Peru

Pharmaceutical Market Intelligence Report

Quarter IV 2008

A World Pharmaceutical Market Report

ISSN 1460-0781

British Library Cataloguing in Publication Data.

A catalogue record for this report is available from the British Library.

Contents

List of Tables

List of Figures

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EXECUTIVE SUMMARY

- **The pharmaceutical market is valued at US$1.1 billion at retail prices in 2008.**

According to the Ministry of Health (MINSA), the pharmacy sector represents 72% of the market at manufacturers' prices, and the hospital sector 28%. Historically, growth in pharmaceutical expenditure has been positive but unstable. Between 2008 and 2013, annual growth in pharmaceutical expenditure at retail prices is expected to be 5%.

- **New counterfeit medicine bill passed.**

In May 2008, the Congressional Health Commission passed a bill to crack down on counterfeit medicines, introducing a maximum 10 year prison sentence for those that sell, store or produce fake medicine. The penal code was amended, making sentencing tougher for counterfeiters, smugglers and dealers. Around 30% of medicine sold in Peru is adulterated.

- **Imports from Europe are slowly decreasing.**

In 2006, imports reached US$280 million, up 16.1% from the previous year. India was the leading supplier. Preferential custom duties and product registration favour Latin American countries. Due to a lack of infrastructure and quality standards, exports were comparatively insignificant.

- **Domestic producers produce branded and unbranded generics.**

Imports of original drugs are generally consumed by the pharmacy sector, whilst locally produced branded and unbranded generics are consumed by the pharmacy and hospital sectors. Leading domestic producers include Farmindustria, Infarmasa Corporation (Magma and Sanitas), Medifarma and Medco Corporation (Cofana and Marfan).

- **Universal Health Insurance Law approved and reverse auctions continue.**

Around 42% of Peruvians are poor and, of these, only 23% can buy medicines. A Universal Health Insurance Law was approved in December 2008, to help the poor access healthcare. The first reverse auction for medicine, worth US$46 million, was held in December 2006, saving around US$12 million. Several further auctions have been held since.

- **Signing of the USA – Peru Trade Promotion Agreement in December 2007.**

The USA - Peru Trade Promotion Agreement (PTPA) finally was signed in December 2007. It will hopefully result in further intellectual property compliance by the pharmaceutical industry.

- **High inflation and a revised GDP forecast.**

Peru has high inflation and a rapid reduction is not foreseen in the near future. The National Statistics Institute found the 2008 domestic inflation level to be 7.3%. Purchasing power has been reduced on a large scale, particularly amongst the poorest regions of the country and the capital, Lima, has high levels of poverty. Short term GDP forecasts have been revised downwards to reflect current global economic conditions. For 2009 the government is activating a US$5,800 million "Anticrisis Plan" to sustain economic growth in the global downturn.

PHARMACEUTICAL MARKET

Current Size

The Peruvian pharmaceutical market is the seventh largest in the region, behind Mexico, Brazil, Argentina, Venezuela, Colombia and Chile. In 2008, the market is estimated to be US$1.1 billion at retail prices, equivalent to US$37 per capita. As a percentage of health expenditure, drugs represent 19.8% of the total in 2008. Annual market growth remains at 5.0%.

Hospital sales account for around 24.0% of the market at retail prices, or 28.0% at manufacturers' prices. According to the Ministry of Health (MINSA), the hospital sector was valued at US$218.5 million at manufacturers' prices in 2007. The leading actors are ESSALUD, MINSA, FFAA and FNP. Domestic producers tend to supply ESSALUD and MINSA, and foreign producers FFAA & PNP.

Around 76.0% of the market at retail prices, or 72.0% at manufacturers' prices, mainly comprises sales through private pharmacies, pharmacy chains and clinics, usually funded either through private health insurance or directly by the patient. The pharmacy sector is estimated at US$562.0 million at manufacturers' prices in 2007. The leading company is B-MS, followed by Pfizer and Farmindustria.

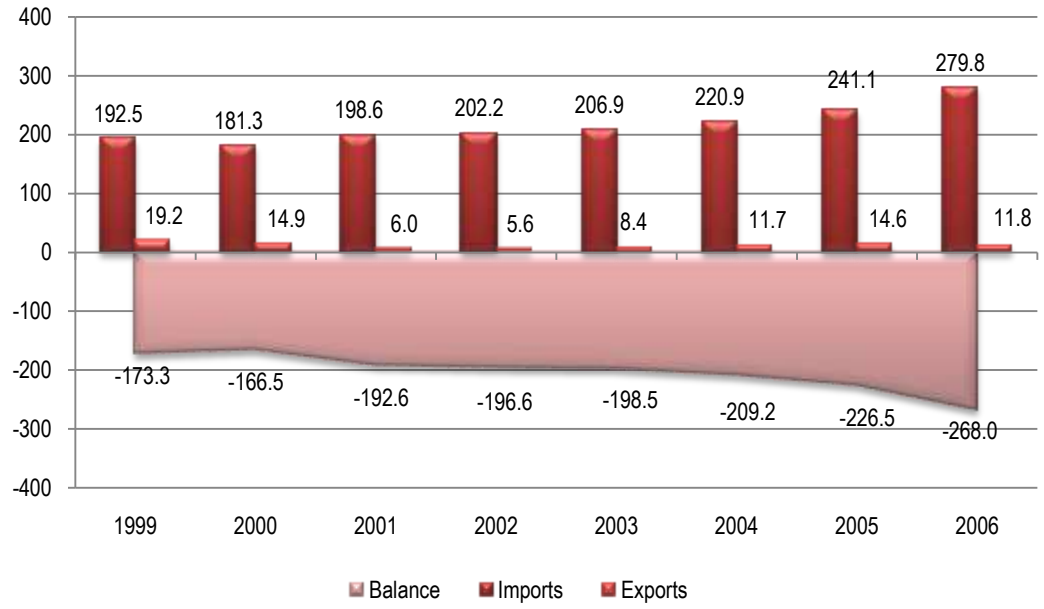
Pharmaceutical imports rose by 16.1% in 2006, reaching US$279.8 million. Local producers are reliant on raw materials imports, equal to US$71.9 million in 2006. The leading importers are foreign producers, including B-MS, Pfizer, Roche, GSK and MSD. Pharmaceutical exports are low, valued at US$11.8 million in 2006; a reduction of 19.1% on the previous year. Infarmasa is the leading exporter, followed by Grünenthal and Lender.

Summary of the Peruvian Pharmaceutical Market, 2008

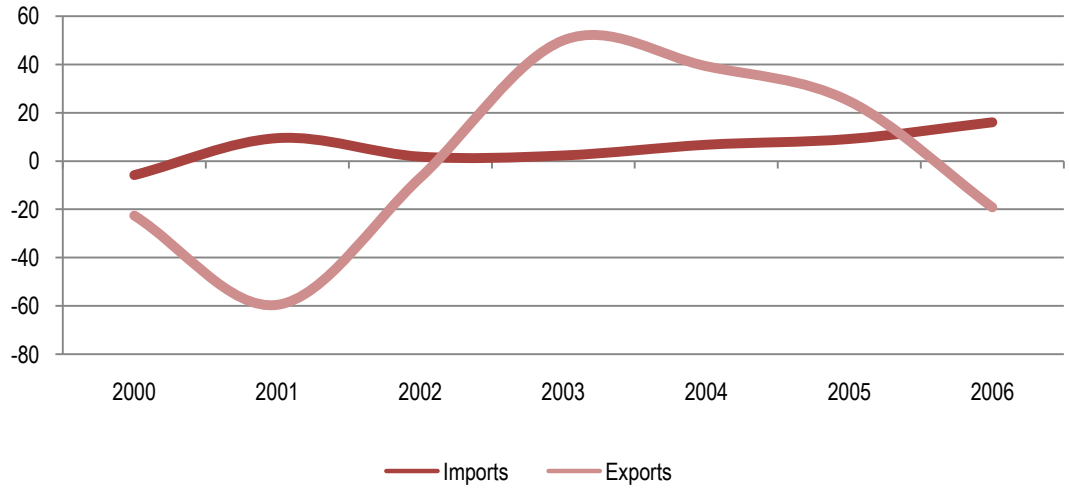
	2008
Market size (US$ million)	1,090
as % of total health expenditure	*19.8*
as % of GDP	*0.9*
as % of world market	*0.1*
Growth rate (%)	5.0
Per capita expenditure (US$)	37

Source: Espicom estimates.

Pharmaceutical Imports, Exports & Balance of Trade, 1999-2006 (US$ Million)



Percentage Change in Exports & Imports, 2000-2006



Projections

The Peruvian pharmaceutical market is expected to increase by 5.0% annually in the next five years, reaching US$1,391 million by 2013. This is, however, a moderate growth rate, compared to Brazil, Mexico and Argentina, which are recording a double digit growth. Generics are expected to grow at a relatively faster rate than original drugs, at between 6.0% and 7.0% annually.

The public sector is making an effort to co-ordinate its leading players, namely MINSA and ESSALUD, in terms of drug purchases, exchange of medical services, common health programmes, investment plans in infrastructure & equipment, development programmes and R&D capabilities. The public sector was valued at 713.0 million soles (US$218.5 million) at manufacturers' prices in 2007.

The government's 2006-2011 National Health Plan (PNS – Plan Nacional de Salud) aims to increase intra-sectoral corporate acquisition of drugs for the public sector; the first example was the reverse auction undertaken in December 2006. The second auction was held on January 16th 2008. Another aim is for better drug regulation which, when improved, should guarantee drug quality and access.

