EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 7
Issue: 7
340-369
Year: 2020

PRESENT SCENARIOS OF PHARMACEUTICAL INDUSTRY IN INDIA

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Article Received on 15/05/2020 **Article Revised on 05/06/2020** **Article Accepted on 25/06/2020**

ABSTRACT
Pharmaceutical industries viz., Ranbaxy, Cipla, Dr. Reddy's, Sun pharma, Lupin, Nicolas, Zydus, Intas etc. are very well establish now-a-days and producing a large variety of medicine useful in the treatment of various diseases. It is now high-end development that is being carried out by leading companies whereas other small companies are finding themselves competing against, or working with, new innovation-based companies to establish themselves in the market in concern to increase their productivity & finally sale. The present study was focused on the current scenario of various pharmaceutical industry.

KEYWORDS: Indian Pharmaceutical Industry, Market share, Net sales, CAGR, Govt. initiatives, Major pharma companies, Growth rate, Patent, Export, Vision 2030.

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 expend at a CAGR of 23.9 percent 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 antibiotic and complex cardiac compound; almost every type of medicine is now made in the Indian pharmaceutical industry.

The Indian pharmaceutical sector is highly fragmented with **more than 20000 registered units**. It has expended drastically in the last two decades. The pharmaceutical and chemical industry in India is extremely fragmented market with severe price competition and government price control. The pharmaceutical industry in India meets around 70% of country's demand for bulk drugs, drug intermediates, pharmaceutical formulation, chemicals, tablets, capsules, orals, injectables. There are approximately **250 large units** and about **8000 small scale units**, which form the core of the pharmaceutical.

The **1st** pharmaceutical company is **Bengal Chemicals and Pharmaceutical Works**, which still exists today as one of 5 government owned drug manufacturers. Bengal Chemicals and Pharmaceutical Works Ltd. (BCPW) is precursor of the present company, Bengal Chemicals and Pharmaceutical Ltd (BCPL). **Acharya P C Ray** took a rented house at 91 Upper Circular Road, Calcutta and started business with a meager capital of Rs 700.00. Since inception of the company he has very much quality conscious and produced various product of British pharmacopoeia standard. Eminent doctors with nationalistic feeling like Dr. R G Kar, Dr. N R Sarkar, Dr. S P Sarbadhikari, Dr. Amulya Charan Bose, etc. came forward and patronized the products. The reputation of the company started enhancing rapidly, when Acharya P C Ray felt for pumping more fund in the company and on 12th April, 1901 the name of company was styled as Bengal Chemicals and Pharmaceutical Works Ltd. (BCPW), retaining the same premises at 91 Upper Circular Road, Calcutta.

Some major factors are there to improve pharmaceutical industry of all over India:

Increasing demand in global markets: Genetic penetration in high value healthcare markets has grown significantly, with India supplying 20+ percent of the generics demand in major geographies.

Stable growth in domestic market consumption: India's pharmaceutical market has grown rapidly over the last decade. Despite recent headwinds, a stable growth of 5-7% was observed last year. India is likely to become one of the Top 3 pharma markets by 2020.

Low cost and at scale manufacturing capability in India: India has the second highest number of US FDA approved facilities and labor costs in India have been lower than other manufacturing hubs by up to 40 percent.

Significance of Pharma Industry

India's pharmaceutical sector is receiving a major boost from population growth. According to UN estimates, the population total looks set to rise from 1.38 bn at present to 1.5 bn in 2030. Up until 2030 India will see as many children being born as there are people living in Germany, France, the UK and Italy together. By 2030, India will probably have overtaken China as the world's most populous country. Its population growth results not least from higher life expectancy. This is attributable, among other things, to improved preventive healthcare. Of course, though, average life expectancy in India is still markedly lower than in western countries. While the figure is 64 years for men and 66 years for women in India, life expectancy in Germany is 76 years for men and 82 years for women.

The ageing of the population in India offers considerable market opportunities. According to a UN estimate, the share of people over the age of 65 in the total population will rise from 5% currently to 8% in 2025. This would mean roughly 55 million more people aged 65 and over than today. As a result, typical age-related illnesses such as cancer and cardio-vascular diseases will be more wide-spread. The pharmaceutical sector will also receive a boost from the gradual spreading of civilization diseases such as obesity and diabetes. According to Price water house Coopers (PwC), the number of Indians with diabetes will reach approximately 74 mn in 2025 (currently 34 mn); this is roughly the population of Turkey today. In developing countries as a whole, there could be just fewer than 230 mn diabetes patients. This development should benefit India's generics manufacturers.

Globalization has not caused traditional medicine to be abandoned but with higher education, rising income and a change in lifestyle, western medical treatment is gaining in importance. At present the population especially in rural areas still sees western medicine as a stop-gap cure which is unlikely, though, to provide a lasting solution to health problems. Today, about 70% of the population on the Indian subcontinent depends entirely or at least in part on traditional Indian medicine which is cheaper and more easily available than western drugs. Firms based in India and China could be among the first to bring bio generics (generic versions of biological products) to the regulated markets and faster than expected. The first biogenetic product was approved by the European Medicines Agency (EMEA) which refers to these products as ―biosimilars.

Advantage of 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 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 education workforce 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
- Establish strengths in information Technology.

Globalization

- The country is committed to a free market economy and globalization
- It has a 70 million middle class market, which is continuously growing.

Consolidation

- The process consolidation, which has become a generalized phenomenon in the world pharmaceutical industry, has started taking place in India.

Cost Efficiency

- Low cost of production R & D boosts efficiency of Indian pharma companies
- India's cost of production is approximately 33 percent lower than that of the US.
- Due to lower cost of treatment, India is emerging as leading destination for medical tourism
- India's ability to manufacture high quality, low priced medicines, presents a huge business opportunity for the domestic industry.

Economic Drivers

- Economic prosperity to improve drug affordability
- Increasing penetration of health insurance

- With increasing penetration of pharmacies, especially in rural India, OTC drugs will be readily available

Diversified Portfolio

- Accounts for over 10 percent of the global pharmaceutical production
- Over 60000 generic brands across 60 therapeutic categories. Manufactures more than 500 different APIs.
- More than half of all 345 drug master filings (DMFIs) in the USA in Q4 2016 and Q1 2017 were from India.

Policy Support

- Government unveiled pharma vision 2030 aimed at making India a global leader in end-to-end drug manufacturing
- Reduced approval time for new facilities to boost investments.

Evolution Of Pharmaceutical Industry

The Indian pharmaceutical industry has come a long way since the time of independence when multinational corporations dominated the industry. Over the years, under a favorable policy regime, the industry has grown phenomenally and has established itself as a major supplier of not only generic products but also new formulations. The industry, in addition to meeting domestic demand, is in a position to export significant volume of pharmaceutical products to various destinations, including the developed markets of USA, EU and Japan. Evolution of Indian pharmaceutical industry can be classified into the following periods:

Pre-independence scenario

During the British Rule, the indigenous forms of drugs were in use viz- **Ayurvedic or Unani** in India. **British Government** first introduced the **allopathic form of drug** in the country. At that time, there were no productions units in the country. Instead**, MNC's** were used to **export the raw material** from India and again **imported** the **finished product** into the country. After putting sincere efforts by the indigenous entrepreneurs towards manufacturing of drugs, India became able to manufacture the drugs. Although the **production of the country** was **very low** and hardly satisfied the **13%** need of the country. The drug industry, however, move forward during the Second World War due to the decreased supply of drugs from multinational companies and many more Indian companies like **Unichem, Chemo Pharma, Zandu Pharmaceutical, Calcutta Chemicals, Standard Chemicals, Chemical Industrial and Pharmaceutical Laboratories (now known as Cipla), East India Pharmaceutical Works** and others were established. With the establishment of new firms in the market, the **production** of medicine increased robustly and domestic firms were able to satisfy the country's need up to **70%**. During this era, all the companies whether **domestic** or **MNCs** were involved in the **manufacturing** of drugs and the significance of R&D was unknown. New inventions were done only by individual efforts of scientists not by the firms.

Post-independence scenario

In the early years following India's independence from the colonial rule of Britain in **1947, Multinational Companies (MNCs)** were allowed to **import** drugs into India – mainly **low-priced generics** and a few high-priced specialty items. When the **Indian government** increased pressure against the **import** of **finished products**, MNCs developed formulation units in India and imported only bulk drugs into India. In the early **1960s,** the Indian **government** encouraged the indigenous manufacture of **bulk drugs.**

The phase of the post - independence scenario can be divided into **six different phases** and these are:

Pre-1970s

The first Indian pharmaceutical company, **Bengal Chemicals and Pharmaceutical Works**, which still exists today as one of 5 government-owned drug manufacturers, appeared in Calcutta in 1930. For the **next 60years**, most of the drugs in India were **imported by** multinationals either in fully-formulated or bulk form. The **government started to encourage** the growth of drug **manufacturing** by Indian companies in the early **1960s**, and with the **Patents Act in 1970**, enabled the industry to become what it is today. This patent act removed composition patents from food and drugs, and though it kept process patents, these were shortened to a period of **five to seven years.** The lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market, and while they streamed out, Indian companies started to take their places. They carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model until the present.

1970-1995

Up to **1970s**, Indian pharmaceutical market was **supplied by international organizations.** Only bulk drugs were produced by domestic producers, these manufacturers were funded by **state owned companies** and **World Health Organization (WHO)**. After that, Indian government has introduced some practices to reduce the import dependence for their pharmaceuticals. Domestic manufacturers started their productions by copying the drugs produced by the foreign producers. This approach became more effective way of development of drugs without investing a huge sum for research initiatives. **80%** of the drugs were sold to the **US and European market,** which benefited the Indian companies due to the higher purchasing power of the population. On the contrary side, traditional sales markets like Russia,

Southeast Asia was losing their importance in the pharmaceutical market. In **1980-1990s,** Indian pharmaceutical industry has the **boom phase** and as a result, more than75 % MNC's holding decreased up to 35 % holdings in India.

Government of India introduced a new Patent Act, which came into effect in 1972, recognizing only process patent and not product patent. The Act, along with Drug Price Control Order, provided little incentive for MNCs to introduce new pharmaceutical products in India.

During this period, the number of domestic pharmaceutical firms increased considerably, from around **2000 units in 1970** to **24,000 units in 1995**. Production of bulk drugs increased from Rs. **18 crores in 1965-66 to Rs. 1518 crores in 1995, while that of formulations increased from Rs. 150 crores to Rs. 7935 crores.** The increase in production was more pronounced in case of formulations due to large-scale production of generics by domestic firms. Low cost and high-volume production have helped the Indian pharmaceutical industry in opening export channels to explore many developed and developing countries. Share of exports as a Percentage of total production has shown significant increase from **3.22% in 1980-81 to 24% in 1994-95.**

1995-2005

As there was no efficient patent protection between 1970 and 2005, many Indian drug producers copied expensive original preparations by foreign firms and produced these generics by means of alternative production procedures. This proved more cost-efficient than the expensive development of original preparations. The competitiveness of generics producers is based on cost-efficient production. At the same time, **India's pharmaceutical companies gained know-how in the manufacture of generic drugs.** Hence, the name ―pharmacy of the poor is frequently applied to India.

India's pharmaceutical industry has been in transition for several years now. This is the result mainly of the changes to **drug patent legislation in 2005**. Prior to the Patent Amendment Bill, not the substance itself but merely the manufacturing process was protected for a period of seven years. India's patent legislation had frequently been the reason for legal disputes with large western drug firms, especially from the US. In line with international standards, the sector is now subject to product and process patents valid for a period of 20 years.

Between **1996 and 2006**, nominal sales of pharmaceuticals on the Indian subcontinent were up **9% per annum** and thus expanded **much faster** than the global pharmaceutical market as a whole (+7% p.a.). Indian companies strongly expanded their capacities, making the country by and large self-sufficient.

This puts the country in twelfth place internationally, even behind Korea, Spain and Ireland and before Brazil, Belgium and Mexico. **Among the Asian countries, India's pharmaceuticals industry ranks fourth at 8%, but has lost market share to China,** as sales growth there was nearly twice as high and sales volumes nearly four times higher than in India.

2005-2015

India's GDP from **2005 to 2009** grew at about **8 per cent**. Growth in medical infrastructure and health insurance coverage has been in line with expectations. The treatment of chronic diseases has gone up. The remarkable success of a few recent launches has demonstrated the true potential of patented products. In 2007, we undertook an exercise to assess the potential of the market by 2015. At that time, the country was beginning to witness greater affordability and higher spending across a range of categories driven by a decade of reforms. The total market for healthcare products and services had grown at a compounded annual growth rate of 14 per cent from 2000 to 2005. The pharmaceutical industry had grown at a **compounded annual growth rate of 9 per cent** during that period. We felt in 2007 that the Indian pharmaceutical market was poised for a clear and discernable step-up in its growth trajectory.

