



Embassy of India
Buenos Aires



**ECONOMIC
DIPLOMACY
DIVISION**

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IndiaInArgentina



IndianembassyBA



MESSAGE

It is my great pleasure to introduce the '**Sectoral Report on Pharmaceutical Market in Argentina & Opportunities for Indian Companies**' to all stakeholders.

India is deservedly called the 'Pharmacy of the World'. Its vast network of state-of-the-art pharma manufacturing units, well established pharma brands and market leadership in generic formulations provide cost effective and quality medicines to over 180 countries of the world. India's prowess was amply demonstrated and well recognised during the global Covid-19 pandemic. India not only supplied vital drugs to over 150 countries, but has also been in the forefront of global fight against the pandemic ensuring production, supply and availability of Covid vaccines.

There is a huge potential for bilateral trade and investment in the sectors of pharmaceuticals, medical devices & instruments, Ayurveda and Homoeopathy, between the two Strategic Partners, India & Argentina. This sector can be tapped for mutual benefit by both – India to increase its exports to a quality conscious and cost-sensitive Argentine market and by Argentina to reduce its expenses on expensive pharma imports. A positive trend seems to be emerging with kind of general queries received by the Embassy and interest being shown by companies in deepening pharma trade, in both countries.

The Sectoral Report is a continuing piece of work and has brought to the fore all aspects related to the Pharmaceutical Sector in Argentina, viz. present scenario of local Pharma market, trade data, major companies and regulatory framework. Detailed analysis of the different drug(s) market in Argentina along with opportunities and challenges for Indian pharmaceutical companies makes it a ready reckoner for traders, investors, students and researchers alike.

The meticulous research work undertaken by the Commerce Wing of the Embassy is praiseworthy and I extend my compliments for their collective effort in bringing out the Sectoral Report at this opportune time.


(Dinesh Bhatia)



Pharmaceutical Sector in Argentina

January 2025



/01

Overview

// OVERVIEW

- Argentina is the **4th largest pharmaceutical market in Latin America**, valued at USD 7.3bn in 2023.
- Prescription drugs dominate, making up 88.5% of the market, with patented drugs accounting for 63.8%.
- Generics represent 24.7% of the market, and OTC drugs account for 11.5%.
- Major international players: Bayer, Roche, Novartis, and Abbott. Prominent local firms: Roemmers, Bagó, Elea, and Gador.
- Private R&D activities focus mainly on experimental development with multinational companies leading clinical studies.
- Argentina's biotechnology sector is competitive in Latin America, but faces challenges in funding and market mechanisms.
- The government supports R&D through various funding programs and public-private partnerships (PPPs).
- Argentina's R&D spending as a percentage of GDP ranks second in Latin America, after Brazil.

// INDUSTRY COMPONENTS

REGULATION STATE

SUPPLY

- Laboratories
- Wholesalers
- Distributors



PRICE



FIXED BY
LABORATORIES



DEMAND

- Pharmacies Hospitals
- Union-run welfare funds (*) and private health insurance
- Users



(*) These entities are responsible for the provision of medical care for workers in Argentina. All workers get medical care through a system of contribution of a certain percentage of salary by both the employer and the employee.

