UNIVERSITI TEKNOLOGI MARA

MEDICO-ETHICAL CONSIDERATIONS FOR LEGALISATION OF MEDICINAL CANNABIS IN MALAYSIA

AIMI BINTI MOHD YUNUS

Master in Medical Ethics and Medical Jurisprudence

February 2022

UNIVERSITI TEKNOLOGI MARA

MEDICO-ETHICAL CONSIDERATIONS FOR LEGALISATION OF MEDICINAL CANNABIS IN MALAYSIA

AIMI BINTI MOHD YUNUS

Dissertation submitted in partial fulfillment
of the requirements for the degree of
Master in Medical Ethics and Medical Jurisprudence

Faculty of Medicine

February 2022

CONFIRMATION BY PANEL OF EXAMINERS

I certify that a Panel of Examiners has met on 7th February 2022 to conduct the final examination of Aimi binti Mohd Yunus on her **Master in Medical Ethics and Medical Jurisprudence** dissertation entitled "Medico-ethical Considerations for Legalisation of Medicinal Cannabis in Malaysia" in accordance with Universiti Teknologi MARA Act 1976 (Akta 173). The Panel of Examiners recommends that the student be awarded the relevant degree. The Panel of Examiners was as follows:

Dr. Zaliha Ismail
Associate Professor
Faculty of Medicine
Universiti Teknologi MARA
(Chairperson)

Dr. Aimi Nadia Mohd Yusof
Lecturer
Faculty of Medicine
Universiti Teknologi MARA
(Internal Examiner)

Dr. Amnah binti Azahar
Lecturer
Faculty of Medicine
Universiti Teknologi MARA
(Internal Examiner)

PROFESSOR IR. DR. ZUHAINA HJ. ZAKARIA
Dean
Institute of Graduates Studies
Universiti Teknologi MARA
Date: 28 February 2022

AUTHOR'S DECLARATION

I declare that the work in this dissertation was carried out in accordance with the regulations of Universiti Teknologi MARA. It is original and is the results of my own work, unless otherwise indicated or acknowledged as referenced work. This thesis has not been submitted to any other academic institution or non-academic institution for any degree or qualification.

I, hereby, acknowledge that I have been supplied with the Academic Rules and Regulations for Post Graduate, Universiti Teknologi MARA, regulating the conduct of my study and research.

Name of Student	:	Aimi binti Mohd Yunus
Student I.D. No.	:	2020669816
Programme	:	Master of Medical Ethics and Medical Jurisprudence – MD775
Faculty	:	Faculty of Medicine
Dissertation Title	:	Medico-ethical Considerations for Legalisation of Medicinal Cannabis in Malaysia
Signature of Student	:	……..
Date	:	February 2022

ABSTRACT

There is an abundance of international studies that have lauded the benefits of medicinal cannabis for various illnesses. Likewise, local studies on cannabis in Malaysia that initially revolve around the harmful effects of cannabis misuse are increasingly shifting towards the benefits of medicinal use. Pursuant to scientific discovery of the medicinal benefits of cannabis, a myriad of literature begins to focus on the legality of utilising cannabis for medicinal purposes. Whilst many countries around the world, some of those including South East Asia countries have legalised medicinal cannabis, Malaysia is still lagging behind. As of now, there is no local study focusing on the legalisation of medicinal cannabis, leaving a gap in providing a reference to Malaysia's way forward on this issue. Under the current legislative regime, the use of cannabis is prohibited under the Dangerous Drugs Act (DDA) 1952 *[Act 234]*. However, the recent case of *Muhammad Lukman Mohamad* has sparked national interest that triggered calls for decriminalisation and legalisation of cannabis for medical reasons. Following these calls, it is pertinent to examine and critically analyse the medical, ethical, and legal considerations on the legalisation of medicinal cannabis in Malaysia. Such consideration is deemed necessary to protect the health and safety of patients. This research adopts an exploratory research design and employs a qualitative research approach in examining medical, ethical, legal, and theological considerations towards the legalisation of medicinal cannabis. Comparative legal analysis covers substantive and procedural components of jurisdictions in selected countries that have legalised medicinal cannabis such as the United Kingdom (UK), Canada, and Thailand. Examination of medico-ethical considerations is done using Biomedical Ethics Theory and Philosophical Theory. These considerations provide a comprehensive analysis of the legalisation of medicinal cannabis in Malaysia that will contribute to the current body of knowledge. This research proceeds to make several recommendations deemed relevant towards the legalisation of medicinal cannabis in Malaysia.

ACKNOWLEDGEMENT

Alhamdulillah, all praises to Allah and His blessing for the opportunity to embark on this master programme and the completion of my dissertation.

Firstly, my sincere gratitude and thanks go to my main supervisor, Associate Professor Dr. Haswira Nor Mohamad Hashim, and co-supervisors, Dr. Mark Tan Kiak Min and Dr. Diana Katiman for all the guidance, understanding, patience, and the encouragement to complete this dissertation.

I would like to thank my family for their enduring support and sacrifices for me during this master journey. To my husband Mohd Nuzul Zahril, thank you for the prayers, understanding and positive words that keep me going. To my sweethearts Muhammad, Abu Bakr, and Aamily, thank you for the unconditional love. To my beautiful parents Mohd Yunus Aminuddin and Kamsiah Minhad, I would never thank them enough for their continuous prayers and endless support that keep me strong.

My deepest appreciation goes to a beautiful soul Helwa Husna who plays important role in my life – as a best friend, colleague, coursemate, study-buddy, supporter, and cheerleader that I have always relied on.

My profound appreciation goes to my mentor, Dr. Muhamad Zaid bin Muuti for all the guidance and encouragement for me in pursuing my master programme. Also, to all my lecturers at the Medical Ethics and Law Department, Faculty of Medicine, UiTM, thank you for all the knowledge and supports given to me throughout this programme.

Special thanks to my superiors in the Private Medical Practice Control Section (CKAPS), Ministry of Health, colleagues, coursemates, and friends for the kindness and advice either directly or indirectly that help me to initiate and complete my journey.

My deep appreciation goes to my siblings, in-laws, extended families, including my neighbours and anybody else who I may have omitted to expressly name here for providing me with the fortitude to accomplish this journey during the toughest period of this pandemic.

Alhamdulillah. I thank you all wholeheartedly.

Finally, this dissertation is dedicated to the loving memory of my late mother-in-law, Nik Semah Nik Jusoh.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURE

LIST OF ABBREVIATIONS

Abbreviations

ASEAN	Association of Southeast Asian Nations
BMJ	British Medical Journal
CBD	Cannabidiol
CBPM	Cannabis-based products for medicinal use in humans
CND	Commission on Narcotic Drugs
DCA	Drug Control Authority
DDA	Dangerous Drugs Act 1952
FDA	Food and Drug Administration
GMC	General Medical Council
IH	Industrial Hemp Regulations SOR/2018-145
IKN	National Cancer Institute
MASA	Malaysia Society of Awareness
MDA	Misuse of Drugs Act 1971
MDR	Misuse of Drugs Regulation 2018
MMC	Malaysian Medical Council
MoPH	Ministry of Public Health
NICE	National Institute for Health and Care Excellence
NGO	Non-governmental Organisation
PENGASIH	Persatuan Pengasih Malaysia

RCT	Randomised Controlled Trial
THC	Delta-9-tetrahydrocannabinol
WHO	World Health Organization
UK	United Kingdom
UN	United Nations
USA	United States of America

LIST OF CASES

Cases

Muhammad Lukman bin Mohamad v Public Prosecutor [2021] 4 MLJ 494

Pendakwa Raya v Mohd Zaireen bin Zainal [2016] MLJU 651

LIST OF STATUTES / LEGISLATIONS

Malaysia

Dangerous Drugs Act (DDA) 1952 *[Act 234]*

Medical (Amendment Act) 2012 *[Act 50]*

Poison Act 1952 *[Act 366]*

Sale of Drugs Act 1952 (Revised 1989) *[Act 368]*

Control of Drugs and Cosmetics Regulations 1984 *[P.U.(A)223/84]*

United Kingdom

Misuse of Drugs Act 1971

The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018

Misuse of Drugs (Licence Fees) Regulations 2010

Human Medicines Regulations 2012

Canada

Cannabis Act, SC 2018, c.16

Controlled Drugs and Substances Act, SC 1996, c.19

Cannabis Regulations SOR/2018-144

Access to Cannabis for Medical Purposes Regulations (ACMPR) SOR/2016-230

Industrial Hemp Regulations SOR/2018-145

Thailand

Narcotics Act B.E. 2522 (1979)

Narcotics Act (No. 7) B.E. 2562 (2019)

Food Act B.E. 2555 (1979)

Cosmetic Products Act B.E. 2558 (2015)

Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Import, Export, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2563 (2020)

CHAPTER ONE
INTRODUCTION

1.1 Research Background

1.1.1 Cannabis

Cannabis, which is the subject matter of this research, is a genus of flowering plants in the *Cannabaceae* family. It has several species namely *Cannabis sativa*, *Cannabis indica, and Cannabis ruderalis* (Clarke & Watson, 2007). The cannabis plant has a wide range of compounds such as cannabinoids, terpenoids, carbohydrates, flavonoids, and nitrogen-containing compounds (Brenneisen, 2007). The two most widely studied cannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Within the endocannabinoid system, these cannabinoids affect the user's physiological and cognitive activities (Qatanani, Umar, & Padela, 2021). THC is the primary psychoactive cannabinoid in cannabis and is intoxicating while CBD is mildly psychoactive but not intoxicating (Shirah & Ahmed, 2020).

Extensive research on cannabis has been conducted following the discovery of THC molecular structure by Gaoni and Mechoulam in 1964 (ElSohly, 2007). THC has a significant impact on cognitive functions such as thinking, memory, attention, and time perception (Qatanani et al., 2021). Most of the medicinal benefits of cannabis are associated with CBD. As opposed to THC, CBD is non-psychoactive and has no harmful effect on memory or motor functions (Pisanti & Bifulco, 2017). CBD has no effects indicative of any abuse or dependency and is *"generally well tolerated with a good safety profile"* (World Health Organization, 2017, p. 1). It is proven that CBD has a protective effect against some negative psychological effects related to THC (Almogi-Hazan & Or, 2020). Cannabinoids concentrations in different cannabis breeds may vary and the THC:CBD amounts in a cannabis product can be genetically modified (Qatanani et al., 2021). Since THC concentration mainly determines the potency, the adverse effects of acute or regular cannabis usage are directly related to THC concentrations in the product. In general, the higher the THC content of a product, the greater the risks (Lafaye, Karila, Blecha, & Benyamina, 2017).

There are a lot of debates on the taxonomic interpretations in which some

researchers used the term ‘hemp’ referring to *Cannabis sativa* and ‘marijuana’ referring to *Cannabis indica* although it has also been used to refer to other fibre crops (Clarke & Watson, 2007; McPartland, 2017). *Cannabis sativa* may primarily be grown for three purposes namely industrial, recreational, and medicinal (Farinon et al., 2020; Rupasinghe et al., 2020). Figure 1 shows that *Cannabis sativa* is a versatile, sustainable, and low-impact crop which has a wide range of applications that may be used in a variety of applications ranging from agriculture and phytoremediation to food and feed, cosmetic, construction, and pharmaceutical sectors (Farinon et al., 2020). Recently, literature has moved towards describing and classifying cannabis based on its cannabinoid profile. Cannabis is classified as hemp if it contains less than 0.3% of THC by weight or 0.2% of the dry weight of the reproductive part of the female plant at flowering and has no psychotropic effects. Because of its high amounts of CBD and low THC, hemp is the ideal source for CBD treatments and products such as CBD oils. Cannabis, on the other hand, is classified as marijuana if it contains more than 0.3% of THC by weight (Clarke & Watson, 2007). The label ‘medical marijuana’ might be misleading as it may include more THC or be made up entirely of CBD. In this research, the term ‘medicinal cannabis’ refers to both hemp and marijuana formulations used for therapeutic purposes. It must be distinguished from recreational cannabis that causes a feeling of euphoria (feeling ‘high’) to its users with a variety of names and slangs including weed, pot, hashish, bud, *ganja*, and others (Harun, 2021).

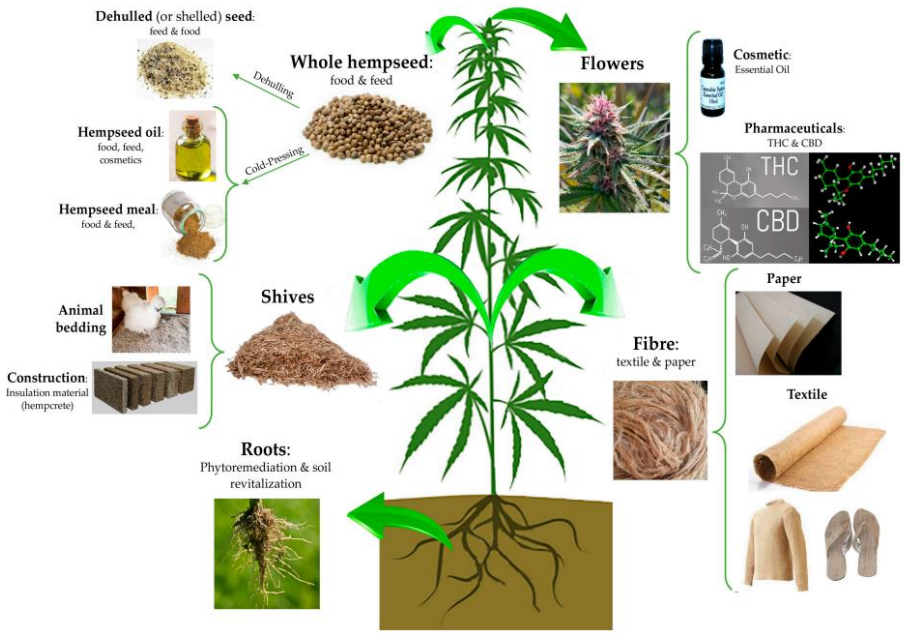

Figure 2 *Cannabis sativa’s* Wide Range of Applications

Source: The Seed of Industrial Hemp (*Cannabis sativa* L.). (Farinon et al., 2020, p. 2)

1.1.2 Recent Development on the Utilisation of Medicinal Cannabis

Cannabis has historically been utilised as indigenous therapy for various medical maladies and diseases in diverse cultures and communities. For example, cannabis was utilised by the ancient Chinese to cure constipation, rheumatoid arthritis, malaria, and beri-beri (Jiang et al., 2006). Besides that, it was documented that ancient Egyptians used cannabis in the treatment of glaucoma, obstetrics-related disease, and fever (Attia, 2017).

The success of chemists in discovering THC has led to another significant finding of the endocannabinoid system, its receptors, and the endogenous chemicals that operate on this signalling system in cannabis research in the 1990s. Advances in understanding the endocannabinoid system and exocannabinoids have demonstrated that cannabis may have substantial medicinal benefits (Lafaye et al., 2017). Thus, the watershed moment marks a new beginning to a revived scientific interest in cannabis's pharmacological characteristics. This event resulted in the publications of hundreds of articles and significant results favouring the cannabis plant's medicinal efficacy in various pathophysiological diseases (Pisanti & Bifulco, 2019).

Current research shows that cannabis interacts with the endocannabinoid system, which is a complex mechanism in the human body. Cannabis's varied and potent effects are due to its interaction with endogenous cannabinoid receptors. When THC and CBD, similar in molecular structure to endocannabinoids, are consumed, these molecules fit into the same receptors and cause a response. The endocannabinoid system regulates pain, mood, feelings, noxious stimuli, appetite, gastrointestinal motility, and immunity system (Shirah & Ahmed, 2020). THC and CBD, on the other hand, have an opposing mechanism of action on the endocannabinoid system. For example, CBD boosted plasma endocannabinoid levels in schizophrenic patients, which linked with the degree of symptom relief (Leweke et al., 2012). When combined with THC, CBD may mitigate some of the adverse effects of THC such as memory impairment and paranoia (Englund et al., 2013). As a result, the balance of THC and CBD may contribute to both safety and medicinal benefits. At large dosages, CBD is well tolerated whereas THC has a higher risk of adverse effects (Mayor, 2019; Whiting et al., 2015).

In the realm of medicinal use of cannabis, the Food and Drug Administration (FDA) has recognised two main forms of cannabis namely cannabis-derived compounds and cannabis-related compounds (synthetic form) (Food and Drug Administration,

2020). Cannabis also has a wide range of modalities of consumption such as inhaled as smoke, ingested in food or other oral preparations, topically administered as oil, oromucosal sprays, rectal suppositories or consumed in other formulations such as high-potency concentrates and innovative delivery devices that offer more accurate dosing (Cyr et al., 2018). Each modality offers a range of therapeutic effects (Cyr et al., 2018; Glickman & Sisti, 2020). There are several distinct products that are available for therapeutic use, each with its own THC/CBD profile, formulation, legal indications, and prescription restrictions (Freeman, Hindocha, Green, & Bloomfield, 2019). In 2018, the United States of America (USA) FDA approved the first cannabis-based medicinal product of Epidiolex (cannabidiol) in the form of an oral, highly purified CBD solution for the treatment of childhood epilepsy associated with Lennox-Gastaut syndrome or Dravet syndrome. With regards to synthetic form, the FDA has authorised three cannabis-related drug products namely Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone). Marinol and Syndros, which contain synthetic THC, are indicated for nausea associated with cancer chemotherapy and for the treatment of anorexia associated with weight loss in patients with AIDS. Cesamet contains the active ingredient of nabilone, which has a chemical structure similar to THC. Like dronabinol-containing products, Cesamet is indicated for nausea associated with cancer chemotherapy. In certain countries such as the USA, the UK, Germany, and the Netherlands, these synthetic cannabinoids are licenced to treat patients who have failed to respond adequately to conventional anti-emetics and are only available with a prescription from a licensed healthcare provider (Food and Drug Administration, 2020).

Apart from the FDA approved cannabis products listed above, there is another form of cannabis that is used for medicinal purposes. Sativex, an oral spray produced from the cannabis plant that contains THC and CBD in a 1:1 ratio, is approved in 29 countries including the UK, Israel, Canada, Brazil, and Australia for the treatment of spasticity in multiple sclerosis (Nutt, Bazire, Phillips, & Schlag, 2020).

1.1.3 Evolution of Law Underpinning Medicinal Cannabis

The modern history of cannabis is complicated because its medicinal use has been heavily influenced and hampered by economic, social, and ethical concerns. The use of cannabis for medicinal purposes is now being reconsidered in the light of scientific evidence, particularly on the efficacy and safety of cannabinoid-based drugs

(Pisanti & Bifulco, 2017). In 1850, cannabis was recognised as an official licit medicine and included in the USA Pharmacopoeia due to its claimed medicinal advantages (Pisanti & Bifulco, 2017). However, during the early twentieth century, it was prohibited in colonial nations mainly due to racial and economic conflicts. In the mid-twentieth century, the international collaboration led to widespread cannabis restrictions across most of the world. As the twenty-first century began, various countries started to modify their attitudes on cannabis with efforts to decriminalise cannabis being implemented (Pisanti & Bifulco, 2019). Currently, the legality of cannabis for medicinal purposes varies greatly by country and area although it is mostly illegal globally. However, to date, more than 50 countries have legalised cannabis for medicinal purposes and the number are increasing (The Week, 2021). Three countries in Asia have taken a move to legalise medicinal cannabis namely South Korea and Thailand in 2018, and recently Lebanon in 2020.

The emerging evidence of cannabis medicinal benefits has led to rapid policy and regulatory changes. This has opened potentially new avenues for treating patients, but they must be weighed up against potential harms. The WHO has suggested that cannabis be reclassified under international law. On 2nd December 2020, the United Nations (UN) Commission on Narcotic Drugs (CND) has re-classified cannabis and cannabis resin under an international listing that recognises its medicinal value (World Health Organization, 2020). The reclassification will most likely bolster medical research and legalisation efforts around the world. At the same time, it is also viewed as a move that could prompt some countries to loosen cannabis restrictions (Kwai, 2020).

At present, the control of cannabis under Malaysian law entails several various Acts and policies. Cannabis, whether in the form of resin cannabis, cannabis extract or cannabis tincture is classified as a dangerous drug subject to the Dangerous Drugs Act (DDA) 1952 *[Act 234]* and also a poison subject to the Poisons Act 1952 *[Act 366]*. Under Section 2 of the DDA 1952:

> *cannabis means any part of the plant of the genus Cannabis from which there is found to be present resin irrespective of its quantity, and by whatever name the plant may be designated.*

A person apprehended in possession of 200g cannabis is assumed by law to be a drug trafficker, which carries the death penalty under Section 37 of the DDA 1952, whereas a person arrested with less than 50g of cannabis faces up to five years of imprisonment.

Cannabis-based products used for human medical treatment are likewise classified as drugs under the Sale of Drugs Act 1952 *[Act 368]*. These Acts and their regulations govern the importation, exportation, sale, supply, manufacturing, cultivation, possession, and use of cannabis. Furthermore, cannabis-containing products must be registered with the Malaysia Drug Control Authority (DCA) in accordance with the Control of Drugs and Cosmetics Regulation 1984 *[P.U.(A) 223/84]* as outlined in the Sale of Drugs Act 1952 *[Act 368]*. With regards to the medicinal use of cannabis, Section 6B (2) of the DDA 1952 provides that the Minister of Health may issue permission to any public officer to cultivate cannabis for research, learning, experimental or medicinal reasons according to the terms and conditions indicated in such authorisation. Under the DDA 1952 and Poison Act 1952, cannabis-based products can only be imported by authorised individuals.

