



Pharmaceutical Industry in Argentina

August 2018

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EXECUTIVE SUMMARY

The structure of the Argentine pharmaceutical industry is divided in three stages: the first is Research and Development, the second is Production and the third is Distribution and Marketing. In 2017, the industry's turnover reached USD 5,774 million, surpassing 2016 turnover by 15.9%. Within this total, antineoplastic and immunomodulatory medicines accounted for the highest turnover. Most of the national pharmaceutical products are manufactured in the City of Buenos Aires and its surroundings. Roemmers, Bayer and Gador were the three laboratories to record the highest turnover figures in 2017.

In addition, the sources of parent drugs used to manufacture pharmaceutical products are mostly national, closely followed by Indian parent drugs. Accordingly, 70% of the domestic market is supplied from locally produced medicines. The average price of pharmaceutical products in 2017 was USD 7,75.

The pharmaceutical industry is the biggest investor in R&D of the Argentine economy: it came to represent 21.5% of the national annual R&D expenditure in 2017.

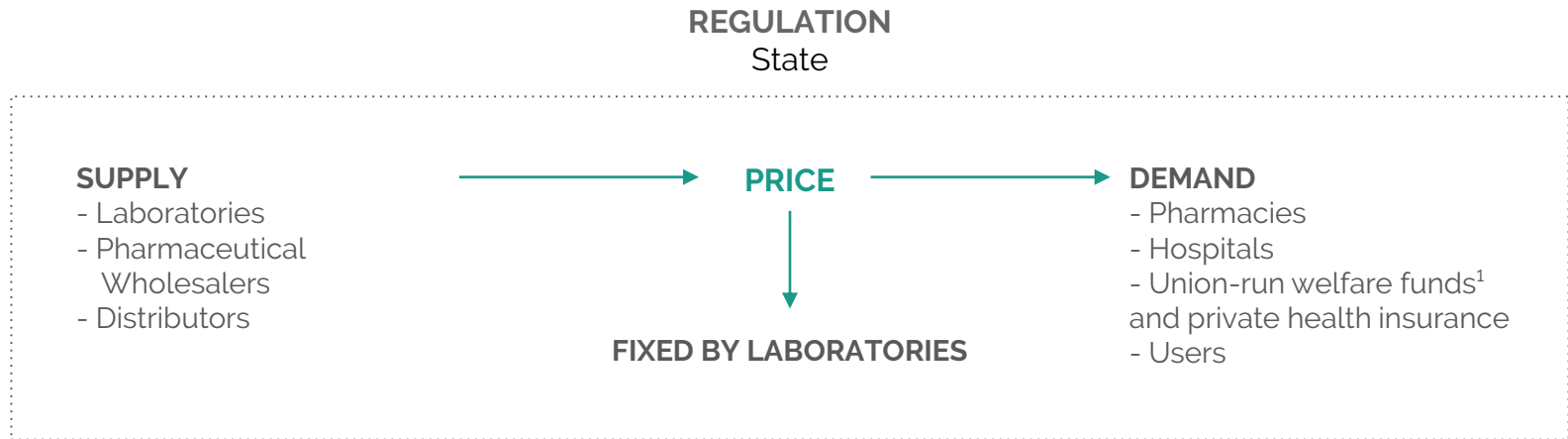
For the second consecutive year, in 2017, Argentine pharmaceutical exports decreased, representing 0.2% of the total exports. Conversely, pharmaceutical imports are following an upward trend. The industry trade balance continues to be in deficit.



MARKET VISION AND STRUCTURE



INDUSTRY COMPONENTS



¹ Entities in charge of organizing the provision of medical care for workers in Argentina. Thus the worker who becomes ill or accident can access medical care, without having to pay all the cost beforehand. By law, all people must have this medical coverage, both the worker and the employer pay a certain percentage of the remuneration in order to finance this coverage.

VALUE CHAIN STRUCTURE

- 1.** The **Research and Development (R&D)** stage is the first link in the value chain. The purpose of this stage is to discover new molecules to regulate biological processes and treat certain diseases or pathologies.
- 2.** The second stage is **Production**, which consists of preparing active ingredients and combining them with excipients and other substances to obtain the final drug product that will be placed for sale.
- 3.** Finally, pharmaceutical wholesalers and distributors play a key role in the wholesale market during the **Distribution and Marketing** stage. Pharmaceutical Wholesalers prepare orders, organize stock and distribute pharmaceutical products. Distributors are made up of laboratories, which emerged with the aim to gain greater bargaining power than pharmaceutical wholesalers.

Both pharmaceutical wholesalers and distributors sell medicines to pharmacies and hospitals. In turn, pharmacies, hospitals and users make up the retail market. Users or consumers can buy pharmaceutical products without any type of insurance, that is, paying 100% of their sale price, or they can buy them with full or partial prescription co-financing under different health coverage schemes (union-run welfare funds or private health insurance).

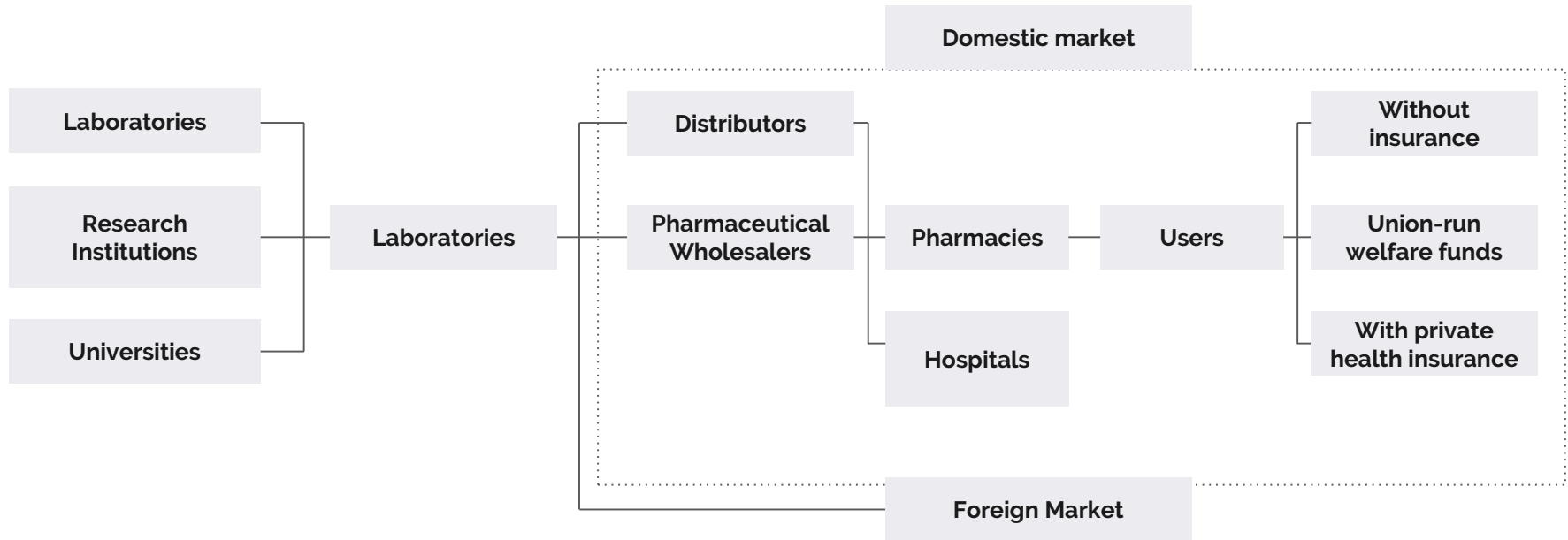


VALUE CHAIN STRUCTURE

R&D

PRODUCTION

DISTRIBUTION AND COMMERCIALIZATION





MARKET SIZE

210

Laboratories

190

Manufacturing Plants

160

National
manufacturing
plants

30

Foreign-capital
manufacturing
plants

43,000

Employees

2017

TOTAL REVENUE
USD 5,774 million

DOMESTIC MARKET
USD 5,400 million

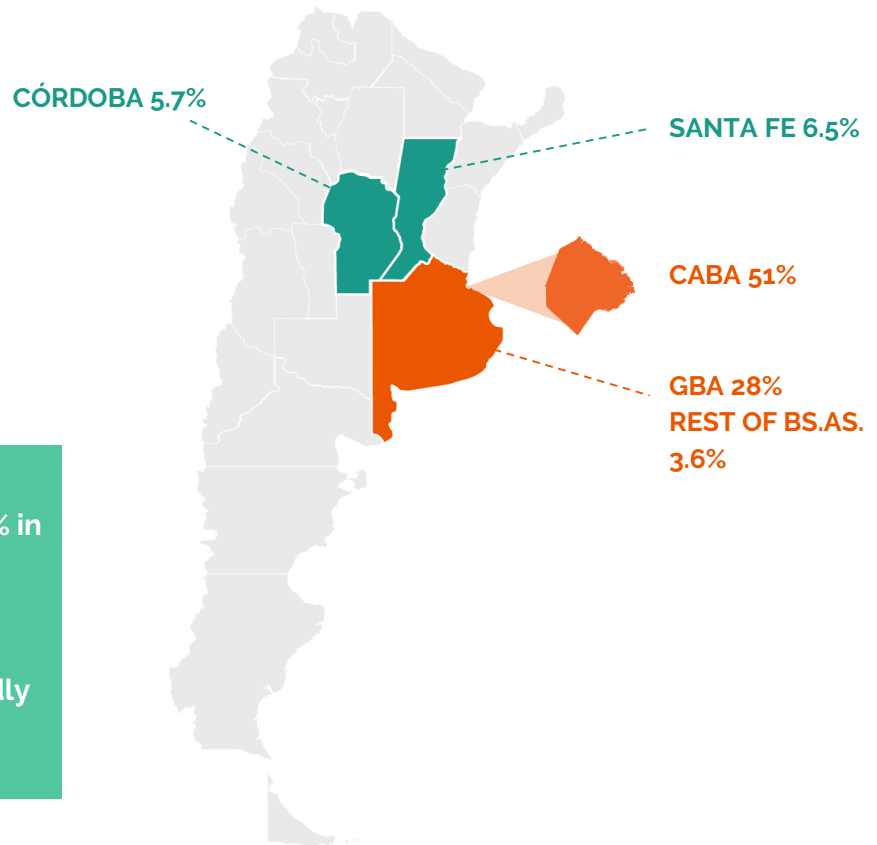
RESALE OF IMPORTED
PRODUCTS
USD 1,620 million

GEOGRAPHICAL DISTRIBUTION OF NATIONAL PRODUCTION

Most of the national production is concentrated in the metropolitan area: **51% in CABA (Buenos Aires City)** and **28% in GBA (Greater Buenos Aires)**.

