

MARKET OVERVIEW - VOLUME I

BRAZCANN

MAGAZINE

CANNABIS REGULATIONS IN BRAZIL

UNDERSTAND THE OPPORTUNITIES EMERGING
FROM THE BIGGEST ECONOMY OF SOUTH AMERICA

2021

SUMMARY

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BACKGROUND

Global Regulations	03
Scientific Support	05
Potential Uses	08



MARKET

Cannabis in Brazil	09
The Industry	12
Be part of it	14

About Brazcann	15
How can Brazcann help my organization?	17



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BACKGROUND

GLOBAL REGULATION

Despite the age-old medicinal, recreational, therapeutic, industrial and religious use of cannabis and hemp derivatives, it began to be banned and criminalized worldwide from 1930, as a result of totalitarian and controlling actions made by governments. These governments were lobbied by large companies from competing markets for hemp fiber and Cannabis, like the pharmaceutical and the textile industry players. The prohibition also expressed the prejudice felt by the majority of society regarding communities of different cultural origin from their own.

The controversy regarding Cannabis is also due to the psychoactive substance Tetrahydrocannabinol - THC, as it can alter the state of consciousness of those who consume it, a fact that caused the therapeutic potential of this plant to be initially misunderstood.

In 1961, the prohibition reached its peak with an United Nations determination, directing all countries to ban Cannabis and placing it on the same level as substances that are harmful and unsafe to health. This prohibitionism has been losing ground since 1986 when Colombia and Paraguay started to try some kind of decriminalization for Cannabis uses, aiming to reduce the negative internal effects that the war on drugs brought to these territories. Then, several countries began to recognize the therapeutic potential of the plant.

In 1996 California was the first US state to legalize the medical use of Cannabis, initiating an investigative and scientific revolution in the comprehension of components and derivatives of the substance.



It is already known that the plant can contain up to 400 types of cannabinoids with medicinal function when connecting with CB1 and CB2 receptors of the human endocannabinoid system, demonstrating the potential to treat or alleviate symptoms of several diseases, such as Alzheimer's disease, loss of appetite and eating disorders, cancer, Crohn's disease, epilepsy, glaucoma, post-traumatic stress and mental illnesses, multiple sclerosis, muscle spasms, nausea, psoriasis, chronic pain and cachexia. It is also known that the plant's fiber can be used for textile, paper or plastic manufacture, as well as for raw material for construction.

In November 2020, the regulation approved by the Court of Justice of the European Union decides that CBD made from Cannabis or hemp flowers can no longer be considered a narcotic. The decision was supported by other spheres of the European bloc. A few days later, the United Nations narcotics commission approved the removal of Cannabis and derivatives from the list of the most dangerous narcotics, assuming the potential medicinal use of the plant. In practice, countries will now be able to regulate the production and use of the substance. However, international transactions will still be subject to interference from the International Narcotics Control of United Nations.

In 2022, the United States government intends to legalize Cannabis at a federal level, because today the legalization made by state governments is not recognized by the country. Thus, from this release, financial systems will be able to process commercial transactions for Cannabis products for the first time since 1961.

Today there are more than 50 countries that have some kind of regulation that gives legality to Cannabis and hemp at least for medical use, including Canada, United States (34 states), Mexico, Jamaica, Colombia, Ecuador, Peru, Uruguay, Chile, Israel, Thailand, Zambia, Lesotho, Australia, New Zealand, Germany, United Kingdom, Switzerland, Spain, Portugal, Norway, Denmark, Holland, Italy and Brazil.

SCIENTIFIC SUPPORT

Cannabis (name in English) or *Cannabis Sativa* (scientific name) is a plant that includes three different varieties: *Cannabis Sativa*, *Cannabis Sativa Indica* and *Cannabis Sativa Ruderalis*, native to Central and South Asia. The plant has been widely used for the manufacture of fibers, for seeds and seed oils, for medicinal purposes and as a psychoactive substance for recreational purposes.





