August 10, 2020

MEXICO CANNABIS UPDATE #19

Draft of Medical Use Rules Published

Finally. On July 27, 2020, a draft of secondary rules for medical cannabis in Mexico were submitted by the Secretary of Health (SSA) to the National Commission for Regulatory Improvement (CONAMER) for the mandatory public consultation and regulatory impact assessment. The rules, titled Rules for the Sanitary Control of the Production, Research and Use of Medican Cannabis and its Pharmacological Derivates (*Reglamento en Materia de Control Sanitario para la Producción, Investigación y Uso Medicinal de la Cannabis y sus Derivados Farmacológicos*, and successively referred to as the "Rules"), come after more than 3 years waiting for this following the 2017 amendments that legalized such uses. These Rules are only intended for medical and research purposes.

General Provisions.

The stated purpose of the Rules is to establish the "…regulation, control, promotion and sanitary oversight of raw material, molecular compounds, pharmacological derivates and medications with production, scientific, industrial and medical purposes."

The contemplated research activities only include those for pharmacological and agronomic purposes. As for "industrial" use, the term is set with the connotation of production of molecular compounds, pharmacological derivates and medications; not as industrial hemp in the broader sense that contemplates its multiple uses. This would contradict the definition set in the general cannabis legalization bill approved by Senate committees last March.

There are some definitions worth noting, some of which have generated feedback from industry advocates suggesting improvement, namely:

- Cannabinoids: Defined as "organic compounds pertaining to the terpenophenolics group, which include CBD and THC" (which, by the way, are the only cannabinoids identified and defined in these rules).
- Cannabis: "Cannabis sativa, indica and americana or marihuana, its resin, preparations and seeds."
- Hemp: "Fibrous product elaborated from the male cannabis sativa plant, without flowers or fruits, which does not contain more than 1% THC."
- CBD: "Cannabidiol and its acid forms, cannabinoid compound that lacks psychoactive properties."

The Federal Commission Against the Protection against Sanitary Risks (COFEPRIS) will be in charge of implementing and managing the traceability system which shall organize the use of specialized technical tools. This may appear strange to those expecting that it be the Secretary of Agriculture (or the tax revenue service, for that matter), who would normally have the best resources and knowledge to manage this area.

In addition to the SSA, the following government agencies will be involved in the application and enforcement of the Rules:

- National Service for Agro-food Sanitation, Inocuity and Quality (SENASICA): oversee and promote cannabis sanitation, as well as managing systems to prevent or reduce contamination at the primary production stage in accordance with the Mexican Law of Vegetal Sanitation;
- National Service for Seed Inspection and Qualification (SNICS): regulate the production of certified seeds, qualification of seeds and sale of cannabis seeds in accordance witht eh Federal Law for the Seed Production, Certificaation and Commerce;
- Secretary of Agriculture (SADER): involved in the review of permits for importation of seeds, through its various agencies that are under its jurisdictional and operative umbrella;
- COFEPRIS: sanitary oversight and control of scientific, industrial and medical use of cannabis in accordance with the General Health Law;
- Mexican Tax Revenue Service (SAT): verify compliance with applicable tax provisions, including but not limited to the import and export taxes, and customs procedures, in accordance with the Customs Law, the Health Law, among others; and
- Secretary of Ecomony (SE): intervene in the determination of applicable tariffs that shall be applied to the import and export of cannabis.

Generally speaking, the Rules insert the aforementioned uses of cannabis into the Mexican healthcare and sanitary legal framework, perhaps even to the extent of overlapping with other health regulations. Each of the existing government agencies mentioned above are assigned with responsibilities that will now cover the respective stages of production, processing, preparation, importation or exportation, sale and prescription for the allowed uses. In other words, no new agencies are created for now, as opposed to the Cannabis Legalization Bill which currently contemplates the creation of the Instituto Mexicano del Cannabis (*Mexican Cannabis Instititute*).

For purposes of this summary and consistent with the terminology used in the Rules, an "establishment" shall be deemed any of the commercial establishments that are mentioned by Mexico's General Health Law, the Medical Supply Regulations (*Reglamento de Insumos para la Salud*) or the rules for health care research (*Reglamento de la Ley General de Salud en Materia de Investigacion para la Salud*). These include medication production facilities or laboratories, pharmacies, drugstores, storage facilities, clinics and hospitals, among others.

Research.

- A research protocol shall be authorized by COFEPRIS for those parties intending to carry out cannabis research. It is worth noting that the abovementioned secondary rules for health care research will be applicable, which for example, sets forth the requirements and credentials that research professionals must meet.
- Research done on human beings shall not only follow applicable laws and regulations, but also "good clinical practices" adopted internationally, which are not clearly defined or identified.
- The SSA, through COFEPRIS, will lead coordination efforts to maintain a national cannabis research inventory.

