

Global Medicinal Cannabis Regulations & Top 10 Advancements



WITH DALTON

Peter Pekos

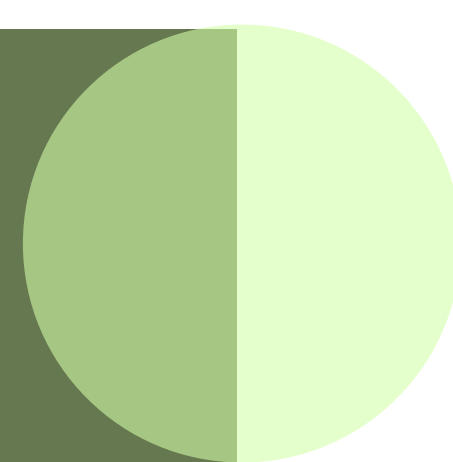
Company Vision

"To make the impossible possible, Dalton Pharma Services uses its scientific and pharmaceutical expertise to bring customer ideas to life. We develop their new drug products, optimize the synthesis of therapeutic candidates, and manufacture them at the highest level of quality."

Disclaimer

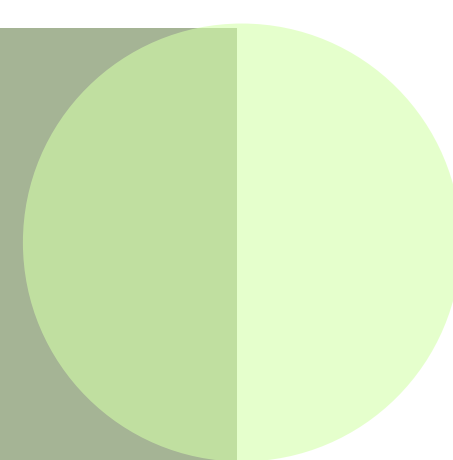
Formerly, the cannabis space was labeled negatively, but with recent regulatory changes demonstrating the use of cannabis products as safe and effective for therapeutic purposes, the use of medicinal cannabis is more widely accepted. Many successful pharmaceutical products contain active pharmaceutical ingredients that naturally originate from botanicals such as the cannabis plant. At the forefront of this move, global regulations on the use of medicinal cannabis have been introduced. This technical report is intended to provide information to quality and regulatory correspondents on recent global cannabis regulations changes and medicinal cannabis regulatory requirements around the world. This technical report should be read in conjunction with the relevant laws, regulations, and guidance's that apply to your situation.

✓ FDA inspected, HC approved, & MRA with EMA



Cannabis Definition based on 1961 Single Convention on Narcotic Drugs:

- 1** Cannabis: ‘the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated’
- 2** Cannabis plant: ‘any plant of the genus Cannabis’
- 3** Cannabis resin: ‘the separated resin, whether crude or purified, obtained from the cannabis plant’



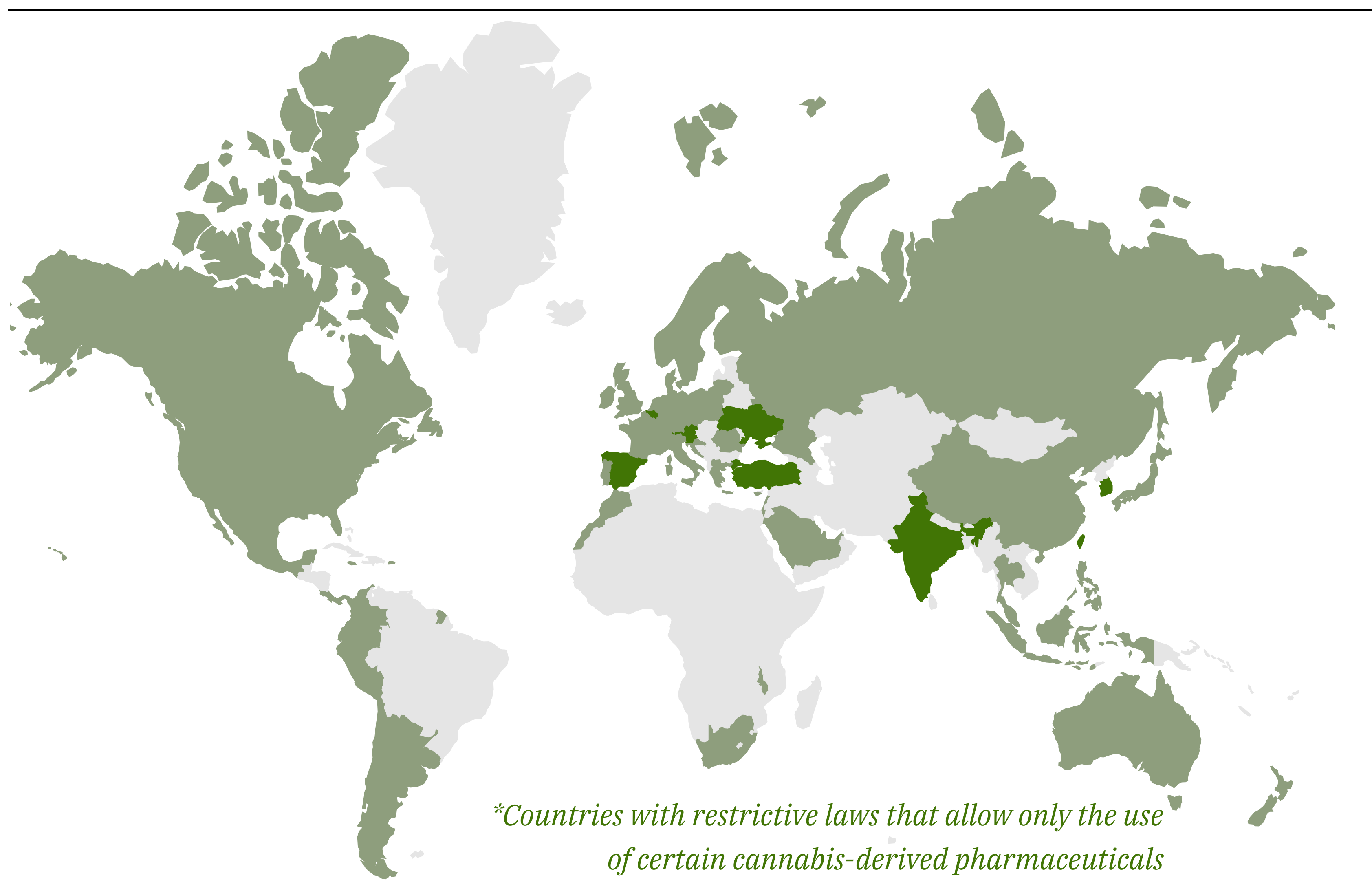
The framework for regulating cannabis as a pharmaceutical product varies widely across the world, with some international efforts put in place.



