





AGENDA

- Global Landscape
- Cannabis Timeline
- Health Canada Regulatory Landscape
 - Cannabis Act Bill C-45
 - LP Licensed Producers
 - Access to Cannabis for Medical Purposes Regulations (ACMPR)
 - Cannabis Federal Licenses
 - Jurisdictional Obligations
- Medical and Recreational Supply Chain
- Canada's Coast to Coast Guide Cannabis Laws
- Transportation
- Canada's Potential
- Future of Cannabis in Canada
- Resources





GLOBAL LANDSCAPES

Cannabis is illegal but the country adopted a "toleration policy" – retailers can sell small amounts

USA

NETHERLANDS

2012 - Colorado 1st jurisdiction in the world to legalize

Within 2 years each state had legal framework governing retailers

U.S. Federal Reserve will not allow ANY banking – resulting in a primarily cash-based industry

U.S. does not permit export of cannabis products

U.K.

UK is the largest exporter of cannabis globally - ahead of Canada

2018 - Reschedules cannabis to a schedule II drug Cannabis is to be available by prescription

GW Pharmaceuticals' monopoly & license to produce medical cannabis could be broken

USA approved importing Epidiolex, child epilepsy drugs based on CBD from UK

Brexit import/export issues – new opportunity for Canada to import

URUGUAY

2017 - 1st country in the world to fully legalize and regulate cannabis

Took 2 years to set up regulatory framework with two approved producers

Crackdown by banks & bureaucratic backlogs, accessing recreational cannabis challenge



CANNABIS TIMELINE

Medical cannabis legalized in Canada by court ruling

Health Canada (HC)
permitted patients to grow or
designated growers to
cultivate on their behalf

2014

Canada's production marketplace single thirdparty grower to over 90 Licensed Producers (LP)

2018

2001

Health Canada (HC)
permitted private companies
Licensed Producers (LP) to
produce cannabis

2017

June 2018 Cannabis Act (C-45) paved the way to the legalization of cannabis

Recreational cannabis was legalized by the Federal government October 17,2018



CANNABIS ACT BILL C-45



Health Canada: Road to Cannabis

Medical and Recreational Cannabis

- LP's regulated by Health Canada's controlled substances, pharmaceutical and health regulations
- Product high-quality, precision balance of the known cannabinoids like THC, CBD
- Over 100 cannabinoids require analysis with strains cultivated & hybridized for specific results
- Advantage high-quality, precisely-tested and measured products we produce and formulate
- Importers to know what they are buying and how to market their product
- Health Canada additive regulations strictest in the world in cannabis cultivation
- Canada's strict additive controls restrict harmful pesticides, chemicals horticultural products



REGULATORY LANDSCAPE

Health Canada and Licensed Producers (LP)



- LP's are required to meet <u>Access to Cannabis for Medical Purposes</u> <u>Regulations (ACMPR)</u>
- LP's are responsible to understand the ACMPR and to be knowledgeable about their obligations
- LP's must also consult the relevant sections of the <u>Food and Drugs</u>
 <u>Act</u> (FDA) and <u>Narcotic Control Regulations</u> (NCR) that apply to cannabis



HEALTH CANADA - REGULATORY LANDSCAPE

Access to Cannabis for Medical Purposes Regulations (ACMPR)

- 1. Physical Security Measures
- 2. Good Production Practices
- 3. Packaging, Labelling and Shipping Requirements
- 4. Cannabis Tracking and Licensing System
- 5. Import and Export permit, if applicable
- 6. Security Clearance
- 7. Compliance and Enforcement under the Cannabis Act
- 8. International Trade and Cannabis





Physical Security Measures

- Production, packaging, labelling and storage activities under ACMPR need conducted indoors, not in a dwelling place
- ACMPR sets physical security requirements necessary secure sites where LP conduct activities with cannabis other than storage
- Guidance Document: Building and Production Security Requirements for Marihuana for Medical Purposes provides technical details on meeting security requirements
- Storage of cannabis, other than marijuana plants, Health Canada's <u>Directive on Physical Security</u> <u>Requirements for Controlled Substances</u> establishes security requirements for the storage of all controlled substances including cannabis by LP
- LP applicants must demonstrate to Health Canada that they meet these security requirements
- LP sites are subject to compliance and enforcement measures, including regular audits and inspections by Health Canada
- HEALTH CANADA AUDIT ISSUES: Pesticides and Mold