Production.

- A permit shall be obtained from SENASICA for cultivation with either research or medication production purposes. SENASICA will keep a National Registry of Cultivation Permits (*Registro Nacional de Permisos de Siembra*). The list of requirements is provided in the Rules.
- Cultivation permits may be granted for **(a)** cultivation, grow and harvest; **(b)** health research; **(c)** production of molecular compounds, pharmacological derivates and medication; or **(d)** production of SNICS-certified seed.
- Cultivation activities shall be carried out within "physical barriers" that limit contact with "people or environment".
- The registration or production of qualified cannabis seeds may be requested into the National Catalogue of Vegetal Varietals (*Catalogo Nacional de Variedades Vegetales*), provided the requirements set forth in the Rules are met. Expert opinions may be sought in order to verify the varietal's distinctiveness, homogeneity and stability.
- A varietal may be registered into a National Program for the Production of Certified Seeds (*Programa Nacional de Produccion de Semillas Calificadas*) by the SNICS. The list of requirements is provided in the Rules.

Medical Use.

- Medical cannabis can only be prescribed by duly licensed medical, homeopathic and dentist professionals. Their prescriptions must carry a bar code to be obtained by COFEPRIS and the prescription books will be subject to strict control and patient information recording practices.
- International travel passengers (Mexican nationals or foreigners) who require cannabis medication use shall carry and present the special, bar code-bearing, prescription with signature by the medical professional, or such be the case, the permit or authorization by the foreign nation's authority.

- Pharmacies, drug stores and establishments that provide diagnosis and treatment services will be subject to strict compliance requirements, starting with those set for by the existing sanitary control and health care regulations.

Industrial Use.

- As hinted above, cannabis raw material is defined as "…cannabis seeds, seedlings, propagative vegetative material, stem, leafs or inflorescences, necessary for the production of molecular compounds, pharmacological derivates or medication".
- Establishments who process, import, export or use raw material shall keep control books authorized by COFEPRIS and a integrate a Custody and Safeguard Security System.
- Production facilities, processing laboratories or storage organizations who handle cannabis as raw material, molecular compounds or medication can only sell it to establishments that hold the corresponding sanitary licenses, such as hospitals, pharmacies and distributors.
- Cannabis in homeopathic medications will only be allowed if presented diluted and dynamized.
- Cannabis (natural or synthetic) is not allowed in herbal remedies.

Import and Export of Raw Material and Medication.

- Raw material, molecular compounds, pharmacological derivates and medications can be imported. Establishments seeking to import cannabis as raw material shall prove to COFEPRIS that such material is legally allowed in the country of origin.
- On the other hand, only pharmacological derivates and medications can be exported.
- In order to obtain a permit for seed import with research and industrial purposes under the Rules, SADER will publish the mandatory phytosanitary requirements.
- The Rules provide in this corresponding section the detailed requirements and logistics that will apply to the importation process of molecular compounds, pharmacological derivates and medications. The process includes prior notices to the port of entry customs office, sampling, import documents to be delivered, and storage facility requirements.
- For the importation of medication intended for personal use, COFEPRIS will be the agency with authority to issue the corresponding permit. Applicants will submit the current medical prescription that includes the medical professional's license number and details the product and quantity.

Import Authorizations.

- SENASICA will issue the phytosanitary import certificates for botanic seed for cultivation, seedlings for cultivation and vegetative propagative material. Such

certificates will be issued under guidelines aimed at preventing entry of plagues or other similar hazards.
- Once raw material enters the country, it shall be movilized to facilities where confined cultivation is allowed under strict custody and control responsibilities.

Establishments for Medical Attention.

- Medical care services that result in the supply or prescription of cannabis medications can be provided in establishments that meet the corresponding requirements for operation.
- Each such establishment shall have a responsible individual who will be in charge of maintaining compliance with a list of reporting, safety, control and record keeping obligations.
- Licenses granted by COFEPRIS for these establishments shall have a duration of 2 years.

Advertisement and Sale.

- The General Health Law provides for two types of advertisement: for healthcare professionals and for the public in general. Cannabis medications can only be advertised to healthcare professionals and not to the public pursuant to guidelines approved by the SSA.
- Establishments that sell pharmacological derivates in cannabis medications shall meet sanitary requirements and qualifications before COFEPRIS.

It is worth reminding that this deadline for medical cannabis use is separate and parallel to the deadline set also by the nation's highest court for December 15 to legalize recreational use.

If you would like an English translation of the proposed law at a discounted price, please reply to this message.

If you would like to consult our previous Mexico Cannabis Updates, please click here.

If you're interested in learning more about the Mexican legalization process and what you or your clients can start doing to enter the Mexican market, please contact us at larmendariz@caamlegal.mx.

Luis Armendariz
LinkedIn: luisarmendariz