Understanding the New Access to Cannabis for Medical Purposes Regulations

Health Canada
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Introduction

The way individuals access cannabis for medical purposes is changing. As of August 24, 2016, the Access to Cannabis for Medical Purposes Regulations (ACMPR) will replace the Marihuana for Medical Purposes Regulations (MMPR).

Legal access to dried marijuana for medical purposes was first provided in 1999 using unique section 56 exemptions under the Controlled Drugs and Substances Act (CDSA). The decision in R. v. Parker in 2000 held that individuals with a medical need had the right to possess marijuana for medical purposes. This led to the implementation of the Marihuana Medical Access Regulations (MMAR) in 2001. The MMAR enabled individuals

with the authorization of their health care practitioner to access dried marijuana for medical purposes by producing their own marijuana plants, designating someone to produce for them or purchasing Health Canada supply.

Over time, court decisions resulted in a number of changes to the MMAR. In June 2013, the Government of Canada implemented the Marihuana for Medical Purposes Regulations (MMPR). The MMPR created conditions for a commercial industry responsible for the production and distribution of marijuana for medical purposes. Under the MMPR, individuals with a medical need could access quality-controlled dried marijuana produced under secure and sanitary conditions.

In June 2015, the Supreme Court of Canada, in R. v. Smith, decided that restricting legal access to only dried marijuana was unconstitutional. The Court decided that individuals with a medical need have the right to use and make other cannabis products. To eliminate uncertainty around a legal source of supply of cannabis, the Minister of Health issued section 56 class exemptions under the CDSA in July 2015, to allow, among other things, licensed producers to produce and sell cannabis oil and fresh marijuana buds and leaves in addition to dried marijuana, and to allow authorized users to possess and alter different forms of cannabis.

The ACMPR is Canada's response to the Federal Court of Canada's February 2016 decision in Allard v. Canada. This decision found that requiring individuals to get their marijuana only from licensed producers violated liberty and security rights protected by section 7 of the Canadian Charter of Rights and Freedoms. The Court found that individuals who require marijuana for medical purposes did not have "reasonable access".

The ACMPR are designed to provide an immediate solution required to address the Court judgement. Moving forward, Health Canada will evaluate how a system of medical access to cannabis should function alongside the Government's commitment to legalize, strictly regulate and restrict access to marijuana.

Overall, the ACMPR contain four parts.

Part 1 is similar to the framework under the MMPR. It sets out a framework for commercial production by licensed producers responsible for the production and distribution of quality-controlled fresh or dried marijuana or cannabis oil or starting materials (i.e., marijuana seeds and plants) in secure and sanitary conditions.

Part 2 is similar to the former MMAR regime. It sets out provisions for individuals to produce a limited amount of cannabis for their own medical purposes or to designate someone to produce it for them.

Parts 3 and 4 include:

- Transitional provisions, which mainly relate to the continuation of MMPR activities by licensed producers
- Consequential amendments to other regulations that referenced the MMPR (i.e., Narcotic Control Regulations, New Classes of Practitioners Regulations) to update definitions and broaden the scope of products beyond dried marijuana
- Provisions repealing the MMPR and setting out the coming into force of the ACMPR on August 24, 2016

As of August 24, 2016, Health Canada will accept applications from individuals who wish to register to produce a limited amount of cannabis for their own medical purposes or to designate someone to produce cannabis for them.

Under the ACMPR, Health Canada will continue to accept and process applications to become a licensed producer that were submitted under the former MMPR. Further, all licences and security clearances granted under the MMPR will continue under the ACMPR, which means that licensed producers can continue to register and supply clients with cannabis for medical purposes. New applicants can continue to apply for licences to produce under the ACMPR.

Health Canada's role

In administering the ACMPR, Health Canada has two main roles:

1. licensing and overseeing the commercial industry; and,
2. registering individuals to produce a limited amount of cannabis for their own medical purposes (or to have another individual produce it for them).

With respect to the licensed producers, Health Canada officials will continue to conduct a thorough review of the information on applications to ensure compliance with the regulations and associated Directives (i.e., the Security Directive). Health Canada will also continue to work closely with producers once they are licensed as a means of monitoring and ensuring compliance with the regulations and the CDSA, including through inspections.

As of August 24, 2016, Health Canada will begin to review applications from individuals who have the authorization of their health care practitioner and who wish to register to produce a limited amount of cannabis for their own medical purposes. This will involve reviewing the information submitted to ensure it complies with the regulations, and responding to requests from law enforcement to confirm the validity of a registration certificate.

In administering the regulations, Health Canada officials will work closely with a range of groups, including law enforcement, municipalities, provincial and territorial medical licensing authorities, and health care professionals, as well as Canadians who are interested in using the program.

