HEALTHCARE & LIFE SCIENCES - PORTUGAL

Cannabis for medicinal purposes: licensing FAQs

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Introduction

In the past three years, significant changes have been made to the legislation that governs the medicinal use of products, substances and preparations based on the cannabis plant.

The main changes were introduced by Law 33/2018 of 18 July 2018 and Decree-Law 8/2019 of 15 January 2019. Provision was also made for the subsequent publication of a ministerial order to define the rules on:

- the security measures to be adopted;
- the application process and procedures to grant authorisations relating to the cultivation, manufacture, wholesale trade, transit, import and export of medicines, substances and preparations based on the cannabis plant for medical, medical-veterinary or scientific purposes; and
- the authorisations required to cultivate the cannabis plant for other purposes, including industrial purposes.

Although this ministerial order has not yet been published, licences for activities relating to cannabis for medicinal purposes have been issued.

This article answers some of the most important questions regarding the use of substances and preparations based on the cannabis plant for medicinal purposes in Portugal.

What activities can be licensed in Portugal?

In Portugal, licences may be obtained to perform the following activities with respect to medicines, preparations or substances based on the cannabis plant where such activities have a medicinal purpose:

- cultivation;
- manufacture;
- wholesale trade;
- import;
- export; and
- transit.

However, the licence holder is not authorised to use these medicines, preparations or substances itself (eg, for self-medication or recreational use). Licences are issued by the National Authority for Medicines and Healthcare Products (INFARMED). Provision has also been made for public or private establishments to supply narcotic or psychotropic substances and preparations thereof for research, teaching or quality-control purposes.

What is the procedure to obtain a licence?

Applications must be submitted on the INFARMED website through a page that has reserved access for each entity. Applications for each of the abovementioned activities are made individually and must be accompanied

by specific documentation, which varies according to the application type. Once an application has been submitted, it is analysed by INFARMED, which assesses the suitability of the applicant and its legal representatives along with the Intervention in Additive Behaviours Service and the police on an ongoing basis.

Authorisations are granted only if they respond to a particular need. Precedence is given to medical, medical-veterinary, scientific and teaching interests. If the applicant meets these requirements and the supporting documents for the application are sufficient and appropriate, INFARMED will issue a decision of documentary suitability that will be communicated to the applicant. From the date of communication, applicants will have six months to ask INFARMED to inspect the facilities where the activity in question will be performed. This period may be extended, usually only once, if the applicant provides a reasonable reason.

Once INFARMED has carried out an inspection and confirmed that the premises meet the legal and regulatory requirements necessary to engage in the activity under the terms set out in the application submitted, it will issue the corresponding authorisation. If anomalies or divergences are detected in the facilities during the inspection, the applicant will be notified by INFARMED and must remedy them within a reasonable time. Failing this, final authorisation will not be granted. The applicant may begin its activity only once final authorisation has been granted.

What are the main requirements to obtain a licence?

The requirements to obtain a licence vary according to the activity in question and the licence to be obtained, but must comply with:

- good agricultural and harvesting practices, as provided for in the European Medicines Agency's Guideline on Good Agricultural and Collection Practice;
- good practices for manufacturing active substances intended for medicinal products for human use, as provided for in Commission Delegated Regulation (EU) 1252/2014 of 28 May 2014 supplementing EU Directive 2001/83/EC;
- good manufacturing practices for medicinal products, as provided for in Decree-Law 176/2006 of 30 August 2006, which sets out the legal framework for medicinal products for human use, with the necessary adaptations; and
- good practices for the distribution of active substances and medicinal products which are in force in the European Union.

For the purpose of examining applications, the following information may also be requested:

- information on any investment and development projects relating to the activity in Portugal;
- information on the facilities to be used for the activity;
- the quantity of product to be used, harvested and obtained, as well as its application and destination;
- the details of the person responsible for performing the activity or the technical director, as well as the details of the person responsible for the security of the facilities and the operations; and
- a description of the security measures to be implemented.

How much does a licence cost?

Licence application processing by INFARMED is subject to payment of the following fees:

- for cultivation – €3,000;
- for manufacture – €3,000;
- for transit – €1,000;
- for import – €1,200;
- for export – €1,200; and
- for wholesale trade, including transport – €1,000.

How long does it take to obtain a licence?

INFARMED will issue a decision on the documentary suitability of a properly completed application approximately 90 to 150 days from the submission date.

Then, work on the implementation, construction or adaptation of the facilities for the activity in question will be carried out prior to INFARMED's subsequent inspection. The duration of this phase will vary depending on how quickly the applicant can work. However, the maximum period granted by INFARMED within which the applicant can request an inspection is six months, which may usually be extended only once.

If INFARMED's inspection confirms that there is no need to make amendments or corrections to the facilities, the final authorisation to engage in the activity is issued within approximately 45 days.

Can licences be transferred?

Licences are non-transferable and cannot be assigned to or used by any other person for any purpose. However, it is possible to transfer the shareholdings representing the capital of a legal entity that is or will be the licence holder.

Further, each specific authorisation will be valid only for the period set out in the applicable order. This period cannot exceed one year, but the authorisation can be renewed or maintained for additional periods of one year.

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