

Investment opportunities

# CANNABIS



Pharmaceutical drying and curing facilities of Fotmer Life Sciences in Nueva Helvecia.

May 2020



**Uruguay XXI**  
INVESTMENT AND EXPORT  
PROMOTION AGENCY

# Contents

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- Contents.....1**
- Main business lines ..... 2**
  - Medical cannabis..... 2
    - Medical cannabis in Uruguay: cannabinoids, terpenes and flavonoids..... 4
    - Flavors and medicines: terpenes ..... 4
    - Flavonoids ..... 4
  - Cannabis as food..... 5
  - Genetics..... 6
  - Flowers ..... 7
- Global cannabis market..... 7**
- Legal regulation of cannabis in Uruguay ..... 9**
- Cannabis Industry in Uruguay ..... 11**
- Uruguay's structural competitive advantages.....13**
- Main actors of the sector.....15**
- Examples of companies installed in Uruguay ..... 17**
- Institutionality ..... 22**
- Prospective ..... 25**
  - Food..... 25
  - Topical Products..... 27
  - Medical cannabis..... 27
  - Genetics..... 28

# Main business lines

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## Medical cannabis.

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The use of cannabis as a medical plant is based on its content of cannabinoids, a group of chemical compounds that Cannabis sativa is the only plant that produces them in significant quantities. Cannabis has been used as a medical plant for thousands of years for many ailments, mainly as a pain reliever.

The understanding and knowledge of cannabis as a plant with medical utility took a qualitative leap in the mid-60s from the studies of Israeli scientist Raphael Mechoulam, who discovered not only cannabinoids such as tetrahydrocannabinol (THC) or cannabidiol (CBD), but also the endocannabinoid system: a network of receptors that works with cannabinoids generated by the body itself as a modulator or regulator of the nervous system.

So there are three types of cannabinoids: phytocannabinoids, i.e. of plant origin; endocannabinoids, which are generated by the organism itself, and synthetic cannabinoids.

Among the more than 120 cannabinoids that the plant has, two stand out for their importance: THC, which reaches concentrations close to 30%, and CBD, which reaches concentrations of 20% in the dried flower. The best known cannabinoid is tetrahydrocannabinol or THC, which causes the psychoactive effect, but also has medical use for various conditions. There is a long trajectory from the 60's onwards of genetic improvement in cannabis to increase the THC content, so there are varieties that approach a 30% THC content in the flower, which is where the highest concentration of trichomes is grouped, the small glands where the plant stores the cannabinoids<sup>1</sup>. The second most important cannabinoid because of its concentration in the plant and because it is not psychoactive - and therefore easier to administer to patients and trade on a global scale - is cannabidiol (CBD), a central product in any country's development strategy. In the case of CBD, the concentration obtained rarely exceeds 15% of the flower mass. The rest of the cannabinoids are present in low concentrations.

Although smaller in concentration, these cannabinoids are important. Raphael Mechoulam also postulates the entourage effect: several cannabinoids together have a better effect on patients than a single cannabinoid. This situation complicates medical use as it hinders the traditional approach of fixed compounds, standardized at 100%.

The study "Cannabic derivatives for medical use in children and adolescents: contributions for a responsible and safe use". The most robust evidence is in the use of CBD for the treatment of the

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<sup>1</sup> The trichomes are also present in the leaves closest to the flower, so in addition to the demand per flower there is a market for "biomass", which is the sum of the flower and the upper third of the plant, close to the inflorescences.

various syndromes that make up what is commonly called "refractory epilepsy. Thus, it could be concluded that there is strong evidence of both the absence of psychoactive effects and severe contraindications of CBD and its usefulness in the treatment of some conditions. For other conditions, it mentions the treatment of chemotherapy-induced vomiting (VIQ).

One of the recent milestones in the scientific validation of the medical use of cannabis was the approval of a drug by the US Food and Drug Administration (FDA). On June 25, 2018 the FDA announced the approval of the use of Epidiolex, from GW Pharmaceutical, for two types of children's refractory epilepsies, through a press release.

So a first recommendation that arises both from the national academy and from demanding bodies such as the FDA seems to be the conviction that for some ailments, in some cases, cannabis and its extracts definitely work as medicinal.

To a large extent, the current scientific challenge is to determine precisely what proportion of cannabinoids is most appropriate for each ailment, as there is anecdotal evidence of favorable effects on a wide variety of health problems, but fine tuning is lacking as to which concentration of CBD, THC and the other cannabinoids works best in each case. The ideal in terms of long-term scientific knowledge may be to understand which cannabis genetics work best for each patient's genetics, once a logic of personalized genomic medicine is arrived at.

In the case of medical cannabis, four main options are open:

- production of the basic cannabis extract (preserving the whole cannabinoid plant)
- production of pure CBD
- production of mixtures that are not classified as drugs (with specific proportions of CBD and other cannabinoids on demand)
- development of medical products with specific concentrations.

In synthesis, in medical cannabis there are already important investments in Uruguay, oriented exclusively to exports given the uncertainty generated by the domestic market, and it is an area in which Uruguay can reap the most tangible results in the short term. It currently has clear advantages over the rest of the Mercosur countries, while other countries such as Chile, Colombia and Mexico are in more advanced stages in the regulatory process. In addition to regional competition, the progress of this industry in countries such as Canada and Israel should be taken into account.

## Medical cannabis in Uruguay: cannabinoids, terpenes and flavonoids

As of December 2018 there is only one line of drugs approved in Uruguay based on CBD and the raw material is imported from Switzerland: Epifractán. A second drug would be in progress.

CBD is the main export product in terms of medical cannabis. In this sense, there are already laboratories in Uruguay interested in the purchase of CBD for the formulation of products. It is feasible that the market will demand in the coming years significant quantities of CBD, despite the fact that it continues to be included in list 1 of psychoactive substances. It is expected that the World Health Organization will review its categorization soon (at the close of this paper the WHO has already revised the categorization as transcended but has not yet been formalized), which will accentuate the current strong growth in demand, which is already widespread in Europe and North America. The change of category will validate its use in the eyes of the public and will accelerate empowerment in the large markets of Asia.

Since there are no reported cases of problems derived from the use of CBD, it is expected that its approval for use in the diet, functioning as a neuroprotective and in the absence of risks, will be carried out in an agile manner. In particular, the use of CBD in food and cosmetics, not in a synthesized state but as a component of the raw material flower or biomass is very relevant, as is the promotion of a local export oriented industry with such products that have no history of problematic use anywhere in the world. Both food and beverages will have as a sales argument the presence of CBD, the same is valid for the cosmetics sector.

### Flavors and medicines: terpenes

Another important component of the cannabis plant is terpenes, a chemical group very close to cannabinoids. Terpenes are the chemical compounds that give the peculiar smell to cannabis and other plants. In this case there are also interesting potentials in medicinal terms.

