

CANNABIS IN LATIN AMERICA:

The Regulations and Opportunities

SECOND EDITION

**Critical analysis
of key markets
in the region**

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CANNABIS IN LATIN AMERICA: THE REGULATIONS AND OPPORTUNITIES



Alfredo Pascual

Latin America and the Caribbean continue to be key pieces of the global cannabis industry puzzle—and difficult to ignore for companies with global aspirations. The sheer number of inhabitants, ideal growing conditions in large parts of the region and many jurisdictions that favor production combine to signal business opportunities.

The geographical region that stretches from the southern border of the United States to the southern tip of South America, including the island nations of the Caribbean, is home to roughly 650 million people—and the vast majority live in countries with some sort of legal medical cannabis.

With this report, our goal is to provide a realistic analysis of the prospects offered by Latin America as a whole and each country in particular. But we also weigh the unique challenges of investing or doing business in these jurisdictions, many of which have struggled to implement their cannabis laws years after approval.

Whenever world maps are created to show the countries with legal medical cannabis frameworks, Latin America is included almost in its entirety. But, as is often the case, the devil is in the details.

Restrictive, compassionate-use special access schemes continue to be the primary access mechanism to commercial cannabis products for patients, including the region's largest market, Brazil. As a result, price is a barrier.

Health insurance coverage for cannabis is rare. And, in most countries, the only commercial products legally available as medicine contain CBD but no meaningful THC. These products are sold only under prescription and, in some places, can be sold only as a last-resort treatment.

Meaningful, immediate revenue opportunities remain limited across the continent as most countries focus more on exporting rather than developing their internal markets. That is why in recent months, several international cannabis companies canceled their planned investments or refrained from making new ones in grow operations.

Some Latin American countries that legalized medical marijuana still have dysfunctional markets, which means patients often turn to decriminalized home-growing for access to cannabis.

These observations are not meant to discourage investors and entrepreneurs. They simply mean there is plenty of room for improvement. And several changes are being considered in different countries that are expected to expand access and create more opportunities for businesses. Throughout this report we analyze the impact these reforms could have.

Because of the ever-changing nature of cannabis regulations, information in this report should be assumed to be updated through July 2020 unless otherwise specified. Prices are always indicated in U.S. dollars.

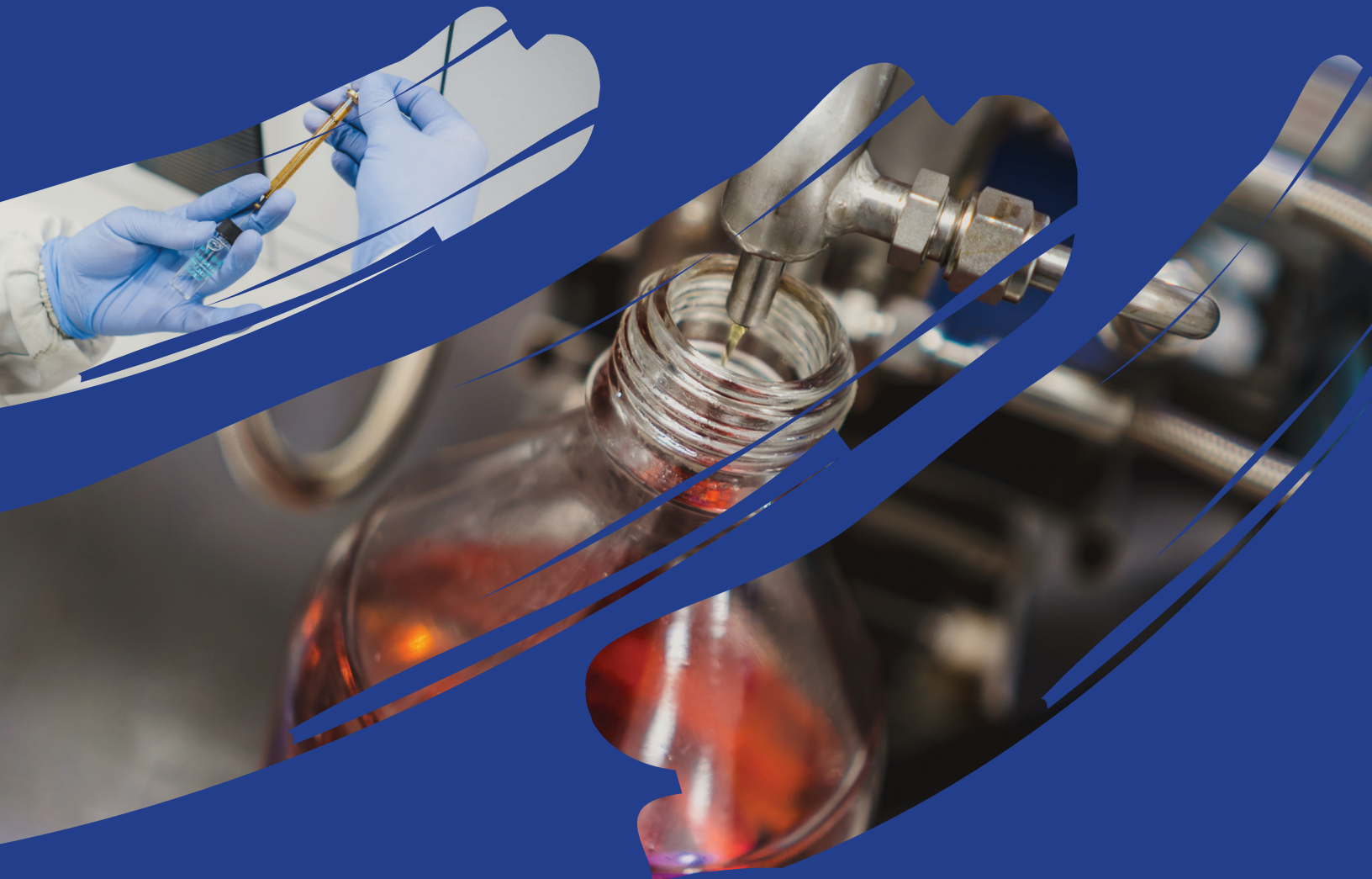
A special thank you to International Editor Matt Lamers for his assistance in the research and writing of the Caribbean section.

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". The signature is written in a cursive, flowing style.

Alfredo Pascual

Marijuana Business Daily International Analyst



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OPEN FOR CANNABIS BUSINESS

Marijuana Business Daily's opportunity ranking of Latin American countries as of mid-2020

- | | |
|-------------|--------------|
| 1. Colombia | 5. Mexico |
| 2. Uruguay | 6. Paraguay |
| 3. Peru | 7. Argentina |
| 4. Brazil | 8. Chile |

Comparisons of different jurisdictions are complex and, to a certain extent, subjective. This is particularly true when looking at the cannabis markets of Latin America, given the big differences in regulatory frameworks and how the governments have approached implementation of cannabis legislation.

Moreover, what is attractive for one business might not be interesting to another. For example, a company that wants to only conduct research might find Chile attractive; another one looking for a low-cost production place might choose Paraguay as the best market to do that. Those interested in generating revenue today might find that only Brazil's market is enticing enough.

Our methodology, even with its limitations, weighed different aspects that are normally important for cannabis businesses:

- The actual domestic market opportunities to generate revenue, in terms of what the regulations allow, what was actually occurring when this report was published and population.
- Production opportunities, including an analysis of what the regulations allow and associated costs.
- How export-friendly the country is and how much companies have been able to export so far.
- Near-term expected changes. Because predicting this industry in the long-term is too uncertain, we considered only what is expected to change before year's end.

The ranking is intended to be a snapshot of the current situation, not a prediction of how these markets will evolve.

The best cannabis regulations are largely useless if the country has an environment unwelcoming to businesses in general. For instance, if enforcement of contracts or conducting international trade is too complex, businesses will be deterred from investing. Using the World Bank's "ease of doing business index," we boosted the sum of "cannabis points" previously calculated for each country.

Countries with no meaningful opportunities for cannabis businesses were excluded from this ranking, as were Caribbean countries.

BEST DOMESTIC MARKET

- | | |
|-----------|-------------|
| 1. Brazil | 2. Colombia |
|-----------|-------------|

With about 15,000 patients authorized to import individually as of mid-2020, Brazil is undoubtedly the largest Latin American market. Although this special-access scheme involves inefficiencies that are analyzed in more detail in the Brazilian chapter, the process has been simplified over time. Since March 2020, the country also established rules that allow companies to obtain a temporary authorization for local manufacturing and distribution to pharmacies for products that have no proven efficacy through clinical trials, but quality requirements are strict.

Colombia's domestic market has advanced in recent months, with sales of magistral preparations with both CBD and THC starting as well as sales of the first registered product with CBD as active ingredient.

BEST PLACES TO PRODUCE

1. Colombia
2. Uruguay

Most countries offer some opportunities to produce. But only Colombia and Uruguay have mature regulations for this, which is reflected in the number of companies and amount of investment they have received for production so far.

LEADING EXPORTERS

1. Uruguay
2. Colombia

Only Uruguay and Colombia have exported medical cannabis with a value of at least \$1 million so far. Uruguay allows the export of flower for commercial purposes.

MOST PROMISING CHANGES AHEAD

1. Mexico
2. Peru

Almost all the countries in this report expect some positive changes before the end of 2020, which for companies is as important as the current situation.

After several delays, we now expect Mexico will achieve significant developments before the end of 2020, including recreational legalization.

Peru, so far totally dependent on imports, might finalize implementing its cannabis legislation and grant the first production licenses.

ADULT-USE MARKET

1. Uruguay

Uruguay is the only country in the region that has legalized the commercial production of adult-use marijuana. Even with the limitations of the framework, about 4,000 kilograms of nonmedical marijuana flower were sold to consumers during the past three years for roughly \$5 million.



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Argentina legalized medical cannabis in March 2017, but more than three years later, implementation of the law has been limited:

- Only a tiny fraction of the patients in need have access to legal, commercially produced cannabis, and that access is typically only through individual imports under a “compassionate use” special-access scheme.
- Business opportunities often are limited to research.
- Businesses might also try to broker deals with provincial governments in a regulatory environment of overlapping powers.

In that regard, little changed from the 2019 edition of *Marijuana Business Daily's* Latin American report. Importing products remains bureaucratic and expensive for most of the population—even more so after years of currency devaluation. So, in practice, most patients that require cannabis products access them only through illegal home grows or associations.

On a positive note, as of July 2020, the government is mulling new regulations that would expand access and allow registered patients to grow at home, but no draft rules have been made publicly available.

Cannabis businesses in Argentina must deal with federal and provincial legislation. The national law gives oversight of domestic production to certain federal agencies, but as of mid-2020, no production at scale had begun. Only one company so far obtained all necessary federal permits to grow in the country—a joint venture between a provincial government-owned company and a U.S.-headquartered firm. Production from the operation still is not available to patients, but in early 2020 the Jujuy province's governor promised via local media that the first oils will be ready before the end of the year.

Legal products in the country all have been imported so far, either for research projects or on a case-by-case basis by individual patients.

Argentina's law created a program to register patients, but the registry's implementation also has been extremely limited, according to local patients. In practice, the only qualifying condition is refractory epilepsy, with an approved treatment of CBD oils. July's proposal is expected to include changes to that framework as well.

Provinces in the country have some autonomy and have followed four distinct 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. Foreign companies often will take this approach in order to establish a presence in a country before expansion of what the regulatory framework allows.

MOST RELEVANT GOVERNMENT AUTHORITIES

Ministry of Health, primarily through the 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, or INASE)
- National Food Safety and Quality Service (Servicio Nacional de Sanidad y Calidad Agroalimentaria, or SENASA)
- National Agricultural Technology Institute (Instituto Nacional de Tecnología Agropecuaria, or INTA).
- National Scientific and Technical Research Council (Consejo Nacional de Investigaciones Científicas y Técnicas, or CONICET)
- National Agency of Public Laboratories (Agencia Nacional de Laboratorios Públicos, or ANLAP).
- Ministry of Safety
- Provincial authorities

MOST IMPORTANT LAWS AND REGULATIONS

- Law 17,818 of 1968 and law 23,737 of 1989, which regulate narcotics and associated penalties.
- Law 27,350 of 2017: “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 by 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 provide more details on some aspects of the law, but as of mid-2020 patients still demanded reform to guarantee access.

The law and the decree created a Ministry of Health program for researching medical cannabis 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 receive the medicines for free. However, local patients report that registering with the program is extremely difficult and getting coverage for cannabis products even more so. That is why there are several reported cases of patients going to court 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, which limited qualifying conditions to only refractory epilepsy. It also allowed for other conditions to be included in the future if scientific evidence supported them.

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

The National Agricultural Technology Institute (INTA) and the National Scientific and Technical Research Council (CONICET) are responsible for cultivation, according to the law and subsequent regulations. The National Agency of Public Laboratories (ANLAP) should be given priority to manufacture.

However, some interpret the law as allowing these government agencies to produce through third parties, such as authorizing individual companies for this purpose. The joint venture between the Jujuy provincial government and a foreign company followed that interpretation.