Good Production Practices

- LP's are subject to Good Production Practices, ensuring the cleanliness of the premises and equipment
- LP's are required to employ a Quality Assurance person with appropriate training, experience, and technical knowledge to approve the quality of fresh and dried marijuana, marijuana plants and seeds, and cannabis oil prior to making it available for sale
- Product Quality: LP must conduct tests on their products, including, as applicable: microbial and chemical contaminants of fresh and dried marijuana, and cannabis oil
- The <u>Technical Specifications for Testing Dried Marihuana for Medical Purposes</u> guidance document provides specific information for LP to help them meet some of these requirements
- LP must meet requirements under Good Production Practices under the ACMPR including, but not limited to:
 - Sanitation Program
 - Standard Operating Procedures
 - Establishment of a Recall System





Good Production Practices

Good Manufacturing Practices & Licensed Producers (GMP)

- GMP standard pharmaceutical companies apply to the production medicines and medical-grade cannabis is no different
- GMP harvesting and production cannabis means end-users assured integrity of product -safe to consume & consistency quality





Packaging, Labelling and Shipping Requirements

ACMPR stringent requirements for packaging, labelling and shipping

- Protect against accidental consumption
- Ensure products are not appealing to children and youth
- Provide consumers with information they need to make informed decisions before using cannabis
- LP are required to attach client-specific label, similar to patientspecific prescription drug label, to container, package or plant
- ACMPR, each shipment sold to client accompanied by a copy current version of the Health Canada document entitled "<u>Consumer</u> <u>Information - Cannabis (Marihuana, marijuana)</u>"
- Health Canada document provides a summary of known information on uses and risks of cannabis for medical purposes so individuals can be informed about their treatment choice



Example of FRONT (principal display panel) with white/plain background and brand/producer name



Example of BACK (secondary display panel) with white/plain background



Example of FRONT (principal display panel) with solid coloured background and brand/producer logo



Example of BACK (secondary display panel) with solid coloured background



3

Packaging, Labelling and Shipping Requirements



- Fresh and dried marijuana, cannabis oil, and marijuana seeds and plants must be sold or provided in tamper-evident containers or packages
- Fresh and dried marijuana and cannabis oil must be sold or provided in childresistant containers
- Separate labelling requirements apply depending on the product type (i.e. fresh and dried marijuana, cannabis oil, cannabis oil in capsule or similar dosage forms, and marijuana plants and seeds)





Cannabis Tracking and Licensing System

- Health Canada launched new online Cannabis Tracking and Licensing System
- Allows industry to submit and view progress of applications online
- Allows industry to submit amendments to licences and inventory reports
- The Health Canada cannabis tracking system will:
 - Enable the tracking of cannabis
 - Prevent legal cannabis from being diverted to the illegal market
 - Prevent illegal cannabis from being introduced into the legal market
- System will track the movement cannabis from cultivation, to processing, to sale
- Health Canada <u>Track & Traceability of Product</u> from raw material through to end user delivery
- System will <u>not</u> include information on individual consumers
- System will protect confidential business information



5 Import and Export Permit

LP must obtain a permit from the Minister of Health prior to importing or exporting marijuana or cannabis for the purpose of testing cannabinoid content

6 Security Clearance

The following individuals are required to have a valid security clearance under the ACMPR: the individual who holds a producer's licence

- All officers and directors of a corporation (if the producer's licence is issued to a corporation)
- The Senior Person in Charge
- The Responsible Person in Charge
- The Alternate Person(s) in Charge

Individuals seeking to obtain security clearance must complete the following forms:

- The <u>Security Clearance Application form</u>
- The <u>Security Clearance Fingerprint Third Party Consent to Release Personal Information form</u> (this form will allow a Canadian police force or a fingerprinting company accredited by the RCMP to submit fingerprints to the RCMP for the purposes of a criminal record check)





Compliance and Enforcement

Health Canada Compliance and Enforcement Policy for the Cannabis Act is intended to help regulated parties comply with:

- Cannabis Act
- Cannabis Regulations
- Applicable administrative policies

Regulated parties are authorized by Health Canada for activities such as:

- Cultivation
- Processing
- Analytical Testing
- Research
- Sale for Medical Purposes
- Import and Export





Compliance and Enforcement

Regulated parties who don't require Health Canada authorization, conduct activities regulated under the Act, such as:

- Promoting and advertising, including broadcasting and publishing
- Packaging and labelling cannabis accessories
- Performing activities related to cannabis accessories and services

People who play a role under the Cannabis Act and its regulations, such as:

- Consumers
- Law Enforcement
- Health care Practitioners
- Provincial and Territorial Governments

Industry (licensed or not) must comply with the Cannabis Act and its regulations and are expected to:

- Understand the law and their obligations
- Understand and cooperate with inspectors
- Comply with orders and prohibitions from Health Canada, if applied





International Trade, Business and Cannabis

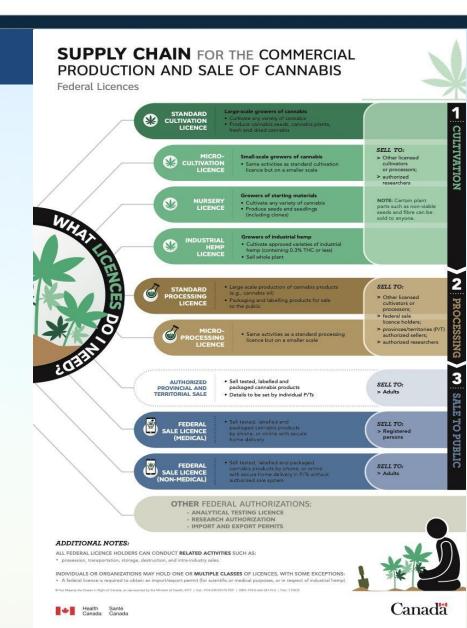
- It is <u>prohibited for any company to export or import cannabis</u> for any purposes other than medical or scientific purposes under the Cannabis Act
- There are risks for companies doing business in the cannabis industry in international markets
- Seek advice from legal counsel in the prospective export market before engaging in any kind of commercial activity related to cannabis abroad
- Any foreign company interested in investing Canada's cannabis industry must fully understand relevant Canadian federal and provincial laws and regulations
- Canadians travelling to the U.S. for reasons related to the cannabis industry may be deemed inadmissible
- Canadian companies engaging in the cannabis industry in the U.S. may face risks of prosecution or penalties under U.S. law and regulations, including those that criminalize the management, financing and possession of equipment and materials associated with cannabis



HEALTH CANADA - LICENSES

Cannabis Federal Licenses

- 1. Cultivation Sell to: other licenced cultivators or processors; authorized researchers
- Standard Cultivation Licence Large-scale growers of cannabis
- Micro-Cultivation Licence Small-scale growers of cannabis
- Nursery Licence Growers of starting materials
- Industrial Hemp Licence
- 2. Processing Sell to: Other licensed cultivators or processors; Federal sale license holders; P/T authorized sellers; authorized researchers
- Standard Processing License
- Micro-processing License
- 3. Sale to the Public
- Authorized Provincial/Territorial (P/T) Sale to Adults
- Federal Sale License (Medical) Sale to registered persons
- Federal Sale License (Non-Medical) Sell to Adults





HEALTH CANADA - LICENSES

Apply License Canada Revenue Agency (CRA) Selling Cannabis

- Cultivators, Producers and Packagers of Cannabis Products are required to obtain a cannabis license from the CRA
- Once licensed, they are also required to:
 - Buy and apply cannabis excise stamps to their products
 - Calculate the duty on their sales
 - File their return and send excise duty to the CRA
- Excise stamp MUST be present on all cannabis products that have been legally produced and are available for purchase
- Cannabis Duty Process:
 - Apply for a Cannabis License
 - Register for the Cannabis Stamp Regime
 - Calculate the Duty on Cannabis
 - Report and Remit Duty on Cannabis
 - Completing a Cannabis Duty Return



Canada's Jurisdictional Obligations

Federal

Responsible for regulating the production of cannabis

Responsible for setting the rules and parameters around possession limits, trafficking, advertising, the tracking of seed to sale, establishing minimum age limits, personal cultivation and the continued oversight of the medical cannabis regime

Provincial and Territorial

Govern many aspects of the legalization framework, including wholesale and retail distribution, the selection of a retail distribution model and workplace safety