Terpenes are particularly interesting from an economic point of view in the area of cosmetics and specifically in perfumery, although they also have functions to share with other areas such as food. The proportion of terpenes in the plant is usually less than 1%, and can reach up to 10% of the composition of the resin.

Their psychoactivity is nil, and unlike cannabinoids, terpenes are found in various aromatic plants. The development of extraction and analysis techniques that will come from the hand of cannabis can help develop an industry of terpenes from native plants, pine and eucalyptus, among other species.

### Flavonoids

A third group of compounds that may be of economic interest are flavonoids. They make up 2.5% of the dried flower. The most important are cannaflavin A, B and C and quercetin, which is also

present in marcela and has been studied at the Clemente Estable Institute with promising antioxidant properties.

Flavonoids are a third component of lesser importance than the previous ones but which may be relevant in the medium term based on the installed extraction capacity and the potential use of plants that are not being used today.

## Cannabis as food

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Food is considered the first use of the cannabis plant. In the case of seeds there are three basic uses: oil, flour and the peeled seed itself, either whole or broken.

The seed has an excellent composition of oils and proteins. The main use of cannabis for food is the production of grain, in which it stands out as oleaginous. With a yield of 1,000 to 2,000 kilos in countries such as Canada, which have experience in cultivation, the grain of cannabis has 30% to 35% oil. This in turn has a very interesting composition, with a high proportion of essential fatty acids. Table oil is a product of high gourmet potential, has excellent taste and can be used alone or in combination with olive oil.

The flour remaining from oil extraction has 20% to 25% protein, 25% to 30% carbohydrate and 10% to 15% fiber. Also from the nutritional point of view, the presence of gamma linolenic acid stands out. Flour can be used in products that replace dairy products, with a strong market among vegetarian or vegan consumers and among athletes who want to consume diets high in protein and low in fat.

The most striking global investments linked to cannabis as food have been those related to the beverage industry. An example of these are the investments made by the brewery Corona, which invested US\$ 3.8 billion to buy 9% of the Canadian Canopy's stock, which shows the potential of cannabis with beverages in general and with beer in particular<sup>2</sup>.

The use of cannabis in beverages has another aspect, perhaps even greater potential, in its inclusion in non-alcoholic beverages. In this sense, both Coca-Cola and Pepsi have evaluated the incorporation of cannabis lines, although no resolutions have been taken so far.

In the case of food and beverages, Uruguay has to develop the concept of traceability in vegetables and in all cases is the great opportunity to develop its organic agriculture in a segment that appreciates this certification and is able to pay for it.

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<sup>2</sup> Source: Bloomberg – [“Corona Beer Giant Puts \\$3.8 Billion Bet on U.S. Love of Cannabis”](#)

## Genetics

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Genetics is one of the aspects where Uruguay's legal framework gives more conclusive potential advantages. It is also the basis for the competitiveness of all agro-industrial sectors, and cannabis in particular. At present, the lack of stable genetics with a high concentration of cannabinoids is a weakness faced by the sector, which represents a bottleneck productively and also at the level of industrial efficiency. Advancing in this aspect is a good opportunity for companies focused on genetic developments.

The possibility of recording, evaluating and measuring with official backing and the trajectory of Uruguay as a multiplier of soybean and corn genetics give the country a highly suitable position for work in cannabis genetics.

In genetic matters the selection objectives are very dissimilar and the work needs in genetics have two aspects. On the one hand, there is a simple and clear business in the mere multiplication of genetic materials from the Northern Hemisphere to the opposite season. On the other hand, there is the possibility of genetics companies not only to multiply but to develop their own genetics here.

The ideal scenario for Uruguay would be to generate its own materials on medical cannabis, high CBD and low THC -less than 0.3%-, similar levels of THC and CBD and also high THC varieties but with freedom of levels of CBD and other non-psychoactive cannabinoids. This would promote local development for food, medical and even textile use.

A competitive network of local breeders and better access to external genetics - which sometimes have no records - will favor local development. The history of self-cultivation and clubs can be used as an avenue for the development of local breeders who have academic backing from the Faculty of Agronomy, Science, Chemistry and Medicine. Uruguay as a platform for exporting genetics to the world is a fundamental part of the opportunity that this crop presents.

## Flowers

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In the flower export market, there is a clear market in non-psychoactive varieties, since many tobacco users try a compulsive exit to consumption with a plant that has a pleasant aroma, does not generate side effects when consumed in moderate amounts and is not addictive as is the plant containing nicotine.

Cannabis without THC and obviously without nicotine is presented as an interesting alternative for smokers in high-income countries.

On the other hand, it is highly likely that exports of flowers and biomass will take place in other countries for extraction, typically a business in areas of high agricultural production cost and high development in the pharmaceutical industry, typically Switzerland or Germany.

## Global cannabis market

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The projection of the cannabis market is limited by the gradual process of legalization in the various countries, so it is not clear how advanced the legal situation will be in 10 years, although it can be discounted that it will be much more open and less restrictive than at present.

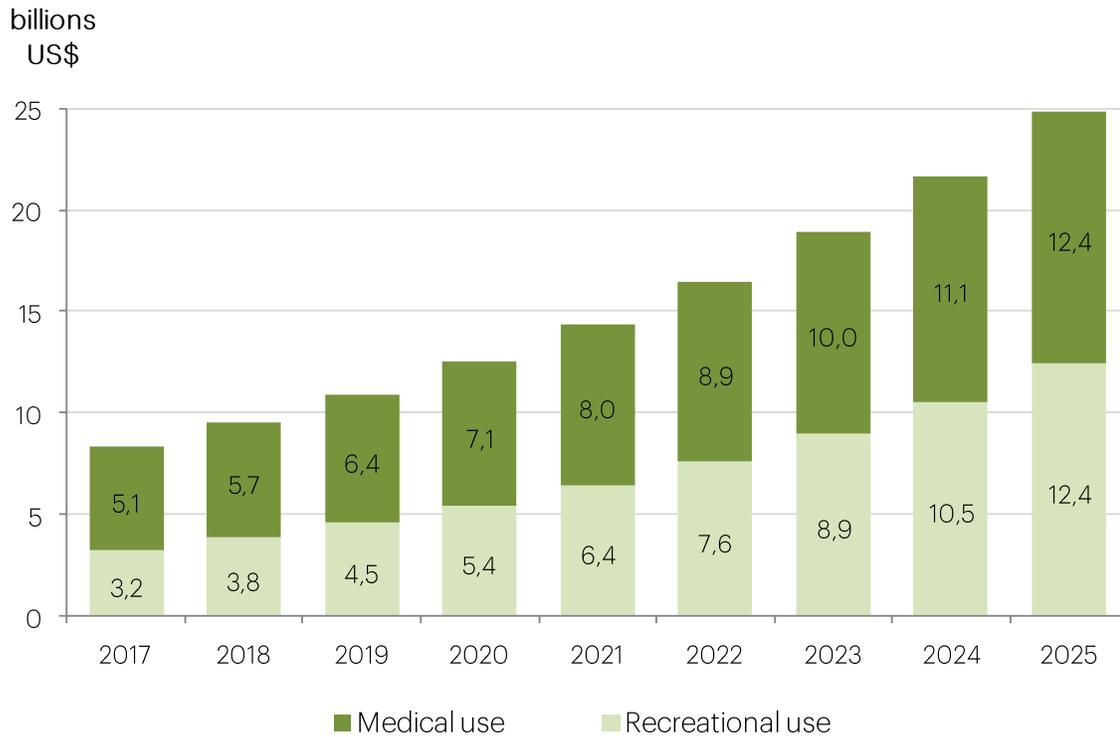
In principle, the most certain sub-sector in generalization in habilitation is in medical cannabis, mainly in low THC forms. THC materials greater than 1% will be gradually enabled, both by their applicability in medical uses<sup>3</sup>, and by the fact that restrictions on recreational use are likely to become more lax.