The United States and Canada are the most advanced countries in the development of the medicinal cannabis industry. The European Union also has advancements; however, there is no harmonized law on cannabis use. Instead, various pieces of legislation have been implemented by individual EU member states to allow for medicinal cannabis usage, with the Netherlands leading the way in 2003 and Ireland not implementing legislation until 2019. In Asia, on the other hand, many countries, including Japan, Vietnam, Pakistan, Cambodia, and Nepal continue to prohibit medicinal cannabis; however, there have been positive developments in several other countries in the region. This technical report will dive into the key regulatory requirements for medicinal cannabis around the globe along with highlighting any recent regulatory developments.



Global



Countries where cannabis is legal for medicinal purposes

- **North America:**
Barbados, Canada, Jamaica, Mexico, Puerto Rico, United States
- **Central America:**
Costa Rica, Panama
- **South America:**
Argentina, Brazil, Chile, Colombia, Ecuador, Peru, Uruguay

Africa: Malawi, Morocco, South Africa

Asia: China, *India, Indonesia, Israel, Japan, Lebanon, Malaysia, Philippines, Qatar, Saudi Arabia, *Singapore, *South Korea, *Taiwan, Thailand, United Arab Emirates

Oceania: Australia, New Zealand

Europe: *Austria, *Belgium, Croatia, Cyprus, Czech Republic, Denmark (pilot plan), Estonia, Finland, France, Germany, Greece, Portugal, Poland, Ireland (pilot plan), Italy, Lithuania, Luxembourg, Macedonia, Malta, Moldavan, Netherlands, North Macedonia, Norway, Romania, Russia, San Marino, *Slovenia, *Spain, Sweden, Switzerland, *Turkey, *Ukraine, United Kingdom

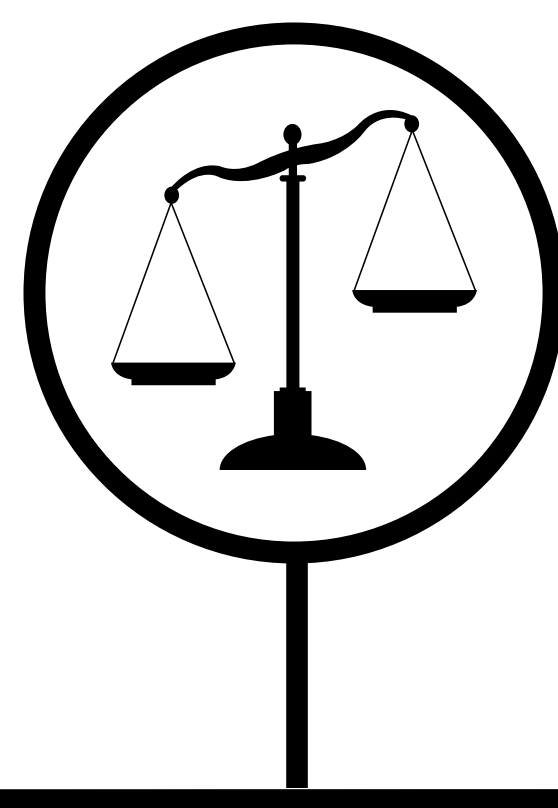
Global Standards for Cannabis

1. [ASTM's \(American Society for Testing and Materials\)](#) Standards:

- D37.01 Indoor and Outdoor Horticulture and Agriculture
- D37.02 QMS
- D37.03 Laboratory
- D37.04 Processing & Handling
- D37.05 Security & Transportation
- D37.06 Personnel Training, Assessment, Credentialing
- D37.07 Industrial Hemp
- D37.08 Cannabis Devices & Appliances
- D37.09 Sustainability

2. ISO has 3 standards under development: [CD IWA 37 - Safety, Security And Sustainability Of Cannabis Facilities And Operations – Safety Of Cannabis Buildings, Equipment, And Oil Extraction Operations](#)

