CANNABIS SECTOR IN URUGUAY


© FLEXTEM BIOPHARMA


© FOTMER LIFE SCIENCES

APRIL 2023

Uruguay XXI
INVESTMENT, EXPORT AND COUNTRY BRAND PROMOTION AGENCY

TABLE OF CONTENTS

WHY THE CANNABIS SECTOR IN URUGUAY?

- **Reliability & Stability.** Uruguay is a reliable country to do business with. It offers political and social stability and a favorable investor grade business climate. This has allowed for the development of an incipient industry such as cannabis, within a stable and predictable legal framework.
- **Favorable and innovative regulatory framework.** Investment in Uruguay, both domestic and foreign, is considered of national interest. There is equal treatment for local and foreign investors, who have a wide range of incentives at their disposal.
- Uruguay offers a variety of business opportunities along the entire value chain, be it research, farming, or industrialization for medicinal, industrial or food purposes. The regulations have allowed for the development of an ecosystem, with more than 100 companies.
- **Easy access to decision-makers.** Uruguay's public-private ecosystem favors the coordination of policies to develop the sector, with close working relations between the different actors in the chain.
- **Focus on exports.** Uruguay has been exporting cannabis-derived products since 2018. This period has seen the export 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.
- **Strong track record in related industries.** Uruguay has cross-cutting strengths, both at the agro-industrial level and in pharmaceuticals and life sciences, which drives the development of industrial hemp or medical cannabis exports.
- **Sustainability.** Uruguay stands out for its precious diversity of natural resources and its commitment to preserving them, achieving a remarkable balance between natural wealth and environmental protection in harmony.

1. EXECUTIVE SUMMARY

- In December 2020, cannabis was removed from Schedule IV of the Single Convention on Narcotic Drugs by the United Nations (UN), thus recognizing its medical utility and safety.

- Following the legalization of cannabis in Uruguay (2013), several countries began to follow similar paths.

- The current main difficulties in international trade are caused both by the rigidities of certain international rules that operate under the scope of the United Nations as well as by the diversity of regulations within countries.

- In 2020, 209 million people were estimated to consume cannabis, which represented 4% of the world's population.

- The cannabis ecosystem in Uruguay is made up of hundreds of projects and directly employs 900 people. Seventy percent of the workers carry out their activities in the countryside.

- Companies in the cannabis sector have export as their main business focus. In 2023, 50% of the companies registered for growing or industrializing cannabis registered exports during the previous year.

- In 2022, the production of medicinal cannabis in Uruguay reached a total of 15.7 tons, which was equally distributed between psychoactive and non-psychoactive cannabis. In addition, as of March 2023, there was a reported stock of 42.5 tons of cannabis crops.

- In Uruguay there are 14 research licenses granted by the Institute for Regulation and Control of Cannabis (IRCCA for its acronym in Spanish), nine are given to private companies and five are intended for research centers. As a result of R&D in the sector, currently there are ten Uruguayan cannabis sativa varieties at the National Seeds Institute (INASE), of which six are hemp and four are psychoactive cannabis.

2. INTERNATIONAL MARKET

Cannabis is currently the most widely consumed narcotic drug worldwide. Although its use is still illegal or limited to medicinal and therapeutic use in many countries.

In general terms, it can be said that regulations on medicinal use are more widespread, and the low THC sub-sector is the fastest growing, although high THC cannabis is gradually becoming available due to its growing medical use.

After its legalization in Uruguay (2013), several countries began to follow suit. In Latin America, countries such as Argentina, Brazil, Colombia, Mexico and Paraguay allowed consumption for medicinal purposes. Other countries around the world such as Germany, Australia, Canada, Spain, Israel, Portugal and Switzerland also followed in this direction. 2022 was a year of progress for cannabis used recreationally by legal adults: the legalization of cannabis with high THC content for non-medical purposes is seen as a real possibility in several countries. For instance, Germany and Colombia recently announced their intention to move forward on this trajectory.

The growth in international cannabis production and trade will be marked by the pace of progress in legalization in the main markets and by the multiple and growing applications that are emerging around cannabis, where medicinal and industrial use for food and beverages, textiles and cosmetics show the greatest potential.

The global supply chain is slowly diversifying with increasing external purchases. Currently, countries such as Germany, Denmark, Finland and Australia have become significant importers.

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

2.1. VALUE CHAINS IN THE CANNABIS INDUSTRY

Cannabis is a complex plant that has been used for medicinal, recreational and industrial purposes since ancient times. The plant contains over five hundred compounds[1], and cannabinoids are the most widely studied and most prominent in terms of their importance.

Cannabinoids are chemical compounds that interact with the endocannabinoid system in the human and animal body, which is responsible for regulating a variety of physiological functions. The cannabis plant contains well over 120 cannabinoids, but the best known are THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol). THC is the main psychoactive component of cannabis and accounts for the psychoactive effects associated with the consumption of the plant. THC concentrations in the dried flower can reach up to 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 dried flowers 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 often the name given to the plants that contain higher levels of THC. Those with low THC content that have an industrial purpose are often referred to as hemp.

In general terms, it can be said that the value chains around cannabis are structured according to their use, be it medicinal, recreational by adults or industrial. Legally, this is reflected in the regulations on THC thresholds and the requirements imposed for each case. Medical and recreationally used cannabis make use of the cannabinoids present in the plant and face strong controls and regulations, both in the production and commercialization stages. Industrial cannabis, which does not contain significant amounts of cannabinoids, faces less rigorous regulations.

Legal thresholds that distinguish cannabis from hemp are not set internationally; in the United States it is below 0.3% in dry weight and in Europe[2] the figure is 0.2%. While in countries such as Australia, Colombia, Switzerland, Czech Republic or Uruguay the threshold reaches 1%. From the production standpoint, this threshold determines the commercial possibilities and the necessary documents required for trade, as well as the

1 Radwan et al. 2017 https://www.argentina.gob.ar/sites/default/files/la_cadena_de_valor_del_cannabis_-10.12.pdf

2 Spain and the Netherlands are the exceptions, setting a limit over 0.3%

regulations and bureaucratic procedures to which the different processes of the production chain are subjected.

Cannabis for recreational use by legal adults is used 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 that has legalized this market 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 growing interest in studying the plant's potential for medicinal use. This industry takes advantage of the chemical components of the cannabis flower - mainly CBD and more recently THC - for the treatment of certain medical conditions. Some individuals use it to relieve 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 medicinal purposes, and has few psychoactive effects which can be mild, while having antioxidant, anti-inflammatory and neuroprotective effects. In many countries the use of medicinal 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 Food and Drug Administration (FDA) [3].

Other plant uses are linked to its industrial use. Hemp has a low THC content and is used to produce 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 it is becoming a more sustainable alternative to many conventional products. The latest United Nations 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, which also helps to reconstitute the soil by removing heavy metals and other pollutants. The report notes, for example, that hemp farming produces a 10% to 20% increase in wheat yields.

3 So far, the FDA has approved four pharmaceutical products related to cannabis, three of which have synthetic cannabinoids. (Marinol, Syndros and Cesamet. Epidiolex is the first pharmaceutical compound that contains cannabis which is FDA approved.

2.2. INTERNATIONAL LEGALIZATION STATUS

In recent decades, drug policies have undergone a significant change in many countries around the world, shifting from being centered on prohibitions and repression to reduce the drug supply to one focused on reducing the drug demand through prevention, treatment and rehabilitation.

This shift in focus is largely due to a greater understanding that drug use and addiction are public health issues and that a focus on repression was not always effective in addressing drug-related problems.

In December 2020, cannabis was removed from Schedule IV of the Single Convention on Narcotic Drugs by the United Nations (UN), recognizing its medical usefulness and safety. This led to a renewed interest in the medicinal use of cannabis due to new discoveries and advances in scientific research. As a result, many countries around the world are debating the legalization of cannabis farming for medical and recreational purposes.

The progress of legalization seems to be inevitable in many countries in Europe and the Americas, and has led to an intense debate on the pros and cons of cannabis legalization. Several countries reviewed their policies and laws in recent years. Some have legalized cannabis medical use and recreational use by legal adults, while others adopted decriminalization policies, meaning that the use and possession of small amounts of cannabis are not criminalized.

Cannabis regulations are segmented according to use: medicinal, recreational by legal adults or industrial. The licenses involve different stages of the chain, from farming, distribution, commercialization, possession and consumption. In this first great wave of regulation, each country is adapting its own legislation on cannabis and they significantly vary between countries in terms of the legality of the use, farming, distribution and consumption of cannabis products.

In this regard, current United Nations (UN) regulations on illicit drugs, which apply internationally, ban the use and distribution of cannabis for non-medical purposes[4].

In turn, certain complexities surround national regulations. THC is the main psychoactive component of the cannabis plant and countries often have maximum limits, which vary

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

from country to country, making international trade for cannabis products particularly difficult.

However, as more countries regulate cannabis, it is possible to develop more consistent and harmonized frameworks, allowing for greater fluidity in international trade.

CANNABIS USE BY ADULTS

The legalization of cannabis with high THC content for recreational use by legal adults had a breakthrough in several countries around the world. Nations such as Germany and Colombia announced serious intentions to legalize it. However, as of 2023, only Uruguay, Canada and some U.S. states have fully legalized the sale of cannabis for recreational use by legal adults. This list is expected to expand in the very short term based on the announcements of some countries such as those listed below.

FIGURE No.1: COUNTRIES WHERE CANNABIS IS LEGAL OR IN THE PROCESS OF LEGALIZATION

Source: 2022 Report - Prohibition Partners.

In December 2021 **Germany's** incoming governmental coalition declared its intent to legalize cannabis commercially for recreational use by legal adults. In October 2022 the government

published a "key points document" outlining its plan for the bill draft and its vote in parliament.

Switzerland and the Netherlands are running pilot tests in which access to cannabis by legal adult consumers is available in certain regions for a limited time. Both schemes suffered delays related to internal and external factors. There is growing support for commercial legalization in several European governments, including the **Czech Republic and Portugal**, and bills for legalization are expected to be introduced in the next two years.

Legalization continues to gain ground in the **United States and 21 states will have legalized cannabis use by legal adults** once laws are regulated in Maryland and Missouri.

President Joe Biden's administration took steps towards decriminalization of cannabis use at the federal level by eliminating prior federal convictions for possession in accordance with his campaign promises. He also ordered a review of the legal status of cannabis. However, in the short to medium term, there are no major advances in this regard.

