MIJARES ANGOITIA CORTES Y FUENTES

Publication of the Regulations on health control for the production and medicinal use of cannabis

Regulatory – January 13, 2021

On January 12, 2021, the Regulations of the General Health Law on sanitary control for the production, research and medicinal use of cannabis [1]and its pharmacological derivatives was published in the Federal Official Gazette (the "Regulations"), the foregoing, pursuant to the amparo ruling issued by the National Supreme Court of Justice on August 2019, which reinforced the obligation of the Ministry of Health to regulate the medicinal use of cannabis.

The Regulations provide for the primary production for the supply and production of seed, research for health and pharmacology, manufacture of pharmacological derivatives and medicines, and the medicinal use of cannabis.

The Regulations determine the functions of certain competent federal authorities, such as the National Service of Health, Safety and Food Quality ("SENASICA"), the Tax Administration Service ("SAT"), the Ministry of Economy ("SE") and the Ministry of Agriculture and Rural Development ("SADER"), among others. The Federal Commission for the Protection against Sanitary Risks ("COFEPRIS") will be in charge of sanitary regulation and the traceability system[2]; no institute or independent agency was created, as various law initiatives had stipulated.

The sowing permit for the manufacture of pharmacological derivatives and medicine shall be processed before SENASICA; such activity must be carried out in a permitted, confined location, which must be restricted from the population and the environment. A requirement to file for this permit is to hold a sanitary registry and manufacturing license. Factories and laboratories that process pharmacological derivatives and medicines may only commercialize them in establishments that have a sanitary license.

[1] "Cannabis" understood as the cannabis sativa, indica and American or marijuana plant, its resin, preparations and seeds.
[2] System that allows to identify the source and different stages of the evolutionary process of cannabis-related products.

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The Regulations allow the import of raw materials, pharmacological derivatives and medicines, and the export of pharmacological derivatives and medicines, exclusively, after obtaining the corresponding certificates and licenses granted by COFEPRIS and SADER, in accordance with their attributions.

However, it bans the advertising of cannabis medicines that targets the general population. Furthermore, the Regulations disregard whether to allow foreign investment or limit the percentage of its investment, the exclusivity of licenses and authorizations, nor does it limit the number of licenses that can be obtained per company or establishment, for one or all the activities.

The Regulations entered into force on the day following its publication. To access the Regulations, please refer to [*].

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