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Medical Cannabis & Cannabinoid Regulation 2022

Portugal: Law & Practice
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Law and Practice

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1. LEGAL/REGULATORY FRAMEWORK

1.1 Source of Regulations

The main rules on the activities regarding controlled substances in Portugal are set forth by the following laws and regulations:

- Decree Law No 176/2006 of 30 August ("Medicines for Human Use"), which establishes the general legal framework for the obtaining of a marketing authorisation (MA) for medicines for human use, including medicines based on the cannabis plant;
- Decree Law No 15/93 of 22 January (DL 15/93), which establishes the Anti-Drug Law and contains the main rules regarding all the activities related to drugs and controlled substances, including for medicinal purposes;
- Regulatory Decree No 61/94 of 12 October (RD 61/94), which develops the legal regime of the DL 15/93 regulating the practical aspects of the activities related to controlled substances, such as the procedures to obtain the relevant authorisations to develop activities related to these substances, including cannabis for medicinal purposes;
- Law No 33/2018 of 18 July ("Medical Cannabis Law"), which allows the use of medicines, preparations and substances based on the cannabis plant for medicinal purposes, and establishes that such medicines, substances and preparations can only be dispensed in pharmacies;
- Decree Law No 8/2019, of 15 January (DL 8/2019), regulating and developing the applicable legal regime established by the Medical Cannabis Law and clarifying some aspects that were not provided by the Medical Cannabis Law, including the terms and conditions under which the Authorisation for Placement in the Market (ACM) can be issued to a preparation or substance based on the cannabis plant;
- Ordinance No 83/2021 of 15 April ("Ordinance 83/2021"), which set forth the requirements and procedures on the granting and maintenance of authorisations for the exercise of activities related to the cultivation, manufacture, wholesale trade, transport, circulation, import and export of medicines, preparations and substances based on the cannabis plant;
- Ordinance No 44-A/2019 of 31 January ("Ordinance 44-A/2019"), which establishes the price regime for cannabis-derived preparations and substances for medicinal purposes;
- Decree Law No 97/2015 of 1 June 2015 (DL 97/2015) establishing the National Evaluation System of Health Technologies (SiNATS), which is subsidiary, applicable to the price aspects not provided by Ordinance 44-A/2019 and also applicable to the price aspects for medicines based on the cannabis plant;
- Resolution No 11/CD/2019 of 31 January 2019 of the Board of Directors of INFARMED, which establishes the therapeutical indications which can be treated with cannabis-derived products;
- Resolution No 010/CD/2019,of 31 January 2019 of the Board of Directors of INFARMED, which establishes the Regulation for monitoring the safety of preparations and substances on the cannabis plant.

The Portuguese legal framework regarding controlled substances has as its basis the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances signed in Vienna in 1971, ratified by the Portuguese state.

As mentioned, the cannabis plant as used for medical purposes has a specific legal regime in Portugal, establishing the rules applicable to the cultivation, manufacture, import, export, wholesale and sale of medicines, preparations

and substances based on the cannabis plant as used for medical purposes. The existence of such a specific framework for cannabis-related products for medical purposes implies that both DL 15/93 and RD 61/94 became only applicable as subsidiary regulation to those matters which are not expressly foreseen in the Medical Cannabis Law, DL 8/2019 and Ordinance 83/2021.

1.2 Regulatory Authorities

The regulatory body enforcing the laws and regulations on cannabis and cannabinoids for medical purposes in Portugal is INFARMED – National Authority of Medicines and Health Products, I.P. – *Autoridade Nacional do Medicamento e Produtos de Saúde,* I.P.

INFARMED is part of the state's indirect administration and is endowed with administrative and financial autonomy. It is responsible for carrying out the responsibilities of the Ministry of Health under the supervision and guidance of the Minister of Health.

