BRAZIL

I. Introduction

1. Identify the geographic scope and limits of your answers to the questions below.

The answers take into consideration Brazil (all 26 States and the Federal District).

II. Legislation

2. Please provide links to applicable statutes and regulations.

Medical cannabis

- Ministry of Health Ordinance No. 344/1998 and its updates - the latest update was made by Brazilian National Health Surveillance Agency ("ANVISA") Resolution No. 325/2019 - (Approves the Technical Regulation on substances and drugs subject to special control):

http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=3&data=15/05/1998 and corresponding pages, as updated by ANVISA Resolution No. 325/2019.

http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=04/12/2019&jornal=515&pagina=85 and corresponding pages.

- Brazilian Narcotics Act (Law No. 11,343/2006) and its updates.
- Federal Council of Medicine ("CFM") Resolution No. 2,113/2014 – (Approves the compassionate use of cannabis for the treatment of epilepsy in children and teenagers):

http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=183&data=16/12/2014 and corresponding pages.

- ANVISA Resolution No. 17/2015 - (Defines the criteria and procedures for the exceptional importation of cannabidiol-based products in association with other cannabinoids by individuals for their own use, by prescription from a legally qualified professional for health treatment):

http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=08/05/2015&jornal=1&pagina=50&totalArquivos=332 and corresponding pages, as updated by: ANVISA Resolution No. 128/2016 and by ANVISA Resolution No. 306/2019

- ANVISA Resolution No. 327/2019 (Provides for the procedures for granting the Sanitary Authorization[1] for manufacturing and importation, establishes requirements for marketing, prescription, dispensing, monitoring and supervision of cannabis products for medical purposes).

Food (supplements)

- Pursuant to the Brazilian Narcotics Act (Law No. 11,343/2006 - Section 2), the exploration of plants and substrates from which illegal drugs can be extracted or produced is prohibited.

http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2006/Lei/L11343.htm

- Furthermore, pursuant to ANVISA Resolution No. 327/2019, Section 10, § 5°, cannabis-food is not considered cannabis-based products for medical purposes.

http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=11/12/2019&jornal=515&pagina=194

Cosmetics

- Pursuant to ANVISA Resolution No. 327/2019, Section 10, § 5°, cannabis-based cosmetics are not considered cannabis-based products for medical purposes.

1The Sanitary Authorization is a specific authorization granted by ANVISA to companies for manufacturing and importation of cannabis-based products, which has a term of five (5) years. Before such term ends, the holder of the Sanitary Authorization must require the register of the cannabis-based product as a drug before ANVISA, pursuant to the corresponding regulations.

- However, pursuant to Law No. 6,360/1976, Section 28 (Provides for the Health Surveillance to which drugs, pharmaceutical inputs and similar items, cosmetics, sanitizers and other products are subject to), cosmetics which contain medical substances, though in concentrations lower than therapeutic doses, are subject to the same rule applicable to the register of drugs before ANVISA.
- Thus, we believe a cosmetic with substances derived from cannabis could be allowed in Brazil, as long as it was registered before ANVISA, based on regulation applicable to drugs: http://www.planalto.gov.br/ccivil_03/LEIS/L6360.htm

A. Is there any pending legislation that could materially alter applicable statutes or regulations?

Yes. Along with the regulation that resulted in ANVISA Resolution No. 327/2019, an ANVISA Resolution regulating cannabis cultivation for medical purposes has been proposed and voted (Public Consultation). However, it has not been approved and did not enter into force, specifically based on the argument that ANVISA, by itself, does not have regulatory power to put out such rules.

The Ministry of Agriculture, Livestock and Supply ("MAPA") may regulate the matter soon.

B. Is there any proposed legislation that could materially alter applicable statutes or regulations?

Yes, future regulation on cannabis cultivation for medical purposes (see above), as well as the following proposed bills in the Brazilian Congress (with votes pending from legislative entities):

- PLS No. 4,776/2019: would reaffirm the possibility of the use of ***Cannabis spp***. for medical purposes and would allow cultivation for medical purposes;
- PLS No. 5,295/2019: would regulate medicinal cannabis and turn industrial cannabis (including derived products) legal;
- PL No. 7,270/2017: would turn recreational cannabis legal;
- PLS No. 514/2017: would turn the cultivation of cannabis for medical purposes, for personal use, legal.