1.1.4 Legalisation of Medicinal Cannabis

Oxford Languages Dictionary (2021) defines legalisation as "*the action of making something that was previously illegal permissible by law*". Legalisation of medicinal cannabis, which becomes the focus of this research, includes the process of removing all legal prohibitions against its possession, use, and trafficking (Svrakic et al., 2012). However, this research will limit the scope of legalisation for medicinal use. The legalisation of cannabis will be followed by the formulation of a regulatory framework that will govern and control the production, distribution, and supply of cannabis. However, the objective of this research does not extend to the formulation of such a regulatory framework.

In addition, legalisation of cannabis may involve decriminalisation of the substance under the DDA 1952. Decriminalisation of cannabis implies that the legal system will not punish a person for possessing less than a certain quantity or for certain legal purposes such as for medicinal use. Decriminalisation of cannabis also means the sanctions for the legal use, possession, and sales will be civil or administrative in nature. In a nutshell, legislation is the genus whilst decriminalisation is a subset of legalisation. Decriminalisation is one of the steps that must be taken for cannabis to be legalised. Therefore, while decriminalisation and legalisation have different connotations and legal effects, they nevertheless complement one another.

1.2 Problem Statement

Three recent cases related to medicinal cannabis in Malaysia have sparked national interests and debates among the public, non-governmental organisations (NGOs), healthcare providers, as well as politicians. The controversial case of *Pendakwa Raya vs Mohd Zaireen bin Zainal* [2016], *Muhammad Lukman Mohamad vs Public Prosecutor* [2016], and Amiruddin @ Nadarajan Abdullah, also known as 'Dr Ganja', are related to charges that carry the mandatory death penalty for selling 'medical marijuana' to treat illnesses (Hussin, 2017). These three cases have provoked heated debates about two critical issues. The first is the harsh legislation that surrounds drug-related offenders, and the second is the concern to decriminalise and legalise cannabis for medicinal purposes. The problem with the existing strict law is that it brings out the uncertainty of the legal situation and anxiety among the public. The scenario in our country is inconsistent with the evolution of cannabis legislation in other nations, which are being actively revised. This is necessary to ensure the clarity of the legal situation in accordance with the needs and evidence provided from scientific research.

The announcement made by the UN to loosen the control on cannabis has provoked various reactions from some countries that do not support the decision, including Malaysia. China and Singapore are the few countries that rejected the WHO's recommendation on rescheduling cannabis as it may promote misuse particularly among teenagers that may cause social and safety issues (Channel News Asia, 2020). As Malaysia DDA 1952 is based on the UN recommendation, it is anticipated that the reclassification move may impact the future of Malaysia's legislation on cannabis. In response to a question raised by a Member of Parliament in November 2021, the current health minister has replied that parties who have sufficient scientific evidence to use cannabis for any medicinal purpose, considering the aspects of quality, safety, and effectiveness, can apply to the DCA, which is an executive body established under the Control of Drugs and Cosmetics Regulations 1984 *[P.U.(A) 223/84]* to be marketed in Malaysia (Parliament of Malaysia, 2021a). This statement changes the perspective on cannabis and gives the impression that the government acknowledges the medicinal use of cannabis. The statement, however, has yet to offer a clear legal position for 'medicinal cannabis' and created uncertainty that needs to be clarified since the ambiguous status has several potential implications in the future. Nevertheless, it gives a glimpse of the legalisation of medicinal cannabis in Malaysia.

Furthermore, the decision of Thailand to legalise medicinal cannabis since 2018 has had an impact on Malaysia's healthcare system. The legalisation of medicinal cannabis in Thailand has enabled Malaysian citizens including patients in need of medicinal cannabis to get the compound directly from the neighbouring country (Yeung, 2021). This condition has been translated into clinical practice thus, posing a dilemma to clinicians. One of the significant impacts is the 'illicit' use of cannabis that can interfere with the medical management of conservative medicine. For example, while doctors are prescribing morphine to the patient for pain management, the patients could be using cannabinoids 'illegally' at the same time. Thus, it is critical that this topic be explored in more detail and breadth to aid physicians in making judgments about delivering the best care to their patients. The disparity between scientific evidence and government stance creates a continuing quandary for clinicians and harms patients who should benefit from the legalisation of medicinal cannabis.

1.3 Research Questions

1. What is the legal position for the legalisation of medicinal cannabis in other countries?

2. What are the medico-ethical considerations for the legalisation of medicinal cannabis?

3. What are the relevant perspectives for the legalisation of medicinal cannabis in Malaysia?

1.4 Research Objectives

1. To compare the laws of selected countries that have legalised medicinal cannabis.

2. To examine the medico-ethical considerations for medicinal cannabis use.

3. To analyse medical, ethical, legal, and theological perspectives that are relevant for the legalisation of medicinal cannabis in Malaysia.

1.5 Literature Review

The literature review revolves around four main aspects of this research that are (1) cannabis; (2) medicinal cannabis; (3) legalisation of medicinal cannabis; and (4) medical, ethical, and legal perspectives. The purpose of this literature review is to gain an understanding of the existing research and to identify the research gap.

Cannabis studies in general cover the use of cannabis for recreational or medicinal purposes (Shover & Humphreys, 2019; Vedelago, Metrik, & Amlung, 2020). Local studies on cannabis that initially revolved around the harmful and consequences of cannabis misuse are increasingly shifting towards medicinal, social, and economic elements (Govarthnapany, Singh, Narayanan, & Vicknasingam, 2021; Maharajan et al., 2020; Yusoff, Yuan, & Yang, 2013).

Literature review on medicinal cannabis at the international level largely focuses on clinical trials and scientific evidence. Furthermore, the research tendency has recently moved from investigating harms to exploring benefits (Herbert & Hardy, 2021). There is an abundance of international literature that lauded the benefits of using cannabis for medicinal purposes (Almogi-Hazan & Or, 2020; Freeman et al., 2019; Herbert & Hardy, 2021; Jugl et al., 2021; Nedelman, 2020). In contrast, other literature laments the benefit of medicinal cannabis (Lee, Cheok, Kandasami, Rapisarda, & Fei, 2016). In Malaysia, although the published academic writings on medicinal cannabis are limited, majority of the studies focus on clinical aspects such as pharmacological properties (Lim et al., 2021) and its therapeutic effects (Maharajan et al., 2020; Yusoff et al., 2013).

In terms of legalisation, at an international level, there is a myriad of literature with different views discussing the legality of medicinal cannabis. Bahji et. al (2019) and Barron et. al (2019) supported medicinal cannabis legalisation while Lee et. al (2016) and Sagy et. al (2018) offer grounds for rejecting the proposition. With regards to the Association of Southeast Asian Nations (ASEAN), literature in this region is divided. Up north, literature in Thailand is very supportive to call for legalisation (Rakpanich et al., 2020; Zinboonyahgoon et al., 2021). In contrast, down south, literature in Singapore holdback the legalisation of medicinal use of cannabis (Lee et al., 2016).

In countries where medicinal cannabis has been legalised, extant literature

highlights the dilemma of the physicians and patients in prescribing the drugs. Literature discovers problems arising from significant information gaps about evidence of therapeutic benefits and possible risks (Arnold, Nation, & McGregor, 2020; Glickman & Sisti, 2020; Panozzo et al., 2020), and the complexity of the issues in the health system and regulatory structure (Barron & Gordon, 2019; Nutt et al., 2020). The situation eventually continues to impede patients' access to medicinal cannabis (O'Brien, 2019). However, there is yet local literature focusing on the legalisation of medicinal cannabis or may not be published thus leaving a significant gap in providing a reference to Malaysia's way forward on medicinal cannabis.

On the other hand, while some literature discussed the medico-ethical and legal concerns for the legalisation of medicinal cannabis, they were inclined to separate medical, ethical, and legal considerations from the research (Hayry, 2004; Vyshka, 2019). This contrasts with this research that integrates medico-ethical considerations towards the legalisation of medicinal cannabis. Furthermore, literature that proposed the legal framework for cannabis legalisation has arrived to the conclusion without examining the laws in the UK, Canada and Thailand, which is the same samples used in this research (Kilmer, 2014; Shover & Humphreys, 2019).

In conclusion, literature on medico-ethical and legal considerations of medicinal cannabis in Malaysia are lacking and the international level literature did not fulfil the objective of this research. Therefore, this research fulfils the gaps of the previous literature by making a medical, ethical, and legal analysis on the legalisation of medicinal cannabis and further contributing to the current body of knowledge.

1.6 Research Methodology

This research adopts an exploratory research design and employs a qualitative research approach. The research methodology is aimed at answering the three research questions developed for this research. A secondary data collection method is used to answer the research questions. Qualitative data analysis method comprising of comparative analysis to answer the first research question, whereas content analysis and doctrinal analysis is used to answer the second and third research questions.

1) Secondary data collection

A desktop or library-based method of data collection has been conducted to collect secondary data that are relevant to answer the research questions. The library-based method involves gathering primary and secondary legal sources from official websites and online databases. The secondary legal sources such as journal articles, reports, theses, and dissertations were collected from online databases such as ScienceDirect, LexisNexis, Google Scholar, BMJ Journal, and PubMed. The keywords used in the search include ‘medical’ or ‘medicinal cannabis’, ‘marijuana’, and ‘legalisation’ in both English and *Bahasa Melayu.* The Boolean operator ‘AND’ was added to combine the keywords in database with ‘legalisation’.

Secondary data in the form of primary legal sources such as statutes, codes, regulations, and case laws have been collected from the official websites of the government agencies of the selected jurisdictions. The legalisation of medicinal cannabis that took place in the UK and Canada have been chosen for analysis due to their similarities to the Malaysian legal system. In addition, Thailand's medicinal cannabis legislation has been examined due to demographic and geographic factors. The legislation from the selected countries that have been identified for analysis are listed in Table 1.

The UK laws can be accessed from the UK National Archives' website. The Canada laws related to the legalisation of cannabis can be sought from the Government of Canada's Justice Laws Website. The Thailand Narcotics Act can be obtained from their Ministry of Public Health website. For medical literature sources, Cochrane Library, PubMed, Google Scholar, and Scopus were utilised.

Table 1
List of Legislations from Selected Jurisdictions

No.	Jurisdiction	Legislations
1.	Malaysia	Dangerous Drugs Act (DDA) 1952 *[Act 234]* Poison Act 1952 *[Act 366]* Sale of Drugs Act 1952 (Revised 1989) *[Act 368]* Control of Drugs and Cosmetics Regulations 1984 [*P.U.(A)223/84]*
2.	United Kingdom	Misuse of Drugs Act 1971 The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales, and Scotland) Regulations 2018 Misuse of Drugs (Licence Fees) Regulations 2010
3.	Canada	Cannabis Act, SC 2018, c.16 Cannabis Regulations SOR/2018-144 Industrial Hemp Regulations SOR/2018-145
4.	Thailand	Narcotics Act (No. 7) B.E. 2562 (2019) Food Act B.E. 2555 (1979) Cosmetic Products Act B.E. 2558 (2015) Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Import, Export, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2563 (2020)

2) Data analysis

Content analysis has been used to analyse academic works (textbooks, theses, dissertations, journals, and reports), and non-academic works (Hansards, newspaper reports, websites, and blogs). In addition, a doctrinal analysis method has been used to analyse primary legal sources (statutes, codes, regulations, and judicial decisions) and secondary legal sources (law textbooks, law journals, and law committee reports). Comparative analysis was also conducted to find the similarities and differences in the legalisation of medicinal cannabis in the selected countries. The scope of the comparison covers both the substantive and procedural aspects of the legislation. The findings from the data analysis will be used as a reference point in identifying medical, ethical, and legal considerations that are relevant for the legalisation of medicinal cannabis in Malaysia.

1.7 Organisation of Chapters

Discussions of this research are divided into five chapters namely Chapter One: Introduction; Chapter Two: Comparative legal analysis; Chapter Three: Examination of medico-ethical considerations; Chapter Four: Identification of relevant principles for Malaysia; and Chapter Five: Conclusion and Recommendations.

Chapter One is the introductory chapter that discusses the research background, problem statement, research questions, research objectives, literature review, research methodology, organisation of chapters, scope and limitations of research, and significance of the research. Chapter Two is on the comparative legal analysis on medicinal cannabis that includes statutory analysis, regulatory analysis, and comparative analysis. Chapter Three examines the medico-ethical considerations of the topic. It describes the medico-ethical considerations using Biomedical Ethics Theory and Philosophical Theory. In Chapter Four, an analysis of the relevant perspectives for Malaysia was made including religious influences. In the final Chapter Five, conclusions of the research findings with some recommendations were made. Synthesis, practical implementation, and expectations were made in this chapter.

1.8 Scope and Limitation of Research

This research focuses on the legalisation of medicinal cannabis use in Malaysia. Therefore, the scope of this research is limited by the types of subject matter, jurisdiction, and relevant perspectives.

In terms of subject matter, this research focuses on the legalisation of medicinal cannabis use, which excludes the recreational use of cannabis. Medicinal cannabis has been selected as the focus of the research due to the recent case law, which sparks debate on the legalisation of medicinal cannabis.

This research is limited to the two Common Law countries namely the UK and Canada in terms of jurisdiction. The selection of the UK and Canada as the sample of analysis is due to the common law heritage that these countries share with Malaysia. As for Thailand, the country is chosen for a sample of analysis due to its demographic and geographic factors. In addition, Thailand is the only ASEAN member that has legalised cannabis for medicinal use. Although other countries such as the United States, Uruguay, and Lebanon have their cannabis legislation, their laws are not suitable for adoption since these countries have different legal systems from Malaysia.

Finally, in terms of perspectives limitation, the analysis is limited to medical, ethical, and legal perspectives. Whilst admittedly, economic, social, political, and religious theories are also relevant considerations in the legalisation of medicinal cannabis, however, they are not included as they are not the focus of this research. Nevertheless, religious elements could be found in the relevant perspectives' discussion.

1.9 Significance of research

While many other nations are debating and studying the prospect of legalisation of medicinal cannabis, Malaysia is yet to take forward action. Recent court cases had triggered a more in-depth discussion regarding the significance of legalising medicinal cannabis in Malaysia. Apart from gaining worldwide attention for the nation's ultra-tough law against drug-related charges, the case attracted attention for the use of cannabis in medicine. Some NGOs such as the Malaysia Society of Awareness (MASA) and *Persatuan Pengasih Malaysia* (PENGASIH) actively advocate medicinal cannabis and policy reform, as well as urging the government to allow for research on cannabis to be conducted in Malaysia. In the recent Parliament Meeting, Syed Saddiq Syed Abdul Rahman, a member of the Parliament, *"calls for the government to look into legalising medical marijuana and hemp"* that leads to the formation of a bipartisan caucus on medicinal cannabis (Parliament of Malaysia, 2021c; The Star, 2021).

Although the findings of international studies and discussion are critical for our country's legislative bodies, policymakers, and healthcare providers to use as a reference, there are other factors that must be taken into considerations due to the distinct demographic, social, cultural, and religious circumstances of Malaysia. Given the necessity to explore this topic in-depth, this research will give an insight into the critical aspect of the legalisation of medicinal cannabis in Malaysia. This research is significant as Malaysia is sharing its international border with Thailand and Singapore, the two countries with a very opposite stand on the legalisation of medicinal cannabis. Therefore, this research is unique as it will fill in the gap and further contribute to the current body of knowledge on the legalisation of medicinal cannabis in Malaysia.

The findings of this research will benefit many others such as the research community, lawmakers, healthcare providers, patients, NGOs, and the public. Firstly, the research community will have a comprehensive analysis of the legalisation of medicinal practice, specifically in Malaysia. Secondly, the results are essential for the

law or policymaker to identify the critical aspects in defining and establishing future legislation for the successful implementation of medicinal cannabis in Malaysia's healthcare. It is recommended that these points of view and strategies be included in the policy and law formulation. Thirdly, the findings will improve healthcare providers' understanding of medicinal cannabis legalisation from a medical, ethical, and legal standpoint. The discussion can guide clinicians when encountering dilemmas while treating patients who are likely to get medicinal cannabis as part of their treatment. Finally, patients who are in dire need of medicinal cannabis in their treatment of diseases and ailments will gain the most from the findings of this research.

CHAPTER TWO
COMPARATIVE LEGAL ANALYSIS

2.1 Introduction

This chapter focuses on the legal position for the legalisation of medicinal use of cannabis in other countries, which is consistent with the first research question. To answer the research question, this chapter analyses the statutes and regulations of the selected countries that have legalised medicinal cannabis and later makes comparative analysis. The selected jurisdictions for the purpose of legal comparative analysis are the UK, Canada, and Thailand. The scope of comparative analysis covers substantive and procedural components of the statutes and regulations. The criteria for comparison are the similarities, differences, and unique features of the statutes and regulations legalising medicinal cannabis between the selected countries. The scope of the comparison comprises of (1) legalisation approach; (2) definition and interpretation; (3) classification; (4) administration and governance; (5) trade (import and export); (6) commercialisation (retail); (7) restriction; and (8) model. The findings from the comparative analysis will be used as part of medical, ethical, and legal considerations for the legalisation of medicinal cannabis in Malaysia.

2.2 Statutory Analysis

2.2.1 United Kingdom

In the UK, cannabis is a Class B controlled drug under Part II, Schedule 2 of the Misuse of Drugs Act 1971 (MDA 1971) . In Section 37 of the MDA 1971, cannabis means:

> *any plant of the genus Cannabis or any part of any such plant (by whatever name designated) except that it does not include cannabis resin or any of the following products after separation from the rest of the plant, namely— (a) mature stalk of any such plant, (b) fibre produced from mature stalk of any such plant, and (c) seed of any such plant.*

Cannabis resin is defined as:

> *the separated resin, whether crude or purified, obtained from any plant of the genus Cannabis.*

The Secretary of State, in the exercise of the powers conferred by Sections 7, 10, 22, 30 and 31 of the MDA 1971, makes the new regulations of The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 (MDR 2018) . In these regulations, 'cannabis-based products for medicinal use in humans' (CBPM), a defined category of cannabis, cannabis resin, cannabinol, and cannabinol derivatives, were removed from Schedule 1 and included in Schedule 2. The amendment permits the use of cannabis-based products for medicinal purposes on a broader scale.

Section 1 of the MDA 1971 outlines the duty of the Advisory Council on the Misuse of Drugs (Advisory Council):

> *to keep under review the situation in the United Kingdom with respect to drugs which are being or appear to them likely to be misused…*

When carried out in accordance with an appropriate licence issued by the UK Home Office, Section 7 of the MDA 1971 states that:

> *it is lawful to produce, supply, offer to supply, import, export, have in possession or cultivate (in the case of the plant) cannabis products, including medicinal products.*

Section 30 of the MDA 1971 provides a provision in terms of licencing and authorities. The Misuse of Drugs (Licence Costs) Regulations 2010, which played out the fees to be paid in respect of the various forms of licences, include a detailed list of the numerous types of licences available. Individual licences for cannabis importation and exportation are available while candidates may also need to have a domestic licence.

2.2.2 Canada

Since 2001, Canada has introduced medical-use cannabis legislative regimes that provide a legal exception from the Controlled Drugs and Substances Act (SC 1996, c.19) for specific cannabis usage. Cannabis was eventually legalised for recreational

use under the enactment of the Cannabis Act, SC 2018, c.16 (the Cannabis Act), and the Cannabis Regulations SOR/2018-144 (the Cannabis Regulations) in which among other things removed cannabis from Schedule II of the Controlled Drugs and Substances Act (S.C. 1996, c. 19). The Industrial Hemp Regulations, SOR/2018-145 (the IH Regulations), which control the cultivation, sale, and use of low-THC cannabis cultivars are annexed to the Cannabis Act and Cannabis Regulations.

Cannabis is defined under the Cannabis Act as *"any part of a cannabis plant, including the phytocannabinoids produced by, or found in, such a plant, regardless of whether that part has been processed or not…,"* (example tetrahydrocannabinol, THC**,** and CBD). However, *"non-viable cannabis seeds, stalks of the cannabis plants without any leaf, flower, seed or branch (including any fibre made from cannabis stalks) and the root of the plant"* is not considered cannabis within the meaning of the Cannabis Act.

The Cannabis Act governs cannabis manufacturing at the federal level whilst provincial and territory laws govern cannabis sales and distribution. The Act only allows for the production and sale of specified cannabis products while the regulations specify the requirements for the production and sale of each kind of cannabis in detail. In general, the Cannabis Act consists of two major components namely (1) cannabis prohibitions and illegal actions; and (2) penalties for violations, as well as other powers of enforcement.

Section 7 of the Cannabis Act outlines the purpose of this Act, which is to (1) keep cannabis out from the youth; (2) keep illicit earnings out of criminals' pockets; and (3) preserve public health and safety by providing adults access to legal cannabis. Section 12 of the Cannabis Act authorises anybody over the age of 18 to cultivate, propagate, or harvest cannabis plants as long as they are authorised to do so. Violation of these provisions will result in the individual facing a sentence of up to 14 years of imprisonment. The licence concerning cultivation could be (1) a cultivation licence under the Cannabis Regulations that allow for the production of cannabis plants with different quantities of THC and CBD; or (2) an industrial hemp licence issued under the Industrial Hemp Regulations that authorise the cultivation of particular types of cannabis plants having a THC level of less than 0.3% in the flowering heads, branches, and leaves (as stated in Regulation 1 of the IH Regulation).

