

A close-up photograph of a cannabis plant with vibrant green and purple leaves, set against a dark purple background. A diagonal yellow line runs across the image from the top right to the bottom left.

Brazcann

Magazine

MARKET OVERVIEW • 2022

MEDICAL CANNABIS IN BRAZIL AFTER SEVEN YEARS OF REGULATION

VOLUME II

MEDICINAL AND THERAPEUTIC PRODUCTS
GENERATE A MILLIONAIRE MARKET, BUT HOW FAR
IS BRAZIL FROM THE INTERNATIONAL INDUSTRY?



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**CONSULTING
SERVICES FOR THE
CANNABINOID INDUSTRY**



INDEX

Introduction	4
Products for Therapeutic and Medicinal Purposes	7
Registered Drugs with Completed Clinical Trials	7
Cannabis Byproducts without Clinical Trials	8
Patient Direct Import	10
Judicial Authorizations	10
Wholesale Distribution and Healthcare Organizations	11
Specialized Clinics and Compounding Pharmacies	12
Research, Cultivation, Extraction and Refinement	13
Cosmetics, Food and Beverages	14
Veterinary Use	17
Industrial Hemp	18
Brazil Inside the International Scene	20
References	21

INTRODUCTION

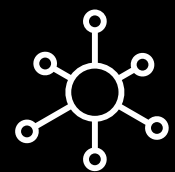
In force since 2006, the Brazilian drug law provides that its governmental federation may authorize the planting, cultivation, harvesting and exploitation of any plant exclusively for medicinal or scientific purposes. However, to this date, the Brazilian federal administration has not yet created a model for regulating such authorizations regarding the cultivation and processing of the *Cannabis Sativa* plant. In this way, Brazil started the process of legalizing Cannabis and hemp for therapeutic and medicinal purposes only in 2014, when the country's Federal Health Surveillance Agency (Anvisa) authorized the import of cannabinoid-based medicines for the first time. However, even with the slow pace of the Brazilian regulatory process, this industry has already reached the mark of approximately BRL 200 million in revenue by 2021, including all current forms of regulation:

- **REGISTERED DRUGS WITH COMPLETED CLINICAL TRIALS**
- **CANNABIS BYPRODUCTS WITHOUT CLINICAL TRIALS**
- **DIRECT IMPORT OF CANNABIS BYPRODUCTS BY PATIENTS**
- **ASSOCIATIONS AND JUDICIAL AUTHORIZATIONS**

In all distribution modalities, the medical prescription of the product is mandatory. Today, according to Anvisa (National Health Surveillance Agency), there are 2,100 prescribing professionals, a growth of 554.2% compared to 2015.



According to a report published by the newspaper Valor Econômico, the medicinal Cannabis industry in Brazil is expected to reach a value of BRL 500 millions in 2022.



In accordance to a survey released by the market intelligence company Kaya Mind and published by Forbes Magazine, a regulation change in Brazil could generate 117 thousand jobs and move BRL 26.1 billions in the country by 2025, if the Brazilian Federation and its entities decide to include industrial, cosmetic, food and recreational purposes within the permitted uses for the Cannabis plant established under the regulatory model.



Anvisa

is the agency that regulates the distribution of medicinal Cannabis in Brazil, as well as, in the future, it should regulate the distribution of cosmetics and food supplements.

THE MINISTRY OF AGRICULTURE AND THE MINISTRY OF HEALTH

are the entities representing the Federation that will regulate the cultivation and transformation of the plant, which remains prohibited until Law 399/2015 or similar is approved in all governmental areas, depending on political movements in the legislative and executive spheres of the government.

For now, the raw material for registered drugs and Cannabis byproducts manufactured in Brazil will depend on Active Pharmaceutical Ingredients (APIs) of foreign origin.



THE INTERNATIONAL REGULATION

is carried out by the International Narcotics Inspection Board (JIFE). Cannabis APIs or finished products international trades are subjected to Anvisa's import authorization and the operation occurs via **SISCOMEX**, a system that registers all the Import and Export procedures in Brazil.

PRODUCTS FOR THERAPEUTIC AND MEDICINAL PURPOSES



Since 2014, Brazilian patients have carried out around 70,000 regulated purchases of cannabinoids for therapeutic purposes, upon medical prescription. The future market scenario is promising, since about 78% of Brazilians are in favor of the use of medicinal Cannabis for the treatment of diseases.

