Paperwork

Theme 2: Legality and Enforcement

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A. Introduction.

The term medical cannabis is not just a recent phenomenon but has long been introduced and used in the community. Many countries have legislatively amended cannabis from controlled to lesser regulated or unregulated substance groups – depending on the approved usage for either one, two, or all purposes of medical, recreational, and industrial purposes. It is not a surprise that cannabis was ranked as the most widely used substance worldwide. The prominent urge for legalisation in several countries is mainly due to industrial and economic pressure and, to a certain extent, for medical reasons[1].

There are at least 540 types of alkaloids and more than 100 phytocannabinoids of cannabis (*Cannabis sativa L.*) identified with the main active compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the one responsible for producing psychoactive effects, whereas it is not the case for CBD. However, both of these cannabinoids have been shown to provide medical benefits and have been widely studied for various indications[1]. At present, the most widely available products in the market are Marinol® (AbbVie Inc) and Syndros® (Benuvia Therapeutics) which contain dronabinol, an isomer of delta-9-tetrahydrocannabinol; Cesamet® based on nabilone (Meda Pharmaceuticals Inc.), another synthetic cannabinoid; Sativex® (GW Pharma Ltd.), based on an ethanol extraction of *Cannabis sativa*; and Epidiolex® (Greenwich Biosciences), which contains almost purely CBD[2].

Dronabinol and nabilone are synthetic THC with a specific indication for chemotherapy-induced nausea and vomiting in patients who are unresponsive to the standard treatment and also for appetite stimulation in HIV-AIDS anorexia[3,4]. They have also shown some positive effects in reducing central neuropathic pain in patients with multiple sclerosis and fibromyalgia[5]. Nabiximols or Sativex® is a 1:1 combination of CBD and THC and is indicated in treating neuropathic pain and spasticity due to multiple sclerosis and intractable cancer pain[6,7]. Sativex® was registered in Malaysia in the year 2014, however, the registration was withdrawn from the company in the year 2017 due to commercial reasons[1]. Cannabidiol is effective in the management of certain treatment-resistant, childhood-onset epilepsy disorders, or associated with Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex in patients aged one year and older[8].

According to recent market research, the global cannabis pharmaceuticals market is expected to grow at a compound annual rate of 76.8% between 2020 and 2027. Europe was the dominant region for the cannabis pharmaceuticals market in 2019 and is home to some of the major manufacturers of the sector[9]. Hence, the Malaysian government specifically the Ministry of Health is receiving overwhelming pressure for decriminalization or even legalization of cannabis (THC/CBD) for this country, claimed as mainly to be used for medical purposes.

However, the current legislation needs to be carefully scrutinized before any amendment is made so that in the long run, the later implementation will not produce any harm to the Malaysian population and the nation as a whole, especially to the young generations.

B. WHO Expert Committee on Drug Dependence 41st Report 2019. Cannabis and cannabis-related substances[10].

The laws governing the use of dangerous drugs in Malaysia are subjected to the 1961 Single Convention on Narcotic Drugs, as participated for implementation. WHO Expert Committee on Drug Dependence in its 41st report has reviewed cannabis and cannabis-related substances as summarized below with the stated recommendation.

Cannabis /cannabis-related substances	**1961 Single Convention on Narcotic Drugs (as amended by the 1972 protocol)**	**1971 Convention on Psychotropics Substances**	**1961 Single Convention on Narcotic Drugs (as amended 2019)**
Cannabis and cannabis resin	Schedule I and Schedule IV.		*Schedule I
Extract and tincture of cannabis	Schedule I		Schedule I
Δ9-tetrahydrocannabinol is included in Schedule II as dronabinol and its stereoisomers.		Schedule II	Schedule I
The tetrahydrocannabinol isomers Δ6a(10a)-tetrahydrocannabinol, Δ6a(7)-tetrahydrocannabinol, Δ7-tetrahydrocannabinol, Δ8-tetrahydrocannabinol, Δ10-tetrahydrocannabinol and Δ9(11) tetrahydrocannabinol are included in Schedule I.		Schedule I	Schedule I
Cannabidiol preparation which contained <0.2% THC.	Schedule I		**Schedule I with a footnote - Not under international control.

