



# Regulating cannabis use in Mexico – current legal framework

By Ingrid Ortiz, OLIVARES

Mexico's current legislation regarding cannabis use is the result of several legal actions. More than five years ago, the first legal actions regarding the prohibition of cannabis use were filed by the authorities, pushing towards a specific legal framework.

These actions involved the use of cannabis for different purposes. The relevant cases addressing the use of cannabis were aimed at obtaining the approval of an allopathic drug with a cannabis-related substance as an active ingredient, and the approval for import of a cannabis-related substance medicine for personal and recreational use.

## Supreme Court of Justice decision

The Federal Commission for Protection against Sanitary Risks (COFEPRIS), which is responsible for applying and enforcing the corresponding regulatory framework in relation to drugs, refused to review the dossier and grant a marketing authorisation for pharmaceutical products containing cannabis and other narcotics as active ingredients.

In September 2015, as a result of one of the legal actions filed by the parents of a young girl suffering from Lennox-Gastaut syndrome (epileptic attacks), COFEPRIS announced the import of a medical treatment containing a cannabis-related substance which was about to be authorised. In November 2015 the Supreme Court of Justice debated whether recreational use of cannabis should be authorised. The court's ruling considered that prohibiting the use of cannabis for recreational purposes is unconstitutional. COFEPRIS complied with the decision on 10 December 2015 by granting only to the plaintiffs (four people) the authorisation to plant, cultivate,

prepare, possess and transport cannabis for self-consumption for recreational use, excluding any commercial activity. The case was significant, but the decision did not constitute binding jurisprudence for other courts.

The precedents set by the case prompted the discussion of a number of key topics (eg, the need to regulate and eventually authorise the medical use of cannabis for any individual) and highlighted the loopholes in Mexico's health system in respect of cannabis. The Supreme Court of Justice held that the General Health Law establishes a prohibitionist system which should not be applied to medical use.

Questions regarding the medical use of narcotic and psychotropic substances such as cannabis were inevitably raised and began to have a considerable effect on the Mexican legal system. As a result, various levels of the federal government began a serious and formal debate regarding the recreational and medical use of cannabis.

## Legislative amendments regarding medical use of cannabis

In 2016 a legislative proposal was presented before Congress to approve the medical use of cannabis. On 13 December 2016 the Senate approved the proposal and the lower chamber of Congress approved the bill on 28 April 2017.

In June 2017 amendments to the General Health Law and the Federal Criminal Code were published in the *Official Gazette*. The amendments aimed to legalise cannabis for medical, scientific and industrial use, as well as for marketing authorisations for medicines in which the active ingredient is tetrahydrocannabinol (THC) and other isomers or stereochemical variants.

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### **COFEPRIS guidelines**

After being in force for only five months, the COFEPRIS Guidelines for Cannabis Control were revoked through an official communication on 26 March 2019 and were published the following day.

COFEPRIS concluded that the guidelines went beyond the scope of the corresponding Health Law provisions, since they allowed for uses other than for medical and scientific purposes of THC, despite THC’s classification as a narcotic or psychotropic substance, as established in the law. However, COFEPRIS may have disregarded Article 245, Section V, that provides for cannabis use with industrial purposes. Thus, contrary to COFEPRIS’s decision to revoke the guidelines, the Health Law and the 2017 amendments do not limit the use of cannabis to use for medical and scientific purposes only. Products containing cannabis derivatives of 1% or less of THC, and which have extensive industrial uses, could be commercialised, exported and imported, thereby fulfilling the requirements established in the sanitary regulation.

In early 2018 General Health Law regulations concerning cannabis were under discussion. However, attempts made to approve such regulations later in 2018 failed to materialise. Instead, on 30 October 2018, COFEPRIS published some guidelines to establish the criteria for the appraisal of the application of authorisations for the commercialisation, exploitation and import of products other than medicines containing cannabis and its derivatives at a concentration of less than 1% THC.