What it means for health care practitioners

The role of health care practitioners is unchanged by the introduction of the ACMPR. As with the previous regulations, an individual who requires cannabis for medical purposes must first get a medical document from an authorized health care practitioner. Like under the MMPR, the medical document contains similar information to a prescription, including:

- the authorized health care practitioner's licence information
- the patient's name and date of birth
- a period of use of up to one (1) year
- a daily quantity of dried marijuana expressed in grams

In a hospital setting, the person in charge of the hospital can allow fresh or dried marijuana or cannabis oil to be administered to a patient or, sold or provided to a patient or an individual responsible for the patient.

Please refer to the guidance available on the Health Canada website for more information about the authorization of cannabis for medical purposes, including the Daily Amount Fact Sheet (Dosage).

What it means for licensed producers

Part 1 of the ACMPR covers the permitted activities and general responsibilities of licensed producers, including:

- requirements to obtain and maintain a licence
- establishment and personnel security measures
- authorized activities, including good production practices, packaging, shipping, labeling, import and export requirements, and record-keeping requirements
- client registration and ordering requirements

Part 1 includes the requirements of the MMPR and the relevant section 56 CDSA exemptions that responded to the decision in R. v. Smith, enabling the production and sale of fresh marijuana and cannabis oil in addition to dried marijuana.

Newly-permitted activities under the ACMPR include the production and sale of starting materials (i.e., marijuana seeds and plants) to those individuals who have registered under Part 2 to produce a limited amount of cannabis for their own medical purposes or to have it produced by a designated person, and the ability to sell an interim supply of fresh or dried marijuana or cannabis oil to registered persons while they wait for their plants to grow.

Licences and licence applications under the ACMPR consolidate the MMPR licence requirements for the production and sale of dried marijuana, the requirements for supplemental licences under the section 56 exemption, and the new requirements for the sale of marijuana seeds and plants.

Other notable changes from the MMPR include:

- New labelling requirements for cannabis oil to include the carrier oil used and for cannabis oil in dosage form to include the number of capsules or units in the container, the net weight, and the volume of each capsule or unit
- New labelling requirements for fresh and dried marijuana to include the percentage of THC and CBD that could be yielded, taking into the account the potential to convert THC-Acid and CBD-Acid into THC and CBD
- Provisions enabling individuals to receive their 30-day supply of cannabis within each 30-day period beginning on the date of the first sale
- Modifying that the accuracy of weight and volume of products in packages must now be between 95% and 105%, as opposed to between 95% and 101%
- Requiring all analytical testing to be done using validated methods (e.g., contaminants, disintegration, and solvent residue testing) and requiring disintegration testing for cannabis oil in capsules or similar dosage forms
- Requiring notification to the Minister of Health **prior** to commencing a recall

What it means for individuals who require access to cannabis for medical purposes

Individuals with a medical need, and who have the authorization of their health care practitioner, will now be able to access cannabis in three ways: they can continue to access quality-controlled cannabis by registering with licensed producers, they can register with Health Canada to produce a limited amount for their own medical purposes, or they can designate someone else to produce it for them.

Under the ACMPR, those who are currently registered to purchase from a licensed producer may continue to do so without any interruptions to their supply.

Individuals who do not currently have access to cannabis for medical purposes need to discuss their options with their health care practitioner. The practitioner may complete a medical document if it is decided that cannabis is a good treatment option.

Individuals can then use their medical document to either register with a licensed producer to obtain fresh or dried marijuana or cannabis oil, or with Health Canada to be able to produce a limited amount of cannabis themselves or designate someone else to produce it for them. As of August 2016, there are 34 licensed producers.

No matter how individuals obtain cannabis (i.e., under Part 1 or 2 of the ACMPR), their possession limit is the lesser of a 30-day supply or 150 grams of dried marijuana or the equivalent amount if in another form.

If an individual wants to produce a limited amount of cannabis for his/her own medical purposes, he/she must submit an application to register with Health Canada. An original medical document from the health care practitioner must be provided and the application must include information such as the location of where cannabis will be produced and stored.

Once successfully registered, the individual will receive a registration certificate from Health Canada. The certificate will include information required for the individual to show his/her legal authority to possess and produce cannabis. It will also include the location and maximum limits of the production and storage activities, as well as the individual's possession limit.

If an individual chooses to designate another individual to produce a limited amount of cannabis for him/her, he/she must submit an application to register with Health Canada (similar to if the individual was to produce it him/herself, but with information from the designated person). An original medical document from the health care practitioner and a declaration by the designated person, including information such as the location of where cannabis will be produced and stored, must be provided. The designated person must include a document issued by a Canadian police force proving the individual has not been convicted or received a sentence for a designated drug offence within the 10 previous years. A designated person can only produce for a maximum of two individuals including him/herself.

