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WHY CANNABIS IN URUGUAY?

Reliability and Stability. Uruguay is a reliable country to do business. It offers political and social stability and a supportive business environment with investment grade rating. This has allowed the development of an emerging industry such as cannabis, in a stable and predictable legal framework.

Supportive and innovative regulatory framework. Investment in Uruguay, both domestic and foreign, is declared of national interest. Local and foreign investors are treated equally, and a wide range of incentives are available to them.

Uruguay offers a wide range of business opportunities along the entire value chain, whether for research, growing or industrialization for medical, industrial or food purposes. Regulations have allowed the development of an ecosystem with more than 100 companies.

Easy access to decision makers. Uruguay's public and private ecosystem promotes the articulation of policies for the development of the industry, with proximity between the different actors in the ecosystem.

Export oriented. Uruguay has been exporting cannabis-derived products since 2018. During this period, exports of seeds, grain, hemp biomass for extraction, industrial hemp flowers for non-medical use, flowers with high-THC content for medical use, as well as active pharmaceutical ingredients and finished products were registered.

Strong track record in related industries. Uruguay has cross-cutting strengths in agribusiness, pharmaceuticals and life sciences. This makes Uruguay a unique space for the development of the cannabis industry.

Sustainability. Uruguay stands out for its valuable diversity of natural resources and its commitment on preservation, achieving a remarkable balance between natural wealth and environmental protection. With more than 90% of the country's energy generation coming from renewable sources, the carbon footprint of cannabis industry on energy consumption is mitigated, allowing a sustainable production over time.



1. EXECUTIVE SUMMARY

- » In December 2020, the United Nations (UN) removed cannabis from Schedule IV of the Single Convention on Narcotic Drugs, recognizing its medical usefulness and safety.
- » After the regulation of cannabis in Uruguay in 2013, several countries began to follow similar paths. An increasing number of European countries are moving forward in several stages of legalization. Countries such as the United States and Brazil showed significant progress in their legislature
- » The main current challenges in international trade are caused by the constraints of international regulations operating under the orbit of the UN and by the diversity of national-level legislation.
- » According to UN data, in 2022, the number of consumers worldwide reached 228 million, representing 4.4% of the world's population aged 18 to 64. This figure shows a 28% increase when compared to the last decade.
- » The cannabis ecosystem in Uruguay is made up of around one hundred projects, employing 756 people in a direct manner. Seventy-seven percent of the workers carry out their activities in the countryside.
- The main business approach of the companies in the industry is exportation. In 2023, 28 companies exported products.
- » In 2023, exports of cannabis products totaled USD 3 million. Flowers for medical use accounted for 51% in total sales, with Germany as the main market. Hemp flowers for non-medical use followed the exports, arriving mainly to Switzerland, Czech Republic and the United States.
- » In 2023, medical cannabis production in Uruguay totaled 28.6 tons. Production was mainly concentrated in non-psychoactive products. In addition, as of March 2024, there was a stock of 46.5 tons of crops.
- » In Uruguay, there are 13 research licenses granted by the Institute for the Regulation and Control of Cannabis (*Instituto de Regulación y Control del Cannabis*, IRCCA), seven of which are held by private companies and six are granted to research centers. As a result of R&D in the industry, there are currently 11 Uruguayan cannabis sativa varieties



at the National Seeds Institute (*Instituto Nacional de Semillas*, INASE); these comprise six are hemp and five are psychoactive cannabis.



2. INTERNATIONAL MARKET

Cannabis is currently the most widely consumed narcotic drug on a global scale¹. However, in many countries, its use is still illegal or limited to medical and therapeutic uses.

In general terms, it can be said that regulations around medical use are more widespread than the rest, with the low-THC and high-CBD subindustry having the fastest expansion – although the use of high-THC cannabis is gradually being allowed due to its growing medical use.

After the 2013 regulation in Uruguay, several countries began to follow similar paths. In Latin America, countries such as Argentina, Brazil, Colombia, Mexico and Paraguay released consumption for medical purposes. Other countries, such as Australia, Canada, France, Germany, Israel, Portugal, Spain and Switzerland did the same. In 2024, many countries began taking steps towards legalization, both for medical and adult uses. A clear example is Germany, which legalized the consumption for the population. The new regulation allows the possession of 50 grams of cannabis and the self-cultivation of up to three plants. France also decided to end the pilot program and standardize cannabis treatment within the general medical system, with a schedule to begin in early 2025.

The expansion of international cannabis production and trade will depend on the pace at which legalization develops in the main markets, and also by the multiple and emergent uses around cannabis, with the medical, industrial food and beverage, textile and cosmetics industries showing the greatest potential.

It is also important to highlight that, regardless of the regulatory frameworks that are sought to be accepted at the national level, there are international treaties that influence the approval of this type of laws. To circumvent international regulatory barriers, European countries, for example, have framed the legalization of cannabis for adult use within scientific research, as seen in Switzerland, the Netherlands and Germany, which intend to use pilot projects to examine the social, health and youth protection effects of legal commercial cannabis supply chains.

In Oceania, import and export regulations are being modified, and Australia is gradually moving towards legalization of adult use.

¹ United Nations Office on Drugs and Crime World Drug Report 2024



CBD markets worldwide are gradually expanding and developing, but the industry still awaits standardization and widespread implementation due to a lack of clear regulations.

The global supply chain is slowly diversifying, and external purchases are increasing. At the moment, countries such as Germany, Denmark, Finland and Australia have become relevant importers.

The key to take advantage of the opportunities offered by this market lies in the establishment of clear and well-defined regulatory frameworks that allow a safe and effective production, distribution and marketing.

As other emerging regions join the international cannabis ecosystem, Latin America is trying, with some degree of success, not to miss the closing window of opportunity to gain and consolidate a key position in this emerging industry by leveraging its competitive advantages while solving its multiple supply, chain, bureaucratic and political challenges. The region has several competitive advantages to become a major player in the global cannabis industry. However, establishing clearer regulatory pathways from seed to product, accessing to capital, reducing bureaucracy and depoliticizing the cannabis debate are prerequisites for success.

Brazil has experienced a substantial growth in medical cannabis consumption over recent years – which continues today – with a 72.8% increase in import authorizations from September 2022 to September 2023. Most of the local demand is covered by imported extracts, since cultivation in the country is not yet permitted. Thus, cannabis imports grew steadily, with a 93% increase in July 2022 to July 2023, while the annual total of medical cannabis import authorizations jumped from 17,812 in 2020 to 80,413 in 2022, and 66,159 were counted as of June 2023. In the short-term and medium-term, Brazil will remain the main market for medical cannabis in Latin America.²

² The Global Cannabis Report, 4th Edition



COUNTRY	MEDICAL CANNABIS PRODUCTION	IMPORTS (MEDICAL CANNABIS)	EXPORTS (MEDICAL CANNABIS)	PATIENT ACCESS TO MEDICAL CANNABIS
Argentina	emergent	Yes	No	Yes
Brazil	emergent	Yes	No	Yes
Chile	No	Yes	No	No
Colombia	Yes	Yes	Yes	Yes
Costa Rica	No	No	No	No
Ecuador	emergent	emergent	No	emergent
Jamaica	Yes	Yes	Yes	Yes
Mexico	No	emergent	No	emergent
Panama	No	emergent	No	emergent
Paraguay	emergent	emergent	emergent	Yes
Peru	emergent	emergent No		Yes
Trinidad y Tobago	No	emergent	No	No
Uruguay	Yes	Yes	Yes	Yes

TABLE 1: LEGISLATION BY COUNTRY

Source: Uruguay XXI based on information from The Global Cannabis Report, 4th Edition

2.1.CANNABIS INDUSTRY VALUE CHAINS

Cannabis is a complex plant that has been used for medical, recreational and industrial purposes since ancient times. It contains more than five hundred compounds³, and cannabinoids are the most studied and distinguished for their importance.

Cannabinoids are chemical compounds that interact with the endocannabinoid system of the human and animal bodies, which is responsible for regulating a variety of physiological functions. The cannabis plant contains more than 120 cannabinoids; the best known are THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol). THC is the main psychoactive

³ Radwan *et al*, 2017 https://www.argentina.gob.ar/sites/default/files/la_cadena_de_valor_del_cannabis_-__10.12.pdf



component of cannabis and is responsible for the psychoactive effects associated with the consumption of the plant. THC concentrations in the dried flower can be as high as 30%. CBD, on the other hand, is non-psychoactive and has been shown to have therapeutic effects in treating a variety of medical conditions. CBD concentrations in the dried flower can reach as much as 20%.

Both cannabis and hemp are varieties of the same plant, *cannabis sativa L.*, although they are used for different purposes. Cannabis or marijuana is usually used to refer to the varieties of the plant containing higher THC values, whereas hemp is usually used to refer to the varieties for industrial use with low or non-THC content.

In general terms, it can be said that the value chains around cannabis are structured according to medical, adult and industrial uses. At the legal level, this is reflected in the regulations on THC thresholds and the requirements imposed for each case. Medical and adult uses of cannabis are based on the cannabinoids present in the plant and face strong controls and regulations at the production and commercialization stages. Industrial cannabis, on the other hand, does not contain significant amounts of cannabinoids; therefore, it faces less rigorous regulations.

