This is the 4th affidavit of Jeannine Ritchot
of Ottawa, Ontario, in this case and was
made on January 15, 2015

Court File No: T-2030-13

Federal Court

Between

NEIL ALLARD
TANYA BEEMISH
DAVID HEBERT
SHAWN DAVEY

Plaintiffs

and

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

Defendant

AFFIDAVIT # 4 OF JEANNINE RITCHOT

I, Jeannine Ritchot, a public servant, residing in the City of Ottawa, in the Province of Ontario, AFFIRM THAT:

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 facts set out in this my affidavit. 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.

4. Marijuana meets the definition of a drug under the *Food and Drugs Act* (FDA). Cannabis, commonly referred to as marijuana, is also a psychoactive substance listed at Schedule II of the *Controlled Drugs and Substances Act* (CDSA). Three products containing cannabinoids have been authorized for therapeutic use in Canada, under the FDA and the *Food and Drug Regulations* (FDR). Sativex® is a buccal spray containing extracts of cannabis with standardized concentrations of tetrahydocannabinol (THC) and cannabidiol (CBD). It is authorized to treat certain symptoms associated with multiple sclerosis. It is also conditionally approved for pain relief in adults with advanced cancer, in limited circumstances. Cesamet® is a capsule containing nabilone, a synthetic cannabinoid. It is authorized for nausea and vomiting associated with cancer therapy. Marinol® is a capsule containing synthetic THC. It was authorized for AIDS-related anorexia and nausea and vomiting due to cancer chemotherapy, but has been discontinued from the Canadian market by the manufacturer.

5. Marijuana is not now, nor has it ever been approved as a therapeutic product under the FDA/FDR. Its efficacy and safety have not been sufficiently demonstrated. Further, no sponsor has made a new Drug submission to Health Canada seeking a Drug Identification Number or a Notice of Compliance for manufacture, sale or distribution of dried marijuana in Canada under the FDA/FDR.

6. Courts have determined, however, that government has a constitutional obligation to provide individuals with reasonable access to marijuana for medical purposes when their medical practitioner indicates it is required.

7. Therefore, it was necessary to create a means by which access to dried marijuana could be provided outside of the generally applicable drug legislative and regulatory regime, given that dried marijuana had not been approved for therapeutic use in Canada.

8. Access to marijuana for medical purposes is provided through the MMPR promulgated under the CDSA.

9. The MMPR have replaced the now-repealed MMAR as the means by which Canadians, with the support of a medical practitioner, may access dried marijuana for medical purposes. The regulations provide for access to dried marijuana only. Individuals who are authorized to possess dried marijuana for medical purposes may consume their dried marijuana in whatever fashion they wish provided they do not use their dried marijuana to produce another controlled substance.

HISTORY OF ACCESS TO MARIJUANA FOR MEDICAL PURPOSES: MARIHUANA MEDICAL ACCESS REGULATIONS (MMAR)

10. Canadians have accessed dried marijuana for medical purposes since 1999, at which time individuals could be authorized to possess dried marijuana and/or

to produce a limited number of marijuana plants for medical purposes *via* section 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.

11. The Ontario Court of Appeal's July 31, 2000 decision in *R. v. Parker* changed that approach. In response to that decision, which stated in part that the section 56 exemption under the CDSA did not provide a well-defined, transparent means to access marijuana for medical purposes given its discretionary nature, the Government promulgated the MMAR in 2001. The MMAR were created to provide access to dried marijuana 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.

12. Over the years, the Regulations have been amended on numerous occasions. The Regulatory Impact Assessment Statements (RIAS) associated with these changes explain the MMAR regulatory history and they are appended at **Exhibit "A"**.

13. In responding to the *Parker* decision, and in the years following, Canada, in the face of a lack of evidence-based efficacy and safety information related to the use of this unapproved, psychoactive substance, strove to strike a balance between providing authorized persons with reasonable access to dried marijuana for medical purposes, while attempting to protect individual and public health and safety, to respect existing federal legislation, and to attend to obligations under United Nations Drug conventions.

14. The MMAR were created to authorize activities related to marijuana that would otherwise have been illegal, specifically, to provide seriously ill individuals whose medical practitioner supported the use of marijuana for medical purposes to obtain access to such marijuana.

15. Upon application, the MMAR provided that an authorization to possess (ATP) marijuana for medical purposes could be issued to persons ordinarily resident in Canada who, with the advice and support of their medical practitioner(s), demonstrated medical need.

16. A license to produce marijuana was issued either to the authorized person, as a Personal-Use Production License (PUPL), or to a person designated by the authorized person to produce marijuana on his or her behalf, as a Designated-Person Production License (DPPL). The license allowed the holder of the license to, among other things, produce marijuana in quantities up to a specified maximum, which was determined using a formula based on the daily amount supported by the authorized person's medical practitioner.

17. The MMAR, as promulgated in 2001, did not authorize the sale or distribution of marijuana. Instead, the MMAR established a framework, overseen by Health Canada, for allowing people suffering from serious illnesses to possess and to produce marijuana for medical purposes, or to have someone produce it for them, where:

    a. conventional treatments were inappropriate, or ineffective in providing relief of the symptoms related to the medical condition, or treatment of the medical condition of the authorized person; and

    b. the use of marijuana was expected to have medical benefits that would outweigh the risks of its use.

THE PLAINTIFFS' HISTORY WITH THE MARIHUANA MEDICAL ACCESS PROGRAM

Neil Victor Allard

18. Neil Victor Allard has held an ATP and a PUPL since 2004; his applications, ATPs and PUPLs as well as his correspondence and related communications

with Health Canada were retrieved after a diligent and thorough search of the Health Canada database by Christina MacInnis, Litigation Support Officer, Litigation Support Office, Health Canada on December 10 and 11, 2013 and December 12, 2014. The documents are attached at **Exhibit "B"**.

19. By way of summary, Mr. Allard's first application under the MMAR was in 2004. In this first application to the program for authorization to possess and a license to produce marijuana for medical purposes, Mr. Allard advised Health Canada in a May 7, 2004 letter that "I am making this application very reluctantly and under Objection. I, and many other Canadians, believe that this process continues to be a Violation of our Civil Rights under the Canadian Charter of Rights and Freedoms....I want to go On Record that I totally disagree with this useless Government application process. It is a violation of my rights and I am applying only to be free from the ramifications of legal persecution."[as written]

20. In May 2004, Mr. Allard's daily dosage was 5 grams per day, and based on the formula set out in the regulations, he was authorized to possess 150 grams (0.33 pound dried marijuana) of marijuana at one time, and to produce 19 plants indoors and 5 plants outdoors. He was authorized to store an additional 1875 grams (4.13 pounds) of dried marijuana.

21. In 2005, Mr. Allard received an ATP authorizing him to possess 150 grams of dried marijuana, based on his daily dosage of 5 grams; he was licensed to grow 25 plants indoors; and he was authorized to store an additional 1125 grams (2.48 pounds) of dried marijuana.

22. In 2006, Mr. Allard's daily dosage doubled from 5 to 10 grams daily; he applied for and was issued an ATP authorizing him to possess 300 grams (0.66 pound) of dried marijuana at one time and was licensed to grow 37 plants indoors and 10 plants outdoors, and to store an additional 3750 grams (approximately 8 pounds 2.7 ounces) of dried marijuana in his home.

23. In 2007, 2008, 2009, 2010, 2011 and 2012, Mr. Allard applied for and received an ATP and a PUPL, which authorized him to possess 300 grams (0.66 pound) of dried marijuana and licensed him to grow 37 plants indoors and 10 plants outdoors; these amounts were calculated based on his continued daily dosage of 10 grams per day and the formula set out in the regulations. He was also authorized to store an additional 3750 grams (approximately 8 pounds 2.7 ounces) of dried marijuana in his home.

24. In 2012, three months after his ATP and PUPL were issued, an amended ATP and PUPL were issued to reflect that Mr. Allard's daily dosage again doubled from 10 g to 20 g per day. As a result he was authorized to possess at any time 600 grams of dried marijuana (approximately 1.32 pounds) at any time, and licensed to produce 98 plants indoors; he was also able to store an additional 4410 grams of dried marijuana (approximately 9.72 pounds of dried marijuana) at his home. Mr. Allard's subsequent applications for ATPs and PUPLs under the MMAR were issued in the same amounts and remain valid on these terms under the Allard injunction order.

Mr. Sean Robert Davey

25. Mr. Davey's complete record of applications, ATPs, PUPLs and related DPPLs as well as any correspondence and related communications with Health Canada were retrieved after a diligent and thorough search of the Health Canada database by Christina MacInnis, Litigation Support Officer, Litigation Support Office, Health Canada, on December 12, 2013 and December 12, 2014. The documents are attached at **Exhibit "C"**.

26. Mr. Davey first sought an ATP and because he planned to have another person grow for him, a DPPL for that designate under the MMAR in December 2009. At that time, Health Canada was experiencing high volumes of applications and contacted Mr. Davey on more than one occasion to indicate there could be a delay in processing his application. He was issued an ATP on July 16, 2010, permitting him to possess 300 grams of marijuana (0.66 pound) at any one

time, based on his daily dosage of 10 grams. His Designated Producer (DP) was also issued a DPPL on July 16, 2010 permitting him to grow 49 plants at one time, indoors, and to store 2205 grams (4.86 pounds) of dried marijuana.

27. In 2011, Mr. Davey again applied for and on July 19, 2011, was issued an ATP, but indicated he no longer wished to use his DP. He applied for a PUPL under the MMAR. His dosage was increased from the previous year by 2 grams a day to 12 grams per day. As a result, according to the formula set out in the MMAR, he was authorized to possess at any time 360 grams of dried marijuana (approximately 79 pounds) at any time, and licensed to produce 59 plants indoors; he was also able to store an additional 2655 grams of dried marijuana (approximately 5.85 pounds).

28. In July 2012, Mr. Davey again applied for and was issued an ATP and PUPL based on an increased daily dosage of 14 grams per day. Again using the formula under the MMAR, he was authorized to possess at any time 420 grams of dried marijuana (approximately 0.925 pounds) at any time, and licensed to produce 69 plants indoors; he was also able to store an additional 3105 grams of dried marijuana (approximately 6.85 pounds).

29. In October 2012, Health Canada received notice that Mr. Davey wishes to change the location of his production site.

30. Mr. Davey was issued a new PUPL dated November 1, 2012, allowing him to grow 69 plants indoors at his new residence and to store 3105 grams of dried marijuana. His ATP was also reissued to show his new address, and allowing him to continue to possess 420 grams of dried marijuana (approximately 0.925 pounds).

31. But on December 7, 2012, Health Canada received another application from Mr. Davey; he sought to switch from using a PUPL, which he had been issued the month before, to using a DP.

32. On February 18, 2013, Mr. Davey wrote to Health Canada returning the ATP and PUPL, issued November 1, 2012, he asked that they be revoked. Mr. Davey explained in his letter that "In regards to section 65(2), due to the startup costs involved, I never started production at my home address once my license change to state it as my production site; therefore I do not have any marihuana to destroy." At that time, Mr. Davey sought and was issued on February 18, 2013, a new ATP authorizing him to possess 420 grams of dried marijuana at any one time; the expiry date was July 19, 2013. Also on February 18, 2013, a DPPL was issued to allow a new individual to grow for Mr. Davey. The DP was permitted to grow 69 plants indoors for Mr. Davey's use and to store 3105 grams of dried marijuana at her residence. The expiry date was July 19, 2013.

33. On September 12, 2013, Health Canada received an application for an ATP for a daily dosage of 25 grams of marijuana. Mr. Davey indicated he wished to inhale and consume his marijuana orally, and in baking, cooking and tea. He sought a PUPL, indicating he was planning to produce his marijuana at his ordinary place of residence. He sought to obtain starting seeds from Health Canada. Mr. Davey provided the consent of the owner of the property where he was residing. Mr. Davey's PUPL allowed him to produce 122 plants indoors and to store 5490 grams (12 pounds) of dried marijuana at his home. Mr. Davey's ATP and PUPL were issued on the September 26, 2013. He was authorized to possess, in addition to the amounts stored, 750 grams (1.65 pounds) of dried marijuana at any one time.

