

SCENARIO AND PERSPECTIVES FOR THE NATIONAL PHARMACEUTICAL INDUSTRY

2018-2021



**INDUSTRIAL CHAMBER OF ARGENTINE PHARMACEUTICAL
LABORATORIES**

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I INTRODUCTION

The local policies of most developed countries consider the pharmaceutical industry a strategic sector. This responds to facts such as knowledge creation, technology, healthcare, and the production of high value-added assets, as well as the need to make all therapeutic innovations available to the population in order to improve national health standards.

The manufacturing and marketing of pharmaceuticals around the world is led by multinational companies present in most markets. In 2017, the global pharmaceutical market size, measured by the volume of sales of all companies in the main markets, amounted to USD 1.099 trillion, 3.2 % higher than the previous year. Global sales increased by 37.1%, rising from USD 801.5 bn. in 2008¹ Such growth rate implies a 3.6% annual accumulated rate for the period 2008-2016.

Market distribution of pharmaceuticals, by region, is as follows:

	2017		
By region	U\$S Bn	Structure	Variation
North America	476.7	43,4%	0.7%
Europe	213.9	19.0%	5.6%
Japan	76.0	6.9%	-5.1%
Latin America	69.5	6.3%	10.9%
AAA	172.2	15.7%	6.0%
Others	91.1	8.3%	8.1%
Totals	1.099,5	100.0%	3.2%

AAA: Asia, Africa and Australia

Source: *IQVIA Argentina*, wholesale prices

The production and consumption of pharmaceuticals in the world is highly concentrated in developed countries that lead the scientific research, innovation and development of new products. In fact, the United States and Canada account for 43.4% of the whole global pharmaceutical consumption, which reaches 69.7% if Europe and Japan are included.

The Latin American pharmaceutical industry accounts for 6.3% of the global pharmaceutical sales, which reached a total of USD 69.47 bn. in 2017². The real exchange rate distortion of some countries shifts the market evolution analysis towards the variation of units traded in the respective countries.

¹ Based on *IQVIA Argentina* data.

² Based on ex-factory prices. In 2008, value was USD 34.32 bn

LATIN AMERICA - PHARMACEUTICAL MARKET - In millions of units

Country	2008	2010	2015	2016	2017	Annual Accumulated Variation 2008-2017
Brazil	1.632	2.067	3.402	3.553	3.922	10,2%
Mexico	933	915	815	832	916	-0,2%
Venezuela	534	581	577	385	288	-6,6%
Argentina	511	587	729	736	741	4,2%
Colombia	296	311	391	387	419	3,9%
Central America	155	166	221	175	232	4,6%
Chile	224	223	280	273	272	2,2%
Ecuador	165	189	217	212	221	3,3%
Perú	101	105	142	148	153	4,7%
Dominican Republic	38	41	44	38	51	3,3%
Uruguay	64	72	88	92	95	4,5%
Paraguay	41	44	57	57	59	4,0%
Bolivia	25	27	38	43	44	6,5%
Total	4.720	5.328	7.001	6.932	7.412	5,1%

Source: IQVIA Argentina

In units, the Latin American total market expanded by a 5.1% annual accumulated rate during the period 2008-2017, led by Brazil (10.2%). Bolivia (6.5%), Peru (4.7%), Central America (32.5%). Uruguay (4.5%) and Argentina (4.2%).

Prospects for the drug consumption growth rate in the main world markets for the period 2018-2019 are as follows:

- World total: between 2.0% and 4% per year
- North America: between 1% and 3% per year
- Europe: between 0.5% and 2.5% per year
- Latin America: between 5% and 8% per year
- Japan: between 1% and 3.5% per year
- Asia, Africa and Australia: between 6% and 9% per year

II. THE PHARMACEUTICAL INDUSTRY IN ARGENTINA

II.1. Added value, sales and employment level

Argentina's national pharmaceutical industry (NFI) is highly competitive and technologically modern, which meets the strategic goal of ensuring an adequate supply of medicines at affordable prices, manufactured according to international standards. Within this context, Argentina is –altogether with countries such as US, Japan, Germany and Switzerland- one of the few countries in the world where the locally-owned laboratories' presence and share in the domestic market are higher than the multinational laboratories.

Also, the pharmaceutical industry in Argentina is the third industrial sector in terms of the industrial added-value that it generates, only behind the oil refinery and the iron and steel sectors. In addition to this fact -not widely known-, it should be noted that this industry also has the highest research and development levels by sector, which generates high quality and professional job positions; it also plays a key role in the local health system since, by providing significant discounts, it facilitates access to medications to social security beneficiaries.

The national accounts show that the added value of the pharmaceutical sector accounts for 4.9% of the total added value of the industry, while the share of the pharmaceutical sector in the gross production value of the whole Argentine industry is 3.3%, according to the latest economic census data³.

These characteristics, together with the key role the industry plays in keeping its competitiveness level in the domestic market and defending the country position in the world in terms of intellectual property, render it a strategic industry from the standpoint of national interests.

In the year 2017, the Argentine pharmaceutical industry sales in the domestic market amounted to USD 177.7 bn, at consumer prices⁴, and 101.28 bn Argentine pesos at ex-factory prices, which accounted for a 27.4 % increase as compared to the previous year. Sales in dollar currency for last year reached 6.1 bn, which accounts for a 14.8% increase as compared to 2016. Unit sales amounted to 741 millions for the year, representing a 0.6% increase as compared to the year 2016.

³ INDEC, 2003.

⁴ Source: QuintilesIMS. Does not include sales to institutions, hospitals, public bids or "Plan Remediar" (a free medicine program).

TOTAL PHARMACEUTICAL MARKET

Year	In values		In units	
	Bn USD	Variation	Million Units	Variation
2003	1.545		346	
2004	1.808	17.0%	387	11.8%
2005	2.039	12.8%	405	4.7%
2006	2.285	12.1%	443	9.4%
2007	2.681	17,3%	485	9.5%
2008	3.242	20.9%	511	5.4%
2009	3.332	2.8%	535	4.7%
2010	4.018	20.6%	588	9.9%
2011	4.923	22.5%	651	10.7%
2012	5.577	13.3%	681	4.6%
2013	5.713	2.4%	711	4.4%
2014	5.201	-9.0%	689	-3.2%
2015	5.756	10.7%	724	5.1%
2016	5.327	-8.1%	736	1.1%
2017	6.117	14.8%	741	0.6%

Source: QuintilesIMS, exfactory prices

An analysis of the whole period mentioned above shows that the behavior of the accrued growth annual rates for the period 2003-2017 is as follows:

- Unit sales: 5.6%
- Sales in USD: 10.3%
- Sales in Argentine \$: 24.9%

The pharmaceutical manufacturing sector has around 190 plants set up in the country, 160 of which are locally-owned. This represents a solid industrial foundation for production growth and expansion. Moreover, some of them have obtained approval from health authorities of developed countries, such as the Food and Drug Administration (USA), the European Agency for the Evaluation of Medicinal Products - EMEA (European Union) and the Therapeutic Goods Administration -TGA- (Australia).

At present, the Argentine pharmaceutical market is being supplied by nearly 230 laboratories that manufacture a wide range of products to meet the domestic and foreign market demand.

The offer of pharmaceutical products in Argentina is divided into three segments: innovative products, licensed products, and multisource products (similar, brand name, similar non-branded, and generics).

Brand name products account for, approximately, 90% of the market in value terms. Prescription drugs account for 89.8 % share of the market in values, and 74.2% share in units; while the remaining 10.2 % and 25.8 % correspond to over-the- counter drugs (OTC).

Around 2,000 active ingredients and their combinations are used as critical supplies in drug manufacturing, and are imported in most cases. The 20 most demanded active ingredients in Argentina account for nearly 30 % of units sold to the domestic market.

The current direct and indirect labor force amounts to 43,000 and 120,000 employees, respectively. The rate of technicians and university graduates in different professions is relatively higher compared to other sectors, which urges the local industry to consider the implementation of corporate policies that promote the repatriation of Argentine scientists. This procedure, applied several times in the past, would enable the availability of highly skilled and experienced human resources that emigrated from the country and gained experience in the developed world.

The economy globalization was accompanied by a process of concentration of industrial plants and, as a result, many of them closed down. Latin America and Argentina, as part of the area, have not been excluded from that process, during which many foreign companies ceased their local manufacturing activities and concentrated their production in few and specific countries in Latin America. In the case of Argentina, these industrial plants were taken over by local companies, which kept the original production and employment sources.

The industry growth during the last years is evidenced by an increase of the installed capacity utilization, plant expansions and the construction of new industrial facilities that incorporate state of the art technology, machinery and production plants, in order to supply the local demand and remain competitive to penetrate new markets overseas.