Registered Drugs with Completed Clinical Trials

Anvisa has regulated Cannabis-based medicines in Brazil since 2014, through Collegiate Board Resolutions 24/2011 and 242/2018, as well as their updates and complementary legislation.

So far, the health agency has authorized the registration of only one drug, Mevatyl, marketed internationally as Sativex. The product of English origin, is manufactured by GW Pharmaceuticals, a company that was recently purchased by Jazz Pharmaceuticals for USD 7.2 billions, and imported by Beaufour Ipsen Pharmaceuticals. The product is not available in most pharmacies at the moment and the company had a batch of the medication suspended by the Santa Catarina state health agency in 2021 due to inconsistencies in the content of cannabinoids. The drug was approved by Anvisa with clinical trials completed for multiple sclerosis and can be found for retail in a few Brazilian pharmacies, for a price that ranges between BRL 2,600 and 3,600. Recently, some national and international companies have expressed their intention to invest in clinical trials to register their Cannabis-based drugs in Brazil, therefore the supply availability of such medicines is expected to increase in the country over the next 4 years.

Cannabis byproducts without clinical trials

According to ANVISA's RDC n°327/2019 and its updates, companies can distribute Cannabis-based products without clinical trials for up to 5 years, provided they comply with the requirements stipulated by the agency, such as certifications, licenses, product and packaging specifications, quality control reports and obligations for the distribution model.

As informed by Anvisa, there are already five products available for sale in pharmacies in this distribution model, and they are sold at pharmacies for a price ranging between BRL 250 and 2,500, depending on the brand and composition. About 15,000 units of products were sold by 2021, all of them for oral use and most containing only the cannabinoid CBD. There are another nine products approved by the agency yet to be commercialized, waiting for the conclusion of API/products import, manufacturing or contracting of suppliers and distributors, in addition to twelve products awaiting for sanitary authorization approval. There are also other Brazilian and foreign companies that have already publicly shown interest in this commercialization model and should enter this market in the next two years. The quality control required by Anvisa still represents an obstacle for the industry, since only few laboratories, enabled by the Brazilian Network of Health Analytical Laboratories (REBLAS) have a determined test protocol for cannabinoids.



A close-up photograph of a cannabis plant with green serrated leaves and budding flowers. A semi-transparent purple trapezoidal shape is overlaid on the right side of the image, containing white text.

MEDICINAL
CANNABIS
IN BRAZIL
BE PART OF THIS
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PATIENT DIRECT IMPORT

Since 2015, Brazilian patients can request authorization to import Cannabis products for individual treatment based on the RDC n°335/20, later replaced by RDC n° 660/22. Unlike the products available in pharmacies, which are allowed for oral and nasal use only, the individual import model allows patient access to more varieties of products, including the importation of ointments, balms and sprays, upon medical prescription and Anvisa's import authorization.

Until August 2021, Brazil had 41,100 people authorized by Anvisa to import Cannabis derivatives for individual treatment and the forecast is that the authorizations issued by the agency will reach the mark of 55,000 approvals by the first quarter of 2022.

Judicial Authorizations

There are around 35 associations in Brazil with judicial authorization to grow, extract or process Cannabis-based products for more than 20,000 associated patients. This type of organization is not-for-profit, offering less costly cannabinoid treatment options for its members. However, the legislative and executive spheres of government do not recognize or regulate this type of distribution, which jeopardizes the continuity of product dispensing in this model. Brazilian judges have also issued individual cultivation authorization for more than 110 patients. On the other hand, multiple requests for habeas corpus from individuals or associations were denied on the grounds that Anvisa regulates the sector and that cultivation in national territory is not permitted under any circumstances.





WHOLESALE DISTRIBUTION AND HEALTHCARE ORGANIZATIONS

Recently, the Unified Health System (SUS), as well as private hospitals and health plans have shown interest in purchasing large amounts of Cannabis-based medication. This occurred after many court decisions stipulated that the SUS and health plans should bear the costs of Cannabis treatments for patients in vulnerable situations. Companies such as GW Pharmaceuticals and Prati-Donaduzzi have already shown interest in wholesales to government entities.

