



Department for
International Trade

Uruguay Market Overview

Pre Medica Market Briefing 2022





Uruguay - Market Overview



Economy



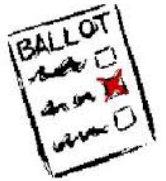
- GDP (\$USD per capita): 16,734
- Average growth in 2021: 4.4%
- 2nd FDI/GDP ratio in LATAM
- Annual inflation: 8.34%
- 11 FTZ: 100% tax free
- Capital city: Montevideo
- Currency: Uruguayan Peso (\$)

Population



- 3.54 million
- Literacy rate: 98.0%
- Urban population: 96%
- HDI: 0.809 (3rd highest in LATAM)
- Life expectancy: 77.6 years, 82W – 74M
- Income inequality: 39.7/100

Government Priorities



- President Luis Lacalle Pou (2020 – 2025):
- Boosting private sector activity and FDI
 - Fiscal consolidation
 - Tackling rising crime
 - Curtailing spending
 - Address salary and labour compensation

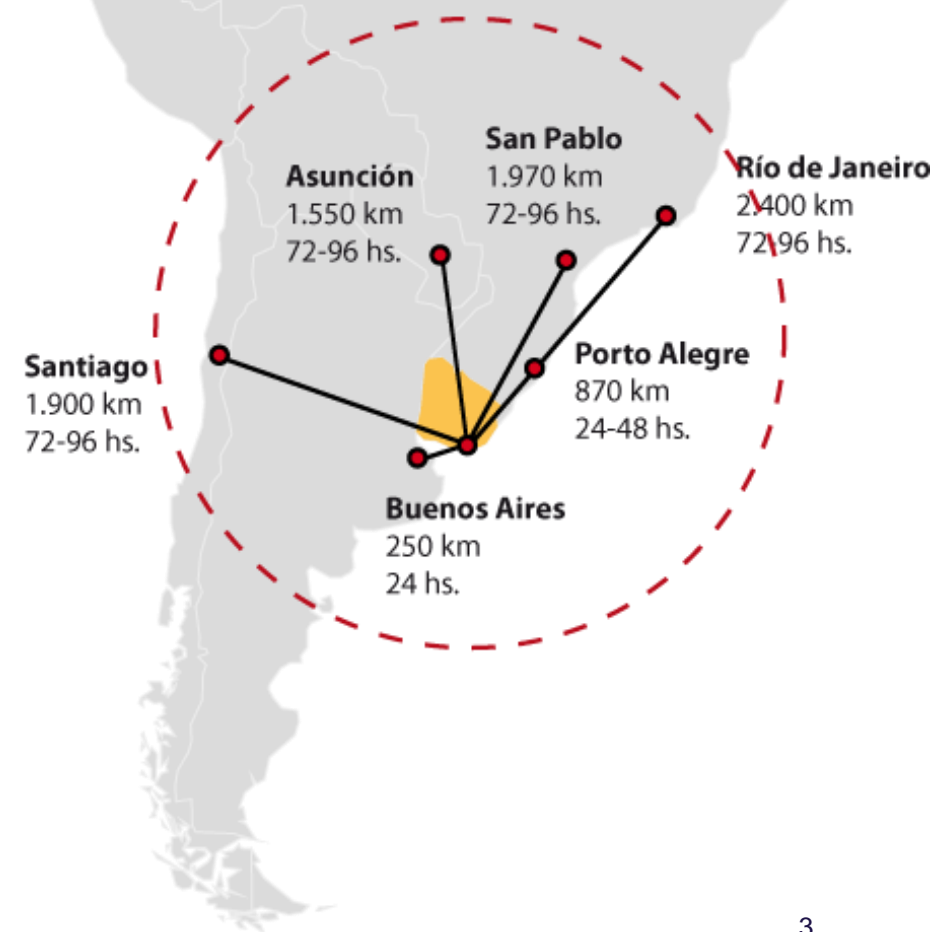


Uruguay as a logistics hub



Secure and reliable entryway to LATAM, having strong democratic traditions and institutions.

