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Association of Canada

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## **NEIGHBOURHOOD PHARMACY ASSOCIATION OF CANADA HEALTH CANADA CANNABIS LEGALIZATION AND REGULATION SECRETARIAT SUBMISSION**

### **A. INTRODUCTION**

Health Canada has launched a public consultation on the regulatory approach for the proposed Cannabis Act, building on the extensive consultations previously conducted by the Task Force on Cannabis Legalization and Regulation and on Canada's existing system of regulated production of cannabis for medical purposes and industrial hemp. The proposed regulatory regime prioritizes the protection of public health and the safety of Canadians, while enabling the development of a legal, stable and competitive industry to produce quality-controlled cannabis.

**The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) supports the Health Canada Cannabis Secretariat's framing of the regulatory approach to protect public health. To that end, we are urging the government to consider adding cannabis used for medical purposes to the Cannabis Act or immediately amend the *Access to Cannabis for Medical Purposes Regulations (ACMPR)* to include pharmacists as a dispensing authority.**

**The Association makes two key requests:**

- 1. To ensure public safety and health, it is important that cannabis used for medical purposes be distributed and dispensed by pharmacists who are highly trained healthcare and medication experts.**
  - a. There is a risk that post-legalization, many patients will opt to self medicate with a recreational strain of cannabis, unnecessarily introducing significant risks to public health.**
  - b. There are over 100 different strains of cannabis with varying strengths of active ingredients that can interact with other substances and it is for this reason that we are calling on the government to include cannabis used for medical purposes in the Cannabis Act to ensure the provinces can adequately protect against misuse.**
  - c. Furthermore, communities across Canada are faced with an increasing opioid crisis with limited treatment options and tools to combat the problem. Cannabis, when used appropriately, is an appropriate secondary or tertiary treatment option for several conditions that could potentially reduce the number and dose of opioid prescriptions.**
- 2. Amend the ACMPR to include pharmacists as authorized dispensers. This will increase controlled and supervised access and include patients in the circle of care.**
  - a. Clinical oversight and safeguards are required as these are applied to every other medication.**

Neighbourhood Pharmacies appreciates the opportunity to provide this Submission Brief regarding cannabis regulation to Health Canada's Cannabis Secretariat.

Neighbourhood Pharmacies represents Canada's leading pharmacy brands who deliver high value, quality care to Canadians in all models including chain, banner, long-term care, specialty and independent pharmacies as well as grocery chains and mass merchandisers with pharmacies. Our members are home to the most trusted providers of drug therapies, pharmacy-based patient services and innovative healthcare solutions. We advocate for community based care through our members' high accessibility and proven track record of providing optimal patient care closer to where patients live, work and play. By leveraging the over 10,000 points of care with pharmacies conveniently located in every neighbourhood across Canada, Neighbourhood Pharmacies aims to advance sustainable healthcare for all stakeholders.

We recognize that the Federal Government's decision to pass Bill C-45 and legalize non-therapeutic, i.e. recreational cannabis, by July 2018 will require the federal, provincial and territorial governments to expeditiously undertake the essential policy, administrative review, and implementation processes for the safety of all Canadians, especially their youth. At the same time, the federal government has turned over the responsibility for access, distribution, pricing, sale and taxation to the provinces and territories. Neighbourhood Pharmacies agrees with the government's stated objectives under this consultation, i.e. keeping cannabis out of the hands of children, keeping impaired drivers off the road, and keeping profits out of the hands of organized crime. Many provinces have already announced the approaches under which recreational cannabis will be distributed, sold, and priced.

However, Neighbourhood Pharmacies is concerned that there has been inadequate attention paid to the issue of cannabis, cannabidiol (CBD), and tetrahydrocannabinol (THC) for therapeutic purposes. Last year, Neighbourhood Pharmacies made a submission to the *Task Force on Cannabis Legislation and Regulation*. We have consistently advocated for the ACMPR under Section 56 of the *Controlled Drugs and Substances Act* to be amended so that pharmacists can be authorized to distribute and dispense cannabis used for medical purposes, consistent with the manner in which hospitals, including, notably hospital pharmacists, and physicians are authorized under the ACMPR. Key provisions of the *Cannabis Act* are summarized with Neighbourhood Pharmacies' recommendations for amendments to help the Government deliver on its commitment to legalize, regulate, and restrict the use of cannabis in a safe and responsible manner. The overarching objectives of the Cannabis Act are to prevent youth from accessing cannabis, promote and protect public health and safety and deter cannabis-related criminal activity. The *Cannabis Act* provides the federal government with significant authority to regulate the possession, production, distribution and sale of cannabis for medical and recreational purposes.

