



HEALTHCARE, LIFE SCIENCES & PHARMACEUTICAL

USE OF THE CANNABIS PLANT FOR MEDICINAL PURPOSES

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This law defines as “Medicines, preparations and substances based on the cannabis plant”, the leaves and flower stalks or fruits of the plant, as well as the oil and other standardised or prepared extracts taken or obtained from the cannabis plant. Also, it is defined as “Use for medical purposes”, the use of medicines, preparations and substances based on the cannabis plant, when prescribed by a doctor, by means of special medical prescription, in order to exploit their medicinal properties.

With regard to production of medicines, preparations and substances of this type, this law provides that the Military Laboratory of Chemical and Pharmaceutical Products may contribute to the production. This opens a way to achieve the aims that have been discussed in the Portuguese Parliament with regard to the eventual creation of a manufacturing sector of medicines of a public nature. Similarly, this law establishes an obligation for the Government to stimulate and support academic research regarding the cannabis plant, its properties and therapeutic applications, to be carried out by the state laboratories, associated laboratories or higher education research units.

It is also stipulated that medicines, preparations and substances of this type shall be subject to a special medical prescription, adapted to electronic format, as is already the case of the prescription of medicines that contain psychotropic and narcotic substances. The template for this electronic prescription shall be regulated by ministerial order of the member of Government responsible for the area of Health, to be approved within 60 days of the publication of this Law. It is also appointed the type of information that shall appear in the medical prescription, determining that it must mention (i) the identification details of the user and the prescribing doctor, (ii) the medicines, preparations and substances based on the cannabis plant to be prescribed, (iii) the quantity and dosage, and (iv) the means and mode of administration.

Under the terms of this law, the prescription of medicines, preparations and substances based shall comply with a double-requirement: (i) it may only occur in cases of therapeutic indications considered appropriate for medicines, preparations and substances based on the cannabis plant intended for human use for medicinal purposes as set out in the list of therapeutic indications to be approved by Infarmed, I.P., and (ii) is only legal when conventional treatments with authorised medicines do not produce the expected therapeutic effects, or when the treatment with other medicines is causing significant side effects.

Subsequent to the publication of this law, INFARMED, I.P. shall approve and make public a list of medicines, preparations and substances based on the cannabis plant that currently exist on the market and, therefore, are suitable to be used for therapeutic and medicinal purposes under the scope of this regime.

As regards the commercialisation, it is stated that these medicines will only be available at pharmacies, and may only be sold upon presentation of a special medical prescription and confirmation of the identity of the patient or their representative. Furthermore, it is established that only pharmacists may sell these medications. In fact, the wording used in this law seems to reveal an intention of the legislator to ensure that only pharmacists belonging to the technical direction of the pharmacy may be evolved in the selling of these medicines, preparations and substances, considering its nature. In other words, it seems that the legislator demands that only the technical director or, in case of absence or unavailability of the technical director, a pharmacist registered as a substitute in INFARMED, I.P. may sell these medicines. Accordingly, it seems that no other members of the pharmacy staff are authorized to sell these medicines, preparations and substances. This law also specifically prohibits the re-use of prescriptions that have already been registered in a sell.



JOÃO PEDRO VALE
English As She Is Spoke #3 (Herbário), 2010
Giz sobre tinta de ardósia e PVC
95 x 130 cm
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Regarding the possession and circulation of these medicines, preparations and substances, it is established that is only permitted when accompanied by the respective medical prescription, and when intended for personal consumption and in accordance with the prescription, within the limit of the quantity prescribed by the doctor.

Under this law, INFARMED, I.P. is responsible for the supervision of the activities of cultivation, production, extraction and manufacture, wholesale, distribution to pharmacies, import and export, transport, acquisition, sale and delivery of medicines, preparations and substances based on the cannabis plant intended for human use and medicinal purposes. It is also established that the commercialization of these medicines, substances and preparations based on the cannabis plant is subject to previous marketing authorisation, to be issued by INFARMED, I.P.

Law no. 33/2018 also determines that the information to be provided to healthcare professionals regarding medicines, preparations and substances based on the cannabis plant for medicinal purposes shall be granted by the Government. This technical information shall be provided through the agencies and organisations integrated in the State's direct or indirect Administration, within the Health Ministry, as well as entities belonging to the State's corporate sector in the health sector.

Law No. 33/2018, of 18 July, comes into force on the 1st of August 2018.

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