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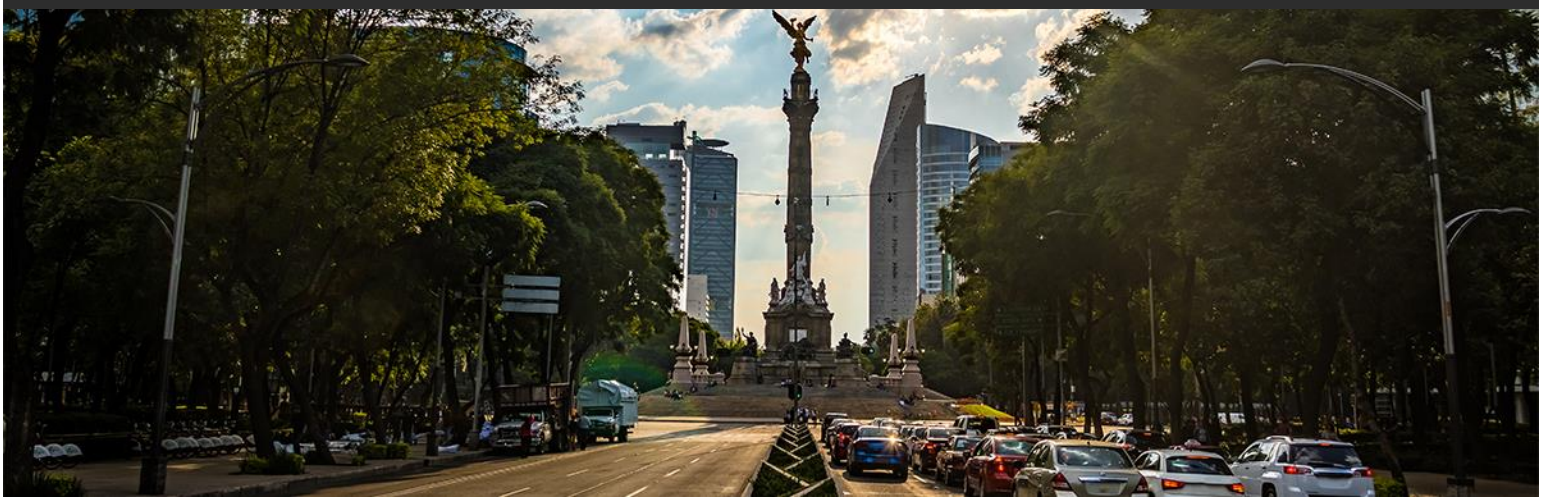

January 2021

Mexico's General Health Law Regulations for the Production, Investigation, and Medicinal Use of Cannabis and Derivatives

Read in Spanish/Leer en Espanol.

On Jan. 12, 2021, the General Health Law Regulations for the Control of Production, Investigation, and Medicinal Use of Cannabis and its Pharmacological Derivatives (the Regulations) were published in the Federal Official Gazette, coming into force Jan. 13, 2021.

The Regulations regulate, control, promote, and monitor the raw materials, pharmacological derivatives, and medicines derived from cannabis, for production, research, manufacturing, and medical purposes. The Regulations apply to activities carried out for the following purposes:

I. Primary production,

II. Health research,

III. Pharmacological research,

IV. Manufacturing of pharmacological derivatives and medicines, and

V. Medical diagnosis, prevention, therapeutics, rehabilitation, and palliative care.

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QUALITY CONTROL LABORATORIES

Each health registration holder must have an independent Quality Control Laboratory[1] under the authority of a qualified person with the required academic background and experience, pursuant to the procedures established in the laboratory's Quality Management System[2].

RESEARCH

Those interested in carrying out cannabis research must obtain authorization for their Research Protocol from COFEPRIS.

PRODUCTION

The cannabis harvesting permit for research and manufacturing must be filed before SENASICA[3], in accordance with the provisions of the Regulations, including the authorization of the research protocol or the sanitary registration for the medicine to be produced.

MEDICAL PURPOSES

Prescription of cannabis medicines must observe the provisions set forth in Article 240 of the General Law of Health[4] and its Regulations. Professionals who wish to obtain a bar code for special prescriptions for cannabis medicine will need a permit from COFEPRIS.

