

A
BRIEF REPORT
ON
PHARMACEUTICAL INDUSTRY IN INDIA

May, 2014



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1. OVERVIEW OF PHARMACEUTICAL INDUSTRY

1.1. An Introduction

The Indian pharmaceutical industry currently tops the chart amongst India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian pharmaceutical industry is estimated to be worth \$ 4.5 billion, growing at about 8 to 9 percent annually. It ranks very high amongst all the third world countries, in terms of technology, quality and the vast range of medicines that are manufactured. It ranges from simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made in the Indian pharmaceutical industry.

The Indian pharmaceutical sector is highly fragmented with more than 20,000 registered units. It has expanded drastically in the last two decades. The Pharmaceutical and Chemical industry in India is an extremely fragmented market with severe price competition and government price control. The Pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals, and injectibles. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units).

The Government has also played a vital role in the development of the India Software Industry. In 1986, the Indian government announced a new software policy which was designed to serve as a catalyst for the software industry. This was followed in 1988 with the World Market Policy and the establishment of the Software Technology Parks of India (STP) scheme. In addition, to attract foreign direct investment, the Indian Government permitted foreign equity of up to 100 percent and duty free import on all inputs and products.

1.2 Current Scenario

Indian pharmaceutical industry is expected to grow at 19% in 2013. India is now among the top five pharmaceutical emerging markets. There will be new drug launches, new drug filings, and Phase II clinic trials throughout the year. On back of increasing sales of generic medicines, continued growth in chronic therapies and a greater penetration in rural markets, the domestic pharmaceutical market is expected to register a strong double-digit growth of 13-14 per cent in 2013.

Moreover, the increasing population of the higher-income group in the country will open a potential US\$ 8 billion market for multinational companies selling costly drugs by 2015. Besides, the domestic pharma market is estimated to touch US\$ 20 billion by 2015, making India a lucrative destination for clinical trials for global giants.

Further estimates the healthcare market in India to reach US\$ 31.59 billion by 2020.

12.1. *Diagnostics Outsourcing/ Clinical Trials*

According to the estimates, the Indian diagnostics and labs test services, in view of its growth potential, is expected to reach Rs159.89 billion by 2013. The Indian market for both therapeutic and diagnostic antibodies is expected to grow exponentially in the coming years. Findings from the report suggest that more than 60% of the total antibodies market is currently dominated by diagnostic antibodies.

Some of the major Indian pharmaceutical firms, including Sun Pharma, Cadila Healthcare and Piramal Life Sciences, had applied for conducting clinical trials on at least 12 new drugs in 2010, indicating a growing interest in new drug discovery research.

12.2. Generics

Generics will continue to dominate the market while patent-protected products are likely to constitute 10 per cent of the pie till 2015, according to McKinsey report 'India Pharma 2015 - Unlocking the potential of Indian Pharmaceuticals market'.

Dr Reddy's Laboratories Ltd has launched Finasteride tablets, a bio-equivalent generic version of Propecia (Finasteride) tablets, in the US market. The tablets are used for treating male pattern hair loss.

1.2 Growth of Import-Export

Imports- As per the Directorate General of Commercial Intelligence and Statistics (D.G.C.I.S.) Kolkata, the value of imports of “Medicinal and Pharmaceuticals Products” for the latest period 2007-08 to 2010-11 is as under:

Year	(Rs in billions)	
	Value of import of “Medicinal and pharmaceuticals products”	Growth%
2007-08	67.34	14.79
2008-09	86.49	28.43
2009-10	99.59	15.15
2010-11*	109.37	9.82

Source: www.pharmaceuticals.gov.in

In the year 2010-11 the imports shown declined in growth compared to previous year. The country is almost self-sufficient in production of most of formulations/ pharmaceuticals products. As such imports are being resorted to on quality & economic considerations and not necessarily due to non-availability from domestic sources. Manufacturers of Drugs & Pharmaceuticals are free to produce any drugs approved by the Drug control authorities.

