



Prepared for:

Canadian Pharmacists Association

# Improving Medical Marijuana Management in Canada

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## **Disclaimer**

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# Executive Summary

## Background

Since the legalization of medical marijuana (MMJ) in 2001, the Government of Canada has endeavored to create an industry framework that protects patient and public safety while providing appropriate access. In 2013, the Government of Canada revised its MMJ regulations to restrict the sale and distribution of MMJ through selective providers in an attempt to increase healthcare professional involvement and further regulate the industry. Despite these regulatory reforms, a number of significant limitations remain. Limited legal access and enforcement is challenged by illicit grey and black markets, while the lack of clinical evidence is a barrier to healthcare professional involvement. These challenges present risks to patient safety and therefore need to be addressed.

The recently elected federal government included in their election platform the legalization of recreational marijuana. While they are currently exploring the issue, having created a task force headed by former Toronto Police Chief Bill Blair, the limited dissemination of information regarding its progress has created uncertainty. In addition, the Federal Court's recent ruling that the MMJ home growing ban is unconstitutional now places increased pressure on the government to respond.<sup>1</sup> With the Federal Court's ruling and the legalization of marijuana for recreational purposes on the horizon, there is a further impetus for MMJ regulatory reform in Canada.

## Understanding the Document

### Terms of Engagement

KPMG was engaged by the Canadian Pharmacists Association (CPhA) to conduct an independent assessment of the MMJ industry in Canada and propose a MMJ framework that could help improve patient safety and access as well as help address other challenges faced by the sector today. Furthermore, KPMG was asked to evaluate whether pharmacy should have a role in this new framework and what benefits it could bring. Our work included an environmental scan and development of key considerations for an industry framework, culminating in this final document. The study also included engaging with a CPhA selected Expert Advisory Panel to provide feedback and inform KPMG on key pharmacy issues in Canada.

The development of this document involved three phases of work:

- *Phase 1: Environmental Scan:* A scan that included review of the Canadian industry context and a key jurisdictions was conducted to understand the current state of the industry with respect to the product, market, regulatory environment and the broader value chain. The work included the following jurisdictions: Australia, California, Colorado, Connecticut, Israel, Netherlands, New York, Uruguay and Washington. The research included a review of the current regulatory context and relevant case studies, as well as interviews with subject matter professionals in key jurisdictions.

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<sup>1</sup> On February 24<sup>th</sup> 2016, the Federal Court ruled that the home growing ban of MMJ under the MMPR is unconstitutional. For the time being the ban will continue, as the Government of Canada have been given six months to revise existing regulations (Michael L. Phelan, 2016). See Figure A in section 3.1 and section 5.1 for more details.

The aim of this phase was to understand the key drivers, leading strategies, practical considerations, as well as the challenges these regions have faced. The lessons learned helped shape the guiding principles and the considerations for a proposed framework for Canada.

- *Phase 2: Development of Industry Framework Considerations:* The research and analysis undertaken in the first part of the engagement helped inform the development of options for an industry framework. Using an iterative, hypothesis-driven approach, considerations for an industry framework were developed. The considerations were discussed with KPMG Health & Life Sciences subject matter professionals and with an Expert Advisory Panel (selected by CPhA), a group composed of a practicing pharmacists and pharmacy regulators. Their role was to provide input and feedback on the feasibility and relevance of pharmacy's potential role under the proposed considerations.
- *Phase 3: Final Document:* Through an iterative review process, incorporating feedback from the CPhA expert panel and our internal advisors, we developed this final deliverable that communicates the rationale for change, the proposed considerations for a framework, future state considerations and associated benefits for Canadians should the changes be implemented.

### Our Limited Procedures

Our role was to outline certain matters that came to our attention during our work and to offer our observations for the Association's consideration. As outlined above, our procedures consisted solely of independent inquiry, observation, comparison, and analysis of targeted CPhA provided data and secondary research based on publically available information. Such work does not constitute an audit. Accordingly we express no opinion on the merits of MMJ as a therapeutic option, MMJ's efficacy, or the non-medical use of marijuana.

### Key Findings

Through our work, we learned that in many parts of the world, including Canada, marijuana has long been an illegal recreational drug. However, there is emerging evidence that suggests that there may be medical benefits in certain circumstances (i.e., for a subset of patients and indications). Increasing discussion related to its purported benefits is garnering attention from key stakeholders within and outside of the MMJ sector. As such, governments around the world are faced with the challenge of the effective management of MMJ to promote patient safety, while enabling appropriate access.

Marijuana can be an inherently risky therapeutic option due to its psychoactive effects, potential for dependence and other health risks including drug interactions and long term effects on brain development in adolescents. Differentiating its medical use from recreational use presents a complex public policy issue. Existing clinical evidence, although growing, is still limited; the majority of studies to date would not necessarily pass traditional drug regulatory approval processes under which new pharmaceuticals are approved. However, there is a drive to advance the knowledge around marijuana's potential benefits and demonstrate stronger clinical evidence. In fact, the global industry has recently witnessed a growing number of research collaborations between producers, academia, healthcare professionals and governments.

With the overarching drive to improve patient safety, our work ultimately informed the development of six key guiding principles (see [section 4](#) for more details). These principles set a foundation upon which to develop key considerations for an MMJ industry framework to help improve the management of and safe access to MMJ in Canada. To that end, this document outlines proposed actions that include incorporating pharmacy into the supply chain, whereby pharmacy would become the sole distributor of MMJ in Canada. This change is largely motivated by the need for therapeutic products that present drug interaction and other risks to patients to be managed by a regulated health professional. As such,

pharmacists were found to be the leading option to take on the role given that they are regulated health professionals with specialized medication management training and experience.

This document (see [section 5.1](#)) outlines nine proposed actions to improve the management of MMJ, which are as follows:

1. Establish a legal framework to incorporate pharmacy in the supply chain
2. Establish clear product regulations for MMJ
3. Enhance clinical guidelines for MMJ
4. Support the development of stronger clinical evidence for MMJ
5. Review the scope of practice regulation for healthcare professionals as it relates to MMJ
6. Enhance MMJ education and training for healthcare professionals
7. Support patient education and awareness of risks and benefits of MMJ
8. Enforce existing home growing ban
9. Continue tight regulation of licensed MMJ producers

Although not yet a reality today, there is a distinct possibility that marijuana could be legalized for recreational use. This could introduce additional risks to patients. Hence, five further considerations are outlined to help prepare Canada in the event that legalization of marijuana for recreational purposes occurs. These considerations help create a legalized recreational marijuana system that could harmoniously coexist with the MMJ system (see [section 5.2](#) for more details):

1. Promote clearer product differentiation between MMJ and recreational marijuana
2. Mandate product warnings for recreational products
3. Implement rigorous product management regulations for the sale of recreational marijuana
4. Mandate training for retail staff selling recreational marijuana
5. Coincide legalization with a public education campaign

## Next Steps

The government and its taskforce on recreational marijuana have not yet communicated their progress or provided guidance as to the likelihood or expected circumstances of legalization. In the event of legalization of marijuana for recreational use, it may require several years for the change to take full effect. The possible transformation of the marijuana industry in Canada would likely occur over multiple phases, offering a unique opportunity for course correction. Through the introduction of the proposed changes, present issues of patient safety and appropriate access could be improved regardless of the future legislative considerations regarding recreational marijuana. Furthermore, the involvement of pharmacy enables the government to better understand retail distribution and its implications to help inform and refine Canada's long term marijuana policy.

The government's window of opportunity may be short. To avoid being saddled with a MMJ regulatory environment that will make eventual change much more challenging, improvements should be initiated quickly.

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# 1 Evolving Canada's Medical Marijuana Industry Framework

In 2001, medical marijuana (MMJ) was legalized in Canada under the Marihuana Medical Access Regulations (MMAR).<sup>2</sup> This allowed eligible patients who could become registered users to access marijuana for medical purposes through Health Canada, or grow marijuana for their own use (Health Canada, 2014). In 2013, the Canadian government introduced the Marihuana for Medical Purposes Regulations (MMPR) to enable the creation of a commercial industry that is accountable for the production and distribution of MMJ. The MMPR were designed to help promote appropriate access to quality-controlled MMJ. Only producers who are authorized to produce and sell to the public may sell or provide dried marijuana, fresh marijuana or cannabis oil to eligible persons (Health Canada, 2015). Over the past few years, there have been concerns around the degree of rigor and limitations of the current industry framework for MMJ. This has led to questions relating to an increased role for healthcare professionals in its management.

This document aims to shed light on potential ways in which some of the industry's key limitations may be addressed. Furthermore, it identifies the benefits of increased healthcare professional involvement. The proposed industry framework considerations outlined in this document are grounded in learnings from other jurisdictions and knowledge of the current industry context in Canada.

## 1.1 A timely impetus for change

MMJ has been a legal therapeutic option in Canada for select groups of patients since 2001. This has been predominantly restricted to patients experiencing compassionate end-of-life care and/or those suffering from debilitating symptoms (Health Canada, 2013). More than fifteen years later, many unresolved issues persist, putting the safety of patients and public at risk (see [section 3](#) for more details). The MMPR were introduced to promote healthcare professional involvement in the supply chain by shifting the gatekeeper responsibility to prescribers. However, while there are pockets of strength (e.g. in pain therapy), the relative lack of clinical evidence continues to limit acceptance of MMJ as a therapeutic option in clinical practice. While the MMPR aimed to improve access while securing the supply chain, they appear to have negligible impact on the thriving grey and black markets. In particular, patient safety and access continue to be major issues within the MMJ system.

Recently, the federal government has reiterated its commitment to legalize, regulate and restrict access to marijuana for recreational use (Liberal Party of Canada, 2016). This promise has stimulated public discussion on broader marijuana policy reform. Marijuana legalization for non-medical purposes would have significant implications for MMJ. Addressing the MMJ system's risks prior to or as part of a broader plan to legalize marijuana would be a timely and prudent move.

The appropriate regulation and management of MMJ is a complex policy problem. The issues at stake share similarities with other major harm reduction policy discussions such as those on alcohol, tobacco and narcotics – all of which were initially medical substances that later became used for recreational purposes (Centre for Addiction and Mental Health, 2014). MMJ, on the other hand, is unique. Its industry has been predicated on regulating a traditionally illegal recreational substance that subsequently demonstrated potential for alleged medical benefits.

To date, no jurisdiction globally appears to have found an optimal MMJ industry model. However, Canada has an opportunity to leverage learnings from other jurisdictions as well as leading practices from

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<sup>2</sup> "Marihuana" is the spelling used in Canadian legislation.

healthcare professions to reflect on the current system limitations as well as prepare for the possibility of legalization of marijuana for recreational purposes. Policymakers in jurisdictions contemplating marijuana legalization, such as California, appear to be focused on first tackling limitations in their existing MMJ ecosystem as ground work for wider legalization (Blue Ribbon Commission on Marijuana Policy, 2015). Policymakers recognize that the level of risk posed to patients and the public can dramatically increase when broad access is granted.

