From: [redacted]
To: consultations-marihuana@hc-sc.gc.ca
Subject: 11-07-30-11 proposed program changes
Date: 2011-07-30 10:52 PM

Dear Sir/Madam,

Among the many proposed changes to the current regulations, I urge you to consider permitting the sale of liquid marijuana tincture, marijuana salve, marijuana juice and even time release patches. It doesn't make sense for sick people to only be permitted to smoke it. There is substantial evidence that the various active ingredients mix in different ways to alleviate many different symptoms. I have done considerable research on this and know that, if allowed, non smoking marijuana relief can be provided for many people suffering from many illnesses. Many of our senior citizens can find huge relief from variously combined genetic types of marijuana. This includes some of our mothers and fathers, who are old and ageing with varying degrees of difficulty. There are many other types of illnesses that these alternative forms of marihuana can help alleviate and even cure.
As I said earlier, I know of many various combinations of many various genetic types, processing methods and administration methods that provide incredible relief for our suffering brothers and sisters. The many illnesses and vast amount of needless suffering that can be addressed eventually touches us all, whether it be friends or family that are suffering and there are keys to unlocking the physiological processes that DO provide relief. Relief can come in the form of easing emotional pain, neuropathic pain, and more. I humbly urge you to allow Canada to lead the world in showing how we can advance care. We need to live in truth and as one of the many additional benefits, we will see many people stay at home to recover, saving many millions of dollars and relieving a huge amount of stress on our hospitals.
I believe this is our greatest opportunity in years to evolve our medical care system and am available to discuss my ideas, should you choose.

Thank you for your consideration

[redacted]
Business Consultant

From: [redacted]
To: consultations-marihuana@hc-sc.gc.ca
Subject: 11-07-30-51 Thoughts on Proposed Changes
Date: 2011-07-30 06:42 PM

Hello,

First, as a patient enrolled in the program, I would like to thank Health Canada regarding their efforts to improve Canada's Medical Marihuana Program. The proposed changes are a great start to remedy many of the problems that have plagued the program from its inception.

For all the positive changes being proposed, I do have serious concerns about the proposal to take away patients rights to grow their own medicine or designate someone to grow it for them. Turning over the right to grow medical marihuana exclusively to approved, commercial, for-profit enterprises, presents a litany of problems for some of Canada's most sick and vulnerable citizens, including myself.

The following are the reasons that I strongly oppose any proposal that takes away a patient's right to grow medical marihuana:

1. There is little to no proof that our communities and children would be any safer if we take away patients rights to grow. The number of fully licensed medical growers who have been charged with overgrowing over the past two years has been less than 1%. That number is not statistically significant enough to take away a privilege that many sick Canadians have used to improve the quality of their lives. There will always be people who break the rules, but we do not take away privileges from the majority of law-abiding citizens because of the callous few.

2. The other 99% of patients who hold production licenses see it as a privilege and an essential part of their health care. These growers play by the rules and do not want to risk losing the right to grow or jeopardize the safety of their homes and properties.

3. There are fewer than 5,000 licensed medical marihuana growers in Canada. It is estimated that there are around 250,000 people involved in the illegal trafficking of marihuana in British Columbia alone. The medical growers are not the ones endangering our communities. Stopping the medical growers will do nothing to improve the safety of Canadians.

4. There are hundreds of different strains of medical marihuana. Each person reacts differently to each strain. Some patients have spent years finding the best strain to suit their condition. If growing is turned over exclusively to commercial growers, only the few and most profitable strains will be available. This will leave sick Canadians to endure a decrease in the quality of their lives or risk having to engage with criminals to obtain their suddenly illegal medicine. Those are two terrible choices.

5. The supplier currently contracted by Health Canada to provide dried marijuana has not been able to produce medicine of the same quality and effectiveness as patients and designated growers. Why should patients be forced to take a lesser quality good?

6. I have found growing my own medicine to have immense therapeutic value. As many of us in the program are dealing with debilitating afflictions, the simple act of grow your own medicine can allow patients to feel that they proactively contributing to your own quality of life. It is cruel to suggest taking away the pride and value we derive from the growing process.

Most importantly:

6. The primary concern of approved, commercial growers will be profit, not the well being of sick Canadians. Currently, the cost for patients to grow their own medicine is very small. Examining two similar industry situations such as telecommunications and petroleum, it is easy to see that customers have only seen their costs go up and up while the companies are making billions upon billions of profit each year.

To Summarize…

Why are we considering taking a privilege away that sick Canadians have used to improve the quality of their lives? Why would we replace it with a higher cost system that will have fewer options for patients and provide a less effective product, while still not improving the safety of our communities?

I do believe that private enterprise should play a role in the growing and supplying of medical marihuana but not at the expense of some Canada's most critically ill. Any change to Canada's Medical Marihuana program must protect the patient's right to grow his or her own medicine. Anything less, is un-Canadian.

Thank you for taking the time to read my thoughts. If you require any additional feedback, or have any questions, please let me know.

[redacted]
Ottawa, ON
613[redacted]
Medical Marihuana Patient

From: [redacted]
To: consultations-marihuana@hc-sc.gc.ca
Subject: 11-07-31-163proposed changes
Date: 2011-07-31 03:22 PM

I am responding to the Proposed Improvements to Health Canada's Marihuana Medical Access Program.

Firstly I would like to commend Health Canada for providing the opportunity to comment on the propsed changes. What better way to have a successful program than to consult with the participants themselves.

As a father myself I understand the need for reducing the risk of exploitation by criminal elements and the importance of keeping our children and communities safe. I can see that creating commercial distribution centres could solve some of the issues that have been brought to Health Canada's attention.

However, I myself, want to produce my own medicinal marihuana. I understand that Health Canada intends on monitoring these commercial producers for quality control, but I prefer being my own grower monitoring my own crop. I grow purely organic and am very particular about the care and maintenence 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 who's hands are touching those plants. I don't know the strength or origin of the product. I appreciate that Health Canada is addressing the one strain availability, but this is also something I prefer to experiment with myself, growing diffrent strains and finding what benefits me most, grown by my own hand.

Registering with a commercial grower also brings to mind concerns of privacy. I do not want to be a number in a system with my personal information on file and accessible to the private sector. I don't want to be limited to buying my medicine at one location. Access and convienence would be limited with the proposition of these commercial distribution centres.

In closing I would like to suggest that Health Canada re-consider phasing out the opportunity for medicinal users to grow their own marijuana. If there are concerns involving the public's safety with regards to small personal grow ops, perhaps Health Canada could provide more information on setting up "safe" houses. A list of qualified electricians, security consultants and knowledgeble retailers who can guide the grower as to what products they should be using for proper air quality etc. I

personally beleive we do not have to move towards a corporate model of marijuana production and distribution.

Thank you for your consideration

From: Minister_Ministre
To: [redacted]@hotmail.com
Cc: consultations-marihuana@hc-sc.gc.ca
Subject: Re: Proposed MMAR regulations will cause difficulties for stakeholders
Date: 2011-07-25 01:19 PM

Thank you for your correspondence of July 23, 2011, addressed to the Honourable Leona Aglukkaq, Minister of Health, regarding the proposed improvements to the Marihuana Medical Access Program. We have forwarded your comments to the following address consultations-marihuana@hc-sc.gc.ca so that your feedback may be included in the consultation process.

----- Forwarded by Minister_Ministre/HC-SC/GC/CA on 2011-07-25 01:18 PM -----

From: [redacted] [mailto:[redacted]@hotmail.com]
Sent: Saturday, July 23, 2011 1:55 AM
To: Aglukkaq, Leona - M.P.; Davies, Libby - M.P.; consultations-marihuana@hc-sc.gc.ca
Subject: Proposed MMAR regulations will cause difficulties for stakeholders

Here are some reasons why the proposed new MMAR regulations will cause difficulties for (1) Medical Marijuana Patients, (2) Commercial growers, (3) Health Canada:

1. Medical Marijuana Patients
Legitimate users of Medical marijuana will find the new system for acquiring their marijuana problematic for the following reasons:
When users have to order their medicine through the mail, they must be able to plan ahead and know exactly how much of the medicine they will need, weeks ahead of time. Since many users will some times require more than usual, due to a flare up of pain or symptoms, this could lead to the user unexpectedly run out of medicine when their pain/symptoms are at the worst. This would force the patient to decide between his/her pain and the law if he/she should need to acquire more medicine quickly. Clearly this would not rectify the problems pointed out in the Mernagh supreme court decision.
When a patient signs on with a commercial grower he/she is subject to the quality, consistency, strain, growing practices and most importantly the pricing practices of the commercial grower. Essentially he/she is stuck.
It is a proven fact that it is extremely difficult to produce high quality marijuana on a very large scale.
Since the commercial growers will be allowed to set their own price there will be no market forces to determine the price, based on the quality of the medicine.
Since the patient will only be able to order the medicine, he or she will not be able to determine the quality of a certain strain offered by a commercial grower without actually purchasing it first. In a dispensary setting, the patient can see and smell the medicine before purchasing it.
Commercial growers will have no incentive to grow certain strains that are low yielding or have an unusually long flowering time especially if they are not demanded by very many users. This will mean that for the most part Cannabis Sativa strains will be difficult for patients to obtain.
Medical patients, especially those who require large doses, will develop a high tolerance for the strains offered by their commercial grower (because of the lack of variety), especially if the medicine is not always of the highest quality.
Since the Cannabis produced will be inspected by Health Canada, I would assume that if the plants were to become infected by powdery mildew, spider mites or botrytis (grey mould) the entire crop would be deemed unacceptable for medical use. Since patients of the commercial grower have no other legal source to get their medicine it is possible that they would not receive the medicine that they ordered. There are many other problems experienced by indoor growers that can cause the quality of the product to be lower than medical grade. This problem could be avoided if patients were able to access their medicine through a dispensing third party with many sources.
The medicine doesn't necessarily need to be infected to be lower than medical quality. The fact that the medicine is grown commercially could mean that it is not of quality comparable to what is being produced on a small scale by personal production licenses and designated grower licenses or even what is available on the black market. The problem is that the patients will be stuck buying low quality product because they have no other legitimate source (no potential for competition between commercial growers) and they have already paid for it without seeing it first.
Patients would not be able to legally access the variety of Cannabis edibles and ointments that could be made available from legitimate dispensaries/compassion clubs.
All this means that patients will most likely only be able to acquire HIGH QUALITY medicine conveniently and at an affordable price from illegal sources or "illegal" compassion clubs.
2. Commercial Growers
The proposed "Commercial grower" regulations are somewhat flawed for the following reasons:
Growing medical marijuana on a very large scale is a huge amount of work and requires a huge financial investment and high overhead. Growers would need thousands of licenses in order to make a profitable business. The main reason for the current abuse of the MMAR designated growers licenses is the fact it requires an investment of upwards of $50,000 to begin cultivation of one 50-100 plant license. There is no way for the grower to recover the start up cost or make a profit without selling the product illegally. This will be an issue for the commercial growers licenses as well. They will need a customer that can buy their product on the same

large scale that it is produced. Commercial growers will NEED a legitimate dispensing third party as customers.
Large scale commercial growers often find that it takes many crops before they get their system to produce a high quality product. Patients may receive inferior medicine for up to a year.
Commercial growers will find it difficult to manage pests without the use of pesticides. It will be very expensive if at all possible for patients to get an organic product.
There is a reason that factories do not sell directly to consumers. To be profitable, they must be efficient. This is no different for the commercial production of marijuana. For commercial marijuana producers to deal with small orders for their product (as stated in the proposed regulations) on a weekly basis from potentially thousands of consumers would be a huge burden on the producer. This would increase the overhead a great deal and it would mean more employees would be needed. Cash flow would be slow and inefficient, especially at the beginning of the program when growers have fewer patients. This makes it more difficult for growers to pay large expenses and recover initial investment, greatly increasing the risk for abuse.
The only way to allow the commercial producers a reasonable profit avoid abuse of the system is to allow them to legally sell it to a distributor/ retailer. Weather this be compassion clubs, dispeneries or London drugs and Shoppers drug mart, it is an essential part of a functioning MMAR system.
3. Health Cannada
The new regulations would cause problems for Health Canada for the following reasons:
Health Canada proposes to conduct inspections to insure that the MMJ produced is of sufficiently high quality. However, Health Canada has no experience in determining the quality of marijuana. Also, the proposal does not specify how the patients will acquire their medicine if the marijuana produced does not meet standards.
The program does not sufficiently make medical marijuana accessible to sick Canadians and the government will continue to face court battles when the flaws of the new program play them selves out.

It is obvious that the government of Canada does not want to legalize the sale of medical marijuana through a third party like dispensaries for logical reasons. However, this is the only real option for making this drug accessible to Canadians that need it and for avoiding abuse of the grow licenses. We live in a capitalist economy and there are many good reasons that the capitalist system uses a supply chain to distribute nearly everything that we produce. In real terms, it does not make sense for manufacturers of Oxycontin to sell their product directly to patients with a prescription, so why would this work for producers of medical marijuana? When medical marijuana is not treated differently than other drugs that are dispensed by a pharmacist or a similarly licensed professional then our government will no longer need to fight court cases against MMJ patients. Their rights will no longer be infringed upon.

Yours truly,
[redacted]

[redacted]

From: [redacted]
To: consultations-marihuana@hc-sc.gc.ca
Subject: 11-07-31-91 Marihuana Consultations - input
Date: 2011-07-31 08:19 PM

-------Original Message-------

From: [redacted]
Date: 31/07/2011 12:41:17 PM
To: [redacted]@telus.net
Subject: report

Thoughts on program changes. With out prejudice.

I feel that a good distribution system is very important. I am very worried that each commercially licensed grower would be packaging and selling their product directly to consumers. For the following reasons.

1. There are in fact compassion groups in place. These need to be encouraged. They need to have a set of common rules and regulations, packaging, weights and strength that can be overseen by inspectors. For Health Canada to inspect every little grower would necessitate a whole new body of people running all over the country to "inspect " commercial growers.

2. 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 designed by people that are not in the know. Has vastly changed technically since its conception.

3. To inspect these sites would take, again, numerous people. Hopefully they

would know the product and the skills required to grow a medical product. For example many are not grown organically using very harmful insecticides throughout the growth period under the guise of being used as medicine. Big plantations with many "clients."

4. Small growers of medical product who produce for themselves, are to my knowledge not part of the huge underground world of drugs. And want no part of it.

5. I am an old registered nurse, have known a lot of Doctors during my working years and very few of them knew the slightest thing about the medical uses of marijuana. Some of course are becoming more learned about the drug and its uses, however few really understand the different strains and the effects they have on differing conditions.

6. Security is the biggest factor when one is growing marijuana. Growers throughout North America, but especially in British Columbia, fear gangs of thieves who invade grow rooms to steal crops and terrorize growers. And of course, we also receive reports about police actions against those who grow herb.

This program change will not help the marijuana culture protect itself against thieves and violence. Big plantations need a lot of security. That's why I would recommend growing just a few plants and only for persons own consumption. Big plantations need many workers and thus word spreads, People get raided by thugs just before the harvest, very dangerous indeed. Investigate those with many clients this is an area of concern. Often producing poor quality product, and clients acquired through suspect means.

There will be those that need others to grow their marijuana for them; this can easily be controlled by severely limiting the number of clients each grower can produce for.

Marijuana culture has changed. Limit the number and size of lights, and plants; anyone can compromise their amount of product by simply counting the number of plants. I would not feel safe under the proposed way of dispersing the product.

Every person on the block, even in rural areas will know what is going on and therefore be at risk. No locks will keep them safe.

I ask that you not stop tiny self-growers, for providing for themselves. We do not want to be any part of the ill-legal drug world. Nor would we want to be exposed to it.

I do not think these changes will change the numbers of growers, as this is a well-established sub-culture not in a hurry to change.

Meanwhile how will affect the many growers without the MM sanction? All the inspectors will be "inspecting" and life will continue unchanged.

I thank you for the opportunity to have a small say. If I can be of any help please contact me,

I believe in this product I am pain free for the first time in 12 years, can walk and live my life with unwanted side effects from pills.

I sincerely wish you well on changes, but it sounds like quality discussion is still needed.

Respectfully [redacted] & [redacted]

From: [redacted]
To: consultations-marihuana@hc-sc.gc.ca
Subject: 11-07-31-103WWW Form Submission
Date: 2011-07-31 07:40 PM

Below is the result of your feedback form. It was submitted by
() on Sunday, July 31, 2011 at 19:40:11

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message: The real problem is all the illegal grow ops that give all the good medical grow-ops a bad name . The proposed changes to not allow patients to safely grow there own supply of medical marijuana is a denial of affordable marijuana to a group of disabled people who can not afford to purchase there supply. This proposed change is a violation to there access and not an improvement to the current program,denying these individuals the access they have legally had for so many years is so wrong to do . Whats next Health Canada ? Are you going to throw us in jail.This proposal is so wrong and should be considered illegal. It will breed many more illegal grow-ops and make life desperate for these sick people. Health Canada have a heart let us grow safely our own supply.Please do not take away this safe and affordable access.

counter: 828

From: [redacted]
To: consultations-marihuana@hc-sc.gc.ca
Subject: 11-08-01-1 my views and opinion
Date: 2011-08-01 02:59 AM

To whom it may concern,

After reading the proposed changes on health canada I have some concerns. I agree that it has been managed to this point allows for criminals to take advantage of the system. However for those of us who make a modest income and help friends and family and I who have made a large investment in equipment, electrical work, and renovations to meet the standards set forth by Health Canada. I don't want to lose the ability for this income, and to produce quality marijuana for my patients and I'd like to add the first two licenses I had to purchase at $250 per plant through a broker, one for a 96 plant and the other for a 72 plant. There has been a great deal of cost to myself and it will take a long time to recuperate the initial investment. I would like to continue to produce strain specific as my patients and I have a good relationship and would like this to continue. My fear is as well that if it were to be put in the hands of commercial growers that it would become far too expensive for all patients. I would be open to regular inspections and audits as I want to do everything to code and regulations set forth by Health Canada. I would appreciate any updates to changes and the times they are to be implemented. At the very least, as I am soon to be applying for a medical license for myself, that I should be able to produce my own medication to ensure quality and specific needs.

Thank you for your time

[redacted]

This is **Exhibit "KK"** 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

DRAFT
02/12/2014

Targeted Consultation Plan – January-March 2012

Stakeholder Group	Stakeholder(s)	Issues to discuss	Date	Location
Physicians	• Individual Physicians through: o *Medical Post* and *L'actualité médicale* o Physician direct email listservs o Targeted online consultation website	• Dosing • Period of use • Route of administration • Medical documentation supporting access	Mid – late January 2012	TBD – on-line web sessions
P/T Ministries of Health	• ADM committee	• Enabling regulations • Nurse Practitioners' role • Pharmacists' role	Mid -January 2012	Ottawa
Federation of Canadian Municipalities	• Big City Mayor Caucus (BCMC) • Chiefs of staff	• Elimination of personal production • Transition period to new program	January 2012 [TBD] BCMC Strategic planning mtg	Ottawa
Courier Companies	• Purolator • FedEx • UPS • DHL • CanPar • ICS	• Process for secure delivery • Safety and security requirements • Geographical issues (use of couriers in the North)	Late January 2012	Ottawa
Canadian Association of Medical Cannabis Dispensaries	• Dispensary representatives TBD	• CAMCD standards and certification recommendations for cannabis dispensaries	January 2012	[TBD] Ottawa
Potential Commercial Producers	• List TBD (based on interest expressed companies, organizations and individuals) • Currently 45 individuals	• Licensing requirements • Proposed quality framework • Proposed record keeping framework • Proposed security framework • Options on labelling	February 2012	Toronto Vancouver Alberta Montreal

Stakeholder Group	Stakeholder(s)	Issues to discuss	Date	Location
	and/or companies have expressed preliminary interest (see Annex A)	• Interest/economic feasibility • Time required to establish full-scale production		
Other LCP interests	• NewAge Medical (Sam Mellace)	• LCP record-keeping framework	February 2012	Vancouver
Colorado	• We Grow Colorado (Drew Milburn) • Colorado Department of Public Health and Environment • Colorado Department of Revenue	• LCP requirements/framework • Lessons learned/ Better understanding of how the "market" was created in other jurisdictions	February 2012	Colorado Springs, CO and/or Denver, CO

2005

This is **Exhibit "LL"** 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

2006

Health Canada Santé Canada

Canada

Drugs and Health Products

Medical Marihuana Regulatory Reform 2011 Consultations Results

In recent years, a wide range of stakeholders including police and law enforcement, fire officials, physicians, municipalities, and program participants and groups representing their interests, have identified concerns with the current Marihuana Medical Access Program (MMAP).

To address these concerns, an online and in-person consultation process was launched between June - November 2011, to gather comments from interested parties on the proposed improvements to the Program. Input from these consultations will be considered in the development of new regulations.

Here's what they said:

Introduction

Background

On June 17, 2011, in response to concerns heard from Canadians, the Minister of Health announced that she is considering improvements to Health Canada's Marihuana Medical Access Program (the Program). The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep our children and communities safe, while significantly improving the way program participants access marihuana for medical purposes.

Health Canada also launched public consultations on the proposed improvements. A consultation document was posted on the Health Canada website which outlines the proposed improvements.

This report serves as a summary of the key themes heard during that consultation process.

The improvements under consideration

See more information on the proposed improvements to the Program.

Who was consulted?

Between June and November 2011, Health Canada consulted with key stakeholders to get their views on the proposed changes and to gain information and knowledge to inform the development of new regulations. Stakeholder groups included:

- authorized and licensed individuals under the current Program;
- compassion clubs and cannabis dispensaries;
- provincial and territorial ministries of health and of public safety;
- physicians, including medical associations and colleges of physicians and surgeons;
- municipalities;
- law enforcement officials;
- fire officials;
- pharmacists; and
- Canadians with an interest in the Program.

The Results

1. Physician - patient interaction

Health Canada's proposal maintains that individuals would still be required to consult a physician to obtain access to marihuana for medical purposes. However, categories of conditions and symptoms would be eliminated. Therefore, there would no longer be a requirement for some individuals to obtain a specialist assessment in addition to their primary care physician in order to access

2007

marihuana for medical purposes. The existing medical declaration would be replaced by a simpler document provided by the physician to the individual.

In response to physicians' request for more information about the use of marihuana to support their patients, Health Canada is consulting with experts in the medical and scientific communities on ways to improve physicians' access in obtaining comprehensive, accurate, and up-to-date information on the use of marihuana for medical purposes.

The role of physicians

All stakeholders welcomed efforts to improve physicians' access to information on the use of marihuana for medical purposes. Program participants, physicians and medical associations indicated that improving access to such information may be helpful in ensuring that physicians are better informed when discussing the use of marihuana for medical purposes as a treatment option.

Clinical guidelines on the use of marihuana for medical purposes, information on potential therapeutic indications and information on the evaluation of potential risks and benefits of marihuana for medical purposes were all identified as principal areas where physicians would like more information.

Categories of conditions and symptoms

The removal of categories of conditions and symptoms is considered a positive step toward improving the application process for program participants, particularly those who have stated that the requirement to get a specialist assessment can take a significant amount of time. Medical associations indicated that, in the absence of regulated categories of conditions and symptoms, they would like to continue to work with Health Canada to develop guidelines that could assist physicians in making informed decisions with respect to the use of marihuana to treat particular symptoms and/or conditions.

The potential role of other healthcare practitioners

Some stakeholders suggested that the list of health care providers who can support an individual's request to use marihuana for medical purposes should be expanded. Suggestions included nurse practitioners, pharmacists, naturopaths, herbalists, practitioners of traditional Chinese medicine and chiropractors.

2. Patient access

Under the proposed redesigned program, individuals would no longer be required to apply to Health Canada to obtain an authorization to possess marihuana for medical purposes. Nor would Health Canada continue to issue personal-use production licenses (PUPLs) or designated person production licenses (DPPLs) to individuals. These forms of production would be phased out. The only legal source of dried marihuana would be licensed producers, which would be licensed by Health Canada to produce and distribute dried marihuana by registered mail or bonded courier.

Application process

All stakeholders welcomed the streamlined process in which Health Canada no longer receives applications or collects personal medical information from program participants.

The establishment of licensed producers and the phasing out of personal and designated production

Federal and provincial public safety officials, municipalities, law enforcement, and fire officials have, in the past, cited a number of serious public health and safety concerns with personal and designated production, including:

- the potential for diversion of marihuana produced for medical purposes to the illicit market;
- the risk of home invasion due to the presence of large quantities of dried marihuana or marihuana plants;
- public safety risks, including electrical and fire hazards, stemming from the cultivation of marihuana in homes;
- public health risks due to the presence of excess mould and poor air quality associated with the cultivation of marihuana plants in homes.

These stakeholder groups indicated that the proposed phase-out of personal and designated production would address their concerns regarding public safety, security and public health risks. Law enforcement representatives indicated that the proposed changes would greatly reduce the potential for diversion of marihuana for medical purposes to the illicit market.

All stakeholders agreed that the public health, safety, and security of residential neighbourhoods and the mitigation of risks associated with personal and designated production are important objectives. However, many current program participants suggested that Health Canada consider strengthening inspection processes for those individuals who hold a PUPL or a DPPL, rather than eliminating personal and designated production. Many stakeholders also agreed that licensed operations would allow for greater regulation and control of production through zoning and by-laws.

