



Marijuana for Medical Purposes

Key Considerations

To continue advancing the clinical evidence base as well as evidence-informed policy, this brief recommends that stakeholders consider the following activities:

- Key stakeholders including federal and provincial governments, professional medical associations, governments, and researchers continue to convene to advance evidence-based dialogue on the medical applications of marijuana, to explore means through which to resource clinical research on the medical applications of marijuana, and to provide up-to-date information and educational opportunities for healthcare practitioners.
- Dialogue continue between stakeholders including federal and provincial governments, healthcare practitioners, licensed producers, and authorized medical users to seek solutions that will address concerns for access, supply, quality, affordability, choice and pharmacovigilance.
- Strategies and knowledge products be developed to reduce the risks associated with marijuana that apply regardless of whether use is for medical or non-therapeutic purposes. These risks include, for example, impaired driving, use during pregnancy, use during adolescence, and use where there is a family history or other predictor of mental health conditions.

The Issue

Marijuana* is the most widely used illicit drug in Canada, with 10.6% of Canadians aged 15 years and older reporting past-year use, according to the 2013 Canadian Tobacco, Alcohol and Drugs Survey (CTADS).¹ The use of cannabis is generally more prevalent among youth, with 22.4% of youth aged 15 to 19 and 26.2% of young adults aged 20 to 24 reporting past year use. Approximately 27% of Canadians aged 15 and older who used cannabis in the past three months reported that they used this drug every day in 2012 (Health Canada, 2013).² Although much research to date has focused on the health risks associated with the use of marijuana, clinical evidence supporting the use of marijuana for specific medical purposes is also beginning to emerge. As a result, policymakers, health professionals and medical regulatory bodies are seeking policy approaches that balance patient needs, emerging knowledge, health risks and concerns about misuse and diversion. This policy brief presents information, options and next steps for developing effective, evidence-based policy for the use of marijuana for medical purposes.

Regulating access to marijuana for medical purposes is complicated by many factors, notably its status as a prohibited substance, associated concerns about diversion for non-therapeutic use, social beliefs and values, and limited research on its clinical efficacy. There are polarized positions

* See Appendix A for a glossary of terms, including other commonly used names for marijuana.



on the issue, ranging from the belief that marijuana has broad healing powers to the belief that the harms associated with marijuana use outweigh any potential therapeutic benefits. Even among advocates for medical use, some think that marijuana should be regulated as any other pharmaceutical, while others think it should be freely available as a naturally occurring substance. Some groups are concerned that promoting marijuana for medical purposes communicates the message that marijuana is safe and therefore promotes recreational use as well. There are also concerns that authorizing the use of marijuana for medical purposes is a strategic stepping stone toward the legalization of marijuana for non-therapeutic use.

Canada's medical bodies, including the College of Family Physicians of Canada, the Canadian Medical Association and the Federation of Medical Regulatory Authorities of Canada, have expressed concern with the process by which dried marijuana has entered medical practice in Canada and especially with the recently introduced *Marihuana for Medicinal Purposes Regulations* (MMPRs). Under the MMPRs, healthcare practitioners, including medical and nurse practitioners, are responsible for providing a medical document (i.e., a prescription) to authorize patient access to marijuana from a licensed supplier. However, healthcare practitioners do not feel that they have the clinical evidence required to do so in an informed way.

Current Status

Legal Status

In Canada, marijuana is regulated under the [Controlled Drugs and Substances Act](#) (CDSA). The CDSA prohibits and identifies criminal sanctions for the production, possession and trafficking of marijuana as a Schedule II substance. Sanctions range from fines to prison, depending on the nature of the offense. Marijuana is also regulated through international treaties to which Canada is a signatory. The *Single Convention on Narcotic Drugs* requires that scheduled substances, including marijuana, be limited to medical and scientific research purposes. The Convention states that use and related activities (production, distribution, etc.) should be punishable offenses; however it also offers the option of diversion to treatment where appropriate.³

To date there has been no application to Health Canada for the approval of dried cannabis for a medical purpose under the *Food and Drugs Act* (FDA), which is the standard process for approval of a therapeutic drug. Therefore dried cannabis is technically not approved for sale as a therapeutic drug and has not been subject to the review, regulations and standards associated with Health Canada's approval process, including clinical testing, quality control, guidelines for dosage, route of administration, contraindications, and reporting and monitoring of adverse reactions.

