Ministry of Health and Wellness

2021

REPORT OF TECHNICAL COMMITTEE ON MEDICINAL CANNABIS

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1. Introduction

*Cannabis sativa*L.,also known as marijuana, cannabis and hemp, has a long history as a medicinal plant. According to the National Health Service (UK), medical cannabis, also known as medicinal cannabis, is "a broad term for any sort of cannabis-based medicine used to relieve symptoms" (House of Lords, Library Briefing, 2020) Medical cannabis and Medicinal cannabis are two terms which are interchangeably used in legislations, reports and peer reviewed publications.

Cannabis has been used in many cultures to treat a cornucopia of ailments, for instance in China, traditional medicine practitioners used the plant for the treatment and management of malaria, menstrual symptoms and constipation while it was prescribed as an analgesic by Western medicine (Shannon *et al.,* 2019). However, by the twentieth century, the medicinal use of marijuana in the US had largely subsided when prohibitions were imposed on its use in 1970 (Shannon *et al.,* 2019). In fact, cannabis is currently classified by the U.S. Drug Enforcement Agency's Comprehensive Drug Abuse Prevention and Control Act of 1970 as a Schedule I controlled substance, defined as having a high potential for abuse, no currently accepted medicinal use in treatment in the United States, and inadequate safety data for use of the treatment under medical supervision (United States Code Controlled Substances Act, 1970). However, its recreational use emerged as an extremely popular activity which prompted countries such as Canada and USA to decriminalise its use, for instance, non-medical use of cannabis is legal in 12 states and the District of Columbia in the United States (Freeman *et al.,* 2019; Levinsohn and Hill, 2020).

In more recent times, the use of cannabis as medicinal therapy has garnered much attention around the globe. Proponents of medical marijuana support its use for an array of medical conditions, most notably for pain management and multiple sclerosis (Freeman *et al.,* 2019). This stems from the substantial interest in the therapeutic potential of cannabis among the medical and scientific community. The *Cannabis* plant contains more than 120 different chemicals unique to the genus *Cannabis*, known as cannabinoids (Pauli *et al.,* 2020). The main psychoactive constituent of *Cannabis* was identified in 1964 as delta-9-tetrahydrocannabinol (THC) by Gaoni and Mechoulam (Gaoni and Mechoulam, 1964). The second most abundant cannabinoid is cannabidiol (CBD) which is non-psychoactive (Shannon *et al.,* 2019). CBD and THC are two of the most extensively studied cannabinoids

and cannabis-based products containing CBD or THC or a combination of both have demonstrated efficacy for treatment and management of myriad health conditions, including multiple sclerosis spasticity symptoms, chemotherapy-induced nausea and vomiting, chronic pain in adults and severe treatment-resistant epilepsy (Freeman *et al.,* 2019; Shannon *et al.,* 2019; Pauli *et al.,* 2020; Sholler*et al.,* 2020).

A number of cannabinoid-containing medicinal products have been authorised for commercialisation in many countries across the world. Epidiolex® which is an oral solution containing plant-derived CBD as the principal ingredient, was licensed in 2018 by the US Food and Drug Administration (FDA) for the treatment of seizures in two rare and severe forms of childhood epilepsy – Lennox-Gastaut and Dravet syndromes (Pauli *et al.,* 2020). Sativex® is an oral spray containing CBD and THC in approximately equal proportions and is indicated for the treatment of muscle spasticity resulting from multiple sclerosis (Freeman *et al.,* 2019). Dronabinol and nabilone are synthetically produced cannabinoids that mimic the effects of THC and are used for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS) and as anti-emetics for chemotherapy-induced nausea and vomiting (Freeman *et al.,* 2019). Non-medicinal CBD products are also marketed in health shops and online in Europe but a legal threshold of 0.2% is imposed on their psychoactive (THC) content (Freeman *et al.,* 2019).

In the light of substantial evidence corroborating the therapeutic virtues of medicinal cannabis, policy surrounding the provision of cannabis for medical use is rapidly evolving, resulting in a number of countries allowing the prescription of cannabis for medicinal purposes, mostly in response to patient's demand or cannabis-based product development (Schlag, 2020). While California was the first state to legalise the medical use of marijuana in 1996, as of January 2020, in the United States, 33 states and the District of Columbia have legalised the use of cannabis for medical purposes (Shannon *et al.,* 2019; Sholler*et al.,* 2020; Levinsohn and Hill, 2020). Cannabis-based products can now be prescribed by medical practitioners on the General Medical Council Specialist Register in the UK, on a named patient basis (Freeman *et al.,* 2019). In 2017, Germany legalised the use of medical marijuana and is now the leading prescriber in Europe (Schlag, 2020). Medical practitioners can legally prescribe medical cannabis in Israel since the 1990s, in Italy since 2006, in The Netherlands since 2003 and in Australia since 2016 (Schlag, 2020). Nevertheless, in spite of

the growing acceptance of medical cannabis, controversies pertaining to the legal, ethical, and societal implications associated with use; safe administration; adverse health consequences and deaths attributed to marijuana intoxication; and therapeutic indications founded on inadequate clinical data impede the use of cannabis on a larger scale (Bridgeman and Abazia, 2017). It is therefore of paramount importance to elicit a comprehensive framework to regulate the use of medicinal cannabis while addressing the complexities stemming from its use as a treatment.

This report has thus been prepared to respond to growing policy interest for the use of cannabis for medical purposes. The sector of medical use of cannabis is increasingly dynamic as both evidence in this area and policies and practices are evolving rapidly.

Part 1 of the report provides an overview on the cannabis plant with respect to its THC and CBD contents, current international drug treaties and available data on legislations in (1) Africa, (2) Asia, (3) Australia/Oceania, (4) Europe, (5) North America and (6) South America.

Part 2 outlines, with the background of market survey, potential pharmaceutical cannabis products than can be envisaged within medical utilization programs. It covers technical data on cannabis products available on the market and gives a non-exhaustive list of companies and manufacturers supplying products to countries like Canada, France, Ireland and UK.

Part 3summarizes the evidence gathered on the medicinal properties of cannabis based medicinal products (CBMPs) following a literature search on controlled clinical trials essentially.

Part 4 provides the basis of setting up of the Technical Committee on medicinal cannabis by the Ministry of Health and Wellness. It provides the terms of reference, composition of main technical committee and subcommittees.

Part 5 spells out the findings and recommendations emanating from the proceedings of the Technical Committee and its subcommittees.

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PART 1

1.1 Cannabis plant and medicinal cannabis

The cannabis plant contains more than 100 biologically active cannabinoids, the two most important ones being Tetrahydrocannabinol (THC) and Cannabidiol (CBD). The amount and relative proportion of cannabinoids in cannabis plants varies considerably among strains.

Tetrahydrocannabinol (THC)

Tetrahydrocannabinol (THC) is the main psychoactive cannabinoid of cannabis. Evidence suggests that THC exhibits medicinal properties that are useful in treating chemotherapy-related nausea, pain and spasticity. THC can also be synthesized in the laboratory.

Cannabidiol (CBD)

Cannabidiol (CBD) is indicated for use in treating conditions such as chronic pain, insomnia and anxiety as well as seizures and spasticity. It is also claimed to have anti-inflammatory and neuroprotective effects. Plant-derived CBD does not have psychoactive properties.

Medicinal cannabis is the term used to indicate all cannabinoid-based therapeutic products whether licensed pharmaceutical or unlicensed cannabis-based products.

Licensed pharmaceutical cannabis products refer to products formulated using pure cannabinoids (either plant-extracted or synthetic) that have been through full clinical trials and licensed as a medicine. Examples of products include:

- Sativex and Epidiolex (natural cannabinoids)
- Cesamet, Marinol and Syndros (synthetic cannabinoids).

Unlicensed medicinal cannabis products refer to plant-based or plant-derived cannabis products prescribed by a medical practitioner for the treatment of a specific condition or disease (e.g. epilepsy, pain, multiple sclerosis). It uses the whole unprocessed plant, the processed plant or the chemicals contained within it. It can include high-CBD and low-THC products or vice versa. Medicinal cannabis products are currently prepared as plant materials, oils, tinctures, edibles or capsules.

1.2 International drug treaties

Cannabis is prohibited in the world under three international drug treaties **(Figure 1)**:

1. The **Single Convention on Narcotic Drugs of 1961** is an international agreement signed between 186 States that encourages the prohibition of certain specific drugs.

2. The **Convention on Psychotropic Substances of 1971**, approved by 184 States, primarily aimed at diversifying and expanding the spectrum of illicit drugs to be controlled.

3. The **UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988** main objective was to promote cooperation among all parties in efforts to combat the various aspects of illicit drug trafficking following a worldwide surge in the use of narcotics in the 1980's.