34. Brian Alexander, an associate of Mr. Davey, has been presented by the Plaintiffs as an individual with information relevant to this matter. Mr. Alexander's complete record of applications, ATP and PUPL, as well as any correspondence and related communications with Health Canada were retrieved after a diligent and thorough search of the Health Canada database by Christina MacInnis, Litigation Support Officer, Litigation Support Office,

Health Canada, on January 14, 2015. The documents are attached at **Exhibit "D"**.

35. Mr. Alexander and Mr. Davey shared a production site from September 26, 2013 to December 18, 2013.

36. Mr. Alexander's ATP and PUPL were issued on December18, 2012, and based on his daily dosage of 30 grams, authorized him to produce 146 plants indoors, and to store 6570 grams (14.48 pounds) of dried marijuana, and to possess 900 grams (1.98 pounds) of dried marijuana at any one time, in addition to the 14.48 pounds in storage.

Tanya Louise Beemish & David Wesley Hebert

37. Ms. Beemish's and Mr. Hebert's complete record of applications, ATPs, PUPLs and related DPPLs as well as any correspondence and related communications with Health Canada were retrieved after a diligent and thorough search of the Health Canada database by Christina MacInnis, Litigation Support Officer, Litigation Support Office, HC Health Canada, on December 12, 2013 and December 12, 2014. The documents are attached at **Exhibit "E"**.

38. On December 3, 2012, Health Canada received Ms. Beemish's application for an ATP for herself and a DPPL for her husband, David Hebert. Ms. Beemish's daily dosage was 3 grams per day, and according to the formula set out in the MMAR, she was authorized by way of ATP issued January 4, 2013 to possess 150 grams (0.33 pound) of dried marijuana at any time. The DPPL issued to Mr. Hebert licensed him to grow 25 plants indoors at their home, in accordance with the formula set out in the MMAR, and to store an additional 1125 grams of dried marijuana (2.48 pounds) at their residence. The expiry dates for both the ATP and the DPPL were January 4, 2014.

MMAR: UNINTENDED CONSEQUENCES

39. From their inception in 2001, and throughout the many amendments made to them, the MMAR attempted to:

- strike a balance between providing legal access to dried marijuana for medical purposes, as required by the courts, with managing access to a controlled substance and unapproved drug, about which there is limited available benefit and risk information, combined with known risk for diversion to the black market;
- respect existing federal legislation, including the FDA and CDSA, as well as Canada's international obligations under the United Nations Drug Conventions; and,
- protect the individual and public health, safety, and security of all Canadians.

40. In the end, as will be explained below, the goals of the MMAR, which were based on the premise of providing reasonable access to marijuana for medical purposes to a small group of seriously ill Canadians, were seriously compromised by the rapid expansion of the number of individuals authorized to possess and to produce increasingly large amounts of marijuana, most of which was grown in dwelling houses that were not constructed to support such large scale production, and in residential areas. This rapid growth led to a series of unintended negative consequences, namely nuisance in communities related to noxious odors, unwanted traffic, lights, noise and the like, challenges for police, hazards for fire officials and communities, and generally negative impacts on public health, safety and security of Canadians, not to mention administrative and financial burden to government and cost to taxpayers.

Exponential Growth

41. I am advised by Kaylene Funk, Senior Policy Analyst at Health Canada, and verily believe, that in 2002, 455 individuals were authorized to possess marijuana for medical purposes and that as of December 31, 2013, this had

grown to 37,151 individuals. At this rate of growth, it was estimated that by the end of 2014, over 50, 000 individuals would have been authorized to possess marijuana for medical purposes under the MMAR, which would in turn increase impacts on communities and opportunities for diversion, as well as make administrative costs unsustainable.

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

43. Despite the fact that few program participants actually purchased their dried marijuana from Health Canada, the department was obliged to maintain a contract for the production and distribution of dried marijuana. As of July 31, 2014, 896 individual accounts for dried marijuana were in arrears to Health Canada in the total amount of $1,448,219.67. One individual owed $37,764.24; three others owed between $10,000 and $20,000; 57 owed between $5,000 and $10,000; 340 owed between $1,000 and $5,000; and 495 individuals owed between $2.00 and $1,000.

44. The Cost-Benefit Analysis of Regulatory Changes for Access to Marihuana for Medical Purposes Report (CBA), prepared as part of the regulatory reform process and attached at **Exhibit "F"** to my affidavit, states that the number of participants in the Marihuana Medical Access Program (MMAP) has grown exponentially over the past ten years, with 40% year on year growth from 2003 to 2010, and then 60% from 2010 to 2011.

45. The RIAS prepared for publication with the MMPR stated that in a status quo scenario under the MMAR, and based on historical patterns of use under that regime, the CBA estimated that a 40% per annum increase in numbers of users would continue to 2024, increasing the number of persons using marijuana for medical purposes to about 433,688 in 2024.

46. Prior to the repeal of MMAR on March 31, 2014, MMAP responsibilities included processing applications and issuing licenses, providing a client services function to field calls from participants and to respond to the police hotline, as well as managing the marijuana production and distribution contract and accepting orders submitted by participants who used this method of accessing dried marijuana, as well as attempting to collect accounts receivable.

47. As part of these responsibilities, MMAP maintained a record keeping system to track information related to the program. The record keeping system consisted of paper files and an electronic database, the Safe Access to Medical Marihuana ("SAMM"). The SAMM database was updated with pertinent information kept in the paper files and included application information and the actual authorizations to possess and licenses to produce marijuana for medical purposes provided by Health Canada, pursuant to the MMAR.

48. The original version of SAMM, the Health Canada database, SAMM I, did not have report generating capabilities. An updated version of SAMM, SAMM II, was established in 2012. The SAMM II database was also used to keep a record of incoming and outbound correspondence and call logs that were generated in the course of these activities, as well as notes made by Health Canada employees in respect of the activities related to the file activity, called "correspondence notes". At this time, the information in SAMM I was migrated to SAMM II. SAMM II has limited report generating capabilities. Due to these limitations and the possibility of human error in the data migration from SAMM I to SAMM II, there may be some minor variance between the information provided in the tables below and previously published

information. Information provided in the past would have been accurate at the time of extraction, as it was done at a specific point-in-time. However, some fields in SAMM II maintain only current information. For example, if there is a change in the daily grams during the year only the last amount would be included in an extract of the data.

49. I am informed by Kaylene Funk, Senior Policy Analyst, Health Canada, and verily believe, that on November 13, 2014, she conducted a thorough and diligent search of the data held by the MMAP, which yielded the following information about the number authorizations to possess (ATP) issued under the MMAR.

Number of Authorizations to Possess (ATP) Issued under the MMAR	
December 31, 2001	89
December 31, 2002	455
December 31, 2003	624
December 31, 2004	743
December 31, 2005	1230
December 31, 2006	1673
December 31, 2007	2398
December 31, 2008	3299
December 31, 2009	4860
December 31, 2010	7587
December 31, 2011	12063
December 31, 2012	26382
December 31, 2013	37151

50. I am informed by Kaylene Funk, Senior Policy Analyst, Health Canada, and verily believe, that on November 13, 2014, she conducted a thorough and diligent search of the data held by the MMAP, which yielded the following information about the number production licenses (both personal-use and designated-person) issued under the MMAR.

Number of Production Licenses Issued under the MMAR	
December 31, 2001	83
December 31, 2002	326
December 31, 2003	482
December 31, 2004	546
December 31, 2005	933
December 31, 2006	1230

December 31, 2007	1740
December 31, 2008	2475
December 31, 2009	3603
December 31, 2010	5395
December 31, 2011	8888
December 31, 2012	19808
December 31, 2013	28228

51. I am informed by Kaylene Funk, Senior Policy Analyst, Health Canada, and verily believe, that on January 8, 2015, she conducted a thorough and diligent search of the data held by the MMAP, which yielded the following information about the number production licenses (both personal-use and designated-person) issued under the MMAR sorted by province, as of December 31, 2013.

Production Licenses By Province (Extracted January 8, 2014 For December 31, 2013)			
	PUPL	**DPPL**	**Total PL**
Alberta	1200	128	1328
British Columbia	13734	2276	16010
Manitoba	636	99	735
New Brunswick	560	49	609
Newfoundland and Labrador	68	8	76
Northwest Territories	6	1	7
Nova Scotia	1278	165	1443
Nunavut	0	0	0
Ontario	6406	916	7322
Prince Edward Island	25	2	27
Quebec	698	193	891
Saskatchewan	368	55	423
Yukon	11	4	15

52. I am informed by Kaylene Funk, Senior Policy Analyst, Health Canada, and verily believe, that on November 13, 2014, she conducted a thorough and diligent search of the data held by the MMAP, which yielded the following information about the number of plants authorized for production indoors and outdoors (based on the authorized daily amounts) under the MMAR.

Number of plants authorized for production indoors and outdoors under the MMAR (based on the authorized daily amounts)				
	2001		2014	
Province	Indoor Plants	Outdoor Plants	Indoor Plants	Outdoor Plants
AB	238	13	122797	695
BC	252	19	1666502	15327
MB	43	2	68420	410
NB	34	5	14126	1034
NL	45	12	2337	50
NS	96	12	30542	1693
NT	0	0	159	3
ON	568	40	429022	12856
PE	0	0	535	73
QC	122	15	70383	908
SK	44	5	16653	287
YT	0	0	735	19
Grand Total	**1442**	**123**	**2422211**	**33355**

53. I am informed by Kaylene Funk, Senior Policy Analyst, Health Canada, and verily believe, that on December 8, 2014, she conducted a thorough and diligent search of the data held by the MMAP, which yielded the following information about the daily grams amount for those individuals issued an ATP under the MMAR.

Daily Grams Amount for Those Individuals Issued an ATP Under the MMAR															
	Year														
Grams	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	TOTAL
Blank	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1
0 - 2.9	17	129	103	90	173	229	360	476	694	1016	1327	2294	2526	366	9800
3.0 - 4.9	23	101	139	141	210	283	493	920	1608	2649	3819	6835	7209	773	25203
5.0 - 9.9	48	215	369	482	745	988	1331	1592	1992	2725	3835	6244	6362	536	27464
10.0 - 14.9	0	7	7	22	77	135	155	205	334	672	1640	4032	4105	316	11707
15.0 - 19.9	1	2	4	6	19	24	33	46	97	213	529	1943	2565	156	5638
20.0 - 29.9	0	0	1	1	6	12	23	49	90	209	634	2857	4609	269	8760
30.0 - 39.9	0	0	1	1	0	1	3	5	20	56	156	1595	5052	226	7116
40.0 - 49.9	0	0	0	0	0	0	0	4	19	35	82	425	2605	136	3306
50.0 - 59.9	0	0	0	0	0	1	1	2	4	7	17	48	662	24	766
60.0 - 69.9	0	0	0	0	0	0	0	0	1	3	12	52	597	30	695
70.0 - 79.9	0	0	0	0	0	0	0	0	1	2	3	13	124	7	150
80.0 - 89.9	0	0	0	0	0	0	0	0	0	0	1	15	201	9	226

90.1 - 99.9	0	0	0	0	0	0	0	0	0	0	1	5	101	3	110
100.0 - 149.9	0	0	0	0	0	0	0	0	0	0	6	19	264	10	299
150.0 - 199.9	0	0	0	0	0	0	0	0	0	0	1	4	65	4	74
200.0 - 249.9	0	0	0	0	0	0	0	0	0	0	0	1	102	10	113
250.0 - 299.9	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
300+	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1

54. I am advised by Kaylene Funk, and believe, that the **average** daily amount (i.e. "dosage") has increased to a level of almost 18.22 g per day, as of December 31, 2013. A person authorized to use 18.22 grams of dried marijuana per day would, under a personal production license and the formula set out in the MMAR, be licensed to grow 89 plants indoors. The Information for Health Care Professionals, attached at **Exhibit "G"**, indicates at page 25 that a "typical joint" contains between 0.5 and 1.0 grams of cannabis plant matter, with this as a guide, an individual would have to consume 18 to 37 joints each and every day to use this amount of dried marijuana.

