

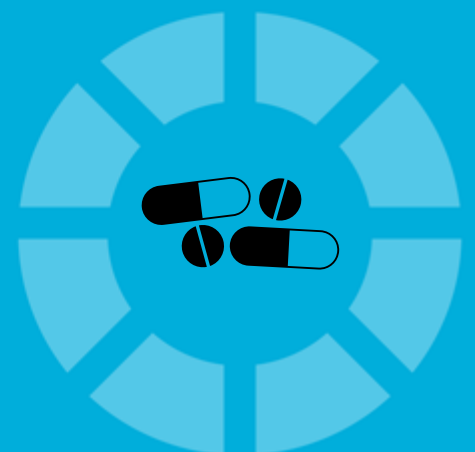
Q1 2016

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MEXICO

PHARMACEUTICALS & HEALTHCARE REPORT

INCLUDES 10-YEAR FORECASTS TO 2024



Mexico Pharmaceuticals & Healthcare Report Q1 2016

INCLUDES 10-YEAR FORECASTS TO 2024

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BMI Industry View

BMI View: The government's efforts to improve competitiveness in Mexico's pharmaceutical sector combined with the country's economic outperformance over large countries like Brazil in 2015 will improve Mexico's attractiveness to drugmakers. As such, Mexico's consumer demand growth has started to pick up, which could be a substantial driver of a more consumer-driven economy. However, overdependence on US economic cycles has held down investment in the domestic pharmaceuticals market.

Headline Expenditure Projections

- **Pharmaceuticals:** MXN172.6bn (USD13.0bn) in 2014 to MXN177.3bn (USD11.4bn) in 2015; +2.8% in local currency terms and -12.0% in US dollar terms. *Forecast broadly unchanged in local currency terms compared with previous quarter. Forecast revised down in USD due to revised exchange rate expectations.*
- **Healthcare:** MXN1.1trn (USD80.8bn) in 2014 to MXN1.2trn (USD74.1bn) in 2015; +7.2% in local currency terms and -8.3% in US dollar terms. *Forecast broadly unchanged in local currency terms compared with previous quarter. Forecast revised down in USD due to revised exchange rate expectations.*

Table: Headline Pharmaceuticals & Healthcare Forecasts (Mexico 2013-2019)

	2013	2014	2015f	2016f	2017f	2018f	2019f
Pharmaceutical sales, USDbn	13.194	12.964	11.404	12.273	13.053	13.660	14.460
Pharmaceutical sales, % of GDP	1.03	0.99	0.97	0.94	0.91	0.88	0.85
Pharmaceutical sales, % of health expenditure	16.8	16.0	15.4	14.8	14.2	13.8	13.3
Health spending, USDbn	78.698	80.840	74.144	83.029	91.657	99.301	108.514

f = BMI forecast. Source: World Health Organization, CANIFARMA, AFAMELA, AESGP, BMI

Risk/Reward Index

Mexico scores 60.6 in BMI's Pharmaceutical and Healthcare Risk/Reward Index (RRI). The Mexican market boasts higher per capita pharmaceutical expenditure than most other markets to its south and its relatively advanced intellectual property protection in comparison with other Latin American markets, with the exception of Puerto Rico. However, its score is brought down by lingering corruption, a large and impoverished rural population and inefficiencies in its pharmaceutical distribution and retail sectors.

Latest Updates

- In October 2015, Israel-based Teva Pharmaceutical Industries announced the acquisition of Mexican drugmaker Representaciones e Investigaciones Médicas in a USD2.3bn deal. The transaction is expected to be completed in early 2016.
- The expanding national drug procurement scheme in Mexico will continue to provide improved pharmaceutical access for patients nationwide. The Mexican Ministry of Health has announced that its annual consolidated procurement of pharmaceuticals will be valued at MXN48bn (USD2.8bn) in 2015. The bulk purchasing, which will supply pharmaceuticals to Mexican patients throughout 2016, involves 21 of the 31 Mexican states and is cited as experiencing a 9% growth in value compared to the 2014 purchase.

BMI Economic View

Mexico remains on track to narrow its fiscal deficit in the coming years, even in the face of structurally lower oil prices. Indeed, the detrimental impact of reduced crude prices will be largely offset by increasing non-oil revenues in the wake of the 2014 tax reform. Moreover, a series of spending cuts mooted by the government in its 2016 budget proposal will further reduce pressure on Mexico's fiscal position. As such, after increased counter-cyclical spending in the wake of the financial crisis has resulted in a widening of the fiscal deficit in recent years, we forecast that it will fall from 3.5% of GDP in 2015 to 3.1% in 2016 and continue to narrow thereafter. The Mexican government's prudent fiscal management, coupled with limited currency and rollover risk, suggests little risk to the country's sovereign credentials.

BMI Political View

A spate of recent corruption scandals and continued elevated criminal activity will continue to undermine public trust in the Mexican government and weigh on President Enrique Peña Nieto's public approval ratings in the coming quarters. Indeed, according to recent polling data, the president's approval ratings have plunged to an all-time low, while 63% of those surveyed believed the country was going in a bad or very bad direction. Peña Nieto has taken some measures to appease the increasingly disgruntled electorate in recent weeks, including an August cabinet reshuffle and promises to improve transparency and rule of law in the September state of the nation. However, all things considered, many of these changes are cosmetic and will be insufficient to assuage growing popular discontent. This will leave the door open for continued social unrest in the coming quarters, with widespread public dissatisfaction likely to persist.

SWOT

Pharmaceutical SWOT Analysis

Strengths

- The second-largest drugs market in Latin America, after Brazil.
- One of Latin America's most developed markets, with regulatory standards superior to most of its southern neighbours.
- Strong trade links to the US, Canada and the EU.
- A competitive and well developed pharmaceutical manufacturing industry, including around 200 companies and substantial presence of multinationals.
- Greater efforts to suppress counterfeit drugs continue to provide upside to patent and generic drugmakers.

Weaknesses

- Despite recent reforms, the enforcement of domestic patent law remains problematic.
- Copy and counterfeit drugs are still prevalent.
- With about 10% of the population lacking health insurance, Mexico's drug market is sensitive to economic shocks.
- An inefficient coordination of regulatory and healthcare policies has contributed to high pharmaceutical prices.
- Pharmaceutical pricing policy does not take into account production costs, which distort price levels without achieving dramatic savings.
- Law enforcement, particularly regarding counterfeit medicines, is sporadic and overshadowed by other major issues, including cartel-related violence.
- Red zones, or black markets, are known to the authorities and private security is a known overhead cost to manufacturers operating in Mexico.

Opportunities

- New legislation on bioequivalence has been approved and may offer potential for generic drug market growth.

Pharmaceutical SWOT Analysis - Continued

- Health sector reform as well as the expansion of programmes such as the Seguro Popular should boost healthcare spending.
- Public purchases, through the IMSS, are increasingly focusing on generic medicines, indicating good potential for generic market expansion.
- End to the 'local plant rule', requiring drugmakers to operate local manufacturing, should open up the market to more competition.
- Pressure on the government to relax classifications of OTC products.
- Medical tourism from US patients is a possibility, particularly in Tijuana.

Threats

- The lack of coordination between IMPI and the COFEPRIS has held back improvements in patent protection.
- Continued failure to enforce domestic patent law may continue to limit investment and product launches by multinationals.
- IMSS and ISSSTE bureaucracy has resulted in long waiting times for clinical trial approvals, representing a threat to investment in clinical development.
- The possible increase in VAT on medicines to hamper access to drugs, especially for patients not covered by any sort of medical insurance.
- Possible reduction of local manufacturing levels due to increasing competition from imports originated from lower cost bases such as China, India and Brazil.
- The establishment of a centralised public procurement mechanism in conjunction with other Latin American countries will have a negative effect on market values.

Industry Forecast

Pharmaceutical Market Forecast

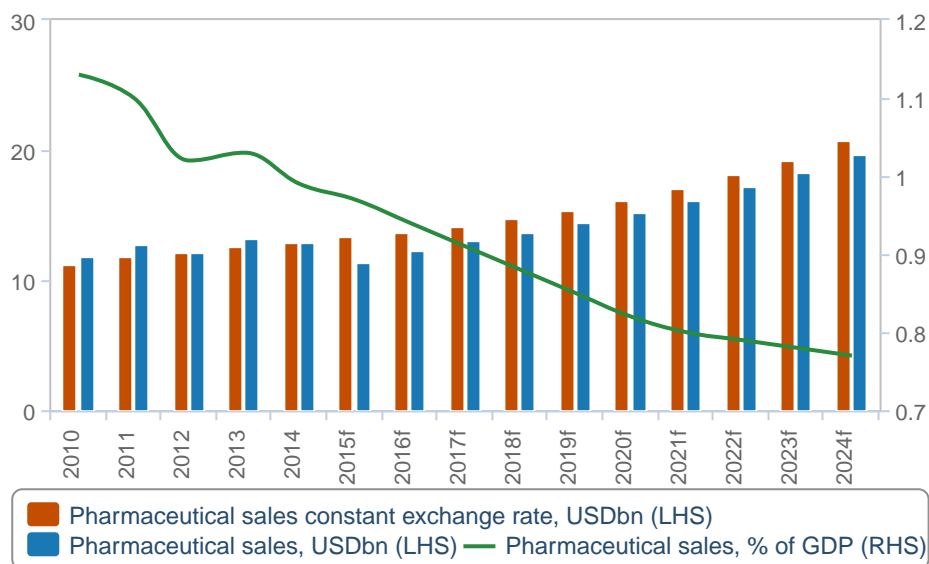
***BMI View:** The Mexican pharmaceutical market will be driven by the expansion of the state-run health insurance scheme for those on low incomes, but hampered by slow growth of consumer spending, drug shortages associated with supply and procurement chain shortcomings and the increased use of generic drugs, especially as the authorities remain committed to facilitating medicine imports from lower-cost manufacturing bases.*

Latest Updates

- The expanding national drug procurement scheme in Mexico will continue to provide improved pharmaceutical access for patients nationwide. The bulk purchasing, which will supply pharmaceuticals to Mexican patients throughout 2016, involves 21 of the 31 Mexican states and is cited as experiencing a 9% growth in value compared to the 2014 purchase.

Pharmaceutical Market Forecast

2010-2024



f = BMI forecast. Source: CANIFARMA, AFAMELA, AESGP, BMI

Structural Trends

The value of Mexico's pharmaceutical market reached MXN172.6bn (USD13.0bn) in 2014 and will grow to MXN275.5bn (USD19.7bn) by 2024. Pharmaceutical spending made up 0.99% of GDP and per capita spending was USD103 in 2014. Mostly driven by an ageing population and the increasing incidence of chronic diseases, **BMI** predicts that over the next 10 years, Mexican pharmaceutical sales will grow at a compound annual growth rate (CAGR) of 4.8% in local currency terms or by 4.3% in US dollar terms.

The country has been boosted by the recovery of US demand for Mexico's manufactured products, though private consumption remains subdued. Mexico's vulnerability to US economic trends means that periods of lower consumer spending and employment are likely to affect the more expensive branded medicines and the OTC market. Nevertheless, the continued modernisation of the healthcare system, with growing health awareness and access to medicines through new clinics, will ensure a constant level of demand, as will a steady population growth. The growth and development of Mexico's economy will also improve its access and consumption of pharmaceuticals over the long term as the country benefits from energy reform and a strengthening peso.

While per capita expenditure on pharmaceuticals in Mexico is high compared with neighbouring countries, **BMI** believes that drugs costing more than USD15 are prohibitively expensive for the average patient. Only 25% of Mexicans have access to a doctor and 40% of mild ailments are treated through self-medication. As a result, expensive drugs could push patients to either forgo treatment or turn to Mexico's unregulated and legally questionable *similares* drug market. While difficult to confirm, it is likely that pharmacists are changing prescriptions to save patients money - albeit at the risk of assigning medicines that interact with medications being consumed or that do not treat underlying conditions.

An area in need of improvement is the ongoing phasing-out of *similares*, which are not bioequivalent. These drugs may only comprise a small proportion of the total market value - as little as 5% - but they continue to pose problems for patented and generic drugmakers in Mexico. While it can be argued that, in terms of value, *similares* are preferred by low-income groups and are therefore not a sizeable determinant of overall healthcare market growth. Lower prices and a related marketing drive have created a loyal consumer base.

The presence and perceived acceptance of *similares* within Mexico questions the regulatory authorities' ability to assure the safety of all medicines available in the country, and could later undermine genuine

generic drugs from gaining a larger market share by value. On the political front, however, wiping out *similares* could alienate low-income groups - an undesirable outcome for the current government.

Table: Pharmaceutical Sales, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
Pharmaceutical sales, USDbn	12.723	12.228	13.194	12.964	11.404	12.273	13.053	13.660	14.460
Pharmaceutical sales, USDbn, % y-o-y	8.05	-3.89	7.90	-1.75	-12.03	7.62	6.36	4.65	5.86
Pharmaceutical sales, MXNbn	158.273	160.837	168.425	172.553	177.330	182.861	189.268	196.699	205.326
Pharmaceutical sales, MXNbn, % y-o-y	6.39	1.62	4.72	2.45	2.77	3.12	3.50	3.93	4.39
Pharmaceutical sales constant exchange rate, USDbn	11.891	12.084	12.654	12.964	13.323	13.738	14.220	14.778	15.426
Pharmaceutical sales, USD per capita	105.7	100.2	106.6	103.4	89.8	95.4	100.2	103.6	108.5
Pharmaceutical sales, % of GDP	1.10	1.02	1.03	0.99	0.97	0.94	0.91	0.88	0.85
Pharmaceutical sales, % of health expenditure	18.2	16.9	16.8	16.0	15.4	14.8	14.2	13.8	13.3

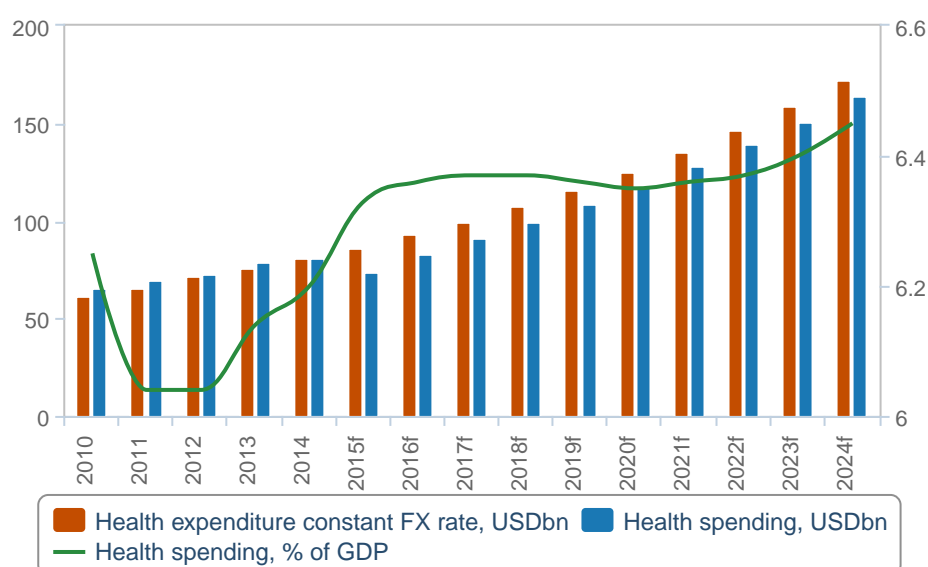
f = BMI forecast. Source: CANIFARMA, AFAMELA, AESGP, BMI

Healthcare Market Forecast

BMI View: Healthcare expenditure in Mexico will retain strong growth over the next decade as the country's strengthening economic outlook promotes increasing access to medical services. Mexico's public insurance programme, Seguro Popular, will also drive expansion of universal healthcare, enhancing appeal to foreign investors, with the country remaining a regional outperformer.

