

PHARMEXCIL

PERU

PERU PHARMACEUTICAL DATA

Contents

Demography.....	3
PERU	Error! Bookmark not defined.
STRENGTH AND WEEKNESS	5
OPPOURTUNITIES.....	5
Pharmaceutical market of Peru	6
Regulatory Regime	7
Regional Harmonisation	9
FTA Agreements:.....	9
Generic Drug Market & Forecast	10
Pharmaceutical trade:	10
MARKET STATISTICS	11

Demography

SL. No	Parameter	Description
1	Region	Latin America
2	Country	Peru
3	Capital	Lima
4	Population	30,741,062 (July 2016 est.)
5	Population growth rate (%)	0.96% (2016 est.)
6	GDP (purchasing power parity)	\$ 409.9 billion (2016 est.)
7	GDP - real growth rate (%)	3.75% (2016 est.)
8	GDP - per capita (PPP)	\$ 13,000 (2016 est.)
9	Exchange rates	One USD is equal to 3.27 of Peruvian Sol on 24 th May 2017
10	Population below poverty line	25.8 %(As per 2012. no updates available)
11	Age structure (%)	0-14 years: 26.62%
		15-24 years: 18.63%
		25-54 years: 39.91%
		55-64 years: 7.62%
		65 years and over: 7.21%
<i>Source: CIA World Fact Book updated to july 2016</i>		

INTRODUCTION

Longstanding trade agreements with the US and EU, along with efficient regulations for quality control will continue to make Peru an appealing destination for drugmakers. Peru is an attractive emerging pharmaceutical market.

Pharmaceutical companies are set to benefit from Peru's increasingly better-regulated biosimilars market. Newly implemented biological legislation will strengthen the country's pharmaceutical regulatory environment and encourage more companies to develop and launch biological drugs.

PHARMACEUTICAL MARKET: It was US\$1.576bn in 2016 with almost no growth. The market has remained static for the last two years. It is expected to touch \$ 1.7 bn in 2017.

Recent development: Peru is moving towards better regulatory standards adopting international accepted norms thus evincing interest of MNCs.

In June 2016, Peru's Ministry of Health (MINSA) activated quarantine-like procedures (cerco epidémico) to prevent a national epidemic upon identifying indigenous cases of the Zika virus. The quarantine has helped the health ministry officials to identify new indigenous cases of Zika.

In May 2016, Quicorp, one of Peru's largest healthcare and pharmaceutical companies, acquired the Arcangel pharmacy chain, which included 340 stores. The acquisition brings Quicorp's total number of stores under its various brands in Peru to over 1,000. However InkaFarma controls a larger share of the market in terms of sales at its 848 stores as of last September.

ECONOMIC View

Peru will remain among the region's brightest growth stories through 2017, as production growth in the mining sector and strengthening public investment lead accelerating economic activity. In recent quarters, growth has accelerated largely due to the beginning of production at Las Bambas,

a massive copper mineset to rank among the world's three largest when it hits full production capacity later this year. Growthreached 4.7% y-o-y in Q415 and 4.4% in Q116. With such elevated growth unlikely to be sustained throughthe end of the year, partially due to base effects, the forecasted real GDP growth of 3.6% in 2016, acceleratingto 4.2% in 2017 as public infrastructure investment rises.

STRENGTH AND WEEKNESS

- The government has made extended healthcare coverage and services a central policy goal, increasing spending on medicines.
- Rapid economic growth is translating into higher out-of-pocket spending on medicines and increased demand for advanced treatments.
- Low-costs and long-term potential of the local market Peru a potentially attractive production site for foreign manufacturers.
- Imports are set to grow as the country implements trade agreements with Europe amid a rise in demand especially for more high-tech medicines.
- Pharmaceutical price controls not enshrined legislation.
- **Government Bias towards non-equivalent generic products has deterred foreign companies from placing their own generic medicines on the market.**
- Test data exclusivity stipulated by the EU FTA may dampen growth in generic drugs.
- Large volumes of counterfeit medicines continue to plague the market.

