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Q3 2016
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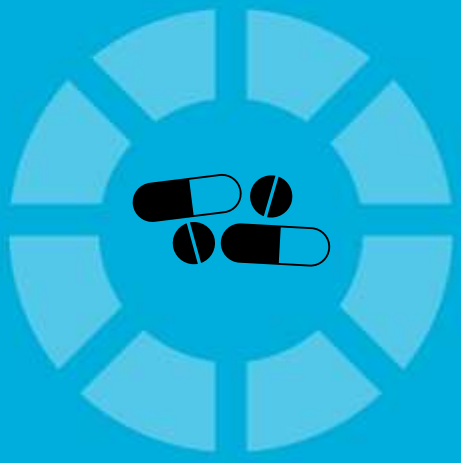
ARGENTINA
PHARMACEUTICALS & HEALTHCARE REPORT

INCLUDES 10-YEAR FORECASTS TO 2025



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Argentina Pharmaceuticals & Healthcare Report Q3 2016

INCLUDES 10-YEAR FORECASTS TO 2025

Part of BMI's Industry Report & Forecasts Series

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BMI Industry View

BMI View: *In the near term, the substandard regulatory and market access environment will continue to tarnish Argentina's appeal to drugmakers. However, in the long term, Argentina stands among the most promising pharmaceutical markets in Latin America in terms of growth. In fact, rising demand and improvements in the business environment are expected to translate in significant commercial and investment opportunities for drugmakers in the country over a multi-year horizon.*

Headline Expenditure Projections

Pharmaceuticals: ARS64.02bn (USD6.91bn) in 2015 to ARS79.31bn (USD5.18bn) in 2016; +23.9% in local currency terms and -25.0% in US dollar terms. *Forecast revised slightly upwards in local currency terms and slightly downwards in US dollar terms from last quarter.*

Healthcare: ARS243.93bn (USD26.33bn) in 2015 to ARS302.47bn (USD19.76bn) in 2016; +24.0% in local currency terms and -25.0% in US dollar terms. *Forecast revised downwards from last quarter.*

Table: Headline Pharmaceutical and Healthcare Forecasts (2014-2020)

	2014	2015	2016f	2017f	2018f	2019f	2020f
Pharmaceutical sales, USDbn	6.760	6.910	5.180	6.550	7.380	8.600	9.750
Pharmaceutical sales, % of GDP	1.13	1.13	1.15	1.16	1.16	1.17	1.16
Pharmaceutical sales, % of health expenditure	26.2	26.2	26.2	26.2	26.3	26.4	26.3
Health spending, USDbn	25.850	26.330	19.760	24.970	28.060	32.610	37.050

Source: The World Health Organization (WHO), BMI

Risk/Reward Index

In Q316, we have revised upwards Argentina's Risk/Reward Index (RRI) score to 57.5 (out of 100) from 55.4 previously. This is above the regional average of 50.1. The score revision was driven by improved industry risks indices. Argentina remains in seventh place out of 19 countries in the Americas region in **BMI**'s proprietary RRI matrix. Argentina's overall score is driven by a large pharmaceutical market and significant urbanization leading to better access to healthcare, but dragged down by poor policy enforcement and lax intellectual property protection.

Latest Updates

April 2016

- On occasion of a short-term agreement established between the public health coverage system for the elderly (PAMI) and associations representing stakeholders across the health system, PAMI authorities stressed their broader goal to achieve a 20% to 25% reduction in spending on medicines by the end of 2016.
- Recent measures in the PAMI system include the reduction of the reimbursement level for 160 medicines to a 50-80% range from 100% previously, and a drug price mechanism that will make prices paid by PAMI to be not higher than the lowest price agreed with other health coverage providers. Additionally, under the recent agreement the pharmaceutical industry will offer a discount on price to grant ARS1.6bn (USD113mn) in savings to PAMI.

March 2016

- A recent report by Endeavour, a foundation focusing on high impact entrepreneurship, highlighted that in the last decade the number of biotech firms in Argentina has duplicated to a total of 178 firms, with this figure expected to increase by 15-25% in the next five years as the sector is showing significant entrepreneurial dynamism.
- US biopharmaceutical Kite Pharma started the process of registration and licensing required to operate and commercialize a range of cancer products and inmunotherapies in the Argentinean market.
- Argentinean drugmaker Savant grew 20% in terms of sales and production in 2015 and expects to reach a similar growth rate in 2016 through a combination of products acquisition, the expansion of industrial capacity in Argentina, and growing market penetration in several Latin American countries.

BMI Economic View

Argentine real GDP growth will accelerate starting in H216 on the back of rising investment in sectors recently liberalised by President Macri. Domestic businesses will invest in expanding housing capacity, while foreign firms will look to acquire assets in Argentina's power sector.

BMI Political View

Argentine President Mauricio Macri will be able to implement the bulk of his reform agenda over the coming months, although he will face resistance from opposition Senators and labour unions. The development of fissures within the Kirchnerist opposition will support the passage of key pieces of legislation.

SWOT

Pharmaceutical SWOT Analysis

Strengths	▪ The country's disease profile is similar to that of developed states and the population is ageing, driving additional demand and consumption of medicines. ▪ Argentina has a well-developed local drug industry, with the pharmaceuticals sector accounting for around 1.1% of GDP. ▪ Well-educated and skilled workforce should help to attract investment from pharmaceuticals firms looking to manufacture high-value products. ▪ Relatively wide-ranging reimbursement coverage from socialised insurance schemes.
Weaknesses	▪ Government policy has been traditionally biased towards local drug producers, with the authorities keen to keep the national drugs bill low via the application of price controls and state-run laboratories. ▪ Domestic patent law remains below international standards and the protection of confidential test data and the approval of copies are key concerns. ▪ Poor regulatory conditions have alienated multinationals, many of which downscaled direct production in the country in the aftermath of the 2001 crisis and which have yet to return. ▪ High inflation is undermining the country's cost advantages - themselves primarily owing to the weakness of the peso.
Opportunities	▪ Government cost containment and relatively price-sensitive consumer demand should benefit the generic drug sector. ▪ Exports are expected to continue to grow as locally based producers benefit from ongoing weakness in the peso. ▪ Exporters should also benefit from regulatory improvements, as this should guarantee the quality of locally made pharmaceuticals and from expansion of domestic production base.

Pharmaceutical SWOT Analysis - Continued

- Government investment in vaccine development could lead to new partnerships with foreign producers - as has occurred in Brazil.
- The regulatory environment should benefit from the collaboration between Latin American regulators and the Spanish and Portuguese medicines agencies.
- Argentina's ongoing transition towards more market-friendly economic policies will significantly benefit growth in the pharmaceutical industry.

Threats

- Government's slow advance in aligning domestic patent law with international norms will continue to weigh on the country's full potential or attractiveness to investors, at least in the short to medium term.
- Failure to revise discriminatory pricing policy will deter multinational expansion.
- The costs of longer-term modernisation may continue to prevent the harmonisation of domestic regulations with international norms.
- Rampant inflation leaving many people unable to seek medical treatment.
- Despite providing export opportunities, the weakening peso will also make purchases of raw materials from abroad more challenging.

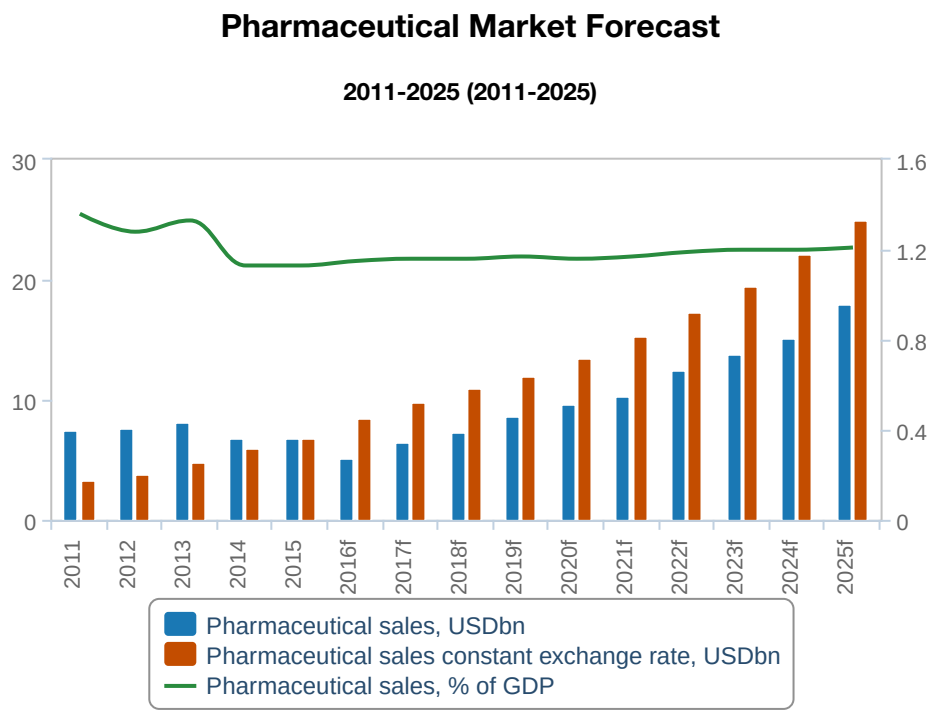
Industry Forecast

Pharmaceutical Market Forecast

BMI View: *Argentina stands among the most promising pharmaceutical markets in Latin America in terms of growth. In fact, commercial and investment opportunities for drugmakers in the country are expected to substantially increase through the forecast period on the back of rising demand and improvements in the business environment. Despite robust long-term growth fundamentals, short-term economic turbulence in 2016 will negatively impact on returns in the pharmaceutical and healthcare sector, with higher investment returns to pick up over a multi-year horizon.*

Latest Updates

- In April 2016, on occasion of a short-term agreement established between the public health coverage system for the elderly (PAMI) and associations representing stakeholders across the health system, PAMI authorities stressed their broader goal to achieve a 20% to 25% reduction in spending on medicines by the end of 2016.
- As of data reported in March 2016, medicine prices in Argentina have significantly raised since December 2015, with increases averaging 30% and reaching as much as 244% according to local consumer associations, with this price rise threatening access while putting financial pressure on pharmacies (Nuevo Diario).



f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Structural Trends

Argentina's pharmaceutical market reached a value of ARS64.02bn (USD6.91bn) in 2015, meaning there was a compound annual growth rate (CAGR) of 17.2% in local currency terms over 2010-2015. The market value is expected to increase to ARS79.31bn (USD5.18bn) in 2016. Despite Argentina's recent deceleration in its economic expansion compared to the previous decade, against a backdrop of current economic rebalancing and healthcare market trends, we expect the total value of the drug market to continue growing over the coming years, posting a five-year CAGR of 14.5% and 7.1% in local currency terms and US dollar terms, respectively, reaching ARS125.74bn (USD9.75bn) in 2020. By 2025, the value of the market is expected to reach ARS232.26bn (USD18.06bn), more than tripling in value in local currency terms over the decade, although with inflation as a contributing factor, observing a 10-year CAGR of 13.8% in local currency terms and 10.1% in US dollar terms.

In line with our view in recent quarters, in H116 the Argentine government started to incorporate some health technology assessment elements (cost-benefit considerations) to define the reimbursement of

medicines, which have recently played a part in the broader context of stakeholders negotiation of price and reimbursement of medicines under the PAMI public coverage system for the elderly. PAMI spending reached ARS17bn (USD1.2bn) in 2015, or 27% of the market, according to PAMI's head Carlos Regazzoni (Pharmabaires).

As the government attempts to improve efficiency and transparency across the health system, a set of new measures have been introduced affecting the PAMI system, which was reportedly facing financial issues due to poor management.

Recent measures in the PAMI system include the reduction of the reimbursement level for 160 medicines to a 50-80% range from 100% previously, and a drug price mechanism that will make prices paid by PAMI to be not higher than the lowest price agreed with other health coverage providers. Additionally, under the recent agreement the pharmaceutical industry will offer a discount on price to grant ARS1.6bn (USD113mn) in savings to PAMI. The agreement will be valid until December 2016, as the economy accommodates.

A rising and aging population will continue to support a growing demand for medicines in the country. In 2015, non-communicable diseases were responsible for around 80% of the total burden of disease, with a notable increase in the burden of cardiovascular disease, mental and behavioural disorders, cancer and diabetes.

In January 2016, Argentina's Health Minister Jorge Lemus announced a new healthcare plan to provide universal healthcare coverage through a more 'integrated' and 'efficient' system, which, in the long-term, is expected to increase revenue streams for pharmaceutical companies and medical device providers and broaden investment opportunities in the healthcare sector in the country.

Argentina is also the regional leader in foreign biological medicine approvals and marketing, making it the most appealing country in Latin America for manufacturers of such drugs. The country's reliance on imported biologics will ensure its continued demand for these imported medicines, particularly as Argentina's negative pharmaceutical trade balance will widen over the next five years, resulting in a deficit of USD2.1bn by 2020. Foreign drugmakers will continue to benefit from commercial opportunities within the country and the improving business environment will better the country's investor sentiment.

Moreover, market development will be benefitted by Argentina's geographical proximity, strong drug production ability and a skilled workforce, which will provide investment opportunities for foreign

drugmakers to expand their presence in Latin America over the forecast period, including through local market leaders.

The Argentine pharmaceutical market operates to some extent as a consumer-driven market where the role of brands, marketing and sale forces has been important in driving market growth in recent years.

Other drivers underpinning increased consumption of drugs include allegedly irrational and defensive prescribing by doctors, while several issues persist in terms of self-medication, abusive use of medicines by patients and irregular supply of medicines, including dispensing of prescription drugs without prescription or the purchase of medicines through the Internet without sufficient control. Regulators are trying to address some of these issues, although many of them are still not fully controlled.

Table: Pharmaceutical Sales, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Pharmaceutical sales, USDbn	7.740	8.090	6.760	6.910	5.180	6.550	7.380	8.600	9.750
Pharmaceutical sales, USDbn, % y-o-y	2.13	4.46	-16.42	2.21	-25.04	26.39	12.73	16.51	13.35
Pharmaceutical sales, ARSbn	35.240	44.300	54.930	64.020	79.310	91.660	101.490	111.800	125.740
Pharmaceutical sales, ARSbn, % y-o-y	12.55	25.72	24.00	16.54	23.89	15.58	10.72	10.16	12.48
Pharmaceutical sales constant exchange rate, USDbn	3.800	4.780	5.930	6.910	8.560	9.900	10.960	12.070	13.570
Pharmaceutical sales, USD per capita	184.0	190.2	157.3	159.2	118.1	147.9	165.2	190.7	214.2
Pharmaceutical sales, % of GDP	1.28	1.33	1.13	1.13	1.15	1.16	1.16	1.17	1.16
Pharmaceutical sales, % of health expenditure	25.4	26.1	26.2	26.2	26.2	26.2	26.3	26.4	26.3

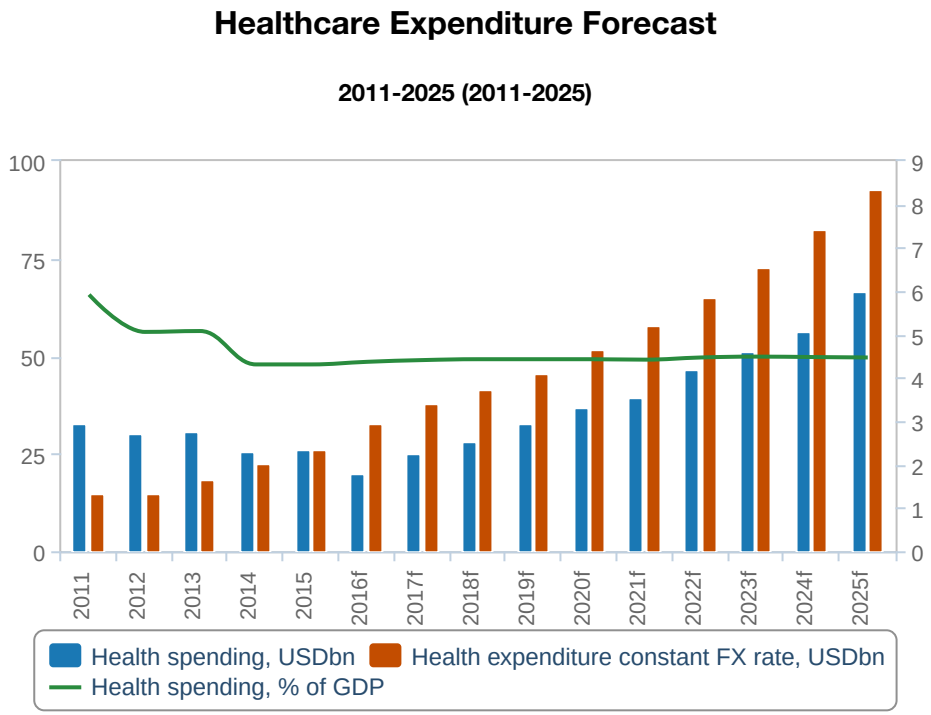
f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Healthcare Market Forecast

BMI View: *Healthcare expenditure in Argentina is expected to more than double over our 10-year forecast period, driven by an ageing population, improving access to healthcare, rising incomes and government programmes.*

Latest Updates

- In April 2016, on occasion of a short-term agreement signed between the public health coverage system for the elderly (PAMI) and associations representing stakeholders across the health system, PAMI authorities stressed their broader goal to achieve a 20% to 25% reduction in spending on medicines by the end of 2016.
- In February 2016, on occasion of the rare disease day to promote the fight against rare diseases, the World Health Organization reported that 7% of the Argentine population (or around 3.5mn individuals) suffer from rare or uncommon diseases, although only 50,000 of the cases have an accurate diagnosis.



f = BMI forecast. Source: World Health Organization (WHO), BMI

Structural Trends

In 2015, healthcare expenditure reached ARS243.93bn (USD26.33bn), and this is expected to increase to ARS302.47bn (USD19.76bn) in 2016. By 2020, healthcare expenditure is projected to increase to ARS477.99bn (USD37.05bn), equating to a 14.4% compound annual growth rate (CAGR) in local currency terms (7.1% in US dollar terms). By 2025, healthcare expenditure is expected to reach ARS860.06bn (USD66.89bn), posting a 10-year CAGR of 13.4% in local currency terms and 9.8% in US dollar terms. The public share is expected to decrease from 56.2% in 2015 to 52.1% of total healthcare spending by 2020.

As the government attempts to improve efficiency and transparency across the health system, as of April 2016, a set of new measures have been introduced affecting the PAMI system which was reportedly facing financial issues due to poor management.

Recent measures in the PAMI system include the reduction of the reimbursement level for 160 medicines to a 50-80% range from 100% previously, and a drug price mechanism that will make prices paid by PAMI to be not higher than the lowest price agreed with other health coverage providers. Additionally, under the recent agreement the pharmaceutical industry will offer a discount on price to grant ARS1.6bn (USD113mn) in savings to PAMI. The agreement will be valid until December 2016, as the economy accommodates. PAMI spending reached ARS17bn (USD1.2bn) in 2015, or 27% of the market, according to PAMI's head Carlos Regazzoni.

Though Argentina has come a long way in improving living standards since its economic crash in 2001-2002, persistent inflation and recurring economic insecurities have left many citizens struggling to meet their medical needs. Several national programmes, especially REMEDIAR and NACER/SUMAR, were implemented to cope with health financing issues across the country, and have become important functions in the health system over the last decade, both in terms of procurement and distribution. These programmes include granting free access to certain basic medicines to around 9mn people. Also, Argentina has a comprehensive system of vaccination, which is universal and mandatory.

On the other hand, the Financial Times (FT) found that healthcare expenditure among the country's well-off has actually increased in recent years, despite of economic volatility. The FT also reported that the affluent classes maintained their private medical plans, the cost of which has soared by about 60% since the start of 2010.

In January 2016, the Argentine government announced that it will create the National Agency for Technology Assessment to define the appropriate medicines, medical devices and medical procedures covered by the social healthcare system, which is in line with our long-standing view that the country will move towards the implementation of cost-effectiveness analysis of health technologies. The government will try to improve efficiency across the healthcare system.

In March 2015 the government announced the expansion of the telemedicine system launched in August 2014 aimed at interconnecting health facilities nationwide to improve access to healthcare and medical specialists across the country. Such developments will boost Argentina's attractiveness to healthcare and pharmaceutical investors who will likely benefit from the population's improved access to medical care.

Table: Healthcare Expenditure Trends, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Health spending, USDbn	30.500	31.020	25.850	26.330	19.760	24.970	28.060	32.610	37.050
Health spending, USDbn, % y-o-y	-7.55	1.69	-16.65	1.85	-24.97	26.41	12.38	16.19	13.64
Health spending, ARSbn	138.810	169.870	210.050	243.930	302.470	349.620	385.890	423.890	477.990
Health spending, ARSbn, % y-o-y	1.88	22.38	23.65	16.13	24.00	15.59	10.37	9.85	12.76
Health expenditure constant FX rate, USDbn	14.980	18.340	22.670	26.330	32.650	37.740	41.660	45.760	51.600
Health spending, USD per capita	724.6	729.1	601.5	606.5	450.6	564.1	628.0	722.9	814.1
Health spending, % of GDP	5.06	5.08	4.31	4.31	4.37	4.41	4.43	4.43	4.43

f = BMI forecast. Source: World Health Organization (WHO), BMI

Table: Government Healthcare Expenditure Trends, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Govt. health spend, USDbn	17.980	17.010	14.330	14.790	11.160	13.840	15.280	17.410	19.300
Govt. health spend, USDbn, % y-o-y	-14.25	-5.40	-15.76	3.22	-24.52	24.00	10.34	13.99	10.85
Govt. health spend, ARSbn	81.830	93.160	116.420	137.020	170.920	193.810	210.030	226.360	248.980
Govt. health spend, ARSbn, % y-o-y	-5.50	13.85	24.97	17.69	24.74	13.39	8.37	7.77	9.99
Govt. health spend, % total health spend	58.95	54.84	55.43	56.17	56.51	55.43	54.43	53.40	52.09

f = BMI forecast. Source: World Health Organization (WHO), BMI

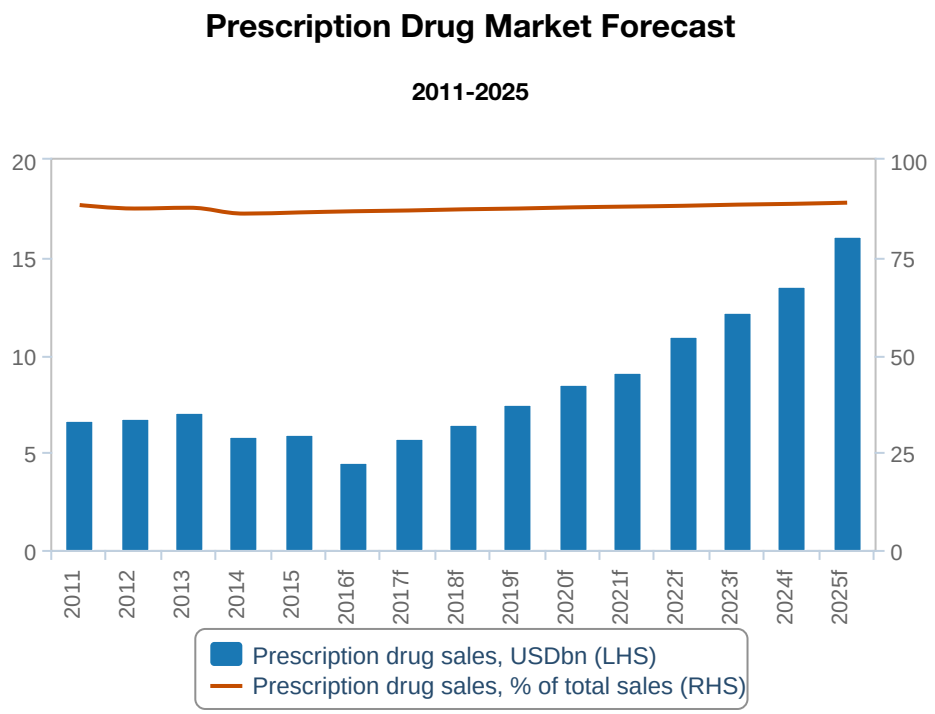
Table: Private Healthcare Expenditure Trends, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Private health spend, USDbn	12.520	14.010	11.520	11.540	8.590	11.130	12.790	15.200	17.750
Private health spend, USDbn, % y-o-y	4.13	11.87	-17.72	0.15	-25.55	29.53	14.92	18.81	16.83
Private health spend, ARSbn	56.970	76.700	93.620	106.920	131.550	155.810	175.860	197.540	229.010
Private health spend, ARSbn, % y-o-y	14.76	34.63	22.06	14.20	23.04	18.45	12.86	12.33	15.93
Private health spend, % total health expenditure	41.05	45.16	44.57	43.83	43.49	44.57	45.57	46.60	47.91

f = BMI forecast. Source: World Health Organization (WHO), BMI

Prescription Drug Market Forecast

BMI View: *Prescription drugs should continue to dominate the market in both value (87% of the total) and volume terms. This situation is partly due to the narrow price gap between prescription drugs (reimbursed) and OTCs (not reimbursed) that resulted from the 2005 price controls. Moreover, improving access to healthcare and rising non-communicable disease burden will continue to drive prescription drugs growth.*



f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Structural Trends

In 2015, prescription drug sales reached a value of ARS55.37bn (USD5.98bn), and this is expected to increase to ARS68.81bn (USD4.49bn) in 2016. Through to 2020, prescription medicine sales are forecast to grow at a compound annual growth rate (CAGR) of 14.8% in local currency terms and 7.4% in US dollar terms, reaching ARS110.35bn (USD8.55bn) in 2020. By 2025, prescription drug sales are expected to reach ARS206.62bn (USD16.07bn), equating to a 10-year CAGR of 14.1% and 10.4% in local currency terms and US dollar terms, respectively.