In Latin America, at least three countries are preparing for the legalization of cannabis recreational use by legal adults.

- Mexico will become the largest country in the world to allow the legal commercialization of cannabis to adults. The country's Supreme Court ruled in late 2018 that cannabis prohibition was unconstitutional and ordered Congress to legislate in order to establish a legal industry. There were years of delay, mainly due to disagreements within the Mexican government over how to best implement legal cannabis commerce in the country. In late 2022 government officials indicated that they are now prioritizing this process.
- In Colombia a bill for the legalization of cannabis passed to the committee stage in the Colombian legislature in October 2022. Colombia's president expressed his support for full commercial legalization.
- The president of Costa Rica sent the Legislative Assembly a bill for the legalization of cannabis use by adults. It is unclear how long it will take the Costa Rican government to debate and adopt this new legislation.

DECRIMINALIZATION

The decriminalization of cannabis use by adults had a major global breakthrough in 2022, which may be an incentive towards future commercial legalization throughout important regions.

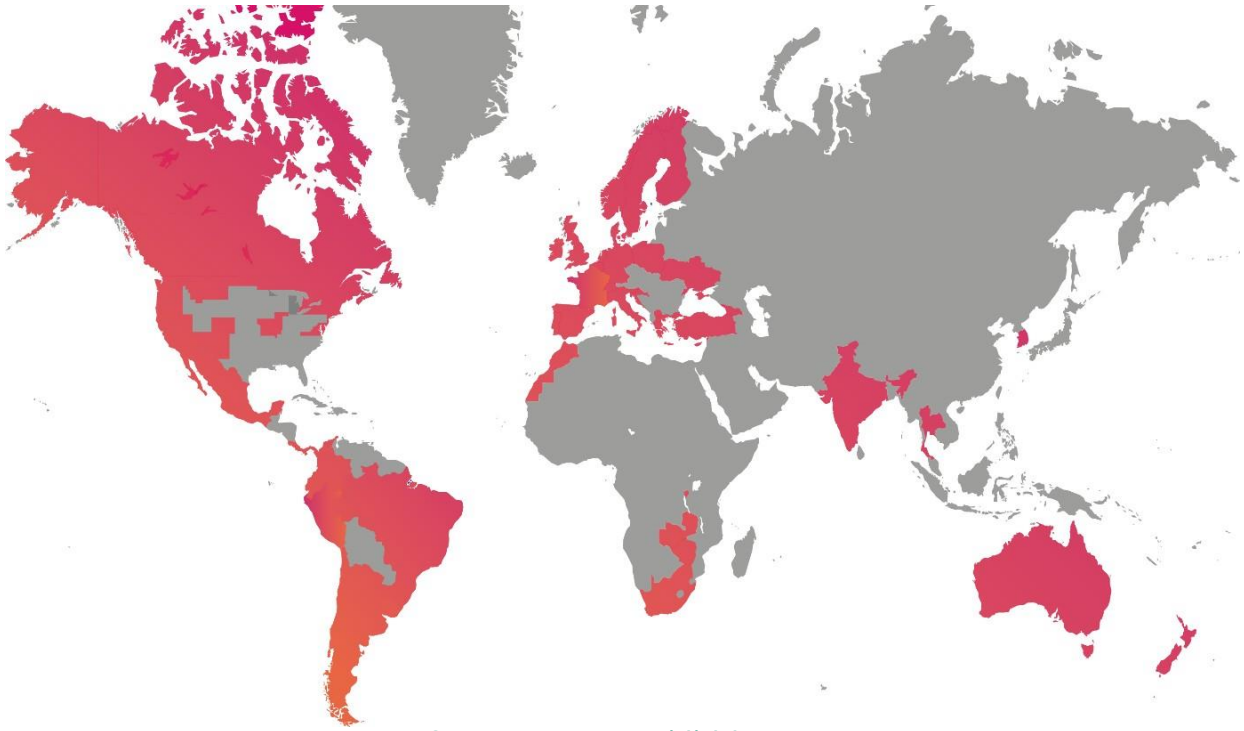
- In December 2021, Malta introduced legislative measures to decriminalize cannabis for personal use, following in the footsteps of countries such as Portugal and Georgia.

- As of April 2022, Israel considers the possession and use of cannabis only as a misdemeanor that does not warrant a criminal record for the offender.
- Thailand passed a law to decriminalize cannabis in June 2022.
- In October 2022, U.S. President Joe Biden announced an amnesty for people incarcerated solely for cannabis possession.

2.2.2 MEDICINAL CANNABIS

The medicinal use of cannabis has strong growth projections for its global market. Many products have conclusive scientific evidence for some diseases such as refractory epilepsy[5], and generally find a less rigid international regulation. Currently, some 50 countries allow its use at the national level[6].

FIGURE N°2: COUNTRIES WITH LEGAL MEDICAL CANNABIS



Source: 2022 Report - Prohibition Partners.

In Europe, legalization continues to advance, although with great supranational dependence due to the legal spaces shared within the union. Spain legalized the medicinal cannabis use for selected health conditions through the country's public health system in June 2022.

In Latin America, Costa Rica and Panama began implementing their approved medical cannabis regulations for the first time in 2021. In Japan, a select panel of the Ministry of Health

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

6 Some of them have pilot programs in place, others only allow use under license or for particular products.

recommended that the government allow the import and use of pharmaceutical cannabis products such as Epidiolex and Sativex, as possible first steps towards broader reform in the coming years. The Malaysian government also declared its intent to legalize along the same lines as occurred in 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 2020, an estimated 209 million people were using cannabis, representing 4% of the world's population[7]. Cannabis crops have experienced an upward trend and the number of people using cannabis has increased by 23% in the last ten years.

Although cannabis production in most countries is illicit and makes it impossible to estimate, it can be argued that farming, production and consumption are now globalized. According to UNODC, cannabis is produced in 190 countries when considering both direct and indirect indicators of crop impounding as well as indoor and outdoor farming trends.

The last decade saw the emergence of new production methods and improved extraction and isolation techniques. In 2019 and 2020, the number of countries reporting an increase in indoor cannabis growing increased, which, according to UNODC data, may have even surpassed outdoor growing[8].

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

In conclusion, the data that arises from different international organizations gathers partial and sometimes incomplete information, however, considering these limitations, they are indicators that as a whole allow to estimate the size of the market and to approximate the evolution of the sector.

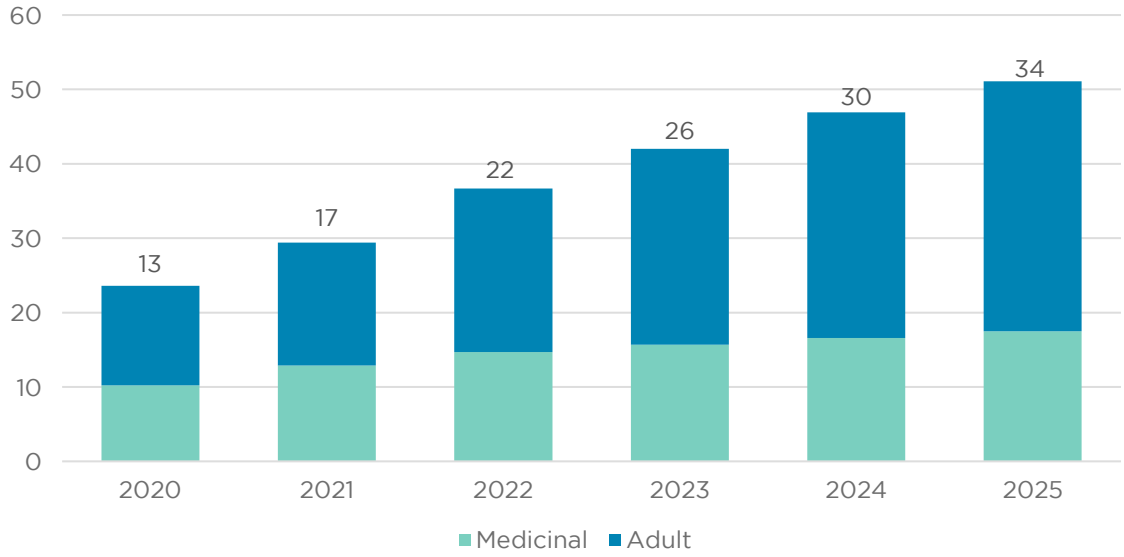
There are international consulting firms that produce global reports on the cannabis sector. Most of them conclude that the sector has positive growth prospects worldwide. The global cannabis report prepared by New Frontier Data[9] estimates that the global legal cannabis market will reach around US$ 42 billion in 2023, with the legal market accounting for less than 10% of the total. The growth of the global cannabis market is expected to be strongly determined by the increase in sales of cannabis

7 World Drug Report 2022, fascicle 3, Drug market trends of cannabis and opioids (United Nations publication, 2022).
8 The Report of the International Narcotics Control Board for 2022. (E/INCB/2022/1)
9 The Global Cannabis Report: Growth & Trends Through 2025 (link).

for recreational use by adults, with a greater dynamic of expansion of the industry in the United States and, to a lesser extent, Canada, where recreational cannabis use is legal.

GRAPH No1: WORLD CANNABIS MARKET

(BILLIONS OF US$)



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

The medicinal market will have a more moderate growth, with demand for cannabis concentrated in the pharmaceutical industry due to a more intense use in cosmetic products and a greater opening of markets, mostly in Europe.

2.3.1. CANNABIS FOR MEDICINAL 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 medicinal purposes.

In 2021 some 25 countries reported to the INCB the cannabis production for medical or scientific use. According to the INCB's 2022 World Drug Report, cannabis production for these purposes reached 764 tons in 2021. However, Canada, the second largest producer in 2020, did not report its production in the latest report. If Canada's unreported production is accounted for at similar values to 2020, the global production figure of legal cannabis for medical or scientific use would reach 1,000 tons.

According to this data, the global production of legal cannabis for medicinal or scientific use is led by the United Kingdom (33%), Canada (23%) and Italy (15%). The strong development of the pharmaceutical industry in the United Kingdom, 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 production of medical cannabis worldwide. Uruguay, with 1%, ranks eleventh in the international ranking.

