

# Embassy of India

**Buenos Aires** 



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भारत का राजदूत अर्सेन्तीना एवं उरूगुआइ Ambassador of India Argentina and Uruguay

#### 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)









- 01/OVERVIEW
- **02/ MAIN COMPETITORS**
- **03/INTERNATIONAL TRADE**
- **04/ OPPORTUNITIES FOR INDIAN COMPANIES**
- **05/ USEFUL INFORMATION**
- **06/ CONCLUSION**

3

15

20

24

28

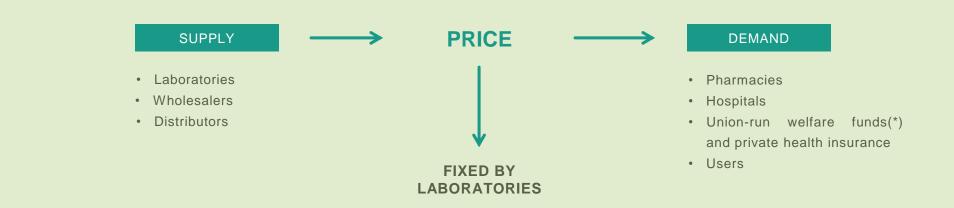




## // INDUSTRY COMPONENTS

#### **REGULATION**

STATE

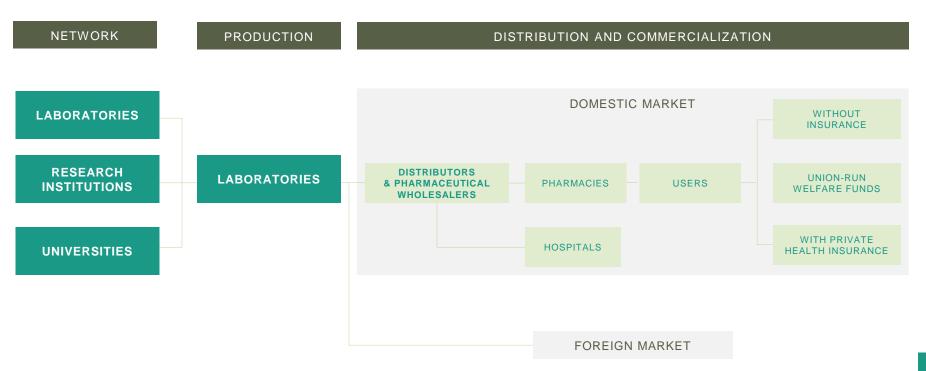


(\*) These entities are responsable for the provision of medical care for workers in Argentina. All workers get medical care through a system of contribution of a certain percentage of salary by both the employer and the employee.





# // VALUE CHAIN STRUCTURE





# // MARKET SIZE

354
LABORATORIES

4.9%

PARTICIPATION IN THE INDUSTRIAL GDP OF ARGENTINA

229
MANUFACTURING PLANTS



43,000
EMPLOYEES - DIRECT OCCUPATION

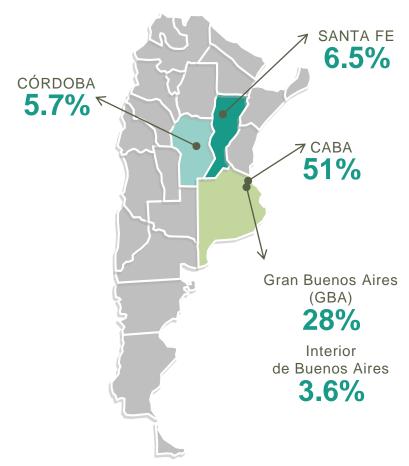
120,000
EMPLOYEES - INDIRECT OCCUPATION

2021

DOMESTIC MARKET USD 8,329 M

EXPORTS USD 836 M (\*)

 $\begin{array}{c} \text{IMPORTS} \\ \text{USD} \ \textbf{2,379} \ \textbf{M} \ (^{\! \cdot}\!) \end{array}$ 



# GEOGRAPHICAL DISTRIBUTION OF NATIONAL PRODUCTION

Produces 690M units (2020),

**68.4%** of which are generated by national laboratories and with a constant growth of the production in recent years

Most of the national production is concentrated in the metropolitan area:

51% in CABA

(Buenos Aires City)

28% in **GBA** 

(Greater Buenos Aires)

The provinces of **Santa Fé (6.5%)** and **Córdoba (5.7%)** follow them with markedly lower figures



# // PHARMACEUTICAL INDUSTRY SALES

Prescription sale	89.8%	89.8%	89.2%	88.1%	89%
Over The Counter Sales	10.2%	10.2%	10.8%	11.9%	11%
Units (in millions)	741	710	681	690	751



