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 28th, 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[1].

1 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 29th, 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 grating of production licenses which includes cannabis growing. This regulation was approved on December 5th, 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 9th, 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[2].

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.

2 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[3].

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[4].

3 These forms are available in the following links: https://bit.ly/2Y6JSAu and https://bit.ly/2LcluIB.

4 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[5].

Moreover, the definition of "psychoactive" cannabis (i.e., with a concentration of THC equal to or exceeding 1% of the product's dry weight[6]) 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[7], 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 ser 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-bases 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[8].

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[9], 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.

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

9 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.

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