

The regulation governing the medical use of cannabis and its pharmacological derivatives is issued

The Regulation of the General Health Act regarding Health Control for the Production, Research and Medical Use of Cannabis and its Pharmacological Derivatives was published today in the Official Federal Gazette and its purpose is to identify and regulate the activities involving cannabis that are considered permitted because they are for a medical use.

The medical use of cannabis includes: (i) research for health and pharmacology, (ii) pharmaceutical production (medicines and pharmacological derivatives), (iii) diagnosis and prescription of cannabis medicines and (iv) primary production destined for obtaining raw material for such purposes. This regulation does not address adult use and industrial use of cannabis which will be regulated separately. To satisfy the different authorized uses, the importing of raw material, pharmacological derivatives and cannabis medicines is permitted, subject to compliance with the established requirements.

The primary production of cannabis requires a permit to plant in a confined site which requires, among other things, having first obtained the authorization of a research protocol or a sanitary registry. It is established that the institutions and laboratories holding a planting permit can contract with an agricultural producer for carrying out the related activities.

The prescribing of cannabis medicines requires the use of special recipes that must include a bar code that will be provided by the Federal Commission for Protection from Sanitary Risks (COFEPRIS). The regulation contains the special requirements for the use and custody of the recipes. The possession of cannabis medicines must always be covered by a medical prescription or the respective invoice.

The manufacturing of pharmacological derivatives and cannabis medicines will be subject to other regulations currently in force that regulate the manufacture of pharmacological derivatives and medicines regardless of whether or not they contain cannabis. In addition, this regulation indicates that the preparation of products with cannabis will also be subject to the control guidelines that the COFEPRIS and other competent authorities determine in coordination, which are pending issuance and may constitute a delay for the implementation of this new legal framework.

The importing of raw material (seeds), pharmacological derivatives and medicines will be permitted provided they have a Sanitary Permit Prior to Import. In turn, obtaining that permit implies, depending on the case, first obtaining a phytosanitary certificate, a sanitary registry and/or a sanitary license, which is also subject to compliance with other sanitary regulations currently in effect. To obtain a sanitary permit prior to import for cannabis medicines for personal use, the petitioner will have to include the medical prescription which will have to be presented together with the permit in the customs dispatch of the merchandise.

Although this regulation will enter into force on January 13, 2021, the Ministry of Agriculture and Rural Development will have 90 business days to make the modifications to the current legal framework that are necessary to implement the provisions of the regulation relative to the primary production of cannabis, including the preparation of the land, planting, development of the crop, harvesting and packaging.

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