OPPOURTUNITIES

- Market conditions for foreign players should improve as a result of various FTAs.
- Government support for the generic drugs industry and improvement of regulations should benefit 'bioequivalent' generic drugs manufacturers over the long term.
- Peru is fast becoming attractive location for clinical trials.
- Foreign retail chain's entry should improves supply chains and reduce the presence of unregistered and fake medicines.
- The Ministry of Health's recently introduced 'reverse auction' bidding system should improve transparency and efficient in tenders.

Pharmaceutical market of Peru

The recent implementation of international manufacturing practice legislation in Peru is a step towards making the country more attractive to international companies and increases the competitiveness of the manufactured medicines.

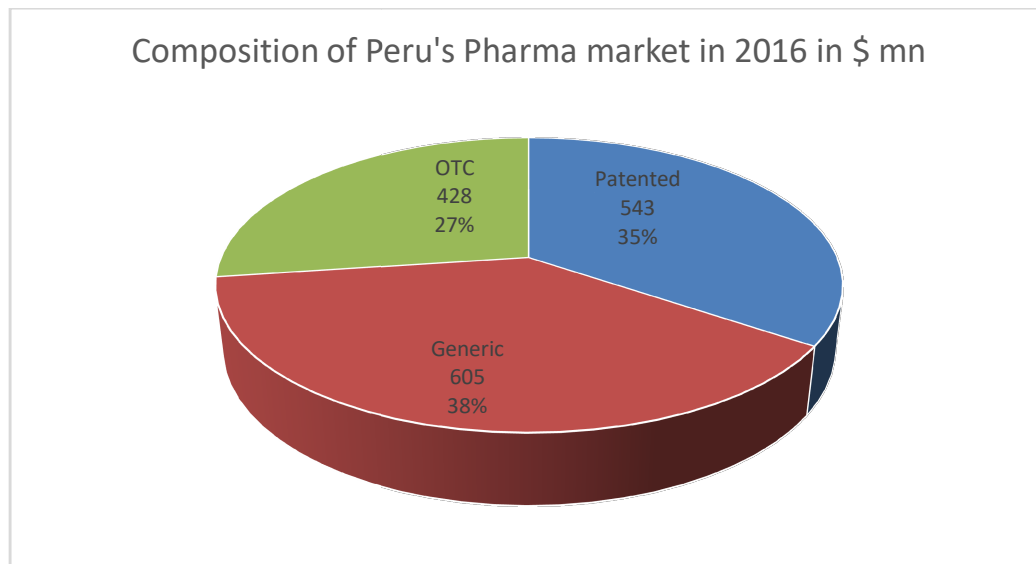
In 2016 Peru's pharmaceutical market was valued at PEN5.32bn (USD1.58bn). Per capita spending for pharmaceutical sales was USD50 and drug expenditure in Peru represented 0.8% of GDP.

Peru's epidemiological profile was dominated by non-communicable diseases in 2016. This is due to the region's decline in infectious diseases through improved sanitation and vaccination, which has positively affected Peru.

The local manufacturing sector is entirely reliant on foreign-sourced APIs, Patented drugs will continue to drive market expenditure, followed by generic drugs and OTC medicines. However, Generic Drug Sector is the largest of the three in the country, with 39% share.

The private sector will continue to offer drugmakers significant revenue earning opportunities. In value terms, the majority of public pharmaceutical spending comes from Peru's Social Security Institute, accounting for 51% of government medicine purchases. The private pharmaceutical sector retains out-of pocket expenditure at 85% of private health spending in Peru, according to the World Bank. Expenditure within the private sector is driven by hiking prices as the cost of pharmaceuticals purchased through private health is nearly four times that of public drug costs, with the price ratio of public and private medicine retail pricing being 1.5:5.6, according to the World Health Organisation. In volume terms, access to essential medicines remains similar in both sectors, at approximately 61% for generic drugs, while patented drugs remain significantly more available in the private sector. This increases the private sector's overall appeal for commercial opportunities, particularly for innovative drugmakers.

