Bill C-45
An Act Respecting Cannabis and to Amend the Controlled Drugs and Substances Act, the Criminal Code and Other Acts

Brief of the Association québécoise des pharmaciens propriétaires

Brief submitted to the Standing Senate Committee on Social Affairs, Science and Technology
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The Association québécoise des pharmaciens propriétaires (AQPP) believes that Bill C-45 is incomplete in its current form, and that it must provide for measures related to the management and distribution of therapeutic cannabis within the overall framework of the legalization of non-therapeutic cannabis. The AQPP is of the opinion that the legalization of non-therapeutic cannabis may have significant impacts on access to this substance for patients who use it therapeutically. In addition, the AQPP suggests that therapeutic cannabis should be considered the same way other prescription drugs are: prescribed by a physician, and, as such, under the responsibility of the network of community pharmacies to distribute it. Pharmacists are the only prescription drug specialists; they are therefore in the best position to provide appropriate therapeutic cannabis management services and thus contribute effectively to the protection of the public.
ABOUT THE AQPP

The AQPP is pleased to submit its brief to the Standing Senate Committee on Social Affairs, Science and Technology to share its views on the principles outlined in Bill C-45.

The AQPP was established under the Professional Syndicates Act and has existed since 1970. It represents all the owner-pharmacists in Quebec: 2,073 pharmacists owning 1,890 pharmacies, whether affiliated or not with a chain or a commercial banner, in all regions of Quebec.

The AQPP is dedicated to the study, protection, and development of the professional and social economic interests of its members. To this end, it interacts with various stakeholders in the health sector and various levels of government.
INTRODUCTION

On April 13, 2017, the federal government introduced Bill C-45, An Act Respecting Cannabis and to Amend the Controlled Drugs and Substances Act, the Criminal Code and Other Acts. With this law coming into effect in the summer of 2018, it is now up to each province to examine the regulatory framework that will govern its application. With this in mind, the Government of Quebec tabled, on November 16, 2017, Bill 157: An Act to Constitute the Société québécoise du cannabis, to enact the Cannabis Regulation Act and to Amend Various Highway Safety-Related Provisions. Bill 157, like C-45, is devoted solely to the issue of non-therapeutic cannabis, while its legalization foreshadows many problems affecting the management and distribution of therapeutic cannabis. The Association québécoise des pharmaciens propriétaires (AQPP) made its position known on this issue during the two consultations conducted by the Quebec government. The AQPP now wishes to sensitize the federal authorities about the dangers of maintaining the current mode of distribution of therapeutic cannabis, namely postal delivery.

It is important to remember that therapeutic cannabis is not a commonplace product. Like any other product that can be prescribed and that has therapeutic effects, it has different features that only a pharmacist can handle because of their unique prescription drug specialist training and expertise, and their understanding of the possible interactions with other treatments. Ignoring this reality could have serious consequences for some patients. We will come back to this in more detail in this document.

Aware of the significant challenges posed by this new legislation, the AQPP fully shares the concerns of both the federal government and the Government of Quebec, and wishes to be a partner in the process leading to the application of this new regulatory framework.

Throughout this brief, the AQPP would like to make senators aware of the importance of considering the issue of therapeutic cannabis in the process of legalizing non-therapeutic cannabis. In this regard, the AQPP also wishes to inform the federal authorities that the issue of the distribution of therapeutic cannabis by pharmacists is a consensus in the entire pharmaceutical industry in Quebec. Second, the AQPP also wants to bring to the government’s attention the various elements that justify giving pharmacists a leading role in the distribution of therapeutic cannabis.

The AQPP’s position is clear:

It is essential to consider the issue of the distribution of therapeutic cannabis throughout the process of legalization of non-therapeutic cannabis and to put an end to its postal delivery. To act otherwise could cause significant harm to patients for whom cannabis is an effective treatment.

AQPP believes that it is up to the network of community pharmacies to distribute therapeutic cannabis, since pharmacists, as part of their current responsibilities for taking charge of the overall health of their patients and their pharmacotherapy - prescribed or not - are best placed to provide appropriate therapeutic cannabis management services, and thus contribute effectively to the protection of the public. Indeed, pharmacists are prescription drug professionals, and, as such, they are able to
ensure the clinical surveillance required for the use of therapeutic cannabis in order to evaluate the effectiveness of the medication, to adjust the dosages, to prevent the undesirable effects that may result from the interaction of therapeutic cannabis with other prescription drugs, or to suggest forms of therapeutic cannabis use other than inhalation.