In April 2018, the Ministry of Safety published a resolution detailing security requirements for cannabis production facilities. It also mandated that companies obtain 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. The resolution noted that companies must have a person responsible for the crop. In addition, the resolution laid 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 legal domestically produced medical cannabis available, access to products depends on imports, through either:

- A registry created by the federal program (Registro Nacional de Pacientes en Tratamiento con Cannabis, or RECANN).
- A mechanism that allows patients to import nonregistered products, also known as “compassionate use” (Régimen de Acceso de Excepción a Medicamentos, or RAEM).

The Ministry of Health determined in mid-2019 via another resolution that only neurologists can prescribe the cannabis products that can be imported as nonregistered products.

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

Resolution 133/2019 also established the period for which patients could import products for personal medical use at 180 days.

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

MJBizDaily isn't aware of any official, public disclosure of the number of patients effectively registered in the RECANN nor how many patients were able to receive the products for free as mandated by the law.

Compassionate use was possible before the 2017 reform, and some argue that the new framework actually restricted this pathway of access, for example, by only allowing refractory epilepsy to be a qualifying condition.

RESEARCH

While production and distribution remain under an unclear framework, a few companies have pursued the path of clinical research to provide access to some of Argentina's patients.

Two examples include Canadian producer Aphria, which has donated cannabis oils for a study undertaken by Buenos Aires-based pediatric hospital Garrahan since end of 2018. In mid-2019, El Cruce, another hospital in Buenos Aires, received approval from the Ministry of Health to initiate another clinical trial to test the use of cannabis in 60 adolescents and adults with refractory epilepsy. U.S.-based HempMeds partnered with the El Cruce to provide the oils at no cost.

Several other research institutions—most of them universities—also are active in the research space.

THE PROVINCIAL CONUNDRUM

Most of Argentina's provinces adopted the federal medical program, primarily by passing simple provincial laws that adhere to federal rules.

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

The following is a list of provinces with laws that adhere 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 constrained because of the limited implementation of the cannabis legislation at a federal level.

While the federal agencies have failed to start production, a provincial law passed in October 2018 in Jujuy created a state-owned company, Cannabis Avatāra Sociedad del Estado (Cannava), to start cultivation there.

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 Players 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."

The partnership with Green Leaf appears to be the most advanced in its development of operations.

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

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

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.

In a shareholder update dated July 21, 2020, CEO Mark Bradley said that "the company filed Chapter 11 to restructure and eliminate most of the company's more than \$4,000,000 in debt." But he remained optimistic about operations in Argentina, saying that the company "harvested its first crop in May" and that the biomass was stored, awaiting a capital raise that would allow building an "extraction facility for processing and oil production."

Jujuy's governor promised earlier this year via local media that the first oils will be ready before the end of the year, but as of mid-2020 it remains unclear how these will be manufactured.

Other provinces—including Chubut, La Rioja, Mendoza, Misiones and Santa Fe—are considering following Jujuy's steps or have already taken meaningful steps in that direction.



BRAZIL

Brazil, the most-populous country in Latin America, has consistently led the region in medical cannabis with regard to number of patients and sales of legal marijuana products, though the market is largely dependent on imports.

As of mid-2020, most sales take place via special authorizations granted by the federal regulatory agency for individual patients to import products for personal medical use. However, there are two pharmaceutical products available in the country. One is registered like any other medicine with proven efficacy, and the other one obtained what Brazilian regulations call “sanitary authorization” which is a special permit for temporary commercialization of a medicinal cannabis product without proven efficacy.

The individual imports access scheme has been simplified several times, giving access to thousands of patients since 2014—though, in most cases only to CBD oils. According to the country’s health agency, more than 8,000 patients were authorized to import in 2019 and nearly 3,000 authorizations were added during the first quarter of 2020.

The health agency approved rules at the end of 2019 to allow the temporary authorization of products without finished clinical trials, but expectations that that would expand access to a range of medicines in Brazilian pharmacies largely have not materialized. Only one product obtained an authorization under these rules, and as of mid-July, not a single application is pending, according to the health agency.

Cultivating cannabis, though arguably legal under the country’s narcotics law, remains impossible because no secondary rules have been created to regulate operations. A proposal to create these rules was rejected by authorities at the end of 2019. However, roughly 100 individual patients obtained permits from the courts to grow for personal medicinal use and two associations grow for their members. As of mid-2020, one authorized association is estimated to serve thousands of patients.

MOST RELEVANT GOVERNMENT AUTHORITIES

Unlike other Latin American countries that have different ministries, agencies and, sometimes, 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, or ANVISA) centralizes most of the medical cannabis-related oversight.

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

MOST IMPORTANT LAWS AND REGULATIONS

- Law 11,343 of August 2006
- Decree 5,912 of September 2006
- RDC ANVISA 16/2014
- RDC ANVISA 325/2019
- RDC ANVISA 327/2019
- RDC ANVISA 335/2020
- Resolution CFM 2,113/2014
- Ministry of Health Directive (Portaria) 344/1998

HOW IT WORKS

The country effectively has three categories of legal, commercially produced medical cannabis:

- Cannabis-derived medicines registered like any other pharmaceutical drug, for which efficacy and safety need to be proved. So far, that includes only GW Pharmaceuticals' Sativex, manufactured in the United Kingdom and registered as Mevatyl in Brazil to treat spasticity of patients with multiple sclerosis.
- Cannabis products with "sanitary authorization," the new category created by ANVISA in December 2019. These products do not require proven efficacy via clinical trials during the first years (for a maximum of five years, but the agency may select the specific time frame) but must comply with stringent quality requirements. Domestic manufacturing and distribution to pharmacies is allowed. As of mid-2020, only one product was authorized—manufactured by Brazilian pharmaceutical company Prati-Donaduzzi—and there are no pending applications.
- Authorizations granted on a case-by-case basis to patients allowing them to import nonregistered cannabis products, which also do not require clinical trials. This has been working since 2014 and is sometimes called "compassionate use."

So far, almost all patients access through the last option, primarily for CBD products.

Home growing and collective growing is, in principle, prohibited, but court rulings have authorized about 100 individual patients and two patients' associations. So it could be said that a fourth category of legal products stems from the judicial-system authorizations.

NONREGISTERED PRODUCTS IMPORTS

To import nonregistered medical cannabis in Brazil, patients must first apply for a federal permit. If successful, the patient receives an authorization for two years. Before January 2020, authorizations were valid for up to one year.

Once an authorization has been issued, patients can buy products directly, without any intervention from ANVISA. Most patients buy online. Many companies exporting to Brazil provide guidance to patients for navigating the application process with ANVISA or have agreements with local consultants who do so. But importing these products in bulk for distribution or reselling is not allowed.

Nonregistered products must be supplied from a legal and known source, but pharmaceutical quality requirements are largely nonexistent. In the country of origin—for instance in the United States—many of these products are commonly sold as dietary supplements. As nonregistered medicines, no medical claims of the products can be made in Brazil.

The first products were imported in 2014. That year, only a few hundred patients obtained authorization from ANVISA. In 2019, the agency granted more than 8,000 authorizations of this kind, adding nearly 3,000 in the first quarter of 2020.

Since January 2020, patients simply need a prescription from their physician with some basic information to obtain the permit to import—a much simpler process than before. The approval time has also improved. Patients now typically receive their permits within days.

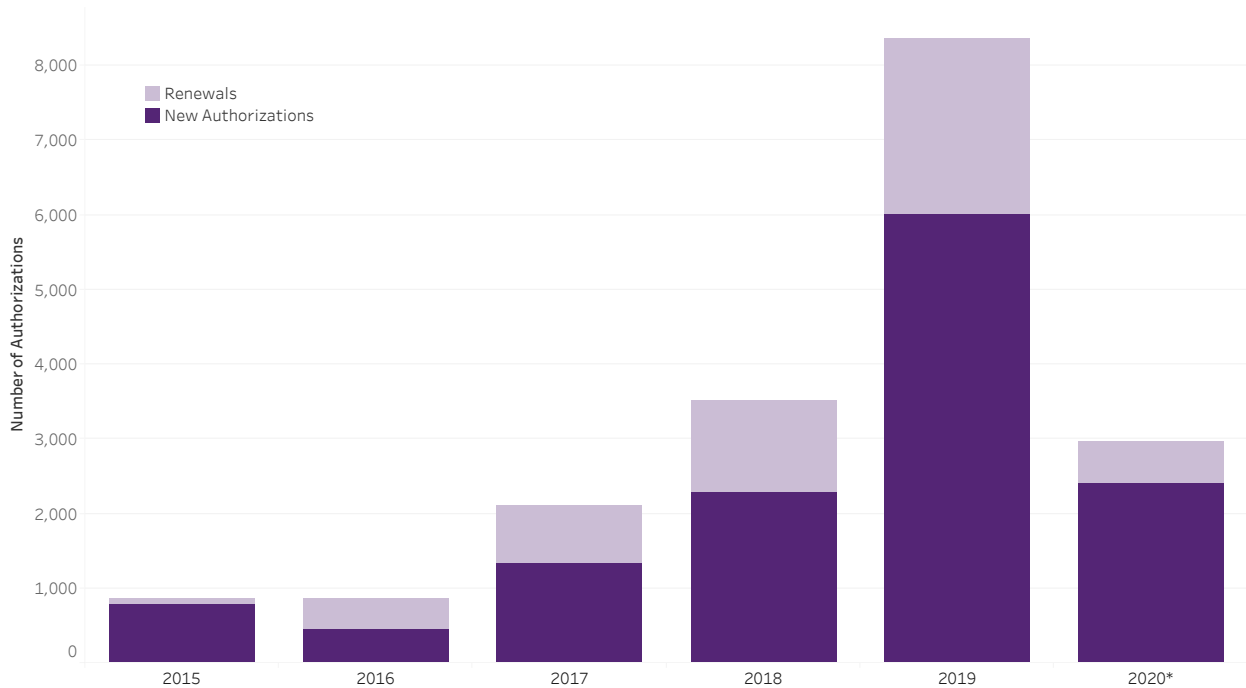
NONREGISTERED PRODUCTS MARKET DATA

ANVISA authorizations through March 2020 surpassed 18,500. The number of accumulated authorizations should not be considered equivalent to the number of active patients, as authorizations have time limits and can be renewed, meaning one patient can be responsible for several authorizations. We estimate active patients to be roughly 11,350 as of March 2020.

In the absence of more reliable and complete data, ANVISA authorizations to import nonregistered products remain the best official indicator of how the Brazilian medical marijuana market is evolving. It just needs to be interpreted in the context of Brazilian regulations.

CHART 1: ANVISA AUTHORIZATIONS FOR INDIVIDUAL PATIENT IMPORTS OF NONREGISTERED CANNABIS PRODUCTS

ANVISA Authorizations for Individual Patient Imports of Nonregistered Cannabis Products



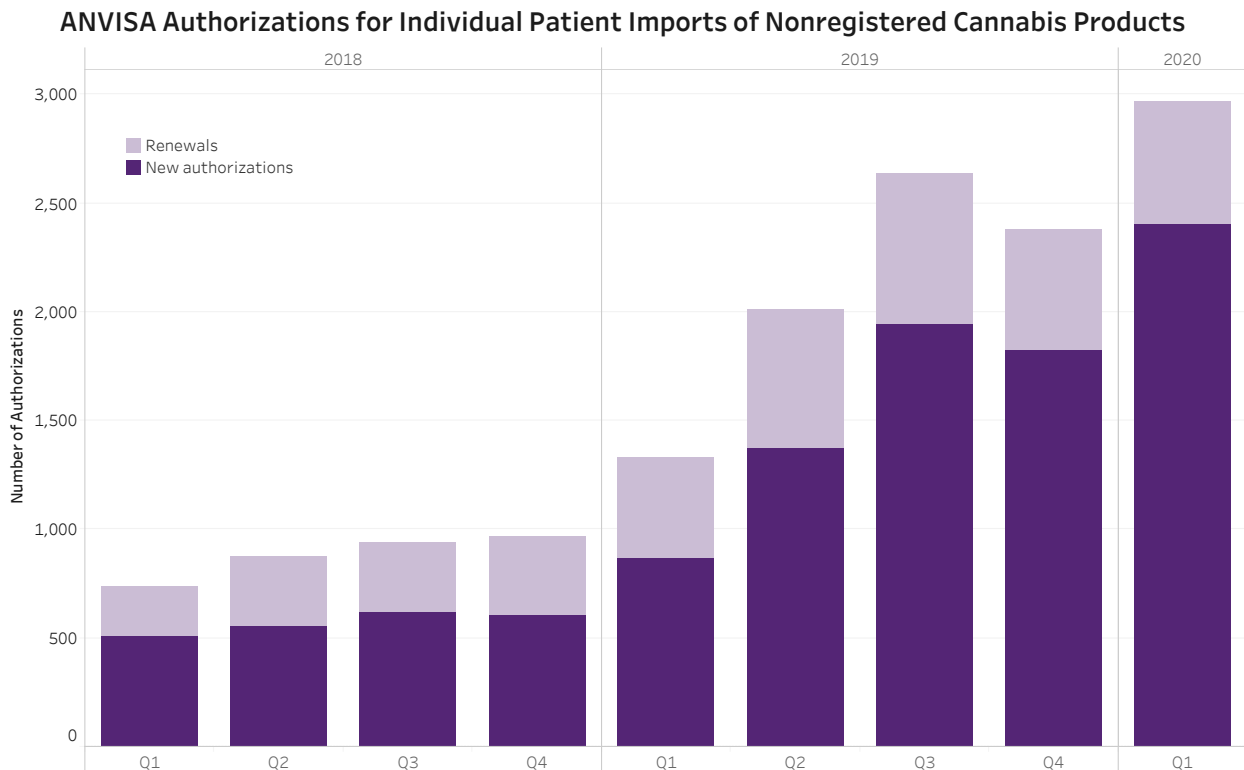
*Authorizations through March 2020.