Healthcare Expenditure Forecast

2010-2024



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

Structural Trends

The key driver of growth in Mexico's healthcare sector will be the expansion of access to medical services, critically promoted through the expansion of universal healthcare in the country since 2004. The Mexican government's increasing focus on the provision of healthcare will be reinforced by a strengthening peso on the back of the recent US dollar growth. Rising household wealth along with rapidly growing enrolment within Mexico's Seguro Popular programme will ensure revenue-generating opportunities for multinational drugmakers and healthcare companies as Mexico further boosts its outperformance status in the region.

Between 2014 and 2024, annual healthcare spending in Mexico will grow from MXN1.1trn (USD80.8bn) to MXN2.3trn (USD163.8bn), equating to a compound annual growth rate (CAGR) of 7.9% in local currency terms and 7.3% in US dollar terms. In 2014, per capita expenditure on healthcare was USD645 and healthcare expenditure accounted for 6.2% of GDP. Public healthcare will remain dominant within the market, accounting for 53% of Mexico's total medical spending in 2014 and 64% in 2024.

BMI's Country Risk team notes that the Mexican peso will be an outperformer in Latin America over the coming years, highlighting positive investment opportunities within Mexico as other countries in the region, primarily Brazil, have already begun experiencing economic contractions.

Public Healthcare

Public health services remain driven by Mexico's primary public medical insurance programme, Seguro Popular, which was established just over a decade ago to provide health insurance for patients unable to afford or access existing health insurance schemes. According to the Ministry of Health, the use of Seguro Popular has significantly reduced out-of-pocket healthcare spending for families as the government now provides the necessary health expenditure, resulting in an 11% reduction of household spending on medical services in Mexico in 2014. Seguro Popular has experienced rapid growth since its first year, with enrolment growing from 5mn in 2004 to 56mn in 2012, accounting for approximately 46% of the Mexican population in 2012.

Shortcomings do exist within the programme's decentralisation of powers, which allows states to autonomously control the federal funds for Seguro Popular recipients. State governments have incentives to enrol large numbers of patients, but they do not face accountability for how the money is spent. Despite this, criticisms of the scheme remain minimal, while rising rates of Seguro Popular beneficiaries highlight Mexico's growing and successful implementation of universal healthcare, boosting the country's appeal to multinational providers of medical services.

Private Healthcare

Private medical services remain driven by Mexico's burgeoning medical tourism sector, which offers modern facilities and significant cost savings to foreigners, particularly appealing to US patients. Mexico offers medical fees which range between 50% and 60% less than healthcare costs within the US. Access to Mexican health provision has garnered such high demand by US citizens in recent years that a special 'medical lane' was constructed at the US/Mexico border to allow US patients quicker access to Mexican medical facilities.

The lane was built in 2012 after heated debates surrounding the introduction of 'Obamacare' led many in Southwest US states to cross the border for medical care, increasing Mexico's already high rates of US patient care. The border city of Mexicali in Baja California alone attracts more than 150,000 US patients each year, generating approximately USD8mn in medical expenditure. Growing focus on medical tourism in the Mexican cities of Cancun and Puerto Vallarta will also generate increased appeal in coming years as patients increasingly choose to undergo medical procedures in resort destinations.

Table: Healthcare Expenditure Trends, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
Health spending, USDbn	69.792	72.460	78.698	80.840	74.144	83.029	91.657	99.301	108.514
Health spending, USDbn, % y-o-y	6.80	3.82	8.61	2.72	-8.28	11.98	10.39	8.34	9.28
Health spending, MXNbn	868.183	953.072	1,004.579	1,075.997	1,152.934	1,237.130	1,329.025	1,429.933	1,540.895
Health spending, MXNbn, % y-o-y	5.16	9.78	5.40	7.11	7.15	7.30	7.43	7.59	7.76
Health expenditure constant FX rate, USDbn	65.227	71.605	75.475	80.840	86.621	92.946	99.850	107.432	115.768
Health spending, USD per capita	579.8	593.6	636.0	644.7	583.7	645.5	703.8	753.5	813.9
Health spending, % of GDP	6.04	6.04	6.14	6.20	6.33	6.36	6.37	6.37	6.36

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

Table: Government Healthcare Expenditure Trends, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
Govt. health spend, USDbn	35.126	37.542	40.715	42.366	39.346	44.638	49.935	54.818	60.696
Govt. health spend, USDbn, % y-o-y	9.74	6.88	8.45	4.05	-7.13	13.45	11.87	9.78	10.72
Govt. health spend, MXNbn	436.947	493.796	519.721	563.892	611.827	665.099	724.053	789.385	861.888
Govt. health spend, MXNbn, % y-o-y	8.05	13.01	5.25	8.50	8.50	8.71	8.86	9.02	9.18
Govt. health spend, % total health spend	50.33	51.81	51.74	52.41	53.07	53.76	54.48	55.20	55.93

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

Table: Private Healthcare Expenditure Trends, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
Private health spend, USDbn	34.667	34.918	37.983	38.475	34.798	38.391	41.722	44.483	47.817
Private health spend, USDbn, % y-o-y	3.98	0.72	8.78	1.29	-9.56	10.33	8.68	6.62	7.50
Private health spend, MXNbn	431.236	459.276	484.858	512.105	541.107	572.031	604.971	640.548	679.007
Private health spend, MXNbn, % y-o-y	2.38	6.50	5.57	5.62	5.66	5.71	5.76	5.88	6.00
Private health spend, % total health expenditure	49.67	48.19	48.26	47.59	46.93	46.24	45.52	44.80	44.07

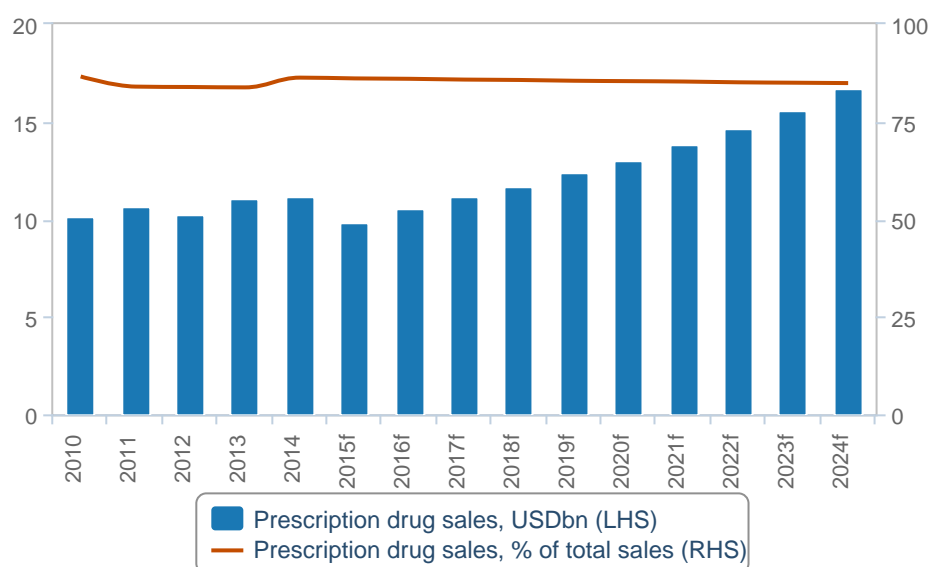
f = BMI forecast. Source: World Health Organization (WHO), BMI

Prescription Drug Market Forecast

BMI View: Prescription drug sales will continue to dominate the Mexican pharmaceutical market over the next 10 years as the country's growing burden of chronic conditions drives its demand for high valued medicine as well as its more affordable generic substitutions. In particular, Mexico's above average consumption rates of generic medicines will ensure that prescription medicines continue to dominate pharmaceutical spending in the country.

Prescription Drug Market Forecast

2010-2024



f = BMI forecast. Source: CANIFARMA, AFAMELA, AESGP, BMI

Structural Trends

We expect the prescription drug market in Mexico to increase from MXN148.9bn (USD11.2bn) in 2014 to MXN233.9bn (USD16.7bn) in 2024, at a compound annual growth rate (CAGR) of 5.2% and 4.1% in local currency and in US dollar terms, respectively. Prescription medicines will account for around 85% of total pharmaceutical expenditure by 2024.

Post-2015, market development will be shaped by the rise in the uptake of generic drugs, which will itself be boosted by the 2015 patent cliff, which will improve government generic substitution policies. Generic drugs are cheaper than patented drugs and thus, although the volume of prescription sales is set to increase, more patients will be willing to accept cheaper generic drug substitutes, which will affect prescription sales growth in terms of value over the long term.

According to doctor groups in Mexico, poor controls mean that patients and pharmacists alter 20% of the country's prescriptions. Drug substitution and dosage changes are more common in the treatment of expensive chronic conditions like hypertension, high cholesterol and diabetes. Most alterations involve cheap 'alternative' medicines being provided instead of expensive patented medicines. It is not clear whether prescriptions are being changed to ease patient spending or allow profiteering by pharmacists.

Acknowledging the cost pressures, Victor Cordova of Mexico's College of Internal Medicine said pharmacists lack medical training and jeopardise patient safety by dispensing unauthorised prescriptions. The General Health Law prohibits anyone that is not a licensed healthcare professional from writing or altering medicine prescriptions.

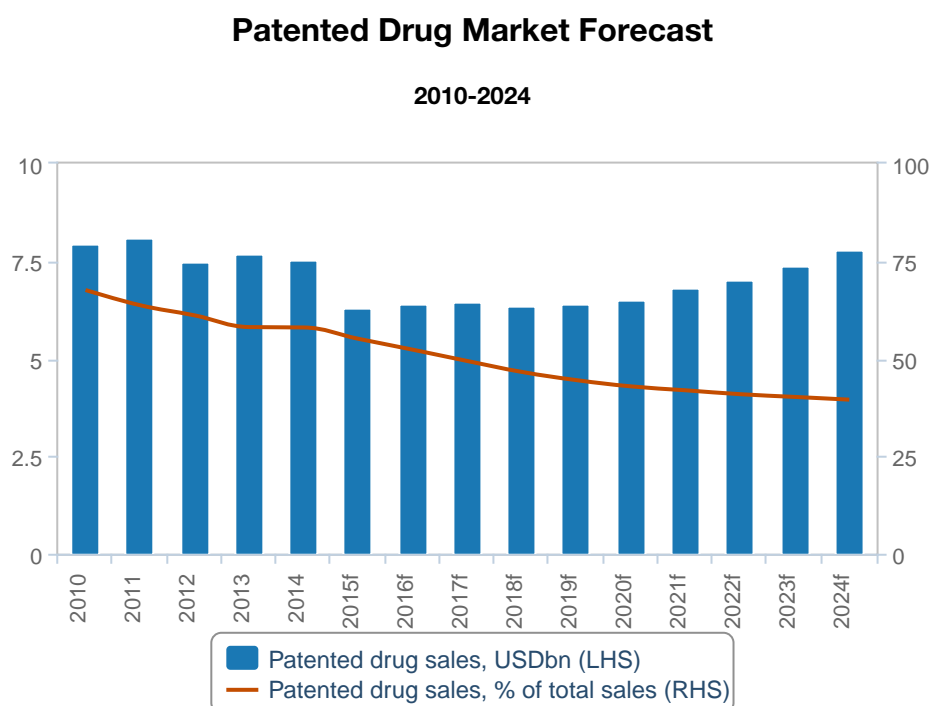
Table: Prescription Drug Market Indicators, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
Prescription drug sales, USDbn	10.688	10.261	11.057	11.187	9.823	10.552	11.204	11.705	12.370
Prescription drug sales, USDbn, % y-o-y	4.81	-4.00	7.76	1.17	-12.19	7.43	6.18	4.47	5.68
Prescription drug sales, MXNbn	132.956	134.959	141.145	148.896	152.743	157.229	162.457	168.549	175.651
Prescription drug sales, MXNbn, % y-o-y	3.19	1.51	4.58	5.49	2.58	2.94	3.33	3.75	4.21
Prescription drug sales, % of total sales	84.0	83.9	83.8	86.3	86.1	86.0	85.8	85.7	85.5

f = BMI forecast. Source: CANIFARMA, AFAMELA, AESGP, BMI

Patented Drug Market Forecast

BMI View: We believe that the lack of a unified reimbursement system, the absence of widespread private health insurance, relatively low healthcare spending and the promotion of generic drugs in Mexico have limited the potential of Mexico's patented drug market.



f = BMI forecast. Source: BMI

Structural Trends

Currently, Mexico's patented drug market is expected to only slightly increase over the next 10 years from MXN100.1bn (USD7.5bn) in 2014 to MXN108.9bn (USD7.8bn) in 2024, with a compound annual growth rate (CAGR) of 0.8% and 0.3% in local currency terms and US dollar terms, respectively.

Although Mexico's Federal Commission for Sanitary Risk Protection (COFEPRIS) has reduced the issue period for innovative drug approval from 360 days to 60 days if medicines are already approved in Europe, Canada, US and Switzerland, innovative drugmakers have to go through additional reviews and price

negotiations from various public institutions, such as the public health sector's insurance provider Instituto Mexicano del Seguro Social (IMSS), Social Services for State Workers (ISSSTE) and Petróleos Mexicanos (PEMEX) oil company insurance programmes.

According to the Pharmaceutical Research and Manufacturers of America (PhRMA), on average in the last four years, only 5% of new medicines submitted for institutional approval (IMSS, ISSSTE and Seguro Popular) have been listed on the key formularies. Furthermore, IMSS approved only four new medicines for reimbursement in 2013 while ISSSTE approved none. We note that in Mexico there are approximately 23mn high-income people that can afford world-class healthcare and treatments; employees often rely on the social security system prepaid through their federal taxes; and 56mn people on low income are expected to rely on Seguro Popular.

Increasing medicine coverage in Mexico's public sector and the promotion of generic drugs has undermined revenue-generating opportunities for innovative drugmakers. Currently the public sector (the IMSS, ISSSTE, Seguro Popular, Pemex and state governments) distribute over 50% of medicines in volume terms in Mexico.

We highlight that low healthcare spending in Mexico is a fundamental factor that hinders the access of innovative medicines in the country. Mexico's healthcare expenditure as percentage of GDP is the lowest among OECD countries. At 6.5% in 2014, it is also significantly lower than other major Latin American countries: Brazil (9.5%) and Chile (7.6%). We expect that it will take a number of years before positive results are felt from the country's oil sector liberalisation. Over the long term, healthier fiscal revenue due to the energy reform will encourage the government to further increase public healthcare spending and improve national healthcare standards.

