Supporting Documentation

Issue: Marijuana (also referred to as Cannabis) for Medical Purposes

Date: January 2017

Date Revised: October 2018

Background

In the 2015 Speech from the Throne, the Government of Canada committed to legalizing, regulating, and restricting access to marijuana.

On June 30, 2016, the Minister of Justice and Attorney General of Canada, supported by the Minister of Public Safety and Emergency Preparedness and the Minister of Health, announced the creation of a Task Force on Marijuana Legalization and Regulation ("the Task Force"). The Task Force was mandated to engage with provincial, territorial and municipal governments, Indigenous governments and representative organizations, youth, and experts in relevant fields, including but not limited to: public health, substance abuse, criminal justice, law enforcement, economics, and industry and those groups with expertise in production, distribution and sales. The Task Force was mandated to provide advice on the design of a new framework. In order to do so, the strategy was for the Task Force to receive submissions from interested parties, including individual Canadians, consult widely, listen and learn, and commission any necessary focussed research to support its work. It was supported by a federal secretariat and was directed to report back to the three Ministers on behalf of the Government in November 2016.

On August 11, 2016, Health Canada announced the new *Access to Cannabis for Medical Purposes Regulations* (ACMPR). These new regulations replaced the *Marihuana for Medical Purposes Regulations* (MMPR) when they came into force on August 24, 2016. The new ACMPR was implemented as a result of the Federal Court ruling in the case of *Allard v. Canada*. These new regulations allow for reasonable access to cannabis for medical purposes for Canadians who have been authorized to use cannabis for medical purposes by their health care practitioner.

As with the MMPR and the Narcotic Control Regulations, the new ACMPR continues to provide some consistency with many established provincial and territorial prescription monitoring programs for controlled substances. Licensed producers of marijuana for medical purposes are required to provide information to provincial and territorial medical licensing bodies upon request, including healthcare practitioner information (name, address and professional license number), daily quantity of dried marijuana supported, period of use, date of document and basic patient information.

The largest single change is the introduction of provisions that allow Canadians who need access to cannabis for medical purposes to produce a limited amount of cannabis for their own medical purposes, or designate someone to produce it for them. Health Canada believes that the addition of these provisions enabling individuals to produce a limited amount of cannabis for their own medical purposes

provides for accessibility and affordability, and addresses the issue of reasonable access identified by the Federal Court.

On November 30, 2016, the Task Force on Cannabis Legalization and Regulation presented its advice on a framework for legalization and regulation of access to cannabis by presenting a report to the Minister of Public Safety and Emergency Preparedness, the Minister of Justice and Attorney General of Canada, and the Minister of Health. The report includes more than 80 recommendations to governments on how to better promote and protect public health and safety, particularly among young Canadians.

The report recommends establishing a minimum age of access and restrictions on advertising and promotion. It recommends well-regulated production, manufacturing and distribution that can displace the illegal market, and provides appropriate safeguards, such as testing, packaging and labelling. It also recommends that Governments educate Canadians about the new system to improve the public's understanding of cannabis, including risks such as impaired driving.

The report includes a section on "medical access". Considerations related to medical access are:

- Continuing to provide patients with reasonable access to cannabis for medical purposes, such that they can acquire and use cannabis to meet their needs while not facing undue constraints of cost or choice;

- Supporting the medical community with ongoing research and evidence on the therapeutic benefits and risks of the use of cannabis for medical purposes; and

- Contributing to the integrity of the overall cannabis framework that the Government will establish and minimizing the potential for abuse and diversion.