Supported by the Canadian Pharmacists Association (CPhA), the AQPP is seeking the inclusion of measures granting the distribution of therapeutic cannabis to pharmacists in Bill C-45.

THE IMPORTANCE OF CONSIDERING THERAPEUTIC CANNABIS IN THE LEGISLATIVE PROCESS

Bill C-45 is very important because it creates the legal and regulatory framework that will prevail in the country after the legalization of non-therapeutic cannabis, scheduled for the summer of 2018. It is this form of cannabis use that raises the most questions, particularly because of its potentially harmful effects, especially among young people. It is definitely wise not to think of cannabis as a harmless substance, since it contains psychoactive elements that can have significant consequences on the person using it. In no case should the use of this substance be trivialized.

Although the issues surrounding non-therapeutic cannabis are of great importance, the AQPP considers it essential not to remove the issue of therapeutic cannabis from the debate. The AQPP believes that C-45 misses the mark by not making any changes to the current distribution pattern of therapeutic cannabis. Senators studying the bill should carefully consider this issue, given there is every reason to believe that the legalization of non-therapeutic cannabis will breach the distribution system and may lead to potentially dangerous abuses regarding access for patients for whom cannabis is an integral part of their prescription drug therapy.

In this sense, the AQPP therefore considers that Bill C-45 must provide for measures related to the management and distribution of therapeutic cannabis within the overall framework of the legalization of non-therapeutic cannabis. It would be unrealistic to believe that the legalization of non-therapeutic cannabis would have no impact on access to the substance for users of therapeutic cannabis. This is why the AQPP wishes to raise five distinct points deserving the consideration by the different levels of government.
1. **THE THERAPEUTIC VALUE OF CANNABIS**

Before looking at why pharmacists are best placed to distribute therapeutic cannabis, a brief discussion of its use and value in the treatment of various conditions is in order. Although research on this subject is still limited, cannabis has a recognized therapeutic value. The Task Force on the Legalization and Regulation of Cannabis in Canada recognizes in its Report that a significant number of patients with various health problems derive therapeutic benefits from cannabis. This finding means that their consumption cannot be compared with that of non-therapeutic users. That being said, there is well-documented clinical evidence concerning, among other things, the use of cannabis for the treatment of chronic neuropathic pain and multiple sclerosis. Other studies are currently attempting to establish clinical evidence for cannabis treatment of nausea and vomiting associated with cancer treatment, inflammatory bowel syndrome, and post-traumatic stress disorder, among other conditions.

In addition, the current crisis caused by the overconsumption of opioids is another factor that strongly supports the proper and well-managed use of therapeutic cannabis. Studies indicate that cannabis may be an interesting alternative to opioids. Several factors explain this hypothesis, namely the fact that it represents a lesser danger in case of overdose and during withdrawal compared with opioids, which, under the same circumstances, present a significantly higher risk of death. Therapeutic cannabis treatment also has fewer negative social issues. As a result, although studies on the subject are still in their infancy, allowing pharmacists to be an integral part of the management of therapeutic cannabis could help reduce the problems and costs associated with the opioid crisis all over Canada.

Science needs to make further progress in order to demonstrate even more precisely and concretely the benefits of therapeutic cannabis. To this end, the AQPP wishes to acknowledge the intention shown by various authorities, notably the Government of Quebec, to invest in studies that will further document the therapeutic value of cannabis. The AQPP wishes to participate actively in such initiatives and offers all its collaboration to the governmental authorities to contribute to the advancement of knowledge on this subject.

2. **SUPERVISING THE USE AND DISTRIBUTION OF THERAPEUTIC CANNABIS**

Despite their common source, the strains and forms used in the composition of non-therapeutic cannabis greatly differ from those of therapeutic cannabis. The AQPP recalls that

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for various reasons, including public health, prevention, differences between substances, and differences in use, it is essential to maintain a separate distribution system for therapeutic cannabis, as provided already in Bill C-45.