- **Free Port and Airport**
- **Free Zones:** industrial, service and logistics and distribution activities, including “Parque de las Ciencias”
- **Customs Warehouses**
- **Temporary Admission**
- **Advantages of an RDC:**
 - Inventory optimisation
 - Costs reductions
 - Improved service





Uruguay as a Hub - Reliability

Uruguay #1 in LATAC

- Democracy Index (Economist Intelligence Unit, 2021)
- Low Corruption (Transparency International, 2021)
- Civil Liberties (Freedom House, 2021)
- Rule of Law Index (World Justice Project, 2021)
- Social Mobility (World Economic Forum, 2021)
- E-Government Development Index (United Nations, 2020)

Easy for business

- Equal treatment for foreigners and locals
- Free foreign exchange market
- One national tax system
- No local counterpart required
- No restrictions for the repatriation of profits



Uruguay as a Hub – Success Stories



- AZ established its regional distribution hub in Uruguay in **2017**.
- They aimed for **excellence in their distribution process**, creating an agile and flexible supply network using the Free Airport model.
- They wanted to deliver a **new alternative** for the entry of products to LATAM and a faster international trade process.





Uruguay as a Hub – Success Stories



- In 2021, GSK installed one of their three **new regional vaccine distribution centres** in Montevideo
- It will handle more than 12 million doses annually destined for six South American countries
- Plans to distribute drugs for the treatment of asthma, COPD, allergic rhinitis, epilepsy, and HIV, among others.





Uruguay – Healthcare System

-Ministry of Public Health (MSP): authority responsible for making and enforcing health regulations

-State's Health Services Administration (ASSE):

- Main state provider of comprehensive healthcare
- Defines which are the products and technologies that can enter into the health technology market

-National Health Plan (FONASA) provides funding to the **Comprehensive Health Care Plan (SNIS)**, guarantying health coverage as a right to all inhabitants of the Republic

-Health Technology Assessment (HTA) Agency: formally created by Law N° 19889 in 2020.



Uruguay – Healthcare System

FONASA

- About 2.5m people have rights acquired by social security (National Health Insurance) and contribute to the National Health Fund (FONASA).
- People who contribute to FONASA can choose their integral health provider, joining one of the **41 private integral providers** or the **public provider, which is the State Health Services Administration (ASSE)**.
- FONASA is funded by:
 - **State contribution** - arises from General Revenue.
 - **Employers** – public and private (5% of nominal wages).
 - **Formal workers** - contribute with a percentage of their salary.





Uruguay – Healthcare System

Health Technology Assessment (HTA) Agency

- The aim of this agency is to be in charge of the **evaluation of the sanitary technologies** according to the policy established by the Executive Power.
- **The Ministry of Health is still in charge of regulation and fiscal control** of these technologies.
- The Technology concept includes, among others:
 - Medicines (raw materials and packaging)
 - Cosmetics
 - Medical products
 - Special purpose foods
 - Household
 - Other medical devices



Uruguay – Regulatory Overview

-Ministry of Public Health (MSP): mandatory registry of high-tech diagnostic and therapeutic technology resources for health services

-Medical Devices and Equipment: [Decree No. 3 of 2008](#) regulates its manufacture, import, registration, use and control.

- Certificate of free sale from the country of origin
- Registration can be approved within 180 days
- Products sold directly to the public may only be commercialised by companies authorised for this purpose



-Pharmaceuticals: [Decree N° 18/020](#) establishes a new procedure for the registration, production, export, import and commercialization of medicines for human use

- Registration of both medicines and companies must be done before the National Agency of Medicines Regulation
- Registry will be valid for 5 years and its renewal has to be requested 90 days before it expires



Uruguay – Regulatory Overview: definitions

A) Diagnostic Reagents

Chemical or biological substances -alone or associated, or presented as systems-, which are used for the **investigation of a physical ailment or psychic information of a human being**, whether by direct reading or through special devices, which can be of two different types: for use "in vitro" or "in vivo".