Against this backdrop, the Bank of Toronto - which already provides credit for cannabis - estimates a global market for medical cannabis at US\$ 194 billion by 2025. Other projections for the cannabis market are more modest, but equally shocking: BDS Analytics expects a US\$ 47 billion market in North America by 2027. In the US projections for medical and recreational use alone show a cumulative growth of 14% per year at least until 2025.

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<sup>3</sup> It should also be noted that for medical use, the plant can be used without activating its psychoactivity.

**Graph 1 - Cannabis Market in the United States**



Source: Own preparation based on data from New Frontier Data

The others are added to the medical market, which makes up a potential that is difficult to evaluate but which, if the Bank of Toronto's estimate is cut sharply, can be calculated at US\$ 150 billion for the medical product and 50 billion for the other uses, which would add up to US\$ 200,000 million. If international trade for cannabis products represented 20% of demand (with 80% supplied in the countries where it is demanded), it would be a global market of US\$ 40 billion, which represents a market size similar globally to that of beef.

If the rest of the cannabis-based products are also considered in Uruguay, the market is potentially the country's main agro-industrial export item. Given the intensity of production, the area would not be limiting and the potential at the level of small producers is not negligible. Uruguay also has the opportunity to position itself as a leader in cannabis traceability, taking into account its experience in other sectors.

An important question is how fast will some important markets that would represent a new leap in demand, such as China, India and Russia, until now with opposite positions in terms of opening, open their market to imports. The opening process in Asia is led by Thailand and South Korea.

In the case of China, textile and food use is already enabled and with the opening of Thailand it can be expected that the flexibilization in medical use occurs between 2020 and 2021, as in India.

Both countries have important internal antecedents of medicinal use of the plant and in certain places of India its cultivation and use are allowed respecting local millenary traditions.

Another important milestone for the global development of the sector is the approval of the Farm Bill <sup>4</sup> in the United States in December 2018. It enabled all products with less than 0.3% THC. This opens the door to strong growth in food and dietary supplements, something that the FDA seems to be starting to consider from the aforementioned agricultural law.

## Legal regulation of cannabis in Uruguay

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Uruguay was the first country in the world to regulate the production of cannabis, both for adult recreational, medical and industrial use, and did so through Law 19.172<sup>5</sup> approved by Parliament on December 10, 2013, which also created the Institute for Regulation and Control of Cannabis (IRCCA), responsible for implementing the regulation and controls related to the plant.

Uruguayan legislation allows overcoming restrictions that operated on a global scale and added to similar decisions approved at the level of member states of the United States, such as Colorado. The use of medical, recreational or textile cannabis under certain circumstances was already in force in countries such as Israel, Holland and some Eastern Europe. But Uruguay was the first to establish a regulatory framework for all the plant's functionalities.

The law and the granting of two licenses for the production of cannabis generated local and global expectations, allowed the development of events such as Expo Cannabis and the arrival of numerous companies interested in investing in Uruguay.

The regulation timeline has a second milestone in February 2015, when regulatory decree 46/105 for medical use and scientific research is approved. The decree ratifies that the State and the IRCCA will promote research that contributes to the knowledge and production of scientific evidence regarding both psychoactive and non-psychoactive cannabis. It also establishes that the elaboration of vegetable and pharmaceutical specialties must be authorized by the Ministry of Public Health (MSP). Both the elaboration and the distribution and sale of the two specialties must go through the registry in the department of medicines of the MSP.

The MSP also has powers over medical planting projects, which must be requested from the IRCCA, justifying to the IRCCA the purpose for which the cannabis produced will be used. To this end, it must submit to the IRCCA the corresponding authorization issued by the Ministry of Public Health authorizing the recipient of the cannabis produced, the development of specialty plants and / or pharmaceuticals for medical use.

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<sup>4</sup> Ver: USDA - USDA Hemp Production Program - <https://nifa.usda.gov/industrial-hemp>

<sup>5</sup> [Law 17.172](#)

The pharmaceutical specialty is basically what we call a drug, which must have a name registered with the Ministry of Public Health, with a declared formula and verifiable therapeutic properties. Meanwhile, the Plant Specialty is defined as "the cannabis herb or mixture of cannabis herbs (psychoactive and non-psychoactive) used for medical purposes".

The sale to the public of both vegetable and pharmaceutical specialties can only be carried out in first- or second-category pharmacies and with an official prescription. Registering a new medicine requires a series of requirements that guarantee safety and efficacy with maximum levels of evidence.

This decree also imposes a prior authorization of the MSP at the time of export. Prior to the approval of an export permit, the Ministry of Public Health will require the applicant to present the import certificate issued by the competent authorities of the importing country, stating that the import of the cannabis product has been authorized. Import and export authorizations shall expire one hundred and twenty and ninety days after they are issued, respectively. They shall be used only once and may not cover the import or export of varieties or products of cannabis of a different nature or in quantities other than those authorized.

A third phase in the regulation came on December 28, 2016 with decree 403/2016, which defines different categories of plant products, including medicinal herbs, plant specialties and phyto-therapeutic products<sup>6</sup>.

At the international level, regulation has also shown significant progress. In particular, in the last weeks of 2018 one of the most restrictive countries, the Philippines, announced the introduction of medical cannabis. One of the reference countries for Uruguayan agriculture, New Zealand, announced the legalization of medical cannabis and the recreational plebiscite in 2020.

But the most important changes due to its size, its potential as a competitor and the transformations it can bring to global financial regulation came from the approval of the Farm Bill, the five-year agricultural law of the United States. Thanks to it, products with less than 0.3% THC have remained in the United States equivalent to any other agricultural product, eligible to receive credits and subsidies and to be marketed without restrictions between states and abroad. This will lead to a strong development of all non-psychoactive products and especially food, something that immediately began to analyze the Food and Drug Administration, which already clarified that seeds, oil and flour are considered safe products.

From the Farm Bill and the FDA statement was announced the enabling of cannabis in Thailand (important for being the first market in Asia to open, bringing closer the possibility that China, India and Russia open their markets), while Israel enabled the export of medical cannabis.