In the medicinal sphere, Cannabis has an antiemetic effect and can be used to relieve cancer-related nausea and depression. It can also be used as a pain reliever. Some studies show that it is capable of significantly reducing intraocular pressure and tear flow in patients with glaucoma, although the effect is short-lived. Cannabidiol or CBD, a cannabinoid component of Cannabis, has a potential seizure inhibitor in animals and humans and can help in the treatment of spasticity and neuropathic pain that can accompany multiple sclerosis and also in the treatment of severe epilepsy in childhood.

Cannabinoids are active compounds present in Cannabis that interact with receptors spread throughout the body through the endocannabinoid system, which is a natural system of our brain and body.

This system is present in all animals, and evolutionarily goes back 600 million years. The job of the endocannabinoid system is to modulate other systems in the body that can become overheated. It is like a breaking system, which can slow down a wide variety of other systems in the body, including pain perception, gastrointestinal motility, memory, sleep, stress response, pain and appetite, to name a few. The endocannabinoid system has unique functions throughout the body, but especially in the brain and the immune system. In fact, receptors in the endocannabinoid system are the most common receptors in the brain and the second most common receptor in the body, showing exactly how important the endocannabinoid system is.



The animal body can naturally produce endocannabinoids that connect with these receptors and in the case of a dysfunction in this system, cannabinoids from the plant can be used. Cannabis can help to regulate the functioning of the endocannabinoid system again. There are about 113 different cannabinoids present in Cannabis that have already been discovered. Scientists are still learning about the behaviors and effects of each cannabinoid, and how they interact with the human body.

Cannabinoids are the chemical components found in Cannabis Sativa, most of which are concentrated within the plant's trichomes. CBD and THC are the most well-known cannabinoids, CBD being the most recommended for medical use, and THC being responsible for psychoactive effects and indicated in specific medical treatments. New research still indicates that cannabinoids are subgroups of terpenes, with wide activity of therapeutic effects.

Terpenes are chemical components that give a unique signature to essences, flavors and effects of major cannabinoids.

CBD stands for cannabidiol, the most prominent naturally occurring cannabinoid component found in hemp. According to the United States government, cannabidiol is "a cannabinoid with no psychoactive effect". After THC (D9-tetrahydrocannabinol), CBD is by far the most studied natural cannabinoid.

According to many researchers, CBD may be the most important cannabinoid ever discovered, and this valuable hemp plant compound promotes and supports the nutritional health of aging bodies*.

THC or D9-tetrahydrocannabinol is generated through decarboxylation, a chemical process that isolates the carboxylic group from the THCA molecule and releases carbon dioxide. When the carboxylic group is removed, it is replaced by a proton, which changes its characteristic abruptly, making the substance psychoactive.

*US Patent #6,630,507



POTENTIAL USES

To comply with the UN Narcotics Convention, some strains of cannabis were created to produce minimal levels of THC, one of the main substances in cannabis and responsible for the psychoactive effect associated with the plant. These high CBD and low THC strains are widely used in the medical and industrial (hemp) fields.

Industrial hemp products are made from selected Cannabis plants to produce a large amount of fiber. Currently, it is known that the use of hemp in the production of industrialized products in general is an emerging ecological alternative. Many companies that are looking for greener and less polluting products found in Cannabis an important tool for changing the scenario. According to a study made by the paper industry, it was proved that in the same area and in the same period of time, it is possible to produce up to 3 times more cannabis paper than in the area of tree paper production. There is also knowledge of a baby diaper company, which would like to produce more environmentally friendly diapers in Brazil, but the industry sector is prevented from such an ecological attitude due to the laws against the industrial use of hemp in Brazil.

Cannabis byproducts are considered to be all processed products that have parts of the Cannabis Sativa plant in their composition, being possible to use the leaf, root, stem, fiber, resin, seed, and isolated components thereof. Some examples are: medicines, plastic alloys, fabrics, fuel, processed foods, construction materials, paper, cosmetics and products for recreational and medical use, such as vaporizers and extractions (distilled resin, live resin, isolates, others).