Distribution

All stakeholders agreed that it is necessary to ensure a secure means of distributing dried marihuana to individuals who use it for medical purposes. Many stakeholders groups requested that Health Canada consider distribution through pharmacies, as pharmacists have extensive knowledge and experience in dispensing therapeutic products. Absent the potential for pharmacy distribution, the majority of stakeholders agreed that distribution of dried marihuana directly to individuals by mail is a secure option as it reduces the potential number of points for diversion. Some stakeholders, particularly law enforcement and representatives of local governments, noted that some citizens may express discomfort with the idea of establishing store-front entities specific to the distribution of marihuana in their communities.

2008

Compassion clubs and cannabis dispensaries asked that Health Canada consider inclusion within the regulatory framework of an option for store-front, community-based dispensaries. They believe that such entities could play an important role in providing education and outreach to individuals who use marihuana for medical purposes.

Dried marihuana only

As in the current program, dried marihuana would be the only product permitted for production, sale and distribution under the proposed new regulations. Due to the unknown health risks associated with products such as cannabis oils, extracts, creams, and edibles, many stakeholders supported the status quo of dried marihuana to other products. On the other hand, compassion clubs and cannabis dispensaries, as well as most program participants, asked that Health Canada consider allowing other forms of products, most notably edibles and extracts.

3. Proof of legal possession

Under Health Canada's proposed improvements, program participants would no longer be required to submit information to Health Canada in order to be authorized to possess dried marihuana. Individuals would no longer receive an authorization to possess or an identification card from Health Canada.

Identification cards

Individuals who use marihuana for medical purposes and law enforcement see the value of an identification card as a convenient means by which to demonstrate that an individual is in lawful possession of marihuana. These stakeholder groups are in agreement that as long as another method to prove lawful possession is determined through this process, the card itself would not be necessary. However, these stakeholders noted the importance of Health Canada advising law enforcement agencies about the mechanism by which patients will be able to demonstrate proof of possession.

4. Licensed production

In order to be licensed by Health Canada, licensed producers would have to demonstrate compliance with requirements related to, for example, product quality, personnel, record-keeping, safety and security, disposal and reporting, as set out in new proposed regulations. These controls would aim to ensure the quality of the product being purchased by program participants, as well as the security of production sites.

Licensed producers would be permitted to produce marihuana indoors and would be able to produce any strain(s) of marihuana.

Cost and choice for patients

Program participants considered the availability of multiple strains a significant improvement to the program. However, they are concerned that the transition to licensed production will render the price of marihuana more costly, given that licensed producers will have to take their overhead costs and profit margins into account when pricing their products. Some individuals also expressed concerns that marihuana may not be covered under provincial and private drug plans. To address these issues, some stakeholders suggested that Health Canada explore means to regulate the price of dried marihuana for medical purposes

Regulatory requirements for licensed producers

All stakeholders welcomed clear regulations that outlined requirements for licensed producers; however, some parties interested in becoming licensed to produce commercially highlighted that requirements should not be so complex that only large businesses could become licensed.

Complying with municipal zoning bylaws and building codes was viewed by all stakeholders as a necessary step to securing a commercial production licence. Municipalities emphasized that it would be important for interested parties to obtain applicable municipal authorization to operate before applying to Health Canada for a commercial production licence. Municipalities, fire officials, law enforcement and potential licensed producers agreed that production sites should not be publicly disclosed, but should be known by municipalities and first responders for inspections and public health and safety reasons.

Conclusion

Overall, the proposal to create a regulated industry is well received, though some program participants have asked that Health Canada consider allowing them to maintain their personal and/or designated production licenses. All stakeholders are supportive of elements of the proposal that would improve and simplify the application process for participants. Finally, there is widespread support for measures that Health Canada could undertake to increase outreach and information for physicians.

Next steps

Input from these consultations is being considered in the development of new regulations, on which Canadians will again have an opportunity to comment when the proposed regulations appear in *Canada Gazette*, Part I, in 2012.

Date Modified: 2013-01-31

This is **Exhibit "MM"** 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

2010

Annex A

CHANGES TO THE *MARIHUANA MEDICAL ACCESS REGULATIONS*: SUMMARY OF STAKEHOLDER INPUT

October 10 2011

REV B.

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1. Introduction

The following report summarized key themes emerging from the written responses provided to Health Canada by stakeholders regarding the proposed changes to the *Marihuana Medical Access Regulations* (MMAR) announced on June 17 2011.

2. Consultation Background

Following the announcement of proposed changes to the MMAR in June 2011, Health Canada welcomed written input from stakeholders. A letter was sent to all program participants inviting them to submit comments. Input was accepted until July 31 by email, fax, letter mail and through submissions of a web-based comment form.

Approximately 2,214 written responses were received, comprising approximately 3,330 pages of material.[1] These responses were summarized analytically and numerically to provide a reliable reflection of stakeholder input.

Targeted stakeholder meetings are currently ongoing.

3. Analytical Approach

The objective of the analytical approach used for this report is to provide an accurate, comprehensive summary of the input provided in writing to Health Canada regarding proposed changes to the MMAR. To that end, simplified Content Analysis was used to capture key information from each submission which, translated into numerical terms, formed a database. That database has been used to describe and quantify the input.

Each item was read and up to 15 specific pieces of information were captured. These were:

- Last name of author
- Organization represented (if applicable)
- Stakeholder type (User, Grower, Police, Citizen, etc.)
- Input type (Email, web, letter, etc.)
- First sentence (used for database search purposes)
- Overall position on amendments
- Up to 9 specific positions or opinions stated by the submission.

[1] See explanation under 3.1 Duplicate and Multiple Submissions.

The nine specific position or opinions were chosen from a comprehensive list of 52 different positions or opinions seen in the input. In other words, we identified 52 unique positions or concerns which occurred with sufficient frequency to warrant tracking and each submission was tacked with up to nine of these. In practice, the average submission was tagged with 3.7 specific position/opinion codes.

Two principles underlie the analytical approach used for this project. The first is that the *strength of feeling* is not quantifiable and is discussed only in a qualitative manner. Although many people in the user/grower community feel very strongly about the proposed changes to MMAR, that intensity of feeling has not been measured or estimated numerically. The second is that, on principle, the analysis limits each individual or group to one submission. Where an individual made more than one submission, they were combined in analysis to give that individual the same weight as every other individual, as discussed below.

It is important to note that the analysis conducted in this report *applies only to the input received.* While the consultation process was intended to provide all Canadians with an opportunity to respond, there is no scientific or statistical basis upon which to generalize the consultation results contained in this report to the wider Canadian population. Percentages used in this report refer only to the body of input received during the consultation and do not purport to describe the views of the wider public overall or within specific populations.

3.1. Duplicate and Multiple Submissions

Given the multiple opportunities for input provided by Health Canada, it was not uncommon for individuals to send the same submission by several different routes. Wherever possible, these duplicate submissions have been identified and removed. This was done by comparing the names of participants and also the first sentence of their submission.

It was also not uncommon for individuals to provide multiple submissions which complemented or augmented each other. In these cases, all the input by a single individual or group has been combined into a single submission, with all the position/opinion codes combined.

Despite these efforts to deal with duplicate and multiple submissions, it is necessary to acknowledge that it is possible for any individual to contribute in these consultations multiple times, especially given the somewhat anonymous nature of web form input. Nonetheless, deliberate multiple submissions by single individuals were, in the opinion of the analytical team, very rare if they occurred at all.

Finally, some submissions were unusable due to a variety of factors, including unrelated subject matter, illegibility, or file corruption.

With the exclusion of duplicates and unusable submissions, and the combination of multiple submissions, the final total of submissions was **2,214.** This included 429 responses which could not be identified by name, usually because they were submitted via web form.

A profile of the participants is provided in the following section.

4. Profile of Participants and Submissions

The overwhelming majority of stakeholders who provided written input on the MMAR changes were people who are currently authorized to possess and/or produce marihuana under the MMAR.[2] They tend to identify themselves as people experiencing a range of chronic medical problems. Most indicate that marihuana for medical purposes was not a first choice for treatment but was chosen due to problems with other treatments, such as pharmaceutical painkillers. A considerable number of these patients report that they are unable to work and are living on CPP/OAP, long-term disability insurance, or disability pensions.

In addition, many private individuals offered input on the MMAR changes who did not identify any personal or professional connection to the issue. These individuals are characterized as "citizens" in this report. Although some may indeed use marihuana for medical purposes, only individuals who explicitly offered this information were classified as users or growers.

As the following figure shows, individuals identified as users, growers, user/growers or citizens provided 2,068 out of 2,214 submissions or 93% of all submissions. Users and growers alone account for 69% of submissions,

Table 1. Stakeholder Type	Number of Submissions	Percentage of Submissions
User	409	18.5%
Grower	149	6.7%
User/Grower	953	43.0%
Citizen	557	25.2%
Fire Services	25	1.1%
Police Services	27	1.2%
Physician	11	0.5%
Pharmacist	5	0.2%
Other Health Care Professional	2	0.1%
Health Association	16	0.7%
Civil Association	35	1.6%
Municipality	17	0.8%
Other	8	0.4%
Total	2,214	100.0%

[2] The distinction between users, growers and user/growers is based solely on the explicit statements provided by individuals in their submission.

Other stakeholders provided responses to the MMAR changes, including fire officials, law enforcement, physicians, pharmacists, other health care providers, health associations and civil associations. Often these responses came from organizations. As such, they are substantively different in weight than the responses of individual Canadians. Thus, while these institutional responses were far fewer in number, they do represent significant numbers of people who belong to (or work for) the organizations involved.

The Civil Associations include a wide variety of interests concerned with MMAR, ranging from compassion clubs and civil liberties associations to Block Watch and the YMCA.

The Health Associations include disease-related organizations and professional groups including pharmacists, nurses and the provincial colleges of physicians and surgeons.

Submissions were generally one or two pages in length (90%), with only 2% exceeding five pages.

Table 2. Length in Pages	Number of Submissions	Percentage of Submissions
1	1644	74.3%
2	352	15.9%
3	98	4.4%
4	36	1.6%
5	28	1.3%
6	13	0.6%
7	8	0.4%
8	3	0.1%
10+	25	1.1%
Other	7	0.3%
Total	2,214	100.0%

Email was by far the most common method by which respondents submitted comments. Two-thirds of responses were provided by email and a further one-quarter were provided through the web form. Faxes and letters combined accounted for less than one-tenth of responses.[3] It was not uncommon for organizations to respond by email including a letter attachment.

[3] Where duplicate responses were sent by one individual, the medium of the first one received has been recorded. In the case of multiple complementary submissions by one individual, the medium of the most substantive submission has been recorded.

Table 3. Method of Submission	Number of Submissions	Percentage of Submissions
Email	1483	66.9%
Web comment	567	25.6%
Fax	57	2.6%
Letter	107	4.8%
Total	2,214	100%

5. Summary of Stakeholder Positions

Stakeholder response is varied and a range of nuanced views is seen across each stakeholder group. Nonetheless, it is possible to summarize the positions of key stakeholder groups.

Overall reactions to the MMAR changes are presented in the following table[4]. A clear majority of submissions from users, growers and citizens may be characterized as "opposed". Among other stakeholder groups, police and fire services tend to be supportive while response from other groups is more mixed. Percentages are provided for large subgroups only. The table totals horizontally.

Table 4.	Unqualified Support	Support w/ concerns	Neutral	Mixed	Opposed	Total
Users, Growers and Citizens combined (n)	60	162	171	200	1,475	2,068
Users, Growers and Citizens combined (%)	3%	8%	8%	10%	71%	100%
User (n)	8	40	51	41	269	409
User (%)	2%	10%	13%	10%	66%	100%
Grower (n)	13	27	19	22	68	149
Grower (%)	9%	18%	13%	15%	46%	100%
User/Grower (n)	6	52	16	72	807	953
User/Grower (%)	1%	6%	2%	8%	85%	100%
Citizen (n)	33	43	85	65	331	557
Citizen (%)	6%	8%	15%	12%	59%	100%
Fire Services	11	9	4		1	25
Police Services	9	10	5	3		27
Physician		4	1	1	5	11
Pharmacist	1	3	1			5
Health Association	1	7	3	3	2	16
Civil Association	4	6	8	9	8	35
Municipality	6	4	4	2	1	17
Other			7	1		8

[4] This judgement - which categorized each submission as unqualified support, support with concerns, neutral, mixed, or opposed – was made qualitatively by the analyst. 'Neutral' submission expressed no opinion, while 'mixed' submissions offered both positive and negative assessments.

It is important to note that the number of submissions from groups other than users and growers is relatively small. The views of each group are discussed in subsequent sections of this memorandum.

The following table provides a qualitative overview of stakeholder positions on key aspects of the proposed changes.

Table 5.	**N***	**Elimination of qualifying categories / symptoms**	**Phase out of personal and designated production**	**Introduction of commercial market**	**Elimination of Health Canada authorization / Physician as gatekeeper**	**Elimination of ID cards**
Users, growers and private citizens	*2,068*	*Neutral*	*Strongly opposed*	*Moderate opposition***	*Neutral****	*Moderate opposition*
Fire services	*25*	*Neutral*	*Strong support*	*Support*	*Neutral*	*Neutral*
Law enforcement	*27*	*Neutral*	*Strong support*	*Support with concerns*	*Support with concerns*	*Moderate opposition*
Municipalities	*17*	*Neutral*	*Strong support*	*Neutral*	*Neutral*	*Neutral*
Physicians	*11*	*Support with concerns*	*Neutral****	*Neutral*	*Support with concerns*	*Neutral*
Pharmacists	*5*	*Neutral*	*Neutral*	*Neutral*	*Neutral*	*Neutral*
Health associations	*16*	*Neutral*	*Mildly Opposed*	*Neutral*	*Support with Concerns*	*Neutral*
Civil associations	*35*	*Support*	*Mixed*	*Support*	*Support*	*Oppose*

** Submissions from each stakeholder group.*
*** Related to commercial market as only option.*
**** Concerns expressed about affordability of medication under new system.*
***** Seen as unworkable due to de facto physician opt-out from MMAR*

6. Detailed Input

6.1. Users, Growers and Private Citizens

The following section of the report outlines the expressed views of individuals in response to the proposed changes to the MMAR. These respondents are presented separately from the professional/institutional participants discussed later. The categorizations of user, grower, user/grower and private citizen are made based on the information provided in each submission. These groups expressed quite similar responses to the proposed changes to MMAR.

6.1.1. Overall Response to Proposed Changes

Among growers and users of marihuana for medical purposes, as well as among citizens, views of the proposed MMAR changes are based primarily on the phase out of personal and designated production. The other aspects of the proposed changes are heavily coloured by their opposition to the phase out of personal and designated production. A key component of the proposed changes – the removal of Health Canada from the authorization process – goes largely unmentioned in the input received from these stakeholders, as does the elimination of qualifying categories of conditions and symptoms. Similarly, the proposed authorization of multiple commercial growers and the creation of a competitive market is criticized primarily because this will be the *only* option open to individuals who currently grow their own. Thus, the phase-out of personal and designated production emerges as the key issue for users and growers of marihuana for medical purpose, as well as for other citizens. Other issues are secondary.

It should be noted that the large majority of users and growers who provided input to Health Canada did not explicitly advocate any form of legalization or decriminalization of marihuana. Only 14% (204 of 1,477) explicitly support decriminalization or legalization. Instead, most users and growers indicated a readiness to operate within a regulatory framework that requires them to justify their medical requirement for marihuana for medical purposes.

6.1.2. Phase out of personal production and designated growing

The most common source of opposition to the proposed changes to the MMAR program is the plan to phase out the option to grow marihuana for medical purposes for personal use or as a designated grower for other authorized users. For a majority of stakeholders in this group, the phase-out of personal and designated production is the most contentious aspect of the proposed changes.

Among users and growers, 62% of submissions (917 out of 1,477) explicitly opposed the phase-out of personal and designated production. In contrast, only 2% (31 submissions) expressed support for this change.

Table 6.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Oppose - End to personal production	917	61%		219	39%
Support - End to personal production	31	2%		22	4%

Without doubt, the strongest message from the user/grower community was that personal and designated production should not be phased out for the reasons discussed in the following sections.

Growers have made financial investments / expect reimbursement

Individuals who grow their own marihuana for medical purposes (or act as a designated grower for someone else) express significant concern that the decision to phase out personal and designated production will erase the value of the investments they have made. These investments include renovations, lighting, ventilation and security measures. Various values are ascribed to these investments, but they typically range from $5,000 to $20,000. These individuals stress that these investments were made on the basis of Health Canada authorization to produce marihuana for medical purposes and in conformance with the requirements laid out by the Department.

This potential loss of their investment leads some personal and designated producers to ask whether the federal government will compensate them for the losses incurred due to the regulatory change.

Roughly 22% of submissions by user and growers explicitly mention the investments made in personal production and 5% specifically ask whether growers will be reimbursed for the investments they have made in production equipment and facilities.

Table 7.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Growers have made significant investments.	328	22%		35	6%
Growers should be reimbursed for their investments in production	69	5%		7	1%

Generally speaking, however, these users and growers also oppose the phase-out of personal and designated production for other reasons as well and are unlikely to be satisfied with compensation alone.

Personal and designated production sites should be inspected and monitored, not phased out.

Where problems are acknowledged to exist with regard to safety and security, stakeholders often state that the solution is an inspection regime and certification for personal and designated production operations, rather than the abolition of this option. Growers indicated a willingness to submit to random inspections by Health Canada to confirm the safety and security of their operations. Further, many argue that random inspection of personal and designated production installations should be mandatory for all growers. More than 15% of submissions say that installation problems (such as fire hazards) should be dealt with through an inspection regime. Although only rarely discussed, there does not appear to be significant concern among growers about letting local fire and police officials know where personal and designated production under the MMAR is taking place.

Table 8.	All Users and Growers	Percentage Users and Growers	Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*	*557*	*100%*
Inspection regime should be used to control problem in personal and desiganted production (rather than phase out)	230	15%	50	9%
Locations of personal production sites should be known to authorities	30	2%	16	3%

Existing laws and regulations already cover potential abuses of the MMAR

A common theme among personal and designated producers who grow marihuana for medical purposes is that the irresponsible or illegal actions of a minority of growers should not result in restrictive action against all growers. They feel that the vast majority of growers comply with the regulations and should not be denied their current authorizations due to the misdeeds of a few. Ten percent of submissions suggest that any contraventions of MMAR, building codes or drugs laws should be dealt with using existing powers of enforcement.

With regard to the illegal sale of marihuana produced by individuals for personal or designated use, they state that such abuses are likely to occur under any system and that illegal sales of marihuana predate the MMAP. Laws already exist to punish such behaviour. With regard to improper construction, electrical service and ventilation, they point to fire regulations and building codes as examples of controls already in force through which problems in the program may be addressed.

Table 9.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Laws already exist to counter problems in MMAR.	148	10%		28	5%

Current personal and designated producers should be "grandfathered"

While most growers and users make impassioned arguments in favour of explicitly preserving the option to grow their own marihuana for medical purposes, a minority say they are willing to accept "grandfathering" if the practice is phased out. In other words, provided they are permitted to continue to grow marihuana for medical purposes for themselves and other authorized people, their concern about the changes will be reduced.

Table 10.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Current growers should be "grandfathered"	111	7%		33	6%

Will continue to produce regardless of regulations

Given their health and financial situations, about 4% of growers and users indicated that they would not comply with any regulations which prevented them from growing their own marihuana for medical purposes. This is because they feel the benefits to their quality of life are too significant to give up.

Table 11.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Will disregard elimination of personal and designated production / Continue to grow.	56	4%		10	2%

6.1.3. Commercial Production and the Market for Marihuana for Medical Purposes

Most users or growers do not object to an expansion of commercial production of marihuana for medical purposes or the creation of a competitive market for suppliers. Taken alone, these changes to the MMAR are received somewhat neutrally or even positively insofar as they may provide more choice for patients who currently rely on Health Canada's supply. In conjunction with the phase out of personal and designated production, however, the commercial market for

marihuana for medical purposes is heavily criticized as inadequate and ill-considered. As an *option* it is accepted, as the *only* option it is roundly rejected.

Patients will not be able afford to purchase commercial marihuana

There is a widespread assumption that marihuana available from commercial growers in the future will not be affordable to patients. This expectation is based on the assumption that prices will be similar or higher than the prices charged for the marihuana for medical purposes currently distributed by Health Canada. Users expect that purchasing commercially-produced marihuana will cost at least five to ten times as much as they currently pay for their supply. Given the high proportion of individuals who report to be on fixed incomes in this population, these increased amounts are considered untenable in the absence of public or private insurance coverage.

Table 12.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Affordability is challenge for users	897	59%		181	32%
Support - Commercial market for marihuana	30	2%		27	5%
Support - Market pricing for marihuana	0	0%		2	0%
Access to medication must be maintained	44	3%		7	1%
Low income patients must be subsidized.	35	2%		17	3%

They do not expect that a competitive market between commercial growers will lower prices and are much more inclined to believe that commercial producers will maximize profit at the expense of low income patients who will be priced out of the market. There is distrust of the motives and goodwill of commercial producers who they believe will be driven primarily by profit motives and not by compassion for low income users.

Some users conclude that if the federal government is to phase out their option to grow their own medicine (or using a designated grower), then provisions must be made to subsidize the price of commercially-produced marihuana for low-income patients.

Patients who need specific strains and strengths will no longer have access

A number of users and growers stressed the importance finding the right strain of marihuana to treat each individual's physiology and specific needs. Some noted that this is a process of trial and error in which they (and sometimes their designated grower) had invested years of experience. They are consequently very concerned that the marihuana available in the future from commercial growers may not include the specific strains they need. These individuals assume that, while a

variety of strains may be available, commercial producers would not be able to provide adequate variety nor work directly with individual patients.

Table 13.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Commercial market will not / cannot provide varieties and strains needed	364	24%		72	13%
Oppose - Commercial market for marihuana	171	11%		62	11%
Oppose - Market pricing for marihuana	107	7%		43	8%
Commercial product is / will be weak.	93	6%		26	5%

More generally, there is an expectation that commercially-produced marihuana will be of low potency. This expectation stems directly from disappointing experiences with the marihuana distributed by Health Canada. That product is widely considered to be too weak to be therapeutic.

Conversely, a very small proportion of stakeholders – often those who use Health Canada's marihuana for medical purposes - are nonetheless optimistic that commercial suppliers will provide access to better quality and more strains of marihuana. (Approximately 2% of user/growers support the move to a multiple-source commercial market for marihuana.)

Distrust of commercial marihuana due to chemicals and irradiation

Based also on their experience with the marihuana provided by Health Canada, users expect that marihuana grown by commercial enterprises will use additives such as chemical fertilizers and pesticides. A key advantage they see in personal and designated production is the control over chemicals and the ability to use more traditional non-chemical management methods when just a few plants are involved.

Table 14.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Commercial products will use chemicals and/or be irradiated	270	18%		31	6%

The belief that Health Canada's current supply of marihuana is irradiated against mould is also disquieting to some users, who assume this process will be used by commercial producers as well.

While issues regarding chemicals and irradiation are of concern to many Canadians when it comes to agricultural products, it seems of special concern to the large proportion of this stakeholder population whose health is already compromised.

Safety and security concerns about personal and designated production are exaggerated/ unproven

Many growers take exception to the Federal Government's position that personal and designated production pose safety or security threats. They consider this claim to be exaggerated or factually inaccurate, based on a perceived lack of evidence and their own experience. Almost all feel that they have taken measures to ensure the safety and security of their growing operation, pointing out these operations usually exist in their personal residence and are therefore of considerable consequence to them personally and to their families. They do not deny that problems exist and should be addressed, but they feel phasing out personal and designated production is an overreaction.

About 14% of users and growers say that concerns about diversion, fire hazards and security problems have been exaggerated.

Table 15.	All Users and Growers	Percentage Users and Growers	Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*	*557*	*100%*
Problems caused by personal production are exaggerated and/or unproven	200	13%	87	16%
Personal production creates a security risk	15	1%	13	2%
Personal production marihuana is illegally diverted	26	2%	17	3%
Personal production sites create dangers	11	1%	13	2%

6.1.4. Other Views Expressed by Users, Growers and Citizens

Proposed changes will encourage organized crime / black market

Many users and growers believe the federal government's intent in revising the MMAR program is to curtail the growth in marihuana for medical use or even reduce access. Given their high reliance on marihuana for medical purposes and the absence of viable alternatives, many suggest that the government will inadvertently increase black market demand for marihuana by forcing patients to buy it illegally. This in turn would increase criminal activity with all the associated negative impacts of crime. Many feel frustrated that they may find themselves forced to choose between either abandoning a medicine which helps them or turning to illicit sources.

Table 16.	All Users and Growers	Percentage Users and Growers	Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*	*557*	*100%*
Changes will encourage crime / black market	210	14%	66	12%

Changes treat all MMAR producers like criminals

Users and growers take exception to the publicly announced reasons underlying the changes to MMAR. They complain that the focus on unsafe growing operations and criminality associated with marihuana for medical purposes serve to further stigmatize patients. Similarly, they feel that the phasing out of personal and designated production amounts to their being "punished" for the crimes of a few growers.

Table 17.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Changes treat users and growers of medical marihuana like criminals	204	14%		32	6%

Distrust of Health Canada and the Federal Government

There is distrust of the federal government among many in the user/grower community. They believe that the government is hostile toward marihuana for medical purposes and is seeking to limit patient access for ideological reasons. They point to the various court decisions which have directed Health Canada to provide access over the objections of the department as evidence that the government does not want to facilitate access.

