que cette adresse ne soit pas également celle du lieu où la marihuana est produite. Toutefois, le paragraphe 50(4) du RAMM exigeait du ministre qu'il modifie une licence de production seulement si le nom du titulaire était modifié. Par conséquent, le paragraphe a été modifié pour exiger également que le ministre modifie la licence lorsque l'adresse de résidence habituelle du titulaire change.

Le CMPER a indiqué que du point du vue logique et syntaxique, il est absurde d'indiquer à l'article 52 du RAMM que la production doit être « suivant » une aire de production. Par conséquent, l'article 52, qui se lit : « Le titulaire d'une licence de production peut produire de la marihuana uniquement dans le lieu de production et suivant l'aire de production autorisés dans la licence », a été changé pour « Le titulaire d'une licence de production ne peut produire de la marihuana que dans le lieu de production et l'aire de production autorisés dans la licence ».

Le CMPER a fait savoir qu'il existait un certain nombre d'incohérences entre les dispositions en matière d'inspection énoncées au paragraphe 57(1) du RAMM et celles qui sont énoncées au paragraphe 31(1) de la *Loi réglementant certaines drogues et autres substances* (LRCDAS), et ce dans les versions anglaise et française. Par exemple, le pouvoir de saisir et de retenir conféré à l'alinéa 57(1)*h)* du RAMM n'était pas assujetti à l'exigence de l'alinéa 31(1)*i*) du LRCDAS que la saisie ou la rétention soient faites « conformément » à la partie IV de la loi. La partie IV de la LRCDAS prévoit qu'un inspecteur qui procède à la saisie de substances désignées prend les mesures justifiées dans les circonstances pour aviser le propriétaire ou le responsable du lieu visité de la saisie et de l'endroit où se trouvent les substances saisies, comme il est indiqué au paragraphe 31(7) de la LRCDAS. De plus, la partie IV prévoit qu'un inspecteur doit restituer, dans certaines circonstances, les substances en question au propriétaire ou au responsable du lieu de la saisie comme il est indiqué au paragraphe 31(8) de la LRCDAS. Par conséquent, les dispositions réglementaires aux alinéas 57(1)*a*), 57(1)*b*), 57(1)*c*), 57(1)*e*), 57(1)*h*), et au paragraphe 57(2), ont été modifiées, et les paragraphes 57(3) et 57(4) ont été ajoutés par souci de conformité au libellé de la loi.

Enfin, plusieurs des préoccupations du CMPER ont donné lieu à d'autres modifications mineures, y compris le remplacement et la renumérotation de certains articles du RAMM.

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Registration
SOR/2009-142 May 14, 2009

CONTROLLED DRUGS AND SUBSTANCES ACT

Regulations Amending the Marihuana Medical Access Regulations

P.C. 2009-746 May 14, 2009

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], hereby makes the annexed *Regulations Amending the Marihuana Medical Access Regulations*.

REGULATIONS AMENDING THE MARIHUANA MEDICAL ACCESS REGULATIONS

AMENDMENT

1. Paragraph 41(*b.1*) of the *Marihuana Medical Access Regulations*[1] is replaced by the following:

(*b*) if the designated person would become the holder of more than two licences to produce; or

COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Executive Summary

Issue: Subsection 41(*b.1*) of the *Marihuana Medical Access Regulations* (MMAR) stipulates that no person shall hold more than one licence to produce. On January 10, 2008, the Federal Court, in coming to a decision in *Sfetkopoulos, Dora et al v. AG of Canada (Sfetkopoulos)*, declared that subsection 41(*b.1*) is invalid on the grounds that it infringes on section 7 of the *Canadian Charter of Rights and Freedoms* (the Charter). In his ruling, Justice Strayer found that the one grower to one user ratio set out in this provision unjustifiably limits the ability of authorized persons to access their marihuana for medical purposes. This decision was confirmed in appeal by the Federal Court of Appeal, on October 27, 2008.

[a] S.C. 1996, c. 19
[1] SOR/2001-227

Enregistrement
DORS/2009-142 Le 14 mai 2009

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales

C.P. 2009-746 Le 14 mai 2009

Sur recommandation de la ministre de la Santé et en vertu du paragraphe 55(1) de la *Loi réglementant certaines drogues et autres substances*[a], Son Excellence la Gouverneure générale en conseil prend le *Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales*, ci-après.

RÈGLEMENT MODIFIANT LE RÈGLEMENT SUR L'ACCÈS À LA MARIHUANA À DES FINS MÉDICALES

MODIFICATION

1. L'alinéa 41*b.1*) du *Règlement sur l'accès à la marihuana à des fins médicales*[1] est remplacé par ce qui suit :

b) dans le cas où la personne désignée deviendrait titulaire de plus de deux licences de production;

ENTRÉE EN VIGUEUR

2. Le présent règlement entre en vigueur à la date de son enregistrement.

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(*Ce résumé ne fait pas partie du Règlement.*)

Résumé

Question : L'alinéa 41*b.1*) du *Règlement sur l'accès à la marihuana à des fins médicales* (RAMM) stipule que personne ne peut être titulaire de plus d'une licence de production. Le 10 janvier 2008, la Cour fédérale, en annonçant sa décision dans l'affaire *Sfetkopoulos, Dora et autres c. PG du Canada (Sfetkopoulos)*, a déclaré que l'alinéa 41*b.1*) est invalide pour motif qu'il enfreint l'article 7 de la *Charte canadienne des droits et libertés* (la Charte). Dans sa décision, le juge Strayer a déclaré que le ratio d'un producteur pour un utilisateur limitait de manière injustifiée la capacité pour les personnes autorisées d'avoir accès à leur marihuana à des fins médicales. Cette décision a été confirmée en appel par la Cour d'appel fédérale, le 27 octobre 2008.

[a] L.C. 1996, ch. 19
[1] DORS/2001-227

Although the Government sought leave to appeal to the Supreme Court of Canada (SCC) and a stay of the execution of the Federal Court of Appeal decision, these requests were dismissed on April 23, 2009, and subsection 41(*b.1*) became invalid immediately. This has created a significant regulatory void in that the Minister of Health no longer has the authority to restrict how many licences to produce a designated person can hold, and thus the size of some marihuana for medical purposes production operations.

Description: This regulatory initiative will amend the MMAR by setting the limit on the number of licenses to produce a designated person can hold to two (2). This is an interim measure intended to address the regulatory void created by the SCC's dismissal of the Government's leave to appeal of the Federal Court of Appeal decision, while the Marihuana Medical Access Program (the Program) and the MMAR that underpin it are reassessed. Such a review is required given that the Program was never intended to facilitate the widespread, potentially large-scale production of marihuana for medical purposes.

Cost-benefit statement: As will be described further below, marihuana cultivation at any level is not without impacts in the form of potential risks to public health, safety and security of not only those persons directly involved, but also those living at the same address, adjacent residential units, and/or in the surrounding community. The most significant of these is the risk that the larger scale production of marihuana for medical purposes may facilitate diversion to the illicit market. Government intervention to introduce a new limit on the number of licences to produce a designated person can hold will provide benefits by constraining the quantity of marihuana produced for medical purposes under the auspices of the designated person production licences issued under the MMAR.

Business and consumer impacts: While implementation of this measure will result in increased administrative burden on Health Canada, the increase will be minimal as systems and processes to administer the MMAR are already in place. The system currently used to track designated persons and authorized persons will be updated.

While the introduction of a new limit on the number of licences to produce a designated person can hold respects the original intent of the Program, i.e., enabling Canadians with life-threatening or chronic medical conditions to access a legal source of dried marihuana for their personal use, the amendments also provide authorized persons with more choice as to how to obtain their legal supply.

That said, this incremental change may be seen by some authorized persons, designated persons and/or marihuana legalization advocates as an infringement of their rights under the *Canadian Charter of Rights and Freedoms*, and may elect to pursue legal challenges in this regard. This may impose costs on the Government in the form of increased burden on law enforcement and the court system.

Bien que le gouvernement ait demandé la permission d'interjeter appel devant la Cour suprême du Canada (CSC) ainsi qu'un sursis d'exécution de la décision de la Cour d'appel fédérale, ces demandes ont été rejetées le 23 avril 2009, entraînant l'invalidation immédiate de l'alinéa 41*b.1*). Cela a créé un vide réglementaire significatif en ce sens que le ministre de la Santé n'est désormais plus habilité à limiter le nombre de licences de production dont une personne désignée peut être titulaire, et ainsi l'ampleur de certaines opérations de production de marihuana pour usage à des fins médicales.

Description : Cette initiative réglementaire modifiera le RAMM en imposant une limite au nombre de licences de production dont peut être titulaire une personne désignée à deux (2). C'est une mesure provisoire qui vise à combler un vide réglementaire créé par le refus de la CSC d'accorder l'autorisation au gouvernement d'interjeter appel de la décision de la Cour d'appel fédérale, pendant que le programme d'accès médical à la marihuana (le Programme) et le RAMM qui le soustend sont réévalués. Un tel examen s'impose puisque le Programme n'a jamais visé à faciliter la production d'envergure et potentiellement à grande échelle de marihuana à des fins médicales.

Énoncé des coûts et avantages : Comme on l'explique dans les paragraphes qui suivent, la culture de la marihuana, à n'importe quelle échelle, n'est pas sans répercussions sous forme de risques potentiels pour la santé et la sécurité publique non seulement des personnes directement touchées, mais aussi pour celles qui vivent à la même adresse, dans des logements adjacents ou dans la collectivité avoisinante. Le plus important de ces risques est que la production à plus grande échelle de marihuana à des fins médicales pourrait faciliter un détournement au marché clandestin de la drogue. L'intervention du gouvernement pour fixer une nouvelle limite au nombre de licences de production dont peut être titulaire une personne désignée présentera l'avantage de limiter la quantité de marihuana produite à des fins médicales sous l'égide des licences de production émises pour la personne désignée en vertu du RAMM.

Incidences sur les entreprises et les consommateurs : Tandis que l'entrée en vigueur de cette mesure alourdira le fardeau administratif de Santé Canada, cette augmentation sera minime, car les systèmes et les processus pour administrer le RAMM sont déjà en place. Le système qui sert actuellement à assurer le suivi des personnes désignées et des personnes autorisées sera mis à jour.

Alors que l'imposition d'une nouvelle limite au nombre de licences de production dont peut être titulaire une personne désignée respecte l'esprit original du Programme, c'est-à-dire de permettre aux Canadiens et au Canadiennes qui souffrent de maladies graves ou de problèmes de santé chroniques d'accéder à une source licite de marihuana séchée pour leur consommation personnelle, les modifications offrent aussi aux personnes autorisées un plus vaste choix quant au moyen de s'approvisionner légalement.

Cela étant dit, cette hausse pourrait être perçue par certaines personnes autorisées ou désignées et par les défenseurs de la légalisation de la marihuana comme une violation de leurs droits en vertu de la *Charte canadienne des droits et libertés*, et ceux-ci pourraient vouloir intenter des poursuites relativement à cette question. Cela pourrait entraîner des coûts pour le gouvernement sous forme d'alourdissement du fardeau de l'application de la loi et du système judiciaire.

Domestic and international coordination and cooperation: This initiative underscores the Government's commitment to maintaining control over the production and distribution of marihuana, as required by the *Controlled Drugs and Substances Act* (CDSA) and the *United Nations Single Convention on Narcotic Drugs, 1961*, to which Canada is a signatory. It is expected that the International Narcotics Control Board and United States law enforcement and regulatory counterparts will be supportive of the amendments because they serve to limit the amount of marihuana for medical purposes a designated person can produce at one time, and thus the potential for diversion to the illicit market.

Coordination et coopération à l'échelle nationale et internationale : Cette initiative fait ressortir l'engagement qu'a pris le gouvernement d'assurer le contrôle de la production et de la distribution de marihuana, comme l'exige la *Loi réglementant certaines drogues et autres substances* (LRCDAS) et la *Convention unique sur les stupéfiants de 1961* des Nations Unies, dont le Canada est signataire. On s'attend à ce que l'Organe international de contrôle des stupéfiants et les organismes d'application de la loi et de réglementation homologues des États-Unis (É.-U.) appuient les modifications puisqu'elles permettent de limiter la quantité de marihuana à des fins médicales que peut produire une personne désignée en une fois et, par conséquent, le potentiel de détournement au marché clandestin de la drogue.

Issue

Marihuana is included in Schedule II to the CDSA, and as such is a controlled substance in Canada. The CDSA prohibits the possession, possession for the purposes of trafficking, production, importation, exportation, trafficking, and possession for the purposes of exporting marihuana except as authorized by regulation.

The Marihuana for Medical Access Program (the Program) was first established in 1999, and the authorization to possess marihuana and/or cultivate a limited number of plants for medical purposes was achieved via the issuance of exemptions under s.56 of the CDSA. In July 2000, however, the Ontario Court of Appeal ruled (*R. v. Parker*) that the prohibition on the possession of marihuana in the CDSA was unconstitutional because of the discretionary way, i.e. via a s.56 exemption, in which individuals were being authorized to obtain marihuana for medical purposes.

In response to the decision, the Government established the MMAR, which set out a scheme by which any seriously ill Canadian can, with the support of a medical practitioner, obtain an authorization to possess marihuana for their own personal medical use.

Under the current MMAR, authorized persons have three options in terms of procuring a supply of dried marihuana:

- they can produce their own supply under a Personal Use Production Licence (PUPL);
- they can designate an individual to produce it on their behalf under a Designated Person Production Licence (DPPL); or
- they can purchase dried marihuana from the Government of Canada, who contracts a private company to produce marihuana for the Program.

While the Program was originally intended to authorize access for a small number of persons, and was never intended to cover the widespread production of marihuana in individual personal residences, it has continued to grow in size since its inception. At present, there are approximately 4 000 persons authorized to possess marihuana under the Program, and this number is expected to grow to at least 6 000 by 2011.

Question

La marihuana figure à l'annexe II de la LRCDAS et par conséquent est une substance désignée au Canada. Cette loi interdit la possession, la possession aux fins de trafic, la production, l'importation, l'exportation, le trafic et la possession aux fins d'exportation de marihuana, sauf dans les cas autorisés aux termes des règlements.

Le programme d'accès à la marihuana à des fins médicales (le Programme) a été d'abord établi en 1999, et l'autorisation de posséder et de cultiver un nombre limité de plantes de marihuana à des fins médicales, a été fournie au moyen de la délivrance d'exemptions en vertu de l'article 56 de la LRCDAS. En juillet 2000, toutefois, la Cour d'appel de l'Ontario a décrété (*R. c. Parker)* que l'interdiction de possession de marihuana stipulée dans la LRCDAS était inconstitutionnelle en raison de la manière discrétionnaire, c'est-à-dire de l'exemption stipulée à l'article 56, par laquelle les personnes étaient autorisées à se procurer de la marihuana à des fins médicales.

En réponse à cette décision, le gouvernement a promulgué le RAMM, qui établit un moyen par lequel tout Canadien et toute Canadienne gravement malade peut, avec l'appui d'un médecin, obtenir l'autorisation de posséder de la marihuana pour sa consommation personnelle à des fins médicales.

En vertu de l'actuel RAMM, les personnes autorisées disposent de trois moyens de se procurer un approvisionnement en marihuana séchée :

- ils peuvent produire leur propre approvisionnement en vertu d'une licence de production à des fins personnelles (LPFP);
- ils peuvent désigner une personne qui assurera la production en leur nom en vertu d'une licence de production à titre de personne désignée (LPPD);
- ils peuvent acheter de la marihuana séchée du gouvernement du Canada, qui charge sous contrat une compagnie privée de produire de la marihuana dans le cadre du Programme.

Bien que le Programme ait eu pour objet, à l'origine, de permettre à un petit nombre de personnes d'accéder à la marihuana et qu'on n'ait jamais envisagé de sanctionner la production à grande échelle de marihuana dans des résidences privées, il n'a cessé de grandir depuis son entrée en vigueur. Actuellement, environ 4 000 personnes sont autorisées à posséder de la marihuana en vertu du Programme, et il est prévu qu'elles seront au moins 6 000 d'ici 2011.

Of those approximately 4 000 authorized persons:

- 60% hold a PUPL;
- 10% access supply produced by a designated person on their behalf;
- 20% purchase dried marihuana from the Government supply; and
- 10% obtain dried marihuana from an unknown source.

It is also important to note that due to amendments to the MMAR in 2005 that sought to introduce a greater sharing of the responsibility between persons seeking to possess marihuana for medical purposes and their medical professional in determining an appropriate daily amount (dosage), an increasing proportion of Program participants are being authorized to possess higher and higher daily amounts of marihuana. Higher daily amounts translate into larger crops for those authorized persons who also hold PUPLs and/or for designated persons cultivating marihuana under DPPLs. For example, approximately 20% of all PUPL-holders and 28% of all designated persons are licensed to produce 25 plants or more, while 1% of all DPPL- and PUPL-holders are licensed to produce at least 100 plants, a quantity that is similar to what is routinely seen by law enforcement agencies investigating illicit "grow ops."

The invalidation of subsection 41(*b.1*), therefore, has the direct result of impeding the Government of Canada's ability to limit the number of authorized persons for whom a single designated person can produce marihuana, thus enabling a situation in which individuals can be licensed to produce large numbers of marihuana plants in "legal" production operations in the absence of the tight controls applied to the production and handling of other controlled substances regulated under the CDSA.

More specifically, this could result in large quantities of marihuana being produced in unsuitable locations or environments, thus potentially

- increasing the risk that marihuana produced for medical purposes will be diverted to illicit markets; and,
- compromising the health of licensed persons, other inhabitants of the same or neighbouring dwellings and/or surrounding community members as a result of mould, infrastructure damage and fire hazards associated with the cultivation of a significant number of plants in a single location.

Health Canada has therefore elected to bring forward amendments to the MMAR that restore a level of control on the amount of marihuana for medical purposes production in Canada. In the absence of such amendments, the Federal Court of Appeal decision may result in the proliferation of large scale marihuana production operations within the context of a program that was never intended to allow more than the production of small amounts of marihuana for personal medical use.

Objectives

The primary objective of these amendments is to address the regulatory void caused by the Federal Court of Appeal decision in *Sfetkopoulos*. Health Canada has elected to examine amendments

Sur ces quelque 4 000 personnes autorisées :

- 60 % détiennent une LPFP;
- 10 % s'approvisionnent auprès d'une personne désignée en leur nom;
- 20 % achètent de la marihuana séchée du gouvernement;
- 10 % obtiennent de la marihuana séchée de source inconnue.

Il importe aussi de souligner qu'en raison des modifications apportées au RAMM en 2005, visant un plus grand partage de la responsabilité entre les personnes cherchant à posséder de la marihuana à des fins médicales et leur professionnel de la santé dans la détermination d'une quantité (dose) quotidienne appropriée, une proportion croissante de participants au Programme sont autorisés à posséder de plus grandes quantités quotidiennes de marihuana. Ces quantités quotidiennes supérieures se traduisent en plus grandes cultures pour les personnes autorisées qui sont aussi titulaires d'une LPFP et pour les personnes désignées qui cultivent de la marihuana en vertu d'une LPPD. Par exemple, environ 20 % de tous les titulaires de LPPD et 28 % de toutes les personnes désignées sont titulaires d'une licence pour produire 25 plantes ou plus, tandis que 1 % de tous les titulaires de LPPD et de LPFP sont autorisés à produire au moins 100 plantes, une quantité similaire à ce que trouvent les organismes d'application de la loi lorsqu'ils enquêtent sur les « installations de culture de la marihuana » illicites.

L'invalidation de l'alinéa 41*b.1*), pour ces motifs, a pour résultat direct de faire obstacle à la capacité du gouvernement du Canada de limiter le nombre de personnes autorisées pour qui une seule personne désignée peut produire de la marihuana, ce qui risque de créer une situation où des personnes peuvent obtenir des licences pour produire de plus grandes quantités de plantes de marihuana dans le cadre d'opérations de production « légales » en l'absence de mesures de contrôle serrées appliquées à la production et à la manipulation d'autres substances désignées et réglementées sous le régime de la LRCDAS.

Plus précisément, cela pourrait entraîner de grandes quantités de marihuana produites dans des lieux ou des environnements non appropriés, ce qui présente le potentiel suivant :

- augmenter le risque que la marihuana produite à des fins médicales soit détournée vers le marché clandestin de la drogue;
- compromettre la santé des titulaires de licence, d'autres occupants des mêmes logements ou de logements voisins ou des membres de la collectivité avoisinante, en conséquence de la moisissure, des dommages à l'infrastructure et des risques d'incendie associés à la culture de grandes quantités de plantes en un même endroit.

Santé Canada a donc choisi de proposer des modifications au RAMM qui rétablissent un degré de contrôle sur la production de marihuana à des fins médicales au Canada. En l'absence de ces modifications, la décision de la Cour d'appel fédérale pourrait engendrer une prolifération d'opérations de production de marihuana à grande échelle dans le contexte d'un programme qui n'a jamais eu pour objet de permettre plus que la production de petites quantités de marihuana pour la consommation personnelle à des fins médicales.

Objectifs

Le principal objectif de ces modifications est de combler le vide réglementaire causé par la décision de la Cour d'appel fédérale dans l'affaire *Sfetkopoulos*. Santé Canada a choisi d'étudier

to the MMAR that restore some level of control on the size of marihuana for medical purposes production operations designated persons are allowed to establish. Marihuana is a controlled substance in Canada and there is concern that in the absence of subsection 41(*b.1*) of the MMAR, the Program that is intended to help Canadians who are seriously ill and/or suffering from debilitating medical conditions will now facilitate the production of larger quantities of marihuana that can be diverted to the illicit market.

Description

The amendments will introduce a new limit on the number of licences to produce a designated person can hold, and thus the number of authorized persons they can supply. By instituting a new limit of no more than two (2) on the number of licences to produce a designated person can hold, the Government is still respecting the original intent of the Program, i.e., allowing Canadians with debilitating medical conditions to access a legal source of dried marihuana for their own personal use. It also restores some level of control over the level of marihuana for medical purposes production in Canada. The amendments also provide authorized persons with an additional supply through the option of selecting a designated person who already holds one licence to produce.

Regulatory and non-regulatory options considered

The dismissal by the SCC of the Government's application for leave to appeal the Federal Court of Appeal decision invalidating subsection 41(*b.1*) of the MMAR has signaled the need to revisit the overall Program as well as the Regulations that underpin it. To be specific, the regulatory regime, which was originally designed to meet the need of a small number of persons producing only small quantities of marihuana under personal production licences, was never intended to regulate larger production operations which may result from the lifting of the restriction on the number of marihuana for medical purposes licences to produce a single designated person can hold.

Three options were considered in addressing the issue.

The first option involves taking no action in response to the invalidation of subsection 41(*b.1*) of the MMAR. However, such a response would not mitigate the potential risk of diversion, or the potential health, safety and security risks that may result from the unsafe levels of production of marihuana for medical purposes in an under-regulated environment.

The second option would make an incremental change to the MMAR in order to allow designated persons to supply more than one authorized person but not more than two authorized persons.

Because this option only requires a relatively simple regulatory change, the advantages of pursuing it are that it allows for a timely response to the court decision. It also re-introduces some level of control on the amount of marihuana produced for medical purposes while minimizing the impact on authorized persons. It also recognizes that doubling the designated person to authorized person ratio may simplify growing for co-located authorized persons who are also PUPL holders, e.g. spouses living in the same

des modifications au RAMM qui rétabliraient un certain degré de contrôle sur l'envergure des opérations de production de marihuana à des fins médicales que les personnes désignées sont autorisées à établir. La marihuana est une substance désignée au Canada et l'on craint qu'en l'absence de l'alinéa 41*b.1*) du RAMM, le Programme qui avait pour objet d'aider les Canadiens et les Canadiennes gravement malades ou ayant un état sous-jacent débilitant facilite dorénavant la production de plus grandes quantités de marihuana qui peuvent être détournées vers le marché clandestin de la drogue.

Description

Les modifications fixeront une nouvelle limite au nombre de licences de production pouvant être délivrées à une personne désignée, et donc le nombre de personnes autorisées que celles-ci peuvent approvisionner. En instituant une nouvelle limite maximale de deux (2) licences de production dont peut être titulaire une personne désignée, le gouvernement respecte encore l'objet original du Programme, c'est-à-dire de permettre aux Canadiens et aux Canadiennes gravement malades ou ayant un état sous-jacent débilitant d'avoir accès à une source licite de marihuana séchée pour leur consommation personnelle. Cela rétablit aussi un certain degré de contrôle sur la production de marihuana à des fins médicales au Canada. Les modifications donnent aussi aux personnes autorisées l'accès à une source additionnelle d'approvisionnement avec la possibilité de choisir une personne désignée qui est déjà titulaire d'une licence de production.

Options réglementaires et non réglementaires considérées

Le refus de la CSC d'accorder au gouvernement l'autorisation d'interjeter appel de la décision de la Cour d'appel fédérale invalidant l'alinéa 41*b.1*) du RAMM a mis en lumière la nécessité de réévaluer le Programme dans son ensemble, ainsi que le Règlement qui le sous-tend. Plus précisément, le régime réglementaire, qui, à l'origine, était conçu pour répondre aux besoins d'un petit nombre de personnes ne produisant que de petites quantités de marihuana en vertu de licences de production à des fins personnelles, n'a jamais eu pour objet de réglementer de plus grandes opérations de production, ce qui pourrait découler de l'élimination de la limitation du nombre de licences de production de marihuana à des fins médicales dont peut être titulaire une seule personne désignée.

Trois possibilités ont été envisagées pour contrer ce problème.

La première consiste à ne rien faire en réponse à l'invalidation de l'alinéa 41*b.1*) du RAMM. Cependant, cette façon de faire n'atténuerait pas le risque potentiel de détournement vers le marché clandestin de la drogue, ni les risques potentiels pour la santé et la sécurité pouvant découler de niveaux dangereux de production de marihuana à des fins médicales dans un environnement sous-réglementé.

La deuxième possibilité serait d'apporter une modification progressive du RAMM afin de permettre aux personnes désignées d'approvisionner plus d'une personne autorisée, mais pas plus de deux.

Comme cette solution ne nécessite qu'une simple modification au Règlement, elle présente les avantages de permettre une réponse opportune à la décision du tribunal. Elle rétablit en outre un certain degré de contrôle sur la quantité de marihuana produite à des fins médicales tout en réduisant au minimum l'incidence sur les personnes autorisées. Elle reconnaît aussi que le fait de doubler la proportion de personnes désignées comparativement aux personnes autorisées pourrait simplifier la culture pour les

household, and may result in reduced production costs for some designated persons.

The disadvantages of this option are that it may result in Health Canada receiving and having to process an increased number of applications from current authorized persons looking to modify their supply arrangements, and may also result in Health Canada having to generate an increased number of licences to produce to designated persons. It may also increase the number of new applications from prospective authorized persons as some people may associate the change with an opportunity to join the Program.

The third option examined in response to this issue would involve the establishment of a new licensing regime for entities interested in being involved in larger scale marihuana production, including for example, comprehensive requirements such as labelling, security, record-keeping, etc., similar to those in place for the production and handling of other controlled substances.

While this option offers the most thorough response to the court decision, the policy development work and stakeholder consultation required to establish a suitable framework would be extensive. Thus, this option would not provide a timely response to the SCC's dismissal of the Government's application for a leave to appeal the decision in *Sfetkopoulos*.

Given the time sensitivity and the minimal impacts of the second option, Health Canada has selected it as an interim measure while a broad review of the Program and the MMAR is undertaken.

Benefits and costs

The cost-benefit analysis pertaining to this proposal has been conducted with the assumption that failing to control the level of marihuana for medical purposes production will lead to increased risk to public health, safety and security. Quantification and/or monetization of these impacts is, however, limited by the availability of quantitative data.

Benefits

In general, social benefits are not limited to reductions in expenses or increased earnings but also include non-monetary gains to society such as avoiding the pain and suffering of illness. In this regard, they can be assessed and measured in terms of avoided social losses.

The two main groups within the Canadian public who will benefit from the amendments are authorized persons and other Canadians.

Because the amendments will enable designated persons to hold more than one licence to produce, some authorized persons may benefit by having more choice as to who to nominate as their designated person. Canadians may benefit from tighter controls on the production of marihuana for medical purposes because of a potential reduction in the risk of marihuana for medical purposes being diverted to the illicit market, and property damage and/or fire hazards associated with the production of a significant number of marihuana plants in one location.

personnes autorisées vivant dans le même milieu qui sont aussi titulaires d'une LPFP, par exemple les conjoints ou conjointes vivant dans le même logement, et pourrait réduire les coûts de production pour certaines personnes désignées.

Les inconvénients de cette solution sont qu'elle pourrait amener Santé Canada à recevoir et à traiter un nombre croissant de demandes émanant des personnes actuellement autorisées cherchant à modifier leurs modalités d'approvisionnement, et elle pourrait aussi engendrer pour Santé Canada l'obligation de délivrer aux personnes désignées un nombre croissant de licences de production. Elle pourrait aussi augmenter le nombre de nouvelles demandes d'autorisation, car certaines personnes pourraient voir dans ce changement une occasion d'adhérer au Programme.

La troisième possibilité étudiée en réponse à ce problème aurait nécessité l'établissement d'un nouveau régime d'octroi de licences pour les entités intéressées à la production de marihuana à grande échelle, y compris, par exemple, des exigences exhaustives en matière d'étiquetage, de sécurité, de tenue de registres, similaires à celles qui existent pour la production et la manipulation d'autres substances désignées.

Bien que cette solution constitue la réponse la plus complète à la décision du tribunal, la démarche d'élaboration de politiques et de consultation des intervenants nécessaire à l'établissement d'un cadre valable serait d'envergure. Cette solution ne permettrait donc pas de répondre de façon opportune au refus de la CSC d'accorder au gouvernement une autorisation d'interjeter appel de la décision rendue dans l'affaire *Sfetkopoulos*.

Compte tenu de l'importance du facteur temps et des répercussions minimales de la deuxième solution, Santé Canada l'a choisie comme mesure provisoire pendant qu'est entrepris un examen général du Programme et du RAMM.

Avantages et coûts

L'analyse des avantages et des coûts de cette proposition s'est faite en partant du postulat que l'absence de contrôle du niveau de production de marihuana à des fins médicales engendrerait un risque accru pour la santé et la sécurité du public. La quantification ou la monétisation de ces répercussions est toutefois limitée par le manque de données quantitatives.

Avantages

En général, les avantages pour la société ne se limitent pas à la réduction des dépenses ou à l'augmentation des gains, mais englobent aussi des gains non monétaires pour la société, tels que l'évitement de la douleur et des souffrances de la maladie. À cet égard, ils peuvent être évalués et mesurés compte tenu des pertes sociales évitées.

Les deux principaux groupes au sein du public canadien qui tireront parti des modifications sont les personnes autorisées et d'autres Canadiens et Canadiennes.

Puisque les modifications permettront aux personnes désignées d'être titulaires de plus d'une licence de production, certaines personnes autorisées pourraient tirer parti du fait d'avoir plus de choix pour sélectionner leur personne désignée. Les Canadiens et les Canadiennes pourraient tirer avantage des mesures de contrôle plus serrées en ce qui a trait à la production de marihuana à des fins médicales en raison de la réduction possible des risques potentiels que la marihuana à des fins médicales soit détournée vers le marché clandestin de la drogue, et de dommages à la propriété ou d'incendies attribuables à la production d'un nombre significatif de plantes de marihuana à un seul endroit.

Costs

The ability to supply up to two authorized persons may result in a small "economy of scale" for some designated persons and this may, if anything, decrease the overall production price for marihuana and therefore the cost to authorized persons. In this regard, there is not expected to be any changes to the costs facing authorizing persons.

The incremental costs to Government associated with the proposed amendments are those related to minor administrative system adjustments that are required to deal with tracking which authorized persons are being supplied by each designated person, and costs associated with the increased burden on law enforcement and the court system. These costs will be absorbed using existing resources.

Overall, the incremental costs of these amendments on society are expected to be negligible. There is also, given the nature of the MMAR, no anticipated impact on competition or domestic/international trade.

Rationale

Without a reasonable limit on production by designated persons, the current street price for marihuana, e.g. $10-15 per gram, may encourage the potential establishment of "grow-op" size crops and the considerable potential that marihuana being produced for medical purposes may be diverted to the illicit market.

Given that the Federal Court of Appeal did not provide any direction as to the number of licences to produce a designated person should be able to hold, the incremental change is an interim step that respects the original intent of the Program while Health Canada undertakes a broader review of the Program and associated regulatory framework.

Immediate amendments to the Regulations are necessary because Health Canada has already received applications from authorized persons wishing to be supplied by a designated person who already holds a licence to produce for another authorized person and/or a new designated person who is also referenced in other pending applications. By way of illustration, Health Canada has already received an expression of interest from a designated person who is capable of supplying marihuana for up to 200 authorized persons.

Consultation

In acknowledgement of the pending SCC ruling with regard to whether or not it would hear an appeal of the *Sfetkopoulos* decision, Health Canada initiated a review of the impacts of potential negative outcomes from the court some months ago. That review entailed a range of limited consultations with relevant federal partners, e.g., Public Safety Canada, the Department of Justice, the Royal Canadian Mounted Police, and the Department of Foreign Affairs and International Trade. Health Canada officials also met with the Canadian Association of Chiefs of Police and representatives from the Office of the Ontario Fire Marshal.

Federal partners were supportive of introducing enhanced controls on the production of marihuana for medical purposes should

Coûts

La capacité d'approvisionner jusqu'à deux personnes autorisées pourrait engendrer de modestes «économies d'échelle» pour certaines personnes désignées, ce qui pourrait, à tout le moins, entraîner une réduction du prix global de la production de marihuana et, par conséquent, des coûts pour les personnes autorisées. À cet égard, aucun changement n'est prévu dans les coûts pour les personnes autorisées.

Les coûts différentiels pour le gouvernement associés aux modifications sont ceux qui sont liés aux ajustements mineurs au système administratif qui sont nécessaires pour composer avec le suivi des personnes autorisées, approvisionnées par chaque personne désignée, ainsi que les coûts associés au fardeau accru de l'application de la loi et du système judiciaire. Ces coûts seront absorbés à l'intérieur des ressources existantes.

Dans l'ensemble, la différence des coûts de ces modifications pour la société devrait être négligeable. On ne prévoit pas non plus, compte tenu de la nature du RAMM, d'incidence sur la compétitivité ni sur le commerce national et international.

Justification

Sans une limite raisonnable à la production par les personnes désignées, le prix dans la rue actuel de la marihuana, par exemple de 10 à 15 $ le gramme, pourrait encourager l'établissement de grandes installations de culture de la marihuana et présenter un risque potentiel considérable que la marihuana produite à des fins médicales puisse être détournée vers le marché clandestin de la drogue.

Comme la Cour d'appel fédérale n'a émis aucune directive sur le nombre de licences dont pourrait être titulaire une personne désignée, le changement progressif est une mesure provisoire qui respecte l'esprit original du Programme tandis que Santé Canada entreprend un examen plus approfondi du Programme et du cadre réglementaire connexe.

Des modifications immédiates au Règlement s'imposent puisque Santé Canada a déjà reçu des demandes de personnes autorisées qui souhaitent s'approvisionner auprès d'une personne désignée qui détient déjà une licence de production pour une autre personne autorisée ou une nouvelle personne désignée qui est aussi nommée dans d'autres demandes à l'étude. À titre d'illustration, Santé Canada a déjà reçu des déclarations d'intérêt d'une personne désignée qui a la capacité de fournir de la marihuana à près de 200 personnes autorisées.

Consultation

En attendant la décision de la CSC d'entendre ou non un appel de la décision dans l'affaire *Sfetkopoulos*, Santé Canada a entrepris, il y a quelques mois, un examen des répercussions d'une décision négative potentielle de la CSC. Dans le cadre de cet examen, un éventail de consultations limitées ont été tenues avec les partenaires fédéraux, par exemple Sécurité publique Canada, le ministère de la Justice, la Gendarmerie royale du Canada (GRC) et le ministère des Affaires étrangères et du Commerce international (MAECI). Les représentants de Santé Canada ont aussi rencontré ceux de l'Association canadienne des chefs de police (ACCP) et du Bureau du commissaire des incendies de l'Ontario.

Les partenaires fédéraux étaient favorables à la mise en vigueur de mesures de contrôle accrues en ce qui a trait à la production

the leave to appeal not be granted. They emphasized the ongoing trend towards increased personal production and the increased risk of diversion to illicit markets this represents.

Law enforcement also raised particular concerns with the potential for situations in which a single address could house multiple authorized persons and/or designated persons all licensed to cultivate increasing numbers of plants, and how these types of situations often hampers their ability to investigate and shut down illicit "grow ops." Law enforcement stressed that the lack of controls on production combined with the possibility of producing a large quantity of marihuana would most certainly lead to increased numbers or licence violations, e.g., where the amount of marihuana being produced is far more than what has been authorized via licence.

The Office of the Ontario Fire Marshal was particularly concerned with the potential risk of fire in situations where large amount of marihuana for medical purposes are being produced. They stressed their preference for the introduction of much tighter security requirements and enhanced controls on the size of production sites allowed under the MMAR.

Implementation, enforcement and service standards

Health Canada will have to review all applications from authorized persons seeking to modify their current supply arrangements via the designation of a new person to produce on their behalf. An assessment of whether or not the changes are allowed according to the new limit on the number of production licences a single designated person can hold will also have to be made. Health Canada will also need to develop a system that tracks exactly which authorized persons are being supplied by which designated persons in order to avoid the issuance of too many licences to produce to existing and new designated persons.

The current service standard for the processing of an application from a prospective authorized person and/or an existing authorized person wishing to make changes to their authorizations and/or licences is up to eight (8) weeks. Despite the increased administrative burden referenced above, it is not expected that this service standard will change with the implementation of the amendments.

At the present time, compliance and enforcement with the MMAR is handled cooperatively with law enforcement in that Health Canada has limited powers for administrative enforcement, e.g., ability to revoke a licence, etc., and is able to share certain information about production licence holders with law enforcement, who can then, as required, carry out criminal investigations and lay associated charges under the CDSA, the *Criminal Code* or other relevant deferral statutes. Implementation of the amendments will not have any direct impact on these arrangements, although increased information exchange with law enforcement may be required as they continue to carry out investigations of suspected illegal marihuana production and require confirmation as to who is licensed by Health Canada, what quantity of marihuana a particular production licence holder is

de marihuana à des fins médicales si la demande d'autorisation d'interjeter appel était rejetée. Ils ont fait ressortir la tendance actuelle vers une production personnelle accrue et le risque accru de détournement au marché clandestin de la drogue qu'elle représente.

Les organismes d'application de la loi ont aussi exprimé des préoccupations particulières à propos du potentiel de situations où une adresse unique pourrait abriter plusieurs personnes autorisées ou personnes désignées, toutes personnes titulaires de licences pour cultiver un nombre croissant de plantes, et de la façon dont ce type de situation fait souvent obstacle à leur capacité d'enquêter et de mettre fin aux installations illicites de culture de la marihuana. Ces organismes ont insisté sur le fait que le manque de mesure de contrôle de la production, conjugué à la possibilité de produire une grande quantité de marihuana, mènerait très certainement à une hausse des infractions aux conditions des licences, par exemple lorsque la quantité de marihuana produite est nettement supérieure à celle qu'autorise la licence.

Le Bureau du commissaire des incendies de l'Ontario s'inquiétait particulièrement du risque potentiel d'incendie dans les situations où de grandes quantités de marihuana à des fins médicales sont produites. Il a insisté sur sa préférence pour l'adoption d'exigences et de mesures de contrôle accrues beaucoup plus rigoureuses relativement à la taille des lieux de production autorisée en vertu du RAMM.

Mise en œuvre, application et normes de service

Santé Canada devra passer en revue toutes les demandes reçues de personnes autorisées qui souhaitent modifier leurs modalités actuelles d'approvisionnement en désignant une nouvelle personne pour produire de la marihuana pour leur compte. Il faudra aussi évaluer si les changements sont permissibles à la lumière de la nouvelle limite fixée au nombre de licences de production dont peut être titulaire une seule personne désignée. Santé Canada devra en outre concevoir un système qui assurera un suivi minutieux des personnes autorisées qui sont approvisionnées par des personnes désignées précises afin d'éviter la délivrance de trop de licences de production aux personnes désignées actuelles et nouvelles.

La norme de service courant pour le traitement des demandes reçues de personnes autorisées éventuelles et de personnes autorisées ou actuelles qui souhaitent modifier les modalités de leurs autorisations ou licences est fixée à un maximum de huit (8) semaines. En dépit de l'alourdissement du fardeau administratif dont il était question ci-dessus, on ne s'attend pas à ce que cette norme de service change avec la mise en œuvre de ces modifications.

Actuellement, l'observation et l'application du RAMM sont assurées en collaboration avec les organismes d'application de la loi puisque Santé Canada ne jouit que de pouvoirs limités d'application de mesures administratives, par exemple la capacité de révoquer des licences, et peut aussi communiquer certains renseignements sur les titulaires de licence de production aux organismes d'application de la loi qui peuvent, au besoin, mener des enquêtes criminelles et porter les accusations connexes sous le régime de la LRCDAS, du *Code criminel* ou d'autres lois pertinentes. La mise en œuvre des modifications n'aura pas d'incidence directe sur ces arrangements, bien qu'un échange accru d'information avec les organismes d'application de la loi puisse être nécessaire à mesure qu'ils mèneront leurs enquêtes sur la production illégale soupçonnée de marihuana et qu'ils auront

authorized to produce, etc. There may also be an increase on the number of marihuana for medical purposes-related cases presented before the courts.

Wider stakeholder consultation will have to be carried out as Health Canada proceeds with its broader review of the Program and related regulations.

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besoin de la confirmation du nom des titulaires de licence de Santé Canada, des quantités de marihuana qu'un titulaire particulier de licence de production est autorisé à cultiver, entre autres. Les tribunaux pourraient aussi devoir entendre plus d'affaires liées à la marihuana à des fins médicales.

Il faudra procéder à une vaste consultation auprès des intervenants tandis que Santé Canada poursuivra son examen général du Programme et du règlement connexe.

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Registration
SOR/2010-63 March 11, 2010

CONTROLLED DRUGS AND SUBSTANCES ACT

Regulations Amending the Marihuana Medical Access Regulations

P.C. 2010-289 March 11, 2010

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], hereby makes the annexed *Regulations Amending the Marihuana Medical Access Regulations*.

REGULATIONS AMENDING THE MARIHUANA MEDICAL ACCESS REGULATIONS

AMENDMENTS

1. Paragraphs 32(*d*) and (*e*) of the *Marihuana Medical Access Regulations*[1] are replaced by the following:

(*d*) the proposed production site would be a site for the production of marihuana under more than four licences to produce; or

(*e*) the applicant would be the holder of more than two licences to produce.

2. Section 54.1 of the Regulations is repealed.

3. Subsection 63(2) of the Regulations is amended by adding the following after paragraph (*c*):

(*c.1*) the holder of a licence to produce contravenes section 52;

4. The Regulations are amended by adding the following after section 63:

63.1 Subject to section 64, if a production site is authorized under more than four licences to produce, the Minister shall revoke the excess licences.

5. The portion of section 64 of the Regulations before paragraph (*a*) is replaced by the following:

64. The Minister shall not revoke an authorization to possess or a licence to produce under any of sections 62 to 63.1 unless

COMING INTO FORCE

6. These Regulations come into force on the day on which they are registered.

[a] S.C. 1996, c. 19
[1] SOR/2001-227

Enregistrement
DORS/2010-63 Le 11 mars 2010

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales

C.P. 2010-289 Le 11 mars 2010

Sur recommandation de la ministre de la Santé et en vertu du paragraphe 55(1) de la *Loi réglementant certaines drogues et autres substances*[a], Son Excellence la Gouverneure générale en conseil prend le *Règlement modifiant le Règlement sur l'accès à la marihuana à des fins médicales*, ci-après.

RÈGLEMENT MODIFIANT LE RÈGLEMENT SUR L'ACCÈS À LA MARIHUANA À DES FINS MÉDICALES

MODIFICATIONS

1. Les alinéas 32*d*) et *e*) du *Règlement sur l'accès à la marihuana à des fins médicales*[1] sont remplacés par ce qui suit :

d) le lieu proposé pour la production de marihuana serait visé par plus de quatre licences de production si la licence était délivrée;

e) le demandeur deviendrait titulaire de plus de deux licences de production si la licence était délivrée.

2. L'article 54.1 du même règlement est abrogé.

3. Le paragraphe 63(2) du même règlement est modifié par adjonction, après l'alinéa *c*), de ce qui suit :

c.1) le titulaire d'une licence de production contrevient à l'article 52;

4. Le même règlement est modifié par adjonction, après l'article 63, de ce qui suit :

63.1 Sous réserve de l'article 64, si le lieu de production est visé par plus de quatre licences de production, le ministre révoque toute licence excédentaire.

5. Le passage de l'article 64 du même règlement précédant l'alinéa *a*) est remplacé par ce qui suit :

64. Le ministre ne peut révoquer l'autorisation de possession ou la licence de production aux termes de l'un des articles 62 à 63.1 que si les conditions suivantes sont réunies :

ENTRÉE EN VIGUEUR

6. Le présent règlement entre en vigueur à la date de son enregistrement.

[a] L.C. 1996, ch. 19
[1] DORS/2001-227

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Executive summary

Issue: On February 2, 2009, the British Columbia Supreme Court (BCSC) in the case of *R. v. Beren and Swallow* declared paragraph 41(*b.1*) and section 54.1 to be invalid on the grounds that it infringes section 7 of the *Canadian Charter of Rights and Freedoms* (the Charter). Section 54.1 of the *Marihuana Medical Access Regulations* (MMAR) stipulated that the holder of a licence to produce shall not produce marihuana in common with more than two other holders of licences to produce. The effect of the declaration of invalidity was stayed for one year, however, in order to provide the Government with time to modify the MMAR as required.

While the Government had already addressed the issue with paragraph 41(*b.1*) in amendments to the MMAR made in May 2009, it sought leave to appeal the BCSC decision to the Supreme Court of Canada (SCC). The leave to appeal was dismissed, however, on January 14, 2010, and thus the stay of the declaration invalidating section 54.1 of the MMAR was set to expire on February 2, 2010.

The Government put forward a motion for a further stay of the declaration of invalidity until May 2, 2010 and the BCSC agreed to extend the stay to March 3, 2010. However, they imposed conditions to consider this request that could not be met in light of the Cabinet confidentiality. Therefore, section 54.1 of the MMAR became invalid on March 3, 2010.

The declaration that section 54.1 of the MMAR is invalid has created a significant regulatory void in that the Minister of Health no longer has the authority to restrict the number of production licences that can be issued with reference to the same site. While the government is still considering longer term options for the Marihuana Medical Access Program (the Program) and the MMAR, these amendments provide a swift response to address the regulatory void created by the declaration of invalidity.

Description: This regulatory initiative amends the MMAR by repealing the current restriction on the number of production licence-holders who can produce marihuana in common, and by introducing a new limit of four (4) on the number of production licences that can be issued with reference to the same production site. The initiative will also introduce two new revocation authorities pertaining to the production of marihuana licensed under the MMAR. The first provides the Minister with the authority to revoke the excess production licence issued with reference to a site already authorized for four (4) production licences. The second provides the Minister with the authority to revoke a production licence in the case where a licence-holder is not compliant with section 52 of the MMAR which stipulates that production licence-holders can only produce marihuana at the production site authorized in their licence and only in accordance with the authorized production area. Finally, the initiative also amends paragraph 32(*e*) of the MMAR in order to increase the maximum

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(Ce résumé ne fait pas partie du Règlement.)

Résumé

Question : Le 2 février 2009, dans l'affaire *R. c. Beren et Swallow*, la Cour suprême de la Colombie-Britannique (CSCB) déclarait invalides l'alinéa 41*b.1*) et l'article 54.1 du *Règlement sur l'accès à la marihuana à des fins médicales* (RAMM) pour motif qu'ils enfreignaient l'article 7 de la *Charte canadienne des droits et libertés* (la Charte). L'article 54.1 du Règlement stipulait que le détenteur d'une licence de production ne peut pas produire de la marihuana en commun avec plus de deux autres titulaires de licences de production. L'exécution de cette décision d'invalidité a fait l'objet d'un sursis d'un an pour donner au gouvernement le temps d'apporter les modifications nécessaires au RAMM.

Bien que le gouvernement ait déjà réglé le problème posé par l'alinéa 41*b.1*) avec la modification apportée en mai 2009, il a demandé à la Cour suprême du Canada (CSC) l'autorisation d'en appeler de la décision de la CSCB. Cette demande a été rejetée le 14 janvier 2010 et, par conséquent, le sursis d'exécution de la décision invalidant l'article 54.1 du RAMM devait expirer le 2 février 2010.

Le gouvernement a présenté une motion de prolongation du sursis d'exécution de la déclaration d'invalidité jusqu'au 2 mai 2010 et la CSCB a convenu de reporter l'échéance du sursis au 3 mars 2010. Néanmoins, la CSCB a imposé des conditions pour l'examen de cette demande, lesquelles ne pouvaient être remplies en raison de la confidentialité en Cabinet. L'article 54.1 du RAMM est donc devenu caduc le 3 mars 2010.

La déclaration d'invalidité de l'article 54.1 du RAMM a créé un grand vide réglementaire en ce sens que le ministre de la Santé n'est désormais plus habilité à restreindre le nombre de licences de production émises pouvant être rattachées au même lieu de production. Bien que le gouvernement étudie encore des solutions à plus long terme pour le Programme d'accès médical à la marihuana (le Programme) et le RAMM, ces modifications constituent une réponse rapide pour combler le vide réglementaire créé par la déclaration d'invalidité.

Description : Cette initiative réglementaire modifie le RAMM en abrogeant la limite en vigueur du nombre de détenteurs de licences de production qui peuvent produire de la marihuana en commun, et en fixant une nouvelle limite de quatre (4) au nombre de licences de production pouvant être émises en rapport au même lieu de production. L'initiative créera en outre deux nouveaux pouvoirs de révocation relativement à la production de marihuana autorisée sous le régime du RAMM. Le premier habilite le ministre à révoquer toute licence de production excédentaire émise à un lieu de production déjà autorisé sous quatre (4) licences de production. Le second habilite le ministre à révoquer une licence de production dans les cas où un détenteur de licence ne se conforme pas à l'article 52 du RAMM, lequel stipule que les détenteurs de licences de production ne peuvent produire de la marihuana qu'au lieu de production autorisé visé par leur licence et seulement dans l'aire de production autorisée. Enfin, l'initiative modifie aussi l'alinéa 32*e*) du RAMM pour augmenter à deux (2) le nombre

number of production licences a holder of a personal-use production licence can hold to two (2). As described in more detail in the Objectives section, this is a consequential amendment aimed at addressing issues arising from the implementation of amendments to the MMAR published under SOR/2009-142.

Cost-benefit statement: As described below, large-scale marihuana production creates potential risks to public health, safety and security of not only those persons directly involved, but also those living at the same address, adjacent residential units, and/or in the surrounding community. The attractive street value of marihuana (approximately $10–15/gram) and the wide use of marihuana as a recreational drug could make large-scale marihuana production operations more vulnerable to theft and diversion which may result in potential risk to public health, safety and security. Government intervention to introduce a new limit on the number of production licences that can be issued with reference to a single site will provide benefits by constraining the number of marihuana plants that can be grown at one site, thereby reducing the aforementioned risks. The amendments also respect the original intent of the Program, (i.e. enabling seriously ill Canadians to have access to marihuana for medical purposes).

Business and consumer impacts: The amendments still provide production licence-holders with a small potential economy of scale as four (4) production licenses for medical marihuana can exist for the same site.

Implementation of the amendments will result in a minimal increase in the administrative burden on Health Canada, as systems and processes to administer the MMAR are already in place, and no changes to the system currently used to track production licence-holders, authorized persons and the amount of marihuana being produced under licence at the same site are required.

Domestic and international coordination and cooperation: This initiative underscores the Government's commitment to controlling the production and distribution of marihuana, as required by the *Controlled Drugs and Substances Act* (CDSA) and the United Nations *Single Convention on Narcotic Drugs, 1961*, to which Canada is a signatory. It is expected that the International Narcotics Control Board and Canada's law enforcement will be supportive of the proposed amendments as they serve to limit the amount of marihuana for medical purposes that can be produced at a single site, reducing the potential for commercial size grow operations, and the potential for diversion to the illicit market.

maximal de licences de production que peut avoir un détenteur de licence de production à des fins personnelles. Comme l'explique plus en détail la section Objectifs, c'est une modification corrélative qui vise à corriger les problèmes posés par la mise en œuvre des modifications au RAMM publiées sous le numéro DORS/2009-142.

Énoncé des coûts et avantages : Comme on l'explique dans les paragraphes qui suivent, la culture de la marihuana, à n'importe quelle échelle, n'est pas sans conséquence, sous forme de risques possibles pour la santé et la sécurité non seulement des principaux intéressés, mais aussi des personnes qui vivent à la même adresse, dans des logements adjacents ou dans le voisinage. L'attrayante valeur dans la rue de la marihuana (de 10 $ à 15 $/gramme) et son utilisation répandue comme drogue récréative pourraient rendre les opérations de production de marihuana à grande échelle plus vulnérables au vol et au détournement vers le marché clandestin, ce qui présente un risque possible pour la santé et la sécurité du public. L'intervention du gouvernement pour fixer une nouvelle limite au nombre de licences de production rattachées à un lieu particulier présentera l'avantage de limiter le nombre de plants de marihuana pouvant être produits en un seul lieu, réduisant ainsi les risques décrits plus haut. Les modifications respectent aussi l'esprit initial du Programme (c'est-à-dire permettre aux Canadiens gravement malades d'accéder à une source licite de marihuana à des fins médicales).

Incidences sur les entreprises et les consommateurs : Les modifications permettent encore aux détenteurs de licences de production de réaliser de modestes économies d'échelle puisque quatre (4) licences de production de marihuana à des fins médicales peuvent être autorisées pour un même lieu.

La mise en œuvre des modifications entraînera une augmentation minime du fardeau administratif de Santé Canada, puisque les systèmes et processus nécessaires pour administrer le RAMM existent déjà et qu'aucun changement ne s'impose au système qui sert actuellement à effectuer le suivi des titulaires de licences de production, des personnes autorisées et de la quantité de marihuana produite sous licence au même lieu.

Coordination et coopération à l'échelle nationale et internationale : Cette initiative fait ressortir l'engagement qu'a pris le gouvernement d'assurer le contrôle de la production et de la distribution de marihuana, comme l'exige la *Loi réglementant certaines drogues et autres substances* (LRCDAS) et la *Convention unique sur les stupéfiants de 1961* des Nations Unies, dont le Canada est signataire. On s'attend à ce que l'Organe international de contrôle des stupéfiants et les organismes d'application de la loi du Canada appuient les modifications puisqu'elles permettent de limiter la quantité de marihuana à des fins médicales qui peut être produite à un même lieu, réduisant le potentiel d'opérations de production à grande échelle et le potentiel de détournement vers le marché clandestin de la drogue.

Issue

Marihuana is included in Schedule II to the CDSA, and as such is regulated as a controlled substance in Canada. The CDSA prohibits the possession, possession for the purposes of trafficking, production, importation, exportation, trafficking, and possession for the purposes of exporting marihuana except as authorized by regulation.

Question

La marihuana figure à l'annexe II de la LRCDAS et est donc une substance désignée au Canada. Cette loi interdit la possession, la possession aux fins de trafic, la production, l'importation, l'exportation, le trafic et la possession aux fins d'exportation de marihuana, sauf dans les cas autorisés en vertu de la réglementation.

The Marihuana for Medical Access Program (the Program) was first established in 1999, and the authorization to possess marihuana and/or produce a limited number of plants for medical purposes was achieved via the issuance of exemptions under section 56 of the CDSA. In July 2000, however, the Ontario Court of Appeal ruled (*R. v. Parker)* that the prohibition on the possession of marihuana in the CDSA was unconstitutional because it violated the right to liberty and security of the person as it did not provide a clear legal standard to allow for an exemption for medical purposes.

In response to this decision, the Government established the MMAR, which set out a scheme by which any seriously ill Canadian can, with the support of a medical practitioner, obtain an authorization to possess and/or a licence to produce marihuana for their own personal medical use.

Under the current MMAR, authorized persons have three options in terms of procuring a supply of dried marihuana:

- they can produce their own supply under a Personal Use Production Licence (PUPL);
- they can designate an individual to produce it on their behalf under a Designated Person Production Licence (DPPL); or
- they can purchase dried marihuana from the Government of Canada, who contracts a private company (currently Prairie Plant Systems, Inc.) to produce and distribute marihuana for the Program.

While the Program was originally intended to authorize access for a small number of persons, it has continued to grow in size since its inception. At present, there are approximately 4 800 persons authorized to possess marihuana under the Program, and this number is expected to grow to at least 6 000 by 2011.

Of those approximately 4 800 authorized persons:

- approximately 60% hold a PUPL;
- approximately 10% obtain their supply from a designated person;
- approximately 20% purchase their supply from the Government; and
- approximately 10% obtain their supply from an unknown source.

The recent invalidation of subsection 54.1 of the MMAR establishes a regulatory void in that the Government of Canada no longer has the ability to restrict the number of production licences (either PUPL or DPPL) that could be issued in reference to the same site. The decision in *Sfetkopoulos, Dora et al v. AG of Canada* invalidated the one to one designated person to authorized person ratio. The MMAR were amended to address the *Sfetkopoulos* court decision in May 2009 (SOR/2009-142) in order to introduce a new limit on the number of production licences a designated person can hold. Currently, a designated person can only cultivate marihuana for a maximum of two authorized persons.

The invalidation of section 54.1 impedes the Government of Canada's ability to limit the number of licences and, by the same fact, the amount of marihuana plants legally produced at a single site. The absence of a limit could, in turn, give rise to situations in which large numbers of marihuana plants could be legally produced at a single site, without the benefit of the tight controls

Le Programme d'accès médical à la marihuana (le Programme) a d'abord été établi en 1999, et il est devenu possible d'autoriser la possession et la culture d'un nombre limité de plants de marihuana à des fins médicales grâce à l'octroi d'exemptions en vertu de l'article 56 de la LRCDAS. En juillet 2000, toutefois, la Cour d'appel de l'Ontario a décidé (*R. c. Parker)* que l'interdiction de possession de marihuana stipulée dans la LRCDAS était inconstitutionnelle parce qu'elle enfreignait le droit à la sécurité et à la liberté de la personne en n'établissant pas clairement une norme légale pour permettre l'exemption de la marihuana à des fins médicales.

En réponse à cette décision, le gouvernement a promulgué le RAMM, qui établit un moyen par lequel tout Canadien et toute Canadienne gravement malade peut, avec l'appui d'un médecin, obtenir l'autorisation de posséder de la marihuana pour sa consommation personnelle à des fins médicales.

En vertu de l'actuel RAMM, les personnes autorisées disposent de trois moyens de s'approvisionner en marihuana séchée :

- elles peuvent produire leurs propres provisions conformément à une licence de production à des fins personnelles (LPFP);
- elles peuvent désigner une personne qui assurera la production en leur nom conformément à une licence de production à titre de personne désignée (LPPD);
- elles peuvent acheter de la marihuana séchée du gouvernement du Canada qui charge sous contrat une compagnie privée (actuellement Prairie Plant Systems Inc.) de produire de la marihuana dans le cadre du Programme.

Bien que le Programme ait eu pour objet, à l'origine, de permettre à un petit nombre de personnes d'accéder à la marihuana, il n'a cessé de prendre de l'ampleur depuis son entrée en vigueur. Actuellement, environ 4 800 personnes sont autorisées à posséder de la marihuana conformément au Programme, et il est prévu qu'elles seront au moins 6 000 d'ici 2011.

Sur ces quelque 4 800 personnes autorisées :

- environ 60 % détiennent une LPFP;
- environ 10 % s'approvisionnent auprès d'une personne désignée;
- environ 20 % achètent de la marihuana séchée du gouvernement;
- environ 10 % obtiennent de la marihuana séchée de source inconnue.

L' invalidation récente de l'article 54.1 du RAMM crée un vide réglementaire du fait que le gouvernement du Canada n'est plus habilité à restreindre le nombre de licences de production (LPFP ou LPPD) pouvant être émises relativement au même lieu. La décision dans l'affaire *Sfetkopoulos, Dora et autres c. AG of Canada* a invalidé le ratio d'une personne désignée pour une personne autorisée. Le RAMM a été modifié à la suite de la décision *Sfetkopoulos* en mai 2009 (DORS/2009-142) afin de fixer une nouvelle limite au nombre de licences de production que peut détenir une personne désignée. Actuellement, une personne désignée ne peut cultiver de la marihuana que pour un maximum de deux personnes autorisées.

L'invalidation de l'article 54.1 entrave la capacité du gouvernement du Canada de limiter le nombre de licences et, de ce fait, la quantité de marihuana produite légalement en un seul lieu. L'absence de limite pourrait à son tour donner lieu à des situations où de grands nombres de plants de marihuana pourraient légalement être produits au même lieu, sans l'avantage des

applied to the production and handling of marihuana by the private company under contract for the government or for other controlled substances regulated under the CDSA. The Government's inability to limit the number of licences and thereby the amount of marihuana plants could compromise the intent of the MMAR, which is to authorize the possession and/or production of marihuana for medical purposes on an individual basis while minimizing the potential risks to public health, safety and security.

The inability of the Government to restrict the number of production licence-holders who can produce at the same site could mean that it would be possible for multiple production licence holders who are authorized to produce a high number of plants to also cultivate at the same site. Such a situation may blur the line for law enforcement between legal production under the auspices of the MMAR and illicit marihuana "grow operations."

The Minister of Health has therefore elected to make amendments to the MMAR which are intended to reduce the possibility that the declaration of invalidity of section 54.1 might result in the proliferation of large scale marihuana production operations within the auspices of its Marihuana Medical Access Program.

Objectives

The primary objective of these amendments is to address the regulatory void resulting from the striking down of section 54.1, thus maintaining a degree of control over the production of marihuana, a controlled substance whose production, except as authorized under the Regulations, is prohibited. The introduction of a new limit on the number of production licences (PUPLs or DPPLs) that can be issued with reference to the same site as well as the introduction of two new revocation authorities pertaining to the production of marihuana licensed under the MMAR is intended to mitigate the potential risks to public health and safety (where this includes the risk of diversion and/or theft) associated with the large-scale under-regulated production of marihuana.

The second objective is to introduce an amendment required to address issues arising out of the amendments published under SOR/2009-142. In the aforementioned amendment, the limit on the maximum number of production licences a designated person can hold was increased to two (2). The Government omitted, however, to consider the impact of this new limit on designated persons who are not currently PUPL-holders but who may wish at some point to hold a PUPL. Accordingly, the Government is now seeking to increase the maximum number of production licences a holder of a PUPL can hold to two (2), so that an individual who is already a designated person can also apply for and be issued with a PUPL.

By instituting these amendments, the Government is still allowing Canadians with debilitating medical conditions to access a legal source of dried marihuana for their own personal use, while minimizing the potential risks to public health, safety and security associated with large-scale production. The amendments may also provide production licence-holders with the opportunity to realize some economies of scale via production in common with other licence-holders.

mesures rigoureuses de contrôle appliquées à la production et à la manipulation de marihuana par la compagnie privée qui en est chargée par contrat pour le gouvernement, ou de toute autre substance désignée visée par la LRCDAS. L'incapacité du gouvernement de limiter le nombre de licences et ainsi le nombre de plants de marihuana pourrait compromettre l'objet du RAMM qui est d'autoriser la possession ou la production de marihuana à des fins médicales pour la consommation personnelle tout en réduisant au minimum les risques possibles pour la santé et la sécurité du public.

L'incapacité du gouvernement de restreindre le nombre de détenteurs de licences qui peuvent produire de la marihuana au même lieu pourrait signifier qu'il serait possible à de multiples détenteurs de licences autorisés de produire un grand nombre de plants et d'en faire aussi la culture au même lieu. Pareille situation pourrait brouiller, pour les services d'exécution de la loi, la limite qui sépare la production licite en vertu du RAMM et les opérations illicites de culture de marihuana.

Le ministre de la Santé a donc choisi d'apporter des modifications au RAMM dans le but de réduire le risque que la déclaration d'invalidité de l'article 54.1 catalyse la prolifération des opérations de production de marihuana à grande échelle sous les auspices de son Programme d'accès à la marihuana à des fins médicales.

Objectifs

Le principal objectif de ces modifications est de combler le vide réglementaire causé par l'invalidation de l'article 54.1, et ainsi de maintenir une certaine mesure de contrôle sur la production de marihuana, une substance désignée dont la production, à l'exception de celle qui est autorisée par le Règlement, est interdite. L'établissement d'une nouvelle limite au nombre de licences de production (LPFP ou LPPD) pouvant être émises pour un même lieu ainsi que la création de deux nouveaux pouvoirs de révocation relativement à la production de marihuana autorisée aux termes du RAMM visent à atténuer les risques possibles pour la santé et la sécurité du public (ce qui comprend les risques de détournement vers le marché clandestin des drogues et/ou de vol) associés à la production sous-réglementée de marihuana à grande échelle.

Le second objectif est de créer une modification visant à corriger les problèmes nés des modifications publiées sous DORS/2009-142. Conformément à cette modification, la limite du nombre maximal de licences de production que peut détenir une personne désignée a été augmentée à deux (2). Le gouvernement a toutefois omis de prendre en compte les répercussions de cette nouvelle limite sur les personnes désignées qui ne détiennent pas actuellement de LPFP mais qui pourraient un jour souhaiter en avoir. Par conséquent, le gouvernement cherche maintenant à augmenter à deux (2) le nombre maximal de licences que peut détenir une personne qui est titulaire d'une LPFP, afin qu'une personne qui est déjà désignée puisse aussi demander et obtenir une LPFP.

En instituant ces modifications, le gouvernement permet encore aux Canadiens souffrant de troubles de santé débilitants d'accéder à une source licite de marihuana séchée à leurs fins personnelles tout en réduisant au minimum les risques possibles pour la santé et la sécurité du public associés à la production à plus grande échelle. Les modifications pourraient aussi offrir aux détenteurs de licences de production l'occasion de réaliser quelques économies d'échelle par la production en commun avec d'autres détenteurs de licences.

Regulatory and non-regulatory options considered

Three options were considered in addressing the invalidation of section 54.1 of the MMAR.

The first option considered was to take no action in response to the invalidation of subsection 54.1 of the MMAR. This would, however, do nothing to mitigate the potential but not insignificant health, safety and security risks associated with large-scale production of marihuana in an under-regulated environment.

The second option considered was to amend the MMAR to introduce security requirements for high-volume production sites (e.g. persons cultivating over a certain number of plants and/or at sites where more than a certain number of persons are cultivating in common). This option would likely restore some level of safety and security over the production of marihuana within the confines of the Program, and it may address some concerns raised by fire chiefs. However, as with the first option, it does not address the potential proliferation of legal commercial-size "grow operations." Furthermore, it does not allow the government to respond swiftly to the regulatory void resulting from this recent court decision.

The third option considered was to repeal section 54.1 of the MMAR and establish a new limit on the number of production licences that can be issued with reference to the same site, and, in order to ensure appropriate enforcement of this limit, introduce new revocation authorities that would allow the Minister to revoke the excess production licences issued with reference to a site authorized under more than four (4) other production licences. The advantages of this option are that it restores a certain level of control over the production of marihuana under the auspices of the MMAR, while not imposing any new restrictions on licensed producers. This option also mitigates the potential health safety and a security risk associated with the large-scale production of marihuana while respecting the original intent of the program, i.e. enabling seriously ill Canadians to have access to marihuana for medical purposes.

Benefits and costs

The cost-benefit analysis assumes that failing to restore a limit on the number of licences will result in larger amounts of marihuana being produced under the auspices of the MMAR at one site, which would lead to increased risk to public health, safety and security. Quantification and/or monetization of these impacts are, however, limited by the availability of quantitative data.

Benefits

In general, social benefits are not limited to reductions in expenses or increased earnings but also include non-monetary gains to society such as avoiding the pain and suffering of illness. In this regard, they can be assessed and measured in terms of avoided social losses.

The three main groups within the Canadian public who will benefit from the amendments are production licence-holders (either PUPL or DPPL), persons who are authorized to possess marihuana for medical purposes, and other Canadians. More specifically, production licence-holders may be able to achieve some economy of scale by growing in common with other production

Options réglementaires et non réglementaires considérées

Trois possibilités ont été envisagées pour répondre à l'invalidation de l'article 54.1 du RAMM.

La première option envisagée consistait à ne rien faire en réponse à l'invalidation de l'article 54.1 du RAMM. Cette option n'atténuerait cependant pas les risques possibles mais non négligeables pour la santé et la sécurité qui sont associés à la production de marihuana à grande échelle dans un environnement sous-réglementé.

La deuxième option serait d'apporter une modification au RAMM pour promulguer des exigences de sécurité visant les lieux de production à gros volumes (par exemple les personnes qui cultiveraient plus d'un certain nombre de plants ou les lieux où plus d'un certain nombre de personnes cultivent la marihuana en commun). Cette option rétablirait probablement un certain degré de sécurité relativement à la production de marihuana dans les limites du Programme, et elle pourrait répondre à des préoccupations qu'ont soulevées les chefs de pompiers. Toutefois, cette solution, comme la première, ne contre pas le potentiel de prolifération « d'opérations de production » commerciales licites. De plus, elle ne permet pas au gouvernement de combler rapidement le vide réglementaire qu'a créé cette décision récente de la Cour.

La troisième option envisagée était d'abroger l'article 54.1 du RAMM et de fixer une nouvelle limite au nombre de licences de production pouvant être émises visant un même lieu et, afin d'assurer l'application appropriée de cette limite, de créer de nouveaux pouvoirs de révocation qui permettraient au ministre de révoquer les licences de production excédentaires émises pour un lieu auquel auraient été octroyées plus de quatre (4) autres licences de production. L'avantage que présente cette option est qu'elle rétablit un certain degré de contrôle sur la production de marihuana en vertu du RAMM tout en n'imposant pas de nouvelles restrictions aux producteurs autorisés. Cette option atténue aussi les risques possibles pour la santé et la sécurité qui sont associés à la production à grande échelle de marihuana tout en respectant l'intention initiale du Programme, soit de permettre aux Canadiens gravement malades d'accéder à de la marihuana à des fins médicales.

Avantages et coûts

L'analyse des avantages et des coûts de cette mesure s'est faite en partant du postulat que l'absence de rétablissement d'une limite du nombre de licences engendrerait une hausse de la production de marihuana en un même lieu sous les auspices du RAMM, ce qui comporterait un risque accru pour la santé et la sécurité du public. La quantification ou la monétisation de ces répercussions est toutefois limitée par le manque de données quantitatives.

Avantages

En général, les avantages pour la société ne se limitent pas à la réduction des dépenses ou à l'augmentation des gains, mais englobent aussi des gains non pécuniaires pour la société, tels que l'évitement de la douleur et des souffrances de la maladie. À cet égard, ils peuvent être évalués et mesurés compte tenu des pertes sociales.

Les trois principaux groupes au sein du public canadien qui tireront avantage des modifications sont les détenteurs de licences de production (LPFP ou LPPD), les personnes autorisées à posséder de la marihuana à des fins médicales et d'autres Canadiens. Plus précisément, les détenteurs de licences de production pourraient être en mesure de réaliser des économies d'échelle en se

licence-holders up to the point where four (4) licences to produce may be issued with reference to the same site. Persons who are authorized to possess marihuana but who do not hold a licence to produce may also benefit but only if they obtain their supply from someone who produces in common with other production licence-holders.

Canadians at large also benefit from the re-establishment of tighter controls on the size of production operation of marihuana for medical purposes because of reduced exposure to the potential health, safety and security risks, including, but not limited to, the risk of theft, diversion and/or fire hazards that could be associated with the production of a significant number of marihuana plants in one site.

Costs

The ability for four production-licence to be issued with reference to a single site may result in a small "economy of scale" for the holders of the licences and this may, if anything, decrease the overall production price for marihuana and therefore the costs borne by PUPL- and DPPL-holders. Thus, there is not expected to be any increase in the costs borne by authorized persons.

The incremental costs to Government associated with the amendments are those related to minor administrative/program adjustments in order to monitor the number of production licences issued with reference to the same site. The costs associated with these changes will be absorbed using existing resources.

The overall costs of these amendments on society are expected to be negligible. There is also, given the nature of the MMAR, no anticipated impact on competition or domestic/international trade resulting from these amendments.

Rationale

Establishing a means by which the Government can control the size of the legal production of marihuana in Canada is consistent with its policy direction on controlling the production and distribution of controlled substances. It also underlines the message that the production of marihuana under the auspices of the MMAR must be limited at providing reasonable access to Canadians suffering from serious illnesses who are authorized to possess marihuana under the same regulations.

In addition, without a reasonable limit on legal cultivation of marihuana under the auspices of the MMAR, the current street price for marihuana (e.g. $10–15 per gram) and the wide use of marihuana as a recreational drug could make large-scale marihuana production operations more vulnerable to theft and diversion, which may result in potential risk to public health, safety and security.

Consultation

Federal partners support the introduction of enhanced controls on the production of marihuana for medical purposes, especially given the increasing numbers of production licences being granted under the MMAR.

joignant à d'autres détenteurs de licences de production jusqu'à l'atteinte de la limite de quatre (4) licences de production pouvant être émises pour un même lieu. Les personnes autorisées à posséder de la marihuana mais ne détenant pas de licence de production pourraient aussi en tirer parti mais seulement si elles s'approvisionnent auprès d'une personne qui produit en commun avec d'autres détenteurs de licences de production.

Les Canadiens dans l'ensemble tireront aussi avantage du rétablissement de contrôles plus rigoureux de l'envergure des opérations de production de marihuana à des fins médicales par leur exposition réduite aux risques possibles pour leur santé et leur sécurité, y compris, sans s'y limiter, le détournement de la marihuana vers le marché clandestin et les risques d'incendie pouvant être associés à la production d'un grand nombre de plants de marihuana en un seul lieu.

Coûts

La possibilité d'émission de quatre licences de production visant un même lieu pourrait être source de petites économies d'échelle pour les détenteurs de licences et cela pourrait, de fait, réduire le prix global de production de la marihuana et, de là, les coûts qu'assument les détenteurs de LPFP et de LPPD. Ainsi, il n'est pas prévu d'augmentation des coûts qu'assument les personnes autorisées.

Les coûts différentiels pour le gouvernement associés aux modifications proposées sont ceux qui sont liés aux ajustements mineurs au système administratif et au Programme qui sont nécessaires pour faire le suivi du nombre de licences de production émises pour le même lieu. Les coûts afférents à ces changements seront absorbés par les ressources actuelles.

Dans l'ensemble, la différence des coûts de ces modifications pour la société devrait être négligeable. On ne prévoit pas non plus, compte tenu de la nature du RAMM, d'incidence sur la compétitivité ni sur le commerce national et international.

Justification

L'établissement d'un moyen par lequel le gouvernement peut limiter l'envergure de la production licite de marihuana au Canada est conforme à l'orientation stratégique en matière de contrôle de la production et de la distribution des substances désignées. Il fait aussi ressortir le message que la production de marihuana sous les auspices du RAMM doit être limitée à l'offre d'une accessibilité raisonnable pour les Canadiens souffrant de maux graves qui sont autorisés à posséder de la marihuana en vertu dudit règlement.

De plus, sans une limite raisonnable à la culture licite de marihuana sous les auspices du RAMM, le prix courant actuel de la marihuana dans la rue (soit de 10 à 15 $ par gramme) et la consommation répandue de marihuana en tant que drogue récréative pourraient exposer les opérations de production de marihuana à grande échelle au vol et au détournement vers le marché clandestin, ce qui pourrait engendrer des risques additionnels pour la santé et la sécurité du public.

Consultation

Les partenaires fédéraux sont favorables au resserrement des mesures de contrôle sur la production de marihuana à des fins médicales, particulièrement à la lumière du nombre accru de licences de production qui sont émises aux termes du RAMM.

The RCMP stressed that the possibility of production licence-holders being allowed to cultivate high numbers of plants in common with an unlimited number of other licence-holders would increase the likelihood of more licence violations (e.g. where the amount of marihuana being produced is far more than what has been authorized via licence).

In additional consultations further to the SCC's dismissal of the Government's request for leave to appeal and subsequent motion for a stay, the RCMP stressed its concern for potential situations in which a single site could house multiple authorized persons and/or designated persons all licensed to produce increasing numbers of plants. They also reiterated that, any time production licences under the MMAR allows for the cultivation of more than 50 plants, their ability to distinguish between licensed production and illicit "grow ops" is seriously hampered. In correspondence to the Department, the RCMP indicated its support for any changes to the MMAR that Health Canada could make expeditiously, thereby avoiding a situation where there would be an influx of current and/or prospective licences issued in reference to a same site further to the invalidation of section 54.1.

Similar views were expressed by the Canadian Association of Chiefs of Police, the Canadian Association of Fire Chiefs and the Office of the Ontario Fire Marshal, with the latter two being particularly concerned with the potential risk of fire in situations where large amounts of marihuana for medical purposes are being cultivated in buildings which are not wired safely and/or are not ventilated appropriately.

Implementation, enforcement and service standards

Promulgation of the amendments will result in Health Canada having to review each incoming application for a production licence (DPPL or PUPL) carefully in order to ascertain that the proposed production site is not already referenced in four (4) other production licences. The same process will apply for applications to renew or amend a production licence. As mentioned previously, Health Canada does not need to modify the system it uses to track authorized persons, DPPL-holders and PUPL-holders.

The current service standard for the processing of an application from a prospective production licence-holder or an existing production licence-holder wishing to make changes to their licence is eight (8) to ten (10) weeks. Despite the increased administrative burden referenced above, it is not expected that this service standard will change with the implementation of the amendments.

Implementation of the amendments is not likely to have an impact on the present way in which compliance and enforcement with the MMAR is handled. Should a scenario arise where excess production licence are authorized at a site, and/or a licence-holder is found to be producing marihuana for medical purposes at a site or production area not authorized on their licence, Health Canada now has the authority to revoke the non-compliant production licences.

La Gendarmerie royale du Canada (GRC) a souligné que le fait que des détenteurs de licences de production soient autorisés à cultiver de grand nombre de plants en commun avec un nombre illimité d'autres détenteurs de licences pourrait être susceptible d'entraîner une augmentation des infractions aux modalités des licences (par exemple que la quantité de marihuana produite soit nettement supérieure à celle autorisée par la licence).

Lors d'autres consultations menées à la suite du rejet de la demande d'interjeter appel qu'avait déposée le gouvernement et de la motion de sursis qui a suivi, la GRC a exprimé sa crainte de situations possibles où un seul lieu de production pourrait héberger de multiples personnes autorisées et/ou personnes désignées, toutes détentrices de licences pour produire un nombre croissant de plants. Elle a aussi réitéré que, dès que les licences de production attribuées en vertu du RAMM permettent la culture de plus de 50 plants, sa capacité de faire la distinction entre une production autorisée et les « exploitations de culture » illicites est gravement compromise. De concert avec le Ministère, la GRC a signifié son soutien pour tout changement au RAMM que Santé Canada pourrait faire rapidement, évitant ainsi une situation où il y aurait un afflux de licences actuelles ou éventuelles émises pour un même lieu de production dans la foulée de l'invalidation de l'article 54.1.

Des points de vue similaires ont été exprimés par l'Association canadienne des chefs de police, l'Association canadienne des chefs de pompiers et le Bureau du commissaire des incendies, ces deux derniers s'inquiétant particulièrement du risque possible d'incendie dans des situations où de grandes quantités de marihuana à des fins médicales sont cultivées dans des immeubles dont les circuits électriques ne sont pas sécuritaires ou qui ne sont pas suffisamment ventilés.

Mise en œuvre, application et normes de service

La promulgation des modifications exigera que Santé Canada examine attentivement chaque demande de licence de production (LPPD ou LPFP) pour s'assurer que le lieu proposé de production n'est pas déjà désigné dans quatre (4) autres licences de production. La même démarche s'appliquera aux demandes de renouvellement ou de modification de licences de production. Comme on l'a déjà dit, Santé Canada n'a pas à modifier le système qu'il utilise pour faire le suivi des personnes autorisées et des détenteurs de LPPD et de LPFP.

La norme de service en vigueur pour le traitement d'une demande émanant d'un détenteur actuel ou possible de licence de production ou souhaitant apporter des modifications à sa licence est de huit (8) à dix (10) semaines. En dépit du fardeau administratif accru dont il est question plus haut, on ne s'attend pas à ce que cette norme de service change avec l'entrée en vigueur des modifications.

La mise en œuvre des modifications est peu susceptible d'avoir des répercussions sur les méthodes actuelles de traitement de la conformité et d'application de la loi relativement au RAMM. S'il advenait qu'un excédent de licences de production ait été émis pour un lieu, ou qu'un détenteur de licence soit pris à produire de la marihuana à des fins médicales en un lieu ou une aire de production non autorisé par sa licence, Santé Canada détient désormais le pouvoir de révoquer les licences de production non conformes.

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This is **Exhibit " C "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

Protected "A"

An Analysis of National Cases Related to the Marihuana Medical Access Regulations

Prepared on behalf of the CACP
by the RCMP
November 2010

Royal Canadian Mounted Police | Gendarmerie royale du Canada

Canada

Acknowledgement

This report could not have been written without the assistance of the following collaborators:

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Table of Contents

Executive Summary

The Canadian Association of Chiefs of Police (CACP) Drug Abuse Committee requested a formal report on any misuse and non-compliance issues of the Marihuana Medical Access Regulations (MMAR) encountered by law enforcement agencies throughout Canada. (U)

This report analyzes national cases of abuse related to the MMAR administered by Health Canada (HC). It examines criminal activity associated with MMAR licences, challenges with the MMAR from a public safety perspective, and provides strategic recommendations on the application of the MMAR. A total of 190 MMAR-related cases submitted by various law enforcement agencies, covering the time frame between August 2003 and April 2010, were examined for this assessment. (A)

This report does not claim to provide a comprehensive review of the MMAR and the Marihuana Medical Access Program, rather it is intended to provide examples of abuses that have come to the attention of the police and which have resulted in enforcement action. In order to produce an accurate scale of abuses, each and every MMAR grow operation would have to be inspected by HC. HC has limited capacity to conduct inspections and during the time period covered by this report had not conducted any inspections, to the knowledge of the authors of this report. (A)

Cases outlined in this report have been investigated by the police across Canada. It is important to note that, in the majority of instances, when police start an investigation into a marihuana grow, they contact HC to confirm if there is a holder of a production licence at that address. If the response from HC is positive, and no further extenuating circumstances exist, the investigation is often concluded and no further action is taken. If information exists about trafficking, overproduction or other issues, then the investigation is continued. Some of those cases are included in this report. (A)

It is important to add that HC licences individuals only, and that it does not licence organizations such as "compassion clubs" to possess, produce, or distribute marihuana for medical purposes. The Department restricts the number of people growing in common through two provisions of the Regulations: by limiting the number of production licences in one location to four, and by limiting the number of people a person can produce for to two. A licensed production holder whose site exceeds these limits would be subject to law enforcement measures. (A)

Key Findings

- Sixty-seven of the 190 cases involved trafficking and/or production of marihuana exceeding the terms of the MMAR authorization or licence. The remaining 123 files involved licence violations, violence against licence holders, and health and safety hazards. (A)
- Thirty-seven of 134 licensees[1] had a minimum of one trafficking and/or production conviction — 67 had a criminal record. (A)

1 There were 134 licensees identified in this review, however, a number of licensees appeared in several of the 190 files.

- The number of Designated Person Production Licences (DPPL) being granted is increasing, and licensees are now permitted to grow more marihuana plants for an increasing number of individuals. (A)
- A single marihuana plant can yield approximately five to six times more dried marihuana than what is estimated by HC in the MMAR. (A)
- The current ratio of HC MMAR inspectors to licensees in Canada is one to 338. (A)
- Marihuana grow operations, legal or otherwise, continue to be a concern for health and safety reasons. There is an increased risk of home invasion, violence, fire, and health related issues. (A)

Introduction

The illicit production of marihuana in Canada has increased steadily in the last 20 years. In 2008, HC reported that marihuana seizures represented nearly 75 percent of all illicit drugs seized by law enforcement agencies in Canada.[i] According to the U.S. National Drug Intelligence Center, while seizures of Canadian marihuana have declined[2] at the U.S.-Canada border, Canada continues to be one of the source countries for high-grade marihuana destined to U.S. illicit drug markets.[ii] Cannabis products have the largest consumer market in the world.[iii] The drugs' popularity with the general public and its potential for profit makes it an attractive market for organized crime (OC) involvement. In 2009, there were 343 Canadian OC groups known to be involved in the marihuana market, 102 of these groups are specifically involved in marihuana grow operations.[iv] (A)

A 2007 study in the Journal of Quantitative Criminology stated that the risk of detection in one year for indoor marihuana grow operations in the province of Quebec[3] was less than 10 percent, even for the largest grow operations.[v] Across Canada the risk of detection of MMAR grow operations that are committing criminal abuses is assumed to be significantly lower than the study found. Unlike illegitimate marihuana grow operations, police do not normally search for and pursue suspected MMAR violators due to the presence of a licence to produce and other law enforcement issues highlighted in this report. (A)

Many law enforcement agencies across the country have voiced similar concerns as those expressed by Cpl. Chris NEWEL of Clearwater RCMP Detachment "E" Division:

> *"The problem is we start an investigation only to find out somewhere along the line that there is a MMAR licence, at that point we basically stop the investigation. Although we "believe" the person is not abiding by the regulations (i.e. too many plants, trafficking, etc.), because we don't execute a warrant we never know for sure. The Crown (prosecutor) has basically told us not to go near a licensed grow." (A)*

The current MMAR and its application have exposed a new avenue for Canadian drug traffickers to produce and sell illicit marihuana with minimal interference from law enforcement agencies. Some police agencies and crown attorneys have shown a lack of appetite to pursue MMAR violators, as an individual's access to medical marihuana can be a sensitive issue. (A)

This assessment of 190 law enforcement cases involving the MMAR across Canada highlights the limitations of the current regulations and provides recommendations for improvements and enhanced controls. (A)

2 The 2010 NDIC National Drug Threat Assessment reported a decrease in the amount of marihuana seized along the U.S.-Canada border from 10,447 kilograms in 2005 to 3,423 kilograms in 2009.

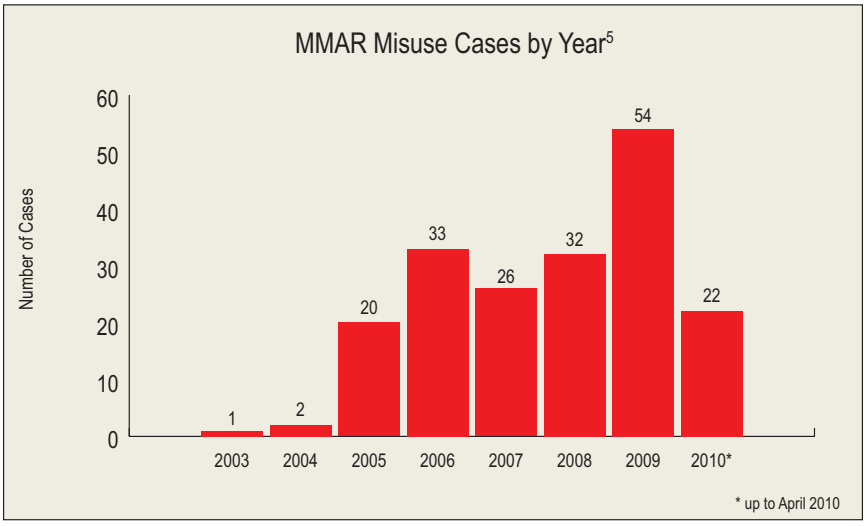
3 The study examined the province of Quebec only, detection rates in other provinces were not provided.

Methodology

In order to obtain a national perspective of MMAR licence misuse in Canada, the CACP requested Canadian law enforcement agencies to participate in an examination of investigational and/or intelligence files held by their agency regarding MMAR infractions. (U)

This report is the result of an analysis of information contained in files, from intelligence reports and other information sources from various law enforcement agencies including: RCMP; Abbotsford Police Department; Calgary Police Service; Edmonton Police Service; Guelph Police Service; Halifax Regional Police; Hamilton Police; Ontario Provincial Police; Ottawa Police Service; Peel Regional Police; Royal Newfoundland Constabulary; Service de police de la Ville de Montréal; Service de police de la Ville de Québec; Sûreté du Québec; Strathroy Caradoc Police Services; Taber Police Service; Toronto Police Service; Vancouver Police Department; Winnipeg Police Service; and, Windsor Police. (U)

A total of 190[4] files dated between August 2003 and April 2010 were reviewed; this included the 70 files previously collected for a RCMP Criminal Intelligence Brief produced in April 2009 on this subject.[vi] (A)



4 On May 27, 2010 a seizure occurred at a MMAR grow operation. The licensee had a licence to produce 75 plants and was found with 1,744 plants growing in the residence. This is the largest known plant seizure at a MMAR licensed grow operation. While this case fell outside the date parameters of data collection for this report, the authors chose to include this example due to the significance of the seizure, for the benefit of the readers.

5 This chart shows the breakdown of the 190 cases in this assessment by year of occurrence.

Background

On July 30, 2001 Health Canada (HC) implemented the MMAR. The objective was to provide Canadians suffering from critical and chronic illnesses (terminal illnesses or severe conditions) a means with which to access a lawful source of marihuana for medicinal purposes. It was created in response to a court decision that identified a need to offer access and a supply of marihuana to those suffering from these illnesses where conventional treatments were not appropriate or providing the necessary relief. (U)

Currently there are three types of authorizations under the MMAR:

- Authorization to Possess (ATP) — licence holder can possess dried marihuana for medical purposes;
- Personal-use Production Licence (PPL) — licence holder can produce marihuana plants for their own personal consumption for medical purposes;
- Designated Person Production Licence (DPPL) — licence holder can produce marihuana for medical purposes on behalf of a person with an ATP. (U)

Holders of an ATP can currently purchase dried marihuana from the Government of Canada supply. Holders of a production licence can purchase marihuana seeds from the Government as well.[6] (U)

Obtaining a Licence

In order to obtain a licence to possess or produce marihuana for medical purposes applicants must be a resident of Canada, complete a detailed written application, include two photos, fall into one of the two eligibility categories,[7] and have the support of a medical practitioner.[8] Licence holders are required to renew their authorization every year, and must include the signed declaration of their medical practitioner with each renewal. A criminal record check is completed on those applicants applying for DPPL and is redone every year upon renewal of the licence. At this time a criminal record check is not completed for those applying to produce or possess for personal use. Once approved, licence holders are issued an identification card that can be shown to law enforcement officials as evidence that they are authorized to possess or produce marihuana for medical purposes. (U)

Based on the type of licence obtained and an applicant's medical needs, there are specific terms and conditions assigned with regards to the amount of marihuana the licence holder can possess for a 30-day treatment supply, or the amount of marihuana plants that can be grown. Growers are told that they need to take the necessary measures in order to protect plants as well as dried marihuana from any potential loss or theft. (U)

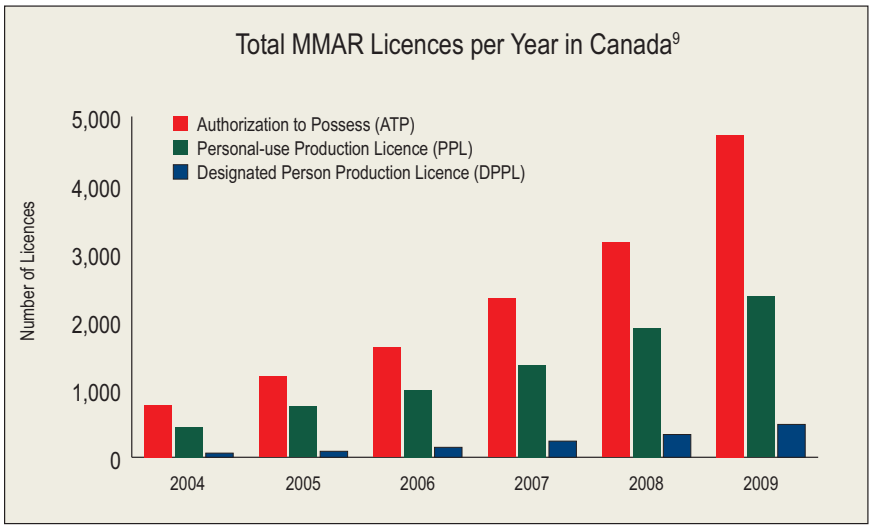
6 Health Canada has a contract with Prairie Plant Systems Incorporated which extends through Fall 2011.

7 Category 1 is compassionate end-of-life care, and Category 2 is symptoms of a serious condition not listed in Category 1. In the case of Category 2, the applicant needs to demonstrate that they have consulted with a Specialist.

8 As of June 2009, 1,977 physicians had referred two patients or more under the MMAR.

Current Status

As of November, 2009 4,728 Canadians were issued authorizations to possess (ATP) dried marihuana. There have been 3,430 production licenses granted, this includes both PPL and DPPL. The program has grown in size since its inception and it is believed that it will continue to increase in number. (U)



9 These are Health Canada statistics for total ATP as of November, 2009, and for PPL, and DPPL as of June 2009.

Criminal Abuses of MMAR Licences

Production and Trafficking of Marihuana for Personal Gain

Many (67) of the cases reviewed for this assessment involved production and/or trafficking violations as outlined under the Controlled Drug and Substances Act (CDSA).[vii] Licence holders, both Personal and Designated Producers, appear to be capitalizing on the excess medical marihuana they produce and are selling it illegally for profit. (A)

On March 2, 2007, police executed a search warrant at a residence in the city of Ottawa, Ontario. Information was received regarding an individual who possessed a licence and was believed to be selling marihuana and hash oil. Two suspects were arrested and charged with numerous offences. Police found 20 marihuana plants, only the one plant over the exemption was seized. Police also seized 271.5 grams of hashish, four vials of hash oil, and a loaded shotgun. The licence holder was convicted of possession for the purpose of trafficking contrary to Section 5(2) CDSA and Unauthorized Possession of a Firearm. (Ottawa Police Service 2007-56620) (A)

In 2008, officers were involved in an undercover operation where they purchased Oxycontin® and marihuana from a male and female residing in Wasaga Beach, Ontario. The undercover officer was shown the suspect's indoor marihuana grow operation where he bragged that he had a licence to grow 25 plants. Police subsequently executed a search warrant at the suspect's residence. The licence stated that he could grow 25 plants, and he was found to be growing approximately 40. (Ontario Provincial Police (OPP) RM08086145) (A)

Police received intelligence that a subject in Saskatchewan had a MMAR grow operation and was selling marihuana to numerous persons. Investigations revealed that the suspect did have a MMAR licence to grow 25 marihuana plants, store 1,126 grams of dried marihuana, and possess 150 grams. In November 2009, two undercover police officers each purchased approximately eight grams of marihuana from the licence holder. (Saskatchewan RCMP 2008-734171) (A)

Producing Over the Legal Limit

In 57 of the 190 files reviewed for this assessment, licensees were found to be cultivating well over their specified legal limit of marihuana plants. In some cases, the excess produced was found to be used in trafficking activities, generating personal profit for the licence holder. This creates a situation where marihuana produced under the cover of a legal licence is diverted to the illicit drug market. In most cases, where the licence holder is producing over their legal limit, law enforcement officials are directed to take the excess plants, leaving the licensee with their legal allowable amount. (A)

In January 2007, police investigated a residential building suspected of having an illegal marihuana grow operation. Upon executing the search warrant, police were confronted by a woman with a knife who was subsequently subdued. The woman believed thieves were trying to steal the marihuana from the grow operation. The male MMAR licence holder responsible for the grow operation was allowed to produce 75 marihuana plants and store 3,375 grams of dried marihuana. Police located a total of 464 marihuana plants. (Service de Police de la ville de Montréal (SPVM) 23-070124-007) (A)

On December 19, 2007, police arrested a MMAR license holder following a search warrant executed at his residence. The MMAR license holder was allowed to grow 14 marihuana plants and possess 5.2 kilograms of dried marihuana. Police found 50 kilograms of dried marihuana, seven marihuana plants, and 195 grams of hashish. Police found evidence of production of hashish, documentation detailing the suspect's illegal trafficking activities and proceeds obtained to finance the purchase of his residence. (Sûreté du Québec 163-071008-009) (A)

On September 10, 2008, the OPP were conducting a marihuana eradication operation and located a marihuana grow operation on a property in Norfolk County, Ontario. The subject had a MMAR licence to produce 38 plants, however, was producing 311 marihuana plants. The Children's Aid Society was involved as children were present on the property being investigated. (OPP RM08110644) (A)

On April 29, 2009, police executed two search warrants at a MMAR licence holder's residence and her separate production site. The licence holder was authorized to produce 39 marihuana plants and allowed to store 1,755 grams (3.9 lbs) of dried product at her residence. The licence holder and her spouse were suspected of producing over 39 plants and trafficking the excess marihuana. At the licence holder's residence, police located 348 marihuana plants and two unsecured firearms; at the production site, police located 26 marihuana plants. On October 19, 2009, police continued their investigation on the same noted couple and executed two additional search warrants. Police seized approximately 48 pounds of marihuana at the licence holder's production site. (Nova Scotia RCMP Coordinated Marihuana Enforcement Team (CMET) 2009-443799 & 2009-1240673) (A)

On June 9, 2009, at the end of a two month investigation, police executed two search warrants at two properties owned by one family. This family had a MMAR license to produce 36 marihuana plants. During searches at the two properties, police found a total of 1,483 marihuana plants, $30,000.00 of growing equipment, $42,400.00 of stolen property, and five firearms with ammunition. (Hamilton Police Service 09-216527) (A)

On October 28, 2009, the Green Team North executed a search warrant at a MMAR grow operation suspected of overproduction. The location had two MMAR licences permitted to grow a total of 50 marihuana plants. Police seized a total of 262 marihuana plants. (Edmonton Police Service 2009-1279457) (A)

In November 2009, the Cowichan RCMP Green Team investigated a report of a suspected marihuana grow operation at a residence. The investigation determined that the suspected grow operation was in fact a MMAR grow operation, whose owner was licensed to grow a maximum of 50 plants. Police found the electrical consumption at the location to be unusually high and suspected overproduction. The licence holder responsible for the MMAR grow operation admitted to overproduction and police seized a total of 866 marihuana plants. (Cowichan RCMP 2009-15782) (A)

On March 10, 2010, the City of Vancouver district electrical inspectors investigated a complaint of faulty wiring at a commercial premise selling marihuana for medical purposes to the general public. Health Canada did not recognize the business in question, but advised that there were two MMAR licences at the premises to produce a total of 58 marihuana plants. The business was found to be producing in excess of their allowed amount. The Vancouver Police Department (VPD) seized 604 excess marihuana plants. While on site, VPD observed at least 10 subjects coming to the business to attempt to purchase medical marihuana. (VPD GO 2010-42983) (A)

Factors Contributing to Criminal Abuses of the MMAR

Several factors likely contribute to this criminal misuse of the MMAR, including: the reasonably low risk of being apprehended within the existing system; the large production and possession amounts being granted to licence holders; the issuance of multiple licences; the excess marihuana being produced per plant; having no controlled manner in place to destroy any excess; the potential for profit gained by trafficking marihuana; and, the lack of both monitoring and penalties that exist under the current MMAR. (A)

Low Risk of Apprehension

Within the current MMAR system there is a relatively low risk that a licence holder will be apprehended when exploiting the terms of their licence. This is partly due to a lack of HC resources to monitor licence holders and a lack of authority in both HC inspectors and law enforcement to enforce licence compliance or revoke licence privileges. In the event a licensee is apprehended, prosecution is unlikely. Public Prosecution Service of Canada (PPSC) often will not entertain a prosecution due to a lack of resources as well as a difficulty in attaining a conviction. (Staff Inspector Mario DI TOMASSO, Drug Squad, Toronto Police Service) (*Please see Lack of Monitoring, page 17*). (A)

Large Licence Amounts

The number of plants and amount of dried marihuana HC authorizes for a MMAR licence holder is based on a specified formula that incorporates a physician's recommended daily amount and the estimated plant yield. For example, the amount allowed for a production licence is calculated by taking the daily amount of dried marihuana needed (as recommended by the physician), while also taking into account the growth cycle of the plants and the estimated yields. The formula is altered based on whether the licence holder will be producing indoors or outdoors, as this affects yield amounts. (See Appendix A) (U)

> *"The marihuana dosage recommended by a physician has many unknowns and is often based on the patient's recommendation of his or her tolerance to marihuana usage. This method for recommending medicinal marihuana by physicians can lead to the issuance of large permits which, in turn, leads to abuses of the MMAR by criminals. These large permits create an environment of legalized commercial production of marihuana where the excess product can be easily diverted to support illicit and lucrative drug trafficking activities with minimal or no intervention by police". (S/Sgt. Darren DERKO, EDGE Unit, Edmonton Police Service) (See Appendix D) (A)*

The daily amount being recommended to medicinal marihuana users does not take into consideration the tetrahydrocannabinol (THC)[10] levels and its subsequent effect on the potency of the marihuana. The average THC content has increased over time — in the 1960s it was three percent whereas today the average is between 12 and 15 percent.[viii] THC levels in marihuana should likely be considered when making licence amount recommendations as potency will impact the effectiveness of the marihuana in alleviating symptoms associated with medical conditions. (A)

Health Canada has reported that an increasing number of MMAR program participants are being authorized to possess higher daily amounts of marihuana.[ix] These higher daily amounts translate into permission to produce larger crops for those who hold PPLs and DPPLs. The files reviewed in this assessment found HC to be granting authorization for large numbers of marihuana plants, as well as high quantities of dried marihuana permitted to be stored. Several of the files in the review (31) found both PPLs and DPPLs to have licences for considerably large amounts of marihuana. Specifically, in the 31 files, the minimum amount permitted for plant production was 44 plants (most being for a larger number), and for authorizations to possess dried marihuana the minimum noted was 1,755 grams to be stored at one time. (A)

For example, one licensee was granted a PPL to produce 273 plants and store 12,285 grams of dried marihuana. This is a large amount for one person to produce for their own personal medical marihuana needs; a producer of medical marihuana only needs nine plants to bud every five months in order to have an adequate supply for one heavy medicinal user.[x] It should be noted that licence holders may need to produce larger amounts of marihuana plants if they will be using the marihuana in baked goods, as this is one available method of consumption, based on the user's preference. However, eating marihuana bud is a less typical and desirable method to consume marihuana as a result of the lessened 'high' experienced due to digestion. The typical amount of marihuana bud consumed at one time by oral ingestion is one gram; the effects last up to four hours.[xi] (A)

10 THC is the psychoactive substance in the cannabis plant. THC levels determine the potency, the higher the level the more potent the marihuana.