In our earlier report, India Pharma 2015 – Unlocking the Potential of the Indian Pharmaceutical Market, we projected that the market would grow at a compounded annual growth rate of 12 to 14 per cent to become a **USD 20 billion to USD 24 billion market by 2015.**

This growth would be driven primarily by rising incomes, and be supported by five other factors:

- Enhanced medical infrastructure;
- Rise in the prevalence and treatment of chronic diseases;
- Greater health insurance coverage;
- Launches of patented products;
- And new market creation in existing white spaces.

Post 2015

The Indian pharmaceuticals market has characteristics that make it unique. First, branded generics dominate, making up for 70 to 80 per cent of the retail market. Second, local players have enjoyed a dominant position driven by formulation development capabilities and early investments. Third, price levels are low, driven by intense competition. While India ranks tenth globally in terms of value, it is ranked third in volumes. These characteristics present their own opportunities and challenges.

The Indian Pharmaceuticals market witnessed growth at a compound annual growth rate of **5.64 percent** during **2011 to 2016**, with the market increasing from **US$ 20.95 billion to 20.95 billion** in **2011 to 2016**. The industry's revenues are estimated to have grown by **7.4 percent in 2017.**

Medicine sales in India increased **8.1 percent year-on-year in November 2017**.

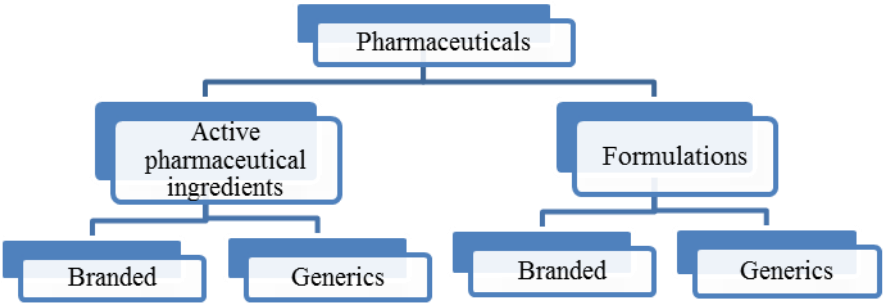
In 2017 India **exported** pharmaceutical products worth **16.8 billion**. During **April-September 2017**, India **exported** pharmaceutical product **US$ 6.4billion**. During **April-October 2017**, India exported pharmaceutical products worth **US$ 7.4 billion**.

On the post 2015 period, Indian drugs are exported to more than 200 countries in the world and India became world's largest provider of generic medicines. The country's generic drugs account for 20% of global generic drug exports.

Pharmaceutical Industry in India is expected to be worth **US$ 55.39 billion by 2020**. India pharmaceutical market is expected to grow at a **compound annual growth rate (CAGR) of 18% by 2020** driven by the aging and growing population, rising income levels, emerging medical conditions and new disease.

MARKET OVERVIEW

STRUCTURE OF PHARMA SECTOR IN INDIA



Flowchart-1: Structure of pharma sector.

IMPORTANT SEGMENT IN INDIAN PHARMACEUTICAL SECTOR

Active pharmaceutical ingredients (APIs)

- India became the third largest global generic API merchant market in 2016, with a 7.2 percent market share.
- The Indian pharmaceutical industry accounts for the 2nd largest number of Abbreviated New Drug Applications (ANDAs), is the world's leader in Drug Master Files (DMFs) applications with the US.

Contact research & manufacturing service (CRAMS)

- Fragmented market with more than 1000 players.
- CRAMS industry is estimated to reach US$ 18 billion in 2018 and expected to witness a strong growth at a CAGR of 18-20 percent between 2013-18.

Formulations

- Largest exporter of formulations in terms of volume, with 14 percent market share and 12th in terms of exports value. Drug formulation exports from India reached US$ 7.25 billion during April-November 2017. Domestic market size currently valued at US$ 11.2 billion.
- Double-digit growth expected over the next five years.

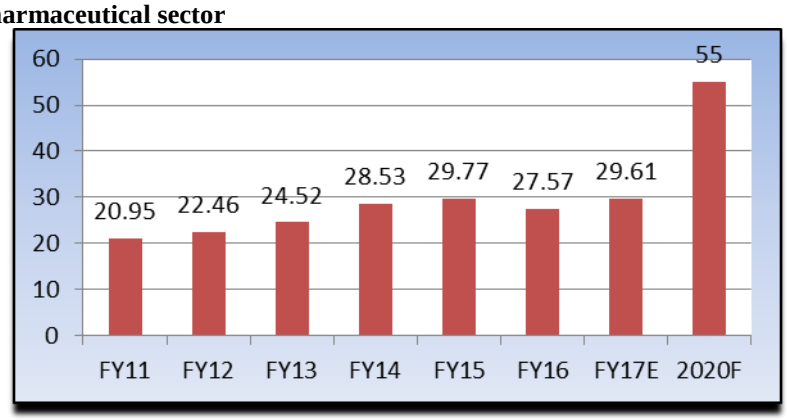
Biosimilars

- The government plans to allocate US$ 70 million for local players to develop Biosimilars.
- The domestic market is expected to reach US$ 40 billion by 2030.

INDIAN PHARMA SECTOR REVENUES TRENDING NORTH

- The Indian pharmaceuticals market witnessed growth at a CAGR of 5.64 per cent, during FY11-16, with the market increasing from US$ 20.95 billion in FY11 to US$ 27.57 billion in FY16. The industry's revenues are estimated to have grown by 7.4 per cent in FY17.
- By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and 6th largest market globally in absolute size.
- India's cost of production is significantly lower than that of the US and almost half of that of Europe. It gives a competitive edge to India over others.
- Increase in the size of middle-class households coupled with the improvement in medical infrastructure and increase in the penetration of health insurance in the country will also influence in the growth of pharmaceuticals sector.

Revenue of Indian pharmaceutical sector

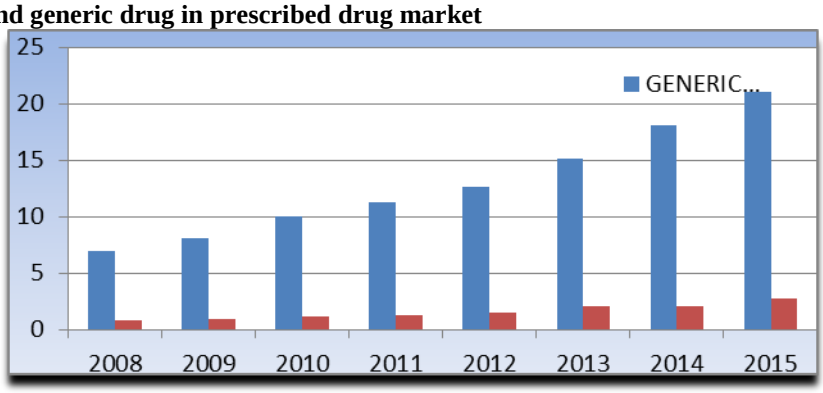


Histogram-1: Revenue of pharma sector.

GENERIC DRUGS FORM THE LARGEST SEGMENT OFINDIAN PHARMA MARKET

- With 70 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector
- India supplies 20 per cent of global generic medicines market exports, in terms of volume, making the country the largest provider of generic medicines globally and expected to expand even further in coming years
- Over the Counter (OTC) medicines and patented drugs constitute 21 per cent and 9 per cent, respectively, of total market revenues of US$ 20 billion
- Indian pharma drug manufacturer Aurobindo Pharma has received the USFDA approval to manufacture oral suspension, which is used for controlling serum phosphorus in patients with chronic kidney disease on dialysis. This drug is a therapeutic equivalent generic version of Genzyme's Renvela oral suspension.
- The share of generic drugs is expected to continue increasing; domestic generic drug market is expected to reach US$ 27.9 billion in 2020
- Due to their competence in generic drugs, growth in this market offers a great opportunity for Indian firms
- Generic drug market is expected to grow in the next few years, with many drugs going off-patent in the US and other countries
- Domestic generic drug market has reached US$ 26.1 billion in 2016.

Share of patented and generic drug in prescribed drug market



Histogram-2: Share of patented & generic drugs.

MARKET DYNAMICS & IMPLICATION FOR INDIA PHARMA

The growth rate for the Indian pharmaceutical market has slowed down consistently over the last five quarters—from 12-15 percent in 2015 to 5-6 percent in 201711. The market growth is driven largely by volume (2016-17 volume growth was 3-4 percent) with an average price increase of 1-2 percent.

Despite the slowing pace of growth, companies have continued to cater to healthcare needs, thereby enriching the quality of lives. Few recent entrants have rapidly achieved top line growth. Institutions (both hospitals and government) have become much larger customers - Government expenditure on healthcare has increased from 22 Bn USD in 2012 to 53 Bn USD in 2016.

The volumes could possibly keep growing due to India's high disease burden, increasingly better access to healthcare (and hence better diagnosis rates) and greater affordability. But the market is also likely to be impacted in the near term due to several forces.

- ***Evolving regulatory landscape:*** The recently proposed pharma policy and several other interventions have an impact across the value chain- from development, manufacturing and supply chain to pricing and customer engagement. There is still potential to systematically strengthen and stabilize the Pharma policy of 2012, and improve the ease of doing business going forward. As the Government continues to play a more proactive role in shaping broader healthcare reforms, the industry environment could see some uncertainty in the near term.
- ***Alternate means of engagement with doctors:*** While doctors are likely to remain the single largest influencer of treatment and medicine choice, alternative means of engaging physicians could gradually become the norm. Doctors' behavior is evolving with increasing time spent online to gain information. Technology-based remote healthcare will continue to expand, significantly increasing the reach and influence of the doctors. The proposed UCPMP will also move to mandatory compliance with oversight.
- ***Increased patient involvement:*** As patients want to be more involved and empowered, their preferences will continue to influence healthcare choices. While this shift is visible across the country, with the trend being much stronger in metro cities –a recent survey in Gurgaon showed that over 60 percent of patients check their doctor / hospital choices on Google before deciding, and the prescribed products thereafter.
- ***Greater role of pharmacists:*** Pharmacists will grow more powerful (e.g., due to INN name) and the market may see another wave of consolidation giving rise to pharmacy chains. E-pharmacies will see a surge with easing regulation and increasing private investment in this space, causing a dramatic shift in generic brands and substitution ability.

Government Initiatives & Investment

Government Initiatives

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$ 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.

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 license 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-specialty 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. Cardila'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 & 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, & Cetuximab.
- Indian Immunologicals Ltd plans to set up a new vaccine manufacturing facility in Pondicherry with an investment of US$ 48.53 million.
- Piramal Enterprises Ltd has acquired US-based Coldstream Laboratories for US$ 30.6 million in an all-cash transaction.
- SRF Ltd has acquired Global DuPont Dymel, the pharmaceutical propellant business of DuPont, for US$ 20 million.

The four bold aspirations for the industry to target Vison 2030 are

1. Growth in domestic market with increased accessibility and affordability.
2. Potential innovations in next generation inventive products.
3. Strong hold in the US market by increasing ANDA filing for upcoming off patent drugs, and potential pricing offers.
4. Grow in unexplored/underutilized markets such as Japan and China.

To achieve this target, the Indian industry requires a huge support from the government and its regulatory bodies either in terms of regulatory policies and a supportive ecosystem or in terms of investment. The government's role is to:

- **Accelerate universal healthcare access by strengthening the healthcare infrastructure -** Improve healthcare infrastructure and increase usability of digital technologies such as telemedicine facilities, artificial intelligence, healthcare apps and, mobile clinics to accelerate the universal health coverage/access. Improved healthcare access offers a sea of opportunities for health industry including the pharma industry.
- **Create a stable and supportive regulatory environment for the industry -** The Government can create a transparent, easy, and coherent regulatory policy which will reduce the uncertainty regarding pricing and drug approval process.
- **Create an independent Ministry for Pharmaceuticals -** In order to promote the industry's interest, a dedicated Union Ministry of Pharmaceuticals can be set up by government to simplify policy making, speed-up the product approval and implementation process, and expedite investment approvals.
- **Primary Focus on API manufacturing to reduce the reliance on imports -** The government can provide infrastructural and regulatory support to industry for manufacturing APIs
- **Expand and consolidate global footprint and collaborate with international regulatory bodies -** The exchange of regulatory best-practices between regulatory agencies of countries will improve the market presence and also help to expedite approvals in large markets like China and Japan. The government can also work closely with the USFDA and other international regulatory bodies to communicate key issues faced by Indian pharma companies and drive the required regulatory changes.