* *While the Committee did not consider that cannabis is associated with the same level of risk to health as that posed by most of the other drugs placed in Schedule I, it noted the high rates of public health problems arising from cannabis use and the global extent of such problems. For these reasons, it is recommended that cannabis and cannabis resin continue to be included in Schedule I of the 1961 Single Convention on Narcotic Drugs.*
Recommendation: *The Committee recommended that cannabis and cannabis resin be deleted from Schedule IV of the 1961 Single Convention on Narcotic Drugs.*

***The committee recommended that a footnote be added to Schedule I of the 1961 Single Convention on Narcotic drugs to read: "Preparation containing predominantly cannabidiol and not more than 0.2% of THC are not under international control.*

[10] * and ** WHO Expert Committee on Drug Dependence Forty-first Report. (WHO Technical Report Series, No. 1018), 2019.

C. Current Laws and Regulations in Controlling of Handling/ Use of Cannabis and Cannabis-related Substances in Malaysia.

i) Dangerous Drug Act (DDA) 1952 (Revised 1980) – Incorporating latest amendment – P.U. (A) 296/2021[11].

ii) Dangerous Drugs Regulations (DDR), 1952 – Incorporating latest amendment P.U. (A) 1/2018[12].

Cannabis and cannabis-related substances are currently listed in Part I and Part II of the First Schedule, Dangerous Drug Act 1952. This act and its regulations are controlling the import, export, possession, cultivation, regulation, storage, consumption, administration, selling (retail/wholesale), supply, and recording of raw cannabis such as seed, plant, resin, and extract (THC/CBD).

Section 6B. Restriction on planting or cultivation of certain plants.

(1) No person shall—

(a) either on his own behalf or on behalf of any other person, plant or cultivate any plant from which raw opium, coca leaves, poppy-straw or cannabis may be obtained either directly or indirectly;

(b) allow any plant, from which raw opium, coca leaves, poppy-straw or cannabis may be obtained either directly or indirectly, to be planted or cultivated by some other person on land owned or occupied by him or in any receptacle on such land; or

(c) allow any plant, from which raw opium, coca leaves, poppy-straw or cannabis may be obtained either directly or indirectly, planted or cultivated by some other person on land owned or occupied by him or in any receptacle on such land, to remain on such land or in such receptacle.

(2) Nothing in this section shall be construed to prevent the Minister from authorizing any public officer to plant or cultivate any plant, from which raw opium, coca leaves, poppy-straw or cannabis may be obtained either directly or indirectly, in places and on such terms and conditions as may be specified in such authorization for research, educational, experimental or medical purposes.

(3) Any person who contravenes this section shall be guilty of an offence against this Act and shall be punished on conviction with imprisonment for life and with whipping of not less than six strokes.

(4) Any person found on land or who occupies land on which, or any person found in possession of any receptacle in which, any plant, from which raw opium, coca leaves, poppy-straw or cannabis may be obtained either directly or indirectly, is planted or cultivated shall be presumed, until the contrary is proved, to be the person who planted or cultivated such plant.

The cultivation and recreational use of raw cannabis is currently prohibited in Malaysia, and possession of 200 grams or more shall be presumed, until the contrary is proved, to be trafficking in the said drugs, which entails a death sentence or imprisonment for life or whipping of not less than 15 strokes if he/she is not sentenced death.

[11] Dangerous Drug Act 1952 (Revised 1980) – Incorporating latest amendment – P.U. (A) 296/2021.
[12] Dangerous Drugs Regulations, 1952 – Incorporating latest amendment P.U. (A) 1/2018.

iii) Poison Act 1952 (Revised 1989) – Latest Amendment made by P.U (A) 8/2019 which came into operation on 10th January 2019[13].

iv) The Poison Regulations 1952[14].

