# PHARMACEUTICAL SECTOR IN URUGUAY
## HUMAN AND ANIMAL USE

SEPTEMBER 2021

Uruguay XXI
INVESTMENT, EXPORT AND COUNTRY BRAND PROMOTION AGENCY

# Content

# WHY TO INVEST IN THE PHARMACEUTICAL SECTOR IN URUGUAY?

- Uruguay has a long history of political, democratic and social stability, as well as macroeconomic soundness, which creates the right environment for productive investments.

- Strategically located, Uruguay offers investors a gateway to the region, first-class logistics infrastructure, state-of-the-art telecommunications technology and the best renewable energy supply in Latin America.

- Uruguay has become the best destination for international companies seeking quality, efficiency, experience and new opportunities. It offers the most stable and reliable business environment in Latin America.

- In Uruguay, investment -both domestic and foreign- is of national interest. Foreign and local investors are treated equally, and have a wide range of incentives available to suit different types of activities, whether industrial, commercial or services.

- The foreign exchange market in Uruguay is free, with total freedom to buy and sell foreign currency. No prior authorization is required for inflows or outflows in foreign currency, and there are no restrictions on capital flows, transfer of profits, dividends, interest, etc. Thus, business can be conducted entirely in dollars, with no loss of profitability associated to foreign exchange risk.

- Uruguay has highly qualified and multilingual talent. The government promotes subsidies to companies for the implementation of tailor-made training programs, both for existing staff and new recruits.

- For the pharmaceutical sector in particular, Uruguay has very competitive human resources, due to the combination of several factors such as excellent education quality, a wide variety of university options specific for the sector, and the flexibility and ease with which workers can adapt to new production processes and technologies.

- In the country there is a critical mass of companies and institutions that allow covering multiple processes and products, which together with a wide network of academic research groups and service provider startups form a functional innovation ecosystem for the development of R&D projects and centers.

- In addition to its privileged location, Uruguay offers science and technology parks with the necessary infrastructure for multiplatform regional hub operations, as well as specific incentives for these activities. It also has a regulatory framework and specific incentives for other sub-sectors of the pharmaceutical industry, such as biotechnology and medical cannabis.

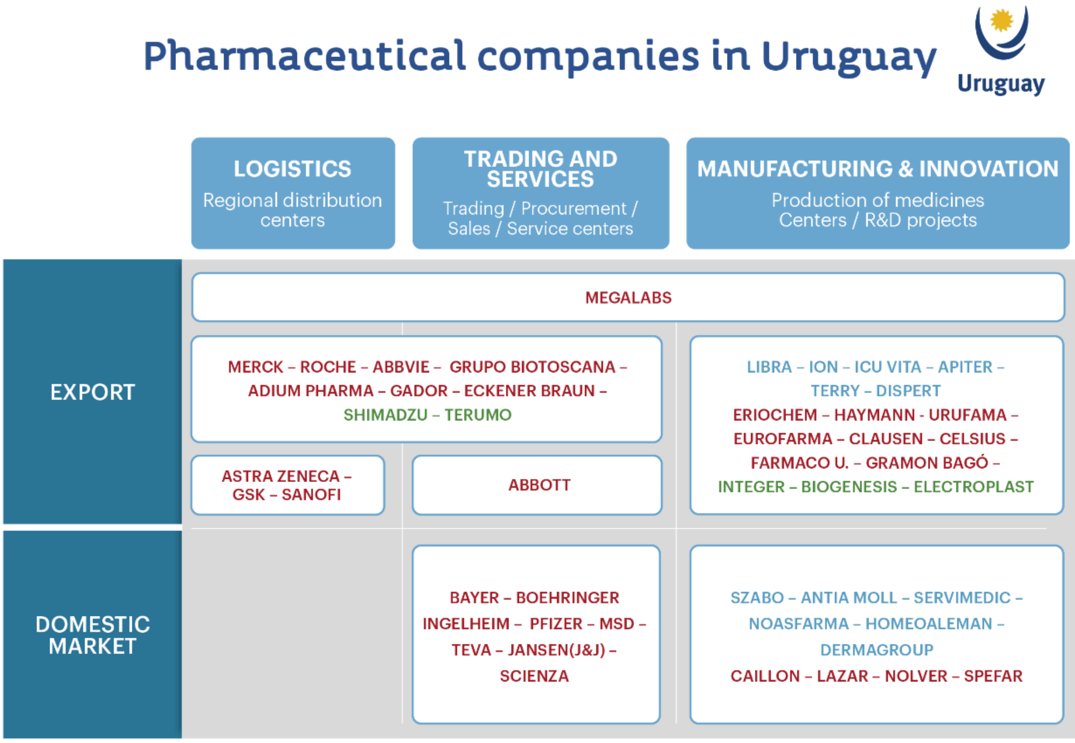
  For more information contact us at the following link.

# 1. EXECUTIVE SUMMARY

The global pharmaceutical sector has grown exponentially in recent decades. Its scope is growing from traditional manufacturing and trading to a major licensing and patenting market. Although the sector is increasingly covering more areas, this report focuses on activities related to products for human and animal use and medical equipment, both traditional and those incorporating biotechnology in their processes.

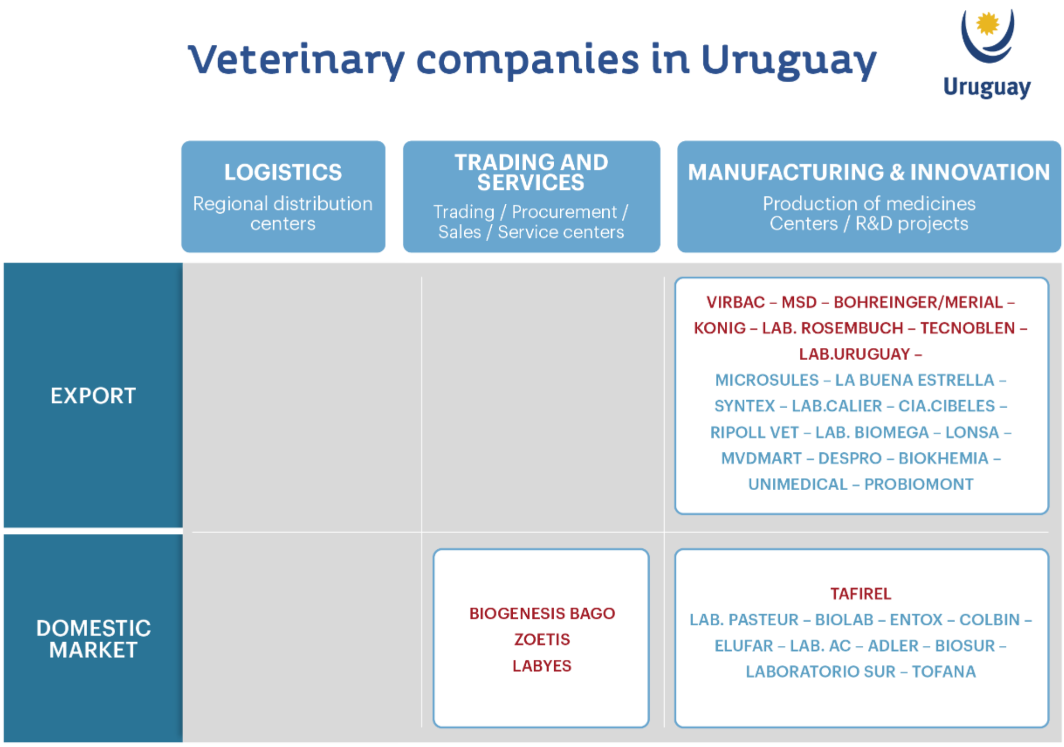
In Uruguay, the pharmaceutical sector has also grown significantly. Although there have been companies related to this industry since the early 20th century, their number has significantly increased in the last 30 years, reaching 80 human health companies and 37 animal health companies that operate in different fields.

Pharmaceutical and veterinary companies operate in Uruguay, using different business platforms and combinations of these. The following table shows some of the companies operating as trade and services hubs, on the one hand, and production and innovation hubs, on the other.




Within these platforms, some companies are more focused on the foreign market, while others operate exclusively in the local market. The sector is so dynamic that the companies usually start out in some of these business sectors, yet over time they incorporate new activities and expand their presence in other platforms. For example, it happens often that international companies, after initiating regional logistics activities in the country, they add other service activities as part of their expansion strategy. It is also common for global companies focused on the domestic market to incorporate trade and services hub activities, and for companies performing production activities for the domestic market to support their growth with exports. A noteworthy example is the case of Megalabs, which operates as a trade and service hub, as well as in the production and innovation platform focusing on the international market.

It is worth mentioning that international companies are in red, and local companies in blue. All of them are companies belonging to the pharmaceutical sector for human use. In green are those companies that make up the medical equipment subsector.




Looking at the animal pharmaceuticals sector from the same perspective, a large majority of companies are mainly focused on the production and innovation hub platform and are strongly focused on exports.

Unlike the human pharmaceuticals sector, there are no companies carrying out regional logistics activities from Uruguay, and only a few international companies have commercial offices to serve the domestic market.

Based on the information available, the following sections describe each of the segments defined. Table N° 3 presents a summary of the sector's main data.

TABLE 1 - MAIN INDICATORS

| | | TRADE AND SERVICES HUB | | MANUFACTURING AND INNOVATION HUB | | TOTAL** |
|---|---|---|---|---|---|---|
| | | Logistics - Trading - SSC Import - Export Representation | Domestic market | Logistics - Trading - SSC Import - Export Representation | Domestic market | |
| **Human pharma** | Companies | 24 | 17 | 21* | 18 | 80* |
| | Employment | 1.200 | 300 | 3.150* | 850 | 5.500* |
| | Value (millions) | U$S 670 Transit | U$S 250 Imports | U$S 188* Exports | U$S 364 Prod. for domestic consumption | U$S 552* Production |
| **Animal pharma** | Companies | 0 | 4 | 21 | 12 | 37 |
| | Employment | 0 | 50 | 1.150 | 150 | 1.350 |
| | Value (millions) | - Transit | U$S 39 Imports | U$S 70 Exports | U$S 38 Prod. for domestic consumption | U$S 108 Production |
| **Total** | Companies | **24** | **21** | **42** | **30** | **117** |
| | Employment | **1.200** | **350** | **4.300** | **1.000** | **6.850** |
| | Value (millions) | **U$S 670** Transit | **U$S 289** Imports | **U$S 258** Exports | **U$S 402** Prod. for domestic consumption | **U$S 660** Production |

* It includes five medical device exporters that employ 450 people and exported US$28 million in 2020, and exports of pharmaceutical products from free trade zones for US$93 million.

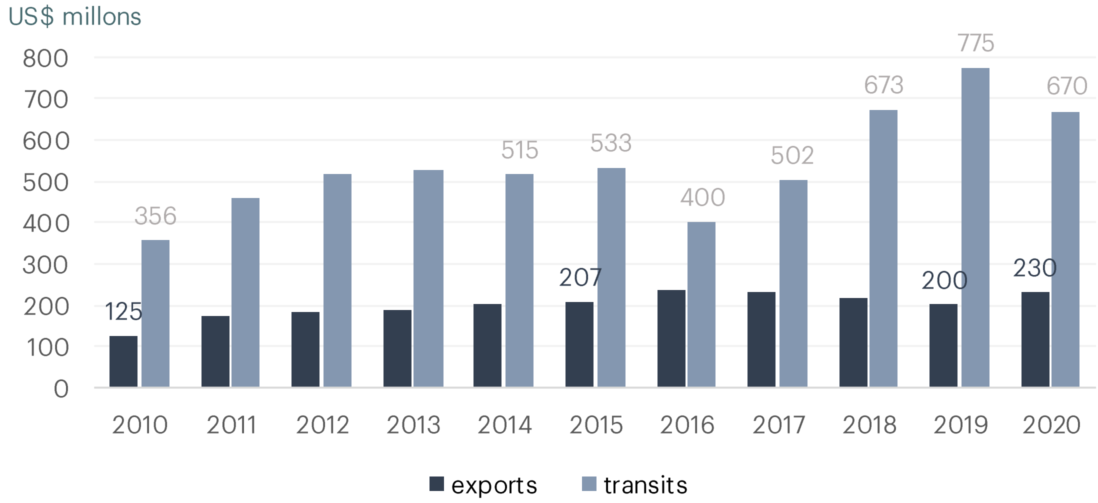
** Total production is the sum of the amount exported and production destined for domestic consumption

Source: Uruguay XXI based on information provided by Customs, Ministry of Labor and Social Security (MTSS) and Exante.

Considering the pharmaceutical sector for human and animal use, and medical devices, the total production of the sector is estimated at US$ 660 million. This represents 12% of Uruguay's industrial GDP and 1.2% of total GDP.

With total exports amounting to US$ 258 million (including medical equipment and exports from free trade zones), the sector accounts for more than 3% of total exports in 2020.

CHART N°1 - TRANSIT AND EXPORTS OF PHARMACEUTICAL PRODUCTS - 2010|2020




Source: Prepared by Uruguay XXI based on information from the National Customs Directorate (DNA).

The sector directly employs almost 6,850 people and consists of a business network with some 117 directly related companies, 80 of which operate within the human pharmaceuticals and medical equipment sector, and the remaining 37 within the animal health sector.

Of total employment, 5,500 jobs correspond to the human pharmaceutical sector. Most of the employment generated (3,150) corresponds to the 21 exporting companies, most of which are foreign-owned or have been acquired by regional foreign economic groups. Companies operating within the trade and services hub are also a significant source of employment. These companies generate around 1,200 direct jobs, including specialized suppliers in the logistics chain mentioned below. On the other hand, companies handling domestic distribution of foreign pharmaceuticals - often local representatives of international laboratories - employ an estimated 300 people.

## 2. INTERNATIONAL TRENDS

The global market for health-related products and services shows a marked growth trend and is currently at a turning point, given that biotechnology (cell and gene therapies), together with artificial intelligence and the intensive use of information, would enable an even more dynamic growth of this market.