3. Are cannabis laws in your jurisdiction pretty well settled or are they constantly changing in material ways?

Since August 2006, when the Brazilian Narcotics Act (Law No. 11,343/2006) was published, it was settled that cannabis and products derived from cannabis could only be explored if granted a federal authorization to the developer of the medical or scientific activity to which the use of cannabis was connected.

In 2014 and 2015, CFM and ANVISA, respectively, regulated the prescription (CFM Resolution No. 2,113/2014) and the patient direct importation (ANVISA Resolution No. 17/2015) of cannabidiol-based products, further developing the matter in Brazil and making way for more advances such as the publication of ANVISA Resolution No. 327/2019 in December 2019, which regulates the procedure of authorization for national manufacturing and importation of cannabis products for medical purposes. ANVISA Resolution No. 327/2019 entered into force in March 10, 2020 and will be reviewed after 3 years.

This new regulation has been allowing patients and market agents to handle cannabis products for medical purposes more safely, but further regulation is expected, including by MAPA, especially concerning cannabis cultivation for medical purposes.

The market also expects ANVISA to put out further regulation on food and cosmetics in the future.

III. General information (e.g. governing bodies, licenses, import/export)

4. What governing body regulates/licenses or enforces activities that are allowed in your jurisdiction?

Medical cannabis

The regulatory agency responsible for medical drugs in Brazil is ANVISA, thus it is also responsible for cannabis products for medical purposes, the only purpose allowed besides from scientific purposes.

As of today (January 2020), ANVISA regulates the patient direct importation of cannabidiol-based products associated with cannabinoids (since 2015 - ANVISA Resolution No. 17/2015) and is responsible for granting a

Sanitary Authorization for the activities of manufacturing and importation, and is also responsible for regulating sale, prescription and dispensing, as well as monitoring and control of cannabis-based products with medical purposes, including registering them as drugs when the holder of (a) Sanitary Authorization(s) requires so within five (5) years of its granting (since 2019 - ANVISA Resolution No. 327/2019).

Discussions remain as to which entity has the power to regulate cannabis cultivation for medical purposes, if it is ANVISA or MAPA. As stated before, along with the regulation that turned out to be ANVISA Resolution No. 327/2019 (provides for the procedures for granting the Sanitary Authorization for manufacturing and importation, establishes requirements for marketing, prescription, dispensing, monitoring and supervision of cannabis products for medical purposes), an ANVISA Resolution regulating cannabis cultivation for medical purposes had been proposed and voted, but has not been approved, specially based on the argument that ANVISA solely does not have regulatory power to put out such rules.

It is expected that MAPA shall regulate the matter soon.

Food (supplements) and cosmetics

The regulatory agency responsible for food and cosmetics in Brazil is ANVISA. However, given that in Brazil the only exception to the prohibition of the exploration of plants and substrates from which illegal drugs can be extracted or produced is the possibility of a federal authorization granted exclusively for medical or scientific purposes - Medical cannabis (Brazilian Narcotics Act - Law No. 11,343/2006, Section 2), as stated above, food containing substances derived from cannabis are not allowed.

That is confirmed by ANVISA Resolution No. 327/2019, Section 10, § 5º, which states that cannabis-food and cosmetics are not considered cannabis-based products for medical purposes.

However, as long as a cosmetic with substances derived from cannabis is registered based on regulation applicable to drugs, we believe it should be possible (Law No. 6,360/1976 - Section 28), pursuant to item II.2 above.

5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.

The recreational use of cannabis is prohibited in Brazil. As for medical purposes, the functions allowed are manufacturing, importation, marketing, prescription and dispensing, as long as the establishment that intends to perform the activities of manufacturing and importation has been granted a Sanitary Authorization by ANVISA or, if after five (5) years of such granting, the corresponding drug has been registered as such before ANVISA (ANVISA Resolution No. 327/2019).

As an exception, the cultivation of cannabis for medical purposes is permitted to some people, under special circumstances, and by a court order (i.e. ***Habeas corpus*** for parents of children with epilepsy that cannot afford the treatment).