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

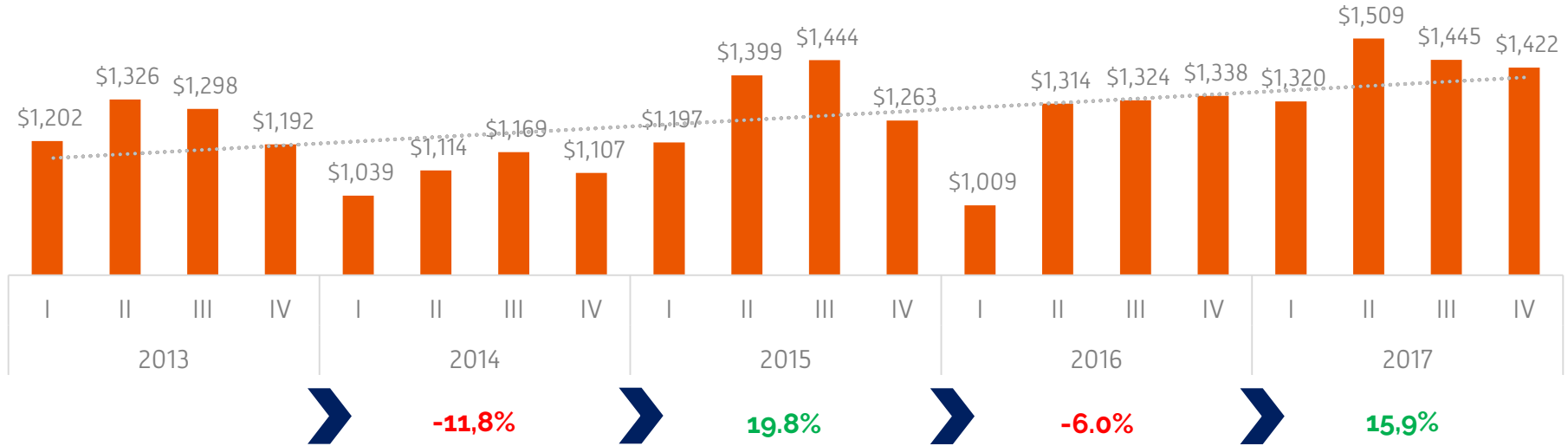
Source: Ministry of Economy





TURNOVER. EVOLUTION AND GROWTH

Total turnover per quarter (in million dollars)



Source: Compiled based on information provided by INDEC (National Institute of Statistics and Census).

The pharmaceutical industry turnover has been increasing over the past 5 years causing an upward growth trend. In 2017 revenue grew 15.9% compared to the previous year. Despite revenue growing and shrinking intermittently over the past years, the increases in revenue were significantly higher than the reductions, which accounts for the current upward trend. Normally, the highest turnover rates are recorded in 2Q and 3Q of the year, as demand rises during winter.

TURNOVER BY ANATOMIC GROUP

RANKING	ANATOMIC GROUP	2017	
		Million USD	%
1	Antineoplastic and immunomodulatory drugs	\$ 954.5	16.8%
2	Digestive system and metabolism	\$ 870.0	15.3%
3	Cardiovascular system	\$ 707.7	12.4%
4	Nervous system	\$ 676.9	11.9%
5	Anti-infective drugs for systemic use	\$ 589.7	10.3%
6	Genitourinary system and sexual hormones	\$ 405.6	7.1%
7	Musculoskeletal system	\$ 365.0	6.4%
8	Respiratory system	\$ 291.3	5.1%
9	Blood and Hematopoietic Organs	\$ 250.4	4.4%
10	Dermatological drugs	\$ 216.6	3.8%
11	Hormones for systemic use, excluding sexual hormones	\$ 143.4	2.5%
12	Miscellaneous	\$ 141.7	2.5%
13	Sense organs	\$ 74.8	1.3%
14	Antiparasitic drugs, repellents and insecticides	\$ 10.9	0.2%
TOTAL 2017		\$ 5,698.5	100.0%

Source: INDEC

Antineoplastic and immunomodulatory **drugs led the market in 2017.**

TURNOVER BY **COUNTRY OF ORIGIN** OF PARENT DRUG

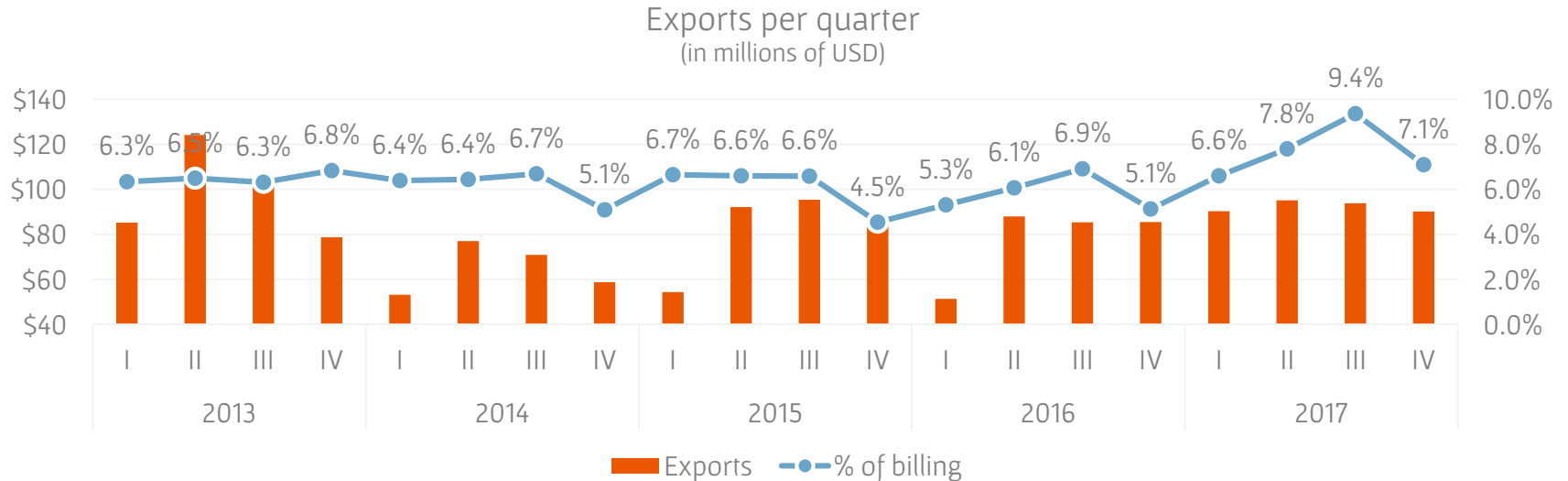
The origin of the parent drug is mostly national. It is closely followed by **India**, one of the world's leading suppliers of active ingredients.

Germany comes at third place with a production almost half as big as the Indian, followed by the **United States**.

Country of Origin	2017		
	Million pesos	Million USD	%
Argentina	\$ 19,133.60	\$ 1,134.99	19.9%
India	\$ 16,917.8	\$ 1,003.55	17.6%
Germany	\$ 9,410.2	\$ 558.21	9.8%
United States	\$ 8,245.0	\$ 489.09	8.6%
China	\$ 8,073.3	\$ 478.90	8.4%
Switzerland	\$ 6,002.7	\$ 356.08	6.3%
Italy	\$ 5,971.4	\$ 354.22	6.2%
France	\$ 1,922.8	\$ 114.06	2.0%
Spain	\$ 2,769.5	\$ 164.28	2.9%
United Kingdom	\$ 1,858.3	\$ 110.23	1.9%
Canada	\$ 1,215.2	\$ 72.08	1.3%
Uruguay	\$ 1,074.9	\$ 63.76	1.1%
Brazil	\$ 1,026.9	\$ 60.91	1.1%
Holland	\$ 780.1	\$ 46.27	0.8%
Ireland	\$ 701.6	\$ 41.62	0.7%
Sweden	\$ 514.3	\$ 30.51	0.5%
Israel	\$ 595.4	\$ 35.32	0.6%
Belgium	\$ 516.0	\$ 30.61	0.5%
Japan	\$ 531.4	\$ 31.52	0.6%
Mexico	\$ 541.7	\$ 32.13	0.6%
SUBTOTAL	\$ 87,802.1	\$ 5,208.3	91.5%
Unidentified countries	\$ 6,495.2	\$ 385.29	6.8%
Others	\$ 1,661.5	\$ 98.56	1.7%
TOTAL	\$ 95,958.8	\$ 5,692.2	100.0%