Canada may now only have a small window to enact change to MMJ regulations to improve patient and public safety prior to wider marijuana legislation. Regardless of future policy decisions on legalization, there is a public safety imperative for the Government of Canada to act and mitigate the risks that exist in the current sector.

## 2 Demystifying Medical Marijuana

A review of the efficacy of MMJ was not a key objective of this work. However, a discussion of its therapeutic attributes helps contextualize some of the complexities related to the management of MMJ.

Marijuana refers to preparations from the hemp plant *Cannabis sativa*. The product contains the psychoactive chemical tetrahydrocannabinol (THC) along with more than 70 other similarly structured compounds called cannabinoids (National Institute on Drug Abuse, 2015). It has long been used as a recreational drug for its mind altering and relaxing effects. According to the World Health Organization, marijuana is by far the most widely cultivated, trafficked and abused illicit recreational substance worldwide (World Health Organization, 2016).

Marijuana has both short- and long-term effects on the brain. Short-term effects can include the alteration of one's senses, coordination impairment, mood heightening and the induction of a "high" for users. Long-term effects include delayed brain development and impaired memory and learning functions. These are some of the major reasons why marijuana use by people under 25 years old has been contraindicated (Health Canada, 2016). Prolonged use of marijuana has also been linked to mental illness in some users (Health Canada, 2016). Evidence suggests that marijuana use that begins early in adolescence, is frequent and continues over time could potentially lead to dependence. It is estimated that 9% of all marijuana users will develop a dependence (Lopez-Quintero, et al., 2011). This number doubles to approximately 17% for those who start using in their teens (Anthony, 2006). Marijuana may also lead to increased risk of adverse effects when combined with certain medications such as anticoagulants, benzodiazepines or those primarily metabolized through the liver's cytochrome P450 enzyme system (Mayo Foundation for Medical Education and Research, 1998-2016). Despite these risks, many patients look to marijuana for relief from debilitating disorders and symptoms (Gupta, 2015).

Cannabinoids, primarily THC and Cannabidiol (CBD), have been associated with therapeutic benefits. These benefits include: the feeling of well-being, muscle relaxation, pain relief, appetite stimulation, antiemetic effects, anticonvulsant and antispasticity effects and lowered intraocular pressure (Parliament of Canada, n.d.). However, a variety of other therapeutic products with more established efficacy and safety profiles exist. Marijuana could arguably be considered a potential last resort therapy for certain disorders and symptoms when others fail. Furthermore, the potential therapeutic and adverse effects associated with marijuana use may vary depending on the amount of marijuana used, the concentration of cannabinoids, the frequency of use, the patient's age, the presence of comorbidities, use of other medications as well as previous experience with marijuana (Health Canada, 2016). Dr. David Juurlink, Head of Sunnybrook's division of clinical pharmacology and toxicology, makes a case for thoughtful prescribing of marijuana. In the CMAJ he discusses "A pragmatic case can be made for the judicious prescribing of cannabis to patients who report meaningful benefit from it, especially when its use minimizes the need for other medications that carry risk" (Juurlink, 2014).

### 2.1 Differentiation between medical and recreational marijuana

Very few regulatory guidelines exist on the types of marijuana for medical use. Multiple types and forms exist although smoking the product is often discouraged by health professionals. The lack of clear distinction between MMJ and recreational marijuana have led to common misconceptions by the public, some patients and even healthcare professionals.

Although derived from the same plant, there are some observed differences between MMJ and recreational marijuana based on inherent properties. For example, MMJ users may seek out types/forms that can provide symptomatic relief, while recreational users may predominantly seek out those with psychoactive effects. Desired effects can be achieved through two major variables: strain and form.

## 2.1.1 Hybridizing strains to achieve desired medicinal properties

MMJ largely comes from two cannabis subspecies, *indica and sativa*. These are cultivated together to create hybrid strains (Americans for Safe Access, 2016). Different strains have varying degrees of potential effects depending on the relative THC and CBD content. Both THC and CBD are associated with pain relieving and anti-inflammatory effects of MMJ. However, THC may produce psychoactive effects while CBD has been linked to anti-nausea, anti-anxiety and muscle relaxing effects (Bedrocan, 2016).

## 2.1.2 A multitude of ingestible forms

There is a wide variety of MMJ forms with unique pharmacokinetic characteristics that determine the onset, duration and intensity of effects. As with medication, different forms of MMJ have varied onset and duration of action. These are part of the key patient considerations when determining their use (Americans for Safe Access, 2016). For example, patients with severe, acute pain may require forms that provide immediate relief whereas those with epilepsy prefer long-lasting symptomatic control (American Academy of Neurology, 2014). The table below provides an overview of the most common forms of MMJ.

**Table 1: Examples of common forms of MMJ**

Form	Description	Potential Risks
<b>Dried herb</b>	<ul style="list-style-type: none"> <li>Dried form of the plant can be smoked or vaporized to provide quick onset of relief. However, effects may wear off between 90 minutes to 4 hours (Harborside Health Center, 2014)</li> <li>Compared to smoking, vaporizing is associated with relatively less respiratory irritation and harm as cannabinoids are extracted below the plant's combustion point (Harborside Health Center, 2014)</li> </ul>	<ul style="list-style-type: none"> <li>Smoked MMJ has similar respiratory implications as tobacco, such as daily cough, phlegm, higher risk of lung infections, lung damage, etc. (National Institute on Drug Abuse, 2015)</li> <li>A recent study showed that vaporizing MMJ can lead to toxic levels of ammonia in the vapor. This can cause lung irritation, nervous system effects and asthma attacks (Colorado Department of Public Health and Environment, n.d.)</li> </ul>
<b>Raw herb</b>	<ul style="list-style-type: none"> <li>Leaves and buds can be ingested straight from the plant, usually by way of juicing (LeafScience, 2014)</li> <li>Without heat to produce THC, juicing has no psychoactive effects (LeafScience, 2014)</li> </ul>	<ul style="list-style-type: none"> <li>Ingestion of raw herb increases susceptibility to mould and other contaminants (LeafScience, 2014)</li> </ul>
<b>Oil Extract</b>	<ul style="list-style-type: none"> <li>Concentrated solvent-extracted oil (known as hash oil) can be smoked with a specialty pipe, with a vaporizer or added to food (Americans for Safe Access, 2016)</li> <li>Contains high proportion of cannabinoids, ranging from 30 to 90% THC (Americans for Safe Access, 2016)</li> </ul>	<ul style="list-style-type: none"> <li>Vaporizing hash oil (known as "dabbing") can deliver extremely large amounts of THC, resulting in potential emergency room visits (National Institute on Drug Abuse, 2015)</li> <li>Hash oil preparation requiring butane has resulted in home fires, explosions and severe burns (National Institute on Drug Abuse, 2015)</li> </ul>

Form	Description	Potential Risks
<b>Edible</b>	<ul style="list-style-type: none"> <li>MMJ can be ingested as edibles such as tea, brownies, cakes, butter, etc. (Americans for Safe Access, 2016)</li> <li>Longer lasting effect (up to 10 hours) due to slower gastrointestinal absorption (Americans for Safe Access, 2016)</li> </ul>	<ul style="list-style-type: none"> <li>The 20- to 60-minute onset delay compared to smoking increases the potential for overconsumption (Americans for Safe Access, 2016)</li> <li>Digestive processes alter the metabolism of cannabinoids and may produce markedly different or negligible effects (Americans for Safe Access, 2016)</li> </ul>

## 2.2 Growing momentum in an under-researched field

Research into cannabinoids has been described as “one of the fastest moving frontiers in pharmacology” (Allsop, Lintzeris, Arnold, & McGregor, 2015). The endocannabinoid system of the brain and body is still largely under-studied. New research has shown a relation to appetite, cognitive function, pain, anxiety, immune function and tumor proliferation. The modulation of these processes through cannabis is thought to have a potential to influence human disease and wellbeing (Allsop, Lintzeris, Arnold, & McGregor, 2015). A recent search of ClinicalTrials.gov indicates that globally there are 182 active cannabinoid-related clinical trials. The US has increasingly been investing in clinical trials and is the site of 97 (over 50% of the world’s total) registered clinical trials (ClinicalTrials.gov, 2016). In contrast, Canada is home to just under 4% of the cannabinoid-related studies. It must be noted that these numbers may underestimate the overall number of trials globally since, unlike in the US, registration of trials on ClinicalTrials.gov is not mandatory in all countries.

**Figure 1: Distribution of cannabinoid-related clinical trials, by select region and number of registered trials**



Note: Results generated using the search term “cannabinoid”, “marijuana” and “cannabis”. The search was focused on active trials, including “active but not recruiting”, “not yet recruiting”, “recruiting” and “expanded access: available”.

Source: KPMG analysis of all registered clinical trials (using the search term “cannabinoid”, “marijuana” and “cannabis”) in ClinicalTrials.gov as of February 29, 2016

It has been suggested that limited clinical evidence in Canada could be attributed to a lack of available research funds to stimulate research in MMJ (Birchard, 2014). However, clinical research in this area is becoming more organized since the introduction of the MMPR and licensed producers. In 2015, the Research Institute of the McGill University Health Centre and the Canadian Consortium for the Investigation of Cannabinoids launched a registry for MMJ users in Quebec (The Canadian Consortium for the Investigation of Cannabinoids, 2015). This registry is the world's first research database on MMJ that will compile four years of clinical data directly from MMJ patients.

At the same time, a number of licensed Canadian producers are solidifying their position through strategic investments and partnerships. For example, MedReleaf in Canada has entered into an exclusive partnership with Tikun Olam, the largest government approved MMJ producer in the State of Israel. The partnership will see the development of proprietary MMJ varieties and access to Tikun Olam's extensive MMJ treatment database. The database is composed of anonymized patient data including optimal strain and dose information for different indications for over 7,000 patients (MedReleaf, 2016). This data helps to inform and optimize MMJ treatment. Many licensed Canadian producers are also conducting or developing clinical trials with universities (Birchard, 2014). One of the more recent clinical trials is CAPRI, a randomized, double blind, placebo controlled trial of vaporized MMJ in adults with painful osteoarthritis of the knee. The trial is conducted by researchers at McGill University Health Centre and Dalhousie Universities and sponsored by Prairie Plant Systems and CanniMed (Zetti, 2015).