In addition, the expected world population growth[1], longevity and an increasingly aged population are additional factors that strengthen the sector's development trend.

At the governmental level, there is a clear readiness to increase investment in public health systems. Furthermore, governments are the main promoters of R&D, generally through fiscal and financial incentives. National authorities also regulate -in part- this sector's prices, since -being their main customers- they can transfer budgetary pressures to suppliers.

This occurred primarily in 2020, when Covid-19 put maximum pressure on national health systems and pharmaceutical companies to produce a vaccine that would slow the pandemic's global advance. The dynamics of the pandemic showed, on the one hand, a sharp increase in demand for antiviral drugs, medical hygiene products and respirators, while demand for other pharmaceutical or medical products decreased due to limited funding, and many medical procedures were put off[2]. According to the World Health Organization, 31% of countries reported discontinuation of treatment for cardiovascular diseases, 42% of cancer treatment and 49% of diabetes treatment[3].

At the product level, the generic drug market is growing together with the brand-name drug market, making them more accessible to the general population. In addition, the existence of new diseases and the demand for new treatments create multiple and highly specific needs that drive the sector and are responded by the so-called orphan drugs[4]. It also brings closer the concept of pharmacogenomics, which is the development of customized drugs that are adapted to the patients' genomic conditions. For this reason, the sector is on the way to representing the convergence of biology and engineering.

---

[1] The United Nations Organization (UNO) estimates a world population of 9 billion by 2050.

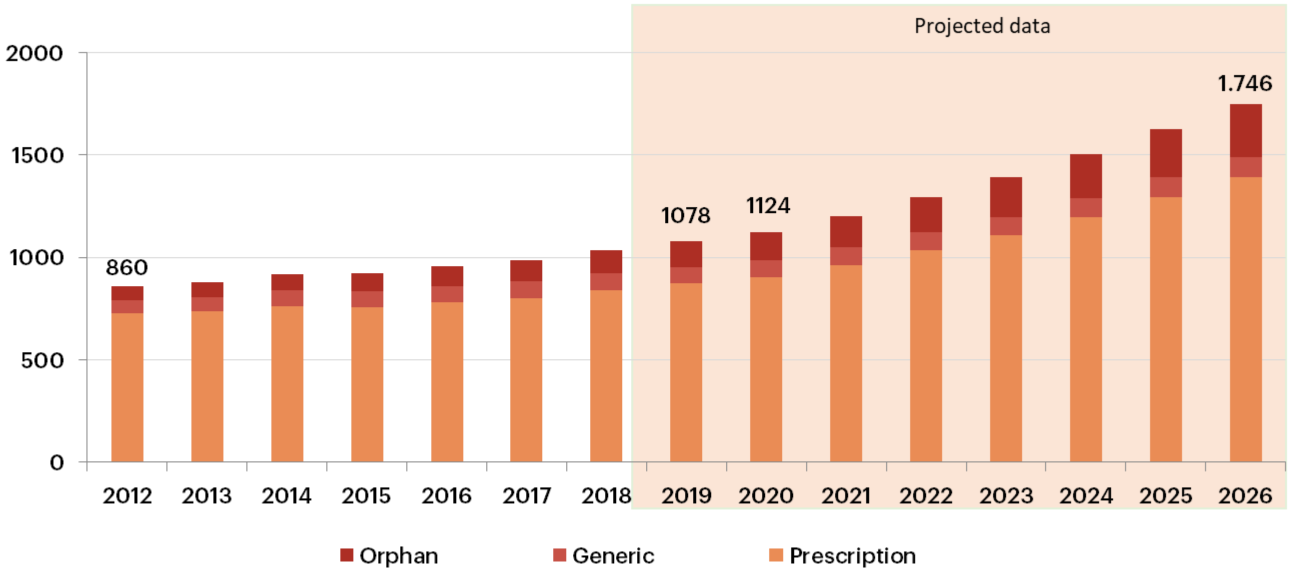
[2] Source: Euromonitor International – "Covid-19 Impact on Pharmaceuticals and Medical Equipment Industry".

[3] Source: Euromonitor International – "Covid-19 Impact on Pharmaceuticals and Medical Equipment Industry".

[4] Orphan drugs are used to treat rare diseases. They usually require long periods of time for their development, as well as significant investments, and are characterized by high levels of uncertainty during the formulation process. For these reasons, as well as for public health reasons, their development plans normally include companies that are supported by the State.

The industry's experienced and projected growth is clearly reflected in the evolution of sales of pharmaceutical and medical technology products, as shown in Chart N°2.

Chart Nº2 – Worldwide drug sales (US$, billions)




Source: EvaluatePharma - "Worldwide Prescription Drug Sales (2012-2026)."

According to Evaluate Group's data and projections, global drug sales in 2018 exceeded the US$ 1,000 billion threshold, and in 2020 they stood at US$ 1,124 billion, representing a 4% growth, as compared to 2019's sales. Similarly, between 2021 and 2026 the trend would continue to grow, with an average annual rate of 8% in the sector's sales.

The aforementioned factors contribute to the significant role innovation has for pharmaceutical companies, but with limitations at the price level, which in turn generate losses in profitability. This context creates opportunities for related services, which may correspond to manufacturing activities, innovation and research services, or even distribution. Many of these opportunities apply to the pharmaceutical sector in Uruguay, as discussed below.

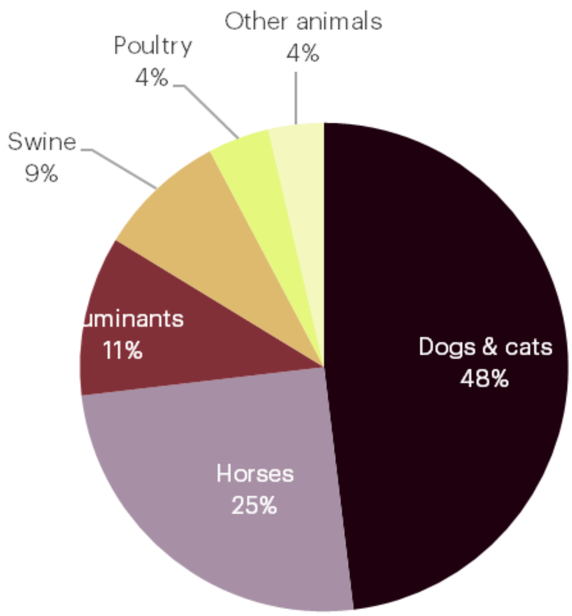
Although veterinary pharmaceuticals share similar characteristics with those for human health, they have a market with its own logic and, thus, it should be analyzed separately.

The global veterinary health market is growing rapidly. Key factors such as technological advances in diagnostics and therapies, as well as increasing productivity - which increases the risk of zoonosis transmission – partially explain this trend. In addition, growing awareness of animal health, as a result of initiatives led by the government and other organizations, is driving the growth of this market, estimated at some US$ 30.8 billion, which is expected to grow to US$ 42.8 billion by 2025[5].

Animal health products are divided into two categories: treatment and diagnostic products. The former represents 75% to 80% of the total market, and include -among others-, vaccines, antiparasitic drugs, antibiotics and medical feed additives.

The market for both categories can also be divided according to their uses, both for pets and production animals.

CHART N°3 - ANIMAL HEALTH MARKET BY TYPE OF ANIMAL - 2020




Source: Mordor Intelligence - Global Veterinary Healthcare Market (2020 - 2025)

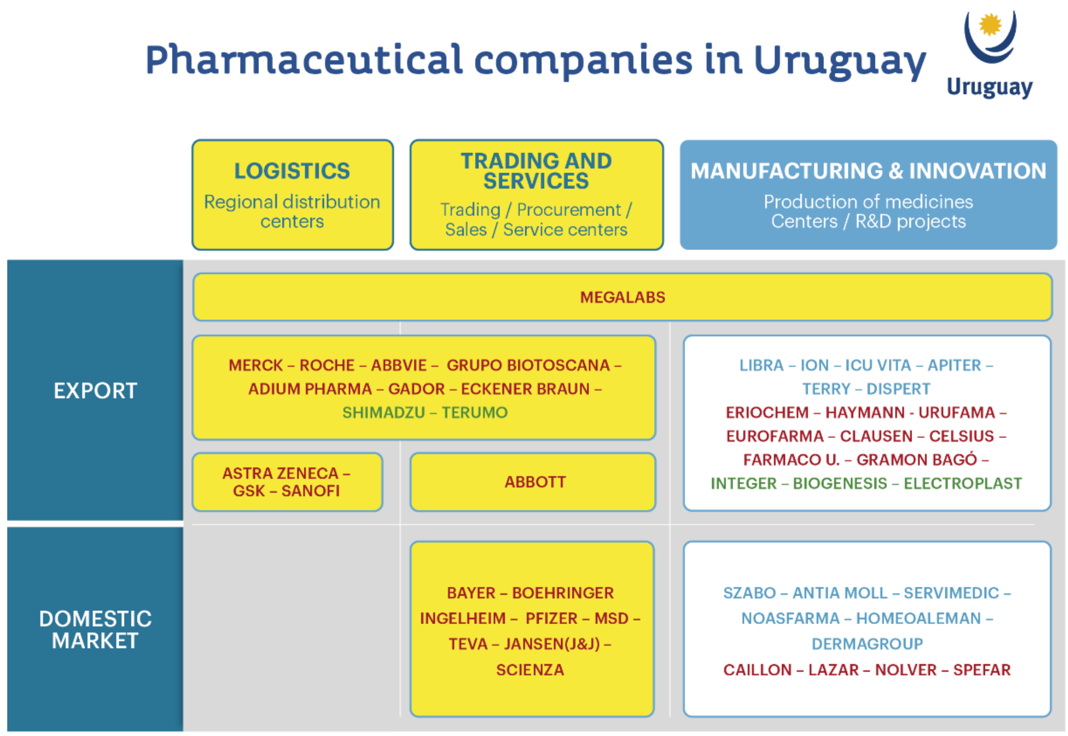
[5] Source: Mordor Intelligence - Global Veterinary Healthcare Market (2020 - 2025)

# 3. TRADE AND SERVICES HUB

Uruguay offers a set of complementary services and investment opportunities, which range from the genesis of the drug to the most advanced services in the value chain of regional distribution and administrative back office or customer service (business service centers), forming a cluster focused on foreign direct investment.

In particular, hub activities are mostly developed in free trade zones (mainly in Parque de las Ciencias and Zonamerica), since these two have the necessary infrastructure to provide logistics and distribution services through their user companies specialized in fractioning, conditioning, and cold storage activities. However, some companies locate their logistics and service operations in other Free Trade Zones.

Twenty-four companies were part of the pharma hub in 2020. This number has remained relatively stable over the last three years, although more relevant multinational companies have joined (Astrazeneca, Sanofi, GSK). Most of these companies are foreign multinationals, employing some 1,200 people in 2020 [6].



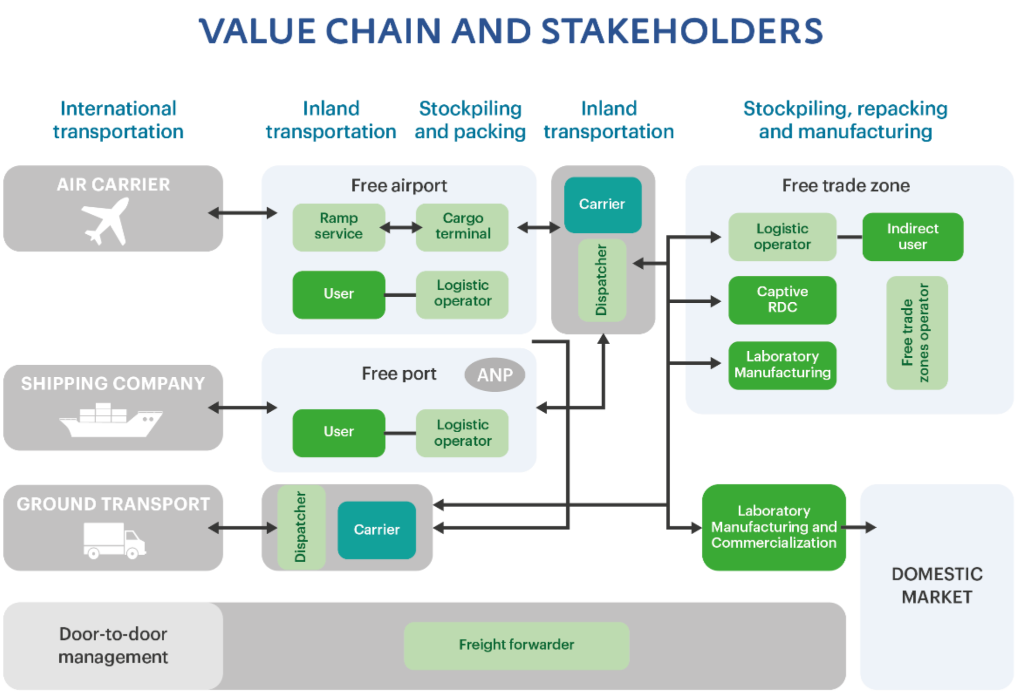

[6] Jobs created by companies that also belong to the Production sector have not been included to avoid double counting.

## 3.1 Regional distribution

Uruguay has a long track record with companies that provide logistics and distribution services for the region. Thus, it a logistics hub of reference. In the country, the sector encompasses various operations carried out at ports, airports and free trade zones.

Pharmaceutical companies are the main players, developing their activities as captive distribution centers or through specialized logistics operators. In addition to these, there are a series of suppliers that complete the chain (carriers, freight forwarders, shippers and specialized cold chain suppliers).

DIAGRAM N°1 - LOGISTICS HUB'S STAKEHOLDERS




For the pharmaceutical sector, in particular, the country has positioned itself as a regional hub for the Southern Cone, offering important advantages for the location of regional distribution centers. The regulatory framework, geographical location and installed infrastructure are Uruguay's main attractions in this segment.

