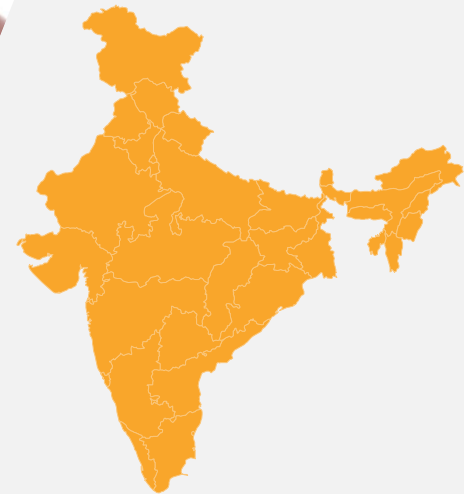


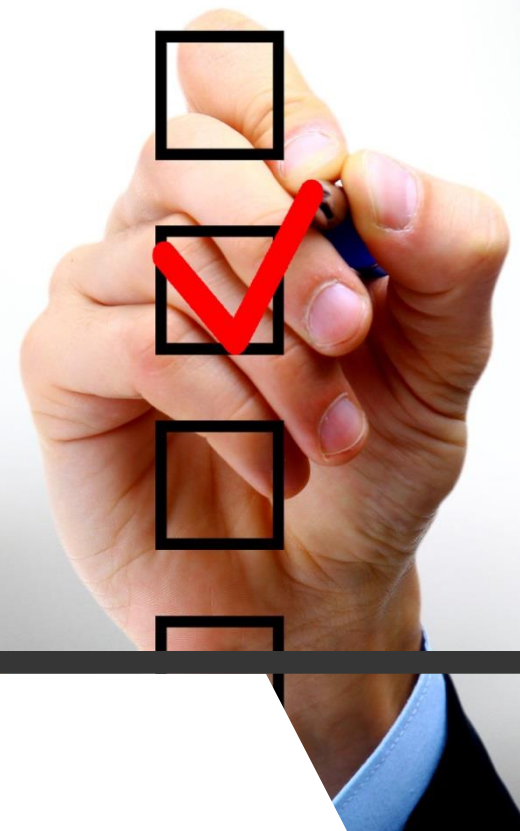


# PHARMACEUTICALS



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# EXECUTIVE SUMMARY

## Leading pharma producer

- Indian pharmaceutical sector is estimated to account for 3.1 – 3.6 per cent\* of the global pharmaceutical industry in value terms and 10 per cent in volume terms. It is expected to grow to US\$100 billion by 2025.

## One of the highest exports

- India accounts for 20 per cent of global exports in generics. India's pharmaceutical exports stood at US\$ 16.84 billion in 2016-17 and are expected to reach US\$ 20 billion by 2020. During April – November 2017, India exported pharmaceutical products worth Rs. 549.56 billion (US\$ 8.49 billion).

## Among fastest growing industries

- The country's pharmaceutical industry is expected to expand at a CAGR of 12.89 per cent over 2015–20 to reach US\$ 55 billion. India is the second largest contributor of global biotech and pharmaceutical workforce.

## Rapidly growing healthcare sector

- Indian healthcare sector, one of the fastest growing sectors, is expected to cross US\$ 372 billion by 2022.

## High potential generics market

- The generics market stood at US\$ 26.1 billion in 2016. India's generics market has immense potential for growth. Indian pharmaceutical companies received record 300 generic drug approvals in USA during 2017 where the generic market is expected to reach US\$ 88 billion by 2021.

## Robust growth in Biotech industry

- By 2024-25, India's biotech industry is estimated to increase to US\$ 100 billion from US\$ 11 billion in FY 2015-16.

