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Mexico Pharmaceuticals & Healthcare Report Q1 2008

Including 5-year industry forecasts

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Mexico Pharmaceuticals & Healthcare Report Q1 2008

Including 5-year industry forecasts by BMI

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Executive Summary

Mexico's market continues to grow robustly in value terms, but volume growth appears to be lagging. **BMI** estimates 2007 market growth at 8.7% year-on-year (y-o-y), reaching a value of US$13.3bn. The new five-year forecast for the period 2007 to 2012 sees average annual growth in dollar terms of 5.4% and in local currency terms of 7.4%. According to **IMS Health**, the market grew 7.5% in value terms y-o-y over the first seven months of 2007, whilst the number of units sold edged up only 0.7%. Local market sources indicate that volumes remain nearly static, despite record spending by the state sector.

One interpretation of this data is that Mexicans continue to pay too much for medicines, a perennial source of controversy. This is attributed, to over-concentration in distribution, corruption and inefficiency in the state sector and generally weak market oversight. Still, with the legitimate generics market thriving – to the long-term detriment of copy drugs or *similares* – and multinationals carrying out new launches, there is also some evidence that more effective medicines are being used in smaller volumes than older drugs. The one certainty is that with a growing population, more pensioners and a surge in the number of obese and those diagnosed with diabetes, Mexico's drugs bill will continue to rise.

With just over 50% of the population having some form of healthcare insurance – mainly through state schemes and private-sector policies – President Felipe Calderón warned in October 2007 that comprehensive universal coverage would not be achieved until 2030. At the same time, more money is going into the system – the government claims total health spending will jump 38% if it remains the same as in draft 2008 budget. One crucial pillar in coverage is the long indebted ISSSTE social security provider. In a step forward, state-run pension fund provider **Afore Pensionissste**. will manage wage contributions from federal workers from 2008 under legislation aimed at keeping the system solvent.

How much state funding goes to medicines will depend on the ability of the authorities to efficiently manage purchasing. The development of the market will also depend on continued improvements of the intellectual property (IP) environment. In **BMI's** new Business Environment Rankings for the Americas, Mexico scores third after the US and Canada, reflecting its relatively strong IP protections and continued growth potential. The opening of a new oncology medicines plant by Swiss drugmaker **Roche** in Toluca, representing a US$60mn investment underlines the attractiveness of the market.

But there is still room for improvement. In October, trade body **La Asociación Mexicana de Industrias de Investigación Farmacéutica** (AMIFA) called for stronger data protection under Mexico's North American Free-Trade Agreement (NAFTA) commitments. One reason for deficiencies is the lack of research and development (R&D) work by both the local private sector and state institutions, driving dependence on copy drugs and generics. Some 98% of patents are of foreign origin, a dismal rate by even emerging market standards. Arguably, the lack of an industrial policy for the sector – such as the twin generics and R&D strategies pursued in Brazil – will leave local players fighting a constant rearguard action against tighter rules and, crucially, better enforcement.

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Mexico Pharmaceuticals And Healthcare Industry SWOT

Strengths	▪ Mexico is the largest market in Latin America along with Brazil, with estimated 8.9% growth in 2007 ▪ Mexico is one of Latin America's most developed markets and regulatory standards are superior to most of its southern neighbours ▪ Mexico has strong trade links outside Latin America to the US, Canada and EU ▪ Mexico has a competitive and well-developed pharmaceutical industry including around 200 companies and a substantial multinational presence
Weaknesses	▪ Despite important recent reforms, the enforcement of domestic patent law remains problematic and counterfeiting is a continuing problem ▪ With nearly half of the population lacking health insurance, Mexico's drug market is particularly sensitive to economic shocks ▪ The Mexican government's drug-pricing policy is focused on cost containment, while an inefficient supply chain leads to high prices for consumers ▪ The expansion of state health coverage has focused on basic, essential drugs and reimbursement for many hi-tech imported drugs remains limited or non-existent
Opportunities	▪ The generics market has strong growth potential as both the government and consumers look to the sector to provide cost-effective coverage in place of less reliable copy drugs ▪ New legislation on bioequivalence has recently been approved in Mexico and may push a number of *similar* or copied products off the market over the next three to five years ▪ Health-sector reform and the expansion of programmes such as the Seguro Popular will drive overall health spending ▪ Further reforms, including better data protection rules, could further boost investment in the sector
Threats	▪ Continuing failures to enforce domestic patent law more robustly will continue to limit both investment and product launches by multinationals ▪ The government will be limited in implementing healthcare reform by tightly constrained funding, corruption and the multiple layers of government involved ▪ Mexico has in the past been subject to periodic economic crises and a regional financial crisis, particularly a devaluation in the value of the peso, could derail market growth

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Mexico Political SWOT	
Strengths	▪ Democracy seems to have taken root after the 71-year tenure of the PRI ended in 2000, and there are effective checks and balances on executive power to prevent a return to one-party rule ▪ Largely free press ensures that there is a lively political debate
Weaknesses	▪ State officials cannot be re-elected, which makes them effectively unaccountable to the electorate and reduces the incentive to pass legislation ▪ A recent spate of local disturbances has highlighted that more work is necessary to reduce regional inequalities
Opportunities	▪ The PRI could form an alliance with the government, which would give President Calderón a two-thirds majority for implenting structural reform
Threats	▪ No party will hold a majority in Congress meaning that the government will still struggle to pass its energy sector, fiscal and legislative reforms ▪ Although his position has drastically improved, President Calderón must still look to canvass support amongst Mexico's poorer classes, given his slender margin of victory in last year's elections

Mexico Economic SWOT	
Strengths	▪ Close proximity and North American Free Trade Agreement (NAFTA) membership gives Mexico an important advantage when trading in the US market ▪ The country has signed a plethora of free trade agreements (FTA) in recent years, fostering rising international trade and investment. Indeed, Mexico has treaties with the US, the eurozone and Japan
Weaknesses	▪ The relatively small domestic market means that the economy is largely tied to economic prospects in the US ▪ With oil production starting to look weak, we are concerned about the fiscal and current accounts over-arching dependence on energy receipts
Opportunities	▪ The government's emphasis on macroeconomic stability has helped improve the fiscal books during its term and contributed to lower inflation and interest rates ▪ Foreign direct investment is set to increase this year despite a slowdown in economic activity
Threats	▪ Increasing Asian (Chinese) competition in the key US export market remains a concern ▪ Recent tightening in global credit markets could have a negative impact on FDI flows

Mexico Business Environment SWOT	
Strengths	▪ The relatively robust financial system means credit is available, and there is substantial foreign involvement in the domestic banking sector
Weaknesses	▪ Education levels are a concern, given the low level of primary school attendance. Indeed, 8.3% of the population were illiterate in 2002, according to the **World Bank** ▪ Regional policy is required to help shift resources from the relatively prosperous North to the poorer South ▪ Labour markets are quite heavily regulated at the moment, making hiring and firing difficult for employers
Opportunities	▪ Rules on foreign investment are relatively relaxed in some sectors, with majority ownership allowed in some circumstances
Threats	▪ Energy prices are likely to rise in forecast period given a lack of investment in the government-owned sector ▪ Rising crime levels have led to social protests, prompting the Calderón government to reassess its crime strategy. Security costs could rise in the forecast period if the government is unsuccessful in curbing rising crime rates

Business Environment Ranking

Pharmaceutical Ratings – Revised Methodology

BMI has revised the methodology of its Pharmaceutical Business Environment Rating. Our approach has been threefold. First, we have redefined the risks rated in order more accurately to capture the operational dangers to companies operating in this industry globally. Second, we have attempted where possible to identify objective indicators that may serve as proxies for issues/trends that were previously evaluated on a subjective basis. Finally, we have used **BMI's** proprietary Country Risk Ratings (CRR) in a more nuanced manner in order to ensure that only the aspects most relevant to the industry have been included. Overall, the new ratings system – which now integrates with those of all 16 industries covered by **BMI** – offers an industry-leading insight into the prospects/risks for companies across the globe.

Ratings Overview

Ratings System

Conceptually, the new ratings system divides into two distinct areas:

Limits of potential returns: Evaluation of sector's size and growth potential in each state, and also broader industry/state characteristics that may inhibit its development.

Risks to realisation of those returns: Evaluation of industry-specific dangers and those emanating from the state's political/economic profile that call into question the likelihood of anticipated returns being realised over the assessed time period.

Indicators

The following indicators have been used. Overall, the rating uses three subjectively-measured indicators, and 41separate indicators/datasets.

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Table: Pharmaceutical Business Environment Indicators

Indicator	Rationale
Limits to potential returns	
Market structure	
Market expenditure, US$bn	Denotes breadth of pharmaceutical market. Large markets score higher than smaller ones
Market expenditure per capita, US$	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 5-year forecast period
Country structure	
Urban-rural split	Urbanisation is used as a proxy for development of medical facilities. Predominantly rural therefore states score lower
Pensionable population, % of total	Proportion of the population over 65 years of age. States with aging populations tend to have higher per-capita expenditure
Population growth, 2003-2015	Fast-growing states suggest better long-term trend growth for all industries
Overall score for *country structure* is also affected by the coverage of the power transmission network across the state	
Risks to potential returns	
Market risks	
Intellectual property (IP) laws	Markets with fair and enforced IP regulations score higher than those with endemic counterfeiting
Policy/reimbursements	Markets with full and equitable access to modern medicines score higher than those with minimal state support for healthcare
Approvals process	High scores awarded to markets with a swift appraisal system. Those that are weighted in favour of the local industry or are corrupt score lower
Country risk	
Economic structure	Rating from CRR evaluates the structural balance of the economy, noting issues such as reliance on single sectors for exports/growth, and past economic volatility
Policy continuity	Rating from CRR evaluates the risk of a sharp change in the broad direction of government policy
Bureaucracy	Rating from CRR denotes ease of conducting business in the state
Legal framework	Rating from CRR denotes the strength of legal institutions in each state – security of investment can be a key risk in some emerging markets
Corruption	Rating from CRR denotes the risk of additional illegal costs/possibility of opacity in tendering/business operations affecting companies' ability to compete

Source: BMI

Weighting

Given the number of indicators/datasets used, it would be wholly inappropriate to give all sub-components equal weight. Consequently, the following weight has been adopted.

Table: Weighting Of Components

Component	Weighting
Limits of potential returns	*60%*
– Pharmaceutical market	– 75%
– Country structure	– 25%
Risks to realisation of potential returns	*40%*
– Market risks	– 60%
– Country risk	– 40%

Source: BMI

Mexico – Business Environment Ranking

Table: Pharmaceutical Business Environment Rankings

	Limits of potential returns			Risks to realisation of returns				
	Pharmaceutical market	**Country structure**	***Limits***	**Market risks**	**Country risk**	***Risks***	**Pharmaceutical rating**	**Regional ranking**
US	80	70	*78*	70	86	*76*	77	1
Canada	73	70	*73*	63	84	*72*	72	2
Mexico	**60**	**57**	***59***	**57**	**59**	***57***	**58**	**3**
Puerto Rico	43	60	*48*	70	62	*67*	55	4
Brazil	57	60	*58*	43	54	*47*	53	5=
Colombia	53	57	*54*	47	57	*51*	53	5=
Chile	40	60	*45*	37	75	*52*	48	7
Argentina	47	67	*52*	30	52	*39*	47	8
Venezuela	43	63	*48*	20	40	*28*	40	9
Peru	27	57	*34*	40	54	*45*	39	10

Scores out of 100, with 100 highest. Source: BMI

In the **BMI** Business Environment Rankings for the ten markets of the Americas, Mexico receives a composite pharmaceutical rating of 58, ranking the country third overall. The key components of its score are:

Limits Of Potential Returns

Pharmaceutical Market

Mexico's pharmaceutical market size and recent record of growth give it the best score in terms of pharmaceutical market potential among the Latin American markets. Beyond its large size, Mexico has higher per-capita pharmaceutical expenditure than most other markets to its south and relatively high prices, albeit due in part to inefficiency and concentration in the distribution sector coupled with a still fragmented retail sector. In terms of country structure, Mexico has a fast-growing population and while its people are living longer, its ratio of pensioners to workers will remain lower than in more developed countries. Key growth constraints include a large and impoverished rural population, under-served urban poor and a lack of hospital and clinical infrastructure.

Country Structure

One of the Mexican markets key attractions is its relatively advanced IP protections in comparison to other Latin American markets, with the exception of Puerto Rico. However, rules are often poorly enforced on the ground and there is a clear lack of co-ordination between regulatory and oversight bodies,

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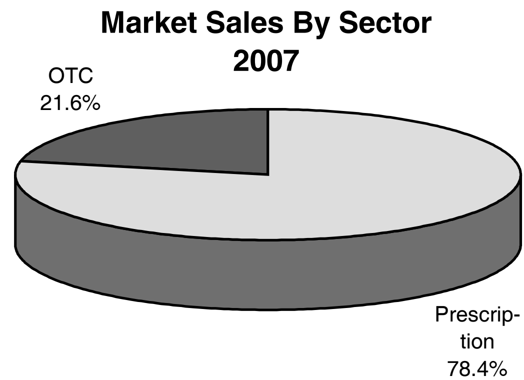
in particular the patent office and drug regulator. Mexico's score reflects substantial increases in medicines availability through state programmes, but also the huge and remaining inequities and lack of access to necessary medicines for millions of poorer Mexicans. The country has a relatively free pricing environment, although the government has put increasing pressure on manufacturers and wholesalers to lower their prices for state purchasers. Still, price controls remain off the agenda – for now.

Mexico – Market Summary



Source: BMI

Mexico is one of the world's 10 largest pharmaceutical markets in value terms. Sales value should grow solidly in the short to medium term, barring any major economic shocks, although volumes have lagged. Key drivers for the pharmaceutical market include such broad factors as the country's economic strength and its trade links to the US as well as the EU. Out-of-pocket spending by middle-class and wealthy Mexicans and increased spending under the Seguro Popular insurance system and target programmes such as Health Caravans are driving demand for modern generics and patented medicines. The country has an established domestic industry, with output accounting for around 2.4% of total GDP in 2006 and 12.9% of manufacturing GDP. However, the market is heavily reliant on imports, especially of raw materials. Pharmaceutical spending is forecast to account for around 1.5% of GDP in 2007.

Out-of-pocket spending accounted for an estimated 85% of drug sales in 2006. Smuggling, illegal copies and unregistered products remain considerable problems, with an executive from US firm **Wyeth** reportedly estimating that the market for illegal medicines was growing at around 40% per year. Self-medication is pervasive, leading to over-consumption of some 'lifestyle' medications and antibiotics, while limiting the market for other medicines. The distinction between prescription and true OTC drugs is blurred in practice, as some 40% of all retail sales take place without a prescription. Despite the proliferation of chains, small pharmacies still dominate, leading to higher costs and generally poorer market surveillance.

There are around 200 registered pharmaceutical companies operating in Mexico, employing around 40,000 people. However, large-scale production is limited to around 40 facilities, which account for around 95% of the market. The leading 10 firms account for around 33% of sales. According to the trade association Canifarma, which includes around 150 facilities, investment in production is expected to be worth US$600mn by the end of 2008. Investment comes as local producers implement Good Manufacturing Practice (GMP) standards, which will allow them to increase exports. Leading local producers include **Armstrong**, **Liomont**, **Sanfer** and **Pisa**. The US and other Latin American markets represent significant export markets, with total pharmaceutical exports estimated at around US$1.49bn in 2007.