Source: The Brazilian Health Regulatory Agency (ANVISA)
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Until January 2020, import authorizations—both new and renewals—were granted for a period of up to one year. That was extended to two years in January 2020. Authorizations granted in the previous 12 months were automatically extended for one more year.

During 2019, an average of 500 new authorizations and almost 200 renewals were granted per month. The total number of authorizations granted in 2019 was 137% higher than the previous year.

During the first quarter of 2020, the number of average new authorizations per month increased to 802, but the renewals decreased to almost 187. The decrease in renewals likely is the result of the automatic extension for prior authorizations.

CHART 2: ANVISA AUTHORIZATIONS FOR INDIVIDUAL PATIENT IMPORTS OF NONREGISTERED CANNABIS PRODUCTS

Source: The Brazilian Health Regulatory Agency (ANVISA)
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ANVISA does not limit imports of nonregistered cannabis products to CBD, but in practice, CBD oils account for most of the imports because:

- In December 2014, the Federal Council of Medicine (Conselho Federal de Medicina) issued a resolution approving the prescription of cannabidiol to treat refractory epilepsy in children and adolescents as “compassionate use” only when conventional medicines have proved ineffective.
- THC-high products are more challenging to ship internationally. For instance, exports from Canada to individual patients in Brazil are rare because Health Canada requires an export permit for each individual shipment. Health Canada charges more than 600 Canadian dollars (\$450) for each permit, which makes the export economically unfeasible.
- Most products come from the United States, where it is not possible to legally export plant-derived high-THC products because they are illegal at the federal level.

REGISTERED PRODUCTS

Sativex—manufactured in the United Kingdom by GW Pharmaceuticals—currently is the only registered cannabis-derived medicine in Brazil with proven efficacy and safety through clinical trials.

Rules created in December 2019 allow cannabis products that have not undergone clinical trials to prove efficacy to obtain a temporary “sanitary authorization,” provided these comply with stringent quality requirements. Doctors can prescribe these products, which do not have official medicines status.

Brazilian pharmaceutical giant Prati-Donaduzzi obtained the first sanitary authorization for a THC-free CBD product in April 2020, according to a notice in the country's official gazette. ANVISA confirmed to Marijuana Business Daily in mid-July that only one product remains approved under this category and the agency had no pending applications to review. That's a sign of how complex it is for most cannabis companies to comply with the stringent pharmaceutical-quality requirements even if no clinical trials to prove efficacy are required.

ANVISA needed only 35 days to analyze and approve Prati-Donaduzzi's application for a sanitary authorization. The product is an oral solution containing 200 milligrams of CBD per milliliter and sells for roughly \$450 a bottle of 30 milliliters as of mid-2020. It first became available for doctors to prescribe and patients to buy in pharmacies in May 2020. Prati-Donaduzzi's authorization is valid for two years.

By rejecting domestic cultivation in 2019 but allowing manufacture, Brazilian health authorities effectively established an import market for raw extracts, isolated cannabinoids or finished products. In the case of the only approved product so far, the active pharmaceutical ingredient (CBD) is imported from an European Union-Good Manufacturing Practice-certified facility in the United Kingdom, according to Brains Bioceutical, the exporting company.

THE DECEMBER 2019 RULES IN DETAIL

In mid-2019, ANVISA proposed resolutions to:

- Regulate the domestic cultivation of cannabis for the first time, exclusively for medical and scientific purposes, in compliance with the 1961 Single Convention on Narcotic Drugs.
- Review the authorization procedures for medical cannabis products.

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 has not regulated cultivation, in practice it is not possible to apply for and obtain a license to grow.

The health agency had the legal mandate to approve the two proposals based on the above-mentioned law and decree, so no legislative change was needed in Parliament. The final resolutions only needed approval from the agency's collegiate board of directors.

After months of public consultation, political intrigue, multiple postponements and intense opposition from high-level officials within the government of President Jair Bolsonaro, the agency approved the proposal to create a special category to authorize cannabis products in December 2019. The new rules took effect in March 2020.

RDC 327/2019 created a temporary scheme allowing the commercialization of products without clinical trials that comply with strict quality requirements. ANVISA called the new rules a "regulated transition" and urged companies to not abandon research to demonstrate the efficacy of their medical marijuana products.

Products approved may be sold for a period of up to five years after the authorization is published in the official gazette. During that period, ANVISA can unilaterally request additional documentation and suspend or even cancel a product's approval. The five-year period cannot be extended. Once it is over, the company must have registered the product to continue selling it, for which efficacy and safety must be proved—as is the case with Sativex.

Although this category does not require clinical trials, the rules are strict, severely limiting the number of companies that, as of today, are able to capitalize on the opportunity. Some of the requirements are:

- Only products for oral or nasal use are allowed. Flower is prohibited—even if it is ground. The importation of plant material or its parts is not allowed, not even as a raw material.
- Good Manufacturing Practice (GMP) certification. The new regulations determined that until December 2022, ANVISA will accept GMP certifications issued by health agencies of Pharmaceutical Inspection Co-operation Scheme (PIC/S) countries. After December 2022, only ANVISA certifications will be allowed. This means that if a company receives an approval to sell cannabis products in Brazil with a GMP certification from another country, an ANVISA certification will be needed to continue selling after 2022.

- Stability studies to demonstrate that the quality of the product remains stable throughout its shelf life in the climatic conditions commonly found in Brazil. ANVISA requires long-term stability studies with a minimum duration of 12 months or, under certain circumstances, accelerated studies that could be conducted in a shorter period.
- Extreme marketing restrictions, including no commercial names for the products. Advertising of any kind is prohibited. Even the use of the word “medical”—or an equivalent term—is banned for these cannabis products.
- The need for a special prescription for every cannabis product, including those with low or no THC, and only after all “other therapeutic options in the Brazilian market” have been tried.
- Products with a THC concentration above 0.2% can be authorized only for palliative care for terminal patients “without any other therapeutic alternative.” If the product has more than 0.2% THC, the package must also include a dependency warning.
- Unlike countries such as Colombia, Germany or Italy, which all allow magistral preparations in pharmacies, Brazilian rules do not allow any manipulation of these products by pharmacies.
- Sales of approved products must start within one year of authorization, or the approval can be canceled. ANVISA’s good storage and distribution practices certification is required.
- Companies will be required to have the ability to monitor adverse effects on patients in the Brazilian market. Each unit sold will be recorded in a national database that monitors the sale of specially controlled medicines throughout the whole supply chain, regardless of THC content.
- Product labels must include a large warning sign with a black background indicating that the medicine can be sold only under prescription. Companies will not be allowed to cite any therapeutic indication for their products.

Distribution can commence only after ANVISA grants an authorization—one for each product—and that approval is published in the Brazilian federal government’s official gazette. Only pharmacies may sell these products to patients.

Companies unable to comply with the quality requirements to obtain a sanitary authorization might still sell medical cannabis in Brazil as “unregistered products,” a category for which entry barriers are much lower. But unlike products with sanitary authorization, unregistered products cannot be imported in bulk or distributed to Brazilian pharmacies.

FOOD AND COSMETICS

The Brazilian narcotics law allows the cultivation of plants from which drugs can be extracted only for medical and scientific uses, restricting any possibility of cannabis-derived foods or nonmedical cosmetics.

ANVISA is not only the main agency responsible for regulating medicines, but it also plays an important role in the food and cosmetics industries. The agency confirmed in December 2019 with RDC 327/2019 that cannabis-derived food and cosmetics are not considered in the regulations.

POSSIBLE LEGISLATIVE REFORM AHEAD

When we published the 2019 edition of this report, possible changes were focused on the two ANVISA proposals. As detailed above, only one of these was approved, allowing to obtain temporary approval for cannabis products under a special category. The other proposal, which was about regulating cultivation, was rejected.

As of mid-2020, no new big changes are expected from the health agency, but local industry players are enthusiastic about the possibility of legislative change. A bill is in the works that would regulate cultivation, differentiating between high- and low-THC cannabis and assigning responsibility for implementation to the Ministry of Agriculture. If and when this project will be approved is still uncertain.

Chile was once considered a cannabis pioneer in Latin America, in part because it was the first country in the region to authorize the first large-scale, high-THC cannabis cultivation. But business opportunities remain extremely limited because the country lacks a cannabis-specific regulatory framework or a special access scheme for medical marijuana.

In practice, most of the access to medical cannabis is provided through decriminalized home growing or collective growing, a situation that has not changed much from the 2019 edition of this report. If anything, that so-called “gray” market has expanded, with even branded, unapproved products now easily found.

Legal commercial opportunities exist because a 2015 decree modified previous health regulations allowing the use of cannabis in medicines. But opportunities largely require following the traditional pharmaceutical route of drug development.

Cultivation is, in principle, prohibited unless the Agricultural and Livestock Service (SAG) grants a license, which it has done on a few occasions, primarily for research purposes. As of mid-2020, the only valid and operational growing licenses are for cultivating low-THC cannabis, according to local sources consulted by *Marijuana Business Daily*. Growing for personal use is decriminalized under certain circumstances.

The Chilean Sanitary Code allows imports of nonregistered products in exceptional cases. Canadian producer Tilray used this exception to export oils in 2017. The second exceptional approval was granted to Chilean laboratory Knop to commercialize a domestically produced oil manufactured using DayaCann’s crop, one of the few previously authorized cultivations in the country. Neither exceptional authorization was renewed, which means Chileans have no access to legal, commercially available cannabis medicines as of mid-2020.

The only exception is GW Pharmaceuticals’ Sativex, a registered pharmaceutical drug manufactured in the United Kingdom and rarely—if ever—sold in Chile due to its high price tag. In addition, Chile allows the direct importation by patients of nonregistered medicines, what is typically called compassionate use in the region.

MOST RELEVANT GOVERNMENT AUTHORITIES

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

KEY LAWS AND REGULATIONS

- Sanitary Code of 1967, with subsequent modifications
- Law 18,164 of 1982
- Law 20,000 of 2005, with subsequent modifications
- Law 20,500 of 2011 regarding associations and citizen participation—used to justify collective grows for personal use
- Law 20,724 of 2014
- Decree 404 and Decree 405 of 1983, both modified by Decree 84 of 2015
- Decree 867 of 2007
- Decree 3 of 2010, with subsequent modifications

HOW IT WORKS

Decree 84 of 2015 explicitly permitted the use of cannabis in medicines by moving it to Schedule II of the country narcotics lists. Chile does not have a cannabis-specific law. Instead, general health-related regulations apply, so medical marijuana products must follow the traditional pharmaceutical drug development route to be approved and commercialized. The ISP—a decentralized and autonomous agency within the Ministry of Health—is responsible for regulating medicines.

Law 20,000 of 2005 in principle prohibits cannabis cultivation but makes an exception that allows the SAG—an agency within the Ministry of Agriculture—to grant licenses. The licensing system is further regulated by Decree 867 of 2007.

Some of the requirements of the applications 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 regulating cultivation also requires security measures and a series of notifications. For example, growers must submit their license application at least four months before sowing, notify the ISP at least 60 days before harvesting and obtain a transport permit before moving the harvest.

Only a handful of companies have obtained cultivation licenses, all limited in time, including:

- Tilray Latin America (formerly Alef Biotechnology), authorized in 2015.
- DayaCann, a joint venture between Fundación Daya and Australian-based AusCann, authorized in 2017.
- Agrofuturo and Austral Hemp are among the companies that have been authorized to produce low-THC cannabis.

Several applications for growing have been rejected for different reasons, including lack of justification of how the harvest will be sold or missing information on the origin of the seeds.

Unlike other countries in the region that have an established THC threshold—often 1%—to distinguish between psychoactive and nonpsychoactive cannabis, no such rule exists in Chilean law, which means all applications to grow cannabis must comply with similar requirements.

The ISP has rejected attempts to register CBD products as food. Although pure CBD is not a controlled substance in Chile, it is considered a psychotropic compound used in a medicine, which means products that contain it must follow the standard pharmaceutical approval route.

EXCEPTIONS

Article 99 of the Sanitary Code allows the ISP to authorize nonregistered products for commercial use on an exceptional basis, provided certain conditions are fulfilled. These provisional 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 permit to export 600 units of oil in 2017. That authorization wasn't renewed, not all products were sold and the remaining oils were destroyed. Tilray products have not been available in Chile for a long time.

The only other nonregistered commercial product with a comparable authorization was Cannabiol, a 30-milliliter oil with a THC concentration of 20 milligrams per milliliter and CBD at 9 milligrams per milliliter that became available in early 2018. Sales of the products ended a few months after the authorization was issued.

Cannabiol was manufactured by Laboratorios Knop using materials from DayaCann under a provisional authorization from the ISP that allowed the manufacture of 3,600 units. Producers announced that up to 2,500 patients had the option to access the subsidized product for a period of up to one year, provided they were residents of one of 15 municipalities. Nonresidents of those municipalities could still access Cannabiol, but they had to pay for it.