On February 25, 2009, police investigated an individual suspected of having two marihuana grow operations at his two residences in the Toronto area. Upon executing search warrants at both locations, police discovered that the main suspect had a MMAR license to produce in one residence and his associate had a MMAR license to produce in the other residence. Both subjects were allowed to produce a total of 138 marihuana plants. Police located a total of 367 marihuana plants. (Toronto Police Service File no. unavailable) (A)

During a court hearing in Quebec for a MMAR licensee charged with trafficking related offences, an anaesthetist testified on her knowledge and experience to treat the chronic pains of the Accused. In her testimony, the physician stated that it was the Accused who had determined his dosage to fight his pain. As a medical specialist, the physician also stated that cannabis resin and cannabis itself were the same substance, which is not exactly the case. In light of the physician's evidence, the judge had to remind the anaesthetist that cannabis resin was not legally admissible under the MMAR. In this case, there was an incomprehension or lack of knowledge in the application of the MMAR. The Accused in this case was found with 50 kilograms of dried marihuana. (*Sgt. Suzanne DE LAROCHELLIÈRE, Drug Specialist, Sûreté du Québec*) (A)

Multiple Licences

Another issue of concern is the recent development of multiple licences. Multiple licences are now being granted to several people who reside at the same location. The licensing developments are a contributing factor to the increased amounts of marihuana being legally grown. The court decision of SFETKOPOULOS v. Canada, 2008, has allowed for a single designated producer of medical marihuana to produce for more than one medical marihuana user, currently set at no more than two; this was previously not authorized under the regulations. The court decision of R. v. BEREN and SWALLOW, 2009, ruled that the restricting of production sites placed undue limits on access to medical marihuana. As a result, HC amended the regulations so that now no more than four production licences are permitted per site. These decisions have created the possibility of individuals running 'legal' large scale marihuana grow operations. (A)

Excess Marihuana Per Plant

As per Section 30 of the MMAR, HC estimates that one indoor marihuana plant will produce approximately 30 grams of dried marihuana.[xii] Although it is difficult to determine the exact amount yielded per plant, various law enforcement expert findings indicate the numbers are a considerably low estimate of what a marihuana plant can actually produce. It appears as though many licence holders are aware of this fact and are using it for their personal gain, as demonstrated by the number of misuses noted in this review of cases. (A)

The yield measurements of dried marihuana per plant as observed by law enforcement agencies in Canada often surpass the 30 gram estimates. (Appendix C shows the type of yield amounts that some law enforcement agencies are finding at illegitimate marihuana grow operations.) It is believed that the 30

gram measurement was established early in the creation of the MMAR and that its conservative amount is a reflection of marihuana plants grown naturally without any specialty growing supplies or techniques. There is a significant risk when the potential yield per plant is estimated without considering the yields that can occur from a three stage grow operation.[xiii] (A)

Sgt. Vincent ARSENAULT of the Surrey RCMP Green Team is a court recognized expert in marihuana production and trafficking. (See Appendix D) He stated the following:

> *"Indoor grown marihuana plants (Indica variety) can yield in excess of two pounds (over 900 grams) of dry bud, depending on the type of operation (i.e. two stage (60 day) 'sea of green' versus the three stage (90 day) operation or the three stage 'monster' plant operations (120 days))" (A)*
>
> *"Two Stage" marihuana plants will max out at approximately 1 ½ feet in height and yield 1-2 ounces of drug bud per plant, however they mature much sooner (60 days). These plants by-pass the vegetative stage of plant growth. (A)*
>
> *"Three stage" marihuana plants take longer to mature (90 days), however they grow much larger (3-5 feet high) and consequently yield considerably more dry bud per plant (3-6 ounces). (A)*
>
> *"Three stage - Monster Grow" operations take even longer for the marihuana plants to mature (120+ days), however the plants yield far more dry bud than other types of operations (between one (1) and two (2) pounds of dry bud per plant). (A)*

There are several factors that will influence how much dried marihuana can be yielded per plant: whether the plants are grown indoor or outdoor; the genetics of the marihuana plants used; growing techniques such as soil-based growing or hydroponics;[11] [xiv] and, the lighting being used. Several cases in this review involved indoor grow operations using varying amounts and types of lights. (A)

These lighting techniques allowed for growth of super-sized marihuana plants — some plants were seven feet tall. These large plants would deliver a high yield of dried marihuana and would allow the licence holder to remain within their legal limit of plants, by number only. (A)

"Growers are not limited to the size or type of plant, only a total number, there is also no limit to the amount of lights they can use. Growers are able to grow large plants (the size of Christmas trees) and produce 1 to 1 ½ pounds per plant". (Cpl Shawna BAHER, Green Team, RCMP "E" Division) (See Appendix D) (A)

11 The term hydroponics refers to an extremely fast and efficient growing method that produces higher yields per plant.

This picture depicts two marihuana plants being grown indoors at a MMAR grow operation in Manville, Alberta. The Edmonton Green Team police officer in the picture measures 6'1" in height. The MMAR licence holder in this case was allowed to grow 73 plants; police located 93 plants in total. The excess 20 plants were between four and six feet in height and growing in a concealed room only accessible through a trap door. (Vermillion RCMP 2006-309269) (A)

The following pictures depict a marihuana grow operation with expired MMAR licences. One of the suspects was in the process of applying for a MMAR licence. The indoor plants in this instance were averaging 7' in height. (Nanaimo RCMP 2009-30970) (A)

In January 2010, Langley RCMP investigated numerous complaints about a strong smell of marihuana in a residential area. The property in question belonged to a MMAR licence holder with two production licences, both for 49 plants. However, there were 28 high intensity lights so the plants were about 7' tall, easily providing a yield of over one pound per plant. This grow operation could yield approximately 100 pounds per crop. The maximum amount of dried product allowed for both parties is 2,205 grams each (or about five pounds). The grow operation was located directly across from a daycare and an elementary school. (Langley RCMP 2010-2735) (A)

No Controlled Manner to Destroy the Excess

The expectation by HC is that licence holders will destroy excess amounts of marihuana they produce. However, there is no policy in place to guide the safe removal and destruction of this excess. Depending on the disposal method chosen by the licensee (e.g. burn the excess or dispose of in the garbage), there is an increased risk that the drugs may find their way into the wrong hands. (A)

"The regulations do not clearly define the manner of destruction of excess marihuana and the security measures that have to be taken, whereas police destruction procedures are clearly defined to ensure safety and to respect the CDSA". (Sgt. Suzanne DE LAROCHELLIÈRE, Drug Specialist, Sûreté du Québec) (See Appendix D) (A)

Potential for Profit

Trafficking the excess marihuana could potentially bring a licence holder a high amount of profit. Even when using the conservative estimates of yield amounts HC utilizes in the MMAR, a licensed grower could sell the excess marihuana they produce and make a substantial personal profit. (A)

The current MMAR does not state any specified terms for a designated producer with regards to the amount of money they are permitted to charge a medical user for the product they sell. This can be seen as a potential opportunity for current and future designated producers to make a personal profit through an untaxed means of income. (A)

"In understanding the issue respecting "amounts or weights" of marihuana, it is important to conceptualize what these amounts signify. One ounce of marihuana equals 28.4 grams, for simplicity 28 grams will be utilized to represent one ounce. The standard street level packaging for marihuana sold at the ounce level is a plastic sandwich bag filled with marihuana. This is still an abstract amount for many individuals to comprehend. To truly understand what this amount represents, in the form that this product is commonly consumed, we need to understand how many marihuana cigarettes or "joints" this represents. On average 1 gram of marihuana produces 3 to 5 marihuana "joints". Therefore 1 ounce or 28 grams would equate to 84 to 140 joints (3 joints /gram x 28 grams = 84 joints or 5 joints / gram x 28 grams = 140 joints). When one is to consider what a MMAR licence holder is permitted to possess at any given time the allocated amount should be considered in terms of what that amount truly represents, and in a term that can be conceptualized". (Sgt. Lorne ADAMITZ, Drugs and Organized Crime Awareness Services, RCMP "K" Division) (See Appendix D) (A)

When you consider the expert yield amounts based on a two stage grow method there is a high potential for the grower to profit. Taking the lowest yield estimate of 28 grams and applying it to a marihuana grow operation where the licensee is growing an excess of 50 plants, this would mean a production of 1,400 grams. If the grower produces four crops in a year and sells their excess product for $2,800, the average market price for a pound,[xv] the annual tax-free profit potential for the marihuana grower would be $33,600.00. (See Appendix B) (A)

On May 6, 2009, police executed a search warrant at the residence of a MMAR licence holder suspected of overproduction. The licence holder was permitted to produce 49 marihuana plants and store up to 2,205 grams of marihuana. At the residence, police located the licence holder, his wife and child. Police seized: 136 marihuana plants; 6,274 grams of dried marihuana; a business plan showing the cost of setting up a grow to produce 200 plants and the estimated profits that could be made; ammunition; unsafely stored shotgun and rifle; brass knuckles; trafficking paraphernalia; and, cannabis oil. The licence holder had high end televisions, an ATV, a ride-on lawnmower, a boat, fly rods, high end appliances, and stereo equipment. (Kamloops RCMP 2008-31825) (A)

On March 18, 2010, Provincial and Municipal inspectors as well as law enforcement conducted an inspection of a building to be used for a MMAR grow operation. The property was in close proximity to the United States border and could accommodate a helicopter landing site. The licence holder was permitted to grow 199 plants and store up to 19 pounds of dried marihuana. The building and electrical set up could accommodate a commercial marihuana grow operation able to produce over 5,000 marihuana plants. The building was approximately 120 feet in length by 50 feet in width. The son-in-law of the licence holder is a helicopter pilot with a known association to the Hells Angels. (Chilliwack RCMP 2010-7736) (A)

There were nine air conditioning units outside (four visible in this picture).

There were four grow rooms each 30 feet by 40 feet. There were ten electrical sockets on the ceiling in each grow room that had three electrical twist plugs.

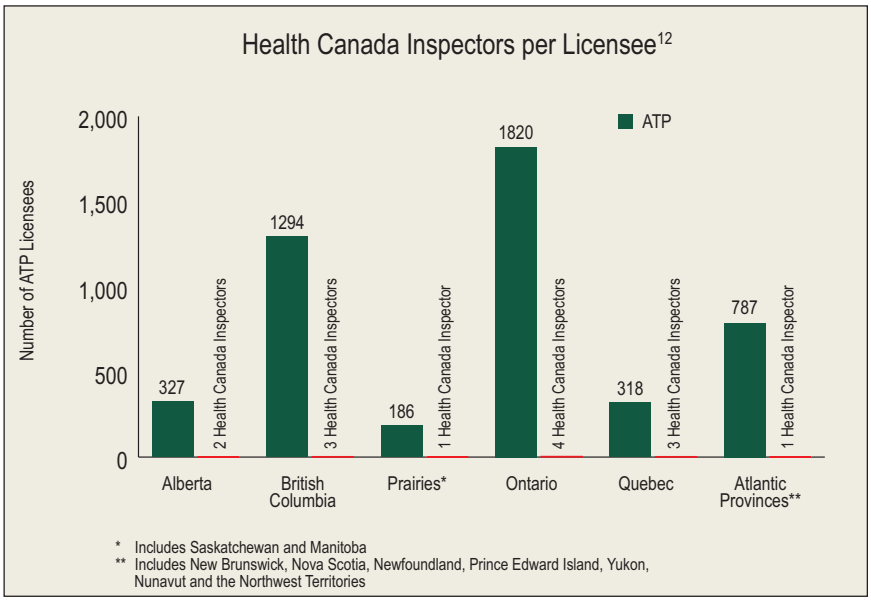
Two 600 amp service panels.

The electrical inspector stated that it would have been easy to install a bypass in this type of set up.

Lack of Monitoring

Depending on the type of licence, a MMAR licence holder is permitted to grow a certain number of plants and possess and store a specific amount of dried marihuana for their daily use. Any excess is expected to be destroyed by the licence holder, as per the MMAR. Adhering to these set legal limits operates mainly on the principle of an "honour" system. The responsibility of staying within the legally permitted amount of marihuana is entrusted to the licence holders. It would appear that this arrangement is flawed. There were several files, 57 of the 190 reviewed, where individuals were found to be producing well over their legally permitted marihuana amounts. (A)

There are insufficient HC inspectors (14 Canada wide) to monitor MMAR licence holders to ensure conformity. They also are responsible for all CDSA inspections. Ontario has the highest number of ATP licences (1,820), and only four HC inspectors to monitor all MMAR licences in that province. These numbers indicate insufficient resources to consistently and effectively inspect and monitor licence holders across the country. The number of licence holders is expected to increase as the program continues to grow. HC estimates that the number of ATP licences will grow to at least 6,000 by 2011 from the 4,728 who are currently licensed.[xvi] (A)



Section 57 of the MMAR outlines the guidelines concerning HC's inspection of medical marihuana grow operations. It states 'an inspection may occur at any reasonable time'.[xvii] However, the guidelines do not state a specified schedule of required inspections (i.e. monthly, quarterly, yearly, etc.). It is possible that an individual authorized to grow medical marihuana may never undergo an inspection of their grow operation. (A)

12 These are the Health Canada statistics for ATP as of November, 2009.

In addition to a lack of resources, inspectors also have a limited authority. A HC inspector can inspect the building specified by the licence holder as the growing site, but they may not inspect dwelling houses.[xviii] Inspectors must have the consent of the occupant prior to entering any residence or dwelling. Police officers do not have the authority to inspect licence holders unless there are sufficient grounds of criminal activity and a search warrant can be obtained. (A)

"There appears to be no person or organization that inspects these licensed grows except for the police when they inadvertently receive information regarding the marihuana grow operation. It appears that once the police receive information from Health Canada that the grow is licensed then it increases the difficulty to obtain a warrant as there must now be evidence to indicate that the amount of marihuana is in excess of the licensed amount". (Sgt. Neil MUNRO, Vancouver Police Department) (A)

"Carrying out such investigations is difficult as the presence of 'normal' signs of an indoor marihuana grow operation are negated by the Health Canada permit. Investigators must therefore resort to other methods of investigation in order to acquire sufficient grounds to support an application for a CDSA search warrant, which is time and resources consuming. In some instances, smaller investigative units often must ignore these investigations as a result of limited resources". (Sgt. Simon ROY, Coordinated Marihuana Enforcement Team, RCMP "J" Division) (A)

Public Safety Issues

The presence of a marihuana grow operation within a community, whether legally permitted by HC or otherwise, is a public safety concern. There are several dangers to public health and safety associated with grow operations: fire, health, electrocution, poisonous gas and chemicals, violence, booby traps and, children being put at risk.[xix] This assessment revealed a number of public health and, safety issues. The health and safety issues seen at illegal marihuana grow operations are also seen at legal grow operations. (A)

Medical marihuana grow operations can affect the safety of a community and its members. Crime tips are often received by concerned neighbours or members of the community who suspect the presence of an illegal marihuana grow operation, and are concerned with the potential for illegal activities and illicit drug trafficking. In several cases police have begun investigations only later to discover it is a licensed MMAR grow operation. In order for police to more effectively monitor and safeguard for safety risks and concerns, they should be made aware of the presence of a legal grow operation. As first responders, the police services or fire departments would benefit from being informed about the presence of medical marihuana grow operations. Having this information before entering a residence could reduce health and safety risks by allowing responders to be appropriately prepared. (A)

Child Endangerment

The MMAR states that medical marihuana being grown outdoors cannot be adjacent to any public property that is mainly frequented by persons 18 years of age or younger, such as a school or public playground.[xx] This rule only pertains to outdoor growing, as an indoor grow operation does not have the same restrictions; children can reside in a dwelling that has been granted a licence to grow medical marihuana. Children who live with a marihuana grower or user have increased access to the drug, exposure to potential illegal activities, as well as all the potential health and safety issues associated with that environment. (A)

Marihuana grow operations require considerable amounts of water, resulting in high levels of humidity within the residence. The presence of continued humidity without proper ventilation can cause a build-up of mould. HC completed two reviews of scientific literature on the effects of indoor moulds and they found that exposure to indoor mould is associated with an increased prevalence of asthma-related symptoms such as chronic wheezing, irritation symptoms, and non-specific symptoms.[xxi] Exposure to emissions from chemicals used at indoor grow operations can also be the cause of respiratory health problems, particularly with regards to children.[xxii] (U)

> *"The immediate risk for children living in a grow operation is the elevated risk of fire, electrocution, inadvertent exposure to harmful chemicals, higher risk of respiratory problems or fungal infections from exposure to mould and carbon monoxide". (S/Sgt. Ian SANDERSON, Drugs and Organized Crime Awareness Service, RCMP "K" Division) (See Appendix D) (A)*

Not only is health an area of concern for children but the presence of a marihuana grow operation increases their risk of exposure to a lifestyle that involves criminal activity or violence, such as grow-rips[13] and home invasions, as well as other serious safety issues such as fires and electrocution. Children present at grow operations are exposed to situations and factors that place them at a higher risk of injury and/or illness.[xxiii] This review found children were present in 15 of the cases examined. A few of the cases also referred to marihuana grow operations discovered in very close proximity to a school or a daycare. While they were not technically contravening the MMAR — as the property would have to be directly adjacent — the proximity could expose children to the health and safety risks referenced in this report. (A)

On September 29, 2006, the Ontario Provincial Police communication centre received a 911 call reporting that a male had been shot at a residence. It was determined that the homeowner resides at the location with her ten year old daughter, twelve year old son, as well as her common-law partner. The homeowner held a Designated Producer licence from Health Canada and was permitted to grow 37 marihuana plants indoors during winter months and 10 plants outdoors during summer months. The license further allowed her to possess 3,750 grams (8.5 lbs) of dried marihuana on behalf of another individual. The homeowner and her family were the victims of a home invasion. Her common-law spouse confronted the two suspects who subsequently shot him in the leg and fled. During the course of the investigation, police located 510 marihuana plants, 14.24 pounds of dried marihuana, digital scales, and $350.00 cash. (OPP RM07016758) (A)

On March 17, 2009, police executed a search warrant at a residence in Prince George, British Columbia. A MMAR grow operation consisting of 21 plants was located in a room adjacent to a child's bedroom. The electrical wiring and connections that powered the grow operation were deemed to be of substandard quality and a fire hazard. The ventilation was poor, likely exposing the kid(s) to chemical fertilizers and mould spores. (Prince George RCMP 2009-6097) (A)

On July 24, 2009, police attended a residence in Windsor, Ontario on an unrelated incident. When police arrived they were approached by an employee of the neighbouring daycare who complained about marihuana plants being grown next door. Police investigated the matter and found marihuana plants growing in the backyard neighbouring the daycare's play yard. The owner of the marihuana plants had a MMAR license to produce 25 indoor plants and was not allowed to grow marihuana plants outdoors. (Windsor Police Service 2009-44525) (A)

13 The term grow-rip refers to a marihuana grow operation which is targeted by criminals who commit a home invasion in order to steal or destroy the crop.

In August, 2009, Kelowna RCMP received a complaint from a neighbourhood appointed spokesperson of the suspicion of a marihuana grow operation in their area. The community was concerned for the potential criminal activity and safety risks associated with the grow operation. Police investigated and found the person living at the location had a MMAR licensed grow operation in the back shed/garage that was accessible to her children. The license holder was allowed to grow 273 marihuana plants and store over 12 kg of dried marihuana for two medical users. Her children were known to brag to local kids at school about their marihuana grow operation. (Kelowna RCMP 2009-4052) (A)

Violence

The MMAR stipulates that it is the responsibility of the licence holder to safeguard the marihuana supply from potential loss or theft in a satisfactory manner. The applicant must provide a description of the security measures that will be implemented at the potential production site as well as the proposed site for the dried marihuana to be stored. This is to ensure that a marihuana supply does not somehow find its way to individuals intending to use it for profit and also to protect the licensee and his/her family from violence. The regulations can work only if the MMAR grower respects the regulations; however, in many reported cases, MMAR licence holders are themselves illegally trafficking the excess marihuana, failing to make any attempts to conceal its presence (i.e. the smell), or growing it openly which may attract violence. (A)

The drug trade is often found to be surrounded by violence or the threat of violence. Weapons such as firearms and knives are known to be used by drug traffickers to protect their drug operations and/or steal someone else's supply. This was reflected in this review as there were cases involving the presence of weapons (16) or that included attacks and home invasion (16). The review also found a few (2) cases where individuals were shot during a home invasion. (A)

These home invasions or "grow-rips" often lead to the violent victimization of the medical grower, or in some cases, the violent victimization of unrelated bystanders. Neighbours who reside close to a grow operation are at an elevated risk of a home invasion, possibly due to a mistaken address. As a result of these violent home invasions there is the potential for legally grown marihuana ending up in the illicit drug market. The difference for a licensed medical marihuana grower is that they are able to contact law enforcement for protection and support in the event of a home invasion. (A)

In 2006, police investigating a residence in Vancouver were confronted by a man with a machete who thought that his legal grow was being "ripped". Police determined that the individual with the machete had a legal grow operation. The MMAR grow operation was located near an elementary school, and was within the limit for the number of plants but failed the electrical inspection. (VPD GO 2006-148108) (A)

In 2009, two individuals living at a residence in Dartmouth, Nova Scotia, were being investigated by the Integrated Drugs Unit (IDU) due to information received that one of them had a grow and was trafficking. The investigation revealed that the individual in question held a valid personal licence to grow 25 plants, store 1,025 grams, and hold 150 grams on his person. The two subjects were victims of a home invasion where the license holder was shot. Police executed a search warrant at this location. Police located approximately 49 plants with dried marihuana and limited evidence of trafficking (scales and score sheet). (Halifax Regional Police 09-139935) (A)

On May 26, 2009, Surrey RCMP received a call from a subject reporting that he had been attacked by masked intruders at his residence. The complainant was walking towards his truck behind his home when he was confronted by three masked men. One of them claimed to be police and was holding a piece of nylon rope. The other two men came around him and the complainant fled. The complainant's girlfriend observed the events unfold from inside the house and reported that one of the masked men was holding a black handgun. The three suspects fled on foot. Police followed the tracks and recovered a backpack filled with break and enter tools, and a pack of three foot zap straps. Police did not locate the suspects. The complainant was uncooperative other then mentioning he had a MMAR license to grow marihuana which was located in his rear outbuilding, the same direction as where the suspects had been. The complainant did not want police near his residence or the outbuilding. (Surrey RCMP 2009-61224) (A)

On March 15, 2010, Chilliwack RCMP responded to a report of a home invasion at a residence. The homeowner was a MMAR licence holder with a marihuana grow operation of approximately 50 plants. Two unknown males entered the licence holder's residence stating they were the RCMP and threatened to shoot the victim who fled to the neighbour's. The suspects fled in a vehicle driven by a third male. (Chilliwack RCMP 2010-7517) (A)

On April 2, 2010, Langley RCMP responded to a home invasion involving five suspects wearing black clothing, balaclavas, and gloves. The male victim awoke to his house alarm and when he went to investigate he found five males in his home. The victim was ordered to kneel on the floor and a gun was put to his head. The individual's wife and seven year old daughter were located by the suspects and ordered to sit by the victim. The suspects then went searching through the residence. Several males remained in the residence and several more tried to gain entry into a shed located at the rear of the residence. This shed contained three medicinal grows each licensed for 50 plants. Attempts to force entry into the shed failed and the alarm to the shed went off, the suspects then fled. The victims had just moved into the residence and had no ties to the shed containing the grow. (Langley RCMP 2010-9910) (A)

See Appendix E for a summary of an incident that occurred in Seattle, Washington.

Health Concerns

The health issues and concerns reviewed with regards to child endangerment are fairly consistent with the risks to the general population, law enforcement, and first responders exposed to marihuana grow operations. Canadian law enforcement agencies have strict policies and procedures in place in order to protect the health and safety of police officers who investigate and dismantle marihuana grow operations. These policies are specifically concerned with protecting officers and emergency workers from the inherent health hazards encountered at marihuana grow sites. (See Appendix F) (A)

The main health hazard encountered in a grow operation is the exposure to mould and chemical contamination including pesticides and fertilizers. Improper ventilation is often an issue at marihuana grow sites as it leads to elevated levels of humidity. The high levels of moisture as a result of the humidity within grow operations expose individuals within the site to mould.[xxiv] (U)

In December, 2009, a public safety team conducted an inspection of a MMAR grow operation. The licensee was wheelchair bound and could not access two of the three grow rooms, indicating other persons were involved in tending to the operation. The public safety team determined the residence was full of mould and presented significant safety hazards. The occupancy permit for the residence was revoked. The residence was owned in part by a member of the Hells Angels who resided next door. (Coquitlam RCMP 2009-39103) (A)

Fire/Electrocution

There is an increased risk of fire associated to marihuana grow operations due to the modifications to the electrical systems that are often made by unqualified individuals. The large amounts of electricity and the illegal tampering with electrical systems can increase the risk of fire or electrocution. The hazard is not only to the dwelling containing the marihuana grow operation but also to the neighbouring buildings. In June, 2009, the Ontario Fire Marshal's office and the OPP reported that over a period of six months they had been called to a fire involving either a marihuana grow operation or illegal drug lab approximately every 15 days.[xxv] It is these types of fires that pose a serious risk to the health and safety of first responders as well as the overall community. (U)

Marihuana grow operations are being set up with lighting and hydroponic growing equipment, and are being unsafely installed without the proper permits or inspections, most often in a residential setting. These operations are being set up by unqualified licence holders, which increases the risk of fires and electrocutions to the entire neighbourhood.[xxvi] An inspection of a MMAR grow operation is not required prior to the issuance of a licence in order to ensure provincial safety codes such as fire, building, or electrical will be met. Some research estimates that marihuana grow operations are at a 24 times greater risk of residential fire than a regular home.[xxvii] The possibility of electrocution when entering a marihuana grow operation, whether it is legally permitted or otherwise, is always a concern and a risk for law enforcement. (U)

In this assessment there were 23 files that specifically mentioned electrical hazards due to unsafe electrical work completed within the residence; there were two cases where an actual fire occurred. Several cases had electrical/fire inspections at the time the search warrant was executed and power was subsequently shut off to the residence due to building code safety violations and potential hazards. (A)

Police were required to respond to three separate complaints (September 2008, October 2009, and March 2010), at an apartment which contained a MMAR grow operation. In September, 2008, authorities had to shut the electricity to the apartment as the altered electrical wiring of the grow operation presented a fire hazard. In March, 2010, police found that the grow operation was unsafe and posed a safety risk to neighbouring apartments. The licensee was charged under the fire code. (Toronto Police file no. unavailable) (A)

On November 20, 2009, Maple Ridge Fire Department responded to a report of smoke emitting from a warehouse complex. Upon arrival, the Fire Department determined the fire came from a marihuana grow operation located in the upper floor of the warehouse complex. It appeared faulty electrical wiring used in the grow site was the cause of the fire. Police determined the two individuals responsible for the grow operation had recently expired MMAR licences allowing a total of 15 plants and 735 grams of dried marihuana. Police found 185 marihuana plants growing in three rooms. The entire unit where the grow operation was located was transformed to accommodate a marihuana grow operation and measured 100' by 60'. The investigator stated the following: "...their intentions were to grow marihuana for illegal purposes. The warehouse they had leased was suitable for an operation far exceeding their allotted limits and had a monthly rental fee of $3,000 dollars a month." (Ridge Meadow RCMP 2009-26815) (A)

Challenges to Law Enforcement

The Privacy Act

The *Privacy Act* presents significant obstacles for law enforcement in dealing with the MMAR. The *Privacy Act* does not permit HC officials to proactively provide law enforcement with a list of those licensed to grow or possess marihuana for medical purposes within the communities that they serve. However, HC can and does provide law enforcement, upon request, with the licence details for specific cases. (A)

Lack of Inspection Capabilities by Law Enforcement

Under the current MMAR system, law enforcement agencies have no authority to conduct an inspection to ensure licence compliance. Police can only inspect a licence holder residing within their jurisdiction if they have reasonable grounds that criminal activity is taking place. Only through investigation, intelligence gathering, tips received, the presence of unusually high electrical consumption, among other factors, are police then able to obtain a search warrant and inspect a MMAR grow operation. Upon inspection, if a licence holder is found to be breaking the terms of the licence by producing over their limit for example, typically police will be directed to simply seize any excess plants and leave the remaining legal amount untouched. Darryl Plecas, a Criminologist at the University of the Fraser Valley, believes it is the inability to monitor the situation due to a lack of inspectors that "in effect, amounts to virtually no enforcement".[xxviii] (A)

Although many law enforcement agencies may feel it is not their responsibility, or may not want the permanent obligation to inspect and monitor MMAR licensed grow operations, it could be a short term option. Police departments already have specially trained units who have experience entering marihuana grow operations. Police have policies and procedures in place that could be used in order to inspect MMAR licensed grow operations. However, designating police officers as inspectors would require the use of already strained police resources, therefore, may not be practical as a long term remedy. Police could use their knowledge and expertise of marihuana grow operations in order to train HC inspectors so they may safely and effectively monitor licensees going forward. (A)

Communication Between Health Canada and Law Enforcement Agencies

There is a lack of communication between HC and law enforcement agencies which has associated costs in terms of time for investigations and the needless seizures and arrests of individuals. (A)

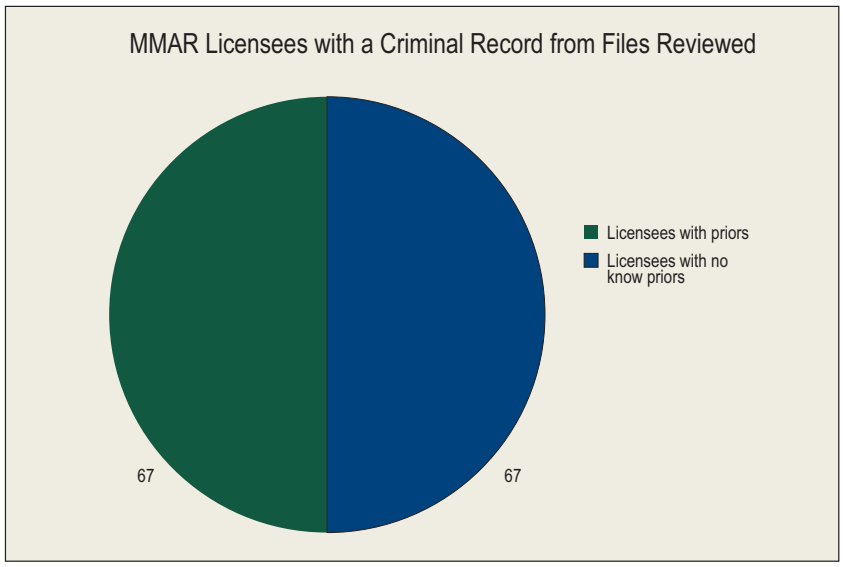
Some positive advances have been made with the establishment of the 24-hour pager system available to law enforcement to obtain licensee information. In most cases a HC official will respond within an hour to the police inquiry with the desired information on the presence of a MMAR licence and its terms. Continued communication between both parties will increase enforcement of, and compliance with, MMAR licences. However, more law enforcement agencies need to be made aware of this resource. If police fail to contact HC, valuable resources can be spent in the processing of files and executing search warrants unnecessarily. (A)

Other Potential Considerations

Criminal Record of MMAR Licensees

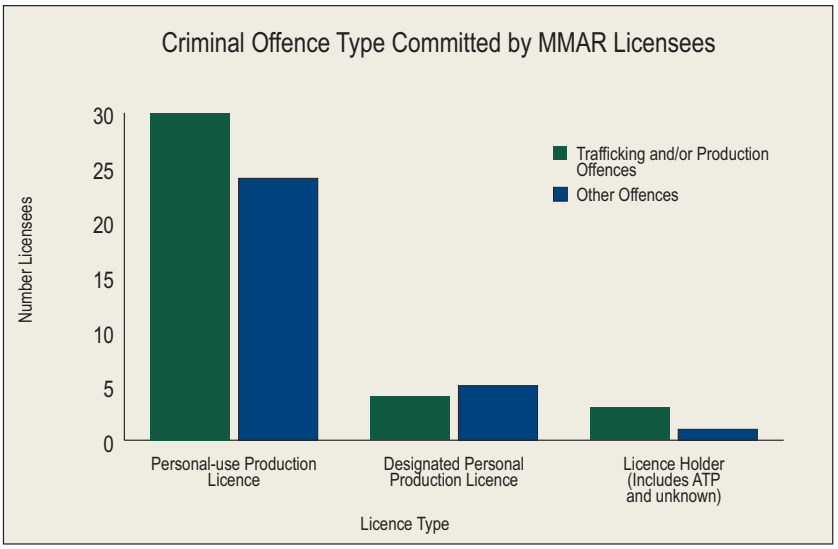
As per the existing MMAR system, criminal record checks are done for those applying for a DPPL[14] but are not completed for PPL or ATP applicants. In order to obtain a licence to produce marihuana on behalf of another individual, a DPPL applicant needs to demonstrate that within the 10 years preceding their application, they have not been convicted as an adult of a designated drug offence. (U)

In the 190 files reviewed for this assessment, there was a total of 134 licensees, as several licensees appeared in multiple files. Of the 134 licensees, 67 (ATP, DPPL and PPL) were found to have a criminal record which included production, trafficking, and importing and exporting of controlled substances. Of the 67 licensees with prior criminal offences one had an ATP, nine had DPPL, 54 had PPL, and the licence information for three licensees was not available. Fifty percent of the 134 licensees captured in this report have a criminal record, the majority of which were PPLs. A criminal record check of all MMAR growers would be needed in order to establish an exact percentage of licensed producers with criminal records. However, based on these findings, the percentage of licensed producers with a criminal record, specifically those individuals with PPLs, would likely be higher than the approximately 12.88%[xxix] of Canadian adults in the general population that have a criminal record. (A)



14 The DPPL applicant must supply a document issued by a Canadian police force establishing that, within the ten years preceding the application, they have not been convicted, as an adult, of a designated drug offence.

As noted above, the largest number of licensees with a criminal record, from the files reviewed in this assessment, are those licensed as PPL. These are the individuals who are given the authority to produce without having a criminal record check as their marihuana is for personal medical use. Consequently, their previous criminal history, particularly designated drug offences committed within the last ten years, is not taken into consideration by HC when granting a MMAR licence. Having a history of designated drug offences could indicate a potential licensee's tendency towards further criminal involvement and lead to a potential misuse of a MMAR licence. Those with such a history would likely be considered a risk and this information should therefore factor into the issuance of a medical marihuana licence. In this review, 54 personal production licensees had a criminal record, 30 had drug-related charges and convictions of trafficking and/or production. (A)



Revoking a MMAR licence is not a simple process. HC will revoke a licence only if the licence holder has been convicted of a designated drug offence. However, law enforcement agencies do not always follow-up with HC to inform them that a licensee has received a criminal conviction. There is no formal process in place to notify HC when a case has been concluded and a conviction received. The difficulty in revoking a licence once one has been obtained demonstrates the need to conduct more rigorous background checks prior to licensing. It should also be noted that even after a conviction, HC must allow the licence holder to maintain their authorization to possess marihuana for medical purposes as it was supported by a physician. (A)

Organized Crime

Marihuana production and trafficking is one of the most lucrative activities for Canadian OC groups. The demand for marihuana, both in Canada and in the United States, creates opportunities to generate large profits. The MMAR lacks checks and balances[xxx] leaving the system open to exploitation by OC groups, enabling them to hide illegal grow operations behind HC exemptions. MMAR licences would enable OC groups to avoid detection and increase their profits. There is current information suggesting at least three OC groups in Canada are trafficking large amounts of marihuana and abusing the MMAR to facilitate their operations.[xxxi] In this review four of the cases mentioned an association between a MMAR licensee and a known OC organization. (A)

Lack of Resources

Investigating the presence of a potential grow operation involves a good deal of law enforcement time and resources. These resources are often used unnecessarily on legal grow operations as the presence of a licence is not discovered until well into an investigation. A tip can be received from a concerned community member detailing the potential presence of what they believe to be an illegal marihuana grow operation, and police, unaware it is a MMAR licensed grow operation, will commence an investigation in order to ensure community safety. (A)

Many law enforcement agencies feel having access to a list of those licensed to grow in their communities would alleviate potential safety risks to those first responders as well as save valuable resources needed for other law enforcement priorities. (A)

> *"The providing of this information would allow for the respective agencies to quickly rule out suspected grow operations that are licensed and allow for our limited resources to be put towards illicit grow operations" (PC Richard KITELEY, Drugs & Guns Enforcement Unit, Windsor Police Services) (A)*

Compassion Clubs

Since the inception of the MMAR there has been an emergence of clubs or stores that are known to sell marihuana and marihuana-based products allegedly for medical purposes. These establishments are commonly known as "compassion clubs". (See Appendix G) (A)

Some MMAR licence holders are using their MMAR authorizations to open compassion clubs. In some cases, police have received information that MMAR licensed producers are supplying compassion clubs with their excess marihuana. Compassion clubs portray themselves as non-profit organizations which sell medicinal marihuana to doctor-recommended persons with medical conditions. These clubs are a means for criminals to illicitly traffic marihuana for personal gain under the guise of selling for medicinal purposes. In the province of Quebec, a large portion of the population believes that compassion clubs are legal, monitored, and regulated by the Federal Government.[xxxii] (A)

Contrary to the general public's belief, compassion clubs are illegal in Canada — the owners and operators are contravening not only the MMAR but the CDSA as well. Police departments and the general public need to be better educated on the MMAR and its application. (A)

Compassion clubs continue to appear in Canadian communities and Canadian internet sites due in part to the reasons mentioned above. Currently, there are at least 16 known compassion clubs in Canada.[xxxiii] The emergence of compassion clubs is a problem that will precipitate the criminal abuses of medicinal marihuana principles. (A)

Lack of Rules Regarding Transportation

The MMAR does not have clearly defined rules regarding the transportation, by various methods, of medical marihuana by licence holders. This was illustrated by a recent incident at an airport in the province of Quebec. (A)

Sgt. Suzanne DE LAROCHELLIÈRE, Drug Specialist, Sûreté du Québec, raised the following issues:

1) The authorized person is not obligated to declare the transportation of an excess supply of medical marihuana he/she may need for extended absences from home. This may cause police to believe the licence holder possesses a controlled substance for the purpose of trafficking contrary to Section 5(2) of the CDSA.

2) Public transportation companies and authorities are not aware, educated, or equipped to handle the MMAR. The detection of marihuana on a licence holder by public transportation staff will result in unnecessary police intervention. Further, it may well be public transportation policy to disallow any controlled drugs on their vehicles and in their buildings.

3) The MMAR does not require a licence holder to maintain control of his/her medicinal marihuana during transportation. This may cause a third party to take possession of the marihuana, which would equate to trafficking of a controlled substance contrary to Section 5(1) of the CDSA.

Conclusion

It should not be solely incumbent upon the MMAR licensed producer to abide by municipal, provincial, and federal laws. Medicinal marihuana is a controlled substance that requires strict oversight mechanisms in order to mitigate criminal abuses through the MMAR. Criminals have been found to be trafficking marihuana for decades. This analysis of national cases related to the MMAR has demonstrated that the current regulations are allowing criminal abuses to occur while increasing the risks to public safety. In the meantime, most police agencies are struggling to enforce the law on those individuals who are suspected of and/or caught abusing their MMAR licences.

The CACP is making recommendations to HC to change the MMAR in a manner that will meet the compassionate needs of the individual while ensuring that the general public's interest and safety are not compromised.

The CACP is presenting 10 principal recommendations for changes to the MMAR in a manner that is fair while minimizing its abuses by criminal elements. The CACP is aware that these principal recommendations may take some time to implement across Canada.

For that reason, the CACP is also presenting 11 additional provisional recommendations, which can be implemented in a short time frame in order to be in place during the transitional period between the current application of the MMAR and the newly proposed one.

Recommendations

Principal Recommendations:

1) The current regulation allowing for PPLs and DPPLs to grow marihuana themselves should be repealed.
2) PPLs and DPPLs should be given a reasonable time limit to cease their marihuana growing activities. This time limit should take into consideration the time it will take HC to have all its approved suppliers in place.
3) HC should contract reputable companies to produce a variety of medicinal marihuana throughout Canada to meet the needs and expectations of most medicinal marihuana users as well as the timely and reliable delivery of the product.
4) Approved medicinal marihuana companies should be located in areas where they are easily accessible to the majority of MMAR licensed users.
5) The approved medical marihuana companies would be subject to HC regulations and inspections; have the necessary standardized security and safety measures in place; have regulated quality control and safety standards for the medicinal marihuana; and, have the ability to deliver the marihuana in a reliable and timely manner. This recommendation will allow HC to conduct regular inspections on and maintain oversight of the MMAR program as the locations to visit will be reduced to a manageable size. This will also limit the criminal abuse of the MMAR and the public safety risks posed by some MMAR grow operations to their communities.
6) The daily amount of marihuana recommended by a physician should be based on recognized training encompassing scientific findings and literature versus the demand of the patient.
7) Physicians who recommend marihuana to their patients should receive an accreditation from their governing bodies who will in turn provide monitoring and compliance support on dispensation.
8) The regulations should have meaningful penalties assessed to MMAR violators which would include criminal prosecution and the immediate suspension and/or revocation of the licence of an individual and/or business believed to be committing abuses.
9) A regulation on the allowable methods of transport of medicinal marihuana should be incorporated in the MMAR to clearly dictate the rules for a licence holder to transport medicinal marihuana via all modes of transportation, whether it be from point A to point B, or for an extended absence from his/her residence.
10) HC and the CACP should improve cooperation, consultation, and communication between agencies to better draft and apply any future regulations or other laws that may cause conflict with the CDSA. Initial consultation and cooperation is vital to prevent the problems experienced today with the current MMAR.

Provisional Recommendations for a Transitional Period:

In the interim, on HC Inspectors:

1) HC inspectors should immediately begin to conduct MMAR grow inspections.

2) HC inspectors should be trained to detect electrical, structural, chemical, and mould hazards often associated to indoor marihuana grow operations.

3) HC inspectors should have the authority to immediately contact police and/or other municipal/provincial agencies to report any violations (suspected or actual) of the MMAR, Criminal Code, and provincial and municipal safety and building codes.

4) HC should have the authority to inspect, within a period of one year, premises on which a MMAR licensed grower had a grow operation, but whose licence has since expired. This would ensure that MMAR growers are not continuing to produce marihuana beyond the expiry of their licence. A number of cases in this report found expired licences at marihuana grow operations investigated by police. This recommendation would ensure that a residence used by a MMAR licensee has been remediated up to code of all potential hazards related to marihuana grow operations such as, but not limited to, mould contamination and structural modifications.

5) HC should engage and consult with law enforcement officials to find ways to increase the number of HC inspectors. With only 14 multi-purpose HC inspectors across Canada, it is and will be extremely difficult for HC to conduct efficient and effective inspections of over 3,400 MMAR growers and counting.

In the interim, for PPLs and DPPLs:

6) HC should not allow medicinal marihuana to be produced on properties accessible to children. Individuals with PPLs who have children should be given the option to purchase medicinal marihuana from an approved supplier; to have a DPPL produce their medicinal marihuana; or to produce their medical marihuana in a separate location not frequented by children. HC should have the authority to impose meaningful sanctions to MMAR licence holders who expose children to the dangers of marihuana grow operations.

In the interim, on the yield of dried marihuana per plant and the patient's daily dosage:

7) After consultations with marihuana production experts, HC should revise their guidelines determining the number of plants needed to produce X amount of dried marihuana (yield per plant). The current HC regulations indicate a yield of 30 grams of dried marihuana per plant to calculate the number of plant required to produce X amount of dried marihuana. This should be revised to a more accurate yield of 90 grams of dried marihuana per plant. As such, all MMAR production licences should be amended accordingly to reduce the number of plants allowed to be grown.

8) HC should add to their regulations a maximum allowable size and height of the plant.

In the interim, on penalties and enforcement of MMAR violators:

9) A subject accused of a designated drug offence involving the trafficking of controlled substances, still before the courts, should not be able to obtain a DPPL MMAR licence until all court proceedings have been dealt with and the accused did NOT receive a conviction for a drug trafficking offence under the CDSA.

10) A DPPL MMAR licence holder charged with a designated drug offence involving marihuana trafficking should have his/her licence temporarily suspended until the conclusion of all court proceedings. In the case of an individual with a PPL charged with a marihuana trafficking offence, there should be measures in place to ensure that the user is still able to obtain medicinal marihuana through HC supplier(s) in a timely manner, should his/her growing equipment and marihuana plants be seized by authorities. The same should apply to an individual with an ATP who can no longer be supplied by his/her designated grower who was the subject of a police intervention.

11) HC should improve its communication strategy with all law enforcement agencies for educational and awareness purposes. Currently, some law enforcement agencies do not have any knowledge of HC's 24-hour pager system.

Legal Context

Previous court decisions have led the Government of Canada to provide reasonable access to a lawful source of marihuana for medical purposes.

WAKEFORD v. the Queen, 1999
This court ruling prompted Health Canada to initiate a centralized federal medicinal cannabis program.

PARKER v. Canada, 2001
This was a landmark decision which first invalidated the marihuana prohibition under the CDSA. The judge ruled that people must be able to access necessary medical treatment without fear of arrest.

HITZIG v. Canada, 2003
This civil case challenged the constitutionality of the MMAR. The ruling found that the federal program gave the 'illusion of access'. The courts ruled that the Marihuana Medical Access Regulations were unconstitutional because they failed to provide a legal supply of the drug. The Government was given six months to remedy the situation, which prompted Health Canada to begin distribution of marihuana grown under contract by Prairie Plant Systems (PPS).

R. v. LONG, 2007
This decision determined that the current medical marihuana exemption created by the Government of Canada was unconstitutional as reasonable access depended on policy rather than law. The ruling challenged the Government to provide eligible persons with reasonable access to the Government supply of marihuana.

R. v. BODNAR/HALL/SPASIC, 2007
The Ontario Court of Justice followed the R. v. Long, 2007 decision, holding that prohibition against possession of cannabis in the CDSA was invalid.

SFETKOPOULOS v. Canada, 2008
This decision allowed a single designated producer of medical marihuana to be licensed to grow for more than one authorized medical user (which was previously not permitted). This situation created the potential for large scale 'legal' marihuana grow operations. The Federal response was an amendment to the MMAR to limit DPPLs to production for no more than two individuals.

R. v. BEREN and SWALLOW, 2009
The court ruled that the MMAR placed undue limits on access to medical marihuana by restricting production sites. As a result Health Canada amended the regulations so that no more than four production licences are permitted per site.

Appendix A — Yield of Dried Marihuana per Plant

Section 30 of the MMAR allocates a yield of 30 grams of dried marihuana per plant grown indoors, which is significant in determining the maximum number of plants a medical grower is allowed to produce.

Health Canada uses the following formula to calculate the maximum number of marihuana plants allowed to be grown entirely indoors:

[(A x 365) / (B x 3C)] x 1.2 = D

Legend:

"A" is the daily amount of dried marihuana.

"B" is 30 grams expected yield of dried marihuana per plant as set in the MMAR.

"C" is a constant equal to 1, representing a growth cycle of a marihuana plant from seeding to harvesting.

"D" is the maximum number of marihuana plants allowed for growing.

Example:

A) A medical grower is allowed to use 5 grams a day.
[(5 x 365)/ (30 x 3)] x 1.2 = 24.33 or 25 marihuana plants (maximum allowed)

B) A medical grower is allowed to use 5 grams a day, but the expected yield per plant in "B" is now 90 grams (just over three ounces).
[(5 x 365)/ (90 x 3)] x 1.2 = 8.11 or 9 marihuana plants (maximum allowed)

As noted above, the yield and consumption measurement determines the maximum number of plants allowed to be grown.

Appendix B — Example of the Estimated Profit to be Made in Trafficking Marihuana

Example: A licensed grower is permitted to produce 25 plants for himself, but in this scenario the licensee produces an extra 50 plants for a total of 75 plants. The chart below details what the potential annual revenue would be for this licensed grower if he/she were to sell the excess dried marihuana for profit.

Estimates with MMAR yield amounts	Estimates with expert yield amounts
Yield: 30 grams of dried marihuana per plant 3 crops a year	Yield: 28 to 56 grams dried marihuana per plant (two stage growing method) 4 to 6 crops a year
Average price of marihuana sold in Canada in the illicit drug market: $2800.00 per pound	
30 grams x 50 plants = 1500 grams 1500 grams x 3 crops a year = 4500 grams 4500 grams / 454 grams (1 lbs) = 9.91 lbs 9.91 pounds x $2800 = $27,753.30 of tax free profits a year if sold at the pound level (profits are higher as you sell in smaller allotments)	28 grams x 50 plants = 1400 grams 56 grams x 50 plants = 2800 grams 1400 grams x 4 crops = 5600 grams 2800 grams x 6 crops = 16800 grams 5600 grams / 454 grams (1 lbs) = 12.33 pounds 16800 grams / 454 grams (1 lbs) = 37 pounds Annual profit potential: $33,600.00 (12 lb x $2800) to $103,600.00 if sold at the pound level.

Appendix C — Sample Yield Amounts of Dried Marihuana

The following table illustrates the yield of dried marihuana per plant sampled by police marihuana enforcement teams at illegitimate marihuana grow operations: (A)

Agency	File #	Plant Height	Yield of Dried Marihuana Per Plant (Indoors)
Edmonton Police Service	2003-36923	3.5 feet	224 grams (8 oz)
Edmonton Police Service	2003-92870	3 feet	68 grams (2.4 oz)
Edmonton Police Service	2003-92870	3 feet	61 grams (2.1 oz)
Edmonton Police Service	2003-174571	4 feet	472.9 grams (16 oz+)
Edmonton Police Service	2004-60602	5.5 feet	454.8 grams (16 oz+)
Edmonton Police Service	2005-155653	3.5 feet	185 grams (6.6 oz)
Edmonton Police Service	2005-19513	2.5 feet	142.9 grams (5.1 oz)
Edmonton Police Service	2007-181086	N/A	125 grams (4.4 oz)
Edmonton Police Service	2007-181086	N/A	101 grams (3.5 oz)
Edmonton Police Service	2007-181086	N/A	233 grams (8.2 oz)
Duncan RCMP	2009-1578	6 feet	376 grams (13 oz)
Duncan RCMP	2010-288	6.5 feet	703 grams (25 oz)
New Brunswick CMET	2010-276011	8 feet	1386.5 grams (49 oz)
Nova Scotia CMET	2009-111060 (MMAR)	4 feet	363 grams (13 oz)

Appendix D — Summaries of Experience of Court Recognized Experts in the Field

Sgt. Lorne ADAMITZ

RCMP Regular Member since 1988

- Has attended in excess of 400 active marihuana grow operations.
- Has assisted in growing marihuana in a controlled environment while working at EPS HQ - Det. Pete CHERNYOSKI had a licence.
- Has manicured seized marihuana plants and obtained yields from the plants.
- Has reviewed seized grow records and yields from accused individuals who recorded their yields. Most recently a 2009 case of an indoor marihuana grow operation of minimal sophistication of only 20 plants, in a very northern environment in a confined space. The grower identified the plant and separately dried the manicured marihuana bud from the plant. The yield per plant was 37.67 grams / plant = 1.345 oz / plant. This was not an experienced grower and the grow conditions were not ideal.
- Continues to attend grow operations with the Edmonton Green Team.
- Current duties are Drugs and Organized Crime Awareness Services which also requires he keep current on drug trends, intelligence, and research.

Sgt. Vincent J. ARSENAULT

RCMP Regular Member since 1978

- Provide instructional training on the history, horticulture, manufacture, usage, stability, toxicology and pharmacological effects of marihuana and cocaine. This course was being instructed jointly with Mr. Wayne JEFFERY, Forensic Toxicologist from the Vancouver Forensic Laboratory in Vancouver. Candidates are shown how to extract weed oil and manufacture "freebase" and "crack" cocaine. Current importation and trafficking trends are also discussed.
- Attended a course instructed by Mr. Richard LAING, Drug Analytical Specialist with the Health Protection Branch Laboratories in Burnaby, B.C. Received hands-on instruction on the scientific methodology for marihuana identification and quantitative analysis. Also conducted marihuana oil extractions using Isopropanol, Methanol, Naphtha and Toluene for marihuana resin yield and THC potency comparisons.
- A three-month training exercise which consisted of growing marihuana under licence from the Bureau of Dangerous Drugs in Ottawa. This involved growing marihuana from seeds and clones to maturity and experimenting with the different elements required for a successful crop, such as lighting, water and nutrients. This exercise also provided "hands on" experience on forcing marihuana plants to flower by modifying light cycles and sources.

- Wrote a paper on marihuana including research conducted on horticulture, cannabis preparations, THC degradation, toxicology, statistics, cultivation and exportation trends, investigative steps/safety procedures and possible solutions to the problem. This document was reviewed and published on the RCMP Infoweb as an educational and investigational tool to law enforcement officers nationwide.
- Conducted yield determination experiments and continues to do so on a regular basis by personally removing marihuana buds from plants and weighing the dry bud to determine the average plant yield. Has used this same method to determine the effects of "Lumen Ratio" and CO2 enrichment on marihuana plant yield.
- Weighed seized marihuana cigarettes to determine the average weight in order to ascertain the average number of cigarettes per gram. This has become especially useful in determining the rate of personal consumption.
- Has been involved in over 2,000 investigations of cultivation of Cannabis marihuana from several plants to over 23,000 plants being grown in soil and hydroponically using Rockwood and lava rock for root system support. Has also been involved in approximately 950 investigations involving the exportation and trafficking of marihuana from grams to the multi-pound level.

Cpl. Shawna BAHER

RCMP Regular Member since 1992

- First encountered marihuana, cocaine, and heroin in 1993 as a general duty police officer.
- Has personally been involved in hundreds of investigations concerning cannabis marihuana, cannabis oil (weed oil), cocaine, heroin, lysergic acid diethylamide (LSD), amphetamines (primarily methamphetamine and ecstasy), psilocybin mushrooms, and designer drugs such as GHB and ketamine.
- Has assisted in several undercover operations involving cocaine, heroin, and marihuana. Has personally been involved in the seizures of cocaine from the quarter-gram to the multi-kilogram level, seizures of heroin at the one-tenth of a gram level to the multi-ounce level, seizures of both dried marihuana and growing marihuana in the gram to multi-pound level.
- Has debriefed undercover operators and confidential informants concerning the use of drugs, trafficking trends, availability, prices, trafficking methods and use, packaging concealment methods, and jargon.
- Has and continues to cultivate and debrief confidential informants who specialize in cocaine, heroin, methamphetamine, and marihuana and rave drugs including ecstasy, GHB and ketamine.

- Has been in charge of three Marihuana Grow Operation "Green Teams" and also been involved in a total of five "Green Teams". Has investigated over 500 grow operations and has seen grows in all stages of growth, in all types of growing mediums. Has observed differences between clones and seedlings and have harvested in excess of 30 plants from different grow operations, which include clipping and drying the marihuana bud.

Sgt. Suzanne DE LAROCHELLIÈRE

Police officer with the Sûreté du Québec since 1988

- Has participated in more than 790 drug investigations. Gained extensive knowledge of the drug world by working for the Quebec Provincial Police as an undercover agent for a period of 10 years, from 1989 to 1999 and also as an investigator of organized crime from 1995 to 2006.
- Since 2006, as Drug specialist in the Operational Support Service (OSS), gives advice which requires maintaining a high level of knowledge in the field of drug criminality to support the field of drug investigations.
- Interactions with various police departments and stakeholders as a trainer promotes trade and knowledge of trends in drug use. Participates in conferences both nationally and internationally, in policing as well as for civil partners.
- Has been an expert witness in over twenty different criminal cases in trial before the Court of Quebec and the Superior Court. Has also contributed to/written more than a dozen expert reports on criminal activities in connection with the production and trafficking of narcotics.
- From 2006 has contributed to the development of the Sûreté du Québec in its fight against crime by:
    - Acting as advisor to the Criminal Investigation Branch, in investigations and proceedings related to drugs;
    - Developing internal procedures and tools relative to drug detection, prevention and repression at the Sûreté du Québec;
    - Presenting and attending various conferences nationally and internationally in connection with enforcement of criminal activity related to drugs;
    - Producing and presenting training relative to drugs to officials of the justice system (from judges to attorneys) and other civilian partners. These courses have also been provided to the École nationale de police du Québec and the Canadian Police College (Ottawa), as well as with various police forces in Quebec;
    - Participating in the management of the Provincial Police bank of expert witnesses;
    - Representing the Sûreté du Québec, on different round tables, symposiums, at the level of police services, at different companies or media, at the provincial, federal and international levels.

S/Sgt. Darren DERKO

Edmonton Police Service since 1988

- Has attended in excess of 400 marihuana grow operations.
- Has grown marihuana in a controlled setting under Health Canada licence #2003/7331.
- Undercover purchases of marihuana in an undercover capacity.
- Has manicured and recorded amounts and potential yields of marihuana plants.
- Qualified as an expert in Provincial and Queen's Bench Courts in marihuana use, packaging, distribution, consumption patterns, paraphernalia, jargon, practices and habits of users and traffickers, observable effects, production including practices and habits of producers.
- Member of the Joint Forces RCMP/Edmonton Police Service "Green Team" (2002-2009).
- Currently assigned to the Edmonton Drug and Gang Unit as the Staff Sergeant i/c drug/gang investigations including the "Green Team".

S/Sgt. Ian SANDERSON

RCMP Regular Member since 1980

- Has 26 years service with the RCMP, all of it in Northern Alberta. Has a varied background of experience including Drug Prevention Education, Media Relations, Detachment Policing and Forensic Identification. Joined the Edmonton Drug Awareness Service in July 2002, and is responsible for Drug Prevention Education, Awareness Programs and Prevention research and strategies for northern Alberta.
- Currently involved with the development of a methamphetamine prevention strategy, which includes work in the areas of Public Awareness, Community Mobilization, Awareness for Police, First Responders, Chemical Companies and Retailers. Has given in excess of 300 presentations in Alberta and across Canada to Police, Government and Community Leaders, Medical Professionals, Industry, Students and the general public.
- Currently the project leader for the Drug Endangered Children Protocol for Canada, a part of the methamphetamine strategy. Was involved in the development of the Alberta Drug Endangered Children Act, introduced in 2006 at the Alberta Legislature.
- Has studied the methamphetamine issue in Canada and the United States. Spoken on the subject across Canada to Police, Professionals and Community leaders. Was recently appointed to the Alberta Meth Task Force, chaired by Dr. Colleen Klein. Also a member of the Alberta Solicitor General's Inter-departmental working group on methamphetamine, and the First Nations and Inuit Health Branch Meth Task Force.

Cpl. Mike WICENTOWICH

RCMP Regular Member since 2000

- Has served as an expert witness in several court cases in British Columbia relating to the use, packaging, production, distribution, pricing, and yield from plants of cannabis marihuana between 2007 and 2009.
- Has conducted multiple investigations into indoor marihuana grow operations and been the main investigator in over twenty outdoor marihuana grow operations.
- Has seized over ten thousand marihuana plants including marihuana clones, juvenile plants, mature plants and moulded marihuana plants.
- Has clipped, dried and weighed marihuana bud from mature marihuana plants to gain experience with yields of marihuana bud.
- Has viewed, weighed, and analyzed drugs such as methamphetamine, heroin, cocaine, marihuana plants, marihuana bud, hash oil, marihuana oil, ecstasy, morphine, and prescription pills.
- Is knowledgeable concerning the equipment, supplies, tools, fertilizers, and chemicals that marihuana growers are currently using to produce marihuana plants outdoors.
- Has clipped marihuana bud from budded out marihuana plants and dried the marihuana bud to add to his knowledge on the potentials yields of marihuana bud produced by his single marihuana plant.
- Has attended the following courses related to controlled drug and substances designed and taught by police officers, civilian members of the RCMP and other field and laboratory personnel:

Basic Thermograph Operator Course	October 25, 2001
Drug Expert Witness Workshop	April 18, 2002
Drug Investigation Techniques Course	November 27, 2003
Drug Expert Witness Workshop	January 30, 2004

- These courses are taught by qualified leading experts in the field area of controlled drugs and substances. These courses are designed to enhance the knowledge, abilities, and technical skills of drug investigators. They are also designed to enhance the Drug Expert Witness's qualifications and credentials in order that they can provide well-informed and accurate expert opinions for court purposes.

Appendix E — Case Summary

Washington State medical marihuana incident

These reports of recent U.S. medical marihuana cases are included due to the proximity of these locations to Canada, and the seriousness of the violence involved.

http://www.nytimes.com/2010/03/17/us/17marihuana.html

Posted by King 5 News (Seattle, Washington), on March 15, 2010:

ORTING, Wash. — A 38-year-old Orting man died over the weekend while trying to protect his medical marihuana plants.

Michael Howard was hit in the head with a crow bar on March 9 by someone trying to break into a shed in his backyard where he was legally growing medical marihuana, according to his father. He died four days later.

Atkins says Howard grabbed a can of pepper spray and ran out to the shed when he heard his dogs barking.

"The intruder had a large iron crowbar in his hand which he was using to break into the shed," said Atkins. "When Mike came around the corner of his house, the perpetrator was waiting for him. He hit our son square in the head."

Posted by King 5 News (Seattle, Washington) on March 15-16, 2010:

SEATTLE — A well-known Washington state medical marihuana activist traded gunfire with robbers who invaded his home early Monday, suffering minor shotgun pellet wounds and sending one intruder to the intensive care unit of a hospital.

Activist Steve Sarich, 59, runs CannaCare, an organization that provides patients with marihuana plants and advice about Washington's law.

He indicated this was their eighth home invasion since last May.

A spokesman for the King County Sheriff's Office says deputies found 385 marihuana plants at the home of a medical marihuana activist who was in a shootout with robbers.

Appendix F — RCMP Policy on Officer Safety

An Excerpt from the RCMP Policy on Officer Safety — Bio-Hazards and Marihuana Cultivation

5. Threat Risk Assessment

1. 5. 1. Before initiating a search of a grow operation, ensure the safety of members and the public by conducting a threat and risk assessment (TRA) of the site.

5. 2. If you are unfamiliar with these types of investigations and dismantling procedures, contact your division drug section for direction or assistance. Be alert and prepared for the following dangers:

5. 2. 1. contaminated air,

5. 2. 2. booby traps,

5. 2. 3. incendiary devices,

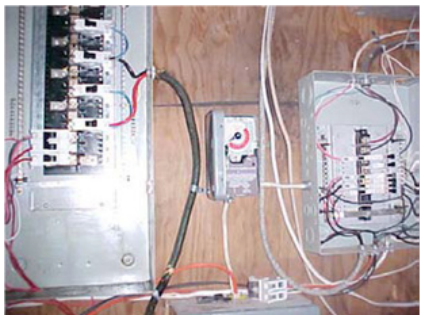
5. 2. 4. volatile/poisonous chemicals,

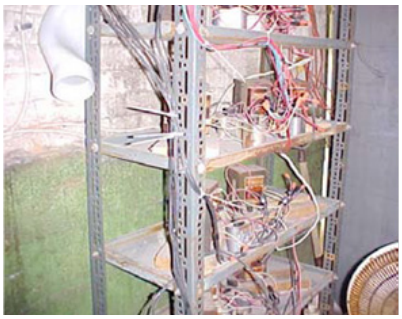
5. 2. 5. potential eye damage from the high intensity bulbs,

5. 2. 6. fire hazards,

5. 2. 7. unsafe electrical modifications, and

5. 2. 8. possibly older (manufactured prior to 1978) ballast boxes (power transformers) that may contain PCBs.





6. Health and Safety Precautions

2. 6. 1. General

6. 1. 1. Exercise extreme caution as marihuana cultivation sites can contain improvised explosive devices and booby traps. The traps could include firearms or crossbows rigged to fire as a person enters a room, floors that are cut away to collapse underfoot or explosives set to detonate, causing serious injury or death to an intruder.

6. 1. 2. Marihuana growers often have loaded weapons in their residences to prevent theft by their rivals.

6. 1. 3. If an improvised explosive device or booby trap is discovered or suspected, seal or secure the site, evacuate the area and call the Explosives Disposal Unit (EDU). Depending on the TRA outcome, consider deploying the Emergency Response Team (ERT).

6. 1. 4. Indoor marihuana cultivation poses unique health and safety hazards because of the type of equipment and chemicals used in these operations. All marihuana cultivation site fires and all extraction laboratories must be treated as clandestine laboratories.

For clandestine drug laboratories, see ch. 6.13.

6. 2. Breathing Apparatus

6. 2. 1. Conduct a pre-assessment of hazards of the marihuana cultivation site and consider using an air monitoring device for the detection of hazardous substances or oxygen deficiency. If possible use environmental monitoring devices for carbon monoxide (CO), lower explosive limit (LEL) and oxygen gas (O2) analyzer.

6. 2. 2. When possible before entering, vent the premises in which marihuana is cultivated and when necessary, wear a respirator to reduce the danger of inhaling hazardous chemicals, airborne toxins, high concentrations of ozone, carbon dioxide (CO2), insecticides, pesticides or fungicides. For protection equipment, see App. 6-12-1.

6. 2. 3. When grow rooms are not or cannot be properly vented, use a NIOSH approved Self-Contained Breathing Apparatus (SCBA), and turn off any ozone (O3) and (CO2) generators found on the premises.

NOTE: *Symptoms of CO2 poisoning include headache, dizziness, fainting and death. Ozone is used to eliminate odour particles and consume excess oxygen created by plants. Ozone is an oxidizing gas which will damage and can cause fluid buildup in the lungs at high concentration levels. Ozone smells like chlorine.*

6. 2. 4. Some liquids used at indoor marihuana cultivation sites produce vapours. Some gas and vapour molecules can irritate the lungs, while others are easily absorbed through the lungs into the blood stream.

Once in the blood stream, some of these chemicals may cause serious, immediate or future health problems.

6. 2. 5. Use a Half Mask but preferably a Full Face Respirator with cartridges when entering all indoor marihuana cultivation sites. The respirator cartridge and pre-filter must be approved for protection against pesticides, organic vapours, dust, fumes and mists. These masks and combined cartridges can be purchased commercially at most emergency/health and safety outlets.

6. 2. 6. Pesticides are absorbed through the respiratory tract and through the skin and eyes. When entering an indoor marihuana cultivation site, wear eye protection, disposable suits, and Nitrile gloves to prevent contaminating clothing and transferral to a vehicle, detachment, or residence.

6. 3. Eye Protection

6. 3. 1. You must wear UV-blocking sunglasses to protect your eyes from damage by the high intensity metal halide and high pressure sodium lights used in growing rooms. For protection equipment, see App. 6-12-1. Exposure to UV radiation has been associated with cancers and other adverse eye conditions.

6. 3. 2. All members engaged in any kind of forced entry must use UV-blocking sunglasses as protection against injury, blood splatter, saliva, UV radiation, chemicals and other liquids, and possible explosion. See ch. 21.3.5.

6. 4. Electrical Hazards

6. 4. 1. Be aware of haphazard electrical wiring when entering indoor marihuana cultivation sites.

6. 4. 2. In the cases of suspected electrical by-passes or meter manipulation, before entering, contact your local electrical power company area investigator for assistance in disconnecting electricity and for measurements relating to the theft of hydro.

6. 4. 3. Electrical power companies may release customer account information in accordance with the provisions of the provincial freedom of information and protection of privacy act. A search warrant may be required.

6. 4. 4. Provincial electrical inspectors will assist in disconnecting electricity where actual or potential electrical hazards exist.

Cultivation Response Team Members

App. 6-12-1 — Protection Equipment for Marihuana

Eyes	Eye protection with non-breakable lenses for prescription wearers, or preferably polycarbonate plastic to provide protection from flying debris, blood, saliva, sharp objects, and UV rays (regardless of tint). You must wear UV-blocking sunglasses to protect your eyes from damage by the high intensity metal halide and high pressure sodium lights used in growing rooms. Exposure to UV radiation has been associated with cancers and other adverse eye conditions.
Gloves	Nitrile, not latex, is a synthetic latex, which has more chemical resistant properties and will not cause an allergic reaction. Over gloves (cut and puncture resistant).
Protective Suit	Tyvek or light-weight saranex type suit prevents contamination from pesticides and fungicides on the members' clothing which may be brought back to a detachment or residence.
Breathing Apparatus	**Full-facepiece SCBA:** Use National Institute for Occupation Safety and Health (NIOSH) certified self-contained breathing apparatus (SCBA) to protect against hazardous substances or oxygen deficiency when grow rooms are not or cannot be properly vented. **Half Mask Respirator:** Fitted with cartridges that are equivalent to MSA GME-P100 that filter dust, molds, pesticides, fungicides, and organic vapours. Reusable with replaceable cartridges when plugged, broken or torn. (To be worn with protective eye wear.) Half mask respirators offer no protection against CO2 or ozone poisoning. **Certification**: Members must be trained and certified in the use of any respiratory device before entering a marihuana grow operation in accordance with the Canada Labor Code.
Shock Resistant Footwear	Must be Canadian Standards Association (CSA) approved.
Hard Hat	Must be CSA approved and mandatory for low ceilings and confined spaces.
Exceptions	Not everyone entering a grow operation requires all of this equipment. Eye protection must be worn by all members; however, the other equipment need only be worn by persons in close proximity to the plants and equipment especially during the dismantling of the operation. Ventilating the grow rooms will reduce exposure.
Cannabis Extraction Labs	For protective equipment applicable to investigating cannabis extraction and other clandestine labs, see App. 6-13-1.

Equipment

Personal Protection Equipment (PPE)

Air Monitoring Device

Appendix G — Example of a Compassion Club Price List

Price List from 'The Medicinal Cannabis Dispensary', Vancouver, BC

http://www.cannabisdispensary.ca/node/13

Today's Menu
updated 05/17/10 @ 4:32pm

CANNABIS BUDS

1. **Island Purple Kush ($10/gram)** Indica. **Organic**. Great pain relief, appetite inducer, sleep aid.
2. **Island Haze ($10/gram)** Sativa. **Organic**. Sweet taste. Very potent. Mood elevator, good for nausea.
3. **OG Kush ($10/gram)** Sativa. Energizing. Very clean burning and tasty.
4. **Bubba Kush ($10/gram)** Mostly Indica. By Boodah Budz. Very potent, somatic body effects. Cerebral high.
5. **René ($10/gram)** Mostly Indica. Good daytime Indica. Pain reliever, appetite inducer.
6. **Happy Dutchman ($10/gram)** Mostly Indica. An 'up' Indica. Good daytime pain relief.
7. **Medicinal Magic Kush ($10/gram)** Mostly Indica.
8. **Master Kush ($10/gram)** Indica. By Magic Gardens. Large nugs, clean burning sedative. Kushy spice flavour.
9. **Captain Jack ($10/gram)** Mostly Sativa **Organic**. Very clean, uplifting, euphoric. Good mood enhancer.
10. **Nebula ($9/gram)** Mostly Sativa. Indoor. Haze genetics. Fruity flavour. Transcendental Nebulous high.
11. **Turbo ($9/gram)** Sativa. Turbo charged Diesel. Very energizing.
12. **Champagne ($8.50/gram)** Mostly Indica. Good daytime Indica for pain.
13. **Hashplant ($8/gram)** Mostly Indica. Classic flavour, fullbody relaxation. Great for pain relief.
14. **Pinewarp ($7.50/gram)** 50/50. Pineberry x Timewarp. Piney taste, energizing high. Nice buds.
15. **007 ($7.50/gram)** Mostly Sativa. Clean, clear, cerebral high. Good pain relief, easy creeper.
16. **Chernobyl Hybrid ($7.50/gram)** Functional, good for daytime pain relief. Appetite inducer. Focusing and energizing.
17. **Cherry Hashplant ($7/gram)** 60/40 Indica. Good for daytime pain relief. Flavourful, Fruity hybrid.
18. **Early Bird Kush Mix ($6/gram also in $20, $40 pre-packs)** Mostly Indica. Clean burning. Does the trick for a low price.

Endnotes

i Report on the Illicit Drug Situation in Canada — RCMP Criminal Intelligence (2009)

ii U.S. Department of Justice National Drug Intelligence Center, National Drug Threat Assessment 2009 & 2010 (Washington: NDIC: December 2008 & February 2010)

iii United Nations Office on Drugs and Crime, World Drug Report 2009 (New York: United Nations, 2009)

iv 2009 National Criminal Intelligence Estimate on Organized & Serious Crime in Canada, Criminal Intelligence Service Canada.

v Bouchard, Martin. "A Capture-Recapture Model to Estimate the Size of Criminal Populations and the Risks of Detection in a Marihuana Cultivation Industry," in Journal of Quantitative Criminology, vol. 23 (2007): pp. 221-241.

vi Criminal Intelligence Brief: A review of cases related to the MMAR, RCMP (April, 2009)

vii Controlled Drug and Substances Act, http://laws.justice.gc.ca/eng/C-38.8/index.html

viii Staff Inspector Mario DI TOMMASO, Drug Squad, Toronto Police Service

ix Regulations Amending the MMAR, http://gazette.gc.ca/rp-pr/p2/2009/2009-05-27/html/sor-dors142-eng.html May 27, 2009

x Cpl. Mike WICENTOWICH, NCO i/c Kootenay Boundary Regional General Investigation Section, RCMP "E" Division (Appendix D)

xi Ibid

xii Marihuana Medical Access Regulations, http://laws-lois.justice.gc.ca/eng/SOR-2001-227/index.html

xiii Sgt. Lorne ADAMITZ, Drugs and Organized Crime Services, RCMP "K" Division (Appendix D)

xiv Dion, Claude, B., and Bouchard, Martin. "Growers and Facilitators: Probing the Role of Entrepreneurs in the Development of the Cannabis Cultivation Industry," in Journal of Small Business and Entrepreneurship, vol. 22, no. 1 (2009): pp. 25-38.

xv Illicit Drug Price List Canada 2008-2009, RCMP Criminal Intelligence (2009)

xvi Regulations Amending the MMAR, http://gazette.gc.ca/rp-pr/p2/2009/2009-05-27/html/sor-dors142-eng.html

xvii Marihuana Medical Access Regulations, http://laws-lois.justice.gc.ca/eng/SOR-2001-227/index.html

xviii Ibid

xix Marihuana Grow Operations, RCMP website, http://www.rcmp-grc.gc.ca/fio-ofi/grow-ops-culture-eng.htm

xx Marihuana Medical Access Regulations, http://laws-lois.justice.gc.ca/eng/SOR-2001-227/index.html

xxi Residential Indoor Air Quality Guidelines, March 31, 2007, Health Canada.

xxii Bradley, Francis. "A Growing Danger: The Risks Posed by Marihuana Grow-Ops" Canadian Electricity Association

xxiii S/Sgt. Ian SANDERSON, Drugs and Organized Crime Awareness Service, RCMP "K" Division (Appendix D)

xxiv Diplock, Jordan, Garis, Len, and Plecas, Darryl. "Commercially viable indoor marihuana growing operations in British Columbia: what makes them such a serious issue?" Submitted to Prosecution Services Division, The Ministry of the Attorney General, Province of British Columbia, October, 2009.

xxv Armon, Rick. "OPP and Fire Marshal form community safety partnership to combat clandestine drug labs," in The America's Intelligence Wire, June 16, 2009.

xxvi Armstrong, Janice, Fassbender, Peter, Garis, Len, Plecas, Darryl, and, Watts, Diane. "Disrupting Canada's marihuana grow industry," a submission to the Standing Committee on Justice and Human Rights on April 30, 2009.

xxvii Plecas, D., Malm, A., & Kinney, B. (2005) "Marihuana growing operations in British Columbia revisited, 1997-2003". Abbotsford, BC: University of the Fraser Valley.

xxviii Medical marihuana rules used to hide grow-ops, CTVBC, June 7, 2009

xxix Canadian population data from Statistics Canada. Canadian Criminal Record data from OIC Criminal Records Operations, RCMP.

xxx Medical marihuana rules used to hide grow-ops, CTVBC, June 7, 2009

xxxi Marihuana Grow Operations Coordinator, RCMP Headquarters Drug Branch

xxxii Sgt. Suzanne DE LAROCHELLIÈRE, Drug Specialist, Sûreté du Québec (Appendix D)

xxxiii Service de police de la Ville de Montréal, Correspondence to Drug Branch, RCMP Headquarters received on May 28, 2010.

This is **Exhibit " D "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

[redacted]

April 22, 2010

The Honourable Leona Aglukkaq, P.C.,
Minister of Health
M.P. Health Canada Brooke Claxton Building,
Tunney's Pasture Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Dear Ms. Aglukkaq,

Re: Medical Use and Growing of Marijuana

As you are aware, Health Canada has issued a number of permits in [redacted] for individuals to legally grow marijuana for pain remediation.

I believe that the original concept of this plan was for individuals to ONLY grow an amount for personal pain relief or to hire a person to do this on his or her behalf. We have found that some of the permit holders have drug trafficking convictions on their records or some of the growing activity has been outsourced to people who have been involved previously in illegal drug activities. Although permit holders are supposed to protect the security of their plants, some plants can and do disappear to trafficking activities and the theft cannot be proven or disproven.

Some of the quantities legal growers are allowed to possess in storage strikes us as particularly large numbers. On your website a person who allegedly grows only outdoors with a prescription for 5 grams per day is allowed to store 3750 gms or over two years supply. In addition this particular individual is allowed 10 plants which can contain an additional 200 gms each for a total of a kilogram. The legal total for this person is now 5750 gms or 38 months supply. We can create equally alarming numbers from a number of options outlined on your website. These are very large numbers and merely allows for many ways of drug trafficking under the veil of a legal operation. Why should anyone possess three years supply as a matter of right? There are too many ways that people growing "legally" can be a source of illegal marijuana and play with the variables like number of plants, indoors, outdoors, storage, leaf on plant to present to law enforcement that they are "legal" when we know that they can easily mask illegal activity.

[redacted] is a prime area for growing marijuana either in the field or in a greenhouse. Plants have extremely high THC content and can easily exceed nine feet in height.

Although the regulations cause us concern the issue for the [redacted] is that Law enforcement cannot determine on a pro forma basis whether a "grow operation" is legal or not and we would like a list of "legal" producers and "legal users" in our county from your Ministry on an on-going basis. We have reasonable grounds to believe that some legal producers are growing for illicit drug trade. If we know which grow operations are legal then by definition we know which are illegal when officers come upon them and can act or investigate as appropriate. We do not believe that the concept of health confidentiality should trump what are important police initiatives for the safety of our county.

I would appreciate the name of a contact person immediately who can keep our police force abreast of legal grow permits as soon as possible.

Thank you for your cooperation in this matter.

Yours truly,

[redacted]

Chair

[redacted]

[redacted]

APR 21 2011

the future lives here.

11-108767-324

April 1, 2011

File: [redacted]

Health Canada
9th Floor Room A909 MacDonald Building
123 Slater Street
Ottawa, Ontario K1A 0K9

Attn: Cathy Sabiston, Director General, Controlled Substances and Tobacco Directorate

Dear Ms Sabiston:

Re: Marijuana Medicinal Access Regulations (MMAR)

The City of [redacted] Electrical Fire Safety Team has discovered 15 Medicinal Grow ops (MMAR's) to date, and inspected 13 in the past three years. Violations of municipal regulations were found at all sites as well as numerous violations of the provincial electrical code, building code, and fire code. Most of the sites required immediate electrical system remediation.

The most recently discovered MMAR License holder was cultivating marijuana in a rented residence at [redacted] in the City of [redacted], under a MMAR "Authorization to Possess" and "Authorization to Produce", granted to Mr. [redacted] to a civic address in the City of [redacted]. A photo of each authorization is attached. The [redacted] EFSI team was led to this residence through a Crime Stoppers tip directed through the RCMP. An inspection of the property revealed multiple electrical, and safety concerns, as well as building alterations in violation of the building code and fire code. With the amount of site contamination from plants, soil, and chemicals, this property will require extensive remediation and professional air quality and mould testing to ensure the safety of future tenants.

This demonstrates that without disclosure of MMAR locations, there are no means for city inspectors to ensure compliance of codes and regulations, or to ensure the home is remediated and rendered a safe and healthy environment after being used for marijuana production.

It would appear that Mr. [redacted] was without his authorization to cultivate marijuana within the City of [redacted] by presenting an "Authorization to Produce" marijuana in the City of [redacted], the City of [redacted] requests that you revoke his MMAR licenses to produce and possess marijuana, and deny any future applications to possess or cultivate marijuana.

The City of [redacted] also requests that you reconsider the issue of disclosure in order to assist the city in managing the safe operation and complete remediation of properties used in the MMAR program.

Regards,

[redacted]

Fire Chief

CC: [redacted]

2 Attachments

Address Locator: 3503B
Ottawa ON K1A 1B9

MMAD-17894-10

PERSONAL-USE PRODUCTION LICENCE
DRIED MARIHUANA FOR MEDICAL PURPOSES

You have met the requirements to be issued a licence pursuant to section 29 of the *Marihuana Medical Access Regulations* (MMAR). You are hereby licensed to produce dried marihuana for your medical purpose in accordance with your licence. This document and/or ID card will serve as proof of your authority to produce marihuana for a medical purpose. You should have at least one of these documents with you at all times in case you are required to show proof to the police.

HOLDER OF LICENCE INFORMATION

NAME:

ADDRESS: [redacted]

MAILING ADDRESS:

DATE OF BIRTH: [redacted]

GENDER: Male

TERMS AND CONDITIONS

PRODUCTION SITE: [redacted]

MODE OF PRODUCTION: Indoors only

PRODUCTION QUANTITIES: The maximum number of marihuana plants that you may have under production at the production site at any time under this *Personal-Use Production Licence* is **30 PLANTS (indoor)**.

STORAGE SITE: [redacted]

STORAGE QUANTITIES: The maximum quantity of dried marihuana that you may keep at the storage site at any time under this *Personal-Use Production Licence* is **1350 grams** and it must be stored indoors.

EXPIRY DATE

Please note this *Personal-Use Production Licence* expires on **December 15, 2011**. Should you wish to renew your *Personal-Use Production Licence*, please submit your renewal application at least **8 weeks prior** to your expiry date.

ISSUED BY:	DATE OF ISSUE:
Jeannine R. Ritchot, Director Medical Cannabis Office of Controlled Substances	DEC 15 2010

PLEASE READ ALL ENCLOSED DOCUMENTS CAREFULLY

ENCLOSED DOCUMENTS. Information you should know about your *Personal-Use Production Licence*

NOTE: Details of this *Personal-Use Production Licence* are summarized on your ID card attached to your *Authorization to Possess*.

All inquiries regarding this licence should be directed to the Marihuana Medical Access Division toll-free phone number: 1-866-337-7705.

03/30/2011 08:06

Ottawa ON K1A 1B9

AUTHORIZATION TO POSSESS DRIED MARIHUANA FOR MEDICAL PURPOSES

You have met the requirements to be issued an authorization pursuant to section 11 of the *Marihuana Medical Access Regulations* (MMAR). You are hereby authorized to possess dried marihuana for your medical purpose in accordance with your authorization. This document and/or ID card will serve as proof of your authority to possess marihuana for a medical purpose. You should have at least one of these documents with you at all times when you are in possession of the substance in case you are required to show proof to the police.

HOLDER OF AUTHORIZATION INFORMATION

NAME: [redacted]
ADDRESS:

MAILING ADDRESS: [redacted]

DATE OF BIRTH: [redacted]
GENDER: Male

TERMS AND CONDITIONS

The maximum quantity of dried marihuana that you may possess at any time under this *Authorization to Possess* is **180 grams**.

MEDICAL PRACTITIONER INFORMATION

NAME: [redacted]

EXPIRY DATE

Please note this *Authorization to Possess* expires on **December 15, 2011**. Should you wish to renew your *Authorization to Possess*, please submit your renewal application **at least 8 weeks prior** to your expiry date.

ISSUED BY:

Jeannine R. Ritchot, Director
Medical Cannabis
Office of Controlled Substances

DATE OF ISSUE:

DEC 15 2010

PLEASE READ ALL ENCLOSED DOCUMENTS CAREFULLY

ENCLOSED DOCUMENTS:

Information you should know about your *Authorization to Possess* dried marihuana

ID CARD AFFIXED HERE

c.c.: [redacted]

03/30/2011 08:07

[redacted]

CITY OF [redacted]
Office of the City Manager

[redacted]

08-103319-496
Health Canada / Santé Canada

January 29, 2008

FEB 04 2008

OCS / BSC

Marihuana Medical Access Division
Drug Stategy and Controlled Substances Programme
Healthy Environmerits and Consumer Safety Branch
Health Canada - 3503B
Ottawa, Ontario K1A 1B9

Dear Sirs/Mesdames:

I have responsibility for the implementation of the Surrey Crime Reduction Strategy. This is an holistic approach to dealing with matters that impact the incidence of crime in our City.

The City of [redacted] is committed to addressing the number of Marijuana Grow Operations in the municipality. To that end we have embarked on an innovative and to date, effective Electrical Fire Safety Initiative. This initiative teams fire officers, police and electrical inspectors who respond to reports of high levels of electricity use in residential settings to identify houses that may be used to cultivate Marijuana. The purpose of the inspections is to identify and remedy the inevitable disregard for electrical fire safety standards found in such establishments and the subsequent threat to public safety. Research has shown that the incidence of fire in a "Grow Op" is 24 times more likely than a normal home.

It has recently come to the notice of the teams that there is at least one (and maybe more) facility in [redacted] that has permission to grow Marijuana for medical purposes. I have researched the matter on your website but can find very little information on the licensing process. From a public safety perspective, the potential risks in a licensed "Grow Op" are similar to that of an unlicensed one. I would be grateful therefore if you can advise me of the following:

- What the licensing process entails?
- What safety advice or guidance is provided to those intending to grow Marijuana?
- How are the facilities monitored?
- What inspection process applies to such facilities to ensure compliance with any requirements?
- How is the existence of such a facility communicated to the Emergency Services in any given area?

Thank you for you consideration.

Sincerley,

[redacted]

Crime Reduction Strategy Manager

----- Original Message -----
From: [redacted]
Sent: 2009-12-16 01:55 PM EST
To: Ronald Denault
Cc: Diane Allan
Subject: Fw: [redacted] Permitted Grow Op
for OCS
----- Forwarded by Bruce Erickson/HC-SC/GC/CA on 2009-12-16 01:53 PM -----

[redacted]
2009-12-16 01:52 PM

To <bruce_erickson@hc-sc.gc.ca>
cc
Subject [redacted] Permitted Grow Op

Hi Mr [redacted]

I am the CAO here in the District of [redacted] and request some help with what is becoming a growing issue in one of my neighborhoods. The residence in question is at [redacted] and is rented by [redacted] who contends he has a legal permit to grow marijuana. This home is right in the middle of a young neighborhood and the smell is unbearable for the two neighbors. One of the neighbors operates a licensed daycare facility at [redacted]. The home that the grow op is located in, is an older double wide trailer so from a District standpoint we are unsure as to its electrical status under the code. I am not sure of our rights in this but it seems odd Health Canada would permit a grow op in a neighborhood and right next door to a licensed daycare facility. The neighbors have approached Mr [redacted] in regard to the smell and the number of cars going in and out at all hours but he is pretty defiant and always says he has a permit.

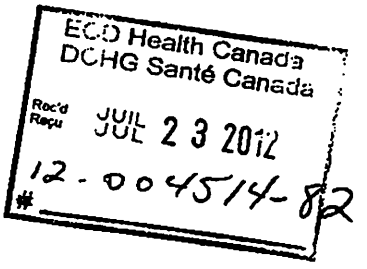
Anything you could do to help the District alleviate this problem would be helpful.

Regards

[redacted]

[redacted]
Chief Administrative Officer
[redacted]

[redacted]
the Mayor



July 13, 2012
Our File: [redacted]
Doc #:

Honourable Leona Aglukkaq
Minister of Health
Health Canada
Brooke Claxton Building, Tunney's Pasture
Ottawa, Ontario K1A 0K9

Dear Minister Aglukkaq:

RE: MEDICAL MARIHUANA ACCESS REGULATIONS

I am writing with regard to the adoption of the *Medical Marihuana Access Regulations* ("MMAR") enacted under the *Controlled Drugs and Substances Act.*

While the City of [redacted] understands the intention behind the adoption of the MMAR, this legislation has regrettably resulted in some adverse consequences for municipalities in Canada. More specifically, we believe that our community is now at greater risk of fires from medical marijuana production sites. Further, it is clear that both illegal and legal marihuana production facilities have the potential to attract crime, including violent crime.

I understand that the MMAR and associated program is currently under review by your Ministry. I also understand that some of the proposed improvements to the MMAR include developing a distribution system whereby marihuana would be supplied by licenced commercial producers, and the production of marihuana by individuals in homes and communities would be phased out. We certainly support the Federal Government's plan to revise the program to limit the potential for abuse and to mitigate the negative ancillary consequences associated with same.

In the interim, on behalf of Council for the City of [redacted] I am writing to request that the Federal Government amend the MMAR such that it becomes a requirement for those persons to whom a licence to produce medical marihuana, either for their own use, or for use by others, be required to notify local law enforcement as to the nature and location of their operations. With all due respect to any privacy issues that may arise, Council for the City of [redacted] believes that having local law enforcement fully apprised of the location of medical marihuana production facilities would assist in

[redacted] Office of the Mayor [redacted]
[redacted]

crime prevention and promote community safety, including the safety of those individuals who have been granted licences under the MMAR.

Thank you for considering this request.

Yours truly,

[redacted]

Mayor

c - Council, City of [redacted]
City Manager
Deputy City Manager

[redacted]

OFFICE OF THE MAYOR

December 28, 2012

The Honourable Leona Aglukkaq, P.C., M.P.
Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Dear Minister Aglukkaq:

The District of [redacted] is encouraged to learn of your government's plans to repeal the Marihuana Medical Access Regulations and replace them with the Marihuana for Medical Purposes Regulations. The District will be providing comments as part of the public review process prior to the February 15, 2013, deadline.

To the best of our knowledge and relative to the size of [redacted] in comparison with other municipalities, an exceptionally high number of Personal-use and Designated Person Production Licences for medical marihuana have been issued within the District of [redacted] It is our understanding that inspections of the licensed premises are not being done by federal government staff. District of [redacted] fire and bylaw inspections regularly determine that the licensed premises are growing more plants than licensed and that the growing is being performed in a manner that poses a fire risk to the licence holder and neighbouring homes and businesses. Based on complaints from neighbours, it is also clear that marihuana being produced at these licensed premises is not being used for personal use in many cases.

At their meeting on November 21, 2012, the Council of the District of [redacted] resolved to send a letter to the Minister of Health requesting that spot inspections be performed for premises that hold licences under the Marihuana Medical Access Regulations within [redacted] The District was very surprised to learn that limited or no inspections are being done. The federal government must recognize that they have an obligation to inspect these premises to ensure that they are in compliance with their licence requirements and to pass on any obvious safety concerns to the local and provincial governments.

The extensive lack of regard and abuse of the regulations makes a mockery of the federal government's process but more importantly presents a safety risk to neighbouring residents and businesses as well as emergency response officials and is causing untold frustration and harm to our community. The District recognizes the validity of the use of medical marihuana in certain circumstances but certainly not with the associated risks that are present in our community today as a result of the complete disregard for the federal regulations and local and provincial building and electrical safety regulations. I do recognize that the proposed regulations will, to a large degree, address the District's concerns, but these concerns will remain for at least another year.

[redacted]

It is important to note that inspections will also be needed during the transition period should the new regulations be enacted to ensure that the previously licensed operations are fully decommissioned. We expect that many of the operations will continue as illegal operations and recommend that the RCMP be allocated additional time-durated resources to deal with the continuing illegal operations. In the interim, I implore you to please provide the necessary resources to carry out frequent and comprehensive inspections of the licensed premises. District staff would be willing to work collaboratively with Ministry staff to ensure that those who need marihuana for legitimate medical purposes can produce the required amounts while not putting the rest of the community at unnecessary risk.

I would also like to add that many of these licensed premises are operating within commercial and industrial areas of [redacted]. While the District is taking action under its zoning bylaw, many medical marihuana license holders do not recognize the legitimate authority that the District has to regulate land use, i.e., where the licensed medical marihuana operations must operate in compliance with the zoning bylaw. It would be very helpful if the federal government would remind licence holders that they may be subject to other government regulations and that they must check with their local government prior to commencing operations to determine any additional applicable requirements.

I would also like to point out that the demands for electricity from exceedingly large marihuana grow operations, some licensed and some not, have caused power outages that have left these legitimate businesses without the ability to function and meet their customers' orders. In addition, the associated odour and safety concerns are affecting legitimate neighbouring commercial enterprises. Given [redacted]'s need to attract new legitimate commercial and industrial business, there is no desire on behalf of the Council of [redacted] to accommodate licensed medical marihuana grow operations within commercially or industrially zoned areas under the current regulations.

I would be pleased to discuss these issues in more detail with you or your staff and invite you to come to [redacted] to speak to residents and business owners that are affected by the non-compliant licensed grow operations. I would appreciate a formal written response to this letter that I can share with Council and senior staff.

Yours truly,

[redacted]

MAYOR

cc: The Honourable Margaret MacDiarmid, Minister of Health

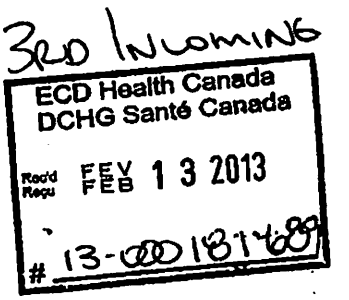
[redacted]

[redacted]

[redacted]

OFFICE OF THE MAYOR

File: [redacted]
Ministry of Health



February 5, 2013

The Honourable Leona Aglukkaq, P.C., MP
Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Dear Minister Aglukkaq:

Re: Proposed Marihuana for Medical Purposes Regulations

The District of [redacted] has reviewed the proposed Marihuana for Medical Purposes Regulations and requests that the following comments be considered prior to finalizing the regulations:

- The District is in general support of the proposed approach. In particular, the abandonment of individual and designated producer licenses and the need to notify local police and fire forces and the local government of the location of licensed producer operations is a positive change.
- The District believes that no new individual or designated producer licenses should be given out prior to the new regulations being enacted. The significant investment required by license holders for a short time until their license expires will likely result in many of these operations remaining active after the new regulations are enacted leading to public safety and enforcement issues for our community for years to come.
- There is a need for inspections of all expiring existing licenses to ensure the production of marihuana has ceased. This should include provision of existing personal and designated license holder information (name and address) to the local detachment of the RCMP as well as additional time-durated resources for the RCMP to perform follow-up inspections once the new regulations are enacted.
- There is a need to ensure potential licensed producers are aware that they will also be subject to provincial regulations (e.g., Building Code, Fire Services Act, Electrical Safety Act) and local government regulations (e.g., Zoning Bylaw, Business Licensing Bylaw, Building Bylaw, Water and Sewer Bylaws). At the very least, the federal government's cover letter for future licenses needs to include a statement that license holders must check with their provincial and local governments to ensure compliance with all applicable legislation. It would be preferred if the local government was involved in a formal referral process for new licenses (see next bullet).

[redacted]

- A referral process from the federal government to the local government in advance of issuing new licenses should be instituted to ensure the licensed producer is aware of all local government requirements.
- The new regulations must be accompanied by adequate resources to support a comprehensive compliance and enforcement inspection program that includes notification of the local and provincial government officials of suspected non-compliance with any applicable regulations.
- New licensed producers must be able to demonstrate that an adequate electrical supply is available without the risk of affecting electrical supply to nearby residences and businesses.
- The new regulations must include good production practices to ensure nuisance factors such as odours, noise and light from their operations does not affect neighbouring residences and businesses.

I would like to congratulate your government on making the changes necessary to ensure that the production of marihuana can be carried out in a way that protects communities and treats marihuana like any other pharmaceutical product. I trust that you will consider the comments supplied here and adjust the regulations as necessary to ensure that the current issues associated with the production of marihuana in our community are prevented from occurring under the new regulations. Thank you for considering our comments, please contact the undersigned with any questions.

Yours truly

[redacted]

MAYOR

cc: [redacted]

[redacted]

BRITISH COLUMBIA

DEC 2 9 2012

[redacted]

Dear Mayor [redacted]:

I am writing further to our meeting on September 27, 2012, at the 2012 Union of British Columbia Municipalities (UCBM) Convention when you spoke about your concerns regarding medical marijuana growing in your community. I will take up your concerns with my federal counterpart, The Honourable Leona Aglukkaq, Minister of Health, at the next available opportunity.

During our meeting you also expressed some concerns regarding escalating costs for the First Responder services provided by the [redacted] Fire/Rescue Service.

As you know, participation in the First Responder program is voluntary and municipalities can determine the extent of their participation. That being said, we are always looking for ways to improve the efficiency of response resources while maintaining high quality care and patient safety.

For further discussion regarding the Emergency & Health Services Commission's First Responder program, I encourage you to contact [redacted]

Thank you and your colleagues for meeting me at the 2012 UBCM Convention and raising these important issues.

Yours truly,

Original
Signed by

Margaret MacDiarmid
Minister

pc: The Honourable Leona Aglukkaq
[redacted]

Ministry of Health
Office of the Minister
Mailing Address:
PO Box 9050 Stn Prov Govt
Victoria BC V8W 9E2
Location:
Parliament Buildings
Victoria

Re: MMAP [redacted]
to:
MMAP-PAMM
2012-01-01 10:02 PM
Cc:
[redacted]
Show Details

Dear Stephane Lessard

Thank you for your last e-mail reply dated Dec. 9th.

Based on the general tone and theme of your response(s), it is clear that your department and Health Canada generally are either unable or unwilling to deal with the concerns and issues expressed in my previous corresondence(s), relative to the marijuana grow op. located at [redacted] B.C. Consequently, it is my intention to focus on a more proactive approach.

1) I have discussed this situation with a couple of local real estate agents, who have confirmed that the market value of my home could be impacted by the existence of the marijuana grow op next door, likely making it difficult to sell for full value. Consequently, as an interm measure, I plan to appeal to the B.C. Assessment Corporation in Victoria, to re-evaluate my property assessment for municipal property tax purposes.

2) I have consulted with a lawyer, for the purpose of exploring other options, and to lay the groundwork for seeking financial compensation from Health Canada for loss of property value when the time comes to sell my home, including possible recourse for "public nuisance".

3) Bring attention to the Provincial Fire Marshall, the electrical safety concerns at [redacted] (expressed in my previous correspondence) for the purpose of enforcing the Safety Standards Act (S.B.C. 2003) which authorizes the entry and inspection of residential premesis for the regulatory purpose of inspecting electrical systems for safety risks, that may be related to marijuana grow ops.

4) Finally, I am taking my concerns to our local Member of Parliament [redacted] not to criticize the intent of the Medical Marijuana legislation, but to question Health Canadas administration of the program, specifically for allowing marijuana grow operations in residential areas, with no apparent oversight or supervision, and the governments insensitivty to municipal licences and community covenants, in the case of apparent commercial operations.

Thank you again for your attempt to deal with my concerns on this troubling issue. The toll free telephone number you offered in the last paragraph of your e-mail mssg. for additional help, is simply a call centre, which was my starting point over three months ago.

Sincerely,

[redacted]

C.C. (with appropriate covering letter)

- [redacted]

- Mayor and Council, Municipality of [redacted]
- Fire Marshall, Prov. of B.C.
- President, [redacted] Community Association
- RCMP, [redacted] Detachment

----- Original Message -----
From: MMAP-PAMM <MMAP-PAMM@hc-sc.gc.ca>
Date: Friday, December 9, 2011 10:49 am
Subject: MMAP
To: [redacted]
Cc: [redacted]

> Dear Mr. [redacted]
>
> Thank you for your
> email of November 21, 2011, regarding your
> concerns about a production site of marihuana for medical
> purposes.
>
> I appreciate the time
> you have taken to express your views and
> concerns with the Marihuana Medical Access Program (MMAP);
> however, due to
> privacy concerns, I can not directly discuss or disclose
> information about
> the location discussed in your letter. I assure you that we take
> your
> concerns seriously. The information you have provided is
> particularly
> relevant given the upcoming reform of the MMAP. I will forward
> your
> request to the appropriate Health Canada officials for their
> consideration.
>
> Health Canada
> officials will consider your request for an
> inspection in the context of the Marihuana Medical Access
> Regulations
> (MMAR) and may contact you for further information. As stated
> previously,
> the activities described may be subject to law enforcement
> action if
> marihuana is being produced outside of the scope of a licence to
> produce.
>
> To assist law
> enforcement officials in the course of an
> investigation, in accordance with section 68.1 of the Marihuana
> Medical

> Access Regulations (MMAR), the Program offers a 24-hour secure
> pager line
> for law enforcement officials to assist in validating
> information that is
> authorized to be communicated to a Canadian police force.
>
> The police pager line
> is strictly for the use of police officers
> who are requesting the information in the course of an
> investigation under
> the Controlled Drugs and Substances Act (CDSA) or its
> regulations. The
> limited information can only be used for the purpose of that
> investigation
> and the proper administration or enforcement of the CDSA or
> associated
> regulations.
>
> Should you have any
> additional concerns, please contact the MMAP
> at mmap-pamm@hc-sc.gc.ca or toll-free at 1-866-337-7705.
>
> Sincerely,
>
> Stéphane Lessard
> Director
> Bureau of Medical Cannabis
> Controlled Substances and
> Tobacco Directorate
> Healthy Environments and
> Consumer Safety Branch
> Health Canada

Medical Marijuana drug factories
[redacted] to: Minister_Ministre 2012-07-05 05:57 PM

From: [redacted]
To: Minister_Ministre@hc-sc.gc.ca

Below is the result of your feedback form. It was submitted by [redacted] on Thursday, July 05, 2012 at 17:57:08

---

firstname: [redacted]

lastname: [redacted]

email: [redacted]

address:

city: [redacted]

province: BC

country: Canada

postal_code: [redacted]

subject: Medical Marijuana drug factories

comments: We dearly love our little neighborhood in [redacted]
But, we have a big problem. We have been struggling to find a solution for this situation.

Four years ago, a family bought a house we built many years ago for our neighbor s sister, [redacted]. Unfortunately, they sold , a new family bought the house and started an indoor marijuana grow op. This is no small operation. They are known cocaine and Ecstasy dealers also. The RCMP busted them for a large quantity of marijuana and cash two years ago. They have never quit growing it because they got a doctor s prescription for medical marijuana and started growing it twice as much while they were waiting to go to court. Then, they were busted again for too many medical marijuana plants in their grow op last year. They secured other licenses to grow more medical marijuana. After they went
to trial last month, their lawyer got them off because they said their rights were being discriminated against because the trial did not take place in a timely way. This is beyond ridiculous. Every day, we see people coming to the house to purchase drugs.

We have this drug factory in a normally great neighborhood with kids and families. One of these young families is thinking of moving because of the gangster activity associated with this drug house. Zoning bylaws in the lower mainland have been very effective in moving this kind of activity to an industrial site. This drug factory, medical marijuana or not, has never been inspected by anyone. They have young children living in the house. Could you please give this some consideration and get back to us.

Best Regards,

[redacted]

[redacted] BC

[redacted]

realname:

Department of Justice Canada | Ministère de la Justice Canada

AUG 16 2012

[redacted]

Dear Mrs. [redacted]:

On behalf of the Honourable Rob Nicholson, Minister of Justice and Attorney General of Canada, I acknowledge receipt of your correspondence concerning Mr. [redacted]

I hope you will understand that, as Minister of Justice and Attorney General of Canada, Minister Nicholson cannot comment on a specific case.

The issue of medical marijuana falls under the purview of the Honourable Leona Aglukkaq, Minister of Health, to whom I note you have sent a copy of your correspondence.

In your correspondence, you indicate that you have already contacted your local police, which is the appropriate course of action if you have reasonable and probable grounds to believe that a crime has been committed. If you believe you are in immediate danger, you should continue to communicate with them. It is for the police to investigate the matter further and lay charges where appropriate. Please note that Minister Nicholson has no authority over police forces and cannot request an investigation on your behalf.

Thank you for writing.

Yours sincerely,

[redacted]

L. Bisson
Manager
Ministerial Correspondence Unit

c.c.: The Honourable Leona Aglukkaq, P.C., M.P.
Minister of Health and
Minister of the Canadian Northern Economic Development Agency

R12- 015567.

MCUED7

140011

*Summary Report + Att.