TABLE No. 1: MAIN MEDICINAL CANNABIS PRODUCING COUNTRIES (2021)

Country	Kg	Part (%)
United Kingdom	329,056	33%
Canada	227,750(*)	23%
Italy	150,023	15%
Israel	89,400	9%
Colombia	45,340	5%
Jamaica	34,859	4%
Denmark	32,433	3%
Spain	20,591	2%
Australia	16,755	2%
North Macedonia	15,075	2%
Uruguay	7,165	1%
Others	23,583	2%
Total	992,030	100%

(*) Data 2020. Source: compiled by Uruguay XXI with data from the INCB.

Meanwhile, data on the global manufacture of tetrahydrocannabinol (THC) published in the INCB's Annual Statistical Report on Psychotropic Substances (2022) indicate that production increased significantly in recent years and reached 911 kg in 2021, representing a 29% increase over 2020 and a 120% increase compared to 2019. The report differs significantly in relation to the main producing countries, which, according to this report, in descending order by amount produced were Australia, Germany, the United States, Switzerland, the Netherlands, Canada, the United Kingdom and India.

According to the consultancy firm Market Research Future, over 70% of the medicinal market is sustained by CBD-based products and the remaining 30% is occupied by those using THC. Pain management products account for around 50% of the market and those targeting the neurological and mental health segment account for almost the entirety of the other 50%.

INTERNATIONAL MEDICAL CANNABIS TRADE

According to INCB data, based on reports from different countries that inform the traded volumes of medical cannabis, in 2021 the main exporter of cannabis was the United Kingdom (212.9 tons) with 58.4% of the world total. Followed by Canada (87 tons) with 23.9%, Finland (28.3 tons) with 7.8%, Portugal (12.1 tons) with 3.3%, the Netherlands (8.1 tons) with 2.2%, Denmark (4 tons) with 1.1% and Uruguay (3.2 tons) with 1%. Exports were also reported by Germany, Australia, Spain, Colombia,

Israel, South Africa, Austria, the United States, Poland, North Macedonia, New Zealand, Belgium and Sweden.

In 2021, the United Kingdom imported 31.5 tons of cannabis, 25.2% of the world total, followed by Israel (25.5 tons) with 20.3%, Germany (22.5 tons) totaling 18%, Ireland (15 tons) which is 12%, Portugal (6.8 tons) with 5.4% and Australia (6.4 tons) which is 5.1% and Australia (6.4 tons) representing 5.1% of the world total. The countries importing less than 4 tons were, in descending order of quantities imported, the Netherlands, Spain, Northern Macedonia, the United States, Italy, Poland, France, Finland, Malta, the Republic of Korea, Denmark, Norway, Sweden and Chile.

2.3.2. HEMP FOR INDUSTRIAL USE

Global hemp production has been increasing in recent years due to the growth in demand for hemp products and the legalization of hemp crops in some countries. In 2022, UNCTAD published a report that examines the economic, environmental and social potential of hemp[10]. According to this report, which surveys production in 40 countries, approximately 275,000 tons of raw or semi-processed industrial hemp were produced worldwide in 2019. The main producers of hemp fiber are China, France, Canada and the United States, which together account for more than 50% of global production.

3. THE CANNABIS SECTOR 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 medicinal, industrial and recreational use (by legal adults). Law 19.172[11] regulated recreational cannabis specifically and medicinal and industrial cannabis more generically. The law also created the Institute for Regulation and Control of Cannabis (IRCCA for its acronym in Spanish), an entity in charge of implementing regulation and controls related to the growing, planting, cultivation, harvesting, production, processing, stockpiling, distribution and distribution of cannabis.

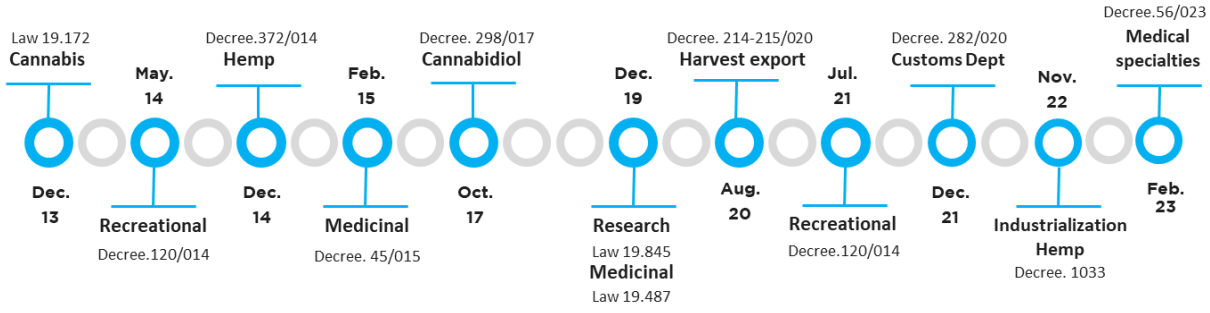
A series of decrees favored the development of growing and industrialization activities, as well as research and export activities, which led to the creation of a significant number of enterprises of various sizes that gained access to cannabis production, industrialization and research licenses.

10 Commodities at a glance: Special issue on industrial hemp (link)
11 Laws related to the Cannabis sector (link)

SUMMARY OF REGULATIONS TO DATE:

- Recreational cannabis was regulated by Decree No. 120/014[12], which established that the IRCCA was responsible for granting the appropriate 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 (MGAP, for its acronym in Spanish) was responsible for authorizing hemp-related activities and granting the appropriate licenses.
- Cannabis for medicinal purposes and research was regulated by Decree No. 46/2015, which authorized the manufacture and distribution of finished or semi-finished products for medicinal use, as well as scientific research on cannabis.
- In 2019, two specific laws for medical cannabis and research were approved, Law No. 19,845 and Law No. 19,847, still pending regulatory development and practical implementation.
- In 2020, two decrees were signed allowing the export of psychoactive cannabis and hemp, which boosted industrial activity for medicinal purposes.
- In 2021, the 2015 legislation on cannabis for medicinal and research purposes was updated.
- In February 2023, regulatory decree 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 No. 3: REGULATORY CHANGES-CANNABIS IN URUGUAY[13]



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

In 2023, the first authorization was granted by the Ministry of Livestock, Agriculture and Fisheries and by the Bromatology department of the Department of Canelones for the use of hemp grain in the food industry. The aim is to take advantage of the quality of hemp as a superfood to develop a previously unexplored industry.

[12] Cannabis Regulatory Decrees (link)
[13] Updated regulatory framework – IRCCA (link)

In short, Uruguay has seen a significant boost in the cannabis industry as a result of a pioneering regulatory framework, which has enabled the development of a new business ecosystem in the country with a significant number of ventures emerging, the establishment of foreign companies and the creation of new jobs in various sectors and industries of the economy.

INSTITUTIONAL FRAMEWORK

Below is a table with the previous information, summarizing the institutions and their roles regarding the regulation and control of cannabis in Uruguay:

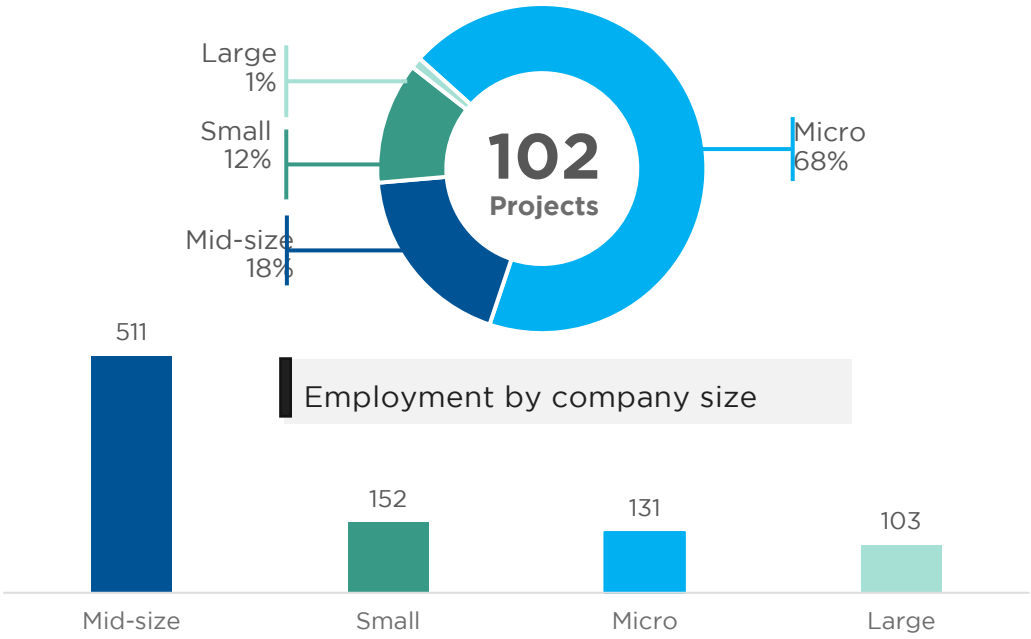
Institution	Functions
Institute for the Regulation and Control of Cannabis (IRCCA for its acronym in Spanish).	» Regulate the growing, cultivation, harvesting, production, processing, stockpiling, and distribution of cannabis. » Promote and propose actions to reduce the risks and damages associated with the problematic use of cannabis. » To oversee compliance with the provisions contained in the cannabis regulations. » To grant all necessary licenses for the production and distribution of psychoactive and non-psychoactive cannabis, including that for medicinal use, for the development of cosmetic specialties and for veterinary use medications.
National Drug Board (JND for its acronym in Spanish)	» Design and approve the National Drug Strategy. » Coordinate and articulate actions: The JND is responsible for coordinating and articulating the actions of the various agencies and entities involved in drug prevention, assistance, treatment and control in Uruguay.
Ministry of Public Health (MSP for its acronym in Spanish)	» Authorize and control cannabis crops for the exclusive purpose of scientific research or for the production of therapeutic products. » Enable interested parties in the production and industrialization of medicinal cannabis and register medicinal products with the Department of Medications.
Ministry of Livestock, Agriculture and Fishery (MGAP for its acronym in Spanish)	» Authorize and control the production of hemp crops (cannabis variety with low THC content). » The General Directorate of Agricultural Services (DGSA for its acronym in Spanish) of the MGAP evaluates hemp production projects for industrial and food purposes. » The General Directorate of Livestock Services (DGSG for its acronym in Spanish) grants authorizations for the veterinary use of medicinal hemp.
National Seed Institute (INASE, for its acronym in Spanish)	» Registration of seeds and varieties.
Anti-Asset Laundering Secretariat (SENACLAFT for its acronym in Spanish)	» Research and control of corporate structures in the cannabis sector. » Checking the origin of funds used in the sector.

