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Medicinal cannabis policies and practices around the world

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Abstract

The global debate about the regulation of cannabis has intensified in recent years, and jurisdictions have increasingly amended their legislation to allow for the medicinal or therapeutic use of the plant. Various countries in the Americas have enacted policies that enable patients to access certain types of preparations to alleviate symptoms, reduce pain or improve their quality of life. However, although all these experiences can be considered as progress, not all regulatory regimes are equal, and not all reforms will have the same impact. This paper aims to enhance our understanding of the state of reforms and their potential, as well as offer some general recommendations in an effort to improve public policies where legislation has already changed and inform decision-making processes where the reform is still pending.

Introduction

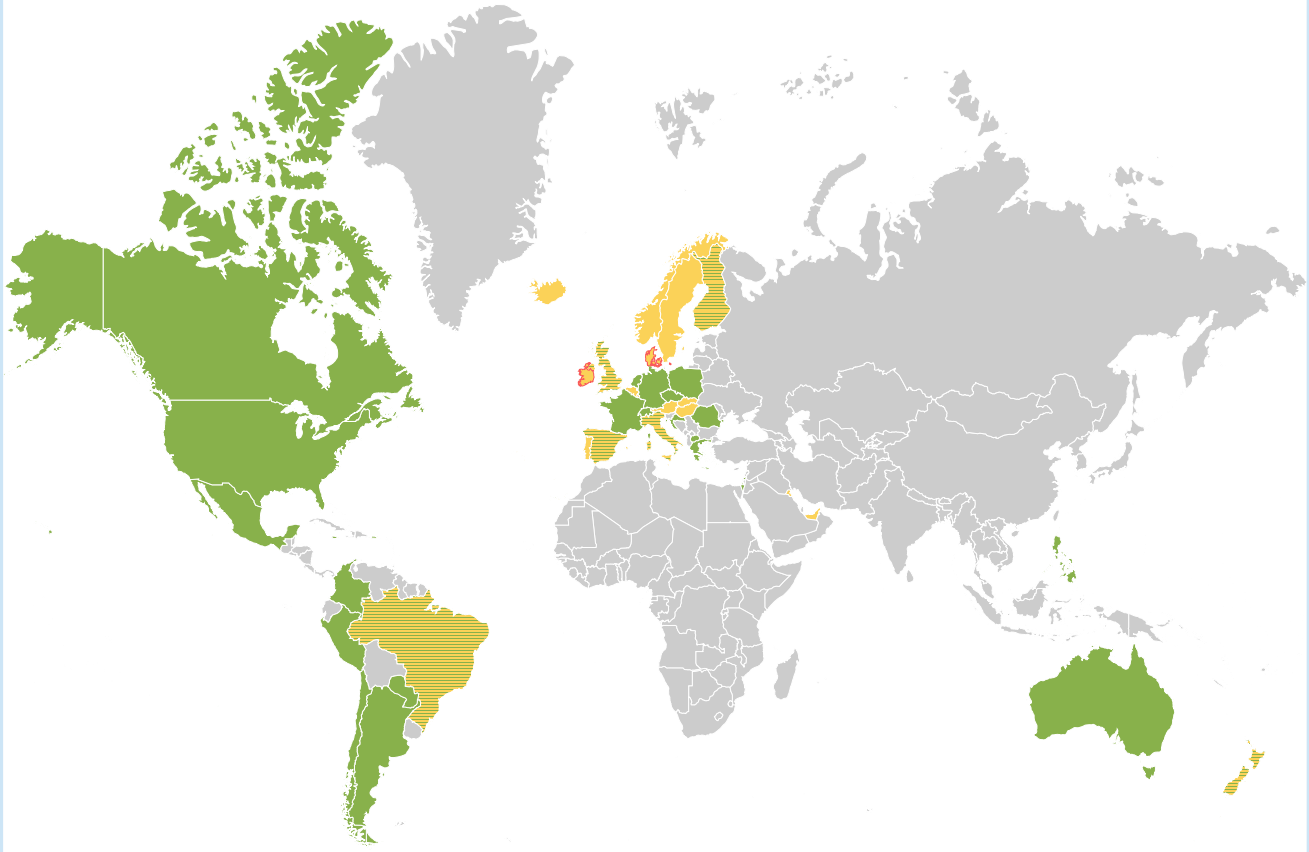
Although cannabis remains a prohibited substance worldwide, in recent decades a series of political, legislative and judicial processes in various parts of the world have given rise to various forms of legal regulatory regimes for the medical and therapeutic use of the plant. This trend seems to be consolidating in the Americas, in particular in Latin America and the Caribbean, where the largest number of available experiences is concentrated, and where the regulatory changes are occurring successively, in a sort of domino effect.

Although this progress is not exclusive to Latin America, and is still far from being a won battle, there is a clear shift in the global drug policy debate, particularly on cannabis. A variety of factors played a role here, including the growing availability of scientific evidence, the inability of the international drug control regime to accommodate and respond appropriately to new evidence, the emergence of a new public health paradigm in the area of drugs, the adoption of alternative policies at local level – sometimes at the expense of the international legal framework – and the growing perception that the costs of the 'war on drugs' far outweigh its benefits.

Unfortunately, and despite the growing number of regulatory experiences, the world has not yet reached a consensus on how to proceed, and continues to resist any possibility of activating the legal and institutional mechanisms within the scope of the United Nations to adapt the current treaty framework to this new situation. The United Nations General Assembly Special Session (UNGASS) on the 'world drug problem' in 2016 was the clearest example of the reluctance to openly discuss cannabis and its regulation.[5] Although it occurred at a historic moment – when the legalisation of medicinal cannabis was already a reality in 16 countries (or 40 jurisdictions if US states are counted individually) – the Outcome Document of the global summit[6] made no mention of the issue, or even acknowledge its existence.

It is in the midst of this contradiction that the legal regulation of medicinal cannabis is currently moving ahead. However, as with all innovative approaches, major obstacles remain in terms of its acceptance and of the restrictions imposed by the rigid international legal framework. Indeed, although medicinal cannabis per se is not prohibited under the UN drug control conventions, the inclusion of the substance in Schedule IV of the 1961 Single Convention on Narcotic Drugs restricts medical research and strict rules must be followed to allow the medicinal and scientific use of the substance. The lack of internationally sanctioned scientific consensus on medicinal cannabis is also a major issue, with no standardised or consistent products being used worldwide. These and additional factors which will be described in this paper have resulted in wide-ranging policies, requiring a certain

Figure 1 Map of countries in which medicinal cannabis is available



Medicinal cannabis regulated
Argentina, Australia, Brazil, Canada, Chile, Colombia, Croatia, Czech Republic, Finland, France, Germany, Greece, Israel, Italy, Jamaica, Macedonia, Mexico, the Netherlands, New Zealand, Peru, the Philippines, Poland, Puerto Rico, Romania, Spain, Switzerland, United Kingdom, United States, Uruguay

Nabiximols (Sativex) authorised
Austria, Belgium, Brazil, Denmark, Finland, Hungary, Iceland, Ireland, Italy, Kuwait, Liechtenstein, Luxemburg, Malta, New Zealand, Norway, Portugal, Slovakia, Spain, Sweden, United Arab Emirates, United Kingdom

Pilot projects on medical cannabis
Denmark,[7] Ireland

degree of compromise (when done at the sub-national level, for example), and governed by a diversity of norms and institutions. Inevitably, the scope and impact of these policies vary greatly.

As will be discussed below, all experiences are different, and no international or regional standards currently exist. While the regulation of medicinal cannabis in Uruguay resulted from government policy and coexists with licit recreational use in a clear effort to improve public health, in countries like Argentina, Brazil and Mexico, timid legislative reforms responded to citizen initiatives which, for lack of political support, only managed to open the minimum space necessary to comply with court orders and allow the importation of pharmacological preparations produced abroad. Meanwhile, North America is silently consolidating industrial-commercial models of regulation. Although not immune to political backlash and court decisions, Canada and the United States are now at the vanguard of scientific innovation, while also meeting clear revenue-collection goals, and providing a solid basis to expand recreational and industrial systems.

This report precisely highlights this diversity of experiences, approaches and directions. The purpose of this analysis is to enhance our understanding of the current state of reforms and the lessons to be learned from them. Although the authors have done their utmost to gather as much information as possible, this paper does not claim to be comprehensive review but rather a selection of key models of medicinal cannabis being developed around the world as of March 2018. Based on the findings, we offer general recommendations, in an effort to improve public policies in areas where legislation has already changed, and inform decision-making processes in countries where reform is still pending.

Definitions

Cannabis

Before describing the various regulatory models, and the differences between them, it is important to recall the basic definitions of 'cannabis' enshrined in the international drug control regime, in particular in the 1961 Single Convention on Narcotic Drugs:[8]

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'.