EXPORTS SHARE

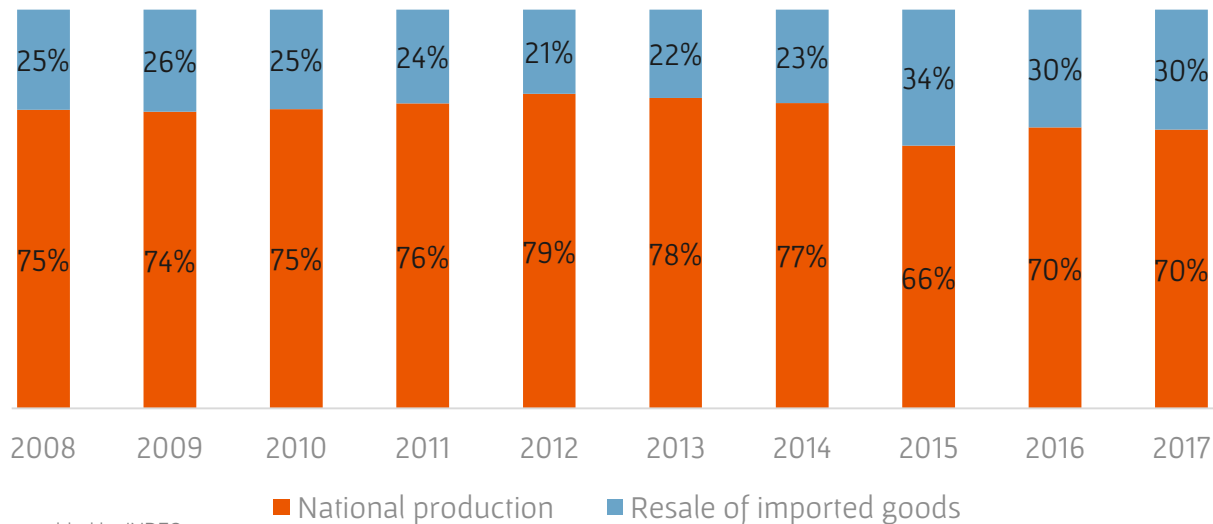


Source: Compiled based on information provided by INDEC.

Exports represent a small part of the industry's turnover: during the Q4 2017 they accounted for 7.1% of the total turnover of the industry.

They hit a record high in the Q3 of 2017, reaching 9.4%, and their lowest fall was recorded in Q4 2015 at 4.5%. Historically, it has ranges around 6% of the total turnover.

NATIONAL PRODUCTION VS. IMPORTS

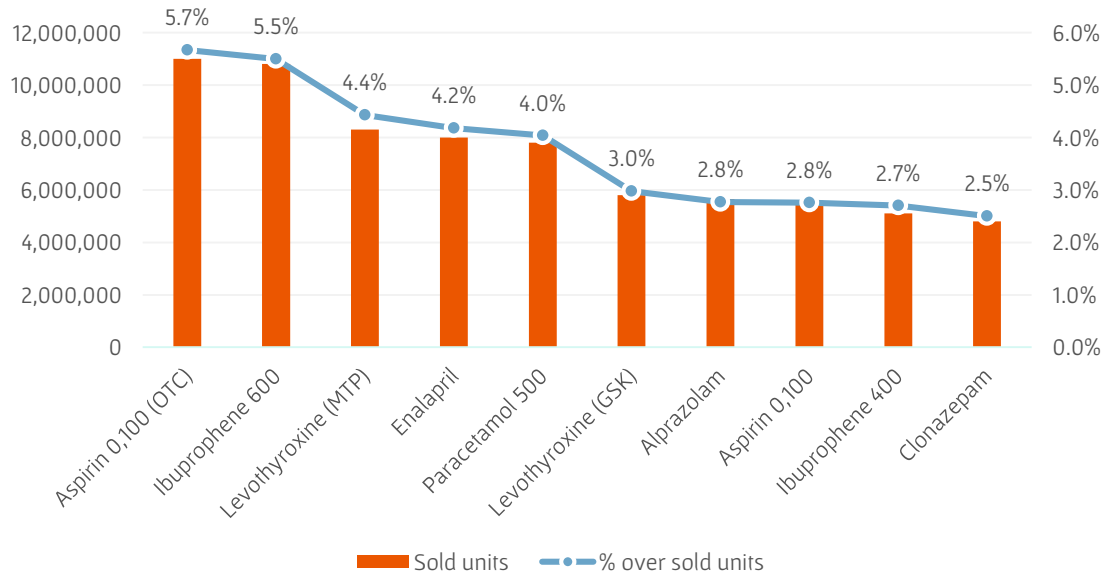


Source: Compiled based on information provided by INDEC.

The domestic market is supplied mostly by locally manufactured medicines. In 2017, 70% of the domestic market turnover was made up of domestically produced medicines, whereas the remaining 30% accounted for resold imports. The share of imported pharmaceutical products in the domestic market has been increasing moderately in recent years.

MAIN PRODUCTS

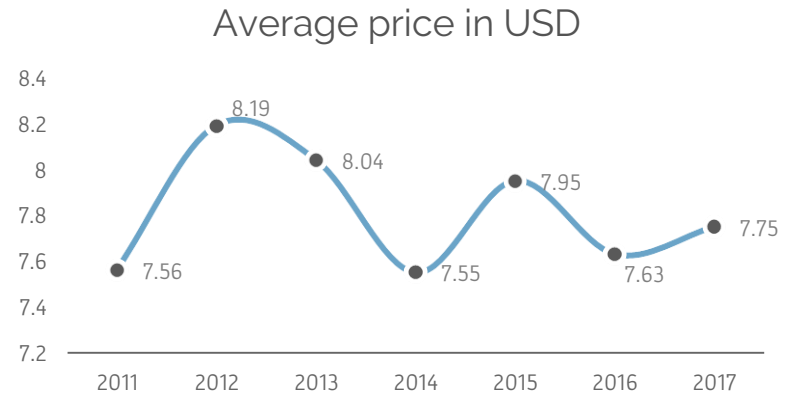
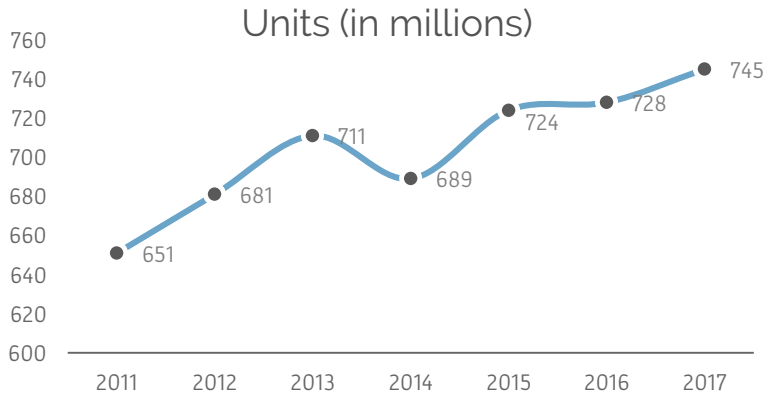
Percentage and volume of the 10 best selling products in 2017



The top 10 most sold products in terms of units in 2017 represented **37.5%** of the market.

Considering that the Argentine pharmaceutical market is composed of approximately **20,000** products, it is easy to conclude that it is a unit-oriented market.

PRICE AND VOLUME



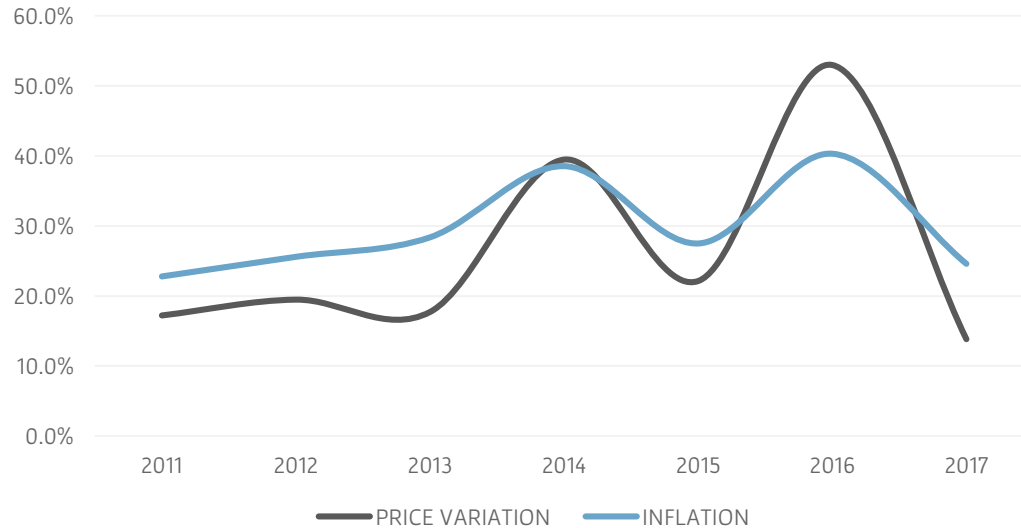
Compiled based on information provided by INDEC, the Ministry of Health and the Central Bank.

In terms of volumes, the market shows a marked upward trend almost uninterrupted since 2011, with a single low in 2014. The number of units sold in 2017 totaled 745 million, which represents a 14,5% increase with respect to 2011.

In dollars, the average price of medicines have been moving in a slight upward trend over the past years; the volatility has been decreasing since 2014.

PRICE EVOLUTION

Average price vs. inflation



Source: Compiled based on information provided by INDEC and the Central Bank.