However, the integrity of the current distribution network, which uses the postal channel and operates without the supervision of a health professional, cannot be guaranteed if the distribution of therapeutic cannabis is not contemplated in the context of the legalization of non-therapeutic cannabis. **It is imperative that patients using cannabis do not go directly to non-therapeutic cannabis sales outlets and abandon the professional supervision they currently receive.** The mail-order system maintained by Bill C-45 poses very real risks to the health of these patients.

The AQPP believes that the management of the use of therapeutic cannabis should be carried out in a precise, organized, and rigorous manner, under easy-to-follow guidelines provided to all health professionals involved in the management of therapeutic cannabis. Similarly, therapeutic cannabis, because of its effects and possible interactions with other prescription drugs, must be distributed under the supervision of a health professional. In this respect, there is no doubt for the AQPP that the pharmacist is the professional best equipped to provide such supervision. **Moreover, among all the jurisdictions that provide therapeutic cannabis (Italy, Germany, Australia, the Netherlands, etc.), only Canada and Puerto Rico do not include pharmacists in their distribution process.**

These measures could also help to minimize the risk of shortages that many patients currently using therapeutic cannabis fear. In fact, they fear that the legalization of non-therapeutic cannabis will lead to the disappearance of certain strains of cannabis intended for therapeutic purposes, which would not be consumed other than in cases of treatment. This shortage would result directly from the confusion between the two types of cannabis use.

Similarly, patients should not have their access to treatment reduced or hindered by the legalization of non-therapeutic cannabis. Clear guidelines will prevent confusion between the two distribution systems. At all costs, patients for whom cannabis has a therapeutic function and acts as a medicine should not have the impression that their consumption is being supervised by a health professional if this is not the case. Stakeholders involved in the current mail distribution are not governed by the professional standards of a professional order, nor are they bound by a rigorous and supervised code of ethics.

AQPP further believes that therapeutic cannabis, because it is prescribed by a physician, must be considered in the same way as any other prescription product, which implies that it must be dispensed by a pharmacist who will then provide therapeutic follow-up. Several factors strongly argue in favour of this; we will come back to this.

Although therapeutic cannabis does not currently have a drug identification number (DIN), many experts suggest that it be managed in the same way as methadone was before obtaining a DIN. In doing so, the number of physicians authorized to prescribe cannabis may be limited and the need for specialized training for prescribers may be considered. Pending the issuing of a DIN, it should also be required that the distribution of therapeutic cannabis be the same as for any other narcotic drug: obtaining the substance from producers approved by Health Canada, ensuring a chain of signatures across the supply chain by professionals (pharmacists, doctors), and performing regular inventory audits with reporting of any discrepancy.
The distribution of therapeutic cannabis in pharmacies would be an effective way for Health Canada to obtain accurate and relevant statistics on the actual number of users of therapeutic cannabis and the indications for which it is prescribed. These data are impossible to obtain with the current postal delivery system.

In addition, it is worth remembering that the network of pharmacies is a rigorously secure network throughout the supply chain and fully computerized, thus providing a system that is both more secure and traceable than that of the current distribution system, mail, or any other distribution system outside of the pharmacy system.

3. CURRENT ACCESS TO THERAPEUTIC CANNABIS

According to an estimate from Statistics Canada, reported by Neighbourhood Pharmacy, more than 400,000 Canadians currently use therapeutic cannabis. This number is seemingly increasing since the announcement of the forthcoming legalization of its non-therapeutic form. Current regulations provide that the therapeutic form of cannabis is prescribed by a doctor and distributed to patients by postal delivery. However, according to Neighbourhood Pharmacy, only 130,000 of these patient users are getting cannabis through this legal postal system. The 300,000 or so other users of therapeutic cannabis would have access to dispensaries, which is in itself an important issue since no professional monitoring is done. There is every reason to believe that, once the legalization is effective, these same patients will buy directly from the various points of sale planned by the provinces where they still will not find the appropriate professional follow-up.