The legal thresholds that separate cannabis from hemp are not standardized at the international level. In the United States it is less than 0.3% in dry weight and 0.2% in Europe⁴; whereas in countries such as Australia, Colombia, Switzerland, Czech Republic or Uruguay, the threshold reaches 1%. From the production point of view, this threshold determines the commercial possibilities and the documentation required for trade, regulations and bureaucratic procedures to which the different processes of the production chain are subjected.

Adult use cannabis is consumed by adults for recreational purposes. The psychoactive effects of cannabis are caused by tetrahydrocannabinol (THC), the plant's main active compound. Uruguay is one of the few countries in the world where this market is regulated and, although many countries have decriminalized its use, there are many limitations and restrictions around the production and trade of high-THC cannabis.

In recent years, there has been a great eagerness to study the plant's potential for **medical use**. This area leverages the chemical components of the cannabis flower – mainly CBD and more recently THC – for the treatment of certain pathologies. Some people use it to relieve

 $^{^4}$ With the exception of Spain, Italy, France, Lithuania, Croatia and the Netherlands, which set an upper limit of 0.3%.



pain, reduce inflammation, treat anxiety and depression, control seizures, reduce the symptoms of Tourette's syndrome, among others. Cannabidiol (CBD) is the most widely used active compound of cannabis for medical purposes and has few psychoactive effects, being able to moderate them. It also has antioxidant, anti-inflammatory and neuroprotective effects. In many countries, the medical use of cannabis is legal, and specific products can be found for this purpose. In this field, there is scientific evidence regarding the effectiveness of cannabis-based medicines for the treatment of some ailments, which is reflected in the approval of medicines by agencies such as the FDA in the United States.⁵

Other applications of the plant are linked to the **industrial use** for the production of paper, textiles, bioplastics, food and personal care products. Hemp is also used in construction as an acoustic and thermal insulator. Industrial use of hemp is legal in many countries and is becoming a more sustainable alternative for many conventional products. The latest UN Conference on Trade and Development (UNCTAD) report on hemp (2022) highlights the crop's versatility and its ability to grow in a wide variety of climates and on land unsuitable for other crops, helping the reconstitution of the soil as well, by removing heavy metals and other pollutants. One of the things the report points is that the previous cultivation of hemp produces a 10% to 20% increase in wheat yield.

2.2. STATUS OF INTERNATIONAL LEGALIZATION

In recent decades, drug policies have undergone a significant change in many countries around the world, shifting from a policy focused on proscription and repression to reduce the supply of drugs to another that focuses on risk reduction and control of the harms associated with drug use.

This shift was largely due to a greater understanding that drug consumption and dependence are matters of public health and that law enforcement has not always been an effective way to address drug-related problems.

In December 2020, the UN removed cannabis from Schedule IV of the Single Convention on Narcotic Drugs in recognition of its medical usefulness and safety. This led to a renewed interest in the medical use of cannabis due to new discoveries and breakthroughs in scientific

⁵ So far, the FDA has approved four cannabis-related pharmaceutical products; three containing synthetic cannabinoids (Marinol, Syndros and Cesamet) and Epidiolex which is the first FDA approved drug containing cannabis (link).



research. As a result, many countries around the world are debating the legalization of cannabis crop for medical and recreational purposes.

The advance of legalization seems to be inevitable in many countries in the Americas and Europe, and has led to an intense debate in which the pros and cons are under discussion. Several countries reviewed their policies and laws over the past years. Some of them legalized the medical and adult uses of cannabis, while others adopted non-criminalization policies, meaning that the use and possession of small amounts of cannabis are not punishable.

Cannabis regulations are classified according to the use type – medical, adult or industrial. Authorizations involve different stages of the chain: cultivation, distribution, commercialization, possession and consumption. In this first great wave of regulation, each country is adapting its own legislation, which varies significantly from one country to another in terms of the lawfulness of the use, production, distribution and consumption of cannabis products.

Within Latin America, Brazil stands out, having liberalized legal possession for its citizens in this year's July. It is presumed that this could be a first step for the expansion towards legal adult use, since today commercialization continues to be illegal.

Colombia joined the green wave in 2016, legalizing medical cannabis, along with its cultivation and exports. However, it has suffered from a lack of specialization, unmet expectations for local producers and a small and still developing local consumer market.

In Peru, consumption grew at an annual compound rate of more than 280% since 2019. As of July 2023, more than 42,000 patients were registered. Projections made by Prohibition Partners in their report <u>The Global Cannabis Report, 4th Edition</u> presume that around 1.5 million patients in Peru could benefit from cannabis treatments.

After a series of advances in Mexico, legislative and regulatory uncertainty, politicization of the debate and a powerful illicit market ecosystem created barriers that restrain the country from becoming the largest adult use market in the world.

Accordingly, current UN regulations on illicit drugs, which apply internationally, prohibit the use and distribution of cannabis for non-medical purposes.⁶

⁶ The governance of the international conventions signed within the UN on narcotic drugs includes three bodies: the Commission on Narcotic Drugs (CND), the International Narcotics Control Board (INCB) and the World Health Organization (WHO).



Besides, there are complexities around national regulations. THC is the main psychoactive component of the cannabis plant, and countries often impose ceilings, which vary across countries, posing an extra difficulty for the international trade of cannabis products.

However, as more countries regulate cannabis, it is possible that more consistent and aligned frameworks that allow greater seamless international trade may develop.

The declassification of cannabis in Germany and the reclassification of cannabis in the United States are very promising breakthroughs for the cannabis industries in each country, which will have an impact on the world because of the size of these markets.

2.2.1. CANNABIS FOR ADULT USE

After the beginning of reforms for the recreational use of cannabis in Uruguay, which occurred under a law that comprehensively covers all stages of the process (possession, commercialization and production), many countries began working on their regulatory frameworks to move in the same direction. Canada and some states in the United States followed these steps, and today more and more countries are adopting policies aimed at noncriminalization and commercialization.

The fourth edition of The Global Cannabis Report estimated that the recreational use segment will lead the market, comprising approximately 70% of the total (including medical and recreational sales), projected to reach a valuation of USD 25 billion by the end of 2023.

In March 2023, **Germany** took a big step within the European Union by adopting the recreational use of cannabis. In this sense, its law stipulates the free possession of 25 grams on public roads for adults over 18 years. It also allows the cultivation of up to 50 grams and the possession of three plants in the house. In addition to setting a trend, this advance shows a regulatory framework that coexists with EU anti-drug treaties and positions itself as a basis for those European countries that seek to follow similar policies. On April 1st this year, Germany implemented the first pillar of cannabis legalization for adults, which excludes cannabis from the list of narcotic substances. This measure authorizes citizens to legally possess, cultivate and consume cannabis.

Switzerland continued making progress and is now the only European country with legal commercial supply chains of cannabis for adult use, from production to the end consumer. Six clinical trials for adult use were approved, four of which are ongoing, and two others are in progress. These trials will involve the distribution of cannabis from legal supply chains to more than 10,000 participants in total. In addition, the country has the most developed regulatory



framework for CBD products in the region, with maximum THC limits of 1% in products, hemp cigarettes regulated as tobacco substitute products, and licenses available for the different stages of production and manufacturing of CBD products and hemp cultivation.

The **Netherlands** made progress in the establishment of the first supply chains in some regions of the country. Both Breda and Tilburg will start operating supply chains for their coffee shops through two authorized producers. The plan is to move forward with the opening of new regions and having new authorized producers.

By the end of January 2024, the first sales of an operational non-profit cannabis association began in **Malta**, two years after the Maltese government had decided to legalize cannabis for adult use.

Portugal moved forward in governmental terms with the intention of elaborating a discussion table on legalization for adult use, which has been accepted by most of the country's parties. This task force, constituted under the Parliament's Health Committee, will carry out a collaboration with specialists and stakeholders to conduct a detailed analysis. The research is expected to be completed by the end of 2024.

Within Africa, **South Africa** stands out, where the Cannabis for Private Purposes Bill 2023, which establishes legal provisions for the cultivation, possession and consumption of cannabis by adults in private residences, has been approved by the National Assembly. The bill is currently under review by the highest body of Parliament, where it is expected to be deliberated throughout 2024.

After the steps taken by the **United States** in recent years, where marijuana has been reclassified as a low-risk drug, the number of states that consider legal the adult and medical uses has increased. Although it is still illegal at the federal level, 24 states have already legalized adult use, while 38 have legalized medical cannabis.



Finally, the cannabis market in **Canada** reached sales close to USD 4.4 billion. Of this figure, 93% corresponds to sales for adult use and 7% to medical use. Since the legalization of cannabis for adult use on October 20th, 2018, the market has shown steady growth. Although consumption among adolescents remains relatively low, market expansion has been significant. Currently, there are about 3,600 stores, and the market has over 900 licensed growers and processors.

FIGURE 1: COUNTRIES WITH REGULATIONS ON MEDICAL CANNABIS OR ADULT USE 2024



Legal for medical use

Legal for adult use

In Latin America, at least three countries are in process of preparing for the legalization of cannabis for adult use.