55. On January 26, 2012, the Terms of Reference for the Expert Advisory Committee on Information fort Physicians on Marihuana for Medical Purposes (EAC) were approved. The EAC was comprised of internationally recognized experts on marijuana for medical purposes, was mandated to provide advice and recommendations to Health Canada on the current information on marijuana for medical purposes and any additional information/education materials that might be of help so that physicians could be better informed of the current science on marijuana for medical purposes and thus better support their discussions with patients. A copy of the Terms of Reference is attached at **Exhibit "H"**. The resulting document is the Health Canada drafted document 'Information for Health Care Professionals" (attached as Exhibit "G"). At page 24, this document states that "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".

56. Individuals who purchase their dried marijuana 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" (attached as Exhibit "G").

57. An RCMP document entitled "Analysis of National Cases Related to the Marihuana Medical Access Regulations" produced by the Royal Canadian Mounted Police on behalf of the Canadian Association of Chiefs of Police, FOR SUBMISSION TO THE Minister of Health in 2010 states at page 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 marijuana cigarettes each and every day. This RCMP document is attached at **Exhibit "I"**.

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

59. Court decisions have resulted in the MMAR being amended to allow authorization of up to four production licenses to operate in the same location. The average daily dosage of 18.22 grams per day (as of December 31, 2013, as set out at paragraph 50 above), could result in an average of 356 plants being grown in a single dwelling by up to four producers (Note: Could be 2 producers with their maximum of 2 licenses each). Under the MMAR, because the regulations did not constrain daily dosages that could be authorized by a medical practitioner, there was no cap on the amount an individual could be authorized to possess, and the numbers of plants that an individual could be licensed to produce was based on a formula based on daily dosage. One dwelling could contain as many plants as the licenses to produce provided and presumably, that the physical space could accommodate.

60. The significant increase in the number of licenses issued, combined with the co-location of up to four licenses to grow marijuana on one site and the authority to possess and to produce increasingly high amounts of marijuana for medical purposes, resulted in large quantities of marijuana being produced in private dwellings not constructed for large-scale horticultural production. Furthermore, as the MMAR did not contain any provisions requiring licensed producers to disclose the address of their production sites, these locations were unknown by local law enforcement and fire authorities. This has resulted in challenges not only for the administration of the MMAR, but more importantly, in risks for the health, safety and security of individuals licensed to produce marijuana for medical purposes and for the public in general.

61. Because the MMAR were never intended to permit such widespread, large-scale marijuana production, they did not adequately address the public health, safety and security concerns that accompany such production.

62. These situations generated complaints to the Minister of Health and to the Program from municipal officials, fire officials, law enforcement, and neighbours. Attached at **Exhibit "J"** are examples of unsolicited correspondence received by Health Canada and the Program outlining community safety, security and quality of life impacts of the MMAR, with personal information redacted for *Privacy Act* purposes.

63. While it is not possible to reproduce salient comments from all of the thousands of pieces of unsolicited correspondence that have been received over the years, I have attempted to capture some of the primary concerns expressed to Health Canada by municipalities and first responders, homeowners, and program participants. Each of the excerpts cited below is representative of the concerns expressed by these stakeholders and have been chosen because they encapsulate the issues raised by these stakeholders.

64. Generally, the unsolicited MMAR feedback set out below speaks to a number of the unanticipated problems with the MMAR's personal production regime, including, but not limited to:

- violence, including home invasion, theft and homicide;
- the presence of firearms;
- diversion to the illicit market;
- producing over the limit authorized by Health Canada;
- mould associated with the presence of excess moisture in the homes;
- fire and electrical hazards;
- the presence of toxic chemicals, like pesticides and fertilizers;
- the emission of noxious odours and; and
- various risks to children living in or near the residential growing operations.

Unsolicited MMAR Feedback from Municipalities & First Responders

65. Municipalities have raised serious public health and safety concerns regarding production of marijuana 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.

66. In an April 1, 2011 letter to Health Canada, a BC Municipal Fire Chief advised that "the … Safety teams has discovered 15 Medicinal Grow Ops (MMARs) 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."

67. In a December 28, 2012 letter to the Minister of Health, the Mayor of another B.C. municipality wrote: "The extensive lack of regard and abuse of the regulations [MMAR] 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 marijuana 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."

68. Another municipality in BC advised 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."

69. 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 marijuana 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 marijuana 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".

70. 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 marijuana. 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".

71. 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 marijuana production sites. Further it is clear that both illegal and legal marijuana 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."

72. And this letter from another BC District not only indicates that "the demands for electricity from exceedingly large marijuana 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."

73. The assistant fire chief of an Ontario city wrote to Health Canada in 2008, indicating that it had been requested to assess the safety of a building following the discovery of a marijuana grow operation in the 3 storey building occupied by a family with two young children. The third storey was converted to allow the production of marijuana and a number of Ontario Fire Code, Electrical

Safety Code and Ontario Building Code violations were identified. "The inspection also revealed evidence of incipient stages of a fire with the discoloration and charring of the floor where the ballasts used in the production of the marijuana 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 an unnecessary risk of injury or even death."

74. Municipalities writing to Health Canada express frustration around the information sharing constraints that apply to licensed marijuana production locations. One letter stated "... having law enforcement fully apprised of the location of the medical marijuana 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.

75. 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 marijuana ($10–$15/gram for dried marijuana) and that production in homes may leave residents and their neighbours vulnerable to violent home invasion by criminals who become aware that valuable marijuana plants are being produced and stored in the home (see RIAS at Exhibit "A").

76. 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."

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

78. 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."

Unsolicited MMAR Feedback from Homeowners

79. Homeowners comprise another group of stakeholders who have expressed health, safety, and security concerns relating to the production of marijuana 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 marijuana in their neighbourhoods and communities.

80. Excerpts from samples of this correspondence, set out below, express frustration, fear and anger about health, safety, and security concerns related to production of marijuana 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".

81. 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 marijuana 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."

82. Another letter related to that same condominium indicates the condominium has had to involve law enforcement to deal with suspicion of trafficking and marijuana 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."

83. 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."

84. 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".

85. 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."

86. 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 marijuana 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]

87. A woman living in a duplex where the adjoining owner has a license to produce marijuana 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."

88. 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."

89. 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."

90. 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".

91. 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."

92. 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."

93. Another homeowner complains about the smell from her neighbour's home, where medical marijuana 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."

94. 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?"

95. 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 ...".

96. 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."

97. 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".

98. Another homeowner writes 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 our home we have raised our teenage children in. None of us want to leave."

99. 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".

100. These unsolicited letters from homeowners are illustrative of concerns routinely raised to Health Canada about the unintended consequences of the marijuana 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 powerlessness in the face of personal or designated production of marijuana for medical purposes in their neighbourhoods.

Unsolicited MMAR Feedback from Program Participants

101. Program participants and their families have also written to Health Canada regarding the MMAP'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..."

102. Another woman writes that her husband, who is licensed to grow marijuana 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."

103. A couple licensed to grow marijuana 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..."

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

Inspection Compliance and Enforcement under the MMAR

105. The MMAR were never intended to permit widespread, large-scale marijuana production. Nor was it conceived that the number of program participants would grow as rapidly or to the extent that it has. While the MMAR did include an inspection regime, it was not adequate to allay public health, safety and security concerns that emerged as the program continued to grow.

106. Under the MMAR, government inspectors were confined to verifying compliance with the MMAR and with the terms of the designated or personal production licence. Because the MMAR did not set out any standards related to the safety of the production site or to the quality of the product, Health Canada inspectors did not have authority to address the risks to public health, safety and security that may be apparent in personal and designated production sites, and could not under the MMAR require adherence to any quality standards for the product, sanitary standards for production facilities or machinery or other aspects of production that are normally controlled by regulation for drugs manufactured, sold or distributed in Canada.

107. In addition, Health Canada compliance and enforcement work was complicated by the number of program participants and impeded by the fact that many were producing marijuana in dwelling places. Under the MMAR, an inspector was authorized to conduct an inspection of a production site at any time. However, in cases where the production site was also a dwelling place, the inspector required the permission of the occupant to enter. Absent such permission, a warrant would be required before being able to enter. The MMAR therefore did not allow Health Canada inspectors to enter production sites marijuana for medical purposes as readily as they could enter other drug production sites which are not in dwelling places. As a result, it was difficult to ascertain compliance with the terms of the personal production licenses issued for a particular location.

108. Inspection was not only difficult, but costly. The CBA, produced as part of the regulatory reform process (attached at Exhibit "F"), recounts at page 80 that in 2010, Health Canada conducted inspections of PUPL/DPPL premises in British Columbia and in Ontario. The 75 production sites identified for the initiative were considered to pose less risk: that is, they were licensed production sites for a smaller number of plants (less than 50) and the licensee had no known law enforcement history per the MMAP records. 27 persons answered the door (36%) and of these 15 allowed inspection (55%), while 12 did not allow inspection (45%). Of the 15 who allowed inspection, 7 were growing more plants than allowed under their licenses. Based on this small sample (n=75), there were 16% of all residences that did not allow inspection and 45% of those residences for which a person was present at the time of the inspection. The cost of conducting this limited inspection initiative was $119,693.

109. The document "Compliance Verification and Voluntary Compliance Promotion Initiative Marihuana Medical Access Regulations Office of Controlled Substances" (the "Compliance Document") summarizes the Health Canada inspections that occurred in May and June 2010 and that are referenced in the paragraph above, and is attached at **Exhibit "K"**. This document also summarizes the cost of this initiative, and states that "[W]hen considering only the production sites where compliance verification and voluntary compliance promotion was conducted the cost of conducting compliance verification was $7,980 per production site, at a success rate of 20% (i.e. a total of 15 compliance verification and voluntary compliance promotion activities were performed at the 75 sites identified)."

110. The Compliance Document (attached at Exhibit "K") states "Were this cost to be extrapolated to conduct compliance verification and voluntary compliance promotion at all 3,439 sites (2,680 sites for personal use production and 759 for designated person production sites, as of May 2010) a total of $27.4 million

would be required assuming that Health Canada was successful in entering each and every dwelling upon first visit.

111. The table in paragraph 50, above, indicates that on December 31, 2013, 28,228 individuals held personal production licenses. While up to four persons could grow together at one site, this was not always the case. By way of example, however, even if every single licensed grower shared a production site with three others, in 2013, inspection of 7,057 sites at a cost of $7890 each would have amounted to a cost of $55,679,730.

112. Therefore, not only was it difficult to implement inspections, Health Canada was aware that it could not reasonably sustain the ongoing cost of the human and financial resources necessary to conduct meaningful compliance and enforcement activities in respect of personal production.

113. The capacity to monitor and inspect drugs and particularly potentially harmful drugs or batches of drugs is an important element of meeting the health and safety objectives of the food and drugs regime in Canada. But under the MMAR, marijuana used for therapeutic purposes was being produced largely in private dwellings, making it difficult for Health Canada to impose the same quality and safety standards on dried marijuana as it does for other products produced for therapeutic purposes. In addition, persons needed no particular expertise or qualifications to apply for a license to produce, the MMAR did not contain good manufacturing standards, and even had such requirements and standards existed, there was limited capacity to monitor and enforce them.