Over the past years, the average price variation of medicines and the general price level of the economy behaved in a similar fashion, although the former had a broader variation.

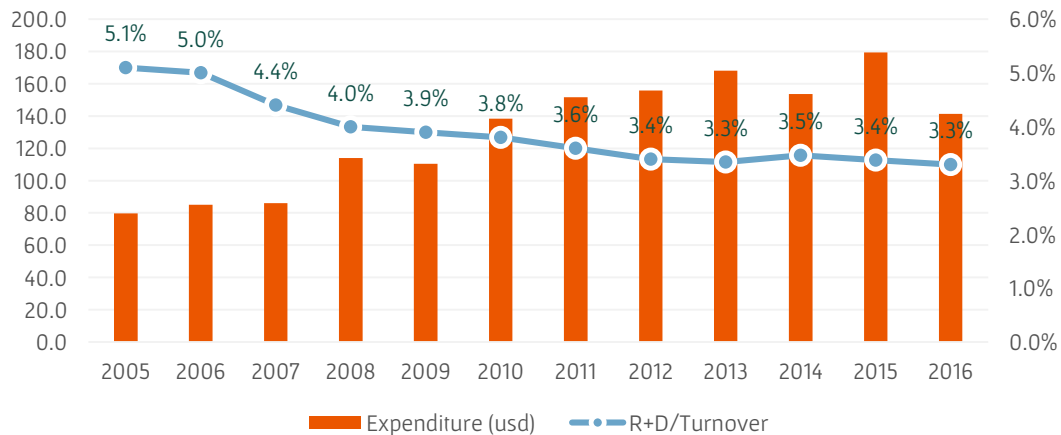
Analyzing the period under review, it is evidenced that prices rocketed in 2014 and 2016. This was mainly due to the high inflation rate recorded during those years, which exerted greater upward pressure on prices, and also to the growing increase in imports combined with sharp devaluations of the Argentine peso.

From 2016 to 2017, the rate of price increase of over-the-counter (OTC) medicines of the best-known ranged between 100% and 200%.

It is a dynamic market in terms of prices, where laboratories fix the retail price. The price they set serves as a reference the other participants of the chain.

RESEARCH AND DEVELOPMENT

Evolution of R+D expenditure in the industry
(millions of USD)



Source: Compiled based on information available at the Ministry of Science, Technology and Productive Innovation.

Industries 2017	Millions of USD	%
Pharmaceutical	\$ 185.21	21.5%
R&D technology and other services	\$ 170.00	19.7%
Seed Companies	\$ 102.38	11.9%
Chemical	\$ 63.00	7.3%
Electrical materials and equipment	\$ 57.20	6.6%
Others	\$ 51.09	5.9%
Software and Informatics	\$ 37.37	4.3%
Food & Beverages	\$ 33.80	3.9%
Machinery and equipment	\$ 32.29	3.7%
Automotive	\$ 31.60	3.7%
Energy	\$ 27.28	3.2%
Steel	\$ 25.36	2.9%
Oil, gas and mining	\$ 20.21	2.3%
Plastics and rubber	\$ 15.45	1.8%
Financial services	\$ 10.29	1.2%
TOTAL	\$ 862.53	100%

Source: Compiled based on information available at the Ministry of Science, Technology and Productive Innovation.

The pharmaceutical industry is the most R&D intensive in Argentina, with a total investment of USD 141 million in 2016. R&D expenditure of pharmaceutical companies has been growing at an average annual rate of 23% in nominal terms, and 6% in real terms, representing 21.5% of the annual national R&D expenditure in 2017. However, the evolution of R&D participation in the revenue is negative for the period. Between 2005 and 2016, it fell from 5.1% to 3.3%, with a marked downward trend.

RESEARCH AND DEVELOPMENT

R&D investment represents 3.3% of the turnover. By contrast, in the pharmaceutical leading countries, R&D expenditure represent between 10% and 15% of sales.

The developments of national laboratories fall within either of the following two categories:

1. New medicines with more than one already existing therapeutic action combined in a single product.
2. Copies of existing medicines whose patent has expired or copies with a different dosage.

In general, the development of new products is carried out by larger national companies, since it requires costly research.

Foreign capital laboratories focus on innovating in quality control and adapting developments of their parent companies.



ACTORS AND COMPETITORS

PUBLIC ORGANIZATIONS INVOLVED

REGULATORY ORGANIZATIONS

ANMAT (Spanish acronym of) : National Administration of Medicines, Food and Medical Technology. It is a decentralized agency of the National Ministry of Health created in 1992 and plays a major role in the regulation of the pharmaceutical industry. Its main function is to ensure the quality of medicines and medical supplies, among other products.

INAME: National Institute of Medicines. Under the authority of ANMAT, its function is to oversee and control pharmaceutical and biological products and the facilities of the entities where these products are elaborated, imported and distributed.

ANLIS: National Administration of Laboratories and Health Institutes. It is an organization under the authority of the Ministry of Health aimed at developing and coordinating actions to prevent infectious diseases.

RESEARCH ORGANIZATIONS

CONICET: National Council of Scientific and Technical Research. It is an autarchic entity under the authority of the Ministry of Science, Technology and Productive Innovation engaged in the promotion of science and technology. Its function is to promote and finance scientific and technological research and to support the development in this field.

ANCYT: National Agency for Scientific and Technological Promotion. It is a national agency under the authority of the Ministry of Science, Technology and Productive Innovation, whose main function is to promote the funding of projects that seek to improve the social, cultural, and economic conditions of the country.

MAIN PRIVATE ORGANIZATIONS INVOLVED

CAEME: Argentine Chamber of Medicinal Specialties. It is a non-for-profit civil association. Its main purpose is to promote and defend the common interests of its associates and the development of the national pharmaceutical industry.

COOPERALA: Pharmaceutical Laboratories Chamber of Commerce. Its main purpose is to coordinate the actions of its members, provide advice and represent their interests before national and international organizations.

CILFA: Industrial Chamber of Argentine Pharmaceutical Laboratories. Founded in 1964, its main goal is to advocate and promote the development of industry and other similar activities related to the national production of medicinal products.

CAPGEN: Argentine Chamber of Generic and Hospitable Drug Manufacturers. This organization comprises national laboratories that manufacture pharmaceutical products in plants located in the country. Its main goal is to develop an industrial pharmaceutical network of nationally manufactured generic medicines that satisfies the demand of the state and the general public.

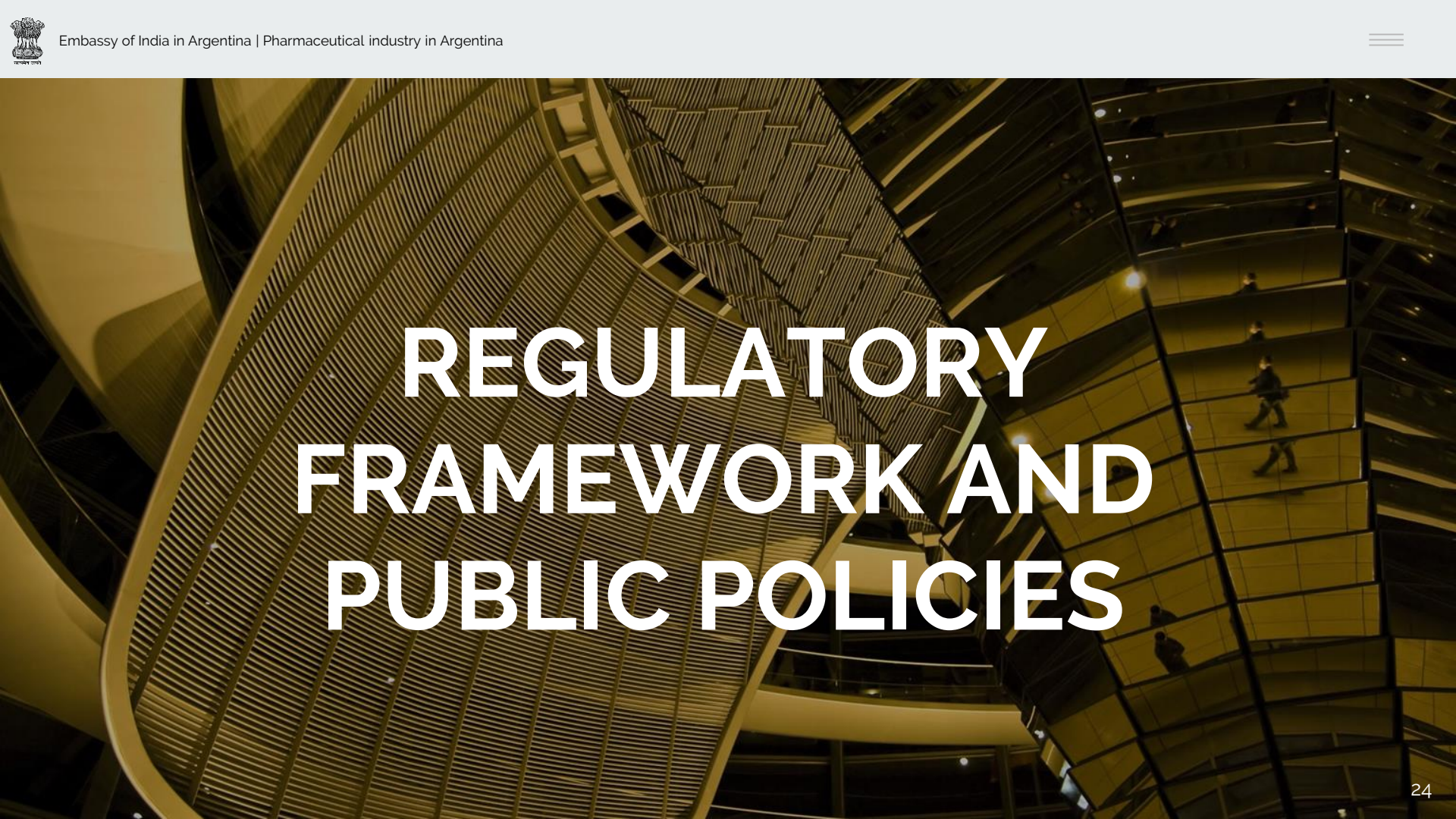
CAPEMVEL: Argentine Chamber of Over-the-Counter (OTC) Medicinal Specialties Manufacturers. This organization is comprised by national and international companies that trade in the Argentine market of OTC medicines. It is a member of the WSMI (World Self-Medication Industry).