 In Brazil, a majority of ministers ruled in favor of decriminalizing the possession of marijuana for personal use, so that this conduct is punished as an administrative and not a criminal offense. The Brazilian Supreme Court decided to decriminalize the consumption of marijuana for personal use, where the threshold to determine the difference between a consumer and a trafficker was set at 40 grams of marijuana or six female plants.



- Mexico will become the largest country in the world to have legal adult use cannabis sales. By the end of 2018, the Supreme Court ruled that cannabis prohibition was unconstitutional, and instructed the Congress to legislate in order to establish a legal industry. There were years of delay, mainly due to disagreements within the Mexican government on how to best implement legal cannabis commerce in the country. As of this year, it remains uncertain how the enactment of this law will be achieved, as a result of political differences and pressure from those operating in the illicit market.
- In **Colombia**, by a narrow margin, the Senate rejected a proposal to legalize the sale of cannabis for adult use. Proponents plan to reintroduce the initiative in the short term.

DECRIMINALIZATION

The decriminalization of cannabis consumption for adult use has shown progress in recent years around the world, with several countries beginning to adopt measures in pursuit of the market. Although in many countries the recreational use of marijuana is illegal, its use or possession in different amounts is not criminalized, which is the case of Chile, Colombia, Estonia and the Netherlands.

- The first sales by a non-profit operating cannabis association began in **Malta** at the end of January 2024, two years after the Maltese government had decided to legalize cannabis for adult use.
- In **Mexico**, the Supreme Court decriminalized the recreational use of marijuana in June 2021 and, in May 2022, the criteria for the possession of this substance was flexibilized, despite continuing parliamentary discussions for the legal use.
- The **Luxembourg** law authorizes from July 2023 the cultivation of cannabis with a limit of four plants per household, and allows consumption in private spaces.
- In **Thailand**, a law to decriminalize cannabis was approved in June 2022.
- In **Spain**, production for personal use in private spaces is tolerated, but commercialization and consumption in public is prohibited.



 In the United States, President Joe Biden decreed that thousands of people convicted at the federal level and in the capital district for consumption and simple possession of marijuana may apply for pardon. Several states have also incorporated this measure, such as Maryland, which pardoned more than 175,000 marijuana convictions.

2.2.2. MEDICAL CANNABIS

The medical use of cannabis has good growth projections for its global market. Many products have conclusive scientific evidence for some diseases, such as refractory epilepsy⁷, generally finding a laxer international regulation. Currently, more than 50 countries allow the use of cannabis at the national level.⁸

The European medical market experienced a remarkable growth, concentrated in key countries, while others showed a more modest progress from a lower base. In 2023, 21 countries offered medical cannabis treatments; however, in many cases, patient numbers remained limited and treatment faced high costs and bureaucratic obstacles. Germany stood out as the leading market, achieving sales of approximately EUR 390 million and serving more than 230,000 patients, which accounted for more than 50% of the regional market. Three other major markets – the United Kingdom, Italy and Poland – presented annualized market sizes ranging from EUR 19 million to EUR 222 million. In contrast, the market in the remaining European countries remained below EUR 5 million in 2023.

The United Kingdom emerged as the main force of the new development in the medical cannabis market, with sales exceeding forecasts due to unusually high consumption per patient.

In October of this year, the Spanish Ministry of Health presented a draft decree proposing the inclusion of the therapeutic use of cannabis in the legislation. The draft establishes that treatments will be carried out in the form of magistral formulas, available exclusively in hospital pharmacies and intended to treat specific pathologies.

France decided to end the pilot program and standardize cannabis treatment within the general medical system, scheduling implementation for early 2025. In Latin America, Ecuador

⁷ In June 2018, one of the major milestones in the development of the market took place, when the World Health Organization (WHO) considered cannabidiol (CBD) to be effective in the treatment of certain epilepsies and both harmless and not linked to recreational use. In December 2020, the UN Commission on Narcotic Drugs removed cannabis from the most restrictive list of controlled substances, following the WHO recommendation.

⁸ Some of them have pilot programs in place; others only allow use under license or certain specific products.



began marketing cannabis-based products after the Ministry of Agriculture and Livestock (*Ministerio de Agricultura y Ganadería*, MAG) issued for the first time, in February 2021, seven licenses to work in this industry. Mexico, despite having a law for the use of medical cannabis that was approved two years ago, continues facing administrative and bureaucratic barriers for families who need access to these products. Costa Rica and Panama began implementing their first approved medical cannabis regulations in 2021.

In Japan, a special panel of the Ministry of Health recommended that the government allows the import and use of pharmaceutical cannabis products such as Epidiolex and Sativex, as possible first steps towards a broader reform for the coming years. The Malaysian government also declared its intention to legalize, following the same line as Thailand.

2.3. MARKET, PRODUCTION AND TRADE

According to the United Nations Office on Drugs and Crime (UNODC), cannabis has long been the most widely consumed drug in the world. In 2022, the number of users reached 228 million, representing 4.4% of the world's population aged 18 to 64. This figure reflects an increase of 28% compared to the last decade. However, at the global level, the crop trend rate decreased by 8%, compared to 2021.

In 2022, the percentage of consumers in North America was around 20%, an outstanding number compared to other regions. In South America, the percentage of consumers remained 3.5% below the global average for that year, indicating a relatively lower consumption level. In contrast, the regions of Oceania and Africa exceeded the global average in terms of the proportion of the consumer population, standing out for their higher market share.

According to UNODC data, the trend continues focusing on indoor growing, where the margin is increasingly greater than in cultivation outdoors. Lower logistical costs and microproduction are some of the reasons for this choice. In 2022, the indoor production rate remained stable compared to a decrease in outdoors production.

Most countries do not collect systematic data on cannabis production, and the countries that do have information on the total area under legal cultivation do not use uniform recording methods, which is why there are limitations in developing international statistics.

In short, the data provided by different international organizations contain partial and sometimes incomplete information. However, considering these limitations, they are indicators



that, as a whole, offer an overall view of the market and an approach to the evolution of the segment.

There are international consulting firms that produce global reports on the cannabis industry. Most of them conclude that the segment has positive growth prospects worldwide. The growth of the global cannabis market is expected to be strongly determined by the increase in sales of cannabis for adult use, with a greater dynamic of expansion of the industry in the United States and, to a lesser extent, Canada. These countries will have the greatest impact on the global market, given that together they account for more than half of the global sales.

The leading industry researcher, BDSA, estimated that by 2024, the adult use cannabis market in the United States would rise significantly above USD 30 billion, compared to the 2023 closing sales value of approximately USD 29 billion. It is estimated that, in fiscal terms for 2023, the North American country collected more than USD 4 billion across all the states with some kind of legal cannabis market.



CHART 1: GLOBAL CANNABIS MARKET



(Billions of USD)

Source: New Frontier Data - The Global Cannabis Report: Growth & Trends Through 2025.

2.3.1. CANNABIS FOR MEDICAL OR SCIENTIFIC USE

UN member states are required to report to the International Narcotics Control Board (INCB) about the production and trade of cannabis for medical purposes.

In 2022, 28 countries reported to the INCB on the production of cannabis for medical or scientific use. According to the INCB's World Drug Report, cannabis production for these purposes reached 707 tons, slightly lower than the 764 tons reported in 2021.

According to these data, the global production of legal cannabis for medical or scientific use is led by Canada (33%), the United Kingdom (26%) and Israel (10%). The strong development of the pharmaceutical industry in the UK, which is the world's leading producer of cannabis extracts, and the pioneering legalization policies in Canada explain the importance of these countries in the global production of medical cannabis. **Uruguay, with 2.1%, ranks among the top 10 countries in the world in this market.**



Country	Kg	Part (%)
Canada	235,900	33%
United Kingdom	180,900	26%
Israel	73,200	10%
Portugal	41,900	5.9%
North Macedonia	40,400	5.7%
Colombia	34,300	4.8%
Australia	24,900	3.5%
Uruguay	15,000	2.1%
Spain	14,100	2.0%
Denmark	10,100	1.4%
New Zealand	10,100	1.4%
Others	26,637	3.8%
Total	707,437	100%

TABLE 2: MAIN MEDICAL CANNABIS PRODUCING COUNTRIES (2022)

Source: Uruguay XXI with INCB data

As for the stocks released by this report, around 1,191.8 tons were surveyed around the world in 2022. The highest concentration was also from the United Kingdom with 75% of the total stock. Colombia ranked second with 85.4 tons, while Uruguay accounted for 1.2% of the global cannabis stock, with 15.3 tons according to the INCB data.

According to Market Research Future, more than 70% of the medical market is supported by CBD-based products and the remaining 30% is comprised of THC-based products. Pain management products account for around 50% of the market and those targeting the neurological and mental health segment represent almost all of the other 50%.

INTERNATIONAL TRADE OF MEDICAL CANNABIS

International trade also highlights the main markets that demand and import cannabis products for medical development. By 2022, according to the UN International Narcotics Control Board Report, the largest importers were Germany, which imported 26.8 tons of cannabis (23.3% of the world total), followed by Finland with 22.5 tons (19.6%), Israel with 14.5 tons (12.6%), Australia with 11.5 tons (10%), Spain with 7.2 tons (6.3%) and the United Kingdom with 6.4 tons (4.4%). The latter developed local production of medical cannabis in the last year, so its external demand decreased while incentives for local production evolved. The countries that imported less than four tons were, in descending order, the Netherlands, Italy,



Poland, France, Peru, Republic of Korea, Japan, Malta, Norway, Sweden, Canada and Luxembourg.