Based on these definitions, different controls were established over the plant and its components and for determining the various behaviours to be prohibited. These definitions also laid the grounds for the gradual stiffening of prohibition – transcending the original meaning of 'cannabis', 'cannabis plant' and 'cannabis resin' to also include their main psychoactive component, tetrahydrocannabinols (THC). As will be explained below, these definitions also serve to understand why the use of cannabis was historically strictly limited to scientific purposes – even to the detriment of its legitimate use for medicinal purposes – and how, even today, the arbitrary invalidation of its therapeutic properties continues to determine the scientific evidence and regulatory possibilities available to UN member states.[9]

Medical and scientific purposes

Although 'medical and scientific' purposes are mentioned at least a dozen times in the 1961 Single Convention on Narcotic Drugs, its Article I does not specify what this means for signatory states – even within the general obligations which establish that 'the Parties shall take such legislative and administrative measures as may be necessary […] to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs'.[10]

With this interpretation left to the discretion of the parties,[11] what is indeed considered to be for 'medical and scientific' purposes has remained undefined until the International Narcotics Control Board (INCB) offered some clarity in its 2003 report:[12]

- **Medical purposes**: 'a medicine (medicinal substance; that is, whether synthetic and/or natural, pure or in the form of a preparation) is a substance used, designed or approved for the following medical purposes: (a) Improving health and well-being; (b) Preventing and treating disease (including the alleviation of symptoms of that disease); (c) Acting as a diagnostic aid; (d) Aiding conception or providing contraception; (e) Providing general anaesthesia'.
- **Scientific purposes:** 'The designation of the use of a drug for "scientific purposes" is appropriate when it is used as a tool for investigating mechanisms of health or disease or when investigating the use of a product as a medicine. In patients, the investigation would be done as part of a clinical trial, which requires prior approval from the research ethics committee'.

Returning to the treaty framework, and adding another layer of complexity, it should be recalled that the therapeutic properties of a substance are a decisive factor in permitting – or not – its medicinal use. Therapeutic potential is therefore used as a criterion for differentiating the types of controls established for a substance, depending on the schedule in which it is classified. That said, according to the conventions, 'therapeutic' use is not synonymous with 'medicinal' use; and resolving what would appear to be a false dichotomy – since all medical usage is, in principle, therapeutic – has not been easy. Indeed, the international community continues to resist discussing 'therapeutic' uses as these would entail the existence of specific requirements for the control of pharmaceuticals (i.e. products for medical use).

This semantic distinction affects the legal machinery of states because it separates between uses that may be included under the regulatory regime for licit usage and uses that will be excluded from such a regime. Beyond this separation, the use of this terminology also has a direct impact on the type of regulations established following a legalisation process in terms of permitted behaviours (such as the sale of drugs, medical prescription or home-growing for personal use), the types of products available (pharmaceuticals only or also 'traditional medicines' and preparations), possible health controls, access (health clinics, postal order, pharmacies or social clubs) and even the price at which the plant or its derivatives can be acquired.

Before going into this discussion, we will first turn back to the conventions and recall the origins of international cannabis prohibition, and explain how the possibility of recognising the therapeutic and medicinal use of the plant and its components was gradually eroded with the inclusion of different definitions of cannabis in the diverse schedules of the drug control treaties.

Cannabis prohibition in the treaty framework

Cannabis prohibition first appeared in the international agenda in an annex to the 1912 International Opium Convention. Italy – with support from the United States – guaranteed that its concern over use of '*cáñamo índico*' would be recorded for posterity, and would later be included in the 1925 Geneva Convention.[13] However, it was not until the approval of the 1961 Single Convention on Narcotic Drugs[14] that cannabis was internationally prohibited, and classified in Schedule I of the treaty. This schedule, which also includes heroin, establishes particularly strict controls over substances considered as 'very addictive', with a potential for 'abuse' and/or used as 'precursors' for other drugs.[15] Cannabis was also added to Schedule IV of the 1961 Convention, recognising a limited or non-existent therapeutic value to the plant. Under this Schedule, cannabis regulation for medicinal and scientific purposes does not violate treaty obligations so long as it follows the rules of articles 23 to 28 of the Single Convention.

This level of prohibition was eventually imposed at multilateral level despite protests from countries such as India, Mexico, Myanmar and Pakistan, all of which attempted to defend the traditional use of cannabis and its legal control, arguing that available evidence at the time showed the medicinal benefits of the plant and little potential for dependence – compared to other substances. The case of India is particularly notable here, as the country played an important role in keeping any reference to the leaves and seeds of cannabis out of the 1961 Convention – enabling India to maintain the traditional and religious uses of *bhang* (a cannabis preparation used at traditional and religious celebrations).[16]

With the failure of all efforts to avoid the inclusion of cannabis in Schedules I and IV of the Convention, a single caveat survived on the use of some pharmaceutical preparations and 'indigenous medicine'. Unfortunately, at the same time that cannabis had fallen under prohibition, the terms 'indigenous medicine' and 'traditional uses' were eliminated from the Convention, limiting legitimate uses to medical and scientific purposes only.[17]

The next phase in the prohibitionist regime came a decade later with the adoption of the 1971 Convention on Psychotropic Substances. The Convention created four levels of classification. THC (the main psychoactive component of cannabis) was listed in Schedule I and described as 'a substance for which control is recommended because it may be abused and pose a particularly severe risk for public health and because its therapeutic value is very limited or inexistent'.[21]

Box 1 The INCB position on the medical and scientific use of cannabis

In its 2014 Annual Report, the INCB clearly recognised medicinal cannabis programmes and enumerated a number of criteria that must be respected for the implementation of such programmes.[18] In June 2017, the INCB published an 'alert' on the therapeutic use of cannabis,[19] in which it noted that a growing number of governments were authorising the medicinal use of cannabis, concluding that the practice was indeed permitted by the 1961 Convention, under several conditions. These include:

- The need for governments to produce estimates of anticipated consumption, which must be submitted to the INCB with details about the number of people using the substance for therapeutic purposes.
- If cannabis cultivation for medicinal purposes is planned, the government is required to submit details to the INCB about the geographic area where cultivation will take place. The process must be supervised by a national cannabis agency.[20]

The 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances completed the global prohibition regime by classifying as criminal offences – under the legislation of States parties – the production, manufacture, supply, distribution, sale, transportation, import or export of any narcotic drug or psychotropic substance, as well as the cultivation of the cannabis plant for the purpose of producing drugs, and the possession or acquisition of any narcotic drug or psychotropic substance for the purpose of any of the aforementioned activities. However, it is worth noting here that consumption was excluded from the list of criminal behaviours.

To summarise, the original prohibition which only recognised limited medical and scientific value for cannabis was followed by another wave of prohibition which classified its main active ingredient as a psychotropic drug and failed once again to acknowledge its therapeutic value. A wide range of behaviours were then defined as criminal offences, further limiting the plant's medicinal uses in the international drug con-

trol framework, and the creation of legal channels for its production, supply and consumption for medical and therapeutic purposes.

As a result, medical and scientific research fell behind, the stigmatisation of people using cannabis became institutionalised, and the number of possible state responses towards cannabis was reduced to criminal justice interventions. Nevertheless, the past decades have seen a growing body of evidence from patients, doctors and scientists demonstrating the benefits of cannabis for treating symptoms and/or the side effects of illnesses such as cancer, anorexia and HIV/AIDS. This has led to a revival of the debate over the potential regulation of cannabis and, with it, the first wave of regulation.[22]

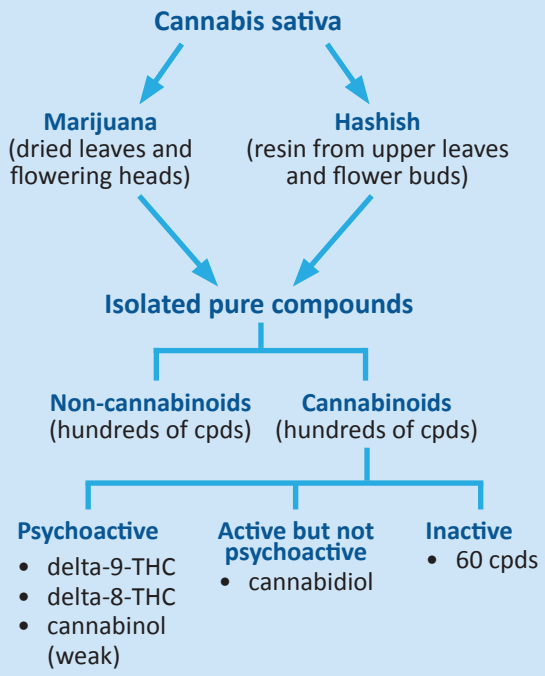
The state of medical and scientific evidence

The cannabis plant has been used as a medicine for thousands of years to treat various illnesses.[23] Its flowers concentrate hundreds of different chemical compounds which produce pleasant reactions, feelings of relief and health improvements for patients suffering from a range of illnesses, when coming in contact with the endocannabinoid system in the human body. THC and cannabidiol (CBD) are the best known and most studied of the more than 100 compounds exclusive to the plant, which are known as cannabinoids. However, new properties for other cannabinoids are constantly being discovered; for example, terpenes and avonoids have also been shown to have therapeutic properties.[24]

The INCB has recognised the medicinal properties of cannabis.[25] In addition to modern medicinal usages, cannabis is also used in 'traditional' or 'alternative' medicine, including in Persian, Siddha, Ayurvedic and Unani medicine for treating various ailments. A review of available scientific evidence[26] supports the potential therapeutic use of cannabis in:

- Neurological diseases:[27] multiple sclerosis,[28] and epilepsy,[29] with preliminary evidence that cannabis may have beneficial effects on Alzheimer's disease,[30] Huntington's disease[31] and Tourette syndrome.[32]
- Diseases and symptoms of the digestive tract and nutritional status: with conclusive evidence of the beneficial effects of cannabis for the treatment of side effects during chemotherapy for cancer (especially for nausea and vomiting)[33] and those associated with HIV/AIDS;[34] and preliminary evidence for ulcerative colitis and Crohn's disease;[35] decrease in gastric secretions, regulation of the lower oesophageal sphincter, inhibiting its relaxation and therefore reflux;[37] decrease in gut motility; decrease in intestinal secretions; control of visceral sensation; action in intestinal inflammation; and action in intestinal motility dysfunction.[38]
- There is conclusive evidence of the positive health effects of cannabis on chronic pain[39] mainly of neuropathic origin.[40] In some US states, access to medical cannabis also led to a reduction in the use of conventional opioid pain medication.[41]
- Drug dependence and mental health problems:[42] with preliminary evidence on the use of cannabis as substitution therapy for opioids,[43] stimulants (particularly cocaine)[44] and alcohol;[45] as well as to address anxiety,[46] post-traumatic stress disorders[47] and sleeping disorders.[48]

Figure 2 Relationships between crude cannabis products and pure cannabinoids



Source: Kalant, 2001[36] (cpd = compound)

It is worth noting here that the findings described above were made against the tide of the current prohibitionist policy. As such, doctors, patients and scientists were faced with many obstacles, including:

- A plethora of biased studies supporting moralistic positions based on insignificant samples or flawed methodologies
- The necessity of relying on possibly contaminated plants for research, since most are derived from the illicit drug market

- The risk of persecution or legal sanctions for researchers found in possession of, or transporting, the substance – although thankfully these cases remain rare
- The bureaucracy associated with conducting clinical trials involving medicinal cannabis
- The lack of financial resources allocated to research and investigation on medicinal cannabis.