There are three forms of marijuana-based pharmaceutical drugs approved by Health Canada for use in Canada: dronabinol (Marinol®), nabilone (Cesamet®) and nabiximols (Sativex®). Dronabinol and nabilone are both synthetic drugs in pill form, while nabiximols is sold as an oral spray derived from plant extracts.⁴

Medical Access Regulations

Canada first introduced regulations for legal access to dried marijuana for medical purposes in 2001 through the *Marihuana Medical Access Regulations* (MMARs). The MMARs were developed after the Ontario Court of Appeal found that the CDSA infringed on Section 7 of the *Canadian Charter of Rights and Freedoms* by failing to provide adequate exemptions for medical use.⁵ Under the MMARs, patients applied directly to Health Canada for an "Authorization to Possess." Applications had to include a medical declaration from a physician. Authorized patients had the option to purchase cannabis from Health Canada directly or to apply for authorization to grow their own individually or



through a designated person.⁶ As of January 2014, 37,844 Canadians were authorized to possess dried marijuana for medical use.

Health Canada introduced the MMPRs in June 2013 with the stated goals of addressing risks to personal safety associated with home production and moving toward a model comparable to that in place for other narcotics used for medical purposes. The MMPRs remove Health Canada from the patient approval process and eliminate authorizations for personal production, including designated growers. Under the MMPRs, Health Canada licenses commercial producers who supply product directly to authorized patients. Authorization for access is now provided directly by healthcare practitioners through a medical document (i.e., a prescription). The medical document must specify the approved daily quantity of dried product and period of authorization (up to one year). Patients can possess up to one month's quantity or a maximum of 150 grams of product at one time. Under the original regulations, producers could only supply marijuana in its dried form. However, as of July 2015, producers can supply marijuana in fresh (i.e., buds and leaves), dried and oil forms.⁷ This change resulted from the June 2015 Supreme Court of Canada decision in *R. v. Smith*,⁸ which found that the prohibition on the possession of non-dried forms of medical marijuana limited the right to liberty of the person.

The MMPRs formally replaced the MMARs on April 1, 2014. However, the new legislation has been challenged in the British Columbia Court of Appeal on the grounds that it requires patients unable to afford commercially grown marijuana to choose between risking their health and breaking the law by continuing to produce their own. The case was heard by the Supreme Court of Canada in February 2015. A federal court judge in British Columbia has issued an interim injunction that extends Authorizations to Possess valid as of March 31, 2014, as well as Personal-Use Production and Designated-Person Production Licenses valid as of September 30, 2013, until a decision in the case is rendered. If the case is successful, possible remedies include the continuation of these licenses, possibly with additional regulations compared to those previously in place, or financial arrangements such as subsidies provided to patients able to demonstrate need to ensure affordable access to commercially grown product.

The Government of Canada also tabled regulatory amendments in June 2014 that will require licensed producers to provide semi-annual reports to healthcare licensing authorities (e.g., provincial medical colleges). These reports will provide information on the healthcare practitioners providing medical documents authorizing medical marijuana use, the quantity of marijuana being authorized and basic patient information. This information is intended to improve the ability to monitor professional practice and to monitor patterns of access.

Physician Guidelines

The College of Family Physicians of Canada (CFPC) released guidelines in September 2014 to assist physicians considering the authorization of marijuana for medical use.⁹ Seven provincial colleges had also previously published guidelines or advice for physicians.[†] There is agreement across these guidelines that clinical evidence on indications, dosage, interactions, risks and benefits of marijuana for medical purposes is lacking.¹⁰ These guidelines are also consistent with international approaches in recommending that physicians first exhaust conventional treatments before issuing medical documents for marijuana. The CFPC guidelines further state that authorizations should be considered only for patients with neuropathic pain that has not responded to standard treatments.