Also related to medical access, The Task Force recommends that the federal government:

- Maintain a separate medical access framework to support patients

- Monitor and evaluate patients' reasonable access to cannabis for medical purposes through the implementation of the new system, with action as required to ensure that the market provides reasonable affordability and availability and that regulations provide authority for measures that may be needed to address access issues

- Review the role of designated persons under the ACMPR with the objective of eliminating this category of producer

- Apply the same tax system for medical and non-medical cannabis products

- Promote and support pre-clinical and clinical research on the use of cannabis and cannabinoids for medical purposes, with the aim of facilitating submissions of cannabis-based products for market authorization as drugs

- Support the development and dissemination of information and tools for the medical community and patients on the appropriate use of cannabis for medical purposes

- Evaluate the medical access framework in five years

For the full document, please visit: http://www.healthycanadians.gc.ca/task-force-marijuana-groupe-etude/framework-cadre/index-eng.php

On June 21, 2018, The Cannabis Act (Bill C-45) received Royal Assent and came into effect on October 17, 2018. On this date, the use of recreational marijuana became legal and the pre-existing framework for medical marijuana also remains in place. The government has committed to reevaluate the medical access framework in five years.

For the full text, please visit: http://laws-lois.justice.gc.ca/eng/acts/C-24.5/

Research/Consultation Highlights gathered to-date

Parkinson Canada surveyed 299 Canadians impacted by Parkinson's – 61% of respondents have Parkinson's disease. The following question was posed:

Another upcoming issue is the legalization of marijuana. What are your thoughts on the use of marijuana by people with Parkinson's as a potential therapy?

243 people answered this question:

- 48% More research is needed
- 27% are in favour of it and believe it is beneficial
- 10% are not in favour of marijuana use under any circumstances
- 9% are calling for standards and protocols for use in people with Parkinson's
- 15% had no comment

Report from Parkinson Canada Information and Referral staff:

In most cases of people asking us where we (Parkinson Canada) stand on marijuana, especially if they are asking for a doctor who will sign off on marijuana, they are already using it and have access to it.

We (Parkinson Canada)speak regularly to people who are either inquiring about, or taking it for:

- *Tremor*
- *Dyskinesia*
- *Anxiety*

- *Nausea (ldopa)*
- *Pain*
- *Depression*

This is not just younger adults – folks in their 60s & 70s are not adverse to it, and folks in 80s and 90s have called because their grandkids got them some. That said, those people may be less likely to self-report.

There are people who are not taking it, but want the research…but it has more to do with legality: they are already using other alternatives i.e. CoQ10, glutathione etc. (therapies where the efficacy has not been proven).

Canadian Medical Association (CMA)

CMA released an updated position statement on medical marijuana in 2015 (their first statement was released in 2015). The statement focuses on "authorizing marijuana for medical purposes". The positon includes:

The Canadian Medical Association has consistently opposed Health Canada's approach which places physicians in the role of gatekeeper in authorizing access to marijuana.
Physicians should not feel obligated to authorize marijuana for medical purposes. Physicians who choose to authorize marijuana for their patients must comply with their provincial or territorial regulatory College's relevant guideline or policy. They should also be familiar with regulations and guidance, particularly:

- Health Canada's *Access to Cannabis for Medical Purposes Regulations (ACMPR),*
- The Canadian Medical Protective Association's guidance and
- The College of Family Physicians of Canada's preliminary guidance *Authorizing Dried Cannabis for Chronic Pain or Anxiety.*

CMA recommends that physicians should:

- Ensure that there is no conflict of interest, such as direct or indirect economic interest in a licensed producer or be involved in dispensing marijuana;
- Treat the authorization as an insured service, similar to a prescription, and not charge patients or the licensed producer for this service;
- Until such time as there is compelling evidence of its efficacy and safety for specific indications, consider authorizing marijuana only after conventional therapies are proven ineffective in treating patients' condition(s);
- Have the necessary clinical knowledge to authorize marijuana for medical purposes;
- Only authorize in the context of an established patient-physician relationship;

- Assess the patient's medical history, conduct a physical examination and assess for the risk of addiction and diversion, using available clinical support tools and tests;
- Engage in a consent discussion with patients which includes information about the known benefits and adverse health effects of marijuana, including the risk of impairment to activities such as driving and work;
- Document all consent discussions in patients' medical records;
- Reassess the patient on a regular basis for its effectiveness to address the medical condition for which marijuana was authorized, as well as for addiction and diversion, to support maintenance, adjustment or discontinuation of treatment; and
- Record the authorization of marijuana for medical purposes similar to when prescribing a controlled medication.

