LEGALINK

INTERNATIONAL BUT PERSONAL

CANNABIS REGULATION AND CANNABIS DERIVED PRODUCTS

INTRODUCTION

As more jurisdictions around the world move to legalize various forms of cannabis, including hemp and CBD products, recreational marijuana, and medical marijuana, the global cannabis industry continue to blaze forward. But changing and even inconsistent laws and an evolving regulatory environment have created legal uncertainties and tensions in the development of the industry and marketplace. This booklet aims to provide practitioners a summary reference for cannabis laws and regulations in various jurisdictions across the globe. Practitioners should note that because cannabis laws are quickly evolving, through the legislative process, ballot initiatives and regulatory rule implementations and changes, each jurisdiction's most recent cannabis laws and regulations should be reviewed and assessed.

A QUICK PRIMER ON CANNABIS BASICS

Cannabis vs. Marijuana vs. Hemp

Cannabis refers to a genus of plants that has three species – indica, sativa, and redueralis. Marijuana and hemp are both cannabis. Despite popular misconception, marijuana and hemp are not different species of cannabis.

Marijuana, in the common parlance, is cannabis that, when consumed, results in a "high." The "high" in marijuana is produced as a result of high tetrahydrocannabinol or THC content. Hemp, again in common usage, does not cause intoxication because it has low levels of THC.

INTRODUCTION

Some jurisdictions around the world still do not distinguish between marijuana and hemp. For example, for decades, the federal government in the U.S. did not distinguish between hemp and marijuana or the level of THC content in either – both were illegal cannabis and a controlled "Schedule I" drug.

As cannabis laws and policy have changed over the years, now, in the U.S. and, as applicable, in other jurisdictions, the legal difference between marijuana and hemp is often based upon THC content level. In the U.S., again by way of further example, the Agriculture Improvement Act of 2018 defines legal hemp as "Plant Cannabis sativa L. and any part of that plant, including cannabinoids with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Thus, under federal law in the U.S., cannabis that has no more than 0.3% THC is legal hemp, but cannabis that contains more than 0.3% remains illegal marijuana. Each jurisdictions' definitions for each should, of course, be consulted to determine whether hemp and marijuana are distinguished from one another and where the lines of cannabis legality or illegality are drawn.

THC vs. CBD

THC and CBD are both cannabinoids found in cannabis. A cannabinoid is a naturally occurring compound that reacts with cannabinoid receptors found in our nervous system that are part of our endocannabinoid system, involved in appetite, mood, and sensing pain.

As noted, THC is a psychoactive cannabinoid in marijuana that produces a "high." CBD, or cannabidiol, is a non-psychoactive cannabinoid that may have some health benefits. But more studies are needed. CBD can be derived or extracted from hemp and marijuana. Many CBD products are derived from hemp, containing low levels of THC and higher levels of CBD. Whether CBD or CBD products are legal in any particular jurisdiction will be driven by legal definitions and parameters established by applicable regulatory authorities.

MALTA
DF ADVOCATES

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Malta?

The regulatory framework for medical cannabis and cannabinoids in Malta is composed of one principal comprehensive piece of legislation, the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta) (the PCMR Act), which is supplemented by other subsidiary and relevant legislation, as well as official guidelines.

The PCMR Act was enacted in April 2018, making Malta one of the first European countries to have specific legislation to permit and regulate the production of cannabis for medicinal and research purposes. This legislation followed amendments to the Drug Dependence (Treatment not Imprisonment) Act (Chapter 537 of the Laws of Malta) (the Drug Dependence Act), which provides for the possibility for medical practitioners to prescribe to patients medicinal preparations of cannabis and cannabinoids.

Other relevant laws applicable to the production and supply of cannabis for medicinal use include the Medicines Act (Chapter 458 of the Laws of Malta) (the Medicines Act), which is the main legislation related to all medicinal products and which transposes Directive 2001/83/EC as amended, and subsidiary legislation entitled the Production of Cannabis for Medicinal and Research Purposes (Fees) Regulations,(Subsidiary Legislation 578.01 of the Laws of Malta) which sets out the fees relating to the application for a licence to cultivate, manufacture and supply medicinal and recreational cannabis products in accordance with the PCMR Act.

Within the regulatory framework relating to the production of cannabis for medicinal use, the Medicines Authority in Malta has published a comprehensive set of general guidelines on the production of cannabis for medicinal and research purposes (the Guidelines) which supplement the provisions of the PCMR Act.

In Malta, the production and use of cannabis for recreational purposes remains a criminal offence, although specific provisions within the Drug Dependence Act provide for lower penalties for minor use-related offences and also aim to rehabilitate persons suffering

from drug dependence. In this regard, the Dangerous Drugs Ordinance (Chapter 101 of the Laws of Malta) provides that no person shall import, bring into or export from Malta any resin obtained from the plant cannabis. It also provides that the possession, production, supply and cultivation (except where these relate to medicinal preparations) of cannabis is a criminal offence.

