SRS ADVOGADOS
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# LIFE SCIENCES AND HEALTHCARE

**The Law for Cannabis for Medical Use was passed in 2018, was regulated in 2019 and since then 11 companies have been licensed by Infarmed for the cultivation of cannabis in Portugal. On 15 April, an Ordinance was published that extended the requirements for obtaining authorizations, in particular the security measures that must be observed by companies already licensed on or before the 15 July 2021.**

## CANNABIS FOR MEDICAL USE - LEGAL FRAMEWORK IN PORTUGAL

In 2018, the "Law for Cannabis for Medical Use", created the legal framework for the use of medicinal products, preparations and substances based on the cannabis plant, for medicinal purposes, in Portugal (Law No. 33/2018 of 18 July).

This law aimed at regulating prescription and dispensation in pharmacy, detention and transportation, scientific research and information for professionals, as well as the regulation and supervision of activities related to the use of cannabis for medicinal purposes.

The law provided the framework for all activities in the chain of this plant, and so the cultivation, manufacture and distribution of cannabis for medicinal purposes now enjoys a more precise legal framework, thus providing legal certainty to interested players in developing this activity in Portugal.

## REGULATION OF THE CANNABIS LAW FOR MEDICINAL PURPOSES

In 2019, in accordance with the regulation of the Cannabis Law for Medicinal purposes, a legal framework was then provided for the entire chain of medicines and preparations and substances based on the cannabis plant intended for human use for medicinal purposes (Decree-Law 8 / January 15, 2019).

These regulations apply not only to specific aspects related to the introduction in the market, prescription and dispensation of these drugs and substances, but also to all activities that are upstream.

Consequently, as of 2019, the cultivation, production, extraction and manufacture, wholesale trade, import and export, transit and acquisition of cannabis in Portugal, acquired a legal framework that allowed the development of this economic activity in Portugal.

For the purpose of controlling these activities, a specific office for Medical Cannabis was created within Infarmed (the National Authority for Drugs and Health Products).

On the other hand, the Military Laboratory of Chemical and Pharmaceutical Products was legally authorized to produce medicinal products, preparations and substances based on the cannabis plant, thus respecting the provisions of international treaties that establish that signatory countries that allow the use cannabis for medicinal purposes should establish structures to control cannabis production and supply.

### PREPARATION OF THE DOSSIER

The activities of cultivation, manufacture, wholesale trade, import, export and transit of medicinal products, preparations and substances based on Medical Cannabis require authorization from Infarmed.

Although the authorizations do not have a validity, the basic information must be updated annually, under penalty of expiration.

The preparatory activities necessary to submit the application for obtaining the authorizations, in particular the cultivation authorization, are time consuming and involve several aspects.

In specific, 1) the regulatory aspect, of identifying and complying with all applicable regulatory and security requirements, 2) the corporate aspect, of creating a company with the necessary characteristics for the exercise of the activity and, finally, 3) the real estate aspect, involving the acquisition or rental of the property and compliance with the requirements relating to the location of the property.

On its website, Infarmed provided models of the application forms to be submitted by applicants and some information on the processing of applications, listing the documents to be attached and their respective content.

In the preparation of the submission form for obtaining the authorizations, applicants are faced with various unresolved questions in relation to the how legal requirements are applied to each specific case, partly due underdeveloped legal requirements. In particular, questions are recurrently raised regarding the identification of the necessary authorizations for the execution of an investment project, regarding the corporate structure and the requirements applicable to the managers, but also regarding the qualifications of the Responsible Technician, with the requirements of the computer system that guarantees product traceability and with the site security requirements.

Between 2019 and 2021, based on this framework, Infarmed issued 11 authorizations for the cultivation of Cannabis for Medicinal Purposes to establishments located in Lisbon, Portalegre, Braga, Setúbal, Coimbra, Faro and Porto.

Two wholesale authorizations were also issued, as well as one import authorization and one export authorization. In Portugal, only one cannabidiol drug is approved.

## ORDINANCE NO. 83/2021 OF 15 APRIL

On 15 April, the Ordinance which determines the requirements and procedures related to the granting of authorizations for the exercise of activities related to the cultivation, manufacture, wholesale trade, transport, circulation, import and export of medicinal products, preparations and cannabis-based substances was finally published (Ordinance No. 83/2021 of 15 April).

The approval of this regulation by joint Ordinance of the members of the Government responsible for the areas of finance, home affairs, justice, health, economy and agriculture, had been expected since 2019.