Major pharmaceutical companies in india

Cipla limited

HISTORY: **Cipla** is an Indian **multinational pharmaceutical** company. Headquarter of Cipla is in **Mumbai, India**. On the early years Cipla develops medicines to treat respiratory, cardiovascular disease, arthritis, diabetes, weight control and depression; other medical conditions.

Cipla was founded by **Khwaja Abdul Hamied** as **'The Chemical, Industrial, & Pharmaceutical Laboratories'** in **1935** in **Mumbai**. The name of the companywas changed to **'Cipla Limited'** on **20 July 1984**. In the year 1985; US FDA approved the company's bulk drug manufacturing facilities. Led by the founder's son **Yusuf Hamied**, a Cambridge-educated chemist, the company provided generic AIDS and other drugs to treat people in the developing world.

In 1995 Cipla launched **Deferiprone**, the **world's first oral iron chelator**. In 2001, Cipla offered medicines for **HIV treatment**.

It is India's fourth largest pharmaceutical company accounting for a market capitalization worth Rs. 47,025.38 crore on 15 June 2015. Its products and services may be categorized as: APIs, Formulations, Veterinary.

MISSION: Cipla's mission is to be a leading global healthcare company which uses technology and innovation to meet every day needs of all patients.

Figure 1: Cipla Limited.

STRATEGIES

Patients

- Focus on impact, and double the number of patients Cipla serve globally
- Transform to be an innovation-led enterprise focusing on unmet patient needs

Leadership in core markets

- Be among the top 3 in home markets and legacy emerging markets
- Be among the fastest growing in emerging economies and Specialty business

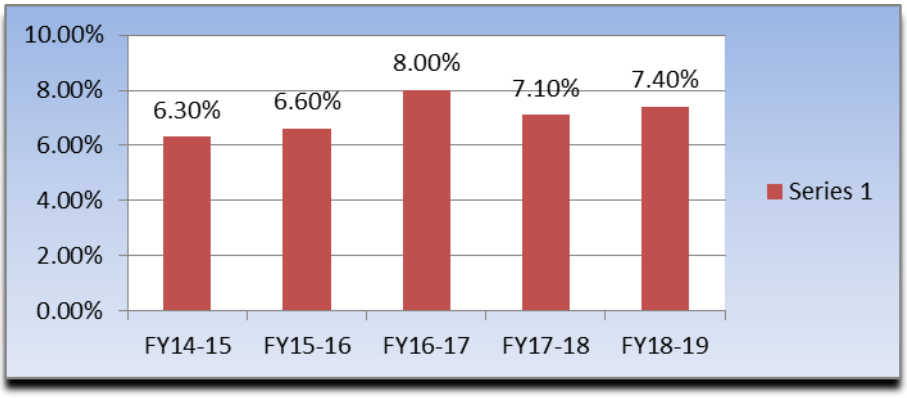
Commercial excellence

- Accelerated revenue growth and sustainable margin expansion

RESEARCH & DEVELOPMENT: Cipla's R&D division focuses on the development of new products and new drug delivery systems across a range of therapies. The company is spending over 4 per cent of its total turnover on R&D activities. It filed 55 ANDAs during 2004-05 and received approval for 11 products from US FDA. The company supplies drugs to treat over 2 lakh HIV-positive patients worldwide. The company has also been among the major suppliers of anti-malarial drugs and drugs for schistosomiasis to international markets. The Company has continuously invested in building a strong product pipeline through R&D. This has contributed significantly in growing the US product portfolio and progress of the clinical trials for Advair. Absolute annual R&D investments at Cipla have crossed 1000crore.

On **14-15 FY** the investment for R&D was **6.3%** and on **18-19 FY** that was increased upto**7.4%.**

R&D Investment



Histogram-3: R&D investment.

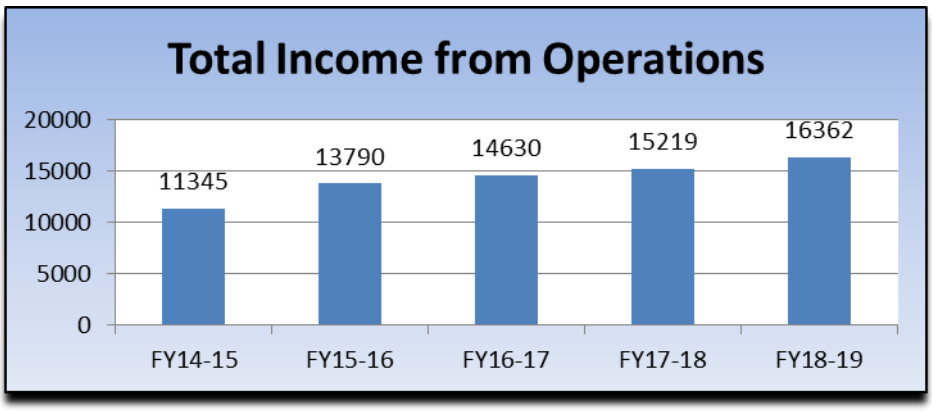
CIPLA'S PRODUCT: Cipla sells active pharmaceutical ingredients to other manufacturers as well as pharmaceutical and personal care products.

Pharmaceuticals: Cipla manufactures anabolic steroids, analgesics /antipyretics, antacids, anthelmintics, anti-arthritis, anti-inflammatory drugs, anti-TB drugs, antiallergic drugs, anticancer drugs, antifungal, antimalarials, antispasmodics, antiulcerants, immunosuppressants etc.

OTC: These include: child care products, eye care products, food supplements, health drinks, life style products, nutraceuticals & tonics, skin care products, and oral hygiene products.

CIPLA'S EXPORT: Cipla exports raw materials, intermediates, prescription drugs, OTC products and veterinary products rugs to more than 160 countries including the U.S., and a number of countries in Europe, Africa, Australia, Latin America and the Middle East. Cipla shipped products worth more than Rs.10,500 million last year. Exports amounted to more than Rs. 10, 500 million.

FINANCIAL: **FY 18-19** revenue stands at **16,362 crores** with **5years CAGR of 10%** has largely been driven by strong performance in home markets of India, North America new launches and acquisitions, and South Africa private market partly offset by challenges in Middle Eastern markets. Our focus for next year is on continuing the growth trajectory in key markets and investments in portfolio for sustainable growth.



Histogram-4: Total Income from revenue.

AUROBINDO PHARMA

HISTORY: **Aurobindo Pharma Limited** is a pharmaceutical manufacturing company headquartered in **HITEC city, Hyderabad, India**. The company manufactures **generic pharmaceuticals** & **active pharmaceutical** ingredients. The company's area of activity includes six major therapeutic/product areas: antibiotic, antiretroviral, cardiovascular products, central nervous system products, gastroenterological, & anti-allergic. The company markets these products in over **125 countries**. Its marketing partners include **AstraZeneca** and **Pfizer.**

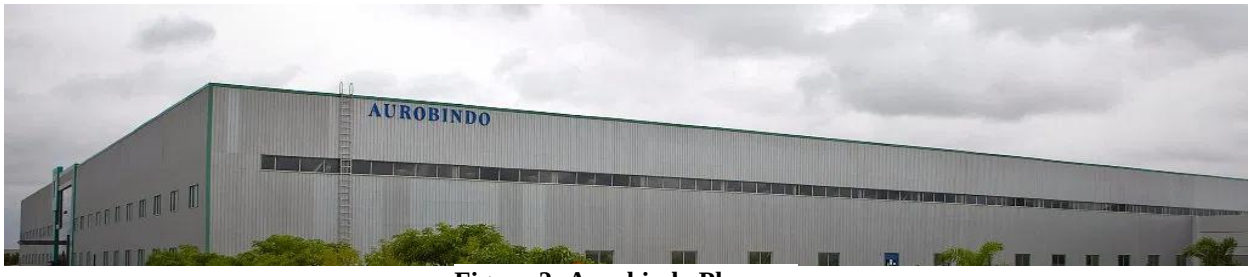


Figure-2: Aurobindo Pharma.

MISSION: Aurobindo pharma started their journey in 1986 with a mission to become the most valued partner to the global pharma fraternity by continuously researching, developing and manufacturing a wide range of pharmaceutical products for patients in need.

STRATEGIES

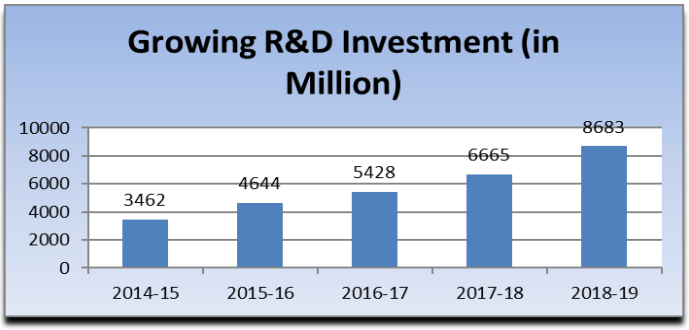
Lead with arrange of products: They have grown to emerge as one of the largest generic companies globally on the back of expansive product portfolio spanning multiple therapeutic areas, dosage forms and geographies. This ensures that we can capture the growth

in multiple products and categories, while reducing the risk of dependence on any single product.

Expand into new areas: Through continuous investment in Research and Development, powered by the efforts of our 1,600+ member R&D team, they are constantly building a portfolio of value-added and complex products for the future. Believe these products are building a sound platform for our Company to LEAP to the next growth altitude.

Attaining capabilities and strengthening compliance: To accelerate progress, it was important for us to strengthen capabilities in various domains. During the year, they acquired assets to strengthen their existing product portfolio, helping them set foot in new markets and augment our research & development and production capabilities.

Promote an Execution-oriented Growth Mindset: To support a growing organization, it is important to build a culture of execution excellence that encourages fast learning and accelerated delivery.



Histogram-5: R&D investment.

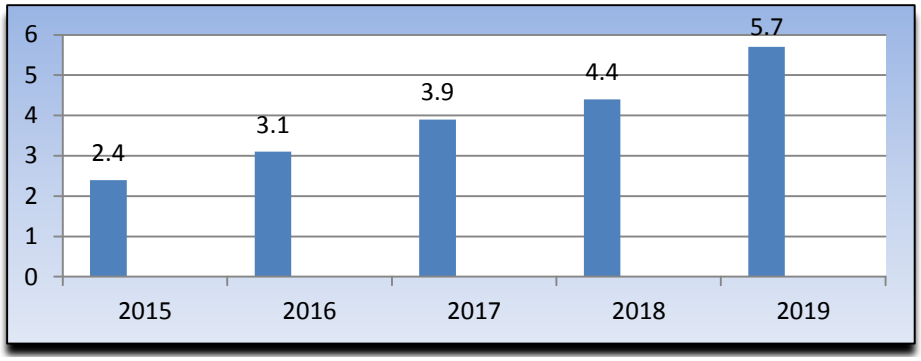
RESEARCH & DEVELOPMENT: The Company's R&D strengths are in developing intellectual property in non-infringing processes and resolving complex chemistry challenges. Aurobindo Pharma is in the process of developing new drug delivery systems, new dosage formulations, and applying new technology for better processes.

The R&D Center, in Hyderabad covers over 13,000 sq.m, and provides a nurturing environment to a multi-disciplinary team of over 700 scientists striving for excellence.

FINANCIAL: For FY19, Aurobindo's consolidated revenues increased by 18.6% to US$195,636 million from US$164,998 million a year ago. EBITDA grew by 4.3% to US$ 39,519 million whereas the EBITDA margin stood at 20.2%. Its research and development expenses stood at US$ 8,683 million, i.e. 4.5% of its total revenues.Aurobindo reported profit after tax of US$ 23,647 million. Earnings per share (EPS) for the year was 40.36.The key reason for decline in EBITDA margin, Net profit margin and Return on Net Worth was due to increase in raw material prices and incremental competition in couple of big products. Interest coverage ratio declined due to increase in interest cost led by increase in LIBOR rate.

MARKET SHARE: With the addition of new businesses, product mix has evolved to be increasingly diverse. Over the preceding few years, there has been an increasing contribution of Injectables, Dietary Supplements and over the counter (OTC) products, to our US portfolio. Out of 164 ANDAs pending for approval as on 31stMar 2019, 48 ANDAs are for injectable products and 9 ANDAs are for OTC products. Going ahead, we are looking to add new products including nasals, inhalers, transdermal patches and topicals to our product mix.

Aurobindo's Market Share



Histogram-6: Market share.