Regarding the structure of the drug domestic consumption, in terms of their local manufacturing and imports, 71.5 % is currently being supplied by locally-manufactured drugs, and the remaining 28.5 % by imported drugs. However, an analysis of the historical evolution of such share shows that imports were significantly lower in the 90's. In fact, they accounted for only 6.9% of the total sales in 1994 while, in the year 2000, it had grown by 19.3 %. Therefore, the share of imported medicines in the Argentine market has grown four times in the last 20 years.

Should this trend continue, a significant amount of the positive results that this sector generates for the rest of the economy will improve, since the economic contribution provided by the local production is much higher than that of imports in terms of employment, tax collections, currency and technological progress.

In fact, it is to be noted that the access to medicines for the population would increase if a higher share of the domestic market were supplied by local production, since the price of imported drugs is growing, in particular, due to the imports of innovative biotechnological medicines (monoclonal antibodies), recently introduced in the market, which treat critical and special pathologies. Therefore, it appears to be important for the public health policy to encourage the local manufacturing of medicines, thus reducing the cost of treatments, while improving their access.

Argentina's pharmaceutical market evidences some differences as compared to the characteristics observed internationally, in particular, in Latin America, due to the higher presence of locally- owned companies. In fact, in Argentina, the pharmaceutical laboratories owned by local entrepreneurs account for 66.4 % of the units sold in the market and 66.1 % of the sector turnover. Foreign companies commercialize 33.6 % of the units sold and 33.9 % of sales in values. Typically, these companies are branches of multinational corporations, mostly North American, German or Swiss.

II.2. Pharmaceutical foreign trade

II.2.1. Trade balance

In 2017, pharmaceutical exports amounted to USD 744.2 million, a 18.0% decline as compared to 2016. However, the exports rate in 2017 was 180% higher than the 2003 value, an accrued annual rate of 7.6%.

In terms of imports, they accounted for USD 2.38 bn in 2017, a 10.4% increase as compared to the previous year. This value is 401% higher than in 2003, evidencing an accrued annual rate of 12.2%.

ARGENTINA: EXPORTS AND IMPORTS OF PHARMACEUTICALS

Año	EXPORTS		IMPORTS	
	Million U\$S	Variation	Million U\$S	Variation
2003	266.4		475.3	
2004	344.8	29.4%	545.1	14.77%
2005	351.4	1.9%	624.6	14.6%
2006	436.3	24.2%	763.1	22.2%
2007	512.7	17.5%	939.2	23.1%
2008	6277	22.4%	1.14 bn	21.5%
2009	6595	5.1%	1.21 bn	5.8%
2010	6932	5.1%	1.56 bn	29.6%
2011	8102	16.9%	1.79 bn	14.4%
2012	9030	11.5%	2.08 bn	16.6%
2013	9123	1.0%	2.13 bn	2.4%
2014	8513	-6.7%	2.14 bn	0.5%
2015	1.048 bn	23.2%	2.40 bn	12.0%
2016	907.9	-13.4%	2.15 bn	-10.4%
2017	744.2	-18,0%	2.38 bn	10.4%

(*) Chapter 30 of the "Pharmaceutical Products" NMC

Source: **ABECEB** based on INDEC data

The abrupt drop of the exports rate in the last two years is due to the fact that exports to Venezuela were brought down to nearly zero on account of the financial crisis that country is going through. Exports to that destination amounted to 259, 167 and USD 3 million in the years 2015, 2016 and 2017, respectively.

As a consequence of the flows of exports and imports, the sector shows, in historical terms, a deficit trade balance, which increased each year until reaching a value of USD 1.63 bn. In 2017.

However, the evolution of the trade exchange of the sector is largely influenced by the variations in its unit prices.

As shown in the table below, where exports measured in quantity evidence a 1.4% fall in 2017 compared to 2016, the average price of the exported ton fell by 12.3%. In the case of imports, its volume grew by 31.1% while the average price of the imported ton decreased by 31.4% compared to the former year.

ARGENTINA: EXPORTS AND IMPORTS OF PHARMACEUTICALS (IN QUANTITY)

Year	Exports		Imports	
	Tons	Variation	Tons	Variation
2005	17,325	11.0%	11,841	-8%
2006	20,879	20.5%	12,507	5.6%
2007	21,632	3.6%	15,130	21.0%
2008	22,371	3.4%	16,007	5.8%
2009	24,151	8.0%	16,509	3.1%
2010	25,080	3.8%	20,847	26.3%
2011	26,562	5.9%	23,904	14.7%
2012	28,629	7.8%	24,359	1.9%
2013	30,926	8.0%	25,016	2.7%
2014	30,534	-1.3%	24,756	-1.0%
2015	30,709	0.6%	23,379	-5.6%
2016	30,348	-1.2%	30,569	30.8%
2017	29,961	-1.3%	25,588	-16.3%

Source: **ABECEB** based on INDEC

II.2.2. Imports and Exports Structure

As mentioned before, the accrued annual growth rate (+12.2%) for imports is higher than the respective export rate (+7.6%) for the period 2003-2017, which leads to an increase of the trade deficit during the last decade. However, the analysis of imports structure shows that each kind of product has a different behavior.

The table below shows the structure of imports and exports, broken down by biological/biotechnological medicines and traditional medicines (synthetic and semisynthetic):

PHARMACEUTICAL IMPORTS/EXPORTS STRUCTURE

In millions of USD

	2003	2005	2010	2015	2016	2017
Exports						
* Biological/Biotechnological Medicines	18.4	23.5	47.2	73.6	72.0	75.0
* Traditional Medicines	248.0	327.9	645.9	975.2	835.9	669.2
* Total	266.4	351.4	693.1	1.04 bn	907.9	744.2
Imports						
* Biological/Biotechnological Medicines	50.2	102.3	419.6	797.4	675.9	751.5
* Traditional Medicines	425.1	522.3	1.1 bn	1.6 bn	1.48 bn	1.63 bn
* Total	475.3	624.6	1.56 bn	2.40 bn	2.15 bn	2.38 bn
Trade Balance						
* Biological/Biotechnological Medicines	-31.8	-78.8	-372.4	-723.8	-603.9	-676.5
* Traditional Medicines	-177.1	-194.4	-500.1	-634.0	-645.6	-960.2
* Total	-208.9	-273.2	-872.5	-1.35 bn	-1.24 bn	-1.63 bn

Source: INDEC

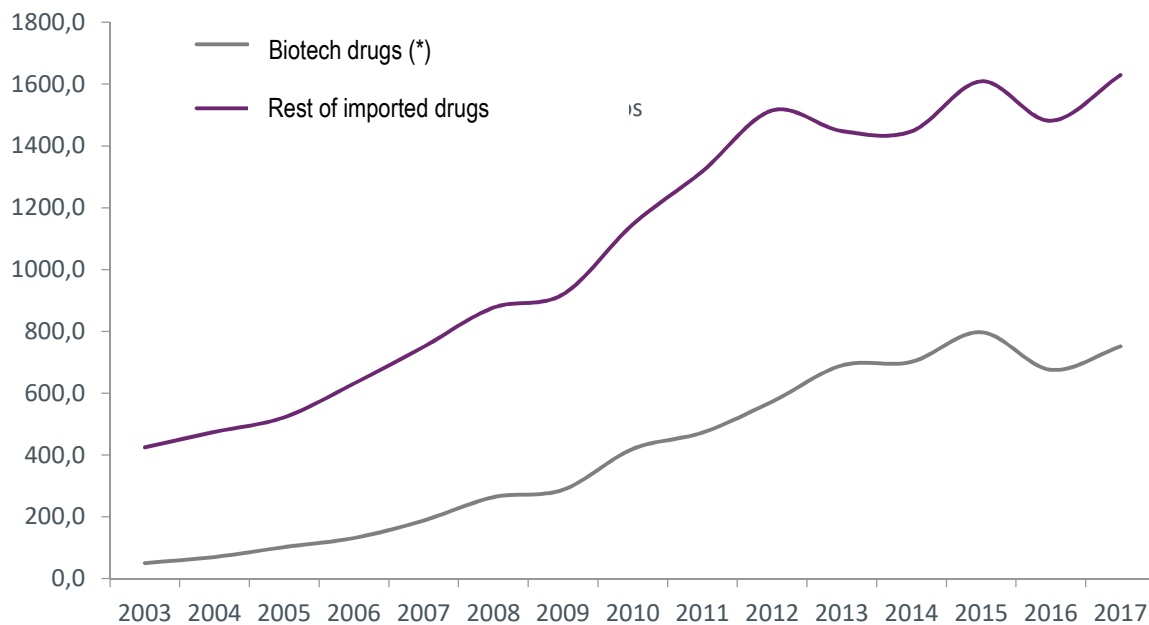
Biological/Biotechnological medicines: comprise the following 8-digit items of the NCM: 2937.11.00, 3002.10.24, 3002.10.26, 3002.10.29, 3002.10.36, 3002.10.38, 3002.10.39, 3004.39.11, 3004.39.19, 3004.39.29

It can be noted that imports of biological and biotechnological medicines increased by a 1.397% between 2003 and 2017, while imports of traditional medicines grew by 283% in the same period.

