Introduction

The growth of the cannabis market is one of the trends on the world scenario nowadays. Whether in the form of medicines, food and cosmetics, or even recreational use of plant substances, all forms of exploration are seen as promising for years to come. The topic has come into global discussion and several countries are positioning themselves.

Since 2018, Canada has allowed recreational use of cannabis for adults, in addition to authorizations for the production and marketing of herbal medicines. Authorization for edible products and extracts is scheduled for October 2019. With this, the country has created a legal and regulatory framework to control the entire cannabis production, distribution, sale and possession chain within its territory, taking a significant step towards exploration of this global market.

Brazil is still in the middle of a great discussion on the subject, with advances in the medical area. Individual authorization for the importation of medicinal products with substances extracted from the plant for personal and prescription use began a little over a decade ago and in 2017 the registration of one of these medicines was allowed for the first time in the country. Justice has also been positive in relation to cultivation for medicinal purposes and has given injunctions to families in this regard. In May 2017, cannabis sativa was included in the category of “medicinal plant” in the list of Brazilian common names.

In the following pages, attorneys Affonso Barros da Cunha and Marcos Eduardo Lagrotta Pregnolato, from Tavaris Novis, and Sandra Gogal, from Miller Thomson, will explain the regulatory situation of cannabis in Brazil and Canada, respectively, and the future prospects for advancing this market in their countries.
Cannabis-Based Medicine and its Regulation in Brazil

Overview of drug regulation in Brazil

The study of the rules governing the import and use of cannabis-based drugs in Brazil should begin with an examination of how Brazilian society and legislation approach the drugs issue in general.

In Brazil, the debate concerning the decriminalization or not of drugs tends, very often, to be based on the lack of contextualization and relativization. Discussions vary from either total condemnation or the defense of unrestricted release and often fail to address in depth the aspects relating to the protection of public health and the harms of overly punitive legislation, failing to address issues such as huge social inequalities and great cultural diversity which are historical characteristics of Brazilian society.

The Federal Constitution considers the illicit trade of narcotics to be an unbailable crime (Article 5, Item XLIII), and also determines the expropriation of any real properties where illegal cultures of psychotropic plants are located (Article 243). Law 11343, of August 23, 2006 (Law 11343/06) is known as the Toxics Law and establishes the National System of Public Policies on Drugs (Sisnad).

Since the enactment of this law in Brazil, small-scale planting and the possession of drugs for personal consumption began to subject the offenders only to socio-educational measures, one of the main changes introduced by Law 11343/06 (Article 28). Personal use is only considered a crime if it is practiced ostensibly, in places with concentration of children and adolescents.

Thus, it is understood that, with Law 11343/06, Brazilian society began a more direct confrontation of the human aspect of issues related to drug use, leaving aside policies based merely on the public security of repression and starting to adopt concepts connected with bioethics and a more contextualized positioning, mirrored mainly in the principles and objectives of Sisnad (Articles 4 and 5 of Law 11343/06).

On the other hand, trafficking continues to be considered a crime, regardless of the amount of drugs involved. Article 33 of Law 11343/06 imposes the penalty of 5 to 15 years of imprisonment for the import, export, transport, production, purchase, sale, storage or prescription of drugs or their raw materials, in that the same punishment applies to anyone who sows, cultivates or harvests plants that constitute raw material, input or chemical used for the preparation of drugs.

It is worth mentioning that Law 11343/06 brings no exact definition of drugs, merely stating that they are substances or products capable of causing dependence. The task of defining specifically these substances
was the responsibility of the National Agency of Sanitary Surveillance (Anvisa), a federal agency responsible for controlling the drugs in use in Brazil for the purpose of evaluating their effectiveness and ensuring the safety of the patients for whom they are intended.