LUPIN LIMITED

HISTORY: **Lupin Limited** is a multinational **pharmaceutical** company based in **Mumbai, Maharashtra, India.** It is the 12th-largest company by **market capitalization**, and the eighth-largest generic pharmaceutical company by revenue globally. The company's key focus areas include paediatrics, cardiovascular, anti-infectives, diabetology, asthma and anti-tuberculosis.

Lupin was founded in 1968 by Desh Bandhu Gupta, who was a professor of chemistry at BITS-Pilani, Rajasthan. Gupta moved to Mumbai in the 60s to work on his business enterprise for which initially he had initially borrowed Rs 5000 from his wife to fund his venture. Subsequent funding from Central Bank of India, the company was able to start their manufacturing facility for producing folic acid and iron tablets for Government of India mother and child health program. Later Lupin started manufacturing anti TB drugs which at one point formed 36% of the company sales and was considered as the largest TB drugs manufacturer in the world.

Figure-3: Lupin Limited.

PRODUCT: Lupin's market capitalization amounted to Rs. 77,115.19 crore on 15 June 2015. Its products and services may be categorized as: Branded Formulations, Advanced Drug Delivery Systems, Generics, Novel Drug Discovery, APIs, Biotechnology.

MISSION: Lupin's mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

RESEARCH & DEVELOPMENT: Lupin's research program covers the entire pharma product chain. The company's R&D program is headquartered in the Lupin Research Park located near Pune that houses over 1400 scientists. Lupin's R&D covers:

- Generics Research
- ✓ Process Research
- ✓ Pharmaceutical Research
- Advanced Drug Delivery Systems (ADDS) Research
- Intellectual Property Management
- Novel Drug Discovery and Development (NDDD)
- Biotechnology Research

STRATEGIES

Sustain and Grow our Strong Foundation

- continue to grow the overall business with a sharp focus on the US and India markets.
- continue to consolidate our leadership in the market, introduce new drugs and add more therapies.

Focus on Execution of Complex Generics

- Execution of Complex Generics pipeline will be critical to ensure that we continue to sustainably improve profitability. They have identified three focus areas, namely Inhalation, Biosimilars and Complex Injectables where they have built a robust product pipeline and continue to add more products.
- On the Inhalation front, they filed our first DPI in the US. They are the only Indian company to have filed a DPI as well as MDI in the US.

Build Specialty Business

On the Specialty front, focus has been on Women's Health in the US and opportunistically on Central Nervous System (CNS) in Europe as well as Japan. Solosec, branded Women's Health product in the US was launched towards end of May'18 and has seen a good build up with a top-notch commercial sales team. will continue to look at potential inorganic opportunities,

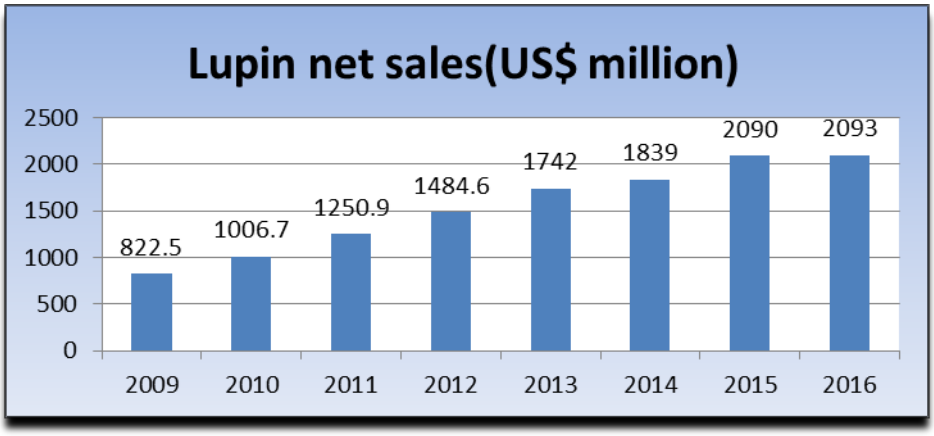
distribution partnerships to add more products and leverage the platform.

Focus on Cost Optimization

In FY2019, Lupin initiated a transformational journey to reshape the company for the future. We worked on sharpening our strategy for stronger growth, and shaping up for new challenges to ensure they are well positioned for future growth.

Regulatory Compliance

Regulatory compliance is a strategic priority, and they continue to remain committed on ensuring the highest standards on the quality and compliance front to ensure all global facilities remain compliant to applicable Good Manufacturing Practice (GMP) standards.



Histogram-7: Lupin sales.

FINANCIAL

- Lupin is a renowned pharma player producing a wide range of quality, affordable generic and branded formulations and APIs
- Lupin is the seventh largest generic pharmaceutical company globally in terms of market capitalisation
- Its revenues increased from US$ 822.5 million in FY09 to US$ 2.1 billion in FY16, at a CAGR of 14.3 per cent during FY09-16. The company had total revenues of Rs 38,696 million (US$ 600.3 million) in Q1 FY18 and Rs 40,260 million (US$ 626.23 million) in Q2 FY18.
- Advanced market formulations comprised nearly 46 per cent of its revenues in FY16.
- Lupin is 3rd largest drug manufacturer in India by sales
- In 2016, Lupin received USFDA nod for its generic version of Diclofenac capsules that are used for treating acute pain and osteoarthritis
- In February 2017, Lupin has received the final approval from USFDA to market potassium sulfate, sodium sulfate and magnesium sulfate oral solutions, which are used to treat a form of cancer.
- In March 2017, Lupin received an approval from United States Food and Drug Administration (US FDA) to market generic version of tobramycin inhalation solution 'Tobi', which is useful to treat cystic fibrosis patients along with P. aeruginosa. It has forayed into OTC segment with plans to touch Rs. 300 crore (US$ 46.34 million) turnover in the vertical over next 5 years.

DR. REDDY'S LABORATORY

HISTORY: **Dr. Reddy's Laboratories** is a multinational pharmaceutical company. The company was founded by Anji Reddy, who previously worked in the mentor institute **Indian Drugs and Pharmaceuticals Limited,** of **Hyderabad, India.** Dr. Reddy's manufactures and markets a wide range of pharmaceuticals in India and overseas. The company has over 190 medications, 60 **active pharmaceutical ingredients** (APIs) for drug manufacture, diagnostic kits, **critical care, & biotechnology** products.

Dr. Reddy's began as a supplier to Indian drug manufacturers, but it soon started exporting to other less-regulated markets that had the advantage of not having to spend time and money on a **manufacturing plant** that would gain approval from a drug licensing body such as the **U.S. Food and Drug Administration** (FDA). By the early 1990s, the expanded scale and profitability from these unregulated markets enabled the company to begin focusing on getting approval from drug regulators for their formulations and bulk drug manufacturing plants - in more-developed economies. This allowed their movement into regulated markets such as the US and Europe. In 2014, Dr. Reddy Laboratories was listed among 1200 of India's most trusted brands according to the Brand Trust Report 2014, a study conducted by Trust Research Advisory, a brand analytics company.

Figure-4: Dr Reddy's Laboratory.

MISSION: Their five promises clarify what they do, what they offer & commitments they make to their stakeholders. Their patients trust their medicines. They focus their energies on renewing this trust every day. As they keep the interests of their patients at the center of all that they do, their promises drive them to reach higher levels of excellence.

- Bringing expensive medicines within reach
- Addressing unmet patient needs
- Helping patients manage disease better
- Working with partners to help them succeed
- Enabling & helping their partners ensure that their medicines are available where needed.

PRODUCT

Global generics: Global generics are Dr. Reddy's biggest business driver. They offer more than 350 high-quality generic drugs.

Biologics: Their biosimilars, generic equivalents of the innovator's biologics, offer affordable yet equally effective alternatives.

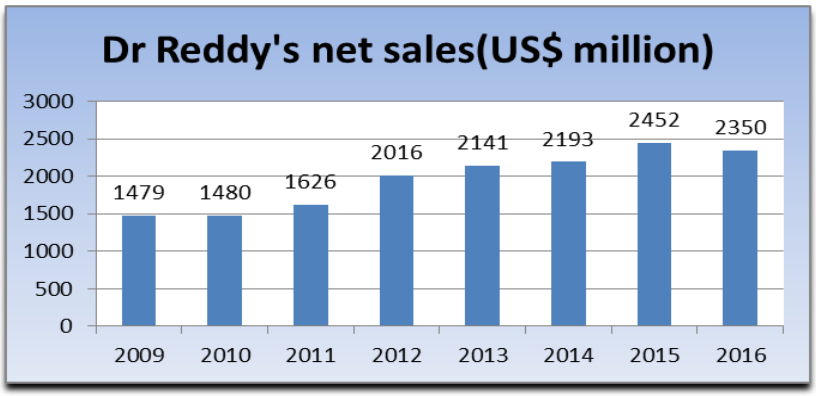
Active Pharmaceutical Ingredients: They are one of the world's largest manufacturers of Active Pharmaceuticals Ingredients (APIs) and partner with several leading generic formulator companies in bringing their molecules first to the market.

Proprietary Products: Their Proprietary Products business focuses on developing differentiated formulations that present significantly enhanced benefits in terms of efficacy, ease of use, and the resolution of unmet and under met patient needs.

RESEARCH & DEVELOPMENT: Targeting the streamlining of new product development processes, Dr. Reddy's implemented Project 'Rachna' using Microsoft Accelerator for Six Sigma. This is helping the company in taking key decisions to launch the right products in the market at the appropriate time. This has also enabled the company to quickly identify opportunities and develop new products catering to those requirements.

Dr Reddy's is investing heavily on R&D to differentiate itself in the market. In FY17 Dr Reddy's spent around **13.9 %** of sales on R&D. Dr Reddy's Laboratories is planning to spend upto **USD 300 million** on research and development (R&D) during this financial year (FY19-FY20).

FINANCIAL: The company's revenues increased from US$ 1.5 billion in FY09 to US$ 2.4 billion in FY16, at a CAGR of 6.84 per cent over FY09-16. In Q1 FY18, revenues reached Rs 33,159 million (US$ 514.4 million) and in Q2 FY18 revenues reached Rs 35,460 million (US$ 551.6 million).



Histogram-8: Dr Reddy's sales.

STRATEGIES

- The management is looking to expand in the U.S. from retail to hospitals, renal clinics and other unexplored channels.
- The management wants to break into the top 10 drug makers by sales in India from the current rank of 16. The management is confident that it will continue to maintain the double-digit growth seen in the recent past in India.
- The management is looking at cost containment as the quality issues have largely been taken care of.The management believes that the cost control impact will be visible in every quarter.
- There is focus on resource allocation and monetizing the biosimilars and proprietary products divisions.

SUN PHARMA

HISTORY: **Sun Pharmaceutical Industries Limited** is an Indian multinational pharmaceutical company headquartered in **Mumbai, Maharashtra,** that 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 **cardiology**, **psychiatry**, **neurology**, **gastroenterology** and **diabetology**. It also provides APIs such as **warfarin**, **carbamazepine**, **etodolac**, and **clorazepate**, as well as **anti-cancers**, **steroids**, **peptides**, **sex hormones**, and **controlled substances**.

Sun Pharmaceuticals was established by **Mr. Dilip Shanghvi** in 1983 in **Vapi, Gujarat**, with five products to treat **psychiatry** ailments. Cardiology products were introduced in 1987 followed by **gastroenterology** products in 1989. Today, it is the largest chronic prescription company in India and a market leader in **psychiatry**, neurology, cardiology, **orthopedics, ophthalmology**, gastroenterology and **nephrology.**

Figure-5: Sun Pharmaceuticals.

MISSION: The mission of Sun Pharmaceutical Limited is good health for all. They believe in utilizing the modern science to bring out essence of nature and provide effective & high-quality medicines at affordable price.

PRODUCTS: Formulations, Active Pharmaceutical Ingredients (APIs), Over-The-Counter (OTC), Antiretrovirals (ARVs).

STRATEGY

SEEK COST LEADERSHIP

Vertical integration: Developing through manufacturing (API & finished dosage) to marketing.
Optimize operational costs.

CREATE SUSTAINABLE REVENUE STREAMS

Focus: Chronic therapies
Differentiation: Technically complex products
Speed to market.