One perceived motive identified by users and growers is a desire by Health Canada to favour large pharmaceutical and agribusiness interests who are believed to covet this potential market.

Despite this distrust, many stakeholders who participated in the consultation process express genuine hope that their concerns and suggestions will be taken into account. Some of the perceived flaws in the proposed regulatory changes are presumed to stem from low awareness and understanding of marihuana for medical purposes at Health Canada.

Table 18.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Federal government not trustworthy on MMAR	112	7%		36	6%
Consultations process is not sincere	43	3%		15	3%
Changes are intended to service interests of pharmaceutical and agriculture corporations	41	3%		20	4%

Notwithstanding the sincere participation of most stakeholders, there remain others who already believe (or are close to believing) that the consultations are *pro forma* and that no concrete changes will be made based on the input of users and growers.

Changes are not believed to respect or reflect past court decisions

Users and growers sometimes remark that the changes to MMAR do not respect the spirit of past court decisions which obligate Health Canada to provide access to marihuana for medical purposes. This view is generally related to whether the cost of commercially-grown marihuana will be prohibitive for users and whether commercial growers will provide the specific strains required by individual patients. There is an expectation that the MMAR changes will face further legal challenges if the MMAR changes are implemented as proposed.

Table 19.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Court decisions are not being respected	82	5%		56	10%

ID cards should be maintained

The discontinuance of identification cards for authorized users of marihuana for medical purposes does not elicit a significant amount of comment from users. Those who comment are concerned that the lack of an official document from Health Canada will lead to increased problems with law enforcement. For those who currently possess cards, there is a sense of insecurity associated with their loss and a fear that they may be detained by the police in the future.

Table 20.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Oppose - End to ID cards	68	5%		39	7%
Support - End to ID cards	0	0%		2	0%

Physician education is important

Users often note the difficulty they experienced in finding a physician who would sign their paperwork to be authorized to possess marihuana for medical use. This was attributed to a number of factors, including a fear of legal liability, unfamiliarity with marihuana as a treatment, and a professional bias in favour of pharmaceutical drugs. As noted in a later section, physicians reflect some of those concerns themselves.

Recognizing the central role of physicians in the new MMAR system, users worry that physicians will be no more willing to endorse marihuana for medical use than they are currently, thereby undermining the value of the changes from the patient perspective. They are concerned that - without significant and successful education efforts - access will deteriorate under a system where Health Canada no longer vets applications and physicians play the primary "gatekeeper" role.

Table 21.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Physicians lack education on MMAR program and medical marihuana	51	3%		20	4%
Physicians will not assist patients to apply for authorization	93	6%		48	9%
Scientific guidance on marihuana use as medicine if lacking.	32	2%		10	2%
Other health care professionals should be able to authorize use, not only physicians.	19	1%		21	4%

Motivated usually by the difficulty in finding cooperative physicians, some respondents suggest expanding the list of health care providers who can authorize the use of marihuana for medical purposes.

Marihuana should have DIN / drug status with health insurance providers

The financial concerns about the affordability of commercially-grown marihuana for medical purposes (and the consequent attachment to personal and designated production) are closely linked to the exclusion of marihuana from the general system used for other medications in Canada. Without a drug identification number (DIN) and the associated status, marihuana for medical purposes is not covered by private insurance or by provincial drug plans. While patients can obtain pharmaceutical drugs at little or no cost, they must pay the full amount for marihuana. Thus, they are very sensitive to price changes in marihuana supply and are drawn to rely on their own production or that of a designated grower which they can obtain at or near cost.

Table 22.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Marihuana for medical purposes should be covered by health insurance	63	4%		17	3%
Marihuana should have same status as any drug	62	4%		13	2%

Alternative ingestion options should be permitted

Although most users and growers ingest their marihuana for medical purposes by smoking, other methods are preferred by other users. A number note that they ingest marihuana in food, which requires that the raw marihuana be processed into an oil or tincture first, contrary to regulations. These users suggest that the regulations should allow for preparation of marihuana used in edible products.

Table 23.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Edible preparations and tinctures should be allowed.	70	5%		12	2%

Interested in becoming commercial producer

A small number of participants express interest in becoming licensed commercial producers. These are often individuals who are designated growers for authorized users and who feel they have developed an expertise in the cultivation of marihuana for medical purposes.

Table 24.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Participants interested in commercial growing.	91	6%		23	4%

6.1.5. Issues of Low Interest to Users, Growers and Citizens

As noted earlier, some aspects of the proposed MMAR reforms generate very little interest among users and growers, often because they are subsumed by larger issues. Of most significance is the scant attention given to the requirement for courier delivery of marihuana for medical purposes and the elimination of the list of qualifying ailments (which essentially removes Health Canada from the process of determining when marihuana is an appropriate treatment for each individual.) As the following table shows, there is very little mention of these two issues among users, growers and private citizens. Opposition to courier-only deliveries generally relates to the parallel replacement of personal and designated production by commercial providers, and also the possibility of lost or stolen packages and a consequent lack of needed medication.

Table 25.	All Users and Growers	Percentage Users and Growers		Private Citizen	Percentage Private Citizens
Total Participants	*1511*	*100%*		*557*	*100%*
Oppose - End to list of qualifying diseases	12	1%		7	1%

Support - End to list of qualifying diseases	37	2%		13	2%
Oppose – Courier delivery only	23	2%		15	3%
Support – Courier delivery only	3	0%		0	0%

6.1.6. Perceptions of the Current MMAR system

Users and growers of marihuana for medical purposes identify a number of flaws with the current MMAR program. That said, most appreciate the program as it stands and do not believe that radical change is required. As noted earlier, many rely heavily on marihuana for medical purposes to treat their symptoms and are thankful to have legal access to this therapy.

Health Canada is faulted for taking too long to process applications and for limiting authorizations to a single year even for patients facing chronic, progressive or terminal illnesses. As noted earlier, the Department is believed to lack compassion for sick individuals who can find relief only through marihuana for medical purposes.

Table 26.	**All Users and Growers**	**Percentage Users and Growers**		**Private Citizen**	**Percentage Private Citizens**
Total Participants	*1511*	*100%*		*557*	*100%*
MMAR reauthorization is too frequent / Period should be lengthened.	47	3%		5	1%
MMAR authorizations are too slow	112	7%		17	3%

As also noted earlier, the marihuana sold by Health Canada is often criticized as low potency, available only in a single strain, irradiated, and cultivated using possibly harmful chemicals. Also, physicians are faulted for low awareness of marihuana's medical benefits, a bias toward pharmaceutical medications especially opiates, and frequent unwillingness to sign applications on behalf of patients. A number of users noted that they had to search far afield to find a physician who would sign their application to Health Canada.

6.2. Input Provided By Institutional and Professional Stakeholders

In addition to the input provided by individuals described in the previous chapter, a number of responses were received from organizations and institutions, or from individuals responding in a professional capacity. This input comprised only 7% of all submissions, but was frequently more detailed in content than the submissions of individuals expressing their personal views.

Given the small number of responses in this category and sub-categories, percentages are not used.

6.2.1. Summary of Institutional and Professional Stakeholder Positions

Many of the institutional, organizational and professional responses received do not take a clear position regarding the MMR changes but instead raise questions or concerns about implementation and outcomes. Pharmacists, for example, tend to raise questions rather than support or oppose specific changes.

Generally speaking, fire, police, and municipalities who responded to the consultation were more supportive of the changes to MMAR which have been proposed. As with individuals discussed in the previous chapter, these professional responses tend to be focused on the elimination of personal and designated production, as shown in the following table. There is concern about the elimination of ID cards. Their support for a commercial market is generally based on the opportunity this provides to eliminate personal production, not any enthusiasm for the commercial market itself. They are focused on minimizing risks to their officers and the public and maximizing compliance with the law. They are consequently less focused on the outcome for patients.

Other professional respondents are less supportive of the proposed end of personal and designated production, usually on the grounds that they believe this will limit access to marihuana for medical purposes among a sick population.

Table 27.	Fire Service	Police Service	Physician	Pharmacist	Other HCP[1]	Health Assoc.	Civil Assoc.	Municipality
Total Participants	*25*	*27*	*11*	*5*	*2*	*16*	*35*	*17*
Oppose - End to personal production	3	0	5	0	0	1	11	1
Support - End to personal production	10	10	0	0	1	2	5	3
Oppose - End to ID cards	2	4	3	0	0	1	8	1
Support - End to ID cards	0	0	0	0	0	0	0	0
Oppose - End to list of qualifying diseases	1	1	3	0	1	2	0	0
Support - End to list of qualifying diseases	0	0	2	0	0	3	5	0
Oppose - Commercial market for marihuana	0	0	1	0	0	0	2	0
Support - Commercial market for marihuana	5	3	1	0	0	2	7	2
Oppose - Market pricing for marihuana	0	1	0	1	0	1	2	0

Support - Market pricing for marihuana	0	1	0	0	0	1	0	0
Oppose – Courier delivery only	0	1	0	0	0	0	0	0
Support – Courier delivery only	0	1	0	0	0	0	0	0

Civil associations included in the foregoing table tend to oppose the end of personal production based on the belief that this change undermines existing civil rights and does not reflect previous direction provided by Canadian courts. As is evident in the following table, the positions of civil associations in general are quite different from those in other stakeholder organizations. Equally evident is the limited number of positions which institutional and organizational respondents take. Despite 138 responses in total, it is rare for more than three or four to express any given view or opinion.

Table 28.	**Fire Service**	**Police Service**	**Physician**	**Pharmacist**	**Other HCP[2]**	**Health Assoc.**	**Civil Assoc.**	**Municipality**
Total Participants	*25*	*27*	*11*	*5*	*2*	*16*	*35*	*17*
Access to medication must be maintained	0	1	0	0	0	1	0	0
Affordability is challenge for users	1	2	2	1	0	2	**9**	1
MMAR authorizations are too slow	0	1	0	0	0	0	2	0
Commercial products will use chemicals and/or be irradiated	0	0	0	0	0	0	3	1
Commercial product is / will be weak.	0	0	1	0	0	0	1	1
Consultations process is not sincere	0	0	0	0	0	0	0	0
Court decisions are not being respected	0	1	1	0	0	0	**8**	0
Federal government not trustworthy on MMAR	0	0	0	0	0	0	1	0
Changes will encourage crime / black market	0	3	0	0	0	2	1	0
Laws already exist to counter problems in MMAR.	**5**	**4**	**3**	0	0	1	0	1
Changes are intended to service interests of pharmaceutical and agriculture corporations	0	0	0	0	0	0	1	0
Current growers should be "grandfathered"	0	0	0	0	0	0	4	0
Growers have made significant investments.	0	1	0	0	0	0	3	0
Inspection regime should be used to control problems in personal and designated production (rather than phase out)	**2**	**2**	1	0	0	0	5	1
Participants interested in commercial growing.	0	0	0	0	0	0	2	0
Participants interested in learning more.	1	**3**	1	1	0	1	3	1
Scientific guidance on marihuana used as medicine is lacking.	0	**2**	**2**	0	0	**4**	**5**	1

Table 28.	Fire Service	Police Service	Physician	Pharmacist	Other HCP[2]	Health Assoc.	Civil Assoc.	Municipality
Locations of personal production sites should be known to authorities	**12**	**9**	0	0	0	0	**3**	**8**
Personal production creates a security risk	**3**	**2**	0	0	0	0	1	1
Personal production marihuana is illegally diverted	1	**3**	0	0	0	0	1	3
Physicians lack education on MMAR program and medical marihuana	0	**3**	**5**	1	0	**6**	**8**	2
Physicians will not assist patients to apply for authorization	0	0	1	0	0	1	**9**	1
Problems caused by personal production are exaggerated and/or unproven	0	0	2	0	0	0	2	0
Marihuana should have same status as any drug	0	1	0	1	1	1	3	1
Commercial market will not / cannot provide varieties and strains needed	0	1	3	1	0	2	9	0
Low income patients must be subsidized.	1	0	0	0	0	0	1	0
Personal production sites create dangers	10	3	0	0	0	1	1	7
Changes treat users and growers of medical marihuana like criminals	1	0	0	0	0	0	2	0
Marihuana should be legalized or decriminalized.	0	0	1	0	0	0	5	0
Marihuana should be available through pharmacies or dispensaries	0	0	1	0	0	0	5	0
Other health care professionals should be able to authorize use, not only physicians.	0	0	1	0	0	1	3	0
Edible preparations and tinctures should be allowed.	0	0	1	0	0	0	3	0

6.2.2. *Input Provided By Fire Services Officials*

Fire departments are generally very supportive of the proposal to eliminate personal and designated production of marihuana for medical purposes, as they feel these installations pose risks to lives and property. They claim that many growers do not meet local fire or building codes.

Firefighters are also concerned that they are unaware of where personal production is being pursued in the community and are therefore unable to monitor their safety or react appropriately in the case of an emergency. They argue that the location and scope of all new commercial operations should be known to emergency responders in each area. Some also express concern about the standards which will be applied in the case of new commercial growers.

6.2.3. Input Provided By Law Enforcement Officials

Law enforcement officials generally endorse the proposed changes to the MMAR, citing the concerns about safety, security and criminality noted in the government's original announcement. They nonetheless express concerns about the new commercial operations, including the possibility that they will be infiltrated by organized crime and the possibility that couriered packages of marihuana will become a target of theft.

Like fire services, police believe that they should be aware of the location of every new commercial operation, as well as all personal and designated production sites for as long as that practice continues.

There is uncertainty about the decision to eliminate the Health Canada-issued identification card for authorized users, as they expect this may lead to confusion. Police services are anxious to assure that whatever system replaces the ID cards is equally reliable.

The RCMP specifically raises the issue of affordability with regard to commercial marihuana, noting the importance of keeping the price of marihuana for medical purposes well below that of black market marihuana.

6.2.4. Input Provided By Physicians

Eleven individual physicians provided input to the consultations, most of whom could claim direct professional experience in the medical issues at hand. In all cases, physicians generally agree that they (rather than Health Canada) should ideally be the arbiters of whether a patient will be treated with marihuana for medical purposes. However, they note that many physicians are ill-equipped to make these judgements due to the absence of training, prescribing guidance and established science for this medication. They urge Health Canada to follow through on its commitment for further consultation with the profession in advance of removing itself from the authorization process.

There is some unease among physicians that changes to the MMAR will place medication financially beyond the reach of patients who need it.

6.2.5. Input Provided By Pharmacists

Pharmacists provided limited input. They frequently ask questions about the potential role of pharmacies in the distribution of marihuana for medical purposes. There is some concern about the "status" of marihuana as a medication which does not have clear associated prescribing information and scientific literature. Pharmacists further echo the concern of physicians that adequate knowledge does

not yet exist in professional ranks to support these patients and their treatment choices.

6.2.6. *Input Provided By Health Associations*

Health organizations, including several disease groups, judge the proposed changes based on whether or not they will maintain and improve access to marihuana for medical purposes among patients who need this treatment. They are generally most concerned that the MMAR changes will limit or eliminate access for low income people. Their support or opposition to the changes will rest not on questions of civil rights but upon whether the new system serves the medical needs of patients.

6.2.7. *Input Provided By Civil Associations*

A number of civil associations active in the field of cannabis advocacy or civil rights expressed grave concern about the proposed changes to MMAR and specifically the decision to phase out personal and designated production. Their concerns mirror those of users and growers, but they are also more likely to claim that the government is acting in bad faith with regard to the directions provided by Canadian courts on this issue.

Other civil associations tend to represent community associations, real estate or safety associations. They are generally in favour of changes to the MMAR which will limit the possibility of marihuana diversion into the general population and minimize any impact of production on property values.

6.2.8. *Input Provided By Municipalities*

Input from municipalities is generally closely in-line with the input of fire and police services. Often, municipalities write in simple support of submissions by their police or fire services. They are concerned about the safety and security of personal production sites and the degree to which this activity may be infiltrated by criminal elements. They are especially likely to say that they should be aware of the location of every new commercial operation, as well as all personal and designated production sites for as long as that practice continues.

6.3. Form Letters

Multiple copies of two different form letters were received during this consultation. These are identical submissions by different people and are therefore reported

separately from the unique individual responses discussed in earlier chapters. These form letters are not included in the total of 2,214 unique submissions discussed in the previous chapters.

6.3.1. Alternate Proposal for Reform

One letter was in the form of a proposal to reform the MMAR along different lines, authored by the Northern Ontario Compassion Club. The proposal provides specific suggestions for ameliorating eleven specific concerns regarding the current MMAR. The proposal does not respond directly to the proposed changes to MMAR which were the subject of this consultation.

Health Canada received 200 copies of this six page document.

6.3.2. Concerns Regarding Health Canada's Proposed Reforms

A second form letter received by Health Canada during this consultation raised specific concerns with the changes proposed by Health Canada. These were:

- That physicians are not cooperating with the MMAR and the proposals contain no measures to solve this major problem. The letter argues that more health care professions should be able to authorize the use of marihuana for medical purposes.

- That the elimination of personal and designated production is not necessary from a safety perspective and that problems have been exaggerated. Furthermore, such elimination would do harm to individuals who have invested in facilities and the development of specific strains.

- That the elimination of formal identification from the program will increase the problems authorized users already experience due to a lack of awareness among law enforcement officers.

- That permitting only commercial production will result in price increases and a reduction in available strains, effectively preventing authorized patients from obtaining appropriate medication. This view is based partly on the perceived failings of the marihuana currently supplied to Health Canada by a commercial producer.

- That Health Canada should address the current existence of marihuana dispensaries by licensing them within the MMAR system.

- That the proposed reforms to MMAR are in open defiance of the directions previously provided to Health Canada by the courts.

- That Health Canada should revise its proposed changes to respect the court directions and create a working system of access to marihuana for medical purposes.

Health Canada received 38 copies of this message by email.

Appendix A: All Codes and Positions for All Stakeholder Groups

Position	Code[4]	Stakeholder Group													Total instances[3]
		User	Grower	User/ Grower	Citizen[1]	Fire Service	Police Service	Phys-ician	Pharm-acist	Other HCP	Health Assoc.	Civil Assoc.	Munic-ipality	Other	
Total Participants		***409***	***149***	***953***	***557***	***25***	***27***	***11***	***5***	***2***	***16***	***35***	***17***	***8***	***2,214***
Oppose - End to personal production	*1*	139	57	721	219	3	0	5	0	0	1	11	1	0	**1157**
Oppose - End to ID cards	*2*	31	4	33	39	2	4	3	0	0	1	8	1	1	**127**
Oppose - End to list of qualifying diseases	*3*	7	1	4	7	1	1	3	0	1	2	0	0	0	**27**
Oppose - Commercial market for marihuana	*4*	45	22	104	62	0	0	1	0	0	0	2	0	1	**237**
Oppose - Market pricing for marihuana	*5*	35	6	66	43	0	1	0	1	0	1	2	0	0	**155**
Oppose – Courier delivery only	*6*	7	1	15	15	0	1	0	0	0	0	0	0	0	**39**
Support - End to personal production	*7*	6	10	15	22	10	10	0	0	1	2	5	3	0	**84**
Support - End to ID cards	*8*	0	0	0	2	0	0	0	0	0	0	0	0	0	**2**
Support - End to list of qualifying diseases	*9*	13	6	18	13	0	0	2	0	0	3	5	0	0	**60**
Support - Commercial market for marihuana	*10*	6	10	14	27	5	3	1	0	0	2	7	2	0	**77**
Support - Market pricing for marihuana	*11*	0	0	0	2	0	1	0	0	0	1	0	0	0	**4**
Support – Courier delivery only	*12*	0	1	2	0	0	1	0	0	0	0	0	0	0	**4**
Access to medication must be maintained	*13*	19	8	17	7	0	1	0	0	0	1	0	0	1	**54**
Affordability is challenge for users	*14*	190	52	655	181	1	2	2	1	0	2	9	1	0	**1096**
MMAR authorizations are too slow	*15*	49	8	55	17	0	1	0	0	0	0	2	0	0	**132**
Commercial products will use chemicals and/or be irradiated	*16*	48	15	207	31	0	0	0	0	0	0	3	1	0	**305**
Marihuana for medical purposes should be covered by health insurance	*17*	15	1	47	17	0	0	0	0	0	0	0	0	0	**80**
Will disregard elimination of personal and designated production	*18*	10	2	44	10	0	0	0	0	0	0	0	0	0	**66**

Position	Code[4]	Stakeholder Group													Total instances[3]
		User	Grower	User/ Grower	Citizen[1]	Fire Service	Police Service	Phys-ician	Pharm-acist	Other HCP	Health Assoc.	Civil Assoc.	Munic-ipality	Other	
MMAR reauthorization is too frequent / Period should be lengthened.	*19*	15	4	28	5	0	0	0	0	0	0	0	0	1	**52**
Commercial product is / will be weak.	*20*	22	5	66	26	0	0	1	0	0	0	1	1	1	**123**
Consultations process is not sincere	*21*	12	4	27	15	0	0	0	0	0	0	0	0	1	**59**
Court decisions are not being respected	*22*	24	5	53	56	0	1	1	0	0	0	8	0	0	**148**
Federal government not trustworthy on MMAR	*23*	31	4	77	36	0	0	0	0	0	0	1	0	0	**149**
Changes will encourage crime / black market	*24*	58	13	139	66	0	3	0	0	0	2	1	0	2	**284**
Laws already exist to counter problems in MMAR.	*25*	23	15	110	28	5	4	3	0	0	1	0	1	0	**190**
Changes are intended to service interests of pharmaceutical and agriculture corporations	*26*	6	0	35	20	0	0	0	0	0	0	1	0	0	**62**
Current growers should be "grandfathered"	*27*	25	14	72	33	0	0	0	0	0	0	4	0	0	**148**
Growers have made significant investments.	*28*	33	42	253	35	0	1	0	0	0	0	3	0	0	**367**
Inspection regime should be used to control problem in personal and designated production (rather than phase out)	*29*	32	33	165	50	2	2	1	0	0	0	5	1	0	**291**
Participants interested in commercial growing.	*30*	8	41	42	23	0	0	0	0	0	0	2	0	0	**116**
Participants interested in learning more.	*31*	7	11	21	25	1	3	1	1	0	1	3	1	0	**75**
Scientific guidance on marihuana use as medicine if lacking.	*32*	6	3	23	10	0	2	2	0	0	4	5	1	0	**56**
Locations of personal production sites should be known to authorities	*33*	6	6	18	16	12	9	0	0	0	0	3	8	0	**78**
Personal production creates a security risk	*34*	7	1	7	13	3	2	0	0	0	0	1	1	0	**35**
Personal production marihuana is illegally diverted	*35*	6	3	17	17	1	3	0	0	0	0	1	3	0	**51**
Physicians lack education on MMAR program and medical marihuana	*36*	18	3	30	20	0	3	5	1	0	6	8	2	1	**97**
Physicians will not assist patients to apply for authorization	*37*	43	3	47	48	0	0	1	0	0	1	9	1	0	**153**
Problems caused by personal production are exaggerated and/or unproven	*38*	41	9	150	87	0	0	2	0	0	0	2	0	0	**291**

Position	Code[4]	Stakeholder Group													Total instances[3]
		User	Grower	User/ Grower	Citizen[1]	Fire Service	Police Service	Phys-ician	Pharm-acist	Other HCP	Health Assoc.	Civil Assoc.	Munic-ipality	Other	
Growers should be reimbursed for their investments in production	*39*	5	8	56	7	0	0	0	0	0	0	0	0	0	**76**
Marihuana should have same status as any drug	*40*	19	8	35	13	0	1	0	1	1	1	3	1	0	**83**
Commercial market will not / cannot provide varieties and strains needed	*41*	96	33	235	72	0	1	3	1	0	2	9	0	1	**453**
Low income patients must be subsidized.	*42*	11	3	21	17	1	0	0	0	0	0	1	0	0	**54**
Personal production sites create dangers	*43*	1	3	7	13	10	3	0	0	0	1	1	7	0	**46**
Changes treat users and growers of medical marihuana like criminals	*44*	32	17	155	32	1	0	0	0	0	0	2	0	0	**239**
Marihuana should be legalized or decriminalized.	*45*	21	6	34	59	0	0	1	0	0	0	5	0	0	**126**
Marihuana should be available through pharmacies or dispensaries	*46*	17	1	14	24	0	0	1	0	0	0	5	0	0	**62**
Other health care professionals should be able to authorize use, not only physicians.	*47*	9	0	10	21	0	0	1	0	0	1	3	0	0	**45**
Outdoor growing should be allowed.	*48*	4	2	4	3	0	0	0	0	0	0	0	0	0	**13**
Edible preparations and tinctures should be allowed.	*49*	21	2	47	12	0	0	1	0	0	0	3	0	1	**87**
Proposed changes undermine privacy of patient information.	*50*	1	0	5	1	0	0	0	0	0	0	0	0	0	**7**

Notes: 1. Includes all individuals who did not self-identify as belonging to other stakeholder groups. 2. . All occurrences of this position across all stakeholder groups.4. Numerical code for each position.