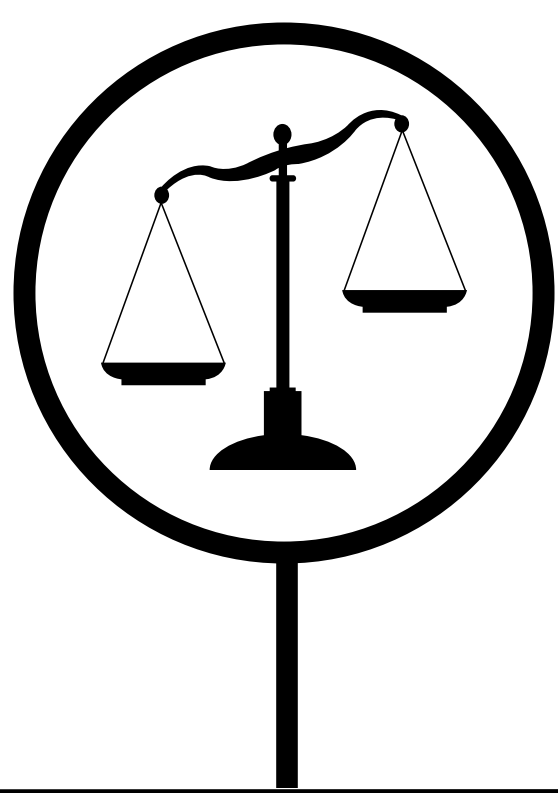
3. The European Compliance Academy's Cannabis Working Group has an online conference on **June 8, 2022** to discuss global GMP requirements and regulatory information on medicinal cannabis (and CBD products).