According to local media reports, the 3,600 units were all dispensed by August 2018, and in April 2019, the producers' request for renewal of the permit was denied.

In January 2019, health authorities denied Laboratorios Knop to register its product as a medicine. Had it been successful, the product would not have needed provisional authorizations anymore. Authorities rejected the request because the company could not prove the stability of the raw material and standardization of the product, among other issues, according to the ISP resolution.

ACCESS IN PRACTICE

Without any products other than Sativex approved and available for patients as of mid-2020, most patients in need access cannabis through decriminalized and widespread home growing or through not-for-profit collectives. Police raids on these operations are still common, however.

The judicial system has been generating jurisprudence allowing cultivation for personal use, but commercialization remains illegal and home growers, particularly if growing collectively, are in a murky legal situation.

Individual imports of nonregistered products by patients under a compassionate-use scheme are also possible.

Colombia is the Latin American country that has attracted the most attention and foreign investment for cannabis production, but much of that enthusiasm cooled in 2020.

Leading international cannabis companies such as Canada-based Canopy Growth and Aphria have halted the large capital expenditures made in the past, and largely retreated from the country. Raising capital for Colombian companies with just basic production licenses, land, teams and a plan is much more challenging today than it was one or two years ago.

The country advanced implementation of its cannabis law and companies operating there already executed some exports and started domestic sales. But the product revenue generated by the Colombian cannabis industry by mid-2020—only a few million dollars even by the most optimistic estimates—pales in comparison with the huge promises many industry players made, which included claims that Colombian cannabis export revenue could surpass that of petroleum.

The country has ideal growing conditions and a regional first-mover advantage, with regulations that promote the creation of a value-added industry for domestic and export markets. This means opportunities are real, they are just more limited than previous unrealistic expectations.

In 2019, companies exported the first CBD isolate and CBD extracts, which do not require a production quota. In 2020, the first export of seeds commenced. But meaningful THC exports remain nonexistent.

In the domestic market, sales of magistral preparations started in 2020, and the first finished product with CBD as an active ingredient obtained its registration and became available to patients as well.

The number of companies licensed to produce in Colombia is in the hundreds, but the license is only a first step in a large regulatory path to market that includes, among other things, registering genetics if the company intends to cultivate its own cultivars and obtaining quotas for high-THC production. As of July 2020:

- The government agricultural agency that oversees genetics registration shows 24 companies have finalized that requirement.
- There is no publicly available information about how many companies received commercial quotas to produce high-THC cannabis, but only a handful have reported doing so.

MOST RELEVANT GOVERNMENT AUTHORITIES

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

KEY LAWS AND REGULATIONS

- Law 1,787 of July 2016
- Decree 613 of April 2017
- Decree 631 of April 2018
- Decree 2106 of November 2019
- 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 of 2017 (Ministry of Health)
- Resolution 2892 of August of 2017 (Ministry of Health)
- Resolution 315 of March 2020 (Ministry of Health)
- Resolution 67,516 of May 2020 (ICA)

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. Resolution 315 of the Ministry of Health regulates the final steps in the supply chain for dispensing magistral formulations and Resolution 67,516 of ICA further regulates the registration of cultivars.

LICENSES

Licenses constitute the beginning of a multistep regulatory process that includes securing additional permits and registrations from 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 is not mandatory, but most 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**

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

It has the following three modalities:

- 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.

As of March 5, 171 manufacturing licenses had been granted, according to the Ministry of Health. It is likely that more licenses were issued by INVIMA, the agency that became responsible at the end of 2019 for processing these applications.

► **Cultivation of cannabis plants**

Two types of cultivation licenses are available:

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

A separate license is available for seeds for commercial use or scientific research and granted by the Ministry of Justice.

As of April 30, 656 licenses were granted by the Ministry of Justice: 394 for nonpsychoactive cannabis cultivation, 164 for psychoactive cannabis cultivation and 98 for seeds.

A single entity may have only one manufacturing license granted by the Ministry of Health or INVIMA, but it could have up to three licenses 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. Licenses may be renewed.

The requirements to obtain a license vary, but most require identification of where the proposed activities will take place and who will serve as representatives for the company. In addition, technical documents for cultivation, manufacturing, 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 to make observations. Cultivation applicants should expect at least one inspection visit, during 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 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 government-granted amnesty for genetics registration ended at the end of 2018. In practice, it meant that all pre-existing genetics in the Colombian territory could have started 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 did not start the registration of their genetics before the end of 2018 must now buy their seeds or clones from another licensee with approved cultivars or import them.

To register genetics, applicants must prove to the ICA that the characteristics of the plants they want to register coincide with reality in their agroecological subregion. For that, they must grow samples of these cultivars for research and development according to specific regulations for agronomic evaluation.

Applicants must grow at least 60 plants of each type they intend to register. An ICA technical team will evaluate 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. Only then can the company start using that cultivar for commercial purposes. (Other restrictions might still apply, especially for psychoactive cannabis.)

The following companies had a total of 243 cultivars registered, according to the ICA database, as of July 2020:

	# Psychoactive	# Nonpsychoactive	Total cultivars
1 Agroidea	3	1	4
2 Aprocor	3	0	3
3 Avicanna	21	8	29
4 Blueberries	0	5	5
5 Clever Leaves	19	13	32
6 Colombian Organics	3	6	9
7 Earth's Healing Colombia	0	2	2
8 FCM Global	4	1	5
9 Foliumed	0	10	10
10 Khiron	21	1	22
11 Laboratorio de Biotecnología y Plantuladora Biominaerales Pharma Seeds	3	3	6
12 LaSanta	10	5	15
13 MED Colombia	9	0	9
14 Medcolcanna	0	8	8
15 Medcann	12	2	14
16 NuSierra	1	2	3
17 One World Pharma	0	3	3
18 Pharmacielo	28	2	30
19 Planta Vida	0	9	9
20 PlantMedCo	0	1	1
21 Plena Global	0	7	7
22 Qualcann	0	11	11
23 Roland Yusti	0	2	2
24 Wellness	0	4	4
	137	106	243

The database, available from the ICA website, does not specify when its most recent update occurred, but the file appeared to be last modified in May 2020. The table, where possible, includes the commercial names with which companies operate when different from their legal names in the database.

In 2020, Colombia and Peru reached an agreement to facilitate phytosanitary requirements for the export of cannabis seeds, a sign of regional cooperation between governments that could have benefits for the industry.

QUOTAS

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

Depending on whether the quota is for cultivation or manufacturing, the authority responsible for granting the license 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 manufacturing 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 and, through research, generates technical information about its own extracts to prove THC content and other specifications. In other words, a process to generate characterization of products, quality specifications and stability data—with a quota for research and development—is required before applying for a commercial quota.

Companies typically apply for quotas before the end of April each year, and the quotas are good for only 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 they have quantifiable demand. In principle, there is no maximum quota per company. But the country, signatory of the 1961 Single Convention on Narcotic Drugs is bound to confirm production estimates every year with the International Narcotics Control Board (INCB).

The system is designed so that national authorities do not grant quotas to domestic producers that exceed the country estimate for internal medical and scientific use. For quantities to be exported, the estimate of the country of destination confirmed with the INCB applies.

EXPORTS HIGHLIGHTS

Information about total exports is not publicly available. But we were able to confirm some activity through publicly available company disclosures or communications with company representatives.

- Pharmacielo’s latest financial results show that the company generated almost \$1 million in export revenue as of March 30, 2020. The majority corresponded to an export to Switzerland of a few hundred kilograms of CBD isolate; the rest corresponded to exports of a few hundred kilograms of CBD isolate to the United States.
- Clever Leaves exports, including both for scientific purposes and for commercial medical purposes, were shipped to: Australia, Brazil, Canada, Chile, Germany, Poland, the United Kingdom, the United States and one country in the Middle East. The company has not revealed exactly how much revenue it made from those shipments.
- Avicanna, through its subsidiary Santa Marta Golden Hemp, exported hemp seeds to the United States in June 2020 for a net revenue of almost \$300,000, according to a company news release. The company acknowledged in its financial statement for the period ended March 30, 2020, that it “has not generated significant revenues from its operations and is considered to be in development stage.”
- Other companies, including FCM Global, Natuera and NuSierra, also have made shipments to the United States and other countries.

No meaningful commercial exports of high-THC cannabis have taken place so far, in part because of stringent quality requirements established by potential destinations such as Germany. Commercial quotas granted by Colombian authorities to produce high-THC cannabis is another regulatory milestone that very few companies have achieved so far.

In July 2020, Clever Leaves was “granted European Union Good Manufacturing Practice certification ... for its pharmaceutical post-harvest facility and laboratory located outside Bogotá, Colombia, to produce Active Pharmaceutical Ingredients (API), semi-finished and finished cannabis products for medical purposes,” according to a company news release. This might be a signal that exports of THC products to the European Union could soon start.

DOMESTIC MARKET

The Colombian regulatory framework establishes two ways of selling medical cannabis in the country:

- Magistral preparations (individual formulations prepared for an individual patient in the pharmacies according to a specific prescription).
- Registered products. Unlike magistral preparations that are adapted to individual prescriptions, a registered product is supposed to be prescribed only for the condition for which it has been authorized, and the pharmacist does not manipulate it.

Registered products have an advantage over magistral preparations in principle because they could be covered by health insurance if prescribed for the indications for which they obtained the approval of the Colombian health agency. Companies producing magistral preparations are not required to register the products proving efficacy as is needed for registered products.

In all cases, a medical prescription is needed, regardless of the THC content or concentration. For products with concentrations above 0.2% THC, a special prescription is needed. Only cosmetics infused with hempseed oil or CBD—which many companies are selling—do not require a prescription.

As of July 2020, one company offers magistral preparations and two companies have one registered product each:

- Khiron Life Sciences said in July 2020 that it remains the only company fully authorized to provide both CBD and THC medical cannabis in the Colombian domestic market as magistral preparations. The company reached 1,000 prescriptions on July 27, 10 weeks after it started selling. Khiron operates a network of medical clinics that it owns, including one in Bogotá specialized in cannabis treatments, for which it invested almost \$8 million dollars, according to local news outlets.
- Colombian company Procaps announced at the end of March that it obtained approval to register a medicine with CBD as an active ingredient. The oil is used to treat refractory epilepsy and is comparable to GW Pharmaceuticals' Epidiolex, as it also has a concentration of 100 milligrams of CBD per milliliter. Each 60-milliliter bottle is sold for almost \$50 as of mid-2020.
- GW Pharmaceuticals' Sativex—a medicine with both THC and CBD and manufactured in the United Kingdom—has been approved in Colombia since before the country implemented its cannabis law.

In early 2020, the Ministry of Health announced its latest guidelines for prescriptions of magistral preparations with cannabis. The agency classified all cannabis products with a concentration of more than 0.2% of THC as medicines requiring a prescription for controlled substances. These cannot be prescribed in quantities larger than what is needed for a 30-day treatment.

The health authority also required pharmaceutical establishments intending to formulate cannabis magistral preparations to first obtain a Good Elaboration Practices certification from INVIMA specific to these products. The formulated products can then be sold in pharmacies without any special cannabis certification. Any pharmacy that wants to dispense THC products must have a narcotics permit.

The 0.2% THC threshold defining what is a narcotic also applies for exports, meaning that any export of products with THC above that concentration requires a special authorization from Colombian authorities, who in turn report the quantities exported to the United Nations International Narcotics Control Board.

B2B deals became more common in Colombia throughout 2020, including:

- An agreement between Canadian company Canopy Growth and Clever Leaves under which Clever Leaves supplies Canopy's subsidiary in Latin America with extracted products in Colombia.
- The collaboration agreement between Blueberries and Medcann to jointly develop and produce THC extracts.

COSMETICS

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

Moreover, it is not necessary to use the company's own crop if it is not operationally ready or the company still needs to overcome regulatory hurdles such as genetics registration. Instead, a company can buy from a domestic producer or import CBD and infuse it into locally manufactured cosmetics. Hempseed oil is another product from cannabis plant approved for cosmetics.

Some smaller companies that focus on cosmetics retail are not interested in applying for a license to cultivate their own crops to obtain raw materials. Instead, they buy from other suppliers, with the potential for buying it in the domestic market in the future.

REFORM AHEAD

The government has been mulling a draft decree since mid-2019 that, if approved, could modify certain aspects of Decree 613 of 2017, which is the foundation of the Colombian cannabis framework. The timeline for approval is still as uncertain as it was when we published the 2019 edition of this report.

Today, exporting flower for commercial purposes is not allowed, and moving any product into a free-trade zone—even if geographically within the Colombian territory—is considered an export. As a result, it is 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 those 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—something not currently required. The new decree would also reaffirm the exclusion of CBD from the controlled substances list.

Today, licensees that want to sell their psychoactive cannabis harvest to a buyer not indicated in the original license must first modify the permit, which is a complicated process. The new decree is expected to resolve this issue by allowing licensees to notify the authority of the change.

Some aspects regarding the production quotas also could become easier for companies, for example, by being granted automatic renewals of quotas for mother plants.

Because integrating small and medium cultivators into the new legal industry has been a challenge, tighter ties with licensed producers would be mandated, as would 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 example, nonpsychoactive cannabis licensees would need to start operations within six months and psychoactive cannabis licensees would need to obtain a quota per year.

