



Latin American

Cannabis Regulatory Framework



March 2023

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Objective

This report aims to present and express both the regulatory framework of the production process of cannabis in several countries of Latin America and the situation of public policies that enhance the current market in those countries.

The main scope of this document is to inform about the current regulations regarding the consumption, possession, production and distribution of cannabis and its derivatives, both for medicinal and recreational use, in order to analyze the possibility of opening the market for this product in Latin America. **The information was prepared by the member firms and collaborating firms of Andersen Global in Latin America.**



Argentina

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Regulatory Framework

Scientific Research – Medicinal and Recreational Use

Currently, the growth, production, and trading of cannabis for medicinal use, as well as its possession and consumption, are subject to several regulations in Argentina. In this regard, we note:

Medicinal Purposes

Medical and scientific research on the medicinal and therapeutic use of cannabis for palliative treatment of pain is regulated by Law 27.350 (March 2017). Its purpose is to support and control the use of cannabis and its derivatives, therefore guaranteeing the integral care of health. Certain government organisms control the process of enrolling and auditing the production, industrialization and trading of these medicinal goods:

- National Scientific and Technical Research Council (CONICET)
- National Institute of Agricultural Technology (INTA)
- National Administration of Drugs, Foods and Medical Devices (ANMAT)
- National Agency of Public Laboratories (ANLAP)
- National Institute of Seeds (INASE)

Recreational Purposes

As regards to the personal consumption of cannabis for recreational purposes, there is no regulation that authorizes its possession. The Narcotic Drugs Act (Law 27.737) sets a distinction between different penalties:

- Simple Possession: This ranges from one to six years of prison
- Personal Consumption: This ranges from one month to two years of prison. In the latter case, there exists the possibility of deviating the judicial process towards a curative (in case of *dependent consumers*) or educational (in case of *beginner consumers* or *proficient consumers*) *security measure*. Similarly, this current law suppresses the sowing, growth and trading of cannabis plants and seeds to produce or manufacture narcotic substances, as well as the trading of elements used for those purposes.

Production

Medicinal Purposes

CONICET, INTA and INASE are the organisms that take part both in authorizing the sowing, growth, harvest, reconditioning and stockpiling of cannabis plants and in the production of cannabis seeds, flowers, slips and sprouts. These institutions are empowered to guarantee the necessary provision of cannabis either for scientific research or for medical use.

Recreational Purposes

In private spheres, patients who are medically prescribed to use cannabis and its derivatives are permitted to grow it for their own use. Licenses to access controlled cannabis growth - on one's own or on behalf of third parties - can be requested at the National Ministry of Public Health through the Registry for the Cannabis Program (REPROCANN).

Industrialization and Trading

Medicinal Purposes

ANMAT is the organism appointed to issue authorized licenses to laboratories in charge of the research and/or the production of medicinal cannabis in the national sphere. Besides, it is this organism which has to authorize the new products made from this plant, either produced locally or imported from abroad for human consumption.

According to data obtained from ANMAT in regards to industrialization and trading, the national laboratories licensed to make certain medicinal products (cannabis oil, anti-inflammatory creams, beauty products, among others) are scarce.

Recreational Purposes

Trading cannabis and its derivatives for recreational use is forbidden. Condemnation for doing so means four to 15 years in prison.

Conclusions

- Argentina has a limited market looking for new projections and a steady growth in time. The national government is focused on promoting and promising the development of quality products, as it aims to legalize all the production and trading links, as well as cannabis derivatives. Legislation is still restrictive on the industry of medicinal cannabis and prohibitive on its recreational use.
- Despite this and regardless of limitations, state organisms are supporting the sector. They are trying to enhance it in order to create diversification alternatives in some regional economies. To date, there are not promotion regimes or tax benefits for this particular industry, but for this sector to be enhanced, it will be convenient to pass investment-attractive laws that guarantee stability and a profitable encouraging market. ■



Bolivia

Indacochea & Asociados

Collaborating Firm of Andersen Global

Regulatory Framework

Consumption

For Medicinal Purposes

In Bolivia, the use of cannabis and its derivatives for medicinal purposes is allowed through an authorization issued by the State Agency of Medicines and Health Technologies (AGEMED).

Currently medicines containing cannabis or its derivatives are not legally marketed.

In September 2020, the case of a 5-year-old girl with spastic cerebral palsy became known. After much media and legal pressure, she finally obtained authorization to import and consume medicines containing cannabis oil in November 2021. As expected, the benefits were immediate.

For Recreational Purposes

Article 49 of Law 1008 prohibits the possession and consumption of controlled substances without authorization from the Ministry of Health.

The consumer found consuming or carrying these controlled substances in the amounts for personal consumption, will be interned in a public or private drug addiction institute for the consumer to receive the appropriate treatment until there is conviction of his rehabilitation.

If the carried amount is higher than the amount for personal consumption, the consumer will be sanctioned according to article 48 of said Law, with imprisonment from 10 to 25 years, depending on the aggravating

or extenuating circumstances of each case in particular.