In the Poison Act 1952, it mentioned that (DD) Cannabis, its resin, extracts, and tinctures of; and cannabin tannate (except in corn pain for external use) is categorised under group B poisons where the supply/selling by retail must be done by a registered medical practitioner, registered dentist Division I or veterinary officer and dispensed by a licensed pharmacist, in accordance with a prescription prescribed by a registered medical practitioner, registered dentist or veterinary officer. This act controls the imports, packaging, labeling, storing, transporting, manufacturing, compounding, selling, and supplying of cannabis-based products in a standard pharmaceutical dosage form.

v) Sales of Drugs Act 1952 (Revised 1989)[15].

vi) Control of Drugs and Cosmetics Regulation (CDCR) 1984[16].

Sales of Drugs Act 1952 (Revised 1989) regulates the sales and supply of cannabis finished products in standard pharmaceutical dosage forms.

"drug" includes any substance, product, or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medicinal purpose;

"medicinal purpose" means any of the following purposes: (a) alleviating, treating, curing, or preventing a disease or a pathological condition or symptoms of a disease; (b) diagnosing a disease or ascertaining the existence, degree, or extent of a physiological or pathological condition; (c) contraception; (d) inducing anaesthesia;

(e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function; (f) controlling body weight; (g) general maintenance or promotion of health or wellbeing;

The CDCR Regulation 1984 Section 7(1) stated that; *No person shall manufacture, sell, supply, import, possess, or administer any product unless:*

a) The product is registered.
b)The person holds the appropriate license required and issued under CDCR.

vii) Drug Registration Guidance Document (DRDG) 3rd Edition 2022[17].

Other than that, Cannabis Spp. (all species) which includes hemp/marijuana is also listed in the **Negative List** for FDI (Food-Drug Interphase) of the Drug Registration Guidance Document (DRDG) 3rd Edition 2022, issued by the National Pharmaceutical Regulatory Agency (NPRA)[17]. This guide serves to assist in determining if a product is regulated by the NPRA or by the Food Safety and Quality Division (FSQD) of the Ministry of Health Malaysia. Hence, all cannabis and cannabis-related products are needed to be classified as either active pharmaceutical ingredient (API) or finished product/drug in a standard pharmaceutical dosage form such as capsule, tablets, sublingual, buccal, etc, and to be registered with the Drug Control Authority before it can be used in this country[17]. It is also included in the prohibited/banned ingredients for botanicals (botanical ingredients)[18] which further explained why the products can only be registered as generic medicines or new chemical entities and NOT permitted as health supplements / natural products (traditional medicine).

[13] Poison Act 1952 (Revised 1989) – Latest Amendment made by P.U (A) 8/2019 which came into operation on 10th January 2019.
[14] The Poison Regulations 1952.
[15] Sales of Drugs Act 1952 (Revised 1989).
[16] Control of Drugs and Cosmetics Regulation (CDCR) 1984.
[17] National Pharmaceutical Regulatory Agency. Drug Registration Guidance Document (DRDG) 3rd Edition, Third Revision July 2022. Appendix 1. Food and Drug Interphase (FDI) Products.
[18] National Pharmaceutical Regulatory Agency. Drug Registration Guidance Document (DRDG) 3rd Edition, Third Revision July 2022. Appendix 7. Guideline on Registration of Natural Products.

D. The Pathways of Cannabis Use for Medical Purposes in Malaysia

The existing laws and regulations are sufficient in allowing the use of the cannabis-based product in pharmaceutical dosage form for medical purposes in Malaysia. It is evident with the registration and clinical use of Sativex® (nabiximols) Oromucosa Spray in Malaysia in the year 2014 (Reg No: MAL14095053ACRZ) which contains about 1:1 of CBD:THC ratio. The discontinuation of the product in 2017 was not due to any breach of laws or regulations but a voluntary withdrawal by the company (GW Pharma) due to commercial reason[19]. The approved indication of Sativex was for the treatment of symptoms improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medications and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial therapy[20].

Cannabis and cannabis-based products might be registered and used in Malaysia within these three (3) pathways[21]:-

i) To register as finished pharmaceutical products (generic drug / new entity)[22].

A pharmaceutical company may apply for registration of the finished product in standard pharmaceutical dosage form with complete product information and robust evidence on quality, safety, and efficacy. Although NPRA does not require local data for registration, studies within the population are highly recommended to enhance the related evidence.

ii) To register as Investigational Products[23].