Schedules under the UN drug control conventions

1961 Single Convention on Narcotic Drugs

SCHEDULE I	SCHEDULE II	SCHEDULE III
Substances that are highly addictive and liable to abuse, and precursors readily convertible into drugs similarly addictive and liable to abuse (e.g cannabis, opium, heroin, methadone, cocaine, coca leaf, oxycodone)	Substances that are less additive and liable to abuse than those in Schedule I (e.g codeine, dextropropoxyphene)	Preparations containing low amounts of narcotic drugs, are unlikely to be abused and exempted from most of the control measures placed upon the drugs they contain (e.g<2.5% codeine, <0.1% cocaine)

SCHEDULE IV
Certain drugs also listed in Schedule I with "particularly dangerous properties" and little or no therapeutic value (e.g cannabis, heroin)

1971 Convention on Psychotropic Substances

SCHEDULE I	SCHEDULE II	SCHEDULE III	SCHEDULE IV
Drugs presenting a high risk of abuse, posing a particularly serious threat to public health with little or no therapeutic value (e.g LSD, MDMA, cathinone)	Drugs presenting a risk of abuse, posing a serious threat to public health, which are of low or moderate therapeutic value (e.g dronabinol, amphetamines)	Drugs presenting a risk of abuse, posing a serious threat to public health, which are of moderate or high therapeutic value (e.g barbiturates, buprenorphine)	Drugs presenting a risk of abuse, posing a minor threat to public health, with high therapeutic value (e.g tranquilizers, including diazepam)

1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

TABLE I	TABLE II
Precursors of psychotropic substances, such as ephedrine, piperanol, safrole, phenylacetic acid, lysergic acid; and a few key reagents such as acetic anhydrate used in the conversion of morphine into heroin and potassium permanganate used in the extraction of cocaine.	A wide range of reagents and solvents that can be used in the illicit production of narcotic drugs and psychotropic substances, but also have widespread licit industrial uses, including acetone, ethyl ether, toluene and sulphuric acid.

Figure 1: Schedules under the United Nations Drug Control Conventions

1.3 Cannabis Legal use worldwide

The debate about the regulation and use of cannabis has increased since a number of years. Many countries have progressively revised their laws to allow for the medicinal or therapeutic use of cannabis and related products and have therefore endorsed policies that enable patients to access certain types of preparations to alleviate symptoms, reduce pain or improve their quality of life. **Figure 2** outlines world regions where medical cannabis is regulated, authorised or/and utilised on pilot basis.

Factors which have prompted various countries globally to enable access to medicinal cannabis vary. Some of the different processes that led to these policies can generally be categorised as follows (Aguilar *et al.,* 2018):

(i) Individual cases defended in the courts which set precedents, or sentences that are applied generally,

(ii) Direct democratic processes, such as referenda and popular consultations,

(iii) Legislative and public policy processes led by national governments,

(iv) Companies developing medicinal cannabis and demanding that government authorities facilitate its licit use

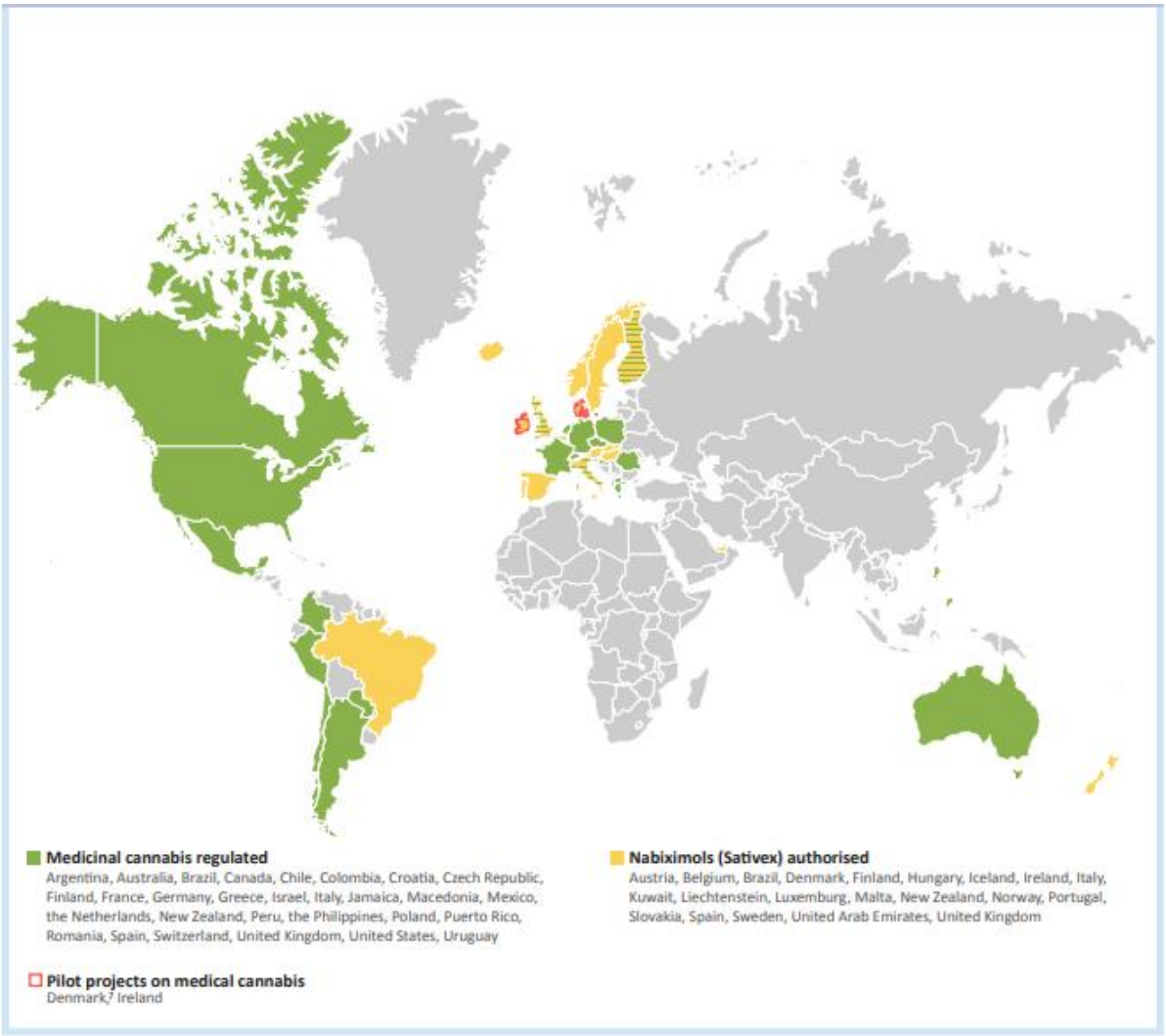


Figure 2: Countries where medicinal cannabis is (a) regulated, (b) authorised and (c) utilised on pilot basis (Source: Aguilar *et al.,* 2018)

Cannabis use in Africa

According to the United Nations Office on Drugs and Crime (UNODC), cannabis use in Africa has increased significantly over the last ten years. The draft technical paper submitted by the African Union Expert Committee on cannabis and cannabis-related products indicate that there are high annual prevalence rates of cannabis use in Africa (7.6%), more prominently in West and Central Africa (13.2%). In the majority of African countries cannabis use, even for medical purposes remain prohibited whilst in others there have been interest and actions to provide a legal basis for utilization.

In 2017, Lesotho was the first African nation to issue licences for the growth of cannabis for medical purposes. The government began licensing cannabis production under existing laws, but did not publish regulations until May 2018 (Duvall, 2019).

The South African parliament authorized medical marijuana in 2017 in order to benefit ill people, while in 2018 the country's high court decided that adults have the right to garden and use cannabisprivately (Jansen, 2017; Zondo, 2018). South Africa also authorised use of medical cannabis in a way that patients may request medical cannabis through authorised health practitioners who are licensed by the South African Health Products Regulatory Authority (SAHPRA). The health practitioner must apply online on their patient's behalf to SAHPRA. Once a prescription has been issued to the patient, it can be fulfilled by pharmacists registered with the South African Pharmacy Council (SAPC). Pharmaceutical firms like Aphria, Aurora and Canopy Growth operates in South Africa, commercialising medical cannabis products.

- In Zimbabwe, the Government published regulations that allowed cannabis growing licenses under existing laws in April 2018 (Duvall, 2019).
- Zambia became the fourth African nation to legalise cannabis production for medicinal purposes to treat specific conditions like chronic pain, nausea and vomiting in chemotherapy, loss of appetite in patients with chronic conditions, epilepsy, glaucoma and multiple sclerosis.
- In Malawi, cannabis was widely used as medicine in treating conditions like anthrax, dysentery, fevers, malaria, or snake bites. In 2016, parliament approved agricultural trials of non-psychoactive cannabis grown for fiber and oilseeds (Duvall, 2019). The country has a Cannabis Regulatory Authority since 2020.
- In Ghana, the Narcotics Control Commission Act, 2020 decriminalises medicinal cannabis, allowing Government to issue licenses for the production of cannabis with less than 0.3% of THC.
- In 2020, Rwanda permitted the production and processing of medical marijuana. Production and use limited to licensed dealers like pharmacies and that cannabis consumption remains illegal.

- In April 2018, a parliamentary committee recommended licensing drug-plant production in Eswatini (Swaziland) (Duvall, 2019).
- Morocco, in May 2021, became the most recent nation to allow the legal use of cannabis for medical, cosmetic and industrial purposes.