Attorney General of Canada
239 Wellington Street
Justice Building
Ottawa, ON
K1A 0H8

Dear Attorney General of Canada:

I recently came across [redacted]'s appeal to the Minister of Health denying him the right to open and run a Compassion Club, the power to license people who require medicinal marihuana as well as the right to operate a privately owned medicinal marihuana growing establishment. On behalf of myself and my neighbours, we commend you on your wise decision and implore the Minister not to reverse her decision and to keep denying Mr. [redacted] the permit to ruin countless innocent lives by operating an illegal marihuana distribution centre in our neighbourhood.

[redacted], who lives at [redacted] ON, has been smoking marihuana for most of his teenage life and all of his adult life. He is a convicted felon and has been charged numerous times for drug possession as well as drug trafficking. He hides behind his license to smoke marihuana and because of that license, the local police as well as the RCMP cannot arrest him for his illegal activities.

Mr. [redacted] often brags about his drug exploits and told me that the reason why he got his license in the first place was because of his asthma, however, last year, he told me it was to forget the sexual abuse he had suffered as a child. He is looking for any reason to be given a license to legally pursue his illegal habits. Personally, I don't think that asthma should be on the list of diseases which require medicinal marihuana. My husband suffers from asthma and if anything, the smell of Mr. [redacted]'s skunk grass is enough to trigger an asthma attack. My husband is also able to manage his asthma through the use of prescription drugs such as Singulair and Simbicort. Why can't Mr. [redacted] do the same? Every time he smokes his drugs, he literally coughs up a lung to the point where he often vomits in his yard. The skunk grass is obviously not helping his condition but he insists that it does because all he wants to do is smoke up on a regular basis.

Mr. [redacted] also told me that the first doctor who had signed for him to get his license did not want to renew his license because he thought that Mr. [redacted] had become psychotic because of all the drugs he had smoked. He smokes so many drugs that his mouth and teeth are permanently stained a yellowish brown. Last year, when my husband built a fence between our yard and his, while he watched my husband work, Mr. [redacted] smoked eight joints during the eight hours it took my husband to erect the fence. Is his asthma that unmanageable that he must smoke so much drugs? We have often seen Mr. [redacted] light up a joint then drive away in his car. There are laws against drunk driving, why aren't there laws against drugged driving? He is permanently high which makes him a dangerous driver.

Over the years, Mr. [redacted] has become an aggressive neighbour. He is often heard cursing and using foul language when addressing the neighbours as well as the workers who work in his marihuana grow-op. We live in constant fear of what he might do to us and our properties. There have been several incidents of sabotage to people's homes and yards in the past two years and Mr. [redacted] admitted to my husband that he had hired teenagers to perform one of those deeds to our elderly neighbours' house. Some of the neighbours have had to install surveillance cameras on their houses because they are afraid of what Mr. [redacted] and his "friends" will do. We live in a very stressful environment which is definitely detrimental to our mental health.

When Mr. [redacted] first moved into the neighbourhood six years ago, his intention was to increase the size of his small bungalow. His building permit stated that the structure was to be a single family dwelling but no family resides there. His family lives with his parents, who are the owners of the property, and the building is primarily a business. During the renovations, no one had any idea that he was building, according to the RCMP, the biggest grow-up in the city of [redacted] and from that point on, our neighbourhood would be polluted with the nauseating smell of skunk grass on a daily basis, not to mention the increase in traffic on our street and criminals in our area.

If Mr. [redacted] wanted to operate a grow-op, why did he establish himself in a residential area? There should be by-laws against that. His illegal business has depreciated the value of every home of every honest working citizen in this area. Some neighbours have tried to sell but to no avail. Would you want to live next door to a marihuana grow-op? I have included pictures of his grow-op so that you may see what it looks like. Would you want to live nextdoor to this? Up until about four months ago, the building didn't even have any windows. The whole top floor contains marihuana plants and most of his backyard is being cultivated as well.

We know for a fact that Mr. [redacted] is distributing drugs to other people for we have recognized certain "visitors" at his establishment and know them to be habitual drug users. He does not grow for only his common-law wife and himself. He would not need a whole top floor full plus a backyard full of plants if he were supplying only himself and his common law wife who also has a license to smoke.

Mr. [redacted] has no job and spends most of his time working in his grow-op along with several workers. How can he afford to light and heat such a big building and how can he pay his workers? I don't believe that the men who work there do it out of the goodness of their hearts. No one works for nothing. Where does he get his money? If you lived next door to him, you would easily be able to answer that question after seeing the numerous people go quickly in and out of his dwelling during all hours of the day and night. What goes on there is very obvious.

Cars with American license plates were often seen at his house last fall and this past winter. It would seem that Mr. [redacted] is also involved in cross-border activities.

After contacting Health Canada and asking who is responsible of monitoring medicinal marihuana grow-ops, we were told that it was the local police, however, after speaking with the local police, they said that Health Canada had that responsibility so in other words, no one is keeping an eye on this situation and there are many illegal drug operations going up across the country because everyone seems to be passing the torch. We are also concerned about the possiblity of black mold which is very common in such establishments. Is that not dangerous for everyone living near the substance? Should there not be an authorized person verifying for black mold in marihuana grow-ops to ensure everyone's safety? Black mold could also make Mr. [redacted]s asthma worse, hence his heavy use of drugs.

Ever since Mr. [redacted] has moved into our neighbourhood, his presence has put an incredible strain on everyone. We want him to leave and take his grow-op and ex-cons with him. We should not have to suffer with the unbearable stench as well as Mr. [redacted]'s aggression. We live in fear and we shouldn't have to. Our neighbourhood was perfectly tranquil until he came to live here which is one of the reasons why we beg that you do not reverse your decision to deny him the power to grow and distribute medicinal marihuana to others and please allow the RCMP to shut down and destroy his grow-op.

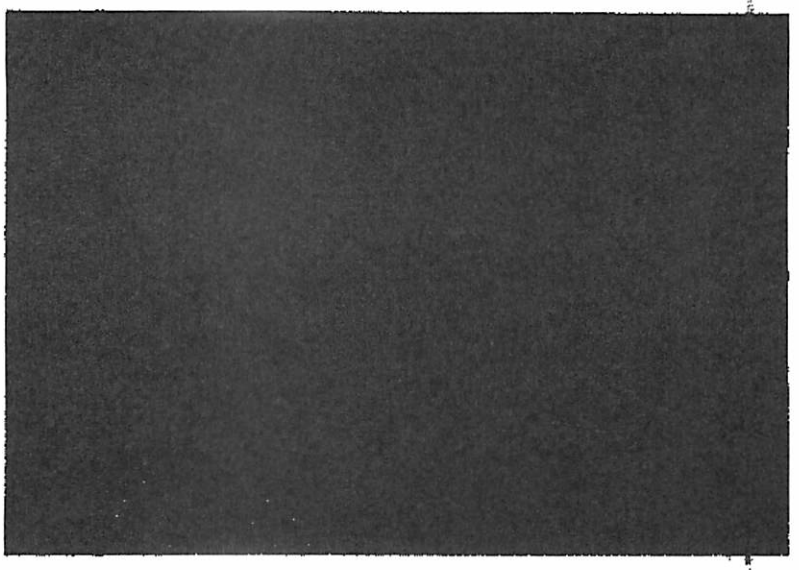
I would also ask that this letter remain confidential for fear of what Mr. [redacted] could do to me, my family, and my property for we live in fear of him and his associates.

Sincerely,

[redacted]

cc The Honourable Leona Aglukkaq, P.C., M.P.
Stéphane Lessard, Director of the Bureau of Medical Cannabis

[redacted] making a mockery of Health Canada's medicinal marihuana licenses



Here is a picture of [redacted] taken from his MySpace site on the internet. [redacted] is seen here smoking a huge joint in the days before he even possessed a medical marihuana licence.

Since Mr. [redacted] has been living at [redacted] he has had a total of three grow-ops.

The first one was in a motorhome in his backyard about five years ago.

The second was in a shed he built in his backyard . He used this one for approximately two years after the motorhome.

The final grow-op is the house which you see in the picture which accompanies this letter.

This is **Exhibit " E "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

About Health Canada

Government of Canada Considers Improvements to the Marihuana Medical Access Program to Reduce the Risk of Abuse and Keep our Children and Communities Safe

News Release
2011-80
June 17, 2011
For immediate release

Backgrounder: Marihuana Medical Access Program

OTTAWA - To reduce the risk of abuse and exploitation by criminal elements and keep our children and communities safe, the Honourable Leona Aglukkaq, Minister of Health, today announced that the Government of Canada is considering improvements to the Marihuana Medical Access Program.

"Our Government is very concerned that the current Marihuana Medical Access Program is open to abuse and exploitation by criminal elements," said Minister Aglukkaq. "That is why we are proposing improvements to the program that will reduce the risk of abuse and keep our children and communities safe, while significantly improving the way program participants access marihuana for medical purposes."

The Government is launching public consultations today with Canadians on the proposed improvements. A consultation document has been posted on the Health Canada website which contains the proposed improvements. Interested Canadians are invited to provide comments until July 31, 2011. Input from these consultations will be considered in the development of new regulations, which Canadians will again have an opportunity to comment on when the proposed regulations appear in *Canada Gazette*, Part I, in 2012.

"These proposed improvements reflect concerns we have heard from all kinds of Canadians including law enforcement, fire officials, municipalities, program participants and the medical profession," said Minister Aglukkaq.

It is important to note that the legalization or decriminalization of marihuana is not a part of these improvements. Marihuana will continue to be regulated as a controlled substance under the *Controlled Drugs and Substances Act*.

Until improvements to the program are in place, the process for applying for an authorization to possess and/or a license to produce marihuana for medical purposes under the *Marihuana Medical Access Regulations* will remain the same.

Canadian Courts have established that individuals who have demonstrated a medical need for marihuana have a right under the *Canadian Charter of Rights and Freedoms* to possess and access a legal supply of marihuana. In recognition of a need for a process to provide seriously ill Canadians with access to marihuana for medical purposes, the Government introduced the *Marihuana Medical Access Regulations* in 2001. Activities including possession, production and trafficking of marihuana other than as authorized under the regulations remain illegal.

The consultation document, "Proposed Improvements to Health Canada's Marihuana Medical Access Program", is available online.

A summary of the proposed changes can be found in the attached backgrounder.

-30-

Media Enquiries:
Health Canada
(613) 957-2983

Cailin Rodgers
Office of the Honourable Leona Aglukkaq
Federal Minister of Health
(613) 957-0200

Public Enquiries:
(613) 957-2991
1-866 225-0709

Date Modified: 2011-06-17

This is **Exhibit " F "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

Health Canada Santé Canada

Canada

Drugs and Health Products

Medical Marihuana Regulatory Reform 2011 Consultations Results

In recent years, a wide range of stakeholders including police and law enforcement, fire officials, physicians, municipalities, and program participants and groups representing their interests, have identified concerns with the current Marihuana Medical Access Program (MMAP).

To address these concerns, an online and in-person consultation process was launched between June - November 2011, to gather comments from interested parties on the proposed improvements to the Program. Input from these consultations will be considered in the development of new regulations.

Here's what they said:

Introduction

Background

On June 17, 2011, in response to concerns heard from Canadians, the Minister of Health announced that she is considering improvements to Health Canada's Marihuana Medical Access Program (the Program). The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep our children and communities safe, while significantly improving the way program participants access marihuana for medical purposes.

Health Canada also launched public consultations on the proposed improvements. A consultation document was posted on the Health Canada website which outlines the proposed improvements.

This report serves as a summary of the key themes heard during that consultation process.

The improvements under consideration

See more information on the proposed improvements to the Program.

Who was consulted?

Between June and November 2011, Health Canada consulted with key stakeholders to get their views on the proposed changes and to gain information and knowledge to inform the development of new regulations. Stakeholder groups included:

- authorized and licensed individuals under the current Program;
- compassion clubs and cannabis dispensaries;
- provincial and territorial ministries of health and of public safety;
- physicians, including medical associations and colleges of physicians and surgeons;
- municipalities;
- law enforcement officials;
- fire officials;
- pharmacists; and
- Canadians with an interest in the Program.

The Results

1. Physician - patient interaction

Health Canada's proposal maintains that individuals would still be required to consult a physician to obtain access to marihuana for medical purposes. However, categories of conditions and symptoms would be eliminated. Therefore, there would no longer be a requirement for some individuals to obtain a specialist assessment in addition to their primary care physician in order to access

marihuana for medical purposes. The existing medical declaration would be replaced by a simpler document provided by the physician to the individual.

In response to physicians' request for more information about the use of marihuana to support their patients, Health Canada is consulting with experts in the medical and scientific communities on ways to improve physicians' access in obtaining comprehensive, accurate, and up-to-date information on the use of marihuana for medical purposes.

The role of physicians

All stakeholders welcomed efforts to improve physicians' access to information on the use of marihuana for medical purposes. Program participants, physicians and medical associations indicated that improving access to such information may be helpful in ensuring that physicians are better informed when discussing the use of marihuana for medical purposes as a treatment option.

Clinical guidelines on the use of marihuana for medical purposes, information on potential therapeutic indications and information on the evaluation of potential risks and benefits of marihuana for medical purposes were all identified as principal areas where physicians would like more information.

Categories of conditions and symptoms

The removal of categories of conditions and symptoms is considered a positive step toward improving the application process for program participants, particularly those who have stated that the requirement to get a specialist assessment can take a significant amount of time. Medical associations indicated that, in the absence of regulated categories of conditions and symptoms, they would like to continue to work with Health Canada to develop guidelines that could assist physicians in making informed decisions with respect to the use of marihuana to treat particular symptoms and/or conditions.

The potential role of other healthcare practitioners

Some stakeholders suggested that the list of health care providers who can support an individual's request to use marihuana for medical purposes should be expanded. Suggestions included nurse practitioners, pharmacists, naturopaths, herbalists, practitioners of traditional Chinese medicine and chiropractors.

2. Patient access

Under the proposed redesigned program, individuals would no longer be required to apply to Health Canada to obtain an authorization to possess marihuana for medical purposes. Nor would Health Canada continue to issue personal-use production licenses (PUPLs) or designated person production licenses (DPPLs) to individuals. These forms of production would be phased out. The only legal source of dried marihuana would be licensed producers, which would be licensed by Health Canada to produce and distribute dried marihuana by registered mail or bonded courier.

Application process

All stakeholders welcomed the streamlined process in which Health Canada no longer receives applications or collects personal medical information from program participants.

The establishment of licensed producers and the phasing out of personal and designated production

Federal and provincial public safety officials, municipalities, law enforcement, and fire officials have, in the past, cited a number of serious public health and safety concerns with personal and designated production, including:

- the potential for diversion of marihuana produced for medical purposes to the illicit market;
- the risk of home invasion due to the presence of large quantities of dried marihuana or marihuana plants;
- public safety risks, including electrical and fire hazards, stemming from the cultivation of marihuana in homes;
- public health risks due to the presence of excess mould and poor air quality associated with the cultivation of marihuana plants in homes.

These stakeholder groups indicated that the proposed phase-out of personal and designated production would address their concerns regarding public safety, security and public health risks. Law enforcement representatives indicated that the proposed changes would greatly reduce the potential for diversion of marihuana for medical purposes to the illicit market.

All stakeholders agreed that the public health, safety, and security of residential neighbourhoods and the mitigation of risks associated with personal and designated production are important objectives. However, many current program participants suggested that Health Canada consider strengthening inspection processes for those individuals who hold a PUPL or a DPPL, rather than eliminating personal and designated production. Many stakeholders also agreed that licensed operations would allow for greater regulation and control of production through zoning and by-laws.

Distribution

All stakeholders agreed that it is necessary to ensure a secure means of distributing dried marihuana to individuals who use it for medical purposes. Many stakeholders groups requested that Health Canada consider distribution through pharmacies, as pharmacists have extensive knowledge and experience in dispensing therapeutic products. Absent the potential for pharmacy distribution, the majority of stakeholders agreed that distribution of dried marihuana directly to individuals by mail is a secure option as it reduces the potential number of points for diversion. Some stakeholders, particularly law enforcement and representatives of local governments, noted that some citizens may express discomfort with the idea of establishing store-front entities specific to the distribution of marihuana in their communities.

Compassion clubs and cannabis dispensaries asked that Health Canada consider inclusion within the regulatory framework of an option for store-front, community-based dispensaries. They believe that such entities could play an important role in providing education and outreach to individuals who use marihuana for medical purposes.

Dried marihuana only

As in the current program, dried marihuana would be the only product permitted for production, sale and distribution under the proposed new regulations. Due to the unknown health risks associated with products such as cannabis oils, extracts, creams, and edibles, many stakeholders supported the status quo of dried marihuana to other products. On the other hand, compassion clubs and cannabis dispensaries, as well as most program participants, asked that Health Canada consider allowing other forms of products, most notably edibles and extracts.

3. Proof of legal possession

Under Health Canada's proposed improvements, program participants would no longer be required to submit information to Health Canada in order to be authorized to possess dried marihuana. Individuals would no longer receive an authorization to possess or an identification card from Health Canada.

Identification cards

Individuals who use marihuana for medical purposes and law enforcement see the value of an identification card as a convenient means by which to demonstrate that an individual is in lawful possession of marihuana. These stakeholder groups are in agreement that as long as another method to prove lawful possession is determined through this process, the card itself would not be necessary. However, these stakeholders noted the importance of Health Canada advising law enforcement agencies about the mechanism by which patients will be able to demonstrate proof of possession.

4. Licensed production

In order to be licensed by Health Canada, licensed producers would have to demonstrate compliance with requirements related to, for example, product quality, personnel, record-keeping, safety and security, disposal and reporting, as set out in new proposed regulations. These controls would aim to ensure the quality of the product being purchased by program participants, as well as the security of production sites.

Licensed producers would be permitted to produce marihuana indoors and would be able to produce any strain(s) of marihuana.

Cost and choice for patients

Program participants considered the availability of multiple strains a significant improvement to the program. However, they are concerned that the transition to licensed production will render the price of marihuana more costly, given that licensed producers will have to take their overhead costs and profit margins into account when pricing their products. Some individuals also expressed concerns that marihuana may not be covered under provincial and private drug plans. To address these issues, some stakeholders suggested that Health Canada explore means to regulate the price of dried marihuana for medical purposes

Regulatory requirements for licensed producers

All stakeholders welcomed clear regulations that outlined requirements for licensed producers; however, some parties interested in becoming licensed to produce commercially highlighted that requirements should not be so complex that only large businesses could become licensed.

Complying with municipal zoning bylaws and building codes was viewed by all stakeholders as a necessary step to securing a commercial production licence. Municipalities emphasized that it would be important for interested parties to obtain applicable municipal authorization to operate before applying to Health Canada for a commercial production licence. Municipalities, fire officials, law enforcement and potential licensed producers agreed that production sites should not be publicly disclosed, but should be known by municipalities and first responders for inspections and public health and safety reasons.

Conclusion

Overall, the proposal to create a regulated industry is well received, though some program participants have asked that Health Canada consider allowing them to maintain their personal and/or designated production licenses. All stakeholders are supportive of elements of the proposal that would improve and simplify the application process for participants. Finally, there is widespread support for measures that Health Canada could undertake to increase outreach and information for physicians.

Next steps

Input from these consultations is being considered in the development of new regulations, on which Canadians will again have an opportunity to comment when the proposed regulations appear in *Canada Gazette*, Part I, in 2012.

Date Modified: 2013-01-31

MMAP Targeted Consultations – Canadian Association of Fire Chiefs

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and November, 2011.

Current Status

On September 27, 2011, representatives from Health Canada met with representatives of the Canadian Association of Fire Chiefs (CAFC), during the organization's Annual General Assembly, in Calgary, Alberta. The CAFC's President, First Vice President, Second Vice President, and the President of the Fire Prevention Officers Association of British Columbia were present.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Questions posed by Health Canada to meeting participants.

Overall, Health Canada's recommendation to create a regulated industry was well received. Fire officials expressed that the proposal alleviates their concerns regarding the fire hazards and public health risks associated with personal production sites. Concerns were expressed regarding a lack of detail in the proposal, although Health Canada noted that consultations with stakeholders were fundamental to being able to determine the details required for the new regulations. Specific concerns relate to a need for a strengthened inspection regime in the interim, and for a strong remediation program to address the residual effects of personal production in sites used for this purpose (ie. mould, chemical contamination, etc) once the new program is in place.

Positive Elements of the Proposal

- Overall agreement with the need for a regulated industry with inspection and compliance components.
- The elimination of personal and designated-person production in residential areas.
- Inspections ensuring quality of product, safety and efficacy of growing procedures.
- The ability to regulate commercial entities through local by-law and zoning regulations.

- Mail-order delivery removes the centralization of crime and stigmatization of neighbourhoods that may result from dispensaries for the sole purpose of marihuana distribution.
- Willingness of Health Canada to continue to engage with key stakeholders through out the regulatory process.

Key Concerns

- The timelines for reform leave a significant period of time where CAFC concerns and challenges with the current program will not be addressed. CAFC representatives are looking for interim measures, such as:
    - Guidelines on safe growing conditions that are sent to all PUPL and DPPL upon application or renewal.
    - Increased communication with fire officials regarding the location and size and scope of personal and designated person production sites. One question in particular was whether or not law enforcement, with whom the program can share information under certain circumstances (i.e. an investigation), can share information that they obtain from Health Canada with them, for the purposes of collaboration.
- The elimination of PUPL and DPPL is welcomed, but questions were raised regarding remediation standards for those dwellings that are currently used as growing sites – the public health and public safety risks will continue after the program sunsets (ie mould spores, pesticide contamination, etc). Specifically, questions were raised regarding whether or not Health Canada has a responsibility to remediate, and what it plans to do in this regard.
- Regulations could push commercial entities into 'unorganized territories' – ie. regions with no/unclear municipal authority – to avoid compliance with municipal regulations. CAFC recommended writing municipal authority into the new MMAR to address these gaps (ie. subject to municipal inspections before applying to Health Canada for commercial licence).

Other Points

- Representatives from the CAFC recommended that Health Canada put together a multi-stakeholder working group (ie. Fire officials, law enforcement and municipal representatives in by-law and zoning) to focus on the public safety and security issues moving into reform and to assist in the development of the regulations.

Next Steps

Health Canada representatives will meet with representatives from the Canadian Association of Chiefs of Police and the Royal Canadian Mounted Police on October 12. An analysis of these consultations will then be written and incorporated in to final reform package.

MMAP Targeted Consultations – Law Enforcement

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and November, 2011.

Current Status

On October 12, 2011, representatives from Health Canada met with representatives of the Royal Canadian Mounted Police (RCMP) and Canadian Association of Chiefs of Police (CACP) at the RCMP headquarters in Ottawa.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Questions posed by Health Canada to meeting participants.

Overall, Health Canada's recommendation to create a regulated industry was well received. Law enforcement officials expressed that the proposal alleviates their concerns regarding the public health and safety risks associated with personal production sites. Representatives noted the proposed framework may be vulnerable to infiltration by organized crime if proper security controls are not in place. However, they also acknowledged that licensed commercial production would greatly reduce the chances that criminal elements will be successful in gaining access to this framework. Other concerns relate to a need for a strengthened compliance and enforcement regime in the interim and for a strong communication channel between law enforcement and Health Canada when the current program sunsets to ensure that individuals with production licenses will cease producing marihuana.

Positive Elements of the Proposal

- The elimination of personal and designated-person production in residential areas is seen to greatly increase safety in communities.
- The location of licensed commercial producers would be known to local governments and first responders.
- Overall agreement with the need for a regulated industry with inspection and compliance components.
- Willingness of Health Canada to continue to engage with key stakeholders throughout the regulatory process.

Key Concerns

- While the chances of organized crime becoming involved in the new framework were deemed to be greatly reduced, law enforcement remains concerned that licensed commercial production could potentially be used as a front through which to divert product to the illicit market. Participants expressed there were a number of points in the authorization/production process that this could happen:
    - Authorization process (ie. physician support) will be difficult to monitor. Physicians will face increased pressure to support patients' access to marihuana for medical purposes. Patients could then divert what they purchase from producers to the illicit market.
    - If there is no cap on the amount to be purchased, this would likely attract organized crime – recommend that regulations include a capped amount.
    - Product labelling could be easily counterfeited – representatives prefer that some type of government ID continue to be issued so that law enforcement knows who can lawfully possess marihuana. .
- Concerns regarding the THC level – cited the Netherlands are re-examining their non-enforcement and have categorized marihuana containing THC over 15% as a 'hard drug' such as heroine and cocaine. Recommended that consideration be given to capping THC levels for LCPs.
- Transition to the new program will be challenging from a law enforcement perspective.
    - How will Health Canada communicate with all the licence holders to inform them of the process for phase out of PUPL and DPPL?
    - How will Health Canada handle licence renewals close to the sunset of the current program?
    - How will Health Canada ensure that personal-use and designated-person producers cease to produce once the program sunsets?
    - What will be the inspection regime upon the sunset of the program?

Questions

If HC were to reconsider small-scale, personal production of marihuana in private dwellings, what program elements would increase your level of comfort?

- Unanimously, participants agreed that personal production should not be continued.
- Concerns with PUPL and DPPL include:
    - Lack of ability to inspect;
    - Most vulnerable to organized crime, who are already using the system to produce and distribute marihuana to the illicit market;
    - Public safety concerns related to the unknown number of production sites, including:
        - Electrical systems that are not adequately upgraded to accommodate excessive utility usage;
        - Explosions or fires due to extraction procedures;
        - Smell and exhaust from production sites in residential areas; and
        - Lack of proper zoning practices for PUPL and DPPL.

- Participants also note inconsistencies in the information received through the 24-hour emergency call service for law enforcement and a perceived lack of service delivery standards.

What are your thoughts on whether marihuana dispensaries have a role in the program? What threats/risks might be involved, and how could they be mitigated?

- Concerns that dispensaries are currently involved in distributing other drugs, and/or marihuana to individuals who do not have an authorization to possess from Health Canada.
- Believe that organized crime could use a legitimate dispensary as a cover for drug trafficking.
- Questioned what control mechanisms/regulations would be in place for dispensaries to distribute marihuana for medical purposes.
- Participants voiced a preference for pharmacy. In the absence of this possibility, participants stated that mail distribution systems would be the most secure option.

What cost-effective and reasonable measures would ensure the security of production/distribution sites? How stringent should security requirements be?

- Non-residential zoning, though not a responsibility of law enforcement, would be welcomed requirement for commercial producers. Though it was noted that it would not change the risk of public safety (ie. invasion).
- Participants clearly stated that they wish to be informed of the location of all commercial producers.
- Chain of production/supply needs to be clearly outlined and regulated, so that the supply to patients can be tracked.
- Participants suggested that Health Canada look at the existing models (ie. PPS, pharmacies) to gauge the level of security required for commercial producers.

What are appropriate sources of seeds for the licensed commercial production of marihuana for medical purposes?

- Participants preferred sourcing seeds from other licit commercial entities such as Bedrocan and other commercial entities in the US.
- While RCMP seizures could be used, there were concerns expressed regarding liability (ie. if patient gets sick). Extensive testing would need to be undertaken to ensure that the strain, THC level etc was known and that there were not any health risks associated with using seeds from seizures.
    - Participants recommended that Health Canada consult with Agriculture Canada regarding testing processes for this option.
- Procuring seeds from current PUPL and DPPL could also involve liability risks and would require extensive testing.

What do you see as your role in a compliance and enforcement program, beyond obvious issues of diversion and theft?

- Capacity/resource issues for law enforcement if Health Canada downloads inspection regime to the provincial or municipal level.

- Participants request that up-to-date information on commercial producers including their location and the size of their operation be kept in a national database that is accessible to law enforcement officials.

Next Steps

Health Canada representatives will meet with representatives from the National Coordinating Committee on Organized Crime on November 24. An analysis of these consultations will then be written and incorporated in to final reform package.

Health Canada's Marihuana Medical Access Regulations Consultations

Meeting with the Canadian Association of Fire Chiefs

September 27, 2011
Calgary, Alberta

Meeting Summary

The following meeting report summarizes the points raised during a meeting with the Canadian Association of Fire Chiefs (CAFC) on the proposed changes to the Marihuana Medical Access Regulations (MMAR) announced on June 17 2011. This 1.5 hour meeting was organized by Health Canada and took place on September 27th, 2011 at the Westin hotel in Calgary, Alberta.

1. Background

Jeannine Ritchot, Director of the Medical Marihuana Regulatory Reform Project, presented an overview of the proposed changes to the MMAR and provided an update on the consultation process to date. She noted that to date, consultations have been had with compassion clubs and cannabis dispensaries in Vancouver, Montreal and Toronto, and she indicated there are upcoming meetings with law enforcement, the medical profession and municipalities.

2. Participants

The CAFC's President, First Vice President, Second Vice President, and the President of the Fire Prevention Officers Association of British Columbia were present.

3. General Feedback

After a brief overview of the proposed changes to the regulations, participants were asked to identify aspects of the proposed changes that they liked and those they had concerns about. They were also invited to make suggestions for improvement.

All participants in the group were strong proponents of phasing out small-scale personal production of marihuana in private dwellings due to serious public safety and public health concerns. They noted a strong hope for an opportunity to accelerate the process and to advance the 2014 timeline.

The group was in agreement that the proposed changes alleviated many concerns related to in-home operations because a model involving larger commercial marihuana producers would eliminate the hazards and concerns associated with smaller home retrofits. In addition, participants appreciated the fact that the proposed model removes the cultivation of marihuana from residential areas, thus making those areas safer. They noted that the move to commercial operations allows for more regulation and control through zoning and by-laws.

Concerns

Participants noted the following concerns related to the proposed changes to the regulations:

- Participants were very concerned that Health Canada would not share information with Fire Chiefs on the location of private dwellings where the personal production of marihuana has or is taking place. They strongly emphasized the serious public safety risks, related to electrical and fire hazards, as well as public health risks, related to excess mould and poor air quality, that are created by the cultivation of marihuana by individuals in homes. Participants highlighted the fact that certain factors such as the heavy use of electricity, poor electrical wiring, as well as products used to grow marihuana, such as fertilizing agents or boosters, often represent serious safety hazards for occupants of the home, neighbours and fire fighting personnel. Advance knowledge of where these homes are located and what the size and scope of the hazards are is critical, at least during the transition period, to help properly prepare first responders teams and ensure the safety of fire fighting personnel. It was noted that because of the close integration of police and fire departments on local issues, Fire Chiefs are currently relying on relationship-building with police at the local level to have access to that information when required and where appropriate.
- Participants expressed very strong concerns regarding the absence of a remediation mechanism for homes where marihuana has been grown. They emphasized that it is critical for structures that may have been contaminated (e.g. with excess mould) be identified so that remedial action can be taken to ensure the safety of the building for its present and future occupants.
- Concerns were expressed over the fact that there is poor recognition of the legal documentation/authorization required by individuals to grow marihuana for medical purposes in their own home.
- Given these safety and health concerns, there was some concern that the proposed timelines would be delayed and that the transition period would be extended beyond 2014.

Suggestions and Recommendations

The group made the following suggestions and recommendations to address the above-listed concerns:

- Until personal production is phased out, make the renewal or issuing of a new personal production license conditional upon demonstration of evidence of compliance with local government zoning and by-laws.
- Provide guidelines and best practices on how to safely grow marihuana to individuals who are granted a license for personal and/or designated production during the transition period.

- Establish timelines for the transition period in consultation with stakeholders to ensure feasibility and buy-in.
- Ensure that wording in the regulations provide enough flexibility for local police agencies to share confidential information provided by Health Canada on the location of private dwellings where marihuana is grown with fire officials, EMS officials, etc., as required and as permitted, in order to protect public safety and ensure that first responders teams are adequately prepared.
- Disseminate information on the legal documentation/authorization for the possession of marihuana for medical purposes to Fire Chiefs during the transition period to ensure they are familiar with it.
- Establish a remediation program to assess all homes where marihuana has been produced and ensure remedial action steps are taken to properly address safety concerns regarding the integrity of the building (e.g. provide access to information on the location of specified homes to Fire Chiefs after a marihuana production license has lapsed so that they may inspect it).
- Ensure individuals who grow marihuana in their own homes are aware of the responsibilities and financial implications associated with remediating the home (spore and mould issues, electrical hazards) for the next owners.
- Invest more resources into undertaking "checks and balances" with commercial marihuana producers.

4. Targeted Discussion Themes

Licensed Commercial Production Framework

- A fire inspection should be mandatory for all premises where marihuana will be produced to mitigate fire threats and risks.
- In principle, the onus should be on the licensed commercial producer to demonstrate compliance with local municipal by-laws and zoning.
- Participants noted that Fire Chiefs may have a role to play in terms of the regular inspection of licensed commercial producers within municipalities.
- The Fire Marshall's office and Commissioner are critical stakeholders that could be engaged to address issues that arise with licensed commercial producers that are located outside of municipal jurisdictions.
- The regulations should reference a minimum standard (e.g. a fire inspection) that must be met before a license will be issued by Health Canada to a commercial producer. This standard could be superseded by municipal standards.

By-laws, Zoning and Codes

- Building and/or fire codes to be considered will depend on the nature of the commercial growing operation (green house/indoor/outdoor).
- Commercial marihuana producers should demonstrate compliance with local zoning, electrical safety and fire codes as a condition for licensing
- Participants strongly felt that commercial marihuana producers should be decentralized in the community and adopt a no store-front model.

5. Conclusion

In conclusion, participants noted they appreciated the opportunity for consultation and indicated their interest in remaining engaged throughout the development of the new regulations. To this end, the idea of establishing a Working Group was proposed by participants as they noted it would provide a place where Fire Chiefs could bring their ideas, suggestions and concerns.

HEALTH CANADA

Marihuana Medical Access Program Reform

Law Enforcement Consultation Meeting Report

October 12, 2011
Royal Canadian Mounted Police Headquarters
Barrhaven, Ottawa, Ontario

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1. Background and Introduction

On June 17, 2001, Health Canada (HC) announced improvements to the Marihuana Medical Access Program (the Program or MMAP) which provides access to marihuana for medical purposes for seriously ill Canadians. The impetus of these changes came from concerns about public safety and security and the potential for illicit use which were raised by police and law enforcement, fire officials, physicians, municipalities, and program participants. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep children and communities safe. To this end, Health Canada is launching public consultations on the proposed improvements. A number of stakeholder groups have been invited to these consultations, including Provinces and Territories, municipalities, compassion clubs and cannabis dispensaries, medical associations, law enforcement, fire officials, and other interested parties.

A consultation meeting with representatives of the Canadian Association of Chiefs of Police (CACP) and the Royal Canadian Mounted Police (RCMP) was held at the RCMP Headquarters, Ottawa, Ontario on October 12, 2011. In this morning meeting, there were 8 (eight) participants representing various police detachments from across the country.

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and underscored the importance of hearing from law enforcement as they go forward with the proposed changes to the Program. In an effort to reform the Medical Marihuana Program, the government is consulting many stakeholders including the provinces and territories, the medical community, compassion clubs and cannabis dispensaries, and other key stakeholders. She noted there was an online consultation which generated over 2600 submissions.

She explained the objective of the meeting:

- to discuss elements of the proposed program changes and gather feedback from participants.

This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

Jeannine Ritchot, Director, Medical Marihuana Regulatory Reform (MMRR) began by thanking participants for attending and acknowledging that the contribution of ideas by law enforcement was critical to the success of improving the Program and to the reform of the regulations.

Jeannine proceeded to set the stage by giving participants a brief overview of the key elements of the proposed improvements to the MMAP. The office of the MMRR was tasked with reviewing and making proposed changes to the Program. The objective of the proposed improvements is to reduce risks to Canadians and keep communities safe, while improving access for Canadians to the use of marihuana for medical purposes. She noted that the legalization or decriminalization of marihuana is not part of the proposed changes.

Jeannine explained that under the current program individuals see their physician in order to have him/her sign a form supporting their use of marihuana for medical purposes. The patient must then apply to Health Canada for an authorization to possess marihuana for medical purposes. The medical practitioner's form and their choice of supply must accompany the application form. The package is reviewed by Health Canada and appropriate authorizations and licences are issued where approved. These authorizations and licences are reviewed on a yearly basis. The process of obtaining marihuana for medical purposes is cumbersome and complicated.

Jeannine stated that Health Canada is proposing that the first step remain the same, the requirement to consult with a physician, as this is the best place to make a decision about a patient's medical condition. The physician no longer needs to fill out the Health Canada declaration. Another document, yet to be created, would be supplied to the patient by the physician. The individual would submit this document to licensed commercial producers (LCPs) in order to obtain marihuana for medical purposes. Health Canada would no longer receive or process applications consequently, a government agency would no longer have access to the sensitive medical records of Canadians. They would no longer be responsible for producing and distributing medical marihuana. Licensed commercial producers would be charged with this responsibility, and Health Canada`s role would be more of a more traditional regulatory role.

After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. They are summarized below.

To the question about educating the medical practitioner in order to support their decision making around "prescribing" the use of medical marihuana, Health Canada stated they are creating an Expert Advisory Committee (EAC) and whose purpose is to ensure that physicians have the most up to date information on the uses of medical marihuana. This is a big concern for the College of Family Physicians of Canada (CFPC) in particular, and the medical community, in general. Health Canada is looking for ways in which to reach out to this community.

To the question about how the physicians will be organized, Health Canada said that other stakeholders suggested creating a registry model similar to that which services the Methadone Program, and Health Canada is currently analyzing this option. If the Personal-Use Production Licenses (PUPLs) are being eliminated, Health Canada needs to ensure a process that will provide adequate access to marihuana for medical purposes. To this end, there will need to be an effective and accessible training program in place, especially for family physicians.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the impact of the changes to the Program would have on their policing role and law enforcement capability. They discussed their likes and dislikes about the proposal. A number of important topics were addressed in each discussion. The thoughts were summarized and are synthesized below.

> *Focus Question: What do you like about the proposed improvements to the Program?*

Participants liked some aspects contained in the proposal including the removal of personal production and the creation of LCPs. The discussions which took place in response to the question above are summarized. The responses have been themed for ease of comprehension.

✓ *Removal of personal production is progressive.*
- Having people growing marihuana for medical purposes in their residences is a serious health and safety risk both to the growers and to those living around them.

✓ *Creating licensed commercial producers (LCPs) is a step forward.*
- Having LCPs take responsibility for producing and distributing marihuana for medical purposes was seen as a positive step.
- It was suggested that local police could be designated inspectors for the LCPs.
- Caution: organized crime could infiltrate LCPs and use them as a legal way to sell illicit marihuana.

> *Focus Question: What are your concerns regarding the proposed change to the Program?*

A number of key issues were identified by the group. These included concerns about personal production/legalizing personal use of medical marihuana, grandfathering PUPLs, keeping organized crime out of LCPs, the continuance of illicit cannabis clubs and dispensaries, and fraud associated with falsifying documents for possession of marihuana for medical purposes. The discussion which took place in response to the question above is themed and summarized in the following bullets.

✓ *Concerns about personal production.*
- A document with a full statement of concerns was submitted to Health Canada; such concerns as, infiltration of organized crime, home invasion, etc.
- Public safety is an enormous concern. Lack of capacity for performing inspections and the inability to share information with the local jurisdictions is problematic.
  - There are an unknown number of grow-ops within the municipalities and communities; under the current structure, these cannot be checked to see if they are up to code and safe.
  - Example: sometimes firemen respond to grow-op where there are unknowns, including toxic chemicals, and this puts them at risk.

✓ *Possibility of grandfathering PUPLs was a serious concern.*
- Participants unequivocally agreed that grandfathering should not be in place; there is no need for people to grow marihuana for medical purposes in their residences. It was recommended that production be removed from residential neighborhoods.

- ✓ *Fear of legalizing the personal use of marihuana for medical purposes.*
  - Every user will have a "prescription" issued by a doctor and the police will not know the source of the prescription.
  - "Prescriptions" are too easy to get; participants suggested that some doctors charge a $100 processing fee in order to "prescribe" this medication.
  - The Quebec College of Physicians refuses to endorse the use of marihuana for medical purposes.

- ✓ *Keeping organized crime out of the LCPs.*
  - Organized crime is very adept at "hiding" in organizations and there was concern that they would infiltrate the LCPs. The group was interested in hearing the steps that would be taken to prevent this from happening.

- ✓ *The continuance of illicit cannabis clubs and dispensaries which are well organized and popular.*
  - They are growing an uncontrolled amount of marihuana and making large profits.
  - They are unwittingly creating health dangers such as moulds.
  - Health Canada noted that because the cannabis clubs are so well organized, they have a large membership that look to them for advice and education.

- ✓ *Vulnerability in the current proposal.*
  - There is concern that the illicit production of marihuana may continue to overshadow the medicinal side.

- ✓ *Fraud: falsifying documents for possession of marihuana for medical purposes is a major concern.*
  - The greatest concern for fraud is in the first contact between physician and patient. Most physicians employ due diligence to this process, but in the underground community, some physicians are known for "prescribing" easily.
  - Participants raised concern with the dosage/amount physicians are "prescribing". High doses are being diverted, therefore participants suggested that limiting the amount of marihuana that can be supported will help ensure that organized crime does not become involved.
  - Concerning the integrity of the identification document used to obtain medicinal marihuana:
    - The new proposal eliminates this step, and thus could facilitate an increase in the use of marihuana for medical purposes.
  - For law enforcement, there is no way to discern if a person's medical marihuana is from a legal source or if the authorization documents are from a doctor.
  - Organized crime will always be able to counterfeit identification documents, but may be slowed down with high integrity government issued identification.

- ✓ *Verifying identification of legitimate licensed holders for medicinal marihuana with Health Canada is problematic.*
  - Currently, communicating with Health Canada is difficult and time consuming.
  - There seems to be no standard answer to law enforcement queries, and an officer is often transferred many times.
  - It can take two (2) to 12 hours to get information.

4. Law enforcements considerations concerning Licensed Commercial Producers and their production operations.

In order to gain an understanding of law enforcement issues and the potential problems foreseen with the proposal for the new Program, the group were asked to give feedback and to share information on a number of key questions relating to the following focused themes.

- *Discussion themes:*
  - *a) Licensed Commercial Production Framework.*
  - *b) Safety and security.*
  - *c) Identification.*
  - *d) Compliance and enforcement.*
  - *e) Diversion.*

Based on their practical experience, participants shared their ideas and made recommendations on the discussion areas. A number of key themes emerged including recommended zoning requirements, minimum information required for law enforcement, methods of assessing threat levels, a potential role for dispensaries, seed sources, and the need for a focused regulatory framework for LCPs. Safety and security discussions included cost effective and reasonable security measures, disposal requirements, and secure delivery methods. Recommended identification requirements, law enforcement's role in inspection, and some thoughts on diversion rounded out discussions. This information was captured and is summarized below.

a. Licensed Commercial Production Framework..

✓ *Recommended zoning requirements.*

- The group unanimously recommended against residential production for public safety reasons.
- The municipalities need to have input on where the LCPs are located.
- Commercial/non-residential locations were thought to be a better option. Some thought that even if it is properly zoned and inspected there would still be problems with invasion and break-ins that would put people around the location at risk.
- Others thought that if security requirements and zoning were properly authorized, a well thought out location with proper fencing, security and alarms could be acceptable.
- In all cases, law enforcement should be informed of the LCPs' locations.
- The idea of having a checklist for inspection by the municipality's fire and law enforcement, adapted to the specific environment and sensitivities of the different communities, was well received. Granting a license to a producer should be dependent on compliance with this check list. The checklist should include all the element of public safety and security, such as:
  - There should be a standard in place for electrical and HVAC.
  - Risk of fire and toxic environments should be on the list.

✓ *Minimum amount of information required by law enforcement.*

- The exact location of LCPs in each of the cities/ communities affected.
- An easily accessible floor plan and an indication of where the safest entrances are located.
- The kinds of chemicals being used in the production operation.
- A point of contact is needed.

- Some participants said the owners and employees names of the LCPs should be required for law enforcement, while others thought that only having the owners name would satisfy the security clearance required.
- It was suggested that the same security checks used by PPS should be employed by the LCPs, ex: criminal checks, etc.
- Maintaining a "hot line" and an updated list of authorized LCPs in order to share information and sustain the partnership with law enforcement would be useful.

✓ *Assessing threat levels to ensure effective security measures.*
- The threats need to be determined in each environment.
    - For example, smaller producers may present less of a risk whereas larger ones, a greater risk.
    - Location is an important variable.
- Consult with local, regional, and provincial law enforcement when an LCP wants to open in a community.
    - Seek out the authority in the communities in order to gather intelligence to perform threat assessments.
    - These authorities are able to determine the threat agents and can help build an appropriate risk assessment model that will help mitigate risks. Include stakeholders in the process.

✓ *Potential role for compassion clubs and dispensaries.*
Note: Participants had differing views on whether to allow compassion clubs and dispensaries to have a role.
- Some participants thought dispensaries should be eliminated.
    - There was concern that the compassion clubs and dispensaries are dispensing more than marihuana. Also, less than 1% of their clientele have valid Health Canada identification cards. These organization's profiles are problematic and therefore should not be part of the supply system for medicinal marihuana.
    - Many patients who have access to marihuana for medical purposes do not have addresses and this is the argument for making medicinal marihuana accessible through compassion clubs or dispensaries.
    - Having LCPs is sufficient and will address the legal accessibility issue.
    - The recommendation was against a store front dispensary model, as it could provide an opportunity for organized crime to infiltrate. There was concern, however, that the community-based model offered by cannabis clubs and dispensaries would eventually allowed by the courts.
- If dispensaries are licensed, they need to be rigorously regulated and have stringent consequences for disregarding the rules.
    - As exemplar, the Dutch cannabis cafés who exceed their allowance of 30grams per café have had their licenses revoked as punishment.
- In conclusion, participants recommended against dispensaries, but if they do exist then they need to well-regulated.
- Health Canada noted that pharmacies have not indicated an interest in dispensing. Additionally, transforming medical marihuana into an authorized drug would involve clinical trials followed by a complicated process involving Provincial and Territorial legislation and regulation. Although this is not being contemplated at this time, it may be considered in future.

✓ *Seed Sources.*
- A few options for seed sourcing were suggested by Health Canada:
    - RCMP seizures;
    - Provide a number of illegal "seed dispensaries" with a Section 56 exemption to sell to LCPs for medical purposes.
    - Allow the LCPs to procure their own supply of seeds, independently.
- There needs to be a starting point for supplying seeds and participants agreed this could come from RCMP seizures where there are a number of strains available.

- Caution: there could be liability around seeds from seizures. From this perspective, it may be more prudent to buy the seeds from an established company.
- To the use of illegal "seed banks", participants were against using an illegal operation to source a legal one.
- Bedrocan BV Medicinale Cannabis and legal suppliers in the U.S. could be other sources for seeds.
- Health Canada noted that procuring from these international companies would involve the acquisition of complicated importation licenses for controlled substances and a time consuming process that may not be in place for the 2014 timeline.

✓ *Include a quality control requirement.*
- Regulate the THC content limit for medicinal marihuana.
    - The percentages of THC have increased over the years; the current average is about 15-17%. This makes the drug too potent. It is no different than any other pharmaceutical where the percentages would be regulated.
    - The Dutch have implemented a 15% THC content limit because they have acknowledged that higher content levels have health and safety risks.
- Physicians need to be educated on the effects of this medication in order to determine the dosage a person would need for therapeutic use. More research needs to be done.

✓ *Complaints about the quality of the current product.*
- Many patients complain about the quality of the medicinal marihuana which is produced and distributed by Prairie Plant System Inc. (PPS); this has driven patients to grow their own product.
- Another complaint is that patients need a variety of strains and contractually PPS is confined to producing one strain only.
- In the new Program, effective regulation of the product is important in order to address these two issues.

✓ *The regulatory framework for LCPs needs to be focused and rigorous.*
- The greatest risk for illicit activity lies with the producers.
- The LCPs should be strictly regulated to ensure the product is used for the medicinal purposes. The regulations should include:
    - A system to determine who is a legal supplier and to be able to trace the source of the product.
    - Regulate the amount of medicinal marihuana patients are allowed to possess.
- The "right regulations" will help eliminate some of the illegal productions.

✓ *Product packaging and warnings.*
- Participants recommended that packaging and warning labels on the product should be similar to those on cigarettes.
- Also they endorsed the idea that the liability for the product and its effects should be assumed by the LCPs.

✓ *Quotas for LCPs.*
- The number of LCPs will be driven by the number of people who demand the product.
- Health Canada stated they are not yet settled on a quota. It is imperative to provide access, and if Heath Canada caps the number of growers, it could be perceived as reducing access.

Question: Have there been any surveys on how many companies would want to become LCPs?
Response: Health Canada noted that there was little interest shown by large companies because of the liability issues. The current proposal is for dried marihuana, however options to allow for the distribution of other forms of medicinal marihuana are being analyzed. Step two (2) of the project will be to test interest in becoming LCPs. There is a list of 15 parties, in addition to PPS, interested in becoming LCPs provided they meet the regulations. There will be people who come forward who are not legal now and if they meet the requirements, they can be licenced and therefore subject to inspections. The existing monies in the program will be reinvested back into an inspection regime.

✓ *Costing and profitability.*
- Participants thought that with the new regulatory regime, it would be difficult for LCPs to be profitable. The market will not be very big. The real profit is in selling illegal marihuana, and therefore illicit grow-ops will not disappear.
- There was concern that the competition between legal and illegal growers could drive the price of the product down and there was a potential for monopolies to emerge.

b. Safety and security.

✓ *Cost-effective and reasonable security measures that will help keep the price of marihuana for medical use affordable.*
- Note: Regardless of the cost set for this product, the black market will always undercut legal market.
- There needs to be an absolute minimum standard set for security.
- The security measures should be similar to those employed by PPS. As noted by Health Canada, at PPS the staff have security clearances, there are storage vaults for the product and a separate storage for emergency stock, they use a bonded courier for transportation, and the location is kept secret.
- It was suggested that the security standards in place for pharmacies could be considered.
- Hire a security consultant to assess the risk assessment for indoor and outdoor production.
    - Regulations should stipulate that security is the responsibility of the LCPs, and they have to ensure appropriate security measures are in place. Obtaining a license should be contingent upon this proviso.
    - The penalty for non-compliance should be a loss of the LCP's license.

✓ *Disposal requirements:*
- Participants recommended a set of stringent guidelines for disposal of unused medical marihuana.
- Health Canada added that there is a regulated system in place for PPS and this could be the framework applied to LCPs.

✓ *Determining cash value of the product.*

- Law enforcement indicated that they could help Health Canada to determine cash value of medicinal marihuana in order to perform a proper cost benefit analysis.
- Caveat: It would be based on illicit values.
- Law enforcement can look at both large and small volumes and assess the market value by using intelligence and input from communities. This information can help Health Canada to build models that will help LCPs determine the appropriate security measures, and whether the business will be viable.

✓ *Security steps for ensuring safe delivery methods.*

- Currently, Health Canada receives a client order, authorizes it and sends it to PPS. PPS forwards the product to the patient by bonded Purolator courier (using vetted employees). The package is tracked through both PPS and the Purolator systems.
- It was noted that most of the courier problems occur when the DP growers send their product to a licensed holder.
- The use of a bonded courier system is the safest way of dispensing the product because it provides the straightest line between producer and patients; there is less opportunity for diversion.
- The risk associated with delivering through Canada Post small outlets is minimal; no more than any other relatively valuable merchandise.
- For those authorized individuals receiving marihuana for medical purposes with no mailing addresses, participants supported the option of their medication sent directly to their doctor's office.

✓ *Creating a working group to build the security regulations for LCPs.*

- Participants were receptive to the idea of establishing a working group who could support the drafting of the security regulations for LCPs.

c. ***Identification requirements.***

✓ *Identification recommended.*

- Participants recommended a card system which could be similar to that of the Firearms Registry.
- Regulating the "prescribed" amounts of marihuana for medical purposes is a key consideration.
    - Indicate the amounts that patients are allowed to possess.
    - Organized crime may not be interested if there are smaller amounts prescribed.

d. ***Compliance and enforcement.***

✓ *Concerning an interest and appetite for inspecting of the LCPs.*

- Law enforcement's resources are limited, so it would be difficult for them to participate in inspections.
- Participants thought that most businesses would comply with standards in place and have an interest in maintaining a clean work place.
- Inspections are not done by law enforcement with other restricted medications, e.g. oxycontin.

e. ***Diversion.***

✓ *Inadequate packaging of medicinal marihuana.*

- Improper packing of the product could lead to diversion.
- Participants agreed that diversion could be mitigated by regulating the LCPs packaging of medicinal marihuana.

After the discussions, there were some further questions and comments. These are summarized below.

To the question about providing law enforcement with the list of growers for the transition period, Health Canada responded by saying that currently, they cannot share lists with fire police and municipalities due to federal privacy legislation.

5. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

Appendix A: Agenda

Health Canada
Marihuana Medical Access Program
Canadian Association of Chiefs of Police and RCMP
Date: October 12, 2010
Time: 9:00-12:30

Item	Time
Introduction	9:00-9:05
Presentation of key elements of the proposal	9:05-9:15
General Discussion 1. Which changes will affect you? Which changes will affect your clients/stakeholders? 2. What do you like about the new proposal? Why? 3. Do you have concerns regarding the proposed changes? What are your concerns? Why? What suggestions for improvement would you make?	9:15-10:15
Break	10:15-10:30
Discussion Themes a. Licensed commercial production framework b. Safety and security c. Identification d. Compliance and Enforcement e. Diversion	10:30-12:15
Next Steps, closing remarks	12:15-12:30

MMAP Targeted Consultations – Medical Associations (CMA, CMPA, CFPC)

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status

On September 29, 2011, representatives from Health Canada met with representatives from the Canadian Medical Association (CMA), the Canadian Medical Protective Association (CMPA), and the College of Family Physicians of Canada (CFPC) for a targeted consultation session at the Capital Hill Hotel and Suites in Ottawa.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Feedback on questions posed by Health Canada to meeting participants.

Medical associations expressed significant concern with respect to what they perceive to be the unchanged role of physicians as "gatekeepers" under the proposed changes. Opinion was divided with respect to the removal of categories of conditions and symptoms: the CMPA viewed this as a positive step in streamlining the application process for participants, while the CFPC felt that this may increase pressure on primary care physicians by no longer requiring a second assessment by a specialist. Participants unanimously expressed the need for further information on the risks and benefits of using marihuana for medical purposes, and welcome the establishment of an Expert Advisory Committee. However, the CMA in particular noted the importance of introducing a research and/or clinical trial component into the reform proposal.

Positive Elements of the Proposal

- Removal of the categories of conditions and symptoms as a means to streamline the application process, though the view was not shared by all.
- Elimination of the requirement to consult a specialist for some patients as a means to streamline the process, though the view was not shared by all.
- Creating the Expert Advisory Committee to assist in the education and training of physicians.
- Health Canada's role in regulating the environment/industry.

Key Concerns

- Participants expressed that a single half-day consultation was an insufficient amount of time. Given the breadth of challenges that physicians face with the current program, participants highlighted that much more work and collaboration was needed to address their community's concerns.
- Participants questioned whether the overall objective of the program is to provide "reasonable access" to marihuana, or is it to provide "medical access".
    - If to provide reasonable access to a controlled substance, then Health Canada could consider expanding the "gatekeeper" role to other regulated health professions, such as naturopaths, pharmacists and nurse practitioners.
    - If the purpose of the program is to provide "medical access" to marihuana, then it may be appropriate for physicians to play this role, but cannot do so as long as marihuana does not follow the established clinical path that physicians are training to work within (i.e. successful clinical trials demonstrate that its benefits outweigh its risks and it is approved under the FDR as a drug).
- Long-term health effects of using marihuana for medical purposes are unknown (ie. smoking, impairment, effects on executive functions, etc)
- Health Canada is setting up a prescription-like process for marihuana, even though it lacks the types of research and information about its uses that doctors have access to for all other prescribed medications.
- The CMPA continues to express significant concern with respect to physician liability and the potential for court cases that determine that doctors are liable for supporting access to a non-approved drug that impairs executive function and is often smoked.
    - It was suggested that liability increases as more information is required (ie. dosage, period of use, etc)
- Sharing of medical information with licensed commercial producers may be in breach of provincial and territorial privacy legislation.
    - Raised the question of whether commercial producers would have to be indicated as 'custodian' within legislation.
- While a regulated industry was welcomed, participants suggested that increasing the number of dispensaries/producers, decreases the standardization of the product. This makes physicians uncomfortable, as they do not know the quality of what they are supporting.
- The proposal does not address research needs. Some participants suggested that Health Canada should consider enrolling every current participant in a clinical trial, and require future participants to be willing participants in a clinical trial as a means of increasing physician comfort with playing this role.

Health Canada Questions

- What role do you believe that physicians should play with respect to the use of marihuana for medical purposes?

- There is a lack of education and information available to doctors on marihuana for medical purposes;
- Removal of categories of symptoms and conditions increases pressure on primary care physicians to support access to marihuana for medical purposes;
- Health Canada should consider other models, such as the registry model (methadone) or the special access program model. Physicians with "prescription rights" should be experts who are educated and trained with expertise in the use of marihuana for medical purposes;
- "Medical certification" programs may also be considered a model to explore (ie. Employment Insurance, Canada Pension Plan);
- Clinical practice guidelines are an important pillar;
- Recommend that Health Canada consult with the provincial and territorial regulatory authorities/Colleges.

- What health care professionals would you like to see involved in the program (ie. gatekeeper role)?
  - Depends on the purpose of the program – if to provide reasonable access to marihuana, then other health professionals should be involved;
  - Collaborative healthcare model could be envisioned, as long as there is communication between physicians and other health care providers (ie. ensuring continuing care, monitoring for contraindications, etc);
  - Nurse practitioners, naturopaths and pharmacists should be consulted.

- What type of information do you view as relevant to include on a form for doctors to support the medical use of marihuana?
  - Participants were reluctant to engage in discussion on what should be contained in a form, but some common themes emerged:
    - The form should be a record of informed consent – outlines limits and purposes of use of marihuana;
    - Patients should be required to sign a liability release to protect physicians;
  - On the issue of dosage and period of use, participants questioned how they could be measured without evidence base – if the Expert Advisory Committee cannot determine dosage guidelines, then dosage and period of use should not be a requirement of the primary care physician;
  - Semantics will be important – "support" and "prescribe" are not different enough when addressing physician liability issues.
  - There was some comfort with Health Canada's proposal to remove the medical declaration currently required on the forms, although this was not enough to alleviate liability concerns.

Next Steps

Health Canada representatives will be consulting with the Federation of Medical Regulatory Authorities of Canada (FMRAC) on October 26. Officials will also have a kiosk at the CFPC's Family Medicine Forum November 3-5 to engage with physicians on

Health Canada's proposed improvements. Officials are also developing a survey and a website to reach out to individual physicians and to seek their views on reform and on their educational and informational needs with respect to the use of marihuana for medical purposes.

An analysis of the three consultations will be written, studied and incorporated in to the final reform package.

HEALTH CANADA

Marihuana Medical Access Program Reform

Federation of Medical Regulatory Authorities of Canada (FMRAC) Meeting Report

September 26, 2011
Fairmont Chateau Laurier
Renaissance Room
1 Rideau Street
Ottawa, Ontario

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1. Background and Introduction

On June 17, 2001, Health Canada (HC) announced improvements to the Marihuana Medical Access Program (the Program or MMAP) which provides access to marihuana for medical purposes for seriously ill Canadians. The impetus of these changes came from concerns about public safety and security and the potential for illicit use which were raised by police and law enforcement, fire officials, physicians, municipalities, and program participants. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep children and communities safe. To this end, Health Canada is launching public consultations on the proposed improvements. A number of stakeholder groups have been invited to these consultations, including Provinces and Territories, municipalities, compassion clubs and cannabis dispensaries, medical associations, law enforcement, fire officials, and other interested parties.

A consultation meeting with representatives from the Federation of Medical Regulatory Authorities of Canada (FMRAC) was held at the Chateau Laurier Hotel, Renaissance Room, Ottawa, Ontario on October 26, 2011. In this morning meeting, there were 19 participants from the Federation of Medical Regulatory Authorities of Canada (FMRAC), representing Colleges of Physicians and Surgeons from 12 of the 13 provinces and territories.

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and underscored the importance of hearing from the medical community as they go forward with the proposed changes to the Program. In an effort to reform the Marihuana Medical Access Program, the government is consulting many stakeholders including the provinces and territories, law enforcement organizations, compassion clubs and cannabis dispensaries, and other key stakeholders. She noted there was an online consultation which generated over 2600 submissions.

She explained the objective of the meeting:

- to discuss elements of the proposed program changes and gather feedback from participants.

This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

Jeannine Ritchot, Director, Medical Marihuana Regulatory Reform (MMRR) began by thanking participants for attending and acknowledging that the contribution of ideas by the medical community is critical to the success of improving the Program and to the reform of the regulations.

Jeannine proceeded to set the stage by giving participants a brief overview of the key elements of the proposed improvements to the MMAP. The office of MMRR was tasked with reviewing and making proposed changes to the Program. The objective of the proposed improvements is to reduce risks to Canadians and keep communities safe, while improving access for Canadians to the use of marihuana for medical purposes. She noted that the legalization or decriminalization of marihuana is not part of the proposed changes.

Jeannine explained that under the current program individuals see their physician in order to have him/her sign a form supporting their use of marihuana for medical purposes. The patient must then apply to Health Canada for an authorization to possess marihuana for medical purposes. The medical practitioner's form and their choice of supply must accompany the application form. The package is reviewed by Health Canada and appropriate authorizations and licences are issued where approved. These authorizations and licences are reviewed on a yearly basis. The process of obtaining marihuana for medical purposes is cumbersome and complicated.

Jeannine stated that Health Canada is proposing that the first step remain the same, the requirement to consult with a physician, as this is the best place to make a decision about a patient's medical condition. The physician no longer needs to fill out the Health Canada declaration. Another document, yet to be created, would be supplied to the patient by the physician. The individual would submit this document to licensed commercial producers (LCPs) in order to obtain marihuana for medical purposes. Health Canada would no longer receive or process applications consequently, a government agency would no longer have access to the sensitive medical records of Canadians. They would no longer be responsible for producing and distributing medical marihuana. Licensed commercial producers would be charged with this responsibility, and Health Canada's role would be more of a more traditional regulatory one.

After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. They are summarized below.

To the question about making marihuana a prescription drug, Health Canada responded that it is not an approved drug and therefore cannot be prescribed through the drug prescription process. The proposal envisions a "prescription" like process for the use of marihuana for medical purposes. After the patient has discussed their case with the physician and there is a recommendation for this treatment, the physician would fill out a document (yet to be designed) that the patient would present to the LCP to obtain their treatment.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the impact of the changes to the Program would have on their role as physicians. They were prompted to discuss their likes and dislikes about the proposal. A number of important topics were addressed in the discussion. These thoughts were summarized and are synthesized below.

> *Focus Question: What do you like about the proposed improvements to the Program?*

Participants were unable to identify any benefits to the proposed improvements to the Program.

> *Focus Question: What are your concerns regarding the proposed change to the Program?*

A number of key issues were expressed by the group. These included concerns about physicians "prescribing" marihuana for medical purposes, the untested status of marihuana as a medical treatment, the unauthenticated information that would be provided by the Expert Advisory Committee (EAC), the use of the Methadone Program as a model, the potential for misuse of marihuana, the lack of regulations and parameters around supporting a patient's access to marihuana for medical purposes, and the ability of overburdened family physicians to take on this responsibility. The discussion which took place in response to the question above is themed and summarized in the following bullets.

✓ *Doctors should not be "prescribing" marihuana for medical purposes.*
- Participants felt that this is not a medical problem, but a political and social issue.
- The burden of controversy will be placed on physicians; they will have to police the use marihuana for medical purposes.
- Competing pressures put physicians in an untenable position. On the one hand, they are required to prescribe medication based on the best evidence available. On the other hand, they are pressured by the courts to provide patients with the option of using marihuana for medical purposes. There is no evidence to recommend this treatment, therefore physicians are "prescribing" blindly. For the physician, this creates a conflict of interest/ethics and a potential for litigation.
- Participants expressed a lack of confidence in the level of understanding of physicians of the effects of medical marihuana. It is difficult to educate when there is little or no evidence to support its use.
- Having doctors support a patient's access to marihuana for medical purposes puts the physician at risk; many agreed that physicians should not be the gatekeepers to access this Program. As well, supporting marihuana for medical purposes goes against many Medical Colleges' recommendations.
- Some participants warned that physicians who do support patient access will be under careful scrutiny by their College.

✓ *Medical marihuana is untested and its effects are unknown.*
- There is no scientific evidence to recommend or not recommend the use of marihuana for medical purposes.
- The use of marihuana for medical purposes should be considered a non-medical intervention because there is no medical evidence to support it.
- Health Canada is asking physicians to authorize the use of marihuana for medical purposes; a doctor's professional authority comes from knowledge and in this case, there is no evidence to support the use of marihuana for medical purposes.

- A doctor cannot do a medical assessment where there is no scientific ground to support the safe use of marihuana.

✓ *An Expert Advisory Committee (EAC) cannot provide authenticated information.*
- There is little evidence to support the use of marihuana for medical purposes, so an advisory committee cannot provide validated information to justify its therapeutic use.

Health Canada's response: The intention of the EAC would be to provide information to physicians who wish to make marihuana for medical purposes available to patients.

✓ *Concern with using the Methadone Program as a model for medical marihuana.*
- Some Colleges refused to be linked with the use of marihuana for medical purposes, even if it was through a methadone-like registry program; they refused to keep records and would continue to urge members to exercise extreme caution in "prescribing" such a treatment.

✓ *Issue of potential misuse of marihuana for medical purposes.*
- Some participants felt that most patients who want marihuana for medical purposes are not those who are desperately ill.
- Participants felt that those who are very sick do not have difficulty in having a doctor recommend this medication for them.

Question: How do you foresee getting past the hurdle of physicians refusing to "prescribe" marihuana for medical marihuana?

Response: Health Canada stated they have lost every court case against the use of marihuana for medical purposes. It has been legislated that the Government of Canada/ Health Canada must ensure that there is a legal supply available to those who require marihuana for medical purposes. The medical benefits have not been well explained to the judges and therefore Health Canada continues to lose court cases. Health Canada ensured participants that their sentiments and concerns would be conveyed to the Director General's superiors.

✓ *The lack of regulations and parameters in supporting access to marihuana for medical purposes is problematic.*
- The lack of guidelines and regulations associated with supporting access to marihuana for medical purposes makes it difficult for physicians to recommend this treatment option.
- Participants acknowledged that the "status quo" (ie. Physician as gatekeeper) is not sustainable, especially in light of the proposal to remove categories of conditions and symptoms from the regulations.

Health Canada stated they would be open to hearing about and discussing categories 1-15, and others if necessary. Others have to do research and set the parameters for the illness-eligible categories for the use of medicinal marihuana. Health Canada is happy to provide information to assist others to educate physicians.

✓ *Overburdened family physicians cannot take on this responsibility.*
- If this change in the Program occurs, already overburdened family physicians will be further encumbered with paperwork and insurance claims. These time-consuming activities could severely disadvantage other patients.
- Some participants disagreed; they noted that this responsibility is already under the purview of physicians and difficult to deal with because it is unregulated. Most deal with it in the context of comfort care.

4. Current physician practices for the use of marihuana for medical purposes and recommendations for regulating the new Program.

In order to gain an understanding of physician and health professional issues and the potential problems foreseen with the proposal for the new Program, the group were asked to give feedback and to share information on a number of key questions relating to the following focused themes.

- *Discussion themes:*
  - *a) Current practices*
  - *b) Suggestions for regulating the new Program*
  - *c) Health Canada's role*
  - *d) The role of other health professionals*

Participants were extremely reluctant to recommend any protocols that would endorse the use of marihuana for medical purposes. When pressed, they did share some ideas and make recommendations that were based on their practical experience. A number of key themes were discussed, including suggestions on clinical protocols and the regulation of the use of medical marihuana, for training and research on the use of marihuana for medical purposes, and finally, on the potential role for Pharmacists. This information was captured and is summarized below.

a. ***Current practices.***

✓ *Clinical protocols established in order to regulate the recommendation of marihuana for medical purposes.*

- One participant recounted their clinic's procedures.
  - the recommendation of medical use of marihuana was a team decision;
  - the team comprised a physician, a nurse, and a psychologist.
- This team was sophisticated and still experienced many challenges. It is difficult to see how supporting marihuana for medical purposes could be routine for every family doctor.
- *Cautions:*
  - Once it is known that a clinic will support patients' access to marihuana for medical purposes, many patients will request it; it is paramount to have an appropriate diagnosis protocol in place to avoid misuse.
  - The physician could be put in danger because some people who request this treatment could be the same as those who struggle with substance abuse and drug dependency; this could pose a significant risk to the physician.

b. ***Suggestions for regulating the new Program.***

✓ *Options proposed for controlling the use of marihuana for medical purposes.*

- One participant proposed three options for dealing with the problem of supporting access to marihuana for medical purposes:
  - *Option 1:* Keep the status quo where the physician can only confirm a medical diagnosis and does not "prescribe" marihuana for medical purposes; have another body judge how the medical condition can be relieved by this treatment.
  - *Option 2:* Treat marihuana like any other drug; do research and approve it through the formal drug approval process.
  - *Option 3:* Legalize marihuana.

Health Canada responded by saying that Health Canada is considering requiring a certification from the physician stating that the patient has a condition which may benefit from the use of marihuana.

✓ *Regulating use of marihuana for medical purposes for cancer patients and terminal patients.*
- The use of marihuana for medical purposes needs to be regulated; only physicians who are education and "specialized" should be allowed to "prescribe" it.
- Most physicians do not have a problem "prescribing" marihuana for medical purposes to the palliative care group.
- If marihuana is to be available for other medical conditions, the physician has to clearly identify the medical conditions appropriate for its use.
- An appropriate medical diagnosis needs to be determined by using evidence to support the "prescription"; there is a need to balance the risk and benefit to the patient.
- It *was recommended* that the medical condition categories be reinstated in order to better regulate the use of marihuana for medical purposes.
    - Less distinct categories make it more difficult to qualify a diagnosis because there is no defined condition. In this case, the risk is increased because there is no clear basis on which to support a patient's use of marihuana.
    - The more specific the categories, the easier it is for physicians to follow a protocol to recommend this therapy.
- Some disagreed with the validity of the "end of life" use of marihuana for medical purposes. They claimed that there is no indication for the use of marihuana for any situation.

✓ *Protocols for the use of complementary therapy.*
- In general, the medical associations allow physicians to use complementary therapy as long as specific protocols have been followed. Once conventional diagnosis and conventional therapies have been exhausted and the "checklist" has been completed, the recommendation to use marihuana for condition or symptom management can be made.

c. ***Health Canada's role.***

✓ *Physicians should be trained in the use of marihuana for medical purposes.*
- "Prescribing" medicinal marihuana should be restricted to specialized physicians; ones who have had specific training in this treatment.

✓ *Research into the medical benefits and risks of marihuana is extremely important.*
- Medicinal marihuana should be subject to scientific investigation; a research protocol should be established.
- *Suggestion:* The EAC should be the body that gives direction to the research on medical uses of marihuana. This research should be regulated and subject to the protocols in place for any new prescription drug.

d. ***The role of other health professionals.***

✓ *Pharmacist involvement.*
- Marihuana for medical purposes should be regulated and pharmacists should be brought in to handle it; this is a safer option.
- It was acknowledged that pharmacists would probably not want to be a distributor for the same reason as doctors are resistant; they fear violence.

Health Canada noted that they would return to the Pharmacists to revisit this issue with them.

5. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

Appendix A: Agenda

Health Canada
Marihuana Medical Access Program

Federation of Medical Regulatory Authorities of Canada

Date: October 26, 2011
Time: 8:00 – 9:30
Chateau Laurier – Renaissance Room

Item	Time
Introduction	8:00-8:05
Presentation of key elements of the proposal	8:05-8:15
General Discussion 1. What do you like about the new proposal? Why? 2. Do you have concerns regarding the proposed changes? What are your concerns? Why? What suggestions for improvement would you make?	8:15-8:35
Discussion Themes a. The role of physicians and other health professionals b. Supporting access to dried marihuana c. Advertising marihuana for medical purposes d. Health Canada's role	8:35-9:25
Next Steps, closing remarks	9:25-9:30

Health Canada's Marihuana Medical Access Regulations Consultations

Meeting with Medical Associations

September 28, 2011
Ottawa, Ontario

Meeting Summary

The following meeting report summarizes the points raised during a meeting with Medical Associations on the proposed changes to the Marihuana Medical Access Regulations (MMAR) announced on June 17 2011. This meeting was organized by Health Canada and took place on the morning of September 28th, 2011 at the Capital Hill Hotel & Suites in Ottawa.

1. Background

Jeannine Ritchot, Director of the Medical Marihuana Regulatory Reform Project, presented an overview of the proposed changes to the MMAR and provided an update on the consultation process to date. She noted that to date, consultations have been had with compassion clubs and cannabis dispensaries in Vancouver, Montreal and Toronto, and she indicated there are upcoming meetings with law enforcement and municipalities.

2. Participants

Participants from the following organizations were in attendance:

- Canadian Medical Association (CMA)
- College of Family Physicians of Canada (CFPC)
- Canadian Medical Protective Association (CMPA)

3. General Feedback

After a brief overview of the proposed changes to the regulations, participants were asked to identify aspects of the proposed changes that they liked and would like to see retained. The following highlights emerged:

- Participants appreciated the fact that there was a component of communication/education/outreach to physicians in the proposal.
- The concept of an expert advisory committee was well-received.
- The elimination of categories, which was previously seen as a barrier, was well-received by some participants, though there was not consensus on this issue.
- Several participants felt that the elimination of the obligation to see a specialist was a positive step forward as they felt this step did not bring any value to the process. Concern was noted however that this may create pressure on the first point of contact, which may then be perceived by an individual as a barrier to

obtaining marihuana for medical purposes. In response to this concern, Health Canada officials noted that the opportunity to consult with a specialist would still exist under the new proposal, it would simply no longer be an obligation.

- The overall streamlining of the regulations was appreciated by participants.
- The involvement of Health Canada in bringing safety controls to the process was generally regarded positively.

Concerns

Participants noted the following concerns related to the proposed changes to the regulations:

- One of the major concerns cited by participants was related to the lack of scientific evidence, information and guidance available for the ordinary physician on the risks and benefits of marihuana for medical purposes. The need for conclusive evidence of the effectiveness of the use of marihuana for medical purposes, and the associated risks, was strongly emphasized.
- Participants were very concerned that there are currently no established regulated standards or clinical guidelines on prescribing practices for marihuana for medical purposes. Clinical practice guidelines should be an important pillar of this initiative.
- Participants noted that physicians have highly diverse backgrounds and prescribing philosophies. There is currently a very small number of physicians (3000 - less than 3-5% of CMPA's membership) who are comfortable prescribing marihuana for medical purposes. These physicians are not equally distributed across Canada. In order to provide Canadians across the country with equal access to marihuana for medical purposes, more family physicians need to be better equipped with knowledge and training about the benefits and risks associated with marihuana for medical purposes.
- Physicians want to help their patients and they feel accountable for the treatment they recommend. Participants reported that many physicians felt uncomfortable providing access to marihuana for medical purposes due to the state of knowledge on its benefits and risks. There was also some concern that this may put physicians in uncomfortable situations with sometimes long-standing patients, and that some physicians could be taken advantage of by patients faking symptoms to gain access to marihuana for medical purposes.
- Physicians want to know that the treatment they prescribe to patients will do some good, and they also need to be protected against legal consequences should they arise.

Suggestions

Participants made the following suggestions to address some of the concerns they noted:

- Disseminate information (a "one-pager") on the use of marihuana for medical purposes that is simple, easily readable and more widely available to physicians.
- Consider a variety of vehicles for consultation with physician, including an online module that physicians can access anytime depending on their time schedule.
- Consult physicians who are currently supporting access to marihuana for medical purposes on their rationalization for the legal liability involved.
- Engage physicians nationally through the College of Family Physicians Canada (CFPC), as well as through provincial chapters.
- Increase dialogue with other players (e.g. homeopaths, osteopaths, alternative care providers) to reflect the nature of today's collaborative care environment.
- Engage the practitioner community, e.g. naturopaths, pharmacists and nurse practitioners.
- Engage Registrars/Colleges of Physicians and Pharmacists in the discussion on standards, guidelines and prescribing practices for marihuana for medical purposes to ensure that the relationship between physicians and regulatory agencies is set up for success. Ensure that they recognize this is a different situation and obtain their buy-in for managing within an uncertain environment.
- Consider providing indemnification to physicians to help mitigate potential court issues.
- Undertake a privacy impact assessment to clarify the implication of physicians sending forms containing potentially sensitive information (e.g. on a diagnosis) to a licensed commercial entity.
- Engage physicians who believe in this cause and who are comfortable supporting access to marihuana for medical purposes and get them to produce some literature and knowledge about what they're doing for their colleagues and peers. Encourage them to build a respected body of knowledge so that the decision to support medical marihuana can be defensible to regulatory bodies and the court system.

4. Targeted Discussion Questions

Role of Physicians and Other Health Professionals

Participants made the following comments with regards to the role that physicians should play with respect to the use of marihuana for medical purposes:

- Several participants strongly articulated that the role of a physician is to treat patients and not to manage access to a controlled substance.

- Many felt that without enough available evidence on the benefit of the treatment, a physician does not have the ability to make a sound clinical judgement, and that without that ability, the role of a physician in this process would be unclear. If access to marihuana for medical purposes requires a clinical decision, then there must be sufficient evidence to link the use of marihuana for medical purposes to the management of a very particular disease and symptom.
- A suggestion was made that additional training should be required for physicians to provide access to marihuana for medical purposes.
- Participants felt that the process proposed by Health Canada to provide access to marihuana for medical purposes is too similar to traditional prescribing practices. Physicians prescribe treatment based on evidence and according to established guidelines. To obtain their buy-in, it will be important to better distinguish between prescribing treatment and providing access.
- With the current state of knowledge as it is, physicians fear they will be legally liable if they recommend a treatment that ultimately harms a patient. From the perspective of a regulatory body or a court, the responsibility for the treatment falls would fall on the physician as he would be seen as the ultimate decision-maker when it comes to administering the treatment.
- Physicians may only be comfortable with confirming a diagnosis, providing the evidence to support that diagnosis, and/or declaring that the patient has symptoms that may benefit from access to marihuana for medical purposes.
- Participants noted that because of the variability of the product offered, physicians do not have the same level of confidence in the treatment the patient is gaining access to (than with a standardized product).

Participants made the following comments with respect to the role of other healthcare professionals to support the use of marihuana for medical purposes:

- Participants felt that medical practitioners may not be the only professionals in healthcare who could be 'gatekeepers' to the Program. Participants indicated they saw a role for other healthcare professionals to support the use of marihuana for medical purposes and suggested exploring the possibility of broadening the scope to include other regulated professionals and health care providers.
- There should be a whole system in place to support the management of the prescribing to the individual, as well as a documented history of the diagnosis.
- Poor communication in a collaborative care environment is an issue that must be addressed. Participants suggested that information on dosage and period of prescribed treatment must be communicated back to the physician by the dispensary.

- A suggestion was made that independent qualified medical professionals, such as the ones used for CPP, Immigration, etc., could be the ones to provide Canadians with access to marihuana for medical purposes.

Supporting Access to Dried Marihuana for Medical Purposes

Participants made the following comments with regards to the removal of regulatory requirements governing symptoms and conditions for which marihuana may be used:

- Some participants supported the removal of regulatory requirements governing the categories of symptoms and conditions for which marihuana may be used, because it provides more leeway to patients and their physicians, but it was not supported by all participants
- Some participants were concerned that the removal of these categories of symptoms and conditions may in fact take away what little guidance is available to physicians on prescribing marihuana for medical purposes.
- It was noted that one of the values of the categories was that it provided a physician the opportunity to decline access to marihuana for medical purposes because the patient's condition did not appear on the list.

Participants made the following comments with regards to Health Canada's proposal that doctors would provide a patient with a document indicating their support for a patient to obtain marihuana for medical purposes from a licensed commercial producer:

- The term "support" caused participants concern because they felt it will be seen as a "prescription".

With regards to what should be on the form, the following comments were made:

- It was unclear to participants what the intent of the form was. Participants suggested that Health Canada should first clarify the intent of the form, and then form would follow function.
- Discussion was had about whether or not the form should include prescribed dosage and period of treatment time:
    - Participants noted they were uncomfortable with the notion of physicians recommending a prescribed dosage and period of treatment due to the fact that most family physicians have no expertise or background in supporting marihuana for medical purposes.
    - Participants also felt that without a research evidence-base to guide dosage, they should not be expected to recommend a dose.
    - If the purpose of the medical practitioner is only to facilitate access to medical marihuana, then the form should not include information on dosage.

    - Participants also felt that recommending a dose to a patient increased legal risks exponentially for physicians.
- Participants were concerned with who would have access to/a copy of the form.
- A suggestion was made to organize a separate workshop dedicated to discussing what information would appear on the form.
- Participants suggested that the form should include a record of informed consent that the patient recognizes the limitations of the treatment, and a release of liability.

Other comments made by participants include:

- Most participants felt that physicians don't have the proper tools to monitor or follow up with a patient afterwards.
- Participants noted concern with the absence of good monitoring tools to evaluate the possibility of harmful interactions with other medications taken by a patient over the long-term.
- Participants made no comment on recommending a route of administration of marihuana for medical purposes.

Patient Education and Outreach

- Participants felt that a physician should play a key role in patient education and outreach but felt that they did not have enough information and training to do so.
- A suggestion was made that Health Canada convey information about the benefits and risks associated with medical marihuana to the public so that they have in their hands the same information as physicians do.
- Participants indicated that outreach to physicians must involve equipping them with proper knowledge about the positive aspects of marihuana for medical purposes; however, they were concerned that there was not enough scientific evidence to support this.

Health Canada's Role

- Many participants were concerned that there would be insufficient consultation with the medical community on the proposed approach. They felt that the establishment of an Expert Advisory Committee was insufficient and wanted to ensure a lot more consultation would take place with physicians.

MMAP Targeted Consultations – Federation of Medical Regulatory Authorities of Canada (FMRAC)

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status

On October 26, 2011, representatives from Health Canada met with representatives from the Federation of Medical Regulatory Authorities of Canada (FMRAC) during a regularly scheduled meeting of FMRAC in Ottawa. FMRAC is the association of all Colleges of Physicians and Surgeons in Canada. Representatives from all Colleges were in attendance, except Nunavut.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on participants' issues/concerns about the proposal.

FMRAC members expressed significant concern with respect to what they perceive to be the unchanged role of physicians as "gatekeepers" under the proposed changes. Their concerns were two-fold. First, there continues to be a lack of scientific evidence pointing to the effectiveness and safety of marihuana for medical purposes. Lacking such evidence, the colleges feel that it is inappropriate for Health Canada to ask physicians to shoulder the decision regarding whether or not an individual should have access to marihuana. Many Colleges acknowledged that they will continue to discourage their members from supporting the use of marihuana for medical purposes under a reformed program. Secondly, as regulators of the profession, the Colleges are concerned about the potential for some medical practitioners to "over-prescribe" marihuana, particularly given the absence of clinical guidelines for its usage. This creates a burden for them from an oversight and monitoring perspective. Many participants noted that physicians would be more comfortable participating in the program if successful research and/or clinical trials established the benefits of marihuana and if it were approved as a therapeutic drug. While they welcome the establishment of an Expert Advisory Committee, participants do not feel that it goes far enough to address the lack of information among physicians. Some advocated for the addition of a research protocol to the proposal.

Key Concerns

- Participants believe that physicians were unwillingly placed in a gatekeeper role which they feel is not appropriate for marihuana.
    - Marihuana has no clear evidence of medical benefit
    - Feeling that the EAC will not address the lack of evidence available to support the use of marihuana for medical purposes.
- Some Colleges recommended a methadone registry-like program, however, it was noted that this model would not be supported by all Colleges.
    - Viewed as a model that would require further intervention from Colleges (i.e. monitoring that only those doctors on the registry are providing access) and which placed further burden on the registrars.
- Removal of categories of symptoms and conditions may increase the number of patients requesting access to marihuana for medical purposes, and thereby increase the pressure on physicians.
    - Registrars raised concerns that it was difficult for them to regulate physicians who are supporting access to marihuana for medical purposes without clinical guidelines for physicians to follow – some felt that the categories were partially serving that purpose.
    - Some Colleges raised concerns for the physicians that are the sole practitioners in their communities (i.e. they feel the most pressure to support the use of marihuana despite their lack of comfort).
    - Concern that the less restrictive access to marihuana for medical purposes could lead to over-prescription.
- Participants noted that if physicians are gatekeepers, then pharmacists should be a part of the program as well – it would provide a regulated, monitored process that would be more in-line with other pharmaceuticals and narcotics.

Next Steps

Health Canada officials will have a kiosk at the CFPC's Family Medicine Forum November 3-5 to engage with physicians on Health Canada's proposed improvements. Officials are also developing a survey and a website to reach out to individual physicians and to seek their views on reform and on their educational and informational needs with respect to the use of marihuana for medical purposes.

An analysis of the consultations will be written, studied and incorporated in to the final reform package.

MMAP Targeted Consultations – Federation of Canadian Municipalities

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status

On September 29, 2011, representatives from Health Canada met with the Federation of Canadian Municipalities for a targeted consultation at the Capital Hill Hotel and Suites, Ottawa. The FCM organized a group of representatives from a number of municipalities that work in policy areas that have an interest/stake in the proposed reform of the Program. Representatives were from the following areas: by-law services, building and regulatory services, inspection services, law enforcement, and fire services.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Feedback on questions posed by Health Canada to meeting participants.

Overall, Health Canada's recommendation to create a regulated industry was well received. There were concerns related to the absence of interim measures to address municipalities' challenges regarding personal production in private dwellings. FCM representatives cautioned that Health Canada should consider the limited availability of inspection resources in some municipalities when designing the program, as there is the potential for increased pressure on municipal resources to monitor and inspect licensed commercial producers.

Positive Elements of the Proposal

- Overall agreement with the need for a regulated industry.
- Appreciation that Health Canada recognized that the current program is flawed.
- The elimination of personal and designated-person production in residential areas.
- Inspections ensuring quality of product and safety of growing procedures.
- The ability to regulate commercial entities through local by-law and zoning regulations.
- Mail-order delivery removes the centralization of crime and stigmatization of neighbourhoods that may result from dispensaries for the sole purpose of marihuana distribution.

Key Concerns

- The timelines for reform leave a significant period of time where municipal concerns and challenges with the current program will not be addressed.
- The elimination of PUPL and DPPL is welcomed, but questions were raised regarding remediation standards for those dwellings that are currently used as growing sites – the public health and public safety risks will continue after the program sunsets (ie mould spores, pesticide contamination, etc). Specifically, questions were raised regarding whether or not Health Canada has a responsibility to remediate, and what it plans to do in this regard.
    - Recommended that Health Canada send information packages to licence holders upon sunset of the program that highlights public health concerns and required steps of remediation.
- Compliance and enforcement framework may create a capacity issue for municipalities - will require clear distinction between federal and municipal jurisdictions. (ie. who inspects for what?)
    - Integrated service teams were highlighted as a model;
    - Communications protocol between municipal and federal inspectors would be imperative;
    - Review period would be required once the new regulations are in place (ie. how's it working? Do changes need to be made?)
    - If PUPL and DPPL are grandfathered, municipalities will not be able to maintain an inspection regime due to the volume of inspections that could be required.
- Questions were raised about how organized crime could be prevented from using the legal market to divert product to the illicit market.

Health Canada Questions

- Do you see a role for yourselves in determining/maintaining the eligibility of a licensed commercial producer? If so, what kind of role? (e.g. approving zoning)
    - Health Canada's licensing of commercial producers could be contingent on interested parties meeting municipal zoning regulations, obtaining municipal approval to operate, inspections, etc first. (eg. checklist to prove complete);
    - Municipalities will need to examine size and use of buildings and be able to assess the residual affects of commissioning old buildings;

- What are your thoughts on whether marihuana dispensaries have a role in the program? What threats/risks might be involved, and how could they be mitigated?
    - Municipalities were not comfortable with the addition of dispensaries to new framework for the program;
    - Recommended that Health Canada explore pharmacy models if seeking to expand beyond the mail delivery option;
    - Concerns with onsite consumption;

- Patients could be at higher risk of robbery if leaving a dispensary with a large amount of dried marihuana;
- Citizens may not welcome or support the addition of dispensaries in their neighbourhoods.

- If HC were to reconsider small-scale, personal production of marihuana in private dwellings, what program elements would increase your level of comfort?
  - Knowledge of location of medical grow operations;
  - Inspection and enforcement of regulations – a stronger accountability mechanism for patients;
  - Annual inspections (ie electrical, safety, etc);
  - Renewals (even in the interim) should be subject to similar regulations and transparency that will be required of commercial producers.

Other Points of Discussion

- The FCM requested that further consultation be undertaken with municipalities, especially if Health Canada's proposal changes;
- Health Canada officials committed to speak with the current program director to assess what can be done in the interim to address challenges of PUPL and DPPL.
- Health Canada committed to providing a breakdown on the number of authorizations to possess and personal and designated production licences by province.

Next Steps

Health Canada representatives will be meeting with members of the Canadian Association of Chiefs of Police and the RCMP on October 12. An analysis of these consultations will be written and incorporated in to the final reform package.

Health Canada's Marihuana Medical Access Regulations Consultations

Meeting with Federation of Canadian Municipalities

September 29, 2011
Ottawa, Ontario

Meeting Summary

The following meeting report summarizes the points raised during a meeting with the Federation of Canadian Municipalities (FCM) on the proposed changes to the Marihuana Medical Access Regulations (MMAR) announced on June 17 2011. This meeting was organized by Health Canada and took place on the afternoon of September 29th, 2011 at the Capital Hill Hotel & Suites in Ottawa.

1. Background

Jeannine Ritchot, Director of the Medical Marihuana Regulatory Reform Project, presented an overview of the proposed changes to the MMAR and provided an update on the consultation process to date. She noted that to date, consultations have been had with compassion clubs and cannabis dispensaries in Vancouver, Montreal and Toronto, with Fire Chiefs and Medical Associations, and she indicated there is an upcoming meeting with law enforcement.

2. Participants

The Federation of Canadian Municipalities organized a group of representatives from a number of municipalities that work in policy areas that have an interest/stake in the proposed reform of the Program. Representatives were from the following areas: by-law services, building and regulatory services, inspection services, law enforcement, and fire services.

3. General Feedback

After a brief overview of the proposed changes to the regulations, participants were asked to identify aspects of the proposed changes that they liked and would like to see retained. The following key messages emerged:

- Overall, participants felt that the proposed changes to the regulations were positive in nature.
- The move from individual licensing to commercial licensing was applauded by the group.
- From a municipal enforcement perspective, the majority of participants were in favour of the fact that production in residential areas would be phased out.

- It was noted that the move to commercial licensing would alleviate some concerns related to public health and the safety of buildings were marihuana will be grown.
- Participants were pleased to hear that Health Canada had plans for the inspection of licensed commercial producers.

General Concerns:

Participants noted the following general concerns:

- One of the most serious concerns raised by participants was related to the critical need to remediate homes where marihuana has been grown to bring them back to an acceptable living standard for future tenants.
- Participants wanted to ensure that municipalities are part of the approval process for commercial licensing.
- Participants were concerned with the potential involvement of organized crime in growing operations. They noted that it would be important for Health Canada and municipalities to work together to monitor for such.
- Participants were concerned that if a grandfather clause was created to maintain the rights of current license holders to the personal production of marihuana, that there would be a substantial surge in applications between now and 2014.

Suggestions

Participants made the following suggestions to address some of the concerns raised throughout the meeting:

- Work with municipalities to develop interim inspection measures for individual producers during the transition period.
- Ensure more consultation with municipalities throughout the regulatory development process.
- Establish a communications channel and review function once the regulations are implemented so that relevant players can discuss what is working and what is not working, and make suggestions for improvement (e.g. minor tweaking to the regulations).
- Participants encouraged Health Canada to look for opportunities to partner with local safety and fire inspectors to conduct inspections.
- Partner with private electrical companies for inspections to ensure there is no resource strain on municipalities.
- Establish a communications protocol to share information after separate inspections (municipal/Health Canada) so all players are on the same page.

- Establish a liaison function between Health Canada and local jurisdictions to ensure that premises where marihuana has been grown are properly remediated so that they meet safety standards for future tenants. At the bare minimum, Health Canada should distribute an information package to current individual license holders advising them of health concerns they may want to look into if they have been growing marihuana in their own residence.
- Develop a guide on safe production practices, including air movement, equipment safety, etc. and distribute to individual producers in the transition period.
- Consider Surrey's electrical fire safety inspection model as a best practice.
- Include cost recovery considerations in permit fees for additional municipal police and fire fighting personnel costs that might be associated with issuing a license.

4. Targeted Discussion Questions

Production and Distribution of Marihuana for Medical Purposes

Participants felt municipalities have a role to play in determining the eligibility of a licensed commercial producer. This role would relate to regulating and monitoring zoning, building codes and safety issues.

Participants made the following comments with regards to the distribution of marihuana for medical purposes:

- There were mixed views with regards to whether marihuana dispensaries should have a role in the program.
- It was noted that the City of Victoria currently hosts 3 dispensaries that have not caused any police disruption or had any social impacts on local communities. Some participants noted that dispensaries are a safe and effective means for Canadians to access marihuana, and that they have been the producer of choice for a large portion of current marihuana users. The Canadian AIDS Society has put forth a discussion position paper that supports the use of dispensaries.
- Onsite consumption is only currently done in a couple dispensaries in Canada and it is not seen as a key role of dispensaries. Key roles of a dispensary would be: providing access, getting information out to patients, and effectively tracking the amount of marihuana patients are taking to reduce diversion or abuse.
- With regards to threats or risks associated with the dispensary model, some participants suggested that awareness-raising could mitigate negative community perception and help obtain buy-in from community stakeholders.
- In the end, the majority of stakeholders did not feel that the proposal should include a role for regulated dispensaries.

- It was agreed different distribution models/options should be available to accommodate the needs of each community.
- Participants noted a preference that marihuana be distributed through a pharmacy if possible.
- It was noted that smaller communities may prefer a bonded mail distribution model.
    - A mail-order distribution model would reduce issues inherent with governing a store-front model.
    - There may be community resistance to a store-front model.
    - It was noted that this model may increase cost to patients and lower access to effective information.
    - A direct mail delivery model would provide some extra security – as product would not be sold from a store front.
    - Some participants did not like the bonded mail model and would like to see other options available.

When asked if there are any program elements that would increase the group's comfort level with reconsidering personal production of marihuana, participants made the following comments:

- A compromise could be achieved if municipalities were informed of the location of buildings where marihuana has been grown so that they could be inspected.
- Individual producers should be required to comply with the same inspections as commercial producers as a condition for licensing.
- Requiring an annual electrical and fire inspection as a condition for licensing for growing marihuana in private homes would alleviate safety concerns in the transition period.

Participants made the following comments with regards to the indoor vs. outdoor cultivation of marihuana:

- All participants agreed these operations should not be located in residential areas.
- Preferably, licensed commercial producers would operate from purpose-built buildings or retrofits that meet all building codes.
- Many participants were strongly in favour of indoor growing operations within an industrial zone, e.g. such as in an anonymous warehouse that is protected from theft.

- Some felt that cultivating marihuana in a greenhouse would have to be done in an agricultural zone.
- Whether they are located indoors or outdoors, municipalities would like to ensure these operations are in secure locations.
- Participants felt that it would be easier to maintain the security of the operation if it were localized indoors. It was felt that indoors, whenever possible, would be the safest approach.
- It was recognized that indoor operations can pose increased fire risk.
- High security requirements will entail a higher cost to the consumer.

Regulations, Zoning and Bylaws

- Participants wanted to ensure that municipalities have the opportunity through planning and zoning mechanisms to determine the most appropriate location for these types of operations so they can be regulated appropriately.
- The group agreed that commercial producers should require municipal approval and demonstrate compliance with municipal building and zoning by-laws as a pre-condition for licensing by Health Canada.
- Participants were concerned that the current proposed regulations largely related to existing buildings and did not encompass the possibility of new constructions. Participants wanted to ensure that building officials/inspectors would be engaged in the process to ensure that new buildings are constructed the proper way and consideration is given to issues such as air circulation in the building.
- The municipal role needs to be more clearly defined in the inspection process.

Compliance and Enforcement

Participants indicated that municipalities would like to play a role in a compliance and enforcement program. They suggested that there may be opportunity for cooperative action between Health Canada inspectors and municipal inspectors, however it was noted that both small and large communities have capacity issues around inspection. Therefore, municipalities would like to be consulted further on compliance and enforcement issues as Health Canada furthers its policy thinking. It was suggested that permit fees could include inspection costs to help municipalities recover the costs associated with this potential new role.

MMAP Targeted Consultations – Provincial and Territorial Ministries of Health

Background:
On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status:
On November 24, 2011, Health Canada representatives met with PT public safety representatives at a regular meeting of the FPT ADM Policing Issues Committee, to discuss Health Canada's proposed improvements to the MMAP.

Meeting Synopsis:
Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on two themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.

Overall, the proposal was well received. A number of participants expressed willingness to discuss the proposal with their PT Health colleagues to ensure PT consensus on key elements of Health Canada's proposal. Specific concerns relate to public safety and public security. One participant highlighted that there could potentially be enforcement issues that would require PT resources to address (DUI, increased use, increased diversion).

Key Concerns:

- Participants raised questions about the increasing growth in the number of program participants. The increased number of participants will likely result in an increased number of PUPLs and DPPLs in the interim.
    - There was concern raised about whether grandfathering would be allowed, and if so, for what period of time.
    - There was concern about whether this could have an impact on public health, safety and security during transition.
- Participants expect that this increase in the number of participants could lead to increased pressures on PT policing resources (ie. monitoring driving while under the influence of a controlled substance)
- Participants are concerned that licensed commercial production could potentially be used as a front through which organized crime could divert product to the illicit market.

This is the first of a series of meetings that will be held with prospective licensed commercial producers; dates are yet to be determined. An analysis of the consultation with Prairie Plant Systems, and other prospective licensed commercial producers will be developed and incorporated in to the final reform package.

Medical Marihuana Regulatory Reform – Meeting with the Province of BC
Victoria, BC
February 14, 2012

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. Meetings with key stakeholders were held between August and November 2011, which included regional teleconferences with provincial and territorial ministries of health. From those calls, Health Canada recognized that there are key issues that require further collaboration with our P/T colleagues, namely the following:

- Whether health care practitioners, other than physicians, should support a patient's access to marihuana for medical purposes;
- Whether pharmacies should play a dispensing role for marihuana for medical purposes, and
- Concerns regarding the potential increased pressure on PT drug plans to cover costs to patients who are purchasing marihuana for medical purposes from licensed commercial producers.

Current Status

On February 14, 2012, representatives from Health Canada met with representatives from the British Columbia provincial government (see Annex A for participant list). While the focus was on health policy and implications for health services, representatives from ministries responsible for public safety, and social and community services were present.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the Marihuana Medical Access Program and provided updates regarding the regulatory development process and timelines. Ensuing discussion centred on four themes:

1. The potential role of other health care professionals;
2. The supply, distribution and dispensing of marihuana for medical purposes and the role of pharmacies;
3. Pressures on BC drug plan to cover patient expenses for marihuana for medical purposes; and
4. Program development/process issues.

Key Discussion Points

The potential role of other health professionals

- BC would be supportive of expanding authority to other health professionals to support access to marihuana for medical purposes, noting that building jurisdictional flexibility into the regulatory framework was a very positive step.
- BC anticipated that Health Canada would provide similar support to build the knowledge and competencies of other health professionals as they are doing for physicians with the Expert Advisory Committee (EAC).

- Participants questioned the role of doctors and how they would be monitored for compliance.

Next Steps:
An analysis of the scheduled consultations with all provinces and territories will be introduced into the final reform package.

This is **Exhibit " G "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

CANADA

CONSOLIDATION

CODIFICATION

Marihuana for Medical Purposes Regulations

Règlement sur la marihuana à des fins médicales

SOR/2013-119

DORS/2013-119

Current to September 4, 2013

À jour au 4 septembre 2013

Published by the Minister of Justice at the following address:
http://laws-lois.justice.gc.ca

Publié par le ministre de la Justice à l'adresse suivante :
http://lois-laws.justice.gc.ca

OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (3) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

Published consolidation is evidence

31. (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

...

Inconsistencies in regulations

(3) In the event of an inconsistency between a consolidated regulation published by the Minister under this Act and the original regulation or a subsequent amendment as registered by the Clerk of the Privy Council under the *Statutory Instruments Act*, the original regulation or amendment prevails to the extent of the inconsistency.

NOTE

This consolidation is current to September 4, 2013. Any amendments that were not in force as of September 4, 2013 are set out at the end of this document under the heading "Amendments Not in Force".

CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (3) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1er juin 2009, prévoient ce qui suit :

Codifications comme élément de preuve

31. (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

[...]

Incompatibilité — règlements

(3) Les dispositions du règlement d'origine avec ses modifications subséquentes enregistrées par le greffier du Conseil privé en vertu de la *Loi sur les textes réglementaires* l'emportent sur les dispositions incompatibles du règlement codifié publié par le ministre en vertu de la présente loi.

NOTE

Cette codification est à jour au 4 septembre 2013. Toutes modifications qui n'étaient pas en vigueur au 4 septembre 2013 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

TABLE OF PROVISIONS

TABLE ANALYTIQUE

Registration
SOR/2013-119 June 7, 2013

CONTROLLED DRUGS AND SUBSTANCES ACT

Marihuana for Medical Purposes Regulations

P.C. 2013-645 June 6, 2013

Whereas a provision of the annexed Regulations provides for the communication of information obtained under the Regulations to certain classes of persons referred to in paragraph 55(1)(*s*) of the *Controlled Drugs and Substances Act*[a] and, in the opinion of the Governor in Council, it is necessary to communicate that information to those classes of persons for the proper administration or enforcement of the Act and the Regulations;

Therefore, His Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act*[a], makes the annexed *Marihuana for Medical Purposes Regulations*.

[a] S.C. 1996, c. 19

Enregistrement
DORS/2013-119 Le 7 juin 2013

LOI RÉGLEMENTANT CERTAINES DROGUES ET AUTRES SUBSTANCES

Règlement sur la marihuana à des fins médicales

C.P. 2013-645 Le 6 juin 2013

Attendu qu'une disposition du règlement ci-après prévoit la communication de renseignements fournis sous son régime à certaines catégories de personnes visées à l'alinéa 55(1)*s*) de la *Loi réglementant certaines drogues et autres substances*[a] et que le gouverneur en conseil estime nécessaire d'aviser ces catégories de personnes pour l'application ou l'exécution de cette loi et du règlement,

À ces causes, sur recommandation de la ministre de la Santé et en vertu du paragraphe 55(1) de la *Loi réglementant certaines drogues et autres substances*[a], Son Excellence le Gouverneur général en conseil prend le *Règlement sur la marihuana à des fins médicales*, ci-après.

[a] L.C. 1996, ch. 19

MARIHUANA FOR MEDICAL PURPOSES REGULATIONS

INTERPRETATION

Definitions

1. (1) The following definitions apply in these Regulations.

"Act" «*Loi*»
"Act" means the *Controlled Drugs and Substances Act*.

"adult" «*adulte*»
"adult" means a person who is 18 years of age or older.

"advertisement" «*annonce*»
"advertisement" has the same meaning as in section 2 of the *Narcotic Control Regulations*.

"brand name" «*marque nominative*»
"brand name" means, with reference to cannabis, the name, in English or French,

(*a*) that is assigned to it;

(*b*) that is used to distinguish it; and

(*c*) under which it is sold, provided or advertised.

"cannabis" «*chanvre indien*»
"cannabis" means the substance set out in item 1 of Schedule II to the Act.