Canada

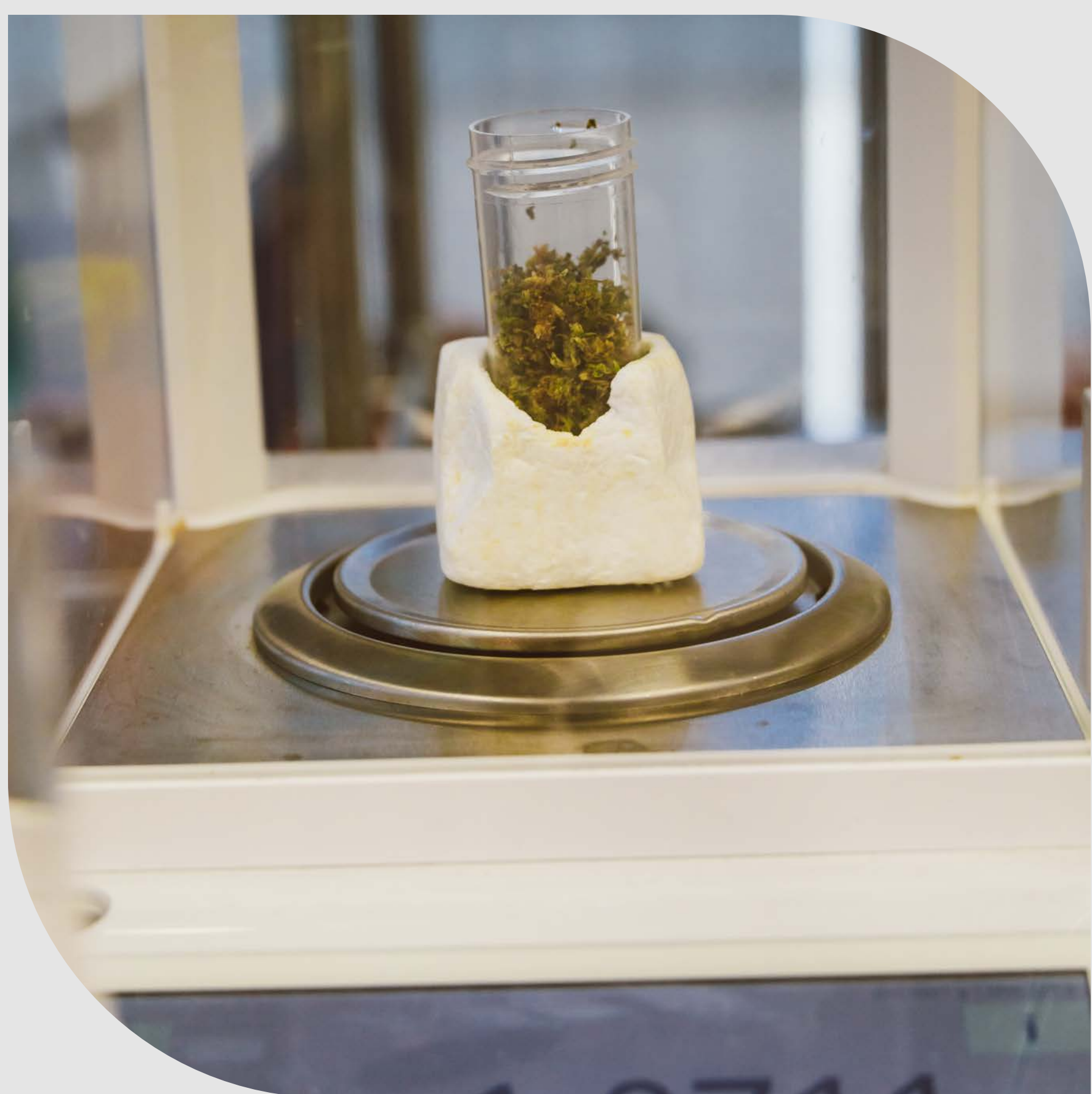


Enabling Law	<p>The Cannabis Act and the Food and Drug Act (FDA). Amendments to the Cannabis Regulations were recently proposed to exclude the FDA.</p> <p><i>Note: In addition to the federal law, each province / territory has its own regime for regulations around possession limits, impaired driving, age limit, public health, education, taxation, and home cultivation.</i></p>
Date approved	2018
Medical/recreational	Legalized for both medical and recreational purposes.
Permissible activities	<p>Provided that a license from Health Canada has been obtained, the following functions are allowed with respect to permitted forms of cannabis:</p> <ul style="list-style-type: none">• Cultivation (including micro and standard cultivation or nursery);• Processing (including micro or standard processing);• Sale for medical or non-medical purposes• Analytical testing;• Research.
Permitted forms of Cannabis	<p>Any part of a cannabis plant can be sold or used for medical and non-medical purposes, including dried cannabis, cannabis oil, fresh cannabis, cannabis plants, cannabis plant seeds, edible cannabis, cannabis extracts, cannabis topicals and tinctures, concentrates, capsules and sprays.</p>



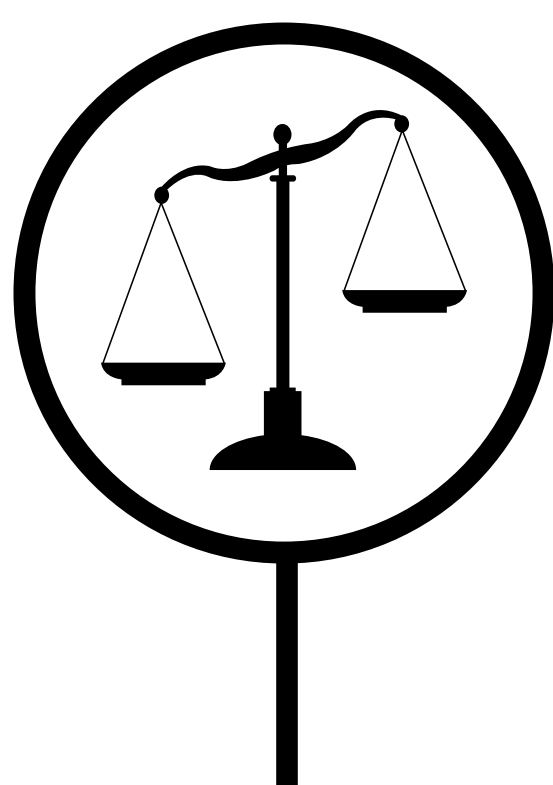
Canada

Content/Potency	Tolerance limits for the net weight and volume depend on the specified cannabis product. Specific levels can be found here .
Point of sale	Postal system by a licenced agency for medical purposes.
Requirements	A medical prescription by an authorised healthcare practitioner, indicating the recommended dose, and a licence granted to the patient.
Prohibition/ Sanction	Production, distribution, and sale outside of the regulated system carry criminal sanction. Sanctions range from fines to up to 14 years in prison.
Taxes	With the exception of Manitoba, each province and territory has placed an extra excise duty on a cannabis product packaged by a cannabis licensee and supplied to a purchaser.



Regulatory body:

Food and Drug Administration (FDA)

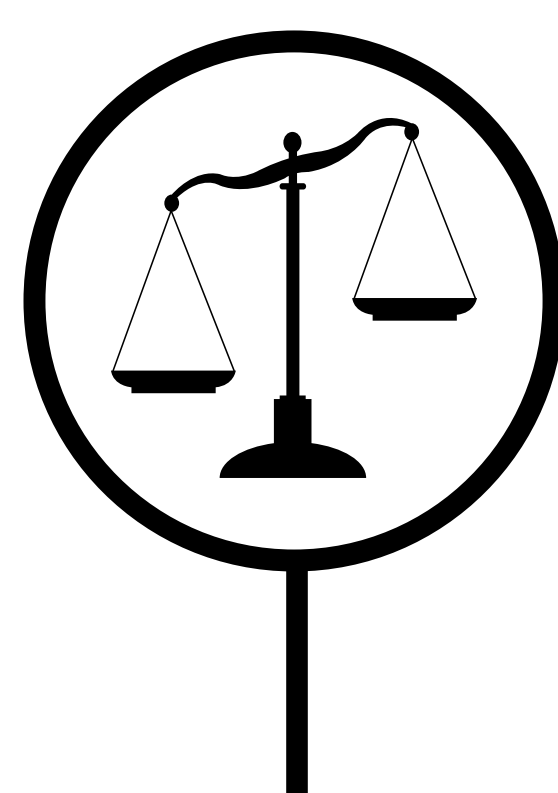


USA

Enabling Law	State regulations
Date approved	1996-2017
Medical/recreational	Medicinal cannabis is legal in 28 states and Washington, D.C. *Recreational cannabis is legal in 18 states, Washington, D.C., and Guam. *California, *Oregon, *Alaska, *Maine, *Nevada, Hawaii, *Colorado, *Montana, Michigan, *Arizona, North Dakota, Florida, Arkansas, *Vermont, Rhode Island, *New Mexico, *New Jersey, Delaware, *Massachusetts, *Connecticut, New Hampshire, *Illinois, *New York, Minnesota, Maryland, Pennsylvania, Ohio, *West Virginia.
Permissible activities	Some states only allow acquisition of pharmaceuticals, while others allow cultivation for personal use, and others use a dispensary model.
Permitted forms of Cannabis	Resins, extracts, oils, edible products or dried plant.
Content/Potency	Varies from 0.3% to 5% THC and 5% to 15% CBD, depending on the state, others may have higher degrees of THC
Point of sale	Clinics and pharmacies
Requirements	Medical prescription indicating recommended dose.
Prohibition/Sanction	The amount that can be possessed is determined by the physician.