Another common problem regarding the acceptance of the therapeutic values of cannabis is that absolute and irrefutable evidence is demanded on the positive effects of cannabis as a medicine, which is not necessarily the case for approving and prescribing other medications. Indeed, whenever a study challenges or contradicts research showing evidence of medical usage for cannabis, this research is immediately side-lined. On this point, it is worth highlighting that the general criterion used for a medication is its *efficacy* within an *acceptable risk* – these risks can generally be minimised by optimising the quality of the product, the conditions of use, dosage, the form of administration and its formula – all of which are impossible to achieve so long as the substance remains prohibited.[49]

Medicinal cannabis around the world

According to the INCB, the 'licit use of cannabis has increased considerably since 2000. Since then, more and more countries have started to use cannabis and/or cannabis extracts for medical purposes, in addition to scientific research. In 2000, total production was 1.3 tons; by 2015, it had increased to 100.2 tons'.[50] Reported requirements for 2017 indicate further growth to nearly 160 tons.[51]

The existing experiences of establishing policies enabling access to medicinal cannabis are varied and the different processes that led to these policies can generally be categorised as follows:

- Individual cases defended in the courts which set precedents, or sentences that are applied generally, as was the case in Mexico and Canada
- Direct democratic processes, such as referenda and popular consultations like in several US states
- Legislative and public policy processes led by national or sub-national governments, as in Uruguay and other US states
- Companies developing medicinal cannabis and demanding that government authorities facilitate its licit use, for example in the UK.

Figure 3 Scientific review of cannabis by the United Nations

The World Health Organisation (WHO) Expert Committee on Drug Dependence (ECDD) is the UN entity responsible for conducting a scientific assessment of psychoactive substances and recommending their possible inclusion in the schedules of the international drug control conventions or recommend changes in existing scheduling for listed substances. Cannabis has never been reviewed by the ECDD and, as noted above, remains controlled in the most restrictive Schedules of the 1961 Convention. Nevertheless, the discussion has been advancing at the ECDD over the past three years. At its 38th session in 2016, the ECDD decided to conduct a pre-review of cannabis and related substances, to be discussed in a special session in June 2018.[52] IDPC considers this review as highly positive and calls on the ECDD to take account of the wide range of available evidence on the therapeutic uses of cannabis at its meeting in June 2018.

Apart from the decision-making process, other factors can influence the type and impact of the various regulatory experiences. These include the kind of society in which the cannabis debate occurs, the degree of development of its educational and academic institutions, the number of professionals dedicated to studying the issue, the existence of an organised civil society, the historical and cultural relationship with the plant, whether or not there are areas where cannabis is already being produced in a country, demand for cannabis and its derivatives for medicinal or therapeutic purposes, and the public policy goals pursued.

This can explain the wide range of responses from countries to the demand for medicinal cannabis use, which may be economically liberal like in the United States, or profoundly statist in the case of Uruguay (where public institutions handle all activities related to the production, processing and sale of cannabis). The experiences also differ with regards to defining medicinal use, the types of products considered as medicines (for example, some countries only authorise pharmaceuticals such as Sativex, while others allow herbal or non-pharmacological preparations), whether cultivation for personal use or the use of ointments and oils is permitted, etc. It is also worth noting here that, even in cases of medicinal regulation, other forms of cannabis use remain prohibited, with its sacramental use only allowed in Jamaica and recreational use only permitted in Uruguay and some US states. Finally, other countries are

at the initial stage of the discussion, with proposed legislation under consideration in Costa Rica,[53] Cyprus,[54] Lithuania,[55] Luxemburg,[56] New Zealand,[57] Saint Vincent and the Grenadines[58] and South Africa.[59]

Latin America and the Caribbean: New leaders in medicinal cannabis reform

Latin America is currently the world leader in the promotion and adoption of policies allowing access to cannabis for therapeutic uses.

Uruguay is the first country in the world to completely legalise the cannabis market for medical and scientific purposes, as well as for industrial and recreational use. In this small country, the state – with support from the Institute for the Regulation and Control of Cannabis – determines who can produce cannabis, as well as how much and who can consume it, under which conditions. On the one hand, the regulatory regime for recreational use is based on issuing licences to individuals interested in planting, growing, harvesting, producing and commercialising cannabis, and includes several forms of access: self-cultivation for personal use, cannabis clubs or purchase in pharmacies. These are mutually exclusive, and the amount of cannabis that can be acquired is limited to 40g a month.[60] On the other hand, the regulatory system for therapeutic cannabis unfortunately continues to face various challenges, including the fact that the Ministry of Public Health does not authorise the domestic sale of medicinal cannabis.[61] As a result, patients wishing to access medicinal cannabis can only acquire it within the system created for recreational purposes (that is, by producing it themselves or accessing/purchasing a product that has not undergone all the scientific testing necessary for a medication). A person needing treatment with Sativex or Marinol must request an 'orange prescription' (the most restricted prescription) and fill out an application addressed to the Ministry of Public Health to obtain the permission to import the product from abroad. If the application is accepted, the cost of the product remains extremely high.[62]

The **Chilean case** is different, although in some ways similar to the Uruguayan experience. Although there was no reform of Law 20,000,[63] patients needing medicinal cannabis can access it via medical prescription (Decree 84 of the Institute for Public Health).[64] In special circumstances, cannabis-based medications can be authorised for import, applications must be sent to the health authority handling registrations. The regulatory agency is called ANAMED (*Agencia Nacional del Medicamiento)*. As the medication remains inaccessible in pharmacies, the medical prescription can be used as legal justification of medicinal use in court, which is allowed under article 4 of Law 20,000. This enables patients to grow plants at home (no specified number) or to be a member of a collective cannabis cultivation club, so long as the latter is regulated under Law 20,500 on non-profit citizen participation. In addition, a project led by the Daya Foundation, in conjunction with the University of Valparaiso, Farmacopea Chilena and Knop Laboratories, aims to develop a phytopharmaceutical that would be economically accessible.[65]

Other countries, such as **Colombia**, have also made some progress. Law 1787, approved in 2015, created a regulatory framework for medical and scientific access to cannabis, within which the state retains control over the market and grants licenses to private entities for production, manufacture, export, transformation and research.[66] When establishing the new regulatory framework, the government took into consideration the fact that cannabis was already being cultivated by subsistence farmers in some regions of Colombia – and the law requests licensed producers to buy their raw material directly from these small growers. This is an important move to incorporate the needs of existing small-scale cannabis farmers in the new policy framework. However, technical assistance is needed for small growers to be able to produce crops that meet the required criteria for medicinal cannabis. Medicines produced are phytopharmaceuticals and can be obtained in authorised pharmacies, without medical prescription. The government will aim to set a price that guarantees access for all. Colombia is currently the country that has registered the highest medicinal cannabis output with the INCB for 2018.

In **Jamaica**, cannabis for medicinal or therapeutic purposes must be recommended or prescribed by a registered physician or a health professional certified by the Ministry of Health. Import of cannabis products by patients is allowed as long as the physician certifies that the patient is suffering from an illness. However, very few practitioners prescribe cannabis as a medicine. Tourists or people who do not reside in Jamaica can apply for a permit that allows them to purchase and possess up to two ounces (56 grams) of *ganja*. To do so, they must present a doctor's prescription or sign a voluntary declaration stating their medical condition.[67]

With the first authorisations dating from 2014, **Brazil** has since allowed the importation of medications based on CBD oil, including THC and marijuana flowers in 2016, for medical and therapeutic use. However, the Brazilian Federal Medical Board prohibits the prescription by doctors of marijuana in its vegetal form – under exceptional circumstances. Import requires compliance with a series of requirements established by the

National Health Surveillance Agency (*Agencia Nacional de Vigilancia Sanitaria*, ANVISA). These include patients' registration, handling administrative procedures for import in person, and applying for a permit from the agency. The possibility of self-cultivation of cannabis for such purposes remains under discussion.[68]

Argentina, Peru and Mexico have also adopted other, less ambitious, regulatory processes. In those countries, reforms resulted from active pressure from civil society and patients' groups, leading to the approval of policies allowing for the sale and use of medicinal cannabis. In October 2017, **Peru** approved its 'Law regulating the medicinal and therapeutic use of cannabis and its derivatives',[69] which was signed by President Pablo Kuczynski on 16th November.[70] The law introduces the use of registries for the various groups who wish to access cannabis (i.e. patients, importers, research entities and public entities), and a system of government licences for research, importation, commercialisation and production. It is worth noting that the country has recognised the benefits of cannabis for the treatment of symptoms caused by diseases such as cancer or multiple sclerosis. However, the regulatory regime that will ensure legal access to the substance remains to be clarified.[71] In **Argentina**, meanwhile, a norm was issued that allows patients to import their medication while the state initiates the local production of pharmaceuticals for the domestic market.[72] In **Mexico**, the reforms to the General Health Law and the Criminal Code in 2017 now allow the use of cannabis for medical and scientific purposes. The Ministry of Health was ordered to issue a public policy on the matter to ensure that patients have access to pharmacological products with and without THC.[73]

Finally, **Bolivia** is the latest Latin American country to date to have amended its drug legislation to allow medicinal cannabis. Agreed within the framework of a broader drug legislation adopted on 16th March 2017,[74] individuals and companies must register and request a prior authorisation to the Ministry of Health for the import, export, trade or production of medicinal cannabis. Exceptional and limited authorisations may also be granted by the Ministry of Health for research on medicinal cannabis.

