

MEDICAL MARIJUANA: A CRITICAL ANALYSIS

A SOCIAL POLICY PAPER
BY **ELSA MALTA**

elsa

The European Law Students' Association

MALTA

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Foreword

ELSA, the European Law Students' Association, aside from being a human rights organisation also seeks to be at the forefront of all legal discussions especially when it comes to controversial topics with contrasting opinions. In fact, ELSA's main purpose is "to contribute to legal education, to foster mutual understanding and to promote social responsibility of law students and young lawyers".

ELSA Malta strives to promote this vision of ELSA in all its projects and in order to do this, it publishes a number of research and policy papers. These papers are done not only to promote this vision of ELSA but also in order to be an active part of the discussion on certain pressing legal and human rights issues. In light of the current ongoing local debate on the use medical marijuana in the Maltese Islands, ELSA Malta's social policy team is proud to present ELSA Malta's research papers titled 'Medical Marijuana: A Critical Analysis'. The aim of this research paper is to explore the various aspects associated with Medical Marijuana in Malta ranging from the licencing to the actual use of medical marijuana through medical prescription. The paper will also touch upon the contrasts which exist between medical marijuana licences in different countries around the world. The scope of all this is to achieve a holistic understanding of all that is associated with medical marijuana in Malta as well as identifying the current issues or shortcomings which are faced at the local level such as pricing and inadequate stock while identifying possible solutions and reform.

This project would not have been possible without the many hours of work and dedication of a highly dedicated group of people, to whom I would like to express my personal gratitude to. First and foremost, I would like to especially thank Sarah Xuereb and Philip Ellul, ELSA Malta's current Director for Social Policy and her predecessor respectively, for taking on such a bold project and for seeing that it was completed successfully. I would also like to thank Ms. Alexandra Gaglione, Ms. Julia Aquilina, Ms. Kristina Apap Gatt, Ms. Marie Georgette Spiteri, Ms. Martina Micallef, Mr. Raoul Ciappara and Ms. Rebecca Galea for their invaluable assistance to the writing of the paper itself. I would also like to extend my gratitude to Dr. Matthew Booker and Dr. Simon Corrieri for taking the time to carefully review the research paper and for giving us feedback and guidance accordingly. Lastly, I would like to thank Kelly Jade Galea and Brittany Wells, ELSA Malta's Vice President for Marketing and Director for Public Relations respectively, for the design of the paper.

On behalf of ELSA Malta, we hope that you enjoy reading our paper, take the time to think about the subject at hand and to evaluate our suggestions, and lastly to follow us and support us in our aim – to always be proactive!

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What is Medical Cannabis?

The Cannabis plant has been a utilized form of medicine for more than 5000 years, due to its useful botanical elements, which encompass various healing properties including providing relief of chronic pain, aids in fighting cancer, alleviates anxiety and many other healing properties. Although there are differing opinions, researchers have arguably concluded that the Cannabis plant has numerous therapeutic properties, as endocannabinoid receptors are present in almost every organ in the human body.¹ Medical Marijuana is essentially the cannabis plant in its purest form. The extracts of such plant are generally used for recreational purposes, however, once prescribed in calculated doses, it provides relief to various different types of medical and also mental strains. Medical marijuana is a botanical medicine which is usually derived from two different kinds of species of Marijuana plants; *Cannabis sativa* and *Cannabis indica*. The latter both produce different effects and differ substantially in their medicinal properties and chemical composition.² There are roughly 100 different kinds of chemicals which are found in the cannabis plant and such chemicals are commonly known as cannabinoids; each having a different effect on the body when ingested. However, for medicinal purposes, the main two branches of chemicals used are the *Delta-9-tetrahydrocannabinol* (THC) and the *Cannabidiol* (CBD).³

Although medical cannabis has only been FDA approved for the treatment of *Dravet Syndrome* and *Lennox-Gastaut Syndrome*, which are both rare epileptic disorders, it has proven highly useful in treating a wide spectrum of illnesses and autoimmune diseases such as Alzheimer's disease, Cancer, Epilepsy, Glaucoma, Post-Traumatic Stress Disorder, Multiple Sclerosis, Crohn's Disease, as well as Schizophrenia. Cannabinoids have multiple similarities to the chemicals which are naturally produced in the human body, for example in individuals who suffer from autoimmune diseases such as Multiple Sclerosis, therefore, medical cannabis acts as a relaxing stimulant for tight muscles. Such treatment also stimulates appetite in individuals suffering from AIDS as well as Anorexia.⁴ Apart from physical treatment and relief, medical marijuana has also been found to improve neuroplasticity in the brain which aids in mood regulation and emotional health; calming individuals who suffer from high anxiety levels and depression.⁵

Patients are prescribed 2mg of CBD every 8 hours, this amount is generally tolerated by most individuals, as high doses can cause side-effects. The said amount may be continuously increased until the patient feels relieved from the symptoms they are experiencing. If a dose exceeds 50mg of CBD, and does not provide the patient with any relief, THC will then be introduced. The starting amount of THC is miniscule, but it is gradually increased until the desired result is established. Most individuals tend to have subsided symptoms when they have

¹'Cannabis As Medicine' (Painclinic.com.mt) <<https://www.painclinic.com.mt/cannabis-as-medicine/>> a

²ProCon.org., 'What Are the Differences between Cannabis Indica and Cannabis Sativa, and How do they vary in their Potential Medical Utility?' (ProCon.Org, 30 May 2008)

<<https://medicalmarijuana.procon.org/questions/what-are-the-differences-between-cannabis-indica-and-cannabis-sativa-and-how-do-they-vary-in-their-potential-medical-utility/>> accessed on 2nd April 2020

³Medical Marijuana FAQ, <<https://www.webmd.com/a-to-z-guides/qa/what-is-medical-marijuana>> accessed on 2nd April 2020

⁴Medical Marijuana FAQ, <<https://www.webmd.com/a-to-z-guides/medical-marijuana-faq>> accessed 2 April 2020

⁵Erica Oberg, 'Medical Marijuana (Medical Cannabis)', (MedicineNet, 14 November 2019)

<https://www.medicinenet.com/medical_marijuana_medical_cannabis/article.htm> accessed 3 April 2020

an equal ratio of 1:1 (THC: CBD) There are a number of ways in which such medical cannabis can be administered; it may be (1) smoked, (2) eaten, (3) taken as liquid droplets sublingually, (4) applied on the skin in the form of a spray or oil, and (5) through vaporization.⁶ Smoking is the least preferred method due to the dangerous effects that are produced in the lungs during combustion, therefore, the most commonly advised method in Malta is that of vaporization. Vaporization entails the heating of the plant to a certain temperature in a specific device called a vapouriser, the chemical vapours are then inhaled. The temperature and dose may be increased by the medical professional administering the treatment.

Legal comparisons between Medical and Recreational Cannabis

There have been a number of legislative developments concerning cannabis in Malta over the past couple of years, most of which reflect a shift in mindset, away from the negative stigma surrounding cannabis and towards an ideology which is more accepting of the medical benefits of the cannabis plant, when used properly. That being said, and while Malta has now enacted a legislative framework controlling the use and cultivation of cannabis for medical purposes, the use and cultivation of cannabis for *recreational* purposes is still prohibited. The production and cultivation of Medical Cannabis is largely regulated by the *Production of Cannabis for Medicinal and Research Purposes Act* which came into force in April 2018. Said act enables certain licensed entities to cultivate, import as well as produce cannabis solely for medical and research purposes.⁷

With regards to recreational marijuana, there are more stringent laws currently in force. Our laws have ‘relaxed’ slightly over the years when it comes to marijuana for personal use, however illicit cultivation, which is not deemed for personal use remains a highly serious offence. The *Drug Dependence (Treatment not Imprisonment) Act 2014* clearly stipulates that any individual found to have a prohibited drug in their possession for personal use will be tried in front of the Commissioner of Justice. In the case of cannabis, possession of less than 3.5 grams carries a fine ranging between 50 to 100 euro.⁸ Furthermore, for repeat offences involving cannabis or cannabis resin, the Commissioner for Justice should however only refer the convicted person to the Drug Offenders Rehabilitation Board (the ‘Board’) if, after considering the circumstances of the offence and of the offender, he is satisfied that there are reasonable grounds to believe that the circumstances of the convicted person give rise to a probability that he is abusing or is likely to abuse prohibited drugs other than cannabis or cannabis resin. The Board has the power to conduct the necessary examinations on the convicted individual and to issue the necessary orders for the purpose of assisting that person to come out of his drug dependence. Any individual who fails to appear before the Board when required and/or fails, without reasonable justification, to comply with an order issued by the Board, would be liable to a fine or even imprisonment for 3 months. However, when it comes to cultivation, any individual found in possession of one cannabis plant is not deemed to be liable to imprisonment. Article 7 of the Drug Dependence Act of 2014, formerly stipulated that

⁶Anne Harding, ‘Medical Marijuana’ (WebMD, 4 November 2013) <<https://www.webmd.com/pain-management/features/medical-marijuana-uses>> accessed 3 April 2020

⁷Gerardo Fortuna, ‘MEP: EU framework on medical cannabis to give ‘peace of mind’ to patients’ (Euractiv, 24 November 2019) <<https://www.euractiv.com/section/health-consumers/news/mep-eu-framework-on-medical-cannabis-to-give-peace-of-mind-to-patients/>> accessed 3 April 2020

⁸Malta Drug Report 2019 - <http://www.emcdda.europa.eu/countries/drug-reports/2019/malta/drug-laws-and-drug-law-offences_en> accessed 4 April 2020

any amount exceeding one plant, no matter the size of the buds, shall be liable to imprisonment for a term of 6 months, however, such article was recently repealed by Act no. IV of 2020.

Countries which have legalised Medical Cannabis

The therapeutic effects which medical marijuana provides to numerous patients have shed a different light on the drug and its usages. So much so, that there are currently thirty countries worldwide that have legalized medical marijuana in its entirety or under strict guidelines. Such countries are Argentina, Australia, Canada, Chile, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Finland, Germany, Greece, Israel, Italy, Jamaica, Lesotho, Luxembourg, Macedonia, Malta, Mexico, Netherlands, Norway, Peru, Poland, Romania, San Marino, Switzerland, Turkey, Uruguay and Zimbabwe.⁹ 33 states in America have legalised such form of medication, with another 11 states allowing such medication to be used in extreme circumstances only.¹⁰ The stance taken in Europe with regards to medical cannabis is developing substantially. Countries which have not yet legalised such drug, such as Slovenia, France and Spain have concluded that in certain circumstances it is permitted to make use of medical marijuana.¹¹

Certain member states have implemented innovative legislation and industries. The Republic of Netherlands legalised medical cannabis in the year 2000; through which the *Bureau for Medicinal Cannabis* was created and expanded. Currently, medical cannabis is readily available in numerous pharmacies across the country, with the ability to acquire such drug over the counter upon presentation of a medical prescription. A study in 2018 showed that there are currently 50,000 patients making use of such healing and relief in the Netherlands. Poland also provides patients with medical cannabis; however, this may only be done upon permission from a regional pharmaceutical inspector as well as a physician appointed by the Ministry of Health, as well as medicines may only be given at specific pharmacies. Whilst it is legal in Poland, the plant is not cultivated or produced domestically as it is strictly imported from The Netherlands. Slovenia also took a similar stance and enacted the *Decree on the Classification of Illicit Drugs* in 2018 which stipulated that medical experts are now able to prescribe medical marijuana as a form of treatment.¹²

A leading member state in the area is Germany. Germany had a complete legislative overhaul in 2017 with regards to medical cannabis. Prior to 2017, individuals seeking the drug required specific authorisation, however, this has been abolished and it is now readily available to anyone who wishes to acquire it. Such legislation also gave authorisation to produce and cultivate the botanical plant domestically although, this has not been utilized yet. The stipulated legislative overhaul introduced the Cannabis Agency under the Federal Institute for Drugs and

⁹Sean Williams, 'These 30 Countries Have Legalized Medical Marijuana in Some Capacity' (TheMotleyFool, 21 July 2018) <<https://www.fool.com/investing/2018/07/21/these-30-countries-have-legalized-medical-marijuan.aspx>> accessed 4 April 2020

¹⁰Medical Marijuana FAQ, <<https://www.webmd.com/a-to-z-guides/medical-marijuana-faq>> accessed 2 April 2020 (n.2)

¹¹ Sean Williams, 'These 30 Countries Have Legalized Medical Marijuana in Some Capacity' (TheMotleyFool, 21 July 2018) <<https://www.fool.com/investing/2018/07/21/these-30-countries-have-legalized-medical-marijuan.aspx>> accessed 4 April 2020 (n.2)

¹²Sofia Aguilar et Al., 'Medicinal Cannabis policies and practices around the world' (April 2018) <http://fileservr.idpc.net/library/Medicinal%20cannabis%20briefing_ENG_FINAL.PDF> accessed 5 April 2020

Medical Devices which oversees the entire process. Moreover, in 2018 Greece implemented the ‘*Provisions for the Production of End Products of Medicinal Cannabis*’ Bill, enabling patients to have access to medical cannabis whenever needed, while also allowing individuals to cultivate the plant specifically for medical reasons. There are various countries which have implemented the cultivation and distribution of medical cannabis in its entirety, however, there are still some member states which pose various problems. The United Kingdom is not in possession of adequate legislation and only allows access to patients suffering from Multiple Sclerosis upon presenting a valid medical certificate. Moreover, medical cannabis was also legalised in 2013 in the Czech Republic however, as of yet, there are no means to cultivate, license or distribute such medical cannabis.¹³ Medical marijuana legislation of various other countries and states, is further explored in this paper.

Legal Framework regarding Cannabis for Medicinal and Research Purposes

The leading legislative framework currently available in Malta was introduced on the 17th April 2018. The *Production of Cannabis for Medicinal and Research Purposes Act*, Chapter 578 of the Laws of Malta deals with the production of medical cannabis in Malta; focusing on a number of provisions in relation to the administration of the same Act and the operational requirements for producing medical cannabis for medicinal and research purposes.¹⁴ Article 4(1) of the *Production of Cannabis for Medicinal and Research Purposes Act* clearly stipulates that¹⁵:

*“No cultivation, importation or processing of cannabis and no production of any products intended for medicinal and, or research purposes deriving from or resulting from the use of cannabis as defined in this Act and no trade in cannabis and, or any preparations intended for medicinal and, or research purposes as deriving from cannabis shall be carried out in Malta prior to obtaining all necessary approvals, authorisations, licenses and, or permits as required by or under all applicable laws including this Act and any regulations subsidiary to it...”*¹⁶

Therefore, the law clearly indicates that the cultivation and importation of cannabis is expressly prohibited unless the necessary authorisation and licenses have been provided. Moreover, the *Production of Cannabis for Medicinal and Research Purposes Act* emphasizes that any research which is conducted, is strictly for “*pharmaceutical, pharmacological and, or clinical purposes...*”¹⁷ In order to import and distribute medical cannabis in Malta, any licensed importer or distributor may send medical products containing cannabis to Malta as well as any synthetic cannabinoid products which are enlisted under the Medicines Act, as long as there are adequate permits granted by the Superintendent of Public Health. The Malta Medicines

¹³ Sean Williams, ‘These 30 Countries Have Legalized Medical Marijuana in Some Capacity’ (*TheMotleFool*, 21 July 2018) <<https://www.fool.com/investing/2018/07/21/these-30-countries-have-legalized-medical-marijuan.aspx>> accessed 4 April 2020 (n.2)

¹⁴Dr Franklin Cachia, ‘Cannabis for Medicinal and Research Purposes in Malta’ (CSB Group, NA) <<https://www.csbgroup.com/articles/cannabis-for-medicinal-and-research-purposes-in-malta/>> accessed 9 April 2020

¹⁵ PRODUCTION OF CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES ACT 2018.

¹⁶ Production of Cannabis for Medicinal and Research Purposes Act, Chapter 578 of the Laws of Malta, Article 4(1)

¹⁷ Production of Cannabis for Medicinal and Research Purposes Act, Chapter 578 of the Laws of Malta, Article 2.

