MIJARES ANGOITIA CORTES Y FUENTES

Draft Regulation of the medicinal use of cannabis and derivatives

Regulatory – July 30, 2020

Regulations of Sanitary Control for the Medical Production, Research and Use of Cannabis and its Pharmacological Derivatives

On July 27, 2020, the National Commission of Regulatory Improvement ("CONAMER") published on its website the draft of the Regulations of Sanitary Control for the Medical Production, Research and Use of Cannabis and its Pharmacological Derivatives (the "Regulation"), which was drafted and submitted by the Ministry of Health. The foregoing derived from the amendment to the General Health Law that was published in the Federal Official Gazette on June 19, 2017, in which established the obligation to the Ministry of Health in order to issue the regulation of medical use of the pharmacological derivatives of cannabis, in a time period of 180 days. Moreover, the ruling of the amparo trail issued by the Mexico´s Supreme Court of Justice, dated August 14, 2019, reinforced the obligation of the Ministry of Health to regulate the medicinal use of cannabis.

The Regulation determines the functions of certain federal authorities, as the National Service of Safety and Quality in Farming Production ("SENASICA"), the Tax Administration Service ("SAT"), Ministry of Economy ("SE"), among others; however, the Federal Commission for the Protection against Sanitary Risks ("COFEPRIS") will manage the health and safety matters, without including the creation of an independent Institution and/or Agency as it was stipulated in previous legislative initiatives.

The Regulation aims at regulating, control and monitoring, health matters of the raw material, molecular complexes, pharmacological derivatives and medicines for the production, research, industrial and medical purposes of cannabis. It incorporates the concept of primary production, which covers the preparation of the soil, sowing, cultivation and harvesting of cannabis, in a permitted confined area, which must be

restricted from the population and the environment. Activities of import and export will be allowed, in the case of export, only for pharmacological derivatives and medicines, after having obtained the corresponding certificates and licenses.

The Regulation fails to determine whether foreign investment will be allowed or to limit the percentage of investment, the exclusivity of the companies for the obtainment of licenses and authorizations, as well as, the number of licenses that can be obtained by companies or establishments, for one or all the regulated activities.

For any additional information, do not hesitate to contact our expert team on regulatory issues, who can help you:

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