6. What sales or use is allowed in your jurisdiction? E.g., edibles, vaping, tinctures, food additives, etc.

In Brazil, neither the cultivation nor the trade or importation of cannabis flowers is allowed (provided the exception above – ***habeas corpus*** granted to parents of children with epilepsy that cannot afford the treatment, allowing cultivation for their child). On that matter, ANVISA Resolution No. 327/2019, Section 10, § 6º, states that cannabis-based products shall not be sold as the ***Cannabis spp.*** plant or its parts, being prohibited even after being submitted to stabilization and drying processes, or cut, grinded or powdered, even if made available in any pharmaceutical arrangement.

The trade (between companies, not for personal use) and importation of extracts and finished medical products containing CBD or/and THC is permitted, provided that ANVISA grants a Sanitary Authorization to those who apply for it and meet the corresponding requirements and provided that the corresponding drug has been registered as such before ANVISA within five (5) years of after such granting. The THC-content in these products must not surpass 0.2%, except if designed to palliative care, exclusively for patients without other therapeutic alternatives and in irreversible or terminal clinical conditions (ANVISA Resolution No. 327/2019, Sections 4, 7 and 8).

Such medical products may only be purchased for personal use if prescribed by physicians (as licensed by the CFM) to patients when there is no other therapeutic alternative and may only be used by oral or nasal administration (ANVISA Resolution No. 327/2019, Sections 5, 10, ***caput***, and 13).

Furthermore, all kinds of advertisements concerning cannabis-based products is prohibited, as is the distribution of free samples and the manufacturing, in compounding pharmacies, of cannabis-based products (ANVISA Resolution No. 327/2019, Sections 12, 14 and 15).

Finally, cannabis-based products shall not be given commercial names but shall be designated based on the correspondent plant or phytopharmaceutical derivative, alongside the name of the company that holds the Sanitary Authorization (ANVISA Resolution No. 327/2019, Section 9).

A. Are the rules different for medical vs. adult recreational use?

The recreational use of cannabis is prohibited in Brazil.

B. Are retail sales of any cannabis products restricted to specific retail channels? E.g., medical dispensaries, government-owned stores, etc.

The retail of finished medical products containing CBD or/and THC is only allowed in drugstores and such drugs must be dispensed by a pharmacist, only if the patient presents his physician's prescription (ANVISA Resolution No. 327/2019, Section 53). Such establishments do not need to be government-owned.

Compounding pharmacies are not allowed to manufacture cannabis-based products for retail (ANVISA Resolution No. 327/2019, Section 15).

C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located? Applicable to all cannabis products?

No.

7. What import and export is allowed in your jurisdiction?

For importation, the importer (company) must have a Sanitary Authorization (ANVISA Resolution No. 327/2019, Sections 7 and 8) or, if the Sanitary Authorization obtained is no longer valid (5 years after it is granted), the relevant cannabis product must be registered as a drug before ANVISA.

In any case, the importer must have licenses applicable to the importation of any drug (not only cannabis-based products): a Federal Operating Permit (AFE), a Special Permit (AE) and a Certificate of Good Practices in Distribution and Storage, documents also granted by ANVISA (ANVISA Resolution No. 327/2019, Section 21, I, II and IV).

Moreover, the importer or the exporter must follow the rules established by ANVISA regarding importation and exportation of drugs in general, as well as of specially controlled products (ANVISA Resolution No. 327/2019, Sections 55 and 56): ANVISA Resolutions No. 11/2013, No. 99/2008, No. 81/2008, No. 201/2002, No. 62/2006 and their corresponding updates.

Furthermore, the importer must be registered under the Customs Participants Operations Register and Track (RADAR).

Finally, ANVISA Resolution No. 17/2015 regulates patient direct importation of cannabidiol-based products, which is possible as long as the patient is enrolled before ANVISA for such purpose and ANVISA has approved such enrollment (ANVISA Resolution No. 17/2015, Section 7).

A. Are there restrictions in relation to the countries of origin, i.e. which countries of origin are permitted?

No.

