

A  
BRIEF REPORT  
ON  
PHARMACEUTICAL INDUSTRY IN INDIA

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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 pharmaceuticals market is expected to expand at a CAGR of 23.9 per cent to reach US\$ 55 billion by 2020. 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

The Indian pharmaceutical industry is estimated to grow at 20 per cent compound annual growth rate (CAGR) over the next five years. 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 pharma market to grow at 10-12 per cent in FY15 as compared to 9 per cent in FY14.

Also, growing at an average rate of about 20 per cent, India's biotechnology industry comprising bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics may reach the US\$ 7 billion mark by the end of FY15, according to an industry body. Biopharma is the largest sector contributing about 62 per cent of the total revenue, with revenue generation to the tune of over US\$ 2.03 billion. The bio-pharma sector comprises vaccines, therapeutics and diagnostics.

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

### 1.2.1 Diagnostics Outsourcing/ Clinical Trials

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.

### 1.2.2 Generics

Generic drugs account for 20 per cent of global exports in terms of volume, making the country the largest provider of generic medicines globally and expected to expand even further in coming years. 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.

## 1.3. Growth of Exports

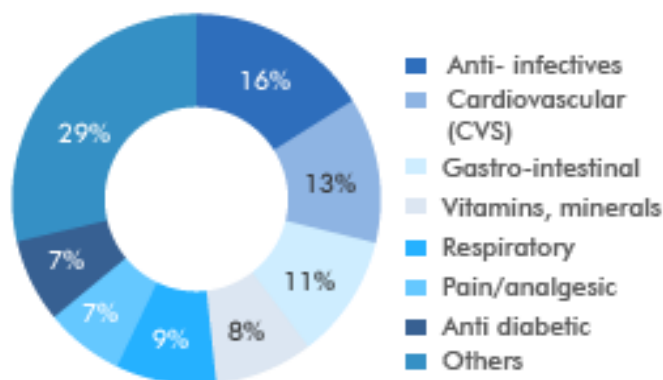
### Export data of Indian pharma industry

In terms of value, exports of Indian pharmaceutical products increased at a CAGR of 26.1 per cent to touch US\$ 10.1 billion during FY06-13.



### Indian pharmaceutical market segments by value

Anti-infective drugs command the largest share (16 per cent) in the Indian pharma market.



## 1.4. 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. 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 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.

Aurobindo Pharma products cover segments like –

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

## 3 GOVERNMENT INITIATIVES AND INVESTMENT

### 3.1 Government Initiative

The Government of India has unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. It has reduced approval time for new facilities to boost investments. Further, the government has also put in place mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to address the issue of affordability and availability of medicines.

Romania is keen to tie up with the Indian pharmaceutical companies for research and develop new drugs. Romania will collaborate with India for license acquisition to sale India's drugs in Europe. The country will tie up with the Indian pharmaceutical companies for research and develop new drugs.

Some of the major initiatives taken by the government to promote the pharmaceutical sector in India are as follows:

- Indian and global companies have expressed 175 investment intentions worth US\$ 161.78 million in the pharmaceutical sector of Gujarat. The memorandums of understanding (MoUs) would be signed during the Vibrant Gujarat Summit.
- Telangana has proposed to set up India's largest integrated pharmaceutical city spread over 11,000 acres near Hyderabad, complete with effluent treatment plants and a township for employees, in a bid to attract investment of US\$ 4.85 billion in phases.

### 3.2 Investment

- Stelis Biopharma has announced the ground-breaking for construction of its customised, multi-product, biopharmaceutical manufacturing facility at Bio-Xcell Biotechnology Park in Nusajaya, Johor, Malaysia's park and ecosystem for industrial and healthcare biotechnology at a total project investment amount of US\$ 60 million.
- Pharma major Strides Arcolab has entered into a licensing agreement with US-based Gilead Sciences Inc to manufacture and distribute the latter's low-cost Tenofovir Alafenamide (TAF) product used for HIV treatment in developing countries. The licence to manufacture Gilead's low-cost drug extends to 112 countries.
- Apollo Hospitals Enterprise (AHEL) plans to add another 2,000 beds over the next two financial years, at a cost of around US\$ 242.57 million
- CDC, the UK's development finance institution, has invested US\$ 48 million in Narayana Hrudayalaya hospitals, a multi-speciality healthcare provider. With this investment, Narayana Health will expand affordable treatment in eastern, central and western India.
- Cadila Healthcare Ltd has announced the launch of a biosimilar for Adalimumab - the world's largest selling drug for rheumatoid arthritis and other auto immune disorders. The drug will be marketed under the brand name Exemptia at one-fifth of the price for the



branded version-Humira. Cadila's biosimilar is the first to be launched by any company in the world and is a finger print match with the original in terms of safety, purity and potency of the product.

- Torrent Pharmaceuticals has entered into an exclusive licensing agreement with Reliance Life Sciences for marketing three biosimilars in India — Rituximab, Adalimumab and Cetuximab.
- Piramal Enterprises Ltd has acquired US-based Coldstream Laboratories for US\$ 30.6 million in an all-cash transaction.
- Indian Immunologicals Ltd (IIL) plans to set up a new vaccine manufacturing facility in Pondicherry with an investment of US\$ 48.53 million.
- SRF Ltd has acquired Global DuPont Dymel, the pharmaceutical propellant business of DuPont, for US\$ 20 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 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 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.