Once cannabis has been legalized, it is absolutely vital to prevent patients from choosing its non-therapeutic form, without professional supervision. In its Report, the Task Force on the Legalization and Regulation of Cannabis in Canada has also brought forth some concerns of patients who fear that their access will be compromised by the new regulation, a situation that could potentially lead to the loss of the recognition of the value of therapeutic cannabis.

These fears are justified because it is true that non-therapeutic cannabis distribution points could compromise safe access. They do not have prevention tools, and, most importantly, do not provide any follow-up, focusing on the health of patients. Even more worrying: distribution is done under the supervision of people who are not health professionals and who are therefore unable to provide adequate therapeutic follow-up.

The AQPP can provide concrete instances of potential abuses. For example, Quebec, via Bill 157, could see problematic situations at the points of sale of the Quebec Cannabis Society (SQDC). Also, a SQDC staff member who, although not properly trained, could provide cannabis to a user who presents his doctor’s prescription; would the employee be required to serve the patient in accordance with his/her order? What would he do with the prescription? Should he establish a registry? There is nothing in the bill that provides guidelines for this type of situation or prevents it. This is where the greatest danger lies: an employee who is not a health professional is not able to provide advice on administration, dosing, prescription drug

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7 Neighbourhood Pharmacy Association of Canada, online
8 Task Force on Cannabis Legalization and Regulation in Canada: https://www.canada.ca/content/dam/hc-sc/healthy-canadians/migration/task-force-marijuana-groupe-etude/framework-cadre/alt/framework-cadre-eng.pdf
9 Neighbourhood Pharmacy Association of Canada, online
interactions and counter-indications for medications with the cannabis he has just sold to the patient. He also has no control over the prescribed doses nor on the conditions of use of the purchased product.

All of these elements jeopardize the reasonable and safe access to desired products for patients whose therapy involves therapeutic cannabis. For these patients, access other than through the pharmacy would entail not only risks, but also significant limitations. These are all strong points arguing in favour of Bill C-45 to consider the issue of distribution of therapeutic cannabis and to prefer its distribution via the pharmacy network.

4. THE ESSENTIAL ROLE OF PHARMACISTS IN THE DISTRIBUTION OF THERAPEUTIC CANNABIS

The pharmaceutical distribution of therapeutic cannabis has many advantages, and pharmacists can be involved in a number of ways. Among these benefits, it is important to consider that the pharmacist could exercise greater control over the minimum age of use, as well as increase monitoring of its use by young adults aged 18 to 21, compared to the distribution of the product by a non-health professional.

In fact, a poll conducted by Leger between from December 22 and 27, 2017, of a representative sample of 1,004 Quebeckers, aged 18 or over, confirms this perception:

- three-quarters (75%) of the population want the sale of therapeutic cannabis to be clearly supervised by structured and credible and trustworthy networks;
- almost one out of two Quebeckers (48%) believe that the network of community pharmacies, present throughout Quebec, is the best vehicle for the sale of therapeutic cannabis;
- only 4% of Quebeckers believe that therapeutic cannabis should be sold online with home delivery (by mail);
- only 3% of respondents believe that the distribution of therapeutic cannabis should be entrusted to cannabis producers.

It should also be noted that pharmacists already have access to specific tools and training related to the safe use of therapeutic cannabis, which further enhances their relevance in the distribution of this substance. Five main factors, detailed below, explain this.

As a first step, the pharmacist is the professional best able to ensure a rigorous therapeutic follow-up with the patients using cannabis. By having access to the complete pharmacotherapeutic profile of the patient through the pharmacy file and the Quebec Health Record (QHR), besides being able to follow up with the patient, the pharmacist can also better advise him on the choice of the type of cannabis and on the form in which it should be administered. The pharmacist is also advantageously placed to follow up with other health professionals involved, including doctors prescribing therapeutic cannabis, given the fact that communication between doctors and pharmacists is already well established. This therapeutic and inter-professional follow-up would not be very difficult to implement in pharmacies, since these already rely on elaborate systems for managing patient data, which immediately facilitate follow-up.
In a second step, cannabis, like any other prescribed product, has different characteristics that require the unique specialized knowledge of a pharmacist. Whether looking at prescription drug interactions that require dosage adjustments, contraindications, which can be severe in many cases, or mild side effects (headaches, dizziness, hallucinations, drowsiness, euphoria, sedation, etc.), the pharmacist is equipped to deal with these situations. Cannabis is contraindicated for certain conditions, such as certain mental illnesses (schizophrenia, bipolar disorder); pharmacists are best able to manage these situations by giving advice, changing dosage or recommending complementary or alternative therapies.