**Source: Prohibition Partners, Africa (2021)*

Cannabis use across other continents

Table 1 summarises regulatory model data for countries in Asia, Australia/Oceania, Europe, North America and South America

Table 1: Regulatory Models for medicinal cannabis around the world by Continent (Adapted from Aguilar et al., 2018)

Country	Aspects	Details
ASIA		
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
Philippines	**Law**	Philippine Compassionate Medical Cannabis Act
	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

Country	Aspects	Details
	Production	Not specified
	Product	Cannabis in its raw form is prohibited
AUSTRALIA/ OCEANIA		
Australia	**Law**	Narcotic Drugs Act 1967 as amended by the Narcotic Drugs Amendment Act 2016
	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
New Zealand	**Law**	Regulation 22 of the Misuse of Drugs Regulations 1977
	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

Country	Aspects	Details
EUROPE		
Croatia	**Law**	None
	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
Czech Republic	**Law**	Criminal Code, 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
Finland	**Law**	Cannabis included in the 'List of medicines' by FIMEA in section 83 of the Medicines Act (395/1987)
	Date Approved	2008
	Generalities	2012: Sativex authorised 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)
France	**Law**	Decree No 2013-473 (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. Sativex is approved by the ANSM, but no commercial agreement has yet been found with GW
Germany	**Law**	Narcotics Law

Country	Aspects	Details
	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
Greece	**Law**	Provisions for the production of end products of medicinal cannabis
	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
Italy	**Law**	Decree modifying Presidential Decree No. 309 (Law 309/90) of 9th October 1990 and its subsequent modifications
	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 MedicinalCannabis. Since 2016, local production in the Military Chemical Pharmaceutical Establishment in Florence
	Product	Cannabis plant-based medicines (including extracts and colorants), Dronabinol, Nabinol and Sativex (to reduce painful spasms from multiple sclerosis)
Macedonia	**Law**	Law on control of narcotic drugs and psychoactive substances

Country	Aspects	Details
	Date Approved	Changes and additions from February 2016 and December 2017
	Generalities	Changes and additions from February 2016 and December 2017
	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.
Netherlands	**Law**	Dutch Opium Act (Opiumwet)
	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.
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
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

Country	Aspects	Details
	Production	Cultivation of medicinal cannabis only by growers authorised by the Drugs Agency
	Product	Cannabis derivatives, but not specified by the law
Switzerland	**Law**	Reform of the Federal Narcotics Act (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 product
	Date Approved	Reform approved: 20th March 2008, entered into force: 1st July 2011
	Generalities	Federal Office of Public Health (OFSP) can grant exceptional permission138 (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
United Kingdom	**Law**	Criminal Justice Act/Schedule 4
	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
NORTH AMERICA		
Canada	**Law**	Controlled Drugs and Substances Act, Access to Cannabis for Medical Purposes Regulations (August 2016)
	Date Approved	1999

Country	Aspects	Details
	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
Jamaica	**Law**	Dangerous Drugs (Amendment) Act1
	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, dried plant, edible products, pharmaceutical medications
Mexico	**Law**	General Health Legislation and Federal Criminal Code
	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
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)
	Date Approved	9th July 2017
	Generalities	Regulates investigation, cultivation, manufacture,

Country	Aspects	Details
		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
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
SOUTH AMERICA		
Argentina	**Law**	Law 27,350 on medical and scientific research on the medicinal use of the cannabis plant and its derivatives
	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
Brazil	**Law**	RDCs ANVISA/MS nº 17/2015 and nº 66/20161
	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
Chile	**Law**	Law 20,000, Decree 84
	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

Country	Aspects	Details
	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
Colombia	**Law**	Decree 2467 and Resolution 1816
	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
Peru	**Law**	Law No. 30681 which regulates the medicinal and therapeutic use of cannabis and its derivatives
	Date Approved	16th November 2017
	Generalities	Regulates the medicinal and therapeutic use of cannabis and its derivatives. Alsoauthorises 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
Uruguay	**Law**	Article 5 of Law 19172 and Decree 46-015
	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

PART 2

This section provides technical data on cannabis products available on the market. Emphasis is made on products which have been legally approved or in process of being approved by external authorities **(Tables 2-4**). The section also covers data on companies and manufacturers supplying products to countries like Canada, France, Ireland and UK **(Tables 5-7)**. As such the lists are not exhaustive and therefore not restrictive.

2.1 Pharmaceutical Market Cannabis Products

1. Cannabidiol (plant-derived)

Table 2: Medical use of Cannabidiol

CANNABIDIOL Indicated for use as adjunctive therapy of seizures in 3 conditions: Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) and Tuberous Sclerosis Complex (TSC).	
Brand name	**Epidiolex® (GW pharmaceuticals)**
Type of product	Natural cannabinoid oral solution 100 mg/ml
Composition & excipients	Each ml of oral solution contains: - 100 mg cannabidiol - 79 mg anhydrous ethanol and 736 mg refined sesame oil.
Posology andmethod of administration	The recommended starting dose of cannabidiol is 2.5 mg/kg taken twice daily (5 mg/kg/day) for one week. Each Epidiolex carton is supplied with: o Two 1 ml syringes graduated in 0.05 ml increments (each 0.05 ml increment corresponds to 5 mg cannabidiol) o Two 5 ml syringes graduated in 0.1 ml increments (each 0.1 ml increment corresponds to 10 mg cannabidiol)
Commonside effects	Diarrhoea and vomiting, loss of appetite and weight loss, malaise (generally not feeling well) and fatigue, skin rash: itchiness and flushing, infections (viral or fungal infections) and pyrexia, somnolence / insomnia, loss of coordination, trouble thinking clearly and abnormal results on liver-function tests.
Serious side effects	Liver problems, sedation (sleepiness, loss of coordination, and trouble thinking clearly), severe allergic reaction (Angioedema (swelling under skin, in eyelids, lips, hands or feet and trouble breathing, suicidal thoughts or behaviour and being unable to safely operate equipment or machinery or driving a car.

FDA approval	FDA-approval received to treat seizures associated with - Lennox-Gastaut syndrome &Dravet syndrome (2018) - Tuberous sclerosis complex (2020).

2. Tetrahydrocannabinol and Cannabidiol in a 1:1 ratio (plant-derived)

Table 3: Medical use of THC and CBD in a 1:1 ratio

Nabiximols **To treat muscle spasticity associated with Multiple Sclerosis**	
Brand name	**SATIVEX® (GW pharmaceuticals)**
Type of product	Formulated cannabis plant extract (Nabiximols)
Formulation	Oro-mucosal spray
Composition	Each ml contains: 27 mg delta-9-tetrahydrocannabinol and 25 mg cannabidiol. Each single100 micro-litre spray contains: 2.7 mg delta-9-tetrahydrocannabinol (THC) and 2.5 mg cannabidiol (CBD) from *Cannabis sativa L.*
Excipient	Each 100 microlitre spray also contains up to 40 mg ethanol
Side effects	The most commonly reported adverse reactions in the first four weeks of exposure are **dizziness**, which occurs mainly during the initial titration period, and **fatigue**. These reactions are usually mild to moderate and resolve within a few days of treatment initiation. Other common side effects of **Nabiximols (Sativex®)** include: i. **gastrointestinal** disorders such as change in appetite, constipation, diarrhea and vomiting. ii. **psychiatric** disorders such as depression, disorientation (confusion), dissociation and euphoria. iii. **nervous system** disorders such as amnesia, disturbances in balance, attention problems and somnolence.
FDA approval	

3. Dronabinol and Nabilone (Synthetic Cannabinoid Products)

Table 4: Medical use of Synthetic Cannabinoid products

Dronabinol and Nabilone To treat chemotherapy-induced **nausea and vomiting** in cancer To treat **appetite and weight loss** in AIDS patient			
	Dronabinol		**Nabilone**
Active ingredient	Dronabinol capsules 2.5mg, 5mg & 10mg	Dronabinol liquid 5 mg/ml	Nabilone capsules 0.25mg & 1mg
Brand name	Marinol®	Syndros®	Cesamet®
Class of drug	Synthetic THC	Synthetic THC	Cannabinoid receptor agonist
FDA-Approval	FDA-approved	FDA-approved	FDA-approved
Side effects	The **commonest** side effects associated with **dronabinol** (synthetic cannabinoid, delta-9-THC analogue) include neuropsychiatric symptoms: dizziness, euphoria, paranoid reactions, hallucinations and psychosis, somnolence and abnormal thinking (cognitive distortion; having untrue thoughts)		
Serious side-effects	• increased risk of **seizures** • gastrointestinal side-effects: paradoxical exacerbation of nausea, vomiting and abdominal pain		

2.2 Unlicensed cannabis-based medicinal products

Unlicensed plant-derived cannabis-based products for medicinal use in humans are produced by a number of manufacturers which include a range of preparations containing delta-9- tetrahydrocannabinol (THC) and cannabidiol (CBD) with differing percentages of the active constituents.

2.3 International firms marketing cannabis-based medical products

The majority of the world's largest cannabis producers by market capital are based in Canada. **Table 5** provides a non-exhaustive list of international medical cannabis marketing firms.

Table 5: International medical cannabis marketing firms

COUNTRIES WHERE INCORPORATED	COMPANIES	Examples of countries where products are available	Examples of cannabis-based products supplied
Canada	Canopy Growth Corporation		
	Aurora Cannabis inc	Ireland	Aurora High CBD Oil Drops CBD 600 mg/ml THC < 30 mg/ml
	Cronos group inc		
	Tilray Inc	France Ireland	Tilray Oral Solution THC 10 mg/ml CBD 10 mg/ml
	Aphria		
USA	Curaleaf Holdings		
	Green Thumb industries Inc		
UK	Emmac Life Sciences Group		
	GW Pharmaceuticals plc	UK & a no. of countries	Sativex Epidiolex

Australia	Little Green Pharma	France	CBD dominant oil CBD > 5 mg/ml &THC < 1mg/ml CBD > 5 mg/ml &THC < 5 mg/ml
	Althea co ltd		
Netherlands	Bedrocan	UK	
Israel	Panaxia Pharmaceuticals	France	THC dominant oil & capsules THC > 5 mg/ml&CBD< 1 mg/ml
Slovenia	MGC Pharmaceuticals	France Ireland	CannEpil™ (CBD dominant) CBD 100 mg/ml&THC 5 mg/ml

Table 6 below shows formulations of medical cannabis used in France and relevant manufacturers.

