The International Regulation of Medicinal Cannabis

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The regulation of medicinal cannabis worldwide is both complex and internationally inconsistent. This article provides a brief introduction and overview of the regulatory framework for the production, manufacture, distribution and supply of medicinal cannabis in different international jurisdictions.

1 CANADA

1.1 Governance

Drugs and controlled substances are primarily regulated by the Controlled Drugs Substances Act (S.C. 1996, c19) (**CDSA**), the Food and Drugs Act (R.S.C., 1985, c.F-27) (**FDA**) and their related regulations. Cannabis is not an approved therapeutic drug in Canada and thus remains a controlled substance scheduled under the CDSA and a narcotic subject to the Narcotic Control Regulations (C.R.C., c.1041).

Health Canada (**HC**) is the primary governing body for the Canadian medicinal cannabis industry.[1] It conducts regular inspections of licensed producers to verify their compliance with the standards set out by the Access to Cannabis for Medical Purposes Regulation (SOR/2016-230) (**ACMPR**) - a set of regulations for the production and distribution of medicinal cannabis - and penalises any party acting in contravention to.[2]

1.2 Production and distribution

Pursuant to the CDSA, cannabis is a Schedule II substance. This means that activities relating to its production and possession are illegal except by licensed producers with import permits[3] granted by the Office of Medical Cannabis, which is a HC department.[4]

The ACMPR allows for the licensing of 'eligible persons'[5] to produce and distribute cannabis for medicinal purposes. In addition to the requirements of the ACMPR, licensed producers are required to comply with all applicable provincial, territorial and municipal legislation and regulations, including zoning restrictions. Producers who are authorized to produce and supply 'eligible cannabis products'[6] may only sell or supply those products to eligible persons, who are typically another licensed producer, licensed dealer, the Minister or an exempt person.[7]

Notably, access to cannabis for medicinal purposes is only permitted under the terms and conditions set out in the ACMPR, any unauthorised activities are considered to be criminal offences and are subject to the penalties set out in the CDSA. Storefront operations selling

[1] *Compliance and Enforcement of Marihuana for Medical Purposes Regulations*, 2015, Health Canada, http://www.hc-sc.gc.ca/dhp-mps/marihuana/compliance-conformite/index-eng.php, viewed on 5 April 2018
[2] *Medical Cannabis Industry*, 2016, MMJ Phytotech, http://www.mmjphytotech.com.au/medical-cannabis-industry/industry-overview/, accessed on 5 April 2018.
[3] ACMPR, regulation 95.
[4] CDSA, Schedule II.
[5] ACMPR, subdivision B.
[6] *Ibid*, regulation 22(3).
[7] *Ibid*, subdivision A.

cannabis – *i.e.* dispensaries and compassion clubs – are not authorized to sell cannabis for medicinal or any other purposes.

There are currently 34 producers licensed by HC.

1.3 Eligibility

Under the ACMPR, a healthcare practitioner can possess, authorise access to and supply cannabis for medical purposes.[8] Once a health care practitioner has provided the relevant medical document, a patient may register with a licensed producer to obtain medicinal cannabis products (up to a 30-day supply only) for their own therapeutic use.

Notably, a patient with the relevant medical documentation can register[9] with HC to produce a limited amount of cannabis for their own therapeutic purposes, or designate[10] someone to produce it for them. Once registered, individuals will be allowed to produce a limited number of plants based on a formula that takes into account the individual's daily dose requirements (*i.e.* as authorized by their physician) and the average yield of a plant under certain growing conditions, such as indoor or outdoor growing.

2 ISRAEL

2.1 Governance

Israeli law defines cannabis as a dangerous drug. The Ministry of Health Medical Cannabis Unit (**MCU**) is the primary governing body regulating the use of cannabis. The MCU is responsible for issuing patients with permits to use cannabis for therapeutic purposes,[11] providing various medicinal cannabis related research bodies with permits in order to support scientific research into medicinal cannabis and managing cannabis regulation through a variety of government departments such as Health, Customs, Police and Agriculture.