PharmaceutLeading local producers include **Cipa, Farmaindustria, Farpasa, Markos, Unimed** and **Infarmasan** (recently taken over by generic drugs giant **Teva**). The local trade association ADIFAN represents 19 local manufacturers. While multinationals dominate the market in terms of sales (more than 65%), very few operate manufacturing facilities in Peru.



Regulatory Regime

The market regulator is the Dirección General de Medicamentos, Insumos y Drogas (Directorate General of Pharmaceuticals, Inputs and Drugs, DIGEMID), which operates under the auspices of the Ministry of Health (locally referred to as MINSA). DIGEMID was formed by MINSA, the Ministry of Economy and Finance and the national competition and patents agency, INDECOPI, in 1990. MINSA also operates CEMIS, a specialised committee in charge of drug-safety evaluations, which – for the purposes of product registrations – differentiates between products that are imported, manufactured locally or produced under licence. Registrations must be renewed every five years. To import or manufacture a medical or pharmaceutical product, the manufacturer/importer must obtain a licence (Registro Sanitario, RS) from DIGEMID. Licences are only granted to Peruvian-based entities.

For imported products, a Certificate of Free Sale (CFS) in the country of origin and proof of inclusion in major international pharmacopoeias must also be included. Importers must sign a

declaration stating that the registration of the product in question would not infringe intellectual property laws in the country of origin. Once DIGEMID is satisfied with the application, the process is reportedly quick and simple. Regulatory delays relating to generic products are far shorter, allowing local marketers to gain a theoretical time advantage in introducing new products.

In July 2012, Peru's Association of National Pharmaceutical Industries (ADIFAN) called for mandatory quality checks on imported drugs in Peru, saying it is an issue of reciprocity as well as quality.

In December 2011, Peru's health ministry made amendments in two legislations of Law 29459, relating to the quality of drugs marketed in the country. The two regulations officially came into effect on January 23 2012.

Law no. 29,459 focuses on the quality control of medicines and medical devices that are produced locally, as well as those products that are imported into the country. The increasingly stringent assessment of products will require drugmakers to provide documentation that ensures product quality as well as certificates that prove GMPs.

Peru previously accepted good manufacturing practice (GMP) certificates from the manufacturer's country of origin, but MINSA successfully petitioned DIGEMID to demand Peruvian certification standards exclusively.

In November 2014, Peru announced a new bilateral trade agreement. Russia has agreed to provide its expertise, knowledge and modern technology to Peru to help the latter develop in fields of medicine, nuclear energy and nuclear science, according to President Vladimir Putin. Russia aims to double bilateral trade between the two countries in the coming few years. The volume of trade between the countries has risen 2.5 times in the past five years.

The pricing and reimbursement system in Peru reflects the market's basic regulatory infrastructure and historic under-funding and fragmentation of state insurance programmes. Since the 1990s, companies have been free to set prices as they wish in the private pharmacy sector. The government cannot regulate prices directly; instead, it can only highlight issues and let Defence of Competition and Protection of Intellectual Property (INDECOPI) investigate.

Active pharmaceutical ingredients (APIs) imported by foreign companies are currently subject to a 12% import tariff. This has led to some unintended consequences.

Regional Harmonisation

Peru is a member of the Andean Health Organisation - Convenio Hipólito Unanue (ORAS/CONHU) – along with Bolivia, Chile, Colombia, Ecuador and Venezuela. On April 1 2011, the countries met up in the PERUII Meeting of Andean Ministers of Health (Reunión de Ministros de Salud del Área Andina, REMMSAA). In this meeting, they agreed the following main measures:

To approve the regional acquisition of pharmaceuticals via the Pan-American Health Organisation (PAHO). Peru is keen to purchase oncological treatments via this organisation, as the public sector is the main purchaser of these high-cost drugs.

To approve and implement an Andean Pharmacovigilance Programme, with the help of PAHO and ORAS/CONHU.

To share experiences with the technical group which aims to guarantee universal access to medicaments, promoted by the Union of South American Nations (UNASUR). UNASUR is an intergovernmental union which integrates the Southern Common Market (MERCOSUR) and the Andean Community of Nations (CAN).