Table 6: Formulations and product manufacturers in France

Formulation	THC & CBD concentration	Relative proportion of THC &CBD	Name of manufacturer
CBD oil	THC < 1mg/ml CBD > 5 mg/ml	**CBD Dominant**	1. Little green Pharma 2. Althea company ltd
Cannabis flower	THC < 5 % CBD > 5 %		1. Aurora Europe 2. Nil supplier chosen
CBD oil	THC < 5 mg/ml CBD > 5 mg/ml		1. Little green Pharma 2. Panaxia
Cannabis flower	THC & CBD > 5%	**CBD & THC in 1:1 ratio**	1. Aurora Europe 2. Tilray
Cannabis oil	THC & CBD > 5 mg/ml		1. Tilray 2. Little Green Pharma
Capsules	THC & CBD > 5mg/ml		1. Panaxia 2. Emmac life sciences
Cannabis flower	THC > 8 % CBD < 1 %	**THC Dominant**	1. Aurora Europe 2. Tilray
Cannabis oil	THC > 5 mg/ml CBD < 1 mg/ml		1. Tilray 2. Panaxia
Capsules	THC > 5 mg/ml CBD < 1 mg/ml		1. Panaxia 2. Emmac life sciences

Table 7 depicts specified controlled cannabis-based products that have been accepted as being suitable for use under the 5-year pilot Medical Cannabis Access Programme since February 2020 in Ireland

Table 7: Formulations and product manufacturers in Ireland

Brandnames	Approxprice	THC&CBD concentration	Proportion of THC & CBD	Name of manufacturer
Aurora High CBD Oil Drops	Oral solution	**THC** < 30 mg/ml **CBD** 600 mg/ml	**CBD Dominant**	Aurora Cannabis Entreprises Inc., Alberta, Canada
CannEpil™	Oral solution	**THC** 5 mg/ml **CBD** 100 mg/ml	CBD 95% THC 5%	MGC Pharmaceu-ticals Ljubljana, Slovenia
Tilray Oral Solution THC10:CBD10 25ml	Oral solution	**THC** 10 mg/ml **CBD** 10 mg/ml	**CBD & THC in 1:1 ratio**	Tilray Canada Ltd., 1100 Nanaimo, Canada
Aurora SedamenSoftgels	Capsules	THC 5mg/capsule CBD < 0.2mg per capsule	**THC Dominant** CBD < 4% THC > 96%	Aurora Inc, 4250 14th Avenue, Markham, Ontario, Canada

2.4 United Kingdom

It is noteworthy thatin the UK, unlicensed specials Suppliers should comply with Medicines and Healthcare Products Regulatory Agency (MHRA) guidance and Good Manufacturing Practice standards. The products are available on a **named patient basis** for indications where there is clear published evidence of benefit or UK Guidelines and in patients where there is a clinical need **which cannot be met by a licensed medicine** and where established treatment options have been exhausted. Specialist doctors on the GMC specialist register **only** can take the decision to prescribe these Schedule 2 medications.

PART 3

This section summarizes existing evidence on medicinal properties of Cannabis Based Medicinal products (CBMPs). Data were gathered on literature search on controlled clinical trials essentially. It is noteworthy that the evidence base is evolving rapidly but what currently exists is in many instances is limited and fragmented. The evidences recapped are those on (1) efficacy (**Table 8)**, (2) safety **(Table 9)** and phase 2 and phase 3 trials conducted in the UK **(Table 10)**.

3.1 Research Evidences on Efficacy

Table 8: Evidence from Clinical trials showing efficacy of CBMPs (Source: Medical Cannabis in the UK: A blueprint for reform, 2019)

Trials examining effects of CBMPs on pain with outcome measures: improvement of quality of life, sleep and anxiety.	**Whole plant**	**Sativex**	**THC**	**CBD**
Total number of studies	14	17	36	3
Number of Positive trials (Percentage of Positive trials)	11 (79%)	11 **(65%)**	16 (44%)	3 (100%)
Number of Negative trials (Percentage of Negative trials)	2 (14%)	1 (6%)	12 (33%)	0 (0%)
Number of Positive trials with >100 patients Percentage of Positive trials with >100 patients	1/1 (100%)	6/8 **(75%)**	1/2 (50%)	0

Trials examining effects of CBMPs on side effects of chemotherapy like nausea, vomiting and appetite stimulation.	**Whole plant**	**Sativex**	**THC**	**CBD**
Total number of studies	3	1	58	1
Number of Positive trials (Percentage of Positive trials)	2 (67%)	1 (100%)	33 (56%)	0 (0%)
Number of Negative trials (Percentage of Negative trials)	1 (33%)	0 (0%)	12 (21%)	0 (0%)
Number of Positive trials with >100 patients (Percentage of Positive trials with >100 patients)	0/1 (0%)	0 (0%)	2/8 **(25%)**	0 (0%)

Trials examining effects of CBMPs in <u>epilepsies</u> associated with Lennox-Gastaut, Dravet, Sturge-Weber syndromes	**Whole plant**	**1:1 THC:CBD**	**Epidiolex**	**CBD**
Total number of studies	1	3	12	1
Number of Positive trials (Percentage of Positive trials)	0	3 (100%)	11 **(92%)**	1 (100%)
Number of Negative trials (Percentage of Negative trials)	0	0	0	0
Number of Positive trials with >100 patients (Percentage of Positive trials with >100 patients)	0	0	5	0

3.2 Research Evidences on Safety

Table 9: Evidence from Clinical trials showing safety of CBMPs (Source: Health guidance levels for THC in CBD products, Centre for medical cannabis, 2021)

	Study	Design	Adverse Effect Findings
1	Ahmed *et al.,* 2015.	Randomized, double-blind, placebo controlled, crossover trial for olderadults with dementia (N = 10; mean age77.3 ± 5.6). For 12 weeks, participantsrandomly received oral THC (0.75 mgduring weeks 1–6; 1.5 mg during weeks 7–12) or placebo twice daily for 3 days.	Relative to placebo, neither dose of THC had any effect on feeling 'high' andexternal perception as measured by the Visual Analog Scale (VAS); body sway(eyes-open); or diastolic blood pressure. Body sway-(eyes-closed) increasedat 1.5 mg but not 0.75 mg. Statistically significant increases in internalperception (VAS), heart rate, and systolic blood pressure relative to placebowere reported at the 0.75 mg dose, but were not considered clinically relevantas they were small and not associated with adverse events.
2	Van den Elsen*et al.,* 2015a.	Randomised, double-blind, placebo-controlled, repeated crossover trial forolder adults with dementia (N = 22; meanage 76.4 ± 5.3), consisting of six treatmentblocks of 2 weeks each. Within each blockTHC (0.75 mg twice daily in blocks 1-3and 1.5 mg twice daily in blocks 4-6) andplacebo were administered in randomorder for 3 consecutive days, followed bya 4-day washout.	THC was well tolerated as assessed by adverse event monitoring, vital signsand mobility. There were no serious adverse events in any group and nosignificant difference in the incidence of adverse events between groups. Intotal, 184 AEs of mild to moderate severity occurred during thecrossoverstudy period, similarly distributed over the THC (91 AEs) and placebo (93AEs) conditions. Relative to placebo, no statistically significant effects werereported on diastolic blood pressure, heart rate, agitated behaviour orcaregiver burden at either dose. High dose THC (1.5 mg) but not low dose(0.75 mg) increased SBD by 2.6 mmHg compared to placebo within four hoursafter first tablet intake

	Study	Design	Adverse Effect Findings
3	Van den Elsen*et al.,* 2015b.	Randomised, double-blind, placebo-controlled trial for adults with dementia(N = 50). Participants were randomised togroups receiving either placebo or THC atdoses of 0.75 mg three times daily	THC was well tolerated at this dose. The number of patients experiencingadverse events and the frequency of adverse events were similar in bothgroups. Known THC-mediated AEs, such as dizziness, somnolence, and falls,were more frequently reported during placebo treatment. None of theparticipants reported a feeling "high," nor was behaving "high" observed bycaregivers or research staff.
4	Kuhlen*et al.,* 2016.	Open-label uncontrolled retrospective study of dronabinol in paediatricparticipants with spasticity (N = 16; aged1.3-26.6 years, median 12.7 years). Thestarting dose was 0.83 mg (one drop)twice daily for all patients. The doseescalation was stopped as soon as a treatment effect was clinically assessed. Therapeutic doses varied from 0.08 to1.0 mg/kg/d with a median of 0.33 mg/kg/d. Only 1 patient (11.3 years, 21kgbodyweight) received a maximum dailydose less than 2.5 mg (1.68 mg) for a totalduration of 118 days.	No adverse effects were reported for this patient. With an escalatingdosage scheme, no side effects lasting more than one week were seen inany patient. However, restlessness and vomiting occurred as side effects inthe case of two patients, who received maximum dose of 0.19 mg/kg (8.17mg/day) and 0.07 mg/kg (3.15 mg/day). None of the children in cohort were verbally communicative, so psychological effects could not be assessed. THCwas well tolerated with 15/16 participants requiring >2.5 mg/day to reachtherapeutic effects and no side effects reported below that dose.
5	Van den Elsen*et al.,* 2017.	Randomised, double-blind, crossoverstudy to evaluate the effects of THCon mobility in dementia patients (N =18; median age 77 years). Participantsreceived 1.5 mg of oral THC twice dailyand placebo, in random order, for threedays, separated by a four-day washout.	THC was well tolerated by patients. There was no difference in theoccurrence of adverse events observed between 1.5 mg of THC twicedaily compared to placebo. Nor were there differences in mobility-relatedadverse events (e.g. dizziness, somnolence and balance disorders) betweengroups and no falls occurred after administration of THC.
6	Carley *et al.,* 2018.		The most frequently reported verbatim adverse effects included sleepiness/drowsiness (N = 25; 8% of total AEs reported), headache (N = 24; 8%),nausea/vomiting (N = 23;

	Study	Design	Adverse Effect Findings
			8%), and dizziness/ light-headedness (N = 12; 4%). There were no statistically significant differences in the frequency of theseadverse events between groups: the average number of adverse eventsreported by the 73 participants was 4.1 ± 4.0 and this did not differ from placebo (3.4 ± 2.9) among participants receiving either 2.5 mg/ day (2.8 ±3.6) or 10 mg/day (5.8 ± 4.7) of dronabinol.