Commercialization

For Recreational Purposes

It is forbidden to sell cannabis or its derivatives with recreational purposes. In case of being found administering for free or selling controlled substances (including cannabis) in higher amounts than those considered as for personal consumption, the administrator or marketer of these will be sanctioned with 10 to 15 years of imprisonment and fines.

The minimum amount for immediate personal consumption will be determined following the opinion of two specialists from a public drug addiction institute. For example, there was a case where an individual was found with 44 grams of marijuana in his possession and was jailed.

In case of carrying a higher amount of the minimum stipulated according to the professional opinion, it would be classified as trafficking of controlled substances, with 10 to 15 years of imprisonment and fines.

For Medical Purposes

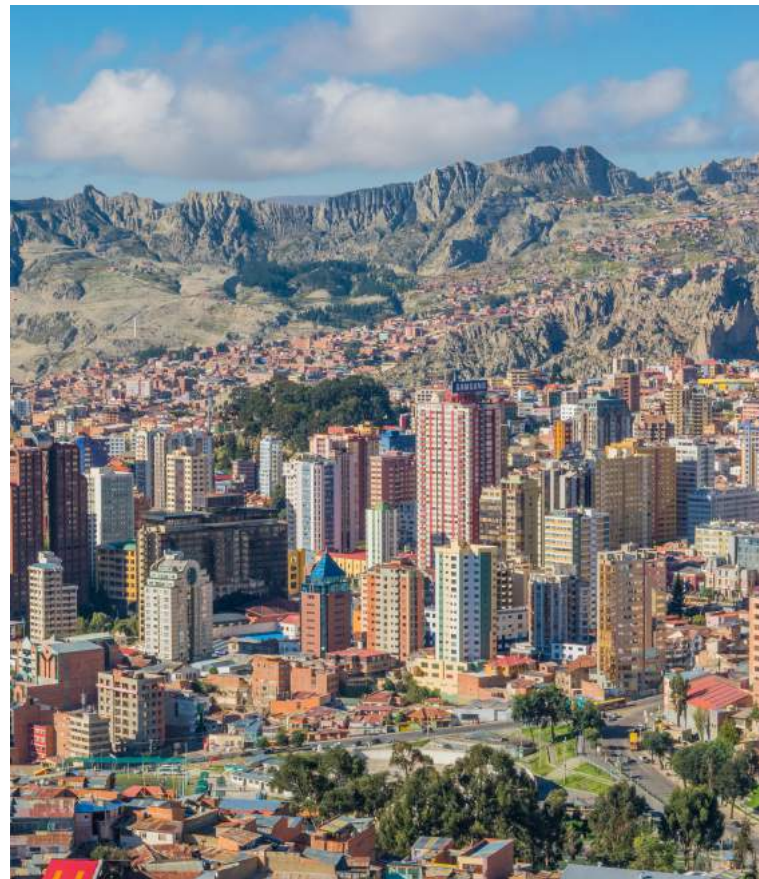
The law allows the importation, commercialization or production of this substance for medicinal purposes, subject to authorization from the corresponding authority, in this case the Ministry of Health. Nevertheless, this authorization has been granted only once and the procedure took more than one year.

Production and Cultivation For Medical Purposes

The production is allowed, as long as it has the corresponding authorization, which must be granted by the competent authority (it can be the Ministry of Government, Ministry of Health or the State Agency of Medicines and Health Technologies – AGEMED, depending on the destination of the production or cultivation).

Conclusions

- In terms of cannabis-derived products, there is no open possibility of generating a market of local consumers for recreational purposes. However, for the consumption of medical cannabis, there is a possibility for personal consumption and importation, for special cases and with prior authorization from the competent health authorities.
- This authorization has only been granted once and after almost a year of wait. It is necessary to regulate the procedure so that the institutions can be more efficient in processing these authorizations and, thus, open a market and industrialize this product for medicinal purposes.
- In regard to the commercialization for medicinal purposes, currently, there are no products containing cannabis in the country's pharmacies because there is no volume of authorized patients to justify the importation of this type of drug. Any person wishing to acquire these drugs must obtain the authorization described and import by themselves said products.
- It is for these reasons that we conclude that the investment and industrialization of this product or its derivatives - under the current legal framework in Bolivia - would not be profitable until regulations are enacted to give slack to this market.



Brazil

Albieri e Associados
Collaborating Firm of Andersen Global

Regulatory Framework

Consumption

For Medical Purposes

In Brazil, the consumption of cannabis and its derivatives for medical purposes is allowed only in situations authorized by the National Health Surveillance Agency (ANVISA), according to the sole paragraph of Article 2 of Law 11.343/2006.

ANVISA authorization can be individual, that is, meeting a specific request from the interested party or collective, when by issuing an administrative resolution, it releases the consumption of a certain product throughout the Brazilian territory. Such is the case of the recent resolution 4.673 of December 2021 that authorized the consumption of the product *ALAFIAMED 200 MG/ML CANNABIS SATIVA EXTRACT*.

Even if authorized by ANVISA, it is necessary for the consumer to have a prescription.

For Recreational Purposes

Law 11.343/2006, in its articles 2 and 28, prohibits the possession and consumption of substances from which drugs can be extracted or produced without authorization from the Ministry of Health, among which cannabis is included.

