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Cannabis Legalization and Regulation Secretariat
Address locator 0602E
Health Canada
Ottawa, Ontario K1A 0K9

By email: cannabis@canada.ca

RE: Proposed Approach to the Regulation of Cannabis

On behalf of the Canadian Pharmacists Association (CPhA) and Canada's 40,000 pharmacists, we thank you for the opportunity to provide the following submission outlining our views on the Proposed Approach to the Regulation of Cannabis.

CPhA is committed to pharmacy practice excellence and optimal health outcomes for Canadians through safe and effective drug therapy. As Canada's medication experts, pharmacists have a unique perspective on the legalization of cannabis, with a particular focus on how the legislation and proposed regulations will impact the medical cannabis regime. While we are pleased that the government has signaled its intention to maintain two different streams of cannabis once cannabis is legalized in 2018, we are becoming increasingly concerned by the government's prioritization of the recreation market over the medical stream and the implications of this prioritization for patients who require cannabis as part of their medication therapy. We would therefore like to focus our feedback on sections 7 and 8 of the consultation document which touch on the current medical cannabis stream and health products containing cannabis.

Under the proposed regulations specific to medical cannabis, the government's stated aims are to maintain a distinct system and facilitate patient access to cannabis for medical purposes. These regulations, however, fall short of a truly differentiated stream for medical cannabis. From the cost of medical cannabis to its more limited access and the absence of oversight from health care providers at the time of dispensing, left unchanged the proposed regulations will likely result in a situation where **Canadians who "want" access to cannabis for recreational purposes will have better access than those Canadians who "require" cannabis for medical purposes.** Patients requiring medical cannabis may end up seeking and purchasing their cannabis from retail outlets that are not equipped to provide health advice or clinical support to patients.

Further, with regard to health products containing cannabis, we strongly believe that any product that makes a health claim should be made available exclusively in pharmacies, where the pharmacist – a medication expert – can provide the appropriate counseling and product information to the public at the point of sale.



CPHA recommends that, through the proposed approach to the regulation of cannabis in Canada, Health Canada:

- Establish clear policies to ensure that patients in the medical cannabis system do not resort to obtaining cannabis from a retail outlet that is not equipped to provide appropriate pharmaceutical care. This includes ensuring patients do not face barriers related to the cost or distribution of medical cannabis.
- Enable pharmacists to dispense cannabis directly to patients in the medical cannabis stream and provide these patients with the same level of clinical oversight and counselling by a licensed pharmacist as is provided for all other prescribed medications.
- Restrict the sale of all products containing cannabis that make health claims to pharmacies.
- Ensure that any assessments related to the placement of natural health products or non-prescription products containing cannabis within a pharmacy be conducted on a case by case basis with regard to safety, and potential for abuse and diversion.

Differentiating medical and non-medical cannabis streams

CPHA is concerned that as governments across the country focus almost entirely on regulating the new recreational cannabis market, they are failing in their responsibilities to protect the health and safety of medical cannabis patients. The proposed regulatory approach, which essentially maintains the current status quo of the medical cannabis regime under the *Access to Cannabis for Medical Purposes Regulations (ACMPR)* will effectively make recreational cannabis easier to access than those requiring cannabis for medical purposes.

Although derived from the same plant, the cannabis supplied in the medical stream can differ chemically from recreational cannabis and they should not be treated as interchangeable products. Medical cannabis users are vulnerable patients who often turn to cannabis after other drug therapy options have been exhausted. Patients who obtain medical cannabis may require strains and forms to alleviate symptoms and minimize intoxication, like those available through cannabidiol, or CBD, whereas recreational users might be seeking euphoric effects in strains with higher THC levels.

Within the current medical cannabis system, patients are required to consult with their physician or nurse practitioner to be issued a medical document for medical cannabis. During this encounter, the health care professional uses their clinical judgment to assess the appropriateness of cannabis as therapy for the patient, determine a safe and effective dose for each patient, and counsel and monitor on the risk of abuse, misuse and diversion. Distribution of cannabis to patients is then strictly regulated and available to patients solely through mail-order licensed distributors or personal cultivation.



As Canada moves to legalize recreational cannabis by July 2018, the proposed regulations for the supply of recreational cannabis will enable convenient access to cannabis for legal age users at brick-and-mortar retailers. While medical oversight is certainly an important aspect of the medical cannabis system, many patients may see the recreational stream as being much more accessible as they would not require a medical document or be restricted to ordering online. Moreover, the Excise Duty Framework proposed by the government will subject medical and recreational cannabis to the same duty rates. These regulations will leave patients in the medical cannabis stream with little incentive to remain in this stream. As a result, we are concerned that patients may obtain a cannabis product through the non-medical stream that is not appropriate for their specific conditions. They are also likely to face increased health risks and complications, especially high-risk patients, as they will lack the necessary medical oversight from a prescribing health care professional that can capture potential drug interactions or contra-indications.