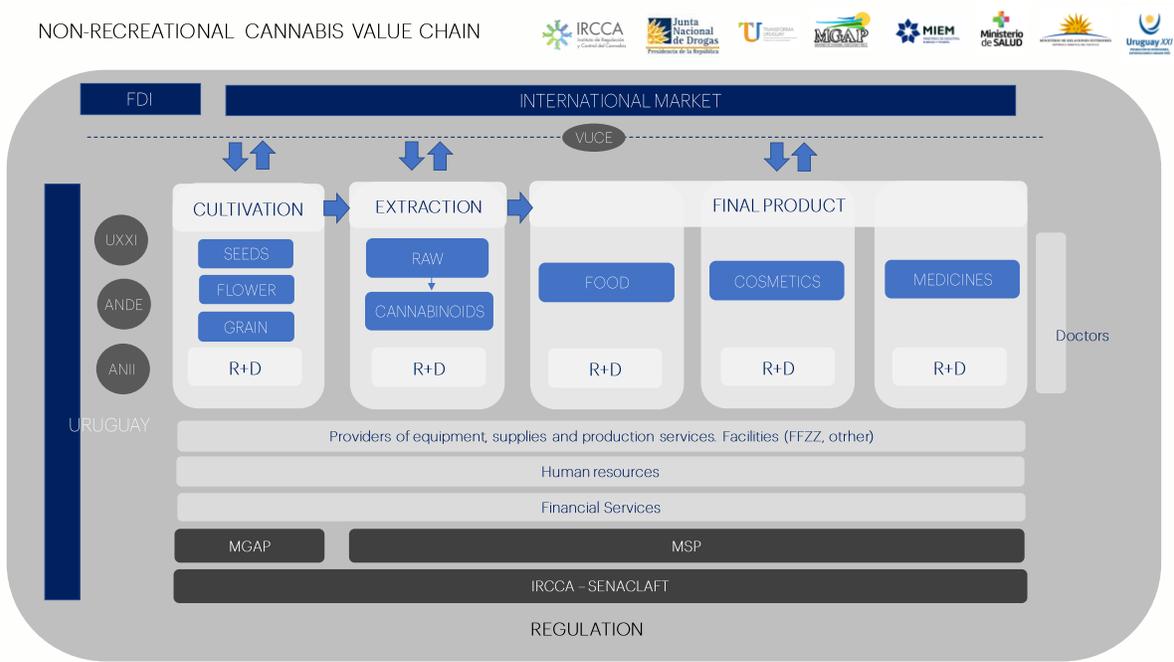
These changes were preceded by a review by the World Health Organization itself, which in June 2018 considered that cannabidiol (CBD) was effective in treating certain epilepsies and at the same time safe and unrelated to recreational use<sup>7</sup>.

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<sup>6</sup> IMPO – [Decree 403/2016](#)

# Cannabis Industry in Uruguay

The activity of companies linked to the cannabis industry in Uruguay is increasingly reaching a wider range of possibilities, and the associated services are multiplying. In particular, authorizations by IRCCA and the Ministry of Public Health reach crops - psychoactive and non-psychoactive - research and industrialization. Although the activity of the main companies is explained by these activities, many others provide associated services and complete the business map of the sector.



As of March 2020, there were 40 non-psychoactive cannabis cultivation ventures in Uruguay authorized by the Ministry of Livestock, Agriculture and Fisheries (MGAP), covering an area of nearly 600 ha, the vast majority of which was open-pit. The yield surveyed is low greenhouse and is located at about 500 to 1,000 kilos per hectare.

Cannabis crops are distributed in different areas of Uruguay, with some predominance in the south of the country, but they are also present in the departments of Artigas, Salto and Paysandú. These crops are in addition to the two psychoactive cannabis ventures located in the Libertad zone, in the department of San José.

<sup>7</sup> Source: WHO – [“CANNABIDIOL \(CBD\) - Critical Review Report”](#)

Additionally, according to IRCCA data, there are currently 9 licenses for psychoactive cannabis (4 for medical use and 5 for recreational use), 9 licenses for industrialization, and 18 for research.

MGAP*	IRCCA				
	Crop		Industrialization		Private
Other THC <1%	Recreative	Medical - THC > 1%	Medicinal extracts	Food	
Aurora / ICC	Simbiosys	Cannapur/ Khiron / Dormul	Aurora / ICC	Di Cianna	Dormul (2)
Raíces Hemp / Colfores	Aurora / ICC	Fotmer Life Sciences	Fotmer Life Sciences		Inverell / Auxly
Los Cardinales	Uruguay Biopharmaceutical Research Company	Grune Labs / Burey S.A.	MedicPlast / RAMM		Grune Labs / Burey S.A.
Fidelroy S.A.	Jabelor S.A.	Algamar S.A.	Innovaterra		Innovaterra
Greenfields / Frenital S.A.	Legiral S.A		Wemblar Corporation S.A.		UCU - GhentHENT
Hemporium			Laboratorio Homeoaleman SRL		Germinar UY
Innovaterra			Caillon Hamonet		Recowen S.A.
Inverell / Auxly			Dermagroup SRL		
YVY / Mechelen					
Heluz / Nordyan					

Note (\*): MGAP licenses are not public; the companies that appear in this column are those that are also licensed by IRCCA, are part of CECAM and/or gave their approval to appear in the promotional material of Uruguay XXI.

Those companies licensed for cultivation with THC > 1%, can also cultivate cannabis with THC < 1%.

The production is mostly done in the open or under greenhouses with LED or sodium lighting, which allows three or up to four harvests per year with an output of about two tons per hectare per harvest, or about six tons per year. In these cases we usually work with controlled climate conditions, irrigation, automated fertilization and other controls, which require a relevant initial investment that marks an entry barrier and usually the need for external partners to provide capital and eventually know-how. This has been the principal form of business in larger ventures.

A third form of cultivation is indoor production, which is rapidly expanding internationally for the production of medical cannabis.

According to MGAP information, 90% of the companies are dedicated to the production of unfertilized or fertilized female flowers for export for the production of phenolic resins and/or cannabinoids. That is to say, extracts that can end up in purified cannabinoids -typically CBD- or in raw or crude or full spectrum extractions in which all cannabinoids are preserved, with the possible exception of THC.

The business is very attractive for Uruguay, both because of the prices and the strong growth in demand. Also, many countries authorize the importation of medical cannabis but not its

production, thus becoming structurally importers. It can be said that this is the highest possible value-added chain of Uruguayan agriculture.

These possibilities, which go beyond the production of flowers, grains and seeds, will burst in, once a volume of biomass is generated from what can be considered by-products: leaves and stems and even roots. All options require the availability of abundant raw material at an accessible price, which must emerge as a by-product of the main products in value. Throughout the process, there will be a feedback loop to other activities such as tourism and education, as well as the development of related sectors that support cannabis, such as measurement and analysis services, congresses, etc.