Almost all major multinationals are present, not least because Mexico's regulatory system has long encouraged local production by requiring a local presence for issuing sanitary certification for manufacturing facilities. This 'local plant' regulation was abolished in October 2007. Its abolition was one of a number of reforms endorsed by Federal Commission for Regulatory Improvement (COFEMER) in mid-2007, aimed at reducing the final cost of medicines on the market through greater competition and lower up-front market entry costs. This move should make life easier for mid-sized foreign producers and generics producers in particular, which are not already present in the country.

Companies with a significant direct manufacturing presence in Mexico include **Boehringer Ingelheim/Promeco**, **Bayer**, **Bristol-Myers Squibb** (BMS), **Eli Lilly**, **GlaxoSmithKline** (GSK), **Merck & Co**, Roche, **Sanofi-Aventis** and **Schering-Plough**. Other companies market products through agreements with third parties.

In the retail sector, leading pharmacy chains include **Fragua**, **Casa Saba** and **Nadro**. Two large players – **Farmacias Similares**, with around 2,200 pharmacies, and fast-growing **Farmacies del Ahorro** – have achieved considerable success and visibility by targeting poorer consumers with a large number of *similares*, or copy medicines, sold at substantial discount. They also provide low-cost clinics and other services in many areas where the government has been absent. The market share of the two leading distributors, Saba and Nadro, is estimated at 70%, with margins estimated at 15%, although in practice margins vary widely according to the cost and availability of the product in question, a point of considerable controversy at present.

Regulatory Regime

A new regulatory authority, the Federal Commission for Sanitary Risk Protection (COFEPRIS), began operation in 2003; the body replaced the previous body, DIGECIS. The regulator is officially autonomous, but operates under the auspices of the Health Secretariat. Mexico's regulatory system is among the most developed in Latin America, and has undergone significant modernisation in recent years. The Mexican regulatory environment is still in the midst of considerable change, with the 20-year-old General Health Law undergoing amendments in 2007 and new law incorporating them now due to reach Congress in 2008. It is hoped the new law will provide greater clarity on a number of fronts while providing rules for products, such as bio-generics, which are not directly addressed by existing legislation.

In May 2007, COFEPRIS endorsed a measure backed by the president that would allow pharmaceutical manufacturers without a local presence to gain sanitary production for their products and in late June, the Secretariat of the Economy submitted a new draft regulation to COFEMER, the federal body overseeing regulatory changes aimed at improving the competitiveness of the Mexican economy. In October, the "local plant" regulation was eliminated and the government justified the move as necessary to drive greater competition and deliver lower costs. Nonetheless, foreign facilities will be required to meet rigorous GMP guidelines to achieve certification, so this move will most likely favour mid to large-sized generics producers, as most research-based manufacturers already have an established presence in the country. One ongoing area of scrutiny is marketing practices. The research-based industry association AMIIF said in mid-2006 that such samples only accounted for 1% of the market and has defended the use of product samples supplied to doctors. COFEPRIS and the health ministry have warned that product samples are widely re-sold in Mexico, creating a significant illicit market for medicines that are either unsafe or simply expired. The World Health Organization (WHO) has estimated that free samples account for as much as 10% of retail sales.

COFEPRIS co-operates closely with the US Food and Drug Administration (FDA), although there are occasional areas of friction. One long-term source of conflict between Mexican and US authorities has been the regulation of the controlled pharmaceutical trade and, in particular, pseudoephedrine products. In the last few years, authorities south of the border had pledged to closely monitor shipments of pseudoephedrine, a key ingredient in the narcotic crystal methamphetamine. Legal shipments of the product, used widely in cold and allergy remedies, were to be closely tracked, with drugmakers monitored for unusual and out-of-season use of the ingredient. In addition, a gradual phasing-out of the ingredient in OTC products was underway.

However, this crackdown accelerated in 2007. By the end of August 2007, Mexican pharmacies were obliged to pull all pseudoephedrine-containing products from OTC sale. The move means drugmakers are obliged to use other formulations, such as phenylephrine and other substances, a transition that in any case was already underway. Drugmakers will be allowed to use the substance in prescription medicines

from the end of August, but reduced use of the chemical will put shipments under renewed scrutiny. Meanwhile, under earlier rules promulgated by COFEPRIS, pseudoephedrine production is limited to three tonnes per year per manufacturer in Mexico. There are six registered pseudoephedrine producers in the country, required under 1994 GMP legislation to produce no more than is required for 'common use'.

The latest crackdown follows an embarrassing political scandal in mid-2007 involving Chinese-Mexican pharmaceutical tycoon, Zhenli Ye Gon, the head of local firm **Unimed**. Zhenli allegedly used the company as a front with which he shipped hundreds of tonnes of pseudoephedrine for processing into methamphetamine. Amid allegations made by Zhenli that narco-traffickers had provided millions of dollars to the ruling PAN, the scandal has also raised fresh questions about oversight of pharmaceutical ingredients shipments in China, the US and Mexico, as it appears the ingredient was relabelled upon shipment from China. The government has also said that a large number of counterfeit COFEPRIS certificates for pseudoephedrine shipments have been discovered.

Intellectual Property Environment

In the past, patent protection has been an area of severe friction between the international pharmaceutical community and the Mexican government. However, reforms over the last few years have been positive in the eyes of research-based manufacturers. Today, the key players opposing further IP protections and better enforcement are local producers, which have been harmed by tougher IP rules, and a coalition of opposition politicians and civic groups who see recent reforms as driving overall price growth. In September 2003, the government updated its 1991 patent legislation, with new measures stipulating that companies require patent protection certification in order to gain marketing approval. In February 2005, Mexico approved a further tightening of its IP legislation, amending Article 376 of the country's General Health Law. The measures, which replace a voluntary code for non-generic drugmakers introduced in 1997, received praise from the research-based sector. The new rules imposed five-year data exclusivity and oblige manufacturers to renew their product registrations and demonstrate bioequivalence and therapeutic efficacy prior to initiating the production of any new drug. COFEPRIS expects all pharmaceutical products to be of proven bioequivalence by February 2010. In principle, this is a major boost for both research-based and international generics makers.

However, data exclusivity continues to be laxly enforced in Mexico, with R&D-based multinationals claiming that copies of at least 20 patented molecules – including atorvastatin, risedronate and azithromycin – remained legally approved in the country in early 2006. Furthermore, claims that bioequivalence for all generics in Mexico will become a reality by the end of the decade appear overly optimistic. A new 'certificate of interchangeability' introduced for generics in late 2005 stops short of demanding the comprehensive testing that is required for generics in advanced markets.

Mexico remained on the US Trade Representative's (USTR) 'Watch List' of countries with significant shortcomings in IP legislation in 2007. The US industry association Pharmaceutical Research and Manufacturers of America (PhRMA) has also been a persistent critic of Mexico's IP legislation. It has

alleged in recent years that the lack of legislation accompanying the North American Free Trade Agreement (NAFTA) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) stipulations relating to data exclusivity violate these key trade accords. A key issue is that although these measures are enshrined in Mexico's cornerstone IP legislation, the Industrial Property Law, there is little detail on the state's duty to enforce the provisions. PhRMA also claims that Mexico has no legal mechanism outlining how agencies should prevent both indirect and direct reliance on protected data by regulators examining product submissions.

PhRMA has also complained that although a linkage mechanism between COFEPRIS and the national patent office (IMPI) was created by decree in 2003, this mechanism has no formal underlying criteria, and registrations remain subject to delays. Furthermore, the decree has been interpreted as referring only to active pharmaceutical ingredients rather than the multiple product patents that protect many pharmaceuticals. PhRMA said in its 2007 'Special 301' submission that Mexico should be subject to a special 'Out-of-Cycle Review' by the USTR to apply clear pressure to address these problems. Still, most observers see considerable progress in recent years, despite substantial domestic opposition. The changes are directly related to achieving the government's stated desire to force all patent-infringing copied products, known locally as *similares*, off the market. In order to preserve public access to affordable medicines, it is hoped that the reforms will instead encourage the penetration of legal and affordable generics. Official sources expect the amendment to mark a further step towards full Mexican compliance with standards in International Conference of Harmonisation (ICH) member countries, which have pledged to harmonise drug regulations in the developed markets of the US, Canada, Japan and the EU.

In mid-2005 legislators approved a law that increased penalties against the illicit copying or counterfeiting of drugs, reclassifying such offences as a federal crime. The bout of reform in recent years also strengthens criminal penalties against producers of so-called 'miracle products' of unproven therapeutic value, with several firms already reported to have suspended manufacturing in advance of government inspections. Notably, COFEPRIS is now tasked with destroying bogus pharmaceuticals, rather than its earlier mandate that products merely be relabelled.

More detailed criteria outlining the definition of generic medicines – aimed at addressing existing loopholes – are outlined in proposed reforms to the General Health Law. The new regulations are likely to clarify legal definitions for generic medicines. Until the newly-amended law's passage and enforcement – presenting a major task in itself – certain ambiguities are likely to remain. According to PhRMA, applicants for product registrations are required to state under oath that their submission complies with Mexican patent law, after which IMPI has just 10 working days in which to issue an opinion. PhRMA has called for the creation of a database of all valid drug patents.

In October 2007, IMPI took a major step by agreeing to put its national patent data on the World Intellectual Property Organization's (WIPO) PatentScope online database. WIPO has also committed to launching a Spanish-language version of the database to make it more accessible for companies and

regulators in Latin America. However, IMPI has made clear that it would oppose extensions of data exclusivity to 20 years, with the head of IMPI's industrial property division saying in Q407 that such extensions granted in other countries would be opposed in Mexico.

In all, Mexico's recent progress on IP matters has been among the most substantial in Latin America – a region traditionally plagued by overpriced and potentially unsafe copied medicines. Testimony to this was the previous Fox administration's pledge to offer universal treatment to all sufferers of HIV/AIDS under the new Seguro Popular healthcare scheme without breaking patents – a pledge with important consequences after recent attempts by opposition politicians to reduce the 20-year term of patents in Mexico, and have the bioequivalency reform declared unconstitutional – have caused controversy, but so far failed to make serious headway.

However, enforcement on the ground, clarity and understanding of regulations and coordination between regulatory bodies remains a major problems. US drugmaker Eli Lilly has been involved in litigation to seek the removal of a copy version of diabetes drug *Actos* (pioglitazone), which it markets in Mexico as part of an agreement with Japanese drugmaker **Takeda**. Despite a July 2006 ruling in Eli Lilly's favour by the IMPI patent office, local firm RIMSA has reportedly continued to market a pioglitazone containing product in Mexico under the trademark *Diaberil* (pioglitazone and glimepiride). Eli Lilly says the current Mexican patent is not due to expire until 2011, while RIMSA claims the patent expired in January 2006 and has questioned the applicability of patent-term restoration to the case. COFEPRIS reportedly refused to enforce the IMPI measure – underscoring the lack of coordination or even cooperation between the two bodies – and the matter has been tied up in the courts. It was reported by local media that the regulator had 'temporarily' revoked RIMSA's authorisation to market the drug in August 2007.

Recent reforms obliging pharmaceutical firms to prove bioequivalence for their products will impose a huge up-front cost borne by local manufacturers and state reimbursement programmes. It is estimated that 3,500 products will have to be re-registered and it is unclear that the government's 2010 deadline can be met, given the reported lack of available testing labs – reportedly COFEPRIS has less than 25 at its disposal as well as a clear budget for the effort. Despite the costs, the reform should boost Mexico's burgeoning clinical testing industry, and multinationals have welcomed the move. On the other hand, cost considerations have unsurprisingly led local manufacturers of *similares* to attempt to block the reforms.

In July 2006, the Mexican Supreme Court upheld the re-registration reform, rejecting a challenge to the new legislation brought by 'a few' unidentified local firms. Significantly, however, the decision upheld the right of manufacturers to continue to commercialise their products during the period of re-registration. Although this will bring greater legal certainty to drug registrations, it may remain possible for copied formulations of patented molecules to remain on sale while a decision by health regulators is still pending. The average drug approval delay in Mexico is estimated at nearly six months, although registration timeframes are officially as little as 60 days.

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Table: Mexican Marketing Applications In Alleged Violation Of Patent Rights

Chemical name	Trade name (US)	US expiration date	Applicant	Originator company
Atorvastatin	*Lipitor*	2010	Hexal	Pfizer
Azithromycin	*Zithromax*	2006	RIMSA	Pfizer
Azithromycin	*Zithromax*	2006	Kendrick	Pfizer
Azithromycin	*Zithromax*	2006	Loeffler	Pfizer
Azithromycin	*Zithromax*	2006	Lemery	Pfizer
Azithromycin	*Zithromax*	2006	Antibioticos de México	Pfizer
Raloxifene	*Evista*	na	Euromex	Eli Lilly
Sertraline	*Zoloft*	2006	Labs Zerboni	Pfizer
Amlodipine	*Norvasc*	2007	Loeffler	Pfizer
Sibutramine	*Meridia*	2007	Investigaciones Farmaceuticas	Abbott
Risedronate	*Actonel*	na	na	Sanofi-Aventis

na = not available. Source: PhRMA, BMI

In late 2005 the previous government published a new strategy for the pharmaceutical industry in Mexico, marking a significant step towards healthcare sector development. Proposals on the regulatory side include the introduction of unit-dose dispensing, which has been (so far unsuccessfully) implemented in Brazil. A prominent member of the ruling PAN and former social security chief has renewed the push for unit-dose dispensing in an initiative launched in May 2007.

This and many other cost-saving plans require changes in the law, which will be much fought over during 2008. Additionally, the study recommends prescribing controls, wider international GMP recognition, the aggressive use of generics and the introduction of true pharmaco-economic pricing criteria for the first time. The plans also envisage national self-sufficiency in vaccines, better deployment of resources in the research and development (R&D) sector and efforts to reverse Mexico's import dependency on active pharmaceutical ingredients (APIs). The strategy was published at the end of the Vicente Fox's presidential term, but its key pillars appear to have been taken up by President Calderón since he took office in December 2006.

Stricter IP rules continue to fuel a backlash in the industry and among politicians. In January 2007, opposition senators called for an investigation of drug distributors supplying public procurement, citing alleged price gouging for medicines used to treat chronic diseases. Proposals, fuelled by media and popular discontent with drug prices and availability of reimbursed medicines, would include a rollback of the recent, hard-won improvements in the IP environment. Such populist calls are supported by many

local producers of copy drugs, but would involve substantial backtracking and violation of Mexico's obligations under NAFTA and WTO guidelines.

On a more positive note for the drug industry, COFEPRIS indicated in Q307 that it intended to accelerate the rate at which it reviews and eliminates non-bioequivalent generics, with a pledge to review an additional 4,000 pharmaceutical presentations before year-end. It is less than clear, however, that COFEPRIS has the manpower or testing infrastructure available, let alone the funding to meet the 2010 deadline for eliminating non-bioequivalent medicines.

Pricing And Reimbursement Issues

The Mexican government focused on pricing and availability of medicines as a key political issue in 2007. That said, the authorities have loosened controls in recent years, giving the industry greater flexibility. Non-patented drugs are priced freely, with maximum prices for patented drugs set in consultation with the industry, the Health Secretariat, the Trade Secretariat and the finance ministry. An assessment of the therapeutic advantage of each product, as well as a basket of prices in the world's six largest drug markets, is also used as reference in drug pricing.

The Health Secretariat claimed in 2006 that Mexico's average drug prices were about 80% of levels in the US, when adjusted for purchasing power. Consumer groups complain that final selling prices are often more than twice the agreed official maximum, with distributors and retailers accounting for a further 43% of the final price. Other surveys have reported mark-ups of between 20% and 100% of the manufacturing price, with smaller, poorer regulated pharmacies – generally located in the poorest regions – often subject to the highest mark-ups. A study published in Q107 by academic Gustavo Leal of the Universidad Nacional Autónoma de México (UNAM) identified that Mexico's medicines prices are the sixth-highest in the world, behind only the largest and richest developed markets. Another study in 2007 indicated that in the previous six years, medicines prices had grown by 45% compared to overall price inflation of 30%. In all, pricing remains a major political issue and a particular sore point for the current government, which has pledged to tackle high prices.