Regulatory body:

Depends on EU member state



Europe

Enabling Law	Individual member states regulations.
Date approved	2003 - Present in certain member states (pilot programs in Denmark & Ireland).
Medical/recreational	Certain forms of cannabis is legal in Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Lithuania, Luxemburg, Macedonia, Malta, Moldavan, The Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, San Marino, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom, Ukraine only for medicinal purposes.
Permissible activities	Varies from cultivating, manufacture, marketing, transport, import, export, possession, supply, acquisition, and use.
Permitted forms of Cannabis	In some countries pharmaceutical products containing cannabis derivatives and THC are permissible. While in others only the use of Marinol or Sativax are approved.
Content/Potency	Varies from THC- content of below 0.2% to 5 g to Marinol only, depending on the EU state member.
Point of sale	Mostly pharmacies.
Requirements	Medical prescription with recommended dose, by a licensed physician.



Asia



In Asia medicinal cannabis continues to be prohibited in Japan, Vietnam, Pakistan, Cambodia and Nepal. However, there have been positive developments in several countries of the region.

In India, provisions for some legal regulations for the medical and scientific use of the plant have been introduced, however they are yet to be applied. In addition, the 2015 Phytopharmaceutical Act was created to expedite research on plant-based medications in the field of medicinal cannabis.

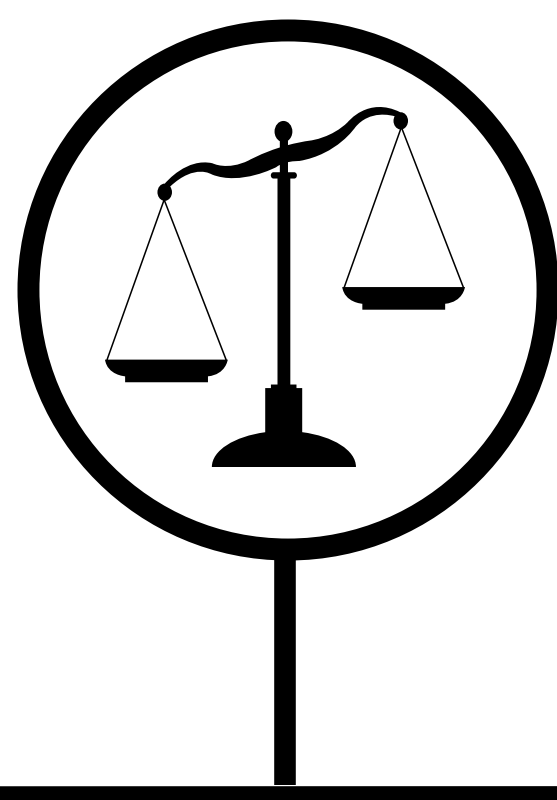


In the Philippines the House Committee on Health approved the *Medical Compassionate Medical Cannabis Act* in September 2016. The law forbids the use of cannabis in its raw form and requires users to obtain prior authorization from a doctor. The Philippine Drug Enforcement Agency is in charge of the regulation and distribution of medicinal cannabis, which can be used to treat a variety of conditions such as arthritis, epilepsy, and multiple sclerosis. The measure also proposes to establish a medicinal cannabis research facility.



Meanwhile, in Thailand, a public discussion was held in August 2016 to remove cannabis from Category 5 of the country's drug regulations, and the Agricultural Council was tasked with developing a proposal for the substance's decriminalisation for consideration by the government. On January 1, 2017, hemp was decriminalised in 15 districts and six provinces of the northern area.





2021 and 2022 Global Regulation Changes to Cannabis



France Legalizes Medical Cannabis Cultivation

An amendment to the French legislation the "Journal officiel de la République française" now permits cannabis cultivation for medical purposes as of March 1.

German Pharmacopoeia Drafts for Cannabis Substances

The Expert Committee for Pharmaceutical Biology has proposed the following revisions to reagent descriptions for inclusion in the DAB: Cannabinol/Cannabidiol *RN*, Cannabidiolsäure *RN*, Delta-8 & Delta-9-Tetrahydrocannabinol *RN*, Delta-9-Tetrahydrocannabinol-Säure *RN*.