North America: Pioneer in the medicinal cannabis industry

The United States and Canada may be the most advanced countries in the development of a medicinal cannabis industry.

In the **United States**, 29 states[75] currently have a legislation allowing medicinal cannabis use, as well as the cultivation, production, processing, sale and taxation of cannabis and its derivatives. The United States is therefore a good example of mixed processes with mixed results – where both referendums and legislative processes responded to different needs and interests – reflecting an interesting melting pot of regulatory regimes that oscillate between those prioritising public health and those pursuing legitimate commercial ends and revenue-generating goals:

- 14 states have legalised medicinal cannabis by referendum: California in 1996; Washington, Oregon and Alaska in 1998; Maine in 1999; Nevada, Hawaii and Colorado in 2000; Montana in 2004; Michigan in 2008; Arizona in 2010; and North Dakota, Florida and Arkansas in 2016
- 15 states have taken the legislative route: Vermont in 2004; Rhode Island in 2006; New Mexico in 2007; New Jersey in 2010; Delaware in 2011; Massachusetts and Connecticut in 2012; New Hampshire and Illinois in 2013; Nueva York, Minnesota and Maryland in 2014; Pennsylvania and Ohio in 2016; and West Virginia in 2017.

In **Canada**, there are about 44 licensed producers authorised by the Ministry of Health,[76] as well as thousands of Canadians licenced to possess and consume medicinal cannabis. In both cases, self-cultivation is allowed so long as it does not exceed six plants and use can be justified.

Europe: Positive but limited steps

In Europe, alongside well-established models of medicinal cannabis as in the Netherlands, the past year has seen the adoption of various medicinal cannabis schemes, in particular in Greece, Poland and Slovenia. Other countries have been more cautious, focusing exclusively on pilot projects.

The **Netherlands**, meanwhile, legalised the medicinal use of cannabis in 2000, and created the Bureau for Medicinal Cannabis (BMC) creating a strong pharmacological industry – led by Bedrocan Medical Cannabis which has the monopoly of all medicinal cannabis production and distribution. All cannabis passing through the BMC is produced by Bedrocan – which developed and standardised domestic demand and export some of the five types of pharmaceutical cannabis flos (flower) medications prepared with different percentages of THC and CBD. Medicinal cannabis is produced nationwide and controlled by the Medicinal Cannabis Agency. It can be purchased in pharmacies for a number of pathologies, only when the patient is in possession of a medical prescription. Medicinal use has increased dramatically over the past decade, with over 50,000 patients now being prescribed cannabis in the Netherlands.

Germany has just completed the legislative reforms necessary to expand the medical use of cannabis. Before the new law passed in January 2017, patients could only gain access to medical cannabis through a special individual authorisation.[77] Germany is now one of the first countries in the world to include medical cannabis in the basic range of medications that must be covered by both private insurers and public health services.[78] A national Cannabis Agency was established under the Federal Institute for Drugs and Medical Devices (BfArM) to oversee the new process, as prescribed by the international drug treaties. The 2017 law also allows the development of domestic production of cannabis – although for now all cannabis medications continue imported, mainly from the Netherlands.

Elsewhere in Europe, a lack of integral regulation of medicinal cannabis in countries like the **United Kingdom** and the Czech Republic has hampered access to these medications for thousands of patients. In the former, the government only permits the use of Sativex for patients with multiple sclerosis, under medical prescription. The public health service in the United Kingdom has also established that every patient must pay for his or her medication, at a cost of about 500 euros a month.[79]

In the **Czech Republic,** although the country legalised medical cannabis in 2013, there is no clear process for acquiring licences to produce, sell or purchase products derived from cannabis. There continues to be uncertainty about the scope and potential of this reform, both for the welfare of the patients and for the development of an industry can contribute to a growth in available supply – which remains inadequate throughout the continent. As in the United Kingdom, the price of the medication is also an important challenge, since medicinal cannabis is not covered by the health insurance system.[80]

As stated above, several countries have recently moved ahead with reform in the area of medicinal cannabis. In **Poland**, for example, 1st November 2017 marked the first day on which medicinal cannabis could be sold in registered pharmacies. Patients need a special permission from a regional pharmaceutical inspector and a physician accredited by the Ministry of Health. The law only allows the importation of cannabis (mainly from the Netherlands), rather than domestic production or self-cultivation.[81]

Similarly, in **Slovenia**, as of February 2018, the Decree on the classification of illicit drugs (Official Gazette of the Republic of Slovenia, no. 45/14, 22/16 and 14/17) allows medical practitioners to prescribe cannabinoid-based drugs (synthetic, natural and the so-called medicinal cannabis), as well as standardised buds and flowering tops of cannabis (although the latter remains to be fully implemented in practice). This policy change required transferring cannabis from Group I to Group II in the list of illicit substances of Slovenia. The Ministry of Health is in charge of implementing the medicinal cannabis scheme.

On 1st March 2018 **Greece** adopted the bill 'Provisions for the Production of end products of medicinal cannabis'. It is noteworthy that the majority of parliamentary political parties supported the bill, although opposition parties voted against the bill in the final vote. The bill proposes that Greece's medical patients can access medicinal cannabis products, in recognition of their benefits for specific illnesses. It also proposes that individuals can cultivate cannabis for the sole purpose of producing medicinal cannabis products in the country. Finally, the bill recognises the economic potential of medicinal cannabis; with the creation of new jobs and the potential of exporting products to the international market.[82]

Finally, in other countries, medicinal cannabis is limited to pilot projects. In **Denmark,** for example, cannabis for therapeutic purposes is still illegal, but a pilot programme will begin on 1st January 2018 for a limited number of patients with specific health problems (i.e. multiple sclerosis, chronic pain and nausea).[83] Medicinal cannabis also remains illegal in **Ireland**, but some pilot projects are under way, and a bill was passed by the Dail (Irish parliament) in December 2016, although the law has not yet come into force.[84]

Israel: The Middle Eastern exception

Today, there are over 50 laboratories conducting research on medicinal cannabis in the various universities and academic institutions of **Israel**. The comprehensive scientific knowledge and exploration of opportunities for scientific and industrial development has led Israel to undertake reforms on cannabis that do not necessarily match with its approach towards other drugs. The country approved the medicinal use of cannabis in 1992 and soon became a centre for scientific research and development of cannabis varieties and industrial products. The legislation is implemented by a specially established unit in the Ministry of Health – the Israeli Agency on Medical Cannabis (IMCA), which established a steering committee in collaboration with the Israeli police, the Ministry of Agriculture and the Ministry of Economy, headed by one of the scientific leaders of the field: Prof Meshulam. The IMCA issues several types of licences for cultivation, extraction and packaging plants, and distribution. The IMCA is also responsible for the authorisation of special clinicians who are allowed to prescribe

cannabis to patients suffering from severe pain and a number of other symptoms. Additional illnesses can be treated in hospitals as part of clinical trials. By 2017, some 40,000 patients were receiving medicinal cannabis.

Asia[85]

Although Asia continues to be at the forefront of repressive drug policies, and medicinal cannabis remains prohibited in **Japan**, **Vietnam**, **Pakistan**, **Cambodia** and **Nepal**. However, there have been positive developments in several countries of the region.

In **India**, the law distinguishes two types of cannabis products: ganja (the flowering or fruiting tops of the cannabis plant) and charash or hashish (cannabis resin) – with regulations being more relaxed for the former. The country already has some legal provisions for the medicinal and scientific usage of the plant, but these provisions have yet to be implemented.[86] Since 2017, various political figures, including Maneka Ghandi and MP Dr. Dharamvir Ghandi, showed their support to cannabis policy reform. In the area of research on medicinal cannabis, the 2015 *Phytopharmaceutical Act* was passed to accelerate investigations on plant-based medicines[87] – a move that has the potential of attracting investments into cannabis research from large businesses.

In the **Philippines**, while President Duterte continued to wage his war on drugs across the country, the House Committee on Health approved the *Medical Compassionate Medical Cannabis Act* in September 2016.[88] The law prohibits the use of cannabis in its raw form, and stipulates that patients need prior authorisation from a doctor, and the treatment will be delivered in dedicated centres with a special licence from the Department of Health, in hospitals. The Philippine Drug Enforcement Agency is responsible for the regulation and dispensation of medicinal cannabis, which can be used to treat various ailments, including arthritis, epilepsy and multiple sclerosis, among others. The bill also plans to create a research facility on medicinal cannabis.

