



SUBMISSION TO THE TASK FORCE ON

Marijuana Legalization and Regulation

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CANADIAN
PHARMACISTS
ASSOCIATION

ASSOCIATION DES
PHARMACIENS
DU CANADA

The Task Force on Marijuana Legalization and Regulation is seeking advice and input from experts and stakeholders on the design of a new framework for legal access to marijuana. The Canadian Pharmacists Association (CPhA), the national voice of Canada's 41,000 pharmacists, makes its submission to the Task Force as health care professionals and recognized drug therapy experts, focused on improving patient outcomes and promoting public health. This submission responds directly to the issues outlined in the Task Force's recent discussion paper ('Toward the Legalization, Regulation and Restriction of Access to Marijuana').

Introduction

Health Canada's announcement of new regulations governing medical marijuana makes clear that the Task Force will have an important role in the development of a longer-term plan for the regulation of access to cannabis for medical purposes. While CPhA is focused on the role of pharmacists in dispensing medical marijuana, Canadian pharmacists recognize that any framework for recreational marijuana will impact medical users. For this reason, CPhA supports immediate action to secure and enhance the existing medical cannabis framework to ensure its integrity once recreational marijuana becomes legal. Furthermore, as health care professionals and drug experts, pharmacists support improving public education and awareness of the potential harms associated with all marijuana use, including drug interactions and addictive behaviour.

CPhA was disappointed that the benefits of pharmacist management and distribution of medical marijuana were not recognized by the Access to Cannabis for Medical Purposes Regulations (ACMPR); however, we recognize the challenges faced by Health Canada in responding immediately to the Federal Court's judgment in *Allard v. Canada*. We note Health Canada's assurance that the ACMPR should not be interpreted as being the longer-term plan for the regulation of access to cannabis for medical purposes, and that it will be determined as part of the Government's commitment to legalize marijuana. For this reason, CPhA's submission to the Task Force primarily addresses issues relating to regulation of medical cannabis arising from the legalization of recreational marijuana.

CPhA's recommendations to the Task Force are informed by:

- A growing concern among the profession about the lack of clinical oversight in the distribution of medical marijuana;
- Consultations and input from pharmacists;
- An independent report by KPMG which identified pharmacy as the leading option to manage and dispense medical marijuana;
- Public opinion polling.

Three clear priorities and recommendations emerged from CPhA's research and consultations that the Association highlights for consideration by the Task Force:

1. Health and Safety: The Role of the Pharmacist in Dispensing and Managing Medical Cannabis

As health care professionals, Canadian pharmacists are concerned with minimizing the harms of use associated with all forms of marijuana. With respect to medical cannabis, the Association has clearly articulated its position that management and dispensing by pharmacists is in the best interest of patient safety. In addition to providing secure and safe access to medications, pharmacists have the necessary expertise to mitigate the potential risks associated with medical marijuana, including harmful drug interactions, contraindications, and potential addictive behaviour.

While CPhA does not endorse any specific production or distribution system for recreational marijuana, pharmacists urge the Task Force to prioritize the health of Canadians in its deliberations and strike an appropriate balance between legalizing marijuana for recreational use without promoting its use by Canadians.

It is widely recognized that cannabis legalization for non-medical purposes would have significant implications for the medical system. Given the continuing need for patients to continue to access safe, medical-grade cannabis, under the supervision of a licensed health care professional, once recreational marijuana is available, CPhA advises the Task Force to ensure the integrity of the medical system going forward and take immediate action to mitigate any unintended effects of legalization. Pharmacist management and dispensing of medical cannabis is the best option to strengthen any future framework and protect patient and public safety.

2. Medical and Recreational Cannabis: A Distinction with a Difference

It is critical that continued access to cannabis for medical purposes is maintained in a legalized context. CPhA is concerned that the recent discussion paper ('Toward the Legalization, Regulation and Restriction of Access to Marijuana') suggests that access to cannabis for medical purposes could be restricted to patients who would be unable to access recreational marijuana to manage their condition. Although derived from the same plant, there are important differences between medical and recreational marijuana. For example, medical users may seek out strains and forms that can provide symptomatic relief (primarily through Cannabidiol or CBD), while recreational users may predominantly seek out those with psychoactive effects (i.e. strains with higher THC). Recreational marijuana is not a substitute for medical cannabis. Diverting patients away from the existing medical stream, absent the care and oversight of a licensed health care professional, would put patient health at serious risk.