[†] British Columbia, Alberta, Saskatchewan, Manitoba, Quebec, New Brunswick, and Newfoundland and Labrador. Ontario, Nova Scotia and Prince Edward Island are in the process of developing guidelines.



Some of the guidelines go beyond clinical considerations to ethical considerations such as prohibiting physicians from charging additional fees for marijuana authorizations and from conducting virtual consultations with patients where no previous patient–doctor relationship exists.†

What Other Countries Are Doing

Marijuana is not an approved therapeutic substance in most countries. Synthetic cannabinoid preparations such as nabilone and dronabinol are approved for prescription in a small number of countries and for limited conditions. Both clinical and observational research is ongoing internationally to build the evidence base needed to be able to evaluate proposals for expanded uses of and access to both plant-based marijuana and synthetic cannabinoids for medical purposes. The following paragraphs provide summary information on a selection of the more developed medical marijuana programs in place in other countries.

The United States: Twenty-three states and the District of Columbia have legislation authorizing the use of marijuana for medical purposes. Most states have mandatory patient registration systems (e.g., Colorado, Oregon, Rhode Island), some have voluntary registration (Maine and California) and Washington simply allows physician documentation as an affirmative defence without maintaining a central registry (i.e., someone arrested for possession can show a valid prescription to avoid prosecution). A small number of other states (Florida, Kentucky and Maine) have recently approved the use of cannabidiol (CBD) extracts, primarily for disorders related to seizures. These extracts must have either no or negligible levels of tetrahydrocannabinol (THC).

Some states restrict use to specific conditions (e.g., AIDS, cancer, Crohn’s disease), while others provide a great deal of breadth (e.g., “any other illness for which marijuana provides relief”).¹¹ Most states have a regulated dispensary system, although there is also considerable variability in the concentration of dispensaries and the range of products available. Minnesota, for example, recently introduced a medical program that limits marijuana products to liquids, oils and pills and not dried plant material.¹² Because marijuana is a Schedule I drug under the *Controlled Substances Act*, physicians cannot prescribe it. Most states, however, require a physician’s recommendation or authorization to validate an individual’s medical use.

There has been some controversy about federal enforcement action on medical dispensaries in states that have approved medical use. In May 2014, the House of Representatives passed the fiscal year 2015 Commerce, Justice, Science, and Related Agencies Appropriations Act, which states that Department of Justice funds are not to be used to prevent states from implementing laws authorizing medical marijuana.¹³ The Act must still pass through the Senate before going to the President for authorization.

The Netherlands: The Dutch medical marijuana program began in 2000. Through this program, the Office of Medicinal Cannabis (OMC), created in 2001, has a monopoly on marijuana production, distribution, importation and export. The OMC offers four types of marijuana with varying levels of THC and CBD, distributed through pharmacies based on physician prescriptions.¹⁴ The OMC’s patient guidelines recommend the use of marijuana as a brewed tea or via a vaporizer.¹⁵ The OMC does not limit the conditions for which marijuana can be prescribed, but it does suggest that doctors prescribe marijuana not as a first line of treatment and only in cases where standard treatments do not have the intended effect or produce unacceptable side effects.

† See, for example, the [Policy Regarding the Authorization of Marijuana for Medical Purposes](#) released by the College of Physicians and Surgeons of Nova Scotia.



The United Kingdom: The United Kingdom has licensed the synthetic cannabinoids nabiximols (i.e., Sativex) and nabilone for a limited number of conditions. These drugs are prescribed by physicians and obtained from pharmacies as regulated pharmaceuticals. Dried plants or plant-based extracts are not licensed for use.

What the Evidence Says

Clinical Evidence: There are a number of high-quality summaries of the current evidence on marijuana's medical properties and applications. Health Canada's report *Information for Health Care Professionals: Cannabis*¹⁶ and CCSA's *Clearing the Smoke on Cannabis: Medical use of cannabis and cannabinoids*³ are two notable Canadian examples. Evidence is also emerging continually as more pre-clinical[§] and clinical studies get underway. Most regulatory frameworks that list specific conditions include those for which there is consistent evidence of efficacy, including chronic musculoskeletal and neuropathic pain; nausea and vomiting due to chemotherapy; appetite stimulation for AIDS-related wasting; and muscular spasticity.