The Health Secretariat acknowledges that the consensual approach to pricing taken with foreign and local drug companies is failing to deliver cost savings. Recent evidence appears to confirm that selling prices frequently exceed the agreed price ceilings, once pricing negotiations are completed.

The distribution sector has also been widely blamed for high private-sector drug prices, as around five major distributors (Nadro, Casa Saba, **Casa Marzam**, **Farmacos Especializados** and **Farmacias Nacionales**) control the national market. Recent figures suggest that Nadro and Saba alone have 70% of the market between them.

In the public sector, although prices are on average a third lower than in the private sector, corruption and poorly co-ordinated procurement procedures have been blamed for relatively high prices and frequent

shortages. In late February 2007, President Calderón signed the 'Compromise for the Guarantee of Sufficiency, Access and Fair Pricing for Medicines' with leading drug distributors and pharmaceutical producers. This deal represents a voluntary code of conduct aimed at promoting transparency in pricing, but many wonder if it will have much effect on waste and corruption. The threat of greater regulation is the primary weapon wielded by the government in negotiations.

The lack of a unified reimbursement system and the absence of widespread private health insurance have limited the market's potential in the past. It was estimated in mid 2007 that although the sector is growing strongly, insurance coverage of all types, including schemes for state employees and **Petróleos Mexicanos** (PEMEX) oil company programmes, covered just 50.1% of the population – itself a major improvement compared with 43% reported in the 2000 census. The private insurance system has been criticised on a cost basis, requiring 12 significant insurers and the accompanying administrative costs. But the main thrust of reform has been to extend coverage through subsidies and state-run programmes, although these themselves have been criticised as grossly inefficient. An additional concern is the million of Mexican nationals working in the US who do not have health insurance. In 2007 the Mexican and US governments discussed bilateral initiatives to provide coverage and set up a working group linking the Health ministries of both countries in October.

Endemic self-medication and lack of prescription controls in many pharmacies have created distortions in the market that leave many chronic conditions untreated. Many of the leading products are related to changes in diet and lifestyle. For example, soaring sales of erectile dysfunction (ED) products are partly attributed to the near-epidemic levels of diabetes in Mexico, indicating that underlying conditions routinely go under-treated. A number of drugs for treating obesity, including higher priced new medicines, have been launched in Mexico. But it is unlikely many of these will reach the poorest segments of the population, where obesity is particularly prevalent. Data published in 2007 suggest as many as 20% of Mexicans over 50 suffer from either Type I or Type II diabetes, with rates of 10.7% reported among those aged 20 to 69. The number of diabetes sufferers in Mexico is forecast to reach 14mn by 2025.

The structure of Mexico's healthcare system partly explains under-treatment of chronic disease and excessive self-medication, and doctors estimate that 40% of adult Mexicans routinely self-medicate with some using up to eight drug products each day. This has raised considerable concerns about overuse of antibiotics in particular, fuelling the spread of antibiotic resistant diseases. Many poorer consumers find doctor visits prohibitively expensive, whereas OTCs are easily available on the street. Meanwhile, 49.9% of Mexicans lack health insurance coverage, and state providers report frequent shortfalls in supplies of essential prescription drugs. Critics have charged that Mexicans essentially pay twice for healthcare services, firstly through wage contributions to mandatory insurance programmes that fail to deliver care and secondly to buy needed medicines or treatment privately when care under insurance proves unavailable.

In January 2006, legislators approved an important reform of pricing regulations. Drug companies opposed the amendment to the General Health Law, which stipulated that prices of the 191 drugs included in Mexico's basket of essential, state-reimbursable pharmaceuticals may not rise above the rate of increase in the national minimum wage. Industry groups pointed out that such prices have historically risen at a lower rate than the rest of the market. In 2004, the increase in the prices for drugs in the basket and the minimum wage were respectively 2.98% and 4.25%, and in 2005 were about 3% and 5.5%. Firms claim that despite extensive consultation on the measure, it was approved suddenly and without warning. In April 2006, research-based industry association AMIIF protested that the reform reflected an 'ignorance' of the subject and a 'lack of logic' on the part of lawmakers.

Other Regulatory Developments

Mexico is currently modernising its public-sector health system. Its Seguro Popular social insurance system was introduced in early 2004 under the Fox administration. The scheme pledged to reimburse treatment in all cases where 'catastrophic' costs are likely to be incurred. Additionally, the government operates a reimbursement scheme for about 47mn formally employed workers known as IMSS, and another system for around 10mn government workers, known as ISSSTE.

Procurement practices in the public sector are a particular concern for brand-name drug manufacturers in recent years. A decree issued in July 2005 granted preference to lower-cost 'substitute products', a provision that patented drug manufacturers claim created a new opening for inferior copy pharmaceuticals. It is argued that the decree incorrectly interpreted an article in the NAFTA treaty that allows governments to tender for 'alternative' products in the absence of competition. Under the decree, procurement agencies are effectively protected from legal claims alleging patent infringement.

Despite the decree, public hospitals continued to report shortfalls in life-saving drugs during 2007. This is attributed problems with the wider distribution system. It has been claimed that wholesalers – which usually agree prices on a case-by-case basis with government agencies – retain medicines that are excluded from the 'basket' of basic drugs until a shortage is generated, and then sell them at higher prices. According to data from Mexico's Hospital Performance Observatory published in 2006, state institutions are failing to provide products included on a list of 31 medicines deemed 'essential' in all hospitals. Studies indicate that the state insurance schemes for workers, IMSS and ISSSTE, have only 90% of these drugs available, while smaller hospitals at the state level offer only 70%.

The Seguro Popular was budgeted at some MXN4.2bn (US$375mn) in 2005, with the 2007 combined budget allocation standing at around MXN45bn (US$4.2bn), while the overall health budget increased14%. Spending directed through the IMSS appears to have been cut back in 2007, however, and the government moved in February 2007 to reduce the number of suppliers in the programme to cut costs. Moves to restrain spending under the ISSSTE have focused on better financial management. Under legislation passed in March 2007, the ISSSTE will see an outside fund manager, Afore Pensionissste, appointed to manage worker contributions in a bid to improve oversight and eliminate perennial deficits.

In January 2007, President Calderón introduced two new elements to the Seguro Popular, known as the New Generation and Health Caravan schemes. The New Generation programme guarantees all children born since the beginning of December 2006 coverage under the IMSS and ISSSTE, coinciding with the start of Calderón's administration. The Health Caravans aim to implement the promise of coverage contained in the broader Seguro Popular scheme, by bringing clinical services to poor and isolated regions. The additional pledges added US$350mn in spending to the Seguro Popular scheme in 2007.

The market is awaiting the final publication of the Five-Year Health Strategy early in 2008. Details published in the Mexican media indicate the government will aim for up to 85% insurance coverage by 2011 – a very ambitious goal – and free-at-point-of-consumption care for up to 11mn families. In late October 2007, President Calderón said that the total healthcare spending in the draft 2008 budget would reach MXN113bn, compared to MXN82bn the year before, representing a 38% y-o-y increase. Some MXN4bn is earmarked for the hospitals and clinics run by the IMSS while MXN3.6bn would go to hospitals and clinics run by the Health Secretariat. Notably, the president said during the same month that Mexicans should not expect a truly universal healthcare system before 2030, given the scope of the challenges involved. He said his government was acting to create foundations for such a system, which he claims were ignored by the previous Institutional Revolutionary Party (PRI), which had occupied the presidency for seven decades before 2000.

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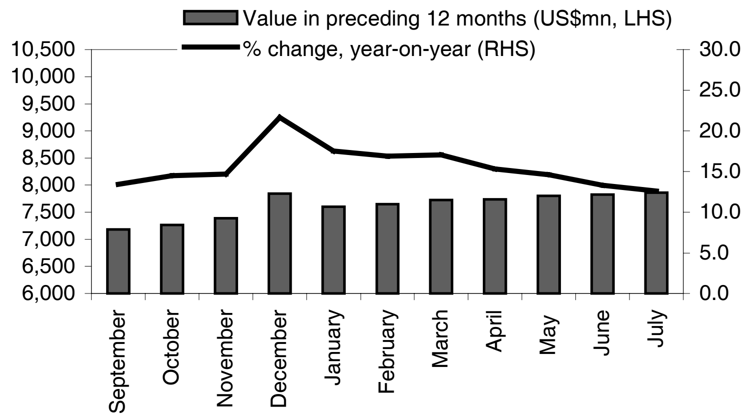
Industry Developments

Pharmaceutical Market Trends

The Mexican pharmaceutical market consists of around 7,000 products in approximately 19,000 presentations. According to data from US manufacturer Merck & Co, some 415 new medicines have been launched on the market since 1999. A chief characteristic of the market is the significant but declining share, in unit and value terms, of older drugs and non-bioequivalent copy medicines.

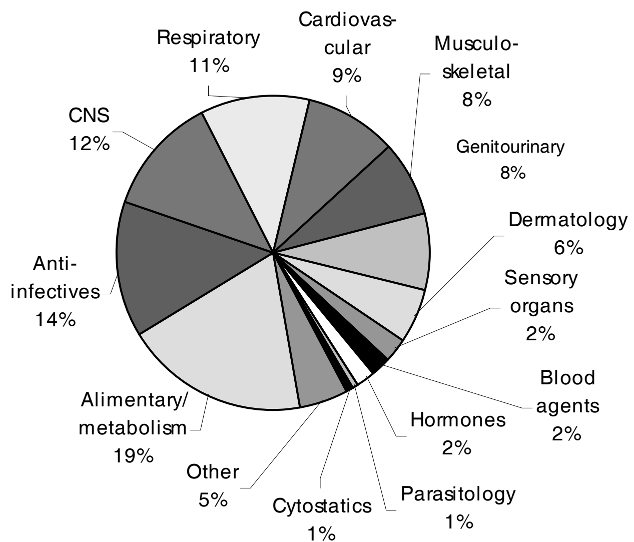
Retail Drug Sales, Preceding 12 Months, 2005-2006



Sources: IMS Health, BMI

Following a recession in 2004, Mexico's private retail drug market recovered in 2005 and 2006, with growth remaining steady in 2007. Currency-adjusted retail pharmacy sales in the 12 months to January 2007 totalled US$8.11bn, indicating a year-on-year (y-o-y) rise of some 8.8%, according to IMS Health data. Official data claim the market was worth US$12.3bn in 2006, although **BMI** puts this figure slightly lower, at US$12.2bn. At the same time, volume growth has been low. IMS Health estimated that the number of units sold increased by 0.7% over the 12 months to July 2007, while the market grew by 7.5%. At least some of this is attributable to greater use of more effective medicines but also supports continued concerns that drug prices as a whole are rising above inflation.

Retail Pharmacy Sales, 12 Months To May 2006



Source: IMS Health, BMI

Surveys highlight the predominance of basic drugs in Mexico, especially anti-infectives and genito-urinary treatments. This further illustrates both the market's emerging nature and the local popularity of so-called 'lifestyle drugs', such as ED products

and obesity treatments. However, the government and health professionals continue to express concern that current drug-consumption patterns reflect a lack of basic health screening, with consumers self-treating the symptoms of preventable or treatable underlying disease. From an economic perspective, this means that existing drug spend is frequently inefficient and the cost-effective advantage of preventative treatment is squandered.

According to local reports, diabetes accounts for 34% of Mexico's public health insurance spending, and local experts predict that on current trends, the number of diabetics in Mexico could rise by a third by 2010. Moreover, some 35% of Mexico's 6.5mn diabetics are reported to be unaware that they have the disease. Reasons given for the near-epidemic levels of diabetes vary, but changes to diet in recent decades, which has seen a major obesity epidemic among younger Mexicans, particularly among the poor.

Mexican patients also consume up to MXN17bn (US$1.6bn) per year on 68mn units of analgesics per year, according to estimates presented by the Mexican Council for Traumatology and Orthopaedics (CMTO) in Q107. However, with some 25mn Mexicans estimated to suffer from acute or chronic pain conditions, most self-treat ineffectively. As many of these patients feel unable to afford a doctor's consultation, they often miss out on newer and more effective medicines now available in the market.

Public-sector expenditure accounts for a large and growing share of Mexico's pharmaceuticals market. Rising state expenditure has focused on the growing costs associated with the three key disease areas of diabetes, cancer and HIV/AIDS. Nonetheless, much of public-sector supply consists of older products or locally-manufactured, inexpensive copies. This is reflected by the public sector's higher share in volume terms.

In a further cost pressure on the healthcare system, retirees also represent a third of all Mexican consumers. Over-65s are forecast to account for a quarter of the population by 2030, a development certain to boost uptake of medicines to treat conditions associated with ageing. On the other end of the scale, in reports published in April 2007, Mexican health experts said at least 30% of under-14s can be classified as overweight or obese, with growing incidence of related metabolic disorders, including hypertension, diabetes and high cholesterol.

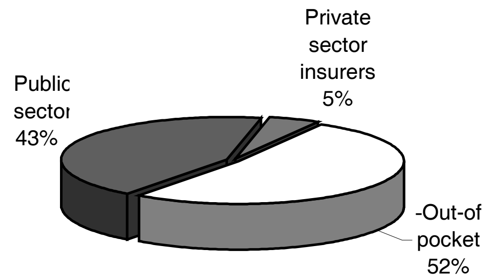
Healthcare Sector

According to the OECD, Mexico's health spending is proportionally one of the lowest of all its member states, although relatively high by regional standards. A bigger concern is a perceived lack of efficiency in the allocation of spending. The data indicate that health expenditure is only around 6.4% of GDP – a figure comparable with levels in Poland, and well below the OECD average of 8.6%, according to 2006 data. However, healthcare spending is increasing at its fastest rate in more than 15 years. The government's overall healthcare budget has nearly doubled from 2000 to 2006, to US$7.5bn. Healthcare spending's share of GDP has risen by a full percentage point (pp) to 6.6% in just six years. A recent

reform mandates that public health expenditure must rise each year, with total spending eventually set to reach about 7.5% of GDP.

Health spending in the 2007 budget was 12% higher than in 2006, with spending expanded to newborns and investments made in travelling clinics to visit impoverished areas lacking existing clinics and hospitals. The lingering question, given chronic problems in government tendering and the need for the central and state governments to work together in a fairly politicised political environment, is whether this spending can deliver change efficiently and make visible gains within the life of the current presidential administration. The administration claimed in October 2007 that total proposed increases in health spending in the draft 2008 budget represented a 38% boost, with funding aimed in particular at the ailing state hospital sector.

Healthcare Spending In Mexico



Source: OECD, BMI

Despite increased spending, inequalities remain entrenched, with out-of-pocket spending accounting for around 51% of healthcare costs and around 85% of pharmaceutical expenditure. Other estimates in recent years, notably by the World Bank, have put true out-pocket-spending levels higher, at up to 94%. The private health insurance sector remains stunted by the dominance of the public sector, capturing a share of only 5% in overall healthcare reimbursement. With the growth of programmes for the poorest, including those working in the large informal economy, as well as growth in the still small private insurance market, the head of the **Banco de México** (Banxico) noted in August 2007 that the so-called 'working poor' – those in low-paid formal employment – were a large portion of the uninsured and that recent reforms had failed to target this less visible group.