2.3.2. HEMP FOR INDUSTRIAL USE

Global hemp production has been increasing in the past years due to the growth in demand for derived products and the legalization of hemp cultivation in some countries. In March 2024, UNCTAD published a report that examines the economic, environmental and social potential of hemp⁹. According to the report, which surveys the production of 40 countries through different sources, the global market value in terms of exports was approximately USD 122 million for seeds and their by-products. On the other hand, exports of hemp fiber and textile derivatives were around USD 50 million in 2022.

Regarding the main products covered in the report, among raw products, hemp seeds are in first place with an export value of USD 112 million, followed by hemp oil residues with USD 8 million exported. Hemp oil came in last with USD 1 million. Within hemp manufactures, semi-processed fiber was the most exported by-product with USD 18 million in 2022, followed by hemp yarn with an export value of USD 16 million and finally hemp raw fiber with USD 12 million exported. Lastly, among the products used as inputs, exports of hemp fiber fabrics stood out, reaching USD 26 million in exports in 2022.

UN Comtrade 2023 data indicate a worldwide export value of USD 112 million for hemp byproducts¹⁰. The Netherlands is the leading exporter, with USD 24 million exported, followed by France (USD 22 million) and Italy (USD 16 million). The main buyers on the world market include China, with an import value of USD 4.3 million, the United Kingdom (USD 3.6 million), and the United States (USD 2.8 million). According to Trade Map data, the average price at which hemp fiber was traded was USD 1,442 per ton in 2023.

Europe has been increasingly developing the hemp industry, due to the advantages it offers as a product, such as being a fast-maturing crop that does not require pesticides and being of great value against CO₂ emissions. In this sense, this market has been demanding more and more raw material, having several final production purposes that also continue to develop, such as the construction industry through blocks, the textile industry for the manufacture of fabrics, the food industry as a vegetable-based food source and the elaboration of cosmetics, among others.

⁹ Measuring global exports of industrial hemp products (<u>link</u>)

¹⁰ NCM: 5302, 530820.



3. THE CANNABIS INDUSTRY IN URUGUAY

3.1. MARKET REGULATION

In December 2013, Uruguay became the first country in the world to legalize the production and consumption of cannabis for adult, medical and industrial uses. Law 19,172¹¹ regulated recreational cannabis in a specific way, and medical and industrial cannabis in a more generic way. The law also created the Institute for Cannabis Regulation and Control (IRCCA), a body in charge of implementing regulation and controls related to the planting, cultivation, harvesting, production, processing, storage, distribution and dispensation of cannabis.

Successive decrees favored the development of cultivation and industrialization activities, as well as research and export activities, which led to the creation of a significant number of enterprises of several sizes that gained access to cannabis production, industrialization and research licenses.

Summary of regulations to date:

- **Recreational cannabis** was regulated by Decree No. 120/014¹², which established that the IRCCA was responsible for granting the corresponding licenses and set the psychoactivity limit at 1%.
- Hemp for industrial purposes was regulated by Decree No. 372/014, which established that the Ministry of Livestock, Agriculture and Fisheries (*Ministerio de Ganadería, Agricultura y Pesca*, MGAP) was responsible for authorizing hemp-related activities and granting the corresponding licenses.
- **Cannabis for medical purposes and research** was regulated by Decree No. 46/2015, which authorized the elaboration and dispensation of finished or semi-finished products for medical use, as well as scientific research on cannabis.
- Two specific laws for medical cannabis and research were passed in 2019: Law No. 19,845 and Law No. 19,847, still pending regulatory development and effective implementation.

¹¹ Laws related to the cannabis industry (<u>link</u>)

¹² Cannabis Regulatory Decrees (<u>link</u>)



- In 2020, two decrees were signed allowing the export of psychoactive cannabis and hemp, which boosted industrial activity for medical purposes.
- In 2021, the 2015 legislation on cannabis for medical and research purposes was updated.
- In February 2023, regulatory Decree No. 56/023 was published, which enables the production and sale of cannabis-derived products through master formulas and establishes a regulatory framework to guarantee the quality and safety of the products.

FIGURE 3: REGULATORY FRAMEWORK - CANNABIS IN URUGUAY ¹³



Source: Uruguay XXI based on information from the IMPO Official Information Center

In 2023, MGAP and Bromatology of the Municipality of Canelones (*Bromatología de la Intendencia de Canelones*) granted the first authorization for the use of hemp grain in the food industry. The aim is to benefit from the quality of hemp as a superfood to develop a previously unexplored industry.

In summary, Uruguay evidenced a strong momentum in the cannabis industry as a result of a pioneering regulatory framework in the world, which allowed the development of a new business ecosystem in the country with the emergence of a significant number of ventures, the settlement of foreign companies and the creation of new jobs in several economic industries and activities.

INSTITUTIONAL FRAMEWORK

Below is a table summarizing the institutions and their functions related to the regulation and control of cannabis in Uruguay:

¹³ Updated regulatory framework – IRCCA (<u>link</u>).



Institution	Functions				
Institute for the Regulation and Control of Cannabis (<i>Instituto de Regulación y Control del Cannabis,</i> IRCCA)	 Regulate the planting, cultivation, harvesting, production, processing, storage, distribution and dispensation of cannabis. Promote and propose actions to reduce the risks and damages associated with the problematic use of cannabis. Oversee compliance with the provisions contained in the cannabis regulations. Grant all required licenses for the production and distribution of psychoactive and non-psychoactive cannabis, including medical use, the elaboration of cosmetic specialties and medicines for veterinary use. 				
 National Drug Board (Junta Nacional de Drogas, JND) Design and approve the National Drug Strategy. Coordinate and articulate actions: The JND is responsible for coordinating and articulating of the several agencies and entities involved in the prevention, assistance, treatment and or drugs in Uruguay. 					
Ministry of Public Health (<i>Ministerio de Salud Pública</i> , MSP)	 Authorize and control cannabis plantations for the exclusive purpose of scientific research or the elaboration of therapeutic products. Provide habilitations for those interested in the production and industrialization of medical cannabis and register medical products in the Department of Medicines. 				
Ministry of Livestock, Agriculture and Fisheries (<i>Ministerio de Ganadería, Agricultura y Pesca</i> , MGAP)	 Authorize and control the production of hemp crops (cannabis variety with low-THC content). The General Directorate of Agricultural Services (DGSA) of the MGAP evaluates hemp production projects for industrial and food purposes. The General Directorate of Livestock Services (DGSG) grants authorizations for the veterinary medical use of hemp. 				
National Seeds Institute (Instituto Nacional de Semillas, INASE)	Seeds and strains registry.				
Secretariat for the Fight against Money Laundering (<i>Secretaría</i> <i>Antilavado de Activos</i> , SENACLAFT)	 Research and control of corporate structures in the cannabis industry. Verification of the origin of funds used in the industry. 				



3.2. PRODUCTIVE ECOSYSTEM

The cannabis value chain in Uruguay is made up of around one hundred projects with 90 licenses for diverse activities. Thirty-six companies are authorized by the MGAP to grow hemp, while seven have licenses to industrialize hemp for the production of extracts/isolates and for food processing. In addition, three companies have brokerage licenses.

In the medical, research and recreational markets, 52 projects are authorized by the IRCCA. Of these projects, 16 are authorized to cultivate, 14 to industrialize, 7 to provide analytical services, 13 to carry out research, 1 company operates as a service provider for third parties and 1 company is authorized to operate in free trade zones. Many of the projects cover more than one activity in the production chain, with end-to-end vertical integration from R&D to drug manufacturing.

According to data from the Ministry of Labor and Social Security (*Ministerio de Trabajo y Seguridad Social*, MTSS), in 2023 the cannabis industry employed 750 people directly. Of these workers, 23% worked in Montevideo, while the remaining 77% worked in other regions of the country: 35% in Canelones, followed by Colonia with 13%.





CHART 2 - COMPANIES AND EMPLOYMENT BY SIZE CANNABIS INDUSTRY IN URUGUAY (2023)

These figures do not include the indirect jobs generated by the industry, which include logistics activities and the sale of agricultural inputs, among others. It also excludes personnel employed in hemp companies during specific stages of the harvest, such as transplanting and harvesting, which require a greater demand of labor. It is estimated that between 8 and 10 people per hectare are needed for transplanting activities and 18 to 22 people for harvesting.

3.2.1. CANNABIS EXPORTS

In Uruguay, the main focus of most of the companies in the cannabis industry is placed on the exports. In 2023, 50% of the companies authorized to grow or industrialize cannabis by IRCCA and MGAP had exportation activity. Since 2019, an increase in cannabis exports was observed¹⁴. That year, three companies registered external sales and managed to sell more

¹⁴ Over the past years, the Uruguayan government has made several changes to the regulatory framework in order to facilitate the sale abroad of raw material and semi-manufactured products containing cannabis. In this line, Decree No. 246/021 annulled the obligation to register with the MSP raw material and semi-manufactured products



than 1.7 tons for USD 3 million; while in 2023, the number of exporting companies was 27, and around 25 tons of cannabis were placed abroad for about USD 3 million.