114. In summary, the MMAR did not require producers to adhere to stringent quality requirements to ensure that they were producing marijuana in sanitary conditions, free from contaminants. Furthermore, the MMAR regime provided only limited authority to inspect, and given the rapid growth of the program, the requirement to obtain consent or a warrant to enter a dwelling-place, and the high costs associated with maintaining an inspection regime, Health Canada had limited capacity to conduct inspections. Health Canada was

concerned that products created in unregulated settings created potential uncertainties and risks for seriously ill individuals using marijuana for medical purposes. Individuals experiencing negative side-effects or interactions with other products may have been unable to indicate to a physician what they had been using to treat themselves, and in what strengths and dosages. Immuno-compromised individuals who consumed marijuana for medical purposes grown in an unregulated environment may have been ingesting marijuana grown in unsanitary conditions, in unclean premises, using unsanitary equipment, or marijuana that was adulterated or contaminated by heavy metals, bacteria and/or mould, pests, and pesticide(s) and fertilizer residues. There was no capacity to recall dried marijuana that may have been found to be contaminated or otherwise unfit for consumption, as these is for other drugs under the FDA/FDR regime.

115. Given the concerns municipalities had expressed to Health Canada regarding the MMAR's negative impacts on their communities, I am advised by Eric Costen, Executive Director of the Office of Medical Cannabis, and verily believe, that in December 2014, Health Canada reached out to a number of communities, seeking information from those with marijuana grow operation inspection teams about their experiences, if any, with inspecting Health Canada licensed grow operations.

116. Respondents who had performed inspections of residential MMAR growing operations indicated they entered residences with permission or, in one case, a municipality noted that when entry was not granted, they obtained a warrant to gain entry. Some of the inspections referred to in these letters were done prior to the March 31, 2014 MMAR repeal. These letters are attached to my affidavit at **Exhibit "L".**

117. The City of Abbotsford indicated in a letter dated December 19, 2014, for example that as far back as 2005, it had adopted a bylaw, subsequently replaced with an amended version in 2006, with the intent of regulating and

remediating health, safety and nuisance concerns associated with properties in the City of Abbotsford used in the cultivation, production, use, sale or trade of a controlled substance, including the cultivation of marijuana and the production of methamphetamines or dextro amphetamines. The health, safety, and nuisance concerns they found in the course of inspecting federally licensed medical marijuana grow ops included unsafe electrical wiring, building code violations, overpowering odors, and fire hazards, including unvented propane burners, and "Numerous serious plumbing code violations, including direct connection of domestic water lines to fertilizer mixing tanks without proper air gaps or backflow prevention, which poses a serious health risk to the City's domestic water system…".

118. In a letter to the Minister of Health dated October 27, 2014, before the Health Canada inquiry into inspections was made, the City of Chilliwack reported that their Health and Safety Inspection Teams generally attended at grow ops as a result of complaints from neighbours of odours, and concerns about the risk of fire, violence, and other nuisance factors. Chilliwack says its Teams have inspected 20 licensed grow ops since 2008, and they note the "most common complaint is with respect to the noxious odors emanating from the property and negative impacts on the complainants quality of life". The City of Chilliwack also expressed concern that cross connections to the City's water supply by way of any unapproved water supply system had the potential to contaminate the City Waterworks as a result of backflow. The letter indicated "The large blue 45-50 gallon water reservoirs that are used for mixing water, nutrients, pesticides etc., located in most medicinal grow operations, are in direct contravention of this by-law".

119. The City of Port Coquitlam indicated in its December 19, 2014 letter to the Office of Medical Cannabis that "While some Medical Marihuana Grow operations were electrically safe and free of hazards, inspections of many of the Medical Marihuana grow operations revealed the same type of public safety risks as illegal grow operations. These risks included mold, electrical

hazards, fire, and neighbourhood safety in terms of complaints about "grow rips" or increased visits by undesirable residents. In addition, plant allocations sometimes exceeded the limit set by the health Canada license." The letter refers to a fire that occurred in one home with an illegal Hydro bypass, where the number of plants exceeded the Health Canada authorized number."

120. The Mayor of the City of Calgary also wrote to Health Canada on December 18, 2014, indicating that his City has formed a Coordinated Safety Response Team (CSRT), and that the "...33 homes inspected containing a Health Canada licensed medical marijuana operation, three were found to have no marijuana present, 26 were issued orders by AHS [Alberta health Services, part of the CSRT] for violations under the Public health Act of Alberta, 29 had safety codes violations identified, and one license holder was charged by Police for trafficking. Twenty five houses were required to be remediated by AHS and were subject to the City of Calgary Environmental Restoration Permit (ERP) process. The ERP process is aligned with the AHS process in returning the affected house to a habitable state. It contains processes that define the environmental scope and remediation activities to achieve an indoor air quality acceptable to AHS, followed by appropriate building, plumbing and gas and electrical safety approvals." The Mayor reported that the cost of this inspection program is approximately $2000.00 for each safety inspection.

Program Participant Dissatisfaction with MMAR

121. Not only was Health Canada concerned about the unintended negative consequences of the MMAR on its own budget and operations and aware of the concerns of municipalities, law enforcement and first responders, but program participants themselves expressed a general dislike for the application process, for Health Canada's involvement in their medical decision making, and for the single strain of marijuana that was available for purchase from Health Canada.

122. Some program participants had a general distaste for the requirement to apply to Health Canada for authorization to possess and to produce marijuana. Mr. Allard's May 7, 2004 letter to Health Canada (attached at Exhibit "B"), is just one example of this view.

123. Program participants were dissatisfied with the nature of the administrative burden required to apply and the time it took Health Canada to review and to issue authorizations and licenses. This general sentiment is expressed in a November 21, 2007 letter (attached at Exhibit "B") to The Office of the Auditor General for Canada (cc to Mr. Tony Clement, [then]Minster of Health), in which Mr. Allard wrote:

> "Even though I have a permanent medical retirement from Health Canada, this Department refuses to respond to my request for a permanent authorization to produce and use medical marijuana, and insists that I complete and bother my doctors with thick forms every year, months in advance. In spite of my compliance with these requirements, they are constantly late with permits. I have had to involve my Member of Parliament, Jean Crowder, to deal with Health Canada on this matter since the first application, simply because I am too unwell to deal with all of their red tape, and their attitude of apparent wrongdoing, which stresses me out badly. This stress can have a dramatic effect on the severity of my symptoms of my conditions, leaving me bedridden and unable to cope with daily life. The staff in this department have a tendency to treat applicants, not as an intelligent taxpayers, but as a criminals. I believe we are dealing with an Abuse of Governmental Power in this Department and I am requesting an investigation. They have been repeatedly late with permits, in spite of my M.P.'s involvement....I need your help to intervene. Health Canada has not responded to my written letters requesting information, suggesting change, or to simply to give me a permanent authorization, or allow my GP to sign the forms, so I can

> avoid all this unnecessary stress. I have enclosed a copy of correspondence from my Member of Parliament supporting me on this issue, and I authorize your department to contact her and discuss the specifics of my case, if necessary and/or appropriate to your mandate. The taxpayers' costs of this program is another matter which I seriously hope you will review. I believe there are millions of wasted dollars on this poorly designed and badly run program. I am able to produce organic, medical grade marijuana for myself, at a fraction of the cost of what Health Canada charges and I incur all my own costs. The taxpayer is being duped here...". [as written]

124. Mr. Allard was not alone in his criticisms of the program. In fact, as Director of the Bureau of Medical Cannabis, I am personally aware that program participants often expressed dissatisfaction with the MMAR and Health Canada processes because I was often called upon to respond to complaints.

125. Increased participation in the program meant an increase in the volume of applications. Between 2008 and 2010 there was such a sharp increase in applications that Health Canada's standard processing time rose to over 20 weeks. This longer processing time precipitated an increase in calls to Health Canada, regarding the status of applications and timing of the issuance of ATPs and licenses. The department had to take specific steps to manage this situation, which resulted in increased staffing costs, and changes to administrative procedures.

126. Many program participants were dissatisfied with the amount of time it took to receive authorizations and licenses under the MMAR. In 2010, applications spiked, creating further delays and requiring significant efforts on Health Canada's behalf to manage the unexpected influx in applications; again, participants were dissatisfied with processing times. Incomplete applications created further delay. As an example, Mr. Allard's 2008 application package was incomplete; the records at Exhibit "B" show that the application package

was returned to him and that there were subsequent telephone calls to clarify what was needed, and that registered Mr. Allard's dissatisfaction with the MMAR process.

Cost of Producing Marijuana and Administering the Program

127. For Health Canada's part, the administrative cost and burden of running the program and supplying dried marijuana for those who chose to buy it from Health Canada became significant drains on the Health Canada budget. The MMAR also placed Health Canada between physicians and their patients, a role it does not take with any other medication.

128. The CBA (attached as Exhibit "F") sets out at page 9 that "Health Canada program administration costs include salary, employee benefits and accommodation costs associated with staff levels, operations and maintenance costs associated with travel, training and supplies and corporate overhead and shared service functions." As program participation grew, so too did the administrative costs associated with it.

129. Under the MMAR, Health Canada also experienced increases in the cost of producing and distributing dried marijuana, which affected the overall Health Canada budget. The last supply contract between Health Canada and Prairie Plant Systems had 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 was exercised. It was estimated that the additional year would cost Health Canada $9.7 million. These high contract costs existed despite the fact that only a minority of Program participants under the MMAR chose to obtain their supply of marijuana from Health Canada.

130. In addition, the CBA (attached at Exhibit "F") sets out at page 21 the costs of the subsidy Health Canada contributed to the purchase of dried marijuana: "persons who rely on the Government Supply pay a flat fee of $5.00 per gram, with no additional shipping cost. The supply cost for the Government Supply

is around $11.00 to $12.00 per gram. As a result, there is an effective subsidy to the use of more than 50% of the product cost (including shipping charge). This price structure was introduced in 2003 and was based on an estimated number of 300 individuals participating each year. About 2,300 persons [were] expected to rely on the government Supply during FY2012-2013."

131. And as noted above at paragraph 43, there were significant uncollected accounts associated with the sale of dried marijuana for medical purposes, many of which remain outstanding.

132. Over all, it had been clear for some time, from the perspective of police, fire fighters municipalities, communities and neighbours, physicians, program participants and Health Canada itself, that the marijuana for medical purposes regime under the MMAR had become unworkable and unsustainable. Reformative change was necessary, because the incremental reworking of the MMAR that had taken place since their promulgation in 2001 had not succeeded in creating a viable regime.

REFORM: MARIJUANA FOR MEDICAL PURPOSES

133. Since it came into force in 2001, the MMAR have been amended a number of times, either in response to court challenges or on Health Canada's initiative to respond to concerns from stakeholders.

134. In 2008 and 2009, MMAR amendments were required as a result of several court decisions. Health Canada understood that the judiciary was of the view that licensed producers having larger operations could achieve economies of scale and a level of income that would allow them to put in place quality control and security measures. The courts had also apparently observed that with fewer producers having larger operations, inspections would be easier to conduct. The amendments introduced by Health Canada to the MMAR at this time were described by the government as interim measures intended to

address the Court's decisions while the Program and the MMAR were being fully reassessed.

135. A document dated February 22, 2010, entitled "Potential Reforms to the Marihuana Medical Access Program," summarizes some of the options considered during this policy review, and is attached at **Exhibit "M"**. As a consequence, Health Canada began an in-depth policy review of the MMAR with a view to creating a more viable regime. The assessment of the MMAR regime included: (1) a review of complaints that had been received by various stakeholder groups over the years, including municipalities, fire officials, law enforcement and program participants; (2) an inspection blitz, as outlined above, to assess the feasibility and affordability of inspections under the MMAR regime; (3) the commissioning of Ms. Margaret Bloodworth, former Deputy Minister of Public Safety and National Security Advisor to the Prime Minister, to undertake a review of the MMAR and to provide an assessment of a more feasible regime going forward; and (4) an analysis of international regimes for the production and distribution of marijuana for medical purposes. Ms. Bloodworth's review is attached at **Exhibit "N"**.