Canada's Health Ministry has broad enforcement authority over anybody licensed to handle cannabis under the Cannabis Act or provincial legislation. The

Ministry of Health enforcement powers includes the ability to compel licensees to disclose certain information to the government, conduct specific activities, examine licenced facilities, and assess fines for noncompliance. Furthermore, in the case of noncompliance, the Ministry of Health has the authority to suspend and revoke a licence issued under the Cannabis Act.

The Minister may grant licences and permits to import or export cannabis solely for medicinal or scientific purposes or for industrial hemp. Furthermore, the Minister may engage the services of individuals with technical or specialised expertise to advise him or her on his or her rights, responsibilities, or functions under this Act.

2.2.3 Thailand

The amendments to the Narcotics Act B.E. 2522 (1979) in December 2018 paved the way for the medicinal use of cannabis and laws governing the cultivation of cannabis in the form of hemp. No specific definition of cannabis is stated in the latest Narcotics Act (No. 7) B.E. 2562 (2019) (Narcotics Act 2019). However, in this Act, the term 'marijuana' is used and is classified as 'narcotics'. Under Section 4, 'narcotics' means:

> *any form of chemicals or substances which, upon being consumed whether by taking orally, inhaling, smoking, injecting or by whatever means, causes physiological or mental effect in a significant manner…*

Section 7 of the Narcotics Act 2019 classifies narcotics into 5 categories in which marijuana (cannabis) is classified as narcotics Category V. The Narcotics Act 2019 differentiates marijuana (cannabis) from hemp in which hemp is referred to as "*a plant of scientific name Cannabis sativa".*

In general, the Narcotics Act 2019 has three main components namely (1) prohibitions and criminal activities relating to narcotics; (2) licensing procedures concerning narcotics including duties of licensees; and (3) administrative, enforcement powers, and penalties for violation. The amended Narcotics Act 2019 contains specific provisions allowing for production, import, and export of cannabis in the following cases:

> *(1) In the case of necessity for the benefits of the authorities, medical purposes, treatment of illnesses, or studying, research, and development…*

> *(2) In the case of hemp which is a plant of scientific name Cannabis sativa L. subsp. sativa…*
>
> *(3) In the case of bringing into or taking out of the Kingdom for personal use not exceeding necessary quantity for treatment of specific diseases and with a prescription or a certificate of a medical profession practitioner, a dental profession practitioner, a Thai traditional medicine profession practitioner, an applied Thai traditional medicine profession practitioner, or a folk healer under the law governing Thai traditional medicine profession...*

Under the Section 26/3 of the Narcotics Act 2019, an authorised person may possess cannabis *"in a quantity not exceeding that is necessary for personal use of treatment of specific diseases, and with a prescription…"* The quantity of the narcotics that are permitted shall be in accordance with the Government Gazette:

> *Possession, production, an importation, or an exportation of cannabis in a quantity from ten kilograms upwards shall be presumed to be a production, an importation, or an exportation of same for distribution*.

An application for a licence and the issue of a licence must follow the basis, procedures, and criteria outlined in the Ministerial Regulations. Under Section 26/5 of the Narcotics Act 2019, the licencing authority may issue a licence to produce, import, export, distribute or possess cannabis for medicinal purposes only. The applicant is limited to a government agency, medical professionals as prescribed in the Narcotics Act 2019, universities, agricultural profession operators, an international public transport business operator, an authorised international travelling patient, and other applicants as prescribed in the Ministerial Regulations by the Minister and approved by the Committee. Section 48 of the Narcotics Act 2019 allows the advertisement of cannabis to be made directly to medical professionals as prescribed in the Act.

The Narcotics Control Board may make a resolution to the Minister with the consent of the Narcotics Control Committee (the Committee) to designate any location for carrying out the cannabis-related activities of (1) to test plants which yield or may be used to produce cannabis; (2) to produce and conduct a test; and (3) to consume or possess cannabis in a prescribed quantity. The committee is responsible for advising and approving the Minister to act in accordance with the Act, approving the licencing authority to suspend or revoke licences, approving the Minister in issuing Notifications related to marijuana, approving the Minister in issuing a Notification prescribing

descriptions of hemp, and performing other duties by virtue of this Act or other laws that are the authorities and responsibilities of the committee or entrusted by the Minister. The Minister, with the committee's consent, shall have the authority to make notices in the Government Gazette.

The amendment of the Narcotics Act 2019 also led to the amendment of two other statutes related to the use of hemp in Thailand governed by the Ministry of Public Health, particularly because of the delisting of certain parts of cannabis and hemp plants. The statutes are the Food Act B.E. 2555 (1979) and the Cosmetic Act B.E. 2558 (2015). The amendment of the Food Act B.E. 2555 (1979) in February and March 2021 allowed for the use of local delisted parts of the hemp plant to be used in food, and subsequently established the rules for using hemp seed, hemp oil, and hemp protein in processed foods (Mullis, 2021). The delisting of certain several parts of hemp plants and cannabis also permits its use in cosmetic products, under the Cosmetic Act B.E. 2558 (2015).

2.3 Regulatory Analysis

2.3.1 United Kingdom

In the UK, the legalisation of medicinal cannabis is governed under The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 (MDR 2018). The Regulations provide lawful access to control drugs that are listed in one of the five Schedules to the preceding of Misuse of Drugs Regulation 2001 (MDR 2001) based on an evaluation of their medicinal or therapeutic usefulness, the requirement for lawful access, and the possible consequences when misused. The legislative controls are applied to control parts of cannabis plants as well as products containing controlled cannabinoids. Only the ‘exempted product’ or ‘cannabis-based products for medical use in humans’ (CBPM) can be legally prescribed, administered or distributed to the public. Other substances or products that include or contain cannabis, cannabis resin, cannabinol or cannabinol derivatives will continue to be classified as Schedule 1 drugs. Cannabis will continue to be classified as a Class B drug under the MDA 1971, and the penalties for unlicensed supply, possession, and cultivation of cannabis will stay the same.

Other than that, the new regulations (MDR 2018) provide a waiver for licence

fees. The definition of ‘cannabis-based product for medicinal use in humans’ is introduced with a definition of:

> *a preparation or other product, which—*
>
> *(a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);*
>
> *(b) is produced for medicinal use in humans; and—*
>
> *(c) is—*
>
> *(i) a medicinal product; or*
>
> *(ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.*

If the definition above is met, the preparation or product is considered as a CBPM and a Schedule 2 drug under the MDR 2018. ‘Medicinal products’ is defined in the Human Medicines Regulations 2012 as:

> *(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or*
>
> *(b) any substance or combination of substances that may be used by or administered to human beings with a view to— (i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or (ii) making a medical diagnosis.*

The MDR 2018 have also imposed special measures of control under the new Regulation 16A for the use, order, and supply of these CBPM for the purpose of administration. Specifically, such order and supply must be:

> *(1) for use in accordance with the prescription or direction of a specialist medical practitioner;*
>
> *(2) an investigational medicinal product for use in a clinical trial in humans; or*
>
> *(3) a medicinal product with a marketing authorisation.*

Regulation 16A(3) states that the consumption of cannabis or cannabis-based products via smoking is prohibited under the MDR 2018, except for research purposes. The MDR 2018 also amend the Misuse of Drugs (Licence Charge) Regulations 2010 (the 2010 Regulations) to clarify that the Secretary of State may decide that *"no licence fee shall be paid where he thinks fit."* According to the Regulation 2(2) Misuse of Drugs (Licence Fees) Regulations 2010, there are two separate licencing regimes connected to cannabis

production in which it depends on the varieties whether they contain high THC (exceeding 0.2%) or low THC (not exceeding 0.2%). The licence only permits for the industrial use of the hemp plant's seed and fibre, which are uncontrolled parts of the plant, and does not permit the use of the flowers or the leaves (‘green’ or controlled materials).

2.3.2 Canada

Since the enforcement of the Cannabis Act 2018, the new Cannabis Regulations replaced the Access to Cannabis for Medical Purposes Regulations (ACMPR) SOR/2016-230. The Cannabis Regulations provide different classes of licenses, authorised activities for each class of license, security requirements for production sites, production quality standards, packaging and labelling requirements, marketing and branding restrictions, record keeping and reporting requirements, import or export rules, and the medical access regime. The IH Regulations are an increasingly important component of Canada’s cannabis regulatory regime owing to the relatively less onerous requirements relating to hemp plants and the increasing market demand for hemp-derived CBD products.

The Cannabis Regulations provide a regulatory framework for licensing and security of cannabis-related activities, the production of cannabis products (including packaging and labelling), quality control, and medical access. There are six classes of licences listed under Regulation 8 namely for “*cultivation, processing, analytical, sale for medical purposes, research, and cannabis drug licence.”* Regulations 231-233 state that licencees that handle cannabis must meet certain production and operating standards (Good Production Practices). Standard operating procedures must be developed and followed for the production, sampling, testing, packaging, labelling, distribution, and storage of cannabis. Additionally, all cannabis sold or exported must undergo analytical testing to verify that the products do not exceed the thresholds for microbial and chemical contaminants. Part 12 of the Cannabis Regulations prescribes certain information on the collection and reporting requirements of sales to medically authorised cannabis users.

The Cannabis Regulations establish the medicinal use and access regime for patients using cannabis with medical authorisation as stated in Part 14. These new Regulations provide improvements in patients’ access to cannabis for medicinal

purposes in terms of medical documents, limitation period to obtain cannabis, a broader range of permitted products, and remove personal storage limits for patients (Posnikoff, 2020). By virtue of Regulation 289, licensed producers may sell cannabis directly to patients that have medical authorisation. In addition, Regulation 312 states that medically authorised patients may produce cannabis on their own behalf, or they may designate a person to produce cannabis on their behalf. A person designated to produce cannabis on behalf of a medically authorised patient must register with the government and abide by the requirements in the Cannabis Regulations. Subject to the legal age limit in each province or territory, medically authorised patients may purchase cannabis at provincial or territorial authorised retail outlets or through provincial or territorial authorised online sales platforms.

Regulation 239-240 permit the import and export of cannabis solely for medicinal or scientific purposes. According to Regulation 26-27, federally licensed cannabis producers and processors are not allowed to sell cannabis to retail consumers except for the sale of cannabis to medically authorised cannabis users.

2.3.3 Thailand

The amendment of the Narcotics Act 2019 to allow cannabis for medicinal and research purposes is regarded as the first relaxation of cannabis regulation in Thailand. The implementation of this Act is through the Ministerial Regulations and Notifications issued by the Ministry of Public Health (MoPH) as the regulatory body. The amendments to the Narcotics Act 2019 also provide a registration pathway for medicinal cannabis by the Thai FDA, a regulatory body under the MoPH. Following the legalisation of hemp and marijuana for medicinal purposes, the Narcotics Control Committee updates the definition of the characteristics of hemp, limiting the amount of THC that a hemp plant and certified hemp seed could contain up to 1% by dry weight. Any plant with a THC content higher than 1% by dry weight is considered marijuana (cannabis) (Notification Of The Narcotics Commission, 2021).

The MoPH further legalised the production and use of hemp by amending the definition of Category V narcotics and delisting certain parts and extract of cannabis and hemp from being classified as a narcotic, provided that such parts or extracts are produced domestically. This measure permits the use of certain parts of the cannabis plant for medical, research, and production of health products only. The exempted parts

for hemp include the bark, tree, fibres, branches, roots, leaves that do not have shoots or inflorescences attached to them, extract containing CBD that does not have THC more than 0.2% by weight, and the residue from the extraction that also does not contain THC more than 0.2% by weight. The exempted parts for cannabis were the same as hemp but excluded cannabis seeds and cannabis seed oil or extract. The imports of these parts, however, remain subject to the import regulations as defined by the Narcotics Act 2019.

The Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Import, Export, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2563 (2020) (the Ministerial Regulations) was released for the purpose of issuing permits related to hemp cultivation and use. It legalises the commercial production, use, and trade of hemp and outlines the procedure by which people or groups could obtain the required permissions to do so.

There are several requirements that the applicant must meet including being of Thai nationality (or partnering with a Thai citizen), age, not being a bankrupt, and no criminal record requirements. In addition, the application must include information pertaining to the location, a detailed plan for production, import, export, sale, distribution or utilisation, and security measures to prevent misuse. The production of hemp will be closely monitored by government officials. An analysis of the THC content must be performed before hemp can be transported from the facility, and the producer must give advance notice to a competent official before moving the product. Farmers are only allowed to use certified seeds in hemp production until five years after the publishing of the regulation. The import of hemp and hemp products is limited to research purposes and government agencies for medicinal purposes for five years until January 2026. The new regulation does stipulate certain conditions on importing and licensing.

Additional Notifications were issued by the MoPH under the Food Act B.E. 2555 (1979) in 2021 that permit the delisted parts of hemp and cannabis as food ingredients such as food items produced in restaurants and bakeries but not in processed food. Furthermore, Thailand’s government has continued to expand regulations to permit hemp and cannabis use in other consumer products such as cosmetics, which has been issued under the Cosmetic Products Act B.E. 2558 (2015).

Thailand's cannabis and hemp regulations continue to shift in favour of greater accessibility not just for medicinal purposes, but also for prospective customers and

business industries. Significant barriers persist in the market including limitations on use and licences to permit for production and distribution. Private and pharmaceutical CBD production remain tough to navigate for international operators interested in joining the local market. Nevertheless, it can be seen that the cannabis and hemp sector in Thailand is becoming more liberalised.

2.4 Comparative Analysis

2.4.1 Legalisation Approach

Comparative analysis finds that all three jurisdictions have different approaches in their legal reform with regards to medicinal cannabis. The UK was found to adopt a patchwork approach since the legalisation of medicinal cannabis is incorporated in the MDA 1971. Unlike the UK, Canada has legalised cannabis for medicinal purposes since 2001 by adopting *sui generis* approach, which is the Cannabis Act. The Cannabis Act and its Regulations exist independently from the Controlled Drugs and Substance Act SC 1996, c.19 that covers recreational and medicinal use of cannabis. This approach enables the inclusion of detailed provisions pertaining to the enforcement and control of cannabis. On the other hand, Thailand adopts a 'piecemeal' approach that involves more than one statute in legalising cannabis for medicinal use. The piecemeal approach can be found in the Narcotics Act 2019, the Food Act B.E. 2522 (1979), and the Cosmetic Act B.E. 2558 (2015). Compared to the UK and Canadian approaches, it is apparent that cannabis relaxation for medicinal use in Thailand is more fragmented.

2.4.2 Definition and Interpretation

Comparative analysis showed that the Cannabis Act (Canada) and MDA 1971 (UK) provide a clear definition of cannabis. Both legislations provide a general reference to the genus *Cannabis* plant. However, not all parts of the plant are considered cannabis within the meaning of the Canada Cannabis Act such as the non-viable part. Compared to the UK MDA 1971, all parts of the cannabis plant were included within its definition but differentiated cannabis resin from its definition. In contrast, no specific definition of cannabis is provided in the Narcotics Act 2019, the Food Act 1979, and the Cosmetic Act 2015. In Thailand, cannabis has been generally classified as a

Category V Narcotic that enables it to be used for medicinal purposes whereby cannabis is defined under the Ministerial Regulations and Notifications issued by the Thailand Ministry of Public Health. In terms of similarity, all three jurisdictions do not specifically use the term 'medicinal cannabis'. However, in the UK, a more elaborate term of medicinal cannabis can be found in the MDR 2018. The regulation specifies medicinal cannabis as 'cannabis-based product for medicinal use in humans' (CBPM). In addition, CBPM refers medicinal cannabis as 'medicinal product'.

2.4.3 Classification

Comparative analysis finds significant differences in the classification of cannabis as seen in the Cannabis Act (Canada). The Canadian law classify cannabis into three different categories namely (1) cannabis for non-medicinal purposes; (2) cannabis for medicinal purposes; and (3) health products containing cannabis or for use with cannabis. In comparison, the UK only classifies cannabis for medicinal purposes. Compared to the UK, Thailand has a broader classification of cannabis since it allows cannabis to be used beyond medicinal purposes. However, Thailand classification is still short of the Canadian Act's classification.

In terms of similarities, all three countries classified cannabis by limiting the THC percentage to distinguish cannabis from industrial hemp. Among the three countries, Thailand has the highest percentage of THC in cannabis plant (hemp) with 1% followed by Canada and the UK (0.3% and 0.2% consecutively). Other than THC content, all three jurisdictions also classified cannabis by limiting only certain components of the plant under the Cannabis Act (Canada), MDA 1971 (UK), and Narcotics Act (Thailand). However, among the three countries, the UK has the least parts that are considered as non-controlled parts. On the other hand, compared to Canada, Thailand has the broadest list of non-controlled parts, provided that the parts are produced domestically and only for medicinal, research, and production of health products.

2.4.4 Administration and Governance

Comparative analysis finds that both Canada's Cannabis Act 2018 and Thailand's Narcotics Act 2019 have regulations to implement a licensing framework

for the production of cannabis for medicinal purposes. However, unlike Thailand, Canada is unique since cannabis activities are not centralised at the federal level, but the jurisdictions were shared with the provincial and territorial. Cannabis production is regulated at the federal level while the sale and distribution of cannabis for medicinal purposes is generally governed by provincial and territorial legislation. Health Canada is the federal body in charge of enforcing the Cannabis Act and regulating cannabis and industrial hemp production. As for Thailand, all activities related to cannabis are centralised and regulated by the Ministry of Public Health (MoPH), specifically under the FDA. A slightly different approach is done in the UK whereby although cannabis is regulated federally and only CBPM is legalised, any activity with regards to cannabis is through the Secretary of State or Home Office.

In terms of differences, the UK government set up several layers of control in prescribing medicinal cannabis. Similar control is not obvious in Canada and Thailand. The UK government has opted to limit the decision to prescribe CBPM to practitioners designated on the General Medical Council's Specialist Register. The National Health Service (NHS) will only prescribe cannabis-based products for medicinal purposes if there is clear published evidence of efficacy, and the patient has a clinical need that cannot be fulfilled by a licenced prescription and has exhausted all existing treatment regimes. Furthermore, a specialist doctor in the General Medical Council (GMC) Specialist Register should only prescribe within their field of practice and training, and the choice to prescribe should be made by a multidisciplinary team. In the usual course, any decision to prescribe unlicenced drugs must consider the applicable GMC recommendations and the appropriate NHS Trust governance processes. The National Institute for Health and Care Excellence (NICE) has produced a clinical guideline on prescribing cannabis-based products for medicinal use in humans to assist specialist doctors in their prescribing decisions.

In addition, the laws in the UK and Thailand prescribed for a statutory body to be established to advise the particular body that enforces cannabis-related laws. For example, in the UK, the Advisory Council on the Misuse of Drugs is established among others to review and advise on the appropriate classification of cannabis. Likewise, in Thailand, the Narcotics Control Committee is in charge of advising the Minister on cannabis-related issues. The situation is different in Canada in which there is no specific council or committee prescribed under the Cannabis Act 2018. The Minister may consult with anyone with technical or specialised expertise about his or her rights,

obligations, or functions under the Act.

2.4.5 Trade (Import and Export)

Under all three jurisdictions, the trade of cannabis and cannabis-product for medicinal purposes is allowed with authorisation from the licencing bodies. However, compared to the UK and Canada, Thailand is different as it specifies the types of hemp plants that can be imported. The regulations in Thailand only allow the importation of dried bark, dried straw, and dried fibre but requires a specific licence from the MoPH.

2.4.6 Commercialisation (Retail)

Canada is the only country that permits the retail sale of cannabis whereas the sale and purchase of cannabis are prohibited in the UK and Thailand. In Canada, federally licensed cannabis cultivators and processors are permitted to sell cannabis to medically authorised cannabis users only. Each province and territory have a separate regulatory regime for the retail sale of cannabis. In some jurisdictions, the retail sale of cannabis is only permitted in government-run outlets. In other jurisdictions, private retailers are permitted to operate under a license from the local jurisdiction. Most jurisdictions require all federal licence holders to sell cannabis products to government-run cannabis wholesalers although as of late 2019, one of Canada's largest jurisdictions is considering allowing private wholesale of cannabis products.

2.4.7 Restriction

Comparative analysis finds that in terms of similarities, firstly, the UK and Thailand only legalise cannabis for medicinal purposes. However, the Thai MoPH expands its use as an additive in certain foods and cosmetics, upon approval by the FDA. Secondly, in all jurisdictions, healthcare practitioner authorisation and prescription are mandatory before an authorised patient can obtain medicinal cannabis. Thirdly, advertisement of medicinal cannabis in all jurisdictions is allowed through the approval of the licencing authority. However, the UK has the most restrictive measures because only specialist medical practitioner is given the authority to prescribe CBPM. Additionally, the UK regulations specifically prohibit smoking of cannabis and CBPM

use other than for research purposes, which is not mentioned in the Canada and Thailand jurisdictions.

On the other hand, Canada has the least restrictive measures. The reason for this is not only due to the legal status of cannabis for both medicinal and recreational purposes, but also to the methods on how patients can obtain cannabis supply. This is particularly unique in Canada whereby authorised patients with prescriptions can have access to medicinal cannabis either from buying it directly from a federally licensed seller, registering with Health Canada to produce a limited amount of cannabis for their own medicinal purposes or designating other parties to produce it for them. Cannabis supply is also available at a provincial or territorial retail outlet or through provincial or territorial authorised online sales platforms. In addition, the restrictions placed on Canada's Cannabis Act are intended mainly to protect the youth, public health, and to reduce criminal activities. The Cannabis Act discourage youth cannabis user by age restriction (18 years old) and restricting promotion and enticement. Under the Cannabis Act, there is no limitation on the amount of cannabis that can be possessed to ensure adequate medical supply.