3.3 Phase 2 and 3 trials in the United Kingdom

There has been an increased growth in the number of clinical trials carried out with CBMPs in the last ten years, and an analysis of ongoing registered trials at ClinicalTrials.gov in 2018 indicated that there were currently about 124 active clinical trials investigating the therapeutic benefit of CBMPs of which 18 were in phase 3 trials (the furthest).

A detailed examination of the types of CBMPs and their objectives are shown in **Table 11**. 44 active clinical trials were investigating CBD in multiple indications. There were 8 clinical active trials investigating a THC: CBD 1:1 product (including but not limited to Sativex). There were 7 clinical trials investigating a THC: CBD product in different ratios. There were 32 clinical studies registered using a product containing THC. 33 studies were registered using a whole plant product.

Table 10: A summary of conditions being investigated using a CBMP at either phase 2 or phase 3 clinical trials (Source: Medical Cannabis in the UK: A Blue Print for reform, 2018)

	CBD	THC	THC:CBD (1:1)	THC:CBD other ratios	Whole Plant
Phase 2 trials	4 Epilepsy 3 Schizophrenia 2 Parkinson's disease 2 Prader-Willi syndrome 1 Anxiety 1 Substance use disorder 1 Fragile X syndrome 1 Bipolar disorder	2 Alzheimer's 1 Low back pain 1 Nausea 1Trichotillomania 1 Tourette's syndrome	1 Multiple Sclerosis 1 HIV infections 1 Chronic non-cancer pain	1 Autistic disorder 1 HIV infections 1Pancreatic cancer (palliative) 1 Cancer pain	2 Cancer pain 1osteoarthritis 1 Low back pain 1 PTSD 1 Chronic obstructive pulmonary disorder (COPD) 1 HIV neuropathic pain 1 HIV cognition/ mobility

	CBD	THC	THC:CBD (1:1)	THC:CBD other ratios	Whole Plant
	1 Crohn's disease 1 PTSD 1 Chronic non-cancer pain 1 Arthritis				1 Tourette's Syndrome 1 Dementia (agitation) 1 Parkinson's
Phase 3 trials	3 Infantile Spasms 2 Epilepsy 2 Tuberous Sclerosis Complex 1 Generalised anxiety disorder 1 Motor neuron disease	1 Marijuana dependence 1 PTSD 1 Tourette's syndrome 1 Medical abortion pain	1 Tourette syndrome 1 Chronic pain	1 Chronic pain	1 Cancer pain 1 Nutrition in haemodialysis patients

PART 4

4.1 Technical Committee on Cannabis

In 2015, the Government set up a Commission of Enquiry on Drug Trafficking and one of the recommendations of the Commission in 2018 was as follows:

> "*The Commission recommends that a study be conducted jointly by the Ministry of Health and Quality of Life and the Ministry of Industry Commerce, and Consumer Protection together with local research institutes in collaboration with foreign research laboratory of repute:*
>
> *(i) to determine the properties of THC level of the locally grown cannabis;*
> *(ii) to determine if the local cannabis may be used for medicinal purposes in light of the evolutions noted in certain countries; and*
> *(iii) to determine whether the local cannabis is the variety which can be used as hemp for industrial purposes and whether the concentration of THC is relatively low as not to have any psychoactive effect. The industrial hemp can be used for many industries including but not limited to food product, cosmetics, and a variety of commercial items including paper clothing, textile, bio-degradable plastics, animal feed, paint, insulation, bio fuel.*

Bearing in mind that the Dangerous Drugs Act in its section7 already provides the granting of licence for the cultivation of cannabis for medical, scientific or teaching purposes;" ***Except from the Recommendations from the Commission on Enquiry (Section 10.8.4, (c) pg 122)***

In January 2019, the World Health Organization (WHO) made a number of recommendations to change the scope of control of cannabis and cannabis-related substances. After deliberations, on the 2nd December 2020 in Vienna, while reviewing these recommendations, the Commission on Narcotic Drugs (CND) took a number of decisions on the international control of cannabis and cannabis-related substances.

It is noteworthy that cannabis and cannabis-related substances have been included in the schedules of the Single Convention of Narcotic drugs of 1961 as amended by the 1972 Protocol (Schedule I and IV: cannabis and cannabis resin; Schedule I: extracts and tinctures of cannabis), as well as in the Schedules of the Convention on Psychotropic Substances of 1971 [Schedule I: tetrahydrocannabinol (6 isomers of delta-9tetrahydrocannabinol); Schedule II: dronabinol and its stereoisomers (delta-9-tetrahydrocannabinol)] **(Figure 1).**

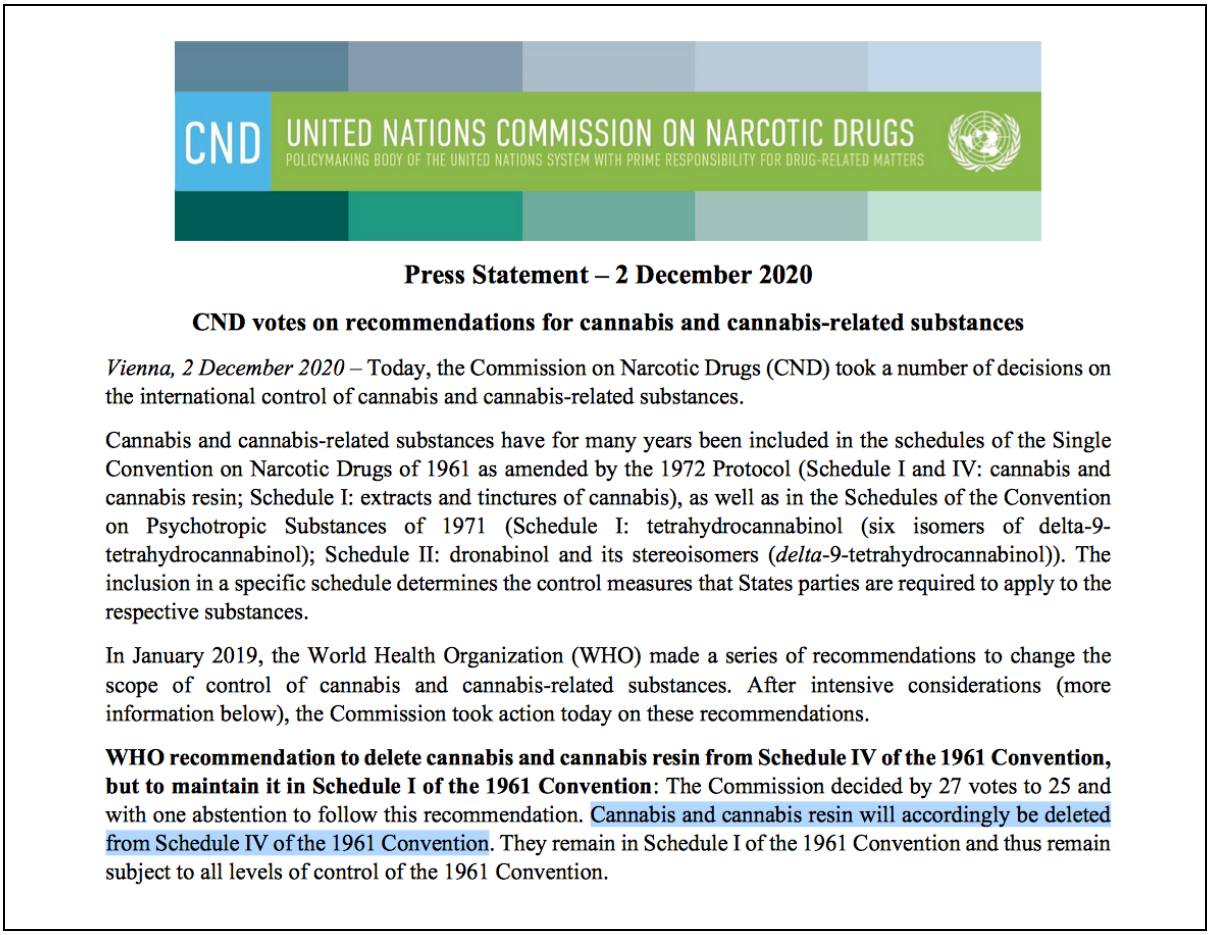
NB. *The inclusion in a specific schedule determines the control measures that States parties are required to apply to the respective substances.*

WHO recommended to delete cannabis and cannabis resin from Schedule IV of the 1961 Convention, while maintaining it in Schedule I of the 1961 Convention.

