pbbr.a SOCIEDADE DE ADVOGADOS, SP, RL

Saúde - 04-2021

Use of cannabis for medicinal purposes – Regulations

The use of the cannabis plant for medicinal purposes is regulated in Law No. 33/2018 of July 18 and Decree-Law No. 8/2019 of January 15, it has been determined that the investigation of applications and procedures relating to the granting of authorisations for the exercise of cultivation, manufacture, wholesale trade, transit, import and export of medicinal products, preparations and substances based on the cannabis plant for medicinal, medical-veterinary or scientific research purposes, as well as authorisations for the cultivation of the cannabis plant for other purposes, in particular industrial purposes, are defined by ordinance.

Thus, Ordinance No 83/2021 was published on 15 April 2021, which defines requirements and procedures for the granting of authorisations for the exercise of cultivation, manufacturing, wholesale, transport, circulation, import and export of medicinal products, preparations and substances based on the cannabis plant, which enter or in force on 16 April.

Applications for authorization for the exercise of activities referred to above must be submitted electronically, on the WEBSITE of INFARMED, I. P., and must be instructed with the following elements:

1. Application with identification of the activities to be carried out, with the name or registered name and domicile or registered residence of the natural or legal person, signed by the person who obliges the legal person;
2. Updated permanent certificate of the commercial register of the company;
3. Criminal records of the applicant, natural person or collective entity, as well as of all the individuals who oblige him, where is mentioned the purpose, which is intended 'Lawful Market for Narcotic Drugs/Psychotropic Substances';
4. Brief description of the project, according to the model available in the Ordinance;
5. Full identification of the technical director and their educational qualifications, professional training and experience;
6. Term of responsibility of the technical responsible for the preparation, conservation and up-to-date maintenance of all records relating to the cannabis plant;
7. Employment contract concluded between the applicant and the technical director;
8. Criminal record of the technical director, which shall contain at the end for which it is intended 'Lawful Market for Narcotic Drugs/Psychotropic Substances';
9. Professional card number of the technical director, if applicable;
10. Proof of authorisation, granted by a competent authority to suppliers or recipients of medicinal products, preparations and substances based on the cannabis plant for medicinal purposes, for activities related to the intra-Community export, import or trade of the cannabis plant;

11. Proof of implementation of the security measures adopted or to be adopted;
12. Description of the computer registration system ensuring traceability and stocks of the product from sowing to harvesting and destination;
13. Lease of the premises or access code to the permanent certificate of the land registry, as applicable;
14. Payment of the respective fee provided for in Article 43 of Regulatory Decree No. 61/94 of 12 October, in its current wording.

Depending on the activity actually pursued, the Ordinance established additional elements to the above, for example:

- When applications for authorisation relate to cannabis cultivation, criminal records of farmers, a term of responsibility of the safety officer, the coordinates of the place of cultivation and quantities to be sowed and collected shall also be submitted.
- In applications for authorization for cultivation for industrial purposes, obtaining fibers and seeds for food or animal feed, producers must refer to the Directorate-General for Food and Veterinary (DGAV) notification of cultivation and comply with other additional requirements provided for in the Ordinance.
- In the case of the manufacture of medicinal products, preparations and substances based on cannabis for medicinal purposes, additional elements such as the complete address and geographical location of the manufacturing facilities, their plant and descriptive memory are required, as well as the identification of the safety measures implemented and of the technical director.
- If the medicinal products are for medical and veterinary purposes, authorisation shall also be submitted for the manufacture of medicinal products for veterinary use.
- Ordinance No. 83/2021, published in Diário da República, also determines the elements to be presented for the purposes of wholesale trade in medicines, preparations and substances based on cannabis for medicinal, medical-veterinary or scientific research purposes, as well as their transport and circulation.
- With regard to the import and export of this type of products, these are dependent on the issue by INFARMED, I.P. certificate proving prior authorisation for each operation and subject to a whole set of specific security measures.

The cultivation, manufacture, wholesale trade, transport and circulation, import and export, associated with these activities, of medicinal products, preparations and substances based on the cannabis plant for medicinal, medical-veterinary or scientific research purposes, implies the adoption of safety systems which are now defined in the Ordinance, in particular Article 7.

It is up to INFARMED, I.P., after examining the application for authorisation made by the applicant and all the required documentation, request an opinion from the Intervention Service on Additive and Addiction Behavior (SICAD), which will speak within 30 days, to the Office of Planning, Policy and General Administration (GPP), to the Directorate-General for Food and Veterinary (DGAV), to IAPMEI - Agency for Competitiveness and Innovation, I. P. (IAPMEI), and to the Judicial Police (PJ), which have 10 days to comment on such a request. The Ordinance consecrates that the non-favorable opinion of SICAD binds INFARMED, I.P. to reject the request, while the other opinions of the other entities referred to are not binding.

After such analysis, INFARMED, I.P. shall notify the applicant of the suitability or inability of the application for authorisation formulated, which does not represent the authorisation for the development of the activity.

Such authorisation, where for medicinal, veterinary or scientific research purposes, shall be published in electronic form and published in an appropriate place on the INFARMED, I.P. website.

Also provided for in the Ordinance are the inspections of INFARMED, I.P. and PSP to the facilities for the manufacture of medicines or cultivation and storage of cannabis, in order to verify that they comply with the legal and regulatory standards.

Entities that already hold an authorization for the cultivation, manufacture or wholesale distribution of medicinal products containing narcotic and psychotropic substances have a period of 90 days to implement the safety measures defined in Ordinance No. 83/2021.

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