"client" «*client*»
"client" means a person who is registered as a client with a licensed producer under section 111.

"competent authority" «*autorité compétente*»
"competent authority" has the same meaning as in section 2 of the *Narcotic Control Regulations*.

"delta-9-tetrahydrocannabinol" «*delta-9-tétrahydrocannabinol*»
"delta-9-tetrahydrocannabinol" means Δ^9-tetrahydrocannabinol ((6aR, 10aR)-6a, 7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo [b,d] pyran-1-ol).

"dried marihuana" «*marihuana séchée*»
"dried marihuana" means harvested marihuana that has been subjected to any drying process.

"health care practitioner" «*praticien de la santé*»
"health care practitioner" means a medical practitioner or a nurse practitioner.

"hospital" «*hôpital*»
"hospital" has the same meaning as in section 2 of the *Narcotic Control Regulations*.

RÈGLEMENT SUR LA MARIHUANA À DES FINS MÉDICALES

DÉFINITIONS ET INTERPRÉTATION

Définitions

1. (1) Les définitions qui suivent s'appliquent au présent règlement.

«administration locale» "*local government*"
«administration locale» S'entend notamment :

a) d'une cité, d'une région métropolitaine, d'une ville, d'un village ou d'une municipalité dotés ou non de la personnalité morale;

b) d'une bande au sens du paragraphe 2(1) de la *Loi sur les Indiens*;

c) d'une bande qui est partie à un accord global sur l'autonomie gouvernementale mis en vigueur par une loi fédérale.

«adulte» "*adult*"
«adulte» Personne âgée d'au moins 18 ans.

«annonce» "*advertisement*"
«annonce» S'entend au sens de l'article 2 du *Règlement sur les stupéfiants*.

«autorité compétente» "*competent authority*"
«autorité compétente» S'entend au sens de l'article 2 du *Règlement sur les stupéfiants*.

«chanvre indien» "*cannabis*"
«chanvre indien» La substance inscrite à l'article 1 de l'annexe II de la Loi.

«client» "*client*"
«client» La personne inscrite comme client du producteur autorisé conformément à l'article 111.

«contenant immédiat» "*immediate container*"
«contenant immédiat» Contenant visé à l'alinéa 64*a*).

«delta-9-tétrahydrocannabinol» "*delta-9-tetrahydrocannabinol*"
«delta-9-tétrahydrocannabinol» Δ^9-tétrahydrocannabinol (tétrahydro-6a,7,8,10a hydroxy-1 triméthyl-6,6,9 pentyl-3 6H-dibenzo[b,d]pyranne-(6aR, 10aR).

«Directive en matière de sécurité» "*Security Directive*"
«Directive en matière de sécurité» La *Directive sur les exigences en matière de sécurité physique pour les substances désignées (Exigences en matière de sécurité*

"immediate container" «*contenant immédiat*»
"immediate container" means the container referred to in paragraph 64(*a*).

"international obligation" «*obligation internationale*»
"international obligation" means an obligation in respect of cannabis set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres.

"licensed dealer" «*distributeur autorisé*»
"licensed dealer" has the same meaning as in section 2 of the *Narcotic Control Regulations*.

"licensed producer" «*producteur autorisé*»
"licensed producer" means the holder of a licence issued under section 25.

"local government" «*administration locale*»
"local government" includes the government of

(*a*) an incorporated or unincorporated city, metropolitan area, town, village or municipality;

(*b*) a band, as defined in subsection 2(1) of the *Indian Act*; and

(*c*) a band that is a party to a comprehensive self-government agreement given effect by an Act of Parliament.

"marihuana" «*marihuana*»
"marihuana" means the substance referred to as "Cannabis (marihuana)" in subitem 1(2) of Schedule II to the Act.

"medical document" «*document médical*»
"medical document" means a medical document referred to in section 129.

"medical practitioner" «*médecin*»
"medical practitioner" means a person who

(*a*) is registered and entitled under the laws of a province to practise medicine in that province; and

(*b*) is not named in a notice issued under section 59 of the *Narcotic Control Regulations* that has not been retracted under section 60 of those Regulations.

physique des substances désignées entreposées chez les distributeurs autorisés), publiée par le ministère de la Santé, avec ses modifications successives.

«distributeur autorisé» «distributeur autorisé» "*licensed dealer*"
«distributeur autorisé» S'entend au sens de l'article 2 du *Règlement sur les stupéfiants*.

«document médical» «document médical» "*medical document*"
«document médical» Document médical visé à l'article 129.

«habilitation de sécurité» «habilitation de sécurité» "*security clearance*"
«habilitation de sécurité» Habilitation de sécurité accordée par le ministre en vertu de l'article 92.

«hôpital» «hôpital» "*hospital*"
«hôpital» S'entend au sens de l'article 2 du *Règlement sur les stupéfiants*.

«infirmier praticien» «infirmier praticien» "*nurse practitioner*"
«infirmier praticien» Infirmier praticien, au sens de l'article 1 du *Règlement sur les nouvelles catégories de praticiens*, qui, à la fois :

a) est autorisé à prescrire de la marihuana séchée dans la province où il exerce;

b) n'est pas nommé dans un avis donné en vertu de l'article 59 du *Règlement sur les stupéfiants* n'ayant pas fait l'objet d'une rétractation en vertu de l'article 60 de ce règlement.

«installation» «installation» "*site*"
«installation» Selon le cas :

a) bâtiment ou local exploité par le producteur autorisé;

b) emplacement occupé exclusivement par les bâtiments exploités par le producteur autorisé.

«Loi» «Loi» "*Act*"
«Loi» La *Loi réglementant certaines drogues et autres substances*.

«marihuana» «marihuana» "*marihuana*"
«marihuana» La substance appelée cannabis (marihuana), inscrite au paragraphe 1(2) de l'annexe II de la Loi.

"nurse practitioner" «*infirmier praticien*»

"nurse practitioner" means a nurse practitioner within the meaning of section 1 of the *New Classes of Practitioners Regulations* who

(*a*) is permitted to prescribe dried marihuana in the province in which they practise; and

(*b*) is not named in a notice issued under section 59 of the *Narcotic Control Regulations* that has not been retracted under section 60 of those Regulations.

"pharmacist" «*pharmacien*»

"pharmacist" means a pharmacist within the meaning of section 2 of the *Narcotic Control Regulations* who is not named in a notice issued under section 48 of those Regulations that has not been retracted under section 49 of those Regulations.

"responsible person in charge" «*personne responsable*»

"responsible person in charge" means, for the purpose of Part 1, the person designated under paragraph 22(1)(*b*).

"security clearance" «*habilitation de sécurité*»

"security clearance" means a security clearance granted by the Minister under section 92.

"Security Directive" «*Directive en matière de sécurité*»

"Security Directive" means the *Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances)* published by the Department of Health, as amended from time to time.

"senior person in charge" «*responsable principal*»

"senior person in charge" means the person designated under paragraph 22(1)(*a*).

"site" «*installation*»

"site" means

(*a*) a building or a place in a building used by a licensed producer; or

(*b*) an area occupied exclusively by buildings used by a licensed producer.

«marihuana séchée» Marihuana qui a été récoltée et soumise à un processus de séchage. «marihuana séchée» "*dried marihuana*"

«marque nominative» Dans le cas du chanvre indien, le nom français ou anglais qui, à la fois : «marque nominative» "*brand name*"

a) lui a été attribué;

b) sert à l'identifier;

c) est celui sous lequel il est vendu, fourni ou fait l'objet d'une annonce.

«médecin» Personne qui, à la fois : «médecin» "*medical practitioner*"

a) est agréée et autorisée, en vertu des lois d'une province, à exercer la médecine dans cette province;

b) n'est pas nommée dans un avis donné en vertu de l'article 59 du *Règlement sur les stupéfiants* n'ayant pas fait l'objet d'une rétractation en vertu de l'article 60 de ce règlement.

«obligation internationale» Toute obligation relative au chanvre indien prévue par une convention, un traité ou un autre instrument multilatéral ou bilatéral que le Canada a ratifié ou auquel il adhère. «obligation internationale» "*international obligation*"

«personne responsable» Pour l'application de la partie 1, la personne désignée aux termes de l'alinéa 22(1)*b*). «personne responsable» "*responsible person in charge*"

«pharmacien» Pharmacien, au sens de l'article 2 du *Règlement sur les stupéfiants*, qui n'est pas nommé dans un avis donné en vertu de l'article 48 de ce règlement n'ayant pas fait l'objet d'une rétractation en vertu de l'article 49 de ce règlement. «pharmacien» "*pharmacist*"

«praticien de la santé» Médecin ou infirmier praticien. «praticien de la santé» "*health care practitioner*"

«producteur autorisé» Titulaire d'une licence délivrée en vertu de l'article 25. «producteur autorisé» "*licensed producer*"

"transfer" «*transférer*»

"transfer" means, except in sections 118, 122 and 132, to transfer, whether directly or indirectly, without consideration.

«responsable principal» Personne désignée aux termes de l'alinéa 22(1)*a*).

«responsable principal» "*senior person in charge*"

«transférer» Sauf aux articles 118, 122 et 132, transférer, même indirectement, sans échange d'une contrepartie.

«transférer» "*transfer*"

Miscellaneous rules

(2) The rules set out in subsections (3) to (6) apply in these Regulations.

(2) Les règles prévues aux paragraphes (3) à (6) s'appliquent au présent règlement.

Règles diverses

Producer's site

(3) A reference to the site of a licensed producer is a reference to the site specified in the producer's licence.

(3) La mention de l'installation du producteur autorisé vaut mention de l'installation visée par la licence de ce dernier.

Installation

Destruction

(4) Cannabis is destroyed when it is altered or denatured to such an extent that its consumption is rendered impossible or improbable.

(4) Le chanvre indien est considéré détruit dès lors qu'il est altéré ou dénaturé au point d'en rendre la consommation impossible ou improbable.

Destruction

Drying

(5) The production of marihuana includes subjecting it to a drying process.

(5) La production de marihuana comprend le fait de la soumettre à un processus de séchage.

Séchage

Transfer

(6) For greater certainty, a reference to "provide" includes "transfer".

(6) Il est entendu que le fait de fournir comprend celui de transférer.

Transfert

Application of *Narcotic Control Regulations*

2. For greater certainty, except in the case of inconsistency with these Regulations, the *Narcotic Control Regulations* also apply to cannabis referred to in these Regulations.

2. Il est entendu que, sauf en cas d'incompatibilité avec le présent règlement, le *Règlement sur les stupéfiants* s'applique également au chanvre indien visé par le présent règlement.

Application du *Règlement sur les stupéfiants*

POSSESSION

POSSESSION

Obtaining dried marihuana or cannabis

3. (1) A person listed in subsection (2) may possess dried marihuana and a person listed in subsection (3) may possess cannabis if the person has obtained it

(*a*) in accordance with these Regulations;

(*b*) in the course of activities performed in connection with the enforcement or administration of any Act or its regulations;

3. (1) La personne visée au paragraphe (2) peut avoir en sa possession de la marihuana séchée et la personne visée au paragraphe (3), du chanvre indien, si elles l'ont obtenu :

a) soit conformément au présent règlement;

b) soit dans le cadre d'activités d'application ou d'exécution d'une loi ou de ses règlements;

Obtention — marihuana séchée ou chanvre indien

(*c*) from a person who is exempt under section 56 of the Act from the application of subsection 5(1) of the Act with respect to the dried marihuana or cannabis; or

(*d*) in the case referred to in subparagraph (2)(*a*)(iii), under subsection 65(2.1) of the *Narcotic Control Regulations*.

c) soit auprès d'une personne qui, en vertu de l'article 56 de la Loi, est exemptée de l'application du paragraphe 5(1) de la Loi à l'égard du chanvre indien ou de la marihuana séchée, selon le cas;

d) soit, dans le cas visé au sous-alinéa (2)*a*)(iii), en vertu du paragraphe 65(2.1) du *Règlement sur les stupéfiants*.

Possession — dried marihuana

(2) The following persons may possess dried marihuana:

(*a*) a person who has obtained the dried marihuana for their own medical purposes or for those of another person for whom they are responsible

(i) from a licensed producer, in accordance with a medical document,

(ii) from a health care practitioner in the course of treatment for a medical condition, or

(iii) from a hospital, under subsection 65(2.1) of the *Narcotic Control Regulations*;

(*b*) a person who requires dried marihuana for the practice of their profession as a health care practitioner in the province in which they have that possession; or

(*c*) a hospital employee, if they possess the dried marihuana for the purposes of and in connection with their employment.

Possession — marihuana séchée

(2) Toute personne peut avoir en sa possession de la marihuana séchée dans les cas suivants :

a) elle l'obtient à ses propres fins médicales ou à celles d'une autre personne dont elle est responsable :

(i) soit auprès d'un producteur autorisé, sur le fondement d'un document médical,

(ii) soit auprès d'un praticien de la santé, dans le cadre du traitement d'un état pathologique,

(iii) soit auprès d'un hôpital, en vertu du paragraphe 65(2.1) du *Règlement sur les stupéfiants*;

b) elle en a besoin pour la pratique de sa profession en tant que praticien de la santé dans la province où elle en a la possession;

c) elle est un employé d'un hôpital et a la marihuana séchée en sa possession dans le cadre de ses fonctions.

Possession — cannabis

(3) The following persons may possess cannabis:

(*a*) a person who requires cannabis for their business as a licensed producer and who possesses it in accordance with section 12;

Possession — chanvre indien

(3) Toute personne peut avoir en sa possession du chanvre indien dans les cas suivants :

a) elle en a besoin pour l'exercice de son commerce en tant que producteur

(*b*) a person who requires cannabis for their business as a licensed dealer;

(*c*) a person who is employed as an inspector, an analyst, a peace officer, a member of the Royal Canadian Mounted Police or a member of the technical or scientific staff of a department of the government of Canada or of a province and who possesses the cannabis for the purposes of and in connection with their employment; or

(*d*) a person who is acting as the agent or mandatary of a person whom they have reasonable grounds to believe is a person referred to in paragraph (*c*) and who possesses the cannabis for the purpose of assisting that person in the administration or enforcement of any Act or its regulations.

autorisé et l'a en sa possession conformément à l'article 12;

b) elle en a besoin pour l'exercice de son commerce en tant que distributeur autorisé;

c) elle est employée en tant qu'inspecteur, analyste, agent de la paix, membre de la Gendarmerie royale du Canada, membre du personnel technique ou scientifique d'un ministère du gouvernement fédéral ou d'une province, et elle a le chanvre indien en sa possession dans le cadre de ses fonctions;

d) elle agit en tant que mandataire d'une personne dont elle a des motifs raisonnables de croire qu'il s'agit d'une personne visée à l'alinéa *c*) et elle a en sa possession le chanvre indien dans le but de l'aider à appliquer ou à exécuter une loi ou ses règlements.

Employee, agent or mandatary — dried marihuana

(4) A person may possess dried marihuana if the person is an employee of or is acting as the agent or mandatary for a person referred to in paragraph (2)(*b*) or (*c*), while acting in the course of their employment or their role as agent or mandatary.

Employé ou mandataire — marihuana séchée

(4) L'employé d'une personne visée aux alinéas (2)*b*) ou *c*), ou la personne qui agit en tant que mandataire de celle-ci, peut avoir en sa possession de la marihuana séchée dans le cadre de ses fonctions ou de son mandat.

Employee, agent or mandatary — cannabis

(5) A person may possess cannabis if the person is an employee of or is acting as the agent or mandatary for a person referred to in paragraph (3)(*a*) or (*b*), while acting in the course of their employment or their role as agent or mandatary.

Employé ou mandataire — chanvre indien

(5) L'employé d'une personne visée aux alinéas (3)*a*) ou *b*), ou la personne qui agit en tant que mandataire de celle-ci, peut avoir en sa possession du chanvre indien dans le cadre de ses fonctions ou de son mandat.

Providing assistance

(6) While in the presence of a person referred to in paragraph (2)(*a*) who has obtained dried marihuana for their own medical purposes, another person may, for the purpose of providing assistance in the administration of marihuana to the person who obtained it, possess a quantity of that dried marihuana not exceeding the daily

Aide fournie

(6) La personne qui aide la personne visée à l'alinéa (2)*a*) qui a obtenu de la marihuana séchée à ses propres fins médicales à s'administrer cette dernière peut, en sa présence, pendant qu'elle lui apporte son aide, avoir en sa possession, à cette fin, une quantité de cette marihuana séchée qui n'excède pas la quantité quotidienne de

quantity of dried marihuana that the person who obtained it is authorized to possess in accordance with section 5.

Obtaining cannabis — *Narcotic Control Regulations*

4. (1) A licensed producer may possess cannabis that they have obtained in accordance with the *Narcotic Control Regulations* if they require it for their business.

Employee, agent or mandatary

(2) A person may possess cannabis referred to in subsection (1) if the person is an employee of or is acting as the agent or mandatary of the licensed producer, while acting in the course of their employment or their role as agent or mandatary.

Possession limit

5. An individual who obtains dried marihuana for their own medical purposes or for those of another individual for whom they are responsible must not possess a quantity of dried marihuana that exceeds the least of the following amounts:

(*a*) in the case of dried marihuana obtained from a licensed producer, 30 times the daily quantity referred to in paragraph 129(1)(*d*);

(*b*) in the case of dried marihuana obtained from a hospital by or for an outpatient, 30 times the daily quantity referred to in subparagraph 65.2(*c*)(iii) of the *Narcotic Control Regulations*; and

(*c*) 150 g.

GENERAL PROVISIONS

Dried marihuana

6. (1) Dried marihuana must not be sold or provided under these Regulations

(*a*) with any additive; or

(*b*) in any dosage form, such as in a roll or capsule.

marihuana séchée que la personne qui l'a obtenue est autorisée à avoir en sa possession conformément à l'article 5.

Obtention du chanvre indien — *Règlement sur les stupéfiants*

4. (1) Le producteur autorisé peut avoir en sa possession du chanvre indien obtenu conformément au *Règlement sur les stupéfiants* s'il en a besoin pour l'exercice de son commerce.

Employé ou mandataire

(2) L'employé du producteur autorisé, ou la personne qui agit en tant que mandataire de celui-ci, peut avoir en sa possession le chanvre indien visé au paragraphe (1) dans le cadre de ses fonctions ou de son mandat.

Limites de possession

5. La personne physique qui obtient de la marihuana séchée à ses propres fins médicales ou à celles d'une autre personne physique dont elle est responsable ne peut avoir en sa possession une quantité qui excède la moindre des quantités suivantes :

a) dans le cas de celle obtenue d'un producteur autorisé, trente fois la quantité quotidienne visée à l'alinéa 129(1)*d*);

b) dans le cas de celle obtenue d'un hôpital, par un patient externe ou pour celui-ci, trente fois la quantité quotidienne visée au sous-alinéa 65.2*c*)(iii) du *Règlement sur les stupéfiants*;

c) 150 g.

DISPOSITIONS GÉNÉRALES

Marihuana séchée

6. (1) La marihuana séchée ne peut être vendue ou fournie en vertu du présent règlement dans les cas suivants :

a) un additif y a été ajouté;

b) elle est sous une forme posologique tels des rouleaux ou des capsules.

Definition of "additive"

(2) For the purpose of paragraph (1)(*a*), "additive" means anything other than dried marihuana, except for any residue of a pest control product that is not in excess of the limit referred to in subsection 54(2).

Définition de «additif»

(2) Pour l'application de l'alinéa (1)*a*), «additif» s'entend de toute chose autre que la marihuana séchée, à l'exception des résidus d'un produit antiparasitaire qui sont en quantité inférieure ou égale à la limite visée au paragraphe 54(2).

Notice of refusal or revocation

7. If the Minister proposes to refuse to issue, amend or renew a licence or permit or proposes to revoke a licence or permit under these Regulations, other than in the case of a revocation under section 35 or subsection 37(4), 81(1) or 88(1), the Minister must

(*a*) send a notice to the applicant or to the holder of the licence or permit together with a written report that sets out the reasons for the refusal or revocation; and

(*b*) give the applicant or holder an opportunity to be heard in respect of the refusal or revocation.

Avis de refus ou de révocation

7. Lorsqu'il envisage de refuser de délivrer, de modifier ou de renouveler une licence ou un permis aux termes du présent règlement ou qu'il envisage de le révoquer, sauf dans le cas de la révocation visée à l'article 35 et aux paragraphes 37(4), 81(1) et 88(1), le ministre prend les mesures ci-après à l'égard du demandeur ou du titulaire :

a) il lui envoie un avis à cet effet accompagné d'un exposé écrit des motifs du refus ou de la révocation;

b) il lui donne la possibilité de se faire entendre à l'égard du refus ou de la révocation.

Further information

8. The Minister may, on receiving an application made under these Regulations, require the submission of any further information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

Renseignements supplémentaires

8. Sur réception d'une demande présentée en vertu du présent règlement, le ministre peut exiger tout renseignement supplémentaire au sujet des renseignements contenus dans la demande dont il a besoin pour traiter celle-ci.

Inspection of site

9. In order to confirm any information submitted in support of an application for a licence or an amendment or renewal of a licence made under these Regulations, an inspector may, at a time during normal business hours and with the reasonable assistance of the applicant, inspect the site in respect of which the application was made.

Inspection de l'installation

9. Afin de vérifier les renseignements fournis à l'appui d'une demande de licence ou d'une demande de modification ou de renouvellement de licence présentée en vertu du présent règlement, un inspecteur peut, durant les heures normales de travail et avec une aide raisonnable de la part du demandeur, inspecter l'installation visée par la demande.

Police enforcement

10. If, under the *Controlled Drugs and Substances Act (Police Enforcement) Regulations*, a member of a police force or a

Exécution policière

10. Dans le cas où, en vertu du *Règlement sur l'exécution policière de la Loi réglementant certaines drogues et autres*

person acting under the direction and control of the member is, in respect of the conduct of the member or person, exempt from the application of subsection 4(2) or section 5, 6 or 7 of the Act, the member or person is, in respect of that conduct, exempt from the application of these Regulations.

substances, le membre d'un corps policier ou la personne agissant sous son autorité et sa supervision est soustrait à l'application du paragraphe 4(2) ou des articles 5, 6 ou 7 de la Loi relativement à ses activités, ce membre ou cette personne est également soustrait à l'application du présent règlement quant à ses activités.

Alteration of documents

11. It is prohibited to mark, alter or deface in any manner a licence or permit issued under these Regulations or a medical document.

Altération d'un document

11. Il est interdit de marquer, d'altérer ou de dégrader de quelque façon que ce soit une licence ou un permis délivrés en vertu du présent règlement ou un document médical.

PART 1

LICENSED PRODUCERS

Division 1

Permitted Activities and General Obligations

Activities

12. (1) Subject to subsections (2) to (7) and to the other provisions of these Regulations, a licensed producer may

(*a*) possess, produce, sell, provide, ship, deliver, transport and destroy marihuana;

(*b*) possess and produce cannabis, other than marihuana, solely for the purpose of conducting in vitro testing that is necessary to determine the percentages of cannabinoids in dried marihuana; and

(*c*) sell, provide, ship, deliver, transport and destroy cannabis, other than marihuana, that was obtained or produced solely for the purpose of conducting the in vitro testing referred to in paragraph (*b*).

PARTIE 1

PRODUCTEURS AUTORISÉS

Section 1

Opérations autorisées et obligations générales

Opérations

12. (1) Sous réserve des paragraphes (2) à (7) et des autres dispositions du présent règlement, le producteur autorisé peut effectuer les opérations suivantes :

a) avoir en sa possession, produire, vendre, fournir, expédier, livrer, transporter et détruire de la marihuana;

b) avoir en sa possession et produire du chanvre indien, autre que de la marihuana, à seule fin d'effectuer les essais *in vitro* nécessaires à la détermination des pourcentages des cannabinoïdes dans la marihuana séchée;

c) vendre, fournir, expédier, livrer, transporter et détruire du chanvre indien, autre que de la marihuana, obtenu ou produit à seule fin d'effectuer les essais *in vitro* visés à l'alinéa *b*).

Restriction — cannabis

(2) A licensed producer may sell or provide a substance referred to in subsection (3) to

(*a*) another licensed producer;

(*b*) a licensed dealer;

(*c*) the Minister; or

(*d*) a person to whom an exemption relating to the substance has been granted under section 56 of the Act.

Restriction — chanvre indien

(2) Le producteur autorisé peut vendre ou fournir une substance visée au paragraphe (3) aux personnes suivantes :

a) un autre producteur autorisé;

b) un distributeur autorisé;

c) le ministre;

d) la personne à qui a été accordée une exemption relativement à la substance en vertu de l'article 56 de la Loi.

Substances

(3) The substances that may be sold or provided under subsection (2) are

(*a*) marihuana; and

(*b*) cannabis, other than marihuana, that was obtained or produced solely for the purpose of conducting in vitro testing that is necessary to determine the percentages of cannabinoids in dried marihuana.

Substances

(3) Les substances qui peuvent être vendues ou fournies en vertu du paragraphe (2) sont les suivantes :

a) la marihuana;

b) le chanvre indien, autre que la marihuana, obtenu ou produit à seule fin d'effectuer les essais *in vitro* nécessaires à la détermination des pourcentages des cannabinoïdes dans la marihuana séchée.

Restriction — dried marihuana

(4) A licensed producer may

(*a*) sell or provide dried marihuana to

(i) a client of that producer or an individual who is responsible for the client,

(ii) a hospital employee, if the possession of the dried marihuana is for the purposes of and in connection with their employment, or

(iii) a person to whom an exemption relating to the dried marihuana has been granted under section 56 of the Act; and

(*b*) ship dried marihuana to a health care practitioner in the case referred to in subparagraph 108(1)(*f*)(iii).

Restriction — marihuana séchée

(4) Le producteur autorisé peut effectuer les opérations suivantes :

a) vendre ou fournir aux personnes ci-après de la marihuana séchée :

(i) l'un de ses clients ou une personne physique responsable de ce dernier,

(ii) l'employé d'un hôpital qui doit l'avoir en sa possession dans le cadre de ses fonctions,

(iii) la personne à qui a été accordée une exemption relativement à la marihuana séchée en vertu de l'article 56 de la Loi;

b) expédier de la marihuana séchée à un praticien de la santé dans le cas visé au sous-alinéa 108(1)*f*)(iii).

Activities limited

(5) A licensed producer may conduct an activity referred to in subsection (1), (2) or (4) if the producer

Restrictions relatives aux opérations

(5) Le producteur autorisé peut effectuer toute opération visée aux para-

(*a*) is licensed to conduct the activity; and

(*b*) conducts the activity in accordance with their licence.

graphes (1), (2) ou (4) s'il satisfait aux conditions suivantes :

a) il est titulaire d'une licence qui l'autorise à effectuer l'opération;

b) il effectue l'opération conformément à sa licence.

Import

(6) A licensed producer may import marihuana if they do so in accordance with an import permit issued under section 75.

(6) Le producteur autorisé peut importer de la marihuana à condition de le faire conformément au permis d'importation délivré en application de l'article 75.

Importation

Export

(7) A licensed producer may

(*a*) possess marihuana for the purpose of export; and

(*b*) export marihuana if they do so in accordance with an export permit issued under section 83.

(7) Le producteur autorisé peut :

a) avoir de la marihuana en sa possession en vue de son exportation;

b) en exporter, à condition de le faire conformément au permis d'exportation délivré en application de l'article 83.

Exportation

Dwelling place

13. A licensed producer must not conduct any activity referred to in section 12 at a dwelling place.

13. Le producteur autorisé ne peut effectuer une opération visée à l'article 12 dans un local d'habitation.

Local d'habitation

Indoor activities only

14. A licensed producer must produce, package or label marihuana only indoors and at the producer's site.

14. Le producteur autorisé ne peut produire, emballer ou étiqueter de la marihuana qu'à l'intérieur et qu'à son installation.

Opérations à l'intérieur seulement

Indoor storage only

15. (1) A licensed producer must store cannabis only indoors and at the producer's site.

15. (1) Le producteur autorisé ne peut stocker du chanvre indien qu'à l'intérieur et qu'à son installation.

Stockage à l'intérieur seulement

Storage of dried marihuana

(2) A licensed producer must store cannabis, other than marihuana plants, in accordance with the Security Directive.

(2) Le producteur autorisé stocke le chanvre indien autre que les plants de marihuana conformément à la Directive en matière de sécurité.

Stockage de la marihuana séchée

Identification of licensed producer

16. A licensed producer must include their name, as set out in their licence, on all the means by which the producer identifies themself in relation to cannabis, including advertising, product labels, orders, shipping documents and invoices.

16. Le producteur autorisé appose son nom tel qu'il figure sur sa licence sur tout ce qui sert à l'identifier à l'égard du chanvre indien, y compris ses annonces, ses étiquettes, ses bons de commande, ses documents d'expédition et ses factures.

Identification du producteur autorisé

Responsible person in charge present

17. A licensed producer must not perform a transaction involving cannabis unless the responsible person in charge or, if

17. Il est interdit au producteur autorisé d'effectuer une transaction relative au chanvre indien à moins que la personne

Présence de la personne responsable

applicable, the alternate responsible person in charge is physically present at the producer's site.

responsable ou, le cas échéant, la personne responsable suppléante, ne soit physiquement présente à son installation.

Safekeeping during transportation

18. A licensed producer must, when transporting imported marihuana between the port of entry into Canada and the producer's site, or when shipping, delivering or transporting any marihuana, including to a port of exit from Canada, take any steps that are necessary to ensure its safekeeping during transportation.

Sécurité durant le transport

18. Lorsque le producteur autorisé transporte de la marihuana importée entre le point d'entrée au Canada et son installation ou lorsqu'il expédie, livre ou transporte de la marihuana, notamment jusqu'au point de sortie du Canada, il prend les mesures nécessaires pour en assurer la sécurité durant le transport.

Report of loss or theft

19. If a licensed producer experiences a theft of cannabis or an unusual waste or disappearance of cannabis that cannot be explained on the basis of normally accepted business activities, the licensed producer must

(*a*) report the occurrence to a member of a police force within 24 hours after becoming aware of it; and

(*b*) provide a written report to the Minister within 10 days after becoming aware of the occurrence.

Rapport de perte ou de vol

19. En cas de perte ou de disparition inhabituelles de chanvre indien ne pouvant s'expliquer dans le cadre de pratiques normales et acceptables d'opération ou en cas de vol de chanvre indien, le producteur autorisé satisfait aux exigences suivantes :

a) il en fait rapport à un membre d'un corps policier dans les vingt-quatre heures suivant la découverte du fait;

b) il présente un rapport écrit au ministre dans les dix jours suivant la découverte du fait.

Destruction

20. (1) A licensed producer may destroy cannabis only if they do so

(*a*) in accordance with a method that

(i) conforms with all federal, provincial and municipal environmental legislation applicable to the location at which it is to be destroyed, and

(ii) does not result in any person being exposed to cannabis smoke; and

(*b*) in the presence of at least two persons who are qualified to witness the destruction, one of whom must be a person referred to in paragraph (2)(*a*).

Destruction

20. (1) Le producteur autorisé ne peut détruire le chanvre indien que si les conditions ci-après sont remplies :

a) il suit une méthode qui, à la fois :

(i) est conforme à la législation fédérale, provinciale et municipale sur la protection de l'environnement applicable au lieu de la destruction,

(ii) fait en sorte qu'aucune personne ne soit exposée à la fumée du chanvre indien;

b) il le fait en présence d'au moins deux personnes qui sont habilitées à servir de témoins de la destruction, l'une d'entre elles étant visée à l'alinéa (2)*a*).

Witness to destruction

(2) The following persons are qualified to witness the destruction of cannabis:

(*a*) the senior person in charge, the responsible person in charge and, if applicable, the alternate responsible person in charge; and

(*b*) a person who works for or provides services to the licensed producer and acts in a senior position.

Transportation of cannabis

(3) If the cannabis is to be destroyed at a location other than the licensed producer's site, the senior person in charge, the responsible person in charge or, if applicable, the alternate responsible person in charge must accompany the cannabis to the location at which it is to be destroyed.

Témoins

(2) A qualité pour servir de témoin de la destruction du chanvre indien :

a) le responsable principal, la personne responsable ou, le cas échéant, la personne responsable suppléante;

b) l'employé du producteur autorisé ou une personne qui lui offre des services et qui, dans l'un et l'autre cas, agit comme cadre supérieur.

Transport du chanvre indien

(3) Si le chanvre indien doit être détruit ailleurs qu'à l'installation du producteur autorisé, le transport jusqu'au lieu de la destruction s'effectue en présence du responsable principal, de la personne responsable ou, le cas échéant, de la personne responsable suppléante.

Division 2

Licensing

Section 2

Licence

Eligible persons

21. The following persons are eligible to apply for a producer's licence:

(*a*) an adult who ordinarily resides in Canada; and

(*b*) a corporation that has its head office in Canada or operates a branch office in Canada and whose officers and directors are all adults.

Personnes admissibles

21. Sont admissibles à demander une licence de producteur autorisé les personnes suivantes :

a) l'adulte qui réside habituellement au Canada;

b) la personne morale qui a son siège social au Canada, ou y exploite une succursale, et dont chacun des dirigeants et administrateurs est un adulte.

Senior person in charge and responsible person in charge

22. (1) A licensed producer must designate

(*a*) one senior person in charge to have overall responsibility for management of the activities carried out by the licensed producer under their licence at their site — who may, if appropriate, be the licensed producer; and

(*b*) one responsible person in charge to work at the licensed producer's site and have responsibility for supervising the

Responsable principal et personne responsable

22. (1) Le producteur autorisé désigne les personnes suivantes :

a) un seul responsable principal chargé de la gestion de l'ensemble des opérations que le producteur autorisé effectue en vertu de sa licence à son installation, étant entendu que le producteur autorisé peut, s'il y a lieu, exercer lui-même cette fonction;

b) une seule personne responsable qui travaille à l'installation du producteur

activities with respect to cannabis conducted at that site by the licensed producer under their licence and for ensuring that the activities comply with the Act and its regulations and the *Food and Drugs Act* — who may, if appropriate, be the senior person in charge.

autorisé et qui est chargée à la fois de superviser les opérations que le producteur autorisé effectue à l'égard du chanvre indien en vertu de sa licence et d'assurer leur conformité avec la Loi, ses règlements et la *Loi sur les aliments et drogues*, étant entendu que le responsable principal peut, s'il y a lieu, exercer lui-même cette fonction.

Alternate responsible person in charge

(2) A licensed producer may designate one or more alternate responsible persons in charge to work at the licensed producer's site and have authority to replace the responsible person in charge when that person is absent.

(2) Le producteur autorisé peut désigner une ou plusieurs personnes responsables suppléantes qui travaillent à son installation et qui sont autorisées à remplacer la personne responsable en cas d'absence de celle-ci.

Personne responsable suppléante

Eligibility

(3) The senior person in charge, the responsible person in charge and, if applicable, the alternate responsible person in charge

(*a*) must be adults; and

(*b*) must be familiar with the provisions of the Act and its regulations and the *Food and Drugs Act* that apply to the licence held by the licensed producer by whom they are designated.

(3) Le responsable principal, la personne responsable et, le cas échéant, la personne responsable suppléante satisfont aux exigences suivantes :

a) ils sont des adultes;

b) ils connaissent bien les dispositions de la Loi, de ses règlements et de la *Loi sur les aliments et drogues* qui s'appliquent à la licence du producteur autorisé qui les a désignés.

Admissibilité

Application for licence

23. (1) To apply for a producer's licence, a person must submit to the Minister an application that contains the following information:

(*a*) if the applicant is

(i) an individual, the individual's name, date of birth and gender and any other name registered with a province, under which the individual intends to identify themself or conduct the activities for which the licence is sought (referred to in this section as "the proposed activities"), or

23. (1) Quiconque entend obtenir une licence de producteur autorisé présente au ministre une demande comportant les renseignements suivants :

a) dans le cas où le demandeur est :

(i) une personne physique, ses nom, date de naissance et sexe ainsi que tout autre nom enregistré auprès d'une province sous lequel elle entend s'identifier ou effectuer les opérations pour lesquelles la licence est demandée (appelées « opérations proposées » au présent article),

(ii) une personne morale, sa dénomination sociale et tout autre nom enre-

Demande de licence

(ii) a corporation, its corporate name and any other name registered with a province, under which it intends to identify itself or conduct the proposed activities, as well as the name, date of birth and gender of each of its officers and directors;

(*b*) the address, telephone number and, if applicable, the facsimile number and email address for

(i) the site for which the licence is sought (referred to in this section as "the proposed site"), and

(ii) if applicable, each building within the site at which the proposed activities are to be conducted;

(*c*) the mailing address for the proposed site and, if applicable, for each building referred to in subparagraph (*b*)(ii), if different from the address provided under paragraph (*b*);

(*d*) the name, date of birth and gender of each of the following persons:

(i) the proposed senior person in charge,

(ii) the proposed responsible person in charge, and

(iii) if applicable, the proposed alternate responsible person in charge;

(*e*) the name and gender of each of the persons authorized to place an order for cannabis on behalf of the applicant;

(*f*) the activities among those referred to in subsection 12(1) that are proposed to be conducted, the purposes for conducting those activities and the substances in respect of which each of the activities is to be conducted;

gistré auprès d'une province sous lequel elle entend s'identifier ou effectuer les opérations proposées, ainsi que les nom, date de naissance et sexe de ses dirigeants et administrateurs;

b) l'adresse, le numéro de téléphone et, le cas échéant, le numéro de télécopieur et l'adresse électronique des endroits suivants :

(i) l'installation pour laquelle la licence est demandée (appelée « installation proposée » au présent article),

(ii) le cas échéant, chaque bâtiment de celle-ci où les opérations proposées seront effectuées;

c) si elle diffère de l'adresse de l'installation proposée et, le cas échéant, de celle de chaque bâtiment visé au sous-alinéa *b*)(ii), l'adresse postale de l'installation proposée;

d) les nom, date de naissance et sexe des personnes suivantes :

(i) le responsable principal proposé,

(ii) la personne responsable proposée,

(iii) le cas échéant, la personne responsable suppléante proposée;

e) les nom et sexe des personnes autorisées à commander du chanvre indien pour le compte du demandeur;

f) les opérations qui sont proposées parmi celles visées au paragraphe 12(1), les buts recherchés, ainsi que les substances à l'égard desquelles chacune de ces opérations sera effectuée;

g) les opérations proposées qui seront effectuées à chaque bâtiment visé au sous-alinéa *b*)(ii), ainsi que les sub-

(*g*) the proposed activities that are to be conducted at each building referred to in subparagraph (*b*)(ii) and the substances in respect of which each of those activities is to be conducted at each building;

(*h*) a detailed description of the security measures at the proposed site, as determined in accordance with the Security Directive and Division 3;

(*i*) a detailed description of the method that the applicant proposes to use for keeping records, which must permit

(i) compliance with the requirements of Part 6,

(ii) the Minister to audit the activities of the licensed producer with respect to cannabis, and

(iii) the reconciliation of orders for cannabis and shipments and inventories of cannabis;

(*j*) if applicable, the maximum quantity (expressed as the net weight in kilograms) of dried marihuana to be produced by the applicant under the licence and the production period; and

(*k*) if applicable, the maximum quantity (expressed as the net weight in kilograms) of dried marihuana to be sold or provided by the applicant under the licence under subsection 12(4) and the period in which that quantity is to be sold or provided.

Multiple sites

(2) If the applicant intends to engage in an activity referred to in subsection 12(1) at more than one site, a separate application must be made for each proposed site.

stances à l'égard desquelles chacune de ces opérations sera effectuée à chaque bâtiment;

h) la description détaillée des mesures de sécurité à l'installation proposée, établies conformément à la Directive en matière de sécurité et à la section 3;

i) la description détaillée de la méthode proposée pour la tenue des dossiers, laquelle doit permettre, à la fois :

(i) le respect des exigences prévues par la partie 6,

(ii) la vérification par le ministre des opérations du producteur autorisé à l'égard du chanvre indien,

(iii) le rapprochement des commandes, des expéditions et des inventaires de chanvre indien;

j) le cas échéant, la quantité maximale (poids net en kilogrammes) de marihuana séchée que le demandeur entend produire au titre de sa licence, ainsi que la période de production envisagée;

k) le cas échéant, la quantité maximale (poids net en kilogrammes) de marihuana séchée que le demandeur entend vendre ou fournir au titre de sa licence en vertu du paragraphe 12(4), ainsi que la période en cause.

Pluralité d'installations

(2) Lorsque le demandeur entend effectuer une des opérations visées au paragraphe 12(1) à plus d'une installation, une demande distincte est présentée pour chaque installation proposée.

Statement by signatory

(3) An application for a producer's licence must

(*a*) be signed and dated by the proposed senior person in charge; and

(*b*) include a statement signed and dated by that person indicating that

(i) all of the information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the applicant.

Accompanying documents

(4) An application for a producer's licence must be accompanied by

(*a*) a declaration, signed and dated by the proposed senior person in charge, stating that the proposed senior person in charge, the proposed responsible person in charge and, if applicable, the proposed alternate responsible person in charge are familiar with the provisions of the Act and its regulations and the *Food and Drugs Act* that will apply to the licence;

(*b*) if applicable, a copy of any document filed with the province in which the proposed site is located that states the applicant's name and any other name registered with the province, under which the applicant intends to identify themself or conduct the proposed activities;

(*c*) if the applicant is a corporation, a copy of the certificate of incorporation or other constituting instrument;

(*d*) a declaration signed and dated by the proposed senior person in charge in-

Signature et attestation

(3) La demande de licence de producteur autorisé satisfait aux exigences suivantes :

a) elle est signée et datée par le responsable principal proposé;

b) elle comprend une attestation signée et datée par ce dernier portant :

(i) d'une part, qu'à sa connaissance, tous les renseignements et documents fournis à l'appui de la demande sont exacts et complets,

(ii) d'autre part, qu'il a le pouvoir d'obliger le demandeur.

Pièces jointes

(4) Elle est accompagnée de ce qui suit :

a) une déclaration, signée et datée par le responsable principal proposé, attestant que lui-même, la personne responsable proposée et, le cas échéant, la personne responsable suppléante proposée, connaissent bien les dispositions de la Loi, de ses règlements et de la *Loi sur les aliments et drogues* qui s'appliqueront à la licence;

b) le cas échéant, une copie de tout document déposé auprès de la province où se trouve l'installation proposée, qui indique le nom du demandeur et tout autre nom enregistré auprès de la province sous lequel il entend s'identifier ou effectuer les opérations proposées;

c) dans le cas où le demandeur est une personne morale, une copie de son certificat de constitution ou de tout autre acte constitutif;

d) une déclaration signée et datée par le responsable principal proposé précisant que le demandeur est, ou n'est pas, propriétaire de la totalité de l'installation proposée;

dicating whether or not the applicant is the owner of the entire proposed site;

(*e*) if the proposed site or any portion of it is not owned by the applicant, a declaration signed and dated by the owner of the site or each portion of the site consenting to the use of it by the applicant for the proposed activities;

(*f*) a declaration signed and dated by the proposed senior person in charge stating that the proposed site is not a dwelling place;

(*g*) a declaration signed and dated by the proposed senior person in charge stating that the notices to local authorities have been provided in accordance with section 38 and specifying the names, titles and addresses of the officials to whom they were addressed and the dates on which they were provided, together with a copy of each notice;

(*h*) a document signed and dated by the quality assurance person referred to in section 60 that includes

(i) a description of the person's qualifications in respect of the matters referred to in subparagraph 60(1)(*a*)(ii), and

(ii) a report establishing that the buildings, equipment and sanitation program to be used in conducting the proposed activities referred to in Division 4 comply with the requirements of that Division; and

(*i*) floor plans for the proposed site.

Security clearance required

24. The following persons must hold a security clearance:

(*a*) the senior person in charge;

(*b*) the responsible person in charge;

e) dans le cas où l'installation proposée, ou toute partie de celle-ci, n'est pas la propriété du demandeur, une déclaration signée et datée par le propriétaire de l'installation, ou par celui de chacune de ces parties, portant qu'il consent à son utilisation par le demandeur pour les opérations proposées;

f) une déclaration signée et datée par le responsable principal proposé attestant que l'installation proposée n'est pas un local d'habitation;

g) une déclaration signée et datée par le responsable principal proposé attestant que les avis aux autorités locales ont été fournis conformément à l'article 38 et précisant les dates auxquelles ils l'ont été ainsi que les nom, fonction et adresse des cadres supérieurs destinataires des avis, la déclaration étant accompagnée d'une copie de chacun des avis;

h) un document signé et daté par le préposé à l'assurance de la qualité visé à l'article 60 qui comprend :

(i) une description de ses compétences eu égard aux éléments visés au sous-alinéa 60(1)*a*)(ii),

(ii) un rapport établissant que les bâtiments, l'équipement et le programme d'hygiène qui serviront lors des opérations proposées visées à la section 4 sont conformes aux exigences prévues à cette section;

i) les plans d'étage de l'installation proposée.

Habilitation de sécurité requise

24. Les personnes ci-après sont tenues d'être titulaires d'une habilitation de sécurité :

a) le responsable principal;

(*c*) if applicable, the alternate responsible person in charge;

(*d*) if a producer's licence is issued to an individual, that individual; and

(*e*) if a producer's licence is issued to a corporation, each officer and director of the corporation.

b) la personne responsable;

c) le cas échéant, la personne responsable suppléante;

d) si la licence de producteur autorisé est délivrée à une personne physique, cette personne;

e) si la licence de producteur autorisé est délivrée à une personne morale, chaque dirigeant et administrateur de cette dernière.

Issuance of licence

25. Subject to section 26, the Minister must, after examining the information and documents required under section 23 and, if applicable, section 8, and after all of the security clearances required by section 24 have been granted under section 92, issue to the applicant a producer's licence that indicates

(*a*) the licence number;

(*b*) the name of the licence holder;

(*c*) the list of permitted activities;

(*d*) the address of the site and, if applicable, of each building within the site at which the licensed producer may conduct the permitted activities;

(*e*) in respect of each building, the activities that may be conducted at that building and, in respect of each activity, the substances in respect of which the activity may be conducted;

(*f*) the security level, determined in accordance with the Security Directive, of each building referred to in paragraph (*d*) at which cannabis, other than marihuana plants, is stored;

(*g*) the effective date of the licence;

Délivrance de la licence

25. Sous réserve de l'article 26, après examen des renseignements et documents visés à l'article 23 et, le cas échéant, à l'article 8, et après que toutes les habilitations de sécurité requises aux termes de l'article 24 ont été accordées en vertu de l'article 92, le ministre délivre au demandeur une licence de producteur autorisé qui comporte ce qui suit :

a) le numéro de la licence;

b) le nom du titulaire;

c) la liste des opérations autorisées;

d) l'adresse de l'installation et, le cas échéant, de chaque bâtiment de celle-ci où le producteur autorisé peut effectuer les opérations autorisées;

e) à l'égard de chaque bâtiment, les opérations autorisées qui peuvent y être effectuées et, à l'égard de chacune de celles-ci, les substances à l'égard desquelles elle peut être effectuée;

f) le niveau de sécurité, déterminé selon la Directive en matière de sécurité, de chaque bâtiment visé à l'alinéa *d*) où est stocké le chanvre indien autre que les plants de marihuana;

g) la date de prise d'effet de la licence;

(*h*) the expiry date of the licence, which must not be later than three years after its effective date;

(*i*) if applicable, the maximum quantity of dried marihuana that may be produced under the licence in a specified period, expressed as the net weight in kilograms;

(*j*) if applicable, the maximum quantity of dried marihuana that may be sold or provided under the licence in a specified period in accordance with subsection 12(4), expressed as the net weight in kilograms; and

(*k*) if applicable, any conditions that the licence holder must meet in order to

(i) comply with an international obligation,

(ii) provide the security level referred to in paragraph (*f*),

(iii) put in place the security measures referred to in Division 3, or

(iv) reduce any potential public health, safety or security risk, including the risk of cannabis being diverted to an illicit market or use.

h) la date d'expiration de la licence, laquelle ne peut suivre de plus de trois ans la date de sa prise d'effet;

i) le cas échéant, la quantité maximale de marihuana séchée (poids net en kilogrammes), qui peut être produite en vertu de la licence pour une période déterminée;

j) le cas échéant, la quantité maximale de marihuana séchée (poids net en kilogrammes), qui peut être vendue ou fournie en vertu de la licence, pour une période déterminée, en vertu du paragraphe 12(4);

k) le cas échéant, les conditions que le titulaire doit respecter à l'une ou l'autre des fins suivantes :

(i) se conformer à une obligation internationale,

(ii) assurer le niveau de sécurité visé à l'alinéa *f*),

(iii) mettre en place les mesures de sécurité visées à la section 3,

(iv) réduire le risque d'atteinte à la sécurité ou à la santé publiques, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites.

Grounds for refusal

26. (1) The Minister must refuse to issue, renew or amend a producer's licence in the following cases:

(*a*) the applicant is not eligible under section 21;

(*b*) the requirements of section 38 or 39 have not been met;

(*c*) an inspector, who has requested an inspection, has not been given the op-

Motifs de refus

26. (1) Le ministre refuse de délivrer une licence de producteur autorisé, de la modifier ou de la renouveler dans les cas suivants :

a) le demandeur n'est pas admissible aux termes de l'article 21;

b) les exigences des articles 38 ou 39 ne sont pas respectées;

c) le demandeur n'a pas fourni à l'inspecteur qui lui en a fait la demande l'oc-

portunity by the applicant to conduct an inspection under section 9;

(*d*) the Minister has reasonable grounds to believe that false or misleading information or false or falsified documents were submitted in or with the application;

(*e*) information received from a peace officer, a competent authority or the United Nations raises reasonable grounds to believe that the applicant has been involved in the diversion of a controlled substance or precursor to an illicit market or use;

(*f*) the applicant does not have in place the security measures set out in the Security Directive and Division 3 in respect of an activity for which the licence is sought;

(*g*) the applicant is in contravention of or has contravened in the past 10 years

(i) a provision of the Act or its regulations or the *Food and Drugs Act*, or

(ii) a term or condition of another licence or a permit issued to it under any of those regulations;

(*h*) the issuance, renewal or amendment of the licence would likely create a risk to public health, safety or security, including the risk of cannabis being diverted to an illicit market or use;

(*i*) any of the following persons does not hold a security clearance:

(i) the senior person in charge,

(ii) the responsible person in charge,

(iii) if applicable, the alternate responsible person in charge,

casion de procéder à l'inspection prévue à l'article 9;

d) le ministre a des motifs raisonnables de croire qu'ont été fournis des renseignements faux ou trompeurs dans la demande ou des documents faux ou falsifiés à l'appui de celle-ci;

e) les renseignements reçus d'un agent de la paix, d'une autorité compétente ou des Nations Unies donnent des motifs raisonnables de croire que le demandeur a participé au détournement d'une substance désignée ou d'un précurseur vers un marché ou un usage illicites;

f) le demandeur n'a pas mis en place les mesures de sécurité prévues dans la Directive en matière de sécurité et à la section 3 à l'égard d'une opération pour laquelle il demande la licence;

g) le demandeur contrevient ou a contrevenu, au cours des dix dernières années :

(i) soit à la Loi, à ses règlements ou à la *Loi sur les aliments et drogues*,

(ii) soit aux conditions d'une autre licence ou d'un permis qui lui a été délivré aux termes d'un tel règlement;

h) la délivrance, la modification ou le renouvellement de la licence risquerait de porter atteinte à la sécurité ou à la santé publiques, notamment en raison du risque de voir le chanvre indien détourné vers un marché ou un usage illicites;

i) l'une des personnes ci-après n'est pas titulaire d'une habilitation de sécurité :

(i) le responsable principal,

(ii) la personne responsable,

(iv) if the applicant is an individual, that individual, and

(v) if the applicant is a corporation, any of its officers or directors;

(*j*) the proposed method of record keeping does not meet the requirements of paragraph 23(1)(*i*); or

(*k*) if applicable, the information required under section 8 has not been provided or is insufficient to process the application.

(iii) le cas échéant, la personne responsable suppléante,

(iv) si le demandeur est une personne physique, cette personne,

(v) si le demandeur est une personne morale, l'un des dirigeants ou administrateurs de cette dernière;

j) la méthode proposée pour la tenue des dossiers ne permet pas de respecter les exigences prévues à l'alinéa 23(1)*i*);

k) le cas échéant, les renseignements visés à l'article 8 n'ont pas été fournis ou sont insuffisants pour traiter la demande.

Exception

(2) Unless it is necessary to do so to protect public health, safety or security, including preventing cannabis from being diverted to an illicit market or use, the Minister must not refuse to issue, renew or amend a licence under paragraph (1)(*d*) or (*g*) if the applicant has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and its regulations and the *Food and Drugs Act*.

Exception

(2) Sauf s'il est nécessaire de le faire en vue de protéger la sécurité ou la santé publiques, y compris en vue de prévenir le détournement de chanvre indien vers un marché ou un usage illicites, le ministre ne peut, dans les circonstances visées aux alinéas (1)*d*) ou *g*), refuser de délivrer, de modifier ou de renouveler la licence si le demandeur a pris les mesures correctives indiquées pour assurer la conformité à la Loi, à ses règlements et à la *Loi sur les aliments et drogues*, ou s'il a signé un engagement à cet effet.

Failure to comply with undertaking

(3) If an applicant fails to comply with an undertaking referred to in subsection (2), the Minister must refuse to issue, renew or amend the licence.

Non-respect de l'engagement

(3) Dans le cas où le demandeur ne respecte pas l'engagement mentionné au paragraphe (2), le ministre refuse de délivrer, de modifier ou de renouveler la licence.

Period of validity

27. A producer's licence is valid until the earlier of

(*a*) the expiry date of the licence, and

(*b*) the date on which the licence is revoked under any of sections 34 to 37.

Période de validité

27. La licence de producteur autorisé est valide jusqu'à celle des dates ci-après qui est antérieure à l'autre :

a) la date d'expiration de la licence;

b) la date de sa révocation au titre des articles 34, 35, 36 ou 37.

Application for renewal

28. (1) To apply to renew their licence, a licensed producer must submit to the

Demande de renouvellement

28. (1) Le producteur autorisé qui entend faire renouveler sa licence présente au

Minister an application that contains the following:

(*a*) the original of the licence; and

(*b*) a declaration signed and dated by the senior person in charge indicating that as of the date of the application

(i) that person has the authority to bind the applicant, and

(ii) to the best of that person's knowledge,

(A) all of the information shown on the producer's licence as specified in paragraphs 25(*a*) to (*f*) and (*i*) to (*k*) is correct and complete, and

(B) if applicable, the requirements of sections 30 and 31 have been met.

ministre une demande comportant les éléments suivants :

a) l'original de la licence;

b) une déclaration signée et datée par le responsable principal portant, qu'à la date de la demande :

(i) il a le pouvoir d'obliger le demandeur,

(ii) à sa connaissance :

(A) tous les renseignements prévus aux alinéas 25*a*) à *f*) et *i*) à *k*) que comporte sa licence sont exacts et complets,

(B) le cas échéant, il a été satisfait aux exigences des articles 30 et 31.

Renewal

(2) Subject to section 26, the Minister must, after examining the information and documents required under subsection (1) and, if applicable, section 8, issue a renewed licence that contains the information set out in paragraphs 25(*a*) to (*k*).

Renouvellement

(2) Sous réserve de l'article 26, après examen des renseignements et documents visés au paragraphe (1) et, le cas échéant, à l'article 8, le ministre renouvelle la licence qui comporte les renseignements prévus aux alinéas 25*a*) à *k*).

Simultaneous processing of applications

(3) If a licensed producer submits an application under section 29 or paragraph 30(1)(*a*) together with an application under subsection (1), the Minister may process them together.

Traitement simultané des demandes

(3) Lorsque le producteur autorisé présente la demande visée à l'article 29 ou à l'alinéa 30(1)*a*) avec celle visée au paragraphe (1), le ministre peut les traiter ensemble.

Application for amendment

29. (1) A licensed producer proposing to amend the content of their licence must provide the Minister with the following documents:

(*a*) an application in writing describing the proposed amendment, as well as any information or documents mentioned in section 23 that are relevant to the proposed amendment;

Demande de modification

29. (1) Le producteur autorisé qui entend faire modifier le contenu de sa licence présente les documents ci-après au ministre :

a) une demande écrite précisant la modification souhaitée et comportant les documents et renseignements visés à l'article 23 qui sont pertinents à l'égard de la demande;

(*b*) if applicable, a declaration signed and dated by the senior person in charge stating that the notices to local authorities have been provided in accordance with section 39 and specifying the names, titles and addresses of the officials to whom they were addressed and the dates on which they were provided, together with a copy of each notice; and

(*c*) the original of the licence.

b) le cas échéant, une déclaration signée et datée par le responsable principal attestant que les avis aux autorités locales ont été fournis conformément à l'article 39 et précisant les dates auxquelles ils l'ont été ainsi que les nom, fonction et adresse des cadres supérieurs destinataires des avis, cette déclaration étant accompagnée d'une copie de chacun des avis;

c) l'original de la licence en cause.

Statement by signatory

(2) The application must

(*a*) be signed and dated by the senior person in charge; and

(*b*) include a statement signed and dated by that person indicating that

(i) all of the information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the applicant.

Signature et attestation

(2) La demande satisfait aux exigences suivantes :

a) elle est signée et datée par le responsable principal;

b) elle comprend une attestation signée et datée par ce dernier portant :

(i) d'une part, qu'à sa connaissance, tous les renseignements et documents fournis à l'appui de la demande sont exacts et complets,

(ii) d'autre part, qu'il a le pouvoir d'obliger le demandeur.

Issuance

(3) Subject to section 26, the Minister must, after examining the information and documents required under this section and, if applicable, section 8, amend the licence accordingly and may add any conditions that the licence holder must meet in order to

(*a*) comply with an international obligation;

(*b*) provide the security level referred to in paragraph 25(*f*) or the new level applicable as a result of the amendment of the licence;

(*c*) put in place the security measures referred to in Division 3; or

Acceptation

(3) Sous réserve de l'article 26, après examen des documents et renseignements visés au présent article et, le cas échéant, à l'article 8, le ministre modifie la licence en conséquence et peut l'assortir de conditions supplémentaires que le titulaire doit respecter à l'une ou l'autre des fins suivantes :

a) se conformer à une obligation internationale;

b) assurer le niveau de sécurité visé à l'alinéa 25*f*) ou le nouveau niveau qui s'impose par suite de la modification de la licence;

c) mettre en place les mesures de sécurité visées à la section 3;

(*d*) reduce any potential public health, safety or security risk, including the risk of cannabis being diverted to an illicit market or use.

Notice to Minister — change of personnel

30. (1) A licensed producer must

(*a*) apply for and obtain the Minister's approval before making a change involving the replacement or the addition of

(i) the senior person in charge,

(ii) the responsible person in charge and, if applicable, the alternate responsible person in charge,

(iii) if applicable, an officer or director referred to in subparagraph 23(1)(*a*)(ii), or

(iv) an individual authorized to place an order for cannabis on behalf of the licensed producer;

(*b*) except in the case referred to in subsection (3), notify the Minister, not later than five days after the event, when a person referred to in any of subparagraphs (*a*)(i), (ii) or (iv) ceases to carry out their duties; and

(*c*) notify the Minister, not later than five days after the event, when a person referred to in subparagraph (*a*)(iii) ceases to be an officer or director.

Accompanying information

(2) The licensed producer must, with the application for approval referred to in paragraph (1)(*a*), provide the Minister with the following information and documents with respect to the new person:

(*a*) in the case of the replacement of the senior person in charge or the responsible person in charge or the replacement

d) réduire le risque d'atteinte à la sécurité ou à la santé publiques, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites.

Avis au ministre — changement de personnel

30. (1) Le producteur autorisé prend les mesures suivantes :

a) il demande et obtient l'approbation du ministre avant de procéder à la désignation d'autres personnes qui remplacent celles qui sont nommées ci-après ou s'ajoutent à celles-ci :

(i) le responsable principal,

(ii) la personne responsable et, le cas échéant, la personne responsable suppléante,

(iii) le cas échéant, l'un des dirigeants ou administrateurs visés au sous-alinéa 23(1)*a*)(ii),

(iv) toute personne physique autorisée à commander du chanvre indien pour le compte du producteur autorisé;

b) sauf dans le cas prévu au paragraphe (3), il avise le ministre, dans les cinq jours qui suivent, qu'une personne visée à l'un des sous-alinéas *a*)(i), (ii) et (iv) a cessé d'exercer ses fonctions;

c) il avise le ministre, dans les cinq jours qui suivent, qu'une personne visée au sous-alinéa *a*)(iii) a cessé d'être un dirigeant ou un administrateur.

Renseignements à fournir avec la demande

(2) En plus de la demande d'approbation visée à l'alinéa (1)*a*), le producteur autorisé, relativement à toute nomination, fournit ce qui suit au ministre :

a) dans le cas du remplacement du responsable principal ou de la personne responsable ou du remplacement ou de

or addition of an alternate responsible person in charge,

(i) the information specified in paragraph 23(1)(*d*), and

(ii) the declaration specified in paragraph 23(4)(*a*);

(*b*) in the case of the replacement or addition of an officer or director, the information specified in subparagraph 23(1)(*a*)(ii) concerning that person; and

(*c*) in the case of the replacement or addition of an individual who is authorized to place an order for cannabis on behalf of the licensed producer, the information specified in paragraph 23(1)(*e*).

l'adjonction d'une personne responsable suppléante :

(i) les renseignements visés à l'alinéa 23(1)*d*),

(ii) la déclaration visée à l'alinéa 23(4)*a*);

b) dans le cas du remplacement ou de l'adjonction d'un dirigeant ou d'un administrateur, les renseignements visés au sous-alinéa 23(1)*a*)(ii) qui concernent cette personne;

c) dans le cas du remplacement ou de l'adjonction d'une personne physique autorisée à commander du chanvre indien au nom du producteur autorisé, les renseignements visés à l'alinéa 23(1)*e*).

Notice to Minister — responsible person in charge

(3) A licensed producer must notify the Minister not later than the next business day if the responsible person in charge ceases to carry out their duties and there is no person designated as an alternate responsible person in charge.

Avis au ministre — personne responsable

(3) Lorsque la personne responsable a cessé d'exercer ses fonctions sans qu'une personne responsable suppléante ait été désignée, le producteur autorisé en avise le ministre au plus tard le jour ouvrable suivant.

Notice to Minister — various changes

31. A licensed producer must, within five days after the change, notify the Minister of any change to

(*a*) the method used for keeping records;

(*b*) the telephone number and, if applicable, the facsimile number and email address for

(i) their site; and

(ii) if applicable, each building within the site at which the activities are conducted under the licence; or

(*c*) the security of their site, other than a changes that affects the security level of any building at which cannabis, other than marihuana plants, is stored.

Avis au ministre — changements divers

31. Le producteur autorisé avise le ministre, dans les cinq jours qui suivent, qu'un changement a été apporté à ce qui suit :

a) la méthode de tenue des dossiers;

b) le numéro de téléphone et, le cas échéant, le numéro de télécopieur et l'adresse électronique des endroits suivants :

(i) son installation,

(ii) le cas échéant, chaque bâtiment de celle-ci où s'effectuent les opérations en vertu de la licence;

c) la sécurité de son installation, sauf s'il s'agit d'un changement qui touche le niveau de sécurité de tout bâtiment où

est stocké le chanvre indien autre que les plants de marihuana.

Statement by signatory of notice

32. An application or notification made under section 30 or 31 must

(*a*) be signed and dated by the senior person in charge; and

(*b*) include a statement signed and dated by that person indicating that

(i) all information and, if applicable, documents submitted in support of the application or notification are correct and complete to the best of their knowledge, and

(ii) they have the authority to bind the licensed producer.

Attestation du signataire de l'avis

32. L'avis ou la demande visé aux articles 30 et 31 satisfait aux exigences suivantes :

a) il est signé et daté par le responsable principal;

b) il comprend une attestation signée et datée par ce dernier portant :

(i) d'une part, qu'à sa connaissance, tous les renseignements et, le cas échéant, les documents fournis à l'appui de l'avis ou de la demande sont exacts et complets,

(ii) d'autre part, qu'il a le pouvoir d'obliger le producteur autorisé.

Suspension

33. (1) The Minister must suspend a producer's licence without prior notice in respect of any or all activities or substances set out in the licence if the Minister has reasonable grounds to believe that it is necessary to do so to protect public health, safety or security, including preventing cannabis from being diverted to an illicit market or use.

Suspension

33. (1) Le ministre suspend sans préavis la licence du producteur autorisé, à l'égard de certaines ou de toutes les opérations ou substances mentionnées dans la licence, s'il a des motifs raisonnables de croire qu'il est nécessaire de le faire en vue de protéger la sécurité ou la santé publiques, y compris en vue de prévenir le détournement de chanvre indien vers un marché ou un usage illicites.

Notice of suspension

(2) The suspension takes effect as soon as the Minister notifies the licensed producer of the decision to suspend and provides a written report that sets out the reasons for the suspension.

Avis de suspension

(2) La décision du ministre prend effet aussitôt qu'il en avise le producteur autorisé et lui fournit un exposé écrit des motifs de la suspension.

Opportunity to be heard

(3) The licensed producer may, within 10 days after receipt of the notice, provide the Minister with reasons why the suspension is unfounded.

Possibilité de se faire entendre

(3) Le producteur autorisé dont la licence est suspendue peut, dans les dix jours qui suivent la réception de l'avis, présenter au ministre les motifs pour lesquels la suspension n'est pas fondée.

Ceasing of suspended activities

(4) If a licence is suspended in respect of any or all activities or substances set out in the licence, the licensed producer must

Cessation des opérations suspendues

(4) Lorsqu'une licence est suspendue à l'égard de certaines ou de toutes les opérations ou substances mentionnées dans la li-

cease conducting those activities with respect to those substances for the duration of the suspension.

cence, le producteur autorisé cesse d'effectuer les opérations en cause à l'égard des substances visées pour la durée de la suspension.

Reinstatement of licence

(5) The Minister must, by notice to the licensed producer, reinstate a licence, in respect of any or all activities or substances affected by the suspension, if the licensed producer demonstrates to the Minister that

(*a*) the failure that gave rise to the suspension has been rectified; or

(*b*) the suspension was unfounded.

Rétablissement de la licence

(5) Le ministre, par avis au producteur autorisé, rétablit la licence à l'égard de certaines ou de toutes les opérations ou substances touchées par la suspension, si celui-ci lui démontre :

a) soit qu'il a remédié au manquement ayant donné lieu à la suspension;

b) soit que la suspension n'était pas fondée.

Revocation following suspension

34. The Minister must revoke a licence if the licensed producer fails to comply with the decision of the Minister to suspend the licence under section 33 or if the failure that gave rise to the suspension is not rectified.

Révocation suivant une suspension

34. Dans le cas où le producteur autorisé ne se conforme pas à la décision du ministre de suspendre sa licence aux termes de l'article 33, ou ne remédie pas au manquement ayant donné lieu à la suspension, le ministre révoque la licence.

Revocation — lost or stolen licence

35. The Minister must revoke a producer's licence on being notified by the licensed producer that the licence has been lost or stolen.

Révocation — perte ou vol de la licence

35. Le ministre révoque la licence du producteur autorisé si celui-ci l'avise de sa perte ou de son vol.

Revocation — other grounds

36. (1) Subject to subsection (2), the Minister must revoke a producer's licence in the following circumstances:

(*a*) the Minister has reasonable grounds to believe that the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;

(*b*) the licensed producer has, since the issuance of the licence, contravened a provision of the Act or its regulations or the *Food and Drugs Act* or a condition of their licence or of an import or export permit issued under these Regulations;

(*c*) the licensed producer is no longer eligible under section 21;

Révocation — autres motifs

36. (1) Sous réserve du paragraphe (2), le ministre révoque la licence du producteur autorisé dans les circonstances suivantes :

a) le ministre a des motifs raisonnables de croire que la licence a été délivrée sur la foi de renseignements faux ou trompeurs fournis dans la demande ou de documents faux ou falsifiés fournis à l'appui de celle-ci;

b) le titulaire a, depuis la délivrance de la licence, contrevenu à la Loi, à ses règlements ou à la *Loi sur les aliments et drogues* ou aux conditions de sa licence ou d'un permis d'importation ou d'exportation délivré en vertu du présent règlement;

(*d*) information received from a peace officer, a competent authority or the United Nations raises reasonable grounds to believe that the licensed producer has been involved in the diversion of a controlled substance or precursor to an illicit market or use; or

(*e*) any of the persons referred to in section 24 does not hold a security clearance.

c) le titulaire n'est plus admissible à la licence aux termes de l'article 21;

d) les renseignements reçus d'un agent de la paix, d'une autorité compétente ou des Nations Unies donnent des motifs raisonnables de croire que le titulaire a participé au détournement d'une substance désignée ou d'un précurseur vers un marché ou un usage illicites;

e) l'une des personnes visées à l'article 24 n'est pas titulaire d'une habilitation de sécurité.

Exceptions

(2) Unless it is necessary to do so to protect public health, safety or security, including preventing cannabis from being diverted to an illicit market or use, the Minister must not revoke a producer's licence in the circumstances described in paragraph (1)(*a*) or (*b*) if the licensed producer has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and its regulations and the *Food and Drugs Act*.

Exceptions

(2) Sauf s'il est nécessaire de le faire en vue de protéger la sécurité ou la santé publiques, y compris en vue de prévenir le détournement de chanvre indien vers un marché ou un usage illicites, le ministre ne révoque pas la licence de producteur autorisé dans les circonstances visées aux alinéas (1)*a*) ou *b*) si ce dernier a pris les mesures correctives indiquées pour assurer la conformité à la Loi, à ses règlements et à la *Loi sur les aliments et drogues*, ou a signé un engagement à cet effet.

Failure to comply with undertaking

(3) If the licensed producer fails to comply with an undertaking referred to in subsection (2), the Minister must revoke the licence.

Non-respect de l'engagement

(3) Dans le cas où le producteur autorisé ne respecte pas l'engagement mentionné au paragraphe (2), le ministre révoque sa licence.

Notice of cessation of activities

37. (1) A licensed producer who intends to cease conducting activities at their site — whether before or on the expiry of their licence — must submit to the Minister a written notice to that effect at least 30 days before ceasing those activities.

Avis de cessation des opérations

37. (1) Le producteur autorisé qui entend cesser les opérations à son installation — avant l'expiration de sa licence ou à l'expiration de cette dernière — présente au ministre un avis écrit à cet effet au moins trente jours avant la cessation.

Content of notice

(2) The notice must be signed and dated by the senior person in charge and contain the following information:

Contenu de l'avis

(2) L'avis est signé et daté par le responsable principal et contient les renseignements suivants :

(*a*) the expected date of the cessation of activities at the site;

a) la date prévue de cessation des opérations à l'installation;

(*b*) a description of the manner in which any cannabis remaining on the site as of the date referred to in paragraph (*a*) will be dealt with by the licensed producer, including

(i) if some or all of it will be sold or provided to another licensed producer who will be conducting activities at the same site, the name of that producer,

(ii) if some or all of it will be sold or provided to another licensed producer or a licensed dealer, the name of that producer and the address of their site or the name of that dealer and the address of their premises, and

(iii) if some or all of it will be destroyed, the date on which and the location at which the destruction is to take place;

(*c*) the address of the location at which the licensed producer's records, books, electronic data and other documents will be kept after activities have ceased; and

(*d*) the name, address, telephone number and, if applicable, the facsimile number and email address of a person who the Minister may contact for further information after activities have ceased.

b) la description de la façon dont le producteur autorisé disposera de la totalité du chanvre indien restant à l'installation à la date visée à l'alinéa *a*), notamment les renseignements suivants :

(i) dans le cas où le chanvre indien sera en tout ou en partie vendu ou fourni à un autre producteur autorisé qui effectuera des opérations à la même installation, le nom de ce producteur,

(ii) dans le cas où il sera en tout ou en partie vendu ou fourni à un autre producteur autorisé ou à un distributeur autorisé, le nom de ce producteur ou distributeur et l'adresse de son installation,

(iii) dans le cas où il sera en tout ou en partie détruit, la date et le lieu de la destruction;

c) l'adresse du lieu où les livres, registres, données électroniques et autres documents du producteur autorisé seront conservés après la cessation des opérations;

d) les nom, adresse, numéro de téléphone et, le cas échéant, numéro de télécopieur et adresse électronique de la personne auprès de qui le ministre pourra obtenir d'autres renseignements après la cessation des opérations.

Update

(3) After having ceased the activities, the licensed producer must submit to the Minister a detailed update of the information referred to in paragraphs (2)(*a*) to (*d*), if it differs from what was set out in the notice submitted under subsection (1). The update must be signed and dated by the senior person in charge.

Mise à jour

(3) Une fois que les opérations ont cessé, le producteur autorisé présente au ministre une mise à jour circonstanciée, signée et datée par le responsable principal, des renseignements visés aux alinéas (2)*a*) à *d*), s'ils diffèrent de ceux indiqués sur l'avis de cessation des opérations visé au paragraphe (1).

Return and revocation of licence

(4) If the activities are ceased before the expiry of the licence, the licensed producer must return to the Minister the original of the licence. The Minister must then revoke the licence.

(4) Si les opérations ont cessé avant l'expiration de la licence, le producteur autorisé retourne au ministre l'original de la licence. Le ministre révoque alors cette dernière.

Retour de la licence et révocation

Notice to local authorities – licence application

38. (1) Before submitting an application for a producer's licence to the Minister under section 23, the applicant must provide a written notice to the following persons in the area in which the site referred to in paragraph 23(1)(*b*) is located:

(*a*) the local government;

(*b*) the local fire authority; and

(*c*) the local police force or the Royal Canadian Mounted Police detachment that is responsible for providing policing services to that area.

38. (1) Avant de présenter au ministre la demande de licence de producteur autorisé visée à l'article 23, le demandeur fournit un avis écrit aux personnes ci-après de la région où l'installation visée à l'alinéa 23(1)*b*) est située :

a) l'administration locale;

b) le service d'incendie local;

c) le corps policier local ou le détachement de la Gendarmerie royale du Canada chargé de la prestation de services de police dans cette région.

Avis aux autorités locales — demande de licence

Content of notice

(2) The notice must contain the following information:

(*a*) the name of the applicant;

(*b*) the date on which the applicant will submit the application to the Minister;

(*c*) the activities referred to in subsection 12(1) for which the licence is to be sought, specifying that they are to be conducted in respect of cannabis; and

(*d*) the address of the site and, if applicable, of each building within the site at which the applicant proposes to conduct those activities.

(2) L'avis comporte les renseignements suivants :

a) le nom du demandeur;

b) la date à laquelle il présentera sa demande au ministre;

c) les opérations visées au paragraphe 12(1) pour lesquelles la licence sera demandée et la mention qu'elles seront effectuées à l'égard du chanvre indien;

d) l'adresse de l'installation et, le cas échéant, de chaque bâtiment de celle-ci où il se propose d'effectuer ces opérations.

Contenu de l'avis

Senior official

(3) The notice must be addressed to a senior official of the local authority to whom it is sent.

(3) Le destinataire de l'avis est un cadre supérieur de l'autorité locale en cause.

Cadre supérieur

Notice to local authorities — amendment application

39. (1) Before submitting a licence amendment application to the Minister under section 29 concerning a change referred to in subsection (2), a licensed pro-

39. (1) Avant de présenter au ministre, en vertu de l'article 29, une demande de modification visant un élément mentionné au paragraphe (2), le producteur autorisé

Avis aux autorités locales — demande de modification

ducer must provide a written notice to the persons referred to in paragraphs 38(1)(*a*) to (*c*) in the area in which the site to be specified in the amended licence is located.

fournit un avis écrit aux personnes visées aux alinéas 38(1)*a*) à *c*) de la région où l'installation visée par la licence — une fois celle-ci modifiée — sera située.

Applicable changes

(2) Subsection (1) applies in respect of an application to amend a licence to change

(*a*) the name of the licensed producer;

(*b*) the activities to be conducted by the producer under the licence; or

(*c*) the address of the site and, if applicable, of each building within the site at which those activities are to be conducted.

Modifications visées

(2) Le paragraphe (1) s'applique à l'égard d'une demande de modification de la licence visant les éléments suivants :

a) le nom du producteur autorisé;

b) les opérations qui seront effectuées par ce dernier en vertu de la licence;

c) l'adresse de l'installation et, le cas échéant, de chaque bâtiment de celle-ci où les opérations seront effectuées.

Content of notice

(3) The notice must contain the following information:

(*a*) the name of the licensed producer and, if applicable, the proposed new name of the producer;

(*b*) the date on which the producer will submit the application to the Minister;

(*c*) the activities referred to in subsection 12(1) that are to be set out in the amended licence, specifying that they are to be conducted in respect of cannabis; and

(*d*) the address of the site and, if applicable, of each building within the site that is to be set out in the amended licence.

Contenu de l'avis

(3) L'avis contient les renseignements suivants :

a) le nom du producteur autorisé et, le cas échéant, le nouveau nom proposé;

b) la date à laquelle le producteur autorisé présentera sa demande au ministre;

c) les opérations prévues au paragraphe 12(1) qui seront mentionnées dans la licence, une fois cette dernière modifiée, avec la mention qu'elles seront effectuées à l'égard du chanvre indien;

d) l'adresse de l'installation et, le cas échéant, de chaque bâtiment de celle-ci qui seront mentionnées dans la licence, une fois cette dernière modifiée.

Senior official

(4) The notice must be addressed to a senior official of the local authority to whom it is sent.

Cadre supérieur

(4) Le destinataire de l'avis est un cadre supérieur de l'autorité locale en cause.

Notice to local authorities — various matters

40. (1) Within 30 days after the issuance, renewal, amendment, suspension, reinstatement or revocation of its licence, a licensed producer must provide a written notice to the persons referred to in para-

Avis divers aux autorités locales

40. (1) Dans les trente jours de la délivrance, du renouvellement, de la modification, de la suspension, du rétablissement ou de la révocation de sa licence, le producteur autorisé fournit un avis écrit aux per-

graphs 38(1)(*a*) to (*c*) in the area in which the site specified in the licence is located and provide a copy of the notice to the Minister.

Content of notice

(2) The notice must contain the following information:

(*a*) the name of the licensed producer and the address of their site; and

(*b*) a description of the applicable matter referred to in subsection (1) and its effective date and, in the case of an amendment to the licence, details of the amendment.

Senior official

(3) The notice must be addressed to a senior official of the local authority to whom it is sent.

sonnes visées aux alinéas 38(1)*a*) à *c*) de la région où se situe l'installation visée par la licence et fournit copie de cet avis au ministre.

Contenu de l'avis

(2) L'avis contient les renseignements suivants :

a) le nom du producteur autorisé et l'adresse de son installation;

b) la description de l'événement en cause et sa date de prise d'effet et, s'il s'agit d'une modification de la licence, les précisions eu égard aux changements apportés.

Cadre supérieur

(3) Le destinataire de l'avis est un cadre supérieur de l'autorité locale en cause.

Division 3

Security Measures

General

Compliance with security measures

41. A licensed producer must ensure that the security measures set out in this Division are carried out.

Unauthorized access

42. The licensed producer's site must be designed in a manner that prevents unauthorized access.

Perimeter of Site

Visual monitoring

43. (1) The perimeter of the licensed producer's site must be visually monitored at all times by visual recording devices to detect any attempted or actual unauthorized access.

Visual recording devices

(2) The devices must, in the conditions under which they are used, be capable of recording in a visible manner any attempted or actual unauthorized access.

Section 3

Mesures de sécurité

Généralités

Respect des mesures de sécurité

41. Le producteur autorisé veille au respect des mesures de sécurité prévues à la présente section.

Accès non autorisé

42. L'installation du producteur autorisé doit être conçue de façon à prévenir tout accès non autorisé.

Périmètre de l'installation

Surveillance visuelle

43. (1) Le périmètre de l'installation du producteur autorisé doit faire l'objet, en tout temps, d'une surveillance visuelle à l'aide d'appareils d'enregistrement visuel, de façon à détecter tout accès ou tentative d'accès non autorisé.

Appareils d'enregistrement visuel

(2) Ces appareils doivent être adaptés aux conditions de leur environnement afin d'enregistrer visiblement tout accès ou tentative d'accès non autorisé.

Intrusion detection system

44. The perimeter of the licensed producer's site must be secured by an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to or movement in the site or tampering with the system.

Système de détection des intrusions

44. Le périmètre de l'installation du producteur autorisé doit être sécurisé au moyen d'un système de détection des intrusions qui est fonctionnel en tout temps et permet la détection de tout accès non autorisé à l'installation ou mouvement non autorisé à l'intérieur de celle-ci ou toute altération du système, ou toute tentative à ces égards.

Monitoring by personnel

45. (1) The system must be monitored at all times by personnel who must determine the appropriate steps to be taken in response to the detection of any occurrence referred to in section 43 or 44.

Surveillance par le personnel

45. (1) Le système doit être surveillé en tout temps par du personnel qui doit déterminer les mesures qui s'imposent en cas de détection d'un événement visé aux articles 43 ou 44.

Record of detected matters

(2) If any such occurrence is detected, the personnel must make a record of

(*a*) the date and time of the occurrence; and

(*b*) the measures taken in response to it and the date and time when they were taken.

Constat des événements détectés

(2) Le cas échéant, le personnel doit consigner les renseignements suivants :

a) la date et l'heure auxquelles l'événement a été détecté;

b) la description des mesures prises en réponse à ce dernier, ainsi que la date et l'heure auxquelles elles l'ont été.

Areas Within a Site where Cannabis is Present

Zones de l'installation où du chanvre indien est présent

Restricted access

46. (1) Access to areas within a site where cannabis is present (referred to in sections 46 to 50 as "those areas") must be restricted to persons whose presence in those areas is required by their work responsibilities.

Accès restreint

46. (1) L'accès aux zones de l'installation où du chanvre indien est présent (appelées « zones » aux articles 46 à 50) doit être limité aux seules personnes dont les fonctions y requièrent la présence.

Responsible person in charge present

(2) The responsible person in charge or, if applicable, the alternate responsible person in charge must be physically present while other persons are in those areas.

Présence de la personne responsable

(2) La personne responsable ou, le cas échéant, la personne responsable suppléante, doit être présente physiquement dans les zones lorsque d'autres personnes s'y trouvent.

Record

(3) A record must be made of the identity of every person entering or exiting those areas.

Registre

(3) Il est tenu un registre de l'identité des personnes entrant dans les zones ou en sortant.

Physical barriers

47. Those areas must include physical barriers that prevent unauthorized access.

Barrières physiques

47. Les zones doivent comporter des barrières physiques qui empêchent tout accès non autorisé.

Visual monitoring

48. (1) Those areas must be visually monitored at all times by visual recording devices to detect illicit conduct.

Surveillance visuelle

48. (1) Les zones doivent faire l'objet d'une surveillance visuelle en tout temps, à l'aide d'appareils d'enregistrement visuel, de façon à détecter toute conduite illicite.

Visual recording devices

(2) The devices must, in the conditions under which they are used, be capable of recording in a visible manner illicit conduct.

Appareils d'enregistrement visuel

(2) Ces appareils doivent être adaptés aux conditions de leur environnement afin d'enregistrer visiblement toute conduite illicite.

Intrusion detection system

49. Those areas must be secured by an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to or movement in those areas or tampering with the system.

Système de détection des intrusions

49. Les zones doivent être sécurisées au moyen d'un système de détection des intrusions qui est fonctionnel en tout temps et permet la détection de tout accès non autorisé aux zones ou mouvement non autorisé à l'intérieur de celles-ci ou toute altération du système, ou toute tentative à ces égards.

Filtration of air

50. Those areas must be equipped with a system that filters air to prevent the escape of odours and, if present, pollen.

Filtration de l'air

50. Les zones doivent être équipées d'un système de filtration de l'air qui empêche les odeurs et, le cas échéant, le pollen, de s'échapper.

Monitoring by personnel

51. (1) The intrusion detection system must be monitored at all times by personnel who must determine the appropriate steps to be taken in response to the detection of any occurrence referred to in section 48 or 49.

Surveillance par le personnel

51. (1) Le système de détection des intrusions doit être surveillé en tout temps par du personnel qui doit déterminer les mesures qui s'imposent en cas de détection d'un événement visé aux articles 48 ou 49.

Record of detected matters

(2) If any such occurrence is detected, the personnel must make a record of

(*a*) the date and time of the occurrence; and

(*b*) the measures taken in response to it and the date and time when they were taken.

Constat des événements détectés

(2) Le cas échéant, le personnel doit consigner les renseignements suivants :

a) la date et l'heure auxquelles l'événement a été détecté;

b) la description des mesures prises en réponse à la détection de ce dernier, ainsi que la date et l'heure auxquelles elles l'ont été.

DIVISION 4

GOOD PRODUCTION PRACTICES

Prohibition — sale or provision

52. (1) A licensed producer must not sell or provide dried marihuana under subsection 12(4) unless the requirements of this Division have been met.

Prohibition — export

(2) A licensed producer must not export dried marihuana unless the requirements of this Division have been met.

Microbial and chemical contaminants

53. (1) The microbial and chemical contaminants of dried marihuana must be within generally accepted tolerance limits for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the *Food and Drugs Act*.

Analytical testing

(2) Analytical testing for those contaminants and for the percentages of delta-9-tetrahydrocannabinol and cannabidiol referred to in these Regulations must be conducted using validated methods.

Pest control product

54. (1) Marihuana must not be treated — before, during or after the drying process — with a pest control product that has not been registered under the *Pest Control Products Act* for use on marihuana for medical purposes.

Residue

(2) Dried marihuana must not contain any residue of a pest control product in excess of any maximum residue limit specified for the product under section 9 of the *Pest Control Products Act*.

Premises

55. (1) Dried marihuana must be produced, packaged, labelled and stored in premises that are designed, constructed and

SECTION 4

BONNES PRATIQUES DE PRODUCTION

Interdiction — vente ou fourniture

52. (1) Le producteur autorisé ne peut vendre ou fournir de la marihuana séchée en vertu du paragraphe 12(4) que si les exigences prévues à la présente section sont respectées.

Interdiction — exportation

(2) Il ne peut exporter de la marihuana séchée que si les exigences prévues à la présente section sont respectées.

Contamination microbienne et chimique

53. (1) La contamination microbienne et chimique de la marihuana séchée se situe dans les limites de tolérance généralement reconnues pour les plantes médicinales destinées à la consommation humaine, lesquelles sont établies dans toute publication mentionnée à l'annexe B de la *Loi sur les aliments et drogues*.

Tests analytiques

(2) Des tests analytiques concernant cette contamination ainsi que les pourcentages de delta-9-tétrahydrocannabinol et de cannabidiol visés par le présent règlement sont effectués suivant des méthodes validées.

Produit antiparasitaire

54. (1) Que ce soit avant, pendant ou après le processus de séchage, la marihuana ne peut être traitée au moyen d'un produit antiparasitaire que si celui-ci a été homologué en vertu de la *Loi sur les produits antiparasitaires* pour utilisation avec la marihuana à des fins médicales.

Résidus

(2) La marihuana séchée ne peut contenir de résidus d'un produit antiparasitaire au-delà de toute limite maximale de résidu fixée pour ce produit en vertu de l'article 9 de la *Loi sur les produits antiparasitaires*.

Locaux

55. (1) La marihuana séchée est produite, emballée, étiquetée et stockée dans des locaux qui sont conçus, construits et

maintained in a manner that permits those activities to be conducted under sanitary conditions, and in particular that

(*a*) permits the premises to be kept clean and orderly;

(*b*) permits the effective cleaning of all surfaces in the premises;

(*c*) permits the dried marihuana to be stored or processed appropriately;

(*d*) prevents the contamination of the dried marihuana; and

(*e*) prevents the addition of an extraneous substance to the dried marihuana.

entretenus de manière à permettre d'effectuer ces opérations dans des conditions hygiéniques, plus particulièrement de manière à :

a) permettre qu'ils soient tenus en état de propreté et en bon ordre;

b) permettre le nettoyage efficace des surfaces qui s'y trouvent;

c) permettre le stockage et le traitement adéquats de la marihuana séchée;

d) prévenir la contamination de la marihuana séchée;

e) prévenir l'introduction de toute matière étrangère dans la marihuana séchée.

Storage

(2) Dried marihuana must be stored under conditions that will maintain its quality.

Stockage

(2) La marihuana séchée est stockée dans des conditions qui préserveront sa qualité.

Equipment

56. Dried marihuana must be produced, packaged, labelled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that

(*a*) permits the effective cleaning of its surfaces;

(*b*) permits it to function in accordance with its intended use;

(*c*) prevents it from contaminating the dried marihuana; and

(*d*) prevents it from adding an extraneous substance to the dried marihuana.

Équipement

56. La marihuana séchée est produite, emballée, étiquetée et stockée au moyen d'un équipement qui est conçu, fabriqué, entretenu, utilisé et disposé de manière à :

a) permettre le nettoyage efficace de ses surfaces;

b) fonctionner adéquatement;

c) prévenir la contamination de la marihuana séchée;

d) prévenir l'introduction de toute matière étrangère dans la marihuana séchée.

Sanitation program

57. Dried marihuana must be produced, packaged, labelled and stored in accordance with a sanitation program that sets out

(*a*) procedures for effectively cleaning the premises in which those activities are conducted;

Programme d'hygiène

57. La marihuana séchée est produite, emballée, étiquetée et stockée en conformité avec un programme d'hygiène qui prévoit :

a) les méthodes de nettoyage efficace des locaux où ces opérations sont effectuées;

(*b*) procedures for effectively cleaning the equipment used in those activities;

(*c*) procedures for handling any substance used in those activities; and

(*d*) all requirements, in respect of the health, the hygienic behaviour and the clothing of the personnel who are involved in those activities, that are necessary to ensure that those activities are conducted in sanitary conditions.

b) les méthodes de nettoyage efficace de l'équipement utilisé pour effectuer ces opérations;

c) les méthodes de manutention de toute substance utilisée pour effectuer ces opérations;

d) les exigences relatives à la santé, au comportement et à l'habillement du personnel qui effectue ces opérations afin que celles-ci soient effectuées dans des conditions hygiéniques.

Standard operating procedures

58. Dried marihuana must be produced, packaged, labelled and stored in accordance with standard operating procedures that are designed to ensure that those activities are conducted in accordance with the requirements of this Division.

Méthodes d'exploitation normalisées

58. La marihuana séchée est produite, emballée, étiquetée et stockée en conformité avec des méthodes d'exploitation normalisées, qui sont conçues de façon à ce que ces opérations soient effectuées conformément aux exigences prévues à la présente section.

Recall

59. A licensed producer must establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of dried marihuana that has been made available for sale.

Retraits du marché

59. Le producteur autorisé établit et tient un système de contrôle qui permet le retrait rapide et complet du marché de tout lot ou lot de production de marihuana séchée mis en vente.

Quality assurance

60. (1) A licensed producer must

(*a*) have a quality assurance person who

(i) is responsible for assuring the quality of the dried marihuana before it is made available for sale, and

(ii) has the training, experience and technical knowledge relating to the activity conducted and the requirements of this Division; and

(*b*) investigate every complaint received in respect of the quality of the dried marihuana and, if necessary, take corrective and preventative measures.

Assurance de la qualité

60. (1) Le producteur autorisé satisfait aux exigences suivantes :

a) d'une part, il a un préposé à l'assurance de la qualité qui, à la fois :

(i) a pour responsabilité d'assurer la qualité de la marihuana séchée avant la mise en vente de celle-ci,

(ii) possède la formation, l'expérience et les connaissances techniques à l'égard de l'opération effectuée et des exigences prévues à la présente section;

b) d'autre part, il examine les plaintes reçues au sujet de la qualité de la marihuana séchée et, le cas échéant, il prend

les mesures correctives et préventives nécessaires.

Methods and procedures

(2) Dried marihuana must be produced, packaged, labelled and stored using methods and procedures that, prior to their implementation, have been approved by a quality assurance person.

(2) La marihuana séchée est produite, emballée, étiquetée et stockée au moyen de méthodes et de procédés qui, avant d'être mis en application, ont été approuvés par un préposé à l'assurance de la qualité.

Méthodes et procédés

Approval prior to sale

(3) Every lot or batch of dried marihuana must be approved by a quality assurance person before it is made available for sale.

(3) Chaque lot ou lot de production de marihuana séchée est approuvé par un préposé à l'assurance de la qualité avant d'être mis en vente.

Approbation préalable à la mise en vente

Returns

(4) Dried marihuana that is sold or provided under subsection 12(4) and subsequently returned to the licensed producer must not be resold or provided again.

(4) La marihuana séchée vendue ou fournie en vertu du paragraphe 12(4) et subséquemment retournée au producteur autorisé ne peut être revendue ou fournie de nouveau.

Retours

Sample of lot or batch

61. (1) Subject to subsection (3), if the Minister has reasonable grounds to believe that a lot or batch of dried marihuana made available for sale or provision by a licensed producer may — by reason of the manner in which it was produced, packaged, labelled or stored — pose a risk to the health of an individual who in accordance with these Regulations obtains the dried marihuana for their own medical purposes, the Minister may require the licensed producer to provide the Minister with a sample of that lot or batch.

61. (1) Sous réserve du paragraphe (3), si le ministre a des motifs raisonnables de croire qu'un lot ou lot de production de marihuana séchée qu'un producteur autorisé a à sa disposition pour le mettre en vente ou le fournir peut, de par la façon dont cette dernière a été produite, emballée, étiquetée ou stockée, poser un risque pour la santé de la personne physique qui, en vertu du présent règlement, obtient la marihuana séchée à ses propres fins médicales, il peut exiger que le producteur autorisé lui fournisse un échantillon de ce lot ou lot de production.

Échantillon d'un lot ou lot de production

Quantity

(2) The sample must be of sufficient quantity to enable a determination of whether the lot or batch of dried marihuana meets the requirements of sections 53 and 54.

(2) L'échantillon est fourni en quantité suffisante pour permettre de vérifier si le lot ou lot de production de marihuana séchée satisfait aux exigences des articles 53 et 54.

Quantité

Period

(3) The Minister must not require a sample to be provided if more than one year has elapsed after the date of the last sale or provision of any portion of the lot or batch of dried marihuana.

(3) Le ministre ne peut exiger que lui soit fourni l'échantillon si plus d'une année s'est écoulée depuis la date de la dernière vente ou fourniture de tout ou partie du lot ou lot de production de marihuana séchée.

Période

Recall reporting

62. A licensed producer who commences a recall of dried marihuana must provide the Minister with the following information in respect of the recalled dried marihuana within three days after the day on which the recall is commenced:

(*a*) its brand name;

(*b*) the number of each lot or batch recalled;

(*c*) if known by the licensed producer, the name and address of each licensed producer who imported or produced any of it;

(*d*) the reasons for commencing the recall;

(*e*) the quantity produced or imported into Canada by the licensed producer;

(*f*) the quantity that was sold or provided in Canada by the licensed producer;

(*g*) the quantity remaining in the possession of the licensed producer;

(*h*) the number of persons referred to in subsections 12(2) and (4) to whom it was sold or provided by the licensed producer; and

(*i*) a description of any other action that the licensed producer is taking in respect of the recall.

Rapports sur les retraits du marché

62. Le producteur autorisé qui entreprend de retirer du marché de la marihuana séchée fournit au ministre les renseignements ci-après à l'égard de celle-ci dans les trois jours qui suivent le jour du début du retrait :

a) sa marque nominative;

b) le numéro de chaque lot ou lot de production qui fait l'objet du retrait;

c) s'il les connaît, les nom et adresse de chaque producteur autorisé qui l'a produite ou l'a importée en tout ou en partie;

d) les raisons qui ont motivé le retrait;

e) la quantité qu'il a produite ou importée au Canada;

f) la quantité qu'il a vendue ou fournie au Canada;

g) la quantité restante qu'il a en sa possession;

h) le nombre de personnes visées aux paragraphes 12(2) et (4) à qui il l'a vendue ou fournie;

i) la description de toute autre mesure qu'il prend à l'égard du retrait.

Adverse reactions

63. (1) A licensed producer who sells or provides dried marihuana must provide the Minister with a case report for each serious adverse reaction to the dried marihuana, within 15 days after the day on which the producer becomes aware of the reaction.

Réactions indésirables

63. (1) Le producteur autorisé qui vend ou fournit de la marihuana séchée fournit au ministre des fiches d'observation sur chacune des réactions indésirables graves à celle-ci, dans les quinze jours suivant le jour où il en a eu connaissance.

Summary report

(2) A licensed producer who sells or provides dried marihuana must annually prepare and maintain a summary report

Rapports de synthèse

(2) Le producteur autorisé qui vend ou fournit de la marihuana séchée établit et conserve, chaque année, un rapport de syn-

that contains a concise and critical analysis of all adverse reactions to the dried marihuana that have occurred during the previous 12 months.

Provide Minister with report on request

(3) If, after reviewing a case report provided under subsection (1) or after reviewing any other safety data relating to the dried marihuana, the Minister has reasonable grounds to believe that the dried marihuana may — by reason of the manner in which it was produced, packaged, labelled or stored — pose a risk to the health of an individual who in accordance with these Regulations obtains the dried marihuana for their own medical purposes, the Minister may request that, within 30 days after the day on which the request is received, the licensed producer

(*a*) provide the Minister with a copy of any summary report prepared under subsection (2); or

(*b*) prepare and provide the Minister with an interim summary report containing a concise and critical analysis of all adverse reactions to the dried marihuana that have occurred since the date of the most recent summary report prepared under subsection (2).

Definitions

(4) The following definitions apply in this section.

"adverse reaction" «*réaction indésirable*»

"adverse reaction" means a noxious and unintended response to dried marihuana.

"case report" «*fiche d'observation*»

"case report" means a detailed record of all relevant data associated with the use of dried marihuana by a person.

"serious adverse reaction" «*réaction indésirable grave*»

"serious adverse reaction" means a noxious and unintended response to dried marihuana that requires in-patient hospitalization or a prolongation of existing hospitaliza-

thèse comportant une analyse critique et concise de toutes les réactions indésirables à la marihuana séchée qui se sont produites dans les douze derniers mois.

Rapports fournis à la demande du ministre

(3) Si, après avoir examiné les fiches d'observation fournies aux termes du paragraphe (1) ou toutes les données concernant l'innocuité de la marihuana séchée, le ministre a des motifs raisonnables de croire qu'elle peut, de par la façon dont elle a été produite, emballée, étiquetée ou stockée, poser un risque pour la santé de la personne physique qui, en vertu du présent règlement, l'obtient à ses propres fins médicales, il peut demander que le producteur autorisé, dans les trente jours qui suivent le jour de la réception de la demande :

a) lui fournisse un exemplaire de tout rapport de synthèse préparé aux termes du paragraphe (2);

b) prépare et lui fournisse un rapport de synthèse provisoire comportant une analyse critique et concise de toutes les réactions indésirables à la marihuana séchée qui sont survenues depuis la date où le dernier rapport de synthèse a été préparé en application du paragraphe (2).

Définitions

(4) Les définitions qui suivent s'appliquent au présent article.

«fiche d'observation» "*case report*"

«fiche d'observation» Rapport détaillé contenant toutes les données concernant l'utilisation de la marihuana séchée par une personne.

«réaction indésirable» "*adverse reaction*"

«réaction indésirable» Réaction nocive et non voulue à la marihuana séchée.

«réaction indésirable grave» "*serious adverse reaction*"

«réaction indésirable grave» Réaction nocive et non voulue à la marihuana séchée qui nécessite ou prolonge une hospitalisa-

tion, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death.

tion, entraîne une malformation congénitale, une invalidité ou une incapacité persistante ou importante, met la vie en danger ou entraîne la mort.

Division 5

Packaging, Labelling and Shipping

Section 5

Emballage, étiquetage et expédition

Packaging

64. A licensed producer who sells or provides dried marihuana under subsection 12(4) must ensure that

(*a*) the dried marihuana is packaged in an immediate container

(i) that is in direct contact with the dried marihuana,

(ii) that keeps the dried marihuana dry and free from contamination,

(iii) that has a security feature that provides reasonable assurance to consumers that the container has not been opened prior to receipt, and

(iv) that is a child resistant package that meets the requirements of subsections C.01.001(2) to (4) of the *Food and Drug Regulations*; and

(*b*) not more than 30 g of dried marihuana is in the immediate container.

Emballage

64. Le producteur autorisé qui vend ou fournit de la marihuana séchée en vertu du paragraphe 12(4) veille à ce que cette substance satisfasse aux exigences suivantes :

a) elle est emballée dans un contenant immédiat qui, à la fois :

(i) est en contact direct avec elle,

(ii) en empêche la contamination et la garde sèche,

(iii) possède un dispositif de sûreté offrant au consommateur une assurance raisonnable que le contenant n'a pas été ouvert avant la réception,

(iv) est un emballage protège-enfants qui satisfait aux exigences des paragraphes C.01.001(2) à (4) du *Règlement sur les aliments et drogues*;

b) au plus 30 g de celle-ci se trouvent dans le contenant immédiat.

Weight of dried marihuana

65. A licensed producer who sells or provides dried marihuana under subsection 12(4) must ensure that the net weight of the dried marihuana in the immediate container is not less than 95% and not more than 101% of the net weight specified on the label in accordance with subparagraph 66(*c*)(v).

Poids de la marihuana séchée

65. Le producteur autorisé qui vend ou fournit de la marihuana séchée en vertu du paragraphe 12(4) veille à ce que le poids net de la marihuana séchée se trouvant dans le contenant immédiat ne soit pas inférieur à 95 % du poids net indiqué sur l'étiquette conformément au sous-alinéa 66*c*)(v) et ne soit pas supérieur à 101 % de celui-ci.

Product label

66. A licensed producer who sells or provides dried marihuana under subsection 12(4) must ensure that the immediate

Étiquette du produit

66. Le producteur autorisé qui vend ou fournit de la marihuana séchée en vertu du paragraphe 12(4) veille à ce qu'une étiquette comportant les renseignements ci-

container carries a label that contains the following information:

(*a*) the name of that licensed producer and the address of their site;

(*b*) the words "Dried marihuana / Marihuana séchée";

(*c*) in respect of the dried marihuana in the container:

(i) its brand name,

(ii) its lot number, preceded by one of the following designations:

(A) "Lot number",

(B) "Lot no.",

(C) "Lot", or

(D) "(L)",

(iii) the percentage of delta-9-tetrahydrocannabinol w/w, followed by the word "delta-9-tetrahydrocannabinol",

(iv) the percentage of cannabidiol w/w, followed by the word "cannabidiol",

(v) its net weight, in grams,

(vi) its recommended storage conditions,

(vii) its packaging date, and

(viii) either

(A) its expiry date, if a stability period for the dried marihuana has been established in accordance with section 71, or

(B) a statement to the effect that no expiry date based on stability data has been determined for the dried marihuana;

(*d*) the symbol "N" set out in the upper left corner of the label in a colour con-

après soit apposée sur le contenant immédiat :

a) le nom de ce producteur autorisé et l'adresse de son installation;

b) la mention « Marihuana séchée / Dried marihuana »;

c) à propos de la marihuana séchée se trouvant dans le contenant :

(i) sa marque nominative,

(ii) son numéro de lot, ce numéro étant précédé de l'une des désignations suivantes :

(A) « Numéro du lot »,

(B) « Lot n° »,

(C) « Lot »,

(D) « (L) »,

(iii) le pourcentage de delta-9-tétrahydrocannabinol p/p, suivi du mot « delta-9-tétrahydrocannabinol »,

(iv) le pourcentage de cannabidiol p/p, suivi du mot « cannabidiol »,

(v) son poids net en grammes,

(vi) ses conditions de stockage recommandées,

(vii) sa date d'emballage,

(viii) l'un ou l'autre des éléments suivants :

(A) sa date limite d'utilisation, si la période de stabilité de la marihuana séchée a été établie conformément à l'article 71,

(B) la mention qu'aucune date limite d'utilisation, fondée sur des données concernant la stabilité de la marihuana séchée, n'a été établie;

trasting with the rest of the label or in type not less than half the size of any other letters used on the label;

(*e*) the warning "KEEP OUT OF REACH OF CHILDREN / TENIR HORS DE LA PORTÉE DES ENFANTS"; and

(*f*) the statement "Important: Please read the Health Canada document provided with this package before using dried marihuana. / Important : Veuillez lire le document de Santé Canada qui accompagne ce colis avant d'utiliser la marihuana séchée.".

d) sur le quart supérieur gauche de l'étiquette, le symbole « N », d'une couleur faisant contraste avec le reste de l'étiquette ou en caractères d'au moins la moitié de la taille de toute autre lettre utilisée sur l'étiquette;

e) l'avertissement « TENIR HORS DE LA PORTÉE DES ENFANTS / KEEP OUT OF REACH OF CHILDREN »;

f) la mention « Important : Veuillez lire le document de Santé Canada qui accompagne ce colis avant d'utiliser la marihuana séchée. / Important : Please read the Health Canada document provided with this package before using dried marihuana. ».