In any arrangement regarding the use of medicinal cannabis, the parties involved are required to comply with the laws imposed under the Dangerous Drugs Ordinance (1973), as well as the provisions of the Single Convention on Narcotic Drugs 1961.[12] It is unlawful to use cannabis recreationally without a licence from an approved physician (see below) and without the relevant permits.

2.2 Production and distribution

In order to cultivate and supply cannabis for medicinal purposes, domestic producers must be licensed by the Israeli Ministry of Health.[13] Growers are required to deliver their produce to a logistics centre operated by a company partly controlled by the government to ensure compliance. It remains unlawful to export cannabis from, Israel and notably, Israel does not import cannabis due to financial viability.[14] In response to high demand internationally,

[8] ACMPR, regulation 7.
[9] *Ibid*, Part 2.
[10] *Ibid*, regulation 178.
[11] Medical Cannabis Unit, 2018, Ministry of Health, Israel, http://www.health.gov.il/English/MinistryUnits/HealthDivision/cannabis/Pages/default.aspx, accessed on 5 April 2018.
[12] *Ibid*.
[13] NSW Parliamentary Research Service, 2014, *Medical cannabis issues backgrounder*, No. 5, NSW Parliamentary Research Service, Sydney.
[14] EverBlu Capital Research 24 November 2017, *Cannabis Industry Report,* www.everblucapital.com/wp-content/uploads/2017/11/EverBlu-Research-Cannabis-Industry-Report.pdf, accessed on 5 April 2018.

Israel's cannabis producers have lobbied for the removal of restrictions surrounding exportation of domestically-produced medicinal cannabis.[15]

2.3 Eligibility

Only certain kinds of patients can apply for a medicinal cannabis permit in Israel, that is, in order to be eligible you must suffer a qualifying condition which includes, *inter alia,* cancer, HIV/AIDS, chronic neuropathic pain, PTSD and epilepsy.[16] Applications for a medicinal cannabis permit must be submitted by a specialist physician, who is specialised in the diagnosed area for which treatment is sought. Applications from general practitioners will not be approved.[17] Applications are then examined by a senior doctor in the MCU and a decision to grant or reject the permit is made. Upon receiving an approval, the permit will be issued and transferred to the supplier, who will then contact the patient to coordinate instructions and supply.[18]

Once a patient is authorised, they are able to access medicinal-grade herbal cannabis products such as cannabis oil extracts, edibles and smokeable dried plant matter. The use of other derivatives is expressly prohibited in order to ensure product quality and the user's safety.[19] Israeli patients are also able to receive compensation for medicinal cannabis from most health insurance providers.

3 UNITED STATES

3.1 Governance

Cannabis is classified by the federal government as a Schedule I controlled substance, meaning that it is classified as having no accepted therapeutic benefit and a high potential for abuse. Because of this classification, researchers interested in medicinal cannabis must first obtain a licence from the Drug Enforcement Agency (DEA), and then apply for access to the supply kept by the National Institutes of Drug Abuse (NIDA) for research purposes. Additionally, they must comply with all applicable state and municipal laws.

In the US, cannabis use is illegal for any reason, with the exception of research programs approved by the US Food and Drug Administration. However, individual states have enacted legislation permitting exemptions for various uses, mainly for medicinal and industrial use. Notably, 29 states have already legalised medicinal cannabis and 8 states in total - including Colorado, Oregon, Washington, California and Alaska - have legalised it for recreational use as well.[20]

Each state regulates and authorises access differently. For example:

a) for a patient to obtain access in Washington, they must get a Medical Marijuana Authorisation from a marijuana-authorised healthcare practitioner and join the medical marijuana authorisation database to get a medical marijuana card;

