## Medical Cannabis in Uruguay

Uruguay

**BUSINESS OPPORTUNITIES** 









#### **EXECUTIVE OVERVIEW**

In December 2013 Uruguay became the first country in the world to regulate the production of cannabis for recreational, medicinal, and industrial use. Successive decrees fostered the development of this industry in Uruguay, both at the production level and regarding the promotion of scientific research and business development.

The activity of companies linked to the cannabis industry in Uruguay is reaching an increasingly wide range of possibilities, while the associated services are multiplying and diversifying. A business ecosystem of more than 100 cultivation, industrialization and research companies has formed.

From 2018 onwards, Uruguay has recorded increasingly diversified exports, both in terms of products and destinations. Exports of seeds, grain, hemp flowers for nonmedical use, flowers with high THC content for medical use, as well as active pharmaceutical ingredients and medicines were finalized. Uruguayan products improved the quality of life of patients in more than ten markets around the world.

Uruguay's legal and regulatory framework is a key factor that attracts companies in the medical cannabis sector. The country has clear and favorable legislation that regulates the production and export of the sector, offering legal certainty and transparency.







#### **VALUE PROPOSITION**

#### **PIONEERING**

As the **first country in the world** to fully legalize cannabis at the national level, Uruguay offers a wide range of business opportunities along the entire value chain, be it research, cultivation or industrialization for medicinal, industrial or food purposes. Ten years of regulatory progress have allowed the development of an ecosystem with more than 100 companies.

### STRONG BACKGROUND IN RELATED INDUSTRIES

Uruguay has several cross-cutting strengths, both in the **agro-industrial** and **life-sciences** sectors, that underpin its value proposition for attracting investment and developing exports focusing on industrial hemp or medical cannabis. The country's history as an exporter of agricultural and pharmaceutical products makes it a **unique location** for the development of the cannabis industry.

## RELIABILITY & STABILITY

Located in an economically attractive region, Uruguay is one of the **most reliable** countries in which to do business. The long history of political, social and economic stability allowed the development of an incipient industry such as cannabis in a stable and predictable legal framework. Uruguay leads Latin America in the rankings of democratic quality, rule of law, low corruption and civil liberties.

#### **SUSTAINABILITY**

With over 90% of the country's energy generation coming from renewable sources, the carbon footprint of the cannabis industry on energy consumption is mitigated, allowing for **sustainable production over time** and marginal impacts on the environment. In this sense, Uruguay has, together with Chile, the best performance in ESG factors in the region.

#### INNOVATION

Research is a key activity for the development of the sector and enables new products and processes. The presence of national and international companies has allowed, from early stages, the development of a solid base for the formation of an **innovative ecosystem**.

## STRONG INSTITUTIONAL FRAMEWORK

As a result of having been a pioneer in integral legalization, Uruguay has consolidated a **public-private ecosystem**, with different institutions with an interest in the development of the industry. In this sense, public articulation favors the development of the private sector, finding proximity at the level of authorities to raise problems or propose improvements.





## SIZE OF THE INDUSTRY IN URUGUAY

#### PRODUCTIVE ECOSYSTEM

Cultivation, industrialization, and research add up to a business ecosystem of more than 100 companies with approximately 750 permanent employees and the need to add fruit harvesters at the time of harvesting and processing.

In order to truly dimension the total ecosystem of the industry, it is necessary to add all the companies that provide related services such as agro-industrial input companies, equipment and machinery suppliers, agronomic consultancy or advisory services, quality process consultancy or legal firms, among others.

Over ten years of development of the industry allowed the generation of innovative products and the possibility of offering highly specialized services in terms of agronomic advice, legal and accounting advice, as well as certification of quality processes. Due to current legislation, companies wishing to focus on different areas of the hemp and CBD industry -whether in cultivation, industrialization, research, or marketing- must comply with a specific licensing system. The requirements for obtaining these licenses vary based on the activity selected.