Despite these problems, the recent wave of healthcare reform has attracted renewed attention and additional investment by multinational drugmakers. The Seguro Popular – newly expanded under the new administration of Felipe Calderón –could bring new consumers into the pharmaceutical market for the first time, albeit initially at the lowest end of the price spectrum. More importantly, the scheme should, over time, allow society to better spread the costs associated with drug treatment. In turn, this should potentially allow large long-term savings through a greater emphasis on preventive medicine, an area that is critically under-served, rather than expensive drug and hospital treatment.

The scheme was introduced in early 2004, aiming to allow low-income families to meet 'catastrophic' treatment costs. By 2010, federal health officials expect the scheme to roll out to 10,000 municipalities and treat 10mn Mexican families in 15 states. The 2006 budget for the initiative was some US$1.7bn, with 42% of this total earmarked for the procurement of pharmaceuticals. Public drug procurement in

Mexico reached a planned US$4.2bn for 2007. In early 2006, local drug retail association ANAFARMEX claimed that 20,000 pharmacies were expected to adhere to the scheme. Shortly thereafter, stakeholders agreed to a distribution plan that envisaged the sharing of commissions between manufacturers and distributors that will supply the scheme. Importantly, current policy demands that some 80% of the medicines dispensed under the scheme must be bioequivalent generics.

Meanwhile, the IMSS, which is 75%-funded by employer contributions, is in a dire state. It is estimated that only MXN2bn (US$184mn) of the funds needed to cover retirement costs for the scheme's 20mn members is actually available. Around US$2.4bn was cut from the institution's budget for 2006, as the government attempted to rein in soaring retirement-age entitlements, but officials have been forced to increase spending to keep it afloat.

However, expectations that the private health insurance sector could help make up some of the expected shortfall in coverage appear optimistic. Tax breaks for insurance contributions were introduced in 2004 to encourage insurers to enter the overall market. Notably, UK insurer **BUPA** said in August 2007 that it would enter the market, which currently covers only around 5% of the population. US company **MetLife**, the overall market leader in the Mexican insurance market, re-launched a key healthcare insurance package in 2007 after reporting growth of 12.1% y-o-y to MXN3.4bn (US$311.9mn) in this segment. The company says it sees a potential US$20bn market for healthcare insurance in Mexico. Insurers have been alarmed by proposals floated in mid-2007 to rescind the 2004 tax breaks as part of broader tax reforms, a move that would negatively impact take-up of insurance plans, adding to public healthcare burden.

The low quality of many private care facilities in Mexico is also an issue, albeit one that has gained less attention than the highly-publicised failings of the state sector. In February 2007, an OECD study found that less than half of private facilities had their own x-ray equipment and a third did not have a full-time doctor on staff. Such poorly equipped facilities are concentrated in the poorer segment of the market but underline an overall shortage of properly equipped facilities across the public and private sectors.

Mexico is one of Latin America's most developed health insurance markets, but the state sector continues to crowd out private players. AMIS estimates the total number of private insurance claims last year at 350,000. AMIS claimed in 2006 that in terms of epidemiological coverage, the average costs reimbursed by its 31 member companies were some MXN14mn (US$1.14mn) per disease.

Pharmaceutical Sector

Pharmaceutical sector development in Mexico has been significant since the approval of laws in the late 1990s allowing greater foreign shareholdings in the sector. A number of factors are currently driving steady market growth since 2004. The continued modernisation of the healthcare system, with growing health awareness and access to medicines through new clinics, has contributed to stronger demand. The gradual alignment of domestic legislation with international norms has also resulted in increased foreign activity and investment. The greater availability of foreign products, which are generally priced above

locally-produced medicines, has driven up spending levels. Underpinning this growth has been the healthy economy, with spending power recovering from 2004 onward after a slowdown in 2003. **BMI** expects Mexican industrial production to strengthen in the medium term, which should bring increased employment and, in turn, boost consumer spending. GDP growth is forecast to average 4.1% between 2007 and 2012.

Still, the pharmaceutical industry continues to face a number of challenges. Despite growing levels of imports, the persistence of a sizeable if shrinking copy drug presence remains a major obstacle to the drug market's value growth. Nevertheless, the expansion of leading copy drug retailers Farmacias Similares and Farmacias del Ahorro into less regulated markets elsewhere in Latin America may be a sign that recent regulatory changes have begun to bite. Notably, Farmacias Similares is reportedly switching more of its product mix to bioequivalent generics.

From a historical perspective, Mexico's pharmaceutical industry has focused on the production of finished drugs, as opposed to active ingredients and intermediate products. The active ingredients industry has declined since the country's entry to the GATT trade tariffs regime in 1986, which opened the sector to foreign competitors. In 1994, there were 48 firms manufacturing 129 active principles and serving 55% of local demand. However, in 2006, only 26 were registered with market regulator COFEPRIS, producing an unknown quantity of APIs. Despite foreign sales of about US$1.37bn in 2006, officials are disappointed with the performance of Mexico's drug exports and manufacturers face strong competition from growing Brazilian exports as well as the ever present threat of Indian generics makers.

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, NSAIDs, cancer drugs and biopharmaceuticals. In late 2005, the Indian generics and raw materials producer **Dr Reddy's** acquired the APIs and bulk drugs business of Swiss-owned **Roche Syntex** for an estimated US$59mn. The deal illustrated a global shift in the sourcing of APIs, which many Asian firms have the technology, low costs and scale to exploit. From this perspective, the consolidation of Mexico's APIs sector was inevitable.

Generics Sector

The Mexican government has committed to encouraging the genuine generics market and battle consumer and prescriber misconceptions over the sector. Generics are set to be a key element of healthcare modernisation, although at present very few advanced generics are included on the government's basic drugs basket (known as the *Cuadro Básico*). Unlike in Brazil, where generics now account for around 15% of the market, the proportion of generics in the overall market is not forecast to reach 5% in Mexico until 2012, despite high growth rates in the sector in recent years.

Some domestic producers have attempted to get around Mexico's distribution oligopoly by developing their own wholesale chains. The decision by the country's largest retailer, **Walmex,** (owned by **Wal-**

Mart, itself the world's largest retailer by turnover) to launch a new low-cost line of essential generics in late April 2007, could be a major boost for long-term growth in the Mexican generics market. The store launched an initial line of around 155 generic drugs to be sold at its more than 560 in-store pharmacies, with plans to expand the line to some 250 medicines. The medicines are priced at a maximum of MXN39 (US$3.50) each as the chain looks to replicate the early success of its US$4 line of generics launched by parent company Wal-Mart in the US market last September.

Today, perhaps the bulk of the Mexican pharmaceutical manufacturing sector has opted to pursue bioequivalent generics. Even manufacturers who have opposed tougher bioequivalence requirements now see legitimate generics as the only way to secure market position domestically and in the regional marketplace over the long term. Walmex is reportedly sourcing many of the medicines in its new, low-cost line from local manufacturers that belong to the **Canifarma** alliance, which will give them a major new outlet for their products. In general, the sector represents an attractive alternative to manufacturing deals with multinationals, at a time when more blockbuster drugs are set to come off patent in the medium term. Alliances with Walmex and other retailers to produce generics under private-label brands are another opportunity, albeit one with slimmer margins than branded generics.

The private-label segment is currently one of the Mexican drug market's fastest growing areas and grew by an estimated 50% in 2005. Large retail chains – such as **El Fenix** and **Benavides**, both owned by Chilean firm **Farmacias Ahumada** – are aggressively promoting private label medicines. There are some concerns, however, that some of these products may not be 'true generics' in the internationally accepted sense, due to loopholes in current legislation defining generics. On the other hand, growing sales by chains such as **Comercial Mexicana** and Walmex should help in the long-term shift towards greater consumer acceptance of generics in Mexico, with cost considerations an obviously critical factor. US-Mexican OTC and generics firm **Quifa-Perrigo** estimates that own-brand off-patent drugs are, on average, roughly half the price of leading patented alternatives.

Indian manufacturers have entered the market in force in recent years, seeking to benefit from the growth of the generics market as well as access other Latin American markets through Mexican-based production. **Wockhardt** has established a new majority-owned venture to market its insulin products in Mexico jointly with the local drug marketer **RIMSA**. Indian concern **Strides Arcolab** already manufactures in Mexico, but has now moved to acquire control of its Mexico-based regional holding company, **Strides Latina**, which has annual revenue of around US$50mn. **Ranbaxy** entered the market through a majority-owned joint venture, supplying its operations from a facility in Brazil. Meanwhile, Dr Reddy's acquired the Mexican API business of Switzerland's Roche in October 2005. In March 2006, Indian firm **Torrent** announced that it was to create a subsidiary in Mexico. The company already has a subsidiary in Brazil, with sales in that country of some US$12.5mn per year. In early 2007, the Indian government and trade organisations renewed its push to sign trade deals with Latin American trade blocs in order to gain tariff-free access to key markets such as Mexico and Brazil. Still, better market and regulatory conditions for generics has meant that the bulk of investments by Indian companies in Latin

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America in 2007 went to the Brazilian market, with few notable deals in Mexico during the year. US investors, too, have also invested in the sector. Private equity fund **Darby Overseas** acquired a controlling stake in **Laboratorios Kendrick**, which claims to be Mexico's second-largest independent generics maker. Fellow local firm **Laboratorios Armstrong** has also expanded its marketing capability, while **Laboratorios Silanes** has pledged to increase output substantially and add new product lines. In August 2007, Silanes signed a deal with Brazilian manufacturer **Aché** to market diabetes and cardiovascular drugs in Brazil.

Meanwhile, global generics makers have also expanded in Mexico since 2004. Swiss major Novartis has launched a number of drugs on the market. US-based **IVAX** – now a part of Israeli generics giant **Teva** – acquired a second manufacturing facility in Mexico in 2004. US-based generics manufacturer **Valeant** has also boosted activities at its Mexican distribution subsidiary. In Mexico, Valeant controls **Laboratorios Grossman**, which fields a number of branded generic anti-infectives, CNS drugs and dermatologicals. Its leading product is vitamin supplement *Bedoyecta*.

Multinational Activity

Mexico's relatively low-cost environment, growing domestic market and NAFTA have made it an attractive export base. State export finance bank **Bancomext** provided finance for around 70 local pharmaceutical makers to expand their exports in 2005. Research-based multinationals have also expanded manufacturing activity. Notably, however, Brazil's lower costs and vastly improved regulatory environment has seen greater recent focus on that market as a Latin American hub, particularly for Indian generics producers as well as some multinational, research-based firms, such as Novartis, which recently made a record investment there to expand its export capabilities. Beyond cost, some producers have expressed frustration that Mexico's regulatory reforms have not progressed as rapidly as promised while enforcement of existing rules remains spotty. Indeed, some have speculated that the elimination of the local plant requirement for manufacturers to receive sanitary certificates could even backfire for the government if companies were to choose to shift their operations to Brazil or elsewhere and import back into the market.

AstraZeneca opened a new manufacturing facility in Naucalpan (near Mexico City) at a cost of US$15mn in 2005. The company claims to have invested US$250mn in Mexico in 2004 and 2005 – equivalent to more than a full year's sales in Mexico. The company launched its cholesterol lowering drug *Crestor* (rosuvastatin) and leading products in the field of oncology including *Arimidex* (anastrozole). The market for oncology medicines in Mexico was estimated at around US$300mn in 2007. In 2007, the UK company also launched OTC pain reliever an anti-inflammatory drug *Gelidol*.

US drugmaker Wyeth invested around US$20mn in updating its Mexican production facility in 2006 and reported sales for the full-year of US$330mn in Mexico. Its upgraded plant is also certified to export to Brazil and Colombia and the company recently invested around US$3.7mn in a new quality control laboratory.

In mid-2005, Germany's Merck KGaA stated that it would upgrade and expand its Mexican manufacturing facility. The plant exports about 30% of production to other Latin American markets, but the company aims over the longer term to boost annual capacity by 15%. The company has also moved to increase exports to the US. In late 2007, Merck KGaA identified Mexico as one of its key growth markets, with 29% y-o-y growth in sales during 2006.

Fellow German drugmaker Boehringer Ingelheim also announced plans to invest up to US$70mn to increase output of its pain drug *Mobicox* (meloxicam) to the US, in order to exploit gaps in the market left by the withdrawals of Cox-2 inhibitors. According to Boehringer, it exported medicines worth US$32mn to the US from its Mexican plants in 2006, making it one of the country's top drug exporters.

Meanwhile, Germany's Bayer has announced plans to invest EUR100mn (US$119.42mn) in Mexico by the end of2008, with around EUR40mn (US$47.75mn) of this total earmarked for expanding its plant in Lerma. However**,** Schering AG, recently acquired by Bayer, had previously announced plans in November 2005 to close its Orizaba, Veracruz facility and transfer production to Germany.

The contract-manufacturing sector in Mexico holds considerable potential. A significant portion of multinational-controlled capacity is estimated to be idle, due to poor market performance in the recent past – mainly linked to a brief recession earlier in the decade. In April 2006, US-based sterilisation equipment manufacturer **Steris** announced the transfer of production assets in Pennsylvania to Guadalupe, Mexico. The new site has been acquired under a deal with local property group **Avante**, and is expected to be operational by end-2007. At the time the deal was announced, Steris anticipated cost savings of some US$30mn per year from the transfer. The company produces sterilisation equipment for hospitals and pharmaceutical production facilities.

In February 2006, Pfizer – which completed a US$22mn upgrade to its distribution facility in Toluca – launched seven new products through mid-2007, although it rapidly withdrew its *Exubera* inhaled insulin product following disappointing sales. In Mexico, according to reports, it had only reached 33% of its planned sales levels in three months on the market.

US pharmaceutical giant **Abbott Laboratories** is reportedly planning to double production volumes in Mexico to 120mn units by 2010 under a three-year plan announced in January 2006. In addition, the company is planning further market launches as well as seeking additional indications for the use of its best-selling anti-rheumatic *Humira* (adalimumab), which was added to the country's national reimbursement list back in 2005. The company already ranks in the top 10 among producers of pharmaceuticals and nutritional supplements in the country. Other key product areas for the company include weight control, with the company's *Reductil* (sibutramine) leading the Mexican market for prescription obesity treatment products in 2006, although it is facing new launches by competitors in this segment. In December 2006, Sanofi-Aventis received registration for *Acomplia* (rimonabant) obesity treatment, a potential blockbuster product.

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Improved performance by the market regulator has allowed Mexico to acquire something of a reputation for early approvals of innovative medicines that meet urgent local epidemiological needs. In 2005, Mexico was first to approve GSK's rotavirus vaccine *Rotarix*. The disease was declared a national priority in 2004 and vaccine coverage is now estimated at around 95% of Mexican children. In June 2006, another Merck & Co product – the HPV vaccine *Gardasil* – also received early approval by the country's Health Secretariat. In August 2006, Merck & Co obtained approval for its new diabetes drug *Januvia* (sitagliptin). In the world's first approval of this breakthrough product, Mexico has become a key battleground for makers of new diabetes treatments.

Switzerland's Roche has invested around US$65mn in recent years to increase output to 120mn units per year at its Mexican subsidiary Roche-Syntex and completed an additional US$60mn investment in a factory in Toluca, in México state, to produce oncology medicines. According to local media reports in May 2007, the company plans to export 10 medicines to the United States within the next few years.

In September 2007, Novartis indicated that it anticipated 15% sales growth by its Mexican subsidiary, with the next 12 months seeing the launch of eight patented medicines as well as six generic products by its subsidiary **Sandoz**. Over the coming year, the company said it would lead the market in the hypertension, oncology and transplants therapeutic categories. The eight innovative drug launches will target hypertension, osteoporosis, asthma, diabetes and ocular disease.