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[15] Victorian Law Reform Commission, 2015, *Medicinal Cannabis*, 32, Victorian Law Reform Commission, Melbourne: 128.
[16] State of Israel, *Ministry of Health Application to hold and use cannabis,* https://www.health.gov.il/English/Services/Citizen_Services/Pages/kanabis.aspx, accessed 10 April 2018.
[17] *Ibid.*
[18] *Ibid.*
[19] Victorian Law Reform Commission, 2015, *Medicinal Cannabis*, 32, Victorian Law Reform Commission, Melbourne.
[20] EverBlu Capital Research 24 November 2017, *Cannabis Industry Report,* www.everblucapital.com/wp-content/uploads/2017/11/EverBlu-Research-Cannabis-Industry-Report.pdf, viewed on 5 April 2018.

b) in Colorado, the Colorado Medical Marijuana Registry allows patients with qualifying, debilitating medical conditions to receive an identification card for legal access to medical marijuana; and

c) in Oregon, the Medical Marijuana Act allows the cultivation, possession and use of marijuana by a doctor recommendation for patients with specific medical conditions.

4 AUSTRALIA

4.1 Governance

Within Australia, the Commonwealth and each individual state and territory government plays a role in the regulation of medicinal cannabis.

The Commonwealth Department of Health regulates medicinal cannabis products through the Office of Drug Control (**ODC**). The ODC is responsible for regulating controlled substances and administers the *Narcotic Drugs Act* 1967 (**ND Act**) so that Australia may satisfy its international obligations under the United Nations Single Convention on Narcotic Drugs 1961. With regard to medicinal cannabis, the ODC grants licences and permits for cultivation, production and manufacture of cannabis for medicinal purposes. Importation of medicinal cannabis products can only occur with an import licence and permit issued by the Drug Control Section (**DCS**) of the Therapeutic Goods Administration (**TGA**).

Additionally, the TGA is responsible for the administration of the *Therapeutic Goods Act* 1989 (**TG Act**) and related subordinate legislation. Under the TG Act, all medicines must be registered or listed in the Australian Register of Therapeutic Goods (**ARTG**) before they can be supplied, unless they are exempt. As most medicinal cannabis products are not entered in the ARTG, they must be supplied via exemption pathways under the TG Act – such as the Authorised Prescriber Scheme (**APS**) or Special Access Schemes (**SAS**).

In addition to the above-mentioned Commonwealth level of regulation, each state and territory has its own bureaucratic layer of regulation specific to, *inter alia,* medicinal cannabis. Notably, each state and territory differs in its regulatory requirements regarding possession, manufacture, distribution and supply of medicinal cannabis products and it is often the case that both Commonwealth and state/territory authorisation is required before dealing with medicinal cannabis products in any manner.

4.2 Production and distribution

The ODC has authority to issue licences and permits with regard to cultivation, research (medical and scientific) activities and commercial supply of medicinal cannabis. The Commonwealth controls the cultivation of cannabis to the exclusion of the states and territories. However, each state and territory has its own process and procedures, administered by their respective health authorities, for the issuing of authorities, licences and permits associated with the possession, manufacture, research into or supply of medicinal cannabis. Accordingly, a state or territory licence/permit/authority as well as the relevant Commonwealth licence is required in order to possess, manufacture and/or supply medicinal cannabis in most jurisdictions in Australia.

Cannabis and cannabis-based products remain excluded, in Australia, from personal importation as cannabis continues to be a prohibited substance under the *Customs Act 1901* (Cth). Accordingly, a person wishing to import medicinal cannabis must apply to the DCS for both a licence and a permission to import.

The exportation of cannabis products was recently enabled by the *Narcotic Drugs Amendment (Cannabis) Regulations 2018* (**Regulations**), which were introduced to facilitate

the possible exportation of medicinal cannabis products manufactured either under the TG Act or the ND Act. At a simplistic level, the need for separate export pathways under the ND Act and TG Act arises because there are effectively two categories of "manufactured" medicinal cannabis products comprising:

a) products which have been manufactured under a manufacturing licence issued under the ND Act; and

b) products which have been prepared for patient access through standardisation of cannabinoid content and conformance with good manufacturing practices (**GMP**) under a manufacture licence granted under the TG Act.