Another significant difference is the medical practice in Thailand, which is different from the other two western countries. In Thailand, traditional medicine is practised alongside modern medicine. Therefore, the healthcare providers that can prescribe cannabis for medicinal purposes are certified doctors and it extends to dentists, Thai traditional medicine practitioners, applied Thai traditional medicine practitioners, and folk healers under the law governing the Thai traditional medicine profession. This extension allows advertisements regarding cannabis that have direct contact with doctors, dentists, Thai traditional medicine practitioners and folk healers through the approval of the licencing authority.

2.4.8 Model

Comparative analysis finds that Canada has a broader model in the legalisation of medicinal cannabis. This is due to the fact that Canada also legalises the recreational use of cannabis. In comparison, the UK and Thailand are adopting a restrictive model. Unlike Canada, both countries only cover the medicinal use of cannabis.

Among the three counties, the Thailand model is unique since it adopts a hybrid model by combining the modern treatment with the traditional treatment using

medicinal cannabis. In addition, the use of medicinal cannabis is further expanded as an additive in foods and cosmetics under the authorisation of the Ministry of Public Health. Furthermore, the regulations also permit government and private agencies, as well as private individuals to manufacture, trade, commercialise or possess hemp for medical benefit. In contrast, patients in the UK have very limited access to medicinal cannabis.

2.5 Conclusion of Chapter Two

This chapter has analysed three statutes and three main regulations concerning medicinal cannabis in the UK, Canada, and Thailand. The major findings from this comparative analysis are all jurisdictions are mostly different with slight similarities, as summarised in Table 2. By using eight themes of the scope of comparison, the comparative analysis finds five differences that can be seen concerning the legalisation approach, administration and governance, commercialisation, restriction, and model that has been used by each jurisdiction. There are three similarities in terms of definition and interpretation, as well as classification of medicinal cannabis and trade (import and export). However, Canada and Thailand have their own unique features. Canada is unique because, in terms of administration, cannabis is not centrally regulated. In addition, apart from possessing medicinal cannabis, an authorised patient can also produce cannabis. Thailand, on the other hand, is unique in its legalisation approach and the application of medicinal cannabis owing to the nature of medicinal cannabis in the Thai's culture, which originates from traditional medicine.

Prior to legalisation of cannabis, the drugs control legislation in the UK and Thailand was similar with Malaysia as these countries also criminalised drug abuse and trafficking[1]. In terms of punishment, the UK MDA 1971 and Thailand Narcotics Act imposed either imprisonment or death penalty. However, the situation changed when these countries amended their cannabis laws. Both countries' legal reforms have opened new avenues in the medical field as well as changed their perceptions towards cannabis in general. The UK patchwork approach is most suited to Malaysia since the focus of legalising cannabis is strictly for medicinal purposes. The *sui generis* approach adopted by Canada would be more suitable if legalisation of cannabis in Malaysia is taking a broad-based approach i.e., legalisation for medicinal, recreational, and industrial.

[1] The legal position of Malaysia's drug law has been discussed in Chapter One.

Likewise, the Thailand piecemeal approach is deemed not suitable as it is fragmented and difficult to implement.

The definition, interpretation, and classification of cannabis under Canada's jurisdiction is the most appropriate as it distinguishes the use of cannabis in terms of medicinal, recreational, and industrial. Parts of the cannabis plant or extract of the cannabis plant that are classified as controlled and regulated substances are properly defined resulting in a clear boundary that aids law enforcement. In terms of administration and governance, the Health Authorities' role in Canada and Thailand as a regulating and licencing body appears to be the most appropriate. Control over the trade and commercialisation of medicinal cannabis in the UK is likewise suitable to be adopted in Malaysia's jurisdiction. On the other hand, while it is crucial to avoid the misuse of controlled substances, the stringent procedures with several levels of control in the UK make it difficult for patients to obtain a supply of medicinal cannabis (Nutt et al., 2020). There is a potential that regulations in Canada and Thailand will be more effective in assuring patients' access to medicinal cannabis. The comparative analysis also demonstrates that administratively, Canada and Thailand treat cannabis as a health concern whereas, in the UK, cannabis is treated as a security issue.

To summarise, the findings in this chapter enable this research to select the best features to be incorporated in the legalisation of medicinal cannabis in Malaysia. Although no single jurisdiction is ideal for adoption, the shortcomings of the legislative reform in one jurisdiction can be dealt with by incorporating the best features from other jurisdictions. The next chapter will examine the medico-ethical considerations for the legalisation of medicinal cannabis in general to identify various perspectives that are relevant for the legalisation of medicinal cannabis in Malaysia.

Table 2
Comparative Analysis

No.	Scope of Comparison	Jurisdiction		
		United Kingdom	**Canada**	**Thailand**
1	Legalisation Approach	Patchwork approach. - The legalisation of medicinal cannabis is incorporated in the MDA 1971.	*Sui generis* approach. - The Cannabis Act & its Regulations exist independently from the Controlled Drugs and Substance Act SC 1996.	Piecemeal approach. - Legalisation of medicinal cannabis is fragmented, incorporated in the Narcotics Act 2019, the Food Act 1979, and the Cosmetic Act 2015.
2	Definition and Interpretation	Do not specifically use the term 'medicinal cannabis'.		
		- The MDA 1971 provides general reference to the genus Cannabis plant. - More elaborate term of medicinal cannabis (CBPM) is defined under the MDR 2018. - CBPM is a 'medicinal product'.	- Clear definition of cannabis is stated in the Cannabis Act. - The Act provides general reference to the genus Cannabis plant, but not all parts of the plant were included in its definition.	- No specific definition of cannabis is provided in the Narcotics Act 2019 (cannabis has been generally classified as a Category V Narcotic). - Cannabis is defined under the Ministerial Regulations and Notifications.
3	Classification	Cannabis is classified by- (1) limiting the THC percentage to distinguish cannabis from industrial hemp; and (2) limiting only certain components of the cannabis plant are being regulated.		
		Industrial hemp contains ≤ 0.2% THC in the hemp plant's seed and fibre.	Industrial hemp contains < 0.3% THC in the flowering heads, branches, and leaves.	Industrial hemp contains ≤ 1% THC by dry weight.
		Non controlled parts: hemp plant's seed & fibre.	Non controlled parts: non-viable cannabis seeds, stalks of the cannabis plant without leaf, flower, seed, or branch (including any	Non controlled parts (produced domestically): the bark, tree, fibres, branches, roots, leaves that do not have shoots or inflorescence attached

No.	Scope of Comparison	Jurisdiction		
		United Kingdom	**Canada**	**Thailand**
			fibre made from cannabis stalks) & the root.	to them.
		Distinguishes the use of cannabis for medicinal (CBPM) and industrial (industrial hemp).	Distinguishes the use of cannabis in terms of medical, recreational, and industrial.	Distinguishes the use of cannabis for medicinal and industrial.
4	Administrati-on and Governance	Cannabis is regulated federally.	Cannabis production is regulated at the federal level while sale and distribution of cannabis for medical purposes is generally governed by provincial and territorial.	Cannabis is regulated federally.
		Governed by the Secretary of State / Home Office, with several layers of control (GMC recommendations, NHS Trust Governance processes, and NICE Guidelines).	Governed by the Health Authority (Health Canada).	Governed by the Health Authority (Ministry of Public Health, MoPH).
		The Advisory Council on the Misuse of Drugs is established to advise the particular body that enforces cannabis-related law.	The Narcotics Control Committee is in charge of advising the Minister on cannabis-related issues.	No specific council or committee prescribed under the Cannabis Act – the Minister may engage anyone with technical or specialised expertise.
5	Trade (Import and Export)	The trade of cannabis and cannabis-product for medical purposes is allowed with authorisation from the licencing bodies.		
				Only dried bark, dried straw, and dried fibre are allowed to be imported.
6	Commerciali-sation (Retail)	Sale and purchase of cannabis are prohibited.	Retail sale of cannabis is permitted.	Sale and purchase of cannabis are prohibited.
7	Restriction	(1) In all jurisdictions, healthcare practitioner authorisation and prescription are mandatory before an authorised patient can obtain medicinal cannabis. (2) Advertisement of medicinal cannabis is allowed through the approval of the licencing authority.		

No.	Scope of Comparison	Jurisdiction		
		United Kingdom	**Canada**	**Thailand**
		Strictly legalise cannabis for medicinal purposes.	Legalise cannabis for medicinal and recreational purposes.	Legalise cannabis for medicinal purposes, with the extension to additive in foods and cosmetics.
		Only specialist registered under GMC's Specialist Register can prescribe medicinal cannabis.	Authorised medical practitioner can prescribe medicinal cannabis.	Medical practitioners, dentist, Thai traditional medicine practitioners, applied Thai traditional medicine practitioners, and folk healers can prescribe medicinal cannabis.
		Smoking of medicinal other than for research purposes is prohibited.	Smoking of medicinal cannabis is not mentioned in the legislation.	Smoking of medicinal cannabis is not mentioned in the legislation.
			Authorised patients can have access to medicinal cannabis either from buying it directly from federally licensed seller, produce on their own, or designating other parties to produce it for them.	
			No limitation on the amount of cannabis than can be possessed to ensure adequate medical supply	
8	Model	Restrictive model. - Strictly medicinal use of cannabis.	Broader model. - Medicinal and recreational use of cannabis.	Hybrid model. - Combining the modern and traditional treatment. - Additive in foods & cosmetics.

CHAPTER THREE
EXAMINATION OF MEDICO-ETHICAL CONSIDERATIONS

3.1 Introduction

The purpose of this chapter is to address the second research question of 'what are the medico-ethical considerations for the legalisation of medicinal cannabis?' Medico-ethical considerations are meant to guide and provide the basis of decision making in medicine towards an ethically acceptable solution in a morally and medically complex situation (van Bruchem-Visser, van Dijk, de Beaufort, & Mattace-Raso, 2020). There are many frameworks, principles, and theories that are available for decision making, however, for this research, the medico-ethical considerations are mainly referred to the Biomedical Ethics Theory by Beauchamp and Childress (2009). This theory, or also known as Principlism, consist of four basic principles of medical ethics namely respect for autonomy, beneficence, non-maleficence, and justice. To answer the research question, this chapter examines the medico-ethical considerations for medicinal cannabis using two different theories: (1) Biomedical Ethics Theory; and (2) Philosophical Theory. First, this chapter will examine the medico-ethical considerations through the ethical principlism approach. Second, this chapter will examine the medico-ethical considerations by utilising Philosophical Theory that includes principles of Utilitarian and Deontological approaches. The findings from the examination of medico-ethical considerations will be used as part of medical, ethical, and legal considerations for the legalisation of medicinal cannabis in Malaysia.

3.2 Examining the Medico-ethical Considerations for Legalisation of Medicinal Cannabis

3.2.1 Biomedical Ethics Consideration

3.2.1.1 Beneficence and the Potential for the Benefit of Medicinal Cannabis

There is extensive literature highlighting the benefit of medicinal cannabis to a patient in alleviating pain and suffering, particularly when other therapeutic measures have been exhausted (Freeman et al., 2019; Grant, 2013; Nutt et al., 2020). This

individual effect may be seen in several cases involving children with catastrophic forms of epilepsies such as Charlotte Web in the United States who inspired parents of children with comparable epilepsies in the UK, most notably the parents of Alfie Dingley and Billy Caldwell (Associated Press, 2020; Hurley, 2018; Mellis, 2018; Nutt et al., 2020). These children were on the verge of death or brain damage due to repeatable seizures that were resistant to legal therapies, and medicinal cannabis returned them to colloquial while also allowing them to discontinue other medications. The medicinal effect of cannabis has been proven in a study in Germany in which a team of scientists discovered that synthetic THC (dronabinol) produces a positive response in children with dystonia and spasticity with patients had either having improved symptom control or needing fewer other medications that cause side effects (Doherty, Power, Attala, & Vadeboncoeur, 2020).

A systematic review of over 10,000 research on medicinal cannabis was undertaken in order to determine the degree of evidence in terms of the benefits and risks involved (The National Academies of Sciences Engineering and Medicine, 2017). The existing scientific evidence was rated as *"conclusive, substantial, moderate, limited, or none/insufficient*" according to the assessment. The review discovered conclusive or substantial evidence that cannabis and cannabinoids are effective medicines for treating (1) chronic pain in adults, (2) nausea and vomiting related to chemotherapy, and (3) spasticity due to multiple sclerosis. Moderate evidence shows that cannabis or cannabinoids can enhance sleep outcomes in those who have sleep problems.

The value of medicinal cannabis's contribution to global health should not be ignored. A rising amount of biological research has lauded the cannabis plant as a potential source of new therapies. Many research and reviews on cannabis have been undertaken over the last few decades providing insight into its usefulness in a variety of medical ailments. For example, a systematic review suggests that cannabis can effectively treat chronic pain, neuropathic pain, spasticity due to multiple sclerosis, and shows a complete response in nausea and vomiting among chemotherapy patients (Freeman et al., 2019). It has fewer harmful side effects compared to traditional treatment regimens (Hill, 2015; Pisanti & Bifulco, 2017). Other clinical studies link cannabis use to decrease inflammation, anxiety and a possible treatment for Parkinson's disease, arthritis, and cancer (Pisanti & Bifulco, 2017; Qatanani et al., 2021). In addition, there is growing evidence that cannabis may be a viable alternative or adjunctive therapy for patients suffering from painful peripheral neuropathy, a disease that can have a

significant impact on the quality of life (Grant, 2013).

Aside from any direct medicinal advantages of cannabis, there are potentially enormous wider benefits. Economic benefits are significant in some nations whereby cannabis cultivation for medicinal and industrial purposes (industrial hemp) is a significant source of revenue (Fakhry, Abdulrahim, & Chahine, 2021). For example, this is highly evident in Lebanon, the first Arab country that has legalised the cultivation of cannabis for medicinal and industrial purposes. Lebanon, a well-known country for its high-quality cannabis, is listed by the United Nations Office of Drugs and Crime (UNODC) as one of the world's largest suppliers of cannabis resin (United Nations Office on Drug and Crimes, 2021). In the United States, where medicinal cannabis is legalised in 37 states, the economic impact of medicinal cannabis usages comes from different factors including increasing revenues without tax, increasing job creation, and decreasing government spending attributable to drugs prohibition (Berke, Gal, & Lee, 2021; Hajizadeh, 2016; Hanyang Division of International Studies, 2021). Furthermore, all states that legalised medicinal cannabis enjoyed higher tax revenue after the law enactment (Agustin, Alvarado, Cardenas, Towe, & Vann, 2020).

Another benefit highlighted in the literature is that the safety profile of CBD whereby it does not cause psychoactivity but has various therapeutic effects. It carries no risk of abuse or dependency and is generally safe in terms of public health (Kogan & Mechoulam, 2007; Mayor, 2019; Qatanani et al., 2021). Cannabis, in contrast to opioids and other current pain medicines, is comparatively non-addictive (P. Lucas, 2017). Furthermore, the growing body of research supporting cannabis's medicinal use as an adjunct or substitute for opioids provides an evidence-based rationale for healthcare providers and scientists to consider implementing and evaluating cannabis-based interventions in the opioid crisis (P. Lucas, 2017). However, more research is warranted to elucidate the medicinal cannabis used to ease this crisis (Okusanya et al., 2020; Rosic et al., 2021).

3.2.1.2 Non-maleficence and Safety of Medicinal Cannabis

The non-maleficence principle, which is the obligation to 'do no harm' is linked to the safety issue of medicinal cannabis. Particularly in providing a novel therapy, many aspects need to be scrutinised from the aspect of safety so that we do not inflict harm on patients and others. The safety issues in medicinal cannabis can be divided into three

categories namely (1) safety profile of medicinal cannabis; (2) potential risk of medicinal cannabis use; and (3) competency of the practitioner and safe practice. Firstly, the concerns about the safety profile of cannabis as a medicinal product are primarily focused upon the statements such as "*insufficient evidence of efficacy"* or *"it is too dangerous"* (Nutt et al., 2020, p. 1). Secondly, the concerns regarding the potential risk of medicinal cannabis use are due to its psychoactive properties, the range of modalities of medicinal cannabis consumption, and its potential social implications. The third issue is related to the competency of the practitioners to practice safely, which includes issues such as education and regulation, working within bounds of competence, and provision of reliable information (National Health Service, 2018).

a) Safety Profile of Medicinal Cannabis

The perceived lack of randomized controlled trial (RCT) evidence according to Nutt et al., (2020) is erroneous because other patient-centred approaches such as patient reported-outcomes, pharmacoepidemiology, and n=1 trials can be used. Healthcare practitioners sometimes assert incorrectly that they cannot prescribe without RCTs. However, it was reported that the FDA and/or the European Drugs Agency have granted over 50 medicines or indications without RCT data. Moreover, the RCT preconception was challenged in 2008 by Harvean Oration by stating that:

> *RCTs, long regarded at the 'gold standard' of evidence, have been put on an undeserved pedestal. Their appearance at the top of 'hierarchies' of evidence is inappropriate; and hierarchies, themselves, are illusory tools for assessing evidence. They should be replaced by a diversity of approaches that involve analysing the totality of the evidence-base. (Rawlins, 2008 cited in Nutt et al., 2020, p. 2)*

In certain countries, the limited number of RCTs for unlicensed cannabis-based products is partly due to regulatory constraints. Thus, the removal of these impediments will result in a more robust evidence base to assist clinical decision-making (Mayor, 2019).

However, because of the variety of cannabis-based products, the side effects of exposure might be unexpected. The variety of cannabis consumption methods, strains, and cannabinoid and terpene concentrations all confound evaluations of the dangers and benefits of therapeutic cannabis usage (Glickman & Sisti, 2020). Several studies on the

management of pain as a symptom of multiple sclerosis, injury, and cancer suggest that mild side effects were often observed (Pratt et al., 2019). Another study on the roles of the endocannabinoid system in immunity identifies the possible detrimental immune-modulatory effects of cannabinoid-based medications in certain circumstances (Almogi-Hazan & Or, 2020). A meta-analysis suggests that the effectiveness of Sativex in the treatment of multiple sclerosis may be limited (Whiting et al., 2015) and is not recommended by the NICE because of poor cost-effectiveness. Whitings et al. (2015) also found the association between cannabinoids (primarily THC) and increasing rates of disorientation and dizziness compared to the placebo or active comparators. Nevertheless, studies on the risk and benefits of medicinal cannabis concluded that most of the side effects are mild.

Due to the concerns that the scientific fact is inconclusive, professional views are divided leading to many researchers and professionals imposing a ban on cannabis (Hayry, 2004). Hayry (2004) argues that it is not morally wrong to allow a patient to undergo unproven or novel medical treatment, especially in a terminally-ill patient. It is immoral to deny them the right to have the option. Many would argue that cannabis confuses the mind and leads to addiction but so are other legal psychoactive drugs or pain killers. In terminally ill patients, where addiction is not the main concern, medicinal cannabis should be allowed because the goal is to relieve the suffering and provide good quality of life.

Although many opposed the legalisation of medicinal cannabis due to the perceived lack of evidence on the effectiveness of medicinal cannabis (Lee et al., 2016; Wilkinson, 2013), there is potential harm if medicinal cannabis remains illegal. As a novel medical treatment, the unlicensed and unregulated status will inevitably reveal safety implications in terms of the dosage, quality, potency, side effects, and drug interactions. For example, before the legalisation of medicinal cannabis in Thailand, there was evidence that seized illegal cannabis-based products were found to be contaminated with heavy metals, pesticides, and fungi, which is harmful (Zinboonyahgoon, Srisuma, Limsawart, Rice, & Suthisisang, 2021). As a result, there are two major standards for the safety of medicinal cannabis products. First, it necessitates worldwide quality control and licencing; second, additional safety data is required to determine the toxicity level, optimal dose and modes of consumption, the risk of side effects, and the possibility for interactions with other medications (Zinboonyahgoon et al., 2021).

b) Potential Risk of Medicinal Cannabis Use

Another safety issue that must be discussed in order to avoid harm is the potential risk of medicinal cannabis on the patient's health (Glickman & Sisti, 2020). A review on the effects of cannabis on behavioural health in people with mental illness suggests that cannabis use is associated with worsening symptoms of schizophrenia, major depressive disorder, bipolar disorder, and anxiety disorders (Lowe, Sasiadek, Coles, & George, 2019). Another study reveals that cannabis use increases the risk of problematic cannabis consumptions such as addiction and habitual use that interfere with daily life (Blanco et al., 2016). These studies, however, are primarily observational and represent recreational cannabis, which has higher THC potency and lower CBD amounts.

Other than that, the range of modalities or methods of medicinal cannabis administration may contribute to the potential risk of medicinal cannabis. For example, inhalation either by smoking combusted plant material or vaporisation remain the popular route of administration because the users can quickly experience the effects (Cyr et al., 2018). Despite the fact that major retrospective research established no significant link between cannabis smoking and cancer, smoking should be avoided owing to the evident risks of bronchial inflammation (Sidney, Charles P. Quesenberry, Friedman, & Tekawa, 1997; Tashkin, 2013). Moreover, given the association between smoking tobacco and THC use, and weak evidence supporting smoked cannabis, the literature concluded that healthcare providers should advise against smoking cannabis in most cases (Cyr et al., 2018; Kahan, Srivastava, Spithoff, & Bromley, 2014).