Unlike pharma-chemically-based drugs, which active ingredient is a substance obtained through chemical synthesis, the manufacture of biotechnological medicines is based on biological matter, i.e., live matter, and they are genetically modified for more specific treatments. The process of research, development and manufacture is more complex in the case of biotechnological medicines than it is for those based on chemical synthesis.

ARGENTINA'S PHARMACUETICAL IMPORTS. Biotech products v. the rest

USD Millions



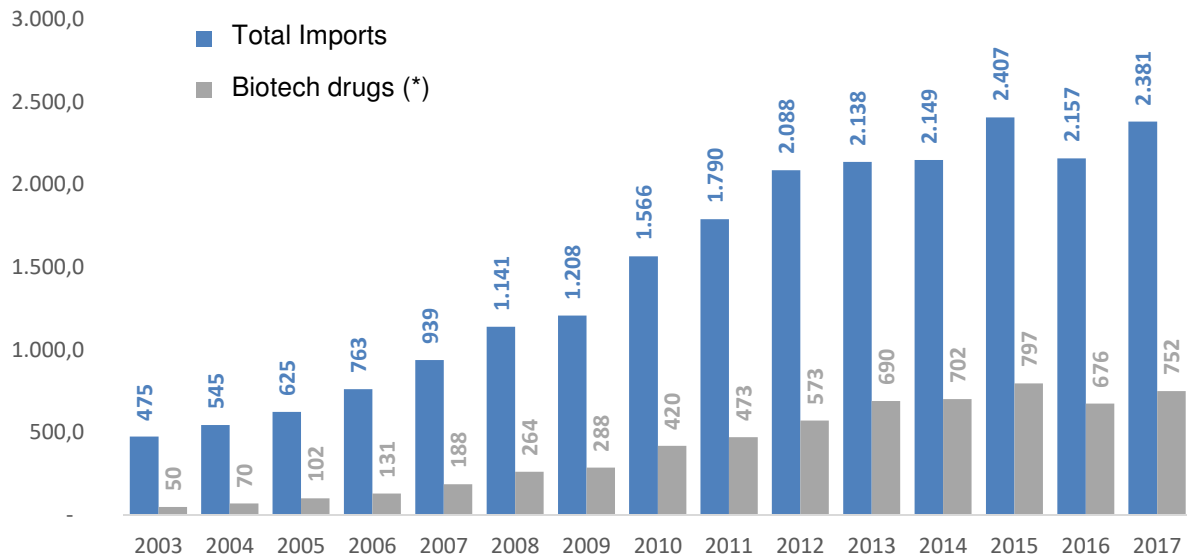
Source: ABECEB, based on INDEC

(*)Comprises the following 8-digit items of the NCM: 2937.11.00, 3002.10.24, 3002.10.26, 3002.10.29, 3002.10.36, 3002.10.38, 3002.10.39, 3004.39.11, 3004.39.19, 3004.39.29

The significant increase in the imports of biotechnological medicines is related to the growing need to purchase innovative products to treat complex and expensive pathologies (oncology, multiple sclerosis, rheumatoid arthritis, etc.). As a consequence of such increase, the share of biotech drugs in the total imports of pharmaceutical products has been gradually growing during the last 13 years from 11% in 2003 to 32% in 2017.

ARGENTINA'S IMPORTS OF PHARMACEUTICAL PRODUCTS. Biotech vs. total

Values in millions of USD



Source: **ABECEB** based on INDEC

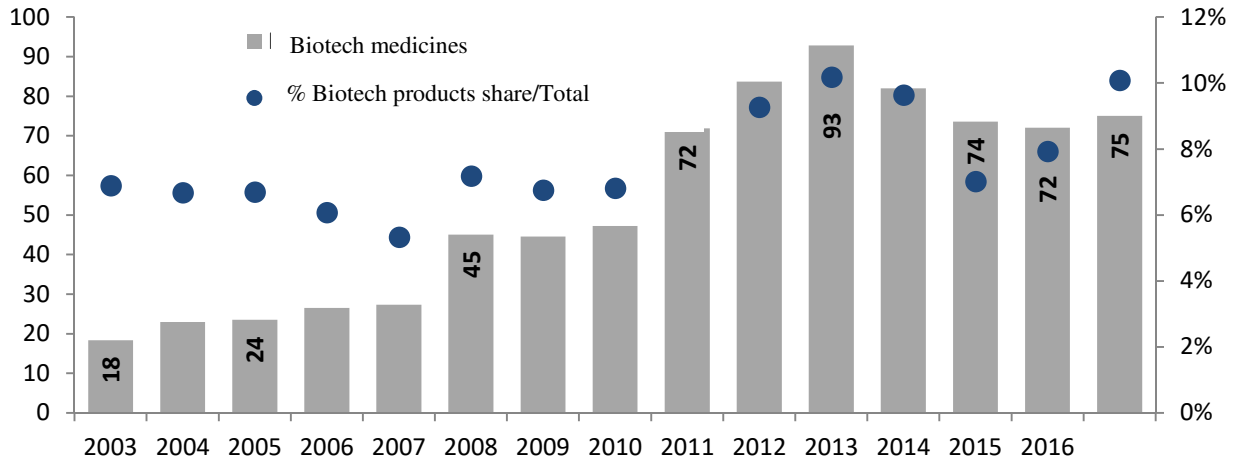
Meanwhile, the pharmaceutical exports performance is still remarkable regardless of the decline that took place during the last two years due to the loss of the Venezuelan market.

Taking into account that the introduction of a medicine in the international market involves a long-term process in which the product must gradually gain market share against the competitors, and if we also consider that it is not possible to transfer the increase in domestic costs to export prices, it becomes clear that the industry has made a remarkable effort in its long term goal of expanding production and exports to reduce fixed costs.

The analysis of exports that distinguishes the evolution of the biotechnological products market vis-a-vis the total exports of medicines shows an increase in the incorporation of technology and value added in the national exports. While the process is relatively recent and there is margin to place the Argentine biotech medicines abroad, the share of that segment related to the Chapter 30 exports was 10.1% in 2017, near the 10.2% peak in 2013. Also, the accrued growth rate of biotech drug exports grew by 309% between 2003 and 2017, while the same rate applied to the total of medicines was 179%.

ARGENTINA'S EXPORTS OF BIOTECH MEDICINES

Values in millions of USD



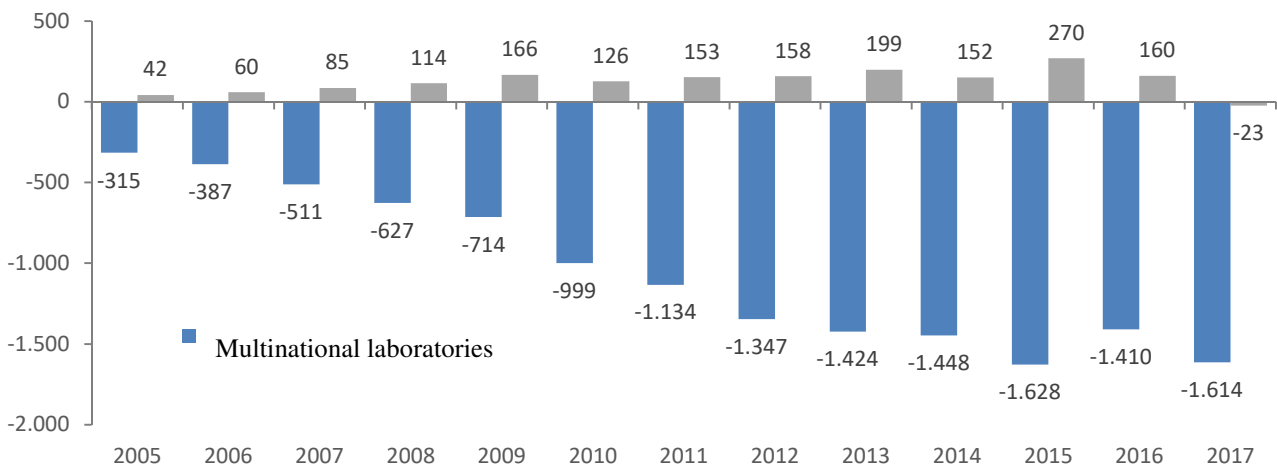
Source: **ABECEB**, based on the INDEC

II.2.3. Evolution as per capital origin

Another way of analyzing the trade evolution of the sector consists in differentiating imports and exports as per the laboratories' capital origin. Such analysis evidences that locally-owned pharmaceutical companies account for a commercial surplus, while multinational corporations show a strong deficit. In 2017, the multinational laboratories' deficit reached USD 1.6 bn., while local laboratories generated a slight deficit of USD 23 million.