MARKET

CANNABIS IN BRAZIL

In Brazil, Medicinal Cannabis starts to be liberated from 2014 when Anvisa (Health Surveillance National Agency) authorizes the medical prescription of Cannabidiol and releases the importation of finished products based on cannabis, for medical purposes, on request from the patient and with a prescription from the health professional. In 2015 Cannabidiol is no longer a prohibited substance and is considered a controlled drug. In 2016, individual prescription and importation of THC drugs was also authorized.

In 2017, Anvisa decided to approve the rules for the registration of medicines that contain cannabinoids in Brazil, but as registration in this modality became very complex, only one company was able to distribute medicines in the country, the British GW Pharma Limited.

Thus, Anvisa decided to prepare a new regulation to facilitate the entry of new products to the national market. So in 2019 the government agency authorized the national manufacture of Cannabis derivatives with imported raw material (Resolution of the Collegiate Board - RDC No. 327, of December 9, 2019), both for CBD and THC, plus other cannabinoids. The regulation came into force in March 2020 and should be reviewed within three years from that date, due to the technical-scientific stage in which cannabis-based products are found worldwide. The cultivation of raw materials for commercial purposes remains prohibited, so Brazilian pharmaceutical companies that intend to offer these products must apply for a special authorization from Anvisa that enables them to purchase foreign raw materials or finished products. Imported Cannabis products must be properly regulated by the competent authorities in their countries of origin.



For the purpose of manufacturing and selling Cannabis products in the Brazilian national territory, one company must import the active pharmaceutical ingredient in the forms of vegetable derivatives, phytopharmaceuticals, in bulk, or industrialized finished products. Cannabis products are not allowed to be commercialized in the form of plant material, from the Cannabis plant or its parts, even after the stabilization and drying process, or in its streaked, crushed or powdered form, even if available in any pharmaceutical form.

The sale of fresh flowers, vaporizers, ointments, creams, cosmetics, perfumes, edibles / foods, cigarettes and smokables will not be allowed.

The regulation foresees that the sale will be made exclusively by pharmacies, with a prescription of special control. The rules vary according to the concentration of tetrahydrocannabinol (THC). In formulations with a THC concentration of up to 0.2%, the product must be prescribed by means of a type B prescription, containing a code number provided by the local Health Surveillance and prescription renewal within 60 days. Products with THC options greater than 0.2% can only be prescribed for terminal cases or in the occurrence of all other therapeutic treatment alternatives have been exhausted. In this case, the receipt of prescription will be of type A, valid for 30 days, provided by the local Health Surveillance, a standard similar to that of morphine, for example. Cannabis products will be authorized for oral or nasal use only and any advertising of Cannabis products is prohibited. With the prescription in hand, the patient can go to a pharmacy and ask about the availability of products. Until May 2020, only two national medicines are available for sale in Brazilian pharmacies. The products available can be for oral use, nasal application, tablets (capsules or softgel), liquids and oily solutions.



The final products must be tested by analytical laboratories providing services that carry out quality control tests on batches of finished products. The laboratory must be qualified in Reblas (Brazilian Network of Health Analytical Laboratories) in the scopes corresponding to the respective category of products analyzed (Cannabis products). In addition, it must have a Good Practices certificate for Quality Control Laboratories and meet the requirements of the Resolution of the Collegiate Board - RDC No. 390, of May 26, 2020. The importer must transmit the analytical data obtained from his supplier when the product listed in Normative Instruction is not subjected to quality control tests - ECQ in an analytical laboratory located in the national territory.

Only manufacturing companies that have a Certificate of Good Manufacturing Practices (CBPF) for medicines issued by Anvisa or importing companies that comply with the Good Distribution and Storage Practices for medicines (PIC/S countries), can apply for Sanitary Authorization and manufacture Cannabis products. Cannabis-based products are also subject to the regulation of herbal medicines, according to ANVISA Resolution - RDC No. 26, of May 13, 2014. The health authorization is valid for 5 years, after that the product can be reevaluated by ANVISA as a medicine, upon request from the national producer or importer.

THE INDUSTRY

Despite the history of prohibitions, more than 263 million people use Cannabis worldwide. The total global cannabis market (regulated and illicit) is estimated at USD \$ 344 billion. In 2018 alone, the global regulated market for Cannabis and derivatives generated around US \$ 18 billion and Euromonitor estimates that by 2025 this niche will generate over US \$ 166 billion, since there are about 1.2 billion people suffering from diseases that can benefit from the therapeutic potential of Cannabis worldwide.