Experience in international jurisdictions has demonstrated the importance of differentiating medical and recreational marijuana by restricting product strains and forms, as well as establishing distinct access channels for medical cannabis.ⁱⁱ For example, stakeholders in Colorado and Washington State agree that when the function of cannabis is medical, it should be treated as such in terms of dosage, guidelines, production, distribution, and form.ⁱⁱⁱ A single system may present administrative efficiencies; however, it would undermine the important distinction between medical and recreational marijuana, and the unique therapeutic requirements of medical cannabis patients.

3. Patient-Focused Pricing

Patient access to safe and affordable medical cannabis within a new framework will be highly dependent upon price. The Task Force should consider the importance of pricing policies that deter recreational use of marijuana, which also ensure that cost is not a barrier to therapy for patients using medical cannabis. Tobacco taxation and pricing policies in Canada clearly demonstrate the effectiveness of higher prices to deter tobacco use and provide an excellent case on which to model a pricing framework for recreational marijuana.

Recreational marijuana should be priced and taxed at levels which do not promote use of the product, and should be significantly higher than the cost of medical cannabis. As such, CPhA recommends that the federal *Excise Tax Act* be amended to zero-rate medical cannabis, in alignment with the tax treatment of prescription drugs and drug dispensing fees.

Recreational marijuana should be subject to sales tax. Price differentiation between medical cannabis and recreational marijuana will also help to ensure that medical cannabis patients are not diverted from the medical system for reasons of cost or convenience, which would remove them from the supervision and oversight of their prescribing physician and other health care professionals, including pharmacists.

RESPONSE TO CONSULTATION: TOWARD THE LEGALIZATION, REGULATION AND RESTRICTION OF ACCESS TO MARIJUANA

CPhA Recommendations

A recent independent report by KPMG ('Improving Medical Marijuana Management in Canada') made a number of key recommendations endorsed by CPhA to improve medical marijuana management in Canada. The same report also identified a number of leading practices for recreational cannabis as part of a regulatory framework to protect both recreational users and medical patients. These observations form the basis of CPhA's submission to the Task Force with respect to Discussion Issues 1 through 4 (Minimizing harms of use; Establishing a safe and responsible production system; Designing an appropriate distribution system; Enforcing public safety and protection). CPhA's response to Discussion Issue 5 (Accessing marijuana for medical purposes) addresses the importance of maintaining a dedicated and robust framework governing access to medical cannabis and outlines the role of community pharmacists in supporting a safe and secure medical market.

DISCUSSION ISSUE 1: MINIMIZING HARMS OF USE

Recommendation: Coincide legalization with a public education campaign

As drug therapy experts, pharmacists urge the government to ensure Canadians are well-informed, and understand the risks associated with using marijuana, including risk of addiction. It is well-known that smoking can harm the lungs; however, Canadian youth in particular may be less aware of increased risk of psychosis and schizophrenia, or long-term negative effects on cognitive and intellectual development. A report from the Canadian Center on Substance Abuse (CCSA) on Canadian youth's perception of marijuana indicated that the youth saw cannabis as natural, safe and not as a drug.^{iv} There is also evidence that youth are more likely to use products in concentrated form with higher levels of THC, and to use marijuana in combination with other substances.^v

Lessons learned from stakeholders in Washington State and Colorado – jurisdictions where both recreational and medical cannabis is legal – have identified the importance of investing proactively in a public health approach that builds capacity in prevention, education and treatment before implementation to minimize negative health and social impacts associated with using marijuana.^{vi} CPhA recommends that any campaign should also educate the public about the potential for harmful interactions between marijuana and prescription drugs.