However, the guideless failed to clear a path for the cannabis business in Mexico. Some days after the guidelines were issued, the Ministry of Economy reacted negatively to the guidelines and the import of products containing cannabis-related substances. The ministry highlighted that the tariff schedules concerning cannabis and its derivatives were forbidden. It transpired that before the guidelines were issued, COFEPRIS had not properly requested a review of the eventual

amendment to the trade regulation regarding cannabis-related substances.

Therefore, even though there were certain guidelines that allowed for the granting of sanitary approvals with respect to the commercialisation, exploitation and import of products containing cannabis-related substances, as long as the modifications to the trade legislation (specifically the tariff schedules) were in place, it seemed that the actual import of such products was not yet possible.

Nevertheless, it might be only a matter of time for the corresponding modifications to make the import of cannabis-related products feasible, as there is a bill presently under discussion in Congress and the new administration has expressed its intention to enact the corresponding law shortly.

### **New laws**

There is a proposal for a new Law for the Regulation and Control of Cannabis. The initiative aims to regulate and control the process of harvesting, storing, transporting, labelling, producing, publicising, sponsoring, selling and commercialising cannabis. However, it remains under discussion by Congress.

The Supreme Court recently confirmed jurisprudence relating to recreational use of cannabis. The court decided that in order to preserve the right to free development of personality it must authorise individual use of cannabis for recreational use. The ruling established that individuals engaging in recreational use of cannabis must be over 18 years old. However, this right for adults to recreationally use cannabis cannot be exercised in the presence of minors or in public places where third parties have not expressed consent.

Over the past five years, Mexico has faced numerous cannabis-related legal issues and questions. Nevertheless, things are expected to change, as Mexican law makers are working hard to resolve the legal issues related to the cannabis industry.

## Cannabis regulation

The sanitary legislation for cannabis-related substances (ie, THC and cannabidiol) in Mexico is the General Health Law, supplemented by guidelines and official norms published by COFEPRIS.

The Guidelines for Cannabis Control issued by COFEPRIS in October 2018 provided for specific criteria in the following areas:

- the protocols for clinical and scientific investigation using cannabis;
- definition, description and limitation of activities related to the medical use of cannabis;
- import and export requirements and conditions;
- rules for the use of THC in food, beverages and supplements;
- traditional herbal medicinal products;
- other industrial uses;
- promotion and advertising; and
- enforcement, inspections and penalties.

The legal value of the guidelines was questionable, as they had not been published in the *Official Gazette*.

The government is still trying to issue a new cannabis law. It has already announced a new bill to regulate and control the entire process of harvesting, storing, transporting, labelling, producing, publicising, sponsoring, selling and commercialising cannabis. The proposal for this new law refers to the creation of the Mexican Institute for Regulation and Cannabis Control. However, this proposal may affect COFEPRIS's role as the main regulatory authority. In addition, the institute will be in charge of the creation of specific regulations and guidelines concerning permitted activities involving cannabis.

Despite the government's efforts to regulate cannabis, many issues remain unaddressed.

### How does Mexican cannabis regulation compare with other jurisdictions?

There are a number of other countries in North America that have gone further with their cannabis regulation than Mexico. Canada is a pioneer of cannabis regulation for multiple uses (eg, medical, scientific and recreational use); and certain states in the United States have also been developing legislation. Nevertheless, Latin American countries are quickly developing their cannabis regulations.

Colombia is leaving behind the stigma over drugs, despite issues surrounding drug cartels in the past. It has issued legislation to regulate

cannabis and some of its uses. Colombian law allows for the possession of cannabis and provides control in respect of cultivation areas and seeds and regulates the production and manufacturing processes relating to cannabis specifically for medical and scientific purposes.

Chile has been discussing cannabis regulation since 2005. The so-called 'Law 20,000', which was modified in 2015, decriminalised growing marijuana for personal and recreational use, as well for medical purposes. Chilean law also covers cannabis harvesting on an industrial scale, focusing specifically on export.