Once successfully registered, the registered person will receive a registration certificate from Health Canada. The designated person will also receive a document from Health Canada containing information outlining what activities are permitted. The certificate and the document could be used by either the registered person or the designated person, respectively, to demonstrate the legal authority to possess and produce cannabis.

Under the former MMAR, the only option to acquire starting materials was seeds obtained from Health Canada. In addition, individuals who were authorized to possess marijuana for their own medical purposes could only purchase an interim supply of dried marijuana from Health Canada while waiting for their production to be ready. The ACMPR permit newly registered persons to register with any of the producers licensed by Health Canada using a copy of their Health Canada registration certificate to obtain starting materials (seeds or plants) for production, and/or an interim supply of fresh or dried marijuana or cannabis oil while their own production is established.

The ACMPR outline in more detail the requirements for registered and designated persons upon successful registration, such as production, storage, transportation, and shipping.

The ACMPR also have formulas that indicate how many plants can be grown and how much cannabis can be stored, based on the daily quantity of dried marijuana authorized in the registered person's medical document.

In general, every one (1) gram of dried marijuana authorized will result in the production of five (5) plants indoors or two (2) plants outdoors. Individuals must indicate in their application whether they intend to produce marijuana plants indoors, outdoors, or partial indoors/partial outdoors. Individuals seeking to produce outdoors must confirm that the production site is not adjacent to a school, public playground, daycare or other public place mainly frequented by children.

Registered and designated persons are required to maintain any measures they think are necessary to protect the security of their cannabis. This could include, for example, installing a home alarm system or securing cannabis in locked cabinets. Health Canada has prepared an information bulletin that highlights the safety and security rules that must be adhered to under the regulations. This document further outlines a number of simple precautions that individuals can take to reduce risks to their health and safety.

If an adult, a registered person who has a designated producer can also participate in all of the activities that the designated person is authorized to conduct. This is a significant change from the former MMAR, which limited the ability of the registered person to take part in production by the designated person.

Another notable change from the former MMAR is that registered persons, as well as designated persons, will have the ability to alter the dried marijuana they harvest into other products, such as oils. In doing so, individuals are prohibited from using organic solvents (e.g., butane), given the health and safety risks posed by use of these products.

The inclusion of provisions enabling the production of products reflects the June 2015 decision in R. v. Smith. It should also be noted that registered clients of licensed producers also have this same ability to alter dried or fresh marijuana or cannabis oil into other products.

It is the responsibility of individuals to ensure that, in performing any alteration, they stay within the possession limit outlined on the registration certificate. Because the possession limit is articulated in grams of dried marijuana, individuals must manage their limit by taking into account the equivalency of their product to dried marijuana as is outlined in the regulations.

Part 2 of the ACMPR also describes other general measures, such as: how to cancel a registration; cannabis destruction requirements once production has stopped; and, instances in which Health Canada can share information with police or provincial/territorial health care licensing authorities.

What it means for law enforcement

Broadly speaking, the role for law enforcement has not changed. Law enforcement officials have a central role in enforcing the CDSA, including whether individuals who possess, produce, sell or provide and transport, deliver or ship cannabis are operating outside of the ACMPR framework.

Law enforcement officers can contact Health Canada to verify that a licensed producer is in fact licensed or that an individual is a registered person or designated person at any time and on a 24 hour basis.

Similarly, a law enforcement officer may contact a licensed producer to verify whether a person is a client of the producer or a person responsible for the client.

When requested, a police officer must be provided with proof that the possession or production of cannabis is legal. Depending on the situation, this could be a:

- Health Canada-issued producer's licence
- Health Canada-issued registration certificate
- Health Canada-issued designated person document
- Licensed producer-issued client label
- Licensed producer-issued "separate document" with the same information as a client label

What remains illegal

With the introduction of additional options, the ACMPR provide for reasonable access to individuals who require cannabis for medical purposes.

However, activities with cannabis conducted outside of the ACMPR, the NCR or an exemption pursuant to section 56 of the CDSA could be illegal.

Access to cannabis for medical purposes is only permitted under the terms and conditions set out in the regulations. Storefronts selling marijuana, commonly known as "dispensaries" and "compassion clubs," are not authorized to sell cannabis for medical or any other purposes. These operations are illegally supplied, and provide products that are unregulated and may be unsafe. Illegal storefront distribution and sale of cannabis in Canada are subject to law enforcement action.

Any individual registered to produce a limited amount of cannabis for him/herself may not sell, provide or give cannabis to another person.

A designated person may not:

- sell, provide or give cannabis to any person, except for the individual for whom he/she is authorized to produce in a registration; and,
- produce cannabis for more than two people registered with Health Canada, including him/herself, for whom he/she is authorized to produce in a registration.

Registered and designated persons may not produce in excess of the maximum limits outlined in a registration certificate.

It remains illegal for a company or an individual to advertise cannabis to the general public.

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