Researchers who would like to conduct a clinical study on cannabis and cannabis-based products need to apply for a clinical trial import license (CTIL) or clinical trial exemption (CTX). The study must first be registered with the National Medical Research Registry (NMRR) and approved by the Medical Research Ethics Committee (MREC).

iii) Possibility to apply for registration under Special Access Scheme (SAS) or Authorised Prescriber (AP) pathway.

These two pathways have been implemented in countries such as the United Kingdom and Australia[24]. In Malaysia, the discussion for this pathway is still ongoing at the higher authority of the Ministry of Health Malaysia and the guideline is still in the process of development.

E. Legislation Issues, Experience, and Lessons Learned from other countries.

i) Legalization vs Decriminalization.

Legalization of cannabis is the process of removing all legal prohibitions against it. Cannabis would then be available to the adult general population for purchase and use at will, similar to tobacco and alcohol. Decriminalization is the act of removing criminal sanctions against an act, article, or behavior. Decriminalization of cannabis means it would remain illegal, but the legal system would not prosecute a person for possession under a specified amount. Instead, the penalties would range from no penalties at all, to civil fines, drug education, or drug treatment[24].

The legislative provision from one country to another is different where few countries adopted the legalization moves which means that people can freely use it for recreational purposes, but others might adopt the decriminalization regulation, especially for medicinal purposes. Among the countries that have allowed the use of cannabis for recreational purposes include Canada, the United States of America, Uruguay, and the Netherlands. Canada and Uruguay allow the sale of cannabis commercially but in the Netherlands, the sale of Cannabis is allowed only in licensed store[1]. To date, a total of 44 countries have allowed cannabis use for medical purposes including Thailand, the only country in South East Asia that has allowed the cannabis-based product for self-medication and own use[1]. In Australia, medicinal cannabis products are classified as prescription medicines. The country's regulations still control the use of medicinal cannabis to minimise the risk of harm from inappropriate use, while ensuring that it is available to appropriate patients[25].

Recommendation: It is believed that cannabis is still needs to be highly regulated in this country due to the high risk of diversion, misuse, and abuse in the population.

Justification: There are worrying facts on the overlapping patterns of recreational and medical cannabis use in a large community sample of cannabis users where 80.1% of the population reported also using them for recreational purposes (MED+REC). Compared to recreational users, medical users reported more problematic cannabis use in addition to greater psychiatric symptomatology (anxiety, depression, and trauma). A large majority of medical users also reported using it recreationally (80.6%), while exclusive medical use was less common (19.3%). This dual motives group reported more daily cannabis use and more alcohol and tobacco use. Compared to medical-only users, individuals using cannabis for both medical and recreational purposes more often used cannabis to treat psychiatric conditions[26].

Another study revealed that cannabis use was strongly associated with psychiatric illnesses such as suicidal attempts, physical fights, low peer support, high alcohol dropouts, and tobacco use among teenagers[27,28]. A report from Thailand stated that the ramifications of medical and recreational legalization of cannabis for the development of youth and emerging adults are significant in terms of diversion of medical and recreational cannabis, significant effect on academic functioning, increase in the risk for psychosis and development of schizophrenia, legal record, especially for minority adolescent and normalization of cannabis use, decreased perception of harm, increased initiation, and habitual use[29,30].

ii) Rescheduling or Descheduling of related laws & regulations and Regulatory framework on the use of CBD.

Recommendation 1: To maintain the current laws and regulations without any further amendment.

Justification: The current laws and regulations are sufficient to allow the use of cannabis / cannabis-based products for medical purposes in Malaysia. The researchers may apply the CTIL for registration and use as investigational products. The legalization might increase accessibility, promote normalization /recreational use in the community, and brings more harmful effect to the community. Cultivation of Cannabis Sativa spp (eg: Hemp) needs to be in balance with its expected usage for medical purposes in this country (not industrial).

