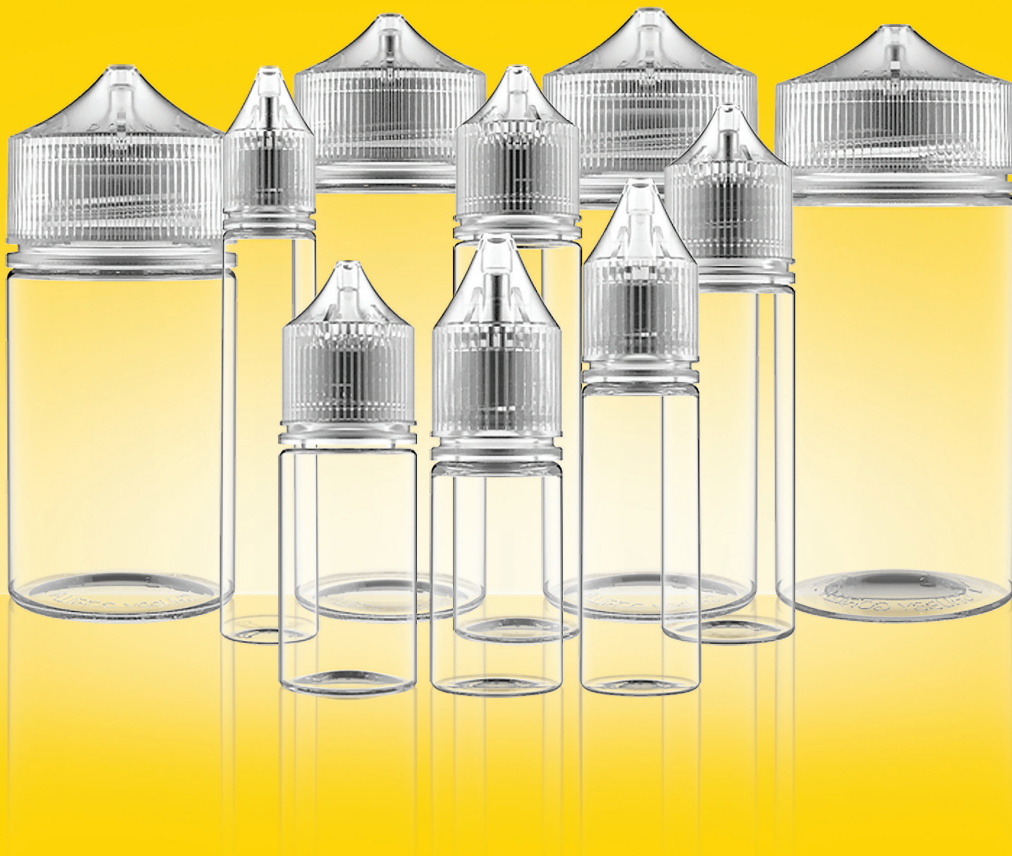


CANNABIS IN LATIN AMERICA:

The Regulations and Opportunities



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CANNABIS IN LATIN AMERICA: THE REGULATIONS AND OPPORTUNITIES



Alfredo Pascual

The marijuana industry continues to expand internationally, with Latin America and the Caribbean becoming increasingly more difficult to ignore for companies with global aspirations.

The geographical region that stretches from the southern border of the United States until the southern tip of South America, including the Caribbean, is home to about 650 million people, of which the vast majority live in a country with some sort of legal medical cannabis.

The sheer number of inhabitants, ideal growing conditions in large parts of the region and jurisdictions in favor of production for export signal potentially huge business opportunities.

With this report, our goal is to provide a sober analysis, recognizing the prospects that the region as a whole and each country in particular offer. But we also pay close attention to the other side of the coin: weighing the unique challenges of investing or doing business in these jurisdictions.

Whenever world maps are colored to show the countries that have some form of legal medical cannabis framework, Latin America is included almost in its entirety. But, as is often the case, the devil is in the details.

Restrictive access schemes, lack of health insurance coverage and widespread home growing moderate any initial excitement about the commercial opportunities in these markets.

A closer look at each country shows that one of the few commonalities across the continent is that most countries that legalized medical marijuana still have nonexistent or dysfunctional markets—sometimes even years after their cannabis laws were approved.

Another commonality is CBD. In Latin America's nascent markets, CBD has an acceptance that THC is far from getting, though it's normally sold only under prescription—a special prescription and case-by-case authorization from the federal government sometimes is needed to import.

In fact, imports are right now more prevalent than exports in Latin America, an opportunity often overlooked. This is the case in most countries that legalized. Even in Uruguay, the first country in the world to legalize recreational use, the only medicinal cannabis product currently available in pharmacies is a CBD oil manufactured locally with imported extracts.

In the Caribbean, Jamaica, St. Vincent and the Grenadines and Antigua and Barbuda already approved laws and regulations to allow for medical cannabis cultivation and sales. And more countries have laws in the legislative pipeline or already allow the import of various forms of medical marijuana.

Because of the ever-changing nature of cannabis regulations, information in this report should be assumed to be updated through the end of June 2019 unless otherwise specified.

A special thank you to International Editor Matt Lamers for his assistance in the research and writing of details on the Caribbean. If you have any questions or comments, feel free to reach out to me at alfredop@mjbizdaily.com.

A handwritten signature in black ink that reads "Alfredo Pascual".

Alfredo Pascual

Marijuana Business Daily International Analyst

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ARGENTINA

The country legalized medical cannabis in March 2017, but 2½ years later:

- Implementation of the law has been extremely limited.
- Patient access remains restricted to just a few hundred who depend on imports.
- Business opportunities are mostly limited to research or finding ways to do deals with provincial governments in an unclear regulatory environment of overlapping powers.

Argentina's regulatory framework is one of the most difficult to understand in Latin America, with countless federal and provincial laws and regulations that aren't always aligned.

The national law allows domestic cultivation through two federal agencies and prioritizes manufacture through a third agency. As of mid-2019, neither agency has started production. All legal products have been imported so far, either for research projects or on a case-by-case basis of individual patients complying with burdensome processes.

The law also created a program to register patients, but its implementation has been extremely limited, according to local patients. In practice, the only qualifying condition for patients is refractory epilepsy with an approved treatment of CBD oils.

Provinces have some autonomy and have followed four regulatory paths:

- Adopted the federal rules as is—this is the path that most provinces took.
- Adopted federal rules with a few changes; for example, expanding the list of qualifying conditions.
- Had rules prior to the federal law and have maintained that structure.
- Have not adopted the federal rules.

The current situation limits access for patients and discourages foreign investment. However, a few foreign companies are active in the country, usually for clinical research or planning production through joint ventures with provincial governments.

Most relevant government authorities

- Ministry of Health, primarily through its National Administration of Drugs, Foods and Medical Devices (ANMAT). ANMAT has nationwide jurisdiction to regulate “drugs, foodstuff, medicinal products, diagnosis reagents, cosmetic products, dietary supplements and household cleaning products.”
- Argentine Seed Institute (Instituto Nacional de Semillas, INASE)
- National Food Safety and Quality Service (Servicio Nacional de Sanidad y Calidad Agroalimentaria, SENASA)
- National Agricultural Technology Institute (Instituto Nacional de Tecnología Agropecuaria, INTA)
- National Scientific and Technical Research Council (Consejo Nacional de Investigaciones Científicas y Técnicas, CONICET)
- National Agency of Public Laboratories (Agencia Nacional de Laboratorios Públicos, ANLAP)
- Ministry of Security
- Provincial authorities

Most important laws and regulations

- Law 27,350: “Medical and Scientific Investigation into the therapeutic use of Cannabis and its derivatives” (Ley 27.350 “Investigación médica y científica del uso medicinal de la planta de Cannabis y sus derivados”).
- Decree 738/2017 (“Decreto reglamentario N° 738/2017”).
- Several resolutions of the Ministry of Health and other ministries, including:
 - 1537-E/2017 (Ministry of Health)
 - 258/2018 (Ministry of Security)
 - 59/2019 (INASE)
 - 133/2019 (Ministry of Health)
 - 361/2019 (Ministry of Health)
 - Several provincial laws

How it works

The foundation of the current framework is Law 27,350 of March 2017. Decree 738/2017 helped to provide more details on some aspects of the law, but much remains to be regulated.

The law and its decree created a program for researching medical cannabis within the Ministry of Health that established a registry of patients, allowed two federal agencies to cultivate, prioritized another agency to manufacture domestically and established ANMAT as the authority for imports.

According to the law, registered patients are supposed to obtain the medicines for free. However, local patients report that registering within the program is extremely difficult and getting coverage for cannabis products even more so. That's why there are several reported cases of patients going to the courts to demand coverage or obtain a permit to grow at home.

In September 2017, the Ministry of Health regulated the program with Resolution 1537-E/2017. The resolution limited the qualifying conditions to refractory epilepsy. It also allowed for other conditions to be included in the future, if scientific evidence supports them.

Several patients obtained authorizations from the courts to use medical cannabis for conditions other than refractory epilepsy.

The INTA and CONICET are the two federal agencies responsible for cultivation according to the law and subsequent regulations.

ANLAP should be given priority to manufacture.

In April 2018, the Ministry of Security published a resolution detailing security requirements for cannabis production facilities. It also mandated an authorization from the Ministry of Security before operations can be initiated.

In 2019, the INASE regulated the importation of seeds and some aspects of cultivation with a resolution. The resolution notes that companies must have a person responsible for the crop. In addition, the resolution lays out inventory procedures, how often stocks need to be reported to the INASE, how to store the seeds and how to identify plants.

Access

Without any domestic products available, access depends on imports, through either:

- A registry created by the federal program (Registro Nacional de Pacientes en Tratamiento con Cannabis, RECANN).
- A mechanism that allows them to import nonregistered products, also known as "compassionate use" (Régimen de Acceso de Excepción a Medicamentos No Registrados, RAEM-NR).

