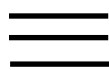


**2020**

**Global Report  
on Cannabis Policy**

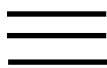




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# WLG CANNABIS GUIDE

## INTRODUCTION

We are very pleased to announce the release of the World Law Group (“WLG”) Cannabis Guide 2020.

In recent years, cannabis and products with cannabis components are one of the “hot topics” in the life sciences industry. Many countries now allow the medical use of cannabis to treat numerous conditions, including chronic pain, cancer, multiple sclerosis, and many others. Additionally, more and more countries have recently allowed the recreational use of cannabis. Finally, hemp (cannabis grown without mind-altering substances), is another burgeoning industry worldwide.

Though there are international treaties in place, the production, distribution, and consumption of controlled substances (including cannabis) are still traditionally regulated by each country individually (even within the EU). Some countries still consider cannabis a dangerous illicit substance. Thus the legal landscape on cannabis and cannabis products is very fragmented and complicated, making it hard to get involved in the cannabis industry.

The aim of this guide is to provide a brief overview of laws and policies regarding the use of cannabis in various jurisdictions. It briefly outlines information on the most important legal issues, from relevant legislation and general information to special requirements and risks.

This guide was composed by members of the WLG Cannabis Group. All information provided in this guide is up to date as of March 1, 2020 unless stated otherwise.

Please note that this guide provides general information only. This guide does not claim to be comprehensive, and laws in this area are quickly evolving. In particular, it does not replace professional and detailed legal advice, as facts and circumstances vary on a case-by-case basis and country-specific regulations may change. We would like to thank the members of the WLG Cannabis Group and all those who contributed to the preparation of this guide.

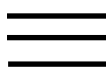
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# BRAZIL

## 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<sup>1</sup> 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](http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2006/Lei/L11343.htm)

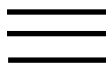
- Furthermore, pursuant to ANVISA Resolution No. 327/2019, Section 10, § 5°, cannabis-food is not considered cannabis-based products for medical purposes.

<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.

<sup>1</sup>The 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](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.

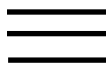
### **III. General information (e.g. governing bodies, licenses, import/export)**

#### **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, § 5<sup>o</sup>, 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.**

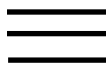
The recreational use of cannabis is prohibited in Brazil. As for medical purposes, the functions allowed are manufacturing, importation, marketing, prescription and dispensing, as long as the establishment that intends to perform the activities of manufacturing and importation has been granted a Sanitary 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, § 6<sup>o</sup>, 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).

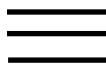
Moreover, the importer or the exporter must follow the rules established by ANVISA regarding importation and exportation of drugs in general, as well as of specially controlled products (ANVISA Resolution No. 327/2019, Sections 55 and 56): ANVISA Resolutions No. 11/2013, No. 99/2008, No. 81/2008, No.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

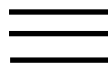
### **9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?**

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

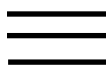
### **13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?**

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.

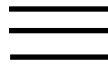
Furthermore, cannabis-based products shall not be given commercial names but shall be designated based on the correspondent plant or phytopharmaceutical derivative, alongside the name of the company that holds the Sanitary Authorization (ANVISA Resolution No. 327/2019, Section 9).

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<sup>2</sup>;
- information that it is composed of the Cannabis plant or phytopharmaceutical derivative;
- quality and quantity composition of the phytopharmaceutical substance;

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

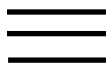


- the expressions “Cannabis-based Product”, “This product’s efficiency and safety has not been evaluated by ANVISA”, (in bold), “This product shall be used only under medical orientation”, “Keep out of reach of children” (in bold), “Do not exceed the use indicated by the prescriber”, “Brazilian industry” (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, customer 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<sup>3</sup>;
- 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.

<sup>3</sup> 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?**

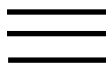
The regulation on manufacturing and special importation of cannabis-based products (not just finished products) is relatively new (published in December 2019 and entered into force on March 10, 2020), so there has not been any significant issue in connection with matter, apart from the fact that there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

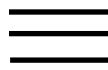
**20. Tell us a little about your cannabis practice and how it interacts with other practices at your firm. Remember to include any recognition awards your firm has received in this practice area. How much experience does your firm have providing services to cannabis companies and how much interest does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

[www.tozzinifreire.com.br](http://www.tozzinifreire.com.br)

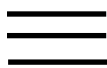
## Contributors

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# CANADA

## I. Introduction

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

The answers refer to Canada and the applicable provinces and/or territories of Canada.

## II. Legislation

### 2. Please provide links to applicable statutes and regulations.

Within Canada's constitutional division of powers, the federal Cannabis Act and its regulations govern the medical and recreational cannabis industry in Canada generally, but with much of the products' regulation in the hands of provinces and territories, including the distribution and retail sale of cannabis and related products. Among other things, the federal statutory regime regulates (\* denotes matters also subject to additional provincial and territorial rules):

- a. Possession limits\*;
- b. Trafficking;
- c. Advertisements and packaging;
- d. Impaired driving\*;
- e. Medical cannabis;
- f. Seed-to-sale tracking system;
- g. Production;
- h. Age limit\*;
- i. Public health\*;
- j. Education\*;
- k. Taxation\*; and
- l. Home cultivation\*.

Within the federally-regulated and permitted scope, each province and territory has its own regime to further regulate the cannabis industry within its respective borders. For example, with respect to the asterisked activities listed above, various provinces and territories have prescribed their own additional rules for the following:

Retail model, including locations, distribution and wholesale

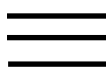
- a. Workplace safety;
- b. Public consumption;
- c. Home cultivation; and
- d. Land use/zoning.

Further, each province and territory has the authority to delegate some regulation responsibility to its municipalities. Some areas of municipal regulation include:

- a. Retail location and rules;
- b. Public consumption; and
- c. Land use/zoning.

The chart below sets out the primary Canadian federal, provincial and territorial statutes and regulations specific to the cannabis industry.

<u>Jurisdiction</u>	<u>Statute(s) and Regulation(s)</u>
Federal	Cannabis Act Cannabis Act (Police Enforcement) Regulations Cannabis Act Regulations Industrial Hemp Regulations Qualifications for Designation as Analyst Regulations (Cannabis)



<b>Jurisdiction</b>	<b>Statute(s) and Regulation(s)</b>
British Columbia	Cannabis Control and Licensing Act Cannabis Distribution Act Cannabis Licensing Regulation Cannabis Control Regulation Cannabis Control and Licensing Transitional Regulation
Alberta	Gaming, Liquor and Cannabis Act Gaming, Liquor and Cannabis Act Regulation
Saskatchewan	The Cannabis Control (Saskatchewan) Act The Cannabis Control (Saskatchewan) Regulations
Manitoba	The Safe and Responsible Retailing of Cannabis Act The Cannabis Harm Prevention Act
Ontario	Cannabis License Act, 2018 Regulation 468/18 (Regulation under the Cannabis License Act, 2018) Cannabis Control Act, 2017 Regulation 327/18 (Regulation under the Cannabis Control Act, 2017) Regulation 20/18 (Regulation under the Cannabis Control Act, 2017)
Québec	Cannabis Regulation Act Regulation respecting training on the retail sale of cannabis and information to be communicated to a purchaser in the course of a cannabis sale
New Brunswick	Cannabis Management Corporation Act Cannabis Control Act Cannabis Education and Awareness Fund Act
Prince Edward Island	Cannabis Control Act Cannabis Control Act Cannabis Control Regulations Cannabis Management Corporation Act Cannabis Management Corporation Regulations
Nova Scotia	Cannabis Control Act Newfoundland and Labrador Newfoundland and Labrador Cannabis Regulations Control and Sale of Cannabis Act
Yukon	Cannabis Control and Regulation Act Yukon Liquor Corporation designated as distributor (Regulation under the Cannabis Control and Regulation Act) Cannabis Control and Regulation (Periods for Transfer of Net Revenue by the Distributor Corporation) (Regulation under the Cannabis Control and Regulation Act) Cannabis Control and Regulation General Regulation (Regulation under the Cannabis Control and Regulation Act) Cannabis Licensing Regulation (Regulation under the Cannabis Control and Regulation Act)
Nunavut	Cannabis Act Northwest Territories Cannabis Legalization and Regulation Implementation Act

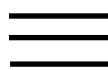
**A. Is there any pending legislation that could materially alter applicable statutes or regulations?**

No, but see #3 below.

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

No, but see #3 below.





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

The Federal laws and regulations establishing the legal and regulatory framework for the production, distribution, sale and possession of cannabis in Canada have been in place since October 2018, with the regulation of the production and sale of three new classes of cannabis, namely edible cannabis, cannabis extracts and cannabis topicals, implemented in October 2019. While no legislation is currently pending or proposed that would reasonably be expected to materially alter the applicable statutes and regulations, given the relative infancy of the industry and the regulated regime, it can be reasonably expected that the applicable rules and regulations to one or more aspects of the industry will be subject to changes, refinements and/or updates in the future.

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

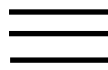
### **4. What governing body regulates/licenses or enforces activities that are allowed in your jurisdiction?**

As noted, the cannabis industry is subject to regulation by different levels of governments depending on the nature of the underlying activity. Below are the main, but is not an exhaustive list of, federal and provincial bodies that have jurisdiction over one or more aspects of the industry and related activities:

<b>Jurisdiction</b>	<b>Governing Body</b>
Federal	Government of Canada Minister of Health (Health Canada)
British Columbia	Government of British Columbia Cannabis Legalization and Regulation Secretariat The Liquor and Cannabis Regulation Branch Liquor Distribution Branch/BC Cannabis Stores Community Safety Unit
Alberta	Government of Alberta Alberta Gaming, Liquor and Cannabis Commission
Saskatchewan	Government of Saskatchewan Saskatchewan Liquor and Gaming Authority
Manitoba	Government of Manitoba Liquor, Gaming and Cannabis Authority of Manitoba
Ontario	Government of Ontario Alcohol & Gaming Commission of Ontario
Québec	Government of Québec
New Brunswick	Government of New Brunswick
Prince Edward Island	Government of Prince Edward Island
Nova Scotia	Government of Nova Scotia
Newfoundland and Labrador	Government of Newfoundland and Labrador Newfoundland and Labrador Liquor Corporation
Yukon	Government of Yukon
Nunavut	Government of Nunavut
Northwest Territories	Government of the Northwest Territories

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

In Canada, cannabis is legalized for both medical and recreational purposes. Provided that a license from Health Canada has been obtained, the following functions are allowed with respect to permitted forms of



cannabis (generally, seeds, flowers, plants, edibles, topicals and extracts):

- Cultivation (including micro and standard cultivation or nursery);
- Processing (including micro or standard processing);
- Sale for medical purposes;
- Analytical testing;
- Research.

In addition, the sale for cannabis for non-medical purposes is also permitted in each province and territory of Canada. Depending on the province or territory (including Ontario, throughout Central and Western Canada as well as Newfoundland and Labrador), the sale of recreational cannabis is done through government-owned licensed retailers or (such as Quebec, most of the Maritime Provinces and the territories) a government-owned and operated entity.

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

In Canada, subject to appropriate licensing under the Federal Cannabis Act and its regulations and the respective provincial or territorial statute and regulations relating to retail sales and consumption, any part of a cannabis plant can be sold or used for medical and non-medical purposes, including dried cannabis, cannabis oil, fresh cannabis, cannabis plants, cannabis plant seeds, edible cannabis, cannabis extracts and cannabis topicals.

As well, limited parts of cannabis or hemp plants (i.e., only parts of the cannabis and hemp plants not considered cannabis under the Cannabis Act or that are excluded from the application of the Cannabis Act, such as non-viable seeds and hemp-seed derivatives that are compliant with the Industrial Hemp Regulations) may be used in a natural health product (under the Natural Health Product Regulations) and veterinary health product (under the Food and Drug Regulation). Mature stalks that do not include any leaves, flowers, seeds or branches and fibre from such stalks are allowed in a natural health product but not in veterinary health products.

Notably, CBD, regardless of whether it is extracted from cannabis or from hemp plants, is subject entirely to the cannabis regulatory regime, and not the more permissive industrial hemp regime.

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

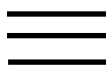
While there is generally no difference in the rules between medical and recreational use cannabis, the following are certain key exceptions:

- Importation/exportation - licenses and permits authorizing the importation or exportation of cannabis may be issued in respect of cannabis for medical but not recreational purposes.
- Sales direct to consumers - to sell medical cannabis to consumers, a prospective seller requires a sale for medical purposes license issued by Health Canada and the sale can only be done online; in contrast, to sell recreational cannabis to consumers, a prospective seller requires a license from the applicable provincial or territorial regulating body, provided the province or territory's retail regime allows for private retailing (as opposed to exclusively government-run retail sales – see #5 above).

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

Retail sales of any cannabis products are restricted to specific retail channels. Each province has their own established retail regime (see #5 above).

Medical cannabis can only be sold by holders of a sale for medical purposes license issued by Health Canada. If authorized by such license, the licensee may sell or distribute cannabis products to a client and sell or distribute cannabis products other than plants or seeds to a hospital employee for the purpose of and in connection with their duties.



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

With respect to recreational retail outlets, each province, territory and municipality in Canada has the authority to determine zoning restrictions on where such retailer may be located. Some municipalities have banned such retailers in their jurisdiction while other jurisdictions have implemented restrictions with respect to distances to schools, for example.

With respect to medical sales, which is limited to direct online distribution directly by the licensed producers to the patient, there are no such restrictions other than general restrictions on the location and licensing of the licensed production facility.

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

The Cannabis Act and its regulations prohibits exporting or importing cannabis for any purposes other than medical or scientific purposes or in respect of industrial hemp (provided that such exporter/importer is duly licensed to do so).

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

An import or export permit may be refused if the Minister has reasonable grounds to believe that the shipment to which the permit application pertains would contravene the laws of the country of export or import, as applicable, or any country of transit or transshipment. Additionally, an export permit may be refused if the Minister has reasonable grounds to believe that the shipment would not comply with the permit for importation issued by the competent authority of the country of import.

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

See #7(A) above.

**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.**

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

The Cannabis Act and its regulations distinguishes between cannabis and industrial hemp. Industrial hemp is defined as a cannabis product with 0.3% THC or less in the flowering head and leaves.

Notably however, only limited parts of cannabis or hemp plants (i.e., only parts of the cannabis and hemp plants not considered cannabis under the Cannabis Act or that are excluded from the application of the Cannabis Act, such as non-viable seeds and hemp-seed derivatives that are compliant with the Industrial Hemp Regulations) are considered to be industry hemp and regulated under Industrial hemp is regulated under the Federal Industrial Hemp Regulations.

In addition, as noted in #6 above, CBD, regardless of whether it is extracted from cannabis or from hemp plants, is subject entirely to the cannabis regulatory regime, and not the more permissive industrial hemp regime.

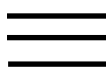
**9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?**

CBD is regulated in the same manner as THC under the Cannabis Act and its regulations and is not regulated under the Industrial Hemp Regulations, regardless of its source.

## IV. Patients and prescriptions

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

There are no specific medical conditions stipulated in or specifically recognized for treatment in the cannabis statutes or regulations.



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

Medical cannabis can be prescribed by a licensed health care practitioner, subject to the provincial or territorial health care licensing authority guidelines and policies.

### **12. Are there patient registration or cardholder requirements?**

There are no patient registration or cardholder requirements, however, similar to the regime for prescription drugs, the patient must be authorized by their licensed health care provider to obtain cannabis for medical purposes.

## **V. Special requirements**

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

Yes. Recordkeeping is regulated pursuant to the Cannabis Tracking System Order issued under the Cannabis Act and applies to (i) a holder of a federal licence for cultivation, a license for processing or a licence for sale for medical purposes that authorizes the possession of cannabis, (ii) a public body authorized under an act of a province to sell cannabis; and (iii) persons other than a public body authorized under an act of a province to sell cannabis.

These requirements apply to all cannabis and cannabis products, which includes dried or fresh cannabis, oil, plants, plant seeds, edibles, extracts and topicals, as well as a cannabis accessory that contains such cannabis after it has been packaged and labelled for sale to a consumer at the retail level, but does not include cannabis or a cannabis accessory that is intended for an animal or a drug containing cannabis.

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

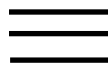
Yes. A federal excise duty is payable by a licensed cannabis producer when the cannabis products they package are delivered to a purchaser. Each province and territory has imposed, with the exception of Manitoba, an additional excise tax on a cannabis product packaged by a cannabis licensee when delivered to a purchaser. A summary of such taxes is available online.

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

Yes. Some key examples include:

**Packaging and Labeling Requirements** – The Federal Cannabis Regulations set out requirements pertaining to how cannabis and cannabis products must be packaged and labeled prior to sale, distribution or export. Specifically, the Cannabis Regulations require plain packaging and labeling for all cannabis products with restrictions on logos, colors and branding. Cannabis products must also be packaged in a child-resistant container and be labeled with the standardized cannabis symbol, the mandatory health warning message and include specific product information (e.g., brand name of the cannabis product, class of cannabis, THC and CBD information, licence holder information).

**Advertising and Promotions Rules** – The Federal Cannabis Act and the Cannabis Regulations contain a number of provisions relating to the prohibition on promotion of cannabis, cannabis accessories and services related to cannabis. For example, it is prohibited to promote cannabis or a cannabis accessory or any service related to cannabis including (i) by communicating information about its price or distribution; (ii) by doing so in a manner that there are reasonable grounds to believe could be appealing to young persons; (iii) by means of a testimonial or endorsement, however displayed or communicated; (iv) by means of the depiction of a person, character or animal, whether real or fictional; or (v) by presenting it or any of its brand elements in a manner that associates it or the brand element with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring. Additionally, it is prohibited to promote cannabis in a manner that is false, misleading or deceptive, promote using foreign



media, display the brand element of cannabis in a promotion that is used in the sponsorship of a person, entity, event, activity or facility, among other prohibitions.

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

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 under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

Yes. Federally, Statistics Canada collects data relating to a number of categories including, health, justice, economy, and prices and is available online.

## VI. Risks and enforcement

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

As the industry and the regulatory regimes remains in relative infancy, critical issues include (i) the effectiveness of the regulatory regimes in light of the government's stated policy objectives, including protection of children and combating the black market; (ii) access to capital and financial services to allow industry participants to succeed; (iii) supply issues, including types of cannabis products; and (iv) health and safety considerations given the general lack of research on the effect of cannabis products, including the efficacy of cannabis in various forms.

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

**A. Does enforcement differ based on quantity?**

**B. Does enforcement differ based on product type?**

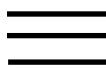
Medical and recreational cannabis is legalized and regulated in Canada. Federal, provincial and territorial governments share responsibility for overseeing the cannabis regulation system. Criminal penalties exist for those acting outside of the legal framework, such as organized crime. Penalties are set in proportion to the seriousness of the offence. Sanctions range from warnings and tickets for minor offences to criminal prosecution and imprisonment for more serious offences. Some offences specifically target people who make cannabis available to youth. For example, possession over the legal limit can range from a ticket (for small amounts) up to five years less a day in jail (for large amounts). Additionally, further penalties related to cannabis-impaired driving are also included in provincial motor vehicle and/or impaired driving statutes.