B. Please describe restrictions on the import of cannabis seeds.

Pursuant to ANVISA Resolution No. 327/2019, Section 18, the imports with purposes of manufacturing and selling cannabis-based products must correspond to a pharmaceutical input in the form of material derived from plant, a phytopharmaceutical material, in bulk or as a manufactured product.

Thus, the importation of the ***Cannabis spp.*** plant or its parts is prohibited, even after being submitted to stabilization and drying processes, or cut, grinded or powdered, even if made available in any pharmaceutical arrangement (ANVISA Resolution No. 327/2019, Section 10, § 6º).

8. Does your region distinguish between different types of cannabis products? (E.g., high or low concentrations of THC.)

A. If so, what distinctions exist?
B. If so, briefly describe the differences.

Yes.

Brazilian law distinguishes recreational cannabis (prohibited in Brazil) from cannabis for scientific and medical purposes.

The latter is allowed, although the cultivation and the trade or importation of cannabis flowers is prohibited (provided the exception of ***habeas corpus*** granted to parents of children with epilepsy that cannot afford the treatment, allowing cultivation for their child). Indeed, pursuant to ANVISA Resolution No. 327/2019, Section 10, § 6º, the cultivation, importation or trade of the ***Cannabis spp.*** plant or its parts is not allowed, even after being submitted to stabilization and drying processes, or cut, grinded or powdered, even if made available in any pharmaceutical arrangement.

The trade (between companies, not for personal use) and importation of extracts and finished medical products containing CBD or/and THC is permitted provided that the objects of importation with purposes of manufacturing and selling cannabis-based products correspond to a pharmaceutical input in the form of material derived from plant, a phytopharmaceutical material, in bulk or as a manufactured product (ANVISA Resolution No. 327/2019, Section 18).

The THC-content in these products must not surpass 0.2%, except if designed to palliative care, exclusively for patients without other therapeutic alternatives and in irreversible or terminal clinical conditions (ANVISA Resolution No. 327/2019, Sections 4, 7 and 8).

C. Identify any related laws that should be considered when answering this question.

Brazilian Narcotics Act (Law No. 11,343/2006) and updates:
http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2006/Lei/L11343.htm

ANVISA Resolution No. 327/2019
http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=11/12/2019&jornal=515&pagina=194

9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?

Identically to the case of products with a THC level of 0.2% or less, companies that import, manufacture or trade CBD products for medical purposes are subject to ANVISA Resolution No. 327/2019, thus should apply for Sanitary Authorization before ANVISA, as well as other licenses necessary to every pharmaceutical industry (AFE, AE, Certificate of Good Practices in Distribution and Storage and RADAR if an importer or Certificate of Good Practices in Drug Manufacturing – CBPF – if a manufacturer).

Differently from THC-based products, which THC-content can only surpass 0.2% if designed to palliative care, exclusively for patients without other therapeutic alternatives and in irreversible or terminal clinical conditions (ANVISA Resolution No. 327/2019, Section 4), there is not a limit CBD rate to cannabis-based products in Brazil.

The correct concentration, based on the quantity of product necessary to have an effect on the patient, shall be defined once the drug is subject to research by ANVISA, when the holder of the Sanitary Authorization applies for a drug register of the CBD-product.

IV. Patients and prescriptions

10. What specific medical conditions, if any, are recognized for treatment with cannabis?

ANVISA Resolution No. 327/2019, which provides for the procedures for granting the Sanitary Authorization for manufacturing and importation and establishes requirements for marketing, prescription, dispensing, monitoring and supervision of cannabis products for medical purposes, does not specify the conditions that shall be treated with cannabis-based products.

The only regulation which does so is CFM Resolution No. 2,113/2014, only mentioning the compassionate use of cannabis for the treatment of epilepsies of children and teenagers refractory to conventional treatments.

In any case, pursuant to ANVISA Resolution No. 327/2019, Section 5, cannabis-based products shall only be prescribed by physicians when there is no other therapeutic option in the Brazilian market (not because it is cheaper or more convenient - ANVISA Resolution No. 327/2019, Section 48, § 1°), and shall only be sold if the patient presents to the pharmacist such prescription.