The PTPA signed in December 2007 represented President George Bush's first legislative trade victory since the Democrats took over Congress in the USA in January. Further intellectual property enforcements will result in increased pharmaceutical expenditure between 2011 and 2017, according to studies undertaken by the National Patent Office (INDECOPI) and MINSA.

Peru is cracking down on the counterfeit drugs trade, destroying 12 tonnes of illegal goods in 2007. CONTRAFALME and DIGEMID are working together to amend the Penal Code to create tougher punishment of counterfeiters, smugglers and dealers. Increased sentences will take place if Congress approves.

In 2005, MINSA indeed analysed potential drug price increases for diseases of high social cost (EACS – Enfermedades de Alto Costo Social), if the PTPA was signed. The study evaluated the impact on MINSA's, ESSALUD's and out-of-pocket pharmaceutical expenditure. However, it assumed the worst-case scenario for Peru and projections over 31 years are difficult to calculate.

Market Projections at Retail Prices, 2008-2013

	Market (US$ Million)	Per Capita (US$)
2008	1,090	37
2009	1,144	39
2010	1,202	40
2011	1,262	41
2012	1,325	43
2013	1,391	44

Source: Espicom projections.

Outlook

SWOT Analysis of the Peruvian Pharmaceutical Market, 2008

Strengths

- The Peruvian pharmaceutical market is small but stable.
- Drug prices were liberalised in the 1990s, resulting in drug price increases, particularly in the pharmacy sector. Producers are free to set up their own prices in the pharmacy sector, and practice vertical distribution system. Drug prices are moderate in the hospital sector, due to tenders and bidding processes.

Weaknesses

- The domestic industry mainly produces copycat generics, and does not invest in R&D. This is not a competitive advantage to compete against foreign innovative producers nationally or internationally.
- Peru gives preferential treatment to indigenous companies. In the hospital sector, indigenous manufacturers are also granted a 20% bonus or bidding preference, against foreign producers.
- Import labelling requirements exclusive to Peru might increase costs for importers and encourage data disclosure.
- Distribution channels are dominated by pharmaceutical producers and importers, which directly distributed 25.3% of the market value and 33.2% of the market volume. The pharmacy branded sector is strong, whereas the hospital sector is restricted to essential medicines.
- Due to pricing deregulation, drug prices in Peru are among the highest in the region. Although this is good for manufacturers, it does not help pharmaceutical coverage of those less well-off.

Opportunities

- With the approval of the PTPA, there are opportunities in terms of data exclusivity for research-based manufacturers to penetrate the market.
- The Peruvian epidemiological profile is characterised by the coexistence of communicable and chronic diseases. As they increase, particularly chronic diseases, there are market opportunities for new drugs. Estimates by MINSA indicate that the number of people affected by cancer, HIV/AIDS, diabetes, hypertension, malaria and mental illness will increase considerably by 2025.
- Around one third of the population does not have access to essential medicines, and coverage is low for the above mentioned diseases. If drug access and coverage are improved, there are opportunities for local producers in the hospital sector. If the economy improves, out-of-pocket pharmaceutical expenditure will also increase, which is good for producers of branded generics and original drugs.
- Health coverage is restricted; there is a need to extend it to the poorest, who only accounted for 4.7% of total out-of-pocket pharmaceutical expenditure in 2003. This means that the hospital sector might grow, which might benefit local producers of copycat generics. For example, public establishments are starting to dispense prescriptions not exclusively issued in their health centres.

Threats

- With the implementation of the PTPA, domestic industry might suffer, as there will be more restrictions on the production of generics.
- Colombian local producers are aggressively challenging Peruvian producers in their own market, participating in public tenders and networking with local distributors. Colombia was the second leading supplier of pharmaceutical imports in 2006, valued at US$26.5 million or 9.5% of the total.

Source: Espicom analysis.

Espicom Analysis of the Peruvian Healthcare Sector, 2008

	Rating	Direction
Demographics	**Fair**	↑

Comment: *Peru is the fourth most populous country in South America, behind Brazil, Mexico and Colombia, with a population of 29.2 million in 2008, an increase of 1.5% over 2007. The birth rate is very high and the death rate is low.*

Economic performance	**Fair**	↑

Comment: *GDP is expected to reach US$129.2 billion in 2008 and fall to US$127.6 billion in 2009. These figures have been revised downwards to reflect current global economic problems. The government is investing USS5,800 million to counter this. Peru has the highest GDP per capita in the current Andean Community (CAN). However, GDP per capita is less than half the level typically found in Chile, Mexico and Venezuela.*

Healthcare expenditure	**Below average**	↑

Comment*: Espicom estimates that health expenditure represents 4.3% of total GDP in 2008. Health expenditure is valued at US$5.5 billion in 2008, equal to US$188 per capita.*

Healthcare system	**Fair**	↑

Comment*: The organisation of healthcare is fragmented. Public and non-public institutions tend to be poorly co-ordinated, both at a national and sub-national level. More recently, however, there have been improvements to co-ordinate health services.*

Pricing & reimbursement	**Below average**	↑

Comment: *In the pharmacy sector, companies are free to set prices and, as a result, drug prices tend to be very high. In the hospital sector, there have been advances to contain drug prices and there is a watchdog to control drug prices.*

Domestic manufacturing	**Fair**	→

Comment: *There are a relatively high number of domestic producers. Leading domestic producers include Farmindustria, Medifarma, Infarmasa and Medco. Most of them produce generics. At 1994 constant prices, domestic production was valued at US$156.6 million in 2006 at 1994 prices, it stood at US$195.6 million in 2003.*

Health policies	**Fair**	↑

Comment: *In December 1999, the World Bank approved a ten-year, US$539.3 million, Health Sector Reform Project in Peru. Phase 1 covered mother & child insurance and health services decentralisation. Phase 2 ran from 2004-2007 and Phase 3 from 2007-2010. In December 2008, a Universal Health Insurance Law was approved, to ensure access for the poorest members of society.*

Use of generics	**Fair**	↑

Comment: *The generics market increased by 7.3% in 2004, reaching US$126 million. The hospital sector accounted for around US$100 million and the pharmacy sector for US$26 million. Between 1999 and 2004, the market value was stable due to a reduction of prices, whilst the market volume increased.*

Intellectual property	**Fair**	↑

Comment: *Current intellectual property rights comprise several Andean agreements and the national Peruvian legislation. However, a number of problems remain; some have been addressed in the PTPA. In 2007, Peru was placed on the 301 Watch List. It remained there for 2008 due to ongoing concerns about IPR. CONTRAFALME is working with a special police department, DINFA, to crackdown on counterfeit goods as well as looking to increase sentencing by amending the Penal Code.*

Radar Graph of the Peruvian Healthcare System, 2008

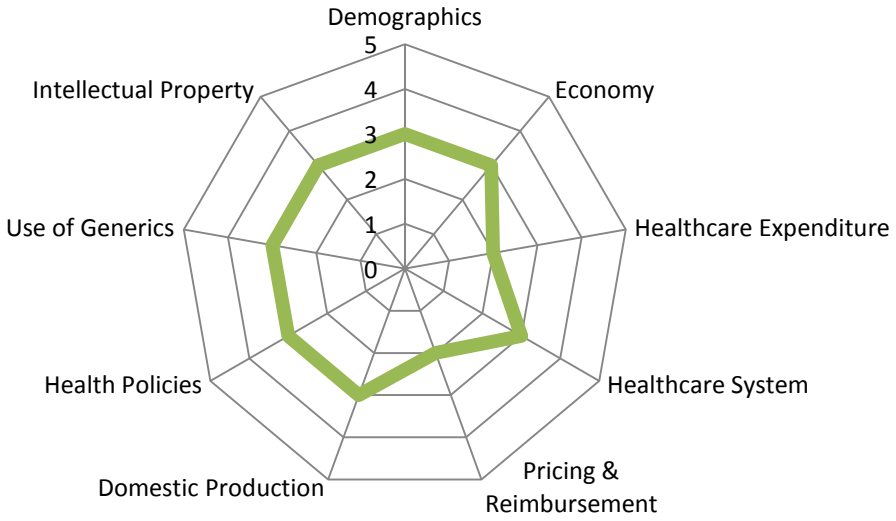


Chart derived from the tables on the previous page. Very strong = 5, Strong = 4, Fair = 3, Below average = 2, Poor = 1.

Market Structure

In November 2006, MINSA projected the hospital sector would be worth 713.0 million soles (US$218.5 million) in 2007, representing 28.0% of the pharmaceutical market, which is understood to be at manufacturers' prices. Based on MINSA's estimates, the market is valued at 2,546.4 million soles (US$780.5 million) at manufacturers' prices in 2007.

Market Value at Manufacturers' Prices, 2007

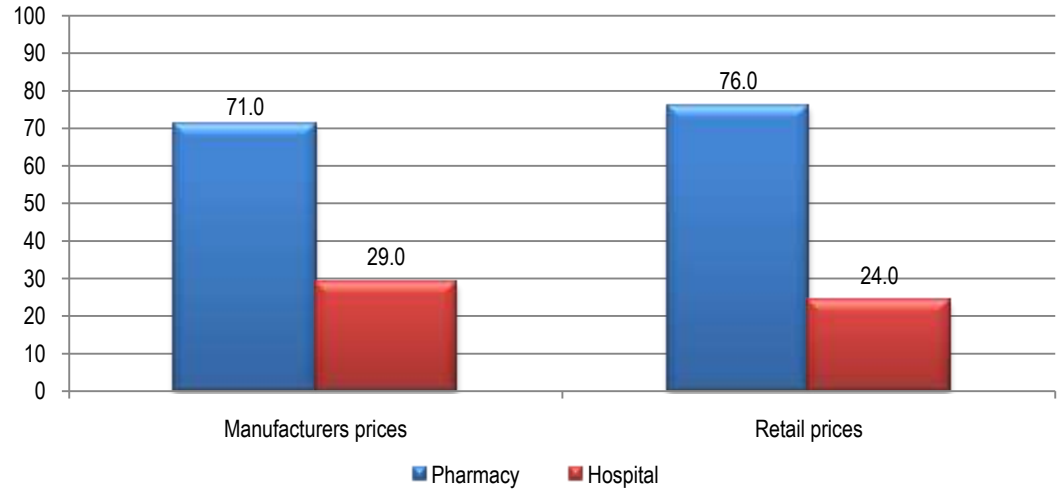
	Million Soles	US$ Million	As % of Total
Pharmacy	1,833.4	562.0	72.0
Hospital	713.0	218.5	28.0
Total	**2,546.4**	**780.5**	**100.0**

Source: Espicom using data from the Ministry of Health (MINSA – Ministerio de Salud).