DRUG EXCHANGE TRADE BALANCE BY LAB CAPITAL ORIGIN

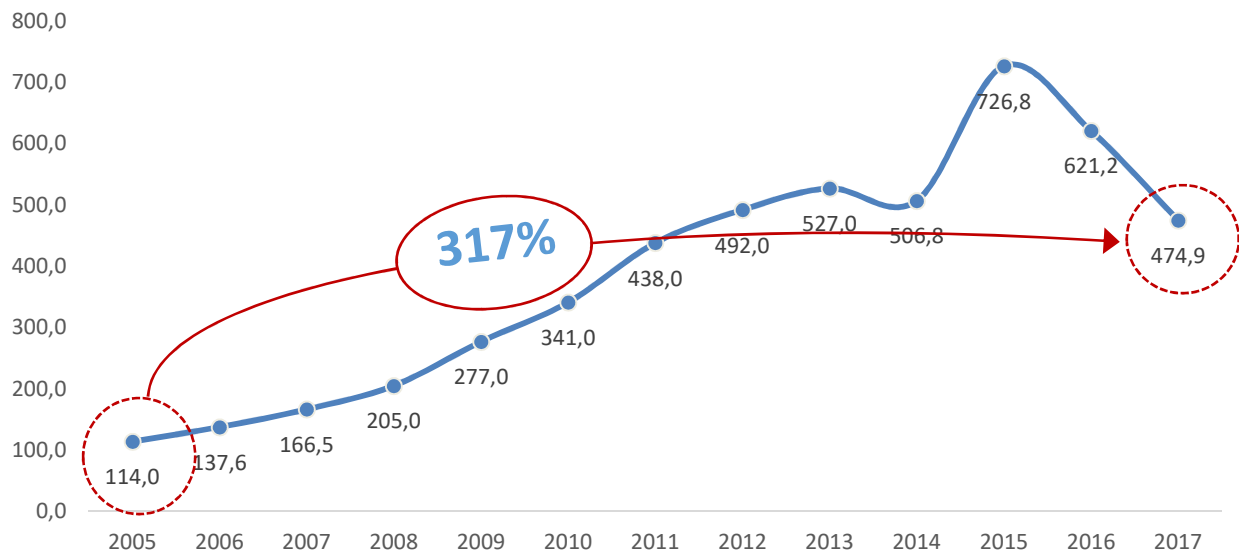
Value in USD million



Source: **ABECEB** based on INDEC and Customs data

Drug exports by locally-owned laboratories reached USD 475 million in 2017. Although this represents a -23.5% fall from 2016, they keep their growing trend throughout the decade, which is evidenced by the local labs exports growth rate, which was 317% between 2005 and 2017.

LOCAL LABORATORIES' EXPORTS EVOLUTION
 Values in USD million. Chapter 30 of the NCM



Source: **ABECEB** based on INDEC and Customs data

As a consequence of such expansion, there was an increase in the local laboratories' share in the total exports of medicines. While in 2006 locally-owned laboratories accounted for 32% of the country's NCM chapter 30 exports, such share rose by 64% in 2017; on the other hand, the exports share of pharmaceutical exports of multinational companies fell from 68.% in 2006 to 36% in 2017.

PHARMACEUTICAL EXPORTS
Structure as per corporate capital - Annual variation

Year	LABORATORIES				Total	
	National		Multinational		USD Million	Variation
	USD Million	%	USD Million	%		
2005	114.0		237.2		351.2	
2006	137.6	20.7%	298.0	25.6%	435.6	24.0%
2007	166.5	21.0%	346.0	16.1%	512.5	17.7%
2008	205.0	23.1%	423.0	22.3%	628.0	22.5%
2009	277.0	35.1%	383.0	-9.5%	660.0	5.1%
2010	341.0	23.1%	352.0	-8.1%	693.0	5.0%
2011	438.0	28.4%	372.0	5.7%	810.0	16.9%
2012	492.0	12.3%	411.0	10.5%	903.0	11.5%
2013	527.0	7.1%	386.0	-6.1%	913.0	1.1%
2014	506.8	-3.8%	344.5	-10.8%	851.3	-6.8%
2015	726.8	43.4%	322.1	-6.5%	1048.8	23.2%
2016	621.2	-14.5%	286.7	-11.0%	907.9	-13.4%
2017	474.9	-23.5%	269.3	-6.1%	744.2	-18.0%
2017/05 Increase:	316.6%		13.5%		111.9%	
Annual accrued growth rate:	12.6%		1.1%		6.5%	

Source: **ABCECB** based on INDEC and Customs data

It is worth pointing out that total exports of pharmaceuticals increased by 112% during the period 2005-2017, while exports by local companies grew by 317% and only 14% in the case of multinationals for that period.

According to the export values included in the above table, the exports annual accrued growth rate of local pharmaceutical laboratories was 12.6%, and 1.1% for the multinational laboratories for the period 2005-2017. The annual accrued growth rate for total exports was 6.5%, for the same period.

II.2.4. Main destinations and origins

After two years where Venezuela was the leading destination for our pharmaceutical exports, Uruguay came up as their number one destination in 2017 with 16% of total exports, leaving Brazil on the second place with a 13.5%.

During the last year, our pharmaceutical exports to MERCOSUR countries reached 36.4%, while the rest of the Latin American countries received 60.8% of those exports. The European Union countries received 7.1% of the Argentinian pharmaceutical exports, the United States and Canada 7%, and non-traditional markets (Thailand, Vietnam, Indonesia, Iran and China, among others) slightly over 18% of total exports.

The ranking of pharmaceutical imports by origin country is led by Germany with 20.5% (USD 489 million), followed by the United States with 17.8 % (USD 425 million) in the year 2017.

An analysis of the structure of imports by region shows that 54.2% of imports come from countries in the European Union, 22.2% from the United States and Canada, and 5.5% from Latin America (of which 4.1% corresponds to Brazil, with USD 98 million).

II.3. The contribution of the pharmaceutical industry to the fiscal income

In the year 2017, the contribution of the sector to the Treasury was \$ 31.36 bn for the main local taxes. This amount implied a 27.3% variation in the year comparison, and reached 1.22% of the national tax revenues. Within this total, the value added tax accounted for 51.1%, which grew at a higher rate than the average, while the income tax accounted for 24.9 %, and social security taxes, 9.5%. It is to be noted that, by the end of 2015, the export taxes on many industrial products, including pharmaceuticals, were eliminated.

Estimation of tax collections broken down by tax item. Pharmaceutical Industry. In \$ million

Impuesto	2013	2014	2015	2016	2017e	Var 17/16
IVA	4.479	6.042	7.664	12.477	16.029	28.5%
Ganancias	2.376	3.302	4.260	6.092	7.810	28.2%
Seguridad Social	944	1.354	1.800	2.431	2.990	23.0%
Aranceles a la Importación	663	991	1.263	1.832	2.232	21.8%
Impuesto al Cheque	526	706	895	1.403	1.781	26.9%
Ganancia Mínima Presunta	154	222	281	406	518	27.6%
Retenciones	113	173	244	0	0	//
Bienes Personales	1	2	2	3	4	24.7%
Total	9.255	12.792	16.411	24.644	31.364	27.3%

The total tax burden of the industry is distributed, by income, as \$ 17.37 bn. contributed by local laboratories and \$ 13.98 bn. contributed by multinational laboratories.

II.4. Technical health regulations

The Argentine pharmaceutical industry complies with the highest quality standards recommended by the World Health Organization (WHO) in terms of good manufacturing and drug control practices. Since its establishment in 1992, the ANMAT (National Administration of Pharmaceuticals, Foods and Medical Technology, or *Administración Nacional de Medicamentos, Alimentos y Tecnología Médica*, in Spanish, has enforced the WHO recommendations on Good Manufacturing and Control Practices (GMP).

As a PIC/S (Pharmaceutical Inspection Cooperation Scheme) member, the ANMAT has updated their BPM regulations based on the PIC/S “Guide to Good Manufacturing Practices for Producers, Importers/Exporters of Medicinal Products for Human Use” and the 2015 WHO recommendations, by means of provision number 3827/18.

It should be noted that the National Institute of Medicines (INAME), which belongs to the ANMAT, was accepted as a PIC’S member effective January 1st 2008, becoming the first Latin American country to be a member of such cooperation plan on good manufacturing and control practices, applied by the main European and Asian health agencies.⁵

In December 2009, The Pan American Health Organization (PAHO) certified the ANMAT as a Health Authority of reference, and it became the first Latin American health agency to obtain such certification, which has been renewed in December 2016.