// VALUE CHAIN COMPONENTS

NETWORK

PRODUCTION

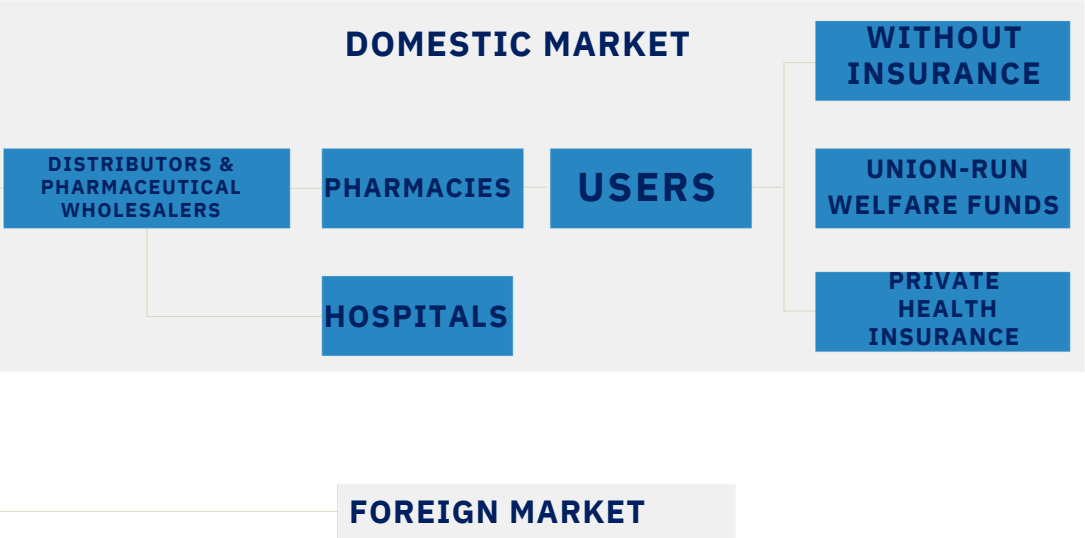
DISTRIBUTION AND COMMERCIALIZATION

LABORATORIES

RESEARCH INSTITUTIONS

UNIVERSITIES

LABORATORIES



// MARKET size

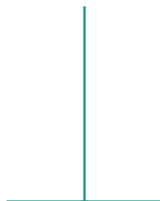
354
LABORATORIES

229
MANUFACTURING
PLANTS

43,070
EMPLOYEES -DIRECT
OCCUPATION

4.9%
PARTICIPATION IN
THE INDUSTRIAL GDP
OF ARGENTINA

181
National
Manufacturing
Plants



48
Foreign -Capital
Manufacturing
Plants

120,000
EMPLOYEES -INDIRECT
OCCUPATION

2024

TOTAL REVENUE

USD **5,207** M (**)

EXPORTS

USD **962** M (*)

IMPORTS

USD **1,559** M (*)

Source: (*) CILFA. September 2024
(**) INDEC. December 2024

// SWOT analysis

Strenghts

- The country's disease profile is similar to that of developed markets, and the population is ageing, which is driving additional demand for and consumption of medicines.
- Well-educated, skilled workforce will help attract investment from pharmaceutical firms looking to manufacture highvalue products.
- Relatively wide-ranging reimbursement coverage from socialised insurance schemes.

Opportunities

- The regulatory improvements should improve the quality of locally made pharmaceuticals; with a weakening peso, exports are likely to increase.
- Universal Health Coverage plan should increase healthcare access for the least affluent, driving up demand for medicines and healthcare services over the long term.
- The nationwide electronic prescriptions mechanism will streamline the disbursement of prescriptions as well as guarantee the provision of medicines in the country.
- A renewed push to leverage the low cost of pharmaceutical production and clinical studies reflects government efforts to bolster the country's position as a leading pharmaceutical market regionally and internationally.
- New technical and scientific partnerships with regional and international bodies will improve the local operational environment and help attract investment.

Weaknesses

- Government policy has been traditionally biased towards local drug producers, with the authorities keen to keep the national drugs bill low via the application of price controls and state-run laboratories.
- Poor regulatory conditions have alienated multinationals and deter companies from establishing production in the country.
- High inflation is undermining the country's cost advantages - primarily owing to the weakness of the peso.