COMPETITORS

Only 3 out of the 15 laboratories with highest revenue are foreign. The laboratory with the highest turnover in 2017 was **Rommers**, a national firm which achieved a market share of 10.4%. **Bayer** follows it closely in second place, after occupying the first place in 2016.

This market is characterized by a high degree of **atomization**: the 15 laboratories with higher revenue concentrate 73% of the market.

RANKING 2017	LABORATORY	CAPITAL	MILLION USD	MARKET SHARE (%)
1	ROEMMERS	NATIONAL	599	10.4%
2	BAYER	FOREIGN	549	9.5%
3	GADOR	NATIONAL	332	5.7%
4	ELEA	NATIONAL	314	5.4%
5	MONTPELLIER	NATIONAL	291	5.0%
6	BAGÓ	NATIONAL	285	4.9%
7	GENOMMA	FOREIGN	237	4.1%
8	CASASCO	NATIONAL	231	4.0%
9	BALIARDA	NATIONAL	225	3.9%
10	PFIZER	FOREIGN	219	3.8%
11	NUTRICIA BAGÓ	NATIONAL	214	3.7%
12	INVESTI	NATIONAL	184	3.2%
13	ANDRÓMACO	NATIONAL	181	3.1%
14	BERNABO	NATIONAL	178	3.1%
15	RAFFO	NATIONAL	172	3.0%

The background of the slide is a photograph of a modern building's interior, featuring a large, curved, multi-level atrium with a glass and metal facade. The lighting is warm and yellow, and several people can be seen walking on the upper levels.

REGULATORY FRAMEWORK AND PUBLIC POLICIES

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.
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.

INCENTIVES FOR THE INDUSTRY

Ministry of Health

Promotes the free distribution of medicines and immunization programs according to population age and risk.

Laws

- ✓ Patents of Invention and Utility Models Law
- ✓ Law on Public Manufacturing of Medicines

Investment Funding

FONAPyME (Spanish acronym): National Fund for the Development of Micro, Small and Medium Enterprises. Its main goal is to provide financial support to MSMB (micro, small and medium businesses) seeking to invest to develop new products, expand their productive capacity and to enhance current processes by acquiring new capital assets or securing new facilities.

ANPCyT: National Agency for Scientific and Technological Promotion. One of the main public agencies that promotes the scientific and technological development of the industry through its different funds, namely:

- ✓ FONTAR: Argentine Technological Fund Provides funding for projects aimed at improving the productivity of the private sector through technological innovation. In 2016, it granted loans to the private sector amounting to 99 million pesos (USD 6.5 million).
- ✓ FONCyT: Fund for Scientific and Technological Research. Provides funding for research projects whose purpose is to generate new scientific and technological knowledge. In 2016, it financed projects for a total amount of 165 million pesos (USD 11 million).



SWOT ANALYSIS

SWOT

STRENGTHS

1. Highly dynamic industry that can overcome successive local economic crises.
2. National companies are accountable for over 50% of production and sales; this gives the industry a competitive edge over its competitors in other countries and regions of the world.
3. National laboratories have become international and extended operations to Latin America, the US, Europe and Asia.
4. It is the industry that allocated the highest proportion of income to R+D and one of the industries with the highest demand of qualified labor.
5. The pharmaceutical industry supplies both the local and foreign markets with high quality products.



SWOT

WEAKNESSES

1. A great proportion of raw materials, inputs and capital goods are imported.
2. Scarce funding for investment and production, which constrains the possibilities of expansion to international markets.

SWOT

OPPORTUNITIES

1. Possibilities to increase the economy of scale in production, which would boost productivity and reduce costs.
2. Argentine exports are destined mainly to Latin America, which means the industry could further expand to new non-traditional markets.
3. It is feasible to substitute imports with locally manufactured products.

OPPORTUNITIES FOR INDIA

1. Generic drug market in Argentina
2. Opportunities for Joint venture with domestic pharma companies or laboratories
3. Market for medical devices used in cardiovascular, respiratory, renal problems, etc.
4. Indian companies manufacture drugs in India and marketed by overseas companies
5. Generic anti-cancer drugs may have potential for Indian companies
6. Argentina specializes in the production of generic medicines, especially in analgesics and anti-inflammatories. This niche presents an investment opportunity for India, the main producer of generics in the world.

SWOT

OPPORTUNITIES FOR MANUFACTURING AND EXPORT TO MERCOSUR

1. Currently India has a preferential agreement with MERCOSUR, which includes pharmaceutical products. This agreement has tariff reductions of up to 20%.
2. Exporting to Argentina can be the gateway to the MERCOSUR. Moreover, producing within it would make it possible to take advantage of the block's benefits even more, achieving better costs. The MERCOSUR is a market of 264 million people and a GDP of 2,781 billion USD in 2017.

OPPORTUNITIES FOR MANUFACTURING AND EXPORT TO SOUTH AMERICA

1. Currently, India exports 10% of its medicines to South American countries, supplying generic medicines at a very competitive price. In addition, Argentina presents an opportunity for Indian companies in the sector to position themselves in one of the largest and most potential markets in the South American region.
2. In South America there is a general interest in developing relations with India. Countries such as Argentina, Brazil, Chile, Colombia, among others, encourage the development of commercial relations with Indian companies, which include pharmaceutical products. Recently, the VIII India-Latin America and Caribbean Conclave was held in Santiago de Chile, exposing investment opportunities for India.
3. The demand for generic drugs is increasing in several countries of South America.



SWOT

THREATS

1. Argentina is weak in terms of incentives, exports, research and innovation compared to countries such as China and India.
2. Execution of commercial agreements that motivate the import of products from countries with subsidies to their production.
3. High inflation rates have an adverse effect on costs.



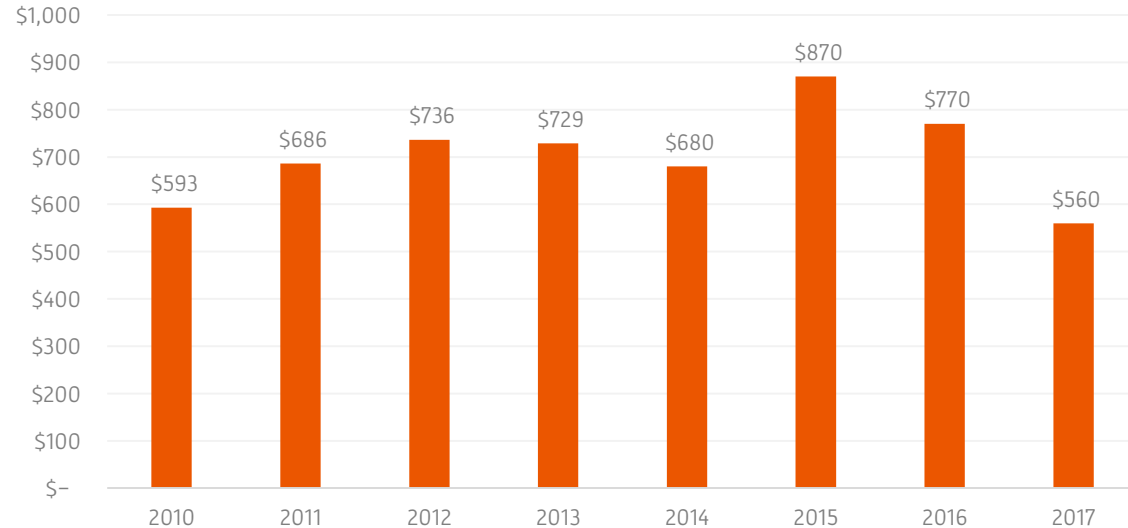
INTERNATIONAL TRADE



EXPORTS

Evolution of Argentina's pharmaceutical exports

(FOB value in million dollars)



Source: Compiled based on information provided by INDEC and Customs.