CHART 3 - VOLUME OF CANNABIS EXPORTS

(TONS)

Source: Uruguay XXI based on data from National Directorate of Customs (*Dirección Nacional de Aduanas*, DNA)

Seeds and low-THC flowers were the main products in terms of volume and accounted for almost 90% of the volume exported.

In 2023, total cannabis exports reached USD 3 million, a decrease of 44% compared to 2022. This drop was mainly due to the low prices at which most of these products were traded. Flowers accounted for 83% of cannabis exports, while exports of medical products increased, accounting for 13% of the value exported. Medical flowers totaled sales of USD 1.5 million in 2023, a slump of 66% compared to 2022.

to be exported, keeping it only for final products. In addition, a registry of products exclusively for export was created, without the need for approval for sale in the Uruguayan market.





CHART 4 - VALUE OF CANNABIS EXPORTS BY PRODUCT (Million USD)

Source: Uruguay XXI based on DNA data

Despite the 66% decrease in exports of high-THC flowers, new markets were opened, such as Australia, New Zealand, Spain, Brazil and the Czech Republic. While Germany became the main export destination, placements in Portugal fell sharply.

On the other hand, despite a 14% drop in volumes, hemp flowers for non-medical use recorded exports of USD 1 million, with a slight increase in sales compared to 2022. The growth in demand during 2023 from the United States and the Czech Republic, as well as the arrival of flowers into Brazil through ANVISA's RDC 660, explained the increase in this item. Switzerland continued to be the main destination, accounting for 50% of hemp flower exports for non-medical use.



			2022			2023			2024*	
Product	Destiny	Companies	FOB USD	Net kg.	Companies	FOB USD	Net kg.	Companies	FOB USD	Net kg.
	Argentina					44,777	11,561			
THC Seeds =<	Costa Rica					2,411	0			
0.5% in weight	Paraguay				28	121	24			
	Spain					4,057	0			
Medicines	Argentina	7	3,184	2	19			2		
ivieuicines	Brazil	/	10,395	8		465,838	1,726		239,557	973
	Germany		346,034	509		1,289,943	562		734,077	717
	Australia					75,555	124			
	Brazil					3,600	1			
THC Flowers	Israel	4 4,053,500 280			7,736	13				
>=1% in	Portugal		4,053,500	1,757	20	93,270	80	15 16	207,131	127
weight	Czech Republic					25,183	15			
	Spain					16,180	16			
	Canada		280	0						
	New Zealand					648	3			
	Brazil		18	0	_	38,520	10	8		
	Denmark					16,040	140			
	Ecuador		9,000	52						
THC Flowers <	United States of America	92	10,820	66	84	201,126	1,628			
1% in weight	Switzerland		834,887	13,159		515,595	6,407		103,060	928
	Paraguay					39,755	460			
	Czech Republic		1,112	7		198,330	2,701		120,147	2,355
	Belgium					3,000	10			
Extract	Peru	1	5,636	2						
Total		104	5,274,867	15,561	151	3,057,715	25,480		1,457,974	5,639

TABLE 3 - URUGUAYAN CANNABIS EXPORTS

Source: Uruguay XXI based on DNA data * Data as of August 2024

In 2023, flowers accounted for almost all exports, but the export of medicines registered significant growth compared to previous years. Brazil is consolidating as one of the main markets for medical cannabis in Latin America. In 2023, almost USD 400,000 were exported and by August 2024, a total of USD 240,000 was achieved.¹⁵

Finally, 2023 also showed the highest export volumes of seeds, with 11.5 tons, mainly to Argentina, but also with exports to Spain, Costa Rica and Paraguay.

¹⁵ Uruguay has participated in important industry events such as <u>ExpoCannabis Brazil</u> y <u>Medical Cannabis Fair</u>, with the aim of positioning itself as a strategic destination in the international market.



3.3. MEDICAL CANNABIS

Uruguay has a long history in the pharmaceutical industry. The production and export of generic drugs and high-quality pharmaceutical products are two of the main strengths in this path. The country offers a solid infrastructure that includes a strong regulatory and sanitary surveillance system, as well as a significant investment in research and development of new technologies in the pharmaceutical field.

Positioned as a regional hub for pharmaceutical products on the Southern Cone, the country offers significant advantages for the location of companies that develop these activities. This know-how places Uruguay as a reference country for the development of a hub for cannabis products, with a special focus on the medical aspect.

In addition, there is a regulation for the cultivation, harvesting, production, manufacture and commercialization of cannabis for the production and extraction of raw material and cannabisbased products for medical use. To carry out activities related to the making of semimanufactured products or final products for consumption, a license from the IRCCA and authorization by the MSP are required.

Uruguayan Decree 282 regulates and controls logistical operations with therapeutic medical cannabis products in customs warehouses authorized by the MSP and IRCCA. This allows them to receive imports, with prior authorization from the MSP, to be redistributed in the region, which would facilitate the entry of medical cannabis products into the Brazilian market. The hub scheme allows importing complete batches, fractioning them and carrying out operations between Uruguay and Brazil.

3.3.1. MEDICAL CANNABIS VALUE CHAIN

The medical cannabis chain is the one that has attracted the greatest commercial interest at a global level, with a higher volume of investment given its greater profitability. Quality and international certifications are a key factor and standardized production methods must be followed since it constitutes a pharmaceutical product.

The main medical cannabis companies in Uruguay are foreign-owned, representing 60% of the authorized ones to operate in this segment. Canada is the leading source with three companies, followed by Brazil and Argentina with two companies each, and the United States with one.



Although there are different business models, a presence of vertically integrated companies prevails, compared to the rest of the industry's value chains. The companies are responsible for genetic selection, cultivation, extraction, production and marketing. They also usually have research and genetic improvement projects and their own analysis laboratory.

The number of licenses is evenly distributed in cultivation, industrialization, research and development. At the cultivation level, the industry has production capacity mainly for flowers with high-THC content intended for medical use. Of the 16 cultivation licenses, seven are authorized to produce non-psychoactive inflorescences. However, currently only two have non-psychoactive medical products.

In addition, some 15 companies are licensed by the MSP for the cultivation and production of medical cannabis. Of these, 11 are licensed for conditioning and drying, of which six are responsible only for non-psychoactive flowers, while only one focuses on flowers with high-THC levels. There are four licenses for both types of flowers, and seven companies are authorized to prepare medicines based on this product.



FIGURE 4: MEDICAL CANNABIS VALUE CHAIN IN URUGUAY ¹⁶

search & Development	Сгор	Industry
13 Licenses	16 Licenses	14 Licenses
7.	Analytical laboratories license	s

Source: Uruguay XXI with data from IRCCA

Among the 14 industrialization companies, four produce cannabis extract – either psychoactive or non-psychoactive – and seven are dedicated to the production of oral solutions, medicines and drops (mother tinctures), always for medical purposes.

In addition, there are four companies that have industrialization licenses for the production of cosmetics based on non-psychoactive cannabis oil. These products are mainly made from domestic inputs, although some companies also operate with imported inputs.

3.3.2. PRODUCTION AND STOCK OF CANNABIS FOR MEDICAL USE

In 2023, the medical cannabis production in Uruguay reached a total of 28.6 tons. Production was mainly centered on non-psychoactive products.

¹⁶ Visit the IRCCA site to access to the complete list of licenses granted and companies (<u>link</u>).



CHART 5: CANNABIS PRODUCTION FOR MEDICAL USE (2023)



Non-psychoactive cannabis

Source: Uruguay XXI with data from IRCCA

Regarding psychoactive cannabis, 72% was used for flower production, 28% for trimming, while biomass recorded a slight production. As for non-psychoactive cannabis, the production consisted of 100% flowers.

Stock

According to data available as of March 2024, a stock of 46.5 tons of cannabis crop was recorded. Of this total, 81% corresponds to non-psychoactive cannabis flowers. Within the production of psychoactive cannabis, which accounts for the remaining 19%, flowers represent 72% with 6.4 tons, while trimming registered 2.5 tons.





CHART 6: CANNABIS CULTIVATION STOCK IN 2024 (TONS)

Source: Uruguay XXI with data from IRCCA

Regarding final products, there is a stock of 253 kg of raw extract, 85 kg of winterized and about 175 kg of purified cannabinoids. As for industrialized products, there are 422 kg of cosmetics and 149 liters of psychoactive oral solutions.

TABLE 4 - STOCK OF CANNABIS-BASED FINAL PRODUCTS

Final product	Kg
Cosmetics	422 kg / 836 L
Psychoactive oral solution	149 L / 8 Kg
Raw extract	253
Purified cannabinoids	175
Winterized extract	85
Enriched extract	15
API Full Spectrum	10

Source: Uruguay XXI with data from IRCCA





The local market for cannabis-based medicines is limited for certain medical conditions (mainly epilepsy). Law 19,847, which established a legal framework for production and medical/therapeutic use, was regulated in Decree No. 56/023 in February 2023. For this reason, there are no THC products authorized yet. In this sense, companies in the medical cannabis chain are strongly oriented to the export market, with a few exceptions that produce specialties from plants with high-CBD content for medical use.