*Notes: CAGR - Compound Annual Growth Rate, \* As of 2016*

*Source: India Biz, PWC, Department of Industrial Policy and Promotion, Deloitte, PharmaBiz, Frost and Sullivan Report on Indian Pharmaceutical Market, McKinsey, Make in India, DGC&S*

ADVANTAGE INDIA



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

## Cost Efficiency

- 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

## Economic Drivers

### ADVANTAGE INDIA

- Accounts for over 10 per cent of the global pharmaceutical production
- Over 60,000 generic brands across 60 therapeutic categories. Manufactures more than 500 different APIs
- More than half of all 345 drug master filings (DMFs) in the USA in Q4 2016 and Q1 2017 were from India.

## Diversified Portfolio

- Government unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacturing
- Reduced approval time for new facilities to boost investments
- In this sector, 100 per cent FDI is allowed under automatic route

## Policy Support

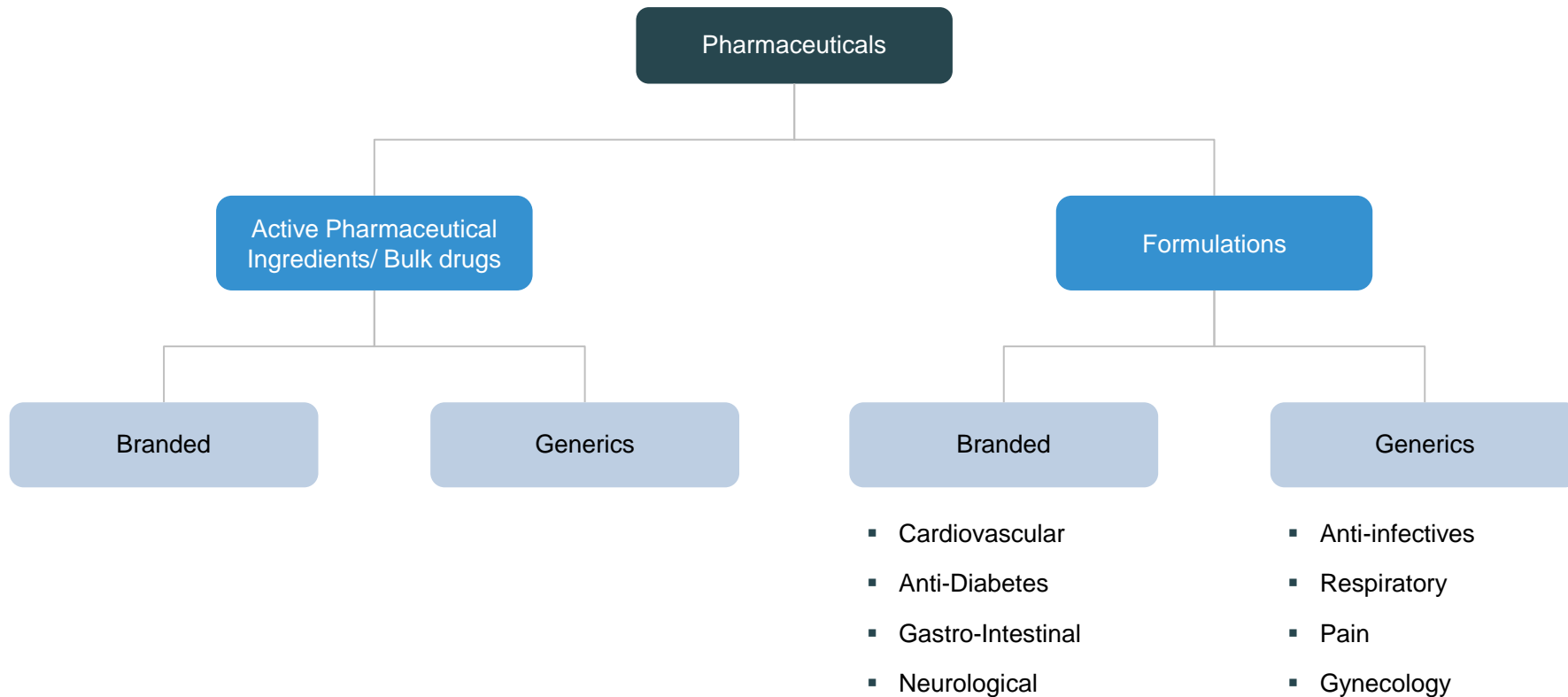
*Note: 2020 revenue forecasts are estimates of McKinsey, API - Active Pharmaceutical Ingredients, F – Forecast, OTC - Over-The-Counter*