Provinces and territories have discretion to set higher age limits or more restrictive possession limits

Bills C-45 and C-46 provide latitude to provinces and territories to develop their own rules and regulations around the distribution and consumption of fresh or dried cannabis, cannabis oil, plants and seeds

Municipal

Municipal regulations set by provinces and territories

Municipal jurisdiction vary in a number of ways

Common Municipal responsibilities include areas of zoning, business licensing, building code, municipal workplace safety and enforcement of regulations around public consumption and impaired driving

Shared Areas of Responsibility

Shared jurisdictional responsibility: public consumption, rules for retail locations, home cultivation, taxation from cannabis sales, public education, public health and law enforcement

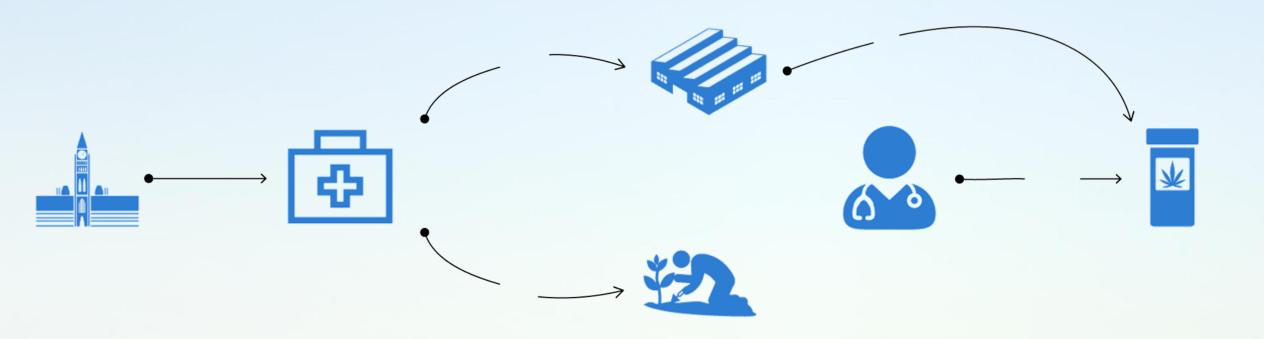
- Land Use Planning and Zoning
- Illicit Dispensaries
- Home Cultivation
- Public Consumption
- Business Licensing
- Human Resources Policy
- Enforcement and Policing

- Impaired Driving Rules and Enforcement
- Public Education
- Public Health
- First Nation and Municipal overlap jurisdiction
- Distribution of Tax Revenue
- Support for implementation Costs



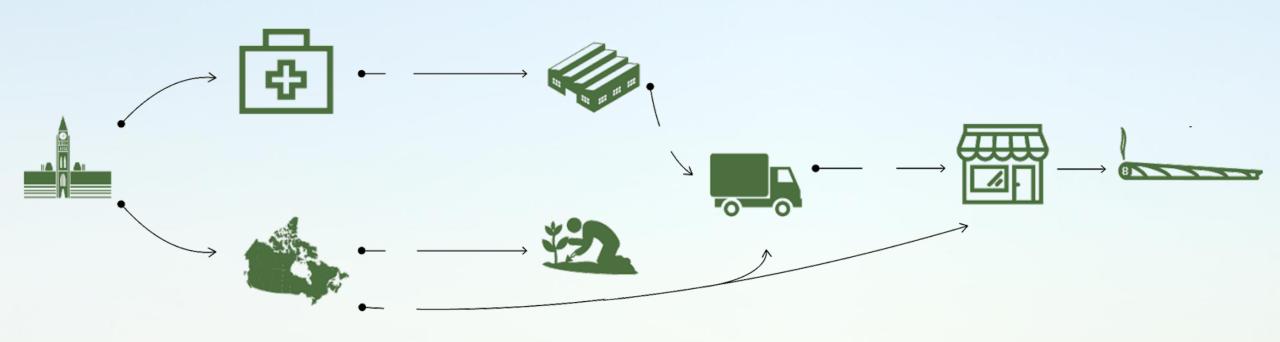
SUPPLY CHAIN

Medical Marijuana Supply Chain



SUPPLY CHAIN

Recreational Marijuana Supply Chain







ONTARIO



Government operated Ontario Cannabis Stores (OCS)