As a consequence, the Ministry of Livestock, Agriculture and Fisheries, through the General Directorate of Agricultural Services, concentrates the issuance of licenses for all activities related to hemp.

including the reproduction of seeds, their marketing, the reproduction of cuttings and seedlings, the cultivation of hemp for grain, fiber or flowers for nonmedical use and the industrialization of hemp for the generation of isolates and extracts with less than 1% THC.

The Institute for the Regulation and Control of Cannabis covers all activities related to cannabis for medical use or with THC content above 1%, including cultivation, industrialization, manufacturing of final products, research, and logistic operations.

In this sense, the industry stands out internationally for its ecosystem of companies and for the knowledge accumulated in the ten years that have elapsed since the regulation of the sector. This early regulation generated a strong interest in foreign direct investment, with installed projects of diverse capital origins and at different stages of the production chain.



RESEARCH AND DEVELOPMENT LICENSES

51 CULTIVATION LICENSES

21 INDUSTRIALIZATION LICENSES

7 ANALYTICAL LABORATORY LICENSES

3 MARKETING LICENSES

FREE TRADE ZONE LOGISTICS OPERATOR LICENSE 15 AUTHORIZED DRYERS

Table 1 - Licenses in force as of May 2024 - Source: Institute for Regulation and Control of Cannabis and Ministry of Livestock, Agriculture and Fisheries.





#### **MEDICAL CANNABIS: PRODUCTIVE CHAINS**

As of May 2024, at the medicinal level, 51 projects between companies and research centers are authorized by the Institute for Regulation and Control of Cannabis (IRCCA).

Of these projects, 13 are authorized to grow crops, 14 to industrialize, 7 to provide analytical services, 13 to carry out research and development, and one company is authorized for logistics operations in free trade zones. Many of the projects cover more than one activity in the production chain, with end-to-end vertical integration from research and development to drug manufacturing.



Table 2 - Licenses in force as of May 2024 - Source: Cannabis Regulation and Control Institute

The number of licenses is evenly distributed between cultivation, industrialization, and R&D. At the cultivation level, the industry has production capacity mainly for flowers for medicinal use with high THC content. However, several companies also produce flowers with high CBD content for medicinal purposes.

In turn, at the level of industrialized products, Uruguay has the potential to supply active pharmaceutical ingredients (APIs), as well as final products. These types of standardized products with higher added value have the potential to access regional and extra-regional markets, as well as to cover Uruguay's domestic market.

Geographically, the largest number of licenses is concentrated in the south of the country, mainly in the departments of Canelones and Maldonado. These areas are strategically located near Uruguay's main ports and airports, making logistics and transportation easier for product exports.

In summary, the value chain of this sector in Uruguay is in full development, with a clear focus on the export of high-THC flowers, active pharmaceutical ingredients, and medicines to improve the quality of life of patients around the world.



Concentration of licenses





## EXPORTABLE SUPPLY

#### INTERNATIONAL TRADE

The industry's legalization in Uruguay led to a significant number of investment inquiries from different world regions. The main sources of investment came from Canada, the United States, Argentina, Brazil, and Germany. The investments made in the country exceed US\$150 million, being the main objective to produce in Uruguay to supply different international markets.

In terms of the international marketing of products, since 2019 Uruguay has recorded six years of increasingly diversified exports, both in terms of products and destinations. This period saw exports of flowers with high THC content, as well as active pharmaceutical ingredients and medicines.



- · Flowers with high CBD content
- Flowers with high THC content
- Active pharmaceutical ingredients (APIs)
- Medications

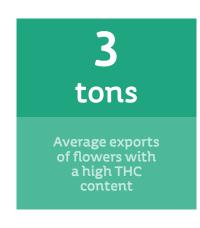
From 2019 onwards, there was a notable increase in cannabis exports, accumulating more than US\$ 20 million in exports in 2019–2023. During those years the main export product was flowers with high THC content with an annual average of 3 tons exported and a maximum in 2021 of 6.3 tons.