Because the draft decree is still unapproved and has been in the works for more than a year, all the changes hinted at in this subsection remain uncertain.

**ECUADOR**

Toward the end of 2019, Ecuador amended its Comprehensive Organic Criminal Code (COIP) to remove cannabis with up to 1% THC from the controlled substances category, effectively decriminalizing its cultivation.

Article 127 of the COIP also mandated the Ministry of Agriculture regulate the implementation of this change and gave that authority 120 days to issue the rules. The deadline is October 2020.

According to statements from public officials to local media, a system of licenses likely will be established, requiring applicants to prove the legitimacy of the capital.

Once the rules are published, the country will join its neighbors in allowing the application for licenses and production opportunities, although the permits will pertain only to nonpsychoactive cannabis.

Article 48 decriminalized the possession of pharmaceutical products derived from cannabis if prescribed by a doctor, but medical cannabis is still unregulated and unavailable in the country in most cases.

MOST RELEVANT GOVERNMENT AUTHORITIES

- Ministry of Agriculture and Livestock (MAG)

KEY LAWS AND REGULATIONS

- Comprehensive Organic Criminal Code (COIP)
- Upcoming rules from the MAG are expected by October 2020 at the latest



Mexico legalized the use of THC in medicines in June 2017, but three years later, the country still does not have procedures in place to allow patients' access to the drug.

In that regard, almost nothing changed from the 2019 edition of our Latin American report.

An August 2019 Supreme Court ruling gave the government 180 working days to regulate medical marijuana, and the government has promised to have a draft by September 2020.

Not everyone in the industry has waited for official authorization, however. The sale of unapproved CBD products by companies has become normalized in the country.

And separate from the medical law-related issues, since 2015, several Supreme Court rulings granted consumers the right of access to nonmedical cannabis. Jurisprudence on this issue was created in October 2018 after a fifth case.

The government has promised full cannabis legalization—industrial, medical and recreational—to adjust legislation to match Supreme Court rulings, but this also has been delayed several times. The latest deadline granted by the Supreme Court to the legislative power is Dec. 15, 2020.

With secondary rules for the medical law still pending and full legalization delayed until at least the end of 2020, commercial opportunities are mostly paralyzed.

MOST RELEVANT GOVERNMENT AUTHORITIES

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

* Expected to be created with the upcoming law

KEY LAWS AND REGULATIONS

- General Health Law (reformed in June 2017)
- Latest version of the full-legalization bill as approved in general terms by three Senate commissions—pending full approval by the Parliament and enactment and promulgation by the Executive
- Several Supreme Court rulings
- COFEPRIS Guidelines for Health Control of cannabis and its derivatives (revoked in March 2019)

MEDICAL LAW

In June 2017, Mexico's Parliament approved a decree reforming the General Health Law to authorize cannabis for medical use, including products high in THC.

The decree eliminated the prohibition of using cannabis as medicine by rearranging THC within the Mexican lists (schedules) of psychotropic substances.

THC now exists in two different categories, depending on its concentration:

- THC in concentrations higher than 1% are included in List II, which corresponds to substances that offer some therapeutic value but represent a risk to public health.
- THC in concentrations equal or lower than 1% are included in List IV, which corresponds to substances with broad therapeutic uses with a minor risk for public health.

An implication is that medicines with 1% THC or more would have the strictest controls, including full traceability of the products and a requirement for a special controlled prescription from the physician. But all THC-containing products, regardless of the concentration, would require a prescription.

Current rules do not distinguish between marijuana and industrial hemp with regards to the THC threshold. The 2017 amendment simply rearranged the Mexican drugs schedules, but THC remained a psychotropic substance even in minimum concentration.

MEDICAL REGULATIONS—OR LACK OF

The 2017 amendment that allowed the use of THC in medicines did not create any specific rules or regulations to facilitate a functioning market. Instead, it mandated the Health Secretariat to “harmonize” regulations within 180 days.

COFEPRIS, a decentralized organ of the Health Secretariat, missed that deadline, but it issued “Guidelines for Health Control of Cannabis and its Derivatives” in October 2018—shortly before the previous government left office. The internal guidelines set up a process to allow companies to apply for import permits. In November 2018, right before their time in office ended, COFEPRIS authorities quickly granted 57 permits to several companies, allowing them to import products with up to 1% THC.

But the authorities that came in with the new government revoked the guidelines in March 2019 and started a process to study the validity of the permits. 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. The guidelines were never submitted to the National Commission for Regulatory Improvement as mandated by the General Law on Regulatory Improvement. In addition, the guidelines were never published in the Official Gazette of the Federation as mandated by the Federal Law of Administrative Procedure and the General Law of Regulatory Improvement.

In practice, all permits appear to continue under review at the time this report was published—authorities haven't made any official announcements about the issue since early 2019—and most of the companies that obtained them remain unable to do business.

However, local media reported at the end of 2019 that one of the companies that had been granted permits under the now-revoked guidelines obtained an injunction through the judicial system that ruled its permits were still valid.

The company still faces custom regulations that have not been drafted to create customs tariffs for these types of products, however. This means legally importing CBD products is challenging unless disguised under an inaccurate customs category of products.

In August 2019, the Second Chamber of the Supreme Court concluded 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 the rights of a minor with a rare form of epilepsy were violated by the failure of the federal government to regulate medical cannabis.

The Ministry of Health accepted the court decision and reiterated that COFEPRIS would comply with the 180-working-days deadline to establish a framework.

In July 2020, the Secretariat of Health said it plans to finalize the medical cannabis regulations by September.

The details of the forthcoming regulations remain unknown at this time, but they will address only medical cannabis, which was the subject of the 2017 law.

Also uncertain is how any new medical regulations approved before Sept. 9 would function alongside a new, more comprehensive cannabis law expected by December.

CURRENT ACCESS TO LEGAL, COMMERCIAL MEDICINAL PRODUCTS

The only fully legal access path for medical cannabis products predates the June 2017 General Health Law reform.

Like many other Latin American countries, Mexico has a mechanism that allows imports for personal use of nonregistered medicinal products. Patients must have an authorization from COFEPRIS, and the products must not contain THC.

The number of patients using this mechanism is believed to be extremely limited, particularly because so many CBD products are now easily found in the gray market.

RECREATIONAL MARIJUANA PROHIBITION UNCONSTITUTIONAL

In November 2015, Mexico's Supreme Court ruled that the prohibition of cannabis is unconstitutional—its first ruling on the issue—saying that the ban violates the fundamental right to the free development of a citizen's personality.

Nearly three years later, in October 2018, the Supreme Court ruled for a 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 but explicitly prohibit commercialization.

To harmonize the legislation with the Supreme Court jurisprudence, Congress has been debating how to fully legalize cannabis for all uses.

When such a bill does get passed, as is expected, Mexico would be the third country—and, by far, the largest with roughly 130 million inhabitants—to fully legalize marijuana nationwide, joining Uruguay and Canada.

About a dozen legalization bills have been presented in Parliament, most of which didn't get far. Since the end of 2019, Congress has been debating a single bill, which has faced modifications and delays multiple times.

The current Mexican government has ample parliamentary majorities to get the bill approved without meaningful resistance, but the process has encountered several roadblocks, the latest being related to the COVID-19 pandemic.

The current expected deadline for legalization in Congress is Dec. 15, 2020.

Even if Mexico has a cannabis law in place by December, actual business opportunities—particularly for domestic production—could be years away because subsequent regulations would still be needed.

And it's uncertain how the new law legalizing cannabis in all forms—industrial, medical and recreational—will be compatible with the June 2017 amendment that allowed the use of THC in medicines and that health authorities are expected to regulate by September 2020.

THE OCTOBER 2019 POSTPONEMENT

The Supreme Court originally set an October 2019 deadline for full legalization, but the court granted the Senate an “exceptional and one-time only” extension after legislators failed to reach a consensus as the deadline neared.

Citing unprecedented pressure from companies trying to influence Mexico's cannabis legislation, voting on the bill was delayed. Ricardo Monreal, president of the Senate's Political Coordination Board (Jucopo)—a governing body of the chamber—told local media in October 2019 that the bill would be discussed in “the first weeks of November.” In addition, Monreal said the Jucopo will ensure that lobbying in the Senate remains under control, “shielding” legislators from external influences.

The responsibility of the bill remained within the combined commissions of Justice, Health and Legislative Studies.

The Senate asked the Supreme Court for an extension to deadline, which was granted until April 2020.

THE MOST LIKELY BILL

Senate commissions approved the general terms of a bill in March 2020, but the document still needs to pass the full Senate and the Chamber of Deputies (the lower house) before being signed into law by the president.

The commissions of Justice, Health and Legislative Studies approved the bill with 26 votes in favor, seven against and eight abstentions after a livestreamed, nearly two-hour debate.

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

The bill establishes that the government will create a cannabis regulatory institute, which will be responsible for drafting important rules, including THC limits, regulating commercial opportunities establishing license requirements and issuing licenses.

The bill also proposes legalizing possession of marijuana of up to 28 grams and decriminalizing up to 200 grams, as well as authorizing limited home growing.

Restrictions on foreign investment and vertical and horizontal integration are included with the intention that domestic, disadvantaged communities would have a priority to reap the benefits of legalization.

The proposed bill has seen many modifications thus far. Its latest version would, among other things:

- Restrict foreign investment in a cannabis business licensee to 49%.
- Block vertical integration by allowing a business to possess only one type of license—cultivation, transformation, commercialization or import and export.
- Limit horizontal integration, for example, by restricting the allowable number of retail points of sale or limiting the area that a cultivation license holder would be able to grow.

Vulnerable domestic agrarian communities that have been affected by prohibition could be exempted from some of these restrictions, according to the draft law.

In addition to recreational marijuana, the bill would legalize cannabis for medical uses and industrial hemp, but it's unclear how its medical part would be compatible with the already existing—but-incomplete—June 2017 medical law.

Despite expectations that the legalization bill will be approved with the ample legislative majorities, a recent sign of concern was that Mexican President Andrés Manuel López Obrador said in early 2020 that he supports only medical cannabis use.

The president's opposition to the recreational cannabis part of the law was raised during the commission debate by legislators who voted against the bill.

Another issue raised by opposition legislators was that legalizing personal production would be enough to comply with the Supreme Court ruling and, thus, there is no need create a commercial market.

THE APRIL 2020 POSTPONEMENT

The COVID-19 pandemic was the latest hurdle for the legalization bill, as the Mexican Legislature suspended most activities in March 2020. The Supreme Court accepted a request from a group of Senators to postpone the April 30 deadline.

The bill is expected to be approved during the next legislative ordinary session period, which starts in September.

To comply with the latest deadline given by the Supreme Court, Parliament is expected to approve legislation by Dec. 15, 2020.

If legislators comply with the new deadline, entrepreneurs and investors should keep in mind that a functional, regulated cannabis market in Mexico could still be years away.

If the legislative power fails again to legalize, the Supreme Court has the option to declare a general declaration of unconstitutionality, meaning the court could eliminate the articles of the legislation it considers unconstitutional.

This would effectively allow home-growing but not create a regulated commercial market.



Paraguay's 2017 medical cannabis law was regulated through a decree in 2018, but implementation did not meaningfully start until the end of 2019. As of mid-2020, the industry still remains in the early stages of development.

Twelve licenses to grow medical cannabis were granted in February 2020. Separately, some experimental hemp grows were authorized recently to test imported genetics.

Domestic patients have access only to one CBD oil (sold in two difference sizes) registered in 2018. The product is manufactured with imported raw material and sold under prescription in Paraguayan pharmacies. Patients can import nonregistered cannabis products individually under compassionate-use rules, as in many other countries of the region.

MOST RELEVANT GOVERNMENT AUTHORITIES

- National Health Surveillance (Dirección Nacional de Vigilancia Sanitaria, or DNVS)
- National Service for Plant and Seed Quality and Health (Servicio Nacional de Sanidad y Calidad Vegetal y de Semillas, or SENAVE)
- National anti-drugs agency (Secretaría Nacional Antidrogas, or SENAD)
- Ministry of Agriculture and Livestock (MAG)
- Ministry of Industry and Commerce (MIC)

KEY LAWS AND REGULATIONS

- Law 1,340/1988 (about narcotics)
- Law 6,007/2017 (about cannabis)
- Decree 9,303/2018 (about cannabis)
- Decree 2,725/2019 (about hemp)
- Decree 3,284/2020 (about cannabis)
- Decree 3,356/2020 (about cannabis)
- Resolution 433/2019 of the Health Ministry (cannabis production)
- Resolution 718/2019 of SENAVE (seed imports)
- Resolution 839/2019 of SENAVE (hempseed imports)
- Resolutions 179/2019, 315/2019 and 130/2020 of the MAG (hemp)
- Resolution 1,595/2019 of the MIC (hemp)

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 created a program called PROINCUMEC, which in addition to promoting research, guaranteed access to medical cannabis, free of cost, for those who register with the program. The program, however, still is not functional.

The law delegates most of the regulatory and implementation responsibility on the DNVS while clarifying that the agency could, in coordination with the SENAVE and the SENAD, authorize domestic production under certain circumstances.

The regulatory decree creates several definitions, including separating “psychoactive” from “nonpsychoactive” cannabis. Unlike Uruguay and Colombia, which use 1% THC as the delineation between the two categories, Paraguayan authorities set the limit at 0.5%.