136. This policy work led to the development of a framework that outlined the objectives of a reformed regime to access marijuana for medical purposes that included treating marijuana as much as possible like other drugs; creating a new supply and distribution system for medical purposes using fully regulated, inspected and audited licensed producers; phasing out personal and designated production of marijuana; shifting the Government's role back to its traditional role of regulator; and providing physicians with up-to-date information on marijuana used for medical purposes.

137. 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. The consultation period included two phases: a 45-day online consultation to reach program participants and

Canadian citizens; and a series of targeted sessions with key stakeholder groups that would be organized throughout the summer and fall of 2011. A copy of this announcement is attached to this my affidavit at **Exhibit "O"**.

138. The development of a new regulatory regime that met government policy objectives and that was also based on input gathered from the consultations was a priority for the Minister of Health. Therefore, in July 2011, I was appointed as the Director of Medical Marihuana Regulatory Reform. In order to permit me to focus exclusively on the development of new regulations, management and oversight of the existing program was assigned to Mr. Stéphane Lessard.

139. In my new capacity, I immediately began to assemble a dedicated team to undertake the development of these new regulations. My team was structured into two sub-teams. The first would be responsible for undertaking the consultations which began in June, as well as for planning and implementing all subsequent consultation and communication activities to be held throughout the life of this project. The second team was responsible for the development of detailed regulatory policy that would inform the drafting of the regulations. Members of this team also worked with the drafters on the eventual drafting of the regulations. These initiatives were pursued concurrently, in a coordinated manner, one informing the other.

140. During the regulatory development process, my team and I held weekly meetings with the then CSTD Director General, Cathy Sabiston. Other Health Canada officials and scientists also attended as appropriate to provide input into the regulatory policy development. The Assistant Deputy Minister (ADM) held bi-weekly meetings with the Director General, myself and other key directors. The purpose of these meetings was to guide and to track progress, and to approve policy and regulatory approaches as they were developed based on input received during consultations. Once policy approaches were approved

by the ADM, members of my team prepared drafting instructions for the regulatory drafters, and sat in on drafting sessions.

141. Development of the new regime was intended to address the significant, health, safety, security, and administrative challenges associated with the MMAR and at the same time to significantly improve the way in which individuals access marijuana for medical purposes. The new regime was intended to reflect certain key principles, including to:

a) treat marijuana as much as possible like any other medication;

b) restore Health Canada to its traditional role of regulator as opposed to gatekeeper by eliminating the requirement that individuals obtain their authorization to possess marijuana for medical purposes from Health Canada;

c) eliminate the Government role in supplying and distributing marijuana for medical purposes;

d) create a new supply and distribution system to provide reasonable access to quality marijuana for medical purposes using fully regulated, inspected, and audited licensed producers;

e) phase out personal and designated production and institute mechanisms for compliance and enforcement;

f) reduce the risk of abuse and exploitation of the regulatory regime, and improve the way program users access marijuana for medical purposes;

g) address the public health and safety risks that police, fire authorities and municipalities had expressed to Health Canada; and

h) provide physicians with up to date information on the use of marijuana for medical purposes.

142. My team was responsible for developing the detailed regulatory policy proposals that would inform the many elements of the eventual regulations. As a starting point, the team separated the framework into three categories: (1) possession, (2) production, and (3) direct sale and distribution of dried marijuana for medical purposes. I then assigned team members to work on specific elements requiring policy development within each of these categories. My regulatory policy development team then began the research and analysis required to put together Issue Analysis Statements (IAS), a tool used to examine various regulatory options and to make policy decisions. A key section of each IAS was a description of stakeholder comments that resulted from the consultations, thus demonstrating how feedback gathered from the consultations directly impacted the policy options being developed. Each IAS considered a specific element of the regulations. These IAS were presented to the ADM for policy approval. Once a specific IAS had been approved, the team could begin drafting instructions to the drafters, who could in turn begin drafting sections of the regulations.

143. These IASs summarize consideration of the following issues:

- Adverse Event Reporting: Marijuana is an unapproved drug and has not been comprehensively evaluated in terms of safety, efficacy, quality, and therapeutic usefulness as required under the FDA for other medications. Canadians expect that a regulated product will be safe for consumption; if not, there should be a mechanism to report safety issues. This IAS is attached at **Exhibit "P"**.

- Advertising: The FDA precludes advertisement of drugs in a manner that is false, misleading, or deceptive or that is likely to create an erroneous impression regarding the character, value, quality, composition, merit or safety of the drug (s. 9 FDA). Marijuana for medical purposes operates outside the FDA, so approaches to providing similar safeguards were examined. This IAS is attached at **Exhibit "Q"**.

- Dispensing though pharmacists: In response to some stakeholder input on the usefulness of a store-front approach, policy work was undertaken to examine the viability of having pharmacists dispense marijuana for medical purposes. This IAS is attached at **Exhibit "R"**.

- Health Care Practitioners: Work was undertaken to determine whether health care practitioners other than physicians should be authorized through regulation to support access to marijuana for medical purposes under the reformed regime. This IAS is attached at **Exhibit "S"**.

- Indoor/Outdoor Cultivation: Under the MMAR cultivation could take place either indoors or outdoors. Policy consideration was given to options for conditions that should apply to cultivation under the new regime, and their benefits and risks. This IAS is attached at **Exhibit "T"**. Ultimately, the decision was made to require indoor cultivation because of quality and security considerations. Marijuana grown outdoors is exposed to the elements such as temperature, air quality, bugs/pests, and that could affect marijuana quality. Indoor production reduces risk of cross pollination to neighbouring crops, provides consistent access to a year round supply of marihuana for patients, of a consistent quality given the ability to control growing atmosphere. In addition, the marijuana would not be openly visible to members of the public and would be easier to physically secure

- International Trade: Policy work was done to analyze whether the new regulatory scheme should enable Licensed Producers to engage in international trade of dried marijuana. This IAS is attached at **Exhibit "U"**.

- Labelling: Marijuana for medical purposes is exempted from the FDA, including labelling requirements for approved drugs, which provide the patient with important information about the product and its use. Because FDA standards would not apply to this exempted product, consideration was given to the types of information that individuals using marijuana for medical purposes should have on their labels. This IAS is attached at **Exhibit "V"**.

- Interaction with local authorities: Consideration was given to whether to require, through regulation, that licensed producers under the new regime obtain appropriate approvals from and /or notify local authorities (i.e.: local governments, law enforcement and fire officials) prior to obtaining a license to produce and distribute marijuana from Health Canada, and whether to prohibit, trough regulation, Licensed Producers from operating in a dwelling place. This IAS is attached at **Exhibit "W"**.

- Potential Business Models for Licensed Producers: Consideration was given to whether the new regulations should require that Licensed Producers undertake directly all aspects of production from seed to sale or whether different business models could be used. This IAS is attached at **Exhibit "X"**. Considerations around business models are set out in a document entitled "Rationale for vertically integrated LCPs", and this model was discussed at a meeting with potential licensed commercial producers, held on February 15, 2012. Both the business model document and discussion notes are attached at **Exhibit "Y"**.

- Physical Security: Health Canada considered how, under a reformed program for access to marijuana for medical purposes, diversion risks could be controlled and control of a narcotic maintained. This IAS is attached at **Exhibit "Z"**.

- Price Regulation: Health Canada considered the policy implications of prices regulation of dried marijuana, the practical implications for encouraging new businesses to enter the market, and the impacts on the government's objective of providing reasonable access to marijuana for medical purposes. This IAS is attached at **Exhibit "AA"**.

- Products: Marijuana is not an approved drug for manufacture, sale and representation for medical purposes in Canada. Dried marijuana has been treated outside the regular drug regulatory scheme. No manufacturer has demonstrated that the benefits of using this drug outweigh its risks and

consideration was given to the implication of possible expansion the number and type of marijuana products for sale and distribution in Canada to which the FDA would not apply. Health Canada considered whether or not Licensed Producers should be authorized to produce and distribute marijuana products for medical purposes as well as dried marijuana under the MMPR framework. Under the FDA/FDR, a framework already exists in Canada for those who wish to make a health claim about a therapeutic product and to bring this product to market. In full awareness that persons wishing to produce and market a marijuana-based product could avail themselves of the FDA/FDR process, Health Canada opted to limit the production and distribution activities of licensed producers under the MMPR to dried only. Health Canada was of the opinion that to further expand the scope of products made available outside of the FDA/FDR framework would undermine the integrity of drug legislation and regulation designed to protect the health and safety of Canadians. Again, three cannabis products have been approved for sale in Canada under the FDA/FDR: Marinol® (no longer available in Canada), Cesamet® and Sativex®. Furthermore, available clinical data regarding the use of marijuana for medical purposes is limited, and what does exist is restricted largely to the use of dried marijuana. Given the lack of sufficient evidence regarding the safety, efficacy and quality of marijuana products, Health Canada opted not to exclude other cannabis related products from the safeguards provided by the FDA/FDR regime. This IAS is attached at **Exhibit "BB"**.

- Product Distribution: Policy consideration was given to alternatives for distributing marijuana for medical purposes to individual users. The preferred option would have to not unduly impede reasonable access, reduce administrative burden for program participants and mitigate potential risks to public safety and security from permissible use. This IAS is attached at **Exhibit "CC"**.

- Proof of Possession: Consideration was given to how, under a reformed program, individuals lawfully authorized to possess marijuana for medical purposes could demonstrate their authorization to possess this controlled substance. This IAS is attached at **Exhibit "DD"**.

- Quality: Consideration was given to what quality requirements should apply to marijuana produced and distributed for medical purposes, given its intended use by seriously ill Canadians. Drugs manufactured for sale and distribution in Canada must meet rigorous Good Manufacturing Practices of the FDA/FDR. This IAS is attached at **Exhibit "EE"**.

- Security Intelligence Background Section: Over the years, law enforcement groups, specifically the Royal Canadian Mounted Police and the Canadian Association of Chiefs of Police, had expressed significant concerns that the MMAR were subject to abuse. In light of these concerns, Health Canada considered the value of an enhanced background screening of individuals seeking to be licensed to operate as Licensed Producers under the new regulatory regime. This IAS is attached at **Exhibit "FF"**.

- Seeds and Other Starting Materials: Because activities such as the possession, sale, import and export of cannabis, including viable cannabis seeds, are prohibited by the CDSA, unless authorized by regulation, policy work was done to consider how Licensed Producers could legally obtain access to seeds and other "starting materials" for cultivation. This IAS is attached at **Exhibit "GG"**.

144. Health Canada also considered whether to grandfather production by existing program participants so that they could continue to produce their authorized amounts, while new program participants would be required to access their marijuana for medical purposes from licensed producers. Ultimately, Health Canada deemed this option unworkable. In a first instance, running two parallel programs would be costly to the department. Inspections of those grandfathered would remain difficult, and there would be no quality-control of

marijuana produced by these individuals. Concerns related to the production of marijuana in private dwellings (i.e. public nuisance, odor, traffic), as well as the risks to first responders, would persist. Finally, Health Canada had questions as to the impact of continued personal production on the viability of the licensed producer market. Therefore, Health Canada determined that grandfathering production under the MMPR was not a viable option.

145. Health Canada established a possession cap for individuals who are authorized to use marijuana for medical purposes. This cap could not exceed an individual's monthly amount (daily dosage times 30), up to a maximum amount of 150 grams. In establishing this, Health Canada took into account a number of factors, including purchasing habits of individuals who bought their dried marihuana from Health Canada; the daily dosage information set out in "Information for Health Care Professionals", which indicates 1-3 grams per day as a reasonable dosage standard; and concerns raised by law enforcement about potential for diversion. A cap of 150 grams would allow an individual who possesses 150 grams who consumed 5 grams of dried marihuana per day, a daily dosage slightly higher than that set out in "Information for Health Care Professionals" to possess a one month supply at any given time.

