

Pharmaceutical Industry Analysis

Introduction

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. Branded generics dominate the pharmaceuticals market, constituting nearly 70 to 80 per cent of the market. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume. India also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level.

The revenue of the Indian pharmaceutical industry stands at US\$ 20 billion in 2015. Biopharma, comprising vaccines, therapeutics and diagnostics, is the largest sub-sector contributing nearly 62 per cent of the total revenues.

- See more at: <http://www.ibef.org/industry/pharmaceutical-india.aspx#sthash.jVziCWJO.dpuf>

Investments

The cumulative inflow of FDI in the sector was US\$ 13.3 billion during April 2000-May 2015. In 2014-15 the industry received FDI of worth US\$ 1.5 billion.

Some of the major investments in the Indian pharmaceutical sector are as follows:

- Cipla announced the acquisition of two US-based companies, InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc., for US\$ 550 million.
- Glaxosmithkline Pharmaceuticals has started work on its largest greenfield tablet manufacturing facility in Vemgal in Kolar district, Karnataka, with an estimated investment of Rs 1,000 crore (US\$ 150 million).
- Lupin has acquired two US based pharmaceutical firms, Gavis Pharmaceuticals LLC and Novel Laboratories Inc, in a deal worth at US\$ 880 million.
- Several online pharmacy retailers like PharmEasy, Netmeds, Orbimed, are attracting investments from several investors, due to double digit growth in the Rs 97,000 crore (US\$ 14.8 billion) Indian pharmacy market.
- Stelis Biopharma announced the breakthrough 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.
- Strides Arcolab entered into a licensing agreement with US-based Gilead Sciences Inc to manufacture and distribute the latter's cost-efficient Tenofovir Alafenamide (TAF) product to treat HIV patients in developing countries. The licence to manufacture Gilead's low-cost drug extends to 112 countries.

- CDC, the UK's development finance institution, invested US\$ 48 million in Narayana Hrudayalaya hospitals, a multi-speciality healthcare provider, with an aim to expand affordable treatment in eastern, central and western India.
- Cadila Healthcare Ltd announced the launch of a biosimilar for Adalimumab - 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 in class and an exact replica of the original in terms of safety, purity and potency of the product, claims the company.
- Torrent Pharmaceuticals entered into an exclusive licensing agreement with Reliance Life Sciences for marketing three biosimilars in India — Rituximab, Adalimumab and Cetuximab.
- Indian Immunologicals Ltd plans to set up a new vaccine manufacturing facility in Pondicherry with an investment of Rs 300 crore (US\$ 45 million).
- SRF Ltd has acquired Global DuPont Dymel, the pharmaceutical propellant business of DuPont, for US\$ 20 million.
- Intas Pharmaceuticals is the first global company to launch a biosimilar version of Lucentis, the world's largest selling drug for treatment of degenerative eye condition called Razumab.

Market structure

Generic drugs form the largest segment of the Indian pharma market with 70 per cent of the market share in terms of revenues. Over the counter (OTC) medicines and patented drugs constitute 21 per cent and 9 per cent respectively of the total market revenues.

Global Trade

India has the highest number of plants approved by the United States Food & Drug Administration (USFDA) outside the US. Around 584 Indian companies/ sites are registered with the USFDA.

India has one of the lowest manufacturing cost in the world. Manufacturing cost in India is 35-40% of that in the US as installation and workforce costs are low.

Country-wise Drug, Pharmaceutical and Fine Chemical Exports from India (2009-10 to 2013-14):

Country	Value in US\$ million		CAGR (in per cent)	
	2009-10	2013-14	2009-10	2013-14
USA	1,954	4,022	19.8	
Russia	275	546	18.7	
UK	349	525	10.8	

South Africa	246	501	19.5
Germany	320	460	9.5

Source: Pharmexcil – The Pharmaceutical Export Promotion Council

India exports to over 200 countries. In 2014-15, pharmaceutical exports totalled US\$ 15.5 billion.

Government policies and Regulations

The Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for Indian pharmaceuticals and medical devices. Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices, under the gamut of Ministry of Health and Family Welfare. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). It is divided into zonal offices which do pre-licensing and post-licensing inspections, post-market surveillance, and recalls when needed.