Meanwhile, in **Thailand** a public forum was held in August 2016[89] to remove cannabis from Category 5 of the country's drug legislation, and the Agricultural Council was tasked with developing a proposal for the decriminalisation of the substance for consideration by the government.[90] From 1st January 2017, hemp was decriminalised in 15 districts and six provinces of the northern region.[91]

Oceania: Australia making strides

There have been significant developments in **Australia** on the medicinal cannabis front in recent years. Since 2016 the country has a new national body that can issue licences to growers and regulate medicinal cannabis crops so that medicinal marijuana can be cultivated in Australia. Medical practitioners may supply a medicinal cannabis product to a patient after notifying the relevant regulatory authority and obtaining prior permission from the state or territory government department. This is done on a patient-by-patient basis and medicinal cannabis can also be used for clinical trials.

Some of the most profound changes have occurred at the state and territory level. The state of New South Wales first instigated wide-ranging medicinal cannabis trials and provides police with the power not to prosecute terminally-ill patients using cannabis for medical purposes. A small number of children with the worst case of drug resident epilepsy can also be prescribed medicinal marijuana under a compassionate access scheme.

Victoria was the first state to establish a state-based medicinal cannabis scheme allowing children with severe epilepsy to be provided with the drug. All of the other states and territories have schemes to enable access to medicinal cannabis via prescription for a range of conditions. Queensland developed the first guidance documents for health practitioners in March 2017. In December 2017, the Commonwealth produced the national guidelines for five conditions and published these on the Therapeutic Goods Administration website.

New Zealand also introduced the *Misuse of Drugs Amendment Bill* in December 2017 with the goal of making medicinal cannabis available without criminal liability.

Considerations for legislative reform

Among the country examples presented above (also see the Annex to this briefing), there is a wide range of mechanisms available to ensure access to medicinal cannabis:

1. Special individual licences to import and use medicinal cannabis, while maintaining overall prohibitions over the plant, but establishing exceptions to the law to ensure patients' access to cannabis (e.g. in Poland).
2. Regulation of supply through the creation of a licence system granted to individuals or private entities according to the type of activity they engage in (production, manufacture, export, processing, research, transport or sale), within which the state can play various roles – from central control to mere arbitration through regulatory bodies (e.g. in Colombia or Peru).[92]

3. Regulation of demand with mechanisms allowing legal access to medications or herbal cannabis preparations through: self-cultivation, cannabis clubs, postal order, sale in clinics or sale in pharmacies (e.g. in Uruguay for recreational, and by default, medicinal use).[93]
4. The design and implementation of public policies that regulate access to certain products, in compliance with the regulatory system in place for medicines (e.g. in Germany).[94]

Depending on the type of regulatory regime and how long it has been in place, various impacts have been identified on the ground – in addition to the evidence already mentioned above regarding the health benefits of medicinal cannabis:[95]

- The myth around increases in illicit cannabis use as a direct result of the implementation of medicinal cannabis regulatory regimes does not hold true, especially among adolescents for whom cannabis use prevalence has remained stable, in countries like the United States.[96]
- Similarly, the number of traffic accidents caused by acute cannabis intoxication has not increased noticeably in jurisdictions where the consumption of preparations with THC or herbal forms of cannabis is permitted.[97]
- There have been no recorded deaths caused by cannabis; on the contrary, the survival rate and quality of life of patients have improved.[98]
- There has been no sharp rise in crime – there is even evidence in some US states implementing a medicinal cannabis scheme that the crime rates have dropped by as much as 13%.[99]

Recommendations

The information available so far makes it possible to outline the following policy recommendations:

- Legalise cannabis for medicinal use, as well as medications and therapeutic substances derived from cannabis, for all ailments identified by scientific research, and not solely limiting access for a few arbitrarily determined illnesses.
- Immediately include medications derived from cannabis in the basic range of medicines – that is, without the need for judicial actions requiring the state to do so, and avoiding also the high costs that individual importation of such medication would involve for each specific case.[100]
- Reform the necessary laws to create and allocate budget to ensure the constant generation of scientific research.
- Coordinate all relevant agencies to streamline the various technical and sanitary processes that allow new medications to reach the market quickly, while always ensuring the highest possible standards for consumer health protection.
- Establish the mechanisms necessary to avoid the creation of monopolies or a restriction of the market to a few specific groups who would hold all patents and sale licences to the detriment of the health and economic welfare of the general population.
- Include the patients in decision-making processes related to the development of general legislation and regulations, so as to establish norms that respond to their needs in the context of each specific state.
- Avoid establishing arbitrary concepts (for example, the concentration of a particular psychoactive substance) that would affect access or result in the prohibition of a medication that contains those substances.
- Offer technical assistance to physicians, giving them the tools they need to understand both the benefits and the health risks of medicinal cannabis.
- Implement public education and awareness-raising campaigns for the general public and patients on medicinal cannabis.
- Every legislative measure should include domestic regulations for production, rather than be limited to the importation of products. The resulting regulatory regimes should also consider all measures necessary to promote the integration of existing small-scale growers and, insofar as possible, do so under conditions equal or more favourable to those granted to new permit-holders and/or capital-intensive foreign industry.
- Small-scale farmers involved in cannabis cultivation for subsistence purposes should be involved in the decision-making processes to enable the incorporation of their needs, and should receive technical assistance so they can participate in the 'business' of medicinal cannabis.

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ANNEX: Regulatory models for medicinal cannabis around the world

Argentina

Law	Law 27,350 on medical and scientific research on the medicinal use of the cannabis plant and its derivatives[101]
Date approved	19th April 2017
Generalities	Allows medical and scientific research
Production	Import until the country is able to establish a domestic industry, special permits for self-cultivation (but need to be registered in the National Voluntary Registry)
Product	Pharmaceuticals and oils
Content/Potency	Regulation to be issued soon
Restrictions	Restriction on all activities related to cannabis consumption without government authorisation
Points of sale	Not specified
Requirements	Physician determines what medication is appropriate, and issues a medical prescription
Prohibition/Sanction	3 to 6 years in prison for anyone providing amounts that do not correspond to medical prescriptions; administrative sanctions
Regulatory body	National Council of Scientific and Technical Research, National Institute of Agricultural Technology
Other	Requires the creation of a programme that determines rules

Australia

Law	Narcotic Drugs Act 1967 as amended by the Narcotic Drugs Amendment Act 2016[102]
Date approved	30th October 2016
Generalities	Access to medicinal cannabis can be granted by a medical practitioner on case-by-case basis, subject to regulatory and state and territory government approval. Cannabis material can be used to conduct clinical trials and for therapeutic products
Production	At the federal level, licences for cultivation are administered by the Office of Drug Control (ODC) within the Department of Health. Because the cultivation and manufacture scheme is new, sponsored import of medicinal cannabis products is allowed via the granting of licenses
Product	Rules relating to medicinal cannabis products vary between states and territories. A variety of products are currently available through import including raw (botanical) cannabis, which is vaporised but not smoked, cannabis extracts in oils, and solvent extracts such as tinctures, and oro-mucosal sprays. Some products for trans-dermal application (patches or topical application of gel or cream) have also been developed and can be imported. Similar products, manufactured from locally grown medicinal cannabis will become available this year
Content/Potency	Not specified
Restrictions	Patients cannot purchase medicinal cannabis or import it themselves. They must obtain it via a prescription from a medical practitioner
Points of sale	Must be prescribed by a medical practitioner and obtained via a pharmacy or hospital (arranged by the medical practitioner)
Requirements	See above
Prohibition/Sanction	Cultivating, distributing and selling cannabis outside of the legal system carries criminal penalties
Regulatory body	Office of Drug Control within the Federal Department of Health and the Therapeutic Goods Administration. Various state and territory government departments also have regulatory responsibility
Other	

Brazil

Law	RDCs ANVISA/MS nº 17/2015[103] and nº 66/2016[104]
Date approved	2014
Generalities	Recognises medicinal use. Importation, distribution and prescription of cannabis-based medications is permitted
Production	Allows import of pharmaceuticals containing cannabis
Product	Pharmaceuticals (Mevatil) and cannabis extracts
Content/Potency	Mevatil is a pharmaceutical with contents similar to those of Sativex
Restrictions	Limited to specific illnesses
Points of sale	Sale of Mevatil under license in pharmacies and import of cannabis extracts by authorized persons or entities
Requirements	Prescription from a legally authorised professional
Prohibition/Sanction	General consumption of unauthorised pharmaceuticals remains prohibited. Administrative and criminal sanctions for all behaviours involving unauthorised products
Regulatory body	Brazilian Health Regulatory Agency (ANVISA). Ministry of Health
Other	The Brazilian Federal Medical Board prohibits doctors from prescribing marijuana flowers in natura

Canada

Law	Controlled Drugs and Substances Act,[105] Access to Cannabis for Medical Purposes Regulations (August 2016)[106]
Date approved	1999
Generalities	Access to medicinal cannabis and research. Medicinal cannabis may be used for severe refractory nausea and vomiting associated with cancer chemotherapy; loss of appetite and body weight in cancer patients and patients with HIV/AIDS; pain and muscle spasms associated with multiple sclerosis; chronic non-cancer pain (mainly neuropathic); severe refractory cancer-associated pain; insomnia and depressed mood associated with chronic diseases (HIV/AIDS, chronic non-cancer pain); and symptoms encountered in the palliative/end-of-life care setting; etc.
Production	Licences for production and for self-cultivation granted by Health Canada
Product	Edible products, tinctures, oils, concentrates, capsules and sprays, dried flowers
Content/Potency	Not specified, depends on the individual and therapeutic needs[107]
Restrictions	It is recommended that pregnant women, people under the age of 25, or people with a history of psychosis, dependence problems, or cardiovascular or respiratory problems do not use medicinal cannabis
Points of sale	Postal system by a licenced agency
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
Regulatory body	Health Canada
Other	Subject to 'Taxes on Goods and Services'. Estimated price between CAD 7 and 12