BALANCE PROFITABILITY & INVESTMENT FOR FUTURE

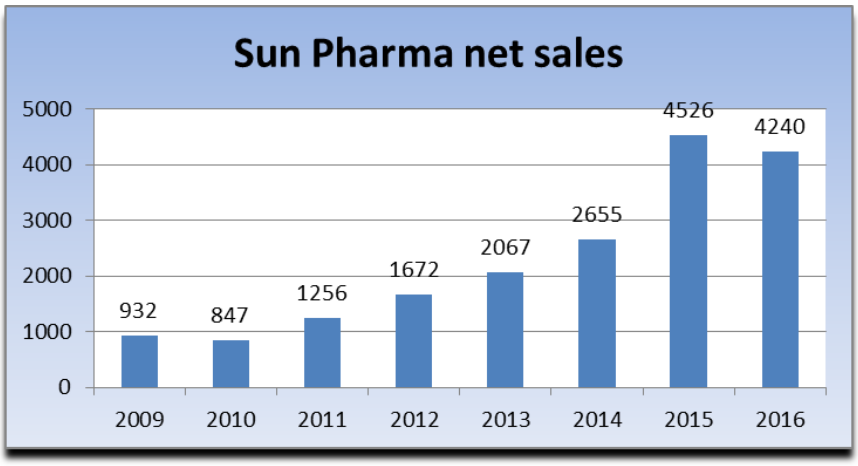
Acquisition yield high ROI
Development of complex generics.

RESEARCH & DEVELOPMENT: Sun pharma were pioneers among Indian pharmaceutical companies to see tremendous value in investing in research & development (R&D). Their early investments in R&D, beginning three decades ago, enabled company to make technology their key differentiator and develop a basket of robust products for diverse markets across the world. Three major points regarding research & developments are:

- Generic R&D spend around 7-8% of net sales
- Strong research teams in generics, finished dosage development, biological support, chemistry
- Sun pharma have around 2000 research scientists working in multiple R&D centers equipped with cutting-edge enabling technologies for research.

FINANCIAL

- It has 48 manufacturing facilities across 5 continents and employs more than 30,0000 people as on FY16
- Nearly 74 per cent of its sales came from international markets in 2016
- Revenues of Sun Pharma increased from US$ 932 million in FY09 to US$ 4.2 billion in FY16, witnessing growth at a CAGR of 24.16 per cent over FY09-16
- In March 2015, Sun Pharma completed the acquisition of Ranbaxy Laboratories Ltd to become the 5th largest global specialty pharma company, No 1 pharma company in India, and ensure a strong positioning in emerging markets
- The company reported net profit of US$ 335.8 million for the period July2016 - September 2016
- In October 2016, the company acquired 100 per cent equity in the US-based eye care specialist 'Ocular Technologies Sarl 'for US$ 40 million.
- The company earned Rs 12,757 crore (US$ 1.98 billion) in the first half of FY18.



Histogram 9: Sun Pharma sales.

RANBAXY

HISTORY: Ranbaxy Laboratories Limited (Ranbaxy), India's largest pharmaceutical company, is an integrated, research based, international pharmaceutical company, producing a wide range of quality, affordable generic medicines, trusted by healthcare professionals and patients across geographies. Ranbaxy today has a presence in 23 of the top 25 pharmaceutical markets of the world. The company has a global footprint in 46 countries, world-class manufacturing facilities in 7 countries and serves customers in over 125 countries. In June 2008, Ranbaxy entered into an alliance with one of the largest Japanese innovator companies, Daiichi Sankyo Company Ltd., to create an innovator and generic pharmaceutical powerhouse. The combined entity now ranks among the top 20 pharmaceutical companies, globally.

Figure-6: Ranbaxy Laboratories Limited.

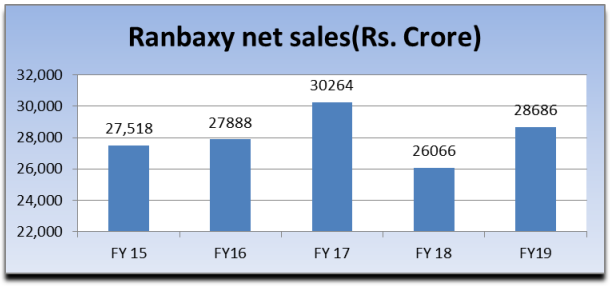
MISSION: Ranbaxy's mission is Enriching lives globally, with quality and affordable pharmaceuticals.

STRATEGY: Ranbaxy is focused on increasing the momentum in the generics business in its key markets through organic and inorganic growth routes. Growth is well spread across geographies with focus on developed and emerging markets. It is the Company‘s constant endeavor to provide a wide basket of generic and innovator products, leveraging the unique Hybrid Business Model with Daiichi Sankyo. The Company will also increasingly focus in high growth potential segments like Vaccines and Bio generics. These new areas will add significant depth to the existing product pipeline.

R&D: Ranbaxy views its R&D capabilities as a vital component of its business strategy that will provide a sustainable, long-term competitive advantage. The company has a pool of over 1,200 R&D personnel engaged in path-breaking research. Ranbaxy is among the few Indian pharmaceutical companies in India to have started its research program in the late 70's, in support of its global ambitions. A first of-its-kind world class R&D centre was commissioned in 1994. Today, the company has multi-disciplinary R&D centers at Gurgaon, in India, with dedicated facilities for generics research and innovative research. Ranbaxy’s first significant international success using the NDDS technology platform came in September 1999, when the Company out-licensed its first once-a-day formulation to a multinational company.

PRODUCTS: Using the finest R&D and Manufacturing facilities, Ranbaxy Laboratories Limited manufacture and markets generic pharmaceuticals, value added generic pharmaceuticals, branded generics, active Pharmaceuticals Ingredients (API) and intermediates. The company remains focused on ascending the value chain in the marketing of pharmaceutical substances and are determined to bring in increased revenues from dosage forms sales.

FINANCIALS: Ranbaxy was incorporated in 1961 and went public in 1973. For the year 2010, the Company recorded Global Sales of US $ 1868 Mn. The Company has a balanced mix of revenues from emerging and developed markets that contribute 50% and 44% respectively. In 2009, North America, the Company's largest market contributed sales of US$ 660 Mn, followed by Europe garnering US $ 272 Mn and Asia clocking sales of US $ 468 Mn.



Histogram-10: Ranbaxy sales.

GLAXO

HISTORY: Established in the year 1924 in India GlaxoSmithKline Pharmaceuticals Ltd. (GSK Rx India) is one of the oldest pharmaceuticals company and employs over 3500 people. Globally, they are a £ 28.4 billion, leading, research-based healthcare and pharmaceutical company. GSK is One of the market leaders in India with a turnover of Rs. 2572 crore and a share of 4.3%. The GSK mission is to improve the quality of life by enabling people to do more, feel better and live longer. This mission drives to make a real difference to the lives of millions of people with commitment to effective healthcare solutions.

The GSK India product portfolio includes prescription medicines and vaccines. The prescription medicines range across therapeutic areas such as anti-infectives, dermatology, gynaecology, diabetes, oncology, cardiovascular disease and respiratory diseases. The company is the market leader in most of the therapeutic categories in which it operates. GSK offers a range of vaccines, for the prevention of hepatitis A, hepatitis B, invasive disease caused by H, influenzae, chickenpox, diphtheria, pertussis, tetanus, rotavirus, cervical cancer and others.

Figure-7: GlaxoSmithKline.

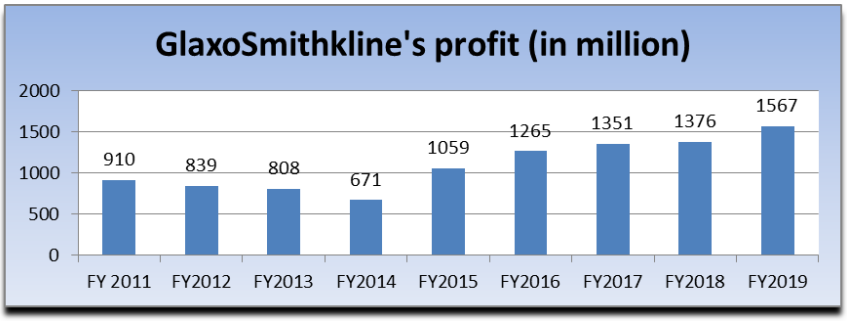
MISSION: GSK is committed to developing new and effective healthcare solutions. The values on which the group was founded have always inspired growth and will continue to do so in times to come.

PRODUCTS: The GSK India product portfolio includes prescription medicines and vaccines. Prescription medicines range across therapeutic areas such as anti-infectives, dermatology, gynecology, diabetes, cardiovascular disease and respiratory diseases. The company is the market leader in most of the therapeutic categories in which it operates. GSK also offers a range of vaccines, for the prevention of hepatitis A, hepatitis B, invasive disease caused by H, influenzae, chickenpox, diphtheria, pertussis, tetanus and others. Analgesic, Anti-Infective, Anti-inflammatory, Anti parasitic, Cardiovascular, Dermatology, Diabetes, Endocrine, Intestinal, Gynecology, Immunosuppressant, Nutritional, Respiratory, CNS, Oncology.

STRATEGY: That deal signified a **strategic** emphasis for **GSK** by focusing on higher-volume, lower-margin businesses of consumer healthcare and vaccines and selectively positioning itself in higher-margin, higher-risk pharmaceuticals only for certain therapeutic areas.

R&D: GSK India's R&D centres at Thane and Nashik have been granted recognition by the Department of Scientific and Industrial Research, Government of India. The number of clinical studies conducted in India is rapidly growing across a range of therapy areas. GSK India's social responsibility program focus on development of under developed villages, women, children and aged, specifically in the areas of healthcare and education.

FINANCIAL: In India, GSK is one of the market leaders with a turnover of Rs. 2572 crore and a share of 4.3 %. GSK leads in several therapeutic segments - dermatology, anti-helmentics, hormones. GSK has 7 products in the top 50 brands, and the top five GSK products are Augmentin, Calpol, Zinetac, Ceftum, and Betnesol. GSK's vaccines division is ranked first in a fast-growing vaccines market. Some leading products in India are Havrix, Varilrix, Rotarix, Hiberix and Cervarix.



Histogram-11: GlaxoSmithKline's Profit.

ZYDUS CADILA

HISTORY: Zydus Cadila, a leading Indian Pharmaceutical company is a fully integrated, global healthcare provider. With in-depth domain expertise in the field of healthcare, it has strong capabilities across the spectrum of the pharmaceutical value chain. From formulations to active pharmaceutical ingredients and animal healthcare products to wellness products, Zydus has earned a reputation amongst Indian pharmaceutical companies for providing comprehensive and complete healthcare solutions.

One of the salient features of Zydus is its rich history and lineage. The origin of the company dates all the way back to the 1950s. The company was founded in the year 1952 by Mr. Ramanbhai B. Patel (late), a first-generation entrepreneur and a doyen in the field of Indian Pharmaceuticals.

In 1995, the group was restructured and thus was formed Cadila Healthcare under the aegis of the Zydus group. From a humble turnover Rs. 250 crores in 1995 the group witnessed a significant financial growth and registered a turnover of over Rs. 12,700 crores in FY19.

Figure-8: Zydus Cadila.

Adhering to its brand promise of being dedicated to life in all its dimensions, Zydus continues to innovate with an unswerving focus to address the unmet healthcare needs. Simultaneously it rededicates itself to its mission of creating healthier, happier communities across the globe.

MISSION: Zydus Cadila is dedicated to life, in all its dimension. Our world is shaped by a passion for innovation, commitment to partners and concern for people in an affort to create healthier communities, globally.

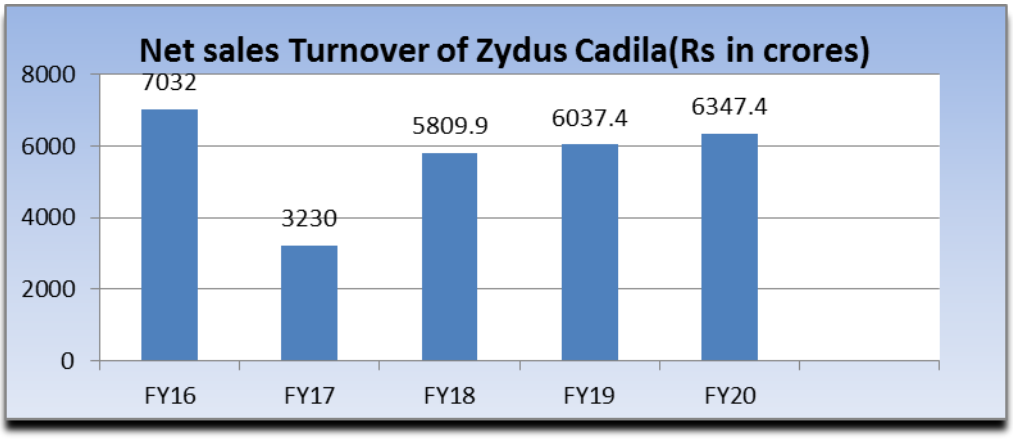
STRATEGY: **Zydus Cadila**, a group company of listed drug-maker **Cadila** Healthcare, is in preliminary talks with several **strategic** and private equity investors to sell two of its divisions — anti-infectives and gynecology — for about Rs 1,000-1,200 crore, seeking to lower debt and strengthen its balance sheet.