## 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?**

Goodmans has a leading cannabis practice in the corporate/commercial field, having been actively involved in the industry from its beginning. Our corporate cannabis lawyers have an extensive knowledge of the various players in the industry and have provided strategic business advice on governance, financing, licensing, regulation, capital markets, mergers and acquisitions and real estate matters. Our clients include start-ups, importers and exporters, and financial institutions related to the cannabis industry.

In addition, Goodmans is uniquely positioned with its extensive regulatory, health and intellectual property practices to advise new and existing market entrants. In particular, given our extensive



work with respect to “traditional” pharmaceuticals regulated under the Food and Drugs Act and its associated Regulations (legislation used, in part, as the model for the Federal Cannabis Act Regulations), Goodmans uniquely understands the industry, is equipped to address regulatory concerns that may arise, and know how to best protect and enforce our clients’ intellectual property. This includes matters such as licensing and regulation in the industry’s preliminary stages and future issues that may arise with regulators and competitors, including with respect to labelling and packaging, patent and trademark applications and prosecutions and the protection of trade secrets and confidential information.

**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.**

**A. Are there any relevant trade organizations?**

Yes. Some examples include:

- [Canadian Chamber of Commerce, National Cannabis Working Group](#)

**B. Are there any relevant lobbying organizations?**

Yes. Some examples include:

- [Cannabis Council of Canada](#)
- [Association of Canadian Cannabis Retailers](#)
- [Hill+Knowlton Strategies](#)

## Contributors

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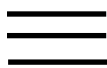
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# CHINA

## I. Introduction

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

People's Republic of China ("PRC")

Please note that, in China, marijuana is strictly prohibited under the PRC Criminal Law and the PRC Anti-Drug Law. Hemp (industrial cannabis) is only legalized in Yunnan Province (in southwest China) and Heilongjiang Province (in northeast China) in terms of planting, processing and sale. Besides, Jilin Province (also in northeast China) is expected to be the third province to legalize this industry.

## II. Legislation

### 2. Please provide links to applicable statutes and regulations.

#### National Legislations

- Article 347 to 357 of the PRC Criminal Law
- The PRC Anti-Drug Law
- Regulation on the Control of Narcotic Drugs and Psychotropic Drugs ("Regulation")
- Amendments to the Regulation in 2013
- Amendments to the Regulation in 2016
- Variety Directory of Narcotic Drugs and Psychotropic Drugs
- Negative List for Market Access

#### Local Regulations

- Regulations of Yunnan Province on License for Planting and Processing Industrial Cannabis
- Chapter IV of the Regulations of Heilongjiang Province on Anti-Drug

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

No.

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

No. Please note that the competent authorities of Jilin Province have proposed amendments to the current Regulations of Jilin Province on Anti-Drug to legalize the planting, processing and sale of hemp in the territory of Jilin Province, which may make the province the third to legalize hemp industry.

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

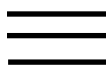
Overall, cannabis laws are not well settled and may evolve from time to time. However, relevant regulations in Yunnan Province are quite settled.

## 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?

#### Yunnan Province

The provincial level Public Security Department ("PSD") is responsible for issuing the license to plant industrial cannabis for purposes of scientific research and seed reproduction.



Local Public Security Bureau (“PSB”) at county level is in charge of 1) issuing the license to plant industrial cannabis for purpose of industrial raw material provision; 2) issuing the license to process the flower and leaf of industrial cannabis; and 3) record filing of industrial cannabis planting for gardening or folk custom purposes.

#### Heilongjiang Province

Department of Agriculture and Rural Affairs of Heilongjiang Province (“DARA”) is responsible for the variety certification of industrial cannabis seeds.

Local PSB at county level is responsible for record filing of the planting, processing and selling of industrial cannabis.

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

Growing, processing and selling of industrial cannabis are allowed in Yunnan Province and Heilongjiang province.

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

Industrial cannabis is mostly used in the PRC for industrial purposes such as using its fiber to produce paper, rope, fabrics, canvas, sails, etc., as well as construction materials. The root and leaf of industrial cannabis can also be used in traditional Chinese medicine without processing. Certain extract (CBD) of industrial cannabis can be used in cosmetics. Use of CBD or THC extracts in edibles, vaping, tinctures, medicine or food additives is currently not allowed.

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

Yes. Under PRC law, recreational use is strictly banned. Though there are no laws prohibiting the use of THC or CBD extracts for medical use, currently no medicine containing THC or CBD has been approved to enter into the market.

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

No. As discussed, adult recreational use and medical use is still highly regulated, which means no retail sales of cannabis products in this regard.

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

No. As discussed, adult recreational, wellness and medical use is still highly regulated. However, there are zoning restrictions on the planting site of industrial cannabis in Yunnan Province. Pursuant to the Regulations of Yunnan Province on License for Planting and Processing Industrial Cannabis, if the planting of hemp is for industrial material provision purpose, the planting site shall be more than 1 km away from tourist attractions and expressways; in case of planting site for seed reproduction, no non-industrial hemp plant within 3km around the planting site is allowed.

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

The import and export of THC and CBD is subject to the import or export license for psychotropic substances.

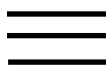
The import and export of hemp seeds is subject to the regulations and permits of competent agriculture and rural affairs authority.

Furthermore, raw or retted hemp, hemp processed but not spun, hemp crude fiber, waste hemp and hemp yarn are allowed to be imported and exported.

#### **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.**

Hemp seed is specified in the Negative List for Market Access. To import hemp seed, the importer shall meet certain requirements including i) the approval issued by competent agriculture and rural affairs authority; and ii) importing only through designated ports of entry after passing the quarantine inspection.

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

Yes.

**A. If so, what distinctions exist?**

Depending on the concentrations of THC.

**B. If so, briefly describe the differences.**

Cannabis with THC content over 0.3% will be classified as marijuana, the planting, and process of which is strictly prohibited. While still highly regulated, the planting, process and selling of industrial cannabis which contains less than 0.3% of THC, have been legalized in Heilongjiang province and Yunnan Province.

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

Regulations of Yunnan Province on License for Planting and Processing Industrial Cannabis

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

Despite high medical value, CBD has not yet been approved to be added as a major active ingredient into medicine in China. Though CBD/THC is recognized in China as major active ingredient of psychotropic substances, currently in Chinese market, no CBD/THC psychotropic substances have been approved to be produced or used.

CBD is not listed as a food additive so far under PRC law.

Hemp seed, oil and leaf extracts are listed as approved materials used in cosmetics. However, the law is silent on whether the extracts refer to CBD and also on the concentration of CBD.

## IV. Patients and prescriptions

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

Despite its psychoactive nature and narcosis effect, in China cannabis has not yet been permitted to be used in medical practice.

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

N/A

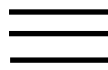
**12. Are there patient registration or cardholder requirements?**

N/A

## V. Special requirements

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

Yes. In Yunnan Province, entities engaged in planting or processing of industrial cannabis shall be equipped with a sound recording system to keep relevant information (including source, storage, disposition, sale, etc.)



on record for at least three years. While in Heilongjiang Province, entities engaged in planting or processing of industrial cannabis shall report to local PSB at county level within 10 working days following any planting, processing or selling activities with respect to the source, purposes, quantities, sales, etc.

**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.**

No special rules or limitations except that, in Yunnan Province, technology transfer by companies licensed to process flower or leaf of industrial cannabis shall be reported to the competent public security authority on a semi-annual basis.

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

No special requirements in terms of financial service to such industry. However, in Yunnan and Heilongjiang, industrial cannabis is an encouraged business sector supported by local governments. In this respect, financing may be less difficult.

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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

No. As discussed, only industrial cannabis with less than 0.3% THC is allowed in China (and in Yunnan and Heilongjiang only) and is mainly for industrial purposes. Therefore, there is no meaningful social or health impact of the rules in China.

## VI. Risks and enforcement

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

Overall, the cannabis industry is still highly regulated in China. The scope of legitimate use of CBD, one of the most valuable extracts of industrial cannabis, is very limited and unspecified. As mentioned above, CBD has not yet been approved to be added as a major active ingredient into medicine or food additive in China, in despite of its high medicinal value and wellness value. Besides, CBD's use in cosmetics remains unclear and unspecified.

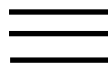
**19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.**

Strict enforcement of marijuana throughout the country and strict enforcement of industrial cannabis in regions other than Yunnan Province and Heilongjiang Province; industrial cannabis legalized but strictly regulated in Yunnan Province and Heilongjiang Province.

**A. Does enforcement differ based on quantity?**

Yes, pursuant to the PRC Criminal Law, the criminal responsibility for the drug-related crimes normally depends on the quantity of drugs, including cannabis.

Any person who smuggles, trades, transports, carries, produces or illegally possesses marijuana may be criminally punished. Depending on the quantities, the depending on the quantity, the punishment could range from fixed term imprisonment (or criminal detention or public surveillance) of no more than 3 years to life imprisonment, in addition to fines.



In addition, whoever illegally cultivates cannabis shall be forced to uproot the plants, and in the event that the quantity of the cannabis plants exceeds 5,000 but less than 30,000, the offender could be sentenced to a fixed term imprisonment (or criminal detention or public surveillance) of no more than 5 years, in addition to fines. In case the quantity exceeds 30,000, the imprisonment could be more than 5 years. However, voluntary uprooting of the plants before harvesting shall be exempted from punishment.

Illegally trading, transporting, carrying or possessing hemp seeds which have not been inactivated may be criminally punished for a fixed term imprisonment (or criminal detention or public surveillance) of no more than 3 years.

**B. Does enforcement differ based on product type?**

Yes, enforcement does vary with different product types, generally, higher concentration of THC, stricter the enforcement. But it also varies with regions.

## 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?**

Given the various legal impediments in this industry, there are few law firms specializing in this practice. However, our law firm, as one of the largest full-service law firms, has relevant professional teams focusing on government regulations and business development of cannabis. We are of the view that industrial cannabis is still in the start-up stage in China with enormous potential and we are very much delighted to take a part in this promising business sector.

We are representing a foreign client to set up two joint ventures in China partnered with a qualified Chinese company to engage in industrial cannabis covering full industry chain, including import and cultivation of hemp seeds, planting of hemp, extraction of CBD and research and development of CBD application (initially in cosmetics which is the only legitimate CBD application so far in China).

**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.**

- Drug Control Authorities: there shall be strict regulations on the application of industrial cannabis
- A Brief Introduction to China's Regulatory Regime for Cannabis
- Regulatory Framework of Industrial Cannabis
- Introduction to CBD Policies in China

**A. Are there any relevant trade organizations?**

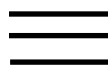
China Bast and Leaf Fibers Textile Association

**B. Are there any relevant lobbying organizations?**

No.

## Contributor

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# COLOMBIA

## I. Introduction

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

The following information is applicable and limited to the territory of Colombia.

## II. Legislation

### **2. Please provide links to applicable statutes and regulations.**

In the following link you can find the applicable regulation for cannabis in Colombia: <https://www.minjusticia.gov.co/Cannabis-Con-Fines-Medicinales-y-Cientificos/Normatividad-Cannabis>.

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

N/A

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

Yes. There is a Decree project that might alter enforcement and current applicable regulation regarding the actual enforcement of non-psychoactive cannabis and its derivatives.

It is important to point out that by means of Decree 2106 of 2019 all the faculties that the Ministry of Health had related to the Cannabis Transformation License ("*Licencia de Fabricación de Derivados de Cannabis*") were transferred to the Colombian Health Registration Institute (INVIMA) -Article 85-.

In the following link you may access to the mentioned Decree: <https://dapre.presidencia.gov.co/normativa/normativa/DECRETO%202106%20DEL%2022%20DE%20NOVIEMBRE%20DE%202019.pdf>

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

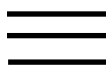
Colombia has a well settled cannabis regulation in the types of licenses, permitted uses of the cannabis seeds, plants and derivatives. Notwithstanding, and as a result of a developing industry such regulation might suffer changes specially as to the import/export process, obtention of quotas for sowing psychoactive cannabis, finished product regulation and response times from the governing bodies.

## 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?**

The following governing bodies regulates the activities related to cannabis industry:

- **Ministry of Justice:** issuance, vigilance and administration of cannabis -psychoactive and no psychoactive- cultivation licenses;
- **Ministry of Health:** issuance, vigilance and administration of the quotas for the cannabis transformation license;
- **INVIMA (National Institute for the Vigilance of Medicines and Foodstuff):** issuance, vigilance and administration of cannabis transformation licenses; and,
- **Agronomical Colombian Institute ("ICA"):** issuance, vigilance and administration of registrations as a seed producer, importer and the corresponding Agricultural Evaluation Tests ("*PEA: pruebas de Evaluación Agronómica*").



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

By means of Decree 613 of 2017 the Government enacted the current regulation for growing/harvesting, processing/transforming, internal commercialization and import/export of cannabis for medical and investigation purposes. Recreational purposes are not allowed.

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

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

Recreational use is not allowed in Colombia.

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

For finished products with a composition of more than 1% of THC, the product should be commercialized by an authorized and registered entity. Such registration is granted by INVIMA. Moreover, such entity must be a titleholder of a cannabis transformation license and should be registered before the Nacional Narcotics Found (hereinafter, "*Fondo Nacional de Estupefacientes – FNE*").

For CBD dominant products, the commercialization is not restrained for any specific entities, but the product should hold the corresponding health registration before INVIMA. (example: facial creams made from CBD extracts)

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

There are no zoning restrictions in place.

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

Decree 613 of 2017 regulates the import and export conditions for cannabis seeds, plants, flower or any derivate product (hereinafter, "Cannabis").

To import psychoactive Cannabis to the Colombian territory the company should obtain the corresponding import license before VUCE ("*Ventana Única de Comercio Exterior*") and should be registered before the FNE ("*Fondo Nacional de Estupefacientes*") and ICA. No license or authorization is required to import CBD predominant cannabis products (non-psychoactive).

To export cannabis from the Colombian territory, the corresponding company should obtain an authorization from the Ministry of Justice (cannabis seeds and/or plants) or FNE (finished products and/or cannabis derivatives products).

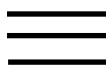
The authorization for cannabis export should be requested through the Window of Foreign Trade ("*Ventanilla Única de Comercio Exterior*" – VUCE). The applicant must hold the corresponding cannabis seeds license and the registration before ICA as a cannabis seeds exporter.

The authorization for the export of cannabis seeds and/or plants is only granted for scientific and investigation purposes.

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

As to the date of, there is no enacted restriction of the countries of origin as long as the provider company complies with the Colombian cannabis regulation and the specifications of the seeds and/or plants required by ICA.

Notwithstanding, due to an internal decision by ICA, imports are only being allowed from BULGARIA and CANADA.



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

As mentioned in point A., no restriction of the countries of origin has been enacted as long as the importer complies with the Colombian cannabis regulation and the specifications of the seeds and/or plants required by ICA.

Notwithstanding, due to an internal decision by ICA, imports are only being allowed from BULGARIA and CANADA.

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

Yes.

**A. If so, what distinctions exist?**

Psychoactive Cannabis and Non-psychoactive Cannabis.

**B. If so, briefly describe the differences.**

- Psychoactive Cannabis: more than 1% of THC in the flower – in dry weight; and,
- Non-psychoactive Cannabis: less than 1% of THC in the flower – in dry weight.

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

The distinction between psychoactive and non-psychoactive cannabis is defined by means of article No. 2.8.11.1.3 of Decree 613 of 2017.

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

As stated under article 2.8.11.3.2 of Decree 613 of 2017 if the final product holds the corresponding health registration (issued by INVIMA) there are no further legal requirements for the commercialization of CBD predominant product within the Colombian territory.

## IV. Patients and prescriptions

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

There is no specific regulation for medical treatments with cannabis.

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

No. As long as the practitioner holds a registered degree as a doctor, the person is able to prescribe cannabis for medical purposes.

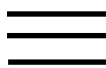
**12. Are there patient registration or cardholder requirements?**

No.

## V. Special requirements

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

Yes. As stated under article 2.8.11.1.2 of Decree 613 of 2017 cannabis license holders must record all the activities related to the seed sowing, growing, cultivation and commercialization of cannabis within the Colombian territory. This rule is applicable for both psychoactive and non-psychoactive cannabis.



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

There is no specific tax imposed for cannabis companies.

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

In terms of special rules or limitations, it is important to mention that the general applicable rules to cannabis industry are restricted considering real estate. If the holder of a cannabis license is interested in cultivating in a different location to the location associated to the cannabis license, it will require to complete a process that can take more than a month, since it is considered as an amendment to the license. This situation is common with owned and leased real estate.

In regard to banking issues, the industry is facing a vast contingency since national banks are not opening bank accounts and/or lending money to companies whose primary activity is related to the cannabis business.

There is no limitation in regards to patent or trademark protection.

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

The access to financial services for cannabis industry is not limited by law. However, in practice the access has been limited, specially to foreign investors seeking to initiate cannabis operations in Colombia. The financial institutions are still reluctant to receive funds for this industry, but progressively foreign banks with presence in Colombia are starting to become more flexible. No regulation has been enacted considering this practical limitation to the industry.

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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

As of the cut-off date, no access has been granted and/or no information has been published in regard to data collection to determine the social or health impact of the cannabis rules in Colombia. However, data protection legislation applies for any sector and/or companies which process personal data which include sensitive data as clinic history, underage-related information, etc.

## **VI. Risks and enforcement**

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

- (i) Huge backlog within the governing bodies in the issuance of cannabis licenses;
- (ii) Huge backlog in the issuance of quotas for sowing psychoactive cannabis; and,
- (iii) Financial institutions are reluctant to open bank accounts and receiving resources from abroad destined for the cannabis industry.

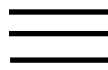
#### **19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization**

**A. Does enforcement differ based on quantity?**

The enforcement does not differ based on quantity.

**B. Does enforcement differ based on product type?**

The enforcement does differ based on product type. As mentioned, the regulation for psychoactive (+1% of THC) and non-psychoactive (-1% of THC) cannabis differs due to the psychoactivity and control of the predominant cannabidiol of the plant/flower.



## 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?**

Our Firm has grown significantly in the Cannabis practice and started to gain more experience since 2018. We initiated by representing companies in the process of obtaining cannabis licenses and then advised companies and banks on corporate and M&A aspects. In addition, our environmental and real estate practices gained ground to provide a more comprehensive advice to our clients.

We offer a new perspective to the way legal counsels operates. We act as a strategic advisor so that our clients get to become the go-to company for the government in helping develop the cannabis industry in Colombia, Chile, Peru and Spain (hereinafter, "Target Countries"). For such purpose, our Firm offers the following services:

- (i) A specialized interdisciplinary team (Corporate, Regulatory, M&A, Intellectual Property, Tax, Real Estate, Environmental, among others), to advice a Cannabis company day to day operations in the Target Countries;
- (ii) We have very strong relations with the different authorities that interact in the Cannabis industry in the Target Countries and are building the bridges toward the interaction between these authorities (Ministry of Health, Ministry of Justice, ICA, INVIMA, DIAN, among others);
- (iii) We are very well-known for providing a very practical approach to the Cannabis industry, which developing requires an out of the box thinking;
- (iv) Our PPU brand means transparency, excellence and the very best legal service. Those elements are key on a growing Cannabis industry with a difficult history in Colombia;
- (v) Our offices in Peru, Colombia, Chile and Spain hold more than 1000 lawyers at your disposal. That means we are a one-stop shop to handle all your legal needs in the Target Countries; and,
- (vi) Our Firm has always been a pioneer in research and promotion of new legislation for new and attractive topics for the Market, such as the Cannabis industry.