Appendix B: All Codes and Positions for Users, Growers and Citizens

Percentage results for users and growers **Percentage results for citizens.**	**User only**	**Grower only**	**User/ Grower**	**All Users and Growers**	**Percentage Users and Growers**	**Citizen[1]**	**Percentage Citizens**
Total Participants	**409**	149	953	1511	100%	557	100%
Oppose - End to personal production	139	57	721	917	61%	219	39%
Oppose - End to ID cards	31	4	33	68	5%	39	7%
Oppose - End to list of qualifying diseases	7	1	4	12	1%	7	1%
Oppose - Commercial market for marihuana	45	22	104	171	11%	62	11%
Oppose - Market pricing for marihuana	35	6	66	107	7%	43	8%
Oppose – Courier delivery only	7	1	15	23	2%	15	3%
Support - End to personal production	6	10	15	31	2%	22	4%
Support - End to ID cards	0	0	0	0	0%	2	0%
Support - End to list of qualifying diseases	13	6	18	37	2%	13	2%
Support - Commercial market for marihuana	6	10	14	30	2%	27	5%
Support - Market pricing for marihuana	0	0	0	0	0%	2	0%
Support – Courier delivery only	0	1	2	3	0%	0	0%
Access to medication must be maintained	19	8	17	44	3%	7	1%
Affordability is challenge for users	190	52	655	897	59%	181	32%
MMAR authorizations are too slow	49	8	55	112	7%	17	3%
Commercial products will use chemicals and/or be irradiated	48	15	207	270	18%	31	6%
Marihuana for medical purposes should be covered by health insurance	15	1	47	63	4%	17	3%
Will disregard elimination of personal and designated production	10	2	44	56	4%	10	2%

Percentage results for users and growers **Percentage results for citizens.**	**User only**	**Grower only**	**User/ Grower**	**All Users and Growers**	**Percentage Users and Growers**	**Citizen[1]**	**Percentage Citizens**
MMAR reauthorization is too frequent / Period should be lengthened.	15	4	28	47	3%	5	1%
Commercial product is / will be weak.	22	5	66	93	6%	26	5%
Consultations process is not sincere	12	4	27	43	3%	15	3%
Court decisions are not being respected	24	5	53	82	5%	56	10%
Federal government not trustworthy on MMAR	31	4	77	112	7%	36	6%
Changes will encourage crime / black market	58	13	139	210	14%	66	12%
Laws already exist to counter problems in MMAR.	23	15	110	148	10%	28	5%
Changes are intended to service interests of pharmaceutical and agriculture corporations	6	0	35	41	3%	20	4%
Current growers should be "grandfathered"	25	14	72	111	7%	33	6%
Growers have made significant investments.	33	42	253	328	22%	35	6%
Inspection regime should be used to control problem in personal and designated production (rather than phase out)	32	33	165	230	15%	50	9%
Participants interested in commercial growing.	8	41	42	91	6%	23	4%
Participants interested in learning more.	7	11	21	39	3%	25	4%
Scientific guidance on marihuana use as medicine is lacking.	6	3	23	32	2%	10	2%
Locations of personal production sites should be known to authorities	6	6	18	30	2%	16	3%
Personal production creates a security risk	7	1	7	15	1%	13	2%
Personal production marihuana is illegally diverted	6	3	17	26	2%	17	3%
Physicians lack education on MMAR program and medical marihuana	18	3	30	51	3%	20	4%
Physicians will not assist patients to apply for authorization	43	3	47	93	6%	48	9%
Problems caused by personal production are exaggerated and/or unproven	41	9	150	200	13%	87	16%

Percentage results for users and growers **Percentage results for citizens.**	**User only**	**Grower only**	**User/ Grower**	**All Users and Growers**	**Percentage Users and Growers**	**Citizen[1]**	**Percentage Citizens**
Growers should be reimbursed for their investments in production	5	8	56	69	5%	7	1%
Marihuana should have same status as any drug	19	8	35	62	4%	13	2%
Commercial market will not / cannot provide varieties and strains needed	96	33	235	364	24%	72	13%
Low income patients must be subsidized.	11	3	21	35	2%	17	3%
Personal production sites create dangers	1	3	7	11	1%	13	2%
Changes treat users and growers of medical marihuana like criminals	32	17	155	204	14%	32	6%
Marihuana should be legalized or decriminalized.	21	6	34	61	4%	59	11%
Marihuana should be available through pharmacies or dispensaries	17	1	14	32	2%	24	4%
Other health care professionals should be able to authorize use, not only physicians.	9	0	10	19	1%	21	4%
Outdoor growing should be allowed.	4	2	4	10	1%	3	1%
Edible preparations and tinctures should be allowed.	21	2	47	70	5%	12	2%
Proposed changes undermine privacy of patient information.	1	0	5	6	0%	1	0%

Notes: 1. Includes all individuals who did not self-identify as belonging to other stakeholder groups.

This is **Exhibit "NN"** 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

HEALTH CANADA

Marihuana Medical Access Program Reform

Compassion Clubs and Cannabis Dispensaries Consultation
Morning Meeting Report

September 7, 2011
Delta Vancouver Suites
Vancouver, British Columbia

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1. Background and Introduction

On June 17, 2001, Health Canada (HC) announced improvements to the Marihuana Medical Access Program (the Program or MMAP) which provides access to marihuana for medical purposes for seriously ill Canadians. The impetus of these changes came from concerns about public safety and security and the potential for illicit use which were raised by police and law enforcement, fire officials, physicians, municipalities, and program participants. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep children and communities safe. To this end, Health Canada is launching public consultations on the proposed improvements. A number of stakeholder groups have been invited to these consultations, including Provinces and Territories, municipalities, compassion clubs and cannabis dispensaries, medical associations, law enforcement, fire officials, and other interested parties.

A consultation meeting with compassion clubs and cannabis dispensaries stakeholders was held at the Simon Fraser University's Morris J Wosk Centre for Dialogue, Vancouver on September 7, 2011. In this morning meeting, there were 18 participants representing 18 different organizations.

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and underscored the importance of hearing from the compassion clubs and cannabis dispensaries as they go forward with the proposed changes to the Program. In an effort to reform the Medical Marihuana Program, the government is consulting with the provinces and territories, the medical community and other key stakeholders. She noted there was an online consultation which generated over 2600 submissions.

She explained the objective of the meeting:

- to discuss elements of the proposed program changes and gather feedback from participants.

This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

Jeannine Ritchot, Director, Medical Marihuana Regulatory Reform (MMRR) began by thanking participants for attending and acknowledging that the contribution of ideas by the compassion clubs and cannabis dispensaries would help improve the program and reform the regulations.

Jeannine proceeded to set the stage by giving participants a brief overview of the key elements of the proposed improvements to the MMAP. The office of the MMRR was tasked with reviewing and making proposed changes to the Program. The objective of the proposed improvements is to reduce risks to Canadians and keep communities safe, while improving access for Canadians to the use of marihuana for medical purposes. She noted that the legalization or decriminalization of marihuana is not part of the proposed changes.

Jeannine explained that under the current program individuals see their physician in order to have him/her sign a form supporting their use of marihuana for medical purposes. The patient must then apply to Health Canada for an authorization to possess marihuana for medical purposes. The medical practitioner's form and their choice of supply must accompany the application form. The package is reviewed by Health Canada and appropriate authorizations and licences are issued where approved. These authorizations and licences are reviewed on a yearly basis. The process of obtaining marihuana for medical purposes is cumbersome and complicated.

Jeannine stated that Health Canada is proposing that the first step remain the same, the requirement to consult with a physician, as this is the best place to make a decision about a patient's medical condition. The physician no longer needs to fill out the Health Canada declaration. Another document, yet to be created, would be supplied to the patient by the physician. The individual would submit this document to licensed commercial producers (LCP) in order to obtain marihuana for medical purposes. Health Canada would no longer receive or process applications consequently, a government agency would no longer have access to the sensitive medical records of Canadians. They would no longer be responsible for producing and distributing medical marihuana. Licensed commercial producers would be charged with this responsibility, and Health Canada`s role would be more of a more traditional regulatory role.

After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. They are summarized below.

To the question about who came up with the new regulatory scheme, Health Canada representatives claimed responsibility for bring the decision to move on the new regulatory framework forth. They stated that during the development of the consultation document, a number of groups were consulted, similar groups to those who were invited to these consultation meetings. The Director General said she was responsible for the proposal document; although data was collected through a consultation process, no one from outside HC participated in writing the document.

To the question about having a specific number of regulated marihuana producers in mind, Health Canada responded that there is not set number. They are looking to the consultation discussions for guidance in this area.

To the question concerning support for producers to do research, Health Canada stated that there were no provisions to support research in the proposed Program. They suggested other avenues for research for example, applications could be made through the Canadian Drug and Substances Act (CDSA).

To the concern with the new regulations about how will sick patients be able to afford the product and if there would be compensation for the patients and for the compassion clubs, Health Canada said that cost is one of the areas of concern for licensed commercial producers. They need to hear from stakeholders about what should be in place to prevent costs from increasing.

To the question about the RCMP being unaware of the consultations are taking place, Health Canada informed the group that they are meeting separately with police and RCMP during this consultation process.

To the question about the role and responsibility of the Expert Advisory Committee (EAC), Health Canada said the committee will be comprised of doctors with a background and knowledge of the Program and the use of marihuana for medical purposes. The focus of this Committee is on how to educate and inform doctors about the use of marihuana for medical purposes.

Concerning the inclusion of other forms of marihuana in the new Program, Health Canada confirmed that the current proposal only offers the dried form of marihuana for medical purposes.

To the question about the rationale and timeline for the elimination of the Personal Production Licences (PPLs) and Designated Production Licences (DPL) and the interim plans, Health Canada said the pre-consultation phase revealed that stakeholders had concerns about the safety and security of personal production. In the current regulatory framework, there is no provision for regulatory zoning to allow for personal production.

To the question requesting Health Canada's help with getting a global amnesty for those legal growers who are charged with possession of marihuana, Health Canada stated that the current consultations are about the Consultation Document only and not about the legalization of marihuana.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the impact of the changes would have on their clients, the proposed changes they liked and those they had concerns about. A number of important topics were addressed in each discussion. The discussions were summarized and synthesized below.

> *Focus Question: What do you like about the proposed improvements to the Program?*

Participants liked a number of aspects contained in the proposal including a simplified process for access, the establishment of the EAC, education of doctors, and the recognition of the need for multiple strains, transferring production to the private sector, and the mail order option for delivery. The discussions which took place in response to the question above are summarized below. The responses have been themed for ease of comprehension.

✓ *Transferring the responsibility of administering the Program.*
- The government getting out of the way of the Program's improvement was seen as positive.

✓ *A more simplified process for access to medical marihuana.*
- Allowing doctors to directly "prescribe" marihuana for medical purposes was applauded as a major step forward.
- A primary benefit in the proposal is the removal of the two categories for eligibility; this minimizes the declarations needed from the doctors.

- One problem is that doctors are allowed to refuse to recommend this medication. Marihuana as a treatment needs to be supported by stakeholder groups (e.g. medical associations) as a viable medication option in order to dispel stigma.

✓ *Education of doctors on the use of medical marihuana, and the role of the EAC.*
- Establishing the EAC and their educative role is an important improvement to the Program; however, this is a long-term plan. In the meantime, interim plans need to be established for the emerging needs of the doctors.

Health Canada question: Do you see the use of a needs assessment for doctors?
Response: A needs assessment would be an excellent first step to address a plan for the emerging needs of doctors.

✓ *Moving toward what the some perceived as a more dispensary-like model for medical marihuana, was applauded.*
- It was agreed that streamlining the process of dispensing would work well from an industry perspective. It takes it into account the industrial agricultural aspect which will contribute to improving the Program.

✓ *Acknowledging the need for multiple strains of marihuana for medical purposes.*
- Recognizing that different strains of marihuana are needed for effective treatment is a positive step forward.
- It is a good idea to have licensed commercial producers growing multiple strains.

✓ *Transferring production to the private sector.*
- Allowing the private sector to produce marihuana for medical purposes will open up the competition. This will help regulate the price of the product.

✓ *Positive aspects of mail order.*
- Mail order is viable; however, it should not be the only option.
- Some producers said they did not have a problem with mailing their product and have never had a package go missing.
- Once in the system, patients pre-order quickly so they are never out of product. It is traceable.
- For the different strains, free samples are sent so patients can find the treatment that is best for them.
- For security reasons, it is important to package the product properly. *Suggestion:* Regulations or recommendations for packaging would be most helpful.

Focus Question: What are your concerns regarding the proposed change to the Program?

A number of key issues were identified by the group. These included the limitation of mail order dispensing, the absence of extracts as a treatment option, the disproportionate focus on security rather than patient needs, the elimination of designated licences, and the stigma associated with the use of medical marihuana. The discussion which took place in response to the question above is themed and summarized in the following bullets.

✓ *The limitations of mail order dispensing as the only option.*
- Mail order is not a familiar model of dispensing medicine.
- The community-based dispensary model is a more effective way to distribute marihuana for medical purposes.
- Dispensing by mail will take too long.
- For this model, payment is required up front; it does not allow the patient to try out the product for fit.
- Mail order only for rural clients presents a problem. Regional production and distribution is important for these areas.
- Currently, some internet based dispensaries refer their clients to compassion clubs because they can offer advice and education.
- Exclusive mail order will limit access to vulnerable populations. The mail order system would not allow for critical one-on-one services offered to those who are most vulnerable, e.g. homeless.

✓ *Exclusion of marihuana extracts as a possibility for treatment.*
- Multiple forms of marihuana like oils and edible products should be included in the proposal.

✓ *The strong focus on safety rather than patient's needs is disturbing.*
- Discussion about security concerns are dramatically overblown and need to be tempered with reality. The sale of medical marihuana is not much different than the sale of wine and liquor. *Suggestion:* A wine industry could be a model for regulating the industry.
- Individual producers of medical marihuana have a vested interest in making their product safe. Security is more of an issue for dispensers rather than the individual producer.

✓ *Elimination of designated licenses (PPL and DPL) and lack of accessibility to and affordability of marihuana for medical purposes.*
- There was concern about the costs associated with those who have invested in production equipment. Participants wanted to know if there would be a plan for remuneration for grow-op equipment already purchased by those with PUPLs and DPPLs. *Suggestion:* Create a new classification and provide subsidies to those who could produce the medicine for their own needs. Alternately, the licenses could grandfathered so these people do not lose their investment.
- Concerning grandfathering, it is a fundamental right for patients to grow their own medication; these rights need to be preserved. Caution: Court cases could ensue because patients would be denied access to medication.

✓ *The stigma attached to growing and using medical cannabis.*
- A common theme identified was the stigma around cannabis. Participants recognized that Health Canada would not promote marihuana for medical purposes, however, they could address the shame and indignity media campaigns and the police have brought to its use. This type of rhetoric discredits the discussion and the topic of marihuana for medical purposes. It is paramount to change this attitude.
- Patients are afraid to talk to the compassion clubs since they were busted. They fear talking to their doctors about their need for this medication. The stigmatization limits accessibility and is real and harmful.

- The problem remains that the physicians have discomfort with this type of therapy. It was suggested that the signing authorities for "prescription" be broadened to include other health professionals, e.g. naturopaths, nurse practitioners, pharmacists, etc. *Caution:* Most of the patients have very complicated symptoms that other health professionals may not be able to manage effectively.

Question: Would PUPL and DPPL growers be willing to divulge their medication condition and grow-op status to the authorities and municipalities?

Response: There is a deep-seated reluctance to divulge such information to municipalities. It would be difficult for municipalities to enforce regulatory by-laws. In the final analysis, people need to be given the responsibility and trusted to protect themselves.

4. Products and services offered by Compassion Clubs and Cannabis Dispensaries

In order to gain an understanding of medical marihuana products and services being offered in compassion clubs and cannabis dispensaries, the group were asked to share information on a number of key questions relating to their operations, products, and security measures. The following focus questions were posed.

- *Discussion themes:*
  - *a) Compassion club and cannabis dispensary business models and services.*
  - *b) Documentation required from clientele.*
  - *c) Products: cultivation and quality control.*
  - d) *Security.*

Based on their practical experience, participants shared their ideas and made recommendations on the discussion themes. A number of key themes emerged including creating an inclusive marketplace, making marihuana for medical purposes affordable, documentation requirements, regulating commercial growers, and unreasonable and reasonable security requirements. This information was captured and is summarized below.

a. *Compassion club and cannabis dispensary business models and services.*

✓ *Make commercial production doable for small scale producers; create a marketplace.*

- It is important to have regulations that ensure product safety as a main concern.
- Inclusivity of growers is the key to success; smaller producers may produce only one strain.
- Health Canada needs to create regulations for testing; ones that have a set of criteria that is possible to meet, even for smaller producers.
- Compile and publish a list of labs that producers could utilize; this would improve the quality of the product (not viable for smaller producers to have their own labs).
- Creating a marketplace with a compassionate care distinction was emphasized; one that would offer auxiliary compassionate services to patients. These family community models need to be included in the Program.
- Increasing the flexibility in the zoning regulations would help increase the number of producers and cut costs.
- Opportunities should be opened up to rural residential properties; this would allow of agricultural producers not just industrial commercial growers.

✓ *Keeping costs down and making marihuana for medical purposes more affordable in the new Program.*
- Put a coupon system in place to keep costs low. Patients who are on disability or welfare could use this system to purchase their medication. It would subsidize the poor. Compassion clubs would not be working with cash so it would cut down on the risk of theft. Some compassion clubs offer their product for free for those who cannot afford it.
- Create a continuum that includes community based producers and commercial producers; these would operate under the laws of supply and demand and would help keep costs down.
- Keep production sites out of residential areas. It is best to have the sites in the agriculture and commercial sectors. It was suggested that production be turned over to farmers to reduce costs.
- The proposal requirement for security recommends growing indoors; this will add to costs.
- Utilizing the sun is a major factor in reducing production costs and is a more "green" method of growing marihuana.
- At Prairie Plant Systems (PPS), the extensive processing (ex: radiation) required is harmful and costly.
- Another cost driver is taxation. HST/ PST are supposed to be charged on marihuana and this will raise the price.

Health Canada question: What if production is done organically?

Response: Participants identified the main problem with organic growing of marihuana are moulds which are a result of the irrigation techniques. Proper growing methods and regular inspections would help regulate this issue.

b. <u>*Documentation required.*</u>

✓ *Documentation needed and the information included on the documents.*
- Primarily, compassion clubs and cannabis distributors require that a diagnosis is included on the documentation.
- It was recommended that a system be put in place where the "prescription" is time limited so the patient can be monitored.
- A *harm reduction tactic* noted was to make sure the patient informs their doctor that they are using marihuana for medical purposes; this establishes a good doctor-patient relationship and allows for a monitoring of other more complex conditions the patient may have.
- The least amount of declarations needed, the easier it is for the patient to have access to the medication.
- Doctors' lack of knowledge about the impact and effects of marihuana for medical purposes makes them reluctant to recommend this course of treatment; it is a "culture of reluctance".
- Also, the current Health Canada forms package is time consuming to complete and some doctors are unwilling to take the time to fill them out.
- It was suggested that doctors have a designation as a "cannabologist" – a sub-specialty or certification that would demonstrate their knowledge and proficiency in the use of medical marihuana.

✓ *Identification system for medical marihuana users.*
- Currently, patients have to carry their authorization to possess with them. There needs to be an alternative method coupled with education.
- Using a card system was generally supported as an effective way of identifying patients who are licensed to use marihuana for medical purposes.
- Police are trained on cards, so a code on the driver's license was suggested.

c. <u>*Products: cultivation and quality control.*</u>

✓ *Regulation and size of operation for commercial growers.*
- A brewery system was proposed for regulation of the industry. Keeping a legal supply and accessibility would make the costs go down.
- There should be a common set of minimum standards with a graduated scheme of security requirements, similar to those in place for research into cannabis. The gradated scheme would be from personal to "mega" producers.
- Regulations should not be based on the number of plants as this is not an effective way to control the industry. *Suggestion:* It was recommended to use wattage, square footage and canopy size when regulating production of marihuana, rather than number of plants.
- Health Canada noted that enforcing the regulations around liquor and tobacco at the retail level is done by the provinces.

d. Security

✓ *Reasonable requirements for security.*
- *For growing outdoors:*
  - Ensure the production facility is not visible from road or outside of the property.
  - Those growing the marihuana are taking the risk.
    - For the individual who is growing the marihuana, they have a vested interest in security because if someone steals their plant, they are losing their medication – possibly for the whole year.
    - For the new licensed, they risk losing their business investment.
- *One participant said the fire chiefs in his area recommended the following safety measures for PPL and DPL growers:*
  - Require an alarm system.
  - Have a floor plan with clear exits indicated.
  - Let fire know the location of the electrical rooms.
  - To the suggestion about sharing information like floor plans and personal information. Personal grower's reluctance to divulge personal information about their condition and their grow-op.
  - Note: It is difficult for the municipality to inspect whether personal growers are abiding by the by-laws.

✓ *Unreasonable requirements for security for growing marihuana and cost considerations.*
- Massive concrete bunkers to grow marihuana are unreasonable and can increase costs; the product can grow in a warehouse with a decent security system.
- Pharmacies store dangerous substances without difficulties. Consider the models that are already exist for securing controlled substances.
- Re-categorizing marihuana as a medicine rather than a dangerous substance would help with keeping security costs reasonable.

✓ *Risk of diversion.*
- Consider the guidelines enforced for tobacco to reduce the risk of diversion.

One member of the group summarized the five (5) primary concerns brought up during the discussions. A number of hands were raised and showed support of the following declarations:
- There should be no phasing out of personal or designated-person production.
- Any commercial licensing scheme should be reasonable for entering marketplace.
- Community based organizations should be licensed and regulated.

- We should expand the range of health care professionals who can support access to marihuana for medical purposes.
- Employ a method of identification so authorized users will not be harassed.

After the discussions, there were some further questions and comments. These are summarized below.

To the question regarding the tendering process for licensed commercial producers, Health Canada said this would be done through MERX. The criteria have yet to be established.

To the question about regulating the strains, Health Canada stated that it will be up to the producers to indicate the contents on the package; they will assume the liability.

5. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

HEALTH CANADA

Marihuana Medical Access Program Reform

Compassion Clubs and Cannabis Dispensaries Consultation
Afternoon Meeting Report

September 7, 2011
Simon Fraser University
Morris J Wosk Centre for Dialogue
Vancouver, British Columbia

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A consultation meeting with compassion clubs and cannabis dispensaries stakeholders was held at the Simon Fraser University Morris J Wosk Centre for Dialogue, Vancouver on the afternoon of September 7, 2011. There were 11 participants in the meeting representing 11 organizations.

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and underscored the importance of hearing from the compassion clubs and cannabis dispensaries as they go forward with the proposed changes to the Program. In an effort to reform the Medical Marihuana Program, the government is consulting with the provinces and territories, the medical community and other key stakeholders. She noted there was an online consultation generated over 2600 submissions.

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This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

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Jeannine explained that under the current program individuals see their physician in order to have him/her sign a form supporting their use of marihuana for medical purposes. The patient must then apply to Health Canada for an authorization to possess marihuana for medical purposes. The medical practitioner's form and their choice of supply must accompany the application form. The package is reviewed by Health Canada and appropriate authorizations and licences are issued where approved. These authorizations and licences are reviewed on a yearly basis. The process of obtaining marihuana for medical purposes is cumbersome and complicated.

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After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. They are summarized below.

To the question about broadening the health professionals who could support/"prescribe" the use of marihuana for medical purposes, Health Canada representatives acknowledged that this question had come up with the other compassion clubs. They assured the group that doctors and other health care professionals are being consulted on this very issue.

To the concern about the lack of consultation with patients, Health Canada said there was a 45-day period during which people had a chance to respond to the Consultation Document. The resounding majority of email responses were from patients. Also, in an effort to provide an opportunity to contribute each of the consultation meetings has included patient groups. Health Canada asked if there were other patient advocate groups they could add to their lists. Participants hoped that in the near future, patients would be consulted directly because they are a key stakeholder group. They requested a follow-up on invitations and an extension of the timeline to give people a chance to give a response.

To the question about the timelines attached to remaining consultation and the proposed changes in the Program, Health Canada described the next few months as busy ones which will lead up to the next phase of the regulatory process. A draft of the regulations will be created and published in Canada Gazette 1, late 2012 or early 2013. The goal is to have the new program in place by 2014.

To the question about whether the information capture from consultations and submissions will be made public, Health Canada stated that an overview summary of the information would be published on their website. As for the roughly 2700 email submissions, analysis is currently underway. Participants were concerned that some of the signed forms were collapsed into one (1) submission; these cases need to reflect the weight of the many names attached to them. It was confirmed that stakeholder group invites included the provinces, fire, and law enforcement, physicians, Canadian Medical Association (CMA), the Colleges of Physicians and Surgeons, among others.

On the concern about the biggest vulnerability being cost, participants suggested that Health Canada request that the provinces cover the cost of marihuana for medical purposes as they do for other medications. Health Canada confirmed they are in discussions with the provinces and that there are a diversity of views on the issue.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the proposed changes to the Program that they liked, and those they had concerns about. A number of important topics were addressed in each discussion. Participant's feedback were summarized and synthesized.

> ✦ *Focus Questions: What do you like about the proposed improvements to the Program?*

Participants welcomed number of aspects of the proposed changes to the Program, such as the inclusion of compassion clubs and cannabis dispensaries in the consultations, the redesign of the Program, a streamlined access process, the recognition of strain diversity, and the creation of an Expert Advisory Committee for education. The discussions which took place in response to the question above are summarized below. The responses have been themed for ease of comprehension.