R&D: As a research-based pharmaceutical company, Zydus' Innovation programme is spearheaded by 1300 researchers across 19 sites, working on differentiated medicines for the future. From NCEs to vaccines, biosimilars and niche technologies, the group is exploring different ideas, concepts and continuously innovating.

PRODUCT

ZYDUS BIOLOGICS: Heptiza, Bionext, Ostivia, Oncosciences, Celexa, Ingenia, Occucare, NephroDialysis**,**etc. **ZYDUS GENERICS:** Product Name: Acefex Forte Tab, Acefex P Tab, ActivaMr Tab, Activa S Tab, Activa Gel, Alermed 120 Tab etc.

FINANCIAL



Histogram-12: Net sales Turnover of Zydus Cadila.

PIRAMAL

HISTORY: In the early 1980s, Ajay Piramal took over the reins of the Piramal. In 1984, the group acquired Gujarat Glass Limited, a manufacturer of glass packaging for pharmaceutical and cosmetic products, followed by Ceylon Glass in 1999. In 1988, the group bought Nicholas Laboratories, the company which later flourished and by 2010 reached the highest valuation in the pharmaceutical industry. Over the decade, the company acquired many business units to strengthen

their presence. In 2006, the company bought Pfizer's UK manufacturing facility, Morpeth.The company also formed Piramal foundation, a philanthropic arm of the group.

Figure 9: Piramal.

MISSION: To enhance value for **pharmaceutical companies** by being a trusted partner to reduce the burden of disease."

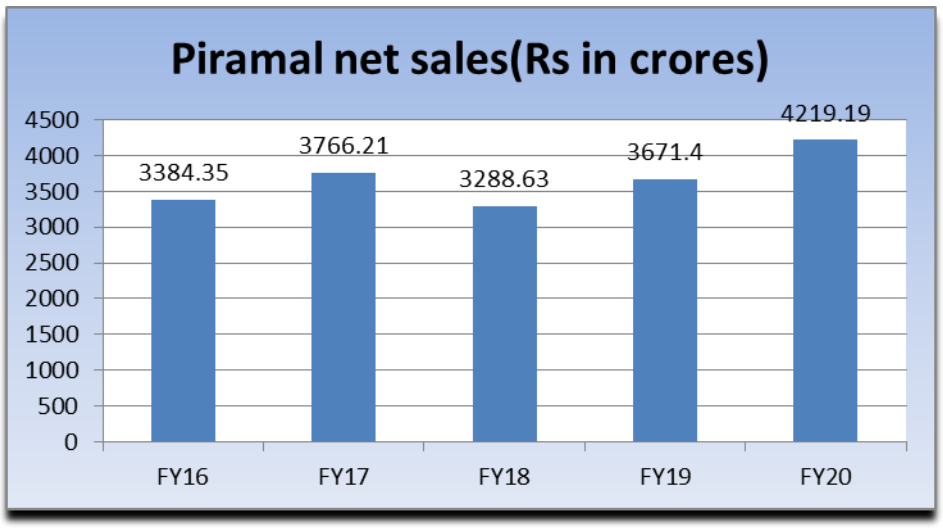
STRTEGY: In the three decades of its existence, **Piramal** Group has pursued a twin **strategy** of both organic and inorganic growth. Driven by its core values, **Piramal** Group steadfastly pursues inclusive growth, while adhering to ethical and values-driven practices.

R&D: We have an experienced team of over 80 scientists (with over 20 Ph.D.'s) dedicated to innovation in new product development, cost optimization, and novel route scouting projects. The R&D team develops novel/non-infringing process for APIs and is supported by a state-of-the-art, 'best in class', analytical research capabilities.

R & D capabilities include: Development of environmentally friendly processes

- Development of chiral APIs
- Ability to comply with ICH guidelines
- Synthesis, Isolation and characterization of impurities
- Expertise in handling pyrophoric reagent
- Expertise in cryogenic reactions (-40 to -100°C)
- Expertise in handling organometallic reactions

FINANCIAL



Histogram 13: Piramal net sales.

NOVARTIS

HISTORY: Novartis was created in 1996 through a merger of Ciba-Geigy and Sandoz. Novartis and its predecessor companies trace roots back more than 250 years, with a rich history of developing innovative products. From beginnings in the production of synthetic fabric dyes, the companies that eventually became Novartis branched out into producing chemicals and ultimately pharmaceuticals.

The history of Novartis traces the converging destinies of three companies: Geigy, a chemicals and dyes trading company founded in Basel, Switzerland in the middle of the 18th century; Ciba, which began producing dyes in 1859; and Sandoz, a chemical company founded in Basel in 1886.These companies shared a common trait which lives on at Novartis: a passion for developing and marketing new products that contribute to human progress through advances in science and health. Building on this heritage, today Novartis focuses its innovation prowess on addressing the unmet needs of patients worldwide.

Figure-10: Novartis.

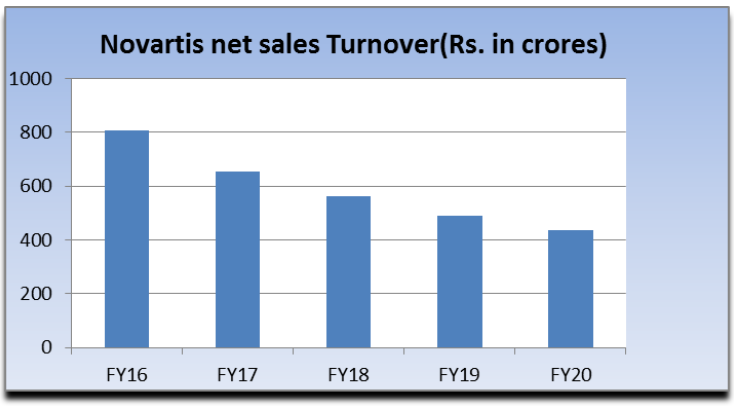
MISSION: At **Novartis**, their **mission** is to discover new ways to improve and extend people's lives. They use science-based innovation to address some of society's most challenging healthcare issues. They discover and develop breakthrough treatments and find new ways to deliver to as many people as possible.

STRATEGY: In their pursuit of transformative treatments, they challenge medical paradigms and explore possibilities to cure disease, intervene earlier in chronic illnesses, and find ways to dramatically improve quality of life.

R&D: Adaptive R&D is the modification of an existing medicine to improve therapeutic efficacy, safety, and access to medicine, and – most importantly – to generate a positive health outcome. Most often, this work is done with a specific focus on poor and vulnerable patient groups, such as children or the elderly. We systematically evaluate and execute adaptive R&D projects related to products in our existing portfolio. We also look for ways to expand the clinical use of existing medicines into new indications and populations.

We continue our longstanding commitment to reduce the burden of infectious and tropical diseases. The Novartis Institute for Tropical Diseases (NITD) is dedicated to finding new medicines for neglected diseases, and we continue to make strides against various **infectious diseases** including malaria, African sleeping sickness, leishmaniasis and Chagas disease.

FINANCIAL



Histogram 14: Novartis net sales Turnover.

RECENT TRENDS & STRATEGIES

NOTABLE TRENDS IN THE INDIAN PHARMACEUTICALS SECTOR

Research and development

- Indian pharma companies spend 8-13 per cent of their total turnover on R&D
- Expenditure on R&D is likely to increase due to the introduction of product patents; companies need to develop new drugs to boost sales

- ***Export revenue***
- India's pharmaceutical export market is thriving due to strong presence in the generics space
- Pharmaceuticals exports from India stood at US$ 16.64 billion in FY 2016-17.

Joint Ventures

- Multinational companies are collaborating with Indian pharma firms to develop new drugs
- Cipla formed an exclusive partnership with Serum Institute of India to sell vaccines in South Africa
- Six leading pharmaceutical companies have formed an alliance 'LAZOR' to share their best practices, so as to improve efficiency and reduce operating costs

Expansion by Indian players abroad

- Cipla, the largest supplier of anti-malarial drugs to Africa, set up a US$ 32 billion plant in Africa for the production of anti-retroviral and anti-malarial drugs.
- Mankind Pharma is planning to enter the US market and might start product filings in 2018.

PPP in R&D

- Indian Government invited multi-billion-dollar investment with 50 per cent public funding through its public private partnership (PPP)
- In April 2017, Clavita Pharma Pvt. Ltd., signed an MoU with GITAM University for research activities, exchange of visits between professionals of Clavita and GITAM University faculty, organize joint meetings and training programmes

Draft Patents (Amendment) Rules, 2015

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

Product Patents

- The introduction of product patents in India in 2005 gave a boost to the discovery of new drugs. India reiterated its commitment to IP protection following the introduction of product patents
- In December 2016, Suven Life Sciences was granted product patent for the treatment of neurodegenerative diseases

Less time for approval

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.

STATES HOSTING KEY PHARMACEUTICAL VENTURES

PUNJAB

Sun Pharma's API manufacturing facility at Toansa, Malanpur, Guwahati, Ankleshwar, Panoli, Ahmednagar, Maduramthakam.

HIMACHAL PRADESH

- Wockhardt's facility covers an area of 40,468 sq meters in Baddi, Himachal Pradesh.
- Baddi is also home to Cipla's formulations manufacturing facility.

DAMAN

Dholka in Gujarat houses a major manufacturing facility of Cadila, which spans over 100 acres.

MAHARASHTRA

Lupin has an USFDA-approved plant at Tarapur, Maharashtra. The facility forms the core of Lupin's fermentation capabilities

HIMACHAL PRADESH

- Wockhardt's facility covers an area of 40,468 sq meters in Baddi, Himachal Pradesh
- Baddi is also home to Cipla's formulations manufacturing facility

MADHYA PRADESH

- Mandideep in Madhya Pradesh is the manufacturing hub for Lupin's cephalosporin and ACE-Inhibitors
- Cipla has a formulations manufacturing plant at Indore

ANDHRA PRADESH

- Piramal's USFDA-approved manufacturing plant in Hyderabad
- GlaxoSmithKline has a major facility at Rajahmundry, Andhra Pradesh

STRATEGIES ADOPTED

Cost leadership: Sun Pharma is trying to achieve cost leadership by

Vertical Integration: Complex API, which require special skills and technology, are developed and scaled up for both API and dosage forms

Differentiation: Players in the sector are trying to strengthen their position in the market and expand themselves by investing heavily in R&D activities, such as:

- Dr Reddy's acquired OctoPlus N.V, a Netherlands-based company, to get access to the Poly Lactic-Co-Glycolic Acid (PLGA) technology for the formulation of complex injectables
- In January 2017, Piramal Enterprises acquired a portfolio of anti-spasticity and pain management

drugs from US based drug maker – Mallinckrodt, for US$ 203 million.

- In May 2017, Lupin has launched erectile dysfunction drug named as Cialis. The company has quoted the market worth for US$ 58.01 million in India. This tablet is available in 20 mg and 10 mg strengths

Focus on new markets

- Lupin is making inroads into new markets such as Latin America, Russia and other East European countries
- Sun Pharma decided to focus on specialty and chronic therapies such as neurology, oncology, dermatology segments
- In January 2017, a subsidiary of Biocon in Malaysia received an order to supply insulin worth US$ 68.42 million

Mergers and Acquisitions in Biotech

- As of October 2016, Advanced Enzyme Technologies, a biotech based firm in Mumbai signed an agreement with JC Biotech - Active Pharmaceutical Ingredient (API) maker in Hyderabad, to acquire 70 per cent stake in the company.
- In December 2017, Torrent Pharmaceuticals completed acquisition of branded business of Unichem

EXPORTS AND REVENUE THEREON

EXPORT

- Indian drug manufacturers currently export their products to more than 65 countries worldwide (Organisation of Pharmaceutical Producers of India, 2004). Their largest customer is the U.S., the world's biggest pharmaceutical market.
- India's pharmaceutical exports constitute almost 40% of total production of pharmaceuticals in India and valued at over USD 3.5 billions of which formulations and bulk drugs constitute 55% and 45% respectively (FICCI Report 2005).
- The export revenue now contributes almost half of the total revenue for the top 3-pharma majors: Dr Reddy's, Ranbaxy and Cipla (ibid).
- In 2006, India's pharmaceutical industry exported products worth EUR 3 bn, up from only EUR 650 mn in 1996, which was due to the fact that demand for lowcost generic drugs is strongly on the rise, above all in the US, Europe and Japan.
- At 22%, export growth in 2006 was even twice as high as the global average and in Germany (roughly 11% each). Meanwhile, India's export ratio has reached 32% – about double the figure registered ten years ago. For some time now, India has exported more pharmaceutical products than it imports.
- Over the last ten years, the export surplus has risen from about EUR 370 mn to currently just under EUR 2 bn.
- Over 60 percent of India's bulk drug production is exported. India's pharmaceutical exports are to the tune of Rs. 87 billion, of which formulations contribute nearly 55 per cent and the rest 45 per cent comes from bulk drugs. In financial year 2005, exports grew by 21 per cent.
- However, Espicom's market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at 11.6 billion USD by 2009. Domestic pharmaceutical exports, growing at 30 per cent per annum, touched a new height of 4.8 billion USD in the financial year 2006-07.
- The growth in drug exports, despite the pressing generic competition in the global markets, is attributed to increased Abbreviated New Drug Applications (ANDAs) approvals in the US market and contribution from unconventional markets in Latin America, Australia and the emerging markets in the Middle East and African Region.
- The export revenue now contributes almost half of the total revenue for the top three pharmaceutical majors Dr Reddy's, Ranbaxy and Cipla. The other major exporters are Wockhardt Limited, Sun Pharmaceutical Industries Ltd. and Lupin Laboratories.