Authority has a number of issued guidelines on the production of cannabis for medicinal and research purposes.

Licensing in Malta

A licensed importer or wholesale distributor may import cannabis-based products or synthetic cannabinoid products to Malta, on the condition that said importer is licensed under the Medicines Act (Chapter 458) and manufactured under EU Good Manufacturing Practice (GMP). However, this is further subject to a number of necessary approvals and permits from the Superintendence of Public Health.¹⁸

Part IV of the Production of Cannabis for Medicinal and Research Purposes Act deals with Operational Requirements, namely the issuance of a license by the Malta Medicines Authority. To operate in the area of Medical Cannabis in Malta. The law itself is very brief, tackling licensing in just one Article (Article 5). Upon the satisfaction of the criteria found in Articles 5(a)-(c), the regulatory authority will then issue the necessary license needed for operation. This system creates a vetting procedure, which has since proven to be relatively selective. Till June 2019, only 20 of the 39 applications were accepted.¹⁹

The first hurdle is the submission itself by the applicant with the evaluation of documents that includes due diligence documentation and any other necessary information needed to fulfil the license requirements. Secondly, the applicant must attain all authorisations, permits, approvals and clearances from any other entities as necessary and applicable under the Act and any other legislation that may be relevant at the time of the application. Lastly, the applicant must comply with any terms and conditions, including the possession of relevant qualifications in line with the Mutual Recognition of Qualifications Act which deals with the structure of certain boards and the power to make regulations under Article 8 of the aforementioned Act. It is also important to note that the proviso gives the discretion to the regulatory authority to request any additional information it may deem necessary when evaluating the application.

Phase 1 of the licensing process, as outlined in Article 5(2) of the same Act, entails the requirement to apply for and obtain a letter of intent issued by Malta Enterprise.²⁰ Malta Enterprise has the discretion to request any further information they deem necessary when evaluating the application. Article 5(3) offers a sense of primacy to the Commissioner of Police who may, despite any issued license, take any action as reasonably necessary²¹ upon the commission or suspicion of a crime taking place on the premises where an authorized activity relating to cannabis takes place. Article 5(4) deals with the prohibition of a holder of a withdrawn, revoked, cancelled or expired license and/or letter of intent to carry out any activity under the Mutual Recognition of Qualifications Act. Needless to say, any activity related to

¹⁸ 'Medicines Authority' (Medicinesauthority.gov.mt) <<http://www.medicinesauthority.gov.mt/cannabisformedicinalandresearchpurposes>> accessed 15 August 2020.

¹⁹ Independent.com.mt. 2020. Medicinal Cannabis Companies to Create 700 Full-Time Jobs, Generate €900M In Exports - PM - The Malta Independent.

²⁰ 'View Document' (Legislation.mt, 2018) <<https://legislation.mt/eli/cap/578/eng/pdf>> accessed 15 August 2020.

²¹ 'Medicines Authority' (Medicinesauthority.gov.mt) <<http://www.medicinesauthority.gov.mt/cannabisformedicinalandresearchpurposes>> accessed 15 August 2020 (n.2)

the production, processing and sale of marijuana without the appropriate licensing is considered to be illegal in nature and will incur the appropriate sanctions.

Upon obtaining a Letter of Intent from Malta Enterprise, which is done so by meeting every requirement laid down in the provisions of the “Production of Cannabis for Medicinal Use Act 2018”, the applicants must get authorisation from the Medicine’s Authority (which they must apply for)²². This may be considered as Phase Two of the process. The application is highly technical and requires a number of documentation and requisites that must be satisfied. These include, evidence of the site, details on destruction, waste management, security measures and monitoring of the site, among others. There is also a due diligence process within this step done by the Medicines Authority itself. This is done through the submission of a due diligence report compiled in accordance with the rules established to the Authority. The law spares the details of the detailed and technical requisites needed for the authorisation. Given their importance, it would merit that such would be included within the law itself, thus giving potential applicants a clearer and more transparent idea of what is required, in the law itself. There is a number of required documentations, forms, reports, certificates and details of qualified personnel needed and have to be presented, in regards to the manufacturing process and the manufacturing facility, and are listed as so;

Required for Manufacture; ²³:

- Manufacturing process;
- Source(s) of raw materials to be used in manufacture;
- Copy of EU-GMP certificate for the source(s), as applicable;
- Copy of EU-GMP certificate for the contractor(s), as applicable; and
- Research proposal if applicable.

Required for the Manufacturing Facility;

- Site Master File in line with EU-GMP guidelines requirements;
- ERA Permits for unlicensed sites listed on the application;
- Building site plans;
- Location survey;
- Name and contact information of the project’s supervisor (if the building is under construction);
- Security and Access details;
- Architect’s report;
- Floor plan of the site and building;
- Environmental, waste management and sanitation plan;
- Proposed work schedule of employees; and
- Disposal and destruction method(s).

²² (Grantthornton.com.mt) <<https://www.grantthornton.com.mt/globalassets/1.-member-firms/malta/pdfs/medical-cannabis-licensing-malta.pdf>> accessed 15 August 2020.

²³ 'Malta Medical Cannabis Licensing Requirements' (Nexiabt.com) <<https://www.nexiabt.com/insights/malta-medical-cannabis-licensing-requirements>> accessed 15 August 2020.

Required for the Company itself and Personnel;²⁴:

- Curriculum vitae of Production Manager;
- Curriculum vitae of Quality Control Manager;
- Curriculum vitae of Qualified Person;
- Copy of Pharmacy Council QP certificate and copy of Pharmacy Council Pharmacist warrant;
- Qualified Person(s);
- Organisation chart;
- Certificate of Registration issued by MFSA (for private & public companies);
- Memorandum and articles of association;
- Malta Enterprise Letter of Intent;
- Notarised identity card/passport copies and due diligence report(s); and
- Power of attorney to sign on behalf of the license holder (if applicable).^[LSEP]

One of the principal requirements noted above is a qualified person or persons. The requirements for a qualified person include, that they must be residing in Malta and are a registered pharmacist at the Maltese Pharmacy Council. This individual is responsible with the immensely important task of ensuring that all the standards of good practice are met repeatedly, meaning that every product that is produced, is produced according to all the laws which are in force. The information that is abstracted from these tests are to be recorded in an official register. Other requirements of a qualified person include; dealing with proper waste management, documentations dealing with imports and exports and lastly requirements surrounding the manufacturing process. It is of utmost importance that every procedure is continuously monitored and adhered to for policy and/or legislative changes.²⁵

Upon obtaining a manufacturing license, the products could undergo partial manufacture (this being processes such as repackaging and relabeling of medicines) or else production of medicines. Pharmaceutical companies have frequent inspections in order to ensure that the “European Union Good Manufacturing Practice” (EUGMP) is fully adhered to. All inspections are carried out in accordance with the legislation which is laid out in Part III of the Medicines Act- Chapter 458 of the Laws of Malta. This chapter also includes legislation for placing a medicinal product on the market upon finishing production. Any individual or business entity that engages in such activities are required to possess authorization to do so.

Part V deals with Appeals of any decisions pertaining to licensing. Article 6 sets up the Licensing Appeals Board set up by the Minister which shall consist of a Chairperson and three members of whom one has practised as a qualified scientist for not less than seven years²⁶.

²⁴ 'Malta Medical Cannabis Licensing Requirements' (Nexiabt.com) <<https://www.nexiabt.com/insights/malta-medical-cannabis-licensing-requirements>> accessed 15 August 2020. (n.2)

²⁵ 'Application for A Licence In Accordance With The Production Of Cannabis For Medicinal And Research Purposes Act' (Servizz.gov.mt, 2020) <<https://www.servizz.gov.mt/en/Pages/Health-and-Community-Care/Health/Medicines/WEB2427/default.aspx>> accessed 24 August 2020.

²⁶ 'Medicines Authority' (*Medicinesauthority.gov.mt*) <<http://www.medicinesauthority.gov.mt/cannabisformedicinalandresearchpurposes>> accessed 15 August 2020 (n.3)

These members are appointed for a five-year period and may be removed only by the Prime Minister on grounds of proved inability to perform the functions expected of their office or proved misbehaviour. Any member of the Board may be challenged or abstained from a decision for any of the same reason for which a judge may be challenged or abstained as per Article 734 of the Code of Organisation and Civil Procedure. If this arises, the Minister shall appoint a person who has the same qualifications as the said member to sit on the board in substitution. Members of the House of Representatives/ Local Council, judges and magistrates are not eligible to sit on such board for so long as he holds that office. The minister may also appoint a secretary.

Article 7 deals with the right of appeal itself. Only the Board is competent to hear such appeals on any decision or regulations made in accordance with this Act. The right of appeal is bestowed upon the applicant showing such interest, who has duly filed an objection or made representations against the grant of the license. Article 7(2) lists the grounds for an appeal which include:

- (a) that a material error as to the facts has been made;
- (b) that there was a material procedural error;
- (c) that an error of law has been made;
- (d) that there was some material illegality, including unreasonableness or lack of proportionality. The Board must, after hearing the appellant, regulator authority and applicant (if he is not the appellant) decide the appeal and give reasons in an open session. In determining the appeal, the Board may either dismiss the appeal or annul the decision and refer it to the respective regulatory authority.

Article 8 goes into the competence of the board to hear and decide any appeal made to it in accordance with the provisions of Chapter 578 of the Laws of Malta. Any person may be summoned to appear and give evidence before the board with the Chairman having the power to administer the oath. Technical experts may also be appointed to advise. Article 8(3) equates the powers of the Board as competent to the First Hall, Civil Court. As per Article 9, the applicant has a further mode of redress if they are aggrieved by the decision of the Board by appealing the decision with the Court of Appeal as per Article 41(9) of the Code of Organisation and Civil Procedure by means of an application filed in the registry of that court within 20 days from the date of the Board's decision²⁷.

In December of the year 2020, Malta issued its very first medical cannabis production license. The license was issued to the Canadian company Aphria, which is a global leader in the sector of medical marijuana. Apart from manufacturing, packing and testing, the company will also be exporting its products from Malta in the form of dried flowers. The company was successfully allowed to operate after inspections from both local and Canadian medical authorities and upon the issuing of the manufacturing license and EUGMP certificate.²⁸

²⁷ 'Medicines Authority' (*Medicinesauthority.gov.mt*) <<http://www.medicinesauthority.gov.mt/cannabisformedicinalandresearchpurposes>> accessed 15 August 2020 (n.4.)

²⁸ Times of Malta, 'Malta Issues First License For Production Of Medical Cannabis' (2020) <<https://timesofmalta.com/articles/view/malta-issues-first-licence-for-production-of-medicinal-cannabis.840506>> accessed 16 January 2021.

Medical Marijuana Licensing in Foreign Jurisdictions

Israel

It is known that Israel's work in this newly, rapidly, growing industry of Medical Marijuana started with Professor Raphael Mechoulam in the 1960s. The professor is considered as a pioneer in the field who identified two of the active ingredients of the plant, tetrahydrocannabinol, or THC, and cannabis oil (CBD).²⁹

In August 2011, Israel's government issued its first resolution to regulate and supervise sources "in the field for medical and research objectives."³⁰ Having started the process four years before Malta's first proposal and seven years before promulgating a full force licensing programme, Israel is, needless to say, more experienced. This is seen through the multiple amendments made throughout the years since.

In April of 2013 Israel established the 'Israeli Medical Cannabis Agency' which is a government agency for medical cannabis. In December of the same year, the first government resolution for the regulation of licenses in all the sectors of the medical marijuana industry was promulgated.

In June of the year 2016, the Israeli government issued Resolution Number 1587.³¹ This resolution seeks to fill the lacunae of international standards that deal with any discrepancies. The main objectives of this resolution were to treat medical marijuana like any other pharmaceutical narcotic drug as it was previously classified as a dangerous drug. Secondly, it further improved medical indications for prescribing Cannabis. Thirdly, it pushed for a higher standard and quality training for medical professionals with regards to medical marijuana. Last but not least, an improved standardisation for medical marijuana products.

In December of 2017 a 'Green Book' was issued by the Israeli Ministry of Health to serve as guidelines for the 'Medicalisation' Reform'. In January of 2019 the Israeli government issued Resolution Number 4490 in order to adopt the Medical Cannabis Agency's recommendations for medical cannabis exports.

A stark difference between the issuing of licenses in Israel and that in Malta, is the level of specification which the issued license's targeted area is. Having been involved in the industry for longer than Malta, Israel has had the time to evolve its legislation with regards to the licensing of companies which produce medical marijuana. While the license which is issued in Malta is quite standard and covers all the sectors of this industry, on the other hand Israel has

²⁹ Shoshanna Solomon, 'Government Throws Its Weight Behind Medical Cannabis Sector' (*Timesofisrael.com*, 2019) <<https://www.timesofisrael.com/government-throws-its-weight-behind-medical-cannabis-sector/>> accessed 5 August 2020.

³⁰ 'Invest In Israel' <<https://investinisrael.gov.il/Pages/default.aspx>> accessed 5 August 2020.

³¹ 'Medical Cannabis Reform In Israel - Food, Drugs, Healthcare, Life Sciences - Israel' (*Mondaq.com*, 2017) <<https://www.mondaq.com/healthcare/589342/medical-cannabis-reform-in-israel>> accessed 5 August 2020.

created further classifications for the issuing of its licenses. The classifications are seven and are as follows:

- Cultivation and Replication (IMC-GAP)
- Production (IMC-GMP)
- Handling of Cannabis Designated for Disposal (IMC-GWDP)
- Research & Development (IMC-GRDP)
- Medical Registration and Practice (IMC-GCP)
- The Security (Chain IMC-GSP)
- Storage, Distribution, and Delivery (IMC-GDP)³²

This further specification has led to much greater development, in research and innovation, and served as boost to the economy as well. The company 'Roots – Sustainable Agricultural Technologies', studied at differing temperatures in order to provide the best optimal conditions for the cannabis plant at every stage of cultivation. Another example is the licensed company 'Syqe', which has developed a medical marijuana inhaler. The company 'DryGair Energies Ltd', studied humidity control for better plant growth.³³

Israel and Malta's differing legislation regarding licensing and regulating the medical marijuana industry is one of notable interest. Due to the fact that Israel started working significantly before Malta in the medical marijuana area. Israel has faced various issues while slowly developing their legislation in relation to this industry, through which Malta can learn from.

The first company in Israel to obtain its license from the Ministry of Health, Tikkun Olam, lost its permits due to police recommendation. Another point to note was Israel's hesitance for industry growth. Seen from the company 'Breath of Life', which failed to list on the Toronto stock exchange, resulting in a short supply of medical marijuana in Israel, leading to an increase in black market activity.

In 2018, the global medical cannabis industry was expected to make an overall net growth from \$13.4 billion to \$44 billion by 2024. In the year of 2019, the Israeli government approved the exportation of medical grade cannabis, to yield back \$1 billion per annum.

Malta through its legislations on medical marijuana, aimed more towards income through exportation. On the other hand, Israel's main aims were to attract foreign investors.

However, in 2017 it was reported that in Israel there was only 9 fully licensed growers of medical cannabis and approximately only 30 authorised physicians to administer medical

³² 'Invest In Israel' (*Invest in Israel*) <<https://investinIsrael.gov.il/Pages/default.aspx>> accessed 5 August 2020. (n.2)

³³ Shoshanna Solomon, 'Government Throws Its Weight Behind Medical Cannabis Sector' (*TimesofIsrael.com*, 2019) <<https://www.timesofisrael.com/government-throws-its-weight-behind-medical-cannabis-sector/>> accessed 5 August 2020. (n.2)

cannabis. These very few companies needed to cater for the medical needs of over 23,000 permit holding patients and for exportation purposes.³⁴

Colombia

Colombia has had its fair share of internal struggles over the past years. Most of these problems have their roots stemmed in drug trafficking. For over 40 years, especially in the 1960s and 1970s, Colombia has been the leading manufacturer of cocaine and marijuana in the world. As a result of the illegality of this industry, guerrilla warfare broke out between different drug organisations which lead to an unforgiving amount of bloodshed. The government through enforcing prohibition laws on such drugs, to try and quell the civil conflict, ended up resulting to a worse situation.