Table: Patented Drug Market Indicators, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
Patented drug sales, USDbn	8.111	7.476	7.671	7.518	6.287	6.416	6.452	6.362	6.430
Patented drug sales, USDbn, % y-o-y	1.94	-7.83	2.61	-2.00	-16.37	2.05	0.56	-1.38	1.06
Patented drug sales, MXNbn	100.893	98.331	97.923	100.059	97.762	95.592	93.546	91.618	91.300
Patented drug sales, MXNbn, % y-o-y	0.37	-2.54	-0.42	2.18	-2.30	-2.22	-2.14	-2.06	-0.35
Patented drug sales, % of prescription sales	75.9	72.9	69.4	67.2	64.0	60.8	57.6	54.4	52.0
Patented drug sales, % of total sales	63.7	61.1	58.1	58.0	55.1	52.3	49.4	46.6	44.5

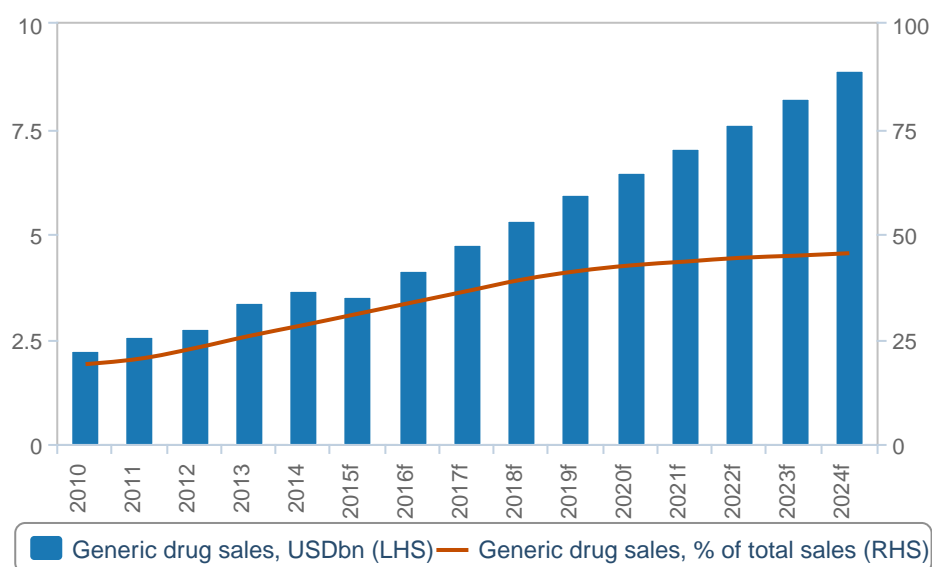
f = BMI forecast. Source: BMI

Generic Drug Market Forecast

BMI View: The rising consumption of generic medicines will reshape Mexico's pharmaceutical industry. We expect the prevalence of generic drugs to increase rapidly over the forecast period - driven by government regulations supporting the sector and rising public awareness of off-patented medicines.

Generic Drug Market Forecast

2010-2024



f = BMI forecast. Source: BMI

Structural Trends

The value of the Mexican generic drug market will increase from MXN48.8bn (USD3.7bn) in 2014 to MXN125.0bn (USD8.9bn) in 2024, reflecting a compound annual growth rate (CAGR) of 9.9% and 9.3% in local currency and US dollar terms, respectively. In 2014, generic medicines accounted for 28% of the total pharmaceutical market. We forecast that by 2019 this will increase to 41% and by 2024 to 45%, showing consistent growth over the next ten years. According to the Federal Commission for the Protection against Sanitary Risk (COFEPRIS), the generic drug market accounted for 52% of Mexico's pharmaceutical market in volume terms in 2012. This increased to 84% in 2014.

Mexico's generic drug sector will continue to expand in value as a result of industry and government initiatives. COFEPRIS has been granted influence over Mexico's general health laws to improve the regulation of generic medicines since 2005. Additionally, in 2013 the Mexican government oversaw revisions to the Agreement for Innovation, which drastically shortens the timeline for generic drug registration. Along with Pan American Health Organization (PAHO) certifications for generic drugs, COFEPRIS has sought to boost the consumption of off-patented medicines through generic drug promotion schemes.

Growing public awareness of generic medicines will fuel demand for off-patented medicines. Market research firm IMS Health states that over 40% of Mexicans will purchase generic equivalents if they are available, driving the motivation for continued generic drug launches in Mexico. With one of the world's highest out-of-pocket medical spending rates, Mexico's citizens will continue to demand inexpensive off-patented medicines.

Table: Generic Drug Market Indicators, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
Generic drug sales, USDbn	2.578	2.785	3.386	3.669	3.536	4.137	4.753	5.342	5.940
Generic drug sales, USDbn, % y-o-y	14.98	8.04	21.59	8.36	-3.64	17.00	14.89	12.41	11.19
Generic drug sales, MXNbn	32.064	36.628	43.222	48.837	54.981	61.637	68.911	76.931	84.351
Generic drug sales, MXNbn, % y-o-y	13.21	14.24	18.00	12.99	12.58	12.11	11.80	11.64	9.64
Generic drug sales, % of prescription sales	24.1	27.1	30.6	32.8	36.0	39.2	42.4	45.6	48.0
Generic drug sales, % of total sales	20.3	22.8	25.7	28.3	31.0	33.7	36.4	39.1	41.1

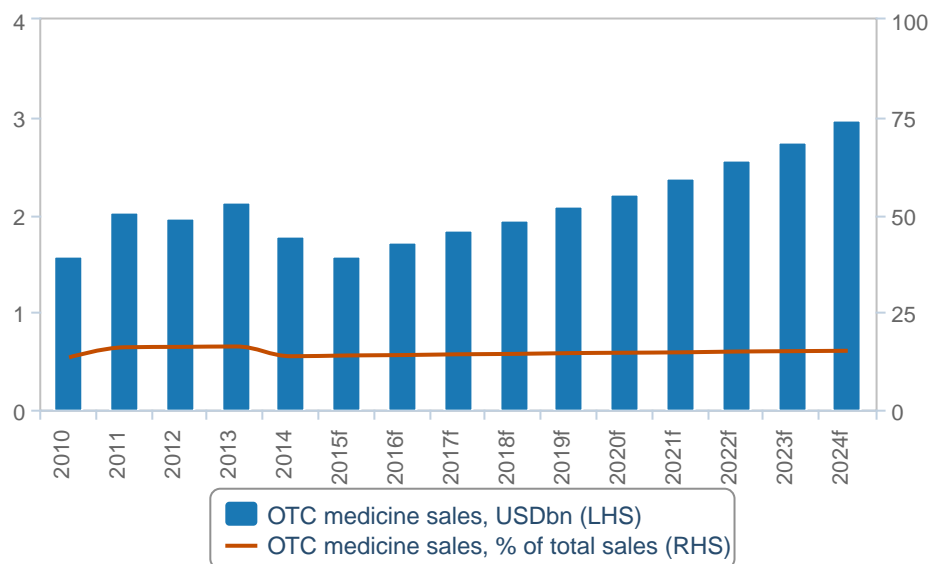
f = BMI forecast. Source: BMI

OTC Medicine Market Forecast

BMI View: Limited household affordability and a growing preference for OTC medicines will ensure that Mexico's demand for non-prescription medications will grow over the long term. As such, the country's appeal to multinational drugmakers focussed on OTC production will improve as Mexico's economy is forecast to maintain inflationary pressures in 2015, limiting consumer spending on health consultations and high-value prescription medicines and ensuring a preference for self medication and OTC medicines. However, we note that prolonged financial pressure brought on by high inflation rates may also lead to a slow-down in the growth of the OTC medicines sector.

OTC Medicine Market Forecast

2010-2024



f = BMI forecast. Source: Association of the European Self-Medication Industry (AESGP), AFAMELA, BMI

Structural Trends

The OTC market will increase from MXN23.7bn (USD1.8bn) in 2014 to MXN41.7bn (USD3.0bn) by 2024, a compound annual growth rate (CAGR) of 5.8% and 5.3% in local currency and US dollar terms respectively. By 2024, the OTC market will account for approximately 14% of the total drug market.

OTC medicine sales in Mexico remain primarily fuelled by the country's low household affordability levels. Limited purchasing power has forced many families to depend upon OTC medicines as they cannot afford doctors' consultations or the higher fees attached to prescription drugs. This has led to a growing culture of self-medication within the country. According to the World Self-Medication Industry, 21% of Mexicans rely on OTC medicines to treat their conditions while 94% of Mexicans report being satisfied with their OTC treatments over prescription drugs.

'Generic' versions of OTC medicines have also become a popularised trend in Mexico. The Mexican pharmacy chain Farmacias Similares, which utilises the slogan 'the same but cheaper', has garnered

significant attention selling cheaper versions of popular OTCs at a fraction of the price of their branded equivalent. These OTC *similares* have, however, received heavy criticism from established OTC drugmakers in Mexico, exhibiting concerns about the safety of these medicines as the term similar implies that such drugs remain unregulated by Mexican authorities.

Competitive Landscape

Multinational pharmaceutical companies including Roche, Bayer, Bristol-Myers Squibb, Perrigo and Boehringer Ingelheim remain the predominant source of OTC medicines in Mexico. With its acquisition of Roche's OTC business, which included the popular Redoxon vitamin C franchise, Bayer has become a leading player in sales in recent years, followed by Bristol Myers Squibb and Boehringer Ingelheim. The country's primary domestic OTC drugmaker is Laboratorios Liomont. Other domestic companies include Compania Internacional de Comercio (CIC), Techsphere and Laboratorios Darier. The country's crowded competitive landscape will ensure a thriving OTC market for Mexico in the coming years, though the optimisation of revenue-generating opportunities will likely be limited for new competitors.

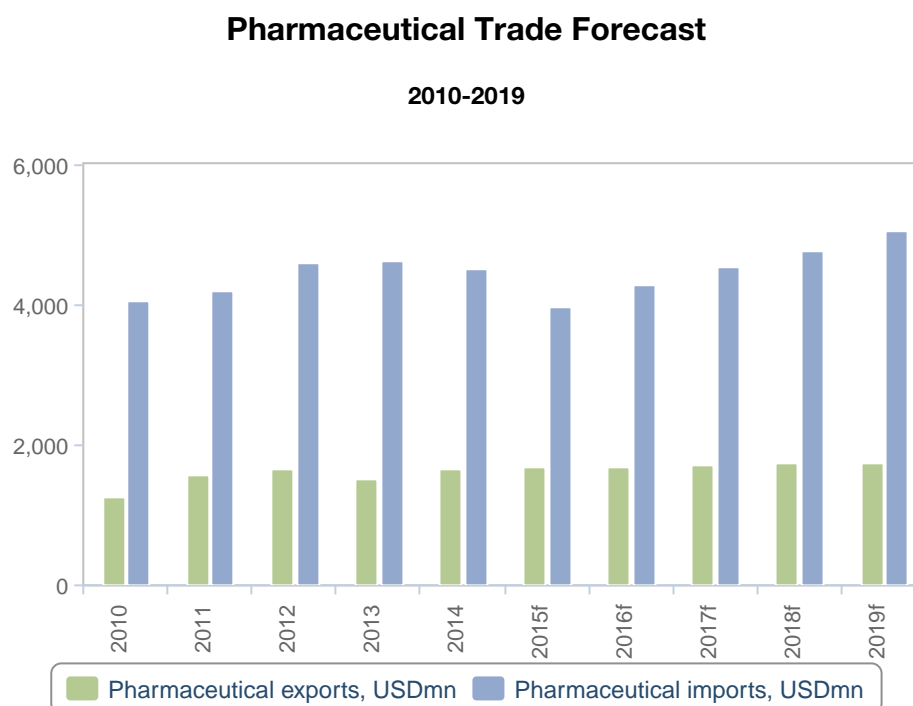
Table: Over-The-Counter (OTC) Medicine Market Indicators, Historical Data And Forecasts (Mexico 2011-2019)

	2011	2012	2013	2014	2015f	2016f	2017f	2018f	2019f
OTC medicine sales, USDbn	2.035	1.967	2.137	1.777	1.581	1.720	1.849	1.955	2.090
OTC medicine sales, USDbn, % y-o-y	29.04	-3.33	8.62	-16.83	-11.04	8.80	7.49	5.72	6.90
OTC medicine sales, MXNbn	25.317	25.878	27.280	23.657	24.587	25.632	26.812	28.150	29.675
OTC medicine sales, MXNbn, % y-o-y	27.05	2.22	5.42	-13.28	3.93	4.25	4.60	4.99	5.42
Over-the-counter (OTC) medicine sales, % of total sales	16.0	16.1	16.2	13.7	13.9	14.0	14.2	14.3	14.5

f = BMI forecast. Source: Association of the European Self-Medication Industry (AESGP), AFAMELA, BMI

Pharmaceutical Trade Forecast

BMI View: Despite increasing rates of pharmaceutical exports, Mexico's negative trade balance will persist over the next five years. The country's demand for foreign finished drugs will remain strong in the absence of a strong domestic manufacturing base.



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

Structural Trends

In August 2015, COFEPRIS, Mexico's Federal Commission for the Protection against Sanitary Risk, announced a 40% increase in medical exports since 2012. The growth has been attributed to Mexico's certification by the Pan American Health Organisation (PAHO), which occurred in 2012, endorsing the safety of the country's pharmaceutical goods. Mikel Arriola, the Director of COFEPRIS notes that 'the increase in exports is a sign that PAHO international certification gives an added value to public institutions, confirms that sanitary control is on track, and encourages competitiveness.'

Mexico's import trade will remain dominant over exports through the next five years while Mexico's domestic pharmaceutical market remains relatively underdeveloped, resulting in a rising demand for foreign finished medicines. In order to begin promoting its own domestic market, the Mexican government is working to develop 'biotech clusters', similar to Cuba's 'scientific poles'. The clusters are meant to operate through public-private partnerships with domestic drugmakers and universities and would be used to boost local medicine discovery and production in the country, affording an increase to drug exports.

Critically, while plans began in 2011 with a USD25mn investment in a new science and technology park in Cuernavaca and a USD29mn investment to the state of Morelos, little known progress has been made since, highlighting its limited influence. While the continued development of such 'clusters' will ultimately help to further increase domestic drug development and export opportunities, contributions will likely be minor over the short-term and Mexico's negative trade balance will be sustained. This will be compounded by the domestic market's historically sluggish development along with the industry's heavy focus on generic drug production, leaving critical demand for foreign innovative medicines, particularly as the country's burden of chronic diseases grows.

Import Forecast

Mexican pharmaceutical imports will grow from a value of MXN60.2bn (USD4.5bn) in 2014 to MXN71.7bn (USD5.0bn) in 2019, resulting in a compound annual growth rate (CAGR) of 3.4% and 2.0% in local currency and US dollar terms, respectively. In 2014, Mexico's top five import partners included the US (USD1.5bn), Germany (USD900mn), France (USD559mn), Switzerland (USD304mn) and Italy (USD215mn). Other top import partners included Canada (USD189mn), Spain (USD112mn), and China (USD99mn).

Export Forecast

Mexico's medicine exports will rise from MXN22.0bn (USD1.7bn) in 2014 to MXN24.9bn (USD1.8bn) in 2019. This will result in a CAGR of 2.5% in local currency terms and 1.2% in US dollar terms. Mexico's top five export partners in 2014 were the US (USD444mn), Switzerland (USD225mn), Panama (USD206mn), Venezuela (USD202mn) and Colombia (USD109mn). Other top export partners include Ecuador (USD77mn), Brazil (USD67mn), and France (USD43mn).