Exports - As Per DGCIS, Kolkata Exports of “Drugs and Pharmaceuticals and Fine Chemicals” for the period 2007-08 to 2010-11 are below:-

Year	(Rs in billions)	
	Value of import of “Medicinal and pharmaceuticals products”	Growth%
2007-08	293.54	14.37
2008-09	398.21	35.66
2009-10	424.56	6.62
2010-11*	475.51	12.00

Source: www.pharmaceuticals.gov.in

1.3 Advantage India

The Indian Pharmaceutical Industry, particularly, has been the front runner in a wide range of specialties involving complex drugs' manufacture, development, and technology. With the advantage of being a highly organized sector, the pharmaceutical companies in India are growing at the rate of \$ 4.5 billion, registering further growth of 8 - 9 % annually.

More than 20,000 registered units are fragmented across the country and reports say that 250 leading Indian pharmaceutical companies control 70% of the market share with stark price competition and government price regulations.

Competent workforce: India has a pool of personnel with high managerial and technical competence as also skilled workforce. It has an educated work force and English is commonly used. Professional services are easily available.

Cost-effective chemical synthesis: Its track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.

Legal & Financial Framework: India has a solid legal framework and strong financial markets. There is already an established international industry and business community.

Information & Technology: It has a good network of world-class educational institutions and established strengths in Information Technology.

Globalization: The country is committed to a free market economy and globalization. Above all, it has a 70 million middle class market, which is continuously growing.

Consolidation: For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. The process of consolidation, which has become a generalized phenomenon in the world pharmaceutical industry, has started taking place in India.

2 MAJOR PHARMACEUTICAL COMPANIES IN INDIA

Some of the leading Indian players by sales (INR Billion)

Company name	Sales in INR billion
Cipla	69.77
Ranbaxy Lab	76.86
Dr Reddy's Labs	66.86
Sun Pharma	40.15
LupinLtd	53.64
AurobindoPharma	42.84
Jubilant Life	26.41
Cadila Health	31.52
Ipca Labs	23.52
Wockhardt	26.50

2.1 Ranbaxy

Ranbaxy is among the predominant pharmaceutical companies in India and was founded in 1961. Ranbaxy is a research based pharma giant and became a public limited company in 1973.

Ranbaxy was recently ranked among the top 10 international pharmaceutical companies in the world have presence across 49 countries.

Ranbaxy is also reputed for its 11 state-of-the-art manufacturing facilities in countries like China, India, Brazil, South Africa, and Nigeria. The company has also won several awards and recognitions for its pioneering initiatives in the developing markets of the world. Ranbaxy is also a member of the Indian Pharmaceutical Alliance and Organization of Pharmaceutical Producers of India. In the present scenario Ranbaxy commands more than 5% share of the Indian pharmaceutical market. Ranbaxy's product portfolio is diverse and includes drugs that cater to nutrition, infectious diseases, gastro-enteritis, pain management, cardiovascular ailments, dermatology, and central nervous system related ailments.

Ranbaxy's operations in India are designed under as many as 9 SBUs which take care of the various categories of medicines and drugs that are manufactured by Ranbaxy. The company is especially well-known for having the highest research and development (R&D) budget among pharma companies in the world which is as high as US\$ 100 million.

Ranbaxy India operations are handled by 2,500 employees and the company's market share in India is worth around US\$6 billion.

2.2 Dr. Reddy's Laboratories

Dr. Reddy's Laboratories is one of the popular pharmaceutical companies with base in more than 100 countries. The medicines of Dr. Reddy's Laboratories Limited are easily available all across the globe.

Dr. Reddy's Pharmaceutical Company is very much customer friendly. It takes care of the fact that maximum people get benefited by the products of this pharmaceutical company. It commercialized various treatments so as to provide high tech treatment to the masses. It tries to meet the medical needs of the people.

Though Dr. Reddy's Laboratories is located in various parts of the world, it has its headquarters in India. The subsidiaries of this company are found at various countries like US, Germany, UK, Russia, and Brazil. 16 countries have the representative offices of Dr. Reddy's Laboratories Limited. 21 countries have third party distribution.