The decree also mandated that DNVS could grant production licenses and assigned the role of security control to SENAD.

Manufacturers must donate 2% of their production to the PROINCUMEC program, but as of mid-2020 there still was no domestic production available.

FIRST LICENSES

In February 2020, Paraguay granted 12 licenses allowing companies to become vertically integrated producers of medical cannabis. The selected companies can import seed, cultivate, manufacture and distribute medical cannabis both domestically and for export.

Paraguay took a novel approach by allowing only pharmaceutical laboratories to apply for licenses. Eighteen applicants were considered in the process.

When the application process originally launched in October 2019, five licenses were up for grabs. But two different government decrees increased the number of licenses to be allowed first to 10 and then to 12. At the end, these organizations receive a license, listed alphabetically:

- Annabelle S.A.
- Comfar S.A.E.C.A.
- Consorcio CannaPar
- Consorcio Fusquim S.A. Improlabs
- Consorcio Green Flower
- Convergencia S.A.
- Dutric S.A.
- Grupo AFA S.A.
- Laboratorio As Farm S.A.
- Pharma Industries S.A.
- Swiss Pharma Group S.A.
- Tavira S.A.

SENAVE Resolution 718 of 2019 established the conditions to import the seeds.

Production must take place under strict security measures and, to keep better control, is allowed only in the Central Department, the smallest and most populated of the nation's 17 geopolitical divisions.

The first products are not expected before 2021.

HEMP

Hemp activity is regulated by Decree 2725 of 2019, which defines industrial hemp or nonpsychoactive cannabis as those varieties with less than 0.5% THC. This is different from other countries of the region, including Colombia, Peru and Uruguay, which set the threshold of nonpsychoactive cannabis at 1% THC.

Decree 2725 mandates that the MAG, in coordination with the SENAD and the MIC, implement the program.

In October 2019, SENAVE Resolution 839 regulated seed importation. The resolution limited each import to 1.5 kilograms per variety and proposed use, listing only fiber and seeds. It also detailed how imported seeds should be registered in the country.

In November 2019, MAG Resolution 315 approved the form to be used to apply for a license to begin an experimental hemp grow. The following month, Resolution 1,595 of the MIC regulated the requirements to apply for a license.

In 2020, experimental hemp grows started in five different regions with seeds imported from Canada, China, Hungary and the United States, among other countries, to evaluate how they would adapt to Paraguayan climate and soil, according to information published on the Senate website.

Authorities stated that the intention is to promote hemp cultivation among small producers, limiting the allowed area to 2 hectares per family, but details about how that will work are scarce.

CURRENT DOMESTIC MARKET

Individual imports for compassionate use were authorized for the first time in mid-2016, albeit with limited use because of the high price of importing individually.

One company, Laboratorios Lasca, imports CBD as an active ingredient to manufacture and distribute CBD oils in Paraguay, after receiving an approval in 2018. These oils are available in Paraguayan pharmacies.

Peru approved a law in November 2017 legalizing cannabis for medicinal and therapeutic uses, and while some progress has been made, implementation of the law remains incomplete. As of mid-2020, some secondary rules needed for production still do not exist and the considerable paperwork and time it takes for companies to comply with existing cannabis and health-related regulations have constrained participation in the market.

But there have been some recent positive developments. In December 2019, the first cannabis product—imported and sold by the country health agency—became available to patients. In addition, during the first seven months of 2020, two companies were able to register three “natural health” products and another business said it obtained all needed authorizations to start commercializing magistral preparations.

However, as of July 2020 the only product available remains the one imported and sold by the government. Individual imports—often called compassionate use—for personal medical use are also possible, but only a few patients likely use this option.

No production license has been issued in Peru yet, so products will need to come from elsewhere for the foreseeable future. The product currently available was imported from the United States and derived from hemp since marijuana remains illegal at the federal level in the U.S. The newly registered products and the extracts for the first magistral preparations will also be imported.

The lack of domestic production creates an opportunity for foreign producers to export to Peru. But with several ministries involved in the regulatory and licensing process and the many health-related legislations that apply to cannabis products, finding local expertise seems to be crucial for expanding the industry.

In the mid- and long-term, Peru’s dependency on imports likely will be reduced, if not eliminated, as regulations that allow domestic production including cultivation come into force. It is just a matter of time until the first production licenses are granted.

MOST RELEVANT GOVERNMENT AUTHORITIES

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

KEY LAWS AND REGULATIONS

- Law 30,681 of November 2017
- Decree DS-005-2019-SA of February 2019
- Several additional regulations related to DS-005-2019-SA
- Several non-cannabis specific health-related regulations

HOW IT WORKS

Law 30,681 of October 2017 is a short and simple document whose objective is to allow access to cannabis for medicinal and therapeutic uses. It explicitly allows production, importation and commercialization of cannabis for medical and scientific purposes, mandating the creation of a series of registries within the Ministry of Health for:

- Patients.
- Importers and retailers.
- Research organizations.
- Producers.

The law also created 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 typically do not grow any plants could end up being the only ones allowed to grow cannabis—or any agricultural company that wants to grow cannabis would need to become a pharmaceutical laboratory first. As of mid-2020, no production license had been granted.

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

The decree defined psychoactive and nonpsychoactive cannabis with the same standard used by many other countries of the region, using 1% THC as the dividing line. It also defined the types of cannabis-derived products allowed.

Product types can be divided between those that do not require a sanitary registry and those for which a registry is needed.

Magistral preparations, formulated by a pharmaceutical chemist in an authorized pharmacy or equivalent according to individual prescriptions are—by definition—heterogeneous, which means these products do not obtain a sanitary registry.

The decree distinguishes among three different types of finished registered products:

- Herbal.
- Pharmaceutical.
- Natural health.

The first two require proven efficacy, safety and quality. Unlike magistral preparations, these already branded and finished products are not manipulated by the pharmacist.

The first registrations of products as well as the needed authorizations for magistral preparations were granted in 2020. Sativex—manufactured by GW Pharmaceuticals in the United Kingdom—was approved as a cannabis-derived pharmaceutical in 2019. In all cases, a special controlled prescription is required unless the products have CBD as the only active ingredient and, thus, can be dispensed with a normal prescription. Only pharmacies or the equivalent are authorized to sell cannabis. Online sales and delivery are not allowed.

Patients can also import products with an exceptional authorization for individual treatment—commonly called compassionate use in the region—but this is not believed to be a popular way of buying because of the bureaucratic and financial difficulties of individual imports.

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.

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.

In February 2019, the agencies were given 60-90 days to issue internal guidelines that would allow the program to effectively start working. However, as of mid-2020, some regulations are still missing.

These rules were published:

- Phytosanitary requirements to import seeds from the United States and Colombia (SENASA).
- Conditions to approve security protocols, a requirement to apply for many of the possible licenses (Dirandro).
- Conditions to approve the agriculture production plan, a requirement for the production license (Ministry of Agriculture).
- Conditions and procedures to obtain an agronomic research license (INIA).
- The patients' registry (Ministry of Health).

To obtain a research, production, import or commercialization license, applicants must submit a security plan that complies with published guidelines. The Dirandro is responsible for approving such plans, which must detail measures to prevent diversion of the plants or products to the illicit market.

The plans must also include a diagnosis of vulnerabilities, the design of risk-control mechanisms and measures for monitoring and evaluation.

Depending on the type of license, approval of the security protocol could be automatic or could require an evaluation that includes on-site inspection. The security protocols for most research and commercialization licenses will be approved automatically. Those for agronomical research licenses or production licenses require evaluation.

DIGEMID opened an online registry of patients, which as of mid-2020 had more than 6,000 names. However, this does not mean that all these patients are accessing medical marijuana. Anyone can register, and there are no requirements other than providing some personal identification details. Being registered is a requirement to access to medical cannabis products but does not guarantee a prescription.

The following rules are not yet published:

- Destroying products remnants after research (Ministry of the Interior).
- Assuring traceability from seed to sale (Ministry of the Interior).
- Canceling or suspending licenses (Ministry of Health and Ministry of the Interior).
- Registering cannabis genetics preexistent in Peru (Ministry of Agriculture).
- Growing hemp (Ministry of Agriculture).

DOMESTIC MARKET

As of July 2020, only one CBD oil product was available to patients in Peru. More are expected to become available soon as several permits were recently granted and the companies are finalizing the last details to start commercializing.

The only product available can be found in one pharmacy in Peru. The pharmacy is owned and operated by DIGEMID and received the first cannabis import license from DIGEMID.

The health agency bought the product through two supply application processes, both times won by Oregon-based Anden Naturals. The product, derived from hemp, has almost 5% CBD and is sold in 10-milliliter bottles for about \$14. Government branding is used for the labels.

More than 300 doctors have already prescribed cannabis according to the country health agency as of mid-2020.

Khiron Life Sciences announced in July 2020 that it received all the needed permits to start exporting full-spectrum CBD extracts from Colombia to Peru and to start selling magistral preparations through its partnership with Peruvian Farmacia Universal. The company anticipates the first sales to begin during the third quarter of 2020.

REGISTERED PRODUCTS

As of Aug. 3, the public database of the Peruvian health authority showed 19 product registrations from seven companies were pending approval.

Three products from two companies have received approval:

- Yellow Oil, registered by the Peruvian subsidiary of Canada-based Canopy Growth.
- Epifractan 2% and Epifractan 5%, both registered by Cannfarm Peru, to be imported from Uruguayan manufacturer Ramm Pharma.

The three products are CBD oils registered under the natural-health category. None were available to patients as of end of July 2020, but sales are expected to start soon.

Sativex also is approved as a cannabis-derived pharmaceutical but is very rarely, if ever, commercialized, according to local sources.

PRODUCTION LICENSES

Only pharmaceutical laboratories authorized by DIGEMID or public entities are allowed to apply for production licenses. As of July 2020, no production licenses had been granted.

To obtain a license for cultivation, an agricultural production plan must be submitted to the Ministry of Agriculture. The plan must detail the production process from sow to harvest and include:

- The procedures that will be implemented at the production site.
- An estimate of the necessary seeds or clones that will be used.
- The genetic material's origin.
- Technical specifications of the inputs that will be used during production.
- Justification for what will happen with the harvests; for instance, where they will be sold, processed or used for research.
- Appointment of a technical person and a detailed list of the staff that will handle the crop. Employees who handle the crop cannot have criminal records related to drugs.
- A detailed agronomic plan covering all agricultural processes, including the number and kilograms of seeds to be used, estimated kilograms of flower to be produced, area to be grown, product descriptions, a description of the field and installations, and more.
- Documentation proving ownership of the land where the crop will be grown or a lease agreement.
- A detailed description of the location, including the names of the owners of neighboring fields.
- A security protocol.

2020 OUTLOOK

The second half of 2020 will certainly be interesting in Peru, as more imported products become available to patients and authorities consider issuing the first licenses for domestic production.



In late 2013, Uruguay became the first country in the world to fully legalize commercial cannabis production in all forms: industrial, medical and recreational. At the time, activists and legislators pushing for legalization were not focused on creating an industry nor filling state coffers with tax revenue. Instead, the conversation was centered on public safety and public health.

Implementation of the law proceeded cautiously, with business opportunities largely limited until a few years ago when investment in the industry started to become more noticeable. Fast forward to mid-2020, when the first meaningful commercial exports of both high- and low-THC cannabis flower were completed successfully, totaling almost \$8 million, and a new government is promising to boost the industry.

Uruguay's domestic population is relatively small at less than 3.5 million, which means most industry players in the country are export-oriented. Uruguay XXI—the government agency responsible for the promotion of exports—is adding fuel to the current enthusiasm, speculating that cannabis could become the country's top agro-industrial export. That optimism is similar to what was seen in Colombia when there were dreams of cannabis exports surpassing petroleum.

Current commercial opportunities in Uruguay can be divided into the three basic sectors: recreational, medical and hemp. Each offers different types of opportunities, though there might be some overlap. Research is also possible.

As of July 2020, each category reported significant increases in the number of licenses issued:

- Nine companies are licensed to grow high-THC cannabis: four for medical use and five for nonmedical adult use.
- More than 40 companies are licensed to cultivate hemp. This license allows firms to grow nonpsychoactive cannabis with less than 1% THC and harvest the flower. It does not allow CBD extraction, which requires a manufacturing license.
- Nine companies have manufacturing licenses. The scope of each of these licenses varies greatly depending on the individual case, but a summary is included below.
- Eighteen organizations have research licenses.

Applications for all types of licenses except recreational can be submitted at any time. The specific application requirements vary depending on the type of license.

Recreational licenses are issued through public tenders, of which there have been only two so far.

The number of licenses might increase rapidly during the second half of 2020 because Uruguay's new government came into power in March 2020 but did not designate the new authorities to grant license approvals until end of July 2020. Several applications might be waiting in the pipeline for approval; it's been five months without any new license being granted.

When it comes to the domestic market, some CBD products are registered as medicines. Patients can also import nonregistered products individually if they get approval from health authorities.

Recreational sales for the first three years of the program totaled about \$5 million.