Table: Pharmaceutical Trade Data And Forecasts (Mexico 2013-2019)

	2013	2014	2015f	2016f	2017f	2018f	2019f
Pharmaceutical exports, USDmn	1,502.52	1,651.04	1,675.07	1,696.79	1,716.44	1,734.20	1,750.26
Pharmaceutical exports, USDmn, % y-o-y	-9.81	9.89	1.46	1.30	1.16	1.03	0.93
Pharmaceutical imports, USDmn	4,629.12	4,525.47	3,980.87	4,284.11	4,556.54	4,768.30	5,047.55
Pharmaceutical imports, USDmn, % y-o-y	0.36	-2.24	-12.03	7.62	6.36	4.65	5.86
Pharmaceutical trade balance, USDmn	-3,126.60	-2,874.43	-2,305.80	-2,587.31	-2,840.11	-3,034.10	-3,297.29

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

Table: Pharmaceutical Trade Data And Forecasts local currency (Mexico 2013-2019)

	2013	2014	2015f	2016f	2017f	2018f	2019f
Pharmaceutical exports, MXNmn	19,179.63	21,975.69	26,047.30	25,282.19	24,888.31	24,972.47	24,853.73
Pharmaceutical exports, MXNmn, % y-o-y	-12.47	14.58	18.53	-2.94	-1.56	0.34	-0.48
Pharmaceutical imports, MXNmn	59,090.72	60,234.82	61,902.49	63,833.17	66,069.84	68,663.53	71,675.18
Pharmaceutical imports, MXNmn, % y-o-y	-2.60	1.94	2.77	3.12	3.50	3.93	4.39
Pharmaceutical trade balance, MXNmn	-39,911.09	-38,259.13	-35,855.19	-38,550.98	-41,181.53	-43,691.06	-46,821.45

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

Industry Risk Reward Index

Americas Risk/Reward Index

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/Rewards 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** Q116 Pharmaceutical RRIs, the Americas scores 48.9 out of 100, below Western Europe (66.8) and Asia Pacific (52.1), Central and Eastern Europe (49.6), and the Middle East and Africa (40.3).

For this quarter's update of the Pharmaceutical RRIs, the indicators used to assess the attractiveness of a pharmaceutical market are now visible. This improves the transparency of the index system and enables the identification of regional or group outperformers across single indicators. A market's RRI score is composed of the 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%.

Q116 Americas Pharmaceutical Risk/Reward Index

Rewards and 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	17.9	12.2	30.0	82.9	1
Canada	30.4	16.1	46.5	14.0	11.8	25.8	72.3	2
Puerto Rico	25.2	15.4	40.6	15.4	7.8	23.2	63.8	3
Mexico	28.4	12.6	41.0	11.2	8.4	19.6	60.6	4
Brazil	23.2	13.7	36.9	11.9	8.7	20.6	57.5	5
Chile	22.8	15.0	37.8	6.7	9.9	16.6	54.4	6
Colombia	19.2	12.6	31.8	9.8	8.7	18.5	50.3	7
Argentina	18.8	15.3	34.1	7.0	8.6	15.6	49.7	8
Peru	17.6	12.6	30.2	8.4	8.1	16.5	46.7	9
Cuba	20.0	13.0	33.0	3.9	8.2	12.1	45.1	10
Panama	16.0	13.1	29.1	5.6	9.3	14.9	44.0	11
Ecuador	18.8	9.8	28.6	9.8	5.1	14.9	43.5	12
Costa Rica	17.2	11.8	29.0	5.6	8.6	14.2	43.2	13
Belize	12.8	10.9	23.7	5.6	9.7	15.3	39.0	14
Guatemala	14.8	11.7	26.5	5.6	6.7	12.3	38.8	15
Venezuela	13.6	13.4	27.0	3.9	5.3	9.1	36.1	16
Nicaragua	12.4	10.7	23.1	5.6	5.6	11.2	34.3	17
El Salvador	9.2	11.3	20.5	5.6	7.7	13.3	33.8	18
Honduras	11.2	11.2	22.4	5.6	5.4	11.0	33.4	19
Regional Average	19.4	13.0	32.4	8.4	8.2	16.6	48.9	

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

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 Q116, the US is ranked as the most attractive market in the Americas region

(scoring 82.9 out of 100), followed by Canada (72.3) and Puerto Rico (63.8). In the same quarter, Honduras is ranked as the least attractive market in the Americas region (scoring 33.4 out of 100), followed by El Salvador (33.8) and Nicaragua (34.3).

With regard 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 rating 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, El Salvador scores a total of 20.5 out of 65, the lowest score in the subsector.

Q116 Americas Pharmaceutical Rewards

Industry Rewards And 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	9.6	4.8	30.4	7.2	6.4	2.5	16.1	46.5
Puerto Rico	12.0	12.0	1.2	25.2	8.0	6.4	1.0	15.4	40.6
Mexico	14.0	4.8	9.6	28.4	6.4	3.2	3.0	12.6	41.0
Brazil	16.0	4.8	2.4	23.2	7.2	4.0	2.5	13.7	36.9
Chile	12.0	4.8	6.0	22.8	7.2	4.8	3.0	15.0	37.8
Colombia	12.0	3.6	3.6	19.2	6.4	3.2	3.0	12.6	31.8
Argentina	14.0	4.8	0.0	18.8	8.0	4.8	2.5	15.3	34.1
Peru	8.0	3.6	6.0	17.6	6.4	3.2	3.0	12.6	30.2
Cuba	8.0	4.8	7.2	20.0	6.4	5.6	1.0	13.0	33.0
Panama	4.0	4.8	7.2	16.0	6.4	3.2	3.5	13.1	29.1
Ecuador	8.0	3.6	7.2	18.8	5.6	3.2	1.0	9.8	28.6
Costa Rica	4.0	4.8	8.4	17.2	5.6	3.2	3.0	11.8	29.0
Belize	2.0	2.4	8.4	12.8	4.0	2.4	4.5	10.9	23.7
Guatemala	4.0	3.6	7.2	14.8	4.8	2.4	4.5	11.7	26.5
Venezuela	10.0	3.6	0.0	13.6	7.2	3.2	3.0	13.4	27.0
Nicaragua	4.0	3.6	4.8	12.4	4.8	2.4	3.5	10.7	23.1
El Salvador	2.0	3.6	3.6	9.2	5.6	3.2	2.5	11.3	20.5
Honduras	4.0	3.6	3.6	11.2	4.8	2.4	4.0	11.2	22.4
Regional Average	9.2	5.2	5.1	19.4	6.3	3.9	2.8	13.0	32.4

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

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. These call into question the likelihood of anticipated returns being realised over the assessed time period. With our economic and political assessment, only the aspects most relevant to the pharmaceutical industry are incorporated. Focusing on the Risks component of the rating system, Venezuela scores a total of 9.1 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 30.0 out of 35, the highest score in the subsector.

Q116 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	5.3	6.3	17.9	2.6	2.4	2.8	2.7	1.8	12.2	30.0
Canada	4.9	4.9	4.2	14.0	2.2	2.7	2.5	2.5	1.8	11.8	25.8
Puerto Rico	5.6	4.2	5.6	15.4	1.7	1.8	1.2	1.5	1.6	7.8	23.2
Mexico	3.5	3.5	4.2	11.2	1.9	2.4	1.9	1.6	0.7	8.4	19.6
Brazil	3.5	3.5	4.9	11.9	2.6	2.1	1.4	1.5	1.2	8.7	20.6
Chile	2.8	1.8	2.1	6.7	2.2	2.7	1.5	1.9	1.6	9.9	16.6
Colombia	2.8	3.5	3.5	9.8	2.3	2.4	1.6	1.5	0.8	8.7	18.5
Argentina	2.1	1.4	3.5	7.0	2.4	2.1	1.4	1.4	1.4	8.6	15.6
Peru	2.8	2.8	2.8	8.4	2.1	2.1	1.3	1.4	1.1	8.1	16.5
Cuba	0.7	1.1	2.1	3.9	1.9	2.4	1.5	1.5	0.8	8.2	12.1
Panama	1.4	2.1	2.1	5.6	2.3	2.1	2.0	1.7	1.2	9.3	14.9
Ecuador	2.8	3.5	3.5	9.8	1.7	0.9	1.0	0.9	0.7	5.1	14.9
Costa Rica	1.4	2.1	2.1	5.6	2.2	2.1	1.2	1.5	1.6	8.6	14.2
Belize	1.4	2.1	2.1	5.6	1.8	2.4	1.9	1.6	2.0	9.7	15.3
Guatemala	1.4	2.1	2.1	5.6	1.8	1.5	1.4	1.1	0.9	6.7	12.3
Venezuela	0.7	1.1	2.1	3.9	1.9	1.2	1.1	0.7	0.3	5.3	9.1
Nicaragua	1.4	2.1	2.1	5.6	1.3	1.2	1.3	1.0	0.8	5.6	11.2
El Salvador	1.4	2.1	2.1	5.6	1.7	2.1	1.5	1.4	1.1	7.7	13.3
Honduras	1.4	2.1	2.1	5.6	1.3	1.5	1.2	0.9	0.5	5.4	11.0
Regional Average	2.5	2.7	3.1	8.4	2.0	2.0	1.6	1.5	1.1	8.2	16.6

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

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.

Q116 Americas Pharmaceutical Risk/Reward Index

Rewards And 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	85	87	86	83	1
Canada	69	77	72	67	85	74	72	2
Puerto Rico	57	73	62	73	56	66	64	3
Mexico	65	60	63	53	60	56	61	4
Brazil	53	65	57	57	62	59	58	5
Chile	52	71	58	32	71	47	54	6
Colombia	44	60	49	47	62	53	50	7
Argentina	43	73	52	33	62	45	50	8
Peru	40	60	46	40	58	47	47	9
Cuba	45	62	51	18	59	34	45	10
Panama	36	62	45	27	67	43	44	11
Ecuador	43	47	44	47	37	43	44	12
Costa Rica	39	56	45	27	61	40	43	13
Belize	29	52	36	27	69	44	39	14
Guatemala	34	56	41	27	48	35	39	15
Venezuela	31	64	42	18	38	26	36	16
Nicaragua	28	51	36	27	40	32	34	17
El Salvador	21	54	32	27	55	38	34	18
Honduras	25	53	34	27	39	31	33	19
Average	44	62	50	40	59	47	49	

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

Mexico Risk/Reward Index

Mexico scores 60.6 in **BMI**'s Pharmaceutical and Healthcare Risk/Reward Index (RRI), making it the fourth-most attractive pharmaceutical market in the Americas. Its score and ranking are unchanged from our assessment for the previous quarter. Both reward and risk components are above the regional average indicating a market with strong potential for returns and relatively stable political and regulatory environment.

Rewards

Industry and Country Rewards scores are weighted and combined to form the score for overall rewards. Mexico's Rewards score of 41.0 remains above the regional average, which is 32.2 this quarter.

Industry Rewards: As well as its large size, Mexico has higher per capita pharmaceutical expenditure than most other markets to its south. It also has relatively high prices, albeit partially owing to inefficiency in the distribution sector, coupled with a fragmented retail sector. Nevertheless, the market is forecast to grow at a higher rate in US dollar terms than in local currency through to 2019. Therefore, the country scores 28.4, well above the regional average of 19.4.

Country Rewards: Mexico has a rapidly growing population and, while its people are living longer, its ratio of pensioners to workers remains lower than in most developed countries. Key growth constraints include a large and impoverished rural population, underserved urban poor and a lack of hospital and clinical infrastructure. The latter is the key factor limiting the ability of the government to translate increased healthcare coverage to delivery of services and consequent improvements in health indicators. That said, the country scores a lower than average, 12.6. Mexico is making efforts though to extend healthcare coverage across the country, which will boost pharmaceutical consumption and healthcare growth.

Risks

Industry and Country Risk scores are weighted and combined to form the score for overall risks. Mexico's score of 19.6, despite being above the regional average of 16.6, continues to indicate some risk to multinationals, with corruption being one of the major unresolved issues. Criminals are known to hijack legal medicine deliveries or loot pharmacies, then going on to selling the products illegally. Consequently, the need for private security is a well-known overhead cost for manufacturing operations in Mexico.

Industry Risks: One of the Mexican market's key attractions is its relatively advanced intellectual property protection in comparison with other Latin American markets, with the exception of Puerto Rico. However, rules are often poorly enforced on the ground and there is a lack of coordination between regulatory and oversight bodies, particularly the patent office and drug regulator. Therefore, Mexico scores an 11.2.

Country Risks: An important test moving forward will be the regulator's ability to upgrade its market authorisation dossiers over the next few years to meet far more stringent bioequivalence rules. The country's score reflects a substantial increase in medicines available through state programmes, but it also has huge and entrenched inequalities, with necessary medicines inaccessible to millions of poorer Mexicans. The country has a relatively free pricing environment based on international prices, though the government has put increasing pressure on manufacturers and wholesalers to lower their prices for state purchasers. Price controls remain off the agenda for now, as the government is opening up key parts of the state pharmaceutical market to greater competition and encourage the use of bioequivalent generic drugs. The country scores an 8.4 in country risks, just higher than the regional average of 8.2.

Regulatory Review

Mexico's Federal National Commission for Protection against Health Risks (Comisión Federal para la Protección contra Riesgos Sanitarios [COFEPRIS]) is decentralised from the Ministry of Health (Secretaría de Salud, SS). It regulates pharmaceuticals and health technologies, occupational and environmental exposures, basic sanitation, food safety and health-related advertisements. Since October 2010, the agency has been undergoing a process of modernization to assist with increasing both pharmaceutical productivity and accessibility in the country.

To the benefit of drugmakers, COFEPRIS has taken a 'more proactive' approach to expand the supply of innovative medicines in Mexico. In March 2014, COFEPRIS shortened the pre-approval time for clinical trials from three months to one month. In August 2014, the World Health Organization also recognised COFEPRIS for its regulatory support of vaccines in Mexico.

However, it still takes an average of 4.3 years for innovative drugs to enter the public healthcare sector in Mexico, according to a study from the primary market research firm IMS Health. This time period is much longer than the two year period in the UK and Japan, 1.8 years in France, and one year in the US and Germany. Within Latin America, Mexico's public sector is even lagging behind Brazil (average 3.4 years) with respect to accessing new medicines.

COFEPRIS has introduced an electronic system for product registration applications, using the National Register of Accredited Persons (RUPA), the Advanced Electronic Signature (FIEL), and the electronic payment tools, is believed to make a significant contribution to saving time and resources, while improving the speed of patients' access to medicines. Additionally, the ministry hopes the service will promote anti-corruption efforts, transparency and flexibility in the registration process, offering greater transparency and allowing the sponsor to monitor the evaluation process.

Advertising

Prescription drugs can only be advertised to healthcare professionals, following guidelines approved by SS. Non-prescription medicines may be advertised to the general public in any media, but must include a written or spoken warning, this being 'consult your physician' ('Consulte a su médico'), along with other warnings determined by SS. Any warning information has a specific letter type, colour and size.

Advertisements need to be approved by SS. Within SS, the Directorate of Advertising Control and COFEPRIS co-operate to ensure advertising standards. AFAMELA, the association of non-prescription producers, has its own Code of Advertising Practice. Since April 2003, AFAMELA's members are exempt from SS approval, providing they comply with AFAMELA's Code. The use of Direct-To-Consumer (DTC) advertising is not approved in Mexico.

In January 2015, Mexico's Ministry of Health and the Federal Commission for the Protection Against Sanitary Risk (COFEPRIS) reported the removal of 119,000 irregular advertisements throughout 2014. All were found to be in violation of Mexico's health legislation. COFEPRIS also removed 1,585 advertisements from medical equipment and food supplement companies. Throughout 2014, these irregular advertisements accrued fines that exceeded MXN70mn (USD4.7mn).

Intellectual Property Issues

The Mexican Institute of Industrial Property (IMPI - Instituto Mexicano de la Propiedad Industrial) was created in 1993. IMPI is responsible for patents and trademarks. An Industrial Property Law (LPI - Ley de Propiedad Industrial) was passed by the government in June 1991, under which patent protection was extended to pharmaceutical processes and products.