The government sought to remedy the situation through an introduction of new legislation. In July of 2016, the Colombian Government promulgated a new law, 'Law 1787'. 'Law 1787' regulated the usage of medical marijuana and trade that the aforementioned plant is involved in. This legislation acts as a catalyst for subsequent resolutions which are added to the legal framework surrounding the industry.³⁵ However, Cocaine in Colombia is still a punitive offence, in terms of sale, use, and production.

The Government of Colombia issues a number of different licenses, all with different classifications and obligations, very similar to the one's which are issued in Israel. Malta has only one standard license, meanwhile in Colombia the licenses are classified into four areas³⁶:

- The cultivation of psychoactive cannabis
- The cultivation of non-psychoactive cannabis
- The use of seeds for planting
- The manufacturing of by-products

Licenses in Colombia are not indefinite and need to be renewed every five years. Such licenses are subject to renewal when necessary, as contrasted with Malta and Israel where a breach of regulations and/or requirements causes an entity's license to be revoked.³⁷

Through the eyes of Colombian law, Medical Marijuana is perceived as an alternative pharmaceutical. Till October 2019 around 300 licenses were issued by the competent authorities.

Colombia is extremely attractive in the eyes. of foreign investors, coming mainly from the United States of America and Canada which is the leading marijuana exporter of the world due

³⁴ 'Medical Cannabis Reform In Israel - Food, Drugs, Healthcare, Life Sciences - Israel' (Mondaq.com, 2017) <<https://www.mondaq.com/healthcare/589342/medical-cannabis-reform-in-israel>> accessed 5 August 2020. (n.2)

³⁵ Alfredo Pascual, 'Colombia Medical Marijuana Sales Expected To Begin Soon' (*Marijuana Business Daily*, 2020) <<https://mjbizdaily.com/first-medical-cannabis-sales-in-colombia-imminent-a-year-later-than-expected/>> accessed 6 August 2020.

³⁶ 'The Challenges Of Medicinal Cannabis In Colombia' (*Transnational Institute*, 2019) <<https://www.tni.org/en/medicinal-cannabis-colombia>> accessed 6 August 2020.

³⁷ 'Colombia Cannabis: A Guide To Recreational And Medical Cannabis Laws' (*Medellin Guru*, 2019) <<https://medellinguru.com/colombia-cannabis/>> accessed 6 August 2020.

to a number of reasons. Colombia's geographical position along the equator makes Colombia's climate ideal and effective for growing cannabis. Secondly, labour and input costs are relatively lower than if the same process had to be conducted in another country. Lastly, the robust legal framework which is built off of 'Law 1787' offers long term guarantees.³⁸

Colombian economists projected an estimated global net growth of the industry of up to \$66.3 Billion by the year 2025. With Colombia producing two-fifths of the world's supply, investors jumped to the opportunity to invest their money.

The first company with all the necessary authorisation and licenses to sell medical marijuana in Colombia goes by the name 'Khiron Life Sciences', which was covered by the Toronto investment bank AltaCorp Capital. An Uruguayan company 'NettaGrowth', brought in various investment deals valued at 13.7 million Canadian dollars in 2019.³⁹ This conveys the potential that such market has for exponential growth, as was the case with investors seeking Malta as a future exporter.

The Company 'Clever Leaves' was the first company to legally export medical marijuana from Colombia to Canada by the Colombian National Narcotics Fund.⁴⁰ Colombian health authorities bestowed the title of "certification of Good Elaboration Practices for Magistral Preparations with Cannabis" to the company. However, despite the laws being promulgated in 2016, the first sale in high-CBD formulations were made in late 2019, with high-THC products coming in later days. Despite all the positive factors of economic growth, and an estimated market of five million patients, this delay has caused a decline in growth.

In an attempt to rebuild the war-torn society, new laws were promulgated with the addition of a which stipulated that ten percent of production had to come from small or medium sized growers. The aim of this clause was for struggling families which were previously involved in the illegal drug production and smuggling business, in order to earn an adequate living.⁴¹ While this solution seems great in theory, the reality is that small and medium sized growers find it extremely difficult to influence the market, especially with high-quality products. Multiple cases of small groups of farmers cooperating together to obtain a license have been reported, however, it is still challenging to compete with larger companies with millions invested.⁴²

³⁸ Sushree Mohanty, 'Why Marijuana Is Thriving In Colombia' (*Market Realist*)

<<https://marketrealist.com/2019/10/why-marijuana-is-thriving-in-colombia/#:~:text=Colombia's%20equatorial%20climate%20is%20the,known%20for%20drug%2Drelated%20violence.>> accessed 6 August 2020

³⁹ Alfredo Pascual, 'Colombia Medical Marijuana Sales Expected to Begin Soon' (*Marijuana Business Daily*, 2020) <<https://mjbizdaily.com/first-medical-cannabis-sales-in-colombia-imminent-a-year-later-than-expected/>> accessed 6 August 2020. (n.2)

⁴⁰ 'Colombia Cannabis: A Guide to Recreational and Medical Cannabis Laws' (*Medellin Guru*, 2019) <<https://medellinguru.com/colombia-cannabis/>> accessed 6 August 2020. (n.2)

⁴¹ 'The Challenges of Medicinal Cannabis in Colombia' (*Transnational Institute*, 2019) <<https://www.tni.org/en/medicinal-cannabis-colombia>> accessed 6 August 2020. (n.2)

⁴² 'The Challenges Of Medicinal Cannabis In Colombia' (*Transnational Institute*, 2019) <<https://www.tni.org/en/medicinal-cannabis-colombia>> accessed 6 August 2020. (n.3)

Licensing Medical Cannabis in the U.S.

Federal legislation

Title 21 United States Code, the Controlled Substances Act, Schedule I stipulates that marijuana is a drug which is deemed to bring about high dependency and carries no medicinal value. Therefore, any use or possession or distribution of the drug is a federal offence⁴³. Nevertheless, the U.S. Department of Justice back in 2013 through the Marijuana Enforcement Policy, provided for eight federal interests regarding marijuana including the drug being sold to minors. However, it was left to the States' legislatures and their independent narcotic laws to legislate outside the eight interests.⁴⁴ Meanwhile in 2018 the Marijuana Enforcement Memorandum was issued and it was stipulated that federal prosecutors when establishing which marijuana activities are to be prosecuted under state laws, Attorney Generals are to consider the “*federal law enforcement priorities*” such as, the gravity of the crime, the disincentive effect of the prosecution and the repercussions of the crime on society as a whole.⁴⁵

NCSL Classification of the programmes available throughout USA

The National Conference of State Legislatures (NCSL) serves as a representative of the legislatures in the states of the U.S. through which it provides anything covered during parliamentary sessions of each state, district and territory.⁴⁶ Its motives are directed towards facilitating coordination between states which are independent. More importantly, NCSL serves as the legislatures' representative when reaching a compromise with the federal government.⁴⁷

Out of the 50 states that make up the United States, 33 of those states, District of Columbia (Washington D.C.), the U.S. Virgin Islands, Guam and Puerto Rico have what is called a Comprehensive Medical Marijuana Program. NCSL uses a number of categories in establishing a benchmark as to whether a state's legislation or program is comprehensive or not. These include: (1) safeguarding an individual from being punished for using medical marijuana; (2) being able to be supplied marijuana through the possibility of cultivating cannabis himself/herself or through pharmacies; (3) a patient is open to more than just low THC; (4) authorising the smoking or vapping of cannabis; (5) a program not limited to a trial.⁴⁸

⁴³‘State Medical Marijuana Laws’ (*National Conference of State Legislatures*, March 2020)

<<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>> accessed 6 April 2020.

⁴⁴ James M. Cole (Deputy AG) ‘*Memorandum for All Unites States Attorneys*’ (Guidance Regarding Marijuana Enforcement, U.S. Department of Justice, 2013)

<www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> accessed 6 April 2020.

⁴⁵ Jefferson B. Sessions (AG) ‘*Memorandum for All Unites States Attorneys*’ (Marijuana Enforcement, Office of Attorney General, 2018) <<https://www.justice.gov/opa/press-release/file/1022196/download>> accessed 6 April 2020.

⁴⁶ (*National Conference of State Legislatures*, March 2020) <www.ncsl.org/> accessed 6 April 2020.

⁴⁷ ‘The NCSL Foundation for State Legislatures’ (*National Conference of State Legislatures*) <www.ncsl.org/aboutus.aspx> accessed 6 April 2020.

⁴⁸ ‘State Medical Marijuana Laws’ (*National Conference of State Legislatures*, March 2020)

<<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>> accessed 6 April 2020. (n.2)

There are 17 states in the U.S. that have proved their effort to authorise low or zero Tetrahydrocannabinol (THC) and high Cannabidiol (CBD) products as medicine, only in limited circumstances. These are not listed as Comprehensive Medical Programs by NCSL⁴⁹ and other organisations like Marijuana Policy Project⁵⁰ and Network for Public Health Law.⁵¹

States having Limited Access Medical Marijuana Laws

These states allow for low THC and high CBD potency marijuana – therefore, being so limited they provide for an insufficient medicine and therefore not accounted as comprehensive medical marijuana laws.

Idaho has no kind of law whatsoever that recognises the medical value of cannabis. However, Idaho Cannabis Coalition advocates are working on being able to legalise medical marijuana through a ballot initiative, for which campaigners require over 55,000 signatures in order to qualify for this year’s ballot (2020).⁵² **South Dakota** is set to vote on adult-use legalisation and medical marijuana at the same time next November.⁵³ Meanwhile **Texas**, being one of the most conservative states in the U.S., allows a low THC medical cannabis program, despite being expanded recently through HB 3703, it remains a very limited program which reaches out to the bare minimum of patients.⁵⁴ **Virginia** is slowly improving towards making CBD and THC-A-rich medical cannabis legal so that patients would be protected from arrest. This is because currently, the law only provides for an “*affirmative defense*.”⁵⁵ The Senate Bill 1015 was approved by Legislature last March, but despite this upgrade in the law, the bill is still deemed as limited due to a limited number of conditions which are eligible for the program.⁵⁶ In **Wyoming** there were efforts to try to legalize medical cannabis in 2019 however this proved to be all in vain.⁵⁷

States with bills to create Comprehensive Medical Cannabis Programs

A number of states are set to approve effective legislation bills in legalising medical marijuana to patients suffering from certain diseases. These states are: Alabama, Georgia, Indiana, Iowa, Kansas, Kentucky, Mississippi, Nebraska, North Carolina, South Carolina, Tennessee and Wisconsin. Some states have yet to complete the whole process of approval meanwhile others

⁴⁹ ‘State Medical Marijuana Laws’ (*National Conference of State Legislatures*, March 2020)

<<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>> accessed 6 April 2020. (n.3)

⁵⁰ ‘2020 Marijuana Policy Reform Legislation’ (*Marijuana Policy Project*, March 2020)

<www.mpp.org/issues/legislation/key-marijuana-policy-reform/> accessed 6 April 2020.

⁵¹ ‘Medical Marijuana Programs; Summary Matrix’ (*The Network for Public Health Law*, February 2019)

<www.networkforphl.org/wp-content/uploads/2020/01/Medical-Marijuana-Programs.pdf> accessed 6 April 2020.

⁵² ‘Idaho’ (*Marijuana Policy Project*, January 2020) <www.mpp.org/states/idaho/> accessed 6 April 2020.

⁵³ ‘South Dakota’ (*Marijuana Policy Project*, January 2020) <www.mpp.org/states/south-dakota/> accessed 6 April 2020.

⁵⁴ ‘Texas’ (*Marijuana Policy Project*, August 2019) <www.mpp.org/states/texas/> accessed 6 April 2020.

⁵⁵ ‘Virginia’ (*Marijuana Policy Project*, March 2020) <www.mpp.org/states/virginia/> accessed 6 April 2020.

⁵⁶ ‘S 1015’ (Virginia’s Legislative Information, 2020) <<https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+SB1015ER>> accessed 6 April 2020.

⁵⁷ ‘Wyoming’ (*Marijuana Policy Project*, December 2019) <<https://www.mpp.org/states/wyoming/>> accessed 6 April 2020.

are close to finalising these implementations which had to be paused and adjourned due to Covid-19.⁵⁸

Alabama

In March 2020, Senate had approved the Compassion Act; when and if this is approved by the House of Representatives, the state of Alabama would provide a Comprehensive Medical Cannabis Program.⁵⁹ Before this act passes and becomes fully in force, Alabama remains a non-legal medical cannabis state due to strictly enacted laws and the absence of legal provisions on distribution and cultivation. Many states that have big industries of medical marijuana are to carry out further regulation of the industry including licensing through subsidiary legislation.

The bill, which is to be entitled an act, SB165, declares that this act does not behold the intent to empower recreational use of cannabis. Furthermore, the act is set to license and regulate “*the cultivation, processing, transporting, testing and dispensing of medical cannabis*”, in fact cultivators, processors, secure transporters, state testing laboratories, dispensaries and integrated facilities shall be licenced entities in order to be able to act in pursuant of the act. This is stipulated in article 3(11) of the bill.⁶⁰

The act lists down the qualifications required for a patient to be prescribed medical cannabis – upon presenting official documentation showing that conventional medicine failed. Amongst others, the act lists down: anxiety or panic disorder, ASD, cancer-related cachexia, nausea or vomiting, weight loss, or chronic pain, Crohn's disease, epilepsy or a condition causing seizures, fibromyalgia, HIV/AIDS, Post Traumatic Stress Disorder (PTSD), Tourette's syndrome and many others.⁶¹ Anyone suffering from such conditions shall be eligible for acquiring a medical card after acquiring a “*registered certifying physician[’s]”* certification and paying a fee. Consequentially, any “*registered qualified patient*” shall be able to “*purchase, possess or use medical cannabis*”.⁶²

The commission that shall be responsible for licensing is the Alabama Medical Cannabis Commission, while the Department of Agriculture and Industries shall be responsible for licensing cultivators. The former is required by law to issue a yearly report enclosing the number of applicants for each type of license and the number of applicants who were not granted a license.⁶³ When it comes to regulating the integrated facilities, the department and commission split regulations, licensing and authorising functions accordingly. Both the commission and the department shall be empowered to (1) supervise the licensed facilities; (2) investigate applicants for licenses and grant them or refuse them accordingly; (3) scrutinise the employees of the licensees; (4) enter into the licensee’s place of business without notice or

⁵⁸ ‘State Medical Marijuana Laws’ (*National Conference of State Legislatures*, March 2020)

<<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>> accessed 6 April 2020. (n.4)

⁵⁹ ‘Alabama’ (*Marijuana Policy Project*, March 2020) <www.mpp.org/states/alabama/> accessed 6 April 2020.

⁶⁰ ‘SB165’ (Title 20, Code of Alabama 1975)

<<http://alisondb.legislature.state.al.us/alison/searchableinstruments/2020RS/bills/SB165.htm?fbclid=IwAR0mNudRltjxGGq9106m1CMh6Cmok7w9NlhJggYoZRHVTpvGHIjAGWSe8dY>> accessed 6 April 2020.

⁶¹ Ibid 60 *SB 165* (n41) §20-2A-3 (19).

⁶² Ibid 60 *SB 165* (n41) §20-2A-30 (a)(2).