The CMA has continued to be active on this file, presenting submissions to the federal Task Force on Cannabis Legalization and Regulation for their 2016 report, to the House of Commons' Standing Committee on Health in August 2017, and to Health Canada in 2018. Through all of these submissions, the CMA stated that they believe that there will be little need for two systems (i.e., one for medical and one for non-medical cannabis use). Cannabis will be available for those who wish to use it for medicinal purposes, either with or without medical authorization (some people may self-medicate with cannabis to alleviate symptoms but may be reluctant to raise the issue with their family physician for fear of being stigmatized), and for those who wish to use it for other purposes. The medical profession does not need to continue to be involved as a gatekeeper once cannabis is legal for all, especially given that cannabis has not undergone Health Canada's usual pharmaceutical regulatory approval process.

However, the CMA supports the government's commitment to reviewing the medical marijuana system within five years of legalization. As the clinical information for cannabis remains limited, many physicians feel uncomfortable prescribing it as a potential medical intervention. Regulatory review processes that all other prescription medicines are subject to provide critical information to physicians such as dosages, clinical indications and potential interactions with other medications. The CMA states that this information is vital to physicians in protecting their patients. The CMA does however recognize that certain individuals suffering from terminal or chronic illnesses mat obtain benefits from the use of cannabis, all the while maintaining that more clinical guidelines are needed.

The Medical Cannabis Research Roundtable (organized by the Arthritis Society, included nearly 40 stakeholders)

The Medical Cannabis Research Roundtable was formed to advance discussion of the therapeutic benefits of medical cannabis in relieving and/or managing chronic pain.

They offer three principal recommendations:

1. Federal Investment – an immediate investment of $25 million dollars over five years to support research into medical cannabis.

2. Additional Investment – a call to others in the private and not-for-profit sector to also commit ongoing resources to research. To this end, The Arthritis Society announced a doubling of its own commitment to a total of $720,000 between 2015 and 2019. The Society also announced the creation of the Medical Cannabis Strategic Operating Grant, an ongoing annual dedication of at least $120,000 towards medical cannabis research.

3. Research Priorities – in keeping with the focus of the roundtable's discussions, a three-fold focus on Basic Science, Clinical Science and Health Services and Policy.

The Arthritis Society

The Arthritis Society offers a guide to accessing medical cannabis, but offers the following statement on their website:

This guide is intended for adults only. The Arthritis Society does not endorse or recommend medical cannabis. This guide has been created for educational purposes to provide information about medical cannabis as a potential treatment option.

The Canadian Nurses Association (CNA)

In May 2018, the CNA prepared a brief for their presentation to the Senate's Standing Committee on Social Affairs, Science and Technology prior to their appearance. In this brief, the CNA explains that it supports the need to preserve access to cannabis for medical purposes based on the principles of access and equity. This includes access to appropriate products, access without undue financial burden, and access to care and clinical oversight for persons using medical cannabis. Without such clinical oversight, we are essentially leaving patients to self-medicate and "figure it out" on their own.

CNA believes the intent of sections 8 and 9 are to govern the use of non-medical cannabis. However, the impact of those provisions on users of medical cannabis has the very real potential of limiting access to a substance that could alleviate serious medical symptoms.

Exempting medical cannabis from the application of sections 8 and 9 of Bill C-45 is necessary not only to preserve appropriate access within a separate medical cannabis regime; it would also protect clinicians — including nurses and nurse practitioners — from liability.

CNA recommends exempting medical cannabis from the application of sections 8 and 9 of the act.