The Association has made other recommendations calling for:

- A dual system utilizing two distinct frameworks for access, a medicinal one for conditions in which there is evidence of therapeutic benefit, in which access would be strictly controlled and restricted, and a recreational one;
- Prescription-based access for cannabis, with formulations and strengths determined by treatment requirements; and,
- The application of federal regulations to determine minimum national standards for but not limited to age restrictions, packaging, wholesale distribution and sale location, form, strength (CBD, THC), amount (CBD, THC), health warnings, promotion, and marketing, with strict limits on personal possession quantities to protect youth and children from any degree of marketing.

## **B. THE NEIGHBOURHOOD PHARMACY ASSOCIATION OF CANADA SUBMISSION**

Neighbourhood Pharmacies members wish to ensure that the legislative and regulatory environment currently being shaped for the legalization of cannabis is one that results in a safe and reliable system, where both medical and recreational cannabis are considered as distinct entities. We believe that Canada's pharmacies are best positioned with the expertise and infrastructure to bring cannabis for medical purposes amongst its rightful peer treatments in the patient-centric health and wellness space of pharmacies. Our members are uniquely positioned for the sale, distribution and dispensing of cannabis for medical purposes. Neighbourhood Pharmacies' recommendation is for Federal Regulations to immediately amend the ACMPR to allow pharmacists to dispense cannabis for medical purposes. Pharmacies play a significant role in managing the distribution of controlled products and they would be committed to working with all levels of government to ensure that cannabis products are safely dispensed in pharmacies.

**In developing our recommendations, we have developed six critical conditions that must be met for Canadians to have safe and increased access to cannabis for medical purposes while ensuring the protection of the public.**

### ***1. IMPROVED PATIENT ACCESS AND CHOICE OF CANNABIS FOR MEDICAL USE WHILE ENSURING PUBLIC SAFETY***

As noted above, the legalization process of cannabis should include two different streams:

1. Medicinal for patients with conditions where there is evidence of the therapeutic benefits; and,
2. Recreational, which should be in a restricted and controlled environment to manage the potential harmful side effects and usage among minors.

Currently, more than 6,000 Canadian physicians are legally authorized to enable access to cannabis for medical use. According to Health Canada's Cannabis Secretariat, as of November 2017, only 236,000 patients were registered with Health Canada and were able to access their cannabis through the Licensed Producer (LP) system.

If Health Canada's priority is increased safety and regulated patient access to cannabis for medical purposes, then the following three questions require resolution:

- What issues need to be considered and resolved in the current environment?
- What are the obstacles and enablers to ensuring that Canadians benefitting from cannabis therapy have the safest possible access?
- What sorts of controls need to be in place?

**The current LP system provides few controls ensuring patient safety and limits increased access.**

**Cannabis authorized by a prescriber has limited choice and support for patients through most LP's.**

- No licensed healthcare professional designation.
- No access to patient's medical record and medication history.
- No checks to ensure proper therapy.
- No narcotic monitoring or eHealth capability.
- No ability to respond to the medical and drug-related questions of patients.
- Some LP's have limited medical professionals on staff: Concern as there is no requirement for LP staff to follow what is written on the medical document aside from quantity and expiry date. Patients can decide what they want with the LP call centre rep who may, or may not, be an nurse or pharmacist, and are most likely not a healthcare professional.

By contrast, Neighbourhood Pharmacies is recommending that medical cannabis still be authorized by a prescriber but that Canadians should have increased access and expert support and counselling from pharmacy and pharmacists, the most accessible health professionals in the Canadian healthcare system.

**Pharmacist counselling and support services would provide clinical oversight on such patient care issues as:**

- Drug to drug interactions
- Contraindications
- Allergies
- Dosing
- Medical history
- Assessment of patient risk of substance dependence and misuse
- Narcotic monitoring and/or eHealth
- Smoking cessation counselling and harm reduction strategies
- Appropriateness of cannabis therapy – especially important when pharmacists are doing the initial consult to decide whether to recommend cannabis at all to the physician and patient
- Health outcomes and adverse event monitoring

In the current environment, most Canadians are unaware that persons receiving cannabis for medical purposes do so without oversight, counselling or advice and support from a recognized medical professional that, by contrast, comes with other prescribed or recommended therapeutic products. This is an unnecessary risk and potentially harmful precedent that does not serve the public health interests of Canadians. Many patients may also be receiving medications for other conditions, e.g. diabetes or high blood pressure. In addition, the consumption of cannabis in combination with blood thinners or benzodiazepines can lead to low blood pressure, increased risk of bleeding, and disruptions in blood sugar levels. Cannabis is also contraindicated in patients with unstable ischemic heart disease or arrhythmias, and pregnant or breastfeeding women. Suboptimal medication management can lead to diminished therapeutic effectiveness, and adverse health events.