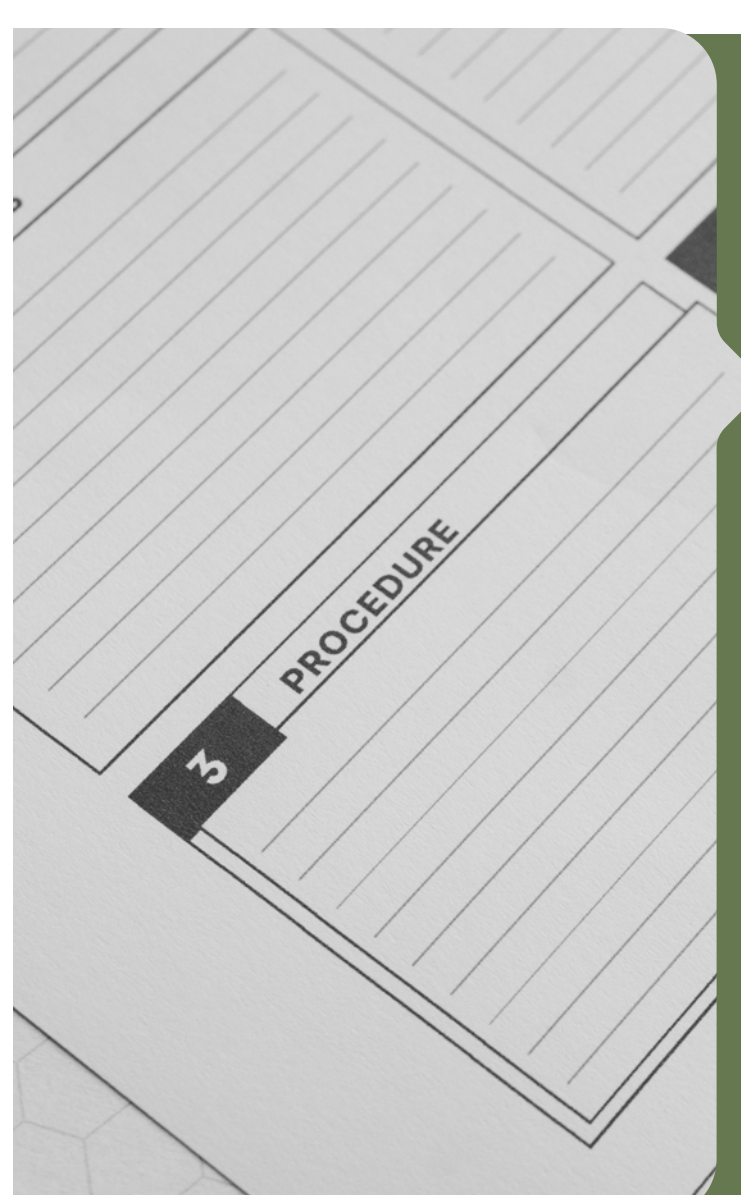


EU Herbal Monograph for Cannabis

The Herbal Medicinal Products Committee (HMPC) of the European Medicines Agency (EMA) has released a number of actions relevant to regulatory requirements for medical cannabis. This includes exploring the viability of establishing a Cannabis herbal monograph in the EU.

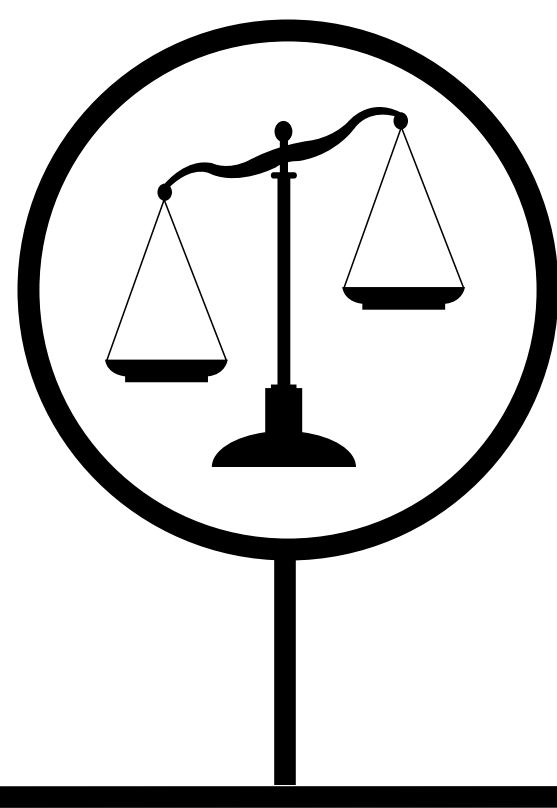
Ph. Eur. Cannabis Monographs

The HMPC has identified three new Ph. Eur. Monographs for Cannabis Flower and Extracts where harmonization may be of interest: Cannabis flos (3028), Cannabis extractum siccum (3068), Cannabis extractum spissum (3069). The drafts are expected to be published for public feedback in [Pharmeuropa](#).



USP Draft Monograph for CBD

There is no USP monograph for Cannabidiol (CBD) at the moment. As a result, a new USP monograph for CBD is being created. The proposed monograph was published in the January 2022 issue of Pharmacopeial Forum (PF) 48(1). The deadline for submission of comments was March 31, 2022.