⁶³ Ibid 60 *SB 165* (n41) §20-2A-9.

warrant to scrutinise their premises, their records, and whether they are in accordance with their license. They may also sanction licensees they deem appropriate.⁶⁴

Depending on one's license, one is authorised to do a number of things; a cultivator's license empowers one to cultivate, sell and/or transfer to the processor or a dispensary if there is a contract between the processor and the cultivator.⁶⁵ A processor's license grants one with the power to purchase or transfer cannabis from the cultivator. Processing shall also include proper packaging and labelling, selling or transferring the medicine to a dispensary.⁶⁶ Meanwhile a dispensary license authorises one to purchase or transfer cannabis from a processor, cultivator or an integrated facility, and the dispensing and sale of medical cannabis only to registered qualified patients or registered care givers.⁶⁷ A secure transporter license empowers one to store and transport the cannabis; however, this license does not empower one to transport the license to a patient or care giver.⁶⁸ A state testing laboratory authorises the possession and testing of cultivated or processed cannabis products⁶⁹. An integrated facility is licensed to: cultivate, process into medical cannabis, dispensing, sale (to registered qualified patient or registered caregiver), transport between facilities or dispensaries. The commission may issue no more than five integrated facility licenses.⁷⁰

The remaining provisions provide the standards required for one to be able to acquire a license and ultimately renew it upon expiry. With regards to cultivation, the commission and department shall institute operating standards that provide for "*health, safety, and security of the public and integrity of medical cannabis facility operations*" as well as conducting on-site inspections, establishing "*testing standards, procedures and requirements*", ensuring that the medical cannabis is secured in enclosed places and locked (amongst other security procedures), they shall also collect fines in case of violation of said act, establish quality standards, providing standards for storing waste product and disposal, standards for ensuring secure transportation and labelling of the medicine, restrictions on advertising and marketing as well as "*renewal, revocation, suspension and nonrenewal of licenses*". This ensures that high quality products are being delivered to the patients while ensuring that public health and welfare are being looked after.⁷¹

In terms of accepting or denying licenses, the commission shall take on a method of looking into the licensee's criminal record, knowing all those interested in the ownership of the license or who has any financial interests, looking into financial information, as well as ensuring the payment of the application fee is settled. Furthermore, the applicant shall provide a written consent to investigations and searches as provided in Section 20-2A-52 (a)(3). Providing false information and applications are concrete grounds of denial of a license.⁷²

⁶⁴ Ibid 60 SB 165 (n41) §20-2A-51(a).

⁶⁵ Ibid 60 SB 165 (n41) §20-2A-62.

⁶⁶ Ibid 60 SB 165 (n41) §20-2A-63.

⁶⁷ Ibid 60 SB 165 (n41) §20-2A-64.

⁶⁸ Ibid 60 SB 165 (n41) §20-2A-65.

⁶⁹ Ibid 60 SB 165 (n41) §20-2A-66.

⁷⁰ Ibid 60 SB 165 (n41) §20-2A-67.

⁷¹ Ibid 60 SB 165 (n41) §20-2A-53.

⁷² Ibid 60 SB 165 (n41) §20-2A-55.

The Commission may also issue temporary a license of 60 days, otherwise issued annually as long as it is not renewed upon payment of a fee and coherence to act regulations.⁷³ According to one's license, one shall provide information to the Commission on the tracking of the plant and its chain custody, the transfers, sales, returns, how much of the plant was destroyed, test results on the plant etc.⁷⁴

The bill provides only a rough sketch of how the whole picture will develop upon implementation. Licenses seem to have not been placed at the reach of citizens who want to register for the medical program. Therefore, the system is still in its early beginnings. Upon successfully passing, one can say that full implementation can take place. In 2019, Alabama decriminalised possession and use of marijuana in small amounts which signifies a step towards development and broadening one's legislation.⁷⁵

States having Comprehensive Medical Marijuana Laws

33 states in the U.S. and the District of Columbia have effective laws legalizing medical marijuana which provides medical cannabis patients with a number of benefits when compared to other states. The first country to have made medical marijuana legal was California. Nevada is portrayed by the majority of patients as being the most satisfactory in terms of the law; in fact, MPP's model state bill was inspired and largely influenced by Nevada's legislation.⁷⁶ On the other hand Montana and Maine have the largest number of patients benefitting from a comprehensive medical marijuana program. Other states include: Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, DC, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Missouri, Nevada, New Hampshire, New Jersey, North Dakota, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Washington and West Virginia.

California

The state of California is the first state to formally legalise medical cannabis in 1996 when voters passed⁷⁷ Proposition 215⁷⁸. Being a pioneer in this medical field, it has been described as the "*largest cannabis market in the country*".⁷⁹ It offers a program to an estimation of

⁷³ Ibid 60 *SB 165* (n41) §20-2A-56.

⁷⁴ Ibid 60 *SB 165* (n41) §20-2A-60.

⁷⁵ (*Marijuana Policy Project*, August 2019) < www.mpp.org/states/texas/> accessed 6 April 2020.

⁷⁶ 'Overview of MPP's Model State Medical Marijuana Bill' (*Marijuana Policy Project*, 2020) <www.mpp.org/issues/medical-marijuana/overview-of-mpps-model-state-medical-marijuana-bill/> accessed 7 April, 2020.

⁷⁷ 'Key Aspects of State and D.C. Medical Marijuana Laws' (*Marijuana Policy Project*, January 2020) <www.mpp.org/issues/medical-marijuana/state-by-state-medical-marijuana-laws/key-aspects-of-state-and-d-c-medical-marijuana-laws/> accessed 7 April 2020.

⁷⁸ 'State Medical Marijuana Laws' (*National Conference of State Legislatures*, March 2020) <<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>> accessed 6 April 2020. (n.5)

⁷⁹ 'Licensing; California Cannabis Portal' (*State of California*, 2020) <<https://cannabis.ca.gov/licensing/>> accessed 7 April 2020.

1,238,136 patients making up 3.44 % of the population; one of the highest percentages of patients in the U.S.⁸⁰

In 1996, the legislature released from prosecution “a patient, or to a patient’s primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.”⁸¹ The Medical Cannabis Regulation and Safety Act was passed in 2015 which established 3 licensing authorities.⁸² Meanwhile, the Adult Use of Marijuana Act was passed in 2016 through Proposition 64. In 2017 the legislature, through Senate Bill 94, integrated the adult-use regulatory system and the medical cannabis system into a dual structure subject to the same licensing agencies and thus enacting the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA). Created in order to regulate the state government and local government in maintaining the state’s legislation by adopting regulations.⁸³

For a patient to be integrated in the medical cannabis program, one must suffer from one of the following qualifying conditions: cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.⁸⁴ Prior to being able to acquire the medicine, one shall first acquire a certified physician’s recommendation, documented medical records, and also pay a fee.⁸⁵

The state has three licensing authorities: The Bureau of Cannabis Control, CalCannabis Licensing and Manufactured Cannabis Safety Branch. The Bureau of Cannabis Control issues licenses for dispersing, retail, testing, event organising and microbusinesses. One can acquire a license through an online licensing system which is accessible to the public through a portal along with an “e-Learning portal” for those who find difficulties when applying online, therefore making the process easily accessible.⁸⁶ The Bureau shall also post “equity ordinances” which are accessible online through the state’s official website as empowered by the relative provisions of the Business and Professions Code.⁸⁷

⁸⁰ ‘Medical Marijuana Patient Numbers’ (*Medical Policy Project*, July 2019)

<<https://www.mpp.org/issues/medical-marijuana/state-by-state-medical-marijuana-laws/medical-marijuana-patient-numbers/>> accessed 7 April 2020.

⁸¹ ‘Health and Safety Code; Division 10; Chapter 6; Article 2; 11362.5.’ (California Legislative Information, 1996)

<https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=11362.5.&lawCode=HSC> accessed 7 April 2020.

⁸² ‘Cannabis Legislation; California Cannabis Portal’ (*State of California*, 2020)

<<https://cannabis.ca.gov/cannabis-legislation/>> accessed 7 April 2020.

⁸³ ‘Cannabis Legislation; California Cannabis Portal’ (*State of California*, 2020)

<<https://cannabis.ca.gov/cannabis-legislation/>> accessed 7 April 2020. (n.2)

⁸⁴ ‘Key Aspects of State and D.C. Medical Marijuana Laws’ (*Marijuana Policy Project*, January 2020)

<www.mpp.org/issues/medical-marijuana/state-by-state-medical-marijuana-laws/key-aspects-of-state-and-d-c-medical-marijuana-laws/> accessed 7 April 2020. (n.2)

⁸⁵ ‘Health and Safety Code; Division 10; Chapter 6; Article 2; 11362.5.’ (California Legislative Information, 1996)

<https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=11362.5.&lawCode=HSC> accessed 7 April 2020.

⁸⁶ ‘Apply for a License; California Cannabis Portal’ (*State of California*, 2020) <<https://cannabis.ca.gov/apply-for-a-license/>> accessed 7 April 2020.

⁸⁷ *Business and Professions Code; Division 10; Chapter 23; 26246 (b)* (California Legislative Information, 2019)

<https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=10.&title=&part=&chapter=23.&article=>> accessed 7 April 2020.

CalCannabis Licensing issues cultivation licenses. It is a division of the California Department of Food and Agriculture (CDFA), and it provides an online licensing system available to the public as well. The license is open for cultivators and for recreational cannabis users. This type of license also requires an additional license for pest and waste management.⁸⁸

Manufactured Cannabis Safety Branch, is a division of the California Department of Public Health (CDPH), which issues manufacturing licenses for both medical cannabis and “nonmedical” recreational cannabis. The licensing system should also be online however, up until now the CDPH is accepting applications in a non-remote way. Applicants are to require “local authorisation” from the city or county without which one cannot proceed any further. An application requires one to provide factual details on the business, the owners and anyone having financial interest in the business.⁸⁹

This licensing system was implemented in 2018 through an amendment to the Medical Marijuana Regulation and Safety Act in 2015. Previously, the law only concerned medical cannabis use until adult use was passed by legislature in 2016, joining the two frameworks under one act in 2017.⁹⁰ The official government website provides for a public research platform through which one can access the commercial licenses issued for cannabis businesses by the collaborating state agencies.⁹¹

All in all, the general framework for marijuana possession, cultivation, manufacturing, dispersing etc. is authorised by the Medicinal and Adult-Use Cannabis Regulation and Safety Act, accessible through the Business and Professions Act, Division 10, Chapter 5 on Licensing. Nevertheless, one finds a multitude of regulations enacted separately for further regulation and guidelines for licensees. The licensing authorities are responsible for publishing standards and regulations on how certain procedures should be implemented especially with regards to “cultivation, extraction and infusion methods, the transportation process, inventory procedures, quality control procedures and security protocols.”⁹²

Licensing authorities have the right to interfere by means of disciplinary actions in cases of lack of compliance to the act or any other legislation, intentional sale to a person who is younger than 21 years or to individuals without a physician’s recommendation, and the inability to sustain “safe conditions for inspection by the licensing authority”.⁹³ The latter has

⁸⁸ ‘Apply for a License; California Cannabis Portal’ (State of California, 2020) <<https://cannabis.ca.gov/apply-for-a-license/>> accessed 7 April 2020.

⁸⁹ ‘Apply for a License; California Cannabis Portal’ (State of California, 2020) <<https://cannabis.ca.gov/apply-for-a-license/>> accessed 7 April 2020. (n.2)

⁹⁰ ‘California’ (Marijuana Policy Projects, 2018) <<https://www.mpp.org/states/california/>> accessed 7 April 2020.

⁹¹ ‘Cannabis License Search; California Cannabis Portal’ (State of California, 2020) <https://cannabis.ca.gov/check_a_license/> accessed 7 April 2020.

⁹² *Business and Professions Code; Division 10; Chapter 5; 26051.5(b)* (California Legislative Information, January 2020) <https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=10.&title=&part=&chapter=5.&article=>> accessed 7 April 2020.

⁹³ *Business and Professions Code; Division 10; Chapter 3; 26030* (California Legislative Information, effective through June 2020) <https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=10.&title=&part=&chapter=3.&article=>> accessed 7 April 2020.

the power to suspend or revoke a license when a licensee fails to comply with the act and other regulations.⁹⁴

Furthermore, under the Business and Professions Code, Division 10, Chapter 3, Section 26033, a patient who “*cultivates, possesses, stores, manufactures, or transports cannabis exclusively for his or her personal medical use but who does not provide, donate, sell, or distribute cannabis to any other person is not thereby engaged in commercial cannabis activity and is therefore exempt from the licensure requirements of this division.*”⁹⁵

This system is highly interactive and effective for the government to ensure that all operations with regards to marijuana; both medical and recreational are operating under a license and complying by all standards created by the agencies responsible for issuing licenses.

Nevada

In the year 2000, Nevada citizens voted in favour of a ballot initiative which brought about legal use of medical cannabis for patients who sustain severe medical issues. This was rather limited and therefore, in 2013 the legislature broadened the existing medical marijuana program. In 2016 marijuana was legalised for adults above the age of 21, regulating the cannabis market.⁹⁶

A patient qualifies for the medical marijuana program if he/she has a “*chronic or debilitating medical condition*”. This is furtherly defined in chapter 453A as: AIDS, an anxiety disorder, an autism spectrum disorder, an autoimmune disease, cancer, dependence upon or addiction to opioids, glaucoma, any medical condition that produces: anorexia or cachexia, muscle spasms, seizures, severe nausea or severe or chronic pain, a medical condition related to acquired immune deficiency syndrome or the human immune deficiency virus or a neuropathic condition, whether or not such condition causes seizures.⁹⁷ One may also prove a chronic and debilitating medical condition by submitting a “*petition*” as directed in NRS 453A.710.⁹⁸ When one acquires a valid registry identification card, they are exempt from prosecution if found in possession of marijuana and/or delivers. Subject to a number of exceptions, one is also able to cultivate one’s own marijuana if there is no dispensary in his county providing such required medication.⁹⁹

⁹⁴ *Business and Professions Code; Division 10; Chapter 23; 26246 (b)* (California Legislative Information, 2019)

<https://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=10.&title=&part=&chapter=23.&article=&> accessed 7 April 2020. (n.2)

⁹⁵ *Business and Professions Code; Division 10; Chapter 23; 26246 (b)* (California Legislative Information, 2019)

<https://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=10.&title=&part=&chapter=23.&article=&> accessed 7 April 2020. (n.3)

⁹⁶ ‘Nevada’ (*Marjuana Policy Project*, November 2018) <<https://www.mpp.org/states/nevada/>> accessed 7 April 2020.

⁹⁷ *Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050* (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020.

⁹⁸ *Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050* (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020. (n.2)

⁹⁹ *Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050* (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020. (n.3)

The accountable authority for the issuing of licenses and regulation of dispensing marijuana is the Department of Taxation. The latter is also responsible for the administration of Nevada's medical marijuana program which was previously administered by the Division of Public and Behavioral Health, within the Department of Health and Human Services. Furthermore, the department administers the Medical Marijuana Patient Cardholder Registry.¹⁰⁰

There are five different types of retail marijuana establishment licenses that must be registered through the Department of Taxation. These are: (1) cultivation facilities, (2) distributors, (3) product manufacturing facilities, (4) testing facilities, and (5) retail stores. All are responsible for the market chain that enables one to acquire high quality marijuana products. A distributor is licensed to deliver marijuana from one establishment to another, whilst a product manufacturing facility shall be able to purchase cannabis, process it (this includes packaging) and sell the products to establishments but not to customers. Testing facilities shall assess the marijuana and the products upon final production stage. Finally, retail stores are able to purchase marijuana from cultivation facilities, product manufacturing facilities or from other retail stores, ultimately selling it to customers.¹⁰¹

When it comes to Medical Marijuana Establishments (MME), despite falling under the Department of Taxation as well, the law does not provide for licensing but rather a “*registration certificate*”, as the state authorises the operation of the MME. All applicants for the said certificate, must pay a fee and abide by all regulations, just like a license would. Although granted, it can be revoked or suspended and it may also be refused on different grounds by the Department of Taxation.