Distribution of therapeutic cannabis through pharmacists is necessary because of the importance of clinical surveillance required for this type of substance. Indeed, cannabis interacts with several commonly used psychotropic drugs (fluoxetine, olanzapine, clozapine, amitriptyline) and certain antibiotics (azithromycin). In addition, recent studies have shown that taking cannabis combined with some over-the-counter anti-inflammatory drugs may increase the risk of gastrointestinal bleeding. All these elements highlight the fact that the pharmacist is the most suitable health professional to distribute therapeutic cannabis, and the most competent distributor.

Thirdly, the drug monitoring systems already in place in the pharmacy are the best tools to protect patient data and to allow the clinical surveillance of fraud, multiple orders from multiple physicians, over-prescribing, high doses, and abuse/harm caused to patients. As well, with the computerization already well established in pharmacies, access to statistics on the use of therapeutic cannabis would be greatly facilitated.

Fourthly, pharmacists have the professional legitimacy required to assist patients who smoke cannabis to quit smoking by recommending alternative methods of consumption that are less harmful to health. Cannabis can be administered in other dosage forms and methods of consumption, such as cannabis oils or sprays. Pharmacists have the necessary clinical credibility and appropriate training to discourage patients from smoking; they also have the ability to prescribe anti-smoking treatments to support the patient's approach.

Lastly, by entrusting the network of community pharmacies with the responsibility for the distribution and management of therapeutic cannabis, the government ensures the transmission of information is facilitated, instantaneous, and standardized, since the AQPP is in direct and daily communication with all Quebec pharmacies.

5. THE IMPORTANCE OF RESEARCH

The AQPP considers that the use of therapeutic cannabis should not only be combined with a prevention and awareness program, but also with research projects and clinical trials. Whether it is the toxicity of the product, the most effective dosage, or the form in which it is consumed, it is essential to encourage patients using therapeutic cannabis to participate in research projects that will make it possible to advance science on these topics.

As such, once cannabis is legalized and safely distributed through pharmacies, it will be relevant and justified for the AQPP to contribute to the research projects envisaged by the various governments to improve the state of knowledge. This research is essential for improving and refining knowledge about cannabis prescriptions based on the disease or requirement for treatment; the pharmacy network is obviously the most appropriate place to...
do so. The AQPP also has the necessary resources and the will to contribute to such research projects, and even to initiate some when relevant.

The AQPP is convinced that by entrusting the distribution of therapeutic cannabis to pharmacists, the competent authorities will be making a beneficial decision for the research sector, since pharmacies already have all the necessary tools to support it. Indeed, with the technological tools already in the pharmacy, such as computerized patient records, it would be easier for pharmacists to do adequate follow-ups with patients participating in a research activity, thus facilitating the work of clinical researchers.

**RECOMMENDATIONS**

Considering the elements described above, the AQPP recommends:

- Including the issue of the distribution of therapeutic cannabis in Bill C-45.
- Treating therapeutic cannabis in the same way as all other prescription products, and, as a result, distribute it to patients exclusively through the network of community pharmacies, under the supervision of pharmacists, in order to guarantee patients access to safe and supervised treatment.
- Putting an end to the current mode of distribution of therapeutic cannabis by mail.
- Supervising the handling of therapeutic cannabis as methadone was when it was a preparation without a DIN, pending the assignment of a DIN.
- Including the AQPP and other pharmacists’ associations in research projects that the government intends to lead or sponsor on the benefits of therapeutic cannabis.

**CONCLUSION**

The AQPP would like to acknowledge the meticulous work of parliamentarians and senators on this issue with its many and delicate implications.

The issue of the distribution of therapeutic cannabis has an important dimension related to the protection of the public. That is why the AQPP wishes to convince the federal government that the distribution of therapeutic cannabis by mail is no longer an appropriate solution in the context of the legalization of cannabis for non-therapeutic purposes, as the poll clearly shows, mentioned in this brief.