



HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Cannabis: first amendment to Ministerial Order 83/2021

Ministerial Order 14/2022 was published on 5 January to introduce the first amendment to Ministerial Order 83/2021 of 15 April. The original Ministerial Order sets out the requirements and procedures for granting authorisations for activities relating to the cultivation, manufacture, wholesale trade, transport, circulation, import and export of medicines, preparations and substances made from the cannabis plant.

The amendment now introduced is intended to address the insufficient regulation of some issues relating to the cultivation of the cannabis plant for medical and non-medical purposes. Specifically, the amendment addresses the cultivation of hemp for industrial purposes and differentiates it from the cultivation of the cannabis plant for other purposes. It also regulates some aspects of the cultivation of the cannabis plant for medicinal purposes.

Article 3-A is added to Ministerial Order 83/2021 and it establishes the technical requirements applicable to the cultivation of cannabis plants for industrial purposes, including the minimum limit of the area of cultivation of the cannabis plant and the sowing density.

Changes are also made to the rules on applications for authorisation for activities relating to the cultivation, manufacture, wholesale trade, import, export, transport and movement of medicinal products, preparations and substances based on the cannabis plant for medicinal, medical or veterinary purposes or for purposes of scientific research. In addition to proof of an authorisation granted by the competent authority to suppliers or recipients of medicinal products, preparations and substances based on the cannabis plant for medicinal purposes, for activities relating to the export, import or intra-EU trade in the cannabis plant, declarations of interest from these entities will also be required.

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Ricardo Rocha

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Furthermore, for activities involving the manufacture of medicines, substances or preparations based on the cannabis plant for medicinal purposes, Ministerial Order 83/2021 will also require the technical manager to be a pharmacist with a pharmaceutical industry specialist qualification only in the case of manufacture of medicines, substances and preparations. The requirement for this specialisation will be waived in cases where only active substances for the pharmaceutical industry are manufactured.

Ministerial Order 14/2022 also introduces changes in the documentation that has to be submitted to engage in the activity of wholesale distribution of medicines, preparations and substances based on the cannabis plant for medicinal purposes. Specifically, it regulates the wholesale trade of the plant, part of the plant or active substances based on the cannabis plant for medicinal purposes.

Finally, in the inspection of facilities for activities for medicinal, medical-veterinary or scientific research purposes, it is no longer necessary to submit proof of industrial licensing at the time of the inspection request. This applies in cases where the operations to be carried out are exclusively primary processing, cutting and drying, carried out in accordance with good manufacturing practice for active substances for medicinal products for human use approved by Commission Delegated Regulation (EU) 1252/2014 of 28 May 2014. ■