The individual who is found consuming or carrying these substances in amounts for personal consumption will be warned by the police authority, provide community services and attend an educational program or course.

If the amount in possession exceeds personal

consumption, it will be considered drug trading/dealing and sanctioned in accordance with the terms of article 33 of the same Law, with imprisonment five to 15 and a fine, depending on the aggravating or mitigating circumstances of the particular case.

Commercialization

For Medical Purposes

In Brazil, the import, commercialization and production (with import of raw material – cannabis) of this substance for medical purposes will only be possible with prior authorization from the corresponding authority (ANVISA).

Since it is a product that has already been widely cleared by administrative resolution of ANVISA, it can be marketed by Brazilian pharmacies that must have a specific authorization to do so.

For Recreational Purposes

The commercialization of cannabis or its derivatives for recreational purposes is prohibited. In the event that an individual is found in possession of controlled substances (including cannabis) in quantities greater than those considered for personal consumption, the authorities will consider this to be commercialization (drug dealing) and the administrator or dealer of these will be punished with five to 15 imprisonment and a fine.

The Brazilian law, despite providing different penalties, does not establish the maximum amount that the individual must carry for personal use, therefore, it will be up to the police and judicial authority to analyze the specific case and define the proper classification.

For example, there are situations in Brazil of individuals who were intercepted and later punished with imprisonment for possessing about 30 grams of marijuana, but had cash in their pockets that was not accounted for, which supposedly could suggest that drug dealing had occurred.

Production and Cultivation

The production of products derived from marijuana is allowed for medical use as long as it's authorized by ANVISA. However, the plant or substance must be imported by the manufacturer, or cultivation is not allowed. It is possible to request judicial authorization for the cultivation and commercialization of cannabis for medical use. For example, Associação Assistencial ABRACE obtained authorization from the Brazilian courts to cultivate, produce and commercialize medical products based on cannabis and authorized by ANVISA.

Conclusions

- Regarding cannabis products, commercialization and recreational consumption are not allowed. However, it is possible to manufacture (by importing the raw cannabis material) and sell for individual consumption for medical purposes in situations previously authorized by the competent health authorities and upon presentation of a medical prescription.
 - The Brazilian health authority (ANVISA) through resolution RDC 327/2019 regulated the manufacture, importation, commercialization and inspection of industrialized products containing cannabis derivatives as an active ingredient, providing objective control criteria to prevent recreational use.
- It is important to mention that the topic is regularly debated in Brazil, and there are bills in Brazilian legislative houses aimed at legalizing the cultivation of cannabis for medical purposes and a lawsuit with general repercussion before the Supreme Court aiming to extinguish the penalty for possession of cannabis for personal use.
 - For these reasons and despite recent developments, we conclude that the investment and industrialization of this product or its derivatives – under the existing legal framework in Brazil – requires a careful technical analysis of its feasibility, until legal provisions are enacted to broadly regulate the market. ■

Chile

SPASA Consultores
Collaborating Firm of Andersen Global

CHIRGWIN
Collaborating Firm of Andersen Global

CHILE

Regulatory Framework

Consumption

In Chile, there is no regulation for cannabis consumption and therefore the production, distribution and sale are still illegal. Nevertheless, the personal use has been decriminalized.

Laws

In December 2015, the President of the republic, authorized the sales for medicinal use of the cannabis if it was prescribed by a medical doctor through Supreme decret n°84.

In July 2015, the lower chamber of the senate, approved a law project that aims to legalize the self-cultivation of cannabis and the decriminalization for commercial medical use.

The fourth article of Law 20.000, issued in February 2005, defines the traffic of drugs and psychotropics as illegal, but does not prohibit the personal and private use of cannabis. ■