One should emphasize that all the provisions mentioned above refer to the recreational use of drugs. However, the use of the Cannabis Sativa plant and its derivatives for medical or scientific purposes already had legal protection in Brazil, as of Decree-Law No. 54216 of Aug/27/1964 and Decree-Law No. 79388 of Mar/14/1977. In addition, a Law 11343/06 has confirmed exceptions to the restrictions, as it establishes respectively in Article 2, Sole Paragraph, and in Article 31 that “the Federal Government may authorize the planting, cultivation and harvesting of the plants referred to in the main clause herein only for medical or scientific purposes, in a predetermined place and time, by means of inspection, subject to the above-mentioned provisos” and that “one must obtain prior authorization by the competent authority to produce, extract, manufacture, process, prepare, hold, store, import, export, re-export, ship, transport, display, offer, sell, buy, exchange, assign or acquire, for any purpose, drugs or raw material intended for preparation thereof.”

Lastly, through Ordinance No. 344 of May/12/1998 (Ordinance 344/98), Anvisa defined and regulated which substances and medicines are subject to special control in the national territory.

Bioethics

Principles considered for the use of Cannabis-based medicines

In the last decade of the twentieth century, bioethics underwent greater advance in Brazil, so considered as “the systematic study of the moral dimensions - including approach, decision, conduct and moral norms - of life sciences and health care”¹, or as the “ethics applied to life, a new domain of reflection and practice that takes, as its specific objective, human questions in their ethical dimension, as formulated in the scope of clinical practice or scientific research, and, as a proper method, the application of ethical systems already established or of theories to be structured”².

This is the context in which authorization for use of cannabis-based medicines is recognized as relevant in the Country, although the importation, by way of exception, was first allowed by Anvisa only in 2014 and despite such right has only effectively materialized in 2015, with the publication of Anvisa’s Executive Board Resolution RDC no. 17 (RDC 17/2015), which defined the criteria and procedures for the exceptional importation of such medicines.

² Neves, Maria do Céu Patrão. A Bioética, 1996.
In addition, for example, the Regional Medicine Board of the State of São Paulo (through Resolution Cremesp no. 268/2014) authorized the prescription of cannabis extract containing high levels of cannabinoïd (CBD), invoking, among other issues, precisely the bioethics principles, namely:

(a) principle of beneficence, which stipulates that the medical professional has an ethical duty to maximize benefit and minimize harm to the patient;

(b) principle of non-maleficence, which determines that the performance of the physician should always cause the least possible harm to the patient;

(c) principle of justice, which obliges medical professionals to treat each person in a morally correct and adequate manner, always offering individualized treatment; and

(d) principle of autonomy, which determines that individuals capable of deliberating on their personal choices must have such a capacity for deliberation respected.

The resolutions of Medicine Boards and the various court decisions authorizing the import of cannabis-based substances for medical treatment have used these principles of bioethics together with two others. One of them is the ethical principle that the aim of all doctor’s attention should be the health of the human being, as well as the understanding that “in the history of Medicine and Pharmacy, the empirical use of plant extracts in the treatment of numerous human diseases has evolved into the isolation and synthesis of active therapeutic principles, and that, under scientifically controlled clinical trials, they can express their effectiveness and tolerance profile” and, ultimately, that Article 196 of the Brazilian Federal Constitution establishes that “health is the right of everyone and the duty of the State”.

CBD, THC and the evolution of Anvisa Regulation

In 2014, the mother of a child suffering from type 2 early childhood epileptic encephalopathy who illegally imported CBD-rich cannabis oil had her parcel seized by customs. A lawsuit was filed against Anvisa, in which the claimant obtained from the 3rd Federal Court of the Federal District a preliminary injunction that allowed the import of the extract of CBD to continue the medical treatment of her daughter. This child, at the time a five-year-old, was the first patient in Brazil to make legal use of cannabis-based products, after obtaining court authorization to import the oil.

In July 2014, the Federal Prosecution Office filed a Public-Interest Civil
Action before the 1st Federal Court of the State of Paraíba, and obtained a preliminary injunction that ordered Anvisa to authorize the import of CBD for use thereof in 16 patients with neurological diseases.

