COLOMBIA MARKET REPORT

PHARMEXCIL Hyderabad

Contents

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Latin America
2	Country	Colombia
3	Capital	Bogota
4	Population	46,736,728 (July 2015 est.)
5	Population growth rate (%)	1.04% (2015 est.)
6	GDP (purchasing power parity)	$ 665 billion (2015 est.)
7	GDP - real growth rate (%)	2.5% (2015 est.)
8	GDP - per capita (PPP)	$ 14,000 (2015 est.)
9	Exchange rates	3067.70 peso of Colombia is equal to a USD as on 28th march 2016
10	Population below poverty line	32.7%
11	Age structure (%)	0-14 years: 24.94%
		15-24 years: 17.81%
		25-54 years: 41.71%
		55-64 years: 8.62%
		65 years and over: 6.93%

Source: CIA World Fact Book updated to july 2015

COLOMBIA:

Introduction

This is the fifth largest Market in LAC region. Market size in 2016 was $ 3.14 billion and has grown by 1% after a negative growth of 24% in 2015.The fact that the market has grown by over 5% in local currency reflects the country's fluctuating currency in 2015 & 2016. However by 2020 it is likely to touch $ 4.1 billion with a Cagr of 7%. Current percapita(Pharmaceutical expenditure) of the Country is $ 64.5.

- Colombia's increased state investment in healthcare services in the past few years has driven strong annual growth in pharmaceutical consumption.
- Increase in the presence of non-profit organizations addressing Colombia's healthcare needs also help expand the market.

Healthcare reforms such as Decree 1782, may force a 30%-60% reduction in pharmaceutical medicine prices. The sharp drop in prices will impair pharmaceutical sales as price controls become more stringent in an attempt to provide less expensive drugs. However such measures are expected to expand the market by volumes. Price control is considered a major challenge while operating in Colombia.

Epidemiology:

Colombia, like many neighbouring developing countries, is seeing a decreased rate of communicablediseases (with the current exception of the emergence of Zika virus), replaced by an increase in non-communicablediseases. This is due to lifestyle changes which include the increased consumption of foodswith higher caloric intake and smoking. These changes are caused by increased household finances fromdeveloping economies. In particular, Colombia's most notorious chronic diseases include neuropsychiatricconditions, depression, cardiovascular disease, also called CVD, cancer, Alzheimer's disease, respiratoryconditions and diabetes. In 2014, the burden of disease from neuropsychiatric conditions significantlyoutweighed the burden of all other chronic diseases. Diabetes will also continue to be a popular topic withinthe market due to its growing global concern.

India has a strong line up of all those therapy areas with most affordable prices meeting best regulatory standards.

Generic Drugs:

Colombia's generic drug market as a percentage of the total market incorporates all non-patented registered medicines. An obstacle to growth of generic drugs is that local players continue to resist stronger bioequivalence standards of the type that have been introduced in Brazil and Mexico. Generic market in 2016 was worth $ 1.4 with a negative growthof 5.8%, after negatively growing by 16% in 2015 and accounts for 44% of the total market. This sector is forecasted to grow in 2017 by12% and reach $ 1.56bn.

Prescribing by INN was also promoted,which helped to increase the share of generic medicines in the pharmacy sector.

Although generic drugs must meet very strict standards, bioequivalence is requested for only a selected number of generic products, most of which are indicated for the treatment of chronic diseases.

Sales of generic drugs in the pharmacy sector have been attractive, but sales of generic medicines in the hospital sector have registered higher growth in recent years. Local pharmaceutical companies, most of which produce generic drugs, have about 45.0% of the pharmacy sector by sales, and 70.0% by volume. Additionally, local pharmaceutical companies, which produce generic medicines, control about 80.0% of the hospital sector by volume.

The market share of generic drugs has increased considerably in recent years, but fierce competition between manufacturers has kept prices down. The largest local companies specialising in generic drug production include GENFAR (now part of Sanofi, GENFAR exclusively produces generic drugs), La Santé, Procaps, Scandinavia Pharma, Tecnoquímicas and Tecnofarma. Tecnoquímicas' generic portfolio, for example, is represented by the MK and McK brands. The company claims to be the market leader, with half of its pharmaceutical sales represented by generic products. In addition to Sanofi, other leading foreign companies with generic market interests include Bayer, GSK and Novartis via Sandoz.