Colombia

Jimenez Higuera Rodriguez & Asociados
Member Firm of Andersen Global

Regulatory Framework Consumption

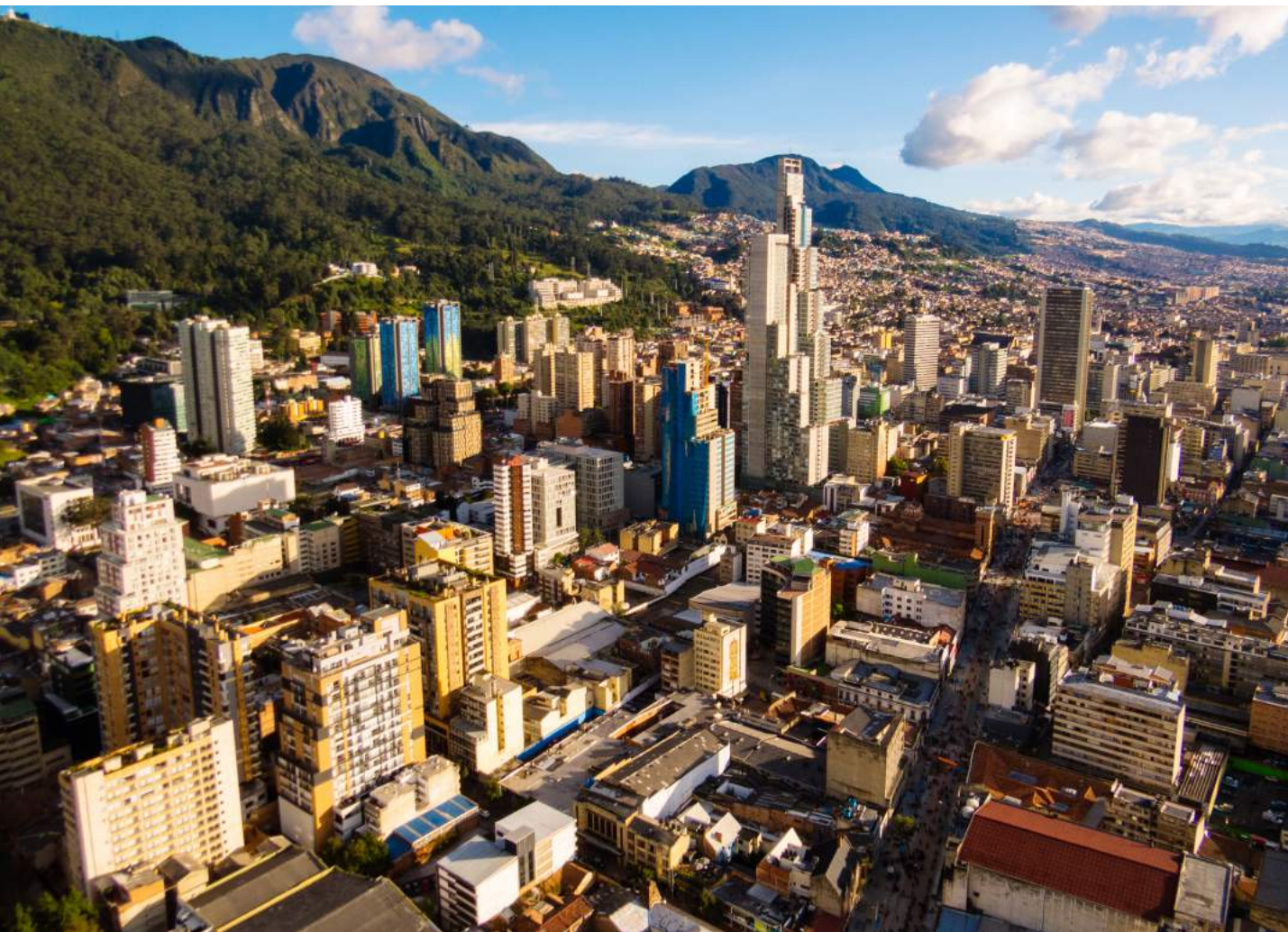
In Colombia, the Constitution establishes that the possession and consumption of narcotic or psychotropic substances is forbidden, unless prescribed by a doctor.

However, both the law and the Courts have recognized the freedom of consumption for recreational purposes of a minimum personal dose, currently set at 20 grams of marijuana. The possession or consumption of a higher

amount is criminally penalized. In any case, the possession of the personal dose with purposes other than self-consumption, is penalized with the seizure and destruction of the good.

Production and Commercialization

In Colombia, the activities of cultivation, production, manufacture, acquisition under any title, importation, exportation, storage, transport, and distribution of cannabis solely for medical and scientific purposes are controlled



and regulated by the State, which authorizes individuals or entities to exercise them. The execution of any of the aforementioned activities carried out without authorization or for other purposes is penalized.

In Colombia, mainly the following licenses can be requested:

- **Manufacture of Cannabis Derivatives:** Granted for the transformation of psychoactive and non-psychoactive cannabis into psychoactive and non-psychoactive derivatives, in the modalities of national use, research and/or export.
- **Seeds for Planting and Grain:** Granted for the handling of seeds for sowing and grain, in the modalities of commercialization or delivery, research and/or transformation of grain.
- **Cultivation of Psychoactive or Non-Psychoactive Cannabis Plants:** For the cultivation of psychoactive or non-psychoactive cannabis plants, in the modalities of production of seeds for sowing, production and transformation of grain, manufacture of derivatives, industrial purposes, research and/or export.

Recently, the mechanisms and procedures for obtaining the necessary licenses for the use of seeds for planting, plant component, grain and non-psychoactive derivatives of cannabis for industrial, horticultural and food purposes were regulated.

Commercialization

In Colombia, the commercialization of cannabis or products derived from cannabis is authorized only for medical or scientific purposes, prior license was granted by the competent authority. For its part, commercialization without authorization is penalized by

the Colombian Criminal Code with a prison sentence of 128 to 360 months and an economic penalty.

Industry Perspectives

At the end of 2020, Colombia was consolidated as the second country in Latin America in medical cannabis exports (after Uruguay), reporting accumulated income of almost 10 million USD. By 2021, the sector had 674 valid licenses for medicinal production for national use, export and scientific research. The quota breakdown includes 116 tons (36 tons more compared to 2020) for both export (87%), research (9%) and national use (4%).