A resolution of the Ministry of Health determined in mid-2019 that only neurologists can prescribe cannabis products and that these could be imported as "nonregistered" products.

Doctors who want to prescribe cannabis need to complete a five-page form justifying the use of cannabis as last resort. Patients need to sign, acknowledging that they'd be using a "nonregistered" product without proven efficacy and safety.

Resolution 133/2019 also extended the period for which patients can import products for personal medical use to 180 days.

Because getting registered in the RECANN is burdensome, those who manage to get a prescription normally access through the compassionate-use path and pay for it directly. There have been a few cases of judicial decisions forcing the state to cover it.

Compassionate use wasn't created by the cannabis law. It was possible before the law, and if anything, the new framework restricted this pathway of access by allowing only refractory epilepsy.

In July 2019, Congresswoman Ivana Maria Bianchi asked the executive government to find out more about the implementation of the medical cannabis law. A few of the issues the congresswoman raised include:

- The number of patients on the registry.
- The delay in domestic production.
- Whether patients in the program are receiving products at no cost as established by the law.
- Why only refractory epilepsy is included in the program.

Research

While there's an unclear framework in place for production and distribution, a few companies have pursued the path of clinical research to access Argentina's market.

Canadian producer Aphria donated cannabis oils for a study undertaken by Buenos Aires-based pediatric hospital Garrahan in October 2018. The research was the first in Latin America to assess the effect on children with refractory epilepsy.

In mid-2019, another hospital, El Cruce, received approval from the Ministry of Health to initiate another clinical trial to test the use of cannabis in adolescents and adults with refractory epilepsy. U.S.-based HempMeds partnered with the hospital to provide the oils.

In August 2019, local media announced an agreement between Canada-based Canopy Growth and the University of Buenos Aires to promote research.

The provincial conundrum

Most of Argentina's provinces adopted the federal medical program, most through passage of simple provincial laws adhering to federal rules.

However, a few of those provinces included provisions that contradicted certain elements of the federal regulations—for example explicitly allowing prescription for conditions other than refractory epilepsy.

Here are provinces with laws that adhered to the federal law.

- Mendoza (April 2017)
- Chubut (May 2017)
- Buenos Aires (May 2017)
- Jujuy (May 2017)
- Tucumán (June 2017)
- La Rioja (August 2017, modified May 2019)
- Santa Cruz (September 2017)
- Catamarca (September 2017)
- Santiago del Estero (November 2017)
- Chaco (December 2017)
- Río Negro (August 2018)
- Corrientes (August 2018)
- Misiones (September 2018)
- Entre Ríos (September 2018)
- Tierra del Fuego (November 2018)
- San Juan (June 2019)

Other provinces already had laws in place before the federal rules went into effect:

- Neuquén (December 2016)
- Santa Fe (December 2016)
- Salta (January 2017)

Implementation across provinces varies wildly, but a common theme is that access remains limited.

ARGENTINA

Local media in Neuquén, for example, reported in July 2019 that only six patients had started legal treatment with cannabis since the law's passage and got it covered by state insurance as the law mandates—and three of them discontinued. That translates to only three active patients in a province with a population of roughly 620,000.

While the federal agencies have failed to start production, in 2019 Jujuy became the first Argentinian province to start cultivation. A provincial law passed in October 2018 created a state-owned company, Cannabis Avatãra Sociedad del Estado (Cannava), for this purpose.

The organization subsequently signed agreements with foreign companies to supply cannabis materials, including:

- Chilean-based Laboratorios Knop to produce on state-owned land and export to Chile.
- Nevada-based Player's Network's subsidiary, Green Leaf Farms, "to supply the country with all the needed oils to conduct its clinical trials."
- Aphria "to enter into a cooperation agreement regarding the cultivation of cannabis."
- Blueberries, a publicly listed company with primary operations in Colombia, to create a joint venture "to develop and cultivate cannabis."

Of the three agreements, the partnership with Green Leaf appears to be most advanced in development of operations.

In February 2019, Cannava received security clearance from the Ministry of Security to start operations and approval from the INTA to start Phase 1 of a crop for research and development purposes.

Though the national law suggests that only INTA and CONICET should cultivate, INTA's authorization of Cannava and Cannava's partnership with Player's Network suggests that the federal agency interprets the law to allow for third-party cultivation as well.

In July 2019, the governor of Jujuy announced that Cannava received the first shipment of seeds, 300 grams, to start the authorized crop.

State-owned Cannava is led by Gaston Morales, son of Gerardo Morales, the governor of Jujuy since 2015. According to local media, the company is being investigated by the provincial justice, accused of violating federal law.

In San Juan, Canada-based Wayland announced that it entered into an agreement to purchase hundreds of hectares of land in the province.

According to local media, Neuquen province is considering creating a state-owned company to cultivate, comparable to the one in Jujuy, and the proposal will be debated in the provincial parliament during August 2019.

BRAZIL

Despite not having a cannabis-specific law, Brazil is currently the largest Latin American cannabis market in terms of number of patients and products being legally sold.

Sales currently take place via special authorizations granted by the federal regulatory agency for individual patients on a case-by-case basis to import products for personal medical use.

Thanks to this restrictive but functioning system, thousands of patients have had access to medical cannabis since 2014, though in most cases the products are CBD oils.

What's promising about Brazil is that, as of this report's deadline, big changes to regulate domestic cultivation and the registration of products without finished clinical trials are being discussed and have a high chance of being approved later in 2019.

So far, domestic cultivation for commercial purposes isn't regulated in Brazil, but if the current proposals are approved, significant new business opportunities would be created in a country with more than 200 million inhabitants.

Most relevant government authorities

Unlike other Latin American countries that have different ministries, agencies and even provincial authorities in charge of implementing a cannabis law, the situation in Brazil is much simpler.

The Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA) centralizes most of the medical cannabis-related issues.

The Federal Council of Medicine (Conselho Federal de Medicina, CFM) serves as the independent agency responsible for regulating the medical profession.

Most important laws and regulations

- RDC ANVISA No. 17/2015 of May 2015
- Resolution CFM N° 2.113/2014 of December 2014
- Law 11,343 of August 2006
- Decree 5,912 of September 2006
- Ministry of Health Directive (Portaria) 344/1998 of May 1998
- RDC ANVISA No. 16/2014 of April 2014

How it works

To access medical cannabis in Brazil, patients must apply for a federal authorization to import nonregistered products.

If successful, the patient receives an authorization for one year—or less if the approved quantities are used before the end of the 12 months.

Once authorized, patients buy the product directly, without any intervention of ANVISA. Most patients buy online.

Importing in bulk or reselling isn't allowed. No pharmacies or dispensaries of any kind distribute any medical cannabis.

Many companies exporting to Brazil provide guidance to patients for navigating the application process with ANVISA.

CBD products being imported, though normally sold as nutritional supplements in the United States and Europe, are sold in Brazil as nonregistered medicines. As nonregistered medicines, no medical claims of the products can be made.

The only cannabis-based registered medicine is Sativex—sold in Brazil as Mevatyl—to treat spasticity of patients with multiple sclerosis.

BRAZIL

Home growing and collective growing isn't allowed, but there are exceptional cases of a few dozen patients and one patients association that obtained permits after lengthy processes. This authorization is provided by the courts, rather than ANVISA.

At the end of 2018, the Committee of Social Affairs of the Senate approved a bill that would modify Law 11,343 of 2006 to allow home growing of medical cannabis in quantities justified by prescription, as well as the importation of seeds and plants.

The bill would legalize home growing for patients, patients associations or relatives. However, it hasn't progressed much in the Parliament since receiving committee approval.

The regulatory process

The first products were imported in 2014. That year, only 200–300 patients obtained an authorization from ANVISA, according to local media.

In December 2014, the CFM issued a resolution, approving neurologists to prescribe cannabidiol to treat refractory epilepsy in children and adolescents as “compassionate use.”

The CFM resolution restricts the prescription to cases for which conventional medicines have proved ineffective and prohibits prescribing cannabis in its “natural form” or any derivative other than CBD.

ANVISA streamlined its process in early 2015 through resolution RDC No. 17/2015. The rule did not restrict cannabis importation to CBD only, but because most doctors also follow the CFM resolution, in practice almost all of what's being imported are CBD products.

ANVISA regulated the whole authorization and importation process, as well as the minimum criteria that products to be imported need to comply with, which include being supplied from a legal and known source.