Despite being a fresh and developing industry, our Firm has been able to accumulate the following relevant experience on the Cannabis sector:

**CONSORCIO DE BANCOS:** Counsel to a consortium of banks in the issuance of shares of a company that supplies medical marijuana.

**TERRAGRANDE S.A.S.:** Counsel to Terragrande S.A.S in obtaining licenses for the cultivation of cannabis. Our advisory included meetings with the Ministries involved, the preparation of the legal documentation required to request the licenses, and general assistance in additional requirements.

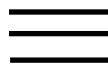
**PROMOTORA TRIPLE A S.A.S.:** Counsel to Promotora Triple A S.A.S. in relation to the contracts for the investigation and the granting of legal opinions to investors.

**INVERSIONISTAS EXTRANJEROS:** Counsel to foreign investors in the acquisition of 51% of a Colombian company specialized in the production of medicinal cannabis and extracts of cannabidiol. This company produces and manufactures cannabis on a large scale, including THC, CBD, CBG, among others.

**FCM GLOBAL S.A.S:** Counsel to FCM Global SAS with the contracts required for the hiring of the scientist in charge of agronomy matters and the research of the cultivation areas.

Counsel to **FCM Global SAS** with the legal opinions regarding the potential financiers interested in investing in the medicinal cannabis cultivation project in Colombia and manufacturing derivatives, in relation to the legality of the business.





Counsel to FCM Global SAS in the intellectual property and patents matters associated to the manufacture of medicinal cannabis derivatives.

**INMOBILIARIA BONDUE S.A.:** Counsel to Inmobiliaria Bondue S.A.S. for entering into a joint investment project with the Canadian company Avicanna Inc. for strengthening and growth of the cultivation of 100% sun grown cannabis.

**ECONNABIS S.A.S – PLENA GLOBAL HOLDINGS:** Counsel to ECONNABIS S.A.S (Plena Global Holdings) in the intellectual property and regulatory matters associated to the medicinal cannabis business in Colombia.

**CONFIDENTIAL:** Counsel to several companies in relation to the analysis and application of the standards that regulate the medicinal and therapeutic use of cannabis and its derivatives for the development of its operations in the field for production, importation, research and marketing.

We have also advised a multinational company in the process of designing the strategy for the launch and subsequent commercialization of a CBD (Cannabidiol) based investigational product, including, particularly (i) the possibility of the product being classified (scheduled) as a narcotic substance and, therefore, being subject to the relevant controlled drug restrictions in Spain; (ii) the procedure for establishing such controlled drug status and how the company may participate in the process; and (iii) the impact of such potential controlled drug status on movement of product (import/export). We have also advised on the availability of compassionate use / named patient programs for CBD based products in Spain and on possible distribution models in cooperation with third parties.

**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.**

The official website of our Firm is <https://www.ppulegal.com/>. The following attorneys have the necessary expertise to provide any advice related to the cannabis industry:

**Mauricio Patiño** – Partner (IP & Regulatory Practice);  
**Hernando Padilla** – Partner (M&A Practice);  
**Nicolás Tirado** – Partner (M&A Practice);  
**Gerardo Flórez** – Principal Associate (IP & Regulatory Area);  
**Paula Buriticá** - Principal Associate (M&A Practice) ;  
**Alexander Acosta** - Principal Associate (Environmental Area);  
**Laura Grisales** – Senior Associate (M&A Area); and  
**Diego Quintero** - Junior Associate (IP & Regulatory Area).

**A. Are there any relevant trade organizations?**

N/A

**B. Are there any relevant lobbying organizations?**

ASOCOLCANNA is one of the most reputable organizations of the cannabis industry with more than 20 active members. Its website is the following: <http://asocolcanna.org>.

RED DE EMPRENDEDORES CANNÁBICOS is one organization focused on entrepreneurship companies within the cannabis industry. Its website is the following: <https://redcannabicos.org>.

## Contributors

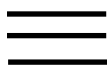
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# GERMANY

## I. Introduction

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

The answers refer to Germany.

## II. Legislation

### **2. Please provide links to applicable statutes and regulations.**

#### Medical cannabis

- [German Narcotics Act \("Betäubungsmittelgesetz", "BtMG"\)](#)
- [German Medicines Act \("Arzneimittelgesetz", "AMG"\)](#)
- [Volume V of the Social Insurance Code \("Fünftes Buch Sozialgesetzbuch", "SGB V"\)](#)

#### Food (supplements)

- [Regulation \(EU\) 2015/2283 on novel foods](#)
- [Novel Food Catalogue](#)

#### Cosmetics

- [Regulation \(EC\) 1223/2009 on cosmetic products](#)

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

No.

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

No.

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

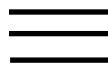
Since March 2017 the laws in connection with (medical) cannabis are pretty well settled.

## 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 German Federal Institute for Drugs and Medical Devices ("Bundesinstitut für Arzneimittel und Medizinprodukte", "BfArM") is responsible (1) for the issuing of licenses to cultivate, produce, trade, import, export, deliver, sell or buy narcotics ("narcotics license"; Section 3 BtMG) and (2) for the tender process regarding the cultivation of cannabis.



An import authorization for medical cannabis (Section 72 AMG) must be granted by the competent authority of the state in which the importer's company is located. The manufacturing permit (Section 13 of the German Medicines Act) and the wholesale permit regarding medicinal products (Section 52a AMG) is issued by the competent authority of the state in which the business premises are located.

Food (supplements) and cosmetics

The competent authority of the state in which the importer's company is located is also responsible for the monitoring of consumer products such as cosmetics and food (supplements).

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

In Germany, only cannabis for medical purposes is legalized, not for recreational use. However, the Berlin state government is currently discussing a pilot project to allow the provision of recreational cannabis to adults under certain circumstances.

Provided that a respective license from the BfArM has been obtained, cultivating, producing, trading, importing, exporting, delivering, selling, marketing and buying is permitted under German Law (Section 3 of the German Narcotics Act).

However, the cultivation of medical cannabis in Germany is subject to a public tender process. Only the companies who won the public tender process are entitled to cultivate medical cannabis in Germany.

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

In Germany, cannabis flowers and extracts are available for medical purposes. It is recommended by the BfArM to inhale cannabis via special vaporizers.

Furthermore, finished medicinal products with THC and/or CBD are available for medical use.

Products with CBD are offered in various forms: cosmetics, food, food supplements and others. The THC-content in these products must be below 0.2%. However, the legal status of these products is unclear at the moment /please see below under no 17.

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

Recreational use is not permitted.

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

Medical cannabis (in the form of dried blossoms, extracts and finished medicinal products) can only be sold in pharmacies.

Products with CBS and a THC content under 0.2% do not fall under the German Narcotics Act and do not have to be sold in pharmacies.

**C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located?**

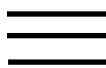
**Applicable to all cannabis products?**

No.

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

The import and export of (medical) cannabis requires a narcotic license (Section 3 BtMG). In addition, the import of medical cannabis requires an import authorization (Section 72 AMG).

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



Prior to importing medical cannabis, the importer has to verify that the cannabis originates from a cultivation under state control in accordance with the UN Convention. According to the German Narcotics Act, only such cannabis can be imported into Germany that has a recognized medical purpose in the country of origin and is subject to control in accordance with the aforementioned requirements under international law; in particular, a national opium agency as outlined in the UN Convention (like the Cannabis Agency in Germany) has to exist in the country of origin.

Currently only medical cannabis from Canada and the Netherlands is imported to Germany on regularly basis. First licenses were issued to Uruguay, Colombia and Denmark.

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

Cannabis seeds are excluded from the German Narcotics Act unless they are intended for unauthorized/illicit cultivation (see Annex I BtMG). Thus, there are no restrictions on the import of cannabis seeds.

**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.**

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

The German Narcotics Act distinguishes between

- cannabis;
- medical cannabis;
- seeds;
- plants and parts of plants that
  - come from a cultivation in EU countries of certified seed, or
  - whose THC content does not exceed 0.2 % and if the trade with them is exclusively for commercial or scientific purposes which exclude any misuse for intoxication purposes (not including cultivation);
- industrial hemp.

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

CBD as such is not subject to the German Narcotics Act unless the possible THC traces do not exceed 0.2%.

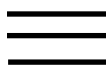
However, regarding CBD products in food (supplements), the German Food Law has to be respected, in particular the European regulations on Novel Foods. For CBD in cosmetics, the European Regulation on Cosmetic Products (No 1223/2009) does apply.

## IV. Patients and prescriptions

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

Under Section 31 (6) SGB V, persons with a serious disease insured in the German Statutory Health Care Insurance (SHI) (approx. 90 % of the population) are entitled to obtain cannabis in the form of dried flowers or extracts of pharmaceutical-grade quality and to medicinal products containing the active ingredients dronabinol or nabilone if

1. a generally recognised treatment in accordance with the medical standard
  - (a) is not available or
  - (b) cannot be applied in individual cases according to the reasoned assessment of the treating physician, taking into account the expected side effects and the state of illness of the insured person,
2. there is a not entirely remote prospect of a noticeable positive effect on the course of the disease or on



serious symptoms.

Private health care insurance funds reimburse the costs of medical cannabis on prescription according to the general rules, i.e. if it is required for an effective curable treatment.

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

Medical cannabis can be prescribed by every licensed physician.

**12. Are there patient registration or cardholder requirements?**

No. However, the costs for prescribed medical cannabis are only reimbursed to patients insured in the SHI provided that the respective health insurance fund has given its approval before the first prescription. The approval of the SHI can only be denied in justified exceptional cases.

## V. Special requirements

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

Yes. Pursuant to Section 17 BtMG, the holder of a license shall be obliged to keep records regarding each receipt and each dispatch of narcotics. This however only applies for cannabis products which are subject to the German Narcotics Act (in particular products with an THC-content over 0.2%).

**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 special requirements regarding the advertising for narcotics. In general, it is forbidden to advertise narcotics. However, it is allowed to advertise medical cannabis towards physicians, dentists and vets.

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

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 under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

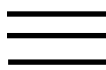
**D. Impact on crime, including drug and alcohol addiction.**

The BfArM carries out a non-interventional study regarding the prescription of medicinal products which shall run until March 31, 2022. Each physician who prescribes medical cannabis is therefore obliged to provide the BfArM with the data required for the study in anonymous form.

## VI. Risks and enforcement

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

At present, the classification of CBD products in Germany is unclear. The BfArM generally considers CBD products as medicinal products assuming pharmacological effects. However, CBD products are also distributed as food, food supplements or cosmetic products in Germany. The compliance with German law of distributing the products as food or food supplements remains uncertain, especially in the light of the recent inclusion of CBD in the Novel Food catalogue by the European Commission. Lately, local food authorities have issued



orders against the distribution of CBD products as food or food supplements.

Furthermore, pursuant to the BfArM, the first German harvest of cannabis can be expected in the fourth quarter of 2020. However, experts doubt that the companies who won the tender process are ready to harvest cannabis by then. In addition, the amount which was awarded during the recent tender process seems already too little. It remains to be seen whether the BfArM will award new amounts any time soon or whether the need will be still covered by imports.

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

The punishability with regard to narcotics is regulated in the Sections 29 et seq. BtMG. Section 29 (1) No. 1 BtMG for example states that a prison sentence of up to five years or a fine shall be imposed on anyone who illicitly cultivates, manufactures, trades in, without trading, imports, exports, sells, gives away, otherwise puts into circulation, acquires or otherwise procures narcotic drugs. Section 29 (1) No. 3 BtMG also makes the possession of narcotics punishable without having a written permission for the acquisition (e.g. a prescription). A prison sentence not less than five years shall be imposed on anyone who cultivates, manufactures, trades in, imports or exports narcotics in no small quantities without permission and acts as a member of a gang.

**A. Does enforcement differ based on quantity?**

Yes. In the case of illicitly trading, manufacturing or selling of narcotics in no small quantities or in the case of possessing narcotics in no small quantities without having obtained them on the basis of a licence, imprisonment cannot be less than a year (cf. Section 29a BtMG). However, the public prosecutor's office may waive prosecution if the offender cultivates, produces, imports, exports, transfers, acquires, otherwise procures or possesses narcotic drugs in small quantities for his own use only. However, the quantity of cannabis which is considered as small – whereas the amount of THC and not the gross quantity is decisive – differs from state to state in Germany.

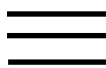
**B. Does enforcement differ based on product type?**

Enforcement does not differ based on the product type in which the cannabis is entailed (e.g. if it is a joint or a hash brownie), rather, the amount of THC is decisive. As regards CBD products which are sold as food (supplements) with a low THC amount (less than 0.2 %), local food authorities can also act on the basis of food law due to the inclusion of CBD in the Novel Food Catalogue. This issue does not exist regarding CBD products distributed e.g. as cosmetic products.

## 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?**

**TW:** Taylor Wessing has demonstrated its interest in the thriving cannabis sector by creating a Cannabis Working Group consisting of experts whose expertise are of special relevance for the cannabis industry hereby following its principle to act as a “one stop shop” for firms. Combining the knowledge and experience of its experts in such areas as M&A, finance, tax, employment, trademarks and regulatory law, Taylor Wessing has advised U.S. and Canadian investors in connection with an investment into a German pharmaceutical wholesaler for medical cannabis and on setting up a business in Germany with the purpose of import and wholesale of medical cannabis in the past. Further, Taylor Wessing has advised leading Canadian growers and suppliers of medical cannabis on setting up a subsidiary in Germany as well as on participating in the tender procedure of the German Federal Institute for Drugs and Medical Devices (BfArM) for the “Cultivation, processing, storage, packaging and delivery of cannabis for medical use”. In addition, Taylor Wessing has also advised CBD-products manufacturers and distributors in disputes with regulatory authorities concerning sale and marketing of CBD-products. Taylor Wessing has won the award for best law firm 2019 for pharmaceutical law due to its expertise in the life sciences sector (awarded by Handelsblatt in cooperation with Best Lawyers).



**CMS:** CMS has put a special focus on the growing cannabis business. To merge the expertise in the cannabis sector within CMS worldwide, CMS has founded a “Cannabis Initiative” within its long existing Lifesciences & Healthcare Sector Group. In this initiative, CMS lawyers from all relevant practice areas connect to discuss and advise on the pressing topics for the cannabis industry. CMS has been active in the sector for more than three years. In Germany, we have in particular advised Canadian and US-based companies in relation the BfArM tender process for cultivation licenses and have been instructed by both investors and private companies in M&A transactions in the sector. Moreover, we regularly advise clients on regulatory and advertising rules for medical cannabis as well as food and cosmetics with CBD. In 2018, CMS has been awarded the JUVÉ Law Firm of the Year Award for Pharmaceuticals & Healthcare with specific reference to our activities in the Cannabis sector.

**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.**

- [Blog article of Dr. Susanne Pech: Medizinisches Cannabis zukünftig auf Rezept \(“Medical cannabis on prescription in future”\)](#)
- [Article of Dr. Jörn Witt und Dr. Susanne Pech in the Online-Magazine Gründerszene: Was Gründer von Cannabis-Startups in Deutschland wissen müssen \(“What founders of cannabis start-ups in Germany need to know”\)](#)

**A. Are there any relevant trade organizations?**

**B. Are there any relevant lobbying organizations?**

<https://hanfverband.de/>

**C. Attorneys**

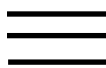
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# ITALY

## I. Introduction

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

The answers below refer to the Republic of Italy.

## II. Legislation

### **2. Please provide links to applicable statutes and regulations.**

The cultivation and the subsequent use of cannabis is regulated by the Presidential Decree No. 309 of 9 October 1990 (the “DPR 309/1990”) and by the Law No. 242 of 2 December 2016 (the “Law 242/2016”). As to the medical use of cannabis, reference has to be made also to the Ministerial Decree of 9 November 2015 of the Ministry of Health (the “Decree”).

The regulation is available (only in Italian) at the following links:

[DPR 309/1990](#)

[Law 242/2016](#)

[Decree](#)

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

No.

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

Possibly yes. In the previous Government, the Interior Minister had declared its intention to enact a stricter regulation with respect to this matter. However, the members of new Government have shown some intention to take a more liberal approach. Therefore, also considering that some kind of intervention to clarify some gray areas is required by scholars, it is possible that the Government will address this topic in the upcoming months.

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

Despite the ongoing political debate, the laws *sub* 2. have been settled throughout the last few years. Moreover, in May 2019 the joint sessions of the Supreme Court of Cassation issued a judgment by which the Court explained how to correctly interpret and apply these provisions.

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

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

The Ministry of Health.

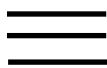
### **5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.**

In general, according to the DPR 309/1990 no function is allowed, as the DPR defines hemp as a narcotic substance and therefore any activity in relation to it exposes the individual to criminal liability.

Nevertheless, art. 17 of the DPR 309/1990 sets forth an important exception to this rule: subjects will be allowed to carry out cultivation, production, import, export and other activities in relation to hemp, provided they request and obtain an authorization from the Ministry of Health pursuant to art. 27 of the same DPR (!).

<sup>1</sup> Please note that according to art. 17 (2) of the DPR 309/1990, drugstores do not need this authorization in order to purchase and sell narcotic or





According to art. 26 (2) of DPR 309/1990, the subjects who can obtain this authorization are universities and public labs for scientific, experimental or academic purposes.

In 2016, the Law 242/2016 changed the situation by allowing the cultivation of hemp for specific purposes only, i.e. the fight against climate change, soil consumption and the loss of biodiversity. Always for the same reasons the Law 242/2016 allows some industrial uses of hemp (for example, pursuant to art. 1 (3) letter c) of the Law 242/2016, hemp might be used for the production of food, cosmetics, biodegradable raw materials and semi-finished products for industries acting in different sectors). For these specific purposes, according to art. 2 of the Law 242/2016 farmers who cultivate hemp do not need the aforementioned authorization by the Ministry of Health, on the condition that the THC content of the cultivation remains below 0.2 %.

Moreover, pursuant to art. 4 of the Law 242/2016, the THC content of the cultivation needs to remain between 0.2% and 0.6 %. In case the THC percentage is higher, the competent authority might confiscate and destroy the concerned goods (please note that even if the percentage is higher, the liability of the farmer will be excluded if he respected all the provisions of law which regulate the way hemp has to be cultivated).

After 2016, although the main aim of the Law 242/2016 was to promote the agricultural uses of hemp for the aforementioned specific purposes, some companies interpreted this provision as a general liberalization of cannabis with a THC content below 0.6%. Therefore products with said THC content started being put on the market and being sold by small retail shops.

In 2019 the Supreme Court of Cassation in its Joint Sections intervened in order to clarify the interpretation of the relevant provisions (Judgment n. 30475/2019). According to the Supreme Court, all the functions that are not explicitly allowed by the Law 242/2016 remain under the scope of DPR 309/1990 and therefore they are not permitted. Further, these activities actually expose the individual executing them to criminal liability pursuant to art. 73 of the DPR 309/1990. In conclusion, according to the interpretation provided by Court of Cassation, the selling of cannabis turn out to be unlawful; nevertheless, the Supreme Court specified that the criminal liability of the seller will be excluded if the product does not actually have any narcotic or psychotropic effect, according to the so-called principle of “principio di offensività” (lit. “principle of offensiveness”).

The situation is therefore presently “unclear”, and press, business operators and scholars are asking the Government for an intervention for clarification purposes.

