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Cannabis in Mexico Report

Assessment of the Draft Mexican Regulations for Medical Use of Cannabis

October 21, 2020

Overview

The *Reglamento en Materia de Control Sanitario Para la Producción, Investigación y Uso Medicinal de la Cannabis u Sus Derivados Farmacológicos*[1], which is currently still out for public consultation under the auspices of the Mexican *Comisión Nacional de Mejora Regulatoria* (CONAMER), has been some three years in the making…or three years delayed in the opinion of advocates for the legalization of cannabis use in Mexico. The order is intended to provide the comprehensive regulatory framework for the range of activities related to the medicinal use of cannabis that has heretofore been missing.

The regulations offer detailed guidance on, for example, cultivating plants, producing seeds, conducting research on new molecular compounds, products, and medications and selling, importing, or exporting medications and compounds.

Large sections of the regulations outline the specific steps and documentation required to obtain certain licenses and permits that allow key activities. As is usual in such regulatory procedures, there can be a sequence of prerequisite steps, where one authorization or registration is needed to be able to obtain another license, and so on. But the regulations serve as a helpful reference tool to understand the different kinds of permitted activity and to point interested parties in the right direction for different licensing requirements.

[1] https://www.snice.gob.mx/~oracle/SNICE_DOCS/REGLAMENTOCANNABISCONAMER-cannabis_20200727-20200727.pdf

Several assumptions underlie the regulations:

- The necessary registrations, authorizations, licenses, permits, etc. that allow certain business activities can only be acquired by citizens of Mexico, which means by definition that foreign involvement must be *indirect*, either by means of investment, strategic partnership, alliance or as vendors or purchasers of products, technology or expertise.
- Provided that the necessary registrations, authorizations, licenses, permits, etc. are obtained, there is nothing that will be *a priori* illegal in the growing, processing, acquisition, commercialization (sale), supply, development and manufacture, consumption, use (subject to a prescription from a bona fide doctor), importation, exportation, and engagement in research and testing related to cannabis or its by-products as a plant, molecular compound, or medication for medicinal end-use.
- Unlike the new draft law on recreational use of cannabis that continues to work its way through the Mexican Congress, these regulations on medical use themselves do not define the specific cannabinoid content limits for medications, so the assumption is that existing guidance from the Secretary of Health (*Secretaría de Salud*) governing the acceptable content of THC, for example, will apply until and unless the new draft cannabis law ends up modifying the basic health law (*Ley General de Salud*) accordingly.
- The regulations are mute on the matter of direct foreign investment in the new space being created for the medicinal use of cannabis and cannabis-derived products, so the assumption is that existing laws and regulations governing foreign investment apply under the auspices of the Secretary of the Economy (*Secretaría de Economia*) and that investment of up to 49% of equity ownership would be permitted.
- There are multiple Mexican state entities engaged - at least four separate ministries and four specialized agencies responsible to those ministries - because of the broad reach of the activities in medical cannabis across different areas of jurisdiction. The single most important agency for many functions of the regulations, including enforcement, inspection and licensing in key areas, will be the *Comisión Federal para la Protección contra Riesgos Sanitarios* (COFEPRIS), reporting to the Secretary of Health.

Those interested in the evolving situation in Mexico related to the regulation and legalization of cannabis use, and to the prospects for stimulated economic growth in a new sector of the Mexican economy, can at long last see concrete possibilities forming. Taken together, these regulations open real opportunities in Mexico for foreign business associated with the medical use of cannabis-derived products at different junctures in the value chain.

The specialist medical cannabis sector can be profitable in its own right and, while its overall size is comparatively smaller relative to what the recreational use of cannabis could be in the future, it may be coming on stream imminently. We also see it as a valuable opportunity to test and run systems, establish supply chains, build relationships, gain access to authorizations, licenses, and permits by means of strategic alliances with Mexican partners, open sales channels and so on. In many ways, the *Reglamento* creates a pilot project space to prove the ability to create business opportunities, build carefully on brands that could then expand to the recreational use space when possible, and execute in the Mexican cannabis space. Strategic investment in medicinal cannabis now could pay significant dividends later when legalization of recreational use of cannabis comes into effect in Mexico.