Impact on Non-Therapeutic Use: One of the primary concerns with allowing the use of marijuana for medical purposes is that it will increase rates of non-therapeutic use at the population level, in particular among youth. This concern is based on the idea that accepting marijuana for medical use will promote the impression that all marijuana use is safe or beneficial,¹⁷ an idea that Canadian youth have already expressed.¹⁸ There is evidence that decreased perception of risk is associated with increased rates of marijuana use among youth.¹⁹

States in the US that have medical marijuana legislation do tend to have higher rates of reported non-therapeutic use. However, this relationship does not necessarily indicate that medical legislation causes increased rates of use and studies have not found support for a causal relationship.^{20,21} Because the higher rates of use predate the introduction of medical marijuana legislation, it is more likely that existing social norms that are supportive of marijuana use also predict stronger public support for medical marijuana legislation.²²

Health and Social Risks: There is consistent evidence that there are risks and harms associated with marijuana use, whether for medical or non-therapeutic purposes. Marijuana impairs driving ability and increases the risk of motor vehicle crashes and fatalities. There is evidence that a dramatic increase in access to marijuana for medical purposes is associated with an increase in fatal motor vehicle crashes in which drivers tested positive for marijuana.²³ Early initiation of marijuana use is associated with increased risk of psychosis among those with pre-existing risk factors. These risks increase with earlier age of initiation and higher levels of use. They further illustrate the importance of ensuring that regulatory policy is informed by both clinical evidence and public health considerations. Preliminary evidence, for example, indicates that commercialization of marijuana for medical purposes is associated with a decreased perception of risk associated with marijuana use.²⁴ This evidence aligns with knowledge of basic marketing, the basis for financial investment in product promotion and availability, to sway social norms and purchasing behaviour.

Limitations

Clinical Evidence: Much of the information available on the clinical efficacy of marijuana for medical purposes is based on studies with small sample sizes and brief durations. The patients involved in these studies are also not consistently representative of most patients seeking medical access. For

[§] Pre-clinical studies take place to establish safety and feasibility prior to beginning clinical trials with human subjects.



example, studies have focused on clients with neuropathic pain, whereas clients seeking access are generally more likely to report with arthritis, back pain and fibromyalgia.²⁵ There is limited clinical trial evidence available, including information about adverse effects, different strains and dosages. This evidence would normally inform clinical guidelines for healthcare practitioners.

Program Implementation: The number of patients registered for medical marijuana programs varies across both time and location.^{26,27} More information is required to better understand to what extent this variability can be attributed to factors such as patient and health practitioner awareness, eligibility requirements, cost and social norms, and what the implications are for meeting patient needs and avoiding misuse. There is also evidence of problematic prescription practices such as a small number of healthcare providers being responsible for a disproportionate number of patient authorizations. Unfortunately, the evidence is primarily anecdotal and problematic practices have not been systematically explored. The proposed amendment to the MMPRs that will require licensed distributors in Canada to provide information to provincial licensing authorities when requested will, if implemented, help to identify trends and irregularities in prescribing practice.

Evidence from tobacco and alcohol policy research can be drawn on to inform policy approaches to reduce rates of marijuana use among youth and to address marijuana-impaired driving. Examples of effective strategies include pricing controls, advertising restrictions and limits on points of sale. However, it is important to recognize that tobacco and alcohol policy does not address medical use. Given this distinction, it will also be useful to look to the emerging knowledge on reducing the misuse of psychoactive pharmaceuticals.

Impact on Non-Therapeutic Use: Studies that have examined the impact of legislation for the medical use of marijuana on recreational marijuana use have been observational and unable to conclusively establish causation or mechanisms of influence. The impacts identified in other countries might not be applicable to Canada given differences in health and social systems, cultural norms, and trends in pharmaceutical and illicit drug use. There are similar limitations on research investigating the ability of different regulatory approaches to meet patients' needs, although there is work underway.²⁸ Finally, there is some evidence that decreased regulation, including flexible arrangements for personal or designated growers and retail sales, is likely to result in increased rates of diversion. Again, more rigorous study is required to determine the optimal regulatory structure.