Recommendation 2: If there is overwhelming evidence, needs, and urgency in usage in a specific group of patients with specific indications (rare diseases, refractory cases, and non-responding to standard treatment), it is recommended to register cannabidiol preparation as an active pharmaceutical ingredient (API) or in standard pharmaceutical dosage form with less than 0.2% THC (eg: Epidiolex®) and to regulate with Poison Act 1952 and Poison Regulation 1952 – safest option. Hence, the raw unprocessed CBD/hemp in the form of resin, seed, and extract of CBD will still be controlled under the Dangerous Drugs Act 1952.

Justification: This recommendation is in line with the 1961 Single Convention on Narcotic Drugs mentioned below: -

'At its fortieth meeting in June 2018, the Committee recommended that cannabidiol in its pure form not be controlled under the conventions. However, if it is obtained as an extract or tincture of cannabis (which is the method of production of the currently registered pharmaceutical product) then cannabidiol could be considered a controlled substance under the 1961 Convention. ***Recommendation:*** *The committee recommended that a footnote be added to Schedule I of the 1961 Single Convention on Narcotic Drugs to read: Preparation containing predominantly cannabidiol and not more than 0.2% of THC are not under international control[10].'*

Recommendation 3: To maintain the registration of cannabis-based products as ONLY Active Pharmaceutical Ingredient and Finished Products in standard pharmaceutical dosage form and to maintain all Cannabis spp. in the negative list of Appendix 1 Drug-Food Interphase.

Justification: It has been found in other countries that there will be a risk of diversion with lesser control from the authority. The removal of hemp from this list may allow it to be extensively registered and used in food & beverage products. A study in Thailand found that one in 10 cannabis beverages in Bangkok had a higher level of THC than suggested. If taking two (2) glasses, about 40% of the products have more than the recommended level of THC[31]. Cannabis-based products will eventually flood the market without any specific indication and will have the same fate as the current alcohol, tobacco vape, and e-cigarette industry where it is currently out of control and significantly contributing to many public health issues.

F. Conclusion

Cannabis might exhibit some medical benefits to specific disease conditions in the population. However, the risk and benefits need to be carefully weighed so that the user is highly regulated and justifiable from a medical perspective and less tendency of being inappropriately used in this country. Different countries might have different recommendations and regulations in dealing with this issue. In Malaysia, the *waqi'* (reality) of the grassroots population needs to also be addressed and considered before any decision is made.

THANK YOU

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THEME 2: LEGALITY AND ENFORCEMENT

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Introduction

- The term medical cannabis is not just recently introduced.
- Many countries have legislatively amended cannabis from controlled to less regulated (decriminalization) or unregulated (legalization) substance groups – depending on the approved usage for either one, two, or all purposes of medical, recreational, and industrial purposes.
- Hence, it is not a surprise that cannabis was ranked as the most widely used substance worldwide.
- The prominent urge for legalisation in several countries is mainly due to political, industrial and economic pressure and, to a certain extent, for medical reasons[1].

Available preparations in the market

Types	Cannabinoid	Brand name	Manufacturing Company	Approved indication
Synthetic THC.	Dranabinol (Isomer of delta-9-THC)	Marinol®	AbbVie Inc.	• Chemotherapy-induced nausea and vomiting in patients who are unresponsive to the standard treatment and also for • appetite stimulation in HIV-AIDS anorexia[3,4] • They have also shown some positive effect in reducing the central neuropathic pain in patients with multiple sclerosis and fibromyalgia[5]
		Syndros®	Benuvia Therapeutics Inc.	
	Nabilone	Cesamet®	Meda Pharmaceuticals	
Hybrid with 1:1 CBD and THC ratio.	Nabiximols	Sativex®	GM Pharma	• indicated in treating neuropatic pain and spasticity due to multiple sclerosis and intractable cancer pain[6,7] • Sativex® was registered in Malaysia in the year 2014, however, the registration was withdrawn from the company in the year 2017 due to commercial reasons[1].
CBD only with less than 0.2% THC.	Canabidiol	Epidiolex®	Greenwich Biosciences Inc.	• Cannabidiol has been shown to be effective in the management of certain treatment-resistant, childhood-onset epilepsy disorders, or associated with Lennox-Gastaut syndrome, Dravet syndrome and tuberous sclerosis complex in patients aged one year and older[8].