In April 2016, on occasion of a short-term agreement established between the public health coverage system for the elderly (PAMI) and associations representing stakeholders across the health system, PAMI authorities stressed their broader goal to achieve a 20% to 25% reduction in spending on medicines by the end of 2016. PAMI accounts for around 27% of the market (*see 'Pharmaceutical Market Forecast'*).

In 2015, non-communicable diseases were responsible for around 80% of the total burden of disease, with a notable increase in the burden of cardiovascular disease, mental and behavioural disorders, cancer and diabetes. Argentina is also the regional leader in foreign biological medicine approvals and marketing, making it the most appealing country in Latin America for manufacturers of such drugs. The country's reliance on imported biologics will ensure its continued demand for these imported medicines, particularly as Argentina's negative pharmaceutical trade balance will dramatically widen over the next five years (*see 'Pharmaceutical Trade Forecast'*).

An additional factor driving high consumption of prescription drugs is the narrow price gap between prescription drugs (reimbursed) and OTCs (not reimbursed) that resulted from the 2005 price controls. Improving access to healthcare and rising incomes will also contribute to high consumption of prescription drugs. Leading drivers of prescription market growth will be volume changes. According to IMS Health figures reproduced in local newspaper Los Andes, on average, annual consumption of medicines per head in Argentina is around 13 boxes, with the country thus ranking third in Latin America, only trailing Venezuela and Uruguay.

About 525.8mn units of medicines were sold in Argentina in the 12 months to August 2009, of which 74% were prescription medicines. In 2011, a total of 649mn units of medicine were sold in the country, marking an 87.6% increase between 2003 and 2011. Despite not being a major health issue in the country, medicines for the treatment of erectile dysfunction are some of the bestsellers and, along with tranquilisers, are thought to be used for purposes other than those intended, based on their volume sales compared with epidemiological trends.

Among other key reasons for this upward trend is a rising interest in self-medication, coupled with the better economic situation, according to Federico Tobar, an international health policy consultant. Marketing and other strategies employed by the pharmaceutical industry are also reportedly responsible for the higher prescribing rates, in addition to an increase in 'irrational' drug prescribing and use.

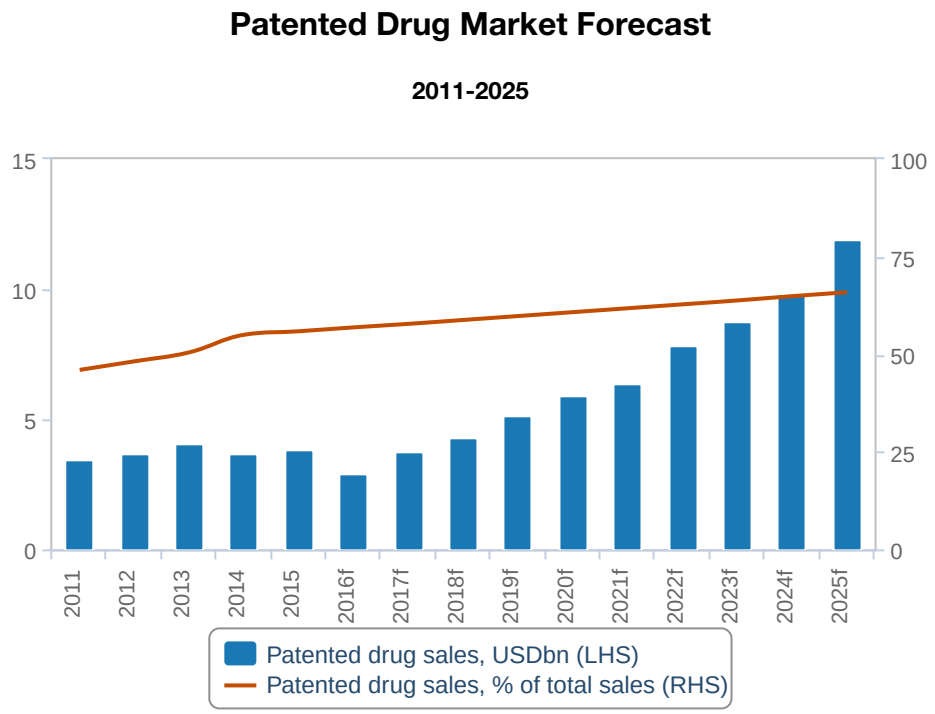
Table: Prescription Drug Market Indicators, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Prescription drug sales, USDbn	6.780	7.090	5.830	5.980	4.490	5.700	6.440	7.530	8.550
Prescription drug sales, USDbn, % y-o-y	1.06	4.67	-17.82	2.57	-24.81	26.76	13.05	16.85	13.67
Prescription drug sales, ARSbn	30.830	38.840	47.350	55.370	68.810	79.760	88.560	97.830	110.350
Prescription drug sales, ARSbn, % y-o-y	11.38	25.97	21.91	16.95	24.26	15.91	11.03	10.47	12.80
Prescription drug sales, % of total sales	87.5	87.7	86.2	86.5	86.8	87.0	87.3	87.5	87.8

f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Patented Drug Market Forecast

BMI View: *Patented drugs will increase as a share of total drug market value in Argentina over our forecast period to 2020 and beyond. This is in part due to the introduction of new products, increasing access to healthcare, rising incomes and improving health awareness.*



f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Structural Trends

In 2015, Argentina's patented drugs market reached a value of ARS35.81bn (USD3.87bn), and this is expected to increase to ARS45.11bn (USD2.95bn) in 2016. By 2020, we expect patented medicine sales to have reached a value of ARS76.41bn (USD5.92bn), equating to a 16.4% compound annual growth rate (CAGR) in local currency terms and 8.9% in US dollar terms. By 2025, the patented drugs market is expected to reach ARS153.08bn (USD11.91bn), posting a 10-year CAGR of 15.6% in local currency terms and 11.9% in US dollar terms.

However, the rise in patented drug market share will be partially offset by efforts to increase the use of generics, the lax regulatory environment, heavy discounts in public sector procurement and the high cost of imports. Additionally, since 2002, doctors have been obliged to prescribe medicines by chemical name in a move intended to discourage the use of costlier patented drugs. However, patented drugs accounted for 56% of the Argentine pharmaceutical market in 2015, with this figure expected to increase to 61% by 2020, and to 66% of total sales by 2025. In September 2015, health ministers of the member countries of MERCOSUR and the Union of South American Nations entered an agreement for the creation of an ad hoc committee for the joint negotiation of medicine prices, especially for expensive medicines, as well as the eventual implementation of a regional bank for the monitoring of drug prices in a bid to avoid excess and ensure accessibility to medicines. The aim of the agreement is to increase the volume of drug purchases in order to counteract rising prices of medicines. The agreement will improve the region's appeal to multinational drugmakers as the bloc's purchasing power increases.

In September 2015, the Argentinean government announced the inauguration of its Centre for Biological Products, Biotechnology, and Radiopharmaceuticals, under the National Institute of Medicine (INAME), which received funding of ARS67mn (USD7mn) and will work to guarantee access to quality drugs and vaccines, while working as a monitoring system to ensure safety and efficacy of the biological drugs that enter the country.

Argentina is also the regional leader in foreign biological medicine approvals and marketing, making it the most appealing country in Latin America for manufacturers of such drugs. The country's reliance on imported biologics will ensure its continued demand for these imported medicines, particularly as Argentina's negative pharmaceutical trade balance will dramatically widen over the next five years, resulting in a deficit of USD2.1bn by 2020. Foreign drugmakers will continue to benefit from commercial opportunities within the country and improving regulatory standards will better the country's investor sentiment.

Several multinationals have opted to freeze or downscale investment in Argentina in the last decade, although several foreign multinationals continue at the top of the ranking in terms of market share. In comparison with other major economies in Latin America, Argentina has offered less scope for drugmakers to expand in the domestic market due to the limited growth in consumer demand in recent years. We have consequently noted that local drugmakers are adopting two expansion types of strategy: one is to increase market share through product acquisitions and licensing agreements; the other is to achieve growth through investment in international expansion.

In 2015, non-communicable diseases were responsible for around 80% of the total burden of disease, with a notable increase in the burden of cardiovascular disease, mental and behavioural disorders, cancer and diabetes (*see 'Market Overview' for more details*).

The huge patent backlog in the country is likely to mitigate access to new treatments. In its 2016 report, PhRMA estimated that the backlog affects around 21,000 applications.

On the other hand, lax patent protection regulation, a factor undermining market growth, could see some improvements over time, provided the ongoing efforts to open the legislative debate on patent rules by the Industrial Chamber of Pharmaceutical Laboratories, or similar claims by the local biotechnology industry, succeed. Also, Argentina's ongoing transition towards more market-friendly economic policies is likely to play a favourable role in terms of improving the regulatory environment in the years ahead.

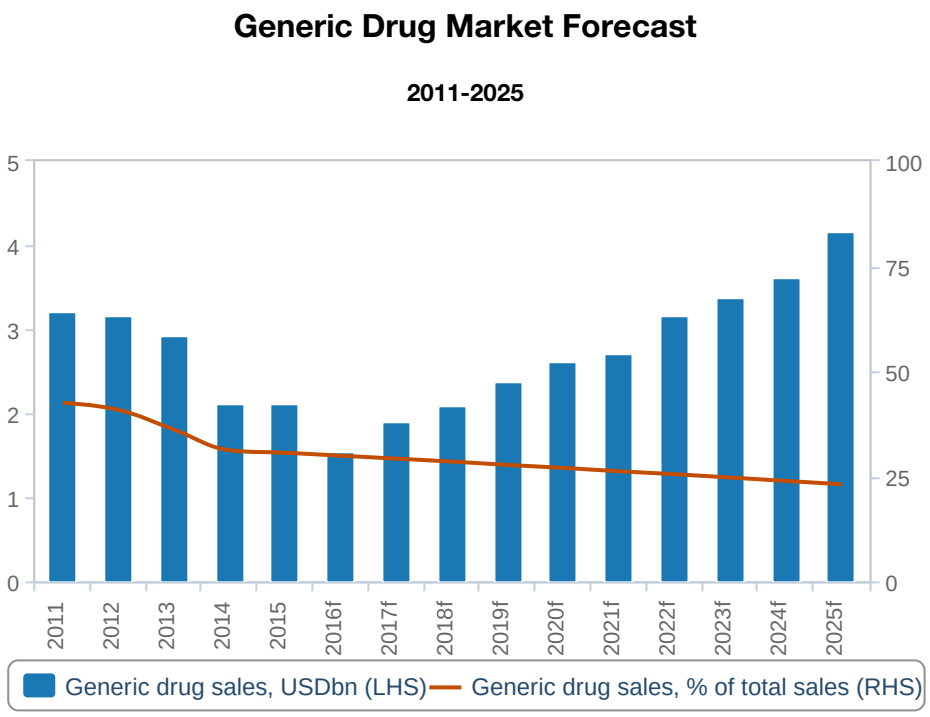
Table: Patented Drug Market Indicators, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Patented drug sales, USDbn	3.730	4.090	3.720	3.870	2.950	3.790	4.340	5.140	5.920
Patented drug sales, USDbn, % y-o-y	7.11	9.50	-9.00	3.95	-23.78	28.51	14.62	18.45	15.23
Patented drug sales, ARSbn	16.980	22.380	30.220	35.810	45.110	53.010	59.680	66.830	76.410
Patented drug sales, ARSbn, % y-o-y	18.04	31.78	35.00	18.52	25.97	17.51	12.57	11.99	14.34
Patented drug sales, % of prescription sales	55.1	57.6	63.8	64.7	65.6	66.5	67.4	68.3	69.3
Patented drug sales, % of total sales	48.2	50.5	55.0	55.9	56.9	57.8	58.8	59.8	60.8

f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Generic Drug Market Forecast

BMI View: *Generic medicines will decrease as a share of the total drug market's value through the forecast period. However, the lax regulatory environment, along with heavy discounts in public sector procurement and the high cost of imports should continue to promote the consumption of generic medicines in the country. The average discount offered by generic drugs in relation to reference-patented products is estimated at 54%.*



f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Structural Trends

In 2015, generic medicine sales reached a value of ARS19.56bn (USD2.11bn), and this is expected to increase to ARS23.70bn (USD1.55bn) in 2016. According to our updated forecast and the latest data, we expect this figure to rise to ARS33.94bn (USD2.63bn) by 2020, equating to a 11.6% compound annual growth rate (CAGR) in local currency terms (4.5% in US dollar terms). By 2025, we expect generic

medicine sales to reach ARS53.54bn (USD4.16bn), posting a 10-year CAGR of 10.6% and 7.0% in local currency terms and US dollar terms, respectively.

Generic medicines will decrease as a share of the total drug market's value, from 30.6% calculated for 2015 to 27.0% in 2020, and 23.1% in 2025. However, the lax regulatory environment in Argentina, along with heavy discounts in public sector procurement and the high cost of imports, should continue to sustain the consumption of generic medicines in the country.

Prices are low due to competition, price freezes, and the existence of a form of therapeutic reference pricing. Government policy has in the past promoted the use of non-bioequivalent generic drugs. These continue to account for up to 80% of the market in volume terms, although this is, in itself, an improvement. New regulations in 2002 obliged doctors to prescribe medicines by chemical name in a move intended to discourage the use of costlier patented drugs, with ANMAT on a number of occasions pledging to strengthen enforcement of often ignored generic prescribing.

In March 2015, ANMAT convened a working group to address the access to expensive drugs under the coordination of Raquel Mendez, director of the National Institute of Medicines (INAME), including the participation of doctors and pharmacists, experts from the Faculty of Medicine and industry representatives of national and international firms, including Novartis, reports PharmaBaires. The working group could unlock the regulatory challenges on biosimilars, for which advances have been sluggish and were one of the causes that accelerated changes in ANMAT and INAME since their previous authorities allegedly delayed the approval of biosimilars and public production.

The former minister of health, Daniel Gollan, stressed a focus on expanding local production capacities and increasing the prescription of generics. Recent agreements between the Argentine government and Chinese firm Sinopharm are aimed at enhancing technology transfer, pharmaceutical ingredients provision and creating complementary production capacities among both countries.

The entry of Indian companies in Argentina - and, in the wake of recent consolidation in the global generic drugs sector, the likes of Teva/IVAX and Sandoz, as well as Brazilian players over the longer term - could add impetus and sophistication to the sector. According to official statistics, Indian companies account for the segment's second-largest share of revenue after domestic manufacturers. Notably, however, they have recently been slow to establish any local production presence in the country, in contrast to a spree of acquisitions in Brazil since 2005. In October 2014, Argentina fully opened its pharmaceutical market to Indian firms, authorising Indian exports of finished formulations to the country. Prior to the decision, Indian firms could export bulk drugs to Argentina.

Indian mid-cap pharmaceutical companies are expected to continue to plan aggressive expansion in South American countries, such as Brazil and Argentina, amid stiff regulatory standards and intensified competition in developed markets. The companies are planning to exploit developing countries where rules are less stringent and demand for medicines is on the rise. In these countries, governments are more concerned with the affordability of healthcare rather than defending patents.

Argentina, for example, has no linkage system between the patent system and the system for marketing new pharmaceutical products, which can result in unauthorised copies being released on the market. Local definitions for generic medicines are lax in Argentina even though this continues to hold back the market for legitimate, bioequivalent generic drugs. ANMAT permits similars to have an identical active pharmaceutical ingredient (API), formulation and dosage strength to original products, although minor differences in presentation, dosage form or period of effect are acceptable for new registrations. Notably, in contrast to Brazil, any similar or copy medicine may have a brand name (further confusing definitions for 'branded generic drugs'), while 'generic medicines' are generally defined as cheap, basic products and off-patent medicines identified only by international non-propriety name (INN).

A further problem is that product registrations are not usually granted if an 'equivalent' similar medicine is currently marketed in Argentina. In the few therapeutic areas where this is not the case, generic registrations may be fast-tracked in 90 days if the product is registered in a list of 15 markets, which includes several developed markets.

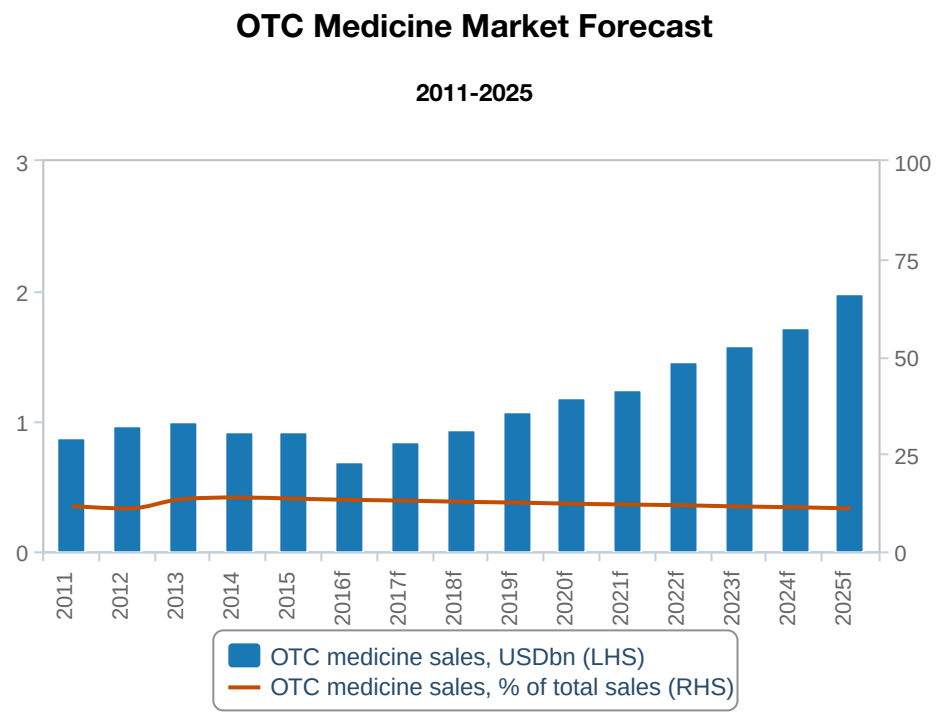
Table: Generic Drug Market Indicators, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
Generic drug sales, USDbn	3.160	2.920	2.110	2.110	1.550	1.910	2.100	2.380	2.630
Generic drug sales, USDbn, % y-o-y	-1.87	-7.65	-27.71	0.14	-26.71	23.43	9.95	13.52	10.32
Generic drug sales, ARSbn	14.380	15.980	17.130	19.560	23.700	26.750	28.880	31.000	33.940
Generic drug sales, ARSbn, % y-o-y	8.15	11.14	7.24	14.18	21.13	12.87	7.98	7.33	9.47
Generic drug sales, % of prescription sales	46.6	41.1	36.2	35.3	34.4	33.5	32.6	31.7	30.8
Generic drug sales, % of total sales	40.8	36.1	31.2	30.6	29.9	29.2	28.5	27.7	27.0

f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

OTC Medicines Forecast

BMI View: *We calculate Argentina's OTC market share of total drug sales will gradually decrease through the forecast period. We believe the OTC sector could achieve a much higher market share, but the lack of an active OTC-switching policy, a fragmented retail pharmacy sector, the rollout of the ban on sales of medicines outside pharmacies and an increase in the share of the prescription medicine market will limit such development.*



f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Structural Trends

In 2015, we calculate Argentina's OTC market reached a value of ARS8.64bn (USD930mn), and this is expected to increase to ARS10.50bn (USD690mn) in 2016. According to our updated forecast and the latest data, by 2020 we expect OTC sales to have grown by a compound annual growth rate (CAGR) of 12.2% in local currency terms (5.0% in US dollar terms), reaching ARS15.39bn (USD1.19bn) in 2020. By 2025, the

OTC market is expected to reach ARS25.64bn (USD1.99bn), equating to a 10-year CAGR of 11.5% and 7.9% in local currency and US dollar terms, respectively.

The OTC sector accounted for 13.5% of total market sales in 2015 and is projected to decline to 12.2% of the market by 2020, and to 11.0% by 2025. We believe the OTC sector could achieve a much higher market share, but the lack of an active OTC-switching policy, a fragmented retail pharmacy sector, the rollout of the ban on sales of medicines outside pharmacies and an increase in the share of the prescription medicine market will limit such development.

The sale of OTC medicines in establishments other than pharmacies (including supermarkets, petrol stations, gyms, hotels and even at newsstands) was previously authorised in 1991 by Decree 2284. The decision was made with the intention of increasing competition in the OTC sector so that consumers could benefit from the resulting reduction in prices of the non-prescription medicines. However, inspectors became concerned about newsagents illegally selling prescription drugs under the counter. In most cases, medicines sold in the informal market are in poor condition or beyond their use-by date.

A series of scandals in early 2011 raised doubts about whether or not the majority of OTCs will continue to be made available outside pharmacies. In June 2011, the regulatory authorities introduced new rules that mean cold remedies, aspirin, decongestants and digestive supplements can only be sold in pharmacies. The potentially dangerous decongestant ephedrine and the anti-migraine drug ergotamine also now require prescription.

The OTC market's growth has been led by local manufacturers, which have made use of heavy advertising and have also offered big discounts. Major local players include Bagó, Elea, and Gramón. Leading multinationals include Bayer, GlaxoSmithKline, and Procter & Gamble. Some of the country's major OTC brands include the systemic analgesics *Bayaspirina* from Bayer and *Ibu-Evanol* from GlaxoSmithKline, the antacids *Alikal* and *Uvasal* from GlaxoSmithKline, and the cold & flu remedy *Vick Vitapyrena* from Procter & Gamble. Both local and multinational players have launched a number of line extensions to their established brands. Recent launches include the laxative *Agarol Emulsión* by Elea, the antispasmodic *Buscopina* by Boehringer Ingelheim, and the antifungal *Empecid Gyno* and the dietary supplement *Berocca*, both by Bayer.

Consumers remain extremely price conscious and they expect branded OTCs to be priced at low levels. On a more positive note, ANMAT encourages the use of OTCs and publishes a regular OTC newsletter for consumers to try to promote the sector. Additionally, as in other Latin American countries, the indigenous

population has a strong tradition of using herbal remedies, and this sector has significant potential for further development.

In March 2015 Argentina's Supreme Court of Justice confirmed a sentence against pharmacy retailer Farmacity, stating that over the counter medicines should be dispensed in person at the counter by pharmacies or persons authorized for the sale, rather than dispensed in shelves, aiming at avoiding self-medication.