Name	Active ingredients	Responsible laboratory	Conditions of sale
Epifractán 2% and 5%	drops	Medic Plast	
Xalex 10 Bidiol 3, 5 and 10	Cannabidiol 100 mg/mL oral drops Cannabidiol 30, 50 and 100 mg/mL oral drops	ICC Labs.	On professional
Bidiol 10 M Xannadiol 5% and 10%	Cannabidiol 100 mg/mL oral drops Cannabidiol 50 and 100 mg/mL oral drops	Haymann	prescription - with additional pharmacovigilance
Epixann 5% and 10%	Cannabidiol 50 and 100 mg/mL oral drops	Caillon & Hamonet Greenmed	
Xpectra 10	Cannabidiol 100 mg/mL oral drops	Processing	

TABLE 5 - CANNABIS MEDICINES REGISTERED IN URUGUAY

Source: Uruguay XXI with data from MSP

At the pharmaceutical level, there are several lines of medicines registered in Uruguay with different presentations, distributed among five companies. The drugs are based on CBD and are sold under professional prescription with additional pharmacovigilance. Their main therapeutic action is anticonvulsant and they are generally used for the treatment of refractory epilepsy. Their use also extends to other ailments such as Parkinson's disease or arthrosis.

On the other hand, there are 18 cosmetic products registered by four companies in the country. The conditions of sale of these products are more permissive than in the case of drugs.


TABLE 6 - CANNABIS-BASED COSMETIC PRODUCTS REGISTERED IN URUGUAY

Type of product	MedicPlast	Lab. Homeoalemán	Lab. Caillon & Hamonet S.A.C.I.	Montjuic
Hair product	2			
Body product	7	2	1	1
Face product	1	1	1	1
Hands and body product				1
TOTAL	10	3	2	3

Source: Uruguay XXI with data from MSP

3.4. RESEARCH

Research plays a fundamental role in the development of the industry and is one of its most important activities. There are 13 licenses in force granted by the IRCCA; seven are licenses for private companies and six are destined to public research centers.

Research allows the development and licensing of new genetics, products, technologies and processes that can position Uruguay as a benchmark in the industry. These types of licenses are granted to private companies as well as public organizations, such as the University of the Republic or Clemente Estable Institute. Some of the items of the licenses are the following:

- Research and development of new psychoactive and non-psychoactive cannabis strains
- Research on optimization of extraction processes
- Development of non-psychoactive cannabis varieties for registration
- Development of a process to obtain cannabis extracts for medical use
- Biotransformation of cannabinoids by microorganisms

Among all the motivations, the need to develop proprietary genetics constitutes a major part of the efforts made by researchers, with five projects linked to this purpose, since genetics is the basis for the competitiveness of any agro-industrial sector.



INASE currently has 11 Uruguayan cannabis sativa varieties registered, six of which correspond to hemp and five to psychoactive cannabis.

Companies focused on genetic developments are the key to achieve the professionalization of the industry; thanks to them, it's possible to have a stable variety, adapted to a specific environment and with the desired quality. Considering the requirements that must be met to register new varieties with INASE, it is essential to achieve easily adaptable seeds. In fact, the development of proprietary varieties is one of the industry's main business opportunities. In view of global and regional trends, the ideal scenario for Uruguay would be to develop high-THC genetics (over 20%) for medical purposes and also genetics of less than 0.3%, which would allow a direct entry into the European market.

TABLE 7: URUGUAYAN REGISTERED VARIETIES

Variety	Crop	Rights Holder	Type of registration	Expiration date
Psychoactive cannabis	ALFA IRCCA	Positronics Seeds S.L.	Protected	01/01/2037
Psychoactive cannabis	BETA IRCCA	Positronics Seeds S.L.	Protected	01/01/2037
Psychoactive cannabis	CÉSAR DÍAZ	Bandera Casamayou, Eduardo	Protected	01/21/2037
Psychoactive cannabis	GAMMA IRCCA	Positronics Seeds S.L.	Protected	01/01/2037
Psychoactive cannabis	ÉPSILON IRCCA	Positronics Seeds S.L.	Protected	02/18/2039
Hemp	BCBD01	Marcelo Gonzalez Machin	Public	
Hemp	BCBD02	BCBD MEDICINAL S.A.	Public	
Hemp	MOCA	Germinaruy	Protected	11/11/2040
Hemp	ALMARO	INVERELL S.A.	Protected	01/06/2040
Hemp	ROMALEX	INVERELL S.A.	Protected	01/06/2040
Hemp	DELTA	AWILDE S.A.	Public	

Source: Uruguay XXI with data from INASE

To this day, imported varieties of hemp seeds play a predominant role in Uruguay while research is being carried out to develop local genetics. The following table illustrates the preeminence of imported varieties compared to the development of domestic varieties, especially in the case of psychoactive cannabis seeds with THC above 1%, which are significantly less developed.





CHART 7: ORIGIN OF SEEDS REGISTERED IN URUGUAY



Source: Uruguay XXI with data from INASE to 2023

Research is one of the aspects in which the current legal framework offers potential advantages for the development of the industry in the country. Uruguay is in a moment of creation of quality scientific knowledge developing its own varieties; this will allow it to position as the main genetics' supplier and as a country that receives foreign investment.

There are still challenges in the area of research, and it is necessary to keep making efforts for this product. The objective of generating proprietary genetics that adapt to the climate and soil conditions continues to be one of the main motivations in the area, where much of what is planted still comes from external genetics, which have different growing conditions.

3.5. INDUSTRIAL HEMP

In Uruguay, the cultivation of non-psychoactive hemp for non-medical use is subject to a series of requirements and authorizations issued by the MGAP and the General Directorate of Agricultural Services (*Dirección General de Servicios Agrícolas*, DGSA). These authorizations cover several activities such as the import, export, commercialization, sowing, cultivation and harvesting of hemp.



TABLE 8: NON-PSYCHOACTIVE CANNABIS VALUE CHAIN

Cultivation licenses		Industry licenses			
31 flower cultivation licenses	63.8 hectares of productive capacity in outdoor production	43,700 m2 of indoor productive capacity	43,700 m2 of	43,700 m2 of	
4 grain cultivation licenses	173 hectares of productive capacity		indoor productive capacity	indoor productive capacity	
l fiber cultivation license	30 hectares of productive capacity				

Source: Uruguay XXI based on MGAP

3.5.1. HEMP CULTIVATION

In Uruguay, 35 companies are authorized by the MGAP to grow non-psychoactive cannabis (2023). These add up to a total area of 335 hectares in outdoor production. In addition, they have indoor growing facilities, totaling 43,000 m² (462848 sq. ft.).

The cultivation of cannabis is distributed in several areas of the country, covering 10 of the 19 departments, with a clear concentration in the south and the coast. Canelones contains 37% of the hemp cultivation firms, with a total of 20 companies, and is also the department with the largest area of greenhouse farming. Colonia holds 20% of the companies and has the largest proportion of outdoor surface with 39% of the total hectares. Montevideo, despite having only one company, is the department with the third largest greenhouse area. Both Paysandú and Soriano do not have many companies; however, they are among the main departments in terms of lands for cultivation under outdoor production.







CHART 11 - HEMP CULTIVATION COMPANIES BY DEPARTMENT ¹⁷

Source: Uruguay XXI based on MGAP

The first challenge for the crop was the learning curve, given that the prohibition meant a generalized lack of instruction. The initial years were, for most of the enterprises, times of learning and modest productive results. However, Uruguay now has the opportunity to be an exporter of services thanks to the know-how accrued during ten years of a regulated market.

Initially, the regulations were intended to cover the production of hemp grain, edible oil and protein, in line with the provisions of the UN Convention. However, as the industry in Uruguay developed, companies showed greater interest on the production of hemp flower for non-medical use, as well as for other by-products, such as CBD (cannabidiol).

Product	No. licenses	Outdoors Hec	Covered m ²
Flowers	22	41	31,690

¹⁷ MGAP and IRCCA licenses for non-psychoactive cultivation are considered. There was no departmental registration for nine additional licenses.



Grains	4	173	0
Seedlings - Flowers	3	12	2,420
Others (Seeds, Seedlings, Cuttings)	9	109	9,590
Total	38	335	43,750

Source: Uruguay XXI based on MGAP

Companies dedicated to grow flowers are more inclined to produce in controlled environments, and in general are those with greater investment and vertical integration. Grain and seed production is done in the open-air and it occupies a large part of the nonpsychoactive cannabis hectares.

According to information from MGAP, approximately 25 companies in Uruguay are engaged in the production of female hemp flowers, either unfertilized or fertilized, with a focus on exports. Around 34,110 m² (367156 sq. ft.) of greenhouses were used for flower production, representing 78% of the industry's total. Also, approximately 53 hectares were cultivated in open-air.

Part of the flower production is intended for the production of phenolic resins and/or cannabinoids, i. e. extracts that can end up in purified cannabinoids – typically CBD – or in raw extractions or full spectrum, in which all cannabinoids are preserved, with the possible exception of THC.

