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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.

PORTUGAL
SÉRVULO & ASSOCIADOS

General

The debate regarding the prohibition or permission of the use and supply of Cannabis has been fuelled by the legalization foreseen for the supply and the use of cannabis for medicinal and recreational uses. Different solutions were adopted across the world. Even in the Europe Union member States the solutions adopted were not harmonized. In fact, Portugal is the third country with approved legislation in this sense, after Uruguay and Canada.

The main concern of legalizing Cannabis drug for all the possible uses, including the recreational use, is linked with the increase of the Cannabis use and serious related side effects, which will have an enormously public health impact.

Notwithstanding, nowadays, national administrations generally oppose the legalization of cannabis for recreational use (and in a few cases even the decriminalization). The medicinal use is allowed if some very specific requirements are fulfilled, and only under certain circumstances. The same applies to Cannabis derived products.

The discussion under decriminalization or legalization of cannabis for recreational use is not over and the direction of this discussion is not still clear, as we will explain below.

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

Related to cannabis and its use and commercialization, three fields must be distinguished: - recreational use, industrial use and medicinal use.

Our focus will be essentially on industrial and medicinal use, since the recreational use of cannabis and cannabinoids is forbidden and constitutes a crime.

Additionally, there are two major regimens:

a) For medicines, the Medicines Act apply and they are subject to a MA *(autorização de introdução no Mercado*);
b) For preparations and substances, they are subject to an authorization of market placement (*autorização de colocação no Mercado* - ACM) subject to more specific regulatory framework.

INFARMED, IP (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.), the national medicines and health products authority – a *Instituto Público* integrated in the Portuguese administration as a part of the so-called indirect administration, subject to supervision (but that may not receive orders) by the Ministry of Health – is the competent regulatory authority in all the *cannabis* regimens.

As it happens with any other medicine for human use, it is mandatory to get a marketing authorization (MA) for the marketing of medicines based on cannabis plant, and the Cannabis legislation determines that the Medicines Act (*Decreto-Lei* no 176/2006) is applicable is all relevant areas. This means that all other legal and regulatory requirements apply, including the ones regarding the use of filing platforms (e.g. Portal SMUH – AIM), filing fees or other administrative costs legislation (e.g. Decree-Law no. 282/95; or https://www.infarmed.pt/documents/15786/2213281/GP_ACMCan%C3%A1bis/8f4e6241-8184-460e-91f1-0ffd0c897a20).

We will mainly focus our attention in the cannabis preparations and substances regimens, which cover the product chain from cultivation to post-market surveillance.

In regard to the industrial use, the regulatory framework is Regulation (*Decreto Regulamentar*) no. 61/94, of 12 of October, on the authorization for the production of hemp, as amended.

As for the medicinal use, the regulatory framework includes (*i*) Law (*Lei*) no. 33/2018 of 18 July, on the use of cannabis for medication, preparations and substances with cannabis for medicinal use, (*ii*) Decree-Law no. 8/2019, of 15 January; (*iii*) Ordinance no. 44-A/2019, of 31 January.

In what concerns to cultivation, manufacture and/or distribution of preparations and substances, the most important requirements to be met may be described as follows:

- The production and supply chain, from planting to distribution, is controlled; an administrative authorization must be obtained at the National Medicines and Health Products Authority (Infarmed, I.P.);
- the MAH (also named TACM – *Titular da Autorização de Colocação no Mercado*) shall maintain updated records of all entries and exits of the plant species;
- INFARMED may set limits on the quantities of substances and preparations to be cultivated, manufactured, subject to wholesale, import and/or export;
- The requests and procedures related to the granting of the authorizations, including for the exercise of the cultivation activity for other non-medicinal purposes, are defined by ordinance of several Government ministries, including the areas of finance, internal administration, justice, health, economics and agriculture;
- The security measures must observe the technical characteristics established in Ordinance no. 273/2013, and the company shall appoint a security officer who fulfils the requirements of the security director category provided for in article 22 of Law no. 34/2013 (Private Security Activity Regime);
- The MAH must comply with all marketing authorization provisions within the Medicines Act;
- The authorization must be renewed annually, under penalty of forfeiture.