In what concerns cannabinoids, for other than medicinal purposes, the competent authority is the General Directorate of Agriculture and Veterinary – *Direção Geral de Alimentação e Veterinár* ia (DGAV). DGAV is responsible for issuing the authorisations for the commercialisation of food supplements and for the surveillance of this market. DGAV is part of the state's direct administration and operates under the Ministry of Agriculture. DGAV is responsible for the definition, implementation and evaluation of food safety, animal protection, animal health, plant protection and plant health policies, and for the functions of national veterinary and phytosanitary health authority, veterinary medicines and the management of the food safety system. For further products involving non-psychotic cannabinoids, please see **1.4 Key Challenges**.

1.3 Self-Regulation

Under the Portuguese legal framework, INFARMED is the sole competent authority for the authorisation and surveillance of the activities related to controlled substances. In what concerns cannabinoids used in general consumer products, such as food supplements with cannabis-derived ingredients, the competent authority is DGAV. In the exercise of their surveillance powers, both INFARMED and DGAV can be assisted by the Food and Economic Safety Authority – *Autoridade de Segurança Alimentar e Económica* (ASAE).

1.4 Key Challenges

Although Portugal has a sympathetic approach to medical cannabis and its regulatory framework is very well established, the use of medical cannabis is still residual, namely due to the following motives.

Availability of Cannabis-Derived Products in the Market

The market does not have a significant number of options. At this moment, only one medicine is sold in Portugal, and it is sold at a relatively high price, even though it is subject to co-payment by the state. In regard to substances and preparations, there are some applications pending before INFARMED, but only one preparation is currently being marketed and it is not subject to any co-payment.

Price

Another problematic aspect is the price. Even with co-payment by the state, the patient still must bear a significant part of the price of these products, which makes access to therapy difficult for a significant proportion of patients. There are certainly situations where the doctors has proposed prescribing medical cannabis products to a patient, but the possibility is refused by the patient since they do not have the necessary financial capacity to cover such treatment.

In this regard, we believe that it is essential to treat products based on the cannabis plant for medical cannabis as "common" medicines and to grant to those products the same level of co-payment granted to other medicines for the same or similar pathologies.

It should also be highlighted that Portuguese law allows the co-payment by the state of medicines, substances and preparations based on the cannabis plant for medicinal purposes. This can be a vicious circle, since if the price is not supportable by patients then the industry has no motivation to invest in R&D and place new products in the market, thus worsening the lack of availability of products in the market, as described above.

Providing the Medical Class with Scientific Evidence

There are also big challenges with the medical class. Indeed, doctors have been expressing some reservations, mainly due to the lack of evidence on the use of medical cannabis in the treatment of pathologies. As the use of cannabis-derived products is dependent on prescription by doctors – in Portugal, a special medical prescription is essential for the acquisition of medicinal cannabis products – it is essential to provide doctors with scientific evidence giving them comfort and confidence when prescribing cannabis products to their patients.

The final decision on the prescription of a medical cannabis product belongs to the doctor and they will only prescribe such a product – either a medicine, a substance or a preparation – if they trust the product. On the other hand, it is also important to provide health education on cannabis treatments to patients, eliminating the stigma that still exists about treatments based on these substances. We strongly believe that this aspect needs broad industry co-operation, both from the classical pharmaceutical industry and the medical cannabis industry.

Thus, there is still some work to be done to have medical cannabis accepted and used by doctors. It should be based in two main vectors: (i) R&D, and (ii) the production or release of scientific evidence on the benefits and efficacy of medical cannabis products in human health.

Limitation on Doctors' Prescriptions of Medicines, Substances and Preparations Based on the Cannabis Plant

As referred in **1.1 Source of Regulations**, through the issuance of Resolution No 11/CD/2019 of 31 January 2019, INFARMED has clearly established the therapeutical indications whereby medical cannabis products can be prescribed by doctors to their patients.

The Resolution also prescribes that substances and preparations based on the cannabis plant can only be prescribed when it is clear that conventional treatments with authorised medicines are not producing the expected effects or are causing significant adverse effects to patients. This restriction means that doctors are obliged to start the treatment with common medicines, relegating medical cannabis to the last part of the treatment possibilities' chain. This, combined with the lack of options available in the market and the price of such alternatives, is preventing access to these treatment technologies by patients and limiting the growth of the medical cannabis market.