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

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

- The Government of India plans to incentivise bulk drug manufacturers, including both state-run and private companies, to encourage 'Make in India' programme and reduce dependence on imports of active pharmaceutical ingredients (API), nearly 85 per cent of which come from China.
- The Department of Pharmaceuticals has set up an inter-ministerial co-ordination committee, which would periodically review, coordinate and facilitate the resolution of the issues and constraints faced by the Indian pharmaceutical companies.
- The Department of Pharmaceuticals has planned to launch a venture capital fund of Rs 1,000 crore (US\$ 154 million) to support start-ups in the research and development in the pharmaceutical and biotech industry.
- Indian and global companies have expressed 175 investment intentions worth Rs 1,000 crore (US\$ 150 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 Rs 30,000 crore (US\$ 4.5 billion) in phases. Hyderabad, which is known as the bulk drug capital of India, accounts for nearly a fifth of India's exports of drugs, which stood at Rs 95,000 crore (US\$ 14.3 billion) in 2014-15.

- At the launch of Cluster Development Programme of pharmaceutical sector, Mr Ananth Kumar, Minister of Fertiliser and Chemicals, announced that six pharmaceutical parks will be approved and established this year which will have sufficient infrastructure and facilities for testing and treatment of drugs and also for imparting training to industry professionals.
- Indian Government plans to involve the private sector in R&D mainly for sectors such as vaccines, drugs and pharmaceuticals.

As on January 2016, the total project cost of healthcare infrastructure project is

USD151.91 million and there are five healthcare projects under PPP. Green Field Super Specialty Hospital (Bathinda), Green Field Super Specialty Hospital (Mohali), Indira Gandhi Government Medical College Complex (Maharashtra), Nephrology and Dialysis unit at Coronation Hospital (Uttarakhand), Nephrology Dialysis unit at Base Hospital (Uttarakhand).

- The time limit given for submitting the application for grant has been reduced to 4 months from 12 months, providing an extension of 2 months under the Draft Patents (Amendment) Rules, 2015. In order to compete with global players in pharmaceutical industries, approval process of drugs have been simplified by the authorities and approval time for new facilities has been drastically reduced.

Top Indian pharmaceutical companies

1. Sun Pharmaceutical Industries

It manufactures and sells pharmaceutical formulations and active pharmaceutical ingredients (APIs) primarily in India and the United States. The company offers formulations in various therapeutic areas, such as gastroenterology, cardiology, psychiatry, neurology, etc. It also provides APIs such as warfarin, carbamazepine, etodolac, and clorazepate. Under its vast product portfolio it also has anticancers, steroids, peptides, controlled substances etc. In 2014 the historic acquisition of Ranbaxy made the company the largest pharma company in India, the largest Indian pharmaceutical company in the US, and the 5th largest speciality generic company globally. Some of its best-selling products are Adcapone, Alzolam, Angizem, Aztor etc. Its revenue for FY 2015 was INR 27718 crores and net profit INR 5488 crores.

2. Lupin Pharmaceuticals

Lupin Pharmaceuticals, India is a wholly owned subsidiary of Lupin Limited U.S. It is a leading global player in Anti-TB, Cephalosporins (anti-infectives) and Cardiovascular drugs (ACE-inhibitors and cholesterol reducing agents) and it has a remarkable presence in the areas of acute diabetes, anti-inflammatory and respiratory therapies. Lupin's research program is typically designed to cover the entire pharma value chain. The company's global

R&D program is headquartered in the Lupin Research Park located near Pune that houses over 1400 scientists. Some of its well-recognized brands are Norvasc, Trizivir, Creftin, Lexapro, Mevacor, Pravacol etc. Its revenue and net profit for FY 2015 are INR 12863 crores and INR 2444 crores respectively.

3. Dr. Reddy's Laboratories

Dr. Reddy's manufactures and markets a wide range of affordable pharmaceuticals for acute therapeutic areas in India and overseas. The company has about 190 medication facilities, 60 active pharmaceutical ingredients (APIs) for drug manufacture, diagnostic kits, critical care, and biotechnology products. Some of their best-selling brands are Allopurinol tablets, Ciprofloxacin Tablets, Clopidogrel Tablets, Famotidine Tablets, Fluoxetine Capsules etc. Its revenue and net profit for FY 2015 are INR 15106 crores and INR 2336 crores respectively.