Threats

- The country's interest in introducing international reference pricing, and the government's increased focus on adapting the reimbursement regime to health technology assessment agencies' practices and preventing reportedly high prices for medicines, pose downside risks to revenues.
- The weakening peso will make purchases of raw materials from abroad more challenging.
- Novartis's decision to withdraw many of its pharmaceuticals and biosimilars from the Argentine market reflects ongoing issues around regulatory complexity as well as the country's ongoing economic issues.
- Rapid inflation-driven price increases continue to disrupt pharmaceutical and medical supplies across the country



/02

MARKET players

PHARMACEUTICAL MARKET STRUCTURE IN ARGENTINA

- Laboratories set prices, margins, financing mechanisms, and payments to wholesalers and pharmacies.
- Suggested retail price (SRP) used as a reference for discounts and margins.
- Not only is there a **high horizontal concentration** (sales by units and value), but there are also **large economic groups with high vertical integration** (Roemmers Group, Bagó Group and Sielecki Group)

Wholesale Distribution

- 4 main wholesalers control 70% of the market. Top wholesalers: Droguería del Sud, Monroe Americana, Suizo Argentina, Barracas, Kellheroff, Sur, Mar Jufec.

Retail Distribution

- Around 13,000 pharmacies in Argentina.

Sales Concentration

- Top 10 companies account for 51% of sales.
- Top 20 companies account for 71% of total sales (CILFA, 2022).

// Market PLAYERS

Unlike other countries in the region, more than half of the pharmaceutical commodities are purchased by Government-funded hospitals.

Pharmaceutical manufacturing companies are concentrated in City of Buenos Aires and the province of Buenos Aires, particularly in the Greater Buenos Aires area.

Laboratory	Origin	Revenue (USD)
ROEMMERS	Domestic	538,0
ELEA PHOENIX	Domestic	497,0
CASASCO	Domestic	404,0
GADOR	Domestic	386,0
MONTPELLIER	Domestic	332,0
BALIARDA	Domestic	327,0
RAFFO	Domestic	318,0
BAGO	Domestic	318,0
BAYER	Foreign	207,0
SANOFI AVENTIS	Foreign	203,0
GSK	Foreign	201,0
NOVO-NORDISK	Foreign	158,0
PFIZER	Foreign	150,0
BERNABO	Domestic	143,0
INVESTI	Domestic	140,0
GENOMMA	Foreign	121,0
TEVA	Foreign	121,0
ANDROMACO	Domestic	118,0
BOEHRINGER ING	Foreign	114,0
ASTRAZENECA	Foreign	107,0



TOP 10 LABORATORIES concentrate **51%** of SALES.

(in USD million, at wholesale prices)

// COMPETITORS STRATEGIES

IMPERFECT COMPETITION	The industry has features of an imperfect competition market: information asymmetry, heterogeneity of products and few suppliers
SALE PRICE	Laboratories fix sale prices. The fixed sale price serves as a benchmark for the other components in the value chain
ADVERTISING	The marketing strategy of large laboratories consists in positioning themselves as leading brands by means of advertising. Such strategy allows them to sell at higher prices
VERTICAL INTEGRATION	Larger laboratories integrated vertically and established their own distributors, taking on a key role in medicine distribution and replacing pharmaceutical wholesalers
DIFFERENTIATION	The leading companies compete against each other to manufacture differentiated products and develop drugs with the greatest potential
PHARMACY CHAINS	Retail sales are mainly concentrated in pharmacies. Pharmacy chains first appeared in the 1990s, introducing a business model that was completely different from traditional pharmacies.



03/

International Trade

// IMPORTS & EXPORTS

Pharmaceutical Exports Trend:

- The value of exports in local currency will increase by 36.2% from 2023 to 2028. However, when converted to USD, the value of exports will decrease by 5.4% per year.
- Efforts will focus on exporting more generic medicines, biopharmaceuticals, and veterinary products.

Pharmaceutical Imports Trend

- The value of imports in local currency is expected to grow strongly by 38.7% per year between 2023 and 2028.
- The country will continue to depend on expensive imported medicines, especially new and innovative products.

Market Dynamics

- Government pushing to increase local drug production but still reliant on imports.
- Rising inflation and limited purchasing power of end consumers impacting both imports and consumption.
- Expected positive outlook for recovery in 2025, which may boost market growth.