It should be noted that, until then, the exceptional import permit for cannabis-based medicines in Brazil referred only to the CBD, which was reclassified at the beginning of 2015 to C1 List (substances subject to special control) of Ordinance 344/98. The reason for this was that the CBD is only one of the 80 cannabinoid substances present in Cannabis Sativa, and that it does not produce the typical effects of the plant, which would result from another cannabinoid, Tetrahydrocannabinol (THC).

Thus, at that time, THC remained on F2 List (psychotropic substances banned in Brazil) of Ordinance 344/98 and Cannabis Sativa itself was on the list of banned plants because it was capable of originating narcotic and/or psychotropic substances, although it also originated a substance permitted under special control, the CBD, and could not be prescribed for treatment under Article 61 of Ordinance 344/98. Moreover, as a direct consequence of this status of regulation, neither import nor registration of cannabis-based medicine in general was permitted, except for the CBD.

Another step ahead took place in August 2014, as the Federal Justice of the State of Minas Gerais ordered Anvisa to authorize the import of a medicine whose composition has not only CBD but also THC. In this case, a carrier of equine tail syndrome, developed after a spondylolisthesis sequel level L5-S1, grade 4, after trying several unsuccessful treatments, started to use Cannabis Sativa in natura, thereby obtaining a significant reduction of pain and spasms of which he suffered.

As a consequence of the results achieved, and considering the impossibility of prescribing the use of the plant in natura, the doctor in charge of her treatment concluded that the best solution would be the immediate prescription of said drug, which did not have prior registration with Anvisa.

In December that year, the Regional Board of Medicine authorized the prescription of cannabinol-based medicine. In the same period, the Federal Prosecution Office filed a Public-Interest Civil Action against the Agency, before the 16th Federal Court of the Federal District, claiming, as an injunctive relief, the following, among other issues:

(a) the exclusion of THC from F2 List (psychotropic substances banned in Brazil) of Ordinance 344/98 and its inclusion in the list of psychotropic substances subject to notification of prescription;

(b) the adaptation of Article 61 and the inclusion of an Addendum at the end of E List of Ordinance 344/98 to “permit the use, possession, planting, cultivation, harvesting, exploitation, handling, manufacture, distribution, marketing, import, export
and prescription, exclusively for medical and scientific purposes, of *Cannabis Sativa* and any other species or varieties of cannabis as well as of products obtained from such plants”;

(c) provisional authorization for the import of cannabis-based products and medicines by any Brazilian, upon medical prescription; and

(d) provisional authorization for the import of seeds for planting with a view to their own medicinal use.

The judge, in turn, was of the opinion that it was precisely because of the omission of the other branches of government that the Judiciary should intervene, in order to guarantee the dignity of the human person and the right to health, both constitutional principles, using as a paradigm the preliminary decision granted in the Ordinary Action filed with the 3rd Federal Court of Brasilia, mentioned above.

Thus, the Federal Prosecution Office obtained, under a preliminary injunction, the authorization for prescription and import, for medicinal purposes, of medicines and products containing both CBD and THC, as well as scientific research with *Cannabis Sativa* L. In addition, after a motion for clarification of judgment was lodged by the Agency, it was determined that THC would remain on the F2 List, but that an Addendum would be made thereto clarifying that such use would be permitted exclusively for medicinal purposes in a supervised manner, thus allowing the substance to be accessed by the mentioned patients.

Anvisa was served subpoena and on the grounds thereof, in April 2016, it published Resolution of the Collective Executive Board RDC No. 66 to comply with such decision through the amendment of Article 61 of Ordinance 344/98.

The stance adopted by the Brazilian Judiciary has been positive towards people who are expected to benefit from cannabis for medical purposes. Such positive bias could be seen, for example, in December 2016, when three families were granted an Habeas Corpus authorizing the planting of *Cannabis Sativa* in their residences to extract its components for their own medicinal use.

In January 2017, the Agency for the first time allowed the registration in Brazil of a drug containing substances extracted from *Cannabis Sativa* (both CBD and THC). In May of the same year, the plant was included in the list of Common Brazilian Denominations, a list of official names for all substances that are or may be of interest to the pharmaceutical industry in Brazil.