MOST RELEVANT GOVERNMENT AUTHORITIES

- Institute for the Regulation and Control of Cannabis (Instituto de la Regulación y Control del Cannabis, or 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, or SENACLAFT)
- Ministry of Livestock, Agriculture and Fisheries (Ministerio de Ganadería, Agricultura y Pesca, or MGAP)
- Ministry of Health (Ministerio de Salud Pública, or MSP)
- General Customs Bureau (Dirección Nacional de Aduanas, or DNA)
- Uruguay XXI

KEY LAWS AND REGULATIONS

The foundation of the Uruguayan cannabis framework is Law 19,172, approved in December 2013. It was later regulated with three decrees focused on different cannabis segments: nonmedical use, medical use and hemp.

In recent years, newer decrees modified specific aspects of the three original regulatory decrees or clarified 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)
- Law 19,845 of 2019 (scientific research)
- Law 19,847 of 2019 (medical access)
- Decree 324 of 1999 (nonregistered products imports)
- Decree 120 of 2014 (nonmedical use regulation)
- Decree 372 of 2014 (hemp regulation)
- Decree 46 of 2015 (medical use)
- Decree 250 of 2015 (modifies previous decrees)
- Decree 79 of 2016 (modifies Decree 120 of 2014)
- Decree 128 of 2016 (cannabis and employment)
- Decree 298 of 2017 (CBD)
- Decree 214 of 2020 (psychoactive cannabis exports)
- Decree 215 of 2020 (nonpsychoactive cannabis exports)
- Resolution 19 of 2016 of the DNA (international trade)

ADULT USE

Recreational cannabis consumers can access adult-use products by registering with one of three options: pharmacies, home-growing or nonprofit cannabis clubs. Users can change their method of access, but they cannot be registered for more than one channel at the same time.

Here is a snapshot of the Uruguayan recreational market as of July 28, 2020:

- 41,598 customers of commercially grown marijuana.
- 8,281 home growers.
- 4,964 who are members of 155 cannabis clubs where noncommercial collective growing is allowed.

Any adult Uruguayan or legal resident can register for access to nonmedical cannabis, which is sold only in authorized pharmacies—14 as of the end of July 2020. The customer registry is confidential. No identification is required to make the purchase. Instead, the pharmacist scans the customer's fingerprints, and government software confirms the customer's registration status and available quota. Registered pharmacies act as the only retail points where registered customers can buy up to 10 grams per week of nonmedical cannabis flower.

The limited number of pharmacies are not distributed evenly across Uruguay so, in practice, some regions do not have access. More pharmacies (there are roughly a thousand in Uruguay) could join the program and sell cannabis, but there has been certain reticence from pharmacy owners because of banking issues that could arise through being associated with the cannabis industry. The government also is not actively encouraging more pharmacies to join the retail network of adult-use marijuana because not enough supply is available.

In the past, other types of retail sales were considered, but because supply is currently facing a bottleneck, this idea has not been pursued. Supply shortfalls have prevented existing pharmacies from being able to effectively provide access to the almost 42,000 customers. Recently deliveries have become more reliable, but these inventories generally are too small to have a significant impact on access and typically sell out immediately.

Since the beginning of the recreational program in 2015, only two companies have grown for commercial purposes and distributed to the authorized pharmacies:

- ICC Labs, which was acquired by Canada-based Aurora Cannabis in 2018.
- Simbiosys.

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

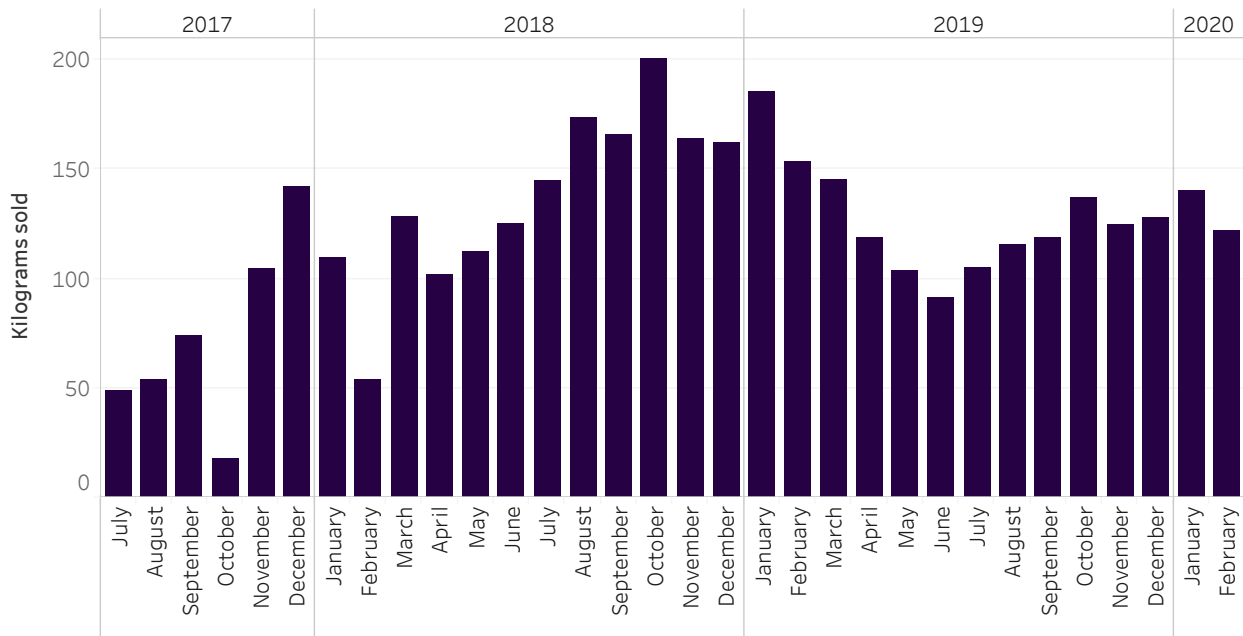
Only flower may be sold commercially in Uruguay as nonmedical marijuana. Wholesale and retail prices are fixed by the government. Producers receive about \$1 per gram, and the retail price in pharmacies is roughly \$1.25 per gram as of July 2020.

The two licensed cultivators grow only two strains, which were originally supplied to the companies by the government. These cultivars are capped at 9% THC and have a minimum CBD content of 3%. Spanish firm Positronics Seeds developed the genetics for the Uruguayan government.

From July 2017 through mid-2020, roughly 4,000 kilograms of flower had been sold in pharmacies to registered customers. That represents more than \$5 million in revenue that did not go to the illicit market. In the past 12 months, 1,125 kilograms of cannabis were sold.

CHART 3: RECREATIONAL MARIJUANA SALES IN URUGUAY

Recreational Marijuana Sales in Uruguay



Source: Uruguayan Institute for the Regulation and Control of Cannabis (IRCCA)
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An average of about 8,000 users purchased marijuana at least once per month at a pharmacy, according to the latest available data. That is roughly 20% of the 41,143 consumers who are registered. Average purchases amounted to roughly 15 grams per month—much less than the 40-gram monthly limit.

The two licensed growers have a production quota of 2,000 kilograms per year, but they have fallen far short of providing that much product. From launch to mid-2020, they sold only about one-third of the 12,000 kilograms possible.

To increase supply, the government launched a call for applications in February 2019 to grow nonmedical marijuana for commercial purposes. Six companies applied, and five of the offers were considered. Because the price of cannabis is fixed by the Uruguayan government, the criteria to select the winners was based purely on technical aspects. Three were approved before the end of 2019 to join the two existing growers:

- Uruguay Biopharmaceutical Research Co.
- Jabelor S.A., also known as Netcann
- Legiral S.A.

The new licensed producers—which still are not operational—will grow in conditions similar to what is required of the existing adult-use cultivators. They will 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 roughly \$1 per gram.

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 does not even include the name or logo of the producing company.

ADULT USE: HOME GROWING AND CANNABIS CLUBS

Commercial sales of recreational cannabis represent only a fraction of the total legal supply of nonmedical marijuana in Uruguay. Most is produced through noncommercial home growing and cannabis clubs.

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 with a minimum of 15 and a maximum of 45 members. They can grow up to 99 plants and deliver up to 480 grams per year to each of their members. Certain registries are required and there are minimum regulations regarding how these associations should grow. Sanctions are possible and have happened in practice when clubs were detected to operate outside of the law.

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

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 is still a long way to go.

In a recent interview with *Marijuana Business Daily*, Diego Olivera, the former head of the country's national drug agency, said that, after years of collecting data post-legalization, "no public-health indicators deteriorated, warning us that we should reverse the path." The former regulator also noted that marijuana-risk perception did not decrease. Consumption rates among high school students remained stable, and rates among adults increased, but at a similar rate to the pre-legalization trend.

MEDICAL SECTOR

The implementation of medical marijuana regulations started after recreational, and legal options for Uruguayan patients remain extremely limited.

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

- Registering medicines to sell in the domestic market.
- Exporting nonregistered products to individual Uruguayan patients, a special access scheme often called “compassionate use” in the region.
- Producing in Uruguay for exporting.

▶ **Registered products**

As of July 2020, Ontario, Canada-based Ramm Pharma, through its Uruguayan subsidiary Medic Plast, is the only company with registered medical cannabis products available in Uruguayan pharmacies.

The Health Ministry medicines database shows two plant-derived, full-spectrum CBD-rich oils with minimal THC registered under the brand Epifractán. The indication is refractory epilepsy. One of the oils has a CBD concentration of 20 milligrams per milliliter; the other offers 50 milligrams per milliliter. The products are sold under prescription.

As of July 2020, suggested retail prices were:

- Epifractán 2%, 10-milliliter bottle, \$20
- Epifractán 2% 30-milliliter bottle, \$65
- Epifractán 5% 10-milliliter bottle, \$50
- Epifractán 5% 30-milliliter bottle, \$130

Medic Plast also registered two over-the-counter cosmetics with the Uruguayan health authority.

The company recently announced approval of a third CBD medicine called Xalex 10, a product with a concentration of 10% CBD from plant-derived isolate.

Patients typically pay for these products, but health insurance might cover the treatment in some cases.

Medic Plast also exports the oils to countries in the region such as Brazil under compassionate-use rules on an individual basis. Recently, Epifractán oils were also registered in Peru as “cannabis-derived natural health product”—a category created by Peruvian regulations that does not require clinical trials to prove efficacy of the products.

A recent report from government agency Uruguay XXI indicated that Medic Plast imports the raw material from Switzerland and finishes the manufacturing process in Uruguay.

▶ **Importing nonregistered products**

Patients can also get a prescription and apply for a permit to import nonregistered medical products from abroad for personal use.

Companies cannot import nonregistered finished products in bulk for distribution. This means individual imports are inaccessible for a large part of the population because of the cost, a common problem with many compassionate-use access schemes in the region.

To import nonregistered products, patients need doctors 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 also need to sign a declaration of acknowledgement that the product has no registry.

▶ **Domestic cultivation for export**

As of July 2020, four companies have a license to grow high-THC cannabis for medical use, two more than one year ago.

Fotmer and Dormul were the two first to get licensed under this category.

Dormul was acquired in 2019 for about \$10 million by Khiron Life Sciences, a company with core operations in Colombia. In September 2019, Khiron announced it had initiated the construction of the facilities in Uruguay. However, in March 2020 Khiron suspended construction of the Uruguayan assets, which were still nonoperational when this report was published.

Earlier this year, *Marijuana Business Daily* reported first that at the end of 2019, Fotmer shipped 1,000 kilograms of high-THC flower to Portugal in exchange for \$3.2 million, according to official customs information.

In June 2020, Fotmer again made another large shipment to Portugal—this time 1.5 metric tons. The identity of the buyer for those two shipments remains unconfirmed. As of mid-2020, Fotmer still does not have a European Union-Good Manufacturing Practice (EU-GMP)-certified facility, so it is possible the flower was exported as raw material for further processing in Europe or for scientific purposes. Because Portuguese patients still have no access to medical marijuana, the products might end up in another market.

Two other companies, Burey S.A.—also known as Grüne Labs—and Algamur S.A. obtained the most recent medical cultivation licenses. The companies appear to be in the development stage.

Most “industrialization” medical licensees, with the exception of Ramm Pharma Uruguayan subsidiary Medic Plast, appear to be in the pre-revenue stage.

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 straightforward, dependent mostly on the Ministry of Agriculture (MGAP) and regulated by Decree 372 of 2014.

SENAFLAFT plays a role making sure the origin of the funds is legitimate. INASE intervenes only after approval by the MGAP to control the origin of the genetics. As of mid-2019, INASE had registered about 60 varieties of nonpsychoactive cannabis.

The MGAP is responsible for authorizing cultivation after evaluating the application, which must include a plan detailing the characteristics of the operation. The license typically authorizes the cultivation process up to the harvest, but it does not permit processing the flower. If, for example, a company wants to extract CBD, an IRCCA industrialization license is needed.

There are currently more than 40 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.

MANUFACTURING

Although it is possible to grow hemp with the license granted by the MGAP, to process the flower, an IRCCA license is needed. Failing to comply with this could carry sanctions. There is at least one example: Inverell, a Uruguayan producer 80% owned by Ontario, Canada-based Auxly Cannabis Group has a license to grow hemp and a research license, neither of which allows the company to extract. The IRCCA found Inverell operating an unauthorized extraction laboratory and sanctioned the company in early 2020.

All manufacturing licenses granted by the IRCCA so far had an initial green light from the MSP. Licenses are granted for a specific period of time but can typically be renewed.