Indicator	2022	2023	2024f	2025f	2026f	2027f	2028f
Pharmaceutical exports (USDmn)	338.83	338.79	293.71	253.32	232.48	233.32	256.6
% y-o-y change in exports	-33.56	-0.01	-13.31	-13.75	-8.23	0.36	9.97
Pharmaceutical imports (USDmn)	2,934.47	3,170.92	1,581.87	1,841.72	2,009.05	2,236.84	2,634.37
% y-o-y change in imports	-7.13	8.06	-50.11	16.43	9.09	11.34	17.77
Pharmaceutical trade balance (USDmn)	-2,595.63	-2,832.13	-1,288.16	-1,588.40	-1,776.57	-2,003.52	-2,377.77

f = BMI forecast. Source: DESA/UNSD United Nations Comtrade Database, ITC, BMI

// Government Policy Shifts

- **Reduction of Import Payment Timelines:** In October 2024, the Central Bank of Argentina (BCRA) issued Communication “A” 8118, which eased the payment terms for imports. Importers can now pay 50% of the total imported value 30 days after the merchandise enters Argentina, with the remaining amount due at 60 days. This adjustment aims to alleviate supply chain challenges and encourage trade. (Central Bank of Argentine Republic)
- **Reduction in Impuesto PAIS Tax Rate:** The Impuesto PAIS tax rate on imports is now 7.5%.
- **Deregulation of Trade Operations:** In October 2024, Argentina's government announced plans to streamline and simplify trade operations by eliminating certain import pricing requirements and a fiscal stamp tax. These measures aim to reduce bureaucracy and enhance market efficiency.
- **Extension of Suspension for VAT and Income Tax Exemption Certificates:** The suspension of VAT and income tax exemption certificates for certain imports has been extended until June 30, 2025. This extension means that importers will continue to be obligated to pay these advance payments, affecting their financial planning and tax obligations.
- As of January 2025, electronic prescriptions are mandatory across Argentina, as established by Decree 345/2024. Prescriptions must be issued exclusively through platforms registered with the National Registry of Digital Health Platforms (ReNaPDiS).



The National Registry of Digital Health Platforms (**ReNaPDiS**), established by Resolution 1959/2024, is managed by the Subsecretariat of Epidemiological Surveillance, Health Information, and Statistics, with operational coordination by the National Directorate of Health Information Systems. This registry aims to promote the development of secure, interoperable, and high-quality digital health platforms, enhancing healthcare accessibility and system integration while ensuring information security.

// RULES and REGULATIONS

Regulation	Year	Name	Description
Law No. 16,463	1964	Medicines Law	Establishes the scientific and sanitary criteria for the marketing of pharmaceutical products.
Decree-Law No. 9763	1964	Medicines Law	Provides for the exercise of health police power, which is exerted by the Ministry of Health.
Law No. 17,565	1967	National Law on the Practice of Pharmacy	Legal regime of the exercise of the pharmaceutical activity, and habilitation of pharmacies, drugs, and herborists.
Decree-Law No. 2284	1991	Economic Deregulation	Provides for the deregulation of medicines trade and import and prices.
Decree-Law No. 150	1992	Regulations	Sets regulations for the registration, manufacturing, fractionation, prescription, marketing, export, and import of medicines.
Law No. 24,766	1996	Confidentiality Law	Provides for the confidentiality of the information provided to the health authority for product registration.
Law No. 24,481	1995	Patents of Invention and Utility Models Law	Grants the owner the exclusive right to manufacture and market new medicines for 20 years. Extended in 2003 to include procedures.
Law No. 25,649	2002	Law of Drug Prescription by Generic Name	Requires every medical prescription to include the generic name, number of units per container, and concentration.
Resolution No. 435	2011	Drug Traceability System	Run by ANMAT to track all medicines in the distribution chain, preventing the marketing of illegitimate medicines.
Law No. 26,688	2011	Law on Public Manufacturing of Medicines	Declares the research and public manufacturing of medicines, medical raw materials, and vaccines of national interest.
ANMAT Provision No. 828/17	2016	Expanded Access	Authorizes laboratories to request Expanded Access Programs (PAE) for unmarketed drugs required by specific patient groups.
Decree 63/2024	2024	Generic Medicines	Mandates prescribing medications by their generic names to reduce costs and improve access. Pharmacists can substitute brands with equivalent affordable options while ensuring safety and efficacy.