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Cannabis & Cannabis resin

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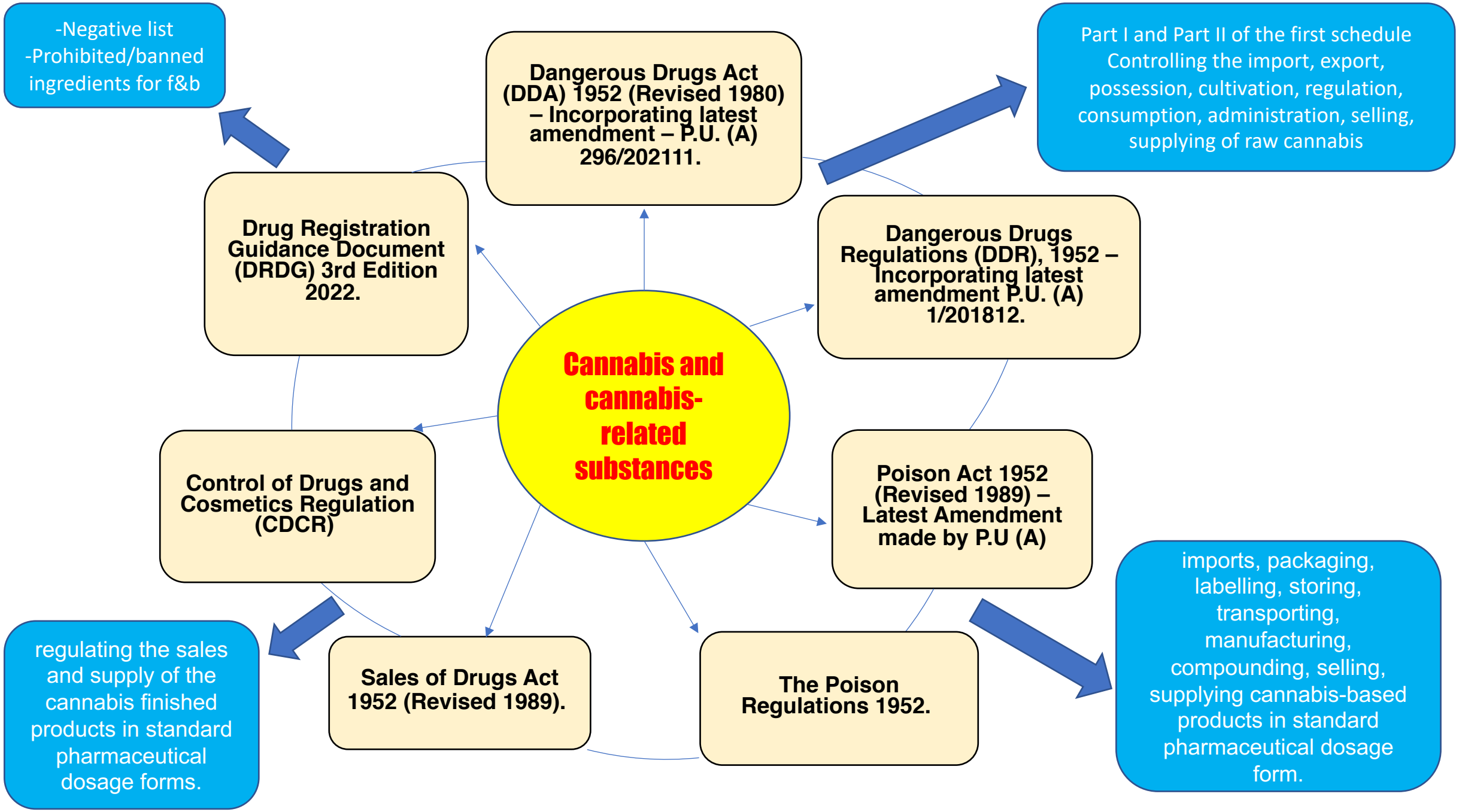
Expert Committee on Drug Dependence Forty-first Report. (WHO Technical Report Series, No. 1018), 2019.

Current Laws and Regulations in Controlling the Handling/ Use of Cannabis and Cannabis-related Substances in Malaysia.