4.3 Eligibility

Medicinal cannabis was rescheduled as a controlled (Schedule 8) drug in the Standard for the Uniform Scheduling of Medicines and Poisons (**Poisons Standard**) on 1 November 2016. As a result of this change, medicinal cannabis can be prescribed as a controlled drug by an authorised medical practitioner. However, the prescription of medicinal cannabis in a particular jurisdiction depends on whether and how the state or territory has chosen to adopt the change to the scheduling of cannabis.[21]

As previously mentioned, in order to access most medicinal cannabis products at a Commonwealth level, they must be supplied via exemption pathways under the *Therapeutic Goods Act 1989* (Cth). The SAS is the predominant exemption pathway whereby a medical practitioner can provide an unapproved medicine to individual patients who are classified as either Category A or Category B patients.[22]

Category A of the SAS applies to patients suffering from a terminal or life-threatening condition. Supply to Category A patients does not require prior approval from the TGA, and is a notification pathway only. This recognises the urgently in Category A patients being able to obtain access to potentially life-saving, life-preserving or life-enhancing medicine.

Category B of the SAS is an approval pathway accessible if adequate clinical justification exists for the prescription of the unregistered medicine. This pathway requires the prescribing doctor to submit an application seeking prior approval to the TGA, including evidence supporting the use of the unregistered medicine, in this case medicinal cannabis.

Notwithstanding the SAS schemes described above, most states and territories have independent legislation in force which effectively neuters the TGA's granting of SAS access to medicinal cannabis. This is because the states and territories require, in most cases, their own separate authorisations or approvals before access can be granted. For example, states such as Queensland require most medical practitioners (unless meet the narrowly defined definition in Queensland legislation of an 'patient-class prescriber' who is prescribing an 'eligible medicinal cannabis product' to a narrowly defined 'eligible patient') to submit an application to both the TGA and Queensland Health for authorisation to prescribe medicinal cannabis products. This duplication in red tape serves no purpose other than to delay access to medicinal cannabis.

Promisingly, however, the COAG[23] Health Council reached agreement on 13 April 2018 to streamline access to medicinal cannabis by developing a single entry point for both the

[21] Australia Government Department of Health, *Therapeutic Goods Administration Access to Medicinal Cannabis Products* https://www.tga.gov.au/medicinal-cannabis-products-overview-regulation, accessed on 10 April 2018.
[22] https://www.tga.gov.au/form/special-access-scheme, accessed on 10 April 2018.
[23] Council of Australian Governments, comprising the Commonwealth and state and territory governments.

Commonwealth and state and territory approval processes for unregistered medicinal cannabis products.[24] This process will eliminative duplicative decision-making regarding clinical appropriateness, but responsibility for appropriate management of access will remain with the states and territories.

It is pertinent to note, therefore, that the relevant state and territory health authorities essentially have the final say in any decision to supply medicinal cannabis within their respective jurisdictions. Accordingly, in order to supply medicinal cannabis products, eligible prescribers and suppliers (typically doctors and pharmacists), will require authority from the relevant state/territory authorising body.

Furthermore, notwithstanding the comprehensive application and assessment processes at both the Commonwealth and state/territory levels, in order to import a relevant medicinal cannabis product, a Commonwealth licence and permit is required.

5 EUROPE

5.1 GERMANY

The German cabinet unanimously approved a medicinal cannabis law in 2016, which came into effect on March 2017. Medicinal cannabis is legal with special permission from the Federal Institute for Drugs and Medical Devices and, accordingly, the drug is available to "seriously ill" patients on a case-by-case basis. It is also possible to obtain a special permission by the "Federal Institute for Drugs and Medical Devices" to obtain, possess and consume cannabis as a part of medically-supervised and accompanied self-therapy. Cannabis cultivation and possession may be permitted to scientific institutions or administrative bodies.

Germany has planned, in 2019, to create a state-regulated program to cultivate cannabis for its medicinal use in the future and to ensure its quality. Until domestic supply can keep up with demand, Germany is turning to Canadian companies to import cannabis products for patients.