Regarding the medicinal use, the marketing of cannabis plant-based preparations and substances is subject to a specific authorization, which is obtained as follows:

- The application is submitted to INFARMED, including all the documentation referred to in article 7 of Decree-Law no. 8/2019;
- INFARMED decides within 90 days and the decision is published in its website;
- After the ACM is granted, its holder shall inform INFARMED of the price to be charged for the preparation of the authorized substance;
- The authorization is valid for a period of 5 years, and after the first renewal may have and undefined duration, unless, for reasons of pharmacovigilance, INFARMED determines that the renewal will be only for 5 years;
- Application for renewal must be submitted with 9 months in advance in relation to the expiration of the period of validity of the initial authorization, under penalty of its expiration at the end of the term;
- The marketing and its interruption date, temporary or definitive, must be communicated to INFARMED.

The holder of the authorization has the obligations set forth in article 12 of Decree-law no. 8/2019, namely to market, ensure the supply and fulfil the pharmacovigilance obligations.

Regarding the price of these products reference is made to Ordinance (*Portaria*) no. 44-A /2019, of 31 of January, that provides the following:

- The price to be practiced is communicated to INFARMED, who will have 15 working days to decide on its adequacy; INFARMED'S silence will correspond to the tacit acceptance of the proposed price;
- INFARMED may oppose the price submitted, when it is disproportionate to the price practiced in the international market, where the said preparation and substance is being marketed;
- The MAH (TACM) is obliged to communicate electronically to INFARMED the commencement of marketing, as well as any decision of suspension or termination of supply to the market.

The application for the marketing authorization, its respective renewal and amendment are subject to the payment fees to INFARMED.

The marketing of preparations and substances is also subject to the payment of the "marketing administrative fee" provided for in Decree-Law no. 282/95 of October 26.

Since even the legalization of cannabis for medicinal uses remains largely a highly controversial issue, the recreational use of cannabis is not legalized, since the legislator is aware of the difficulty in establishing the limits to its use, and above all, aware of the consequences that the use of cannabis may eventually cause, such as traffic accidents, violence and suicide, death by overdose, HIV and Hepatitis, Liver cirrhosis, among others.

However, some legislative initiatives to legalize it, even with clear limitations, have been lodged and as yet did not progress to legislation.

As to the medicinal use of cannabis, Portugal has moved to a system where the medicinal use of cannabis is controlled, with controllable side effects. The legislator must always have in mind the consumption patterns, particularly to detect at an early stage any attempts to buy it unlawfully.

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

See question no 1.

We highlight the importance of Decree-law no. 8/2019, laying down the principles and objectives regarding prescription, dispensing in pharmacy, detention and transportation, scientific research, information to professionals, as well as regulation and supervision of activities related to the use of the cannabis plant for medicinal purposes were established, and, most important the Decree-Law expedited patient access to treatments using cannabis-based preparations and substances, which had no legal provision, and represented a huge paradigm shift in Portugal.

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

In Portugal, the entity that monitors the application of the legal framework applicable to cannabis and its derivatives, such as CBD, is INFARMED.

Law no. 33/2018 states, in article 2, that all cannabis-based medicines, preparations and substances are subject to authorization by INFARMED.

Article 9 also tasks INFARMED with the regulation and supervision of the cultivation, manufacture, extraction and production, wholesale commerce. Distribution to pharmacies, importations and exportations, traffic, acquisition, sales and deliveries of cannabis-based medicines, preparations and substances. INFARMED is also the body responsible for approving the therapeutic indications of these products.