Other than that, among the heated discussions on medicinal cannabis focus not only on its ability to alleviate patients' symptoms, but also on its potential harm to the society. It is argued that public perception of its benefits will lead to increased abuse and stimulate drug use throughout society as a whole (Mack & Joy, 2000). The potential risk of cannabis usage is related to the controversial 'gateway hypothesis', which states that cannabis acts as a 'gateway' drug thus, increasing the possibility that users would use harder and more harmful drugs in the future (Kandel, Yamaguchi, & Chen, 1992; Lynskey et al., 2003). According to Mack et al. (2000), the potential risk of cannabis as a gateway drug stems from two behaviours: (1) the belief that cannabis has pharmacological properties that persuade users to explore harder drugs; and (2) cannabis opens a door to the world of illegal substances. When young people are introduced to illegal drug use through cannabis, they are subjected to increased peer pressure to try

other drugs and obtain easy accessibility (Mack & Joy, 2000). There is also a misconception on cannabis in general, particularly among the youth that cannabis is not addictive, not harmful, and the effects depend on the person's attitude (McKiernan & Fleming, 2017).

However, it is important to note that assumption of harder drug abuse stems from multiple factors such as the heavy cannabis use, psychiatric disorders, as well as a family medical history of psychological issues or alcohol addiction. In addition, research on drug progression has focused mainly on recreational use (Cerda et al., 2020; Mack & Joy, 2000; Monte, Zane, & Heard, 2015). For example, the legalisation of recreational cannabis in Colorado increases the traffic fatalities and impaired driving. In the context of medicinal cannabis, where the supply is only available by prescription, the pattern of subsequent drug progression among patients will differ from that of recreational users (Pacula, Jacobson, & Maksabedian, 2016). Previous studies on the non-medicinal use of psychoactive prescription drugs, such as sedatives, antidepressants, and opiate painkillers unable to identify a clear or consistent sequence of drug use following abuse of these drugs (Mack & Joy, 2000). Currently, data on drug use neither supports nor refutes claims that legalising cannabis for medicinal purposes will lead to an increase in drug abuse among medicinal cannabis patients. However, a survey conducted in four states in the USA reveals that approximately 86% of the medicinal cannabis users also use the drug recreationally (Pacula et al., 2016). Despite some limitations, this study provides evidence about cannabis use patterns in states where medicinal cannabis is legal.

The gateway hypothesis leads to the argument on the 'slippery slope' whereby the worry is that with medicinal cannabis legalisation, there will be an increase in recreational use, which in turn leads to an increase in overall public abuse (Haigh, Wood, & Stewart, 2016). The slippery slope arguments are frequently used in political, legal, and ethical debates, particularly among opponents (Haigh et al., 2016). In the USA, although medicinal cannabis has been legalised in many states, the debates among the law enforcement officers and medical practitioners are still ongoing due to public concerns over slippery slope arguments (Collins, 2019; Higdon, 2021). Similarly, in Canada, the legalisation of medicinal cannabis followed by the government's decision to legalise recreational cannabis raised concerns that it could lead to the legalisation of other illicit drugs, hence crippling the youth (Khizar, 2017).

However, philosophically, to sustain a slippery slope argument, there must be

valid evidence that *"one event in the sequence will cause the next"* (Davies, 2005). There are four distinct components to prove the slippery slope argument:

> *(a) An initial proposal (A);*
> *(b) An undesirable outcome (C);*
> *(c) The belief that allowing (A) will lead to a re-evaluation of (C) in the future; and*
> *(d) The rejection of (A) based on this belief (Corner et al. 2011 cited in Haigh et al., 2016, p. 2)*

To apply the above components, the *"initial proposal"* is usually states as *"if A.."*, while the undesirable outcome is stated as the consequence *("... then C").* Belief in a slippery slope argument is determined by the perceived likelihood that allowing (A) increases the risk of (C) in the future. With regards to the slippery argument for the legalisation of medicinal cannabis, if medicinal cannabis is legalised, it will increase the likelihood of further drugs to be legalised (e.g., cocaine). The degree of belief established relies on the categorisation of the item. For example, classifying cannabis into a new drug class, i.e., 'legal drugs' increases the likelihood of other drugs (e.g., cocaine) being classified in the same class. According to Haigh et al. (2016, p. 2):

> *a consequence of this mechanism is that the more similar the items at the top (e.g., cannabis) and bottom (e.g., cocaine) of the slippery slope, the stronger the argument is perceived to be.*

The decision to accept or reject this argument as convincing will be determined by whether or not to accept the conditional premise that leads down the slippery slope, namely that the legalisation of medicinal cannabis will lead to the legalisation of recreational cannabis and ultimately the legalisation of other illicit drugs. Thus, it is critical for this type of argument to be grounded by a valid data, which is currently unavailable. All substances should be treated based on its relative harms and facts surrounding it, same goes to cannabis. As all drugs are not the same, the law regulating it must be able to reflect it.

The slippery slope argument fails to provide grounds for prohibiting the use of medicinal cannabis because the '*initial proposal'* that leads to '*the undesirable outcome'* is not convincing. Studies have shown that there is no conclusive evidence that medicinal cannabis is causally linked to the subsequent abuse of other illicit drugs (Joy, Watson, & Benson, 1999; Melberg, Jensen, & Jones, 2007; Secades-Villa, Garcia-Rodríguez, Jin, Wang, & Blanco, 2015; Williams, 2020). Experts agree that this theory is a

misconception, and the legalisation of medicinal cannabis would not result in increased use among the general population (Nkansah-Amankra & Minelli, 2016; Pfeifer, 2011). This evidence suggests that generally, cannabis use does cause users to move on to harder drugs due to their illegal status, like any other hard drug (Davies, 2005).

Aside from that, the use of medicinal cannabis creates several societal and moral concerns for various religious communities. For instance, since THC has intoxicating effects, Islamic scholars must determine if cannabis use is subject to the same prohibitions as alcohol and other intoxicants that are normatively banned under Islamic law. Furthermore, scholars must assess if medicinal usage comes within the category of dire necessity (*ḍarūrah*) in which forbidden substances are deemed contingently allowed (Isa, 2016).

c) Competency of the Practitioner and Safe Practice

In terms of non-maleficence, do no harm also means that a medical practitioner has to be competent. Incompetency may pose risks and safety issues to patients, particularly in novel therapies. Medical practitioners have a duty to remain current and engage in self-education on novel therapies, new screening, and diagnostic methods if it is within the practitioner's expertise. It is hard to manage a treatment plan without a comprehensive understanding of what is accessible to patients in local contexts. According to Glickman and Sisti (2019), there are substantial knowledge gaps among medical practitioners about evidence of clinical benefits and possible risks of medicinal cannabis. This is perhaps one of the reasons why in some countries, only registered medical specialists within their expertise can prescribe medicinal cannabis (National Health Service, 2018). Patients must also be closely monitored for the effectiveness and side effects of cannabis. Incompetence on the practitioner side might have catastrophic consequences. Thus, it is especially important for a medical practitioner to have the skill, knowledge, and training before being authorised to prescribe medicinal cannabis.

Medical practitioners might face several ethical dilemmas in dealing with patients who are more knowledgeable in medicinal cannabis. To uphold the principles of beneficence and non-maleficence, medical practitioners commonly will only recommend any novel therapies for diseases with a strong evidentiary foundation. For example, in a situation where the negative effects of medicinal cannabis and its derivatives are well-known, such as addiction and mental health issues, when making

prescribing decisions, medical practitioners must weigh the risk for harm against the potential for benefit for particular patients (World Health Organization, 2017). The inadequacy of data to support its use puts medical practitioners in dilemma and resistance to acknowledge the medicinal use of cannabis.

However, with mounting evidence showing cannabis is safe and effective for a variety of various ailments and subpopulations, the fear that some patients may seek medicinal cannabis just to 'get high' is exaggerated. This is because these people could simply seek out recreational cannabis, which is far more potent, cheaper, and easier to access compared to medicinal cannabis (Glickman & Sisti, 2020).

3.2.1.3 Respect for Autonomy

The principle of respect for autonomy in healthcare is commonly related to the capacity of the autonomous person for self-determination to make their own decisions about which healthcare interventions they will or will not receive. It is argued that respect for patients' autonomy is a justified ethical reason to allow the use of cannabis in medicine (Hayry, 2004). Using this argument, the patient should be allowed to choose provided that the patient has the capacity for self-government. However, there are different categories of patients who may benefit from medicinal cannabis. For example, some patients may have the capacity despite suffering from severe pain. In this category, we should respect their autonomy. However, for a subset of a patient who may not have the capacity or may use it as a last resort just to get rid of the pain without undue consideration, it might not be applicable.

a) Making an Informed Choice About the Use of Medicinal Cannabis

Many medical practitioners are hesitant to recommend cannabis-based treatment to their patients due to a perceived lack of established data on the efficacy and negative effects of various cannabis-based treatments in various medical problems (Almogi-Hazan & Or, 2020). However, denying a patient knowledge about and access to medicinal cannabis as a medication that relieves pain and suffering, especially if the patient has a terminal condition, breaches a medical practitioner's basic obligation. As a result, medical practitioners find themselves at the centre of this quandary by attempting to strike a balance between medical needs and legal constraints (Clark,

Capuzzi, & Fick, 2011).

Informed choice is a crucial component of patient autonomy and it is dependent on the quality and dependability of information (Have, 2016). To make an informed decision about their treatment, patients must first have the capacity to make a decision. They must be able to comprehend the information given in order for them to receive full disclosure and have a comprehensive discussion of all available treatment options from their medical practitioner (Jackson, 2019). With regards to the use of cannabis in medicine, respect for patient autonomy sometimes clashes with a health practitioner's judgment of possible benefit and damage, especially in terminally ill patients. In such cases, it is essential to determine that a patient has the capacity to make an informed choice. Otherwise, the principle of respect for autonomy solely could not be used to justify the use of medicinal cannabis.

The argument used by the opponents is overly emphasising on autonomy and freedom of choice without considering other values. For example, it is a question of whether a patient is truly making an autonomous decision when they are terminally ill or in great pain. Do they have the capacity to make an informed decision when they are in the worst state of health? It is important to note that a person must act rationally in order to be truly autonomous (Jackson, 2019). Therefore, although autonomy necessitates some degree of independence, in order to make an informed decision, patients must avoid self-deception and irrationality. Their choices should be based on natural tendencies rather than random choices as individual autonomy is entirely lost when a patient pursues solely on bodily needs (Pfeifer, 2011).

However, we cannot deny that certain terminally ill patients have the capacity to make an informed decision. In this case, when they consulted their medical practitioner after attempting other conventional medicines, it is rational for them to conclude that medicinal cannabis is the only viable alternative medication. Thus, in a situation where medicinal cannabis is the only effective option to relieve patients' suffering, there should be no hurdles to its use. These patients made informed decisions guided not only by reason but also by the pursuit of individual happiness (Pfeifer, 2011). In fact, access to timely medications that alleviate pain such as cannabis is both a human right and a medical obligation (O'Brien, 2019). However, the illegality of medicinal cannabis will eliminate the chance of a patient making a meaningful choice for their health.

b) Doctor-Patient Relationship

Another factor to consider is the doctor-patient connection. Ezekiel and Emanuel (1992) defined four doctor-patient relationship models that are paternalistic, informative, interpretative, and deliberative. Some argued that among the four approaches, the deliberative approach inspires more confidence, higher patient satisfaction, and better outcomes (Patel & Ayung, 2016). The new paradigm of the doctor-patient relationship emphasises the patient's right to receive full disclosure and discussion of all available treatment options from their medical practitioners. Furthermore, the GMC advice on good medical practice states unequivocally that all licenced doctors must consider and respect patients' perspectives and experiences (2020). While it is prohibited to suggest cannabis for ailments other than those stated by the state legislation, medical practitioners are morally justified in doing so if relevant data support medicinal cannabis usage for a specific patient's condition. Similarly, in cases when the evidence of efficacy is ambiguous, medical practitioners should not rely on legality as the ethical foundation for recommending medicinal cannabis (Glickman & Sisti, 2020).

Decisions concerning when it is permissible and ethical to override a patient's autonomy in order to get medicinal cannabis in the interest of well-being are complicated and entail numerous aspects. Overprotection may intrude the autonomy of a patient, invoking paternalism while under protection may lead to harm (Have, 2016). The way these two considerations are balanced varies by country and practice, but generally, to the greatest extent feasible, patients must be informed about the anticipated benefits and risks of undergoing any kind of treatment.

3.2.1.4 Justice

In terms of justice, the argument revolving around medicinal cannabis focuses on patients' accessibility, human rights, and discrimination. In certain countries that have legalised medicinal cannabis, limited patients' access is one of the implementation issues. This is mainly due to the complex regulatory system surrounding medicinal cannabis and the resistance among the medical practitioners to discuss medicinal cannabis as the treatment option with their patients (Nutt et al., 2020; O'Brien, 2019). Besides that, the present argument over medicinal cannabis access is an issue of human

rights. Healthcare must shift towards a more patient-centred paradigm that empowers and respects patients' rights to choose how they will manage their health. When it comes to evidence and how we utilise it in medicine, we need to reintroduce the human element. Cannabis has the potential to alleviate suffering. Perhaps we should return to the definition of evidence-based medicine by Sackett et. al. (1996, p. 71) that is often not quoted, which includes:

> *the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care….and in developing public policy in healthcare.*

By definition, public policy should benefit the people rather than deny them their human rights (O'Brien, 2019).

Aside from that, despite numerous approval of medicinal cannabis as a legitimate medical therapy, studies in the US revealed that the government fail to sufficiently safeguard the patients from discrimination (Swinburne, 2021). It was reported that medicinal cannabis patients are treated differently and are discriminated against employment, education, home rental or custody and visitation of their children (LaFree, Wong, & Swinburne, 2021). The impact of discrimination will lead to unwanted health consequences such as stress due to stigma and worsening health conditions. As a result, patients tend to sue the employer or firm for discrimination after being fired or refused employment due to their medicinal cannabis usage. Therefore, the law must be able to address and provide protection against discrimination (Greenwald, 2019; LaFree et al., 2021; Swinburne, 2021).

3.2.2 Philosophical Theory Consideration

a) Utilitarianism Principle

Legalisation of medicinal cannabis can be discussed from the utilitarian perspective that was popularised by John Stuart Mill. The utilitarian perspective enables us to estimate the ratio between the possible negative and positive effects of the legalisation of medicinal cannabis. The utilitarian principle focuses on the consequence of action whereby:

> *the proper course of action is the one that maximises utility i.e. providing maximum happiness to the most number of people and reducing suffering to*

> *the least number of people. (Amer, 2019, p. 189)*

Conclusive evidence on medicinal cannabis effectiveness and safety are currently limited to certain diseases such as chronic pain in adults, chemotherapy-related nausea and vomiting, multiple sclerosis, and a number of treatment-resistant paediatric epilepsies. Although it might not fulfil the criteria of 'the greatest number of people', the fact that medicinal cannabis reduces suffering should not be underrated. Furthermore, 'happiness' is not only applicable to the patients that benefit from the treatment, but also to the medical providers, family members, and society as a whole who are affected by the suffering of their loved ones.

In general, utilitarianism holds that an action can be morally justifiable if it results in more benefits than harms. Mill adhered to the utility principle, which states that:

> *actions are right in proportion as they tend to promote happiness; wrong as they tend to produce the reverse of happiness. By happiness is intended pleasure and the absence of pain; by unhappiness, pain and the privation of pleasure. (Pfeifer, 2011, p. 343)*

Mill defined utility as happiness that might be maximised if the individual knew what caused personal happiness and is free to act on that knowledge. The utility of an action is determined by its inclination to cause or enhance happiness (Pfeifer, 2011).

The action of legalisation of medicinal cannabis means that patients will be monitored. From a clinical standpoint, the positive effects of medicinal cannabis would seem to greatly outweigh the negative effects in controlled situations (Clark, 2000). Looking at a wider perspective, legalisation has opened a door to robust and more comprehensive studies, benefit to the patients, a lesser burden on the criminalisation aspect, as well as a positive economic impact which are more favourable than being unregulated (Bahji & Stephenson, 2019; Hajizadeh, 2016; O'Brien, 2019).

However, according to Mill, an individual cannot seek his or her own pleasure at the expense of others. Mill believes that while the essence of happiness is the only desirable goal, he advised that seeking happiness is not purely individual in nature. Nevertheless, an action does not have to be motivated by a goal for universal happiness in order for it to be morally right by societies (Pfeifer, 2011). Hence, when pursuing individual happiness, a person must also consider the public's well-being, but only to the extent that it does not infringe on the rights of others. This is applicable to terminally-ill patients because they did not endanger the health of others by using

medicinal cannabis to treat profoundly debilitating medical illnesses if it is used in private (Pfeifer, 2011).

b) Deontological Approach

Deontological approach is rather different from utilitarianism where according to Mandal et al. (2016, p. 1):

> *deontology is ethics of duty where the morality of an action depends on the nature of the action, i.e., harm is unacceptable irrespective of its consequences.*

This notion originated from a philosopher Immanuel Kant, hence why it is commonly referred to as Kantian deontology (Mandal et al., 2016). Deontological approach places a greater emphasis on preserving the human capacity to reason. This ethical philosophy prioritises moral rules and action intentions, in which *"if a certain action incapacitates the ability to reason, deontology would reject it"* (Leo, 2018). Kant emphasises that it is a basic duty of self-respect for a person to maintain his or her rationality at all times. The use of cannabis recreationally that leads to 'high', addiction, or even cognitive damage due to overuse will cause a person incapable of acting in a rational way or treating others rationally (Mintz, 2017). Thus, in the context of recreational cannabis, the action of using it and movements towards legalisation is morally wrong.

The morally and ideologically driven drug policies that have dominated in many western countries are based on the 'deontological approach' to illicit drugs (Wodak, 2007). For example, prior to the legalisation of medicinal cannabis in Canada, it was argued that the decision of the federal government to continue defending a medicinal cannabis programme that only protects a small percentage of the medicinal cannabis population is largely based on a deontological approach that prioritises maintaining an ideologically driven 'war on drugs' over a constitutional obligation to protect legitimate medicinal cannabis patients from stigma, persecution, and arrest (Lucas, 2009).

On the other hand, by exploring the philosophy of Immanuel Kant, the existing denial of access to medicinal cannabis infringes upon patients' ability to practice their autonomy and pursue adequate healthcare decisions and treatments. According to Kant, the basic principle of morality lies in the respect for persons as moral agents. This includes respect for personal autonomy. Patients should be respected as self-

determining subjects or as rational agents. They must be treated as ends in themselves and never merely as objects. However, according to Kant, while patients are free to pursue their personal convictions about what is right, autonomy requires that rational self-determination be made in accordance with the universal moral law. For Kant, *"an action is morally good only if it is guided by reason"* (Pfeifer, 2011, p. 372). In circumstances where medicinal cannabis solely provides relief for a patient, it gives a valid reason for cannabis therapeutic use. Thus, no barriers should be imposed on the only effective method of avoiding pain. Kant argued that the autonomy of the patients that include rational self-determination should be celebrated because it makes us moral (Hayry, 2004). Other than that, considerations must be made upon the morality of ignoring clear scientific evidence thus causing unnecessary sickness and suffering (Lucas, 2009).

3.3 Conclusion of Chapter Three

This chapter has examined the medico-ethical considerations for the legalisation of medicinal cannabis using Biomedical Ethics Theory and Philosophical Theory. From Biomedical Ethics Theory, the push for legalising cannabis for medicinal purposes is motivated in part by the assumption that it provides medicinal benefits. However, there is some disagreement on this topic. Whatever the medical advantages or risks of cannabis, there is also debate over the unexpected positive and negative implications of legalising cannabis for medicinal use. Considerations of the principles of beneficence and non-maleficence may give rise to many arguments. Beneficence is the ethical virtue that can be described as 'doing as much good as you can' while non-maleficence is a phrase in the ancient Hippocratic Oath that translates as 'do no harm'. Those who witness patients' unrelieved suffering and opt to advocate for legislation that does not deny patients access to medicinal cannabis are frequently driven by a great value of beneficence. On the other hand, those who emphasise on cannabis' possible adverse effects may argue non-maleficence.

A more liberal view can be seen from the examination of Philosophical Theory, using both utilitarianism principle and Kantian theory (deontological approach). According to utilitarianism, instead of criminalisation, it seems that legalisation and regulation of medicinal cannabis bring about the best net utility. Similarly, the Kantian theory is against any infringement of autonomy that is embedded in laws that

criminalised medicinal cannabis.

In conclusion, based on this chapter, while the worldwide legislation is shifting towards the legalisation of medicinal cannabis, there are still significant ethical issues that must be addressed along the road. Moreover, cannabis's distinct legal and social position necessitates numerous special considerations. Indeed, cannabis is a complex class of treatments that requires specific management and adjustment according to individual patients, not a simple medication that can be prescribed. The findings in this chapter will help to steer the discussion in the next chapter on the identification of relevant principles for the legalisation of medicinal cannabis in Malaysia.

CHAPTER FOUR
ANALYSIS OF MEDICAL, ETHICAL, LEGAL, AND THEOLOGICAL PERSPECTIVES

4.1 Introduction

The previous chapter examined the medico-ethical considerations for the legalisation of medicinal cannabis. Apart from the medico-ethical considerations, it is deemed important to identify various perspectives relevant for the legalisation of medicinal cannabis. Therefore, the purpose of this chapter is to answer the third research question, which is what are the relevant perspectives for the legalisation of medicinal cannabis in Malaysia? In answering this research question, this chapter will analyse medical, ethical, legal, and theological perspectives that are relevant for the legalisation of medicinal cannabis in Malaysia. These four perspectives were derived from the findings of comparative legal analysis and medico-ethical considerations in the previous chapters. An in-depth analysis of these four perspectives will enable medico-ethical considerations for the legalisation of medicinal cannabis in Malaysia to take into consideration the socio-cultural fabrics of Malaysian society.