Despite this recent flurry of research, the quality of clinical data has been inconsistent and there are significant gaps in understanding of the therapeutic efficacy of MMJ for many conditions (Victorian Law Reform Commission, 2015). Governments have, nonetheless, developed guidance for their healthcare professional community on matters such as patient eligibility and indications for which the evidence may be stronger. Example indications where MMJ has shown promise include (Health Canada, 2016) (Victorian Law Reform Commission, 2015):

- Severe refractory nausea and vomiting associated with cancer chemotherapy;
- Loss of appetite and body weight in patients with cancer or HIV/AIDS;
- Pain and muscle spasms associated with multiple sclerosis;
- Severe refractory seizures where other treatments have proved ineffective or have generated intolerable side effects; and
- Severe chronic pain (mainly neuropathic).

Although MMJ research is increasingly taking place around the world, healthcare professional communities globally still believe there is insufficient scientific and clinical evidence to support the use of MMJ (Victorian Law Reform Commission, 2015).

## 2.3 Lesson learned from around the globe

The recent wave of MMJ reform occurring around the world provides Canada with an opportunity to leverage key learnings from different regulatory approaches. A number of jurisdictions have been studied in the development of this document. These include: Australia, California, Colorado, Connecticut, Israel, Netherlands, New York, Uruguay and Washington. Each have focused on different issues with varying degrees of success.

While our research concluded that no single jurisdiction has implemented an optimal industry model, some key themes have emerged:

- 1) **Differentiating MMJ from those for recreational use:** Defining what constitutes MMJ has been a challenge globally as legal recreational use of marijuana is becoming increasingly prevalent. All jurisdictions investigated have attempted to differentiate MMJ and recreational marijuana through various methods. These have primarily focused on restricting product strains and forms as well as

establishing distinct access channels for MMJ. For example, Florida has defined strains with high CBD content (with little to no THC) as MMJ products given its purported therapeutic benefits and limited psychoactive effects (Americans for Safe Access, 2014).

- 2) Fostering the development of clinical evidence:** Robust clinical evidence is key to enabling the development of therapeutic guidelines supporting safe and quality patient care. Israel has been at the forefront of MMJ research for over 50 years (Sohn, 2015). Its advanced MMJ program is enabled by the government's mandate to regulate the quality and safety of the product (Wilson, 2013). Their regulatory framework supports basic and clinical research. As a result, Israel's industry hub has attracted foreign companies and researchers, and numerous international partnerships (Sohn, 2015). This thriving ecosystem fosters start-ups by allowing innovators to take advantage of the expertise in agricultural technology such as seed breeding, precision agriculture, natural pesticides, water-efficient drip irrigation and hydroponics (Kloosterman, 2015).
- 3) Involving healthcare professionals:** As more clinical evidence emerges, there has been increasing interest in managing MMJ similarly to pharmaceutical medications. This requires the enhanced involvement of healthcare professionals in the supply chain. Increasing healthcare professional involvement in MMJ management has been a recent trend observed in all jurisdictions studied. For example, patients require an authorized physician's recommendation to access MMJ in US states where it has been made legal. Certain states have introduced an additional level of rigor by including pharmacists in the management of the product. This can be observed in Connecticut where pharmacists manage and dispense MMJ through licensed non-pharmacy retailers (Department of Consumer Protection). Similarly, Israel will likely be moving towards the dispensing of MMJ through pharmacy in the near future (Surkes, 2016). Jurisdictions such as the Netherlands manage MMJ like any prescription medication. Accountability is shared between prescriber (physician in most jurisdictions) and pharmacist with the prescriber determining patient eligibility and the pharmacist dispensing the product.
- 4) Enabling appropriate retail access:** Point of access varies across jurisdictions. Potential access points include: non-government retailers, not-for-profit distributors (i.e. compassion clubs), government retailers, pharmacies and MMJ producers (Victorian Law Reform Commission, 2015). Policymakers have struggled to strike a balance between enabling appropriate patient access while limiting diversion to illegal users. The following illustrates two distinct models for patients accessing MMJ:
  - **California's free market model:** MMJ was legalized in 1996. The state adopted an unregulated, not-for-profit model with cooperatives and collectives responsible for distributing MMJ. Licenses were not required and few quality controls were in place (California Department of Public Health, 1996). While this model has been considered successful in providing access to patients (Americans for Safe Access, 2014), product diversion (i.e. leakage of MMJ for illegal consumption) has been rampant. It has been reported that since the list of qualifying conditions is quite liberal, many patients have gained access to the system for conditions such as mild back pain. This has led to speculation that recreational users are exploiting the MMJ system (Blue Ribbon Commission on Marijuana Policy, 2015). To address this issue, California has recently begun a reform of its MMJ industry towards greater regulation, requiring grower and distributor licenses (California Department of Public Health, 2016).
  - **New York's restrictive model:** Compared to California, the legal MMJ industry is in its infancy. MMJ was only legalized in 2014 and a highly stringent model is in place. In order to gain access to MMJ, a patient must obtain a physician's recommendation and have a condition that is listed in the limited qualifying conditions list. The physician must be registered with the Department of Health that requires the completion of a 4-hour Department of Health online course on MMJ (New York State Department of Health, 2015). Patients can only access their MMJ through one

of 20 licensed dispensaries. Critics of the model have expressed concern over inadequate patient access to MMJ (Warner, 2016).

- 5) Reinforcing patient education:** A number of jurisdictions such as Australia and Israel include regulations to promote that patients are adequately educated and supported. Australia recommends that the prescriber plays an active role in educating patients on the product's benefits, side effects, risks and long-term effects (Victorian Law Reform Commission, 2015). Whereas, eligible patients in Israel must receive appropriate training from their designated MMJ producer prior to receiving supplies. An example of this comes from Israel's biggest producer, Tikun Olam, who have established a nurse clinic where registered and trained nurses educate and support patients throughout their treatment course of MMJ (Tikun Olam, 2016).

These learnings represent practices from around the world that could help inform Canada's approach in managing MMJ to promote patient safety and appropriate access. The next section provides an overview of Canada's MMJ industry, highlights its regulatory evolution and identifies key challenges that will need to be addressed.

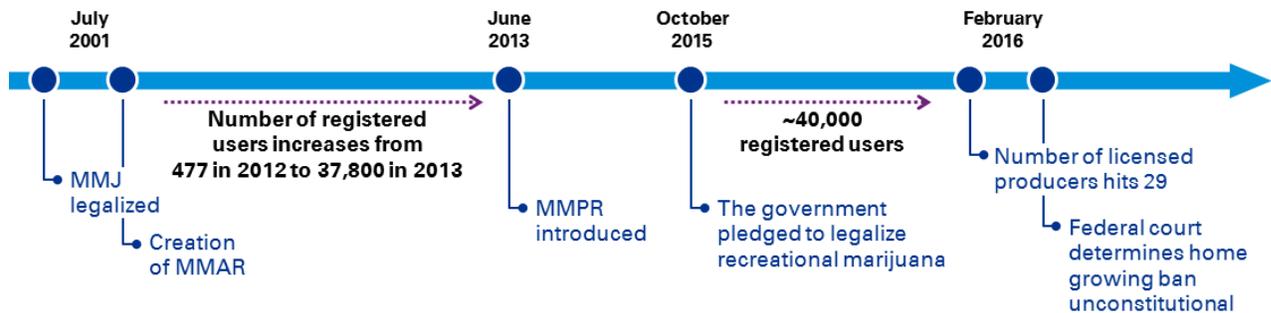
# 3 A Snapshot of Canada's Medical Marijuana Industry Today

A robust industry framework for MMJ in Canada requires a regulatory structure that places patient safety at the core. Understanding the current state of the MMJ industry brings to light the limitations of the current model and some of the key issues that Canadian patients are facing.

## 3.1 A regulatory environment in flux

In 2001, MMJ was legalized in Canada under the Marihuana Medical Access Regulations (MMAR). This allowed eligible patients who could become registered users to access MMJ through Health Canada. Under MMAR, patient eligibility was determined based on a list of qualifying conditions with eligible patients being issued a MMAR license by Health Canada. MMAR-licensed patients could either access MMJ directly from Health Canada (marijuana was cultivated by one government selected producer), or grow MMJ for personal use (Health Canada, 2014).

Figure 2: The evolution of Canada's MMJ regulatory environment



Sources: (KPMG Analysis), (Health Canada, 2012), (Health Canada, 2013)

In 2013, the Government of Canada privatized MMJ through the introduction of the Marihuana for Medical Purposes Regulations (MMPR) (Health Canada, 2012). Drivers for reform included:

- Creating a more tightly regulated industry;
- Limiting the government's involvement in the supply chain;
- Increasing the involvement of healthcare professionals in the supply chain; and
- Reducing the risks to patient safety and security associated with home growing.

These regulations helped limit Health Canada's role in the supply chain by shifting the gatekeeper responsibility to healthcare professionals (primarily prescribing physicians as well as nurse practitioners in some provinces). Under MMPR, Health Canada licenses and regulates producers to cultivate MMJ, subjecting them to quality controls such as testing for contamination and batch consistency (Government of Canada, 2013). There is mixed public opinion on the change from MMAR to MMPR. The quality of MMJ produced by MMPR-licensed producers is reportedly superior to that produced under MMAR and distributed by Health Canada. However, affordability could be an issue for some patients with average prices estimated to be \$7.50/gram (KPMG Research, 2016).

The Canadian regulatory landscape is likely set to change once again. The newly elected federal government's platform included a commitment to legalize recreational marijuana. According to a Nanos

research poll conducted in 2016, the vast majority of the Canadian public supports a loosening of the law around marijuana. Some 39% of Canadians support legalization of marijuana for recreational purposes while a further 29% somewhat support legalization (Nanos Research, 2016). Recently, the government created a task force headed by former Toronto Police Chief Bill Blair to explore the issue further. While little information has been shared to date, the government has indicated that legalization will not be driven by tax generation goals. Rather it would focus on promoting the safety of all Canadians (Riches, 2016). Any new legislation will require consultation and collaboration with provincial governments. The recent prominence of this topic has led some provincial government representatives to issue statements around who should sell recreational marijuana. British Columbia, Manitoba and Ontario have proposed government-run liquor authorities (and store network) while the positions of other provinces remain unclear (Morrow, 2015).