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

As anticipated in the previous point, pursuant to art. 1 (3) letter c) and art. 2 (2) of the Law 242/2016, the cultivation of hemp may be aimed at obtaining food, cosmetics, semi-finished products (such as fiber, oils or fuels), organic material for bioengineering or bio-construction or it might also serve educational, demonstrative or research purposes carried out by public or private institutes. Moreover, the cultivation of hemp is permitted for medical use pursuant to the Ministerial Decree of 9 November 2015 of the Ministry of Health.

The use of hemp for recreational purposes debated, but the case-law seems somehow to admit products not having any narcotic or psychotropic effect.

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

Yes, in relation to the medical use of cannabis, higher percentages of THC are allowed.

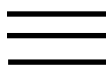
##### **B. Are retail sales of any cannabis products restricted to specific retail channels? E.g., medical dispensaries, government-owned stores, etc.**

The sale of cannabis products for medical use is allowed only through medical dispensaries.

With reference to the purposes set forth by Law 242/2016, the farmers who cultivate hemp can sell it without authorization on the condition that they respect the provisions of the same law.

Private retained hemp shops have become quite frequent, but the relevant legal status is uncertain.

psychotropic substances in the dose and form of medications.



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

No, there are not.

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

**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.**

The import of hemp and its derivatives in the EU is regulated by Regulation (Eu) No 1308/2013 of the European Parliament And of the Council and more specifically by art. 189. The regulation establishes that in order to be imported in the EU, the percentage of THC contained in cannabis seeds must be below 0.2%. This rule applies both to seeds used for planting and those used for different purposes, which can be imported only by subjects who are recognized by the member State.

Further, pursuant to art. 1 of the Ministerial Decree of 9 November 2015 of the Ministry of Health, the Ministry of Health has the authority to import and export plants and vegetal material containing cannabis.

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

Yes, it does.

**A. If so, what distinctions exist?**

The distinction refers to the percentage of THC contained in the hemp cultivation.

**B. If so, briefly describe the differences.**

Please refer to the answer *sub* 6.

**C. Identify any related laws that should be considered when answering this question. Please refer to the following:**

DPR 309/1990; Law 242/2016; Ministerial Decree of 9 November 2015 of the Ministry of Health; Council Directive 2002/53/EC.

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

No, there are not.

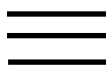
## IV. Patients and prescriptions

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

According to the Ministerial Decree of 9 November 2015 of the Ministry of Health, cannabis can be prescribed by doctors:

- for analgesic purposes to patients who suffer from illnesses which cause chronic pain and who show symptoms of nausea and vomit caused by chemo;
- for stimulating appetite in patients diagnosed with tumors, AIDS or anorexia nervosa;
- for hypotensive effect in glaucoma;
- for reducing involuntary movements of the body and of the face in patients diagnosed with Tourette syndrome.

Please note that for all the above mentioned purposes, cannabis can be prescribed only if other traditional treatments have shown to be ineffective.



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

Yes, there is. Only a fully recognized practitioner can prescribe such medication.

**12. Are there patient registration or cardholder requirements?**

According to the Ministerial Decree of 9 November 2015 of the Ministry of Health, the “Istituto Superiore della Sanità” (lit. the Higher Health Institute) must keep a register in which all the information about patients prescribed with cannabis have to be reported. Therefore, the “Aziende Sanitarie Locali” (lit. the local health authorities), on behalf of the doctors who prescribe the medication, have to file the register with the patients’ personal information, the reasons why the medication was prescribed and the outcomes of the treatment.

## V. Special requirements

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

Pursuant to art. 3 of the Law 242/2016, farmers must keep the relevant tags of the seeds they purchase for at least 12 months. For the same amount of time, farmers must also conserve the invoices of the purchase of the seeds.

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

No, there are not.

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

No, there are not.

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

There is no special regulation in access to financial services for subjects operating in cannabis sector.

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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

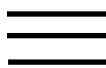
Not by any official source, apart from what already specified in question no. 14.

## VI. Risks and enforcement

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

The crucial issue the industry is facing in Italy is uncertainty, following the decision of the Supreme Court of Cassation previously mentioned *sub.* no. 6 in connection with the sale of products without any narcotic or psychotropic effect. Such uncertainty can expose to the risk of criminal prosecution and is likely discouraging several business operators from engaging in the market.

Furthermore the political debate on the issue is still ongoing and it is not sure if and when the new Government will enact an amendment to the current legislation.



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

**A. Does enforcement differ based on quantity?**

Yes it does. Pursuant to the DPR 309/1990, the possession of narcotic substances for personal use only does not result in the criminal liability of the possessor who will be punished with administrative sanctions (e.g., suspension of driving license for a period up to three years) <sup>(2)</sup>. On the other hand, dealing with relevant quantities of such substances can result in the exposure of the dealer to criminal liability, if such substance has any psychotic effect.

**B. Does enforcement differ based on product type?**

Yes, as clarified above, it may differ based on the THC percentage contained in the product.

## 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?**

Due to legal uncertainty, the interest in the cannabis industry is still limited; therefore the recourse to legal consulting is still not very frequent.

**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.**

**A. Are there any relevant trade organizations?**

**B. Are there any relevant lobbying organizations?**

Yes, the “Consorzio Nazionale per la tutela della canapa” (lit. “National Consortium for the protection of hemp”), reachable at the following link:  
<https://www.consorziotutelacanapa.it/>

## Contributors

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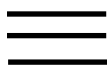
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<sup>2</sup> Please consider that according to art. 75-bis of the DPR 309/1990, if by complying with art. 75 a risk for the public safety may occur (e.g. if the possessor has been previously found guilty for crimes against a person), it will be possible for the authority to apply criminal sanctions as well.



# PARAGUAY

## I. Introduction

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

Republic of Paraguay.

## II. Legislation

### **2. Please provide links to applicable statutes and regulations.**

Law No. 1340/1988 which “Represses the illicit trafficking of hazardous drugs and drugs and other related crimes and establish dependent drug prevention and recovery measures” – [Link](#)

Law No. 6007/2017 which “Creates the National Program for Scientific and Medical Investigation and Research of the Medical Use of the Cannabis Plant and its Byproducts (Crea el Programa Nacional para el Estudio y la Investigacion Medica y Cientifica del Uso Medicinal de la Planta del Cannabis y sus Derivados)” – [Link](#)

Decree No. 9303/2018 which “Regulates Law No. 6007/2017” – [Link](#)

Decree No. 2725/2019 “Whereby the general conditions for the production of industrial hemp (non-psychoactive cannabis)” – [Link](#)

Decree No. 3284/2020 which “Modifies Decree No. 9303/2018” – [Link](#)

Decree No. 3356/2020 which “Modifies Decree No. 3284/2018” – [Link](#)

Resolution No. 433/2019 issued by the Ministry of Health and Public Welfare – [Link](#)

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

Currently, there is no pending regulation under study by congress or the executive.

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

Currently, there is no proposed regulation under study by congress or the executive.

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

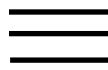
Cannabis regulation is fairly recent, the law was only enacted in 2017 and implemented in late 2018. Some changes have been introduced to regulatory decrees, but these are exclusively related to how many permits may be requested.

## 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?**

The Cannabis byproducts oversight is segmented into two industries, which are (i) industrialization of non-psychoactive hemp (mainly intended for exports), and (ii) research of medicinal and/or therapeutic uses of cannabis (psychoactive and non-psychoactive) and its industrialization and commercialization.

The first one is overseen by the Ministry of Agriculture (“MAG”), which shall regulate the application of the Decree in coordination with the Ministry of Industry and Commerce (“MIC”) and the National Anti-narcotics Agency (“SENAD”); while the latter is overseen by the National Directorate of Sanitary Supervision (“DINAVISA”) under the Ministry of Health and Public Welfare.



All cannabis related activities must be conducted under specific licenses granted by the overseeing authorities. The number of licenses that may be granted by the Ministry of Health and Public Welfare is capped at 12.

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

The following activities are permitted in Paraguay (subject to regulatory authorizations):

Cultivation (Sowing - Harvest):

- Development of derivatives of the cannabis plant.
- Final disposal of remains.

Industrialization:

- Production.
- Fractioning.
- Quality control.
- Storage.
- Transportation.
- Final disposal of waste.
- Commercialization.

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

Solely medicinal and therapeutic uses.

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

No. Recreational use is not permitted.

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

Yes, sales in drugstores under prescription and government owned programs for certain beneficiaries determined in the regulation.

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

Not under cannabis byproducts specific regulations. Zoning regulations may vary depending on the municipalities for clinics, hospitals, cultivation, processing, and disposal of wastes.

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

Both finished products and raw materials may be imported, subject to regulatory authorizations.

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

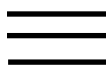
Not under cannabis byproducts specific regulations.

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

N/A.

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

Yes.



**A. If so, what distinctions exist?**

Distinction is non-psychoactive cannabis (content of THC is inferior to 0.5% on dry weight) and psychoactive cannabis (content of THC is superior to 0.5% on dry weight).

**B. If so, briefly describe the differences.**

See above.

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

Law No. 6007/2017; Decree No. 9303/2018; Decree No. 2725/2019.

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

Regardless of whether the on Cannabidiol (CBD) products contain THC, they are subject to regulation under Law No. 6007/2017. However, current regulation only focuses on Cannabidiol (CBD) products with THC.

## IV. Patients and prescriptions

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

There are no specific medical conditions recognized under cannabis byproducts specific regulations.

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

While there is no licensing requirement under cannabis byproducts specific regulations for medical practitioners, the medical practice is a regulated industry.

**12. Are there patient registration or cardholder requirements?**

There are no patient registration or cardholder requirements, provided a prescription is given. But patient registration or cardholder requirements are available for patients who are part of the experimental program regulated by the government, under which such patients may receive cannabis products free of charge.

## V. Special requirements

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

No.

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

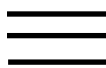
No.

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

No, other than those applicable for all pharmaceutical products in terms of labeling and the above-mentioned licensing requirements.

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

N/A



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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

Yes. Data is collected by the Ministry of Public Health and Social Welfare on the medicinal use of cannabis and its effects on patients.

## VI. Risks and enforcement

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

For medicinal uses, the regulation is still quite new, and the first licenses were only been granted last month (12 in total).

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

In terms of medicinal use, it is leaning towards legalization (subject to licensing requirements, e.g. homemade production is not permitted, even for self-consumption). In all other aspects the regulation remains strict.

**A. Does enforcement differ based on quantity?**

No.

**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 have advised the foreign partner (which formed joint venture with a local partner that is one of the largest pharmaceutical laboratories in Paraguay) for the production of cannabis byproduct which has been recently granted a license. in this sense, we had advised and participated in the making of the relevant regulation.

**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.**

<https://www.bizlatinhub.com/market-entry-opportunities-paraguay-cannabis/>

**A. Are there any relevant trade organizations?**

No.

**B. Are there any relevant lobbying organizations?**

No.

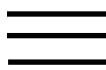
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# PERU

## I. Introduction

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

The main legislative framework for the cannabis industry is set by a law approved by the Peruvian Congress (Law 30681) and its regulations approved by the Ministry of Health. Therefore, this legislation is mainly applicable at the national level to activities carried out within Peruvian territory. However, the relevant statutes contain references to both import and export activities of cannabis and products derived from cannabis.

It must be noted that both the legal framework and the overall regulatory regime remain at an early stage of development, with many technical rules and regulations pending approval by the relevant government authorities, amid a still nascent network of market agents and stakeholders.

Finally, as will be explained in detail below, please note that the entire legal framework for the cannabis industry is solely restricted to medical and therapeutic uses and activities.

## II. Legislation

### **2. Please provide links to applicable statutes and regulations.**

The relevant statutes and regulations are available in the following link: <https://bit.ly/2rHCZcK>.

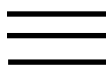
#### **A. Is there any pending legislation that could materially alter applicable statutes or regulations?**

Considering the early stage of development of the legal framework, the Regulations established a schedule of between sixty (60) to ninety (90) business days to several government entities to approve various technical rules and regulations in order to operationalize cannabis-related activities with medical and therapeutic purposes.

However, despite these deadlines, only a limited amount of these complementary rules and regulations have been approved. Some examples of rules and regulations that have already been approved are listed below:

- (i) Sanitary and phytosanitary conditions and criteria applicable to customs proceedings for imports of cannabis plant material for medical and therapeutic use, for both research and production purposes. The National Plant Health Institute (“SENASA”) has approved the phytosanitary requirements applicable for cannabis seeds imports from Colombia and the United States of America.
- (ii) Technical rules regarding the conditions and criteria for security protocols preventing thefts, larceny or similar actions in seeking to divert products derived from cannabis in licensed or approved activities to unlawful purposes, per article 16 of the regulations. These regulations were approved on November 28<sup>th</sup>, 2019, by virtue of Ministerial Resolution 1969-2019-IN and are under the jurisdiction of the National Drug Control Office within the National Police Department.
- (iii) National Registry of Pharmaceutical Establishments and Individuals Authorized for Imports or Commercialization of Cannabis and products derived from cannabis, to be implemented by DIGEMID, which has recently made available the forms to request both a cannabis imports or trading license as well as a health authorization to operate as a pharmaceutical establishment carrying out cannabis activities (a prerequisite to obtain the aforementioned licenses). For more information on these forms, please refer to Section 5 of this Report.
- (iv) National registries of institutions authorized to carry out research activities, comprising those institutions authorized to carry out research in cannabis, products derived from cannabis and cannabis finished goods for medical and therapeutic use:
  - a. National Registry for Health Research Institutions, overseen by the National Institute of Health<sup>1</sup>.

<sup>1</sup> The registry —which does not yet provide detail on any authorized research entity— and the requirements to obtain an inscription in said registry are available in the following link: <https://bit.ly/2RcdTxk>



b. National Registry for Agriculture Research Institutions, overseen by the National Agricultural Innovation Institute. On November 29<sup>th</sup>, the National Agricultural Innovation Institute approved Resolution 282-2019-INIA which set forth the proceeding to request and obtain an agricultural research license in cannabis.

(v) Guideline for the elaboration of Medical Cannabis Agricultural Production Plan. This document will be used for the granting of production licenses which includes cannabis growing. This regulation was approved on December 5<sup>th</sup>, 2019, by virtue of Ministerial Resolution 433-2019/MINAGRI.

Technical guideline for the use of medical cannabis and products derived from cannabis. This regulation was approved on December 9<sup>th</sup>, 2019, by virtue of Ministerial Resolution 1120-2019/MINSA.

Relevant technical rules and regulations that remain pending involve (i) safety and oversight protocols for activities involving cannabis plants, (ii) sanctioning proceedings for the suspension and removal of licenses and authorizations for breaches of the Medical Cannabis Law and its Regulations, (iii) medical treatment protocols for patients receiving cannabis prescriptions, and (iv) the rules applicable to the sowing and industrialization of hemp, which must be approved by the by the Ministry of Agriculture<sup>2</sup>.

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

Yes. As referred in section A of Question 2, several technical rules and regulations remain pending. Their approval would complement the regulatory and licensing regime approved by the Medical Cannabis Law and its Regulations.

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

Neither. The Peruvian legal framework on cannabis has only recently been approved, with Regulations entering into force in early 2019, and many of the technical rules and regulations are still pending. In that sense, beyond the pending technical rules and regulations, we do not envision any changes to the legal regime that has been already approved.

### 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?**

The main competent authorities in accordance to the Medical Cannabis Law are:

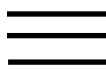
- (i) DIGEMID, the pharmaceuticals and pharmaceutical establishments regulator, issuing cannabis licenses for production, imports and commercialization.
- (ii) National Health Institute, the competent authority to issue and oversee health research licenses.
- (iii) National Agricultural Innovation Institute and the National Agricultural Health Agency, competent authorities to assess and oversee licenses for agricultural licenses and registration of cannabis genetic material.
- (iv) National Drug Control Office, in charge of oversight and approval of security protocols required to requestors of research, imports, production and trading licenses in cannabis.

These protocols must include an Integral Safety Plan, the naming of a Risk Management Officer and the implementation of an Internal Operations Registry and Control system (i.e., detailing entry and departure of vehicles, visitors, precursors, etc.).

Additionally, as noted above, the Ministry of Health and the Ministry of Agriculture and the Ministry of the Interior oversee complementary legislation and registries required by the Regulations.

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<sup>2</sup> For more information on the conditions applicable to production and industrial activities regarding hemp, please refer to Section 8 of this Questionnaire.



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

The Medical Cannabis Law authorizes, if accompanied with the proper license and/or authorization, the production (encompassing acquisition of seeds, growing and harvesting cannabis as well as manufacturing products derived from cannabis), research, imports, trading in both national and international markets, and the informed use of cannabis and products derived of cannabis. The entirety of these activities and products must be exclusively destined for medical and therapeutic uses.

Considering that each of these activities requires a license, a brief summary of the licensing regime created by the Medical Cannabis Law can be found below:

### **Scientific Research Activities**

- **Health Research:** Issued by the National Health Institute, part of the Ministry of Health, in favor of accredited universities or health research institutions. Research projects regarding clinical trials may involve research activities on humans, in which case additional requirements are applicable.
- **Agricultural Research:** Issued by the National Agricultural Innovation Institute, part of the Ministry of Agriculture.

Given the broad scope of scientific research projects, these licenses comprise all necessary activities to carry out the research protocol authorized as part of the licensing proceeding, including imports, storage, growing, harvest, transport and manufacturing of cannabis and products derived from cannabis, respectively.

- The National Agricultural Innovation Institute has recently approved the forms to request these licenses. These forms are enclosed in Resolution 282-2019-INIA as annexes.

### **Imports and Trading**

- License for imports and trading of cannabis or products derived from cannabis for medical and therapeutic purposes, issued by DIGEMID in favor of individuals and legal entities incorporated as pharmaceutical establishments.

These pharmaceutical establishments must have previously obtained proper authorizations and certifications by DIGEMID, in compliance with the Pharmaceutical Establishment Regulations, approved by Supreme Decree 14-2011-SA.

- DIGEMID has recently approved the forms to request these licenses<sup>3</sup>.

### **Production**

- License issued by DIGEMID authorizing the following activities: acquisition of cannabis seeds and seedlings, sowing and growing, harvest, post-harvesting of cannabis as well as manufacturing products derived from cannabis for medical purposes.

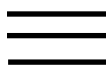
- Three categories of licenses may be issued:
  - Production license involving growing cannabis.
  - Production license not involving growing cannabis.
  - Production license including seeds production.

These licenses are issued by DIGEMID in favor of public entities or authorized and certified laboratories, in compliance with the Pharmaceutical Establishment Regulations, approved by Supreme Decree 14-2011-SA.

DIGEMID has recently approved the forms to request these licenses<sup>4</sup>.

<sup>3</sup> These forms are available in the following links: <https://bit.ly/2Y6JSAu> and <https://bit.ly/2LclUIB>.

<sup>4</sup> This form is available in the following link: <https://bit.ly/2OCzu01>.



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

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

No. Under the Peruvian legal framework, only medical and therapeutic uses are permitted, whereas the Peruvian Criminal Code only exempts the growing, harvesting, trading, importing and exporting of cannabis from criminal penalties insofar as the agent has received a license according to the Medical Cannabis Law framework. Thus, recreational use is not only unauthorized, but persons may face criminal sanctions because recreational use is considered a felony according to Peruvian criminal law<sup>5</sup>.

