



# Cannabis Not Federally Legal in the United States

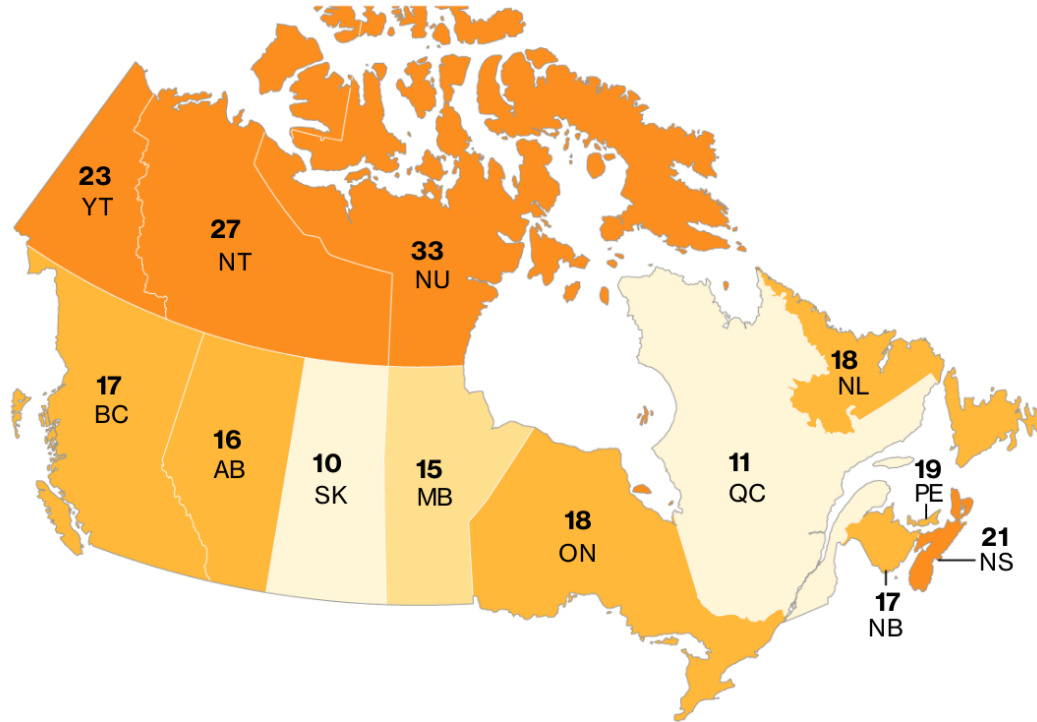
- MORE Act
- Senate Democrat Discussion Draft
- House Mace Bill

# U.S. Federal Legalization Bills

- Descheduling
- Criminal Reform/Social Justice
- Regulations (Medical, Adult Use)
- Interstate Commerce/State-Federal
- Taxes

# Demand

Share of population who are users ● <12% ● 12-15 ● 16-19 ● >19

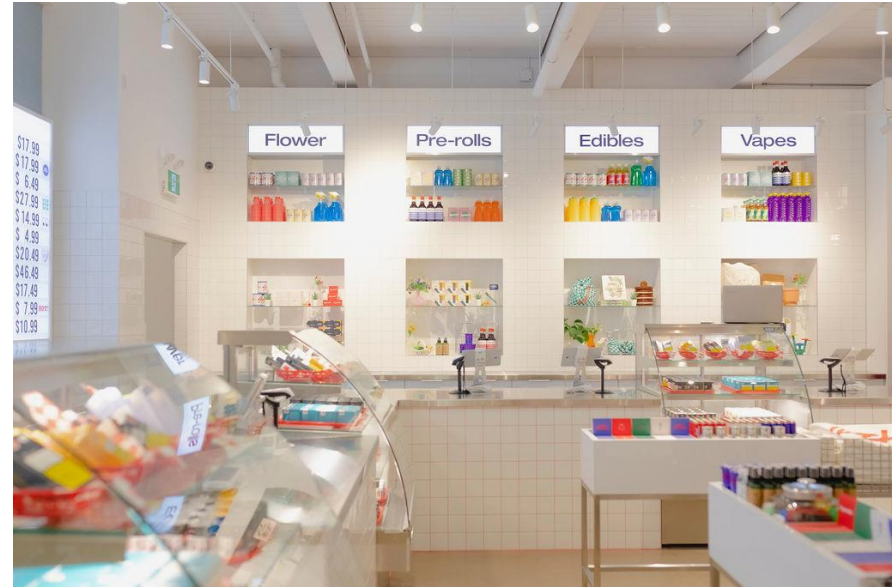


Source: Statistics Canada

# Retail: Public vs Private



Public SQDC Store in Montreal



Private Superette Store in  
Toronto

# Marketing Enforcement



Early Lifestyle Advertising Removed from Producer's Website After Health Canada Objected



**International Cannabis Regulation: Impact  
and Considerations for a U.S. Framework,**  
Thursday, December 2, 2021

# Cannabis Regulation in Israel

*Dr. Joe Wyse, Patent Attorney  
Partner, Head of Patent Dept.  
Bressler IP Israel*

[Joe Wyse, Pat. Attny. wyse@bressler.co.il](mailto:wyse@bressler.co.il) ++972 (0) 542320475