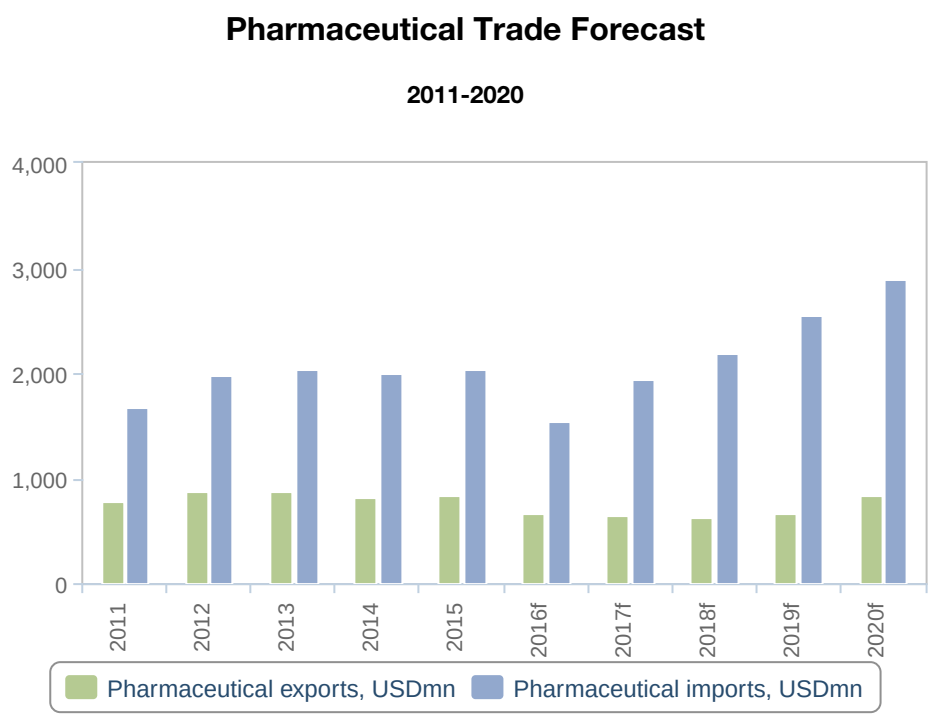
Table: Over-The-Counter (OTC) Medicine Market Indicators, Historical Data And Forecasts (Argentina 2012-2020)

	2012	2013	2014	2015	2016f	2017f	2018f	2019f	2020f
OTC medicine sales, USDbn	0.970	1.000	0.930	0.930	0.690	0.850	0.940	1.070	1.190
OTC medicine sales, USDbn, % y-o-y	10.25	3.00	-6.42	-0.01	-26.48	24.01	10.56	14.23	11.08
OTC medicine sales, ARSbn	4.410	5.460	7.580	8.640	10.500	11.910	12.930	13.960	15.390
OTC medicine sales, ARSbn, % y-o-y	21.51	23.95	38.83	14.01	21.50	13.40	8.59	8.00	10.22
Over-the-counter (OTC) medicine sales, % of total sales	11.0	13.4	13.8	13.5	13.2	13.0	12.7	12.5	12.2

f = BMI forecast. Source: AAPM (Associacion Agentes de Propaganda Medica), AESGP, BMI

Pharmaceutical Trade Forecast

BMI View: *Despite the government's increased focus on stimulating domestic pharmaceutical production, Argentina will retain its negative pharmaceutical trade balance. Rising demand and improved access to healthcare will drive the import of patented drugs. Meanwhile, improvements in Argentina's business environment attracting foreign investment, local pharmaceutical players push to expand their international reach and the government's promotion of public-private partnerships and local manufacturing capacity, will all act as long-term drivers increasing domestic drug production and exports.*



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

Structural Trends

In 2015, pharmaceutical exports reached ARS7.8bn (USD840mn), and this is expected to increase to ARS10.3bn (USD672mn) in 2016, and to ARS10.7bn (USD830mn) in 2020. Within the 2015-2020 forecast period, drug exports are expected to observe a compound annual growth rate (CAGR) of 6.6% in local currency terms and -0.2% in US dollar terms.

In 2014 Argentina's top five export countries included Brazil (USD147mn), Uruguay (USD96mn), Venezuela (USD61mn), Chile (USD44mn), and Paraguay (USD42mn). Other top export partners include Mexico (USD39mn), Colombia (USD35mn), and Ecuador (USD30mn).

In 2015, pharmaceutical imports reached ARS19.0bn (USD2.0bn), and this is expected to increase to ARS23.5bn (USD1.5bn) in 2016, and to ARS37.3bn (USD2.9bn) in 2020. Within the 2015-2020 forecast period, drug imports are expected to experience a CAGR of 14.5% and 7.1% in local currency and US dollar terms, respectively.

Argentina's top five importers in 2014 were Germany (USD445mn), the US (USD390mn), Switzerland (USD183mn), France (USD173mn), and Ireland (USD143mn). Other top import partners include Italy (USD141mn), Canada (USD84mn), and the UK (USD71mn).

In 2011, the Argentine Ministry of Industry launched the Industrial Strategic Plan 2020, which includes the goals of stimulating the expansion of the pharmaceutical industry domestic capacity, revert the pharmaceutical balance deficit by 2020, increasing import substitution and diversifying exports markets. The plan follows the government introduction in 2010 of subsidised credit lines for expanding production plants and industrial capacity in the country, known as Bicentenario credits. The implementation of public-private partnerships has also been observed in recent years, especially in the biotechnology sector.

Having said this, a note of caution with regards to the ultimate government objective of reverting the pharmaceutical trade deficit is necessary, especially due to the effects of high inflation and drug pricing controls that have eroded domestic drugmaker margins in recent years, hampering investment. Also, the Argentine government's recent authorisation for Indian firms to export finished pharmaceutical formulations to Argentina may act as a new source of pressure over the trade balance deficit in the long-term, especially as Indian officials have claimed to be able to supply generic drugs at nearly half the price of Argentina's locally made drugs.

Leading local exporters included BioSidus, Laboratorios Bagó, Phoenix and Gador. CILFA expects that over the next few years, domestic drug companies will ambitiously shift the focus of exports away from the Americas to Asia and the Middle East. In July 2010, Laboratorio Farmacéutico Chemo Argentina (Romikin) signed a USD73mn deal with China's Fosun Pharma to build a Shanghai-based plant for the production of generic drugs and biosimilars destined for the Asian market. According to the country's former Minister of Industry, Débora Giorgi: 'This deal is a concrete example of the governments of China and Argentina rethinking and relaunching bilateral relations.'

Reinforcing this view, in H214 and Q115 bilateral meetings aimed at signing investment agreements and fostering trade and business opportunities were held between Argentina and countries including China, Russia and India. The pharmaceutical sector was present in the meetings and Argentine drugmakers highlighted their interest in expanding exports to Asian destinations.

Also, a free-trade agreement (FTA) was signed between Egypt and the Mercosur countries (Brazil, Argentina, Uruguay and Paraguay) during a 2010 Mercosur summit. The FTA is expected to give Mercosur access to a market of 76mn new consumers. The removal of tariffs for industrialised goods, such as pharmaceuticals, was aimed at taking place gradually over four-to-five years. In 2013 Egypt ratified the FTA.

Due to strong local competition, **BMI** believes that it will be difficult for Argentine firms to expand in Europe and North America in the short-to-medium term. However, Eastern Europe could present a sizeable opportunity as these markets are growing at breakneck speed and have strong demand for generic drugs. Laboratorios Bagó, for example, is specifically targeting countries in the Commonwealth of Independent States (CIS) in its 2012-2020 expansion plan. The recent creation of an export-focused drug-manufacturing hub in Buenos Aires indicates exports have been identified as a key source of revenue for the indigenous industry.

Table: Pharmaceutical Trade Data And Forecasts (Argentina 2014-2020)

	2014	2015	2016f	2017f	2018f	2019f	2020f
Pharmaceutical exports, USDmn	819.53	839.87	671.75	651.14	629.36	670.02	829.91
Pharmaceutical exports, USDmn, % y-o-y	-6.86	2.48	-20.02	-3.07	-3.35	6.46	23.86
Pharmaceutical imports, USDmn	2,002.94	2,047.22	1,534.60	1,939.65	2,186.57	2,547.61	2,887.66
Pharmaceutical imports, USDmn, % y-o-y	-1.56	2.21	-25.04	26.39	12.73	16.51	13.35
Pharmaceutical trade balance, USDmn	-1,183.41	-1,207.35	-862.85	-1,288.51	-1,557.21	-1,877.59	-2,057.75

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

Table: Pharmaceutical Trade Data And Forecasts local currency (Argentina 2014-2020)

	2014	2015	2016f	2017f	2018f	2019f	2020f
Pharmaceutical exports, ARSmn	6,658.18	7,780.18	10,284.43	9,116.03	8,653.70	8,710.21	10,705.82
Pharmaceutical exports, ARSmn, % y-o-y	38.16	16.85	32.19	-11.36	-5.07	0.65	22.91
Pharmaceutical imports, ARSmn	16,272.69	18,964.61	23,494.72	27,155.16	30,065.28	33,118.93	37,250.85
Pharmaceutical imports, ARSmn, % y-o-y	46.04	16.54	23.89	15.58	10.72	10.16	12.48
Pharmaceutical trade balance, ARSmn	-9,614.50	-11,184.43	-13,210.29	-18,039.13	-21,411.58	-24,408.72	-26,545.03

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

Industry Risk Reward Index

Americas Risk/Reward Index

***BMI View**: Geographic diversification may be a favourable strategy for multinational pharmaceutical companies, but it is vital that firms recognise both the rewards and the risks present in a market, whether developed or emerging. **BMI**'s Risk/Reward Index (RRI) tool, which provides a globally comparative and numerically based assessment of a market's attractiveness, was established to address this.*

In **BMI**'s Q316 Pharmaceutical RRI, the Americas scores 50.1 out of 100, below Western Europe (70.3), Central and Eastern Europe (52.2) and Asia Pacific (52.3), and above the Middle East and Africa (41.3). The indicators used to assess the attractiveness of a pharmaceutical market are now visible, improving the transparency of the index system and enabling the identification of regional or group outperformers across single indicators. A market's RRI score is made up of a sum of the Rewards score (Industry Rewards + Country Rewards) and the Risks score (Industry Risks + Country Risks).

The weight assigned to each subsector (such as Industry Rewards or Industry Risks) shows its influence within the final Rewards or Risks score and the final RRI score. The Rewards component accounts for 65% of the final RRI, while the Risks component accounts for 35%.

Q316 Americas Pharmaceutical Risk/Reward Index

Rewards & Risks Scores

	Industry Rewards	Country Rewards	Rewards	Industry Risks	Country Risks	Risks	RRI	Ranking
Weighting	44	21	65	21	14	35	100	
US	36.8	16.1	52.9	18.9	12.1	31.0	83.9	1
Canada	28.0	16.9	44.9	14.7	11.8	26.5	71.4	2
Puerto Rico	25.2	15.4	40.6	16.1	7.8	23.9	64.5	3
Brazil	28.0	13.7	41.7	12.6	8.3	20.9	62.6	4
Chile	26.4	15.0	41.4	10.9	9.7	20.6	62.0	5
Mexico	28.4	12.6	41.0	11.2	8.4	19.6	60.6	6
Argentina	24.8	15.3	40.1	9.1	8.3	17.4	57.5	7
Colombia	22.8	12.1	34.9	9.8	8.3	18.1	53.0	8
Peru	18.8	12.6	31.4	9.1	7.7	16.8	48.2	9
Costa Rica	16.0	13.4	29.4	9.8	8.3	18.1	47.5	10
Panama	14.8	12.3	27.1	9.8	9.6	19.4	46.5	11
Cuba	20.0	13.8	33.8	3.9	7.6	11.5	45.3	12
Ecuador	20.0	9.8	29.8	9.8	5.0	14.8	44.6	13
Venezuela	20.4	13.4	33.8	2.1	4.8	6.9	40.7	14
Guatemala	16.0	11.2	27.2	5.6	6.7	12.3	39.5	15
Belize	10.4	9.6	20.0	5.6	9.6	15.2	35.2	16
El Salvador	9.2	11.6	20.8	5.6	7.8	13.4	34.2	17
Honduras	5.6	10.7	16.3	5.6	5.6	11.2	27.5	18
Nicaragua	5.6	10.2	15.8	5.6	5.7	11.3	27.1	19
Regional Average	19.9	12.9	32.8	9.2	8.1	17.3	50.1	

**RRI scores out of 100, with 100 highest. Source: BMI.*

The Industry Rewards, Country Rewards, Industry Risks and Country Risks subsectors are each made up of a number of indicators. The weighting of each indicator (such as market expenditure which is used to assess Industry Reward or economic diligence which is used to assess Country Risk) reflects its relative importance to the pharmaceutical industry and subsequently the relative reward or risk that each factor poses to drug companies. In Q316, the US is ranked as the most attractive market in the Americas region (scoring 83.9 out of 100), followed by Canada (71.4) and Puerto Rico (64.5). In the same quarter, Nicaragua is ranked as the least attractive market in the Americas region (scoring 27.1 out of 100), followed by Honduras (27.5) and El Salvador (34.2).

With regards to assessing rewards, we identify industry-specific factors, such as the size of the pharmaceutical market, and country-specific factors, such as the size of the pensionable population, which represent opportunities to would-be investors. Focusing on the Rewards component of the index system, the US scores a total of 52.9 out of 65, the highest score in subsector. The US' score is boosted by the large multi-billion dollar drug market (market expenditure score of 20.0 out of 20) and high urbanisation rate (urban/rural split score of 7.2 out of 8), but dragged down by a declining pharmaceutical market (sector value growth score of 4.8 out of 12) and a declining population growth (population growth score of 2.5 out of 5). Meanwhile, Nicaragua scores a total of 15.8 out of 65, the lowest score in the subsector.

Q316 Americas Pharmaceutical Rewards

Industry Rewards & Country Rewards Scores

	Market Expenditure	Spending Per Capita	Sector Value Growth	Industry Rewards	Urban/Rural Split	Pensionable Population	Population Growth	Country Rewards	Rewards
Weighting	20	12	12	44	8	8	5	21	65
US	20.0	12.0	4.8	36.8	7.2	6.4	2.5	16.1	52.9
Canada	16.0	8.4	3.6	28.0	7.2	7.2	2.5	16.9	44.9
Puerto Rico	12.0	12.0	1.2	25.2	8.0	6.4	1.0	15.4	40.6
Brazil	16.0	3.6	8.4	28.0	7.2	4.0	2.5	13.7	41.7
Chile	12.0	4.8	9.6	26.4	7.2	4.8	3.0	15.0	41.4
Mexico	14.0	4.8	9.6	28.4	6.4	3.2	3.0	12.6	41.0
Argentina	14.0	4.8	6.0	24.8	8.0	4.8	2.5	15.3	40.1
Colombia	12.0	3.6	7.2	22.8	6.4	3.2	2.5	12.1	34.9
Peru	8.0	2.4	8.4	18.8	6.4	3.2	3.0	12.6	31.4
Costa Rica	4.0	4.8	7.2	16.0	6.4	4.0	3.0	13.4	29.4
Panama	4.0	4.8	6.0	14.8	5.6	3.2	3.5	12.3	27.1
Cuba	8.0	4.8	7.2	20.0	6.4	6.4	1.0	13.8	33.8
Ecuador	8.0	4.8	7.2	20.0	5.6	3.2	1.0	9.8	29.8
Venezuela	6.0	2.4	12.0	20.4	7.2	3.2	3.0	13.4	33.8
Guatemala	4.0	3.6	8.4	16.0	4.8	2.4	4.0	11.2	27.2
Belize	2.0	2.4	6.0	10.4	4.0	1.6	4.0	9.6	20.0
El Salvador	2.0	3.6	3.6	9.2	5.6	4.0	2.0	11.6	20.8
Honduras	2.0	3.6	0.0	5.6	4.8	2.4	3.5	10.7	16.3
Nicaragua	2.0	3.6	0.0	5.6	4.8	2.4	3.0	10.2	15.8
Regional Average	8.7	5.0	6.1	19.9	6.3	4.0	2.7	12.9	32.8

**RRI scores out of 100, with 100 highest. Source: BMI.*

With regards to assessing risks, we identify industry-specific dangers - such as approvals expediency - and those emanating from the state's political and economic profile - such as bureaucracy - which call into question the likelihood of anticipated returns being realised over the assessed time period. With regards to the economic and political assessment, only the aspects most relevant to the pharmaceutical industry are incorporated into the assessment. Focusing on the Risks component of the index system, Venezuela scores a total of 6.9 out of 35, the lowest score in subsector. Compared to its peers, Venezuela's score is dragged down by Country Risk components such as weak legal diligence (0.7 out of 3) and business transparency (0.3 out of 2). Meanwhile, the US scores a total of 31.0 out of 35, the highest score in the subsector.

Q316 Americas Pharmaceutical Risks

Industry Risks And Country Risks Scores

	Patent Respect	Policy Enforcement	Approvals Expediency	Industry Risks	Economic Diligence	Policy continuity	Lack of Bureaucracy	Legal Diligence	Business transparency	Country Risks	Risks
Weighting	7	7	7	21	3	3	3	3	2	14	35
US	6.3	6.3	6.3	18.9	2.5	2.4	2.8	2.7	1.8	12.1	31.0
Canada	4.9	4.9	4.9	14.7	2.2	2.7	2.5	2.5	1.8	11.8	26.5
Puerto Rico	5.6	4.9	5.6	16.1	1.8	1.8	1.2	1.5	1.6	7.8	23.9
Brazil	3.9	3.9	4.9	12.6	2.2	2.1	1.4	1.5	1.2	8.3	20.9
Chile	3.5	3.5	3.9	10.9	1.9	2.7	1.5	1.9	1.6	9.7	20.6
Mexico	3.5	3.5	4.2	11.2	1.9	2.4	1.9	1.6	0.7	8.4	19.6
Argentina	3.2	2.5	3.5	9.1	2.1	2.1	1.4	1.4	1.4	8.3	17.4
Colombia	2.8	3.5	3.5	9.8	2.2	2.1	1.6	1.5	0.8	8.3	18.1
Peru	2.8	2.8	3.5	9.1	1.8	2.1	1.3	1.4	1.1	7.7	16.8
Costa Rica	2.8	3.5	3.5	9.8	2.0	2.1	1.2	1.5	1.6	8.3	18.1
Panama	2.8	3.5	3.5	9.8	2.5	2.1	2.0	1.7	1.2	9.6	19.4
Cuba	0.7	1.1	2.1	3.9	1.3	2.4	1.5	1.5	0.8	7.6	11.5
Ecuador	2.8	3.5	3.5	9.8	1.5	0.9	1.0	0.9	0.7	5.0	14.8
Venezuela	0.7	0.7	0.7	2.1	1.5	1.2	1.1	0.7	0.3	4.8	6.9
Guatemala	1.4	2.1	2.1	5.6	1.8	1.5	1.4	1.1	0.9	6.7	12.3
Belize	1.4	2.1	2.1	5.6	1.7	2.4	1.9	1.6	2.0	9.6	15.2
El Salvador	1.4	2.1	2.1	5.6	1.8	2.1	1.5	1.4	1.1	7.8	13.4
Honduras	1.4	2.1	2.1	5.6	1.5	1.5	1.2	0.9	0.5	5.6	11.2
Nicaragua	1.4	2.1	2.1	5.6	1.5	1.2	1.3	1.0	0.8	5.7	11.3
Regional Average	2.8	3.1	3.4	9.2	1.9	2.0	1.6	1.5	1.1	8.1	17.3

**RRI scores out of 100, with 100 highest. Source: BMI.*

In the table below, the subsector scores (ie, Industry Rewards) and full component scores (ie, Rewards) have been expressed as a percentage of the total weight or as a percentage of the maximum score that can be achieved. This allows for the identification of the sub-sector or component that will most positively or negatively affect a single market.

Q316 Americas Pharmaceutical Risk/Reward Index

Rewards & Risks Scores As A Percentage Of The Maximum Score

	Industry Rewards	Country Rewards	Rewards	Industry Risks	Country Risks	Risks	RRI	Ranking
US	84	77	81	90	86	89	84	1
Canada	64	80	69	70	84	76	71	2
Puerto Rico	57	73	62	77	56	68	65	3
Brazil	64	65	64	60	59	60	63	4
Chile	60	71	64	52	69	59	62	5
Mexico	65	60	63	53	60	56	61	6
Argentina	56	73	62	43	60	50	58	7
Colombia	52	58	54	47	59	52	53	8
Peru	43	60	48	43	55	48	48	9
Costa Rica	36	64	45	47	59	52	48	10
Panama	34	59	42	47	68	55	46	11
Cuba	45	66	52	18	54	33	45	12
Ecuador	45	47	46	47	36	42	45	13
Venezuela	46	64	52	10	34	20	41	14
Guatemala	36	53	42	27	48	35	40	15
Belize	24	46	31	27	68	43	35	16
El Salvador	21	55	32	27	56	38	34	17
Honduras	13	51	25	27	40	32	28	18
Nicaragua	13	49	24	27	41	32	27	19
Average	45	62	50	44	58	49	50	

**RRI scores out of 100, with 100 highest. Source: BMI*

Argentina Risk/Reward Index

In Q316, we have revised upwards Argentina's Risk/Reward Index (RRI) score to 57.5 (out of 100) from 55.4 previously. This is above the regional average of 50.1. The score revision was driven by improved industry risks indices. Argentina remains in seventh place out of 19 countries in the Americas region in **BMI**'s proprietary RRI matrix. Argentina's overall score is driven by a large pharmaceutical market and significant urbanization leading to better access to healthcare, but dragged down by poor policy enforcement and lax intellectual property protection.

Rewards

Industry and country rewards are weighted and combined to form the score for overall rewards. Argentina's score of 40.1 stands above the regional average of 32.8 for Q316.

Industry Rewards

This category is a measure of the size of the market and its potential for growth. Argentina's relatively large pharmaceutical market, buoyed by the population size of more than 40mn, as well as several recent years of economic growth, continues to provide a number of incentives for international pharmaceutical firms. In the long term, rising incomes and increased health insurance coverage will drive increasing consumption of higher value, innovative medicines, with public spending remaining constrained in absolute terms and focused on lower-cost medicines. An important long-term driver of consumption is Argentina's ageing population. A study released in September 2008 as part of the Argentine Health Congress forecast that over 65s will represent 25% of the population in 2050.

Country Rewards

Argentina's score for this category is one of the strongest out of the Latin American countries, at 15.3 for the quarter, and is boosted by the highly urbanised population. Also, the pensionable population is expanding, which suggests that Western-style disease patterns will translate into a growing demand for medicines.

Risks

Industry and country risks are weighted and combined to form the score for overall risks. Argentina's score of 17.4 stands slightly above the regional average of 17.3.

Industry Risks

In Q316, we have revised upwards Argentina's score for this component of the rating system to 9.1 from 7.0 previously. Improvements in the business and operating environment have started to take place under reforms carried out by the new government in H116. However, the potential of the Argentine pharmaceutical market, underlined by a growing population and resurgent economy, is still undermined by a poor intellectual property (IP) and market access environment (*see 'Intellectual Property Issues' for more details*). Argentina is present on Pharmaceutical Research and Manufacturers of America (PhRMA)'s Special 301 submission in 2016 as a priority watch list country, as it has been for the previous 15 years.

Country Risks

Argentina's score for this component of the ratings system is 8.3, above to the average score for the region at 8.1. Argentina's regulatory environment and healthcare infrastructure remain superior to markets such as Venezuela. However, the lax IP regulation and enforcement will continue to weigh on the market's full potential. The private pension fund seizure in late 2008, the threat of rising taxes, fear over a devaluation, the lack of political consensus and private property rights have all undermined investor confidence over the past few years. However, an ongoing transition towards more market-friendly economic policies are starting weigh risks to the upside for this score component.

Regulatory Review

The main regulatory authority in Argentina is the National Administration of Drugs, Food & Medical Technology (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, ANMAT). Working under the direct supervision of the Ministry of Health (Minsa), ANMAT is not an independent agency, which makes it vulnerable to political influence. Apart from being responsible for the regulation of all medicines, ANMAT also supervises dietary supplements, although they are not classed as medicines, through its National Foods Institute (INAL) division. ANMAT is the first Latin American country to join the Pharmaceutical Inspection Convention and Cooperation Scheme (PIC/S) in international Good Manufacturing Practices (GMP) control. In several domains, there are signs that ANMAT is making steps towards becoming more assertive as a regulator, which could translate into improvements in the regulatory environment.