In USD billion, at laboratory exit prices



## **// TURNOVER**

RANK	MEDICINES	2020
1	Digestive system and metabolism	17.2%
2	Antineoplastic and immunomodulatory drugs	15.7%
3	Cardiovascular system	12.4%
4	Nervous system	12.2%
5	Anti-infectives for systemic use	9.3%
6	Genitourinary system and sex hormones	6.9%
7	Blood and hematopoietic organs	6.1%
8	Musculoskeletal apparatus	4.7%
9	Dermatological drugs	4.0%
10	Respiratory apparatus	3.9%
11	Hormones for systemic use, excluding sex hormones	2.5%
12	Sense organs	1.7%
13	Antiparasitic drugs, insecticides and repellants	0.2%
14	Various	3.1%

RANK	COUNTRY OF ORIGIN OF THE MAIN DRUG	2020
1	Germany	17.0%
2	United States	14.0%
3	Italy	9.0%
4	Ireland	9.0%
5	Switzerland	8.0%
6	France	8.0%
7	Brazil	3.0%
8	Belgium	3.0%
9	Denmark	3.0%
10	Canada	3.0%
11	United Kingdom	3.0%
12	China	3.0%
13	Spain	2.0%
	Others	15.0%



# // MAIN MEDICINES SOLD IN ARGENTINA

Top 15 products sold (in units)	2020	2019	Variation (in units)
Levothyroxine (MTP)	10.358.270	9.160.210	13.08%
Ibuprofen 600 RA (BAY)	8.963.099	9.805.724	-8.59%
Enalapril (RMM)	7.080.868	6.786.162	4.34%
Paracetamol 500 (G3A)	6.976.307	5.136.287	35.82%
Aspirin 100 (BAY)	6.308.489	5.289.611	19.26%
Levothyroxine (GSK)	6.151.651	5.428.993	13.31%
Paracetamil + Diclofenac (G3A)	5.502.857	4.182.266	31.58%
Clonazepam (B+L)	4.945.261	4.758.252	3.93%
Alprazolam (GAD)	4.833.298	4.546.497	6.31%
Aspirin 100 (BAY) VL	4.775.057	4.611.878	3.54%
Ibuprofen 400 RA (BAY)	4.670.180	4.731.386	-1.29%
Paracetamol 1g (G3A)	4.598.442	2.681.877	71.46%
Bisoprolol (RMM)	4.435.666	3.880.867	14.30%
Losartan (RMM)	4.206.619	3.841.604	9.50%
Ibuprofen 400 (PFZ)	3.344.288	3.365.249	-0.62%

The **15 products most sold** in units represent

13.84%

of the total market

There exist more than 20,000 products in the Argentine drug market









# **M** COMPETITORS

Only 2 of the top 10 laboratories in Argentina are Foreign Laboratories

This market is characterized by a high degree of concentration: **20 laboratories** account for

70% of the market

RANK 2020	LABORATORY	CAPITAL	USD million
1	ROEMMERS	National	423
2	ELEA PHOENIX	National	374
3	GADOR	National	297
4	CASASCO	National	296
5	MONTPELLIER	National	250
6	BAGÓ	National	248
7	BALIARDA	National	246
8	RAFFO	National	232
9	SANOFI AVENTIS	France	182
10	BAYER	Germany	175
11	GSK PH	UK	162
12	NOVO-NORDISK	Denmark	148
13	PFIZER	United States	126
14	BERNABO	National	108
15	BOEHRINGER ING	Germany	102
16	INVESTI	National	101
17	ANDROMACO	National	99
18	TEVA	National	99
19	GENOMMA	National	91
20	NOVARTIS PHARMA	Switzerland	87

(in USD million, at wholesale prices)