4.2 Analysis of Medical, Ethical, Legal, and Theological Perspectives for the Legalisation of Medicinal Cannabis in Malaysia

4.2.1 Medical

Much of the consideration on legalising medicinal cannabis in Malaysia lies in the medical evidence. The opponents for the legalisation of medicinal cannabis in Malaysia argued that despite many studies on the benefits and harms of cannabis in medicine, a consensus agreed upon by medical bodies has yet to be reached. Despite extant literature describing the therapeutic benefits of medicinal cannabis, local studies argued that there is a paucity of evidence to support cannabis' medicinal usage with limited high-quality clinical data for any specific therapeutic indication (Lim et al., 2021; Maharajan et al., 2020; Razali, Zainal, & Islam, 2019). As a result, professional views are still divided due to the perception that modern medicines rely on well-

established scientific evidence. According to a local literature review, robust trials of cannabis-based medicines should be done to provide more data that may help healthcare providers to make an appropriate clinical judgement on chronic pain management (Maharajan et al., 2020). The proponents, however, argued that although cannabis possesses side effects, nobody seems to deny that it can also benefit some groups of individuals. Therefore, the therapeutic effects of cannabis should not be denied and underestimated. Indeed, greater efforts should be made to further explore the potential of cannabis in patient care. The existence of high-quality international evidence concerning cannabis therapeutic use and the benefit it brings to patients greatly outweighs the harm and is proven to treat certain diseases that have failed with other traditional treatment regimes. In fact, the UN's reclassification of cannabis under international law proves that there is international consensus that recognises the medicinal effect of cannabis that will further expedite more clinical trials and enhance high-quality data to emerge.

Another aspect that must be considered is the knowledge among medical practitioners on cannabis and its therapeutic effects. Currently, there is an uneven distribution of knowledge relating to cannabis, cannabis products, and their effects, not only in Malaysia but also in other countries worldwide. One of the reasons is that the endocannabinoid system is not currently taught in many medical school curricula. As a result, not all medical practitioners have a solid understanding of the fundamental principles of cannabis, cannabinoids, and the human body system. This scenario will get more problematic if the patient has more knowledge on cannabis, where at present, there are no restrictions for patients to have access to the information. In fact, this knowledge gap has been proven in several studies (Glickman & Sisti, 2020; Nutt et al., 2020; O'Brien, 2019). Medical practitioners are likely to encounter experienced patients who have used cannabis medicinally either through a legal prescription in another nation or by self-medicating with home-grown strains or black-market supplies. Thus, medical practitioners will require greater assistance and counsel in navigating this tough terrain, as well as taking into consideration patients' experiences where applicable.

Other than that, the illegal use of cannabis for medicinal purposes is evident in Malaysia through several court cases and stories reported in the local media. These cases show that there is increasing demand for 'medicinal cannabis' among individuals who suffered from chronic and severe diseases such as cancer. Besides that, it reveals

the existence of a ‘bogus doctor’ who illegally supplied cannabis-based medicinal products such as CBD oil to ‘patients in need’. This issue is a medical concern with regards to patient safety because patients are not appropriately monitored, particularly in terms of dosing, reaction to other medications, efficacy, and side effects. In cases where the patient developed side effects and complications, the subsequent management and ‘burden’ will fall on to the medical practitioners. While the opponents are against the legalisation of medicinal cannabis due to the interference of cannabis in medical therapy, the proponents warrant the government to look into the legalisation of medicinal cannabis due to its therapeutic benefits.

Proponents of the legalisation of medicinal cannabis argue that allowing the use of medicinal cannabis would not be too difficult because the government could use the current prescription framework of medications containing controlled substances such as opioids and methadone. Patients will be prescribed by a trained, skilled, and certified medical practitioner who will make a diagnosis. A prescription will not be issued if there is no accurate diagnosis and if there is a suspicion that the individual is only a recreational user. The use of the medical card as identification of authorised patients will help them in case, they are stopped by law enforcement personnel at any point.

Several countries have had similar experiences with the legalisation of medicinal cannabis followed by relative inaccessibility such as the UK, Australia, and New Zealand (Nutt et al., 2020; O’Brien, 2019). Malaysia also has the potential to experience the same issue if there are still concerns about the lack of randomised controlled trials as discussed above. Affordability and continued problems with accessing prescriptions are also among the things to be anticipated. In a situation where the scientific evidence is still being questioned, therefore, another approach must be undertaken. Classification of medicinal cannabis as an alternative medicine rather than a pharmaceutical medicine should be heavily considered. Above all, this would recognise the patients' right to therapeutic self-determination and improved access while relieving medical practitioners on the burden of prescribing "medicines" that lack clinical trial data in many circumstances.

4.2.2 Ethical

The underlying ethical debates in the legalisation of cannabis for medicinal use in Malaysia heavily rely on the Biomedical Ethics Theory. The debates generated

ethical dilemmas in which both parties have valid ethical arguments to support their stands. Opponents may argue non-maleficence due to the lack of clinical evidence, particularly in Malaysia, as well as the possible harmful effects of cannabis. The stigma surrounding cannabis is prominent not only among the public but also among healthcare practitioners. This situation stems from the prevalence of cannabis abuse in Malaysia, which reflects the negative side of cannabis use and is typically considered an immoral act. In addition, Malaysia has adopted a zero-tolerance policy on drugs. Therefore, to change perceptions of something that has long been considered immoral is difficult but possible if it is supported by credible data and strong evidence.

Some may use the value of paternalism to oppose the medicinal use of cannabis. Due to cultural influence, the essence of protecting others with less knowledge or ability than themselves, is much like a father protecting a child, plays a role, particularly in Malaysia. Those who argue about this may conclude that medical practitioners or policymakers have the competency and think that they should protect patients from themselves by putting strong barriers against cannabis. Conflict arises when those who value autonomy and diversity argue that a person must make the best decisions for himself or herself.

The proponents for the legalisation of medicinal cannabis may argue on a strong value of beneficence. Those who support the use of cannabis in medicine are driven by several factors. They are equipped with scientific data at the international level as well as the experience of foreign countries that have legalised medicinal cannabis. Seeing the unrelieved pain and suffering of a patient motivates the proponent to intervene to change laws denying that patient access to therapeutic cannabis. Moreover, the benefits gained by patients suffering from diseases that are difficult to treat with standard medicines open their eyes to the fact that Malaysia should adopt the same policy for the benefit of patients.

The motivation to use medicinal cannabis in a desperate situation is mostly driven by autonomy and freedom, which includes the right to life, the right to health, the right to liberty, and the right to bodily integrity. Numerous stories featured by the media in Malaysia of family members who willingly took risks in order to obtain a supply of CBD oil that has been proved to be effective for the treatment of their sick family members. This includes the case of *Muhammad Lukman bin Mohamad v Public Prosecutor* [2021], *Pendakwa Raya vs Mohd Zaireen bin Zainal* [2016], and several other cases like ‘Dr. Ganja’ where the rationale was ‘helping the ill in need’. However,

the conflict that can be seen in these circumstances is between the pure intentions to help people who are truly suffering from agony and violation of law which are not grounded by ethical principles. In this case, individuals who supply 'medicinal cannabis' have no competency to safely provide the drugs to patients. Monitoring was not conducted under a controlled medical setting. The suppliers did not understand the effects and consequences of the drugs is questioned and the patient's safety is thus being compromised. Therefore, despite good intentions, the acts of a person with no medical expertise have no credibility in supplying or prescribing cannabis. This is consistent with the court's ruling in *Muhammad Lukman's* case whereby:

> *the contention by the appellant that the manufacturing of the cannabis was for medicinal purposes for public good, is not caught within the mischief of the DDA, has no merits.*

Other than that, the debate regarding the legalisation of medicinal cannabis should also focus based on the principle of justice. Among the issues being debated is the accessibility of patients to medicinal cannabis. Taking into account the distribution of health access in Malaysia is more concentrated in major cities, patients who are within the city centre will have more benefits and access to medicinal cannabis. This situation will give rise to unequal access. For example, cancer treatment is more concentrated in National Cancer Institute (IKN) which is located near Kuala Lumpur city. Thus, most likely, only patients living close to the city will be preferred to be listed as participants in a clinical trial on medicinal cannabis. Moreover, by setting certain criteria in prescribing medicinal cannabis that is focused on individual patients, this situation will raise the issue of unfair access to other patients. For example, treatment for nausea and vomiting will be prescribed only for cancer patients associated with chemotherapy on the grounds of indications authorised by the FDA, but not to other patients despite suffering from the same symptoms. If the patient's access to plant-based medication is deprived while other plant-based medicines, such as opioids, are permitted to be used, justice may not be served. Both exert benefit and harmful effects, but opioids have long been recognised as legitimate modern medicine. This raises the issue of discrimination against cannabis. The right of people to access medicinal cannabis should not be denied just because other people are abusing it. Therefore, medical practitioners and the law must be able to differentiate between the real patient who may benefit from it and the drug abuser.

This chapter shows that according to the four principles of biomedical ethics, this ethical discussion frequently turns into data-driven disagreements over what exactly are the benefits and drawbacks of legalisation. This gives rise to the impression that individuals on both proponents and opponents of the legalisation of medicinal cannabis are primarily concerned with the real benefits and drawbacks of legalisation. Thus, we should consider other ethical values such as removing pain and suffering, human rights, and liberty. In Malaysia, although no studies or evidence have been reported, stories on the use of CBD oil that helps in treating individual cancer patients who had previously failed standard treatment regimes are widely featured in the websites and blogs, where many parties are willing to bear legal risks in order to treat the disease (Yeung, 2021). In such instances, denying a patient of medicinal cannabis just because they are utilising an 'illegally' procured preparation according to Nutt et. al (2020, p. 3) is *"illogical and could be construed as being unethical".* Depriving other people's right to be cured is unethical. Instead, they should be allowed to access to medicinal cannabis and be given the liberty to decide what type of treatment they want to have.

4.2.3 Legal

Statutory and regulatory comparisons between Malaysia and other countries that have legalised medicinal cannabis could not be made due to the difference in legal the position towards cannabis. In the absence of legislative reform, the legal position of Malaysia on medicinal cannabis remains unclear. Furthermore, the government's stance on medicinal cannabis as announced by the Health Minister contradicts the court's verdict in the previous local cases related to the use of cannabis for medicinal purposes (Parliament of Malaysia, 2021b). The uncertainty in legal position will lead to insecurity in medical practice and hamper the further development of medicinal cannabis.

Other countries' experience in legalising medicinal cannabis provides perspectives in terms of policy, implementation, and implication. From a legal point of view, based on the comparative legal analysis of three jurisdictions, there are eight relevant aspects that need to be considered to legalise medicinal cannabis in Malaysia. These aspects are (1) legalisation approach; (2) definition and interpretation; (3) classification; (4) administration and governance; (5) trade (import and export); (6)

commercialisation (retail); (7) restriction; and (8) model.

A comparison of different legalisation approaches adopted by the UK, Canada, and Thailand allows due consideration to be made for the legalisation of medicinal cannabis in Malaysia. Section 47 of the Dangerous Drugs Act 1952 (DDA) provides a provision whereby a Minister may reschedule the drug and make regulations pertaining to the use of cannabis for medicinal purposes.

In terms of definition and interpretation, Malaysia's DDA 1952 makes no difference between ‘hemp’ and ‘marijuana’ instead of using only the term ‘cannabis’ to refer to *"any part of any plant of the genus Cannabis"*. As a result, hemp and marijuana are commonly used interchangeably, which leads to perplexity and confusion regarding cannabis plants, industrial cannabis, cannabis-based products, and synthetic cannabinoids. A clear definition, interpretation, and classification will determine the subsequent enforcement measures against cannabis and to draw a clear line between medicinal and recreational use.

In terms of governance and administration, the control of cannabis in Malaysia is under the purview of the Ministry of Health. As a controlled drug, it is anticipated that only registered medical practitioners under the Medical (Amendment) Act 2012 [*Act 50*] can prescribe medicinal cannabis. Currently, there is no clinical and ethical guideline for registered medical practitioners with regards to cannabis for medicinal use prescribed by the responsible professional body. Control measures are critical to prevent the misuse and abuse of medicinal cannabis. Regulation must be tightened once cannabis is legally allowed for medicinal purposes. The control established, however, should be adequate and not limit patients’ access to medicinal cannabis unnecessarily.

With regards to trade (import and export) and commercialisation (retail), although the existing provisions state that only qualified and licensed individuals are allowed to perform such activities, there is a need to be cleared on the types of cannabis that are allowed in the activity such as certain parts or strains of the cannabis plant, cannabinoids, synthetic cannabis, and other cannabis-based products. Additionally, if medicinal cannabis were to be legalised, it would be especially important to regulate the amount of THC as it is the most psychoactive substance in cannabis and has the potential to be misused and abused. We must anticipate that technology will evolve rapidly leading to the invention of something outside the purview of any act or law.

Finally, in considering the appropriate model of cannabis legalisation, the decision will depend on the availability of data and scientific evidence where at this

point, the benefits of cannabis in medicine outweigh the risks. The harm caused by uncontrolled cannabis usage for purposes other than medical is undeniable. Therefore, an appropriate model should be able to restrict the use of cannabis for medicinal purposes.

4.2.4 Theological

Theological perspective must also be taken into consideration prior to the legalisation of medicinal cannabis in Malaysia. As religion is a very important component in the Malaysian social construct, any decision to legalise medicinal cannabis needs to take into account the delicate, nature of religious beliefs, faith, and sensitivities among the general population of Malaysia. The recent census in 2010 shows that 61.3% of Malaysians practise Islam, 19.8% Buddhism, 9.2% Christianity, 6.3% Hinduism, and the rest are Confucianism, Taoism, Sikhs and others (Department of Statistics Malaysia, 2011). In this context, Islam and Christianity are the two major theological religions in Malaysia hence their theological doctrines should be considered.

As a Muslim-majority country, an Islamic perspective is very crucial and opinions from religious bodies are highly emphasised. Particularly when using a substance with harmful elements. Although the permissibility of medicinal cannabis is not directly stated in the Quran and Sunnah, there are other formal sources and methods such as *qiyas* (analogical reasoning), *ʻijmāʿ, qawāʿid, and maqāṣid al-Sharīʿah* that can be utilised to find the definitive answers as to whether the use of medicinal cannabis meets God's approval or disapproval. Interpretations of biological evidence in Islamic bioethics discussion might move the discussions toward the permissibility or prohibition of novel therapies (Qatanani et al., 2021). This particular issue is still a debate and to date, no fatwa has been issued by a recognised Islamic body in Malaysia regarding the use of cannabis in medicine. However, much discussion has taken place regarding the use of illicit substances in medicine. For example, Islam permits the use of some narcotics such as opioids (morphine and tramadol), which are more harmful than cannabis in certain medical circumstances including anaesthesia and management of pain (Shirah & Ahmed, 2020). The concept of dire necessity or *ḍarūrah*, which is addressed in the *qāʿidah "dire necessity renders the impermissible to be permissible"* is particularly relevant in discussing medical treatments (Isa, 2016; Qatanani et al.,

2021, p. 3). The majority of scholars describe *ḍarūrah* as a situation in which any of the five vital human values (religion, life, mind, progeny/integrity, and property) is legitimately endangered (al-Bakri, 2019). These five essential human interests are the fundamental grounds for all Islamic ethics and law. THC-based medications may fit the definition of dire necessity as they fulfil the aspect of preservation of life, one of the five essentials of *maqāṣid*. In general, legal schools permit the medicinal use of impermissible substances when:

> *(1) the illness that is being treated significantly impairs life functions;*
> *(2) the normatively prohibited substance is consumed only to the extent it is needed for treatment efficacy;*
> *(3) there is lack of a viable alternative; and*
> *(4) there is certainty of treatment efficacy.* (Qatanani et al., 2021, p. 4)

However, *darūrah* cannot be invoked with the existence of alternative therapy that does not possess the intoxication effects of cannabis or cannabinoids while providing comparable effectiveness. Thus, a critical assessment of the status of scientific evidence surrounding medicinal cannabis is of paramount importance. Otherwise, inconclusive or absence scientific evidence of cannabis and cannabinoids-base formulations would be deemed impermissible.

From a Christianity point of view, recreational cannabis use is prohibited due to its psychoactive effects, highly deleterious, and proclivity to maintain a sluggish and selfish lifestyle. However, since cannabis is rapidly becoming legalised for medicinal use, particularly in Western countries, a fresh debate within the church is arising regarding whether its usage would be suitable. Christianity permits the medical use of cannabis for the same reasons Islam permits it in particular when conventional medications have failed. From the biblical point of view, every Christians should be submissive to the law and regulations of his authorities. In Roman 13:1, it is stated in the Bible:

> *let every soul be subject unto the higher powers, for there is no authority except that which God has established.*

However, when authority and Biblical precepts contradict, there are definitely limitations to this submissiveness. In states where medicinal cannabis is legalised, it is important that only approved, safe, and licenced medicinal cannabis is prescribed for

which the benefits outweigh the potential adverse effects (Christian Medical & Dental Association, 2019). Through the value of *"promotion of the good"* as stated in Matthew 22:36-40, the Christians believe that society should approve the use of any medication only if medicinal cannabis is proven in terms of safety and its effectiveness in relieving specific symptoms or treating specific medical conditions. The *"creation mandate"* stated in Genesis 1:28 provides instructions for a human to use whatever that has been given to the best of their ability and for the greatest good. The cannabis plant has the potential to be beneficial to humanity in terms of medicine. It may, however, do harm to individuals, society, and the environment. Therefore, medicinal cannabis should have to be the last resort for all reasons in treating diseases.

As both theological religions of Malaysia made an exception for the use of cannabis under special circumstances, the proposed legal reforms find their theological justification.

4.3 Conclusion of Chapter Four

This chapter has examined four main perspectives that are fundamental in considering the legalisation of medicinal cannabis in Malaysia. From a medical perspective, there is evidence of cannabis's positive medicinal effects although it is not conclusive. Despite the perceived inconclusive clinical evidence, the fact that this evidence exists cannot be underestimated and ignored. From the ethical perspective, the debates to ethically justify the legalisation of medicinal cannabis in Malaysia revolve around the two groups of competing points. In recognising cannabis for medicinal purposes, paternalism, and non-maleficence (threats of harm such as potential addiction) sometimes conflict with the beneficence and autonomy principles. In other circumstances, both those promoting paternalism and those promoting autonomy value beneficence (doing good) and non-maleficence (avoiding harm). However, weighing the risk and benefit, as well as considering other ethical values such as removing pain and suffering, human rights, and liberty, it is argued that legalising medicinal cannabis in a regulated and controlled situation is ethically justified. From a legal point of view, legislative reform is required to clear the uncertainty in Malaysia's legal position towards cannabis. Finally, from theological perspectives, two major theological religions in Malaysia namely Islam and Christianity provide flexibility to permit the medicinal use of cannabis under certain conditions and medical necessities.

In conclusion, the aim towards the legalisation of medicinal cannabis in Malaysia requires continuous efforts and roles from a wide range expert in the fields of medicine, ethics, and morals, legal, as well as religion. Although the move towards legalisation is supported by several members of Parliament, decisions towards legalisation of medicinal cannabis must always be supported by various perspectives.

CHAPTER FIVE
CONCLUSION AND RECOMMENDATIONS

5.1 Synthesis

This research has answered the research questions in three chapters. The first research question has been answered in Chapter Two of this research. In Chapter Two, this research has analysed statutes and regulations of the UK, Canada, and Thailand that have legalised medicinal cannabis. It compares the similarities, differences, and unique features of the statutes and regulations legalising medicinal countries between these three jurisdictions. The scope of comparison comprises of (1) legalisation approach; (2) definition and interpretation; (3) classification; (4) administration and governance; (5) trade (import and export); (6) commercialisation (retail); (7) restriction; and (8) model. All three jurisdictions basically have the same legal position on legalising medicinal cannabis. However, Canada has taken another step ahead by legalising its recreational use. The legal position of cannabis in the UK and Thailand is similar to Malaysia before these two countries underwent policy changes on medicinal cannabis. The comparative analysis finds that cannabis legalisation in the three jurisdictions is mostly different with slight similarities. The significant difference can be seen in terms of the legalisation approach and model used. Uniquely in Thailand, cannabis is used as both modern and traditional medicine. The comparative analysis also demonstrates that cannabis is a health concern in Canada and Thailand, whereas, in the UK, cannabis is seen as a security issue. While both the UK and Canada underwent legal reforms in 2018, Thailand's regulations related to cannabis and hemp continue to evolve towards wider accessibility beyond medicinal purposes. Therefore, the first research question has been answered and the respective research objective has been achieved by the comparative legal analysis of the countries that have legalised medicinal cannabis.

The second research question has been answered in Chapter Three. In Chapter Three, this research has examined the medico-ethical considerations for the legalisation of medicinal cannabis. First, it examines the considerations using Biomedical Ethics Theory followed by Philosophical Theory. The Biomedical Ethics Theory highlights that the essence of beneficence, non-maleficence, respect for autonomy, and justice is crucial in considering the legalisation of medicinal cannabis. These elements of ethical

theories are then extended to the arguments of evidence-based practices, the potential for the risks and benefits of medicinal cannabis, the safety of the practitioner, informed choice on the use of medicinal cannabis, and doctor-patient relationship. On the other hand, the Philosophical Theories provide different considerations from a liberal point of view that includes Utilitarianism Principles and Deontological Approach. By following Mill's principle of utility and Kant's theory, the use of cannabis for medicinal purposes can be considered for terminally ill patients. Therefore, the second research question has been answered. The respective research objective has been achieved by examining the Biomedical Ethics Principles and the Philosophical Theory as to the underlying theories and principles for legalising medicinal cannabis.