Consultation

146. Consultations are a key component of the federal regulatory process, so I created a dedicated team to manage all consultation and public outreach activities to be undertaken during the course of this initiative. Consultation activities began prior to my appointment as Director of Medical Marijuana Regulatory Reform and continued until the publication of the final regulations in *Canada Gazette,* Part II on June 6, 2013. Consultation activities included the following:

- the development of the June 17, 2011 consultation announcement and document;

- the establishment and management of a contract with Intersol, a company retained to take notes, provide a summary, and to analyze and report on the results of the 45-day online consultation;

- planning and coordination of targeted stakeholder sessions across the country, including the management of a contract with Intersol to take detailed notes of these consultation sessions;

- collection and analysis of comments received following the publication of the draft regulations in *Canada Gazette*, Part I, which informed changes that were incorporated in the final draft; and

- the development of public communications material, including summaries for the Health Canada website and for the RIAS of all consultation activities.

147. Details of the distinct consultation processes are outlined below.

Process #1-Electronic Consultation

148. Following the Minister of Health's June, 2011, public announcement of the program changes, a consultation document entitled "Proposed Improvements to the Marihuana Medical Access Program" was posted on the Health Canada website and a 45-day public consultation was launched. This document is appended to my affidavit at **Exhibit "HH".**

149. Health Canada also sent a letter dated June 20, 2011, to program participants, announcing that improvements to the MMAP were being considered; this letter is attached at **Exhibit "II"**. Individuals were invited to visit the Health Canada website to review the Proposed Improvements document referred to above, and to submit comments on or before July 31, 2011, either by email, fax, or regular letter mail. This first consultation exercise generated 2,624 submissions.

150. Of the 2,624 submissions received in this electronic consultation exercise, 55% were from existing program participants; another 10% were submissions from persons representing "compassion clubs", marijuana storefronts whose operation are not authorized by regulation. 91% of the "compassion club" submissions were in the form of letter petitions from one specific group. The bulk of the remaining submissions were made by spouses/parents of program participants, or by individuals using form letters (sometimes submitting more than once), and lobby groups, such as Why Prohibition?, the Church of the Universe, and the BC Civil Liberties Association who support the decriminalization/legalization of marijuana generally. Submissions by police officers (28/2,624=0.01%), fire fighters (24/2,624=0.01%), and members of the medical community (917/2614= 0.01%) and governments of different levels (18/2624= 0.01%) were at this stage insignificant.

151. For the most part, this initial response from current program members, particularly those producing marijuana for medical purposes, activists, and lobby groups supportive of legalization of marijuana generally, was negative, but for the exclusion of Health Canada from the access process. Participants cited a number of reasons for their negative responses:

- Control: Some expressed the view that that there should not be any government or even medical practitioner involvement in the personal decision to use marijuana for medical purposes. Others noted that "Control over the quality and strain of my plants will be lost. I take great care in growing and feeding of my plants. No one will grow a plant the way I do for myself. I am always thinking this is my pain relief and quality of life, when caring for my plants."

- Cost: Many individuals who are either growing for themselves or who have others growing for them expressed the view that the cost of purchasing dried marijuana for medical purposes would be prohibitive for them; most commented that they could produce marijuana for themselves more

affordably than they could purchase it. One individual summarized that along with cost, the growing process itself was therapeutic: "Having to purchase all of my medications is a significant drain on our money and having to pay for my marijuana would be crippling. Taking away my ability to provide myself my medication will be inhuman. One of the only things I find joy in anymore is growing my medicine, being able to work in my garden is a significant stress reducer. The benefit I draw from growing marijuana is immeasurable. I take great pride in what I do and with it being in my home it allows me to work when I can and I also have the ability to leave it when I need to. Very few things allow me this kind of flexibility."

- Large Financial Investments to Construct and Equip Personal Grows: While individuals licensed to grow marijuana for medical purposes expressed concern that the cost of purchasing would exceed the cost of personal production, many expressed the concern that they had made large financial investments in personal grows and that this money would be wasted: "This investment, my co-operative patients and I have made is quite substantial and has driven a few into debt. The financial pay off to this was to have access to our larger than average prescription medication dosages at a fraction of the retail prices we have been forced to pay in the past." One designated producer stated: "Firstly, as a grower for a patient who is seriously ill, I have invested a lot of time and money to set up the growing conditions appropriate for my client's needs. This has involved getting a building permit, having licensed electrical and carpentry work completed, and installing some expensive equipment, including air conditioning, exhaust system and lights, all of which I had to purchase." Another commenter noted "I have spent a tremendous amount of money on home security system, contractor, construction, plumber, and electrician and all proper permits" not to mention thousands on equipment that is all CSA and UL certified, and have just recently got my license and haven't even produced my first crop yet...and to add insult to injury I would have to pay to take it all down and restore my basement room back to the way it was...". And still another indicated that "I

have been growing at my home for about 3 years now. I have a significant investment in my setup. $3,000 for the shed, probably another thousand in equipment. Additionally I have just built a $25,000 specially constructed garage with in-floor heating and fully insulated. This garage was built to home standards for the express reason of accommodating my growing needs." There are numerous such examples among the responses to the initial request for feedback, but this one acknowledges Health Canada concerns: "I believe that the production facilities belong in commercial, secured, and monitored areas. Yes away from residential areas. This will stop some of the crime related to these residential operations. My big question is I guess, how will I be compensated for my initial investment to build this safe facility. To date I have invested over $40,000."

- Privacy: Program participants expressed opposition to having to provide a medical document to a producer to get their marihuana. Others indicated that they did not want to receive their marijuana by post or courier: "I do not feel comfortable buying marihuana from an unknown source and have it shipped through the post office or registered mail. Now everyone will know what I do."

- Quality: Many individuals opposed what they described as a "corporate" approach to growing marijuana for medical purposes and stated their products were safer, organic, and specifically developed for their own use: "I use only organic fertilizers and specific strains for my personal issues, I put lots of my own time into growing my plants and play them classical music to help them grow. Will Health Canada put this much care and love into my medicine? I think not." "I grow purely organic and am very particular about the care and maintenance of my garden. Growing my own medicine is also spiritual for me. I drum with my plants and try to give them my positive essence. A commercial grower is just that. I don't know what chemicals they are using, I don't know whose hands are touching those plants. I don't know the strength or origin of the product. I understand Health Canada is

addressing the one strain availability, but this is also something I prefer to experiment with myself, growing different strains and finding what benefits me most, grown by my own hand."

- Abuse by a Minority: While many agreed that there may be abuse of the MMAR system and criminal involvement, they expressed the view that the abusers represented a fraction of the total number of individuals who were participating in the program. "The real problem is all the illegal grow ops that give all the good medical grow-ops a bad name". "Small growers that have a license to grow for themselves are as I see it not the trouble. People who grow for others have learned that they can 'legally' acquire a large number of 'clients' to grow for. There should be a major concern about this. They have gathered enough clients to form consortiums; that put together huge indoor grows. There is a huge loophole in the system that has been designed by people that are not in the know."

152. As noted above, 55% of the initial comments came from persons who were at that time authorized to possess or licensed to produce marihuana for medical purposes. Other respondents expressed different views, including this comment by a chronic pain specialist who noted "I have significant concern regarding the program as proposed. We already have a huge problem due to lack of accountability. Organized crime is involved in the trade of marijuana from people with exemptions.... In _____[province, redacted for privacy purposes] we are already seeing patients counselled and paid to obtain exemption applications from unsuspecting physicians. Police are finding completed, signed forms in stacks in grow-ops raided for selling. Creating a system that removes, rather than enhances the accountability in the system will expand these problems." One individual wrote to say "it should be noted that these innocent bystanders, whose well-being has been jeopardized by involuntary exposure to the drug marijuana, in any form, would have no choice but to vacate the neighbourhood...". Another person, a member of the real estate sector, wrote to say that "As much as I am sympathetic to health care

patients who suffer from chronic pain that can only be managed through effective drugs, I can see that the current Health Canada policies for Medical Marijuana need more effective regulation so, I support the recommended program changes that are being considered, at this time. ...Health Canada must recognize that agricultural operations are not suitable for residential buildings. In my region, there are thousands of "grow op" houses that are deemed to be "toxic properties" by the real estate industry and health care professionals. Local authorities are scrambling to establish standard remediation practices for these properties and restore them to acceptable health and safety standards; if possible. Certainly, Health Canada's Program should not license marijuana grow operations in private residences, especially when these unhealthy grow operations are not regulated by local health and safety authorities."

153. One group submission stated "There are still some hours left for us citizens to have our SAY on medicinal marihuana grow-ops in residential areas which our government had allowed out of compassion for some sick individuals—but forgot to consider that growing this Drug in homes, would contribute to many problems in neighbourhoods. ...Many of us, who have had the misfortune having a marijuana grow-op in our area, are familiar with the stench these create and how our homes have been filled with that offensive smell in the middle of the night; fouling the air we and our children breathe." Another person writes "We have suffered for too many years because of marijuana grow-ops in our neighbourhood. First there were illegal grow-ops and then legal ones. No-one knew the locations but the horrible odour emanating from them was evidence enough that they were about, interrupting all the neighbours sleep. This is still going on. In our family this is still raising chaos because my life has been challenged with hypersensitivity to multiple chemical and marijuana odor has triggered many attacks. My husband and I have often thought of moving away from this area; but we are seniors, of a moderate financial standing and being forced out of our home at our age is a very disturbing feeling. And this entire trauma because of marijuana grow-ops! And a legal one on top of it."

154. A cancer patient who represents a coalition of citizens, who writes to say "As a cancer patient I must have fresh clean air to breathe and neither do I or other ill people, or anyone who cares and is concerned, want their health and safety further jeopardized from community toxic woodsmoke, tobacco smoke or marijuana smoke." Another couple wrote in that having bought one half of a commercial building to operate a small family business, they realized the other half was occupied by someone growing marijuana for medical purposes. "The owner of the other half of our building is supplying more than just patients with post and is taking in approximately $40,000 cash per month...We did NOT and WOULD NOT sign up for the incredible stress this has caused us. We do not want to be exposed (nor do our customers) to the horrid odors (we call it the smell of money) and criminal elements that the production of marihuana brings. ...The facility next door grows 74 plants for one patient and 49 plants for a second patient. These plants are seven feet high and four feet across. We have no idea how any person could possibly smoke that much pot every single day of the year. His hydro bill is $3,500 per month. No one would supply medicine out of the goodness of their heart and "eat" that hydro bill. Another individual wrote that "My family has lived next door to a medical marihuana grow-op for about a year. We have had to endure the noxious fumes and the potential of a violent grow rip occurring next door for too long. We are constantly trying to decide if we should move out of our home to get away from these issues. We have had to retreat indoors and keep the windows closed many times because of the fumes. Having this next door has caused a great deal of stress on our family. I am not against LEGITIMATE uses of medical marihuana, but removing grow ops from residential neighbourhoods is essential."

155. Clearly, strong views were expressed on a number of fronts. Some sought the status quo, others asked that existing producers be grandfathered and only new persons seeking to use marijuana for medical purposes be required to use licensed producers. Many cited cost as a critical factor in accessing marijuana for medical use; some cited the comfort and therapeutic value of gardening in

and of itself. Some worried that effective strains would no longer be available and still others spoke of intolerable conditions in communities arising out of "legal grow-ops". A sampling of the responses received is attached at **Exhibit "JJ"**, including those cited in paragraphs 150 to 153. Health Canada considered this input as it charted its way forward in developing policy and planning for the new regulatory regime, while continuing to engage in further consultation.

Process #2-Targeted Stakeholder Meetings

156. While the 45-day online consultation was ongoing, my team planned a comprehensive face to face process with a broad array of stakeholders and partners who would be asked to provide their input on the development of the new regulatory regime. Attached at **Exhibit "KK"** is a Targeted Consultation Plan dated June 28, 2011 that sets out the preliminary planning for these sessions.

157. Targeted stakeholder meetings were scheduled to unfold between June and November 2011, during which time Health Canada officials met personally with the following groups: provincial and territorial ministries of health and public safety, municipalities, law enforcement and fire officials, medical associations, prospective licensed producers and "compassion clubs".