REVENUE FROM EXPORT

- India accounts for less than two per cent of the world market for pharmaceuticals, with an estimated market value of 10.4 billion USD in 2007 at consumer prices, or around 9 USD per capita.
- India currently represents just 6 billion USD of the 550 billion USD global pharmaceutical industries but its share is increasing at 10 % a year, compared to 7 % annual growth for the world market overall. Also, while the Indian sector represents just 8 % of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 %by value, and its drug exports have been growing 30 % annually.
- Cipla, Nicholas Piramal, Ranbaxy, Zydus Cadila, Dr. Reddy's are the few Indian pharmaceutical companies, which are known at the global level due to their quality products.
- The Indian market for overthe-counter medicines (OTCs) is worth about 940 million USD and is growing 20 % a year, or double the rate for prescription medicines.
- The industry's exports were worth more than 3.75 billion USD in 2004-05 and they have been growing at a compound annual rate of 22.7 % over the last few years, according to the government's draft National Pharmaceuticals Policy for 2006, published in January 2006.
- The Policy estimates that, by the year 2010, the industry has the potential to achieve 22.40 billion USD in formulations, with bulk drug production going up from 1.79 billion USD to 5.60 billion USD Indian exports are to more than 200 countries around

the globe including highly regulate markets of US, Europe, Japan and Australia.

- More than 400 Bulk Drugs and about 60,000 Formulations (60 categories) are produced in India. Imports have registered a CAGR of only 2 % in the past 5 years. Import of bulk drugs have slowed down in the recent years.

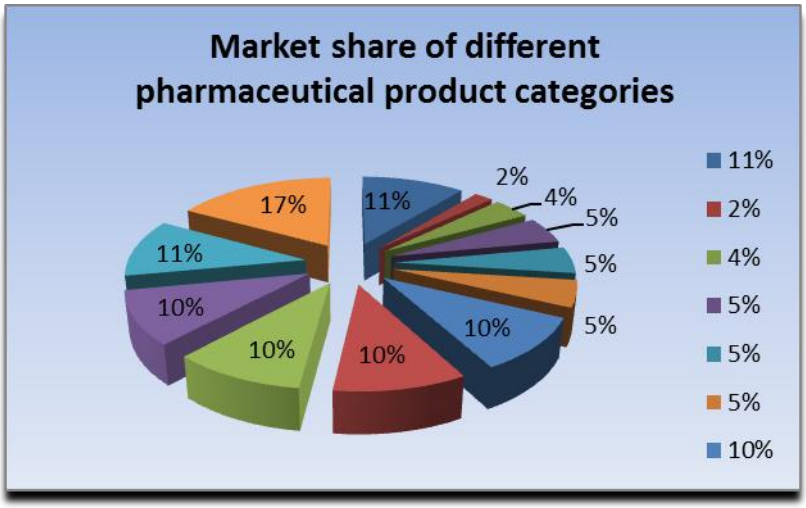
PRODUCT CATEGORIES AND MARKET SHARE

The pharmaceutical industry can be divided on the basis of therapeutic application and on the basis of foam. On the basis of application, the industry can be divided into therapeutic segments, while on the basis of foam; the industry can be divided into bulk drugs and formulations. On the basis of application, the key segments in the pharmaceuticals Industry are as under, however some of the therapeutic segment are overlapping because of multiple applications (ICRA Report 2002).

1. ***Anti-infective:*** (penicilium, sulphonamides Aminoglycosides tetracyclines, macrolides, cepholsporins, auinolonesetc) anti –parasites (anti-protozoa, antimalarias, anti-fungals, anti-helminticetc), anti-tuberculosis and vaccines.
2. ***Antipyretics and analgesics:*** pain killers, non steroidalanti inflammatory drugs (NSAIDs) and drugs for fevers.
3. ***Cardivascular (CVS) drugs:***cardiac therapy, anti-hypertensives and antihypotensives.
4. ***Central Nervous system (CNS) drugs:*** analgesics, psycoleptics, anti-epilepsy, tranquilisers and sedatives and anti-Parkinson's disease.
5. ***Dermatological preparations:*** topical corticosteroids, antiseptics and anti-fungals.
6. ***Gastrointestinals:*** antacids, anti-ulcerants, anti-helmintics, anti-flatulents and anti-diarrhoeals.
7. ***Genitourinary and sex hormones:*** corticosteroids, sex hormones and stimulants.
8. ***Haematologicals:*** anti-anaemic preparations.
9. ***Muscular Drugs:*** anti-inflammatory and anti-rheumatics.
10. ***Respiratory Drugs:*** cough and cold preparations, anti-asthmatics, antihistamines, rubs and anti-tuberculosis.
11. ***Other drugs:*** General nutrients, minerals and vitamins.

Market share of different pharmaceutical product categories

SL NO.	CATEGORY	VALUE(Rs. Bn.)	MARKET SHARE (%)
1.	Anti-infective	32.8	16.4
2	Gastro-intestinal	21.8	10.9
3.	Cardiac	20.7	10.3
4.	Respiratory	20.4	10.2
5.	Vitamins/minerals/nutrients	19.3	9.6
6.	Pain/ analgesic	19.1	9.5
7.	Dermatological	10.8	5.4
8.	Gynaecology	10.7	5.3
9.	Neuro psychiatry	10.6	5.3
10.	Anti-diabetics	8.8	4.4
11.	Opthologicals	3.5	1.7
12.	Others	22	11



Pie Chart-1: Market Share of pharma products

Growth

Growth drivers

Supply-side Drivers

- Cost advantage
- Skilled manpower
- India a major manufacturing hub for generics
- India accounts for 22 per cent of overall USFDA approved plants
- Increasing penetration of chemists

Demand-side Drivers

- Increasing fatal diseases
- Accessibility of drugs to greatly improve
- Increasing penetration of health insurance
- Growing number of stress-related diseases due to change in lifestyle
- Better diagnostic facilities

Policy support

- National Health Policy 2015, which focuses on increasing public expenditure on healthcare segment
- Reduction in approval time for new facilities
- Plans to set up new pharmaceutical education and research institutes
- Exemptions to drugs manufactured through indigenous R&D from price control under NPPP-2012.

GROWING RESEARCH & DEVELOPMENT:

- PwC estimates that India's 10 largest drug firms spent US$480 million on R&D in 2008. The bulk of this investment went towards developing new formulations, however R&D in the Indian pharmaceuticals industry is changing.
- The new patent regime means companies need to be more innovative, rather than relying solely on reverseengineering existing formulations. The reliance on anti-infectives is also likely to lessen. As already noted, as the illnesses of affluence and age increase, the demand for many other types of pharmaceuticals will rise, and Indian pharma companies needto begin transforming their portfolios accordingly.
- India has widely acknowledged chemistry skills. Several leading domestic producers have begun to conduct original research into new chemical entities and novel drug delivery systems.
- Amongst others, Ranbaxy has commenced phase-III clinical trials for its new anti-malarial combination drug. Other companies are looking to shift to clinical areas with a growth opportunity, such as diabetes.
- Piramal Life Sciences has initiated phase-I trials of a new experimental drug for diabetesmetabolic syndrome in Canada. DRL is conducting phase–III trials for its Type II diabetes drug.
- Despite Indian pharma companies' growing expertise in later stages of the R&D process, many of the drug candidates initially formulated in India are likely to be further developed by Western drug makers, because few Indian companies can afford the high costs and failure rates associated with pushing a drug right through the pipeline.
- Several Indian firms have already entered into research partnerships with multinationals; DRL and Torrent have joined forces with Novartis, for example, while Ranbaxy has formed alliances with GSK and Schwarz Pharmaceuticals. Glenmark has formed an alliance with Napo Pharmaceuticals and Piramal Healthcare has formed an alliance with Eli Lilly. By selling developing and licensing rights for the US, Japan and Western Europe, but retaining rights within emerging markets, some Indian pharmaceutical companies are able to gain immediate revenues, while retaining future access to India's growing domestic market.

CLINICAL TRIALS

- India's developing research skills are matched by its growing involvement in clinical testing. The country historically lacked the expertise to perform clinical trials because most companies only tested different processes for producing copycat versions of Western products and the rules were quite lenient.
- The Supreme Court and Drug Controller General of India (DCGI) have criticized a few India pharma companies for testing new drugs without getting patients' consent or for violating protocol.
- In January 2005, the federal Government amended Schedule Y of the Drugs and Cosmetics Act to make the rules on clinical trials more consistent with international practice.
- At present, though, the industry still lacks a strong regulatory framework. Good Laboratory Practices (GLP) certification remains a voluntary process, although most Indian pharma companies dealing with international clients or exporting to foreign regulated markets look to attain such certification.
- Expectations are already high; some observers expect the market could reach US$2 billion annually by 2012, up from just US$300 million in 2008.86 The strong anticipated growth reflects some of the attractions India holds for this market.

SUPPLY-SIDE DRIVERS OF INDIAN PHARMA SECTOR

- ***Reduction in approval time for new facilities:***Steps taken to reduce approval time for new facilities. NOC for export licence issued in two weeks compared to 12 weeks earlier
- ***Collaborations:*** MoUs with USFDA, WHO, Health Canada, etc. to boost growth in the Indian Pharma sector by benefiting from their expertise. In 2015, NIPER (Mohali) signed MoUs with pharmaceutical industry leaders Bharat Biotech, Dr Reddy, Cadila Healthcare, Sun Pharma and Panacea Biotech. In 2016, Strides Arcolab and US-based Gilead Sciences Inc. entered into a licensing agreement for manufacturing and distributing Gilead Sciences' cost-efficient Tenofovir, Alafenamide (TAF)

product in order to treat HIV patients in developing economies

- ***Support for technology upgrades and FDIs:*** Government is planning to relax FDI norms in the pharmaceutical sector In March 2017, the government to create a digital platform to regulate and track the sale of quality drugs, and it can be used by people living in the country as well as abroad
- ***Industry infrastructure:*** Under the Union Budget 2017-18, the government has announced to set up 1.5 lakh Health Care Centres and open 2 new AIIMS in Jharkhand and Gujarat. In 2016, the government has planned to set up 6 pharma parks at an investment of about US$ 27 million
- ***Pharma Vision 2020:*** Pharma Vision 2020 by the government's Department of Pharmaceuticals aims to make India a major hub for end-to-end drug discovery
- ***Exceptions:*** Full exemption from excise duty is being provided for HIV/AIDS drugs and diagnostic kits supplied under National AIDS Control Programme funded by the Global Fund to fight AIDS, TB and Malaria (GFATM). The customs duties on the said drugs are also being exempted
- ***Bulk Drug Parks:*** Government of India is planning to set up mega bulk drug parks in order to reduce industry's dependency on raw material imports.
- ***OTC drugs:*** A new category of over the counter (OTC)drugs has been given in-principle approval. The category includes muscle relaxants, decongestants, anti-inflammatory drugs, antacids, external preparations for skin and hormonal contraceptives.
- ***Online Pharmacies:*** Government of India is planning to set up an electronic platform to regulate online pharmacies under a new policy
- ***National Biopharma Mission:*** The Industry – Academia mission was launched in June 2017 to boost development of biopharmaceuticals in India.