For more information on Medical Marijuana in Canada, please visit Health Canada's website:
http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos-eng.php

Health Canada Information for Health Care Providers (May 2013) Addendum to the *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013 version) (sourced from http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/infoprof-eng.php#chp4813)

Parkinson's Disease

Endocannabinoid ligands, their synthesizing and degrading enzymes, and cannabinoid-activated receptors are highly abundant in the basal ganglia, the brain structures primarily affected in Parkinson's disease (PD)[Footnote 560]. Newly diagnosed PD patients and those undergoing PD medication washout were reported to have more than double the level of anandamide in their cerebrospinal fluid compared to controls, and these results parallel those seen in animal models of PD where dopamine cell loss is accompanied by elevations in anandamide levels[Footnote 589]. In animal models of PD the levels of CB_1 receptors appear to be downregulated during the early, pre-symptomatic stages of the disease, but during the intermediate and advanced phases of the disease there is an increase in CB_1 receptor density and function and an increase in endocannabinoid levels[Footnote 590,Footnote 591]. Together, these studies suggest a complex link between the pathophysiology of PD and changes in the endocannabinoid system.

Results from animal studies suggest cannabinoid receptor agonists induce hypokinesia and thus are reported to be unlikely as suitable first-line treatments for PD[Footnote 560,Footnote 592]. On the other hand, cannabinoid-induced hypokinesia could be useful in attenuating the dyskinesia observed in PD patients on long-term levodopa treatment[Footnote 592]. Cannabinoids having mixed CB_1 antagonist/CB_2 agonist properties as well as anti-oxidant effects (such as THCV) may possibly hold some therapeutic potential, but much further research is required to determine whether the beneficial effects of THCV observed in animal models of PD can find applicability in humans[Footnote 593].

Clinical Data

The results of clinical trials examining the role of cannabinoids (cannabis, nabilone and a standardized oral cannabis extract) in the treatment of PD are mixed. One study involving five patients suffering from idiopathic PD found no improvement in tremor after a single episode of smoking cannabis (1 g cigarette containing 2.9% Δ^9-THC, 29 mg total available Δ^9-THC), whereas all subjects benefited from the administration of levodopa and apomorphine[Footnote 594]. A small randomized clinical trial of the synthetic cannabinoid nabilone (0.03 mg/kg) in seven patients with PD found that the treatment reduced levodopa-induced dyskinesia[Footnote 595]. In contrast, a four-week, randomized double-blind, crossover study demonstrated that an oral cannabis extract (2.5 mg Δ^9-THC and 1.25 mg cannabidiol per capsule, b.i.d.; maximum daily dose 0.25 mg/kg Δ^9-THC) did not produce any pro- or anti-parkinsonian action[Footnote 596].

National Parkinson's Foundation (excerpts from their information on "medical marijuana") (Sourced from http://www.parkinson.org/understanding-parkinsons/treatment/complementary-treatment/medical-marijuana-and-parkinsons-disease)

Researchers are testing marijuana, which they call cannabis, as a treatment for many illnesses and diseases, including neurological conditions, with Parkinson's disease (PD) high on the list. But despite several clinical studies, it has not been demonstrated that cannabis can directly benefit people with Parkinson's.

"Marijuana should never be thought of as a replacement for dopaminergic and other approved therapies for Parkinson's disease," said Dr. Michael S. Okun, NPF's National Medical Director. Research is still needed to determine how medical marijuana should be administered and how its long-term usage can effect Parkinson's disease symptoms.

Parkinson Canada's Medical Advisory Committee (MAC)

The MAC was provided with consultation questions. Below is a summary of their responses:

- There are no new or planned studies in the near future in Canada that address the use of medical marijuana in the management of Parkinson's disease symptoms.
- Physicians do have patients with Parkinson's requesting medical marijuana; however doctors are reluctant to offer this due to the lack of evidence and inconsistency in products (i.e. strength).
- Overall health care professionals see a value in more research being done on the safely and efficacy of medical marijuana for people with Parkinson's.