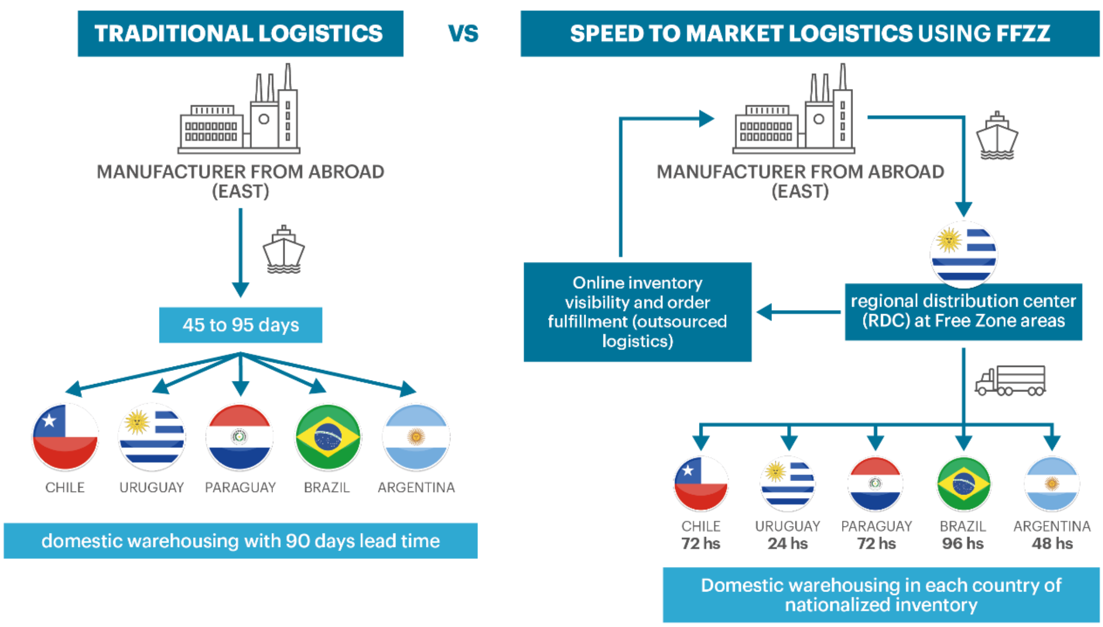
Uruguay offers important regulatory advantages for logistics operations, with incentives for the installation of regional distribution centers (RDCs) and for the handling of goods in transit. These operations are carried out directly by international pharmaceutical companies, or through outsourced logistics operators (3PL). These incentives include the free trade zone, free ports and airport, customs warehouses and temporary admission regimes, all of which are detailed in the section: Regulatory Framework.

The country's geographical location also allows easy access to the region’s main cities, in addition to having two ports at the main gateway to the southern Atlantic coast, with direct access to the Paraná-Paraguay-Uruguay waterway. In addition, the modern Carrasco airport and the densest road transportation network in Latin America are other attributes to be highlighted in terms of infrastructure. Uruguay is the ideal solution for a hub in the Southern Cone to complement the northern hub (Panama).

In addition to the purely pharmaceutical activities, there are also those related to the transit of cannabis-based medicines. Uruguayan legislation provides for the promotion of these activities in Decree 282/2020, which governs the regulation and control of logistical operations with therapeutic medical cannabis products in customs warehouses authorized by the Ministry of Public Health (MSP) and the IRCCA. This way, warehouses will be able to receive imports -with the prior authorization of the MSP- to be redistributed in the region.

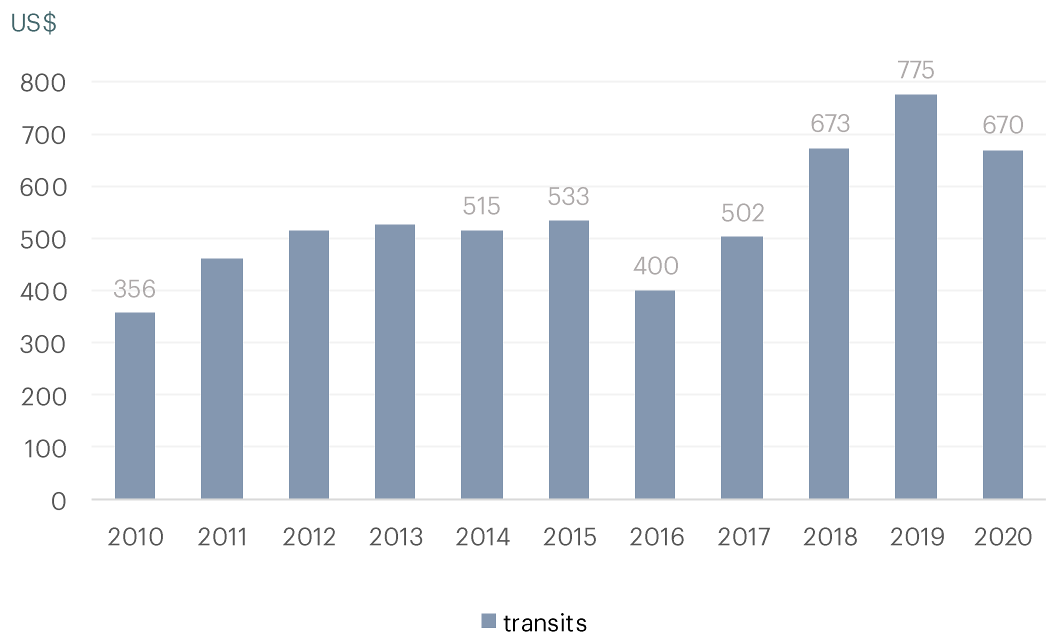
This scheme would enable, for instance, the entry of medical cannabis products into the Brazilian market, whose imports are specific for each patient. The hub makes it possible to import complete batches, split them up and carry out operations between Uruguay and Brazil.

DIAGRAM 2 - TRADITIONAL LOGISTICS VS. STM LOGISTICS



Growth of this business sector can be clearly seen in chart N°3. Transit of pharmaceutical products presented a sustained growing trend from 2010 to 2015, going from 356 to 533 million. In 2016 a drop is observed, and then it resumed a sustained growth from 2017 to 2019 reaching a peak of 775 million. Last five-year average is US$ 600 million. In 2020, transit of pharmaceutical products reached US$ 670 million, an almost threefold increase of the amount exported by the sector. This business model has established itself as an outstanding alternative for companies serving the sector in the region.

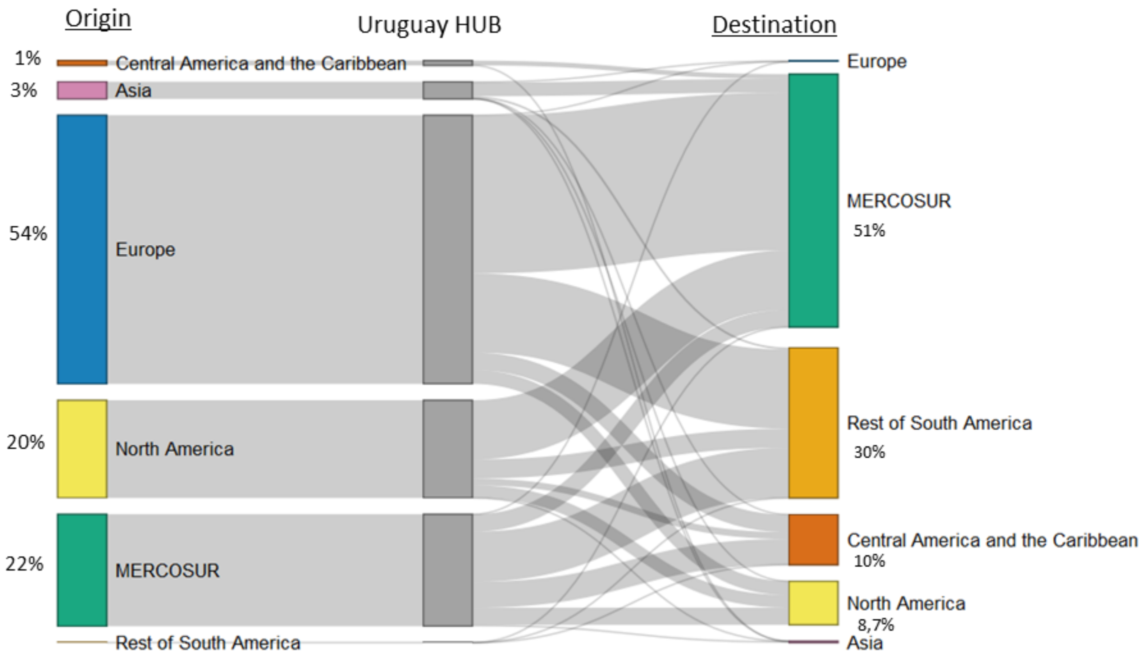
CHART N°4 - TRANSITS AND EXPORTS OF PHARMACEUTICAL PRODUCTS - 2010|2020




Source: Prepared by Uruguay XXI based on information from the National Customs Directorate (DNA).

The main transit flows of pharmaceutical products enter the continent from Europe and the United States and are destined to Brazil and Argentina.

DIAGRAM N°3 - TRANSIT FLOWS - PHARMACEUTICAL PRODUCTS




Source: prepared by Uruguay XXI based on DNA.

In 2020, transit operations were concentrated in 10 companies, which accounted for more than 98% of operations. The cases of Adium Pharma, AstraZeneca and Sanofi stand out.

Adium Pharma **Adium Pharma,** established in Uruguay (Zonamerica), is a regional distribution center from which the company carries out secondary packaging of finished generic drugs and raw materials, as well as their distribution to most Latin American countries.

AstraZeneca Headquartered in London, **AstraZeneca** is engaged in the marketing and distribution of specialty pharmaceuticals. Since 2016, its regional distribution center has been located in Uruguay. From here, the company develops logistics operations for the supply of finished products to Argentina and Brazil. The cargo coming from Europe by air and sea is consolidated in trucks at the hub located inside the free trade airport, and then transported by land to Buenos Aires and Sao Paulo.

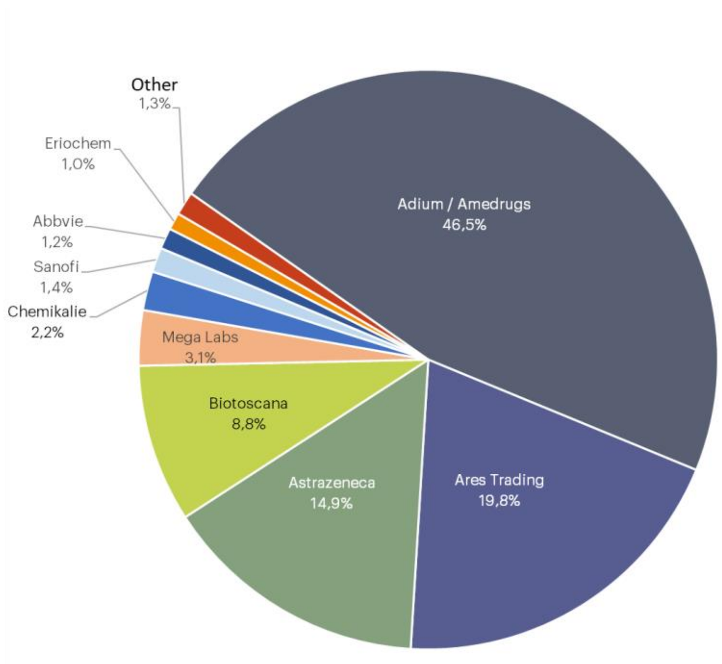
SANOFI **Sanofi Aventis**. This French-German company operates in seven main therapeutic areas (cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines). It is promotes its products in Uruguay through its own sales representatives, and conducts logistics hub activities. Its flows have been focused on the bringing pharmaceuticals from Europe to South America, mainly Argentina.

## TABLE N°2 - MAIN ORIGIN - DESTINATION FLOWS, 2020

| Origin | Destination | US$ millons | % of total |
|---|---|---|---|
| United States | Brazil | 73,3 | 10,9% |
| Ireland | Argentina | 50,9 | 7,6% |
| Switzerland | Colombia | 42,8 | 6,4% |
| Sweden | Brazil | 30,1 | 4,5% |
| Argentina | Panama | 27,1 | 4,0% |
| Italy | Brazil | 26,7 | 4,0% |
| Argentina | Ecuador | 24,4 | 3,6% |
| Argentina | Mexico | 23,0 | 3,4% |
| Germany | Argentina | 20,8 | 3,1% |
| Italy | Argentina | 17,8 | 2,7% |
| Argentina | Brazil | 17,6 | 2,6% |
| Argentina | Colombia | 17,3 | 2,6% |
| United States | Mexico | 16,9 | 2,5% |
| China | Brazil | 15,9 | 2,4% |
| Germany | Brazil | 15,7 | 2,3% |
| United Kingdom | Brazil | 12,3 | 1,8% |
| Argentina | Peru | 11,4 | 1,7% |
| Switzerland | Chile | 11,2 | 1,7% |
| Italy | Mexico | 10,9 | 1,6% |
| Switzerland | Argentina | 10,1 | 1,5% |
| Others | | 193,7 | 29% |
| Total | | 669,8 | 100% |

Source: Uruguay XXI based on information provided by DNA.

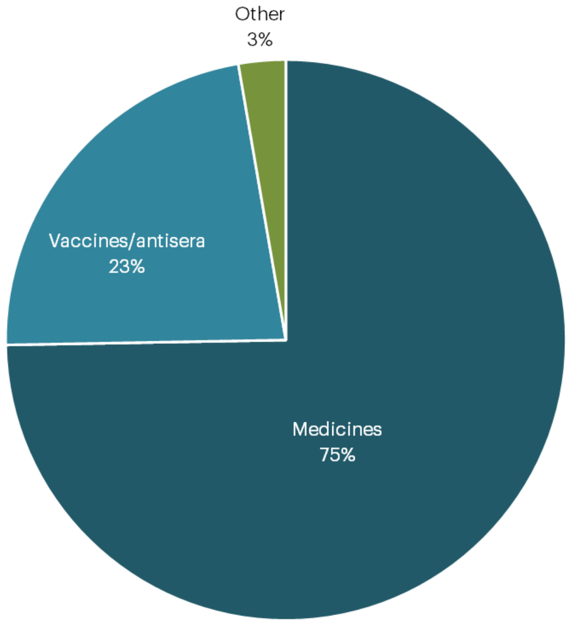
## CHART N°5 - MOVEMENTS IN THE PHARMACEUTICAL HUB BY COMPANY - 2020




Source: Uruguay XXI based on information provided by DNA.