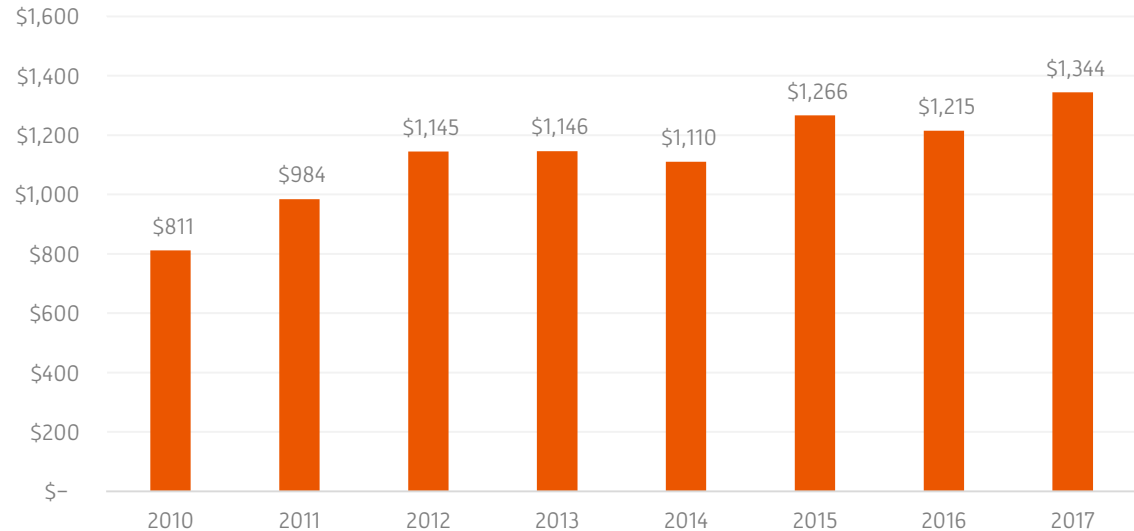
Since 2015, there is a marked downward trend in exports, which is currently hitting a record low in the last eight years, such adverse scenario results from the exchange rate lag that strikes the country and high inflation rates that impact costs. Exports totaled USD 240 million during the first semester of 2018.



IMPORTS

Evolution of Argentina's pharmaceutical imports

(FOB value in million dollars)



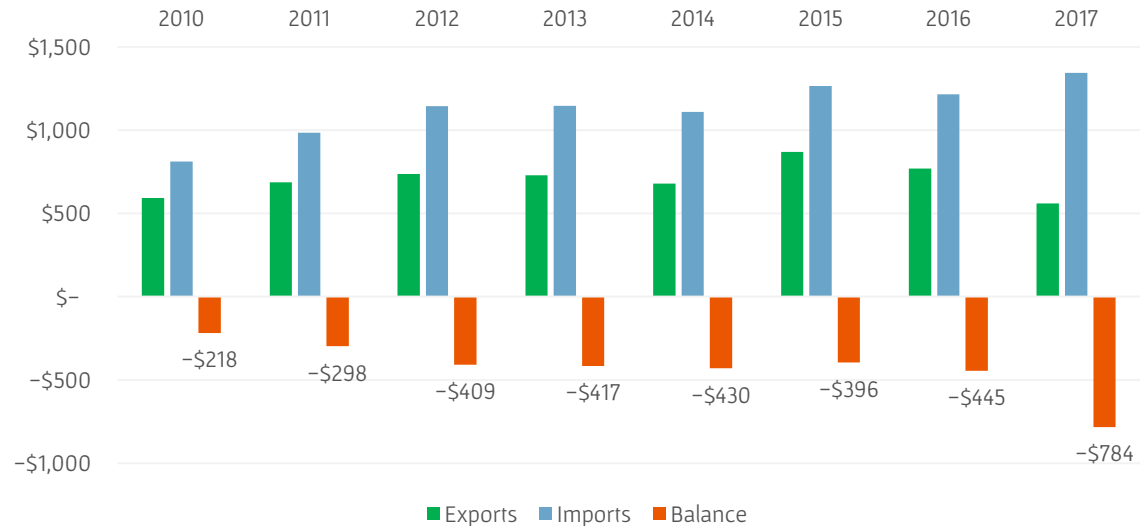
Source: Compiled based on information provided by INDEC and Customs.

In contrast to exports, imports of medicines have increased in the past years slowly and gained ground in the domestic market. During the period 2013-2017, sales in dollars in the domestic market increased by 17%, but imports in that period increased in the same proportion. Such phenomenon demonstrates that the pharmaceutical industry is heavily reliant on imports of raw materials and capital goods.

TRADE BALANCE

Trade Balance Evolution

(FOB value in million dollars)



Source: Compiled based on information provided by INDEC and Customs.

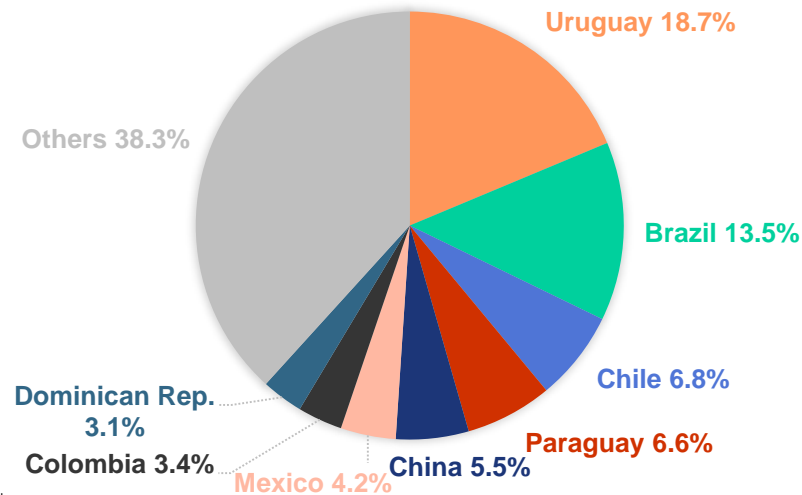
The industry presents a structural trade deficit, stemming from a decline in exports and an increase in imports, a trend that was further accentuated in the past years. From 2016 to 2017, deficit increased by 76%, which mirrors the contrast exports and imports during 2017: while exports fell to record lows since 2010, imports hit a peak since that year.

— MAIN EXPORT COUNTRIES

EXPORT TRADING PARTNERS

Evolution of Argentina's pharmaceutical exports

(FOB value in million dollars)



Source: Compiled based on information provided by INDEC and Customs.

The main destinations of Argentina's pharmaceutical exports are Latin American countries. Uruguay was the first importer in 2017 accounting for 18,7% of total exports.

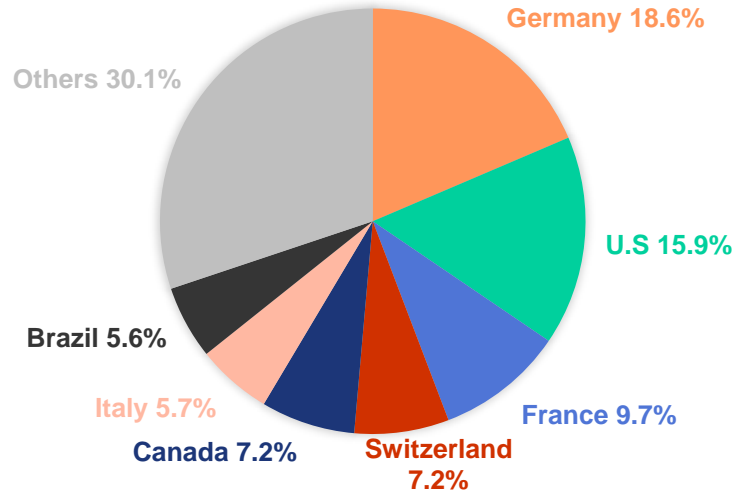
China is the only non-Latin American country among Argentina's main trading partners and ranks fifth.

— MAIN IMPORT COUNTRIES

IMPORT TRADING PARTNERS

Evolution of Argentina's pharmaceutical imports

(FOB value in million dollars)



Source: Compiled based on information provided by INDEC and Customs.

Argentina's main imports trading partner is Germany representing 18.6% of the total products imported in 2017.

United States follows Germany closely providing 15.9% of the total imports .

ARGENTINE MARKET SHARE

EXPORTS

Argentine pharmaceutical exports represented **0.2%** of the total worldwide pharmaceutical exports in 2017.

IMPORTS

Argentine pharmaceutical imports represent **0.4%** of the total worldwide pharmaceutical imports in 2017.

FUTURE PERSPECTIVES

- 1.** Argentina's foreign trade of pharmaceutical products has been in deficit for a large part of its existence. Deficit rose in the past years and future perspectives are inauspicious in the medium term due to the economic crisis the country is currently undergoing.
- 2.** Overall, worldwide pharmaceutical exports have increased. In 2017, the total global pharmaceutical exports rose 3% compared to the previous year. Such world scenario, together with the decline of Argentine exports, could cause Argentina to lose market share in foreign markets.
- 3.** By contrast, the rise in pharmaceutical imports is expected to be in tune with the growth in national production, as many inputs and capital goods are imported.



INDUSTRY TRENDS AND STRATEGIES

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.

CURRENT TRENDS

- 1.** Pharmaceutical and input imports are growing: from 2016 to 2017 they edged up to 10.6% in dollars.
- 2.** Exports have been falling since 2015. They are expected to pick up slowly in the short run; nevertheless, but the industry will continue to run a trade deficit.
- 3.** The domestic market continues to consolidate as sales increase year after year.
- 4.** Increase in national production: it is expected to rise 23% by 2020.
- 5.** It is expected that by 2020 there will be 1,000 new jobs.
- 6.** Pharmaceutical companies invest 3.3% of their total sales in R&D. Such percentage went down in recent years due to lack of incentives and limited access to financing.