This does not mean that *Cannabis Sativa* has been recognized as a medicinal plant, but only that it has the potential to be one. In other words, it is the first step for a company to file an application to register a drug made with the plant itself.
It is worth mentioning that the prescription of THC-containing medicines, although legal, can lead the doctor to face ethical-disciplinary penalty, since the Federal Medicine Board (CFM) remains prohibiting such a prescription. The Public-Interest Civil Action filed by the Federal Prosecution Office in 2014 remains with the judge for the rendering of the judgment, whereupon one shall also adjudicate on the claim for the import authorization of Cannabis Sativa seeds for planting for purposes of own medicinal use.

This last claim, in particular, gives rise to a discussion on relevant issues such as bureaucracy, the CFM bans on prescriptions, and the lack of production of such medicines in the country, which make treatments based on the vegetable more expensive. Consequently, patients who cannot afford the cost of such treatment in an attempt to assert themselves a constitutional right, may be forced to resort to clandestine planting and domestic preparation of cannabis-based products, which is an illegal conduct that can lead them to face consequences in the criminal sphere.

Given the difficult access generated by the high cost of cannabis sativa medicines, the Federal Court of Paraiba State adopted a different position and authorized, in April 2017, that an association of the city of João Pessoa, State of Paraiba, cultivate the Cannabis Sativa, for medicinal purposes. Shortly thereafter, in May of the same year, Cannabis Sativa was included in the category of “medicinal plant” in the list of Brazilian common names.

It is worth mentioning that, despite its response to the Public-Interest Civil Action of 2014, Anvisa issued in 2017 a Technical Note stating: (i) not to oppose the use of cannabis for medicinal purposes, (ii) that the regulation for the purposes of research and production of medicines is already at an advanced stage of preparation and (iii) that the agency’s concern refers to the effectiveness of control mechanisms to ensure that an occasional planting of Cannabis Sativa in Brazil has the exclusive purpose of research and production of medicines.

Among the measures taken by the Agency to advance said preparation is the creation of a specific Working Group which, in addition to having held internal meetings, has discussed the issue with health authorities from countries such as Canada, the Netherlands, Israel, the United States and Chile.

Currently, the list of cannabis products included in the simplified import procedure of the Agency contains more than 10 medicinal products.

Recently, Anvisa has adopted a new position regarding the use of medicines produced from cannabis sativa, based on what other countries already apply. Anvisa is mainly motivated by the difficulty of the population to get access to such medicines, generated by their high cost of importation, since the average monthly price of these treatments can range from R$ 2,000 (two thousand reais) to R$ 8,000.00 (eight thousand reais) and the National Minimum Wage in 2019 is R$ 998.00 (nine hundred and ninety eight reais).
In this sense, since several families were granted, through court action, the right to undertake treatments funded by the Government or health plans, Anvisa seeks to reduce the production costs of medicines, in order to enable the entire population to have access to these medicines, in addition to allowing for supply thereof by the Single Health System - SUS. This new stance also aims to comply with the provisions of the Brazilian Federal Constitution, which determines that health must be assured to all citizens.

Therefore, in June 2019, Anvisa approved two important proposals to advance the production of cannabis-based medicines in Brazil. The proposals have already been published in the Federal Official Register and will, until August 2019, be in the process of studying and receiving research contributions. These proposals were registered as follows:

- Public Consultation 654/2019 – Procedures required for registration and monitoring of Cannabis Sativa-based drugs and their derivative.

This resolution is limited to regulating the production, manufacture, export, import, distribution, trade, use and possession of narcotic drugs for medical and scientific purposes, which shall be in capsule, tablet, powder, liquid, solution or suspension form, and whose administration should be oral.

- Public Consultation 655/2019 – Technical and administrative requirements for the cultivation of Cannabis Sativa for medicinal and scientific purposes.

This resolution defines the safety and control requirements necessary for the authorization of cultivation solely for medicinal and scientific purposes of cannabis by a duly authorized legal entity.