SPECIALIZED CLINICS



There are already more than 12 clinics specialized in the endocannabinoid system in Brazil, serving around 10,000 patients. These clinics bring together health professionals from different specialties, including neurologists, pediatricians, rheumatologists, psychiatrists, general practitioners, family doctors, among others, who are trained to prescribe Cannabis-based products, as well as monitor the patient's therapeutic progress.

COMPOUNDING PHARMACIES



Even with the prohibition of the compounding of Cannabis-based medicines, stipulated by Anvisa in the resolution n° 327/19, compounding pharmacies in the State of São Paulo guaranteed the right to manipulate and commercialize Cannabis byproducts through a writ of mandamus that goes against the regulation of the sanitary surveillance agency, since it limits the distribution of such products only to conventional drugstores.



Judge Rubens Rihl, rapporteur of the appeal, stated that, **“by allowing conventional pharmacies (drugstores) to dispense Cannabis products, [Anvisa] ended up making an undue distinction between these and compounding pharmacies, given the absence of a law that makes such discrimination”** and addressed that despite the federal law n° 13.021/2014 place conventional pharmacies and compounding pharmacies in different categories, the activities of compounding pharmacies include the activities of drugstores, **“so that, if any restriction were to be considered, it should be related to conventional pharmacies, never the opposite”**. According to Rubens Rihl, **“no legal support is identified for a greater restriction related to compounding pharmacies, being referred to illegal discrimination, and should be removed”**. Ideally, Anvisa would amend its resolutions and include the new changes, since the process to prepare and continue a writ of mandamus generates additional costs for the companies involved and also for government agencies that must intervene and spend public resources in legal battles to fix these flaws in the legislation.

RESEARCH, CULTIVATION, EXTRACTION AND REFINEMENT



Since the cultivation of Cannabis for commercialization purposes continues not to have an specific regulation, what has been seen in Brazil lately are research institutions, mostly universities, requesting a judicial authorization for investigative cultivation. This authorization allows researchers to investigate the Cannabis plant, as well as cultivation, extraction, refinement and transformation techniques.

Some Brazilian states are already creating rules for the legislative authorization of the cultivation and processing of Cannabis for medicinal purposes, as in Brazil the states have autonomy for decisions on matters related to public health, and some of this states do not want to wait for the federal regulation. In this way, national institutions can now turn to local governmental representatives in order to launch research programs, as happened in Rio de Janeiro in the case of Canapse, an organization that brings together scientists, agronomists and lawyers with the aim of planting, harvesting and testing the Cannabis plant, with support from Brazilian universities.

There are also some non profit organizations authorized by local courts of justice to cultivate, extract and prepare cannabis byproducts for associated patients in a small scale.

As for the regulation of cultivation at a federal level, the Bill (PL) 399/2015, which is not yet in force, is the most complete and closest legislation to be approved regarding the cultivation, research and commercialization of medicinal Cannabis in Brazil. The proposal of PL 399/15 is to modify and establish procedures of Law 11,343/06, which establishes the National System of Public Policies on Drugs and which authorized the cultivation of herbs such as Cannabis for scientific or medicinal purposes in a specific place and period, subjected to inspection.

COSMETICS, FOOD AND BEVERAGES

It is clear that the Cannabis market is better developed in countries where regulatory models for medicinal, recreational and industrial cannabis have prevailed for more than 20 years, such as in Canada, for example, where citizens have been able to legally access these products since 2001 and recently had the model of legalization for recreational purposes approved, in 2018.



In North American countries the social treatment towards Cannabis, its byproducts and the subject in general is very progressive if compared to Latin American countries, as the majority of their population ceased to see the plant as something negative, a long time ago.

“Today you can find a regulated dispensary in almost every neighborhood from the city of Toronto, both for medical and recreational use, with a multitude of products being offered in the market, demonstrating how the demand is already developed in the country”,

shares Willian Gonzaga, co-founder of Brazcann.

At the moment, the international cosmetics, food and beverage market continues to grow with new products being launched daily. There are Cannabis treats options that mimic traditional versions of famous foods, which sparked a discussion on the topic as consumers were confusing Cannabis-based foods with traditional foods. After that, the companies responsible for such products had to make changes to their packaging and labels to clarify the composition with the active ingredients used, CBD or THC.



The regulation also made room for a new category of non-alcoholic beverages to enter the market, mainly in the United States, where cases of alcoholism are alarming, with about 88,000 deaths annually due to alcohol consumption, according to statistics from the Caron Treatment Center.