Mexico's pharmaceutical market is well placed to satisfy international intellectual property (IP) patent standards. However, developed-world reforms in a developing-world context have created a black market for low-cost medicines. **BMI** believes that unless the government balances the need for patent rights with the need for affordable medicine prescriptions, Mexicans will continue to turn to self-medication and self-prescription to offset rising costs. While IP developments have improved the business environment significantly for patent holders, they have failed to provide Mexicans with affordable medicines.

For its part, COFEPRIS points out that many patent-infringing copied products, known locally as *similares*, on the market have been around for 60 years or more and pose a substantial public health threat. **BMI** notes the Mexican market is unique in that many patients, in an attempt to protest against the high prices of authentic drugs, choose to purchase drugs from the black market, regardless of the legal and quality standards of the medicine.

PhRMA has released its Submission for 2015. Mexico remains on the Watch List. The association highlighted that it is imperative that Mexico review and update its current pharmacovigilance regulations, given the recent inter-institutional agreements allowing for recognition of COFEPRIS in some Latin American countries. Other main concerns continue to be over Mexico's IP protection and market access

delays. Although PhRMA members have appreciated the increasing anti-counterfeiting achievements from Mexico's regulatory agencies, they require more investigations and consequent prosecutions of pharmaceutical counterfeiting crimes.

Mexico has been listed as a Watch List country by PhRMA for more than five years, generating continued concern around the country's patent law enforcement. The United States Trade Representative (USTR) has also named Mexico as a Watch List country in 2015. Mexico has maintained this status since 1999 as USTR remains cautious in regard to the country's application of general intellectual property regulation.

PhRMA members have recognised Mexico's commitment to strong IP protection within the Trans-Pacific Partnership (TPP) agreement. **BMI** notes that Mexico is in favour of supporting the maintenance of 20-year patent protection and tightening the IP right regulation in the country, despite the fact that TPP allows the period of patent protection for innovative drugs to be shortened in developing countries like Malaysia, Vietnam and Mexico.

However, PhRMA members remain concerned with the apparent distinction made by the regulatory authorities between the provision of regulatory data protection (RDP) to small and large molecule drugs. 'It is the view of the innovative biopharmaceutical industry that, consistent with TRIPS, RDP should be provided regardless of the manner in which the medicine is synthesized.'

A lack of verification for patent infringement and an inability to remove any such infringing products continues to threaten patents being utilised in Mexico. PhRMA has recommended uniform criteria for the provision of data protection consistent with the court precedent issued in the Linkage Decree but changes have yet to occur.

The 'Bolar' exemption has also generated concern from innovative drugmakers. The 'Bolar' exemption allows for the import of active pharmaceutical ingredients (APIs) and raw materials for Mexican generic drugmakers. A failure to impose limits on these imports has led to serious concern surrounding potential abuse of the exemption, allowing for stockpiling or selling of patent-infringing medicines in Mexico.

Mexico currently utilises a five-year registration renewal process, significantly exceeding the stated time frame for formulary inclusion. PhRMA states that such an excessive timeframe generates 'delays beyond the control of the research based industry, contributing to the unavailability of new pharmaceutical therapeutic options for Mexican patients'. This concern is warranted as only 5% of innovative medicines submitted for approval have been listed on key formularies in the last three years.

Counterfeit Medicines

Counterfeit medicines have also caused significant problems in the Mexican pharmaceutical market. The regulatory authorities in Mexico are not coherent in their definitions of patented, generic and OTC medicines. This, coupled with a lack of clear policy alignment to eliminate *similares* (copy products) from the market, represents some of the shortcomings of the country's operating environment. Worse, issues regarding counterfeit medicines (the supply, distribution or records of adverse drug reactions) are not handled by a single, designated authority and therefore implementing existing anti-counterfeiting policies is a seemingly protracted effort with limited results.

The distinction between prescription and true OTC drugs is also blurred in practice. This is not due to an unclear distinction, but rather lax law enforcement and a general prevalence of pharmacists selling prescription drugs as OTC or illegal under-the-counter (UTC). Some 40% of all retail sales take place without prescriptions.

COFEPRIS has identified 'red zones' where stolen medicines are commonly destined, including the areas of El Santuario, Jalisco, Baja California, Tepito, Tijuana and Sahuayo. **BMI** notes that the disorganised efforts made by various health authorities and policing must be urgently addressed to eradicate such zones.

Pricing Regime

The Ministry of Economy (SE) has regulated the prices of patented medicines since 2005. The terms of the regulation are defined by the Programme of Modernisation of the Pharmaceutical Industry in Terms of Prices (PROMIF - Programa de Modernización de la Industria Farmacéutica en Materia de Precios) agreed in October 2004. Pharmaceutical companies participate voluntarily. They must report the maximum retail price for the patented drug and information about ex-manufacturers' prices in the six most important markets where the drug has the highest sales. These six markets are used to estimate the international reference price. The maximum retail price for the drug must not exceed the estimated international reference price.

According to the SE, only 3.3% of the private pharmacy sector by volume has drug prices registered under the pricing system. The remaining 96.7% have their prices liberated. Therefore, growth in the private pharmacy sector by value has increased at a higher rate than by volume in recent years. The industry has been dissatisfied with the existing pricing system since 2005. Some organisations consider that other initiatives should be put in practice to bring patented drug prices down, including the development of the

national pharmaceutical industry and increasing consumption of generic medicines. It has also been discussed whether wholesale margins are too high in the final cost of pharmaceuticals at retail prices.

The Mexican Association of Pharmaceutical R&D Industries (AMIIF) has asked for the savings obtained via centralised purchases to be invested in additional drug purchases. AMIIF has also asked for public institutions to have an annual pharmaceutical expenditure plan, in order to help their members to assess production and import needs. Public institutions mainly buy patented medicines by volume, not by tender, as the patent holder is only one company. However, when the contract is going to be signed, some public institutions reduce their volume needs, bringing prices up. AMIIF has also asked to have a clause for special market conditions, such as economic recession or devaluation, in order to reduce the discount percentage if needed.

According to AMIIF, patented drugs represent between between 13% and 15% of the public sector by volume. By investing any savings obtained via centralised purchases, AMIIF believes that the market share of patented drugs in the public sector would only increase by one or two percentage points. Some specialists estimate savings of around MXN5bn (USD466.1mn) per year. However, the impact will be minimal regarding the composition of the public sector. The commission will benefit small providers particularly. Transparency is another reason to use the commission, as some state and municipal institutions acquire their drugs from private pharmacies or small wholesalers, resulting in drug overspending.

Reimbursement Regime

The lack of a unified reimbursement system and the absence of widespread private health insurance have limited the market's potential in the past. The private insurance system has been criticised on a cost basis, requiring 12 significant insurers and the accompanying administrative costs. The main thrust of the reform has been to extend coverage through subsidies and state-run programmes, but these have been criticised as grossly inefficient.

In the meantime, endemic self-medication and a lack of prescription controls in many pharmacies have created distortions in the market, leaving many chronic conditions untreated. Many of the 7 leading products are related to changes in diet and lifestyle. For example, soaring sales of ED products are partly attributable to the near-epidemic levels of diabetes in Mexico, indicating that underlying conditions routinely go untreated. A number of drugs for treating obesity, including higher-priced new medicines, have been launched in Mexico. However, it is unlikely that many of these will reach the poorest segments of the population, where obesity is particularly prevalent.

The expanding national drug procurement scheme in Mexico will continue to provide improved pharmaceutical access for patients nationwide. The Mexican Ministry of Health has announced that its annual consolidated procurement of pharmaceuticals will be valued at MXN48bn (USD2.8bn) in 2015. The bulk purchasing, which will supply pharmaceuticals to Mexican patients throughout 2016, involves 21 of the 31 Mexican states and is cited as experiencing a 9% growth in value compared to the 2014 purchase. The government notes that this procurement of medicines guarantees medical supplies for the population for 2016.

Mexico's drug procurement system has been in effect since 2013, with this 2015 purchase being its third procurement. In this time the scheme has grown to include 21 Mexican states, after beginning with only 5 states in its first year and 16 in its second year. The Ministry of Health has highlighted that in the first two years of procurement, the government experienced savings of MXN8.4bn (USD501mn). Increasing the volume of purchases remains a critical objective for the Mexican government as it provides value savings and underscores the public health system's ability to increase pharmaceutical access for patients in need.

Value savings and patient accessibility will be of particular concern for the Mexican government in coming years as BMI's Country Risk team expects a slight slowdown for the country's economic outperformance in 2016. This will be compounded by the country's growing burden of chronic diseases, namely diabetes and cardiovascular diseases, ensuring a rising medical demand. Large-scale federal drug procurements will therefore remain a necessary venture to ensuring medical treatment in the midst of tempered economic expansion, particularly as the government accounts for the majority of healthcare expenditure in the country. However, the country's still generally positive economic outlook will allow Mexican states to continue committing local government funding to the national scheme, affording commercial opportunities for pharmaceutical companies.

The 2015 drug procurement value of MXN48bn accounts for 28% of total pharmaceutical spending in Mexico in 2014 in local currency terms, highlighting the significance of this scheme.

Market Overview

The government's efforts to improve competitiveness in Mexico's pharmaceutical sector combined with the country's economic outperformance over large countries like Brazil in 2015 will improve Mexico's attractiveness to drugmakers. As such, Mexico's consumer demand growth has started to pick up, which could be a substantial driver of a more consumer-driven economy. However, overdependence on US economic cycles has limited investment in the domestic pharmaceuticals market.

Mexico is one of the largest consumers of generic medicines in the world and is home to the second largest pharmaceuticals market in Latin America, after Brazil. Pharmaceuticals accounted for 16.0% of healthcare spending in 2014 with MXN172.55bn (USD12.96bn) in sales. In 2014, the country's per capita spending amounted to USD103 while pharmaceutical sales as a percentage of GDP came to 1%.

In 2014 Mexico spent MXN1,076.00bn (USD80.84bn) on total healthcare expenditure. In 2014 Mexico's per capita spending was USD645, while the percentage of healthcare expenditure on GDP came to 6%. Public healthcare spending amounted to MXN563.89bn (USD42.37bn).

According to **BMI's Burden of Disease Database** (BoDD) communicable diseases are in decline while non-communicable diseases are seeing a significant increase. The number of disability adjusted life years (DALYs) lost to non-communicable diseases will increase from 9.9mn in 2014 to 10.7mn in 2030, a rise of 8%. However, the number of DALYs lost to communicable diseases will significantly decrease, from 1.6mn to 1.0mn - a decline of 38%. The highest burden of disease currently comes from diabetes, cardiovascular disease, cancer, and neuropsychiatric conditions.

Foreign companies continue to invest in Mexico's emerging market, taking advantage of the country's high consumption rate of branded medicines as well as its newer uptake in generic drugs. Pfizer, GlaxoSmithKline, Roche, Bayer, and Bristol-Myers Squibb are just a few companies which continue their business in Mexico. Domestic players include Genomma Labs, Laboratorios Diba, and Laboratorios Limont.

Healthcare Sector

According to former health secretary José Ángel Córdova Villalobos, the country's healthcare provision has improved. The health secretariat's budget for its Seguro Popular health scheme gives adequate funds for new clinics, hospitals and other subsidies. He indicated that generic substitution would become a more

prominent issue, with implications for pricing controls for the same medicines in the public and private health sectors.

Table: Healthcare Resources (Mexico 2009-2014)

	2009	2010	2011	2012	2013	2014
Hospitals, total	4,332	4,388	4,402	4,381	4,406	4,430
Hospitals, public	1,222	1,244	1,314	1,312	1,335	1,366
Hospitals, private	3,110	3,144	3,088	3,069	3,071	3,063
Hospitals, beds	114,190	119,506	120,416	120,076	121,939	123,957
Hospitals, beds, per '000 population	0.98	1.01	1.00	0.98	0.99	0.99

Source: BMI Espicom

Table: Healthcare Personnel (Mexico 2009-2014)

	2009	2010	2011	2012	2013	2014
Physicians, total	232,796	238,784	253,976	258,800	267,848	277,120
Physician, per '000 population	1.99	2.01	2.11	2.12	2.16	2.21
Nurses, total	279,946	291,259	306,917	321,789	333,204	347,510
Nurses, per '000 population	2.40	2.46	2.55	2.64	2.69	2.77
Dentists, total	12,101	13,225	13,451	13,677	14,494	15,150
Dentists, per '000 population	0.08	0.08	0.08	0.08	0.08	0.08
Pharmacists, total	58,407	59,308	60,182	61,035	61,870	62,692
Pharmacists, per '000 population	0.50	0.50	0.50	0.50	0.50	0.50

Source: BMI Espicom

Table: Healthcare Activity (Mexico 2009-2014)

	2009	2010	2011	2012	2013	2014
Public inpatient admissions, '000	7,342.24	7,238.26	7,454.45	7,617.86	7,785.05	7,956.11
Public inpatient admissions, per '000 population	62.85	61.02	61.93	62.41	62.91	63.45
Hospitals, average length of stay, days	3.6	3.5	3.6	3.6	3.6	3.6
Surgical procedures, '000	4,346.73	4,285.17	4,413.16	4,509.90	4,608.88	4,710.15
Outpatient visits, '000	315,764.50	317,002.81	326,632.30	335,088.15	343,766.55	352,673.47
Outpatient visits, per '000 population	2,703.10	2,672.48	2,713.68	2,745.03	2,778.13	2,812.71

Source: BMI Espicom

Mexico is also one of Latin America's most developed health insurance markets, but the state sector continues to crowd out private players. Approximately 88mn Mexicans have health insurance through the IMSS, the government operated a reimbursement scheme for approximately 47mn formally employed workers, or through the ISSSTE.

Mexico's private sector currently accounts for 90% of pharmaceutical spending as private insurance holders tend to consume greater amounts of branded drugs. However, 92% of private healthcare expenditure is out-of-pocket spending, which is forcing many to favour Mexico's public healthcare scheme, Seguro Popular (SP).

SP is a public voluntary insurance programme that has offered free healthcare since 2004. The scheme was designed to tackle widespread inefficiencies and inconsistencies in the country's healthcare system, and aimed to provide health insurance coverage for those in Mexico who were not already covered by another programme.

SP has seven main components:

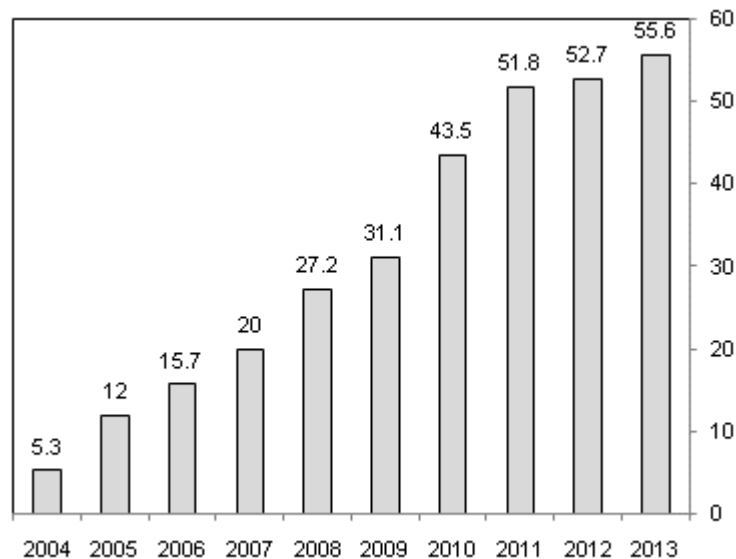
- The System of Social Protection in Health (SPSS - Afiliación al Sistema de Protección Social en Salud) provides public and voluntary health insurance to people who are not beneficiaries of any other health social security institution.
- The Fund for Protection against Catastrophic Expenses (FPGC - Fondo de Protección contra Gastos Catastróficos) finances high cost diseases.
- The Medical Insurance for a New Generation (SMNG - Seguro Médico para una Nueva Generación) aims to reduce the incidence of diseases and disabilities in children aged less than five years. It covers

128 infant diseases for children born after December 1 2006, additional to those covered by FPGC and CAUSES.