As explained, INFARMED is also the body responsible for authorizing the practice of the activities of cultivation, manufacture, use, commerce, distribution, importation, exportation, traffic, transport, detention and use of plants, substances or preparations, of the plants, preparations and substances specified in tables I to IV of Decree-Law no. 15/93, pursuant to its articles 2(4) and 4.

Cannabis and cannabis oil are part of Table I-C, and, as such, all activities above are subject to authorization by it.

Even if the activities are pursued under a MA or an ACM approved under Decree-Law no. 8/2019, article 3 of that diploma is clear in demanding the authorization referred in Decree-Law no. 15/93. Non-compliance with this framework constitutes a criminal offence, punishable with up to 12 years of prison, under article 21(1) of Decree-Law no. 15/93.

4. Is there any possibility to commercialize CBD products without a Novel Food approval or medicinal product marketing authorization in Portugal?

No, currently it is impossible to commercialize CBD products without Novel Food approval or a marketing authorization.

Regarding commercialization of food containing CBD, it is important to clarify that it constitutes a novel food for the purposes of Regulation (EU) no. 2015/2338. Given the European Commission's view that CBD is a novel food product, expressed in the Novel Foods Catalogue, an authorization is needed for its commercialization. The authorization is granted by the European Commission, after an Opinion of the European Food Safety Authority, pursuant to article 9 of Regulation no. 2015/2338.

Regarding the commercialization of medicines containing CBD, we recall that, as explained, there is a need for the medicine to have a MA and to comply with the Medicines Act.

Should the product amount to a cannabis-based preparation or substance, article 6 of Decree-Law no. 8/2019, requires a ACM. The procedure to obtain this authorization was introduced in our answer to question 1.

It is important to note that, in addition to these specific authorizations, it is also necessary to obtain the authorization to exercise the activities in question, under Decree-Law no. 15/93 (as explained in question 3).

5. What are the testing specifications in Portugal 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?

Under Portuguese legislation, commercialization of CBD products is exceptional and always subject to authorization. The product quality control is centralized on INFARMED.

With regards to cannabis-based medicines, article 15(1)(j) of Decree-Law no. 176/2006 demands the presentation of results from clinical and pre-clinical trials in order to obtain a MA. Under this framework, there are situations where clinical and pre-clinical trial evidence may not be given to INFARMED, namely when there is a well-established clinical use, in the sense of article 20 of the same diploma, which means that the medicine active substances have been in use for a period longer than 10 years with recognized efficiency and an acceptable safety level.

Moving to cannabis-based preparations and substances, article 7 and Annex I of Decree-Law no. 8/2019 state that, in order to obtain a ACM, the applicant must provide INFARMED with the identification of the cannabis-based preparation/ substance which must include, amongst other information, a declaration of its composition and a certificate. It must also present the following documents, aiming at ensuring the quality and safety of the product to be commercialized:

a) Copies of the manufacturing authorization and a certificate of medicines good manufacturing practices (EU and national legislation apply);
b) Declaration by the supplier of the cannabis regarding compliance with the good practices on agriculture and harvest;
c) Certificate regarding the supplier compliance with existing legislation on cultivation of cannabis on its country of origin;
d) For the importation of cannabis-based preparations and substances, a certificate that the manufacture of the preparation or substance complies with the national legislation of the country of origin;
e) Documentation that proves the quality of the cannabis-based preparation or substance, in line with the guidelines applicable to plant-based medicines and preparations published by EMA (European Medicines Agency).

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

Purchase and importation of CBD is covered by the strict rules of Decree-Law no. 15/93.

Even when the product is intended for medicinal use, article 3 of Decree Law no. 8/2019 still makes the diploma applicable. This means that, similarly to the commercialization of CBD products, the activity is subject to previous authorization by INFARMED, and that purchase and importation with no authorization is a criminal offence, pursuant to article 21.

However, seemingly there is no limit to the quantity of CBD that the authorization may cover. Under article 23 of Regulation no. 61/94, the quantity of the product to import is indicated by the applicant.

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