3.2. PRODUCTION ECOSYSTEM

The cannabis value chain in Uruguay is made up of around one hundred projects that hold 120 licenses for various activities. Fifty-eight companies are authorized by the MGAP to grow hemp, while 10 companies have licenses to commercialize these products, usually acting as traders/brokers. In the medicinal, research and recreational market, 39 projects are authorized by the IRCCA. Of these projects, 12 are authorized to grow, 13 to industrialize, 5 to provide analysis services, 14 to carry out research and only one company is authorized to operate in free trade zones. Many of the projects encompass more than one activity.

According to data provided by the IRCCA and the Ministry of Labor and Social Security (MTSS for its acronym in Spanish), in 2023 the cannabis sector will employ 900 people directly. Of these, 32% work in Montevideo, while the remaining 68% work in other regions of the country. Around 30% of workers are in Canelones, while Colonia and Salto account for 10% each.

GRAPH No. 2 – COMPANIES AND JOBS ACCORDING TO CANNABIS COMPANY SIZE IN URUGUAY (2023)



Source: Uruguay XXI based on data from the IRCCA and the MTSS.

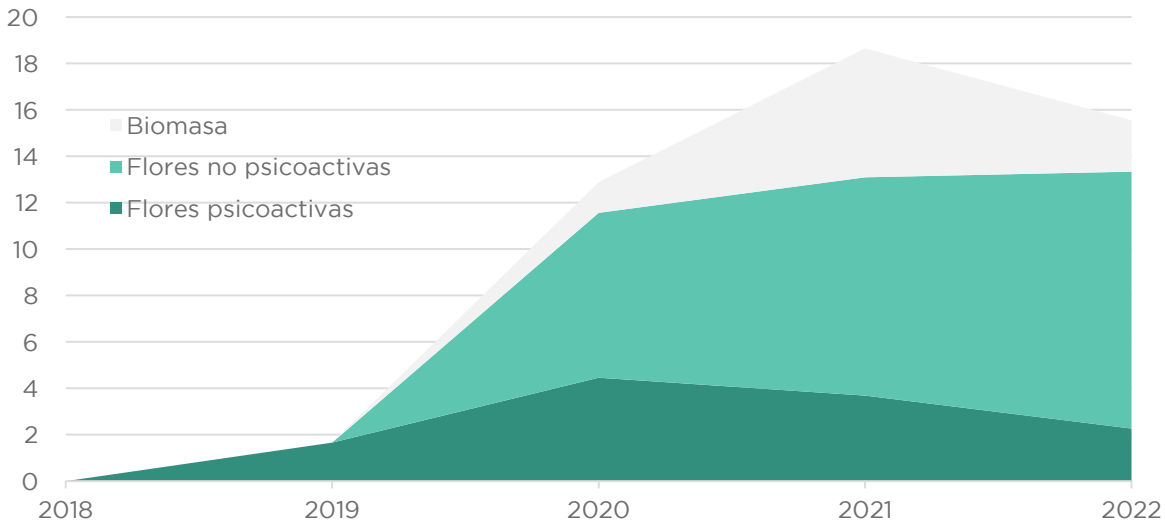
These figures do not include the indirect jobs created by the sector, which include logistics activities and the sale of agricultural inputs, among others. They also do not include the personnel employed

in hemp companies during specific stages of the harvest, such as transplanting and harvesting, which require a much greater use of manpower. It is estimated that between 8 to 10 people per hectare are needed for transplanting activities, and about 18 to 22 people for harvesting.

3.3 CANNABIS EXPORTS

In Uruguay, for most of the cannabis companies export is their main activity. In 2023, 50% of the companies authorized to grow or industrialize cannabis by the IRCCA and MGAP had exported the previous year. Since 2019 there has been a remarkable increase in cannabis exports[14]. This year only three companies registered external sales, managing to sell more than 1.7 tons for US$ 3 million. In 2022 the number of exporting companies increased to over 41 and around 16 tons of cannabis have been traded abroad for just over US$ 5 million.

GRAPH No. 3 – VOLUME EXPORTED BY THE CANNABIS SECTOR (TONS)



Source: Uruguay XXI with data from the National Customs Department (DNA for its acronym in Spanish).

The increase in cannabis export volumes and the number of export companies in the sector is explained by the performance of sales of non-psychoactive flowers and, to a lesser extent, biomass for extraction. These goods have a lower market value compared to psychoactive flowers for medicinal use and are subject to less rigorous certifications.

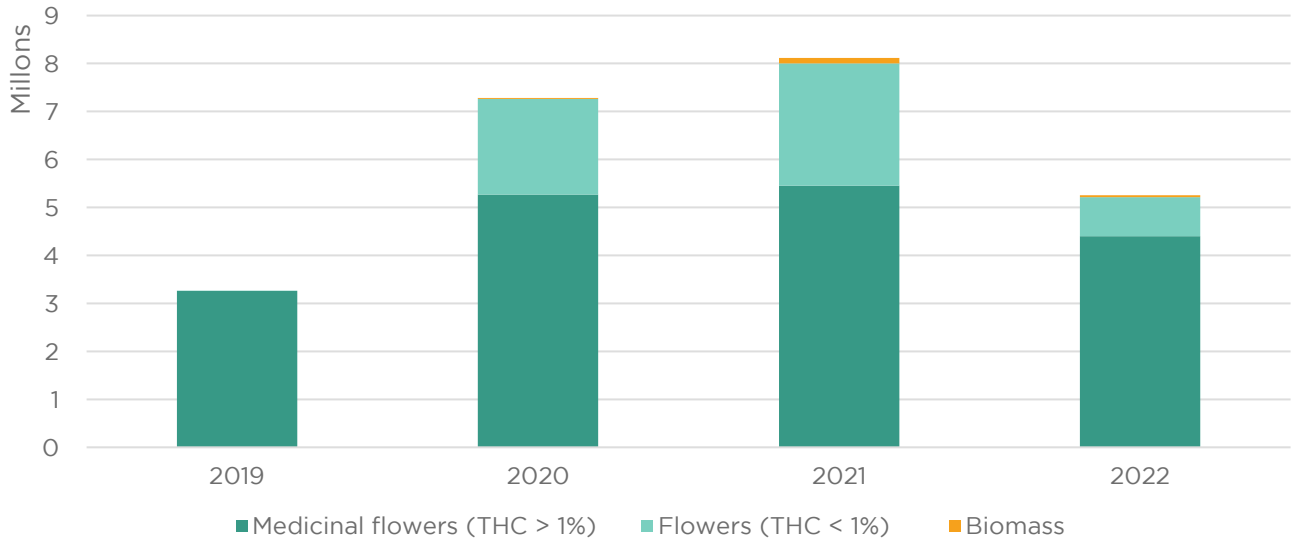
On the other hand, cannabis for medicinal use experienced growth between 2018 and 2020 and a decrease in volume in the following two years. In 2022, the exported volume

14 In recent years, the Uruguayan government has made several changes to the regulatory framework in order to facilitate the export of both raw material and semi-finished products containing cannabis. In this sense, Decree Nº246/021 eliminated the obligation to register with the MSP raw material and semi-finished products to be exported, maintaining it only for final products.

share among these products was distributed as follows: 71% for non-psychoactive flowers, 15% for psychoactive flowers and 14% for biomass.

In 2022, total cannabis exports reached US$ 5.3 million, a decrease of 35% compared to 2021. This drop was mainly the result of the sharp decline in the prices of non-psychoactive cannabis. It is worth noting that 99% of cannabis exports pertained to flowers. Medicinal flowers sales amounted to US$ 4.4 million in 2022, showing a 19% drop compared to 2021. Despite this, the sales price of these flowers was higher and less variable than the rest of the sector's products.

GRAPH No. 4 – CANNABIS EXPORT VALUE BY PRODUCT
(Millions US$)



Source: Uruguay XXI based on data from the DNA.

On the other hand, non-psychoactive flowers exports were of US$ 0.8 million, with a 70% drop in sales, despite an 18% increase in volume, which did not offset the sharp decline in the average price of these flowers. There were several reasons for the drop in sales prices, ranging from the entry of competing countries into the market such as Colombia, Ecuador, and South Africa, as well as greater regulatory restrictions in Switzerland, which led many companies to relocate or seek cheaper raw materials.

Regarding export markets, the main destinations for cannabis flowers for medicinal use are Portugal, Germany, Israel and Canada. These countries have legalized medical cannabis use and have a significant domestic demand. Portugal acts as a logistic hub, and from there it is distributed to England, Germany and other countries.

TABLE No. 2 – URUGUAYAN CANNABIS SECTOR EXPORTS

			2021			2022	
Product	Destination	No. of Companies	FOB US$	Net KG	No. of Companies	FOB US$	Net KG
EXTRACT	Brazil	1	394	0,12	1		
	Peru					5.636	2
MEDICATIONS (Epifractan)	Argentina	1	2.075	3,1	1	3.184	1,5
CBD	Brazil		30.740	25,67		10.395	8,08
	Peru						
FLOWERS (Medicinal use)	Germany	1	1.205.896	1340,192	1	346.034	508,874
THC > 1%	Canada					280	1
	Peru						
	Israel		3.396.928	1.918			
	Portugal		854.492	427,246		4.053.500	1.757
FLOWERS (Uso NO medicinal)	Brazil	18			36	18	0
THC < 1%	Ecuador		8.915	30		9.000	52
	United States					10.820	66
	Unidos Czech Republic					1.112	7
	Suiza		2.540.295	9.385		796.967	10.944
BIOMASS	Brazil	2	500	50	2		
	Peru		109.304	5.496		37.920	2.215
Total			**8.165.134**	**18.696**		**5.274.867**	**15.563**

Source: Uruguay XXI based on data from the DNA.

As previously mentioned, the value per kilo shows a clear advantage in the price of cannabis with high THC for medicinal purposes, which is the most appealing product of the sector. Non-psychoactive high-CBD flowers are usually sold as a substitute for tobacco or psychoactive cannabis. The producers, either individually or through traders, export mainly to Switzerland, which has been the main destination of these exports, since in this country the THC threshold is the same as in Uruguay and it has positioned itself as a business hub for the industry in Europe. In Switzerland, the flower is industrialized in companies that carry out remediation to reduce THC levels to the values accepted in other European Union countries (0.2% or 0.3%).