- The Healthy Pregnancy (Embarazo Saludable) provides health insurance to children and mothers during pregnancy, delivery and puerperium.
- The Opportunities (Oportunidades) strategy provides a free health basic package to promote nutritional vigilance and control, and encourage healthcare. It covers children aged between six and 59 months, pregnant women and the lactancy period.
- The National Programme of External Surgeries (PNCE - Programa Nacional de Cirugía Extramuros) provides general surgery, ophthalmology, orthopaedics and reconstructive surgery services for people that do not have regular access to surgical services.

Seguro Popular Enrolment Growth Rate

2004-2013



Source: World Health Organization, WorldBank, US Department of Justice, Harvard University, Journal Of Health Economics

BMI believes regular access to healthcare through social protection schemes will directly contribute to the fight against poverty by avoiding out-of-pocket payments, preventing debts and the sale of family assets, thereby freeing up resources for needy families. According to the Ministry of Health, the use of Seguro Popular has significantly reduced out-of-pocket healthcare spending for families, resulting in an 11% reduction of household spending on medical services in Mexico in 2014.

However, the Ministry of Health, the IMSS and the ISSSTE each negotiate their own purchasing and distribution contracts. In the case of Seguro Popular, the country's largest scheme, which is said to cover 90% of the insured, procurement is left to individual states. As a result, an otherwise cohesive healthcare policy is fragmented into contrasting regional clusters with little or no collaboration, leading to an increased problem of medicine shortages in public pharmacies.

The private health insurance sector remains stunted by the dominance of the public sector, capturing a share of only 5% in overall healthcare reimbursement. Private healthcare retains strong growth despite this as Mexico's medical tourism sector grows. In order to boost the national economy and grow its pharmaceutical and healthcare markets, Mexico's government has looked to boost its medical tourism, which is in direct conflict with Cuba's cheaper prices. Its strategy to encourage US patients to come across the border is expected to increase the country's US dollar revenue.

Its high-tech hospitals with international accreditation have received many foreign patients seeking cost-effective medical treatments. However, we believe that the expected increase in the number of medical tourists will put more pressure on existing medical facilities and medical staff. Foreign medical service companies and patients have found the Mexican health tourism sector to be a particularly attractive prospect, with fewer barriers to entry, a ready market and existing healthcare infrastructure. The potential savings range from 20% to 90% reductions in price compared with US inpatient prices, depending on the type and location of the procedures. However, we note that the lower cost of healthcare services is not necessarily the main driver of medical tourism - the availability and quality of the treatments, as well as factors such as political stability also dictate a patient's choice to travel to another country for medical treatments.

However, in March 2015, eight plastic surgery facilities in Mexico, settled in premier medical tourism locations, like Cancun, were fully or partially shut down due to health violations, suggesting that Mexico's status as a premium medical destination is yet to be fully developed.

Mexico has also been working to improve medical infrastructure throughout the country. In February 2015, the government invested MXN56mn (USD) to expand public health laboratories, neonatal intensive care units and a clinical laboratory and hospital for woman and palliative care. Investment in healthcare infrastructure will continue in 2015 and coming years as the government maintains its focus on refurbishing medical facilities in the country.

Table: List Of Hospitals In Mexico With Joint Commission International Accreditation

Organisation	Location	Accreditation/ Certification	Status
Asisteeo Mexico S.A. de C.V.	Mexico City	Care Continuum Program	Accreditation Expired March 15 2015
Centro Oncologico de Chihuahua	Chihuahua	Ambulatory Care Program	Since April 12 2014
Clinica Cumbres Chihuahua	Chihuahua	Ambulatory Care Program	Since April 23 2008
Hospital Angeles Chihuahua	Chihuahua	Hospital Program	Voluntarily Withdrawn from Accreditation August 30 2015
Hospital Angeles Valle Oriente	Nuevo Leon	Hospital Program	Since December 19 2008
Hospital Galenia	Cancun	Hospital Program	Since October 05 2012
Médica Sur S.A.B. de C.V.	Mexico City	Hospital Program	Since May 10 2014
The American British Cowdray Medical Center IAP - Observatorio Campus	Mexico City	Hospital Program	Since December 06 2008
The American British Cowdray Medical Center IAP - Santa Fe Campus	Mexico City	Hospital Program	Since December 12 2008

Source: Joint Commission International

Research And Development

It is **BMI's** view that governments in emerging markets are increasing investment in local biopharmaceutical R&D as they become increasingly aware of the importance of the sector to promoting economic growth and fostering global competitiveness. Improving R&D can also ultimately result in reductions to the financial burden of disease on local citizens by improving access to innovative medicines.

This percentage is expected to increase, as the country works to increase access to medicines and advance local R&D to further its global competitiveness. With a growing pool of skilled labour, government incentives and the country's demographic trends favouring clinical research, **BMI** believes that Mexico is set to become a hub for early and late phase pharmaceutical development in the long term. Over the past decade, the National Council for Science and Technology, the principal government funding agency for scientific research in Mexico, has actively encouraged public-private partnerships between the Mexican government, academia and industry.

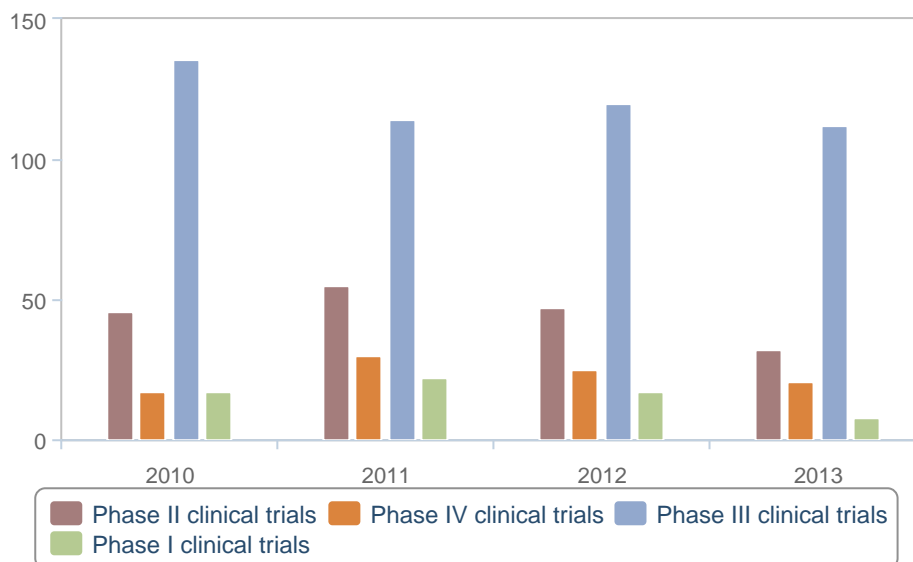
Mexico's biopharmaceutical sector employs nearly 25,000 people at more than 32 biotechnology companies. The number of highly skilled workers entering the marketplace is predicted to continue to increase steadily. Nonetheless, Mexico's progress has been hindered by institutional shortcomings, and regulatory agencies have been criticised for their weak reinforcement of regulations. This is a challenge that remains unaddressed, as the public institutions remain underfunded and lack well trained and experienced staff.

Clinical Trials

The presence of clinical trials in Mexico has seen slight declines in recent years, with the total number of clinical studies conducted in the country falling from 208 in 2009 to 173 in 2014. The decline in clinical trial numbers occurred primarily in 2012 - the same year that the country's economic expansion began to see signs of a slowdown. However, Mexico's status as an economic outperformer has begun to pick up once again, highlighting the country's likelihood for increased clinical trial figures. The most common type of research conducted in Mexico is Phase III trials, accounting for 59% of all clinical trials conducted since (710 of 1,203). Phase II and IV remain the next most prevalent clinical trials in the country.

Clinical Trial Registrations

2009-2013 (2010-2013)



N.B. Sourced by date of initial registration. Includes clinical trials of drugs, medical devices, surgical procedures and behavioural interventions. Source: ClinicalTrials.gov, BMI

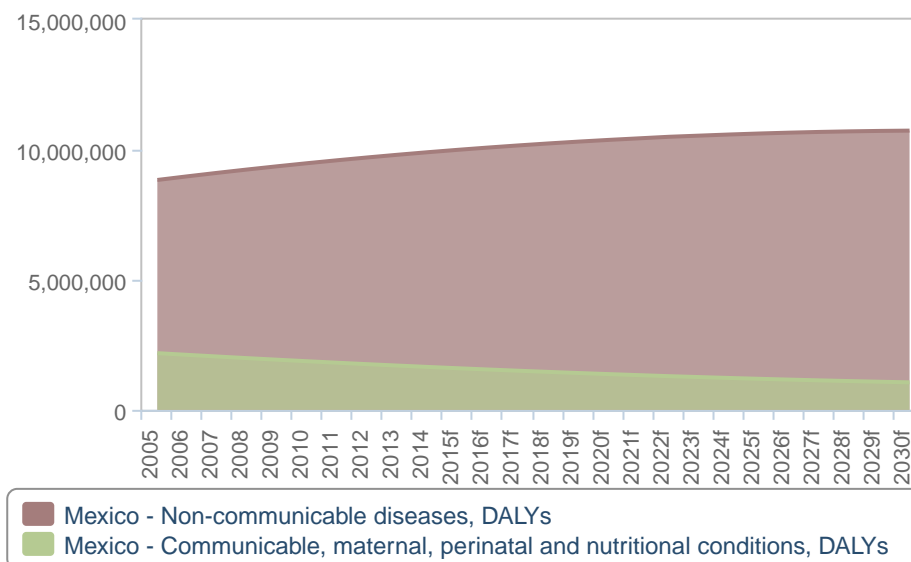
COFEPRIS acts as the regulatory authority for clinical trials and is acknowledged by the Pan-American Health Organisation (PAHO) and World Health Organization as a National Regulatory Authority of Regional Reference of Medicines and Biological Products. In March 2014, COFEPRIS changed its clinical research protocol to reduce the pre-approval time for clinical trials from three months to one month. COFEPRIS has also authorised the National Institutes of Health, as well as speciality hospitals, to assist its clinical trial evaluation process. We believe that the new policy designed to tackle the regulatory issues will improve Mexico's clinical trial regulation regime, if reinforced properly.

Epidemiology

Mexico's epidemiological profile will ensure that it remains an attractive destination for pharmaceutical manufacturers. The country will continue to see significant rises in chronic diseases over the coming years, despite national campaigns to improve general healthcare. Mexico's growing disease rates will, therefore, generate increased demand for medicines, improving investment opportunities for drugmakers.

Burden Of Disease Projection

2005-2030



f = forecast. DALYs = disability-adjusted life years. Source: BMI's Burden of Disease Database (BoDD)

According to **BMI's** BoDD, Mexico is currently experiencing increases in the burden of non-communicable diseases while the burden of communicable diseases is declining. The number of DALYs lost to non-communicable diseases will increase from 9.9mn in 2014 to 10.7mn in 2030, a rise of 8%. However, the number of DALYs lost to communicable diseases will significantly decrease, from 1.6mn to 1.0mn - a decline of 38%. The highest burden of disease currently comes from diabetes, cardiovascular disease, cancer, and neuropsychiatric conditions.

Economic Burden

Over 90% of private healthcare expenditure in Mexico is out-of-pocket, making some chronic diseases financially catastrophic for many households. A major economic burden in Mexico is attributed to diabetes. The government has stated that the country's inability to control this single chronic disease could bankrupt the entire healthcare system. In 2012, the financial requirements for treating diabetes increased by a third. This financial outlay is followed by hypertension, which combined with diabetes, would require the national health budget to increase by 5-7% annually.

Diabetes

According to the International Diabetes Federation (IDF), approximately 12% of Mexico's population has diabetes, with 9mn diabetics in total. The IDF also estimates that 2.2mn Mexicans are living with undiagnosed diabetes, while nearly 69,000 people died from diabetes-related diseases in 2014. The average annual cost of living with diabetes in Mexico is MXN13,000 (USD892) and the number of diabetics in Mexico is expected to grow from 9mn in 2014 to 16mn in 2035. However, the country's introduction of taxation on sugary drinks has seen some slight improvements on overall consumption of such products, while raising awareness of obesity and diabetes.

Cancer

Globocan calculates that the number of cancer cases in Mexico will increase from 147,985 in 2012 to 222,427 in 2025. It is estimated that the majority of these new cases will come from females under the age of 65. The number of new cases of cancer in females during this period is expected to be two-thirds higher than cases found in males. Currently, prostate cancer is the most common cancer among men, followed by colorectal, stomach, lung, and larynx. Breast cancer is most common among women, followed by cervical, colorectal, endometrial, and ovarian cancers.

Cardiovascular Conditions

The InterAmerican Heart Foundation notes that 'cardiovascular disease is the number one killer in Mexico'. The OECD found that in 2011 while most other countries had decreased the prevalence of ischemic heart disease (IHD), Mexico's prevalence of IHD had increased. The World Heart Federation has also reported that approximately 30% of Mexicans have hypertension, while 68% of the population is overweight. BMI's BoDD forecasts a rise in cardiovascular disease DALYs from 835,000 in 2014 to 900,000 in 2030.

Neuropsychiatric Conditions

According to the BoDD, the number of DALYs lost to neuropsychiatric conditions between 2014 and 2030 will increase by 9% (3.4mn to 3.7mn). A 2013 National Institute of Health study reported a 29% prevalence rate for cognitive impairment conditions in Mexico. Dementia is becoming a growing concern within the country. A 2013 study found a 6% prevalence rate for dementia within the Mexican population. Patient group Alzheimer's Mexico notes that there are currently 800,000 people living with dementia in Mexico, with expectations that this number will grow to 3mn people by 2050.

Competitive Landscape

Research-Based Industry

It is **BMI's** view that the acquisition of a Mexican pharmaceutical company will become increasingly important for foreign drugmakers looking to expand their presence in Mexico as well as the broader Latin American market. Local firms' most important assets in this regard are their long-established relationships with prescribers and intimate knowledge of the market, which can be used to accelerate market penetration for new entrants and minimise risks.

There are around 200 registered pharmaceutical companies operating in Mexico, employing around 40,000 people. However, large-scale production is limited to approximately 40 facilities, which account for about 95% of the market. The leading 10 firms accounted for around 40% of total pharmaceutical sales in Mexico, and Genomma was the only domestic drugmaker listed among the top 10 companies in terms of sales in 2011. We note that due to the lack of support from the government's favourable policies, local manufacturers in Mexico are not as competitive as Brazilian drugmakers in terms of domestic sales and economies of scale. This will make them cheaper and easier acquisition targets for multinationals seeking regional expansion.

The manufacturing sector is highly dependent on imported raw materials and APIs. Around 30% of exports are in a semi-finished form. Since the elimination of discriminatory tariff structures in the mid-1980s, the Mexican API sector declined from 94 companies to less than 20. The decline of the industry has been attributed to competition from low-cost Asian producers, high investment costs, weak product development and a lack of intermediate materials.