With a growing number of clinical trials, evidence suggests that marijuana may increase the risk of bleeding when taken with anti-inflammatory drugs such as Aspirin®, ibuprofen, or naproxen. It may also affect blood sugar levels, which could require medication adjustments for diabetes medication. Marijuana may increase the amount of drowsiness caused by some drugs, including benzodiazepines, narcotics, some antidepressants, and alcohol.^{vii} Finally, misconceptions around the difference between medical versus recreational use continue to persist. Increasing public awareness of the health risks associated with marijuana, particularly as they relate to smoking, will be critical in promoting responsible use.^{viii} Pharmacists are well-positioned to help educate the public about these health risks as highly accessible health care professionals within their communities.

Recommendation: Minimum age for legal purchase

There is clear evidence to support the establishment of a minimum age for legal purchase of recreational marijuana. In establishing a minimum age, jurisdictions should be guided by scientific evidence. CPhA supports the evidence presented by the Task Force's discussion paper ('Toward the Legalization, Regulation and Restriction of Access to Marijuana') that risks from marijuana usage are elevated until the brain fully matures (i.e. when a person reaches about the age of 25). For this reason, CPhA recommends that jurisdictions explore options other than tying the minimum age for legal purchase of recreational marijuana to the minimum age of purchase for other controlled substances (e.g. alcohol or tobacco).

DISCUSSION ISSUE 2: ESTABLISHING A SAFE AND RESPONSIBLE PRODUCTION SYSTEM

Recommendation: Mandate product warnings

Marijuana used for recreational purposes carries potential health risks that exceed any apparent benefit, similar to tobacco and alcohol.^x Emphasizing risks associated with marijuana use is therefore required to discourage its use. Public health and harm reduction strategies will play a critical role in situations where marijuana is readily accessible.^x CPhA recommends that at minimum, recreational product packaging should contain clear and explicit warnings. Using tobacco as an example, marijuana product packaging could display product content as well as written and visual information on potential health hazards and adverse drug reactions.^{xi} Taken together with other measures, this or a similar strategy would allow users to be better informed of the risks of recreational cannabis.

DISCUSSION ISSUE 3: DESIGNING AN APPROPRIATE DISTRIBUTION SYSTEM

Recommendation: Implement rigorous product management regulations

A March 2016 independent report by KPMG ('Improving Medical Marijuana Management in Canada') found that recreational marijuana products should be managed in a manner that is consistent with many of the distribution requirements for medical cannabis because of the inherent product risks. Recreational marijuana retailers should be expected to meet strict criteria – similar to pharmacy – in order to qualify for a distribution license. It is recommended that the criteria focus on risk management and product quality. As an example, criteria could include:

- Secure, behind-the-counter storage to limit uptake and the opportunity for diversion and/or theft;
- Climate controls to ensure product stability;
- Signage to indicate age restrictions and potential harm;
- Banning advertising which can encourage use.

Recommendation: Mandate training for retail staff

CPhA is particularly concerned about medical cannabis patients who may choose to access marijuana through recreational channels in the self-management and treatment of their condition. To help address this concern, any retail personnel with direct contact with users should receive training from accredited health care professionals on the differentiation between medical and recreational products. Furthermore, all staff should be trained to direct users, particularly medical marijuana patients, to licensed health care professionals. This is critical in maintaining a clear distinction between medical and recreational cannabis markets, which will ensure that medical cannabis patients have access to therapeutically appropriate products under the oversight of a licensed health care professional.

Recommendation: Maintaining distinct medical and recreational markets

Given the importance of maintaining distinct streams for medical and recreational marijuana, experience in jurisdictions where medical and recreational systems coexist should be applied to the design of an appropriate distribution system for the retail market. As the Task Force develops recommendations for a comprehensive regulatory framework, care should be taken to ensure that the design of a recreational distribution system does not negatively impact patient access to medical cannabis.

Recommendation: Patient-focused pricing

The Task Force should consider the importance of pricing policies that deter recreational use of marijuana, which also ensure that cost is not a barrier to therapy for patients using medical cannabis. Tobacco taxation and pricing policies in Canada demonstrate the effectiveness of higher prices to deter tobacco use and provide an excellent case on which to model a pricing framework for recreational marijuana. Recreational marijuana should be priced at levels which do not promote use of the product, and which are significantly higher than the cost of medical cannabis. Cost barriers limiting access to recreational marijuana will also help to ensure that medical cannabis patients are not diverted from the medical system for reasons of cost or convenience, which would remove them from the supervision and oversight of their prescribing physician and other health care professionals, including pharmacists.