Moreover, the definition of “psychoactive” cannabis (i.e., with a concentration of THC equal to or exceeding 1% of the product’s dry weight<sup>6</sup>) under Peruvian law expressly forbids all cannabis use involving combustion and/or smoking.

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

Yes. Imports and trading licenses for cannabis and products derived from cannabis are solely issued to pharmacies, drugstores, and pharmacies located within health establishments (i.e., within clinics or hospitals) authorized and certified as pharmaceutical establishments before DIGEMID. These establishments, when requesting for the imports and trading license, must fill an affidavit stating that sales of cannabis and products derived from cannabis will be carried out exclusively to patients registered as cannabis users in the proper registry implemented by the Ministry of Health.

Delivery or internet sales are excluded from the authorized activities under the Medical Cannabis Law, as well as the supply or sales of pharmaceutical preparations of cannabis or products derived from cannabis in professional consultancies or any other locale outside of authorized and certified pharmaceutical establishments.

Finally, international trade of cannabis requires obtaining an Official Export Certificate, as required for narcotic and psychotropic drugs, per the Regulations on Narcotic Drugs, Psychotropics and other Substances Subject to Sanitary Oversight, approved by Supreme Decree 23-2001-SA.

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

Since only medical and therapeutic uses are allowed under the Medical Cannabis Law, trading of cannabis and products derived from cannabis is limited to licensed pharmaceutical establishments. Thus, there are no provisions set at the national level imposing additional zoning restrictions on the location of pharmacies, drugstores or other pharmaceutical establishments.

Nevertheless, the security protocols issued by the National Drug Control Office, restrict cannabis production in areas subject to the special oversight regime to controlled chemical precursors and machinery (i.e., areas of high incidence of illicit drug production or trade).

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

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

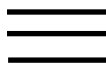
The Medical Cannabis Law does not set forth restrictions specifically applicable to cannabis in relation to the countries of origins.

In addition to having to comply with the imports and exports regime applicable to authorized narcotic drugs and psychotropics<sup>7</sup>, all requestors of cannabis imports must have previously obtained the applicable imports

5 Please note that the Peruvian Criminal Code references cannabis sativa as a species, and therefore is considered to include all sub-species of said plant (i.e. Sativa, Indica, Cannabis Sativa, Ruderalis, Spontanea and Kafiristanca).

6 For a more detailed description of this definition, please refer to Question 8 of this Questionnaire.

7 Per the Regulations on Narcotic Drugs, Psychotropic and other Substances Subject to Sanitary Oversight, approved by Supreme Decree 23-2001-SA.



or research license. It must be noted that the Regulations establish an exceptional simplified regime for individual requests to import cannabis and products derived from cannabis.

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

Importation of seeds is only admissible if the import requestor has either a research or production license (i.e., to sow, grow and harvest the seeds in Peruvian territory). These seeds must comply with post-entry plant quarantine proceedings to be established by the Ministry of Agriculture.

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

Yes. The Medical Cannabis Law sets forth a definition of the cannabis plant as all herbal plants from the genus cannabis and is divided in two (2) varieties:

- (i) Psychoactive Cannabis: Flowering tops of the cannabis plant, excluding seeds and leaves not joined to the flowering tops, with resin and with a concentration of THC equal to or exceeding 1% of the product's dry weight.
- (ii) Non-Psychoactive Cannabis: Cannabis plant or any part of said plant, with a THC concentration below 1% of the product's dry weight. Under the Medical Cannabis Law this variety is named hemp, or "cáñamo" in its original language.

**A. Psychoactive Cannabis**

The Regulations explicitly include the following definitions for cannabis and cannabis products:

- (i) Herbal medicine derived from cannabis for medical use
- (ii) Pharmaceutical preparations derived from cannabis
- (iii) Natural product derived from cannabis for health use

Additionally, the Regulations set forth six (6) tariff headings for imports of cannabis and products derived from cannabis:

- (i) Cannabis seeds
- (ii) Cannabis resin
- (iii) Cannabis extract, tinctures and oils
- (iv) Nabiximol (standardized mix of THC and CBD)
- (v) Nabilone (synthetic THC)
- (vi) Dronabinol (analog semi-synthetic THC)

**B. Hemp**

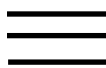
Hemp is considered a non-controlled substance and is therefore exempt from (i) any restrictions applicable to substances subject to controls under Regulations on Narcotic Drugs, Psychotropics and other Substances Subject to Sanitary Oversight, approved by Supreme Decree 23-2001-SA; and (ii) any medical use licenses.

Additionally, production, research, manufacturing, imports and trading of hemp are exempt from the obligation to obtain the licenses set forth by the Medical Cannabis Law and described in the present Questionnaire. In accordance to the Regulations, the regulatory regime applicable to hemp is to be issued by the Ministry of Agriculture and its approval remains pending, with some baseline conditions set forth by the Regulations.

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

CBD-based products are classified as pharmaceuticals and must have exclusively medical purposes. Thus, according to the Regulations, CBD-based products must be sold upon the issuance of a medical prescription.

Additionally, the sales and supply of CBD-based products must comply with the general trading and advertisement conditions and restriction for pharmaceuticals, such as conditions for mass media advertising and limits for free sampling.



## IV. Patients and prescriptions

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

The Medical Treatment Protocols for patients of medical use cannabis are yet to be approved by the Ministry of Health.

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

Yes. In accordance to the Regulations, only surgeons can prescribe the special medical prescription for products derived from cannabis, whereas CBD-based products only required regular medical prescriptions.

### **12. Are there patient registration or cardholder requirements?**

Yes. DIGEMID is in charge of implementing the National Registry for Patients using Cannabis and Products derived from Cannabis for medical and therapeutic use<sup>8</sup>.

## V. Special requirements

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

Yes. All production units require both an Agricultural Production Plan and Safety Protocols to be submitted and approved by the Ministry of Agriculture and National Drug Control Office within the National Police Department, respectively, as prerequisites to obtain a production license.

Moreover, the supply of cannabis and products derived from cannabis to patients as end-users is subject to verification of the patient as a registered cannabis user with a valid special prescription<sup>9</sup>, writing down the purchase in the aforementioned patient registry, amongst other steps.

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

There are no special taxes that apply to the industry. Thus, please consider as applicable the corporative income tax that applies to every profit-making activity, consisting of a 29.5% charge over the generated income.

### **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 rules or limitations that apply to the industry in relation with banking, trademark protection or patents.

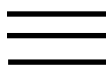
### **16. What is the legal status of access to financial services, including banking, merchant services, and cash handling?**

Laboratories that legally grow, process, or retail cannabis (and its derivatives) can potentially access all financial services available in Peru, just like any other company conducting business in Peru. In this sense, a laboratory will need to be duly incorporated under Peruvian law to be able to access all available financial services.

However, because activities regarding cannabis were prohibited until 2017, it is possible that financial entities' internal regulations set forth additional requirements for granting loans, opening accounts, making deposits, and other activities. In addition, they could apply more strict criteria about the anti-money laundering rules.

<sup>8</sup> This Registry is available in the following link: <https://bit.ly/2KmVOse>

<sup>9</sup> According to the Regulations, special prescriptions can only be issued by surgeon specialists, have a unique ID numbering system and must be retained by the pharmaceutical establishment supplying cannabis or the product derived from cannabis for two (2) years.



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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

The various registries created by the Medical Cannabis Law do not appear to have as purpose—as hinted by this question—to generate data that would enable regulatory impact assessments or guide future regulatory actions in the industry. The objective of these registries appears to lean towards traceability in the industry, seeking to curb the purchase of unregulated medical products and to reduce the possibility of leaks diverting cannabis to non-medical or unlawful purposes.

However, the Medical Cannabis Law does set forth the obligation for the Ministry of Health to develop yearly assessment reports regarding the application of said law, particularly in regard to “benefits or obstacles” encountered in its implementation.

## VI. Risks and enforcement

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

Currently, the main challenge consists of the pending technical rules and regulations preventing the legal framework to be completed and, therefore, fully operational.

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

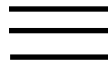
## VII. Your practice and useful links

First, the limited scope of the Medical Use Cannabis must be noted, seeking to only authorize economic activities related to medical and therapeutic use cannabis. The Peruvian government has not implemented a liberalized scheme allowing for recreational uses, but a more cautious approach. However, no enforcement activities have occurred to date, considering the nascent status of the industry and its regulations.

**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?**

As previously mentioned, the legal framework remains in a nascent state and market agents acknowledge the situation, with various players from related industries expressing preliminary interest and submitting queries to our Firm regarding the applicable legislation. Nevertheless, our Firm has a top-tier Regulation and Administrative Law Practice Group with vast experience in both the agricultural and pharmaceutical and healthcare industry. In that sense, the members of this Practice Group have an unparalleled track record in matters before government entities for the issuance of permits, licenses and authorizations, including those entities in charge of regulating and issuing licenses for the cannabis industry.

Our leading specialists on the regulation of cannabis and pharmaceutical regulation are Mr. Gerardo Soto, partner of our Firm and leader of the Regulation and Administrative Law Practice Group, and Ms. Brenda Sarrín, associate in the Regulation and Administrative Law Practice Group. Additionally, the cannabis practice is profoundly strengthened by the Antitrust and Intellectual Property Law Practice Group of our Firm, led by partner Carlos Patrón and senior associate Giancarlo Baella. This practice group also has vast experience in the registration and obtention of permits, licenses and authorization regarding industrial and intellectual property rights.



**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.**

Considering the nascent aspect of the industry, no relevant trade or lobby organizations are currently in place in Peru. There are, however, several market players interested in entering the industry once the regulatory framework is completed. Additionally, consultancies and specialized agricultural engineering practitioners have been constantly providing guidance from the technical aspects of the industry.

Our leading specialists, as noted above, are Mr. Gerardo Soto, Mr. Carlos Patrón, Ms. Brenda Sarrín and Mr. Giancarlo Baella.

## Contributors

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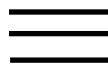
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# SOUTH AFRICA

## I. Introduction

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

South Africa.

## II. Legislation

### **2. Please provide links to applicable statutes and regulations.**

[Medicines and Related Substances Act 101 of 1965 \(“Medicines Act”\)](#)

[Pharmacy Act 53 of 1974 \(“Pharmacy Act”\)](#)

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

No.

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

Proposed legislation with regard to medicinal use:

Certain CBD preparations have been excluded from the operation of the Schedules of the Medicines Act by the Minister of Health for a time-limited period, as per the Exclusion Notice. The time-limit expired on May 15, 2020, thus it is expected that further regulation will be published after this date.

Proposed legislation with regard to recreational use:

In the Constitutional Court case, Minister of Justice v Prince, the court gave parliament 24 months from the date of the judgment to bring the ruling in line with South African laws, with a new bill expected to be released soon.

For further background, in September 2018, the Constitutional Court ruled that it is not a criminal offence for an adult citizen to use, possess or grow cannabis in private for personal consumption. However, the Constitutional Court did not define the scope of private, rather they left this to the discretion of those who enforce the law – the police, prosecutors and the courts. The Constitutional Court did not prescribe the quantity of cannabis that would qualify for personal use. Until these provisions are made, South Africa’s law enforcement officials have the discretion to decide whether the amount of cannabis in a person’s possession could reasonably be believed to be more than what is necessary for private use. If so, the individual could be considered to be “dealing” in cannabis in contravention of the Drugs and Drug Trafficking Act 140 of 1992.

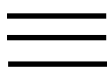
### **3. Are cannabis laws in your jurisdiction pretty well settled or are they constantly changing in material ways?**

Constantly changing in material ways.

## 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?**

SAHPRA (South African Health Products Authority), previously known as the MCC (Medicines Control Council) for the medicinal use of cannabis and the South African Police Service for recreational use.



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

Cultivation, production, manufacturing and the use thereof for medicinal and research purposes. The cultivation, production, manufacture and use of medicinal Cannabis products may only occur through a licence issued by the SAHPRA (under the Guideline on the Cultivation of Cannabis and Manufacture of Cannabis-Related Pharmaceutical Products for Medicinal and Research Purposes) and a permit issued by the Department of Health (under the Medicines Act). Additionally, a manufacturer would need to be licensed to manufacture medicines in terms of section 22C(1)(b) of the Medicines Act. This process takes around a year (including obtaining a premises license under the Pharmacy Act and being recorded as a manufacturing pharmacy with the South African Pharmacy Council ("SAPC"). A manufacturer also needs to engage a full time responsible pharmacist, recorded as such with the SAPC.

The use, possession and growing of cannabis in private for personal consumption.

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

Certain processed hemp and cannabis seeds products may be sold. CBD containing medicinal products that have been excluded from the Schedules to the Medicines Act in terms of the Exclusion Notice may also be sold in general outlets, including health shops and from pharmacies. CBD as an additive or ingredient is not permissible in foodstuffs. Only the naturally occurring trace amounts are allowed in foodstuffs.

All cannabis cultivated in a private place for a person's own use may only be used by the grower/ cultivator and may not be sold/supplied to others.

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

See above.

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

See above.

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

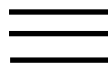
No recreational outlet is permitted. No zoning restrictions as far as we are aware in terms of building regulations, of course the Medicine Act restrictions would apply.

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

In general no person, other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, shall sell (which includes importing) or export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to paragraph (b), been obtained from the Director-General for such purpose. This provision will apply relevant to the schedule the product one is trying to import/export is locating in.

Thus, CBD, as an active pharmaceutical ingredient (API) intended for the production of a medicine, is currently listed as a Schedule 4 substance in the Schedules to the Medicines Act and has not been excluded except as outlined in the Exclusion Notice. An importer of CBD, as an API or raw material, must be in possession of a section 22C(1)(b) licence issued by SAHPRA.

Manufacturers and importers of CBD-containing processed products which fall within the parameters of paragraph (b) of the Exclusion Notice, and which are not intended for medicinal purposes, do not require a licence to manufacture or import in terms of section 22C of the Medicines Act, but must be able to provide verifiable proof of the CBD and/or THC content of the product and comply with the provisions of other applicable legislation (for example, the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 "Foodstuffs Act").



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

None.

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

See above, read with the fact that processed cannabis seed products (e.g. hemp seed oil, cosmetics containing hemp seed oil) are specifically excluded from Schedule 7 of the Medicines Act when: (a) the THC concentration is  $\leq 0,001\%$  and (b) the product does not contain whole cannabis seeds. Therefore, inferring that cannabis seeds may not be imported.

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

Yes.

**A. If so, what distinctions exist?**

Cannabis (the whole plant or parts or products thereof) and THC are currently listed as Schedule 7 substances in terms of the Medicines Act, 1965, except when present in processed hemp fibre and products thereof, in a form not suitable for ingestion, smoking or inhaling purposes, and containing not more than 0,1 % THC; or when present in processed products from cannabis seed containing not more than 0.001 % THC; or when separately specified in Schedule 6 for therapeutic use.

Synthetic cannabinoid substances are also listed separately in Schedule 7.

THC (also known as the synthetic variant, dronabinol) is listed in Schedule 6, when intended for therapeutic purposes.

CBD is listed as a Schedule 4 substance. Certain CBD preparations have been excluded from the operation of the Schedules by the Minister of Health for a time-limited period, as mentioned above.

**B. If so, briefly describe the differences.**

Schedule 7 substances are deemed to have no legitimate medicinal use and can only be accessed by means of a permit issued by the Director- General of the National Department of Health (NDoH). Medicines and substances categorised as Schedule 4 or Schedule 6 are only available on the prescription of an authorised prescriber and can only be obtained from a pharmacy or the holder of a dispensing licence issued in terms of the Medicines Act.

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

Drugs and Drug Trafficking Act 140 of 1992 and Prevention of and Treatment for Substance Abuse Act No. 70 of 2008.

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

Cannabidiol, when intended for therapeutic purposes is a schedule 4 medicine in terms of the Medicines Act.

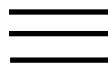
## IV. Patients and prescriptions

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

None.

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

Yes, one must be a medical practitioner and comply with the Medicines Act.



**12. Are there patient registration or cardholder requirements?**

Yes, in terms of the Medicines Act, a medical practitioner must get a permit for a particular patient.

## V. Special requirements

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

Not for recreational products, but for medicinal products, yes.

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

Not as far as we are aware.

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

Normal rules would apply, for example, the labelling requirements for medicines in terms of the Medicines Act and for foodstuffs in terms of the Foodstuffs Act.

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

There is access.

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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

Not as far as we are aware.

## VI. Risks and enforcement

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

The need for legal certainty.

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

As mentioned above, until more detailed provisions are made regarding the personal use of cannabis, South Africa's law enforcement officials have the discretion to decide whether the amount of cannabis in a person's possession could reasonably be believed to be more than what is necessary for private use. If so, the individual could be considered to be "dealing" in cannabis in contravention of the Drugs and Drug Trafficking Act 140 of 1992. This will of course be effected by what product type the cannabis is in.

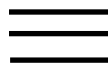
For the medical use of cannabis in South Africa, enforcement with the law is strict.

**A. Does enforcement differ based on quantity?**

Yes, see above.

**B. Does enforcement differ based on product type?**

Yes, see above.



## 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?**

Since regulation in South Africa is new, no one has immense experience. We have a very keen interest of growing our cannabis practice as the industry grows in South Africa.

**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.**

**A. Are there any relevant trade organizations?**

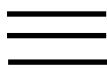
No.

**B. Are there any relevant lobbying organizations?**

No.

### Contributor

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# SPAIN

## I. Introduction

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

Our outline corresponds to the Spanish jurisdiction.

## II. Legislation

### **2. Please provide links to applicable statutes and regulations.**

#### *Cannabis in general*

- [United Nation's Single Convention on Narcotic Drugs](#), 1961 (the "Single Convention").
- [Act 17/1967](#), of April 8, updating former norms on narcotics to adapt them to the Single Convention on Narcotic Drugs ("Act 17/1967").
- [Statute of the Spanish Agency of Medicines and Health Products](#), approved by Royal Decree 1275/2011 (the "Statute of the Spanish Medicines Agency").
- [Act 10/1995 of November 23](#), on the Criminal Code (the "Spanish Criminal Code").
- [Act 4/2015](#), of March 30, on the Protection of Public Safety ("Act 4/2015").

#### *Cannabis in foodstuffs*

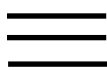
- [Royal Decree 1487/2009](#), of September 26, on food supplements ("RD 1487/2009").
- [Regulation \(EU\) 2283/2015](#) of the European Parliament and of the Council of November 25, 2015, on novel foods, amending Regulation (EU) 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) 1852/2001 (Regulation 2283/2015).
- [Regulation \(EU\) 1307/2013](#) of the European Parliament and of the Council of December 17, 2013, establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) 637/2008 and Council Regulation (EC) 73/2009 ("Regulation 1307/2013").
- [Royal Decree 191/2011](#), of February 18, on the General Health Registry of Food Business Operators (RD 191/2011).

#### *Cannabis for medicinal use*

- [Royal Legislative Decree 1/2015](#), of July 24, passing the Act on Guarantees and Rational Use of Medicinal Products and Medical Devices ("RDL 1/2015").
- [Royal Decree 1345/2007](#), of October 11, on the authorization, registry and dispensing proceedings regarding medicinal products for human use.