Market data

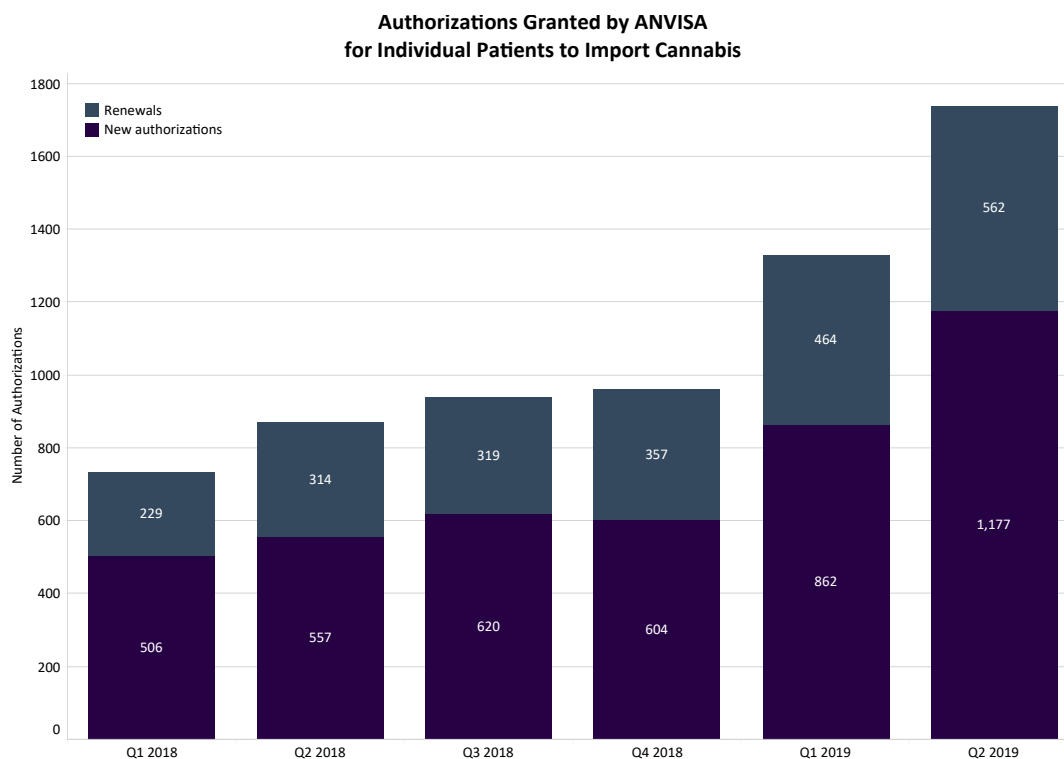
ANVISA authorizations since the program started in 2014 have surpassed 10,000.

These were all granted to individual patients, allowing them to import medical cannabis on a case-by-case basis, each for a period of up to one year, including renewals.

The number of authorizations should not be considered equivalent to the number of active patients, because authorizations last a maximum of one year and were first issued in 2014.

The total number of current patients is unknown, but the number of authorizations granted in the 12 months ended June 30 was 4,965. This number represents the maximum theoretical “active” patients as of the end of June. But in practice, many of these likely used the maximum quantities that were authorized before that date.

During the first half of 2019, an average of 340 new authorizations and 171 renewals were granted per month.

CHART: Authorizations Granted by ANVISA for Individual Patients to Import Cannabis

Source: Agência Nacional de Vigilância Sanitária
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Most imports are supplied from the United States. Several U.S. companies (including Isodiol, Charlotte's Web, Bluebird Botanicals and Elixinol) are known to export CBD oils to patients on a case-by-case basis.

Exports from Canada are rarer because no bulk exports are possible to Brazil, and Health Canada requires an export permit for each shipment, for which it charges 600 Canadian dollars.

Research

Imports of high-THC flower are possible for research, based on the Ministry of Health directive 344/1998, but cultivation for research purposes still isn't regulated as of mid-2019. This could change if the current proposals are approved.

ANVISA's RDC No. 16/2014 of April 2014 mandates special authorizations for companies that want to conduct research with controlled substances.

São Paulo-based firm Entourage is an example of a company focused on cannabis scientific research.

The proposals

Law 11,343 from 2006 allows cultivation of cannabis and other controlled plants "exclusively for medicinal and scientific purposes." Decree 5,912, also from 2006, confirms this possibility. However, because ANVISA hasn't regulated cultivation, in practice it's not possible to apply for a production license.

But in mid-2019, ANVISA proposed two resolutions that, if adopted, would:

- Regulate—for the first time—the domestic cultivation of cannabis, exclusively for medical and scientific purposes, in compliance with the 1961 Single Convention on Narcotic Drugs.
- Review the registration procedures for medicines manufactured with marijuana, its derivatives or synthetic analogues, possibly allowing the commercialization of products that have completed only the second phase of clinical trials.

BRAZIL

The agency says it has the legal mandate to do this based on the above-mentioned law and decree, so no legislative change is needed in the Parliament for these proposals to go into effect.

The agency received 1,554 comments from the public through Aug. 19, and it's expected that authorities will address the feedback to draft the final resolutions before the end of the year.

The final resolutions would need to receive approval from the agency's collegiate board of directors.

One of the motivations behind the proposals to create a new framework was the increasing number of patients applying to obtain an exceptional authorization to import.

Even after the proposals are approved, imports of nonregistered medicines are expected to continue to be possible.

The cultivation proposal includes strict security requirements, background checks and the involvement of the federal police. Only cultivation in closed and controlled environments would be allowed.

Producers would be able to sell their harvested crops only to research institutions or to manufacturers of registered cannabis-based medicines. Sales to individuals, wholesalers or for pharmacy compounding would remain prohibited. A production quota system would be established.

Home growing and cultivation by patients associations would remain illegal.

The products-registration proposal would regulate the registration of cannabis-based medicines, requiring producers to prove the quality, safety and efficacy of their goods.

What's original about the proposed resolution is that under certain circumstances, products that finished Phase 2 of clinical trials could be allowed to be registered and commercialized immediately.

Any initial registration of cannabis-based medicines would have a validity of three years. Depending on the case, ANVISA might require documentation of Phase 3 of the clinical trials for the first renewal.

Good Manufacturing Practice (GMP) certification would be a requirement in all cases.

Only products intended for oral consumption would be allowed, something that civil society representatives criticized. They argued it would prevent other methods of administration that could make sense for certain patients.

Cannabis medicines would be allowed to be prescribed only to patients with serious debilitating diseases or terminal diseases and as a last resort.

ANVISA's president, William Dib, estimates that 13 million Brazilians suffering from different conditions could benefit from these proposals.

As of August 2019, there's some uncertainty regarding the likelihood of approval of the proposals, with the fiercest opposition coming from Osmar Terra, the minister of citizenship.

The CFM also opposes ANVISA's proposal.

Brazilian President Jair Bolsonaro said he was against ANVISA's move but conceded he has "zero influence" over the independent agency.

CHILE

Chile is one of the cannabis pioneer countries in Latin America, in part because it was the first nation in the region to authorize large-scale, high-THC cannabis cultivation.

But most of the access to medical cannabis is provided through decriminalized home growing or collective growing. Commercial opportunities exist, albeit on a limited basis that are hard to understand.

The Chilean drug control law makes an exception to prohibition by authorizing cultivation—with a license from the Agricultural and Livestock Service—and decriminalizing home growing under certain circumstances.

This is how a handful of organizations obtained cultivation licenses, but the application process is not streamlined.

The Chilean Sanitary Code allows the importation of nonregistered products in exceptional cases. Tilray used this exception to export a few oils in 2017.

Domestic laboratory Knop said it has provisional authorization to commercialize a domestically produced oil. This is manufactured using Dayacann's crop, one of the few authorized domestic cultivations.

Most relevant government authorities

- Public Health Institute (Instituto de Salud Pública, ISP)
- Agricultural and Livestock Service (Servicio Agrícola y Ganadero, SAG)

Key laws and regulations

- Sanitary Code
- Law 20,000
- Decree 404 of 1983
- Decree 405 of 1983
- Decree 867 of 2007
- Decree 84 of 2015

How it works

The ISP—a decentralized and autonomous agency within the Ministry of Health—is responsible for regulating medicines.

Article 99 of the Sanitary Code makes the exception of authorizing nonregistered products provisionally, provided certain conditions are fulfilled. Authorizations could be for clinical trials or other scientific investigations, or for urgent medical needs derived from scarcity or inaccessibility.

This is how Tilray received its exceptional authorization to export 600 units of oil in 2017. According to the ISP website, Tilray products are no longer available. Because not all were sold within the allowed time frame, some had to be destroyed.

SAG—an agency within the Ministry of Agriculture—is responsible for any application to cultivate cannabis in Chile.

Law 20,000 prohibits cannabis cultivation but makes an exception for SAG to grant a license.

The licensing system is regulated with Decree 867 of 2007.

CHILE

Applications must include:

- Identification data of the applicant.
- The location where the applicant intends to cultivate.
- Crop characteristics and timeline.
- Justification of where the harvest will be sold.

The decree also requires security measures and a series of notifications. For instance, growers must notify the ISP at least 60 days before harvesting and obtain a transport permit before moving the harvest.

As far as it's publicly known, only the following companies have been able to obtain cultivation licenses:

- Dayacann, a joint venture between Fundación Daya and Australian-based Auscann.
- Alef Biotechnology, a subsidiary of Tilray in Chile.
- Agrofuturo, for low-THC cannabis.

Access

Most access to medical cannabis appears to be through decriminalized and widespread home growing or not-for-profit collectives.

There is only one registered product: Sativex, manufactured in the United Kingdom by GW Pharmaceuticals and imported by Laboratorio Biopas. It obtained approval in October 2016.

There's only one nonregistered product available for commercial sales in the Chilean market: Cannabiol.

Cannabiol is a 30-milliliter oil with a THC concentration of 20 milligrams per milliliter and CBD at 9 milligrams per milliliter. It received a provisional authorization from the ISP while the product is used for clinical trials.

Cannabiol is manufactured by Knop using materials from Dayacann.

Up to 2,500 patients can access Cannabiol for free for a period of up to one year, provided they're registered in one of the 15 municipalities that provide the treatment.

Certain bureaucratic requirements need to be fulfilled.

Those who aren't patients in these 15 municipalities can still access Cannabiol, but they must buy it in authorized pharmacies at a price of about \$60 per unit.

In all cases, a medical prescription is needed.

Hemp

Unlike Uruguay or Colombia, which have separate regulations for hemp, all cultivation permits in Chile are granted by SAG.

Agrofuturo is the only company that has received authorizations from SAG to cultivate low-THC cannabis.

The company expects to commence commercial sales of hempseed oil and other related products before the end of 2019.

COLOMBIA

Of all Latin American countries, Colombia has attracted the most attention and foreign investment commitments for cannabis production.

This reflects the country's ideal growing conditions and first-mover advantage. It was one of the first Latin American countries to legalize the production of medical cannabis, with regulations that promote the creation of a value-added industry for domestic and export markets.