A large percentage of exports is focused on final products, while only 3% corresponds to raw materials for pharmaceutical manufacturing. Transit of veterinary products is almost nonexistent, and all of it corresponds to products for human use.

CHART N°6 - TRANSITS BY PRODUCT TYPE
2020




Source: Uruguay XXI based on information provided by DNA.

## 3.2 Trading and global service centers

Uruguay has several cross-cutting strengths for the development of business-related services activities, generating opportunities to conduct captive operations as regional headquarters or service centers (e.g., foreign trade, supply chain, finance and accounting, human resources, customer service, and research and analysis) to support regional and global businesses.

The country is positioned as a reliable platform for the provision of high-quality services at competitive costs. This has allowed international companies to establish service centers, improving their business processes and regional insertion.

In the pharmaceutical field, some companies with regional distribution centers have incorporated support and/or commercial service activities without transferring merchandise, while others develop only this type of services without physical operations. The cases of Abbott, Adium, Grupo Biotoscana, Megalabs, Megalabs[7] and Merck stand out.

**Abbott** is a global healthcare company dedicated to the discovery of new medicines, technologies and ways of managing healthcare. Its product portfolio ranges from nutritional supplements and laboratory diagnostics to medical devices and pharmaceutical therapies. In 2015, the company set up its regional offices in Zonamerica and currently supports all Latin America and the Caribbean in finance, procurement, sourcing and distribution, and quality control activities.

**Grupo Biotoscana** is a multi-Latin company engaged in trading and marketing of international companies' product licenses, distributing oncology, HIV, rare disease, and respiratory products for Latin America. They were acquired by Knight Therapeutics, a Canadian company. In Uruguay, they have a RDC and a Supply Chain managed through a logistics provider in Parque de las Ciencias, as well as regional offices in WTC Free Zone.

Established in Zonamerica since 1996, **Merck** operates in Uruguay as a regional distribution hub and as a provider of regional and global corporate services. Its operations have expanded steadily, in line with the company's growth in Latin America. Currently, 175 people work on all its platforms. With respect to logistics, Merck carries out packaging and distribution activities in the country for biotechnology products manufactured in Europe, which are then shipped to various countries in the region. In terms of services, the company has been operating a center for corporate services (Merck Business Services LATAM) since 2018, which include commercial activities, procurement, financing and administration, supply chain and legal support for the region.

**Roche** has a regional distribution center (RDC) in Uruguay, which coordinates all logistics operations in Latin America and manages the supply chain from production centers to its regional subsidiaries. The main activities of the RDC include: order management, invoicing and customer service. The center has three different departments: Intrafirm Operations, Supply Chain, and Transportation. Each area works in strict alignment with regional interests and requirements.

## 3.3 Domestic market

Another operation that can be classified within the trade and services hub is the domestic distribution of foreign pharmaceutical products. This is often carried out by local representatives of international laboratories that do not have production plants in the country and import their products to supply the domestic market.

In addition to the international pharmaceutical companies that participate in the aforementioned sectors and also distribute in the domestic market, other international laboratories have commercial offices in Uruguay. Within the human use pharmaceutical category, we can mention: Bayer, Boehringer Ingelheim, Pfizer, Johnson & Johnson or MSD. Among the veterinary pharmaceutical companies, we find Biogénesis Bagó, Zoetis and Labyes, which are the most important examples.

## 3.4 Specialized suppliers

For setting up and developing activities related to the trade and services hub, there are different business platforms and specialized suppliers for the pharmaceutical logistics chain. This business and support services ecosystem offers support to those companies setting up in the country throughout the logistics chain according to the degree of specialization required. This makes the country even more attractive for this demanding industry, and allows constantly improving the services provided. The following is a list of suppliers who provide services to foreign companies:

**Parque de las Ciencias**[8] covers an area of 55 hectares and is located in the department of Canelones, on 101 highway and only one kilometer away from the Carrasco International Airport, which makes it a strategic location. It has the capacity to accommodate commercial, industrial and service activities. Its construction began in mid-2010, with pioneering projects in the production and development of medicines for human use and others related to life sciences, animal health and -in recent years- to the production of medicinal cannabis. The park is currently home to more than 50 users in various fields of activity and employs approximately 1,000 people.

There are currently more than 50 users operating in the park, with a wide range of activities and approximately 1,000 employees. Among them, there are several

[8] Source: Information provided by Parque de las Ciencias Free trade zone. Link

pharmaceutical and technology companies, raw material suppliers, medical device retailers, logistics operators and service providers, among others.

**Zonamerica**[9] is a free trade zone with more than 30 years of experience that includes more than 350 companies from different industries: pharmaceuticals, biotechnology, logistics, financial services, IT, among others. With a strategic location, just 5 minutes from Carrasco International Airport and 40 minutes from the International Port of Montevideo, it produces more than 68% of the movements of farma*. It is characterized by a flexible and scalable ecosystem, which allows the operation of different complementary activities of the same business; logistics, value addition, distribution and commercialization centers, as well as shared services centers

**MVD Free Airport** is the only free airport in South America. It is a strategic business unit of Terminal de Cargas del Uruguay (TCU) dedicated to the commercialization and provision of regional distribution services in several industry verticals, including pharmaceuticals, clinical trials, animal health, medical devices, high technology and spare parts.

**Selenin** is a logistics operator specialized in pharmaceutical products (medical equipment, diagnostic reagents, therapeutic devices, cosmetics, nutritional supplements, food, etc.) founded in 2008. It operates under the free trade zone regime and is located in Parque de las Ciencias. Its services range from the storage of raw materials and pharmaceutical specialties to the secondary packaging of finished products.

**Costa Oriental**, headquartered in Zonamerica and Colonia free trade zone, is a major logistics operator in Uruguay. The company currently operates as a regional distribution center for international companies in a wide variety of sectors (pharmaceutical, chemical, electronics, retail, response and raw materials), optimizing logistics costs by combining regional inventory from Brazil, Argentina, Chile, Paraguay and Uruguay in its facilities.

**Grupo RAS** is an international company specialized in the planning and management of logistics services since 1991. The company offers customized solutions in infrastructure and warehousing; customs; regional and international distribution; maritime, air and ground transportation; foreign trade services and industrial projects.

[9] Source: Information provided by Zona Franca Zonamerica. Link

**Farmalog** is a pharmaceutical warehousing and logistics company founded in 2010. Its facilities (located in Zonamerica) include a 3,000 m2 warehousing plant and a quality control laboratory.

**Supramar** is a Uruguayan company with 25 years of experience that offers logistic solutions to national and international companies under the free port and free zone regime for goods in transit; from its domestic warehouse for nationalized products. It also provides local distribution services (only in Uruguay) using its own fleet of trucks.

**Va-Q-Tec** is a German company specialized in high-efficiency thermal containers and boxes for temperature-controlled logistics that expanded its global presence in 2018 with a new headquarters and operations center located at MVD Free Airport from where it offers solutions for the transportation of pharmaceutical products to its various customers in Uruguay, Chile, Argentina, Paraguay and Brazil. Its facilities in Uruguay serve as a key point for va-Q-tec's rental services in Latin America and as a logistics distribution hub for the Southern Cone.

**Cold Chain Technologies** is a global provider of advanced thermal packaging solutions for the shipment of temperature-sensitive drugs, vaccines and biological products, primarily serving the pharmaceutical industry. In Uruguay, the company operates its regional distribution center through a 3PL provider (Farmalog) located in the Zonamerica free trade zone.

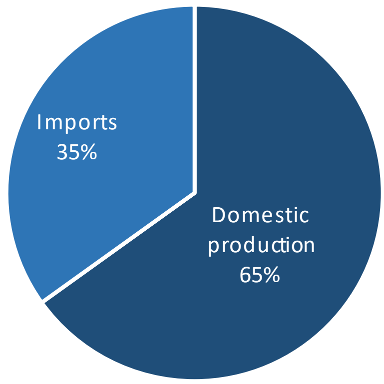
# 4. PRODUCTION AND INNOVATION HUB

The total pharmaceutical market value in Uruguay reached US$ 828 million in 2020, of which 65% corresponds to domestic production and the remaining 35% to imports. These figures correspond to both human and animal health products.

Of these products, US$ 136 million are exported, the rest supply the domestic market. It should be clarified that this analysis does not include pharmaceutical products produced in free trade zones, since they are sold entirely abroad. As explained below, about US$ 93 million are produced and exported from free trade zones (year 2020).

TABLE 3 - PHARMACEUTICAL MARKET STRUCTURE

| Uruguayan market structure in 2020 (US$ millions) | | | |
|---|---|---|---|
| | Total | Human | Animal |
| Domestic production | 539 | 431 | 108 |
| Imports | 289 | 182 | 36 |
| Market size | 828 | 613 | 144 |
| Apparent consumption | 692 | 546 | 74 |
| Exports | 136 | 67 | 69 |
| Exports ZZFF | 93 | 93 | 0 |




ote (*): Exante projections

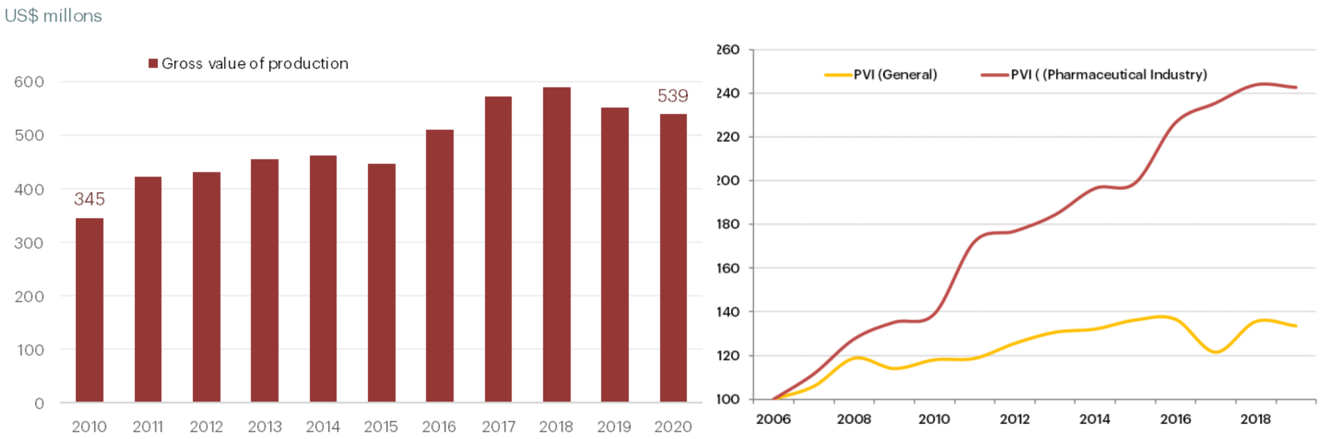
Source: Prepared by the author based on information provided by Customs and Exante.

This table does not include the medical equipment, which is mentioned below. If exports of these devices (US$ 28 million) and exports of pharmaceutical products made from free trade zones were included, total exports in 2020 would reach about US$ 258 million, and the total production value would amount to US$ 660 million.

The Gross Value of Production (GVP) of the pharmaceutical industry reached US$ 539 million in 2020, according to estimates by the consulting firm EXANTE. This represents 9.8% of industrial GDP and more than 1% of Uruguay's GDP. Although in the last two years there has been a drop in turnover (in dollars), the industry's trend over the last 10 years has been upward (see chart N°6). In fact, pharmaceutical industry's production -

considering its physical volume- has grown above that of the total manufacturing sector in recent years. This is the result of investments in the sector in the last decade, which exceeded US$ 326 million and were focused on new industries and research centers[10].

CHART N°7 - GROSS VALUE OF PRODUCTION AND PHYSICAL VOLUME INDEX (MILLION US$ AND BASE 2006=100)



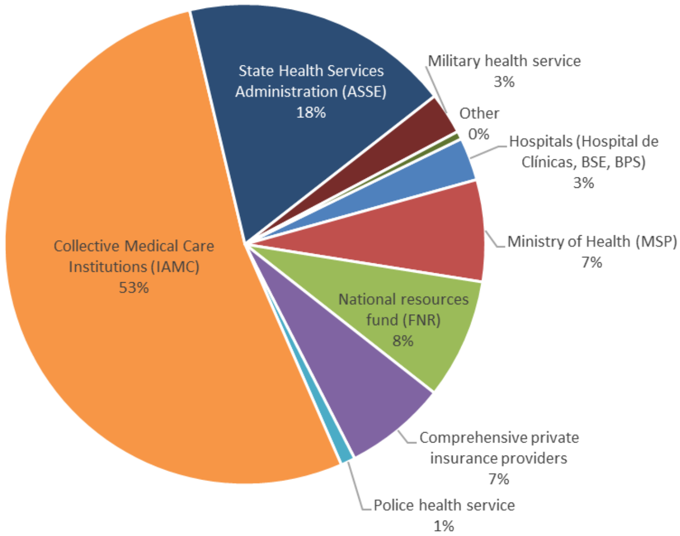

Source: Uruguay XXI based on information provided by Exante and National Institute of Statistics (INE).

Regarding drug spending, the role played by the health system's stakeholders in Uruguay is important. The National Integrated Health System (SNIS) provides coverage to all inhabitants through a mixed public-private system. The main public healthcare organizations are the State Health Services Administration (ASSE), the Military Health Service, the Police Health Service and the Hospital de Clínicas. The private sector is made up of Collective Medical Care Institutions (IAMC) and private insurance providers.