The final research question has been answered in Chapter Four. In Chapter Four, this research has analysed the medical, ethical, legal, and theological perspectives for the legalisation of medicinal cannabis in Malaysia. These four perspectives were found to be relevant in the analysis of the medico-ethical considerations for the legalisation of medicinal cannabis in Malaysia by taking into account the socio-cultural background of Malaysian society. Currently, scientific data and evidence are sufficient to warrant the government to reclassify cannabis in the DDA 1952. The existing international evidence is reliable and extant studies have shown that the benefits of medicinal cannabis greatly outweigh the risks. This chapter utilises the biomedical ethics principles explicitly in considering the legalisation of medicinal cannabis in Malaysia. Although there is a competing argument between the principles of beneficence and non-maleficence, considering other values such as respect for autonomy and justice to patients favour the legalisation of medicinal cannabis. In essence, changes in the government policy on cannabis for medicinal purposes require legislative reform similar to other countries that have legalised medicinal cannabis. This is because the existing DDA 1952 does not provide a special provision that expressly states the permissibility of medicinal cannabis. Finally, from the theological perspective, both Islam and Christianity forbid the use of any substance that has the potential to intoxicate the body and mind. However, under some cases classified as 'necessity' when the patient's life is in danger, the prohibited substances may be permitted if they can preserve the patient's life with minimum harm and when safer alternatives or conventional treatments have failed. Therefore, the third research question has been answered and the respective research objective has been achieved as a relevant consideration for the legalisation of medicinal cannabis in Malaysia.

5.2 Conclusion

This research concludes that it is medically and ethically justified for Malaysia to take measures toward the legalising medicinal cannabis. While international studies have demonstrated that the benefits of medicinal cannabis greatly outweigh its harm, certain parties in Malaysia including healthcare professionals might disagree with the move to legalise medicinal cannabis. This research argues that the resistance towards legalisation of medicinal cannabis is not due to the lack of scientific evidence but due to internal factors such as insufficient knowledge and information, lack of data or lack of confidence to join the paradigm shift. If healthcare professionals are doubted with the international trend and the so-called move towards legalisation, it is their duty to explore more profound knowledge or conduct experiments to refute the international findings. As long as there is a clear indication, well-established dosing, safe delivery system, careful monitoring and clear judgement on the risk-benefit ratio that can be applied to individual patients, there is no justifiable reason to oppose the legalisation of medicinal cannabis. Regardless of the cost of implications, the initiative towards the legalisation of medicinal cannabis is something that should be looked forward to.

International data from credible sources cited in this research suggest that medicinal cannabis may represent a reasonable alternative or adjunct to the treatment of patients diagnosed with certain diseases for whom other treatments have not delivered completely satisfactory outcomes. It is argued that if the legalisation of medicinal cannabis would bring more benefits than harm, then it should be more than sufficient to warrant the legalisation of medicinal cannabis. Failure to do so will result in injustice to individuals in need of medicinal cannabis as an alternative treatment or to those who prefer to use a novel cannabis medication that has been proven as effective in some countries and for certain diseases.

The ethical debate regarding the legalisation of medicinal cannabis will continue to occur due to the nature of the cannabis itself. There are possibilities of disagreements when it comes to the rationale for legalising medicinal cannabis. Nonetheless, despite the contradictions in ethical principles, we have to find ways to harmonise these principles to make something positive for Malaysia and ultimately, patient care.

Above all, the government and the medical community should be concerned about the quality of life of individuals suffering from neurological and mobility

problems, and cancer, among others. Medicinal cannabis has shown to be vital in the fight against terminal illnesses and ease a great deal of pain. Unless the government legally recognises this fact, many dying patients will continue to suffer in vain. The battle against drug abuse is critical because many lives are lost as a result of drug addiction, but the ramifications of terrible illnesses affect a far more significant number of people. Medicinal cannabis can be an essential treatment for medical practitioners who are dealing with the issues of their patient's pain and suffering. We must prioritise the dignity and respect of all people. It is time to stand up for the most vulnerable and legalise medicinal cannabis because it is truly a medical necessity for many patients.

5.3 Recommendations

Based on various medical, ethical, and legal considerations that have been discussed in the earlier chapters, this research proceeds to make the following recommendations deemed relevant towards the legalisation of medicinal cannabis in Malaysia.

First, to adopt a patchwork approach instead of *sui generis* and piecemeal approach. Based on the comparative legal analysis, the patchwork approach adopted in the UK to legalise medicinal cannabis is most suited to Malaysia because it is more practical and feasible. Under the recommended patchwork approach, the legalisation of medicinal cannabis is to be incorporated in the Dangerous Drugs Act (DDA) 1952.

Second, to have a clear legal definition and interpretation of cannabis plant, cannabis extract, and other related terms such as hemp and marijuana. Based on the comparative analysis, it is further recommended that the definition of medicinal cannabis from the UK to be adopted in Malaysia.

Third, to have a clear classification and permitted level of THC and CBD in a cannabis-based medicinal product. In addition, the classification of cannabis should include parts of the cannabis plant or extract of the cannabis plant that is classified as controlled and regulated substances. Based on the comparative analysis, it is further recommended that the classification from Canada's jurisdiction to be adapted. The classification will enable differentiation in terms of its medicinal, non-medicinal, and industrial purposes.

The fourth recommendation is for the legalisation of medicinal cannabis to be regulated under the Ministry of Health. It is further recommended that cannabis-related

law enforcement activities to be conducted in collaboration with other enforcement agencies such as Royal Malaysia Police.

Fifth, to provide a clear guideline for the legalisation of medicinal cannabis to Medical Practitioners. The guideline should include the clinical and ethical framework in prescribing medicinal cannabis. In addition, the guideline should be developed by the Malaysian Medical Council being the professional regulatory body in Malaysia.

Sixth, the trade (import and export) of cannabis and cannabis-product for medicinal purposes should be allowed with authorisation from the licencing bodies. In addition, commercialisation (retail) of medicinal cannabis should be prohibited to avoid any potential abuse of medicinal cannabis.

Seventh, to strictly legalise cannabis for medicinal purposes. Therefore, it is recommended for medicinal cannabis to be a controlled medicine, which can only be purchased based on the prescription of a specialist registered under the Malaysian Medical Council. This is followed by the ban on advertisements pertaining to medicinal cannabis.

Eighth, to regulate modalities of medicinal cannabis consumption. It is further recommended that medicinal cannabis be permitted by way of oral preparation, spray, or external oil application. Therefore, consumption of medicinal cannabis through smoking should be prohibited in Malaysia.

Ninth, to adopt a restrictive model in legalising medicinal cannabis where only specialists registered under Malaysia Medical Council can prescribe medicinal cannabis in a controlled environment for specific diseases as approved by the National Pharmaceutical Regulatory Agency. However, a specialist must be given the privilege to prescribe medicinal cannabis based on their clinical judgement to avoid unnecessary restriction that limits patients' access to medicinal cannabis in Malaysia.

5.4 Practical Implication

The decision to legalise medicinal cannabis in Malaysia requires several measures to be undertaken by the government, in particular the Ministry of Health. The first measure is related to talent or human resources. The government should appoint an expert task force to initiate concrete steps towards legalisation of medicinal cannabis in Malaysia. In order to achieve this, the government should be proactive to play an essential role in investing and providing pathways to produce experts in this particular

field. Although expertise may be recruited from overseas, it is preferable to have local professionals in order to have a solid foundation in legalising medicinal cannabis.

The second measure is relating to the training and empowerment of the medical professionals and medical students as the main stakeholders in the legalisation of medicinal cannabis. An initiative should be made by the government to strengthen the knowledge of medicinal cannabis among medical professionals. In terms of basic education, the government should consider incorporating the subject of the endocannabinoid system in a medical school syllabus. In addition, the government's initiative such as offering a scholarship to conduct clinical trials or postgraduate training overseas in the medicinal cannabis domain may encourage medical practitioners to embark in this area.

The third measure is relating to the classification of medicinal cannabis within the medical service domain. The Ministry of Health needs to decide whether to classify medicinal cannabis as pharmaceutical medicine or alternative and complementary medicine. This situation is analogous to our acceptance of chiropractic and homoeopathy as complementary medicine. Although it has not been scientifically proven, these two practices were recognised under the Traditional and Complementary Medicine (T&CM) Act 2016 *[Act 775]* in Malaysia and have been proven to treat people. Looking at the current situation, the local institution seen to be able to gain benefit from medicinal cannabis is the IKN. Moreover, IKN has already integrated modern medicine with traditional and complementary medicine in treating cancer patients.

5.5 Future Research

As this research that supports for the legalisation of medicinal cannabis is only based on secondary data analysis, future research in this area should conduct a nationwide survey to determine public opinions on the legalisation of medicinal cannabis in Malaysia. In addition, this research mainly examines the medical, ethical, and legal perspectives in the legalisation of medicinal cannabis. Therefore, future research should study the social and economic impacts of the legalisation of medicinal cannabis in Malaysia.

Word Count: 21,076

REFERENCES

Access to Cannabis for Medical Purposes Regulations (ACMPR) SOR/2016-230.

Agustin, A., Alvarado, J., Cardenas, G., Towe, T., & Vann, B. (2020). The Economic Rise of Marijuana. Retrieved from https:// storymaps.arcgis.com/stories/ 4c839fb0499a453d88be4ab862a96f37 [accessed 30 November 2021]

al-Bakri, Z. b. M. (2019). Bayan Linnas Siri Ke-189: Maqasid Syariah Dalam Perubatan. Retrieved from https://muftiwp.gov.my/artikel/bayan-linnas/3541-bayan-linnas-siri-ke-189-maqasid-syariah-dalam-perubatan [accessed 4 December 2021]

Almogi-Hazan, O., & Or, R. (2020). Cannabis, the Endocannabinoid System and Immunity-the Journey from the Bedside to the Bench and Back. *Int J Mol Sci, 21*(12). doi:10.3390/ijms21124448

Amer, A. B. (2019). Understanding the Ethical Theories in Medical Practice. *Open Journal of Nursing, 09*(02), 188-193. doi:10.4236/ojn.2019.92018

Arnold, J. C., Nation, T., & McGregor, I. S. (2020). Prescribing medicinal cannabis. *Aust Prescr, 43*(5), 152-159. doi:10.18773/austprescr.2020.052

Associated Press. (2020). Girl who inspired Charlotte's Web marijuana oil dies. Retrieved from https://www.usatoday.com/story/news/nation/2020/04/09/girl-who-inspired-charlottes-web-marijuana-oil-dies/5120478002/ [accessed 25 December 2021]

Attia, V. (2017). Cannabis (marijuana- hemp) in Ancient Egypt. Project: Medicinal plants in ancient Egypt. *Egyptian Ministry Of Tourism& Antiquities*. Retrieved from https://www.researchgate.net/publication/321420351_Cannabis_marijuana-_hemp_in_Ancient_Egypt

Bahji, A., & Stephenson, C. (2019). International Perspectives on the Implications of Cannabis Legalization: A Systematic Review & Thematic Analysis. *Int J Environ Res Public Health, 16*(17). doi:10.3390/ijerph16173095

Barron, L., & Gordon, D. (2019). Cannabis in primary care. *British Journal of General Practice*, 594-595. doi:https://doi.org/10.3399/bjgp19X706673

Beauchamp, T. L., & Childress, J. F. (2009). *Principles of Biomedical Ethics* (Vol. 6th Edition). Oxford: Oxford University Press.

Berke, J., Gal, S., & Lee, Y. J. (2021). Marijuana legalization is sweeping the US. See every state where cannabis is legal. Retrieved from https://www.businessinsider.com/legal-marijuana-states-2018-1 [accessed 30 November 2021]

Blanco, C., Hasin, D. S., Wall, M. M., Florez-Salamanca, L., Hoertel, N., Wang, S., . . . Olfson, M. (2016). Cannabis Use and Risk of Psychiatric Disorders: Prospective Evidence From a US National Longitudinal Study. *JAMA Psychiatry, 73*(4), 388-395. doi:10.1001/jamapsychiatry.2015.3229

Brenneisen, R. (2007). Chemistry and Analysis of Phytocannabinoids and Other Cannabis Constituents. In M. A. ElSohly (Ed.), *Forensic Science and Medicine: Marijuana and the Cannabinoids* (pp. 17-50).

Cannabis Act, SC 2018, c.16

Cannabis Regulations SOR/2018-144.

Cerda, M., Mauro, C., Hamilton, A., Levy, N. S., Santaella-Tenorio, J., Hasin, D., . . . Martins, S. S. (2020). Association Between Recreational Marijuana Legalization in the United States and Changes in Marijuana Use and Cannabis Use Disorder From 2008 to 2016. *JAMA Psychiatry, 77*(2), 165-171.

doi:10.1001/jamapsychiatry.2019.3254
Channel News Asia. (2020). Singapore 'disappointed' with UN move to loosen controls on cannabis: MHA. Retrieved from https://www.channelnewsasia.com/singapore/cannabis-united-nations-un-drugs-vote-singapore-disappointed-452991 [accessed 13 September 2021]
Christian Medical & Dental Association. (2019). CMDA Statement on Medical Marijuana. Retrieved from https://cmda.org/article/cmda-statement-on-medical-marijuana/ [accessed 12 December 2021]
Clark, P. A. (2000). The Ethics of Medical Marijuana: Government Restrictions vs. Medical Necessity *Journal of Public Health Policy, 21*, 40-60. Retrieved from http://www.jstor.org/stable/3343473
Clark, P. A., Capuzzi, K., & Fick, C. (2011). Medical marijuana: Medical necessity versus political agenda. *Med Sci Monit, 17*, RA249-261.
Clarke, R. C., & Watson, D. P. (2007). Cannabis and Natural Cannabis Medicines. In M. A. ElSohly (Ed.), *Forensic Science and Medicine: Marijuana and the Cannabinoids* (pp. 1-16).
Collins, J. (2019). SC law enforcement still harshly against medical marijuana. Retrieved from https://apnews.com/article/marijuana-sc-state-wire-legislation-medical-marijuana-south-carolina-bb2bb26b2e3c4ba08525bd19501a7fb7 [accessed 16 February 2022]
Control of Drugs and Cosmetics Regulations 1984 *[P.U.(A) 223/84]*.
Controlled Drugs and Substances Act (SC 1996, c.19), (1996).
Cosmetic Products Act B.E. 2558 (2015), (2015).
Cyr, C., Arboleda, M. F., Aggarwal, S. K., Balneaves, L. G., Daeninck, P., Neron, A., . . . Vigano, A. (2018). Cannabis in palliative care: current challenges and practical recommendations. *Ann Palliat Med, 7*(4), 463-477. doi:10.21037/apm.2018.06.04
Dangerous Drugs Act 1952 *[Act 234]*.
Davies, R. (2005). Analogies, Slippery Slopes & the Prohibition of Cannabis. Retrieved from https://philosophynow.org/issues/51/Analogies_Slippery_Slopes_and_the_Prohibition_of_Cannabis [accessed 4 December 2021]
Department of Statistics Malaysia. (2011). Laporan Taburan Penduduk dan Ciri-Ciri Asas Demografi 2010 (Kemas kini: 05/08/2011). Retrieved from https://www.dosm.gov.my/v1/index.php?r=column/ctheme&menu_id=l0pheu43nwjwrwvszklwdzq4tlhuut09&bul_id=mdmxdhzjwtk1sjfztznkrxyzcvzjdz09 [accessed 15 February 2022]
Doherty, M., Power, L., Attala, M., & Vadeboncoeur, C. (2020). Use of oral cannabis extracts in the pediatric palliative care setting: A retrospective chart review. *Palliat Med, 34*(3), 435-437. doi:10.1177/0269216320904315
ElSohly, M. A. (2007). *Forensic Science and Medicine: Marijuana and the Cannabinoids*. In M. A. ElSohly (Ed.), (pp. 322).
Emanuel, E. J., & Emanuel, L. L. (1992). Four Models of the Physician-Patient Relationship. *JAMA, 267*(16), 2221-2226. doi:10.1001/jama.1992.03480160079038
Englund, A., Morrison, P. D., Nottage, J., Hague, D., Kane, F., Bonaccorso, S., . . . Kapur, S. (2013). Cannabidiol inhibits THC-elicited paranoid symptoms and hippocampal-dependent memory impairment. *J Psychopharmacol, 27*(1), 19-27. doi:10.1177/0269881112460109
Fakhry, B., Abdulrahim, M., & Chahine, M. N. (2021). Medical Cannabis in Lebanon:

History & Therapeutic, Ethical, and Social Challenges. A Narrative Review *Archives of Clinical and Biomedical Research, 5*(April 2021), 137-157. doi:10.26502/acbr. 50170156

Farinon, B., Molinari, R., Costantini, L., & Merendino, N. (2020). The seed of industrial hemp (Cannabis sativa L.): Nutritional Quality and Potential Functionality for Human Health and Nutrition. *Nutrients, 12*(7). doi:10.3390/nu12071935

Food Act B.E. 2555 (1979), (1979).

Food and Drug Administration. (2020). FDA and Cannabis: Research and Drug Approval Process. Retrieved from https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process [accessed 2 December 2021]

Freeman, T. P., Hindocha, C., Green, S. F., & Bloomfield, M. A. P. (2019). Medicinal use of cannabis based products and cannabinoids. *BMJ, 365*, l1141. doi:10.1136/bmj.l1141

Guidance on professional standards and ethics for doctors: Decision making and consent, (2020).

Genesis 1:28.

Glickman, A., & Sisti, D. (2020). Prescribing medical cannabis: ethical considerations for primary care providers. *J Med Ethics, 46*(4), 227-230. doi:10.1136/medethics-2019-105759

Govarthnapany, N., Singh, D., Narayanan, S., & Vicknasingam, B. (2021). Motives and Perceptions of Cannabis Use among a Sample of Employed Graduates in Malaysia: A Qualitative Study. *Emerging Trends in Drugs, Addictions, and Health, 1*. doi:10.1016/j.etdah.2021.100013

Grant, I. (2013). Medicinal Cannabis and Painful Sensory Neuropathy. *Virtual Mentor. American Medical Association Journal of Ethics, 15*, 466-469.

Greenwald, J. (2019). Medical marijuana trend means growing discrimination exposures. Retrieved from https://www.businessinsurance.com/article/20191210/NEWS06/912332111/Medical-marijuana-trend-means-growing-discrimination-exposures [accessed 26 December 2021]

Haigh, M., Wood, J. S., & Stewart, A. J. (2016). Slippery slope arguments imply opposition to change. *Memory & Cognition, 44*(5), 819-836. doi:10.3758/s13421-016-0596-9

Hajizadeh, M. (2016). Legalizing and Regulating Marijuana in Canada: Review of Potential Economic, Social, and Health Impacts. *Int J Health Policy Manag, 5*(8), 453-456. doi:10.15171/ijhpm.2016.63

Hanyang Division of International Studies. (2021). The Economic Impact of Medical Marijuana. Retrieved from http://dis.hanyang.ac.kr/lyceum-vol-1/the-economic-impact-of-medical-marijuana/ [accessed 30 November 2021]

Harun, H. N. (2021, 18 February 2021). PM: Malaysia will not legalise cannabis. *New Straits Times*. Retrieved from https://www.nst.com.my/news/nation/2021/02/666896/pm-malaysia-will-not-legalise-cannabis [accessed 14 October 2021]

Have, H. t. (2016). *Encyclopedia of Global Bioethics. Volume 1. A-D*. Switzerland: Springer International Publishing.

Hayry, M. (2004). Prescribing cannabis: freedom, autonomy, and values. *J Med Ethics, 30*(4), 333-336. doi:10.1136/jme.2002.001347

Herbert, A., & Hardy, J. (2021). Medicinal cannabis use in palliative care. *The Royal Australian College of General Practitioners, 50*. Retrieved from ajgp@racgp.org.a

Higdon, M. (2021). Medical marijuana steps away from legalization in South Carolina. Retrieved from https://www.live5news.com/2021/05/10/medical-marijuana-steps-away-legalization-south-carolina/ [accessed 16 February 2022]

Hill, K. P. (2015). Medical Marijuana for Treatment of Chronic Pain and Other Medical and Psychiatric Problems: A Clinical Review. *JAMA, 313*(24), 2474-2483. doi:10.1001/jama.2015.6199

Human Medicines Regulations 2012.

Hurley, R. (2018). Cannabis, cannabis everywhere: UK to review medical cannabis policy as Canada plans imminent legalisation for all uses. *BMJ*. doi:10.1136/bmj.k2695

Hussin, K. A. (2017, 9 June 2017). 'Dr Ganja' hadapi 36 tuduhan kaitan dadah. *Berita Harian*. Retrieved from https://www.bharian.com.my/taxonomy/term/11/2017/06/291351/dr-ganja-hadapi-36-tuduhan-kaitan-dadah [accessed 14 October 2021]

Industrial Hemp Regulations, SOR/2018-145, (2018).

Isa, N. M. (2016). Darurah (Necessity) and Its Application in Islamic Ethical Assessment of Medical Applications: A Review on Malaysian Fatwa. *Sci Eng Ethics, 22*(5), 1319-1332. doi:10.1007/s11948-015-9698-1

Jackson, E. (2019). *Medical Law Text, Cases, and Materials* (5 ed.). Oxford: Oxford Universiti Press.