As of August 2019, there are still no medical cannabis products available in Colombia, in part because the framework was designed for companies to first go through a research and development stage to ensure certain standards before sales commence.

However, a few firms are selling cosmetics infused with imported extracts or CBD isolate—so far, the only legal cannabis revenue in the country.

Despite the large number of licensed companies, as of Aug. 13, only eight have finalized registering at least one cultivar with the government, a necessary step to start growing commercially.

As of the end of July, no commercial quotas for high-THC products have been announced, meaning no company has exported any THC-high cannabis for commercial purposes nor supplied the domestic market.

The first exports of CBD isolate or CBD-high extracts—which don't require a production quota—are just starting.

Most relevant government authorities

- Ministry of Health and Social Protection (Ministerio de Salud y Protección Social)
- National Narcotics Fund (Fondo Nacional de Estupefacientes, FNE)
- National Food and Drug Surveillance Institute (Instituto Nacional de Vigilancia de Medicamentos y Alimentos, INVIMA)
- Ministry of Justice and Law (Ministerio de Justicia y del Derecho)
- Colombian Agricultural Institute (Instituto Colombiano Agropecuario, ICA)
- ProColombia

Key laws and regulations

- Law 1,787 of July 2016
- Decree 613 of April 2017
- Decree 631 of April 2018
- Resolution 0577 of August 2017 (Ministry of Justice)
- Resolution 0578 of August 2017 (Ministry of Justice)
- Resolution 0579 of August 2017 (Ministry of Justice)
- Resolution 2891 of August 2017 (Ministry of Health)
- Resolution 2892 of August 2017 (Ministry of Health)

The foundation of the legal framework is Law 1787 of 2016 and its regulatory Decree 613 of 2017. Resolutions 577, 578 and 579 of the Ministry of Justice and Resolutions 2891 and 2892 of the Ministry of Health further regulate the industry and establish fees and procedures.

Licenses

Licenses constitute the beginning of a multistep regulatory process that includes securing further permits and registrations with several government agencies.

The framework was designed to ensure a rigorous medical and scientific program compliant with the international drug control conventions and to minimize diversion.

Vertical integration isn't mandatory, but at this early stage, most of the leading companies appear to want to do everything from seed to sale. Specialization could become more common once the market is more developed.

Businesses can apply for the following licenses:

► **Manufacture of cannabis derivatives, issued by the Ministry of Health**

This license covers the manufacturing, acquisition, import, export, storage, transportation, marketing and distribution of cannabis derivatives. It's not required for nonpsychoactive cannabis.

It has the following three modalities that companies can apply for:

- National use (for distribution within Colombia)
- Scientific research
- Export

All flower must be processed before reaching domestic patients or being exported. It can be exported only for scientific research.

► **Cultivation of cannabis plants, issued by the Ministry of Justice**

Two types of cultivation licenses can be applied for:

- Psychoactive cannabis plants (THC of 1% or higher)
- Nonpsychoactive cannabis plants (THC less than 1%)

In addition, the license for seeds for commercial use or scientific research is granted by the Ministry of Justice.

All licenses are nontransferable—though ownership of the company holding the license can change—and valid for five years, with a renewal option.

As of Aug. 2, 121 manufacture licenses had been granted according to the Ministry of Health.

As of July 30, 258 licenses were granted by the Ministry of Justice: 139 for nonpsychoactive cannabis cultivation, 89 for psychoactive cannabis cultivation and 30 for seeds.

A single entity may have only one manufacture license granted by the Ministry of Health, but it could have up to three licenses granted by the Ministry of Justice.

The requirements to obtain a license vary, but most require disclosure of where the proposed activities will take place and who will serve as representatives for the company. In addition, technical documents for cultivation, manufacture, security, research and export plans could be required depending on the license and modality that's applied for.

The relevant ministries are supposed to issue the licenses within 30 days, provided all requirements are fulfilled. The term can be longer if the ministries ask for more information or make observations.

As of mid-2019, reports from local players complaining that the government is taking longer to evaluate licenses applications are common.

Applicants should expect at least one inspection visit during the cultivation application process, in which regulators will verify that no illegal crops exist at the location, among other things.

Manufacturers of cannabis derivatives may source flower from their own crops—if they have the appropriate cultivation licenses—or buy them from other legal cultivators.

At least 10% of raw material must be sourced from small- or medium-sized growers. These are cultivators with up to 0.5 hectares (1.2 acres) of area dedicated to growing cannabis.

Two of the nation's 32 departments—geopolitical divisions akin to states or provinces in other countries—are home to almost half of the licensed companies: Cundinamarca, the region surrounding Bogotá, the capital of Colombia and known for its flower industry, and Antioquia, a department recognized for its high-quality coffee crops.

Genetics registration

The Colombian government-granted amnesty for genetics ended at the end of 2018. In practice, it meant that all pre-existing genetics in the Colombian territory could begin the registration process—necessary for those strains to be grown for commercial purposes—through the end of that year, regardless of origin.

Licensees that want to grow but didn't start the registration of their genetics before the end of last year must buy their seeds or clones from another licensee or import them.

Those that began the process before the deadline need to prove to ICA that the characteristics of the plants that they want to register coincide with what can be grown in their agroecological subregion. For that, they must grow samples of these cultivars for research and development according to specific regulations for agronomic evaluation.

Dozens of companies are estimated to be doing that at the moment.

Companies need to grow 60 plants of each genetic they intend to register. An ICA technical team evaluates descriptors during the vegetative and flowering phase of growth.

If the agronomical evaluation is successful, the technical team of the ICA issues an "Acta" that allows the applicant to register the genetics in the national database.

This last step is purely administrative, ending with a specific resolution for each successfully evaluated cultivar.

When a genetic is fully registered, the ICA issues a resolution. Only then can the company start using that cultivar for commercial purposes. (Other restrictions may still apply, especially for psychoactive cannabis. See quotas on next page.)

The following companies had a total of 70 cultivars registered, according to the ICA database updated as of Aug. 13, 2019:

Company (operating as)	NUMBER OF REGISTERED CULTIVARS		Total cultivars
	Psychoactive	Nonpsychoactive	
Medcann	5	0	5
Avicanna	3	1	4
FCM	4	1	5
Clever Leaves	15	5	20
Pharmacielo	19	1	20
Qualcann	0	3	3
LaSanta	6	4	10
TOTAL	52	15	67

Source:ICA Database

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Companies and investors interested in knowing which companies have fully registered cultivars can do so by consulting the ICA website: "Certificación de semillas".

The cannabis cultivars database—Registros de Cannabis—is typically updated several times each month.

Quotas

Quotas are another regulatory challenge after obtaining a license, but they are relevant only for companies producing what the Colombian government defines as “psychoactive cannabis”: 1% THC or more.

Depending on whether the quota is for cultivation or manufacture, the authority responsible for granting it is the Ministry of Justice or the Ministry of Health, respectively. However, a working group that includes representatives of both ministries as well as the FNE, INVIMA and ICA was created to study applications.

Cultivation quotas are measured in number of plants, while manufacture quotas are measured in weight of dried flower (which may be used to manufacture derivatives).

Cultivation quotas for commercial purposes cannot be obtained until the company registers at least one psychoactive cultivar with the ICA (see “Genetics registration” on the previous page) and, through research, generates technical information about its own extracts to prove THC content and other specifications.

Companies typically apply for quotas before the end of April each year. If granted a quota, the company can use it only during the following year. Applying for supplementary quotas is possible and can be done at any time of the year.

Commercial quotas are granted based on legitimate demand. The production capacity of the companies applying for the quotas is irrelevant if they cannot prove that they have quantifiable demand.

As of end of July, all quotas granted by the Colombian government have been for research and development only:

- In 2017, two companies obtained quota to grow a combined total of 7,300 plants.
- In 2018, 17 companies obtained quota to grow a combined total of 101,609 plants.
- Partial data for 2019 indicates that at least 15 companies obtained quota to grow a combined total of at least 27,672 plants.

A process to generate characterization of products, quality specifications and stability data—with a quota for research and development—is required before applying for commercial quota.

Access

As of August 2019, there's no legal access to medical cannabis because no products are available in the domestic market.

The framework establishes two ways of selling medical cannabis in Colombia:

- Magistral preparations (individual formulations prepared for an individual patient in the pharmacies according to a specific prescription).
- Registered products.

In all cases, a medical prescription is needed.

Companies producing the ingredients for magistral preparations aren't required to register the products proving efficacy and safety like they do for final products with marketing authorization.

Details about how sales of magistral preparations will work are still unknown, but according to several company presentations, sales are expected to begin before the end of 2019.

To register final products, companies must prove the efficacy and safety of their products—normally through clinical trials—to INVIMA, like any other medicine.

Cosmetics

Cosmetics were identified by a few companies as the quickest path to revenue, because registering these products with INVIMA is easier than medical cannabis.

Moreover, it's not necessary to use the company's own crop if it's not operationally ready or the company still needs to overcome regulatory hurdles such as genetics registration.

Instead, a company can import CBD and infuse it into locally manufactured cosmetics while it finalizes the registration of genetics with the ICA and gets an extraction laboratory ready. Hempseed oil is another product from cannabis plant approved for cosmetics.

Some smaller companies that focus on cosmetics retail aren't interested in applying for a license to cultivate and use their own crops to obtain raw materials. Instead, they import from other countries, with the potential for buying it in the domestic market in the future.

North American companies in Colombia

A number of Canadian and U.S. companies are active in Colombia, including:

- New York-based investment firm Northern Swan, via its investment in Colombian cannabis company Clever Leaves.
- Subsidiaries or joint ventures of major Canadian licensed producers, including Ontario-based Canopy Growth, Alberta-based Aurora Cannabis, Ontario-based Aphria and Ontario-based Cronos.
- Companies publicly listed in North America with main operations in Colombia include Pharmaciolo, Khiron Life Sciences, Blueberries Medical and Avicanna.