While there is evidence that cannabis used for medical purposes can be effective in treating chronic pain, chemotherapy-induced nausea and multiple sclerosis symptoms, clinical evidence is limited and inconclusive on its efficacy for many other conditions. There is research underway with a few large-scale, peer-reviewed randomized clinical trials in the international medical and pharmacological literature. This limited scope and scale, and emerging nature of conclusive clinical evidence underscores the critical need for pharmacists' oversight and counselling advice on medical cannabis use, and providing access in pharmacies will improve the likelihood of safely achieving optimal therapeutic outcomes. Pharmacists, as regulated healthcare professionals, can provide patients with the most current research updates and educate patients on the best medical cannabis treatment options available. As regulated healthcare professionals, pharmacists can also collect data to help monitor the impact of additional medical cannabis research developments.

- Canadians trust their pharmacist; more than 40% had reported going to the same pharmacist for more than 5 years.
- The College of Family Physicians of Canada has developed treatment guidelines for the use of cannabis for medical purposes.
- Our members have appropriate systems and processes already in place to manage medications effectively – pharmacies are equipped with sophisticated software to monitor drug therapies, monitor usage and to track drug interactions.

Cannabis for medical purposes should be available through pharmacies by authorization, or through pharmacists as authorizers, in a system in which a healthcare provider can assess and continually monitor use, dosage and duration.

For recreational cannabis containing THC, the product should be accessible in different strengths and forms to differentiate it from medicinal products. The labelling for cannabis for medical cannabis should also be clearly indicated on the product. This is vital in helping to reduce the stigma many patients may feel and this will be an even more important consideration once cannabis is legalized for recreational usage. Another opportunity to differentiate medical cannabis from recreational products would be for differential taxation, such as emulating the tax exemption on prescription drugs for human consumption.

**Neighbourhood Pharmacies' recommendation is for the Federal Regulations to immediately be amended within the ACMPR to allow pharmacists to dispense medical cannabis. The value of pharmacists' clinical oversight is twofold:**

- Cannabis like any other drug has the potential for harmful drug interactions, contraindications, and adverse side effects.
- Pharmacists can manage these events through counselling, dosage regimen adjustments, and adjunctive or alternative therapies, etc.

**Pharmacists have the necessary tools to begin pharmacy dispensing of medical cannabis. Tools have been created to train pharmacists on dispensing medical cannabis:**

- *Cannabis Reference Guide*: provides robust clinical information and evidence including dosing, side effects, and indications for pharmacists.
- *Strain Selection Tool*: guidance for physician/pharmacist strain selection based on indication, THC levels, medical conditions, etc.
- *eLearning Modules*: a number of CCCEP accredited online courses for pharmacists to learn about cannabis and its place in therapy.

**Given the very high degree of opioid use in Canada compared to other countries, cannabis used for medical purposes can be a viable alternative and/or complement to the use of opioids:**

- Opioids can pose significant risk to patient health and safety.
- Pharmacists can make informed recommendations that patients consider cannabis as an alternative.
- Cannabis can be delivered in other dosage forms that do not require smoking and pharmacists have the clinical credibility to steer patients away from smoking and ensure that they receive the safest and most appropriate form combined with smoking cessation counselling and therapies to achieve their treatment goals.

There are several additional benefits to pharmacist oversight:

- i. **Adherence**: Continuous monitoring both to ensure adherence to regulatory restrictions such as possession limits, and dispensing quantity specifications; as well as adherence to therapeutic regimens to improve patient outcomes.
- ii. **Smoking Cessation**: Pharmacists across Canada are actively involved in smoking cessation programs and can encourage patients to quit smoking cannabis and prevent related harms (i.e., detrimental respiratory and cardiovascular well-being).
- iii. **Alternative Dosage Forms**: There exists alternative dosage forms and methods of consumption such as a cannabis oils and vaporizers; pharmacists can steer patients towards dosage forms and modes of administration that achieve maximal therapeutic benefit, with minimal risk of harm.

## 2. PATIENT CARE - DIFFERENTIATION OF CANNABIS AS A TREATMENT OPTION

Medical cannabis is already a medically authorized therapy and the courts have ruled the public has a constitutional right to its access. Making a clear distinction between appropriate access to a prescribed or authorized treatment option by a healthcare professional compared to recreational cannabis is important to ensure the credibility of the treatment. As with any prescription, clinical advice and usage guidelines would differentiate it from the recreational product.