The National Government and the private sector focus their efforts on the diversification in the production and supply of new products, the technification in the country to supply the international demand and the development of policies that, from a controlled framework, allow the free commercial development of the sector in Colombia. ■

Costa Rica

Central Law

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Regulatory Framework

Consumption

For Medical and Therapeutical Purposes

In Costa Rica, the use of cannabis and its derivatives is only authorized for medical and therapeutical purposes. Such authorization will be granted by the Executive Branch and issued by the Ministry of Agriculture and Farming, the Ministry of Public Security and the Ministry of Health.

Currently medicines containing cannabis or its derivatives are not legally marketed

For Recreational Purposes

Currently the Costa Rican legislation does not authorize the recreational usage of cannabis and its derivatives.

Production and Cultivation

The production is allowed, as long as it has the corresponding authorization and license for production and cultivation. Such permits will be granted by the Ministry of Agriculture and Farming.

The final product will only be sold to the Costa Rican Welfare System and/or the laboratories or establishments dully authorized.

Conclusions

- Nonetheless, self-consumption and self-cultivation is prohibited.
- Only individuals or companies that fulfill all the necessary requirements, may request a license and authorization to plant, cultivate, harvest, store, transport and distribute any cannabis derived product.
- Regarding all of the above-mentioned, we conclude that the investment and industrialization of this product and its derivatives, pursuant to the current legislation, will have a restrict offer and demand, and may not result as profitable. It will depend on the administrative process of requesting and granting the necessary licenses by the competent offices. ■
- Currently the recreational use of cannabis is prohibited in Costa Rica.
- Cannabis is only authorized for medical and therapeutical usage, and only individuals with medical conditions dully recognized, can request cannabis as a medical product.

El Salvador

Central Law

Collaborating Firm of Andersen Global

Regulatory Framework

Consumption

For Recreational Purposes

In principle, the possession and recreational use of cannabis is prohibited in El Salvador.

The possession of up to two grams of cannabis is punishable by one to three years imprisonment, but it can apply alternative measures to prison. The possession of more than two grams could be punishable with six years of prison.

For Medical Purposes

The consumption of cannabis is not permitted, but cannabis-derived products for medicinal purposes is allowed as long as it is prescribed by means of a special prescription and under control of National Directorate of Drugs.

Commercialization

In the case of pharmaceutical products, it is necessary to have a sanitary registration that must be processed before the National Directorate of Drugs. It is important to point out that the DNM has a list of pharmacological data sheets of approved active ingredients, among which none of the active ingredients of cannabis are found.

On the other hand, in the case of cosmetic products, the sanitary registration must be made before the National Directorate of Drugs, however, it is necessary to make a previous integral evaluation before the DNM.

In addition to the sanitary registration, both types of products must have the necessary

permits to carry out the manufacturing and commercialization process, which are also granted by the DNM. Among the permits granted by DNM are those for the manufacturing of pharmaceutical products, in the category of psychotropic and narcotic drugs, and for the importation of psychotropic and narcotic substances.

Cultivation

In principle, the cultivation of cannabis is prohibited, even criminalized in El Salvador. However, an authorization may be granted to the chemical or pharmaceutical industry, and biological science research laboratories.

Conclusions

- The use of cannabis in El Salvador for recreational purposes is prohibited and it is not possible to generate a market in that area. Regarding the use of cannabis-derived products for medicinal purposes, there is the possibility of its consumption, as well as its production and importation, as long as it has the respective authorizations.
- Although there are mechanisms to obtain authorizations for the production, commercialization and importation of products derived from cannabis for medicinal purposes, the truth is that such authorizations are at the discretion of the health authorities, and so far, we are not aware of any case in which such authorizations have been granted. ■