11. Is there a licensed practitioner requirement in order to prescribe cannabis for medical purposes?

Although medical cannabis can be prescribed by every licensed physician (ANVISA Resolution No. 327/2019, Section 13), recent data showed that only 1,200 physicians in Brazil do prescribe it.

The indication and use of cannabis-based products are a responsibility of the physician, but the patient (or its representative) must sign a Free and Informed Consent Form (TCLE), which shall detail the specific cannabis-based product information (ANVISA Resolution No. 327/2019, Section 50, §§).

The Prescribing Physician should use Brazil's Type B Prescription for products with THC concentration up to 0.2% and Brazil's Type A Prescription (similar to that used for morphine) for products with concentrations greater than 0.2% THC (ANVISA Resolution No. 327/2019, Sections 51 and 52).

12. Are there patient registration or cardholder requirements?

Before the patient's physician prescribes them the relevant cannabis-based drug, as stated above, the patient (or their representative) must sign a TCLE, indicating they are fully aware of the prescription and effects that may be caused by the cannabis-based drug (ANVISA Resolution No. 327/2019, Section 50, §§).

Also, pharmacists are only allowed to dispense cannabis-based drugs to patients who present them the corresponding prescription signed by a licensed physician.

V. Special requirements

13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?

The cultivation of cannabis, even for medical purposes, is prohibited in Brazil.

However, in Brazil the following requirements concerning recordkeeping must be observed by the relevant interested party regarding the manufacturing, importation, prescription or dispensing of all cannabis-based products.

The holder of a Sanitary Authorization, thus a manufacturer or an importer of cannabis-based products, must keep the technical documents on which the authorization application is based up until one (1) year after the expiration date of the corresponding batch or up until five (5) years after sales authorization, whichever is the longest. In case such documents are not properly presented to ANVISA, if so requested, ANVISA may make requests it finds suitable to the manufacturer or importer (ANVISA Resolution No. 327/2019, Section 16, §§ 6 and 7).

Moreover, the company responsible for applying for the Sanitary Authorization must keep, for possible sanitary inspections, (i) the documents presented to ANVISA for such application, including all technical

documents concerning the quality levels of the product during manufacturing or importation processes, (ii) a list with all batches manufactured or imported within the relevant year (containing date of manufacture, number and size – weight/volume and number of units - of the batch), (iii) technical records and supports to changes performed on the product after the Sanitary Authorization has been granted, even if not filed before ANVISA, (iv) last versions of documents regarding control tests performed by the company, (v) stability studies reports, (vi) technical records and supports to the creating of the product and determination of the administration (oral or nasal), and (vii) Risk-Benefit Evaluation of Cannabis-based Product Periodic Report (see below) (ANVISA Resolution No. 327/2019, Section 19).

Concerning prescription, one copy of the TCLE, signed by the patient or their representative, is kept by them, and the other copy is kept by the assistant physician (ANVISA Resolution No. 327/2019, Section 50, §§ 3°).

Furthermore, the trade history of cannabis-based products in drugstores must be uploaded into the National Controlled Products Management System (SNGPC) (ANVISA Resolution No. 327/2019, Section 55).

Finally, the holder of the Sanitary Authorization must maintain a data-base for systematic, updated and periodic register of activities and information concerning received notifications on adverse events and quality deviations. From this information, the holder of the Sanitary Authorization must draw up annual Risk-Benefit Evaluation of Cannabis-based Product Periodic Reports, which may be requested by ANVISA at any time (ANVISA Resolution No. 327/2019, Section 61, §§).

14. Are special taxes imposed? On what and when?

No.

15. Are there any special rules or limitations that apply to the industry? E.g., banking, patent or trademark protection, labeling requirements.

There are no special requirements concerning banking.

Regarding patent or trademark protection, pursuant to Law No. 9,279/1996 (regulates rights and obligations in connection with intellectual property), Section 124, III, any expression, figure, drawing or any other signal contrary to moral and good manners is not subject to register as trademark.

Thus, considering that only medical cannabis is legal (with restrictions) in Brazil, and recreational cannabis and cultivation, for whatever purposes, is prohibited, the Brazilian National Institute of Intellectual Property (INPI) tends to deny register to trademarks associated with cannabis.