### 3.1.1 Canada's international treaties: an obstacle to recreational marijuana legal reform

#### Figure A: The home growing controversy

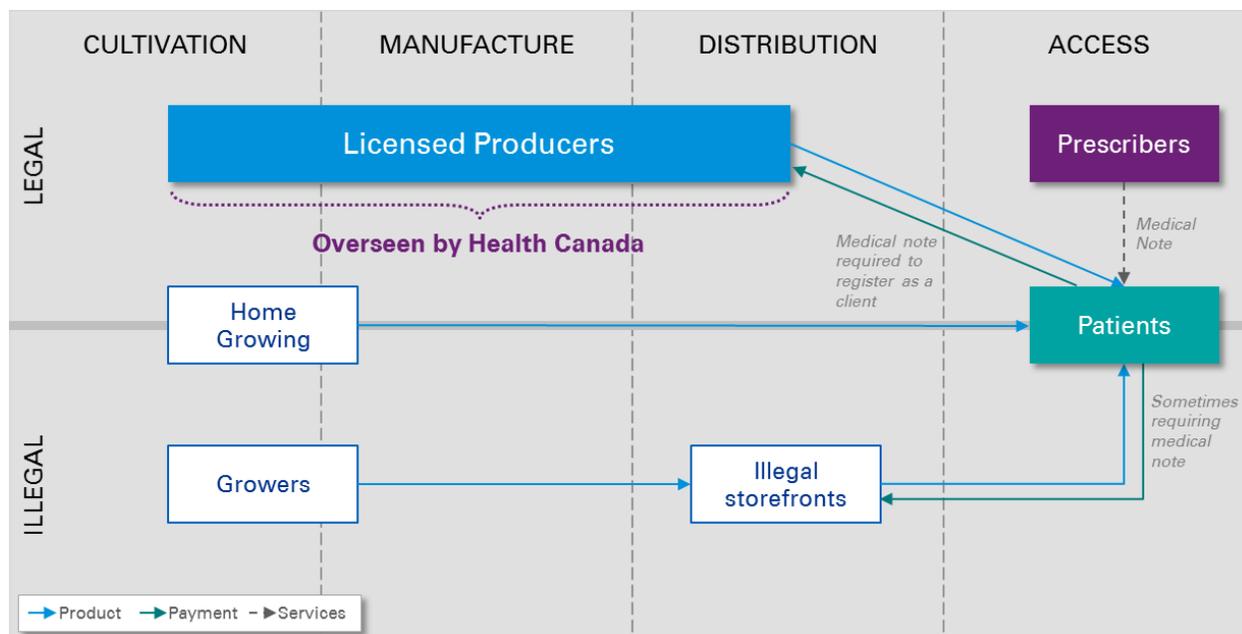
The home growing ban stemming from the MMPR has been highly controversial. Although home growing is viewed as a cost effective option that significantly improves patient access, it was prohibited under the MMPR due to concerns around product quality, safety and potential for diversion and home invasions (Michael L. Phelan, 2016). In 2013, there were only 15 Health Canada inspectors for the 30,271 licensed home growers with only a handful of growers being inspected. With no database to track these home growers, diversion to the grey and black markets became an issue and law enforcement proved challenging (Freeman, 2015).

A constitutional challenge was launched by British Columbia (BC) resident Neil Allard and three other BC residents who argued that the MMPR introduced by the previous government violated their charter rights (Michael L. Phelan, 2016). They argued that the disparity of product prices between home growing and licensed producers compromised patient access, and should be protected through the Canadian constitution. The case reached the Federal Court. In February 2016, the Federal Court judge decided that the ban was unconstitutional because it limited patient access to necessary medical therapies. The Federal Court has suspended its declaration granting the government six months to respond to the ruling and implement an MMJ system that does not impact the charter rights of MMJ patients and their providers if the ban is to continue. The government also has an opportunity to appeal the decision (Hager, 2016).

Legalizing marijuana for recreational use will be a complex business due in no small part to Canada's participation in a number of international treaties. These treaties include *The Single Convention on Narcotic Drugs of 1961*, *The Convention on Psychotropic Substances of 1971* and the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988* – all of which criminalize the possession and production of marijuana. These international obligations may limit Canada's ability to legalize marijuana (Blanchfield, 2016). To address these obligations, the Government of Canada would need to build a case for change demonstrating to the international community that legalization would help combat illicit drug use (Blanchfield, 2016). This and other legislative barriers will potentially delay legalization. It has been predicted that the legalization process may take several years (Lindeman, 2016).

## 3.2 Supply of Canadian medical marijuana: a mix of legal and illegal channels

Figure 3: Canada's current MMJ supply chain



Health Canada currently oversees 29 licensed producers that cultivate, manufacture and distribute MMJ (Health Canada, 2016). Stringent regulations have been implemented to assure product quality and safety in the legal market. These regulations require: analytical testing to detect and limit contamination as well as assess consistent and appropriate cannabinoid levels in the product; designation of a quality assurance person to oversee quality controls; and the development of a sanitation program (Health Canada, 2015).

Legal access to MMJ requires a medical note from a prescriber (typically a physician or nurse practitioner in certain provinces) that clearly indicates the dosage and the indication for which the product is being prescribed. While Health Canada provides a list of qualifying conditions, it is merely suggestive. It remains the healthcare professional's prerogative to prescribe MMJ if the benefits are deemed to outweigh the risks. Once the patient obtains a medical note, they must register with a licensed producer of their choice and provide the original medical note.

In addition to the legal route, many patients access MMJ product primarily through two alternative illegal channels.<sup>3</sup> These are outlined below.

- Illegal store fronts or grey market:** A number of illegal store fronts have emerged across Canada selling a wide variety of MMJ products. These store fronts, referred to as "dispensaries", or colloquially as "pot shops", are illegal. However, patients are drawn by their supplemental services such as referrals to a willing prescriber, on-site naturopathic services, and prescriber consultation via video chat (Keller, 2015). Some also require the presentation of a medical note. There is an expansive network of such illegal store fronts across the country, with an estimated 94 store fronts in Vancouver alone. Vancouver has opted to address the proliferation of illegal store fronts to manage patient safety and access. The new municipal rules require illegal dispensaries to pay for a \$30,000

<sup>3</sup> Excludes small-scale illegal growers who may or may not supply the grey or black markets

operational license and be located at least 300 metres away from schools, community centres and other illegal store fronts (City of Vancouver, 2015).

- **Black market:** Run primarily through organized crime networks, this channel supplies illegal, unregulated marijuana. Patients can gain ready access to marijuana without a medical note. The black market is a distinct channel from the grey market from both the patient and public perspective. The black market is generally seen as illicit trade with law enforcement more inclined to pursue fines and criminal charges.

### 3.3 Key challenges faced by Canada's medical marijuana industry

#### Suboptimal access compelling patients to use illegal grey and black market channels

Under the current regulatory framework, patients are faced with two key challenges in access: a single legal channel for product access (via mail, direct from producers); and prohibitive pricing. It has been reported that only 8% of Canadians who use MMJ are registered through legal channels (Beeby, 2014). This means that a significant majority of those who use MMJ are obtaining supplies from illicit markets where products are unregulated, with unclear quality and/or safety control measures (Levy, 2015).

Since the introduction of MMJR, affordability has become an increasing concern and barrier for some patients (Michael L. Phelan, 2016). Although MMJ is a medical expense tax benefit (Canada Revenue Agency, 2016), most insurance providers do not provide coverage unless by exception (Teotonio, 2015). Major insurers have suggested that they may be more willing to provide coverage for MMJ if it has a drug identification number (DIN) and more involvement from health professionals (Greenshield, 2014). The lack of coverage means that most patients are obliged to pay out-of-pocket, which can quickly become burdensome. This was indeed a consideration in the recent Federal Court ruling against the home growing ban.

#### Limited involvement by the healthcare professional community due to the lack of clinical evidence

According to a 2014 survey by Environics Research Group, almost 70% of physicians report being uncomfortable with prescribing MMJ. The majority also feel that they lack knowledge on the product (Environics Research Group, 2014). This prescribing unease may compromise patient access and inadvertently encourage patients to seek illicit markets. The key reason given by physicians for the reluctance to prescribing MMJ is the lack of sufficient clinical evidence compared to other therapies with demonstrated efficacy and safety. The Alberta College of Pharmacists has set forth a policy for MMJ but suggests restrictions including that MMJ must not be produced in the premises of a licensed pharmacy and that no regulated member of the college may engage in MMJ production (Alberta College of Pharmacists, 2014). The British Columbia Pharmacy Association Board has stated that there is a need to undertake more scientific research on MMJ in order to assure patient safety and improve health outcomes. (British Columbia Pharmacy Association, 2015)

The lack of quality clinical evidence also makes it challenging for healthcare professional associations and regulators to establish clear clinical guidelines. The Canadian Medical Association, the College of Physicians and Surgeons of Ontario, and the College of Family Physicians of Canada caution their members on the limited evidence behind MMJ (The College of Family Physicians of Canada, 2013) (Canadian Medical Association, 2011) (College of Physicians and Surgeons of Ontario, 2015). There is clear agreement across these associations that more clinical evidence is required on indications, dosage, interactions, and the risks and benefits of MMJ (CMPA, 2015). While Health Canada has published guidelines that include available clinical evidence, potential risks, and daily use limits, there is still insufficient discussion regarding strains, dosages and forms (Health Canada, 2016).

### Inconsistent enforcement of grey and black markets

Law enforcement of marijuana is inconsistent across Canada. Policing is focused towards more harmful drugs such as heroin, cocaine and other illicit substances available on the black market. As a result, a blind eye is often turned to marijuana (Boyd, 2013). The recent discussion around potential legalization of recreational marijuana and the rapid proliferation of illegal store fronts has made law enforcement of marijuana an increasingly confusing and complex topic (Slaughter, 2016). The grey market continues to thrive during this uncertain period especially in the absence of a national policy. As it stands, provinces and territories are tasked with tackling this issue individually.

Canada has made significant efforts to strengthen its MMJ regulations. However, there is room for further important enhancements. MMJ is slowly being accepted as a late-stage therapeutic option. It is therefore critical that policymakers address these key issues through a concerted public health approach that promotes patient and public safety. With the current government's discussion surrounding the legalization of marijuana for recreational use, this may be the right time to reassess the current MMJ regulations and enact reform.

## 4 Guiding Principles

To guide the evolution and strengthening of MMJ in Canada, it is critical to put in place a foundation upon which to build a framework that can lead to success. This includes aligning on the appropriate priorities, developing the right systems and practices, addressing specific issues and risks that either exist today or could arise tomorrow, and implementing checks and balances to help guide the system to deliver what it sets out to accomplish.

Our work involved researching nine international jurisdictions, gathering information on the current context in Canada and developing a thorough understanding of key industry limitations. We also engaged with the Canadian Pharmacists Association Expert Advisory Panel on Pharmacy as well as with key informants familiar with MMJ and health system reform. These activities informed the development of a set of key principles and nine changes that represent considerations for the industry framework.