#### *Cannabis in cosmetic products*

- [Royal Decree 85/2018](#), of February 23, on Cosmetic Products ("RD 85/2018").
- [Regulation \(EC\) 1223/2009](#) of the European Parliament and of the Council of November 30, 2009, on Cosmetic Products (Regulation 1223/2009).



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

There are no pending regulations.

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

In December 2019, the European Observatory for Cannabis Consumption and Cultivation, a private organization, proposed a law to regulate the therapeutic use of the cannabis plant (other than its use in the manufacturing of authorized medicines, which is already established by the current regulations). If this regulation were passed, it would make possible the therapeutic use of cannabis in Spain, other than its incorporation as the active substance of medicines. However, this proposal has not been processed yet and it is not expected in the near future.

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

In Spain, there are very few regulations on cannabis. The ones that exist are well settled; one of the most common criticisms is that they may have become obsolete.

### **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?**

The Spanish Agency on Medicines and Medical Devices (“AEMPS”).

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

In Spain, section two of Act 17/1967 defines as narcotic drugs all substances included in list I and II of the Single Convention and assigns to the State the regulation on storage and distribution of narcotic products for use by laboratories, drugstore offices, hospitals and authorized distribution centers for the manufacture of medicines.

The plant, its resin, extracts and dyeing are included in list I of the United Nation’s Single Convention, whose article 1 defines cannabis as the “flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.”

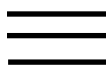
Under sections 8, 12 and 16 of Act 17/1967, cultivation, production, storage, import, export acquisition and transit of narcotic drugs are subject to prior authorization of the relevant authorities. Currently, under section 27 of article 7 of the Statute of the Agency of Medicines, AEMPS will develop the functions and be responsible for examining and controlling licit traffic and the use of narcotics and psychotropic substances. This authorization is only granted if the purpose of the above “functions” or processes is industrial, therapeutic, scientific or educational uses that are permitted in Spain (discussed in section 6 below), or the exportation of the production to a company authorized in the country of destination.

Without authorization, all activities entailing the cultivation, production, storage import, export, acquisition and transit of narcotic drugs will be considered illegal, under article 15 of Act 17/1967.

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

It is necessary to keep in mind the distinction between the parts considered a “narcotic drug” under the definition referred to in section 5 above. This distinction is relevant because the Spanish regulations only prohibit or subject to specific authorization the activities using the parts of the cannabis plant that fall under this definition.

As Act 17/1967 refers to list I of narcotic drugs of the United Nation’s Single Convention, in Spain the flowering or fruiting tops of the cannabis plant (resin not extracted), the separated resin, crude or purified, obtained from the cannabis plant and its tinctures are considered a narcotic drug. However, the seeds and leaves when not accompanied by the tops, which are expressly excluded from the scope of the Single Convention, are not considered a narcotic drug.



Activities using the parts of the plant considered a narcotic drug

- (i) Recreational use: Recreational use of the parts of the plant classified as a narcotic drug is strictly forbidden.
- (ii) Use as active substance for medicines: This is not prohibited, but all operations concerning medicines including narcotic drugs are subject to authorization by AEMPS. Only one medicine containing cannabis has been authorized in Spain. Additionally, only pharmaceutical companies authorized for this purpose and registered with AEMPS can manufacture, distribute and commercialize medicines incorporating narcotic drugs. These authorizations require undeniable proof and technical grounds of their effectiveness for therapeutic indications and a specific evaluation of their adverse effects.
- (iii) Scientific/research uses: These uses are not forbidden, but they are subject to authorization by AEPMS (both for the use itself and for the company).
- (iv) Therapeutic use (other than incorporating cannabis into a medicinal product): There is a legal gap on the therapeutic use of cannabis in Spain. Although Act 17/1967 refers to the therapeutic use of narcotic drugs and the possibility of their authorization, it defers its regulation to a further regulatory development that has never taken place. This means that all operations concerning the therapeutic use of cannabis (from the manufacturing of the products to its distribution and commercialization) would be subject to AEMPS' authorization, although the regulations governing the basis of these authorizations and making them possible do not exist yet.
- (v) Cosmetic use: The use of narcotic drugs in cosmetic products is specifically prohibited by Regulation 1223/2009. As this regulation refers to the Single Convention to define what is considered a narcotic drug for its purposes, cosmetic products using flowering or fruiting tops of the cannabis plant from which the resin has not been extracted cannot be marketed.
- (vi) Use in foodstuffs (including food supplements): Not permitted. Only foodstuffs using cannabis seeds (e.g., oils or flours) of the "Cannabis sativa L" plant variety (particularly if its THC content does not exceed 0.2%) present a significant record of safe consumption, making its commercialization possible. Any other foodstuff incorporating other parts of the cannabis plant, other cannabinoids (e.g., CBD and CBG) will be considered novel foods, which, to place the product on the market legally, entails the obligation to apply to the European Commission for authorization,<sup>1</sup> proving it is safe for consumption. Thus, the commercialization of any foodstuff containing these ingredients are not currently authorized in the EU.
- (vii) Industrial use: Any industrial use of the parts of the cannabis plant considered a narcotic drug is subject to prior authorization. However use of the parts of the plants for industrial purposes if the "active narcotic substance" has been previously extracted does not need authorization, as it is excluded from Act 17/1967.
- (viii) Export: Exporting the parts of the cannabis plant considered a narcotic drug (or the whole plant) requires prior authorization, which is granted if it can be proved that the importer is authorized in the country of destination to carry out its activity.

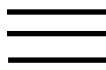
Activities using the parts of the plant considered a narcotic drug

Assuming the legal origin of the plant and its cultivation has been duly authorized, when required:

- (i) Recreational use: The recreational use of the parts of the cannabis plant that are not considered a narcotic drug would be expressly prohibited.
- (ii) Use as active substance for medicines (plants are also considered active substances for medicines): The use of the parts of the cannabis plant (that are not considered a narcotic drug) in medicines will not be subject to further requirements or obligations other than those applicable to medicines, since the product will be considered a plant-based medicine. That means that marketing authorization must be obtained from the AEMPS or the European Medicines Agency ("EMA") and the medicine must be manufactured by an authorized pharmaceutical company.

<sup>1</sup> Pursuant to Regulation 2283/2015





(iii) Scientific/research uses: The use of the parts of the cannabis plant not considered a narcotic drug for research activities is not subject to further obligations other than those applicable to research activities in each field.

(iv) Therapeutic use (other than use of cannabis in medicines): A product for therapeutic use constituted by the parts of the cannabis plant that do not constitute a narcotic drug and that are not classified as a medicine can be considered (i) an homeopathic medicine, if it is obtained through homeopathic stocks by means of a homeopathic procedure; or (ii) a traditional medicine based on plants, if it is conceived for its use without a doctor's control, it is used externally, by inhalation or orally, and that it holds a sufficient record of traditional and safe use for at least 30 years (from which at least 15 must correspond to its use within the EU). Homeopathic medicines are subject to specific authorization procedures by the AEMPS, while traditional medicines based on plants must be registered in the corresponding AEMPS registry.

(v) Cosmetic use: A cosmetic product containing cannabis may be legal if it has been elaborated using only the parts of the cannabis plant not considered a narcotic drug (mainly the seeds or the leaves not accompanied by the tops, but also other parts if the plant resin has been extracted) and has been produced, packed and labelled according to the regulations generally applicable to cosmetic products, so it does not entail any risk for people's health.

(vi) Use in the elaboration of foodstuffs (including food supplements): As stated above, only the foodstuffs derived from hemp seeds have a record of safe and significant consumption, enough to be considered authorized foodstuffs under Regulation 2283/2015. However, it will still be necessary to comply with general requirements and regulations on the commercialization of foodstuffs. To commercialize any foodstuff in Spain, all companies must be registered with the Health Registry of Food Business Operators, under RD 191/2011. If the products commercialized are food supplements, further requirements would apply (the obligation to submit a communication of placement in the market to the relevant authorities and to ensure compliance with the legal labelling specifications).

(vii) Industrial use: The use of the part of the cannabis plants not considered a narcotic drug for industrial purposes, or of the parts considered narcotic drugs from which the active narcotic substance has been extracted, is not subject to any specific requirements.

(viii) Export: Exporting the parts of the cannabis plant that are not considered a narcotic drug is not subject to any specific authorization or requirement.

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

Yes, as stated above, recreational use of the parts of the plant considered a narcotic drug is not permitted, while medical use is subject to authorization by AEMPS.

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

Provided the recreational use of the parts of the cannabis plant considered a narcotic drug is not permitted, only medicines containing cannabis are restricted to specific retail channels, as the retail sale of all medicines is limited to authorized pharmacies.

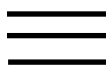
#### **C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located? Applicable to all cannabis products?**

There are no restrictions. The recreational use of the parts of the cannabis plant considered a narcotic drug is prohibited, and the therapeutic use of cannabis (not related to medicines) is not regulated.

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

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

To import cannabis seeds, documentation must be provided proving their licit origin. There are no restrictions on their specific geographic origin. However, the seeds imported from countries that are not part of the EU



must correspond to species for which the production procedures and seed requirements are equivalent to those applicable in the EU.<sup>2</sup>

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

Cannabis seeds are expressly excluded from the definition of narcotic drug; there is no restriction on importing cannabis seeds and no authorization is required.

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

All distinctions are related to certain parts of the cannabis plant being considered a narcotic drug, and other parts not being considered a narcotic drug, as explained above.

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

All specific legal requirements refer to the parts of the plant considered a narcotic drug. For products made using the parts of the cannabis plant not considered a narcotic drug, there are no specific requirements due to the fact that they may incorporate cannabidiol.

## IV. Patients and prescriptions

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

The therapeutic use of cannabis (not related to its incorporation into medicines) is not regulated in Spain. Only one medicine containing cannabis has been authorized in Spain, for the treatment of moderate or severe spasticity due to multiple sclerosis (“MS”) in patients who have not responded adequately to other anti-spasticity medications and have shown clinically significant improvement in spasticity-related symptoms during the treatment’s initial trial period.

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

This question depends on the type of product:

- (i) Only medical practitioners can prescribe medicines containing cannabis (as well as any other kind of medicine).
- (ii) There are no special requirements for any other products containing cannabis whose use is permitted according to section 6 above.<sup>3</sup>

**12. Are there patient registration or cardholder requirements?**

No. The therapeutic use of cannabis, other than its incorporation as an active substance in a medicine, has not been regulated yet, and for the only medicine authorized in Spain a valid prescription issued by a doctor is required.

## V. Special requirements

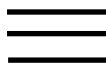
**13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?**

All companies authorized to cultivate cannabis, incorporating the active narcotic substance, must keep accurate records of their production.

Also, all companies authorized to import, acquire, store, transit or export narcotic drugs must keep accurate records of the volumes they are handling.

<sup>2</sup> See Order ARM/3372/2010 of December 27, passing the Technical Regulation of Control and Certification of Seeds of Textile Plants.

<sup>3</sup> Those based on the parts of the cannabis plant not considered a narcotic drug.



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

Only products for recreational use (smoking) made with the parts of the plant not considered a narcotic drug could be subject to the excise duties on tobacco products.

### VI. Risks and enforcement

All activities entailing the cultivation, production, import, acquisition, storage, transit or export of narcotic drugs contravening the applicable regulations or carried out without the corresponding authorizations will be considered illegal, under article 15 of Act 17/1967, which states that:

*“All operations of cultivation, acquisition, alienation, import, exportation, deposit, storage, transport, distribution and trafficking of narcotic substances that do not comply with the provisions of this Act or with nonperformance of its prescripts will be considered traffic.”*

Illegal traffic of narcotic drugs may constitute a crime:

- (i) A criminal offense against public health under article 368 of the Spanish Criminal Code, which reads: “those who carry out acts of cultivation, preparation or trafficking, or who otherwise favor or facilitate the unlawful consumption of toxic drugs, narcotics or psychotropic substances, or who possess them for those purposes, will be punished with imprisonment from three to six years and a fine of one to three times the value of the drug the offense concerns, if they are substances or products that cause serious damage to health, and of imprisonment from one to three years and a fine from one to two times the amount in the remaining cases.”
- (ii) Or at least an administrative infringement, which can be penalized in two ways:
  - Under articles 32 and 33 of Act 17/1967, which states that all actions or omissions contrary to the effectiveness of the administrative norms passed by administrative and governmental bodies under the provisions of this Act (specifically non-compliance with the formalities established in the Act or the non-existence of mandatory declarations or controls) will constitute administrative infringements. These infringements may be sanctioned with fines up to EUR 3,005.06, the revocation of all authorizations or licenses granted, early termination of any public procurement agreements awarded, the closure of the facilities, and disqualification from developing any activity related to producing, manufacturing and trafficking narcotic drugs.
  - Under sections 16 and 18 of article 36 of Act 4/2015, the following is a serious offense: “...the illicit consumption or possession of poisonous, narcotic drugs or psychotropic substances, even if they were not destined for trafficking, in places, routes, public establishments or collective transports, as well as the abandonment of the instruments or other effects used for such consumption or possession in these places” and also “the execution of acts of illegal cultivation of narcotic drugs in visible locations.”

These offenses are sanctioned with fines up to EUR 30,000, the seizure of the products, the temporary suspension of all granted licenses and authorizations for up to six months and the temporary closure of the facilities for up to six months.

### VII. Your practice and useful links

For further information, please contact our firm and our lawyers at [www.cuatrecasas.com](http://www.cuatrecasas.com).

#### Contributors

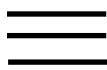
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# THAILAND

## I. Introduction

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

Thailand.

#### **History** [ref. 3 Wikipedia]

The marijuana/cannabis market in Thailand has a long history. Cannabis had been part of Thai culture (as a traditional medicine) until it was banned in 1930's. Thailand was once the land of the world's most powerful "ganja." It appears to have been introduced to Thailand from India. Cannabis has historically been used in Southeast Asia as an ingredient, a kitchen condiment, a medicine and a source of fiber. Laborers were known to use it as a muscle relaxer.

Cannabis can be found sold in bars and restaurants in certain parts of Thailand. Cannabis dealers sometimes work with police who shakedown customers and demand a bribe.

#### **Criminalization** [ref. 3 Wikipedia]

The possession, sale and use of marijuana/cannabis in Thailand was criminalized by the Cannabis Act BE 2477 (1935), the Narcotics Act BE 2522 (1979) and the Psychotropic Substances Act BE 2518 (1975).

The weed industry resulted in draconian drug laws applicable to both users and dealers.

Thailand reportedly has the largest prison population in Southeast Asia. Inmates convicted of drug offenses make up the largest percentage of the population.

Given the fact that the new Thai government appears supportive of developing the cannabis industry, it is likely that foreign investors will be encouraged by liberal policies, and need to establish medical grade cannabis facilities, and in due course recreational cannabis.

#### **Cannabis Industry Overview**

Investors should spend some time understanding how the cannabis industry is growing in recent years in states in the USA, Canada, etc. which have legislation and safeguards in place. On the one hand, Thailand has a grass-roots culture hundreds of years old. However, recent advances in regulation in a number of jurisdictions provide a number of guidelines which are relevant to growing the industry in Thailand. Each of the following subjects is very relevant:

1. Cultivation. Problems of over-production and low crop prices.
2. Extraction. Capital intensive, with many brands, concentrates and vape pens. Testing labs and ancillary firms.
3. Retail. Medical marijuana dispensaries and retail stores.
4. Export. Challenges of foreign market entry.
5. Import. Need for high standards for imports into Thai market.

The vertically-integrated cannabis companies provide helpful guidance.

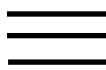
## II. Legislation

### 2. Please provide links to applicable statutes and regulations.

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

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

See attachment, [“Narcotics Act B.E. 2522 \(1979\) as amended up to Narcotics Act \(No. 7\) B.E. 2562 \(2019\).”](#)



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

No. The legalization of medical cannabis was enacted only in February 2019. There are a number of draft notifications and ministerial regulations under review. The amendment to the Narcotics Act allow cannabis to be used only for medical, science and research and development.

#### **Recent Thai Legislation**

Hemp has been approved for use in industry since 2018. Under a regulation, which came into effect on January 5, 2018, licenses for growing of hemp for industrial and medical purposes could be obtained. It did not address marijuana or any other forms of cannabis.

Thailand made history in December 2018 by becoming the first country in Southeast Asia to legalize medical marijuana. The Narcotics Act BE 2522 (1979) as amended up to Narcotics Act (No. 7) BE2562 (2019) (“NA”) came into effect on 19 February 2019. This followed years of efforts to legalize medical marijuana, based on evidence that the plant can be used to treat diseases, etc. See summary of the NA which focuses on cannabis after paragraph 9 below.

## **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?**

Under the Narcotics Act, the Ministry of Public Health.

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

See “Cannabis Industry Overview” above, and question 6 below.

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

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

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

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

N/A

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

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

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

N/A

### **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.**

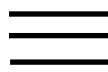
**C. Identify any related laws that should be considered when answering this question.**

N/A

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

This summary of the NA focuses on cannabis, not the many other narcotics governed by the NA.

- The NA includes 106 Sections.



- The Minister of Public Health is responsible for execution of the Act.
- The licensing authority (see Chapter 2) is the Secretary-General of the Food and Drug Board.
- There is a Narcotics Control Committee (see Chapter 1).
- The NA repealed 7 laws (Narcotics Act, no. 2, no. 3, no. 4, no. 5, Marijuana Act and Kratom Plant Act).
- Narcotics are classified into 5 categories. Category V consists of narcotics which are not included in categories I to IV, such as marijuana, kratom plant, (including cannabis). Section 26/5 provides that the licensing authority may issue a license to produce, import, export, distribute or possess narcotics of category 5 only when the applicant is:
  1. A government agency whose duty is to conduct study, research or teach re medicines, pharmacy, sciences agricultural sciences, etc.;
  2. A medical, pharmacy, dental, veterinary, Thai traditional medicine, applied Thai traditional medicine, folk healer profession practitioner, etc.;
  3. A university;
  4. Agricultural profession operators who have registered a community enterprise group, etc.;
  5. An international public transport business operator;
  6. An international travelling patient; or
  7. Other applicants as prescribed in Ministerial Regulations.
- Applicants under (7) in the case of ordinary person must be a Thai national domiciled in Thailand, and in the case of juristic person must be registered under Thai law and at least 2/3 of directors and shareholders must be Thai nationals, and have an office in Thailand.
- Duties of Licensees (Chapter 3) include Section 34/1, 34/2, 34/3 and 34/4 applicable to production, import, export, distribution or possession of narcotics of category V.
- Rules governing advertising are prescribed in Chapter 7.

There has been further clarification by Ministry of Public Health (MoPH) notifications that identify forms of medical cannabis allowed for approved use. These include (1) registered drugs per the Drug Act; (2) Thai traditional medicines having approved compositions (now 16 formulas); and (3) drugs approved for the Special Access Scheme. There have been clarifications of specific qualifications of Thai traditional practitioners having authority to prescribe traditional cannabis medicines. There is a complex network of who can be licensed for what purposes under draft implementing regulations.

The pathway for FDA medical cannabis licensing will be set out in implementing regulations, which have been circulated for comment. There is a complex network of who can apply for licenses, which seeks to ensure control over the process. Participation by foreigners is strictly restricted for the first 5 years, starting February 19, 2019. During this period, state agencies may obtain licenses to produce, import or export cannabis; and a private entity may act only jointly with a state agency to acquire a license.