04/

Useful Information



// REGULATION



THE NATIONAL ADMINISTRATION OF MEDICINES, FOOD AND MEDICAL TECHNOLOGY (**ANMAT**) IS A DECENTRALIZED BODY OF THE NATIONAL PUBLIC ADMINISTRATION OF THE ARGENTINE REPUBLIC CREATED IN 1992 AND DEPENDENT ON THE MINISTRY OF HEALTH OF THE NATION.

Decree 150/92 regulates the registration, sale, and importation of medications in Argentina, aiming to enhance transparency and competition. It requires products to be registered with the Ministry of Health, meeting strict labeling and quality standards.

Companies approved by ANNEX I countries can register their products in Argentina.

For more details, visit:
<https://www.argentina.gob.ar/normativa/nacional/decreto-150-1992-8196>

- ANNEX I**
- UNITED STATES
 - JAPAN
 - SWEDEN
 - SWISS
 - ISRAEL
 - CANADA
 - AUSTRIA
 - GERMANY
 - FRANCE
 - UNITED KINGDOM
 - NETHERLANDS
 - BELGIUM
 - DENMARK
 - SPAIN
 - ITALY

- ANNEX II**
- AUSTRALIA
 - MEXICO
 - BRAZIL
 - CUBA
 - CHILE
 - FINLAND
 - HUNGARY
 - IRELAND
 - CHINA
 - LUXEMBOURG
 - NORWAY
 - NEW ZEALAND
 - INDIA

If the Indian laboratory holds a relevant certification of compliance with Good Manufacturing Practices (GMP), issued by a high-level health surveillance agency of country listed in Annex I of Decree 150/92, there are no barriers to the entry of Indian products. Such products has to be authorized by ANMAT under the simplified system outlined in Article 4 and marketed in Argentina for human consumption.

Source: ANMAT. PIC'S. CILFA.

Manufacturing & Marketing

- Foreign pharmaceutical companies must set up a local entity or partner with a local laboratory to obtain manufacturing approval in Argentina. Only local labs can register products with ANMAT (National Administration of Medicines, Food and Medical Technology).
- Medicines are classified into prescription-only, recorded prescription sale, and free sale categories. OTC medicines can no longer be sold over the counter, and their marketing is strictly regulated.

Regulatory Process

- The approval process for medicines typically takes 12 months, even though laws suggest a 90-day timeframe. Once approved, marketing approval lasts for five years and requires renewal.
- Product advertising must comply with ANMAT regulations, including clear warnings and restrictions on certain types of claims.

Post-Marketing and Pharmacovigilance

- ANMAT's pharmacovigilance department monitors adverse effects and counterfeiting. New technologies like tracking systems are being used to address counterfeiting.

Intellectual Property

- Argentina is under scrutiny for weak intellectual property rights, which affects patent protection and regulatory data protection, especially for pharmaceutical companies.

Reimbursement Regime

- Prescription drugs may be reimbursed up to 70% under social welfare programs, while OTC medicines are excluded. PAMI, the largest health insurer, continues to update its coverage system.



PAMI stands for the National Institute of Social Services for Retirees and Pensioners in Argentina. It is a government agency that provides health care services, medicines, and other social benefits to retirees, pensioners, and certain other vulnerable groups. It plays a key role in Argentina's healthcare system, particularly for the elderly population.

Economic Challenges

- Government aims to implement free-market policies and fiscal reforms.
- High inflation (166% at end-2024) and subsidy cuts drive short-term instability.

Healthcare Spending Trends:

- 2022-23: Real-term healthcare spending declined due to post-pandemic slowdown and inflation.
- 2023: Healthcare spending dropped to 9.1% of GDP, down from 9.7% in 2021.
- Recovery expected from 2025, with spending projected to reach 9.7% of GDP by 2028.

Government Policy Impact

- Presidential decree No. 63/2024 abolished price limits on medicines and private health insurance plans.
- Health insurance premiums increased up to 40%, raising costs for individuals.
- Potential for reduced public health contributions, though politically difficult.