An MME is defined under chapter 453A, 116 as: an independent testing laboratory, a cultivation facility, a facility for the production of edible marijuana products or marijuana-infused products, or a medical marijuana dispensary. As established by Chapter 453A, all individuals who wish to operate an MME (no matter what kind of operation), must go through the same procedure of registration by submitting an application form with the name of the proposed MME, the address where such operation will take place, financial evidence that the applicant has not less than \$250,000 in liquid assets, that the applicant owns the land, fingerprints, names, addresses and date of birth of the applicant, owner, officer, board members of the MME as well as the name, address and date of birth of each employee of the proposed MME. The MME shall follow all rules as stipulated by the Department of Taxation including using adequate security measures, the use of “*an electronic verification system and an inventory control system*”. If the MME delivers or sells marijuana products, there are external procedures which must be abided by when it comes to handling the products. In some cases of existing restrictions which are imposed by the local government, one must provide evidence that the MME is fully complied with the restrictions and requirements that the Department may ask for.¹⁰²

¹⁰⁰ ‘Marijuana in Nevada’ (State of Nevada, 2019) <<http://marijuana.nv.gov/Businesses/GettingALicense/>> accessed 7 April 2020.

¹⁰¹ ‘Marijuana in Nevada’ (State of Nevada, 2019) <<http://marijuana.nv.gov/Businesses/GettingALicense/>> accessed 7 April 2020. (n.2)

¹⁰² Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050 (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020. (n.4)

An independent testing laboratory is responsible for testing the marijuana products produced and conducting any testing to obtain a “certification” from the Department upon paying a fee and “agree[ing] to become accredited pursuant to standard ISO/IEC 17025 of the International Organization for Standardization within 1 year after certification.”¹⁰³ A cultivation facility license enables one to acquire, possess, cultivate, deliver, transfer, supply, and/or sell marijuana to medical marijuana dispensaries, production facilities, and/or other cultivation facilities.¹⁰⁴ A production facility upon fully licensed, shall to be able to: “acquires, possesses, manufactures, delivers, transfers, transports, supplies or sells edible marijuana products or marijuana-infused products to medical marijuana dispensaries.”¹⁰⁵ Whilst a dispensary is an entity that “Acquires, possesses, delivers, transfers, transports, supplies, sells or dispenses marijuana or related supplies and educational materials to the holder of a valid registry identification card or to another medical marijuana dispensary”.¹⁰⁶

Therefore, in Nevada recreational marijuana use and medical marijuana use are distinctive. Although they fall under the scrutiny of the same agency, the Department of Taxation, the licenses which are issued are different and the laws regulating the two are separated. The official website provides for the two applications, therefore the two types of facilities have different purposes and different means in attaining a structured regulatory framework.

Other states that provide Comprehensive Medical Marijuana Laws

In the state of **Alaska**, medical marijuana was first legalised in 1999. For a patient to acquire medical cannabis, one has to register with the Division of Public Health, forming part of the Department of Health and Social Services.¹⁰⁷ In 2014 adult use marijuana was legalised and the regulation of sales and production of marijuana started taking place. The Alcohol and Marijuana Control Office, forming part of the Department of Commerce, Community and Economic Development, caters for the applications of marijuana licenses.¹⁰⁸ This licensing process was not available prior to the implementation of adult use/ recreational cannabis.¹⁰⁹ **Arizona** initially legalised medical marijuana in 2010. Due to a recent amendment in the law, patients’ registry cards are applicable for two years instead of one.¹¹⁰ Patients are also allowed to cultivate their own if they live far away from a dispensary. Care givers, dispensaries, and laboratory operators, have to apply for an application and be granted approval from the Arizona

¹⁰³ Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050 (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020. (n.5)

¹⁰⁴ Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050 (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020. (n.6)

¹⁰⁵ Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050 (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020. (n.7)

¹⁰⁶ Title 4 – Public Health and Safety; Chapter 453A – Medical Use of Marijuana; Section 050 (Nevada Legislature) <<https://www.leg.state.nv.us/NRS/NRS-453A.html>> accessed 7 April 2020. (n.8)

¹⁰⁷ ‘Medical Marijuana Registry (State of Alaska, 2019) <<http://dhss.alaska.gov/dph/VitalStats/Pages/marijuana.aspx>> accessed 8 April 2020.

¹⁰⁸ ‘Alcohol and Marijuana Control Office’ (State of Alaska, 2019) <<https://www.commerce.alaska.gov/web/amco/MarijuanaLicenseApplication.aspx>> accessed 8 April 2020.

¹⁰⁹ ‘Marijuana Use and Public Health in Alaska’ (Alaska Department of Health and Social Services, 2020) <http://dhss.alaska.gov/dph/Director/Documents/marijuana/MarijuanaUse_PublicHealth_Alaska_2020.pdf> accessed 8 April 2020.

¹¹⁰ ‘Arizona’ (Marijuana Policy Projects, January 2020) <<https://www.mpp.org/states/arizona/>> accessed 8 April 2020.

Department of Health Services.¹¹¹ **Arkansas** has recently amended its medical marijuana laws by establishing a system for the cultivation, acquisition, and distribution of marijuana for all qualifying patients through licensed medical marijuana dispensaries and cultivation facilities. Licenses in the state of Arkansas are issued by the Medical Marijuana Commission.¹¹²

Other states include: Colorado, Connecticut, Delaware, DC, Florida, Hawaii, Illinois, Louisiana, Maine, Montana Massachusetts, Maryland, Michigan, Minnesota, Missouri, Nevada, New Hampshire, New Jersey, North Dakota, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Washington and West Virginia.

Conclusion

U.S. medical marijuana laws are implemented differently in all the federative states, with diverse licensing systems. States that have legalised recreational marijuana use distinguish medical use from adult-use. This is done so by issuing different licenses for medical use and for recreational use (Nevada). Other states however, created a dual structured licensing system (California, Arizona).

The most effective licensing systems are those that provide a license for every step of the way rather than leaving production in the hands of dispensaries as Alaska did prior to 2014. Allowing more types of licenses is deemed by many to be the best way forward for the well-being of patients whom are in severe need of medical marijuana. However, for bureaucrats it may be deemed better to have less diversified economic activities. If one establishment is carrying out cultivation, production, supplying etc. the best way forward is to have different licenses for the whole process, rather than one license granting approvals for different stages of the production process.¹¹³ When it comes to the field of research on medical marijuana, the U.S. seems to be quite on hold. Although licenses are issued to laboratories which carry out tests on marijuana, when it comes to research per se it seems to be lacking when compared to other medical marijuana industries like Israel.

Licensing Medical Cannabis in other Countries: Luxembourg

In July 2018 the Act on the sale of drug substances was amended in order to have medical marijuana more easily accessible to patients and thus ensuring that all individuals in Luxembourg receive the best medical treatment.¹¹⁴ Marijuana use is stringently coordinated and must take place only in medical settings. As stated in a brochure published by the Division of Pharmacy and Medicines of the Health Directorate, upon acquiring a prescription, the medicine can then be picked up free of charge. However, there are only 5 hospital pharmacies

¹¹¹ Department of Health Services (State of Arizona, 2020) <<https://azdhs.gov/licensing/medical-marijuana/index.php>> accessed 8 April 2020.

¹¹² Dr. Joseph Rosado, 'Arkansas Medical Marijuana Laws' (Marijuana Doctors, August 2018) <<https://www.marijuanadoctors.com/medical-marijuana/ar/state-laws/>> accessed 8 April 2020.

¹¹³ 'Licensing' (Marijuana Policy Project, 2016) <<https://www.mpp.org/wp-content/uploads/2016/01/LicensingLevels.pdf>> accessed 8 April 2020.

¹¹⁴ 'Cannabis' (*State of Luxembourg*, 2018) <<https://sante.public.lu/fr/politique-sante/priorites-politiques/05-cannabis/index.html>> accessed 8 April 2020.

which provide such service.¹¹⁵ For one to obtain medical marijuana, they must be prescribed by a doctor who is authorized to practice in Luxembourg and trained in medical marijuana as certified by the Health Directorate. A patient must also have one of the qualifying conditions: Severe, advanced or terminal illnesses causing chronic pain, cancer treated with chemotherapy that induces nausea or vomiting and multiple sclerosis with muscle spasticity.¹¹⁶ In Luxembourg the legislature is showing remarkable efforts in making marijuana completely legal from both a recreational and medical standpoint. This innovative step has created a ‘domino effect’ in other European Union member states.¹¹⁷ The drug will be imported from countries which make use of a specialized agency such as Canada's cannabis agency.¹¹⁸ Therefore, cultivation and production until now henceforth do not take place in Luxembourg, as licensing does not form part of the medical marijuana program.

Republic of North Macedonia

In 2019 the legislature in North Macedonia conducted a draft bill, although not yet implemented in their laws, it is deemed to widen the exportation industry of the Republic of North Macedonia. Exportation (along with cultivation and production) has been legal since 2016, but this new amendment shall bring about a larger medical marijuana industry by exporting even the marijuana flower (smokable bud).¹¹⁹ The draft bill of 2019 is also expected to bring about more stringent rules on the licensing of applicants (mostly limited liability companies) despite being an already extremely strict and time-consuming licensing system. The draft bill¹²⁰ will substitute the Law on Control of Narcotic Drugs and Psychotropic Substances. Some of the most striking changes are the establishment of an independent regulatory agency for cannabis, Control of the Cultivation and Extraction of Cannabis and Cannabis Products for Medical and Scientific Purposes, and making the licensing process more rigorous than it already is.¹²¹ Although these amendments are just proposals as the legislature has yet to vote on them and even presumably change some provisions. Although cultivation and exportation are legal, cultivating and selling marijuana for recreational purposes is illegal.¹²²

¹¹⁵ ‘Cannabis Medicinal’ (Authorise au Luxembourg, Government of Luxembourg, September 2019) <<https://sante.public.lu/fr/publications/c/cannabis-medicinal-autorise-au-luxembourg-fr/cannabis-medicinal-autorise-au-luxembourg.pdf>> accessed 8 April 2020.

¹¹⁶ ‘Comment Acceder au Cannabis Medicinal’ (Authorise au Luxembourg, Government of Luxembourg, September 2019) <<https://sante.public.lu/fr/publications/c/cannabis-medicinal-comment-acceder-fr/cannabis-comment-acceder-cannabis-medicinal.pdf>> accessed 8 April 2020.

¹¹⁷ Jillian Deutsch, ‘Pass the Duchy: Luxembourg’s grand plan to legalize Cannabis’ (Politico, July 2019) <<https://www.politico.eu/article/luxembourg-legalize-cannabis/>> accessed 8 April 2020.

¹¹⁸ Adam Walder, ‘Luxembourg’s medical cannabis law nears completion’ (Luxembourg Times, April 2018) <<https://luxtimes.lu/luxembourg/33522-luxembourg-s-medical-cannabis-law-nears-completion/>> accessed 8 April 2020.

¹¹⁹ David Segal, ‘North Macedonia waits for Green Light, and a Lucrative High’ (the New York Times, March 2020) <<https://www.nytimes.com/2020/03/25/business/north-macedonia-marijuana.html/?2020-03-25T09%3A00%3A29%2000%3A00>> accessed 8 April 2020.

¹²⁰ ‘Law Proposal for the control of narcotic drugs and psychotropic substances’ (The Government of the Republic of North Macedonia, October 2019) <https://mjbizdaily.com/wp-content/uploads/2019/10/predlog_na_zakon_10102019.pdf> accessed 8 April 2020.

¹²¹ The Government of the Republic of North Macedonia (n 107).

¹²² Alfredo Pacual, ‘North Macedonia’s medical cannabis overhaul would allow flower exports – but also create entry hurdles’ (Marijuana Business; Daily International, March 2020) <<https://mjbizdaily.com/north-macedonias-medical-cannabis-overhaul-would-allow-flower-exports-but-also-create-entry-hurdles/>> accessed 8 April 2020.

The Netherlands

In 2018, the Netherlands placed third as the largest medical cannabis market in Europe. However, its medical marijuana system is the most expensive due to government providing no remuneration for medical marijuana.¹²³ Licenses are issued by the Office of Medical Cannabis (OMC).¹²⁴ The OMC is also responsible for maintaining its monopoly when it comes to supplying medical marijuana to pharmacies. It is also responsible for a number of products and services; it supplies medical marijuana to pharmacies and hospitals as well as to research facilities in the scientific field, and it is also responsible for allowing exemptions from the Opium Act. Most evident is that it issues licenses for importation and exportation of “*cannabis, cannabis extracts and cannabis resin*”¹²⁵ The OMC tightly regulates the cultivation and production of medical marijuana in the Netherlands by issuing tenders to cultivators in order to serve the Dutch Government.¹²⁶

For an applicant to acquire an importation license, one must fill an application form and forward it to the OMC, which will formulate a contract and an invoice for the transfer of the marijuana. The OMC will then apply to the Healthcare Inspectorate for the license which is sent to the business abroad. At that point the alien exporter can acquire an export license from the body eligible to provide such licenses. For an exportation license one requires the two importation licences of the company abroad (buying the marijuana) and the export license application form, which is to be forwarded to the OMC, which shall formulate a contract and an invoice. The OMC shall then demand the Healthcare Inspectorate for the license. Once the licenses are acquired, the exportation and importation take place via OMC. The applicant shall pay a fee for the license, contract, and delivery.¹²⁷

On the 13th of January 2019 a new Act, the ‘Controlled Cannabis Supply Chain Experiment Act’, was published and sent to the ministries and bodies responsible for the medical cannabis industry to implement the said act.¹²⁸ The ‘Controlled Cannabis Supply Chain Experiment Act’ regulates a systematic experiment for the cultivation and sale of cannabis for recreational use precisely that marijuana can be available in Dutch coffee shops. The act decriminalises marijuana for ‘coffeeshops’, but the latter must adhere to certain rules when it comes to selling marijuana. It shall be an experiment overseen by researchers who shall provide guidance and evaluation, meanwhile an independent advisory Committee shall provide recommendations on

¹²³ Alfredo Pascual, ‘Global Cannabis: The Netherlands’, (Marijuana Business Daily International, September 2019) <<https://mjbizdaily.com/global-cannabis-netherlands/>> accessed 8 April 2020.

¹²⁴ ‘Dutch Patients and Businesses’ (Ministry of Health, Welfare and Sport, 2019) <<https://english.cannabisbureau.nl/import-and-export/dutch-patients-and-businesses>> accessed 8 April 2020.

¹²⁵ Office of Medical Cannabis (Ministry of Health, Welfare and Sport, 2019) <<https://english.cannabisbureau.nl/>> accessed 8 April 2020.

¹²⁶ ‘OMC publishes tender for grower(s)’ (Ministry of Health, Welfare and Sport, March 2018) <<https://english.cannabisbureau.nl/latest/news/2018/02/01/omc-publishes-tender-for-growers>> accessed 8 April 2020.

¹²⁷ <https://english.cannabisbureau.nl/import-and-export/dutch-patients-and-businesses>

¹²⁸ ‘Controlled cannabis supply chain experiment’ (Government of the Netherlands, November 2019) <<https://www.government.nl/topics/drugs/controlled-cannabis-supply-chain-experiment>> accessed 8 April 2020.

the experiment and is responsible for keeping the Minister of Justice and the Minister for Healthcare updated as to how the system's implementation is developing.¹²⁹

New Zealand

In New Zealand, everything related to cultivating, manufacturing and supplying of medical marijuana requires acquiring a license issued by the Medicinal Cannabis Agency, as regulated by the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. There are 5 different activities which a certified license holder is able to conduct, depending on which specified areas of activities are permitted by the license. One may need more than one activity in order to operate a business, nevertheless an applicant would only need one license for all activities. The activities provided by the license are cultivation, nursery, research, possession for manufacture, and supply.¹³⁰ Medical marijuana licensees require an import or export license from the Medicines Control. One of the requirements is that from beforehand, one must have a certified medical marijuana license. Moreover, one must apply to the Medical Cannabis Agency to test any cannabis products which are intended for exportation.¹³¹ The Ministry of Health provides for a number of regulations which are found online, through which it provides for the requirements that anyone holding a medical marijuana license should abide by. These include the requirements for possessing the cannabis and/or the cannabis products in a secure way, and ensuring the quality and compatibility of the cannabis and its products by reaching the minimum quality standard.¹³² A new referendum is set to take place in September 2020 for the legalisation of recreational marijuana.¹³³

Peru

In November 2017, medical marijuana was legalized through Peru Law 30681. Until March 2018 no regulations were passed by the legislature, thus leaving both medical marijuana users and potential users in the grey as what is expected from them in order join the medical program, as well as businesses who want a license to cultivate, produce, and/or supply marijuana.¹³⁴ The licensing regulations were passed in February 2019 through Directive No 005-2019-IS, which established a registration system allowing the medical program to remain up to standard and

¹²⁹ 'Committees involved in the controlled cannabis supply chain experiment' (Government of the Netherlands) <<https://www.government.nl/topics/drugs/controlled-cannabis-supply-chain-experiment/committees-involved-in-the-controlled-cannabis-supply-chain-experiment>> accessed 8 April 2020.