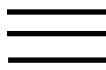
On August 31, 2019, a new notification of Ministry of Public Health came into effect, providing new exceptions for the following:

#### For marijuana and hemp:

- Marijuana or hemp stalks, stem cores and fibers, if dried, and products made of such dry parts;
- CBD extracted from marijuana or hemp, if having at least 99% purity and no more than 0.01 percent by weight of THC;
- Extracts have CBD as main constituent and no more than 0.2% by weight of THC, which are considered “drugs” under the Drug Act, or Herbal Products under the Herbal Products Act.

#### For hemp only:

- Hemp seeds or hemp seed oil, which are considered food under the Feed Act;
- Hemp seed oil or hemp seed extracts, which are considered cosmetics under the Cosmetics Act.



There are 2 draft Ministerial Regulations under review:

- Draft Ministerial Regulation re: Application for License and License for Production, Import, Export, Distribution or Possession of Narcotic under Category 5, only Cannabis, B.E.....
- Draft Ministerial Regulation re: Application for License and License for Production, Import, Export, Distribution or Possession of Narcotic under Category 5, only Hemp, B.E.....

#### IV. Patients and prescriptions

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

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

**12. Are there patient registration or cardholder requirements?**

The Patent Office has taken action to prevent foreign competition by rejecting patent applications from foreign applicants.

#### V. Special requirements

Thailand is intentionally excluding foreign participation at the early stage of the cannabis industry, which may raise questions under WTO treaties.

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

Yes.

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

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

Yes.

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

No restrictions.

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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

N/A

#### VI. Risks and enforcement

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

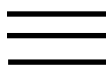
**19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.**

**A. Does enforcement differ based on quantity?**

**B. Does enforcement differ based on product type?**

There has been no mention of the UN Drug Treaties:

- 1961 Single Convention on narcotic Drugs,
- 1971 Convention on Psychotropic Substances, and
- 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.



## 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?**

At our website <https://www.chandlermhm.com/> you can find full information on our firm services and areas of practice.

**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.**

See References below.

**A. Are there any relevant trade organizations?**

**B. Are there any relevant lobbying organizations?**

References:

1. "Cannabis Overview", by Judith Lee von Nostitz.
2. "Medical Cannabis Regulations: Understanding the Roadmap Towards Legalization in Thailand", 28 March 2019, by Chokwan Kitty Chopaka.
3. "Cannabis in Thailand", Wikipedia 8/4/2019.
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5. "Transnational Organized Crime in Southeast Asia: Evolution, Growth and Impact", United Nations Office on Drugs and Crime, Southeast Asia and the Pacific, 2019.
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7. Client Alerts, Thailand, Tilleke & Gibbins, various.
8. "Annual Marijuana Business FACTBOOK", 7<sup>th</sup> Edition, 2019.
9. "The Green Regulatory Arbitrage: A Case of Investing in US Multi-State Vertically-Integrated Cannabis Companies", by David Wenger, September 6, 2018.
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11. "Guns Girls Gambling Ganja, Thailand's Illegal Economy and Public Policy," Pasuk Phongpaichit, 1998.
12. Baker McKenzie, Peerapan Tungsuwan, "Thailand's Cannabis Legalization," November 6, 2019.
13. Attachment: consolidated Narcotics Act.

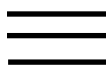
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# URUGUAY

## I. Introduction

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

The answers below are applicable to the Republic of Uruguay.

## II. Legislation

### 2. Please provide links to applicable statutes and regulations.

The general legal framework regarding cannabis is set forth in Law N° 19,172 and Law N° 14,294.

<https://www.impo.com.uy/bases/leyes/19172-2013>

<https://www.impo.com.uy/bases/decretos-ley/14294-1974/11>

Further, two new laws were approved in December 2019:

- [Law 19,485 on Scientific Investigation of Cannabis](#), that promotes research on cannabis by a new public legal entity to be created called the Uruguayan Center for Advance Studies on Cannabis. Under this Law the Executive Branch is empowered to exonerate from any tax the importation of laboratory equipment and inputs of any kind intended for cannabis research.
- [Law 19,847 on Medical and Therapeutic Cannabis](#) that introduced several changes to the legal structure for accessing to medicine containing cannabis. Mainly, that patients shall be able to create Association of Patients for the Use of Cannabis with Medical Purposes in order to access this kind of medicine.

Besides, there are three (3) relevant Decrees:

1. [Decree No. 120/014](#) refers to Recreational use of cannabis.
2. [Decree No. 372/014](#) refers to hemp.
3. [Decree No. 46/015](#) refers to medical or research use of cannabis.

In addition, please note that the National Institute for the Control and Regulation of Cannabis (“IRCCA”) regularly enacts many Resolutions related to cannabis.

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

No.

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

Yes, there is a bill regarding the control applicable to psychoactive cannabis, submitted in September 2018 which pretends to make amendments to the control system of substances with psychoactive cannabis.

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

Cannabis laws have been quite well settled since 2014.

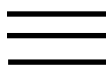
IRCCA often enacts Resolutions that set guidelines for activities related with cannabis, but these usually regulate specific aspects that are already broadly regulated in the general legal framework which remains unchanged.

## 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?

Any activity related with cannabis requires a license/register issued by the corresponding authority.

-Activities with cannabis for medicinal use and scientific research are controlled by: IRCCA, Ministry of



Health (“MSP”) and the National Secretary for the Fight against Money Laundering and the Financing of Terrorism (“SENACLAFT”).

-Activities with Recreational Cannabis are controlled by: IRCCA and by SENACLAFT (except when it comes to self-cultivation and cannabis clubs).

-Activities with hemp are controlled by: IRCCA; Ministry of Livestock, Agriculture and Fishery (“MGAP”) and SENACLAFT.

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

The activities allowed, subject to obtaining the requires authorization/permit, are: cultivation, harvest, production, storage, industrialization, commercialization, distribution, importation and exportation.

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

Cannabis regulation does not establish any specific prohibition regarding products, reason why prima facie any product properly authorized by the corresponding governing body is allowed. Some of the products that have already been authorized include cosmetics, gels, yerba mate with added non-psychoactive cannabis and medication.

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

Yes. Medical use is regulated in Decree No. 46/015, recreational use is regulated in Decree No. 120/014.

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

Yes, depending on the product:

1. Pharmaceutical specialties or vegetable specialties based on psychoactive cannabis can only be sold by pharmacies of first or second category.
2. Psychoactive cannabis for personal recreational use is only sold in first category pharmacies and in community pharmacies, which have obtained the license of the IRCCA.
3. Other products, such as yerba mate, have no restrictions as to the establishments in which they may be sold.
4. Medical products prescribed under master formulas elaborated by Pharmaceutical Chemists can be sold by pharmacies duly authorized to such effects.

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

Resolution 9/2018 issued by IRCCA establishes that Cannabis Clubs must be located a more than 150 meters from (i) educational, cultural and/or sports centers where children under the age of 18 attend, and (ii) institutions for the care and treatment of addictions. In urban areas, the Club may not coexist with a particular domicile and/or trade in the same register.

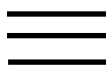
#### **7. What import and export is allowed in your jurisdiction?**

The following are allowed in our jurisdiction:

Importation and exportation of cannabis seeds/plants/finished or semi-finished products for medicinal or scientific research purposes; importation or exportation of hemp and seeds; importation of seeds or cuttings for the cultivation of psychoactive Cannabis plants for: producers of psychoactive Cannabis for Pharmacies, self-growers and Cannabis Clubs. In all cases, customs licences issued by the competent authorities are required

##### **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.**

In order to import Cannabis seed a phytosanitary authorization from the country of origin is needed as well as Registration of the seed before the National Institute of Seed.

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

Yes.

**A. If so, what distinctions exist?**

Regulation distinguishes between psychoactive and non-psychoactive cannabis; regulation is organized based on the use given to cannabis.

**B. If so, briefly describe the differences.**

Our regulation defines Psychoactive and Non-psychoactive cannabis as follows:

- **Psychoactive Cannabis** - Flowery branch ends with or without fruit of the cannabis female plant, excluding the seeds and leaves separated from the stalk, but including oils, extracts, and any preparations with potential pharmaceutical use, whose natural THC equals or exceeds 1% of its volume.
- **Non-psychoactive Cannabis** (hemp) - those plants or parts of plants of the cannabis genus, leaves and flower tips, containing no more than **1% THC**, including derivatives of such plants and parts of plants.

The uses allowed by our regulation are as follows:

- **Recreational use** of Psychoactive Cannabis,
- **Medical or research use** of either psychoactive and non-psychoactive cannabis,
- **Use of hemp** (Non-Psychoactive Cannabis).

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

Law N° 14.294 and Law N° 19.172 establish these distinctions which are reinforced in the Decrees 120/014, 372/015 and 46/015.

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

Yes, there are.

As mentioned above, Decree 372/015 regulates products without THC. If products without THC are medicine or vegetable specialties they will also be regulated by Decree 46/015.

## IV. Patients and prescriptions

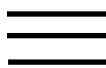
**10. What specific medical conditions, if any, are recognized for treatment with cannabis?**

Our regulation does not recognize specific medical conditions for cannabis treatment. Regulation and the government's position so far has been to promote cannabis medical treatment. In fact, the recently approved Law 19847 declares of national interest all actions aiming to protect, promote and improve public health through products based on cannabis or cannabinoids.

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

In order to prescribe cannabis for medical purposes you have to be a Doctor of Medicine.

Law 19847 has now stated that the MSP shall develop recommendations for the formation of professionals to participate in cannabis health programs and further prescribes the due formation of human resource within the health system, on medical and therapeutic cannabis use.



## **12. Are there patient registration or cardholder requirements?**

Registration is a consequence of purchasing medicines based on psychoactive cannabis. The purchaser is automatically registered in the Acquirers of Medical Psychoactive Cannabis section of the Register of Cannabis, being prevented from acquiring psychoactive cannabis or products elaborated based on psychoactive cannabis for a term of 30 days.

## **V. Special requirements**

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

All activities linked with cannabis products are, at minimum, under the control of IRCCA. In particular, recordkeeping is regulated for Cannabis Club which must keep information and provide it to IRCCA, if requested, regarding the production, the delivery to its members and the destiny of the exceeding cannabis.

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

There are no specific tax on cannabis. However, certain regulations do apply:

- Agricultural Goods Transfers Tax (“IMEBA” as per its acronym in Spanish) for generative events related to psychoactive and non-psychoactive cannabis is established the rate of 0%.-Value Added Tax (“VAT”) levies valuable transactions consisting of internal circulation of goods, rendering of services within the national territory, introduction of goods to the country and value added over real property under works by means of administration performed by those who are not IRAE taxpayers, at a 22% basic rate. Cannabis transaction are taxed by Agricultural VAT, which applies to both psychoactive and non-psychoactive cannabis. Under Uruguayan law, psychoactive cannabis is understood to be the flowering tops with or without the fruit of the female Cannabis plant, with the exception of the seeds and leaves separated from the stem, whose natural tetrahydrocannabinol (THC) content is equal to or greater than 1% (one percent) by weight. The particularity of the Agricultural VAT refers to the fact that circulation of the goods previously established shall not be included in the invoice or equivalent document and shall remain suspended for tax purposes until the nature of the goods is transformed or altered.
- No other indirect taxes (such as “IMESI” as per its acronym in Spanish) applies to cannabis circulation.
- Income Tax on Economic Activities (“IRAE” as per its acronym in Spanish) at a rate of 25% on the net income derived from Uruguayan source. Bear in mind that according to Uruguayan regulations, it will be considered from Uruguayan source the income derived of activities developed, assets located or rights economically in Uruguay.

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

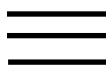
Regarding banking regulation, please see answer to question 16.

As regards patent or trademark protection, the general framework for other products applies, there is no special regime. No patent is required for the sale of cannabis. As regards labeling requirements the general regulation applies too; for instance, medicine based on cannabis will have to comply with general medicine labeling rules, and so on.

Recreational cannabis sold in pharmacies has a specific label which pre-established by IRCCA.

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

As mentioned, in Uruguay it is legal to operate with cannabis, provided the corresponding permits are obtained. Further, under the Financial Inclusion Law cash handling in most commercial and civil transactions is restricted: in general terms, all transactions over certain thresholds need to be paid through authorized banking mechanisms (for example checks, certified checks, wire transfer) and salaries have to be paid by wire transfer or bank deposits.



However, in practice, it has proven almost impossible for companies dealing with cannabis to fully operate with Uruguayan banks. To a large extent, local Banks are subject through their headquarters, to foreign regulations, in particular to the United States Federal Reserve's prohibition from participating (directly or indirectly) in cannabis-related operations as well as international provisions on money laundering. Therefore, in order to avoid any potential inconvenience Uruguayan banks have been reluctant to participate in operations of this kind or to open bank accounts for these companies.

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

**A. Impact on use by under age/minors.**

**B. Impact on beer, wine and spirit sales.**

**C. Tax revenue.**

**D. Impact on crime, including drug and alcohol addiction.**

IRCCA collects and publishes information regarding cannabis. Further, fulfilling the tasks assigned by law 19.172 it advises on the implementation of preventive measures to help raise awareness among users and the general public of the risks and possible harms of cannabis use, in areas such as education, work environment, driving and transit.

In particular one of IRCCA's tasks is to advise the Executive Branch on the development of strategies aimed at delaying the age at which consumption begins, increasing the perception of the risk of abusive consumption and reducing problematic consumption. IRCCA also works with the National Board of Drugs of the Presidency of the Republic.

## VI. Risks and enforcement

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

In general term the main issue that the industry has been facing in Uruguay is the government's learning curve on cannabis. As stated, the first laws and regulations were sanctioned in 2014 and since then the government's intention to promote and develop the cannabis industry has faced practical inconveniences that are yet to be solved.

Excessive bureaucratic barriers, for example, have proven to be one of the main challenges faced by both investors and producers. Different governmental agencies are overseeing or at least participating to some extent in licensing processes (IRCCA, MSP, MGP, INASE) and their timing are different, and requirements sometimes overlap.

Similarly, as mentioned, the local banking system is reluctant to accepting clients from the cannabis and an adequate solution has not yet been provided to producers, investors and even pharmacies.

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

**A. Does enforcement differ based on quantity?**

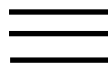
**B. Does enforcement differ based on product type?**

The enforcement landscape is tending to legalization through all the above mentioned regulation, accompanied, however by a strict enforcement of the permits and prohibitions set forth in the laws and decrees.

## 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?**

At Guyer & Regules, we have an active and growing cannabis practice within our Environmental and Regulatory team. We have advised companies in setting up their businesses, carrying out application processes before the



authorities (in particular MSP, IRCCA and SENAFLACT) as well as assisted investors in due diligence processes of local cannabis companies.

This team actively interacts with the Real Estate Department in all matters related to land zoning, land acquisition and lease agreements of the plots of land for cultivation as well as with the Corporate Department with regards to corporate structuring and M&A processes of cannabis companies.

We expect this industry to grow and develop in Uruguay in the coming years, and our teams are looking forwards to accompany current and future clients in this process.

**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.**

**A. Are there any relevant trade organizations?**

**B. Are there any relevant lobbying organizations?**

At our website [guyer.com](http://guyer.com) you can find full information on our firm services, areas of practice and our international recognition.

As for relevant organizations, we recommend that any foreign investor to contact [UruguayXXI](#) the Uruguayan Investment and Promotion Agency. Further, in general terms it is always useful to reach out to the local embassy. At Guyer we have fluent and frequent contact with embassies, Uruguay XXI and bilateral chambers of commerce and can therefore easily help in reaching out to the relevant contacts.

## Contributors

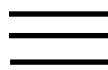
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# U.S.A. - CALIFORNIA

## I. Introduction

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

California, U.S.A.

## II. Legislation

### 2. Please provide links to applicable statutes and regulations.

#### Relevant Statutes

Business & Professions Code – Sections 26000, et seq.

Health & Safety Code – Sections 11000, et seq.; 11357, et seq.; 11362.7, et seq.

#### Relevant Regulations

Bureau of Cannabis Control – Regulations

California Department of Food and Agriculture – Regulations

California Department of Public Health – Regulations

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

The Bureau of Cannabis Control recently issued Proposed Emergency Regulations (February 3, 2020) that could alter its regulations.

There are various bills concerning cannabis, including AB 286 (which would give tax relief to legal cannabis business), AB 228 (which would allow hemp-derived CBD products to be included in any food, beverage or cosmetic without restriction) and SB 658 (which would require licensed retailers and delivery drivers to display emblems showing that they are licensed), which the Legislature has considered, but which have been tabled for now.

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

See answer to Question 2(A) above.

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

The overarching state legislation governing cannabis in California seems well-settled. The regulations governing cannabis are not. Although the foundational regulations probably will not materially change in the near term, there often are emergency regulations that are proposed to address ambiguities in existing regulations and to address new issues. Local laws and regulations are in even greater flux.

## 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?

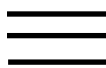
The Bureau of Cannabis Control, California Department of Food and Agriculture and California Department of Public Health are the agencies that regulate cannabis-related activities in California. State and local law enforcement primarily enforce cannabis-related activities.

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

Growing, processing, and retail of both cannabis and hemp.

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

Flower, edibles, vapor oil, other types of oil, and other concentrates are all allowed to be sold and consumed.



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

There are some minor differences. For example, medical users can grow as much cannabis as required for their personal medical needs whereas non-medical growers are limited to six plants per residence. Likewise, medical marijuana patients who present a valid marijuana identification card do not have to pay certain taxes when purchasing cannabis and cannabis-related products.

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

Yes – licensed retail stores. Cannabis products also may be delivered in California, subject to compliance with state regulations.

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

Yes – for example, cannabis outlets cannot be located near schools. Localities have the discretion to enact their own zoning restrictions, including to ban cannabis altogether.

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

No cannabis may be imported or exported across California state lines. Hemp may be imported and exported across state lines, including derivatives such as CBD.

**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.**

See answer to Question No. 7 above.

**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?**

(see answer to Question No. 8 above)

**B. If so, briefly describe the differences.**

(see answer to Question No. 8 above)

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

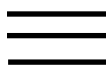
(see answer to Question No. 8 above)

The 2018 Farm Bill federally legalized hemp-derived CBD products that contain less than 0.3% THC. However, the U.S. Food and Drug Administration (“FDA”) then clarified that it was not signing off on food, beverages or cosmetics containing such products and, further, that it would subject products that are marketed as having material health benefits to scrutiny. California has more or less said that it will follow federal direction on this issue.

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

See answer to Question No. 8 above.





## IV. Patients and prescriptions

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

It depends on state or federal law. Currently, the FDA has licensed only one use in the form of the medicine Epidiolex, which is CBD used for the treatment of certain types of seizures in children.

In California, qualifying conditions to become a cannabis patient include:

- Cancer
- Anorexia
- AIDS
- Chronic pain
- Spasticity
- Cachexia
- Persistent muscle spasms, including those associated with multiple sclerosis
- Seizures, including, but not limited to, those associated with epilepsy
- Severe nausea
- Glaucoma
- Arthritis
- Migraines
- Any other chronic or persistent medical symptom that substantially limits the ability of the person to conduct one or more major life activities (as defined by the Americans with Disabilities Act of 1990) or, if not alleviated, may cause serious harm to the patient's safety or physical or mental health

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

Cannabis prescriptions must be obtained from licensed healthcare practitioners. The Medical Board of California has published Guidelines for the Recommendation of Cannabis for Medical Purposes for practitioners to follow.