Honduras

Central Law

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Regulatory Framework

Consumption

For Medicinal Purposes

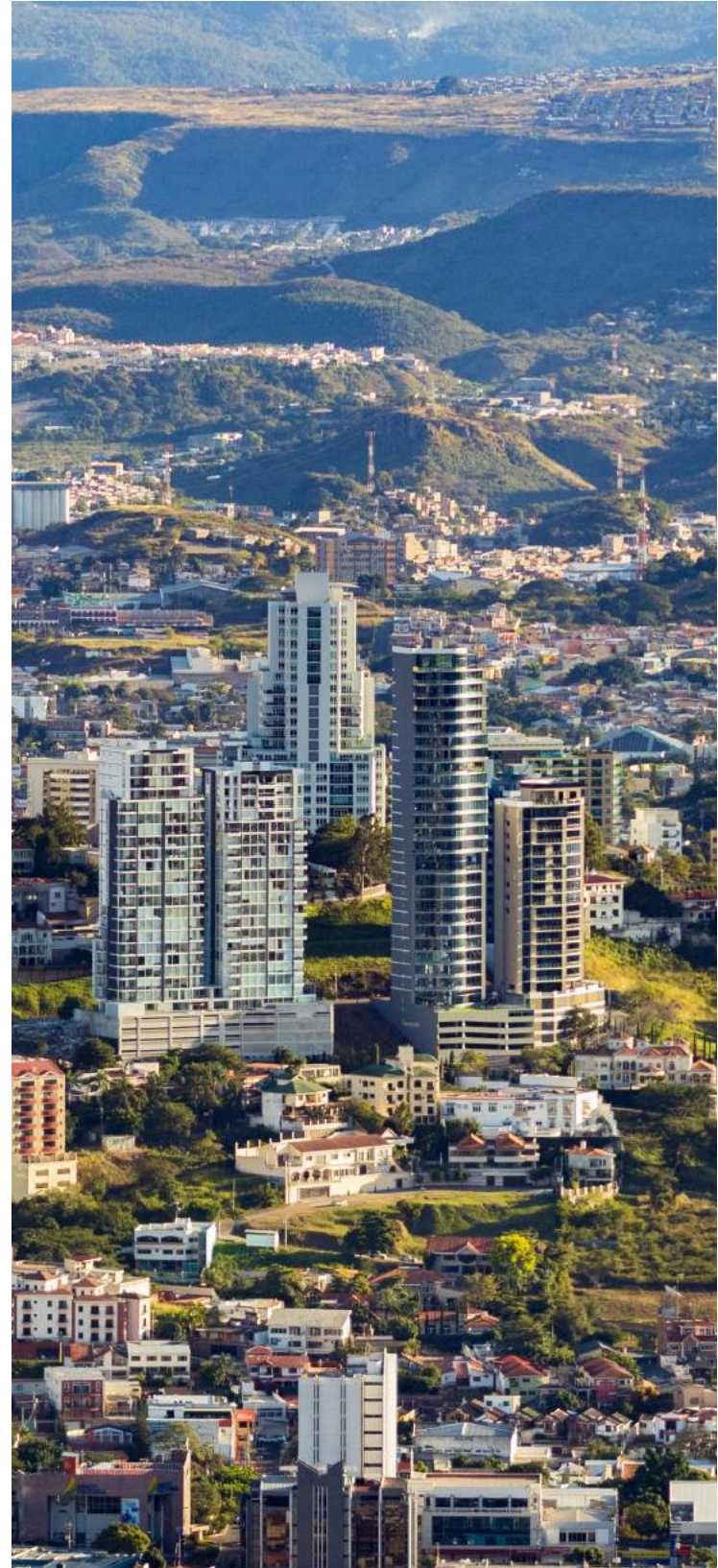
In Honduras, the consumption of cannabis and its derivatives for medicinal purposes is not allowed. Currently, there aren't any medicines containing cannabis or its derivatives that are legally marketed.

It is worth mentioning that at the end of 2021, in the month of October, a bill was presented that aims to regularize the medicinal use of cannabis, which reflects that there is an interest with medical support and supported by political channels for a future industry. But to date, it is still a project under discussion and there is no planning or resources allocated for its development.

For Recreational Purposes

As a result of recent reforms made to the Penal Code in Honduras, it has been established as part of the definition of a drug, and clear exclusion that "It is understood that derivatives of Indian or American hemp or cannabis Sativa do not cause serious damage to health". However, it does establish a limitation on the amount of possession of the drug. "By quantity of special importance, the following are understood: 1) 10,000 grams of marijuana, 2) 1,000 grams of hashish..."

In case the amount carried is greater than that of personal consumption, it will be sanctioned four to seven years of imprisonment, in addition to a fine of 100 to 500 days.



Commercialization

For Medicinal Purposes

The law does not allow the importation, commercialization or production of this substance for medicinal purposes.

For Recreational Purposes

It is prohibited to commercialize cannabis or its derivatives for recreational purposes. In case of being found administering controlled substances (including cannabis) free of charge or onerously in quantities superior to those considered for personal consumption, the administrator or marketer of these shall be sanctioned with the same penalty established above of four to seven years of imprisonment, in addition to a fine of 100 to 500 days.

Production and Cultivation

Production and cultivation are not allowed in Honduras.

Conclusions

- There isn't a favorable environment in the country to develop a cannabis market for recreational consumption.
- Regarding the consumption of medical cannabis, the outcome of the proposed law presented at the end of October 2021 must be awaited.
- Drug distribution channels (pharmacies and laboratories) do not handle inventories of products containing cannabis, since there isn't a legal demand for such products.
- Any investment for the distribution, cultivation and production of products derived from cannabis is subject to the enactment of permissive regulations. We do not see, on the legislative horizon, intentions to enact such regulations, except for the regularization for medicinal use. ■

Mexico

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Regulatory Framework

Consumption

Medicinal Purposes

As of June 2017, the medicinal consumption of cannabis and its pharmacological derivatives is regulated in the General Health Law (LGS) and in the Regulations of the General Health Law. It should be noted that possession is limited up to only five grams of cannabis.

Recreational Purposes

According to current legislation, consumption for recreational purposes is not allowed in México. However, in June 2021, Mexico's Supreme Court (SCJN) declared the prohibition of recreational consumption of marijuana stated in Mexican laws as unconstitutional. As a result of this, at the compliance of several requirements, it is possible to request for an authorization for the personal consumption of cannabis before the Federal Commission for the Protection against Sanitary Risks (COFEPRIS).

Commercialization

Medicinal Purposes

In the same sense of the matters mentioned in the consumption section, the medicinal commercialization of cannabis is regulated in the General Health Law (LGS) and in the Regulations of the General Health Law. It should be noted that the authorization of COFEPRIS is necessary for commercialization purposes.

