

**A BRIEF REPORT PHARMACEUTICAL INDUSTRY IN INDIA**

**March, 2012**

# 1. OVERVIEW OF PHARMACUETICAL 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

India's pharmaceutical market grew at 15.7 per cent during December 2011. Globally, India ranks third in terms of manufacturing pharma products by volume. The Indian pharmaceutical industry is expected to grow at a rate of 9.9 % till 2010 and after that 9.5 % till 2015. The Indian pharmaceutical market is expected to touch US\$ 74 billion sales by 2020 from US\$ 11 billion. The market has the further potential to reach US\$ 70 billion by 2020 in an aggressive growth scenario.

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 FY2013. 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, Cadilla 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.

### 1.2.2 *Generics*

India tops the world in exporting generic medicines worth US\$ 11 billion and currently, the Indian pharmaceutical industry is one of the world's largest and most developed.

Moreover, the Indian generic drug market to grow at a CAGR of around 17 per cent between 2010-11 and 2012-13. Union Minister of Commerce and Industry and Minister for Trade and Industry, Singapore, have signed a 'Special Scheme for Registration of Generic Medicinal Products from India' in May 2010, which seeks to fast-track the registration process for Indian generic medicines in Singapore.

## 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 organised 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 53 year old democracy and hence 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.

*Globalisation:* 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 (US\$ million)

Company name	Sales in US\$ million	Year End
Cipla	6,368.06	March 2011
Ranbaxy Lab	5,687.33	December 2010
Dr Reddy's Labs	5,285.80	March 2011
Sun Pharma	1,985.78	March 2011
LupinLtd	4,527.12	March 2011
Aurobindo Pharma	4,229.99	March 2011
Piramal Health	1,619.74	March 2011
Cadila Health	2,213.70	March 2011
Matrix Labs	1,894.30	March 2010
Wockhardt	651.72	December 2011

### 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 Laboratorie 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) include 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. Aurobindo Pharma 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. Aurobindo Pharma operates in over 100 countries across the world. Further, the pharmaceutical major markets 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.

Aurobindo Pharma products cover segments like –

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

## 3 GOVERNMENT INITIATIVES AND INVESTMENT

### 3.1 Government Initiative

100 per cent foreign direct investment (FDI) is allowed under the automatic route in the drugs and pharmaceuticals sector including those involving use of recombinant technology. (DIPP)

The Government plans to set up a US\$ 639.56 million venture capital (VC) fund to give a boost to drug discovery and strengthen the pharma infrastructure in the country.

The Government had issued an expression of interest (EoI) for technical and financial bids for the selection of a global level consultant (GLC) for the preparation of a detailed project report (DPR) in order to develop India as a drug discovery and pharma innovation hub by 2020. The Drugs and Pharmaceuticals Manufacturers Association has received an in-principle approval for its proposed special economic zone (SEZ) for pharmaceuticals, bulk drugs, active pharmaceutical ingredients (APIs) and formulations to be located at Nakkapalli mandal in Visakhapatnam district.

The Department of Pharmaceuticals has prepared a "Pharma Vision 2020" for making India one of the leading destinations for end-to-end drug discovery and innovation and for that purpose 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.

The government plans to open 3,000 Jan Aushadhi stores, which sell unbranded generic drugs at heavy discounts to branded drugs, in the next two years.

### 3.2 Investment

The healthcare sector has attracted growing investor support in 2010 with nearly a tenth of the total private equity funding going to this sector. In the third quarter the calendar year 2010, a total of US\$ 2,047 million was invested across 88 deals, of which 9 per cent were healthcare deals.

The pharma, healthcare and biotech sector witnessed five merger and acquisition transactions (M&A) worth US\$ 250 million.

The drugs and pharmaceuticals sector has attracted FDI worth US\$ 1,825.43 million between April 2000 and September 2010.

Some of the major investment developments in the sector include:

- Hyderabad-based Natco Pharma plans to raise US\$ 22.22 million to fund its expansion plans and research activities.
- Private equity major Sequoia Capital has made its first investment in the pharmaceutical sector in the country by investing US\$ 15.86 million into Celon Labs, which will use the funds to double its manufacturing facility.

- Belgium based Helvoet Pharma, part of the Daetwyler Group is setting up its first greenfield production facility in Khandala Industrial Area, phase I (SEZ), on Pune- Bangalore Highway, near Pune. The company has invested US\$ 26.56 million for the plant.
- Swiss Pharma major Lonza AG, would invest around US\$ 55.33 million through its Indian subsidiary in a phased manner in Genome Valley project, Hyderabad, said Stefan Borgas, CEO, Lonza.
- Chennai-based Bafna Pharmaceuticals plans to raise around US\$ 4.43 million for its future expansion by issuance of warrants and shares.
- Hyderabad Menzies Air Cargo Private Limited, a joint venture between GMR Hyderabad International Airport Limited (GHIAL) and Menzies Aviation, has launched India's first airport-based pharma zone, dedicated pharmaceutical cargo storage and handling facility, at Hyderabad. The project involved an investment of US\$ 1.22 million.

## 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

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

### 4.2 Growth

The Indian pharmaceutical market reached US\$ 10.04 billion in size, with a value-wise growth rate of 20.4 per cent over the previous year's corresponding period on a Moving Annual Total (MAT) basis for the 12 months ended July 2010.

Cipla maintained its leadership position in the domestic market with 5.27 per cent share, followed by Ranbaxy. The highest growth in the domestic market was for Mankind Pharma,

which grew 37.2 per cent. Leading companies in the domestic market such as Sun Pharma (25.7 per cent), Abbott (25 per cent), Zydus Cadila (24.1 per cent), Alkem Laboratories (23.3 per cent), Pfizer (23.6 per cent), GSK India (19 per cent), Piramal Healthcare (18.6 per cent) and Lupin (18.8 per cent) had impressive growth during July 2010, shows the data.

The pharmaceuticals industry in India will grow by over 100 per cent over the next two years. The pharmaceutical industry is currently growing at the rate of 12 per cent, but this will accelerate soon. The sale of all types of medicines in the country stands at US\$ 9.61 billion, which is expected to reach around US\$ 19.22 billion by 2012.

India's domestic pharmaceutical market is valued approximately at US\$ 12 billion in 2010, and has shown a strong growth of 21.3 per cent for the 12 months ending September 2010. It estimates that over the next 10 years, the domestic market will grow to US\$ 49 billion, at a compounded annual growth rate (CAGR) of 15 per cent.

The formulations industry is expected to prosper parallel to the pharmaceutical industry. It is expected that the domestic formulations market in India will grow at an annual rate of around 17 per cent in 2009-10, owing to increasing middle class population and rapid urbanisation.