Switzerland accounted for 97% of Uruguay's non-psychoactive flower exports in 2022. Other destinations were the United States, Ecuador, Czech Republic and Brazil.

In the case of the United States, the opportunity for entry opened up in mid-2022 through a massive shipment of samples from producers. Likewise, the Czech Republic, with its increase of the THC threshold from 0.3% to 1%, seeks to position itself as a hub for the sector within the European Union, and compete with Switzerland.

While flower exports accounted for almost all exports between 2021 and 2022, external sales of other products were reported. For extracts, shipments were destined for Brazil and Peru. Medicine exports correspond to Epifractan, which was mainly destined for Common Market of the South countries such as Brazil and, to a lesser extent, Argentina.

3.4. MEDICINAL CANNABIS

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

The country is positioned as a regional hub for pharmaceutical products for the Southern Cone and offers important advantages for the location of companies that develop these activities. This know-how places Uruguay as a reference country for the establishment of a cannabis product hub with a focus on medicinal use.

In addition, there is a regulation in place for the growing, harvesting, production, manufacturing and commercialization of cannabis intended for the production and extraction of raw material and cannabis-based products for medicinal use. To carry out activities related to the production of semi-finished or end products for consumption, it is necessary to have a license from the IRCCA and to be authorized by the MSP.

Uruguay's Decree 282 regulates and controls logistical operations involving therapeutic medical cannabis products in customs warehouses authorized by the MSP and IRCCA. This allows warehouses to receive imports, subject to authorization by the MSP, to be redistributed in the region, which would facilitate the entry of medical cannabis products into the Brazilian market. This hub scheme allows imports of complete batches, fractioning them and carrying out operations between Uruguay and Brazil[15].

3.4.1. MEDICINAL CANNABIS VALUE CHAIN

The medical cannabis chain has attracted the greatest commercial interest globally, with a larger volume of investment due to its higher profitability. High quality and

15 Source: El Observador -"Otro negocio para el cannabis medicinal: Uruguay como hub de distribución regional".

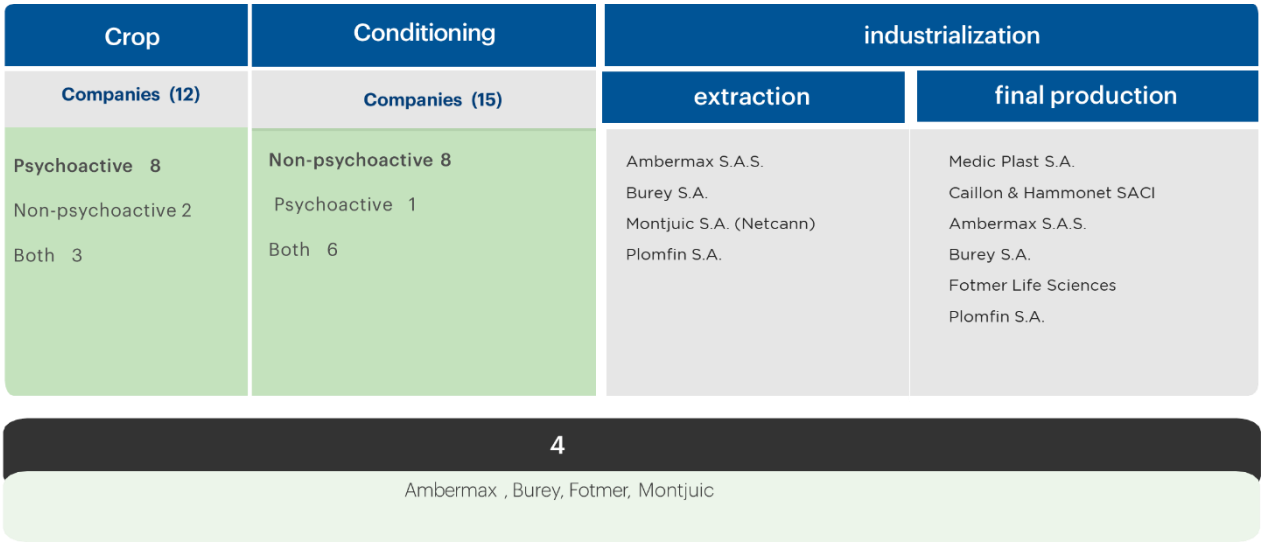
international certifications are key factors and it is necessary to follow standardized production methods because it is a pharmaceutical product.

The main medical cannabis companies in Uruguay are foreign-owned, accounting for 41% of those authorized to operate in this sector. Canada is the leading source with three companies, followed by the United States, Brazil and Argentina with two companies each.

Although there are different business models, there are more vertically integrated companies than in the rest of the sector's value chains. The company is responsible for genetic selection, growing, extraction, production and trade. They usually also have research and genetic improvement projects and their own analysis lab.

There are currently 22 IRCCA licenses to operate in the medicinal chain, nine companies are operating in the growing, harvesting and post-harvesting phase, ten companies in the industrial phase and three companies have both growing and industrialization licenses.

FIGURE No. 4: MEDICAL CANNABIS VALUE CHAIN SCHEME IN URUGUAY[16]



Source: compiled by Uruguay XXI with data from IRCCA.

Of the 12 total growing licenses for medicinal purposes in effect, eight are exclusively for psychoactive cannabis, as the high THC flower is the most valuable product for medicinal use, two are for non-psychoactive cannabis and three companies grow both psychoactive and non-psychoactive cannabis.

[16] To access the complete list of licenses granted and companies access the IRCCA website (link).

In addition, some 15 companies are licensed by the MSP for drying plants. Of these, eight are engaged in the processing of non-psychoactive cannabis, six in the processing of both types of cannabis, and one company is exclusively focused on processing psychoactive cannabis.

Of the ten companies that take part in industrialization, four produce cannabis extract, both psychoactive and non-psychoactive, and six companies are devoted solely to the preparation of oral solutions, medications and drops (mother tinctures), always for medicinal purposes.

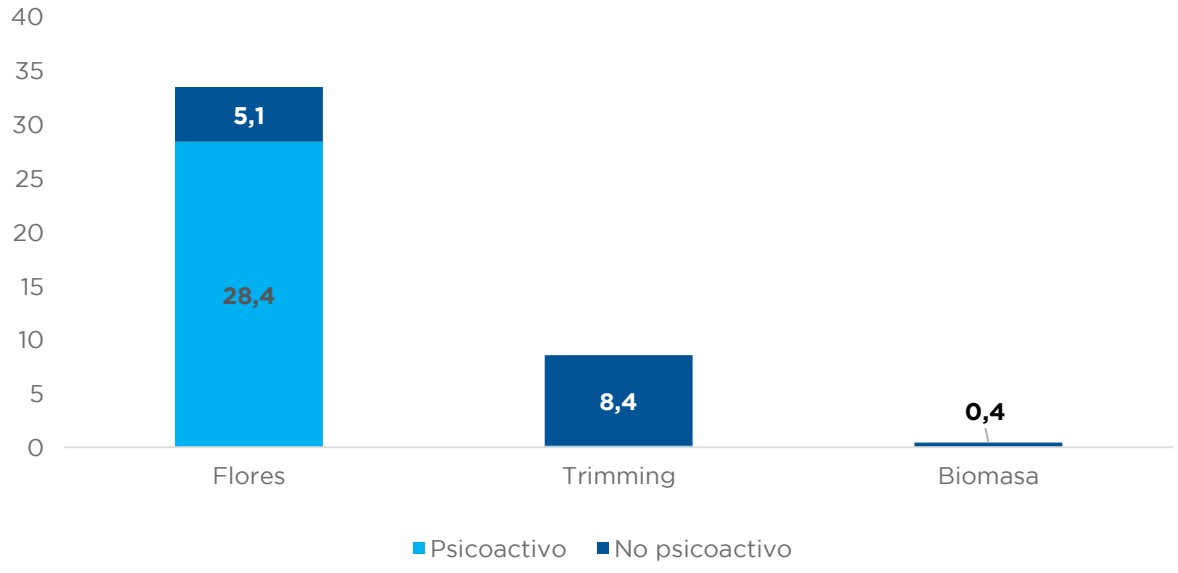
Furthermore, there are three companies that have an industrialization license for the manufacture of cosmetics based on non-psychoactive cannabis oil. All these products are made from imported active ingredients. Finally, two other companies are licensed to market products, although they are not licensed to produce.

3.4.2 CANNABIS PRODUCTION AND STOCKS FOR MEDICINAL USE

In 2022, the total production of medical cannabis in Uruguay reached 15.7 tons. It was evenly distributed between psychoactive and non-psychoactive cannabis.

Regarding psychoactive cannabis, 56% was used for flower production, 38% for *trimming* and the remaining 6% was used for the biomass production of cannabis. As for non-psychoactive cannabis, the vast majority consisted of flowers, accounting for 99% of total production, while only 1% was used for biomass production.

GRAPH No. 5: CANNABIS PRODUCTION FOR MEDICAL USE (2022)

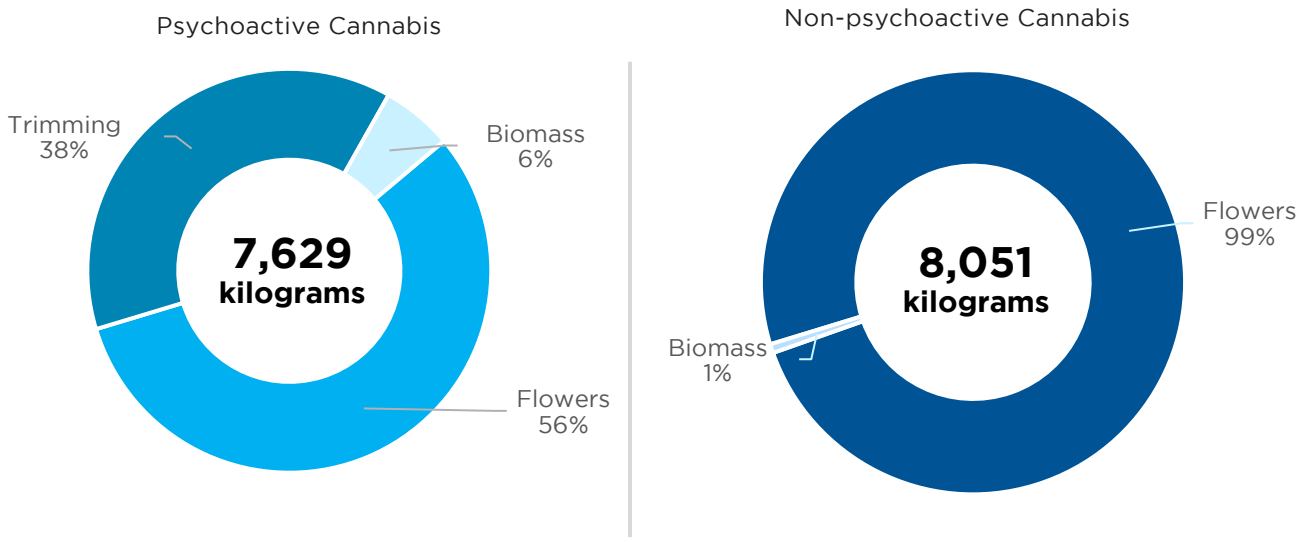


Source: compiled by Uruguay XXI with data from IRCCA.