Thus, it will be necessary to wait for the result of the Public Consultations to follow the next advances on the subject, as well as to know if after these regulations Brazil will definitely make room for this new trend of the pharmaceutical industry.

**Import**

**Simplified procedure**

Individuals wishing to import cannabis-based medicines must register on the Anvisa website. Subsequently, the product is imported individually, for their own use, through a request for electronic authorization, also made through Anvisa’s website.

The importer must submit a medical prescription determining the use of
the product based on the clinical condition and other treatments already tested. Since Anvisa does not claim the ability to evaluate the practice of medicine, there is no restriction as to which medical specialties may prescribe such medicines. The prescription must identify the doctor and contain, in addition to the patient’s name, the commercial name of the product, the dosage, the amount needed and the duration of the treatment.

A medical report should also be submitted, identifying the disease to be treated with the respective International Classification of Diseases (ICD) and the description of the case. In addition, an electronic form must be completed. The request is then sent electronically to Anvisa, which estimates an average term of 20 days for analysis and issuance of a response.

If the authorization is granted, it will be sent to the applicant’s e-mail with an electronic signature and a verification code confirming its authenticity. The Agency does not intervene in the form of acquisition of the product by the patient, which may be intermediated by a hospital entity, a governmental institution linked to the health area, a health insurance company or a civil entity legally appointed to represent the interests of patients. The only restriction is that the shipment cannot be made by the Correios (the Brazilian Postal Service), and must be carried out by Express Shipping, Import Licensing in the Integrated Foreign Trade System (Siscomex) or via accompanied baggage. The required inspection at the airport of entry into the country is incumbent upon Anvisa.

Perspectives

Thus, the discussion involving the liberation of cannabis-based medicine production and use in Brazil has already been established towards the need thereof, and today its main purpose is to balance the individuals’ constitutional right to health in relation to the duty of the State to provide therefor while, at the same time, fighting any illegal use. Anvisa, in turn, is promoting substantial breakthroughs towards definitively regulating the medical planting and use of cannabis, in order to ease patients’ access without undermining governmental control. ■

Updated on August 2019.
Overview

The legalization of recreational cannabis on October 17, 2018\(^4\) spurred an industry reminiscent of the “.com” days. Unlike other growth sectors, the production and sale of a once Schedule 1 narcotic, has raised moral, ethical and legal debates worldwide.

Compared to its predecessor vices, alcohol and tobacco, cannabis carries with it the stigma of “refer madness”, the fear of the drug cartels, and the weight of International Treaties against drug trade.\(^5\) Notwithstanding its legacy, the production and sale of cannabis has spurred an industry of vast economic proportion.

The *Cannabis Act* creates a legal and regulatory framework for controlling the production, distribution, sale and possession of *cannabis* in Canada. Implementation of the new law is a shared responsibility between the federal, provincial and territorial governments.

Responsibilities

At the federal level, Health Canada is the regulatory body overseeing the licensing for production and sale of medical cannabis throughout Canada. The sale and distribution of recreational cannabis is regulated by each provincial and territorial government throughout Canada and is done so through either a provincial government owned entity or a mix of private and public retailers.

Subject to differing provincial or territorial restrictions, adults who are 18 or 19 years or older are able to legally purchase limited amounts of fresh and dried cannabis, cannabis oil, seeds or plants from cannabis retailers authorized by the respective provinces or territories. Adults may possess up to 30 grams of dried cannabis (or equivalent in non-dried forms) in public, consume in authorized locations, grow up to 4 plants per household and share up to 30 grams with other adults.

Municipal governments were given the ability to opt out of having cannabis sold within their municipal boundaries, those who opted to allow cannabis to be produced and sold, have exercised regulatory jurisdiction over such matters as zoning, location of production facilities and restrictions as to location of dispensaries.

Perspectives

Health Canada has recently published draft regulations for the production and sale of cannabis edibles, cannabis extracts and cannabis topicals. While the sale of such products will not be legalized until the latest October,
2019, many cannabis businesses are conducting product research and development in preparation for what is expected to be another booming segment in the cannabis industry.