Furthermore, cannabis-based products shall not be given commercial names but shall be designated based on the correspondent plant or phytopharmaceutical derivative, alongside the name of the company that holds the Sanitary Authorization (ANVISA Resolution No. 327/2019, Section 9).

In addition, there are strict labeling requirements, as defined by ANVISA Resolution No. 327/2019, Sections 32 to 38:

Mandatory items on the label, package or information leaflet:

- must always be printed in Portuguese;
- must have a black stripe, in the same tone as the black color applicable to drug labels and printed horizontally, covering all sides of the product, with specific dimensions. For products containing up to 0,2% THC level, inside the stripe it must be written "SOLD UNDER MEDICAL PRESCRIPTION" and "MAY ONLY BE SOLD IF PRESCRIPTION IS WITHHOLD"; and for products containing more than 0,2% THC level, inside the stripe it must be written "SOLD UNDER MEDICAL PRESCRIPTION" and "WARNING: THE USE OF THIS PRODUCT MAY LEAD TO PHYSICAL OR PSYCHOLOGICAL ADDICTION";
- name of the product[2];
- information that it is composed of the Cannabis plant or phytopharmaceutical derivative;
- quality and quantity composition of the phytopharmaceutical substance;

2 Designated based on the correspondent plant or phytopharmaceutical derivative (ANVISA Resolution No. 327/2019, Section 9).

- the expressions "Cannabis-based Product", "This product's efficiency and safety has not been evaluated by ANVISA", (in bold), "This product shall be used only under medical orientation", "Keep out of reach of children" (in bold), "Do not exceed the use indicated by the prescriber", "Brazilian industry" (when applicable), "This product shall not be used by children under two (2) years old", "This product does not substitute the use of registered drugs", "This product has not been subject to full clinic tests that could prove its efficiency and safety", "There are uncertainties as to long-term safety of the use of Cannabis-based products as a medical therapy", "The use of a Cannabis-based product is admitted when there is a clinic condition to which it is stated that there is no other therapeutic alternative and to which scientific data state that Cannabis may be effective", "While using the product, the patient must not drive vehicles or operate machinery or perform activities that involve risks (to the patient and to third parties), for their abilities and attention may be affected", "Warning: risk to pregnant and breastfeeding women" and "This product is for individual use, being any transfer to another person prohibited";
- characteristics that prevent dispensing and administration mistakes, exchanges or misuse;
- information on the product's physical and sensory characteristics, including after reconstitution and/or dilution;
- how to use;
- administration mode;
- warnings regarding the use of the product, including adverse effects, potential interactions with food, drugs or lab exams (when known);
- corporate name, address, custumer hotline and number of the Sanitary Authorization of the company holder of the Sanitary Authorization in Brazil;
- name, enrollment number and professional class council of the technical responsible;
- manufacture date, batch number and expiration date of the product;
- specific care regarding preservation of the product, indicating the appropriate temperature range and storage conditions, pursuant to stability study;
- net weight, volume and units, as applicable;
- care in use;
- safe disposal.

Prohibited items on the label, package or information leaflet:

- designations[3];
- geographic names;
- symbols;
- figures;
- drawings or any indication that may lead to false interpretations, mistakes or confusion concerning the origin, source, nature, composition or quality of the products, ascribing them purposes or characteristics different from those they actually hold;
- terms "drug", "medicine", "phytopharmaceutical", "supplement", "natural" or any similar;
- indications as to use purposes, especially therapeutic or medical allegations (directly or not);
- images of people using the cannabis-based product or images that may lead to the association with any flavor;
- layout similar to a drug registered before ANVISA or before other international sanitary authority;
- seals or brands from any association (governmental or not), including seals concerning the quality of the product (except if required by specific regulation);
- expressions or images that may suggest one's health may be affected if they do not use the product;
- colors that may cause confusion or mistake concerning the identification of the black stripe that does need to be printed on the label.

3 As stated before, cannabis-based products shall not be given commercial names but shall be designated based on the correspondent plant or phytopharmaceutical derivative, alongside the name of the company that holds the Sanitary Authorization (ANVISA Resolution No. 327/2019, Section 9).