Another key therapeutic battleground in Mexico at present is the market for erectile dysfunction (ED) medicines. *Cialis* (tadalafil), made by Eli Lilly, eclipsed sales of Pfizer's *Viagra* (sildenafil) during the first nine months of 2007, according to data cited by *Reforma* newspaper, with Cialis capturing 40.2% of the market compared to 36.9% for Viagra. Bayer's *Levitra* (vardenafil) accounted for 20% of the market, while another Pfizer product, *Patrex*, a different dosage and formulation of sildenafil accounting for a further 2.7%. The ED market in Mexico is currently estimated at around US$170mn but is expected to continue to develop – Eli Lilly estimated in 2006 that there could be around 6mn ED sufferers, with only around 10% currently receiving treatment.

Research And Development Sector

Mexico's R&D sector has expanded steadily in recent years and the number of clinical trials has increased. The industry federation AMIIF estimates that investment in local R&D was MXN1bn (US$92mn) in 2006. The vast majority of R&D activity in Mexico relates to clinical trial work rather than product development. Major local universities still account for the vast majority of Mexico's discovery work, although GSK's new *Rotarix* vaccine is something of an exception, as the product was partly developed in Mexico. Still, despite having the strongest data protection regime in Latin America and abundant 'treatment naïve' volunteers, R&D activity accounts for an estimated 5% of pharmaceutical company budgets in the country, while 96% of patents are granted for products developed overseas, according to a 2007 report by the OECD. This reflects generally low R&D spending in the economy as a whole, with spending estimated at 0.32% of GDP, far short of the 1% target set by the government. Other

technical issues include reports that clinical trials permit in Mexico can take up to nine months to arrive, compared with three months in most West European countries

Still, the presence of foreign clinical research organisations (CROs) in Mexico increased substantially in 2006, reflecting an improving regulatory environment. The international CROs **Chiltern**, **Kendle** and **Parexel** have all expanded activity in Mexico, following rivals such as **Quintiles**. US-based Parexel pledged to 'formalise' its presence in Mexico, opening a consulting and clinical research office in Mexico City. The company is already present in Brazil, Argentina and Chile. Parexel is to offer a range of services including project, site and data management, as well as regulatory advice for drug development and medical services for phase II-IV clinical trials.

US-based **ReSearch Pharmaceutical Services** (RPS), a contract manufacturer, announced in Q406 that it would add to current operations in Brazil, Argentina and Chile by expanding into Mexico, Peru and Colombia and expand its CRO capacity in the region. UK-based Chiltern has described Mexico as being 'of great interest' to the pharmaceuticals industry. A number of multinational drug firms have increased investment, with Anglo-Swedish firm AstraZeneca recently allocating about US$50mn to research in Mexico. Germany's Boehringer Ingelheim estimates its local R&D spending at about US$2mn per year.

Table: Clinical Research In Mexico, 2003-2004	
Total volunteers enrolled in clinical studies in 2003	26,322
Total volunteers enrolled in clinical studies in 2004 (estimated)	37,561
Clinical research investment in 2004 (US$)	64.3
% year-on-year increase in clinical research investment	16.9
Active research centres	1,135
Of which public	923
Of which private	213
Research staff	1,816
R&D staff directly employed by pharmaceutical companies	289

Source: AMIIF

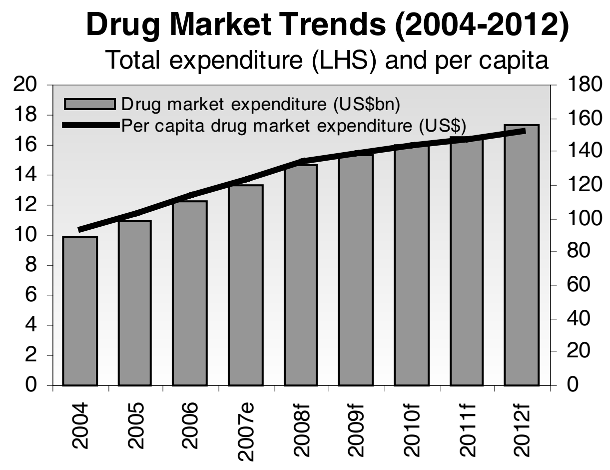
Table: Clinical Studies In Mexico By Therapeutic Area, 2004			
Allergies	2	Immunology/transplant	3
Analgesia/anaesthesiology	2	Infections	7
Bone diseases	1	Neurology	3
Cardiovascular	6	Oncology	7
Dermatology	2	Respiratory	2
Endocrinology	4	Rheumatology	2
Gastroenterology	3	Sleep disorders	1
Gynaecology/Contraception	4	Urology	1

Source: AMIIF

Industry Forecast Scenario

Overall Market Forecast

Drug market growth has been strong in Mexico in recent years. Changes in government policy and stable economic expansion since 2004 have put in place the essential elements for long-term growth. Over the next five years, this steady pattern should see the Mexican drug market attract the most investment, second to fast-growing Brazil, of any of the Latin American markets. With the modernisation of the healthcare sector, total drug spending is likely to reach around US$17.3bn at consumer prices in 2012.



Source: OECD, UN, Ministry of Health, AMIIF, National Statistics Office, BMI research. e/f=estimate/forecast.

Prescription drug spending should grow steadily as consumers continue to favour branded and patented products. The OTC market is also forecast to grow, although its overall share of the market will likely decline slightly. Government policy is having an increasing impact on the retail sector, but out-of-pocket spending continues to account for a majority share of the market. The prescription sector should reach US$14.4bn at retail prices by 2012, with the OTC market at US$2.94bn. A major problem for the sector as a whole, is the continued influx of counterfeit drugs. The growth of chain stores and the promiseof stronger oversight of independents should make life more difficult for counterfeiters over the longer term, although the share of fake medicines is reportedly still growing.

The bioequivalent generics market is expected to grow substantially from a low base, with a key growth driver being the aggressive government promotion of the sector and favourable regulation. The sector's value is forecast to rise from its 2007 level of 3.0% of the total market to 5.0% by 2012. Currently, the main constraints on the market include slow acceptance by consumers and doctors, coupled with the still widespread use of poorer quality copy medicines. Meanwhile, low-cost Indian players may be best positioned to benefit from volume growth in the market and have invested substantially in establishing channels to the market.

The greater enforcement of patent law and the expansion of sophisticated foreign competitors are expected to drive faster value growth in the generics market in the longer term and help build consumer confidence in the products. Since early 2005, generics manufacturers have had to submit their drugs to bioequivalence trials, which could filter through into greater consumer confidence in the sector. Market regulator COFEPRIS has targeted 2010 to complete this process, theoretically eliminating most copy

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drugs from the market. In practice, the regulator appears to lack both the budget and facilities to meet this rapidly approaching deadline and copy drugs are likely to remain a factor for several years yet.

The continued harmonisation of local manufacturing processes with international standards is likely to boost export trade further. Domestic producers are continuing to target the export market in the face of strong domestic competition and due to their relatively basic product offering. The market's reliance on imported drug products – notably raw materials and hi-tech drugs – is unlikely to change in the foreseeable future.

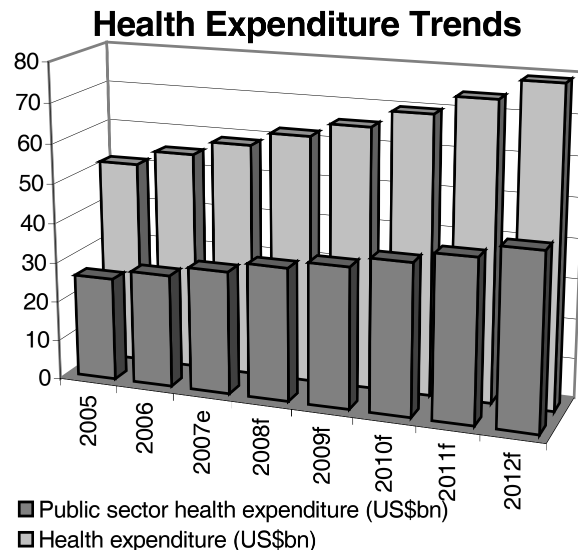
Table: Drug Market Trends

	2006	2007e	2008f	2009f	2010f	2011f	2012f
Drug market expenditure (US$bn)	12.2	13.3	14.7	15.4	16.0	16.6	17.3
Drug market expenditure (MXNbn)	133.5	146.3	166.7	178.7	188.5	197.8	209.3
Per capita drug market expenditure (US$)	114.5	123.2	134.9	139.6	143.9	147.6	152.9
Drug market expenditure as % GDP	1.5	1.5	1.6	1.6	1.6	1.5	1.5

e/f = estimate/forecast. Source: OECD, SSA, AMIIF, Afamela, Canifarma, UN, BMI

Key Growth Factors – Industry

Aside from a rise in consumer spending, Mexico's continued dependence on imported raw materials coupled with high wholesale and retail mark-ups are likely to preserve relatively high final retail price levels. Recent efforts, backed by major initiatives and additional spending by the government to extend healthcare coverage to a greater proportion of the population will also boost the overall market. Tougher controls on counterfeit drugs and dubious 'miracle drugs' should also have a positive impact on the industry. Few expect these issues to disappear in the short term, particularly given difficulties in enforcement in Mexico's decentralised governing environment.



e/f = BMI estimate/forecast. Source: OECD, UN, Health Secretariat, INEGI, BMI

The level of growth, however, will be somewhat more modest in comparison with the period 1998-2002, as the government pledges to pursue health reform on a cost-conscious basis and applies considerable pressure on manufacturers to lower their prices, particularly under the industry pact agreed with local producers and wholesalers in February 2007. The government will continue to promote generic alternatives to patented imports, although as such efforts are at an early stage, the impact of generics on overall market value is likely to be relatively low in the short term. The popularity of low-priced private label drugs is more likely to bring benefits to domestic manufacturers and low-cost foreign producers, rather than multinationals. The greatest gains in value terms in the generics market are likely at the hi-tech end of the scale.

Table: Health Expenditure Indicators

	2005	2006	2007e	2008f	2009f	2010f	2011f	2012f
Health expenditure (US$bn)	51.5	55.1	58.7	62.2	65.5	69.8	74.3	79.2
Health expenditure (% GDP)	6.7	6.6	6.6	6.8	6.8	6.9	6.9	7.0
Health expenditure per capita (US$)	485.9	515.4	543.6	570.3	595.2	628.2	663.1	699.9
Public sector health expenditure (US$bn)	25.9	28.4	31.0	33.6	35.4	38.0	40.9	44.0
Public sector health expenditure (%)	50.4	51.6	52.7	53.9	54.0	54.5	55.0	55.6

e/f = estimate/forecast. Source: OECD, SSA, AMIIF, Afamela, Canifarma, UN, BMI

Key Growth Factors – Macroeconomic

Growth Down, But Not Out

The Mexican story remains healthy in the medium term, and we are confident that the economy is making strides towards securing a sustainable rate of economic expansion. Having said that, the country is likely to be tested by a series of challenges in the next two years that could put pressure on our growth forecast.

When looked at from a panoramic perspective, **BMI** believes that the overall macroeconomic outlook for Mexico is positive. After years of unpredictable and often volatile expansion, the economy appears to be on the path towards sustainable growth. Recent tremors in the global financial markets are likely to confirm our view of weaker Mexican economic expansion in 2007: we are currently estimating real GDP growth of 3.1%, with the risks firmly weighted to the downside. Beyond this point, however, we see economic growth smoothing out towards 4.0% over our five-year forecast period. The rising of a more affluent middle class with growing levels of disposable income (GDP per capita is expected to surpass US$10,000 by 2012), and the government's ambitious plan to give the country's infrastructure a much-needed facelift should keep private consumption and fixed investment growth on the up. Indeed, we anticipate that domestic demand will grow by a yearly average of 7% between 2007 and 2012. Meanwhile, both unemployment and underemployment should soften, as more Mexicans become integrated into the formal labour market, and consumer price inflation should ease to historical lows of around 3%.

Having said that, Mexico is likely to come up against some considerable challenges over the next twelve months that could potentially knock the economy off course. Economic activity has struggled to gather pace in 2007 – real GDP growth (as measured by the IGAE index) and industrial production averaged a lacklustre 2.7% and 0.7% respectively in H107 – and the prospects for 2008 remain clouded. In recent months, we have revised down our 2008 growth forecast from 3.6% to 3.4%, a decision that takes into account not only the latent fragilities of the local economy, but also a violent hurricane season and souring of global financial markets in 2007.

Weathering The US Storm

One risk to growth that cannot be ignored emanates north of the border. Our outlook for US GDP growth is coloured by a very negative view on the local real estate sector. We see real GDP expanding by 2.1% in 2008 and 2.7% in 2009, after estimated growth of just 2.0% in 2007. Indeed, the picture emerging from Q207 GDP data was somewhat grim. Residential investment knocked 0.5pps off of overall growth, while personal consumption expenditures contributed only 0.9pps to the headline figure of 3.4%. On the flipside, if the **Federal Reserve** continues to trim its funds rate (our core scenario), we could see a rally in US economic activity. However, loosening monetary policy is unlikely to mask the shortcomings in the US housing sector over the medium term, in our view.

What does this mean for the Mexican economy? A US slowdown could have any number of effects on Mexico given their close economic and geo-political proximity, rendering the Central American country much more exposed than the majority of other large EM states. The most severe cracks are likely to appear in the external accounts. A sustained slowdown in US industrial production and domestic consumption would have a knock-on effect on the exports of Mexican intermediates and consumables – the lion's share of which are destined for the US market. The maquiladora sector, which has been a key contributor to industrial production and job creation in recent years, would also suffer as a result. In particular, we hold reservations about the local automotive industry, which has already started to feel the pinch of waning overseas demand. After a rip-roaring 2006, export sales on Mexico's new car market have looked sluggish in 2007, rising by 5.2% y-o-y between January and September, with sales to the US market staying almost flat (up by 0.9% y-o-y).

The second risk to growth from the US is in the form of a slowdown in workers remittances. The release of positive data for remittance growth in July comes amid heightened concerns about the impact of a stuttering US construction sector on Mexican labourers north of the border. According to central bank, **Banxico**, between 20-25% of Mexicans living in the US are employed in the sector, leaving the flow of remittances vulnerable to a downturn in construction activity. Indeed, a fall in remittance flows in Q207 was a reflection of the US housing sectors current woes, in our view. Looking ahead, we maintain our view that a slight recovery in remittance flows is still on the cards (we estimate an end 2007 level of US$24.9bn, up 8% from last year). Indeed, we expect a surge in remittances in the wake of Hurricanes Dean and Felix. Nevertheless, the days of double-digit growth in remittances appear to be over for now, especially as the US enforces stricter border controls. The net effect of lower export growth and stalling remittances is a widening of a current account deficit (we expect it to slip from 0.2% of GDP in 2006 to 1.0% by 2009), which will undoubtedly drag on overall growth.

The Commodity Conundrum

Unsurprisingly, perhaps, supply-side risks to growth also exist: most notably, stubborn food and commodity inflation. As far as corn (a staple of the local diet) is concerned, we see solid longer-term support for prices, as US farmers continue to profit off the biofuels boom, which is bad news for Mexican food-related inflation. If price pressures remain rigid, Mexico's monetary authorities would have to consider tightening interest rates, even though such a strategy would undermine an already-shaky economy. Meanwhile, we see further upside ahead for global energy prices. One could argue that this would be beneficial to the economy given Mexico's status as a net exporter of oil. However, higher energy costs would feed through to headline prices (especially transport costs), putting additional strain on consumer inflation. Furthermore, with production ostensibly on the decline, oil revenues should not be regarded as a long-term driver of economic growth.