# Background

- **Cannabis in Israel : permitted for** specified medical usage (1990's) illegal but partially decriminalized for recreational use, benign unenforcement
- [Raphael Mechoulam](#) and Yechiel Gaoni [Hebrew University](#) isolated [THC](#) from [cannabis](#) in 1964
- 27% of Israelis 18 - 65 highest rates of annual cannabis usage in the world, followed by Iceland and the US at 18% and 16% respectively
- 60,000 Israelis use medical cannabis, consuming an estimated 25 tonnes per year.
- Research and innovation in the area is supported by the Ministry of Health
- Israel one of three countries in the world where cannabis research is sponsored by the government. Canada and Netherlands

# Background (Consensus)

- It is the State's duty to supervise the cannabis market through the various governmental organizations (Health, Police, Customs, Agriculture), to grant permits when needed and to take all actions needed to protect public welfare and health and to prevent misuse and criminal activity associated with the drug.





# Israel Medical Cannabis Agency IMCA

International - Single Convention on Narcotic Drugs 1961

Cannabis is not registered as a remedy (as a medication) and is defined as a "dangerous drug" in accordance with the [Dangerous Drugs Ordinance \[New Version\] 1973](#) Clarification June 2021

BUT :

Ministry of Health – the Israel Medical Cannabis Agency IMCA, operates according to medical principles for registered medical remedies

[Joe Wyse, Pat. Attny. wyse@bressler.co.il](mailto:wyse@bressler.co.il) ++972 (0) 542320475

# IMCA

- [Government Resolution No. 105](#)
- Principles for examining medical indications
- Optimizing dispensing proceedings
- Appointing administrators
- Ensuring accessibility to patients
- IMCA is in charge of supervising and regularizing the field of cannabis for medical and research use.

# IMCA

- Field of research and development - to promote the scientific research of the field of cannabis.
- Promoting the creation of a common pharmacological-regulatory common denominator alongside a clear and defined medical practice, outlining the way to a regulated medical field that includes products that have a research-based medical benefit - Medicine based Evidence.
- Encouraging research and research proposals, for multidisciplinary research, to promote the innovation of agricultural-oriented research
- Applicable purpose and to promote the current research of the cannabis plant (its active ingredients, its physiological effects,
- Pharmacology and biochemistry (, the benefits of using it along with the risk involved).

# Cannabis Regulation in Israel

- According to the [Government Resolution No. 1587](#) 2016, the "[medicalization](#)" outline of cannabis products
- appropriate indication for patients, accessibility to care and supply of medical grade cannabis products,
- appropriate oversight of a product that is defined as a "dangerous drug".

# Principles

Medicalization – The use of Cannabis for medical purposes  
Standardization of Medicinal Cannabis products – Medical Grade Cannabis (MGC) products, constant & controlled concentrations, practitioners safely prescription, sold in pharmacies.

Medical indications for prescribing Cannabis – professional teams, IMA experts, supervision & learning from medical practice

Training of Physicians, pharmacists to treat with MGC using a systematic method of medical practice IMC-GCP (the "green book").

Regulation of Research and Development

# Cannabis Regulation in Israel

- The treated patients and those applying to be treated with cannabis
- Specializing Physicians
- "Administrators" – Physicians who are qualified to approve recommendations for the use of cannabis
- Breeding and growing cannabis sites, manufacturing enterprises, department stores for cannabis products and companies that transport cannabis
- Pharmacies that dispense cannabis
- Professional consultants, quality control laboratories and quality certification entities
- Researchers and research entities in the field of cannabis
- Parallel governmental agencies of countries who are signed on the Single Convention on Narcotic Drugs, 1961
- Organizations and associations: the Israel Medical Association (IMA), the Pharmaceutical Association of Israel, the professional medical associations (to fields relevant to the indications), public associations

# Cannabis Regulation in Israel

- Ensuring the quality of supply chain links.
- In accordance with "Procedures for Proper Quality Conditions", which define the main lines of activity of the chain links and
- The criteria for which they are required

# Cannabis Regulation in Israel

- IMC-GAP

Growing in Proper Conditions of Cannabis for Medical Use - Guidelines, Quality Requirements and Standards are required

- Quality guideline for cultivation and multiplication of Cannabis strains, genetically defined. Supervised range of concentrations of several active ingredients.
- IMC-GMP
- Production under proper conditions of medical cannabis products.
- Quality guideline for production of generic and uniform Medical Grade Cannabis (MGC) products.



# Cannabis Regulation in Israel

- IMC-GDP: Distribution under proper conditions of medical cannabis products
- IMC-GSP - Guideline for ensuring the safety , security, prevention of diversion and supervision of adequacy of medical practice.
- IMC-GCP Prescription of Medical Grade Cannabis Products and a License issued by Trained Physician according to the Green Book – GCP standards

# Export

- Export license
- Export applications will include an import permit for the specific shipment obtained by the importer from the relevant authorities in the buyer's country.
- B2B, with the importers that obtain the license not to individual patients
- Finished goods as permitted for sale in the Israeli market. Currently, this includes dried flowers, pre-rolls, tinctures, cartridges for inhalers

# Way ahead, next steps

- Evidence Based Medicine, Clinical Trials

Thank you !

- *Dr. Joe Wyse, Patent Attorney*
- *Partner, Head of Patent Dept.*
- *Bressler IP Israel,*
- [wyse@bressler.co.il](mailto:wyse@bressler.co.il) ++972 (0) 542320475