CREEL GARCÍA-CUÉLLAR AIZA Y ENRÍQUEZ

Regulations of the General Health Law on Sanitary Control for the Production, Investigation and Medicinal Use of Cannabis and its Pharmacological Derivatives

In compliance with the mandate of the Supreme Court of Justice of the Nation, the Ministry of Health published on January 12, 2021 in the Official Gazette of the Federation the "*Regulations of the General Health Law in Matters of Sanitary Control for the Production, Investigation and Medicinal Use of Cannabis and its Pharmacological Derivatives*", (the "Regulation") which entered into effect the day following its publication.

The purpose of the Regulation is the control, promotion and sanitary surveillance of raw materials, pharmacological derivatives and medicines of Cannabis, with production, research, manufacturing and medical purposes.

It is important to point out that the Regulation does not regulate other uses of Cannabis, other than therapeutic (medical) and research uses.

Key Highlights:

- The Regulations establish the requirements and authorizations necessary for the use of cannabis for the following purposes:

  a) Primary production (to supply manufacture for medical purposes, generate raw material for research and to produce seeds).
  b) Health and pharmacological research.
  c) Manufacture of pharmacological derivatives and medicines.
  d) For Physicians, for diagnostic, preventive, therapeutic, rehabilitation and palliative care.

- It grants powers within the scope of its duties to the Ministries of Health (COFEPRIS), Agriculture (SENASICA and SNICS), Finance (SAT) and Economy.

- Regarding Research purposes, it establishes the obligation to have a Research Protocol authorized by COFEPRIS.

- As for Production, it establishes the requirements by which SENASICA will grant permits for the planting of cannabis for research purposes and the manufacture of pharmacological derivatives and medicines.

- The Regulation points out the requirements that must be fulfilled by health professionals authorized to prescribe cannabis medicines, as well as the establishments authorized to provide the public with cannabis medicines.

- Establishments destined to the manufacturing process or the import, export or use of raw material, pharmacological derivatives or cannabis medicines, must have Control Books authorized by COFEPRIS.

- The Regulations establish the requirements and restrictions for the import and export of pharmacological derivatives or cannabis medicines (raw material may only be imported).

- Article 72 provides the requirements under which the import of cannabis medicines for personal use and medical purposes is allowed.
- The Regulations limit advertising of cannabis medicines to health professionals (prohibits advertising to the general public).
- COFEPRIS has powers of health surveillance and verification.

The preceding information is intended as a timely update on the relevant laws. This content is informational only and does not constitute legal or professional advice. To obtain such advice or a deeper summary of the legal developments addressed in this document, please do not hesitate to contact our partner Begoña Cancino (begona.cancino@creel.mx) or our counsel Guillermo Govela (guillermo.govela@creel.mx).

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