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Malta?

The use of medicinal cannabis in Malta is mainly regulated by Article 10 of the Drug Dependence Act. This provision has addressed the main legal challenge relating to the prohibition of the use of cannabis in Malta. By virtue of this provision, any licensed medical practitioner who is registered to practice in Malta is entitled to prescribe to patients medicinal preparations of cannabis and synthetic cannabinoid products, licensed under the Medicines Act or manufactured under Good Manufacturing Practice. Thus, patients are allowed to use medical cannabis upon prescription only. Being a thoroughly regulated medicinal preparation, the prescription and thereby the use of medical cannabis may only be considered where there is no viable alternative to such prescription and use, after due consideration is taken of any protocols which may be in force from time to time in respect of the prescription of medicines, of the interests of the patient and of the costs. Moreover, an application for such medicinal preparations may only be made on a named patient basis following approval by the Superintendent of Public Health.

Other challenges which may be encountered, though not essentially of a purely regulatory nature, include the identification of medical conditions to be treated with medicinal cannabis products, the reluctance of medical practitioners to prescribe cannabis preparations and uncertainty about clinical indications and dosing.

The use of cannabis for recreational purposes remains a regulatory challenge since, as provided in question 1 above, it is until today not permitted and, although certain mitigation provisions have been included into our legal framework for minor personal use, it is considered to be a criminal offence.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Malta?

The PCMR Act is the principal legislation that regulates production, including the cultivation of cannabis for medicinal and/or research purposes. According to this Act, the cultivation, importation or processing of cannabis or production of any products intended for medicinal and/or research purposes deriving or resulting from the use of cannabis, as well as any trade in cannabis and/or any preparations intended for medicinal and/or research purposes as deriving from cannabis, may take place in Malta upon the issuance of the necessary approvals, authorisations, licences and/or permits under the PCMR Act and all other applicable laws. The latter, though very widely drafted, essentially refers to the Medicines Act and certain subsidiary legislation which is also relevant to the manufacturing and supply of medicinal cannabis products.

In Malta, as stated in question 1 above, the Dangerous Drugs Ordinance makes the cultivation, manufacture and supply of cannabis for any other purpose that is not medicinal or research purposes a criminal offence.

4. Which body is responsible for legislative controls relating to CBD?

The Medicines Authority, established in terms of the Medicines Act, is the body responsible for legislative controls relating to CBD.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Malta?

Presently in Malta CBD products which are required for medicinal purposes require an authorisation, as specified under the PCMR Act.

6. What are the testing specifications in Malta for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Testing specifications are provided for in the Guidelines, which require that cannabis plants are identified using microscopic examination, microscopic identification and

chromatographic procedures. Tests should comply with the guidelines provided by the European Medicines Agency, which provide, among others, guidelines on the quality of herbal medicinal products, testing procedures, accepted product criteria and product preparation.

A certificate of analysis, based on the respective European Pharmacopoeia methods and limits, must provide, but is not limited to, the following set of tests:

- Aflatoxins (Ph Eur 2.8.18)
- Pesticides (Ph Eur 2.8.13)
- Foreign matter (Ph Eur 2.8.2)
- Heavy metals (Ph Eur 2.4.27)
- Loss on drying (Ph Eur 2.2.32)
- Content Tetrahydrocannabinol (THC)
- Content Cannabidiol (CBD)

The CBD (as well as THC) levels should be tested using validated chromatographic methods following samples as per Ph Eur 2.8.20. These tests should also be accompanied by a description of the validated analytical procedure and the specifications and limits applied.

The level of CBD (and THC) in a representative sample of cannabis flowers must correspond with the product specifications and labelling of the product, as a minimum, to not less than 90% and not more than 110%. CBD (and THC) levels in cannabis oil products must be at least 95% and not more than 105%.

Mandatory tests regarding the certificate of analysis should include:

- Content THC
- Content CBD
- Loss of drying
- Microbiology
- Pesticide analysis
- Heavy metal analysis
- Aflatoxins
- Foreign matter
- Identity tests

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

While Maltese law does not specify any limits on the quantity of CBD that can be imported for processing, the Guidelines stipulate that the Medicines Authority will, at periodic intervals, require the licence holder to submit estimates of the intended amount of cannabis that it will import for further processing over a stipulated period. The licence holder must also furnish the Medicines Authority with details regarding the number of finished product packs that shall be produced over the subsequent quarter.

For end consumers, a licenced medical practitioner who is duly registered in accordance with the Health Care Professions Act is entitled to prescribe to patients medicinal preparations of the plant cannabis and synthetic cannabinoid products licensed under the Medicines Act or manufactured under Good Manufacturing Practice, in the doses he deems fit, if it is considered that there is no viable alternative to such prescription, due account being taken of any protocols which may be in force from time to time.

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