Use of Cannabinoids in Cosmetics, Food and Food Supplements and Veterinary Foods

The use of cannabinoids (CBD) in cosmetics, food and food supplements and veterinary foods is also a key challenge that the market players are facing right now. EU member states have different approaches, with some of them allowing its use (ensuring that it comes from *Can-*

nabis Sativa L. and contains less than 0,2% of THC), some of them are ignoring its use, and the remaining jurisdictions banning its use in cosmetics, food and food supplements and veterinary foods.

Portugal is currently in the last group, restricting the use of CBD in these products. In what concerns cosmetics, INFARMED – which is also the competent authority for cosmetic products – have recently issued an informative letter highlighting that the use of CBD is not allowed in cosmetics as it is a substance coming from the cannabis plant, being a controlled substance under the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances signed in Vienna in 1971.

In what concerns food supplements, CBD is considered a "novel food" as per Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015, and DGAV does not allow the use of CBD in food supplements based on this aspect. The same applies to food and veterinary foods. Until CBD is considered an authorised novel food – and there are applications currently ongoing for such purpose – it is not expected that DGAV will change its position in the short term.

Effects of the COVID-19 Pandemic

As in the majority of sectors, the COVID-19 pandemic highly impacted the Portuguese medical cannabis market, taking the industry by surprise. During the height of the pandemic, stakeholders were waiting to see to what extent it would impact the medicinal cannabis market and considering how to overcome the new circumstances it caused. Several projects were suspended and a lot of applications for obtaining cultivation and manufacture authorisations were dropped by their promoters. Notwithstanding, Portugal has continued to attract a lot of world players, who maintained and strengthened their investments in the country.

Fortunately, the market has begun to show clear signs of recovery and there are a significant number of projects starting to resume their course, with several companies still investing in Portugal – including some of the biggest global companies in this sector. This is quite clear if we look at the number of investment rounds in cannabis companies and the number of M&A transactions in this sector since the beginning of 2022.

Without prejudice of the above-mentioned challenges, which we are confident will be overcome, we strongly believe that Portugal is the place to be in terms of the cannabis industry, and that prosperous times are ahead for this sector in Portugal.

1.5 Level of Regulation

The regulation of controlled substances in Portugal started in 1993, with the publication of DL 15/93, followed in 1994 by RD 61/94, which established the general framework applicable to controlled substances and, specifically, the rules in regard to the legal market of these substances.

Subsequently, in 2001, Portugal became the first European country to abolish all criminal penalties for drug consumption, under Law No 30/2000 of 29 November. Consuming drugs is now treated as an administrative offence, as long as the possessed quantity does not exceeds the average for individual consumption for a ten-day period. If the quantity is above this ten-day limit, it is deemed to be for drug trafficking, being punishable with (i) four to 12 years, (ii) five to 15 and (iii) one to five years of imprisonment, depending on the concrete crime and the type of controlled substances.

In 2018, Law 33/2018 was published; it was specifically intended to frame the activities related to the cannabis plant for medicinal purposes, and subsequently settled by DL 8/2019. Finally, Ordinance 83/2021, regulated the practical aspects of the applications for authorisations for cultivation, manufacture, import, export and wholesale of medicines, preparations and substances based on the cannabis plant for medicinal purposes.

As described, the regulatory regime for medical cannabis is comprehensive, covering all the stages of the value chain. Despite being a very demanding framework – which is to be expected, considering the nature of this industry – the Portuguese medical cannabis framework is clear and reasonable in what concerns the legal requirements applicable to these activities, allowing stakeholders to be very well-informed about the requirements to ensure a successful application to obtain authorisation for the exercise of such activities.

In addition, Portuguese law has developed creative solutions to allow the growth of the medicinal cannabis market, ensuring at the same time safety in the use of the products and the protection of public health.