In a report published by Deloitte in 2018 entitled, “A society in transition, an industry ready to bloom,” the total cannabis sales in Canada are expected to exceed $7 Billion in 2019. However, the cannabis play is not for the faint of heart.

Health Canada’s regulatory framework for the production, manufacturing and sale of cannabis resembles a blueprint for nuclear disarmament. It creates a web of permitted activities shrouded with a blanket of prohibitions. Operating within this framework requires not only significant capital, but a team of highly skilled advisors who can help navigate and guide the business through all stages of the supply chain, from seed to sale.

Once cannabis edibles become legal for sale in October, 2019, including cannabis extracts, concentrates, and topicals, companies will face another layer of regulatory compliance with restrictions on ingredients and flavors, limitations on THC dosing, child resistant packaging, restrictions related to production facilities, just to name a few. Cannabis infused alcoholic products will be prohibited.

Looking beyond the Canadian border, no other industry has opened its doors so quickly to global trade in technology, IP, and Research and Development. While Canada was the first G7 nation to legalize recreational cannabis nationwide, other countries around the world are changing their regulations to embrace international trade in cannabis and its derivatives. The international arena will become a platform to share innovation and research resulting in higher quality products and competitive pricing.

International Scene

To compete in the global cannabis market, it will be critical to understand the legal and political landscape of the country in which you will do business. While Health Canada has published little guidance with respect to the requirements for importing, companies are slowly paving the road for importing from countries such as Jamaica and Colombia.

Jamaica, through Timeless Herbal Care, was one of the first countries to export cannabis oil into Canada. No doubt its similar legislative framework eased the concerns of Health Canada with respect to the safety and quality of the cannabis being imported into Canada. Less than a year later, Colombia, through Clever Leaves, received authorization

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6 Proposed Regulations and Regulatory Impact Analysis Statement (RIAS) were published in the Canada Gazette, Part 1 on December 22, 2018 for consultation.

7 Importing and exporting cannabis is permitted under the Cannabis Act for medical and scientific purposes and for industrial hemp.
from Health Canada to import cannabis for scientific purposes. If it meets Health Canada’s quality standards for medical purposes and is free of contaminants, the door may open further to position Latin America to join in the global cannabis supply chain.8

Surprisingly, Canada to date, has not been able to trade with its closest neighbour, the United States. The US has been struggling with the states jurisdictional authority to determine whether the production and sale of cannabis will be permitted in each state, and the federal government’s unwavering stance that cannabis will remain an illegal narcotic. However, change must happen for the United States to take advantage of the worldwide cannabis market.

The recent passing of the Farm Bill9 which legalized hemp and hemp products federally, may be the first step in this direction. Businesses now are eyeing CBD derived from hemp as the gateway to the Canadian market. If Health Canada determines that such products can in fact be imported on the basis it is no longer illegal, it must also grapple with the lack of uniform standards and regulations in place as to quality control standards for production.

Notwithstanding these regulatory hurdles and legal challenges, now is the time for budding entrepreneurs to start making strategic decisions to secure their place in this new international marketplace. Establishing a clear business strategy with a working knowledge of the legal and political landscape of targeted jurisdictions will help ensure success in a competitive and highly-evolving market. With Canada steaming ahead, the opportunities domestically and internationally are open to all those with a clear vision and strong constitution for change and challenge. ■

8 Columbian Company Clever Leaves To Export Cannabis Sample To Canada, Sara Brittany Somerset. Forbes, February 7, 2019, 5:00am.
9 Agriculture Improvement Act 2018 was passed by the Senate on December 11, 2018 and by the House on December 12. It received the President’s signature on December 20, 2018 and became law.

Updated on August 2019.
Reference Legislation

Brazilian Laws:

- Brazilian Federal Constitution - Article 5°, Item XLIII;
- Decree Law n° 54,216/1964
- Decree Law n° 79,388/1977

Leis do Canadá:

- Cannabis Act, (S.C. 2018, c.16)