While these are the main challenges that lie in wait over the next few years, there are measures that the authorities can adopt to tackle inherent problems in the economy. Opening up the state-owned energy sector to private investment will remain a critical and contentious issue. Despite the government's

impressive record on reform to date, an overhaul of Mexico's archaic energy laws still appears out of the question in 2008. Nevertheless, the debate is set to rage on. Meanwhile, the central bank could yet provide relief for the economy in 2008 by cutting rates (we forecast an end-08 benchmark interest rate of 6.75%) – a scenario that would have positive implications for economic growth.

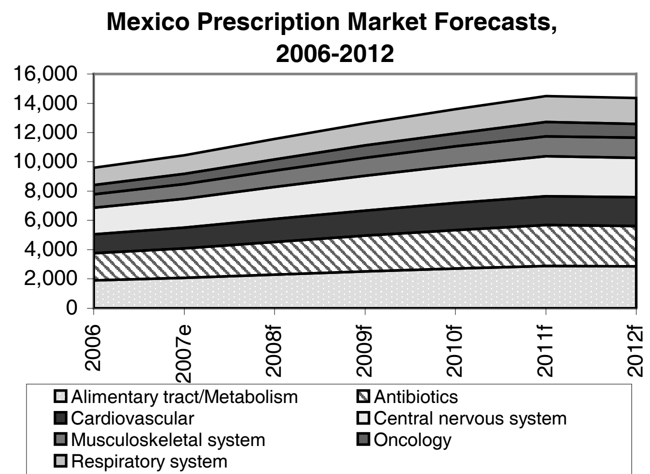
Table: Mexico - Economic Activity

	2005	2006	2007e	2008f	2009f	2010f	2011f	2012f
Nominal GDP, MXNbn [1]	8,374.4	9,083.3	9,712.7	10,383.8	11,134.3	11,937.5	12,785.7	13,703.6
Nominal GDP, US$bn [2]	768.44	833.39	883.74	916.49	958.20	1,012.94	1,070.38	1,132.53
Real GDP growth, % change y-o-y [1]	2.7	4.8	3.1	3.4	3.7	3.8	3.8	4.1
GDP per capita, US$ [2]	7,256	7,789	8,179	8,401	8,702	9,116	9,548	10,013
Population, mn [3]	105.91	106.99	108.06	109.10	110.12	111.12	112.11	113.11
Unemployment, % of labour force, eop [1]	2.8	3.5	3.5	3.3	3.1	3.0	3.0	3.0

e/f = BMI estimate/forecast. Source: [1] INEGI. [2] BMI calculation. [3] IADB

Prescription Market Forecast

Self-medication and the availability of prescription medicines under the counter (UTC) remains a key issue in Mexico. This also means many consumers have only a vague notion of the difference between OTC and prescription products. In many consumers' minds, the major visible difference between the two categories is advertising. OTC advertising is permitted in the mass media, and is a powerful tool for generating brand awareness and sales. OTCs are also widely available in street kiosks, although there are moves to ban this form of drug retailing.



e/f = estimate/forecast. Source: OECD, SSA, AMIIF, Afamela, Canifarma, UN, BMI

Officially, Mexico's market regulation separates drug products into five main categories. Classes 1, 2 and 3 consist of prescription-only, 'high-risk' drugs. Class 4 includes antibiotics, antihypertensives and antihypoglycaemia drugs, which may be directly advertised to consumers if a warning of prescription-only status is given. Class 5 represents all OTC and non-prescription drugs, although this category may include some relatively powerful products by EU or US standards.

Using these definitions, prescription drug sales account for approximately 78% of the market. As doctor visits can be relatively expensive, pharmacists often act as both prescribers and dispensers. The prescription market is expected to perform strongly in the coming years, as the prices of innovative drugs remain high and demand increases from both the private and state sectors. The promised tightening of regulations on the advertising of many 'prescription' products – which do not currently require the prior approval of COFEPRIS – may lead to an increase in consumer confidence in branded prescription drugs. A fully-fledged advertising code for prescription drugs should be put in place in 2008, when (or if) the new General Health Law is finally passed. Furthermore, rising public health expenditure should spur growth in sales of some high-priced medicines, although most purchases are likely to be lower cost generics. Manufacturers will note with caution that the government has proved unable to meet its purchasing needs for essential drugs in the past, despite major increases in spending.

'Specialist' drugs, outside Mexico's basic basket of remedies, are sometimes subject to shortages. Wholesalers reportedly stockpile the products, in order to sell them at higher prices once shortages are registered. Greater use of generic drugs has been urged in order to help deal with this problem, which undermines confidence in legal prescription drugs.

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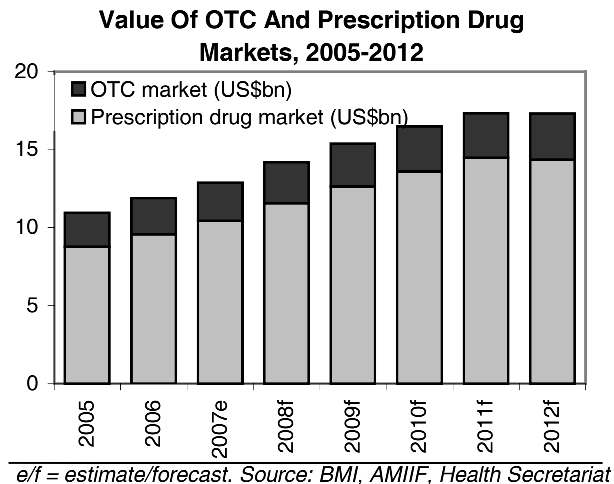
Table: Prescription Market Forecasts

	2006	2007e	2008f	2009f	2010f	2011f	2012f
Prescription drug market (US$bn)	9.6	10.4	11.6	12.6	13.6	14.5	14.4
Prescription drug market (MXNbn)	104.3	114.7	131.0	146.9	160.4	173.1	173.7
Prescription drug market as % total market	78.2	78.4	78.6	82.2	85.1	87.5	83.0

e/f = estimate/forecast. Source: OECD, SSA, AMIIF, Afamela, Canifarma, UN, BMI

OTC Market Forecast

The vast majority of OTCs in Mexico fall into Category 5, and there has recently been pressure to ban sales of OTCs in kiosks and supermarkets, where certain products have been sold under a previously existing Category 6. In practice, the categories have been merged under recent legislation. However, senior officials at Mexico's OTC industry association, AFAMELA, have commented that the change of government in December 2006 created some uncertainty in the market in early 2007, which are estimated to show some short-term distortions in final, full-year 2007 market figures.



e/f = estimate/forecast. Source: BMI, AMIIF, Health Secretariat

In practice, product classification has only limited relevance, given that the UTC sale of prescription products is widespread. Many UTC sales result from the inability of consumers to afford a doctor's consultation fee in addition to the price of the medicine, and so the practice is very hard to eliminate. In addition to distorting the market, the practice is widely blamed for widespread overuse of powerful antibiotics, creating treatment resistant disease strains as well as masking symptoms of critical underlying diseases.

Price increases for OTCs are subject to authorisation from the Secretariat of Trade and Industry. However, since 1996, marketers have been able to request approval for price rises at any time, and OTC pricing rules are not considered a major regulatory barrier. One contentious aspect of the OTC market is the lack of a simplified and clear prescription-to-OTC switching mechanism. AFAMELA has spent many years campaigning for such a mechanism to be introduced. Despite these difficulties, Mexico has one of the highest number of active ingredients officially available OTC in the world. One of the most high-profile switches in recent years was that of the emergency contraceptive, levonorgestrel, which has been officially available OTC in Mexican pharmacies since the beginning of 2006 while its availability in other Latin American markets remains the subject of considerable controversy.

AFAMELA's lobbying has had greater success in relation to consumer advertising. Up until a few years ago, consumer advertising of OTCs was subject to pre-approval by COFEPRIS. However, COFEPRIS relented in the face of AFAMELA's campaign for self-regulation.

In 2006, Mexico's OTC market grew 6.5% to US$2.31bn and saw estimated y-o-y growth of 6.2% in 2007, representing a slowdown from 16% growth a year earlier. Many consumers remain unaware of the

difference between 'self-medication' and 'self-prescription'. The problem is so widespread that AFAMELA was prompted to launch a new campaign in June 2006 aimed at clearing up the confusion. Another recent trend has been the rapid rise of private label drugs, both at established chains such as Saba and Walmex as well as at copy-drug pharmacy chain Farmacias Similares. Using the slogan 'the same but cheaper', Farmacias Similares specialises in providing 'generic' versions of popular OTCs at a fraction of the price of their branded equivalents. However, several established manufacturers of branded OTCs have criticised the lack of quality controls at Farmacias Similares.

Most of the leading OTC companies in Mexico are North American or European multinationals, while the leading local company is **Laboratorios Liomont**. With its acquisition of Roche's OTC business – which included the popular *Redoxon* vitamin C franchise – Bayer became the leading player overall in terms of sales. Even before the acquisition, Bayer was ranked in the top three (behind BMS and Boehringer Ingelheim), thanks to best-selling brands such as the antacid *Alka-Seltzer*, the antifungal *Canesten* and the analgesic *Aspirina*.

Leading OTC cough & cold remedies include Schering-Plough's *Desenfriol D Plus* and *Afrinex*, GSK's *Contac Ultra*, Bayer's *Tabcin*, Liomont's *Sensibit D* and Boehringer Ingelheim's *Mucosolvan*. In 2006, *Desenfriol D Plus* had to be reformulated owing to the fact that its active ingredient, pseudoephedrine, was reverse-switched (i.e. back to prescription status) owing to safety concerns. This is the second time that the brand has had to be reformulated, as it previously contained phenylpropanolamine (PPA)-query-chem names for whole paragraph?].

In terms of future growth, **BMI** expects Mexico's OTC market to achieve a turnover of US$2.94bn by 2012, which corresponds to an annual growth rate of around 5.0%. Part of this growth will be fuelled by economic factors, with the country's GDP estimated to approach US$9,000 per capita over the same period.

Despite the continuing lack of a formal Rx-to-OTC switch mechanism, it is likely that Mexico will continue to be one of the most dynamic markets in Latin America in terms of bringing new active ingredients to the OTC market. However, marketers of branded OTCs will need to increase their ad spending in order to compete with the growing threat posed by low-priced own-label products. That said, although prescription drugs are likely to continue rising in price at a faster rate than OTCs, the latter sector is likely to remain an appealing proposition.

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Table : OTC Market Forecast

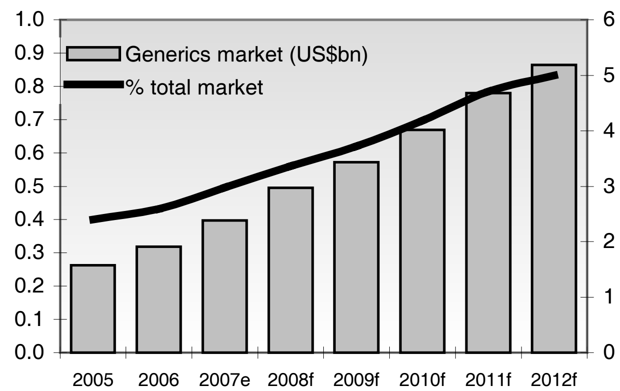
	2006	2007e	2008f	2009f	2010f	2011f	2012f
OTC market (US$bn)	2.31	2.45	2.63	2.76	2.88	2.85	2.94
OTC market (MXNbn)	25.19	26.98	29.75	32.04	33.97	34.02	35.58
OTC market as % total market	18.9	18.4	17.8	17.9	18.0	17.2	17.0

e/f = estimate/forecast. Source: OECD, SSA, AMIIF, Afamela, Canifarma, UN, BMI

Generics Market Forecast

The market share of off-patent, bioequivalent (i.e. true) generics in Mexico is one of the lowest in Latin America, estimated at no more than 5% in value terms even by the most liberal measures, with **BMI** estimating the level at 3.0% in 2007 and forecasting penetration of 3.4% for 2008. This is linked to structural factors including the dominant market share of brand-name, patented products, as well as non-bioequivalent *similares* and lower margin private label drugs. Despite major challenges, the share of bioequivalent or 'interchangeable' generics, according to trade association Amegi, is growing substantially faster than the market as a whole. Amegi estimated that the market grew by 19% in value terms and by 26% in volume terms in 2006. **BMI** puts the figure at around 17% in value terms for 2006. Nonetheless, generic growth is from a very low value base and higher volume growth indicates that market penetration is at the lower price end of the market.

Size (RHS) And Proportion (LHS) Of Generics Market, 2005-2012



e/f = estimate/forecast. Source: BMI, AMIIF, Health Secretariat

Mexico is still awaiting legislative approval for further reforms to regulations relating to generic medicines, and this expected to be included in the updated General Healthcare Law due in 2008. There has been clear solid recent progress on issues such as bioequivalence. Still, originator firms still complain that a 2003 decree linking products filed with market regulator COFEPRIS to the patents recognised by the national IP office fails to adequately protect pharmaceutical patents. An additional problem is that officials have not yet put in place clear regulations regarding so-called 'biogenerics', or indeed biotechnology products in general.

In recent years, Mexico has made progress in modernising the regulatory regime for generics and clarifying the status of their innovative equivalents. Yet perhaps the most substantial change has been the introduction of new five-year drug registrations that will include much tougher quality requirements and impose heavy testing costs on producers of *similares*.

As it stands, the core piece of generics sector legislation in Mexico – NOM-177-SSA1-1998 – mentions patents only once in its text. Indeed, according to official definitions, the country's drug market is divided between new drug products that have not been previously registered, so-called 'free sale' drugs that are sold without a prescription, and 'interchangeable generics'. This reflects the greater emphasis on bioequivalence and quality, but appears to do little to enshrine the status of innovative patented products in law or practice. In product submissions in Mexico, the inclusion of patent certificates is merely

recommended, rather than obligatory. Moreover, the fact that the reference product for each generic is selected by the Health Secretariat is a concern. In future, therefore, **BMI** expects the re-registration process to be the key driver in improving the quality of generics in Mexico. Market share gains by generics will be substantial in value terms, but still represent only around 5.0% of the total market in 2012.

In late 2006, COFEPRIS said that locally-registered generic medicines are already able to treat 90% of the population's therapeutic needs. Officials noted at the time that novel drugs were on average 57% more expensive than their 'equivalent' copy products. Still, Health Secretariat data published at the same time confirmed the continued challenges facing the generics sector. In a market where the public sector accounts for roughly 70% of prescriptions, just 615 generic brands for 377 APIs have achieved official recognition, and even that total is disputed.

It is now mandatory for suppliers registering products under the government's Generics Programme to demonstrate some form of therapeutic equivalence. The public sector pricing environment for pharmaceuticals remains difficult. Mexico has a basket of essential drugs that are reimbursable under public procurement schemes, which in total account for approximately US$1.5bn per year. However, health legislation was amended in 2006 to ensure that the prices of these products would be prevented from rising above the rate of increase in wages. This is likely to restrict margins for marketers of genuine generics, despite the expected rise in public sector drug spending under the expanded Seguro Popular reimbursement subsidy scheme. In the future, higher state procurement spending is thus most likely to benefit low-cost foreign producers of basic medicines such as antibiotics. The growing effort aimed at the rationalisation of fragmented public tender procedures suggests that the government is adopting an increasingly cost-conscious stance as overall spending rises substantially. But waste and mismanagement in state-run programmes remain an ongoing headache.

While the manufacturing sector expects a rise in generics output, much of this will be focused on the private label market, which is growing at some 50% per year. Significantly, the US-based drug major Abbott Laboratories has said that it expects this trend to reduce ethical drug firms' potential sales in Mexico by as much as 10% by 2010.

The Mexican generics sector boasts an advanced regulatory regime and substantial unmet demand, but weak law enforcement and opposition by some domestic drugmakers and low-cost 'popular' pharmacy chains will continue to limit the market's potential in the medium term. Despite this, generics in Mexico represent an excellent long-term prospect, with public sector procurement conditions set to improve markedly for marketers of low-cost bioequivalent basic products.