MANUFACTURING

Public and private establishments involved in the manufacturing process, import, export, or use of raw material, pharmacological derivatives[5] or cannabis medicines will be required to maintain a specific control book that complies with the requirements established in the Regulations, and to implement security systems in compliance with Article 46 of the Regulation of Inputs for Health and Pharmacopoeia of the United Mexican States[6] and satisfy all of the requirements established by the Regulations.

The control book must be authorized by COFEPRIS and must contain a record of the manufacturing of the pharmacological derivatives for which the sanitary registration for sale is being requested. It must also include, as applicable, the following information:

I. Name of the pharmacological derivatives;

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[1] Authorized by Federal Commission for the Protection against Sanitary Risks (COFEPRIS) to carry out the analytical tests required for monitoring and control during the different stages of the cannabis process.
[2] Mechanism through which the Quality Control Laboratory complies with the provisions of Article 8 of the Health Supplies Regulation and controls quality-related activities.
[3] National Service for Agro-Alimentary Public Health, Safety and Quality.
[4] Article 240. Only the following professionals may prescribe drugs, if they have a degree registered by the competent educational authorities, fulfill the conditions set forth in the Law, its regulations, and the requirements determined by the Ministry of Health: I. medical surgeons; II. veterinary doctors, when prescribed for animals, and III. dental surgeons, for dental cases. Medical interns will be able to prescribe narcotics with the limitations determined by the Secretary of Health.
[5] All cannabinoids and their acidic forms, including the mixture or composition thereof, that have some pharmacological activity, that are identified by their physical, chemical or biological action properties, that are not in pharmaceutical form and that meet the conditions to be used as an active ingredient of a Medicine.
[6] Article 46. Public and private establishments that process, import, export, or use narcotics or psychotropic substances for human use shall have control books authorized by the Ministry and a security system for their safekeeping and custody. […]

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II. Lot number;

III. Quantity to be used and balance remaining;

IV. Origin;

V. Use and destination that will be given, and

VI. Process summary.

Producers that consistently require raw materials, pharmacological derivatives, or cannabis medicines must notify COFEPRIS, in January and May, of the quantities that will be needed the following year.

Factories or laboratories that process pharmacological derivatives and storage facilities that hold these products will only be able to sell them to establishments with a valid sanitary license for such purpose.

Owners of pharmacological derivatives must give written notice to COFEPRIS and other relevant authorities of any shortages or waste in their inventories to avoid unintended distribution of such substances.

DESTRUCTION

The destruction of pharmacological derivatives must be communicated to COFEPRIS and carried out in the presence of a health authority or verifier.

IMPORT AND EXPORT

Raw materials, pharmacological derivatives, and cannabis drugs may be imported into Mexico with customs clearance from the competent authority.

Pharmacological derivatives and cannabis medicines may be exported from Mexico, if they comply with the legal requirements in the destination country.

For the import and export of the above-mentioned products, a previous sanitary permit granted by SADER[7] or COFEPRIS must be obtained.

Import and export may not be carried out by ordinary mail under any circumstances.

Importers must keep the import and export permits for a minimum of three years.

SALE AND ADVERTISING

Advertising of cannabis medicines must be directed to health professionals only. Promotion and advertising to the general public is not permitted.

Establishments that sell cannabis medicines must fulfill the applicable legal provisions, and must have the following documentation:

I. Sanitary license;

[7] Ministry of Agriculture and Rural Development.

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II. Sanitary responsible notice;

III. Control books;

IV. Federal taxpayer registry; and

V. Permission of acquisition in market.

For more information regarding cannabis in Mexico please see our prior GT Alerts:

December 2020 – Mexican Senate Approves New Provisions and Amendments for the Regulation of Cannabis (Marijuana) in Mexico.

March 2020 – Update on Cannabis (Marijuana) Regulations in Mexico.

June 2019 – Update on Cannabis (Marijuana) Regulations in Mexico.

January 2019 – Regulation of Cannabis Regulations in Mexico.

** This GT Alert is limited to non-U.S. matters and law.*

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