2.3 Cipla

Cipla was founded by Khwaja Abdul Hamied in 1935 and was known as The Chemical, Industrial and Pharmaceutical Laboratories, though it is better known by the acronym Cipla today. Cipla was registered in August, 1935 as a public limited enterprise and it began with an authorized capital of Rs. 6 lakh.

Though set up in 1935, it was only in 1937 that Cipla began manufacturing and marketing its pharmaceutical products. Today, the company has its facilities spread across several locations across India such as Mumbai, Goa, Patalganga, Kurkumbh, Bangalore, and Vikhroli.

Apart from its strong presence in the Indian market, Cipla also has an extensive export market and regularly exports to more than 150 countries in regions such as North America, South American, Asia, Europe, Middle East, Australia, and Africa. For the year ended 31st March, 2007 Cipla's exports were worth approximately Rs. 17,500 million. Cipla is also considerably well-known for its technological innovation and processes for which the company received know-how royalties to the tune of Rs. 750 million during 2006-07.

2.4 Sun Pharmaceuticals

Sun Pharmaceuticals was set up in 1983 and the company started off with only 5 products to cure psychiatric illness. Sun Pharma is known worldwide as the manufacture of specialty Active Pharmaceuticals Ingredients and formulations.

However, the company is also concerned with chronic treatments such as cardiology, psychiatry, neurology, gastroenterology, diabetology, and respiratory ailments. Active Pharmaceuticals Ingredients (API) includes peptides, steroids, hormones, and anti-cancer drugs and their quality is internationally approved. The international offices of Sun Pharmaceuticals Industries Ltd. are located in British Virgin Islands, Russia, and Bangladesh. In India, the offices are in Vapi, Silvassa, Panoli, Ahmednagar, and Chennai.

There are 3 major group companies of Sun Pharmaceuticals Industries are:

- Caraco Pharmaceuticals Laboratories (based in Detroit, Michigan)
- Sun Pharmaceuticals Industries Inc. (Michigan)
- Sun Pharmaceuticals (Bangladesh)

2.5 Aurobindo Pharma

Aurobindo Pharma, an India-based private pharmaceutical company having presence around the world. AurobindoPharma was set up in the year 1986 and started its operations in 1988-89 in Pondicherry, India. Now, the company is headquartered at Hyderabad, India.

Aurobindo Pharma is one of the most respected generic pharmaceuticals and active pharmaceutical ingredients (API) manufacturing company of the world. AurobindoPharma operates in over 100 countries across the world. Further, the pharmaceutical major markets are over 180 APIs and 250 formulations throughout these destinations. This Indian pharmaceutical major has filed over 110 DMFs and 90 ANDAs for the USA market. So far, Aurobindo has received 45 ANDA approvals (both final and tentative) from USA alone.

AurobindoPharma products cover segments like –

- Antibiotics,
- Anti-Retro Virals
- CVS
- CNS
- Gastroenterological
- Anti-Allergic

3 GOVERNMENT INITIATIVES AND INVESTMENT

3.1 Government Initiative

The Union Finance Minister highlighted few points in union budget 2012-13:

- It is proposed to extend concessional basic customs duty of 5 per cent with full exemption from excise duty/CVD to six specified life-saving drugs/ vaccines. These are used for the treatment or prevention of ailments such as HIV-AIDS, renal cancer, etc.
- Probiotics are a cost-effective means of combating bacterial infections. It is proposed to reduce the basic customs duty on this item from 10 per cent to 5 per cent
- Basic customs duty and excise duty reduced on soya products to address protein deficiency among women and children. Basic customs duty and excise duty reduced on Iodine

Marking a new trend of investments from foreign players in the Indian pharma sector, the need for overseas investors to get a no-objection from their JV partner before venturing out on their own or roping in another local firm has been removed by the Pharmaceuticals Export Promotion Council (Pharmexcil). It is expected that this measure will promote the competitiveness of India as an investment destination and be instrumental in attracting higher levels of FDI and technology inflows into the country.

The Department of Pharmaceuticals has prepared a 'Pharma Vision 2020' document for making India one of the leading destinations for end-to-end drug discovery and innovation and for that purpose, the department provides requisite support by way of world class infrastructure, internationally competitive scientific manpower for pharma research and development (R&D), venture fund for research in the public and private domain and such other measures.