The basis for market regulation in pharmaceutical law is Decree 150, which was implemented in 1992, updating Decree 9.763 of 1964. There have been a number of revisions since 1992, including Decree 177 in 1993 and Law 25.649 in 2002. The latter measure, which was enforced by presidential decree in 2003, required doctors to prescribe medicines using products' chemical names. Physicians must justify reasons for prescribing by a brand name. Legislation stipulates that a decision regarding marketing authorisations must be announced within 120 days, unless technical issues need to be further examined.

Herbal products are mostly classified as medicines and are covered by Resolution No. 144/98 and Dispositions No. 2671, 2672, and 2673, adopted in 1999. Since 2004, all herbal medicines must comply with good manufacturing practices (GMPs), which follow the EU and WHO guidelines. Herbal medicines can be classified as either prescription or non-prescription, but cannot be approved as injectable products. Most herbal medicines found on the market in Argentina are either topical or oral formulations.

With few exceptions, medicines on sale in Argentina are classed into one of the three following categories: prescription-only medicines, medicines dispensed as recorded prescription sale and free sale medicines. Products such as morphine are classified within a fourth category, namely 'with prescription and decree'. However, illegal, under-the-counter (UTC), sales of prescription medicines without a script are rife in Argentina, with authorities often accused of not doing enough to stop the practice.

A new product must be registered at ANMAT, which has up to 120 days to respond. Registration of locally innovative drugs is restrictive and depends on clinical trials. Imported products are automatically registered

from countries listed in Annex I; ANMAT has up to 90 days to respond. The first manufactured or imported batch requires approval before commercialisation, under Decree No. 6,877/2000.

Drugs that are sold in the countries listed in Annex I do not require local clinical trials showing safety and efficacy parameters. Drugs that are sold in the countries listed in Annex II do not require local clinical trials, but clinical trials performed in their origin country are necessary. Locally developed products or products to be imported from non-listed countries in Annex I and II must perform all the clinical phases in Argentina, under Decree No. 5,330/1997.

In Q108, ANMAT and Brazil's regulator ANVISA agreed to harmonise their respective pharmacopoeias, or drug classification and listing systems. The agencies also pledged to pool resources by sharing analytical expertise. Under the agreement, if facilities for analysing a particular compound are lacking in one country, it can be passed to the other for study. Further efforts by Argentina and Brazil to maintain and strengthen this alliance will attract pharmaceutical companies to invest confidently in Latin America.

The above development was followed by the November 2008 announcement that Latin America is collaborating with Spain and Portugal to share vital information, which it is hoped will lead to better regulatory services in the region. A web portal was developed by the Spanish medicines agency and was met with widespread approval during a meeting in late October 2008. Latin American medicine authorities have recognised the necessity of such a collaboration with their European counterparts as a significant advance towards improving regulations, including drug approvals, intellectual property law enforcement and action against counterfeiting, which would serve to promote the region as an important site for clinical trials and research.

Table: Product Registration, Annex I & II Listed Countries

Annex I	Annex II
Austria	Australia
Belgium	Brazil
Canada	Chile
Denmark	China
France	Cuba
Germany	Finland
Switzerland	Hungary
Israel	Ireland
Italy	Luxembourg

Product Registration, Annex I & II Listed Countries - Continued	
Annex I	**Annex II**
Japan	Mexico
Netherlands	New Zealand
Spain	Norway
Sweden	-
UK	-
US	-

Note: Listed countries under Decrees No. 150/1992-177/1993. Source: Management Forum's Seminar on Pharmaceutical Regulatory Affairs in Latin America

By law, product approvals should take place within 90 days after application; this would be a fast-track approval. However, approval timelines are difficult to foresee. They depend on each product and its health impact, whether a product is a priority for the government, and how effective the regulatory affairs department is. Realistically, product approvals take at least 12 months. The registration is valid for five years and renewals must be submitted one month before the expiry date.

Clinical Trials

Under Resolution No. 4/2011, the Commission for the Development of Clinical Research (CODEINFAC) was established. It aims to encourage pharmaceutical research, maintain and develop clinical pharmacological research, and monitor any actions to generate a superavit. The commission is formed by representatives from the Ministry of Health, the Ministry of Science, Technology & Innovation, the Ministry of Industry, the Interior Trade Secretariat, the Federal Administration of Public Revenue and trade associations. This resolution was published in the Official Gazette in January 2011.

Advertising

Under Resolution No. 627/2007, the Ministry of Health regulates the promotion of prescription-only medicines (POM) targeting health professionals. This regulation aims to bring objectivity to the sector and encourage the rational use of drugs. This is a response to marketing and promotion irregularities, perks and corruption particularly found in the Argentine prescription sector. Under Decree No. 4,980/2005, which updated Decree No. 3,186/1999, ANMAT's Commission for the Evaluation of Advertising & Propaganda (Comisión Evaluadora de Publicidad y Propaganda [CEPP]) is already responsible for approving mass

media advertising campaigns of non-prescription medicines. On its own initiative, the Argentine Association of OTC Producers (Cámara Argentina de Productores de Especialidades Medicinales de Venta Libre [CAPEMVeL]) has its own ethics code.

Traceability

On May 16 2011, ANMAT announced the implementation of the pharmaceutical traceability system in order to control drug safety and help to eradicate drug counterfeiting in the country. Resolution No. 435/2011 regulates the new system. Initially, the traceability system will be applied to 88 active ingredients that comprise about 200 pharmaceutical presentations. These are medicaments of high cost and low incidence used for the treatment of complex diseases, including cancer and HIV/AIDS.

The new traceability system is a step ahead of the Drug Counterfeiting Programme (PPMI), launched by ANMAT in May 1997. Under the PPMI, inspections are undertaken in wholesalers, distributors, private clinics, pharmacies, drugstores and kiosks, in co-operation with provincial health authorities. ANMAT also works in co-operation with the Prosecuting Commission, created by Resolution No. 54/1997, which deals with any irregularities. Between August 1997 and May 2008, ANMAT undertook 31,756 inspections, which resulted in 547 complaints to the Prosecuting Commission.

Pharmacy Regulation

Published in the Official Gazette in December 2009, Law No. 26,567/2009 modified Articles 1 and 2 of Law No. 17,565 and eliminated Articles 14 and 15 of Decree 2,284/1991. Under the law, medicaments, with or without prescription, can only be sold by pharmacists or persons authorised to dispense in pharmacies. Effectively, OTC medicines are no longer available over the counter. Buenos Aires was the last district to adopt this ban - although it remains controversial and new legislative proposals to roll it back are under consideration.

The law aims to stop the incidence of self-medication. The CAPEMVeL supports the sale of pharmaceuticals in pharmacies, but believes that some products, such as analgesics and antacids, should be liberalised. The Union of Kiosks in the Republic of Argentina (UKRA) has criticised the law, because it responds to pharmacists' rather than patients' needs.

Biological Market Regulation

ANMAT is the body responsible for the regulation of biologicals in Argentina. Under the Argentine Pharmacopoeia, 7th Edition, Chapter 1,120, biological products are defined as biopharmaceuticals derived from a living organism. Under Order ANMAT 705/2005, vaccines are defined as preparations containing antigen substances which improve active and specific immunity to a particular disease. Under Order ANMAT 2,819/2004 (Annex X), haemoderivatives are defined as biological products derived from blood or human plasma.

In September 2015, the Argentinean government announced the inauguration of its Centre for Biological Products, Biotechnology, and Radiopharmaceuticals, under the National Institute of Medicine (INAME), which received funding of ARS67mn (USD7mn) and will work to guarantee access to quality drugs and vaccines, while working as a monitoring system to ensure safety and efficacy of the biological drugs that enter the country.

Generic Regulation

Law No. 25,649/2002 orders doctors to use the generic name for medicines on all prescriptions. Doctors may also include a brand name, but pharmacists can substitute the drug unless the doctor gives reasons for not doing so on the prescription. PhRMA believes this law discriminates against innovative products in favour of patent-infringing copy products, arguing that true generics do not exist in Argentina and claiming the law is an 'unjustifiable restriction of the use of trademarks'.

According to the National Commission for Healthcare Research Programmes (CONAPRIS), which depends on support from the Ministry of Health, generic prescribing was valued at 79% of the total in the federal capital and greater Buenos Aires region in 2005. It reached 71% in the rest of the country. The Ministry of Health claims that Argentina is the country with the highest percentage of medicines prescribed by using their generic name in the world.

The international industry argues that most of the 'generics' available in Argentina are copycat products rather than true generics because they do not have to demonstrate bioequivalence with the originator products. Some argue that there are no generic products in Argentina, just generics by name only. Bioequivalent generic sales represented about 5% of the pharmacy sector by value in 2010, which indicates a low penetration. Generic hospital sales are higher than pharmacy sales, but no figures are publicly

available. Also, it has been noted that pharmacies have limited incentives for substituting brand drugs that often have higher margins with alternative lower-cost generics.

OTC Regulation

All medicines in Argentina are regulated by ANMAT, but it was not until the publication of Decree 2266 in 1991 that official recognition was granted to OTC products. OTCs are not eligible for reimbursement. This is in contrast to prescription medicines, which can be reimbursed for up to 70% of their value under social welfare schemes, such as the *obras sociales* and PAMI.

Non-prescription (free sale) medicines can be advertised to the public, but free samples can only be distributed by medical professionals. According to the Centre of Media Communications, in 2005, some 80% of the USD88mn advertising budget was spent on television advertising, with the remainder divided between printed media (15%) and radio (5%).

In the past, OTC advertising has been accused of making unscrupulous claims. This led to a tightening of advertising regulations in 2005, with the publication of Decree 4980 and Resolution 20/2005. For OTCs, one of the main restrictions is that all advertising must carry a written warning: 'Always read the label, and consult your doctor and/or pharmacist if you have any doubts.' Meanwhile, advertising for herbal remedies must be accompanied by the words: 'Herbal medicine traditionally used for…'

Notably, the regulations introduced in 2005 allow OTC adverts to be aired prior to being approved by ANMAT. In the past, the OTC industry was restricted by a pre-control system. The new legislation, which had been put forward by the Argentina's Self-Medication Association (CAPEMVeL) approved by the Ministry of Health, was soon complemented by Disposition No. 4980 - stipulating ethical and therapeutic - requirements for OTCs - requirements to create a better regulatory environment. Specifically, the changes eliminated unfair advertising by companies that had previously been able to wrongly market foodstuffs as having therapeutic properties.

In November 2014, a segment of Argentine lawmakers proposed to discuss the ban of OTC medicine advertising. If enacted, the law will create operating challenges for companies selling their products in Argentina, impacting companies' revenue streams from a well-developed market segment. However, a strong lobbying presence from drugmakers could eradicate the legislation.

In 2007, CAPEMVeL drafted a proposal for switching of prescription-only medicines to OTC status. Following a review by the regulatory agency, some 75 active ingredients (out of the total of 78 that were

proposed) were approved for switching, of which 46 were approved directly and 32 with restrictions. Since 2000, the following medicines have been switched to OTC status, among others: Phoenix's loratadine 10 mg (*Loremex Antialérgico*), Novartis' nicotine chewing gum (*Nicotinell Chicles*) and Bagó's famotidine (*Actual*).

Surveys revealed that 54% of the consumers questioned buy OTCs on the recommendation of a medical professional and have been using the medicines for three or more years. Only 5% stated that they were having difficulties using an OTC medicine, while 87% of those surveyed declared that they do not use a product if they are not sure that it will cure the ailment. The vast majority (90%) were confident in using OTCs for minor problems, with 82% reporting that they understand labelling and usage instructions easily.

Local regulations have been more conducive to the development of an OTC market than those in most other Mercosur countries - notably Brazil. These include free pricing for OTCs and, until recently, the fact that mass-market sales were permitted.

Despite some concerns over its actual implementation and ongoing controversies in some regions, recent legislation (Law 26.567) nevertheless lays down restrictions on both self-service and the sale of OTCs in non-pharmacy outlets, effective since the start of 2010. The law also limits the growth of pharmacy chain stores, establishing a minimum distance of three city blocks between any new pharmacies. At the same time, a pharmacist would be obliged to be present during opening hours and each pharmacy would have to be owned by an individual pharmacist, rather than by a company.

In June 2011, ANMAT clamped down on medicine vendors by restricting the sale of some OTC drugs. Cold remedies, aspirin, decongestants and even digestive supplements can only be sold in pharmacies. In addition to requiring pharmacies be run by trained professionals, the law required the potentially dangerous decongestant ephedrine and the anti-migraine drug ergotamine be dispensed only with a prescription.

Counterfeit Pharmaceuticals

Under Law 26,524/2009, the Argentine penal code was modified in November 2009, incorporating drug counterfeiting, not just adulteration and poisoning, and including prison sentences and fines for drug robbery, counterfeiting and adulteration, which substantially strengthened legislation. ANMAT first started its Drug Counterfeiting Programme in 1997. In co-operation with provincial health authorities, inspections are undertaken in any establishment, including wholesalers, distributors, private clinics, pharmacies, drug stores and kiosks. ANMAT also works in co-operation with the Prosecuting Commission (Comision de Fiscales) created by Resolution N. 54/1997, which deals with any irregularities. More recently,

sophisticated tracking systems and electronic tags for medicines through the supply chain is also contributing to deal with counterfeiting problems.

Oncology and antihaemophilic antiretrovirals are among the drugs that can face counterfeiting and adulteration, according to ANMAT representatives as of September 2011. Figures from the agency show that criminals are involved in unlawful trafficking of cancer drugs, antiretrovirals and AHF in the country. Another frequently smuggled product is the erectile dysfunction remedy *Viagra* (sildenafil). In October 2011, Argentine customs officials seized 29,000 doses of the product from a tourist bus coming from Ciudad del Este in Paraguay. The public's attention on drug counterfeiting was raised with a high-profile case involving the death of two patients and the hospitalisation of eight others, injected with a counterfeit version of AstraZeneca's *Yectafer* (iron sorbitol) in 2004.

According to the Pharmaceutical Security Institute (PSI), Latin America showed the highest increase in the number of reported counterfeiting incidents and ranked the second highest number of counterfeit, diverted and stolen medicine incidents (348) in 2009, behind Asia (1,073) and ahead of Europe (327). Alimentary drugs such as cholesterol-lowering medicines and diet pills accounted for a significant proportion of the incidents.

Health Technology Assessment

As in other Latin American countries, the role of Health Technology Assessment (HTA) to inform market access and reimbursement decisions is rising. In Argentina, the Institute of Clinical and Sanitary Effectiveness (IECS) is an independent, non-profit organization serving as HTA agency since 2001, informing technology incorporation decisions across several points of the system (reimbursement schemes, hospitals, public authorities). However, HTA is not yet formally required by central authorities for products to access the public system (as in Brazil or Mexico), although this could be introduced in Argentina in the next few years.

In January 2016, the Argentine government announced that it will create the National Agency for Technology Assessment to define the appropriate medicines, medical devices and medical procedures covered by the social healthcare system, which is in line with our long-standing view that the country will move towards the implementation of cost-effectiveness analysis of health technologies.

Intellectual Property Issues

The National Intellectual Property Institute (Instituto Nacional de la Propiedad Intellectual [INPI]) regulates IPR. INPI's National Patent Authority regulates patent applications. INPI is a self-governing body within the Ministry of Industry.

Under Joint Resolution No. 118/2012, No. 546/2012 and No. 107/2012, the Ministry of Industry, the Ministry of Health and INPI adopted guidelines to examine pharmaceutical patent applications in May 2012, 'Guidelines for Patentability of Patent Applications relating to Chemical and Pharmaceutical Inventions'. These guidelines are based on the working paper 'Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective', published by the WHO, ICTSD and UNCTAD. These guidelines were published in the Official Gazette on May 8 2012, and have taken effect since then.

The concept of patent protection is a relatively new one in Argentina, with the filing of pharmaceutical patents only permitted since 1995. Despite a Patent Law introduced in October 2000, the copying of brand-name pharmaceuticals remains a significant and lucrative part of the national pharmaceutical industry.

In February 2016, the Pharmaceutical Research and Manufacturers of America (PhRMA) group released its Special 301 Submission for 2016. Argentina featured on the Priority Watch list again due to its continuing lack of protection for undisclosed test data, increasing restrictions on patentability criteria, and foreign exchange restrictions. PhRMA members are also concerned about Argentina's discriminatory reimbursement policies.

New Challenges Highlighted In The 2016Special 301 Submission

On October 1 2015, the Ministry of Health and the Secretary of Commerce issued a joint resolution establishing a 'preferential' reimbursement system for national generic medicines and biosimilar products, to the potential detriment of manufacturers producing medicines outside Argentina.

On October 5 2015, INPI issued a new resolution (No. 283/2015), which further burdens biopharmaceutical innovation. This resolution regulates patent filings on living matter and natural substances, including biologics. It burdens the patentability process on biologics, among others, by adding more requirements and formalities. This resolution contradicts Patent Law 24,481 regarding living matter because Law 24,481 excludes patentability of all preexisting living matter, while this resolution bans patentability of all living matter.

In 2015, innovative pharmaceutical companies estimate a combined foreign currency shortfall of approximately USD1.5bn in Argentina, because drugmakers have inadequate access to US dollars to pay their suppliers and repatriate funds.

Repeated Concerns From Previous Year

Patentability Restrictions: PhRMA members believe that a significant number of pharmaceutical patent applications are being unfairly rejected due to the 'Joint Regulation', which was published on May 8 2012.

Regulatory Data Protection: The lack of protection for undisclosed test data in Argentina and the country's reliance on data submitted by originators to approve marketing requests by competitors for similar products - following the approval of the product associated with the original submitted data - are viewed negatively by PhRMA.

Moreover, the productivity of the INPI has dropped in recent years, causing the average wait time for patent approvals to take eight to nine years, significantly impairing Argentina's efficacy for patent approvals, sustaining a backlog of around 21,000 applications.

Despite efforts in 2002 to speed up the processing of patent applications, subsequent changes to laws governing the handling of patent infringement disputes have made it more difficult to halt copy-product launches. The burden of evidence falls on companies attempting to obtain injunctions, as firms must first prove ownership of their patents.

The law also requires consideration of which side in the case would suffer the greater economic damage, upon the outcome of the case. In addition, the testimony of expert witnesses is now a key element in such cases. An essential characteristic is that the courts no longer regard a patent decision as final. R&D-based companies complain this has had the effect of significantly slowing the process of obtaining injunctions, allowing rival manufacturers to continue marketing copies in the meantime.

Furthermore, US companies said a Supreme Court ruling has effectively blocked applications to convert their process patents into full product patents, under intellectual property measures passed in December 2003. The patent office also explicitly forbids so-called 'second use' patents, making further therapeutic indications difficult to obtain.

Some foreign drugmakers argue that legislation relevant to data exclusivity, Law 24.766, violates the National Constitution, as well as the WTO's TRIPS agreement. The role of ANMAT is also crucial in

Argentina, as the agency has little direct linkage with the national patent office. In regulatory submissions, ANMAT requests only details of a drug's ingredients, manufacturing process and clinical trial data - with no requirement to provide information on the product's patent status. Further, ANMAT has regarded partially disclosed clinical data as being in the public domain and thus offers little protection against copiers in possession of confidential information.

In addition, Argentina has no clear rules obliging manufacturers to prove bioequivalence before introducing a new generic product. ANMAT is empowered to establish the reference drug for bioequivalence studies, but the reluctance of innovator companies to surrender confidential data, and the expense of human trials for local firms have led to approvals of many products that are simply claimed to be similar or therapeutically equivalent to the original product.

Local manufacturers claim that obtaining bioequivalence certification - although not a necessity for the local market - has hindered the development of exports. Laboratorios Roemmers has estimated that bioequivalence investment accounts for a quarter of the value of its annual exports, which total some USD10-15mn. Laboratorios Lazar has said that tests and quality upgrades for a new product for the Turkish market have cost some USD250,000. Accordingly, domestic firms have called for greater efficiency at the medicines evaluation office, INAME. The issue also underlines that local generic drugs face significant regulatory obstacles abroad.

Previously, Argentina's government justified the lack of significant progress in IP issues by citing the country's economic woes and the consequent financial troubles of the national healthcare system. However, with the economy growing at relatively fast rates in Latin America, the main policy drivers now seem to be continued cost containment, protection of local manufacturers, and the restraint of overall consumer price inflation.

IP Disputes

In 2009, Sanofi filed a request for temporary injunction against Sandoz for infringement of the patent on the manufacturing process of the API irbesatan. Following a court order to disclose the process Sandoz used to obtain the API, the Appeals Court issued a temporary injunction against the generic drugmaker and rejected its subsequent appeals. This represented a landmark court decision in favour of the enforcement of a pharmaceutical patent, raising confidence in the country's patent laws.

In a case that was seen as setting an important precedent, US company Bristol-Myers Squibb successfully defended the patent for its HIV/AIDS drug *Videx* (didanosine) against Laboratorios Richmond in

Argentina's highest commercial court in April 2007. For Bristol-Myers Squibb, key to its victory was that its patent had been granted by Argentina's INPI. The ruling prevented Richmond from participating in government health tenders for AIDS medicines. Local industry associations CILFA and COOPERARLA strongly criticised the court's ruling.

However, a second infringement case was brought before Argentina's courts a short time later, by a new plaintiff against the same defendant. Novartis prosecuted Laboratorios Richmond for an alleged infringement of the patent on its product *Glivec* (imatinib). After a court-appointed expert released a report, complying with the requirements of the new procedural regulation introduced in 2004, a temporary injunction was issued against Laboratorios Richmond. Nonetheless, Laboratorios Richmond appealed the court decision and in July 2009, the Appeals Court revoked the temporary injunction.

Pfizer reported problems in 2004 over the misuse of its trademark by the local manufacturer of a copy of the anti-impotence blockbuster *Viagra* (sildenafil citrate). Schering-Plough complained that local company Monteverde had copied its *Temodar* (temozolomide) brain cancer drug, co-marketed with Novartis.

In mid-2005, five local copy manufacturers - Roemmers, Lazar, Gador, Elea, and Phoenix - and US-based IVAX were ordered to cease production of ezetimibe, the active principle in *Zetia* (a cardiovascular therapy marketed by Merck & Co and Schering-Plough). However, ANMAT failed to implement the ruling, which also applied to a number of patented cancer drugs with copies pending approval. The same presiding judge later overturned the decision, purportedly on the basis of the TRIPS provisions harmonised into domestic law as part of WTO membership.

Worryingly, Argentine politicians continue to applaud Brazil's move in May 2007 to invoke compulsory licensing on Merck & Co's efavirenz HIV/AIDS treatment and also pledged to cooperate with Brazil on developing a broader range of locally produced generic drugs for the treatment programmes in the two countries. So far, there have been no reports that Brazil has exported its generic efavirenz, made by state-run producer Farmaguinhos to Argentina or elsewhere.

In February 2011, in Novartis Pharma AG v Monte Verde SA, the federal civil and commercial court of appeals ruled that while the TRIPS agreement establishes confidentiality protections on applications seeking market approval, Argentine law has no requirements when similar products have already been approved in other countries. The court noted Novartis had, in the past, obtained marketing approval for several products based on the same Argentine rules that establish the abridged registration procedure.

Other Regulatory Issues

The need for healthcare cost controls aside, many of the market's major regulatory issues, in particular the tolerance of a sizeable copy sector, can be attributed to the government's desire to protect its own manufacturing industry and develop its import-substitution capability. In July 2011, the senate passed a bill to increase production at state-run pharmaceutical companies and in December 2014, the senate sanctioned a law aimed at creating a new entity to promote the public production of medicines.

Foreign companies continue to complain about excessive tariffs and red tape on imported drugs, which are subject to additional quality checks - even if approved by US or European authorities. ANMAT also reportedly lacks the resources and budget to pursue its own investigations, forcing it to rely on foreign regulators. The impact of a tariff subsidy scheme offered to local manufacturers was significantly reduced under reforms to the customs code in late 2005.

There are some signs of regulatory improvements. ANMAT, which refused to fully recognise US or EU certification in the past, has fast-tracked applications from these markets. ANMAT has also shown a tendency to 'shadow' the US FDA, such as the November 2007 decision to suspend the sale and manufacture of drugs containing aprotinin (prescribed to reduce bleeding during surgery), close on the heels of a similar move by the US regulator. In March 2012, ANMAT set the scientific and technical needs, as well as limits, for the operation of blood banks. They will have to apply to ANMAT for authorisation to function as suppliers of human plasma, which is used as a primary material for producing blood products. The banks also need to submit documents illustrated in the document's annex. After receiving the authorisation request, ANMAT will assess the submitted documents and inspect the bank to confirm compliance with the good manufacturing practices relevant to the human plasma and blood products industry.