Optional items on the label, package or information leaflet:

- anatomic figures, with the purpose of guiding the physician or the patient on the correct use of the product;
- the product's flavor.

Finally, as stated before, all kinds of advertisements concerning cannabis-based products is prohibited, as is the distribution of free samples and the manufacturing, in compounding pharmacies, of cannabis-based products (ANVISA Resolution No. 327/2019, Sections 12, 14 and 15).

16. What is the legal status of access to financial services, including banking, merchant services, and cash handling?

There are no special requirements.

17. Is data collected to determine the social or health impact of the rules in your jurisdictions? E.g.,

A. Impact on use by underage/minors.
B. Impact on beer, wine and spirit sales.
C. Tax revenue.
D. Impact on crime, including drug and alcohol addiction.

The trade history of cannabis-based products in drugstores must be uploaded into the National Controlled Products Management System (SNGPC) (ANVISA Resolution No. 327/2019, Section 55), thus providing ANVISA cannabis-based drugs production, distribution, prescription, dispensing and consumption data (ANVISA Resolution No. 22/2014, Section 1).

In addition, the holder of the Sanitary Authorization, thus a manufacturer or an importer of cannabis-based products, must maintain a database for systematic, updated and periodic register of activities and information concerning received notifications on adverse events and quality deviations. From this information, the holder of the Sanitary Authorization must draw up annual Risk-Benefit Evaluation of Cannabis-based Product Periodic Reports, which may be requested by ANVISA at any time and when done so, ANVISA then shall have access to the health impact the corresponding cannabis-based product is causing (ANVISA Resolution No. 327/2019, Section 61, §§).

Moreover, the patient or their representative interested in patient direct importation of cannabidiol-based products must be enrolled before ANVISA for such purpose and ANVISA has to have approved such enrollment (ANVISA Resolution No. 17/2015, Section 7). Thus, ANVISA keeps track of the patient direct importations and their health conditions whilst the use of the cannabis-based drug.

VI. Risks and enforcement

18. What are the most critical issues currently facing the industry in your jurisdiction?

The regulation on manufacturing and special importation of cannabis-based products (not just finished products) is relatively new (published in December 2019 and entered into force on March 10, 2020), so there has not been any significant issue in connection with matter, apart from the fact that there cannot be a cannabis-based drug totally produced in Brazil, given that cultivation is prohibited.

19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.

Medical cannabis:

all enforcement measures applicable to drugs are also applicable to cannabis-based products: inspections for good practices in manufacturing and control, in storage, in distribution and in transport certification purposes (ANVISA Resolution No. 327/2019, Section 68).

Sanitary surveillance shall carry out inspections in all establishments involved in the production, distribution and trade chain at any time, as well as seize samples for fiscal analysis and demand the parties responsible for the cannabis-based product the presentation of information or documents requested (ANVISA Resolution No. 327/2019, Sections 69 and 70).

Also, if it is proved that a cannabis-based product is harmful to patients' health or does not meet requirements established on sanitary regulations, the sanitary surveillance may demand the product is altered, may cancel the corresponding Sanitary Authorization and/or may demand the company recalls the units all over Brazil, without prejudice to further penalties also applicable to drugs in general (e.g. warning, fine) (ANVISA Resolution No. 327/2019, Section 71).

Recreational cannabis or ***Cannabis spp***. plant (regardless of the intended purpose):

Pursuant to Brazilian Narcotics Act (Law No. 11,343/2006), Section 28, if one, for personal use, acquires, keeps, storages, transports, brings drugs with them or plants, cultivates or harvests plants from which products that can cause physical or psychological addiction can be extracted, and if not authorized to do so or not observing the authorization that has been granted to them, such person shall be (i) warned on the effects of drugs, (ii) forced to perform community service for up to five (5) months (or for up to ten months in case of recidivism) and (iii) forced to take part in an educational course or program for up to five (5) months (or for up to ten months in case of recidivism).

On the other hand, if one imports, exports, prepares, manufactures, acquires, sells, offers, etc. drugs, not for personal use, they shall be criminally prosecuted and eventually apprehended, being subject to several years in prison, depending on the crime they have committed and the circumstances involved (e.g. quantity) (Law No. 11,343/2006, Sections 33 and the following).