Jiang, H. E., Li, X., Zhao, Y. X., Ferguson, D. K., Hueber, F., Bera, S., . . . Li, C. S. (2006). A new insight into Cannabis sativa (Cannabaceae) utilization from 2500-year-old Yanghai Tombs, Xinjiang, China. *J Ethnopharmacol, 108*(3), 414-422. doi:10.1016/j.jep.2006.05.034

Joy, J. E., Watson, S. J., & Benson, J. A. (1999). *Marijuana and Medicine: Assessing the Science Base* Retrieved from Washington, DC: [accessed

Jugl, S., Okpeku, A., Costales, B., Morris, E. J., Alipour-Haris, G., Hincapie-Castillo, J. M., . . . Goodin, A. (2021). A Mapping Literature Review of Medical Cannabis Clinical Outcomes and Quality of Evidence in Approved Conditions in the USA from 2016 to 2019. *Medical Cannabis and Cannabinoids, 4*(1), 21-42. doi:10.1159/000515069

Kahan, M., Srivastava, A., Spithoff, S., & Bromley, L. (2014). Prescribing smoked cannabis for chronic noncancer pain: preliminary recommendations. *Canadian family physician Medecin de famille canadien, 60*, 1083–1090.

Kandel, D. B., Yamaguchi, K., & Chen, K. (1992). Stages of progression in drug involvement from adolescence to adulthood: further evidence for the gateway theory. *Journal of Studies on Alcohol., 53*, 447–457. doi:https://doi.org/10.15288/jsa.1992.53.447

Khizar, J. Q. (2017). Marijuana legalization a slippery slope. Retrieved from https://www.toronto.com/opinion-story/7247226-marijuana-legalization-a-slippery-slope/ [accessed 16 February 2022]

Kilmer, B. (2014). Policy designs for cannabis legalization: starting with the eight Ps. *Am J Drug Alcohol Abuse, 40*(4), 259-261. doi:10.3109/00952990.2014.894047

Kogan, N. M., & Mechoulam, R. (2007). Cannabinoids in health and disease *Dialogues in Clinical Neuroscience, 9*, 413–430. doi:https://doi.org/10.31887/DCNS.2007.9.4/nkogan

Kwai, I. (2020). U.N. Reclassifies Cannabis as a Less Dangerous Drug. *December 2, 2020*. Retrieved from https://www.nytimes.com/2020/12/02/world/europe/cannabis-united-nations-drug-policy.html [accessed 13 September 2021]

Lafaye, G., Karila, L., Blecha, L., & Benyamina, A. (2017). Cannabis, cannabinoids, and health. *Dialogues in Clinical Neuroscience, 19*(3).

LaFree, A., Wong, E., & Swinburne, M. (2021). *State Laws Addressing Discrimination Against Medical Cannabis Patients*. Retrieved from https://www.oregon.gov/oha/ph/diseasesconditions/chronicdisease/medicalmarijuanaprogram/documents/issue-brief-state-laws-addressing-discrimination-against-medical-cannabis-patients-1.pdf [accessed 29 December 2021]

Lee, J., Cheok, C., Kandasami, G., Rapisarda, A., & Fei, H. N. (2016). *A Literature Review on Medical Cannabis*. Retrieved from https://www.mha.gov.sg/docs/default-source/media-room-doc/a-literature-review-on-medical-cannabis.pdf [accessed 24 November 2021]

Leo, W. (2018). Reconciling Drug Use With Ethics and Religion. Retrieved from https://thehoya.com/reconciling-drug-use-ethics-religion/ [accessed 17 February 2022]

Leweke, F. M., Piomelli, D., Pahlisch, F., Muhl, D., Gerth, C. W., Hoyer, C., . . . Koethe, D. (2012). Cannabidiol enhances anandamide signaling and alleviates psychotic symptoms of schizophrenia. *Transl Psychiatry, 2*, e94. doi:10.1038/tp.2012.15

Lim, X. Y., Tan, T. Y. C., Muhd Rosli, S. H., Sa'at, M. N. F., Sirdar Ali, S., & Syed Mohamed, A. F. (2021). Cannabis sativa subsp. sativa's pharmacological properties and health effects: A scoping review of current evidence. *PLoS One, 16*(1), e0245471. doi:10.1371/journal.pone.0245471

Lowe, D. J. E., Sasiadek, J. D., Coles, A. S., & George, T. P. (2019). Cannabis and mental illness: a review. *Eur Arch Psychiatry Clin Neurosci, 269*(1), 107-120. doi:10.1007/s00406-018-0970-7

Lucas, P. (2017). Rationale for cannabis-based interventions in the opioid overdose crisis. *Harm reduction journal, 14*(1), 58-58. doi:10.1186/s12954-017-0183-9

Lucas, P. G. (2009). Moral regulation and the presumption of guilt in Health Canada's medical cannabis policy and practice. *Int J Drug Policy, 20*(4), 296-303. doi:10.1016/j.drugpo.2008.09.007

Lynskey, M. T., Heath, A. C., Bucholz, K. K., Slutske, W. S., Madden, P. A., Nelson, E. C., . . . Martin, N. G. (2003). Escalation of drug use in early-onset cannabis users vs co-twin controls. *JAMA, 289*(4), 427-433. doi:10.1001/jama.289.4.427

Mack, A., & Joy, J. (2000). *Marijuana as Medicine? The Science Beyond the ControversyHow Harmful is Marijuana?* Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK224396/

Maharajan, M. K., Yong, Y. J., Yip, H. Y., Woon, S. S., Yeap, K. M., Yap, K. Y., . . . Yap, K. X. (2020). Medical cannabis for chronic pain: can it make a difference in pain management? *J Anesth, 34*(1), 95-103. doi:10.1007/s00540-019-02680-y

Mandal, J., Ponnambath, D. K., & Parija, S. C. (2016). Utilitarian and deontological ethics in medicine. *Trop Parasitol, 6*(1), 5-7. doi:10.4103/2229-5070.175024

Matthew 22:36-40.

Mayor, S. (2019). WHO proposes rescheduling cannabis to allow medical applications. *BMJ, 364*, l574. doi:10.1136/bmj.l574

McKiernan, A., & Fleming, K. (2017). *Canadian Youth Perceptions on Cannabis* Retrieved from Ottawa: https://www.ccsa.ca/sites/default/files/2019-04/CCSA-Canadian-Youth-Perceptions-on-Cannabis-Report-2017-en.pdf [accessed 16 February 2022]

McPartland, J. M. (2017). Cannabis sativa and Cannabis indica versus “Sativa” and

"Indica". In *Cannabis sativa L. - Botany and Biotechnology* (pp. 101-121).
Medical (Amendment) Act 2012 [*Act 50*].
Melberg, H. O., Jensen, A., & Jones, A. (2007). Is cannabis a gateway to hard drugs? *Empirical Economics, 38*. doi:10.1007/s00181-009-0280-z
Mellis, C. (2018). Cannabidiol for drug-resistant seizures in the Dravet syndrome. *Journal of Paediatrics and Child Health, 54*(1), 101-102. doi:10.1111/jpc.13802
The Ministerial Regulation on Application for Licenses and Grant of Licenses to Produce, Import, Export, Dispose or Possess Narcotics of Category V Concerning Hemp, B.E. 2563 (2020)
Mintz, S. (2017). Should Marijuana Be Permitted? An Ethical Analysis. Retrieved from https://www.ethicssage.com/2017/05/should-marijuana-be-permitted-an-ethical-analysis.html [accessed 17 February 2022]
The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018.
Misuse of Drugs (Licence Fees) Regulations 2010.
Misuse of Drugs Act 1971
Misuse of Drugs Regulation 2001.
Monte, A. A., Zane, R. D., & Heard, K. J. (2015). The implications of marijuana legalization in Colorado. *JAMA, 313*(3), 241-242. doi:10.1001/jama.2014.17057
Muhammad Lukman bin Mohamad v Public Prosecutor [2021] 4 MLJ 494 (2021).
Mullis, E. (2021). *Industrial Hemp Report 2021*. Retrieved from Bangkok: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Industrial%20Hemp%20Report%202021_Bangkok_Thailand_04-01-2021 [accessed 1 November 2021]
Narcotics Act (No. 7) B.E. 2562 (2019).
Narcotics Act B.E. 2522 (1979)
National Health Service. (2018). Medical cannabis (and cannabis oils). Retrieved from https://www.nhs.uk/conditions/medical-cannabis/ [accessed 13 August 2021]
Nedelman, L. (2020). *Is Cannabis a Safer and Equally Effective Medication for the Treatment of Chronic Pain as Compared with Opioids?* (Degree of Doctor of Nursing Practice). College of Health Sciences, Walden University, United States.
Nkansah-Amankra, S., & Minelli, M. (2016). "Gateway hypothesis" and early drug use: Additional findings from tracking a population-based sample of adolescents to adulthood. *Prev Med Rep, 4*, 134-141. doi: 10.1016/j.pmedr.2016.05.003
Notification of the Narcotics Commission Re: Handling of Narcotics of Category V with Respect to Hemp Containing Tetrahydrocannabinol (THC) in the Amount Exceeding the Specified Amount, B.E. 2564 (2021)*1, (2021).
Nutt, D., Bazire, S., Phillips, L. D., & Schlag, A. K. (2020). So near yet so far: why won't the UK prescribe medical cannabis? *BMJ Open, 10*(9), e038687. doi:10.1136/bmjopen-2020-038687
O'Brien, K. (2019). Medicinal Cannabis: Issues of evidence. *European Journal of Integrative Medicine, 28*, 114-120. doi:10.1016/j.eujim.2019.05.009
Okusanya, B. O., Asaolu, I. O., Ehiri, J. E., Kimaru, L. J., Okechukwu, A., & Rosales, C. (2020). Medical cannabis for the reduction of opioid dosage in the treatment of non-cancer chronic pain: a systematic review. *Systematic Reviews, 9*(1), 167. doi:10.1186/s13643-020-01425-3
Oxford Languages Dictionary. (Ed.) (2021) Oxford Languages Dictionary.

Pacula, R. L., Jacobson, M., & Maksabedian, E. J. (2016). In the weeds: a baseline view of cannabis use among legalizing states and their neighbours. *Addiction, 111*(6), 973-980. doi:10.1111/add.13282

Panozzo, S., Le, B., Collins, A., Weil, J., Whyte, J., Barton, M., . . . Philip, J. (2020). Who is asking about medicinal cannabis in palliative care? *Intern Med J, 50*(2), 243-246. doi:10.1111/imj.14732

Parliament of Malaysia. (2021a). *Mesyuarat Kedua, Penggal Keempat; Parlimen Keempat Belas; Jawapan-Jawapan Bagi Pertanyaan-Pertanyaan Jawab Lisan Yang Tidak Dijawab Di Dalam Dewan; (Soalan No. 12 Hingga No. 33)*. Retrieved from https://www.parlimen.gov.my/jawapan-lisan-dr.html?uweb=dr& [accessed 30 December 2021]

Parliament of Malaysia. (2021b). *Penyata Rasmi Parlimen Dewan Rakyat; Parlimen Keempat Belas; Penggal Keempat; Mesyuarat Kedua*. Retrieved from https://www.parlimen.gov.my/hansard-dewan-rakyat.html?uweb=dr&arkib=yes [accessed 30 December 2021]

Parliament of Malaysia. (2021c). *Penyata Rasmi Parlimen Dewan Rakyat; Parlimen Keempat Belas; Penggal Keempat; Mesyuarat Pertama*. Retrieved from https://www.parlimen.gov.my/hansard-dewan-rakyat.html?uweb=dr& [accessed 30 December 2021]

Patel, A., & Ayung, M. (2016). Informed Consent And The Physician-Patient Relationship. *Retina Today, April*, 52-53. Retrieved from https://retinatoday.com/articles/2016-apr/informed-consent-and-the-physician-patient-relationship [accessed 6 December 2021]

Pendakwa Raya v Mohd Zaireen bin Zainal [2016] MLJU 651 (2016).

Pfeifer, D. J. (2011). Smoking Gun: The Moral and Legal Struggle for Medical Marijuana *Touro Law Review*, *27*(Article 7), 339-377. Retrieved from https://digitalcommons.tourolaw.edu/lawreview/vol27/iss2/7

Pisanti, S., & Bifulco, M. (2017). Modern History of Medical Cannabis: From Widespread Use to Prohibitionism and Back. *Trends Pharmacol Sci, 38*(3), 195-198. doi:10.1016/j.tips.2016.12.002

Pisanti, S., & Bifulco, M. (2019). Medical Cannabis: A plurimillennial history of an evergreen. *J Cell Physiol, 234*(6), 8342-8351. doi:10.1002/jcp.27725

Poison Act 1952 [*Act 366*].

Posnikoff, M. (2020). Canadian legislative overview. Retrieved from https://www.nortonrosefulbright.com/en/knowledge/publications/958ed547/canadian-legislative-overview [accessed 30 December 2021]

Qatanani, A., Umar, M., & Padela, A. I. (2021). Bioethical insights from the Fiqh Council of North America's recent ruling on medical cannabis. *Int J Drug Policy, 97*, 103360. doi:10.1016/j.drugpo.2021.103360

Rakpanich, W., Panomai, N., & Laohasiriwong, W. (2020). Determinants of Intention to Use Medical Cannabis among People in the Northeast of Thailand. *Indian Journal of Public Health Research & Development, 11*(July 2020), 1548-1555.

Razali, H. Y., Zainal, H., & Islam, M. N. (2019). Cannabis: The myth and medico-legal issues in current medical practice in Malaysia. *Int J Eth Trauma Victimology, 5*, 25-30. doi:10.18099/ijetv.v3i02.5

Roman 13:1.

Rosic, T., Kapoor, R., Panesar, B., Naji, L., Chai, D. B., Sanger, N., . . . Samaan, Z. (2021). The association between cannabis use and outcome in pharmacological treatment for opioid use disorder. *Harm reduction journal*, *18*(1), 24. doi:10.1186/s12954-021-00468-6

Rupasinghe, H. P. V., Davis, A., Kumar, S. K., Murray, B., & Zheljazkov, V. D. (2020). Industrial Hemp (Cannabis sativa subsp. sativa) as an Emerging Source for Value-Added Functional Food Ingredients and Nutraceuticals. *Molecules, 25*(18). doi:10.3390/molecules25184078

Sackett, D. L., Rosenberg, W. M. C., Gray, J. A. M., Haynes, R. B., & Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't. *BMJ, 312*, 71-72. doi:https://doi.org/10.1136/bmj.312.7023.71

Sagy, I., Peleg-Sagy, T., Barski, L., Zeller, L., & Jotkowitz, A. (2018). Ethical issues in medical cannabis use. *Eur J Intern Med, 49*, 20-22. doi:10.1016/j.ejim.2018.01.016

Sale of Drugs Act 1952 (Revised 1989) [*Act 368*].

Secades-Villa, R., Garcia-Rodríguez, O., Jin, C. J., Wang, S., & Blanco, C. (2015). Probability and predictors of the cannabis gateway effect: a national study. *The International journal on drug policy, 26*(2), 135-142. doi:10.1016/j.drugpo.2014.07.011

Shirah, B. H., & Ahmed, M. M. (2020). The Use of Cannabis for Medical Purposes in the Arab World. *Medical Cannabis and Cannabinoids*, 1-3. doi:10.1159/000510824

Shover, C. L., & Humphreys, K. (2019). Six policy lessons relevant to cannabis legalization. *Am J Drug Alcohol Abuse, 45*(6), 698-706. doi:10.1080/00952990.2019.1569669

Sidney, S., Charles P. Quesenberry, J., Friedman, G. D., & Tekawa, I. S. (1997). Marijuana use and cancer incidence (California, United States). *Cancer Causes and Control, 8*, 722-728. doi:10.1023/a:1018427320658

Svrakic, D. M., Lustman, P. J., Mallya, A., Lynn, T. A., Finney, R., Svrakic, R. M., & Svrakic, N. M. (2012). Legalization, Decriminalization & Medicinal Use of Cannabis: A Scientific and Public Health Perspective. *Missouri Medicine, 109*(April), 90-98.

Swinburne, M. R. (2021). Legal Protections to Prevent Discrimination against Medical Cannabis Patients. Retrieved from https://www.networkforphl.org/resources/legal-protections-to-prevent-discrimination-against-medical-cannabis-patients/ [accessed December 26, 2021]

Tashkin, D. P. (2013). Effects of marijuana smoking on the lung. *Ann Am Thorac Soc, 10*(3), 239-247. doi:10.1513/AnnalsATS.201212-127FR

The National Academies of Sciences Engineering and Medicine. (2017). The health effects of cannabis and cannabinoids the current state of evidence and recommendations for research. doi:10.17226/24625

The Star. (2021). Bipartisan caucus to study medical marijuana. Retrieved from https://www.thestar.com.my/news/nation/2021/10/15/bipartisan-caucus-to-study-medical-marijuana [accessed 30 December 2021]

The Week. (2021). Where is cannabis legal? Retrieved from https://www.theweek.co.uk/cannabis/90671/california-legalises-cannabis-is-europe-next [accessed 24 December 2021]

United Nations Office on Drug and Crimes. (2021). *World Drug Report 2021*. Retrieved from Vienna, Austria: https://www.unodc.org/res/wdr2021/field/WDR21_Booklet_3.pdf [accessed 20 December 2021]

van Bruchem-Visser, R. L., van Dijk, G., de Beaufort, I., & Mattace-Raso, F. (2020). Ethical frameworks for complex medical decision making in older patients: A narrative review. *Arch Gerontol Geriatr, 90*, 104160. doi:10.1016/j.archger.2020.104160

Vedelago, L., Metrik, J., & Amlung, M. (2020). Differentiating Medicinal and Recreational Cannabis Users via Cannabis Use Motives. *Cannabis*, *3*(1), 52-63. doi:10.26828/cannabis.2020.01.006

Vyshka, G. (2019). The unlikely legalization of medical cannabis in Albania: a case study. *Journal of Medical Ethics and History of Medicine*, *12*(10).

Whiting, P. F., Wolff, R. F., Deshpande, S., Di Nisio, M., Duffy, S., Hernandez, A. V., . . . Kleijnen, J. (2015). Cannabinoids for Medical Use: A Systematic Review and Meta-analysis. *JAMA*, *313*(24), 2456-2473. doi:10.1001/jama.2015.6358

Wilkinson, S. T. (2013). Medical and Recreational Marijuana: Commentary and Review of the Literature. *Missouri Medicine*, *110*, 524-528. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6179811/

Williams, A. R. (2020). Cannabis as a Gateway Drug for Opioid Use Disorder. *J Law Med Ethics*, *48*(2), 268-274. doi:10.1177/1073110520935338

Wodak, A. (2007). Ethics and drug policy. *Psychiatry*, *6*(2), 59-62. doi:https://doi.org/10.1016/j.mppsy.2007.01.001

World Health Organization. (2017). *Cannabidiol (CBD). Pre-Review Report*. Retrieved from Geneva: https://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf [accessed 20 November 2021]

World Health Organization. (2020). UN Commission on Narcotic Drugs reclassifies cannabis to recognize its therapeutic uses. Retrieved from https://www.who.int/news/item/04-12-2020-un-commission-on-narcotic-drugs-reclassifies-cannabis-to-recognize-its-therapeutic-uses [accessed 13 August 2021]

Yeung, Y.-G. (2021). Cannabis can mean death in Malaysia. For one dad, it also meant life for his daughter. Retrieved from https://coconuts.co/kl/features/cannabis-can-mean-death-in-malaysia-for-one-dad-it-also-meant-life-for-his-daughter/ [accessed 25 December 2021]

Yusoff, N., Yuan, J., & Yang, J. (2013). A Review of Neuropsychological Status in Cannabis Users. *Procedia - Social and Behavioral Sciences*, *97*, 2-11. doi:10.1016/j.sbspro.2013.10.198

Zinboonyahgoon, N., Srisuma, S., Limsawart, W., Rice, A. S. C., & Suthisisang, C. (2021). Medicinal cannabis in Thailand: 1-year experience after legalization. *Pain*, *162*(Suppl 1), S105-S109. doi:10.1097/j.pain.0000000000001936

AUTHOR'S PROFILE

Aimi binti Mohd Yunus is a postgraduate student in Medical Ethics and Law Department, Faculty of Medicine, Universiti Teknologi MARA (UiTM). She received her Medical Degree from Faculty of Medicine, Padjadjaran University, Bandung, Indonesia in 2011. She is currently on full time study leave, funded by the Government of Malaysia. Previously she was a Principal Assistant Director at the Private Medical Practice Control Section, Medical Practice Division in Ministry of Health, Malaysia.

List of conference:

1. Mohd Yunus, Aimi; Katiman, Helwa Husna; Muuti, Muhamad Zaid. Ethical and Legal Issues in Remote Medical Consultation – Advocating Regulatory Oversight on Telemedicine in Malaysia. Oral presenter in the 8th USIM National Health Seminar. Digital Healthcare: Stepping Into the Future of Medicine. Universiti Sains Islam Malaysia. 7 October 2021.
2. Katiman, Helwa Husna; Mohd Yunus, Aimi; Muuti, Muhamad Zaid. Promoting Ethical Use of Social Media Among Healthcare Professionals in the Digital Era. Poster presentation in the 8th USIM National Health Seminar. Digital Healthcare: Stepping Into the Future of Medicine. Universiti Sains Islam Malaysia. 7 October 2021.