Stock

According to data available as of March 2023, a stock of 42.5 tons of cannabis crops was recorded. Of this total, two thirds refer to non-psychoactive cannabis flowers, amounting to approximately 67% of the total stock. Psychoactive cannabis represents 33% of the total stock and is made up of 60% trimming, 37% flowers and 3% biomass.

GRAPH No. 6: CANNABIS CROP STOCK (TONS)



Source: compiled by Uruguay XXI with data from IRCCA.

Regarding the final products, there is a stock of 247 kg of raw extract and 38 kg of winterized, about 119 kg of purified cannabinoids, 58 liters of psychoactive oral solutions and 933 liters of non-psychoactive oral solutions.

TABLE No. 6 – STOCK OF CANNABIS-BASED END PRODUCTS

End Product	Kg
Raw extract	247 kg
Winterized extract	38 kg
Purified cannabinoids	119 kg
Oral solutions (psychoactive)	58 kg
Oral solutions (non-psychoactive)	933 l

Source: compiled by Uruguay XXI with data from IRCCA.

The local market for cannabis-based medications is limited for certain medical conditions (mainly epilepsy). Law 19,847 which established a legal framework for cannabis production and medicinal

and therapeutic use, was regulated in Decree 56/023 of February 2023. For this reason, there are no authorized THC products yet. Companies in the medical cannabis chain are strongly geared towards the export market, with rare exceptions that produce specialties from plants with a high CBD content for medicinal use.

TABLE No. 7 – CANNABIS MEDICATIONS REGISTERED IN URUGUAY

Name	Active ingredients.	Main Lab	Sales Conditions
Epifractan 2% y 5%	Cannabidiol 20 and 50 mg/mL Oral drops	**Medic Plast**	Under prescription - with additional monitoring
Xalex 10	Cannabidiol 100 mg/mL Oral drops		
Bidiol 3	Cannabidiol 30 mg/mL Oral drops	**ICC Labs.**	
Bidiol 10	cannabidiol 100 mg/mL Oral drops		
Xannadiol 5% y 10%	Cannabidiol 50 or 100 mg/mL Oral drops	**Caillon & Hamonet**	

Source: compiled by Uruguay XXI with data from MSP.

At the pharmaceutical level, there are three lines of medications registered in Uruguay with different presentations and run by two companies. All three are based on CBD and are sold solely by prescription with additional pharmaceutical monitoring. 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 osteoarthritis.

On the other hand, there are 14 cosmetic products registered by three companies in the country. The sales conditions for these products are less strict than it is for medications.

TABLE No. 8 – COSMETIC PRODUCTS REGISTERED IN URUGUAY

Product Type	MedicPlast	Dermagroup	Homeoaleman Lab
Liquid soap	1		
Hair products	2		
Body products	6	2	1
Facial products	2		

Source: compiled by Uruguay XXI with data from MSP.

3.5 RESEARCH

Research plays a key role in the growth of the industry and is one of its most vital activities. There are 14 licenses currently in force granted by the IRCCA, nine are issued to private companies and five are for public research centers.

Research makes it possible to develop and enable new genetics, products, technologies and processes that position Uruguay as a reference in the sector. These types of licenses are granted to both private companies and public organizations, such as the University of the Republic or the Clemente Estable Institute. Some of the purposes of the licenses include:

- Research and development of new psychoactive and non-psychoactive cannabis crops.
- Research on optimizing extraction processes.
- Development of non-psychoactive cannabis varieties to register.
- Develop a process to obtain cannabis extracts for medicinal use.
- Biotransformation of cannabinoids by microorganisms.

Among all the drivers, the need to develop in-house genetics occupies a large 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.

Currently, there are ten Uruguayan cannabis sativa varieties are currently registered with INASE, six of which correspond to hemp and four to psychoactive cannabis.

Companies focused on genetic developments are the key to achieve the professionalization of the industry, as this makes it possible to have a stable variety, adapted to a specific environment and with the desired quality. In terms of 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. Considering global and regional trends, the ideal scenario for Uruguay would be to develop high THC genetics (over 20%) for medicinal purposes and genetics under 0.3%, which would allow direct entry to Europe.

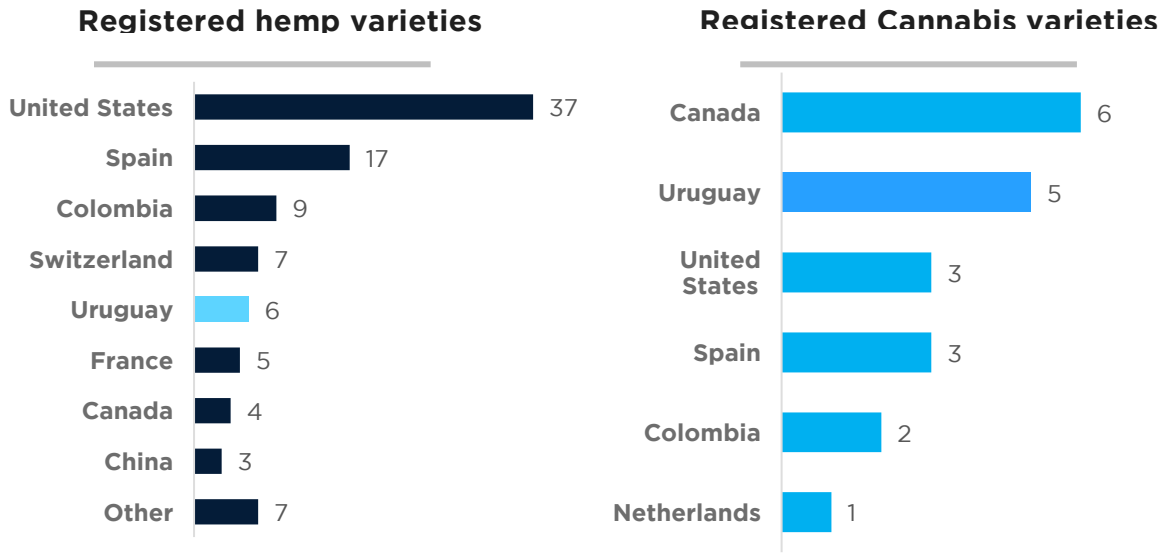
TABLE No. 9: URUGUAYAN REGISTERED VARIETIES

Species	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	**21/01/2037**
Pyschoactive Cannabis	GAMMA IRCCA	Positronics Seeds S.L.	Protected	**01/01/2037**
Pyschoactive Cannabis	ÉPSILON IRCCA	Positronics Seeds S.L.	Protected	**18/02/2039**
Hemp	BCBD01	Bcbd Medicinal S.A.	Public	
Hemp	BCBD02	Bcbd Medicinal S.A.	Public	
Hemp	MOCA	Germinaruy	Protected	**11/11/2040**
Hemp	ALMARO	Inverell S.A.	Protected	**06/01/2040**
Hemp	ROMALEX	Inverell S.A.	Protected	**06/01/2040**
Hemp	DELTA	Awilde S.A.	Public	

Source: compiled by Uruguay XXI with data from INASE.

So far in Uruguay, imported varieties have a greater relevance, while researchers are working to develop their own genetics. The following table shows the predominance of imported varieties in the development of hemp seeds, which is significantly lower for psychoactive cannabis varieties with THC>1%.

GRAPH No. 7: ORIGIN OF SEEDS REGISTERED IN URUGUAY (2023)



Source: compiled by Uruguay XXI with data from INASE.

Research is one of the fields in which the current legal framework offers potential advantages for the development of the industry in the country. Uruguay is undergoing a period of creation of quality scientific knowledge, and is developing its own varieties that will allow it to position itself as a major supplier of genetics and a recipient of foreign investment.

3.6. INDUSTRIAL HEMP

In Uruguay, the farming of non-psychoactive hemp for non-medicinal use is subject to a series of restrictions and authorizations issued by the MGAP and the General Directorate of Agricultural Services (DGSA for its acronym in Spanish). These authorizations cover a variety of activities such as the import, export, commercialization, sowing, planting, and harvesting of hemp.

TABLE No. 10: NON-PSYCHOACTIVE CANNABIS VALUE CHAIN

Crop	industrialization
Companies (58)	**Companies (2)**
Flower 38 Grain 8 Other 12	Goland Group S.A. Qualified to industrialize grain to obtain oil, flour and proteins for human consumption Verdetech S.A.S. Qualified to industrialize hemp flowers for extraction of cannabinoids and
Commercialization (10)	
AMBERMAX S.A.S - CLAUDIO VALENTI LOPEZ - CLORIS S.A.S - FRENITAL GEBRIN S.A. - LIGENOY S.A. - SEMAFIL S.A. - SEVEN URUGUAY - SILK HEMP URUGUAY S.R.L - TECNOFIN	

Source: compiled by Uruguay XXI with data from MGAP.