3.2 Investment

- Israel-based Teva Pharmaceuticals in collaboration with Procter & Gamble (P&G) plans to set up world's largest over-the-counter (OTC) medicine facility at Sanand, Gujarat
- GlaxoSmithKline (GSK) and the Hyderabad-based Biological E Ltd have teamed up for early stage research and development (R&D) of a six-in-one combination pediatric vaccine against polio and other infectious diseases
- Claris Life sciences Ltd has entered into joint venture (JV) agreement with two Japan-based drug makers Otsuka Pharmaceutical and Mitsui & Co Ltd for its injectable business in India and other emerging markets
- Nipro Corporation has set up India's first dialyser manufacturing facility at Shirwal near Pune, with an investment of Rs 700 crore (US\$ 130.60 million)
- AurobindoPharma Ltd has received approval from the US Food and Drug Administration (USFDA) to manufacture and market various medicines namely Oxacillin injections and Rizatriptan Benzoate tablets in the US, besides Nafcillin and Ondansetron injection
- Eli Lilly and Strides Arcolab have inked a pact to increase delivery of cancer medicines in emerging markets. Agila Specialties, the specialties division of Strides Arcolab, will make cancer medicines and Eli Lilly will market them in emerging geographies

4 CHALLENGES& FUTURE GROWTH

4.1 Challenges

Over the past decade, pharmaceutical companies have entered a difficult period where shareholders, the market, and regulators have created significant pressures for change within the industry. The core issues for most of drug companies are declining productivity of in-house R & D, patent expiration of number of block buster drugs, increasing legal and regulatory concern, and pricing issue. As a result larger pharmaceutical companies are shifting to new business model with greater outsourcing of discovery services, clinical research and manufacturing.

Current global financial conditions and the threat of a broad recession accelerated the timetable for implementing transformational changes in global organizations, as the industry confronts lower corporate stock prices and an increasingly cost-averse customer. Leaders of the largest global pharmaceutical companies recognize the need for transformational change in their organizations, but will need to move swiftly to ensure sustained growth.

Transformations in the business model of larger pharmaceutical industry spell more opportunities for Indian pharmaceutical companies. Pharmaceutical production costs are almost 50 percent lower in India than in western nations, while overall R&D costs are about one-eighth and clinical trial expenses around one-tenth of western levels.

The Indian stock market may be dreading a possible recession but Indian pharma companies seem unfazed by slowdown fears. Riding on better sales in the domestic and export markets, Indian pharmaceutical industry is expected to continue with its good performance. Today Indian pharmaceutical Industry can look forward to the years to come, with great expectations. There are opportunities in expanding the range of generic products as more molecule come off patent, outsourcing, and above all, in focusing into drug discovery as more profits come from traditional plays. At the same time, the Indian pharma industry would have to contend with several challenges, particularly the following

- Effects of new product patent
- Drug price control
- Regulatory reforms
- Infrastructure development
- Quality management and
- Conformance to global standards.

4.2 Future Growth

India will see the largest number of merger and acquisitions (M&A) in the pharmaceutical and healthcare sector, according to consulting firm Grant Thornton. A survey conducted across 100 companies has revealed that one-fourth of the respondents were optimistic about acquisitions in the pharmaceutical sector.

The Indian pharmaceutical market is expected to grow at a CAGR of 15.3 per cent during 2011-12 to 2013-14, according to a Barclays Capital Equity Research report on India Healthcare & Pharmaceuticals. The growth of Indian pharma companies will also be driven by the fastest growing molecules in the diabetes, skincare, and eye care segment.

In addition, the pharmaceutical companies such as Cipla, Ranbaxy, Dr Reddy's Labs and Lupin might soon be part of the government's ambitious 'Jan Aushadhi' project. In an attempt to commercialize the project, the Government is likely to rope in the private sector to bulk-procure generic drugs from them. There are 117 Jan Aushadhi stores across the country and the plan is to expand to at least 600 in the next two years and 3,000 by 2016.