

**HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS**

Medical Cannabis in Portugal

The production of controlled substances for the pharmaceutical industry already has something of a tradition in Portugal. In recent years, licences have been granted to cultivate controlled substances, such as opium poppy and substances intended for the pharmaceutical industry to produce opioid medicines.

In view of the considerable progress made in scientific studies on the medicinal use of the cannabis plant, an urgent need has arisen for legislative action to regulate this "thriving" market, in particular, a market that is predicted to become one of the fastest growing markets in the coming years in a wide range of therapeutic areas.

In the last two years, Portugal has therefore adopted specific legislation aimed at regulating the use of cannabis for medical purposes, allowing the cultivation of the plant and the production of cannabis-based medicines, preparations and substances in accordance with the legislation applicable in the legal narcotics market. The aim was and still is to take an active leadership role in Europe in this field, a goal that can also be expected to be achieved due to the excellent climate conditions in this country.

As a result, Law No. 33/2018 was published on 18 July 2018. This law regulates the use of medical products, preparations and substances based on cannabis for medical purposes. It also lays down, in general terms, the conditions under which medicines, preparations and substances based on cannabis may be prescribed by doctors and, moreover, grants pharmacies the exclusive right to dispense these medical products.

Subsequently, Legislative Decree No 8/2019 was published on 15 January 2019. The main purpose of this piece of legislation is to define and classify operations such as cultivation, production, extraction and manufacturing, wholesale, import and export, transit, acquisition, sale and supply of medicines. It also covers placement on the market of medicines, preparations and substances based on cannabis intended for human use for medical purposes.

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"In Portugal it is now possible to obtain licences for the cultivation, manufacturing, import, export and wholesale marketing of medical cannabis."

The two pieces of legislation mentioned above give INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (National Authority for Medicine and Health Products) the power in Portugal to issue licences for the (i) cultivation, (ii) manufacturing, (iii) import and export and (iv) wholesale marketing. In fact definitive licences to carry out these activities have already been issued.

In practice, the licensing procedure is relatively unbureaucratic and is divided into two stages: the first relates to the pre-licence and the second to the licence allowing the activity in question to be carried out. The granting of the pre-licence requires the company to submit an application with all the necessary documents and the complete project. This application will set out, among others, the measures that the company undertakes to carry out once the licence is granted, without, however, assuming any final obligations. The second licence can only be issued after the successful completion of these measures and marks the end of the licensing procedure.

"The regulatory and legal stability in the sector in Portugal is attracting the world's biggest players in this industry."

Portugal is currently experiencing growing and significant investment in this sector. The regulatory and legal stability existing in the sector is attracting the world's largest players in this industry.

In conclusion, considering the development and expansion of this sector in the country, Portugal is taking the necessary steps to become a world benchmark for the cultivation and production of medicinal cannabis-based substances in the medium term. ■