Cannabis and cannabis-related substances
Dangerous Drugs Act (DDA) 1952 (Revised 1980) – Incorporating latest amendment – P.U. (A) 296/202111.
Part I and Part II of the first schedule Controlling the import, export, possession, cultivation, regulation, consumption, administration, selling, supplying of raw cannabis
Drug Registration Guidance Document (DRDG) 3rd Edition 2022.
-Negative list -Prohibited/banned ingredients for f&b
Dangerous Drugs Regulations (DDR), 1952 – Incorporating latest amendment P.U. (A) 1/201812.
Control of Drugs and Cosmetics Regulation (CDCR)
regulating the sales and supply of the cannabis finished products in standard pharmaceutical dosage forms.
Sales of Drugs Act 1952 (Revised 1989).
Poison Act 1952 (Revised 1989) – Latest Amendment made by P.U (A)
The Poison Regulations 1952.
imports, packaging, labelling, storing, transporting, manufacturing, compounding, selling, supplying cannabis-based products in standard pharmaceutical dosage form.

Are the existing laws and regulations sufficient?

- The existing laws and regulations are sufficient in allowing the use of the cannabis-based product in pharmaceutical dosage form for medical purposes in Malaysia.
- It is evident with the registration and clinical use of Sativex® (nabiximols) Oromucosa Spray in Malaysia in the year 2014 (Reg No: MAL14095053ACRZ) which contains about 1:1 of CBD:THC ratio. The discontinuation of the product in 2017 was not due to any breach of laws or regulations but a voluntary withdrawal by the company (GW Pharma) due to commercial reason19.
- The approved indication of Sativex was for the treatment of symptoms improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medications and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial therapy20.

The possible pathways of Cannabis Use for Medical Purposes in Malaysia

To register as finished pharmaceutical products (generic drug / new entity)[22].

To register as Investigational Products[23].

Possibility to apply for registration under Special Access Scheme (SAS) or Authorised Prescriber (AP) pathway.

Legislation Issues, Experience, and Lessons Learned from other countries.

i) Legalization vs Decriminalization.

- Legalization of cannabis is the process of removing all legal prohibitions against it. Cannabis would then be available to the adult general population for purchase and use at will, similar to tobacco and alcohol.
- Decriminalization is the act of removing criminal sanctions against an act, article, or behavior. Decriminalization of cannabis means it would remain illegal, but the legal system would not prosecute a person for possession under a specified amount. Instead, the penalties would range from no penalties at all, to civil fines, drug education, or drug treatment[24].

i) Legalization vs Decriminalization.

- Among the countries that have allowed the use of cannabis for recreational purposes include Canada, the UK, USA (21 states – Schedule I in Federal Law), Uruguay, and the Netherlands. Canada and Uruguay allow the sale of cannabis commercially but in the Netherlands, the sale of Cannabis is allowed only in licensed store[1].
- To date, a total of 44 countries have allowed cannabis use for medical purposes including Thailand, the only country in Southeast Asia that has allowed the cannabis-based product for self-medication and own use[1].
- In Australia, medicinal cannabis products are classified as prescription medicines. The country's regulations still control the use of medicinal cannabis to minimise the risk of harm from inappropriate use, while ensuring that it is available to appropriate patients[25]
- In UK, the clinical use of cannabis-based products is strictly controlled under medicine legislation. Cultivation and processing of hemp plant is lawful (hemp licence – with specific seed type). Separate licence for f&b usage[32].

https://cms.law/en/int/expert-guides/cms-expert-guide-to-a-legal-roadmap-to-cannabis/united-kingdom

i) Legalization vs Decriminalization.