Leading local producers include Armstrong, Laboratorios Liomont, Sanfer and Pisa. Smaller companies include Laboratorios Diba, which in October 2008 was acquired by US-based Perrigo. The US and other Latin American markets represent significant export markets for Mexican players.

Companies with a significant direct manufacturing presence in Mexico include Boehringer Ingelheim/Promeco, Bayer, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Merck & Co, Roche and Sanofi. Others market products through agreements with third parties.

Although the export industry is largely in multinational hands, Mexico is an important production hub for hi-tech medicines, including fermentation-based and semi-synthetic antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs), cancer drugs, and biopharmaceuticals. A growing trend is a number of

Mexican pharmaceutical manufacturing firms opting to pursue bioequivalent generic drugs. Even manufacturers that have opposed tougher bioequivalence requirements now see legitimate generic drugs as the only way to secure market position domestically and in the regional marketplace in the long term.

Latest Updates:

- In October 2015, Israel-based Teva Pharmaceutical Industries announced the acquisition of Mexican drugmaker Representaciones e Investigaciones Médicas (RIMSA) in a USD2.3bn deal. RIMSA's acquisition will provide a portfolio of differentiated, patent-protected products, a promising pipeline, significant relationships with physicians, patients and healthcare providers and strong commercial presence, Teva's CEO Erez Vigodman noted. Rimsa reported revenues of USD227mn in 2014 with an annual growth rate of more than 10.6% since 2011. The transaction is expected to be completed in early 2016.
- In October 2015, Spanish drugmaker Ferrer announced plans to set up a plant in Mexico for the production of cardiovascular polypill. CEO Xavier Rams stated that Mexico was the first country where the drug was launched in 2013 to provide patients who have had heart attacks with better adherence to medical treatment and prevent secondary cardiovascular events. The polypill capsule contains three drugs - an antihypertensive, statin and aspirin.
- In May 2015, Mexico-based Genomma Lab Internacional recorded 'very solid' sales outside the domestic market in Q115, especially in the US, on the back of successful marketing to Hispanics in the US. Improved sales in the international markets is helping the company reverse declines in earnings before interest, taxes, depreciation, and amortisation (EBITDA) in 2014, with EBITDA expected to increase 15% in 2015, according to CEO Rodrigo Herrera. Also, international sales in 2015 are expected to exceed the domestic market sales.
- In April 2015, Mexico's Federal Commission for Protection against Health Risks (COFEPRIS) and the Caribbean Public Health Agency entered a memorandum of understanding (MoU) to support generic production in 16 countries and eight Caribbean territories. The MoU will help strengthen the Caribbean's regulatory framework, remove entry barriers and facilitate access to drugs at a lower cost, benefitting 17.2mn Caribbean people, according to Mikel Arriola, head of the COFEPRIS.

Table: Multinational Market Activity

Company	Operations
Novartis	Novartis is active in two key divisions in Mexico: pharmaceuticals and consumer health, with its OTC portfolio boosted by the acquisition of business from Bristol-Myers Squibb. The pharmaceuticals division markets products in a variety of therapeutic classes, including gastroenterology, diabetes, cardiovascular, dermatology, respiratory, rheumatology, oncology, immunology and ophthalmology. Its consumer health unit produces infant nutritional products (Gerber), OTC medicines, contact lenses (Ciba Vision) and animal health products.
Pfizer	Founded in 1951, Mexico is one of Pfizer's 11 leading markets, and the second market in Latin America. The company has four main divisions: Pfizer Pharma, Pfizer Animal Health, Pfizer Nutrition and Pfizer Consumer. Pfizer's acquisition of Wyeth strengthened the company's operations in Mexico. Headquarters are located in Santa Fe in Bosques de las Lomas, Mexico City. It employs more than 2,000 people.
Roche	Grupo Roche Syntex is a Mexican subsidiary of the Swiss pharmaceutical major, created following the acquisition of local oral contraceptives producer Syntex. Roche also has a diagnostics business in Mexico.

Multinational Market Activity - Continued

Company	Operations
	<p>The company produces, distributes, and sells pharmaceuticals and diagnostics in Mexico. In 2000, the company opened a vitamin pre-mix plant in El Salto, Jalisco state, producing blends of various vitamins and other micronutrients for further processing and integration into food, feed, pharmaceutical, and cosmetic products. The plant was capable of producing 1,800 tonnes of premix vitamins per annum.</p> <p>Roche has a 32,000-square metre plant for the production of innovative medicines, located in the company's manufacturing complex in Toluca, in the state of Mexico. It produces about 250 tons of innovative medicines and employs about 120 people</p>
Sanofi	<p>Founded in 1973, the company now employs around 600 people. The company runs two manufacturing sites in Ocoyoacac and Textitlán, as well as a distribution centre. Sanofi's portfolio in Mexico contains over 200 products in more than 400 presentations and is focused on the following therapeutic areas: cardiovascular, oncology, diabetes, internal medicine, vaccines, central nervous system and thrombosis.</p>
Merck & Co	<p>Merck has operated in Mexico since 1930.</p>
GlaxoSmithKline	<p>Established in Mexico in 1964, GlaxoSmithKline is a leading producer of pharmaceuticals and vaccines. The company has two divisions, Pharmaceuticals and Consumer Care, headquartered in Xochimilco, in Tlalpan, in the Federal District. It employs more than 1,600 people in Mexico.</p> <p>Around 70% of the output at its Mexican production facilities is meant for the local market. The company's manufacturing facilities have an output of 45mn to 70mn units per annum, including 24 product lines and 12 dosages.</p> <p>GlaxoSmithKline's Mexican plants manufacture a wide range of medicines. Major product areas include antibiotics, vaccines, anti-virals, cardiovascular, gastrointestinal, respiratory system, central nervous system, diabetes, and HIV/AIDS drugs. The company is also a leader in antibiotics and products for the treatment of asthma. GlaxoSmithKline fields more than 80 products in around 200 presentations in Mexico</p>
AstraZeneca	<p>AstraZeneca is the third largest drugmaker in Mexico.</p>
Takeda	<p>Takeda has been operating in Mexico since 2009.</p>

Source: BMI

Generic Drugmakers

As one of the largest consumers of generic medicines in the world, Mexico is home to many prominent generic drugmakers, including Teva in Israel, Mylan in the US and Perrigo in Ireland. Other major generic pharmaceutical companies include Ranbaxy in India, and Aspen Pharmacare Holdings from South Africa. Generic drugmakers will continue to be attracted to Mexico, as the country's increasing rates of generic drug consumption drives its demand for more affordable medicines over the next ten years. Other domestic pharmaceutical companies include Grupo Bruluart, Cinfa, PiSA and Sanfer. In May 2015, Ireland-based generic drugmaker Perrigo acquired the Mexican operations of US-based Patheon in a USD34mn cash deal. The move is expected to further strengthen the company's supply chain capabilities, with the addition of softgel manufacturing technology, and broaden its presence, product portfolio and customer network in Mexico.

Pharmaceutical Distribution

Wholesale

The majority of pharmaceuticals are channelled through the private pharmacy sector, with most retailers purchasing from 30 regional and local distributors. In the private pharmacy sector, the leading three distributors include NADRO and Marzam. Before Grupo Casa Saba (GCS) sold its distribution sector, the three companies controlled nearly 50.0% of the sector. Additionally, Almacén de Drogas, Fármacos Nacionales and Provedora de Medicamentos account for a further 30%. The public sector, which represents around 27.0% of the pharmaceutical market, distributes and retails through hospitals, health centres and institutional pharmacies. In recent years, the increasing direct agreements between pharmaceutical companies and pharmacies have diminished the sector's growth potential. Between 2007 and 2012, the market shares of Mexico's top four pharmaceutical wholesalers decreased from 71% to 58%.

Marzam

Established in 1934, Marzam is the third leading pharmaceutical distributor. Headquartered in Mexico City, the company employs about 2,300 people, of whom 800 are sales representatives. In 2005, JP Morgan Partners sold its participation in Marzam to a group of private investors; JP Morgan Partners had acquired 80.0% of Marzam in 2002. The details of the transaction were not disclosed but there are rumours that some investors are linked to GCS. In 2005, Marzam acquired the regional distributor Medicinas del Pacífico, which had operations in the Northeast of Mexico.

Marzam uses around 350 providers. The company has an extensive product portfolio, including over 10,000 pharmaceutical and other products. Marzam has a network of 12 distribution centres, 50 regional centres and over 400 transport vehicles servicing 18,000 pharmacies.

NADRO

Founded as Nacional de Drogas in 1943, NADRO is the second leading distributor of pharmaceutical, healthcare and personal hygiene products. The US wholesale pharmaceutical distributor McKesson Corporation has a 49.0% interest in NADRO, as stated in its 2011 annual report. NADRO's headquarters are in the district of Sante Fe, in Mexico City. The company started to trade in the Mexican Stock Exchange (BMV) in 1985 but was delisted in 2005. Sales were valued at MXN22,000mn (USD1,613.0mn) in 2009.

The company has 15 distribution centres and a fleet of over 500 delivery vehicles. The distribution centres are located in Chihuahua, Culiacán, Guadalajara, Hermosillo, La Paz, León, Mérida, México Norte, México Sur, Monterrey, Morelia, Puebla, Tijuana, Tuxtla and Veracruz. NADRO operates two pharmacy chains; Cofar and Farmacias de Dios.

Grupo Casa Saba

Grupo Casa Saba (GCS) used to be a multi-channel, multi-product national wholesale distributor in Mexico. Its retail pharmacy sector has over 900 pharmacies in 19 Mexican states and an extensive distribution chain across Brazil, Chile and Peru, with more than 350 pharmacies in Chile through the acquisition of Farmacias Ahumada (FASA) in 2010, which operated around 1,200 drug stores at the time. GCS has more than 85 pharmacies in Brazil.

In December 2013, GCS signed a stock purchase agreement with Pharma Equity Global Fund and World Global Equity Fund to sell all of its subsidiaries dedicated to the pharmaceutical products wholesale and distribution business for a total consideration of approximately MXN4,500mn (USD349mn). The transaction includes the assumption of all liabilities related to this business as well as the entirety of its operational and real estate assets. GCS will use the net proceeds from this transaction to reduce debt level and strengthen its balance sheet. GCS will focus exclusively on its pharmacy retail business in Mexico and Chile, and its GNC franchise in Brazil.

In May 2014, GCS agreed to sell its pharmaceutical retail business to Alliance Boots. The transaction requires Alliance Boots to launch an all cash tender offer for the outstanding fully diluted share capital of Farmacias Ahumada (FASA), which is listed on Chile's Santiago Stock Exchange. The acquisition comprises two main businesses with combined revenues of around GBP835mn (USD1.4bn): Farmacias Benavides, the third largest retail pharmacy chain in Mexico with around 1,000 stores; and Farmacias Ahumada, one of the three largest retail pharmacy chains in Chile with around 400 stores. We note that although GCS has been troubled with high debt issues and limited revenue growth, its subsector assets remain attractive to multinationals with ambitions to expand in Latin American markets.

Pharmaceutical Retail Sector

Traditionally very fragmented, the private pharmacy sector has been consolidated by big pharmacy chains in recent years. Independent pharmacies have lost market share as they have a smaller range of supplies and lower purchasing power, due to excessive regulation. There were 25,000 pharmacies in 2011; IMSS operated 748. Small and medium pharmacies represented about 70% of the total, whilst pharmacy chains

and supermarkets accounted for the remaining 30.0%. In value terms, small and medium pharmacies accounted for 60.0% of the total, whilst pharmacy chains and supermarkets represented the remaining 40.0%.

IMSS represents nearly half of public drug expenditure, therefore it is able to negotiate competitive drug prices due to the volume of its acquisitions. Using reported financial information, IMSS spent MXN36.0bn (USD2.9bn) on goods consumption for disease & maternity insurance in 2011; a detailed breakdown has not been provided. However, Espicom presumes that two-thirds of this consumption is accountable to pharmaceuticals. About 10.2% was spent in the South Federal District, followed by México Oriente (9.3%), the North Federal District (8.8%) and Nuevo León (8.0%). The leading supplier was Grupos Fármacos Especializados, followed by Farmacéutica Maypo.

Table: IMSS Financial Indicators, 2000-11 (MXNmn)

	Payments	Expenditure	Of Which Goods Consumption	Of Which for Disease & Maternity	% Change
2000	121,915	108,991	15,867	14,426	12.0
2001	132,553	124,040	16,274	14,797	2.6
2002	140,214	126,730	17,075	15,511	4.8
2003	152,879	133,570	18,806	17,087	10.2
2004	163,371	145,961	22,030	20,011	17.1
2005	177,718	155,036	21,170	19,399	-3.1
2006	178,621	170,176	21,541	19,681	1.5
2007	202,826	183,040	22,890	20,930	6.3
2008	215,694	194,705	28,049	25,725	22.9
2009	225,479	212,679	31,659	29,073	13.0
2010	251,521	238,332	36,257	33,175	14.1
2011	274,676	264,197	39,230	36,024	8.6

Source: IMSS

Company Profile

Boehringer Ingelheim

- Strengths**
- A well-established market position, with a long history of operations in Mexico, including local manufacturing.
 - Presence in animal health, OTC, and prescription sectors provide strong market coverage in Mexico.
 - Expanded export capability has allowed the company flexibility to target US, regional and world markets.
- Weaknesses**
- The company has limited its presence in the fast-growing generic drugs market.
 - Inadequate enforcement of IP rules continues to threaten existing top-selling medicines.
- Opportunities**
- The market for patented medicines and OTCs is expected to increase steadily.
 - Regulatory environment is improving, with the government appearing committed to dialogue with stakeholders.
- Threats**
- Government failure to enforce new IP laws and pricing structures remain long-term challenges to growth.
 - Increased multinational interest in emerging markets, coupled with an influx of Indian generic-makers, making for a more competitive environment.

Company Overview Founded in 1954, Mexico is Boehringer Ingelheim's largest operating unit in Latin America. Boehringer Ingelheim has two subsidiaries in Mexico, where it employs about 1,200 people: Boehringer Ingelheim Vetmedica specialises in animal health and is located in Guadalajara, in the state of Jalisco.

German Boehringer Ingelheim has invested heavily in Mexico over its 50-year presence in the country. Its continued presence highlights that, despite the regulatory shortcomings of Mexico's pharmaceutical industry, the firm is making a profit. The drug

maker is keen to develop more niche medicines to cater for the country's epidemiological profile. The firm has a manufacturing facility that produces solids, liquids and inhalers, and also offers contract manufacturing services.

Product Portfolio

The antihypertensive *Micardis* (telmisartan) is a bestselling product, due to strong sales to the leading social security institutions; *Combivent* (ipratropium bromide and albuterol sulphate), which ranks third in the company's portfolio, has become one of the fastest-growing products in the respiratory area; *Flomax* (tamsulosin) Oral Controlled Absorption System (OCAS), a leading treatment for the symptoms of Benign Prostatic Hyperplasia (BPH), was launched in 2007; *Buscapina Fem* (butylscopolamine), a product for menstrual pain, was also launched in 2007; the sore throat drug *Mucoangin* (ambroxol) is sold in Mexico, which represents one of the three biggest markets for the product.

Research and development investment was valued at USD70mn in Mexico in 2008. Added support on drug formulation and the manufacture of medication for clinical trials comes from Boehringer Ingelheim's support centre in Buenos.