### **12. Are there patient registration or cardholder requirements?**

Yes – but they are fairly minimal. You need to be a California resident, present a valid form of identification and be diagnosed as having one of the qualifying conditions set forth in the answer to Question No. 9 above.

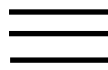
## V. Special requirements

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

Yes – the California Cannabis Track-and-Trace system is being used statewide to record the inventory and movement of cannabis and cannabis products through the commercial cannabis supply chain. This system must be used by all annual and provisional cannabis licensees, including those with licenses for cannabis cultivation, manufacturing, retail, distribution, testing labs, and microbusinesses. A five-step guideline for using this system is available here.

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

Yes – all adult-use purchases are subject to a 15% cannabis excise tax, an 8-10% city tax, and a 7.25-11% sales and use tax, depending on location. Medical marijuana users do not have to pay sales and use taxes when making retail purchases of cannabis and cannabis-related products.



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

Yes – for example, California has fairly stringent labeling requirements, which are available here. Likewise, as is the case throughout the United States, it can be difficult to get an account for cannabis-related activity with a federally insured bank. Credit unions in California are more willing to take cannabis-related funds but there are caps on how much money they will take.

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

See answer to Question No. 14 above.

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

**A. Impact on use by under age/minors.**

Not to our knowledge by the California government.

**B. Impact on beer, wine and spirit sales.**

Not to our knowledge by the California government.

**C. Tax revenue.**

Yes – the California Department of Tax and Fee Administration tracks this information.

**D. Impact on crime, including drug and alcohol addiction.**

Not to our knowledge by the California government.

## VI. Risks and enforcement

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

By far the biggest issue in California is the black market. Recent data shows that there are three times as many illegal sellers as legal ones. Black market operators undercut licensed ones by selling product for a much lower price. There are relatively minimal resources available for the government to take action against these illegal operators. Coupled with the steep startup costs and taxes that licensed operators must pay, this has given black market operators a major advantage over licensed ones. Many licensed operators are struggling to make a profit and are clamoring for more enforcement activity.

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

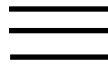
Relatively lax. The government has been more focused on launching the regulatory and licensing regime governing cannabis than taking action to enforce that regime. That said, state and local law enforcement officials have launched targeted strikes against illegal operators.

**A. Does enforcement differ based on quantity?**

Our sense is that law enforcement officials are more likely to target operators handling a lot of product.

**B. Does enforcement differ based on product type?**

Not to our knowledge.



## 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?**

Our firm, Greenberg Glusker, acts as outside general counsel for the Bob Marley estate. In 2014, our firm, led by Bonnie Eskenazi, worked on a landmark deal to help launch the Marley Natural brand of cannabis and cannabis-related products. The deal required us to develop expertise in the cannabis space. Since then, we have grown this expertise, advising existing and new clients who are involved in or are interested in getting involved in this space. We are a full-service business law firm of about 100 attorneys and, as a result, have the expertise to advise cannabis and cannabis-related clients on a range of issues, from tax to real estate to intellectual property to litigation. We launched our Cannabis Industry Group last year.

**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.**

[Main website](#)

[Cannabis Industry Group page](#)

**A. Are there any relevant trade organizations?**

California Cannabis Industry Association  
United Cannabis Business Association  
Southern California Coalition

**B. Are there any relevant lobbying organizations?**

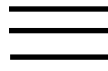
See answer to Question 21(A) above.

### Contributor

**Greenberg Glusker**

Steven Stein

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# U.S.A. - OREGON

## I. Introduction

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

Oregon, U.S.A.

## II. Legislation

### 2. Please provide links to applicable statutes and regulations.

ORS 475B – Cannabis Regulation  
 ORS 571.300 et seq – Industrial Hemp Growers and Handlers  
 OAR 845-025 – State regulations regarding recreational marijuana  
 OAR 603-048 – State regulations on industrial hemp  
 OAR 333-007 – State regulations regarding testing and labeling of marijuana and hemp

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

SB 5318 has passed but the drafted rules have not yet been implemented. These rules will significantly alter enforcement of cannabis licenses.

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

Legislature is not currently in session.

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

Early on, someone described the regulation of the Oregon cannabis industry as building a car while the car is being driven. Things have settled down somewhat since then, but the Oregon legislature and Oregon Liquor Control Commission (“OLCC”) do regularly tinker with the rules. These changes range from minor technical fixes all the way up to giving the OLCC the authority to deny applications to grow marijuana based on market conditions, an ability they did not have until this year.

## 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?

The Oregon Liquor Control Commission issues cannabis licenses, regulates cannabis licenses, and oversees cannabis business activities across the state.

The Oregon Health Authority (“OHA”) administers Oregon’s medical marijuana program.

The Oregon Department of Agriculture (“ODA”) regulates the production and processing of hemp in Oregon.

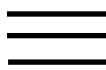
### 5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.

The OLCC issues five types of cannabis licenses – production, processing, wholesale, retail, and laboratory.

The OHA allows registrants to grow cannabis for card-holding medical marijuana patients. The ODA registers growers and handlers of industrial hemp.

Hemp products may be sold at retail without a license or registration.

Oregon residents may grow up to four marijuana plants for personal use. No license or registration is required.



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

The OLCC allows the sale of flower, edibles, concentrates, extracts, and topical products to Oregon consumers over the age of 21. Recent emergency rulemaking banned the use of certain non-cannabis-derived flavoring compounds in products for use in vaporizers, although Oregon courts temporarily stayed the ban as part of pending litigation.

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

Somewhat. Medical patients are able to purchase products with higher amounts of cannabinoids, and Oregon does not assess its point-of-sale tax on medical cannabis products. Despite ongoing conversations about integrating medical and recreational cannabis under a single regulator, for now Oregon continues to regulate medical and recreational cannabis through separate agencies.

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

Yes, only licensed retail stores may sell cannabis. It is still technically possible to operate a medical marijuana-only dispensary in Oregon, although only three are currently registered with the OHA.

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

Yes. Retail stores must be more than 1,000 feet from schools. These restrictions do not apply to other classes of licenses. Cannabis business are subject to local zoning codes and other laws and rules of general applicability. Cities and counties may place additional time, place, and manner restrictions on cannabis businesses. Shortly after Oregon legalized cannabis, certain cities and counties had a short window to ban cannabis business altogether, and much of eastern Oregon did so.

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

Current federal enforcement guidelines do not allow interstate commercial cannabis activity. Oregon has passed legislation that would allow the state to enter into agreements to import and export cannabis with other states, but only after federal law or enforcement guidelines change to allow such activity.

Hemp and hemp products may be freely imported and exported.

### **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.**

Marijuana seeds may not be imported or exported. Hemp seeds may be freely imported and exported.

## **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?**

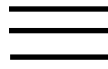
### **B. If so, briefly describe the differences.**

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

Not within OLCC regulations. Medical marijuana patients can purchase products with higher quantities of THC.

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

Not with respect to Oregon law. Products containing hemp-derived CBD may be freely sold without a license.



## IV. Patients and prescriptions

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

- Cancer, glaucoma, a degenerative or pervasive neurological condition, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, or a side effect related to the treatment of those medical conditions;
- A medical condition or treatment for a medical condition that produces, for a specific patient, one or more of the following:
  - (A) Cachexia;
  - (B) Severe pain;
  - (C) Severe nausea;
  - (D) Seizures, including seizures caused by epilepsy; or
  - (E) Persistent muscle spasms, including spasms caused by multiple sclerosis;
- Post-traumatic stress disorder; or
- Any other medical condition or side effect related to the treatment of a medical condition adopted by the Oregon Health Authority by rule or approved by the authority pursuant to a petition filed under ORS 475B.946.

Historically, this list of conditions has been interpreted broadly, and obtaining a medical marijuana card was not difficult. The number of cardholders in Oregon has dropped significantly since Oregon legalized adult-use cannabis.

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

Yes.

### **12. Are there patient registration or cardholder requirements?**

Yes.

## V. Special requirements

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

Yes. Oregon tracks cannabis from seed to sale using the METRC platform.

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

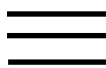
Yes. There is a 17% tax levied by the state at the point of retail sale. Cities and counties may levy an additional 3% local tax.

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

“White labeling” and other types of contract manufacturing are common in Oregon. There are rumors that the OLCC may be clarifying or changing the rules governing such agreements, but it is unclear what form such regulations would take. There are significant labeling requirements, most surrounding having certain disclaimers included on products, as well as prohibiting labeling and advertising likely to be attractive to children. With respect to cannabis, Oregon does not place any restrictions on banking, trademarks, insurance, or other common business needs, though federal law does limit or restrict the availability of such services.

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

Banks are theoretically allowed to service the industry, subject to “Know Your Customer” requirements and significant compliance obligations. In practice, most banking institutions still do not provide services to cannabis businesses nationwide. There are currently two credit unions in Oregon that provide basic commercial banking services to cannabis businesses.



Despite the changes to federal law, hemp businesses face the same difficulties finding banking services, though some banks have indicated willingness to offer services to the hemp industry as the federal government clarifies how hemp will be regulated.

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

**A. Impact on use by under age/minors.**

Yes, information available [here](#).

**B. Impact on beer, wine and spirit sales.**

No.

**C. Tax revenue.**

Yes.

**D. Impact on crime, including drug and alcohol addiction.**

Yes.

## VI. Risks and enforcement

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

Access to banking, tax issues (under the U.S. tax code, cannabis businesses cannot currently deduct business expenses), lack of funding for the OLCC and other regulators, the export of black or grey market cannabis across state lines.

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

The possession and use of cannabis use has been fully legalized, although there are limits on the amounts that may be possessed. Enforcement of laws related to personal possession and use has been deprioritized.

Oversight of licensed businesses is quite strict, although a large number of licensees compared to the number of regulators can lead to spotty enforcement.

**A. Does enforcement differ based on quantity?**

Yes, see above.

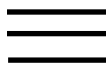
**B. Does enforcement differ based on product type?**

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?**

Lane Powell's core cannabis team consists of four attorneys split between Seattle and Portland, all of whom have been working with cannabis businesses since their respective states legalized cannabis. The core team members act as liaisons between the cannabis industry and nearly two hundred other attorneys at the firm. As a full-service business law firm, Lane Powell provides a full range of transactional and litigation legal services to the cannabis industry. Lane Powell was ranked by Chambers & Partners as one of the top seven cannabis



law firms in the U.S., and two team members were ranked among the top corporate/transactional cannabis attorneys in the U.S. While cannabis remains somewhat novel in the U.S. legal community at large, Lane Powell understood early on that cannabis businesses would need the full range of legal services provided by larger law firms. Lane Powell's cannabis practice has grown with the industry and its clients, and will continue to be a leading provider of quality legal services to the cannabis industry.

**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.**

[Main site](#)

[Practice group webpage](#)

[Practice group blog](#)

**A. Are there any relevant trade organizations?**

Oregon Retailers of Cannabis Association  
National Cannabis Industry Association  
Oregon Cannabis Association

**B. Are there any relevant lobbying organizations?**

See above.

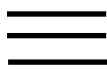
## Contributor

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# U.S.A. - WASHINGTON

## I. Introduction

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

Washington, U.S.A.

## II. Legislation

### 2. Please provide links to applicable statutes and regulations.

RCW 69.50 – State Controlled Substances Act

WAC 314-55 – State regulations on cannabis licenses and businesses

RCW 15.120 – State regulations on hemp production

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

SB 5318 has passed but the drafted rules have not yet been implemented. These rules will significantly alter enforcement of cannabis licenses.

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

The state legislature is currently in session and numerous bills have been proposed, but it is currently too early to tell which bills will proceed to a vote, much less become law.

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

Overall, pretty well settled. However, important laws and rules are revised or newly passed every year. It is settled compared to the Washington cannabis regulations in the first few years following state-legalization, but it is still quickly evolving when compared to other industries or regulatory areas.

## 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?

The Washington State Liquor and Cannabis Board (“WSLCB”) issues cannabis licenses, regulates cannabis licenses, and enforces cannabis business activities across the state.

The Washington State Department of Agriculture (“WSDA”) issues hemp licenses, regulates hemp licenses, and enforces hemp business activities across the state, though enforcement activities are less involved than WSLCB’s activities.

The Washington State Department of Health (“WSDOH”) regulates cannabis medical patients.

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

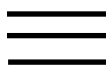
Growing, processing, and retail of both cannabis and hemp.

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

Flower, edibles, vapor oil, other types of oil, and other concentrates are all allowed to be sold and consumed. Recent rulemaking banned the use of non-cannabis-derived compounds in vapor oil products.

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

Overall, no. However, there are a few special rules regarding having a retail store be “medically endorsed” to sell medical cannabis products to patients registered with the Washington State Department of Health.



Patients can purchase products at licensed retail stores and waive the sales tax. Otherwise, medical & adult use are regulated the same.

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

Yes, licensed retail stores only.

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

Yes, for all types of licenses (restrictions are on the business locations, not on the products). State mandated minimum of 1000 feet distance from a business and schools and playgrounds, and a minimum of 100 feet for other sensitive areas such as public transit centers, libraries, recreation facilities, and public parks. Local governments can set their own limits (except for schools and playgrounds) between 100 and 1000 feet.

Local governments can also enact bans on cannabis licenses within their jurisdiction.

Finally, local governments have general jurisdiction to enact other zoning requirements of cannabis businesses.

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

No marijuana may be imported or exported across WA state lines. As described more fully in the separate chapter on hemp, hemp may be imported and exported across state lines, including derivatives such as CBD.

Hemp can be imported and exported freely across state lines, though local law enforcement can still cause businesses problems.

**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.**

Cannabis seeds are still considered a Schedule I substance under the federal Controlled Substances Act, and are therefore prohibited from being imported into the United States.

At the state level, cannabis businesses licensed by the WSLCB may purchase cannabis seeds from other licensed businesses.

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

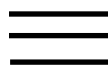
The only significant legal distinction is the difference between marijuana and hemp. Hemp is defined under federal law as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”

Washington businesses do have to list on their products the total amounts of THC, THCA, and CBD in terms of percentage of the product.

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

The WSDA regulates the production of hemp and its derivatives, and has also made statements regarding the sale of foods containing CBD, but its jurisdiction over this issue is questionable. See discussion in the separate chapter on Hemp for US federal rules.

Yes. CBD products are regulated depending on whether they are sourced from marijuana or hemp, as described elsewhere in this document.



## IV. Patients and prescriptions

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

It depends on state or federal law. Currently, the U.S. Food and Drug Administration (“FDA”) has licensed only one use in the form of the medicine Epidiolex, which is CBD used for the treatment of certain types of seizures in children.

In Washington state, the WSDOH recognizes the following medical conditions for treatment with cannabis:

- Cancer, human immunodeficiency virus (HIV), multiple sclerosis, epilepsy or other seizure disorder, or spasticity disorders.
- Intractable pain, limited for the purpose of this chapter to mean pain unrelieved by standard medical treatments and medications.
- Glaucoma, either acute or chronic, limited for the purpose of this chapter to mean increased intraocular pressure unrelieved by standard treatments and medications.
- Crohn’s disease with debilitating symptoms unrelieved by standard treatments or medications.
- Hepatitis C with debilitating nausea or intractable pain unrelieved by standard treatments or medications.
- Diseases, including anorexia, which result in nausea, vomiting, wasting, appetite loss, cramping, seizures, muscle spasms, or spasticity, when these symptoms are unrelieved by standard treatments or medications.
- Chronic renal failure requiring hemodialysis.
- Posttraumatic stress disorder.
- Traumatic brain injury.

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

Cannabis prescriptions must be obtained from licensed healthcare practitioners, but there is no license unique to prescribing cannabis. The WSDOH has published Authorization Practice Guidelines for practitioners to follow. Further, the WSDOH and state law requires that patients either (a) grow their own cannabis, or (b) obtain cannabis from a designated provider.

### **12. Are there patient registration or cardholder requirements?**

Yes to both – more information available here.

## V. Special requirements

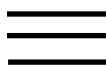
### **13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?**

Yes, for all products, and the tracking system is colloquially called the traceability system or seed-to-sale tracking. Producers and processors must tag and log each plant that is grown, and each final product that is produced. Further, each product sold to another licensee must be logged. Retailers must also log their product purchases from other licensees and sales to customers (end users).

This system is regulated and tracked by the WSLCB, and failure to maintain these logs is a regulatory violation.

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

Sales and excise taxes are imposed. The excise tax is 37%, imposed at retail sale.



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

At the state level, certain branding and trademark agreements of cannabis licensees must be disclosed to the WSLCB. There are significant labeling requirements, most surrounding having certain disclaimers included on products, as well as prohibiting labeling and advertising likely to be attractive to children.

At the federal level, the FDA will enforce federal consumer protection rules where health claims are made with respect to cannabis and hemp products, particularly where such claims lack sufficient medical evidence.

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

In practice, most banking institutions still do not provide services to cannabis businesses nationwide. A small number of state-chartered banks and credits do provide services to cannabis businesses.

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

**A. Impact on use by under age/minors.**

Yes, information available [here](#).

**B. Impact on beer, wine and spirit sales.**

Not by the government.

**C. Tax revenue.**

Yes, information available [here](#).

**D. Impact on crime, including drug and alcohol addiction.**

Certain studies are conducted at universities, in particular the University of Washington Alcohol and Drug Abuse Institute.

## VI. Risks and enforcement

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

Federally: Access to banking and federal taxation, most importantly Section 280E, which prevents normal business deductions for cannabis businesses (both federal issues).

State: traceability, out-of-state financing/ownership, and regulatory enforcement.

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

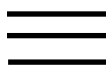
The answer depends on whether we are addressing personal cannabis use or the production & sale of cannabis.

Generally, enforcement of personal cannabis use in Washington state is lax but depends widely on local government policies. Personal cannabis use for any purpose has been legalized and possession of up to one ounce is legal.

Enforcement of cannabis businesses is much more strict, and numerous factors prompted the passing of SB 5318 (mentioned earlier), which significantly reigned in enforcement activities by the WSLCB.

**A. Does enforcement differ based on quantity?**

Yes, see above.



### **B. Does enforcement differ based on product type?**

Laws on personal possession depends on type, and a broad breakdown of these laws are publicly available provided by NORML (a non-profit advocacy organization).

## 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?**

Lane Powell's core cannabis team consists of four attorneys split between Seattle and Portland, all of whom have been working with cannabis businesses since their respective states legalized cannabis. The core team members act as liaisons between the cannabis industry and nearly two hundred other attorneys at the firm. As a full-service business law firm, Lane Powell provides a full range of transactional and litigation legal services to the cannabis industry. Lane Powell was ranked by Chambers & Partners as one of the top seven cannabis law firms in the U.S., and two team members were ranked among the top corporate/transactional cannabis attorneys in the U.S. While cannabis remains somewhat novel in the U.S. legal community at large, Lane Powell understood early on that cannabis businesses would need the full range of legal services provided by larger law firms. Lane Powell's cannabis practice has grown with the industry and its clients, and will continue to be a leading provider of quality legal services to the cannabis industry.

### **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.**

[Main site](#)

[Practice group webpage](#)

[Practice group blog](#)

#### **A. Are there any relevant trade organizations?**

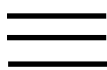
Washington Craft Cannabis Coalition  
 Washington CannaBusiness Association  
 Cannabis Alliance  
 Washington Sun growers Alliance

#### **B. Are there any relevant lobbying organizations?**

See above.

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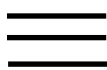
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