In 2004, MINSA valued the pharmaceutical market at between 2.1 billion soles (US$600.0 million) and 2.3 billion soles (US$650.0 million) at retail prices. The pharmacy sector reached US$494.0 million, equal to 76.0% of the market at retail prices. The hospital sector reached US$156.0 million, accounting for the remaining 24.0% of the market.

The market at manufacturers' prices excludes a mark-up of around 33% and VAT. Espicom estimated the market at manufacturers' prices at US$515.8 million in 2004, of which US$366.3 was pharmacy and US$149.5 million was hospital. The pharmacy sector accounted for 71.0% of the total, and the hospital sector for the remaining 29.0%.

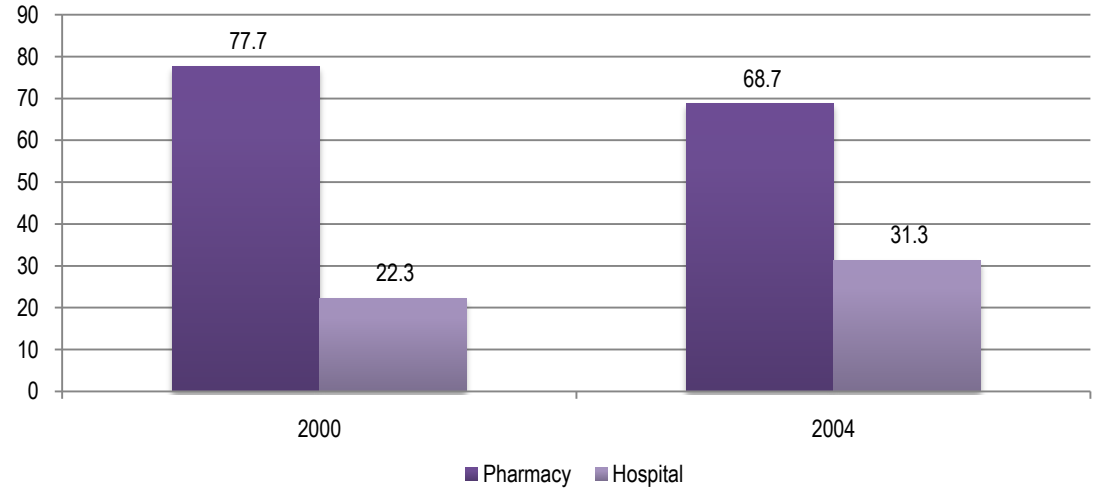
Market Value at Manufacturers' & Retail Prices, 2004 (%)



Source: MINSA.

Between 2000 and 2004, the pharmacy sector increased in value, but decreased in volume. By using copycat generics, the hospital sector decreased slightly in value, but increased considerably in volume. In 2004, the hospital sector represented 31.3% of the market volume, compared to 22.3% in 2000.

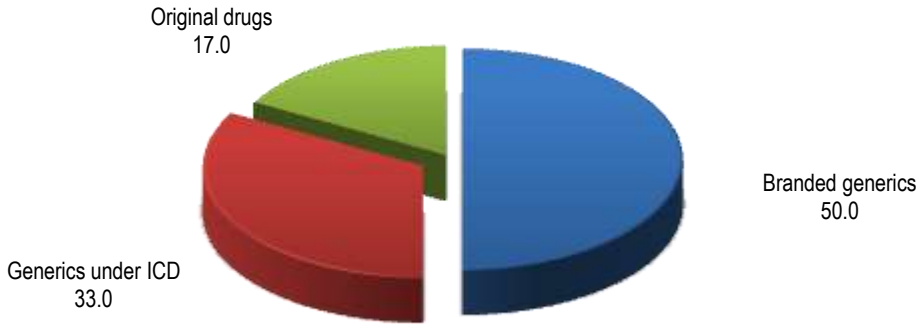
Market Volume, 2000 & 2004 (%)



Source: MINSA.

The cumulative number of drug registrations reached 13,933 by August 2004. Branded generics accounted for around 50% of the total, followed by generics under ICD (33%) and original drugs (17%). Due to the speculation of branded generics and generics under ICD, however, only 4,379 product registrations were marketed in the pharmacy sector by August 2004.

Market Value by Registration Status, 2004 (%)



Source: MINSA.

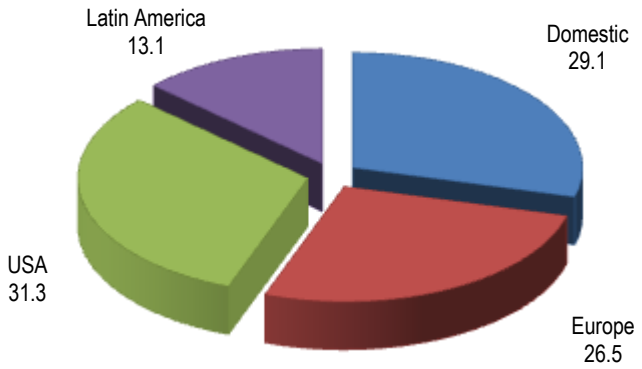
The market is heavily influenced by overseas companies, particularly the USA and Europe, with 31.3% and 26.5% of the market value in 2003, respectively. In recent years, however, the domestic industry and companies from other Latin American countries have increased their share, valued at 29.1% and 13.1% in 2003, respectively.

Market Value by Country/Region of Origin, 1999-2003 (%)

	Domestic	Europe	USA	Latin America
1999	26.4	30.9	33.2	9.3
2000	26.0	30.2	33.5	10.3
2001	26.8	29.1	33.0	11.1
2002	27.3	28.2	33.0	11.5
2003	29.1	26.5	31.3	13.1

Source: MINSA.

Market Value by Country/Region of Origin, 2003 (%)



Source: MINSA.

The Pharmacy Sector

The pharmacy sector is estimated at US$562.0 million at manufacturers' prices in 2007. According to MINSA, the sector was valued at US$366.3 million at manufacturers' prices in 2004, which represented a 15.0% increase over 2000, at US$318.6 million. By volume, the sector was valued at 66.6 million units in 2004, which represented a 12.7% increase over 2000, at 59.1 million units.

In 2001, the pharmacy sector by value was valued at US$335.0 million and the pharmacy sector by volume at 60 million units. The domestic industry accounted for around 30% of the market value, equal to US$100.5 million, and 40% of the market volume, equal to 24 million units. The remainder was accountable to foreign imports.

The ethical sector accounted for around 85% of the market value and 79% of the market volume in 2004. However, it was estimated that 70% of patients bought ethical drugs without a prescription. This tendency to dispense prescription drugs "under the counter" has traditionally diminished the OTC sector.

Pharmacy Market Value by POM & OTC, 2004 (%)

Source: MINSA.

Drugs for the digestive system and metabolism accounted for 18.2% of the market value and 19.9% of the market volume in 2004, followed by drugs for the respiratory system (13.4% of the market value and 15.9% of the market volume) and anti-infectives (11.8% of the market value and 14.4% of the market volume).

The demand for drugs to treat EACS diseases, including diabetes, hypertension, cancer, depression, psychosis, tuberculosis, malaria and HIV/AIDS, was low. In 2004, they represented 7.2% of the pharmacy sector by value, equal to US$29.2 million, and 3.7% by volume, equal to 2.4 million units. The demand has increased since then.

The leading companies operating in the pharmacy sector are American, European and Latin American. Most of them import products either from their country of origin or other Latin American subsidiaries, and are registered as importers by the national medicines agency, DIGEMID. Most of these companies are associated to ALAFARPE.

Major American representatives include Bristol-Myers Squibb (B-MS), Pfizer, Merck Sharp & Dohme, Abbott, Key and Eli Lilly. European companies include GlaxoSmithKline (UK), Sanofi-Aventis (France), Merck Peruana (Germany), Roche (Switzerland), Grünenthal (Germany), Novartis (Switzerland), Boehringer Ingelheim (Germany) and Schering Peruana (Germany).

Latin American companies include Roemmers, Bago and Tecnofarma (Argentina), ABL Pharma and Newpharm (Chile) and Genfar (Colombia). Roemmers and Bago import branded generics. Tecnofarma, ABL Pharma and Newpharm import branded and unbranded generics. Genfar exclusively imports generics under ICD.

The leading company in the pharmacy sector is Bristol-Myers Squibb (BMS), with sales reaching US$31.6 million in 2003, followed by Pfizer (US$24.0 million). In the top ten ranking, however, there are three domestic producers, including Farmindustria (US$18.5 million), Medifarma (US$10.7 million) and Magma (US$8.6 million).