Gaps

Clinical Evidence: From a medical perspective, the key information gaps are in the clinical evidence healthcare practitioners need to advise patients on optimal dosages, strains and methods of ingestion for specific conditions and on contraindications, possible interactions with other medications or medical conditions, adverse effects and risks associated with long-term use. This information is emerging, but the body of evidence is not currently at the level deemed acceptable to Canada's medical colleges. This information is also important to policy makers establishing eligibility guidelines, whether at the federal, provincial or college level.

Program Implementation: There are also gaps about how best to balance patient rights with safety, security and public health. For example, current smoking laws ban the use of tobacco in public places and in the workplace, but are silent about marijuana. Employers have a duty to accommodate the legitimate health concerns of employees, which extend both to individuals who use marijuana for medical purposes and to employees who are not comfortable being exposed to second-hand marijuana smoke.

Health and Social Risks: There are many known harms associated with marijuana use, such as cognitive impairment and increased risk of psychosis among those with pre-existing risk factors. These risks increase with earlier age of initiation and higher levels of use, raising particular concerns



for use among youth. There are recognized best practices in preventing substance abuse among youth generally, such as ensuring age-appropriate, fact-based messaging and building resilience. However, there are also gaps in knowledge specific to the use of policy to prevent the diversion or misuse of substances intended for medical use. Experience in the United States indicates that decreased regulation, including flexible arrangements for personal or designated growers and retail sales, is likely to result in increased rates of diversion; however more systematic analysis is necessary. It is also unclear to what extent individuals exaggerate or create symptoms to justify marijuana use for non-approved conditions or for non-therapeutic purposes.

Changing Policy Context: An additional gap in knowledge concerns the impact that changes to recreational marijuana policies, such as decriminalization or legalization, would have on use for medical purposes. For example, some patients might choose simply to access product from non-medical suppliers. There is preliminary support for this possibility, as medical marijuana sales in Colorado have decreased in March and April 2014 and recreational sales have increased steadily since the legalization of retail sales on January 1, 2014.²⁹ Longer-term trend data as well as qualitative information are needed to understand this relationship.

Options for Change

Developing policy that satisfies the broad range of interests on this issue has been and will continue to be a daunting task. However, given that Health Canada has been ordered by the courts to ensure Canadians have reasonable access to marijuana for medical purposes, it is a task that must continue.

Clinical Practice: The Collège des médecins du Québec and the Canadian Consortium for the Investigation of Cannabinoids are establishing a pharmacovigilance project to monitor outcomes and adverse events related to the use of marijuana for medical purposes in Canada. This project will provide observational but not clinical trial data. To date only one controlled clinical trial under the MMPRs has been announced in Canada, which will look at the use of marijuana as an analgesic for osteoarthritis of the knee. There are a number of options to support research into the use of marijuana for medical purposes that can be explored, including government grants and financial incentives, and partnerships with private companies, medical bodies and academia. All options have resource implications that can pose a significant challenge in a context of fiscal austerity.

In the absence of the standard prescribing guidance that accompanies drugs approved by Health Canada, medical organizations and practitioners are seeking information that will help them better meet the needs of their patients without assuming undue liability. There is an opportunity to draw on the guidelines released by medical colleges to provide a consistent reference across Canada. This reference could also build on the information provided in Health Canada's report, *Information for Health Care Professionals: Cannabis*,¹³ which has been well received by the medical field. A useful addition would be practical advice for prescribing physicians, such as an emphasis on informed consent, information on safety concerns such as driving, diversion of medical supply or supply from illicit sources, and secure storage and destruction.

Continuing clinical trials for synthetic cannabinoids can and should accompany ongoing research into the use of plant-based preparations. Research on methods of ingestion that reduce the harms associated with smoking cannabis and that allow for more controlled dosages will also benefit both patients and health practitioners.