*Source: PwC, McKinsey, Pharmaceuticals Exports Promotion Council of India*

# MARKET OVERVIEW



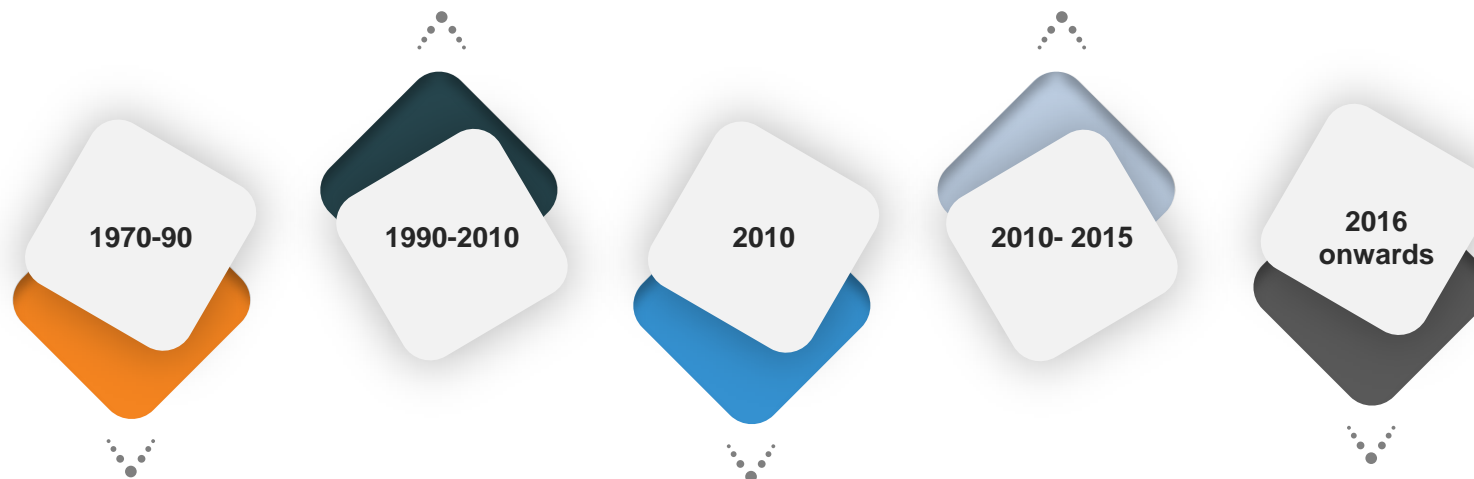
# STRUCTURE OF PHARMA SECTOR IN INDIA



Source: Dun and Bradstreet, Aranca Research

# EVOLUTION OF INDIAN PHARMACEUTICAL SECTOR

- Liberalised market
- Indian companies increasingly launch operations in foreign countries
- India a major destination for generic drug manufacturing
- Approval of Patents (Amendment) Act 2005, which led to adoption of product patents in India
- 2013: New Drug Pricing Control Order issued by Directorate of Food and Drugs this will reduce the prices of drugs by 80 per cent
- 2014: 100 per cent FDI allowed in medical device industry. The investment will be routed through automatic route
- Leading Indian pharma companies are raising funds aggressively to fund acquisition in domestic as well as international market to increase their product portfolios
- 2015: India has 10,500 manufacturing units and over 3,000 pharma companies
- National Health Policy Draft 2015 to increase expenditure in health care sector
- Patent Act Amendment 2015, it includes amendments in Patent Act 2002



- Indian Patent Act passed in 1970
- Several domestic companies start operations
- Development of production infrastructure
- Export initiatives taken

- Increased patent filings by pharma players
- Likely adoption of newer sales models such as channel management, KAM and CSO
- The National Pharmaceutical Pricing Policy, 2012 (NPPP-2012)

- In Union Budget, 2016, FDI increased to 74 per cent in existing pharmaceutical companies
- The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments.