SWOT Analysis Of Indian Pharmaceutical Industry

Strengths	Weaknesses	Opportunities	Threats
•Low cost of skilled manpower •Access to large pool of highly trained scientists •Strong marketing and distribution network •Proven track record in design of high technology manufacturing devices •Low cost of innovation, manufacturing and operations	•Stringent pricing regulations •Poor transport and medical infrastructure •Lack of data protection •Very competitive environment •Poor health insurance coverage •Production of low quality drugs tarnishes image of industry abroad •Low investment in innovative R&D	•Increase in per capita income •Global demand for generics rising •Increasing population with more sedentary lifestyle •Increasing health insurance sector •Significant investment from MNCs •Medical tourism •Cheap, diverse clinical trials •Global outsourcing hub due to low cost of	•Other low cost countries affecting demand •Government regulations changing •Expanding of Drugs Price Control Order •Lack of investment in infrastructure •Wage inflation •R&D restricted by lack of animal testing and outdated patient office •Counterfeiting threat

PATENT

The Pharma industry is one of the most intense "knowledge driven" sectors. Pharmaceutical research is very costly and unpredictable in nature. Outcome of the research can be in the form of a new, inventive and useful product or process. In this highly competitive market, it is imperative for the pharmaceutical companies to protect their inventions from any unauthorized commercial use by acquiring patent rights over the invented product or process.

TYPES OF PHARMACEUTICAL PATENTS IN INDIA

- Drug compound patents
- Formulation/ composition Patents
- Synergistic combination Patents
- Technology Patents
- Polymorph Patents
- Biotechnology patents
- Process patents

CRITERIA OF PATENTABILITY

Patents are granted to those inventions which satisfy certain conditions called as criteria of patentability. According to the Indian Patent Act, a patentable invention is defined as "a new product or process involving an inventive step and capable of industrial application". Therefore, following are the basic requirements for any invention to be patentable.

Newness: To be patentable the subject matter of the invention must not be known before the date of patent filing. An invention is considered new if it is not published in any document or not used in the country or elsewhere in the world.

Inventive Step: It is defined as the feature of an invention that involve technical advancement as compared to existing knowledge or having economic significance or both, that makes the invention not obvious to a person skilled in the art.

Industrial Applicability: The invention must be capable of being made or used in an industry.[7] For example, a new and inventive method of removing tumor cells from patient's body is industrially not applicable, thus can not be patented.

PATENT INFORMATION

- As it expands its core business, the industry is being forced to adapt its business model to recent changes in the operating environment. The first and most significant change was the January 1, 2005 enactment of an amendment to India's patent law that reinstated product patents for the first time since 1972.
- The legislation took effect on the deadline set by the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years.
- Under this new law, India will be forced to recognize not only new patents but also any patents filed after January 1, 1995.
- Indian companies achieved their status in the domestic market by breaking these product patents, and it is estimated that within the next few years, they will lose 650 million USD of the local generics market to rightful patent-holders.
- The multinationals narrowed their focus onto high-end patients who make up only 12% of the market, taking advantage of their newly-bestowed patent protection.
- Meanwhile, Indian firms have chosen to take their existing product portfolios and target semi-urban and rural populations.
- These transactions provide Indian companies with access to foreign markets and facilitate the process of seeking regulatory approval for new products, which can be quite daunting for a company that only has operations on Indian soil.

THE INDIAN PHARMA INDUSTRY- THE WAY FORWARD

VISION 2030–DEFINING THE GROWTH

The Indian pharmaceutical industry is poised for growth. Even at current rates of seven to eight percent CAGR, the industry's annual revenues can grow to about USD 80 to 90 billion by 2030. However, it could also set bold aspirations of eleven to twelve percent CAGR, and grow to annual revenues of about ~USD 65 billion by 2024 and about ~USD 120 to 130 billion by 2030.

Industry can work towards four primary goals as part of this vision for 2030.

Accelerate the goal of universal health care across India and the world by providing access to high-quality affordable drugs: Keeping in line with the Government of India's vision of providing universal healthcare for India, the industry can support this goal by providing access to quality medicines at affordable prices. In India, as more and more patients come under treatment, this could help reduce the disease burden substantially. The aspiration could be to make the DALY (Disability Adjusted Life Years) in India and other emerging markets comparable to the developed economies such as the US and UK by 2030 (currently India's DALY is 72 percent higher than China's).

Emerge as an innovation leader to build a globally recognized position for India: We believe the industry can aspire to build a strong innovation pipeline (with three to five new molecular entities launched or in late clinical trial phases and 10–12 incremental innovation launches per year by 2030) and enhance Indian pharma's significance beyond generics, to biologics, new drug development and incremental innovations.

Become the world's largest and most reliable drug supplier and reach USD ~120-130 billion by 2030: The Indian pharmaceutical industry can aspire to become the world's largest supplier of drugs by volume. This can be achieved by establishing a leadership position in the US generics space, focusing on building one to two 'home' markets outside India, and developing a strong presence in all large markets such as Japan and China. *f*

Contribute significantly to the growth of the Indian economy: The Indian pharmaceutical industry can contribute substantially to the growth of the Indian

economy. The industry can aspire to push the net foreign exchange earnings to around USD 30 billion to 40 billion annually by 2030 from current levels of ~USD 11 billion. The industry can also create one to two million16 additional jobs for the country in the same period, boosting consumption in the local economy.

OPPORTUNITIES & CHALLENGES FOR ACHIEVING VISION 2030

The Indian pharmaceutical industry's success has been built on the foundations of its distinctive capabilities in key areas of the value chain, such as manufacturing, product development and process innovation. Recently, the industry has been facing headwinds both domestically, and in key global markets (like the US) which have subdued its growth to the existing CAGR of seven to eight percent. Nonetheless, many opportunities still exist across new geographies and product classes for Indian pharmaceutical players to chart an accelerated growth path.

Opportunities

- Supporting state-sponsored health coverage programs and a focus on chronic healthcare could enable universal drug access
- Capitalizing on its rich demographic dividend – India has a large skilled, yet cost-efficient workforce
- Leveraging the patent cliff, with drug sales worth USD 251 billion going off-patent
- A footprint in underpenetrated international markets could increase exports
- Leverage India's strengths in IT and ITES – optimize new avenues such as OTC

Challenges

- India is yet to achieve universal healthcare access
- Lack of a stable pricing and policy environment favourable for long-term investment decisions
- Dependence on external markets for intermediates and APIs
- Dependence on external markets for intermediates and APIs
- Indian pharma's eroding competitive advantage in the US generics market and limited presence in other markets and products
- Increased scrutiny in quality compliance when supplying to international markets

ACTION NEEDED TO ACHIEVE VISION 2030

The Indian government and its regulatory bodies have a bigger-than-ever role to play in driving the next wave of growth for the pharmaceutical industry. Enabling policies and a supportive ecosystem would help the industry achieve Vision 2030. The government has already launched some initiatives that could strengthen the industry:

- Increased budgetary allocations for healthcare to boost the domestic market
- Increased focus on attracting pharma investment

Accelerate universal healthcare access by strengthening the healthcare infrastructure and using digital technologies

The government could consider taking initiatives along two axes – creating primary healthcare infrastructure and making healthcare facilities affordable to the public.

- **Provide infrastructural and investment support:** Investments are needed to bring India's doctor-patient ratio in line with WHO's global benchmark49. To increase supply of doctors, the government could consider upgrading district hospitals into medical colleges. Further, the use of digital/remote consultation facilities can ensure increased utilization of these doctors. Today, less than 10 percent of India's more than 26,000 Primary Healthcare Centres have telemedicine facilities.
- **Empower citizens to bear the costs of medical care:** by expediting the implementation of universal health coverage. Ayushman Bharat can bring 40 percent of the marginalized population under state-funded insurance cover. All intended beneficiaries can be adequately covered by ensuring implementation across hospitals.

Create a stable and supportive regulatory environment for the industry

Two areas where regulatory interventions can aid the growth of the industry are:

- Reducing the uncertainty around pricing
- Simplifying the regulatory approval processes

Explore the creation of an independent Ministry for Pharmaceuticals

To protect and promote the industry's interest, the government could set up a dedicated Union Ministry of Pharmaceuticals.With an independent secretariat, the ministry may be able to simplify policy making and expediate investment approvals.

Focus on API manufacturing to reduce the reliance on imports:

- Constructing large dedicated zones and leasing them to private players for operating manufacturing plants. Geographically, such SEZs could ideally be situated next to ports (for easy global trade) and away from densely populated areas
- Extending pre-approval of environmental clearance and easing other regulatory clearances (like simplifying the license renewal process)
- Setting up common utilities such as solvent recovery and distillation plants, power and steam units, effluent treatment plants, warehousing, etc., to make smaller units economically viable in these zones
- Adopting innovative models for land acquisition and commercialization to minimize upfront capex investments for the industry. For example, leasing out land to the industry by charging minimal upfront costs followed by annual rent to recover land costs.

Promote innovation by creating a research ecosystem, and make India a life sciences innovation hub:

- Targeted regulatory and tax interventions by the government
- Support streamlined norms for clinical trials
- Support health-tech start-ups and create an investor-friendly environment for PE/VC players
- Creating anchor educational institutions known for cutting-edge research

Expand and consolidate global footprint and collaborate with international regulatory bodies:

- Strengthen the exchange of regulatory best-practices
- Work closely with the US FDA and other international regulatory bodies
- Communicate the contributions of Indian generics

OPPORTUNITIES FOR INDIA AS A GLOBAL SUPPLY DESTINATION

India's strong position as a pharma supplier rests on its ability to provide high quality medicines backed by strong innovation capabilities and a structural cost advantage.

The cost of manufacturing formulations in India remains 30-40 percent lower than other comparative manufacturing hubs such as China and Eastern Europe, notwithstanding low productivity levels. This is driven by lower labour costs vis-à-vis other geographies. Despite inflationary trends, India's labour cost advantage will sustain in the medium to long term, especially if Indian companies can improve productivity through operational excellence and digital initiatives.

The supply of local talent into the pharma industry (e.g., B.Pharm, M.Pharm, B.Sc.) is stronger than in countries such as China. Indian pharma companies are foraying into complex products (e.g., microspheres, liposomes, emulsions), building capabilities in R&D and the manufacturing of these products while still ensuring the required quality.

However, the industry is also facing several challenges in supplying to export markets, which must be addressed going forward.

- The increasing pricing pressure in the regulated market is squeezing margins and profitability. Key drivers include customer consolidation, greater competition in commoditized, easy-to- manufacture products with increased ANDA approvals, and a slowdown in new launches.
- Another key challenge stems from compliance issues affecting the reliability of supply. While many Indian companies have fared well in regulatory audits over the last year and seem to be emerging out of remediation, others continue to face challenges.
- India continues to rely on imports of key starting materials, intermediates and API's for, China with the share of dependence increasing over time. This potentially exposes us to raw material supply disruptions and pricing volatility.
- There is an opportunity for India Pharma to drive growth by building on the cost advantage, and improving reliability of supply—major buying criteria for customers. Three priority areas thus emerge for Indian pharmaceutical companies:
- Build stronger quality systems and achieve full compliance
- Re-focus efforts on operational excellence
- Alternate sourcing and self-sufficiency in APIs / intermediates

These imperatives are inter-related—operational excellence is a strong enabler of quality and supply reliability. Analysis based on McKinsey's proprietary POBOS database of global pharmaceutical manufacturing sites shows that the sites with the best quality performance also often have the best operations performance.

CONCLUSION

Future of Pharmaceutical Industry: Competitive and technological changes in the pharmaceutical industry-from powerful new drug chemistries to innovative R&D partnerships and marketing plans-are reshaping the business strategies of many pharmaceutical and biotechnology companies.

Pharmaceutical venture: The Indian pharmaceutical industry has made no secret of its desire to globalize and eventually compete with its counterparts in Europe, Japan and the USA – as it has done in other industrial sectors. This is an ambitious aim because most of the Indian pharmaceutical industry's current success has been achieved in the area of generics rather than innovative new drugs, and its multinational competitors have decades more experience in global drug development and much greater financial power.

Incentives for R&D: The Indian pharmaceutical industry has long campaigned for better incentives from the government to help them rival foreign companies when it comes to carrying out innovative R&D. In 2003, the Indian Pharmaceutical Alliance (IPA), which represented 11 major domestic companies, submitted a pre-budget memorandum to the Indian government outlining the scope of the tax concessions that it wished to see. Their

proposals included tax concessions for conducting clinical trials abroad, research alliances with educational institutions and a system that would aid them in setting up the necessary basic R&D infrastructure for new operations.

Moving towards innovation: Judging by the total levels of R&D investment, there are signs that the R&D intensity of the Indian pharmaceutical industry is growing. The presence of low-cost production facilities and a large science base in India will help drive this trend over time.

Although innovative R&D remains a long-term ambition, in the near term, there is likely to be enhanced generic activity from Indian companies. This is because a number of high-profile drugs have come off patent and this has opened up an opportunity for various Indian companies to develop generic versions for sale in the US and European markets.

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