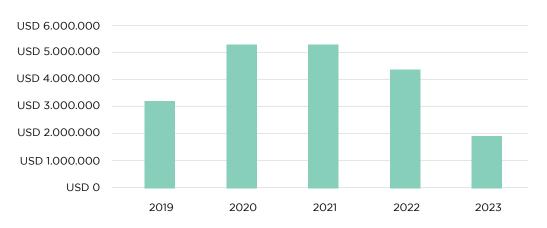
However, in recent years, the export of medicines and finished products, especially to the region, has increased its share. The growing interest in the Brazilian market, the most important market for medical cannabis in the region, could make it one of the main export destinations in the short term.





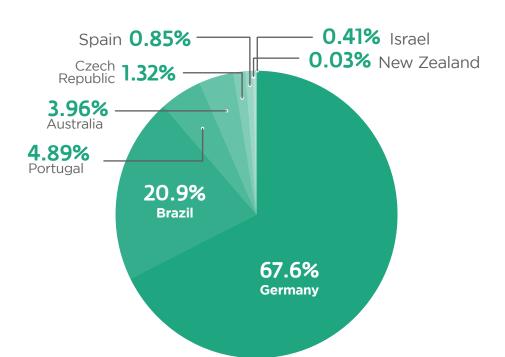
#### **MEDICAL CANNABIS EXPORTS 2019–2023**





Regarding export markets, the main destinations for flowers for medicinal use have been Portugal, Germany, and Israel. These countries legalized medical cannabis and have a domestic demand that exceeds their domestic production.

At the Uruguayan industry level, increasingly more companies offer product quality and have the certifications (EU-GMP/CUMCS) required to enter this type of market.



7 exporting companies

USD 1.977.951

Despite a lower performance than in other years, there was a significant increase in the number of exporting companies in 2023. This increase is a sign that medium and long-term negotiations typical of the pharmaceutical industry are beginning to crystallize.

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## TRADE OPPORTUNITIES WITH URUGUAY



#### BUY FROM URUGUAYAN EXPORTERS

The medical cannabis industry in Uruguay has a strong capacity for exporting high-quality products and has consistently demonstrated its ability to enter markets with demanding patients and strict regulations. The industry has earned a reputation for meeting the highest international quality and safety standards, which has allowed it to access a wide range of global markets. Uruguay was able to open markets in Brazil, Argentina, and Peru in South America; Portugal, Spain, Germany, and the Czech Republic in Europe; Israel in the Middle East; and Australia and New Zealand in Oceania. This expansion into several international markets proves the global confidence in the quality of Uruguayan products and the ability of producers to meet the needs and expectations of different destinations.

After six years of uninterrupted and increasingly diversified products and destinations of exports, Uruguay is positioned as an ideal and reliable partner for the production and supply of medical cannabis products. Uruguayan producers offer a diverse range of products, including flowers with high CBD or THC content, active pharmaceutical ingredients, and medicines. In addition, the medical cannabis industry in Uruguay benefits from a favorable regulatory environment and strong government support, ensuring that products are grown, processed, and exported under strict quality controls. The Cannabis

Regulation and Control Institute, in conjunction with the Ministry of Public Health, oversees and regulates all hemp-related activities, ensuring compliance with national and international regulations. This strict regulation provides an additional guarantee of the quality and safety of Uruguayan products.

The experience accumulated by Uruguayan producers in these six years of exporting has enabled them to perfect their production and logistics processes, guaranteeing a constant and reliable supply of high-quality hemp products. This experience has also encouraged innovation and the adoption of sustainable practices, which not only improve the quality of the final product but also contribute to environmental sustainability.

Finally, Uruguay's strategic geographical location, with access to major ports and airports, facilitates export logistics and ensures efficient delivery times to international destinations. Proximity to key markets in South America and seamless connections to North America and Europe position Uruguay as an ideal export hub for medical cannabis products.





## SETTING UP PRODUCTION IN URUGUAY

The option of **setting up in Uruguay** to produce and export medical cannabis products is **profitable and interesting**. Uruguay has become the destination par excellence for international companies seeking quality, efficiency, experience and new opportunities.