Domestic Producers Rankings by Market Value & Volume, 2003

Rank	Company	US$ Million	As % of Total	Million Units	As % of Total
3	Farmindustria	18.5	5.3	4.6	7.2
6	Medifarma	10.7	3.1	2.8	4.4
10	Magma	8.6	2.5	2.3	3.6
12	Hersil	8.2	2.4	2.3	3.7
21	Sanitas	5.6	1.6	1.7	2.7
26	Medco	3.7	1.1	0.5	0.8
29	Alfa	3.4	1.0	0.5	0.7
32	Cipa	3.2	0.9	0.6	0.9
33	Refasa Carrion	3.2	0.9	0.7	1.1
35	Cofana	3.1	0.9	1.0	1.6
39	Trifarma	2.7	0.8	1.6	2.6
49	Quimioterapico	1.8	0.5	0.5	0.8
50	Gloria	1.7	0.5	0.7	1.2
51	Markos	1.7	0.5	0.3	0.5
Total	**~**	**346.8**	**100.0**	**63.6**	**100.0**

Source: MINSA.

International Producers Rankings by Market Value & Volume, 2003

Rank	Company	US$ Million	As % of Total	Million Units	As % of Total
1	Bristol-Myers Squibb	31.6	9.1	5.8	9.2
2	Pfizer	24.0	6.9	3.7	5.7
4	Roche	16.8	4.8	1.8	2.8
5	GlaxoSmithKline	14.6	4.2	1.6	2.5
7	Merck Sharp Dohme	9.5	2.8	0.5	0.8
8	Abbott	9.2	2.7	0.9	1.4
9	Aventis	8.9	2.6	0.6	1.0
14	Novartis Pharma	7.3	2.1	0.5	0.8
15	Merck	7.2	2.1	1.2	2.0
16	Boehringer Ingelheim	6.6	1.9	1.0	1.5
17	Grünenthal	6.6	1.9	1.2	1.9
19	Schering Peruana	6.2	1.8	1.1	1.7
24	Wyeth Ayerst	4.2	1.2	0.4	0.7
25	Sanofi-Synthélabo	4.0	1.1	0.3	0.4
30	Bayer	3.3	1.0	0.5	0.8
31	Plough Consumo	3.2	0.9	0.6	1.0
34	Organon	3.1	0.9	0.2	0.4
36	Lilly	3.0	0.9	0.1	0.2
41	Novartis Consumer	2.5	0.7	0.5	0.7
42	AstraZeneca	2.3	0.7	0.2	0.2
Total	**~**	**346.8**	**100.0**	**63.6**	**100.0**

Source: MINSA.

The sector is relatively fragmented. The top leading companies have 41.5% of the market, Bristol-Myers Squibb being the leader (9.1%), followed by Pfizer (6.9%) and Farmindustria (5.3%). By therapeutic groups, the economic concentration is low. However, by therapeutic sub-groups, there is a high economic concentration, particularly in cancer immunosupressants (96.6%).

Economic Concentration by Therapeutic Areas, 1999-2003 (%)

	1999	2000	2001	2002	2003	Average
Diabetes	43.5	43.2	37.7	34.4	33.1	38.4
Hypertension	75.7	81.4	80.5	77.3	74.1	77.8
Tuberculosis	49.6	52.7	55.6	47.7	49.6	51.0
HIV/AIDS	36.9	32.9	34.0	32.0	30.1	33.2
Cancer alkylating agents	41.5	50.5	46.6	55.5	55.2	49.9
Cancer cytostatics	44.4	64.7	54.2	44.8	43.7	50.3
Cancer immunostimulants	70.7	72.1	86.9	70.7	85.8	77.2
Cancer immunosupressants	97.8	95.1	99.3	96.2	94.5	96.6
Psychosis	24.7	22.9	21.0	20.8	20.9	22.1
Depression	24.8	22.4	22.2	21.5	21.0	22.4

Source: MINSA.

The Hospital Sector

ESSALUD (the former Social Security Institute), and the Ministry of Health (MINSA) are the major providers of drugs in the hospital sector. They account for 70% and 20% of the hospital sector, respectively. The remaining 10% is provided by the Armed Forces (FFAA) and the National Police (PNP), through their specialised departments;

- Health Department for the Peruvian War Navy (DISAMAR - Dirección de Salud de la Marina de Guerra del Perú).
- Health Fund for the Army Personnel (FOSPEME - Fondo de Salud para el Personal Militar del Ejército).
- Health Fund for National Police Personnel (FOSPOLI - Fondo de Salud para el Personal de la Policía Nacional).

ESSALUD

ESSALUD operates centralised purchases for national distribution. Historically, it covers most of the chronic diseases, including cancer, HIV/AIDS, diabetes mellitus (DM), hypertension and mental diseases. ESSALUD covers over two thirds of all cancer, DM and hypertension cases in the country.

ESSALUD's pharmaceutical expenditure was valued at 367.6 million soles (US$105.7 million) in 2003. Expenditure on drugs to treat cancer represented 8.0% of the total, equal to 29.3 million soles (US$8.4 million). ESSALUD also spent a considerable amount on drugs to treat hospital infections, kidney disease, HIV/AIDS, mental illness, hypertension and DM.

ESSALUD's Pharmaceutical Expenditure, 2003

	Million Soles	US$ Million	As % of Total
Cancer	29.3	8.4	8.0
Intra-hospital infections	22.7	6.5	6.2
Kidney disease	17.2	4.9	4.7
HIV/AIDS	17.1	4.9	4.6
Mental illness	11.4	3.3	3.1
Hypertension	9.3	2.7	2.5
Diabetes mellitus	5.9	1.7	1.6
Subtotal	*112.8*	*32.4*	*30.7*
Total	**367.7**	**105.7**	**100.0**

Source: ESSALUD.

MINSA

Under Resolution No. 336, published in June 2001, MINSA created an Integrated Medical & Pharmaceutical Supplies System (SISMED – Sistema Integrado de Suministro de Medicamentos y Material e Insumo Médico Quirúrgico). SISMED centralised purchases to obtain discounts by buying in bulk quantities.

MINSA's pharmaceutical expenditure was valued at US$48 million in 2003. According to figures from April 2002, MINSA mainly purchased anti-infectives (50%), vitamins (9%) and antiparasitics (8%). Historically, MINSA covers emergent and re-emergent diseases, including around 75% of all tuberculosis and malaria cases in the country.

MINSA's market is very fragmented. MINSA's leading domestic suppliers included Corporación Infarmasa, Instituto Quimioterápico, Hersil and Laboratorio Farmacéutico San Joaquín R (SJR) in 2004. Their compounded sales amounted to 23.5 million soles (US$6.8 million) in 2004, compared to 37.6 million soles (US$10.8 million) in 2003.

In 2004, Infarmasa's sales amounted to 10.9 million soles, a fall compared to 15.0 million soles in 2003. Instituto Quimioterápico sales nearly halved, from 18.6 million soles in 2003 to 9.1 million soles in 2003. Hersil's and SJR's sales, however, increased. Hersil passed from 2.6 million soles in 2003 to 3.6 million soles in 2004, and SJR from 1.3 million soles in 2003 to 1.9 million soles in 2004.

Public Tenders

ESSALUD, MINSA, FFAA and PNP are exempt from the application of Article 14, so they do not have to distinguish between national and foreign goods in their purchase selection. Consequently, national and foreign companies, whether they manufacture domestically or import products, can participate in public purchase tenders.

According to Law 27,633, producers that tender domestically manufactured products receive a mark-up of 20%. This preference suggests an increasing spending and lesser quality purchasing for some governmental institutions. Indeed, this process needs review so it is compatible with the offer and demand in the pharmacy sector, and public funds are maximised.

Foreign producers have overcome this favouritism by using local third-party manufacturing. Referring to public tenders in 2002, INDECOPI stated that several foreign producers, including Grünenthal, Roemmers, Genfar, Rambaxy, ABL Pharma and Farmo Andina, did not have manufacturing sites in Peru but were given the 20% mark-up.

In 2002, domestic producers accounted for 40% of the hospital sector, followed by foreign producers with a 37% market share. The remaining 23% of the market belonged to distributors/importers. By analysing purchases undertaken by MINSA, ESSALUD, FFAA and PNP, domestic producers are the leading suppliers for MINSA and ESSALUD, whereas foreign producers are for FFAA and PNP.

Original Medicines

Almost 100% of all registered original drugs are marketed. Original drugs target the more affluent population in the pharmacy sector, and the contributive population to ESSALUD in the hospital sector. Marketing and promotion activities guarantee brand trust among the population. Most of these drugs are offered in various presentations, and have good distribution channels in the pharmacy sector.

Generic Medicines

True generics have yet to gain much prominence in the Peruvian market, as bioequivalence standards are not enforced. There are two types of generics in Peru, including generics under International Common Denomination (ICD) and branded generics. There are many registrations of these drugs.

Generics under ICD are local copies of successful branded generics. Of 13,933 product registrations recorded between 2000 and 2004, generics under ICD accounted for 33% of the total, equal to 4,598. However, only 37% were marketed, most of them to the hospital sector via tenders and bidding process, as they lack good distribution channels in the pharmacy sector.

Generics under ICD are not very popular in the pharmacy sector. Prescribers still favour original drugs and branded generics. Only around half of the population are aware of generics under ICD. To make things worse, the population perceives generics under ICD as drugs of lesser quality, and are confused by the ICD. Also, these drugs lack good distribution channels.

Branded generics are more competitive. They are local copies of successful original drugs, made or patented elsewhere. Between 2000 and 2004, they accounted for 50% of all product registrations, equal to 6,967. Of these, a further 50% were marketed. With good distribution channels, they tend to penetrate the market share of original drugs in the pharmacy sector.