It is also worth mentioning that the manufacture of pharmaceuticals is considered a clean activity, as its environmental impact is very low.

There is, then, the challenge to continue generating business opportunities in the country and abroad, where the quality of Argentine medicines is widely acknowledged and valued. Therefore, in order to compete at a global scale, it is essential to encourage investments in new industrial plants and refurbishment, extension and technological updating of the existing ones.

⁵ For a full member list, visit www.picscheme.org

ARGENTINA'S KEY PHARMACEUTICAL SECTOR DATA

1) Structure	2017
Laboratories	230
Manufacturing Plants	190
* Locally-owned laboratories	160
* Multinational laboratories	30
Labor force	43,000
Average number of employees per laboratory	195
Utilization of installed capacity	86%
Turnover of the top ten laboratories/total turnover(*)	44.6%
Industry GPV/ 2423GPV(**)	3.3%
Industry GPV/ 2423GPV(**)	4.9%
2) Performance	2017
Sales growth in units (2017-2003 annual accrued rate)	5.6%
Sales growth in USD (2017-2003 annual accrued rate)	10.3%
Turnover (current \$ billions) (**).	101.28
Imports Chapter 30 NCM (billions of USD)	2.38
Percentage fluctuation 2017/2003	401%
Exports Chapter 30 NCM (millions of USD)	744
Percentage fluctuation 2017/2003	179%
Trade balance Chapter 30 NCM (billions of USD)	-1.63

(*) 2017 data

(*) GPV: gross production value. GVA: gross value added

(**) Ex-factory prices (IQVIA Argentina)

III. SCENARIO AND PERSPECTIVES FOR THE ARGENTINE PHARMACEUTICAL INDUSTRY

This section provides a forecast on the pharmaceutical sector, and takes into account following pivotal items: investment, financing, exports and R&D.

The aim is to identify the typical characteristics of the sector which may exert an influence on its competitiveness, such as potential, strengths and weaknesses, as well as opportunities for development and future threats faced by the activity.

Strengths

Among the main identified strengths, we can highlight the high versatility and dynamics that have made it possible for this sector to overcome the successive economic crises of the Argentine economy.

The Argentine pharmaceutical sector has an important comparative advantage over the other nations of the region and a large number of the emerging world markets: it is one of the few that concentrate over 60% of the production and sales in domestically-owned companies.⁶ This percentage has reached 66.1% in 2017, measured in values, and 66.4% if measured in units.

During the last ten years, the manufacture of biotechnology medicines in local plants has experienced a significant boost as a result of the installment of local plants to manufacture biotech active ingredients, the growth of first-generation biotech drugs (interferon, erythropoietin, growth hormone and others), biosimilar monoclonal antibodies (rituximab and bevacizumab) and the exports of these to non-traditional markets.

Argentine has locally-owned laboratories that have become multinationals, with subsidiaries in most of the Latin American countries, USA, Europe and some Asian countries.

The pharmaceutical industry has managed to “...significantly increase work productivity, becoming one of the industrial sectors that allocate the highest amount of its income to R&D efforts and one of the most intensive sectors in terms of qualified workforce”.⁷

The Ministry of Science, Technology and Productive Innovation published the results of a survey on Research and Development (R&D), addressed to the corporate sectors, in which 1,225 companies participated. Of this total, 571 firms spent and invested in R&D; they declared a total amount of \$ 7.8 billion in the year 2015 (approximately USD 840 million) and a workforce of 10,514 employees working on R&D.

⁶ González García, Catalina de la Puente, Sonia Tarragona, *Medicamentos - Salud, Política y Economía -*, 2005, Editorial Isalud, page 106: “In the domestic market, local labs account for over a 50% share in the industry’s total sales. This situation is atypical and almost unprecedented for developing countries and only occurs in those with major world manufacturing companies, such as the United States, Japan and Germany.”

⁷ González García et al, 2005, pp 103-104

Distribution of R+D by sectors

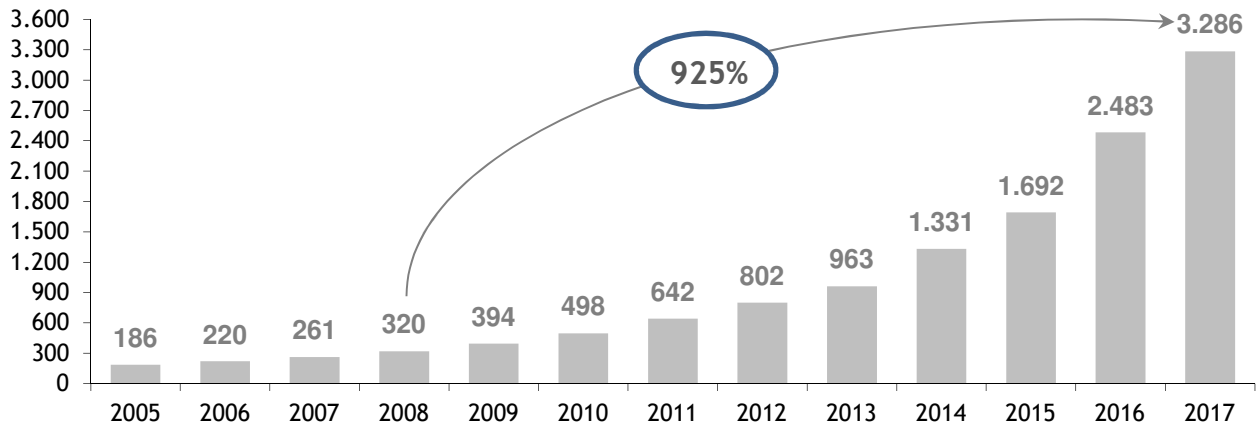
	B Billions of pesos	% Share
Pharmaceutical	1.69	21.6%
R&D. technology and other business services	1.54	19.7%
Seed companies	0.93	12.0%
Chemical	0.53	6.8%
Electrical equipment and supplies	0.52	6.7%
Others	0.46	6.0%
SSI	0.34	4.4%
Food and beverages	0.30	3.8%
Machinery and equipment	0.29	3.8%
Automobile	0.28	3.7%
Energy	0.24	3.2%
Steel and Metal	0.23	3.0%
Oil. gas and mining	0.18	2.4%
Plastics and rubber	0.14	1.8%
Financial brokerage services	0.94	1.2%
Total	7.82	100.0%

Source: Ministry of Science, Technology and Productive Innovation, November 2015.

The above table shows the pharmaceutical industry sector is the leader in terms of volume of R&D investment in the Argentine economy, with a total of \$ 1.69 bn. in 2015, followed by R&D and Technology Services and Seed Companies.

In terms of the research, innovation and development processes carried out by local firms, it is worth while highlighting two cases that evidence the strategic significance of the combined efforts of the public and private sectors in the realization of research, development and innovation projects to manufacture new medicines.

>> **Estimated R&D of the pharmaceutical industry in the 2005-2017 period**



Source: Own estimates based on the Science and Technology Ministry.

The first case is benznidazole, medicine used to treat the Chagas disease, discontinued worldwide in 2011, and developed by a private and public consortium between the Ministry of Health, Maprimed SA (which manufactures the active ingredient) and Elea S.A. (which produces the medicine specialty). Production started in April 2012.

The second case to be noted is the worldwide launch of the therapeutic vaccine against lung cancer, racotumomab (Vaxira), approved by the ANMAT and the CECMED (Cuba). This research, development and innovation effort was carried out by a public and private consortium consisting of the Universidad Nacional de Quilmes (Quilmes National University), the Angel Roffo Oncology Institute, the CONICET, the Garrahan Hospital, the Center of Molecular Immunology (Cuba) and the Insud Group. The vaccine will be marketed in Argentina by the Elea SA laboratory and, in Brazil, by the Eurofarma SA laboratory.