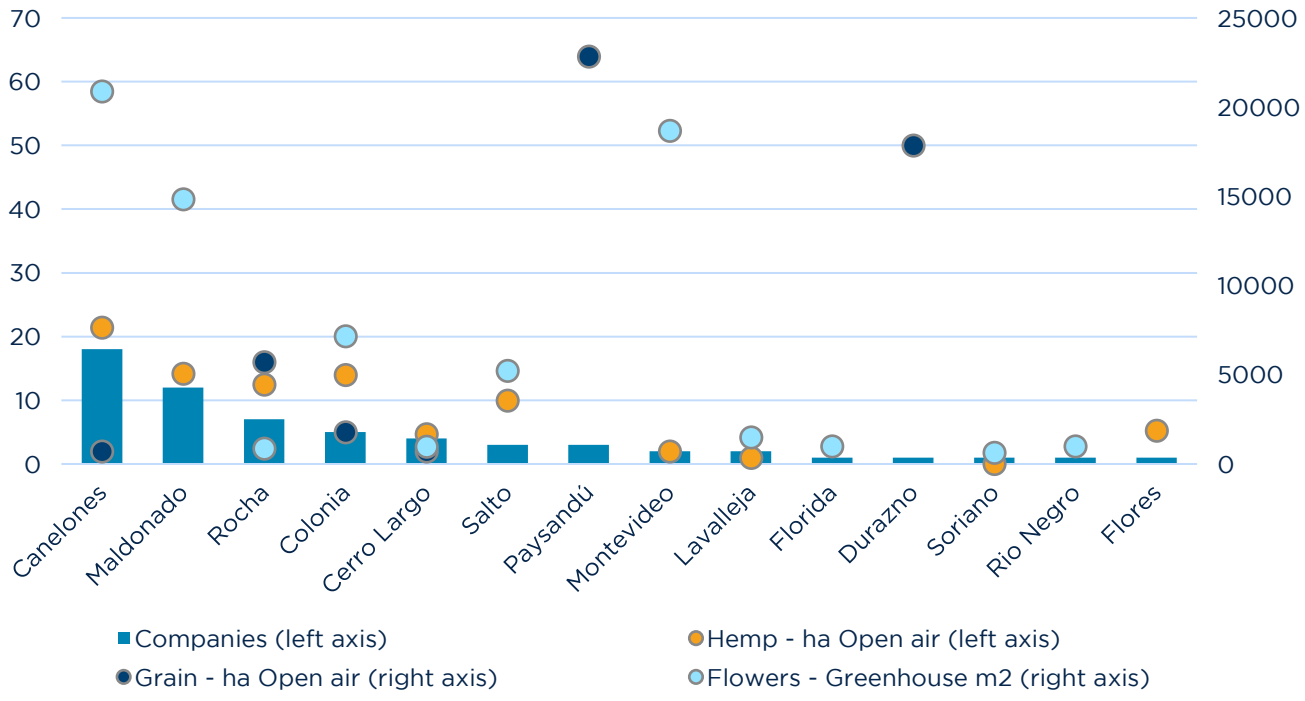
3.6.1. HEMP FARMING

In Uruguay there are 58 companies authorized by the MGAP to grow non-psychoactive cannabis (2023). These cover a total area of 231 hectares planted in open air. In addition, they have indoor growing facilities totaling 83,000 m2. It is estimated that the average yield in greenhouse crops ranges between 500 and 1,000 kilograms per hectare.

Cannabis crops are distributed in several areas of the country, covering a total of 14 of the 19 departments, but with a clear concentration in the southern and coastal areas. Canelones has 30% of

the hemp growing businesses, with a total of 18 companies, and is also the department with the largest area of open air and greenhouse crops. Maldonado, on the other hand, has 20% of the businesses, 17% of the open-air hectares and 20% of the greenhouse crops. It is also important to mention that Montevideo, despite having only two businesses, is the second largest department in terms of greenhouse area, with a total of 186 hectares. Both Paysandú and Durazno are characterized by having few companies but concentrate large extensions of grain crops.

GRAPH No. 11 – HEMP FARMING COMPANIES BY DEPARTMENT[17]



Source: compiled by Uruguay XXI with data from the MGAP.

A first challenge faced by this crop is the learning curve, given that the ban implied a general lack of training, both on the craft of farming it and on previous research that would allow the precise determination of planting dates and other farming management practices, which are basically learned as the projects progress. The first years have been, for most of the enterprises, a learning experience with modest productive results. However, Uruguay now has the opportunity to be an exporter of services through the accumulated know-how of ten years in the regulated market.

Initially, the regulations were designed with the production of hemp grain, edible oil and protein in mind, in line with the provisions of the UN Convention. However, as the industry in Uruguay developed, there was a greater focus by companies on the production of hemp

17 Licenses from the MGAP and IRCCA for non-psychoactive crops are considered. There was no data by department for nine additional licenses.

flower for recreational use by legal adults, as well as on other derivative products, such as CBD (cannabidiol).

The companies devoted to flowers are more focused on producing in controlled environments, and are usually those with higher investment and vertical integration, which require at the same time authorizations from the MGAP and in some cases from Bromatology. Grain and seed production is carried out in the open air and accounts for a large part of the non-psychoactive cannabis hectares.

According to information from the MGAP, approximately 38 businesses in Uruguay are engaged in the production of female fertilized or unfertilized hemp flowers, in order to export them. Some 60,000 m2 of greenhouses are used for flower production, accounting for 72% of the industry's total, and some 73 hectares are open air crops.

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

TABLE No. 11 - NUMBER OF LICENSES AND AREA BY TYPE OF CROP

Product	No. licenses	Open air ha	Covered m²
Flowers	38	73	59.776
Grain	5	87	0
Grain – Seeds	3	54	360
Others (Seeds -Seedlings -Cuttings)	12	17	22.849
Total	**58**	**231**	**82.985**

Source: compiled by Uruguay XXI with data from MGAP.

Eight companies focus mainly on hemp production for grains. Around 140 hectares were farmed in open fields, which accounts for 61% of the total open-air crops. There are other companies that focus on obtaining seeds, grains or oil derived from hemp grain for non-medicinal use.

Growing hemp for grain and growing hemp to obtain non-psychoactive flowers have important differences in the production process, packaging and marketing. One of these differences lies in the variety of seed or cuttings used, which has a high or low CBD content and affects the cost of the seeds. For cannabinoids, a density of 10 plants per square meter is generally considered the optimal economic density. For seed or grains, 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 sowing densities demonstrate that growing hemp for

different purposes requires specific approaches and considerations to achieve optimal results and maximize profitability[18].

3.6.2. HEMP FOR NON-PSYCHOACTIVE FLOWERS

In terms of the product, what characterizes non-psychoactive cannabis are the seed varieties used in these crops, since they have a CBD content greater than 10%, and a low THC content.

Post-harvest is critical for the quality of the final product, which depends as much on genetics and growing practices and methods as on the drying or conditioning stage, which can have up to a 60% impact on the final quality of the product[19].

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

Drying plants must be registered with the MGAP and play a critical role, since quality is a key factor for placing products in the United States or Europe. Several of the companies that carry out drying also provide shredding.

In Uruguay, non-psychoactive flowers cannot be commercialized for recreational use by adults because the regulatory decree for recreational cannabis only allows inflorescences with THC. They can be used by the cosmetic and medicinal industry, or must be exported.

In order to export, the production of CBD flowers must be authorized by the MGAP for non-medicinal use. In addition, it is necessary to certify in local labs that the flowers contain less than 1% THC and are free of heavy metals and microbiological substances.

However, not all of the harvests meet the quality standards required for export, due to irregularities in flower size or formation. Flowers that do not meet the quality requirements or are poorly prepared, together with the residues resulting from this preparation may be used in the processing industry, where they are converted into biomass and used as an input for extraction.

3.6.3 INDUSTRIAL USE HEMP

The majority (61%) of the open-air hectares used for hemp in Uruguay are devoted to industrial hemp. The growing of industrial hemp can be aimed at obtaining fiber, grain

18 Report: *Consultoría sobre la caracterización de la cadena agroindustrial del cannabis* CINVE – INEFOP – *2023.*
19 Report: *Consultoría sobre la caracterización de la cadena agroindustrial del cannabis* CINVE – INEFOP – *2023.*

or have a dual purpose. The choice of varieties and the moment of harvest are key factors to optimizing results in each case.

The industrial hemp chain is similar to other agricultural chains such as oleaginous crops. Hemp crops may be included in the crop rotation, complementing other winter crops and alternating with other summer crops. No large investments in infrastructure are required, except for an irrigation system, since the plants require a lot of water.

So far, there hasn't been a hemp grain industrialization project developed in Uruguay. Only one application was registered with the MGAP. In 2019 this ministry issued a decree recognizing hemp grain as a food product.

In order to produce food from hemp grain, it is necessary to be authorized by the bromatology unit of each department where the plant is located. Currently, the department of Canelones is the only one that has authorized companies to produce from hemp grain. This situation indicates that the industrialization of hemp grain in Uruguay is still at an incipient stage and limited to this department.

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 on a local level, either for use in the textile industry or in construction.

3.7. CANNABIS USE BY LEGAL ADULTS

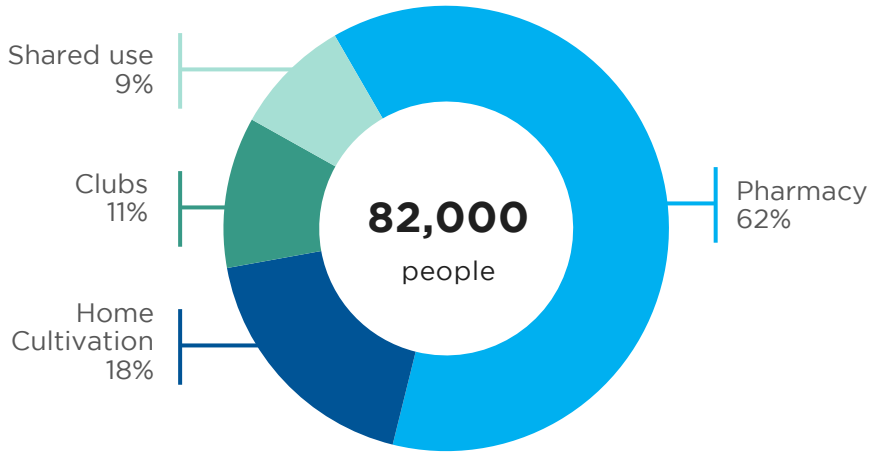
Uruguay legalized the production, commercialization and consumption of psychoactive cannabis for recreational purposes by legal adults. The law regulated three legal forms of access: pharmacies, cannabis membership clubs and home cultivation. For any of the three ways it is necessary to be of legal age and be a legal or natural Uruguayan citizen or to have accredited permanent residence in the country. It is estimated that in Uruguay the consumption of cannabis by adults recreationally is between 44 and 50 tons per year and that there are approximately 250,000 consumers.