A. Does enforcement differ based on quantity?

Yes, concerning recreational cannabis: as explained above, less severe penalties are established if the drug is intended for personal use.

The corresponding judge shall determine if the drug is for personal use or not based on the nature and quantity of the seized substance, the site in which the "action" was developed and under which conditions as well as social and personal circumstances it was developed, and finally the behavior and criminal records of the person (Law No. 11,343/2006, Section 28, § 2).

B. Does enforcement differ based on product type?

No.

VII. Your practice and useful links

20. Tell us a little about your cannabis practice and how it interacts with other practices at your firm. Remember to include any recognition awards your firm has received in this practice area. How much experience does your firm have providing services to cannabis companies and how much interest does your firm have to grow its cannabis practice?

We are proudly the only law firm in Brazil with a Life Sciences and Healthcare Transactional and Regulatory Practice in one team, providing a comprehensive business-oriented legal assistance to clients in the industry.

The services provided by our practice group include a wide variety of matters, such as advice on regulatory issues involving company licensing; product registration; negotiation and drafting of distribution contracts; clinical research; and administrative, judicial proceedings involving sanitary authorities, among others.

Our team is widely experienced in working with regulatory agencies, including ANVISA. Recently, we have advised clients on the Brazilian regulation scenario concerning medical cannabis at the time (2019), when ANVISA Resolution No. 327/2019 had not been published yet, and possible business models considering such regulation.

In December 2019, when the ANVISA Resolution No. 327/2019 was published, TozziniFreire hosted an event about the cannabis market in Latin America to clients and other market players, in partnership with the Latin American law firm Ferrere Abogados. The meeting aimed to talk about the recent changes in Brazilian regulation and the experience Ferrere has had in Uruguay, where both medical and recreational use of Cannabis are allowed.

We are very interested providing further services concerning medical cannabis in Brazil and have been playing close attention to regulation and the market.

21. Please provide links to any firm website, blogs, reputable trade publications, or attorneys that would help others understand the state of the law in your jurisdictions.

Cannabis: decisão da ANVISA é passo regulatório sólido
Cannabis: ANVISA's decision is a solid regulatory step
December 19, 2019

Article available on Fausto Macedo Blog by the Brazilian newspaper Estadão, partners Elysangela Rabelo Maurer and Marco Aurélio Torronteguy, from our Life Sciences & Healthcare practice group, comment about the regulation approved by ANVISA that allows the sale of cannabis-derived medicines in Brazil. Beyond that, they point out how the pharmaceutical industry will adjust to the new measure.
Link: https://politica.estadao.com.br/blogs/fausto-macedo/tags/maconha/

Mercado aplaude nova regulamentação da Cannabis medicinal
Market applauds new regulation on medical Cannabis
December 4, 2019

Article authored by Marco Torronteguy, Life Sciences partner, on the online newspaper Folha de S.Paulo.
Link: https://cannabisinc.blogfolha.uol.com.br/2019/12/04/mercado-aplaude-nova-regulamentacao-da-cannabis-medicinal/

Empresários levantam investimentos à espera de um Mercado medicinal de maconha no Brasil
Entrepreneurs raise investments awaiting medical marijuana market in Brazil
May 11, 2019

In article published by the newspaper O Globo, partners Elysangela Rabelo Maurer and Marco Torronteguy spoke on the difficulty of regulating the sector.
Link: https://oglobo.globo.com/economia/empresarios-levantam-investimentos-espera-de-um-mercado-medicinal-de-maconha-no-brasil-23651901

A. Are there any relevant trade organizations?

Not yet.

B. Are there any relevant lobbying organizations?

AMA+ME *(Associação Brasileira de Pacientes de Cannabis Medicinal),* Abrace *(Associação Brasileira de Apoio Cannabis Esperança),* Apepi *(Apoio à Pesquisa e Pacientes de Cannabis Medicinal),* Acuca *(Associação Cultural Cannábica de São Paulo),* Cannab *(Associação para Pesquisa e Desenvolvimento da Cannabis Medicinal no Brasil),* SBEC *(Sociedade Brasileira de Estudos da Cannabis).*

C. Attorneys

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