2021 and 2022 Global Regulation Changes to Cannabis

Canada & ISO to develop Global Cannabis Standards



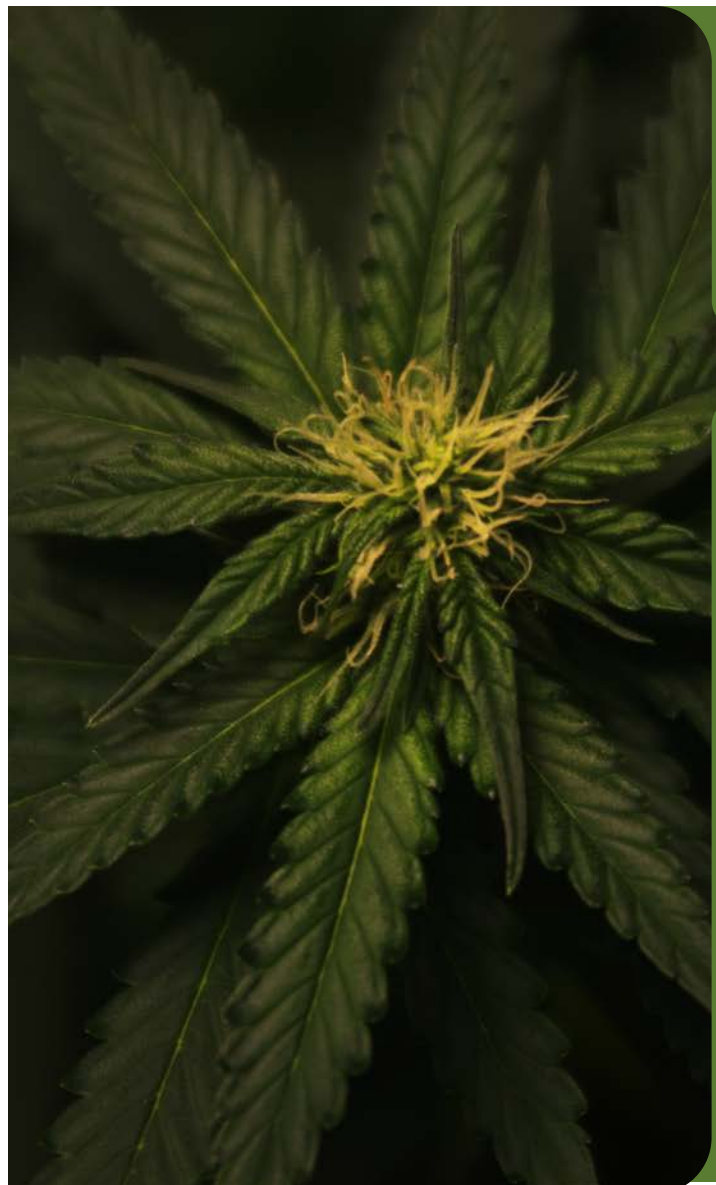
The Standards Council of Canada & ISO to develop guidelines for the global legal cannabis market to address the Good Production Practices, safety, security, and sustainability of buildings, facilities, equipment, and systems used for cannabis cultivation, production, processing (oil extraction), transportation and sale.

Medical Cannabis in Panama

Medical cannabis became legal in Panama on October 2021, permitting for its use for therapeutic, medical, veterinary, scientific, and research purposes. Imports, exports, cultivation, manufacturing, storage, transit, and distribution are all subject to the law's monitoring and regulation.



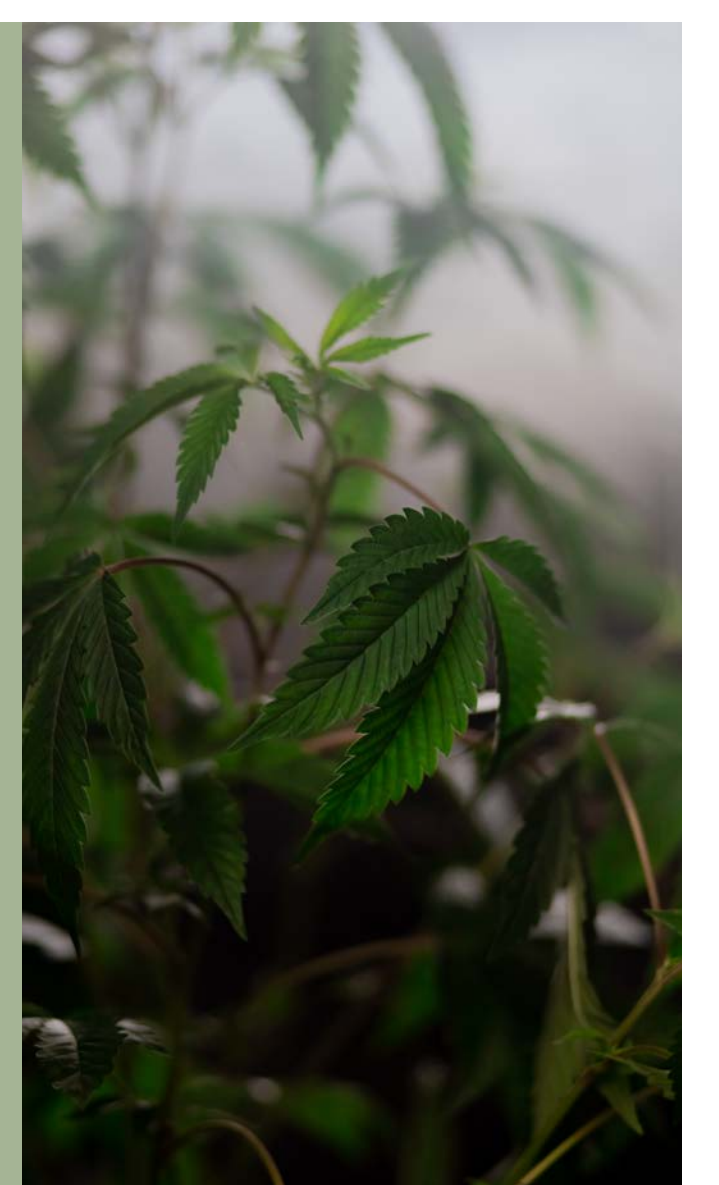
ANVISA List of approved Cannabis Products



The Brazilian Health Regulatory Agency (ANVISA) introduced cannabis products that will be automatically approved for individual importation. Imports continue to be subject to inspection by competent authorities at ports, airports, and borders, and certain documentation is required to be presented.