In 2019, the first exports linked to the sector were registered. Some of these were sales of hemp biomass, and cannabis-based medicines, but still in relatively low amounts. The most relevant export of the year corresponded to a shipment of flowers over US\$ 3.2 million, by Fotmer, which became the first company in Latin America to commercialize this product<sup>8</sup>.

A first challenge that the crop faces is the learning curve, given that the prohibition has led to a lack of official and regulated instances of teaching about the arts of cultivation and prior research to determine with precision the dates of sowing and other practices of crop management, which is basically learned as the projects advance. As happened with the two psychoactive crops, the first years have been, for most of the undertakings, of learning and with modest productive results.

## Uruguay's structural competitive advantages

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In this sense, the structural competitive advantages that Uruguay has are:

- to have been a pioneer in regulation.
- privileged location - at a latitude comparable to the best production zones, allowing off-season production in the Northern Hemisphere.
- the good functioning of the same industry so far.
- its historical commitment to land-based, high value-added exports.
- its smallness and facility to control a sector that has in security an important competitive factor.
- traceability systems already implemented.
- the ability to prevent money from the illegal past of the crop from infiltrating a framework regulated by the State.
- the investment grade of the country.

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<sup>8</sup> Source: El Observador – [“Empresa uruguaya realizó la primera exportación de cannabis medicinal de América Latina”](#)

- the work of promoting the Country Brand, as a natural country.

Starting first and implementing it in a parsimonious but orderly manner represents a favorable framework for investors in comparison with other countries. With respect to Latin American countries, Uruguay competes for the absence of a history of large-scale illegal crops and of gangs dedicated to the production or protection of illegal crops.

As a corollary, it can generate hundreds of jobs in vulnerable areas (e.g. Bella Unión and Juan Lacaze) and for populations with limited employment options, such as rural women. For this potential to be captured in a sustained manner over time and in harmony with the rest of the economic activities, it must be compatible with certain characteristics of Uruguay.

# Main actors of the sector

### ADVANCED REGULATION

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COUNTRY IN THE WORLD TO LEGALIZE INTEGRALLY

### RELIABILITY

**Democracy Index**  
Economist Intelligence Unit, 2018

**E-Gov Development Index**  
United Nations, 2018

**Lowest Corruption**  
Transparency International, 2018

**The Least Tax Complex Country**  
University of Paderborn & LMU Munich

**Adoption of ICTs**  
World Economic Forum, 2018

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#1 IN LATAM

### OUTSTANDING TAX BENEFITS

 FREE TRADE ZONES

 FREE PORT

 FREE AIRPORT

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 OECD COMPLIANT

### STRONG REGULATORY INSTITUTIONS

AUDIT BODIES



**IRCCA**  
Instituto de Regulación y Control del Cannabis



**Ministerio de SALUD**



MINISTERIO DE GANADERÍA AGRICULTURA Y PESCA



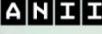
**Junta Nacional de Drogas**  
Presidencia de la República URUGUAY

## MEDICAL CANNABIS HUB

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### SUPPORTIVE INNOVATION ECOSYSTEM

















### WORLD CLASS FACILITIES



ZONA FRANCA PARQUE DE LAS CIENCIAS



ZONAMERICA



Parque Científico Tecnológico de Pando



MVD FREE AIRPORT



Zona Franca Colonia Suiza



**Uruguay XXI**  
INVESTMENT, EXPORT AND COUNTRY  
BRAND PROMOTION AGENCY

LICENCES	 CROPS	 MANUFACTURING	 R&D	 COMPANIES
 GRANTED	48	8	19	55
 UNDER EVALUATION	20	14	9	31
 TOTAL (March 2020)	68	22	28	86



## Examples of companies installed in Uruguay

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### AURORA (ICC Labs)<sup>9</sup>

In 2015 it was selected as one of the two suppliers of psychoactive cannabis of the Uruguayan State, after big investments and with a promising panorama for its growth, it was acquired by Aurora in 2018, in a transaction close to US\$ 290 million. This Canadian company is a global leader in the cannabis industry, with a presence in 14 countries. Currently, the company's assets exceed US\$ 16.6 million, with significant investments in technical advice and procedures for obtaining authorizations and licenses for both its recreational cannabis and CBD extraction projects.

It is located in Parque de las Ciencias, where it has a processing laboratory for pharmaceutical products derived from cannabis. There are also two subsidiaries in Uruguay: Tersum S.A. and Salesol S.A.

ICC has licenses to sell cannabis for recreational use distributed through the network of pharmacies, and the first laboratory to manufacture pharmaceutical-quality medical products derived from cannabis in Latin America. In its facilities in Uruguay and Cikinbua has two greenhouse facilities currently in operation, totaling 28,000 square meters. It also has three open-air cultivation sites, with a total potential area of more than 300 hectares, of which almost 240 are in Uruguay.

### TERSUM

Tersum is authorized to develop certain activities with hemp and its derivatives, as well as for the extraction of cannabinoids. This company is also authorized to import and plant hemp seeds as well as trade in the Uruguayan market. It will also be able to export hemp fibres and oils with hemp extracts. The investment in these projects in terms of plants, properties, biological assets and inventories amounted to US\$ 4.8 million.

### KHIRON LIFE SCIENCES (DORMUL S.A.)<sup>10</sup>

This company's project is located in the city of Juan Lacaze (Colonia), and is one of the first companies in Uruguay to have a license for the cultivation and commercialization of medical cannabis. In May 2019, Canada's Khiron Life Sciences signed an agreement to acquire 100% of NettaGrowth International, the company that owns Uruguay's Cannapur. The acquisition is estimated at about US\$ 13 million.

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<sup>9</sup> Source: <https://www.búsqueda.com.uy/nota/duenos-de-empresa-que-produce-marihuana-quieren-dejar-el-negocio>  
Fuente: [https://www.180.com.uy/articulo/76036\\_empresa-canadiense-compra-principal-productor-de-cannabis-recreativo-en-uruguay](https://www.180.com.uy/articulo/76036_empresa-canadiense-compra-principal-productor-de-cannabis-recreativo-en-uruguay)

<sup>10</sup> Source: <http://marcapaisuruguay.gub.uy/empresa-canadiense-compro-a-una-uruguaya-de-cannabis-medicinal/>  
Source: <https://findesemana.ladiaria.com.uy/articulo/2018/10/empresas-de-cannabis-medicinal-se-instalaran-en-nueva-helvecia-y-juan-lacaze/>

The company's objective is to produce cannabidiol extract (CBD) for therapeutic purposes, with a focus on export to the Latin American market. The company produces in greenhouses and has cannabis oil extraction plants..

The central operation of Khiron Life Sciences is in Colombia, but the purchase of Cannapur aims to cover a market of 75 million people in southern Brazil.

### **FOTMER LIFE SCIENCES<sup>11</sup>**

A company of American and Uruguayan capital, it is located since 2018 in the Free Zone of Nueva Helvecia, and its crops are exported to destinations such as Australia, Canada, Israel and European countries for medical use.