This business environment, the most stable and reliable in Latin America, offers first-class logistics infrastructure, cutting-edge technology and telecommunications, and the best energy supply in Latin America based on renewable sources.

Investment in Uruguay, both domestic and foreign, is declared of national interest according to Act 16.906.

Foreign and local investors are treated equally and a wide range of incentives are adapted to different types of activities, be it industrial and commercial or services, to be carried out in the country.

Uruguay's legal and regulatory framework is another key factor that attracts companies in the medical cannabis sector. The country has clear and friendly legislation that regulates the production and export of the sector, offering legal certainty and transparency. Companies can operate with the certainty that their investments are protected and that their operations will meet international standards.







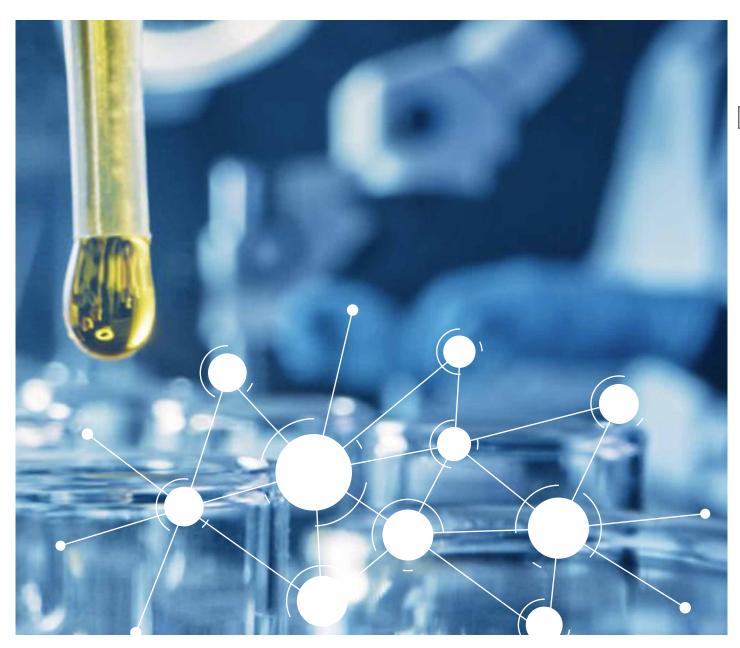
#### URUGUAY AS A LOGISTICS HUB FOR MEDICINAL PRODUCTS

With geographic proximity to the main medical cannabis markets in South America, shipping products to third markets through Uruguay is a cost-effective option for companies looking to store products for subsequent fractionation and shipment.

Through the free airport regime, the transit of goods is allowed without the requirement of authorizations or formal procedures. Goods are exempted from all

import taxes and duties, and primary and secondary conditioning activities, labeling, parceling, grouping, order preparation, packaging, and fulfillment are allowed.

This business model is of particular interest to foreign companies seeking to enter the Brazilian market through ANVISA's RDC 660.







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#### **EXPOCANNABIS**

It is the first and main information and articulation platform on cannabis and hemp in Uruguay. It is the only one in the world where the State, social organizations, private agents, the academia, users, and the live cannabis plant coexist. Since 2019, it has been declared of National Interest by the Presidency

of the Republic and has been supported since its beginnings in 2011 by the Institute for Regulation and Control of Cannabis, the National Drug Board, and several ministries. ExpoCannabis does not promote cannabis consumption but provides information for the normalization of regulation in Uruguay.



## ANNEX 1 SECTORAL INSTITUTIONAL FRAMEWORK

#### GOVERNMENTAL





The Institute for Regulation and Control of Cannabis (IRCCA) was created as per Act 19.172 to regulate the planting, growing, harvest, production, processing, storage, distribution, and dispensation of cannabis. Its purpose is to promote and propose actions to reduce the risks and damages associated with the problematic use of cannabis and to monitor compliance with the provisions of the law and the current regulations, without prejudice to the constitutional and legal competences attributed to other public bodies and entities. The National Drug Board of the Presidency of the Republic is responsible for setting the national policy on cannabis, with the advice of the IRCCA.