Reform ahead

The government recently published a draft decree that, if approved, could modify certain aspects of Decree 613 of 2017, the foundation of the Colombian cannabis framework. The timeline for approval is uncertain.

Today, exporting flower for commercial purposes isn't allowed, and moving any product into a free trade zone—even if geographically within the Colombian territory—is considered an export.

This means it's not possible to manufacture cannabis extracts in a free trade zone using flower as raw material unless the cultivation also takes place within the zone.

The draft decree would allow exports of flower into Colombian free trade zones for further processing, benefiting companies that use this opportunity to take advantage of the financial incentives of free trade zones.

It could be especially beneficial for companies that still have not built their manufacturing facilities, giving them an advantage over companies that have sunk significant capital into their laboratories outside free trade zones.

Another change that the draft decree would bring is a requirement that applicants for a nonpsychoactive cultivation license with the purpose of obtaining extracts must also have a manufacturing license. It also reaffirms the exclusion of CBD from the controlled substances list.

Because integrating small and medium cultivators into the new legal industry has been a challenge, tighter ties with licensed producers would be mandated, as well as the transfer of knowledge and technology.

Certain new measures would be adopted with the objective to have a more rigorous control of the industry, intended in part to avoid the trade of licenses. For instance, those with a nonpsychoactive cannabis license would need to start operations within six months and those with a psychoactive cannabis license would need to obtain a quota per year.

MEXICO

Mexico legalized medical cannabis in June 2017, but two years later, the country still doesn't have procedures in place.

An August 2019 Supreme Court ruling seeks to change the situation, giving the government 180 days to regulate medical marijuana.

Other Supreme Court rulings have been granting consumers the right of access to nonmedical cannabis since 2015, and jurisprudence was created in October 2018 after the fifth case.

Commercial opportunities are mostly paralyzed. Entrepreneurs and investors are awaiting not only the regulation of medical cannabis but also a new law that is expected to fully legalize marijuana in all forms—including recreational—during the second half of the year.

Most relevant government authorities

- Ministry of Health (Secretaría de Salud)
- Federal Commission for the Protection against Sanitary Risk (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS)
- Mexican Institute for Regulation and Cannabis Control (Instituto Mexicano para la Regulación y Control de Cannabis, IMRCC)*

* Expected to be created with the upcoming law

Key laws and regulations

- General Health Law (as reformed in June 2017)
- COFEPRIS Guidelines for Health Control of cannabis and its derivatives—Revoked in March 2019

Medical regulations

In June 2017, Mexico's Parliament approved a decree reforming the General Health Law.

The decree rearranged cannabis and THC within the Mexican schedules of psychotropic substances to allow for medicinal use. It also mandated the Ministry of Health to regulate the use of medical cannabis within 180 days.

COFEPRIS, a decentralized organ of the Ministry of Health, missed that deadline but issued "Guidelines for Health Control of Cannabis and its Derivatives" in October 2018—shortly before the previous government left office. Those internal guidelines set up a process to allow companies to apply for import permits for products with less than 1% THC.

In November 2018, right before ending their time in office, COFEPRIS authorities quickly granted 57 permits to several companies, allowing them to import products with up to 1% THC.

New authorities revoked the COFEPRIS guidelines in March 2019 and started a process to study the validity of the previously granted permits. In practice, all permits appear to be suspended at time of publication.

The new government said the guidelines contravened:

- The reform of the General Health Law of June 2017, because they allowed the importation of products for nontherapeutic or scientific reasons.
- The Foreign Trade Law, because they didn't have approval from the Foreign Trade Commission. The guidelines also allowed the importation of prohibited categories under the General Import and Export Taxes Law.
- The Federal Law of Administrative Procedures and the General Law of Regulatory improvement. Among other issues, the guidelines were not submitted to the National Commission for Regulatory Improvement as mandated by the General Law on Regulatory Improvement. In addition, the guidelines were not published in the Official Gazette of the Federation as mandated by the Federal Law of Administrative Procedure and the General Law of Regulatory Improvement.

MEXICO

In August 2019, the Second Chamber of the Supreme Court concluded in a ruling that the federal government is still in omission as medical cannabis isn't properly regulated.

The ruling was in favor of a minor with a rare epilepsy. The court declared that his rights were violated by the omission of the federal government to regulate medical cannabis.

The Ministry of Health replied to the ruling with a statement accepting the decision of the court and emphasizing that COFEPRIS will comply with the 180-day order to establish a framework.

Current access

Pending regulation of the June 2017 General Health Law reform, the only legal access path predates that legislation.

Like many other Latin American countries, Mexico has a mechanism to allow imports for personal use of nonregistered medicinal products. To do this, patients need an authorization from COFEPRIS. The products cannot contain THC.

However, the number of patients using this legal pathway is extremely limited. In a communication from September 2018, COFEPRIS authorities stated that they had granted just 305 permits. Mexico has a population of about 130 million.

Recreational marijuana prohibition unconstitutional

Mexico's Supreme Court ruled for the first time in November 2015 that the prohibition of cannabis is unconstitutional, saying it violates the fundamental right to the free development of the personality.

Almost three years later, in October 2018, the Supreme Court ruled for the fifth time in a similar way, crossing the threshold that establishes jurisprudence in the country.

These rulings allow for personal cultivation and use of marijuana for those who went through the judicial channel, but they explicitly prohibit distribution or commercialization.

Reform ahead

To comply with the 180-day deadline given by the Supreme Court, the Parliament is expected to approve legislation in October 2019.

However, that may only be the first significant step in the process, with the committees that are currently drafting the unified bill greenlighting it.

Approval from the majority of the Senate and the Chamber of Deputies would still be needed. Assuming everything goes smoothly, the law could go into effect by the end of the year.

Because the government has parliamentary majorities and has publicly stated the willingness to legalize, the debate is centered on how to do it.

If Mexico moves ahead as expected in the following months, it would become the third country to federally legalize the production and commercialization of nonmedical cannabis, behind Uruguay and Canada. It would also be the largest country by population to do so.

The Mexican Parliament created a website to announce a series of events and receive feedback from the public about legalization.

Ten bills currently are being considered by the parliamentary commissions, who must propose a single bill.

Most observers assume that the foundation of the unified bill will be the "General Law for the Regulation and Control of Cannabis" filed last November by Secretary of Interior Olga Sanchez Cordero.

The bill tries to balance public health with commercial interests. To achieve these goals, the law would create a regulated market for medical, recreational and industrial cannabis that, among other things, prohibits advertising.

MEXICO

The Mexican Institute of Regulation and Control of Cannabis (IMRCC) would be created to regulate and implement the law.

Examples of the tasks that the IMRCC would have include:

- Prioritize public health and harm reduction over commercial interests.
- Regulate, monitor and evaluate the implementation of the law.
- Draft guidelines for the granting of licenses.
- Register home growers and cannabis clubs.
- Determine maximum and minimum THC and CBD limits.
- Establish quality standards.
- Determine the type of products that will be allowed.
- Establish the maximum number of licenses nationwide and per state.
- Set the maximum number of retail stores a single person or company will be allowed to own.
- Create regulations regarding retail stores, including zoning restrictions and opening hours.

Home growing would be allowed under the new regulations, with a limit of 20 plants and a maximum annual production of 480 grams. Home cultivators would be required to register.

The legislation also would allow for cannabis cooperatives with a minimum of two and a maximum of 150 members, created exclusively to produce cannabis for its members. Members would be allowed to receive 480 grams per year.

The bill categorizes the licenses by the intended use of the products, including:

- Pharmaceutical use.
- Therapeutic use.
- Adult use.
- Industrial use.

Details about how exactly these licenses would be categorized and the requirements would be regulated by the IMRCC. Edibles would be prohibited.

Even if the cannabis law is approved during the second half of 2019, it's unlikely the still-to-be-created IMRCC that would oversee the industry would have the necessary resources to start work before the end of the year.

Even in the most optimistic scenarios, business opportunities are unlikely to be available until 2020.

PARAGUAY

The Parliament of landlocked Paraguay has a medical cannabis law from 2017 that was regulated with a decree in 2018, but effective implementation hasn't started.

In recent months, government authorities said the final regulations of the relevant agencies are about to be published. Once that happens, five licenses will be up for grabs.

In the meantime, one company found a way to import CBD isolate and, with it, manufacture an oil that is being sold under prescription as medical cannabis.

Most relevant government authorities

- National Health Surveillance (Dirección Nacional de Vigilancia Sanitaria, DNVS)
- National Service for Plant and Seed Quality and Health (Servicio Nacional de Sanidad y Calidad Vegetal y de Semillas, SENAVE)
- National anti-drugs agency (Secretaría Nacional Antidrogas, SENAD)

Key laws and regulations

- Law 6,007 of December 2017
- Decree 9,303 of August 2018

How it works

Law 6,007 is a short and simple document for creating a regulatory framework “to promote the study and the medical and scientific investigation” of cannabis.

It creates a program called PROINCUMEC, which, in addition to promoting research, guarantees access to medical cannabis, free of cost, for those who register with the program.

The law delegates most of the regulatory and implementation responsibility on the DNVS.

It also clarifies that the DNVS could, in coordination with the SENAVE and the SENAD, authorize domestic production under certain circumstances.

The regulatory decree creates certain definitions, such as separating “psychoactive” from “nonpsychoactive” cannabis. Unlike Uruguay and Colombia, which use 1% THC as the limit separating the two categories, Paraguayan authorities established the threshold at 0.5%.

The decree also establishes that the DNVS could grant up to five manufacturing licenses and assigns the role of security control to the SENAD.