TOP 10
REPRESENT

49%
OF THE SALES







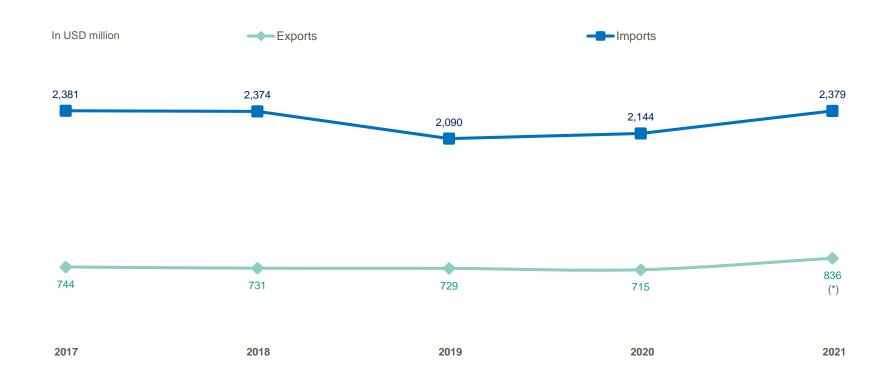


# **M** RULES AND REGULATIONS

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 of the 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	Set 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 as a requirement for the approval to register or trade a product.
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 a term of 20 years. This law was amended in 2003 to extend protection to procedures.
Law no.25,649	2002	Law of Drug Prescription by Generic Name	Establishes that every medical prescription must include the generic name of the drug, 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. It seeks to prevent marketing illegitimate medicines.
Law no.26,688	2011	Law on Public Manufacturing of Medicines	Declares the research and public manufacturing of medicines, medical raw materials, vaccines and medical products of national interest.
ANMAT Provision no. 828/17	2016	Expanded access	Laboratories authorized by the National Administration as importers and / or manufacturers of medicinal specialties may request the authorization of Expanded Access Programs (PAE) to drugs for groups of patients that require treatment with drugs not yet marketed in the country.



# **// EXPORTS AND IMPORTS**





# **// LABORATORY EXPORTS**

YEAR	NATIONALS LABORATORIES		MULTINATIONAL LABORATORIES		TOTAL	
TEAR	In USD million	VARIATION	In USD million	VARIATION	In USD million	VARIATION
2017	464.9	-25.2%	279.3	-2.5%	744.2	-18.0%
2018	529.4	13.9%	201.7	-27.8%	731.1	-1.8%
2019	502.3	-5.1%	226.5	12.3%	728.8	-0.3%
2020	515.5	2%	199.2	-12.1%	714.7	-1.9%



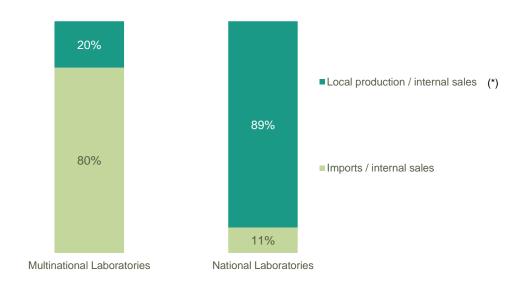
# **// LABORATORY IMPORTS**

CONSUMPTION OF IMPORTED MEDICINES IN ARGENTINA

**2020** → **30%** 

1994 → 6.9%

## SHARE OF IMPORTS AND LOCAL PRODUCTION 2020



(\*) It refers to production within the country destined for the domestic market carried out by both national and multinational laboratories.









# **III FUTURE PROSPECTS OF THE ARGENTINE**MARKET

Indicator		2020	2021 (*)	2025 (Projections)	Comments
TOTAL SALES	in USD million	5,463	6,058	6,812	Improve the productivity rates through investments in capital goods and improved participation production in sales
DOMESTIC MARKET SALES	in USD million	4,748	5,222	5,792	Consolidation of the domestic market
EXPORTS	in USD million	715	836	930	+ 30% Greater number of destinations and improvement of product diversification
IMPORTS	in USD million	2,144	2,379	1,678 (**)	(**) Finished medicines (item 3004 of the NCM) at CIF values
EMPLOYMENT	in thousand	43	43	45	+2,000 jobs increased in employed labor in the industry

Expectations for the year 2025 - growth in the production, domestic sales, exports and employment

Investments from India could help with this growth in supply





### **MAPI TRADE AND PHARMA PRODUCTS TRADE WITH INDIA**

#### ARGENTINA HAS A TRADE DEFICIT WITH INDIA IN MEDICINES AND ACTIVE PHARMACEUTICAL INGREDIENTS (API).

API (in USD million)						
YEAR	EXPORTS	IMPORTS	BALANCE			
2015	0.812	103,365	-102,553			
2016	0.441	99,070	-98,629			
2017	3.263	97,710	-94,447			

Top 5 Imports of API

Top 5 Imports of All		
Description	USD million	%
Sulfonamides	63	15%
Heterocyclic compounds c/nitrogen heteroatoms, c/fluorine, bromine or both, nec.	28	7%
Atrazine	17	4%
Heterocyclic compounds c/nitrogen heteroatoms, c/chlorine but without fluorine or bromine, nec.	14	3%
Heterocyclic compounds with nitrogen heteroatoms, with a pyrimidine cycle, nec.	13	3%

Pharma products (in USD million)						
YEAR	EXPORTS	IMPORTS	BALANCE			
2015	0.113	26,930	-26,817			
2016	0.140	30,876	-30,735			
2017	1.005	31,647	-30,642			

Top 5 Imports of Pharma prod	ucts	
Description	USD million	%
Heparin and its salts	6	9%
Medications with penicillins, without packaging for retail sale	5	9%
Medications with carboxylic acids and esters of inorganic acids, nec., without conditioning for retail sale	5	8%
Vaccines for human medicine nec. Packaged for retail sale	4	7%
Medications with paracetamol, bromopride, without conditioning for retail sale	3	5%