It is the ministry responsible for helping improve the health of the inhabitants of the Republic, creating health promotion and prevention policies, standardizing and regulating the treatment and rehabilitation of the disease under the guiding principles of universality, equity, quality, solidarity, sustainability and efficiency. Act 19,172 establishes that this ministry is responsible for authorizing and controlling plantations or crops exclusively for scientific research purposes or for the production of therapeutic products for use. Also within its orbit is the Specialized Unit for Evaluation and Monitoring of the policies issued by the act.







Its duties include contributing to the permanent development of the agricultural, agro-industrial and fishing sectors, as well as organizing and developing the protection of the health and quality of the production processes of plant and animal products. Act 19,172 establishes that the ministry must authorize and control the planting or cultivation of cannabis for non-psychoactive use (hemp).



The main goal of the National Seed Institute is to promote the production and use of the best seed with proven identity and superior quality, fostering the development of the national seed industry. At the same time, it supports the breeding and use of new national and foreign phylogenetic materials that are suitable for Uruguayan conditions. Regarding the cannabis market, INASE is responsible for the General Register of Seed Breeders (RGS) and the National Register of Cultivars (RNC).



The National Drug Board is responsible for designing and approving the National Drug Strategy (END) and the respective Operational Action Plan (PAO), establishing the political guidelines for the different areas of drug policy. Through the National Drug Secretariat, it articulates, coordinates, and monitors the implementation of the actions defined through the articulation with the different institutions involved in drug policies.



Canelones is the department with the highest number of licenses for the cultivation or industrialization of medical cannabis and industrial hemp. The departmental government plays an active role in promoting the industry through participation in international events, as well as through the organization of business roundtables.





#### BUSINESS ASSOCIATIONS





Civil association that watches over the rights and interests of medical cannabis companies in Uruguay, building bridges of communication between members. It contributes to the development of the production, industrialization, research, marketing and export of medical cannabis.





The Institute belongs to the School of Chemistry of the University of the Republic, which serves as a center for research, development and innovation in the following fields: chemistry, biotechnology, material science and environment. It specializes in Uruguay's most productive industries and services.



The experimental neuropharmacology department of the Clemente Estable Biological Research Institute focuses on understanding the neurobiological with bases associated neuropsychiatric pathologies such as depression, schizophrenia, and addiction to drugs, and the study of the mechanism of action of psychotropic drugs (antidepressants, anxiolytics, and antipsychotics).





## FREE ZONES AND INDUSTRIAL PARKS





Parque de las Ciencias (PDLC) is a logistics, industrial, services, and high technology park that offers companies the possibility of operating under the Uruguayan Free Trade Zone regime, in an area of 85 hectares, that constitutes one of the main life sciences, high technology and value-added clusters in the region. In operation since 2010, over 90 companies use its infrastructure to develop their regional or global business from Uruguay.



The Pando Science and Technology Park (PCTP) is an innovation and development center located in the department of Canelones, Uruguay. It is a unique environment in the country, promoting collaboration between academia, business and government. The main focus of the PCTP activities are the sectors of biotechnology, nanotechnology, chemistry, and pharmaceutical technologies.

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#### **ANNEX II URUGUAY IN** BRIEF

#### Official name: Oriental Republic of Uruguay

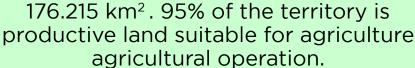


location

Geographical South America (neighboring with Argentina and Brazil)



#### Surface area





GDP per capita (2023) USD 22.421





**Currency** Uruguayan peso(\$)



3.44 million



Literacy rate 0.98







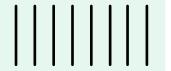
Life expectancy at birth 77.9 years



Form of

Democratic Republic with government a presidential system







Political division 19 departments



Time zone GMT-03:00



Official language Spanish

#### Buy innovation, buy from Uruguay



For additional information or contact with Uruguayan companies in the sector, please contact us.