In February 2012, ANMAT proposed a national pharmaceutical traceability scheme. This would allow full tracking of the medicine supply chain, from production to dispensation, to tackle the issues of counterfeit, stolen, unlicensed and other illegal medicines.

After the publication of Resolution 435/2011 in April 2011, the first stage of the proposal, which started on December 15 2011, covered the federal medicine distribution chain, including manufacturers, distributors and logistics providers. The second stage will be executed from mid-2012 to bring in regulations for pharmacies and public hospitals, as well as private distribution channels. It will allow consumers to verify the legitimacy of medicines through the ANMAT website. Based on the proposal, Argentine pharmaceutical

manufacturers can apply 2D data-matrix codes or RFID tags to their products with standard GS1 barcodes. The verification coding should also appear in human-readable form for consumer verification.

ANMAT has hosted training programmes and workshops to support the implementation of these new guidelines and has encouraged collaboration between the different sectors involved in the traceability system. It plans to first apply the system on critical, high-cost drugs, such as cancer and HIV/AIDS remedies, and will eventually apply it to all the pharmaceutical products in Argentina. There is a trend for improved pharmaceutical regulation in the country, which has also published stricter guidelines for OTC drug leaflets, which puts more pressure on the illegal medicines market.

Argentina imposes additional tariffs on all pharmaceutical imports originating outside the Mercosur trade bloc, including samples. There have been reports in the past that the government is considering imposing a 'local manufacturing requirement' on all products marketed, but not produced, in Argentina. Such a development would hit foreign companies hardest and would penalise firms that divested local production facilities in the wake of the 2002 economic crisis. Among others, Novartis handed over its facility to local firm Phoenix in 2002 and Dutch Organon divested its plant to local firm Richmond in 2004.

Argentina also inadequately enforces rules on packaging inserts, which has reportedly enabled copy manufacturers to use foreign companies' patent information and falsely claim bioequivalence. A new measure introduced in 2005, known as Resolution 20/2005, initiated 'objective and rigorous' labelling criteria. Drug marketers are now unable to use any material that 'provokes anxiety' or makes mention of indications not expressly approved by the regulator. The guidelines also apply to wording such as 'clinically proven' or 'natural', with new consumer labelling now necessary for dietary supplements.

Pricing Regime

The government's intervention in pharmaceutical pricing, particularly repeated price freezes, has been heavy-handed in recent years. Medicine prices in Argentina were liberalised in 1992, but Argentina's drug classification system effectively amounted to a form of reference pricing. Under Resolution 310 of 2004, drugs for certain major diseases were eligible for a 70% public subsidy in retail pharmacies, with non-patented medicines attracting the highest level of coverage. Less positively for generic drugs firms, public healthcare schemes demand heavy discounts. Direct price controls remain in effect, in part at least, to combat overall inflation.

In 2010, industry trade associations maintained pharmaceutical prices in alignment with inflation guidelines issued by the government. According to CILFA, the drug price index has risen at a lower rate than the consumer price index (CPI) in recent years.

In November 2015 Argentina's commerce ministry approved another 3% increase in drugs prices. It is the fifth price increase so far in 2015 after the industry was allowed to raise prices by 3% in February, 2% in May, and 3% in both July and August. The cumulative price increases are less than the more than 33% wage increase agreed upon with the Guild of Health in 2015. Local drugmakers have also complained that the drug price increase was slower than the real rate of inflation. Pharmacies that receive a percentage of the retail price will be relieved from the price increase. However, the move will not solve the financial problem faced by pharmacies, which is leading many to operate with a minimum stock of drugs (lanacion.com.ar).

Since the country's January 23 2014 currency devaluation, the average prices of approximately 20,000 medicines sold through Argentina's pharmacies have increased dramatically. Some product prices even rose by nearly 50% due to the devaluation of the peso. In early February 2014, the government tried to negotiate with the pharmaceutical companies to have rolled-back drug prices to January 21 2013. However, none of the drugmakers have complied. So the government had to suspend the price cuts on the selected medicines until another round of negotiations begins. On February 24, the government authorised an average increase of 4% in medicine prices after the Secretariat of Commerce entered an agreement with the industry chambers representing laboratories. In September 2014, after two months of controversy the Argentine government allowed an average increase of 3% to 5% in medicine prices, which is below the industry claim although represents official recognition of cost increases.

OTCs are priced freely and cannot be reimbursed. Maximum pharmaceutical prices are the same in all retail outlets and must be published on a monthly basis in the Manual Farmacéutico and Kairos magazines. Chain pharmacies have the advantage of buying in bulk and thus can offer more competitive prices and special offers. The wholesale price mark-up is estimated to stand at an average 16% and the pharmacy retailer mark-up represents a further 25% on the market value.

Table: Pharmaceutical Price Build-Up

	% from MPS as base	As % of final consumer price
Manufacturer's selling or ex-factory price (MPS)	100.0	57.0
Wholesale price (mark-up = 16%)	116.0	66.1
Pharmacy price excluding sales tax (mark-up = 25%)	145.0	82.6
Pharmacy price including value-added tax (VAT)/consumer price (VAT = 21%)	175.5	100.0

Source: AESGP's Economic and Legal Framework for Non-Prescription Medicines, June 2011

According to CILFA, the pharmaceutical industry paid ARS2,822.8mn (USD911.9mn) in taxes to the government in 2007, which represented an increase of 28.1% in local terms over 2006. Value-added tax (VAT) represented 51.1% of the total in 2007, equal to ARS1,443.0mn (USD466.1mn). Local producers provide more money in taxes to the government. They accounted for 55.4% of all taxes in 2007, whilst foreign producers represented the remaining 44.6%.

Drug companies and pharmacies continue to balk at the continuation of discounted drug pricing schemes introduced during the crisis years, which envision sharing the burden of price cuts between manufacturers, retailers, and health insurance schemes. Arguably, the government's strong-armed tactics to restrain inflation have stored up higher price increases for the future. With spikes in food and energy prices already pushing up prices, healthcare costs represent another worry for Argentine consumers.

Reimbursement Regime

OTCs are not reimbursed, with prescription products receiving up to a 70% subsidy. Argentina's reimbursement system is in fact somewhat more comprehensive than most other Latin American countries and this has acted to limit the growth of the pharmaceutical sector's value.

The country's main socialised reimbursement system, known as the *obras sociales*, is comprised mainly of trade union-administered schemes covering around 50% of the population. A further major programme known as PAMI offers drug benefits for pensioners and the disabled, and was expanded significantly during 2007. Privately run discount schemes for uninsured patients include *Vale Salud* and *Receta Solidaria*.

These programmes were introduced in the aftermath of the financial crisis to provide discounts at the point of sale in large pharmacies and were primarily underwritten by pharmacies and manufacturers. However, due to cost and the improving economic situation, the discounts offered on medicines were reduced from 40% to 20%, beginning in July 2007.

Market Overview

Argentina's pharmaceutical market, calculated to have reached ARS64.02bn (USD6.91bn) in 2015, is the third largest in Latin America, behind Brazil (the largest market in the region) and Mexico. In 2015, Argentina's per-capita drug expenditure at USD159 was significantly higher than per-capita drug spending in Brazil and Mexico, standing only behind Chile, Panama and Costa Rica in the region. Pharmaceutical expenditure currently accounts for around 1.13% of Argentina's nominal GDP and for 16.3% of healthcare spending. Prescription drugs dominate the overall market: 86.5% in value terms in 2015. Generic drugs account for a marginally decreasing proportion of the market, standing at 30.6% of total sales in 2015. Patented drugs dominate the market at 55.9% of total sales. **BMI** calculates that OTC drugs accounted for 13.5% of the market in 2015.

Argentina's healthcare spending reached ARS393.10bn (USD42.43bn) in 2015, or 6.9% of GDP, and per-capita health expenditure of USD977. The government accounted for 67.8% of total health spending in 2015, with this figure expected to moderate over the next years.

In 2015, communicable diseases were responsible for only 915,288 disability-adjusted life years (DALYs) lost in Argentina according to **BMI**'s Disease Database. Rising non-communicable diseases were responsible for as much as 8.79mn DALYs lost in the same year (accounting for 80% of the total disease burden). The leading causes of DALYs lost to disease in Argentina include cardiovascular diseases (17% of total disease burden), cancer (14%), mental and behavioural disorders (13%), musculoskeletal disorder (11%) and diabetes, urogenital, blood and endocrine diseases (7%). On the other hand, HIV/AIDS account for 10% of the burden posed by communicable disease. HIV/AIDS is the only communicable disease that is projected to increase over the forecast period. Although gradually decreasing in terms of disease burden, other communicable diseases have not been fully eradicated, suggesting eventual demand for infectious disease treatments, such as chagas disease and tuberculosis (TB).

The Argentinean pharmaceutical market presents a number of challenges, which continue to limit its attractiveness to foreign firms, including a lax regulatory environment. Leading multinationals in terms of market share include Bayer, Roche and Novartis (given its long history in Argentina); as well as Abbott and GlaxoSmithKline, which in mid-2010 acquired Argentina's Laboratorios Phoenix; and France-based Sanofi. US-based IVAX, owned by Israel's Teva, is also an important local player and operates manufacturing facilities in the country. Mexico's Grupo Techsphere also owns production facilities in the country and has looked into acquiring local producers. The data illustrate the increasing strength of indigenous manufacturers in Argentina, with leading players Roemmers and Bagó jointly accounting for over 10% of

sales. Other prominent homegrown firms include Elea - which has a strong presence in the OTC sector - Raffo and Gador. Also, Sidus has drawn international attention for its work developing human insulin from transgenic cattle through its BioSidus biotechnology subsidiary (*see 'Competitive Landscape' for more details*).

Healthcare Sector

Argentina's healthcare system mixes public and private provision and there are significant disparities in the quality of healthcare both at federal and provincial levels, as well as between the different income groups. Studies indicate that less than 10% of the population have private health plans, while public sector health insurance nominally covers 93% of citizens.

According to the representative of the Pan-American Health Organization (PAHO) and the WHO in Chile, Ruben Torres, although all Argentines have coverage and access to healthcare, poorer patients unable to pay for private services have little access to high-quality care. For instance, public hospital patients usually have to wait approximately six months to see a specialist.

Private healthcare accounts for almost 50% of the country's total expenditure on medical services. Out-of-pocket contributions are very high, with private services and practitioners usually expecting an immediate cash payment from those not covered by private insurance (as many as 95% of the population). A consultation with a specialist costs around USD50, which will continue to encourage substantial usage of private facilities by public sector patients.

One of the issues contributing to the current high levels of health expenditure in Argentina has been termed 'defensive medicine'. Almost a fifth of the healthcare budget is spent on treatments that doctors perform without considering them necessary, to avoid being sued for alleged malpractice.

Healthcare Insurance

As in other Latin American countries, Argentina has a fragmented or mixed health system, composed of four coverage subsectors:

Public Hospitals: granting universal access to the whole population, although in practice mostly the uninsured groups depend only on this base.

Social Health Insurance System: formed by institutions known as *obras socials* (OS), which are designed for population segments with fixed salary and organised by fields of labour activity.

Private Medical Insurance (known as *prepagas*): gathering those who can afford pre-determined services.

PAMI: designed for the elderly, similar to Medicare in the US.

In the public hospitals' subsector, the financing and delivery of healthcare is the responsibility of the provinces and municipalities, configuring a decentralised system. Provinces have their own Ministry of Health managing provision and municipalities also have health authorities. The National Ministry of Health holds technical and coordinating functions. The quality of public services can vary depending on the province. About 34% of the population has no insurance and relies solely on public hospitals.

Concerning the second subsector, 50% of the population receives healthcare and pharmaceutical coverage from OS. There are around 300 OS in the country, varying in scope and size, yet 70% of the insured population is concentrated in 30 OS. Most OS operate as national insurance schemes funded by compulsory payroll contributions (regulated under the Superintendence of Health Services). Secondarily, there are some provincial OS for government workers of the provinces and other public workers. Often, due to familiar relations enabling access to different OS, overlapping of coverage systems is possible, creating wider freedom of healthcare choice and reimbursement options.

In terms of the third subsector, mainly the higher-income groups contract private insurance firms, known as *prepagas*, covering 10% of the population. There are around 300 *prepagas* in the country, observing a higher concentration in the Buenos Aires area, with five companies sharing 60% of the market.

Finally, about 3.5 million older people and some individuals with disabilities are covered by PAMI nationwide insurance plan, which is financed through active and passive workers contributions.

The funding structure is divided among the public system (national, provincial, municipal), which accounts for 21.48% of the health budget, the so-called Social Security System (including national and provincial OS and PAMI) at 30.27%, and private spending (including insurance premiums and substantial co-payment across all coverage subsectors) at 48.25%.

Since the economic crisis of 2001-2003, the government introduced a scheme known as *Remediar* (Remedy), using 6,600 primary care health centres to distribute free medicines to 2mn people from vulnerable subgroups or those who lacked any kind of health insurance. The scheme has since been

repackaged as *Remediar + Redes* ('Remedy + Network') (with three core objectives: strengthening health networks, providing essential care and medicine and training healthcare professionals), and expanded to cover around 4mn people. Since March 2008, the program has been financed with funds from the national budget; until then, financing was credited by the Inter-American Development Bank (IDB). Around 75% of all medicines used in the scheme are reported to be generic drugs or copies.

However, the scheme has expanded more slowly than promised, with widespread reports of inefficiency and waste. Detractors say that *Remediar* offers only a very limited range of medicines, comprising just 58 active pharmaceutical ingredients (APIs). The WHO list of essential medicines, for example, recommends 350 key active principles as the necessary minimum. As of October 2015, the program supplies 74 medicaments.

Significantly, a number of local drug firms opted to reduce discounts to state programmes in late 2005, claiming that the move was necessary in order to maintain profitability after a round of mandatory price cuts. As noted above, drug companies have moved to reduce discounts first offered to the *obras sociales* in the wake of the crisis. In mid-2007, these were reduced from 40% to 25%.

Cimara is a trade association representing health insurers. Private insurers have often clashed with the authorities over the price of their prepaid plans (*prepagas*). Officials have moved to increase regulation of the health insurance sector, in a bid to assure affordable prices, although this is often below the financial feasibility levels of healthcare plan managers, especially when healthcare provision prices increase.

Medical Tourism

In September 2010, the government launched the Argentine Initiative for Medical Tourism, a plan to develop the country's medical tourism industry. Hospitals and clinics benefiting from the initiative include Hospital Austral, Italiano y Alemán, Institute Fleni and Cardiovascular de Buenos Aires, the Foundation Favaloro, and clinics and services specialised in various other fields of health.

Latin America's political stability, cost-effective private healthcare system and its established tourism sector are fundamental factors contributing to the expansion of its medical tourism industry.

In 2014, more than 14,000 foreigners spent an estimated USD182mn on medical tourism in Argentina, according to data from the National Institute of Tourism Promotion (reports International Medical Travel Journal). The Argentine government has launched a new five-year plan aimed at increasing medical tourism revenue to USD500mn annually and become the leading medical tourism destination in Latin America. According to such data, a great proportion of the medical tourists were from Latin American countries (41%

from Chile, 29% from Uruguay, and 30% divided among Ecuador, Bolivia, Peru, Colombia and other Central American countries). Around 67% of patients visit Argentina in search of medical surgery and treatment, while 33% of tourists seek cosmetic surgery and treatment.

Table: Healthcare Resources (Argentina 2010-2015)

	2010	2011	2012	2013	2014	2015
Hospitals, total	3,304	3,304	3,303	3,303	3,303	3,302
Hospitals, public	1,306	1,310	1,313	1,317	1,321	1,324
Hospitals, private	1,998	1,994	1,990	1,986	1,982	1,977
Hospitals, beds	185,502	187,450	189,428	191,422	193,410	238,792
Hospitals, beds, per '000 population	4.50	4.50	4.50	4.50	4.50	5.50

Source: BMI Espicom

Table: Healthcare Personnel (Argentina 2010-2015)

	2010	2011	2012	2013	2014	2015
Physicians, total	155,790	159,686	160,041	164,152	168,369	172,694
Physician, per '000 population	3.78	3.83	3.80	3.86	3.92	3.98
Nurses, total	18,988	19,868	20,790	21,754	22,759	23,806
Nurses, per '000 population	0.46	0.48	0.49	0.51	0.53	0.55
Dentists, total	38,267	38,669	39,077	39,488	39,898	39,075
Dentists, per '000 population	0.93	0.93	0.93	0.93	0.93	0.90
Pharmacists, total	20,976	21,196	21,420	21,645	21,870	21,708
Pharmacists, per '000 population	0.51	0.51	0.51	0.51	0.51	0.50

Source: BMI Espicom

Table: Healthcare Activity (Argentina 2010-2015)

	2010	2011	2012	2013	2014	2015
Public inpatient admissions, '000	1,768.42	1,691.33	1,617.60	1,547.08	1,479.64	1,415.14
Public inpatient admissions, per '000 population	42.90	40.60	38.43	36.37	34.43	32.59
Hospitals, average length of stay, days	6.4	6.2	6.1	5.9	5.8	5.6
Surgical procedures, '000	742.74	710.36	679.39	649.78	621.45	594.36
Outpatient visits, '000	124,093.10	128,200.14	132,450.42	136,837.86	141,350.83	145,980.43
Outpatient visits, per '000 population	3,010.30	3,077.62	3,146.45	3,216.82	3,288.76	3,362.31

Source: BMI Espicom

Research & Development

Private R&D

Pharmaceutical R&D activities in the private sector are limited as local companies are more focused on experimental development, including new combinations, dosages and forms of well-known drugs. Some have developed new products using available scientific information, created new methods of administering drugs or developed second uses. These activities are less risky and require less investment. Only a few of the local companies have independent R&D units. Foreign producers with local manufacturing capabilities tend to undertake clinical studies.

According to CAEMe, its associated companies account for around 95% of all clinical trials approved by ANMAT. The association estimates that its members spent a cumulative investment of USD700mn in clinical trials in the 2001-10 period; the annual investment in clinical trials amounted to USD100mn in 2010. According to CILFA, annual R&D investment rose to ARS390.5mn (USD46.08mn) in 2011, the latest year for which annual data are available; total pharmaceutical investment was estimated at ARS1,325mn (USD428mn) in 2007, when R&D investment equalled ARS207mn.

Biotechnology

Independent from the Argentina's political and economic turbulence, R&D in the country's national pharmaceutical industry has been kept high. Especially in the biotechnology sector, R&D spending accounts for around 5% of revenues, whereas, the average Argentine drugmaker only reinvests 0.5% of sales in

R&D. Local drugmakers seem to be split into two categories: the companies that aim at high-end markets such as Eriochem, Amega Biotech and Sidus; and drugmakers that target emerging markets such as Roemmers, Bagó and Phoenix.

As of April 2016, a recent report by Endeavour, a foundation focusing on high impact entrepreneurship, highlighted that in the last decade the number of biotech firms in Argentina has duplicated to a total of 178 firms, with this figure expected to increase by 15-25% in the next five years as the sector is showing significant entrepreneurial dynamism.

Benefiting from a relatively low-cost base, the biotechnology industry is capitalizing on the country's high-quality professionals. Argentina has the largest percentage of scientists as a share of the active population in the region, while the country stands as the fourth most populous in Latin America.

Major bottlenecks in the sector development have limited market mechanisms and venture capital available in the country in recent years. While most biotech firms are small and medium-sized enterprises, some companies have carried out substantial R&D work and made significant establishments. For example, Sidus has drawn international attention for its work on developing human insulin from transgenic cattle through its biotechnology subsidiary, BioSidus. Also, Grupo Chemo and Inmunova are recognized firms carrying out R&D. Some firms are integrating services to their business such as gene testing and bioinformatics.

The sector has benefited from public funding through several programs. We note that although the Argentine biotechnology sector is relatively advanced, the lack of market mechanisms enabling risk distribution in R&D and low access to R&D funding have hindered local biotechnology companies from developing technology and production capabilities along the industry's value chain.

Public R&D

There are several public agencies, credit stimuli and programmes that act as a source of funding in the Argentine R&D sector. These include:

- Credits of *Bicentenario*, which consist of subsidized credits for incrementing industrial capacity. In 2012, the pharmaceutical industry was the leading sector benefiting from such credits, at ARS1,024mn (USD120.6mn).
- Argentine Technological Fund (FONTAR), which finances investment activities in the private sector. Between 2005 and 2010, 200 projects from the pharmaceutical industry were identified under this system, at ARS80.2mn.
- Integrated Projects from Productive Agglomerates (PITEC), which finances R&D activities and modernisation across sectors.

- Funds for Scientific and Technological Research (FONCyT), which represents the major public funding source system promoting domestic R&D capacity.
- Argentine Sectorial Fund (FONARSEC), which focuses on funding technological transfer into productive and marketable projects.

Argentina's biotechnology sector has been relatively competitive in Latin America due to high quality professionals, low-cost operations and export-oriented policies. Most of companies in the biotechnology sector are small- and medium-sized enterprises (SMEs), with an average of 25 employees. Over half of the companies supply human healthcare products. The geographical distribution of Argentine biotechnology enterprises are in line with the general distribution of the Argentine population, as well as its academic and industrial activities. Buenos Aires, Santa Fe and Rosario are the main locations of biotech companies.

Historically, public investment in pharmaceutical innovation activities is low, concentrated on basic science and developed by public institutions. In the past two decades, government investment has gradually co-operated with the private sector and provided more commercial incentives for the sector. However, compared with its neighbour Brazil, Argentina's policy incentives in the biotechnology sector have been low, scattered across the country and there is a lack of continuity.

- In 1982-1991, the National Biotechnological Program was launched, which financed projects in the sector.
- In the early 1990s, the National Agency for Scientific and Technical Promotion (ANCYPT) started supporting a series of advanced science-based industries, such as biotechnology.
- In 1993, FONTAR began to distribute both national and multinational funds to local biotechnology firms. FONTAR also attributes tax credits for R&D. At a national level, biotechnology sector R&D receives 20% of such credits.
- In the early 2000s, FONAPYME was created to support SMEs with loans for productive and R&D investment. By 2005, the loans for new firms amounted to about USD5,000 and for existing firms up to USD60,000 or 70% of the investment.
- As Argentina has no national development bank, in 2006, the Central Bank provided soft credit lines (with interest rates around 50% that of private banks) for SMEs, with amounts up to USD3mn and reimbursement periods up to 10 years.
- In 2006-2010, the National Strategic Plan in Science, Technology and Innovation *Bicentenario* and the law No. 270/07 for the promotion of biotechnology were launched, which included an increase in public and private investment in the sector, and tax benefits to R&D projects.
- In 2007, Argentina approved a National Biotechnology Plan, but the law was not implemented and no financial support accompanied this Plan.
- In 2010, the Ministry of Industry & Tourism, Science & Technology and Agriculture, Federal Planning launched Pilar Biotechnology Park.

In recent years, Argentina has also started the public sector incubation of new technology-based companies with local research institutions such as the National University of Buenos Aires and La Plata. The Ministry of Science & Technology also provided an extra grant for public-private partnerships (PPPs) in biotechnology. Among recent successful PPPs that lead to the development, patenting and global commercialization of biotechnological products stand Biomatter and Raomed. Biomatter involved investments worth ARS4mn from FONARSEC, complemented by private sector funding and was based on a consortium among universities, research agencies and the Argentine company Medipharma. Biomatter developed bioengineering products for dermal regeneration in severely burned patients. Raomed was also based on a PPP and developed biocompatible materials for cranial reconstruction.

However, Argentina lacks sufficient commercial funding and market mechanisms to minimise risks in R&D. Private capital has not been widely used in Argentina as in other countries due to the long-term absence of orthodox economic policy in the country. Venture capital (VC) is hardly used by biotechnology companies in Argentina. Compared with its peers in Latin America, Argentina's private equity investment still lags behind.

In July 2012, Argentina's Chamber of Biotechnology (CAB) signed a cooperation agreement with the Association of Shanghai Biopharmaceutical Industries (SBIA) under which the two partners will carry out research projects and encourage the development and production of biotechnology. Both CAB and SBIA follow national industrial policies to support the strategic development of the sector and to integrate R&D, production, marketing and the export of biotechnology products, as well as create opportunities to establish networks for their members. The agreement will promote and improve the exchange of information, experiences and business opportunities among member of SBIA and CAB and help them to enter relevant markets and sponsor training in technical and scientific research.