The market of generics under ICD increased by 7% in 2004, reaching US$126 million. The hospital sector accounted for around US$100 million and the pharmacy sector for US$26 million. Between 1999 and 2004, the market value was stable due to a reduction of prices, whilst the market volume increased.

Major generic producers are domestic and Latin American. Domestic producers include Farmindustria, Marfan (from Medco Corporation) and Magma (from Infarmasa Corporation). Latin American producers include the Colombian Genfar and the Chilean Newpharm (from Laboratorios Chile). The top four companies control over 50% of the sector.

Proposals to Introduce Bioequivalence & Bioavailability Tests

Currently, there is a proposal to gradually establish bioequivalence and bioavailability studies to selected pharmaceutical drugs. First of all, a commission will be created to draft technical and regulatory proposals, including Good Manufacturing Practices (GMP), bioequivalence and bioavailabity.

Secondly, the National Institute of Health (INS – Instituto Nacional de Salud) will be appointed as the entity responsible for undertaking bioequivalence and bioavailability tests. Thirdly, a list of drugs requiring bioequivalence and bioavailability for product registration will be drafted. Fourthly, a regional lab network will undertake bioequivalence and bioavailability tests.

It is clear that bioequivalence and bioavailability will only be enforced in drugs which present high clinical and sanitary risks. For the remainder, other technical alternatives will be applicable. Bioequivalence and biovailability will remain as additional quality standards, in a way that they are not barriers to the introduction of alternatives to high priced original drugs.

Generic Substitution

Decree 020-90-SA, issued in 1990, and Resolution 0022-93-SA/DM, issued in 1993, authorised pharmacies and drugstores to undertake generic substitution. Also, these two regulations made it obligatory to prescribe by the International Common Denomination (ICD).

Domestic Production

Domestic producers concentrate on the production of copycat generics, branded or unbranded, whereas leading foreign international companies import branded ethical and OTC drugs. Over 90.0% of them are based in the department of Lima. Using 1994 constant prices, domestic production increased by over a quarter, at 27.8% in 2006, reaching 343.7 million soles (US$156.6 million), equal to 0.2% of Peru's GDP. DIGEMID had 89 pharmaceutical producers registered in 2006.

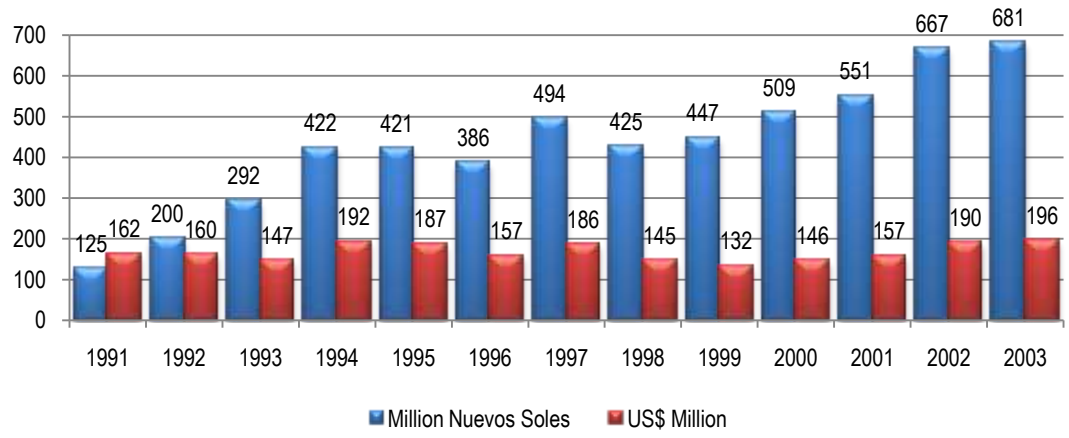
Domestic Production at 1994 Constant Prices, 1991-2006

	Million Soles	As % of GDP	Volume Index	Price Index
1991	477.6	0.6	113.1	26.1
1992	418.8	0.5	99.2	47.7
1993	367.4	0.4	87.0	79.4
1994	422.3	0.4	100.0	100.0
1995	357.9	0.3	84.7	117.5
1996	301.3	0.3	71.3	128.1
1997	374.4	0.3	88.7	132.0
1998	281.6	0.2	66.7	150.8
1999	265.9	0.2	63.0	168.0
2000	264.2	0.2	62.6	192.6
2001	271.6	0.2	64.3	203.8
2002	314.2	0.2	74.4	212.1
2003	309.0	0.2	73.2	220.2
2004	244.3	0.2	57.8	232.5
2005	269.0	0.2	63.7	244.1
2006	343.7	0.2	81.4	252.3

Source: INEI.

At current prices, domestic production increased by 2.0% in local terms in 2003, reaching 680.5 million soles (US$195.6 million), equal to 0.3% of Peru's GDP and 29.1% of the pharmaceutical market at retail prices. Domestic producers had a high market share in anti-inflammatories, analgesics, calcium bone regulators and antacids. In 2003, leading domestic producers included Farmindustria, Medifarma, Magma and Hersil. Domestic producers also undertake third-party manufacturing for international producers.

Domestic Production, 1991-2003



Source: INEI.

Trade Associations

ADIFAN

The National Association of Pharmaceutical Industries (ADIFAN - Asociación de Industrias Farmacéuticas Nacional) represents 19 Peruvian producers, which includes the Infarmasa and Medco corporate groups. ADIFAN's members produce branded and unbranded generics and also undertake third-party manufacturing. ADIFAN separated from ALAFARPE over 20 years ago due to different positions on issues such as patents, governmental purchases and drug imports.

ALAFAL

The Association of Latin American Pharmaceutical Producers (ALAFAL - Asociación de Laboratorios Farmacéuticos Latinoamericanos) represents nine Latin American producers with interests in Peru. These include ABL Pharma, Farmacéutica Latina, Grupo Farma, Maver Perú, Roemmers, Sanderson, Tecnofarma, Terbol and Unimed del Perú.

ALAFARPE

The Association of Pharmaceutical Producers from Peru (ALAFARPE - Asociación de Laboratorios Farmacéuticos del Perú) has 17 members, most of which are foreign research-based producers. These producers tend to not have manufacturing facilities or undertake major R&D activities in Peru. They usually import most of the finished products from other Latin American subsidiaries, particularly from Mexico, Argentina and Ecuador, and/or their headquarters.

COMSALUD

The Committee for Health Products & Sciences (COMSALUD - Comité de Productos para la Salud y Ciencias Afines) is integrated within the Chamber of Commerce in Lima (Cámara de Comercio de Lima). COMSALUD represents producers specialised in pharmaceuticals, medical supplies, apparatus & equipment and clinical laboratory products. Within COMSALUD, there is a subcommittee of medicaments which represents 16 pharmaceutical producers.

Imports

Since the mid 1990s, pharmaceutical imports have increased considerably. Major importers include international producers such as Abeefe Bristol-Myers Squibb, Pfizer, Roche, GlaxoSmithKline, Merck Sharp & Dohme, Abbott and Sanofi-Aventis. They tend to import from their other Latin American subsidiaries. Other importers include indigenous distributors such as Química Suiza.

In 2006, Peru imported pharmaceuticals from 50 countries worth US$279.8 million. Imports fell by 5.8% in 2000, but recovered by 9.5% in 2001, when import duties were reduced. In 2006, imports of retail medicaments reached US$205.1 million, equal to 73.3% of total imports. Local producers continue to be reliant on imports of raw materials, valued at US$71.9 million in 2006.

Pharmaceutical Imports, 2002-2006 (US$000s)

	2002	2003	2004	2005	2006
Raw materials	35,946	41,097	50,038	55,646	71,865
Semi-finished medicaments	2,000	2,092	2,680	2,401	2,797
Retail medicaments	164,285	163,718	168,162	183,060	205,144
Total	**202,231**	**206,907**	**220,880**	**241,107**	**279,806**

Import Trends, 2005-2006 (US$000s)

	2005	2006	% of Total	% Change, 2006	5-yr % Change
Raw materials	55,646	71,865	25.7	29.1	99.9
Semi-finished medicaments	2,401	2,797	1.0	16.5	39.9
Retail medicaments	183,060	205,144	73.3	12.1	24.9
Total	**241,107**	**279,806**	**100.0**	**16.1**	**38.4**

India was the leading supplier of raw materials for Peru in 2006, with US$13.9 million or 19.3% of the total. China supplied another 16.5% of raw materials. Supplies were spread across many areas; Asia, South America, North America and Europe were all represented as leading suppliers in 2006.

The EU-15 supplied US$27.4 million, equal to 38.2%. Leading EU suppliers were Belgium (US$6.9 million), France (US$6.2 million) and Germany (US$5.0 million). The US also featured as a top raw materials supplier with 6.2% or US$4.5 million worth of supplies.

Leading Suppliers of Raw Materials, 2006 (US$000s)

	Raw materials	% of Total
India	13,886	19.3
China	11,865	16.5
Belgium	6,990	9.7
France	6,216	8.6
Germany	5,049	7.0
USA	4,475	6.2
Spain	4,360	6.1
Brazil	3,566	5.0
Switzerland	2,813	3.9
UK	1,772	2.5
Korea	1,348	1.9
Mexico	1,262	1.8
Grand Total	**71,865**	**100.0**
EU-15	27,431	38.2

Colombia was the leading supplier of medicaments in 2006, with US$25.8 million, equal to 12.4% of the total. In fact, Latin America was well represented in this category, with six out of the 12 top medicaments suppliers (45.9% of total supplies or US$95.5 million) from this continent. The US was also an important source, supplying US$19.9 million or 9.6% of the total.

The EU-15 supplied for US$48.1 million or 23.2% of Peru's medicaments. EU suppliers in the top 12 were Germany and France (both supplying 5.3%) and Italy (supplying 3.1%).