According to data from the Ministry of Public Health (Ministerio de Salud Pública, MSP)[11], spending on medicines and pharmaceutical supplies by the Uruguayan health system reached 16.503 billion pesos (US$ 469 million) in 2019. This represents 8% of the health system's total current spending.

[10] Source: Ministry of Economy and Finance – Committee for the Enforcement of Investment Law (MEF - COMAP) || Investments by Mega Pharma, for US$ 110 million, and Eriochem, for US$ 7.5 million, both in free trade zones, are also included.
[11] Health Accounts 2018-2019: Health spending and financing in Uruguay, MSP.

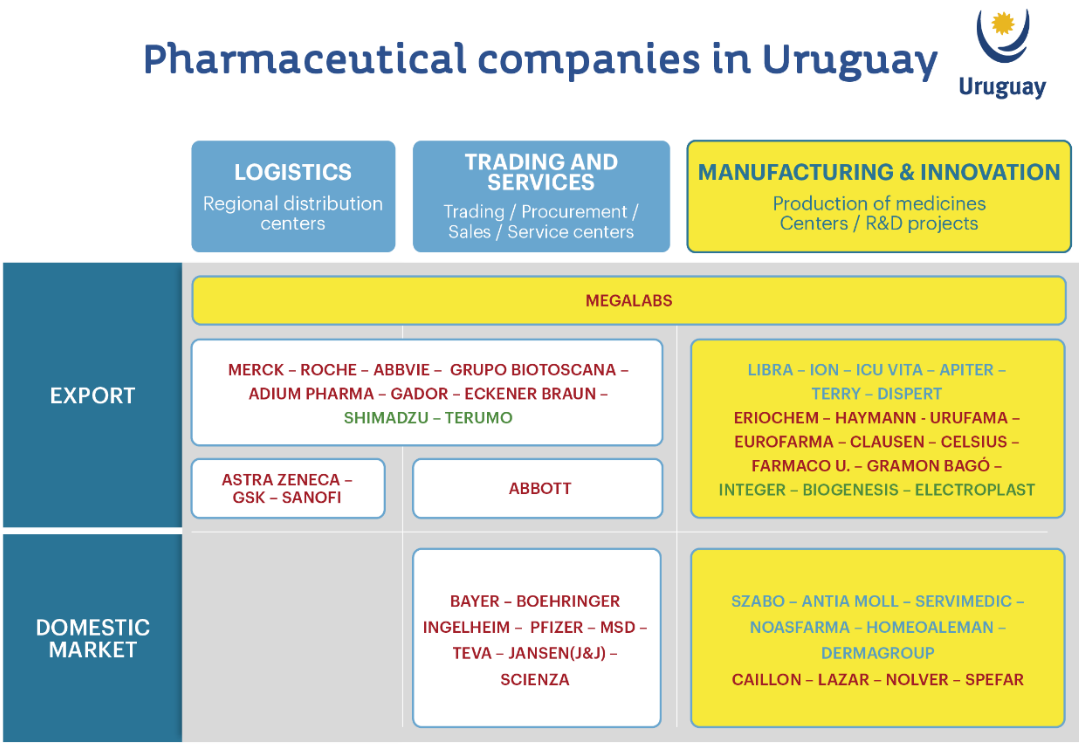
CHART N°8 - SPENDING ON MEDICINES AND PHARMACEUTICAL SUPPLIES BY HEALTH CARE PROVIDER (YEAR 2019).




Source: MSP

## 4.1 Human use

Human pharmaceutical manufacturing is the longest-standing segment of the pharma industry in Uruguay. The first companies started operating in Uruguay in the late 1960s. Over the last few years, following an international trend, multiple mergers and acquisitions (M&A) have taken place in the local market, with domestic and international companies absorbing smaller domestic laboratories.



Within the pharmaceutical industry, drugs for human use account for approximately 80% of total production[12].

The national drug regulatory authority in Uruguay is the Department of Medicines of the Ministry of Public Health (MSP). This agency grants authorization to companies importing, representing, producing, processing and marketing drugs, which must be registered with it. There are some 93 companies authorized by the MSP for these purposes[13].

Some 34 companies participated in the manufacturing sector in 2020; this figure has remained stable in recent years despite the fact that domestic laboratories are being acquired by foreign companies, since the former remain as independent business units of the latter. Of the total number of manufacturing companies, about half of them are exporters, and the others serve exclusively the domestic market.

Thus, 16 companies participated in the sector's exports in 2020[14], totaling US$ 160 million, which represents 2% of the country's exports. Although most of them export domestically manufactured products, some examples such as Abbvie and Roche export products that have been manufactured abroad, thus their activities are comparable to foreign trade. Regarding employment, according to the Ministry of Labor and Social Security (MTSS), about 3,550 people are employed by this sector. About 2,700 of these work for export companies.

Concerning the industry model, pharmaceutical labs (human use) are mainly comprised by multinational companies developing products with worldwide patents, or local companies manufacturing and/or selling similar or generic pharmaceuticals. The former are grouped in the Chamber of Pharmaceutical Specialties and related products (CEFA). The latter are grouped in the National Laboratory Association (ALN).

The main customers are primarily the foreign market, the government, private health service suppliers (*mutuas*) and drugstores.

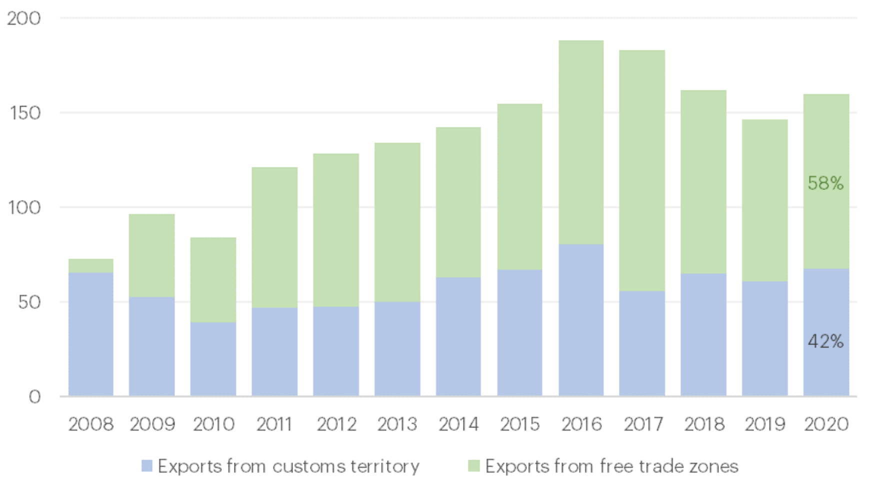
Since 2010, human pharmaceutical exports have systematically exceeded 100 million dollars, specially driven by several companies opening in Zonamérica and Parque de las Ciencias free trade zones. The free trade zone regime enabled dynamic operations and a significant synergy among the pharma companies.

Products exported from free trade zones enter under the "in transit" regime and may be subject of certain intermediate operations before being exported.

---

[12] Own estimate based on INE's Annual Survey of Economic Activities 2018.
[13] The list of medicines, together with the responsible laboratories, is available online: LINK
[14] Only companies with more than 90% of their exports linked to pharmaceutical products, and with exports of more than US$ 100,000 in the year, are considered.

CHART 9 - EXPORTS OF PHARMACEUTICAL PRODUCTS - HUMAN USE (MILLIONS OF US$)



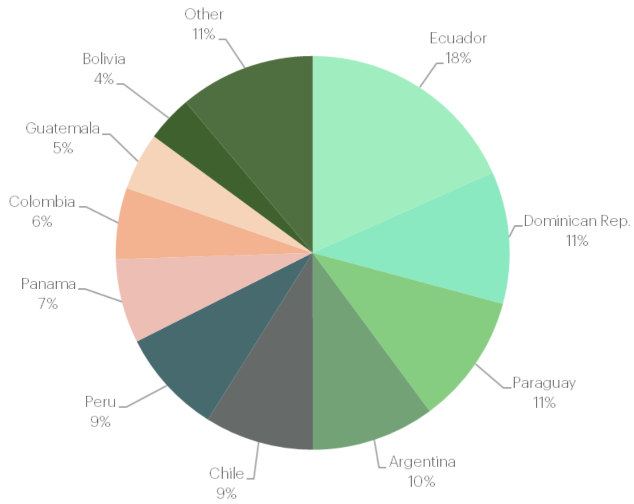

Source: Prepared by Uruguay XXI based on data from the National Customs Directorate and INE.

In total, exports of human pharmaceuticals increased from US$ 84 million in 2010 to US$ 160 million in 2020. Five of the 18 exporting companies accounted for almost 90% of exports in 2020. Likewise, 95% of exports were conducted by foreign companies.

Uruguayan exports are basically concentrated in two products: medicines and vaccines. Nearly 90% of exports in the human-use segment correspond to medicines, which include a wide range of applications and uses. In turn, 12% of exports correspond to vaccines.

Moreover, they mainly go to other countries in the region. In 2020, 70% of total exports went to South America, with Ecuador, Paraguay and Argentina standing out as the main destinations. Central America also has a relevant share as a destination, with 27% of total exports in 2020. The Dominican Republic, Panama and Guatemala are the main markets in this region.

## CHART N°10 - EXPORTS OF HUMAN PHARMACEUTICAL PRODUCTS BY DESTINATION - 2020




Source: Uruguay XXI based on information provided by the National Customs Directorate.

The number of exporting companies has been increasing over the last three years. However, the main exporting company - Megalabs - maintained a similar market share in the human-use segment during this period, at around 55%. Furthermore, the Megalabs group controls other companies, some of them exporters, bringing its total share in the human-use segment to around 70%.

## TABLE N°4 - URUGUAYAN EXPORTS BY COMPANY

| | 2018 | 2019 | 2020 |
|---|---|---|---|
| Exporting companies | 14 | 16 | 18 |
| MegaLabs S.A | 55% | 56% | 55% |
| Iclos Uruguay | 12% | 11% | 14% |
| Urufarma | 13% | 13% | 10% |
| Fármaco Uruguayo | 5% | 7% | 7% |
| Gador | 4% | 2% | 3% |
| Libra | 2% | 3% | 3% |
| Haymann | 1% | 0% | 1% |
| Other | 6% | 4% | 3% |

Source: Uruguay XXI based on information provided by the National Customs Directorate.

The main exporting companies today are mainly of foreign origin. The most important ones are described below.

**Megalabs** is a multi-Latin company with 17 production plants and six R&D centers in Latin America. In Uruguay, the Megalabs campus, located in Parque de las Ciencias (Canelones), is comprised by a production plant, a development center that carries out R&D projects for the entire region, a quality control sector and a corporate center conducting tasks in administrative, financial and technological areas that impact the company's operations across Latin America. The Megalabs campus in Uruguay is a space enabling the exchange of knowledge, technical updating and providing a unique infrastructure capable of hosting highly complex industrial projects.

Megalabs' presence in the country was also strengthened through the acquisition of local laboratories such as: **Celsius, Spefar, Iclos and Haymman**, all of which carry out production activities both for the domestic and the regional market.

**Eriochem** is a pharmaceutical company dedicated to the synthesis of active pharmaceutical ingredients and the production of liquid and lyophilized injectables. The company was born in Argentina and over time has expanded to produce oncology drugs for Latin America, Asia Pacific, Europe and North America.

In Uruguay, Eriochem performs secondary packaging activities and analysis of oncology pharmaceuticals to be exported to several countries. The company has a pre-filled syringe plant in the Parque de las Ciencias free trade zone, as well as its administrative and operations offices for the region.

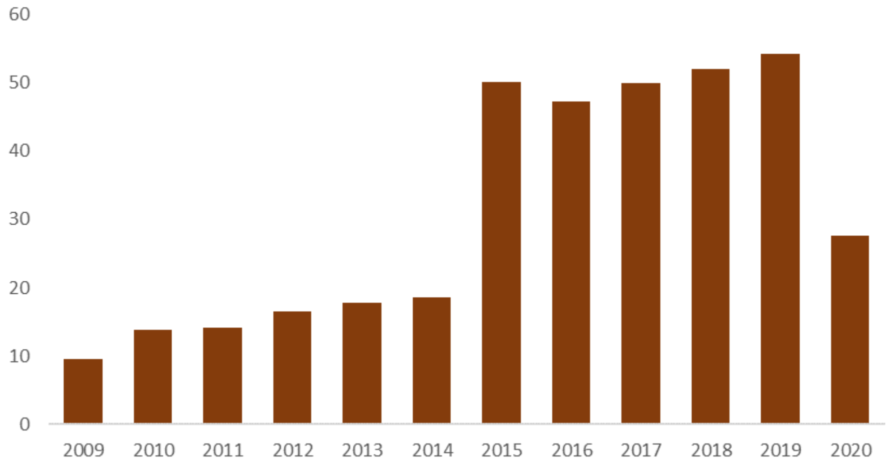
Founded in 1946, **Urufarma** is a Uruguayan company with a modern industrial complex (GMP + GLP certified) for the manufacture of oral contraceptives and other hormonal products. In addition to having a strong impact on the local market, a large part of its production is exported to countries such as Argentina, Chile, Colombia, Paraguay, Peru, Mexico and Venezuela, among others.

## Medical devices

In addition to medicines, some companies manufacture and export medical devices from Uruguay.

The significant increase in exports of these products is largely due to the company Integer that sells them to the US since 2015, after its customers achieved approval to sell medical products in that market, reaching almost U$S 50 million in 2019. From 2020 onwards, exports dropped mainly because of two reasons: (i) the impact of COVID-19 that led to the cancellation or delay of surgeries, impacting the demand for its products, and (ii) a change in this company’s operational strategy that focuses more on exporting the design of devices and low volume production, transferring high volume production to other plants of the corporation. These design services are not reflected in the exports of goods, which totaled US$28 million.

CHART N°11 - URUGUAYAN EXPORTS OF MEDICAL DEVICES (MILLIONS U$S)




Source: Uruguay XXI based on information provided by the National Customs Directorate.

The remaining exports of these items are concentrated in two other companies, Electroplast and Biogenesis, which increased their share of exports in 2020.

