

**HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS**

Three Years of the Portuguese Medical Cannabis Law

Three years have passed since the approval of the Portuguese medical cannabis law. In this period, many changes have taken place in this area, but the main one has probably been the fact that Portugal has started to build a medical cannabis market.

Since the approval of Law no. 33/2018, of 18 July, Portugal has become one of the most sought-after countries in Europe for the development of cannabis projects. Many leading worldwide players turned their attention to Portugal and the country currently has a very significant number of projects in the pipeline promoted or endorsed by these companies.

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From a regulatory point of view, after the publication of Law no. 33/2018, the Government issued Decree-Law no. 8/2019, of 15 January, which framed the activities of cultivation, production, extraction and manufacturing, wholesale trade, import and export, transit, acquisition, sale and delivery of medicines, preparations and substances based on the cannabis plant for medical purposes. This Decree-Law also covers the placing on the market of medicines, preparations and substances based on the cannabis plant for medical purposes, and it establishes the terms and conditions under which such products can be marketed, prescribed and sold.

For its part, the mentioned Decree-Law refers to a ministerial order that would establish the process of application for authorisations to work with medical cannabis, regardless of whether it is cultivation, manufacture or marketing. This was finally published in 2021 as Ministerial Order no. 83/2021, of 15 April.

The publication of this ministerial order had been long-awaited because it establishes the practical aspects of the applications to obtain an authorisation to engage in activities relating to medical cannabis. Although the competent authority – Infarmed – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (“**Infarmed**”) had adopted an internal procedure to these applications – which closely followed the applications relating to the opening of pharmacies – the ministerial order has clarified a lot of practical aspects of the application requirements.

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Moreover, before the publication of the above ministerial order, Informed's approach had been very proactive and collaborative. In fact, it continued to insist on high standards and to make it clear that the restrictions and safety requirements applicable to working with controlled substances had to be followed. Thus, Informed has created concepts and mechanisms to allow applicants to proceed with their application projects without being blocked due to the absence of a regulatory ministerial order and this approach allowed companies to develop these projects.

From a practical point of view, the publication of the regulation was delayed. Nevertheless, the Government was more diligent providing in regulating the mechanism for price setting of preparations and substances. In fact, Ministerial Order no. 44-A/2019, of 31 January, establishes the mechanisms under which the price of medicines and preparations and substances based on the cannabis plant intended for medical purposes should be set. In general, the framework establishes that the price should be proposed by the holder of the authorisation to place the substance on the market to Informed, with reference to the current price on the international market. The price will then be approved or refused by Informed. In case of refusal, the holder of the authorisation to place the substance on the market should propose a new price.

When it comes to setting the prices of medicines based on the cannabis plant, the pricing mechanisms are the same as those that apply to common medicines.

Furthermore, in January 2019, a resolution of Informed's Board of Directors established the first seven therapeutic indications for preparations and substances based on medical cannabis. These indications relate in the main to pain pathologies, such as multiple sclerosis, oncology and epilepsy.

Although the regulatory framework is established, the truth is that the use of medical cannabis products is still residual. On the one hand, the market does not have a significant number of alternatives. In the case of medicines, at the moment only Sativex is sold on the Portuguese market at a relatively high price¹, even though it is subject to co-payment by the State. As regards substances and preparations, there are some applications pending before Informed, but, for the moment, only one preparation is currently being marketed and it is not subject to co-payment by the State. Besides, the medical world has been expressing reservations, mainly due to the lack of evidence on the use of medical cannabis.

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In fact, there are some essential issues to allow the development of the market that need to be clarified.

The first one relates to the need for medical professionals to clarify their doubts and fears about medical cannabis. The final decision on the use of a medical cannabis product is in the hands of the doctors and they will only use such a product – either a medicine, a substance or a preparation – if they trust the product.

¹ Sativex is co-funded by Portuguese State under the general regime at a rate of 37% of a selling price of EUR 475.27.

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The second aspect is the price. As we have said, there is only one medicine currently being marketed in Portugal with the price of EUR 475.27. Even with co-payment at the rate of 37%, the patient still has to bear a significant part of the price, which makes the access to therapy difficult to a significant proportion of patients. In what concerns to substances, there is also one being currently marketed in Portugal², which has no co-payment by the Portuguese State.

In our view, the solution to the problem lies in rebalancing the margins of the different players in the value chain by reviewing the prices of these substances, particularly by considering increasing the co-payments granted to these medicines, preparations or substances. This rebalancing would, on one hand, make these therapies more accessible to users – which is very relevant when these therapies are most often the last resort for the treatment or control of symptoms associated with serious pathologies – and, on the other hand, make this market more attractive for the pharmaceutical industry, justifying investment in R&D and the launch of new products on the market.

Finally, the Portuguese Parliament has started the discussions on the liberalisation of cannabis for personal use. The bills were submitted by the parties Bloco de Esquerda (“Left Block”) and Iniciativa Liberal (“Liberal Initiative”) and intends to allow the consumption of recreational cannabis, without prescription, under certain circumstances. The voting on the bills was postponed to the next legislative session, which will start on 7 September. However, to date, there has been no vote on the bills.

It is unlikely that these bills will be approved for the time being. However, considering the political composition of the parliament and the majority’s agenda, the bill will certainly be up for discussion again in the near future. In this regard, it is possible that the market of recreational cannabis will become a reality in Portugal by 2023, when the current legislative parliament ends.

Finally, it is important to mention that the Covid-19 pandemic also impacted the Portuguese medical cannabis market, taking the industry by surprise. Players are now awaiting to see the extent to which the pandemic will impact the medical cannabis market and how they will overcome the delay caused by it.

Nevertheless, Portugal continues to attract a lot of global players, which are maintaining and even increasing their investments in Portugal. Considering that the recovery is already underway, we have very good reasons to believe that prosperous times are on the horizon for this sector in Portugal. ■

² Dry flower for inhalation, with the selling price of EUR 150.87.