5.2 UNITED KINGDOM

Currently, medicinal cannabis is illegal – with the exception of the rarely prescribed (NADAQ-listed GW Pharmaceutical's) Sativex – with cannabis classed as a Schedule 1, Class B drug in the UK. Home growing for medicinal use is illegal and patients are strictly prohibited from importing medicinal cannabis into the country, even if it has been legally obtained in another country.

In October 2017 the Legalisation of Cannabis (Medicinal Purposes) Bill 2017 - a Bill to allow the production, supply, possession and use of cannabis and cannabis resin for medicinal purposes - was introduced to Parliament. The Bill is due to have its second reading debate on Friday 6 July 2018.

5.3 THE NETHERLANDS

The Dutch Government has established the Office of Medical Cannabis (**DOMC**) as the primary organisation responsible for the production of cannabis for medicinal and research purposes. The DOMC controls all supply to licensed research facilities, pharmacies and practitioners, as well as all import and export activities relating to medicinal cannabis

[24] https://www.coaghealthcouncil.gov.au/Portals/0/CHC%20Communique%20130418.pdf, accessed on 13 April 2018.

products.[25] Applicants for licences granted through the DOMC are subjected to a review of financial reports and additional security screening to determine any ongoing or potential illegal activities. The adoption of such a framework aligns the Netherlands with Article 28 of the Single Convention on Narcotic Drugs (1961).

Production and Distribution

The DOMC is responsible for delivering medicinal cannabis to pharmacies and overseeing the distribution from pharmacies to eligible patients who have received approval from their practitioners.[26] Notably, unlike other jurisdictions, producers are restricted from selling to the market directly.

The Dutch government procures cannabis from a single authorised agricultural company, Bedrocan BV, who is under contract with the DOMC. Bedrocan is ISO9001 certified and also adheres to the Code of Good Manufacturing Practice (**GMP**). Similarly, the company's production procedure is in compliance with the guidelines set out by the internationally recognized Good Agricultural Practice (**GAP**) standards.[27] The quality and safety of the final products are guaranteed through mandatory testing by certified laboratories. The final products are then provided to patients, in their raw form, via pharmacies for those with a valid doctor's prescription.

Bedrocan is permitted to export its produce through the DOMC. Countries including Finland, Germany and Italy have all imported from the Netherlands (produced by Bedrocan). Patients from these regions can obtain prescriptions from their doctors and provide them to a pharmacy, which then applies for an import licence from their home jurisdiction to be approved by the Dutch government.

Eligibility

Medicinal cannabis is available on prescription only, recommended mainly for the treatment of, *inter alia,* chronic neuropathic pain, multiple sclerosis, cancer and HIV/AIDS. It can be dispensed by all Dutch pharmacies. There is no limit to the amount of cannabis a doctor can prescribe. Physicians will usually start by recommending a small dose and may increase the dose as necessary. Permission to use medicinal cannabis is at the doctor's discretion; however the standard of the prescription issued must comply with the conditions stated in the Dutch-Opium law. [28] Smoking cannabis is actively discouraged due to health concerns, so once granted access, patients are recommended to use medicinal cannabis in the form of tea or inhalation after vaporisation.[29]

[25] CIBG Minsterie van Volksgezondheid, Welzijn en Sport *Office of Medicinal Cannabis,* https://english.cannabisbureau.nl/import-and-export, accessed on 10 April 2018.
[26] < https://english.cannabisbureau.nl/>, accessed on 10 April 2018.
[27] Victoria Law Reform Commission, 2015, *Medical Cannabis: Issues Paper, Victorian Law Reform Commission*, Melbourne: 123.
[28] *I am a doctor: how do I prescribe cannabis?* 2011, Dutch Association for Legal Cannabis and its Constituents as Medicine, http://ncsm.nl/english/practical-considerations/how-to-prescribe-cannabis, viewed on 10 April 2018.
[29] *Medicinale Cannabis Informatiebrochure voor artsen en apothekers*, 2009, Ministerie van VWS en Instituut voor verantwoord, http://www.ncsm.nl/english/the-dutch-medicinal-cannabis-program/bedrocan-bv-cannabis-grower, accessed on 10 April 2018.