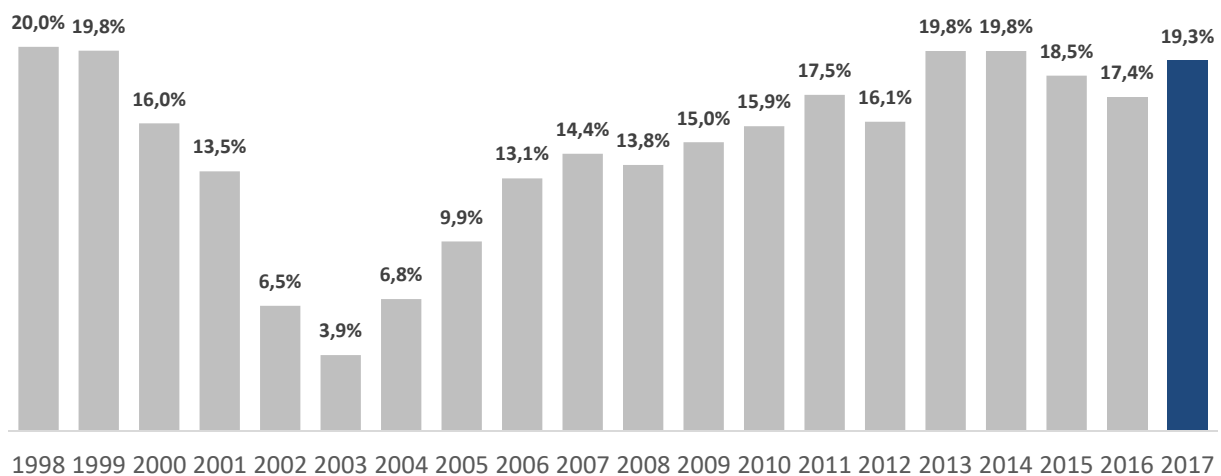
The commitment the industry has undertaken with regards to its investment and productivity standards has made it possible to maintain its prices in levels that ensure massive access to medicines by the population. In order to export to the markets of developed countries, which demand high regulatory standards, local companies that export to such markets have their industrial plants approved and technically verified by the national health agency (ANMAT); therefore, they offer high quality and reliable products to both foreign and domestic markets.

Weaknesses

One of the weaknesses of the sector consists in the fact that a significant part of the supplies and capital assets must currently be imported. The strong influence of scale economies on the manufacturing of active ingredients has led to their manufacture being centered on Asian countries, in particular, China and India. This phenomenon has contributed to the growing need of importing raw material.

Also, the availability of loans for production and investment development is a factor that limits the chances of expansion, particularly in the international markets.

> **Pharmaceutical sector financing. Ratio of loan stock to the pharmaceutical sector/Sales of the sector**



Source: abeceb.com, based on BCRA and sector data.

In 2017, the loan stock granted to the pharmaceutical sector grew at a slower pace in comparison with the loans granted to the overall industry, with a year-to-year fluctuation of around 49%, while the manufacturing total grew by 55%. Regarding turnover in 2017, the loan stock averaged 19.3%, higher than the previous year.

This good performance allowed the loans to the pharmaceutical industry, in terms of sales, to return to the levels existing in 2013/2014. This reflects the investment efforts carried out by local firms, which will then be able to increase employment opportunities and the offer of medicines for the domestic market and exports.

Opportunities

The Argentine pharmaceutical and chemical-pharmaceutical industry exports are still centered on the Latin American countries mainly, which represents an important base to have access to non-traditional markets and for expanding the reach of the sector abroad.

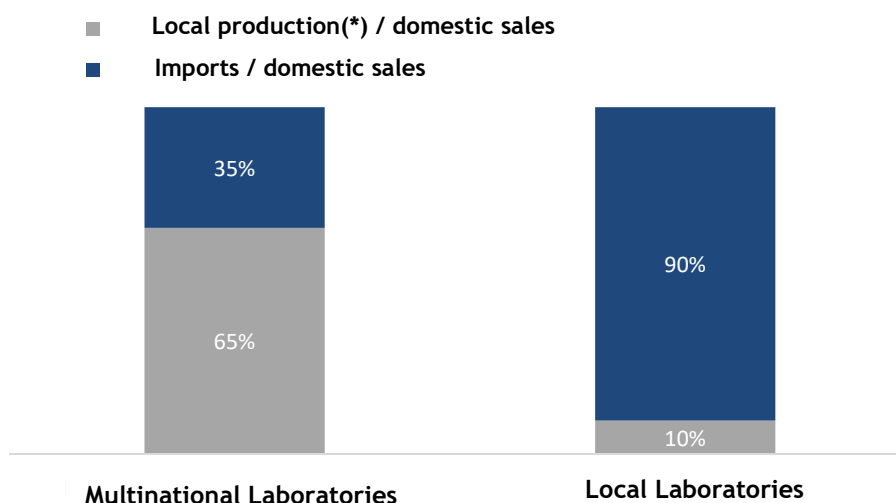
The deficit reduction in the pharmaceutical trade balance will depend on the pace of the exports growth, but also on substituting the imports of a wide range of medicine specialties for which local production is absolutely feasible, even by multinationals that may engage in such production in their establishments or in third parties facilities, if they do not have a manufacturing plant.

One of the most significant restrictions in the sector is the growing relevance of imports in the overall sales to the domestic market. In fact, in the year 2017, 28.5% of the medicines purchased in the country were imported. In 1994, that percentage was only 6.9%.

It should be noted that the domestic pharmaceutical market is split differently between local and multinational laboratories. Indeed, in the year 2017, the local laboratories accounted for 66.1% of the total domestic sales, while multinational labs had the remaining 33.9%.

Their market share is very different if we consider where the drug was manufactured. According to data for the year 2017, and in the case of local laboratories, 90% of the pharmaceuticals sold locally was manufactured in the country, while only the 10% remaining was covered by imports of finished products. In the case of multinational laboratories, their share is around 35% and 65%, respectively.

DOMESTIC SALES STRUCTURE. YEAR 2017



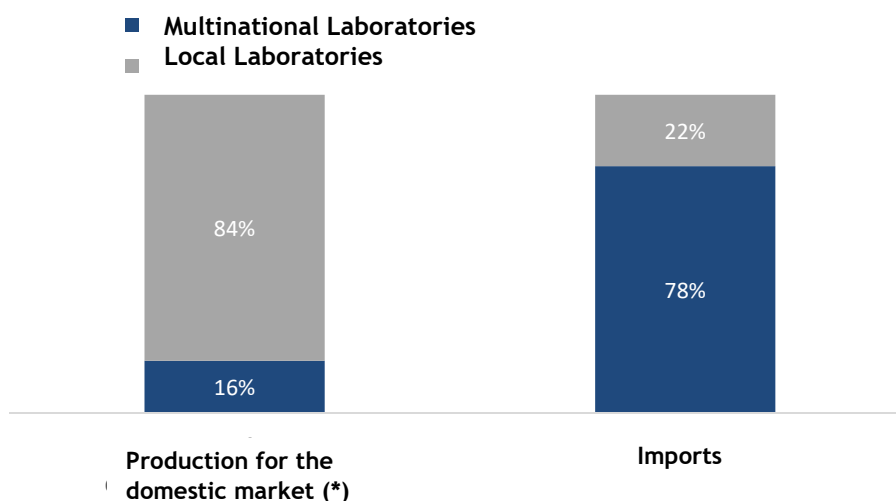
(*) Manufactured inside the country for the domestic market, by both local as well as multinational laboratories.

Source: **ABECEB**, based on IQVIA Argentina and INDEC

An analysis of the total number of medicines manufactured in the plants operating in the country shows that domestically-owned companies account for 84% of the production, while multinational companies manufacture the remaining 16%.

Regarding the annual volume of imports of finished pharmaceuticals, the domestically-owned companies only import 22% of the total, while multinational corporations account for the remaining 78%.

Production and Imports Structure. Year 2017



(*) Manufactured in the country for the domestic market, by both local and multinational laboratories.

Source: **ABECEB**, based on IQVIA Argentina and INDEC

This scenario makes it possible to foresee an opportunity to encourage the local manufacturing of medicines, which will tend to substitute products being currently imported, in particular, those of low incidence and high cost for social security.

Threats

One of the issues that Argentina must face is its relative weakness to face the significant capacity of countries such as China and India in terms of incentives to production, exports and research, development and innovation.

Another threat that the pharmaceutical industry faces is the FTAs between some Latin American countries⁸ and USA, which provide for standards and legal requirements in their patents and protection of undisclosed information sections that are stricter than those undertaken by each country in the multilateral frame under the provisions of the WTO's TRIPs Agreement. The same applies to the participation of the Pacific Latin American countries in the Transpacific Partnership (TPP) agreement.

On the same note, there is the current negotiation of the FTA between Mercosur and the European Union, where the latter is proposing requirements on data protection and patent extension that exceed the commitments

⁸ Chile, El Salvador, Honduras, Guatemala, Costa Rica, Dominican Republic, Colombia, Ecuador and Peru.

of the Mercosur member countries in the WTO TRIPs Agreement. Also, the incipient negotiations between Mercosur and Canada, EFTA and South Korea could become a threat.

The table below analyzes the main characteristics of the Argentine economic scenario of the pharmaceutical and chemical-pharmaceutical industry, in terms of strengths, opportunities, weaknesses and threats.