The beauty products industry is also taking advantage of the medicinal benefits of Cannabis to manufacture cosmetics with active ingredients, bringing the antioxidant potential of cannabinoids to anti-aging cosmetic treatments, in addition to other benefits for healing the skin and other organs of the body. These factors contributed to a rapid acceptance of such products, especially by the elderly public as they are the ones that most feel the therapeutic and cosmetic support that Cannabis provides.

Globally, in the last two years, the edibles and dietary supplements categories have seen strong growth compared to the Cannabis-based medicines or smoking-related products. One of the reasons for this increase in the demand for such products was the series of eventualities caused by the COVID-19 pandemic, as people confined to their homes sought other ways to consume Cannabis therapeutically or recreationally.



In Brazil, the categories of food, beverages, cosmetics, topical medicinal products, smokable products and the *in natura* plant are prohibited indefinitely, both for production and commercialization in the national territory, since Anvisa does not recognize the properties of Cannabis for this type of use. However, it is possible to individually import some products from these categories through special permissions and a doctor's prescription.



VETERINARY USE

Veterinary use has also gained evidence both for the therapeutic treatment of animals and for feeding purposes by using seeds, leaves, branches and oils extracted from industrial hemp.

A

The aliments for livestock, poultry, fish, domestic animals and others come from the grinding of seeds, branches and leaves as the basis for these foods.

G

The grains are used both for food and for the manufacture of oils used in agricultural products.

R

The resin is used to manufacture medicines and can also be used as a vegan glue or as an option for animal feed.

O

Oils, both essential and extracted from the whole plant or seeds, can be used in the manufacture of medications, food and animal treatment products.

Among other varied options for the use of hemp for the agricultural industry, is the possibility of using hemp hay as a lining for facilities where animals are handled, which has proved to be more efficient for maintaining these environments, where animals usually feed or rest, keeping the area cleaner for longer thanks to a better absorption of moisture and debris than with regular hay.

In Brazil, the production and sale of veterinary products are prohibited indefinitely, since Anvisa does not recognize the properties of such products for this purpose. However, it is possible to find some non-profit associations that distribute cannabis-based veterinary products under judicial authorization.



INDUSTRIAL HEMP

Historically, industrial hemp has experienced a setback around the world since cannabis was banned internationally through the War on Drugs mandated by the US government in the mid-1970s. Previously, industrial hemp was fundamental to human expansion, with several historical uses, such as ropes and candles used in the colonial era and even used as paper for important constitutional documents for humanity.

Hemp cultivation came to be encouraged by the governments of different countries at different times of civilization, as the governors of the time recognized the its uses and knew the variety of derived products that the plant has the potential to provide. After the ban, few countries continued to produce hemp on a small scale, for industrial purposes of manufacturing thread and rope, fabrics and garments, oils and grains, leaving the market dormant for many years.

In December 2018 in the United States, during the administration of Donald Trump, the Farm Bill was approved, which regulates the production of hemp low in THC (>0.3%). This has resulted in an exponential increase in new companies producing hemp for industrial and medicinal use, as added to the legislation on CBD, which is legalized at national level, has opened the door for companies to produce cannabis for both purposes. This generated a large increase in the raw material available for both industrial and medicinal use, causing a drop in the prices of these inputs and consequently more accessible products on the market.

In Brazil, these industrial cultivation practices are vetoed until further notice, delaying the development of the national market indefinitely. Companies that previously had judicial authorization from a local courts to plant industrial hemp, judicially lost their prerogative when the new Anvisa regulation came into force in 2019. There is great controversy regarding this issue, since the body responsible for controlling national crops is the Ministry of Agriculture and not Anvisa, author of the current regulation.

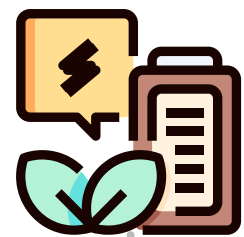
INDUSTRIAL PRODUCTS

The time lost from not using industrial hemp will never come back and materials that could have been invented and improved from industrial hemp have been greatly delayed.

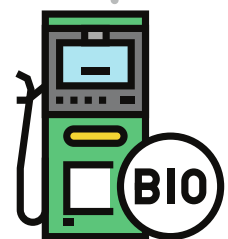
But today's new technologies are making it possible for new uses for hemp, never before imagined, to become a reality.