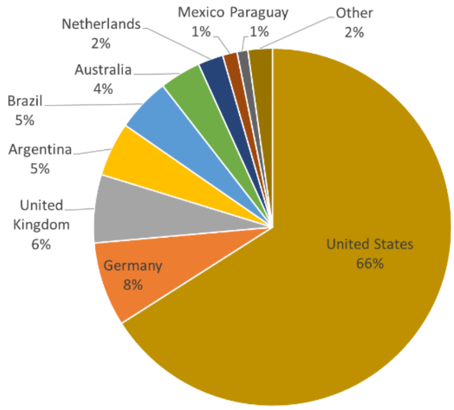
TABLE 5 - EXPORTS BY COMPANY

| Exporting companies | 2018 | 2019 | 2020 |
|---|---|---|---|
| Integer | 90% | 90% | 81% |
| Electroplast | 6% | 6% | 11% |
| Biogénesis | 1% | 1% | 3% |
| Covidien Uruguay S.A. | 0% | 1% | 1% |
| Emedical S.A. | 0% | 0% | 0% |
| Other | 3% | 2% | 4% |

Source: Uruguay XXI based on information provided by the National Customs Directorate.

As for the destinations of these products' exports, developed countries stand out as the main buyers of devices produced by Integer. Electroplast and Biogenesis, on the other hand, are more focused on the region.

CHART N°12 - URUGUAYAN EXPORTS OF MEDICAL DEVICES - 2020




Source: Uruguay XXI based on information provided by the National Customs Directorate.

In total, these companies directly employ close to 450 employees. The most important characteristics of these companies are as follows:

With more than 35 years in the market, Integer Montevideo (formerly CCC Medical Devices) is dedicated to the design and manufacture of implantable medical devices. The company serves mainly the U.S. market and has 250 employees, out of which 60 are engineers (electrical, systems, mechanical and chemical) dedicated to R&D activities.

Electroplast S.A. is a worldwide supplier of medical devices for hospital services in different specialties. Its products are used in anesthesiology, urology, surgery, gastroenterology, emergency care, adult and pediatric intensive care. In its factory in Uruguay, the company employs more than 130 people, being one of the domestic companies in its field, who has ISO and CE (European Community 93/42/EEC) certification.

Its export markets are: Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Egypt, Germany, Kazakhstan, Lithuania, Mexico, Nicaragua, Paraguay, Peru, Trinidad and Tobago and Turkey.

Biogénesis (2002) is engaged in the design and production of medical devices for oxygen saturation, temperature, electrocardiogram, invasive arterial pressure, non-invasive arterial pressure and electroencephalogram. The company currently employs about 20 people and has two lines of business: the manufacture of original and compatible products. In both cases they are positioned as a company strongly focused on quality.

Biogenesis exports to more than 70 countries through a wide network of distributors (345) worldwide.

## 4.2 Veterinary use

The veterinary pharmaceutical manufacturing sector in Uruguay focuses mainly on the production and marketing of treatment products, which are widely used both for pets and for those animals that are part of some of the main productive activities in the country -cows, horses, sheep, etc.-.

The health authority for veterinary drugs is the Ministry of Livestock, Agriculture and Fisheries (MGAP) through its Veterinary Laboratories Division (DILAVE). Companies engaged in the processing, fractioning, import and distribution of veterinary products must request authorization from this agency. At present, 142 companies in these areas are authorized.

The veterinary pharmaceutical production sector in Uruguay is made up of some 33 companies[15] which produce a wide range of products such as medicines, vaccines, as well as serums and proteins for animal use. In the veterinary segment, there is no record of companies operating under the free trade zone regime.

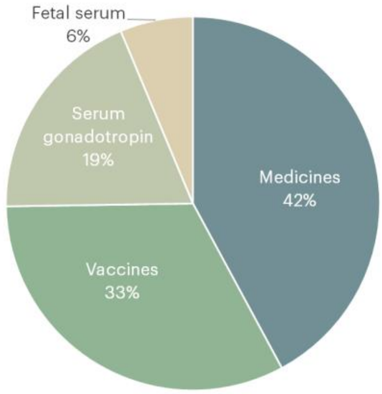
This segment employed about 1,350 people in 2020. Only two companies employed more than 100 people, while the vast majority employed between 10 and 30 employees. Companies marketing a single product within the segment - primarily bovine serum and gonadotropin - employed fewer than 10 employees directly.

The animal pharmaceutical manufacturing segment accounts for about 20% of total production. The estimated PPV is US$ 110 million. Meanwhile, exports in 2020 were carried out by 21 companies, which exported a total of US$ 70 million. The veterinary pharmaceutical segment also shows a relative concentration of exporting companies, although less than in the human pharmaceutical segment. In this case, five companies accounted for 80% of last year's exports.

In terms of products, the segment presents a relative variety, ranging from medicines per se to vaccines, as well as proteins and supplements for both feed and animal performance. One example is PMSG, serum gonadotropin, which together with bovine fetal sera accounted for a quarter of the segment's exports last year.

[15] Companies that are qualified to produce veterinary specialties, but that is not their main line of business are excluded from this group. For example, laboratories of pharmaceutical products for human use, producers of food or cleaning products.

CHART N°13 - VETERINARY SEGMENT EXPORTS BY PRODUCT - 2020

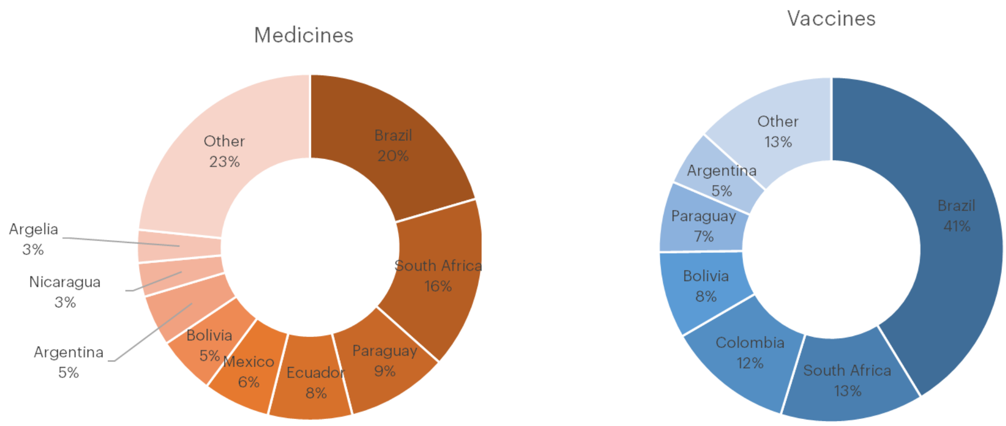



Source: Uruguay XXI based on information provided by the National Customs Directorate.

In 2020, veterinary pharmaceuticals reached more than 50 markets. More than half of total exports went to South America, with Brazil, Paraguay and Argentina as the main destination markets. Vaccines show a higher concentration in destinations with respect to medicines, while exports of PMSG and fetal serum were concentrated in a few countries. In the first case, in 2020 exports went only to France, Brazil and Argentina, while fetal serum was destined only to China and France.

Among the medicines and vaccines that were produced in, and exported from, Uruguay, those with antiparasitic, tickcide, anti-rabies and immunobiological features stand out.

CHART N°14 - VETERINARY PHARMA EXPORTS BY PRODUCT - 2020




Source: Uruguay XXI based on information provided by the National Customs Directorate.

The number of exporting companies has remained stable in recent years. The first five companies in the ranking of exporters account for more than 80% of total exports.

TABLE N°6 - EXPORTS BY COMPANY

| | 2018 | 2019 | 2020 |
|---|---|---|---|
| Exporting companies | 22 | 21 | 21 |
| Laboratorios Microsules Uruguay S.A. | 35% | 38% | 34% |
| Virbac Uruguay S.A. | 18% | 20% | 19% |
| Syntex Uruguaya S.A. | 15% | 10% | 14% |
| Prondil S.A. (MSD Animal Health) | 10% | 10% | 9% |
| Laboratorio Biomega S.A. | 4% | 4% | 5% |
| Despro S.A. | 4% | 3% | 3% |
| Mvdmart S.A. | 1% | 1% | 3% |
| Boehringer Ingelheim Animal Health Uruguay S.A. | 1% | 2% | 2% |
| Probiomont S.A. | 1% | 1% | 2% |

Source: Uruguay XXI based on information provided by the National Customs Directorate.

These companies are both domestic and foreign and produce a variety of veterinary products. The following is a brief description of the most relevant ones.

**MSD – Prondil S.A.** is a biotechnology laboratory specialized in the development and production of vaccines for veterinary use. Mainly devoted to export activities (its products are marketed in more than 20 countries in Latin America, Africa, Europe and the Middle East), Prondil has adopted the most relevant and demanding international standards in the field of biologicals (US CFR, Ph. Eur., OIE, WHO and GMP of Mercosur). Its production plant, located in Montevideo, has state-of-the-art equipment and facilities that guarantee biosafety and environmental care.

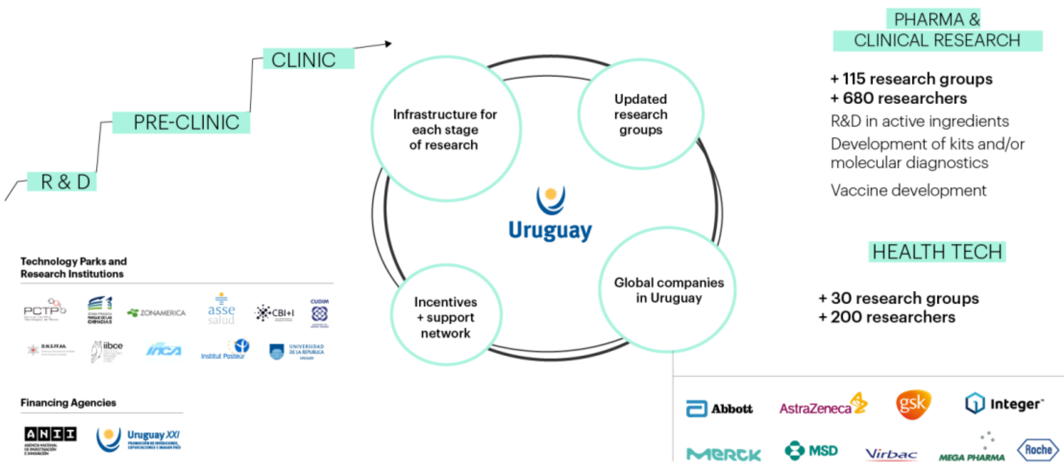
**Virbac** Uruguay (until 2010, Laboratorio Santa Elena S.A.) mainly dedicates to the production, distribution and export of animal health products. In addition to a production plant, Virbac Uruguay has a research and development center for biological products (vaccines).

**Laboratorios Microsules** has been operating in the local and international market for more than thirty years, manufacturing, synthesizing, marketing and distributing veterinary drugs. The company has six production plants in Canelones, which allow exporting its products to more than 40 countries in Africa, America, Asia, Europe and the Middle East, and a state-of-the-art experimental field with animal welfare certification.

## 4.3 R&D Ecosystem

In addition to the pharmaceutical production activities in general, there is a dynamic ecosystem that supports innovation contributing to the incorporation of new product lines or to the development of innovation projects between companies and research groups. This ecosystem includes sectors such as food, veterinary, human pharmaceutical and cannabis by-products, and has set strong foundations for innovation supported by specific institutions that favor such an environment.

DIAGRAM N°4 - ECOSYSTEM




There are more than 150 research groups that bring together more than 800 researchers, driving the emergence of startups. Research groups are capable of developing processes and products with quality control systems that meet international standards.

In Uruguay, the pharmaceutical sector has a wide network of research institutions and incubators with state-of-the-art technological platforms, as well as competent human resources. In addition to collaborating to the development of pharmaceutical-related projects, these ecosystem's stakeholders also have the capacity to provide specific training for sector personnel. This network of academic research groups and service provider startups constitute a functional innovation ecosystem for the development of projects and R&D centers focused on exporting and attracting investment.

Among these organizations are: the Pasteur Institute, the Pando Technological Pole, the Clemente Estable Institute, the Biomedical Research Center, the Uruguayan Molecular Imaging Center (CUDIM), the Technological Laboratory of Uruguay (LATU), the Hygiene

Institute and the Biotechnological Center for Research and Innovation (CBI+I). In addition, the University of the Republic has more than 145 research groups in different schools and more than 880 researchers involved.

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

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

The institute **"Polo Tecnológico de Pando"** of the School of Chemistry (University of the Republic) serves as a research, development and innovation center in the following fields: Chemistry, Biotechnology, Material Science and Environment. It specializes in the most productive industry and service sectors in Uruguay.

The institute works in the promotion and development of R&D activities through:

- Technology transfer.
- Design, development and participation in research and innovation projects, both in-house 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 **Clemente Estable Biological Research Institute** is a non-profit public institution under the Ministry of Education and Culture (MEC), which brings together several groups dedicated to research in different fields of the biological sciences with the following objectives:

- Generate and develop scientific research to obtain new knowledge in the field of life sciences and related areas.

- To train scientific and technical researchers, being a reference in science, technology and innovation at national and regional level.
- Contribute to the country's scientific and cultural development and to its scientific policy planning.

Based in the Department of Biochemistry of the School of Medicine, the **Center for Biomedical Research** (CEINBIO) works as an interdisciplinary and multi-institutional academic space where researchers and topics in the fields of chemistry, biochemistry, cell biology, physiopathology and pharmacology of oxidation-reduction processes converge. In addition, it interacts with multiple departments and research units of Schools of Medicine, Sciences, Chemistry, the Institute of Biological Research and the Pasteur Institute of Montevideo..

Among its activities, it has significantly contributed to the training of high-quality human resources. Many students completed doctoral studies at PROINBIO, PEDECIBA-Biology, PEDECIBA-Chemistry. Moreover, foreign interns (students and professors) have researched chemical, biological, pathophysiological and pharmacological aspects of free radicals and antioxidants in the different laboratories of the center.