Client label

67. A licensed producer who sells or provides dried marihuana to a client or an individual who is responsible for the client must ensure that

(*a*) the immediate container carries a label that contains the following information:

(i) the given name and surname of the client,

(ii) the given name, surname and profession of the health care practitioner who provided the client's medical document,

(iii) the name of the licensed producer,

(iv) the daily quantity of dried marihuana indicated on the client's medical document, expressed in grams,

(v) the expiry date of the client's registration referred to in section 112,

(vi) the shipping date, and

Étiquette concernant le client

67. Le producteur autorisé qui vend ou fournit de la marihuana séchée à un client ou à une personne physique responsable de ce dernier veille au respect des exigences suivantes :

a) une étiquette comportant les renseignements ci-après est apposée sur le contenant immédiat :

(i) les nom et prénom du client,

(ii) les nom, prénom et profession du praticien de la santé qui a fourni le document médical du client,

(iii) le nom du producteur autorisé,

(iv) la quantité quotidienne de marihuana séchée, en grammes, indiquée sur le document médical du client,

(v) la date d'expiration de l'inscription du client visée à l'article 112,

(vi) la date d'expédition,

(vii) la date visée au paragraphe 124(2);

(vii) the date referred to in subsection 124(2); and

(*b*) a separate document containing the information referred to in paragraph (*a*) accompanies each shipment of the dried marihuana.

b) un document distinct, comportant les renseignements visés à l'alinéa *a*), accompagne chaque expédition de marihuana séchée.

Combined label

68. In the case of dried marihuana to be sold or provided to a client or an individual who is responsible for the client, the information required under section 66 and paragraph 67(*a*) may be set out on one label.

Étiquette unique

68. Dans le cas de la marihuana séchée destinée à être vendue ou fournie à un client ou à une personne physique responsable de ce dernier, les renseignements visés à l'article 66 et à l'alinéa 67*a*) peuvent figurer sur la même étiquette.

Department of Health document

69. A licensed producer who sells or provides dried marihuana under subsection 12(4) must ensure that each shipment of the dried marihuana is accompanied by a copy of the current version of the document entitled *Information on the Use of Marihuana for Medical Purposes*, published by the Department of Health.

Document du ministère de la Santé

69. Le producteur autorisé qui vend ou fournit de la marihuana séchée en vertu du paragraphe 12(4) veille à ce que chaque expédition de marihuana séchée soit accompagnée d'une copie à jour du document intitulé *Renseignements sur l'usage de la marihuana à des fins médicales*, publié par le ministère de la Santé.

Presentation of information — label

70. (1) All information that is required under section 66 and paragraph 67(*a*) to appear on a label must be

(*a*) in English and in French;

(*b*) clearly and prominently displayed on the label; and

(*c*) readily discernible under the customary conditions of use.

Présentation des renseignements — étiquette

70. (1) Tous les renseignements qui doivent figurer sur une étiquette conformément à l'article 66 et à l'alinéa 67*a*) sont :

a) en français et en anglais;

b) clairement présentés et placés bien en vue sur l'étiquette;

c) faciles à apercevoir dans les conditions ordinaires d'usage.

Presentation of information — document

(2) All information in a document that is required under paragraph 67(*b*) or section 69 must be in English and in French and readily discernible under the customary conditions of use.

Présentation des renseignements — document

(2) Tous les renseignements que comportent les documents visés à l'alinéa 67*b*) ou à l'article 69 sont en français et en anglais et faciles à apercevoir dans les conditions ordinaires d'usage.

Expiry date

71. (1) A licensed producer must not include an expiry date on a label referred to in section 66 unless

(*a*) the licensed producer has submitted data to the Minister that establishes the stability period during which, after the

Date limite d'utilisation

71. (1) Le producteur autorisé ne peut inscrire de date limite d'utilisation sur l'étiquette visée à l'article 66 que si les conditions ci-après sont remplies :

a) il a présenté au ministre des données établissant la période de stabilité de la

dried marihuana is packaged in accordance with section 64 and when it is stored under its recommended storage conditions referred to in subparagraph 66(*c*)(vi),

(i) the dried marihuana maintains not less than 80% and not more than 120% of the percentages of delta-9-tetrahydrocannabinol w/w and cannabidiol w/w indicated on the label in accordance with subparagraphs 66(*c*)(iii) and (iv), and

(ii) the microbial and chemical contaminants of the dried marihuana remain within the limits referred to in subsection 53(1); and

(*b*) in the opinion of the Minister the data submitted by the licensed producer meets the requirements of paragraph (*a*) and has notified the producer to that effect.

marihuana séchée durant laquelle, une fois celle-ci emballée conformément à l'article 64 et stockée conformément aux conditions recommandées visées au sous-alinéa 66*c*)(vi), les exigences ci-après sont respectées :

(i) la marihuana séchée conserve au moins 80 %, et au plus 120 %, des pourcentages de delta-9-tétrahydrocannabinol p/p et de cannabidiol p/p inscrits sur l'étiquette conformément aux sous-alinéas 66*c*)(iii) et (iv),

(ii) la contamination microbienne et chimique de la marihuana séchée se maintient dans les limites visées au paragraphe 53(1);

b) le ministre est d'avis que les données présentées satisfont aux exigences de l'alinéa *a*) et il l'en a avisé.

Definition of "expiry date"

(2) For the purpose of subsection (1) and subparagraph 66(*c*)(viii), "expiry date" means the date, expressed at minimum as a year and month, that is the end of the stability period.

Définition de « date limite d'utilisation »

(2) Pour l'application du paragraphe (1) et du sous-alinéa 66*c*)(viii), « date limite d'utilisation » s'entend de la date, indiquée au moins par l'année et le mois, qui correspond à la fin de la période de stabilité.

Reference to Acts or regulations

72. It is prohibited to include a reference, direct or indirect, to the Act, the *Food and Drugs Act* or any regulations made under those Acts on a label of or in an advertisement for dried marihuana unless the reference is a specific requirement of either of those Acts or those regulations.

Mention d'une loi ou d'un règlement

72. Aucune mention, directe ou indirecte, de la Loi, de la *Loi sur les aliments et drogues* ou de leurs règlements ne peut figurer sur une étiquette ou une annonce de marihuana séchée, à moins que cette mention ne soit précisément requise par l'une de ces lois ou l'un de leurs règlements.

Shipping

73. (1) A licensed producer who ships dried marihuana to a person referred to in subsection 12(2) or (4) must

(*a*) ship the marihuana in only one shipment per order;

Expédition

73. (1) Le producteur autorisé qui expédie de la marihuana séchée à une personne visée aux paragraphes 12(2) ou (4) se conforme à ce qui suit :

a) il effectue une seule expédition de marihuana par commande;

(*b*) prepare the package in a manner that ensures the security of its contents, such that

(i) the package will not open or permit the escape of its contents during handling and transportation,

(ii) it is sealed so that it cannot be opened without the seal being broken,

(iii) it prevents the escape of marihuana odour, and

(iv) it prevents its contents from being identified without it being opened;

(*c*) use a shipping method that ensures the tracking and safekeeping of the package during transportation;

(*d*) ship it only to the following address:

(i) in the case of a client or an individual who is responsible for that client, the shipping address specified in the client's registration document referred to in paragraph 111(2)(*a*), and

(ii) in the case of any other person referred to in subsection 12(2) or (4), the shipping address indicated in the order referred to in section 131; and

(*e*) in the case of a client or an individual who is responsible for that client, ship the marihuana in a quantity that does not exceed 150 g.

b) il prépare son colis de façon à assurer la sécurité du contenu, conformément aux exigences suivantes :

(i) le colis ne peut s'ouvrir ou laisser son contenu s'échapper pendant la manutention ou le transport,

(ii) il est scellé de sorte qu'il soit impossible de l'ouvrir sans en briser le sceau,

(iii) son étanchéité est telle qu'aucune odeur de marihuana ne peut s'en échapper,

(iv) le contenu du colis ne peut être connu à moins d'ouvrir ce dernier;

c) il emploie un moyen d'expédition qui permet d'assurer le repérage et la sécurité du colis durant le transport;

d) il expédie le colis uniquement à l'adresse suivante :

(i) dans le cas d'un client ou d'une personne physique responsable de ce dernier, à l'adresse d'expédition indiquée sur le document d'inscription du client visé à l'alinéa 111(2)*a*),

(ii) dans le cas de toute autre personne visée aux paragraphes 12(2) ou (4), à l'adresse d'expédition indiquée sur la commande visée à l'article 131;

e) dans le cas d'un client ou d'une personne physique responsable de ce dernier, il expédie une quantité de marihuana qui n'excède pas 150 g.

Shipping — cannabis other than dried marihuana

(2) A licensed producer who ships cannabis other than dried marihuana to a person referred to in subsection 12(2) must

(*a*) use a shipping method referred to in paragraph (1)(*c*); and

(2) Le producteur autorisé qui expédie du chanvre indien autre que de la marihuana séchée à une personne visée au paragraphe 12(2) se conforme à ce qui suit :

Expédition — chanvre indien autre que de la marihuana séchée

a) il emploie le moyen d'expédition prévu à l'alinéa (1)*c*);

(*b*) ship it only to the shipping address indicated in the order referred to in section 131.

b) il l'expédie uniquement à l'adresse d'expédition indiquée sur la commande visée à l'article 131.

Division 6

Import and Export

Application for import permit

74. (1) To apply for a permit to import marihuana, a licensed producer must submit the following information to the Minister:

(*a*) their name, address and licence number;

(*b*) in respect of the marihuana to be imported,

(i) an indication of whether it is in the form of seeds, plants or dried marihuana,

(ii) its intended use,

(iii) if applicable, its brand name,

(iv) its quantity, and

(v) in the case of dried marihuana, its percentages of delta-9-tetrahydrocannabinol w/w and cannabidiol w/w;

(*c*) the name and address of the exporter in the country of export from whom the marihuana is being obtained;

(*d*) the port of entry into Canada;

(*e*) the address of the customs office, sufferance warehouse or bonded warehouse to which the marihuana is to be delivered; and

(*f*) each mode of transportation used, the country of export and, if applicable, any country of transit or transhipment.

Section 6

Importations et exportations

Demande de permis d'importation

74. (1) Le producteur autorisé qui entend obtenir un permis d'importation de marihuana présente au ministre une demande qui comporte les renseignements suivants :

a) ses nom, adresse et numéro de licence;

b) relativement à la marihuana à importer :

(i) une mention précisant si elle est sous forme de graines, de plantes ou de marihuana séchée,

(ii) son usage envisagé,

(iii) le cas échéant, sa marque nominative,

(iv) sa quantité,

(v) s'il s'agit de marihuana séchée, ses pourcentages de delta-9-tétrahydrocannabinol p/p et de cannabidiol p/p;

c) les nom et adresse de l'exportateur duquel il obtient la marihuana dans le pays d'exportation;

d) le point d'entrée au Canada;

e) l'adresse du bureau de douane, de l'entrepôt d'attente ou de l'entrepôt de stockage où la marihuana sera livrée;

f) les modes de transport utilisés, le pays d'exportation et, le cas échéant, tout pays de transit ou de transbordement.

Statement by signatory

(2) An application for an import permit must

(*a*) be signed and dated by the responsible person in charge or, if applicable, the alternate responsible person in charge at the licensed producer's site; and

(*b*) include a statement, signed and dated by that person, indicating that all information submitted in support of the application is correct and complete to the best of the signatory's knowledge.

Issuance of import permit

75. (1) Subject to section 76, the Minister must, after examining the information and documents required under section 74 and, if applicable, section 8, issue to the licensed producer an import permit that indicates:

(*a*) the permit number;

(*b*) the information referred to in paragraphs 74(1)(*a*) to (*f*);

(*c*) the effective date of the permit;

(*d*) its expiry date, which is the earlier of

(i) the 180th day after the effective date, and

(ii) December 31 of the year of the effective date; and

(*e*) if applicable, any conditions that the permit holder must meet in order to

(i) comply with an international obligation, or

(ii) reduce any potential public health, safety or security risk, including the risk of the marihuana being diverted to an illicit market or use.

Signature et attestation

(2) La demande de permis d'importation satisfait aux exigences suivantes :

a) elle est signée et datée par la personne responsable ou, le cas échéant, par la personne responsable suppléante à l'installation du producteur autorisé;

b) elle comprend une attestation signée et datée par la même personne portant qu'à sa connaissance tous les renseignements fournis à l'appui de la demande sont exacts et complets.

Délivrance du permis d'importation

75. (1) Sous réserve de l'article 76, après examen des renseignements et documents visés à l'article 74 et, le cas échéant, à l'article 8, le ministre délivre au producteur autorisé un permis d'importation qui contient ce qui suit :

a) le numéro du permis;

b) les renseignements visés aux alinéas 74(1)*a*) à *f*);

c) la date de prise d'effet du permis;

d) la date de son expiration, correspondant à celui des jours ci-après qui est antérieur à l'autre :

(i) le 180e jour suivant la date de prise d'effet,

(ii) le 31 décembre de l'année de la prise d'effet;

e) le cas échéant, les conditions que le titulaire doit respecter à l'une ou l'autre des fins suivantes :

(i) se conformer à une obligation internationale,

(ii) réduire le risque de porter atteinte à la sécurité ou à la santé publiques, notamment celui de voir la marihuana détournée vers un marché ou un usage illicites.

Duration of permit

(2) An import permit is valid until the earliest of

(*a*) its expiry date or the date on which it is suspended or revoked under section 80 or 81,

(*b*) the expiry date of the producer's licence to which the permit pertains or the date on which the that licence is suspended or revoked, and

(*c*) the expiry date of the export permit that applies to the marihuana to be imported and that is issued by a competent authority in the country of export or the date on which that permit is suspended or revoked.

Validity

(3) A permit issued under this section is valid only for the importation in respect of which it is issued.

Refusal to issue import permit

76. The Minister must refuse to issue an import permit if

(*a*) in respect of the application for the permit, there exists a circumstance described in paragraph 26(1)(*d*), (*e*), (*f*) or (*h*), with any modifications that the circumstances require;

(*b*) the applicant does not hold a producer's licence with respect to the marihuana that is to be imported;

(*c*) the applicant has been notified that one of the following applications submitted by the applicant in respect of the producer's licence to which the requested permit pertains is to be refused under section 26:

(i) an application under section 23 for a producer's licence,

(ii) an application under section 28 for the renewal of a producer's licence, or

Période de validité du permis

(2) Le permis d'importation est valide jusqu'à celle des dates ci-après qui est antérieure aux autres :

a) la date d'expiration du permis, ou celle de sa suspension ou de sa révocation au titre des articles 80 ou 81;

b) la date d'expiration, de suspension ou de révocation de la licence de producteur autorisé à laquelle le permis se rattache;

c) la date d'expiration, de suspension ou de révocation du permis d'exportation délivré par l'autorité compétente du pays d'exportation à l'égard de la marihuana à importer.

Application

(3) Le permis délivré en application du présent article ne s'applique qu'à l'importation pour laquelle il a été délivré.

Refus de délivrer le permis d'importation

76. Le ministre refuse de délivrer le permis d'importation dans les cas suivants :

a) une circonstance visée à l'un des alinéas 26(1)*d*), *e*), *f*) ou *h*) s'applique à la demande de permis, avec les adaptations nécessaires;

b) le demandeur ne détient pas de licence de producteur autorisé eu égard à la marihuana à importer;

c) le demandeur a été avisé que l'une des demandes ci-après qu'il a présentées à l'égard de la licence de producteur autorisé à laquelle le permis demandé se rattache sera refusée en application de l'article 26 :

(i) la demande de licence de producteur autorisé présentée aux termes de l'article 23,

(ii) la demande de renouvellement de la licence de producteur autorisé présentée aux termes de l'article 28,

(iii) an application under section 29 for the amendment of a producer's licence; or

(*d*) the Minister has reasonable grounds to believe that

(i) the shipment for which the permit is requested would contravene the laws of the country of export or any country of transit or transhipment, or

(ii) the importation is for the purpose of re-exporting the marihuana.

(iii) la demande de modification de la licence de producteur autorisé présentée aux termes de l'article 29;

d) le ministre a des motifs raisonnables de croire :

(i) soit que l'expédition visée par la demande de permis contreviendrait aux règles de droit du pays d'exportation ou de tout pays de transit ou de transbordement,

(ii) soit que l'importation de la marihuana est effectuée aux fins de réexportation.

Provision of copy of import permit

77. On request of a customs officer, the holder of an import permit must provide a copy of the permit to the customs office, sufferance warehouse or bonded warehouse, as the case may be, at the port of entry into Canada at the time of importation.

Production d'une copie du permis d'importation

77. Sur demande d'un agent de douane, le titulaire du permis d'importation en produit une copie, selon le cas, au bureau de douane, à l'entrepôt d'attente ou à l'entrepôt de stockage du point d'entrée au Canada, au moment de l'importation.

Declaration after release from customs

78. The holder of an import permit must provide the Minister, within 15 days after the day of release, in accordance with the *Customs Act*, of a shipment that contains marihuana, with a declaration that contains the following information:

(*a*) the name of the licensed producer and the numbers of the producer's licence and import permit in respect of the shipment;

(*b*) the date of release of the shipment; and

(*c*) in respect of the marihuana received,

(i) an indication of whether it is in the form of seeds, plants or dried marihuana,

(ii) its intended use,

(iii) if applicable, its brand name,

(iv) its quantity, and

Déclaration après le dédouanement

78. Le titulaire d'un permis d'importation remet au ministre, dans les quinze jours suivant le jour du dédouanement en vertu de la *Loi sur les douanes* d'une expédition contenant de la marihuana, une déclaration comportant les renseignements suivants :

a) son nom et les numéros de sa licence de producteur autorisé et du permis d'importation relatif à cette expédition;

b) la date de dédouanement de l'expédition;

c) relativement à la marihuana reçue :

(i) une mention précisant si elle est sous forme de graines, de plantes ou de marihuana séchée,

(ii) son usage envisagé,

(iii) le cas échéant, sa marque nominative,

(v) in the case of dried marihuana, its percentages of delta-9-tetrahydrocannabinol w/w and cannabidiol w/w.

(iv) sa quantité,

(v) s'il s'agit de marihuana séchée, ses pourcentages de delta-9-tétrahydrocannabinol p/p et de cannabidiol p/p.

Transportation of marihuana

79. The holder of an import permit must ensure that, after the imported marihuana clears customs, it is transported directly to the site specified in their producer's licence.

Transport de la marihuana

79. Le titulaire d'un permis d'importation veille à ce que la marihuana importée soit, après son dédouanement, directement transportée au site visé par sa licence de producteur autorisé.

Suspension of import permit

80. (1) The Minister must suspend an import permit without prior notice if

(*a*) the Minister has reasonable grounds to believe that it is necessary to do so to protect public health, safety or security, including preventing the marihuana from being diverted to an illicit market or use; or

(*b*) the importation would contravene the laws of any country of transit or transhipment.

Suspension du permis d'importation

80. (1) Le ministre suspend le permis d'importation sans préavis dans les cas suivants :

a) il a des motifs raisonnables de croire qu'il est nécessaire de le faire en vue de protéger la sécurité ou la santé publiques, y compris en vue de prévenir le détournement de la marihuana vers un marché ou un usage illicites;

b) l'importation contreviendrait aux règles de droit de tout pays de transit ou de transbordement.

Notice of suspension

(2) The suspension takes effect as soon as the Minister notifies the permit holder of the decision to suspend and provides a written report that sets out the reasons for the suspension.

Avis de suspension

(2) La décision du ministre prend effet aussitôt qu'il en avise le titulaire et lui fournit un exposé écrit des motifs de la suspension.

Opportunity to be heard

(3) The permit holder may, within 10 days after receipt of the notice, provide the Minister with reasons why the suspension is unfounded.

Possibilité de se faire entendre

(3) Le titulaire peut, dans les dix jours qui suivent la réception de l'avis, présenter au ministre les motifs pour lesquels la suspension de son permis n'est pas fondée.

Revocation of import permit

81. (1) The Minister must revoke an import permit

(*a*) at the request of the holder;

(*b*) if the holder informs the Minister that the permit has been lost or stolen; or

(*c*) if the permit is being replaced by a new permit.

Révocation du permis d'importation

81. (1) Le ministre révoque le permis d'importation dans les cas suivants :

a) le titulaire lui en fait la demande;

b) le titulaire l'informe de la perte ou du vol du permis;

c) celui-ci est remplacé par un nouveau permis.

Other revocation circumstances

(2) Subject to subsection (3), the Minister must revoke an import permit in the following circumstances:

(*a*) there exists a circumstance described in any of paragraphs 36(1)(*a*) to (*e*) in respect of the producer's licence pertaining to the permit;

(*b*) the Minister has reasonable grounds to believe that the import permit was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application for the permit; or

(*c*) the importation is for the purpose of re-exporting the marihuana.

Exceptions

(3) Unless it is necessary to do so to protect public health, safety or security, including preventing the marihuana from being diverted to an illicit market or use, the Minister must not revoke an import permit in the circumstances described in paragraph (2)(*b*) or 36(1)(*a*) or (*b*) if the permit holder has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and its regulations and the *Food and Drugs Act*.

Failure to comply with undertaking

(4) If the licensed producer fails to comply with an undertaking mentioned in subsection (3), the Minister must revoke the permit.

Revocation following suspension

(5) The Minister must revoke a permit if the licensed producer fails to comply with the decision of the Minister to suspend the permit under section 80 or if the situation giving rise to the suspension is not rectified.

Application for export permit

82. (1) To apply for a permit to export marihuana, a licensed producer must sub-

Autres causes de révocation

(2) Sous réserve du paragraphe (3), le ministre révoque le permis d'importation dans les circonstances suivantes :

a) une circonstance visée aux alinéas 36(1)*a*) à *e*) existe à l'égard de la licence de producteur autorisé à laquelle le permis se rattache;

b) le ministre a des motifs raisonnables de croire que le permis d'importation a été délivré sur la foi de renseignements faux ou trompeurs fournis dans la demande de permis ou de documents faux ou falsifiés fournis à l'appui de celle-ci;

c) l'importation de la marihuana est effectuée aux fins de réexportation.

Exceptions

(3) Sauf s'il est nécessaire de le faire en vue de protéger la sécurité ou la santé publiques, y compris en vue de prévenir le détournement de marihuana vers un marché ou un usage illicites, le ministre ne révoque pas le permis d'importation dans les circonstances visées aux alinéas (2)*b*) ou 36(1)*a*) ou *b*) si son titulaire a pris les mesures correctives indiquées pour assurer la conformité à la Loi, à ses règlements et à la *Loi sur les aliments et drogues*, ou a signé un engagement à cet effet.

Non-respect de l'engagement

(4) Dans le cas où le producteur autorisé ne respecte pas l'engagement mentionné au paragraphe (3), le ministre révoque son permis.

Révocation suivant une suspension

(5) Dans le cas où le producteur autorisé ne se conforme pas à la décision du ministre de suspendre son permis aux termes de l'article 80, ou ne corrige pas la situation ayant donné lieu à la suspension, le ministre révoque le permis.

Demande de permis d'exportation

82. (1) Le producteur autorisé qui entend obtenir un permis d'exportation de

mit the following information and statements to the Minister:

(*a*) their name, address and licence number;

(*b*) in respect of the marihuana to be exported,

(i) an indication of whether it is in the form of seeds, plants or dried marihuana,

(ii) its intended use,

(iii) if applicable, its brand name,

(iv) the quantity to be exported, and

(v) its percentages of delta-9-tetrahydrocannabinol w/w and cannabidiol w/w;

(*c*) the name and address of the importer in the country of final destination;

(*d*) the port of exit from Canada and, if applicable, any country of transit or transhipment;

(*e*) the address of the customs office, sufferance warehouse or bonded warehouse at which the shipment is to be presented for export;

(*f*) each mode of transportation used; and

(*g*) a statement that, to the best of their knowledge, the shipment does not contravene the laws of the country of final destination or any country of transit or transhipment.

marihuana présente au ministre une demande qui comporte les éléments suivants :

a) ses nom, adresse et numéro de licence;

b) relativement à la marihuana à exporter :

(i) une mention précisant si elle est sous forme de graines, de plantes ou de marihuana séchée,

(ii) son usage envisagé,

(iii) le cas échéant, sa marque nominative,

(iv) sa quantité,

(v) les pourcentages de delta-9-tétrahydrocannabinol p/p et de cannabidiol p/p;

c) les nom et adresse de l'importateur dans le pays de destination ultime;

d) le point de sortie du Canada et, le cas échéant, tout pays de transit ou de transbordement;

e) l'adresse du bureau de douane, de l'entrepôt d'attente ou de l'entrepôt de stockage où l'expédition sera acheminée pour exportation;

f) les modes de transport utilisés;

g) une déclaration portant qu'à la connaissance du demandeur, l'expédition ne contrevient à aucune règle de droit du pays de destination ultime ou de tout pays de transit ou de transbordement.

Accompanying document

(2) An application for an export permit must be accompanied by a copy of the import permit issued by a competent authority in the country of final destination that sets out the name and address of the site of the importer in the country of final destination.

Pièce jointe

(2) La demande de permis d'exportation est accompagnée d'une copie du permis d'importation délivré par l'autorité compétente du pays de destination ultime, qui précise le nom de l'importateur et l'adresse de son installation dans ce pays.

Statement by signatory

(3) An application for an export permit must

(*a*) be signed and dated by the responsible person in charge or, if applicable, the alternate responsible person in charge at the licensed producer's site; and

(*b*) include a statement, signed and dated by that person, indicating that all information submitted in support of the application is correct and complete to the best of the signatory's knowledge.

Issuance of export permit

83. (1) Subject to section 84, the Minister must, after examining the information and documents required under section 82 and, if applicable, section 8, issue an export permit to the licensed producer that indicates:

(*a*) the permit number;

(*b*) the information referred to in paragraphs 82(1)(*a*) to (*f*);

(*c*) the effective date of the permit;

(*d*) its expiry date, which is the earliest of

(i) the 120th day after the effective date,

(ii) December 31 of the year of the effective date, and

(iii) the expiry date of the import permit issued by a competent authority in the country of final destination; and

(*e*) if applicable, any conditions that the permit holder must meet in order to

(i) comply with an international obligation, or

(ii) reduce any potential public health, safety or security risk, including the risk of the marihuana being diverted to an illicit market or use.

Signature et attestation

(3) La demande de permis d'exportation satisfait aux exigences suivantes :

a) elle est signée et datée par la personne responsable ou, le cas échéant, la personne responsable suppléante à l'installation du producteur autorisé;

b) elle comprend une attestation signée et datée par la même personne portant qu'à sa connaissance, tous les renseignements fournis à l'appui de la demande sont exacts et complets.

Délivrance du permis d'exportation

83. (1) Sous réserve de l'article 84, après examen des renseignements et documents visés à l'article 82 et, le cas échéant, à l'article 8, le ministre délivre au producteur autorisé un permis d'exportation qui contient ce qui suit :

a) le numéro du permis;

b) les renseignements visés aux alinéas 82(1)*a*) à *f*);

c) la date de prise d'effet du permis;

d) la date de son expiration, correspondant à celui des jours ci-après qui est antérieur aux autres :

(i) le 120^{e} jour suivant la date de prise d'effet,

(ii) le 31 décembre de l'année de la prise d'effet,

(iii) la date d'expiration du permis d'importation délivré par l'autorité compétente du pays de destination ultime;

e) le cas échéant, les conditions que le titulaire doit respecter à l'une ou l'autre des fins suivantes :

(i) se conformer à une obligation internationale,

(ii) réduire le risque de porter atteinte à la sécurité ou à la santé publiques, notamment celui de voir la marihuana détournée vers un marché ou un usage illicites.

Duration of permit

(2) An export permit is valid until the earliest of

(*a*) its expiry date or the date on which it is suspended or revoked under section 87 or 88,

(*b*) the expiry date of the producer's licence to which the permit pertains or the date on which the that licence is suspended or revoked, and

(*c*) the expiry date of the import permit that applies to the marihuana to be exported and that is issued by a competent authority in the country of final destination or the date on which that permit is suspended or revoked.

Période de validité du permis

(2) Le permis d'exportation est valide jusqu'à celle des dates ci-après qui est antérieure aux autres :

a) la date d'expiration du permis, ou celle de sa suspension ou de sa révocation au titre des articles 87 ou 88;

b) la date d'expiration, de suspension ou de révocation de la licence de producteur autorisé à laquelle le permis se rattache;

c) la date d'expiration, de suspension ou de révocation du permis d'importation délivré par l'autorité compétente du pays de destination ultime à l'égard de la marihuana à exporter.

Validity

(3) A permit issued under this section is valid only for the exportation in respect of which it is issued.

Application

(3) Le permis délivré en application du présent article ne s'applique qu'à l'exportation pour laquelle il a été délivré.

Refusal to issue export permit

84. The Minister must refuse to issue an export permit if

(*a*) in respect of the application for the permit, there exists a circumstance described in paragraph 26(1)(*d*), (*e*) or (*h*), with any modifications that the circumstances require;

(*b*) the applicant does not hold a producer's licence in respect of the marihuana to be exported;

(*c*) the applicant has been notified that one of the following applications submitted by the applicant in respect of the producer's licence to which the requested permit pertains is to be refused under section 26:

Refus de délivrer le permis d'exportation

84. Le ministre refuse de délivrer le permis d'exportation dans les cas suivants :

a) une circonstance visée à l'un des alinéas 26(1)*d*), *e*) ou *h*) existe et s'applique à la demande de permis, avec les adaptations nécessaires;

b) le demandeur ne détient pas de licence de producteur autorisé eu égard à la marihuana à exporter;

c) le demandeur a été avisé que l'une des demandes ci-après qu'il a présentées à l'égard de la licence de producteur autorisé à laquelle le permis demandé se rattache sera refusée en application de l'article 26 :

(i) an application made under section 23 for a producer's licence,

(ii) an application made under section 28 for the renewal of a producer's licence, or

(iii) an application made under section 29 for the amendment of a producer's licence;

(*d*) the Minister has reasonable grounds to believe that the shipment for which the permit is requested would contravene the laws of the country of final destination or any country of transit or transhipment; or

(*e*) the shipment would not be in conformity with the import permit issued by a competent authority of the country of final destination.

(i) la demande de licence de producteur autorisé présentée aux termes de l'article 23,

(ii) la demande de renouvellement de la licence de producteur autorisé présentée aux termes de l'article 28,

(iii) la demande de modification de la licence de producteur autorisé présentée aux termes de l'article 29;

d) le ministre a des motifs raisonnables de croire que l'expédition visée par la demande de permis contreviendrait aux règles de droit du pays de destination ultime ou de tout pays de transit ou de transbordement;

e) l'expédition ne serait pas conforme au permis d'importation délivré par l'autorité compétente du pays de destination ultime.

Provision of copy of export permit

85. On request of a customs officer, the holder of an export permit must provide a copy of the permit to the customs office, sufferance warehouse or bonded warehouse, as the case may be, at the port of exit from Canada at the time of exportation.

Production d'une copie du permis d'exportation

85. Sur demande d'un agent de douane, le titulaire du permis d'exportation en produit une copie, selon le cas, au bureau de douane, à l'entrepôt d'attente ou à l'entrepôt de stockage du point de sortie du Canada, au moment de l'exportation.

Declaration after export

86. The holder of an export permit must provide the Minister, within 15 days after the day on which a shipment that contains marihuana is exported, with a declaration that contains the following information:

(*a*) the name of the licensed producer and the numbers of the producer's licence and export permit in respect of the shipment;

(*b*) the date of export;

(*c*) in respect of the exported marihuana,

Déclaration après l'exportation

86. Le titulaire du permis d'exportation remet au ministre, dans les quinze jours suivant le jour de l'exportation d'une expédition contenant de la marihuana, une déclaration comportant les renseignements suivants :

a) son nom et les numéros de sa licence de producteur autorisé et du permis d'exportation relatif à cette expédition;

b) la date d'exportation;

c) relativement à la marihuana exportée :

(i) an indication as to whether it is in the form of seeds, plants or dried marihuana,

(ii) its intended use,

(iii) if applicable, its brand name, and

(iv) its quantity.

(i) une mention précisant si elle est sous forme de graines, de plantes ou de marihuana séchée,

(ii) son usage envisagé,

(iii) le cas échéant, sa marque nominative,

(iv) sa quantité.

Suspension of export permit

87. (1) The Minister must suspend an export permit without prior notice if

(*a*) the Minister has reasonable grounds to believe that it is necessary to do so to protect public health, safety or security, including preventing the marihuana from being diverted to an illicit market or use;

(*b*) the exportation is not in conformity with an import permit issued by a competent authority of the country of final destination; or

(*c*) the exportation would contravene the laws of the country of final destination or any country of transit or transhipment.

Suspension du permis d'exportation

87. (1) Le ministre suspend le permis d'exportation sans préavis dans les cas suivants :

a) il a des motifs raisonnables de croire qu'il est nécessaire de le faire en vue de protéger la sécurité ou la santé publiques, y compris en vue de prévenir le détournement de la marihuana vers un marché ou un usage illicites;

b) l'exportation de la marihuana n'est pas conforme au permis d'importation délivré par l'autorité compétente du pays de destination ultime;

c) l'exportation contreviendrait aux règles de droit du pays de destination ultime ou de tout pays de transit ou de transbordement.

Notice of suspension

(2) The suspension takes effect as soon as the Minister notifies the permit holder of the decision to suspend and provides a written report that sets out the reasons for the suspension.

Avis de suspension

(2) La décision du ministre prend effet aussitôt qu'il en avise le titulaire et lui fournit un exposé écrit des motifs de la suspension.

Opportunity to be heard

(3) The permit holder may, within 10 days after receipt of the notice, provide the Minister with reasons why the suspension is unfounded.

Possibilité de se faire entendre

(3) Le titulaire peut, dans les dix jours qui suivent la réception de l'avis, présenter au ministre les motifs pour lesquels la suspension de son permis n'est pas fondée.

Revocation of export permit

88. (1) The Minister must revoke an export permit

(*a*) at the request of the holder;

(*b*) if the holder informs the Minister that the permit has been lost or stolen; or

Révocation du permis d'exportation

88. (1) Le ministre révoque le permis d'exportation dans les cas suivants :

a) le titulaire lui en fait la demande;

b) le titulaire l'informe de la perte ou du vol du permis;

(*c*) if the permit is being replaced by a new permit.

c) celui-ci est remplacé par un nouveau permis.

Other revocation circumstances

(2) Subject to subsection (3), the Minister must revoke an export permit in the following circumstances:

(2) Sous réserve du paragraphe (3), le ministre révoque le permis d'exportation dans les circonstances suivantes :

Autres causes de révocation

(*a*) there exists a circumstance described in any of paragraphs 36(1)(*a*) to (*e*) in respect of the producer's licence to which the permit pertains; or

a) une circonstance visée aux alinéas 36(1)*a*) à *e*) existe à l'égard de la licence de producteur autorisé à laquelle le permis se rattache;

(*b*) the Minister has reasonable grounds to believe that the export permit was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application.

b) le ministre a des motifs raisonnables de croire que le permis d'exportation a été délivré sur la foi de renseignements faux ou trompeurs fournis dans la demande de permis ou de documents faux ou falsifiés fournis à l'appui de celle-ci.

Exceptions

(3) Unless it is necessary to do so to protect public health, safety or security, including preventing the marihuana from being diverted to an illicit market or use, the Minister must not revoke an export permit in the circumstances described in paragraph (2)(*b*) or 36(1)(*a*) or (*b*) if the permit holder has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and its regulations and the *Food and Drugs Act*.

(3) Sauf s'il est nécessaire de le faire en vue de protéger la sécurité ou la santé publiques, y compris en vue de prévenir le détournement de marihuana vers un marché ou un usage illicites, le ministre ne révoque pas le permis d'exportation dans les circonstances visées aux alinéas (2)*b*) ou 36(1)*a*) ou *b*) si son titulaire a pris les mesures correctives indiquées pour assurer la conformité à la Loi, à ses règlements et à la *Loi sur les aliments et drogues*, ou a signé un engagement à cet effet.

Exceptions

Failure to comply with undertaking

(4) If the licensed producer fails to comply with an undertaking mentioned in subsection (3), the Minister must revoke the permit.

(4) Dans le cas où le producteur autorisé ne respecte pas l'engagement mentionné au paragraphe (3), le ministre révoque son permis.

Non-respect de l'engagement

Revocation following suspension

(5) The Minister must revoke a permit if the licensed producer fails to comply with the decision of the Minister to suspend the permit under section 87 or if the situation giving rise to the suspension is not rectified.

(5) Dans le cas où le producteur autorisé ne se conforme pas à la décision du ministre de suspendre son permis aux termes de l'article 87, ou ne corrige pas la situation ayant donné lieu à la suspension, le ministre révoque le permis.

Révocation suivant une suspension

DIVISION 7

SECURITY CLEARANCES

Eligibility

89. Only the following persons may submit to the Minister an application for a security clearance:

(*a*) a person named in an application for a producer's licence as

(i) the proposed senior person in charge,

(ii) the proposed responsible person in charge, or

(iii) if applicable, the proposed alternate responsible person in charge;

(*b*) if a producer's licence is sought by an individual, that individual;

(*c*) if a producer's licence is sought by a corporation, each officer and director of the corporation;

(*d*) a person referred to in any of subparagraphs 30(1)(*a*)(i) to (iii); and

(*e*) the holder of a security clearance who is seeking to obtain a new security clearance before the end of the validity period of their current clearance.

Application for security clearance

90. (1) An application for a security clearance must include the following information and documentation, to be used only for the purposes of sections 91 and 92:

(*a*) the applicant's usual given name used, other given names, surname, all other names used and details of any name changes;

(*b*) the applicant's date of birth, gender, height, weight, and eye and hair colour;

SECTION 7

HABILITATIONS DE SÉCURITÉ

Admissibilité

89. Seules les personnes ci-après peuvent présenter une demande d'habilitation de sécurité au ministre :

a) celles qui sont nommées dans la demande de licence de producteur autorisé, à savoir :

(i) le responsable principal proposé,

(ii) la personne responsable proposée,

(iii) le cas échéant, la personne responsable suppléante proposée;

b) si la licence de producteur autorisé est demandée par une personne physique, cette personne;

c) si elle est demandée par une personne morale, chacun des dirigeants et administrateurs de cette dernière;

d) les personnes visées aux sous-alinéas 30(1)*a*)(i) à (iii);

e) les titulaires d'une habilitation de sécurité qui cherchent à obtenir une nouvelle habilitation avant la fin de la période de validité de celle qu'ils détiennent.

Demande d'habilitation de sécurité

90. (1) La demande d'habilitation de sécurité comprend les renseignements et documents ci-après devant être utilisés exclusivement pour l'application des articles 91 et 92 :

a) le prénom usuel, les autres prénoms, le nom de famille, les autres noms utilisés et le détail de tout changement de nom du demandeur;

b) la date de naissance, le sexe, la taille, le poids et la couleur des cheveux et des yeux du demandeur;

(*c*) if the applicant was born in Canada, the number and province of issue of their birth certificate;

(*d*) if the applicant was born outside Canada, their place of birth, the port and date of entry into Canada, and, in the case of a naturalized Canadian or permanent resident, the number of the applicable certificate issued under the *Citizenship Act* or the *Immigration and Refugee Protection Act*;

(*e*) either of the following documents:

(i) a copy of a valid piece of photo identification of the applicant issued by the government of Canada or of a province, or

(ii) a copy of the applicant's passport that includes the passport number, country of issue, expiry date and the applicant's photograph;

(*f*) the addresses of all locations at which the applicant resided during the five years preceding the application;

(*g*) an identification of the applicant's activities during the five years preceding the application, including the names and addresses of the applicant's employers and any post-secondary educational institutions attended;

(*h*) the dates, destination and purpose of any travel of more than 90 days outside Canada, excluding travel for government business, during the five years preceding the application;

(*i*) the information referred to in subsection (2) respecting

(i) the applicant's spouse or common-law partner, and

c) si le demandeur est né au Canada, le numéro et la province de délivrance de son certificat de naissance;

d) si le demandeur est né à l'extérieur du Canada, le lieu de naissance, le point d'entrée et la date d'arrivée au Canada et, dans le cas d'un citoyen naturalisé canadien ou d'un résident permanent, le numéro du certificat applicable délivré aux termes de la *Loi sur la citoyenneté* ou de la *Loi sur l'immigration et la protection des réfugiés*;

e) l'un ou l'autre des documents suivants :

(i) une copie d'une pièce d'identité valide du demandeur qui comporte sa photo et qui est délivrée par le gouvernement du Canada ou celui d'une province,

(ii) une copie du passeport du demandeur sur laquelle figurent notamment le numéro du passeport, le pays de délivrance, la date d'expiration et la photo du demandeur;

f) les adresses des lieux où le demandeur a résidé au cours des cinq années précédant la date de la demande;

g) la mention des activités du demandeur durant les cinq années précédant la date de la demande, y compris le nom et l'adresse de ses employeurs et des établissements d'enseignement postsecondaire fréquentés par le demandeur;

h) les dates, la destination et le but de tout voyage de plus de quatre-vingt-dix jours à l'extérieur du Canada, à l'exclusion des voyages pour affaires gouvernementales, durant les cinq années précédant la date de la demande;

(ii) any former spouses or common-law partners with whom the relationship ended within the preceding five years;

(*j*) the applicant's fingerprints, taken by a Canadian police force or by a private company that is accredited by the Royal Canadian Mounted Police to submit fingerprints to it for the purpose of a criminal record check; and

(*k*) a statement signed and dated by the licensed producer or the applicant for a producer's licence certifying that the applicant for the security clearance requires or will require a security clearance and specifying the reasons for that requirement.

i) les renseignements visés au paragraphe (2) en ce qui concerne les personnes suivantes :

(i) l'époux ou le conjoint de fait du demandeur,

(ii) le cas échéant, ses ex-époux ou anciens conjoints de fait avec lesquels la relation a pris fin au cours des cinq dernières années;

j) les empreintes digitales du demandeur, prises soit par un corps policier canadien, soit par une société privée accréditée par la Gendarmerie royale du Canada pour lui transmettre de telles empreintes aux fins de vérification de l'existence d'un casier judiciaire;

k) une déclaration, signée et datée par le producteur autorisé ou par le demandeur de la licence de producteur autorisé, attestant que le demandeur de l'habilitation de sécurité est tenu ou sera tenu d'être titulaire d'une habilitation de sécurité et précisant les raisons à l'appui de cette exigence.

Spouse or common-law partner

(2) The information required in respect of any of the persons referred to in paragraph (1)(*i*) is

(*a*) in the case of the applicant's spouse or common-law partner, the following information:

(i) their gender, full given name, surname and, if applicable, maiden name,

(ii) their date and place of birth and, if applicable, date of death,

(iii) if born in Canada, the number and province of issue of their birth certificate,

(iv) if born outside Canada, their place of birth, their nationality and the

Époux ou conjoint de fait

(2) Les renseignements exigés à l'égard des personnes visées à l'alinéa (1)*i*) sont les suivants :

a) dans le cas de l'époux ou du conjoint de fait du demandeur :

(i) le sexe, les prénoms au complet, le nom de famille et, le cas échéant, le nom de jeune fille,

(ii) la date et le lieu de naissance et, le cas échéant, la date du décès,

(iii) si la personne est née au Canada, le numéro de son certificat de naissance et la province de délivrance,

(iv) si la personne est née à l'extérieur du Canada, le lieu de naissance,

port and date of entry into Canada, and

(v) their present address, if known; and

(*b*) in the case of former spouses and common-law partners with whom the relationship ended within the preceding five years, the information referred to in subparagraphs (*a*)(i), (ii) and (v).

la nationalité et le point d'entrée et la date d'arrivée au Canada,

(v) l'adresse actuelle, si elle est connue;

b) dans le cas des ex-époux et des conjoints de fait avec lesquels la relation a pris fin au cours des cinq dernières années, les renseignements visés aux sous-alinéas *a*)(i), (ii) et (v).

Signed by applicant

(3) The application for a security clearance must be signed and dated by the applicant.

(3) La demande d'habilitation de sécurité est signée et datée par le demandeur.

Signature du demandeur

Definition of "common-law partner"

(4) In this section, "common-law partner" means any person who is cohabiting with the applicant in a relationship of a conjugal nature and has done so for a period of at least one year.

(4) Dans le présent article, « conjoint de fait » s'entend de toute personne qui vit avec le demandeur dans une union de type conjugal depuis au moins un an.

Définition de « conjoint de fait »

Checks

91. On receipt of a fully completed application for a security clearance, the Minister must conduct the following checks for the purpose of assessing whether an applicant poses a risk to the integrity of the control of the production and distribution of cannabis under the Act and its regulations, including the risk of cannabis being diverted to an illicit market or use:

(*a*) a criminal record check in respect of the applicant; and

(*b*) a check of the relevant files of law enforcement agencies, including intelligence gathered for law enforcement purposes.

91. Sur réception d'une demande d'habilitation de sécurité dûment remplie, le ministre effectue les vérifications ci-après afin de déterminer si le demandeur pose un risque pour l'intégrité du contrôle de la production et de la distribution du chanvre indien dans le cadre de la Loi et de ses règlements, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites :

a) une vérification du casier judiciaire du demandeur;

b) une vérification des dossiers pertinents des organismes chargés d'assurer le respect des lois, y compris la vérification des renseignements recueillis pour assurer le respect des lois.

Vérifications

Minister's decisions

92. The Minister may grant a security clearance if, in the opinion of the Minister, the information provided by the applicant and that resulting from the checks is reliable and is sufficient for the Minister to determine, by taking into account the follow-

92. Le ministre peut accorder l'habilitation de sécurité si, à son avis, les renseignements fournis par le demandeur et ceux obtenus par les vérifications sont fiables et s'ils sont suffisants pour lui permettre d'établir, par une évaluation des facteurs

Décision du ministre

ing factors, that the applicant does not pose an unacceptable risk to the integrity of the control of the production and distribution of cannabis under the Act and its regulations, including the risk of cannabis being diverted to an illicit market or use:

(*a*) whether the applicant has been found guilty as an adult, in the past 10 years, of

(i) a designated drug offence as defined in section 2 of the *Narcotic Control Regulations*,

(ii) a designated criminal offence as defined in that section, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(*b*) whether it is known or there are reasonable grounds to suspect that the applicant

(i) is or has been involved in, or contributes or has contributed to, illicit activities directed toward or in support of the trafficking or diversion of controlled substances or precursors,

(ii) is or has been a member of a criminal organization as defined in subsection 467.1(1) of the *Criminal Code*, or participates or has participated in, or contributes or has contributed to, the activities of such an organization as referred to in subsection 467.11(1) of the *Criminal Code*,

(iii) is or has been a member of an organization that is known to be involved in or to contribute to — or in respect of which there are reasonable grounds to suspect involvement in or

ci-après, que le demandeur ne pose pas un risque inacceptable pour l'intégrité du contrôle de la production et de la distribution du chanvre indien dans le cadre de la Loi et de ses règlements, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites :

a) au cours des dix dernières années, le demandeur a été reconnu coupable en tant qu'adulte :

(i) d'une infraction désignée en matière de drogue, au sens de l'article 2 du *Règlement sur les stupéfiants*,

(ii) d'une infraction désignée en matière criminelle, au sens de cet article,

(iii) d'une infraction commise à l'étranger qui, si elle avait été commise au Canada, aurait constitué une infraction visée aux sous-alinéas (i) ou (ii);

b) il est connu — ou il y a des motifs raisonnables de soupçonner — que le demandeur, selon le cas :

(i) participe ou contribue, ou a participé ou a contribué, à des activités illicites visant ou tendant à favoriser le trafic ou le détournement d'une substance désignée ou d'un précurseur,

(ii) est ou a été membre d'une organisation criminelle au sens du paragraphe 467.1(1) du *Code criminel* ou participe ou contribue, ou a participé ou a contribué, aux activités d'une telle organisation tel qu'il est mentionné au paragraphe 467.11(1) du *Code criminel*,

(iii) est ou a été un membre d'une organisation connue pour sa participation ou sa contribution — ou à l'égard de laquelle il y a des motifs raison-

contribution to — activities directed toward or in support of the threat of or the use of acts of violence against persons or property, or is or has been involved in, or is contributing to or has contributed to, the activities of such an organization, or

(iv) is or has been associated with an individual who is known to be involved in or to contribute to — or in respect of whom there are reasonable grounds to suspect involvement in or contribution to — activities referred to in subparagraph (i), or is a member of an organization referred to in subparagraph (ii) or (iii);

(*c*) whether there are reasonable grounds to suspect that the applicant is in a position in which there is a risk that they be induced to commit an act or to aid or abet any person to commit an act that might constitute a risk to the integrity of the control of the production and distribution of cannabis under the Act and its regulations, including the risk of cannabis being diverted to an illicit market or use;

(*d*) whether the applicant has had a security clearance cancelled; and

(*e*) whether the applicant has submitted false or misleading information or false or falsified documents in or with their application for a security clearance.

nables de soupçonner sa participation ou sa contribution — à des activités qui visent ou favorisent la menace ou l'exécution d'actes de violence contre des personnes ou des biens, ou participe ou contribue, ou a participé ou a contribué, aux activités d'une telle organisation,

(iv) est ou a été associé à une personne physique qui est connue pour sa participation ou sa contribution — ou à l'égard duquel il y a des motifs raisonnables de soupçonner sa participation ou sa contribution — à des activités visées au sous-alinéa (i), ou est membre d'une organisation visée à l'un des sous-alinéas (ii) ou (iii);

c) il y a des motifs raisonnables de soupçonner que le demandeur est dans une situation où il risque d'être incité à commettre un acte, ou à aider ou à encourager toute personne à commettre un acte, qui pourrait poser un risque pour l'intégrité du contrôle de la production et de la distribution du chanvre indien dans le cadre de la Loi et de ses règlements, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites;

d) le demandeur a déjà été titulaire d'une habilitation de sécurité qui a été annulée;

e) le demandeur a fourni des renseignements faux ou trompeurs dans sa demande d'habilitation de sécurité ou des documents faux ou falsifiés à l'appui de celle-ci.

Outstanding criminal charge

93. If there is an outstanding criminal charge against the applicant that could, if the applicant were found guilty, be taken into account by the Minister under para-

Accusations criminelles en instance

93. Si des accusations criminelles — qui pourraient être évaluées par le ministre en vertu de l'alinéa 92*a*) si le demandeur en était reconnu coupable — ont été por-

graph 92(*a*), the Minister may decline to process the application until the charge has been disposed of by the courts, in which case the Minister must notify the applicant in writing.

tées contre le demandeur, le ministre peut refuser de traiter la demande jusqu'à ce que les tribunaux aient tranché, auquel cas il en avise par écrit le demandeur.

Refusal to grant security clearance

94. (1) If the Minister intends to refuse to grant a security clearance, the Minister must notify the applicant in writing to that effect.

Refus d'accorder l'habilitation de sécurité

94. (1) Le ministre avise par écrit le demandeur de son intention de refuser d'accorder l'habilitation de sécurité.

Content of notice

(2) The notice must set out the basis for the Minister's intention and fix a period of time within which the applicant may make written representations to the Minister, which period of time must start on the day on which the notice is served or sent and must be not less than 20 days.

Contenu de l'avis

(2) L'avis indique les motifs de son intention et le délai dans lequel le demandeur peut présenter ses observations par écrit au ministre, ce délai commençant le jour où l'avis est signifié ou envoyé et ne pouvant être inférieur à vingt jours.

Opportunity to make written representations

(3) The Minister must not refuse to grant a security clearance until the written representations have been received and considered or before the period of time fixed in the notice has expired, whichever comes first. The Minister must notify the applicant in writing of any refusal.

Possibilité de faire des observations écrites

(3) Le ministre ne peut refuser d'accorder l'habilitation de sécurité avant la réception et la prise en considération des observations écrites ou avant que ne soit écoulé le délai indiqué dans l'avis, selon la première de ces éventualités à survenir. Le ministre avise par écrit le demandeur dans le cas d'un refus.

Validity period

95. (1) The Minister must establish a period of validity for a security clearance in accordance with the level of risk posed by the applicant as determined under section 92, but the period must not exceed five years.

Période de validité

95. (1) Le ministre établit la période de validité d'une habilitation de sécurité, laquelle ne peut dépasser cinq ans, en fonction du niveau de risque que pose le demandeur, établi en application de l'article 92.

Extension of period

(2) If the validity period is less than five years, the Minister may extend the period to a total of five years if the Minister determines under section 92 that the holder does not pose an unacceptable risk to the integrity of the control of the production and distribution of cannabis under the Act and its regulations, including the risk of cannabis being diverted to an illicit market or use.

Prolongation de la période

(2) Dans le cas où il l'a établie à moins de cinq ans, il peut la prolonger jusqu'à un maximum de cinq ans s'il établit, en application de l'article 92, que le titulaire ne pose pas de risque inacceptable pour l'intégrité du contrôle de la production et de la distribution du chanvre indien dans le cadre de la Loi et de ses règlements, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites.

Security clearance no longer required

96. A licensed producer must notify the Minister in writing not later than five days after the holder of a security clearance is no longer required by these Regulations to hold a security clearance. The Minister must then cancel the clearance.

Cas où l'habilitation de sécurité n'est plus requise

96. Lorsque le titulaire d'une habilitation de sécurité n'est plus tenu par le présent règlement d'avoir une telle habilitation, le producteur autorisé en avise le ministre par écrit dans les cinq jours qui suivent. Le ministre annule alors cette dernière.

Suspension of security clearance

97. (1) The Minister may suspend a security clearance on receipt of information that could change the Minister's determination made under section 92.

Suspension d'une habilitation de sécurité

97. (1) Le ministre peut suspendre une habilitation de sécurité lorsqu'il reçoit des renseignements qui pourraient modifier sa décision prise en application de l'article 92.

Written notice to holder

(2) Immediately after suspending a security clearance, the Minister must notify the holder in writing of the suspension.

Avis écrit au titulaire

(2) Immédiatement après avoir suspendu l'habilitation de sécurité, il en avise le titulaire par écrit.

Content of notice

(3) The notice must set out the basis for the suspension and must fix a period of time within which the holder may make written representations to the Minister, which period of time must start on the day on which the notice is served or sent and must be not less than 20 days.

Contenu de l'avis

(3) L'avis indique les motifs de la suspension et le délai dans lequel le titulaire peut présenter ses observations par écrit au ministre, ce délai commençant le jour où l'avis est signifié ou envoyé et ne pouvant être inférieur à vingt jours.

Reinstatement of clearance

(4) The Minister may reinstate the security clearance if the Minister determines under section 92 that the holder does not pose an unacceptable risk to the integrity of the control of the production and distribution of cannabis under the Act and its regulations, including the risk of cannabis being diverted to an illicit market or use.

Rétablissement de l'habilitation

(4) Le ministre peut rétablir l'habilitation de sécurité s'il établit, en application de l'article 92, que le titulaire de l'habilitation ne pose pas de risque inacceptable pour l'intégrité du contrôle de la production et de la distribution du chanvre indien dans le cadre de la Loi et de ses règlements, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites.

Cancellation of clearance

(5) The Minister may cancel the security clearance if the Minister determines under section 92 that the holder may pose an unacceptable risk to the integrity of the control of the production and distribution of cannabis under the Act and its regulations, including the risk of cannabis being diverted to an illicit market or use. The

Annulation de l'habilitation

(5) Il peut annuler l'habilitation de sécurité s'il établit, en application de l'article 92, que le titulaire de l'habilitation peut poser un risque inacceptable pour l'intégrité du contrôle de la production et de la distribution du chanvre indien dans le cadre de la Loi et de ses règlements, notamment celui de voir le chanvre indien détourné vers un marché ou un usage illicites.

Minister must notify the holder in writing of any cancellation.

Le cas échéant, il avise le titulaire par écrit de l'annulation.

Opportunity to be heard

(6) The Minister must not cancel the security clearance until the written representations referred to in subsection (3) have been received and considered or before the time period fixed in the notice referred to in that subsection has expired, whichever comes first.

(6) Il ne peut l'annuler avant la réception et la prise en considération des observations écrites visées au paragraphe (3) ou avant la fin du délai indiqué dans l'avis visé à ce paragraphe, selon le premier de ces événements à survenir.

Possibilité de se faire entendre

New applications

98. If the Minister refuses to grant or cancels a security clearance, an applicant may submit a new application only if

(*a*) a period of five years has elapsed after the day on which the refusal or cancellation occurs; or

(*b*) a change has occurred in the circumstances that led to the refusal or cancellation.

98. Si le ministre lui refuse ou annule une habilitation de sécurité, le demandeur ne peut présenter une nouvelle demande que dans les cas suivants :

a) une période de cinq ans s'est écoulée après le jour du refus ou de l'annulation;

b) un changement est survenu dans les circonstances qui avaient entraîné le refus ou l'annulation.

Nouvelle demande

Sending of notices by Minister

99. The Minister must send any notice to be given under this Division to the person at their last known address by using a method of sending that involves

(*a*) a means of tracking it during transit;

(*b*) the safekeeping of it during transit; and

(*c*) the keeping of an accurate record of the signatures of any persons having charge of it until it is delivered.

99. Le ministre envoie tout avis qu'il doit donner en application de la présente section à la dernière adresse connue de la personne, par tout moyen d'expédition qui permet d'assurer :

a) le repérage de l'avis durant le transport;

b) la sécurité de l'avis durant le transport;

c) la tenue d'un registre exact des signatures de toutes les personnes responsables de l'avis jusqu'à sa livraison.

Envoi d'un avis par le ministre

False or misleading information

100. It is prohibited to knowingly submit to the Minister an application containing false or misleading information in order to obtain a security clearance.

100. Il est interdit de présenter sciemment au ministre une demande comportant des renseignements faux ou trompeurs en vue d'obtenir une habilitation de sécurité.

Renseignements faux ou trompeurs

Division 8

Communication of Information

Information concerning clients and responsible individuals

101. (1) Subject to subsections (2) and (3), if a licensed producer is provided with the given name, surname, date of birth and gender of an individual by a member of a Canadian police force who requests information in the course of an investigation under the Act or these Regulations, the producer must provide as soon as feasible, within 72 hours after receiving the request, the following information to that Canadian police force:

(*a*) an indication of whether or not the individual is

(i) a client of the producer, or

(ii) an individual who is responsible for a client of the producer; and

(*b*) the daily quantity of dried marihuana that is specified in the medical document supporting the client's registration.

Verification

(2) Before providing the requested information, the licensed producer must verify in a reasonable manner that the person requesting the information is a member of a Canadian police force.

Use of information

(3) Information provided under this section must be used only for the purposes of the investigation referred to in subsection (1) and for the proper administration or enforcement of the Act or these Regulations.

Information concerning health care practitioners

102. A licensed producer must provide in writing, as soon as feasible, any factual information that has been obtained about a health care practitioner under the Act or these Regulations to the licensing authority

Section 8

Communication des renseignements

Renseignements concernant un client ou une personne physique responsable

101. (1) Sous réserve des paragraphes (2) et (3), lorsqu'un membre d'un corps policier canadien communique au producteur autorisé les nom, prénom, date de naissance et sexe d'une personne à propos de laquelle il entend obtenir des renseignements dans le cadre d'une enquête tenue en application de la Loi ou du présent règlement, le producteur autorisé communique aussitôt que possible dans les soixante-douze heures qui suivent la réception de la demande les renseignements ci-après à ce corps policier canadien :

a) une indication précisant si la personne en cause est ou n'est pas :

(i) l'un de ses clients,

(ii) responsable d'un de ses clients;

b) la quantité quotidienne de marihuana séchée indiquée dans le document médical fourni à l'appui de l'inscription.

Vérifications

(2) Avant de communiquer les renseignements demandés, le producteur autorisé vérifie de façon raisonnable que la demande provient bien d'un membre d'un corps policier canadien.

Utilisation des renseignements

(3) L'utilisation des renseignements communiqués en application du présent article est limitée à l'enquête visée au paragraphe (1) et à l'application ou à l'exécution de la Loi ou du présent règlement.

Renseignements concernant un praticien de la santé

102. Le producteur autorisé communique par écrit, aussitôt que possible, tout renseignement factuel obtenu en vertu de la Loi ou du présent règlement au sujet d'un praticien de la santé, à l'autorité attributive

responsible for the registration or authorization of the practise of the profession

(*a*) in the province in which the health care practitioner is authorized to practise if the authority submits to the licensed producer a written request that sets out the practitioner's name and address, a description of the information being sought and a statement that the information is required for the purpose of assisting an official investigation by the authority; or

(*b*) in a province in which the health care practitioner is not authorized to practise, if the authority submits to the licensed producer

(i) a written request for information that sets out the name and address of the practitioner and a description of the information being sought, and

(ii) either

(A) documentation that shows that the practitioner has applied to that authority to practise in that province, or

(B) documentation that shows that the authority has reasonable grounds to believe that the practitioner is practising in that province without being authorized to do so.

de licences ou chargée d'autoriser l'exercice de la profession :

a) dans la province où le praticien de la santé en cause est autorisé à exercer, s'il reçoit de l'autorité une demande écrite mentionnant les nom et adresse du praticien de la santé et la nature des renseignements demandés et précisant que les renseignements visent à aider l'autorité à mener une enquête officielle;

b) dans une province où le praticien de la santé en cause n'est pas autorisé à exercer, s'il reçoit de l'autorité les documents suivants :

(i) une demande écrite précisant les nom et adresse du praticien de la santé, ainsi que la nature des renseignements demandés,

(ii) des documents démontrant :

(A) soit que le praticien de la santé lui a présenté une demande d'exercer dans cette province,

(B) soit qu'elle a des motifs raisonnables de croire que le praticien de la santé exerce dans la province sans autorisation.

Information concerning licensed producers

103. The Minister is authorized to provide any information set out in a notice referred to in section 38, 39 or 40 to a Canadian police force or a member of a Canadian police force who requests the information in the course of an investigation under the Act or these Regulations, subject to that information being used only for the purpose of that investigation and the proper

Renseignements concernant un producteur autorisé

103. Le ministre est autorisé à communiquer tout renseignement mentionné dans l'avis visé à l'un des articles 38, 39 ou 40 à tout corps policier canadien ou à tout membre d'un tel corps policier qui en fait la demande dans le cadre d'une enquête tenue en application de la Loi ou du présent règlement, sous réserve que son utilisation soit limitée à l'enquête en cause et à l'ap-

administration or enforcement of the Act or these Regulations.

Information concerning import or export permit

104. The Minister is authorized, for the purpose of verifying whether an importation or exportation of marihuana complies with these Regulations, to provide to a customs officer in Canada any information referred to in sections 74, 75, 78, 82, 83 and 86 and to inform them whether a permit has been suspended or revoked.

Providing information to foreign organizations

105. The Minister is authorized, for the proper administration or enforcement of the Act or these Regulations and for the purpose of enabling Canada to fulfill its international obligations under section 12 of the United Nations' Single Convention on Narcotic Drugs, 1961, to provide the following information or documents to the International Narcotics Control Board or a competent authority:

(*a*) any information or document that a licensed producer is required to provide to the Minister under Part 1;

(*b*) any information pertaining to an activity authorized by a licence or permit issued to a licensed producer under these Regulations, including the licensed producer's name, the nature of the authorized activity and any conditions specified in the licence or permit;

(*c*) in respect of cannabis that a licensed producer receives from another licensed producer or a licensed dealer, the following information:

(i) in the case of dried marihuana, its quantity and the date on which it was received, or

(ii) in the case of cannabis other than dried marihuana, the name of the sub-

plication ou à l'exécution de la Loi ou du présent règlement.

Renseignements concernant un permis d'importation ou d'exportation

104. Le ministre est autorisé, pour vérifier si l'importation ou l'exportation de marihuana est conforme au présent règlement, à communiquer aux agents des douanes au Canada les renseignements visés aux articles 74, 75, 78, 82, 83 et 86 et à les aviser qu'un permis a été suspendu — ou révoqué — ou non.

Renseignements communiqués à un organisme étranger

105. Le ministre est autorisé, pour l'application ou l'exécution de la Loi ou du présent règlement et en vue de permettre au Canada de remplir ses obligations internationales aux termes de l'article 12 de la Convention unique sur les stupéfiants de 1961 des Nations Unies, à communiquer à l'Organe international de contrôle des stupéfiants et à toute autorité compétente :

a) tout renseignement ou document qu'un producteur autorisé est tenu de fournir au ministre aux termes de la partie 1;

b) tout renseignement portant sur les opérations autorisées au titre d'une licence ou d'un permis délivré au producteur autorisé en vertu du présent règlement, notamment le nom du producteur autorisé, la nature des opérations et les conditions dont sont assortis la licence ou le permis, le cas échéant;

c) à propos du chanvre indien que le producteur autorisé reçoit d'un autre producteur autorisé ou d'un distributeur autorisé, les renseignements suivants :

(i) s'il s'agit de marihuana séchée, sa quantité et sa date de réception,

(ii) s'il s'agit de chanvre indien autre que de la marihuana séchée, le nom de

stance in question, its quantity and the date on which it was received;

(*d*) in respect of an order that a licensed producer fills under section 121, the quantity of dried marihuana and the date on which it was shipped;

(*e*) in respect of an order that a licensed producer fills under subsection 131(1) or (2), the following information:

(i) in the case of dried marihuana, its quantity and the date on which it was shipped, or

(ii) in the case of cannabis other than dried marihuana, the name of the substance in question, its quantity and the date on which it was shipped;

(*f*) any record that a licensed producer is required to keep under subsection 143(2) or section 144 or 146; and

(*g*) a copy of any permit issued under section 75 or 83.

la substance en cause, sa quantité et sa date de réception;

d) à propos d'une commande qu'exécute le producteur autorisé conformément à l'article 121, la quantité de marihuana séchée expédiée et sa date d'expédition;

e) à propos d'une commande qu'exécute le producteur autorisé conformément aux paragraphes 131(1) ou (2), les renseignements suivants :

(i) s'il s'agit de marihuana séchée, la quantité expédiée et la date d'expédition,

(ii) s'il s'agit de chanvre indien autre que de la marihuana séchée, le nom de la substance en cause, la quantité expédiée et la date d'expédition;

f) les renseignements dont le producteur autorisé tient registre conformément au paragraphe 143(2) ainsi que les renseignements que consigne ce dernier conformément aux articles 144 et 146;

g) une copie de tout permis délivré en application des articles 75 et 83.

Security clearance — Minister

106. The Minister is authorized to communicate to a law enforcement agency information concerning an application for a security clearance for the purpose of conducting the checks and verifications referred to in section 91, subject to that information being used by that agency only for that purpose.

Habilitation de sécurité — ministre

106. Afin d'effectuer les vérifications visées à l'article 91, le ministre est autorisé à communiquer les renseignements concernant une demande d'habilitation de sécurité à tout organisme chargé d'assurer le respect des lois, sous réserve que leur utilisation par l'organisme soit limitée à cette fin.

PART 2

CLIENT REGISTRATION AND ORDERING

Registration

Eligibility

107. An individual is eligible to be a client of a licensed producer only if they ordinarily reside in Canada.

Registration application

108. (1) Before registering an individual as a client, a licensed producer must obtain from the individual or an individual who is responsible for the individual an application that contains the following information:

(*a*) the applicant's given name, surname, date of birth and gender;

(*b*) either,

(i) the address of the place in Canada where the applicant ordinarily resides, as well as, if applicable, the applicant's telephone number, facsimile number and email address, or

(ii) if the applicant ordinarily resides in Canada but has no dwelling place, the address, as well as, if applicable, the telephone number, facsimile number and email address of a shelter, hostel or similar institution, located in Canada, that provides food, lodging or other social services to the applicant;

(*c*) the mailing address of the place referred to in paragraph (*b*), if different from the address provided under that paragraph;

(*d*) if applicable, the given name, surname, date of birth and gender of one or more individuals who are responsible for the applicant ;

PARTIE 2

INSCRIPTION DU CLIENT ET COMMANDE

Inscription

Admissibilité

107. Seule la personne physique qui réside habituellement au Canada peut devenir le client d'un producteur autorisé.

Demande d'inscription

108. (1) Avant d'inscrire une personne physique comme client, le producteur autorisé obtient de celle-ci ou d'une personne physique responsable d'elle une demande comportant les renseignements suivants :

a) ses nom, prénom, date de naissance et sexe;

b) ses coordonnées, à savoir :

(i) soit l'adresse de son lieu de résidence habituelle au Canada et, le cas échéant, son numéro de téléphone, son numéro de télécopieur et son adresse électronique,

(ii) soit, dans le cas où elle est sans abri et réside habituellement au Canada, l'adresse et, le cas échéant, le numéro de téléphone, le numéro de télécopieur et l'adresse électronique d'un refuge, centre d'accueil ou autre établissement de même nature situé au Canada, qui lui offre le gîte, le couvert ou d'autres services sociaux;

c) l'adresse postale du lieu visé à l'alinéa *b*), si cette adresse diffère de celle fournie aux termes de cet alinéa;

d) le cas échéant, les nom, prénom, date de naissance et sexe d'une ou plusieurs personnes physiques responsables d'elle;

e) lorsque le lieu visé au sous-alinéa *b*)(i) n'est pas une habitation privée, le

(*e*) if the place referred to in subparagraph (*b*)(i) is an establishment that is not a private residence, the type and name of the establishment; and

(*f*) an indication as to which of the following is to be their shipping address:

(i) the address referred to in subparagraph (*b*)(i),

(ii) the mailing address of the place referred to in subparagraph (*b*)(i), or

(iii) subject to section 109, the address of the health care practitioner who provided the medical document referred to in subsection (2).

type d'établissement dont il s'agit et son nom;

f) une mention indiquant laquelle des adresses ci-après servira d'adresse d'expédition :

(i) l'adresse visée au sous-alinéa *b*)(i),

(ii) l'adresse postale du lieu visé au sous-alinéa *b*)(i),

(iii) sous réserve de l'article 109, l'adresse du praticien de la santé qui a fourni le document médical visé au paragraphe (2).

Medical document

(2) The applicant must include with the application the original of their medical document.

(2) Le demandeur joint à sa demande l'original de son document médical.

Document médical

Statement by applicant or responsible individual

(3) The application must be signed and dated by the applicant or an individual who is responsible for the applicant and include a statement that

(*a*) the applicant is ordinarily resident in Canada;

(*b*) the information in the application and the medical document is correct and complete;

(*c*) the medical document is not being used to seek or obtain dried marihuana from another source;

(*d*) the original of the medical document accompanies the application; and

(*e*) the applicant will use dried marihuana only for their own medical purposes.

(3) La demande est datée et signée par le demandeur ou par une personne physique responsable de ce dernier et comprend une attestation portant :

a) que le demandeur réside habituellement au Canada;

b) que les renseignements inclus dans la demande et le document médical sont exacts et complets;

c) que le document médical ne sert pas à obtenir ou à chercher à obtenir de la marihuana séchée d'une autre source;

d) que l'original du document médical est joint à la demande;

e) que le demandeur utilisera la marihuana séchée uniquement à ses propres fins médicales.

Attestation du demandeur ou d'une personne physique responsable

Statement by responsible individual

(4) If the application is signed and dated by an individual who is responsible for the applicant, it must include a statement by

(4) Si la demande est signée et datée par une personne physique qui est responsable du demandeur, cette dernière inclut une at-

Attestation de la personne physique responsable

that individual that they are responsible for the applicant.

Homeless applicant

(5) If an application includes the information referred to in subparagraph (1)(*b*)(ii), the applicant must include with the application an attestation of residence signed and dated by a manager of the specified shelter, hostel or similar institution confirming that the institution provides food, lodging or other social services to the applicant.

Health care practitioner's consent to receive dried marihuana

109. (1) If the shipping address specified in a registration application is the one referred to in subparagraph 108(1)(*f*)(iii), the applicant must include with the application a statement signed and dated by the health care practitioner who provided the medical document to the applicant indicating that the practitioner consents to receive dried marihuana on behalf of the applicant.

Withdrawal of consent

(2) If the applicant becomes a client of a licensed producer in accordance with section 111 and the health care practitioner ceases to consent to receive dried marihuana on behalf of the client, the practitioner must send a written notice to that effect to the client and the licensed producer.

No further shipments

(3) A licensed producer who receives such a notice must not send any further shipments of dried marihuana to that health care practitioner for that client.

Amendment to registration

(4) A client who receives such a notice and wishes to specify a new shipping address must submit to the licensed producer a registration amendment application in accordance with section 115.

Verification of medical document

110. A licensed producer who receives an application under section 108 and intends to register the applicant must ensure that

testation portant qu'elle est responsable du demandeur.

Demandeur sans abri

(5) Le demandeur qui donne les renseignements visés au sous-alinéa (1)*b*)(ii) dans sa demande joint à cette dernière une attestation de résidence, signée et datée par un gestionnaire du refuge, centre d'accueil ou autre établissement de même nature mentionné dans la demande, qui confirme que cette institution lui offre le gîte, le couvert ou d'autres services sociaux.

Consentement du praticien de la santé à recevoir de la marihuana séchée

109. (1) Si l'adresse d'expédition mentionnée dans la demande d'inscription est celle visée au sous-alinéa 108(1)*f*)(iii), le demandeur joint à sa demande une attestation, signée et datée par le praticien de la santé qui lui a fourni le document médical, portant que ce dernier consent à recevoir de la marihuana séchée au nom du demandeur.

Retrait du consentement

(2) Si le demandeur devient le client d'un producteur autorisé conformément à l'article 111 et que le praticien de la santé retire son consentement à recevoir de la marihuana au nom du client, le praticien de la santé envoie un avis écrit à cet effet à la fois au client et au producteur autorisé.

Cessation des expéditions

(3) Le producteur autorisé qui reçoit un tel avis ne peut expédier d'autre marihuana séchée au praticien de la santé pour ce client.

Modification de l'inscription

(4) Le client qui reçoit un tel avis et qui entend indiquer une nouvelle adresse d'expédition présente au producteur autorisé une demande de modification de son inscription conformément à l'article 115.

Vérification du document médical

110. Le producteur autorisé qui reçoit la demande visée à l'article 108 et qui entend inscrire le demandeur s'assure de ce qui suit :

(*a*) the medical document accompanying the application meets all of the requirements of section 129;

(*b*) the person who provided the applicant with the medical document

(i) is a health care practitioner,

(ii) is entitled to practise their profession in the province in which the applicant consulted with that person, and

(iii) is not named in a notice issued under section 59 of the *Narcotic Control Regulations* that has not been retracted under section 60 of those Regulations; and

(*c*) the applicant has consulted with the person referred to in paragraph (*b*) and that the information set out in the medical document is correct and complete, by confirming these matters with the office of that person.

a) le document médical joint à la demande satisfait aux exigences de l'article 129;

b) la personne qui a fourni le document médical au demandeur satisfait aux exigences suivantes :

(i) elle est un praticien de la santé,

(ii) elle est autorisée à exercer sa profession dans la province où le demandeur l'a consultée,

(iii) elle n'est pas nommée dans un avis donné en vertu de l'article 59 du *Règlement sur les stupéfiants* n'ayant pas fait l'objet d'une rétractation en vertu de l'article 60 de ce règlement;

c) le demandeur a consulté la personne visée à l'alinéa *b*) et les renseignements qui sont inscrits dans le document médical sont exacts et complets, le tout étant confirmé auprès du bureau de cette personne.

Registration of client

111. (1) Subject to section 113, a licensed producer may register an applicant as a client.

Inscription du client

111. (1) Sous réserve de l'article 113, le producteur autorisé peut inscrire le demandeur comme client.

Registration document and unique identifier

(2) If the licensed producer registers the applicant as a client, the producer must

(*a*) send the client a registration document that contains the following information:

(i) the name of the producer, and

(ii) in respect of the client,

(A) the client's given name, surname, date of birth and gender,

(B) the address referred to in subparagraph 108(1)(*b*)(i) or (ii),

(C) the client's shipping address in Canada, and

Document d'inscription et identificateur unique

(2) Le producteur autorisé qui procède à l'inscription prend les mesures suivantes :

a) il fait parvenir au client le document d'inscription comportant les renseignements suivants :

(i) à l'égard du producteur autorisé, son nom,

(ii) à l'égard du client :

(A) ses nom, prénom, date de naissance et sexe,

(B) l'adresse visée aux sous-alinéas 108(1)*b*)(i) ou (ii),

(C) son adresse d'expédition au Canada,

(D) the expiry date of the registration; and

(*b*) provide the client with information that will permit the client to use a unique identifier for the purpose of ordering dried marihuana.

(D) la date d'expiration de l'inscription;

b) il communique au client les renseignements qui lui permettront d'utiliser un identificateur unique pour commander de la marihuana séchée.

Expiry of registration

112. A client's registration expires at the end of the period of validity of the medical document supporting the registration, as determined in accordance with subsections 129(2) and (3).

Expiration de l'inscription

112. L'inscription du client expire à la fin de la période de validité du document médical fourni à l'appui de l'inscription, établie conformément aux paragraphes 129(2) et (3).

Refusal to register

113. A licensed producer must refuse to register an applicant as a client if

(*a*) the application does not meet the requirements of section 108;

(*b*) the licensed producer has reasonable grounds to believe that false or misleading information or false or falsified documents were submitted in or with the application;

(*c*) the requirements of section 110 are not met;

(*d*) the medical document that is submitted with the application is no longer valid;

(*e*) the given name, surname or date of birth of the applicant is different from the given name, surname or date of birth that appears on the medical document;

(*f*) the health care practitioner who provided the medical document to the applicant notifies the licensed producer in writing that the use of dried marihuana by the applicant is no longer supported for clinical reasons; or

(*g*) the address specified in the application under subparagraph 108(1)(*b*)(i) or (ii) is not in Canada.

Refus d'inscrire

113. Le producteur autorisé refuse d'inscrire le demandeur dans les cas suivants :

a) la demande ne satisfait pas aux exigences de l'article 108;

b) il a des motifs raisonnables de croire qu'ont été fournis des renseignements faux ou trompeurs dans la demande ou des documents faux ou falsifiés à l'appui de celle-ci;

c) les exigences de l'article 110 n'ont pas été respectées;

d) le document médical joint à la demande n'est plus valide;

e) les nom, prénom ou date de naissance du demandeur diffèrent de ceux indiqués sur le document médical;

f) le praticien de la santé qui a fourni le document médical au demandeur avise le producteur autorisé, par écrit, que l'usage de la marihuana séchée n'est plus soutenu cliniquement pour cette personne;

g) l'adresse indiquée dans la demande en application des sous-alinéas 108(1)*b*)(i) ou (ii) n'est pas au Canada.

Notice — refusal to register

114. (1) A licensed producer who proposes to refuse to register an applicant for a ground set out in section 113 or for a business reason must without delay send the applicant a notice that indicates the reason for the refusal.

Avis — refus d'inscrire

114. (1) Le producteur autorisé qui envisage de refuser d'inscrire le demandeur pour l'un des motifs visés à l'article 113 ou pour des raisons d'affaires lui envoie sans délai un avis exposant les motifs du refus.

Opportunity to be heard

(2) The applicant may, within 10 days after receipt of the notice, provide the licensed producer with reasons why the refusal is unfounded.

Possibilité de se faire entendre

(2) Le demandeur peut, dans les dix jours qui suivent la réception de l'avis, présenter au producteur autorisé les motifs pour lesquels le refus n'est pas fondé.

Return of medical document

(3) A licensed producer who refuses to register an applicant must return the medical document to the applicant without delay.

Retour du document médical

(3) Le producteur autorisé qui refuse d'inscrire le demandeur lui retourne sans délai le document médical.

Application to amend registration

115. (1) An application to amend a registration must be made to the licensed producer by the client or an individual responsible for the client when a change occurs in respect of any of the information provided under subsection 108(1).

Demande de modification de l'inscription

115. (1) Le client ou une personne physique responsable de ce dernier présente au producteur autorisé une demande de modification de son inscription dans le cas où un changement survient à l'égard de l'un des renseignements visés au paragraphe 108(1).

Content of application

(2) The application must include

(*a*) the requested amendment;

(*b*) in the case of a change to any of the information provided under paragraph 108(1)(*a*), proof of the change; and

(*c*) in the case of a change to the information provided under subparagraph 108(1)(*f*)(iii), the statement referred to in subsection 109(1).

Éléments à fournir

(2) La demande de modification comporte les éléments suivants :

a) la mention de la modification demandée;

b) dans le cas d'un changement apporté à l'un des renseignements visés à l'alinéa 108(1)*a*), une preuve du changement;

c) dans le cas d'un changement apporté au renseignement visé au sous-alinéa 108(1)*f*)(iii), l'attestation visée au paragraphe 109(1).

Statement

(3) The application must be signed and dated by the client or an individual who is responsible for the client and include a statement that

(*a*) the client is ordinarily resident in Canada; and

Attestation

(3) La demande est signée et datée par le client ou par une personne physique responsable de ce dernier et comprend une attestation portant que :

a) le client réside habituellement au Canada;

(*b*) the information contained in the application is correct and complete.

b) les renseignements inclus dans la demande sont exacts et complets.

Statement by responsible individual

(4) If the application is signed and dated by an individual who is responsible for the client, it must include a statement by that individual that they are responsible for the client.

(4) Si la demande est signée et datée par une personne physique responsable du client, elle comporte une attestation portant qu'elle est responsable de ce dernier.

Attestation de la personne physique responsable

Amendment

116. (1) A licensed producer must amend a client's registration if the client's amendment application meets the requirements of subsections 115(2) and (3).

116. (1) Le producteur autorisé modifie l'inscription si la demande est conforme aux exigences des paragraphes 115(2) et (3).

Modification

Amended registration document

(2) If the licensed producer amends the client's registration, the producer must send the client an amended registration document that contains the information referred to in subparagraphs 111(2)(*a*)(i) and (ii).

(2) Le cas échéant, il envoie au client le document d'inscription modifié comportant les renseignements visés aux sous-alinéas 111(2)*a*)(i) et (ii).

Document d'inscription modifié

Cancellation of registration

117. (1) A licensed producer must cancel the registration of a client if

117. (1) Le producteur autorisé annule l'inscription du client dans les cas suivants :

Annulation de l'inscription

(*a*) the client or an individual who is responsible for the client requests the licensed producer to cancel the registration;

a) le client ou une personne physique responsable de ce dernier lui en fait la demande;

(*b*) the client dies, ceases to be ordinarily resident in Canada or ceases to have a shipping address in Canada;

b) le client décède ou n'a plus sa résidence habituelle au Canada ou une adresse d'expédition au Canada;

(*c*) the licensed producer has reasonable grounds to believe that

c) le producteur autorisé a des motifs raisonnables de croire :

(i) the registration was made on the basis of false or misleading information or false or falsified documents submitted in or with the registration application, or

(i) que l'inscription a été faite sur la foi de renseignements faux ou trompeurs fournis dans la demande d'inscription ou de documents faux ou falsifiés fournis à l'appui de celle-ci,

(ii) false or misleading information or false or falsified documents were submitted in or with the application to amend the registration;

(ii) que des renseignements faux ou trompeurs ont été fournis dans la demande de modification de l'inscription ou que des documents faux ou falsifiés ont été fournis à l'appui de celle-ci;

(*d*) the health care practitioner who provided the medical document to the client

notifies the licensed producer in writing that the use of dried marihuana by the client is no longer supported for clinical reasons; or

(*e*) the health care practitioner who provided the medical document to the client is named in a notice issued under section 59 of the *Narcotic Control Regulations* that has not been retracted under section 60 of those Regulations.

d) le praticien de la santé qui a fourni le document médical au client avise le producteur autorisé, par écrit, que l'usage de la marihuana séchée n'est plus soutenu cliniquement pour ce client;

e) le praticien de la santé qui a fourni le document médical au client est nommé dans un avis donné en vertu de l'article 59 du *Règlement sur les stupéfiants* n'ayant pas fait l'objet d'une rétractation en vertu de l'article 60 de ce règlement.

Time of cancellation

(2) The licensed producer must cancel the registration of the client without delay if the producer

(*a*) receives a request referred to in paragraph (1)(*a*) or a written notice under paragraph (1)(*d*);

(*b*) becomes aware of a ground referred to in paragraph (1)(*b*) or (*e*) and has verified in a reasonable manner the existence of the ground; or

(*c*) has reasonable grounds to believe that a ground referred to in subparagraph (1)(*c*)(i) or (ii) exists.

(2) Il l'annule dès que, selon le cas :

a) il reçoit la demande visée à l'alinéa (1)*a*) ou l'avis écrit visé à l'alinéa (1)*d*);

b) il apprend les faits mentionnés aux alinéas (1)*b*) ou *e*) et en a raisonnablement vérifié l'existence;

c) il a des motifs raisonnables de croire qu'un fait visé à l'un des sous-alinéas (1)*c*)(i) ou (ii) existe.

Moment de l'annulation

Cancellation of all registrations

(3) A licensed producer must cancel the registrations of all of its clients without delay if the producer's licence is revoked.

(3) Le producteur autorisé dont la licence a été révoquée annule sans délai l'inscription de tous ses clients.

Annulation de toutes les inscriptions

Cancellation by producer for business reason

(4) A licensed producer may cancel the registration of a client for a business reason.

(4) Le producteur autorisé peut, pour des raisons d'affaires, annuler l'inscription du client.

Annulation pour des raisons d'affaires

Notice

(5) Except in the case of the death of a client, a licensed producer who proposes to cancel a client's registration must without delay send a notice that indicates the reason for the cancellation to the client.

(5) Sauf dans le cas du décès du client, le producteur autorisé qui envisage d'annuler une inscription envoie sans délai un avis motivé au client.

Avis

Opportunity to be heard

(6) Within 10 days after receipt of the notice, the client or an individual responsible for the client may provide the licensed

(6) Le client ou une personne physique responsable de ce dernier peut, dans les dix jours qui suivent la réception de l'avis, pré-

Possibilité de se faire entendre

producer with reasons why the cancellation is unfounded.

Medical document

(7) A licensed producer who cancels a client's registration must not return the medical document.

Prohibition — transfer of medical document

118. A licensed producer must not transfer to any person a medical document on the basis of which a client has been registered.

New Medical Document

New application

119. A licensed producer must not sell or provide dried marihuana to a client or an individual who is responsible for the client on the basis of a new medical document unless the client or the individual submits to the producer a new registration application that meets the requirements of section 108.

Applicable provisions

120. Sections 109 to 114 apply to an application under section 119 in the same way that they apply to an application under section 108.

Processing an Order

Order required

121. (1) A licensed producer must not sell or provide dried marihuana to a client or an individual responsible for the client unless the producer has first received, from the client or the individual, a written order in accordance with subsection (2) or a verbal order recorded in accordance with subsection (3).

Written orders

(2) A written order for dried marihuana must

(*a*) be dated as of the day on which it is made;

(*b*) set out

senter au producteur autorisé les motifs pour lesquels l'annulation n'est pas fondée.

Document médical

(7) Le producteur autorisé qui annule l'inscription ne peut retourner le document médical.

Interdiction — transfert d'un document médical

118. Le producteur autorisé ne peut transférer à qui que ce soit le document médical sur le fondement duquel un client a été inscrit.

Nouveau document médical

Nouvelle demande

119. Le producteur autorisé ne peut vendre ou fournir de la marihuana séchée au client ou à une personne physique responsable de ce dernier, sur le fondement d'un nouveau document médical, que si le client ou une personne physique responsable lui présente une nouvelle demande d'inscription qui satisfait aux exigences de l'article 108.

Dispositions applicables

120. Les articles 109 à 114 s'appliquent à la demande visée à l'article 119 de la même façon qu'ils s'appliquent à la demande visée à l'article 108.

Exécution de la commande

Commande nécessaire

121. (1) Le producteur autorisé ne peut vendre ou fournir de la marihuana séchée au client ou à une personne physique responsable de ce dernier que s'il a reçu au préalable du client, ou d'une personne physique responsable, une commande écrite conforme au paragraphe (2) ou une commande verbale consignée conformément au paragraphe (3).

Commandes écrites

(2) La commande écrite satisfait aux exigences suivantes :

a) elle est datée du jour où la commande est passée;

(i) the given name, surname and date of birth of the client for whom the order is made,

(ii) the given name and surname of the individual making the order,

(iii) the shipping address specified in the client's registration document, and

(iv) the client's unique identifier; and

(*c*) set out the quantity and the brand name of the dried marihuana being ordered.

b) elle comporte les renseignements suivants :

(i) les nom, prénom et date de naissance du client en cause,

(ii) les nom et prénom de la personne physique qui passe la commande,

(iii) l'adresse d'expédition indiquée sur le document d'inscription du client,

(iv) l'identificateur unique du client;

c) elle indique la quantité et la marque nominative de la marihuana séchée commandée.

Verbal orders

(3) A licensed producer who receives a verbal order must, before filling the order, make a record of the information referred to in section 137.

Commandes verbales

(3) Le producteur autorisé qui reçoit une commande verbale consigne, avant de l'exécuter, les renseignements visés à l'article 137.

Shipping

122. In filling an order referred to in section 121, a licensed producer must not transfer physical possession of the dried marihuana to the client or to an individual responsible for that client other than by shipping it to that person.

Expédition

122. Lorsqu'il exécute la commande visée à l'article 121, le producteur autorisé ne peut transférer la possession matérielle de la marihuana séchée au client ou à une personne physique responsable de ce dernier qu'en lui expédiant cette substance.

Refusal

123. (1) A licensed producer must refuse to fill an order referred to in section 121 if

(*a*) the order does not meet the requirements of section 121;

(*b*) any of the information that is referred to in subparagraph 121(2)(*b*)(i) or (iii) does not correspond to the information set out in the client's registration document in accordance with clause 111(2)(*a*)(ii)(A) or (C);

(*c*) the client's unique identifier referred to in subparagraph 121(2)(*b*)(iv) is not correct;

Refus

123. (1) Le producteur autorisé refuse d'exécuter la commande visée à l'article 121 dans les cas suivants :

a) la commande ne satisfait pas aux exigences visées à l'article 121;

b) les renseignements visés aux sous-alinéas 121(2)*b*)(i) ou (iii) ne correspondent pas à ceux qui figurent sur le document d'inscription du client conformément aux divisions 111(2)*a*)(ii)(A) ou (C);

c) l'identificateur unique du client visé au sous-alinéa 121(2)*b*)(iv) n'est pas le bon;

(*d*) the client's registration has expired or been cancelled;

(*e*) the order specifies a quantity of dried marihuana that exceeds 150 g;

(*f*) the order has been previously filled in whole or in part; or

(*g*) more than 30 days have elapsed since the date referred to in paragraph 121(2)(*a*) or 137(*a*).

d) l'inscription du client est expirée ou a été annulée;

e) la commande indique une quantité de marihuana séchée supérieure à 150 g;

f) la commande a été précédemment exécutée en tout ou en partie;

g) il s'est écoulé plus de trente jours depuis la date visée aux alinéas 121(2)*a*) ou 137*a*).

Notice of refusal to fill order

(2) The licensed producer must send the client a written notice of the reason for the refusal.

(2) Il envoie alors un avis écrit au client l'informant du motif du refus.

Avis de refus d'exécution d'une commande

Thirty-day limit

124. (1) A licensed producer must not sell or provide to a client or an individual responsible for the client in any 30-day period a total quantity of dried marihuana that exceeds 30 times the daily quantity referred to in paragraph 129(1)(*d*).

124. (1) Le producteur autorisé ne peut vendre ou fournir au client, ou à une personne physique responsable de ce dernier, au cours de toute période de trente jours, une quantité totale de marihuana séchée qui excède trente fois la quantité quotidienne visée à l'alinéa 129(1)*d*).

Limite pour trente jours

Date of sale

(2) A quantity of dried marihuana is deemed to be sold or provided, for the purpose of subsection (1), on the date that the licensed producer reasonably anticipates that it will be received by the client.

(2) Une quantité de marihuana séchée est réputée être vendue ou fournie, pour l'application du paragraphe (1), à la date à laquelle le producteur autorisé prévoit raisonnablement qu'elle sera reçue par le client.

Date de la vente

Return

(3) If the client or an individual responsible for the client returns to the licensed producer dried marihuana that the producer sold or provided to them, the producer may replace the returned marihuana with an equal quantity, to a maximum of 150 g.

(3) Lorsque le client ou une personne physique responsable de ce dernier retourne la marihuana séchée au producteur autorisé qui la lui a vendue ou fournie, le producteur autorisé peut remplacer la même quantité que cette dernière, jusqu'à une limite de 150 g.

Retour

Exclusion

(4) The quantity of any dried marihuana that the licensed producer provides to the client or an individual responsible for the client to replace the returned marihuana is to be excluded for the purpose of calculating the total quantity referred to in subsection (1).

(4) La quantité de marihuana séchée que le producteur autorisé fournit au client ou à une personne physique responsable de ce dernier pour remplacer la marihuana retournée ne compte pas dans le calcul de la quantité totale visée au paragraphe (1).

Quantité soustraite

PART 3

CLIENTS AND OTHER AUTHORIZED USERS

Proof of authority to possess

125. On demand, an individual who, in accordance with these Regulations, obtains dried marihuana for their own medical purposes must show to a police officer proof that they are authorized to possess the dried marihuana.

Prohibition — obtaining from more than one source

126. It is prohibited to seek or obtain dried marihuana from more than one source at a time on the basis of the same medical document.

Return

127. (1) An individual who, in accordance with these Regulations or subsection 65(2.1) of the *Narcotic Control Regulations*, obtains dried marihuana for their own medical purposes or for those of another individual for whom they are responsible may return the dried marihuana to the person who sold or provided it to them if that person accepts the return of that dried marihuana.

Return by shipping

(2) If the individual returns the dried marihuana by means of shipping it to the person who sold or provided it to them, they must

(*a*) ship it in a package that meets the requirements of paragraph 73(1)(*b*); and

(*b*) use a shipping method that meets the requirements of paragraph 73(1)(*c*).

Return to licensed producer

(3) If the individual returns the dried marihuana to the licensed producer who sold or provided it to them, they must do so by shipping it to the producer's site in accordance with paragraphs (2)(*a*) and (*b*).

PARTIE 3

CLIENTS ET AUTRES UTILISATEURS AUTORISÉS

Preuve de la possession autorisée

125. La personne physique qui, en vertu du présent règlement, obtient de la marihuana séchée à ses propres fins médicales présente à tout agent de police qui lui en fait la demande une preuve qu'elle est autorisée à avoir cette substance en sa possession.

Interdiction — obtention de plus d'une source

126. Il est interdit d'obtenir ou de chercher à obtenir de la marihuana séchée de plus d'une source à la fois sur le fondement du même document médical.

Retour

127. (1) La personne physique qui, en vertu du présent règlement ou du paragraphe 65(2.1) du *Règlement sur les stupéfiants*, obtient de la marihuana séchée à ses propres fins médicales ou à celles d'une autre personne physique dont elle est responsable peut retourner cette substance à la personne qui la lui a vendue ou fournie si cette dernière y consent.

Retour par expédition

(2) Le cas échéant, elle peut le faire en la lui expédiant, auquel cas elle doit, à la fois :

a) l'expédier dans un colis qui satisfait aux exigences de l'alinéa 73(1)*b*);

b) utiliser un moyen d'expédition qui satisfait aux exigences de l'alinéa 73(1)*c*).

Retour au producteur autorisé

(3) Lorsqu'elle la retourne au producteur autorisé qui la lui a vendue ou fournie, elle le fait en l'expédiant à son installation conformément aux alinéas (2)*a*) et *b*).

PART 4

HEALTH CARE PRACTITIONERS

PARTIE 4

PRATICIENS DE LA SANTÉ

Authorized activities

128. (1) In addition to being authorized to possess dried marihuana in accordance with section 3, a health care practitioner may perform the following activities in regard to a person who is under their professional treatment:

(*a*) transfer or administer dried marihuana; or

(*b*) provide a medical document.

Opérations autorisées

128. (1) En plus d'être autorisé à posséder de la marihuana séchée aux termes de l'article 3, le praticien de la santé peut effectuer les opérations ci-après à l'égard de la personne soumise à ses soins professionnels :

a) transférer ou administrer de la marihuana séchée;

b) fournir un document médical.

Transfer

(2) The health care practitioner may also transfer dried marihuana to an individual who is responsible for the person under their professional treatment.

Transfert

(2) Il peut également transférer de la marihuana séchée à une personne physique responsable de la personne soumise à ses soins professionnels.

Medical document

129. (1) A medical document provided by a health care practitioner to a person who is under their professional treatment must indicate

(*a*) the practitioner's given name, surname, profession, business address and telephone number, facsimile number and email address, if applicable, the province in which the practitioner is authorized to practise their profession and the number assigned by the province to that authorization;

(*b*) the person's given name, surname and date of birth;

(*c*) the address of the location at which the person consulted with the practitioner;

(*d*) the daily quantity of dried marihuana to be used by the person, expressed in grams; and

(*e*) the period of use.

Document médical

129. (1) Le document médical fourni par le praticien de la santé à la personne soumise à ses soins professionnels comporte les renseignements suivants :

a) les nom et prénom du praticien de la santé, sa profession, les adresse et numéro de téléphone de son lieu de travail, la province où il est autorisé à exercer sa profession, le numéro d'autorisation attribué par la province et, le cas échéant, son numéro de télécopieur et son adresse électronique;

b) les nom, prénom et date de naissance de la personne;

c) l'adresse du lieu où cette personne a consulté le praticien de la santé;

d) la quantité quotidienne de marihuana séchée, en grammes, qui sera utilisée par la personne;

e) la période d'usage.

Period of use

(2) The period of use referred to in paragraph (1)(*e*)

Période d'usage

(2) La période d'usage visée à l'alinéa (1)*e*) :

(*a*) must be specified as a number of days, weeks or months, which must not exceed one year; and

(*b*) begins on the day on which the medical document is signed by the health care practitioner.

a) s'exprime en jours, semaines ou mois et ne peut excéder un an;

b) commence le jour où le praticien de la santé signe le document médical.

Validity of medical document

(3) A medical document is valid for the period of use specified in it.

(3) Le document médical est valide pour la durée de la période d'usage qui y est mentionnée.

Validité du document médical

Attestation

(4) The medical document must be signed and dated by the health care practitioner providing it and must attest that the information in the document is correct and complete.

(4) Le document médical est signé et daté par le praticien de la santé qui le fournit et comporte une attestation portant que les renseignements qui y figurent sont exacts et complets.

Attestation

Thirty-day limit

130. (1) A health care practitioner must not transfer to a person under their professional treatment or an individual who is responsible for that person (both of whom are referred to in this section as "the transferee") in any 30-day period a total quantity of dried marihuana that exceeds 30 times the daily quantity to be used by the person under their professional treatment, as specified in the medical document on the basis of which the transfer is made.

130. (1) Le praticien de la santé ne peut transférer à la personne soumise à ses soins professionnels ou à la personne physique responsable de celle-ci (appelées « destinataire » au présent article), au cours de toute période de trente jours, une quantité totale de marihuana séchée qui excède trente fois la quantité quotidienne que la personne soumise à ses soins professionnels peut utiliser aux termes du document médical sur le fondement duquel le transfert est effectué.

Limite pour trente jours

Additional limit

(2) A health care practitioner must not, at any one time, transfer to the transferee a quantity of dried marihuana that exceeds 150 g.

(2) Il ne peut, à aucun moment, transférer au destinataire une quantité de marihuana séchée qui excède 150 g.

Limite additionnelle

Exclusion

(3) The quantity of any dried marihuana that the health care practitioner transfers to the transferee to replace any dried marihuana that the transferee has returned under section 127 is to be excluded for the purpose of calculating the total quantity referred to in subsection (1).

(3) La quantité de marihuana séchée qu'il transfère au destinataire pour remplacer celle que celui-ci a retournée en vertu de l'article 127 ne compte pas dans le calcul de la quantité totale visée au paragraphe (1).

Quantité soustraite

PART 5

SALE OR PROVISION BY A LICENSED PRODUCER TO A PERSON OTHER THAN A CLIENT

Order required — cannabis

131. (1) A licensed producer must not sell or provide cannabis under subsection 12(2) unless the producer has first received a written order in accordance with subsection (3) from

(*a*) in the case of a licensed dealer or another licensed producer, an individual who is authorized to place an order for cannabis on behalf of that dealer or producer; and

(*b*) in any other case, the person to whom the cannabis is to be sold or provided in accordance with the Act and these Regulations.

Order required — dried marihuana

(2) A licensed producer must not sell or provide dried marihuana under subparagraphs 12(4)(*a*)(ii) or (iii) unless the producer has first received a written order in accordance with subsection (3) from

(*a*) in the case referred to in subparagraph 12(4)(*a*)(ii), a pharmacist practising in the hospital or a health care practitioner authorized to place orders for dried marihuana on behalf of the hospital; and

(*b*) in the case referred to in subparagraph 12(4)(*a*)(iii), the person to whom the dried marihuana is to be sold or provided.

Requirements

(3) The written order must

(*a*) be signed and dated by a person described in subsection (1) or (2) and indicate their name;

PARTIE 5

VENTE OU FOURNITURE PAR LE PRODUCTEUR AUTORISÉ À UNE PERSONNE AUTRE QUE LE CLIENT

Commande obligatoire — chanvre indien

131. (1) Le producteur autorisé ne peut vendre ou fournir du chanvre indien en vertu du paragraphe 12(2) que s'il a reçu au préalable une commande écrite conforme au paragraphe (3), provenant :

a) dans le cas d'un distributeur autorisé ou d'un autre producteur autorisé, d'une personne physique autorisée à commander le chanvre indien au nom de l'un ou l'autre;

b) dans les autres cas, de la personne à qui le chanvre indien est destiné à être vendu ou fourni conformément à la Loi et au présent règlement.

Commande obligatoire — marihuana séchée

(2) Le producteur autorisé ne peut vendre ou fournir de la marihuana séchée en vertu des sous-alinéas 12(4)*a*)(ii) ou (iii) que s'il a reçu au préalable une commande écrite conforme au paragraphe (3), provenant :

a) dans le cas visé au sous-alinéa 12(4)*a*)(ii), d'un pharmacien exerçant dans l'hôpital ou d'un praticien de la santé autorisé à commander de la marihuana séchée pour l'hôpital;

b) dans le cas visé au sous-alinéa 12(4)*a*)(iii), de la personne à qui la marihuana séchée est destinée à être vendue ou fournie.