✓ *Inclusion in the consultation process was much appreciated.*
- Participants welcomed the opportunity to provide face-to-face feedback on the proposed changes to the Program. They did note that it is difficult to take part in a consultation process when the dispensaries are under legal threat.

✓ *The redesign of the Program.*
- The concept of decentralization to remove Health Canada from the registration, production and distribution process was acknowledged as a significant step forward.

✓ *A simplified process for accessing marihuana for medical purposes. .*
- Removal of the federal approval process was supported by many in the group.
- The new role for physicians was applauded. The simple doctor's recommendation requirement and the elimination of the 33 page Health Canada document was seen as expedient. Other programs (in the U.S.) have a two page application form.

- The long Health Canada application form is confusing and some patients have paid costs up to $400. to have it interpreted and filled out.

✓ *Recognition of the importance of the diversity of multiple strains.*
- Including multiple strain production is a key upgrade to the Program.
- Strain selection is considered a real benefit for patients.

✓ *The creation of an Expert Advisory Committee (EAC).*
- The proposal to create an EAC is a significant step forward; even practitioners have difficulty in interpreting the long Health Canada form and understanding the information that is pertinent.
- One group commented that it had compiled a physician's manual on recommendations for medical marihuana usage.

Health Canada question: It was suggested that pilots may help increase understanding on how the changes to the Program would work. Would this group support pilot projects? (Caveat: providing Health Canada could secure the authority to conduct them.)

Response: The pilot project model was supported by participants. They were grateful to see the government demonstrating seriousness about collecting data. However, participation in a pilot project would be difficult for compassion clubs because of the legal issues. One of the barriers to participation in this pilot program is the inadequate Health Canada verification system for authorized individuals; it is difficult and time consuming for the RCMP to perform checks on licence holders.

✓ *Focus Question: Do you have concerns regarding the proposed changes? What are your concerns? Why? What suggestions for improvement would you make?*

A number of important concerns were raised by participants including the validity of concerns about the Program, stigmatization of marihuana for medical purposes, miscommunication with authorities about authorizations to possess, removing PPLs and DPLs, the composition of the Expert Advisory Committee, the potential elimination of community-based dispensaries, and expanding the list of authorized people to support/ "prescribe". The results of these deliberations are summarized in the following bullets:

✓ *The validity of the key concerns which caused a change in the Program.*
- The first five concerns in the Consultation Document are not about the patient, but come from the police, CMA and others, and have nothing to do with patient access. Some issues are not valid and need to be weighted as such, for example, other pharmaceutical opiates pose bigger risks, home invasion is not exclusive to marihuana for medical purposes, fire and health and safety concerns are overblown.
- The Program should be patient focused and ensure access to those with the greatest need.

✓ *Stigmatization of compassion clubs and of the use of marihuana for medical purposes.*
- When Health Canada makes statements about the compassion clubs being illegal, it stigmatizes their effectiveness and makes patients reluctant to seek help from them.
- One of the clubs engaged a medical advisor and submitted a 10-page report to the College of Physicians that supports the effectiveness of marihuana, however, it was rejected.
- These types of biases send mixed messages that contradict the use of marihuana as a viable medication option.

✓ *Miscommunication with authorities' vis-à-vis authorized possession.*
- RCMP cannot confirm if a person is authorized to possess medical marihuana or not. As a result, innocent patients are being victimized. *One suggestion* on dealing with this miscommunication is to proactively inform the RCMP of the people who have valid authorizations and licenses. The reality is that some detachments will listen, and some will not.

✓ *Removing Personal Production Licenses (PPL) and Designated Production Licenses (DPL).*
- Many people with a PPL have invested a lot of time and money into their productions. Some have a bill of up to $80,000, and some patients have gone into debt. Their medicine is now free. If this eliminated you will have civil law suits.
- Rising costs is a huge issue when considering the removal of PPL and DPL; continuing this licensing is an important option that could be regulated.
- The message relayed by the group was "don't throw out the old".

✓ *The composition of the Expert Advisory Committee.*
- Participants supported the creation of the advisory committee but were concerned about its make-up. They recommended a balanced representation of patients, physicians, and experts on the topic of medical marihuana use (not necessarily the doctors).

✓ *Potential elimination of the community-based system of medical marihuana distribution centers (compassion clubs and cannabis dispensaries).*
- Participants considered this result as a step backward that would have serious implications. Community based models are a helpful system that ensures safe access, education, and monitoring of patients.

✓ *Allow other health professionals to support/"prescribe" marihuana for medical use.*
- It was suggested that other health professionals be allowed to recommend marihuana for medical purposes as a treatment. Some of these would include nurse practitioners, naturopaths, herbalists (when accredited), chiropractors, and pharmacists.

Suggestion: Regulation should be done through the province. The model is there through the Methadone Program.

Response: Health Canada commented that there are issues with this program as a model; not everyone has access. Doctors have to join the Program and some do not.

Health Canada comment: If patients are relying on Provinces and Territories (PT) for cost coverage for medicinal marihuana, there could be a problem in identifying them when they cross PT boundaries.

Suggestions:
- Create a centralized dispensary system that buys from licensed producers could be a solution to tracking medical marihuana authorizations across PT boundaries. This would be a "buy local" system.
- If the provinces are unwilling to include marihuana for medical purposes in their health insurance, the subsidy issue could be tackled by offering a deduction on the income tax.

4. Products and services offered by Compassion Clubs and Cannabis Dispensaries

In order to gain an understanding of medical marihuana products and services being offered in compassion clubs and cannabis dispensaries, the group were asked to share information on a number of key questions relating to their operations, products, and security measures. The following focus areas were posed.

- *Discussion themes:*
  - a) *Compassion club and cannabis dispensary business models and services.*
  - b) *Documentation required from clientele.*
  - c) *Products: cultivation and quality control.*
  - d) *Security.*

Based on their practical experience, participants shared their ideas and made recommendations on the discussion themes. A number of key themes emerged including the community-based model as intermediary, a balance of non-profit and profit dispensaries, dispensing marihuana by mail, the benefit and economy of dispensaries, and cost cutting measure; participants offered a number of models for consideration. Reasonable minimum product standards were discussed, along with other inspection options. Creating an identification system and concerns about diversion were also addressed. This information was captured and is summarized below.

a. *Compassion club and cannabis dispensary business models and services.*

✓ *The community-based model operates like a middle person and can broker between the patient and the producer.*
- Dispensaries could procure strains from different producers for patient use. This method cuts through trial and error by allowing patients to try different products that would suit their needs. It also provides a tracking method.
- Mail order only gives access to some unknown organization and this lack of support can be intimidating for some. In the community-based model, people can learn how to use the product. Dispensary-like entities created do not have to be called compassion clubs, but their activities should be similar.
- Community-based models could be regulated, as are similar programs in the U.S. in Oregon and Rhode Island.

✓ *Non-profit dispensaries versus for profit dispensaries.*
- Not-for-profit dispensaries buy medical marihuana to benefit their patients. The selection shows up on a menu of 8 to 10 strains for treatment.
- The profit focus of for profit dispensaries could drive abuses.

✓ *Limiting the number of dispensaries.*
- Participants thought that regulating the number of dispensaries is unnecessary. The market would self-regulate; those who provide a quality product will flourish.

✓ *Dispensing medical marihuana through the mail.*
- No other medicine is dispensed this way.
- Cannabis could be accessible through pharmacies; however, the community based model is an incredibly important part of the system.

- Some areas have had a big issue with theft when shipped through the mail. Having thousands of small packages going through the mail is more risky than having one large shipment going to a dispensary.

✓ *The benefits of the community-based dispensary models:*
- Considerable time is spent (90 minutes in some cases) reviewing the medical history of the patients; this is an effective harm reduction approach. When people are sick, it is more helpful to have the one-on-one interactions.
- Patients are given a full education on safe use of marihuana for medical purposes. A significant trend observed in the compassion clubs is that more patients are seniors. This demographic requires a lot of education.
- Non-smoking strains are another advantage offered by dispensaries.
- Dispensaries can help vulnerable demographics and are able to make appropriate referrals for them.
- Participants believed that dispensaries can fill the gap. Currently, some doctors refer patients to dispensaries because they are educators and the program works.

✓ *The economy of dispensaries.*
- Dispensaries can act as an intermediary between the purchaser and the grower.
- Patients can "shop" for different strains instead of engaging in a one-on-one relationship with a commercial producer. This amalgamation would allow for better competition and lower prices.
- It is more efficient and less costly to go to "shop" in one place for many products than it is to go to each individual producer for one product.
- The end cost of the product will be higher if you order and pay per shipment than if there is face-to-face buying.
- Records are kept by dispensaries and information on dosage and tincture is readily available.
- Some dispensaries charge a $15.00 membership fee, some do not.

✓ *The benefit of competition and multiple models.*
- Competition is needed. Many agreed that it is important to have more than one growing/distributing model operating for medical marihuana, e.g. for profit and not for profit.
- Having for-profit production as the only production model is rife with problems that will escalate prices.
- A suggested fee was $5.00 gram for the product and $1.00 dispensary fee.

✓ *Keeping costs down.*
- In the non-profit organizations, the members demand and get transparency. If the costs are too high, members can vote out the administration so there is a direct impact and accountability.
- Developing a relationship between the producers and the members helps keep costs lower. Some growers will give away free product to lower income patients.
- All the dispensaries would like to cut down costs. One way to make this happen is through regulation; it was predicted that the costs for producing marihuana for medical purposes would decrease by 50% if it is regulated.

The following models were offered by participants:

✓ *A community based dispensery that operates on a for profit basis.*
- They contract with growers to grow specifically for them and produce at below black market prices.
- Their model does well in the community and is competitive.
- The concern is that some compassion clubs are too big and their costs are high, therefore their prices are higher. It is important to keep prices affordable.

✓ *Another model offered was similar the previous one, except it was more streamlined.*
- There is no drop-in center; patients are consulted by appointment only.

- The model works remarkably well.

✓ *Another non-profit distribution center characterized themselves as values based organization operating since 1999.*
- Their focus is on maximum care for patients, and they seek to meet the best standards of product.
- The organization offers 10 types of treatments at $5.00 a gram; the actual costs are subsidized.
- Additionally, acupuncture, rakki, yoga, infrared sauna, and other health services are available in their health center.
- They endorse the compassion clubs as being the appropriate body to consult in order to establish a set of standards for marihuana production that could apply across the country.
- They presented a number of letters from patients attesting to the satisfaction individuals have with the dispensary services.

✓ The "social enterprise" was another for profit model presented.
- Running as a business, this is a model that turns its profits into social value.
- The price of a gram is capped at $9.00 a gram, and they also offer subsidized medicine.
- Participants saw room for many models in the new marketplace.
- They are exclusive with 30 compassionate cultivators which allows them to serve the needs of their clients.
- They have a Point-of-sale system that allows them to track sales and make notations in individual patient's files – this allows for individual care and follow-up.
- They noted that it is important to open up the lines of communication; 80-90% of dispensaries want to do a good job and want to solve the issue of variance.

b. *Documentation required.*

✓ *Documentation requirements.*
- The intake process should be clear and efficient.
- Maintaining open communication with doctors is important.
- One organization said their intake process parallels that of Health Canada's.

c. *Products: cultivation and quality control.*

✓ *Reasonable minimum standards.*
- There are regulations for cultivation and quality control recommended in the Good Manufacturing Practices (GMP) Health Canada guidance document. This could be a starting point that will help ensure the quality and safety of the product.
- Some organizations are regulating their own market without regulation.
- There is a need for guidelines and regulations as some organization are operating without them.
- Any well run dispensaries are operating with their own guidelines and standards (some use the WHO as a guide).
- Input on the regulations need to come of all stakeholder groups.
- Addressing the stigma in the regulations is an important consideration.
- It could be stipulated that larger designated producers (five or more patients) could pay for the audit.
- Square footage and wattage regulation is an effective and reasonable way to standardize production.

✓ *Organic production.*
- Participants encouraged the support of organic production of marihuana for medical purposes.

✓ *Other inspection options.*
- It was suggested that Provincial inspectors could appropriate inspection responsibilities.
- Electrical and safety inspection could be handled by municipalities.

- Caution: if municipalities to do inspections (e.g. fire) it is important for them to be trained for confidentiality; this is a particular problem with small communities.

✓ *Responsibilities of the smaller regional models.*
- They will produce it, label it and the patients can choose the product that best meets their needs.

✓ *Doing research on the effects of medical marihuana.*
- Providing an avenue to allow for research would help contribute to the product quality.

d. <u>*Security.*</u>

✓ *Create an identification system.*
- For safety and security purposes, it is important to patients to have legal proof that they can possess marihuana for medical purposes.
- There is a need to centralized identification system because the current card system is not working.
- *Suggestion:* Use a prescription bottle for identification.

✓ *Problem of diversion of marihuana for medical purposes.*
- Regional growers/distributors do not have the problem with security, the costs of transportation, and the risk involved in mail. This may reduce the problems with diversion.

✓ *Undue concern about security – the fear factor - is problematic.*
- Discuss this issue with law enforcement in an effort to reduce fear, anxiety and lack of trust. Secrecy and shame makes people/patients vulnerable.
- Ensure there are alarm systems.
- Security should be commensurate with any other medication.
- Security measures need to be reasonable.
- Avoid having diversion as being the main driver of the design.

Health Canada Question: Clearly there is a concern in the community about PPL and abuse of the product. What do we do about people who are abusing the Program?

Response: Diversion needs to be put into perspective and not overblown. There is abuse – patients are abused by growers. The patients are the victims. In response to Health Canada's enquiry, the group suggested that according to their estimate, there are about 20 to 30 thousand members using marihuana for medical purposes. Considering the size of the illegal market, this number is a "tiny drop in the bucket".

✓ *Other concerns and suggestions:*
- Risk of arrest for staffs is real and needs to be addressed.
- End the legal contradiction. Recognize the compassion clubs as a resource that could provide credibility, the loyalty of its patients.
- Open up the program to the store-front options where they could offer wholesale catalogs to the retailers; this will promote competition and keep the price of the product reasonable.
- Dispensers have wanted to open businesses.

One member of the group brought up seven (7) declarations for the group to consider. A number of hands were raised in support of the following declarations:

1. Be it so moved that patients should be considered the primary stakeholders of the Marihuana Medical Access Regulations, and involved in any and all public engagement regarding potential changes to the federal medical cannabis programme and all associated policies and practices.
2. Be it so moved that removing the option for patients to produce their own medicine is contrary to both the wishes and well-established constitutional rights of Canada's authorized patient population.

3. Be it so moved that Health Canada will work with the Provincial Health Authorities to ensure cost-coverage for cannabis for low-income patients, as has been proposed in recent motions by the Federation of Canadian Municipalities and the Union of British Columbia Municipalities.
4. Be it so moved that Health Canada will work with individual dispensaries and representative organizations like the Canadian Association of Medical Cannabis Dispensaries to develop regulations that further legalize and legitimize community-based, patient-centered access strategies, and to better integrate these facilities into the federal medical cannabis access programme.
5. Be it so moved that Health Canada will develop a cultivation scheme that includes multiple production licenses in order to increase options for patients and offer opportunities to benefit from the extensive expertise of Canada cannabis production community.
6. Be it so moved that Health Canada will work in cooperation with Provincial Health Authorities to establish a system of inspections for personal production facilities that will ensure the safety of individual and communities be cost-neutral and authorized patients.
7. Be it so moved that Health Canada will develop a production strategy that includes multiple commercial licenses with clear guidelines for safety, security, transparency and accountability in order to meet the needs of patients who cannot or choose not to produce their own medication.

5. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

HEALTH CANADA

Marihuana Medical Access Program Reform

Compassion Clubs and Cannabis Dispensaries Consultation
Morning Meeting Report

September 15, 2011
Toronto Airport Hotel
Humber Room
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1. Background and Introduction

On June 17, 2001, Health Canada (HC) announced improvements to the Marihuana Medical Access Program (the Program or MMAP) which provides access to marihuana for medical purposes for seriously ill Canadians. The impetus of these changes came from concerns about public safety and security and the potential for illicit use which were raised by police and law enforcement, fire officials, physicians, municipalities, and program participants. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep children and communities safe. To this end, Health Canada is launching public consultations on the proposed improvements. A number of stakeholder groups have been invited to these consultations, including Provinces and Territories, municipalities, compassion clubs and cannabis dispensaries, medical associations, law enforcement, fire officials, and other interested parties.

A consultation meeting with compassion clubs and cannabis dispensaries stakeholders was held at the Toronto Airport Hotel, Toronto, Ontario on September 15, 2011. In this meeting, there were 17 participants representing 17 different organizations.

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and underscored the importance of hearing from the compassion clubs and cannabis dispensaries as they go forward with the proposed changes to the Program. In an effort to reform the Medical Marihuana Program, the government is consulting with the provinces and territories, the medical community and other key stakeholders. She noted there was an online consultation which generated over 2600 submissions.

She explained the objective of the meeting:

- to discuss elements of the proposed program changes and gather feedback from participants.

This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

Jeannine Ritchot, Director, Medical Marihuana Regulatory Reform (MMRR) began by thanking participants for attending and acknowledging that the contribution of ideas by the compassion clubs and cannabis dispensaries would help improve the program and reform the regulations.

Jeannine proceeded to set the stage by giving participants a brief overview of the key elements of the proposed improvements to the MMAP. The office of the MMRR was tasked with reviewing and making proposed changes to the Program. The objective of the proposed improvements is to reduce risks to Canadians and keep communities safe, while improving access for Canadians to the use of marihuana for medical purposes. She noted that the legalization or decriminalization of marihuana is not part of the proposed changes.

Jeannine explained that under the current program individuals see their physician in order to have him/her sign a form supporting their use of marihuana for medical purposes. The patient must then apply to Health Canada for an authorization to possess marihuana for medical purposes. The medical practitioner's form and their choice of supply must accompany the application form. The package is reviewed by Health Canada and appropriate authorizations and licences are issued where approved. These authorizations and licences are reviewed on a yearly basis. The process of obtaining marihuana for medical purposes is cumbersome and complicated.

Jeannine stated that Health Canada is proposing that the first step remain the same, the requirement to consult with a physician, as this is the best place to make a decision about a patient's medical condition. The physician no longer needs to fill out the Health Canada declaration. Another document, yet to be created, would be supplied to the patient by the physician. The individual would submit this document to licensed commercial producers (LCPs) in order to obtain marihuana for medical purposes. Health Canada would no longer receive or process applications consequently, a government agency would no longer have access to the sensitive medical records of Canadians. They would no longer be responsible for producing and distributing medical marihuana. Licensed commercial producers would be charged with this responsibility, and Health Canada`s role would be more of a more traditional regulatory one.

After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. They are summarized below.

To the concern expressed about the future to the Program, and the legitimacy of the consultation process Health Canada responded they have tried to be as inclusive as possible in the consultation process, and have set up separate sessions in different regions in order to achieve this.

To the concern about the expected pricing of medical marihuana under the new Program, and possible coverage under health insurance plans, Health Canada stated that according to the Proposal, the pricing would be set by the market place. Coverage under health insurance plans is a provincial and territorial matter and Health Canada could not speak to it. The provinces are stakeholder groups invited to the consultations, and will be engaged in the discussions about the Proposal.

To the question about educating the client on medical marihuana dosage, strain efficacy and side effects, Health Canada said offering ancillary services would be the responsibility of the licenced commercial producers.

To the question about the source of the seeds and if they will be controlled and radiated, Health Canada said that these were some of the details they wished to examine and they invited participants to share their thoughts on the

topic. Compliance to the appropriate production codes would be a business responsibility and decision that would be made by the licenced commercial growers.

To the question about whether the advisory board's information and membership would be made public, Health Canada responded that the Expert Advisory Committee would be responsible for maintaining and updating Health Canada's website publication called "Information for Health Care Professionals" with the latest information on marihuana for medical purposes. The document is posted on the website for easy public access. Also, the names of the EAB members will be posted on the website.

On the question about the source of the information for the education of physicians, Health Canada said that the Expert Advisory Committee will have the international experts; the committee will be made up of internationally renowned researchers and experts in this area. These consultations will be working with the medical community to find out what it is they need and how they need to be educated.

On the question of regulating the seed or the genetics that come out of the commercial venues, Health Canada said that currently, they do not plan to put any parameters around the seed and its genetics; the LCPs would make decisions in this area.

On the question about exceptions covering other forms of cannabis (suspensions, tinctures and eatables) Health Canada said that the current Proposal is only considering dried marihuana; this issue has been raised often and they are taking it into consideration as the process moves forward.

To the question on capping potency under the new commercial licence and the possibility of getting a DIM number for marihuana for medical use, Health Canada responded they have no plans to cap potency. Acquiring a DIM number is an onerous process which requires clinical trials and currently it is not included in Health Canada's plans for this Proposal.

On the question about to whom licenced commercial growers would be compliant, Health Canada said they would regulate the industry by inspecting and auditing the producers. The LCPs would be compliant to the new regulations developed by Health Canada. Furthermore, the Proposal does not contemplate a separation between LCPs and dispensaries; a storefront model is not being considered. The production and/or dispensing model chosen would be a business decision made by the LCPs.

One suggestion for the commercial production was to have a corporate model where there are qualified producers and qualified vendors in the community; there is a niche for everyone.

Another suggestion made was to have Health Canada and the LCPs work in partnership with the compassion clubs and dispensaries in order to educate and guide them about the all-important counselling and emotional support needed around the production and dispensing of marihuana for medical purposes.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the impact of the changes would have on their clients, the proposed changes they liked and those they had concerns about. A number of important topics were addressed in each discussion. The discussions were summarized and synthesized below.

✳ *Focus Question: What do you like about the proposed improvements to the Program?*

Participants liked a number of aspects contained in the proposal including an admission that the Program is flawed, the inclusion of multiple stakeholders in the consultations, the streamlining and increased efficiency of having producer processed applications, and the creation of the Expert Advisory Committee. The discussions which took place in response to the question above are summarized below. The responses have been themed for ease of comprehension.

✓ *The admission by Health Canada that the program is flawed.*
- The Program is understaffed and under-educated.

✓ *Inclusion of multiple stakeholder groups in the consultation was much appreciated.*
- Involving the provinces in the consultations is progressive and constructive.
- One patient group thanked Health Canada for being included in the stakeholder consultations.

✓ *The fact that Health Canada is streamlining the process for the patient is a step forward.*
- Making the process of obtaining marihuana for medical purposes easier for patients was applauded.

✓ *Having the producer process the application is a move that will make the process more efficient.*
- Giving the producer the responsibility of processing applications and renewals would reduce wait times for applications and for renewals.

✓ *The Proposal addresses many patient concerns.*
- The Proposal is very much in line with what medical cannabis dispensaries are doing.
- If LCPs should offer ancillary services such as education and support; this would address patient concerns.
- It was noted that dispensaries are in a particularly good position to offer education and guidance, and to become LCPs.

✓ *The recognition of strain- differentiation was seen as a positive step.*

✓ *Creation of the Expert Advisory Committee (EAC) to educate the medical community was applauded.*
- The Advisory Committee addresses a lot of concerns around informing and educating the medical community.
- Suggestion: This could evolve into assisting universities in developing a training program for medical professionals and law enforcement.
- Currently, one compassion club is working with Queens University to develop a training program for pharmacologists, doctors and residents to learn about medical cannabis.

Focus Question: What are your concerns regarding the proposed change to the Program?

A number of key issues were identified by the group. These included the lack of trust in the Proposal and the consultation process, the potential phasing out of cannabis clubs, the fear that costs will increase and compassion will decrease, the elimination of PPLs and DPLs, the onerous renewal process, the contentious issue of doctor as gatekeeper, and the need to overhaul the dosage for marihuana for medical purposes. The discussion which took place in response to the question above is themed and summarized in the following bullets.

✓ *Lack of trust in the Proposal and the consultation process.*
- Doubt and mistrust prevail about whether the process is truly concerned about the well-being of patients.
- There is a serious question about good faith and Health Canada needs to do a lot of work to restore trust.

✓ *Concerns about the phasing out of cannabis clubs and dispensaries.*
- There was concern that this Proposal will cause the phasing out of cannabis clubs. These entities exist for valid reasons; they provide emotional, psychological and physical, elements of support for the client.
- The compassion clubs feel they should be recognized and included in the Proposal.

✓ *Fear that if large companies take over production, compassion will decrease and costs will increase.*
- Larger organizations may only be interested in shipping the product out and not providing support services.
- The reality is that patients who are eligible for this Program are disadvantaged.
- Production companies need to find ways to include ancillary activities that are now offered in the dispensary models.
- *Suggestion:* A dispensary-like model/service could help LCPs recruit patients and assist with paper work.
- Both mail order and storefront options for dispensing were recommended.

✓ *Elimination of Personal Production Licenses (PPL) and Designated Production Licenses (DPL).*
- Growing is a big issue - people grow for financial reasons; being able to grow and provide for yourself is important.
- The phasing out of a system that works was considered a negative step. Patients have developed their own their own therapies that are unique to their condition. They may not be able to get or to afford their treatment in the new Program.
- Grandfathering those with PPL's and DPL's was recommended by the group.
- Participants warned that many licensed patients intend to fight the new Program and there will be court cases launched to recover their production costs.