158. I attended at all of these consultations. The Medical Marihuana Regulatory Reform 2011 Consultations Results were published on the Health Canada website. The consultation summary can be found at http://www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/_2011/program/consult_reform-eng.php and is attached at **Exhibit "LL"**.

159. The Consultation Results Summary indicates the following groups were consulted. A general Summary Document is attached at **Exhibit "MM"**, but the outcomes are referred to briefly below:

- **"Compassion clubs" and "cannabis dispensaries"**: Health Canada conducted four consultation sessions with "Compassion Clubs". Two sessions were held in British Columbia, one in Ontario and one in Quebec. Generally, these groups, for which the MMAR made no provision, supported the view that health care professionals other than licensed physicians should be able to support the use of marijuana for medical purposes. They also welcomed a number of the proposed changes to the Program, such as the establishment of a regulated regime that would ensure quality controlled marijuana production in secure environments, and that they were being included in the consultations. They welcomed the approach to multiple strain availability envisioned for the new program and Health Canada's proposal to create an expert advisory committee to provide medical practitioners with more and current information about marijuana for medical purposes. The groups felt that those concerns noted in the June 2011 consultation document were not from patients, but from police, the CMA and others. Compassion clubs expressed their sense of stigmatization when Health Canada makes statements about their illegality; they objected to the elimination of personal production, noting that many people with a PPL have invested a lot of time and money into their productions—some with a bill up to $80,000 and some patients have gone into debt. Compassion clubs favoured a community dispensary model, which could procure strains from different producers for patient use. They indicated that in community-based models, people could learn how to use the product in a safe manner. They disagreed with providing marijuana through the mail. They presented ideas for different "models" that might provide workable, affordable in-community dispensaries. The complete meeting summaries are attached at **Exhibit "NN"**. A letter dated March 5, 2012 from the Canadian Association of Medical Cannabis Dispensaries also speaks to some of these concerns. The letter is attached at **Exhibit "OO"**.

- **Provincial and territorial ministries of health and public safety**: On November 24, 2011, Health Canada, during a regular meeting of the Federal-Provincial-Territorial ADM Policing Issues Committee, discussed the proposed new approach to medical marijuana, and sought their views. Overall these groups welcomed the proposal for the new approach to making marijuana available for those with medical need. Their specific concerns related to public health and safety and the possibility that there may be grandfathering of personal production. They were concerned that increased numbers of participants could lead to increased pressures on provincial and territorial public safety resources (DUI, increased use, increased diversion). Health Canada met with provincial and territorial Health and Public Health officials on numerous occasions. Health Canada held a series of teleconference meeting with provinces and territories, as well as a meeting with the Federal-Provincial-Territorial Pharmaceuticals Directors Forum, between August 2011 and September 2011. Copies of the summaries of these meetings are attached to my affidavit at **Exhibit "PP"**.

- **Physicians, including medical associations and colleges of physicians and surgeons**:

    - On September 29, 2011, Health Canada representatives met with representatives from the Canadian Medical Association (CMA), the Canadian Medical Protective Association (CMPA), and the College of Family Physicians of Canada (CFPC). These associations expressed significant concern with respect to the role of physicians in access to marijuana for medical purposes. Whether under the current program or the proposed regulations, medical associations expressed concerns with medical practitioners supporting access to a drug that did not follow the established clinical path that physicians are trained to work within (i.e. successful clinical trials that demonstrate that the drug's benefits outweigh its risks and it is approved under the FDA/FDR). They expressed concern that the long term health effects of using marijuana for

medical purposes are unknown and expressed significant concern regarding liability stemming from the role of supporting access. Participants felt that the Health Canada proposed process for accessing marijuana for medical purposes was too similar to traditional prescribing practices, which rely on evidence and established guidelines. Given the lack of information about the use of marijuana for medical purposes, physician associations did welcome the creation of the Expert Advisory Committee, to review current literature and provide some guidance for physicians.

- On September 26, 2011, Health Canada representatives met with representatives from the Federation of Medical Regulatory Authorities of Canada (FMRAC); FMRAC is the association of all Colleges of Physicians and Surgeons in Canada. Representatives from all colleges, except Nunavut, were present. FMRAC expressed the same concern over the physician role as Health Canada heard at the September 28, 2011 meeting with medical associations and colleges. Their concerns focussed on the lack of scientific evidence pointing to the effectiveness and safety of marijuana for medical purposes. Some colleges noted that they would continue to discourage their members from supporting the use of marijuana under a reformed program. As regulators of the profession, Colleges also expressed concern about the potential for some medical practitioners to "over-prescribe" marijuana, particularly given the absence of guidelines for its use; this situation creates an oversight and monitoring problem for the Colleges. The complete medical consultation summaries are attached to my affidavit at **Exhibit QQ"**.

- In November 2011, Health Canada attended the 2011 Family Medicine Forum in Montreal, Quebec. Health Canada manned a booth and conducted a health needs assessment survey with family physicians. The summary of this meeting is attached to my affidavit at **Exhibit "RR"**.

- **Pharmacists:** On September 28, 2011, Health Canada held a bilateral meeting with the Canadian Pharmacists Association (CPhA). Medical marijuana regulatory reform was added to the agenda of this meeting after Health Canada officials had heard from multiple stakeholders and partners, including provinces/territories, that pharmacists be consulted regarding whether or not they should have a role in dispensing marijuana under the renewed regime. On June 12, 2012, Health Canada officials held a consultation session regarding the proposed new regulations with the Council of Pharmacy Registrars of Canada (an advisory committee to NAPRA). Participants to both sessions were generally not opposed to pharmacists dispensing marijuana for medical purposes, so long as provinces and territories were on side, as they are jurisdictionally responsible for regulating the profession. Some concerns were noted with security of pharmacies that may be storing dried marijuana. Pharmacists also noted that they would require information regarding the uses of marijuana for medical purposes, and requested that any materials being developed for physicians should also be available to them. The summaries for these meeting are attached at **Exhibit "SS"**.

- **Municipalities**: While Health Canada has received unsolicited correspondence from Municipalities over the years, it also met with the Federation of Canadian Municipalities (FCM) on September 29, 2011, for a formal consultation on the proposed new approach to regulating marijuana for medical purposes. Representatives of municipalities were highly supportive of the proposed regime, but expressed concerns that in the interim, while the MMAR were still in effect, they would continue to be subjected to public health and safety risks associated with growing marijuana in dwellings of which the locations were not known to local authorities. With respect to the proposal, FCM representatives clearly expressed that they were not in favour of cannabis dispensaries or store-front distribution in their communities, stating a clear preference for the

provision of marijuana for medical purposes through the mail, which, from their perspective, would remove the centralization of crime around a distribution centre and reduce stigmatization of neighbourhoods that may result from the existence of community based dispensary models established for the purpose of distributing marijuana. Participants welcomed the elimination of personal production, but did raise concerns about remediation of existing grow sites, where public health and safety risks would continue to exist after the program sunsets. The complete summary of this consultation is attached to my affidavit **at Exhibit "TT"**.

- **Law enforcement officials, fire officials**:

  - On October 12, 2011, Health Canada representatives met with representative of the RCMP, and the Canadian Association of Chiefs of Police. Law enforcement indicated that the creation of a regulated industry which does not include personal production would alleviate the concerns that they have expressed throughout the years related to public health and safety under the MMAR. The elimination of personal and designated production in residential areas was seen as greatly increasing safety. Law enforcement officials also felt strongly that the proposed regime should include requirements that licensed producers disclose their locations to governments and public safety officials in order to receive a license. The lack of capacity to disclose information about the locations of production sites under the MMAR had been problematic for law enforcement in the past, and they wished to ensure that this would not be a problem going forward. The complete summary of the Law Enforcement Consultation is attached to my affidavit **at Exhibit "UU"**. Health Canada set out the CAP's principal concerns in a document entitled "CACP Recommendations to Health Canada regarding the Marihuana Medical Access Program", attached at **Exhibit "VV"**.

- On September 27, 2011, Health Canada met with representatives of the Canadian Association of Fire Chiefs (CAFC). The CAFC expressed support for the elimination of personal and designated production in residential areas, and welcomed the ability to regulate commercial entities through local by-law and zoning regulations. Again, questions were raised about remediation of properties that had been used as grow sites. There was concern that public health and safety concerns would persist after the MMAR were repealed (mould, pesticide contamination, etc.). They strongly emphasised the public health and safety risks associated with marijuana production in dwellings, citing electrical and fire hazards related to the heavy use of electricity, poor electrical wiring, and the presence of fertilizers and other chemicals that present serious hazards not only for residents, but for neighbours and for fire- fighting personnel. The complete summaries of the law enforcement and fire fighter consultations are included at **Exhibit "WW"** to my affidavit.

160. Briefly, we heard that current participants in the program wished to maintain their personal and/or designated production licenses; they expressed serious concerns about being able to afford to purchase marijuana for medical purposes, often on fixed disability pensions. At the same time, federal and provincial public safety officials, municipalities, law enforcement and fire officials expressed serious public health and safety concerns with personal and designated production. The medical community expressed ongoing concern at the role they were being asked to play in providing access to an unapproved drug, but welcomed efforts to improve physician information on the use of marijuana for medical purposes. All stakeholders welcomed the prospect of an improved and simplified application process.

Process #3-75 days post CGI

161. The draft MMPR were first published in *Canada Gazette*, Part I (CGI) on December 15, 2012. As per the federal regulatory process, publication of draft

regulations provides another opportunity for stakeholder input. Also as per the regulatory process, Health Canada must provide a response to the comments that it receives. During the 75-day comment period following CGI publication of the proposed MMPR, Health Canada received a total of 1,663 comments: 1,433 of those were submitted by current license holders and individuals; 93 were from prospective industry; 54 were from municipalities, fire officials and law enforcement agencies; 43 were from health care practitioners, medical associations and pharmacists; 6 from provinces and territories; 3 from Members of Parliament; and 31 from other organizations. In addition, Health Canada received 212 comments that were sent automatically from a public petitions website; these comments were pooled together and counted as one individual. The comments are summarized in the RIAS published with the MMPR and attached at Exhibit "CCC".

Program Participants and Individual Canadians

162. The 1,433 participants and individuals referred to in paragraph 161 above who provided feedback expressed concerns over elimination of personal production and the impact it would have on an individual's capacity to purchase dried marijuana from licensed producers. Some suggested that Health Canada should consider "grandfathering" current personal production licenses to ensure these individuals could continue to afford their supply of dried marijuana.

163. Health Canada's response to this view was that licensed production of marijuana in private dwellings has been associated with increased risks to public health and safety of communities in which such growing operations took place. The MMAR never intended to support the exponential growth in the number of participants that has taken place since 2001. This rapid growth in participation placed a significant and unsustainable strain on the Department's resources. The elimination of personal production under the MMPR responded 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.

164. The movement to licensed producers under the MMPR was not intended only to address the health, safety and security issues I have discussed. The movement to licensed producers also recognized that growing marijuana, particularly marijuana of a quality suitable for ingestion by seriously ill individuals for therapeutic purposes, is not a simple matter. Some growers may lack the requisite skills to grow marijuana for medical purposes, some may lack the facilities and others may be unable to grow given the effort involved and the state of their health. In a September 6, 2012, letter to Health Canada (attached at Exhibit "B"), Mr. Allard noted, that "I am growing organically with very minimal yields, nowhere near 10 grams a day. I have had problems with clones not rooting; plants stressed by heat, cold, and insects, and plant sickness, just to mention a few problems. Unfortunately, I have not always been able to give due care and attention to my plants because of my own health problems, the cramped production site, and a previously unsuitable home and living situation".

165. The new supply and distribution mechanism is intended to increase access to quality marijuana for medical purposes for all individuals whose medical practitioner supports use of marijuana for medical purposes.