To create an Andean Observatory of Medicaments.

To create an Andean Network for Epidemiological Surveillance.

FTA Agreements:

Peru has FTA with USA which calls for elimination of duties on Imports from USA. Exclusivity of data protection for five years. Peru like any other country retained rights under WTO TRIPPS, compulsory licensing and Parallel imports to safeguard its national health.

Peru maintains strong trade relations with eleven country's including Japan, Mexico, Chile, China and the US. Peru also maintains trade relations with the European Union, the European Free Trade Association (EFTA), the MERCOSUR community and the Andean community.

The country's focus on productive global trade agreements allows Peru to remain one of the top markets for pharmaceuticals and healthcare in the Latin American region.

Generic Drug Market & Forecast

The drug market in Peru is patented, generic and over-the-counter (OTC). The emerging markets including Peru, the definitions between generic and 'branded' drugs can sometimes be blurred, while the presence of *similares* (Not Bioequivalent and other wise similar to Generics) is also an unclear (and soon to be phased out) segment.

True generics have yet to gain much prominence, as bioequivalence standards are not enforced. There are two types of generics; generics under International Common Denomination (ICD) and branded generics.

One of the key drivers of the generic drugs market will be the government's decision to make improving access to healthcare a priority, complete with pushing the use of generic medicines.

Pharmacies and drugstores are legally authorised to undertake generic substitution. Regulations also make it obligatory to prescribe by the ICD. There are proposals to gradually establish bioequivalence and bioavailability studies to selected pharmaceutical drugs.

Doctors are asked to suggest generic alternatives while prescribing. Monetary penalties are levied on doctors for not suggesting generic alternatives while prescribing patented brands.

The Generic market constituting 38% of the total market, is slated to grow from value of US\$605mn in 2016 (with a negative growth of over 0.15%) to reach US\$882 million in 2021 with a CAGR of 6.2%.

Pharmaceutical trade:

Generally speaking, local drugmakers have become more competitive in generic drug production, not only to meet local consumption demand but also to increase Peru's pharmaceutical product exports. In absolute terms, exports are likely to remain relatively small,

and limited to modest and lightly regulated Latin American markets, although foreign investment in local manufacturing will boost its potential.

Imports of Peru is likely to grow from \$ 753 million in 2016 to \$ 1.180 million in 2021.

The country's top import partners in 2016 were the US(USD121mn), Germany, (USD73mn), Colombia (USD56mn), Argentina (USD 44mn) and France (USD 42 mn).

MARKET STATISTICS

India's Exports Of Pharmaceuticals to PERU in \$ mn					
Category	2013-14	2014-15	2015-16	GR%	contbn%
Bulk drugs	9.76	11.05	14.74	33.39	23.47
Formulations	33.58	36.91	46.59	26.24	74.20
Ayush	0.01	0.01	0.08	939.32	0.13
Herbal products	0.03	0.13	0.04	-70.75	0.06
Surgicals	1.14	1.37	1.34	0.00	2.14
Total	44.53	49.47	62.80	26.95	100.00

Source: DGCIS

During April-Jan 2016-17 India has exported \$ 40 million with a negative growth of 25%.

Imports of Formulations of Peru in \$ mn						
Rank	Country	2012	2013	2014	% Gr	% contbn
1	USA	83	97	100	3.33	13.81
2	Germany	49	63	67	5.38	9.02
3	Colombia	46	53	52	-0.52	7.51
4	Belgium	27	45	46	2.83	6.42
5	India	33	39	44	11.43	5.58
6	Argentina	39	42	39	-7.61	6.06
7	France	38	36	39	8.11	5.13
8	Mexico	33	36	35	-0.23	5.07
9	Brazil	29	28	28	-2.32	4.05
10	Chile	23	28	27	-3.87	3.98
	Total Imports	575	682	700	2.62	97.45

Source: UN Comtrade

Note: There are no issues brought to Pharmexcil by any of our members even during the recent visit.