CPhA recommends that the federal government establish clear policies to ensure that patients in the medical cannabis system do not resort to obtaining cannabis from a retail outlet that is not equipped to provide appropriate pharmaceutical care. This includes ensuring patients do not face barriers related to the cost or distribution of medical cannabis.

The need for pharmacist oversight of medical cannabis patients

Canadians requiring medical cannabis as part of their prescribed therapy should have the same clinical supports as they do when accessing other prescription medications, including the benefits of consulting with a regulated health care professional at the time of dispensing. For many patients, medical cannabis is a third- or fourth-line treatment, and there is currently a lack of clinical evidence as to the role of medical cannabis in treating certain diseases and its effects in relation to other medications. With more than 400 chemical agents, Health Canada attests to the chemical complexity of cannabis and its potential interaction with other medications, including the negative effects from smokable forms. Therefore, the need for medication experts to provide clinical oversight to help support patients becomes even more important.

Within the current medical cannabis supply process, where distribution is managed through mail-order distributors or patient-grown cannabis, none of these access points include consultations with medication experts at the time of dispensing to ensure patients understand why they have been prescribed the medication, the method of administration, appropriate dosing, and any risks or adverse effects to expect from medication therapy, including potential interactions with other drugs. This is a critical gap that is putting patients' health and safety at risk in the medical cannabis system.

CPhA believes that it is essential for patients in the medical cannabis system to have as much support from qualified health care providers as possible. With over 10,000 community pharmacies in Canada, pharmacists are highly accessible health care providers and well-positioned to manage medical cannabis as a form of clinical therapy and



provide the appropriate access and oversight to patients. As medication experts, pharmacists have the necessary expertise to mitigate the potential risks associated with medical cannabis, including harmful drug interactions, contraindications and potentially addictive behaviour. Pharmacists can further help prevent, monitor and report side effects to help build a body of evidence and synthesize this evidence as it becomes available to support patients in navigating the use of medical cannabis.

CPhA would therefore like to put forward two regulatory options that would enable pharmacists dispense cannabis directly to patients, providing patients with the same level of clinical oversight and counselling by a licensed pharmacist as is provided for all other prescribed medications:

- 1) A national approach to dispensing medical cannabis: CPhA recommends that the government amend the ACMPR to include pharmacists as a category of health care practitioner who may possess and dispense/sell fresh or dried cannabis or cannabis oil for medical purposes. By amending the ACMPR, pharmacists across Canada would be granted the authority to dispense medical cannabis directly to patients, allowing for regular clinical oversight, monitoring and opportunities for patient counseling.
- 2) A province by province approach to dispensing medical cannabis: A secondary approach that would build on the federal cannabis framework and leave it up to the provinces and territories to define their own retail models is to include a specific provision under the new federal regulatory framework that would allow for provinces and territories to seek an exemption to include medical cannabis as part of their overall cannabis frameworks. This would therefore enable provinces and territories to determine on a case by case basis, with the support of their regulatory authorities, whether cannabis could be dispensed through pharmacy.

Sale of natural and non-prescription health products

CPhA is pleased that under Section 8 of the proposed regulations, Health Canada is proposing a scientific, evidence-based approach for the oversight of health products approved with cannabis, and that these products will be subject to FDA regulations and applicable safety, efficacy and quality requirements. This approach would restrict the sale of all health products containing cannabis to those that have been approved by Health Canada following a scientific review, including prescription and non-prescription drugs, natural health products (NHPs) and medical devices.

We, therefore, believe that the sale of any health product containing cannabis, which makes a health claim – from an NHP containing less than or equal to 10 ppm THC to a non-prescription product – should be restricted to sale in pharmacy. This would enable pharmacists to provide proper counseling and product information to the public at the point of sale.

We also understand that Health Canada is considering measures that would potentially require pharmacists to control the sale of health products containing cannabis, in particular of NHPs, by placing some of these products



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behind the counter, to deter youth access. CPhA feels strongly that assessments should be conducted on a case by case basis based on the safety, and potential for abuse and diversion of each product. With 220 NHPs already on the market, we can expect that the number of combination and non-prescription products containing cannabis could increase rapidly once approvals for sale get underway. We caution that sweeping regulations may result in unintended consequences for patients and pharmacists. CPhA is committed to working with Health Canada to assess feasible options to control the sale and display of these health products containing cannabis to youth.

Conclusion

For pharmacists, the health and safety of patients is paramount. The proposed approach to the regulation of cannabis must ensure that medical cannabis users are supported and protected through a medical stream once recreational cannabis is legal. Medical cannabis patients should be entitled to the same rights and expectations as all other Canadians with regards to medication access, affordability and clinical oversight.

CPhA is firmly committed to working collaboratively with the federal government to eliminate barriers faced by patients in accessing medical cannabis and improve patient and public safety by establishing pharmacies as the appropriate point-of-sale for cannabis-containing health products. We thank you for the opportunity to provide comments on the proposed approach to the regulation of cannabis. Should you have any questions related to this submission, please do not hesitate to contact me or my team.

Sincerely,

Iris Krawchenko, RPh BScPhm ACPR
Senior Pharmacist Advisor