Leading Suppliers of Medicaments, 2006 (US$000s)

	Medicaments	% of Total
Colombia	25,765	12.4
Argentina	23,141	11.1
USA	19,925	9.6
Mexico	17,300	8.3
India	12,826	6.2
Brazil	12,648	6.1
Chile	11,123	5.3
Germany	11,081	5.3
France	11,011	5.3
Switzerland	9,768	4.7
Italy	6,499	3.1
Uruguay	5,567	2.7
Grand Total	**207,941**	**100.0**
EU-15	48,146	23.2

Parallel Imports

According to MINSA and Peruvian Customs, it is very difficult to estimate the value of parallel imports in the country; there are no official figures. Parallel importers must obtain a certificate of product registration (CRS – Certificado de Registro Sanitario), but many appeal against it, so that the process is easier. Some claim that they are merging with other companies. Others allege exclusive representation of products already registered by the original manufacturer.

According to DIGEMID, there were 2,114 CRS' issued in the country in 2003, of which 684 were pharmaceutical. Macrinsey was the leading parallel importer with 103 CRS', of which 98 were for branded products and five for generics, followed by Farmabell (15 CRS') and Cafarma (seven CRS'). Other companies such as Nordic Pharmaceutical and El Samaritano only imported generics.

Exports

After a steady increase since 2002, 2006 saw exports fall by 19.1% to US$11.8 million. This was due to a 20.1% decrease in exports of retail medicaments, the largest export category for Peru, which made up 95.6% of the total.

Due to a lack of infrastructure, pharmaceutical exports contracted from US$19.2 million in 1999 to US$5.6 million in 2002 and exports are yet to recover to this level. Prior to 2001, penicillins in bulk were the biggest export category, worth US$9.6 million in 2000.

Exports of Pharmaceuticals, 2002-2006 (US$000s)

	2002	2003	2004	2005	2006
Raw materials	696	841	404	463	520
Semi-finished medicaments	170	0.0	0.0	0.0	0.0
Retail medicaments	4,721	7,554	11,274	14,128	11,286
Total	**5,587**	**8,395**	**11,678**	**14,591**	**11,806**

Export Trends, 2005-2006 (US$000s)

	2005	2006	% of Total	% Change 2006	5-yr % Change
Raw materials	463	520	4.4	12.3	-25.3
Semi-finished medicaments	0.0	0.0	0.0	n/a	-100.0
Retail medicaments	14,128	11,286	95.6	-20.1	139.1
Total	**14,591**	**11,806**	**100.0**	**-19.1**	**111.3**

Exports are almost exclusively destined for other Latin American countries. In 2006, Ecuador was the lead destination with 35.1% or US$4.1 million, followed by Bolivia and Argentina, each US$1.8 million, and Venezuela US$1.4 million. These four destinations dominated exports as they accounted for 76.9% of the total. As lead destinations, the UK and France were the only non Latin-American countries to appear. The whole of the EU-15 only accounted for 3.9% of the total.

Leading Destinations, 2006 (US$000s)

	Exports	% of Total
Ecuador	4,144	35.1
Bolivia	1,771	15.0
Argentina	1,756	14.9
Venezuela	1,409	11.9
Panama	726	6.1
Colombia	603	5.1
Guatemala	287	2.4
Chile	257	2.2
UK	203	1.7
Costa Rica	137	1.2
France	110	0.9
Total	**11,806**	**100.0**
EU-15	463	3.9

Most of the producers exporting pharmaceuticals are foreign companies, although there are some important local exporters. Pharmaceutical exports are concentrated on ten companies which represented 69.1% of total exports in 2005. The leading exporter was Corporación Infarmasa, with exports valued at US$2.6 million in 2005, equal to 15.6% of the total, followed by Grünenthal (13.3%) and Ilender (9.8%).

Leading Exporters of Pharmaceuticals, 2003-2005 (US$000s)

	2003	2004	2005	As % of Total	Change (%)
Corporación Infarmasa	139.7	3,313.4	2,571.2	15.6	-22.4
Grünenthal Peruana	472.4	1,210.3	2,202.8	13.3	82.0
Ilender Perú	630.7	1,394.7	1,621.1	9.8	16.2
Cirugía	309.7	623.0	1,020.2	6.2	63.7
Corporación Medco	505.1	419.5	939.5	5.7	123.9
Novartis Biosciences Perú	86.1	26.2	858.8	5.2	3,175.8
Agrovet Market	127.6	313.7	834.1	5.0	165.9
Ranbaxy Perú	361.1	108.6	523.1	3.2	381.7
B. Braun Medical Perú	388.4	411.4	493.5	3.0	20.0
Laboratorios Biomont	115.6	113.0	355.5	2.2	214.6
Subtotal	*3,136.4*	*7,933.8*	*11,419.8*	*69.1*	*43.9*
Others	7,338.5	6,265.2	5,100.6	30.9	-18.6
Total	**10,474.9**	**14,199.0**	**16,520.3**	**100.0**	**16.3**

Source: Peruvian Export Promotion Agency (PROMPEX – Comisión para la Promoción de Exportadores).

Research & Development

Some foreign producers undertake local clinical studies to test imported drugs and determine correct drug usage. This spending is estimated at between US$6 and US$7 million annually. When Peruvian companies engage in R&D activity, however, they are invariably concerned with the development of copycat drugs, either generic or branded, or manufacture for foreign laboratories.

In 2007, the new government decided to modify Decree No. 17-2006-SA, which established the regulation of clinical studies. Several consumer organisations are against some of the new proposed measures: no obligation for producers to get insurance in case that something goes wrong; no co-responsibility for the research centre; clinical studies on young people; and the possibility of undertaking clinical studies in private consulting rooms.

After two and a half years of debate, Decree No. 17-2006-SA was approved in July 2006, and represented a milestone in clinical studies regulation in Latin America. The regulation has 12 main points, referring to the product in research, administrative files & databases, the information & publication of clinical studies, safety during research, supervision of clinical studies and infringement & fines.

Market Developments

Universal Health Insurance Law Approved

On 17th December 2008, the Council of Ministers approved the "Ley Marco de Asugaramiento Universal en Salud" Universal Health Insurance Law. The law allows everybody, especially the most poor, to access health services. The document was then sent to the Congress of the Republic.

The initiative will be accompanied by an infrastructure and equipment plan, which will identify priority zones where universal health insurance will take place in co-ordination with regional governments.

The application and implementation of the Ley de Asuguramiento Universal (Universal Insurance Law) will allow people from the most excluded areas in Peru to have their health needs attended to, considered a representative from the Colegio Medico de Peru (the Peruvian Doctor's College).

Economic "Anticrisis" Plan

In December 2008, the President, Alan Garcia, announced that the government will act in response to the effects of the global financial crisis, by spending US$5,800 million to maintain economic growth. Peru has experienced the highest growth in Latin America recently. Of the total set aside for the "Plan Anticrisis", US$2,800 million will come from Peru's public treasury, the remainder, US$3,000 million, will be sourced from World Bank and Interamerican Development Bank loans.

In September 2008, Peru experienced its first overall trade deficit in five years. On a separate day, Mr Garcia announced a plan to increase public spending on housing, roads and social programmes and raise investment to US$13,200 million.

Anti-poverty plans which will improve the infrastructure in public services, in the health and education sectors, should lead to an improvement in the quality of services accessed.

Doctors Strike over Pay and Working Conditions

In September 2008 doctors went on strike after the Peruvian Medical Federation failed to come to an agreement with the government over pay and working conditions. Most of the doctors that participated were union members but patients were not left unattended, reported the La República newspaper. The organisation has recently called for the replacement of the Health Minister, Hernán Garrido Lecca, as they have alleged that he has "begun a campaign to defame doctors and the Medical Federation".

On the evening the strike began, the President of Peru, Alan Garcia, spoke out saying that the pay increase demanded by doctors could not be met because of limits in the budget. He said that he had great respect for doctors and requested that doctors respect the Minister of Health. With both sides unwilling to move, the strike could go on indefinitely, although all doctors are covering emergency care and the majority have not left their posts. The Ministry of Health had previously affirmed that a strike would be an illegal move.

ESSALUD Resource Problems

In September 2008, the national newspaper El Comercio released an article warning that ESSALUD is in danger. They cited facts such as patients having to wait for up to 40 days to get a doctor's appointment, 60 days for an operation and patients not receiving all their medication as being evidence of the poor state of the system.

In July 2008, the Health Minister admitted that in order to reach WHO standards, Peru would need to hire 7,000 more doctors, 7,000 nurses and 2,500 obstetricians which would cost 1 billion soles (US$347.3 million). He also suggested redistributing personnel so that there is even coverage in the regions and the capital. Currently, Lima has around 15 health personnel per 10,000 population but there are only 4-5 per 10,000 in the regions.

The government has been investing in ESSALUD, hiring 2,500 more doctors and had spent 400 million soles on medical equipment by September 2008. 15 new hospitals are being built by ESSALUD over the next two years, which will increase capacity by 40%, equal to 1,800 new beds. Unfortunately, there are still problems with inadequate resources which will worsen as the number of people with access to ESSALUD grows. The number of ESSALUD members is 7.5 million and within three years is predicted to reach 10 million.

New National Blood Bank

The Ministry of Health is planning a new national blood bank for Peru. Peru has suffered from a lack of donors as well having 269 blood banks. The profusion of blood banks makes control of the supply difficult and there is no national standard for screening blood. The new facility will be housed in Lima as 70% of the blood is used there. Hopefully this will stop illegal blood sales and prevent further infections.