The center also established contacts with the pharmaceutical and food industry, providing advice in the fields of Chemistry and Biology of Free Radicals and Antioxidants. The industry has also shown a growing interest in the development of antioxidant compounds that are being developed and evaluated in their laboratories, as well as in the functional analysis and antioxidant characteristics of their own natural products and foods.

The Uruguayan Center of Molecular Imaging (CUDIM) is committed to the development of research, training and applications in health sciences. In particular, the following activities are promoted:

- Diagnosis: clinical examinations to patients with public and private health insurance coverage, mainly in the areas of oncology and neurology.
- Training: to promote teaching, professional and technical improvement.
- Clinical and biomedical research: evolution of the impact of cyclotron-PET in various pathologies and in the evaluation of new drugs in research and development.

In addition to research and support institutions in the industry, there are several examples of incubators operating nationwide, which promote early-stage projects. In general, the profile of these centers is defined by their objectives, mentors and companies supported. Some of those whose profile is more closely related to the pharmaceutical sector include:

**Khem.** This incubator focuses on the development of technology-based companies. It is located on the premises of the Pando Technological Pole, and has 350m2 of laboratories for the work of incubating companies. It also has the KhemBIO platform, through which biotechnology ventures can be sponsored.

The **Centro Biotecnológico de Investigación e Innovación** (CBI+I), together with Technological University of Uruguay (UTEC) and the Centro de Innovación y Emprendimientos (CIE – Innovation and Entrepreneurship Center) of ORT University of Uruguay, are in charge of the CIE BIO incubator. This incubator promotes and implements actions for the development, strengthening and coordination of the biotechnology-based ecosystem, seeking to turn entrepreneurial initiatives into innovative ventures that add value to society.

**Technological Laboratory of Uruguay.** Organization created in 1965 as a joint effort by the public and private sectors. Its mission is to promote the sustainable development of the country and its international insertion, through innovation and the transfer of value solutions in analytical, metrological, technological, management and conformity assessment services in accordance with the applicable regulations.

**Institute of Hygiene.** It is a specialized agency of the School of Medicine of the University of the Republic (UdelaR). Its objective is health promotion and disease prevention, as well as teaching at all levels. It also carries out research work focused on health problems and creates knowledge on specific topics. Traditionally, it has been active in the field of communicable diseases. This institute was the first of its kind in Latin America and one of the first in the world.

# 5. HUMAN CAPITAL - TALENT

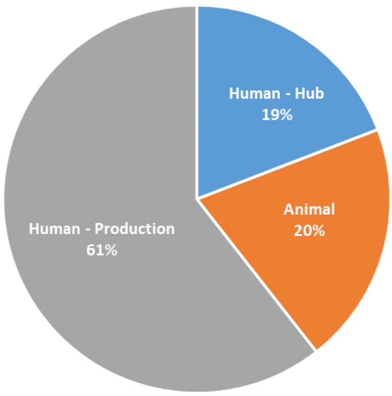
## 5.1 Employment

It is estimated that the personnel employed by the different segments of the pharma sector reaches a little bit more than 6,850 workers[16], and it is mostly highly qualified personnel. This figure does not include the indirect jobs generated by the sector, which include marketing and product sales activities, as well as health services.

The human health segment employs more staff, with more than 5,400 people, most of whom work in the export sector (some 2,700 in pharmaceutical companies and some 450 in medical equipment). For their part, companies focused on trade and services hub activities are also important generators of employment. These companies generate around 1,200 direct jobs, including the specialized suppliers in the logistics chain mentioned below. On the other hand, companies that handle the domestic distribution of foreign pharmaceuticals - often local representatives of international laboratories - employ an estimated 300 people.

Meanwhile, the animal health segment generates some 1,350 direct jobs.

CHART N°15 - EMPLOYMENT IN THE PHARMACEUTICAL SECTOR - BY SEGMENT

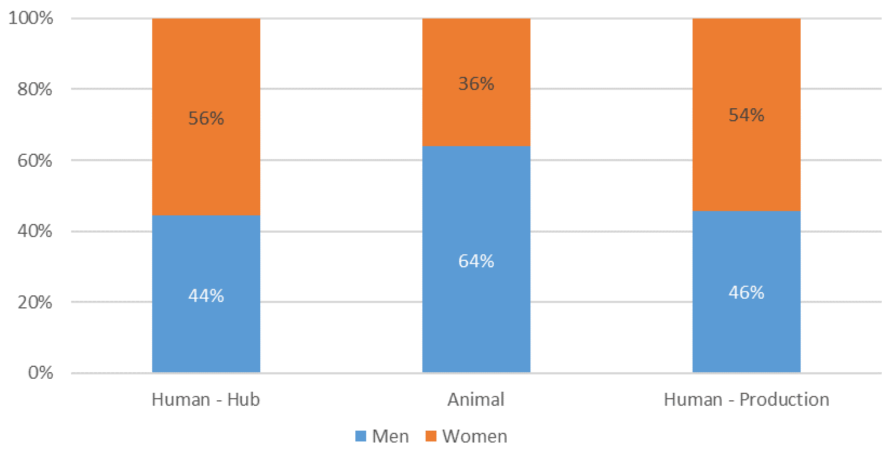



Source: Uruguay XXI based on MTSS data.

The gender distribution shows a general parity in the pharmaceutical sector, with 51% of men and 49% of women working in the sector. Distribution within each segment can be seen in Chart N°14, which shows a higher participation of women in the segment with the highest labor demand, human manufacturing.

[16] Data as of June 2021. Based on data from the Ministry of Labor and Social Security (MTSS) and information provided by the companies.

CHART N°16 - DISTRIBUTION OF PERSONNEL BY GENDER AND SEGMENT




Source: Uruguay XXI based on MTSS data.

## 5.2 Education

The development of the pharma sector in Uruguay generated a growing educational market aiming at quality training according to the high demands of the industry.

For the services sector associated with the pharmaceutical and health industry, we are considering university courses directly related to this segment, such as research services, manufacturing or the provision of health services.

It should be noted that other university courses, such as those associated with business services and ICT, are also relevant to this segment. These provide professionals for shared service centers that develop foreign trade activities, supply chains, administration and accounting, human resources management or market analysis associated with the pharmaceutical sector.

TABLE N°7 - NUMBER OF UNIVERSITY STUDENTS - 2019

| Studies related to Pharma and Health | |
|---|---|
| Bachelor's degree or equivalent | |
| University schools/Training centers | 20 |
| Total enrolled students | 53.689 |
| Total admissions | 9.828 |
| Total graduating students | 2.097 |
| Master's or Postgraduate degrees | |
| Students enrolled | 2.731 |
| Total annual enrolled students | 1.342 |
| Total annual graduating students | 759 |

Source: prepared by Uruguay XXI based on information provided by the Ministry of Education and Culture - "Anuario Estadístico de Educación 2019."

More than 56,000 students are enrolled in courses directly related to pharmaceutical and health services. Medicine studies clearly prevail over the other university courses associated with the sector. In addition to the volume of annual graduates, there is a high level of university students in the labor market with many of the skills required for this business segment.

TABLE N°8 - STUDENTS BY FIELD - 2019

| | **Undergraduate or Graduate/Master's Degree** |
|---|---|
| Agro/Food | 5.401 |
| Biotechnology | 346 |
| Life Sciences | 2.146 |
| Medicine | 15.336 |
| Chemistry/Biochemistry | 6.777 |
| Veterinary | 5.093 |
| Other - Human Health | 21.321 |
| Total associated with the sector | **56.420** |

Source: prepared by Uruguay XXI based on information provided by the Ministry of Education and Culture - "Anuario Estadístico de Educación 2019."

The technological development of the sector has resulted in a greater demand for highly qualified labor. In this sense, a wide range of related careers and educational institutions make up the sector's education ecosystem:

**University of the Republic (UdelaR).** Several schools have research groups linked to the sector, focused on basic and applied research. Chemistry, Science, Veterinary Medicine, Engineering, Agronomy and Medicine schools are among these. These research groups carry out teaching, research, dissemination and engagement activities with the productive sector for the solution of specific problems in industrial food production.

The **Technological University of Uruguay (UTEC)** has a public university higher education proposal with a technological profile, oriented to research and innovation. As for its link with the sector, through several careers in different departments of the country, it has developed laboratories, undergraduate and graduate programs according to the needs of companies, cooperatives, among others.

In the private sector, **ORT University** is the only one that offers Biotechnology degrees (undergraduate and engineering) in its engineering school. The university has an academic infrastructure that includes laboratories for practice and experimentation in biotechnology.

The **Catholic University of Uruguay** offers health related academic programs in its Schools of Health Sciences and Dentistry. In them, the university offers nursing, dentistry and psychology degrees, among others.

**Universidad de la Empresa** offers physiotherapy, imaging and physiotherapy degrees at its School of Health Sciences in Montevideo and Colonia.

**CLAEH** is the only private university with a degree in medicine in Maldonado.

# 6. GENERAL AND SECTORAL REGULATORY FRAMEWORK

## 6.1 Incentives

### Promotion of domestic and foreign investments

Uruguay has a legal and incentive framework very that is well aligned with the needs of companies setting up in the country.

The Investment Law No. 16,906 (1998), which declares the promotion and protection of domestic and foreign investments to be of national interest, is one of the main incentives for investments. One of its main characteristics is that foreign investors are granted the same incentives as local investors, and there is no tax discrimination or restrictions for the transfer of profits abroad. Decrees 455/007, 002/012, 143/018 and 268/020 updated the rules of this regulation. This regime allows the investor to pay less tax on corporate income and wealth.

Thus, for all investment projects under this regime and promoted by the Executive Power, it is possible to consider 30% to 100% of the amount invested as part of the tax payment (IRAE - tax on income from economic activities), depending on the type of project and the score obtained based on different indicators present in a matrix. The fixed rate of IRAE at the national level is 25%.

Wealth tax on movable fixed assets and civil works is also exempted, and the VAT included in the purchase of materials and services for civil works may be refunded. In addition, movable fixed assets that have been declared non-competitive with domestic industry are exempted from import duties or taxes.

### Free trade zone regime

Free trade zones are part of a set of policies whose main objective is to encourage investment in Uruguay, which include the Investment Promotion and Protection Law, free port and free airport regimes, the Public-Private Participation Law (PPP), the Industrial Parks Law, among others.

The first two free zones in Uruguay were established in 1923 by Law No. 7,593 with the purpose of developing industrial poles in different provinces of the country. Later they were reformulated by Law № 15.921 of December 17, 1987.[17] and Regulatory Decree

[17] Law 15.921

454/988 of July 8, 1988. In December 2017, and through Law No. 19.566[18] the regulation was updated.

Free trade zones may be operated by the State or by duly authorized private individuals. The private ones are managed by individuals and authorized by the government, which supervises and controls them through the Free Trade Zone Department of the General Directorate of Commerce[19]. For establishing a free zone in Uruguay, a governmental resolution is required, detailing information such as: period of authorization of operation, area occupied by the free zone, minimum investment to be made by the operator(s) and the fee to be paid by the operator(s), among others.

The interested party in carrying out activities in a free zone must submit to the government the authorization application accompanied by an investment project that proves the undertaking is economically and financially viable and the benefits thereof for the country.

Any type of activity may be developed in the free zones: commercial, industrial or services.

Commercial activities are understood as the purchase and sale of goods or merchandise that enter the free zone where the activity is carried out or another free zone, and that have as origin and destination the outside of the national territory or the national territory. Logistic activities[20] are also included in commercial activities.

Service activities include the rendering of all types of services from the free trade zone, either within the same zone, to users or developers of other free trade zones or to third countries. According to the new law, free zone users may also provide services within the rest of the national territory[21] to companies that are IRAE taxpayers, as well as other types of services such as call centers, mailboxes, among others[22].

The companies authorized to develop activities in the free zones may be individuals or legal entities under any corporate form, with bearer shares being admitted. Through article 14 of the new law, users within a free zone are required to have as their exclusive purpose any of the activities provided for in the law. There are no difference between foreign and domestic investments, so they do not require special procedures or requirements to establish themselves.

[18] Law 19,566

[19] Website: http://www.zfrancas.gub.uy/

[20] Understood as operations that may modify the state or nature of the merchandise without implying in any case a process of industrial transformation. Art. Nº 5 - Law Nº 19.566.

[21] Monopolies, state exclusivities or public concessions must be respected. Services provided to the rest of the national territory will receive the same tax treatment as services provided from abroad.

[22] Excluding those whose only or main destination is the rest of the national territory.

The activities of free zone users are exempt from all national taxes, created or to be created, and -in particular- they enjoy the following benefits:

- Exemption from income tax on economic activities (IRAE), wealth tax (IP) and any other national tax.

- Tax exemption on dividends paid to shareholders domiciled abroad.

- Option for foreign personnel (up to 25% of the total number employed[23]) to exempt social security contributions in Uruguay. In the case of service activities, the minimum percentage of Uruguayan citizens may be 50%, when the nature of the business developed so requires it, and always seeking the highest feasible levels of participation of Uruguayan citizens.

- Sales and purchases abroad are not subject to value added tax (VAT), nor are sales and services rendered within the free zone. The update given by Law 19.566 includes in this point the sale and purchase of goods that enter the free zone, and that have as origin and destination the national territory.

- Goods traded between free trade zones and the rest of the world are exempt from customs duties.

Likewise, and as detailed in Article 25 of the law: "The State shall assure the user the tax exemptions, benefits and rights granted to it during the agreement's timeframe or shall otherwise be held liable for any damages".

Sales from the rest of the country to the respective free zones are considered exports from Uruguay, and sales from the free zones to the rest of the Uruguayan territory are considered imports, subject to the corresponding customs duties and national taxes.

Sales from free zones to Mercosur are subject to the common external tariff (CET) of the bloc that applies to goods from third countries. This is due to the fact that goods from free trade zones do not have preferential access, except for exceptions specifically established in bilateral agreements negotiated by Uruguay.