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Table: Generic Market Forecast

	2006	2007e	2008f	2009f	2010f	2011f	201f
Generics market (US$bn)	0.32	0.40	0.50	0.57	0.67	0.78	0.86
Generics market (MXNbn)	3.46	4.36	5.62	6.65	7.89	9.32	10.46
Generics market as % total market	2.6	3.0	3.4	3.7	4.2	4.7	5.0

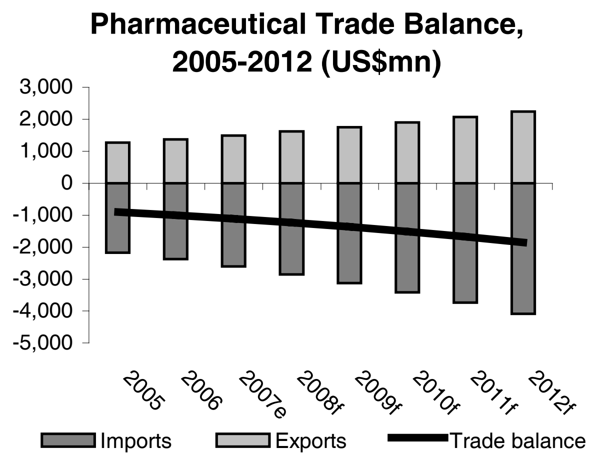
e/f = estimate/forecast. Source: OECD, SSA, AMIIF, Afamela, Canifarma, UN, BMI

Table: Patented Market Forecast

	2006	2007e	2008f	2009f	2010f	2011f	2012f
Patented products (US$bn)	11.9	12.9	14.2	14.8	15.3	15.8	16.4
Patented products (MXNbn)	130.1	142.0	161.1	172.0	180.6	188.5	198.8
Patented market as % total market	97.4	97.0	96.6	96.3	95.8	95.3	95.0

e/f = estimate/forecast. Source: OECD, SSA, AMIIF, Afamela, Canifarma, UN, BMI

Export/Import Forecasts



e/f = BMI estimate/forecast. Source: OECD, UN, SSA, Canifarma, BMI

In the wake of new pharmaceutical sector legislation since 2004, drug producers in Mexico are expanding their capacity to supply regional and international markets in the face of competition in the domestic market. If the bulk of market-friendly reforms are incorporated in the new General Healthcare Law in 2008, this trend should intensify. Multinational production has driven much of the expansion, but surveys suggest that capacity utilisation in the sector is around 60%, indicating that existing facilities are adequate to meet rising demand from regional markets in the short to medium term. Mexican law has forced drug companies to operate local plants in the country, although these rules were scrapped by decree in Q407. Importers, however, will need to secure COFEPRIS licensing for their plants overseas, a process that could in itself prove costly and time consuming.

Nevertheless, there are nearby alternatives in low-cost manufacturing that also have privileged access to the US market, such as Puerto Rico and, more remotely, given a lack of production capacity, the members of the Central American-Dominican Republic Free Trade Area (CAFTA-DR). Brazilian manufacturers perhaps represent the most substantial regional threat. Argentine manufacturers have benefited from the comparatively weak value of the Argentine peso, but should see many of their products barred from the market by robust implementation of IP and quality regulations.

Meanwhile, Mexico is expected to retain its demand for imported innovative medicines wherever there is not sufficient incentive to manufacture locally, fuelling a sustained rise in imports. This trend is likely to drive a reduction in the share of locally-produced medicines in overall sales, especially as medicines patented in developed markets tend to be more expensive.

The manufacturing sector is also highly dependent on imported raw materials and APIs, and some 30% of exports are in semi-finished form. Since the elimination of discriminatory tariff structures in the mid-1980s, the Mexican APIs sector declined from 94 companies to fewer than 20, meeting 55% of national demand by 2005 and reportedly declining further in 2006 and 2007. The decline of the industry has also been attributed to competition from low-cost Asian producers, high investment costs, weak product-development efforts and a lack of intermediate materials.

The smuggling and counterfeiting of pharmaceuticals remains a considerable problem for manufacturers in Mexico, and creates difficulties for legitimate enterprises. The two activities are valued at more than US$100mn and US$850mn a year, respectively.

Table: Sectoral Trade Indicators (US$mn)

	2006	2007e	2008f	2009f	2010f	2011f	2012f
Imports	1373.61	1490.37	1617.05	1754.50	1903.63	2065.44	2241.00
Exports	2374.61	2600.20	2847.22	3117.70	3413.88	3738.20	4093.33
Balance	-1001.00	-1109.83	-1230.17	-1363.20	-1510.25	-1672.76	-1852.33

NB Drug market = local production + imports-export. e/f = estimate/forecast. Source: US Commercial Service, WHO, INEGI, Roche AG, AIPM, RMBC, BMI

Table: Healthcare Sector Data & Forecasts

	2006	2007e	2008f	2009f	2010f	2011f	2012f
Hospitals	4,071	4,113	4,154	4,195	4,226	4,240	4,250
Beds per ‘000 population	1.1	1.0	1.0	1.0	1.0	1.0	1.1
Hospital admissions per ‘000 population*	58.6	58.9	58.8	58.6	58.7	58.8	59.0
Doctors per ‘000 population	1.8	1.8	1.8	1.9	1.9	1.9	1.9
Births per ‘000 population	29.2	29.4	29.6	30.0	30.0	30.1	30.1
Deaths per ‘000 population	4.3	4.2	4.1	4.1	4.1	4.1	4.1

e/f = estimate/forecast. Source: OECD, UN, BMI, AMIIF, Canifarma

Key Risks To BMI’s Forecast Scenario

While the generics market remains underdeveloped, slower-than-anticipated growth in the sector could maintain the market value of patented pharmaceuticals. However, due to the consequent effect of continued high drug prices, overall market growth could slow while many drugs remain unaffordable. This scenario would be aggravated by any failure on the part of the government to boost reimbursement, as **BMI** thinks this would concentrate drug spending even further on out-of-pocket expenditure. Additionally, a return to economic recession and a consequent dip in consumer confidence – or a series of negative currency events – could result in a return to the stagnant market performance of 2002 and 2003.

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Company Monitor

Leading Foreign Companies

Pfizer

SWOT Analysis

Strengths

- As the world's leading pharmaceutical manufacturer, located close to its US home market, Pfizer México's position is very strong
- Presence in patented drugs, OTCs and animal health provides wide exposure to growing market segments

Weaknesses

- The increasing trend towards the use of generic medicines is impacting sales of medicines coming off patent
- One of the company's best-selling drugs in the local market, *Viagra*, has seen its market share sharply reduced by Eli Lilly's *Cialis*

Opportunities

- Mexico's Westernising disease profile, including growing obesity and an ageing population, is positive for Pfizer's innovative product lines
- Pfizer's expanded Mexican distribution capacity should provide greater efficiency and geographic reach

Threats

- Government failure to reform more rapidly and enforce policy threatens to constrain growth
- Pfizer's leading patented drugs are targets for copiers and counterfeiters
- The government push generics and low-cost healthcare limits Pfizer's potential for benefiting from increased healthcare spending

Company Data, 2006

- Market share: 9%
- Sales: US$500mn (est., human use only)

Overview

Pfizer has been present in Mexico since 1951. In 1997, Mexico became Pfizer's main office for Northern Latin America. Pfizer's operations in Central America are managed from its Mexico office. A distribution facility is located in Toluca, and other facilities are located in Tlalpan and Puebla.

Pfizer's ED drug, *Viagra* has been one of Mexico's best-selling drugs in recent years, although it ceded market leadership in the ED segment to *Cialis* in 2006. The company received a market authorisation for its smoking cessation drug *Champix*in October 2006. In April 2007, the company applied for wider indications for cholesterol-lowering drug *Lipitor* (atorvastatin), mirroring similar moves in the US. The Mexican market for such therapies is around US$125mn and growing.

Pfizer divested its Calzada de Hueso manufacturing facility to generics major IVAX in 2004. However, in February 2006, Pfizer completed a MXN230mn (US$22mn) refurbishment of its distribution facility in Toluca, Mexico.

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GlaxoSmithKline (GSK)

SWOT Analysis

Strengths

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- GSK México has a strong product portfolio, holding a dominant position in the key markets for antibiotics and anti-asthma drugs
- Vaccines have been a high-growth area in recent years, with the global launch of a major new vaccine product, *Rotarix*, taking place in Mexico

Weaknesses

- Official pricing and reimbursement policy aims at cost-containment and favours generics medicines
- Export sales of GSK México, a regional manufacturing base supplying 12 other Latin American markets, have been hit by regional economic instability in recent years

Opportunities

- Positive economic performance, and healthcare-sector modernisation, should underpin solid development
- GSK has a strong OTC product portfolio
- GSK México, as a regional manufacturing base, is well placed to take advantage of strong growth in other Latin American markets.

Threats

- Resistance to enforcing new IP legislation fully remains a major long-term issue
- Government enthusiasm for generics and low-cost healthcare limits GSK's potential for benefiting from increased healthcare spending

Company Data, 2006

- Market share: 8% (est.)
- Sales: US$400mn (est.)

Overview

GSK operates in Mexico through its wholly owned subsidiary GSK México, and is one of the country's leading pharmaceutical companies. GSK has been active in Mexico since Glaxo Wellcome México was founded in 1964. The unit employs around 2,000 staff and operates the Pharma and Consumer Health Care divisions. GSK operates three manufacturing facilities: two in Mexico City and one in the CIVAC Industrial Park in Morelos. The majority of output at these plants is destined 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.

The Mexican subsidiary exports to 12 other Latin American countries, with trade worth over US$40mn per annum. GSK México's sales represent 25-30% of the pharmaceutical major's total regional sales.

In July 2005, GSK launched its chronic hepatitis B drug *Adevofir* in Mexico. The company notes that the condition is significantly under-treated in Mexico, where about 1.5mn people suffer from the disease. The drug is effective in the treatment of conditions associated with HIV/AIDS.

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Product Portfolio

GSK's Mexican plants manufacture a wide range of medicines. Major product areas include antibiotics, vaccines, anti-virals, cardiovascular, gastrointestinals, respiratory system, CNS, diabetes and HIV/AIDS drugs. The

Leading Products

- *Augmentin*
- *Adefovir*
- *Avandia*

company is also a leader in antibiotics and products for the treatment of asthma. GSK fields over 80 products in around 200 presentations in Mexico. In July 2004, GSK received a marketing approval for *Rotarix*, a novel orally-administered two-dose vaccine for rotavirus infection in infants. GSK used Mexico as the starting point for *Rotarix*'s global rollout. In June 2006, GSK was awarded exclusive rights to market Canadian drugmaker Labopharm's once-daily analgesic tramadol in Mexico. The agreement extends an existing licensing deal covering Latin America and the Caribbean arranged between the two firms in September 2005. No financial details were disclosed.	▪ *Azantac* ▪ *Flixotide* ▪ *Rotarix*

Sanofi-Aventis

SWOT Analysis

Strengths

- The merger of Aventis and Sanofi-Synthélabo's local market presence has consolidated a strong market position in Mexico
- Sanofi-Aventis offers prescription drugs, OTCs, vaccines and also animal health products through its Merial joint venture with Merck & Co

Weaknesses

- Restructuring could distract the company from important opportunities
- Cost-conscious official pricing & reimbursement policy

Opportunities

- Recent IP reforms have improved conditions for new product launches
- The company's new Latin American generics business provides strong potential sales growth in Mexico and Brazil in particular
- Health reforms could boost the modernisation and consumption of Sanofi-Aventis' patented and high-quality OTC products

Threats

- Mexico's illegal copy-drug sector still poses a threat, in view of the limited enforcement of new IP laws
- The government drive toward generics and low-cost healthcare limits Sanofi-Aventis' potential for benefiting from increased healthcare spending

Company Data, 2006

- Market share: 8% (est.)
- Sales: US$550mn (est.)

Overview

The integration and reorganisation of Sanofi-Synthélabo and Aventis in 2004 saw the merger of the two firms' local clinical research operations. In 1997, Sanofi-Synthélabo acquired the Mexican producer Rudesfa, which is now a 100%-owned subsidiary.

Founded in 1973, the company employs around 600 people. Manufacturing operations are based in Cuautitlán Izcalli, with the plant capable of producing 900mn tablets, 27mn bottles of syrups, 12mn tubes of cream and 10mn capsules per annum. There are also two warehouses and packaging facilities located on site. The company's sales in Mexico represent around 25% of its regional turnover, and it claims to be the third-largest player in the country.

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Product Portfolio

Sanofi-Aventis produces prescription drugs, OTCs and dermatological products. Results have been solid in recent years despite a difficult economic period, mainly due to strong sales of leading products *Aprovel* (hypertension), *Plavix* (thrombosis), *Stilnox* (insomnia), as well as *Taxotere* and *Lantus*. Sanofi-Aventis' antithromobotic *Clexane* (enoxaparin) was withdrawn in Mexico in February 2006 following safety fears.

In the OTC sector, Sanofi markets *Histiacil* and *Novalgin*, as well as a number of cough and cold remedies.

Mexico's market regulator, COFEPRIS, approved Sanofi-Aventis' novel obesity treatment *Acomplia* (rimonabant) in November 2006.

Leading Products

- *Plavix*
- *Aprovel*
- *Stilnox*
- *Actonel*
- *Acomplia*

Eli Lilly

SWOT Analysis

Strengths

- Eli Lilly is among the top selling multinationals present in Mexico
- As one of the world's largest pharmaceutical companies, Eli Lilly has solid resources, product lines and industry experience
- Eli Lilly's *Cialis* emerged as one of the three top-selling prescription medicines in 2006

Weaknesses

- Government drug-pricing and reimbursement policy is increasingly aimed at cost-containment
- Eli Lilly México is a regional hub for the company and exposed to tough market conditions in Venezuela and Argentina in particular

Opportunities

- Given its strong market share in Mexico, Eli Lilly is in a good position to benefit from growing demand for sophisticated treatments
- Positive economic performance, with an increase in spending power, should underpin growing patented product demand
- Tighter patent laws will encourage new product launches

Threats

- Continued downward pressure on prices by the government along with growth in the generics sector could limit company expansion
- Counterfeit copies of costly drugs pose a continued threat to Eli Lilly's patented medicines
- The expanding private-label market could threaten Lilly's strong branded product lines

Company Data, 2006

- Market share: 6% (est.)
- Sales: US$300mn (est.)

Overview

Eli Lilly operates in Mexico through its 100%-owned subsidiary Eli Lilly y Compañía de México SA, which was established in 1943 and employs around 500 staff. The company has two main manufacturing facilities: its main plant in Calzada de Tlalpan near Mexico City, opened in 1956, and the Cefalosporinas plant, which produces antibiotics, was completed in 1995. In Mexico, the US firm specialises in the production and sale of anti-diabetes, anti-cancer, women's health, antibiotics, CNS and veterinary products. In recent years, Eli Lilly has pledged to invest heavily in the further expansion of its manufacturing facilities.

Eli Lilly exports to over 54 countries from Mexico, mainly to markets in Latin America. Around 15% of the company's output – including diabetes, neuroscience, women's health, oncology and animal health products – are exported, representing approximately 4mn units per year.