Boehringer Ingelheim claims to be the only FDA/EMA approved facility to manufacture POM and OTC products in Mexico. In 1998, the company inaugurated its industrial complex in Xochimilco. During the 1990s, it developed its manufacturing site for the production of human pharmaceuticals in the site. Investments were allocated to complete modernization of ampoule production to meet worldwide quality standards.

Strategy

Boehringer is tentative about licence deals with generic drug manufacturers and, although no disclaimer has been released, we believe this could be key to protecting sales as the 2011-2013 patent cliff takes hold. This move would not be unique to Boehringer, but with time running out investing in this area must be urgently considered. Protecting sales aside, the firm retains a broad product offering in Mexico, with the OTC segment providing another revenue stream.

Boehringer re-emphasised its focus on Mexico's patented drug sector. The president and CEO of Boehringer Ingelheim Mexico, Miguel Salazar, said the company will not launch entirely new lines of generic drugs in Mexico as other multinational drugmakers have done. It will introduce innovative drugs as well as products that have lost patent protection but only if they have been created and developed by Boehringer Ingelheim. Salazar told the Milenio newspaper he expects sales to grow by 4.7% in 2012, exceeding the 3% Mexican pharmaceutical market growth rate. In 2011, Boehringer Ingelheim generated MXN5.6bn (USD404mn) in revenue and sales are forecast to reach MXN5.86bn (USD422mn) by 2012.

Developments 2014

- Boehringer Ingelheim announced it plan to invest more than MXN363mn (USD28.12mn) between 2014 and 2017 in infrastructure and new equipment at its plants in Guadalajara, Jalisco and Xochimilco in Mexico City. The planned investment is 29.6% more than the MXN280mn (USD21.69mn) the company has invested in its plants in the country over the past two years. Boehringer Ingelheim will invest MXN273mn (USD21.5mn) in the plant in Guadalajara to get new equipment and upgrade the infrastructure.

Financial Data 2013

- Boehringer Ingelheim's total 2013 net sales were EUR14bn (USD15bn), a 4.1% reduction from 2012's EUR14.7bn (USD15.7bn). Total revenues for 2013 were EUR15bn (USD16bn) and the company's net income was EUR1bn.

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Genomma Labs

Strengths

- One of the most prominent domestic OTC drug makers, with strong sales growth in the past few years.
- Produces a range of OTC drugs, mainly covering dermatologicals and drugs in the high-growth categories of this therapeutic area.
- In-house advertising production allows rapid responses to consumer demand giving it a good grasp of marketing and branding.
- Nationwide distribution through wholesalers, pharmacies and department stores ensures sales are maximised.
- Uses television and other media to advertise directly to its target consumer group, which has proven to be a successful strategy.

Weaknesses

- Genomma is heavily focused on dermatology; diversifying its therapeutic area into related products would give it more leverage when entering other markets.
- OTC market vulnerable to wider economic fluctuations.
- OTC switching procedures could be streamlined.

Opportunities

- The firm has made good progress on sales outside Mexico with a launch of new products giving its overseas presence a boost.
- The company is expanding its geographical reach.
- Consistently strong share performance boding well for investment.
- Strategy of buying out smaller, poorly performing brands that are potentially lucrative, and re-launching them using its experience and expertise.

Threats

- Focused on OTCs in one therapeutic area, leaving it exposed to competition.
- Lifting of requirement for drug companies to set up local operations to increase competition from imports.

- Entry into well-established markets was costly, negatively affecting 2011's profitability.
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Company Overview Genomma Labs is an OTC drugmaker in Mexico, with an increasing multinational presence in other Latin American countries. In June 2008, Genomma was added to Mexico's leading stock index, the Índice de Precios y Cotizaciones. It produces more than 90 products ranging mostly in the dermatological therapeutic area, such as scar removal creams, anti-acne treatments, anti-wrinkle creams and varicose vein treatments. Genomma's products are targeted through successful and targeted advertising across all socioeconomic groups and via a national distribution network.

Strategy Genomma Labs' long-term strategy is to market new products, strengthen its generic drug business and expand operations beyond Mexico. At an investor day in New York City to discuss its growth plans, Rodrigo Herrera, the company's chairman and chief executive officer, said Genomma, which produces and distributes OTC medicines, prescription generic drugs and cosmetic products, will exploit recovering consumer demand by launching new products and expanding its operations beyond Mexico. Genomma is also expanding its consumer health products portfolio with the addition of body lotions and hair colouring, with this direction expected to gain importance in the coming years.

Furthermore, Genomma has overseas sales offices in Spain, Argentina, Peru, China and India.

However, since Genomma's bestsellers abroad are personal care products, it needs a deeper understanding of local consumption trends to promote products. In countries such as the US and Brazil, where consumers have already formed certain consumption habits and loyalties to brands and products, Genomma cannot simply replicate its domestic success. It is costly to break into new markets like these and that is one of the main reasons the company's profit margin dropped in 2011.

Genomma's international expansion, especially in the US market, will be crucial to the performance of the company's shares in 2013. The Mexican drugmaker has gradually shifted its strength from pharmaceutical products to consumer healthcare goods. As a result, investors believe its brand awareness among the growing Hispanic population in the US will be the key driver of the company's revenue growth. Genomma's struggling share price performance in 2012 indicates that companies with ambitions of establish themselves abroad need to be cautious with the timing and methods of international

expansion. Territorial and culture difference need to be taken into account, in addition to whether the expansion is in line with a company's long-term strategic development.

In 2014, Genomma expects to expand internationally, mainly focusing on Brazil as well as other Latin American countries. Sales growth should be mainly driven by international market expansion.

Developments

2015

- Genomma Labs received 'AA' rating by the Fitch Group.

2014

- Genomma acquired a 50% interest in Marzam Commercial and Industrial Group for MXN600mn (USD45.15mn). The company signed an agreement in which it also has the option to acquire 100% of Marzam Commercial and Industrial Group. The transaction is subject to various conditions, including approval from the Federal Competition Commission. The transaction is expected to be completed in Q214.

2013

- Genomma signed a contract to secure rights to Losec AMR, which is one of the leading brands in the category of acid inhibitors. The deal, worth MXN286mn (USD23.18mn), consolidates Genomma's presence in the category of acid inhibitors. The deal was funded with long credit lines within the company. Losec AMR had a market share of more than 30% in March 2013, according to IMS Health.
- Genomma acquired Argentine analgesic brand Tafirol for ARS133.7mn (USD26.9mn), reports Reuters. The acquisition of Tafirol, whose products include acetaminophen, decongestants and analgesics for infants, has been made by Genomma to strengthen local supply of its drugs in Argentina.

Financial Data

2014

- In 2014, Genomma saw only slight revenue growth. Genomma's total 2014 net sales was MXN11.5bn (USD753mn), a 1.6% increase from 2013 sales of MXN11.4bn (USD747mn). Total gross profit for 2014 was MXN8bn (USD524mn), a 0.7% increase from total 2013 sales of MXN7.9bn (USD518mn).

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Mexico

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.

Population

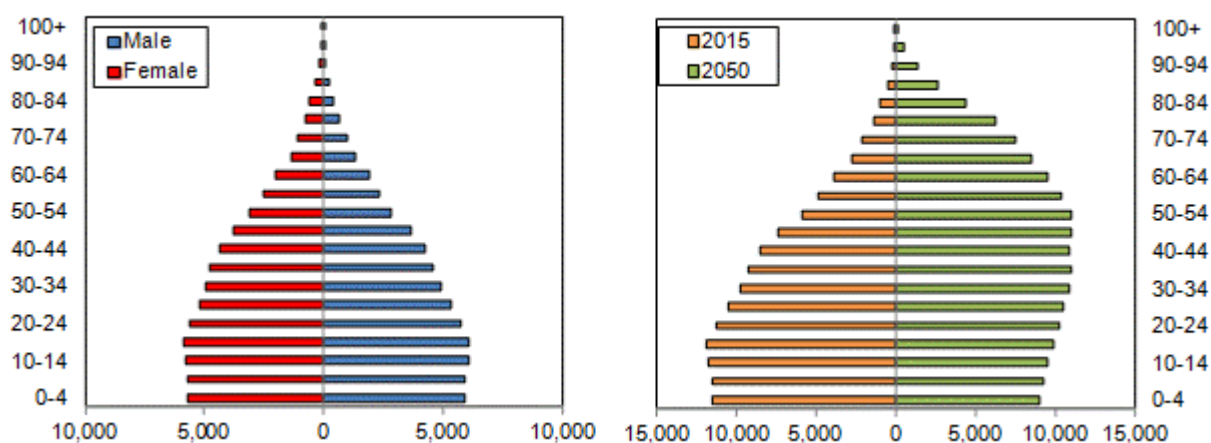
(1990-2050)



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

Mexico Population Pyramid

2015 (LHS) & 2015 Versus 2050 (RHS)



Source: World Bank, UN, BMI

Table: Population Headline Indicators (Mexico 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Population, total, '000	85,609	102,808	109,747	118,617	127,017	134,837	141,923
Population, % y-o-y	na	1.5	1.4	1.5	1.3	1.1	1.0
Population, total, male, '000	42,576	51,039	54,534	58,988	63,181	67,078	70,601
Population, total, female, '000	43,032	51,768	55,213	59,629	63,835	67,758	71,322
Population ratio, male/female	0.99	0.99	0.99	0.99	0.99	0.99	0.99

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

Table: Key Population Ratios (Mexico 1990-2025)

	1990	2000	2005	2010	2015f	2020f	2025f
Active population, total, '000	48,602	62,392	68,299	76,092	83,739	90,157	95,535
Active population, % of total population	56.8	60.7	62.2	64.1	65.9	66.9	67.3
Dependent population, total, '000	37,006	40,415	41,448	42,525	43,277	44,680	46,387
Dependent ratio, % of total working age	76.1	64.8	60.7	55.9	51.7	49.6	48.6

Key Population Ratios (Mexico 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Youth population, total, '000	33,362	35,266	35,585	35,552	35,063	34,493	33,835
Youth population, % of total working age	68.6	56.5	52.1	46.7	41.9	38.3	35.4
Pensionable population, '000	3,644	5,149	5,863	6,972	8,214	10,186	12,552
Pensionable population, % of total working age	7.5	8.3	8.6	9.2	9.8	11.3	13.1

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

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

	1990	2000	2005	2010	2015f	2020f	2025f
Urban population, '000	61,141.4	76,820.6	83,746.4	92,314.1	100,656.1	108,619.3	116,029.6
Urban population, % of total	71.4	74.7	76.3	77.8	79.2	80.6	81.8
Rural population, '000	24,468.0	25,988.0	26,001.5	26,303.4	26,361.2	26,217.7	25,893.9
Rural population, % of total	28.6	25.3	23.7	22.2	20.8	19.4	18.2
Life expectancy at birth, male, years	67.9	71.9	72.9	73.7	74.6	75.7	76.8
Life expectancy at birth, female, years	73.8	76.8	77.8	78.5	79.4	80.3	81.1
Life expectancy at birth, average, years	70.8	74.4	75.3	76.1	77.0	78.0	78.9

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

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

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 0-4 yrs, total, '000	11,567	12,218	11,947	11,653	11,616	11,366	10,985
Population, 5-9 yrs, total, '000	10,976	11,831	12,059	11,891	11,606	11,574	11,328
Population, 10-14 yrs, total, '000	10,818	11,215	11,579	12,007	11,839	11,553	11,521
Population, 15-19 yrs, total, '000	10,432	10,627	10,818	11,494	11,914	11,745	11,459
Population, 20-24 yrs, total, '000	8,178	10,079	10,095	10,700	11,362	11,779	11,612
Population, 25-29 yrs, total, '000	6,785	9,270	9,535	9,967	10,557	11,215	11,633
Population, 30-34 yrs, total, '000	5,680	7,908	8,835	9,417	9,836	10,423	11,083
Population, 35-39 yrs, total, '000	4,740	6,425	7,599	8,726	9,297	9,716	10,306
Population, 40-44 yrs, total, '000	3,506	5,395	6,192	7,494	8,603	9,174	9,598
Population, 45-49 yrs, total, '000	2,989	4,497	5,197	6,084	7,362	8,464	9,037

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

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 50-54 yrs, total, '000	2,394	3,291	4,316	5,073	5,940	7,201	8,295
Population, 55-59 yrs, total, '000	2,122	2,763	3,125	4,168	4,903	5,755	6,995
Population, 60-64 yrs, total, '000	1,771	2,132	2,582	2,965	3,962	4,679	5,513
Population, 65-69 yrs, total, '000	1,372	1,808	1,937	2,385	2,744	3,692	4,384
Population, 70-74 yrs, total, '000	904	1,406	1,575	1,715	2,121	2,460	3,339
Population, 75-79 yrs, total, '000	673	980	1,154	1,311	1,435	1,795	2,104
Population, 80-84 yrs, total, '000	399	533	713	872	1,002	1,112	1,410
Population, 85-89 yrs, total, '000	202	282	314	466	582	682	767
Population, 90-94 yrs, total, '000	70	103	126	165	252	322	384
Population, 95-99 yrs, total, '000	17	29	33	48	65	102	133
Population, 100+ yrs, total, '000	3	5	7	7	11	17	28

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

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

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 0-4 yrs, % total	13.51	11.89	10.89	9.82	9.15	8.43	7.74
Population, 5-9 yrs, % total	12.82	11.51	10.99	10.02	9.14	8.58	7.98
Population, 10-14 yrs, % total	12.64	10.91	10.55	10.12	9.32	8.57	8.12
Population, 15-19 yrs, % total	12.19	10.34	9.86	9.69	9.38	8.71	8.07
Population, 20-24 yrs, % total	9.55	9.80	9.20	9.02	8.95	8.74	8.18
Population, 25-29 yrs, % total	7.93	9.02	8.69	8.40	8.31	8.32	8.20
Population, 30-34 yrs, % total	6.64	7.69	8.05	7.94	7.74	7.73	7.81
Population, 35-39 yrs, % total	5.54	6.25	6.92	7.36	7.32	7.21	7.26
Population, 40-44 yrs, % total	4.10	5.25	5.64	6.32	6.77	6.80	6.76
Population, 45-49 yrs, % total	3.49	4.37	4.74	5.13	5.80	6.28	6.37
Population, 50-54 yrs, % total	2.80	3.20	3.93	4.28	4.68	5.34	5.84
Population, 55-59 yrs, % total	2.48	2.69	2.85	3.51	3.86	4.27	4.93
Population, 60-64 yrs, % total	2.07	2.07	2.35	2.50	3.12	3.47	3.88
Population, 65-69 yrs, % total	1.60	1.76	1.77	2.01	2.16	2.74	3.09
Population, 70-74 yrs, % total	1.06	1.37	1.44	1.45	1.67	1.82	2.35
Population, 75-79 yrs, % total	0.79	0.95	1.05	1.11	1.13	1.33	1.48
Population, 80-84 yrs, % total	0.47	0.52	0.65	0.74	0.79	0.83	0.99

Population By Age Group % (Mexico 1990-2025) - Continued

	1990	2000	2005	2010	2015f	2020f	2025f
Population, 85-89 yrs, % total	0.24	0.27	0.29	0.39	0.46	0.51	0.54
Population, 90-94 yrs, % total	0.08	0.10	0.12	0.14	0.20	0.24	0.27
Population, 95-99 yrs, % total	0.02	0.03	0.03	0.04	0.05	0.08	0.09
Population, 100+ yrs, % total	0.00	0.01	0.01	0.01	0.01	0.01	0.02

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 *similares* 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 M = 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