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Preview of Medical Cannabis Rules by COFEPRIS

Dr. Jose A. Novelo, director of the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) appeared before the Mexican Senate's Health Committee to discuss the current government's public health agenda. Not surprisingly, one of the main subjects discussed was the status of the long-awaited regulations for medical cannabis products. Dr. Novelo mentioned that COFEPRIS' focus is mainly on health and sanitary risks, including scientific and research activities focused on public health needs, not recreational use.

In his responses to inquiries by Sen. Patricia Mercado and Sen. Jesusa Rodriguez -main champions at the Senate of cannabis legalization- Dr. Novelo mentioned the various issues COFEPRIS is evaluating as they work on a new set of rules:

- Pharmacological cannabis derivatives;
- Which pharmaceutical professionals will be authorized to issue prescriptions;
- Requirements for the importation for pharmaceutical cannabis derivatives;
- Which agencies or entities will carry out commercialization of cannabis products;
- Clinical and research protocols;
- Review the Mexican Official Norms (Normas Oficiales Mexicanas, specifically NOM-072-SSA1-2012) for medicine labeling, warning statements, bottling/packaging, how to close them and child-protection features such as seals;
- Review NOM-012-SSA3-2012 which regulates protocols for clinical research projects that include testing on humans;
- Research criteria for cannabis pharma products;
- Review possible rules for synthetic THC; and
- Specific types of filings that private companies would have to carry out before COFEPRIS.

Dr. Novelo was questioned about COFEPRIS' position on vaporizers to which he mentioned that there is a current prohibition of selling or advertising tobacco vapes and the agency would seek a strict enforcement.

Proposed Tax on Cannabis; Additional Rules Proposed

Amidst the debate for tax reform and the 2020 national budget, Mario Delgado, majority leader in the Mexican Lower House (*Camara de Diputados*) announced on September 30, 2019 that he would introduce a bill that includes the issuance of a new law, an inter-agency regulatory commission and a state-owned company for cannabis wholesale.

In the announced bill (<u>in addition to 13 bills already in the Senate</u>) Mr. Delgado proposes to create an inter-agency commission in charge of issuing the licenses. The frontrunner bill in the Senate already contemplates the creation of a federal cannabis institute, but it is not

clear if such institute would have the same structure as the proposed commission (i.e. comprised of representatives of two or more government ministries).

Mr. Delgado mentioned that his proposal includes (1) the creation of a state-owned agency that purchases cannabis and its derivates from licensed producers and controls the wholesale market to the pharmaceutical industry. He even proposed a name: Cannsalud, and (2) a proposal to amend the Special Tax on Products and Services Law (*Ley del Impuesto Especial Sobre Productos y Servicios*) whereby a 12% tax would be levied on the sale of cannabis products.



Professional Market Research

De La Riva Group, a market research and innovation firm based in Mexico City, performed a market study called "CANNABI\$NE\$". Interesting results were published in various digital media outlets, such as 90% of Mexicans being open to the possibilities that marihuana legalization can bring, especially for medical and therapeutic purposes. The study also found that 27% of Mexicans over 20 years of age admitted to using cannabis with different frequencies. More interestingly, most of users and non-users are waiting for government, companies and brands to play their role and make a Mexican cannabis market a reality. This should be something to consider when making a market entry timeline.

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.

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