Pharmacists can evaluate the safety and appropriateness of cannabis for each patient, but can also evaluate the place in therapy of cannabis when the patients' entire medication regimen is considered. Only Canada's retail pharmacies have the capacity to electronically monitor their patients' complete medication history and when clinically appropriate, reduce the risk of harm. These have been described above but are outlined in greater detail below.

1. Cannabis has the potential for **drug-to-drug interactions**, meaning other drugs, including tobacco, alcohol and natural health products can impact the effectiveness, dosing and safety of cannabis; and cannabis can in turn impact the effectiveness, dosing and safety of these other drugs. Cannabis will affect the blood concentrations of over a quarter of all drugs (including cardiovascular medications, benzodiazepines, warfarin, antiretrovirals, antidepressants, and opioids) potentially increasing their toxicities. Therefore:
  - a. Pharmacists are well positioned to identify and initiate necessary dose adjustments of cannabis or patients' other medications.
  - b. Pharmacists are well positioned to evaluate for discontinuation/alteration of patients' medications.
  - c. Pharmacists are well positioned to consider patients' full medications regimen to evaluate appropriateness and safety of cannabis for the individual patient.
2. Cannabis has **drug-disease interactions**, meaning that patients with certain diseases or medical conditions, would require specific dosing considerations for cannabis, or may consider alternative or complimentary therapy to achieve the best therapeutic outcomes. Cannabis use and strength have been correlated with psychosis, cardiovascular and pulmonary diseases.
3. Cannabis has **contraindications** which make it inappropriate and unsafe for some patients, such as those with psychiatric disorders, severe cardiovascular, immunological, liver or kidney disease, and pregnant or breastfeeding women.
  - a. Pharmacists maintain patients' medical records and are well positioned to assess appropriateness and safety of patients' medications.
4. Cannabis has **significant side effects**.
  - a. The safety and efficacy of each drug in a patient's medication regimen must be weighed to ensure that benefits of overall therapy outweigh the risks.
5. Cannabis has the potential for **psychological and physiological dependence**.
  - a. Pharmacists are well positioned to have ongoing face to face consultations with patients and to follow patients through therapy, to effectively identify and address dependence and risk of dependence.
6. Cannabis **dosing and dosage forms** are patient specific and require ongoing monitoring and adjustments.
  - a. Pharmacists are well positioned to understand, follow, and guide patients through dosing guidelines to achieve optimal therapeutic effect with minimal risk of adverse events.
  - b. Pharmacists are best suited to understand the pharmacology that underlies appropriate dosing and dosing regimens of cannabis, including the evaluation of different forms (i.e., ingested, inhaled, topical, etc.), and onsets and duration of action for optimal therapeutic effect.

7. Cannabis as **alternative and/or complementary therapy**.
  - a. Pharmacists routinely monitor and evaluate patients for alternative or complementary therapies, including prescription, non-prescription pharmacological therapies, herbal therapies, and non-pharmacological therapies. By facilitating the distribution of cannabis through pharmacy, patients can have this relatively safe alternative at their disposal with careful guidance and close monitoring by their pharmacist.

### **3. ESTABLISHMENT OF PROPER TRAINING FOR PHYSICIANS AND PHARMACISTS**

As the body of evidence regarding cannabis as an effective therapy continues to emerge, it is important for patients' information to be centralized and maintained by a healthcare professional who can track medication history to ensure compliance with current treatment recommendations. However, given the absence of well-established treatment guidelines, or any sort of accredited clinical treatment recommendations, it is critical that regulated health professionals, including pharmacists, nurses and physicians, who are required to maintain standards of practice and continuous professional development and education, take responsibility for managing patients using medicinal cannabis. By limiting the care of cannabis patients to regulated health professionals, we ensure that prescribing, follow-up, dosing and patient management follows an evidence based practice, to ensure patient safety and optimal therapeutic outcomes.

### **4. INTEGRITY OF THE SUPPLY CHAIN - UTILIZING EXISTING INFRASTRUCTURE ENSURING SAFETY AND PRODUCT INTEGRITY**

Continuing best practices from the existing ACMPR system and those already in place when dealing with narcotics in pharmacy care, it is integral to the system to ensure safe delivery of the product from producer to patient. This ensures quality control and product integrity, while limiting the potential for diversion and related potential harms and unintended consequences.

Only pharmacies can claim to have a broad and reliable distribution system for medications nationally. Today, our members play an integral role in delivering the right medications to the right patients at the right time from coast to coast in rural, urban, suburban, and remote communities to ensure provision of equitable care to all Canadians. Duplication of this system through a patchwork of models provincially may lead to unnecessary risks and higher costs for taxpayers and greater potential for diversion and inconsistencies in the supply chain.