Fotmer Life Sciences was the first company in Latin America to make a commercial export of medical cannabis with high THC content. It is licensed by IRCCA (Institute for the Regulation and Control of Cannabis) to grow, harvest, dry and store psychoactive cannabis and employs around 70 people, producing up to 10 tons of dried flowers per year, using a hydroponic technique. Its licence was the first for the production of psychoactive cannabis for medical use. In Nueva Helvecia it currently has 18 large greenhouses.

The company produces medical cannabis, used for the production of inputs for human consumption. In this sense, Fotmer is committed to the highest standards and practices for cultivation and manufacturing in the sector. Fotmer's facilities have been built to comply with the European Union's Good Manufacturing Practices and are already GACP (Good Agricultural Practices) and GMP Uruguay (Good Manufacturing Practices) certified.

With an initial investment of U\$S 10 million, the company generates 70 direct jobs per year and 190 during the harvest season, which generates around 250 indirect jobs. It also has facilities in the Free Zone of Parque de las Ciencias where the production process begins, through the cloning of the mother plants and maintaining the genetics.

### **SIMBIOSYS<sup>12</sup>**

The company Simbiosys, together with ICC, was the first licensee, in 2015, to produce and distribute psychoactive cannabis for recreational use. The company's greenhouses have a harvesting capacity of 170 kilos per month, i.e. about two tonnes per year. The number of female plants is around 10,000, and the seeds, of Dutch genetics, were germinated at the National Seed Institute.

The crops are located in the town of Libertad, some 60 kilometers west of Montevideo, on state-owned land.

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<sup>11</sup> Source: Information provided by the company

<sup>12</sup> Source: <https://www.infobae.com/america/america-latina/2017/07/20/como-son-los-invernaderos-donde-crece-el-cannabis-que-uruguay-vende-en-las-farmacias/>

## **INNOVATERRA<sup>13</sup>**

Innovaterra is a Uruguayan company dedicated to the research, production and industrialization of nutraceutical, cosmetic and medical hemp. It has Research and Development, Production and Extraction licences from the Institute for the Regulation and Control of Cannabis (IRCCA). Its main objective is the production of resin, especially CBD. It has facilities in El Espinillar, Salto, Uruguay, a phytocannabinoid extraction plant designed and built in Uruguay with a capacity to process 1,500 kilos of dry matter per day. It also has an extension of 480 hectares of agricultural land. Innovaterra also focuses on research and development of varieties with a high CBD and low THC content (less than 0.5%)

The company is committed to research and development of varieties, technology packages, products and processes. Since 2018 it has registered its first variety: Interra 1801, with approximately 15% CBD and less than 0.5% THC. The varieties developed are not genetically modified. Crops are grown in strict compliance with national regulations, using our own registered varieties and agricultural protocols throughout the world, and respecting Good Agricultural Practices. It is also working on GMP (Good Manufacturing Practices) certifications. In the current campaign (2019-2020) the production was 50 hectares with Interra 1801.

Innovaterra is committed to the development of new efficient producers of this crop through the associated producers program, which consists of a selection of producers in different areas of the country to present them with hemp production under the Innovaterra licence. Once the field delivers the biomass to the plant, it is classified, dried and prepared for the extraction process. The phytocannabinoid extraction plant works as a solvent with ethanol. The distillation process for solvent recovery is done under vacuum, which provides optimal purity to the resins.

It is currently working on achieving a complete extraction, purification and distillation laboratory, with the aim of achieving a high quality product faster and in larger volumes than most CBD suppliers. The laboratory process will start from the arrival of the raw extract from the extraction plant.

## **BCBD<sup>14</sup>**

This Uruguayan company emerged in 2014 and was one of the first to start cultivation of non-psychoactive cannabis. It is the first and only company in Uruguay that has a species of non-psychoactive cannabis with its own genetics, developed, registered and internationally recognized. This genetics, whose CBD content reaches or exceeds 8% and a minimal amount of the psychoactive component, is demanded by the growing use of CBD for nutritional and medical purposes.

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<sup>13</sup> Source: Information provided by the company

<sup>14</sup> Source: <http://www.lr21.com.uy/comunidad/1377341-cannabis-verba-mate-venta-empresa>

Currently, its business is to provide raw material for high level Cannabidiol (CBD) weeds. In fact, the company was in charge of designing the process of incorporating the CBD into the product.

At the same time, the company seeks to develop articles and processes with CBD as raw material for their incorporation into food, beverages, cosmetics, as well as products intended to improve human and animal welfare. Today the company has more than 20 registered trademarks as well as several genetics designed to achieve different characteristics. Likewise, the company is building its CBD oil extraction plant with a production capacity of 2,000 liters per month, the production of this plant may also be applied in the manufacture of cosmetics, nutraceuticals, food and nutritional supplements.

It plans to harvest more than 40,000 plants next season. The harvested biomass will be used to produce oil, except for flowers that will be exported mainly to Europe, where there is a sustained demand for flowers with high CBD content without psychoactive effect.

#### **AUXLY (INVERELL)<sup>15</sup>**

Headquartered in Montevideo, it is licensed to grow and harvest a strain -RU- patented by the company, which contains 0.5% THC and 8% Cannabidiol (CBD). The destination of this production is the medical cannabis market in Uruguay. The crops accumulate 16 hectares, although the total land of the company is around 600 hectares. They also have a solid platform for Research and Development, with permits for the development of original strains, extracts and other derivatives are being processed.

Invernell had an investment of US\$ 15 million by the Canadian Cannabis Wheaton, with which it bought 80% of Inverell.

#### **INNOVA LIFE<sup>16</sup>**

This Spanish company shares a project with the Instituto Nacional de Investigación Agropecuaria (INIA) to research and develop medical marijuana in Uruguay. The total planned investment is US\$ 100,000. The objective of the project is the development and exploitation of genetic varieties, in principle three varieties of industrial hemp for medical applications and uses. The developments are located in the experimental station of the Inia Las Brujas, located in the department of Canelones.

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<sup>15</sup> Source: <https://nacioncannabis.com/canada-invierte-uruguay-usd15-millones-la-compra-inverell/>

<sup>16</sup> Source: <https://negocios.elpais.com.uy/noticias/nueva-empresa-apuesta-marihuana-medicinal-uruguay.html>

## **NUBE SERENA<sup>17</sup>**

Nube Serena was born thanks to the concern of a group of Danish businessmen who saw an opportunity in the Uruguayan legislation to carry out the production of cannabis for medical use. They formed a company in Denmark (Nube Serena Holding), and settled in Paysandú, Uruguay with the same name.

They started activities in 2016, and in 2017 they had the first crops. Simultaneously, research work began to optimize an oil extraction process of CBD.

Unfortunately, the last harvest of 2017 had to be incinerated because the THC level was not allowed. In 2018 the license renewal process began, but with Hardolin S.A, which is obtained in December 2018.