*Notes: KAM - Key Account Management, CSO - Contract Sales Organisation*

*Source: Aranca Research*

## Active Pharmaceutical Ingredients (APIs)

- India became the third largest global generic API merchant market in 2016, with a 7.2 per cent 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

## Contract Research and Manufacturing Services (CRAMS)

- Fragmented market with more than 1,000 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 per cent between 2013-18

## Pharmaceutical industry

## Formulations

- Largest exporter of formulations in terms of volume, with 14 per cent market share and 12th in terms of export value. Drug formulation\* exports from India reached US\$ 9.57 billion during April – December 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

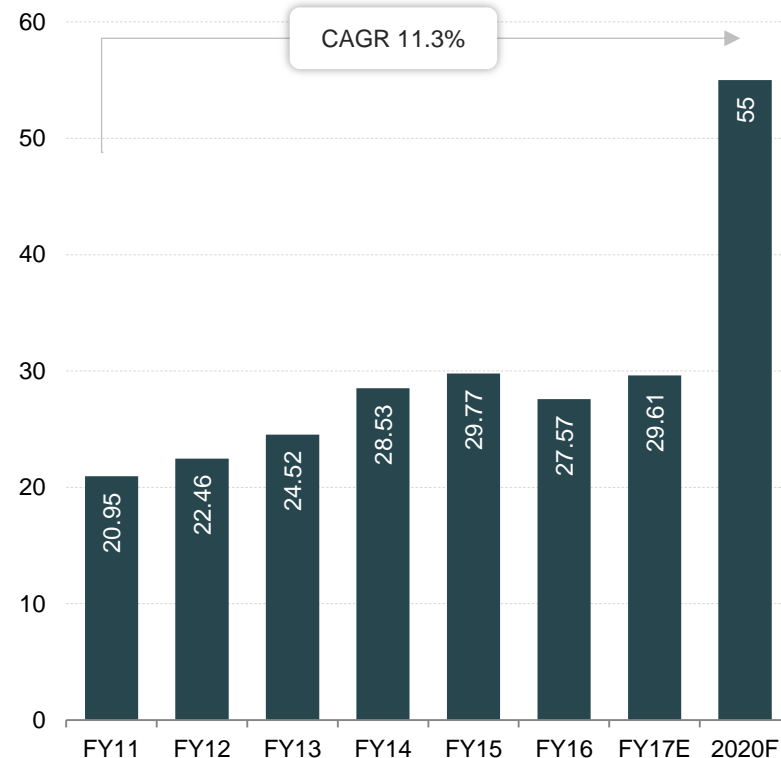
**Notes:** OTC - Over The Counter, \* including biologicals

**Source:** BMI, Datamonitor, Kemwell Biopharma, Chemical Pharmaceutical Generic Association, ICRA Report estimates, pharmanewsprwire.com, DGCI&S

# 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.
- Indian pharmaceutical market grew 5.5 per cent in CY2017 in terms of moving annual turnover.
- 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.
- Medicine sales in India increased 8.1 per cent year-on-year in November 2017.

Revenue of Indian pharmaceutical sector (US\$ billion)