✓ *Renewal process in the new Program.*
- Renewal of licenses is an onerous process.
- The group recommended that dosage and renewal should be left up to the expertise of the doctor. Patients should be able to inform the LCPs that nothing has changed in their medication.

✓ *Having the doctor in the role of gatekeeper was identified to be problematic by the Taliano Decision.*
- In the experience of many patients, doctors are not receptive to prescribing marihuana for medical purposes.
- The outdated information on Health Canada's website does not dispel fears about the use of marihuana for medical purposes.
- The doctor's main issue with prescribing marihuana for medical purposes is liability.
- In addition, there is a serious lack of doctors in general and those who are willing to sign for the use of medical marihuana. There was a suggestion to open up "prescriptions" to other health professionals.

Health Canada stated they had heard from medical practitioners that liability is a key issue when recommending this medication. During upcoming consultations, the medical community will be asked if the removal of the declaration will alleviate their concerns.

✓ *Issuance of identification cards to patients.*
- There was concern about if identification cards would be issued and by whom.
- Participants acknowledged that these cards are extremely useful in the right situations.

✓ *The grams per day allowance needs to be overhauled.*
- If patients are growing marihuana for medical purposes, they need more grams per day because the dosage is not enough. For those who are consuming it, the current gram allowance is sufficient. There seems to be a disconnect between reality and licensing that needs to be to be addressed.

Question: Will licensing of licensed commercial growers be a source of revenue for the Heath Canada/ government e.g.: licensing fees?

Health Canada response: The product is taxable under GST/ HST laws. Health Canada would revert to a traditional regulatory model; before being licenced, there would be an inspection of the potential producer, followed by periodic inspections to ensure accurate record keeping. At the moment, a licensing fee is not being contemplated; the funds used to run the Program will be converted into an inspector regime.

Question about the current Program: When will the current permits to expire? Will they be allowed to expire? Has there been any thought to making the exemptions valid until 2014?

Health Canada Response: The plan is to have a new program in place by 2014, and production would be phased out before this time. Health Canada is aware that sufficient notice needs to be given to people who have licences and this will be done. Concerning exemptions until 2014, this has been considered, but no decision has been made.

Suggestion for education: In the U.S. there is ongoing education for people in the health care industry both for doctors and nurses. "Patients out of Time" offered by Mary Lynn Mathre is an example of such a program. Also, the Cannabis Consortium created an accredited program for physicians.

Question: Is there a quota for LCPs?

Health Canada's response: No quote is contemplated and as long as the regulatory requirements are met any number of potential LCPs can be eligible for licencing; there is an obligation for Health Canada to ensure access to marihuana for medical purposes.

4. Products and services offered by Compassion Clubs and Cannabis Dispensaries

In order to gain an understanding of medical marihuana products and services being offered in compassion clubs and cannabis dispensaries, the group were asked to share information on a number of key questions relating to their operations, products, and security measures. The following focus questions were posed.

- *Discussion themes:*
  - a) *Compassion club and cannabis dispensary business models and services.*
  - b) *Documentation required from clientele.*
  - c) *Products: cultivation and quality control.*
  - d) *Security.*

Based on their practical experience, participants shared their ideas and made recommendations on the discussion themes. A number of key themes emerged including requirements for documentation, approved signing authorities, dosage requirements and renewals, the creation of an identification system, practical production standards, the need for laboratory testing, reasonable security requirements, methods of disposal, and advertising and insurance considerations. This information was captured and is summarized below.

a. *Compassion club and cannabis dispensary business models and services.*

✓ *One group identified that they had established a Canadian coop with over 10,000 members.*

- They have six (6) people on staff who conduct rigorous and effective verifications.
- They created a centralized data base that allows for a management of patient data files that support dispensaries.
- They created a nation-wide support system that educates health professionals and others.
- They have an extensive list of people who could be potential members of the new advisory board.
- They have addressed many issues around dosaging and strain efficacy that can help doctors make informed decisions.
- They recommend offering other forms of ingestion, and more research.
- They offered a model for commercial large scale grow-ops that have brought production costs down to under $1./gram for marihuana for medical purposes.

b. *Documentation required.*

✓ *Requirements for documentation.*

- A diagnosis is required; this information is then verified. The criteria on who can diagnose needs to be made clear for the new Program.
- Include a space for doctor information and the CPSO number.
- If the doctor is to decide on dosage, include a space for dosage. Also include spaces for the date, for repeats of the medication, and the signatures of the doctor and the patient.
- Other suggestions were to include: name, date of birth, and symptomology and space to indicate if there are follow-ups, if needed.

✓ *The question about who can sign the forms.*

- It was recommended that the person who has the right to prescribe the medication in each province should be the one to sign the form.

- Because of the doctor shortage issue and some reluctance to "prescribe" this medication, the group recommended expanding the signing authorities to include other health professionals such as nurse practitioners, homeopaths, naturopaths, eye doctors, etc.
    - Example: In Ontario, nurse practitioners sign prescriptions for pharmaceuticals as a matter of practicality; allowing them to sign would make it easier to access the marihuana for medical purposes.

✓ *Health Canada noted that the province is the governing body for medical experts* and they regulate the signing authorities for prescriptions. Currently three (3) doctors can prescribe controlled substances: dentists, doctors, and psychiatrists.

✓ *One concern raised* was if patients are no longer allowed to produce for themselves, the LCPs may not be able to meet the needs of the patients.
- There was a suggestion to extend the contract with Health Canada's licensed producer in order to ensure the needs for marihuana for medical purposes are met.

✓ *Dosage.*
- A more effective way of controlling production for personal production is by limiting the space (square footage) and amperage/ wattage rather than by grams per day.
- Regulating dosage is less important because toxicity is not the same as it is with narcotics, and addiction is not a problem.
- "Prescribing" a dosage could be a problem for some doctors because there is a lack of quantifiable dosages; doctors do not know what they are prescribing to patients. Levels of THC and CBD ratings are not well defined. This is where testing becomes a key component in the production of marihuana for medical use.
- Participants recommended that a trained health professional on the staff of the LCPs.

To the question about who will set the dosage for medical marihuana, Health Canada responded that this is not included in the Consultation Document; recommendations in this area would be welcomed during the consultation.

✓ *An identification system needs to be put in place.*
- Law enforcement has little awareness of the rights of patients to use marihuana for medical purposes and this causes legal issues for a vulnerable population.
- It was suggested that the identification cards currently used, have less information; include a name, a reference number and a picture.
- A national centralized database used in conjunction with identification cards and a toll free telephone number, would help authorities and others verify and validate patients' authorizations.

Health Canada stated that they have heard loud and clear that there is a need for a recognizable identifier and this needs to be coupled with an education component for law enforcement.

c. *Products: cultivation and quality control.*

✓ *Acceptable standards that will help keep production costs reasonable.*
- Retrofitting industrial buildings should be acceptable for the new regulatory requirements and this will keep costs reasonable.
- Zoning by local municipalities should be adequate, and will be cost efficient.

✓ *Laboratory testing of the quality of marihuana for medical purposes should be required.*
- Mold and fungus are the greatest issues encountered when growing marihuana for medical purposes; laboratory testing will help to control these problems.
- There was a debate about whether in-house testing or external testing was the best approach, each had advantages and disadvantages.
    - Some thought having a quality controlled laboratory on site would be more effective in monitoring the issues with the product throughout the plant life cycle.
    - Others thought that having laboratories accessible would suffice, and requiring an on-site laboratory would incur unnecessary increased expense.
- If external laboratories are used, bonded couriers could transport the products.
- It was suggested that the results of the tests for molds, fungus and heavy metals and pesticides from laboratories be made available to patients so the client would know the quality of the product they are using.
- Create a safety document/ material sheet/ data sheet for LCPs that outline the safety requirements for marihuana for medical use.
- Caution: Do not over-regulate.
- *Note:* The stigma and legal issues make independent laboratories reluctant to be involved with the testing of marihuana for medical purposes. Health Canada needs to address this stigma in order to make these labs more amenable to testing.

✓ *Involving Provincial Agriculture in the production of marihuana for medical purposes.*
- This is a body that deals with deals with growing, production, storing and retailing, and is fully equipped to handle all these issues associated with producing marihuana for medical purposes.
- *Health Canada responded* that this is a provincial area.

✓ *Fire hazard and molds issues related to the production of marihuana for medical purposes.*
- Proper plumbing and electrical installations should take care of safety hazards.
- Participants stated that producers would be willing to work with local authorities to get appropriate zoning, inspections and electrical and plumbing permits, as needed; if this is a requirement, they would comply.

Health Canada noted that the issue about ancillary services is an important one being considered in their deliberations.

d. Security

✓ *Reasonable requirements for security.*
- *For growing indoors:*
    - Industrial buildings would meet the criteria very well.
    - Security equipment is needed:
        - ensure alarms are connected to the local police;
        - have few windows, and those that exist should be secured with bars;
        - put security cameras should be in place;
        - include a security protocol for staff.
- *For growing outdoors:*
    - Outdoor production should include a combination of fencing and 24 hour surveillance;
    - Use video footage; it can be very effective.
    - Less costs for electricity are incurred when using outdoor grow-ops.

- *Consider using outdoor models* for production of marihuana for medical purposes, especially greenhouses; many of these are pushing the extent of their use and lowering the costs, some greenhouses can operate for nine (9) months (March to November). There are some off the grid systems.

✓ *Methods of disposal.*
- During lab testing for high quality there is a certain amount of powdery residue that is above the limits allowed for medical marihuana. This could be a security risk, and would need to be securely disposed of.
- An incinerator should be used to securely dispose of medical marihuana residue.
- Licensed commercial producers should have the option of working with the community so they do not have to have the expense of an incinerator.
- A medical arts facility incinerator could be used to incinerate superfluous medical marihuana; one person suggested having an RCMP officer or government official witness the destruction, many did not agree with this suggestion.

Other considerations:

✓ *Retailing and advertising of marihuana for medical purposes by the LCPs.*
- To the question concerning how LCPs could promote their product, Health Canada stated they consider advertising important and they would maintain a list of commercial producers on their website. They asked participants to share ideas on how marketing could be done for LCPs. The following suggestions were made:
  - LCPs services would need to be described on a website.
  - The model should include a couple of hundred producers offering different services, similar to that of pharmaceuticals companies.
  - The storefront model describing their product would be more effective.
  - Public Service Announcements (PSAs) could market cannabis as an important option to other medications.

- Concern: Forcing a grower to be a retailer.
  - The focus on retailing the product may divert producers' attention away from producing and reduce the quality of the product.

✓ *Costs, insurance coverage and subsidies.*
- Some insurance companies are reimbursing medical patient's expenses for marihuana for medical purposes as long as receipts are provided.
- Any other medication is covered especially if the patient is on a pension, a number of examples exist:
  - In Ontario, the Ontario Disability Support Program (ODSP) (a mandatory special necessities benefit) covers the cost of medicine that is not included in any other area. Participants suggested that Health Canada address this issue when they consult with the provinces. Marihuana for medical purposes should be recognized as a medicine on these plans.
  - There are some cases where people have been reimbursed in Quebec; the CSST & SAQ have reimbursed patients for costs when the product was purchased from Heath Canada.
  - There is a program with the Aids Foundation where they will reimburse half the cost of marihuana for medical purposes.
- Subsidized substitution for poor people is critical to the success of the proposed changes to the Program.
- Insurance companies are worried about stigma and thus some do not reimburse for this medication; this is a stigma that needs to be addressed.

After the discussions, there was a question and answer which is captured below.

Question: What about the retail industry involved? What about including this seed business, hydroponics?
Health Canada responded by saying that these sorts of ideas are welcomed when building the regulations.

5. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

HEALTH CANADA

Marihuana Medical Access Program Reform

Compassion Clubs and Cannabis Dispensaries Consultation Meeting Report

August 17, 2011
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Montreal, Quebec

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1. Background and Introduction

On June 17, 2001, Health Canada (HC) announced improvements to the Marihuana Medical Access Program (the Program or MMAP) which provides access to marihuana for medical purposes for seriously ill Canadians. The impetus of these changes came from concerns about public safety and security and the potential for illicit use which were raised by police and law enforcement, fire officials, physicians, municipalities, and program participants. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep children and communities safe. To this end, Health Canada is launching public consultations on the proposed improvements. A number of stakeholder groups have been invited to these consultations, including Provinces and Territories, Mayors/ municipalities, compassion clubs and cannabis dispensaries, medical associations, law enforcement, and other interested parties.

A consultation meeting with compassion clubs and cannabis dispensaries stakeholders was held at the Delta Centre-Ville Hotel in Montreal, Quebec on August 17, 2011. There were six (6) participants in the meeting representing four organizations.

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and explained the objective of the meeting:

- to discuss elements of the proposed program changes and gather feedback from participants.

This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

Jeannine Ritchot, Director, Medical Marihuana Regulatory Reform (MMRR) began by thanking participants for attending and acknowledging that the contribution of ideas by the compassion clubs and cannabis dispensaries would help improve the program and reform the regulations.

Jeannine proceeded to set the stage by giving participants a brief overview of the key elements of the proposed improvements to the MMAP. She stated that the program has been in place for 10 years and was created because of a court decision that recognized the right for seriously ill individuals to possess and access a legal supply of marihuana for medical purposes. She noted that in recent years, concerns about the Program have been expressed by various groups. Some of these concerns included the complexity and length of the application process for authorizations/ licensing, and, the public health and safety risks, including poor air quality and electrical and fire hazards associated with the cultivation of marihuana plants in homes.

The office of the MMRR was tasked with reviewing and making proposed changes to the Program, The objective of the proposed improvements is to reduce risks to Canadians and keep communities safe, while improving access for Canadians to the use of marihuana for medical purposes. She noted that the legalization or decriminalization of marihuana is not part of the proposed changes.

She sketched out some of the changes that are being considered in the MMAP proposal. Some advantages she identified were:

- ✓ *Consulting the physician will be made easier.*
  - The medical practitioner will no longer need to sign the Health Canada declaration which should reduce the length of the application process; the medical specialist requirement has been eliminated.
- ✓ *Improving physician access to comprehensive, accurate and up-to-date information.*
  - An Expert Advisory Committee will be struck in order to gather and share updated information on the use of medical marihuana. This will allow the medical community to make informed decisions.
- ✓ *Sources of supply of marihuana for medical purposes.*
  - New sources of supply would favour creating a marketplace which could increase the number of licensed commercial companies who would produce and distribute medical marihuana to individuals who have documents supporting their use of marihuana for medical purposes. These commercial companies will have to meet regulatory requirements regarding product quality and security, among other things.
  - Health Canada would carry out a more traditional regulatory role of auditing and inspecting and will cease being a supplier and issuer of licences.
- ✓ *Streamlining the administrative process for program participants.*
  - Health Canada will no long hold personal medical information of Canadians.
  - Elimination of databases and yearly renewal checks will reduce the burden of administration both for patients and Health Canada.

After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. These are summarized below.

To a question about the specific requirements for the commercial production licences Health Canada representatives stated that the requirements have not yet been defined. They are looking to the stakeholders for suggestions on the appropriate requirements for the commercial licences.

To a question about whether or not stakeholders would have other opportunities to provide input on the reform, Health Canada assured participants that they would indeed have other opportunities to give further feedback. It was noted that the federal regulatory process does have a built-in consultation process which includes a mandatory 30 to 60-day comment period after it reaches the *Canada Gazette* 1 (one) stage.

Concerning the number of growers/producers that will be necessary in Canada, Health Canada stated that they do not know at this point and welcome any thoughts from stakeholders on such questions and others regarding the best way to supply the demand in the market.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the proposed changes to the Program that they liked, and those they had concerns about. A number of important topics were addressed in each discussion. The discussions were summarized and synthesized.

> ✚ *Focus Question: What do you like about the proposed improvements to the Program?*

The discussions which took place in response to the question above are summarized below. The responses have been themed for ease of comprehension.

✓ *The recognition and inclusion of compassion clubs and cannabis dispensaries in the consultation process.*
- Invitation of the compassion clubs and cannabis dispensaries is ground-breaking and the group appreciated the acknowledgement.

✓ *Reduced administration burden for Health Canada.*
- Health Canada no longer keeps patient health records.
- Health Canada is no longer in the business of marihuana production and dispensing.

✓ *Increased education.*
- Educating doctors about the risks and benefits of the use of medical marihuana.
- This is an opportunity for commercial producers to connect with the medical community in an effort to "speak" the same language and share information.

✓ *Simplification of supporting documentation for the use of marihuana for medical purposes.*
- Facilitating the process by allowing doctors to "prescribe" the use of medical marihuana through supporting documentation. The word "prescription" is a word the public can relate to. It was suggested that allowing other health professionals to provide a prescription for this medication would be helpful, ex: nurse practitioners, pharmacists, etc.
- The use of simple documentation. For 15 years, medical cannabis dispensaries have been using a one-page statement of diagnosis successfully.
- The elimination of the need for a specialist to authorize use of medical marihuana for Category 2 symptoms and conditions, was strongly supported.

- ✓ *Facilitating better doctor / patient relations.*
  - Simplifying and facilitating the doctor/patient interactions was strongly supported.

- ✓ *The use multiple strains of medical marihuana for a variety of patient needs.*
  - Acknowledging the importance of having multiple strains is a significant improvement to the quality of the Program. Patients need access to a variety of strains and different products because the use of different strains correlates with different conditions. Note: evidence on this is anecdotal and needs to be validated by conducting more research. Pursuing research is beneficial.

- ✓ *Quality control standards, regulations, and licensing of the commercial production of medical marihuana.*
  - Recognizing that commercial production should have quality control standards and be licenced was seen as a positive and progressive step. Also, this licencing addresses problems with safety. Caveat: this measure should not come at the expense of personal production.
  - Many dispensaries and current production sites have little access to labs to assess the quality of their product, and as a result are currently implementing their own quality control standards.
  - Barriers to entry into commercial production should not be onerous; opportunities should be accessible to both large and small production companies.
  - This proposal should encourage potential producers because of the introduction of quality control and production regulations and standards.
  - Commercial producers may find they will have access to greater research facilities and opportunities.
  - The development of these regulations should include provincial, territorial and municipal involvement.
  - Caution: be sure to have regulations in place before the standards are enforced.

Questions and other issues which emerged during the discussion revolved around:

Issue: A concern expressed about how the existing compassion clubs and cannabis dispensaries would be integrated into the plan.

Question: A question about the Advisory Committee's role and makeup sparked a discussion in which participants emphasized the importance of having a balanced representation of key stakeholder groups on the Committee.

> *Response:* Health Canada's representative explained that the Expert Advisory Committee (EAC) is tasked to work with international peers to provide current information to the medical community about the benefits and risks related to the use of medical marihuana.

Focus Question: What are your concerns regarding the proposed change to the Program?

The discussion which took place in response to the question above is summarized in the following bullets:

About the commercial producers:

✓ *Disproportionate focus on security.*
- The level of restrictiveness makes it difficult for suppliers to do a good job. There is a need for security; however, it should not be at the cost of patients' rights. Going forward the government needs to access a reasonable amount of risk and create regulations that provide appropriate security measures.
- Historically, theft has not been a problem for commercial or personal production of medical marihuana.

✓ *Affordability of medical marihuana.*
- The new production requirements may make it very challenging to provide an affordable product; this could be a significant issue in getting some stakeholder groups to accept the regulations.
- Affordability will make or break the program. There needs to be accessible mechanisms in place for cost coverage. Working with the provincial and territorial authorities on this issue would be positive.

✓ *Removal of personal production licences.*
- The removal of licences for personal production is a rights issue. Elimination of personal production licences could lead to more court time. Participants thought that there can be sensible ways to regulate personal production without eliminating it. Some felt violated that they could lose their personal right to medicate.
- It was agreed that personal production is a zoning issue not a crime issue. New regulations need to make a clear distinction between personal production, caregiver cooperative production (designated-person production), and commercial scale production; it is important to work with provinces, territories, and municipalities on this issue. Regulation of personal growing spaces is a province/ municipal task, e.g. Limit on square footage and wattage.
- Poverty is an issue related to personal production. Home grown marihuana can make medication more accessible to and affordable for the poor.
- Personal production allows the patient to have some control over their medication.
- If the licencing regulations are done well, it could provide affordable medication.
- Participants felt strongly that those who have personal-use production licenses should have the right to keep them; they need to be grandfathered in some way.

✓ *A suggestion for the Regulatory framework and the new marketplace.*
- It was suggested that in the new marketplace for production companies, inspections could be streamlined by using existing services, e.g. firefighters who already inspect for health and safety hazards.

✓ *The lack of trust and existing scepticism from this stakeholder group vis-à-vis Health Canada.*
- Health Canada has a past history of reluctance and resistance in working with dispensaries, which has led to an atmosphere of distrust and scepticism.
- In order to restore trust, Health Canada needs to show evidence of good faith and work to build and restore confidence and integrity in the process of working with compassion clubs and dispensaries.

- *Health Canada responded* by emphasizing their intent is to do things differently and to work with the regulatory process which guarantees transparency. They pointed out that the compassion clubs were consulted before the consultation document was written.

✓ *Maintaining access to compassion organizations.*
- There was concern over the glaring omission/acknowledgement of the work that compassion clubs have been doing; these models were not included in the discussion paper. Also, there was no mention of temporary exemptions for the licencing of compassion organizations.
- There was concern about the possible closing of the compassion clubs and the fate of the patients associated with them.
- Maintaining access to compassion clubs and organizations is important because it is a point of contact and helps facilitate patient needs.

✓ *Medical marihuana distribution methods.*
- The consultation document outlines *mail order only for dispensing medical marihuana,* which was a concern to participants. They noted many advantages to having a community based model:
    - On-site dispensing can allow for monitoring;
    - In person is more effective because they can offer a point of service providing education and other health services to patients. For example, there is a B.C. Compassion Club that subsidises a massage wellness club. Other services can also be offered such as community kitchens which can provide edible products;
    - Mail order will not give access to patients in hospices, to those in shelters and those who are homeless.
    - Community and compassion is missing with mail order only dispensing model.
    - Community based programs have a record of success.

✓ *Distribution, administration, and model concerns.*
- The creation of the forms for access to medical marihuana was of concern. All the compassion groups have a document which summarizes the doctor's recommendation for medication.
- There is already a model/ a marketplace for distribution, but it is not legal. It has met the demands of people for years. A regulatory model for dispensaries would help improve the Program.
- There was a suggestion to create a pilot project which has two separate entities - production and retailing. This model, if accepted by the federal government, could be a model for going forward.

✓ *Availability of different forms of medical marihuana.*
- There was no mention of oral ingestion in the consultation document. Oral ingestion can offer a safer method of intake of medical marihuana, and there are existing food and safety protocols that can regulate this.

✓ *Elimination of identification cards/ having a medical marihuana patient identification system in place.*
- In the proposed changes to the Program, there would be no more identification cards issued by Health Canada.
- Participants recommended that an identification system be put in place in order to eliminate confusion and undue risk to registered medical marihuana patients.
- The current identification cards have too much information on them. Should a similar system be implemented in future by the regulated party (commercial producers/distributors), it was recommended that it contain only the name, member number, and date of birth (possibly height and eye colour) for the authorized patient (no address).
- Participants liked the idea of having a sticker on their health card indicating the patient's medical authorization.

- It was suggested that a registry or database of registered patients be created; one that could be accessed by doctors, health professionals, law enforcement, etc.
- There is a need to have sensitivity training for law enforcement to ensure registered patients are treated respectfully.

4. Products and services offered by Compassion Clubs and Cannabis Dispensaries

In order to gain an understanding of medical marihuana products and services being offered in compassion clubs and cannabis dispensaries, the group were asked to share information on a number of key questions relating to their operations. The following focus questions were posed.

Focus questions:

✓ *For whom do you offer these products and services?*

Additional related questions:

a) *What documentation do you require from a client prior to providing them with products or services?*
b) *What, if anything, do you require of doctors or other health care providers before you offer your products and services to a client?*
c) *Do you limit the people to whom you offer your products and services? On what basis?*
d) *Do you sometimes interact with caregivers instead of with the clients directly? Does this cause any issues?*

Each of the four groups discussed and highlighted key points about their services and their operations. This information was captured and is summarized below.

✓ The *first group identified their model as being different from the others* as they are mandated to educate. Their mandate is:
- To help people locate doctors.
- To assistant in obtaining Health Canada information packages for people.
- To educate and help patients get into the Program.
- To educate the police about the compassion club's purpose.
- Note: They have a proposal for a community based model.

The *second group offered a website where their products and services can be found.*

✓ The *third group described their purpose and operations as revolving around distribution.*
- They proactively help people access Canada's MMR Program and facilitate their interactions with them.
- They accept patients in Category 1 who have a medical licence for medical marihuana, and dispense according to the recommended dosage.
- They help locate doctors for people in need, and psychologists, when necessary.
- They address questions patients have about the process and the MMAP.
- The group offered to share their application form for the diagnostic information with Health Canada.

- ✓ *Group number four indicated that they also function as a distributor (similar to Group 3), with a main focus on food products.*
  - They became a limited dispensary in order to fill a void.
  - They have a closed, private resource centre which works closely with patients and caregivers.
  - They provide marihuana cuttings to patients who have a personal-use production licence (PPL), and to people who have a designated-person production licence (DPL).
  - Their main focus is on providing edible products for other dispensers. They are a community based kitchen.

Health Canada's representatives had a number of questions for the participants concerning the production and distribution of medical marihuana. Key questions were:

Question: Can others be designated to pick up orders for patients?