The Portuguese law distinguishes: (i) MA, which is the authorisation for marketing a medicine, whether based on the cannabis plant or not, and ruled by DL 176/2006; and (ii) the authorisation for placement in the market – *Autorização de Colocação no Mercado* (ACM) – which is applicable only to preparations and substances based on the cannabis plant. Considering that preparations and substances are less complex than common medicines, Portuguese law establishes a less demanding procedure to apply for an authorisation for marketing of such a preparation or substance. As opposed to medicines, to apply to obtain an ACM, further to the information of the applicant, the applicant shall provide the following information:

- proof of compliance by the grower with the Good Agriculture and Collection Practices (GACP);
- proof of compliance by the supplier of the plant with the applicable local laws of the country of origin for the cultivation of the cannabis plant for medical purposes;
- proof of compliance by the manufacturer of the substance or preparation with the Good Manufacturing Practices (GMP), as well as the copy of the manufacture authorisation;
- proof that the manufacture preparation or substance is in compliance with the applicable laws of the country of origin, in case of imported preparations or substances;
- a dossier able to ensure the quality of the preparation or substance in accordance with the specific guiding standards to medicines and preparations based on plants which was published by the European Medicines Agency and is available in its website.

This is probably the most innovative solution created by Portuguese law to allow the access to cannabis-derived treatments. Although there are some challenges to ensuring full access by the patients who need these kinds of therapies, we believe that the legal and regulatory framework is suitable to such purpose. For further developments on the access issues, please see **3.1 Legal Elements Affecting Access to Medical Cannabis**.

1.6 Legal Risks

The activities related to medical cannabis are highly regulated in Portugal, with very restrictive and concrete, applicable rules. Stakeholders' compliance with the relevant provisions is closely monitored by INFARMED. The stakeholders shall ensure at all time their compliance with all requirements established by law for the activities

of cultivation, manufacture, import, export and wholesale of medicines, substances and preparations based on the cannabis plant for medical purposes. Any breach of compliance with such provisions can result in severe fines and, in the worst-case scenario, withdrawal of the authorisation to exercise the activity.

In what concerns non-psychoactive cannabinoids, there are also several challenges, which are perhaps more difficult to overcome. As the use of these substances are not subject to a European common regulation, the room for different interpretations is significant and is able to cause considerable damage to the stakeholders. For further development on non-psychoactive cannabinoids, please see **3.2 Use of Non-controlled Cannabinoids in Food**.

1.7 Enforcement

The authorities responsible for enforcement of compliance are: INFARMED for medical cannabis; and DGAV for foods and food supplements. INFARMED's and DGAV's decisions regarding medical cannabis and non-psychoactive cannabinoids may be challenged through administrative and/or judicial channels, within a given period.

Individuals and entities who are affected by these decisions can appeal against them, namely on the grounds of breach of the law.

In what concerns criminal enforcement, it is the competence of the Public Prosecutor's Office, assisted by the Judiciary Police (*Polícia Judiciária*), the National Republican Guard (*Guarda Nacional Republicana*) and the Public Safety Police (*Polícia de Segurança Pública*) and is judged in the general criminal courts.

Regarding administrative offences, the applicable penalties vary according to the concrete violations. As for infringements to DL 15/93 and RD 61/94, the main sanction for non-compliance is an economic sanction, which may be minor, severe or very severe, punishable as per Decree Law No 9/2021 of 29 January, which establishes the Legal Framework for Economic Offences – *Regime Jurídico das Contraordenações Económicas* (RJCE).

In what specifically concerns DL 8/2019, the violation of its provisions is considered an administrative offence, punished with a fine between EUR1,500 and EUR3,740.98 in the case of natural persons and EUR3,000 to EUR44,891.81 in the case of legal persons. It is important to underline that both negligence and attempt are punishable, with the minimum and maximum amounts of the fine being reduced to half of the amounts set out if negligence is proven (rather than intent).

The violation of the rules applicable to the activities of cultivation, production, manufacture, import, export, transport, transit, distribution, commercialisation and possession, and parallel regulation such as production quotas, exceeding crop, entities allowed to acquire cannabis plants, substances and preparations, registration obligations, delivery conditions, communications, reports, packaging and labelling set forth in DL 15/93, as well as the provisions of DR 61/94, are considered severe administrative offences, punishable as per RJCE.