CONSIDERATIONS FOR FOREIGN INVESTORS



COUNTRY OVERVIEW

44.494.502

Total population

21.824.372

Men

22.670.130

Women

ARGENTINE

PESO

National currency

2018

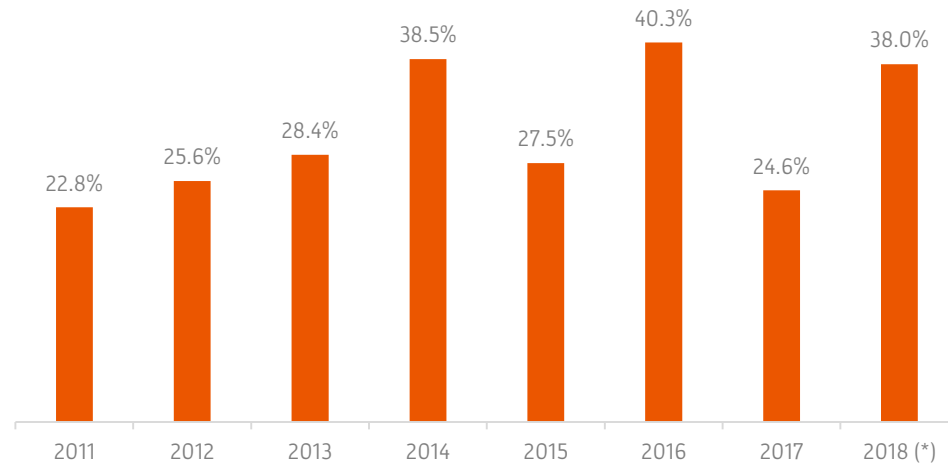
ESTIMATED INFLATION
38%

ESTIMATED GDP GROWTH
-1.5%



CURRENT **ECONOMIC** CONTEXT

Inflation



Source: Compiled based on information provided by INDEC.

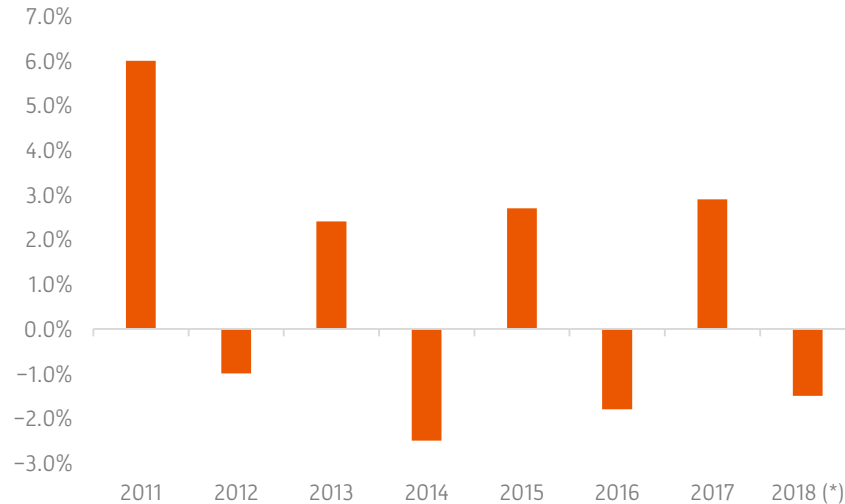
(*) Estimated

Argentina is one of the countries with the world's highest inflation rate. The inflation rate is expected to reach 38% by late 2018, outperforming last year's inflation. Such scenario creates an extra difficulty at the time of conducting businesses that does not occur in other countries: prices increase, on average, 3,15% per month. Consequently, individuals spend more because the Argentine peso nominally loses purchasing power as time goes by. The Argentine economy lacks stability in terms of prices.



CURRENT **ECONOMIC** CONTEXT

GDP



Source: Compiled based on information provided by INDEC.

9%

**Unemployment
rate**

Argentina's GDP has been expanding and shrinking alternatively portraying the volatility of the economy.

GDP is expected to contract 1.5% in 2018.

During the first semester of 2018, the unemployment rate reached 9%, a rate that remains stable in relation to last year's statistics.



TAXATION AND LABOR

In Argentina, tax collection efforts are carried out at national, provincial, and municipal level by levying taxes on income, assets, and consumption.

The agency in charge of collecting taxes, monitoring, and controlling taxation at national level is AFIP (Spanish acronym for Argentine Revenue Service).

Consequently, taxes are classified into three tiers: national, provincial, and municipal.

TAXATION AND LABOR. NATIONAL TAXES.

<p>INCOME TAX</p>	<p>All income is subject to tax. Local subsidiaries of foreign legal entities are regarded as resident businesses and are, therefore, subject to tax. The applicable tax rate is 35% and applies to total income. Non-resident businesses with no branches or permanent offices in Argentina are only subject to local income tax.</p>
<p>VALUE ADDED TAX (VAT)</p>	<p>VAT applies to the values of goods and services at every stage of production. General VAT rate is 21%; nevertheless, the rate for certain goods and services is set at 10,5% or 27%. Imports are subject to the same VAT rate as local goods and services. Exports are exempt from VAT.</p>
<p>MINIMUM PRESUMED INCOME TAX</p>	<p>Minimum Presumed Income Tax is payable by legal entities, which are imposed a 1% rate on the value of all their assets located either in Argentina or abroad. It is also applicable to assets located in Argentine and owned by foreign individuals or legal entities with a permanent establishment in the country. This tax will be eliminated in 2019.</p>
<p>PERSONAL PROPERTY TAX</p>	<p>This tax is imposed on individuals and undivided estates with respect to assets valued at over ARS 1.050.000 (USD 27.000 approx.) as of 2018. As of this year, residents are taxed 0,25% on personal property.</p>
<p>EXCISE TAXES</p>	<p>Excise taxes are levied on the consumption of specific goods, such as tobacco, alcoholic drinks, and luxury items; they are payable by manufactures or importers.</p>
<p>FINANCIAL TRANSACTION TAXES - CREDITS AND DEBITS ON BANK ACCOUNTS AND OTHERS.</p>	<p>A 0,6% general tax is levied on withdrawals and credits on bank accounts transacted by entities governed by the Financial Institutions Act. Furthermore, transactions in cash are subject to a 1.2% rate if conducted through payment systems in lieu of current accounts.</p>

TAXATION AND LABOR. **NATIONAL TAXES.**

DOUBLE TAXATION AGREEMENTS

Argentina has entered into double taxation agreements with the following countries to provide relief from double taxation on businesses, personal income, capital, and assets:

- ✓ Australia
- ✓ United Kingdom
- ✓ Chile
- ✓ Denmark
- ✓ Germany
- ✓ Belgium
- ✓ France
- ✓ Italy
- ✓ Sweden
- ✓ Canada
- ✓ Bolivia
- ✓ Brazil
- ✓ Finland
- ✓ Norway
- ✓ Spain
- ✓ Switzerland
- ✓ The Netherlands
- ✓ Russia
- ✓ Mexico

TAXATION AND LABOR. **PROVINCIAL TAXES.**

GROSS INCOME TAX	Gross Income tax is applicable to the revenue generated by businesses engaged in trade, industrial activities, agriculture, finance, or professional services. It is levied on each commercial transaction at a rate that ranges from 1,5% to 5%, according to the industry and area. Nevertheless, certain primary and industrial activities are exempted from this tax.
STAMP DUTY	This is a provincial tax placed on the execution of notarial and private documents, including agreements and other large-amount transactions.
REAL ESTATE TRANSFER TAX	Real estate owners are subject to an annual tax on their real property based on the fiscal value of the land free of any improvements and on the improvements of land, if any. The payable amount is estimated pursuant to the laws in force each fiscal year, which set forth the applicable values and rate scales according to the type of property.

TAXATION AND LABOR. **MUNICIPAL TAXES.**

Municipalities collect taxes imposed on industrial safety services, lighting and cleaning services, etc. These taxes are calculated based on public revenue or other criteria, such as the number of employees.

TAXATION AND LABOR. **TAX INCENTIVES.**

Tax regulations provide for incentives for certain activities such as mining, forestation, software development, renewable energies, research, biotechnology, and biofuel production.

Generally, such incentives consist in:

- ✓ **Tax stability for a specified period**
- ✓ **Tax credits**
- ✓ **Preferred tax rates**
- ✓ **VAT Exemption**

A tax-free area has been established in southern Tierra del Fuego where all the activities and transactions conducted are exempted from all national taxes, except for specific activities and transactions, which are levied a reduced rate.

TAXATION AND LABOR. **LABOR LAW.**

Labor Law no. 20,744



Permanent employment contract

Employment contracts in Argentina generally fall within this category, which means the labor relationship may extend permanently unless a cause of termination arises. The law provides for a three-month probation period. The employer must register the relationship with the relevant authority before the lapse of this period. Moreover, the parties are subject to the rights and obligations arising out the employment contract during this period, but either party may terminate the employment without cause. In such case, the employee is not entitled to severance payment.

Special employment contracts

In order to provide an adequate framework, the law sets forth special forms of employment:

1. Fixed-term contracts
2. Seasonal employment contracts
3. Contingency employment agreement
4. Team employment contracts

TAXATION AND LABOR. **LABOR REGULATIONS.**

COMPENSATION (SALARIES AND WAGES)

Employees' compensation may be fully paid in cash or it may be paid both in cash and in kind, i.e. food or accommodation. In such case, payments in kind cannot exceed 20% of the total compensation amount.

The employer has the obligation to:

- ✓ Wire-transfer the employee's salaries to a bank account on their names.
- ✓ Provide a salary slip
- ✓ Comply with the statutory term of payment: salaried employees must be paid at the end of the month, whereas wage earners must receive their compensation on a weekly or monthly basis.

STATUTORY ANNUAL EXTRA PAY

All workers are entitled to a thirteenth salary, which is officially referred to as Statutory Annual Extra Payment. Such payment is made in two installments: 50% of the total amount is granted by June 31 and the remaining 50% by December 31.

MINIMUM SALARY AND WAGE

The law establishes the minimum salary and wage amount. As of July 2018, such amount is set at ARS 10.000 (USD 260 approx.) for monthly salaries and ARS 50 (USD 1.30) for hourly wages.

Given Argentina's high inflation rates, salaries are adjusted several times a year.

TAXATION AND LABOR. **LABOR REGULATIONS.**

ANNUAL VACATION

Annual vacation is paid time off employers grant to their employees.