Opportunities for importing API		Opportunities for the importation of pharmaceutical products	
Sulfonamides		Heparin and its salts	
Heterocyclic compounds/nitrogen heteroatoms, c/fluorine, bromine or both, nec.		Medications with penicillins, without packaging for retail sale	
Atrazine	Heterocyclic compounds nec. whose structure contains a triazole cycle nec.	Medications with carboxylic acids and esters of inorganic acids, nec., without conditioning for retail sale	Medicament/composition heterocyclic w/heteroatoms of nitrogen, nec., s/a cond. p/la retail sale
Heterocyclic compounds c/nitrogen heteroatoms, c/chlorine but without fluorine or bromine, nec.	Heterocyclic compounds w/oxygen heteroatom exclusively, nec.	Vaccines for human medicine nec. Packaged for retail sale	Topotecanorithydrochloride, uracil and tefagur, ritonavir, teniposide, fosfato de fludarabine, conditioned p/la retail
Heterocyclic compounds with nitrogen heteroatoms, with a pyrimidine cycle, nec.	Heterocyclic compounds nec.	Medications with paracetamol, bromopride, without conditioning for retail sale	Medications w/antibiotics nec., without conditioning for retail sale

// USEFUL links

INDEC National Institute of Statistics and Census	Address: Av. Pres. Julio A. Roca 609 -City of Buenos Aires Postal Code: C1067 Phone: (+54 11) 4349-9200 Website: https://www.indec.gob.ar/	MINISTRY of ECONOMY	Address: Av. Hipólito Yrigoyen 250 -City of Buenos Aires Postal Code: C1085 AAB Phone: (+54 11) 4349-5000 Website: https://www.argentina.gob.ar/ economia
MINISTRY of FOREIGN AFFAIRS, INTERNAYTIONAL TRADE and WORSHIP	Address: Esmeralda 1216 -City of Buenos Aires Postal Code: C1007 Phone: (+54 11) 4819-7000 -Website: https://www.cancilleria.gob.ar/	ANMAT National Administration of Medicines, Food and Medical Technology	Address: Av. Belgrano 1480 -City of Buenos Aires Postal Code: C1093AAP Phone: (+54 11) 0800-333-1234 Website: http://www.anmat.gov.ar
MINISTRY of HEALTH	Address: Edificio del Ministerio de Obras Públicas, Av. 9 de Julio1925 -City of Buenos Aires Postal Code: C1073ACA. Phone: (+54 11) 0800-222-1002 Website: https://www.argentina.gob.ar/salud	CILFA Industrial Chamber of Argentine Pharmaceutical Laboratories	Address: Av. del Libertador 602 -City of Buenos Aires Postal Code:C1001 Phone: (+54 11) 4819-9550 Website: https://cilfa.org.ar/wp1/
SECRETARIAT for PRODUCTION COORDINATION	Address: Av. Pres. Julio A. Roca 651 Postal code: C1067ABB Phone: (+54 11) 0800-333-7963 Website: https://www.argentina.gob.ar/produccion		

// India & Argentina



The Ambassador of India to Argentina, Dinesh Bhatia, met with Dr. Mario Lugones, Minister of Health of the Republic of Argentina in October 2024, to discuss strengthening cooperation in the healthcare and pharmaceutical sectors between India and Argentina.

In September 2024, Ambassador Dinesh Bhatia met with Mr. Rodolfo Montero, Minister of Health of Mendoza Province, to establish the groundwork for the importation of pharmaceuticals from India. This initiative culminated in December 2024, when Mendoza successfully completed its first purchase of medicines from India, valued at USD150,000.-



In April 2023, Ambassador Dinesh Bhatia met with Carla Vizzotti, Minister of Health, at the Ministry of Health. Discussions focused on advancing the agenda set by Prime Minister Narendra Modi and President Alberto Fernández to enhance cooperation in health, pharmaceutical products, and vaccines, as well as collaboration between regulatory authorities.



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