Ultimately, although there are relevant learnings, there is no single industry model that another jurisdiction currently has in place that Canada could mimic. Overall there is consensus that MMJ presents potential risks to patient safety and that there is significant room to improve the management of MMJ. To that end, the following six guiding principles were developed to guide the industry to a better future. These principles collectively represent the vision that underpins the industry framework considerations that are described in this document (see [section 5](#) for more details):

- 1 Protecting patient and public safety** – Promoting the protection of patient and public safety is paramount to any framework for the MMJ industry. The aim should be to move the bar as high as we'd expect for any product that is used for medical purposes.
- 2 Differentiating between MMJ and recreational marijuana** – Making a clear distinction between MMJ and recreational marijuana will help to improve clinical credibility of MMJ and manage patient risk. Adoption of prescription drug-like attributes for MMJ leads to appropriate controls being in place to better protect public health safety.
- 3 Reducing risks to patients through evidence-based clinical practice** – Promoting healthcare professional access to relevant training and continuing education, evidence-based therapeutic guidelines and other relevant knowledge and resources to provide safe and quality patient care.
- 4 Securing the supply chain** – Promoting a secure and reliable end-to-end supply chain to help maintain product integrity, enable traceability and limit diversion.
- 5 Leveraging existing infrastructure** – Using existing infrastructure wherever possible to reduce unnecessary complexity, delay and cost, while limiting the impact on areas of the supply chain that are functioning effectively.
- 6 Improving on the industry status quo** – Creating a proposed future state model that helps address key industry limitations. These include limited legal access, discordant enforcement of the illegal grey and black markets and suboptimal healthcare professional involvement – all of which ultimately present risks to patients.

**Figure 4: Proposed guiding principles for the MMJ industry framework in Canada**



Grounded in these principles, a set of changes have been proposed that together with the aforementioned principles, provide considerations for a framework that could help improve upon and begin to address the key limitations of the Canadian MMJ sector.

# 5 Moving the Medical Marijuana Industry Forward

## 5.1 Enabling the transformation of medical marijuana management in Canada

Canada's MMJ system has fluctuated significantly over the past few years and this is expected to continue as stakeholders work to address a number of gaps. To help address these gaps and avoid having to contend with a regulatory environment that will make subsequent amendments difficult, nine changes have been proposed. To enable the transformation of MMJ management in Canada, the enactment of these changes will likely require cooperation amongst key stakeholders, including the provincial, territorial and federal governments. These proposed changes are relevant regardless of what the future holds for the legislation of recreational marijuana and are directly informed and aligned with the guiding principles set out in [section 4](#).

### 1. Establish a legal framework to incorporate pharmacies in the supply chain

#### Allowing pharmacy to distribute and manage MMJ supply to patients

Access is a major challenge under the current MMJ industry framework. This can be partly attributed to the lack of legal store fronts (Hager, M, 2016). In developing the proposed framework considerations, different retail model options for MMJ were explored. These options include: legalising privately-owned marijuana dispensaries, pharmacies, government-managed stores such as the LCBO in Ontario, not-for-profit entities and direct shipment from licensed producers (see [Figure 5](#) below for the results of the options analysis). Strengths, weaknesses and implications for patients and the public of each model were analyzed against the guiding principles laid out earlier.

The analysis concluded that pharmacy is the leading option to distribute and manage MMJ. Pharmacy can simultaneously enhance patient safety and access by addressing a number of different needs including healthcare professional involvement, medication management and patient education. This change is largely motivated by the need to assure that therapeutic products that present drug interaction and other risks to patients are managed by a regulated health professional.

Drug interactions present a risk to patients that pharmacy is strongly positioned to help manage. Drug interactions are described as adverse effects that result from taking two or more drugs (or substances) concurrently. Drug interactions are of particular concern for patient safety as they have the potential to cause severe health consequences for patients including disability, hospitalization or even death. For example, sildenafil (medication for erectile dysfunction) taken with isosorbide mononitrate (medication for angina) may dramatically drop blood pressure, potentially leading to death (Burns & Kelly, 2002). Another example is the simultaneous use of amiodarone (heart medication) and simvastatin (cholesterol lowering medication) that could result in severe muscle breakdown, leading to acute kidney damage in extreme cases (U.S. Food and Drug Administration, 2008). As noted in [section 2](#), clinical research on MMJ is still in its early phase. However, some medications, such as anticoagulants and benzodiazepines, when taken concurrently with MMJ have been determined to cause potential adverse effects. The involvement of pharmacists in dispensing MMJ would enable the identification, mitigation and management of drug interactions, thus limiting risks to patient safety.

Moreover, pharmacy is accustomed to managing controlled substances (e.g. narcotics, etc.) as part of standard practice. Measures include: secure storage; security mechanisms to deter diversion, theft and robbery; and infrastructure to enable product traceability for recalls (KPMG Analysis). Additional details on pharmacy's potential role in the MMJ industry are outlined in Figure B.

**Figure 5: Analysis of potential regulated distribution options for MMJ in Canada**

Options	Overall assessment				
<b>Pharmacy</b>	Pharmacy has a vast network of storefronts to enhance patient access. It brings infrastructure and controls to help secure the supply chain to limit diversion and ensure product integrity. The pharmacist's role in interdisciplinary care can help monitor drug-related therapy thus improving patient safety.				
<b>Government-managed store</b>	This option mimics the government-run retailer model like LCBO in Ontario. There is strong infrastructure that could be leveraged to manage the product. Personnel can be trained to provide basic product information, refuse service when necessary and direct patients to healthcare professionals where relevant. This option would ultimately be limited in its ability to address patient safety given their lack of clinical knowledge.				
<b>Marijuana dispensary</b>	Marijuana dispensaries are currently considered illegal. While there is existing infrastructure to build on, additional investments would likely be required to further secure the supply chain and limit supply leakage. And although personnel may have been trained on the product, they lack the clinical knowledge and expertise to support evidence-based practice.				
<b>Direct shipment from producer</b>	This is the existing model for medical marijuana distribution in Canada. Licensed producers have proven their ability to limit diversion to illegal users and protect patient and public safety. However, concerns around limitations in access and healthcare professional involvement remain.				
<b>Not for profit distributor</b>	Not-for-profit distributors, such as compassion clubs, exist illegally in small numbers across Canada. In some US states, these organizations aim to provide quality medical marijuana to their members at no/minimal profit. Based on our analysis, they are ill-equipped to limit diversion and are unable to meet healthcare professional standards of care.				

 Patient Safety	 Clinical training	 Enhanced Security	 Existing infrastructure	<b>Legend (Alignment with Guiding Principles)</b>
				
				High Significant Moderate Minimal

<sup>1</sup> Any privately-owned retailer in the future will likely follow the marijuana dispensary model that specializes in MMJ products.

<sup>2</sup> Pharmacy represents both community and hospital pharmacies

<sup>3</sup> This analysis excludes non-specialized retailers that may in the future include MMJ as part of its broader product offering.

### Amending MMPR and establishing guidelines to enable supply through pharmacy

Pharmacy possesses much of the infrastructure required to immediately assume responsibility for MMJ management (Neighbourhood Pharmacy Association of Canada, 2016). However, there is currently no policy framework articulating the role of pharmacy in the supply chain. Legislative amendment to the MMPR would be required to allow for the sale of MMJ through pharmacy or any other storefronts in Canada. Collaboration with provincial regulators would be required to enable this. Furthermore, Health Canada would likely need to simultaneously prohibit producers from directly distributing MMJ to patients. Guidelines would also be required to clearly identify the products sold through pharmacy including product strain and form, available accessories or paraphernalia as well as other restrictions pharmacy may need to comply with. A similar transition from producers to pharmacies for MMJ distribution is currently being considered by the Israeli government (Surkes, 2016).

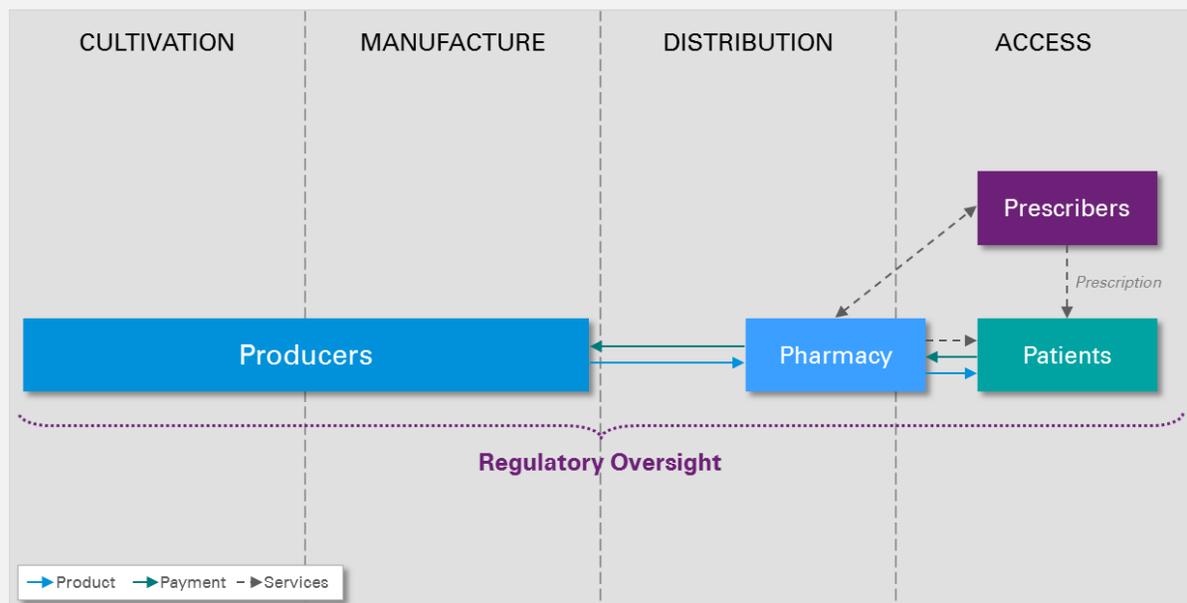
## Figure B: The Role of Pharmacy in the Proposed Framework

Pharmacy is strongly positioned to manage the distribution of MMJ in the proposed framework. Its expansive network as well as involvement in healthcare management make pharmacy the most suitable option for improving access, promoting patient safety, and providing enhanced patient education. These benefits are described in more detail in the pages that follow.

There are 9,500+ regulated pharmacies across Canada that could quickly and significantly expand access to MMJ should pharmacies become legal access points (National Association of Pharmacy Regulatory Authorities, 2015). They are supported by an infrastructure that is readily equipped to handle narcotics and controlled substances, which could also be well-suited to manage MMJ (CPhA Expert Advisory Panel, 2016).

Arguably, the main advantage of pharmacy in the proposed framework is the presence of a pharmacist. Pharmacists have experience in medication and broader healthcare management making them a unique asset in this model. Pharmacists are also often patients' first point of contact into the healthcare system. Indeed, 43% of Canadians rely on pharmacists for health advice (Health Canada, 2005). Not only can they identify product-related problems, monitor drug adherence, counsel patients on appropriate and safe use of medications and flag drug-seeking behaviours, pharmacists can also communicate crucial information to the patient's prescriber to provide the best possible coordination of care. Importantly, 90% of pharmacists surveyed by the Canadian Pharmacists Association reported that if they were properly trained on MMJ they would be comfortable dispensing it. The figure below illustrates what the supply chain may look like under the proposed framework.