Medical Cannabis in Malta

Malta's Medicines Authority issued a document outlining broad guidelines for cannabis cultivation for medical and research purposes. Before cannabis production activities may begin, the agency states that production applications must be completed and the licence and EU-GMP certificate must be obtained.



Asia-Pacific Roundup: TGA changes medicinal cannabis approval process, plans further reforms



The Therapeutic Goods Administration (TGA) has revised the application process for medicinal cannabis products under Australia's Special Access Scheme (SAS) and Authorised Prescriber scheme.

Dalton's *Services*

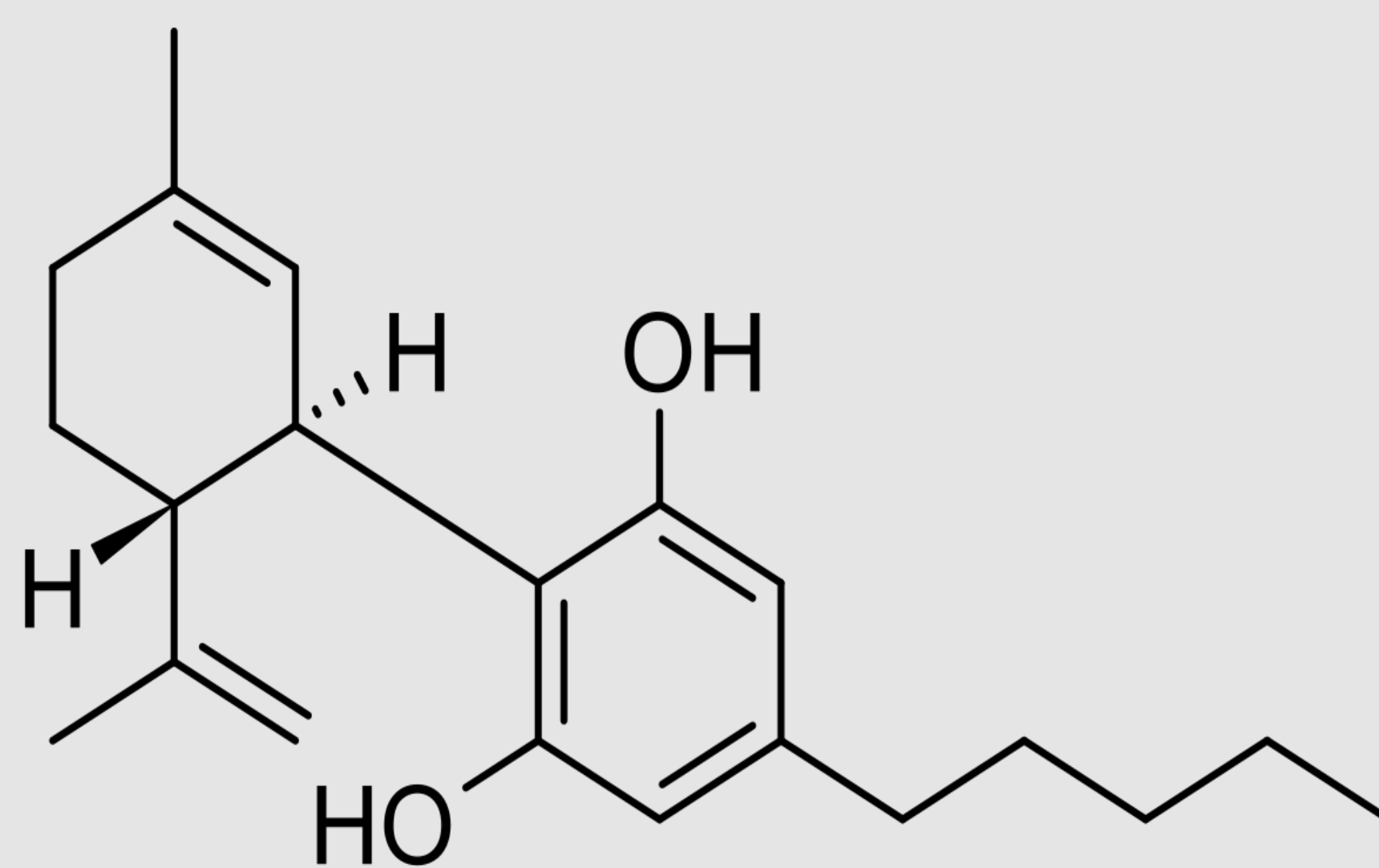


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- Synthetic route development
- Feasibility studies & tech transfer
- Process optimization & scale-up
- Scale-up troubleshooting
- Engineering batches
- cGMP API manufacturing



Dalton is Health Canada licensed to manufacture, test, and package complex pharmaceutical products for global markets. US FDA inspected; Dalton manufactures commercial products for the USA. The MRA (Mutual Recognition Agreement), recognizes Health Canada Licensed facilities in seven countries.



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References



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