The company has 6,000 m<sup>2</sup> of nurseries, and will add 3,000 m<sup>2</sup> more soon. During 2019 it successfully produced indoors and submitted the application for an extraction license.

The final objective of the company is the production of oil with medical quality to be used in the manufacture of different pharmaceutical (drops, capsules and inhalers) and veterinary presentations.

## **Medicplast**

Uruguayan capital company present in the Uruguayan market since 1988, dedicated to the production, import and marketing of medical products and pharmaceutical specialties, among other products. Medicplast elaborates the medicine Epifractán, the first one based on cannabis. Nowadays, it is elaborated in presentations with concentrates of CBD of 2% and 5%. The development of this drug began some years ago, and in December 2017 received the authorization of the MSP for sale to the public.

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<sup>17</sup> Source: Information provided by the company

## Institutionality

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- **Institute for the Regulation and Control of Cannabis**



The Institute for the Regulation and Control of Cannabis (IRCCA) was created by Law No. 19.172 with the purpose of regulating the planting, cultivation, harvesting, production, processing, collection, 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 oversee compliance with the provisions contained in the law and these regulations, without prejudice to the constitutional and legal powers attributed to other bodies and public entities. The National Board of Drugs of the Presidency of the Republic is responsible for setting national policy on cannabis, with the advice of the IRCCA. The IRCCA, within its Board of Directors, has 4 members and 4 substitutes: Ministry of Public Health (MSP), Ministry of Livestock, Agriculture and Fisheries, National Drug Secretariat and Ministry of Social Development.

Website: <https://www.ircca.gub.uy/>

- **Ministry of Public Health**



Ministerio de Salud Pública  
MSP

The ministry is responsible for contributing to the improvement of the health of the inhabitants of the Republic, elaborating health promotion and prevention policies, normalizing and regulating the treatment and rehabilitation of the disease, under the guiding principles of universality, equity, quality, solidarity, sustainability and efficiency. Law 19.172 establishes that the Ministry of Public Health is responsible for authorizing and controlling plantations or crops for the exclusive purpose of scientific research or for the production of therapeutic products for use. Also in its orbit is the Specialized Unit in Evaluation and Monitoring of policies issued by law.

Website: <https://www.gub.uy/ministerio-salud-publica/>

- **Ministry of Livestock, Agriculture and Fisheries**



Its mission is to contribute 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 products of plant and animal origin. Law 19.172 establishes that the MGAP must authorize and control the planting or cultivation of non-psychoactive cannabis (hemp).

Website: <http://www.mgap.gub.uy/>

- **Directorate-General for Agricultural Services**



This Directorate of the MGAP works to protect and improve 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, on phytosanitary matters, quality and safety of plant foods and animal feeds. One of the most important public policy definitions in recent 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 grains, stems, flowers and leaves. This Directorate carries out the RUO (Unique Registry of Operators), and there the operation applications and the work plans are processed.

Website: <https://www.gub.uy/ministerio-ganaderia-agricultura-pesca/dgsa>

- **National Seed Institute**



The main objective of INASE 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 obtaining and use of new national and foreign phylogenetic materials that are adapted to the conditions of Uruguay. Its role also contemplates the protection of creations and phytogenetic discoveries, granting the corresponding property titles.

As for the cannabis market, INASE is responsible for the RGS (General Registry of Seedlings), and the RNC (National Registry of Cultivar).

Website: <https://www.inase.uy/>

- **Anti-Money Laundering Secretariat**



The National Secretariat for Combating Money Laundering and Financing of Terrorism (SENACLAFT) is responsible for drawing up and submitting to the Executive Branch for consideration national policies to combat these objectives. It also proposes to the Executive Branch the national strategy to combat money laundering (LA) 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 that make it possible to identify vulnerabilities and risks, in order to make 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 companies linked to the sector, and the identification of the final beneficiaries and origin of the funds to be used.

Website: <https://www.gub.uy/secretaria-nacional-lucha-contra-lavado-activos-financiamiento-terrorismo/>

- **Chamber of Medical Cannabis Companies (CECAM)**



This chamber brings together some 14 companies linked to the local development of the market for cannabis 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.

Website: <http://cecam.com.uy/>

- **The Southern Innovation Consortium**



CISUR is an alliance of scientific-technological cooperation between the Uruguayan Center for Molecular Imaging (CUDIM), the Clemente Estable Biological Research Institute (IIBCE), the National Institute for Agricultural Research (INIA), the Pasteur Institute of Montevideo (IPMont) and the Pando Science and Technology Park (PCTP), created with the aim of generating, capturing and transferring scientific-technological knowledge that contributes to improving the competitiveness of national companies in a global environment.

It has a prioritized line of work specific to the medical use of Cannabis, working from the design of the genetics of the plant to the clinical evaluation of phytocannabinoids.

Website: [www.cisur.org](http://www.cisur.org)

- **National Drug Board**



Its mission is to design and approve the National Drug Strategy (END) and the respective Operational Action Plan (PAO), establishing the political guidelines referring to the different areas of drug policy. Through the National Secretariat for Drugs, to articulate, coordinate and monitor the implementation of the actions defined through articulation with the different institutions involved in drug policies.

Website: <https://www.gub.uy/junta-nacional-drogas/>

- **Biological Research Institute Clemente Estable**



The Department of Experimental Neuropharmacology focuses on understanding the neurobiological bases associated with neuropsychiatric pathologies, such as depression, schizophrenia and drug abuse addiction and the study of the mechanism of action of psychopharmaceuticals (antidepressants, anxiolytics and antipsychotics). Its purpose is to know the physiology of the systems involved in these pathologies and to find new therapeutic targets that allow the design of more specific, 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, among which are the medical use of Cannabis and Cannabinoids.

Website: <http://www.iibce.edu.uy>

## Prospective

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This section analyses the potential exportable products linked to or derived from Cannabis Sativa. It is understood that there will be four sectors that should have a short-term export impact: food, clichés, medicines and genetics.

### Food

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Cannabis has a strong potential as an export item in food and beverages, and Uruguay has the possibility of offering proven safe food with a plant that generates both curiosity and apprehension. But it will not be able to position itself as an exporter until it develops its domestic market in a reliable, transparent and agile manner.

Cannabis will enter a high-growth segment of global consumption, such as chia and quinoa, and as a food of excellence in terms of health will be extremely important.

In the same way, the sale of table oil has a high potential, of a higher price than olive oil, of a very high quality due to its composition, with a very characteristic taste, and which can also be mixed with olive oil, generating a unique product with a Uruguayan double seal. Once the oil has been elaborated, there remains protein flour that also has an excellent composition as food for both humans and other animals.

On the other hand, it is feasible to develop an industry that generates CBD simply to be added to traditional foods and beverages. It has already happened with yerba mate, in other countries there is a market for coffee or chocolate with CBD, which the public chooses because they consider it "neuroprotective".