Exigences

(3) La commande écrite satisfait aux exigences suivantes :

a) elle indique le nom d'une personne visée aux paragraphes (1) ou (2) et est signée et datée par cette dernière;

(*b*) indicate the shipping address in Canada; and

(*c*) specify whether dried marihuana or cannabis other than dried marihuana is being ordered and include the following information:

(i) in the case of dried marihuana, its quantity and brand name, or

(ii) in the case of cannabis other than dried marihuana, the substance ordered, its quantity, description and, if applicable, brand name.

b) elle indique l'adresse d'expédition au Canada;

c) elle indique si elle vise de la marihuana séchée ou du chanvre indien autre que de la marihuana séchée et elle comprend les renseignements suivants :

(i) s'il s'agit de marihuana séchée, sa quantité et sa marque nominative,

(ii) s'il s'agit de chanvre indien autre que de la marihuana séchée, le nom de la substance en cause, sa quantité, sa description et, le cas échéant, sa marque nominative.

Signature

(4) A licensed producer must verify in a reasonable manner the identity of the person who placed the order if the signature on the order is not known to the producer.

Signature

(4) Le producteur autorisé effectue une vérification raisonnable de l'identité de la personne qui passe la commande s'il ne connaît pas la signature apposée sur la commande.

Shipping

132. In filling an order referred to in subsection 131(2), a licensed producer must not transfer physical possession of the dried marihuana to the person to whom it is sold or provided other than by shipping it to them.

Expédition

132. Lorsqu'il exécute la commande visée au paragraphe 131(2), le producteur autorisé ne peut transférer la possession matérielle de la marihuana séchée à la personne à qui cette substance est vendue ou fournie qu'en la lui expédiant.

Refusal

133. (1) A licensed producer must refuse to fill an order referred to in subsection 131(1) or (2) if

(*a*) the order does not meet the requirements of subsection 131(3); or

(*b*) in the circumstances described in subsection 131(4), the identity of the person cannot be verified.

Refus

133. (1) Le producteur autorisé refuse d'exécuter une commande visée aux paragraphes 131(1) ou (2) dans les cas suivants :

a) elle ne satisfait pas aux exigences du paragraphe 131(3);

b) dans le cas visé au paragraphe 131(4), l'identité de la personne n'a pu être vérifiée.

Notice of refusal to fill order

(2) The licensed producer must send the person who placed the order a written notice of the reason for the refusal.

Avis du refus d'exécution d'une commande

(2) Il envoie alors à la personne qui a passé celle-ci un avis écrit l'informant du motif du refus.

PART 6

RECORD KEEPING BY LICENSED PRODUCERS

TRANSACTIONS

Cannabis received

134. Except in the case referred to in section 139, a licensed producer who receives cannabis must record the following information:

(*a*) the name of the person from whom it was received;

(*b*) the address of the site at which it was received;

(*c*) the date on which it was received; and

(*d*) an indication of whether dried marihuana or cannabis other than dried marihuana was received, as well as the following information:

(i) in the case of dried marihuana, the quantity and, if applicable, brand name, or

(ii) in the case of cannabis other than dried marihuana, the substance ordered, its quantity, description, intended use and, if applicable, brand name.

Imported marihuana

135. A licensed producer who imports marihuana must retain a copy of the declaration required by section 78 and of the export permit issued by a competent authority in the country of export.

Exported marihuana

136. A licensed producer who exports marihuana must retain a copy of the declaration required by section 86 and of the import permit issued by a competent authority in the country of final destination.

PARTIE 6

TENUE DES DOSSIERS PAR LE PRODUCTEUR AUTORISÉ

TRANSACTIONS

Chanvre indien reçu

134. Sauf dans le cas visé à l'article 139, le producteur autorisé qui reçoit du chanvre indien consigne les renseignements suivants :

a) le nom de la personne de qui il est reçu;

b) l'adresse de l'installation où il est reçu;

c) la date à laquelle il est reçu;

d) une mention précisant que la substance reçue est de la marihuana séchée ou du chanvre indien autre que de la marihuana séchée, ainsi que les renseignements suivants :

(i) s'il s'agit de marihuana séchée, sa quantité et, le cas échéant, sa marque nominative,

(ii) s'il s'agit de chanvre indien autre que de la marihuana séchée, la substance commandée, sa quantité, sa description, son usage envisagé et, le cas échéant, sa marque nominative.

Marihuana importée

135. Le producteur autorisé qui importe de la marihuana conserve une copie de la déclaration visée à l'article 78 et du permis d'exportation délivré par l'autorité compétente du pays d'exportation.

Marihuana exportée

136. Le producteur autorisé qui exporte de la marihuana conserve une copie de la déclaration visée à l'article 86 et du permis d'importation délivré par l'autorité compétente du pays de destination ultime.

Record of verbal order

137. A licensed producer who receives a verbal order referred to in subsection 121(3) must record the following information:

(*a*) the date on which the order was made and the order number;

(*b*) the information referred to in paragraphs 121(2)(*b*) and (*c*); and

(*c*) the name of the individual recording the order.

Consignation de la commande verbale

137. Le producteur autorisé qui reçoit la commande verbale visée au paragraphe 121(3) consigne les renseignements suivants :

a) la date où la commande est passée et le numéro de la commande;

b) les renseignements visés aux alinéas 121(2)*b*) et *c*);

c) le nom de la personne physique qui consigne la commande.

Filling of order from client

138. (1) A licensed producer who fills an order referred to in section 121 must record the following information:

(*a*) the given name, surname and date of birth of the client for whom the order is placed;

(*b*) the given name and surname of the individual placing the order;

(*c*) the quantity, brand name and lot number of the dried marihuana sold or provided;

(*d*) the date on which the order was received;

(*e*) the date on which the dried marihuana was shipped; and

(*f*) the address to which the dried marihuana was shipped.

Exécution de la commande d'un client

138. (1) Le producteur autorisé qui exécute la commande visée à l'article 121 consigne les renseignements suivants :

a) les nom, prénom et date de naissance du client pour qui la commande est passée;

b) les nom et prénom de la personne physique qui passe la commande;

c) la quantité, la marque nominative et le numéro du lot de la marihuana séchée qu'il vend ou fournit;

d) la date de réception de la commande;

e) la date d'expédition de la marihuana séchée;

f) l'adresse à laquelle la marihuana séchée a été expédiée.

Retention of documents

(2) A licensed producer must retain a written order referred to in subsection 121(2) or a written record of a verbal order referred to in subsection 121(3).

Conservation des documents

(2) Le producteur autorisé conserve la commande écrite visée au paragraphe 121(2) ou le document utilisé pour consigner la commande verbale visée au paragraphe 121(3).

Refusal to fill an order

(3) A licensed producer who refuses to fill an order referred to in section 121 must retain a copy of the written notice referred to in subsection 123(2).

Refus d'exécuter la commande

(3) Le producteur autorisé qui refuse d'exécuter la commande visée à l'article 121 conserve une copie de l'avis écrit visé au paragraphe 123(2).

Dried marihuana returned by client

139. A licensed producer who receives dried marihuana that is returned under sec-

Marihuana séchée retournée par le client

139. Le producteur autorisé qui reçoit la marihuana séchée retournée en vertu de

tion 127 must record the following information:

(*a*) the given name and surname of the individual who returned it;

(*b*) the address of the site at which it was received;

(*c*) its quantity and brand name; and

(*d*) the date on which it was received.

l'article 127 consigne les renseignements suivants :

a) les nom et prénom de la personne physique qui la retourne;

b) l'adresse de l'installation à laquelle elle est reçue;

c) sa quantité et sa marque nominative;

d) la date à laquelle elle a été reçue.

Order from person other than client

140. (1) A licensed producer who fills an order referred to in subsection 131(1) or (2) must record the following information:

(*a*) the name of the person to whom the cannabis or dried marihuana was sold or provided;

(*b*) the shipping address;

(*c*) an indication of whether dried marihuana or cannabis other than dried marihuana was ordered, as well as the following information:

(i) in the case of dried marihuana, its quantity and, if applicable, brand name, or

(ii) in the case of cannabis other than dried marihuana, the substance ordered, its quantity, description and, if applicable, brand name; and

(*d*) the date on which the cannabis or dried marihuana was shipped.

Commande d'une personne autre que le client

140. (1) Le producteur autorisé qui exécute une commande visée aux paragraphes 131(1) ou (2) consigne les renseignements suivants :

a) le nom de la personne à qui est vendu ou fourni le chanvre indien ou la marihuana séchée;

b) l'adresse d'expédition;

c) une mention précisant que la substance commandée est de la marihuana séchée ou du chanvre indien autre que de la marihuana séchée, ainsi que les renseignements suivants :

(i) s'il s'agit de marihuana séchée, sa quantité et, le cas échéant, sa marque nominative,

(ii) s'il s'agit de chanvre indien autre que de la marihuana séchée, la substance commandée, sa quantité, sa description et, le cas échéant, sa marque nominative;

d) la date d'expédition du chanvre indien ou de la marihuana séchée.

Refusal to fill an order

(2) A licensed producer who refuses to fill an order referred to in subsection 131(1) or (2) must retain a copy of the written notice referred to in subsection 133(2).

Refus d'exécuter une commande

(2) Le producteur autorisé qui refuse d'exécuter une commande visée aux paragraphes 131(1) ou (2) conserve une copie de l'avis écrit visé au paragraphe 133(2).

CLIENT REGISTRATIONS

Information

141. (1) A licensed producer must record the following information:

(*a*) details of the verifications performed under subsection 101(2), section 110 and paragraph 117(2)(*b*); and

(*b*) what will serve as the unique identifier referred to in paragraph 111(2)(*b*) and the manner in which and the date on which it was communicated to the client.

Documents

(2) A licensed producer must retain the following documents:

(*a*) a registration application referred to in section 108;

(*b*) a medical document referred to in section 108, or, if the document has been returned in accordance with subsection 114(3), a copy of it;

(*c*) a copy of a registration document referred to in paragraph 111(2)(*a*);

(*d*) an application for the amendment of a registration referred to in section 115;

(*e*) a copy of an amended registration document referred to in subsection 116(2); and

(*f*) a copy of a notice referred to in section 114 or subsection 117(5).

SECURITY, PRODUCTION AND INVENTORY

Security

142. A licensed producer must keep

(*a*) the visual recordings referred to in sections 43 and 48;

(*b*) the records referred to in subsections 45(2) and 51(2); and

(*c*) the record referred to in subsection 46(3).

INSCRIPTION DU CLIENT

Renseignements

141. (1) Le producteur autorisé consigne les renseignements suivants :

a) le détail des vérifications effectuées en application du paragraphe 101(2), de l'article 110 et de l'alinéa 117(2)*b*);

b) ce qui servira d'identificateur unique visé à l'alinéa 111(2)*b*), la façon dont ces renseignements ont été communiqués au client ainsi que la date de la communication.

Documents

(2) Le producteur autorisé conserve les documents suivants :

a) la demande d'inscription visée à l'article 108;

b) le document médical visé à l'article 108 ou, s'il a été retourné en application du paragraphe 114(3), une copie de celui-ci;

c) une copie du document d'inscription visé à l'alinéa 111(2)*a*);

d) la demande de modification de l'inscription visée à l'article 115;

e) une copie du document d'inscription modifié visé au paragraphe 116(2);

f) une copie de l'avis prévu à l'article 114 ou au paragraphe 117(5).

SÉCURITÉ, PRODUCTION ET INVENTAIRE

Sécurité

142. Le producteur autorisé conserve ce qui suit :

a) les enregistrements visuels visés aux articles 43 et 48;

b) les constats visés aux paragraphes 45(2) et 51(2);

c) les registres visés au paragraphe 46(3).

Good production practices and packaging, labelling and shipping

143. (1) A licensed producer must keep

(*a*) records demonstrating that each lot or batch of dried marihuana that they sold or provided under subsection 12(4) was produced, packaged and labelled in accordance with Divisions 4 and 5 of Part 1;

(*b*) a list of all brand names of dried marihuana that they produced, packaged or labelled;

(*c*) a copy of the sanitation program referred to in section 57 in use at their site;

(*d*) a copy of the standard operating procedures referred to in section 58 in use at their site;

(*e*) documentation concerning the control system referred to in section 59 in use at their site;

(*f*) a description of the qualifications of the quality assurance person in respect of the matters referred to in subparagraph 60(1)(*a*)(ii); and

(*g*) records of every complaint referred to in paragraph 60(1)(*b*) and of any corrective action taken.

Sale or provision

(2) A licensed producer who sells or provides dried marihuana

(*a*) must keep records of any testing conducted by or on behalf of the licensed producer in respect of any lot or batch of the dried marihuana;

(*b*) must keep records of information necessary for the system of control referred to in section 59; and

(*c*) must keep a record of the information that the licensed producer is re-

Bonnes pratiques de production; emballage, étiquetage et expédition

143. (1) Le producteur autorisé satisfait aux exigences suivantes :

a) il tient un registre montrant que chaque lot ou lot de production de marihuana séchée vendue ou fournie en vertu du paragraphe 12(4) est produit, emballé et étiqueté conformément aux sections 4 et 5 de la partie 1;

b) il tient une liste des marques nominatives de la marihuana séchée qui est produite, emballée ou étiquetée;

c) il conserve un exemplaire du programme d'hygiène visé à l'article 57 utilisé à son installation;

d) il conserve un exemplaire des méthodes d'exploitation normalisées visées à l'article 58 utilisées à son installation;

e) il conserve la documentation concernant le système de contrôle visé à l'article 59 utilisé à son installation;

f) il conserve une description des compétences du préposé à l'assurance de la qualité eu égard aux éléments visés au sous-alinéa 60(1)*a*)(ii);

g) il tient un registre des plaintes visées à l'alinéa 60(1)*b*), ainsi que des mesures correctives qu'il a prises.

Vente ou fourniture

(2) Le producteur autorisé qui vend ou fournit de la marihuana séchée tient les registres suivants :

a) un registre des analyses effectuées par le producteur autorisé ou pour son compte à l'égard de tout lot ou lot de production de cette substance;

b) un registre dans lequel sont consignés les renseignements nécessaires au système de contrôle visé à l'article 59;

quired by section 62 to provide to the Minister in respect of the recall of dried marihuana.

c) un registre des renseignements que le producteur autorisé doit fournir au ministre en application de l'article 62 à propos du retrait du marché de la marihuana séchée.

Propagated, sown, harvested, dried, packaged and destroyed marihuana

144. A licensed producer must keep a record of the following information concerning each lot or batch of marihuana that they propagate, sow, harvest, dry, package or destroy:

(*a*) the date on which marihuana plants are propagated by means other than sowing seeds and the total number of new plants propagated in this manner;

(*b*) the date on which marihuana seeds are sown and their total net weight on that date;

(*c*) the date on which marihuana is harvested and its net weight on that date;

(*d*) the date on which the drying process for marihuana is completed and its net weight on that date;

(*e*) the date on which marihuana is packaged and its net weight on that date; and

(*f*) the date on which marihuana is destroyed and its net weight on that date, before the destruction.

Marihuana multipliée, semée, récoltée, séchée, emballée ou détruite

144. Le producteur autorisé consigne les renseignements ci-après concernant tout lot ou lot de production de marihuana qu'il multiplie, sème, récolte, sèche, emballe ou détruit :

a) la date à laquelle les plants de marihuana sont multipliés autrement qu'en semant des graines, ainsi que le nombre total de nouveaux plants ainsi multipliés;

b) la date à laquelle les graines de marihuana sont semées, ainsi que leur poids net total à cette date;

c) la date à laquelle la marihuana est récoltée, ainsi que son poids net à cette date;

d) la date à laquelle le processus de séchage de la marihuana est complété, ainsi que son poids net à cette date;

e) la date à laquelle la marihuana est emballée, ainsi que son poids net à cette date;

f) la date à laquelle la marihuana est détruite, ainsi que son poids net, à cette date, avant la destruction.

Destroyed cannabis

145. (1) A licensed producer must keep, for each instance in which they destroy cannabis, a record of the following information:

(*a*) the date on which the cannabis was destroyed, the name of the substance destroyed and its net weight on that date, before the destruction;

(*b*) the location at which it was destroyed;

Chanvre indien détruit

145. (1) Le producteur autorisé consigne les renseignements ci-après à chaque destruction de chanvre indien qu'il effectue :

a) la date à laquelle le chanvre indien est détruit, le nom de la substance détruite ainsi que son poids net, à cette date, avant la destruction;

b) le lieu de la destruction;

(*c*) a brief description of the method of destruction;

(*d*) the names of the witnesses to the destruction that are referred to in paragraph 20(1)(*b*) and the basis on which they are qualified to be witnesses under subsection 20(2); and

(*e*) if applicable, the name of the person who accompanied the cannabis in accordance with subsection 20(3).

Statement by witnesses

(2) A licensed producer must keep, for each instance in which they destroy cannabis, a statement signed and dated by each of the witnesses referred to in paragraph 20(1)(*b*) stating that they have witnessed the destruction and that the cannabis was destroyed in accordance with section 20.

Inventory

146. A licensed producer must keep a record of the net weight of each of the following that are in inventory at their site at the end of each quarter of the calendar year:

(*a*) marihuana seeds;

(*b*) harvested marihuana in respect of which the drying process has not been completed, other than marihuana referred in paragraph (*d*) or (*e*);

(*c*) harvested marihuana in respect of which the drying process has been completed, other than marihuana referred in paragraph (*d*) or (*e*);

(*d*) marihuana that is destined for destruction;

(*e*) packaged marihuana; and

(*f*) cannabis other than marihuana, specifying the name and net weight of each of the substances in question.

c) un bref exposé de la méthode de destruction;

d) les noms des témoins de la destruction visés à l'alinéa 20(1)*b*) et leur qualité pour servir de témoins aux termes du paragraphe 20(2);

e) le cas échéant, le nom de la personne en présence de laquelle s'effectue le transport du chanvre indien en application du paragraphe 20(3).

Attestation des témoins

(2) Le producteur autorisé conserve, après chaque destruction de chanvre indien qu'il effectue, une attestation, signée et datée par chacun des témoins de la destruction visés à l'alinéa 20(1)*b*), portant qu'il a été témoin de la destruction de chanvre indien et que celle-ci s'est effectuée conformément à l'article 20.

Inventaire

146. Le producteur autorisé consigne, à la fin de chaque trimestre de l'année civile, le poids net de chacun des éléments ci-après qu'il a en stock à son installation :

a) les graines de marihuana;

b) la marihuana récoltée, autre que celle visée aux alinéas *d*) et *e*), pour laquelle le processus de séchage n'est pas complété;

c) la marihuana récoltée, autre que celle visée aux alinéas *d*) et *e*), pour laquelle le processus de séchage est complété;

d) la marihuana destinée à être détruite;

e) la marihuana emballée;

f) le chanvre indien autre que la marihuana, en précisant le nom et le poids net de chacune des substances dont il s'agit.

Notices to Local Authorities

Notices

147. A licensed producer must keep a copy of

(*a*) each notice sent to local authorities under sections 38 to 40; and

(*b*) each notice sent to the Minister under section 40.

General Obligations

Manner of keeping records

148. (1) A licensed producer must ensure that the records, documents and information referred to in this Part

(*a*) are kept in a manner that will enable an audit of them to be made in a timely manner; and

(*b*) are available at their site.

Retention period

(2) A licensed producer must retain the records, documents and information for the following periods:

(*a*) in the case of a written notice that the producer is required to send under these Regulations, for a period of two years after the day on which the notice is sent;

(*b*) in the case of information that the producer is required to record under sections 134 and 137, subsection 138(1), section 139, subsections 140(1) and 141(1) and sections 144 and 146, for a period of two years after the day on which the information is recorded;

(*c*) in the case of the documents referred to in sections 135 and 136, for a period of two years after the day on which the declaration referred to in section 78 or 86, as applicable, is sent to the Minister;

(*d*) in the case of the documents referred to in subsection 138(2) and paragraphs 141(2)(*a*) to (*e*), for a period of

Avis aux autorités locales

Avis

147. Le producteur autorisé conserve une copie des avis :

a) envoyés aux autorités locales en application des articles 38 à 40;

b) envoyés au ministre en application de l'article 40.

Obligations générales

Méthode de conservation des dossiers

148. (1) Le producteur autorisé veille à ce que les registres, documents et renseignements visés par la présente partie soient, à la fois :

a) conservés de façon à permettre leur vérification en temps opportun;

b) accessibles à son installation.

Durée de la conservation

(2) Il les conserve pour les périodes suivantes :

a) s'agissant de tout avis écrit qu'un producteur autorisé doit envoyer dans le cadre du présent règlement, pour une période de deux ans suivant son envoi;

b) s'agissant des renseignements qui doivent être consignés conformément aux articles 134 et 137, au paragraphe 138(1), à l'article 139, aux paragraphes 140(1) et 141(1) et aux articles 144 et 146, pour une période de deux ans suivant le jour de leur consignation;

c) s'agissant des documents visés aux articles 135 et 136, pour une période de deux ans suivant le jour où la déclaration visée aux articles 78 ou 86, selon le cas, a été envoyée au ministre;

d) s'agissant des documents visés au paragraphe 138(2) et aux alinéas 141(2)*a*) à *e*), pour une période de deux ans suivant leur obtention par le producteur au-

two years after the day on which the producer obtained them or, in the case of documents made by the producer, the day on which they were made;

(*e*) in the case of the visual recordings or the records referred to in section 142, for a period of two years after the day on which they were made;

(*f*) in the case of the records referred to in paragraphs 143(1)(*a*) and (2)(*b*), for a period of two years after the date of the last sale or provision of any portion of the lot or batch of dried marihuana under subsection 12(4);

(*g*) in the case of a document referred to in paragraph 143(1)(*b*), (*c*), (*d*) or (*e*), for the period during which it is current and for an additional period of two years after the day on which it is replaced by a new version;

(*h*) in the case of a document referred to in paragraph 143(1)(*f*), for the period during which the quality assurance person acts in that capacity and for an additional period of two years after the day on which the person ceases to do so;

(*i*) in the case of the records referred to in paragraph 143(1)(*g*), for a period of two years after the day on which the complaint was recorded;

(*j*) in the case of the records referred to in paragraph 143(2)(*a*), for a period of two years after the date of the last sale or provision of any portion of the lot or batch, other than a sale or provision for destruction;

(*k*) in the case of the records referred to in paragraph 143(2)(*c*), for a period of two years after the day on which the dried marihuana was recalled; and

torisé ou, s'agissant des documents créés par le producteur autorisé, leur création;

e) s'agissant des enregistrements visuels, des constats et des registres visés à l'article 142, pour une période de deux ans suivant leur création;

f) s'agissant des registres visés aux alinéas 143(1)*a*) et (2)*b*), pour une période de deux ans suivant la date de la dernière vente ou fourniture de tout ou partie d'un lot ou lot de production de marihuana séchée effectuée en vertu du paragraphe 12(4);

g) s'agissant d'un document visé à l'un des alinéas 143(1)*b*) à *e*), pour la période pendant laquelle il est à jour ainsi que pour une période supplémentaire de deux ans suivant le jour où il est remplacé par une nouvelle version;

h) s'agissant du document visé à l'alinéa 143(1)*f*), pour la période pendant laquelle le préposé à l'assurance de la qualité agit à ce titre ainsi que pour une période supplémentaire de deux ans suivant le jour où il cesse de le faire;

i) s'agissant du registre visé à l'alinéa 143(1)*g*), pour une période de deux ans suivant le jour de la consignation des plaintes;

j) s'agissant du registre visé à l'alinéa 143(2)*a*), pour une période de deux ans suivant la date de la dernière vente ou fourniture de tout ou partie de lot ou de lot de production autre qu'une vente ou fourniture aux fins de destruction;

k) s'agissant du registre visé à l'alinéa 143(2)*c*), pour une période de deux ans suivant le jour du retrait du marché de la marihuana séchée;

(*l*) in the case of the records and documents referred to in section 145, for a period of two years after the day on which the cannabis was destroyed.

l) s'agissant des renseignements et des documents visés à l'article 145, pour une période de deux ans suivant le jour de la destruction du chanvre indien.

Case reports and summary reports

(3) A licensed producer must retain the serious adverse reaction case reports and the summary reports referred to in subsections 63(1) and (2) for a period of 25 years after the day on which they were made.

(3) Le producteur autorisé conserve les fiches d'observation sur les réactions indésirables graves et les rapports de synthèse visés aux paragraphes 63(1) et (2) pour une période de vingt-cinq ans suivant le jour de leur création.

Fiches d'observation et rapports de synthèse

Information required by Minister

149. A licensed producer must provide the Minister with any information that the Minister may require in respect of the records, documents and information referred to in this Part, in the form and at the times that the Minister specifies.

149. Le producteur autorisé fournit les renseignements demandés par le ministre concernant les registres, documents et renseignements visés par la présente partie, sous la forme et aux moments que fixe le ministre.

Renseignements demandés par le ministre

Former licensed producers

150. If a licence to produce expires without being renewed or is revoked, the former licensed producer must comply with the requirements of paragraph 148(1)(*a*), subsections 148(2) and (3) and section 149.

150. Lorsqu'une licence de producteur autorisé est révoquée ou expire sans être renouvelée, son ancien titulaire est soumis aux obligations prévues à l'alinéa 148(1)*a*), aux paragraphes 148(2) et (3) ainsi qu'à l'article 149.

Anciens producteurs autorisés

[**151** to **199** reserved]

[**151** à **199** réservés]

PART 7

CONSEQUENTIAL AMENDMENTS, TRANSITIONAL PROVISIONS, REPEAL AND COMING INTO FORCE

Consequential Amendments

Narcotic Control Regulations

200. [Amendments]

201. [Amendment]

202. [Amendments]

203. [Amendments]

204. [Amendment]

PARTIE 7

MODIFICATIONS CORRÉLATIVES, DISPOSITIONS TRANSITOIRES, ABROGATION ET ENTRÉE EN VIGUEUR

Modifications corrélatives

Règlement sur les stupéfiants

200. [Modifications]

201. [Modification]

202. [Modifications]

203. [Modifications]

204. [Modification]

205. [Amendment]

206. [Amendments]

207. [Amendment]

208. [Amendment]

209. [Amendments]

210. [Amendments]

211. [Amendment]

212. [Amendments]

213. [Amendment]

214. [Amendments]

215. [Amendments]

216. [Amendment]

217. [Amendments]

218. [Amendments]

219. [Amendment]

220. [Amendments]

221. [Amendments]

222. [Amendments]

223. [Amendment]

224. [Amendment]

225. [Amendments]

226. [Amendment]

227. [Amendment]

228. [Amendment]

Marihuana Medical Access Regulations

229. [Amendment]

230. [Amendment]

231. [Amendment]

232. [Amendment]

233. [Amendment]

205. [Modification]

206. [Modifications]

207. [Modification]

208. [Modification]

209. [Modifications]

210. [Modifications]

211. [Modification]

212. [Modifications]

213. [Modification]

214. [Modifications]

215. [Modifications]

216. [Modification]

217. [Modifications]

218. [Modifications]

219. [Modification]

220. [Modifications]

221. [Modifications]

222. [Modifications]

223. [Modification]

224. [Modification]

225. [Modifications]

226. [Modification]

227. [Modification]

228. [Modification]

Règlement sur l'accès à la marihuana à des fins médicales

229. [Modification]

230. [Modification]

231. [Modification]

232. [Modification]

233. [Modification]

234. [Amendment]

235. [Amendment]

236. [Amendment]

237. [Amendment]

238. [Amendment]

239. [Amendment]

240. [Amendment]

241. [Amendment]

242. [Amendments]

243. [Amendment]

244. [Amendment]

245. [Amendment]

246. [Amendment]

247. [Amendment]

248. [Amendment]

249. [Amendment]

250. [Amendment]

234. [Modification]

235. [Modification]

236. [Modification]

237. [Modification]

238. [Modification]

239. [Modification]

240. [Modification]

241. [Modification]

242. [Modifications]

243. [Modification]

244. [Modification]

245. [Modification]

246. [Modification]

247. [Modification]

248. [Modification]

249. [Modification]

250. [Modification]

New Classes of Practitioners Regulations

251. [Amendment]

252. [Amendment]

Règlement sur les nouvelles catégories de praticiens

251. [Modification]

252. [Modification]

Transitional Provisions

Dispositions transitoires

Interpretation

Définitions et interprétation

Definitions

253. (1) For the purpose of sections 254 to 266, "authorization to possess", "designated-person production licence", "medical practitioner" and "personal-use production licence" have the same meaning as in subsection 1(1) of the *Marihuana Medical Access Regulations*.

Définitions

253. (1) Pour l'application des articles 254 à 266, «autorisation de possession», «licence de production à des fins personnelles», «licence de production à titre de personne désignée» et «médecin» s'entendent au sens du paragraphe 1(1) du *Règlement sur l'accès à la marihuana à des fins médicales*.

Medical declaration

(2) For the purpose of sections 254 to 266, "medical declaration" means a

Déclaration médicale

(2) Pour l'application des articles 254 à 266, «déclaration médicale» s'entend

medical declaration that is made by a medical practitioner in accordance with sections 6 and 8 of the *Marihuana Medical Access Regulations*.

de la déclaration médicale fournie par un médecin conformément aux articles 6 et 8 du *Règlement sur l'accès à la marihuana à des fins médicales*.

Registration Based on an Authorization to Possess

Inscription sur le fondement d'une autorisation de possession

Applicable period

254. Sections 255 and 256 apply until March 31, 2015.

Période applicable

254. Les articles 255 et 256 s'appliquent jusqu'au 31 mars 2015.

Registration based on authorization to possess

255. (1) For the purpose of subsection 108(2), an individual applying to become a client of a licensed producer may include an authorization to possess with their application, instead of a medical document.

Inscription sur le fondement d'une autorisation de possession

255. (1) Pour l'application du paragraphe 108(2), la personne physique qui présente une demande d'inscription à un producteur autorisé peut joindre à celle-ci une autorisation de possession au lieu d'un document médical.

Ongoing validity of authorization to possess

(2) An authorization to possess that was valid immediately before the repeal of the *Marihuana Medical Access Regulations* remains valid solely for the purpose of being used as specified in subsection (1).

Validité de l'autorisation de possession

(2) L'autorisation de possession qui était valide avant l'abrogation du *Règlement sur l'accès à la marihuana à des fins médicales* demeure valide à seule fin d'être utilisée aux termes du paragraphe (1).

Modified application of Regulations

256. If, in accordance with section 255, a registration application under section 108 is made on the basis of an authorization to possess, the provisions of these Regulations, other than section 129, apply with the following modifications:

(*a*) a reference in sections 1 to 150 to a "medical document" is to be read as a reference to an authorization to possess, except in the case of

(i) the definition "medical document" in subsection 1(1),

(ii) paragraph 128(1)(*b*), and

(iii) a provision referred to in paragraph (*b*); and

Application modifiée du Règlement

256. Lorsque, aux termes de l'article 255, la demande d'inscription visée à l'article 108 est présentée sur le fondement d'une autorisation de possession, les dispositions du présent règlement, à l'exception de l'article 129, s'appliquent avec les adaptations suivantes :

***a*) la mention de « document médical » aux articles 1 à 150 vaut mention de l'autorisation de possession, sauf aux endroits suivants :**

(i) la définition de « document médical » au paragraphe 1(1),

(ii) l'alinéa 128(1)*b*),

(iii) la disposition visée à l'alinéa *b*);

(*b*) a provision that is referred to in column 1 of the table to this section is to be read as set out in column 2.

TABLE

Item	Column 1 Provision	Column 2 Modified text
1.	paragraph 5(*a*)	(*a*) in the case of dried marihuana obtained from a licensed producer in accordance with an authorization to possess, the quantity specified in the authorization;
2.	subparagraph 67(*a*)(ii)	(ii) the name of the medical practitioner that appears on the authorization to possess,
3.	subparagraph 67(*a*)(iv)	(iv) the daily quantity of dried marihuana determined by the formula A / 30 where A is the maximum quantity of dried marihuana specified in the authorization to possess,
4.	paragraph 101(1)(*b*)	(*b*) in respect of a individual who is a client of the producer, the daily quantity of dried marihuana determined by the formula A / 30 where A is the maximum quantity of dried marihuana specified in the authorization to possess supporting the client's registration.
5.	subparagraph 108(1)(*f*)(iii)	(iii) subject to section 109, the address of the medical practitioner who made the medical declaration supporting the authorization to possess referred to in subsection 108(2).
6.	subsection 109(1)	(1) If the shipping address specified in a registration application is the one referred to in subparagraph 108(1)(*f*)(iii), the applicant must include with the application a statement, signed and dated by the medical practitioner who made the medical declaration supporting the authorization to possess referred to in subsection 108(2), indicating that the practitioner consents to receive dried marihuana on behalf of the applicant.

***b*) la disposition visée à la colonne 1 du tableau du présent article porte le texte modifié visé à la colonne 2.**

TABLEAU

Article	Colonne 1 Disposition	Colonne 2 Texte modifié
1.	Alinéa 5*a*)	*a*) dans le cas de celle obtenue d'un producteur autorisé sur le fondement d'une autorisation de possession, la quantité indiquée dans cette dernière;
2.	Sous-alinéa 67*a*)(ii)	(ii) le nom du médecin mentionné dans l'autorisation de possession,
3.	Sous-alinéa 67*a*)(iv)	(iv) la quantité quotidienne de marihuana séchée calculée selon la formule suivante : A / 30 où : A représente la quantité maximale de marihuana séchée indiquée dans l'autorisation de possession,
4.	Alinéa 101(1)*b*)	*b*) s'agissant d'un de ses clients, la quantité quotidienne de marihuana séchée calculée selon la formule suivante : A / 30 où : A représente la quantité maximale de marihuana séchée indiquée dans l'autorisation de possession à l'appui de son inscription.
5.	Sous-alinéa 108(1)*f*)(iii)	(iii) sous réserve de l'article 109, l'adresse du médecin qui a fourni la déclaration médicale à l'appui de l'autorisation de possession visée au paragraphe 108(2).
6.	Paragraphe 109(1)	(1) Si l'adresse d'expédition mentionnée dans la demande d'inscription est celle visée au sous-alinéa 108(1)*f*)(iii), le demandeur joint à sa demande une attestation, signée et datée par le médecin qui a fourni la déclaration médicale à l'appui de l'autorisation de possession visée au paragraphe 108(2), portant que ce médecin consent à recevoir de la marihuana séchée au nom du demandeur.

Item	Column 1 Provision	Column 2 Modified text
7.	**section 110**	**110. (1) A licensed producer who receives an application under section 108 and intends to register the applicant as a client must communicate with the Minister to confirm the date of issue and date of expiry of the authorization to possess and, if applicable, the reference date indicated on the authorization and to confirm that the authorization has not been revoked.** **(2) If the licensed producer registers the applicant as a client, the licensed producer must immediately notify the Minister in writing of the registration and the date of the registration, and provide the Minister with a copy of the authorization to possess.**
8.	**section 112**	**112. A client's registration expires at the earlier of** **(*a*) the date that is one year after the date of issue of the authorization to possess supporting the registration, and** **(*b*) either** **(i) the reference date indicated on that authorization, or** **(ii) the date of expiry of that authorization, if that authorization has no reference date.**
9.	**paragraphs 113(*d*) to (*f*)**	**(*d*) the registration would begin after the reference date indicated on the authorization to possess submitted with the application;** **(*d.1*) in a case in which the authorization to possess has no reference date, the authorization has expired;** **(*e*) the name or date of birth of the applicant is different from the name or date of birth that appears on the authorization to possess;** **(*f*) the Minister informs the licensed producer that the authorization to possess has been or will be revoked; or**
10.	**paragraphs 117(1)(*d*) and (*e*)**	**(*d*) the Minister informs the licensed producer in writing that the medical practitioner named in the authorization to possess supporting the client's registration with the licensed producer has advised the Minister in writing that the continued use of dried marihuana by the client is no longer supported for clinical reasons; or** **(*e*) the medical practitioner named in the authorization to possess is named in a notice issued under section 59 of the *Narcotic Control Regulations* that has not been retracted under section 60 of those Regulations.**

Article	Colonne 1 Disposition	Colonne 2 Texte modifié
7.	**Article 110**	**110. (1) Le producteur autorisé qui reçoit la demande visée à l'article 108 et qui entend inscrire le demandeur comme client communique avec le ministre afin de confirmer la date de délivrance et la date d'expiration de l'autorisation de possession et, le cas échéant, la date de référence qui est indiquée dans l'autorisation, afin de confirmer que cette autorisation n'a pas été révoquée.** **(2) Le producteur autorisé qui procède à l'inscription du demandeur en avise sans délai le ministre par écrit, en précisant la date de l'inscription, et lui fournit une copie de l'autorisation de possession.**
8.	**Article 112**	**112. L'inscription du client expire à celle des dates ci-après qui est antérieure à l'autre :** ***a*) la date qui suit d'un an la date de délivrance de l'autorisation de possession à l'appui de l'inscription;** ***b*) selon le cas :** **(i) la date de référence indiquée dans l'autorisation,** **(ii) la date d'expiration de l'autorisation si celle-ci ne porte pas de date de référence.**
9.	**Alinéas 113*d*) à *f*)**	***d*) l'inscription du client débuterait à une date postérieure à la date de référence indiquée dans l'autorisation de possession jointe à la demande d'inscription;** ***d.1*) l'autorisation de possession ne portant pas de date de référence est expirée;** ***e*) le nom ou la date de naissance du demandeur diffèrent du nom ou de la date de naissance indiqués dans l'autorisation de possession;** ***f*) le ministre avise le producteur autorisé que l'autorisation de possession a été ou sera révoquée;**

Item	Column 1 Provision	Column 2 Modified text
11.	subsection 124(1)	(1) A licensed producer must not sell or provide to a client in any 30-day period a total quantity of dried marihuana that exceeds the maximum quantity specified in the authorization to possess supporting the client's registration.

Article	Colonne 1 Disposition	Colonne 2 Texte modifié
10.	Alinéas 117(1)*d*) et *e*)	*d*) le médecin nommé dans l'autorisation de possession à l'appui de l'inscription du client auprès du producteur autorisé avise le ministre par écrit que l'usage continu de la marihuana séchée n'est plus soutenu cliniquement pour ce client, et le ministre en avise le producteur autorisé par écrit; *e*) le médecin nommé dans l'autorisation de possession est nommé dans un avis donné en vertu de l'article 59 du *Règlement sur les stupéfiants* n'ayant pas fait l'objet d'une rétractation en vertu de l'article 60 de ce règlement.
11.	Paragraphe 124(1)	(1) Le producteur autorisé ne peut vendre ou fournir au client, au cours de toute période de trente jours, une quantité totale de marihuana séchée qui excède la quantité maximale indiquée dans l'autorisation de possession à l'appui de l'inscription de ce client.

Registration Based on a Medical Declaration

Applicable period

257. Sections 258 and 259 apply until March 31, 2014.

Registration based on medical declaration

258. For the purpose of subsection 108(2), an individual applying to become a client of a licensed producer may include a medical declaration with the application instead of a medical document.

Modified application of Regulations

259. If, in accordance with section 258, a registration application under section 108 is made on the basis of a medical declaration, the provisions of these Regulations, other than paragraph 110(*a*) and section 129, apply with the following modifications:

(*a*) a reference in sections 1 to 150 to a "medical document" is to be read as a reference to a medical declaration, except in the case of

Inscription sur le fondement d'une déclaration médicale

Période applicable

257. Les articles 258 et 259 s'appliquent jusqu'au 31 mars 2014.

Inscription sur le fondement d'une déclaration médicale

258. Pour l'application du paragraphe 108(2), la personne physique qui présente une demande d'inscription à un producteur autorisé peut joindre à celle-ci une déclaration médicale au lieu d'un document médical.

Application modifiée du Règlement

259. Lorsque, aux termes de l'article 258, la demande d'inscription visée à l'article 108 est présentée sur le fondement d'une déclaration médicale, les dispositions du présent règlement, à l'exception de l'alinéa 110*a*) et de l'article 129, s'appliquent avec les adaptations suivantes :

***a*) la mention de « document médical » aux articles 1 à 150 vaut mention de la déclaration médicale, sauf aux endroits suivants :**

(i) the definition "medical document" in subsection 1(1),

(ii) paragraph 128(1)(*b*), and

(iii) a provision referred to in paragraph (*b*); and

(*b*) a provision that is referred to in column 1 of the table to this section is to be read as set out in column 2.

TABLE

Item	Column 1 Provision	Column 2 Modified text
1.	paragraph 5(*a*)	(*a*) in the case of dried marihuana obtained from a licensed producer in accordance with a medical declaration, 30 times the daily amount specified in the medical declaration;
2.	subparagraph 67(*a*)(ii)	(ii) the name of the medical practitioner who made the client's medical declaration,
3.	section 112	112. (1) A client's registration expires at the earlier of (*a*) the day that is one year after the day on which the medical declaration supporting the registration was signed by the medical practitioner, and (*b*) if applicable, the day on which the period of usage specified in the medical declaration expires. (2) For the purpose of paragraph (1)(*b*), the period of usage begins on the day on which the medical declaration was signed by the medical practitioner.
4.	paragraphs 113(*d*) to (*f*)	(*d*) more than one year has elapsed since the day on which the medical declaration submitted with the application was signed by the medical practitioner; (*d.1*) if applicable, the period of usage specified in the medical declaration has expired, with that period being deemed to have commenced on the day on which the medical declaration was signed by the medical practitioner; (*e*) the name or date of birth of the applicant is different from the name or date of birth that appears on the medical declaration; (*f*) the medical practitioner who made the medical declaration informs the licensed producer in writing that the use of dried marihuana by the applicant is no longer supported for clinical reasons; or

(i) la définition de « document médical » au paragraphe 1(1),

(ii) l'alinéa 128(1)*b*),

(iii) la disposition visée à l'alinéa *b*);

***b*) la disposition visée à la colonne 1 du tableau du présent article porte le texte modifié visé à la colonne 2.**

TABLEAU

Article	Colonne 1 Disposition	Colonne 2 Texte modifié
1.	Alinéa 5*a*)	*a*) dans le cas de celle obtenue d'un producteur autorisé sur le fondement d'une déclaration médicale, trente fois la quantité quotidienne indiquée dans cette dernière;
2.	Sous-alinéa 67*a*)(ii)	(ii) le nom du médecin qui a fourni la déclaration médicale au client,
3.	Article 112	112. (1) L'inscription du client expire à celle des dates ci-après qui est antérieure à l'autre : *a*) la date qui suit d'un an la date à laquelle la déclaration médicale à l'appui de son inscription a été signée par le médecin; *b*) le cas échéant, à l'expiration de la période d'usage indiquée dans la déclaration médicale. (2) Pour l'application de l'alinéa (1)*b*), la période d'usage débute à la date à laquelle la déclaration médicale a été signée par le médecin.

Item	Column 1 Provision	Column 2 Modified text
5.	subsection 124(1)	(1) A licensed producer must not sell or provide to a client or an individual who is responsible for the client in any 30-day period a total quantity of dried marihuana that exceeds 30 times the daily amount specified in the medical declaration supporting the client's registration.

Article	Colonne 1 Disposition	Colonne 2 Texte modifié
4.	Alinéas 113*d*) à *f*)	*d*) il s'est écoulé plus d'un an depuis la date à laquelle la déclaration médicale jointe à la demande a été signée par le médecin; *d.1*) le cas échéant, la période d'usage indiquée dans la déclaration médicale est expirée, cette période étant réputée avoir débuté à la date à laquelle la déclaration médicale a été signée par le médecin; *e*) le nom ou la date de naissance du demandeur diffèrent du nom ou de la date de naissance indiqués dans la déclaration médicale; *f*) le médecin qui a fourni la déclaration médicale au demandeur avise le producteur autorisé, par écrit, que l'usage de la marihuana séchée n'est plus soutenu cliniquement pour cette personne;
5.	Paragraphe 124(1)	(1) Le producteur autorisé ne peut vendre ou fournir au client ou à une personne physique responsable de ce dernier, au cours de toute période de trente jours, une quantité totale de marihuana séchée qui excède trente fois la quantité quotidienne indiquée dans la déclaration médicale à l'appui de l'inscription de ce client.

Sale or Provision of Marihuana to Licensed Producer

Applicable period

260. Sections 261 to 266 apply until March 31, 2014.

Sale or Provision by Holder of a Personal-use Production Licence

Authorized sale

261. The holder of a personal-use production licence may sell or provide marihuana plants or seeds to a licensed producer if the holder does so in accordance with a notice of authorization issued by the Minister under subsection 263(2).

Application for authorization

262. (1) The holder of a personal-use production licence who proposes to sell or provide marihuana plants or seeds to

Vente ou fourniture de marihuana à un producteur autorisé

Période applicable

260. Les articles 261 à 266 s'appliquent jusqu'au 31 mars 2014.

Vente ou fourniture par le titulaire d'une licence de production à des fins personnelles

Ventes autorisées

261. Le titulaire d'une licence de production à des fins personnelles peut vendre ou fournir des plants ou des graines de marihuana à un producteur autorisé s'il le fait conformément à l'avis d'autorisation donné par le ministre en application du paragraphe 263(2).

Demande d'autorisation

262. (1) Le titulaire d'une licence de production à des fins personnelles qui entend vendre ou fournir des plants ou

a licensed producer must submit to the Minister an application for authorization of the proposed sale or provision that contains the following information:

(*a*) in respect of the holder of the personal-use production licence:

(i) their name and date of birth,

(ii) the number of their licence,

(iii) the address of the place where they ordinarily reside, and

(iv) the address of the site where the production of marihuana is authorized;

(*b*) in respect of the licensed producer:

(i) their name,

(ii) the number of their licence,

(iii) the address of their site, and

(iv) the name of their senior person in charge; and

(*c*) a description of the marihuana plants or seeds that are to be sold or provided and their quantity.

Signature

(2) The application must be signed and dated by the holder of the personal-use production licence and by the licensed producer's senior person in charge and include a statement by each of them indicating that all of the information submitted in support of the application is correct and complete to the best of that person's knowledge.

Verification by Minister

263. (1) The Minister must, after examining the application and information required under section 262, verify if the following conditions are met:

des graines de marihuana à un producteur autorisé présente au ministre une demande d'autorisation de la vente ou de la fourniture proposée qui comporte les renseignements suivants :

***a*) s'agissant du titulaire de la licence de production à des fins personnelles :**

(i) ses nom et date de naissance,

(ii) le numéro de sa licence,

(iii) l'adresse de son lieu de résidence habituelle,

(iv) l'adresse du lieu où la production de marihuana est autorisée;

***b*) s'agissant du producteur autorisé :**

(i) son nom,

(ii) le numéro de sa licence,

(iii) l'adresse de son installation,

(iv) le nom de son responsable principal;

***c*) la description des plants ou des graines de marihuana qui seront vendus ou fournis, ainsi que leur quantité.**

Signature

(2) La demande est signée et datée par le titulaire de la licence de production à des fins personnelles et par le responsable principal du producteur autorisé et comprend une attestation de chacun de ces derniers portant qu'à leur connaissance, tous les renseignements fournis à l'appui de la demande sont exacts et complets.

Vérifications par le ministre

263. (1) Le ministre, après examen de la demande et des renseignements visés à l'article 262, vérifie que les conditions ci-après sont respectées :

(*a*) the personal-use production licence and the licensed producer's licence are valid; and

(*b*) the number of marihuana plants to be sold or provided, if any, does not exceed the maximum number of plants specified in the personal-use production licence.

a) la licence de production à des fins personnelles et la licence du producteur autorisé sont valides;

b) le cas échéant, le nombre de plants de marihuana qui seront vendus ou fournis n'excède pas le nombre maximal de plants indiqué dans la licence de production à des fins personnelles.

Notice of authorization

(2) If the conditions are met, the Minister must send to both parties a notice of authorization of the proposed sale or provision that

(*a*) specifies the names of the parties, the type of licence held by each party and the licence numbers;

(*b*) describes the marihuana plants or seeds that are to be sold or provided and their quantity;

(*c*) specifies that the notice is valid only for the sale or provision in respect of which it is issued;

(*d*) specifies that the notice is valid only if the licences referred to paragraph (1)(*a*) are valid at the time of the sale or provision; and

(*e*) specifies that the sale or provision must be completed not later than 30 days after the date of the notice.

Avis d'autorisation

(2) Si les conditions sont respectées, le ministre envoie aux deux parties un avis autorisant la vente ou la fourniture proposée et comportant les renseignements suivants :

a) le nom des parties, le type de licence que chaque partie détient et le numéro de chaque licence en cause;

b) la description des plants ou des graines de marihuana qui seront vendus ou fournis, ainsi que leur quantité;

c) la mention que l'avis n'est valide que pour la vente ou la fourniture pour laquelle il a été donné;

d) la mention que l'avis n'est valide que si les licences visées à l'alinéa (1)*a*) sont valides au moment de la vente ou de la fourniture;

e) la mention que la vente ou la fourniture doit être effectuée dans les trente jours suivant la date de l'avis.

Notice of refusal

(3) If the conditions are not met, the Minister must send to each of the parties a notice of refusal of the proposed sale or provision that sets out the reasons for the refusal.

Avis de refus

(3) Si les conditions ne sont pas respectées, il leur envoie un avis de refus de la vente ou de la fourniture proposée et il donne les motifs du refus.

Opportunity to be heard

(4) The parties may, within 10 days after the receipt of a notice of refusal, provide the Minister with reasons why the refusal is unfounded.

Possibilité de se faire entendre

(4) Les parties, dans les dix jours qui suivent la réception de l'avis, peuvent présenter au ministre les motifs pour lesquels le refus n'est pas fondé.

Sale or Provision by Holder of a Designated-person Production Licence

Authorized sale

264. The holder of a designated-person production licence may sell or provide marihuana plants or seeds to a licensed producer if the holder does so in accordance with a notice of authorization issued by the Minister under subsection 266(2).

Application for authorization

265. (1) The holder of a designated-person production licence who proposes to sell or provide marihuana plants or seeds to a licensed producer must submit to the Minister an application for authorization of the proposed sale or provision that contains the following information:

(*a*) in respect of the holder of the designated-person production licence:

(i) their name and date of birth,

(ii) the number of their licence,

(iii) the address of the place where they ordinarily reside, and

(iv) the address of the site where the production of marihuana is authorized;

(*b*) in respect of the holder of the authorization to possess on the basis of which the designated-person production licence was issued:

(i) their name and date of birth,

(ii) the number of their authorization,

(iii) the address of the place where they ordinarily reside, and

(iv) an indication that they consent to the proposed sale or provision;

Vente ou fourniture par le titulaire d'une licence de production à titre de personne désignée

Ventes autorisées

264. Le titulaire d'une licence de production à titre de personne désignée peut vendre ou fournir des plants ou des graines de marihuana à un producteur autorisé s'il le fait conformément à l'avis d'autorisation donné par le ministre en application du paragraphe 266(2).

Demande d'autorisation

265. (1) Le titulaire d'une licence de production à titre de personne désignée qui entend vendre ou fournir des plants ou des graines de marihuana à un producteur autorisé présente au ministre une demande d'autorisation de la vente ou de la fourniture proposée qui comporte les renseignements suivants :

***a*) s'agissant du titulaire de la licence de production à titre de personne désignée :**

(i) ses nom et date de naissance,

(ii) le numéro de sa licence,

(iii) l'adresse de son lieu de résidence habituelle,

(iv) l'adresse du lieu où la production de marihuana est autorisée;

***b*) s'agissant du titulaire de l'autorisation de possession sur le fondement de laquelle la licence de production à titre de personne désignée a été délivrée :**

(i) ses nom et date de naissance,

(ii) le numéro de son autorisation,

(iii) l'adresse de son lieu de résidence habituelle,

(iv) la mention qu'il consent à la vente ou à la fourniture proposée;

(*c*) in regard to the licensed producer:

(i) their name,

(ii) the number of their licence,

(iii) the address of their site, and

(iv) the name of their senior person in charge; and

(*d*) a description of the marihuana plants or seeds that are to be sold or provided and their quantity.

Signature

(2) The application must be signed and dated by the holder of the designated-person production licence, the holder of the authorization to possess and the licensed producer's senior person in charge and include a statement by each of them indicating that all of the information submitted in support of the application is correct and complete to the best of that person's knowledge.

Separate applications

(3) If a person is the holder of more than one designated-person production licence and proposes to sell or provide marihuana plants or seeds produced under each of those licences, a separate application must be submitted in respect of each licence.

Verification by Minister

266. (1) The Minister must, after examining the application and information required under section 265, verify if the following conditions are met:

(*a*) the designated-person production licence, the authorization to possess and the licensed producer's licence are valid;

(*b*) the designated-person production licence was issued on the basis of the authorization to possess;

***c*) s'agissant du producteur autorisé :**

(i) son nom,

(ii) le numéro de sa licence,

(iii) l'adresse de son installation,

(iv) le nom de son responsable principal;

***d*) la description des plants ou des graines de marihuana qui seront vendus ou fournis, ainsi que leur quantité.**

Signature

(2) La demande d'autorisation est signée et datée par le titulaire de la licence de production à titre de personne désignée, le titulaire de l'autorisation de possession et le responsable principal du producteur autorisé et comprend une attestation de chacun d'eux portant qu'à leur connaissance, tous les renseignements fournis à l'appui de la demande sont exacts et complets.

Demandes distinctes

(3) Lorsqu'une personne est titulaire de plus d'une licence de production à titre de personne désignée et qu'elle entend vendre ou fournir des plants ou des graines de marihuana produits au titre de chacune des licences qu'elle détient, une demande distincte doit être présentée pour chaque licence.

Vérifications par le ministre

266. (1) Le ministre, après examen de la demande et des renseignements visés à l'article 265, vérifie que les conditions ci-après sont respectées :

***a*) la licence de production à titre de personne désignée, l'autorisation de possession et la licence du producteur autorisé sont valides;**

***b*) la licence de production à titre de personne désignée a été délivrée sur le fondement de l'autorisation de possession;**

(*c*) the holder of the authorization to possess has signed the application; and

(*d*) the number of marihuana plants to be sold or provided, if any, does not exceed the maximum number of plants specified in the designated-person production licence.

Notice of authorization

(2) If the conditions are met, the Minister must send to the holder of the designated-person production licence, the holder of the authorization to possess and the licensed producer a notice of authorization of the proposed sale or provision that

(*a*) specifies the names of those persons, the type of licence or authorization held by each person and the numbers of the licences and the authorization;

(*b*) describes the marihuana plants or seeds that are to be sold or provided and their quantity;

(*c*) specifies that the notice is valid only for the sale or provision in respect of which it is issued;

(*d*) specifies that the notice is valid only if the licences referred to paragraph (1)(*a*) are valid at the time of the sale or provision; and

(*e*) specifies that the sale or provision must be completed not later than 30 days after the date of the notice.

Notice of refusal

(3) If the conditions are not met, the Minister must send to each of the persons referred to in subsection (2) a notice of refusal of the proposed sale or

***c*) le titulaire de l'autorisation de possession a signé la demande;**

***d*) le cas échéant, le nombre de plants de marihuana qui seront vendus ou fournis n'excède pas le nombre maximal de plants indiqué dans la licence de production à titre de personne désignée.**

Avis d'autorisation

(2) Si les conditions sont respectées, le ministre envoie au titulaire de la licence de production à titre de personne désignée, au titulaire de l'autorisation de possession et au producteur autorisé un avis autorisant la vente ou la fourniture proposée et comportant les renseignements suivants :

***a*) le nom des destinataires de l'avis, le type de licence ou d'autorisation que chacun d'entre eux détient et le numéro de chaque licence ou autorisation en cause;**

***b*) la description des plants ou des graines de marihuana qui seront vendus ou fournis, ainsi que leur quantité;**

***c*) la mention que l'avis n'est valide que pour la vente ou la fourniture pour laquelle il a été donné;**

***d*) la mention que l'avis n'est valide que si les licences visées à l'alinéa (1)*a*) sont valides au moment de la vente ou de la fourniture;**

***e*) la mention que la vente ou la fourniture doit être effectuée dans les trente jours suivant la date de l'avis.**

Avis de refus

(3) Si les conditions ne sont pas respectées, il leur envoie un avis de refus de la vente ou de la fourniture proposée et il donne les motifs du refus.

provision that sets out the reasons for the refusal.

Opportunity to be heard

(4) The recipients of a notice of refusal may, within 10 days after the receipt of the notice, provide the Minister with reasons why the refusal is unfounded.

Possibilité de se faire entendre

(4) Les destinataires de l'avis de refus peuvent, dans les dix jours qui suivent la réception de l'avis, présenter au ministre les motifs pour lesquels le refus n'est pas fondé.

Repeal

267. [Repeal]

Abrogation

267. [Abrogation]

Coming into Force

Registration

268. (1) Subject to subsections (2) to (4), these Regulations come into force on the day on which they are registered.

Enregistrement

268. (1) Sous réserve des paragraphes (2) à (4), le présent règlement entre en vigueur à la date de son enregistrement.

October 1, 2013

(2) Section 244 comes into force on October 1, 2013.

1er octobre 2013

(2) L'article 244 entre en vigueur le 1er octobre 2013.

March 31, 2014

(3) Subsections 203(2), 217(2), 221(3) and 222(3) and section 267 come into force on March 31, 2014.

31 mars 2014

(3) Les paragraphes 203(2), 217(2), 221(3) et 222(3) et l'article 267 entrent en vigueur le 31 mars 2014.

March 31, 2015

(4) Subsections 221(4) and 222(4) come into force on March 31, 2015.

31 mars 2015

(4) Les paragraphes 221(4) et 222(4) entrent en vigueur le 31 mars 2015.

October 1, 2013 **(2) Section 244 comes into force on October 1, 2013.**

March 31, 2014 **(3) Subsections 203(2), 217(2), 221(3) and 222(3) and section 267 come into force on March 31, 2014.**

March 31, 2015 **(4) Subsections 221(4) and 222(4) come into force on March 31, 2015.**

1er octobre 2013 **(2) L'article 244 entre en vigueur le 1er octobre 2013.**

31 mars 2014 **(3) Les paragraphes 203(2), 217(2), 221(3) et 222(3) et l'article 267 entrent en vigueur le 31 mars 2014.**

31 mars 2015 **(4) Les paragraphes 221(4) et 222(4) entrent en vigueur le 31 mars 2015.**

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the regulations.)

Executive summary

Issues: In 2001, the *Marihuana Medical Access Regulations* (MMAR) were promulgated. The MMAR set out a scheme for Canadians to access marihuana for medical purposes, if they have the support of a medical practitioner.

Over the years, stakeholders expressed various concerns about the Marihuana Medical Access Program (the Program or MMAP). Program participants generally disliked the application process, and the fact that only a single strain of marihuana was available for purchase from Health Canada. Other stakeholders expressed health, safety, and security concerns relating to the production of marihuana by individuals in homes and communities. Their specific concerns related to the potential for diversion of marihuana to the illicit market due to limited security requirements, the risk of violent home invasion by criminals attempting to steal marihuana, fire hazards due to faulty or overloaded electricity installation to accommodate high intensity lighting for its cultivation, and humidity and poor air quality. Individual producers who were ill may have been more vulnerable to health risks associated with mould. As more individuals received licences to produce marihuana for medical purposes, the overall risk to Canadians increased.

Rapid growth in the number of authorized users also had significant implications for the administration of the Program, leading sometimes to long application processing times and higher Program administration costs for Health Canada. Finally, over the years, Canadian courts found various parts of the MMAR to be invalid, resulting in changes that affected program delivery.

Description: The *Marihuana for Medical Purposes Regulations* (MMPR, or the Regulations) will treat dried marihuana as much as possible like other narcotics used for medical purposes by creating a licensing scheme for the commercial production and distribution of dried marihuana for medical purposes. The MMPR will modify the *New Classes of Practitioner Regulations* (NCPR) and the *Narcotic Control Regulations* (NCR) and eventually repeal the MMAR. At the same time, changes to the *Marihuana Exemption (Food and Drugs Act) Regulations* (MER) will also be made. Health Canada will no longer issue

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(Ce résumé ne fait pas partie des règlements.)

Résumé

Enjeux : En 2001, le *Règlement sur l'accès à la marihuana à des fins médicales* (RAMM) est entré en vigueur. Le RAMM établit un cadre pour que les Canadiens aient accès à la marihuana à des fins médicales, s'ils ont l'appui d'un médecin.

Au cours des années, les intervenants ont soulevé diverses préoccupations au sujet du Programme d'accès à la marihuana à des fins médicales (le Programme ou PAMM). De façon générale, les participants au Programme n'ont pas apprécié le processus de demande, ainsi que le fait que Santé Canada n'offrait qu'une seule souche de marihuana. D'autres parties intéressées ont exprimé des inquiétudes sur le plan de la santé et de la sécurité en ce qui concerne la production de marihuana par des personnes dans des résidences et dans les collectivités. Leurs principales préoccupations avaient trait à la possibilité de détournement vers le marché clandestin de la marihuana en raison des exigences limitées sur le plan de la sécurité, du risque de braquage violent à domicile par des criminels qui tenteraient de s'emparer de la marihuana, du risque d'incendie causé par des installations électriques mal branchées ou surchargées afin d'assurer un éclairage intense pour la culture de la marihuana, ainsi que de l'humidité et la mauvaise qualité de l'air. Les producteurs particuliers qui étaient malades étaient peut-être plus vulnérables aux risques pour la santé liés à la moisissure. Puisque le nombre de particuliers ayant obtenu une licence pour produire de la marihuana à des fins médicales a augmenté, le risque global a aussi augmenté pour les Canadiens.

La croissance rapide du nombre d'utilisateurs autorisés a aussi eu d'importantes incidences sur l'administration du Programme qui ont parfois occasionné de longs temps de traitement des demandes et des coûts accrus liés à l'administration pour Santé Canada. Enfin, au fil des ans, les tribunaux canadiens ont déterminé que plusieurs parties du RAMM étaient invalides, ce qui a entraîné des modifications qui ont eu des répercussions sur l'exécution du Programme.

Description : Le *Règlement sur la marihuana à des fins médicales* (RMFM), ou le Règlement, traitera la marihuana séchée autant que possible comme les autres stupéfiants utilisés à des fins médicales en élaborant un cadre d'homologation pour la production et la distribution commerciales de la marihuana séchée à des fins médicales. Le RMFM modifiera le *Règlement sur les nouvelles catégories de praticiens* (RNCP), le *Règlement sur les stupéfiants* (RS) et, à terme, abrogerait le RAMM. En parallèle, des changements au *Règlement d'exemption de la marihuana (Loi sur les aliments et drogues)* [REM]

authorizations to possess marihuana for medical purposes to individuals. This is expected to make accessing marihuana for medical purposes more efficient for individuals. It will also give them more options with respect to obtaining the support of an authorized health care practitioner, more choices of strains and suppliers, and provide increased access to quality-controlled marihuana. This, as well as ending Health Canada's role in the production and supply of marihuana, will also reduce the cost of running the Program.

Following a transition period, individuals will no longer be licensed to produce marihuana, an activity which often occurs in homes. This will address the public health, safety and security concerns raised by stakeholders.

The MMPR will authorize three key activities: the possession of dried marihuana for medical purposes by individuals who have the support of an authorized health care practitioner; the production of dried marihuana by licensed producers; and the sale and distribution of dried marihuana by licensed producers and hospitals to individuals who can possess it. Licensed producers will be subject to regulatory requirements related to security; good production practices; packaging, labelling and shipping; record keeping and reporting; and distribution. They will also be subject to Health Canada inspections.

Upon coming into force, the MMPR will allow the holder of an authorization to possess or an individual who had obtained a medical declaration from their medical practitioner under the MMAR to obtain their supply of marihuana from a licensed producer by registering as a client with that producer. The MMAR will be repealed on March 31, 2014. All authorizations and licences issued under the MMAR will no longer be valid after this date. However, individuals will be able to use their expired authorizations to possess to register as a client with a licensed producer for up to one year after their date of issue, unless a period of usage of less than 12 months had been indicated in the medical declaration. No new Personal Use Production Licences (PUPLs) and Designated-Person Production Licences (DPPLs) will be issued if the application is submitted after September 30, 2013. Similarly, existing PUPL and DPPL holders will not be able to apply to change the location of their production site or to increase the daily amount as of this date.

Cost-benefit statement: The main economic cost associated with the MMPR will arise from the loss to consumers who may have to pay a higher price for dried marihuana. The analysis assumes a price increase from an estimated $1.80/g to $5.00/g in the status quo to about $7.60/g in 2014, rising to about $8.80/g, with a corresponding average annualized loss to consumers (in consumer surplus terms) due to higher prices of approximately –$166.1M per year for 10 years. The major benefits of the MMPR are projected to include reduction in safety and security risks posed by marihuana cultivation in homes, reduction in Program administrative costs, and benefit to producers due to a higher market price and a reduction in economic inefficiency from the removal of government subsidies on marihuana sold by Health Canada. On average, the

seront également apportés. Santé Canada n'accordera plus d'autorisation de posséder de la marihuana à des fins médicales aux particuliers. Il est prévu que cela améliorera l'efficacité de l'accès à la marihuana à des fins médicales pour les personnes physiques. Ils se verront également offrir davantage d'options pour l'obtention de l'appui d'un praticien de la santé autorisé, de même qu'un plus grand choix de souches et de fournisseurs, et un plus grand contrôle de la qualité de la marihuana serait effectué. En plus de mettre fin au rôle de Santé Canada dans la production et l'approvisionnement de marihuana, cela réduira également les coûts liés à l'exécution du Programme.

À la suite d'une période de transition, les particuliers n'obtiendront plus de licence pour la production de marihuana, une activité qui se pratique souvent dans leur résidence. Cela réglera les préoccupations soulevées par les intervenants sur le plan de la santé et de la sécurité publiques.

Le RMFM autorisera trois activités clés : la possession de marihuana séchée à des fins médicales par des particuliers qui ont l'appui d'un praticien de la santé autorisé, la production de marihuana séchée par des producteurs autorisés, ainsi que la vente et la distribution de la marihuana séchée par des producteurs autorisés et les hôpitaux aux particuliers qui peuvent en posséder. Les producteurs autorisés seront assujettis à des exigences réglementaires liées à la sécurité, aux pratiques de production adéquates, à l'emballage, à l'étiquetage et à l'expédition, à la tenue de dossiers et à l'établissement de rapports, de même qu'à la distribution. Ils feront également l'objet d'inspections menées par Santé Canada.

À son entrée en vigueur, le RMFM permettra au titulaire d'une autorisation de possession ou à un particulier ayant obtenu une déclaration médicale de son praticien en vertu du RAMM d'obtenir son approvisionnement de marihuana auprès d'un producteur autorisé en s'inscrivant en tant que client auprès de ce producteur. Le RAMM sera abrogé le 31 mars 2014. L'ensemble des autorisations et des licences émises en vertu du RAMM seront invalides après cette date. Toutefois, les particuliers pourront utiliser leur autorisation de possession expirée pour s'inscrire comme client auprès d'un producteur autorisé jusqu'à un an après sa date d'émission, à moins qu'une période d'utilisation de moins de 12 mois ait été précisée dans la déclaration médicale. Aucune nouvelle licence de production à des fins personnelles (LPFP) et licence de production à titre de personne désignée (LPPD) ne sera émise si l'application est présentée après le 30 septembre 2013. Dans le même sens, à partir de cette date, les titulaires actuels d'une LPFP et d'une LPPD ne pourront plus demander de changer l'emplacement de leur installation de production ou d'augmenter la quantité quotidienne.

Énoncé des coûts et avantages : Le principal coût lié au RMFM proviendra de la perte pour les consommateurs qui pourraient devoir payer un prix plus élevé pour la marihuana séchée. L'analyse suppose une augmentation du prix actuel de 1,80 $ à 5,00 $ le gramme, dans le cas du statu quo, à environ 7,60 $ le gramme en 2014, pour atteindre environ 8,80 $ le gramme, avec une perte moyenne correspondante calculée sur une année pour les consommateurs (en termes de surplus du consommateur), attribuable à l'augmentation du prix, d'approximativement –166,1 millions de dollars par année pendant 10 ans. Les principaux avantages du RMFM sont projetés en vue d'inclure une réduction des risques pour la sécurité qu'entraîne la culture de la marihuana dans des résidences, une réduction des coûts administratifs du Programme, des bénéfices pour

estimated total annualized benefit is $149.8M per year. Consequently, the quantitative analysis indicated an overall discounted net loss of –$109.7M for the first 10 years of the MMPR (2014 to 2024) or, an annualized average value of approximately –$16.35M a year.

Given the unique nature of the Regulations and the need to make assumptions about some aspects of what, until now, has been an illicit market with the exception of the supply produced under licences to produce, and under contract with Health Canada, the quantitative analysis was supplemented by a comprehensive qualitative evaluation of potential benefits which could not be quantified or monetized. These were considered highly contingent on a number of economic, social and regulatory factors which have been factored into the Program evaluation, but which may not emerge until near the end of, or after, the 10-year projection period for the quantified cost-benefit analysis (CBA). The qualitative analysis, however, showed that these benefits are likely to be significant. Further details can be found in the "Non-quantified benefits" section of this document.

"One-for-One" Rule: Canadian courts have determined that, under the *Canadian Charter of Rights and Freedoms*, individuals who have demonstrated a medical need for marihuana have a right to reasonable access to a legal source of marihuana for medical purposes. At the same time, marihuana is a controlled substance for which there is considerable risk of diversion to the illicit market. Thus, there is a need to ensure that sites which produce marihuana for medical purposes are secure and have secure distribution methods. Hence, while it is recognized that the MMPR will impose administrative burden on business, it is also recognized that the unique and exceptional circumstances, in combination with the findings of Canadian courts that individuals who need marihuana for medical purposes have a right to reasonable access to a legal source of marihuana under the Charter, merit an exemption from the "One-for-One" Rule. Health Canada will not be required to offset the burden associated with this proposal with an equivalent reduction in administrative burden.

Domestic and international coordination and cooperation: The MMPR is consistent with Canada's international trade obligations, as well as its commitment to maintain control over the production and distribution of marihuana, as required by international conventions on the control of narcotic drugs and psychotropic substances. In addition, Health Canada notified the United States Drug Enforcement Administration that a new program was under consideration in which individuals would no longer be licensed to produce their own marihuana and licensed producers would be the only legal source of marihuana supply. Federally, the MMPR establish new requirements that are consistent with Health Canada's responsibility to regulate activities with controlled substances. The Regulations take provincial/territorial jurisdiction into consideration, particularly concerning issues such as establishing requirements for local businesses and the delivery of health services.

les producteurs en raison d'un prix plus élevé sur le marché, ainsi qu'une réduction de l'inefficience économique à la suite du retrait des subventions du gouvernement sur la marihuana vendue par Santé Canada. En moyenne, le bénéfice total évalué sur une année est de 149,8 millions de dollars par année. Par conséquent, l'analyse quantitative indiquait une perte globale actualisée de –109,7 millions de dollars pour les 10 premières années du RMFM (2014 à 2024) ou, une valeur moyenne sur une année d'environ –16,35 millions de dollars par année.

Étant donné la nature unique du Règlement et la nécessité de formuler des hypothèses au sujet de certains aspects de ce qui a été un marché illicite jusqu'à maintenant, à l'exception de l'approvisionnement produit dans le cadre de licences de production et dans le cadre d'un marché avec Santé Canada, l'analyse quantitative a été complémentée d'une évaluation qualitative exhaustive des avantages potentiels qui ne pouvaient pas être quantifiés ou monétisés. Il a été considéré que ces avantages dépendaient grandement de certains facteurs économiques, sociaux et réglementaires qui ont été pris en compte dans l'évaluation du Programme, mais qui pourraient ne pas faire surface avant la fin de la période de projection de 10 ans, ou après cette période, pour l'analyse coûts-avantages (ACA). Cependant, l'analyse quantitative a démontré que ces avantages sont probablement importants. On peut trouver plus de détails dans la section « Avantages non quantifiés » de ce document.

Règle du « un pour un » : Les tribunaux canadiens ont déterminé qu'en vertu de la *Charte canadienne des droits et libertés*, les personnes qui ont démontré un besoin médical pour de la marihuana ont le droit d'avoir un accès raisonnable à une source d'approvisionnement légale de marihuana à des fins médicales. En même temps, la marihuana est une substance désignée pour laquelle il existe un risque considérable de détournement vers le marché illicite. Par conséquent, il est nécessaire de veiller à ce que les installations qui produisent la marihuana à des fins médicales soient sécuritaires et aient des méthodes de distribution sécuritaires. Bien qu'il soit reconnu que le RMFM imposera un fardeau administratif aux entreprises, il est également reconnu que les circonstances uniques et exceptionnelles, combinées aux conclusions des tribunaux canadiens que les personnes qui ont besoin de marihuana à des fins médicales ont le droit d'accès raisonnable à une source licite de marihuana en vertu de la Charte, justifient une soustraction à la règle du « un pour un ». Santé Canada n'aura pas à compenser le fardeau lié à cette proposition par une réduction équivalente du fardeau administratif.

Coordination et coopération à l'échelle nationale et internationale : Le RMFM est conforme aux obligations commerciales internationales du Canada, ainsi qu'à son engagement de maintenir un contrôle sur la production et la distribution de la marihuana, tel qu'il est requis par les conventions internationales sur le contrôle des stupéfiants et des substances psychotropes. De plus, Santé Canada a informé la Drug Enforcement Administration des États-Unis qu'un nouveau programme, dans le cadre duquel les particuliers n'obtiendront plus de licence leur permettant de produire leur propre marihuana, était pris en considération et que les producteurs autorisés seront la seule source d'approvisionnement légale de marihuana. Au niveau fédéral, le RMFM établit de nouvelles exigences qui correspondent à la responsabilité de Santé Canada de réglementer les activités qui ont trait aux substances désignées. Le Règlement tient compte des compétences provinciales et territoriales, particulièrement

Performance measurement and evaluation: An evaluation of the MMPR will occur five years after implementation and every five years thereafter. The evaluation will assess the achievement of outcomes of the MMPR along with those of any administrative and program support systems put in place.

Mesures de rendement et évaluation : Une évaluation du RMFM sera effectuée après les cinq premières années de mise en œuvre et tous les cinq ans par la suite. Elle aura pour but d'évaluer l'obtention des résultats du RMFM, ainsi que ceux de tout autre système de soutien administratif et de programme mis en place.

Background

Marihuana for medical purposes is regulated under both the *Controlled Drugs and Substances Act* (CDSA) and the *Food and Drugs Act* (FDA). The CDSA and its regulations provide a legislative framework for the control of substances that can alter mental processes and that may produce harm to the health of an individual and to society when diverted or misused. The legislative framework prohibits the possession, trafficking, production, importation and exportation of controlled substances except where authorized, such as under regulations.

The FDA and its regulations provide a framework to regulate the safety, efficacy and quality of drugs. The *Food and Drug Regulations* (FDR) set out a framework for the authorization of drugs for sale in Canada. Drug manufacturers submit evidence on the efficacy dosage, route of administration, contraindications, side effects, and quality of a drug. If Health Canada reviewers conclude that the overall benefits of the drug outweigh its risks, the product will be authorized for sale in Canada.

There are a number of products containing cannabis which have been authorized for sale under the FDR in Canada. These include

- Sativex®, a buccal spray containing extracts of cannabis with standardized concentrations of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). It is authorized to treat certain symptoms associated with multiple sclerosis. It is also conditionally authorized for pain relief in adults with advanced cancer;
- Marinol®, a capsule containing synthetic THC. It was authorized for the treatment of AIDS-related anorexia, and nausea and vomiting due to cancer chemotherapy, but was discontinued in Canada; and
- Cesamet®, a capsule containing nabilone, a synthetic cannabinoid. It is authorized for the management of nausea and vomiting associated with cancer therapy.

In all of these cases, the manufacturers were required to meet the requirements of the FDA and its regulations in order to sell these products in Canada.

To date, scientific studies do not demonstrate conclusively that dried marihuana is safe and effective for medical use. Most scientific studies to date focus on chemicals sourced from marihuana, not dried marihuana itself. Consequently, dried marihuana has not been authorized as a therapeutic product in Canada or in any other country. However, Canadian courts have found that individuals who need marihuana for medical purposes have a right to reasonable access to a legal source of marihuana. Therefore, production

Contexte

La marihuana à des fins médicales est réglementée par la *Loi réglementant certaines drogues et autres substances* (LRCDAS) et la *Loi sur les aliments et drogues* (LAD). La LRCDAS et ses règlements offrent un cadre législatif pour la réglementation de drogues pouvant modifier les processus mentaux et avoir des effets nocifs pour la santé d'une personne et la société lorsqu'elles sont détournées et utilisées d'une façon malveillante. Le cadre législatif interdit la possession, le trafic, la production, l'importation et l'exportation de substances désignées, sauf lorsque ces activités sont autorisées, par exemple en vertu d'un règlement.

La LAD et ses règlements offrent un cadre visant à réglementer la sécurité, l'efficacité et la qualité des médicaments. Le *Règlement sur les aliments et drogues* (RAD) établit un cadre pour l'autorisation des médicaments pour la vente au Canada. Les fabricants de médicaments présentent la preuve quant à la définition efficace des doses, à la voie d'administration, aux contre-indications, aux effets secondaires et à la qualité d'un médicament. Si la conclusion des examinateurs de Santé Canada est que les avantages globaux du médicament l'emportent sur ses risques, le produit sera autorisé pour la vente au Canada.

Il existe un grand nombre de produits qui contiennent du chanvre indien qui, en vertu du RAD, ont été autorisés pour la vente au Canada. En voici quelques-uns :

- Sativex®, un vaporisateur buccal qui contient des extraits de chanvre indien avec des concentrations normalisées de delta-9-tétrahydrocannabinol (THC) et de cannabidiol (CBD). Il est autorisé pour traiter certains symptômes associés à la sclérose en plaques. Il est également autorisé sous condition pour soulager la douleur chez les adultes qui souffrent d'un cancer avancé;
- Marinol®, une gélule qui contient une forme synthétique du THC. Il a été autorisé pour combattre l'anorexie liée au SIDA ainsi que les nausées et les vomissements attribuables à la chimiothérapie contre le cancer, mais sa distribution a été interrompue au Canada;
- Cesamet®, une gélule qui contient du nabilone, une forme synthétique de cannabinoïde. Il est autorisé pour combattre la nausée et les vomissements associés à la thérapie contre le cancer.

Dans chaque cas, les fabricants devaient respecter les exigences de la LAD et de ses règlements pour vendre ces produits au Canada.

À ce jour, les études scientifiques ne démontrent pas avec certitude que la marihuana séchée est sécuritaire et efficace à des fins médicales. La plupart des études scientifiques menées à ce jour se penchent principalement sur les produits chimiques tirés de la marihuana, et non sur la marihuana séchée en tant que telle. En conséquence, la marihuana séchée n'a pas été autorisée en tant que produit thérapeutique au Canada, ni ailleurs dans le monde. Toutefois, les tribunaux canadiens ont déterminé que les personnes qui

of dried marihuana in the past was exempted from application of the FDA and its regulations with the exception of marihuana sold or imported to be used for the purpose of a clinical trial.

Canadians have been able to access dried marihuana for medical purposes since 1999, when the Marihuana Medical Access Program (the Program) was first established. At the time, individuals were authorized to possess dried marihuana and/or produce a limited number of marihuana plants for medical purposes via the issuance of an exemption under section 56 of the CDSA.

In 2000, the Ontario Court of Appeal (*R. v. Parker*) held that the prohibition on the possession of marihuana violated the right to liberty and security of a person under the Charter, because Mr. Parker could not find a practically available legal route to possess dried marihuana for medical purposes. In response, the MMAR were established in 2001 and set out a scheme by which seriously ill Canadians could, with the support of a medical practitioner, obtain an authorization to possess dried marihuana for their own personal medical use. Under the MMAR, authorized persons had three options to obtain a supply of dried marihuana:

- They could produce their own supply under a Personal Use Production Licence (PUPL);
- They could designate an individual to produce it on their behalf under a Designated Person Production Licence (DPPL); or
- They could purchase dried marihuana from Health Canada, which contracts a private company — Prairie Plant Systems Inc. (PPS) — to produce and distribute marihuana for the Program.[1]

The supply and distribution scheme established by the MMAR was amended several times. In some cases, this was the result of concerns expressed by stakeholders; in others, it was to address Court decisions that invalidated sections of the Regulations, which were found to hinder access.

In 2003, the Ontario Court of Appeal (*Hitzig v. Canada*) held that the MMAR were constitutionally defective because they did not provide for reasonable access to a legal source of supply of marihuana for medical purposes. The Court invalidated five provisions of the MMAR that it found constituted barriers to eligibility and supply but acknowledged that the Government could choose to adopt a fundamentally different approach. The MMAR were amended to give national effect to certain elements of the Court's remedy, and also to implement an option for authorized persons to obtain access to a legal supply of dried marihuana and marihuana seeds. However, the requirements for a medical document and for a daily limit fixed by a medical practitioner were found to be reasonable by the Court.

In 2005, based on a broader review of the MMAR and on input received from stakeholders during a comprehensive consultation

[1] Marihuana produced under contract with Her Majesty in right of Canada or under a DPPL, other than marihuana sold or imported to be used in clinical trials, is exempted from the application of the *Food and Drugs Act* and its regulations.

ont besoin de marihuana à des fins médicales ont le droit d'avoir un accès raisonnable à une source d'approvisionnement légale de marihuana. Par conséquent, dans le passé, la production de la marihuana séchée était exemptée de l'application de la LAD et de ses règlements à l'exception de la marihuana vendue ou importée dans le but d'une utilisation dans des essais cliniques.

Les Canadiens ont été en mesure d'avoir accès à de la marihuana séchée à des fins médicales depuis 1999, lorsque le Programme a été établi. Les particuliers étaient alors autorisés à avoir en leur possession de la marihuana séchée et/ou de cultiver un nombre limité de plants de marihuana à des fins médicales, grâce à l'octroi d'exemptions en vertu de l'article 56 de la LRCDAS.

En 2000, la Cour d'appel de l'Ontario (*R. c. Parker*) a décidé que l'interdiction de possession de marihuana enfreignait le droit à la liberté et à la sécurité de la personne, en vertu de la Charte, puisque M. Parker n'avait pas la possibilité de trouver un moyen pratique et légal d'avoir en sa possession de la marihuana séchée à des fins médicales. En réponse à cette décision, le RAMM a été établi en 2001 et met en place un moyen par lequel tout Canadien et toute Canadienne gravement malade pourrait, avec l'appui d'un médecin, obtenir l'autorisation de posséder de la marihuana pour sa consommation personnelle à des fins médicales. En vertu du RAMM, les personnes autorisées disposaient de trois moyens de s'approvisionner en marihuana séchée :

- elles pouvaient produire leurs propres provisions conformément à une licence de production à des fins personnelles (LPFP);
- elles pouvaient désigner une personne qui assurera la production en leur nom conformément à une licence de production à titre de personne désignée (LPPD);
- elles pouvaient acheter de la marihuana séchée de Santé Canada qui charge sous contrat une compagnie privée (actuellement Prairie Plant Systems Inc. [PPS]) de produire de la marihuana dans le cadre du Programme[1].

Le cadre d'approvisionnement et de distribution établi par le RAMM a été modifié plusieurs fois. Dans certains cas, ces modifications ont été effectuées en raison des préoccupations exprimées par les intervenants. Dans d'autres, elles l'ont été en vue de tenir compte des décisions du tribunal qui invalidaient des articles du Règlement qui entravaient l'accès.

En 2003, la Cour d'appel de l'Ontario (*Hitzig c. Canada*) a décidé que le RAMM était inconstitutionnel, puisqu'il n'offrait pas un accès raisonnable à une source d'approvisionnement légale de marihuana à des fins médicales. La Cour a invalidé cinq dispositions du RAMM qui constituaient des obstacles à l'admissibilité et à l'approvisionnement, mais a reconnu que le gouvernement pouvait choisir d'adopter une approche fondamentalement différente. Le RAMM a été modifié afin de donner un effet national à certains éléments du recours accordé par la Cour, ainsi qu'afin d'offrir une option visant un accès à un approvisionnement légal de marihuana séchée et de graines de marihuana aux personnes autorisées. Cependant, la Cour a estimé que les exigences relatives à l'obtention d'un document médical et à une limite quotidienne établie par un médecin praticien étaient raisonnables.

En 2005, en fonction d'un examen élargi du RAMM et des commentaires reçus des intervenants au cours d'un processus de

[1] La marihuana produite en vertu du contrat avec Sa Majesté du chef du Canada ou d'une LPPD, autre que la marihuana vendue ou importée pour la tenue d'essais cliniques, est exemptée de l'application de la *Loi sur les aliments et drogues* et de ses règlements.

process, Health Canada proceeded with a second phase of amendments to the MMAR. The primary objective of the amendments was to streamline the regulatory requirements associated with applying for an authorization to possess. Both the applicant's declaration and the medical declaration were therefore simplified. The MMAR were also amended to provide limited authority for pharmacists to supply marihuana to authorized persons. These amendments were intended to maintain an appropriate balance between providing seriously ill persons with reasonable access to a legal source of marihuana for medical purposes and the need to regulate it.

In 2009, the MMAR were amended to raise the limit on the number of production licences a designated person could hold from one to two. This followed a 2008 Federal Court of Appeal decision (*Sfetkopoulous v. Canada*) to uphold the Federal Court's declaration that the one producer to one user ratio set out in the MMAR unjustifiably limited the ability of authorized persons to access marihuana for medical purposes. The Federal Court was of the view that licensed producers having larger operations could make economies of scale and a level of income that would allow them to put in place quality control and security measures. The Court also observed that with fewer producers having larger operations, a system of inspection would be much easier to sustain than the system of one consumer to one producer. The amendment was an interim measure intended to address the Court's decision while the Program and the MMAR were being reassessed.

In 2010, Health Canada amended the MMAR to address the 2009 British Columbia Supreme Court decision (*R. v. Beren*) that struck down the one producer to one user ratio as well as the limit of three producers per location. The Court adopted the reasoning in *Sfetkopoulos* and was of the view that licensed producers having larger operations could provide an adequate supply, carry out research on the efficacy of varying strains of marihuana and make economies of scale. The Government had already addressed the producer to user ratio issue by raising the limit on the number of production licences a designated person can hold from one to two. This regulatory initiative introduced a new limit of four to the number of production licences that could be issued with reference to the same production site. In other respects, the Court ruled that the MMAR requirement for the support of a physician was justified.

The Court decisions leading to the 2009 and 2010 amendments support Health Canada's position that dried marihuana for medical purposes should be produced and distributed as much as possible like other narcotics used for medical purposes.

Issue

Growth in Program participation has had unintended consequences for the administration of the MMAR, but more importantly, for public health, safety and security as a result of authorizing individuals to produce marihuana for medical purposes under PUPLs and DPPLs in private dwellings.

In 2002, 477 individuals were authorized to possess marihuana for medical purposes. As of April 16, 2013, this had grown to 29 888 individuals. If the Program continues to grow at this pace,

consultation approfondi, Santé Canada a entrepris une deuxième phase de modifications au RAMM. L'objectif principal des modifications était de simplifier les exigences réglementaires liées à la demande d'une autorisation de possession. Par conséquent, la déclaration du demandeur et la déclaration médicale ont été simplifiées. Le RAMM a également été modifié en vue de fournir une autorisation limitée aux pharmaciens de fournir de la marihuana aux personnes autorisées. Ces modifications avaient pour but de maintenir un équilibre convenable entre un accès raisonnable à une source licite de marihuana à des fins médicales aux personnes gravement malades et la nécessité de la réglementer.

En 2009, le RAMM a été modifié pour augmenter de un à deux le nombre de licences de production qu'une personne désignée peut obtenir. Cette modification est attribuable à la décision de la Cour d'appel fédérale en 2008 (*Sfetkopoulous c. Canada*) de confirmer la déclaration de la Cour fédérale selon laquelle le ratio d'un producteur pour un usager établi dans le RAMM limite de façon injustifiable la capacité des personnes autorisées à avoir accès à la marihuana à des fins médicales. La Cour fédérale estimait que les producteurs autorisés qui ont de plus grandes exploitations pouvaient réaliser des économies d'échelle et obtenir un niveau de revenu qui leur permettrait de mettre en place des mesures de contrôle de la qualité et de sécurité. La Cour a également constaté qu'en ayant moins de cultures plus importantes, le système d'inspection serait plus facile à opérer que le système où les producteurs n'ont qu'un seul client. Il s'agissait d'une mesure provisoire ayant pour but de tenir compte de la décision du tribunal, alors que le Programme et le RAMM faisaient l'objet d'une réévaluation.

En 2010, Santé Canada a modifié le RAMM afin de tenir compte de la décision de 2009 de la Cour suprême de la Colombie-Britannique (*R. c. Beren*) qui invalidait le ratio d'un producteur pour un usager, ainsi que la limite de trois producteurs par emplacement. La Cour a adopté le raisonnement dans l'affaire *Sfetkopoulos* et était d'avis que les producteurs autorisés qui ont de plus grandes exploitations pouvaient fournir un approvisionnement adéquat, mener des recherches sur l'efficacité des différentes souches de marihuana et réaliser des économies d'échelle. Le gouvernement avait déjà traité de la question relative au ratio producteur-usager en augmentant le nombre de licences qu'une personne désignée pouvait posséder de une à deux licences. L'initiative de réglementation adoptait une nouvelle limite de quatre licences de production qui pouvaient être délivrées au même site de production. Par ailleurs, la Cour a décidé que l'exigence du RAMM relativement à l'appui d'un médecin était justifiée.

Les décisions juridiques qui ont mené aux modifications de 2009 et de 2010 appuyaient la position de Santé Canada selon laquelle la marihuana séchée à des fins médicales devait être produite et distribuée, dans la mesure du possible, de la même manière que les stupéfiants utilisés à des fins médicales.

Enjeux

La croissance du taux de participation au Programme a eu des conséquences inattendues sur l'administration du RAMM, mais également et de façon plus importante sur la santé et la sécurité publiques, à la suite de la décision d'autoriser les particuliers à cultiver de la marihuana à des fins médicales grâce aux LPFP et aux LPPD dans des habitations.

En 2002, 477 personnes ont obtenu l'autorisation de posséder de la marihuana à des fins médicales. En date du 16 avril 2013, ce nombre avait augmenté à 29 888. Si le Programme continue de

it is estimated that by 2014, over 50 000 individuals will be authorized to possess marihuana for medical purposes.

One result of increased participation in the Program is increased application volume for Health Canada. This results in increased staffing costs, but more importantly, it results in a 10-week service standard for processing applications. Many Program participants have expressed concerns regarding the length of time it takes to obtain an authorization to possess.

Of the 29 888 Program participants on April 16, 2013, 12% access Health Canada's supply of dried marihuana, 67% produce under a PUPL, and 16% produce under a DPPL. The remaining 5% indicate in their application that they will buy from Health Canada, but ultimately do not. Health Canada does not have access to information regarding where these Program participants obtain their supply of marihuana for medical purposes.

Increases in the number of licences, as well as the co-location of up to four licences on one site, can result in large quantities of marihuana being produced in homes and communities. In addition, the average daily amount (i.e. "dosage") has continually increased since 2002 to almost 10 g per day now which, if produced indoors, is approximately 49 plants. Under the MMAR, the number of plants that may be produced under a licence to produce is calculated based on the daily amount agreed upon by the medical practitioner and the applicant. Program participants who either produce their own or have designated producers are the group where the daily amount has increased the most. There are now approximately 70% who produce 25 plants or more.

Municipalities and first responders, such as fire and police officials, have raised serious public health and safety concerns regarding production of marihuana in private dwellings. Under the Program, applicants are not required to disclose their intent to produce to local authorities. Production sites, most often in private dwellings that are not constructed for large-scale horticultural production, are often in locations unknown by local authorities. Production activities are also linked to the presence of excess moisture in homes creating a risk of mould (particularly associated with drying of marihuana); electrical hazards creating a risk of fire; and exposure to toxic chemicals like pesticides and fertilizers creating risk to residents, including children. Such issues may not only have an impact on individual producers, but also potentially on those living at the same address, adjacent residential units, and/or in the surrounding community, who may not even suspect the existence of these risks. Because the MMAR were never intended to permit larger-scale marihuana production, they do not adequately address these public health, safety and security concerns. There are practical difficulties in imposing stringent quality and safety standards on production operation by producers of marihuana for medical purposes that may lack the capacity to implement them.

croître à ce rythme, il est prévu que d'ici 2014, plus de 50 000 personnes seront autorisées à posséder de la marihuana à des fins médicales.

L'un des résultats de la participation accrue au Programme est le volume de demandes supplémentaires pour Santé Canada. Cela a entraîné des coûts accrus en dotation, mais une incidence encore plus importante est la norme de service de 10 semaines pour le traitement des demandes. De nombreux participants au Programme ont exprimé leurs préoccupations au sujet de la période d'attente pour obtenir une autorisation de possession.

Des 29 888 participants au Programme le 16 avril 2013, 12 % ont accès à l'approvisionnement de marihuana séchée de Santé Canada, 67 % la produisent en vertu d'une LPFP et 16 % la produisent en vertu d'une LPPD. Les autres 5 % indiquent dans leur demande qu'ils s'approvisionneront auprès de Santé Canada, mais en réalité, ils ne le font pas. Santé Canada ne sait pas où ces participants au Programme se procurent la marihuana à des fins médicales.

Les augmentations du nombre de licences ainsi que la colocation qui peut atteindre jusqu'à quatre licences sur un seul site peuvent faire en sorte que de grandes quantités de marihuana soient produites dans des résidences et des collectivités. De plus, la quantité quotidienne moyenne (c'est-à-dire « définition des doses ») a continuellement augmenté depuis 2002 pour atteindre maintenant presque 10 g par jour, ce qui, si produite à l'intérieur, correspond à approximativement 49 plants. Sous le RAMM, le nombre de plants qui peuvent être produits en vertu d'une licence de production est calculé sur la base de la quantité quotidienne entendue entre le médecin et le demandeur. Les participants au Programme qui produisent pour eux-mêmes ou qui ont désigné un producteur sont le groupe pour lequel la quantité quotidienne a augmenté le plus. Il y en a maintenant approximativement 70 % qui produisent 25 plants ou plus.

Les municipalités et les premiers répondants, tels que les responsables des services d'incendie et des services de police, ont soulevé d'importantes préoccupations sur le plan de la santé et de la sécurité publiques en ce qui concerne la production de marihuana dans des habitations. En vertu du Programme, les demandeurs n'ont pas à divulguer leur intention de produire aux autorités locales. Les sites de production, dont la plupart sont situés dans des habitations privées qui ne sont pas construites pour la production horticole à grande échelle, se trouvent souvent dans des endroits inconnus des autorités locales. Les activités de production sont également liées à la présence d'humidité dans les résidences, ce qui crée un risque de moisissure (en particulier à cause du séchage de la marihuana); au danger électrique qui entraîne un risque d'incendie, ainsi qu'à l'exposition à des produits chimiques toxiques comme des pesticides et des fertilisants qui entraîne des risques pour les résidents, y compris les enfants. De tels enjeux peuvent avoir des incidences sur les producteurs individuels, mais également sur les personnes qui vivent à la même adresse, dans des logements adjacents et/ou dans le voisinage qui peuvent même ne pas soupçonner l'existence de ces risques. Puisque le but du RAMM n'a jamais été de permettre la production de marihuana à plus grande échelle, il ne traite pas de ces préoccupations relatives à la santé et la sécurité publiques. Il existe des difficultés pratiques sur le plan de l'imposition de normes de qualité et de sécurité rigoureuses pour la production de marihuana à des fins médicales par des producteurs qui pourraient ne pas avoir la capacité de les mettre en œuvre.

Police have also raised concerns that residential production activities leave the Program vulnerable to abuse, including criminal involvement and diversion to the illicit market, particularly given the attractive street value of marihuana ($10–$15/gram for dried marihuana). It is impossible to conduct effective inspection of the numerous production sites across the country, particularly given the legal requirement to obtain either permission or a warrant to enter a private dwelling. Finally, production in homes may leave residents and their neighbours vulnerable to violent home invasion by criminals who become aware that valuable marihuana plants are being produced and stored in the home.

Another implication of Program growth is an increase to the cost of producing and distributing dried marihuana for Health Canada. The existing supply contract has a value of $16.8 million (excluding GST) for a three-year period, ending on March 31, 2013. An additional option year has been built into the contract, and has been exercised. It is estimated that this additional year will cost Health Canada $9.7 million. These high contract costs are despite the fact that only a minority of Program participants indicate this supply option in their application. Health Canada heavily subsidizes the cost of marihuana for medical purposes by covering the shipping costs and charging only $5/gram, an amount substantially below the cost of production and distribution. The Government collected approximately $1,686,600 in revenue from sales of dried marihuana and seeds in the 2011–2012 fiscal year.

Objectives

The objective of the MMPR is to reduce the risks to public health, security and safety of Canadians, while significantly improving the way in which individuals access marihuana for medical purposes.

To reduce the risks to public health, security and safety of Canadians, a new supply and distribution system for dried marihuana that relies on commercial production of marihuana for medical purposes will be established. Security requirements will be in place for the production site and key personnel of the licensed producer. Standards for packaging, transportation and record keeping will contribute to achieving security objectives.

The process for individuals to access marihuana for medical purposes will no longer require applying to Health Canada. Individuals will be able to obtain marihuana, of any strain commercially available, with information similar to a prescription from an authorized health care practitioner (a physician or, potentially, a nurse practitioner, where supporting access to marihuana for medical purposes is included under their scope of practice or in legislation). Quality and sanitation standards appropriate for a product for medical use will be in place. In line with other controlled substances, personal and designated production will be phased out. This will reduce the health and safety risks to individuals and to the public while allowing for a quality-controlled and more secure product for medical use.

Health Canada will no longer receive and process applications or issue authorizations and licences for personal production, nor continue to produce and supply marihuana for medical purposes.

La police a également soulevé des préoccupations selon lesquelles la production résidentielle rend le Programme vulnérable sur le plan des abus, y compris la participation de groupes criminels et le détournement vers le marché clandestin de la drogue, en particulier à cause de l'attrayante valeur de revente de la marihuana (de 10 $ à 15 $ le gramme de marihuana séchée). Il est impossible d'inspecter efficacement les nombreux sites de production au pays, particulièrement à cause de l'exigence juridique d'obtenir la permission, ou un mandat, pour entrer dans une habitation privée. Finalement, la production dans les résidences peut accroître la vulnérabilité des résidents et des voisins à de violents braquages à domicile perpétrés par des criminels qui sont au courant que des plants de marihuana d'une grande valeur sont cultivés et entreposés dans la résidence.

Les augmentations du coût de production et de distribution de la marihuana séchée pour Santé Canada font partie des incidences de la croissance du Programme. La valeur du marché d'approvisionnement actuel est de 16,8 millions de dollars (sans la TPS) pour une période de trois ans qui prendra fin le 31 mars 2013. Une année d'option supplémentaire a été intégrée dans le marché et a été mise à exécution. Il est prévu que cette année supplémentaire coûtera 9,7 millions de dollars à Santé Canada. Ces coûts contractuels élevés sont à prévoir, malgré le fait qu'une minorité de participants au Programme indiquent cette option d'approvisionnement dans leur demande. Santé Canada subventionne lourdement le coût de la marihuana à des fins médicales en assumant les frais d'expédition et en la vendant 5 $ le gramme seulement, un montant nettement inférieur au coût de production et de distribution. Le gouvernement a recouvré approximativement 1 686 600 $ en revenu provenant de la vente de marihuana séchée et de graines au cours de l'année fiscale 2011-2012.

Objectifs

L'objectif du RMFM est de réduire le risque pour la santé et la sécurité publiques et pour la sécurité des Canadiens, tout en améliorant de façon considérable la manière dont les particuliers ont accès à la marihuana à des fins médicales.

Afin de réduire les risques pour la santé et la sécurité publiques et pour la sécurité des Canadiens, un nouveau système d'approvisionnement et de distribution de la marihuana séchée qui repose sur la production commerciale de la marihuana à des fins médicales sera établi. Les exigences en matière de sécurité seront en place pour l'installation de production et le personnel clé du producteur autorisé. Des normes pour l'emballage, le transport et la tenue de dossier contribueront à l'obtention de cet objectif.

Le processus pour que les particuliers aient accès à la marihuana à des fins médicales n'exigera plus de faire une demande à Santé Canada. Les particuliers seront en mesure de se procurer de la marihuana, de n'importe quelle souche commerciale disponible, avec de l'information similaire à une prescription obtenue d'un praticien de la santé autorisé (un médecin ou, potentiellement, une infirmière praticienne, où le soutien à l'accès de la marihuana à des fins médicales est inclus dans la portée de la pratique ou dans la loi). Des normes de qualité et d'hygiène appropriées pour un produit à usage médical seront en place. Comme dans le cas des autres substances désignées, la production personnelle et désignée sera éliminée graduellement. Cela réduira les risques pour la santé et la sécurité des particuliers et du public et permettra d'offrir un produit de qualité contrôlée et plus sécuritaire à des fins médicales.

Santé Canada ne recevra et ne traitera plus les demandes ou les questions relatives aux autorisations et aux licences pour la production personnelle, et cessera la production et

Health Canada will not enter into future contractual arrangements for the production and distribution of marihuana for medical purposes. The new regulatory scheme returns Health Canada to its traditional role of regulator rather than producer and service provider, while striking a better balance between access and risks to public health and safety.

Description

The *Marihuana for Medical Purposes Regulations* will authorize the following key activities:

- the possession of dried marihuana by individuals who have the support of an authorized health care practitioner to use marihuana for medical purposes;
- the production of dried marihuana by licensed producers only; and
- the sale and distribution of dried marihuana by licensed producers and hospitals to individuals who can possess it.

The MMPR will also allow individuals who hold an authorization to possess under the MMAR to transition to the new framework using their authorization for up to one year after its date of issue (unless a period of usage of less than 12 months has been indicated in the medical declaration). Individuals could also transition using a medical declaration issued under the MMAR.

Licences to produce issued under the MMAR will be phased out, while renewals will continue normally. New licences to produce will not be issued if the application is submitted after September 30, 2013, because there will not be enough time to produce a crop before the repeal of the MMAR on March 31, 2014. Applications to amend a licence for a site change or increase the daily amount will not be issued if the application is submitted after September 30, 2013, for the same reason (see "Implementation, enforcement and service standards"). All personal production licences (i.e. PUPL and DPPL) will end on March 31, 2014.

1. Possession of dried marihuana by individuals who have the support of an authorized health care practitioner

Possession of dried marihuana

Individuals will no longer have to apply to Health Canada for an authorization to possess dried marihuana for medical purposes. Instead, individuals who require marihuana for medical purposes will be able to legally possess dried marihuana if it was obtained under the MMPR from a licensed producer with a supporting medical document from an authorized health care practitioner. Similarly, an individual responsible for a person who requires marihuana for medical purposes will be able to legally possess dried marihuana under these circumstances. Individuals will be authorized to possess the lesser of 150 g or 30 times the daily quantity stipulated by the authorized health care practitioner.

Under the MMPR, individuals will be able to demonstrate that they are in legal possession of dried marihuana by showing a law enforcement official a client-specific label affixed to the product, or an accompanying client-specific document, as well as an appropriate piece of photo identification (see "Packaging and

l'approvisionnement en marihuana à des fins médicales. Santé Canada ne conclura plus d'ententes contractuelles pour la production et la distribution de la marihuana à des fins médicales. Ce nouveau régime réglementaire ramènerait Santé Canada à son rôle traditionnel de régulateur plutôt que celui de producteur et fournisseur de services, tout en établissant un équilibre entre l'accès et les risques de santé et de sécurité publiques.

Description

Le *Règlement sur la marihuana à des fins médicales* autorisera les activités clés suivantes :

- la possession de marihuana séchée par des particuliers qui ont l'appui d'un praticien de la santé autorisé pour consommer de la marihuana à des fins médicales;
- la production de marihuana séchée par des producteurs autorisés seulement;
- la vente et la distribution de la marihuana séchée par des producteurs autorisés et les hôpitaux aux particuliers qui peuvent en posséder.