B) Medical Equipment

Instruments or apparatus, whether mechanical, electrical, electronic or logic ("hardware or software"), **used for diagnostic purposes** (chemical, biological, imaging or therapeutic).

Equipment and materials for chemical or biological diagnosis: allow us to visualize directly or through the use of any substance, the integrity or alteration of tissues, organs, apparatus or systems, or their functions.

C) Therapeutic Devices

Instrument, material or equipment, including its accessories, for "in vitro" or "in vivo" use, **intended for the prevention, control, treatment or relief of illness or injury, substitution or modification of the anatomy, or of a physiological process.**



Uruguay – Registry of medical equipment and therapeutic devices

- The **Medical Technology Department** (DTM) within the MoH is responsible for evaluating the documentation submitted and for communicating to the applicant any comments arising from that study, if any.

- **Process:**
 1. Payment (around GBP 720 per “product family” and GBP 150 per product)
 2. Submission of the application
 3. Stage within the DTM involving:
 - i. Receiving the folder, assignment to a technician for its evaluation and study of information.
 - ii. Notification to the requesting company of the observations to the folder, if any.
 - iii. Receipt of replies to comments.
 - iv. Approval or Denial of Registration.
 - v. In the case of approval, issuance of the corresponding Certificate.



Uruguay – Medical devices market

- Market depends on **imports** (around **£106m in 2021**)
- **95%** of purchases made by the **private sector**, **5%** by the **public sector**
- **Significant investments are needed** in primary care, home care and telehealth
- **Main medical devices imports in 2021:**

HS code	Product	£ CIF value
9018	Instruments	40,111,910
9021	Orthopaedic appliances	25,583,725
8419	Machinery, plant (not domestic), or laboratory equipment	24,227,893
9019	Mechano-therapy, massage appliances	6,395,724
9022	X-ray, alpha, beta, gamma radiation apparatus	5,889,090
9402	Furniture; medical, surgical, dental or veterinary	2,600,212
7324	Sanitary ware and parts thereof, of iron or steel	2,482,276



Uruguay – Medical devices market

Main medical devices imports in 2021 - Definitions

Ranking	Product
1	Instruments and appliances used in medical, surgical, dental or veterinary sciences , including scintigraphic apparatus, other electro-medical apparatus and sight testing instruments
2	Orthopaedic appliances ; including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other which are worn, carried or implanted in the body to compensate for a defect or disability
3	Machinery, plant (not domestic), or laboratory equipment ; electrically heated or not, (excluding items in 85.14) for the treatment of materials by a process involving change of temperature; including instantaneous or non electric storage water heaters
4	Mechano-therapy, massage appliances; psychological aptitude testing apparatus ; ozone, oxygen, aerosol therapy, artificial respiration or other therapeutic respiration apparatus
5	X-ray, alpha, beta, gamma radiation apparatus ; x-ray tubes, x-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like
6	Furniture ; medical, surgical, dental or veterinary (e.g. operating tables, hospital beds, dentists' chairs) barbers' chairs; parts
7	Sanitary ware and parts thereof , of iron or steel



Uruguay – Opportunities on medical devices market

- Intravenous transfusion/infusion devices
- Needles and syringes
- Electro diagnostic and scintigraphy devices
- Ophthalmology devices
- Orthopaedic items
- Implant and pacemakers and prosthesis
- Global providers of **R&D or manufacturing services**
- Branded or high **R&D content manufactures**





Tips for doing business in Uruguay

- Develop a **market strategy**
- Be aware of your **competitors** and get to know the niches
- Understand the **regulations** that apply to your product and/or service
- **Post sales service**, which is especially crucial for medical equipment
- Recommended to have a **local agent or subsidiary**





Uruguay – Events



- **November 1-4 2022:** [Test & Invest Uruguay Business Summit](#). Tour 2 - Biotech tour. Venue: Montevideo and Punta del Este.
- **TBC September 2023:** International Agroindustrial and Commercial Exhibition ([Expo Prado](#)). Venue: Lucas Obes 1011, Montevideo.



Thank you!

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Department for
International Trade