In the last four years the regulated market has doubled the number of registered users. During that time, the market grew from 35,000 to 75,000 registered users. The latest regulated market report from the IRCCA (December 2022) indicated that there are 51,249 registered individuals in the registry of pharmacy purchasers, 14,766 are registered as home growers and there are 8,876 members of 268 membership clubs.[20]

20 Report on the regulated cannabis consumer market IRCCA-December2022 (link).

Survey indicators[21] show that one of the main sources of access to cannabis is shared use among consumers. When considering both those formally registered in the regulated market and those who access cannabis through shared legal use, it is estimated that the real regulated market reaches 39% of cannabis consumers. It is also estimated that a large number of home growers, whose license has expired, are likely to continue growing. If this hypothesis holds, the regulated market could reach up to 56% of cannabis users.

GRAPH No. 12 –SHARE BY ROUTES OF LEGAL ACCESS TO CANNABIS[22]



Source: compiled by Uruguay XXI with data from the MGAP.

The law appears to be meeting its objective of reducing drug trafficking, as access through that route decreased from 58.2% in 2014 to 24% in 2022[23]. However, unregistered growers still have an important weight that must be addressed by the authorities. There are limits on quantities available for purchase in pharmacies, home cultivation and for clubs. There is also a THC concentration limit (9%) that only covers the production of corporations or clubs.

Five companies are authorized to distribute cannabis for recreational use by legal adults in pharmacies, but only two are in operation. In Uruguay, advertising is illegal and packaging cannot include the name or logo of the company that produced it.

21 VII National Survey on Drug Use in the General Population (2018) and Online survey for purchasers in pharmacies implemented by the IRCCA in 2021.
22 In Uruguay it is legal to share or give away legal cannabis.
23 VII National Survey on Drug Use in the General Population (2018) - link.

4. INSTITUTIONAL FRAMEWORK

The Institute for the Regulation and Control of Cannabis (IRCCA for its acronym in Spanish) 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.

The Ministry of Public Health (MSP for its acronym in Spanish) is responsible for contributing to the improvement of the health of all inhabitants of Uruguay, developing health promotion and prevention policies, standardizing and regulating the treatment and rehabilitation of diseases under the guiding principles of universality: equity, quality, solidarity, sustainability and efficiency. Law 19,172 establishes that the MSP is responsible for authorizing and controlling plantations or crops exclusively for scientific research purposes or for the development of therapeutic products for use. Also within its orbit is the Specialized Unit for Evaluation and Monitoring of the policies issued by the law.

The Ministry of Livestock, Agriculture and Fisheries (MGAP for its acronym in Spanish) has among its duties contributing to the permanent development of the agricultural, agro-industrial and fishing sectors, as well as to organize and develop 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 General Directorate of Agricultural Services 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, the 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 few years was the regulation of cannabis, which, among other aspects, includes the development of hemp -cannabis for non-psychoactive use- for industrial and food purposes from its grains, stems, flowers and leaves. This directorate is in charge of the Single Registry of Operators (RUO for its acronym in Spanish), where applications for operations and work plans are processed.

The main objective of the National Seed Institute is to foster the production and use of the best seed with proven identity and superior quality, encouraging the development of the national seed industry. At the same time, it supports the procurement and use of new national and foreign phylogenetic materials that are suitable for Uruguayan conditions. Its role also includes the protection of phytogenetic creations and discoveries, granting the corresponding property titles.

Regarding the cannabis market, INASE is responsible for the General Register of Seed Growers (RGS for its acronym in Spanish), and the National Register of Cultivars (RNC for its acronym in Spanish).

The National Secretariat for the Fight against Money and Asset Laundering and Terrorism Financing (SENACLAFT for its acronym in Spanish) is in charge of preparing and submitting to the Executive Branch a proposal of national policies for the fight against the above mentioned objectives. It also proposes to the Executive Branch the national strategy to combat money laundering (ML) and terrorism financing (FT for its acronym in Spanish) based on the preparation 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 towards 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 sector, identifying the final beneficiaries and the origin of the funds to be used.

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

The Chamber of Medicinal Cannabis Companies (CECAM for its acronym in Spanish) gathers companies linked to the local development of the cannabis market for medicinal use. The idea of this alliance is to promote the cannabis industry in Uruguay, and so it is vital to have an organized private sector.

Uruguayan Cannabis Producers Network (called Uruguay Cannabis Network) has the mission to create communication and collaboration bonds between those involved in the value chain of non-psychoactive Cannabis for non-medical use in order to develop the industry, watching over the interests and rights of the cannabis companies. Its vision is to articulate the development and improvement of the productive, logistic and commercial process of non-psychoactive cannabis for non-medicinal use, creating an efficient value chain with a clear objective to bring about a standardized and validated country brand for domestic trade with recognition abroad.

The Pando Technological Pole is an institute belonging to the Chemistry College of the University of the Republic, which serves as a research, development and innovation center in the following fields: chemistry, biotechnology, material science and environment. It specializes in Uruguay's most productive industrial and service sectors. It works in the promotion and development of R&D activities through:

- The transfer of technological processes and knowledge.
- Designing, developing and participating in research and innovation projects, both of their own proprietorship and in conjunction with other companies.
- Joint projects with companies seeking financing.
- Incubation and technical support to entrepreneurs.
- Courses, seminars and other forms of training for companies.

The Khem incubator focuses on the development of technology-based companies. It is located on the premises of the Pando Technological Pole with 350 m2 of labs at the disposal of the incubating enterprises. It also has the KhemBIO platform, through which biotechnology ventures can be sponsored.

The Biotechnological Center for Research and Innovation (CBI+I for its acronym in Spanish), together with the Technological University of Uruguay (UTEC for its acronym in Spanish) and the Center for Innovation and Entrepreneurship (CIE for its acronym in Spanish) of the ORT University of Uruguay, are in charge of the CIE BIO incubator, which promotes and executes actions to develop, strengthen and coordinate the biotechnology-based ecosystem, seeking to turn entrepreneurial initiatives into innovative ventures that add value to society.

The experimental neuropharmacology department of the Clemente Estable Institute for Biological Research focuses on understanding the neurobiological bases associated with neuropsychiatric pathologies such as depression, schizophrenia and drug addiction as well as the study of the action mechanism 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 those existing, they are beginning to develop different lines of research, among which can be found the medicinal use of cannabis and cannabinoids.

Institut Pasteur of 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 science companies. The institute works on integrated projects in biotechnology related to human and animal health sectors, among others. Within this framework, it provides biotechnology services for foreign and national companies, including Biopolis (Spain), Danone (France), Gema Biotech (Argentina), Santa Elena (Uruguay) and Microsules (Uruguay).

These institutes, in addition to contributing to industry projects, provide specific training and special equipment and infrastructure required to finish these projects, which would otherwise have to be provided for by the company, hindering daily operations. Most of these institutions, as well as free zones with specific platforms, technologies and services for Life Sciences companies (e.g. Zonamerica and Parque de las Ciencias) are located in the metropolitan area of Montevideo, creating a hub for innovatio

5. URUGUAY AT A GLANCE

URUGUAY IN NUMBERS

Official name	Oriental Republic of Uruguay
Geographic location	South America, located between Argentina and Brazil
Capital	Montevideo
Surface area	176,215 km^2.
Population size (2022)	3.57 million
Population growth (2022)	- 0,1% (annual)
GDP per capita (2022)	US$ 21.164
Currency	Uruguayan Peso ($)
Literacy rate	0,98
Life expectancy	77,9 years old
Type of government	Democratic Republic with presidential system
Political division	19 departments
Time Zone	GMT - 03:00
Official Language	Spanish

MAIN ECONOMIC INDICATORS

Indicators	2017	2018	2019	2020	2021	2022
GDP (YoY %)	1,74%	0,16%	0,74%	-6,26%	5,28%	4,92%
GDP (Millions US$)	64.995	65.118	61.992	53.613	61.380	74.182
Population (Millions of people)	3,49	3,51	3,52	3,53	3,54	3,55
GDP per Capita (US$)	18.606	18.573	17.619	15.184	17.324	20.867
Unemployment rate – Annual average (% workforce)	7,9%	8,3%	8,9%	10,4%	9,3%	7,9%
Exchange Rate (Pesos per US$, Annual Average)	28,7	30,8	35,3	42,1	43,6	39,5
Exchange Rate (Annual Average Variation)	-4,8%	7,3%	14,7%	19,2%	3,6%	-9,4%
Consumer Prices (Annual Cumulative % Change)	6,6%	8,0%	8,8%	9,4%	8,0%	8,3%
Exports of goods and services (Millions US$)**	16.845	17.216	17.185	13.735	19.336	22.605
Imports of goods and services (Millions of US$)**	13.367	13.964	13.499	11.364	14.903	18.716
Trade Surplus / Deficit (US$ Millions)	3.478	3.252	3.687	2.371	4.433	3.889
Trade Surplus / Trade Deficit (% of GDP)	5,4%	5,0%	5,9%	4,4%	7,2%	5,2%
Overall Fiscal Result (% of GDP)	-3,2%	-3,9%	-4,4%	-5,8%	-4,1%	-3,4%
Gross Capital Formation (% of GDP)	16,3%	14,9%	14,3%	16,4%	19,2%	18,8%
Gross Public Sector Debt (% of GDP)	59,8%	59,1%	60,1%	74,5%	69,1%	64,3%
Direct Foreign Investment (US$ Millions)**	-590	-11	2.018	746	2.244	3.839
Direct Foreign Direct Investment (% of GDP)	-0,9%	0,0%	3,3%	1,4%	3,7%	5,2%

Sources: Central Bank of Uruguay (BCU), National Statistics Institute (INE), Ministry of Economy and Finance (MEF) and estimated data (*). Fiscal result data include the effect of Law N°19,590. 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 are available since 2012. Data are net flows, so they may show negative values. (**).

Uruguay XXI
PROMOCIÓN DE INVERSIONES,
EXPORTACIONES E IMAGEN PAÍS

www.uruguayxxi.gub.uy
info@uruguayxxi.gub.uy
UruguayXXI