On the other hand, four companies focus mainly on the production of hemp for grain. They cultivated 173 hectares in open-air, which represents 65% of the total cultivated outdoors. In addition, there are other companies that focus on the production of seeds, grains or oil derived from hemp grain for non-medical use.

Growing hemp for producing grains or non-psychoactive flowers involves important differences in production, conditioning and marketing. One of these differences lies in the variety of seed or cuttings used, which must have a high or low-CBD content, which affects the cost of the seeds. For cannabinoid production, a density of 10 plants per square meter is generally considered economically optimal. For seed or grain production, on the other hand, a density of 30 plants per square meter can be used. And for fiber production, the ideal density is between 90 and 250 plants per square meter. These differences in the choice of varieties, seed costs and planting densities demonstrate that growing hemp for different purposes



requires specific approaches and considerations to achieve optimal results and maximize the profitability.¹⁸

3.5.2. HEMP FOR NON-PSYCHOACTIVE FLOWERS

At the product level, what characterizes non-psychoactive cannabis are the seed varieties used in these plantations, since they have a high-CBD content, higher than 10%, and a low-THC content. Post-harvest is a critical stage for the quality of the final product, which depends as much on genetics and cultivation practices/methods as on the drying or conditioning stage, which can affect up to 60% in the final quality of the product.¹⁹

In recent years, there has been a growing trend in the CBD flower industry towards greenhouse farming, where better plant quality and more stable production can be assured.

Drying facilities must be registered under MGAP; they play a critical role in the practice, since quality is a key factor for placing the production in the United States or Europe. Several of the companies that carry out drying also provide trimming.

In Uruguay, non-psychoactive flowers cannot be marketed for adult use, since the regulatory decree for recreational cannabis only allows inflorescences with THC. However, they can be used by the industry, both cosmetic and medical, or they must be exported.

In order to export, the production of CBD flowers must be authorized by MGAP for nonmedical use. In addition, it is necessary to certify in local laboratories that the flowers contain less than 1% THC in the cannabinoid analysis.

However, not all of the harvest meets the quality standards required for export, due to problems of flower size or formation. Flowers that do not meet quality requirements or are poorly prepared, along with the residues resulting from their preparation, may be destined for the processing industry, where they are converted into biomass used as an input for extraction.

CBD flowers are processed in the non-medical extraction industry, where several products are obtained for use in other industries. These products include isolated CBD (95% pure), full spectrum extract (a mixture of CBD, CBG and THC at 4%) and other components. Extraction levels are low, with every 1,000 kg of material yielding about 1 kg of pure essential oil.

¹⁸ Report: <u>Consulting on the characterization of the cannabis agro-industrial chain</u> CINVE - INEFOP - 2023

¹⁹ Report: <u>Consulting on the characterization of the cannabis agro-industrial chain</u> CINVE - INEFOP - 2023



However, since it is used at very low doses, it is a highly valued product, and the extraction process requires specialization.

3.5.3. HEMP FOR INDUSTRIAL USE

Most of the outdoors hectares cultivated with hemp in Uruguay (55%) are destined to industrial hemp. The cultivation of industrial hemp can be focused on obtaining fiber, grain or have a dual purpose. The choice of varieties and the time of the harvest are key factors to optimize the results in each case.

The industrial hemp chain is like other agricultural chains such as oil crops. Hemp can be incorporated into crop rotation, complementing other winter crops and alternating with other summer crops. Large investments in infrastructure are not required, except for an irrigation system, since the plant demands a lot of water.

So far, no hemp grain industrialization projects have been developed in Uruguay. Only one application to the MGAP has been submitted. In 2019 this ministry issued a decree that recognized hemp grain as a food input.

To produce food from hemp grain, an authorization by the bromatology unit of each department where the plant is located is required. Currently, the Municipality of Canelones is the only one that has authorized companies to produce from hemp grain. This situation shows that the industrialization of hemp grain in Uruguay is still at an incipient stage and is limited to this administration.

The export of raw hemp fiber is not profitable due to its low value and significant volume. Therefore, the viability of the hemp fiber chain lies in its industrialization at the local level, either for use in the textile industry or in construction.

3.6. CANNABIS FOR ADULT USE

Uruguay legalized the production, marketing and consumption of psychoactive cannabis for adult use. Three legal forms of access were regulated by law: purchasers in pharmacies, cannabis membership clubs and home farming. For any of the three ways, it is required to be of legal age and be a legal or natural Uruguayan citizen or to have a proved permanent residence in the country. It is estimated that in Uruguay the consumption of cannabis for adult use is between 44 and 50 tons per year and that there are approximately 250,000 consumers.



With the implementation of the new regulation 10 years ago, the institute's records indicate that the formal cannabis market is reaching approximately 36% of consumers. Due to divergences between cultivation license holders and shared use of cannabis, it is presumed that this market could represent an even higher proportion. If license holders were to comply with renewal requirements, the share on the regulated market could increase by six percentage points, reaching 42% of cannabis users in formal terms. This estimate does not include those who, although not registered, consume cannabis from the regulated market due to shared use practices. Incorporating shared use and considering growers whose license has expired, the real market could reach up to 63% of cannabis users, based on annual prevalence.

According to information from IRCCA, about the number of registered individuals, it was observed that, between June 2018 and June 2023, the increase in pharmacy registration was 144%, from 35,246 to 86,207. In contrast, the growth in the number of club members during the same period was 348%, increasing from 2,339 in June 2018 to 10,486 in June 2023. This growth rates disparity between the two segments could have been even more pronounced had the Gamma variety not been launched. The introduction of this variety led to an increase of 10,000 pharmacy registrants in a six-month interval. This number, by the end of 2023, grew to 90,000 people within the regulated market. ²⁰

Survey indicators²¹ show that one of the most common sources of access to cannabis is shared use among consumers. When considering not only the people who are formally registered in the regulated market, but also those who access cannabis from this source through shared use.

²⁰ Regulated market for adult consumer Report IRCCA, December2023 (<u>link</u>)

²¹ VII National Survey on Drug Use in the General Population (2018) and Online survey for purchasers in pharmacies implemented by the IRCCA in 2023.





CHART 12 - PARTICIPATION BY ACCESS ROUTES TO LEGAL CANNABIS $^{\rm 22}$

The law has managed to gather a greater number of consumers within the regulation, as the presence of parallel market access decreased from 58.2% in 2014 to 24% in 2022²³. However, unregistered growers still have an important weight that must be addressed by the authorities. There are limits on quantities for purchase in pharmacies, home farming and clubs. There is also a THC concentration limit (9%) that only reaches the production of companies or clubs.

One of the fastest growing segments in terms of consumption within the legal market has been cannabis clubs. More and more consumers are turning to clubs as their main source of access, which also has an impact on shared consumption. As of 2023, 345 cannabis clubs were registered, which signified a 28% growth compared to those registered the previous year. This means that these associations attracted almost 3,000 new members to the market.

CHART 13 - CLUB MEMBER REGISTRATION

²² In Uruguay, it is legal to share or give away legally sourced cannabis.

²³ VII National Survey on Drug Use in the General Population (2018): link







Consumption in pharmacies has remained constant and captive until 2022 compared to the alternatives that have existed to access cannabis. Despite this, during the last year there has been a significant increase in consumption, both in terms of transactions and volume sold, reaching the maximum since the legal sales channel are being used. Likewise, there is a certain confidence in terms of purchases in pharmacies, so a new growth could be expected for the next harvest. As of December 2023, there were 19,730 purchasers (those who bought at least once) with an average of 15.2 grams per person. This represented a 34.5% increase in purchasers compared to the end of the previous year.

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CHART 14 - EVOLUTION OF TRANSACTIONS AND GRAMS SOLD

Source: IRCCA based on daily register of pharmacies

There are three companies authorized to produce and distribute cannabis for adult use in pharmacies. In Uruguay, advertising is illegal and the packaging cannot include the name or logo of the producing company. In this regard, IRCCA opened last year a call to extend the granting of licenses to produce, process, store and distribute psychoactive cannabis for the dispensing points authorized by the institute.

4. INSTITUTIONAL FRAMEWORK

The Institute for Regulation and Control of Cannabis (IRCCA) was created by Law No. 19,172 with the purpose of regulating the planting, cultivation, harvesting, production, processing, storage, distribution and dispensation of cannabis. Its purpose is to promote and propose actions aimed at reducing the risks and damages associated with the problematic use of cannabis and to supervise compliance with the provisions contained in the law and this regulation, 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 establishing the national policy on cannabis, with the advice of the IRCCA.





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Ministerio de Ganadería, Agricultura y Pesca

Among the functions of the Ministry of Livestock, Agriculture and Fisheries

(MGAP) is the contribution to the permanent development of the agricultural, agro-industrial and fishing industries, as well as the organization and development of the protection of the health and quality of the production processes of plant and animal products. Law 19,172 establishes that the MGAP must authorize and control the planting or growing of cannabis for non-psychoactive use (hemp).