The length of vacations varies according to the employee's seniority:

1. From 6 months to 5 years of service: 14 calendar days
2. From 5 to 10 years of service: 21 calendar days
3. From 10 to 20 years of service: 28 calendar days
4. Over 20 years of service: 35 calendar days

New employees who have rendered services for less than half the business day of the year are entitled to one vacation day for every 20 days of service.

PAID MATERNITY LEAVE

The law provides for paid maternity leave which extends from 45 days before childbirth to 45 days after delivery.

Once this period elapses, women workers can choose to:

1. Resume working under the working conditions before the leave.
2. Terminate the employment contract unilaterally.
3. Request an unpaid extension of the maternity leave for an additional period ranging from three to six months.

Women workers are entitled to a daily thirty-minute break to breastfeed her child. This entitlement lasts for one year after childbirth.

TAXATION AND LABOR. **LABOR REGULATIONS.**

LABOR RISKS

Employers have the obligation to provide insurance to employees to cover labor risks. To such end, they must either self-insure or hire a risk labor risk insurance company (in Spanish Aseguradoras de Riesgos del Trabajo or ART), in order to compensate in the event of work accidents and diseases.

SOCIAL SECURITY

Businesses undertake to make the relevant contributions in connection with social security services for their employees. Such contributions include family allowances, union health insurance, pensions, and contributions to unemployment funds. Contributions represent 27% of the gross salary of employees that render services and 23% of the gross salary of the rest of the employees.

COMPULSORY LIFE INSURANCE

The employer must obtain an insurance policy within thirty days of the commencement of the employment relationship.

MINIMUM WORKING AGE

The minimum working age is 16 years old.

TAXATION AND LABOR. **LABOR REGULATIONS.**

DISMISSAL

None of the parties can terminate the employment contract without giving prior notice. The minimum notice period is set by the law as follows:

1. For the employee: 15 days
2. For the employer: 15 days for employees under probation period, one month when the worker's length of service is less than five years, and two months, when the length of service exceeds five years.

EMPLOYMENT RELATIONSHIP RECORDS

The employer has the obligation to register the employment relationship with the relevant authorities. In the event of termination of contract, the employer must give relevant notice to the Social Security Registry.

The duly registration of the employment relationship allows workers to enjoy the social security benefits granted by the law.

TAXATION AND LABOR. **LABOR REGULATIONS.**

OVERTIME

In Argentina, working time is 48 hours per week with a limit of nine hours a day (six hours a day for work performed under hazardous conditions). Night working time is limited to seven-hour shifts. Overtime is permitted with certain restrictions. Overtime rate is 50 per cent, for work performed on weekdays and Saturday mornings, and 100 per cent for work performed thereafter and on public holidays. The law establishes the maximum overtime limit which shall not exceed 200 hours per year or 30 hours per month.

LABOR UNIONS

Most workers are unionized. Historically, the power and influence of union was moderate, but it has increased in the last few years to such an extent that workers are also protected by collective bargaining agreements. Moreover, these workers may also opt for joining a union.

RELEVANT LEGISLATION

LEGAL FRAMEWORK	<p>The Argentine Law provides for the protection of foreign investors and their projects. Argentina has entered into several bilateral investment treaties with other countries. It is a member country of the Multilateral Investment Guarantee Agency (MIGA), which provides guarantees to protect investments against non-commercial risks.</p>
INVESTMENT MODEL	<p>Foreign investors can start their businesses in three ways: setting up a foreign branch, acquiring ownership in an existing company or creating a new company.</p>
CORPORATE AND BUSINESS ACT	<p>Law No. 19,550 (amended and renamed as General Corporate and Business Law No. 26,994). Sets forth the different business forms available. The most popular business forms among foreign investors are Sociedades Anónimas (S.A.)— Corporations— and Sociedades de Responsabilidad Limitada (S.R.L.) — Limited Liability Companies or LLCs.</p>
FOREIGN INVESTMENT LAW	<p>Law No. 21,382 Sets forth the conditions for foreign investors to invest and transact business in the country. It further provides for the expansion of existing investment undertakings.</p>
TRANSFER OF FUNDS	<p>The funds received as capital contribution from foreign residents can be entered into the country or be kept abroad, there are no regulations in this respect.</p>

EXCHANGE RATES

Date	ARS/USD
jan-13	4.96
feb-13	5.02
mar-13	5.09
apr-13	5.17
may-13	5.25
jun-13	5.34
jul-13	5.44
aug-13	5.49
sep-13	5.75
oct-13	5.86
nov-13	6.03
dec-13	6.33
jan-14	7.07
feb-14	7.86
mar-14	7.94
apr-14	8.01
may-14	8.06

Date	ARS/USD
jun-14	8.14
jul-14	8.18
aug-14	8.33
sep-14	8.43
oct-14	8.49
nov-14	8.53
dec-14	8.56
jan-15	8.61
feb-15	8.70
mar-15	8.79
apr-15	8.88
may-15	8.96
jun-15	9.05
jul-15	9.16
aug-15	9.26
sep-15	9.38
oct-15	9.50

Date	ARS/USD
nov-15	9.64
dic-15	13.30
jan-16	13.93
feb-16	15.04
mar-16	15.22
apr-16	14.70
may-16	14.43
jun-16	14.44
jul-16	15.17
aug-16	15.13
sep-16	15.32
oct-16	15.45
nov-16	15.57
dec-16	16.10
jan-17	16.21
feb-17	15.91
mar-17	15.83

Date	ARS/USD
apr-17	15.67
may-17	16.00
jun-17	16.37
jul-17	17.44
aug-17	17.72
sep-17	17.55
oct-17	17.76
nov-17	17.79
dec-17	18.05
jan-18	19.36
feb-18	20.17
mar-18	20.56
apr-18	20.54
may-18	24.19
jun-18	27.26
jul-18	28.29
aug-18	30.96

Monthly average exchange rates.

The Argentine peso was subject to a sharp devaluation in August 2018:

- In early August, the Argentine peso traded at 28.23 against the dollar.
- By the end of the month, it traded at 39.15 against the dollar.
- The Argentine peso depreciated by 38% against the US dollar during this month.



CONCLUSION

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The Argentine pharmaceutical industry, undoubtedly, produces high-quality products; it has been growing both in volume and turnover and is expected to continue expanding in the upcoming years. In this context of increasing demand, it is possible to expand the economy of scale, which will boost productivity and reduce costs. Such scenario secures an auspicious future for laboratories, which still have a long way to go in terms of market development. Nevertheless, it will be a tough undertaking due to the lack of incentives from the State and the limited access to financing.

With respect to foreign markets, it is about time to export products to non-traditional markets as Argentina is already a renowned exporter in Latin America. Its vast experience and sound structure, in addition to its high-quality pharmaceutical products, makes Argentina an exporter with great potential.

Moreover, the pharmaceutical industry is the most intensive in terms of science and innovation, which renders it a very dynamic and strategic area for the development of the domestic economy. Its development requires a high investment in R&D. Nevertheless, the industry cannot profit from its social and economic potential benefits given the current disinvestment strategies adopted by laboratories, the increase in imports and the very weak legal framework that fails to provide policies and incentives. Consequently, it is recommended that economic policies be made to encourage investment in R&D and to fully leverage the industry's contributions in terms of knowledge, employment and productivity.



USEFUL INFORMATION

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National Agency for Scientific and Technological Promotion (ANCYT, Spanish Acronym).	Address: Godoy Cruz 2370 – City of Buenos Aires Postal Code: C1425FQD Phone: (54-11) 4899-5300 www.agencia.mincyt.gob.ar
National Institute of Medicines (INAME)	Address: Av. Caseros 2161 – City of Buenos Aires Postal Code: C1264AAB Phone: (54-11) 4340-0800 (under the authority of ANMAT)
National Administration of Laboratories and Health Institutes (ANLIS)	Address: Av. Caseros 563 – City of Buenos Aires Postal Code: C1282AFF Phone: (54-11) 4303-1807/11 www.anlis.gov.ar
Argentine Chamber of Medicinal Specialties (CAEME)	Address: Arias 1636 – 6th Floor – City of Buenos Aires Postal Code: C1429DWA Phone: (54-11) 4507-9000 www.caeme.org.ar
National Council of Scientific and Technical Research (CONICET)	Address: Godoy Cruz 2290 – City of Buenos Aires Postal Code: C1425FQB Phone: (54-11) 4899-5400 www.conicet.gov.ar

USEFUL INFORMATION

Argentine Chamber of Medicinal Specialties (CAEME)	Address: Arias 1636 – 6th Floor – City of Buenos Aires Postal Code: C1429DWA Phone: (54-11) 4507-9000 www.caeme.org.ar
Pharmaceutical Laboratories Chamber of Commerce (COOPERALA)	Address: Sarmiento 1113 – City of Buenos Aires Postal Code: C1041AAW
Industrial Chamber of Argentine Pharmaceutical Laboratories (CILFA)	Address: Av. del Libertador 602 - 6th Floor – City of Buenos Aires Postal Code: C1001ABT Phone: (54-11) 4819-9550 www.cilfa.org.ar
Argentine Chamber of Generic and Hospitable Drug Manufacturers (CAPGEN)	Address: Mariano Acha 2102 – City of Buenos Aires Postal Code: C1430DUR Phone: (54-11) 4545 8029 www.capgen.com.ar
Argentine Chamber of Over-the-Counter Medicinal Specialties Manufacturers (CAPEMVEL)	Address: Av. Santa Fe 1845 - 4th Floor , apt. "A" – City of Buenos Aires Postal Code: C1123AAA Phone: (54-11) 4812-9759 www.capemvel.org.ar



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