Chile

Law	Law 20,000,[108] Decree 84[109]
Date approved	7th December 2015
Generalities	Allows therapeutic use of cannabis for a short amount of time. Special regulations established to grant licences, for control and oversight for industrial and commercial cultivation, as well as for scientific research or the elaboration of phytopharmaceuticals containing THC
Production	Self-cultivation is decriminalised, registries for cannabis pharmaceuticals, collective cultivation clubs and industrial production are authorised for medicinal usage and scientific investigation
Product	Cannabis flower, resin, extracts, tinctures, oils and tropical creams
Content/Potency	The state can authorise cannabis regardless of THC levels
Restrictions	Not recommended for use by minors, but access allowed as long as cannabis is not smoked and this requires a diagnosis from a medical practitioner
Points of sale	Access via cultivation for personal use and collective cultivation. There is no established maximum numbers of plants. The medical prescription indicates daily consumption in grams and has to justify medicinal use
Requirements	Medical prescription retained under inventory control
Prohibition/Sanction	Administrative and criminal sanctions in case of non-compliance with regulations
Regulatory body	SENDA
Other	

Colombia

Law	Decree 2467[110] and Resolution 1816[111]
Date approved	22nd December 2015
Generalities	Allows medical and scientific research
Production	4 types of licenses granted by the state: production and manufacturing, export, processing and research. Self-cultivation has been allowed since the 1986 *Estatuto Nacional de Estupefacientes*
Product	Cannabis resin, tincture, extracts and preparations
Content/Potency	Not specified
Restrictions	Prescriptions cannot be given to people dependent on drugs
Points of sale	In pharmacies
Requirements	Medical prescription required. Can be provided to minors under physician's care and with parents' permission
Prohibition/Sanction	Administrative and criminal sanctions in case of non-compliance with regulations
Regulatory body	Office of Control and Oversight of Chemical Substances and Drugs
Other	Does not generate tax revenue

Croatia

Law	
Date approved	October 2015
Generalities	Legal reform recommended by a medical committee established by the Ministry of Health in January 2015
Production	Importation by pharmaceutical wholesalers, distribution by the Institute of Immunology
Product	Pharmaceuticals, teas and ointments containing THC. Herbal products can also be used, as additional medicine, to treat tumours, AIDS, multiple sclerosis and epilepsy in children
Content/Potency	0.75 grams of THC per month
Restrictions	Medicinal cannabis cannot be used for people suffering from Parkinson's, ordinary epilepsy, depression and other psychiatric illnesses
Points of sale	In pharmacies
Requirements	Medical prescription by a general practitioner, with recommendation from a specialist. Prescription cannot exceed 30 days
Prohibition Sanction	Smoking or vaping cannabis is not permitted; cultivation for personal use is not allowed
Regulatory body	Ministry of Health responsible for deciding which medicines can be imported and consumed
Other	Importation of medicinal cannabis from Canada began in June 2016. Not covered by health insurance system

Czech Republic

Law	Criminal Code,[112] Acts No. 167/1998, 634/2004 and 378/2007
Date approved	2013
Generalities	Production, sale and consumption of medicinal cannabis are allowed, but only for a limited number of illnesses. Self-cultivation of up to five plants and up to 30 grams a month
Production	Domestic production and import are permitted
Product	Pharmaceuticals and herbal medicine
Content/Potency	Not specified
Restrictions	Only permitted by electronic prescription from specialist physicians, for patients with certain pathologies
Points of sale	In pharmacies which have acquired the medication from specialised, government-licenced companies
Requirements	Any domestic company can engage in production after obtaining licence
Prohibition/Sanction	Medications can only be imported from the Netherlands, because the only varieties that are legal for medical use are produced by Bedrocan
Regulatory body	Not specified
Other	In practice, no Czech company has yet received a permit to cultivate medicinal cannabis, so all medications in the country are currently imported from the Netherlands by Bedrocan. Medicinal cannabis is not covered by health insurance

Finland

Law	Cannabis included in the 'List of medicines' by FIMEA in section 83 of the Medicines Act (395/1987)[113]
Date approved	2008
Generalities	2012: Sativex authotised to be prescribed by a neurological specialist without a special permit. Other products (cannabis flos) can be used under special permission for one year at a time
Production	Import from the Netherlands (Bedrocan and Bediol)
Product	Sativex (spray)
Content/Potency	Not specified
Restrictions	Cannabis is only offered as an option when all other treatment options have failed; mostly for multiple sclerosis, but also in some instances for Parkinson's disease, rheumatism, cancer and chronic migraines
Points of sale	In pharmacy which requires a special permission from FIMEA (currently limited to two pharmacies)
Requirements	Medical prescription by a neurological specialist
Prohibition/Sanction	Not specified
Regulatory body	Finnish Medicines Agency (FIMEA), under the Ministry of Social Affairs and Health
Other	Number of patients who benefit from medicinal cannabis is currently limited to about 220 – and only about 20 doctors prescribe Sativex. Treatment is not covered by the national social insurance (Kela)

France

Law	Decree No 2013-473[114] (modifying Article R. 5132-86 of Public Health Code)
Date approved	5 June 2013
Generalities	Authorisation of medications containing cannabis or derived products, and their manufacture, transport, import, export, possession, supply, acquisition and use
Production	Possibility of production and manufacture of pharmaceuticals containing cannabis and THC if previously authorised
Product	Pharmaceutical products containing cannabis, derivatives and THC, with prior authorisation. Currently, only Marinol is approved. Sativax is approved by the ANSM, but no commercial agreement has yet been found with GW
Content/Potency	Marinol
Restrictions	Only medication which is authorised by the French or European Union government, under Regulation (EC) No 726/2004 of the European Parliament
Points of sale	To be defined under process of 'implementation authorisation'
Requirements	Temporary permission for use: special permission from a doctor for each patient granted by the National Health Products Agency (ANSM). Temporary permission for use must be renewed for each new prescription
Prohibition/Sanction	Illicit production, sale and use are punishable under the 1970 drug law
Regulatory body	National Agency for the Safety of Medicines and Health Products
Other	The only product currently available in France is Marinol, to treat central neuropathic pain, under temporary permission

Germany

Law	Narcotics Law
Date approved	19th January 2017
Generalities	Access to medicinal cannabis products for ailments such as epilepsy, multiple sclerosis, chronic pain or nausea, and for research
Production	Importation of cannabis from other countries until it can be replaced by domestic industrial production (expected in 2019). Self-cultivation is not allowed
Product	Pharmaceutical products, cannabis extracts or dried flower buds
Content/Potency	Same as contained in existing medications
Restrictions	Only as a last resort for certain pathologies
Points of sale	In pharmacies
Requirements	Medical prescription with recommended dose, by a licensed physician
Prohibition/Sanction	Limited to amount indicated on prescription
Regulatory body	National Ministry of Health and Federal Institute for Drugs and Medical Devices (BfArM)
Other	Medicinal cannabis is covered by the health insurance system

Greece

Law	Provisions for the production of end products of medicinal cannabis[115]
Date approved	1 March 2018
Generalities	Allows licensed businesses to cultivate and process cannabis for medical purposes
Production	Cultivated land must be at least 4,000 square metres in size and secured by fencing. Cannabis processing must take place within the same grounds where it is grown to avoid extra transportation of the drug. Applications for a licence must be accompanied by a certified title or lease or free concession, the copy of the person's ID card, criminal record, certificate of non-bankruptcy, tax and insurance briefing, certificate from the relevant police department
Product	Cannabis Sativa L and cannabis varieties containing more than 0.2% of THC
Content/Potency	Not specified
Restrictions	A licence cannot be granted to natural or legal persons whose management involves people who have been convicted of a felony, theft, fraud, bribery, etc., are being summoned by a final court orer of a felony, or are in custody
Points of sale	In licensed pharmacies
Requirements	Be at least 21 years old
Prohibition/Sanction	If the conditions for granting the authorisation are violated, the Ministers responsible will withdraw the licence, after a deadline of compliance of up to 30 days has been set. Trafficking illegally is punished by a prison sentence of at least 8 years and a fine of up to EURO 300,000
Regulatory body	Ministry of Health & Ministry of Agricultural Development and Food
Other	The stated benefits of this measure include: access to finished cannabis products for medical cannabis patients, job creation, economic benefits from the state

Israel

Law	Hazardous Substances Law
Date approved	1992
Generalities	Allows for medicinal cannabis and research with strict regulations for regulated companies headed by a pharmacist who needs to send a report on research conducted each year to the local pharmacy
Production	Cultivation and production under a licencing system from the Israeli Agency on Medical Cannabis (IMCA) granted to companies which comply with health standards
Product	Oil, capsule or flower
Content/Potency	CBD and THC potency varies depending on the medical condition, whether the person is an adult or a child, etc.
Restrictions	Between 30 and 40g a month, as established by permit determined by Ministry of Health
Points of sale	The patients pay a fixed monthly price which is independent of dosage. Distribution is through specially authorised dispensaries belonging to the growers or home distributers. It is planned that pharmacies will provide cannabis in the near future
Requirements	The patient has to send an application through a doctor, or can access via a doctor who already has a licence. The application should include the dosage for treatment. Alternatively, patients can access medicinal cannabis in hospital under clinical trial. Access restricted to chronic and severe pain related to cancer. For other diseases, treatment must be under clinical trial
Prohibition/Sanction	Administrative sanctions in case of non-compliance with health measures
Regulatory body	IMCA, under the Ministry of Health
Other	Millions of dollars have been invested in clinical research since 1990. Many research laboratories active in universities since 1960