In October 2014, *BioArgentina 2014* gathered in Buenos Aires potential strategic partners in the biotechnology sector. The session was designed to link researchers, biotechnology companies, start-ups and public sector agencies. The event counted with the participation of world-renowned researchers, including Dr Craig Venter (US). As the share of biotechnologies within the innovative global pharmaceutical market increases, Argentina's highly developed and lower cost biotechnology industry is poised for increased investments over the medium-to-longer-term.

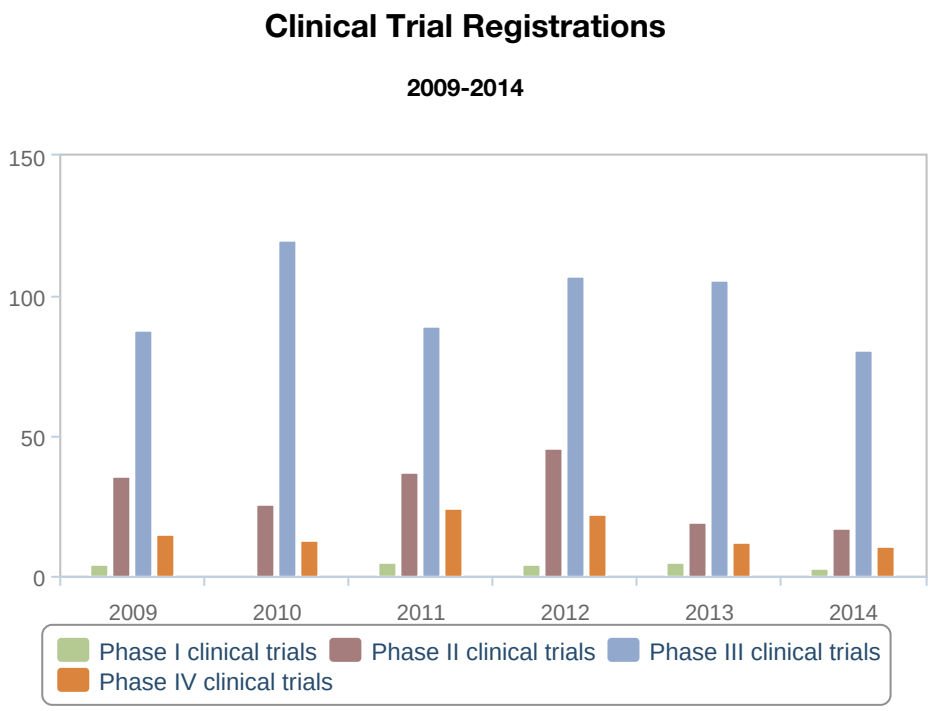
Clinical Trials

Clinical trials are regulated by ANMAT. Its regulations contain detailed provisions outlining the obligations of sponsors and investigators and the participation of independent ethics committees or review boards. In

addition to approving and monitoring functions, ANMAT also audits clinical trials. In March 2008, the government recognised the necessity of aligning Argentina's quality standards with Europe's. On March 21 2016, ANMAT released a statement stressing the importance of clinical research. The statement sustains that ANMAT 'adopts a proactive stance to promote the development of clinical research.'

Although the current operating environment has presented pharmaceutical companies with difficulties, the healthcare infrastructure in Argentina is considered to be one of the more sophisticated in Latin America and this has helped maintain the interest of companies in using it as a location for clinical research. All of Argentina's provinces have an organised network of hospital and outpatients services, supported by a skilled labour force and well-developed infrastructure. Multinationals have also reported that testing costs in Argentina are a third of US levels and remain significantly cheaper than in India. Long-term trials are particularly suitable for the environment, given a high level of retention.

Most clinical trials in Argentina are Phase III studies. In terms of newly registered clinical trials, the number of Phase III studies decreased from 120 in 2010 to 81 in 2014. Also, the number of new registrations of Phase II studies decreased from 26 to 17 in the same period, and Phase IV studies decreased from 13 to 11. However, newly registered Phase I studies increased from 0 to 3 in the same period.



Source: ClinicalTrials.gov, BMI. N.B. Sourced by date of initial registration.

Epidemiology

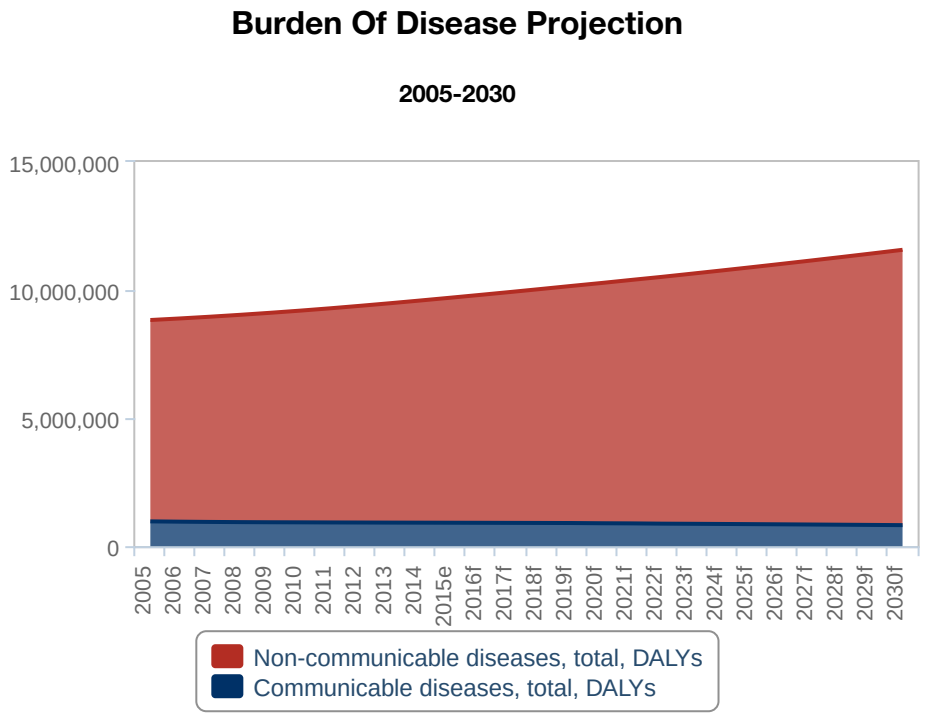
BMI's Disease Database records the number of DALYs that are lost as a result of having, or having had, a disease. Therefore, our measure of DALYs is a measure of lost productivity. According to our Disease Database, DALYs lost to non-communicable disease in Argentina reached 8.79mn in 2015, accounting for 80% of the total burden of disease.

We expect the number of DALYs lost to all disease to increase from 9.70mn DALYs in 2015 to 11.57mn DALYs in 2030, marking a 16% increase. The distribution of DALYs lost during this period will reflect a rise in the burden posed by non-communicable disease (from 8.79mn DALYs in 2015 to 10.75mn DALYs in 2030) and a decrease in the burden posed by communicable disease (from 915,288 DALYs in 2015 to 820,961 in 2030). The leading causes of DALYs lost to disease in Argentina include cardiovascular diseases (17% of total disease burden), cancer (14%), mental and behavioural disorders (13%), musculoskeletal disorder (11%) and diabetes, urogenital, blood and endocrine diseases (7%).

Within non-communicable disease (NCD), cardiovascular disease burden is expected to rise from 1.82mn DALYs in 2015 to 1.93mn DALYs in 2030, marking a 5% increase. We expect a more pronounced rise in

cancer disease burden from 1.51mn DALYs in 2015 to 1.93mn DALYs in 2030, posting a 22% increase. Reflecting an ageing population, we forecast a continued rise in mental and behavioural disorders (from 1.44mn DALYs in 2015 to 1.93mn DALYs in 2030, or a 25% increase). Western dietary patterns and sedentary lifestyle will continue to translate in a growing burden of diseases such as diabetes, which is forecast to rise from 274,408 DALYs in 2015 to 336,529 DALYs in 2030, posting a 18% increase.

HIV/AIDS accounts for around 10% of the burden posed by communicable disease (CD) in Argentina. Moreover, we project the burden posed by HIV/AIDS to increase from 95,954 DALYs in 2015 to 112,749 DALYs by 2030, posting a 15% increase. This is in contrast with most CD sub-categories, which are expected to decrease in terms of DALYs during the same period. For example, pre-birth term complications are expected to drop from 245,238 DALYs in 2014 to 187,178 DALYs by 2030, decreasing by 11%. This long-term trend is due in part to greater access to healthcare, earlier diagnoses of medical conditions and the increasing and more widespread use of pharmaceuticals.



f = forecast. DALYs = disability-adjusted life years. Source: BMI's Disease Database

Competitive Landscape

Despite robust market growth fundamentals, the Argentinean pharmaceutical market still presents a number of challenges, which limit its attractiveness to foreign firms, including a lax regulatory environment.

However, despite the government's increased focus on domestic pharmaceutical production, Argentina will retain its negative pharmaceutical trade balance and reliance on foreign patented drugs. Argentina is also the regional leader in foreign biological medicine approvals and marketing, making it the most appealing country in Latin America for manufacturers of such drugs. The country's reliance on imported biologics will ensure its continued demand for these imported medicines, particularly as Argentina's negative pharmaceutical trade balance will dramatically widen over the next five years.

While foreign research-based and many generic drugmakers have superior product portfolios, local firms account for a share of the local market not seen elsewhere in the region. Most local players are focused on branded generic drugs, some of which were developed without much regard for IP provisions. Domestic manufacturers supply around 50% of the retail market as consumers remain faithful to brands. However, recent years have seen increased pressures on the local industry, in terms of price, competition and pressure to improve intellectual property (IP) compliance, with some players increasingly looking abroad for growth. The highly developed biotechnology industry, one of the most advanced subsectors in Argentina, is pressuring the government for improvements in the IP protection system.

Around 71.8% of the domestic market demand is met by locally produced pharmaceuticals, while imported products supply the other 28.2%. Local production is strongly dependent on imports of active ingredients (APIs), contributing to a trade balance deficit. The country exports around 20% of local production. In 2013, 230 pharmaceutical laboratories were registered in Argentina. The 10 leading companies - among which five are Argentine laboratories - account for 46.2% of total sales. There are 110 industrial plants in the country, of which 93 are part of domestic-capital firms and 17 of foreign-capital firms. Domestic-capital laboratories account for 59.5% of sales in value terms and 65% in volumes, while foreign-capital firms account for 40.5% of sales in value terms and 35% in volumes.

Leading multinationals in terms of market share include Bayer (which stands as the market leader), Roche and Novartis (given its long history in Argentina); as well as Abbott and GlaxoSmithKline, which in mid-2010 acquired Argentina's Laboratorios Phoenix; and France-based Sanofi. US-based IVAX, owned by Israel's Teva, is also an important local player and operates manufacturing facilities in the country. Mexico's

Grupo Techsphere also owns production facilities in the country and has looked into acquiring local producers.

The data illustrate the increasing strength of indigenous manufacturers in Argentina, with leading players Roemmers and Bagó jointly accounting for over 10% of sales. Other prominent homegrown firms include Elea - which has a strong presence in the OTC sector - Raffo and Gador. Also, Sidus has drawn international attention for its work developing human insulin from transgenic cattle through its BioSidus biotechnology subsidiary.

Research-Based Industry

According to CILFA, there were 110 industrial plants in Argentina in 2011. Of these, 93 were national, equal to 84.5% of the total, and 17 were foreign, equal to the remaining 15.5% of the total. About 79% of the pharmaceutical producers were located in the city and the province of Buenos Aires in 2011; about 51% in the city, 28% in Gran Buenos Aires and 3.5% in the remaining area. Additionally, about 6.5% of the pharmaceutical producers were located in Santa Fe, followed by Córdoba (5.7%), Tucumán (1.7%), la Rioja (0.7%), Entre Ríos (0.7%), Mendoza (0.7%), Río Negro (0.3%), Neuquén (0.3%), Catamarca (0.3%), Chaco (0.3%) and Misiones (0.3%).

Many foreign producers have sold their manufacturing plants to local producers to regionalise production elsewhere. Altana Pharma sold its plant to Richmond in 2006, Bristol-Myers Squibb sold its plant to Roemmers in 2006, ICN sold its plant to Craveri in 2005, Sanofi sold its plant to HLB Farma in 2004, Schering sold its plant to LKM - Gobbi Novag in 2004, Wyeth sold its plant to Fada Pharma in 2003, Novartis sold its plant to Phoenix in 2002, Janssen Cilag sold its plant to Casasco in 2002 and Roche sold its plant to Roemmers in 2000. As a result, many foreign producers are developing clinical studies and contracting third-party local manufacturing.

Recent years have seen the downscaling or the exit of many subsidiaries of multinational pharmaceutical companies in Argentina. From 2001, this was closely linked to the then mounting economic crisis. However, comparatively weak IP protection and the weakness of the peso relative to the US dollar and other regional currencies have meant relatively few companies have returned or new players entered the market. Given the market's large size and the growing demand for medicines, however, multinationals' presence in the country has remained active through imports and eventual new investments in the last years. Local research and development (R&D) is mainly driven by an advanced biotechnology sector and public sector incentives to promote innovation, including public and private partnerships and the construction of Pilar Biotechnology Park.

US chemicals group 3M opened a new plant for producing inhaled asthma medicines in the suburbs of Buenos Aires in November 2007, representing an ARS6mn (USD1.9mn) investment. The new production base supplies export markets in Africa and Asia as well as Latin America. The company had total healthcare and non-healthcare sales of around USD100mn in Argentina in 2006, which are estimated to have doubled since.

Argentina has seen some investment in recent years from pharmaceutical producers based in other Latin American countries. Between 2003 and 2010, a Chilean investment group - the Weinstein family, which controls Recalcine Laboratorio Chile - acquired majority stakes in several Argentine generic producers. The series of acquisitions that gave Recalcine's group control of over 70% of the Argentine generic drug market include: Northia Laboratorios - which belonged to Southern Cross Group; Ahimsa and Hexa Medinova, acquired in 2003; Atlas Farmaceutica, bought in 2005; and Fada Pharma, acquired in 2006. Northia, a generic specialist for infectious diseases, anaesthesia, cardiology and gastroenterology and a regional exporter, was acquired in 2010 for USD25mn.

In June 2011, Recalcine merged two Argentine operations, Fada Pharma and Northia, to form Laboratorio Internacional Argentino. Recalcine listed on the Santiago Stock Exchange in May 2011, raising CLP172.7bn (USD369.3mn) through its initial public offering. The shares amounted to 25% of the company's equity. Despite allocating some of the capital to debt refinancing (15%) and working capital (20%), the company set aside most of the capital raised (65%) to fund expansion across Argentina, Colombia, Mexico, Thailand and Vietnam.

In March 2012, Corporación Farmacéutica Recalcine invested USD20mn in a facility at the Pilar Industrial Park in Argentina. The new manufacturing plant will have initial capacity to produce 50mn units of injectable oncology drugs a year. The products, which are 20% cheaper than those from multinationals, will be distributed in Argentina and abroad. They will generate estimated revenue of USD20-30mn a year.

Local Developments In Biotechnology Production

As of March 2016, a report by Endeavour, a foundation focusing on high impact entrepreneurship, highlighted that in the last decade the number of biotech firms in Argentina has duplicated to a total of 178 firms, with this figure expected to increase by 15-25% in the next five years as the sector is showing significant entrepreneurial dynamism (*see 'Research and Development'*).

Pharmaceutical R&D activities in the public sector are focused on biotechnology. Historically, investments have been low, concentrated on basic science and developed by public institutions. The 2008-2011 National

Programme for the Public Production of Medicaments, Vaccines & Medical Products, however, has gradually increased the public supply of pharmaceuticals. Developments include the launch of a new consortium to develop monoclonal antibodies for the treatment of cancer, in co-operation with the private sector; a plan to create the Pilar Biotechnology Park; the launch of a consortium to produce vaccines against seasonal influenza and influenza A (H1N1), in co-operation with the private sector; and technology transference for the local production of the yellow fever vaccine in Argentina, among others.

The Pilar Biotechnology Park aims to bring together companies specialised in biotechnology, including those focused on agriculture, medicines, food and the environment.

In February 2010 the ministry of health announced that the consortium Sinergium Biotech, formed by two national companies, Biogénesis Bagó and Elea, and the foreign producer Novartis, won the tender to create a plant for the production of vaccines against seasonal influenza and influenza A (H1N1) in Escobar, Buenos Aires. The Ministry projects investments of USD60mn; construction was expected to start in early 2011 and will finish five years later. With this plant, Argentina would become the tenth worldwide producer of vaccines against influenza A (H1N1).

Brazil and Argentina signed a technology transference agreement for the local production of yellow fever vaccines. The technology transference started in March 2010. With this plant, Argentina would become the third worldwide producer of yellow fever vaccines.

Company Developments

March 2016

- Bristol-Myers Squibb's *Opdivo* (nivolumab) is the first immunotherapy approved in Argentina for three different types of cancer, including small cell lung carcinoma, metastatic melanoma and renal cancer (PMpharma).
- US biopharmaceutical Kite Pharma started the process of registration and licensing required to operate and commercialize a range of cancer products and inmunotherapies in the Argentinean market (Mirada Profesional).

February 2016

- Scientists of Argentinean Leloir Institute and National Scientific Agencies signed an agreement with US-based company Unleash Immuno Oncolytics to transfer the license of a patent that will allow the latter to develop an immunotherapy against cancer based on genetically modified virus UIO-512.
- Pfizer launched in Argentina its new drug for breast cancer *Ibrance* (palbociclib).

January 2016

- Observing a turnover of around ARS540mn (USD27mn), Argentinean drugmaker Savant grew 20% in terms of sales and production in 2015 and expects to reach a similar growth rate in 2016 through a combination of products acquisition, the expansion of industrial capacity in Argentina, and growing market penetration in several Latin American countries, reports La Voz.
- Savant announced the acquisition of Laboratorio Beta products to its portfolio of drugs, in the context of Savant's commercial expansion strategy to increase its presence in the areas of cardiometabolism and clinical practice. In December 2015, the firm acquired NAF Laboratorio, a recognised brand in the market of odontological health. Savant is also duplicating the manufacturing capacity of its antibiotics plant in Cordoba (Argentina), which is expected to be operative in March 2016.

December 2015

- German-based Stada Arzneimittel and its subsidiary, BEPHA Beteiligungsgesellschaft fur Pharmawerte mbH, signed a contract to purchase the Argentinean generics producer, Laboratorio Vannier, with the transaction to reach a maximum of USD13mn in cash, including a small performance-related component.

Table: Multinational Market Activity

Company	Operations
Novartis	Novartis operates production, sales and R&D facilities in Argentina, employing around 617 people (Novartis Argentina: 509, Sandoz: 108). In 2012 the firm spent around USD23.4bn on clinical research in Argentina (mainly in general practice medicine, oncology and vaccines). The company's main area is prescription medicines. Novartis was a co-founder of distribution operation Farmanet, with Boehringer Ingelheim, Bayer, Casasco, and Gador.
Pfizer	Pfizer has been present on the Argentine market since the 1950s and manufactures at a facility in Buenos Aires. The plant's annual output is around 700mn pills and 75mn capsules. About 70% of production is distributed locally, with 20% exported within the Mercosur region. Pfizer also has a pilot plant in Argentina, which it uses to design, manufacture and study different formulations for production. The company employs around 600 staff.
Roche	Roche has been present in Argentina since 1930, through its subsidiary Productos Roche SA Química e Industrial. The company operates production, distribution and marketing facilities in the country. Local offices are located in La Plata, Rosario, Corrientes, Tucumán, Córdoba, Mendoza, and Bahía Blanca.
Sanofi	Prior to the merger of Aventis and Sanofi-Synthélabo, Argentina was Aventis' base for operations in the Southern Cone region. The company fields most of its key drugs in Argentina - for example, launching Aprovel in the fast-growing and lucrative angiotensin II receptor antagonist segment. The company's vaccines unit Sanofi-Pasteur opened a new EUR60mn (USD80mn) manufacturing plant for its hepatitis B vaccine in the city of Pilar in 2007, with the first investment of its kind in Latin America. Sanofi Argentina has commercial offices in the area of San Isidro. In September 2015 Brazilian Europharma acquired Sanofi's manufacturing plant in Lomas del Mirador in Argentina for USD18mn, although Sanofi's products will continue to be manufactured in the facility through third-party manufacturing agreements. Sanofi has around 650 employees in Argentina, as Europharma acquired Lomas del Mirador plant with its 200 employees.
Merck & Co	Merck & Co has been present with a commercial sales office in Argentina since 1953. The company operates modern quality assurance facilities in Pilar and conducts some R&D locally, but its production facility was sold to local firm Sidus in 1981. Merck licenses production and carries out local co-marketing activities with the Argentine company. In December 2013, Merck Sharp & Dohme launched a new facility to check the quality of all molecules, biologics and vaccines in Pilar, Argentina. The new facility will also have a packaging line and was built with a total investment of USD11mn, including infrastructure, incorporation of new technologies and the purchase of 17 pieces of equipment. In February 2013, Merck Sharp & Dohme signed a trade agreement with Argentinean local drugmaker Laboratorios Bago to promote its products used in the country's primary care system.
Johnson & Johnson	Johnson & Johnson has been present in Argentina since 1958. The firm has manufacturing plants in Buenos Aires in the city of Pilar, central offices in San Isidro, and commercial offices in the provinces of Cordoba and Rosario.
GlaxoSmithKline	GlaxoSmithKline has been present in the Argentine market since 1922. GlaxoSmithKline operates a manufacturing facility in San Fernando, Buenos Aires, as well as marketing and distribution offices, employing around 600 people in the country. GlaxoSmithKline's Argentine site acts as a regional manufacturing centre, supplying Brazil, Paraguay, Chile, Ecuador and Peru, in addition to the local market.
AstraZeneca	AstraZeneca Argentina operates a manufacturing plant and a complete clinical research team in the country. AstraZeneca has more than 470 employees in Argentina with an extra 25 people working on clinical research (as of July 2014, Pharmaboardroom).
Takeda	Takeda has an office in Buenos Aires. In Argentina Takeda focuses on areas such as gastroenterology, respiratory diseases and pain treatment, among others, as well nonprescription drugs.
AbbVie	Abbvie has an office in the Autonomous city of Buenos Aires, Argentina.

Source: BMI

Generic Drugmakers

Local production is dominated by Roemmers, Bagó, Elea, Raffo and Gador. Other leading local producers include Phoenix, Casasco and Baliarda. A number of local generic producers have modernised and created new manufacturing plants, including Savant, Hexa Ahimsa, Denver Farma, Fabop, Fada Pharma, Richet, Richmond and Veinfar. Traditionally, they have supplied the public sector, but now they are looking to supply the private pharmacy sector. The government runs state producers; they manufacture copycats for the public sector. State producers can be national, provincial, municipal, university and military. Advancements have been made to realign them, specialise them in certain therapeutic lines, concentrate production in key products and promote Good Manufacturing Practice (GMP) standards. Laboratorio Central de Salud Pública in the province of Buenos Aires produces the BCG vaccine. Administración Nacional de Laboratorios e Institutos de Salud Dr Carlos G. Malbrán (ANLIS) produces many vaccines against typical diseases affecting the country. Instituto Nacional de Enfermedades Virales Humanas Dr Julio I. Maiztegui (INEVH) produces viral vaccines and other immunobiologicals.

In June 2011, the Senate approved a law to regulate the public production of medicaments, vaccines and medical products in the country. With the new law, all 39 public producers will be regulated by ANMAT; only 12 public producers were regulated by ANMAT, as the remaining ones followed provincial regulations. As a result, public producers are expected to have preferential treatment when dealing with the government, provinces or the autonomous city of Buenos Aires in the near future.

In March 2015, the former minister of health, Daniel Gollan, stressed a focus on expanding local production capacities and increasing the prescription of generics. Recent agreements between the Argentine government and Chinese firm Sinopharm are aimed at enhancing technology transfer, pharmaceutical ingredients provision and creating complementary production capacities among both countries.

In 2008 the Ministry of Health launched the National Programme for the Public Production of Medicaments, Vaccines & Medical Products. Between 2008 and 2011, the programme was extended to supply pharmaceuticals to the REMEDIAR, and Tuberculosis, Chagas and Sexual & Reproductive Health programmes.