¹³⁰ 'Medicinal Cannabis Agency - Licence activities' (Ministry of Health, April 2020) <<https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-industry/medicinal-cannabis-agency-licence-activities>> accessed 8 April 2020.

¹³¹ 'Medicinal Cannabis Agency - Importing and exporting' (Ministry of Health, April 2020) <<https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-industry/medicinal-cannabis-agency-working-medicinal-cannabis/medicinal-cannabis-agency-importing-and-exporting>> accessed 8 April 2020.

¹³² 'Medicinal Cannabis Agency - Advertising products' (Ministry of Health, April 2020) <<https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/medicinal-cannabis-agency-information-industry/medicinal-cannabis-agency-working-medicinal-cannabis/medicinal-cannabis-agency-advertising-products>> accessed 8 April 2020.

¹³³ Eleanor Ainge Roy, 'New Zealand passes laws to make medical marijuana widely available' (The Guardian, December 2018) <<https://www.theguardian.com/world/2018/dec/11/new-zealand-passes-laws-to-make-medical-marijuana-widely-available>> accessed 8 April 2020.

¹³⁴ Alexandra Hicks, 'Peru Medical Cannabis Regulations Announced' (CPD Testers, 2019) <('https://cbdtesters.co/2019/03/17/peru-medical-cannabis-regulations/)> accessed 8 April 2020.

reach its ultimate aim i.e. to provide the fundamental right to health.¹³⁵ Article 4 of the directive stipulates that a number of governmental agencies of the Ministry of Health and the Ministry of Agriculture, including the National Institute of Health (El Instituto Nacional de Salud), and the National Agrarian Health Service (El Servicio Nacional de Sanidad Agraria), are responsible to promulgating the regulation which establishes a number of licenses. Without these licenses, as stipulated in article 5, no research, production, importation, and/or marketing activities of Cannabis for medicinal use shall take place. The different licenses are for research, wholesale, importation and commercialisation, retail commercialisation, and production.¹³⁶

Poland

Medical marijuana was legalised in the year of 2017. Recreational use is still illegal however, the Polish authorities tolerate small amounts of possession. Domestic cultivation and/or production is illegal along with cultivation and production of cannabis for commercial and/or medical use.¹³⁷ Although, one may get a permit from the Poland State to cultivate hemp and poppies. Poland places no restrictions on these two plants, allowing individuals to take part in the operation of hemp and poppies which is an industry which is gradually growing. The purchase of the latter requires a permit from the State authorities however, there are no open applications whatsoever for a permission to cultivate cannabis per se, not even for medical use.

When it comes to medical marijuana, one must first acquire a permission from a doctor similar to getting a prescription like any other medicine, along with getting authorisation from the region's pharmaceutical inspector.¹³⁸ The legislature did not include a list of qualifications that a patient must have in order to be able to qualify for medical marijuana, due to establishing this step through research. Although not having a medical marijuana program, Polish authorities allow pharmacies and dispensaries to produce medicine from imported cannabis, which is quite a costly and slow process.¹³⁹

Portugal

By means of the decree-law No. 33/2018, of July 2018, the legislature adjusted the regulations on medical cannabis which brought about a broader industry for companies willing to invest in this industry.¹⁴⁰ This decree brought about a regulatory framework which was then further regulated through Decree-Law No. 8/2019, of January 2019 which provides for a “*normative framework*” regarding the prescription for patients, pharmacies and dispensaries, storage

¹³⁵ Alfredo Pasual, ‘Peru lays groundwork for commercial medical cannabis production, sales’ (Marijuana Business Daily International, February 2019) <<https://mjbizdaily.com/peru-lays-groundwork-for-commercial-medical-cannabis-production-sales/>> accessed 8 April 2020.

¹³⁶ ‘Normas Legales (Legal Rules)’ (State of Peru, February 2019) <<https://mjbizdaily.com/wp-content/uploads/2019/02/decreto-supremo-que-aprueba-el-reglamento-de-la-ley-n-30681-decreto-supremo-n-005-2019-sa-1744045-2-peru-cannabis-regulations.pdf>> accessed 8 April 2020.

¹³⁷ ‘Poland Legalizes Medical Cannabis | Leafly’ (Leafly, 2020) <<https://www.leafly.com/news/politics/poland-legalizes-medical-cannabis>> accessed 10 April 2020.

¹³⁸ ‘Poland Medical Marijuana Card & Program Information | Marijuana Doctors’ (Marijuana Doctors) <<https://www.marijuanadoctors.com/international-patients/poland-medical-marijuana-card/>> accessed 10 April 2020.

¹³⁹ ‘Poland Legalizes Medical Marijuana | High Times’ (High Times) <<https://hightimes.com/news/poland-legalizes-medical-marijuana/>> accessed 10 April 2020.

¹⁴⁰ (Mjbizdaily.com) <<https://mjbizdaily.com/wp-content/uploads/2018/06/pj1726-XIII-portugal.pdf>> accessed 10 April 2020.

(detention of the plant and its derivatives) and transport, scientific research, information to professionals, and any other activity involving the use of the cannabis plant for medicinal purposes. Article 3(4) provides that for an individual to be able to cultivate, manufacture, wholesale, import, export, and transit (deliver / transport), one must acquire an authorisation from INFARMED – National Authority of Medicines and Health Products, I.P through the online website. It is also stipulated that any of the latter activities (cultivation etc.) are not permitted for one's own personal use, (article 3(5)). INFARMED is a government agency within the Ministry of Health that deals with licenses and inspecting manufacturers, wholesalers, and pharmacies, as well as ensuring all that is stipulated in article 4, respects the rules in accordance with their operation: Good Manufacturing Practices (GMP's), Good Distribution Practices (GDP's) and Good Pharmacy Practices (GPP's). A discrepancy is found between the official website of INFARMED and in the decree, claiming that the latter agency shall also be responsible for cultivation and thus ensuring that the guidelines on Good Agricultural and Collection Practice (GACP) are followed.¹⁴¹

Sri Lanka

According to Sri Lanka's *'The Poisons, Opium and Dangerous Drugs Ordinance'* of 1935, cannabis is illegal. However, by means of the Ayurveda Act which amended certain provisions of the Ordinance, the use of cannabis in small portions is legal for medical use as prescribed by Ayurveda practitioners.¹⁴²¹⁴³ Up until a year ago, the drug used to be acquired through the black market, although the medicine is proven to be less effective due to the cannabis used would be old and starting to delipidate.¹⁴⁴ Therefore through the efforts of the Minister of Health, Nutrition, and Indigenous Medicine Senaratne, in 2018 the government announced to news portals that cultivation plans are under way so that Ayurvedic practitioners would be able to produce medicines using effective and high quality cannabis for all patients. In fact, the cultivation was planned to begin at the end of 2018. The Minister also exclaimed that the cannabis cultivated shall also be exported to U.S. Farmers for cultivation, which are to be hired by the State and the military would be responsible for inspecting the production. As quoted by the Minister: *"If the private sector is given the green light for cannabis cultivation it will require permits and other regulatory mechanisms will have to be imposed. This way, there will be no need to issue permits, since no private parties are involved."* However, all this does not seem to be accessible from the official state site.¹⁴⁵

¹⁴¹ 'About Infarmed' (*Infarmed.pt*) <<https://www.infarmed.pt/web/infarmed-en/about-infarmed>> accessed 10 April 2020.

¹⁴² (*Nddcb.gov.lk*) <<http://www.nddcb.gov.lk/Docs/acts/25345.pdf>> accessed 10 April 2020.

¹⁴³ <<https://www.lawnet.gov.lk/1946/12/31/ayurveda-4/>> accessed 10 April 2020.

¹⁴⁴ 'Cannabis In Sri Lanka – Laws, Use, Attitudes And Other Info' (*Sensi Seeds*) <<https://sensiseeds.com/en/blog/countries/cannabis-in-sri-lanka-laws-use-history/>> accessed 10 April 2020.

¹⁴⁵ 'Sri Lanka To Open South Asia's First Medical Cannabis Plantation' (*TalkingDrugs*) <<https://www.talkingdrugs.org/sri-lanka-asia-first-cannabis-plantation>> accessed 10 April 2020.

Thailand

The 2019 Narcotics Act B.E.2562 amended the Narcotics Act of 1979, when it was passed by the National Legislative Assembly¹⁴⁶ in order to completely legalise medical marijuana. The legislation provides for 5 categories of drugs and narcotics where the issuing of licenses shall be done by the Food and Drug Administration (FDA) as the licensing authority.¹⁴⁷ Section 26(2) stipulates that the production, import, and export of cannabis shall be allowed for officials, medical benefits, treating patients, anything related to research and development, agricultural reasons, commercial reasons, scientific benefits, and for industrial reasons when it regards medical benefits. The FDA, as stipulated in section 26(5), shall only issue a license for production, importation, exportation, distribution or possession if the applicant for the license is a government department for research and testing of medical cannabis, pharmaceuticals and pharmacies, science departments, agriculture, medical and scientific services, the Thai Red Cross, and the Resolution on narcotic problems.¹⁴⁸ The Narcotic Control Board as established in the Narcotics Act B.E. 2522, shall keep its supervisory role over the FDA (just as it did over the Ministry) (as seen majorly in section 13 of the previously non-amended act), however as amended by the legislature, the Board shall have more members to broaden the membership from only law-enforcement to members specialising in agricultural, medicinal, and scientific sections.¹⁴⁹

United Kingdom

Medical marijuana was legalised in 2018 in an older version of the act as enacted by Parliament, stipulating that a patient shall acquire medical cannabis by first obtaining a special license from the Home Secretary for researchers. Although this was overturned when the legislature decided to loosen up the provisions of the act and thus making medical marijuana as broad and efficient as possible.¹⁵⁰ Drug licensing in the UK is brought about by the different issued licenses: domestic licensing, industrial hemp, import and export licensing, and personal fees.¹⁵¹

Uruguay

Uruguay was the first country to fully legalise marijuana; industrial, recreational, and medical in 2013 outside of the U.S. Nevertheless, implementation has been so deliberately slow, that

¹⁴⁶ 'Thailand's New Medical Marijuana Laws Described In Detail, How Foreigners Fit In - The Pattaya News' (*The Pattaya News*) <<https://thepattayanews.com/2019/01/24/thailands-new-medical-marijuana-laws-described-in-detail-how-foreigners-fit-in/>> accessed 10 April 2020.

¹⁴⁷ 'Narcotics Act B.E. 2522 (1979) - Thailawonline' (*Thailawonline.com*) <<https://thailawonline.com/en/thai-laws/laws-of-thailand/135-narcotics-act-be-2522-1979>> accessed 10 April 2020.

¹⁴⁸ Translation/Summary 2019, 'Translation/Summary Of NARCOTIC ACT. (ISSUE 7) BE. 2562 Published 17Th February 2019' (*Elevated Estate*) <<https://elevatedestate.asia/translation-summary-of-narcotic-act-issue-7-be-2562-published-17th-february-2019/>> accessed 10 April 2020.

¹⁴⁹ 'Thai Law: Foreigners And The Medical Marijuana Law, Explained' (*Khaosod English*) <<https://www.khaosodenglish.com/news/business/2019/01/24/thai-law-foreigners-and-the-medical-marijuana-law-explained/>> accessed 10 April 2020.

¹⁵⁰ 'United Kingdom Legalizes Medical Cannabis Prescriptions' (*Marijuana Business Daily*) <<https://mjbizdaily.com/united-kingdom-legalizes-medical-cannabis-prescriptions/>> accessed 10 April 2020.

¹⁵¹ 'Drugs Licensing' (*GOV.UK*) <<https://www.gov.uk/government/collections/drugs-licensing>> accessed 10 April 2020.

the areas of licensing were not fully implemented until 2017. There are three ways in which one can access the substance. Firstly, individuals can purchase from licensed pharmacies which provide the cannabis cultivated by marijuana cultivators.¹⁵²¹⁵³ For a pharmacy to acquire marijuana, for multiple uses, registration through the offices of the Uruguayan Post is a must.¹⁵⁴ Secondly, adults can apply to be home-cultivators of cannabis which may be consumed by the applicant alone or by the people living in the household. Lastly, adults may join what are called ‘Cannabis Clubs’ which are non-profit organisations where cannabis is cultivated by a group of persons and it is only accessible to that group of persons.¹⁵⁵ The IRCCA issues licenses for scientific research (both those financed by a private sector and even those funded publicly), cultivation of crops for medical users, industrialisation and commercialisation of cannabis, and cannabis for transit.¹⁵⁶ These regulations establish that medical users and recreational users shall both be able to acquire cannabis and cannabis products from pharmacies. However, in order to distinguish the two process and to encourage the separation of medical marijuana from recreational marijuana, as well decreasing the recreational users from abusing from the medical marijuana products, medical users shall have to present a prescription for a general practitioner every 30 days.¹⁵⁷

Are there any restrictions with regards to THC levels?

Israel

With regards to Israel, the Green Book gives meticulous detail to the doctors prescribing medical cannabis. It provides doctors with information on the effects of the medicine, how they should be administered, and also the potency they should have. In general, there is no capping for the THC or CBD levels nevertheless, as provided by the Ministry of Health, these usually do not exceed 20% and 24% respectively. Nevertheless, medicines are balanced in a way that if a medicine is rich in THC, CBD is lowered coherently and vice versa. A medicine may also be balanced in a way that the percentage of CBD equals the percentage of THC; this depends on the product whether efflorescence, oil of cookies.¹⁵⁸

United States of America

Potency allowed at the moment (some have already started the process to make more comprehensive medical marijuana laws)

¹⁵² (Wola.org) <<https://www.wola.org/wp-content/uploads/2016/09/Getting-Regulation-Right-WOLA-Uruguay.pdf>> accessed 10 April 2020.

¹⁵³ 'Cultivadores Domésticos | Ircca | Instituto De Regulación Y Control Del Cannabis' (*Ircca.gub.uy*) <<https://www.ircca.gub.uy/cultivo-domestico/>> accessed 10 April 2020.

¹⁵⁴ 'Adquirentes En Farmacias | Ircca | Instituto De Regulación Y Control Del Cannabis' (*Ircca.gub.uy*) <<https://www.ircca.gub.uy/adquirentes/>> accessed 10 April 2020.

¹⁵⁵ 'Clubes De Membresía | Ircca | Instituto De Regulación Y Control Del Cannabis' (*Ircca.gub.uy*) <<https://www.ircca.gub.uy/clubes-membresia/>> accessed 10 April 2020. (n.2)

¹⁵⁶ 'Proyectos Cannabis | Ircca | Instituto De Regulación Y Control Del Cannabis' (*Ircca.gub.uy*) <<https://www.ircca.gub.uy/proyectos-cannabis/>> accessed 10 April 2020.

¹⁵⁷ (Wola.org) <<https://www.wola.org/wp-content/uploads/2016/09/Getting-Regulation-Right-WOLA-Uruguay.pdf>> accessed 10 April 2020.

¹⁵⁸ Mgr. Yuval Landschaft, Boaz Albo (M.Sc.), Prof. Rafael Mechoulam, Prof. Arnon Afek, ‘Medical Grade Cannabis Clinical Guide IMC-GCP (Green book)’ (Ministry of Health, State of Israel, January 2017) <www.docdroid.net/E2wicok/20180105142901-watermark-watermark-pdf> accessed 10 April 2020.