DISCUSSION ISSUE 4: ENFORCING PUBLIC SAFETY AND PROTECTION

Recommendation: Protect public safety through secure medical distribution

CPhA's submission is focused on patient safety for medical cannabis users. However, the Association supports measures proven to protect public safety; for example, education and enforcement tools to discourage marijuana-impaired driving. In particular, CPhA encourages the Task Force to consider options to protect non-users from second-hand smoke and vapours, and limit practices which may encourage the normalization of smoked products.

While maintaining a separate stream for medical cannabis users is in the best interest of patients, it also offers clear advantages in the enforcement of public safety and protection. Pharmacy offers a safe and secure supply chain with top-level security and tracking for narcotics and controlled substances already in place to ensure that medical cannabis is not diverted for the purpose of recreational use. Given that recreational marijuana should be priced at levels greater than medical cannabis, the importance of secure management and distribution of medical cannabis will take on even greater importance following legalization of recreational marijuana.

DISCUSSION ISSUE 5: ACCESSING MARIJUANA FOR MEDICAL PURPOSES

CPhA recognizes that the Task Force has a clear mandate to review the existing regulations governing access to cannabis for medical purposes. Furthermore, it is understood that the ACMPR will continue to be evaluated in an effort to ensure that individuals authorized to access cannabis for their own medical purposes have reasonable access. Consequently, CPhA understands that the Task Force is committed to studying other models, including pharmacy distribution, to provide dedicated access to cannabis for medical purposes.

Recommendation: Pharmacist management and dispensing of medical cannabis

CPhA believes that pharmacist management and dispensing of medical cannabis is in the best interest of patient safety. In March 2016, the Association updated its policy on medical marijuana to reflect a growing body of evidence, and professional concerns with respect to clinical oversight:

Based on expert consultations, third-party research, and input from our members and their patients, CPhA believes that the best way to enhance patient safety, education, and appropriate access is through pharmacist dispensing and management of medical marijuana, while promoting the use of non-smokeable products as opposed to smokeable forms.

As experts in medication management, with a vast network of existing infrastructure and proven ability to secure the supply chain, pharmacists are natural partners in the development of patient focused framework for dispensing and managing medical marijuana.

CPhA advocated strongly in favour of including pharmacists in the ACMPR introduced in response to the Federal Court's decision in *Allard v. Canada*; however, the Association appreciates the challenges facing the government in meeting the time constraints imposed by the deadline. Given that Health Canada has indicated that the new ACMPR do not represent the longer-term plan for the regulation of access to cannabis for medical purposes, and that pharmacy distribution will be considered as a new model, CPhA urges the Task Force to consider pharmacists' representations in this regard.

CPhA's proposal would authorize pharmacists to dispense cannabis for medical purposes to an individual with a medical document. The proposed framework would not only enhance the safety, quality and accessibility of medical cannabis, but would also benefit patients by providing access to medication counseling and chronic disease management by a licensed pharmacist. Pharmacists have the necessary expertise to mitigate the potential risks associated with medical marijuana, including harmful drug interactions, contraindications, and potential addictive behaviour. Under the proposed framework, Canadians who require cannabis for medical purposes would be able to access the product in person at urban, rural and remote locations across Canada, building on pre-existing relationships with patients and prescribers, through an established distribution system proven to protect patient and public safety.

Pharmacists are well-equipped to take swift action to implement the dispensing of medical cannabis in community pharmacies. The existing pharmacy-distribution infrastructure, managed by over 40,000 pharmacists at nearly 10,000 locations across Canada, is supported by a sophisticated distribution network designed to effectively and efficiently handle narcotics and controlled substances. This network maintains rigorous controls to reduce the risk of diversion and to ensure that the distribution of controlled substances is safe, reliable, and maintains product quality. Existing pharmacy distribution networks are fully compliant with Health Canada regulations, are equipped to handle temperature sensitive products through a fully supported cold chain, and have a proven record of safe, accurate and efficient handling.