Latin American countries are working hard to provide a consistent legal framework to carve out their own cannabis industry. They are following the example of countries that have advanced further with their cannabis legislation. Hopefully, Mexico will soon have proper authorisations in place regarding cannabis possession, seeds for sowing and control of cultivation areas, as well as



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She is a member of the life sciences and pharmaceutical law group at OLIVARES. Her practice is mainly focused on IP litigation, regulatory and administrative litigation; as well as regulatory and compliance advice. Her main areas of practice allow her to interact with the Mexican Sanitary Agency, the COFEPRIS and IMPI, as well as the Federal Court of Administrative Affairs, the Federal District Courts and the Federal Circuit Courts.

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production and manufacturing processes intended strictly for medical and scientific purposes, which will establish a legal framework that allows for useful and safe cannabis use.

### **Intellectual property and cannabis**

Cannabis legalisation has affected the regulatory and sanitary fields, but intellectual property also plays a key role in the cannabis industry.

Patents related to cannabis have become increasingly common since the end of the 1990s. Individuals and big companies, as well as those in between, have filed applications or been granted with patents related to cannabis. In addition, plant strains, extraction processes and production have become targets for protection.

Trademark applications and registrations for cannabis-related products have also increased in Mexico and other countries. In Mexico, the criteria established by the authorities concerning types of trademark application remains unclear.

The cannabis industry is growing and will affect many sectors, including the IP arena, so authorities and governments must be prepared for the ensuing changes. Thus far, it is possible to say that in general terms the IP sector is prepared to move forward with cannabis-related topics.

### **Multinational cannabis companies doing business in Mexico**

The cannabis industry is growing all over the world. Mexico and other Latin American countries have shown that they are working hard to provide a proper legal framework which will open the door for business opportunities.

So far, Mexico has started to build a legal framework that allows cannabis use. However, remaining loopholes in the legislation are preventing an open market. For instance, there are still prohibitions in international trade law preventing the import of certain derivatives or other forms of cannabis.

However, the government is working on a new law and regulations are expected soon. Moreover, the Mexican Supreme Court of Justice has ruled on recreational use of cannabis, while the use

of cannabis for medical, research and scientific purposes is gathering significant support. Thus, despite the lack of a specific law or regulation, and with guidelines and a general legal framework which concern only healthcare-related cannabis use, Mexico remains a country of opportunities for the cannabis industry as it continues to move towards proper legislation in this regard.

### **Comment**

Issues are still pending and must be addressed in order to establish a solid legal framework for cannabis in Mexico and other countries around the world.

In Mexico, cannabis is already legal for:

- medical and scientific use;
- industrial use (ie, food, non-alcoholic and alcoholic beverages, food supplements and cosmetics, among other things); and
- recreational use by some adult individuals, under certain conditions.

A new law is expected to finally legalise and control cannabis use in Mexico. Legal steps are breaking the old taboo in Mexico regarding legalisation and control of marijuana. This new legal scenario for cannabis and other narcotics is expected to have significant and rapid influence on the life sciences industry in Mexico, especially once a new law or regulation is issued.

Other Latin American countries have broken barriers surrounding the stigma over narcotics by legalising cannabis. Colombia and Chile are becoming a point of reference in this regard for other countries, including Mexico, particularly in respect of the harvesting and control of cannabis crops.

The legalisation of cannabis will continue to affect other areas and will push policy makers to address upcoming challenges. So far, the IP sector looks prepared for the cannabis industry. However, intellectual property will continue to be a key factor in the cannabis industry, meaning that the IP authorities must continue to observe developments enabling them to apply the appropriate criteria as the industry moves forward.

Multinational companies focused on the cannabis industry will have to work alongside governments in order to address the most relevant issues that will allow for the industry's proper development. *iam*

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