Neighbourhood Pharmacies urges the federal government to amend the ACMPR, to permit retail pharmacies and pharmacists distribute and dispense cannabis for medical purposes, mirroring how hospital and physicians are in the ACMPR. This would allow pharmacies and pharmacists to be part of the "circle of care" for those patients using cannabis, as other healthcare providers who are already playing this role.

This can be undertaken by some minor amendments to the ACMPR:

1. Add "pharmacy" to the definitions;
2. Possession 2 (a) add to the list (iv) "from a pharmacy";
3. Possession 2 (c) add the words "or pharmacy employee"; and,
4. Part 1, Division 1, 4 (a) (ii) add the words "or pharmacy employee".

Implementing a standardized tracking number, e.g. a "Pseudo DIN", or Product Identification Number (PIN), for cannabis would allow a pharmacy to properly document, track and record the dispensation of and ensure the appropriate and intended use of the dispensed product.

Cannabis regulations should remain under Federal Regulations which determines a national minimum standard that includes but is not limited to: age restriction, product packaging, wholesale distribution and sale location, form, strength (THC, CBD), health warning messages, advertising, marketing, access and limits on personal possession quantity to protect youth and children and prevent unscrupulous marketing practices.

Neighbourhood Pharmacies members strongly recommend packaging that clearly differentiates the two streams of cannabis, by identifying cannabis for medical use on all packaging. Developing a regulatory framework is only the first piece of this complex public policy challenge. Implementing the framework and ensuring that there is the capacity and infrastructure needed to support it is also vital. A review should be undertaken for medical and recreational cannabis to provide the product a controlled identifier, similar in nature to a Natural Product Number (NPN), to control the allowable strength and form of the product and increase the traceability of the product. This will ensure a safe distribution and tracking of the product. All dispensing of cannabis should be entered in patients' electronic health records to manage potential drug interactions and contraindications. This would also allow for the product to be appropriately tracked and where appropriate, limit the quantity or reduce the frequency of dispensing.

In addition, while others may try to step into the role of selling cannabis, Canada's over 10,000 pharmacies are the right channel for distribution and dispensing of cannabis for medical use for the following reasons:

1. Pharmacies are readily accessible across Canada in all communities – a ready-made rural, suburban, urban and remote network.
2. Proper clinical advice would help ensure those with medical needs are receiving proper treatment and use guidelines. It would allow easier supervision to reduce the risk of dependency. It would also ensure there would be no interference with other prescription treatments the patient may be using.
3. Like so many natural health products, cannabis is known to have serious side effects and potential interactions with prescription medications increasing its' potential to negatively impact the health and safety of the public. Research indicates a strong association of cannabis use with the onset of psychiatric disorders, development and cognitive effects, in addition to breathing problems, increased heart rate, and the increased possibility of addiction in individuals who frequently smoke. Health Canada warns that the use of cannabis while intoxicated with alcohol presents an acute health risk. Distribution through liquor retail channels may lead to higher co-consumption and under-representation of potential harms.
4. Patients and doctors rely heavily on pharmacists to advise on all medications and medication management, including herbal products.
5. Neighbourhood Pharmacies members are well positioned to manage the distribution and patient access effectively, to achieve optimal outcomes for patients taking medical cannabis therapy and mitigating adverse events.
6. Pharmacies can leverage an existing pharmacy network, supported by a robust Health Canada-regulated pharmaceutical distribution network that currently handles controlled substances safely. Our members and supply chain partners have safeguards in place for medication inventory management and to prevent theft and diversion.
7. Our members offer the security of sale:
  - Pharmacies are already set up with secure premises, alarm monitoring systems, visual monitoring/video monitoring (in most pharmacies), with only authorized personnel having access to narcotics. This positions pharmacies as a natural fit for maintaining inventory of a restricted drug.
  - Pharmacies comply with the security requirements outlined including:
    - Secure perimeter that prevents unauthorized access, including physical barriers.
    - Visually monitored by a visual recording device.
    - Premises secured by an intrusion detection system that operates at all times.

8. Our members provide a robust record keeping and reporting system:
  - Pharmacies are set up and routinely collect and maintain patient records.
  - Pharmacies already set up to track purchase and sale of narcotics, and so have a system in place to track restricted drugs.
  - Pharmacies are set up and have traceable processes for narcotic destruction and disposal, so are well positioned to implement similar standards for destruction and disposal of cannabis.
  - Pharmacies already comply with the record keeping requirements for sale of cannabis for medical purposes and are routinely collecting and maintaining these patient records, including details on:
    - Medical client registration information.
    - Filling of orders and refusal to fill orders.
    - Medical documents provided by clients.
9. Our members assist with recall management:
  - Leveraging the existing infrastructure of pharmacy and its supply chain partners for record keeping and product tracking provides an effective and reliable mechanism to ensure that any recalls can be rapidly identified and removed from distribution to minimize harm to patients.