An article of the decree mandates that manufacturers might have to donate up to 2% of their production to the program.

As of August 2019, the PROINCUMEC isn't effectively working and no licenses have been granted under the framework created by the medical cannabis law and its regulatory decree.

In practice, implementation of the law and the decree has been almost nonexistent, but authorities said last June that the relevant ministries and agencies are finalizing the conditions under which companies will be able to apply for licenses.

Once the final regulations are ready, the government plans to open a public consultation process.

The SENAD minister said that five companies will be able to get licenses to produce up to 5 hectares (12.4 acres) with an option to eventually double that area.

He also remarked that cultivation would be possible in only two small geographical areas of the country, which are the two smallest departments by area: Distrito Capital (where the capital Asunción is located)

and its contiguous Departamento Central.

Current access

Individual imports for “compassionate use” were authorized for the first time in mid-2016, albeit barely used because of the high price tag of imported products.

However, one company, Laboratorios Lasca, imported CBD as an active ingredient to manufacture and distribute a registered medical cannabis product at a lower price than the average imported product.

The company imports CBD isolate and manufactures oil in Paraguay with a concentration of 25 milligrams per milliliter of CBD. The product indications include refractory epilepsy, muscular spasticity, cancer and neuropathic pain.

A bill that would legalize home growing for patients is currently being debated in the parliament.

PERU

Medical marijuana is technically legal in Peru—the country approved a law in 2017—but authorities have been so cautious and slow to regulate and implement the program that there's no access to any cannabis products in the domestic market nor immediate business opportunities.

The only way to legally access MMJ is similar to what's called "compassionate use" in other South American countries: obtain an exceptional authorization to import a nonregistered product for personal medical use.

There's no publicly available data about how many patients have used this option, but it's not likely to be more than a handful.

Business opportunities for companies will remain practically nonexistent until the different ministries issue their guidelines and allow companies to start applying for the different types of licenses.

However, companies can start preparing for when the regulations are rolled out, as this country of more than 30 million people is poised to eventually allow domestic production and international trade.

Current legislation indicates that only pharmaceutical laboratories will be allowed to produce. Setting up a business and registering it as a pharmaceutical laboratory takes time, so companies that lay this groundwork in advance of regulatory changes may have a leg up.

Most relevant government authorities

- Ministry of Health - DIGEMID (Dirección General de Medicamentos, Insumos y Drogas, DIGEMID)
- Ministry of Health - INS (Instituto Nacional de Salud, INS)
- Ministry of Agriculture - SENASA (Servicio Nacional de Sanidad Agraria, SENASA)
- Ministry of Agriculture - INIA (Instituto Nacional de Innovación Agraria, INIA)
- Ministry of Interior - Dirandro (Dirección Antidrogas, Dirandro)

Key Laws and Regulations

- Law 30,681 of October 2017
- Decree 005-2019-SA of February 2019

How it works

Law 30,681 of October 2017 is a short and simple document that has the objective of allowing access to medical cannabis.

The law explicitly allows domestic production, importation and commercialization of cannabis for medical and scientific purposes.

It also mandates the creation of a series of registries within the Ministry of Health:

- Patients
- Importers and retailers
- Research organizations
- Producers

The law also creates the following types of licenses:

- Human and plant research
- Importation and/or commercialization
- Production

Under the Peruvian law, only certified pharmaceutical laboratories can apply for a production license. This means that companies that don't typically grow any plants could end up being the only ones allowed to cultivate cannabis—or any agricultural company that wants to grow cannabis would need to become a pharmaceutical laboratory first.

PERU

In February 2019, 15 months after the law was approved, the government approved the regulatory decree, which estimates that “a minimum of 7,596” people urgently need access to medical cannabis in the country.

The decree defines psychoactive and nonpsychoactive cannabis the same way as Uruguay and Colombia, using 1% THC as the dividing line. It also includes other relevant definitions such as the types of products that are allowed.

Within the Ministry of Health, the DIGEMID was given authority over the production, importation and commercialization licensing processes and the INS over the research license.

Within the Ministry of Agriculture, the SENASA was made responsible for seeds regulations and the INIA for the agricultural research licenses.

The Dirandro of the Ministry of Interior was assigned the responsibility for security-related issues.

The agencies were given 60 to 90 days to issue their internal guidelines that would allow the program to effectively start working. However, as of August 2019, almost nothing was further regulated.

The DIGEMID published details on its website about which types of cannabis products will be allowed:

- Pharmaceutical products with DIGEMID sanitary registration.
- Imported products with an exceptional authorization for individual treatment.
- Magistral preparations for individual treatment, prepared by a pharmaceutical chemist in an authorized pharmacy or equivalent.

In all cases, medical prescription is needed, and products can be acquired only in pharmacies or equivalent outlets authorized to sell cannabis.

Cannabis can be prescribed only as a last resort, and the document lists only four qualifying conditions:

- Nausea and vomiting stemming from chemotherapy.
- Weight loss and appetite loss from cancer or HIV.
- Pain and spasms associated with multiple sclerosis.
- Seizures related to Lennox-Gastaut and Dravet syndromes.

The DIGEMID also opened an online registry of patients, but as long as there are no products available, being registered makes no difference.

URUGUAY

At the end of 2013, Uruguay became the first country in the world to completely legalize cannabis in all forms: industrial, medical and recreational.

But back then, Uruguayan activists and legislators pushing for legalization weren't thinking about creating an industry. Their focus was public safety.

Implementation of the law proceeded slowly, with business opportunities remaining largely limited until about one year ago, when investment in the industry started to become more noticeable.

Current commercial opportunities can be divided into the three sectors: recreational, medical and hemp/CBD. These sectors have different types of opportunities, though they sometimes overlap.

Research is also possible.

As of August 2019:

- Only four companies were licensed to grow high-THC cannabis: two for medical use and other two for nonmedical use.
- About 20 companies were licensed to cultivate hemp. This type of license allows them to grow nonpsychoactive cannabis with less than 1% THC and harvest the flower. It didn't allow CBD extraction, which requires a manufacturing license.
- Only five companies had manufacturing licenses. The scope of each license was very different and depended on the individual case.
- Sixteen organizations had research licenses.

Applications for all types of licenses except recreational can be done on an ongoing basis. Recreational licenses have so far been granted only through public tenders.

Most relevant government authorities

- Institute for the Regulation and Control of Cannabis (Instituto de la Regulación y Control del Cannabis, IRCCA).
- National Secretariat for the Fight Against Money Laundering and Terrorism Financing (Secretaría Nacional para la Lucha contra el Lavado de Activos y el Financiamiento del Terrorismo, SENACLAFT)
- Ministry of Livestock, Agriculture and Fisheries (Ministerio de Ganadería, Agricultura y Pesca, MGAP)
- Ministry of Health (Ministerio de Salud Pública, MSP)
- General Customs Bureau (Dirección Nacional de Aduanas, DNA)

Key laws and regulations

The foundation of the Uruguayan cannabis framework is the law approved in December 2013. Cannabis was later regulated with three decrees that each focuses on one area of application: nonmedical use, medical use and hemp.

Other laws are relevant, such as one in 2014 regarding money laundering.

In recent years, newer decrees modified specific aspects of the three original regulatory decrees or added clarification on certain issues.

Resolutions of the cannabis agency and other government organizations complete the regulatory framework:

- Law 19,172 of 2013 (cannabis law)
- Law 19,574 of 2014 (anti-money laundering law)
- Decree 120 of 2014 (focus on nonmedical use regulation)
- Decree 372 of 2014 (focus on hemp regulation)
- Decree 46 of 2015 (focus on medical use)
- Decree 250 of 2015 (modifies previous decrees)
- Decree 79 of 2016 (modifies Decree 120 of 2014)
- Decree 128 of 2016 (regulates cannabis and employment)
- Decree 298 of 2017 (further regulates CBD)
- Resolution 19 of 2016 of the DNA

Adult use

Users can access recreational cannabis three ways: sales in pharmacies, home growing or nonprofit cannabis clubs.

Here's a snapshot of the recreational market as of mid-August 2019:

- 36,956 customers.
- 7,224 home growers.
- 3,900 people are members of 125 cannabis clubs where collective growing is allowed.

Adult-use customers

Any adult Uruguayan or legal resident may register for access to nonmedical cannabis, which is sold only in certain authorized pharmacies.

The customer registry is confidential. When a registered user makes a purchase in an authorized pharmacy, no identification is required. The pharmacist scans the fingerprints of the customer, and the government software confirms that the user is correctly registered and has available quota.

Seventeen pharmacies act as the only retail points where registered customers are allowed to buy up to 10 grams per week of nonmedical cannabis flower.

The very limited number of pharmacies aren't distributed evenly across the Uruguayan territory, so in practice, vast regions do not have access.

More pharmacies (there are more than a thousand in Uruguay) could join the program and sell cannabis, but since the program's inception, there has been a certain lack of interest from pharmacies because of banking issues that could arise through being associated with the cannabis industry.

The government looked for alternatives and considered adding other types of retail points. However, because supply is currently the main bottleneck, this idea has not been implemented.

Supply shortfall prevents the pharmacies from having adequate product to provide the roughly 37,000 customers with effective and regular access. As of August 2019, the 17 registered pharmacies are receiving only about 2 kilograms per week, which sells out almost immediately.

Since the beginning of the recreational program in 2015, only two companies have been growing for commercial purposes and distributing all the supply to the authorized pharmacies: ICC Labs, which was acquired by Canada's Aurora Cannabis last year, and Simbiosys.

Both companies grow in greenhouses they built on state-owned land that was assigned to them for the exclusive purpose of growing nonmedical cannabis.