Most consumers are unaware of any distinction between non-bioequivalent copies of patented products and legal, off-patent generic drugs. Indeed, with no modern legislation pertaining to bioequivalence, distinctions between copies and genuine generic products are likely to remain blurred. Nevertheless, legislation does provide for the substitution of patented drugs with generic drugs in the public sector, as the inclusion of brand names (as opposed to INN) on prescription scripts is optional. Additionally, many public sector pharmacies do not stock patented drugs at all, which will continue to boost the use of generic medicines.

Opportunities:

- Most of the local production is dependent on imported active pharmaceutical ingredients (APIs).
- The implementation of tighter regulations on bioequivalence should drive rapid growth in the bioequivalent generic drug market. (Like other LAC countries, Colombia has similares, which are copies only chemically equivalent and not necessarily bioequivalent). Increased bioequiovalent laws would make the local production expensive and opens ample opportunities for India's Generics which are bioequivalent and still competitively priced.
- Opportunities exist for manufacturers of anti-retrovirals, given the prevalence of HIV/ AIDS in the country. India is the strongest generic producer of this range.
- India's exporters could obtain better access of LAC market by operating from Colombia inclusive of manufacture as Colombia has one of the most qualified workforces in the Andean Community and Latin America, with an adult literacy rate of almost 93% and a female literacy rate just 0.2% less than that of males. World Competitiveness Yearbook (WCY) indicators show that hourly wages in the industrial sector and yearly wages in the service sector in Colombia are extremely competitive compared to those in other developing and industrialised countries. The same survey placed Colombia 24th in terms of the availability of information technology skills, ahead of countries such as Brazil and Mexico.
- Foreign Investment Incentives: The Colombian government provides incentives for importers of capital goods using a number of drawback and duty deferral programmes. Examples of these programmes are the free trade zones (FTZs) and 'special import-export systems' located throughout the country. Colombia has 11 FTZs, which are exempt from import tariffs and VAT on imports, and have access to special credit lines offered by Colombia's foreign trade bank, Bancoldex. Barranquilla, Cartagena, Santa Marta and Pacífico are on the coast and within easy access of the main ports. The others are strategically located to serve different production centres. There are also five economic export zones where special tariffs apply.
- Skilled Labour Force: Colombia has one of the most qualified workforces in the Andean Communityand Latin America, with an adult literacy rate of almost 93% and a female literacy rate just 0.2% less thanthat of males. World Competitiveness Yearbook (WCY) indicators show that hourly wages in theindustrial sector and yearly wages in the service sector in Colombia are extremely competitive comparedto those in other developing and

industrialised countries. The same survey placed Colombia 24th in termsof the availability of information technology skills, ahead of Brazil and Mexico.

Regulatory

The main regulatory authority is the National Institute of Medication and Food Surveillance (INVIMA), which operates under the auspices of the Ministry of Social Protection (MSPS). All drugs must be registered with INVIMA, which recognises six types of registration: manufacturing/sales, importing/sales, importing/ packaging/sales, importing/part of manufacturing/sales, part of manufacturing/sales and manufacturing/ export. The basis for market regulation is Decree 2092 of 1986 and Decree 677 of 1995, although there have been a number of amendments to both since they were published.

Colombia's new Decree 1782, or the biological medicines decreewill enforce revised regulatory standards for the approval of biotech medicines in the country. The decree provides three routes for drug approval, each of which must offer prerequisiteimmunogenicity testing before undergoing clinical studies and a series of nine tests. The decree will beginoperating when the Ministry of Health has issued further regulations (such as on immunogenicity testing),for which the Ministry is allowed up to one year

The decrees allow for drug registration through either a complete, a comparability, or an abbreviated route.The complete route, for new drugs, will necessitate pre-clinical and clinical testing as well as extensivetesting in both ill and healthy animals and humans. The comparability route will be used for drugs that areknown but not sufficiently understood, and will undergo any necessary clinical studies. The abbreviatedroute, for well-known drugs in which the active pharmaceutical ingredient (API)'s behaviour is understood,will require no clinical studies.