## **5. AN IMPROVED, PROFESSIONAL ENVIRONMENT**

Pharmacies are strongly aligned in involving patients in the circle of care by leveraging the inter-professional collaboration with physicians in support of optimal patient outcomes for Canadians. There is a need for health providers to play an active role in the discussion regarding how best to provide proper care to patients regarding the government's plans for cannabis legalization, ensuring quality care to both patients and consumers. A functioning regulated model should address the current limitations of the ACMPR system, as well the parallel markets where cannabis is currently traded to ensure in-depth clinical advice, ease of access, security, and optimal quality care to patients. Our professional experience with the complexities of managing controlled products and reputation among Canadians, enable pharmacy to be the ideal channel for recreational cannabis to be sold legally and safely within the legal age requirements. Our members are also uniquely positioned for the sale, distribution and dispensing of cannabis for medical purposes and should be at the table to ensure that recreational cannabis is implemented in a safe and secure manner.

Furthermore, given the Bill establishes a national cannabis tracking system, pharmacies will be able to assist with this objective given our members already leverage an existing and effective pharmacy distribution network that currently handles controlled substances safely.

- Pharmacies routinely submit information to provincial databases that maintain and monitor the dispensing of drugs through systems such as the Narcotic Monitoring System (limited to the dispensing of monitored drugs) and BC Pharmanet (for all drugs).
- Pharmacies are a natural fit to monitor and report on the sale of cannabis.

Our members have safeguards in place for medication inventory management and to prevent theft and diversion. Implementation of a standardized tracking PIN for pharmacy to ensure proper documentation and tracking of the intended use of the dispensed product.

Further, pharmacists are essential to and readily available to provide patients with information on recalls and related notices from manufacturers.

## **6. SAFER ACCESS TO OVER THE COUNTER PRODUCTS, CANNABIS, NATURAL HEALTH PRODUCTS, MEDICAL DEVICES AND COSMETICS**

Neighbourhood Pharmacies is working with Health Canada and the National Association of Pharmacy Regulatory Authorities to examine the future option in providing medical and recreational cannabis a controlled identifier, similar to a Natural Product Number, with a prescription for medicinal cannabis to control the allowable strength and form of the product and increase the traceability of the product. This will ensure a safe distribution and tracking of the product for both medicinal and recreational purposes. All dispensing of cannabis would be entered into a patient's electronic health record to help manage potential drug interactions and contraindications. This would also allow for the product to be appropriately tracked for limiting the quality or frequency of dispense. All pharmacies today have direct and secure connection with provincial electronic health systems and monitoring systems.

A controlled supply chain keeps community's safe. Canada should leverage its sophisticated pharmacy distribution network which currently handles controlled substances safely. Our members have safeguards in place for medication inventory management and to prevent theft and diversion. Both the Canadian Association for Pharmacy Distribution Management and Health Canada have rigorous standards and protocols in place to ensure the safe delivery of narcotics from manufacturer to front line distributors:

- Canada's pharmacy distributors already have standards for driving safety.
- High security distribution centres - fully compliant to Health Canada regulations.
- Top level security and tracking for narcotics and controlled substances.
- Fully supported cold chain for temperature sensitive products.
- Driving efficiency and performance.
- Canada's pharmaceutical distributors execute over 240 million order lines annually with greater than 99.9% accuracy.

## C. RECOMMENDATIONS

With July 2018 approaching quickly, we urge Health Canada's Cannabis Secretariat and the Government of Canada to engage with Neighbourhood Pharmacies, as the voice of Canada's pharmacy business who deliver care to Canadians, on this critical public health policy issue.

In developing our recommendations, we have applied six critical conditions that must be met for Canadians to have safe access to cannabis while ensuring the protection of the public. To summarize, they are:

1. **Improved Patient Access and Public Safety:** As with any medical treatment, there should be as high a standard as possible of protection set for the medical cannabis industry. From production to distribution, the treatment must be secure and the product free of tampering.
  - Recommend medical cannabis in pharmacy.
  - Increased patient access to cannabis for medical purposes through pharmacy not LP
  - Long-Term Care (LTC) facility exemption for cannabis for medical purposes similar to hospitals. The ACMPR and Section 56 Exemptions under the *Controlled Drugs and Substances Act* (CDSA) provide for third-party administration of a medical dosage of marijuana in a hospital setting, where "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." Nurses and pharmacists in hospitals are addressed in the regulations. We recommend that a similar approach to hospitals be taken regarding medical cannabis use in LTC homes.
  - Pharmacist on prescribers list for cannabis for medical purposes.
  - Medical cannabis regulation changes – administrative and will not substantially increase patient access.
  - Smoking Cessation Program.
  - Eliminate cannabis stigma associated with the use of cannabis for medical purposes.
  - Manage drug interactions.
  - Ensure public health and limit youth access.
  - Cosmetic and NHP cannabis regulations and health hazards to public.
  - Tracking system through validated supply chain.
  - Pharmacist expertise managing controlled products – validated Canadian supply chain.
  - Labelling cannabis for medical purposes needs to be have its own specialized label differentiating it from recreational cannabis.
2. **Differentiation of Cannabis as a Treatment Option:** Medical cannabis is already an authorization-based therapy and the courts have ruled the public has a constitutional right to access. Making a clear distinction between appropriate access to a physician authorized treatment option opposed to recreational cannabis is vital to ensure the credibility of the treatment. As with any prescription, clinical advice and usage guidelines would differentiate it from a recreational product. Another opportunity to differentiate medical cannabis from recreational products would be for differential taxation, such as emulating the tax exemption on prescription drugs for human consumption.
3. **Establishment of Proper Training for Physicians and Pharmacists on cannabis for medical purposes:** With an aim of reducing risk to patients, education and training should be provided with evidence-based guidelines to provide patients with secure and appropriate care.
4. **Integrity of the Supply Chain:** Continuing best practices from the existing ACMPR system and those already in place when dealing with narcotics in pharmacy care, it is integral to the system to ensure safe delivery of the product from producer to patient. This maintains the integrity of the product, while limiting its diversion.

5. **Utilizing Existing Infrastructure:** Exploiting current practices and infrastructure to reduce unnecessary duplication and delay. This promotes the safety of the product by better leveraging the existing pharmacy system. Only pharmacies and their distributor partners have the necessary broad and seamless distribution system across Canada.
  
6. **Improved Environment:** Pharmacies are strongly aligned in bringing cannabis patients into the circle of care by leveraging the inter-professional collaboration with physicians in support of optimal patient outcomes for Canadians. There is a need for health providers to play an active role in the discussion regarding how best to provide proper care to patients in the government's plans for cannabis legalization. A properly functioning regulated model that incorporates pharmacies should address the current limitations of the ACMPR system, as well as deal with the challenges inherent in the illegal market. Only pharmacies can offer the in-person clinical advice, ease of access, security, and high-quality care to patients. Our professional experience with the complexities of managing controlled products and reputation among Canadians, enable pharmacy to be the perfect retail space for recreational cannabis to be sold legally and safely within the legal age requirements. Our members are uniquely positioned for the sale, distribution and dispensing of cannabis for medical purposes and should be at the table to ensure that the legalization of cannabis is implemented in a safe and secure method.

## D. CONCLUSION

In summary, Neighbourhood Pharmacies reiterates its two primary requests:

1. Health Canada **MUST** ensure public safety and health. For these reasons, our Members are recommending that cannabis used for medical purposes be distributed and dispensed by pharmacists who are highly trained healthcare experts.
  - a. There is a risk that once legalization occurs patients will opt to self medicate on a recreational strain of cannabis which unnecessarily introduces significant risks to public health.
  - b. There are over 100 different strains of cannabis with varying strengths of active ingredients that can interact with other substances and it is for this reason that we are calling on the government to include cannabis used for medical purposes in the Cannabis Act to ensure the provinces can adequately protect against misuse.
  - c. Furthermore, communities across Canada are faced with an increasing opioid crisis with limited treatment options and tools to combat the problem. Cannabis, when used appropriately, is an appropriate secondary or tertiary treatment option for several conditions that could potentially reduce the number **and dose** of opioid prescriptions.
2. Health Canada amend the ACMPR to include pharmacists as a dispensing authority. This will increase **controlled and supervised** access and include patients in the circle of care.
  - a. Clinical oversight and safeguards are required as these are applied to every other medication.

As we have previously stated in this submission, our members strongly believe that the ACMPR under Section 56 of the Controlled Drugs and Substances Act should be amended so that pharmacists and pharmacies can be authorized to distribute and dispense medical cannabis, consistent with the manner in which hospitals and physicians are authorized under the ACMPR.

In addition, the Association has made other recommendations calling for:

- A dual system utilizing two frameworks for access; a medicinal one where there is some evidence of therapeutic benefit, in which access would be strictly controlled and restricted, and a recreational one;
- Prescription-based access for cannabis for medical purposes, with formulations and strengths determined by treatment requirements; and,
- Strength: THC has increased dramatically from where it was in the 70's and now can be upwards of 25% vs. less than 1% years ago.