Italy

Law	Decree[116] modifying Presidential Decree No. 309 (Law 309/90) of 9th October 1990 and its subsequent modifications[117]
Date approved	23rd January 2013
Generalities	Decree includes cannabis plant-based medicines in the list of soft drugs authorised for therapeutic and medicinal purposes under Law No. 309/90. Ministry of Health grants permits for cultivation for scientific and research purposes to university institutes and public laboratories
Production	Ministry of Health authorises production, manufacture, sale, export, transport and purchase, with an annual list of licensed enterprises. Initially, substances imported from the Netherlands by the Office of Medicinal Cannabis. Since 2016, local production in the Military Chemical Pharmaceutical Establishment in Florence[118]
Product	Cannabis plant-based medicines (including extracts and colorants), Dronabinol, Nabinol and Sativex (to reduce painful spasms from multiple sclerosis)[119]
Content/Potency	500 mg of THC, equivalent to 5 g of raw substance (active ingredient: 10%).[120] Cannabis FM-2 (which contains 5-8% of THC and 7.5-12% of CBD)121
Restrictions	Only used when conventional and standard therapies prove ineffective[122] for chronic pain, multiple sclerosis, spinal cord injury, nausea from chemotherapy, radiation treatment, AIDS treatment, cachexia, anorexia, loss of appetite in AIDS or cancer patients, anorexia nervosa, glaucoma, Tourette syndrome.[123] The prescription is valid only during the treatment phase, which cannot exceed three months[124]
Points of sale	In public pharmacies
Requirements	With a medical prescription which indicates the amount, dose, type of product and form of administration
Prohibition/Sanction	Fines, suspension and/or revocation of Ministry of Health permit. Military personnel from the Finance Guard conduct periodic checks. Ministry of Health sets quotas for manufacture (surplus must be subtracted from the next year's quota or incinerated)
Regulatory body	Each region and province must monitor prescriptions, provide annual data on patients to the Superior Health Institute, and inform the State Cannabis Organization of the amounts necessary for the next year
Other	

Jamaica

Law	Dangerous Drugs (Amendment) Act[125]
Date approved	24th February 2015
Generalities	Decriminalises possession and legalises cultivation for personal use for medical and spiritual purposes
Production	Under licences issued by the Cannabis Licensing Authority
Product	Extracts, nutraceuticals,[126] dried plant, edible products, pharmaceutical medications
Content/Potency	Distinction between high and low levels of THC, but both are permitted
Restrictions	Regulations being developed; proposals to limit distribution and promotion of products derived from cannabis
Points of sale	Pharmacies or tea houses
Requirements	Medical prescription
Prohibition/Sanction	Administrative sanctions in case of failure to comply with health regulations
Regulatory body	Cannabis Licensing Authority (CLA)
Other	Tourists with medical prescriptions can acquire medications

Macedonia

Law	Law on control of narcotic drugs and psychoactive substances
Date approved	Changes and additions from February 2016 and December 2017
Generalities	Regulates import, export, research, production and prescription of medicinal cannabis
Production	Imported and domestic industrial production. High requirements are set forth for the domestic production, such as 4 meters high fence topped with 3 levels of barbed wire, constant physical security and video surveillance, as well as mandatory specialized staff. Self-cultivation is not allowed
Product	Cannabis oil, ointment, suppositories and vagitories.
Content/Potency	Range of combinations of THC and CBD content. There is no upper limit of the potency defined in the Law
Restrictions	Products containing more than 0,2% THC can only be prescribed to patients with malignant diseases, multiple sclerosis, juvenile epilepsy syndromes and HIV
Points of sale	In pharmacies
Requirements	No prescription required for products containing less than 0,2% THC. Physicians can prescribe products containing more than 0,2% THC only upon recommendation from a specialist in oncology, neurology or infectiology working in a public hospital, and with a written consent from the patient
Prohibition/Sanction	An article of the Law for the first time criminalises possession of a controlled substance for employees in production plants who take out seeds, seedlings or leaves for personal use, contrary to the provisions in the Criminal code according to which possession and personal use are not sanctioned, and in direct violation of the Constitutional principal for legal security
Regulatory body	Varies for specific aspects of the Law: National Government, Ministry of health, Agency of medicines and medical devices, Ministry of agriculture, forestry and water, and Ministry of interior
Other	The indication areas and the specialist branches who can prescribe medical cannabis are defined with articles within the Law itself, therefore requiring parliamentary procedure for any future changes Market prices are too high for most patients and physicians are sceptical in prescribing cannabis products, leading to flourishing of black market and self-cultivation / production, as well as unsupervised treatment

Mexico

Law	General Health Legislation[127] and Federal Criminal Code[128]
Date approved	Approved: 28th April 2017 Published: 10th June 2017
Generalities	Allows medical and scientific research and medical prescription
Production	To be determined. To date, only individual importation of medications is permitted, but there is a mandate to create and promote a national medicinal cannabis industry
Product	Initially only pharmaceuticals. Specific products will be determined in enabling legislation
Content/Potency	To be determined
Restrictions	To be determined under secondary enabling legislation
Points of sale	To be determined
Requirements	Medical prescription, with state control over dispensing
Prohibition/Sanction	To be determined under secondary enabling legislation
Regulatory body	To be determined under secondary enabling legislation
Other	To be determined under secondary enabling legislation

Netherlands

Law	Dutch Opium Act (Opiumwet)[129]
Date approved	2001
Generalities	Access to medicinal cannabis, research and herbal medicine
Production	Cultivation and processing by Bedrocan under government supervision
Product	Standardised cannabis flos of pharmaceutical quality.
Content/Potency	Percentage of THC between <1% and 22%, percentage of CBD between <1% and 9%
Restrictions	Sativex and five different types of cannabis are available
Points of sale	In pharmacies
Requirements	Medical prescription issued by a certified physician
Prohibition/Sanction	Prohibition of cultivation for personal use remains in force; can only be acquired and produced with authorized agents. Non-compliance is punishable by prison
Regulatory body	Medicinal Cannabis Office, under the Ministry of Health, Welfare and Sport
Other	No insurance company covers the cost of treatment

New Zealand

Law	Regulation 22 of the Misuse of Drugs Regulations 1977[130]
Date approved	1977
Generalities	Allows the prescription of Sativex for spasticity related to multiple sclerosis and CBD. Ministerial approval required for other cannabis-based products to be prescribed, supplied or administered
Production	Produced in New Zealand (Emerge Health NZ Ltd)
Product	For now, only Sativex is approved by the Ministry of Health
Content/Potency	Oromucosal Spray 10 mL
Restrictions	Applications to the Ministry of Health for approval to prescribe a pharmaceutical grade cannabis-based product are only accepted if a number of criteria are fulfilled (application from an appropriate specialist, a manufacturer with the commitment to develop the pharmaceutical product, clearly described characteristics and formulation of the pharmaceutical product, completion of animal studies proving clinical benefits, etc.). Applications to the Ministry of Health for approval to prescribe a non-pharmaceutical grade cannabis-based product are only accepted if a number of criterial are fulfilled (severe or life-threatening condition, evidence that reasonably applicable conventional treatment have been trialled and the symptoms are still poorly controlled, evidence that the risk/benefit of the product has been considered by qualified clinical specialists, application from a specialist, adequate peer review sought, provision of Certificate or Analysis, patient or guardian has provided informed consent)
Points of sale	In pharmacy
Requirements	Prescription from a specialist physician who must conduct a thorough assessment of how bad the patient's spasticity is, and how it has responded to other treatment. The patient will then start a 4-week trial of Sativex after which the specialist does another assessment to see the impact of Sativex treatment. If there is significant improvement, treatment can continue beyond 4 weeks[131]
Prohibition/Sanction	Cannabis-based products remain Class B1 controlled drugs and Ministerial approval is required before they are prescribed, supplied or administered
Regulatory body	Ministry of Health
Other	

Peru

Law	Law No. 30681 which regulates the medicinal and therapeutic use of cannabis and its derivatives[132]
Date approved	16th November 2017
Generalities	Regulates the medicinal and therapeutic use of cannabis and its derivatives. Also authorises research, production, importation, commercialisation and informed use of medicinal cannabis
Production	3 types of licenses: 1) scientific research, 2) import and/or commercialisation, and 3) production, which is granted exclusively to public entities and laboratories registered with and certified by the Ministry of Health
Product	Cannabis and its derivatives
Content/Potency	Not specified
Restrictions	Restriction on all activities related to consumption of cannabis without authorisation from the Executive Branch through the Ministry of Health
Points of sale	Not specified
Requirements	Access by medical prescription. The Ministry of Health will create a registry of patients certified by the physician. The registry will include information about the illness, treating physician, dose and frequency of treatment. This registry will be confidential
Prohibition/Sanction	Non-compliance with regulations results in suspension or withdrawal of license. Sanction governed by the provisions of Law 30057, the Civil Service Law, and its enabling and complementary legislation
Regulatory body	The Ministry of Health; General Office of Medications, Inputs and Drugs; National Institute of Health and other agencies involved establish the conditions, requirements and process of production and supply of inputs for cannabis research, and issue permits
Other	Provision of the law to modify the criminal code, so that possession and commercialisation of cannabis and its derivatives are not punishable when the respective permit has been granted for medicinal and therapeutic uses or to registered persons