According to a New Frontier Data report, only in Brazil this industry can move another 4.6 billion reais in the next three years. Brazil, with its more than 200 million citizens, has about 4 million potential medicinal users. Among the countries that are prepared to plant Cannabis and make the transformation of the raw material to export to Brazil are: Canada, United States, Jamaica, Colombia, Ecuador, Paraguay, Israel, Zambia, Lesotho, Australia, Denmark and England. All of these countries are capable of complying with Brazilian regulations. Each foreign producer must have a certificate of good manufacturing practices (GMP) issued by an institution accredited by a government agency (PIC/S countries). The countries with the most advanced legislation and procedures are England (largest exporter), Australia, Canada, Israel and Colombia.

According to Prohibition Partners, the Paraguayan hemp industry is poised for expansion with strong government support, while Latin American pioneers Uruguay and Colombia are expected to earn more GMPs and achieve record-breaking exports, gaining international momentum. Throughout Latin America, with a focus on Brazil and Colombia, there will be an exponential growth in the number of patients, helped by the growing role that patient associations and specialized clinics are playing.





There are currently several Cannabis corporations being traded on the stock market, some of which are:

Canopy Growth Corp. (CGC)
Cronos Group Inc. (CRON)
GW Pharmaceuticals PLC (GWPH)
Harvest Health & Recreation Inc. (HARV.CX)
Village Farms International Inc. (VFF.TO)
Aphria Inc. (APHA.TO)
The Valens Co. (VLNS.TO)
4Front Ventures Corp. (FFNT.CX)
Green Thumb Industries Inc. (GTII.CX)
Sprott Inc. (SII.TO)
Amyris Inc. (AMRS)
Trulieve Cannabis Corp. (TRUL.CX)
ETFMG Alternative Harvest ETF (MJ).

Brazil, due to the millions of hectares of arable land and the vast experience in agribusiness, is very well positioned to stand out in this market if local legislation advances *.

* Study of Você S / A

Medicines are only a part of the sector, which can expand for recreational, veterinary, textile, cosmetic and even food use. In the next five years, according to different estimates, 60 to 80 nations will have authorized medical and / or recreational use. With this, the Cannabis plant is on its way to becoming a global agricultural commodity, traded internationally like coffee, for example.



BE PART OF IT

To participate in the emerging Cannabis industry under ANVISA rules, national companies should consider the following opportunities:

➔ Import the active pharmaceutical ingredient or final product



(company with Anvisa's operating authorization)

➔ Manufacture cannabis-based product



(pharmaceutical)

➔ Distribute cannabis products



(pharmacies and hospitals)



LONG TERM SUPPLY

For foreign players, Brazilian legislation opens the opportunity to commercialize Active Pharmaceutical Ingredients or final cannabis-based products produced outside the Brazilian national territory.

Since the legislation requires that the foreign supplier, the national importer or manufacturer and the distribution pharmacy are linked to the product's health authorization, a long-term contract between the business participants is necessary.

WHO IS BRAZCANN?

Company founded in 2020 aiming to promote Brazilian pharmacies and pharmaceutical companies to produce and distribute Cannabis byproducts, considering the Resolution of the Collegiate Board 327/2019 of ANVISA that listed the necessary requirements for the regularization of Cannabis byproducts without clinical trials in Brazil.

The company was established in the city of Curitiba-PR by the partners Ali Ferreira and Willian Gonzaga, based on three years of research and immersion in the international cannabis industry, through participation in fairs and events in the sector, visits to large-scale crops and transformation industrial plants, translation of books and scientific articles and relationship with brands from different nationalities.

Given that the cultivation of the Cannabis plant remains prohibited in the national territory, organizations that wish to manufacture and distribute such products must import the raw material in extraction format (API) or also the final product, as the import of plants or parts is not allowed.

In this way, Brazcann plays a fundamental role in the search and validation of international suppliers that are prepared to export to Brazil, as well as demonstrating the potential to represent Brazilian industry players in events and interactions with the foreign market.