The application of federal regulations to determine minimum national standards for, but not limited to, age restrictions, packaging, distribution and sale location, form, strength (THC, CBD), health warnings, promotion, and marketing, with strict limits on personal possession quantities to protect youths and children from any degree of commercialization.

Neighbourhood Pharmacies members, who account for the vast majority of Canada's 10,000 pharmacies, unanimously support statutory and regulatory changes that would permit pharmacies to dispense cannabis for medical purposes. Our members have signalled their willingness to immediately begin the important work to affirm pharmacy as a responsible and low-risk option to increase access while safely dispensing cannabis for medical purposes.

Health Canada **MUST** safeguard the health and wellbeing of all Canadians.

Our members and other healthcare service professionals respectfully insist on working with Health Canada and provincial authorities to ensure that Canadians can access cannabis for medical purposes while providing Canadians with the highest level of medication management and risk reduction.

Our members are aligned with other healthcare professionals like Bertrand Bolduc, the président de l'Ordre des pharmaciens du Québec (OPQ), who presented, on January 17, 2018, the Order's position on Bill 157 to the Ministère de la Santé et des Services sociaux.

- Patients prescribed cannabis therapeutic treatment should have access to the services of a health professional, just like any other patient.
- OPQ is requesting distribution of therapeutic cannabis be entrusted, under certain conditions, to pharmacists to ensure that patients receive their care and services from a regulated professional, subject to professional regulations, a code of ethics, respect for professional/patient confidentiality and ability to manage analysis of patient drug therapy.
- OPQ is requesting that cannabis for non-medical purposes be subject to the same framework as tobacco, including the rules on advertising.
- As previously stated, the use of non-medical cannabis is not without risk, especially for people who suffer from health problems. OPQ is recommending that consumers be made aware of possible drug interactions and contraindications related to its consumption. In addition, the Order is asking that pharmacists have access to service corridors to direct patients with signs of psychosis or who need addiction support.
- OPQ supports the Quebec government's intention to maintain a ban on non-medical cannabis cultivation at home.

*In Colorado, the number of pediatric emergency visits for cannabis intoxication doubled after legalization and a 34% increase in cases referred to the Poison Control Center was noted. Whether access to a plant or processed products, the more access to minors, the greater the risk of intoxication.*

***l'Ordre des pharmaciens du Québec***

- OPQ is recommending the creation of a “vigilance committee” whose role will be to advise the Health Minister on any question relating to cannabis. Due to growing Canadian opioid and illicit drug crisis, the expertise of pharmacists is crucial. OPQ is requesting that a seat be provided for a pharmacist on this committee.

*“Cette prise de position est le résultat d’une longue réflexion, a confié. Nous en sommes venus à la conclusion que, malgré le statut particulier du cannabis médical, les patients qui l’utilisent ne sont pas différents des utilisateurs de n’importe quel autre médicament. C’est pourquoi nous demandons au gouvernement du Québec de nous accompagner dans des représentations pour qu’une modification à la réglementation fédérale soit apportée.”*

*“Il faudrait éviter que les patients qui ont de tels besoins se retrouvent à l’urgence.”*

**Bertrand Bolduc, président de l'Ordre**

If the federal government does not permit pharmacy dispensing through the C-45 framework, they should create a pathway that would enable any willing province or territory to pursue pharmacy dispensing of medical cannabis.

The Association believes it is vital the federal government implement rules that treat the distribution and dispensing of medical cannabis and recreational cannabis, based on its use, differently. As we look for solutions to the opioid crisis gripping communities across Canada, the use of cannabis for medical purposes for several conditions is a reasonable alternative to higher risk narcotics:

- *Cannabis for medical purposes represents a safer alternative to opioid therapy for pain and has been shown to reduce the consumption of opioids.*
- *There have been no documented deaths from an overdose of cannabis.*
- *In comparison with the hazards of different drugs, cannabis showed lower physical dependency, psychic dependency, neural toxicity, overall toxicity and social hazards than opiates, cocaine, alcohol, benzodiazepines and tobacco.*

Your support on this significant and timely public health issue is vital, and so we respectfully request that Health Canada undertakes amendments to the ACMPR that would authorize pharmacies to take their rightful place in the safe distribution of cannabis for medicinal purposes. We thank the Health Canada Cannabis Legalization and Regulation Secretariat for its consideration of this submission.

Sincerely,

A handwritten signature in black ink, appearing to be 'Justin J. Bates', written in a cursive style.

Justin J. Bates  
Chief Executive Officer