The 53 Member States of the CND, the UN's central drug policy-making body, voted to remove cannabis from that Schedule – where it had been placed for 59 years – and to which the strictest control measures apply, that generally discouraged its use for medical purposes.

With a vote of 27 in favour, 25 against, and one abstention, the CND opened the door to recognizing the medicinal and therapeutic potential of the drug, although its use for non-medical and non-scientific purposes will continue to remain illegal.

As such, **cannabis and cannabis resin will accordingly be deleted from Schedule IV of the 1961 Convention (Figure 3). They however, remain in Schedule I of the 1961 Convention and thus remain subject to all levels of control of the 1961 Convention.**



CND UNITED NATIONS COMMISSION ON NARCOTIC DRUGS
POLICYMAKING BODY OF THE UNITED NATIONS SYSTEM WITH PRIME RESPONSIBILITY FOR DRUG-RELATED MATTERS

Press Statement – 2 December 2020

CND votes on recommendations for cannabis and cannabis-related substances

Vienna, 2 December 2020 – Today, the Commission on Narcotic Drugs (CND) took a number of decisions on the international control of cannabis and cannabis-related substances.

Cannabis and cannabis-related substances have for many years been included in the schedules of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (Schedule I and IV: cannabis and cannabis resin; Schedule I: extracts and tinctures of cannabis), as well as in the Schedules of the Convention on Psychotropic Substances of 1971 (Schedule I: tetrahydrocannabinol (six isomers of delta-9-tetrahydrocannabinol); Schedule II: dronabinol and its stereoisomers (*delta*-9-tetrahydrocannabinol)). The inclusion in a specific schedule determines the control measures that States parties are required to apply to the respective substances.

In January 2019, the World Health Organization (WHO) made a series of recommendations to change the scope of control of cannabis and cannabis-related substances. After intensive considerations (more information below), the Commission took action today on these recommendations.

WHO recommendation to delete cannabis and cannabis resin from Schedule IV of the 1961 Convention, but to maintain it in Schedule I of the 1961 Convention: The Commission decided by 27 votes to 25 and with one abstention to follow this recommendation. Cannabis and cannabis resin will accordingly be deleted from Schedule IV of the 1961 Convention. They remain in Schedule I of the 1961 Convention and thus remain subject to all levels of control of the 1961 Convention.

Figure 3: Extract of press statement by UN's Commission on Narcotic Drugs (CND) on 2nd December 2020 on Deletion of cannabis from Schedule IV 1961 UN Convention

Implications of voting -1961 UN Single Convention on Narcotic drugs: Deleting "cannabis and resin" from schedule IV implies that "cannabis and resin" is no longer regarded as having **"particularly dangerous properties"** and as being of **"little or no therapeutic value**".

Maintaining "cannabis and resin" in Schedule I of the 1961 Convention implies that "cannabis and resin" is still regarded as being "**highly addictive and liable to abuse**".

With the background of the recommendation made by the Commission of Enquiry on Drug Trafficking and the recommendations of the United Nations Commission on Narcotic Drugs, a Technical Committee on medicinal cannabis was set up by the Ministry of Health and Quality of life with a set of terms of reference (detailed below). The Cabinet of ministers has been informed on 11 December 2020 of the setting up of this Technical Committee.

4.2 Composition of Technical Committee

The Technical Committee was set up under the Chairmanship of Professor TheesanBahorun, G.O.S.K, Chair in Applied Biochemistry and Executive Director of the Mauritius Research and Innovation Council. The composition of the committee is given in **Table 11**.

Table 11: Composition of Technical Committee on medicinalcannabis

Chairperson: Professor T. Bahorun	**Mauritius Research and Innovation Council**
Representatives of the Ministry of Health and Wellness	
Mrs C. Jhowry	Permanent Secretary
Dr M. Timol	Director General Health Services
Mr D. Dassaye	Deputy Permanent Secretary
Mrs R. D. Bissessur	Deputy Permanent Secretary
Dr B. Caussy	Director Health Services
Mr H. Bucktowar	Director Pharmaceutical Services
Dr S. Kowlessur	Chief Health Promotion & Research Coordinator
Mrs S. Kalasopatan – Chellen	Acting Deputy Permanent Secretary
Mrs B.A. Hossen	Assistant Permanent Secretary

Dr N.R. Sookool	Ag. Officer-in-Charge, Harm Reduction Unit
Dr A. Jhugroo	Consultant Psychiatrist & Addiction Treatment Specialist/Adviser MOHW
Mr D.Jawaheer	Pharmacist/Senior Pharmacist
Ms A. Mangatha	Senior Pharmacist, Pharmacy Unit
Mrs N. Busawon	Office Management Executive (Secretary)
Miss G. Daby	Management Support Officer
Representatives of other ministries/departments	
Mr C. Bhojoo	Deputy Commissioner, Police Department
Dr S. K. Gungadin	Chief Police Medical Officer, Prime Minister's Office
Mrs G. M. Madhub – Dassyne	Director Forensic Science Laboratory
Mr A. Toofany	Forensic Scientific Officer
Mrs G. Topsy – Sonoo	Parliamentary Counsel, Attorney General's Office
Dr A. Appadoo	Officer-in-Charge, National Drug Secretariat
Mrs N. Bundhoo	Adviser, Prime Minister's Office (NDS Secretariat)
Mr R. Gokulsing	Ag. COSHO, Ministry of Labour, Human Resource Development and Training
Miss P. Tajoo	OSHO, Ministry of Labour, Human Resource Development and Training
Mr Z. Jhumka	ACF, Forestry Service, Ministry of Agro – Industry and Food Security
Dr S. Nahaboo	Ag. SEP, Ministry of Education, Tertiary Education, Science and Technology, NECS Zone 1
Miss N. Chackhoor	Senior Probation Officer, Ministry of Education, Tertiary Education, Science and Technology
Mrs S. Sanasy	Analyst (Trade), Ministry of Commerce and Consumer Protection
Representatives of Other Organisations	
Dr H. Li Kam Wah	Professor, University of Mauritius
Dr V.S.Neergheen	Associate Professor, University of Mauritius
Mr D.Mungla	Senior Head, Mauritius Revenue Authority (Customs Dept)

Mr G.K Juglall	Technical Officer, Mauritius Revenue Authority (Customs Dept)
Mr R. Bissessur	Registrar, Pharmacy Council
Mr S. Khodabaccus	Member, Pharmacy Council
Dr D. Oaris	President, Private Clinics Association
Co-opted Members	
Dr S.B.M. Gaya	Senior Consultant in Charge, Internal Medicine, J. Nehru Hospital
Dr (Mrs) S. Sewsurn	Consultant in Charge, Radiotherapy Department, Victoria Hospital
Dr (Mrs) T. Hemoo	Consultant in Charge, Radiotherapy Department, Victoria Hospital
Dr H.Reesaul	Consultant Neurology
Mrs S. Naik	Clinical Cannabidiol Pharmacist

4.3 Sittings of Technical Committee

The Technical Committee conducted 7 meetings on the following dates:

1. 9 November 2020 Introductory meeting chaired by DrM.Timol, then Director General Health Services
2. 15 December 2020
3. 18 January 2021
4. 9 March 2021
5. 18 May 2021
6. 21 September 2021
7. 29 October 2021

Proceedings of the Technical Committee meetings addressed the following:

A. establishing the terms of reference of the Technical Committee

B. discussion on the draft Technical Paper on cannabis and cannabis related products from the African Union and the decisions of the Commission on Narcotic Drugs (CND)" on narcotics at the Committee held on 2nd December 2020

C. Public Consultation for views/comments/inputs on medicinal cannabis

D. setting up of 4 subcommittees to provide recommendations on:

   (i) Use of cannabis for medicinal purposes

   (ii) Therapeutic use of cannabis for medical use

   (iii) Scientific evidence for the use of cannabis for medical purposes

   (iv) Legal implications of the use of cannabis for medical purposes

4.4 Terms of Reference of Technical Committee

The Technical Committee consulted and led on the following:

(i) advising on the rescheduling of cannabis, based on the WHO-recommendations of January 2019 and decisions of the UNODC's Commission on Narcotics Drugs

(ii) providing advice and recommendations to the Ministry of Health and Wellness and to the Government regarding policies and guidance pertaining to the use of medical cannabis and establishing the basis of a non-recreational cannabis industry in Mauritius.

As per discussion, the mandate of the Technical Committee also extends to the following:

(1) to gauge country readiness and capacity for action-oriented policy interventions for medicinal cannabis use and exploitation in the immediate and longer term

(2) to conduct a baseline assessment, stakeholder meeting and mapping exercise of requirements (including legal, institutional, educational, social, health, economic)

(3) to set up subcommittees to address the following:

(i) to advise on the state and level of evidence regarding the safety, efficacy and quality of locally grown cannabis, including specific phyto-cannabinoids such as THC or CBD used for therapeutic purposes;

(ii) to develop a regulatory framework for importation, cultivation and manufacture of standardized cannabis/hemp products;

(iii) to advise whether local cannabis is the variety which can be used as hemp for industrial purposes (cosmetic, food products, commercial items etc);

(iv) Advise on the agronomy of locally-grown cannabis;

(v) to advise on R&D matters related to use of different forms of medicinal cannabis and standards for cannabis/hemp products and processes;

(vi) to advise on the development of test methods, practices and guides for cultivation (indoor and outdoor) and maintain proper quality assurance and management;

(vii) to look into laboratory considerations, processing and handling, security and transportation and personnel training; and

(viii) to advise on the socio-economic impact of medical and industrial cannabis use.