Health Care Practitioners

166. 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 marijuana for therapeutic purposes. They expressed the view that Health Canada was setting up a prescription like process for dried marijuana, even though dried marijuana 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 or a Notice of Compliance.

Physicians in particular noted that this could affect their ability to make informed decisions in the interests of their patients and increase their liability risks. The Canadian Medical Association also prepared and submitted a document to Health Canada entitled "CMA Response: Health Canada's Medical Marihuana Regulatory Proposal" dated February 28, 2013. This document is attached at **Exhibit "XX"**.

167. Health Canada's response to this view was that 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 dried marijuana for medical purposes, despite the fact that dried marijuana has not been through the standard FDA/FDR process. Since marijuana is not an approved therapeutic substance in Canada, no formal, comprehensive, scientific and medical information (e.g. a formal drug monograph) on the risks and benefits of marijuana for therapeutic purposes has ever been published by any commercial sponsor. Health Canada did, however, establish an Expert Advisory Committee to provide advice and recommendations to Health Canada on the current information on marijuana for medical purposes, and any additional information/education materials that might of assistance so that physicians can be better informed of the current science on marijuana. This document is entitled "Information for Health Care Professionals" and is attached at Exhibit "G". Between May and July 2012, physicians were invited to participate in an electronic survey to obtain their views on the proposed improvements to the MMAP. The Summary Report: Physician Needs Assessment – 2012 is attached at **Exhibit YY"**.

Municipalities, Law Enforcement and Fire Officials

168. These groups were 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. But, 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 marijuana 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. On February 5, 2013, the District of Mission wrote to the Minister of Health to make suggestions for the new regime and to congratulate the government on "... making the changes necessary to ensure that the production of marihuana can be carried out in a way that protects communities ...", this letter is attached at **Exhibit "ZZ"**. In a January 30, 2013, letter to Health Canada, the City of Surrey indicated its full support for the MMPR, as set out in CGI, but also provided a document entitled "What the Marihuana for Medical Purposes Regulations Overlook: Disclosure and Remediation of Inappropriately Used Dwellings, this letter and document are attached at **Exhibit "AAA"**.

169. In response to similar concerns raised by municipalities during preliminary consultations, the MMPR require potential applicants for a license to notify local government, police and fire officials in writing of their intention to apply for a producer's license and to submit proof in their application that this requirement has been complied with. The notice must specify the activities for which the license will be sought, and the address of the site at which activities will be conducted. In response to comments received in CGI, the draft MMPR were revised to include a provision to require a licensed producer to also notify these same authorities when the license is granted, when an amendment to the license is approved by the Minister, when the license is suspended or revoked for any reason, or when the license is reinstated. Further, the revised Regulations enable the Minister of Health to confirm license information to the

authorities originally notified by an applicant when the Minister receives such a request.

170. In its response to issues concerning remediation and location of existing MMAR production sites, Health Canada noted that 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.

Provinces and Territories

171. Six provinces, including British Columbia, Alberta, Manitoba, Ontario, Quebec and Nova Scotia, 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 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 marijuana is recommended as a medical therapy, especially given the health implications of using a smoked form of marijuana for medical purposes. Provinces and territories noted that a potentially higher price for dried marijuana under the proposed MMPR may put pressure on their governments to subsidize the costs incurred by patients. They also noted that, without a common drug review and a drug identification number, marijuana for medical purposes is not likely to be dispensed by pharmacists nor covered under provincial drug plans.

172. In its response, Health Canada noted that the MMPR aimed to treat dried marijuana as much as possible like other narcotics used for medical purposes by creating conditions for a new, commercial industry that would produce and distribute dried marijuana. This new system would introduce a secure and efficient system that provides access to marijuana for those who suffer from illness or disease, while saving taxpayers' money and reducing risks that are felt by Canadian communities. Licensed producers would be responsible for setting the price. The Regulations would introduce, however, the conditions necessary for a competitive industry, which would potentially contribute to prices falling over time in response to competition and technological innovation that could reduce cost of production. Health Canada also removed pharmacists as a dispensing option from the MMPR, in part based on pharmacists' responses and in part based on PT comments.

Prospective Industry

173. 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 marijuana. Based on the price projected in Health Canada's cost-benefit analysis for the Regulations (which estimated that an Licensed Producer (LP) producing 500 kg of dried marijuana 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, may 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. Prairie Plant Systems, for example, wrote to Health Canada on February 20, 2013, and provided a 27 page report commenting on the proposed MMPR. This letter and report are attached at **Exhibit "BBB"**.

174. Health Canada's response to these concerns included that the new system will introduce a secure and efficient system that provides access to marijuana, while saving taxpayers' money and reducing risks that are felt by Canadian communities and other harms that have been cited by law enforcement, fire officials and municipalities. Since 2001, the cost of the Program (issuing authorization/licenses and subsidizing supply of dried marijuana) 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 marijuana for medical purposes through a government supply contract or by issuing licenses for personal production (i.e. PUPL/DPPL) is unsustainable.

175. Some potential Licensed Producers expressed dissatisfaction that under the proposed MMPR, marijuana would be available in dried form only; they criticized the lack of product alternatives as a limitation on client choice. Some felt that the restriction to dried marijuana deprived registered clients and patients of access to marijuana in forms they may prefer in terms of desired effects, routes of administration (e.g. ingestion or topical) and "dosage." They noted some users of marijuana for medical purposes may prefer marijuana-based products that are ingested or applied topically to those used primarily *via* inhalation, given the known dangers of smoking.

176. Health Canada's response to these concerns was that the new Regulations would limit licensed producers to the production and distribution of dried marijuana only. The MMPR would not authorize extractions of active ingredients (e.g. resin) to be sold for the therapeutic purposes. The clinical studies on the therapeutic uses of marijuana that have been carried out to date have used dried marijuana that was either smoked or vaporized. There are no clinical studies on the use of cannabis edibles (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 FDR. The limited clinical data that exists is restricted to dried

marijuana that was either smoked or vaporized and to the cannabinoid-based medicines (dronabinol, nabilone, and nabiximols) that have gone through the appropriate drug approval channels. Under the MMPR, licensed producers would be required to include information leaflets prepared by Health Canada, which warn consumers of the adverse effects of using marijuana.

177. Health Canada listened carefully to the many varied, and often conflicting views and concerns expressed by the broad array of stakeholders, then weighed and considered this input against the policy objectives that guided reform of the marijuana for medical purposes regime. Health Canada's responses to the views expressed during the multi-phased consultation and to unsolicited comment it received as well as the impact this information had on the regulatory scheme as it was ultimately promulgated are detailed in the RIAS published in CG II with the MMPR as they came into force. The MMPR and its associated RIAS are attached at **Exhibit "CCC"**.

MARIHUANA FOR MEDICAL PURPOSES REGULATIONS (MMPR)

178. The MMPR were published in *Canada Gazette*, Part II (CGII) and came into effect on June 7, 2013. They created a new framework for provision of reasonable access to dried marijuana for medical purposes that would rely on commercial production of quality product in regulated circumstances that allowed for inspection, compliance and enforcement. To allow for smooth and successful transition from one access, supply, and distribution regime to the other, the MMPR operated in tandem with the MMAR until the MMAR repeal on March 31, 2014.

179. The RIAS (attached at Exhibit "CCC"), 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."

180. The MMPR approach to providing access to dried marijuana for medical purposes is intended to address many, if not all, of the significant negative consequences that resulted from the MMAR, such as the practical difficulties in imposing quality and safety standards on production by personal producers of marijuana for medical purposes, who may lack the capacity, knowledge or motivation to implement them; individual health and safety risks to those seriously ill persons who consume cannabis of uncertain quality, strength and/or microbial or chemical (fertilizer and pesticide) contamination. The MMPRs are also intended to address the problems associated with personal production in dwelling houses reported by municipalities, first responders, police, and neighbours, and recognize that an inspection regime of private dwelling places would be neither a cost effective nor an efficient, manageable means of addressing the myriad unintended negative consequences of personal production of marijuana for medical purposes.

181. The MMPR are intended to improve access to quality dried marijuana for medical purposes, which is produced in regulated, sanitary, and secure premises. Accordingly, the new MMPR aim to:

- increase individual and public health and safety and security; cultivation of marijuana in individual residences under the MMAR ran contrary to these objectives;
- treat marijuana, to the extent possible, as much as possible like other drugs for medical use;
- provide that medical marijuana be manufactured in accordance with good production practices, in sanitary secure premises, and require that marijuana products be labelled to show levels of THC and CBD;
- facilitate access to multiple strains;
- eliminate government involvement in authorizing possession of marijuana for medical purposes;
- expand the scope of persons who may sign a medical document to include nurse practitioners, where their licensing bodies permit;

- streamline the medical document and eliminate categories of medical conditions
- return Health Canada to its traditional role of regulator;
- create a legitimate, regulated business environment in which:
  a. dried marijuana 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 marijuana for medical purposes and minimizing negative impacts resulting from its production in dwelling houses.

182. The MMPR authorize the following key activities:
- possession of dried marijuana by individuals who have the support of a licensed health care practitioner to use marijuana for medical purposes;
- production of dried marijuana by licensed producers only; and
- sale and distribution of dried marijuana by licensed producers and hospitals to individuals who can possess it.

183. Up until March 31, 2014, the MMPR also allowed individuals who held 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 to obtaining their legal supply of dried marijuana for medical purposes under the MMPR by using a medical declaration issued under the MMAR to register with a licensed producer, which could then provide them with dried marijuana for medical purposes.

184. Under the MMPR, personal and designated licenses to produce dried marijuana for medical purposes issued under the MMAR were to be valid until March 31, 2014, when the MMAR were slated for and indeed were repealed. It was expected that at that time all personal and designated production licenses would become invalid and that persons authorized to use marijuana for medical purposes would obtain quality controlled dried marijuana from licensed producers, whom Health Canada could monitor and inspect. Production of marijuana in dwelling places was to have ended. This situation did not materialize, however, because the March 21, 2014 Federal Court injunction order allowed that certain persons who were authorized to possess and to produce marijuana for medical purposes and who met the terms of the order, to continue to do so in accordance with the existing terms of their licenses and authorizations, with the exception that possession would be capped at 150 grams at any one time.

185. Throughout the transition period and still, Health Canada's website provides detailed information for persons transitioning to the MMPR, persons seeking to use marijuana for medical purposes, or entities applying to be a LP under the MMPR: http://www.hc-sc.gc.ca/dhp-mps/marihuana/transition-eng.php. These materials are attached at **Exhibit "DDD"**.

186. Health Canada continued to accept applications for renewal of personal and designated production licenses until September 30, 2013. After September 30, 2013, submissions to Health Canada with applications for new ATPs and/or new production licenses, applications for increases to ATPs (and their associated production licenses), as well as changes to production sites were no longer accepted. The rationale underlying this deadline was that applications submitted beyond October 1, 2013, would have had inadequate time for new producers to cultivate, harvest and dry a marijuana crop prior to the repeal of the MMAR on March 31, 2014.

187. On repeal of the MMAR, Health Canada no longer accepts, processes, or issues applications for authorizations to possess and licenses for personal or designated production of marijuana for medical purposes. Health Canada no longer maintains a contract for production of dried marijuana for medical purposes; nor does it supply marijuana for medical purposes.

AFFIRMED BEFORE ME)
At the city of Ottawa,)
in the Province of Ontario,)
on the 15th day of January, 2015)
)
)
Commissioner for Taking Affidavits)

JEANNINE RITCHOT

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 15th day of January 2015.

A Commissioner for Taking Affidavits

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.

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

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.

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,

$$E = D \times B \times 1.5$$

where B is 30 grams, being the expected yield of dried marihuana per plant,

(*b*) if the production area is entirely outdoors,

$$E = D \times B \times 1.5$$

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,

$$E = D \times B \times 1.5$$

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

$$E = D \times B \times 1,5$$

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 :

$$E = D \times B \times 1,5$$

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 :

$$E = D \times B \times 1,5$$

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