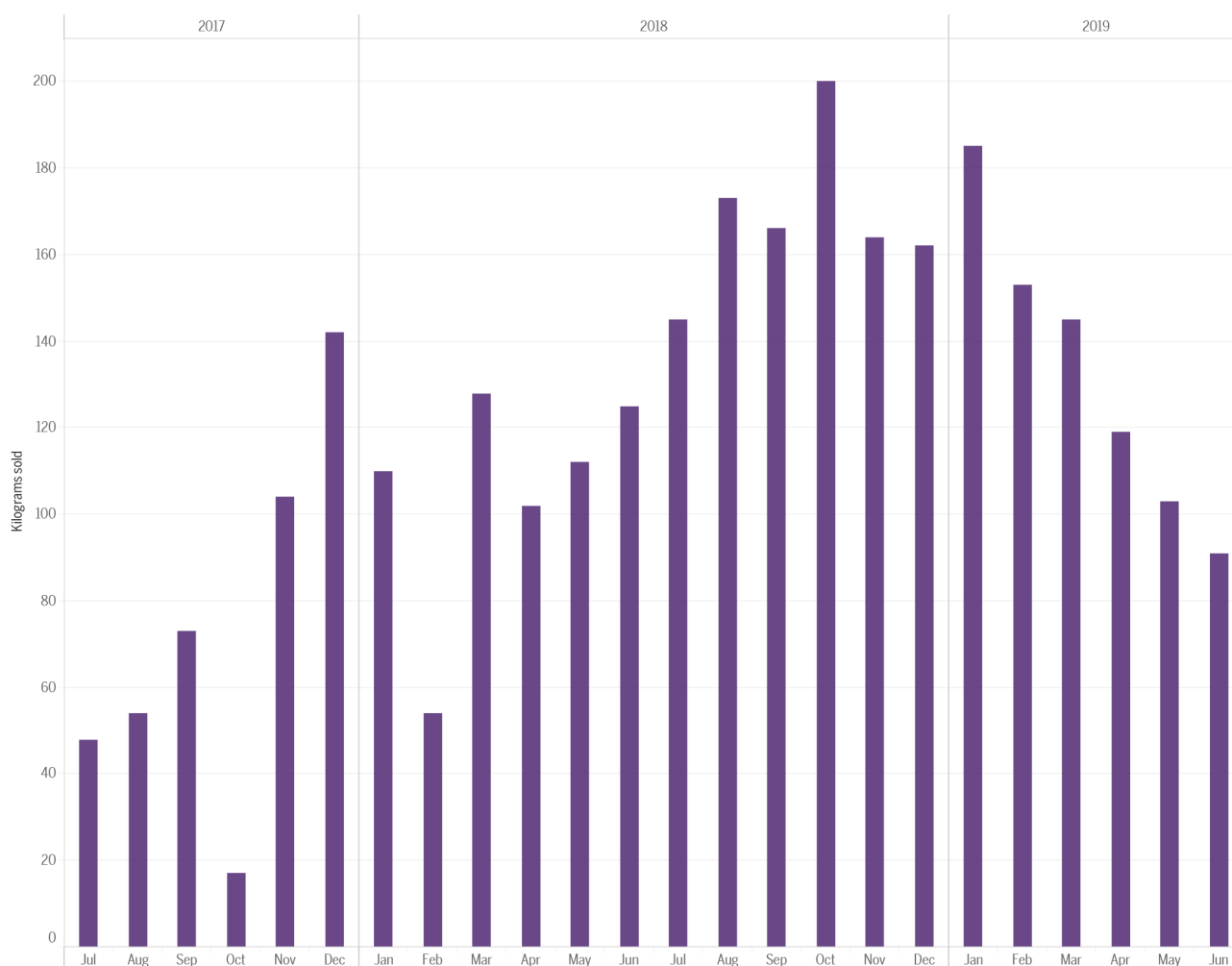
For the quarter ended June 30, 2018—the last one reported before its acquisition by Aurora—ICC Labs totaled sales of \$ 151,518, all from the recreational sector.

The wholesale and retail prices are fixed by the government. Producers receive about \$1 per gram, and the retail price in pharmacies is roughly \$1.30 per gram as of August 2019.

The two licensed cultivators grow only two strains that were originally supplied to the companies by the government. These cultivars are capped at 9% THC and have a minimum CBD content of 3%. Only flower may be sold commercially as nonmedical marijuana.

As of the end of June 2019, 2,875 kilograms of flower had been sold in pharmacies to registered customers.

CHART: Kilograms Sold



Source: IRCCA

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Shortages have been common since the beginning, and the government has identified supply as the main bottleneck preventing a more rapid growth of the market.

The two growers have a production quota of 2,000 kilograms per year. This means they could have already grown 12,000 kilograms, but they supplied less than 3,000 kilograms.

To increase supply, the government launched a call in February 2019 for applications to grow nonmedical marijuana for commercial purposes. Six companies applied. It's expected that three new growers will be selected before the end of the year.

The new recreational licensed producers will grow in similar conditions required of the existing growers. This means they'll be assigned a piece of state-owned land and allowed to grow 2,000 kilograms per year of the strains provided by the government to be sold at a wholesale price of almost \$1 per gram.

So, with five growers, a yearly supply of 10,000 kilograms will be theoretically possible.

Advertising is and will remain strictly prohibited. The packaging of recreational cannabis doesn't even include the name or logo of the producing company.

Adult use: Home growing and cannabis clubs

Sales of recreational cannabis represent only 10%–15% of the total legal supply of nonmedical marijuana, according to a recent report from the IRCCA. About two-thirds of the supply is produced through home growing and roughly 20% through cannabis clubs.

Consumers who want access to legal nonmedical cannabis need to choose one of the three options (registered customer, home grower or member of cannabis club) and register for it. Changing from one way of access to another down the road is possible, but consumers cannot access it through more than one channel at the same time.

Home growers may cultivate a maximum of six plants per household and harvest no more than 480 grams per year.

Cannabis clubs are nonprofit organizations that have a minimum of 15 and a maximum of 45 members that can grow up to 99 plants and deliver up to 480 grams per year to each of the members. Certain registries are required, and there are minimum regulations regarding how these associations should grow.

Because recreational marijuana being sold through pharmacies is capped at 9% THC, consumers who want legal access to a higher-THC content need to do so via home growing or cannabis clubs.

Almost six years after legalization, a dent has been made on the black market, but illicit cannabis is far from disappearing.

The most recent estimate of the IRCCA concluded that at least one out of five adults who used nonmedical marijuana in the past 12 months did so from a legal supply, which suggests there's still a long way to go.

Medical sector

The implementation of recreational-use regulations predated medical-use ones, and the Uruguayan medical program remains extremely limited.

Opportunities within the medical sector can be divided into three categories that might have some overlap:

- Registering products for the domestic market.
- Exporting nonregistered products to domestic patients.
- Growing high-THC cannabis in Uruguay.

Medical sector: registered products

There's only one company with registered products available in pharmacies as medical cannabis: Medicplast.

The company doesn't grow cannabis in Uruguay. It imports extracts from Switzerland and finalizes the manufacturing process domestically.

Medicplast sells two CBD-rich oils with minimal THC as medical cannabis and one over-the-counter cream in the domestic market. It also exports the oils to Brazil, where patients import under the "compassionate use" access on an individual basis.

One of the oils has a concentration of CBD of milligrams per milliliter and the other 50 milligrams per milliliter. These are the only registered medical cannabis products in Uruguay, currently available in pharmacies and sold under prescription.

Patients typically need to pay for such products as insurance doesn't cover it.

Medical sector: importing nonregistered products

In addition to getting a prescription for the Medicplast products available locally, patients could also get a prescription and apply for a permit to import nonregistered products from abroad for personal use.

So far, no company is authorized to import nonregistered finished products in bulk for distribution.

To import nonregistered products, doctors need to complete a detailed form that, among other things, asks them to justify the risks and benefits of the product to be imported and compare them with options currently available as registered medicines.

Patients need to sign a declaration of acknowledgement that the product has no registry.

Medical sector: cultivation and manufacture

As of August 2019, only two companies had a license to grow high-THC cannabis for medical use: Fotmer and Dormul.

Dormul was acquired earlier this year for about \$10 million by Khiron Life Sciences, a company with core operations in Colombia.

Of the two companies, Fotmer has more developed operations. The company is already producing and received authorization to send samples for testing to Germany in April 2019, but it hasn't started commercial shipments.

In May 2019, Fotmer became the first company to obtain a license to process psychoactive cannabis. It allows the company to obtain up to 5,000 kilograms of raw extract during a period of five years.

To do that, Fotmer can use up to 10,000 kilograms of cannabis flower and 10,000 kilograms of other parts of the cannabis plant from its own psychoactive crop.

Two other companies, ICC Labs and Innovaterra, also have manufacturing licenses, but the licenses allow these companies only to manufacture nonpsychoactive cannabis, using raw material from their hemp crops.

Hemp and CBD

One of the advantages that Uruguay offers is that the cultivation of cannabis with THC up to 1% is considered "nonpsychoactive" and the process to obtain a license is very straightforward, dependent mostly on the Ministry of Agriculture and regulated by Decree 372 of 2014.

SENACLAFT plays a role in ensuring the origin of the funds is legitimate. INASE intervenes, only after approval from the Ministry of Agriculture, to control the origin of the genetics. As of mid-2019, INASE had about 50 registered varieties of nonpsychoactive cannabis, but more could be added.

The Ministry of Agriculture is responsible for authorizing cultivation after evaluating the application. It can also grant a manufacture license but only for industrial uses or to produce food (for instance hempseed oil) after registration of the product with the Ministry of Health.

There are currently about 20 companies licensed to grow hemp. About half of them are in the department of Canelones, with most of the remaining companies in the western part of the country.

Over a thousand hectares were reported to be licensed at the end of 2018, when the number of companies was just 14. As of August 2019, the total licensed area was likely to be much higher.