4.5 UNODC decisions on cannabis & cannabis-related substances taken in December 2020

On 2nd December 2020, in the UNODC HQ, in Vienna, Austria, the UNODC's Commission on Narcotic Drugs (CND) took a number of decisions on the international control of cannabis and cannabis-related substances. Cannabis and cannabis-related substances have for many years been included in the following schedules for the purpose of international control:

Single Convention on Narcotic Drugs of 1961 (amended by the 1972 Protocol):

- Schedule I and IV: cannabis and cannabis resin
- Schedule I: extracts and tinctures of cannabis

Convention on Psychotropic Substances of 1971:

- Schedule I: Tetrahydrocannabinol (six isomers of delta-9-THC)
- Schedule II: Dronabinol and its stereoisomers (delta-9-THC)

Following a critical review of cannabis & cannabis-related substances by the WHO's Expert Committee on Drug Dependence (ECDD), the WHO submitted eight recommendations in 2019 to UNODC's Commission of Narcotic Drugs.

After intensive considerations, the Commission decided (by 27 votes to 25 and with one abstention) to delete cannabis and cannabis resin from Schedule IV of the 1961 Convention. Cannabis and cannabis resin, however, remain in Schedule I of the 1961 Convention and thus remain subject to all levels of control of the 1961 Convention. The Commission decided not to follow the other seven recommendations made by the WHO, so that the schedules regarding the respective substances will otherwise remain unchanged.

The eight WHO recommendations submitted in January 2019:

Below is an extract of the UN document outlining the recommendations by the WHO's Expert Committee on Drug dependence (ECDD) at its 40th meeting in June 2018 on cannabis and cannabis-related substances for action to be taken by the Commission on Narcotic Drugs (CND) pursuant to the international drug control treaties:

Implications of voting -1961 UN Single Convention on Narcotic drugs:

Deleting "cannabis and resin" from schedule IV implies that "cannabis and resin" is no longer regarded as having "particularly dangerous properties" and as being of "little or no therapeutic value".

Maintaining "cannabis and resin" in Schedule I of the 1961 Convention implies that "cannabis and resin" is still regarded as being "highly addictive and liable to abuse".

The findings and recommendations of this Technical Committee on medical use of cannabis would represent the views of the Ministry of Health and Wellness on the decisions of the UNODS's Commission on Narcotics Drugs

4.6 Public Consultation for views/comments/inputs on medicinal cannabis

In December 2020, the Ministry of Health and Wellness requested views of the general public with regards to the use of cannabis for therapeutic purposes. Seventy-seven emails were received and the demand for therapeutic use of medical cannabis was overwhelming (76 out of 77 emails).

A significant proportion of the email respondents were health professionals who wanted to share their views. Some were patients who had prior treatment with cannabis-based medicinal products abroad and expressed their views. Some of the patients were also contacted by telephone to get more details of their experiences and views.

Some of the medical conditions which the email respondents have been requesting medical cannabis for treatment include:

- Pain
- Cancer
- Epilepsy
- Psoriasis
- Systemic Lupus Erythematous
- Alcohol addiction treatment
- Nausea/vomiting side effects of chemotherapy
- Anxiety/depression
- Parkinson's disease

4.7 Subcommittees of the Technical Committee

The Technical Committee recommended the setting up of 4 subcommittees to (i) spell out the specifics of cannabis use for medical purposes, (ii) provide therapeutic indications for the use of medical cannabis (iii) provide scientific evidence for the use of medical cannabis for medical purposes (iv) make recommendations on the legal implications for the use of medical cannabis. The Terms of reference, compositions and number of sittings are provided in **Table 12.**

Table 12: Terms of references, composition and sittings of subcommittees

Subcommittee	Terms of Reference	Chairperson	Members	Sittings
Cannabis Use For Medical Purposes	Specific use of Cannabidiol (CBD), Tetrahydrocannabinol (THC) and combination of CBD and THC for medicinal purposes	**Mrs G.M Madhub-Dassyne**, Director, Forensic Science Laboratory	1. **Dr S.K Gungadin**, Chief Medical Officer, Police Medical Unit 2. **Mrs G. Topsy-Sonoo**, Parliamentary Counsel, State Law Office 3. **Dr A. Jhugroo**, Adviser, Substance Abuse, MOHW 4. **Dr H. Li Kam Wah**, HOD, Professor Faculty of Science, University of Mauritius 5. **Mr A. Toofany**, Forensic Scientist, Forensic Science Laboratory	21 Dec 2020

Subcommittee	Terms of Reference	Chairperson	Members	Sittings
Therapeutic use of cannabis for medical use	Provide recommendations on the Therapeutic use/dosage of Cannabidiol (CBD) and Tetrahydrocannabinol (THC) for medical use	**Dr B.S Caussy**, Director Health Services, MOHW	1. **Mr D. Dassaye**, Deputy Permanent Secretary, MOHW 2. **Dr (Mrs) T. Hemoo**, Consultant in Charge (Radiotherapy), Victoria Hospital 3. **Dr H. Reesaul**, Neurologist, Victoria Hospital 4. **Dr K.S. Ng Miao Kwong**, Consultant Paediatrician, Victoria Hospital 6. **Dr A. Jhugroo**, Adviser, Substance Abuse, MOHW 5. **Mr D. Jawaheer**, Senior Pharmacist/Pharmacist 6. **Dr S.P.WMaharahaje**, Registrar, Medical Council of Mauritius 7. **Mr R. Bissessur**, Registrar, Pharmacy Council of Mauritius 8. **Mrs N.Bundhoo**, Adviser, Prime Minister's Office (National Drug Secretariat) 9. **Dr D. Oaris**, President, Private Clinics Association 10. **MissM.Emamboccus**, Office Management Assistant (Secretary)	15 Feb 2021
Scientific evidences for the use of cannabis for medical purposes	1. With regards to CBD and THC (for ease of reference we are hereby alluding to 2 utilised derivative drugs - Epidiolex and Sativex): To survey and bring up comprehensive sets of evidence (clinical and other studies)	7. **Dr A. Jhugroo**, Adviser, Substance Abuse, MOHW	1. **Ms A. Mangatha**, Senior Pharmacist, Pharmacy Unit. 2. **Dr (Mrs) S.Sewsurn**, Consultant in Charge, Radiotheapy Department, Victoria Hospital	22 April 2021

Subcommittee	Terms of Reference	Chairperson	Members	Sittings
	to support prescription / utilisation for pathologies that this subcommittee would recommend. 2. With regards to CBD and THC (for ease of reference we are hereby alluding to 2 utilised derivative drugs-Epidiolex and Sativex): Survey the literature to come up with recommendations on dosage and usage mode. 3. Spell out any Counter indications of the use of CBD and THC (for ease of reference we are hereby alluding to 2 utilised derivative drugs-Epidiolex & Sativex). 4. Interaction with other drugs- With regards to CBD and THC (for ease of reference we are hereby alluding to 2 utilised derivative drugs-Epidiolex and Sativex). 5. Any other scientific data deemed important on the utilisation of CBD and THC (for ease of reference we are hereby alluding to 2 utilised derivative drugs-Epidiolex and Sativex)		3. **Dr (Mrs) T. Hemoo**, Consultant in Charge (Radiotherapy), Victoria Hospital 4. **Dr H. Li Kam Wah**, Professor HOD, Faculty of Science, University of Mauritius 5. **Mr R. Bissessur**, Registrar Pharmacy Council 6. **Mr S. Khodabaccus**, Member of Pharmacy Council 7. **Mrs S.Nathoo-Naik**, Clinical Cannabidiol Pharmacist 8. **Dr V.SNeergheen**, Associate Professor, University of Mauritius	

Subcommittee	Terms of Reference	Chairperson	Members	Sittings
Legal implications of the use of cannabis for medical purposes		**Mrs G.Topsy-Sonoo**, Parliamentary Counsel, State Law Office	1. **Mr C. Bhojoo**, Deputy Commissioner of Police 2. **Dr S.K Gungadin**, Chief Police Medical Officer, Police Medical Unit 3. **Mrs G.M Madhub-Dassyne**, Director, Forensic Science Laboratory 4. **Dr A. Jhugroo**, AdviserSustanceAbuse, MOHW 5. **Mr G. Juglall**, Technical Officer, Mauritius Revenue Authority (Customs Department 6. **Mr H. Bucktowar**, Director, Pharmaceutical Services, MOHW 7. **Mr R. Gokulsing**, Ag COSHO, Ministry of Labour, Human Resource Development and Training	11 Feb 2021 10 Sept 2021

PART 5

5.1 Findings and Recommendations

The technical discussions were focused on the use/dosage of Cannabidiol (CBD), Tetrahydrocannabinol (THC) and combination of CBD and THC for medicinal purposes. Cannabis for recreational purposes and use of CBD-based food supplements and cosmetics were not considered. The use of Dronabinol and related isomers are not to be considered.The committees highlighted thatdifferent drugs with varied dosages of THC are used for various specialities and that many countries use different percentage concentrations of THC which are recommended and approved by UNODC and FDA.