The absence of clinical trial evidence raises the question of whether and how to determine which medical conditions or symptoms qualify a patient to use marijuana for medical purposes. More restrictive requirements for patient use allow medical professionals to stay within the more robust evidence available. They will also limit the number of patients participating in the program. These



restrictions do, however, face the possibility of a legal challenge from patients who do not meet the criteria. There is also the moral dilemma of whether it is preferable to have a patient using marijuana under a physician's supervision or covertly, particularly considering the issue of access to a quality controlled versus black market supply.

Role of the Healthcare Practitioner: The Royal College of Physicians and Surgeons of Canada has recommended that the current “medical document” requirement be replaced by a physician declaration.⁷ Such a declaration would confirm that the patient meets broad criteria for the use of marijuana for medical purposes or that the physician does not oppose the patient's choice to use marijuana for medical purposes. The declaration would not, however, carry the same level of professional responsibility and accountability that a prescription would.²²

Another alternative would be to create a designated license for physicians specializing in the use of marijuana for medical purposes, similar to that in place for methadone. This restriction would have the advantage of providing patients access to physicians with specialized expertise. This specialization might be particularly helpful given the challenge of staying apprised of emerging evidence in an area where clinical evidence is still in the early stages of development. However, using the methadone model as an example, challenges such as limited access to licensed specialists, particularly in rural or remote communities, could be anticipated.

Personal and Designated Production Licenses: The MMPRs eliminated personal and designated grower licenses to address concerns for safety and security associated with unsafe growing conditions (e.g., mold, electrical fires) and theft or other diversion of product to the black market. Canada is not alone in having these concerns, with several US states implementing regulatory changes over time to try to close existing loopholes that have been exploited to support criminal activity. If production licenses were to be introduced in a way that addressed these concerns, they would have to be implemented with more stringent requirements that would be more costly for both licensees to meet and for the state to monitor.

Distribution through commercially licensed producers facilitates product regulation and control. However, this approach has been criticized as it restricts the choices of product available to patients, particularly in the short term, and increases costs in comparison with patients growing for personal use. The outcome of the current court challenge to the removal of personal and designated grower licenses will shape the direction of future legislative options relating to product sources.

Impact on Non-Therapeutic Use: Experience with regulating use by youth of tobacco and alcohol has generated an applicable body of evidence that can be drawn on to reduce rates of use. Examples include bans on advertising and accessibility.³⁰ Similarly, the body of knowledge generated by efforts to reduce alcohol-impaired drivers can be drawn on to inform efforts to reduce marijuana-impaired driving. Clear messaging emphasizing the distinction between medical and non-therapeutic use would contribute to greater understanding of the harms associated with marijuana use by clarifying the limitations of medical applications (i.e., beneficial for certain conditions and patients only).

Changing Policy Context: Although unlikely in the short term in Canada, the legalization of marijuana would impact medical access. Under a legalized policy framework, regulations for non-therapeutic and for medical use would most likely continue to be distinct from one another. In Colorado, for example, the taxes on marijuana sold for non-therapeutic use are considerably higher than those on marijuana sold for medical use.



Conclusion

The use of psychoactive substances is a health issue. This statement perhaps holds true most strongly when applied to the use of psychoactive substances for medical purposes. Providing the best care available to Canadians should therefore guide discussion of policy options on this complex issue. Moving toward solutions will require collaboration between the many stakeholders involved. This collaboration has already begun through expert advisory committees and consultations conducted by Health Canada.

Appendix A: Glossary

Cannabidiol (CBD): A cannabinoid that lacks detectable psychoactivity.¹³

Cannabinoid: A group of compounds that share a common chemical structure found in the cannabis plant.³

Cannabinol (CBN): A product of THC oxidation, with significantly lower psychoactivity.¹³

Cannabis: A tobacco-like greenish or brownish material consisting of the dried flowers, fruiting tops and leaves of the cannabis plant, *Cannabis sativa*.³

Cannabis resin (hashish): The dried brown or black resinous secretion of the flowering tops of the cannabis plant.³

Marijuana / marihuana: The common name given to cannabis, most often spelled with a “j.”

Synthetic cannabinoid: A cannabinoid produced through artificial means in a laboratory.

Tetrahydrocannabinol (THC): A cannabinoid known for its psychotropic effects.¹³





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