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Mexico City, january 18, 2021.

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

Dear customers and friends,

On January 12, the *Regulations of the General Health Law for the Sanitary Control of Production, Investigation and Medicinal Use of Cannabis and its Pharmacological Derivatives* (the "Regulations") were published in the Federal Official Gazette. Their purpose is the regulation, control, promotion and sanitary surveillance of raw materials, pharmacological derivatives and medicines of Cannabis, for production, research, manufacturing and medical purposes.

1. In general terms, the Regulations cover:
   a. Primary production, including supply, manufacture for medical use, raw material for research, and production of seeds;
   b. Research for health;
   c. Pharmacological research;
   d. Manufacturing of pharmacological derivatives and medicines and;
   e. Diagnostic, preventive, therapeutic, rehabilitation and palliative care.

2. The Regulations establish as competent authorities: the Federal Commission for Protection Against Sanitary Risks ("**COFEPRIS**"); the National Service for Agriculture Health, Safety and Quality ("**SENASICA**"); the National Service for Seed Inspection and Certification ("**SNICS**"); the Ministry of Economy ("**SE**") and the Ministry of Finance and Public Credit ("**SHCP**"), through the Tax Administration Service ("**SAT**"), which will exercise the powers conferred upon them by their own laws, regulations and other applicable provisions.

   a. SENASICA is in charge of regulating and promoting the quality of Cannabis, as well as the application, verification and certification of systems to reduce the risk of physical, chemical and microbiological contamination in primary production, in accordance with the Federal Law of Plant Health and other applicable legal provisions;

   b. SNICS will regulate the production of certified seeds, the qualification of seeds and the marketing and circulation of all cannabis seeds, in accordance with the Federal Law on the Production, Certification and Trade of Seeds and other applicable legal provisions;

   c. COFEPRIS is responsible for the regulation, control and health promotion related to the research, manufacture and medical purposes of cannabis, its pharmacological derivatives and medicines, as well as the control and monitoring in the testing and traceability, in accordance with the provisions of the General Health Law and other applicable legal provisions;

   d. SAT will verify compliance with the legal provisions applicable to imports and exports, and

   e. SE will intervene, according to its attributions, in the determination of the tariffs that should correspond to import and export.

3. With respect to the purposes contemplated in the Regulations, these are divided into research, production, medical purposes, manufacturing, and destruction:

a. **Research:** COFEPRIS must authorize the research protocol, and maintain and update annually the national inventory of research conducted in the country on cannabis.

b. **Production:** permission must be obtained from SENASICA for planting of cannabis for research and manufacture. The application must be accompanied by the corresponding research protocol. Permits to plant authorized species or varieties will be granted for planting, cultivation, harvest, research and manufacture of pharmacological derivatives and medicines.

c. **Medical purposes:** medical prescription will require compliance with the provisions of Article 240 of the General Health Law. The drugstores, pharmacies or drugstores authorized to prescribe cannabis medicines, must have a register of patients, according to applicable legal provisions on protection of personal data. Possession of medicines derived from cannabis shall be accredited with the copy of the special prescription that contains the bar code and the autograph signature of the authorized professional that extends it or, in its case, the corresponding invoice.

d. **Manufacturing:** The guard and custody of the raw material, pharmacological derivatives, or medicines of cannabis, will be responsibility of the holder who must have the documents demonstrating their legal possession. The public and private establishments that are destined to the manufacturing process or that import, export or use raw material, pharmacological derivatives, or cannabis medicines, will have control books authorized by COFEPRIS, and a security system for their safekeeping. During the months of January to May, the producers that regularly need raw materials, pharmacological derivatives or cannabis medicines must communicate by means of a notice to COFEPRIS, a forecast of the quantities that they will demand during the following year. Cannabis medicines cannot be presented in the form of a medical sample or original gift. The owners of raw materials, pharmacological derivatives, or cannabis medicines, as well as those responsible for specific actions and other actions that they carry out in compliance with other applicable legal provisions, must give written notice to COFEPRIS and other corresponding authorities about the disappearance of the same, in order to avoid their deviation.

e. **Destruction:** must be communicated to COFEPRIS and carried out in the presence of a certified third party.

4. With respect to **export and import**, the Regulations allow for the import of raw materials, pharmacological derivatives, and cannabis medicines. For export only pharmacological derivatives, and cannabis medicines are allowed.

A sanitary permit prior to import, granted by SADER or COFEPRIS, must be obtained. Likewise, none of these actions are to be carried out by mail or by using the services of courier or parcel service companies, or in any other case indicated by the regulations on customs clearance.

In the case of raw materials, pharmacological derivatives, and cannabis medicines from abroad, only authorized customs clearance will be allowed. The import of raw material, pharmacological derivatives, and cannabis medicines will not be allowed in cases where they are prohibited in the country of origin or not allowed for import in accordance with applicable regulations.

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5. Persons holding a marketing authorization must have an independent **Quality Control Laboratory** under the authority of a person certified according to quality management procedures. COFEPRIS may verify the control laboratories to check their operating conditions, infrastructure, procedures and analytical tests.

6. Finally, **advertising and marketing** is only allowed for cannabis medicines that are directed to health professionals, so it is prohibited to make promotion and advertising aimed at the general population. At any time, COFEPRIS may carry out verification proceedings and visits for this purpose.

The Regulations will enter into force the day after its publication in the DOF, that is, on January 13, 2021. Likewise, all administrative provisions that are contrary to the Regulations will be repealed.

The attorneys of Mañón Quintana are at your service in relation to any questions or comments regarding this client alert.

Sincerely,

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