Recreational Purposes

Currently, in concordance with the criteria of the Supreme Court, the consumption is limited for personal use (self-generation), for which authorization issued by COFEPRIS does not allow commercialization.

Production and Cultivation

Medicinal Purposes

Notwithstanding the regulations previously mentioned, such as the General Health Law (LGS) and in the Regulations of the General



Health Law, where production for medicinal purposes is allowed, the agricultural laws lack cultivation regulation procedures. Nevertheless, production of cannabis for medical purposes and its pharmaceutical derivatives is allowed according to such laws, and an authorization to be obtained before the National Service for Agrifood Health, Safety and Quality (SENASICA) is necessary.

Recreational Purposes

The authorization issued by COFEPRIS that fulfills with the Supreme Court's resolution is limited for personal use, including harvesting, sowing, planting and cultivation, as long as these activities are carried out at self-home of the consumer. However, the maximum amount limit to cultivate is still unknown.

Conclusions

- Production, research, commercialization, consumption and use of cannabis and its pharmacological derivatives for medicinal purposes is permitted and regulated in the General Health Law (LGS) and in the Regulations of the General Health Law.
- On the other hand, production, research, commercialization, consumption and use for recreational purposes is forbidden according to legislative materials. Nevertheless, a permission for personal use can be requested according to judicial resolutions.
- There is a lack of proper legislation from regulatory institutions to enforce the resolution of the Supreme Court. ■

Panama

Central Law

Collaborating Firm of Andersen Global

Regulatory Framework

Consumption

For Medicinal Purposes

In Panamá, the use and access to cannabis and its derivatives is permitted for therapeutic, medical, veterinary, scientific and research purposes.

Law 242 of October 2021 regulates the therapeutic use of cannabis and its derivatives.

Law 242 establishes the safety, control, quality, and surveillance for products that are imported, exported, manufactured, transported, stored and marketed, including cultivation, production, and the final disposal of medicinal cannabis derivatives, provided that they are for medical, veterinary, therapeutic, scientific and research purposes.

Law 242 also promotes the study and research on medicinal cannabis, allowing the development of laboratories and research centers.

For Recreational Purposes

The sale, commercialization, exchange and illegal storage of drugs, including cannabis, is prohibited and criminalized in Panama in accordance with the Criminal Code.

The purchase or possession of drugs for personal consumption (scarce), is also typified in the Criminal Code as criminal conduct, with minimum penalties such as community work or some security measure at the discretion of the judge.

The Institute of Legal Medicine and Forensic Sciences determines what is meant by a small amount in each case.

Commercialization

For Recreational Purposes

It is forbidden to sow, cultivate, store or guard seeds or plants with which illicit drugs or their derivatives can be produced for sale, resulting in prison sentences ranging from 10 to 15 years. However, lawful activities related to the use of cannabis for medicinal, therapeutic, or scientific purposes are not considered a crime.

The purchase or possession of drugs for consumption in small quantities is punishable by a 50 to 250 day fine, arrest on weekends or community work.

When the person who acquires or possesses drugs is physically or mentally dependent on it and the amount is scarce (meant for personal use), a security measure will be imposed.

For a small amount destined for personal use, it will be determined by the Institute of Legal Medicine and Forensic Sciences in each case and according to the state of dependence of the person.

For Medical Purposes

The import, export, cultivation, production, manufacture, laboratory analysis, acquisition in any capacity, storage, transportation, commercialization, distribution, final disposal and use of seeds duly authorized for sowing

the cannabis plant, as well as derivatives of medicinal cannabis, for medical, veterinary, therapeutic, scientific and research purposes are allowed.

Production and Cultivation

For the acquisition, storage, transport, dispensation, commercialization, consumption and export of cannabis and its derivatives, it is necessary to obtain a license granted for 10 years:

- License for the Manufacture of Medicinal Cannabis Derivatives
- License for the Scientific Research of Medicinal Cannabis

The Ministry of Health (MINSa) is the competent control authority for the approval and cancellation of licenses for human consumption and the Ministry of Agricultural Development (MIDA) is the competent authority for veterinary use.

For the use of seeds and the cultivation of plants, authorization from MIDA, must be obtained after obtaining a License for the Manufacturing of Medicinal Cannabis Derivatives and includes the activities related to the import, acquisition of seeds, cannabis seedlings and/or plant tissues of the cannabis plant, sowing, propagation, cultivation, harvesting, post-harvest, as well as the activities of storage, transport, laboratory analysis, export and final disposal of seeds, seedlings, plant tissues, cannabis plants and flowers and the final agronomic product of cannabis for medicinal use.

The holder of a License for the Manufacture of Cannabis Derivatives may export their products by obtaining an export certificate for each shipment. It is also allowed to export seeds for planting, cannabis plants, cannabis, cannabis derivatives and products



obtained from cannabis derivatives from the national territory to the rest of the world.

Licensees established in free or special zones may re-export finished products or products derived from medicinal cannabis.