Philippines

Law	Philippine Compassionate Medical Cannabis Act[133]
Date approved	30 June 2016
Generalities	The law prohibits the use of cannabis in its raw form, and stipulates that patients need prior authorisation from a doctor, and the treatment will be delivered in dedicated centres with a special licence from the Department of Health, in hospitals. Can be used to treat various ailments, including arthritis, epilepsy, cancer, HIV, multiple sclerosis, among others
Production	Not specified
Product	Cannabis in its raw form is prohibited
Content/Potency	Not specified
Restrictions	Medical cannabis can only be accessed via a Medical Cannabis Compassionate Center, which is a licenced centre located in a hospital
Points of sale	Medical Cannabis Compassionate Center
Requirements	Can only be prescribed by a qualified medical cannabis physician, who has a personal knowledge of the use of medical cannabis, has a licence to prescrive drugs, has a doctor's degree in medicine and has a bona fide relationship with the patient
Prohibition/Sanction	Cannabis is a controlled substance, and possessing and smoking cannabis remains criminalised in the country. Any violation of the Act is punished by a fine and revocation of licences
Regulatory body	Department of Health
Other	Research facility created to investigate the effectiveness of medicinal cannabis

Poland

Law	State Emergency Medical Service Act
Date approved	November 2017
Generalities	The law does not mention specific illnesses, but authorises treatment for a variety of ailments, including chronic pain, side effects of cancer treatment, multiple sclerosis and refractory epilepsy
Production	Only importation; domestic production and self-cultivation are not permitted
Product	Pharmacies can process cannabis tinctures, resins, concentrates, oils and other non-herbal forms. Dried flowers can also be sold
Content/Potency	The law eliminates restrictions on THC in cannabis oil; patients can now acquire cannabis oil with a high CBD or THC content depending on their symptoms
Restrictions	The medication must be registered with the Office for the Registration of Medicinal Products
Points of sale	In registered pharmacies. Exception for patients who cannot acquire medicinal cannabis in Poland: they can visit one of the 13 EU member states where medicinal cannabis is legal to acquire their medication
Requirements	Special authorisation by a regional pharmaceutical inspector and a physician accredited by the Ministry of Health
Prohibition/Sanction	Not specified
Regulatory body	Office for the Registration of Medicinal Products, under the Ministry of Health
Other	Cost per gram of approximately 50-60 zl (13-16 US dollars) – approximately 2,000 zl (550 US dollars) per month

Puerto Rico (unincorporated territory of the United States)

Law	Law 42-2017 to Manage the Study, Development and Investigation of Cannabis for Innovation, Applicable Norms and Limitations (Medicinal Law)[134]
Date approved	9th July 2017
Generalities	Regulates investigation, cultivation, manufacture, laboratories, transport and distribution of cannabis
Production	Allows all stages of production through licences issued for specific activities
Product	Any compound, product, derivative, mixture or preparation from any part of the plant
Content/Potency	Only content not exceeding 0.03% of dry weight is considered for industrial use
Restrictions	Can only be prescribed by authorised physicians in accordance with state and federal laws
Points of sale	Authorised clinics which were granted a licence
Requirements	Prescription from authorised physicians recommending use of medicinal cannabis in accordance with Regulation 8766[135]
Prohibition/Sanction	Administration fines of up to US$100,000 per violation for any person failing to comply with the provisions of the law or its enabling legislation
Regulatory body	Regulatory Board of Medicinal Cannabis establishes every detail for regulations (forms of administration, medical issues, maximum period of treatment per condition, etc.)
Other	50% of the fines collected for violating this law and its regulations will be allocated to the operative budget of the University of Puerto Rico

Romania

Law	Law No 339/2005
Date approved	October 2013
Generalities	Cannabis derivatives can now be used to treat diseases such as epilepsy, cancer and multiple sclerosis, under strict regulations
Production	Cultivation of medicinal cannabis only by growers authorised by the Drugs Agency
Product	Cannabis derivatives, but not specified by the law
Content/Potency	No more than 0.2% THC
Restrictions	Manufacturers must have the approval of the National Agency on Medicines for products derived from cannabis
Points of sale	Medicinal cannabis is currently not available in the country
Requirements	Medical prescription
Prohibition/Sanction	Not specified
Regulatory body	National Agency on Medicines
Other	The lack of clarity in the law on regulations has, in practice, prevented implementation of the medicinal cannabis system

Switzerland

Law	Reform of the Federal Narcotics Act[136] (art. 8 modified by c. I of the FL of 20 March 2008, RO 2009 2623, 2011 2559, FF 2006 8141 8211) Law on therapeutic products[137]
Date approved	Reform approved: 20th March 2008, entered into force: 1st July 2011
Generalities	Federal Office of Public Health (OFSP) can grant exceptional permission[138] (since 2012) for cultivation, importation, manufacture, sale for limited medical use, scientific research and development of medications
Production	Domestic cultivation or importation of cannabis used to manufacture therapeutic products, with exceptional permission for products containing more than 1% THC Dronabinol is imported from Germany, under exceptional permission from the OFSP and permission from Swissmedic. Exportation of cannabis flos and cannabis products produced in Switzerland is authorised
Product	Magistral preparation (natural or synthetic extracts) and Sativex, but the flower is not allowed. Exceptional permission from the OFSP is needed for manufacture and sale[139]
Content/Potency	Therapeutic products which include synthetic THC (Dronabinol) or based on the cannabis flower, with variable THC and CBD potency
Restrictions	Only applications signed by a doctor authorised to work in Switzerland are allowed, to treat patients who are residents in Switzerland – the application should include information on the patient, the doctor, the disease, etc.[140] The OFSP is the entity responsible for providing exceptional authorisations for treatment
Points of sale	In pharmacies that have obtained special permission for manufacture and sale, or via postal order
Requirements	Medical prescription from a general practitioner who has obtained permission from OFSP Medical prescription of Sativex can be done without exceptional authorisation for moderate to severe spasticity due to multiple sclerosis for patients who have failed other treatments and have showed a clear improvement of their symptoms at the initial phase of treatment.[141] In all other cases, an exceptional authorisation is necessary.
Prohibition/Sanction	The use of any other type of cannabis products is prohibited
Regulatory body	OFSP and Swissmedic
Other	Very slow, costly, bureaucratic model, but with medical approach accepted by health professionals. Treatment not covered by the health insurance system, with the exception of some accidental cases

United Kingdom

Law	Criminal Justice Act/Schedule 4[142]
Date approved	2006
Generalities	Access to medicinal cannabis through the decriminalisation of prescription and consumption of Sativex
Production	Cultivation of cannabis plants by GW Pharmaceuticals to produce Sativex and other cannabis extracts
Product	Sativex
Content/Potency	Sativex
Restrictions	Can only be prescribed for multiple sclerosis and by physicians specialised in neurology, rehabilitation and pain
Points of sale	In pharmacies
Requirements	Medical prescription and treatment follow-up by a specialist. If no considerable improvement in health is demonstrated within four weeks, the prescription is interrupted
Prohibition/Sanction	Medical prescription to possess and consume the medication; otherwise, it is a criminal offence. Prosecution is the responsibility of public security agencies
Regulatory body	Medicines and Healthcare products Regulatory Agency (MHRA)
Other	Cannabis remains prohibited in the country; only the import, production, prescription and use of Sativex are permitted

United States

Law	State regulations
Date approved	1996-2017
Generalities	Legal in 28 states and the District of Columbia
Production	Some states only allow acquisition of pharmaceuticals, while others allow cultivation for personal use, and others use a dispensary model
Product	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
Restrictions	Medical prescription
Points of sale	Clinics and pharmacies
Requirements	Medical prescription indicating recommended dose
Prohibition/Sanction	Physician determines the amount that can be possessed
Regulatory body	Food and Drug Administration (FDA)
Other	Each state establishes its own regulations

Uruguay

Law	Article 5 of Law 19172[143] and Decree 46-015[144]
Date approved	7th January 2014
Generalities	Authorises use of cannabis for scientific and medical purposes, industrialisation for pharmaceutical use
Production	Under licences from the Institute for the Regulation and Control of Cannabis, for research purposes or pharmaceutical uses. Self-cultivation is allowed
Product	All simple or compound cannabis-based medications with therapeutic properties and plant specialties
Content/Potency	THC inferior or equal to 9%, CBD superior or equal to 3%
Restrictions	Maximum 40 g a month. All forms of direct or indirect advertising, promotion or sponsorship in any way are prohibited
Points of sale	Clinics and pharmacies, or through the recreational system (self-cultivation and social clubs)
Requirements	Medical prescription indicating the amount and type of product and form of administration For Sativex or Marinol: orange prescription (most restricted prescription) and special authorisation from the Ministry of Public Health to import the product from abroad
Prohibition/Sanction	Warning, fines, administrative sanctions and possible criminal charges
Regulatory body	Institute for the Regulation and Control of Cannabis
Other	Average price: $1.17 cents (price set by the Institute $1.10 dollars)

Endnotes

1. Licentiate in Political Sciences and Public Administration from the Iberoamerican University and participant in associate degree program on "Drug policy, health and human rights" at the Center for Economic Research and Teaching, Central Region. Former collaborator in the Drug Policy Program of México Unido Contra la Delincuencia A.C.
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3. Master's in Management and Public Governance from the London School of Economics and Director of the Drug Policy Program of México Unido contra la Delincuencia A.C.
4. Head of Research and Communications, International Drug Policy Consortium
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About this Briefing Paper

This paper seeks to enhance our understanding of the state of medicinal cannabis reforms and their potential, as well as offer some general recommendations in an effort to improve public policies where legislation has already changed and inform decision-making processes where the reform is pending.

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About IDPC

The International Drug Policy Consortium is a global network of non-government organisations that aims to promote objective and open debate on the effectiveness, direction and content of drug policies at national and international level, and supports evidence-based policies that are effective in reducing drug-related harm. It produces briefing papers, disseminates the reports of its member organisations, and offers expert advice to policy makers and officials around the world.

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