4. Cipla

Cipla's product portfolio includes over 1,500 world class products across various therapeutic segments, with more than sixty dosage forms. Some of its revolutionary brands are Acarboze, Natamycin, Terazocin, Ciclesonide etc. The revenue and net profit of Cipla for FY 2015 were INR 11454 crores and INR 1254 crores respectively.

5. Aurobindo Pharma

In addition to being the market leader in Semi-Synthetic Penicillins, Aurobindo Pharma has a strong foothold in key therapeutic categories such as neurosciences, cardiovascular, anti-retrovirals, anti-diabetics, gastroenterology and cephalosporins, etc. Aurobindo Pharma exports its formulations to more than 125 countries across the world with more than 70% of its revenues generated out of off-shore operations. Its' best known brands are Aurox, Cedbrox, Tripcut, Cefactam, ProxtL, AxtL, Recipro, Diceta etc. Its revenue for FY 2015 was INR 8245 crores with a net profit of INR 1516 crores.

Comparison with Global Peers

1. Johnson & Johnson

With a revenue of US\$ 74.331 billion, Johnson & Johnson tops the list of global pharma companies. Its presence spans across a range of industries from medical devices to pharmaceutical and consumer goods, with market leadership in hepatitis C, arthritis, HIV/AIDS and digestive conditions.

2. Novartis

Novartis, having a revenue of US\$ 57.996 billion, specializes in the development of biological therapies. The company, which consists of specialist divisions for prescription pharmaceuticals, eye care and generics and biosimilars, has a combined workforce of more than 100,000 employees, with operations in more than 140 countries worldwide. Its current top grossing pharmaceutical drugs include Gleevec for cancer and Gilenya for multiple sclerosis.

3. **Roche**

Swiss pharmaceutical and biotechnology company Roche is well known for its innovative range of diagnostic solutions and medicines. Its best selling drugs include cancer treatments MebThera, Avastin, Herceptin and Xeloda. Roche is a front runner in personalised medicines and was one of the first companies to bring targeted treatments to patients. Its revenue stands at US\$ 49.86 billion.

4. **Pfizer**

Pfizer develops and produces medicines and vaccines for a wide range of therapeutic areas including oncology, cardiology and immunology. Some of its highest selling drugs include Celebrex, Liptor and Viagra. Pfizer recently acquired leading sterile injectables company Hospira in a \$17 billion (£11 billion) deal, which gives them access to a large portfolio of generics and biosimilar products. Pfizer's revenue stands at US\$ 49.605 billion.

5. **Sanofi**

French pharmaceutical company Sanofi specialises in prescription and over the counter (OTC) medicines in seven major therapeutic areas: cardiovascular, central nervous system, diabetes, internal medicine, oncology, thrombosis and vaccines. Diabetes blockbuster Lantus remains the source of much of the company's turnover, supported by vaccines and multiple sclerosis therapies at its biotech unit Genzyme, and antihistamine Allegra in Sanofi's consumer health division. Its total revenue is US\$ 43.07 billion. At the beginning of February 2015, the Sanofi's R&D pipeline contained 43 projects (excluding Life Cycle Management) and vaccine candidates in clinical development of which 14 are in phase 3 or have been submitted to the regulatory authorities for approval.

Porter's Five Forces Analysis

1. **Threat of the entry of new competitors**

- Threat of new entrants is low, because:
 - Huge initial investment and high gestation period makes survival difficult.
 - Strict government regulations create compliance burden.

2. **Threat of substitute products or services:**

- It is low, on account of following factors:
 - Alternative remedies like homoeopathy and Ayurvedic medicines can be used as substitutes; however, they have their own limitations.

3. **Bargaining power of customers**

- It is moderate:
 - In case of innovative drugs, customers do not possess any bargaining power, due to monopoly of the drug producing company.
 - However, in case of generic drugs, bargaining power of customers is significant.

4. **Bargaining power of suppliers**

- This is moderate:
 - In case of patented drugs, which are difficult to manufacture, bargaining power of suppliers is high.
 - However, for generic drugs, where replicating the product is easy, bargaining power of the supplier is low.

5. **The intensity of competitive rivalry within the industry**

- **Competitive rivalry is high in the pharmaceutical industry:**
 - Indian pharma companies will continue to face competition from global pharma giants, with easing of FDI norms.
 - With liberalization of patent regulations, competition within the industry is likely to be high.

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