**Figure 6: Proposed model for the MMJ industry with pharmacy as the point of access**



*Note: Options reflect the most probable, realistic scenario given the context*

Note: Option reflects the most probable, realistic scenario given the context

## 2. Establish clear product regulations for MMJ

### Adoption of prescription drug-like regulatory attributes for public health safety

The health risks associated with MMJ and the breadth of products available could pose a significant public health issue in the absence of appropriate regulations. Strict product regulations that are aligned to existing drug regulations are critical for enabling appropriate controls to protect patients and the public.

The clinical evidence around MMJ's safety and efficacy is weak and falls far short of Health Canada's requirement for a DIN. Therefore, MMJ cannot be integrated into existing drug schedules and be managed as such by the health care system. However, lending certain attributes from the current drug regulatory pathways would be enormously beneficial in enhancing the safety, quality and accessibility of the product. Health Canada may even wish to consider developing a unique class for MMJ.

At a minimum, MMJ regulation should adopt similar attributes to those required by Health Canada for prescription drugs, specifically:

- **Prescription** – access to MMJ currently requires a prescription which should continue in the future as it will help limit diversion to illegal users and provide prescribers the opportunity to discuss other therapeutic options;
- **Pharmacist intervention** – pharmacist intervention would support the identification of potential drug-related problems (e.g. drug interactions, contraindications and potential addictive behaviour) and the opportunity for patient counselling on appropriate use; and
- **Behind-the-counter storage** – the product should be kept behind the counter in a secure location to limit opportunity for theft or diversion.

### Leveraging controlled substance handling procedures to enhance supply chain security

Given the psychoactive nature of MMJ and its potential for dependence, additional controls used for narcotics and controlled substances could be considered for implementation (see [Figure 2](#) below).

**Figure 2: Narcotics and controlled substances supply chain controls**



## Defining what constitutes MMJ to discourage the use of high risk-low benefit products

Beyond federal product classification, regulatory parameters to clearly define the strains and forms permitted for dispensing through pharmacy would be required. For example, listed MMJ products may exclude smoke-able forms given the negative health impacts associated with smoking. Indeed, the healthcare professional community in many jurisdictions including Canada, New York and the Netherlands have strongly recommended against smoking MMJ (Canadian Medical Association, 2013) (New York State Assembly, 2013) (Cannabis Bureau, 2011).

## Regulating price to promote affordability and access

Pricing is a key component of product regulation and has significant ramifications on access. However, enhanced regulation may unintentionally lead to increased manufacturing costs for producers and ultimately drive up prices for patients (Stoecker, 2014). To make legally produced and distributed MMJ affordable, government may wish to consider regulating price to some extent. As an example, this could include producer or patient subsidies to limit price inflation. Alternatively, MMJ could be considered for drug plan coverage especially for low-income patients.

Pricing, in combination with better enforcement, may also play a role in the decline of illegal grey and black markets. Pricing MMJ low enough may sufficiently deter a large proportion of current and/or potential users from accessing these sources.

### **3. Enhance clinical guidelines for MMJ**

Healthcare professionals and their associations continue to express concern over current clinical guidelines, which are perceived as inadequate. Greater clarity around MMJ's role in clinical practice is required (Canadian Medical Association, 2011) (College of Physicians and Surgeons of Ontario, 2015). Under the current system, many prescribers liken the prescribing of MMJ to off-label prescribing of medications. This is, and remains, a physician's prerogative. However, most agree that in the absence of stronger safety and efficacy data, clearer clinical guidelines may be required in order to appropriately recommend MMJ as a therapeutic option when other therapies fail.

While there are existing clinical practice guidelines, they should be enhanced to include a list of qualifying conditions as well as the recommended strain, form and dosing for each eligible indication. The development of clearer clinical guidelines that are informed by clinical evidence will likely improve healthcare professional acceptance of MMJ as a potential last line therapy, thus improving patient access and augmenting patient safety.

### **4. Support the development of stronger clinical evidence for MMJ**

Given the limited clinical evidence of MMJ relative to other medications, the proposed considerations for an industry framework should foster clinical research. There are a number of ways for stakeholders to collaborate together to enhance existing and generate fresh clinical evidence. One example is matched government funding to support universities and research institutions in conducting clinical trials (Parliament of Canada) (Colorado Legislative Council, 2014). Alternatively, one of the requirements for obtaining and/or maintaining a production license could be a commitment to invest a specified proportion of their revenue into basic or clinical research.

Indeed, the growing collaboration between producers and academia may be an early indication of industry's interest in advancing clinical research for MMJ. Helping to grow the evidence base is a core enabler of many aspects required to enhance patient safety and protect the public interest. These aspects include engaging larger numbers of healthcare professionals, enabling the development of stronger clinical guidelines and increasing the likelihood of insurance coverage.

## **5. Review the scope of practice regulation for healthcare professionals as it relates to MMJ**

Any regulatory change that may touch healthcare professional scope and standards of practice would require a review by the relevant provincial regulatory colleges. The review would help to determine whether health care professionals are empowered to practice in accordance with all relevant and applicable legal and professional obligations. It is critical that regulatory colleges are engaged early on to enable any changes that would fall out of current scope of practice and clearly define roles and responsibilities related to the management of MMJ.

For pharmacy, MMJ management falls under the practice of medication management. Potentially, minimal or no scope of practice regulatory changes would be required. Currently, pharmacy's scope of practice could encompass secure handling and dispensing of MMJ, identification of drug-related problems and patient counselling. The US state of Minnesota has chosen to expand MMJ management to include the selection of the strain, dosage and form based on the therapeutic goal determined by the patient and physician (American Pharmacists Association, 2016). In the event that the Government of Canada adopts a similar approach, it has been suggested that the expanded role could potentially fall under prescription adaptation – a practice that has already been conferred to pharmacists across many provinces in Canada (CPhA Expert Advisory Panel, 2016).

## **6. Enhance MMJ education and training for healthcare professionals**

Surveys suggest that the majority of healthcare professionals do not feel properly equipped or comfortable in providing MMJ as a therapy. Indeed, over 40% of pharmacists and almost 70% of physicians have expressed this view (British Columbia Pharmacy Association, 2016) (EnviroNics Research Group, 2014). This sentiment may negatively impact patient access as physicians (and nurse practitioners) are the gatekeepers of the MMJ system in Canada. Knowledge gaps clearly could be addressed by developing and tailoring education and training programs for healthcare professionals.

As with any training, the format should differ according to the level of experience: an undergraduate in training versus a practicing professional. For healthcare professionals-in-training, MMJ could be incorporated into the curriculum as a late-stage (e.g. third- or fourth-line) therapeutic option for particular indications, while a continuing education module could be developed to educate and train practicing clinicians, nurse practitioners and pharmacists. Equipping healthcare professionals with the appropriate training and resources will enable them to provide safe and quality patient care.

## **7. Support patient education and awareness of risks and benefits of MMJ**

As previously mentioned, a number of misconceptions among patients (and the general public) persist over the risks and benefits of MMJ. From a public health perspective, patient education and awareness is a key enabler of system improvement and risk management. In an era of increasing data availability and patient engagement, access to appropriate patient resources will be important for patients to be well informed of their choice of therapy (Canadian Medical Protective Association, 2015).

Addressing common misconceptions and differentiating MMJ from illegally sold marijuana could be key themes of patient education. The objective here is not to highlight MMJ as a therapeutic option, but rather promote harm reduction. Potential areas of focus may include: MMJ's influence on driving, potential harms of MMJ use, harm reduction strategies and benefits of accessing MMJ through legal channels (Centre for Addiction and Mental Health, 2014). The government may also consider a multi-channel approach through online resources, information pamphlets and public service announcements, as well as leveraging healthcare professional direct patient care responsibilities to educate and counsel patients. In Israel, a patient education course is offered to all patients receiving MMJ that trains patients on how to properly use marijuana (Short, 2014).

## **8. Enforce existing home growing ban**

Home growing was prohibited with the introduction of the MMPR. However, the recent Federal Court decision declaring the ban unconstitutional obliges the government to amend the current MMPR within the next six months such that they do not impact the charter rights of MMJ patients and their providers (Michael L. Phelan, 2016). Since the Government of Canada has the opportunity to appeal the decision, it is unclear at present whether home growing of MMJ will continue to be legal.

Home growing brings inherent risks. Beyond the lack of pharmacist involvement in managing a number of the aforementioned MMJ risks, there are additional considerations such as possible contamination from mould and other substances. Such contamination may result due to a lack of product quality oversight. (Health Canada, 2012). As such, the enforcement of the home growing ban and the continued phasing out of grandfathered licenses should be reconsidered. Indeed, the government would need to amend the MMPR to protect the patient charter rights to address the issue of access at a minimum (Michael L. Phelan, 2016).

The Federal Court decision referred to issues surrounding accessibility (point of access and affordability), which was discussed in [section 3.3](#). Incorporating the pharmacy network into the distribution of MMJ would largely resolve the issue around points of access. Meanwhile, affordability is a more complex matter and difficult to address particularly for low-income patients. Options that could be considered include: drug plan coverage for low-income people; means-tested programs to determine eligibility for home growing of MMJ; government rebates or out of pocket maximum limits similar to catastrophic type coverage. Although home growing is not an ideal option for patient safety, in certain instances where affordability is a barrier to access, and alternatives are not made available, it may need to co-exist with pharmacy as another access point of MMJ.

## **9. Continue tight regulation of licensed MMJ producers**

Product regulations are critical for the development of high quality, safe MMJ products. Current manufacturing oversight by Health Canada assures minimum product quality and should continue. Licensed producers should continue to be subjected to Good Production Practices (GPP) requirements as well as rigorous quality testing (Health Canada, 2015). Tight regulations that ensure batch consistency and product standardization are a requirement of all regulated food and drug products. Continuing to demonstrate a high quality product should contribute to improving product credibility amongst the healthcare professional community. Discussions with health professionals have indicated that part of their discomfort is related to the vast array of products and forms that are available on the market (KPMG Analysis).

## Figure C: Key benefits of the proposed considerations for an MMJ industry framework

The main goal of the proposed framework considerations is to improve patient and public safety related to MMJ. A number of changes have been proposed, some of which are transformative in nature e.g. the incorporation of pharmacy and the introduction of product regulations similar to prescription drugs. Others are more incremental but will support a number of improvements on the status quo. Below, a number of key benefits have been highlighted that could be expected from implementing the proposed changes.