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Product Portfolio

In August 2003, Eli Lilly launched its ED product *Cialis* marketing Mexico. In 2007, it had become one of the country's top-three selling drugs, eclipsing Pfizer's *Viagra* for the first time. In April 2005, Eli Lilly announced two product launches planned for Mexico during the course of the year: *Yentreve* (duloxetine hydrochloride), indicated in the US for moderate-to-severe stress urinary incontinence in women and *Alimta* (pemetrexed for injection), a novel product for malignant pleural mesothelioma, a cancer associated with

asbestos exposure. In 2005, the FDA and the National Association of Boards of Pharmacy identified a counterfeit of Eli Lilly's osteoporosis treatment, *Evista*, which was sold as a 'generic'.		

Bristol-Myers Squibb

SWOT Analysis

Strengths

- BMS has a long-established presence in the Latin American market
- The company has benefited from open markets provisions of the NAFTA agreement with the US

Weaknesses

- The sale of its OTC portfolio to Novartis limits its exposure to this sector
- The growth of the generic sector is eroding BMS market share

Opportunities

- The recent modernisation of production facilities should allow BMS the flexibility to target US, Latin American and world export markets
- New intellectual property legislation should lead to new product launches of high-value pharmaceuticals

Threats

- The government's cost-cutting reimbursement policy and promotion of generic alternatives to patented drugs presents a long-term threat

Company Data, 2005

- Market share: 6% (est.)
- Sales: US$300mn (est.)

Overview

BMS manufactures and markets pharmaceuticals and OTC medicines, specialising in the production of anti-infectives, as well as dermatological, cardiovascular, oncology and AIDS drugs.

BMS has invested heavily in the expansion of its Mexican operations in recent years. A recent project has been the construction of a new manufacturing plant in Mexico City, which produces anti-infectives, dermatologicals and cardiovascular preparations, as well as aspirin and vitamins. In 1996, the company modernised the manufacturing operations of its nutritionals business (operating under the Mead Johnson brand), creating a global production base for infant formulas and nutritional products.

Prior to these developments, BMS consolidated a number of its operations, transferring its non-penicillin production from the Naucalpan site to its manufacturing and packaging plant in Tlalpan. The restructuring was part of a US$20mn project to modernise and improve its Naucalpan, San Angel and Tlalpan facilities.

Leading products include *Pentrexyl* (antibiotic), *Capotena* (anti-hypertension), *Pravacol* (cholesterol reduction) and *Iscover* (cardiovascular). The OTC division's leading products include *Tempra* (analgesic), *Sal de Uvas Picot* (antacid) and *Graneodín* (cough pastilles).

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Novartis Farmaceutica

SWOT Analysis

Strengths

- Novartis has capital strength and a diverse business portfolio, comprising ethical drugs, OTCs, eye care and infant products
- Sandoz generics division is well placed to exploit any expansion in the country's legitimate generics market

Weaknesses

- Ineffective government enforcement of new laws on intellectual property and generics could threaten development

Opportunities

- The generic sector is a major opportunity for Novartis in Mexico
- Recent investments in export capacity in Brazil could provide low-cost sourcing for the Mexican market

Threats

- The market entry of Indian and other global generics makers will put continued downward pressure on generics prices
- Cost-conscious official drug pricing and reimbursement policy could limit growth in original medicines

Company Data, 2006

- Market share: 7.5% (est.)
- Sales: MXN6.288bn (US$577mn)

Overview

Novartis is active in two key divisions in Mexico: pharmaceuticals and consumer health. 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. The company planned to launch eight new drugs in Mexico in 2007, including its osteoporosis drug *Aclasta* (zoledronic acid), aimed at the country's small but fast-growing market for osteoporosis treatments.

In 1997, Novartis acquired local generic drugmaker Suipharm, now a part of the company's branded generics business, Sandoz. Following Mexico's new law obliging generics manufacturers to submit their products to bioequivalence tests, In its patented, prescription drug business, Novartis has said it is focused on biopharmaceuticals and cancer drugs in a bid to win market share. In addition, the company has recently invested in major export capacity expansion in Brazil, which should provide extra capacity at lower cost for the Mexican market.

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Bayer

SWOT Analysis

Strengths

- Bayer has a strong presence in the OTC market, which is one of the most developed in the region
- As part of a diversified chemicals giant, Bayer's leading position in other sectors adds to its financial resources in Mexico

Weaknesses

- Bayer may be less able to benefit from Mexico's drug market reforms, due its presence in OTC and its limited patented offering

Opportunities

- The acquisition of Roche's OTC portfolio is a significant opportunity in Mexico
- Bayer markets erectile dysfunction product *Levitra*, in a segment where per capita consumption in Latin America exceeds levels in the US

Threats

- The ED market is highly competitive and the drugs are among the most frequently copied and counterfeited pharmaceutical products in the region
- Expanding chain pharmacies will mean increased competition from private label variants of its successful OTC product lines

Company Data, 2006

- Market share: 9% (est.)
- Sales: US$800mn (est., all products)

Overview

Bayer de México distributes raw materials for prescription and non-prescription (OTC) medicines, diagnostics, consumer goods, agrochemicals and health and grooming products for livestock and pets. It is the largest subsidiary of the German pharmaceutical giant in Central America, and significant pharmaceutical products include erectile dysfunction drug *Levitra*.

Bayer has a large production site in Lerma, which manufactures OTC pharmaceuticals including *Aspirin* and *Alka-Seltzer*. The company claims that its Lerma plant, opened in 1997, is one of the largest and most technologically advanced production facilities of its type in the world. Between 1999 and 2003, the plant tripled its aspirin production from 550mn units to 1,500mn units per annum, and increased its employees from 160 to 350. Bayer has invested a total of EUR180mn (US$215mn) in Mexico since the mid-1990s.

Local sales accounted for around 24% of Bayer's total regional turnover in 2005, with Mexico representing the company's second-largest market in Latin America. The company's 2004 acquisition of Roche's OTC portfolio has given its consumer healthcare division a significant boost in turnover.

In October 2005, Bayer announced plans to invest EUR100mn (US$119.42mn) in Mexico by the end of 2008, describing the country is its 'engine of growth' in Latin America. Around EUR40mn (US$47.75mn) of this total will be earmarked for expanding the plant in Lerma.

Top-selling products, such as analgesics *Aspirin* and *Naproxen*, have reportedly made Bayer the leading consumer-care business in the country.

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Boehringer Ingelheim Promeco

SWOT Analysis

Strengths

- A presence in animal health, OTC, and prescription sectors provides strong market coverage in Mexico
- Boehringer Ingelheim has expanded its export capability, allowing the company flexibility to target US, regional and world markets
- The company's background as a leading drugmaker in Mexico should be considered a valuable asset

Weaknesses

- The company has limited its presence in the fast-growing generics market

Opportunities

- The market for patented medicines and OTCs demand is expected to increase steadily

Threats

- Government failure to enforce new IP laws and pricing structures remains a long-term challenge to growth

Company Data, 2006

- Sales: US$630mn (est.)

Overview

Boehringer-Ingelheim Promeco is the Mexican subsidiary of German drug major Boehringer Ingelheim (BI). BI acquired Laboratorios Promeco in 1971. The company manufactures and markets a range of ethical and OTC pharmaceuticals, with brands available in Mexico including cardiovascular drug *Micardis* (telmisartan), anti-inflammatory *Mobicox* (meloxicam), respiratory drugs *Spiriva* and *Flurinol*, as well as prescription products *Bispasmin, Buscapina*, *Mucosolvan*, *Mobicox*, *Prodolina* and *Perlutal* and *Pharmaton*, *Bisolvon*, *Isodine* and *Kiddi* (consumer health products). Some 70% of the company's sales in Mexico are on prescription medicine products.

During the 1990s, BI developed its pharmaceutical site at Xochimilco with considerable investments allocated to complete the modernisation of ampoule production, in order to meet the accepted international quality standards. The complex opened in 1998 and supplies products primarily to the US, but also to other countries in Central and Southern America, as well as Asia. Capacity is estimated at 200mn units per year.

Boehringer Ingelheim's estimated annual sales in Mexico were around US$630mn in 2006, with exports of around 32mn units, with a focus on exports to the US market.

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Merck KGaA

SWOT Analysis

Strengths

- Merck KGaA fields a strong mix of generic and patented products in the country

Weaknesses

- The seasonal nature of sales of leading cold remedy *Sedalmerck* could lead to uneven revenue growth

Opportunities

- Performance in the export sector is likely to increase in the short term following manufacturing plant modernisation
- The firm will benefit from rapid growth and government promotion of the generics segment

Threats

- The market entry of Indian generics makers and other low-cost drug firms will put downward pricing pressure on the generics market
- Any failure to enforce full bioequivalence laws by 2010 will negatively impact the company

Company Data, 2006

- Market share: 6% (est.)
- Sales: US$325mn (est.)

Overview

Germany's Merck KGaA produces and distributes antibiotics, anti-inflammatories, anaesthetics, neurology and paediatric treatments in Mexico. The company also produces products and chemicals for pharmaceutical analysis. The pharma division operates in allergies & immunology, anaesthesiology, cardiovascular, dermatology, gastroenterology and psychiatry/neurology. The company's plant is located in Naucalpan.

Currently, the company's Mexican plant exports about 30% of production to other Latin American markets. Merck said in 2005 that it aimed to boost annual capacity by 15% to some 65mn units, with a focus on exports to the US market.

In June 2005, Merck KGaA reported that it its cold & flu remedy *Sedalmerck* had had significant success in Mexico, with annual sales of US$150mn, and that it hopes its recently launched cancer drug, *Erbitux*, will shortly be added to the national reimbursement list. The company has already invested substantially in modernising production, and has targeted the US market, especially with painkiller *Mobicox*.

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Roche

SWOT Analysis

Strengths

- Roche is a leading producer of key drugs in high-value product segments, including oncology
- Recent government healthcare investment has boosted demand for the company's diagnostic products

Weaknesses

- The sale of OTC operations to Germany's Bayer limits exposure to this major market segment in Mexico

Opportunities

- Mexico's increasingly Westernised disease profile is positive for Roche's sophisticated product lines
- The expansion of Mexico's clinical trial base provides relatively low-cost R&D potential

Threats

- Cost-conscious government policy and continued shortcomings in the enforcement of more stringent IP laws threaten to limit long-term growth potential

Company Data, 2006

- Market share: 4% (est.)
- Sales: US$200mn (est.)

Overview

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.

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. Roche also has a manufacturing plant in Toluca.

However, the sale of its OTC division to Bayer, completed in 2004, effectively marks Roche's exit from the OTC market.

In November 2005, Indian generics maker Dr Reddy's announced the acquisition of Roche's API business in Mexico, in a deal worth US$59mn. The plant manufactures and sells bulk drugs to Roche and other research-based pharmaceutical companies. The company invested US$65mn on expanding output in Mexico to 120mn units per year. In May 2007, the company reportedly was targeting the export of 10 medicines to the United States by the end of the decade.

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Indigenous Manufacturer Profile

Liomont

SWOT Analysis

Strengths

- Liomont is among Mexico's leading home-grown drug firms, with a significant regional presence
- The company has strong OTC product lines and offers key hi-tech generics, including ulcer drug *Inhibitron*

Weaknesses

- The company has no internationally-patented products
- Current manufacturing standards may prevent exports to some markets

Opportunities

- The generics sector is an opportunity, and Liomont is well placed to benefit from favourable regulation
- Latin America's generics sales are growing, and governments and consumers are likely to be receptive to Liomont's products

Threats

- The market entry of major foreign generics manufacturers represents a long-term threat as market regulation and enforcement improves towards international standards

Company Data, 2006

- Market share: 2% (est.)
- Sales: US$120mn (est.)

Overview

Liomont was founded in 1938 by Martin Lewinberg, a German chemist, and has grown into an important domestic player, which still maintains its family roots. The company employs around 1,000 people in Mexico.

The company ranked 10th among Mexico's pharmaceutical firms in volume terms in 2006. In early 2007, the company had capacity for 120mn units.

Liomont was the first Mexican company to receive ISO 900 certification; by 2000, its manufacturing plant had capacity for over 100mn units per annum.

Prescription drugs account for around two-thirds of sales. The company's leading brands include the systemic analgesic *Supradol*; antihistamine *Sensibit;* and the proton pump inhibitor *Inhibitron*. The company also has a successful OTC division, spanning several therapeutic areas. The company's leading OTC products include cold-sore treatment *Cicloferon*; cold and flu range *Sensibit D,* and H2 antagonist *Facidex*. Liomont focused on its domestic market until recently. In 2002, just 3% of its products were exported – mainly to Central America – but the firm has seen exports as a key growth area in more recent years. Recent expansions have included Venezuela, Colombia, Ecuador and Peru, where Liomont expects to generate growth.

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BMI Forecast Modelling

How We Generate Our Industry Forecasts

BMI uses its extensive database of macroeconomic and sector-specific data to generate its industry forecasts. A keystone of the forecasting process is our in-house global econometric model, which ensures the consistency and integrity of our macroeconomic data through its foundation in sound economic theory and the dynamic interaction of our individual country forecasts. At any point in time, the global model incorporates the latest forecast assumptions of **BMI**'s country risk analysts, encompassing coverage of over 50 developed and emerging markets. We use historical data sets of macroeconomic and industry variables to derive rigorous statistical relationships, anchored in advanced linear regression techniques. Based on a monthly cycle of updates to our global model, these relationships allow us the to forecast with precision the impact on an industry of a change in the macroeconomic climate. They also give us the capacity to capture the consequences for industry of specific, hypothetical macroeconomic scenarios.

We begin our forecasting process by transforming all our historical data sets into natural logarithms, which are defined for non-negative macroeconomic and industry variable values. Data expressed in logarithmic form has several advantages, including a reduction in problems associated with non-linearity, heteroskedasticity and normality, as well as the ability to interpret coefficients as elasticities.

In order to render the statistical properties of the data invariant to time, we then differentiate the data an appropriate number of times to make it stationary. Forecasting in differences, rather than levels, also assists with the identification of structural breaks. Where necessary, historical data sets are tested for stationarity using the Augmented Dickey Fuller (ADF) regression.

The transformed data sets are subsequently used to develop a series of bi-variate or multi-variate linear regression models. A separate model is estimated for each industry-specific variable, using an appropriate number of macroeconomic indicators as explanatory variables. These indicators are selected on the basis of their historical correlation with industry variables, as well as the standard error of the resulting regression model.

Each model is then subjected to a range of diagnostic tests to ensure its integrity. These include Lagrange multiplier tests for serial correlation, heteroskedasticity, non-linearity and normality, as well as tests for structural stability of the parameters. Should the model fail any of the assumptions consistent with the classic linear regression model, estimators other than Ordinary Least Squares (OLS) are considered. In the case of certain, especially demographic, industry indicators, the lack of an effective set of explanatory macroeconomic variables leads us to use Vector Autoregressions (VARs) to arrive at our projections. VARs allow us to use a combination of a variable's own history and possibly one or more exogenous indicators to project the evolution of an industry variable.

Finally, our forecasting process is also informed by the active involvement of our analysts, the judgement and occasional intervention of whom represents a necessary and desirable check on the results produced by the models we have created.

Pharmaceutical Industry

There are a number of principal criteria that drive our forecasts for each pharmaceutical variable.

Figures for the Pharmaceutical and Healthcare sector data are based, where possible, on primary national industry association, global healthcare organisation and government/ministry sources and official data. Where these are unavailable, pharmaceutical expenditure forecasts are based on a range of variables:

- Government policy, industry trends and expenditure levels stated in international and national press;
- Industry trends and expenditure levels stated in pharmaceutical company official financial reports or releases;
- Likely expenditure patterns owing to major healthcare (disease) and demographic patterns;
- Likely alterations in expenditure patterns owing to economic/political activity.

Expenditure per capita/% of GDP is calculated using **BMI**'s own macroeconomic and demographic forecasts.

Sources

Sources used include national industry associations, government ministries, global health organisations, officially released pharmaceutical company results and international and national news agencies.