However, Decision 33/15 of July 2015 of the Mercosur Common Market Council (CMC) introduced amendments to the previous Decision 8/94 (the regulation came into effect on 07/21/2019 and is regulated by Decree 253/019[24]). This decision states that all merchandise originating from a Mercosur State party (or from a third country with the

[23] In justified cases, the percentage may be increased, with prior authorization from the government.

[24] https://www.impo.com.uy/bases/decretos-originales/253-2019

same rules of origin, as agreed with Mercosur) will not lose its originating character when it transits through a Free Trade Zone, provided that such area is under state control. In this sense, within the enclosures, only those operations intended to ensure merchandise sales, conservation, fractioning, or other operations with similar purposes, may be carried out, without altering its tariff classification or its verified originating character [25].

Prior to Decision 33/15, Uruguay already had agreements with Argentina and Brazil for certain products from the free trade zones of Colonia and Nueva Palmira (including goods produced by PepsiCo, wheat, barley, barley malt and soybeans)[26]. Sales from free trade zones are also included in trade agreements with Chile, Israel, Mexico, India, Ecuador, Venezuela and Colombia.

Finally, it is important to note that Uruguay has signed 30 Agreements for the Promotion and Reciprocal Protection of Investments (APPRIs) with third countries[27], therefore, many of the foreign companies that operate and use free trade zones are covered by these agreements.

### Free ports and airport regime

Since the Port Law No. 16,246 of May 1992 -and its subsequent regulations- entered into force, Montevideo is the first terminal on the Atlantic coast of South America to operate under a "free port" regime. This regime also applies to the commercial ports of Colonia, Fray Bentos, La Paloma, Nueva Palmira, Paysandú and Puerto Sauce, as well as Carrasco International Airport.

By operating in a free port, goods will be able to move freely without the need for authorizations or formal procedures. During their stay in the port customs area, goods will be exempt from all taxes and surcharges applicable to the import. Thus, it is possible to carry out: operations related to the goods or operations related to the services rendered to the goods.

In addition to the aforementioned customs benefits, the circulation of goods and the rendering of services carried out in port customs areas are exempt from the value added tax. Likewise, goods stored under the free port regime are not included in the taxable base of the wealth tax or income tax. Several of the agreements entered into by Uruguay, including Mercosur and that with Israel, include a system of derived certificates of origin that enable operations envisaged in the free port regime.

### Customs Warehousing

[25] See http://www.adau.com.uy/innovaportal/file/13024/1/dec_033-2015_es_zonasfrancas.pdf
[26] The agreement with Argentina only covers Z.F. Colonia.
[27] For more information see: International Agreements - Investor's Guide - Uruguay XXI. Link.

Foreseeing that the port area might be insufficient for storage and logistics activities, Decree Law No. 15,691 of 1984 (Customs Code) allowed the establishment of bonded warehouses. These are enclosed, closed or open spaces (*ramblas*), boats and pontoons (floating warehouses) and tanks where goods are stored with customs' authorization. Goods of foreign origin are considered in transit within the national customs territory and may be unloaded and reshipped at any time, free of import or export duties imposed by any domestic tax.

According to the regulations, customs warehouses may be official or fiscal, belonging to the State or leased by it, and may also be private-owned. These may also be categorized as commercial, free or industrial warehouses. The existence of special warehouses for the fractioning of packages is also permitted.

The operation of bonded warehouses is similar to that of free ports, with the difference that industrial activities may be carried out in bonded warehouses, i.e., operations aimed at changing the goods' nature, such as:

- incorporating parts, items and products from the market (such as industrialization of raw materials and semi-finished products),
- adjusting, assembling, mounting and finishing vehicles, machinery and appliances,
- any other similar processing operation.[28]

Goods may remain under this regime for a period no longer than one year, regardless of whether they are transferred to another warehouse belonging to the same or another holder[29], in contrast to the free port regime where there is no such limitation. The new CAROU proposes a new classification of warehouses that includes logistic warehouses, where changes of nature but not of origin shall be allowed.

## Refund of VAT paid on commodity purchases

VAT paid on purchases is generally recovered by deducting it from the VAT invoiced on sales made within the national territory, thus paying only the difference to the State. In the case of exports (of goods and services) this tax is not invoiced, so the refund of VAT paid in purchases of commodities is authorized directly at the company's request. The tax authority (DGI) issues credit certificates that may be used to pay other taxes.

Decree No. 220/998 lists the operations included in the "exports of services" item. By way of example, the following are mentioned: broadcasting of TV material -produced in the country- abroad; logistic support services to film and television productions of foreign companies; advisory services rendered to persons abroad; services rendered to persons abroad for the design, development and implementation of specific software; services rendered by international call centers, provided that the main activity is carried

28 Article 100 of the Customs Code.

29 Law No. 16,736 of January 5, 1996, Article 180; and Decree No. 216/06 of July 10, 2006, Article 21.

out abroad and only for what is referred to such activity; data processing; services rendered for the design, development and implementation of digital contents; market research and social research services; and, advertising services rendered by advertising agencies to clients abroad.

### Trading (Resolution 51/997)

In Uruguay, the general income tax rate (IRAE) is 25%. For trading operations, the special regime, instead of the 25% income rate, it imposes a 3% rate to the difference between the operation's sale price and its purchase price, and then applies the 25% IRAE rate to that result. Thus, the effective income tax rate is 0.75%.

This regime applies to trading operations of both products and services, as long as the following conditions are met:

- the goods do not physically move across Uruguay;
- the services are not rendered or used in Uruguay (they must be rendered or used abroad), and
- the supplier and the customer of the Uruguayan company are not from the same country.

The company must also have a physical presence in the country and be able to demonstrate it has actual operations.

### Logistical operations with medical cannabis products (Decree 282/020)

Uruguayan legislation provides for the promotion of these activities in Decree 282/020, which governs the regulation and control of logistical operations with therapeutic medical cannabis products in those customs warehouses authorized by the Ministry of Public Health (MSP) and the IRCCA. So, these warehouses will be able to receive imports -prior authorization from the MSP- to be redistributed in the region.

Customs warehouses regulated in Decrees 97/015 and 99/015 that have the Ministry of Public Health's authorization to conduct activities as pharmaceutical operators with cannabis products and the corresponding valid license from the Institute for Regulation and Control of Cannabis, are authorized to carry out operations as commercial or storage warehouses of cannabis-based products derived from cannabis or cannabinoids, plants, or finished or semi-finished products of cannabis for medicinal purposes, provided that such operations do not involve alterations in the nature of the products.

## 6.2 Sector incentives

### Promotion of biotechnological activity

Decree No. 011/013 sets forth the promotion of the generation of biotechnological products, services and processes with application in strategic productive sectors, prioritizing the agricultural, environmental, energy, human and animal health sectors.

The Government, in consultation with the Biotechnology Sectorial Council, will review this prioritization every two years and may include new biotechnological development sectors to be promoted.

For benefits to be granted, pursuant the abovementioned decree, one of the following requirements shall be met: implementation of a program for the development of suppliers of biotechnological products and services; the company shall be a micro, small or medium-sized company producing biotechnological services and/or products; or, it shall be a new company that is going to produce biotechnological products and/or services.

Regulations establish the exemption from IRAE on income originated in the promoted activities, in accordance with the following percentages and terms:

- fiscal years beginning on January 1, 2018, and ending on December 31, 2019: 75%.
- years beginning on January 1, 2020, and ending on December 31, 2021: 50%.

### Public Procurement Subprogram for the Pharmaceutical Industry

Decree 194/014 creates the Public Procurement Sub-program for the Pharmaceutical Industry, which grants in public bids the possibility of applying a market reserve for pharmaceutical industries with goods and services they produce, which qualify as domestic products.

It applies to contracts entered into by the three branches of government, the Court of Audits, the Electoral Court, the Court of Administrative Litigation, departmental governments, autonomous entities and decentralized services, public education entities and, in general, all state agencies, services or entities.

These regimes are explained in detail in the Investor's Guide.

## TABLE Nº9- COMPARISON OF LEGAL REGIMES FOR THE DEVELOPMENT OF LOGISTICS ACTIVITIES[30]

| | FREE TRADE ZONE | PORT AND FREE AIRPORT | CUSTOMS WAREHOUSE |
|---|---|---|---|
| Payment of tariffs on entry of goods: | No | No | No |
| Payment of tariffs on entry into Uruguay (import) of goods of Mercosur origin: | No[31] | No | No |
| Payment of duties on entry into another Mercosur State party (import) of goods of Mercosur origin: | No[32] | No | No |
| Payment of duties on entry into a Mercosur State party (import) of goods from the rest of the world: | Yes | Yes | Yes |
| Possibility of non-industrial logistical handling, including change of destination of goods. | Yes | Yes | Yes |
| Possibility of industrial handling | Yes | No | Yes |
| Maximum timeframe | indefinite | 5 extendable years | 24 months |
| Payment of taxes by the user (income tax, wealth tax) | No[33] | Yes[34] | Yes[35] |
| Payment of taxes on the circulation of goods (value-added tax) within the premises | No | No | No |
| Possibility to change ownership within the premises | Yes | Yes | Yes |
| Possibility of NOT paying social security contributions for foreign personnel | Yes | No | No |
| Validity of state monopolies | No | Yes | Yes |
| The rights to carry out activities require executing contracts and/or special registrations in Uruguay. | Yes[36] | No[37] | No |
| In order to carry out transit operations it is necessary to obtain authorizations or formal procedures before the agencies involved (customs, etc.). | Yes | No | Yes |

[30] Source: prepared by Uruguay XXI. We are grateful for the collaboration of Dr. Daniel Olaizola of the firm Jaume & Seré.
[31] Provided that it meets the conditions established by Decision 33/15 of Mercosur.
[32] Provided that it meets the conditions established by Decision 33/15 of MercosurThere are exceptions expressly established in bilateral agreements with Brazil and Argentina for specific products from Uruguayan free trade zones, such as the export of grains from the Nueva Palmira Free Trade Zone and soft drink concentrates from the Colonia Free Trade Zone.
[33] Uruguayan companies that are not using the free trade zone, but are owners of the goods, would be taxed with the IRAE in case profits are generated.
[34] Revenues from profit-generating activities carried out by non-resident or resident entities with goods of foreign origin in warehouses shall be exempted when they are not originated in the national customs territory and are not destined to it. If the holders are individuals or legal entities located abroad, their merchandise will not be included in the taxable base of the wealth tax either.
[35] Ibidem
[36] It is required to be a direct or indirect user, executing special contracts, duly registered with and approved by the Free Zone Directorate.
[37] It is sufficient to establish commercial agreements with operators that provide services under these regimes. It is not required to register a company with any entity in Uruguay.

# URUGUAY IN BRIEF (2021)

## URUGUAY IN FIGURES

| Official Name | Oriental Republic of Uruguay |
|---|---|
| Geographical location | South America, bordering Argentina and Brazil |
| Capital | Montevideo |
| Area | 176,215 km2. 95% of the territory is productive land suitable for agriculture and livestock farming.7777 |
| Population (2019) | 3.52 million |
| Population growth (2019) | 0.3% (annual) |
| GDP per capita (2020) | US$ 15,173 |
| Currency | Uruguayan peso ($) |
| Literacy rate | 0,98 |
| Life expectancy at birth | 77.6 years |
| Form of government | Democratic republic with presidential system |
| Political division | 19 departments |
| Time zone | GMT - 03:00 |
| Official language | Spanish |

## MAIN ECONOMIC INDICATORS

| Indicators | 2016 | 2017 | 2018 | 2019 | 2020 | 2021* |
|---|---|---|---|---|---|---|
| GDP (Annual % Variation) | - | 1.6% | 0.5% | 0.4% | -5.9% | 3,0% |
| GDP (Millions US$) | 57,287 | 64,223 | 64,431 | 61,176 | 53,575 | 57.977 |
| Population (Million people) | 3.48 | 3.49 | 3.51 | 3.52 | 3.53 | 3,54 |
| GDP per Capita (US$) | 16,461 | 18,385 | 18,377 | 17,387 | 15,173 | 16.364 |
| Unemployment Rate - Annual | 7.8% | 7.9% | 8.3% | 8.9% | 10.4% | 10,9% |
| Exchange Rate (Pesos per US$, | 30.1 | 28.7 | 30.8 | 35.3 | 42.1 | 42,9 |
| Exchange Rate (Annual Average | 10.1% | -4.8% | 7.3% | 14.7% | 19.2% | 2,0% |
| Consumer Prices (Annual Cumulative | 8.1% | 6.6% | 8.0% | 8.8% | 9.4% | 7,2% |
| Exports of goods and services | 15,460 | 16,798 | 17,038 | 16,992 | 13,552 | 17.454 |
| Imports of goods and services | 12,441 | 13,338 | 13,816 | 13,311 | 11,285 | 13.961 |
| Trade Surplus / Deficit (US$ | 3,019 | 3,460 | 3,222 | 3,681 | 2,267 | 3.493 |
| Trade Surplus / Trade Deficit (% of | 5.3% | 5.4% | 5.0% | 6.0% | 4.2% | 6,0% |
| Overall Fiscal Result (% of GDP) | -3.4% | -3.2% | -3.9% | -4.4% | -6.0% | - |
| Gross Capital Formation (% of GDP) | 17.5% | 15.8% | 15.0% | 14.6% | 17.0% | - |
| Gross Public Sector Debt (% of GDP) | 58.5% | 60.5% | 59.6% | 60.8% | 74,5% | - |
| Foreign Direct Investment (US$ | -1,825 | -601 | 163 | 1,837 | 2,630 | - |
| Foreign Direct Investment (% of GDP) | -3.2% | -0.9% | 0.3% | 3.0% | 4.9% | - |

Sources: BCU, INE, MEF and estimated data (*). Fiscal result data include the effect of Law N°19590 (fifty-year old people). In 2017 the BCU adopted the methodology of the 6th edition of the Balance of Payments Manual. Data based on this new methodology include purchase and sale of goods and re-exports and are available since 2012. Data show net flows so they may take negative values (**).

Uruguay XXI
PROMOCIÓN DE INVERSIONES,
EXPORTACIONES E IMAGEN PAÍS

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