States to enact effective medical marijuana laws¹⁵⁹

Alabama	Extracts that are low THC (below 3%) THC
Georgia	Cannabis oils with low THC (below 5%) THC and at least an equal amount of CDB.
Indiana	At least 5 percent CBD by weight. No more than .3 percent THC by weight.
Iowa	Less than 3 percent THC
Kansas	
Kentucky	Only "cannabidiol".
Mississippi	"CBD oil" - more than 15% or at least 50mg CBD but not more than one-half of one percent (0.5%) of tetrahydrocannabinol (THC)
North Carolina	"Hemp extracts" with less than 0.9% THC and at least 5% CBD.
South Carolina	Cannabidiol or derivative of marijuana that contains 0.9% THC and over 15% CBD, or least 98% CBD and not more than 0.90% THC.
Tennessee	"Cannabis oil" with less than 9% THC.
Wisconsin	possession of "cannabidiol in a form without a psychoactive effect." THC or CBD levels are not defined.

States with limited access medical marijuana laws¹⁶⁰

Idaho	no more than 0.3% THC and at least 15 times more CBD than THC and no other psychoactive substance.
Texas	Low-THC Cannabis - not more than 0.5% THC.
Virginia	Cannabis oils with at least 15% CBD or THC-A and no more than 5% THC.
Wyoming	"Hemp extracts" with less than 0.3% THC and at least 5% CBD by weight.

States with Comprehensive Medical Marijuana Laws

California	Industrial hemp shall consist of <i>"no more than three-tenths of 1 percent tetrahydrocannabinol (THC)"</i> . ¹⁶¹
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¹⁵⁹ State Medical Marijuana Laws' (National Conference of State Legislatures, March 2020)

<<https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>> accessed 10 April 2020.

¹⁶⁰ National Conference of State Legislatures (n145).

¹⁶¹ 'Health and Safety Code; Division 10; Chapter 1;11018.5.' (California Legislative Information, 1996)

<https://leginfo.ca.gov/faces/codes_displaySection.xhtml?sectionNum=11362.5.&lawCode=HSC> accessed 10 April 2020.

	<p>Edible cannabis products shall no contain more than 10 mg THC per serving and 100mg THC per package.</p> <p><i>“THC Concentration Limits. (a) An edible cannabis product shall not contain more than: (1) 10 milligrams THC per serving; and (2) 100 milligrams THC per package. (b) Notwithstanding subsection (a), a package containing an edible product that is an orally-dissolving product, such as sublingual lozenges or mouth strips, may contain up to 500 milligrams THC per package, if: (1) The cannabis product consists of discrete servings of no more than 10 milligrams THC per piece; (2) The cannabis product is labeled “FOR MEDICAL USE ONLY;” and (3) The cannabis product is only available for sale to a medicinal-use customer. (c) A topical cannabis product or a cannabis concentrate shall not contain more than 1,000 milligrams THC per package. (d) Notwithstanding subsection (c), a topical cannabis product or a cannabis concentrate may contain more than 1,000 milligrams THC per package, but not more than 2,000 milligrams THC per package, if the product is labeled “FOR MEDICAL USE ONLY” and is only available for sale to a medicinal-use customer.”</i>¹⁶²</p>
<p>Nevada</p>	<p>Edible marijuana products and marijuana-infused products shall “not exceed 10,000 milligrams of THC per patient per 14-day period” AND “is equivalent to 2 1/2 ounces of usable marijuana”.</p> <p><i>“Maximum allowable quantity of edible marijuana products and marijuana-infused products. (NRS 453A.370) For the purposes of subparagraph (3) of paragraph (b) of subsection 3 of <u>NRS 453A.200</u>, the maximum allowable quantity of edible marijuana products and marijuana-infused products is an amount that:</i></p> <ol style="list-style-type: none"> <i>1. Is equivalent to 2 1/2 ounces of usable marijuana; and</i>

¹⁶² California Code of Regulations; Title 17; Division 1; Chapter 13; Subchapter 1; Article 2; §40315 (State of California,

	2. Does not exceed 10,000 milligrams of THC per patient per 14-day period.” ¹⁶³
Alaska	Edibles can have no more than 5 mg THC per serving and units with multiple servings must not exceed more than 10 single serve units. ¹⁶⁴

Arizona, Arkansas, Colorado, Connecticut, Delaware, DC, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Missouri, Nevada, New Hampshire, New Jersey, North Dakota, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Washington and West Virginia.

Other states THC concentration limits

Luxembourg	<p>Industrial hemp – THC rate below 0.3%</p> <p>Medical marijuana shall contain defiant levels of THC and CBD.</p> <p>Sativex is the only cannabinoid-drug allowed.¹⁶⁵</p> <p>Medicines with a Marketing Authorisation.</p> <p>Cannabis oil was not available until September 2019 was not available in Luxembourg.¹⁶⁶</p> <p>Potency registered in Luxembourg (Min and Max):</p> <p>Herbal – 0.3-23.8% THC</p> <p>Resin – 0-34.9% THC¹⁶⁷</p>
Republic of North Macedonia	Equal to or less than 0.2% THC concentrations. ¹⁶⁸

¹⁶³ NAC 453A.704

¹⁶⁴ ‘Marijuana Use and Public Health in Alaska’ (Alaska Department of Health and Social Services, 2020) <http://dhss.alaska.gov/dph/Director/Documents/marijuana/MarijuanaUse_PublicHealth_Alaska_2020.pdf> accessed 8 April 2020.

¹⁶⁵ ‘Cannabis Medicinal’ (Authorise au Luxembourg, Government of Luxembourg, September 2019) <<https://sante.public.lu/fr/publications/c/cannabis-produits-derives-du-cannabis-et-du-chanvre-fr/cannabis-produits-derives-du-cannabis-et-du-chanvre-fr.pdf>> accessed 10 April 2020.

¹⁶⁶ ‘Cannabis Medicinal’ (Authorise au Luxembourg, Government of Luxembourg, September 2019) <<https://sante.public.lu/fr/publications/c/cannabis-medicinal-comment-acceder-fr/cannabis-comment-acceder-cannabis-medicinal.pdf>> accessed 10 April 2020.

¹⁶⁷ ‘Luxembourg – Country Drug Report 2018’ (European Monitoring Centre for Drugs and Drug Addiction, 2018) <http://www.emcdda.europa.eu/countries/drug-reports/2018/luxembourg/key-statistics_en> accessed 10 April 2020.

¹⁶⁸ ‘Law Proposal for the control of narcotic drugs and psychotropic substances’ (The Government of the Republic of North Macedonia, October 2019) <https://mjbizdaily.com/wp-content/uploads/2019/10/predlog_na_zakon_10102019.pdf> accessed 10 April 2020.

	<i>"Hemp Seed Oil"</i> - does not contain more than 10 mg / kg of tetrahydrocannabinol (THC).
The Netherlands	<p>Medical Marijuana</p> <ul style="list-style-type: none"> - maximum 22% and minimum less than 1% THC. - maximum 9% and minimum less than 1% CBD. <p>CBD Oil with or without THC available in pharmacies. ¹⁶⁹</p>
New Zealand	<p><i>CBD product – contains THC (or specified substances) not more than 2% of the sum of THC (or specified substances) and CBD</i></p> <p><i>“CBD product means a product that—</i></p> <p><i>(a) contains cannabidiol; and</i></p> <p><i>(b) either—</i></p> <p><i>(i) does not contain a specified substance; or</i></p> <p><i>(ii) contains specified substances in an amount that is no more than 2% of the sum of the amount of cannabidiol and the number of specified substances in the product; and</i></p> <p><i>(c) does not contain any other controlled drug; and</i></p> <p><i>(d) does not contain any other psychoactive substance (as defined in section 9 of the Psychoactive Substances Act 2013).”¹⁷⁰</i></p>
Peru	<p>“Cannabis Plant: All herbaceous plants of the Cannabis genus. It is divided into two (2) varieties according to the following classification for regulatory purposes.</p> <p>a) Psychoactive cannabis: tops, flowery or with fruit, from the Cannabis plant (except for the seeds and leaves not attached to the tops) of the which resin has not been removed, whatever the name by which they are designated, whose delta content 9-</p>

¹⁶⁹ ‘Medical Cannabis; Information Brochure for Patients’ (Ministry of Health, Welfare and Sport, June 2019) <<https://english.cannabisbureau.nl/medicinal-cannabis/documents/circulars/2018/02/20/patients-guide-medicinal-cannabis>> accessed 10 April 2020.

¹⁷⁰ Misuse of Drugs Act 1975; Article 2A(1) (New Zealand Legislation, 2018) <http://www.legislation.govt.nz/act/public/1975/0116/latest/LMS148483.html?search=ts_act%40bill%40regulation%40deemedreg_misuse+of+drugs+act_resele_25_a&p=1#LMS148483> accesses 10 April 2020.

	<p><i>tetrahydrocannabinol (THC) is equal to or greater than 1% in dry weight, and which are used for medicinal purposes and therapeutic, as palliative therapy for some psychoactive cannabis smoker. It is part of the process of audit in these regulations with the name from “Cannabis for medicinal use”.</i></p> <p><i>b) Non-psychoactive cannabis: The Cannabis plant, and any part of said plant, the content of delta-9-tetrahydrocannabinol (THC) is less than 1% in dry weight. Non-psychoactive cannabis, its parts and its derivatives, are uncontrolled substances, and therefore are excluded from the Narcotics Regulation, Psychotropic and other Controlled Substances Sanitary, approved with Supreme Decree No. 023-2001-SA. In these regulations called like "hemp" or "hemp.”¹⁷¹</i></p>
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¹⁷¹ ‘Normas Legales (Legal Rules)’ (State of Peru, February 2019) <<https://mjbizdaily.com/wp-content/uploads/2019/02/decreto-supremo-que-aprueba-el-reglamento-de-la-ley-n-30681-decreto-supremo-n-005-2019-sa-1744045-2-peru-cannabis-regulations.pdf>> accessed 8 April 2020.

Importation and wholesale distribution in Malta

There is a rather rigorous process for these medical products to reach our islands. First and foremost, any activity in relation to the production of cannabis whether for medicinal and/or research purposes requires a Letter of Intent (LOI) from Malta Enterprise, followed by, an application through the common EU Submission Portal to the Medicines Authority and for eligibility review. This application regarding the importation and/or wholesale distribution of cannabis-based products or synthetic cannabinoid products, in accordance with the Medicines Act and the Drug Dependence (Treatment not Imprisonment, Act) form is made available online. Once deemed eligible, one would obtain the required license to become a wholesale dealer or licensed manufacturer.¹⁷² The Medicines Authority's product review procedure considers a range of stipulations before approving a product for the local market. A GMP certification, along with various analytical parameters, stability data and labelling are required. With regards to the label, a serialized tamper-evident label is to be issued for each individual patient pack, sustaining traceability of the products through the controlled supply chain.¹⁷³ Moreover, both the facilities in Malta and third country sites, forming part of the local manufacturer's plans are to be thoroughly and regularly inspected by the Inspectorate and Enforcement Directorate within the Medicines Authority through EU-GMP inspections. Despite this rigorous process, it is very similar to the one used in the pharmaceutical industry.

Malta upon opening its shores to the Medical Marijuana market, Maltese pharmaceutical companies managed to import and distribute a total of 3.55 kilograms of medical cannabis. In 2018, our main importers were 'Cherubino' who imported from Aurora's German subsidiary 'Pedanios' and 'PharmaMT' who from their end imported from 'Bedrocan', through the Office of Medical Cannabis of the Republic of Netherlands¹⁷⁴. One can still find the same medical cannabis products in Malta, without any relatively huge changes, and the main distributed medicines are; Bedrocan (22% THC), Bediol (6.3% THC, 8% CBD), Pedanios (22% THC) and Pedianos (20% THC).¹⁷⁵ All of these four products are mostly comprised of THC and hence are not as effective in pain alleviating as they lack the vital component, CBD. Unfortunately, CBD oil is still unattainable from all local pharmacies. Moreover, CBD-only preparations have not been approved by the Medicines Authority and patients have resulted to purchasing CBD oil from the black market. This poses a high risk of obtaining products of an inferior quality. Patients in a number of countries which are undergoing some form of medical treatment, are legally encouraged to attain medical cannabis originating within the EU when shopping online. Although, one must have a doctor's prescription illicitly claiming that it is for their own personal use.¹⁷⁶

¹⁷² < <https://www.servizz.gov.mt/en/Pages/Health-and-Community-Care/Health/Medicines/WEB2241/default.aspx>

Accessed on 18 August 2020

¹⁷³ Medical Cannabis Network, 'Medicines Authority Malta: cannabis for medicine and research' (2020) <<https://www.healtheuropa.eu/medicines-authority-malta-cannabis-for-medicine-and-research/97401/>>

¹⁷⁴ Alfredo Pascual, 'Future Exporters in Marijuana Business daily' (2019)

<https://mjbizdaily.com/wp-content/uploads/2019/04/Medical-Cannabis-in-Europe-Report_FINAL_REV2.pdf>
Accessed on 18 August 2020

¹⁷⁵ Medical Cannabis Network, 'Policy, Accessibility, and Human Rights in Malta' (2020) <<https://www.healtheuropa.eu/policy-accessibility-and-human-rights-in-malta/101059/>>
Accessed on 18 August 2020

¹⁷⁶ Medical Cannabis Network, 'Medicines Authority Malta: cannabis for medicine and research' (2020) <<https://www.healtheuropa.eu/medicines-authority-malta-cannabis-for-medicine-and-research/97401/>>

Towards a European Common Market

Each country has a highly distinct framework which creates a sort of vagueness and confusion at the European Level, hence why the European Union aims to try to harmonize the importation and wholesale distribution procedures. This concept was pushed forward by the European Union Parliament, which passed a resolution towards the European Commission in order to promote co-operation within the member states as well as within the World Health Organization. If this were to work out, according to Article 14 of the resolution in question, one would call *“on the commission to work with Member States to ensure that safe and controlled cannabis used for medical purposes can only be in the form of cannabis-derived products that have gone through clinical trials, regulatory assessment and approval.”* This would mean that up until further notice only Sativex and Canemes would be authorised to be imported to Malta.

The Process of obtaining Medical Cannabinoid Products

Eligibility

With the introduction of Chapter 578 of The Laws of Malta¹⁷⁷, pharmacies are legally allowed to dispense government sanctioned cannabis on a prescription basis. However, this is only on a case-by-case basis, such as those patients suffering from Fibromyalgia¹⁷⁸, or any other chronic condition for which they have tried at least one medication which has not relieved them or caused side effects. Hence, the first step to be able to purchase this form of medication is to check whether one qualifies for it. Initially, three conditions were approved of; (i) chronic pain, (ii) spasticity in multiple sclerosis and (iii) side effects of chemotherapy¹⁷⁹. In 2018, government had planned to issue an in-depth qualification manual for individuals who are eligible, yet to date there is no information with regards to eligibility. Doctors are obliged to follow the government's guidebook, explaining which patients they believe will benefit from this form of medication¹⁸⁰. Moreover, back in 2018, patients seeking to obtain medical marijuana could only do so by visiting a government-approved physician to receive a prescription for Sativex¹⁸¹. With recent amendments in place, patients can now opt for a prescription from their general practitioner as long as they are registered with Malta's Medical Council.