The company acts as a consultant in the purchase, import, formulation, registration and distribution of cannabis active pharmaceutical ingredient or final products in large quantities (industrial / laboratory level), since it has the following objectives:

- Support Brazilian pharmaceuticals and pharmacies that wish to manufacture or distribute Cannabis byproducts in Brazil, carrying out the selection and validation of suppliers, as well as subsidizing the scientific basis for the formulation, manufacture and sanitary authorization of products.
- Represent national players in the global Cannabis industry scene, participating in events, fairs and meetings in the sector.
- Participate actively in the national dialogue on the subject, aiming to follow the legislative advances of agencies and public organizations, preparing for the possibility of liberation for the cultivation of medical and industrial Cannabis in national territory by 2023.

FAE INCENTIVA 2020

In 2020 the company joined the FAE Business School acceleration program, FAE Incentiva (fae.edu) and will receive support to expand its operations in the Brazilian Cannabis market.



HOW CAN BRAZCANN HELP MY ORGANIZATION?

We offer personalized consultancies to help your company to enter or expand in the Brazilian market of cannabinoids

- unique negotiation opportunities with international suppliers;
- know how about legislations, registrations and processes with Anvisa and Siscomex;
- networking and marketing strategies for propagation and distribution of products;
- templates for Anvisa processes;
- recommendations for formulation, packaging, shipping and distribution;
- representation of your brand in Brazil.

If your company is either an international supplier of Cannabis byproducts or a national importer, manufacturer (pharmaceutical companies) or distributor (drugstores), you can now start operating in the Brazilian market.

Participate in the pre-selection to be part of the pilot project orchestrated by Brazcann.

Know more at:

WWW.BRAZCANN.COM

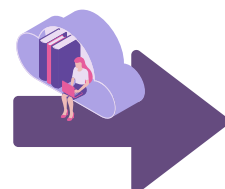
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RDC N°327 ANVISA

Resolution that regulates the use and commercialization of Cannabis-based products in Brazil.



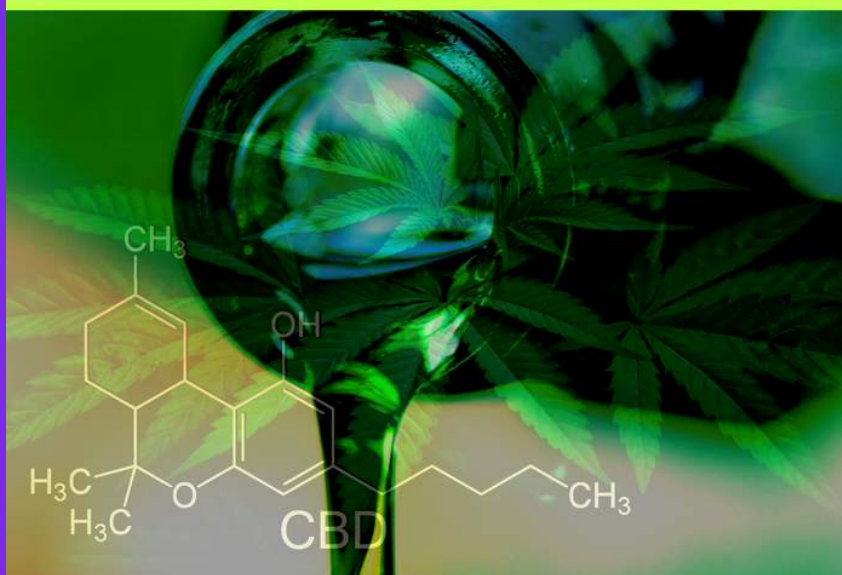
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TRADUZIDO POR WILLIAN GONZAGA E ALINE FERREIRA

CANABIDIOL: TUDO QUE VOCÊ PRECISA SABER SOBRE O CBD

DOSAGENS PARA PRINCIPAIS
ENFERMIDADES TRATÁVEIS COM CBD



DR. GREGORY SMITH

CANNABIDIOL: EVERYTHING YOU NEED TO KNOW ABOUT CBD

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