- **Increased patient access:** Legalizing storefront sales of regulated MMJ will significantly improve patient access. Dispensing through pharmacy would provide patients with 9,500 or more points of access (National Association of Pharmacy Regulatory Authorities, 2015). Pricing controls and insurance coverage could help address affordability issues especially for patients with lower socioeconomic status.
- **Greater participation of the healthcare professional community:** Enhanced education and training efforts, clearer practice guidelines and increased high-quality clinical evidence would better equip prescribers and other healthcare professionals with resources to support decision making. The inclusion of pharmacists in distributing MMJ could also improve therapy management through the existing interdisciplinary care relationship. Dr. Ed Schollenberg, registrar at the College of Physicians and Surgeons of New Brunswick, recently weighed in on the issue and expressed that physicians may have greater control over MMJ therapies if the product is dispensed through pharmacy (CBC News, 2015). Moreover, studies demonstrate that pharmacist intervention can support improvements in medication adherence, and thereby improve patient outcomes (Business Wire, 2015) (National Association of Boards of Pharmacy, 2010) (Janice L. Pringle, 2014).
- **Secure supply chain:** Mitigating diversion while promoting appropriate access to MMJ users without impacting product integrity is a key concern of any industry. Regulating MMJ using processes similar to those for narcotics and/or controlled substances appears to be the most effective mechanism to date. The required infrastructure is already in place. Pharmacy is well-equipped to regularly handle controlled substances as part of their standard practice requirements. Some suggest implementing even greater security measures such as time-delay safes making diversion a less likely event (College of Pharmacists of British Columbia, 2015).

## 5.2 Preparing for potential legalization of recreational marijuana

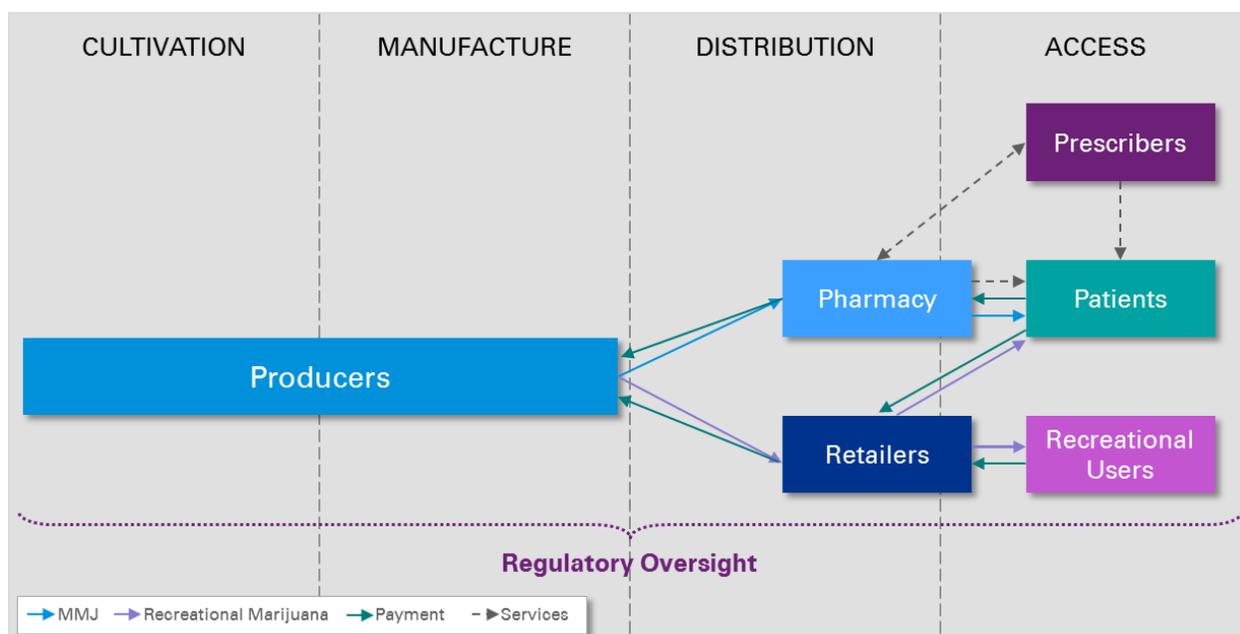
There is a distinct possibility that the legal recreational use of marijuana could become a reality in the next few years. A scenario where marijuana for recreational purposes is legal would bring additional risks and challenges for the MMJ industry. In this potential scenario, patients could have the option of accessing marijuana for recreational purposes, where the product may or may not be subject to the same quality and access controls as MMJ. The recreational sector would be unlikely to bring a similar degree of healthcare and medication management expertise to adequately counsel patients on the most appropriate choice of product or the associated risks. Furthermore, there would be no feedback mechanism allowing regulators to monitor the safety of marijuana (e.g. adverse event reporting), particularly for those who are on other medications.

The enhanced level of access as a result of legalization of marijuana for recreational purposes would require the creation of a safety net with incentives to encourage patients to continue accessing their supply through medical channels. To this end, we re-iterate the proposal for pharmacy to distribute MMJ, and for recreational marijuana to be accessed through alternative means. Furthermore, we outline five further considerations that government may wish to incorporate into any new policy should it move ahead with legislation of marijuana for recreational purposes.

### Safeguarding the MMJ industry in an open recreational market

Six jurisdictions worldwide (Alaska, Colorado, Oregon, Uruguay, Washington State and Washington DC) have legalized both MMJ and recreational marijuana. Key learnings from the experience in these jurisdictions offer a number of leading practices that informed the following considerations.

**Figure 7: Proposed supply chain for MMJ (in a scenario where recreational marijuana is legal)**



<sup>1</sup> Option reflects the most probable, realistic scenario given the context

<sup>2</sup> Patients have the choice of accessing MMJ through retailers, however this option is not recommended.

## 1. Promote clearer product differentiation between MMJ and recreational marijuana

Legalizing recreational marijuana will likely provide broad access to the majority of Canadians (some exclusions will likely apply e.g. minors). Some patients may choose to access their supply through recreational channels, which may not meet the same standards as MMJ. This could potentially elevate the risks for health complications for high-risk patients, such as those with prior cardiovascular events or those with a history of mental illness, who should ideally be more closely monitored by a healthcare professional such as a pharmacist. In this new policy environment, regulators and policymakers would need to contemplate strategies to encourage patients to source MMJ through the appropriate channels. This aim could largely be achieved through clearer differentiation between recreational marijuana and MMJ products beyond those outlined in [section 5.1](#) (i.e. regulation with similar attributes to those used for prescription drugs). The following strategies could be used to achieve product differentiation:

- **Restricting particular strains from recreational use:** Marijuana products with high THC-CBD ratios are known to have potential psychoactive adverse effects. Jurisdictions such as Colorado have considered restricting those strains from recreational users (Damewood, 2013).
- **Excluding smokeable forms from medical use:** A common method for consuming marijuana is smoking. The health risks associated with smoking are well documented and strongly discouraged by all governments and healthcare professionals. To this end, regions such as New York, only authorize non-smokeable forms (such as oils and capsules) of MMJ (New York State Department of Health, 2015).
- **Varying allowance limits according to use:** In all US states where both MMJ and recreational marijuana have been legalized, regulators have opted to set different allowance limits for medical versus recreational users. In these states, recreational users are allowed to carry 1 ounce (28 g) of marijuana at any given time (KPMG Analysis), whereas medical users may possess significantly higher amounts contingent on their prescribed dose.
- **Lower pricing for medical use:** As described earlier, pricing may be an effective tool in directing patients to the appropriate channels for MMJ. For example, Colorado taxes recreational marijuana at a much higher rate than MMJ, incenting patients to access their marijuana through medical channels. The differentiated tax rates have successfully increased the number of users accessing medical channels post-legalization of recreational marijuana (Hudak, 2014). However, critics speculate that medical channels are being exploited by recreational users due to lower prices (Hudak, 2014). The challenge will be finding the right balance to encourage users to obtain their supply through the appropriate channels while also discouraging illegal sources such as the black market.

## 2. Mandate product warnings for recreational products

Marijuana used for recreational purposes carries potential health risks that exceed any apparent benefit, similar to tobacco and alcohol.<sup>4</sup> Public health and harm reduction strategies would play a focal role in situations where marijuana is readily accessible (Centre for Addiction and Mental Health, 2014). Emphasizing risks associated with marijuana use would be required. At a minimum, one could expect explicit messaging on recreational product packaging. Using tobacco as an example, marijuana product packaging could display product content as well as written and visual information on potential health hazards (Health Canada, 2015). Taken together with other measures, this or a similar strategy would allow users to be better informed of the risks of marijuana.

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<sup>4</sup> While these health risks also apply to medical marijuana, there are potentially sufficient benefits to offset the risk from patient and prescriber perspectives.

### **3. Implement rigorous product management regulations for the sale of recreational marijuana**

Recreational marijuana products should be managed in a manner that is consistent with much of the distribution practices required for MMJ because of their inherent risks (see [section 5.1](#)). Recreational marijuana retailers could be expected to meet strict criteria in order to qualify for a distribution licence. The criteria should ideally focus around risk management and product quality practices. As an example, the criteria could include:

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

### **4. Mandate training for retail staff selling recreational marijuana**

Some patients may choose to access marijuana through recreational channels. To manage this, retail personnel that have direct contact with users should ultimately receive basic training on marijuana including the risks, differentiation between medical and recreational products, and identification of drug seeking behaviour. These training requirements follow a similar model as the Liquor Control Board of Ontario (LCBO), a government-run distribution of alcohol in Ontario (LCBO, 2016). Further, all staff should be informed of their right to refuse service and should be trained to direct customers, particularly MMJ patients, to healthcare professionals where relevant.

### **5. Coincide legalization with a public education campaign**

Misconceptions around the difference between medical versus recreational use continue to persist. Increasing public awareness of the intrinsic risks related to marijuana use will be critical in promoting responsible use (Centre for Addiction and Mental Health, 2014). It is also important to educate the general public that multiple channels (legal, grey, and black markets) exist and that there are particular risks and potential consequences.

#### **5.2.1 Transitional Considerations**

The current government and its taskforce on recreational marijuana have not provided any clarity on the likelihood or nature of the regulatory change that could occur. In the event of any significant policy change on recreational marijuana legalization, it may require several years for the amendments to take full effect and eventually coexist alongside the MMJ sector (Lindeman, 2016). In preparation for the possible overhaul of the marijuana industry in Canada, there will likely be a transition period where interim improvements to the MMJ supply chain could be made. Implementing the proposed modifications to the current MMJ industry framework in a phased approach could be part of the solution for the broader recreational legalization issue. In particular, introducing the role of pharmacy in the supply chain could help tackle any immediate issues that may compromise patient safety and appropriate access. More importantly, the incorporation of pharmacy in the MMJ supply chain could offer a unique opportunity for government to better understand retail distribution and other refinements to help inform Canada's long term marijuana policy.