The growing importance of generic drug manufacturing in Argentina owes much to the country's traditional strengths as well as its recent problems over the protection of patents on innovative drugs. The market share of domestic manufacturers was 59.5% in value terms in 2010, compared to 56.4% in 2007, although in volume terms, local players have seen their share slip steadily from around 75% in 2005 to 71.3% in 2006,

to 61.4% in 2007 and reportedly to 35% in 2010. This could reflect the influx of cheaper generic products from manufacturers in other low-cost Latin American markets and, more recently, Asian countries.

In an attempt to offset exposure to the domestic market, local firms are entering new export markets as far afield as Yemen, Pakistan, and Singapore. In their approach to boosting pharmaceutical exports, both government officials and leading local companies are focusing energetically on so-called South-South trade and industrial collaboration - including growing relations with China, India and other emerging markets rather than the richer and more regulated countries of the Northern Hemisphere.

In late July 2007, Gador, part of the same industrial group as Roemmers, received US Food and Drug Administration certification for its plant in Pilar, enabling it to export to the US, a market where Argentine players have a strong price advantage, but so far a relatively limited track record. In April 2007, the company received a similar certificate for the Mercosur trade bloc. The company exports around 15% of its annual production and partners local companies in Lebanon and South Korea.

In H214 local pharmaceutical Savant was awarded a 2014 Palladium Balanced Scorecard Hall of Fame (Harvard business case) for Executing Strategy. Savant was founded in 1993 and successfully grew market share and increased profits during its first 12 years, with best total cost strategy through an integrated production process. A new Vision -launched in 2005- focused on a new Value Proposition: to generate higher margins for pharmacists and more affordable drugs for end consumers. This transformation required the acquisition of intangible assets and development of new internal capabilities. Growth resulted from focus on international business development, innovative market segmentation, and continuing efforts to provide more and better products. After eight years (2005-2012) and completion of two successive strategic plans, Savant multiplied its revenue twelve-fold. Over this same period the number of active clients grew by a factor of ten. Overall equipment effectiveness doubled, revenue per employee grew by 3.5 times, and employee satisfaction reached 80%.

In December 2014 the Argentine government reported the creation of a National Agency of Public Laboratories and Medicines (ANLAP). ANLAP, which was established through the Argentine legislature and operates under the Ministry of Health, is responsible for 'coordinating the work of 40 state-run pharmaceutical laboratories to ensure equal market access.' The objectives of ANLAP remain focussed on the promotion of research, industry and technology development along with the promotion of policies which seek to improve medicine accessibility.

Pharmaceutical Distribution

There are around 150 pharmaceutical wholesalers in Argentina. The distribution sector is oligopolistic, with the leading three distribution concerns - Disprofarma, Rofina Farmanet and Globalfarm - accounting for over 65% of sales. By contrast, the retail market is highly fragmented, in part due to legislation attempting to discourage the concentration of large pharmacy chains in urban areas.

The main purchasers remain wholesalers and retail pharmacies, accounting for around 94.2% of the pharmacy sector. CILFA estimates that 86.3% of pharmaceuticals are bought by wholesalers, of which 9.1% goes to hospitals and 77.2% is distributed to pharmacies. Pharmacies purchase a further 7.9% directly from manufacturers. The remaining 5.8% is distributed directly from manufacturers to hospitals, syndicates and co-operatives.

Manufacturers entered the wholesale market in the late 1990s. They formed three main wholesalers, Disprofarma, Farmanet and Rofina, which joined forces to create the mega wholesaler FarmaStar and collectively acquire 70% of Droguería Americana, 41% of Droguería Helman and 100% of Droguería Suizo-Barracas and Droguería Sur Bahía Blanca. FarmaStar has around 85% of the retail pharmacy sector.

An additional actor in the flow of the pharmaceutical chain is made by institutions called *gerenciadoras* or *mandatarias*. There are two firms under this sector, Farmalink and Preserfar, which represent leading local and multinational producers and negotiate contracts with key actors in the health system, including *obras sociales*, hospitals and PAMI, among others, on their behalf.

In December 2011, Marken, a leading global clinical supply chain service provider headquartered in the US, said it will build a pharmaceutical depot in Buenos Aires. It will offer a full range of temperature-controlled storage capabilities, supplementing its already operational depots in Mexico and Singapore. The company aims to increase the supply of drugs to previously limited-supply areas, offering a novel service to clients. The new depot will help international pharmaceutical companies distribute drugs to Argentina in a regulated manner.

Pharmaceutical Retail Sector

The Argentine retail pharmacy sector, which is dominated by branded patented and generic medicines, has been the key driver of market growth in the past decade, posting double-digit growth rates. Hospital sales account for around 13% of the total pharmaceutical market, while out-of-pocket spending at pharmacy

retailers represents a considerable 86%. Other distribution channels account for the remaining 1% of the total market value.

Pharmacy locations and ownership rules differ between different provinces, but a qualified pharmacist must be present in a pharmacy at all times. Since 2011, the discussion over the sale of OTC medicines in non-pharmacy outlets has intensified. In fact, Buenos Aires district, which was the last region to adopt the ban of OTC sales in non-pharmacy outlets, introduced a legislative proposal to roll back the ban as of H214. Congress previously passed law No. 26,567 for the adoption of the rule that medicines could be only dispensed through pharmacies in 2009.

The legislation effectively bans the popular practice of purchasing everyday medicines, such as aspirin, antacids and analgesics, through street kiosks. Supermarkets, gyms, newsagents and hotels were allowed to sell OTC medicine since 1991, but public safety concerns over dispensing violations led to calls for change. Opponents, however, point out that the ban will discriminate against patients unable to afford dispensing fees and also monopolises the country's growing OTC market.

According to the Association of the European Self-Medication Industry (AESGP) figures published in its 2010 update of the 'Economic and Legal Framework for Non-Prescription Medicines' report, Argentina boasts some 12,000 pharmacies. Chains account for only around 5% of the total number of pharmacies, but for as much as 20% of the total annual turnover recorded by the retail sector, supported by marketing.

Nevertheless, having won their battle against kiosk owners, Buenos Aires' independent pharmacies have shifted their focus to taking on larger retail pharmacies. Aizcorbe said in late 2011: 'Our next goals are to regulate the number of pharmacies within a certain population density and prohibit the sale of medicines and food in one location.' **BMI** has previously reported on new pharmacies opening at a rate of 1,500 a year. Local data imply that the local drug retail sector is expanding at 10% per annum, while drug sales have expanded by an annual average of 11% since 2001.

The leading chain is Farmacity, which accounts for 1.4% of total pharmacies in the country (189 pharmacies) and 5% of sales as of H213. In 2010, Farmacity had a 10% value share of the retail market, substantially ahead of its main rival Vantage. Unlike smaller independent pharmacies, some of Farmacity's outlets are open 24 hours. Additionally, Farmacity has positioned itself as the market leader by offering a mix of consumer and health products alongside traditional prescription and OTC medicines.

In September 2011, however, the province of Mendoza's health ministry said Farmacity's planned acquisition of 23 pharmacies will not be approved by state regulators. The company intended to rebrand 17

Mitre and six Del Aguila pharmacy chains in 2008 but faced a series of challenges from COFA. COFA and its members, comprised largely of independent operators, said the merger would monopolise the market, introducing unfair competition to the region's already fragile pharmacy sector.

The main contention stemmed from a 2004 provincial law (legislation 7303) that forbids an individual entity from owning more than two pharmacies. In 2008, when the deal was first floated, Mitre and Del Aquila operated more than two pharmacies but were exempt under the law's non-retroactivity clause. Farmacity is expected to appeal but **BMI** believes the ministry's blockade reflects the increasing difficulties faced by pharmacy chains throughout much of Latin America. Independent pharmacies across Argentina, Brazil and Mexico have complained about large pharmacy chains driving them out of business, but the Mendoza case is the first time a chain operator has had its expansion plans stopped by direct government intervention.

The national government has passed laws to prevent the larger drug retail chains from building a dominant market share, as is the case in neighbouring Chile. Individual provinces have also passed laws to prevent pharmacy concentration, limiting the opening of new outlets within 300m of existing outlets. The policy has preserved locally-owned pharmacies but prevented the achievement of economies of scale or more tightly controlled supply chains seen in more concentrated markets.

Cooperative Farmacia Social Congreso is the number-three player in terms of turnover, and Mexican low-price brands Farmacias Similares (Dr Simi) and Farmacias Ahorro (Dr Ahorro), rank fourth and fifth respectively. The former has reportedly closed its remaining outlets in Argentina, citing excessive retail market regulations, but the latter has around 55 locations and continues to open around 10 outlets a year, primarily through franchise agreements. According to local auditing firm BDO Argentina, pharmacies' profitability has also become under higher pressure in recent years, and suffers from 'discount' arrangements that *obras sociales* and *prepagas* offer to patients.

There are 230 pharmaceutical companies operating in the pharmacy sector, of which 122 are local and 108 foreign. There were about 13,500 private pharmacies in 2011, of which 3,000 were located in Gran Buenos Aires; the city of Buenos Aires alone had 1,350. The presence of a pharmacist is obligatory in each pharmacy, but this does not mean that the owner must be a pharmacist. Pharmacy deregulation has resulted in an increasing number of pharmacies in the city of Buenos Aires and other commercial areas.

Leading pharmacy chains include Farmacity and Vantage. Pharmacy chains specialised in generics include Dr Ahorro and Economed; due to bad performance, the Mexican Farmacias de Similares (Dr Simi) has closed its retail operations in Argentina.

Company Profile

GlaxoSmithKline

Strengths	▪ Strong drug portfolio, with substantial marketing, local experience and capital resources.
	▪ Diverse product portfolio, ranging from OTC medicines to diabetes and HIV/AIDS treatments.
	▪ The company is focusing on expansion in emerging markets and is piloting a tiered pricing model.
Weaknesses	▪ The persistence of copy drugs represents an ongoing threat.
	▪ Not present in the fast-growing generic drugs sector.
	▪ Not present in animal health.
Opportunities	▪ The launch of new vaccines for diseases that are a major cause of infant mortality is a key regional opportunity for GlaxoSmithKline.
	▪ Rising demand for sophisticated medicines on a regional basis, with Argentina used for exports to neighbouring markets.
	▪ Argentina's ongoing transition towards more market-friendly economic policies will benefit key economic sectors in the years ahead, including the pharmaceutical industry.
Threats	▪ Continued government resistance to improving patent law remains a major obstacle.
	▪ Challenges posed by the nationwide restrictions on OTC sales outside pharmacies.
	▪ Despite Argentina's long-term growth favourable outlook, short-term economic turbulence will negatively impact on returns in the pharmaceutical and healthcare sector through the next few quarters.

Company Overview

GlaxoSmithKline has been present in the Argentine market since 1922. GlaxoSmithKline operates a manufacturing facility, as well as marketing and distribution offices, employing around 600 people in the country.

GlaxoSmithKline's Argentine site acts as a regional manufacturing centre, supplying Brazil, Paraguay, Chile, Ecuador and Peru, in addition to the local market. Investment in Argentina over the past decade has been relatively limited, further deterred by the currency crisis.

In 1995, GlaxoSmithKline invested USD27mn to construct a new antibiotics manufacturing plant and upgrade its existing production facilities in Victoria, Buenos Aires. In early 2004, the plant was integrated into GlaxoSmithKline's consumer healthcare division and assumed management of production operations in Barros Filho, Brazil. In the same year, a USD3.5mn liquids and creams unit and a new distribution centre were opened.

Products manufactured in Argentina are mainly restricted to the company's consumer healthcare lines. Among the more recent product launches is *Avodart* (dutasteride), a treatment for benign prostatic hyperplasia, introduced in July 2006. GlaxoSmithKline's *Zovirax* (acyclovir) has been switched to OTC status.

Strategy

GlaxoSmithKline is present in most other Latin American markets. In Brazil, the company employs over 1,400 people, with the Rio de Janeiro office acting as the regional headquarters for Latin America. The UK-based company's production is focused on two factories in Rio de Janeiro that supply the entire Brazilian market and other Mercosur countries.

Developments

2015

- As of October 2015, GlaxoSmithKline will invest USD11mn in expanding its production plant in San Fernando, Argentina, to produce the OTC brand *Corega*, which will generate annual savings in imports of about USD2mn and will focus on supplying the domestic market and other markets in the region, including Brazil, Chile, Uruguay, Paraguay, Peru, Colombia, Venezuela, Ecuador and Bolivia.

2013

- In March 2013, GlaxoSmithKline invested USD123mn to establish a new quality control and production site at Phoenix, an Argentinean subsidiary GlaxoSmithKline acquired in mid-2010. The project aims to develop and produce high quality, affordable medicines for Argentina's and other Latin American markets.

Company Details

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Laboratorios Bago

Strengths

- Strong international presence based on its diversified regional presence with manufacturing facilities in Chile and a subsidiary in Mexico.
- Bagó holds local co-marketing arrangements with leading research-based foreign players.
- As an Argentine company, Bagó benefits from favourable government regulation.
- Second-largest domestic player, with a presence in the nascent biotech market.

Weaknesses

- The company is largely reliant on the erratic Latin American market.
- Capital base is sound, but the company is still small compared to multinationals.
- Many of the company's products exploit Argentina's weak intellectual property (IP) environment and any notable tightening would impact sales.

Opportunities

- The export market provides added exposure to growth, with recently established marketing presence in markets such as Russia and Vietnam as well as Pakistan.
- Argentina's nutraceuticals and generic drugs markets are expected to see strong growth in the medium term.
- Expansion in Eastern Europe could help drive export growth to 2022.
- The company has benefited from the switching of some of its products to OTC status.
- Argentina's ongoing transition towards more market-friendly economic policies will benefit key economic sectors in the years ahead, including the pharmaceutical industry.

Threats

- The market entry of foreign generic drugs players, especially Indian firms and other major manufacturers.
- The government is likely to retain tight cost controls and freezes for the foreseeable future.

- Uncertain economic outlook and potentially social policies may represent a risk to investment.

Company Overview

As well as generic drugs, the company produces biotech medicines through its joint venture (JV) plant with Pakistani firm Ferozsons. The February 2009 tie-up will create a new USD10mn plant in the South Asian country, producing biogeneric therapies for cancer and hepatitis.

Bagó Group has an industrial complex comprising 17 production facilities distributed in different countries (Argentina, Bolivia, Brazil, Chile, Colombia, Mexico, Pakistan and Uruguay): 11 of them are pharmaceutical plants (two specialized in biotechnology and oncology products, and one plant specialized in influenza and pandemic vaccines), two bulk chemical plants, four animal health care plants, and its own R&D Center. As of April 2015, the company claims to have developed 85 patents under its own research. Also, Bagó Group operates insurance company Vitoria Seguros, claiming USD35mn in premiums annually.

In addition to human-use pharmaceuticals, Bagó is active in animal health and biotechnology via Biogénesis-Bagó, following the merger of its animal health business with Instituto San Jorge-Bagó in 2005. The new entity saw USD15mn investment in a new plant and has annual turnover estimated at around USD75mn. It is also present in distribution via Disprofarma, which has a 25% share of the wholesale market.

As of April 2015, Bagó Group has a number of strategic commercial agreements and joint ventures with multinationals, including Pfizer, Astellas, Bayer, AstraZeneca, Boehringer Ingelheim, Merck Sharp & Dohme, Eli Lilly, Ferrer, Ferozsons, Fidia, Novartis and UCB, among others. In 2000, Bagó entered into a joint venture with Netherlands-based Nutricia, marketing baby milk, nutraceuticals and other food products in Argentina. Bagó also has a co-operation agreement with Germany's Merck KGaA to distribute generic drugs in Brazil. Bagó also carries out a limited amount of proprietary discovery work, in addition to having offices throughout the continent, managing the company's distribution and production operations.

The company products are commercialized in more than 47 countries around the world. Bagó Group controls local drugmaker Montpellier in Argentina as well as Uruguayan pharmaceutical firm Gramón Bagó. In Chile, Bagó operates a Good Manufacturing Practice (GMP)-certified, export-focused plant, with sales in Chile totalling some 3.4mn units in 2005. Production was some 20mn units. The company offers a portfolio of around 70 branded generic medicines in Chile.

In Mexico, the company has acquired Laboratorios Armstrong, a leading ISO-9001 certified generic drugs manufacturer, from IVAX-owned LabChile. The company

markets a number of generic central nervous system (CNS) products, including sleep-apnoea aid *Modiodal*. Armstrong is also a distributor for Japanese major Astellas.

Strategy

Laboratorios Bagó announced an ambitious overseas expansion plan for the next decade, according to reports in La Nacion. In the late 1990s, Laboratorios Bagó had a strong regional presence but then began expanding in South East Asia, the Middle East, Africa and the Commonwealth of Independent States (CIS). The company is now looking to expand further into emerging markets during the 2012-2020 period. This includes opening markets such as Armenia, Syria and Cambodia, before heading into South Africa and Indonesia. In mature markets such as Europe and the US, barriers to entry are high and so the company is primarily targeting developing markets. By 2012, Laboratorios Bagó aimed to have a presence in 40 countries in Eastern Europe and Asia.

Bagó's pharmaceutical product lines mainly comprise generic medicines, ranging from basic anti-infectives to anti-hypertensives and more sophisticated treatments for CNS disorders. Bagó's key pharmaceutical products include its ethical anti-inflammatory Talniflumate, marketed by US drugmaker Genaera as *Lamucin*, a treatment for catarrh. A number of its products, including *Anaflex* (diclofenac oral) and *Actual* (famotidine), have been switched to OTC status since 2000.

The company has carried out a series of strategic expansions in recent years, forming a distribution partnership with German drug major Merck KGaA in Brazil in 2004. In 2009, it signed an agreement with Pakistani firm Ferozsons Laboratories to manufacture therapies for cancer and hepatitis near Lahore. The JV includes a new biotech unit, BF Biosciences. The plant - which specialises in hepatitis and cancer products - is designed to meet EU and US FDA regulatory standards.

Developments

2013

- In May 2013, Bagó was awarded a new patent in Europe. The patent follows the development of a compressed innovative drug specifically designed to allow administration of alprazolam sublingual. The patent includes the formulation of the procedure, in addition to the production processes for the alprazolam sublingual tablet and its specific applications. Alprazolam is for the treatment of primary insomnia and insomnia associated with states of anxiety.

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Novartis

Strengths

- Strong market position and capital base give Novartis a good presence.
- A diverse business portfolio, with the company present in the patented pharmaceuticals, OTC, generic drugs, baby foods and animal health sectors.
- Opening of a generic plant for oncology products shows commitment to Argentina as a manufacturing base.

Weaknesses

- Lax domestic patent regulations remain a key hurdle.
- Opaque government drug pricing and reimbursement policies deter new product launches.
- Certain amount of corruption in government tenders.

Opportunities

- Sandoz has a significant opportunity in the fast-growing generic medicines sector, as substantial unmet demand for affordable healthcare exists.
- Rising demand for sophisticated treatments for diseases such as cancer and cardiovascular disorders.
- The new plant should increase Novartis Argentina's export capacity.
- New swine flu vaccine production line to boost Novartis' standing in the country, as well as volume of medicines sold.
- Argentina's ongoing transition towards more market-friendly economic policies will benefit key economic sectors in the years ahead, including the pharmaceutical industry.

Threats

- Government resistance to improving domestic intellectual property (IP) rights will likely persist.
- Emerging markets to increasingly attract multinationals' attention, despite certain regulatory and IP deficiencies, which will increase competition.

- Challenges posed by the recently legislated nationwide restrictions on OTC sales outside pharmacies.
- Competitive threat from other leading global generic producers, including large Indian producers, some of which are expanding through local acquisitions.

Company Overview

Novartis operates production, sales and R&D facilities in Argentina, employing around 617 people (Novartis Argentina: 509, Sandoz: 108). Novartis brought its local generic operations (including local manufacturer Labinca, acquired in 2001) under the Sandoz name in 2003. Novartis was a co-founder of distribution operation Farmanet, with Boehringer Ingelheim, Bayer, Casasco, and Gador. A manufacturing facility was divested to domestic firm Phoenix in 2002. In 2012 the firm spent around USD23.4bn on clinical research in Argentina (mainly in general practice medicine, oncology and vaccines). The company's main area is prescription medicines, which accounted for around 90% of local revenue in 2006.

Strategy

The company's key therapeutic areas are oncology, rheumatology, cardiovascular, central nervous system (CNS), transplant medicine and gastrointestinal diseases. In the OTC sector, Novartis manufactures the nasal decongestant *Otrivine* (xylometazoline), which has been switched to OTC status, and a number of Ciba Vision eye care products, such as *SoloCare* and *AoSept*, as well as two contact lens brands. The company also distributes *Lamisil* (terbinafine) cream for athlete's foot.

The company operates clinical trials phases II, III and IV in multiple therapeutic areas (cardiovascular disease, respiratory diseases and infectious diseases, among many others).

From Argentina, Novartis exports to Europe, Brazil and Colombia, while also expanding coverage to Mexico and Peru in 2004. Its generic arm, Sandoz, is using Argentina to supply its operations in advanced markets such as Europe, the US and Japan. Company sources said exports rose by 30% per year through to 2008, from approximately ARS32mn (USD10.4mn) in 2006. The firm has invested ARS36mn (USD11.7mn) on increasing the output of its oncology product line.

Developments

2015

- In April 2015, Novartis sold *Reliverán*, a widely used Argentine medicine against nausea and vomiting, to Argentine firm Gador, reported Pharmabiz.net. The companies did not disclose the operation value, which the media outlet suggests to be around ARS128mn (USD14.4mn). Novartis' strategy is to focus on high technology products, while *Reliverán* is instead a mature product. In turn, Gador was interested in adding a key product to its line of primary healthcare. About 2.2mn *Reliverán* units are sold each year (Clarin.com). Gador, founded in 1940, currently has 850 employees in the country and 120 in the region, with offices in Chile, Colombia, Paraguay, Peru and Uruguay.

2013

- In December 2013, ANMAT approved Novartis' meningococcal conjugate vaccine *Menveo* for use in infants aged two months and older.

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Sanofi

Strengths

- Aventis and Sanofi-Synthélabo had an established presence in Argentina prior to their merger, with the combined operations providing greater scale and synergies.
- It is present in the key animal health segment through the Merial joint venture.
- The acquisition of an OTC portfolio from Gramon will help Sanofi expand in the consumer health sector.
- Sanofi's vaccines arm has a prominent presence in Argentina.

Weaknesses

- Sanofi's high-priced patented medicines may struggle to compete against locally produced drugs.
- The company's products are targets for Argentina's sizeable copy drug sector.

Opportunities

- The company can build on a significant presence in OTC, patented drugs and vaccines.
- New Latin American generic drugs business should benefit from growth in the generic medicines sector.
- New vaccines plant in Pilar should boost the local subsidiary's revenues and it remains one of the most active multinationals in this category.
- Argentina's ongoing transition towards more market-friendly economic policies will benefit key economic sectors in the years ahead, including the pharmaceutical industry.

Threats

- Government support for generic drugs could undermine the company's patented medicines business.
- Continued problems over patent protections are a key hurdle to further expansion.
- Despite Argentina's long-term growth favourable outlook, short-term economic turbulence will negatively impact on returns in the pharmaceutical and healthcare sector through the next few quarters.

Company Overview

Prior to the merger of Aventis and Sanofi-Synthélabo, Argentina was Aventis' base for operations in the Southern Cone region. The company fields most of its key drugs in Argentina, for example, launching Aprovel in the fast-growing and lucrative angiotensin II receptor antagonist segment.

Sanofi Argentina operates a vaccine plant in Pilar Industrial Park and has commercial offices in the area of San Isidro. In September 2015 Brazilian Europharma acquired Sanofi's manufacturing plant in Lomas del Mirador in Argentina for USD18mn, although Sanofi's products will continue to be manufactured in the facility through third-party manufacturing agreements. Sanofi has now around 650 employees in Argentina, as Europharma acquired Lomas del Mirador plant with its 200 employees.

The company's 2010 annual report mentioned three industrial divisions that were to be more closely integrated with regional markets and distribution channels. As a part of this expansion, the group acquired a plant in Argentina. According to its own estimates, Sanofi ranks among the 10 largest pharmaceutical concerns in Argentina. Its product portfolio in the country includes prescription medicines, OTCs and vaccines, as well as animal health products.