Based on discussions and findings, recommendations were made by the Technical Committee on Medicinal Cannabis on (1) Indications of treatment, (2) Licensing of medical specialists and pharmacists, (3) Training of professionals, (4) Dispensing model, (5) Electronic register of patients, (6) Pharmacovigilance, (7) Monitoring and evaluation (8) Legal regulatory framework for medical cannabis

1. Indications of Use and Treatment

Rec 1: The Technical Committee recommends that Plant-derived Cannabidiol (CBD), Tetrahydrocannabinol (THC) and combination of CBD and THC be used for medical purposes in Mauritius.

Rec 2: Only FDA approved Cannabis based medications are to be considered.

Rec 3: Only importation of medicinal cannabis products would be considered in the initial stage by the Ministry of Health and Wellness.

Rec 4: Patients attending public health establishments and requiring medicinal cannabis would need to be assessed by a specialist committee at the level of Regional Hospitals and Cancer Centre. This specialist committee will be the utmost authority to allow the use of medicinal cannabis.

Rec 5: A patient registration or card holder system should be put in place.

Rec 6: Cannabis medicinal products (CBD/THC) will only be used in hospitals. As per the Pharmacy Act, when a product is imported for use in hospitals only, there will not be any need for an import permit.

Rec 7: The medication containing CBD and/or THC will be stored in a government pharmacy in an earmarked hospital.

Rec 8: The Ministry of Health and Wellness would need to define the medicinal cannabis formulations.

Rec 9: Only licensed Government specialists/senior Government specialists would be authorized to prescribe cannabis based drugs and provide treatment to patients following approval by their respective consultants in charge.

Rec 10: A board of specialists comprising public and private specialists would also be able to recommend and endorse prescriptions to private patients referred to the board by a private specialist.

Rec 11: A Protocol will have to be worked out to cater for overseas visiting patients who are on medicinal-based cannabis.

Rec 12: The Technical Committee recommends to use the National Institute for Health and Care Excellence (NICE) guidelines (UK) published in November 2019 and/or the AgenceNationale de Sécurité du Médicament et des Produits de Santé (ANSM's) "*5 indications thérapeutiques*" guidelines (France) which restrict prescribing medicinal cannabis to the following specific conditions:

- **Spasticity associated with multiple sclerosis (NICE & ANSM)**
- **Some forms of treatment-resistant juvenile epilepsies (NICE & ANSM)**
- **Nausea/vomiting side effects assoc. with cancer chemotherapy (NICE & ANSM)**
- **Chronic Neuropathic pain unresponsive to conventional treatment (NICE & ANSM)**
- **Treatment-resistant symptoms in Palliative care/Oncology (ANSM-France only)**

<u>Ancillary recommendations</u>

- **Cannabidiol (CBD) with THC not exceeding 0.2% to be considered for treating seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome**
- **A 4-week trial of Tetrahydrocannabinol (THC): Cannabidiol (CBD) be used to treat moderate to severe spasticity in adults with multiple sclerosis. Treatment to be continued only if at least 20% improvement in spasticity reduction is reported/observed**

- **Formulation consisting of plant-derived Tetrahydrocannabinol (THC) be considered to treat chemotherapy-induced nausea and vomiting in adult patients whose nausea and vomiting persists despite optimized conventional anti-emetics**

Rec 13: The following routes of administration of cannabis-based medicines are being recommended:

- **Oral**
- **Inhalation**
- **Vaporisers**
- **Topical treatments**

2. Licensing of Medical Specialists and Pharmacists

The Technical Committee recommends:

i. that a licence to prescribe medicinal cannabis be issued by the Ministry of Health and Wellness

ii. that the criteria for licensing be as follows:

   a. **Prescribers should be Specialists/Medical Consultants employed by the Ministry of Health and Wellness. (This applies also to Government Pharmacists and Government dispensers)**
   b. **Prescribers should prescribe only in their field of speciality and not prescribe outside their field of speciality.**
   c. **Prescribers should have completed a training course (including on-line courses) accredited by a recognized institution.**

3. Training of Health Professionals

The Technical Committee recommends that a number of interested Medical Specialists in field of Internal Medicine, Oncology, Neurology, Pain Specialists, Pediatricians and other relevant medical specialities, and Pharmacists would need to follow an on-line accredited training course from a recognized institution and be issued with a certificate of completion of training on medical cannabis. Some of the institutions offering such courses are the International Committee of the Society of Cannabis Clinicians (SCC) and the Academy of medical cannabis (UK).

4. Dispensing model

Rec 1: The Technical Committee recommends that the cannabis-based medication be dispensed initially by trained pharmacists from the Ministry of Health and Wellness's Regional Hospitals and Cancer Centre. The medication is to be dispensed to the patient or an agreed nominated family member or carer of the patient upon presentation of ID documents.

Rec 2: Medication will be dispensed and records will be kept under the Dangerous Drugs Act 2000 of Mauritius at the Regional Hospitals and Cancer Centre.

Rec 3: A Central Electronic Register will be kept at the Regulatory Unit of the Pharmacy Division of the Ministry of Health and Wellness by a dedicated team.

Rec 4: Monthly reports will be sent by the Regional Hospitals and Cancer Centre to the Director, Pharmaceutical Services for updating the Electronic Register.

Rec 5: Patients attending Regional Hospitals and Cancer Centre will receive the medication free of cost.

Rec 6: Patients referred from the private sector, following approval of the board of specialists, will purchase the medication at an approved cost.

5. Electronic register of patients

The Technical Committee recommends maintaining an electronic register for patients prescribed cannabis-based medication by a team of pharmacist and medical specialist.

The electronic register is recommended to include the following details:

Demographic details:

- age
- gender
- marital status
- occupation & employment status
- area of residence

Clinical details:

- clinical features
- diagnosis
- medication
- investigation results
- response to treatment
- prognosis

Outcome of treatment:

- response to treatment: subjective and objective reports
- follow clinical markers of progress
- occurrence of any adverse events
- complications encountered during treatment
- attempts to trace patients lost to follow up

6. Legal Regulatory framework for medical cannabis

Rec 1: The following regulations are recommended to be made by Hon Minister of Health and Wellness under section 60 of the Dangerous Drugs Act, 2000.

The First Schedule to the Act beamended –

(a) in Part I, by deleting the item "Cannabis (also known as *Gandia* or Indian Hemp)" and replacing it by the following item –

Cannabis (also known as *Gandia* or Indian Hemp), excluding –

(a) a liquid formulation containing a botanical extract of cannabis –

(i) with a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of delta-9-tetrahydrocannabinol per milliliter; and

(ii) where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 and 1.3,

which is dispensed through a metered dose pump as a mucosal mouth spray;

(b) cannabidiol product that –

(a) contains cannabidiol;

(b) does not contain a specified substance;

(c) contains specified substances in an amount that is more than 0.2 per cent of the sum of the amount of cannabidiol and the amount of specified substances in the product; or

(c) does not contain any other controlled drug.

(b) in Part II, by deleting the item "Cannabis Resin" and replacing it by the following item –

Cannabis Resin, excluding –

(a) a liquid formulation containing a botanical extract of cannabis –

(i) with a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of delta-9-tetrahydrocannabinol per milliliter; and

(ii) where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 and 1.3,

which is dispensed through a metered dose pump as a mucosal mouth spray;

(b) cannabidiol product that –

(a) contains cannabidiol;

(b) does not contain a specified substance;

(c) contains specified substances in an amount that is more than 0.2 per cent of the sum of the amount of cannabidiol and the amount of specified substances in the product; or

(c) does not contain any other controlled drug.

The Second Schedule to the Act be amended by adding the following new paragraph

A liquid formulation –

(a) containing a botanical extract of cannabis –

(i) with a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of delta-9-tetrahydrocannabinol per milliliter; and

(ii) where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 and 1.3,

(b) which is dispensed through a metered dose pump as a mucosal mouth spray.

The Third Schedule to the Act beamended by adding the following new paragraphs

Cannabidiol product

1. Cannabidiol means a product that –

(a) contains cannabidiol; and

(b) either –

(i) does not contain a specified substance; or

(ii) contains specified substances in an amount that is more than 0.2 per cent of the sum of the amount of cannabidiol and the amount of specified substances in the product; and

(c) does not contain any other controlled drug.

2. In this section –

"specified substances" means a substance –

(a) naturally occurs in cannabis; and

(b) is –

(i) a tetrahydrocannabinol;

(ii) an isomer, ester, or ether of a tetrahydrocannabinol;

(iii) an ester or ether of an isomer of a tetrahydrocannabinol;

(iv) a salt of any substance described in subparagraphs (i) to (iii); or

(v) a substance that has a structure substantially similar to that of any substance described in subparagraphs (i) to (iv).

Rec 2: The Technical Committee recommends increasing the prescription limit for supply of Schedule 2 controlled drugs from 10-day to 14-day treatment

Rec 3: A guideline is recommended to be prepared by the Ministry of Health and Wellness for Pharmacists in the private sector to inform them of the nature of cannabis products expected to be sold once the Dangerous Act 2000 be amended.

7. Pharmacovigilance

The Technical Committee recommends the setting up of adequate pharmacovigilance mechanisms for cannabis-based products with easy access to adverse events reports.

8. Monitoring and evaluation

The Technical Committee recommends that risks and benefits of medical cannabis prescription in Mauritius should be assessed by a team of health professionals regularly, preferably on a 3-monthly basis initially and regular reports should be submitted to the Ministry of Health and Wellness.

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