Areas	Strengths	Opportunities	Weaknesses	Threats
Investment and Production	Very important business sector in the economy, with solid links in the production chain.	The existence of a wider net of suppliers could improve the manufacturing efficiency	Still in need of medium and long term public funding.	Signing of trade agreements that facilitate imports of finished products from countries that apply production subsidies.
	High capabilities of management, adaptability to change and generation of qualified jobs.	Increases in exports would boost the available supply of medicines	Most of the machinery is imported, which implies a huge economic and financial effort for laboratories, which affects the trade balance.	Lack of incentives may lead to future investment being relocated to other marketplaces.
	Technological capacity based on investment in state of the art installed machinery and equipment. Skilled workforce.	Higher levels of investment in production will lead to more medicines available at more competitive prices.	Highly dependent on imported supplies and raw material.	Stricter standards on data protection as compared to those currently being applied by the WTO, which could be implemented through a Free Trade Agreement between the Mercosur and the European Union.
	Strong R&D+i sector, capable of generating new pharmaceutical alternatives.			
	Leading laboratories stand out on account of the significant regional and worldwide presence of their international subsidiaries.			

➤ Analysis of the Domestic Pharmaceutical Sector for the period 2018 -2021

Areas	Strengths	Opportunities	Weaknesses	Threats
Financing and domestic market	Efficient retail and wholesale distribution structure, which allows for the availability of all medicines in all the pharmacies of the country, at the same suggested retail price.	Possibilities of reducing the transportation and logistics costs.	Lack of suitable financial tools to support the expansion and growth of the demand.	High inflation rates in the economy are significantly increasing the manufacturing and production costs in the sector.
	High coverage of each therapeutic segment need.	Generation of new skilled job positions	Lack of “venture capital” culture to incentive corporate rationing and growth of small and medium size companies.	The permanent and excessive delays in collecting high debts from some provincial medical insurance companies and from PAMI may affect corporate finances.
	Local laboratories portray a very good brand image in the domestic market.	Promote a steady recovery of the domestic market, both in units and values.	There is no adequate law to enable donations for R+D+i or research institutions	
	The competitiveness and diversification of the offer of local laboratories allow maintaining affordable prices for the population.			
	The drug supply system that belong to health insurance entities awards special discounts that benefit users.			

Analysis of the Domestic Pharmaceutical Sector for the period 2018 -2021



Areas	Strengths	Opportunities	Weaknesses	Threats
Exports	High quality of exported medicines. Many laboratories with exports experience.	Wide scope of diversification of external markets and increase of exports.	Lack of financial support from the State in the process of selling abroad added-value products and technology.	Growing competition from Asian countries in the world market as a result of strong national policies to promote the sector.
	State-of-the-art industrial plants, which comply with the highest international standards in terms of good manufacturing and control practices.	Possibilities of penetrating markets of developed countries, with a more stable demand and medicines of higher value.	Difficulties to enter foreign markets due to the complexity and cost of certifications and registration of pharmaceuticals.	
	International ANMAT/INAME recognition for its adherence to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and its status as Health Reference Authority for the PHO.	Reinforce the association of exported local medicines to the Argentine brand.	State Resources assigned to scattered research centers, without a defined allocation plan.	
R&D	Highly qualified and experienced human resources.	Room to intensify R&D efforts and create high capacity to generate knowledge and innovation.	Lack of financing lines and R&D+I investment incentives, in particular, on the biological and biotech fields.	Poor educational orientation towards professions of strategic demand.
	Development of scientific innovation activities to generate new products and accumulate knowledge.	Promote a closer link between universities and research institutes, with the private sector.		
		Encourage the repatriation of scientists based abroad.		

IV. FORECAST FOR THE ARGENTINE ECONOMY AND THE PHARMACEUTICAL SECTOR

V.1. Macroeconomic Perspectives

The current administration intends to stabilize the economic situation and correct its imbalances, namely, the fiscal deficit, foreign trade deficit, high inflation rate, recovery of foreign reserves, distorted relative prices, Argentine currency appreciation, outdated tariffs for public services in CABA and greater Buenos Aires, and logistic costs out of date for the international levels. The goals set by the Administration were the following: a) to solve the pending issue of payment of the foreign debt (resolved in 2016); b) order macroeconomics; c) reinvigorate a sustained growth process driven by investment and exports rather than consumption and public expenditure as in the previous decade; and d) reduce poverty.

Although the Administration set a 15% inflation rate goal for 2018, foreseeing a 5 point reduction per year, the exchange rate turmoil in the first two weeks of May has led to an increase of the foreign currency that compromises such rate, which will most probably be around 28%. The Administration has also set the goal of reducing the public expenditure in new works at half point of the gross domestic product (GDP). The announcement of financial aid from the International Monetary Fund seeks to have a more affordable and accessible source of financing than that of international markets, within a global economic context of appreciation of the U.S. dollar, rise of interest rates and the oil price (which in a few months rose from USD 35 to 70 per barrel). This also implies restoring trust from the financial sectors and avoid a crisis in the local banking system.

Undoubtedly, this scenario will imply an economic growth of around 1.5%, taking into account that the growth of the agricultural sector will be less than expected⁹, as compared to the year 2017.

It is necessary that, in this new macroeconomic context, the predominance of investment within the components of aggregate demand persists, followed by private consumption (albeit with a certain lag). In turn, largely thanks to Brazil's recovery, exports are expected to once again have a positive and significant impact on GDP.

In sum, this year appears to be critical and challenging for the economic authorities to achieve the normalization of economic fluctuations, facilitate development, employment and investment conditions of companies, boost exports, reduce the primary fiscal deficit while maintaining social plans and gradually accommodating relative prices.

⁹ The drought in the agricultural core zone affected significantly the growth prospects for 2018. Draught impacts directly the gross production value of the coarse crop and the loss of the producers: almost 30% volumen loss in the case of soybeans and 21.8% for corn.

➤ **Summary of the Economic Forecast**

	2015	2016	2017	2018	2019	2020	2021
Real GDP (Var. %)	2.6	-2.2	2.7	1.5	2.1	2.7	2.9
Inflation (%) (December vs December)	29.2	36.0	25.0	28.0	20.0	16.0	10.0
Exchange Rate (ARS/USD) (end of period)	11.50	16.11	18.05	32.00	38.40	44.6	49.00
Per capita GDP (current USD)	13,467	12,440	12,674	12,734	12,871	13,087	13,332
Primary result, 2017 Methodology (% of GDP)	-	-4.2	-3.8	-2.6	-2.2	-1.2	-0.1
Exports (USD bn FOB)	56.8	57.9	58.4	62.0	65.1	69.0	73.4
Imports (USD bn CIF)	59.8	55.9	66.9	71.6	77.0	82.4	87.7
Trade Balance (USD bn FOB-CIF)	-3.0	2.0	-8.5	-9.7	-11.9	-13.4	-14.3

IV.2. Prospects for the Pharmaceutical Sector

The goals of the Argentine pharmaceutical industry for the next five-year period arise within the frame of a steady growth in production, domestic sales and exports.

A gradual increase of production and sales in the domestic market is being sought, with a view to improving the population's access medicines. As far as exports are concerned, an increase of the sales flow and the diversification of destinations and products are planned.

Following is a production and sales forecast for the pharmaceutical sector for the period 2018-2021, goals set, and data broken down in domestic sales and exports.

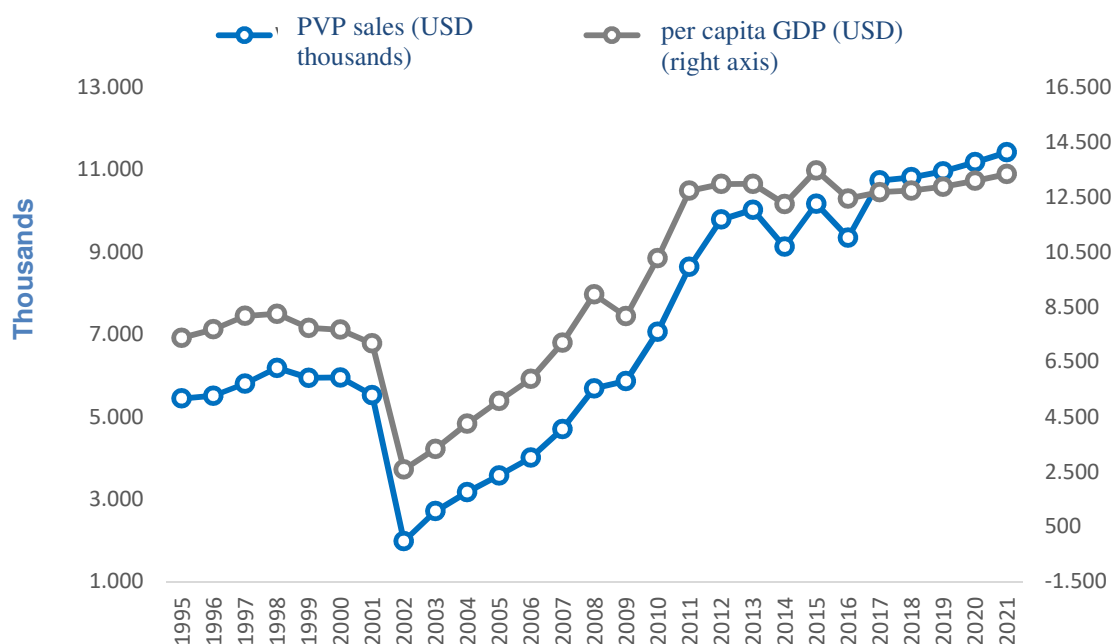
IV.2.1. Domestic Sales Estimation

To estimate the domestic sales in dollars, we proceeded to analyze the relationship between the size of the domestic market and different variables, such as the GDP per capita, changes in the level of GDP per capita, and indicators of distribution of income and public spending on health, among others.