Ontario will also rely on private sector to sell recreational cannabis

Adults (19+) can grow up to 4 plants per household

Legal to smoke anywhere cigarettes are permitted except for vehicles

Government operated BC Cannabis Stores

Adults (19+) can grow up to 4 plants per household – cannot be visible to public/No home daycares

Legal to smoke anywhere cigarettes are permitted except for vehicles

No smoking around children





QUEBEC

Government operated Société Québécoise du cannabis (SQDC)

Adults (18+) cannot grow their own cannabis plants

Prohibited on University and CEGEP grounds and where tobacco use is prohibited



ALBERTA

Privately-licensed retailers

Adults (19+) can only grow with a medical license

Only in private residences

Use in public spaces and in vehicles prohibited





SASKATCHEWAN

Privately-licensed retailers and online sales

Adults (19+) can grow up to 4 plants per household, subject to landlord restrictions

Only in private residences, restricted around minors



MANITOBA

Privately-licensed stores and governmentcontrolled online sales

Adults (18+) can grow up to 4 plants per household

Prohibited to smoke where children are present

Legal to smoke anywhere cigarettes are permitted except for vehicles





YUKON



NORTHWEST TERRITORIES

Government operated store front and online sales, and in future at licensed, privately run retailers

Adults (19+) can grow up to 4 plants per household

Restricted to private residences and adjoining properties

Prohibited around children, or inside daycares, preschools or licensed child care homes regardless if children are present

Government operated NWT Liquor Commission stores and online, door left open to future private sales

Adults (19+) can grow up to 4 plants per household

Prohibited in places used by children and where tobacco is prohibited

Legal to use in public places like trails and parks, but not during public events





NUNAVUT



PRINCE EDWARD ISLAND

Government operated online sales and licensed, privately run retailers

Adults (19+) can grow up to 4 plants per household, subject to landlord restrictions

Prohibited in places used by children and where tobacco is prohibited

Government operated PEI Cannabis Corp storefronts in Charlottetown, Summerside, Montague, West Prince and online

Adults (19+) can grow up to 4 plants per household provided they are not accessible to minors

Restricted to private residences, with the exception of some public places





NOVA SCOTIA

Government operated online Nova Scotia Liquor Corporation

Adults (19+) can grow up to 4 plants per household, subject to potential restrictions based on municipal by-laws

Prohibited in vehicles and where tobacco use is currently not allowed



NEW BRUNSWICK

Government controlled Cannabis NB storefronts and online

Adults (19+) can grow up to 4 plants per household

Only in private residences

Used in public places will not be allowed





NEWFOUNDLAND AND LABRADOR

Licensed, privately run retailers and online

Adults (19+) can grow up to 4 plants per household

Restricted to private residences



MUNICIAPL RESTRICTIONS AND BY-LAWS

FCM Federation of Canadian Municipalities has developed two reference documents to help municipalities address cannabis legalization locally

Provides general information and steps for consideration for municipalities to introduce by-laws, zoning and business practices

FCM website provided in Resources Slide

TRANSPORTATION

The movement of cannabis product is an important aspect of a company's operations

"Logistics now becomes a core competency of the larger company, because we don't yet have all the details as to what the transportation requirements are going to be province by province,"

"What we're going to do is be incredibly agile and make sure we've got the manpower required to process and make sure we have secure deliveries to all of our customers across the country."



Cam Battley, the chief corporate officer at Aurora Cannabis Inc.

TRANSPORTATION

- Federal government officials advise there will not be a specific licence requirement for the transportation of cannabis
- Under new regulations unveiled by Health Canada, all federal licence holders will be responsible and accountable for the safekeeping of cannabis, which includes the distribution and transportation process
- Health Canada advises that any company or person who is retained by a licensed company to transport cannabis will be subject to the provisions of the Cannabis Act
- Provinces have announced plans for zero-tolerance laws while operating a vehicle, as well as increased penalties for impaired driving
- Federal Transport Minister Marc Garneau says the federal government is working to put policies to address impairment especially as it affects Transportation Industry