Prescription

Multiple different factors come into play with regards to medical marijuana. Article 10 of the Drug Dependence act deals with the prescription of medical cannabis which can only be given by any licensed medical practitioner registered with Malta's Medical Council, who is entitled to "prescribe to patients medicinal preparations of the plant cannabis and synthetic Cannabinoid products¹⁸²". However, the prescription for medical preparations which is listed under the Medicines Act, is only the first step in the lengthily process to purchase this medication. Firstly, the prescription is only given as a measure of last resort and only when there are "no other viable alternatives to such prescription", as marijuana products cannot be used as first line treatments. Any licensed medical practitioner is required to send a request to the Superintendent for Public Health (SPH), citing the specific illness or condition, as only stating that one suffers from chronic pain alone does not suffice¹⁸³. Following this request, the outcome will then be communicated back to the medical practitioner. If the application is not approved, the applicant will be notified stating the reasons why his/her application was

¹⁷⁷ 'Production of Cannabis for Medicinal and Research Purposes Act', Chapter 578, Laws of Malta

¹⁷⁸ 'Fibromyalgia' (The Pain Clinic) < <http://www.painclinic.com.mt/fibromyalgia/> > Accessed 28th March 2020

¹⁷⁹ 'Malta has officially legalised medical cannabis' (Malta Today) < https://www.maltatoday.com.mt/news/national/85616/malta_has_officially_legalised_medical_cannabis#.XoTDHNMzZhE > Accessed 28th March 2020

¹⁸⁰ Daily CBD by Lubiano Katrina, <<https://dailycbd.com/en/malta/>> Accessed 28th March 2020

¹⁸¹ 'Qualifying for Medical Marijuana in Malta' (Marijuana Doctors A new kind of HealthCare) < <https://www.marijuanadoctors.com/international-patients/malta-qualifications/> > Accessed 28th March 2020

¹⁸² 'Drug Dependence Act', chapter 573, Laws of Malta

¹⁸³ 'Medical Cannabis Laws of Malta' (Nexia BT) < <https://www.nexiabt.com/insights/medical-cannabis-laws-of-malta> > Accessed 29th March 2020

refused¹⁸⁴. If approved, the medical practitioner is then required to fill in the relevant prescription and the control card for narcotic and psychotropic drugs¹⁸⁵. Upon purchasing medication, without the presentation of a control card, one would not be allowed to purchase. The patient would then have to show these papers for further prescriptions and to a pharmacist for dispensing; (i) a valid prescription from a doctor, (ii) a control card, (iii) the application form endorsed by the SPH. These papers deem a person eligible to purchase medical marijuana.

Dispensing

After obtaining the above-mentioned documents, one can obtain the medication from a licensed pharmacy as stipulated in article 10(5) of the Drugs Ordinance. Medical Cannabinoid products can be dispensed by any pharmacy, upon the presentation of the SPH approved application, the prescription, and a control card. Every patient's details, date, product dispensed, dose, and the details of the prescribing doctor are to be kept by the pharmacist in the dispensing register. To date, patients receiving this form of medical treatment are only allowed to purchase commercially produced preparations of medicinal cannabis from a pharmacy and personal cultivation of marijuana remains illegal.

Choice of Medical Cannabinoid

Normally a CBD-only preparation is prescribed¹⁸⁶, however one may also opt for a prescription containing THC (tetrahydrocannabinol), by starting at the lowest dosage and increased proportionately until an appropriate therapeutic effect is ultimately reached. Even so, THC is a compound containing a high abuse potential and with the likelihood of producing serious side effects thus a prescription is not easily obtained. Various restrictive measures have had to be taken to exclude certain individuals from using this drug. Following a decision taken in 2019, among the Medicines Authority, the SPH, psychiatrists, and the police department, persons (i) having ongoing problems with the police, (ii) have detoxed at some point in their lives,¹⁸⁷ and (iii) individuals who work as drivers are not allowed to legally obtain THC in Malta¹⁸⁸. Moreover, individuals who have been previously under the care of a psychiatrist, need to be reviewed again prior to applying for this treatment.

Preceding the introduction of Chapter 578, in 2015, Malta had already a medical marijuana program in place. Patients were able to visit a government-approved physician to receive a prescription for Sativex. Sativex (Nabixmols) is an oromucosal spray which is an approved

¹⁸⁴ 'Standard Operating Procedure to authorise prescription and dispensing of Medical Cannabinoid Preparations' (Health.gov.mt) < https://deputyprimeminister.gov.mt/en/Pharmaceutical-Unit/Documents/Medical_Cannabinoid_Information/Standard_Operating_Procedure_to_Authorise_Prescription_and_Dispensing_of_Medical_Cannabinoid_Preparations.pdf > Accessed 30th March 2020

¹⁸⁵ 'MedicalCannabinoids Information' (Health.gov.mt) < https://deputyprimeminister.gov.mt/en/Pharmaceutical-Unit/Documents/Circulars/SPH_Circular_2-2018.pdf > Accessed 30th March 2020

¹⁸⁶ 'Cannabis as Medicine' (The Pain Clinic) < <http://www.painclinic.com.mt/cannabis-as-medicine/> > accessed 1st April 2020

¹⁸⁷ 'Maltese Patients denied medical Cannabis-because of rehab 10 years ago' (The Leaf Desk) < <https://theleafdesk.com/maltese-patients-denied-medical-cannabis-because-of-rehab-10-years-ago/> > Accessed 29th March 2020

¹⁸⁸ 'Prescribing THC' (The Pain Clinic) < <http://www.painclinic.com.mt/thc/> > Accessed 29th March 2020

treatment of neurotic pain, as well as any other underlying conditions¹⁸⁹. It is a cannabis-based extract containing 2.7mg THC and 2.5mg CBD per spray. Due to the requirement of certain high doses, and the price ranges up to € 500 per 10ml, patients favour other therapeutic options and thus no patient has opted to participate in this programme. The introduction of chapter 578 and certain amendments, allowed pharmacies in Malta to stock other alternatives of cannabinoids. The first pharmacy in Malta to stock this form of medication was ‘Verdala Pharmacies’ in Cospicua, which started stocking two choices of strains of cannabis flowers produced by the German Pedanios brand. Medicines, Sativa and Indica are both high in THC and low in CBD, (i) Sativa containing 22% THC and the (ii) Indica containing 20% THC and 1% CBD¹⁹⁰. These two strains amounted to approximately € 15-17 a gram¹⁹¹, which as of yet are more or less the same prices as per gram. Presently, there are four varieties of dried cannabis flowers in Malta; Pedanios 22/1 Sativa, Pedanios 20/1 Indica, Bedrocan 22/1 Sativa and Bediol containing 6% THC and 8% CBD¹⁹². THC is contraindicated in patients with a history of psychotic disorders; thus, restrictions have been taken. As of yet, no restrictive measures have been taken with regards to the percentage of concentration of THC. In foreign countries, efforts to limit the THC content in the flower have been taken in the states of Missouri and Colorado¹⁹³. Florida’s House Health and Human Services Committee, last October aimed to cap THC in medical cannabis to 10% or less for patients under the age of 21¹⁹⁴. In addition, law makers in Arizona introduced a bill in February 2020¹⁹⁵ which would potentially limit THC content to 2%. However, a week following the ballot referral with a five to four vote to advance the bill, the Republican House Speaker Rusty Bowers agreed to get rid of the 2% cap¹⁹⁶. It can be said that limiting the THC potency in medical cannabis is a global concern which some states have already tried to introduce in their respective jurisdictions. In light of this, Malta as of yet, has not taken any legal steps in controlling the concentration levels of THC.

Present Issues

Certain lacunae in our law still remain, with regards to preparation of the medicines. Firstly, present legislation does not have a specific manual indicating who qualifies for such treatment as it all depends on the medical practitioner’s report and approval of the Health Superintendent, if a doctor willingly fills in your prescription as some doctors are still hesitant to prescribe this

¹⁸⁹ ‘Malta has officially legalised medical cannabis’ (Malta Today) <

https://www.maltatoday.com.mt/news/national/85616/malta_has_officially_legalised_medical_cannabis#.XoTDHNMzZhE> Accessed 28th March 2020 (n.2)

¹⁹⁰ Cilia J, ‘Medical Cannabis Is Finally Available in Maltese Pharmacies’ (Lovinmalta.com) <<https://lovinmalta.com/lifestyle/health/medical-cannabis-is-finally-available-in-maltese-pharmacies/>> accessed 1st April 2020.

¹⁹¹ ‘Cannabis Patients Being Left High and Dry’ (Times of Malta) <<https://timesofmalta.com/articles/view/cannabis-patients-being-left-high-and-dry.696543>> accessed 1st April 2020.

¹⁹² ‘Prescribing THC’ (The Pain Clinic) < <http://www.painclinic.com.mt/thc/>> Accessed 1st April

¹⁹³ Elizabeth Stuyt, ‘The Problem With The Current High Potency THC Marijuana From The Perspective Of An Addiction Psychiatrist’ [2018] The Journal of Missouri state Medical Association <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6312155/>> accessed 2nd April 2020.

¹⁹⁴ Jeff Smith, ‘Marijuana Firms Fight Efforts To Limit THC Levels In Flower’ (Marijuana Business Daily, 6th March 2020) <<https://mjbizdaily.com/marijuana-firms-fight-efforts-to-limit-thc-levels-in-flower/>> accessed 2nd April 2020.

¹⁹⁵ Enacting and ordering the submission to the people of a measure relating to medical marijuana, H.R. (HCR 2045) (2020) < <https://www.azleg.gov/legtext/54leg/2r/bills/hcr2045p.pdf>> Accessed 2nd April 2020

¹⁹⁶ Jeff Smith, ‘Marijuana Firms Fight Efforts To Limit THC Levels In Flower’ (Marijuana Business Daily, 6th March 2020) <<https://mjbizdaily.com/marijuana-firms-fight-efforts-to-limit-thc-levels-in-flower/>> accessed 2nd April 2020.

form of medication. According to the official medical cannabinoid application form, full responsibility is placed upon the medical practitioner for the “prescribing, monitoring and the use of the product by the patient¹⁹⁷. The first Medical Cannabis World summit held in November 2019¹⁹⁸, with a second summit scheduled to take place in November 2020. The summits offer the chance for patients, doctors and relevant individuals in the sector to appreciate the health benefits this medication provides. Other issues relate to cost. Prices prove to be a barrier for patients who are financially unable to keep up with such expenses on a long-term basis. As stated previously, government sanctioned cannabis can cost around € 15-17 per gram, whilst cheaper options can be found through the black market¹⁹⁹. However, buying cannabis through the black market, besides being illegal, is extremely dangerous as one would not know what chemical substances are present in the product. These costs add up to the initial assessment, application costs, follow up consultations, renewal applications, which have to be undergone. Also, patients do not have the option of accessing CBD products online, which could cost less than what is being sold at local pharmacies. Moreover, the importation of CBD products online may also provide for a wider choice of strains.

As this type of medication is still novel, the majority of certified practitioners are still reluctant to issue prescriptions, thus the issue of stigma surely needs to be dealt with further. Undoubtedly, the first step towards aiding individuals who require such medication has been taken but further measures have to be implemented so as to address legal and social issues.

¹⁹⁷ ‘Medical Cannabinoids Information’ (Health.gov.mt) <https://deputyprimeminister.gov.mt/en/Pharmaceutical-Unit/Documents/Application_Forms/Request_for_Approval_for_Prescribing_of_Medical_Cannabinoid_by_a_Licensed_Medical_Practitioner.pdf> Accessed 2nd April 2020.

¹⁹⁸ ‘Medical Cannabiz World 2020’ (Medical Cannabiz World) <<https://cannabizsummit.world/>> Accessed 3rd April 2020

¹⁹⁹ ‘Serious lack of information on medical marijuana in the medical profession’ (Times of Malta) <<https://timesofmalta.com/articles/view/serious-lack-of-information-on-medical-marijuana-in-the-medical.696237>> Accessed 3rd April 2020.

Research and Recommendations

An issue explored throughout the Paper is market shortages. Cannabis Advocacy Group, ReLeaf Malta, have often highlighted a current shortage in medicinal marijuana brands, Bedrocan and Pedanois. For context, these two brands are potent brands of medicinal cannabis, whose THC content is at 22%. The main reason for such shortages is a delay in the renewal processes for licenses to import such medicinal cannabis. The issue lies in the fact that once importers obtain these licenses, patients have to wait roughly three weeks until the licenses are renewed and the final product reaches Malta.

Many resort to purchasing from the Black Market, but the shortage has reached such a dire state, where even the Black Market is short of supply, emphasising how broken the current system is. ReLeaf are currently calling for more accessible prices and better availability in order to prevent a similar situation from arising again. Another issue that needs to be addressed is the lack of diversified medicinal marijuana products in Malta. Malta has recently issued its first license for production of medicinal cannabis to a Canadian company known as Aphria. Although this is a crucial step forward towards a more diversified market, there is more room for growth in Malta's medical marijuana market which could even prove to aid Malta's economy by exporting its medicinal products.

Thus, the first recommendation would be re-evaluating and possibly amending the licensing process in a way where obtaining the renewal is shorter. The law as it stands in the Production of Cannabis for Medicinal Purposes Act, does not specify a specific process for renewal, thus leading one to the assumption that the licensing process for the renewal is the same as the first-time application which is rather cumbersome and tedious. By including a provision within the law, provides for a more expedient and efficient renewal process where certain documents and requirements do not require re-submission and approval. This would ensure that companies waiting for their license renewal do not have to wait as long as they waited the first time.

Various MEPs and MPs, have called upon the Government and the respective regulatory authority to work on legislative reforms, so that within Maltese Markets there is a more adequate choice of medicinal cannabis products which doctors may prescribe. Another issue which was brought up by ReLeaf. The second recommendation is for a legislative reform and effort to be made towards diversifying the Medicinal Cannabis Market which is not merely restricted to 2 or 3 companies. This will have several benefits both for the stability of the market itself and also for ensuring as many viable options and alternatives as possible for patients taking such medication.

As seen in the comparative licensing section of the paper, many countries have legally allowed for various households to legally grow their own marijuana plant at home, which is used strictly for medicinal purposes. Although it might be deemed as controversial, by growing one's own marijuana plant, it has proven to eliminate a number of issues when it comes to medical marijuana.

This recommendation also sheds light to another issue explored throughout the paper-exorbitant pricing. The reality is that prices are currently ridiculously expensive, creating situations where eligible patients cannot obtain such medication due to financial reasons. Assuming a patient uses 1 gram of Medicinal Cannabis a day for 13 months of treatment, the

patient will have spent around €5,390. This is problematic and to a certain extent discriminatory as it creates a situation where a last-resort medication is only accessible to patients from a certain financial bracket.

The €5,390 figure does not include the €70 application, €20 prescription and application renewal which is a further €70. These exorbitant fees serve as a justification and strengthen the rationale behind both recommendations. High pricing is seemingly ‘allowed’ due to the lack of competition within the market. The main importers are hardly at risk of losing out to other competitors, thus creating a breeding ground for overly exorbitant prices. Diversifying the market will only humble such companies and lower their pricing to conform and keep up with a more competitive market.

However, even if the market is diversified, this may not necessarily solve the pricing issue for all financial demographics. By growing one’s own marijuana plant, low-income patients are offered with a further incentive in obtaining cheaper medicinal marijuana by creating a system subject to a number of requirements.

The means needed to grow such marijuana could be regulated by the Production of Cannabis for Medicinal Purposes Act, and sold at pharmacies upon the presentation of the adequate authorisation to do so. This must be done with precaution as such a recommendation may have negative impacts on the market itself as patients would prefer to grow their marijuana as opposed to purchasing it ‘ready-grown’ from pharmacies at a much higher price. Though this recommendation may become the eventual norm, in order to safeguard the stability of the entire market, it would be precautionary and prudent to introduce such a measure slowly to low-income patients. However, once the market stabilises and settles, such a recommendation should extend to all patients and become the norm.

Naturally, this goes without saying that systems and incentives should also be in place for low-income applicants to access ready-grown medical cannabis from pharmacies at lower and subsidised prices. This may be done through creating a system whereby applicants would present necessary documentation (Bank Statements & FS3s) highlighting their financial impediments. This could be monitored by the Superintendent for Public Health and subject to a yearly review.

There is ample room for further amendments and improvements. As noted above, the heart of such amendments is of a human nature. Despite the economic opportunity such an industry may offer to a country, and regardless of how attractive such opportunity may be, stakeholders must take into consideration the vulnerability such patients may face, as the good health and safety of our citizens ought to be a top priority.

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