The lack of donors may be due in part to the problems with contaminated blood experienced in the country. In September 2007, four patients were infected with HIV/AIDS through transfusions. MINSA declared an emergency in the 200 blood banks, closed a hospital and prohibited blood donations in public hospital laboratories. Eight patients were also infected with HIV/AIDS in 2005. It is common for people to go to emergency centres to sell their blood, as a way of making money.

Doctors Fined for Ignoring Generics

In June 2008, the Ministry of Health brought in a resolution to punish doctors if they do not tell their patients about generic options alongside brand name ones when prescribing medicine. Ignoring the new ruling will result in a warning if it happens once and a small fine if it happens again. If doctors break the rule three times, they will have to pay a 1,750 soles fine (around US$608) and 7,000 soles (US$2,471) if they break it four times.

Apparently the Ministry of Health have brought in this measure to encourage doctors to change their habit of only prescribing brand-name medication and not taking into account their patients level of income.

Congressional Health Commission Passes Counterfeit Medicine Bill

In May 2008, the Congressional Health Commission passed a bill to crack down on counterfeit medicines, introducing a maximum 10 year prison sentence for those that sell, store or produce fake medicine. The maximum sentence would be applicable if the medication caused physical harm or killed the person that purchased it. If a company or person who is authorised to sell medicine sells goods which are not the kind, quality or quantity on the customer's prescription, it is proposed they be sentenced to three to six years. The Congressional Health Commission's reports have stated that around 30% of medicine sold in Peru is adulterated.

This change has been considered for the past 20 years. The counterfeit drugs trade costs the industry 25% in lost revenue per year. In 2007 alone, around 12 tonnes of counterfeit medicines were destroyed as the result of actions taken by DIGEMID, (General Department of Medicines, Supplies and Drugs).

Between 2005 and May 2006, DIGEMID reported 62 actions against drug counterfeiting. As a result, 18 tonnes of illegal drugs were found, valued at US$5.0 million. Around 60.0% of the adulterated drugs in Peru are sourced from other countries. Drug counterfeiting represents around 10% of the pharmaceutical market in Peru, and mainly affects anti-inflammatories, vitamins and antibiotics.

This is one of the results CONTRAFALME, the multi-sectoral technical group made up of, amongst others, ADIFAN, the national pharmaceutical trade association. Another initiative is the creation of DINFA (Investigative Division of Fraudulent Medicaments) within the national police force. Officers will carry out intelligence work and there will be a separate bureau specialising in medicaments.

CONTRAFALME is led by DIGEMID and includes the Ministry of Production, the pharmaceutical industry, municipalities and others. Under Resolution No. 047/2006, the group has four sub-divisions; legal norms, fiscalisation & health intelligence, promotion & education and financing.

Peru to Export Powdered Snake Poison Antidote

From 2009, Peru is going to export a snake poison antidote in a powder presentation form to Latin American countries including Bolivia and Ecuador. The antidote, an anti-ophidic serum freeze-dried into powder, has to be dissolved before being injected and has been developed by the National Institute of Health (INS). In the Latin American area, only Colombia and Costa Rica have developed this antidote in powder form which has the same properties as the liquid presentation.

Hepatitis B Vaccination Campaign

In May 2008, it was reported that in the past couple of months around 9.2 million people had been vaccinated against Hepatitis B as part of a campaign against the disease. The campaign has apparently cost 69 million soles (US$24 million).

Economic Progress for Peru

In April 2008, Peru became only the third Latin American country to achieve an investment grade rating for its foreign currency debt, following an export-led surge in commodities and improved economic management.

Peru's finance minister, Luis Carranza, welcomed the triple B rating by Fitch. The new rating places the Peru in the same category as India, and puts Peru "on the road to first world" status. The sovereign credit analyst at Fitch, said a strong improvement in the country's solvency ratios had been brought about by economic growth and a concerted campaign by President Alan García's administration to reduce debt.

The decision to re-classify Peru is the result of Peru achieving a triple B level of public debt in 2007, and announcing in 2008 that they will prepay their multilateral debts to the World Bank and the IDB.

Peru's Poverty Figures Released

In May 2008, the National Statistics Institute released a report "Peru's Poverty Figures 2004-2007". Poverty is gradually decreasing in Peru, particularly in urban areas. The amount of poverty in Peru, that is all people living underneath the poverty line including those in extreme poverty, reduced by 5.2%, from 44.5% to 39.3% from 2006 to 2007. There has been a reduction of 9.3% since 2004.

The largest reduction in poverty was seen in urban areas. This decreased from 31.2% to 25.7% between 2006 and 2007, and poverty in urban areas was 11.4% down from 2004 figures. In rural areas poverty reduced from 69.3% to 64.6% between 2006 and 2007. Extreme poverty also reduced from 2006-2007, but by a smaller margin of 2.4%, taking it to 13.7% of the total population. However the percentage of the population living in poverty varies widely from only 15.1% in Ica and 19.4% in the capital Lima, to a high 85.7% in Huancavelica.

Percentage of Poverty by Department, 2007

Ranking	Region	% in Poverty
1	Huancavelica	85.7
2	Apurimac	69.5
3	Ayacucho	68.3
4	Puno	67.2
5	Huanaco	64.9
6	Cajamarca	64.5
7	Pasco	64.3
8	Cusco	57.4
9	Amazonas	55.0
10	Loreto	54.6
11	Piura	45.0
12	Ucayali	45.0
13	San Martin	44.5
14	Junin	43.0
15	Ancash	42.6
16	Lambayeque	40.6
17	La Libertad	37.3
18	Mocquegua	25.8
19	Arequipa	23.8
20	Tacna	20.4
21	Lima	19.4
22	Tumbes	18.1
23	Madre de Dios	15.6
24	Ica	15.1
Peru Average	**-**	**39.3**

Another Reverse Auction Held for Peru's Public Sector Drug Needs

Another reverse auction was held on January 16th 2008 for Peru's drug needs. Medicine contracts worth 135.4 million soles were up for grabs. Out of the 174 approved medicines MINSA wanted to acquire 146 medicines worth a reference price of 43.2 million soles and ESSALUD 39 medicines worth 3.4 million soles. Also the Ministry of Defence (MINDEF) wanted to buy 137 types of medicine at a reference price of 4.2 million soles and the Ministry of the Interior (MININTER) 98 medicines at 4.6 million soles.

The first reverse auction took place in 2006, the aim is to save money in the public drugs acquisition process. The public sector wants to buy drugs of better quality at more cost-effective prices. According to MINSA, around 12.1 million Peruvians are poor in 2007. Of these, about 23% (2.8 million) cannot purchase medicines. By organising corporate purchases using the reverse auction process, the Ministry of Health expects to increase drug access amongst the poorest.

The reverse auction process is a new procurement option in which the government establishes technical specifications and quantity requirements of goods, in this case drugs. Suppliers then enter a bidding process. The supplier which offers the best price wins the bid. Importantly, the government must prequalify all the suppliers. The reverse auction offers transparency, speeds up the procurement process and results in considerable savings.

On 27th December 2006, MINSA, ESSALUD, FFAA and PNP completed the corporate acquisition of 166 essential medicines for the value of 149.8 million soles (US$45.9 million). Instead of using public tenders, MINSA organised an in-person reverse auction process (subasta inversa presencial). About 48 local and foreign producers, most of them engaged in generic production, participated.

The initial tender comprised 188 medicines for the value of 190.3 million soles (US$58.3 million); the public sector uses about 400 essential medicines and is valued at 714.0 million soles (US$218.5 million) in 2007. MINSA had projected to spend 125.1 million soles, ESSALUD 64.7 million soles and FFA 391,000 soles. The actual value of the acquisition was 103.9 million soles for MINSA, 45.8 million soles for ESSALUD and 130,152 soles for FFAA. In total, the sector saved over 40.5 million soles (US$12.4 million).

Public Drug Auction Expenditure by Sector, December 2006 (Million Soles)

	Projected Auction Value	Actual Auction Value	Savings
MINSA	125.1	103.9	21.3
ESSALUD	64.7	45.8	19.0
FFAA	0.4	0.1	0.3
PNP	n/a	n/a	n/a
Total	**190.3**	**149.8**	**40.5**

Source: MINSA.

Public Drug Auction Expenditure by Sector, December 2006 (%)

	Projected Expenditure	Actual Expenditure	Savings
MINSA	65.8	69.4	52.5
ESSALUD	34.0	30.6	46.8
FFA	0.2	0.1	0.6
PNP	~	~	~
Total	**100.0**	**100.0**	**100.0**

Source: MINSA.

The State Superior Council of Contracts & Acquisitions (CONSUCODE – Consejo Supervisor de Contrataciones y Adquisiciones del Estado), established the technical requirements for each of the drugs in a tender. Technical requirements included technical and quality data, including quality controls undertaken by the National Network of Quality Control Labs and certifications issued by the National Institute of Health.

The public sector aims to buy drugs of better quality at more cost-effective prices. According to MINSA, around 42% of the Peruvian population are poor, equivalent to 12.1 million in 2007. Of these, about 23% cannot purchase medicines, which equals 2.8 million in 2007. By organising corporate purchases using the reverse auction process, the Ministry of Health expects to increase drug access among the poorest Peruvians.

The reverse auction process is a new procurement option in Peru by which the government establishes technical specifications and quantity requirements of goods, in this case drugs. Suppliers then enter a bidding process. The supplier which offers the best price wins the bid. Importantly, the government must prequalify all the suppliers. The reverse auction offers transparency, speeds up the procurement process and results in considerable savings.