Le RMFM permettra également la transition des particuliers qui sont titulaires d'une autorisation de possession en vertu du RAMM vers le nouveau cadre à l'aide de leur autorisation de possession pour une période d'un an après son émission (à moins qu'une période d'utilisation de moins de 12 mois ait été indiquée dans la déclaration médicale). Les particuliers pourraient aussi faire la transition en utilisant la déclaration médicale émise en vertu du RAMM.

Les licences de production émises dans le cadre du RAMM seront graduellement supprimées, mais les renouvellements continueront normalement. Aucune nouvelle licence de production ne sera émise si la demande est présentée après le 30 septembre 2013, puisqu'il n'y aura pas assez de temps pour produire une récolte avant l'abrogation du RAMM le 31 mars 2014. Les demandes visant la modification d'une licence pour un changement de site ou l'augmentation de la quantité quotidienne ne seront pas traitées si elles sont présentées après le 30 septembre 2013 pour la même raison (voir « Mise en œuvre, application et normes de service »). Toutes les licences de production personnelle (c'est-à-dire LPFP et LPPD) expireront le 31 mars 2014.

1. Possession de marihuana séchée par les particuliers qui ont l'appui d'un praticien de la santé autorisé

Possession de marihuana séchée

Les particuliers n'auront plus à présenter une demande auprès de Santé Canada pour obtenir l'autorisation de posséder de la marihuana séchée à des fins médicales. Les personnes ayant besoin de la marihuana à des fins médicales seront autorisées légalement à posséder de la marihuana séchée en l'obtenant en vertu du RMFM auprès d'un producteur autorisé, en présentant un document médical obtenu d'un praticien de la santé autorisé. De façon semblable, une personne responsable d'un particulier ayant besoin de la marihuana à des fins médicales sera autorisée légalement à posséder de la marihuana séchée dans ces circonstances. Les particuliers seront autorisés à posséder entre le moindre de 150 g ou 30 fois la quantité quotidienne précisée par le praticien de la santé autorisé.

En vertu du RMFM, les particuliers seront en mesure de prouver qu'ils sont en possession légale de marihuana séchée en présentant à un responsable de l'application de la loi une étiquette particulière au client qui serait apposée sur le produit, ou un document accompagnateur particulier au client, ainsi qu'une carte d'identité à photo

labelling"). Licensed producers will also be required to confirm to a member of a Canadian police force, in the context of an investigation, whether a named individual is a registered client or an individual responsible for a registered client.

Obtaining a supply of dried marihuana

To obtain dried marihuana for medical purposes, an individual will see an authorized health care practitioner and obtain a medical document, requirements for which are specified in the MMPR, signifying the health care practitioner's support for their access to marihuana and indicating, among other things, the supported daily quantity in grams. Individuals can then send the original medical document to a licensed producer of their choice. A medical document will allow an individual to register with a licensed producer for the period of use indicated by the authorized health care practitioner, but for no more than one year. After registering as a client, individuals will be able to order dried marihuana from the licensed producer. However, licensed producers will not be allowed to sell or provide more than 30 times the daily amount in any 30-day period, taking into consideration the expected length of time for the shipment to reach the registered client, nor will they be able to ship more than 150 g at a time. Health Canada will publish the name and contact information of each licensed producer on its Web site to help individuals select a supplier. If an individual wishes to purchase a variety of strains that are not all available from one licensed producer, the MMPR will permit the individual to do so by obtaining a new medical document. They will have to discuss this with their health care practitioner. The health care practitioner will have to divide the daily quantity between multiple medical documents.

A registration will not be transferable from one licensed producer to another. If an individual wants to change licensed producers, they will be required to obtain a new original medical document which they will use to register with another licensed producer. This is consistent with practices for prescription narcotics, as these are not transferable from pharmacy to pharmacy. The CDSA requires individuals seeking or obtaining an authorization to obtain a controlled substance from a practitioner to disclose to the practitioner the particulars of any controlled substance they obtained or any authorization to obtain any controlled substance that they received in the 30 previous days.

Authorized health care practitioners

Health Canada maintains that the determination as to whether the use of dried marihuana for medical purposes is appropriate for a particular individual is best made through a discussion with their authorized health care practitioner. The MMPR will include a new definition of authorized health care practitioner that includes physicians in all provinces and territories (P/Ts), and will also include nurse practitioners in P/Ts where supporting access to marihuana for medical purposes is included under their scope of practice or in legislation. This is consistent with Health Canada's approach to other controlled drugs and substances used for medical purposes in the *New Classes of Practitioners Regulations* (NCPR).

In the NCPR, marihuana is listed as a substance that nurse practitioners are not able to prescribe; however, following

appropriée (voir « Emballage et étiquetage »). Les producteurs autorisés auront également l'obligation de confirmer à un membre d'une force policière canadienne, dans le cas d'une enquête, qu'un particulier est un client inscrit ou une personne responsable d'un client inscrit.

Obtention d'un approvisionnement de marihuana séchée

Dans le but d'obtenir de la marihuana séchée à des fins médicales, un particulier s'adressera à un praticien de la santé autorisé afin d'obtenir un document médical. Les exigences de ce document sont précisées dans le RMFM, précisant qu'il appuie l'accès à la marihuana et indiquant, entre autres choses, la quantité quotidienne en grammes supportée. Il peut ensuite envoyer le document médical original à un producteur autorisé de son choix. Un document médical permettra à un particulier de s'inscrire auprès d'un producteur autorisé pour la période d'utilisation prescrite par le praticien de la santé autorisé, mais sans excéder un an. Après l'inscription en tant que client, les particuliers seront en mesure de commander de la marihuana séchée du producteur autorisé. Cependant, les producteurs autorisés ne seront pas autorisés à vendre ou à fournir plus de 30 fois la quantité quotidienne pendant une période de 30 jours, en prenant en considération la durée de temps estimée pour que l'expédition parvienne au client inscrit, et ils ne pourront pas expédier plus de 150 g à la fois. Santé Canada publiera le nom et les coordonnées de chaque producteur autorisé sur son site Web afin d'aider les particuliers à choisir un fournisseur. S'il arrivait qu'un particulier souhaite se procurer différentes souches qui ne sont pas toutes disponibles auprès d'un seul producteur autorisé, le RMFM lui permettra de le faire en obtenant un nouveau document médical. Il aura la responsabilité d'en discuter avec son praticien de la santé. Le praticien de la santé aura la responsabilité de diviser la quantité quotidienne entre les multiples documents médicaux.

Aucune inscription ne pourra être transférée d'un producteur autorisé à un autre. Si un particulier souhaite changer de producteur autorisé, il devra obtenir un nouveau document médical original qui l'autorisera à s'inscrire auprès d'un autre producteur autorisé. Cela est conforme aux pratiques relatives aux stupéfiants vendus sur ordonnance; ils ne sont pas transférables d'une pharmacie à une autre. La LRCDAS exige que les particuliers qui souhaitent obtenir une autorisation de se procurer une substance désignée auprès d'un praticien divulguent au praticien les particularités de toute substance désignée qu'ils obtiennent ou de toute autorisation visant à obtenir une substance réglementée qu'ils ont reçue au cours des 30 jours précédents.

Praticiens de la santé autorisés

Santé Canada soutient que la meilleure façon pour une personne en particulier de déterminer que l'usage de la marihuana séchée à des fins médicales est adéquat est de discuter avec son praticien de la santé autorisé. Le RMFM comprendra une nouvelle définition de praticien de la santé autorisé afin d'inclure les médecins dans toutes les provinces et les territoires et comprendra également des infirmières praticiennes pour les provinces et les territoires dans lesquels le soutien de l'accès à la marihuana à des fins médicales est compris dans le champ de pratique ou dans la législation. Cela correspond à l'approche de Santé Canada pour les autres médicaments et substances réglementés utilisés à des fins médicales dans le *Règlement sur les nouvelles catégories de praticiens* (RNCP).

Dans le RNCP, la marihuana est inscrite comme une substance que les infirmières praticiennes ne peuvent pas prescrire;

consideration of feedback received during stakeholder consultations, the MMPR amend the NCPR to remove this exclusion.

This role will not be expanded beyond nurse practitioners. Nurse practitioners are regulated professionals in all provinces and territories. With the exception of Yukon, they are authorized to autonomously diagnose and treat health conditions and prescribe medications. This is because they have gained additional competencies through training and education, as well as substantial clinical experience. In most jurisdictions, they have also been deemed to have the competencies required to prescribe medications that contain controlled substances.

The MMPR do not include categories of symptoms and conditions, and there will no longer be a requirement for some individuals to obtain the support of a specialist in addition to that of their primary care physician in order to access marihuana for medical purposes. An individual who needs to access dried marihuana for medical purposes could obtain a medical document from an authorized health care practitioner. The medical document will contain similar information to that on a prescription. Specifically, the authorized health care practitioner will have to indicate their licence information, the location of the medical assessment, the name and date of birth of their patient, a period of use of up to one year, and a daily quantity of marihuana in grams.

The ability of authorized health care practitioners to sell or provide marihuana for medical purposes to patients under their care has been removed from the MMPR, following publication of the proposed Regulations in the *Canada Gazette*, Part I (i.e. prepublication). Health care practitioners, medical associations, professional regulatory bodies and others submitted strong objections during the comment period concerning the potential for conflict of interest affecting physicians and nurse practitioners who may have been in the position to both prescribe and also sell dried marihuana (see section on consultation). In response to such comments, Health Canada made the decision to remove the authority for health care practitioners to sell or provide dried marihuana to patients under their care from the Regulations. This has been replaced with the authority for health care practitioners to "transfer" (that is, provide dried marihuana without consideration) to a person under their professional care or to an individual who is responsible for that person. The authority to "transfer" does not permit an authorized health care practitioner to provide dried marihuana in exchange for something of value from an individual. In their role as health care providers and first point of contact for patients, authorized health care practitioners support access by signing the medical documents with which an individual may obtain dried marihuana under the MMPR. In a hospital setting, a health care practitioner may administer or transfer dried marihuana to a patient as permitted by the person in charge of the hospital and as authorized under the NCR.

These revisions address some significant concerns expressed by stakeholders. However, it is not expected to adversely affect an individual's access to marihuana for medical purposes from licensed producers.

Under the MMAR, physicians who sign medical declarations must sign a statement indicating they are aware that no notice of compliance has been issued under the FDR relating to the safety or efficacy of dried marihuana, as well as a statement indicating that

cependant, après examen des commentaires reçus lors des consultations avec les intervenants, le RMFM modifiera le RNCP afin de retirer cette exclusion.

Ce rôle ne sera pas attribué au-delà des infirmières praticiennes. Les infirmières praticiennes sont des professionnelles réglementées dans l'ensemble des provinces et des territoires. À l'exception du Yukon, elles sont autorisées à diagnostiquer et à traiter de façon autonome des problèmes de santé et à prescrire des médicaments, puisqu'elles ont acquis des compétences supplémentaires par la formation et l'éducation, ainsi qu'une expérience clinique considérable. Dans la plupart des provinces et des territoires, on a également jugé qu'elles avaient les compétences requises pour prescrire des médicaments qui contiennent des substances désignées.

Le RMFM ne comprend pas les catégories de symptômes et d'états de santé, et il ne sera plus nécessaire pour certains particuliers d'obtenir l'appui d'un spécialiste, en plus de celui d'un médecin de premier recours, pour avoir accès à la marihuana à des fins médicales. Une personne qui a besoin de se procurer de la marihuana séchée à des fins médicales pourrait obtenir un document médical auprès d'un praticien de la santé autorisé. Le document médical comprendra des renseignements semblables à ceux qui figurent sur une ordonnance. De façon plus précise, le praticien de la santé autorisé sera obligé d'indiquer les renseignements relatifs à sa licence et à l'emplacement de l'examen médical, le nom et la date de naissance de son patient, la période de consommation qui peut atteindre un an, ainsi que la quantité quotidienne de marihuana en grammes.

La capacité des praticiens de la santé autorisés de vendre ou de fournir de la marihuana à des fins médicales à des patients qu'ils soignent a été retirée du RMFM à la suite de la publication. Les praticiens de la santé autorisés, d'organismes de réglementation professionnelle et d'autres parties concernées ont exprimé une forte opposition durant la période des commentaires au sujet de la possibilité d'un conflit d'intérêts touchant les médecins et les infirmières praticiennes qui peuvent avoir été en position de prescrire et de vendre de la marihuana séchée (voir la section sur la consultation). Par conséquent, Santé Canada a pris la décision de retirer du Règlement l'autorisation aux praticiens de la santé de vendre ou de fournir de la marihuana séchée aux patients qu'ils soignent. Dorénavant, les praticiens de la santé ont plutôt une autorisation de « transfert » (c'est-à-dire fournir de la marihuana séchée sans échange d'une contrepartie) à des personnes à qui ils fournissent des soins professionnels ou à des particuliers qui sont responsables de ces personnes. L'autorisation de « transfert » ne permet pas à un praticien de la santé autorisé de fournir de la marihuana séchée à un particulier en échange d'objets de valeur. À titre de fournisseurs de soins de santé et de premier point de contact pour les patients, les praticiens de la santé autorisés appuient l'accès en signant les documents médicaux à l'aide desquels un particulier peut obtenir de la marihuana séchée en vertu du RMFM. Dans un hôpital, un praticien de la santé peut administrer ou transférer de la marihuana séchée à un patient si cela est approuvé par la personne responsable de l'hôpital et en fonction de l'autorisation en vertu du RS.

Ces révisions traitent de certaines préoccupations importantes exprimées par les intervenants. Cependant, elles ne devraient pas avoir de répercussions négatives sur l'accès d'un particulier à la marihuana à des fins médicales auprès des producteurs autorisés.

En vertu du RAMM, les médecins qui signent une déclaration médicale doivent aussi signer une déclaration indiquant qu'ils sont au courant qu'aucun avis de conformité n'a été émis en vertu du RAD en relation avec l'innocuité et l'efficacité de la marihuana

conventional treatments have been tried or considered and are ineffective or medically inappropriate. The MMPR will not require authorized health care practitioners to make specific declarations with respect to the use of marihuana for medical purposes, the effectiveness or appropriateness of other therapies, or the regulatory status of marihuana. This is expected to reduce the complexity of the physician's role in access to marihuana for medical purposes.

Authorized health care practitioners may wish to receive more comprehensive information about the potential risks and benefits of using marihuana for medical purposes in order to guide them in their discussions with their patients. Health Canada has established an expert advisory committee to assist in providing comprehensive scientific information about the uses of marihuana to authorized health care practitioners.

2. Production of dried marihuana by licensed producers

The MMPR set out a licensing scheme that is intended to allow for larger-scale production, comparable to that for other narcotics used for medical purposes. This will permit commercial production while regulating the quality and security of dried marihuana, thus reducing public health, safety and security risks.

Production sites will only be located indoors, and not in a private dwelling. This will reduce the risks of diversion posed by outdoor production and the health and safety risks associated with producing marihuana in a private dwelling. Indoor production also addresses the risk of cross-contamination with other nearby crops, particularly industrial hemp.

Licensing

Either an individual or a corporation will be eligible to become a licensed producer. In their application, applicants will have to describe the activities they wish to conduct with marihuana and the purpose for conducting those activities. Licensed producers could also become licensed to conduct certain activities with standardized samples of chemicals that occur naturally in the marihuana plant in order to conduct analytical testing of dried marihuana. For example, they will need to possess pure samples of THC and cannabidiol in order to determine the percentage of THC and cannabidiol in marihuana. In the MMPR, and in this document, cannabis is an inclusive term that is used to capture all of the substances in the scope of the MMPR (e.g. substances such as THC and cannabidiol, as well as marihuana).[2]

A number of conditions will have to be met before the issuance of a licence. The licensed producer will have to designate key personnel under their licence. The senior person in charge will have overall responsibility for management of the activities carried out at the licensed site, while the responsible person in charge (RPIC), and alternate RPICs if applicable, will supervise all activities being carried out with marihuana and cannabis other than marihuana (i.e. pure samples of THC and cannabidiol). Key personnel, along with directors and officers in the case of a corporation, will have to hold

séchée, de même qu'une déclaration indiquant que les thérapies conventionnelles ont été tentées ou considérées et sont inefficaces ou médicalement inappropriées. Le RMFM ne nécessitera pas que les praticiens de la santé autorisés fassent des déclarations particulières relativement à l'usage de la marihuana à des fins médicales, à l'efficacité ou au caractère approprié d'autres thérapies, ou à l'état de la réglementation sur la marihuana. Il est prévu que ceci réduira la complexité du rôle des médecins dans l'accès à la marihuana à des fins médicales.

Les praticiens de la santé autorisés pourraient souhaiter obtenir de l'information plus exhaustive sur les risques et les avantages potentiels de l'usage de la marihuana à des fins médicales afin de s'orienter dans leurs discussions avec leurs patients. Santé Canada a mis sur pied un comité consultatif d'experts afin de faciliter la transmission des renseignements scientifiques exhaustifs sur les usages de la marihuana aux praticiens de la santé autorisés.

2. Production de marihuana séchée par les producteurs autorisés

Le RMFM établit un cadre d'octroi de licence qui devrait permettre une production à grande échelle comparable à ce qui se fait pour d'autres stupéfiants utilisés à des fins médicales. Cela permettra une production commerciale, tout en réglementant la qualité et la sécurité de la marihuana séchée, réduisant ainsi les risques pour la santé et la sécurité publiques.

Les installations de production seront situées à l'intérieur uniquement, et non dans une habitation privée. Cela réduira les risques de détournement que pose la production à l'extérieur et les risques pour la santé et la sécurité associés à la production de marihuana dans une habitation privée. De plus, la production à l'intérieur éliminerait le risque de contamination croisée avec d'autres récoltes avoisinantes, en particulier le chanvre industriel.

Délivrance de licence

Une personne ou une société sera admissible à devenir un producteur autorisé. Dans leur demande, les demandeurs auront à décrire les activités qu'ils souhaitent mener avec la marihuana et le but de ces activités. Les producteurs autorisés pourraient également obtenir une licence pour mener certaines activités avec des échantillons normalisés de produits chimiques qui se trouvent naturellement dans le plant de marihuana afin de mener des tests analytiques de la marihuana séchée. Par exemple, ils seront tenus de posséder des échantillons de THC et de cannabidiol purs en vue de déterminer le pourcentage de THC et de cannabidiol dans la marihuana. Dans le RMFM, ainsi que dans le présent document, le chanvre indien est un terme inclusif utilisé pour saisir toutes les substances précisées dans le RMFM (par exemple des substances telles que le THC et le cannabidiol, de même que la marihuana)[2].

Il sera exigé que certaines conditions soient respectées avant la délivrance d'une licence. Le producteur autorisé aura à désigner le personnel clé lié à sa licence. Le responsable principal (RP) assumera la responsabilité globale de la gestion des activités menées à l'installation autorisée, alors que la personne responsable (PR) et son ou ses remplaçants, le cas échéant, surveilleront toutes les activités menées avec la marihuana et le chanvre indien autre que la marihuana (c'est-à-dire des échantillons de THC et de cannabidiol purs). Le personnel clé, ainsi que les directeurs et les dirigeants

[2] Under Schedule II of the CDSA, cannabis includes cannabis, its preparations, derivatives and similar synthetic preparations. This will include substances such as THC and cannabidiol, as well as marihuana.

[2] En vertu de l'annexe II de la LRCDAS, le chanvre indien comprend le cannabis, ainsi que ses préparations et dérivés et les préparations synthétiques semblables. Cela comprend les substances telles que le THC et le cannabidiol, de même que la marihuana.

a valid security clearance, issued by the Minister of Health (see "Security" section for further details).

The applicant for a production licence would also have to provide a written notification of their application to the local police force, local fire authority and local government. The notice will have to specify the activities for which the licence will be sought, and the address of the site at which activities would be conducted. In response to comments received during prepublication, the MMPR have been revised to include a requirement for licensed producers to also communicate with local authorities when there is a change in the status of their licence. A provision has been added to the revised Regulations to require a licensed producer to notify the same authorities previously notified, when the licence is granted, an amendment is approved, the licence is suspended or revoked for any reason, or when the licence is reinstated. Further, the revised Regulations allow the Minister of Health to confirm licence information to the authorities originally notified by an applicant upon receipt of such a request.

The applicant will have to provide information that allows Health Canada to assess whether the applicant has certain key measures in place. The applicant will have to provide the following:

- a detailed description of the physical security measures that will be put in place at the site;
- a detailed description of how the licensed producer will keep records of their activities with marihuana and cannabis other than marihuana;
- a quality assurance report that shows that the buildings, equipment and proposed sanitation program to be used meet the good production practices (see "Good production practices" section) requirements;
- a copy of the notices provided to the local police force, local fire authority, and local government;
- the maximum quantity of dried marihuana to be produced and sold or provided under licence (if applicable); and
- floor plans of the site.

The MMPR also outline a number of reasons for which the Minister of Health (the Minister) will be required to refuse to issue, renew or amend a licence. These include

- grounds to believe that false or misleading information has been provided with the application;
- information received from a peace officer or other authority that gives the Minister reasonable grounds to believe that the applicant has been involved in diversion of a controlled substance;
- the issuance or continuation of the licence will likely create a risk to public health, safety or security, including diversion; and
- key personnel do not hold a valid security clearance.

Once issued, a licence will be valid for up to three years, and could be renewed. The MMPR also set out a process for amendments to any information on the licence (e.g. the licensed producer wishes to increase its production yield or change sites).

Obtaining starting materials

Licensed producers will be able to legally obtain their starting materials in several ways. With a specific authorization from

dans le cas d'une société, auront l'obligation de détenir une cote de sécurité valide émise par le ministre de la Santé (voir la section « Sécurité » pour d'autres détails).

Le demandeur d'une licence de production aura également à fournir un avis écrit de sa demande au service de police local, au responsable du service d'incendie local et à l'administration locale. L'avis précisera les activités pour lesquelles la licence serait demandée, ainsi que l'adresse de l'installation auquel les activités seront menées. En réponse aux commentaires reçus dans le cadre de la publication préalable, le RMFM a été révisé afin d'inclure l'exigence que les producteurs autorisés communiquent également avec les autorités locales lorsqu'un changement est apporté au statut de leur licence. Une disposition a été ajoutée au Règlement révisé en vue d'exiger qu'un producteur autorisé informe ces mêmes autorités si une licence est accordée, si une modification est approuvée, si la licence est suspendue ou révoquée pour une raison quelconque, ou lorsque la licence est rétablie. De plus, le Règlement révisé permet au ministre de la Santé de confirmer les renseignements liés à la licence aux autorités ayant été informées par un demandeur, à la réception d'une telle demande.

Le demandeur aura l'obligation de fournir des renseignements qui permettent à Santé Canada d'évaluer s'il a mis certaines mesures clés en place. Le demandeur aura à fournir ce qui suit :

- une description détaillée des mesures de sécurité physique qui seront mises en place à l'installation;
- une description détaillée de la façon dont le producteur autorisé tiendra les dossiers relatifs à ses activités avec la marihuana et le chanvre indien autre que la marihuana;
- un rapport d'assurance de la qualité qui prouve que les bâtiments, l'équipement et le programme d'hygiène proposé à utiliser répondent aux exigences en ce qui a trait aux bonnes pratiques de production (voir la section « Bonnes pratiques de production »);
- une copie des avis fournis au service de police local, au responsable du service d'incendie local et à l'administration locale;
- la quantité maximale de marihuana séchée à produire et à vendre ou à fournir en vertu de la licence (s'il y a lieu);
- les plans d'étage de l'installation.

Le RMFM précise également des raisons pour lesquelles le ministre de la Santé aura l'obligation de refuser de délivrer, de renouveler ou de modifier une licence. En voici quelques-unes :

- il y a des motifs de croire que des renseignements faux et trompeurs ont été fournis dans la demande;
- les renseignements reçus d'un agent de la paix ou d'une autre personne autorisée qui donnent au ministre des motifs raisonnables de croire que le demandeur a participé au détournement d'une substance désignée;
- la délivrance ou la continuité d'une licence créera vraisemblablement un risque pour la santé et la sécurité publiques, y compris un détournement;
- le personnel clé n'est pas titulaire d'une cote de sécurité valide.

Une fois délivrée, la licence sera valide pour une période pouvant atteindre trois ans et pourrait être renouvelée. Le RMFM établit également un processus de modification de tous renseignements sur la licence (par exemple le producteur autorisé souhaite accroître son rendement de production ou changer d'emplacement).

Approvisionnement en matières premières

Les producteurs autorisés pourront obtenir légalement leurs matières premières de plusieurs façons. Au moyen d'une

Health Canada, they will be able to purchase marihuana seeds or marihuana plants from individuals who hold valid PUPLs and DPPLs, or they will be able to import marihuana with the appropriate permits (see "Import and export"). They could also purchase Crown stock seeds from Health Canada. Finally, the MMPR will permit licensed producers to obtain marihuana from one another or from a licensed dealer under the NCR.

Import and export

Licensed producers will be permitted to engage in the import or export of marihuana if they have obtained an import or export permit from Health Canada. The import/export permit scheme will be similar to that for other controlled substances and is intended to maintain control over the movement of controlled substances, consistent with Canada's obligations under international conventions on the control of narcotic drugs and psychotropic substances.

Good production practices

The FDA will apply to marihuana produced under the MMPR and will prohibit licensed producers from selling dried marihuana that had been produced under unsanitary conditions or that had been adulterated.

Licensed producers will also be subject to good production practices (GPPs) outlined in the MMPR. These requirements will require cleanliness of the premises and equipment. The licensed producer will also be required to employ a quality assurance person with appropriate training, experience, and technical knowledge to approve the quality of dried marihuana prior to making it available for sale. Finally, licensed producers will have to test dried marihuana for microbial and chemical contaminants and ensure they are below generally accepted tolerance limits for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the FDA (i.e. various pharmacopoeia and formularies). These requirements will provide individuals who require marihuana for medical purposes with access to a product that does not — by reason of the manner in which it was produced, packaged, labelled or stored — pose undue risk to the health of an individual.

To date, dried marihuana has not been subject to all requirements of the FDA and its Regulations. Therapeutic products, such as echinacea or acetaminophen used for medicinal purposes, are subject to manufacturing controls. In moving to treat marihuana as much as possible like other narcotics used for medical purposes and taking into consideration concerns about quality control and other aspects governed by the FDA, the FDA will apply to activities of licensed producers. The FDR will apply as set out in the new MER.

Packaging and labelling

Dried marihuana will have to be packaged in a tamper-evident and child-resistant container. The maximum package size will be 30 g. Each package will contain standard information about the product, including the weight in grams, the percentage by weight of delta-9-tetrahydrocannabinol (THC) and of cannabidiol, the packaging date, the expiry date if one has been established by

autorisation précise de Santé Canada, ils pourront acheter les graines de marihuana ou les plants de marihuana auprès des personnes titulaires d'une LPFP ou d'une LPPD, ou importer la marihuana au moyen des permis appropriés (voir « Importation et exportation »). Ils pourraient aussi acheter des graines, propriétés de la Couronne, par l'entremise de Santé Canada. Enfin, le RMFM permettrait aux producteurs autorisés d'obtenir la marihuana les uns auprès des autres ou auprès d'un fournisseur en vertu du RS.

Importation et exportation

Les producteurs autorisés auront la possibilité de procéder à l'importation ou à l'exportation de la marihuana après avoir obtenu un permis d'importation ou d'exportation auprès de Santé Canada. Le cadre d'octroi de permis d'importation ou d'exportation sera semblable à celui des autres substances désignées et aura pour but d'exercer un contrôle sur le mouvement des substances désignées, conformément aux obligations du Canada en vertu des conventions internationales sur le contrôle des stupéfiants et des substances psychotropes.

Bonnes pratiques de production

La LAD s'appliquera à la marihuana cultivée en vertu du RMFM et interdira aux producteurs autorisés de vendre la marihuana séchée cultivée dans des conditions insalubres ou ayant été altérée.

Les producteurs autorisés seront également assujettis aux bonnes pratiques de production (BPP) précisées dans le RMFM. Ces exigences nécessiteront que les lieux et l'équipement soient propres. Les producteurs autorisés auront également l'obligation d'embaucher une personne pour l'assurance de la qualité ayant suivi la formation adéquate et possédant l'expérience et les connaissances techniques appropriées en vue d'approuver la qualité de la marihuana séchée avant d'en permettre la vente. Enfin, les producteurs autorisés seront obligés de tester la marihuana séchée à la recherche de contaminants microbiens et chimiques et de s'assurer qu'ils sont inférieurs aux limites de tolérance généralement reconnues pour les plantes médicinales pour la consommation humaine, telles qu'elles sont établies dans l'une ou l'autre des publications présentées à l'annexe B de la LAD (c'est-à-dire différentes pharmacopées et divers formulaires). Ces exigences permettront aux particuliers qui ont besoin de la marihuana à des fins médicales d'avoir accès à un produit qui ne pose aucun risque inutile pour eux quant à la façon dont il a été cultivé, emballé, étiqueté ou entreposé.

Jusqu'à maintenant, la marihuana séchée n'a pas été assujettie à toutes les exigences de la LAD et de son règlement. Les produits thérapeutiques utilisés à des fins médicales, comme l'échinacée ou l'acétaminophène, sont assujettis à des contrôles de fabrication. En traitant la marihuana comme d'autres stupéfiants utilisés à des fins médicales et en tenant compte des préoccupations relatives au contrôle de la qualité et aux autres aspects gouvernés par la LAD, la LAD s'appliquera aux activités des producteurs autorisés. Le RAD s'appliquera tel qu'il est établi dans le nouveau REM.

Emballage et étiquetage

Il sera obligatoire que la marihuana séchée soit emballée dans un contenant inviolable et protège-enfant. Chaque emballage ne pourra contenir une quantité de marihuana séchée excédant 30 g. Chaque paquet contiendra des renseignements normalisés au sujet du produit, y compris la quantité en grammes, le pourcentage de delta-9-tétrahydrocannabinol (THC) et de cannabidiol en fonction

stability testing, and a warning statement to "KEEP OUT OF REACH OF CHILDREN."

The licensed producer will also have to affix a client-specific label, similar to a patient-specific prescription drug label, to the package of dried marihuana. This label will contain the names of the client and the authorized health care practitioner who provided the medical document, the daily quantity of dried marihuana and the end of the validity period as indicated on the medical document. The label will also include the shipping date and the anticipated date of delivery to the registered client. The licensed producer will have to produce a separate duplicate document of this label to send to clients. This duplicate document or the product label, as well as an appropriate piece of photo identification, could serve to demonstrate legal possession (see "Possession of dried marihuana" above).

Each package of dried marihuana sold to a client will also need to be accompanied by a copy of the most recent version of the Health Canada document entitled *Information on the Use of Marihuana for Medical Purposes*. This document indicates that the safety and efficacy of dried marihuana for medical purposes has not been established and provides a summary of the known information about the uses and risks of marihuana for medical purposes so that individuals could be informed about their treatment choice.

The FDA provisions will also apply to prohibit labelling, packaging or selling in a manner that is false, misleading or likely to create an erroneous impression about the character or safety of the drug. For example, unsubstantiated health claims cannot be put on product packaging. Advertising any narcotic to the general public is prohibited under the NCR, and this prohibition will continue to apply to dried marihuana. As with other narcotics, this is intended to prevent known and potential harms to the health of Canadians who are vulnerable with respect to advertising of prescription drugs because they do not have the level of expertise to make informed choices regarding their use. To help individuals select a supplier, Health Canada will publish the name and contact information of licensed producers on its Web site.

3. Direct sale and distribution of dried marihuana to individuals authorized to possess it

Individuals who require marihuana for medical purposes have different avenues to obtain it under the MMPR. Dried marihuana could be sold or provided directly to registered clients by the licensed producer through secure shipping only. It could also be sold or provided by hospitals, which could purchase it directly from licensed producers.

Distribution through licensed producers

The primary means of distribution of dried marihuana will be directly from the licensed producer to the registered client using secure shipping methods, as the MMPR do not allow for storefront or retail distribution centres. This is how PPS has distributed dried marihuana and marihuana seeds to Program participants since 2003. This method has proven to be secure and to adequately mitigate the risk of diversion.

du poids, la date d'emballage, la date d'expiration, si une telle date a été établie à la suite d'un test de stabilité, ainsi qu'un avertissement de « GARDER HORS DE LA PORTÉE DES ENFANTS ».

Le producteur autorisé aura également l'obligation d'apposer une étiquette particulière au client sur le paquet de marihuana séchée, comme dans le cas de l'étiquette d'un médicament prescrit pour un patient en particulier. Cette étiquette présentera le nom du client et celui du praticien de la santé autorisé qui a fourni le document médical, la quantité quotidienne de marihuana séchée, ainsi que la fin de la période de validité telle qu'elle figure sur le document médical. L'étiquette indiquera aussi la date d'expédition et la date anticipée de livraison au client inscrit. Le producteur autorisé aura l'obligation de produire un double distinct de cette étiquette et de l'envoyer au client. Ce double de document ou l'étiquette du produit, ainsi qu'une carte d'identité avec photo appropriée, pourront permettre de démontrer la possession légale (voir « Possession de marihuana séchée » ci-dessus).

Il sera également obligatoire que chaque paquet de marihuana séchée vendu à un client soit accompagné d'une copie de la version la plus récente du document de Santé Canada intitulé *Renseignements sur l'usage de la marihuana à des fins médicales*. Ce document indique que la sécurité et l'efficacité de la marihuana séchée à des fins médicales n'ont pas été confirmées et fournit un résumé des renseignements connus au sujet des usages et des risques de la marihuana à des fins médicales, afin que les particuliers soient informés au sujet du traitement qu'ils choisissent.

Les dispositions de la LAD s'appliqueraient aussi pour interdire l'étiquetage, l'emballage ou la vente d'une manière fausse, trompeuse ou susceptible de créer une fausse impression quant à la nature ou à la sûreté de la drogue. Par exemple, des déclarations non fondées sur la santé ne peuvent être placées sur l'étiquette. La publicité relative à tout stupéfiant auprès du public est interdite en vertu du RS, et cette interdiction continuera d'être appliquée à la marihuana séchée. Comme dans le cas des autres stupéfiants, cela a pour but d'éviter tout danger connu et potentiel pour la santé des Canadiens qui sont vulnérables sur le plan de la publicité des médicaments vendus sur ordonnance, puisqu'ils n'ont pas le niveau d'expertise requis pour faire des choix éclairés relativement à leur utilisation. Santé Canada publiera le nom et les coordonnées des producteurs autorisés sur son site Web.

3. Vente et distribution directes de la marihuana séchée aux particuliers autorisés à en posséder

Les particuliers qui ont besoin de la marihuana à des fins médicales ont différents moyens de l'obtenir en vertu du RMFM. La marihuana séchée pourrait être vendue ou fournie directement par le producteur autorisé aux clients inscrits au moyen d'une expédition sécurisée seulement. Elle pourrait également être vendue ou fournie par les hôpitaux, qui pourraient l'acheter directement des producteurs autorisés.

Distribution par les producteurs autorisés

Le principal moyen de distribution de la marihuana séchée sera la distribution directe par le producteur autorisé au client inscrit en utilisant des méthodes d'expéditions sécurisées, puisque le RMFM n'a pas pour objet de permettre la vente au comptoir ou dans des centres de distribution au détail. Il s'agit de la façon dont PPS a distribué la marihuana séchée et les graines de marihuana aux participants au Programme depuis 2003. Cette méthode s'est avérée sécuritaire et atténue adéquatement le risque de détournement.

Health Canada will not regulate the price of marihuana under the MMPR. It will be up to licensed producers to set the price.

Before selling dried marihuana to an individual, a licensed producer will have to register the individual as a client. In the process of registering a client, licensed producers will have to verify that the supporting authorized health care practitioner is entitled to practice their profession in the province in which they were consulted by the prospective client and that they have not been prohibited from prescribing narcotics. These tasks are similar to those conducted by a pharmacist when filling out a prescription. The licensed producer will also have to confirm with the office of the authorized health care practitioner that the information in the medical document, including the daily quantity, is correct and complete.

Shipping

Dried marihuana will have to be shipped directly to a registered client using a shipping service that includes a means of tracking the package during transit. It will have to be sent in only one shipment per order. Finally, dried marihuana will have to be securely packed and shipped in a container that will not allow the contents to be identified visually or by odour.

Dispensing dried marihuana through pharmacists

The MMAR enabled pharmacists to dispense marihuana that had been produced by a licensed dealer under contract with Her Majesty in right of Canada to the holder of an authorization to possess. This provision was added in 2005 when some provinces and territories expressed an interest in allowing pharmacists to undertake this activity. Dispensing of marihuana for medical purposes by pharmacists has never been done to date.

The ability of pharmacists to dispense marihuana for medical purposes has been removed from the MMPR, following prepublication. Pharmacists and pharmacists' associations and professional licensing bodies, as well as provinces and territories, submitted comments expressing concerns with the dispensing of dried marihuana through pharmacies (see "Consultation" section). To address these concerns, Health Canada has revised the MMPR to remove the authority for pharmacists to dispense marihuana for medical purposes as long as their activities were also authorized under P/T legislation. Like other hospital employees, a pharmacist who is a hospital employee may order, administer or sell or provide dried marihuana to a patient at the hospital, if permitted by the person in charge of the hospital to do so, and as authorized under the NCR.

Other overarching requirements

Security

According to law enforcement officials, organized crime groups are involved in the trafficking of marihuana, and the profits derived from this activity allow them to support themselves and participate in the trade of other illicit commodities. The security measures required in the MMPR are therefore designed not only to ensure that licensed producers take steps to ensure the physical security of their site, but also to prevent infiltration by criminal groups who

Santé Canada ne réglementera pas le prix de la marihuana en vertu du RMFM. Les producteurs autorisés établiront eux-mêmes le prix de leurs propres produits.

Avant de vendre de la marihuana séchée à un particulier, un producteur autorisé aura l'obligation d'inscrire le particulier en tant que client. Dans le cadre du processus d'enregistrement d'un client, les producteurs autorisés seront obligés de s'assurer que le praticien de la santé autorisé répondant a le droit de pratiquer sa profession dans la province dans laquelle il a été consulté par le client potentiel et qu'il ne fait pas l'objet d'une interdiction de prescrire des stupéfiants. Ces fonctions sont semblables à celles assumées par un pharmacien au moment de remplir une ordonnance. Le producteur autorisé aura aussi l'obligation de confirmer auprès du bureau du praticien de la santé autorisé que les renseignements inscrits sur le document médical, y compris la quantité quotidienne, sont corrects et complets.

Expédition

Il sera obligatoire que la marihuana séchée soit expédiée directement à un client inscrit à l'aide d'un service d'envoi qui comprend des moyens d'assurer le suivi du paquet pendant le transport. Elle sera expédiée en un seul envoi par commande. Finalement, la marihuana séchée sera emballée de façon sécuritaire et expédiée dans un contenant qui empêchera d'identifier le contenu visuellement ou par l'odeur.

Distribution de la marihuana séchée par les pharmaciens

Le RAMM permet aux pharmaciens de distribuer la marihuana qui a été produite par un fournisseur autorisé en vertu d'un marché avec Sa Majesté du chef du Canada au titulaire d'une autorisation de possession. La disposition a été ajoutée en 2005, lorsque des provinces et des territoires ont exprimé leur intérêt de permettre aux pharmaciens d'exécuter cette fonction. La distribution de la marihuana à des fins médicales par les pharmaciens n'a jamais eu lieu jusqu'à maintenant.

La capacité des pharmaciens de distribuer de la marihuana a été retirée du RMFM à la suite de la publication préalable. Les pharmaciens et les associations de pharmaciens, les organismes de réglementation professionnelle de même que les provinces et les territoires ont présenté des commentaires qui soulèvent des préoccupations en ce qui concerne la distribution de la marihuana séchée par les pharmacies (voir la section sur la consultation). Dans le but d'aborder ces préoccupations, Santé Canada a révisé le RMFM en vue de retirer l'autorisation aux pharmaciens de distribuer de la marihuana à des fins médicales, à condition que leurs activités fussent également autorisées en vertu des lois provinciales et territoriales. À l'instar des autres employés d'un hôpital, un pharmacien qui fait partie des employés de l'hôpital peut commander, administrer, vendre ou fournir de la marihuana séchée à un patient à l'hôpital, si la personne responsable de l'hôpital le permet, et en fonction de l'autorisation accordée conformément au RS.

Autres exigences très importantes

Sécurité

Selon les responsables de l'application de la loi, les groupes criminels organisés sont impliqués dans le trafic de la marihuana et les profits provenant de cette activité leur permettent de subvenir à leurs besoins et de prendre part au commerce d'autres produits illicites. Par conséquent, les mesures de sécurité requises dans le RMFM sont conçues pour garantir que les producteurs autorisés prennent les mesures qui conviennent pour veiller à la sécurité

may wish to exploit the lawful production of marihuana for medical purposes for illicit purposes. In contrast, licences to produce issued under the MMAR did not carry any prescriptive physical security requirements; therefore, the associated production sites are more vulnerable to violent intrusions, theft and diversion.

Health Canada's *Directive on Physical Security Requirements for Controlled Substances* establishes security requirements for the storage of all controlled substances. These requirements are scaled to the illicit market value of the controlled substance and to the crime rates in various areas. This directive will apply to the storage of cannabis other than marihuana plants, by licensed producers.

The MMPR also set out physical security requirements for the entire site, as well as for areas within a site where cannabis is present. These will include all areas where a licensed activity is conducted with marihuana and cannabis other than marihuana (i.e. a lab, the production room, the area where dried marihuana is packaged and labelled). Access to these areas will have to be restricted only to individuals whose presence is required because of their work responsibilities. Licensed producers will have to put systems in place to ensure that access is controlled at all times, as well as 24-7 visual monitoring systems to detect unlawful conduct. The restricted areas will also have to be secured by an intrusion detection system that will detect attempted or actual unauthorized access to the area. The same principles of visual monitoring and intrusion detection will apply to the perimeter of the entire site. Licensed producers will also have to ensure the site and its restricted areas include physical security barriers designed to prevent unauthorized entry. Personnel monitoring the security and surveillance systems of a licensed site must take action in response to a detected incident and record the details of the action(s) taken. Should an applicant for a licence fail to demonstrate that they have put in place appropriate physical security measures as outlined in the MMPR, the production licence will be refused.

The MMPR also include requirements that the holder of the production licence, directors and officers (in the case of a corporation) and all key personnel must hold enhanced security clearances prior to the issuance of a producer's licence. To obtain an enhanced security clearance, these individuals will be required to submit an application with personal information and documents to Health Canada, so that checks and verifications of relevant files of law enforcement agencies could be conducted. As well as criminal record checks, these clearances will involve a global evaluation of the applicant's potential associations with criminal or violent organizations, associations with individuals linked to such organizations, and the risk of whether the applicant might be induced to assist, abet or commit any act that will pose a risk to the control of the production and distribution of cannabis. Should the applicant not successfully obtain a security clearance, the production licence will be refused.

physique de leur installation, ainsi que pour éviter l'infiltration par les groupes criminels qui pourraient vouloir exploiter la production légale de la marihuana à des fins médicales dans des activités illicites. Quant aux licences autorisant la production délivrée en vertu du RAMM, elles n'étaient assorties d'aucune exigence sur le plan de la sécurité physique et, en conséquence, les lieux de production qui leur sont associés sont plus vulnérables aux intrusions violentes, au vol et au détournement.

La *Directive sur les exigences en matière de sécurité physique pour les substances désignées* de Santé Canada établit des exigences de sécurité pour l'entreposage de toute substance réglementée. Ces exigences sont établies en fonction de la valeur du marché illicite de la substance réglementée et des taux de criminalité dans différents secteurs. Cette directive s'appliquera à l'entreposage de chanvre indien autre que des plants de marihuana, par les producteurs autorisés.

Le RMFM établit des exigences en matière de sécurité physique pour l'installation au complet, ainsi que pour les zones dans une installation où se trouve du chanvre indien. Ces zones comprendront toutes les zones dans lesquelles une activité autorisée est menée avec la marihuana et le chanvre indien autre que la marihuana (c'est-à-dire un laboratoire, une salle de production, la zone où la marihuana séchée est emballée et étiquetée). L'accès à ces zones sera réservé uniquement à certaines personnes dont la présence serait requise pour le travail. Les producteurs autorisés auront l'obligation de mettre en place des systèmes pour assurer le contrôle de l'accès en tout temps, ainsi que des systèmes de surveillance visuelle tous les jours 24 heures sur 24 afin de détecter toute conduite illicite. Il sera également obligatoire que les zones à accès restreint soient protégées par un système de détection des intrusions qui détectera les tentatives d'accès ou les accès non autorisés dans la zone. Les mêmes principes de surveillance visuelle et de détection des intrusions s'appliqueront à l'ensemble de l'installation. Les producteurs autorisés auront également l'obligation de s'assurer que l'installation et ses zones à accès restreint comprennent des barrières de sécurité conçues pour empêcher toute entrée non autorisée. Le personnel qui contrôle la sécurité et les systèmes de surveillance d'une installation autorisée doit prendre des mesures pour répondre à un incident détecté et enregistrer les détails de ces mesures. Si un demandeur d'une licence n'arrive pas à démontrer qu'il a mis en place les mesures de sécurité physique telles qu'elles sont décrites dans le RMFM, la licence de production sera refusée.

Le RMFM comprend également des exigences selon lesquelles le producteur autorisé, les directeurs et les dirigeants (dans le cas d'une société), ainsi que l'ensemble du personnel clé doivent être titulaires d'une habilitation de sécurité approfondie avant la délivrance de la licence au producteur. Pour obtenir une telle habilitation de sécurité approfondie, ces personnes auront l'obligation de présenter une demande comportant des renseignements personnels et des documents à Santé Canada afin que des vérifications des dossiers pertinents des organismes d'application de la loi soient menées. En plus d'une vérification du casier judiciaire, ces habilitations entraîneront une évaluation globale des associations potentielles du demandeur avec des groupes criminels organisés ou violents, des associations avec des individus reliés à de tels groupes et du risque que le demandeur puisse être persuadé d'assister à tout acte qui posera un risque pour le contrôle de la production et de la distribution du chanvre indien, de l'encourager ou de le commettre. Si les demandeurs ne réussissent pas à obtenir une habilitation de sécurité, la licence de production sera refusée.

Information sharing

The MMPR include provisions that will require licensed producers to share information with appropriate authorities in certain circumstances. For example, as with the MMAR, law enforcement needs a way to verify whether a named individual is a registered client of the producer. If a member of a Canadian police force requires information in the course of an investigation, a licensed producer will be required to confirm as soon as practicable whether the individual is a registered client or an individual who is responsible for a registered client and the daily quantity of dried marihuana specified in the medical document.

Record keeping

As described under the MMPR, licensed producers will have to keep records of their activities with cannabis, including all transactions (sale, exportation, and importation), all dried marihuana returned from clients, and an inventory of cannabis (e.g. seeds, fresh harvested marihuana, dried marihuana and packaged marihuana). All records will have to be kept for a period of at least two years, in a format that will be easily auditable, and will have to be made available to Health Canada upon request.

In addition to the revisions to the MMPR following prepublication in the *Canada Gazette*, Part I, on December 15, 2012, described above, other changes have been made to clarify and/or refine the Regulations as well as to make minor corrections. Of more significance were the following:

- Section 1 — Section 1 provides definitions for terms used elsewhere in the Regulations. The prepublished definition of "local governments" has been revised to include a band, as defined in subsection 2(1) of the *Indian Act*, and a band that is a party to a comprehensive self-government agreement given effect by an Act of Parliament. This was added to the definition for greater clarity with respect to the definition of local government.
- Section 1 — Section 1 provides definitions for terms used elsewhere in the Regulations. The prepublished MMPR did not include a definition for "transfer" which has been defined, except in sections 118, 122 and 132, to mean "transfer, whether directly or indirectly, without consideration." This definition has been added to clarify the authority for health care practitioners.
- Section 12 — Section 12 describes permitted activities and general obligations for a licensed producer. This section has now been modified to allow a licensed producer to possess, produce, ship, deliver, transport and destroy cannabis, other than dried marihuana that is used for the determination of percentages of cannabinoids in dried marihuana.
- Section 15 — Section 15 describes the storage of cannabis and dried marihuana. Subsection 15(2) has been changed to clarify "that the licensed producer must store cannabis, other than marihuana plants, in accordance with the Security Directive" as the Security Directive does not address storage with respect to plants.
- Sections 38, 39 and 40 — Section 38 describes notification to local authorities when making an application for a producer's licence to the Minister. Section 39 describes a notification to the same local authorities named under section 38 when a licence amendment is being sought. However, a similar provision was needed to address a change of licence status as a result of a review done by the Minister. A new provision has been

Échange d'information

Le RMFM comprend des dispositions qui nécessiteront que les producteurs autorisés échangent des renseignements avec les autorités appropriées dans certaines circonstances. Par exemple, comme dans le cas du RAMM actuel, les responsables de l'application de la loi ont besoin d'un moyen de vérifier si une personne visée est un client inscrit du producteur. Si un membre d'une force policière canadienne demande des renseignements dans le cadre d'une enquête, un producteur autorisé sera tenu de confirmer dans les meilleurs délais que la personne est un client inscrit ou une personne responsable d'un client inscrit, ainsi que la quantité quotidienne de marihuana séchée précisée sur le document médical.

Tenue des dossiers

Tel qu'il est décrit dans le RMFM, les producteurs autorisés auront l'obligation de conserver les dossiers relatifs à leurs activités liées au chanvre indien, y compris toutes les transactions (vente, exportation, importation), toute la marihuana séchée retournée par les clients et un inventaire du chanvre indien (par exemple les graines, la marihuana fraîchement récoltée, la marihuana séchée et la marihuana emballée). Tous les dossiers devront être conservés pendant une période minimale de deux ans, dans un format facile à vérifier, et être fournis à Santé Canada sur demande.

En plus des révisions au RMFM faites à la suite de la publication préalable dans la Partie I de la *Gazette du Canada* le 15 décembre 2012 et décrites ci-dessus, d'autres changements ont été apportés en vue de clarifier et/ou de mettre au point le Règlement, ainsi que de procéder à des corrections mineures. Les plus importants sont les suivants :

- Article 1 — L'article 1 fournit la définition des termes utilisés autre part dans le Règlement. La définition publiée au préalable de « administration locale » a été révisée afin de comprendre une bande, telle qu'elle est définie au paragraphe 2(1) de la *Loi sur les Indiens*, et une bande qui est partie à un accord global sur l'autonomie gouvernementale mis en vigueur par une loi fédérale. Cela a été ajouté à la définition afin d'en favoriser la clarté sur le plan de la définition de gouvernement local.
- Article 1 — L'article 1 fournit la définition des termes utilisés autre part dans le Règlement. Le RMFM publié au préalable ne comprenait aucune définition pour le terme « transfert » qui a été défini, sauf aux articles 118, 122 et 132, en vue de signifier « un transfert, directement ou indirectement, sans considération ». Cette définition a été ajoutée afin de clarifier l'autorisation des praticiens de la santé.
- Article 12 — L'article 12 décrit les activités permises et les obligations générales d'un producteur autorisé. Cette section a été modifiée afin de permettre qu'un producteur autorisé possède, produise, expédie, livre, transporte et détruise du chanvre indien autre que de la marihuana séchée qui est utilisée pour la détermination des pourcentages de cannabinoïdes dans la marihuana séchée.
- Article 15 — L'article 15 décrit l'entreposage du chanvre indien et de la marihuana séchée. Le paragraphe 15(2) a été modifié afin de clarifier que « le producteur autorisé doit entreposer le chanvre indien autre que les plants de marihuana en conformité avec la Directive sur la sécurité », puisque la Directive sur la sécurité ne traite pas de l'entreposage relatif aux plants.
- Articles 38, 39 et 40 — L'article 38 décrit l'avis aux autorités locales lors de la présentation d'une demande pour une autorisation de production au ministre. L'article 39 décrit un avis aux

added in which a licensed producer must notify the same authorities given the initial notification of intent to apply for a licence (in section 23) when the licence is granted, an amendment is approved by the Minister, the licence is suspended or revoked for any reason, or when the licence is reinstated. A copy of these notifications will need to be sent to the Minister within 30 days of the notification being made, according to section 40. The licensed producer will be required to maintain a record of such notifications for two years as per record-keeping requirements.

- Division 3 — Division 3 outlines the general restricted areas and site security measures. The titles "Restricted Areas" and "Site" have been modified to refer to "Areas Within a Site where Cannabis is Present" and "Perimeter of Site" respectively. These changes are for clarification purposes only.
- Section 43 — Section 43 sets out the requirements for visual monitoring of the site perimeter. To clarify the intent of this requirement, the section has been revised to indicate that visual monitoring must be accompanied by visual recording devices to detect attempted or actual unauthorized access. Furthermore, all visual monitoring devices must be able to visually capture and record attempts of actual unauthorized access. In accordance with record keeping requirements, these records must be kept for two years.
- Section 44 and section 45 — Sections 44 and 45 set out the requirements for the site perimeter intrusion detection system and its monitoring. This section has been revised to include the new requirement that personnel must determine the appropriate steps to take in response and must record specified details of a detected occurrence.
- Section 46 — Section 46 describes restricted access to areas where cannabis is present and the keeping of records of personnel accessing or vacating these areas. A new subsection has been added that requires the responsible person in charge (or the alternate) to be physically present while others are in areas where cannabis is present. This provision was added to clarify that key personnel must always be present to monitor areas where activities with cannabis are occurring.
- Section 47 — Section 47 is a new section which has been added to require the presence of physical barriers that prevent unauthorized access to restricted areas. This change further clarifies what security measures will be considered acceptable under the Regulations.
- Section 48 — Section 48 sets out the requirements for visual monitoring of areas within a site where cannabis is present. To clarify the intent of this requirement, this provision has been revised to specify that visual monitoring must be accompanied by visual recording devices to detect illicit conduct. Furthermore, all visual monitoring devices must be able to capture in a visible manner illicit conduct. In accordance with record keeping requirements, these records must be kept for two years.
- Section 49 — Section 49 sets out the requirements for the restricted area's intrusion detection system and its monitoring. Monitoring is moved into a new section addressing monitoring by personnel and recording of detected occurrences. The previous provision has been modified to clarify that personnel must determine the appropriate steps to take in response and record specified details of any detected occurrence. In accordance with record keeping requirements, these records must be kept for two years.

mêmes autorités locales nommées dans l'article 38 lorsqu'une modification à une licence est demandée. Cependant, une disposition semblable était requise en vue d'aborder le changement du statut de licence à la suite d'un examen effectué par le ministre. Une nouvelle disposition a été joutée et exige qu'un producteur autorisé informe les autorités ayant été informées de l'intention de demander une licence (à l'article 23) si la licence est accordée, si une modification est approuvée par le ministre, si la licence est suspendue ou révoquée pour une raison quelconque, ou lorsque la licence est rétablie. Une copie de ces avis devra être envoyée au ministre dans les 30 jours de l'avis, conformément à l'article 40. Le producteur autorisé devra conserver un dossier de ces avis pendant deux ans, conformément aux exigences relatives à la tenue de dossiers.

- Section 3 — La section 3 donne un aperçu des zones restreintes générales et des mesures de sécurité dans les installations. Les titres « Zones restreintes » et « Installation » ont été modifiés afin de renvoyer à des « Zones de l'installation où du chanvre indien est présent » et « Périmètre de l'installation » respectivement. Ces changements sont apportés à des fins de clarification seulement.
- Article 43 — L'article 43 formule les exigences relatives à la surveillance visuelle dans le périmètre de l'installation. Dans le but de clarifier l'intention de cette exigence, l'article a été révisé afin d'indiquer que la surveillance visuelle doit être complémentée par des appareils d'enregistrement visuel pour détecter toute tentative d'accès ou tout accès non autorisé. De plus, tous les appareils de surveillance visuelle doivent être en mesure de saisir visuellement et d'enregistrer toute tentative d'accès ou tout accès non autorisé. Conformément aux exigences relatives à la tenue de dossiers, ces enregistrements doivent être conservés pendant deux ans.
- Articles 44 et 45 — Les articles 44 et 45 établissent les exigences pour le système de détection des intrusions dans le périmètre de l'installation et sa surveillance. Cet article a été révisé afin de comprendre la nouvelle exigence selon laquelle le personnel doit déterminer les mesures adéquates à prendre et doivent enregistrer les détails précis de toute détection.
- Article 46 — L'article 46 décrit l'accès restreint aux zones de l'installation où du chanvre indien est présent et la tenue des dossiers des membres du personnel qui entrent dans ces zones ou en sortent. Un nouveau paragraphe a été ajouté et nécessite que la personne responsable (ou son remplaçant) soit présente physiquement lorsque d'autres personnes sont dans les zones de l'installation où du chanvre indien est présent. Cette disposition a été ajoutée en vue de clarifier le fait que le personnel clé doit toujours être présent afin de surveiller les zones où des activités sont accomplies avec du chanvre indien.
- Article 47 — L'article 47 est un nouvel article qui a été ajouté afin d'exiger la présence de barrières physiques qui empêchent l'accès non autorisé aux zones restreintes. Ce changement clarifie davantage les mesures de sécurité qui seront considérées comme acceptables en vertu du Règlement.
- Article 48 — L'article 48 établit les exigences relatives à la surveillance visuelle des zones de l'installation où du chanvre indien est présent. Dans le but de clarifier l'intention de cette exigence, cette disposition a été révisée en vue de préciser que la surveillance visuelle doit être accompagnée d'appareils d'enregistrement visuel pour la détection de toute conduite illicite. De plus, tous les appareils de surveillance visuelle doivent

- Section 50 — Section 50 describes the requirements for the filtration of exhaust air to prevent the escape of pollen and odours. This section has been revised to have the filtration of exhaust air for pollen, only if present. This change was made to recognize the possibility that pollen may not be present at a licensed site.
- Section 63 — Section 63 describes the requirements for adverse reaction reporting as well as the accompanying summary report. In the prepublished version of the MMPR, Health Canada did not specify a retention period for these records. To align with record keeping requirements for adverse reactions for other health products, a retention period of 25 years has been added for records.
- Section 64 — Section 64 sets out licensed producer requirements for the packaging of dried marihuana. In the prepublished version of the Regulations, the maximum quantity of dried marihuana allowed per package was 15 g. This quantity has been corrected to a maximum of 30 g of dried marihuana per package to be consistent with the maximum package size which was available for purchase from Health Canada under the MMAP.
- Section 65 — Section 65 sets out the limits of variability with respect to the weight of dried marihuana in packages being sold to registered clients. The net weight variability of dried marihuana in a package has now been narrowed slightly from a range of 90% to 101% to 95% to 101%.
- Deleted (section 99) — This section formerly set out the authority under which the Minister could receive information from law enforcement, peace officer and international organizations such as the International Narcotics Control Board and the United Nations. This provision was removed as unnecessary since the Minister already has the ability to receive such information from these entities.
- Deleted (section 101) — This provision formerly described the authority for law enforcement to share information with the Minister with respect to security checks and verifications. This section was removed since the Minister already has the ability to receive information from law enforcement with respect to security clearances.
- Section 115 — Section 115 outlines the requirements for amending a client's registration. Additional authorities were added to allow individuals responsible for the client to make an application on behalf of the client to amend their registration if permitted to do so by the client.
- Section 117 — Section 117 outlines the requirements for the cancellation of registration. Subsection 117(2) describes the timing of cancellation and has been modified to also allow, in the case of a cancellation of a registration by a licensed producer, the individual responsible for the client (and not simply the client) to provide reasons as to why they may feel that the cancellation was not justified.
- Section 124 — Section 124 sets out a limit on the quantity of dried marihuana a licensed producer may sell or provide to a client in any 30-day period. This provision has been revised to clarify that a licensed producer may also sell or provide to the individual responsible for the client.
- Sections 13, 114, 118, 129, and 134 in the prepublished Regulations (and relevant consequential amendments) have been subsequently amended to remove the authority for health care practitioners to "sell or provide" dried marihuana to patients under their care. This has been replaced with the authority to "transfer" (i.e. provide without consideration). Consequential

être en mesure de saisir visiblement toute conduite illicite. Conformément aux exigences relatives à la tenue de dossiers, ces enregistrements doivent être conservés pendant deux ans.

- Article 49 — L'article 49 établit les exigences relatives au système de détection des intrusions dans les zones restreintes et à sa surveillance. La surveillance est déplacée à l'intérieur d'un nouvel article qui traite de la surveillance par le personnel et de l'enregistrement des détections. La disposition antérieure a été modifiée afin de clarifier que le personnel doit déterminer les mesures adéquates à prendre et enregistrer les détails précis de toute détection. Conformément aux exigences relatives à la tenue de dossiers, ces enregistrements doivent être conservés pendant deux ans.
- Article 50 — L'article 50 décrit les exigences relatives à la filtration de l'air d'évacuation afin d'éviter que le pollen et les odeurs s'échappent. Cet article a été révisé afin que l'air d'évacuation pour le pollen soit filtré uniquement en présence de pollen. Ce changement a été apporté en vue de reconnaître la possibilité que le pollen ne soit pas présent dans une installation autorisée.
- Article 63 — L'article 63 décrit les exigences relatives au signalement d'effets indésirables ainsi qu'à l'établissement d'un rapport sommaire connexe. Dans la version publiée au préalable du RMFM, Santé Canada ne précisait aucune période de conservation pour ces dossiers. Aux fins d'harmonisation avec les exigences en matière de tenue de dossiers pour les effets indésirables d'autres produits de santé, une période de conservation des dossiers de 25 ans a été ajoutée.
- Article 64 — L'article 64 établit les exigences du producteur autorisé relativement à l'emballage de la marihuana séchée. Dans la version publiée au préalable du Règlement, la quantité maximale de marihuana séchée permise par emballage était de 15 grammes. Cette quantité a été corrigée pour un maximum de 30 grammes de marihuana séchée par emballage, afin de correspondre à la taille maximale d'emballage disponible pour l'achat auprès de Santé Canada en vertu du RAMM.
- Article 65 — L'article 65 établit les limites de variabilité relativement au poids de la marihuana séchée dans les emballages vendus aux clients inscrits. La variabilité du poids net de marihuana séchée dans un emballage a été resserrée légèrement, passant d'un écart de 90 % à 101 % à un écart de 95 % à 101 %.
- Supprimée (article 99) — Cet article établissait le pouvoir qui permettait au ministre de recevoir des renseignements de la police, d'agents de la paix et d'organismes internationaux comme l'Organe international de contrôle des stupéfiants et les Nations Unies. Inutile, cette disposition a été retirée puisque le ministre a déjà la capacité de recevoir de tels renseignements de ces entités.
- Supprimée (article 101) — Cette disposition décrivait le pouvoir qui permettait à la police d'échanger des renseignements avec le ministre relativement à des vérifications de sécurité. Cet article a été retiré, puisque le ministre a déjà la capacité de recevoir des renseignements de la police relativement à des autorisations de sécurité.
- Article 115 — L'article 115 donne un aperçu des exigences relatives à la modification de l'inscription d'un client. D'autres pouvoirs ont été ajoutés afin de permettre aux personnes responsables des clients de présenter une demande au nom d'un client en vue de modifier son inscription, si le client le permet.
- Article 117 — L'article 117 donne un aperçu des exigences relatives à l'annulation de l'inscription. Le paragraphe 117(2) décrit le moment de l'annulation et a été modifié afin

amendments have been made to the NCR and MMAR to ensure consistency on this issue under all schemes.

- References to pharmacist dispensing under sections 3, 4, 11 and consequential amendments to the NCR in the prepublished version of the MMPR have been removed to reflect the decision to remove dispensing of dried marihuana by pharmacists outside of a hospital context.

Regulatory and non-regulatory options considered

In addition to the approach described above, the following options were considered.

Health Canada continues to authorize individuals to possess dried marihuana for medical purposes, but the MMAR supply options would be replaced with licensed production by private industry

Under this option, Health Canada would establish a licensing framework to allow for a commercial industry for the production and distribution of dried marihuana for medical purposes. Personal and designated production of dried marihuana for medical purposes would be eliminated, and Health Canada would no longer produce and distribute marihuana directly to individuals, eliminating related contract costs. However, Health Canada would continue to authorize individuals to possess dried marihuana for medical purposes. This would mean that individuals would have to apply to Health Canada for an authorization prior to registering as a client with a licensed producer. Health Canada would continue to issue authorization documents and maintain a database of all authorized persons.

This is not the preferred option because it is inconsistent with one of the key objectives of reform, which is to treat marihuana as much as possible like other narcotics used for medical purposes. Furthermore, as the numbers of users of marihuana for medical purposes are expected to continue to grow, Health Canada would continue to incur high administrative costs by maintaining this role.

Status quo

Under this option, Health Canada would maintain the Program under the MMAR in its current form. Health Canada would continue to issue authorizations to possess, PUPLs and DPPLs to

de permettre à la personne responsable du client (et pas uniquement le client) de demander la possibilité de fournir les raisons pour lesquelles elle estime que l'annulation était injustifiée.

- Article 124 — L'article 124 établit une limite quant à la quantité de marihuana séchée qu'un producteur autorisé peut vendre ou fournir à un client au cours d'une période de 30 jours. Cette disposition a été révisée afin de clarifier qu'un producteur autorisé peut également en vendre ou en fournir à la personne responsable du client.
- Les articles 13, 114, 118, 129 et 134 dans le Règlement publié au préalable (et les modifications pertinentes qui en découlent) ont été modifiés ultérieurement afin de retirer l'autorité aux praticiens de la santé de « vendre ou fournir » de la marihuana séchée aux patients qu'ils soignent. Dorénavant, ils ont plutôt une autorisation de « transfert » (c'est-à-dire fournir sans échange d'une contrepartie) à des personnes à qui ils fournissent des soins professionnels ou à des particuliers qui sont responsables de ces personnes. Les modifications qui en découlent ont été apportées au RS et au RAMM afin d'assurer l'uniformité de cette question dans le cadre de tous les mécanismes.
- Les références à la distribution par les pharmaciens aux articles 3, 4 et 11 et les modifications qui en découlent dans le RS dans la version préalable publiée du RMFM ont été retirées afin de tenir compte de la décision de retirer la distribution de la marihuana séchée par les pharmaciens en dehors des hôpitaux.

Options réglementaires et non réglementaires considérées

En plus de l'approche décrite ci-dessus, les options suivantes ont été prises en considération.

Santé Canada continuerait d'autoriser des particuliers à posséder de la marihuana séchée à des fins médicales, mais les options d'approvisionnement du RAMM seraient remplacées par la production autorisée par l'industrie privée

Selon cette option, Santé Canada établirait un cadre de délivrance de licence visant à permettre la mise sur pied d'une industrie à l'échelle commerciale pour la production et la distribution de la marihuana séchée à des fins médicales. La production personnelle et désignée de la marihuana séchée à des fins médicales serait éliminée et Santé Canada ne produirait et ne distribuerait plus la marihuana directement aux particuliers, éliminant ainsi les coûts contractuels. Cependant, Santé Canada continuerait d'autoriser les particuliers à posséder la marihuana séchée à des fins médicales. Cela signifierait que les particuliers auraient l'obligation de faire une demande d'autorisation auprès de Santé Canada avant de s'inscrire comme client auprès d'un producteur autorisé. Santé Canada continuerait de délivrer des documents d'autorisation et de tenir à jour une base de données sur toutes les personnes autorisées.

Il ne s'agit pas de l'option privilégiée, puisqu'elle ne correspond pas à l'un des principaux objectifs de la réforme selon lequel la marihuana doit être traitée comme d'autres stupéfiants utilisés à des fins médicales. De plus, puisqu'il est prévu que le nombre d'usagers de la marihuana à des fins médicales continuera d'augmenter, Santé Canada continuerait d'assumer des coûts administratifs élevés en conservant ce rôle.

Statu quo

Santé Canada maintiendrait le Programme dans le cadre du RAMM sous sa forme actuelle. Santé Canada continuerait de délivrer des autorisations de possession, des LPFP et des LPPD aux

program applicants. In order to manage the expected growth in applications, Health Canada would have had to review its administrative processes and its Program infrastructure to look for additional efficiencies. Given that the numbers of individuals in the Program continued to rise, costs for such a contract would have also continued to rise on an annual basis.

Additionally, Health Canada could consider raising the price of dried marihuana to cover the actual cost of production and distribution.

Health Canada could also have expanded its capacity to inspect PUPLs and DPPLs. However, an effective inspection program for thousands of sites across the country would have been costly. In addition, Health Canada's inspectors would not have been able to address public health, safety and security concerns expressed by stakeholders, such as electrical hazards, humidity and poor air quality in personal and designated production sites.

The status quo did not respond to stakeholder concerns about the health and safety risks of personal production. Also, as legal challenges against the MMAR continue, and as the number of individuals entering the Program would continue to rise, Health Canada would face rising pressures that would be difficult to contain.

Benefits and costs

The cost-benefit analysis (CBA) was based on a projected scenario that represents the most likely outcome of the regulatory change. A sensitivity analysis of the results was undertaken for a range of key parameters to capture the effect of uncertainty for each variable used in the analysis of the estimated costs and benefits.

The study focused on the consumption of marihuana, obtained from legal sources of supply, for medical purposes. The broader issue of illicit market supply and use was considered to be outside the scope of the analysis.

Marihuana for medical purposes is not an approved therapeutic product and the scientific studies of its safety and efficacy are not conclusive. The CBA made no attempt to measure real or perceived health costs or benefits in terms of therapeutic effects or improvements to quality of life. Instead, the study relied on estimating purely economic impacts on the basis of a change in consumer surplus that could arise from the MMPR.

Projected number of potential users

The number of persons using marihuana for medical purposes was projected over the 10-year forecast period, from 2014 to 2024, based on historical patterns of use under the Program and an estimated upper limit. This limit represents the number of people who indicated they used marihuana for medical purposes in the most recent (2011) population-level survey of Canadians aged 15 years and over.

Under both the status quo scenario and the MMPR, the analysis assumed the historical growth rate in authorized users of approximately 40% per annum to continue over the policy impact period (2014–2024). Under the status quo scenario, the number of potential users of marihuana for medical purposes was projected to

demandeurs du Programme. Dans le but de gérer l'augmentation prévue des demandes, Santé Canada a dû examiner ses processus administratifs et son infrastructure de programme afin de réaliser de l'efficience additionnelle. Puisque le nombre de particuliers qui participent au Programme a continué d'augmenter, les coûts d'un tel marché continueraient également d'augmenter chaque année.

De plus, Santé Canada pourrait examiner la possibilité d'augmenter le prix de la marihuana séchée pour assumer le coût réel de la production et de la distribution.

Santé Canada a renforcé sa capacité d'inspecter les LPFP et les LPPD. Toutefois, un programme d'inspection efficace pour des milliers de sites au pays aurait été coûteux. De plus, les inspecteurs de Santé Canada n'auraient pas été en mesure de répondre aux préoccupations en matière de santé et de sécurité publiques exprimés par les intervenants, comme les dangers électriques, l'humidité et la mauvaise qualité de l'air dans les sites de production personnels et désignés.

Le statu quo ne répondait pas aux préoccupations des intervenants au sujet des risques de la production personnelle pour la santé et la sécurité. De plus, étant donné que les contestations judiciaires contre le RAMM se poursuivent et que le nombre de particuliers qui prennent part au Programme continue à augmenter, Santé Canada ferait face à des pressions accrues qui seraient difficiles à contenir.

Avantages et coûts

L'analyse coûts-avantages (ACA) était fondée sur un scénario projeté qui représente le résultat le plus vraisemblable du changement de la réglementation. Une analyse de sensibilité des résultats a été entreprise relativement à un éventail de paramètres clés afin de saisir l'effet d'incertitude pour chaque variable utilisée dans l'analyse des coûts et des avantages prévus.

L'étude était concentrée sur la consommation de la marihuana, obtenue auprès d'une source d'approvisionnement légale, à des fins médicales. Il a été considéré que la question plus large relative au trafic et à l'usage illicites ne faisait pas partie de la portée de l'analyse.

La marihuana à des fins médicales n'est pas un produit thérapeutique approuvé et les études scientifiques sur sa sécurité et son efficacité ne sont pas concluantes. L'ACA ne comprenait aucune tentative de mesurer les coûts ou les avantages réels ou perçus pour la santé sur le plan des effets thérapeutiques ou des améliorations de la qualité de vie. L'étude reposait plutôt sur l'estimation des incidences purement économiques sur la base d'un changement relatif au surplus du consommateur qui pouvait survenir à la suite de l'entrée en vigueur du RMFM.

Nombre projeté d'usagers potentiels

Le nombre de personnes qui consomment la marihuana à des fins médicales a été projeté en fonction de la période de prévision de 10 ans, débutant en 2014 et prenant fin en 2024, selon des modèles historiques d'usage dans le cadre du Programme et une limite maximale prévue. Cette limite représente le nombre de personnes qui ont indiqué qu'elles consommaient la marihuana à des fins médicales dans le plus récent sondage (2011) mené auprès d'une population de Canadiens âgés de 15 ans et plus.

Pour le scénario de statu quo ainsi que celui du RMFM, l'analyse a supposé que le taux de croissance historique du nombre d'usagers autorisés d'environ 40 % par année allait demeurer constant durant la période d'incidence de la politique (2014-2024). Dans le scénario de statu quo, le nombre de base d'usagers

increase from a base number of 57 799 in 2014 to about 433 688 in 2024, slightly below the upper limit of 450 000. While the absolute number of legal users is still expected to increase over time, this increase was projected to be approximately 30% less over the 10-year period under the MMPR compared to the status quo scenario. This will mean an increase from a low projected estimate of 41 384 in 2014 to approximately 308 755 users by the end of the 10th year of implementation.

Benefits

The analysis quantified and monetized the beneficial impacts of the MMPR in terms of the reduction in risks associated with residential marihuana cultivation such as electrical fire hazards, potential home intrusions by criminals and the risks of sustaining serious injury or death in either case. Benefits were also estimated in terms of economic efficiency impacts.

Reduction in residential fire risks

The focus on safety impacts was on the risk and consequence of residential fires resulting from faulty electrical wiring, overloading of electrical circuits, tampering with electrical usage monitoring and other electrical system malfunction arising from indoor marihuana cultivation. The analysis assumed that under the MMPR, the risks of property damage, personal injury or death resulting from marihuana production-related fires will be significantly reduced but not completely eliminated. The social cost of adverse safety events related to the production of marihuana for medical purposes was estimated to be reduced, over the period from 2014 to 2024, by about 40% under the MMPR, at a total present value of $64.32 million. This represents annualized savings (avoided costs of property damage, injury and death from residential fires) of approximately $9.58 million per year for 10 years.

Reduction in risk of break-ins / home invasions

The focus of the security impacts was on the risk and consequences of home invasion, violence targeting residential production involved in misuse, and criminal activity related to marihuana distribution on the illegal market. Information from Canadian law enforcement authorities on misuse of production licences, home invasions and shootings was used as the basis to estimate the risk of violence. Overall, the analysis valued the projected reduction in the risks of break-ins / home invasions due to the MMPR at $0.38 million in 2014, rising to $26.48 million in 2024. The present value of security cost savings under the MMPR was estimated at approximately $89.03 million over the policy impact period, with an average annualized value of $13.27 million. The MMPR will have lower security costs (over 40% lower than under the status quo) due to the reduction in misuse activity that results from the expectation that eliminating personal and designated production in favour of a commercial licensing scheme will deter individuals interested in exploiting the Program.

potentiels de la marihuana à des fins médicales devrait augmenter de 57 799 en 2014 à environ 433 688 en 2024, un nombre légèrement inférieur à la limite maximale de 450 000. Alors que le nombre absolu d'utilisateurs licites devrait continuer d'augmenter au fil du temps, cette augmentation a été estimée approximativement à 30 % de moins au cours de la période de 10 ans pour le RMFM comparativement au scénario du statu quo. Cela signifiera une augmentation d'une estimation faible projetée de 41 384 en 2014 à environ 308 755 usagers d'ici la fin de la période de mise en œuvre de 10 ans.

Avantages

L'analyse a quantifié et monétisé les incidences avantageuses du RMFM sur le plan de la réduction des risques liés à la culture de la marihuana dans les résidences, comme les dangers d'incendie électrique et de braquage à domicile potentiel par des criminels, ainsi que les risques de blessures ou de mort dans l'un ou l'autre des cas. Des incidences avantageuses ont également été estimées sur le plan de l'impact de l'efficience économique.

Réduction des risques d'incendie résidentiel

En ce qui concerne les incidences sur la sécurité, l'analyse ciblait le risque d'incendie résidentiel et les conséquences d'une mauvaise installation des câbles électriques, d'une surcharge des circuits électriques, de l'altération du contrôle de la consommation d'électricité et d'autres défaillances du système électrique causées par la culture de la marihuana à l'intérieur. L'analyse a supposé qu'en raison du RMFM, les risques de dommages à la propriété, de blessures ou de décès à la suite d'un incendie lié à la culture de la marihuana seront grandement réduits, mais pas complètement éliminés. Il a été prévu que les coûts sociaux des effets indésirables sur le plan de la sécurité qui sont liés à la production de la marihuana à des fins médicales diminueraient d'environ 40 %, durant la période de 2014 à 2024, en vertu du RMFM, pour atteindre une valeur actualisée totale de 64,32 millions de dollars. Cela représente des économies calculées sur une année (coûts évités relatifs aux propriétés endommagées, aux blessures et aux décès attribuables aux incendies résidentiels) d'environ 9,58 millions de dollars par année pendant 10 ans.

Réduction du risque d'introduction par effraction et de braquage à domicile

En ce qui concerne les incidences sur la sécurité, l'analyse ciblait le risque et les conséquences de braquage à domicile et de violence visant la production autorisée dans les résidences qui fait l'objet d'un usage non conforme, ainsi que sur les activités criminelles relatives au trafic de la marihuana sur le marché illicite. Les renseignements fournis par les responsables des organismes canadiens chargés de l'application de la loi sur l'utilisation non conforme des licences de production, les braquages à domicile et les fusillades ont servi de base pour l'estimation du risque de violence. Dans l'ensemble, l'analyse a évalué la réduction prévue des risques d'introduction par effraction et de braquage à domicile attribuable au RMFM à 0,38 million de dollars en 2014 pour atteindre 26,48 millions de dollars en 2024. La valeur actualisée des économies des coûts en matière de sécurité dans le cadre du projet de RMFM a été estimée à environ 89,03 millions de dollars pendant la période d'incidence de la politique, avec une valeur moyenne calculée sur une année de 13,27 millions de dollars. Dans le cadre du RMFM, les coûts liés à la sécurité diminueront (plus de 40 % inférieurs aux coûts dans le scénario du statu quo) grâce à la réduction des activités non conformes qui découlent de la prévision selon laquelle l'élimination de la production personnelle et

Program administration cost savings

Government administration costs of the Program have increased significantly as the number of Program participants has grown. In the absence of regulatory changes, the analysis assumed a continuation of the growth in Program applications and corresponding substantial increases in the cost to Health Canada to authorize legal possession and license production of marihuana for medical purposes. The CBA estimated that the administration cost of the Program would have increased from $20.63 million in 2014 to over $120 million in 2024, in the absence of any changes. These costs include salary, employee benefits and accommodation costs associated with dedicated staff, operations and maintenance costs, training, supplies and other corporate overhead costs.

Under the MMPR, Health Canada will eliminate the role it plays in determining the eligibility of persons to access a legal supply of marihuana for medical purposes and return to its traditional role as a regulator of industry. This will result in significant administrative cost savings over the policy impact period. Under the scenario assumed for the new regulated market, the regulatory proposal was estimated to lead to more than a 90% reduction in Health Canada's administrative expenditures. The present value of administration cost savings over 10 years was estimated at $478 million. On average, the MMPR are expected to generate annualized administrative cost savings of approximately $71.24 million per year over this period. (This estimate does not include potential savings in contract supply costs or subsidies.)

Producer surplus gains[3]

The MMPR will establish a regulated commercial market for the production and sale of marihuana for medical purposes. Private industry participation in the regime is expected to yield benefits to society. Under the status quo, marihuana is either produced through private arrangements or at a cost to the taxpayer. There were no benefits to society at large beyond the benefits to the individuals involved. Under the MMPR, there will be beneficial impacts for the industry, over and above the benefits to the individuals involved in the market. The analysis measured this change in welfare by estimating a change in producer surplus gains under the policy. No producer surplus is derived in the status quo. The CBA found that the new regulated market will generate an overall producer surplus of $2.64 million in the first year of implementation (2014–15), rising to about $110 million in 2024 as the market expands. The present value of producer surplus gains over the policy horizon (2014–24) was estimated at $339.85 million or about $50.65 million (annualized average) per year for 10 years.

[3] Producer surplus is an economic measure of the difference between the amount the producer of a good or service actually receives, and the minimum amount he or she will accept.

désignée en faveur d'un cadre d'octroi de licences commerciales découragera les personnes intéressées à exploiter le Programme.

Économie des coûts d'administration du Programme

Les coûts d'administration du gouvernement pour le Programme ont augmenté de façon considérable, puisque le nombre de participants au Programme a augmenté. En l'absence des changements de réglementation proposés, l'analyse a prévu une continuité de la croissance des demandes de participation au Programme et des augmentations importantes correspondantes du coût pour Santé Canada pour l'autorisation de possession légale et la délivrance de licences autorisant la production de la marihuana à des fins médicales. Selon l'ACA, si aucun changement n'est apporté, le coût de l'administration du Programme passera de 20,63 millions de dollars en 2014 à plus de 120 millions de dollars en 2024. Les coûts comprennent les salaires, les avantages sociaux des employés et les coûts des installations pour le personnel spécialisé, les coûts de fonctionnement et d'entretien, la formation, les fournitures et les autres coûts organisationnels indirects.

En vertu du RMFM, Santé Canada éliminera le rôle qu'il joue sur le plan de la détermination de l'admissibilité des particuliers à avoir accès à un approvisionnement légal de marihuana à des fins médicales et reprendrait son rôle traditionnel à titre d'organisme de réglementation de l'industrie. Cela permettra de réaliser d'importantes économies en ce qui concerne les coûts administratifs pendant la période d'incidence de la politique. Selon le scénario présumé pour le nouveau marché réglementé, il a été estimé que la proposition de réglementation permettrait une réduction de plus de 90 % des dépenses administratives de Santé Canada. La valeur actualisée des économies liées aux coûts d'administration sur 10 ans a été évaluée à 478 millions de dollars. En moyenne, le RMFM prévoit générer des économies de coûts administratifs calculées sur une année d'environ 71,24 millions de dollars par année au cours de cette période. (Cette estimation ne tient pas compte des économies potentielles relatives aux coûts d'approvisionnement en vertu de contrats ou aux subventions.)

Surplus de gains des producteurs[3]

Le RMFM établira un marché commercial pour la production et la vente de la marihuana à des fins médicales. La participation de l'industrie privée dans le régime devrait permettre un rendement avantageux pour la société. Si le statu quo était maintenu, la marihuana continuerait d'être produite dans le cadre d'ententes privées ou aux frais du contribuable. Ce scénario ne comporte aucun avantage pour la société en général, outre celui pour les personnes visées. Dans le cadre de la nouvelle réglementation, il y aura un avantage pour l'industrie en plus des avantages aux particuliers participant au marché. L'analyse a mesuré ce changement relatif au bien-être en évaluant un changement au niveau du surplus de gains en raison de la politique. Aucun surplus pour les producteurs n'est possible si l'on maintient le statu quo. Selon l'ACA, le nouveau marché réglementé générera un surplus global pour les producteurs de 2,64 millions de dollars au cours de la première année de la mise en œuvre (2014-2015), pour atteindre environ 110 millions de dollars en 2024, à la suite de l'expansion du marché. La valeur actualisée des surplus de gains des producteurs pendant la période de la politique (2014 à 2024) a été évaluée à 339,85 millions de dollars, ou environ 50,65 millions de dollars (moyenne calculée sur une année) par année pendant 10 ans.

[3] Le surplus des producteurs est une mesure économique de la différence entre le montant qu'un producteur de biens reçoit réellement et le montant minimum qu'il ou elle accepterait.

Reduction in deadweight loss[4]

The CBA also estimated the deadweight loss under the marihuana access regime from the effective subsidy to supply that resulted in excess demand relative to what a market equilibrium quantity will be. The value of this economic efficiency loss was relatively small as the Government supply component in the CBA model was comparatively small. The analysis assumes the imposition and payment of the regular consumption tax (HST) by consumers of marihuana under the framework. Both the presence of an effective subsidy in the Government supply market for the status quo and the assumed, potential imposition of tax on purchases in the commercial market were projected to cause welfare losses to society by distorting market signals and causing sub-optimal allocation of scarce resources.

The economic efficiency loss under the status quo was estimated to be reduced by about $1.51 million during the first year of implementation (2014) of the MMPR, rising to about $7.70 million in 2024. This represents an average annualized reduction of about $5.03 million or a total present value of approximately $33.74 million over 10 years. Overall, the reduction in deadweight loss is small and not a significant benefit of the regulatory change.

In total, the present value of benefits of the MMPR was estimated to be $1.005 billion from 2014 to 2024. On average, this represents an annualized savings of approximately $149.77 million each year for 10 years.

Costs

The CBA projected the negative impacts of the MMPR on social welfare on the basis of a change in the welfare of the individuals most directly affected by the regulatory change. Because the available scientific evidence does not conclusively support the use of dried marihuana for therapeutic purposes, the causal relationships between the use of the substance and purported medical benefits are inconclusive. Thus, the analysis measures the change in individual welfare under the policy directly by estimating the change in users' consumer surplus. Economic theory does not require the existence of scientifically proven medical benefit in order to measure the welfare implications of a public policy change. The observation that some in society are willing to pay to obtain marihuana for medical reasons was deemed as a sufficient basis for measuring a change in consumer welfare.

Loss of consumer surplus[5]

Consumer surplus was estimated as the area under the demand curve and above the price consumers will potentially pay for marihuana under the MMPR. Under the MMPR, the analysis projected a reduction in the number of legal marihuana users vis-à-vis the status quo, and a reduction in the quantity consumed due to a potential increase in the price of marihuana in the regulated

[4] Deadweight loss is the cost to society created by market inefficiency.

[5] Consumer surplus is an economic measure of user benefit over and above what is reflected in the price users pay for acquiring the good.

Réduction de la perte de poids mort[4]

L'ACA a également évalué la perte de poids mort sous le régime d'accès à la marihuana à partir de la subvention en vigueur d'approvisionnement qui a entraîné une demande excessive, par rapport à ce que sera la quantité dans un marché équilibré. La valeur de cette perte d'efficience économique était relativement petite puisque l'élément d'approvisionnement du gouvernement dans le modèle d'ACA était petit, en comparaison. L'analyse présume l'imposition et le paiement de la taxe de consommation régulière (TVH) par les consommateurs de la marihuana, dans le cadre. Il a été prévu que les deux (la présence d'une subvention efficace dans le marché d'approvisionnement du gouvernement pour le statu quo et l'imposition potentielle présumée de la taxe sur les achats dans le marché commercial) allaient causer des pertes sur le plan du bien-être pour la société en déformant les signaux du marché et en causant une allocation non optimale des ressources peu abondantes.

Il a été estimé que la perte d'efficience économique du maintien du statu quo serait réduite d'environ 1,51 million de dollars au cours de la première année de la mise en œuvre (2014) du RMFM, pour atteindre environ 7,70 millions de dollars en 2024. Cela représente une réduction moyenne calculée sur une année d'environ 5,03 millions de dollars, ou un total de la valeur actualisée d'environ 33,74 millions de dollars sur 10 ans. Dans l'ensemble, la réduction de la perte de poids mort est faible et il ne s'agit pas d'un avantage considérable du changement de la réglementation.

Au total, la valeur actualisée des avantages du RMFM a été évaluée à 1,005 milliard de dollars de 2014 à 2024. En moyenne, cela représente des économies calculées sur une année d'environ 149,77 millions de dollars chaque année pendant 10 ans.

Coûts

L'ACA a projeté les répercussions négatives du RMFM sur le bien-être social en fonction d'un changement au niveau du bien-être des particuliers qui sont le plus directement touchés par le changement de la réglementation. Puisque les preuves scientifiques disponibles actuellement n'appuient pas de façon concluante l'usage de la marihuana séchée à des fins thérapeutiques, les liens causals entre l'usage de la substance et les avantages médicaux prétendus ne sont pas concluants. Par conséquent, l'analyse a plutôt mesuré directement le changement du niveau de bien-être dans le cadre de la politique en évaluant le changement lié au surplus du consommateur des usagers. La théorie économique ne requiert pas l'existence d'un avantage médical prouvé scientifiquement en vue de mesurer les incidences d'un changement de politique publique sur le bien-être. L'observation selon laquelle certaines personnes de la société consentent à payer pour obtenir de la marihuana à des fins médicales a été jugée suffisante pour mesurer un changement au niveau du bien-être des consommateurs.

Perte du surplus du consommateur[5]

Le surplus du consommateur a été évalué comme le secteur sous la courbe de demande et au-dessus du prix que les consommateurs pourront payer en vertu du RMFM. Dans le cadre du RMFM, l'analyse projetait une réduction du nombre d'usagers de la marihuana autorisés par rapport au statu quo, ainsi qu'une réduction de la quantité consommée en raison d'une augmentation potentielle

[4] La perte de poids mort est le coût pour la société créé par l'inefficacité du marché.

[5] Le surplus du consommateur est une mesure économique de l'avantage de l'usager qui est supérieur à ce qui est reflété dans le prix que les usagers payent pour se procurer le bien.

market. Under this scenario, the CBA predicted a significant loss of consumer surplus from this policy change. The analysis assumes a price change from about $7.60 per gram to about $8.80 per gram over the 10-year period. This assumption reflects the potentially higher cost of producing marihuana in the new commercial market, compared to personal or designated production under the MMAR. The higher price also reflects the potentially higher product quality due to quality control measures to limit contaminants and toxic substances and to ensure a product of consistent quality over time. The analysis assumes that this projected price change will lead to a decrease in the relative number of legal users by about 30% over the next 10 years compared to the status quo. The total quantity of marihuana consumed was also estimated to decrease. On average, the loss in consumer surplus (representing the total social costs of the MMPR) was estimated to be about –$166 million per year. The present value over 10 years was estimated to be about $1.115 billion. (The study did not estimate consumer surplus for any consumption derived from illicit supply sources.)

Business compliance costs

Business compliance costs were estimated as 10% of overall supply cost. Based on this, the CBA estimated that business compliance costs will be about double under the MMPR. As business compliance costs are already included in the supply cost estimate for both the status quo and policy cases, they were not independently estimated again in the analysis.

Net benefits

The scenario representing the most likely outcome of the cost-benefit model was the focus of the quantified results for estimating the present value of the net benefits of the regulatory proposal. The estimated net present value (NPV) was –$109.7 million, with an average annualized value of –$16.35 million. This represents an overall net loss to society due solely to a reduction in consumer surplus.

This loss in consumer surplus results from reduced relative growth in consumption and a higher supply price due mostly to the shift from cheaper home production to a commercial market with appropriate regulatory controls and oversight.

A full assessment of the sensitivity of the NPV to all key variables was undertaken using Monte Carlo probabilistic methods. The results showed that there was substantial variability in the estimate (range: –$26 billion to +$10 billion; mean: –$1,688 million).

The status quo scenario was modelled on the assumption that Government resources required to administer the MMAP would continue to grow over time to fully accommodate the required Program uptake in terms of numbers of persons wanting to access a legal source of marihuana for medical purposes. The Program administration cost was projected to increase from $13.8 million (FY 2013–14) to over $120 million (FY 2023–24). In reality, it is highly unlikely that such additional resources would be available to

du prix de la marihuana sur le marché réglementé. Dans ce scénario, l'ACA a prévu une perte considérable du surplus du consommateur à la suite de ce changement de politique. L'analyse suppose que le prix passera d'environ 7,60 $ à environ 8,80 $ le gramme pendant la période de 10 ans. Cette hypothèse reflète le coût supérieur potentiel de la production de la marihuana dans le nouveau marché commercial, comparativement au coût de la production personnelle ou désignée en vertu du RAMM. Le prix plus élevé reflète également la qualité potentiellement supérieure du produit en raison des mesures de contrôle de la qualité visant à limiter les substances contaminées et toxiques et à assurer un produit de qualité constante avec le temps. L'analyse présume que ce changement de prix projeté entraînera une diminution du nombre relatif d'usagers autorisés d'environ 30 % au cours des 10 prochaines années, comparativement au statu quo. Une diminution de la quantité totale de marihuana consommée a également été prévue. En moyenne, la perte de surplus du consommateur (qui représente le total des coûts sociaux du RMFM) était évaluée à environ –166 millions de dollars par année. La valeur actualisée sur 10 ans a été évaluée à environ 1,115 milliard de dollars. (L'étude n'a pas évalué le surplus du consommateur pour toute consommation dérivée de sources d'approvisionnement illicites.)

Coûts d'observation des entreprises

Les coûts d'observation des entreprises ont été évalués à 10 % du coût global d'approvisionnement. En conséquence, l'ACA a évalué les coûts d'observation des entreprises à environ le double, dans le cadre du RMFM. Puisque les coûts d'observation des entreprises sont déjà incorporés dans l'estimation des coûts d'approvisionnement pour le statu quo ainsi que pour la politique, ils ne furent pas réévalués indépendamment dans cette analyse.

Avantages nets

Le scénario qui représentait le résultat le plus vraisemblable du modèle coût-avantage était le centre d'intérêt des résultats quantifiés pour l'évaluation de la valeur actualisée des avantages nets de la proposition de réglementation. La valeur actualisée nette (VAN) était de –109,7 millions de dollars, avec une valeur moyenne calculée sur un an de –16,35 millions de dollars. Cela représente une perte globale nette pour la société attribuable uniquement à une réduction du surplus du consommateur.

Cette perte de surplus du consommateur découle de la croissance relativement réduite de la consommation et d'une augmentation du prix d'achat en grande partie attribuable au transfert d'une production résidentielle moins dispendieuse vers un marché commercial qui comporte des contrôles et une surveillance réglementaires appropriés.

Une évaluation complète de la sensibilité de la VAN pour l'ensemble des principales variables a été entreprise à l'aide des méthodes probabilistes de Monte-Carlo. Les résultats ont révélé que la variabilité était considérable dans l'estimation (étendue : –26 milliards de dollars à +10 milliards de dollars; moyenne : –1,688 million de dollars).

Le scénario du statu quo a été modélisé sur l'hypothèse que les ressources du gouvernement requises pour administrer le Programme continueront de croître avec le temps en vue de tenir compte de l'intérêt manifesté pour le Programme sur le plan du nombre de personnes en attente d'avoir accès à une source d'approvisionnement légale de marihuana à des fins médicales. Il était prévu que les coûts d'administration du Programme allaient augmenter de 13,8 millions de dollars (exercice financier 2013-2014)

accommodate the forecast increase in Program participation in an era of fiscal restraint.

This qualification is useful when interpreting the overall results. The impact of a resource constraint was analyzed using a simulation model. The simulation results indicated that the number of authorizations to possess in a constrained status quo scenario might be only one-third of the unconstrained case (i.e. perhaps only 150 000 authorizations to possess could be accommodated in the Program over the forecast period in practice, compared with the assumed unconstrained growth of up to 450 000 users).

Non-quantified benefits

Not all significant impacts of the MMPR were included in the quantitative results presented above. A few of these potential impacts were not quantified due to insufficient data on which to base estimates. Others were felt to be smaller in magnitude than the costs and benefits which were estimated. Nonetheless, some were considered to be substantial over the longer term but were excluded from the quantitative analysis because they were considered highly contingent on a number of economic, social and regulatory factors and will likely start to be measurable only near the end of, or after, the 10-year projection period assumed for the quantified CBA.

These impacts were assessed qualitatively. Major attention was given to (i) additional safety and security issues, impacts and possible benefits; (ii) reductions in information, administration and other transactions costs for users, the medical community and other stakeholders; (iii) the possible longer-term benefits from the full establishment of a large, competitive and innovative legal industry for marihuana users, the economy and Canadian society; and (iv) the longer-term possibility that a fully functioning and reasonably competitive, efficient and innovative market will promote increased uptake by individuals who obtain marihuana through the illicit market.

The results of the qualitative analysis showed potentially highly beneficial effects. The results of the qualitative assessment are included in the full CBA report, which is available upon request.

à plus de 120 millions de dollars (exercice financier 2023-2024). En réalité, il est très peu probable que de telles ressources supplémentaires soient disponibles pour répondre à l'augmentation prévue de la participation au Programme en cette période de restriction budgétaire.

Cette qualification est utile lorsqu'il s'agit d'interpréter les résultats globaux. Les répercussions des limites financières ont été analysées à l'aide d'un modèle de simulation. Les résultats de la simulation ont indiqué que le nombre d'autorisations de posséder dans un scénario de statu quo restreint pourrait être seulement environ le tiers du cas non restreint (c'est-à-dire que peut-être que seulement 150 000 autorisations de posséder pourraient être accordées dans le Programme au cours de la période de prévision, en pratique, comparativement à la croissance illimitée présumée pouvant atteindre 450 000 usagers).

Avantages non quantifiés

Toutes les incidences importantes du RMFM n'ont pas été mentionnées dans les résultats quantitatifs présentés ci-dessus. Quelques-unes de ces incidences éventuelles n'ont pas été quantifiées faute de données pour appuyer les estimations. Les autres ont été jugées moins importantes par rapport aux coûts et avantages évalués. Néanmoins, certaines incidences sont importantes pour le long terme, mais elles n'ont pas été prises en compte dans l'analyse quantitative, car elles sont fortement dépendantes d'un certain nombre de facteurs économiques, sociaux et réglementaires et elles ne pourront probablement être évaluées que vers la fin ou après la période de projection de 10 ans visée par l'analyse coût-avantage (ACA) quantifiés.

Ces incidences ont été évaluées qualitativement. Une grande attention a été accordée aux points suivants : (i) les questions liées à la sécurité, aux incidences et aux avantages éventuels; (ii) la réduction des coûts d'information, d'administration et des autres coûts de fonctionnement pour les consommateurs, le corps médical et les autres intervenants; (iii) les avantages potentiels à long terme liés à la mise en place d'une grande industrie légitime compétitive et innovante pour les consommateurs de marihuana, l'économie et la société canadienne; (iv) la possibilité à plus long terme offerte par un marché pleinement opérationnel et raisonnablement compétitif, efficace et innovant qui pourra attirer un nombre croissant de consommateurs qui obtiennent de la marihuana sur le marché noir.

Les résultats de l'analyse qualitative ont montré des effets potentiellement très bénéfiques. Les résultats de l'évaluation qualitative sont inclus dans le rapport global de l'ACA, qui est disponible sur demande.

Cost-benefit statement

		Year 1 (2014)	Year 5 (2019)	Year 10 (2024)	Present Value	Annualized Average
A. Quantified impacts (million CAN$, 2012)						
Benefits						
Canadians	Reduction in risk of residential fire	$1.16	$7.19	$19.26	$64.32	$9.58
	Reduction in risk of home invasion	$0.38	$16.79	$26.48	$89.03	$13.27
Industry*	Producer surplus gain	$2.64	$44.33	$110.03	$339.85	$50.65
Government	Program administration costs savings	$18.70	$70.66	$117.50	$478.01	$71.24
	Reduction in deadweight loss	$1.51	$5.55	$7.70	$33.74	$5.03
Total benefits		**$24.40**	**$144.52**	**$281.00**	**$1,004.94**	**$149.77**

Cost-benefit statement — Continued

		Year 1 (2014)	Year 5 (2019)	Year 10 (2024)	Present Value	Annualized Average
A. Quantified impacts (million CAN$, 2012) — *Continued*						
Costs						
Consumers	Loss of consumer surplus (years 3–10)	$11.21	–$135.39	–$410.37	–$1,114.66	–$166.12
Net present value (NPV at 8%)					**–$109.72**	**–$16.35**
B. Quantified impacts in non-$ — e.g. from a risk assessment						
Positive impacts						
Canadians	Residential production licences avoided	38 481	178 451	289 065		
Industry*	New businesses established	51	61	61		
Negative impacts						
Consumers	Consumers projected to pay potentially higher prices for marihuana	41 384	189 486	308 755		
	Relative reduction in legal consumers	–16 415	–78 283	–124 933		
	Relative reduction in legal quantities consumed	–40 838 kg	–203 098 kg	–357 221 kg		
C. Qualitative impacts						
Consumers **Participants in MMAP:** Reduced risk of illness due to mould caused by improper growing methods. Continued access to marihuana for medical purposes. Better-quality product, on average. Treatment is driven by relationship with authorized health care practitioners instead of Health Canada. **Non-participants in MMAP:** Potential availability of more data on impact of use of marihuana for medical purposes due to possible licensed producers (LP) R&D investments. **Government:** Reduced criminal activity in residential areas due to banning of legal marihuana production. Property taxes / local jobs for areas with LPs in their jurisdiction.						

Note: Policy impact period from 2014 to 2024, assumed social discount rate of 8%.

*Accrue to businesses.

Énoncé des coûts-avantages

		Année 1 (2014)	Année 5 (2019)	Année 10 (2024)	Valeur actualisée	Moyenne calculée sur une année
A. Incidences chiffrées (en millions de dollars canadiens de 2012)						
Avantages						
Canadiens	Réduction des risques d'incendies résidentiels	1,16 $	7,19 $	19,26 $	64,32 $	9,58 $
	Réduction des risques de braquage à domicile	0,38 $	16,79 $	26,48 $	89,03 $	13,27 $
Industrie*	Gain lié au surplus du producteur	2,64 $	44,33 $	110,03 $	339,85 $	50,65 $
Gouvernement	Économies en coûts d'administration du Programme	18,70 $	70,66 $	117,50 $	478,01 $	71,24 $
	Réduction de la perte de poids mort	1,51 $	5,55 $	7,70 $	33,74 $	5,03 $
Total des avantages		**24,40 $**	**144,52 $**	**281,00 $**	**1 004,94 $**	**149,77 $**
Coûts						
Consommateurs	Perte de surplus du consommateur (des années 3 à 10)	11,21 $	–135,39 $	–410,37 $	–1 114,66 $	–166,12 $
Valeur actualisée nette (VAN à 8 %)					**–109,72 $**	**–16,35 $**
B. Incidences chiffrées non en dollars, par exemple à partir d'une évaluation des risques						
Incidences positives						
Canadiens	Évitement des licences de production dans des résidences	38 481	178 451	289 065		
Industrie*	Nouvelles entreprises établies	51	61	61		

Énoncé des coûts-avantages (suite)

		Année 1 (2014)	Année 5 (2019)	Année 10 (2024)	Valeur actualisée	Moyenne calculée sur une année
B. Incidences chiffrées non en dollars, par exemple à partir d'une évaluation des risques (*suite*)						
Incidences négatives						
Consommateurs	Les consommateurs devraient, selon les prévisions, payer plus cher pour la marihuana	41 384	189 486	308 755		
	Réduction relative chez les consommateurs légaux	–16 415	–78 283	–124 933		
	Réduction relative de quantités consommées légales	–40 838 kg	–203 098 kg	–357 221 kg		
C. Incidences qualitatives						
Consommateurs						
Participants au PAMM : Risque réduit de maladies dues à la moisissure causée par des méthodes de culture inadéquates; maintien de l'accès à la marihuana à des fins médicales; meilleure qualité du produit, en général; traitement effectué en relation avec les praticiens de la santé autorisés à la place de Santé Canada.						
Personnes ne participant pas au PAMM: Un plus grand nombre de données éventuellement disponibles sur les effets de la consommation de la marihuana à des fins médicales en raison des investissements potentiels en recherche et développement des producteurs autorisés (PA).						
Gouvernement : Moins d'activités criminelles dans les zones résidentielles en raison de l'interdiction de la production légale de la marihuana. Impôts fonciers et emplois locaux des PA dans leur région.						