Pharmaceutical approval in Colombia can take anywhere from 80-200 days, while marketing authorisation lasts five years for new drugs and 10 years for all others. Colombia's drug approval timeframes remain one of the fastest in Latin America, offering further appeal for foreign innovative drugmakers.

Recent Price Developments:

- Under Resolution No. 01/2012, published in September 2012, the National Price Commission of Pharmaceuticals and Medical Devices (Comisión Nacional de Precios de Medicamentos y DispositivosMédicos, CNPMDM) reviewed the prices of 189 products in August 2013.

- In December 2013, President Juan Manuel Santos announced another list of 334 drugs under price control.
- In January 2014, the Colombian Medical Federation released a new list of the 39 most expensive medicines that will be targeted under government price controls in 2014.
- In mid-February 2014, the Minister of Health and Social Protection announced that as of February 13 2014, price cuts have been enforced on 523 active pharmaceutical ingredients (APIs) and that 95% of the drugmakers complied with the regulations.
- At the end of February 2014, the government published the final list of medicines subject to price controls and announced that it planned to save over CLP90bn (USD160mn) from the scheme.
- In March 2014, Colombia's Superintendency of Industry and Commerce (SIC) charged Abbott Colombia a CLP3,080mn (USD5.48mn) fine for selling Kaletra (lopinavir + ritonavir), an AIDS treatment, at a price between 53% and 66% above the price set by the government.
- In April 2014, multinationals with significant presence in Colombia's generic drug market, such as Sanofi (which accounts for 30% of total generic sales in the country) noted that although the government tries to promote the use of generic drugs, its bioequivalence regulation is not up to the standards of developed states. Multinationals were worried that price caps and the prevalence of poor quality, low-value generic drugs will undermine branded generic drug sales.

  (India's generics are more affordable in comparison, it affects them too, though to a lesser extent)

Statistics

Exports of India

India's Exports Of Pharmaceuticals to COLOMBIA in $ mn					
Category	**2013-14**	**2014-15**	**2015-16**	**GR%**	**contbn%**
Bulk drugs	31.68	26.96	29.32	8.75	40.20
Formulations	43.86	37.91	41.07	8.34	56.31
Ayush	0.02	0.00	0.01		0.02
Herbal products	0.48	0.94	0.72	-23.39	0.99
Surgicals	2.03	1.64	1.81	0.00	2.48
Total	78.08	67.46	72.94	8.13	100.00

During April-Jan2016-17 India has exported $ 58 million with a negative growth of 10 %.

Imports of Colombia

Imports of Formulations of Colombia in $ mn						
Rank	**Countries**	**2013**	**2014**	**2015**	Gr%	Contbn%
1	USA	481	416	460	10.70	19.78
2	Germany	317	398	393	-1.32	16.89
3	Switzerland	235	208	197	-5.35	8.45
4	France	140	177	160	-9.81	6.85
5	Mexico	101	108	112	3.24	4.79
6	Italy	136	123	100	-18.78	4.29
7	Spain	70	87	95	8.28	4.07
8	Brazil	91	95	85	-10.33	3.67
9	United Kingdom	67	83	80	-3.77	3.45
10	Ireland	67	70	75	7.51	3.23
11	Canada	54	68	66	-3.93	2.82
12	India	78	65	63	-2.94	2.71
	World	2314	2378	2327	-2.14	100.00

Pharmexcil's Effort:

During IPHEX for,2013, 2014, & 2015 India has invited and hosted 19, 25 &12 delegates respectively. During Global Pharma business meet held in Hyderabad between 22nd to 24th September 2015 one company delegate has participated in b2b meet.

Details are separately attached in an excel sheet.

ISSUES: Generally, Colombia is considered a smooth regulatory agency and a country with congenial atmosphere.