Based on that approach, the most consistent relationship was the one between domestic sales, measured in terms of retail prices, and the per capita GDP (both in dollars), since a higher average income level for the population is expected to result in a higher consumption of pharmaceuticals. The forecast method was based on an econometric regression between both variables, considering the expected per capita GDP outlined before¹⁰.

As per this estimation, the level of sales at retail prices (PVP) in the domestic market projected to the year 2021 will be US \$ 6.67 billion, or 9.1% more than in 2017.

> Prospect of Domestic Sales (USD bn) and per capita GDP (USD) 2018-2021



Source: abeceb.com

IV.2.2. Estimation of exports

The dynamics of the pharmaceutical exports in Argentina is determined by the international demand, the real exchange rate and the level of competitiveness of this industrial sector.

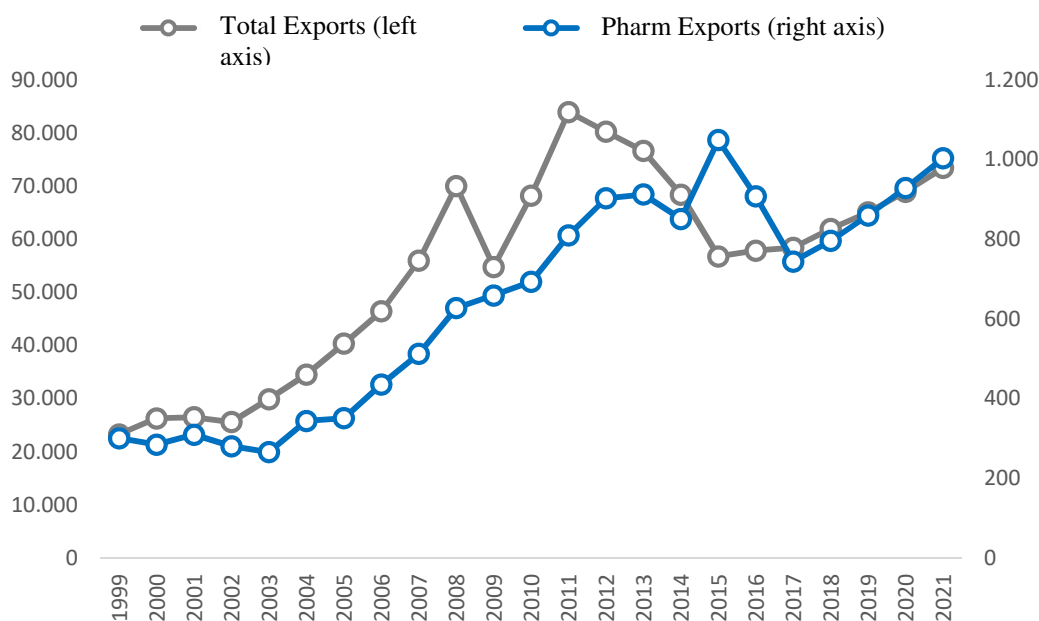
¹⁰ From the econometric standpoint, such regression showed a good adjustment between both variables, since $R^2=0.94$.

For the pharmaceutical exports forecast, a singular relationship between the level of total exports and the sector exports could be observed, which implies that the pace at which the sector penetrates the market could be related to that of the total of assets of the Argentine economy.

The forecast of the industry's future sales abroad considered the structural transformation that the world and the regional pharmaceutical sectors are undergoing, which will most certainly be evidenced in the performance displayed in the upcoming years. This effect is related to the process of relocation and concentration of industrial plants that some multinational laboratories.

In any case, the results of this projection show a favorable evolution on the level of exports of pharmaceutical products (Chapter 30 of the Mercosur Common Denominator) which, by 2021, would reach approximately USD 1 bn, 34% more than in 2017.

> Forecast of Exports of Chapter 30 of the NCM (pharmaceuticals)
In millions of U\$D. 2018-2021



Source: abecb.com

IV.2.3. Consolidated Turnover Estimations

Taking into account the consolidations of the results outlined and the inertial behavior of the Argentine industry and economy, the turnover of the pharmaceutical sector would amount to USD 7.8 bn. by the end of the year 2017, as can be inferred from the following chart.

➤ **Turnover forecast, broken down in domestic sales and exports**
In thousands of USD 2018 - 2021

Year	Base Scenario			
	Domestic Sales* USD Thousand	Exports USD Thousand	Total Revenue USD Thousand	Imports (NCM 3004) USD Thousand
2001	3.150.000	310.200	3.460.200	455,365
2002	1.128.448	281.100	1.409.548	289,356
2003	1.544.853	266.400	1.811.253	331,780
2004	1.808.103	344.800	2.152.903	361,244
2005	2.039.116	351.408	2.390.524	394,986
2006	2.285.130	436.286	2.721.416	460,344
2007	2.681.153	512.677	3.193.830	532,987
2008	3.241.782	627.664	3.869.446	614,794
2009	3.343.966	659.482	4.003.447	658,846
2010	4.025.862	693.246	4.719.109	794,810
2011	4.923.190	810.162	5.733.352	971,263
2012	5.576.724	903.005	6.479.730	1.129,055
2013	5.712.931	912.328	6.625.259	1.125,995
2014	5.200.517	851.292	6.051.809	1.097,836
2015	5.797.069	1.048.818	6.845.887	1.231,960
2016	5.326.724	907.896	6.234.620	1.186,638
2017	6.117.241	744.200	6.861.441	1.291,769
2018	6.160.841	796.294	6.957.135	1.229.621
2019	6.243.944	859.998	7.103.942	1.202.945
2020	6.369.325	928.797	7.298.122	1.218.134
2021	6.506.414	1.003.101	7.509.515	1.249.954

* Ex factory prices.

** Finished medicines (lot 3004 of the NCM) at CIF values.

Source: Abeceb based on INDEC and IMS Health

V. CONCLUSIONS

The national pharmaceutical industry is building a long-term vision, in terms of its expansion and development both in the domestic as well as in the international markets, through the increase in the volume of exports to non-traditional markets as well as by the establishment and consolidation of subsidiaries in the main countries of Latin America and other nations.

The macroeconomic and sector projections will include a substantial increase of investment, employment and offer of medicines for the population, which will contribute to promoting their accessibility.

The pharmaceutical industry is an industrial branch with highly qualified labor force, and one of the sectors that manufacture high added-value products.

The structure of the Argentine pharmaceutical industry shows that the domestically-owned pharmaceutical laboratories have a more significant presence or share in the market than the multinational companies.

In sum, we consider that the Argentine pharmaceutical industry represents a strategic industry for the socially-inclusive economy development project being underway in our country:

1. The pharmaceutical industrial plants based in the country ensure its population the normal **supply of affordable medicines, their quality being internationally acknowledged.**
2. The existence of locally-owned pharmaceutical companies makes it possible to facilitate the **competition in the market**, thus avoiding the existence of monopoly prices.
3. This is a **highly technologic** industry, with a remarkably skilled workforce in terms of technology and education; therefore, the result is high added-value production.
4. The 741 million units produced per year by the pharmaceutical industry account for **4.9 % of the industrial added value of this country.** There are **43,000 direct jobs and 120,000 indirect jobs.**
5. The industry employs Argentine researchers and scientists, and includes the **repatriation of Argentine scientists that had emigrated.** An evidence of this is the **human health-related biotech and bioengineering developments**, which are part of the agenda, and projects from Argentine pharmaceutical laboratories, which add to the growing generation of human capital and ensure sustainable development.
6. The **pharmaceutical industry exports** reached USD 744 million in the year 2017 and they are expected to grow in the next years. The commercial activities developed by companies abroad are **diversifying the destination markets** of their products. In fact, exports to non-traditional markets grew more than six times between the years 2003 and 2017.

7. This industry has a project to increase and expand its activities in the country and abroad, and represents the sector with the **highest number of Argentine companies that develop activities with international outreach.**

In sum, the local pharmaceutical industry is able to maintain their development trend and increase the supply of goods and services, as well as its productive employment and exports.