Opportunities for Foreign Business

Setting aside the activities associated with pure scientific research into new varieties of cannabis plants, new molecular compounds, new medications and so on, most normally associated with universities, research institutes, and laboratories, the *Reglamento* points the way to at least five (5) broad possible opportunities for foreign business in Mexico:

1. **Specialist Laboratory Services**:

   The regulations devote an entire section to the need for and detailed requirements related to the establishment of quality control laboratories (Title II, Articles 9-11). The regulations require that: “Each legal person holding a health license [related to the sale of cannabis-derived products and medications] must have an independent quality control laboratory…” (*cada persona titular de un Registro Sanitario debe tener un laboratorio de control de calidad independiente…*). This indicates a legally determined and identified market that will grow in parallel as the cannabis space in Mexico expands for both medicinal, and future recreational use, assuming similar treatment in the regulations to be associated with the new draft

law for recreational use of cannabis. Opportunities and activities for foreign businesses could include, but would not be limited to, investing in or forming a strategic partnership with a Mexican lab, selling specialized laboratory equipment or providing technical know-how, and consulting services for the operation of cannabis-related quality control labs.

Interested foreign parties could include companies that specialize in such laboratory services or vendors of specialized laboratory equipment.

2. **Seeds, Genetics and Cloning**:

There is detailed attention to the place of seeds throughout the *Reglamento*, most importantly in the following two parts:

a) Title III, Chapter Two, Section Two, Articles 27 and 28 related to the registration by the *Servicio Nacional de Inspección y Calificación de Semillas* (SNICS)**,** and production of certified cannabis seeds; and

b) Title V, Articles 70-74 related to importation authorizations, including for seeds.

These sections of the regulations open the way for foreign participation in either the introduction of new seed or plant varieties into the Mexican cannabis space or the imported supply of seeds for already-approved plant varieties for production/growing activities under license. Regarding (a), this could allow adaptation to the Mexican market of certain varieties that are already used in Canada or the United States, thereby creating greater continental harmonization as well as expanded markets for seed producers. There may also be opportunities for research and development based on geographic and climatological factors. Regarding (b), foreign vendors could save Mexican producers and growers time and money.

Interested foreign parties could include companies that cultivate and produce seeds and/or plant seedlings for the cannabis industry, wholesale or retail seed vendors specializing in cannabis, as well as those involved in the development of new strains, cloning, and genomic analysis.

3. **Production and Growing**:

   Title III, Chapter Two, Section One, Articles 20-26 of the regulations allow for the production and growing of cannabis for various purposes under a Cultivation License (*permiso de siembra*), including sale for research into new compounds, but, most important, for medicinal use under a doctor's prescription and the manufacture of registered medications and products. Only a Mexican legal person can hold a Cultivation License, but there could be new opportunities created for foreign businesses to participate in these activities, including, but not be limited to, investing in or forming a strategic partnership with a Mexican cannabis grower, selling specialized agricultural equipment or technology to be used in, for example, the cultivation of cannabis in greenhouses, or providing technical know-how and professional consulting services for the different stages in the production of medical-grade cannabis.

   Interested foreign parties could include companies that specialize in the agronomy and cultivation of medical-grade cannabis, consultants in construction and facilities development, as well as experts in the manufacturing certifications that would also allow participation of Mexican producers in international markets (see item 5 below).

4. **Sales of Existing Products**:

   There are two separate and significant sections of the regulations that deal with importation and exportation: Titles IV and V in their entirety, which include Articles 50-74. This is approximately one-fifth of the entire text, more than one might have expected, which signals that the import-export functions are recognized as an important aspect. The import and export of goods and services imply, by definition, foreign markets and the participation of foreign business in some way. The overall thrust of the *Reglamento* encourages these activities more explicitly than what has been contained to date in the draft law of recreational use of cannabis now in the Mexican Congress.

   Regarding the importation of products into Mexico, the regulations open the way for possible vendor relationships to sell raw materials, existing medications, pharmacological compounds, and other products to new Mexican clients. In the case of existing cannabis-derived medications produced by foreign companies,

there would be the possibility of seeking registration and inclusion on the Lists of Registered Medications *(Listados de Registros Sanitarios de Medicamentos*) of various kinds, including homeopathic, issued by COFEPRIS, either directly or in strategic alliance with a Mexican entity, such as, for example, a pharmacy or drugstore chain, etc. However, for clarity, registration of a product in Mexico is not alone sufficient to allow importation; a separate import license would also be required. Alternatively, a Mexican client in possession of a Health Importation Certificate (*Permiso Sanitario de Importación*) can import medications of various kinds, provided the shipment is accompanied by a Certificate of Manufacturer's Analysis (C*ertificado de Análisis del Fabricante*) from the foreign manufacturer as per Article 57.B.III.

We have covered the importation into Mexico of seeds and cannabis plant seedlings separately above.