- **Recommendation:** It is believed that cannabis still needs to be highly regulated in this country due to the high risk of diversion, misuse, and abuse especially in the population.
- **Justification:** There are worrying facts on the overlapping patterns of recreational and medical cannabis use in a large community sample of cannabis users where 80.1% of the population reported also using them for recreational purposes (MED+REC). A large majority of medical users also reported using it recreationally (80.6%), while exclusive medical use was less common (19.3%) [26].

i) Legalization vs Decriminalization

- Another studies revealed that cannabis use was strongly associated with psychiatric illnesses such as suicidal attempts, physical fights, low peer support, high school dropouts, and tobacco use among teenagers[27,28].
- A report from Thailand stated that the ramifications of medical and recreational legalization of cannabis for the development of youth and emerging adults are significant in terms of diversion of medical to recreational cannabis use, significant effect on academic functioning, increase in the risk for psychosis and development of schizophrenia, legal record, especially for minority adolescent and normalization of cannabis use, decreased perception of harm, increased initiation, and habitual use[29,30].

ii) Rescheduling or Descheduling of related laws & regulations and Regulatory framework on the use of CBD.

- **Recommendation 1**: To maintain the current laws and regulations without any further amendment.
- **Justification**: The current laws and regulations are sufficient to allow the use of cannabis / cannabis-based products for medical purposes in Malaysia. The researchers may apply the CTIL for registration and use as investigational products. The legalization might increase accessibility, promote normalization /recreational use in the community, and brings more harmful effect to the community. Cultivation of Cannabis Sativa spp (eg: Hemp) needs to be in balance with its expected usage for medical purposes in this country (not industrial).

Rescheduling or Descheduling of related laws & regulations and Regulatory framework on the use of CBD.

- **Recommendation 2**: If there is overwhelming evidence, needs, and urgency in usage in a specific group of patients with specific indications (rare diseases, refractory cases, and non-responding to standard treatment), it is recommended to register cannabidiol preparation as an active pharmaceutical ingredient (API) or in standard pharmaceutical dosage form with less than 0.2% THC (eg: Epidiolex®) and to regulate with Poison Act 1952 and Poison Regulation 1952 – safest option. Hence, the raw unprocessed CBD/hemp in the form of resin, seed, and extract of CBD will still be controlled under the Dangerous Drugs Act 1952.
- **Justification:** This recommendation is in line with the 1961 Single Convention on Narcotic Drugs mentioned below: -

Rescheduling or Descheduling of related laws & regulations and Regulatory framework on the use of CBD.

- *'At its fortieth meeting in June 2018, the Committee recommended that cannabidiol in its pure form not be controlled under the conventions. However, if it is obtained as an extract or tincture of cannabis (which is the method of production of the currently registered pharmaceutical product) then cannabidiol could be considered a controlled substance under the 1961 Convention.* ***Recommendation:*** *The committee recommended that a footnote be added to Schedule I of the 1961 Single Convention on Narcotic Drugs to read: Preparation containing predominantly cannabidiol and not more than 0.2% of THC are not under international control10.'*

Rescheduling or Descheduling of related laws & regulations and Regulatory framework on the use of CBD.

- **Recommendation 3:** To maintain the registration of cannabis-based products as ONLY Active Pharmaceutical Ingredient and Finished Products in standard pharmaceutical dosage form and to maintain all Cannabis spp. in the negative list of Appendix 1 Drug-Food Interphase.

Rescheduling or Descheduling of related laws & regulations and Regulatory framework on the use of CBD.

- **Justification:** It has been found in other countries that there will be a risk of diversion with lesser control from the authority. The removal of hemp from this list may allow it to be extensively registered and used in food & beverage products. A study in Thailand found that 1 in 10 cannabis beverages in Bangkok had a higher level of THC than suggested. If taking two (2) glasses, about 40% of the products have more than the recommended level of THC[31]. Cannabis-based products will eventually flood the market without any specific indication and will have the same fate as the current alcohol, tobacco vape, and e-cigarette industry where it is currently out of control and significantly contributing to many public health issues.

Conclusion

- Cannabis might exhibit some medical benefits to manage specific disease conditions in the population.
- The current laws and regulation is sufficient to allow the clinical use of cannabis in this country.
- the risk and benefits need to be carefully weighed so that the use is highly regulated and justifiable from a medical perspective and less tendency of being inappropriately used in this country.
- Different countries might have different recommendations and regulations in dealing with this issue. In Malaysia, the *waqi'* (reality) of the grassroots population needs to also be addressed and considered before any decision is made.

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