CPhA believes that pharmacist management and distribution would help provide reasonable access to cannabis for medical purposes as required by the Federal Court in the *Allard* decision. In *Allard*, the Court recognized the importance of ease of access and assurance of supply for patients who have a medical requirement for cannabis to manage their health, and that a critical restriction under the previous regime was that the only legal option for patients to purchase marijuana was by mail, directly from licensed producers. Improving the manner in which patients can legally obtain medical cannabis is at the heart of medical cannabis access. Through the proposed pharmacy-based distribution system, pharmacists are well-positioned to provide an alternative method for Canadians to legally obtain medical cannabis that meets the objectives of ease of access and assurance of supply.

Recommendation: Implement controlled identification number for medical cannabis

A Drug Identification Number (DIN) is a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products by properties including manufacturer, product name, and active ingredients. The DIN is located on the label of prescription and over-the counter drug products that have been evaluated and authorized for sale in Canada. CPhA recommends that the Task Force work with pharmacy stakeholders to examine the future option of providing a controlled identifier for medical cannabis similar to a DIN to promote safe distribution by pharmacists. This will help to ensure proper documentation, manage the strength and form of the product, and track usage.

Conclusion

Medical and recreational marijuana are fundamentally different products, intended for use in very different ways. International best practices in jurisdictions contemplating marijuana legalization demonstrate that addressing risks associated with the existing medical marijuana regulations prior to the full-scale implementation of broader marijuana policy reform would be prudent and timely.^{xiv} By immediately authorizing pharmacy management and distribution of medical cannabis, a sophisticated pharmacy distribution system would already be in place once recreational marijuana is legalized, ensuring the integrity of the medical system and helping to prevent the emergence of a grey market.

ⁱ KPMG. *Improving Medical Marijuana Management in Canada. March 2016*. Retrieved from: http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/March2016_Improving_Medical_Marijuana_Management_in_Canada_vf.pdf.

ⁱⁱ For example, Florida has defined strains with high CBD content (with little to no THC) as MMJ products given its purported therapeutic benefits and limited psychoactive effects.

ⁱⁱⁱ Canadian Centre on Substance Abuse. *Cannabis Regulation: Lessons Learned in Colorado and Washington State*. November 2015. Retrieved from: <http://www.ccsa.ca/Resource%20Library/CCSA-Cannabis-Regulation-Lessons-Learned-Report-2015-en.pdf>.

^{iv} Canadian Centre on Substance Abuse. *What Canadian Youth Think About Cannabis*. September 2013. Retrieved from: <http://www.ccsa.ca/Resource%20Library/CCSA-What-Canadian-Youth-Think-about-Cannabis-2013-en.pdf>.

^v Canadian Centre on Substance Abuse (2015).

^{vi} Canadian Centre on Substance Abuse (2015).

^{vii} The Mayo Clinic. *Marijuana (Cannabis sativa)*. November 2013. Retrieved from: <http://www.mayoclinic.org/drugs-supplements/marijuana/interactions/hrb-20059701>.

^{viii} Centre for Addiction and Mental Health. *Cannabis Policy Framework*. October 2014. Retrieved from: http://www.camh.ca/en/hospital/about_camh/influencing_public_policy/Documents/CAMHCannabisPolicyFramework.pdf.

^{ix} While these health risks also apply to medical marijuana, there are potentially sufficient benefits to offset the risk from patient and prescriber perspectives.

^x Centre for Addiction and Mental Health (2014).

^{xi} Health Canada. *Tobacco Products Labelling Regulations*. May 2015. Retrieved from: <http://hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/reg/label-etiquette/indexeng.php>.

^{xii} Canadian Pharmacists Association. *CPhA Position Statement: Medical Marijuana*. March 2016. Retrieved from: http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/CPhAPosition_MedicalMarijuana.pdf.

^{xiii} Health Canada. *Drug Identification Number (DIN)*. Retrieved from: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/dinfs_fd-eng.pdf.

^{xiv} KPMG (2016).

About CPhA

The Canadian Pharmacists Association (CPhA) is the uniting national voice of pharmacy and the pharmacist profession in Canada. As pharmacists undertake an enhanced role in the delivery of health care services, CPhA ensures that the profession is recognized as a national leader in health care, influencing the policies, programs, budgets and initiatives affecting the profession and the health of Canadians. More information is available at www.pharmacists.ca.

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