An associated idea relates to training. By virtue of Title VI of the *Reglamento*, all establishments that provide health advice (*los establecimientos en los que se presten servicios de atención médica*), which would be selling cannabis products subject to a doctor's prescription, must have a qualified and knowledgeable in-house "responsible person" assigned to the cannabis sales, in order to assist clients with questions and provide health information. This is a similar arrangement to that in place in Canadian pharmacies in different jurisdictions. Given that every pharmacy and drugstore must have such a "responsible person" in place in short order, this may present an opportunity to reach agreement with Mexican pharmacy chains and other retailers with the appropriate vendor license (*Certificado de Libre Venta*) to provide professional training for such a function and to a cadre of such "responsible persons."

Interested foreign parties could include companies that manufacture and sell medicines, therapeutics, or any cannabis-related products for medicinal use subject to a doctor's prescription, or that might provide training to medical advisors on the appropriate use of cannabis products for pharmacies, drugstores, etc.

5. **Export of Mexican-produced Medications and Other Products**:

The distinct emphasis placed on the exportation of Mexican pharmacological derivatives and cannabis-based medications in Title IV, and especially Articles 51,

68 and 69, encourages a longer-term possibility in which a foreign manufacturer of cannabis-based medications or products could ally with a Mexican peer to focus on a coordinated export strategy to sell product into the broader North American and Latin American national markets as the latter develop and medical use of cannabis expands. There may well be expertise and know-how on the part of the foreign company that would benefit the Mexican partner, and the Mexican partner may well have a network of relationships and a capacity to work in Latin America (including the use of Mexico's network of free trade agreements such as the USMCA and the Trans-Pacific Partnership) that the foreign manufacturer does not share.

Status of the Regulations

The *Reglamento* has been caught in a bureaucratic knot. In mid-August, CONAMER returned it back to its sponsor COFEPRIS on the grounds that the latter had failed to properly document the regulatory impact of the regulations in an exercise known as the *Análisis de Impacto Regulatorio* (AIR) that accompanies any new regulatory proposal. There is a view among some Mexican legal observers that the Secretariat of Health, the parent of COFEPRIS, could make the argument that the health of patients, for whom access to medicinal cannabis is a "case of emergency," justifies a legal exemption from the need for the AIR process though it has not yet done so. Meanwhile, in July, the Federal Judiciary Council (*Consejo de la Judicatura Federal*) extended the deadline to have regulations for the medical use of cannabis issued to September 9, 2020, and instructed the general counsel of the Secretariat of Health to act with urgency. Acknowledging that it had missed the deadline, in late September the Secretariat of Health advised the court that it was still working on the regulation. The presiding judge granted the secretariat an additional extension of 70 working days, which moves the deadline into January 2021.

Despite the delay, and especially because of our belief that the medical use of cannabis is an important preparatory ground for the fuller legalization of cannabis for recreational use to follow, it is our assessment that interested parties need to accelerate planning for market entry in Mexico. This could take the form of investment targeting, formation of key strategic relationships with Mexican partners, and identification of new clients, all of which necessitate navigation of often complex regulatory channels and processes. Strategic

objectives may determine what authorizations, licenses, and permits may be required in advance by Mexican partners.

Lastly, we note that the cross-border sale of cannabis products for medicinal use raises some novel international trade issues, such as their treatment under the USMCA, which will need to be explored and assessed once the regulations have been finalized. At this time, it is unclear how customs agencies in any of the North American countries will treat exports or imports of cannabis products, especially those of the United States where federal prohibitions remain in place despite the legalization of medicinal cannabis in a number of individual states. Individual companies with commercial interests in the sector may wish to take advice on ways to involve themselves in the positive resolution of these USMCA trade policy aspects.

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Monarch Global Strategies and Privus Capital

The steadily increasing commercial interest in cannabis, its derivatives, and ancillary products and services (for recreational and medicinal use) across North America creates business opportunities. Yet rapidly evolving legal and regulatory frameworks, which differ among jurisdictions, together with the associated complex domestic and cross-border politics, warrant careful analysis and well-planned strategies for entry into any aspect of the sector, especially for firms seeking cross-border partnerships, distribution channels, or investment opportunities.

Monarch Global Strategies LLC and Privus Capital, Inc. work together to help clients navigate this complex environment, offering unique skills, experience, and relationships to successfully expand into the legalized cannabis sector across North America.

Services include:

- Market entry support
- Risk analysis and strategic planning
- Match making for strategic partnerships, distribution agreements, start-ups, and M&A
- Private equity and corporate strategic investment
- Regulatory filings and trademark registrations
- Government relations, advocacy, and stakeholder engagement

To discuss business matters related to the emergent cannabis space in Mexico, contact us at:

Monarch Global Strategies
Andrew Rudman
Managing Director
arudman@monarch-global.com

Privus Capital
Francisco Padilla
Managing Director
fpadilla@privuscapital.com

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