Within the aforementioned portfolio, the <u>General Directorate of Agricultural Services (DGSA)</u> works on the protection and improvement of the phytosanitary status and the quality and safety of plant products in order to contribute to sustainable development, agricultural trade, preservation of the environment and the health of the population. This executing unit of the MGAP is the official authority, recognized locally and internationally in phytosanitary matters, quality and safety of plant food and animal feed. One of the most transcendental public policy definitions of the last years was the regulation of cannabis, which among other aspects includes the development of hemp – cannabis of non-psychoactive use – for industrial and food purposes from grains, stalks, flowers and leaves. This directorate is in charge of the Single Registry of Operators (*Registro Único de Operadores*, RUO), where applications for operations and work plans are processed.

The main objective of the <u>Nacional Seed Institute (INASE</u>) is to promote the production and use of the best seed with proven identity and superior quality, stimulating the development of the national seed industry. At the same time, it supports the breeding and use of new national and foreign plant genetics materials that are suitable for Uruguayan conditions. Its role also includes the protection of plant genetics creations and discoveries, granting the corresponding property titles.



Regarding the cannabis market, INASE is responsible for the General Register of Seed Growers (*Registro General de Semilleristas*, RGS) and the National Register of Strains (*Registro Nacional de Cultivares*, RNC).

The National Secretariat for the Fight against Money Laundering and Financing of Terrorism



(Secretaría Nacional para la Lucha contra el Lavado de Activos y Financiamiento del Terrorismo, SENACLAFT) is in charge of elaborating and submitting to the consideration of the Executive Power the national policies for the fight against the mentioned targets. It also proposes to the Executive Branch the national

strategy to combat money laundering (ML) and financing of terrorism (FT), based on the development of the preventive, repressive and financial intelligence components of the system. At the same time, it carries out periodic and general diagnoses to identify vulnerabilities and risks in order to enable the necessary adjustments in terms of objectives, priorities and action plans.

Its participation in the cannabis market consists of researching and controlling the corporate structures of the companies linked to the industry, the identification of the final beneficiaries and the origin of the funds to be used.



The <u>National Drug Board (JND)</u> is responsible for designing and approving the National Drug Strategy (*Estrategia Nacional de Drogas*, END) and its respective Operational Action Plan (*Plan de Acción Operativo*, 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 connection with the different institutions involved in drug policies.

 Junta Nacional de Drogas
 The Chamber of Medical Cannabis Companies (Cámara de Empresas de Cannabis Medicinal, CECAM) gathers companies linked to the local

development of the cannabis market for medical use. The idea of this alliance is to guarantee the development of the cannabis industry in Uruguay, for which it is essential to have an organized private sector.

Uruguayan Cannabis Producers Network: <u>Uruguay Cannabis Network</u> has the mission to create communication and collaboration links between those involved in the value chain of non-psychoactive cannabis for non-medical use in order to develop the industry, safeguarding the interests and rights of cannabis companies. Its vision is to articulate the development and



improvement of the productive, logistic and commercial process of non-psychoactive cannabis for non-medical use, generating an efficient value chain with the clear goal of setting a standardized and validated country brand for domestic trade with recognition for foreign trade.



<u>Polo Tecnológico de Pando</u> is an institute that 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 industrial and service segments. The institute works on the promotion and development of R&D activities through:

- Technology transfer
- Design, development and participation in research and innovation projects, whether owned or in collaboration with other companies
- Projects in collaboration with companies seeking financing
- Incubation and technical support to entrepreneurs
- Courses, seminars and other forms of training for companies

The <u>Khem</u> incubator focuses on the development of technology-based companies. It is located on the premises of Polo Tecnológico de Pando,

with a laboratory total area of 350 m² (3767 sq. ft.) for the incubating companies to work in. It also has the KhemBIO platform, through which biotechnology ventures can be sponsored.

Centro Biotecnológico de Investigación e Innovación

The <u>Biotechnology Center for Research and Innovation (Centro</u> <u>Biotecnológico de Investigación e Innovación, CBI+I)</u>, along with the Technological University of Uruguay (Universidad Tecnológica del Uruguay,

UTEC) and the Center for Innovation and Entrepreneurship (*Centro de Innovación y Emprendimientos*, CIE) of the ORT Uruguay University (*Universidad ORT Uruguay*), are in charge of the CIE BIO incubator, which promotes and executes actions to develop, strengthen and coordinate the biotechnology-based ecosystem, aiming to turn entrepreneurial initiatives into innovative ventures with a positive impact on society.



The Experimental Neuropharmacology Department of <u>Clemente Estable</u> <u>Biological Research Institute (Instituto de Investigaciones Biológicas Clemente</u> <u>Estable</u>, IIBCE) focuses on understanding the neurobiological bases associated

with neuropsychiatric pathologies such as depression, schizophrenia and addiction to drugs of abuse and the study of the mechanism of action of psychotropic drugs (antidepressants,





anxiolytics and antipsychotics). The aim is to understand the physiology of the systems involved in these pathologies and to find new therapeutic targets that allow the design of more specific and selective pharmacological strategies with fewer side effects. In the search for alternative therapeutic strategies to the existing ones, they are beginning to develop different lines of research, including the medical use of cannabis and cannabinoids.



Institut Pasteur de Montevideo. Non-profit foundation created in 2004 by the Institut Pasteur in Paris and the University of the Republic. It has highly qualified human resources and modern equipment available to the entire

scientific community and life sciences companies. The institute works on integrated projects in biotechnology related to human and animal health industries, among others. Within this framework, it provides biotechnological services for foreign and national companies, including Biopolis (Spain), Danone (France), Gema Biotech (Argentina), Santa Elena (Uruguay) and Microsules (Uruguay).

These institutes, apart from contributing to industry projects, provide specific training with special equipment and infrastructure to complete them, which would otherwise have to be provided by the company, hindering daily operations. Most of these institutions, as well as free trade zones with specific platforms, technologies and services for life sciences companies (e. g., Zonamerica and Parque de las Ciencias), are concentrated in Montevideo metropolitan area, creating a hub of innovation activities.

5. URUGUAY IN BRIEF

URUGUAY IN NUMBERS

Official name	República Oriental del Uruguay				
Geographical location	South America, bordering Argentina and Brazil				
Capital	Montevideo				
Surface area	176,215 km ² . 95% of the territory is productive land suitable for agricultural and livestock exploitation				
Population (2023)	3.44 million				
GDP per cápita (2023)	USD 22,421				



Currency	Uruguayan peso (\$)				
Literacy rate	0.98				
Life expectancy at birth	77.9 years				
Form of government	Democratic republic with a presidential system				
Political division	19 departments				
Time zone	GMT - 03:00				
Official language	Spanish				

MAIN ECONOMIC INDICATORS

Indicators	2017	2018	2019	2020	2021	2022	2023	2024*
GDP (Annual % Var)	1.74%	0.16%	0.93%	-7.38%	5.56%	4.71%	0.37%	3.35%
GDP (Million USD)	64,995	65,259	62,166	53,615	60,728	70,236	77,131	79,715
Population (Million people)	3.43	3.43	3.44	3.44	3.44	3.44	3.44	3.44
GDP per cápita (USD)	18,949	19,010	18,095	15,593	17,648	20,395	22,422	22,267
Unemployment Rate - Annual Average (EAP %)	7.9%	8.3%	8.9%	10.4%	9.3%	7.9%	8.3%	8.6%
Exchange Rate (Pesos per USD, Annual Average)	28.7	30.8	35.3	42.1	43.6	41.1	38.9	40.0
Exchange Rate (Average Annual Variation)	-4.8%	7.3%	14.7%	19.2%	3.6%	-5.6%	-5.5%	2.9%
Consumer Prices (Cumulative Annual % Variation)	6.6%	8.0%	8.8%	9.4%	8.0%	8.3%	5.1%	5.2%
Exports of goods and services (Million USD)**	16,845	17,283	17,254	13,909	19,639	22,611	25,353	25,886
Imports of goods and services (Million USD)**	13,367	13,973	13,504	11,431	15,134	18,993	18,865	19,997
Trade surplus/deficit (Million USD)	3,478	3,309	3,750	2,477	4,505	3,618	6,488	5,889
Trade Surplus/Deficit (GDP %)	5.4%	5.1%	6.0%	4.6%	7.4%	5.2%	8.4%	7.4%
Global Tax Result (GDP %)	-3.2%	-3.9%	-4.4%	-5.8%	-4.1%	-3.4%	-3.6%	-
Gross Capital Formation (GDP %)	15.9%	14.9%	14.1%	16.4%	18.3%	18.9%	17.3%	-
Public Sector Gross Debt (GDP %)	59.8%	58.9%	59.9%	74.5%	69.8%	68.1%	0.69	-
Direct Foreign Investment (Million USD) ***	-590	-11	2,018	756	1,937	3,456	3,429	-
Direct Foreign Investment (GDP %)	-0.9%	0.0%	3.2%	1.4%	3.2%	4.9%	4.4%	-

* Projected data in red. Sources: Central Bank of Uruguay (BCU), National Statistics Institute (INE), Ministry of Economy and Finance (MEF) and estimated data (*). The tax result data include the effect of Law No. 19,590 (fifty percent). In 2017, the BCU adopted the methodology of the 6th Balance of Payments Manual. Data based on this new methodology includes purchase and sale of goods and re-exports, and is available since 2012. Data are net flows, so they may take negative values (**).