Under Article 18 of RJCE, the fines for administrative offences are as follows.

In the case of minor administrative offences:

- between EUR150 and EUR500 in the case of single persons;
- between EUR250 and EUR1,500 in the case of micro companies (ie, companies with less than ten employees);

- between EUR600 and EUR4,000 in the case of small companies (ie, companies with between ten and 49 employees);
- between EUR1,250 and EUR8,000 in the case of medium companies (ie, companies with between 50 and 249 employees);
- between EUR1,500 and EUR12,000 in the case of big companies (ie, companies with 250 or more employees).

In the case of severe administrative offences:

- between EUR650 and EUR1,500 in the case of single persons;
- between EUR1,700 and EUR3,000 in the ase of micro companies (ie, companies with less than ten employees);
- between EUR4,000 and EUR8,000 in the case of small companies (ie, companies with between ten and 49 employees);
- between EUR8,000 and EUR16,000 in the case of medium companies (ie, companies with between 50 and 249 employees);
- between EUR12,000 and EUR24,000 in the case of big companies (ie, companies with 250 or more employees).

In the case of very severe administrative offences:

- between EUR2,000 and EUR7,500 in the case of single persons;
- between EUR3,000 and EUR11,500 in the case of micro companies (ie, companies with less than ten employees);
- between EUR8,000 and EUR30,000 in the case of small companies (ie, companies with between ten and 49 employees);
- between EUR16,000 and EUR60,000 in the case of medium companies (ie, companies with between 50 and 249 employees);
- between EUR24,000 and EUR90,000 in the case of big companies (ie, companies with 250 or more employees).

Moreover, in addition to the economic sanctions, INFARMED may decide to apply ancillary actions, such as the interdiction of the exercise of an activity for a period of time, the suspension of authorisations, licences, permits or the loss of objects and deprivation of the right to participate in public tenders.

2. CROSS-JURISDICTIONAL ISSUES

2.1 Cross-Jurisdictional Standards

As an EU member state, Portugal is subject to EU law and regulations. Considering that medical cannabis and cannabinoids are a recent field of activity, the member states have still not established a common basis for legislation in this area (as is the case with mainstream medicines, for example).

In the absence of a common EU legislation, there have been some recent examples of different interpretations between member states on cannabis and cannabinoids regulation. Some of these conflicts have arrived at the ECJ as there were different interpretations regarding the free movement of goods and the internal market. Case C-663-18 (the Kanavape case) is currently the textbook case in which these matters were discussed in the European Court of Justice. Given the current inconsistencies on cannabis and cannabinoids regulation across the EU, it is likely that cross-jurisdictional issues may arise in near future.

3. FUTURE DEVELOPMENTS

3.1 Legal Elements Affecting Access to Medical Cannabis

The Portuguese medical cannabis market is very well-regulated and well-established, being sym-

pathetic to stakeholders interested in investing in this activity. Despite being in the regulatory vanguard, there are still some obstacles to overcome to allow access to medical cannabis products by those patients who need such products to treat their pathologies.

As referred to in **1.4 Key Challenges**, there are some aspects which need to be worked out to make medical cannabis accessible to patients.

The first is the products available on the market. Portugal currently has on the market only one preparation based on the cannabis plant (dry flower) and one medicine, which is a very limited range on offer for patients. In fact, scientifically and medically, different pathologies need different solutions and the only way to allow this to be properly addressed is to increase the range of products available for prescription by doctors.

The second aspect is the price. The products currently available in the market are very expensive and not economically accessible to a significant number of patients. Being a last resort solution, as per the therapeutical indications approved by INFARMED, medical cannabis should be co-paid by the state in the same terms as other last-resort medicines used – oncology treatments, for example, which are fully supported by the state. Portuguese law already provides this possibility, and it is now for the stakeholders to give evidence of a positive cost-benefit relationship of medical cannabis, thus allowing the increase of its co-payment by the Portuguese state.

For further details, please see **1.4 Key Challenges**.