With the publication of these rules, the intention was to clarify the rules, requirements, and procedures for the licensing of activities related to Cannabis for Medicinal Purposes, with the expectation that it will dispel any doubts that have arisen so far that have contributed to the lengthy preparation of the application dossier.

These rules also apply to cannabis for medical-veterinary, food and industrial purposes.

### REQUIREMENTS FOR OBTAINING AUTHORIZATIONS

Obtaining authorizations depends on meeting a set of legal requirements, which can be summarized in two large groups (below specifically regarding the authorization for cultivation):

**(a) Quality guarantees:**

- For the location and facilities, the geographic location of the place where the cultivation activity will be carried out must be provided, as well as the respective plant and the description and location of the warehouse facilities where the product is stored, and a lease or certificate of land registry;
- Regarding the absence of restrictions on the cultivation of the cannabis plant by the City Council where the land or facilities where the activity will be carried out are located;
- As for the consistency of the project, a business plan for the project must be submitted, including the 3-year forecast of the financial investment plan and growth in the number of employees and indication of quantities of product to be sown or planted, as well as the estimated quantity of the product to be harvested, its use and destination and the identification of the stages of development of the plant and description of the techniques used in each stage of cultivation and the beginning of the cultivation and harvesting activity (after issuance of the authorization);
- Regarding compliance with good practices in Agriculture and Harvesting - Guideline on Good Agricultural and Collection Pratice (GACP), published by the European Medicines Agency, through the implementation of procedures related to the activities carried out by the entity, namely regarding reception, storage, process plant cultivation and harvesting, packaging, product shipping, personnel involved in the activities, transportation, product traceability records, security of the facilities;
- As for the compliance with technical standards and responsibility for setting them by the Responsible Technician and proof of the respective technical qualifications;
- And also with regard to the identification of the farmer(s), in case this is not the applicant, and the identification of suppliers and/or recipients of the products, proof of authorization by the respective national or foreign competent regulatory authority must be provided.

**(a) The safety guarantees:**

- As for the people involved, criminal records are required for all members of the board of directors or the manager(s) of the company, as well as the technical person in charge, the person in charge of security and the farmer;
- As for the implementation of security measures, proof of implementation of such measures is required, as well as the identification of the security director, who must sign a term of responsibility.

## THE PROCEDURE FOR OBTAINING AUTHORIZATIONS

Finally, with regard to the procedure for obtaining authorizations, it should be noted that the submission of the application and accompanying documentation is done online, on the Infarmed website.

After submission, a period of analysis and opinions follows, during which the following opinions are requested by Infarmed:

(i) from SICAD - Service for Intervention in Addictive Behaviors and Dependencies (which will do so within 30 days, the opinion being mandatory and binding) and,

(ii) from the Office of Planning, Policies and General Administration (GPP), the Directorate-General for Food and Veterinary (DGAV), to IAPMEI - Agency for Competitiveness and Innovation, IP (IAPMEI), and to the Judicial Police (PJ), (which shall issue their respective opinions within 10 days, within the scope of

their respective competences and attributions, and whose opinions are not binding).

After analyzing the opinions received by the aforementioned entities, Infarmed makes a decision regarding the documentary aptitude or the documentary inaptitude of the request.

The documentary aptitude decision does not grant authorization to the applicant, it merely indicates that the next stage can begin, with the necessary logistical measures carried out so that Infarmed can inspect the site.

The inspection must be scheduled within six months from the date of receipt of the notification of the documentary aptitude decision. However, it can be extended twice, for an equal period, provided that such extension it is duly justified and authorized by Infarmed.

After the inspection and before the decision, Infarmed requests the National Directorate of PSP (Police) to carry out an inspection of the security conditions of the site and of the technical equipment.

If the facilities are found to comply with legal and regulatory standards, the respective authorization is issued, it is published in the Official Gazette (Diário da República) and communicated to the applicant and the entities that were called to give their opinion, as well as to the National Republican Guard and Public Security Police.

## APPLICATION OF THE NEW SECURITY REQUIREMENTS TO ENTITIES ALREADY LICENSED

The published Ordinance describes the security measures that must be complied with, stating that such measures must be complied with by the entities that, at the date of its publication on 15 April 2021, already held an authorization for cultivation, manufacture and wholesale distribution of drugs containing narcotic and psychotropic substances, granted under the legislation previously in force on that date.

For this purpose, a period of 90 days is established for these entities to adopt the security measures provided for in this Ordinance, meaning entities already licensed must comply with the security measures specified in this Ordinance by 15 July 2021.

Lisbon, 10 May 2021

## CONTACTS

The Curricula of the contacts can be seen in **www.srslegal.pt**

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