# Next Steps

In the coming months, regulatory changes to Canada's MMJ industry may be expected following the Federal Court's recent ruling on the home growing ban. The Government of Canada is obliged to amend the MMPR if it chooses not to appeal, creating a burning platform for change. This presents a unique opportunity for Canada to act quickly to avoid being burdened with a MMJ regulatory environment that could make subsequent change much more of an uphill battle.

Furthermore, the legalization of marijuana for recreational purposes may be on the horizon. The government has reiterated its promise that legislation would have public safety at the forefront; however, the taskforce with this mandate has yet to issue its recommendations. It is an opportune time for government to reflect on the existing regulation and management of MMJ and address major limitations to help pave the way for long term sustainability.

This document has outlined proposed considerations for an industry framework for MMJ in Canada. The considerations focus on improving patient and public safety, access and healthcare professional involvement, while capitalizing on available infrastructure and resources to avoid unnecessary additional burden. Nine proposed changes to improve on the current MMJ context, and five additional key considerations, should recreational marijuana become legalized, have been discussed.

Given that these proposed changes are largely a responsibility of either the federal or provincial government, a degree of federal-provincial cooperation will be necessary for successful implementation. These proposed amendments have the potential to lead to significant improvements in the organization and control of MMJ to help promote patient and public safety. They call for better leveraging of Canadian assets and infrastructure and closer collaboration between key stakeholders to achieve a common goal: providing patients with access to therapies in a safe and secure manner.

Canada currently faces a crossroads, and policymakers and key stakeholders have an opportunity to contemplate the current limitations of the MMJ industry and implement meaningful changes that could ultimately lead to the betterment of Canadian patients, and society as a whole.

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# Appendix

## Appendix A: Jurisdiction Profiles

As part of the development of this document, 9 international jurisdictions with varying marijuana legalization were studied. The goal was to identify practices that could be informative for the Canadian context. The tables below highlight a number of characteristics of each jurisdiction:

**Table 2: Jurisdictional Comparison**

Jurisdictions studied that have legalized MMJ use only				
Jurisdiction	Product Regulations	Production	Distribution	Clinical Considerations
<b>Australia</b>	<p>Although new legislation exists, product regulations have not yet been published at the time of writing this document.</p> <p>MMJ was legalized in 2016.</p>	<p>The recent amendment to the Narcotic Drugs Act has legalized MMJ (Australian Government Department of Health). Some sources indicate that Australia is looking to create an authority to regulate and oversee MMJ cultivation (Australian Government Department of Health).</p>	<p>The Victorian Law Reform Commission proposed a distribution model involving pharmacies that opt into the scheme (Victorian Law Reform Commission, 2015).</p>	<p>It has been suggested that the MMJ program should be modelled after the opioid replacement therapy distribution program, which requires a prescription and pharmacist intervention (Victorian Law Reform Commission, 2015).</p>
<b>California</b>	<p>Currently, there are no restrictions on MMJ. There is a lack of regulatory oversight on products. However California's MMJ industry is undergoing regulatory reform (California Department of Public Health, 2016).</p> <p>MMJ was legalized in 1996.</p>	<p>It is unknown how many producers there are in California, however reports note that the number is considerable (Blue Ribbon Commission on Marijuana Policy, 2015).</p> <p>Home growing is also permitted (California Department of Public Health, 1996).</p>	<p>MMJ is distributed through cooperatives and collectives that must be operated as non-profit entities. While MMJ identification (ID) cards are not required for purchase, they help to protect patients from product seizure and arrest (California Department of Public Health, 2016).</p>	<p>Physician recommendation is required for patients to access MMJ. While there is a list of eligible conditions, physicians have full discretion to prescribe MMJ (California Department of Public Health, 2016).</p>

**Jurisdictions studied that have legalized MMJ use only**

<b>Jurisdiction</b>	<b>Product Regulations</b>	<b>Production</b>	<b>Distribution</b>	<b>Clinical Considerations</b>
<b>Canada</b>	<p>Health Canada only permits oil and herb forms of MMJ. Product regulation is focused on quality assurance including lab testing to allow for appropriate and consistent cannabinoid levels and minimal contamination (Health Canada, 2015).</p> <p>MMJ was legalized in 2001.</p>	<p>Health Canada regulates and oversees 29 licensed producers. The producers are allowed to set their own prices (Health Canada, 2016).</p>	<p>MMJ products are shipped directly from producer to patient (Health Canada, 2015). However, there is a growing number of illegal store fronts across the country from which many patients choose to obtain their MMJ. (Hager, M, 2016)</p>	<p>Access to MMJ requires a medical note (similar to a prescription) from a physician or nurse practitioner (in some provinces).</p> <p>Health Canada published a list of qualifying conditions as guidance for healthcare professionals. However, it is merely suggestive (Health Canada, 2015).</p>
<b>Connecticut</b>	<p>The Department of Consumer Protection (DCP) has approved the following forms for MMJ: ground-up herb, oils, and edibles. All products must be tested by an independent lab (Department of Consumer Protection).</p> <p>MMJ was legalized in 2012.</p>	<p>DCP regulates and oversees 4 state-selected, licensed producers (Department of Consumer Protection, 2014).</p>	<p>MMJ products are distributed through state-run dispensaries and dispensed by pharmacists who have a MMJ dispensary license. In order to obtain MMJ, patients must have a state issued MMJ ID card (Department of Consumer Protection).</p>	<p>Patients must be certified eligible by a physician in order to access the MMJ system. The DCP has approved 11 qualifying debilitating conditions to help guide physicians in determining patient eligibility for certification (Department of Consumer Protection).</p>

## Jurisdictions studied that have legalized MMJ use only

Jurisdiction	Product Regulations	Production	Distribution	Clinical Considerations
<b>Israel</b>	<p>The Health Ministry's Medical Cannabis Unit is set to approve the sale of MMJ products in the form of cigarettes, cookies and oils for pharmacy (Surkes, 2016).</p> <p>MMJ was legalized in 2007.</p>	<p>The Medical Cannabis Unit issues production licenses to producers that meet eligibility requirements. Currently, there are eight licensed producers, but that number is expected to grow (Surkes, 2016).</p>	<p>MMJ is currently being distributed through a central government distribution centre (MECHKAR) that operates within a mental health institution (Short, 2014). Pharmacy is now being considered as a potential distribution channel (Surkes, 2016).</p>	<p>The Medical Cannabis Unit has outlined a list of eligible conditions for MMJ treatment (Wilson, 2013).</p> <p>Access to MMJ must be prescribed by 1 of 36 authorized physicians (Surkes, 2016). The physician must submit an application for a patient permit, which is reviewed by the Medical Cannabis Unit for approval (Wilson, 2013).</p>
<b>Netherlands</b>	<p>The Office of Medical Cannabis (OMC) has approved five strains of MMJ. Regular independent lab testing is required for quality assurance (Cannabis Bureau).</p> <p>MMJ was legalized in 2003.</p>	<p>Overseen by the OMC, there is one licensed producer (Bedrocan) that produces all legal MMJ for the country. Bedrocan follows Good Agricultural Practices (NCSM, 2016).</p>	<p>Distribution of MMJ is through pharmacies (Cannabis Bureau, 2011). There is an illegal but tolerated market consisting of coffee shops that sell recreational marijuana (Government of the Netherlands).</p>	<p>Patients must obtain a prescription from a physician to access MMJ. The OMC has provided a suggestive list of eligible conditions to help guide therapeutic decisions (Cannabis Bureau).</p>
<b>New York</b>	<p>The Department of Health (DOH) has authorized non-smokeable forms of MMJ including oils, capsules and sublingual forms. All products must be tested by an independent lab (New York State Department of Health, 2015).</p> <p>MMJ was legalized in 2014.</p>	<p>There are 5 state-selected producers that have been issued a production license by the DOH. The DOH also has a role in pricing regulation to determine maximum profit levels (Department of Health, 2015).</p>	<p>MMJ is dispensed by trained pharmacists in state-selected dispensaries. Each patient must present their registry ID card to access MMJ (New York State Department of Health, 2015).</p>	<p>Physicians must register with the DOH in order to be eligible for issuing certificates to patients for MMJ access. (New York State Department of Health, 2015).</p> <p>In order to qualify, physicians must complete a 4-hour online DOH course. There is a list of 10 qualifying conditions to help guide physicians in certifying patients (New York State Department of Health, 2015).</p>

## Jurisdictions studied that have legalized both MMJ and marijuana for recreational use

Jurisdiction	Product Regulations	Production	Distribution	Clinical Considerations
<b>Colorado</b>	<p>Currently, there are no restrictions on MMJ products allowed for consumption (Hudak, 2014).</p> <p>MMJ was legalized in 2000 and recreational marijuana was legalized in 2012.</p>	<p>There are currently hundreds of licensed producers and home growing is permitted. As such access is not much of a concern. Prices are set by the free market. The Marijuana Enforcement Division Marijuana Inventory System tracks all marijuana plants in the state from seed to sale (Swedberg, 2013).</p>	<p>MMJ is distributed through a network of store fronts. In order to access MMJ, patients must obtain a patient ID card (Colorado Department of Public Health and Environment).</p>	<p>A physician recommendation is required for patient access to MMJ. The Department of Health has issued suggestive guidelines on qualifying conditions (Colorado Department of Public Health and Environment).</p>
<b>Uruguay</b>	<p>Three MMJ strains are available for specific indications based on potency (Reuters, 2015).</p> <p>MMJ and recreational marijuana were legalized in 2013.</p>	<p>There are two main commercial producers, alongside with home growing. Production licenses are required for commercial as well as home growers. There is a secure national database that keeps track of all growers (Reuters, 2015).</p>	<p>MMJ distribution through cannabis clubs and pharmacies is being explored by the government (Reuters, 2015).</p>	<p>It is the physician's prerogative to prescribe MMJ in the absence of a state-issued list of eligible conditions and clinical guidelines (Reuters, 2014).</p>
<b>Washington</b>	<p>Currently, there are no restrictions on MMJ products allowed for consumption (Washington State Department of Health, 2016).</p> <p>MMJ was legalized in 1998 and recreational marijuana was legalized in 2012.</p>	<p>The Washington Liquor and Cannabis Board oversees production and issues licenses for production and processing. There are hundreds of producers in the market including collectives (which will be phased out by July 2016). Home growing is also permitted (Washington State Department of Health, 2016).</p>	<p>MMJ is available through recreational retailers that possess a MMJ endorsement. A patient ID card will be required for all purchases (in 2016), and the state is undergoing implementation of a patient registration system that enables tracking of all purchases (Washington State Department of Health, 2016).</p>	<p>For patients to access MMJ, they must obtain a recommendation by a physician. There is a list of qualifying conditions by the Washington Liquor and Cannabis Board to help guide physician recommendations (Washington State Department of Health, 2016).</p>

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