To extract CBD, a manufacture license from IRCCA is needed, as shown by the cases of ICC Labs and Innovaterra described at the end of the medical section.

URUGUAY

One additional manufacturing license was granted to process hemp to be added to mate, a popular hot drink in Uruguay.

Uruguayan company Di Cianna is allowed to use up to 750 kilograms of hemp per month to add to two brands of yerba mate: Abuelita and Cosentina.

The hemp is grown by one of the licensed hemp growers, BCBD, and only the variety registered as BCBD 01 can be used for this process.

Ontario-based Auxly Cannabis Group is active in the hemp sector in Uruguay through the acquisition of Inverell, a domestic hemp grower.

Reform ahead

Uruguay is getting ready for general elections at the end of October 2019.

Two of the three presidential candidates representing the three largest political parties are in favor of keeping the marijuana law. One of the two opposition candidates proposed expanding business opportunities in the medical sector.

The other opposition candidate, Luis Lacalle Pou, has been more hesitant to support the current law because, in his view, it didn't help reduce "narco" violence, which was the main objective.

However, local industry sources don't expect that a return to the situation before December 2013 is a likely scenario.

Two bills are currently being discussed in the parliament and have a chance to be approved before the end of the current legislative period, which ends at the beginning of 2020.

One of the bills would increase access to medical cannabis; the other would promote research.

THE CARIBBEAN

Legal barriers for cannabis businesses are falling one country after another in the Caribbean, with a growing number of islands establishing regulatory foundationa for marijuana enterprises.

In front of the pack are Antigua and Barbuda, Jamaica as well as St. Vincent and the Grenadine, having already approved laws and regulations to allow for medical cannabis cultivation and sales.

More countries have laws in the legislative pipeline, including Barbados, Bermuda, and St. Kitts and Nevis.

A number of other nations, such as Barbados and the Cayman Islands, currently only allow the importation of various forms of medical marijuana.

Other nations are taking a different approach: Bermuda is lifting a regulatory ban on cannabis investment funds so the country's Monetary Authority (BMA) can register funds with investment strategies linked to the cannabis industry. That paves the way for open-ended funds, where investors may redeem their investment on a predetermined schedule, subject to registration and/or authorization by the BMA.

The Caribbean is one of the most dynamic regions to watch in this fast-developing industry, offering an array of business opportunities across the cannabis spectrum.

But prepare for hurdles such as strict residency requirements in some cases.

Though these are not the only places in the Caribbean presenting business opportunities, we chose to highlight three countries that already have laws and thorough regulations on the books: Antigua and Barbuda, Jamaica, and St. Vincent and the Grenadines.

ANTIGUA AND BARBUDA

Antigua and Barbuda's Misuse of Drugs (Amendment) Act, 2018, updated the Misuse of Drugs Act to stipulate that "a person who is in possession of a maximum of 15 grams of the drug Cannabis or Cannabis resin is not guilty of an offence."

It also makes it "lawful" to cultivate up to four cannabis plants per household and expunges marijuana convictions involving a quantity of 15 grams or less.

The amendment stopped short of legalization, however, as it does not remove legal penalties for the sale of cannabis.

The Cannabis Act formally laid the legal footing for the medical industry in January, opening the door to business opportunities in such areas as cultivation and export.

The Cannabis Regulations were finalized in April to make the Act workable for businesses and patients.

Most relevant government authorities

- Antigua and Barbuda Medicinal Cannabis Authority
- Ministry of Legal Affairs

Key Laws and Regulations

- The Cannabis Act, 2018
- The Cannabis Regulations, 2019
- Misuse of Drugs (Amendment) Act, 2018

How it works

The Antigua and Barbuda Medicinal Cannabis Authority—responsible for regulating and controlling the licensing of the medical and sacramental sectors—only came into effect in April, so the industry is still in a nascent stage.

As such, the regulator is still getting a handle on the new industry. For example, the newly formed Medicinal Cannabis Authority suffers from a lack of transparency.

The Authority has not distributed digital copies of the Cannabis Regulations, 2019, which is required reading for any entrepreneur interested in engaging in the new sector.

The Authority makes prospective entrepreneurs shell out 120 Eastern Caribbean dollars (\$50) just for a copy of the 319-page document, which spells out the key rules governing the industry.

That will be a hurdle to generating interest in the nascent industry.

So far, the board secretary of the Medicinal Cannabis Authority has not disclosed basic information on the industry, such as the number of applications for each classification of cannabis license or whether any licenses have been granted.

Nonetheless, the island is one of only a very small number of countries in the Caribbean to have finalized a legal and regulatory foundation for the cannabis industry.

Licenses are available for cultivation, manufacture, processing, extraction, import, export, testing, research, distribution and sale of cannabis for both medical and sacramental purposes.

Applications for the licenses must be in the prescribed form outlined in the Cannabis Regulations, 2019, and submitted via a scanned copy and emailed to ABMedicinalCannabisAuthority@gmail.com and also submitted in hard copy to the board secretary at the Ministry of Legal Affairs.

Business opportunities may exist in the tourism industry, as tourist establishments are allowed to set aside "open areas" where guests can smoke cannabis.

Noncitizens are allowed to own cannabis licenses, but there is an important caveat: A medicinal cannabis business license that is 31%-100%-owned by a foreign entity "shall issue to the government not more than a 15% risk-free perpetual equity ownership of that company," according to the law.

JAMAICA

In 2015, Jamaica amended its so-called Dangerous Drugs Act, which prohibited and punished marijuana cultivation, distribution and consumption, to establish the Cannabis Licensing Authority and develop a regulated industry. In 2016, authorities finalized regulations and began accepting business license applications.

The industry didn't explode out of the gate, mostly because the country's biggest banks continue to turn down businesses out of fear of angering U.S. and foreign banking partners. A lack of capital has slowed the country's rollout.

Another major hurdle is the Cannabis Licensing Authority's slow introduction of rules for exporting medical cannabis—a key plank for many businesses there. The regulations were expected to be published earlier this year, but that has been pushed to this fall at the earliest.

Most relevant government authorities

- Cannabis Licensing Authority
- Cannabis Licensing Appeals Tribunal
- Ministry of Industry, Commerce, Agriculture and Fisheries

Key Laws and Regulations

- Dangerous Drugs Act of 1948
- 2015 Amendments to the Dangerous Drugs Act
- Cannabis Licensing Authority Regulations of 2016

How it works

Jamaica has what it takes to develop a robust medical marijuana economy: license categories for small and large cultivators, regulations that allow a wide breadth of products, no license caps and a reputation as a world cannabis capital.

Jamaica awarded its first medical cannabis business license in 2017. The first dispensary opened in March 2018, but a relatively small number of cultivators and retailers are operating at this time.

The Cannabis Licensing Authority told *Marijuana Business Daily* that it had issued 40 cannabis business licenses as of the end of July and granted 54. (Before a license is issued, the Authority requires certain action from the applicant, such as the payment of corresponding licensing fees and security bonds.)

- Seven Tier 1 (up to one acre) and eight Tier 2 (between 1 and 5 acres) cultivation licenses have been issued.
- Five Tier 1 (up to a 200-square-meter facility) and no Tier 2 (more than 200 square meters) processing licenses have been issued.
- Only one transportation license has been issued.

On the retail side, eight licenses have been issued for “Herb Houses”—stores which sell marijuana for medical, scientific and/or therapeutic purposes—with facilities for consumption, and no licenses have yet been issued for “Herb Houses” without a consumption space.

Three retail licenses have been issued for therapeutic or spa services.

No licenses had been issued for analytical services as of July 31.

Businesses that apply for a license must be more than 50% owned by people who are at least 18 years old and have been living in Jamaica for at least three consecutive years immediately preceding the date of the application.

ST. VINCENT AND THE GRENADINES

The southern Caribbean nation of St. Vincent and the Grenadines approved the Medicinal Cannabis Industry Act late last year, establishing a firm legal foundation for the medical marijuana sector.

The law is very comprehensive and came with the regulations inserted, significantly reducing the time it took to get the industry off the ground. (Some countries take years to develop workable industry regulations after passing a cannabis law.)

Most relevant government authorities

- Medicinal Cannabis Authority (MCA)
- Ministry of Agriculture, Industry, Forestry, Fisheries and Rural Transformation

Key Laws and Regulations

- Medical Cannabis Industry Act
- Cannabis Cultivation Amnesty Act
- Regulations for the Issuing of Licences (First Schedule)

How it works

St. Vincent and the Grenadines awarded the islands' first-ever licenses in July, and hundreds of permits to cultivate commercial medical cannabis are in the pipeline.

The types of licenses granted by the MCA include:

- Cultivation (five levels, based on size of operation)
- Research
- Manufacturing
- Dispensing
- Import
- Export
- Transport

Cultivation license fees range from 2.67 million Eastern Caribbean dollars (roughly \$1 million) for a Class E permit to EC\$100,000 for Class A.

As of July, 10 companies with international board members were among those who won the first licenses.

Another 24 licenses went to local individual farmers or farming cooperatives with an aggregate membership of more than 100 cultivators.

The Medicinal Cannabis Authority said it expects to approve 200 more cultivation licenses by early fall.

Medical cannabis can be prescribed by doctors and dispensed only in authorized pharmacies.

The regulations designate a long list of qualifying medical conditions, which include multiple sclerosis, sleep disorders and chronic pain.

The rules come with strict residency requirements. Traditional cultivator licenses "shall be issued solely to a person who is a citizen of St. Vincent and the Grenadines," according to the Medical Cannabis Industry Act.

Citizenship in St. Vincent and the Grenadines is listed as a "basic qualification requirement" for license applicants.

Residency requirements are not unusual in many Caribbean countries in order to conduct any business activity.