Nota : Période d'analyse des répercussions de la politique de 2014 à 2024 et taux d'actualisation social prévu de 8 %.

* Valable pour les entreprises.

Revisions to the CBA following prepublication

The revised Regulations include changes and clarification of wording related to specific requirements including security. These changes were considered to have an impact on the cost of compliance for licensed producers. In the CBA, however, business compliance cost was included as a component of the supply cost of marihuana produced by licensed producers and did not independently enter into the analysis. To determine whether, a revision of the CBA results was necessary as a result of the revisions to the Regulations, the effect of the changes in requirements on business compliance cost was first assessed. The results showed that the impact of the revisions to the Regulations on business compliance costs was insignificant and would not affect the magnitude of the estimates or the conclusions made in the CBA.

Impacts on economy, businesses and consumers

Government, and ultimately, the Canadian taxpayer, are the main beneficiaries of regulatory change through the reduction in Program administration costs. Business, especially medium-sized business, is also a beneficiary in terms of producer surplus benefits and the expansion of the legal marihuana supply industry that could grow to more than $1.3 billion per year in annual sales by the end of the forecast period. It is important to note that producer surplus is not related to profitability and should not be taken as an indicator of profitability.

Users of a legal source of marihuana for medical purposes are the stakeholder group that is impacted in terms of the reduced consumer surplus. The general public, in contrast, benefits slightly in terms of reduced deadweight loss and the reduced safety costs which will be borne through residential insurance.

The principal impact on the economy will be the replacement of the MMAR regime — a combination of personal production by private citizens and a heavily subsidized Government supply

Révisions apportées à l'ACA à la suite de sa publication préalable

La version révisée du Règlement comprend des changements et des clarifications de la formulation liée à des exigences particulières, dont la sécurité. Il a été estimé que ces changements auraient des répercussions sur le coût d'observation des producteurs autorisés. Dans l'ACA, toutefois, le coût d'observation des entreprises a été inclus en tant qu'élément du coût d'approvisionnement de la marihuana produite par des producteurs autorisés et il n'a pas été pris en compte de façon indépendante dans l'analyse. Pour déterminer si, une révision des résultats de l'ACA devait être effectuée à la suite des révisions apportées au Règlement, l'effet des changements liés aux exigences sur le coût d'observation des entreprises a tout d'abord été évalué. Les résultats ont indiqué que l'effet des révisions apportées au Règlement sur les coûts d'observation des entreprises était négligeable et que cela n'aurait aucune incidence sur l'ampleur des estimations ou sur les conclusions présentées dans l'ACA.

Incidences sur l'économie, les entreprises et les consommateurs

Le gouvernement et le contribuable canadien, au bout du compte, sont les principaux bénéficiaires du changement réglementaire grâce à la réduction des coûts d'administration du Programme. Les entreprises, et plus particulièrement les entreprises de taille moyenne, seront également des bénéficiaires du surplus des producteurs et de l'expansion de l'industrie d'approvisionnement légal en marihuana qui pourrait atteindre plus de 1,3 milliard de dollars par an en chiffre d'affaires annuel d'ici la fin de la période de prévision. Il est important de noter que le surplus du producteur n'est pas lié à la rentabilité et ne doit pas être considéré comme un indicateur de rentabilité.

Les utilisateurs d'une source légale de marihuana à des fins médicales sont les plus touchés par la baisse des surplus du consommateur. Le grand public, en revanche, pourra légèrement profiter des pertes de poids mort et de la baisse des coûts de la sécurité qui seront pris en charge par l'assurance d'habitation.

La principale incidence sur l'économie sera le remplacement du système du RAMM, qui consiste en une combinaison de production personnelle par des particuliers et une option

option — by a commercial industry. This will significantly reduce the burden on the Government of Canada and Canadian taxpayers. By 2024, rather than attempting to regulate potentially up to 450 000 individuals, Health Canada will likely be dealing with a significantly smaller number of licensed businesses.

Much of the societal risk and burden created by the MMAR are created from the indirect impacts of allowing individuals to produce marihuana at home. By shifting the production of marihuana for medical purposes from seldom-inspected private homes to more rigorously regulated, secure licensed producers, these impacts will be significantly reduced or altogether eliminated.

Additionally, there is a significant impact on "enforcement clarity" for law enforcement. Since producing marihuana for medical purposes in private dwellings is legal under the existing regime, police have sometimes expressed difficulty investigating suspected illicit production sites operating under the cover of a licence. Under the MMPR, all home production of marihuana will be illegal and only licensed producers will be authorized for legal production.

Health Canada anticipates that the social ills caused by home production of marihuana for medical purposes would have increased if the Program had continued. Due to the rapid historical growth of the Program, the adverse consequences would only have compounded over time. The Program participant base under the MMAR has been difficult to monitor and regulate effectively, and exponential growth would have made it more so. The MMPR are designed to minimize the detrimental impacts of the MMAR.

Moreover, with commercial entities cultivating marihuana for medical purposes, it is reasonable to expect that resources will be invested in improving the quality of the product and in researching the effects of marihuana. This could result in a growing body of scientific information that could advance society's knowledge about uses of the plant.

Impacts by region

Several regions will have negative overall impacts because they have a high concentration of Program usage; thus, they have disproportionate shares of consumer surplus reduction. These regions are British Columbia and the Atlantic (primarily Nova Scotia). Other regions will have positive overall impacts. Savings from lower administrative costs will positively impact Ontario, because the Program is largely administered from Ontario. It will also positively impact the Prairie region because that is where government-contracted marihuana production occurs.

"One-for-One" Rule

While the MMPR could impose administrative burden costs on business, they are exempted from the "One-for-One" Rule because they are addressing unique and exceptional circumstances. Canadian courts have found that individuals who have demonstrated a medical need for marihuana have a right under the Charter to reasonable access to a legal source of marihuana for medical purposes.

d'approvisionnement fortement subventionnée par le gouvernement, par une industrie commerciale. Cela permettra de réduire considérablement le fardeau du gouvernement du Canada et des contribuables canadiens. D'ici 2024, plutôt que de tenter de réglementer potentiellement jusqu'à 450 000 personnes, Santé Canada aura probablement affaire à un nombre considérablement plus petit d'entreprises agréées.

Une grande partie du risque sociétal et du fardeau créé par le RAMM est liée aux incidences indirectes des autorisations de produire de la marihuana à la maison. En déplaçant la production de marihuana à des fins médicales des maisons de particuliers rarement inspectées vers les plantations des producteurs autorisés sécurisées et réglementées de façon plus rigoureuse, ces incidences seront considérablement réduites, voire éliminées.

En outre, il existe des incidences significatives quant à la « clarté dans l'exécution de la loi » pour les responsables de l'application de la loi. Étant donné que la production de la marihuana à des fins médicales au foyer est légale sous le régime actuel, la police parle parfois de difficultés à mener des enquêtes dans de présumés sites de production illicite opérant sous le couvert d'une licence. Dans le cadre du RMFM, toute production de marihuana au foyer sera illicite et seuls les producteurs autorisés seront autorisés à une production légale.

Santé Canada estime que les maux sociaux causés par la production au foyer de la marihuana à des fins médicales se seraient aggravés si le Programme avait été poursuivi. En raison de la croissance historique rapide du Programme, les conséquences néfastes engendrées par le programme ne se seraient qu'aggravées avec le temps. Les participants au Programme du RAMM ont été difficiles à surveiller et leurs modes de consommation ont également été difficiles à réglementer de façon efficace, et la croissance exponentielle aurait aggravé cette situation. Le RMFM permettra de réduire les effets néfastes du RAMM.

En outre, avec des entités commerciales qui cultivent de la marihuana à des fins médicales, il est raisonnable de présumer que les ressources seront investies dans l'amélioration de la qualité du produit et les recherches sur ses effets. La population pourrait ainsi disposer de plus de données scientifiques qui lui permettraient de mieux connaître les différents usages de cette plante.

Incidences par région

Les incidences seront négatives dans plusieurs régions où l'utilisation du Programme est très répandue et où il y a des disparités importantes en ce qui concerne la réduction du surplus du consommateur. Ces régions sont la Colombie-Britannique et l'Atlantique (principalement la Nouvelle-Écosse). Par contre, les incidences seront globalement positives dans d'autres régions. Les économies réalisées grâce à une réduction des coûts administratifs auront des incidences positives en Ontario, parce que le Programme est administré en grande partie de la province d'Ontario. Les incidences dans la région des Prairies seront également positives, car la production de marihuana y est sous-traitée par le gouvernement.

Règle du « un pour un »

Même si le RMFM peut engendrer des coûts liés au fardeau administratif pour les entreprises, il sera exclu de la règle du « un pour un », car il traite des cas uniques et exceptionnels. Les tribunaux canadiens ont conclu que les personnes qui ont démontré un besoin médical pour la marihuana ont le droit, en vertu de la Charte, à un accès raisonnable à une source d'approvisionnement légale de

Therefore, the Government must establish a legal framework which provides access to this controlled substance.

According to the United Nations World Drug Report, marihuana is the most trafficked illicit drug in North America. The Royal Canadian Mounted Police (RCMP) estimate that the illegal marihuana market in Canada alone represents a multi-billion dollar per year industry. Because marihuana is a highly divertible controlled substance, and given that all controlled substances must be tracked and reported internationally, some administrative burden is justified. Security measures therefore account for a large portion of the administrative burden on industry in the MMPR. These measures are included to address the risks to public health, safety and security that are associated with marihuana production.

Additionally, as there is no licit Canadian industry for the production of marihuana for medical purposes, the MMPR set out a scheme in which interested individuals or corporations could elect to participate in or not — it will not place an administrative burden on any existing business activities.

Consultation

Consultation prior to publication of the proposed Regulations in the *Canada Gazette*, Part I, on December 15, 2012 (prepublication)

Following the announcement of the changes to the Program by the Minister of Health on June 17, 2011 (the original proposal), a consultation document was posted on the Health Canada Web site and a 45-day public consultation was launched. Health Canada also organized targeted stakeholder consultations between August and November 2011 to gather comments on the proposed improvements to the Program. In addition, Health Canada notified the United States Drug Enforcement Administration and the International Narcotics Control Board that a new program was under consideration in which individuals would no longer be licensed to produce their own marihuana and supply would come from licensed producers.

A detailed summary of these consultations was published in June 2012. Most stakeholder groups welcomed Health Canada's efforts to create a regulated industry. In particular, law enforcement, municipal governments and fire officials were supportive of the plans to eliminate personal and designated production in dwellings and to establish a commercial market. A large number of entities expressed an interest in becoming licensed to produce under the regulatory framework. Program participants, however, indicated that they did not want to give up the ability to produce their own marihuana, and expressed concerns that they would face higher costs for marihuana for medical purposes in the future. The medical community voiced its continued concerns with the lack of scientific evidence regarding the use of marihuana for medical purposes.

The full consultation report can be found on the Health Canada Web site at www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/_2011/program/consult_reform-eng.php.

marihuana à des fins médicales. Par conséquent, le gouvernement doit établir un cadre légal qui permet l'accès à cette substance désignée.

Selon le Rapport mondial sur les drogues publié par les Nations Unies, la marihuana est la drogue illicite la plus trafiquée en Amérique du Nord. La Gendarmerie royale du Canada (GRC) estime que le marché illicite de la marihuana à lui seul représente une industrie de plusieurs milliards de dollars par année. Parce que la marihuana est une substance désignée à haut risque de détournement, et considérant que toutes les substances désignées doivent être surveillées et rapportées de façon internationale, un certain fardeau administratif est justifié. Les mesures de sécurité, par conséquent, représentent une grande partie du fardeau administratif pour l'industrie dans le RMFM. Ces mesures ont été adoptées pour faire face aux risques pour la santé et la sécurité publiques inhérents à la production de marihuana.

De plus, étant donné qu'il n'y a pas d'industrie licite de production de marihuana à des fins médicales au Canada, le RMFM établit un cadre qui permet aux personnes ou aux sociétés intéressées d'y souscrire, ce qui n'imposera aucun fardeau administratif sur les activités actuelles.

Consultation

Consultation antérieure à la publication du règlement proposé dans la Partie I de la *Gazette du Canada*, le 15 décembre 2012 (publication préalable)

À la suite de l'annonce des changements au Programme par la ministre de la Santé le 17 juin 2011 (la proposition initiale), un document de consultation a été affiché sur le site Web de Santé Canada et une consultation publique d'une durée de 45 jours a été lancée. Santé Canada a également organisé des consultations ciblées avec les intervenants qui ont eu lieu d'août à novembre 2011 en vue de recueillir des commentaires sur les améliorations proposées au Programme. De plus, Santé Canada a informé la Drug Enforcement Administration des États-Unis et l'Organe international de contrôle des stupéfiants qu'un nouveau programme était pris en considération, dans le cadre duquel les particuliers n'obtiendraient plus de licence leur permettant de produire leur propre marihuana et l'approvisionnement proviendrait de producteurs autorisés.

Un résumé détaillé de ces consultations a été publié en juin 2012. La plupart des groupes d'intervenants ont souligné les efforts de Santé Canada pour créer une industrie réglementée. En particulier, les responsables de l'application de la loi, les gouvernements municipaux et les responsables des services d'incendie ont soutenu les plans visant à éliminer la production personnelle et désignée dans les habitations et à établir un marché commercial. Un grand nombre d'entités ont exprimé leur intérêt d'obtenir une licence leur permettant de produire en vertu du cadre réglementaire. Cependant, les participants au Programme ont indiqué qu'ils ne voulaient pas perdre la capacité de cultiver leur propre marihuana et ont exprimé leurs préoccupations quant à l'augmentation future du coût de la marihuana à des fins médicales. La communauté médicale a exprimé ses préoccupations continues en ce qui concerne le manque de preuve scientifique au sujet de l'usage de la marihuana à des fins médicales.

Le rapport complet sur la consultation figure sur le site Web de Santé Canada à l'adresse suivante : www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/_2011/program/consult_reform-fra.php.

Comments received during the 75-day comment period following prepublication

Health Canada received a total of 1 663 comments during the 75-day comment period following prepublication. Of these, 1 433 comments were submitted by current licence holders and individuals; 93 were from the prospective industry; 54 were from municipalities, fire officials and law enforcement agencies; 43 were from health care practitioners, medical associations and pharmacists; 6 were from provinces and territories; 3 were from members of Parliament; and 31 were from other organizations. In addition, the Department also received 212 comments sent automatically from a public petitions Web site. These comments were pooled together and counted as one individual comment.

Program participants and individual Canadians

Issue: Elimination of personal production will adversely affect Program participants and individuals

Current program participants and individuals expressed concerns over the elimination of personal production and the impact it would have on an individual's ability to purchase marihuana from licensed producers. Some suggested that Health Canada should consider "grandfathering" current personal production licences to ensure that these individuals could continue to afford their supply of dried marihuana.

Department of Health response

One of the objectives of the MMPR is to treat marihuana as much as possible like other narcotics used for medical purposes. Over the years, licensed production of marihuana in private dwellings has been associated with increased risks to public health and the safety of communities in which such growing operations take place. The MMAR were never intended to support the exponential growth in the number of participants that has taken place since 2001. In 2002, 477 individuals were authorized to possess marihuana for medical purposes. As of April 16, 2013, program participation had grown to 29 888 individuals. This rapid growth in program participation has placed a significant strain on the Department's resources to supply, authorize possession, licence personal production and to monitor numerous production sites. The elimination of personal production under the MMPR is in response to concerns raised by many stakeholders including police, fire officials and municipalities regarding the public health, safety and security risks such growing poses to individual Canadians, first responders and communities at large. During prepublication, Health Canada also received a number of comments from individuals which were supportive of the elimination of personal production. Many of those who were in favour of the planned phase-out cited concerns such as the presence of strong odours, the increased risk of theft and a general sense of insecurity in affected residential neighbourhoods, and the lack of enforcement to ensure risks of diversion to the "street" was minimized. The MMPR address these risks by replacing licensed personal production with a new regulated system of commercial production that will be inspected and monitored to minimize these risks.

Commentaires reçus pendant la période de consultation de 75 jours à la suite de la publication préalable

Santé Canada a reçu au total 1 663 commentaires pendant la période de consultation de 75 jours à la suite de la publication préalable. De ces commentaires, 1 433 ont été soumis par des détenteurs actuels de licence et par des particuliers; 93 provenaient des industries potentielles; 54 de municipalités, des services d'incendie et d'organismes d'application de la loi; 43 de praticiens de la santé, d'associations médicales et de pharmaciens; 6 des provinces et des territoires; 3 des députés et 31 d'autres organismes. De plus, le ministère a également reçu 212 commentaires envoyés automatiquement d'un site Web de pétition d'intérêt public. Ces commentaires ont été regroupés et comptabilisés comme un unique commentaire.

Les participants au programme et les particuliers canadiens

Question : l'élimination de la production à des fins personnelles aura un effet négatif sur les participants du programme et sur les particuliers

Des participants au programme actuel et des personnes ont exprimé leurs préoccupations concernant l'élimination de la production à des fins personnelles et l'effet que cela aurait sur la capacité des personnes à acheter de la marihuana auprès de producteurs autorisés. Certains ont suggéré que Santé Canada devrait songer à une disposition de droits acquis pour les licences actuelles de production à des fins personnelles afin de s'assurer que ces personnes continuent à avoir les moyens de se procurer de la marihuana séchée.

Réponse du ministère de la Santé

L'un des objectifs du RMFM est de traiter la marihuana dans la mesure du possible comme d'autres stupéfiants utilisés à des fins médicales. Au fil des ans, la production autorisée de marihuana dans des habitations privées a été associée à des risques accrus pour la santé publique et la sécurité des communautés dans lesquelles ces activités de culture ont lieu. Le RAMM n'a jamais eu pour objet de soutenir la croissance exponentielle du nombre de participants connue depuis 2001. En 2002, 477 personnes ont été autorisées à posséder de la marihuana à des fins médicales. Au 16 avril 2013, le nombre de participants au programme avait grimpé jusqu'à 29 888 personnes. Cette croissance rapide de la participation au programme exerce une forte pression sur les ressources du ministère pour l'approvisionnement, l'autorisation de la possession, la délivrance de licences de production à des fins personnelles et la surveillance des nombreux sites de production. L'élimination de la production à des fins personnelles dans le cadre du RMFM résulte de préoccupations soulevées par de nombreux intervenants, y compris la police, les services d'incendie et les municipalités concernant les risques pour la santé publique, la sécurité et la sûreté que la culture de la marihuana pose pour les Canadiens, les premiers intervenants et les communautés de manière générale. À la suite de la publication préalable, Santé Canada a également reçu plusieurs commentaires de particuliers qui se montraient favorables à l'élimination de la production à des fins personnelles. Un grand nombre des personnes favorables à l'élimination progressive prévue ont exprimé des préoccupations telles que la présence d'odeurs fortes, le risque accru de vols et un sentiment général d'insécurité dans les quartiers résidentiels concernés, ainsi que le manque d'application de la loi pour veiller à ce que les risques de détournement vers le marché clandestin soient réduits au minimum. Le RMFM traite ces risques en remplaçant la production à des fins personnelles autorisée par un nouveau

Health care practitioners, medical associations and pharmacists

Issue: There is a lack of scientific evidence regarding dosage, safety and efficacy of marihuana for medical purposes

Health care practitioners (physicians and nurse practitioners), pharmacists and their respective professional associations expressed concern about the absence of scientific evidence regarding issues such as dosage, safety and efficacy of dried marihuana for therapeutic purposes. They were of the opinion that Health Canada, under the MMPR, is setting up a prescription-like process for dried marihuana, even though it (dried marihuana) lacks the research and information about its uses that health care practitioners are accustomed to for all other prescribed medications that have been issued a Drug Identification Number (DIN) or Notice of Compliance (NOC). Physicians in particular noted that this could affect their ability to make informed decisions in the interest of their patients and increase their liability risks. It was suggested that Health Canada establish standardized and mandatory education or licensure for practitioners who support the use of dried marihuana to partly mitigate these risks.

Department of Health response

Although clinicians have had at their disposal the ability to prescribe cannabinoid-based medicines that have gone through the standard drug approval process and that have been issued DINs, the courts have said there must be reasonable access to a legal source of marihuana for medical purposes, even though marihuana has not gone through the standard FDA/FDR process. Since marihuana is not an approved therapeutic substance in Canada, no formal, comprehensive, scientific and medical information (e.g. formal drug monograph) on the risks and benefits of marihuana for therapeutic purposes has ever been published by any commercial sponsor. Health Canada has established an expert advisory committee (EAC) to provide advice and recommendations to Health Canada on the current information on marihuana for medical purposes, and any additional information/education materials that might be of assistance so that physicians can be better informed of the current science on marihuana. The EAC has assisted Health Canada in its efforts to revise an information document, similar to a formal drug monograph, containing comprehensive and up-to-date information on the potential risks and benefits associated with the use of marihuana for medical purposes. This revised information document will be made available to health care practitioners who may wish to receive such information to guide them in discussions with their patients. The Department considered the suggestion for mandatory education and decided not to impose additional requirements. Health care practitioner licensing and accreditation of continuing medical education are administered by provincial licensing bodies. A mandatory education requirement would create a barrier for practitioners who may be willing to support their patients' use of dried marihuana and would not be consistent with the objective of reducing administrative burden or of maintaining access to marihuana for medical purposes for patients under the MMPR.

système réglementé de production commerciale qui sera inspecté et surveillé afin de réduire au minimum ces risques.

Les praticiens de la santé, les associations médicales et les pharmaciens

Question : Il y a un manque de preuves scientifiques concernant le dosage, la sécurité et l'efficacité de la marihuana à des fins médicales

Les praticiens de la santé (les médecins et les infirmiers praticiens), les pharmaciens et leurs associations professionnelles respectives ont fait part de leurs préoccupations concernant l'absence de preuves scientifiques concernant des questions telles que le dosage, la sécurité et l'efficacité de la marihuana séchée à des fins thérapeutiques. Selon eux, Santé Canada, dans le cadre du RMFM, établit un processus similaire à la prescription pour la marihuana séchée, alors qu'il existe un manque de recherche et d'information au sujet de son utilisation, comme les praticiens de la santé y sont habitués pour tous les autres médicaments prescrits pour lesquels un numéro d'identification du médicament (DIN) ou un avis de conformité a été émis. Les médecins, en particulier, ont fait remarquer que cela pourrait avoir des répercussions sur leur capacité à prendre des décisions éclairées dans l'intérêt de leurs patients et que cela augmenterait leurs risques liés à la responsabilité. Il a été suggéré que Santé Canada établisse une formation ou délivre une autorisation d'exercer normalisée et obligatoire pour les praticiens qui appuient l'utilisation de la marihuana séchée afin d'atténuer partiellement ces risques.

Réponse du ministère de la Santé

Bien que les cliniciens aient la possibilité de prescrire des médicaments à base de cannabinoïde qui ont été soumis au processus d'homologation normalisé des médicaments et pour lesquels des DIN ont été délivrés, les tribunaux ont établi qu'il doit y avoir un accès raisonnable à une source d'approvisionnement légale de marihuana à des fins médicales, même si la marihuana n'a pas été soumise au processus normalisé de la *Loi sur les aliments et drogues* (LAD) et du *Règlement sur les aliments et drogues* (RAD). Étant donné que la marihuana n'est pas une substance thérapeutique approuvée au Canada, aucune information officielle, exhaustive, scientifique et médicale (par exemple une monographie de drogue officielle) sur les risques et les avantages de la marihuana à des fins thérapeutiques n'a jamais été publiée par un promoteur commercial. Santé Canada a établi un Comité consultatif sur l'information (CCI) dont la mission est de fournir des conseils et des recommandations à Santé Canada sur l'information actuellement disponible sur la marihuana à des fins médicales, et toute information/document pédagogique supplémentaire pouvant être utile pour mieux informer les médecins sur les données scientifiques actuelles liées à la marihuana. Le CCI a aidé Santé Canada dans son travail de révision d'un document d'information, similaire à une monographie de drogue officielle, comportant de l'information à jour sur les risques potentiels et sur les avantages liés à l'utilisation de la marihuana à des fins médicales. Ce document d'information révisé sera mis à la disposition des praticiens de la santé qui souhaitent recevoir de tels renseignements pour les guider dans leurs discussions avec leurs patients. Le ministère a examiné la suggestion d'offrir une formation obligatoire et a décidé de ne pas imposer d'exigences supplémentaires. Les autorisations d'exercer données aux praticiens de la santé et les agréments des formations médicales continues sont administrés par des organismes provinciaux d'attribution de permis. Une exigence de formation obligatoire créerait une barrière pour les praticiens pouvant être disposés à

Issue: Sale of dried marihuana by health care practitioners would create a potential conflict of interest

Regulatory colleges expressed concern that the dispensing of dried marihuana by physicians/nurse practitioners enabled by the MMPR would place them in a potential conflict of interest situation by authorizing them to dispense a drug they may also "prescribe." It was pointed out that physicians, for example, are required by their code of ethics to dispense medications only in situations where it can be demonstrated that dispensing of medication cannot be done by a third party, such as a pharmacist. Others in this stakeholder group noted that authority to "sell or provide" dried marihuana may also put the practitioner at risk and make his or her facility a target for increased crime.

Department of Health response

The Regulations have been revised to remove the authority for a health care practitioner to "sell or provide" dried marihuana to a patient. This has been replaced with the authority for the practitioner to "transfer" (that is, "provide dried marihuana without consideration") to a registered client of a licensed producer who designates the practitioner's office as their shipping address. The provision to "transfer" does not permit an authorized health care practitioner to provide dried marihuana in exchange for something of value from an individual. The revised provision allows the authorized health care practitioner to continue to support access as required while removing the potential incentive to prescribe higher doses had "providing with consideration" been retained.

Municipalities, law enforcement and fire officials

Municipalities, law enforcement agencies and fire officials from across Canada, including associations such as the Federation of Canadian Municipalities, the Canadian Association of the Chiefs of Police and the Canadian Association of Fire Chiefs, submitted comments during prepublication. These groups were very supportive in their feedback of the overall framework, viewing the elimination of personal production as a means to significantly reduce public health, safety and security risks in their communities. In the absence of pharmacy distribution (their preferred method of distribution), the move to commercial licensed production was well received. These groups of stakeholders were, however, concerned that the proposed Regulations did not go far enough with respect to the obligations placed on licensed producers and former personal production licence holders to ensure the safety and security of Canadians.

Issue: Licensed producers must be required to demonstrate compliance with applicable local laws as a condition for licensing

Municipalities raised the issue that, under the proposed Regulations, applicants were not required by law to demonstrate to Health

soutenir l'utilisation de marihuana séchée par leurs patients et elle ne serait pas conforme à l'objectif de réduction du fardeau administratif ou de maintien de l'accès à la marihuana à des fins médicales pour les patients dans le cadre du RMFM.

Question : la vente de marihuana séchée par des praticiens de la santé créera un conflit d'intérêts potentiel

Les organismes de réglementation ont fait part de leurs préoccupations concernant le fait que la délivrance de marihuana séchée par les médecins et les infirmiers praticiens autorisés à le faire en vertu du RMFM les place dans une situation de conflit d'intérêts potentiel en les autorisant à délivrer une drogue qu'ils peuvent également « prescrire ». Il a été souligné que les médecins, par exemple, sont tenus en vertu de leur code de déontologie de délivrer des médicaments uniquement dans les situations dans lesquelles il peut être démontré que la délivrance du médicament ne peut être faite par un tiers, tel qu'un pharmacien. D'autres personnes faisant partie de ce groupe d'intervenants ont soulevé le fait que l'autorisation de « vendre ou de fournir » de la marihuana séchée peut également exposer le praticien à des risques et faire de son établissement la cible d'une criminalité accrue.

Réponse du ministère de la Santé

Le Règlement a été révisé pour enlever l'autorité accordée à un praticien de la santé de « vendre ou de fournir » de la marihuana séchée à un patient. Cette autorité a été remplacée par celle accordée aux praticiens de « transférer » (c'est-à-dire « fournir de la marihuana séchée sans échange d'une contrepartie ») à un client inscrit d'un producteur autorisé qui désigne le bureau du praticien comme leur adresse d'expédition. La disposition relative au transfert ne permet pas à un praticien de la santé autorisé de fournir de la marihuana séchée à une personne en échange d'un article de valeur. La disposition révisée permet à un praticien de la santé autorisé de continuer à soutenir l'accès, au besoin, tout en supprimant l'incitation potentielle à prescrire des doses plus élevées, si la formulation « fournir avec contrepartie » était retenue.

Les municipalités, les organismes d'application de la loi et les services d'incendie

Les municipalités, les organismes d'application de la loi et les services d'incendie de tout le Canada, y compris des associations telles que la Fédération canadienne des municipalités, l'Association canadienne des chefs de police et l'Association canadienne des chefs de pompiers ont présenté des commentaires pendant la période de consultation. Ces groupes se sont montrés très favorables dans leurs commentaires sur le cadre global, percevant l'élimination de la production à des fins personnelles comme un moyen de réduire de façon significative les risques pour la santé publique, la sécurité et la sûreté au sein de leurs communautés. Compte tenu de l'absence de la distribution en pharmacie (leur méthode de distribution privilégiée), le passage à un système de production commerciale autorisée a été bien reçu. Ces groupes d'intervenants étaient, toutefois, inquiets du fait que le règlement proposé n'allait pas assez loin quant aux obligations imposées aux producteurs autorisés et aux anciens détenteurs de licence de production à des fins personnelles pour assurer la sécurité et la sûreté des Canadiens.

Question : les producteurs autorisés doivent être obligés de démontrer qu'ils respectent les lois locales applicables pour pouvoir obtenir une licence

Les municipalités ont soulevé la question selon laquelle, en vertu du règlement proposé, les demandeurs n'étaient pas tenus par

Canada that they were in compliance with all applicable local zoning, fire, health, safety, building or other by-law prior to being granted a licence to produce marihuana. They requested that the MMPR be amended to require that they be notified when a producer licence is granted, modified, revoked or suspended.

Department of Health response

In response to similar concerns raised by municipalities during preliminary consultations, the MMPR require potential applicants for a licence to notify local government, police and fire officials in writing of their intention to apply for a producer's licence and to submit proof in their application that this requirement has been complied with. The notice must specify the activities for which the licence will be sought, and the address of the site at which activities will be conducted. A provision has been made in the revised Regulations to require a licensed producer to also notify these same authorities when the licence is granted, when an amendment to the licence is approved by the Minister, when the licence is suspended or revoked for any reason, or when the licence is reinstated. Further, the revised Regulations enable the Minister of Health to confirm licence information to the authorities originally notified by an applicant when the Minister receives such a request.

Issue: The MMPR must require the remediation of dwellings used for production under the MMAR

In their comments, fire officials and municipalities highlighted their concern that the proposed MMPR fail to address the issue of remediating buildings that may have been damaged as a result of their use for licensed marihuana production under the MMAR. These stakeholders further indicated in their comments that they would like Health Canada to disclose the addresses of such sites and accept responsibility for the remediation of affected buildings.

Department of Health response

The federal government does not have jurisdiction over land use patterns, local zoning laws or the issuing of building or construction permits in municipalities across Canada. Health Canada understands the issue of remediation to be a matter for local government which is best handled, as appropriate, by the local authorities most familiar with the issue. In addition, there are privacy concerns with broad disclosure of all addresses of individuals who were authorized to produce marihuana for medical purposes under the MMAR.

Provinces and territories (P/T)

Six provinces, including British Columbia (BC), Alberta, Manitoba, Ontario, Quebec (QC) and Nova Scotia (NS), and three elected officials, including two members of Parliament, submitted comments during the 75-day comment period. Overall sentiments were similar to those expressed during preliminary consultations held in 2011. Consistently, provinces raised concerns about the role of health care practitioners and pharmacists under the proposed MMPR. Provinces emphasized a need for more education and guidelines for physicians and/or other health care

la loi de démontrer à Santé Canada qu'ils respectaient tous les règlements administratifs locaux applicables sur le zonage, la prévention des incendies, la santé, la sécurité, les constructions ou autre avant de se voir accorder une licence pour produire de la marihuana. Ils ont demandé que le RMFM soit modifié pour exiger qu'ils soient avisés lorsqu'une licence est accordée, modifiée, retirée ou suspendue.

Réponse du ministère de la Santé

En réponse à des préoccupations similaires soulevées par les municipalités au cours des consultations préliminaires, le RMFM exige que les demandeurs de licence potentiels avisent l'administration, les services de police et d'incendie locaux par écrit de leur intention de demander l'obtention d'une licence de producteur et de soumettre une preuve dans leur demande que cette exigence a été respectée. L'avis doit préciser les activités pour lesquelles la licence sera demandée, ainsi que l'adresse de l'installation dans laquelle les activités seront menées. Une disposition est prévue dans la version révisée du Règlement pour exiger que le producteur autorisé avise également les mêmes autorités lorsque la licence est accordée, lorsqu'une modification de la licence est approuvée par le ministre, lorsque la licence est suspendue ou retirée pour une raison ou une autre, ou lorsque la licence est restituée. De plus, la version révisée du Règlement permet au ministre de la Santé de confirmer l'information d'une licence aux autorités initialement visées par un demandeur lorsque ces dernières en font la demande au ministre.

Question : le RMFM doit exiger la remise en état des habitations utilisées pour la production en vertu du RAMM

Dans leurs commentaires, les services d'incendie et les municipalités ont exprimé leurs inquiétudes quant au fait que le RMFM ne fait aucune mention de la question liée à la remise en état des bâtiments qui auraient pu être endommagés en raison de leur utilisation pour la production de marihuana autorisée en vertu du RAMM. Ces intervenants ont d'autre part indiqué dans leurs commentaires qu'ils souhaiteraient que Santé Canada divulgue les adresses de ces installations et accepte la responsabilité de la remise en état des bâtiments concernés.

Réponse du ministère de la Santé

Le gouvernement fédéral n'est pas habilité à exercer un contrôle sur les modes d'utilisation des terres, les règlements administratifs de zonage ou la délivrance de permis de construction dans les municipalités de l'ensemble du pays. Santé Canada comprend que la question liée à la remise en état des habitations constitue un problème pour les administrations locales, laquelle est mieux traitée, au besoin, par les autorités locales qui ont une meilleure connaissance de cette question. De plus, la divulgation générale de toutes les adresses des personnes autorisées à produire de la marihuana à des fins médicales en vertu du RAMM soulève des inquiétudes reliées à la protection de la vie privée.

Les provinces et les territoires (P/T)

Six provinces, dont la Colombie-Britannique (C.-B.), l'Alberta, le Manitoba, l'Ontario, le Québec (Qc) et la Nouvelle-Écosse (N.-É.) et trois représentants élus (dont deux députés) ont formulé des commentaires pendant la période de consultation de 75 jours. Dans l'ensemble, les sentiments exprimés étaient similaires à ceux exprimés au cours des consultations préliminaires organisées en 2011. Les provinces ont régulièrement soulevé des préoccupations concernant le rôle des praticiens de la santé et des pharmaciens en vertu du RMFM proposé. Les provinces ont souligné la nécessité

professionals in order to be able to make informed recommendations for their patients. Dosage was highlighted as a key concern in that area. Concerns included lack of research and lack of an evidence base on which marihuana is recommended as a medical therapy, especially given the health implications of using a smoked form of marihuana for medical purposes. Three of the six provinces, BC, NS and QC, raised concerns with the ability of health care practitioners to sell and provide marihuana for medical purposes. They expressed concerns that it is a conflict of interest for health care practitioners to both support a patient's access and sell marihuana directly to their patients. These comments were similar to concerns raised directly by health care practitioners and the Department's response has been provided earlier in the RIAS under the issues raised by "Health care practitioners, medical associations and pharmacists." In addition, provinces and territories also expressed concern with the implications of a higher cost of dried marihuana to patients under the proposed MMPR.

Issue: Cost of dried marihuana under the MMPR will impact provinces and territories

Provinces and territories noted that a potentially higher price for dried marihuana under the proposed MMPR would put pressure on provinces and territories to subsidize the costs incurred by patients. They also noted that, without a common drug review and a drug identification number, marihuana for medical purposes is not likely to be dispensed by pharmacists nor covered under provincial drug plans.

Department of Health response

The MMPR will treat dried marihuana as much as possible like other narcotics used for medical purposes by creating conditions for a new, commercial industry that will produce and distribute dried marihuana. This new system will introduce a secure and efficient system that provides access to marihuana for those who suffer from illness or disease, while saving taxpayers' money and reducing risks that are felt by Canadian communities. It is unknown at this time what the cost of marihuana for medical purposes will be under the new system as licensed producers will be responsible for setting the price. The Regulations introduce conditions for a competitive industry and it is possible that prices will fall over time in response to competition and technological innovation that could reduce cost of production.

Prospective industry

Issue: The price of dried marihuana under the MMPR may be unaffordable

Comments were received from a variety of parties interested in becoming a licensed producer under the proposed MMPR, including compassion clubs. The majority of comments received expressed concern over consumer cost for dried marihuana. Based on the price projected in Health Canada's cost-benefit analysis for

d'offrir plus d'information et de lignes directrices aux médecins et/ou aux autres praticiens de la santé afin que ces derniers puissent formuler des recommandations éclairées à leurs patients. Le dosage a été souligné comme l'une des préoccupations majeures dans ce domaine. Les préoccupations comprenaient le manque de recherche et le manque de données probantes sur lesquelles on se fonde pour recommander la marihuana comme thérapie médicale, en particulier compte tenu des implications d'ordre sanitaire de l'utilisation de la marihuana à fumer à des fins médicales. Trois des six provinces, la C.-B., la N.-É. et le Québec ont exprimé des inquiétudes concernant la capacité des praticiens de la santé à vendre et à fournir de la marihuana à des fins médicales. Elles ont exprimé leurs préoccupations quant à la situation de conflit d'intérêts dans laquelle se trouvent les praticiens de la santé lorsqu'ils soutiennent l'accès d'un patient à la marihuana et dans un même temps, la vendent directement à leurs patients. Ces commentaires étaient similaires aux préoccupations soulevées directement par les praticiens de la santé et la réponse du ministère a été fournie plus tôt dans le RÉIR dans la section des questions soulevées par « Les praticiens de la santé, les associations médicales et les pharmaciens ». De plus, les provinces et les territoires ont également fait part de leurs inquiétudes concernant les implications d'une marihuana séchée à coût plus élevé pour les patients aux termes du RMFM.

Question : le coût de la marihuana séchée aux termes du RMFM aura des incidences sur les provinces et les territoires

Les provinces et les territoires ont fait remarquer qu'une possible hausse du prix de la marihuana séchée aux termes du RMFM pourrait contraindre les provinces et les territoires à subventionner les coûts encourus par les patients. Ils ont également noté le fait que, sans un Programme commun d'évaluation des médicaments et sans numéro d'identification du médicament (DIN), la marihuana à des fins médicales ne serait probablement pas délivrée par des pharmaciens ni remboursée par les régimes d'assurance-médicaments provinciaux.

Réponse du ministère de la Santé

Le RMFM traitera la marihuana séchée dans la mesure du possible comme d'autres stupéfiants utilisés à des fins médicales en créant les conditions propices à une nouvelle industrie commerciale qui produira et distribuera la marihuana séchée. Ce nouveau système mettra en place un régime efficace et sécurisé qui assurera un accès à la marihuana aux personnes qui souffrent d'une maladie, tout en économisant l'argent des contribuables et en réduisant les risques ressentis par les communautés canadiennes. On ne connaît pas encore ce que coûtera la marihuana à des fins médicales aux termes de ce nouveau régime puisque les producteurs autorisés seront chargés d'établir le prix. Le Règlement établit les conditions favorables à une industrie concurrentielle et il est possible que les prix diminuent avec le temps grâce à la concurrence et à l'innovation technologique qui pourrait permettre de réduire le coût de production.

Les industries potentielles

Question : le prix de la marihuana séchée aux termes du RMFM pourrait être inabordable

Des commentaires ont été reçus de la part de différentes parties intéressées à devenir des producteurs autorisés en vertu du RMFM proposé, y compris des clubs compassion. La majorité des commentaires reçus portaient sur des inquiétudes concernant le coût de la marihuana séchée pour le consommateur. En se fondant sur le

the Regulations (which estimated that an LP producing 500 kg of dried marihuana per year could set a price of $7.60/gram and maintain a profitable operation), many potential LPs felt that registered clients, especially those in the low income category due to a disability, would not be able to afford the quantities they need or are accustomed to. This was seen as a significant risk to the viability of the commercial market considering the size of the investment that the group believes will be necessary to enter the market. It was suggested that Health Canada work with P/Ts to explore the possibility of insurance coverage or consider some alternative forms of subsidy for individuals who may be unable to afford the price in the regulated market.

Department of Health response

The MMPR will treat dried marihuana as much as possible like other narcotics used for medical purposes by creating conditions for a new, commercial industry that will produce and distribute dried marihuana. This new system will introduce a secure and efficient system that provides access to marihuana for those who suffer from illness or disease, while saving taxpayers' money and reducing risks that are felt by Canadian communities. Since 2001, the cost of the Program (issuing authorization/licences and subsidizing supply of dried marihuana) under the MMAR has consistently been rising as program participation has continued to experience exponential growth. With this growth projected to continue, the system of providing access to marihuana for medical purposes through a government supply contract or by issuing licences for personal production (i.e. PUPL/DPPL) is unsustainable. It is unknown at this time what the cost of marihuana for medical purposes will be under the new system as licensed producers will be responsible for setting the price in a manner similar to how prices for other narcotics used for medical purposes are set by their manufacturers. The Regulations introduce conditions for a competitive industry and it is possible that prices will fall over time in response to factors such as competition and changing technology. Health Canada has made available all relevant information and will continue to work with potential licence producers to help them make an informed decision on whether or not to enter the regulated market but the decision to do so will be a private business decision.

Issue: Marihuana-infused products should be allowed under the MMPR

Some potential licence producers expressed their dissatisfaction with the fact that under the proposed MMPR, marihuana will be available in dried form only and criticized the lack of product alternatives as a limitation on client choice. Some felt that the restriction to dried marihuana deprived registered clients and patients of access to marihuana in forms that may be preferred in terms of desired effects, routes of administration (e.g. ingestion or topical) and "dosage." They noted that some users of marihuana for medical purposes may prefer marihuana-based products that are ingested or applied topically to those used primarily via inhalation, given the known dangers of smoking.

prix anticipé déterminé dans l'analyse des coûts et des avantages de Santé Canada pour le Règlement (dans laquelle il était estimé qu'un PA produisant 500 kg de marihuana séchée par année pourrait fixer un prix de 7,60 $/gramme et conserver une activité rentable), de nombreux PA potentiels estimaient que les clients inscrits, en particulier ceux faisant partie de la catégorie des personnes à faible revenu en raison d'un handicap, ne pourraient pas se permettre de se procurer les quantités dont ils ont besoin ou auxquelles ils sont habitués. Cela a été perçu comme un risque important pour la viabilité du marché commercial compte tenu de l'ampleur des investissements qui, selon le groupe, seront nécessaires pour accéder au marché. Il a été suggéré que Santé Canada collabore avec les P/T pour examiner la possibilité de rembourser ces coûts dans le cadre de régimes d'assurance-médicaments ou examiner d'autres formes de subventions pour les personnes qui pourraient ne pas avoir les moyens de payer le prix sur le marché réglementé.

Réponse du ministère de la Santé

Le RMFM traitera la marihuana séchée dans la mesure du possible comme d'autres stupéfiants utilisés à des fins médicales en créant les conditions propices à une nouvelle industrie commerciale qui produira et distribuera la marihuana séchée. Ce nouveau système mettra en place un régime efficace et sécurisé qui assurera un accès à la marihuana aux personnes qui souffrent d'une maladie, tout en économisant l'argent des contribuables et en réduisant les risques ressentis par les communautés canadiennes. Depuis 2001, le coût du Programme (la délivrance d'autorisations/de licences et le subventionnement de l'approvisionnement de la marihuana séchée) aux termes du RAMM a constamment augmenté alors que la participation au programme a continué à connaître une croissance exponentielle. Cette croissance devant se poursuivre, un système offrant un accès à la marihuana à des fins médicales au moyen d'un contrat d'approvisionnement conclu avec le gouvernement ou par la délivrance de licences de production à des fins personnelles (c'est-à-dire LPFP/LPPD) n'est pas viable. On ignore actuellement ce que coûtera la marihuana à des fins médicales en vertu de ce nouveau régime puisque les producteurs autorisés seront chargés de fixer le prix d'une manière similaire à la façon dont les prix d'autres stupéfiants utilisés à des fins médicales sont établis par leurs fabricants. Le Règlement établit les conditions favorables à une industrie concurrentielle et il est possible que les prix diminuent avec le temps grâce à des facteurs tels que la concurrence et les nouvelles technologies. Santé Canada a rendu publique toute l'information pertinente et le ministère continuera à travailler avec des producteurs autorisés potentiels afin de les aider à prendre des décisions éclairées quant à leur entrée ou non sur le marché réglementé, mais leur décision de le faire restera une décision d'entreprise privée.

Question : les produits infusés à la marihuana devraient être autorisés en vertu du RMFM

Certains producteurs autorisés potentiels ont fait part de leur mécontentement dû au fait qu'aux termes du RMFM proposé la marihuana sera offerte sous forme séchée uniquement et ils ont critiqué le manque de produits de remplacement comme une limitation du choix du client. Certains ont estimé que la restriction à la marihuana séchée privait les clients inscrits et les patients d'avoir accès à de la marihuana sous d'autres formes pouvant être privilégiées du point de vue des effets souhaités, des voies d'administration (par exemple ingestion ou topique) et du « dosage ». Ils ont fait remarquer que certains consommateurs de marihuana à des fins médicales pourraient préférer des produits à base de marihuana qui sont ingérés ou appliqués de façon topique plutôt que ceux utilisés

Department of Health response

The new Regulations will limit licensed producers to the production and distribution of dried marihuana only. The MMPR will not authorize extractions of active ingredients (e.g. resin) to be sold for the therapeutic purposes. The only clinical studies on the therapeutic uses of marihuana that have been carried out to date have only used dried marihuana that was either smoked or vaporized. There are no clinical studies on the use of cannabis edible (e.g. cookies, baked goods) or topical products for therapeutic purposes. As with other drugs, all products that claim to have a health benefit must first go through the drug approval process as outlined in the *Food and Drug Regulations* (FDR). The limited clinical data that exists is restricted to dried marihuana that was either smoked or vaporized and to cannabinoid-based medicines (dronabinol, nabilone, and nabiximols) that have gone through the appropriate drug approval channels. Under the MMPR, licensed producers will be required to include information leaflets prepared by Health Canada which warn consumers of the adverse effects of using marihuana. There are no restrictions on how dried marihuana is to be ingested or inhaled, and patients may choose to use it, for example in foods or by vaporizing. HC does not limit or recommend a particular method of administration.

Issue: Distribution by mail only is not a reliable system of delivery

Many potential LPs raised concerns with the requirement to distribute dried marihuana to clients by mail only. They argued that this system is not well tested and may fail to provide timely access to dried marihuana for registered clients and may even pose security risks to courier companies and their personnel. Others noted that this limitation may provide incentive for some to try to work around the shipping requirement under the proposed MMPR by hiring a health care practitioner or pharmacist to dispense dried marihuana directly to clients on-site.

Department of Health response

Secured mail-only delivery by companies specializing in mail delivery has been used under the MMAR to provide access to dried marihuana for clients who obtain their supply from Health Canada. Under the Program, dried marihuana is shipped by courier or, in remote locations, by Canada Post, to the authorized person, unless the authorized person has arranged for their medical practitioner to receive the dried marihuana on their behalf. In the absence of a role for pharmacies, P/T ministries of public safety, law enforcement, municipalities and fire officials indicated a preference for this system of delivery over the establishment of storefront retail outlets. Secured mail-only delivery is seen by this stakeholder group and others as a safer alternative to direct storefront retail and a way to minimize the potential for diversion. Health Canada believes that secured mail delivery strikes an appropriate balance between individuals' need for access and communities' need for safety and security.

principalement par inhalation, puisque l'on sait que fumer présente des dangers.

Réponse du ministère de la Santé

Le nouveau règlement limitera les producteurs autorisés uniquement à la production et à la distribution de la marihuana séchée à des fins médicales. Le RMFM n'autorisera pas l'extraction des principes actifs (par exemple la résine) pour qu'ils soient vendus à des fins thérapeutiques. Les seules études cliniques qui ont été effectuées à ce jour sur les utilisations thérapeutiques de la marihuana n'ont utilisé que de la marihuana séchée qui était soit fumée ou vaporisée. Il n'existe pas d'études cliniques sur l'usage des produits comestibles (biscuits, produits cuits) ou des produits topiques du chanvre indien à des fins thérapeutiques. Comme c'est le cas pour d'autres drogues, tous les produits ayant la prétention d'avoir un effet bénéfique sur la santé doivent d'abord être soumis au processus d'autorisation des médicaments comme l'exige le *Règlement sur les aliments et drogues* (RAD). Les données cliniques restreintes qui existent ne portent que sur la marihuana séchée qui était soit fumée ou vaporisée et les médicaments à base de cannabinoïde (dronabinol, nabilone, and nabiximols) qui ont été soumis aux processus d'approbation des médicaments appropriés. Aux termes du RMFM, les producteurs autorisés seront tenus d'inclure des dépliants d'information préparés par Santé Canada qui avertissent les consommateurs des effets indésirables de la consommation de la marihuana. Il n'existe aucune restriction quant à la façon dont la marihuana séchée doit être ingérée ou inhalée, et les patients peuvent choisir de la consommer, par exemple dans leur alimentation ou par vaporisation. SC ne limite pas les modes d'administration ni n'en recommande un en particulier.

Question : la distribution par la poste uniquement n'est pas un système de livraison fiable

De nombreux producteurs autorisés potentiels ont exprimé leurs inquiétudes concernant l'exigence de distribuer la marihuana séchée par courrier postal uniquement. Ils estiment que ce système n'est pas bien éprouvé et pourrait ne pas assurer un accès opportun à de la marihuana séchée aux clients inscrits et qu'il pourrait même poser des risques de sécurité pour les entreprises de messagerie et leur personnel. D'autres personnes ont fait remarquer que cette limitation peut inciter certaines personnes à contourner cette exigence du RMFM proposé en embauchant un praticien de la santé ou un pharmacien pour délivrer de la marihuana séchée directement aux clients se trouvant sur place.

Réponse du ministère de la Santé

Un système de livraison sécurisée par courrier postal uniquement effectuée par des entreprises spécialisées dans la livraison du courrier a été utilisé dans le cadre du RAMM pour assurer un accès à de la marihuana séchée aux clients qui obtiennent leur approvisionnement auprès de Santé Canada. Aux termes du Programme, la marihuana séchée est livrée par messagerie ou, dans les régions éloignées, par Postes Canada, à la personne autorisée, à moins que la personne autorisée n'ait pris d'autres dispositions avec son praticien de la santé pour recevoir la marihuana séchée en son nom. En l'absence d'un rôle joué par les pharmacies, les ministères de la sécurité publique des P/T, les organismes d'application de la loi, les municipalités et les services d'incendie ont indiqué une préférence pour ce système de livraison plutôt que l'établissement de comptoirs ou de points de vente. Un système de livraison sécurisée par courrier postal uniquement est perçu par ce groupe d'intervenants et par d'autres personnes comme une solution de rechange plus sécuritaire aux comptoirs de vente directe et un moyen de

Health Canada considered carefully the suggestion that enabling pharmacist dispensing could potentially lead to circumventing the restriction to distributing dried marihuana only by secured mail. However, Health Canada is of the opinion that as an employee of an LP, a pharmacist will be held to the same regulatory requirements and have the same prohibitions (i.e. secure shipping only) on direct sale to registered clients as an LP without a pharmacist on staff. Therefore, direct hiring of a pharmacist by an LP does not enable a storefront distribution model. However, in response to the concerns raised by pharmacists and pharmacists' associations as well as by provinces and territories (see comments by provinces and territories), the MMPR have been revised to remove the authority for pharmacists to dispense dried marihuana outside a hospital, as long as their activities were also authorized under P/T legislation.

Other groups

Other groups who submitted comments include a wide range of non-governmental organizations. A majority of comments received in this category were from compassion clubs and marihuana advocacy groups. Stakeholders generally supported the removal of Health Canada's application process and the categories of symptoms and conditions. Concerns similar to those raised by other stakeholders were also expressed. In particular, this group indicated dissatisfaction with physicians' reluctance to support access to marihuana for medical purposes, the elimination of personal production licences, including designated person production, and the absence of authority under the proposed MMPR allowing for the production of cannabis-infused products.

Rationale

In recent years, a wide range of stakeholders have voiced concerns about the MMAP. Concerns include the risk of diversion of marihuana, the complexity and timeliness of the application and authorization process, health, safety and security issues associated with the production of marihuana in homes and communities, and the lack of adequate scientific evidence for the medical use of marihuana. A new regulatory framework is required to address these and other issues by providing reasonable access to a legal source of marihuana for medical purposes while continuing to regulate marihuana as a controlled substance.

The MMPR will impose a significant compliance and administrative burden on businesses that may wish to enter the market. However, the requirements included in the MMPR are considered necessary to achieving the goal of reducing the potential for abuse and exploitation of the system and reducing the risks to public health, safety and security, while still maintaining reasonable

réduire davantage le risque de détournement. Santé Canada estime que la livraison par la poste uniquement établit un équilibre approprié entre le besoin d'accès des personnes et le besoin de sécurité et de sûreté des communautés.

Santé Canada a examiné attentivement la suggestion selon laquelle autoriser les pharmaciens à délivrer la marihuana pourrait éventuellement permettre de contourner la restriction de la distribution de la marihuana séchée par courrier sécurisé uniquement. Toutefois, Santé Canada est d'avis qu'en tant qu'employé d'un PA, un pharmacien sera tenu de respecter les mêmes exigences réglementaires et qu'il sera soumis aux mêmes interdictions (par exemple des méthodes de livraison sécurisées uniquement) sur les ventes directes à des clients inscrits que les PA ne comptant pas de pharmacien dans leur personnel. Par conséquent, l'embauche directe d'un pharmacien par un PA ne lui permet pas d'offrir un modèle de distribution au comptoir. Toutefois, compte tenu des préoccupations soulevées par les pharmaciens et par leurs associations ainsi que par les provinces et les territoires (voir les commentaires formulés par les provinces et les territoires), le RMFM a été révisé pour supprimer l'autorisation donnée aux pharmaciens de délivrer de la marihuana séchée en dehors d'un hôpital, à condition que leurs activités fussent également autorisées par la loi provinciale ou territoriale.

Autres groupes

D'autres groupes d'intervenants ayant présenté des commentaires comprenaient un vaste éventail d'organisations non gouvernementales. Une majorité de commentaires reçus dans cette catégorie provenaient de clubs compassion et de groupes de revendication de la marihuana. De manière générale, les intervenants se sont montrés favorables au retrait du processus de demande de Santé Canada et à l'égard des catégories de symptômes et d'états de santé. Des préoccupations similaires à celles exprimées par d'autres intervenants ont également été soulevées. En particulier, ce groupe a indiqué son mécontentement concernant la réticence des médecins à soutenir l'accès à la marihuana à des fins médicales, l'élimination des licences de production à des fins personnelles, y compris celles pour la production par une personne désignée et l'absence d'autorité conférée par le RMFM proposé qui permettrait la production de produits infusés de chanvre indien.

Justification

Au cours des dernières années, un grand nombre d'intervenants ont formulé leurs préoccupations au sujet du RAMM. Ces préoccupations comprennent le risque de détournement de la marihuana, la complexité et la rapidité d'exécution de la demande et du processus d'autorisation, des questions de santé et de sécurité associées à la production de la marihuana dans les résidences et les collectivités, ainsi que le manque de preuves scientifiques adéquates en ce qui a trait à l'usage de la marihuana à des fins médicales. Un nouveau cadre de réglementation est requis en vue de régler ces questions, entre autres, en fournissant un accès raisonnable à une source légale de marihuana à des fins médicales, tout en continuant de réglementer la marihuana à titre de substance désignée.

Le RMFM imposera un fardeau considérable au niveau administratif et en matière de conformité pour les entreprises qui pourraient vouloir intégrer le marché. Cependant, les exigences formulées dans le RMFM sont jugées nécessaires pour atteindre le but de réduire la possibilité d'abus et d'exploitation du système et de réduire les risques pour la santé et la sécurité publiques, tout en

access to a legal source of marihuana for medical purposes, as per the decisions of Canadian courts, for Canadians with medical need.

The MMPR will provide a more efficient way of accessing marihuana for medical purposes, particularly by affording individuals with a medical need increased choice in terms of authorized health care practitioners, marihuana strains, and suppliers. Eliminating licensed marihuana production in homes will eliminate public health, safety and security concerns relating to those licensed activities, as well as eliminate ambiguities for law enforcement. Finally, the elimination of Health Canada's role in authorizing individual access to marihuana for medical purposes, and production and distribution of marihuana, will significantly reduce the cost of administering the Program.

Implementation, enforcement and service standards

Repeal of the MMAR

The MMPR include a number of consequential changes to the MMAR, as well as two transitional registration schemes that will allow for gradual transition to the new regulatory regime. Upon coming into force, the MMPR will allow the holder of an authorization to possess to obtain their supply of marihuana from a licensed producer by registering as a client with that producer. Similarly, an individual who had obtained a medical declaration from their medical practitioner under the MMAR could register as a client with a licensed producer instead of applying to Health Canada for an authorization to possess.

The MMAR will be repealed on March 31, 2014. At that point, all authorizations and licences issued under the MMAR will no longer be valid. However, individuals will be authorized to use their expired authorizations to possess to register as a client with a licensed producer for up to one year after their date of issue, unless a period of usage of less than 12 months has been indicated in the medical declaration.

New PUPL and DPPL will no longer be issued if the application is submitted after September 30, 2013. Similarly, existing PUPL and DPPL holders will not be able to apply to change the location of their production site on the licence as of the same date. This is to avoid situations where a person receives a PUPL or DPPL as their supply option, but will not be able to produce a crop before the repeal of the MMAR.

Compliance and enforcement

In general, compliance and enforcement activities will be subject to the broader Health Canada compliance and enforcement policy for controlled substances and precursors. Compliance verification will largely take the form of pre-licensing inspections, and inspections of licensed sites. Inspections will occur under existing legislative authorities. Compliance will be assessed against the MMPR, the FDA, the NCR, and, during transition, the MMAR, as well as any relevant directives and guidelines. Potential responses to non-compliance could include placing conditions on a licence, the full or partial suspension of a licence, the revocation of a licence or permit, and the refusal to issue, amend, or renew a licence, or prosecution under the CDSA or FDA.

maintenant un accès raisonnable à une source légale de marihuana à des fins médicales pour les Canadiens qui en ont besoin, comme l'ont décidé les cours canadiennes.

Le RMFM fournira une façon plus efficace d'avoir accès à la marihuana à des fins médicales, particulièrement en offrant aux particuliers qui en ont besoin sur le plan médical un choix accru quant aux praticiens de la santé autorisés, aux souches de marihuana et aux fournisseurs. L'élimination de la production autorisée de la marihuana dans les habitations permettra d'éliminer les préoccupations en matière de santé et de sécurité publiques qui ont trait à ces activités autorisées, ainsi que les ambiguïtés pour les responsables de l'application de la loi. Enfin, l'élimination du rôle de Santé Canada d'autoriser l'accès à la marihuana à des fins médicales à des particuliers ainsi que de produire et de distribuer la marihuana réduira de façon considérable les coûts d'administration du Programme.

Mise en œuvre, application et normes de service

Abrogation du RAMM

Le RMFM comprend certaines modifications corrélatives au RAMM, ainsi que deux systèmes d'inscription transitoires qui permettront une transition graduelle vers le nouveau régime réglementaire. Dès son entrée en vigueur, le RMFM permettra au titulaire d'une autorisation de possession d'obtenir son approvisionnement de marihuana auprès d'un producteur autorisé en s'inscrivant comme l'un de ses clients. Dans le même ordre d'idées, un particulier ayant obtenu une déclaration médicale de son praticien de la santé autorisé en vertu du RAMM pourrait s'inscrire comme client auprès d'un producteur autorisé, au lieu de faire parvenir une demande d'autorisation de possession à Santé Canada.

Le RAMM sera abrogé le 31 mars 2014. À ce moment, toutes les autorisations et les licences délivrées en vertu du RAMM ne seront plus valides. Toutefois, les particuliers pourront utiliser leur autorisation de possession expirée pour s'inscrire comme client auprès d'un producteur autorisé dans l'année suivant la date de délivrance, à moins qu'une période d'usage inférieure à 12 mois soit indiquée sur la déclaration médicale.

Aucune nouvelle LPFP ou LPPD ne sera délivrée si la demande est soumise après le 30 septembre 2013. Dans le même ordre d'idées, à partir de cette date, les titulaires d'une LPFP ou d'une LPPD ne seront pas autorisés à faire une demande pour changer l'emplacement de leur site de production qui figure sur la licence. Cela a pour but d'éviter des situations où un particulier obtiendrait une LPFP ou une LPPD comme option d'approvisionnement, mais ne pourra pas produire une récolte avant l'abrogation du RAMM.

Observation et exécution

De façon générale, les activités d'observation et d'exécution seront assujetties à la politique élargie d'observation et d'exécution de Santé Canada pour les substances désignées et les précurseurs. L'observation sera principalement vérifiée par la tenue d'inspections préalables à la délivrance de licences, ainsi que des inspections des installations autorisées. Les inspections seront menées en vertu des autorités législatives en place. L'observation sera évaluée par rapport au RMFM, à la LAD et au RS et, pendant la transition, au RAMM, ainsi qu'à toutes les directives et lignes directrices pertinentes. Les réponses potentielles à l'inobservation pourraient comprendre l'ajout de conditions sur une licence, la suspension totale ou partielle d'une licence, la révocation d'une licence ou d'un permis, le refus de délivrer, de modifier ou de renouveler une licence, ou une poursuite en vertu de la LRCDAS ou de la LAD.

Performance measurement and evaluation

Health Canada has developed a Performance Measurement and Evaluation Plan (PMEP) to measure the performance and conduct an evaluation of the MMPR. This plan specifies the methods selected for ongoing monitoring of the MMPR, performance targets, indicators and data sources. These will be comprehensively tracked as part of the performance measurement strategy outlined in the PMEP. This PMEP is available upon request.

Contact

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Mesures de rendement et évaluation

Santé Canada a élaboré un Plan de mesure et d'évaluation du rendement (PMER) pour évaluer la performance et le rendement du RMFM. Ce plan précise les méthodes sélectionnées pour la surveillance continue du RMFM, des objectifs de rendement, des indicateurs et des sources de données. Ceux-ci seront surveillés dans le cadre de la stratégie de mesure du rendement énoncée dans le PMER. Ce PMER est disponible sur demande.

Personne-ressource

Réforme réglementaire de la marihuana à des fins médicales
Direction des substances contrôlées et de la lutte au tabagisme
Direction générale de la santé environnementale et de la sécurité des consommateurs
Santé Canada
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Published by the Queen's Printer for Canada, 2013 Publié par l'Imprimeur de la Reine pour le Canada, 2013

This is **Exhibit " H "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

Health Canada Santé Canada

Canada

Drugs and Health Products

Transition and the Marihuana for Medical Purposes Regulations

How the new regulations affect you

Information about the Transition Period

The *Marihuana for Medical Purposes Regulations* (MMPR) were published on June 19, 2013, and are now in force. There will be a period of time until March 31, 2014 when both the MMPR and the *Marihuana Medical Access Regulations* (MMAR) are in force to help facilitate the transition to the system of licensed producers.

During this period, you will be able to access marihuana for medical purposes under either the MMAR or the MMPR, but not both. **The transition period will end on March 31, 2014, after which time only the MMPR will be in force.**

Key points about the transition period:

1. Effective October 1, 2013, you can no longer apply for a new Personal-Use Production Licence or Designated-Person Production Licence, change the location of your production site or increase the number of plants associated with your licence.

   You may continue to renew your existing Authorization to Possess (ATP), Personal-Use Production Licence (PUPL) or Designated-Person Production Licence (DPPL); however, your new documents will expire on March 31, 2014.

2. All marihuana possessed or produced under your Authorization to Possess and/or Personal-Use or Designated-Person Production Licence must be destroyed no later than March 31, 2014.

3. The production of marihuana in homes will no longer be permitted beginning April 1, 2014.

4. You may use your ATP to register with a licensed producer until the expiry date shown on the document, however, as of April 1, 2014, your Authorization to Possess marihuana for medical purposes issued under the MMAR cannot be used as proof that you are authorized to possess marihuana for medical purposes. Only the label on the package from the LP or a separate document accompanying your shipment of dried marihuana from your licensed producer can be used as proof of authorization to possess marihuana for medical purposes.

Questions and Answers: How transition and the *Marihuana for Medical Purposes Regulations* (MMPR) affect you

The following pages contain answers to questions you may have about how the MMPR and the transition period will affect you. The questions you will find in this document include:

Q1: How do I access marihuana during the transition period?

A1: If you have the support of a health care practitioner, you may access marihuana for medical purposes through either:

1. The current *Marihuana Medical Access Regulations* (by applying to Health Canada); or
2. The new *Marihuana for Medical Purposes Regulations* (by registering with a licensed producer).

Please note that you may only access marihuana for medical purposes under the *Marihuana Medical Access Regulations* or the new *Marihuana for Medical Purposes Regulations*, but not both.

Under the *Marihuana Medical Access Regulations*, you can apply to Health Canada to access one of the three sources of supply: Health Canada supply; Personal-Use Production Licence; or Designated-Person Production Licence. For more information on how to apply, please visit the "How to Apply" web page.

Please note that effective October 1, 2013, you can no longer apply for a new Personal-Use Production Licence or Designated-Person Production Licence or change the production site address or increase the number of plants associated with your licence to produce.

Under the new *Marihuana for Medical Purposes Regulations*, the original medical document signed by your health care practitioner can be submitted directly to a licensed producer along with a completed registration form from the licensed producer of your choice.

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Q2: During the transition period, what is my proof of authority to possess marihuana?

A2: If you continue to access marihuana under the *Marihuana Medical Access Regulations*, your Authorization to Possess (ATP) will remain your proof of authority to possess until March 31, 2014. As of April 1, 2014, your ATP can no longer be used as proof that you are authorized to possess marihuana for medical purposes.

If you register with a licensed producer under the new *Marihuana for Medical Purposes Regulations* (regardless of whether it is before or after March 31, 2014) your proof of authority to possess will either be the label on the packaging or a separate document accompanying your shipment of dried marihuana from your licensed producer.

Q3: I have a valid Authorization to Possess. When can I transition to a licensed producer?

A3: You can transition anytime until the validity date shown on your Authorization to Possess. If you do not register with a licensed producer before your validity date, you can register using a medical document completed by your health care practitioner.

Health Canada has begun issuing licences to LPs. Contact information for LPs is available on the Health Canada website. This page will be updated regularly as new LPs are approved.

Q4: If I apply for or renew my Authorization to Possess now, when will it expire?

A4: Starting June 19, 2013, the Program began issuing Authorizations to Possess (ATPs) containing three dates: an issue date, an expiry date and a validity date.

The **issue date** is the date your ATP is issued to you. Your **expiry date** is March 31, 2014. At this time you will no longer be permitted to access the sources of supply available under the MMAR (Personal-Use Production Licence, Designated-Person Production Licence, or Health Canada supply). You will be able to use your ATP, instead of a medical document, to register with a licensed producer until the **validity date**, which is one year from the issue date.

Q5: My Authorization to Possess has an expiry date after March 31, 2014. How do the *Marihuana for Medical Purposes Regulations* affect me?

A5: The repeal date of the *Marihuana Medical Access Regulations* (MMAR) is March 31, 2014.

As of April 1, 2014, the Authorization to Possess (ATP) issued to you under the MMAR cannot be used as proof of authority to possess, even if your ATP shows an expiry date later than March 31, 2014. However, you may use your ATP in place of a medical document to register with a licensed producer prior to your expiry date.

Q6: If my Authorization to Possess expires before March 31, 2014, what are my options for continuing to access marihuana for medical purposes?

A6: Until March 31, 2014, if you have the support of a health care practitioner, you may access marihuana for medical purposes through either:

1. The *Marihuana Medical Access Regulations* (by applying to Health Canada); or
2. The new *Marihuana for Medical Purposes Regulations* (by registering with a licensed producer).

Under the *Marihuana Medical Access Regulations*, you can apply to Health Canada to access one of the three sources of supply: Health Canada supply; Personal-Use Production Licence; or Designated-Person Production Licence. For more information on how to apply for one of these sources of supply, please visit the "How to Apply" web page at URL. Please note that effective October 1, 2013, you can no longer apply for a new Personal-Use Production Licence or Designated-Person Production Licence or apply to change the production site address or increase the number of plants associated with your licence to produce.

Under the new *Marihuana for Medical Purposes Regulations*, your health care practitioner must complete a medical document that you submit to a licensed producer along with a completed registration form from the licensed producer of your choice.

Please note that you may only have access to marihuana for medical purposes under either the *Marihuana Medical Access Regulations* or the new *Marihuana for Medical Purposes Regulations*, but not both.

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Q7: My Personal-Use Production Licence/Designated-Person Production Licence expires after March 31, 2014. Does that mean I can continue to produce or store marihuana until the expiry date?

A7: No. The *Marihuana Medical Access Regulations* (MMAR) will be repealed on March 31, 2014. Any Personal-Use Production Licences and Designated-Person Production Licences issued under the MMAR are no longer valid as of that date, even if your licence shows a later expiry date. If you were issued a Personal-Use Production Licence or a Designated-Person Production Licence between April 1, 2013 and June 19, 2013, you will receive a letter that explains this in further detail.

The production of marihuana for medical purposes in private dwellings beyond March 31, 2014, is not permitted.

Q8: I have a Personal-Use Production Licence/Designated-Person Production Licence that expires after September 30, 2013. Can I still apply for a renewal?

A8: Yes. You can continue to apply to renew your Authorization to Possess and any associated Personal-Use or Designated-Person Production Licence; however, your new documents will expire on March 31, 2014.

Please note that effective October 1, 2013, you can no longer apply for a new PUPL or DPPL, or change the location of your production site or increase the number of plants associated with your Personal-Use or Designated-Person Production Licence.

Q9: I currently hold an Authorization to Possess and I would like to amend my source to have a Personal-Use Production Licence/Designated-Person Production Licence. Are these still being issued?

A9: To comply with the *Marihuana for Medical Purposes Regulations*, effective October 1, 2013, Health Canada can no longer accept applications for new Personal-Use and Designated-Person Production Licences.

In addition, effective October 1, 2013, Health Canada will not accept applications to change the production site or increase the number of plants associated with a Personal-Use and Designated-Person Production Licence. Applications for new PUPLs and DPPLs, or amendments to existing PUPLs/DPPLs received on or after October 1, 2013, will be returned.

It is important to note that as of March 31, 2014, you will only be able to legally access marihuana for medical purposes through licensed producers.

Q10: I currently hold a Personal-Use Production Licence/Designated-Person Production Licence. Can I make changes to my licence after September 30, 2013?

A10: It depends on the change. Effective October 1, 2013, you can no longer apply to change the location of your production site or increase the number of plants associated with your production site.

Any applications to change the production site address or the number of plants associated with a licence received by Health Canada on or after October 1, 2013, will be returned to you.

You should also note that while applications to change the address of a production site must be received prior to October 1, 2013, the address change must take effect before December 15, 2013. If your application identifies that a change in the production site address will occur after December 15, 2013, it will be returned to you.

You can continue to renew your Personal-Use or Designated-Person Production Licence with no production site changes or increase in numbers of plants. In addition, Health Canada will continue to accept applications for Authorizations to Possess and renewals for Authorizations to Possess, including increases in daily amounts, until March 31, 2014.

Q11: What is the last date on which I can submit an application to the Marihuana Medical Access Program?

A11: Health Canada will issue and renew Authorizations to Possess marihuana for medical purposes and will renew Personal-Use Production Licences and Designated-Person Production Licences that do not change the production site address or increase the number of plants associated with the licence until March 31, 2014. Please note that the service standard for processing incoming, complete applications is up to 10 weeks. **Therefore, if you wish to continue to apply to the Marihuana Medical Access Program, you are strongly advised to submit your completed application to Health Canada no later than 10 weeks prior to March 31, 2014.**

It is important to note the MMAR will be repealed on March 31, 2014. As of March 31, 2014 the only legal means to access dried marihuana for medical purposes is through the system of licensed producers.

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Q12: Can I still order dried marihuana from Health Canada during the transition period?

A12: Yes. Health Canada will continue to supply dried marihuana until March 31, 2014. In order to access Health Canada's supply, you must have a valid Authorization to Possess and you must have submitted a complete Form E1 "Application to Obtain Dried Marihuana" with your most recent application to the Marihuana Medical Access Program.

Q13: Where is the list of Health Canada approved licensed producers?

A13: Health Canada has begun issuing licences to LPs. Contact information for LPs is available on the Health Canada website. This page will be updated regularly as new LPs are approved.

Q14: Can I register with a licensed producer and still access my source of supply under the *Marihuana Medical Access Regulations*?

A14: No. You can either choose to switch to the system of licensed producers by registering with a licensed producer **OR** continue to access marihuana through a Personal-Use Production Licence, Designated-Person Production Licence, or through Health Canada supply under the *Marihuana Medical Access Regulations* until March 31, 2014. Once you register with a licensed producer you may not access your previous source of supply.

Note: After March 31, 2014, the only legal supply of marihuana for medical purposes is via a licensed producer.

Q15: I currently hold a Personal-Use Production Licence. If I switch to a licensed producer, can I continue to produce marihuana until March 31, 2014?

A15: No. Once you register with a licensed producer your Authorization to Possess and Personal-Use Production Licence will be revoked and all marihuana in your possession must be destroyed.

All Personal-Use and Designated-Person Production Licences expire on March 31, 2014. As of April 1, 2014, the only legal means to access to dried marihuana for medical purposes will be through the system of licensed producers.

Q16: I currently have a designated person producing marihuana for me. Can I still receive marihuana from him/her if I switch to the system of licensed producers?

A16: No. Once you register with a licensed producer, your Authorization to Possess and the associated Designated-Person Production Licence will be revoked. When these licences are revoked, your designated person must destroy all marihuana and marihuana plants produced under the licence.

All Personal-Use and Designated-Person Production Licences expire on March 31, 2014. As of April 1, 2014, the only legal means to access to dried marihuana for medical purposes will be through the system of licensed producers.

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Q17: I have a Designated-Person Production Licence. Can I continue to produce marihuana if the person I produce for switches to the system of licensed producers?

A17: No. If the authorized person associated with your licence registers with a licensed producer your Designated-Person Production Licence will be revoked and you are required to immediately destroy the marihuana and marihuana plants in your possession.

If you have a second DPPL to produce for another individual who has not yet switched to the system of licensed producers, you may continue to produce for that individual under a valid licence until March 31, 2014. The amount produced should be in line with the maximum amount listed on the remaining licence.

Q18: If I switch to the system of licensed producers will I have to dispose of my dried marihuana and/or marihuana plants?

A18: Yes. Once you are registered with a licensed producer you must dispose of any dried marihuana and/or marihuana plants in your possession.

Q19: How do I dispose of my dried marihuana and/or marihuana plants?

A19: To dispose of your dried marihuana and/or marihuana plants you must first render it unfit for use or consumption.

One way is to blend the marihuana with water and mix it with cat litter to mask the odour. This can then be placed in your regular household garbage. **You must dispose of your dried marihuana and marihuana plants on or before March 31, 2014.**

Please use discretion when destroying or disposing of your dried marihuana and/or marihuana plants. Health Canada will communicate with you at a later date to provide additional information on destruction. You may also contact your local law enforcement agency for information.

Q20: How do I register with a licensed producer using my Authorization to Possess document?

A20: You can use your Authorization to Possess (ATP) to register with a licensed producer until the validity date shown on the ATP. In order to do so, you must send your original ATP to the licensed producer. Once registered, your licensed producer will return the ATP to Health Canada so that it can be formally revoked. Your new proof of authority to possess will either be the label on the packaging or a separate document accompanying the shipment of dried marihuana provided by the licensed producer.

Please note that you must contact the licensed producer to obtain a registration form, if required, to complete and submit with your medical document. The registration form, along with your ATP, must be submitted directly to the licensed producer. **Do not send your medical document or registration form to Health Canada.**

Health Canada has begun issuing licences to LPs. Contact information for LPs is available on the Health Canada website. This page will be updated regularly as new LPs are approved.

Q21: How do I register with a licensed producer using a medical document?

A21: If your health care practitioner supports the use of marihuana for medical purposes in your case, he/she must complete a medical document on your behalf.

You must contact the licensed producer to obtain a registration form, if required, to complete and submit along with your medical document. The registration form and medical document must be submitted directly to the licensed producer. **Do not send your medical document or registration form to Health Canada.**

The licensed producer will process your registration application and once you have been approved, you will place orders directly through your licensed producer.

Health Canada has begun issuing licences to LPs. Contact information for LPs is available on the Health Canada website. This page will be updated regularly as new LPs are approved.

Q22: Where can I obtain a medical document to access dried marihuana under the system of licensed producers?

A22: You can download and print a template medical document from Health Canada's website.. If your health care practitioner chooses to use a different template, you must ensure that all required information, as described in the medical document template, is provided.

Health Canada has begun issuing licences to LPs. Contact information for LPs is available on the Health Canada website. This page will be updated regularly as new LPs are approved.

Q23: Can I use Form B "Medical Practitioner's Form" to register with a licensed producer?

A23: Form B should only be used for applications to Health Canada for an Authorization to Possess under the *Marihuana Medical Access Regulations*. However, if your health care practitioner has already filled out the Form B, you can use it to register with a licensed producer instead of a medical document until March 31, 2014.

Q24: If I decide to register with a licensed producer, what information do I need to send to Health Canada?

A24: None. Health Canada is not involved in processing applications under the new system. Your original medical document must be sent directly to the licensed producer, not Health Canada.

Q25: Are licensed producers only allowed to produce/sell dried marihuana?

A25: Yes. Licensed producers are only allowed to provide dried marihuana for medical purposes.

Q26: Will licensed producers have more strain varieties than Health Canada?

A26: The *Marihuana for Medical Purposes Regulations* do not restrict licensed producers to any one strain of marihuana.

Q27: How do I know if the marihuana produced by licensed producers is quality controlled?

A27: Licensed producers are required to follow the Technical Specifications for Dried Marihuana for Medical Purposes. This document is available on the Health Canada website and outlines the conditions that must be met for quality assurance. Health Canada will inspect licensed producers to ensure they meet all requirements of the regulations, including these specifications.

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Q28: How much will licensed producers charge per gram?

A28: Under the new *Marihuana for Medical Purposes Regulations*, licensed producers are responsible for setting their own prices.

Q29: Will Health Canada continue to charge the same prices for its supply of dried marihuana for medical purposes?

A29: No. Health Canada will change the price of its own supply to match the price set by the licensed producers.

Q30: Under the new regulations, is there a limit to how much marihuana I can possess at any point in time?

A30: Yes. Under the *Marihuana for Medical Purposes Regulations*, there is a possession cap of either 30 times the daily quantity of dried marihuana indicated by your health care practitioner on your medical document, or 150 grams of dried marihuana, whichever is less. You cannot possess or store an amount of marihuana that exceeds this amount.

Q31: How can I become a licensed producer?

A31: Information on how to become a licensed producer is available on the Health Canada website.

Q32: How can I obtain updated information about the transition period?

A32: Health Canada will continue to communicate updated information to you throughout the transition period through inserts in authorization and licence packages, direct mail and via the website.

You may also contact us at:
Email: mmap-pamm@hc-sc.gc.ca
Toll-free: 1-866-337-7705
Mail: Marihuana Medical Access Program
Health Canada
Address Locator: 0300A
Ottawa, ON K1A 0K9

Glossary of terms

Transition Period - The period between June 19, 2013, and March 31, 2014, in which you can access dried marihuana for medical purposes under either the *Marihuana for Medical Purposes Regulations* (MMPR) or the *Marihuana Medical Access Regulations* (MMAR), but not both.

Terms specific to the MMAR:

Authorization to Possess (ATP)
Authorization to Possess dried marihuana for medical purposes under the MMAR.

Personal-Use Production Licence (PUPL)
Licence to produce marihuana for the applicant's own medical purposes under the MMAR.

Designated-Person Production Licence (DPPL)
Licence to produce marihuana for a named authorized individual's medical purposes under the MMAR.

Issue Date
The date on which your ATP/PUPL/DPPL was issued.

Expiry Date
The date on which your ATP/PUPL/DPPL expires. Since the MMAR will be repealed on March 31, 2014, all ATPs, PUPLs and DPPLs will expire no later than this date.

Validity Date
The last date up to which you can use your ATP in place of a medical document to register with a licensed producer under the MMPR.

Terms specific to the MMPR:

Medical document
The document your health care practitioner completes and that you must submit directly to a licensed producer to register for access to dried marihuana for medical purposes under the MMPR.

Licensed Producer
A producer licensed by Health Canada to produce dried marihuana for medical purposes under the MMPR.

The *Marihuana for Medical Purposes Regulations* (MMPR) and the *Marihuana Medical Access Regulations* (MMAR) at a glance

Questions	MMAR	MMPR
How do I obtain access to marihuana for medical purposes?	Complete Health Canada application forms and submit to Health Canada.	Have your health care practitioner complete a medical document and submit the original directly to a licensed producer.
What are my options for obtaining supply?	Three options: Health Canada supply, Personal-Use Production Licence (PUPL), or Designated-Person Production Licence (DPPL).	One option only: from a licensed producer.
What is my proof of authority to possess?	Health Canada-issued Authorization to Possess (ATP).	The label on the packaging and a separate document accompanying the shipment of dried marihuana provided by the licensed producer. Photo identification may also be requested.
Can I produce for myself or have someone produce for me?	Yes, with a PUPL or a DPPL.	No.
How do I renew?	You can renew using Health Canada application forms. Effective October 1, 2013, Health Canada is no longer accepting applications for new PUPLs/DPPLs and applications with changes to production sites and increases to the number of plants associated with licences.	Have your health care practitioner complete a medical document and submit the original directly to a licensed producer. You will be required to renew annually (or sooner, depending on the duration indicated on your medical document).
How do I make changes to my address/personal information?	Submit an amendment application to Health Canada. Effective October 1, 2013, Health Canada is no longer accepting applications for new PUPLs/DPPLs or applications with changes to production sites and increases to the number of plants associated with licences.	Contact your licensed producer to make any changes to your address/personal information.
How do I place orders for dried marihuana or marihuana seeds?	By using the Health Canada order form.	Order dried marihuana directly from your licensed producer.

Can I possess marihuana for medical purposes after March 31, 2014?	No. All marihuana must be destroyed on or before this date.	Yes, you can possess marihuana that has been shipped to you from a licensed producer.
Can I produce marihuana for medical purposes after March 31, 2014?	No. All marihuana must be destroyed on or before this date.	No.
Can I apply for access to marihuana for medical purposes between now and March 31, 2014?	Yes. Health Canada will accept applications for ATPs until this date. Effective October 1, 2013, Health Canada is no longer accepting applications for new PUPLs/DPPLs and applications with changes to production sites and increases to the number of plants associated with licences.	Yes. You may register with a licensed producer at any time.

Date Modified: 2013-11-26

This is **Exhibit " I "** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me
at the City of Ottawa,
in the Province of Ontario,
this 7 day of February 2014.

A Notary Public in for the Province of Ontario

Health Canada Santé Canada

Healthy Environments and Consumer Safety Branch (HECSB)
Direction générale de la santé environnementale et de la sécurité des consommateurs (DGSESC)

Office of Controlled Substances

GUIDANCE DOCUMENT

APPLICATION TO BECOME A LICENSED PRODUCER UNDER THE *MARIHUANA FOR MEDICAL PURPOSES REGULATIONS*

(Disponible en français)

This guide does not have any official legal status. It is a reference document and appropriate official documents should be consulted.

June 19, 2013

Canada

Pub: 130076

TABLE OF CONTENTS

1. PURPOSE

This Guidance Document is intended to help a potential licensed producer understand how to complete the ***Application to Become a Licensed Producer under the Marihuana for Medical Purposes Regulations*** (the application). Activities that require a licence under the MMPR include:

- possessing, producing, selling, providing, shipping, delivering, transporting, and destroying marihuana;
- possessing and producing cannabis, other than marihuana, solely for the purpose of conducting *in vitro* testing that is necessary to determine the percentages of cannabinoids in dried marihuana;
- selling, providing, shipping, delivering, transporting, and destroying cannabis, other than marihuana, that was obtained or produced solely for the purpose of conducting *in vitro* testing that is necessary to determine the percentages of cannabinoids in dried marihuana.

Other guidance documents and directives are mentioned throughout this document. Please refer to them as you complete your application to be sure that all appropriate information is included.

This is a guidance document only. It is intended to facilitate the process of completing the application. If there is any inconsistency between this document and the *Controlled Drugs and Substances Act* (CDSA) or the *Marihuana for Medical Purposes Regulations* (MMPR), the CDSA and the MMPR will take precedence. The CDSA and the MMPR are available online at http://canada.justice.gc.ca or you can obtain a copy by contacting Government of Canada Publication, Ottawa, Ontario, K1A OS9.

Please note that it is the responsibility of the applicant to ensure that all relevant sections of the applications are completed. Incomplete applications may be returned to the applicant. Priority will be given to complete applications.

2. DEFINITIONS AND ACRONYMS

The terms used in this document are defined in the CDSA and in the MMPR. Please refer to section 2 of the CDSA and section 1 of the MMPR for a complete list of definitions. For ease of reference, the definitions of dried marihuana, marihuana and cannabis have been set out below.

- **"Dried marihuana"** means harvested marihuana that has been subjected to any drying process.

- **"Marihuana"** means the substances referred to as "Cannabis (marihuana)" in subitem 1(2) of Schedule II to the CDSA.

  Please note that this includes the plant itself and parts of the plants (seeds, clippings) as well as dried marihuana.

- **"Cannabis"** means the substance set out in item 1 of Schedule II to the CDSA.

Please note that the term “Cannabis, other than marihuana” in the MMPR is used exclusively to refer to derivatives of cannabis, cannabis preparations and similar synthetic preparations that are used for testing, such as reference standards for delta-9-tetrahydrocannabinol or cannabidiol. These can be obtained or produced solely for the purpose of conducting *in vitro* testing that is necessary to determine the percentages of cannabinoids in dried marihuana.

3. COMPLETING THE APPLICATION TO BECOME A LICENSED PRODUCER UNDER THE *MARIHUANA FOR MEDICAL PURPOSES REGULATIONS*

SECTION 1: Preferred Language of Communication

Please indicate the applicant’s preferred language of communication.

SECTION 2: Applicant Name

Who can apply to become a licensed producer under the MMPR?

1. Individual adults of 18 years of age or older who ordinarily reside in Canada; or

2. Corporations that have a head office or a branch office in Canada and whose officers and directors are all adults.

2.a. Applicant Name

This section should be completed by both individual applicants and, in the case of corporations, their authorized corporate representatives.

Please provide the applicant’s full legal name and any other name(s) registered with the province, under which the individual intends to identify himself or herself or conduct the activities for which the licence is sought. Please also provide contact information for the applicant, as well as the applicant’s gender and date of birth.

2.b. Corporate Applicant

If the applicant is a corporation, please complete section 2.b. of the application. Please provide the legal name(s) of the corporation, and other name registered with a province, under which the corporation intends to identify itself or conduct the activities for which the licence is sought.

As part of the application, the applicant will be required to provide proof of the corporation’s name in the form of a photocopy of a certificate of incorporation and, if applicable, a copy of any document filed with the province that states the corporation’s name.

A corporate applicant will also be required to provide a list of its officers and directors of the corporation, including the full legal name, date of birth, and gender of each individual, and whether each officer and director holds a valid security clearance.

SECTION 3: Proposed Personnel

The applicant must designate personnel who will oversee licensed activities at the site. The designated persons must be adults, and must be familiar with the CDSA and its regulations, and the *Food and Drugs Act*.

3.a. Proposed Senior Person in Charge (Senior PIC)

The applicant must designate a Senior Person in Charge (Senior PIC) who has overall responsibility for management of the activities carried out by the licensed producer under their licence at their proposed site. Note: The applicant can be the Senior PIC.

The Senior PIC is considered the representative of the applicant and must have the authority, as an authorized official, to bind the applicant.

Please specify the proposed Senior PIC's full name, title (if applicable), gender and date of birth. Please also provide the telephone number, facsimile number, and e-mail address of the Senior PIC in order to facilitate contact.

3.b. Proposed Responsible Person in Charge (RPIC)

The applicant must designate a Responsible Person in Charge (RPIC) who will work at the site and will be responsible for supervising licensed activities, and for ensuring that the activities comply with the CDSA, its regulations and the *Food and Drugs Act*.

Please provide the proposed RPIC's full name, gender and date of birth. Please also provide the proposed RPIC's title and proposed work hours.

Note: The proposed Senior PIC can also be the proposed RPIC.

3.c. Proposed Alternate Responsible Person in Charge (A/RPIC)

The applicant may designate one or more Alternate Responsible Persons in Charge (A/RPIC) who will work at the site and have the authority to act for the Responsible Person in Charge (RPIC) when that person is absent.

Please provide the full name, gender and date of birth for the proposed A/RPIC(s). Please also provide the title and proposed work hours for the proposed A/RPIC(s).

If the applicant designates more than one A/RPIC, please indicate the ranking of each A/RPIC (i.e. first alternate, second alternate, etc.).

3.d. Proposed Persons Authorized to Place Orders for Cannabis on Behalf of the Applicant

In order to place orders for cannabis on behalf of the applicant, individuals must be authorized. For example, if you want to order cannabis from another Licensed Producer, the employee placing the order on your behalf first must be authorized before the order can be placed.

Please provide the full name of each individual to be authorized to place orders for cannabis, along with his or her gender. These individuals may include the Senior Person in Charge, the Responsible Person in Charge, and the Alternate Responsible Person(s) in Charge.

SECTION 4: Security Clearance

The following individuals are required to have a valid security clearance:

- An individual applicant
- All officers and directors of a corporate applicant (as identified in section 2.b.)
- The proposed Senior Person in Charge (as identified in section 3.a.)
- The proposed Responsible Person in Charge (as identified in section 3.b.)
- The proposed Alternate Person(s) in Charge (as identified in section 3.c.)

The individuals identified above **must** hold a valid security clearance. A producer's licence will not be issued if all the security clearances required under the MMPR have not been granted.

If any of these individuals already hold a valid security clearance, please attach the confirmation of the security clearance to the application.

If any of the individuals listed above do not already hold a valid security clearance, they will be required to complete the **Security Clearance Application Form**. The form can either be sent with the completed application, or it can be sent separately. If sent separately, please attach a note to clearly indicate under which name and for which site the application was made. The **Security Clearance Application Form** can be found online at: http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/securit-eng.php

As part of the Security Clearance Application process, each of the individuals identified above will be required to complete the **Security Clearance Fingerprint Third Party Consent to Release Personal Information** form that will allow a Canadian police force or a fingerprinting company accredited by the RCMP to submit fingerprints to the RCMP for the purposes of a criminal record check. A list of agencies accredited by the RCMP can be found at: http://www.rcmp-grc.gc.ca/rtid-itr/vulner-eng.htm. The **Security Clearance Fingerprint Third Party Consent to Release Personal Information** form can be found online at http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/third_party-tierce_partie-eng.php. Health Canada does not need to be provided with a copy of this consent form.

Note: Applications will not be processed until all completed Security Clearance Application forms associated with this application have been received.

SECTION 5: Activities and Substances to be specified on the Licence

5.a. Activities with Marihuana

In this section, the applicant must indicate: the type of activities they propose to carry out; a description of the substances for each activity (i.e., whether the activities involve dried marihuana, marihuana plants and/or marihuana seeds); the building name and address where each of the activities will be taking place; and the purposes for conducting those activities.

The applicant may request a licence to conduct any or all of the following activities for dried marihuana and/or marihuana, other than dried marihuana, which means the plant itself or seeds:

a) Possession;
b) Sale or Provision;

c) Shipping, Transportation or Delivery;
d) Destruction; and/or
e) Production

Note: If a licence allows possession of marihuana it is not necessary to have the licence allow the holder to purchase marihuana, be it dried marihuana, the plant itself or seeds.

For example:

- If you want to produce dried marihuana, the purpose could be to produce for the purpose of selling or providing to registered clients.
- If you wish to ship marihuana, the purpose could be to ship to registered clients, another licensed producer, or a licensed dealer for testing.

5.a.i. Maximum Quantity of Dried Marihuana to be Produced (if applicable)

Please indicate the maximum quantity of dried marihuana (net weight in kilograms) that you intend to produce and the production period. The maximum quantity and specified period will be indicated on your licence.

5.a.ii. Maximum Quantity of Dried Marihuana to be Sold or Provided to Persons Referred to in the MMPR (if applicable)

Please indicate the maximum quantity of dried marihuana (net weight in kilograms) that you intend to sell or provide to eligible persons (i.e. a registered client, an individual who is responsible for a registered client, a hospital employee or person to whom an exemption relating to dried marihuana has been granted under s.56 of the CDSA). Please also specify the period in which that quantity is to be sold or provided.

Note: In your application you do not need to indicate the amount you intend to sell or provide to another licensed producer, to a licensed dealer, or to the Minister. However, any sales or provision of cannabis to another licensed producer, licensed dealer or the Minister requires a written order and for records of that transaction to be kept.

5.b. Activities with Cannabis (*in vitro* testing)

Note: You only need to complete this section if you intend to conduct activities with cannabis derivatives, preparations and similar synthetic preparations, other than marihuana, necessary to conduct *in vitro* testing (for example, reference standards for delta-9-tetrahydrocannabinol or cannabidiol) to determine the percentages of cannabinoids in dried marihuana.

In this section, the applicant must indicate: the type of activities they propose to carry out; a description of the substances for each activity; the building name and address where each of the activities will be taking place; and the purposes for conducting those activities.

The applicant may request a licence to conduct any or all of the following activities with cannabis, other than marihuana (intended for conducting *in vitro* testing):

a) Possession;
b) Sale or Provision;
c) Shipping, Transportation or Delivery;
d) Destruction; and/or
e) Production

You can possess and produce cannabis, other than marihuana, solely for the purpose of conducting *in vitro* testing that is necessary to determine the percentages of cannabinoids in dried marihuana. You can also sell, provide, ship, deliver, transport and destroy cannabis, other than marihuana, obtained or produced solely for the purpose of conducting *in vitro* testing that is necessary to determine the percentages of cannabinoids in dried marihuana.

For example:

- If you intend to possess derivatives of cannabis, such as THC or cannabidiol found in reference standards, the purpose could be to conduct *in vitro* testing of dried marihuana you produce to determine the percentages of cannabinoids in dried marihuana.
- If you intend to produce derivatives of cannabis from marihuana, the purpose could be to conduct *in vitro* testing of dried marihuana you produce to determine the percentages of cannabinoids in dried marihuana.
- If you intend to provide cannabis, other than marihuana, the purpose could be to provide solely for the purpose of determining the percentages of cannabinoids in dried marihuana (for example, providing marihuana produced to another licensed producer for testing).

SECTION 6: Proposed Site Information

Site Information

The MMPR defines a "site" as (a) a building or a place in a building used by a licensed producer; or (b) an area occupied exclusively by buildings used by a licensed producer.

Please provide the address, telephone number and, if applicable, the facsimile number and email address of the proposed site. If the site's mailing address is different than the site's municipal address, please provide the site's mailing address.

The proposed site must be located indoors and **must not** be a dwelling-place (i.e. a place of residence).

The proposed site may consist of an area occupied **exclusively** by buildings used by the applicant. If you intend to conduct licensed activities at more than one site, a separate application must be submitted for each site.

Regardless of the scope of your licensed activities, you will need a separate application for each physical site where you are proposing to undertake activities licensed under the MMPR.

Note: Your site must be available for a pre-licence inspection by Health Canada for compliance with the MMPR.

Building Information

If the proposed site is an area comprised of more than one building, please provide information on each building on the site. Please provide, the building name (if applicable), street address, city, telephone and, if applicable, facsimile numbers, and email address.

Example:

If a proposed site is an area which contains three buildings, you would need to provide information on the site, as well as all three buildings on the site. All three buildings on the site must be used by the applicant only.

If there are buildings on a site that are not exclusively used by the applicant, then these buildings must be treated as separate sites. In this instance, a separate application would be required for each site.

Note: The applicant is encouraged to use their site floor plan, as required under Section 8: Proposed Site and Physical Security, to clarify their site and building information.

SECTION 7: Ownership of Property

If the applicant is the owner of the entire proposed site, the declaration in this section must be signed by the proposed Senior Person in Charge (Senior PIC) as the person authorized to bind the applicant.

If the proposed site, or any portion of the proposed site, is not owned by the applicant, the declaration in Appendix A must be completed. To complete Appendix A, the applicant must provide the full address of the proposed site, or any portion of the proposed site, for which the applicant is not the owner. The applicant must also provide a description of the activities that will be conducted at that site. The owner/co-owners of the site must then complete and sign the declaration, stating that they: are the owner/co-owner of the proposed site; are fully aware of the activities that the applicant proposes to conduct at that site; and consent to those activities being carried out at the site.

If the proposed site, or any portion of it, is owned by more than one individual, the declaration in Appendix A of the application form must be signed by each owner.

Appendix A must be submitted with applications where the applicant proposes to undertake licensed activities on property not owned by the applicant.

SECTION 8: Proposed Site and Physical Security

The applicant must comply with the site and physical security requirements under the MMPR. Please attach a detailed description of the security measures and floor plans of the site, including each of the buildings within the proposed site where any licensed activities are to be conducted. The applicant must also include floor plans for the site, including each building of the proposed site where proposed licensed activities are to be conducted.

Your proposed site must be designed in a manner that prevents unauthorized access.

To determine the security measures required for proposed licensed activities, please refer to the *Marihuana for Medical Purposes Regulations,* the *Guidance Document – Building and Production Security Requirements for Marihuana for Medical Purposes* at: http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/bp-securit-eng.php, and the Health Canada *Directive on Physical Security Requirements for Controlled Substances at:* http://www.hc-sc.gc.ca/hc-ps/pubs/precurs/dealers-distrib/phys_securit_directive/index-eng.php.

The MMPR set out physical security requirements that are necessary to secure sites where licensed producers conduct activities with marihuana, other than storage. The Guidance Document – *Building and Production Security Requirements for Marihuana for Medical Purposes* provides technical details on how to meet these security requirements.
For storage, Health Canada's *Directive on Physical Security Requirements for Controlled Substances* establishes security requirements for the storage of all controlled substances including dried marihuana, marihuana seeds, and cannabis (for the purposes of conducting *in vitro* testing only) by licensed producers. The applicant is encouraged to follow the *Directive on Physical Security Requirements for Controlled Substances,* as much as possible, in developing the storage elements of their plan.

Please note that the level of security for storage may be different for each building on the proposed site. Please indicate on the building's floor plan the proposed level of security for storage of that building in accordance with the Directive listed above.

The proposed security measures must meet the requirements set out in the *Directive on Physical Security Requirements for Controlled Substances* and in the MMPR, including:

- The perimeter of the licensed producer's site must be visually monitored at all times by visual recording devices to detect attempted or actual unauthorized access.
- The areas within a site where cannabis is present must be visually monitored at all times by visual recording devices to detect illicit conduct.
- The visual recording devices must be capable of recording attempted or actual unauthorized access in a visible manner.
- The perimeter of the site and areas within a site where cannabis is present must be secured at all times by an intrusion detection system capable of detecting attempted and actual unauthorized access to or movement in the site, or tampering with the system.
- The intrusion detection system must be monitored at all times by personnel who can determine the appropriate steps to take in response to any detected activity that is unauthorized.
- In the case of any detected activity, the personnel must record the date and time of the detected matter and the measures taken in response to it. Personnel must also record the date and time when measures were taken.
- Access to areas within a site where cannabis is present must include physical barriers that prevent unauthorized access and must be limited to personnel who require access to the areas to perform their work responsibilities. Records must be kept of each person entering or exiting these areas.
- All areas within a site must be equipped with a system that filters air to prevent the escape of odours and, if present, pollen.

Note: Before a licence can be issued, your compliance with the site and physical security requirements under the MMPR and Health Canada *Directive on Physical Security Requirements for Controlled Substances* will be verified through a pre-licence inspection conducted by Health Canada.

SECTION 9: Notice to Local Government, Police and Fire Authorities

Prior to submitting an application to become a licensed producer of marihuana for medical purposes, the applicant must provide a written notice to local authorities to inform them of their

intention to submit an application. The notice must include the applicant's name, the activities for which the licence is sought (i.e. that activities are to be conducted in respect of cannabis), the site address (and of each building on the site, if applicable) at which the applicant proposes to conduct those activities, as well as the date when the application will be submitted to Health Canada.

In the application to become a licensed producer of marihuana for medical purposes, please identify the name, title and address of the senior official for each of the following local authorities, as well as the date when the notification was provided:

- the local police force or Royal Canadian Mounted Police detachment responsible for providing policing services to the area in which the proposed site is located;
- the local fire authority of that area; and
- the local government (for example, municipality) of that area.

The Senior Person in Charge must sign the declaration in this section confirming that they have provided the required notice to local authorities. A copy of each notice must be provided with the application.

SECTION 10: Quality Assurance Pre-Licensing Report

A licensed producer must have an employee designated as a quality assurance person who is responsible for assuring the quality of the dried marihuana, before it is made available for sale. This employee must have the training, experience and technical knowledge related to the proposed licensed activities and the requirements of the MMPR.

The applicant must submit a document signed and dated by the quality assurance person that includes:

i. a description of the quality assurance person's qualifications in respect of the proposed licensed activities and the requirement of the MMPR; and
ii. a report establishing that the buildings, equipment and proposed sanitation program to be used in conducting the proposed activities referred in the MMPR comply with the regulatory requirements.

The accuracy of the information contained in the report will be verified by Health Canada inspectors during the pre-licence inspection of the proposed site.

For more information on quality requirements, please refer to the *Guidance Document – Technical Specifications for Testing Dried Marihuana for Medical Purposes at: http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/techni-eng.php*.

SECTION 11: Record Keeping

The applicant must submit a detailed description of their proposed record keeping methods. This must include a description of the process that will be used for recording transactions relating to licensed activities, including maintaining appropriate records of transactions and dealings with both suppliers and clients.

The method of record keeping proposed by the applicant must permit compliance with the requirements of Part 6 of the MMPR. The record keeping must allow for the reconciliation of orders for cannabis (including marihuana) and shipments and inventories of cannabis (including marihuana).

Note: The Minister of Health can request that a licensed producer provide records, documents and information referred to in the MMPR in the form and at the time specified by the Minister.

SECTION 12: Declarations and Attestations

The declarations and attestations in the application form must be signed and dated by the proposed Senior Person in Charge.

SECTION 13: Submission

Please submit your completed application to become a Licensed Producer under the *Marihuana for Medical Purposes Regulations*, including all applicable attachments by mail to:

Controlled Drugs Section
Licences and Permits Division
Office of Controlled Substances
Controlled Substances and Tobacco Directorate
Health Canada
150 Tunney's Pasture Driveway, Tunney's Pasture, A.L.: 0300B
Ottawa, ON K1A 0K9

All relevant sections of the application form must be completed and all required documents must be submitted. An incomplete application will not be processed. If your application is incomplete, it may be returned to you.

A Health Canada representative is available to assist you if you have any questions pertaining to these requirements and the application process. You can send us your questions by email at MMPR-RMFM@hc-sc.gc.ca or call us at 1-866-337-7705.