Conclusions

- Although the Law was enacted and published in the Official Gazette on October 15, 2021, and is in force, it has not been regulated by the Executive Body, which to date, has not been implemented.
- Law 242 is a robust law that creates the regulatory framework that allows the use and monitored access of medicinal cannabis and its derivatives for therapeutic, medical, veterinary scientific and research purposes in Panama, which guarantees stability, security, and confidence for the start of operations in Panama.
- The Regulations of the Law must establish the specific protocols and guidelines for obtaining licenses, management, and specific mechanisms for the development of the activity, as well as the fixing of the annual rates and franchises that the Panamanian State will charge.
- We see great challenges of acceptance by the banking sector and it is necessary to strengthen, train and develop agreements with this sector for the development of activities. ■

Uruguay

Andersen in Uruguay

Member Firm of Andersen Global

Regulatory Framework

Introduction

On December 20, 2013, Uruguay became the first country to approve a law that allows the state to regulate activities around cannabis. This law was initially conceived with the intention of protecting the country's inhabitants from the risks implied by the link with illegal trade and drug trafficking, reducing the incidence of drug trafficking and organized crime, and attacking the health, social, and economic consequences of problematic psychoactive substance use.

Since then, the sector has experienced great development and part of this growth has been driven from the sphere of regulation.

Regulatory Framework

The Uruguayan regulatory framework allows both natural and legal persons to produce cannabis for recreational, industrial and medicinal purposes. Interested parties must previously meet certain administrative requirements, such as obtaining authorizations and licenses where different state agencies are involved in obtaining them.



The state assumes, through the Institute for the Regulation and Control of Cannabis (IRCCA acronym in Spanish), the control and regulation of the import, export, planting, production, storage, marketing and distribution of cannabis and its derivatives, both, non-psychoactive type cannabis (hemp) and the psychoactive type.

In both cases, import and export, the interested party must register in the Cannabis Registry in charge of the IRCCA and fulfill a procedure through a website of the Single Window for Foreign Trade (MUCE acronym in Spanish). The IRCCA may request from the interested party, among others, information regarding the corporate structure in order to identify the final beneficiary and the origin of the funds to be used.

Recently, a new decree of 2021 introduced some modifications allowing the planting, drying, conditioning, storage, production, manufacture and commercialization of psychoactive and non-psychoactive cannabis to be used exclusively for scientific research or the production, extraction and manufacture of raw material, finished and semi-finished products, based on cannabis or cannabinoids for medicinal use. Therefore it makes possible to produce and market not only finished products, but also products considered to be raw material or semi-finished products.

This raise possibilities for different types of products, such as dried flowers, extracts and others that can be used in processes for a finished product to be exported from Uruguay.

This modification comes to satisfy a demand that exists at a global level and places like Uruguay by opening up many possibilities.

Growth Perspectives

The development of the industry has had an exponential growth if we take into account that in 2019, it achieved its first export and in 2020, external sales that were registered exceeded USD \$7.5 million. In the first half of 2021, seven tons of only cannabis flower exports were registered.

In summary, we believe that Uruguay has followed a regulatory path that can be considered disruptive one the international level and is currently building a true state policy around this industry. ■

Venezuela

Leğa

Collaborating Firm of Andersen Global

Regulatory Framework

Cultivation

In principle, the cultivation of cannabis is prohibited, even criminalized in Venezuela, unless it is carried out for scientific purposes and with the authorization of the People's Ministry of Health.

Consumption

For Medical Purposes

The consumption of cannabis and cannabis-derived products for medicinal purposes is allowed, as long as it is prescribed by means of a special prescription that can be found in special forms issued by the Ministry of People's Power for Health.

For Recreational Purposes

In principle, the possession and recreational use of cannabis is prohibited in Venezuela, unless a Judge determines, based on expert evidence, that it is for personal use.

The possession of up to 20 grams of cannabis or up to five grams of genetically modified cannabis is punishable by one to two years of imprisonment.

Commercialization

In the case of pharmaceutical products, it is necessary to have a sanitary registration that must be processed before the National Institute of Hygiene Rafael Rangel (INHRR). It is important to point out that the INHRR has a list of pharmacological data sheets of approved active ingredients, among which none of the active ingredients of cannabis are found.



On the other hand, in the case of cosmetic products, the sanitary registration must be made before the Autonomous Service of Sanitary Control (SACS), however, it is necessary to make a previous integral evaluation before the INHRR.

In addition to the sanitary registration, both types of products must have the necessary permits to carry out the manufacturing and commercialization process, which are also granted by the SACS. Among the permits granted by SACS, are those for the manufacture of pharmaceutical products, in the category of psychotropic and narcotic drugs, and for the importation of psychotropic and narcotic substances.

Conclusions

- The use of cannabis in Venezuela for recreational purposes is prohibited and it is not possible to generate a market in that area. Regarding the use of cannabis for medicinal purposes, there is the possibility of its consumption, as well as its production and importation, as long as it has the respective authorizations.
- Although there are mechanisms to obtain authorizations for the production, commercialization and importation of cannabis and products derived from cannabis for medicinal purposes, the truth is that such authorizations are at the discretion of the health authorities, and so far, we are not aware of any case in which such authorizations have been granted.
- By virtue of this, we consider that the cannabis industry in Venezuela is not viable at this moment until the respective steps are taken before the health authorities, who must grant the corresponding authorizations. ■

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