MINSA has also announced that from now onwards, all public procurement processes, undertaken by public tender or direct sales, either public or selective, will be monitored by international organisations. The Pan-American Health Organisation (PAHO) will be the first to monitor public drug purchases in Peru. MINSA is also dealing with other bodies, including;

- The United Nations Office of Project Services (UNOPS),
- The United Nations Children's Fund (UNICEF),
- The Andean Health Agency (ORAS - Organismo Andino de Salud), and
- The United Nations Population Fund (UNFPA).

MINSA Increases Outpatient Consultations by 20% Thanks to Late Shifts

A year into a new treatment timetable, in November 2007, almost a million outpatient consultations have taken place in Lima and Callao. A total of 999,485 consultations in hospitals, institutes and health posts have been carried out in the first year of widening the late shift hours, initiated by the Minister Carlos Vallejos Sologuren. The move was taken to increase coverage of outpatient consultations and in effect, has increased the number of outpatient consultations by 20%.

Advances in Intellectual Property Rights

After 43 months of negotiations, the US Senate approved the Peru Trade Promotion Agreement (PTPA) in December 2007 – it will be fully implemented in January 2009. In June 2007, the United States Trade Representative (USTR) announced that an agreement had been reached with Peru on amendments to the PTPA.

With the approval of the PTPA, the Peruvian pharmaceutical market is expected to be more competitive. Import and export duties will be eliminated or reduced, increasing the number of drugs in the market. Also, it is expected that local producers will lose the 20% mark-up received when participating in public tenders. This will encourage the government to use more generics.

Prior to the amendments, Peru was able to avoid the granting of second uses, or diagnostic, surgical & therapeutic proceedings. However, it agreed to a five-year data exclusivity period. There were some improvements in terms of linkage. Compulsory licensing and parallel imports remain, guaranteeing healthcare access in the country.

Initially, Peru, along with Colombia and Ecuador, and Bolivia as observer, had been negotiating the Andean Free Trade Agreement (FTA) with the USA. Negotiations halted in the XIII round in Washington in November 2005. Colombia and the USA continue their negotiations to approve a trade agreement. Negotiations between Ecuador and the USA also remain.

Improved GMP Compliance

The Peruvian Department of Medicines, Supplies & Drugs (DIGEMID – Dirección General de Medicamentos, Insumos y Drogas) has announced that all pharmaceutical producers registered with DIGEMID in 2007 meet GMP standards. In comparison, of the 89 pharmaceutical producers registered in 2006, DIGEMID inspected 36 but only 28 were certified with GMP standards. About one third of the producers did not meet GMP standards in 2006.

DIGEMID had 24 pharmaceutical producers certified with GMP standards in the first half of 2006. These included Vitalab, Portugal, Naturales y Genéricos, Americanos, Carrión Cirugía Peruana, San Joaquín Roxfarma, Infarmasa, Messer Gases del Perú, Induquímica, Textiles Los Rosales, B. Braun Medical Perú, Farmacéutica del Pacífico, Industrias Algotec, Vitaline, Yobel Supply, Trifarma, Lab. Cipa, Unilene, Comiesa Druc, Miralles & Burga, Indes del Perú, Hersil, Laboratorios Farmacéuticos and AC Farma.

Price Regulation in the Public Sector

The Peruvian Department of Medicines, Supplies & Drugs (DIGEMID) has created a watchdog to monitor the prices of essential medicines (Observatorio de Precios). MINSA believes that the population will have access to drug prices which might lead to the self-regulation of the sector.

About 36 essential medicines had been monitored by July 2006; the National List of Essential Medicines (Petitorio Nacional de Medicamentos) includes about 400 medicines in 2007. These medicines are used by MINSA, ESSALUD and FFAA. Domestically produced medicines represent 70.0% of the total.

DIGEMID has also reinforced its capabilities to ensure the quality of drugs in the public sector, most of them generics. Prior to their introduction in the market, all medicines have to go through quality controls of the first batch (control del primer lote) in laboratories approved by DIGEMID. The results are evaluated by DIGEMID prior to the market launch of these drugs.

HIV/AIDS Developments

The President, Alan García, approved the 2006-2011 Multisectorial Strategic Plan (PEM – Plan Estratégico Multisectorial) for the Prevention & Control of STDs & HIV/AIDS, under Decree No. 05-2007/SA. PEM's objectives are to optimise the use of resources and encourage all the society groups for the prevention and care of all Peruvians, especially those people living with HIV.

There were 47,116 reported cumulative cases of HIV/AIDS in Peru in 2006, of which 61.0% were in Lima and 7.5% in Callao. There were 19,353 cumulative AIDS cases, equal to 41.1% of the total. Men represented 78.6% of the cumulative AIDS cases. Sexual transmission was responsible for 97.0% of the cumulative AIDS cases, followed by mother-to-child transmission (2.0%) and blood transfusions (1.0%).

According to MINSA, 8,912 people infected with HIV/AIDS were receiving free antiretroviral treatment in October 2006. MINSA provides this treatment since 2004 and covered 5,892 patients in 56 hospitals and 14 centres in October 2006. ESSALUD and the National Police (PNP) were the other two main entities providing free treatment.

Under Resolution No. 124-2004/MINSA, about 90.0% of the patients who access MINSA's High-Level Antiretroviral Treatment (TARGA – Tratamiento Antiretroviral de Gran Actividad) are located in Lima and Callao. Any person who meets certain clinical and immunological criteria can access the TARGA treatment. Nevertheless, admissions are voluntary.

Under Decree No. 93-2006/EF, the Ministry of Economy & Finance published the new list of medicines for the treatment of cancer and HIV/AIDS; it included 83. These medicines are exempt from taxes (IGV – Impuesto General a las Ventas) and customs duties. Under Law No. 27,450, enforced in 2001, this list is updated annually, following MINSA's evaluation.

MINSA estimates that annual public expenditure on antiretrovirals and medicines to treat STDs amounts to around US$40.0 million in 2007. Under the Global Fund to Fight AIDS, Tuberculosis & Malaria, set-up in 2001, Peru received a total of US$95.8 million, which covered all the needs for antiretrovirals until 2006. Between 1999 and 2000, around US$40 million was spent, of which US$36.0 million was out-of-pocket.

KEY NATIONAL DATA PROJECTIONS

Key Data Projections, 2008-2013

	2008	2009	2010	2011	2012	2013
Population (millions) *	29.0	29.4	29.8	30.1	30.5	30.8
% Growth *	1.3	1.2	1.2	1.2	1.1	1.1
Number Aged 65+ (millions) *	1.6	1.7	1.7	1.8	1.9	1.9
% Aged 65+ *	5.5	5.7	5.8	5.9	6.0	6.0
GDP (US$ billions) *	129.2	127.6	135.0	143.8	151.4	159.0
Per Capita (US$) *	4,440	4,340	4,530	4,770	4,970	5,160
% Real Growth *	9.1	5.5	5.9	5.3	4.9	4.7
Total Health Expenditure (US$ billions)	5.5	5.9	6.2	6.7	7.1	7.4
Per capita (US$)	188	199	206	218	228	237
% of GDP	4.3	4.6	4.6	4.6	4.7	4.7
% Private	53.1	53.1	53.1	53.1	53.1	53.1
Hospital Beds (000s)	35.1	35.6	36.1	36.7	37.1	37.6
% Private	21.2	21.2	21.2	21.2	21.2	21.2
Rate/000	1.2	1.2	1.2	1.2	1.2	1.2
Physicians (000s)	43.8	44.5	45.2	45.8	46.4	47.0
% Private	n/a	n/a	n/a	n/a	n/a	n/a
Rate/000	1.5	1.5	1.5	1.5	1.5	1.5

*Source: Ministry of Health, *EIU, Espicom estimates.*

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Methodology and Sources

How does Espicom define the pharmaceutical market?

Figures for the national pharmaceutical markets are Espicom estimates, in current US dollars. Pharmaceuticals include retail prescription and over the counter medications and hospital only pharmaceutical products.

The markets have been estimated using a variety of data, including public and private pharmaceutical expenditure, domestic production and international trade.

Domestic production data is sourced from national estimates from governments and industry associations, where possible. It has then been adjusted to take account of re-exporting, stockpiling and differences in the definition of medical production. Where this data is not available from a local source, the information has been estimated by Espicom.

What is the basis for our market projections?

The growth rate given for the market in this report is a real annual average rate for the five year period in question. The rate does take inflation into account, but makes no attempt to predict exchange rate movements. It does not attempt to track year by year fluctuations in growth, but rather provides a projection of the likely size of the market in five years' time.

The rate is calculated by looking at a number of factors. These include economic performance, health expenditure levels, provision of medical staff and hospital beds, trends in medicament and raw material import levels, size and performance of domestic manufacturing sector, national healthcare development plans, and international aid projects.

Need more information?

We welcome feedback on all our reports. If you have any further questions or comments about the contents of this report, send them to the editor, at:

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SOURCES

World Pharmaceutical Markets Outlook is compiled using, where possible, primary data from local sources. This comprises national Ministries/Departments of Health, statistical bodies and professional associations. Market profiles draw on detailed statistical work by our Healthcare Markets Team. This is undertaken specifically for this report, and also in the course of research for other Espicom services, principally World Pharmaceutical Markets (WPM).

World Pharmaceutical Markets (WPM). Published by Espicom Business Intelligence, Lincoln House, City Fields Way, Tangmere, West Sussex PO20 2FS. http://www.espicom.com

Forecast data for GDP and demographics is sourced from the **Economist Intelligence Unit** (http://www.eiu.com), where indicated.

Reference may also be made to a number of secondary sources, and these are listed below.

OECD Health Data, http://www.sourceoecd.org

PC-TAS trade data, published by International Trade Centre, UNCTAD/WTO, United Nations.

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