There are currently studies and prototypes of:

Batteries made from components extracted from Cannabis



Biofuels and lubricants for machines and vehicles



Biodegradable material options as substitutes for plastic, wood and minerals



Replacement of other natural resources with extraction methods that are aggressive to nature



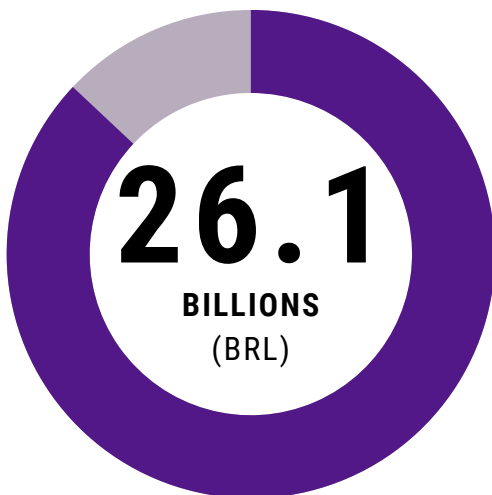
BRAZIL INSERTED IN THE INTERNATIONAL SCENE

Despite the limitations in the regulation of Cannabis in Brazil, national companies are starting to position themselves in the international market. The greatest interaction with this market takes place through the search for foreign suppliers of raw materials that meet Anvisa's requirements, mainly suppliers of isolated CBD.

A peculiarity of Brazilian regulations is the fact that health surveillance requires that the API or products to be imported must contain less than 0.2% THC, whereas in the United States and other countries this requirement is that it be less than 0.3% THC, generally. In Colombia, this maximum THC tolerance rate is up to 1%. This causes many high quality suppliers to be disqualified as a possible partners for Brazilian manufacturers and importers.

**IT IS
EXPECTED**

that in the near future the regulations will be reformulated so Brazil can take advantage of its vastness of arable land to enter as a major exporter of industrial and medicinal Cannabis, which can boost a market up to:



**IN THE
NEXT**





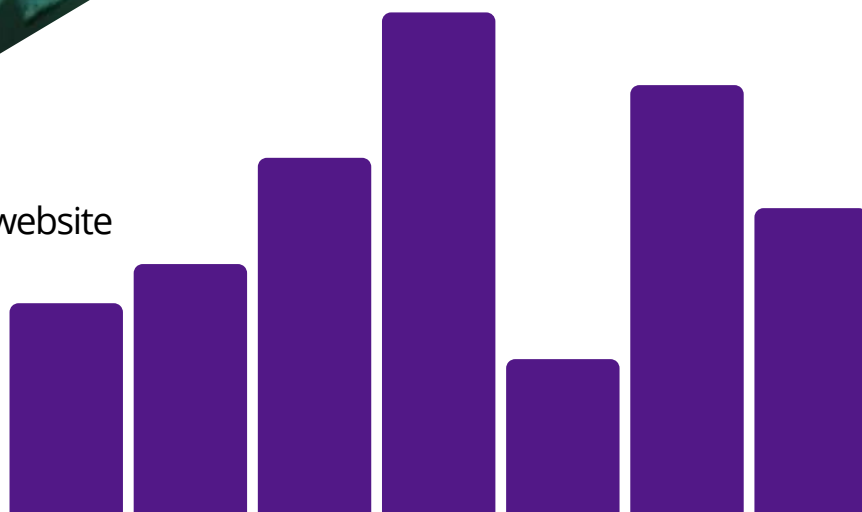
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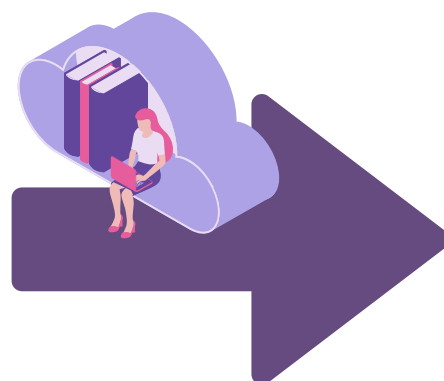
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to know more details about specialized consulting services for the Brazilian medical Cannabis market and how Brazcann can help your company to position itself properly to enter or expand in this industry, according to the parameters established by Anvisa.

REFERENCES

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