Strategy

In May 2009, with the aim of entering Argentina's OTC drug market, Sanofi acquired 18 medicines from local drugmaker Gramon. The brands are widely recognised in the local market and will provide the multinational drugmaker with significant opportunities for revenue growth. The product line acquired by Sanofi has sales of around USD6mn per year. According to the OTC director for Sanofi Argentina, the company will support the new brands with significant media campaigns. The OTC market has been growing rapidly in recent years and Sanofi was targeting 10% of the market in 2011. Bayer leads the OTC market, followed by GlaxoSmithKline.

The company has benefited from growing demand for its diabetes treatment products and opened a new diabetes consulting centre in Buenos Aires in late 2007. The

company's vaccines unit Sanofi-Pasteur opened a new EUR60mn (USD80mn) manufacturing plant for its hepatitis B vaccine in Pilar in 2007, with the first investment of its kind in Latin America.

Developments

2015

- In September 2015 Brazilian Europharma acquired Sanofi's manufacturing plant in Lomas del Mirador in Argentina for USD18mn, although Sanofi's products will continue to be manufactured in the facility through third-party manufacturing agreements.

2014

- In June 2014, ANMAT approved Genzyme (Sanofi)'s *Lemtrada* (alemtuzumab) for adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.

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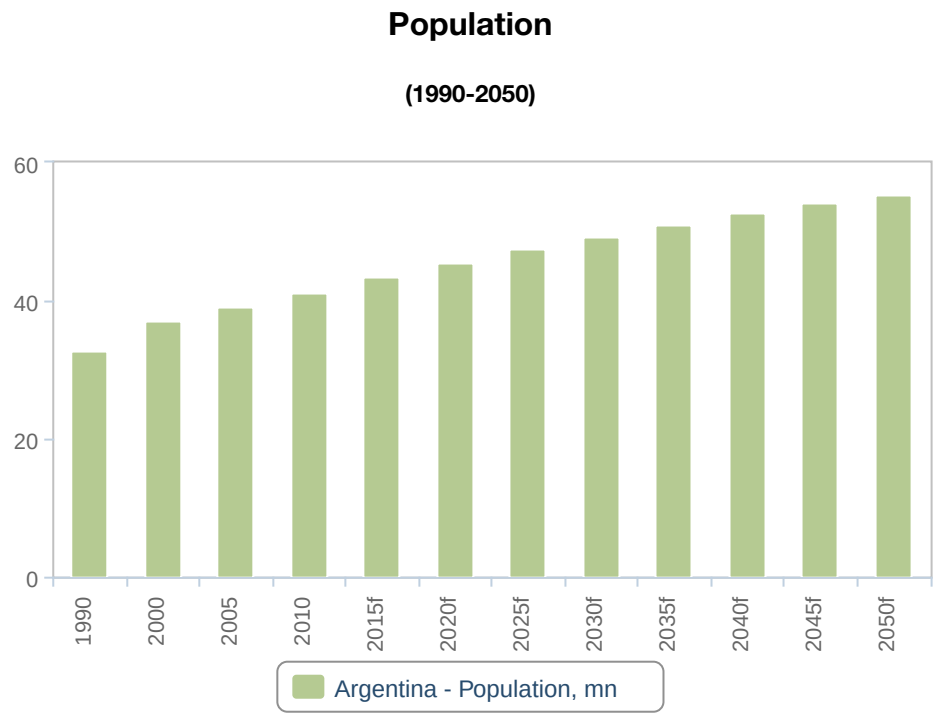
Demographic Forecast

Demographic Outlook

Demographic analysis is a key pillar of **BMI**'s macroeconomic and industry forecasting model. Not only is the total population of a country a key variable in consumer demand, but an understanding of the demographic profile is essential to understanding issues ranging from future population trends to productivity growth and government spending requirements.

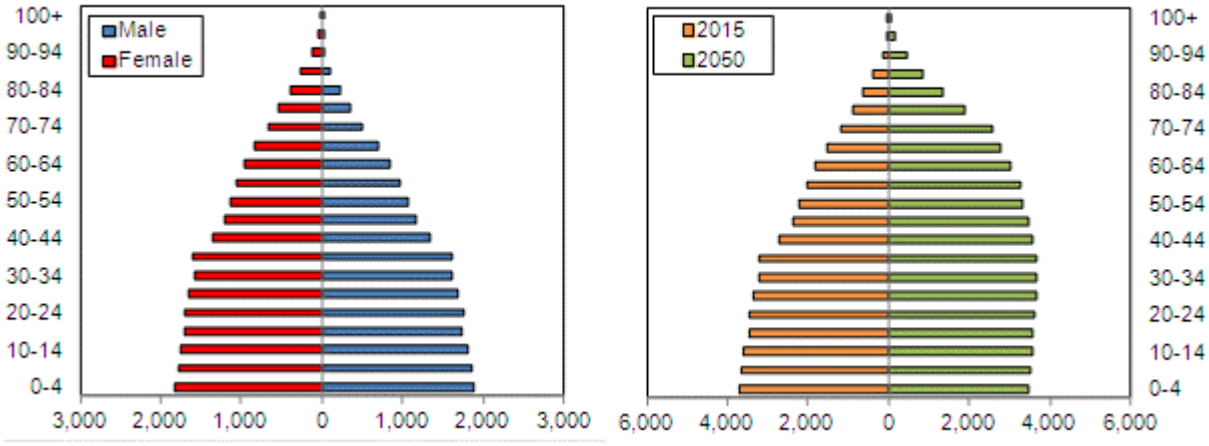
The accompanying charts detail the population pyramid for 2015, the change in the structure of the population between 2015 and 2050 and the total population between 1990 and 2050. The tables show indicators from all of these charts, in addition to key metrics such as population ratios, the urban/rural split and life expectancy.



f = BMI forecast. Source: World Bank, UN, BMI

Argentina Population Pyramid

2015 (LHS) & 2015 Versus 2050 (RHS)



Source: World Bank, UN, BMI

Table: Population Headline Indicators (Argentina 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Population, total, '000	32,729	37,057	39,145	41,222	43,416	45,516	47,499
Population, % y-o-y	na	1.1	1.1	1.0	1.0	0.9	0.8
Population, total, male, '000	16,047	18,131	19,148	20,163	21,244	22,287	23,277
Population, total, female, '000	16,682	18,926	19,996	21,059	22,172	23,229	24,222
Population ratio, male/female	0.96	0.96	0.96	0.96	0.96	0.96	0.96

na = not available; f = BMI forecast. Source: World Bank, UN, BMI

Table: Key Population Ratios (Argentina 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Active population, total, '000	19,746	23,014	24,650	26,268	27,734	29,166	30,537
Active population, % of total population	60.3	62.1	63.0	63.7	63.9	64.1	64.3
Dependent population, total, '000	12,982	14,043	14,495	14,954	15,682	16,350	16,962
Dependent ratio, % of total working age	65.7	61.0	58.8	56.9	56.5	56.1	55.5

Key Population Ratios (Argentina 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Youth population, total, '000	10,019	10,370	10,537	10,665	10,938	11,053	11,078
Youth population, % of total working age	50.7	45.1	42.7	40.6	39.4	37.9	36.3
Pensionable population, '000	2,963	3,672	3,957	4,289	4,743	5,296	5,884
Pensionable population, % of total working age	15.0	16.0	16.1	16.3	17.1	18.2	19.3

f = BMI forecast. Source: World Bank, UN, BMI

Table: Urban/Rural Population & Life Expectancy (Argentina 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Urban population, '000	28,469.6	33,033.8	35,263.8	37,498.8	39,835.3	42,064.0	44,161.5
Urban population, % of total	87.0	89.1	90.1	91.0	91.8	92.4	93.0
Rural population, '000	4,260.1	4,023.7	3,881.7	3,724.1	3,581.4	3,452.9	3,338.3
Rural population, % of total	13.0	10.9	9.9	9.0	8.2	7.6	7.0
Life expectancy at birth, male, years	68.1	70.1	71.0	71.7	72.6	73.7	74.7
Life expectancy at birth, female, years	75.2	77.5	78.6	79.4	80.2	80.9	81.6
Life expectancy at birth, average, years	71.6	73.8	74.8	75.6	76.5	77.4	78.2

f = BMI forecast. Source: World Bank, UN, BMI

Table: Population By Age Group (Argentina 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 0-4 yrs, total, '000	3,414	3,471	3,594	3,644	3,718	3,702	3,668
Population, 5-9 yrs, total, '000	3,274	3,504	3,458	3,581	3,638	3,713	3,697
Population, 10-14 yrs, total, '000	3,330	3,393	3,484	3,439	3,582	3,638	3,712
Population, 15-19 yrs, total, '000	2,805	3,255	3,372	3,464	3,437	3,580	3,635
Population, 20-24 yrs, total, '000	2,483	3,299	3,231	3,348	3,456	3,430	3,572
Population, 25-29 yrs, total, '000	2,347	2,771	3,271	3,204	3,336	3,444	3,419
Population, 30-34 yrs, total, '000	2,241	2,448	2,744	3,243	3,189	3,320	3,428
Population, 35-39 yrs, total, '000	2,104	2,309	2,422	2,718	3,222	3,168	3,300
Population, 40-44 yrs, total, '000	1,898	2,192	2,278	2,393	2,693	3,193	3,142
Population, 45-49 yrs, total, '000	1,664	2,038	2,152	2,240	2,359	2,657	3,153

Population By Age Group (Argentina 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 50-54 yrs, total, '000	1,496	1,810	1,984	2,100	2,192	2,312	2,607
Population, 55-59 yrs, total, '000	1,404	1,547	1,737	1,912	2,031	2,124	2,245
Population, 60-64 yrs, total, '000	1,299	1,340	1,454	1,642	1,815	1,934	2,030
Population, 65-69 yrs, total, '000	1,075	1,191	1,220	1,332	1,513	1,682	1,802
Population, 70-74 yrs, total, '000	808	1,014	1,034	1,065	1,173	1,343	1,505
Population, 75-79 yrs, total, '000	574	733	815	837	873	974	1,127
Population, 80-84 yrs, total, '000	329	437	516	588	616	654	740
Population, 85-89 yrs, total, '000	132	209	250	313	368	394	426
Population, 90-94 yrs, total, '000	35	69	93	117	153	185	203
Population, 95-99 yrs, total, '000	5	14	22	29	39	53	66
Population, 100+ yrs, total, '000	0	1	3	4	5	8	12

f = BMI forecast. Source: World Bank, UN, BMI

Table: Population By Age Group % (Argentina 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 0-4 yrs, % total	10.43	9.37	9.18	8.84	8.56	8.13	7.72
Population, 5-9 yrs, % total	10.00	9.46	8.83	8.69	8.38	8.16	7.78
Population, 10-14 yrs, % total	10.18	9.16	8.90	8.34	8.25	7.99	7.82
Population, 15-19 yrs, % total	8.57	8.79	8.61	8.40	7.92	7.87	7.65
Population, 20-24 yrs, % total	7.59	8.90	8.26	8.12	7.96	7.54	7.52
Population, 25-29 yrs, % total	7.17	7.48	8.36	7.77	7.68	7.57	7.20
Population, 30-34 yrs, % total	6.85	6.61	7.01	7.87	7.35	7.29	7.22
Population, 35-39 yrs, % total	6.43	6.23	6.19	6.59	7.42	6.96	6.95
Population, 40-44 yrs, % total	5.80	5.92	5.82	5.81	6.20	7.02	6.62
Population, 45-49 yrs, % total	5.08	5.50	5.50	5.43	5.44	5.84	6.64
Population, 50-54 yrs, % total	4.57	4.89	5.07	5.10	5.05	5.08	5.49
Population, 55-59 yrs, % total	4.29	4.18	4.44	4.64	4.68	4.67	4.73
Population, 60-64 yrs, % total	3.97	3.62	3.72	3.98	4.18	4.25	4.28
Population, 65-69 yrs, % total	3.29	3.21	3.12	3.23	3.49	3.70	3.79
Population, 70-74 yrs, % total	2.47	2.74	2.64	2.58	2.70	2.95	3.17
Population, 75-79 yrs, % total	1.76	1.98	2.08	2.03	2.01	2.14	2.37
Population, 80-84 yrs, % total	1.01	1.18	1.32	1.43	1.42	1.44	1.56

Population By Age Group % (Argentina 1990-2025) - Continued							
	1990	2000	2005	2010	2015f	2020f	2025f
Population, 85-89 yrs, % total	0.41	0.57	0.64	0.76	0.85	0.87	0.90
Population, 90-94 yrs, % total	0.11	0.19	0.24	0.28	0.35	0.41	0.43
Population, 95-99 yrs, % total	0.02	0.04	0.06	0.07	0.09	0.12	0.14
Population, 100+ yrs, % total	0.00	0.01	0.01	0.01	0.01	0.02	0.03

f = BMI forecast. Source: World Bank, UN, BMI

Glossary

- **Pharmaceuticals, medicines, drugs:** synonym terms used interchangeably.
- **Pharmaceutical market/sales:** the sum of revenues generated by generic, patented, and over-the-counter (OTC) drugs through hospitals, retail pharmacies and other channels. Unless otherwise stated, market value is reported at final consumer price including mark-ups, taxes, etc.
- **Prescription drugs:** patented and generic drugs regulated by legislation that requires a physician's prescription before they can be sold to a patient.
- **Patented drug:** an innovative medicine granted intellectual property protection by the patent and trademark office. The patent may encompass a wide range of claims, such as active ingredient, formulation, mode of action, etc, giving the patent holder the sole right to sell the drug while the patent is in effect.
- **Generic drug:** a bioequivalent medicine that contains the same active ingredient as an originator drug. The originator drug is an innovative medicine that no longer has intellectual property protection due to patent expiry.
- **OTC drug:** a medicine that does not require a prescription to be sold to patients. Also known as non-prescription medicines.
- **Counterfeit drugs:** unregistered and illegal medicines which have not been subject to regulatory assessments to ensure quality, safety, efficacy and manufacturing standards.
- ***Similares*:** non-bioequivalent alternatives to either an originator patented drug or a generic drug. While s*imilares* and the originator/generic drug have a common indication, *similares* do not always contain the same active ingredient as an originator and invariably have a different pharmacokinetic and pharmacodynamic profile. Prevalent in select South American countries, *similares* are legal. **BMI** does not include their sales in total pharmaceutical market values.
- **Health expenditure:** the sum of the funds mobilised by government and private systems for the operation of a healthcare system, according to the WHO. It includes the purchase of healthcare services and goods by public entities such as ministries and social security institutions; or by private entities such as non-profit institutions, commercial insurances and households acting as complementary funders to the previously cited institutions or unilaterally disbursing health commodities. The revenue base of these entities varies by country and comprises multiple sources. The inclusion of this in **BMI's** forecasts necessitates taking into account the essential attributes of country-specific health accounting such as comprehensiveness, consistency, standardisation and timeliness.
- **Government health expenditure:** the sum of outlays for health maintenance, restoration or enhancement paid by government entities such as a ministry of health, other ministries, parastatal organisations and social security agencies, including transfer payments to households to offset medical care costs and extra-budgetary funds to finance healthcare provision.
- **Private health expenditure:** the sum of outlays for health by private entities such as commercial or mutual health insurance, households, non-profit institutions serving households, resident corporations and quasi-corporations not controlled by governments, according to the WHO.
- **Medical devices:** products used for diagnosis or therapy in patients. Whereas pharmaceuticals achieve their principal action by pharmacological, metabolic or immunological means, medical devices act by physical or mechanical means. Medical devices include a wide range of products, including syringes, thermometers, blood-sugar tests, prosthetic limbs, ultrasound scans and X-ray machines.

- ***Burden of Disease Database*** **(BoDD): BMI**'s disease database incorporates WHO, World Bank, IMF and BMI'**s own** data to create a proprietary dataset. BoDD data are quantified as the sum of disability-adjusted life years lost to a disease in a particular country.

- **Disability-adjusted life years (DALYs):** the sum of the years of life lost (YLL) due to premature mortality in a population and the years lost due to disability (YLD) for incident cases of the health condition. The DALY is a health gap measure that extends the concept of potential years of life lost due to premature death (PYLL) to include equivalent years of 'healthy' life lost in states of less than full health (broadly termed 'disability'). One DALY represents the loss of one year of equivalent full health.

Methodology

Pharmaceutical Expenditure Forecast Model

Historic pharmaceutical market data is collected from a range of sources, including:

- regulatory agencies;
- pharmaceutical trade associations;
- company press releases and annual reports;
- subscription information providers;
- local news sources;
- information from market research firms that is in the public domain.

Currently available data varies in confidence levels, so it is calibrated by **BMI**'s Pharmaceuticals & Healthcare analysts. In the absence of a complete time series of numbers, intermediate years are calculated from secondary sources. This 'composite' approach is used to ensure the accuracy and consistency of historic data, which is crucial for reliable forecasts.

To remove the effect of inflation, real pharmaceutical expenditure figures are then calculated by removing the annual average consumer price index (CPI).

Real per-capita pharmaceutical expenditure numbers are calculated by dividing by population figures.

A linear regression (*see Note 1 for explanation*) is then performed on five years of real per-capita pharmaceutical expenditure against real per-capita final consumption (*see Note 2*). From analysis of the top 130 economies, **BMI** has established a strong statistical relationship between pharmaceutical expenditure and final consumption expenditure (r = 0.985).

Healthcare Expenditure Forecast Model

Historic public and private healthcare expenditure data is sourced from the World Health Organization (WHO)'s Global Health Expenditure Database, which contains the National Health Accounts (*see Note 1 for methodology*).

Data is provided in nominal local currency terms.

To remove the effect of inflation, real healthcare expenditure figures are then calculated by removing the annual average CPI.

Real per-capita healthcare expenditure numbers are calculated by dividing by population figures.

A linear regression is then performed (*see Note 2 for explanation*). This is first on five years of real per-capita public healthcare expenditure against real per-capita government final consumption expenditure (*see Note 3 for definition*). This generates a 10-year forecast of future of real per-capita public healthcare expenditure figures from 'known' projected real per-capita government final consumption expenditure figures. Another linear regression is simultaneously performed on real per-capita private healthcare expenditure against real per-capita private final consumption expenditure (*see Note 4 for definition*).

To generate the nominal public healthcare spending forecast, population and CPI numbers are returned to both real per-capita public healthcare expenditure figures and real per-capita private healthcare expenditure figures.

The overall healthcare expenditure forecast is then calculated by combining public and private healthcare expenditure.

Notes On Methodology

Note 1: National Health Accounts methodology. The global health expenditure database that the WHO has maintained for the past 10 years provides internationally comparable numbers on national health expenditures. The WHO updates the data annually, taking, adjusting and estimating the numbers based on publicly available reports (national health account reports, reports from ministries of finance, central banks, national statistics offices, public expenditure information and reports from the World Bank, the IMF, etc). The estimates are sent out to the ministries of health for validation prior to publication, but users are advised that country data may still differ in terms of definitions, data collection methods, population coverage and estimation methods used. This database is the source of the health expenditure tables in the World Health Statistics Report and the WHO Global Health Observatory.

Note 2: Linear regression equation.

y = mx + b

Where y = unknown variable, m = slope of gradient, x = known variable, and b = where the line crosses the y-axis.

Note 3: Final consumption is the sum of government final consumption expenditure and private final consumption expenditure. Government final consumption expenditure is the sum of expenditure on final goods and services by the government. Included in this are public sector salaries, but it does not include transfer payments such as unemployment benefits or pensions. Private final consumption expenditure is the sum of all private consumption of goods and services within the economy, including both durable and non-durable goods. Housing purchases, however, are excluded. Government final consumption expenditure and private final consumption expenditure are the 'G' and 'C' in this equation:

GDP = C + I + G + (X - M)

Where GDP = gross domestic product, C = private final consumption expenditure, I = gross investment, G = government final consumption, X = exports, and I = imports.

Risk/Reward Index Methodology

Geographic diversification may be a favourable strategy for any multinational pharmaceutical company but it is vital that a company recognises both the rewards and the risks present in a market, in both developed and emerging pharmaceutical markets. **BMI**'s index, which provides a globally comparative and numerically based assessment of a market's attractiveness, was established to address this.

BMI's Pharmaceutical Risk/Reward Index (RRI) analyses and assesses a market's attractiveness to multinational drugmakers looking to launch innovative medicines in the country. Our approach in assessing the risk/reward balance incorporates our industry-leading Country Risk Index (CRI), drawing on our 25-year expertise in assessing political, economic and business operational risk, as well as our in-depth knowledge of the global pharmaceutical industry.

It should be emphasised that the Pharmaceutical RRIs broadly assess the rewards and the risks that a company will face when looking to launch an innovative drug in a market. For example, we do not differentiate between drugs that are a part of different therapeutic groups or whether the drug being

launched is the first to be launched in the market or will be one of the many different drugs of the same therapeutic class that has been launched in the market.

Index Overview

With regards to assessing rewards, we identify industry specific factors (such as the size of the pharmaceutical market) and country specific factors (such as the size of the pensionable population) that represent opportunities to would-be investors.

With regards to assessing risks, we identify industry specific dangers (such as approvals expediency) and those emanating from the state's political/economic profile (such as bureaucracy) that call into question the likelihood of anticipated returns being realised over the assessed time period. With regard to the economic and political assessment, only aspects most relevant to the pharmaceutical industry are incorporated in the assessment.

Table: Pharmaceutical Risk/Reward Index Indicators

	Rationale
Rewards	
Industry Rewards	
Market expenditure, USDbn	Denotes breadth of pharmaceutical market. Large markets score higher than smaller ones
Market expenditure per capita, USD	Denotes depth of pharmaceutical market. High value markets score better than low value ones
Sector value growth, % y-o-y	Denotes sector dynamism. Scores based on annual average growth over five-year forecast period
Country Rewards	
Urban-rural split	Urbanisation is used as a proxy for development of medical facilities. Predominantly rural states score lower
Pensionable population, % of total	Proportion of the population over 65 years of age. States with ageing populations tend to have higher per-capita expenditure
Population growth, 2003-2015	Fast-growing states suggest better long-term trend growth for all industries
Risks	
Industry Risks	
Patent respect	Markets with fair and enforced IP regulations score higher than those with endemic counterfeiting
Policy reinforcement	Markets with full and equitable access to modern medicines score higher than those with minimal state support
Approvals expediency	High scores awarded to markets with a swift appraisal system. Those that are weighted in favour of local industry or are corrupt score lower

Pharmaceutical Risk/Reward Index Indicators - Continued	
	Rationale
Country Risks	
Economic diligence	Evaluates the structural balance of the economy, noting issues such as reliance on single sectors for exports/growth, and past economic volatility
Policy continuity	Evaluates the risk of a sharp change in the broad direction of government policy
Lack of bureaucracy	Denotes ease of conducting business in the state
Legal diligence	Denotes the strength of legal institutions in each state. Security of investment can be a key risk in some emerging markets
Business Transparency	Denotes the risk of additional illegal costs/possibility of opacity in tendering/ business operations affecting companies' ability to compete

Source: BMI

Indicator Weightings

	Market Expenditure	Spending Per Capita	Sector Value Growth	Industry Rewards	Urban/Rural Split	Pensionable Population	Population Growth	Country Rewards	Rewards	Patent Respect	Policy Enforcement	Approvals Expediency	Industry Risks	Economic Diligence	Policy continuity	Lack of Bureaucracy	Legal Diligence	Business transparency	Country Risks	Risks	RRR
Weighting	20	12	12	44	8	8	5	21	65	7	7	7	21	3	3	3	3	2	14	35	100

Source: BMI

The weighting of each indicator reflects its relative importance to the pharmaceutical industry and the relative reward or risk that each factor poses to drug companies. The score assigned to each sub-sector (ie Industry Rewards) indicates the weighting of the sub-sector segment in the final RRI, and the score assigned to each indicator shows each indicator's influence within the sub-sector and the final RRI. All the indicators and their weightings are visible, improving the transparency of the index, allowing for the identification of regional (or group) outperformers across one indicator.

Uses For BMI's Pharmaceutical RRIs

- Strategic decision making and country/market comparisons, providing quantifiable reasons as to why one market is more attractive than another.
- Assessing the viability of new markets.
- A benchmark for internal rating systems.
- Assessing frontier markets or markets in which data collection is difficult.
- Internal presentations.

Principals Likely To Derive Benefit

- Disease manager
- Country manager
- Regional manager
- CEO and other senior executives involved in high level strategic decisions
- Business development team
- Credit risk team