3.2 Use of Non-controlled Cannabinoids in Food

The interpretation of the Portuguese authorities is very restrictive on the use of cannabinoids in foods.

In what concerns food supplements, DGAV – Portugal's competent authority for food supplements – is very restrictive on the use of cannabinoids in food supplements. As CBD is considered a novel food under the Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015, DGAV does not allow use of CBD in any food supplements. The only exception to this rule is the use of *Cannabis Sativa L.* usually referred to as hemp, provided it is registered in the EU's Common Catalogue of Varieties of Agricultural Plant Species and its tetrahydrocannabinol (THC) content does not exceed 0.2%.

In addition, it should be noted that Portuguese authorities understand CBD to be a controlled substance, as per the United Nations Convention on Narcotics, and do not allow the use of CBD in any consumer products. The competent authority for general market surveillance is ASAE.

The changing of this approach by the Portuguese authorities will largely depend on the path followed by European authorities in this field. Portugal usually closely follows European standards and positions in regulatory matters, and it is not expected that there will be an exception regarding this particular matter.

From an EU law perspective, there are also several aspects that need to be clarified. The harmonisation of the inconsistent medicinal cannabis and cannabinoids regulations across EU member states is essential to allow the growth of this market in Europe.

As per the scientific evidence already in place, it is now more or less clear that non-psychoactive cannabinoids, such as CBD, are safe and have several beneficial effects. This should be enough to make European authorities objectively face reality and create a reasonable framework for all

stakeholders, thereby ensuring that all the people who need this substance have access to it, guaranteeing the quality of the products placed in the market and preventing the flourishing of a black market as a consequence of legal "grey zones".

3.3 Decriminalisation or Recreational Regulation

As referred to in **1.5 Level of Regulation**, Portugal became the first European country to abolish all criminal penalties for drug consumption, under Law No 30/2000, of 29 November; since then, Portugal has faced drug dependence as a public health problem and not as a legal or criminal problem.

Beyond the decriminalisation, Portugal has put in place several programmes in order to help drug-dependent individuals to overcome their dependence through alternative drug programmes managed by public health authorities, such as the provision of methadone to heroin dependents who are in the process of recovery.

Indeed, the decriminalisation of drug consumption was a further step forward in regard to Portuguese drug politics. In 1977, Portugal started to treat drug addicts with methadone as substitute for heroin. This programme has had a significant success, with an appreciable number of recuperations of drug-addicted persons.

Another initiative, back in 1993, was the syringe-exchange programme, through which drug dependents could replace used syringes for sterilised new ones. This exchange was made in community pharmacies, which entered a protocol with the Ministry of Health and the National AIDS Commission. As a consequence, Portugal achieved a massive reduction of infections by HIV, whose main transition vehicle was precisely the sharing of syringes between drug dependents. Considering the close connection of drug dependents with other social issues, such as prostitution and homelessness, this was the perfect environment for the spreading of the virus.

In what concerns "recreational" cannabis regulation, the Portuguese Parliament has started discussions on the liberalisation of cannabis for personal use. The bills were submitted by the party *Bloco de Esquerda* (Left Block) and *Iniciativa Liberal* (Liberal Initiative) in 2021, and aim to allow the consumption of recreational cannabis, without prescription, under certain circumstances. Although the bills were submitted, they have not yet been voted on, mainly due to the political crisis in Portugal in the last months of 2021.

Portuguese society is currently having a wide-ranging discussion on the allowance of recreational cannabis for personal use. The discussions are now, in our opinion, clearly moving towards a relative consensus around the allowance of use of cannabis for recreational purposes. Considering the composition of the Parliament arising from the general election held in January 2022, it is likely that recreational cannabis for personal use will be allowed and regulated in the short-to-medium term.

As it is highly likely that recreational use of cannabis will be allowed in the not-too-distant future, it is essential to develop a reasonable framework for this new reality and to avoid mixing it with the framework for medical cannabis. Medical cannabis and recreational cannabis have totally different targets and functions, and it is essential to define and clearly distinguish the two fields of activity.

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