Response: Patients who are too ill to pick up their own medication can sign a proxy and inform the distribution organization when they need to have someone else pick up their medication.

Question: Concerning the Proposal to eliminate personal production, if personal production were to continue, were you suggesting that growers would allow municipal inspectors into their homes (e.g. firefighters, etc.) for inspections?

Response: There needs to be more cooperation on the part of personal producers and a willingness to submit to inspections on a regular basis. Having these inspections would raise the quality of the product.

Question: How do you think producers would feel about having a government inspector coming into their home?

Response: They would prefer that to losing their licence. They already have a high quality; they are expecting inspection.

5. Interest in becoming a licensed commercial producer.

As part of the consultation process, Health Canada is interested in finding out which organizations are interested in becoming licensed commercial producers of medical marihuana. This last part of the meeting was reserved for identifying participant interest and some factors involved in licensing commercial production of medical marihuana. Discussion questions were posed, and participants provided advice and feedback on each of the topics.

- *Focus questions:*
  - ✓ *Would you, or have you considered becoming a licensed commercial producer? What would your considerations be?*

    Additional related questions:

    a) *What would be the best way (including cost-effective) to ensure the quality of your product?*
    b) *What would be an adequate and affordable level of security and how would you assure it?*
    c) *What would be your considerations regarding cultivation?*
    d) *What would your considerations be in pricing your product?*

The following were key considerations relating to quality, affordability, security, cultivation and product pricing that were identified by the participants.

✓ *Cost effectiveness*
- The product should not be so onerous or expensive so that only big corporations can produce it. Marihuana production is a trade that half a million Canadians are involved in; there is an expertise in the population that should be tapped into. Small cultivation companies should be supported.

✓ *Quality of product*
- It is important to have standards that include organic requirements/certifications for medical marihuana production.
- Health Canada noted that during the pre-report consultations, there was a clear desire to be regulated expressed by the compassion clubs and cannabis dispensaries.

✓ *Security issues*
- Implement reasonable security measures for the security of the employees and of the product; let common sense prevail. Such measures as closed circuit cameras, fences, security guards on location were suggested. Ensure there is no visible signage.
- Make security requirements for hiring employees reasonable; have personnel who are appropriate; allow the commercial market to determine the skills and knowledge that is required.
- Small productions could be developed as long as they adhere to security procedures.

✓ *Considerations regarding cultivation*
- Outdoor cultivation is less expensive and there is less installation involved, however it is difficult to control and security is more of a challenge.
- Indoor cultivation is more expensive; however it is easier to control the environment to get a consistent product. Security is more easily controlled.

✓ *Interest in becoming an authorized distributor*
- Some participants were interested in becoming an authorized distributor.
- Concerning profit and competition, it was thought that a variety of commercial growers and individual growers would be healthy for the market.
- Ideally, the grower and dispenser could work together to produce and deliver the product.

✓ *Other considerations about the compassion clubs*
- The compassion clubs and cannabis dispensaries are important because they are not-for-profit and their main concern is to protect the rights of the person and to maintain compassion.
- They work closely with cannabis cultivators and can help provide regulations that are not obstructive.
- They are interested in being involved in an integrated framework as long as it meets the needs of the people who need the medical cannabis. The regulations need to have credibility.
- There was a concern about people the involved in the compassion clubs people who have experience with marihuana; many of them are involved in legal procedures. This could pose a problem for becoming producers and distributors.
- The compassion club models have been in existence for 15 years and have been audited; the model works.

✓ *Education about cannabis*
- In future it would be helpful to have educational materials available to patients in the health care centres as well as compassion clubs/organizations.

Health Canada's representatives had a number of questions and comments for the participants concerning various aspects licensed commercial production and producers. The questions and responses are summarized below.

Question: If we allow personal production and dispensaries and commercial growers, will the marketplace idea work? Will there be enough people to buy the product?

Response: The participants indicated that they see marihuana production as a growth industry. That the three facets of the industry: licenced commercial grower and producer and dispenser can be one and the same; in particular, the grower and producer. Participants also indicated that if personal production failed, there needed to be other sources of supply, such as commercial growers.

Question: It is a security issue to have production and distribution in the same area. Are you thinking that distribution sites would be more known? But not production sites?

Response: For security purposes, Health Canada forms ask if the cannabis is stored where it is grown; this is a distribution issue.

Question: People want to know where production sites are, e.g. Next to a playground. Should this be publicized?

Responses: Publicizing where production sites are should be on a need to know basis, e.g. the municipality for inspection purposes. The knowledge of where the production is, is tied into security, the less people know, the safer it is. This is part of risk management; a balanced approach needs to be reflected in the regulations covering security.

Comment: Health Canada thought delivery by direct mail was the best approach.

Responses: People need to have information first; to make a connection and have questions answered in order to feel comfortable.
- Sending large quantities of cannabis by mail can be a security risk.

6. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

Appendix A: Agenda

Health Canada
Marihuana Medical Access Program

Montreal - Compassion Clubs and Cannabis Dispensaries
Date: August 17, 2011
Time: 13:30-16:00

Item	Time
Registration	13:00-13:30
Introduction	13:30-13:35
Presentation of key elements of the proposal	13:35-13:45
General Discussion 1. Which changes will affect you? Which changes will affect your clients/stakeholders? 2. What do you like about the new proposal? Why? 3. Do you have concerns regarding the proposed changes? What are your concerns? Why? What suggestions for improvement would you make?	13:45-14:30
Break	14:30-14:45
Discussion Themes a. Compassion club and cannabis dispensary business models and services b. Documentation required from clientele c. Products: cultivation and quality control d. Security	14:45-15:50
Next Steps, closing remarks, meeting evaluation.	15:50-16:00

This is **Exhibit "OO"** 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

CAMCD ACDCM
CANADIAN ASSOCIATION OF MEDICAL CANNABIS DISPENSARIES
ASSOCIATION CANADIENNE DE DISPENSAIRES DE CANNABIS MÉDICAL

March 5, 2012

Ms. Jeannine Ritchot
Director, Medical Cannabis
Medical Marihuana Regulatory Reform
Controlled Substances and Tobacco Directorate
Health Canada
Mail Room, Federal Records Centre - Bldg 18
1st Floor, 161 Goldenrod Driveway, Tunney's Pasture
Ottawa ON K1A 0K9

Dear Ms. Ritchot,

On behalf of Canadian Association of Medical Cannabis Dispensaries (CAMCD), I am writing to thank you for sitting down with us during our visit to Ottawa last month. We appreciated the opportunity to be a part of the consultation process, as well as our thoughtful exchange on medical cannabis, dispensaries and the Medical Marihuana Access Program (MMAP).

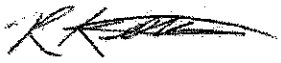
As you know, we have been developing and implementing a dispensary standards and certification program to reflect and coincide with the goals and timeline of Heath Canada's recent proposed amendments to the MMAP. Certified dispensaries will help ensure patient access to this medical product, product safety, facilitate patient education and support strategies that promote the safe and effective use of medical cannabis.

We believe dispensaries are ideally positioned to fill these roles within the national framework to ensure patients have safe, secure and reliable access to medical cannabis and related services. We welcome further discussions on our model regarding refinements that would better meet Health Canada's needs, and help incorporate dispensaries into the regulatory framework.

Dispensaries reflect a community-based response to the suffering of critically and chronically ill Canadians who benefit from the medical use of cannabis. CAMCD believes the spirit of the amendments proposed to the MMAP are in line with the community-based dispensary model, and that the remaining gaps in the proposed amendments can be filled by the inclusion of dispensaries into this regulatory framework.

If I can provide any additional input or insight on our dispensaries, standards, or the issues we spoke about (safety and security, advantages to patients of access to different strains and modalities), please do not hesitate to contact me at (519) 780-7830 or rade@camcd.ca.

Sincerely,



Rade Kovacevic, CAMCD President and Director and Medical Cannabis Centre of Guelph Inc.

c. Cathy Sabiston, Director General, Controlled Substances and Tobacco Directorate, Health Canada
Deidre Pollard-Bussey, Senior Policy Analyst, Medical Marihuana Regulatory Reform, Health Canada
Blaine Dowdle, CAMCD Secretary and Director and MedCannAccess (Etobicoke)
Neev Tapiero, CAMCD Treasurer and Director and Cannabis as Living Medicine (Toronto)
Adam Greenblatt, CAMCD Director and Medical Cannabis Access Society (Montreal)
Jeet-Kei Leung, CAMCD Director and BC Compassion Club Society (Vancouver)
Rielle Capler, CAMCD Advisory Board Member (Vancouver)

This is **Exhibit "PP"** 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

MMAP Targeted Consultations – Provincial and Territorial Ministries of Health

Background:
On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status:
On November 24, 2011, Health Canada representatives met with PT public safety representatives at a regular meeting of the FPT ADM Policing Issues Committee, to discuss Health Canada's proposed improvements to the MMAP.

Meeting Synopsis:
Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on two themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.

Overall, the proposal was well received. A number of participants expressed willingness to discuss the proposal with their PT Health colleagues to ensure PT consensus on key elements of Health Canada's proposal. Specific concerns relate to public safety and public security. One participant highlighted that there could potentially be enforcement issues that would require PT resources to address (DUI, increased use, increased diversion).

Key Concerns:

- Participants raised questions about the increasing growth in the number of program participants. The increased number of participants will likely result in an increased number of PUPLs and DPPLs in the interim.
    - There was concern raised about whether grandfathering would be allowed, and if so, for what period of time.
    - There was concern about whether this could have an impact on public health, safety and security during transition.
- Participants expect that this increase in the number of participants could lead to increased pressures on PT policing resources (ie. monitoring driving while under the influence of a controlled substance)
- Participants are concerned that licensed commercial production could potentially be used as a front through which organized crime could divert product to the illicit market.

MMAP Targeted Consultations – Provinces and Territories

Background

During August and September, Health Canada held meetings with representatives from ministries responsible for health to engage in comprehensive discussion regarding the impact of the proposed changes on provincial and territorial health care systems, including the role of physicians in the program, the impact of the changes on provincial drug plans and other provincial health care policies.

Context

A total of four (4) teleconferences were held with provincial and territorial representatives from ministries responsible for health – three were regional teleconferences in addition to a conference call with the federal-provincial-territorial Pharmaceutical Directors Forum (PDF). Currently, despite the invitation to participate, the territories have not been consulted. Quebec has been consulted within the PDF call, but has expressed interest in providing further comments.

Meeting Synopsis

Positive Elements of the Proposal

Overall, Health Canada's proposal was not well received. Provinces and territories clearly expressed that they did not endorse Health Canada's proposal as it stands. Measures reducing administrative burden on program participants, particularly the application to Health Canada for access were welcomed changes, however, participants felt that their concerns overshadowed the positive elements of the improvements.

Key Concerns

General concerns were expressed regarding a lack of detail in the proposal. Provinces felt that they needed more information on the proposal to ensure they could offer constructive feedback. Concerns were expressed on the missing role for the provinces and territories in Health Canada's consultation process and the regulatory development for new *Marihuana Medical Access Regulations* (MMAR). Provinces recommended a more collaborative federal-provincial partnership moving forward on the proposed improvements.

Cost

Specific concerns relate to a potentially higher priced product as a result of the changes, putting pressure on provinces and territories to subsidize increasing costs incurred by patients. Provinces and territories also suggested that patients may be faced with other increasing costs/fees (e.g. higher fees for doctors to complete documentation, dispensing fees). Without a common drug review and a drug identification number, participants stated that marihuana for medical purposes is not likely to be covered under provincial drug plans.

To address the possibility of unfair pricing by licensed commercial producers, PDF members suggested Health Canada investigate the feasibility of controlling pricing

MMAP Targeted Consultations – Provincial and Territorial Ministries of Health

Background:
On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status:
On August 31, 2011, Health Canada representatives and health representatives at provincial and territorial level from Prince Edward Island and Ontario teleconferenced, to discuss Health Canada's proposed improvements to the MMAP.

This is the first of a series of four (4) teleconferences held with provincial and territorial ministries responsible for health services in Canada.

Meeting Synopsis:
Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Posed questions from Health Canada to meeting participants.

Overall, the foundation of the proposal was well received, including Health Canada's recommendation to create a regulated industry. Specific concerns relate to a potentially higher priced product as a result of the changes, putting pressure on provinces and territories to cover the cost of marihuana for medical purposes under provincial drug plans. Concerns were also raised on the lack of scientific evidence to support the use of marihuana for medical purposes.

Key Concerns:

- Provinces are pleased that Health Canada is streamlining the process, including the physicians' medical declaration and the application process for a client's authorization to possess.
- General concerns include lack of research and lack of an evidence base on which marihuana is recommended as a medical therapy, especially given the health implications of using an inhaled form of marihuana for medical purposes.
- Dosage is a specific concern; provinces emphasize a need for more education and guidelines for physicians in order to be able to make informed recommendations for their patients.

- Provinces also raised concerns regarding the market price of marihuana under a commercial production framework. High prices could impact a client's ability to access marihuana for medical purposes, which could, in turn, place pressure on provincial drug plans.
- Without a drug identification number or supporting evidence on the risks and benefits, marihuana for medical purposes is not likely to be supported by provincial drug formularies.
- Doctors are uncomfortable with the current medical declaration process and provinces view an expanding role of alternate gatekeepers with prescription authority, such as nurse practioners as being beneficial.
- For the safety of patients however (i.e. the ability to register complaints with a regulatory authority), provinces recommend that patients consult with licensed and/or registered health professions currently in possession of prescription rights.
- Provinces forsee a role for Health Canada is creating and maintaining "prescription" guidelines for doctors and other practitioners, if the categories of conditions will be eliminated under the proposed improvements.
- In terms of creating and maintaining a record-keeping system for licensed commercial producers, provinces express concerns regarding program clients' privacy rights. There is some allowance for the inter-provincial sharing of information, however, more work needs to be undertaken to ensure it does not interfere with regulatory frameworks in conjunction with the disclosure of medical information, especially to private industry. It was suggested that a record-keeping system maintained by Health Canada would alleviate such concerns.
- Ontario and PEI agreed there is a role for pharmacists under the proposal, but recommend that Health Canada consult with the pharmacist regulatory authorities.

Next Steps:
Representatives from Health Canada will conduct three (3) consecutive teleconferences on September 14 and September 19 with provincial and territorial representatives from ministries responsible for health.

An analysis of the scheduled consultations with all provinces and territories will be introduced into the final reform package.

MMAP Targeted Consultations – Provincial and Territorial Ministries of Health

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status

On September 14, 2011, Health Canada representatives held a teleconference with provincial and territorial representatives from the FPT Pharmaceuticals Directors Forum (PDF) to discuss Health Canada's proposed improvements to the MMAP.

This is the second of a series of four (4) teleconferences held with provincial and territorial ministries responsible for health services in Canada.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Posed questions from Health Canada to meeting participants.

Overall, the foundation of the proposal was not well received. PDF members were focused on concerns regarding the potential increased pressures for provinces and territories to cover marihuana for medical purposes under drug plans. Specific concerns were related to a potentially higher priced product as a result of the changes and the fact that marihuana is regulated differently from other drugs. Without a DIN or supporting evidence on the risks and benefits, marihuana for medical purposes would not qualify for listing on provincial drug formularies. PDF representatives were vocal regarding the need to place the distribution of marihuana for medical purposes within existing pharmacy models to ensure patient safety and to alleviate concerns regarding the sharing of health information.

Positive Elements of the Proposal

- Provinces are pleased that Health Canada is streamlining the process, allowing for easier patient access to marihuana for medical purposes.

Key Concerns

- Provinces are pleased that Health Canada is streamlining the process, allowing for easier patient access to marihuana for medical purposes.

- Provinces raised concerns regarding the market price of marihuana under a commercial production framework. High prices could impact a client's ability to access marihuana for medical purposes, which could, in turn, place pressure on provincial drug plans.
    - To address the possibility of unfair pricing by licensed commercial producers, PDF members suggested Health Canada investigate the feasibility of controlling pricing through regulations.
- Without a DIN or supporting evidence on the risks and benefits, marihuana for medical purposes will not be supported by provincial drug formularies.
- The MMAP will remain a federal program; however, provinces indicated that they will bear the brunt of patients' frustrations regarding the potential increased cost of their marihuana under the licensed commercial production framework.
- There was expressed interest in creating and maintaining a Pan-Canadian marihuana subsidy program to alleviate the financial stress on patients with specific eligibility criteria that outline who may use marihuana under what purposes, and when it would be reimbursed.
- Provinces and territories view marihuana for medical purposes as a "drug" and therefore view pharmacies as the most appropriate method of distribution.
    - Participants did not endorse the creation of a parallel distribution system that used dispensaries, even if these facilities were required to have a health professional on staff.

Next Steps

Representatives from Health Canada will conduct two (2) consecutive teleconferences on September 19 with provincial and territorial representatives from ministries responsible for health.

An analysis of the scheduled consultations with all provinces and territories will be introduced into the final reform package.

MMAP Targeted Consultations – Provincial and Territorial Ministries of Health

Background
On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and October, 2011.

Current Status
On September 19, 2011, Health Canada representatives and health representatives at provincial and territorial level from Nova Scotia and Newfoundland and Labrador teleconferenced, to discuss Health Canada's proposed improvements to the MMAP.

This is the third of a series of four (4) teleconferences held with provincial and territorial ministries responsible for health services in Canada.

Meeting Synopsis
Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. Elements of the proposal that participants found to be positive.
2. Issues/concerns about the proposal.
3. Posed questions from Health Canada to meeting participants.

Overall, the foundation of the proposal was not well received. Provinces are pleased that Health Canada is eliminating personal-use and designated-person production. However, they expressed significant concerns with a number of other elements of the proposal. Specific concerns relate to a potentially higher priced product as a result of the changes, putting pressure on provinces and territories to cover the cost of marihuana for medical purposes under provincial drug plans. Concerns were also raised regarding patient safety and the lack of a drug monitoring system under the current proposal.

Key Concerns

- Marihuana for medical purposes is the only controlled substance in which a patient would directly submit a prescription-like document directly to the producer, which poses a number of concerns:
    - Monitoring and preventing illegal activities such as overproduction and diversion.
    - Inhibits record-keeping through provincial drug-monitoring system which are imperative for tracking of contraindications, drug interactions, and prescription monitoring for narcotics control.

- Provinces advocated strongly for the involvement of pharmacists – they provide appropriate counselling on drug interactions, methods of ingestion, and progression of treatment.
- Dosage is a specific concern; provinces emphasize a need for more education and guidelines for physicians in order to be able to make informed recommendations for their patients.
- There were concerns regarding the removal of the categories of symptoms and conditions – they act as guidelines for how and when physicians support a patient's access to marihuana for medical purposes.
    - Specifically, the removal of category 2 places greater pressure on primary care physicians.
    - Recommend that primary care physicians be supported by physicians who have undergone significant education and training (similar to methadone prescribing rights)
- Provinces also raised concerns regarding the market price of marihuana under a commercial production framework. High prices could impact a client's ability to access marihuana for medical purposes, which could, in turn, place pressure on provincial drug plans.
- Without a drug identification number or supporting evidence on the risks and benefits, marihuana for medical purposes is not likely to be supported by provincial drug formularies, but questioned whether it could be provided a Product Information Number (PIN).
- Doctors are uncomfortable with the current medical declaration process and provinces view an expanding role of alternate gatekeepers with prescription authority, such as nurse practioners as being beneficial.
    - Recommended that the scope be narrow – for safety and efficacy of patient care, they should be practitioners recognized by provincial drug monitoring systems.
- Provinces foresee a role for Health Canada is creating and maintaining "prescription" guidelines for doctors and other practitioners, if the categories of conditions will be eliminated under the proposed improvements.
- Provinces voiced their interest in partnering with Health Canada.

Next Steps

Representatives from Health Canada will meet with Canadian Association of Fire Chiefs in Calgary on September 27.

An analysis of the scheduled consultations with all provinces and territories will be introduced into the final reform package.

MMAP Targeted Consultations – Provinces and Territories

Background

On June 17, 2011, the Government of Canada announced the proposed reform of the Marihuana Medical Access Program (MMAP) and the beginning of a public consultation period. A consultation document was posted on the Health Canada website, where stakeholders and the public were invited to submit comments on or before July 31, 2011. Pursuant, meetings with key stakeholders will be held between August and October, 2011. The target audience will include: law enforcement; parties interested in becoming licensed commercial producers; compassion clubs; the medical community; municipal representatives; and provinces and territories, and will be conducted between August and November, 2011.

Current Status

On September 19, 2011, representatives from Health Canada met with representatives from British Columbia, Alberta, Manitoba and Saskatchewan provincial governments. While the focus was on health policy implications, representatives from ministries responsible for public safety, justice, social and community services, and agriculture were also present on the call.

Meeting Synopsis

Representatives from Health Canada outlined the key elements of the proposed changes to the MMAP. Ensuing discussion centred on three themes:

1. The consultation process and the role of provinces and territories in the regulatory reform.
2. Issues/concerns about the proposal.
3. Posed questions from Health Canada to meeting participants.

Overall, Health Canada's proposal was not well received. Concerns were expressed regarding a lack of detail in the proposal. Provinces felt that they needed more information on the proposal to ensure they could offer constructive feedback. Concerns were expressed on the missing role for the provinces and territories in Health Canada's consultation process and the regulatory development for new *Marihuana Medical Access Regulations* (MMAR). Discussion regarding Health Canada's proposal centred on the role of pharmacies and physicians under a new framework.

Positive Elements of the Proposal

- Measures reducing administrative burden on program participants, particularly the application to Health Canada for access.

Key Concerns

- The elimination of personal production will potentially put the cost of marihuana out of reach of many individuals in need, which will place pressure on provincial drug plans to subsidize increasing costs incurred by patients.
- Without a common drug review and a drug identification number, marihuana for medical purposes is not likely to be covered under provincial drug plans.
- Patients may be faced with other increasing costs/fees (e.g. higher fees for doctors to complete documentation, dispensing fees). Both will add to the pressure on provinces and territories to fund access to marihuana for medical purposes.
- Physician as sole gatekeeper to the program.
    - Provinces would not identify other potential health care professionals that could support patient access to marihuana for medical purposes, but suggested that the issue required further analysis and consultation.
- With other controlled substances, physicians and pharmacists share the gatekeeper roles and responsibilities; changing that relationship creates problems:
    - Improvements currently do not involve provincial drug monitoring systems which allow for pharmacists to track distribution and use of controlled substances;
    - Pharmacists are not able to check dosage and routes of administration nor engage in patient consultations;
    - Increases the risk of diversion and/or double doctoring;
- Patients living in long-term care facilities will not necessarily have access to marihuana for medical purposes through a mail order only service.
- Many long-term care facilities have no smoking policies, therefore the inability to access other marihuana products will prove to be challenging for those patients.
- Absence of an on-going collaborative federal-provincial-territorial partnership to discuss the reforms of the Marihuana Medical Access Regulations (MMAR).

Other Points of Discussion

- Health Canada committed to providing updated statistics on the number of current licence holders.
- Provinces recommended that Health Canada consult with pharmacist associations regarding their willingness to be involved.
- Provinces recommended exploring other forums for federal-provincial-territorial collaboration.
- Health Canada welcomed any further recommendations from provinces following the conference call.

Next Steps

Health Canada representatives held four (4) teleconferences with provincial and territorial counterparts. Ministries responsible for public safety will be consulted through the National Coordinating Committee on Organized Crime at a later date (TBD).

An analysis of these consultations will be written and incorporated in to the final reform package.

through regulations. There was expressed interest in creating and maintaining a Pan-Canadian marihuana subsidy program to alleviate the financial stress on patients with specific eligibility criteria that outline who may use marihuana under what purposes, and when it would be reimbursed.

The role of physicians and other health care professionals

There were mixed views about the removal of the categories of symptoms and conditions, as they were viewed by some participants as guidelines for how and when physicians support a patient's access to marihuana for medical purposes. Specifically, some representatives stated that the removal of category 2 places greater pressure on primary care physicians. Provinces recommended that primary care physicians be supported by physicians who have undergone significant education and training (similar to methadone program).

Provinces emphasize 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. Provinces foresee a role for Health Canada is creating and maintaining "prescription" guidelines for doctors and other practitioners, if the categories of conditions will be eliminated under the proposed improvements.

Doctors are uncomfortable with the current medical declaration process and provinces view an expanding role of alternate gatekeepers with prescription authority, such as nurse practitioners as being beneficial. Participants recommended that the scope be narrow. For the safety and efficacy of patient care, they recommended that patients consult with licensed and/or registered health professions currently in possession of prescription rights and practitioners recognized by provincial drug monitoring systems.

With other controlled substances, physicians and pharmacists share the gatekeeper roles and responsibilities; changing that relationship creates problems. Representatives were vocal regarding the need to place the distribution of marihuana for medical purposes within existing pharmacy models to ensure patient safety, to track drug abuse and double doctoring and to alleviate concerns regarding the sharing of health information with private industry. Provinces recommended that Health Canada consult with pharmacist associations regarding their willingness to be involved.

Record-keeping

In terms of creating and maintaining a record-keeping system for licensed commercial producers, provinces express concerns regarding program clients' privacy rights. There is some allowance for the inter-provincial sharing of information, however, more work needs to be undertaken to ensure it does not interfere with regulatory frameworks in conjunction with the disclosure of medical information, especially to private industry. It was suggested that a national record-keeping system maintained by Health Canada would alleviate such concerns.