Consequently, it is considered of great importance to achieve clear and delimited regulations and procedures in their categorization and in the time by which food intended for the internal market is approved or disapproved. It should be clarified what is defined as a plant specialty, what is a food supplement, what is a medicine and if there is any other categorization.

In grain-based foods, the presence of cannabinoids will be almost nil. In other foods, the presence of CBD and other non-psychoactive cannabinoids in low concentrations is positive for consumers because of their properties as nervous system modulators and neuroprotectors, among other perceived benefits.

This process of evaluation of seed and leaf derivatives of low THC cannabis strains should be radically different from that of drugs, and should be more related to that of a plant specialty or ingredient with supposed neuroprotective properties and with no expected harms of any kind as long as they are foods with less than 1% THC. In the case of foods, Swiss legislation is a good reference; food products with less than 1% THC and CBD-free content are considered to provide potential benefits to the consumer that are sufficiently demonstrated at the international level.

In Uruguay, the precedent generated by yerba mate can be used to facilitate the approval of other beverages and foods. On a worldwide scale, the so-called "edibles", typically chocolate with seeds, cannabinoids and terpenes, similar milk, proteins for vegetarians and sportsmen, seeds bathed in chocolate and combinations with coffee are some of the ways in which fruits and leaves of cannabis are developed as food.

In other cases in which a therapeutic effect is sought without dealing with a food, a possible route is to treat low THC cannabis as a food supplement, so as to incorporate it into a treatment similar to that which other herbs already have.

### **Animal feed**

An area related to the use of cannabis in food is animal feed, differentiating the use for feeding cattle, pigs or chickens on the one hand and the use as a dietary supplement in pets, a market in strong development in the U.S. It could be a segment in which to develop an organic certification. On the other hand, a way of differentiation of Uruguayan products could be explored through the inclusion of CBD in low proportions.

In particular, it is understood that there is a differentiation potential for Uruguayan meat, which can be valued through a fed cannabis seal. This, beyond the novelty it represents for a consumer, seems to have scientific support in analyses that have been made using cannabis in corral feed.

It makes sense to use something that can work as a painkiller given the importance of stress on animal performance and meat quality. In that sense, it is understood that it can be a super gourmet line of work to be developed for example with the Wagyu cattle breeders society and the Veterinary Faculty. A correlation between cannabis intake and the lower stress level of the animals results in better weight gain, better fat infiltration into the muscle mass and thus better quality. In

addition, a lower proportion of dark cuts should be achieved because of the muscle acidification that occurs in animals that suffer from pre-slaughter stress.

## Topical Products

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A second branch that is understood will be important and in a certain sense comparable but distinguishable from medical products is that of cosmetics. In this case, too, those with a higher THC content and less than 1% THC must be differentiated, with less restrictive regulations in those with a lower THC content, but which do not close the doors to products with a higher THC content, mainly intended for export. Specific curative properties should not be awarded unless there is sufficient scientific evidence. However, the development of moisturizers, sunscreens and analgesics with a low THC content should be allowed, following criteria similar to those of Switzerland.

The topical market is extremely important in the states of the United States where its use has been liberalized, and many consider that the use of cannabis to relieve muscular pains derived from stress, bad positioning at work or blows is one of the most promising segments of the market. Although this is a topic that must be taken into account in addition to the precautions of, for example, seed-based foods, there are already important advances in this area outside Uruguay.

In the European Union, cannabidiol has been listed in CosIng (Cosmetic Ingredient Database) with four functional claims: "antioxidant, skin conditioning, skin protection and anti-seborrheic", and "without any restriction"<sup>18</sup>.

Inclusion of cannabidiol appears to facilitate approvals in the domestic market.

## Medical cannabis

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In the evolution of the demand for medical cannabis it will be considered that in addition to having a proven therapeutic value for some ailments, there is a very persistent approach in the public: cannabinoids and in particular CBD are perceived as preventive, neuroprotective, and as such will have a strong and persistent demand.

A frequent misconception is to believe that the cannabis business is psychoactivity. And that it is a youth-oriented sector. Low THC cannabis will be increasingly important as a preventive food, but it will also have a growing market as an alternative to opiates (including THC or THCA) and to deal

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<sup>18</sup> [Anexo II / III del Reglamento 1223/2009](#)

with ailments such as epilepsy, and will move in an intermediate plane between the preventive and the curative, as an analgesic capable of significantly reducing pain without side effects.

The only drug approved in the country is Epifractan, which only contains 2% and 5% CBD. Its impact on the market is limited. According to Monitor Cannabis more than 80% of people who use oils, extracts, tinctures, creams or other preparations based on cannabis, get it from the "gray market", ie without health licenses.

In principle medical cannabis will tend to focus on three types of products: CBD, THC and full spectrum extracts, which contain a set of cannabinoids from the plant but from which THC has been extracted.

From the WHO Report on CBD of June 2018 there is a climate more than favorable to be enabled in different countries, specifically opens a great opportunity within the regulation of Uruguay, which is reinforced by the approval of the Epidiolex, CBD-based drug, by the FDA in October 2018. Important and concrete investments have already arrived in Uruguay for this purpose.

The use of traceability and the advance of exports before other countries, as well as a differential prestige with respect to low price competitors, can mean an enduring advantage that allows products to be placed with more value than African countries, with more security for investors than Colombia and Mexico, and with concentrated competition in European countries with similar costs to those of Uruguay, such as Greece, Portugal, Croatia, Czech Republic, among others. It is understood that production will migrate from higher-cost countries (Switzerland, Canada) to countries capable of achieving similar levels of quality at lower prices.

## Genetics

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The development of the cannabis agro-industrial chain starts, like all the others, from the genetic base, and as in the others, it is crucial to have national genetics, adapted to local conditions but also with clear rules for the incorporation of genetics from abroad, as well as the development of local breeding programs.

In this way, it is expected that there will be a process of capturing external genetics, development of national genetic research, both to achieve an autonomous and adapted production and to generate the genetic development service to entrepreneurs who have legal restrictions to do so in their own countries or who need to multiply in off-season.

On the other hand, Uruguay must have a policy for the development of national cannabis genetics, which must be based on a survey of existing genetics and a call for the validation of cannabis genetics. In the development of genetics, the aforementioned objectives should be considered: food, medicine, topics, but also medium-term objectives: textiles, bioplastics, paper.

In all cases the development should aim to achieve adapted genetics on which are known in detail optimal planting date, density of planting with and without irrigation, fertilization and control of local pests. Given the rusticity of the crop for food and textile purposes and the high density to which it could be planted for seed, comparable with sorghum, Uruguay could incorporate it in some segments as a component of the extensive rotations, with advantages for the soils given the correct carbon balance and the depth of its root system.

### **Medium-term development sectors**

Along with these priority agro-industrial chains and those that will emerge in parallel or later taking advantage of the volume of biomass that will be generated from these three main branches, there are developments that must take place transversally and that are considered pillars of the future competitiveness of the sector, fundamentally services for the development of cannabis, and the use of cannabis as a textile, paper and bioplastic.