

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.

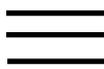
IRCCA often enacts Resolutions that set guidelines for activities related with cannabis, but these usually regulate specific aspects that are already broadly regulated in the general legal framework which remains unchanged.

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?

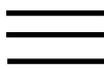
The following are allowed in our jurisdiction:

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** - Flowering 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?

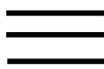
Our regulation does not recognize specific medical conditions for cannabis treatment. Regulation and the government's position so far has been to promote cannabis medical treatment. In fact, the recently approved Law 19847 declares of national interest all actions aiming to protect, promote and improve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

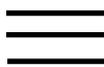
As regards patent or trademark protection, the general framework for other products applies, there is no special regime. No patent is required for the sale of cannabis. As regards labeling requirements the general regulation applies too; for instance, medicine based on cannabis will have to comply with 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?

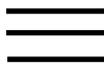
B. Does enforcement differ based on product type?

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 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.

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