Marihuana for medical purposes is the only controlled substance in which a patient would directly submit a prescription-like document directly to the producer, which poses concerns, such as monitoring and preventing illegal activities (i.e. overproduction and diversion). Provincial drug-monitoring systems were highlighted as imperative for tracking of contraindications, drug interactions, and prescription monitoring for narcotics control.

Scientific research and evidence
General concerns include lack of research and lack of an evidence base on which marihuana is recommended as a medical therapy, especially given the health implications of using an inhaled form of marihuana for medical purposes.

Delivery of marihuana for medical purposes to institutionalized patients
Patients living in long-term care facilities will not necessarily have access to marihuana for medical purposes through a mail order only service. Additionally, many long-term care facilities have no smoking policies, therefore the inability to access other marihuana products will prove to be challenging for those patients.

- Participants questioned the role of doctors and how they would be monitored for compliance.

Next Steps:
An analysis of the scheduled consultations with all provinces and territories will be introduced into the final reform package.

This is **Exhibit "QQ"** 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

HEALTH CANADA

Marihuana Medical Access Program Reform

Federation of Medical Regulatory Authorities of Canada (FMRAC) Meeting Report

September 26, 2011
Fairmont Chateau Laurier
1 Rideau Street
Renaissance Room
Ottawa, Ontario

Prepared by:
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Table of Contents

1. Background and Introduction

On June 17, 2001, Health Canada (HC) announced improvements to the Marihuana Medical Access Program (the Program or MMAP) which provides access to marihuana for medical purposes for seriously ill Canadians. The impetus of these changes came from concerns about public safety and security and the potential for illicit use which were raised by police and law enforcement, fire officials, physicians, municipalities, and program participants. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep children and communities safe. To this end, Health Canada is launching public consultations on the proposed improvements. A number of stakeholder groups have been invited to these consultations, including Provinces and Territories, municipalities, compassion clubs and cannabis dispensaries, medical associations, law enforcement, fire officials, and other interested parties.

A consultation meeting with Federation of Medical Regulatory Authorities of Canada (FMRAC) stakeholders was held at the Chateau Laurier Hotel, Renaissance Room, Ottawa, Ontario on October 26, 2011. In this morning meeting, there were 19 participants representing the Federation of Medical Regulatory Authorities of Canada (FMRAC).

Cathy Sabiston, Director General of the Controlled Substances and Tobacco Directorate of Health Canada welcomed participants and underscored the importance of hearing from law enforcement as they go forward with the proposed changes to the Program. In an effort to reform the Medical Marihuana Program, the government is consulting many stakeholders including the provinces and territories, law enforcement organizations, compassion clubs and cannabis dispensaries, and other key stakeholders. She noted there was an online consultation which generated over 2600 submissions.

She explained the objective of the meeting:

- to discuss elements of the proposed program changes and gather feedback from participants.

This report summarizes the discussion that took place at this consultation meeting.

2. Presentation of the key elements of the proposed improvements to the Program

Jeannine Ritchot, Director, Medical Marihuana Regulatory Reform (MMRR) began by thanking participants for attending and acknowledging that the contribution of ideas by the medical community is critical to the success of improving the Program and to the reform of the regulations.

Jeannine proceeded to set the stage by giving participants a brief overview of the key elements of the proposed improvements to the MMAP. The office of the MMRR was tasked with reviewing and making proposed changes to the Program. The objective of the proposed improvements is to reduce risks to Canadians and keep communities safe, while improving access for Canadians to the use of marihuana for medical purposes. She noted that the legalization or decriminalization of marihuana is not part of the proposed changes.

Jeannine explained that under the current program individuals see their physician in order to have him/her sign a form supporting their use of marihuana for medical purposes. The patient must then apply to Health Canada for an authorization to possess marihuana for medical purposes. The medical practitioner's form and their choice of supply must accompany the application form. The package is reviewed by Health Canada and appropriate authorizations and licences are issued where approved. These authorizations and licences are reviewed on a yearly basis. The process of obtaining marihuana for medical purposes is cumbersome and complicated.

Jeannine stated that Health Canada is proposing that the first step remain the same, the requirement to consult with a physician, as this is the best place to make a decision about a patient's medical condition. The physician no longer needs to fill out the Health Canada declaration. Another document, yet to be created, would be supplied to the patient by the physician. The individual would submit this document to licensed commercial producers (LCPs) in order to obtain marihuana for medical purposes. Health Canada would no longer receive or process applications consequently, a government agency would no longer have access to the sensitive medical records of Canadians. They would no longer be responsible for producing and distributing medical marihuana. Licensed commercial producers would be charged with this responsibility, and Health Canada's role would be more of a more traditional regulatory one.

After the presentation of the principle elements of the MMAP proposed improvements, there were questions of clarification and comments. They are summarized below.

To the question about making medicinal marihuana a prescription drug, Health Canada responded that it is not an approved drug and therefore cannot be prescribed through the drug prescription process. The Proposal envisions a "prescription" process for the use of marihuana for medical purposes. After the patient has discussed their case with the physician and there is a recommendation for this treatment, the physician would fill out a document (yet to be designed) that the patient would present to the LCP to obtain their treatment.

3. Reactions to the proposal for improvements to the Program

Participants were asked to identify the impact of the changes to the Program would have on their role as physicians. They were prompted to discuss their likes and dislikes about the Proposal. A number of important topics were addressed in the discussion. These thoughts were summarized and are synthesized below.

> *Focus Question: What do you like about the proposed improvements to the Program?*

Participants were unable to identify any benefits to the proposed improvements to the Program.

> *Focus Question: What are your concerns regarding the proposed change to the Program?*

A number of key issues were expressed by the group. These included concerns about physicians "prescribing" marihuana for medical purposes, the untested status of medical marihuana, the unauthenticated information that would be provided by the Expert Advisory Committee (EAC) the use of the Methadone Program as a model, the potential for misuse of medicinal marihuana, the lack of regulations and parameters around "prescribing" medicinal marihuana, and the ability of overburdened family physicians to take on this responsibility. The discussion which took place in response to the question above is themed and summarized in the following bullets.

✓ *Doctors should not be "prescribing" marihuana for medical purposes.*
- This is not a medical problem, but a political and social issue.
- The burden of controversy will be placed on physicians; they will have to police the use marihuana for medical purposes.
- Competing pressures put physicians in an untenable position. On the one hand, they are required to prescribe medication based on the best evidence available. On the other hand, they are pressured by the courts to provide patients with the option of using marihuana for medical purposes. There is no evidence to recommend this treatment, therefore physicians are "prescribing" blindly. For the physician, this creates a conflict of interest/ethics and a potential for litigation.
- Participants expressed a lack of confidence in the level of understanding of physicians of the effects of medical marihuana. It is difficult to educate when there is little or no evidence to support its use.
- Having doctors "prescribe" marihuana for medical purposes puts the physician at risk; many agreed that physicians should not be the gatekeepers to access this Program. As well, "prescribing" marihuana for medical purposes goes against the Medical Colleges recommendations.
- One doctor went on record for the Colleges he represented --"they will not touch it, prescribe it, or endorse it"; additionally, he warned that those physicians who do "prescribe" it will be under careful scrutiny.

✓ *Medical marihuana is untested and its effects are unknown.*
- There is no scientific evidence to recommend or not recommend the use of medicinal marihuana.
- The use of marihuana for medical purposes a non-medical intervention.
- Health Canada is asking physicians to authorize medical marihuana; a doctor's professional authority comes from knowledge and in this case, the knowledge is absent because there is no evidence to support the use of marihuana for medical purposes.
- A doctor cannot do a medical assessment where there is no scientific ground to support the safe use of medicinal marihuana.

✓ *An Expert Advisory Committee (EAC) cannot provide authenticated information.*
- There is little evidence to support the use of medicinal marihuana so an advisory committee cannot provide validated information to justify its therapeutic use.

Health Canada's response: The intention of the EAC would be to provide information to physicians who wish to make marihuana for medical purposes available to patients.

✓ *Concern with using the Methadone Program as a model for medical marihuana.*
- The associations in Ontario refused to be linked with the use of marihuana for medical purposes, even if it was through a methadone-like program; they refused to keep records and would continue to urge members to exercise extreme caution in "prescribing" such a treatment.

✓ *Issue of potential misuse of marihuana for medical purposes.*
- Most patients who want medicinal marihuana are not those who are desperately ill; those who are very sick receive this treatment.

Question: How do you foresee getting past the hurdle of physicians refusing to "prescribe" marihuana for medical marihuana?

Response: Health Canada stated they have lost every court case against the use of marihuana for medical purposes. It has been legislated that the Government of Canada/ Health Canada must ensure that there is a legal supply available to those who require medicinal marihuana. The medical benefits have not been well explained to the judges and therefore Health Canada continues to lose court cases. Health Canada ensured participants that their sentiments and concerns would be conveyed to the Director General's superiors.

✓ *The lack of regulations and parameters in "prescribing" medicinal marihuana is problematic.*
- The lack of guidelines and regulations associated with "prescribing" medical marihuana makes it difficult for physicians to recommend this treatment option.
- Participants acknowledged that the "status quo" is not sustainable, especially in light of the proposed changes to the Program.

Health Canada stated they would be open to hearing about and discussing categories 1-15, and others if necessary. The intention is to have others set the parameters on the use of medicinal marihuana. Health Canada is happy to provide information to assist others to educate physicians.

✓ *Overburdened family physicians cannot take on this responsibility.*
- If this change in the Program occurs, already overburdened family physicians will be further encumbered with paperwork and insurance claims. These time-consuming activities could severely disadvantage other patients.
- Some participants disagreed; they noted that this responsibility is already under the purview of physicians and difficult to deal with because it is unregulated. Most deal with it in the context of comfort care.

4. Current physician practices for the use of marihuana for medical purposes and recommendations for regulating the new Program.

In order to gain an understanding of physician and health professional issues and the potential problems foreseen with the Proposal for the new Program, the group were asked to give feedback and to share information on a number of key questions relating to the following focused themes.

- *Discussion themes:*
  - *a) Current practices*
  - *b) Suggestions for regulating the new Program*
  - *c) Health Canada's role*
  - *d) The role of other health professionals*

Participants were extremely reluctant to recommend any protocols that would endorse the use of marihuana for medical purposes. When pressed, they did share some ideas and make recommendations that were based on their practical experience. A number of key themes were discussed, including suggestions on clinical protocols and the regulation of the use of medical marihuana, for training and research on the use of marihuana for medical purposes, and finally, on the potential role for Pharmacists. This information was captured and is summarized below.

a. ***Current practices.***

✓ *Clinical protocols established in order to regulate the recommendation of marihuana for medical purposes.*

- One participant recounted their clinic's procedures.
  - the recommendation of medicinal marihuana was a team decision;
  - the team comprised a physician, a nurse, and a psychologist.
- This team was sophisticated and still experienced many challenges. It is difficult to see how "prescribing" marihuana for medical purposes could be routine for every family doctor.
- *Cautions:*
  - Once it is known that a clinic will "prescribe" medicinal marihuana, many patients will request it; it is paramount to have an appropriate diagnosis protocol in place to avoid misuse.
  - The physician could be put in danger because the people we who request this treatment usually the same as those who struggle with substance abuse and drug dependency; this could pose a significant risk to the physician.

b. ***Suggestions for regulating the new Program.***

✓ *Options proposed for controlling the use of medicinal marihuana.*

- One participant proposed three options for dealing with the problem of "prescribing" medicinal marihuana:
  - *Option 1:* Keep the status quo where the physician can only confirm a medical diagnose and does not "prescribe" marihuana for medical purposes; have another body judge how the medical condition can be relieved by this treatment.
  - *Option 2:* Treat medical marihuana like any other drug; do research and approve it through the formal drug approval process.
  - *Option 3:* Legalize marihuana for medical purposes.

Health Canada responded by saying that Health Canada is considering requiring a certification from the physician stating that the patient has a condition which may benefit from the use of medicinal marihuana.

✓ *Regulating use of marihuana for medical purposes for cancer patients and terminal patients.*
- The use of marihuana for medical purposes needs to be regulated.
- Most physicians do not have a problem "prescribing" to the palliative care group.
- If medicinal marihuana is to be available for other medical conditions, the physician has to clearly identify the medical conditions appropriate for its use.
- An appropriate medical diagnosis needs to be determined by using evidence to support the "prescription"; in some medical conditions, there is a need to balance the risk and benefit to the patient.
- It *was recommended* that the medical condition categories be reinstated in order to regulate the use of marihuana for medical purposes.
    - Less distinct categories make it more difficult to qualify a diagnosis because there is no defined condition. In this case, the risk is increased because there is no basis to regulate the use of medical marihuana.
    - The more specific the categories, the easier it is for physicians to follow a protocol to recommend this therapy.
- Some disagreed with the validity of the "end of life" use of medicinal marihuana. They claimed that there is no indication for the use of medicinal marihuana for any situation.

✓ *Protocols for the use of complementary therapy.*
- In general, the medical associations allow physicians to use complementary therapy as long as specific protocols have been followed. Once conventional diagnosis and conventional therapies have been exhausted and the "checklist" has been completed, the recommendation to use medicinal marihuana for terminal or comfort can be made.

c. *Health Canada's role.*

✓ *Physicians should be trained in the use of marihuana for medical purposes.*
- "Prescribing" medicinal marihuana should be restricted to specialized physicians; ones who have had specific training in this treatment.

✓ *Research into the effects of medicinal marihuana is extremely important.*
- Medicinal marihuana should be subject to scientific investigation; a research protocol should be established.
- *Suggestion:* The EAC should be the body that gives direction to the research on medical marihuana. This research should be regulated and subject to the protocols in place for any new prescription drug.

d. *The role of other health professionals.*

✓ *Pharmacist involvement.*
- Marihuana for medical purposes should be regulated and pharmacists should be brought in to handle it; this is a safer option.
- It was acknowledged that pharmacists would probably not want to be a distributor for the same reason as doctors are resistant; they fear violence.

Health Canada noted that they would return to the Pharmacists to revisit this issue with them.

5. Closing Remarks and Next Steps

Jeannine Ritchot closed the meeting by thanking participants for taking time to share their perspectives and for the honesty in answers to the questions. She assured the group that the discussions and opinions shared in the meeting would help build the regulations. She noted that the regulatory process is a transparent one and encouraged participants to make submissions by email to the website or by fax, for an additional two (2) weeks. She outlined the next steps, as follows:

- ✓ The Regulatory process is in its beginning. The consultations will yield clearer recommendations that will be published in the *Canada Gazette* 1 in 2012;
- ✓ The goal is to have the new Program in place by 2014.
- ✓ In the meantime, the program will continue to operate in the way it has in the past.

Appendix A: Agenda

Health Canada
Marihuana Medical Access Program

Federation of Medical Regulatory Authorities of Canada

Date: October 26, 2011
Time: 8:00 – 9:30
Chateau Laurier – Renaissance Room

Item	Time
Introduction	8:00-8:05
Presentation of key elements of the proposal	8:05-8:15
General Discussion 1. What do you like about the new proposal? Why? 2. Do you have concerns regarding the proposed changes? What are your concerns? Why? What suggestions for improvement would you make?	8:15-8:35
Discussion Themes a. The role of physicians and other health professionals b. Supporting access to dried marihuana c. Advertising marihuana for medical purposes d. Health Canada's role	8:35-9:25
Next Steps, closing remarks	9:25-9:30

Health Canada's Marihuana Medical Access Regulations Consultations

Meeting with Medical Associations

September 28, 2011
Ottawa, Ontario

Meeting Summary

The following meeting report summarizes the points raised during a meeting with Medical Associations on the proposed changes to the Marihuana Medical Access Regulations (MMAR) announced on June 17 2011. This meeting was organized by Health Canada and took place on the morning of September 28th, 2011 at the Capital Hill Hotel & Suites in Ottawa.

1. Background

Jeannine Ritchot, Director of the Medical Marihuana Regulatory Reform Project, presented an overview of the proposed changes to the MMAR and provided an update on the consultation process to date. She noted that to date, consultations have been had with compassion clubs and cannabis dispensaries in Vancouver, Montreal and Toronto, and she indicated there are upcoming meetings with law enforcement and municipalities.

2. Participants

Participants from the following organizations were in attendance:

- Canadian Medical Association (CMA)
- College of Family Physicians of Canada (CFPC)
- Canadian Medical Protective Association (CMPA)

3. General Feedback

After a brief overview of the proposed changes to the regulations, participants were asked to identify aspects of the proposed changes that they liked and would like to see retained. The following highlights emerged:

- Participants appreciated the fact that there was a component of communication/education/outreach to physicians in the proposal.
- The concept of an expert advisory committee was well-received.
- The elimination of categories, which was previously seen as a barrier, was well-received by some participants, though there was not consensus on this issue.
- Several participants felt that the elimination of the obligation to see a specialist was a positive step forward as they felt this step did not bring any value to the process. Concern was noted however that this may create pressure on the first point of contact, which may then be perceived by an individual as a barrier to

obtaining marihuana for medical purposes. In response to this concern, Health Canada officials noted that the opportunity to consult with a specialist would still exist under the new proposal, it would simply no longer be an obligation.

- The overall streamlining of the regulations was appreciated by participants.
- The involvement of Health Canada in bringing safety controls to the process was generally regarded positively.

Concerns

Participants noted the following concerns related to the proposed changes to the regulations:

- One of the major concerns cited by participants was related to the lack of scientific evidence, information and guidance available for the ordinary physician on the risks and benefits of marihuana for medical purposes. The need for conclusive evidence of the effectiveness of the use of marihuana for medical purposes, and the associated risks, was strongly emphasized.
- Participants were very concerned that there are currently no established regulated standards or clinical guidelines on prescribing practices for marihuana for medical purposes. Clinical practice guidelines should be an important pillar of this initiative.
- Participants noted that physicians have highly diverse backgrounds and prescribing philosophies. There is currently a very small number of physicians (3000 - less than 3-5% of CMPA's membership) who are comfortable prescribing marihuana for medical purposes. These physicians are not equally distributed across Canada. In order to provide Canadians across the country with equal access to marihuana for medical purposes, more family physicians need to be better equipped with knowledge and training about the benefits and risks associated with marihuana for medical purposes.
- Physicians want to help their patients and they feel accountable for the treatment they recommend. Participants reported that many physicians felt uncomfortable providing access to marihuana for medical purposes due to the state of knowledge on its benefits and risks. There was also some concern that this may put physicians in uncomfortable situations with sometimes long-standing patients, and that some physicians could be taken advantage of by patients faking symptoms to gain access to marihuana for medical purposes.
- Physicians want to know that the treatment they prescribe to patients will do some good, and they also need to be protected against legal consequences should they arise.

Suggestions

Participants made the following suggestions to address some of the concerns they noted:

- Disseminate information (a "one-pager") on the use of marihuana for medical purposes that is simple, easily readable and more widely available to physicians.
- Consider a variety of vehicles for consultation with physician, including an online module that physicians can access anytime depending on their time schedule.
- Consult physicians who are currently supporting access to marihuana for medical purposes on their rationalization for the legal liability involved.
- Engage physicians nationally through the College of Family Physicians Canada (CFPC), as well as through provincial chapters.
- Increase dialogue with other players (e.g. homeopaths, osteopaths, alternative care providers) to reflect the nature of today's collaborative care environment.
- Engage the practitioner community, e.g. naturopaths, pharmacists and nurse practitioners.
- Engage Registrars/Colleges of Physicians and Pharmacists in the discussion on standards, guidelines and prescribing practices for marihuana for medical purposes to ensure that the relationship between physicians and regulatory agencies is set up for success. Ensure that they recognize this is a different situation and obtain their buy-in for managing within an uncertain environment.
- Consider providing indemnification to physicians to help mitigate potential court issues.
- Undertake a privacy impact assessment to clarify the implication of physicians sending forms containing potentially sensitive information (e.g. on a diagnosis) to a licensed commercial entity.
- Engage physicians who believe in this cause and who are comfortable supporting access to marihuana for medical purposes and get them to produce some literature and knowledge about what they're doing for their colleagues and peers. Encourage them to build a respected body of knowledge so that the decision to support medical marihuana can be defensible to regulatory bodies and the court system.

4. Targeted Discussion Questions

Role of Physicians and Other Health Professionals

Participants made the following comments with regards to the role that physicians should play with respect to the use of marihuana for medical purposes:

- Several participants strongly articulated that the role of a physician is to treat patients and not to manage access to a controlled substance.

- Many felt that without enough available evidence on the benefit of the treatment, a physician does not have the ability to make a sound clinical judgement, and that without that ability, the role of a physician in this process would be unclear. If access to marihuana for medical purposes requires a clinical decision, then there must be sufficient evidence to link the use of marihuana for medical purposes to the management of a very particular disease and symptom.
- A suggestion was made that additional training should be required for physicians to provide access to marihuana for medical purposes.
- Participants felt that the process proposed by Health Canada to provide access to marihuana for medical purposes is too similar to traditional prescribing practices. Physicians prescribe treatment based on evidence and according to established guidelines. To obtain their buy-in, it will be important to better distinguish between prescribing treatment and providing access.
- With the current state of knowledge as it is, physicians fear they will be legally liable if they recommend a treatment that ultimately harms a patient. From the perspective of a regulatory body or a court, the responsibility for the treatment falls would fall on the physician as he would be seen as the ultimate decision-maker when it comes to administering the treatment.
- Physicians may only be comfortable with confirming a diagnosis, providing the evidence to support that diagnosis, and/or declaring that the patient has symptoms that may benefit from access to marihuana for medical purposes.
- Participants noted that because of the variability of the product offered, physicians do not have the same level of confidence in the treatment the patient is gaining access to (than with a standardized product).

Participants made the following comments with respect to the role of other healthcare professionals to support the use of marihuana for medical purposes:

- Participants felt that medical practitioners may not be the only professionals in healthcare who could be 'gatekeepers' to the Program. Participants indicated they saw a role for other healthcare professionals to support the use of marihuana for medical purposes and suggested exploring the possibility of broadening the scope to include other regulated professionals and health care providers.
- There should be a whole system in place to support the management of the prescribing to the individual, as well as a documented history of the diagnosis.
- Poor communication in a collaborative care environment is an issue that must be addressed. Participants suggested that information on dosage and period of prescribed treatment must be communicated back to the physician by the dispensary.

- A suggestion was made that independent qualified medical professionals, such as the ones used for CPP, Immigration, etc., could be the ones to provide Canadians with access to marihuana for medical purposes.

Supporting Access to Dried Marihuana for Medical Purposes

Participants made the following comments with regards to the removal of regulatory requirements governing symptoms and conditions for which marihuana may be used:

- Some participants supported the removal of regulatory requirements governing the categories of symptoms and conditions for which marihuana may be used, because it provides more leeway to patients and their physicians, but it was not supported by all participants
- Some participants were concerned that the removal of these categories of symptoms and conditions may in fact take away what little guidance is available to physicians on prescribing marihuana for medical purposes.
- It was noted that one of the values of the categories was that it provided a physician the opportunity to decline access to marihuana for medical purposes because the patient's condition did not appear on the list.

Participants made the following comments with regards to Health Canada's proposal that doctors would provide a patient with a document indicating their support for a patient to obtain marihuana for medical purposes from a licensed commercial producer:

- The term "support" caused participants concern because they felt it will be seen as a "prescription".

With regards to what should be on the form, the following comments were made:

- It was unclear to participants what the intent of the form was. Participants suggested that Health Canada should first clarify the intent of the form, and then form would follow function.
- Discussion was had about whether or not the form should include prescribed dosage and period of treatment time:
    - Participants noted they were uncomfortable with the notion of physicians recommending a prescribed dosage and period of treatment due to the fact that most family physicians have no expertise or background in supporting marihuana for medical purposes.
    - Participants also felt that without a research evidence-base to guide dosage, they should not be expected to recommend a dose.
    - If the purpose of the medical practitioner is only to facilitate access to medical marihuana, then the form should not include information on dosage.

    - Participants also felt that recommending a dose to a patient increased legal risks exponentially for physicians.
- Participants were concerned with who would have access to/a copy of the form.
- A suggestion was made to organize a separate workshop dedicated to discussing what information would appear on the form.
- Participants suggested that the form should include a record of informed consent that the patient recognizes the limitations of the treatment, and a release of liability.

Other comments made by participants include:

- Most participants felt that physicians don't have the proper tools to monitor or follow up with a patient afterwards.
- Participants noted concern with the absence of good monitoring tools to evaluate the possibility of harmful interactions with other medications taken by a patient over the long-term.
- Participants made no comment on recommending a route of administration of marihuana for medical purposes.

Patient Education and Outreach

- Participants felt that a physician should play a key role in patient education and outreach but felt that they did not have enough information and training to do so.
- A suggestion was made that Health Canada convey information about the benefits and risks associated with medical marihuana to the public so that they have in their hands the same information as physicians do.
- Participants indicated that outreach to physicians must involve equipping them with proper knowledge about the positive aspects of marihuana for medical purposes; however, they were concerned that there was not enough scientific evidence to support this.

Health Canada's Role

- Many participants were concerned that there would be insufficient consultation with the medical community on the proposed approach. They felt that the establishment of an Expert Advisory Committee was insufficient and wanted to ensure a lot more consultation would take place with physicians.