CANADA'S POTENTIAL

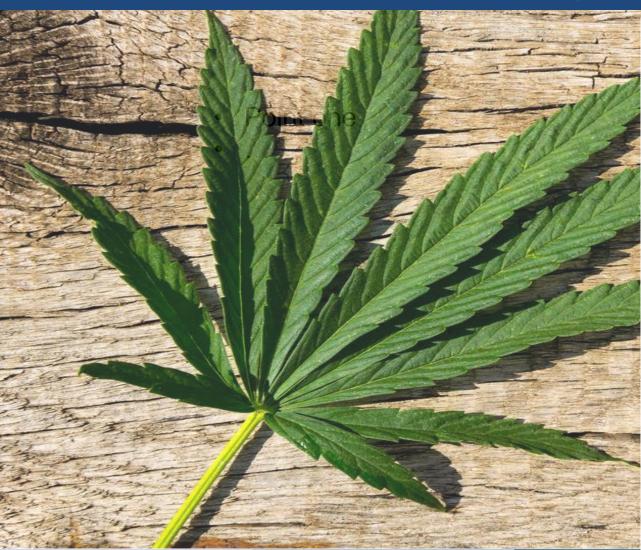
Canada Global Cannabis Export Leader

- Canada 1st national legal multi-use cannabis within highly controlled legal & regulatory environment
- Canada 1st country in the world to federally export worldwide with a competitive producer landscape
- Global markets recognize Canada medical legal cannabis in regulated, stable, quality supply chain
 - Global markets are already recognizing Canada for our superior (and greener) products
 - Made in Canada stamp has significant meaning in navigating foreign import controls
 - Federal regulation allows for a common quality-derived brand based on country of origin
 - o Canada exported medical cannabis known commodity with uniformly recognized high standard
- Canadian cannabis exported Germany, Australia, New Zealand, the EU, and South America
- Global imports of legal quality cannabis 2017 \$7.7 billion USD and by 2021 \$31.4 billion USD
- Export promotion as Canada positioned for significant oversupply relative to domestic need
- Canadian government needs to actively endorse cannabis as an export commodity
- 2018 Barton Panel Report recommends Canada as an Agri-product cannabis export superpower
- Canada export promotion & facilitation agencies Cannabis Export Promotion Framework
- Strategically leverage our position to identify markets, map partners and navigate import rules
- Canada has what it takes to be for medical cannabis what Switzerland was for pharmaceuticals



FUTURE OF CANNABIS IN CANADA

What are the next steps for cannabis in Canada?



- Canada Leader in the World Focus on Research & Medicine
- Economic Impact: Canada's cannabis market \$7 billion by 2019
- Benefit Billions New Taxes
- Health Canada: Medical Cannabis Regime next 5 years
- Federal Government Commitment to Research, Broad Base Coverage
- Medical Cannabis: Research, Clinical Trials,
 Education, Colleges, Medical Profession, Pharmacy
- Legitimacy of Medical Cannabis Part of the Medication Regime
- Recreational Cannabis Stream Must be Legal
- Federal, Provincial, Municipal Align to Educate and Prevent Harm
- Global Leader New Economy



RESOURCES

Health Canada – Cannabis in Canada, Get the facts

https://www.canada.ca/en/services/health/campaigns/cannabis.html?utm_campaign=cannabis-18&utm_medium=vurl-en&utm_source=canada-ca_cannabis

Health Canada website – Cannabis Industry Guidelines and requirements

https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers.html

Health Canada website – Licensed Producers

https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/licensed-producers/authorized-licensed-producers-medical-purposes.html

Guidance Document - Building and Production Security Requirements for Marihuana for Medical Purposes

https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/licensed-producers/guidance-document-building-production-security-requirements-cannabis-medical-purposes.html

Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances)

https://www.canada.ca/en/health-canada/services/health-concerns/reports-publications/controlled-substances-precursor-chemicals/directive-physical-security-requirements-controlled-substances-licensed-dealers-security-requirements-storage.html

Health Canada Inspections & Audits

https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/licensed-producers/policies-directives-guidance-information-bulletins/inspections-what-expect-information-package.html

Barton Panel Recommendations

https://www.budget.gc.ca/aceg-ccce/home-accueil-en.html

FCM Federation of Canadian Municipalities

https://fcm.ca/home/issues/emergency-preparedness-and-response/cannabis-legalization/cannabis-legalization-primer.htm

Department of Justice

https://www.justice.gc.ca/eng/cj-jp/cannabis/