# **M** 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 were integrated vertically and set up distributors Thus, they adopted a key role in the distribution of medicines and replaced 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. Pharmacies chains first appeared in the 90's and introduced a business model that was totally different from that of traditional pharmacies		







## **MREGULATORY ENTITY OF THE SECTOR**



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 NO. 150/1992**

ESTABLISHES THE RULES FOR THE REGISTRATION, PREPARATION, DIVISION, PRESCRIPTION, SALE, MARKETING, EXPORT AND IMPORT OF MEDICINES.

THE STANDARD INCLUDES 2
ANNEXES OF COUNTRIES WITH
DIFFERENTIAL TREATMENT:

#### 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

Pharmaceutical products imported from Annex II require visit and approval by a physical delegation from Argentina. India was escalated to Annex II list of Argentina in 2014.

-25





# **M PROGRAMA DE ATENCIÓN MÉDICA INTEGRAL (PAMI)**



Healthcare network for retirees and pensioners in Argentina.

It is present throughout the country with more than **650 offices** and serving more than **4,800,000** affiliates, including retirees and their dependents, the disabled, pensioners and Malvinas veterans.

PAMI is the mechanism of largest social insurance in the country and represents approximately 1% of the GDP

Out of a total 7 million adults in Argentina, PAMI caters to more than 4.4 million people for their medical requirements. **PAMI is thus the main state buyer of medicines in the country** 

PAMI consumes more than 40% of total medicines in Argentina

Address: Piedras 801 - City of Buenos Aires Postal Code: C1070AAQ

> Phone: (+54 11) 4339-7341 Website: https://www.pami.org.ar/



# **WUSEFUL INFORMATION**

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 FOREIGN AFFAIRS, INTERNATIONAL TRADE AND WORKSHIP	Address: Esmeralda 1216 - City of Buenos Aires Postal Code: C1007 ABR Phone: (+54 11) 4819-7000 - Website: https://www.cancilleria.gob.ar/
MINISTRY OF HEALTH	Address: Edificio del Ministerio de Obras Públicas, Av. 9 de Julio 1925 - City of Buenos Aires Postal Code: C1073ACA Phone: (+54 11) 0800-222-1002 Website: https://www.argentina.gob.ar/salud
MINISTRY OF PRODUCTIVE DEVELOPMENT	Address: Av. Hipólito Yrigoyen 250 - City of Buenos Aires Postal Code: C1086 Phone: (+54 11) 0800-333-7963 Website: https://www.argentina.gob.ar/produccion

#### Address: Av. Hipólito Yrigoyen 250 - City of Buenos Aires **MINISTRY** Postal Code: C1085 AAB OF ECONOMY Phone: (+54 11) 4349-5000 Website: https://www.argentina.gob.ar/economia Address: Av. Belgrano 1480 - City of Buenos Aires ANMAT Postal Code: C1093AAP National Administration of Medicines, Food and Medical Phone: (+54 11) 0800-333-1234 Technology Website: http://www.anmat.gov.ar Address: Av. del Libertador 602 - City of Buenos Aires CILFA Postal Code: C1001 Industrial Chamber of Argentine Pharmaceutical Phone: (+54 11) 4819-9550 Laboratories Website: https://cilfa.org.ar/wp1/





## **M** CONCLUSION

- Argentina is the third largest market in Latin America after Brazil and Mexico
- Argentina has an important pharmaceutical sector, which in 2020 had sales of USD 8,329 million, with a production of 690 million units.
  6.7% growth of the pharmaceutical market in 2020
- · Laboratories from France, Germany, Denmark, United States, UK and Switzerland work in Argentina
- The Argentine market has extensive experience in the incorporation of foreign investments for the sector and offers multiple business opportunities, while representing a commercial access to Mercosur
- Argentina has a historic trade deficit with India for active ingredients and pharmaceutical products

Opportunities f	or importing API	Opportunities for the importation of pharmaceutical products		
Sulfon	amides	Heparin and its salts		
Heterocyclic compounds c/nitrogen hete	roatoms, 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	Medicam.c/comp.heterocyclics w/heteroatoms of nitrogen, nec., s/acond.p/la retail x sale	
Heterocyclic compounds c/nitrogen heteroatoms, c/chlorine but without fluorine or bromine, nec.	Heteroxylic compounds w/oxygen heteroatom exclusively, nec.	Vaccines for human medicine nec. Packaged for retail sale	Topotecan or its hydrochloride; uracil and tefagur;ritonavir;teniposide;fosf ato of 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 sale retail	



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