The following companies have IRCCA manufacturing licenses as of July 2020. With limited publicly available information about the scope of the different licenses, we simplified and grouped companies into different categories, but the companies listed below might be authorized for other activities as well.

► **Nonpsychoactive food and cosmetics**

- Di Cianna can infuse yerba mate—a plant used for a popular hot drink in Uruguay—with nonpsychoactive plant material sourced from Uruguayan hemp grower BCBd.
- Dermagroup can import hempseed oil from Hemp Oil Canada to manufacture cosmetics in Uruguay.

► **CBD medicines with imported raw material**

- Ramm Pharma, through its subsidiary Medic Plast, can import CBD extracts and manufacture finished, registered products in Uruguay.
- Laboratorio Homeoaleman can manufacture CBD medicines and cosmetics using CBD isolate imported from Canadian company Isodiol, but the license also allows the company to use plant material from Innovaterra, a Uruguayan hemp grower.
- Caillon & Hamonet can produce CBD medicines using synthetic CBD isolate imported from a facility owned by Canadian firm Canopy Growth in Germany.

► **Nonpsychoactive crude extract with own hemp plant material**

- Innovaterra can process its own hemp plant material.
- Plomfin, a subsidiary of Canada-based Aurora Cannabis, has a license to extract from its own hemp grow. The license also allows the company to import raw material.

► **THC extracts**


- Fotmer, which has a license to grow high-THC cannabis, also has a manufacturing license to process that plant material into extracts for medicinal use.
- Wemblar Corp. has a license to manufacture psychoactive and nonpsychoactive active pharmaceutical ingredients, using plant material from Algamur, a company with a license to grow high-THC cannabis for medical purposes.



APPROVED LICENSES SUMMARY

Uruguay has more than 50 companies licensed to operate in some way in the cannabis industry. Although their stages of development, size and scope of their activities vary widely, the majority are involved in the cultivation of hemp, the extraction of CBD or the manufacture of CBD products.

Most of the manufacturing licenses appear to be in development stage.

We created the following tables using limited publicly available information about the scope of the different licenses. We simplified and grouped companies into different categories we created, but cannot ensure that these companies are authorized only for the activity the title of the category suggests.

MGAP		IRCCA	
			
HEMP (MAX. 1 % THC) <i>More than 40 licenses. The list is not public.</i>	RECREATIONAL ICC (Aurora) Jabelor Legiral Uruguay Biopharmaceutical Research Company Symbiosys	MEDICINAL (THC > 1 %) Algamur Burey (Grüne Labs) Dormul (Cannapur / Khiron) Fotmer Life Sciences	

IRCCA					
 MANUFACTURE				 RESEARCH	
NON-PSYCHOACTIVE FOOD & COSMETICS	CBD MEDICINES WITH IMPORTED RAW MATERIAL	NON-PSYCHOACTIVE CRUDE EXTRACT WITH OWN HEMP PLANT MATERIAL	THC EXTRACTS	COMPANIES	RESEARCH INSTITUTIONS
Dermagroup Di Cianna	Caillon & Hamonet Laboratorio Homeoaleman Medic Plast (Ramm Pharma)	Innovatterra Plomfin (ICC / Aurora)	Fotmer Wemblar Corp.	Burey (Grüne Labs) Dormul (Khiron), x2 Germinaruy Innovatterra Inverell (Auxly) Recowen	Facultad de Ciencias (UDELAR) Facultad de Química Facultad de Química y Medicina Facultad Medicina Facultad Odontología Fundaquim IIBCE, x2 Proy. Facultad Agronomía Proy. Facultad Veterinaria UCU- Universidad Ghent de Bélgica

EXPORTS

As of Aug. 4, 2020, Uruguay had generated nearly \$8 million dollars in flower export revenue, which positions the country as the regional leader. This figure does not include exports of products to countries in the region for compassionate use.

Almost all the flower export revenue corresponds to high-THC shipments, with only 6% related to hemp. The higher revenue for THC exports is explained by a much higher average price per gram. THC flower exports cost about \$2.50 per gram on average, while hemp flower was exported for an average of roughly 16 cents per gram.

Our analysis below is based on official customs information. We considered only flower shipments of 10 kilograms or larger that appear to have been for commercial purposes.

URUGUAYAN NONPSYCHOACTIVE FLOWER EXPORTS THROUGH AUG. 4, 2020

Date	Exporter	Country of destination	Kilograms	Average USD per gram
17-Jul-20	Cplant	Switzerland	442	0.18
22-Jul-20	Cplant	Switzerland	82	0.24
29-Jul-20	Cannabis Uruguay	Switzerland	50	0.44
4-Aug-20	Cplant	Switzerland	2,260	0.15
Total			2,834	0.16

URUGUAYAN PSYCHOACTIVE FLOWER EXPORTS THROUGH AUG. 4, 2020

Date	Exporter	Country of destination	Kilograms	Average USD per gram
3-Sep-19	Fotmer	Australia	10	5.00
23-Oct-19	Fotmer	Portugal	1,000	3.20
13-Apr-20	Fotmer	Israel	500	2.15
19-May-20	Fotmer	Portugal	1,421	2.05
Total			2,930	2.47

The Ministry of Health is responsible for all exports of medical cannabis. In other words, hemp growers licensed only by the Ministry of Agriculture (MGAP) cannot export the flower as medical cannabis without also obtaining Health Ministry authorizations. This is part of the reason hemp exports from Uruguay were virtually nonexistent until mid-2020.

In July 2020, Uruguayan hemp growers were authorized by the MGAP to export flower to Switzerland because the European country allows the importation of flower with less than 1% THC to be used for nonmedical purposes, such as tobacco substitution.

To comply with the 1961 Single Convention on Narcotic Drugs, the Uruguayan Ministry of Health requires an import certificate from the country of destination before authorizing any export. But the MSP also requires that the goods to be exported be registered as a medicinal product, a complex process that in practice limits activity and makes exports of raw materials virtually impossible.

On Aug. 6, 2020, the Uruguayan government approved two decrees to facilitate exports. These allow the exportation plant material harvested between 2018 and 2020 for medicinal purposes without first registering it as medicine with the MSP.

REFORM AHEAD

Two laws were approved in 2019 that are still awaiting secondary rules before they can be implemented. One law intends to increase access to medical cannabis by allowing new types of products. The other law aims to promote research, for example, by exempting laboratory equipment for cannabis research from import taxes.

Uruguay's new government came into power in March 2020, but it did not designate new cannabis agency authorities until the end of July 2020. This delay in appointments likely hindered application reviews and other developments.

Two issues are commonly cited by local entrepreneurs as demotivating: excessive bureaucracy and reluctance of local banks to work with cannabis companies. While the banking issue is unlikely to be resolved before the United States takes action in this area, it is encouraging that in recent weeks, before this report was published, the new government promised to support this industry and get rid of unnecessary bureaucratic roadblocks.

Several Caribbean nations have passed medical marijuana laws providing the legal foundation for businesses. Importantly, those places are also enacting detailed regulations to establish the boundaries in which those businesses must play—the crucial missing component for many nascent medical markets around the world.

But the industry is developing slowly, and that has to be baked into any business plan. Businesses likely will fail if their success is predicated on the quick development of medical marijuana markets (at least in the immediate months and years). This is especially true in the Caribbean, where countries such as Bermuda and Jamaica likely will have robust local markets someday—but not until 2022 or later.

For example, in the 2019 edition of this report, we noted that legal barriers for cannabis businesses were falling in the Caribbean. But it takes longer to create regulatory regimes than it does to smash down the initial legal barriers.

The COVID-19 pandemic has not helped, as countries and bureaucracies prioritized pandemic responses over other legislative priorities.

Some countries have cited the pandemic as a reason to legalize cannabis and boost economies, but in practice, little progress on that front has been made.

Some recent developments:

- The British Virgin Islands passed the Cannabis Licensing Act in July 2020, putting the nation on track to establish a medical industry. It also approved a companion bill (Drug Prevention of Misuse Amendment Act, 2020) that expunged the records of some people convicted for small amounts of marijuana.
- Dominica is “forging ahead” with plans to decriminalize marijuana and establish a local industry via the country’s Drugs (Prevention of Misuse) (Amendment) Bill 2020, which is expected to be brought to Parliament this fall, according to Prime Minister Roosevelt Skerrit.
- In Saint Vincent and the Grenadines, some medical cannabis businesses experienced delays because of the pandemic. But in July, the nation’s regulatory body said the industry remains “resilient” and that several of those operations “are expected to launch in the upcoming months.” Vincentians received their first licenses in 2019.
- Saint Lucia established a Cannabis Commission to engage the public on cannabis reform, which might end up being a recreational proposal.

As in the 2019 report, we are highlighting a few of the countries that have laws and regulations on the books for legal cannabis businesses to grow (slowly): Bermuda, Jamaica and Antigua and Barbuda.



Antigua and Barbuda remains one of the more promising cannabis markets in the Caribbean because of the strong legal and regulatory groundwork completed in 2019.

The country's Cannabis Regulations were finalized in the first half of 2019.

Since then, the Medicinal Cannabis Authority Board commenced operations—kind of.

Disclosure by relevant authorities remains a major obstacle for this potential market, as the board has disclosed very little to the public. There seems to be no proactive disclosure on who is licensed to do what, for example. The board itself does not seem to have a website, nor does it appear to have issued any official notices since its formation in March 2019.

So while Antigua and Barbuda gets full marks for completing a law and functional regulations in a relatively short period of time, it is unclear what has been accomplished since then, and investors ought to exercise extreme caution.

Nonetheless, Prime Minister and Minister of Finance Gaston Browne remains committed to establishing this industry.

In his 2020 Budget Statement earlier this year, Browne said the government “will now focus on encouraging entry into the midstream market of the industry, which involves manufacturing of products such as creams, tinctures, aromatherapy oils and confectionary made from cannabis.”

Browne said his government will “make amendments to the laws regulating the cultivation and use of hemp and its byproducts in Antigua and Barbuda.”

If the country's industry stands any chance of being successful, a significant improvement is needed by all pertinent government and regulatory authorities on information disclosure.

MOST RELEVANT GOVERNMENT AUTHORITIES

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

KEY LAWS AND REGULATIONS

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



BERMUDA

Bermuda is among a small group of countries where the establishment of a regulated industry for recreational marijuana is under active consideration.

The country is essentially attempting to skip medical-only—the path taken by most countries moving into the legal cannabis arena—and go straight to recreational/medical.

A refined draft bill laying the legal groundwork for a regulated adult-use cannabis regime in Bermuda will soon be presented to the island's Legislature.

The proposal is a major pivot from the government's previous plan, announced in late 2019, to establish a medical industry. That plan was scrapped after it was concluded it "did not go far enough to meet public expectation," the attorney-general said.

Under the latest proposal, licensed retail shops would be allowed to sell cannabis to patrons to carry out or for on-site consumption, according to the consultation document.

Products that might be allowed include dried cannabis, oil, edibles, extracts and topicals.

Bermuda said it also intends to expunge criminal records for people with convictions for less than 7 grams of cannabis.

The government said it is committed to opening up economic opportunities related to cannabis for underserved and marginalized communities. It plans to formalize a program so some of the licenses specifically benefit disadvantaged groups.

The draft bill proposes to create licenses including:

- Cultivation by commercial growers.
- Cannabis retail shops.
- Manufacturing.
- Research.
- Import and export.

MOST RELEVANT GOVERNMENT AUTHORITIES

- Cannabis Advisory Authority
- Ministry of Legal Affairs

KEY LAWS AND REGULATIONS

- The Cannabis (Licensing and Regulation) Act 2020



Perhaps no other country in the Caribbean can match Jamaica's potential, both domestically and internationally, when it comes to legal cannabis.

Jamaica has an existing consumer base to sustain a local industry, something lacking on most Caribbean islands, and its cannabis is already "branded" in much of the world.

Local and international entrepreneurs have been pouring money into the country's cannabis industry for the past several years, but it is yet to take off.

The reason is banking.

Hyacinth Lightbourne, chair of the Cannabis Licensing Authority, said banking remains one of the biggest obstacles facing Jamaica's cannabis businesses. In late 2019, she said: "The CLA couldn't get a bank account for nearly a year, and we are a regulator."

Retail sales are not released by the regulator or government, so even approximate sales data is not available.

From May 2019 to May 2020, roughly \$1.25 million worth of cannabis was traded among licensees.

Exporting has also been a major issue in Jamaica, though perhaps not as big a problem as some would suggest.

Jamaica's agriculture minister dismissed claims that long-delayed regulations for medical cannabis exports was causing international companies to exit the country. The regulator also published interim import/export measures to its website this spring, though the agency said the measures have been in place for more than a year. No logical explanation was provided for why they were not released to the public earlier.

Those regulations have been used to facilitate 15 export authorizations, but they all appear to be for scientific or testing purposes. We don't believe any commercial exports have happened yet.

Licensing is happening slowly—likely a symptom of the banking problems.

In October 2019, there were 22 licensed cultivators, 14 retailers and six processors. Nine months later, the country added five cultivators, 11 retailers and five processors.

Despite the hurdles, Jamaica has one major advantage: A government that is actively supportive of the industry and business. After the banking problem is resolved, the Jamaican industry should take off, but that's not expected to happen until the United States ends its national prohibition.

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