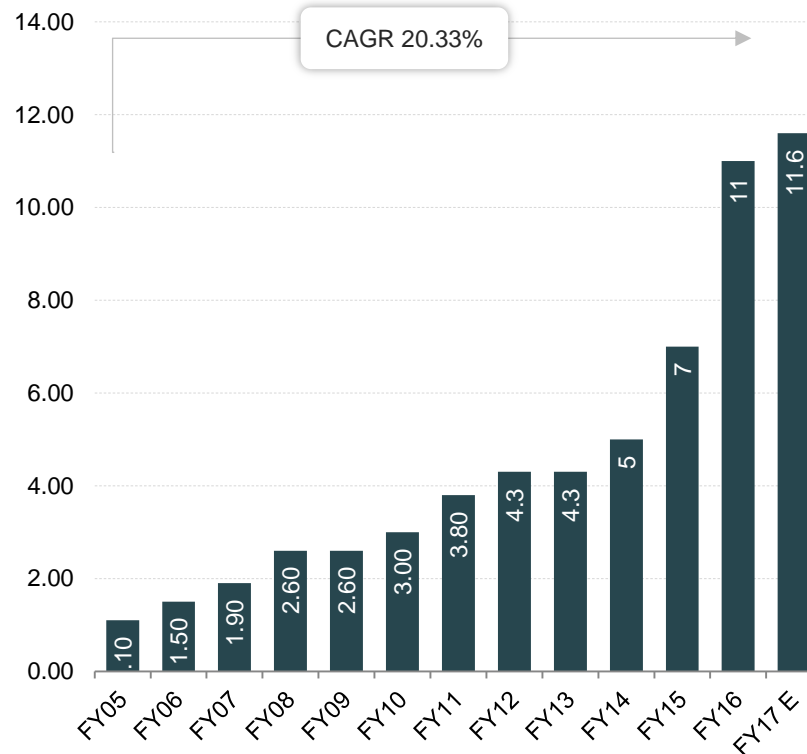
*Note: F - Forecast, CAGR - Compound Annual Growth Rate, CY - Calendar Year*

*Source: Department of Pharmaceuticals, PwC, McKinsey, AIOCD AWACS*

# ROBUST GROWTH IN BIOTECH INDUSTRY

- Growing at a faster pace, in comparison with the previous years, the Indian biotech industry witnessed YoY growth of 57.14 per cent in FY16; the total industry size stood at US\$ 11 billion by FY16 and is estimated to have reached US\$ 11.6 billion in FY17
- Fast-paced growth is likely to continue; the industry is driven by a range of factors such as growing demand, intensive R&D activities and strong government initiatives
- The Indian biotech industry comprises of around 800 companies. In order to achieve market size of US\$ 100 billion by 2025, the industry has requested Government of India to invest US\$ 5 billion to initiate research activities and develop infrastructure as well as human capital.
- Clinical capabilities are developing fast and the country is becoming a popular destination for clinical trials, contract research & manufacturing activities
- India biotech start-ups attracted investments worth US\$ 2.8 billion between 2012 and February 2017.
- Indian bioeconomy, which includes biopharma, bioagri, IT services, biofuels and bioservices were estimated at US\$ 35.1 billion in 2016.

Market Size of Biotech Industry (US\$ billion)



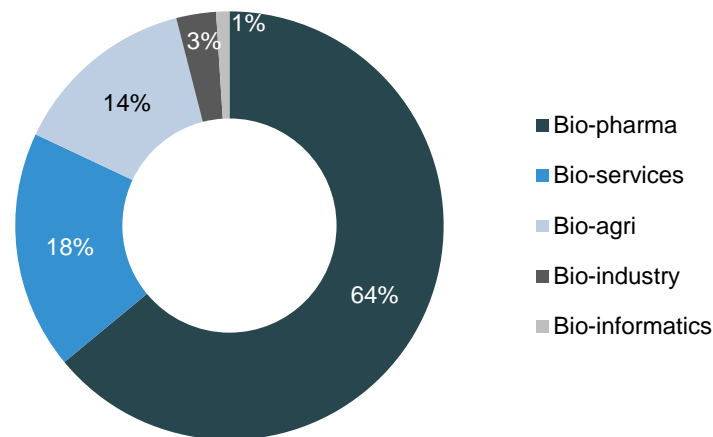
**Note:** CAGR - Compound Annual Growth Rate, FY16: As of April 2016., F-Forecast

**Source:** ABLE - Biospectrum Industry Survey, Makeinindia, Ministry of External Affairs, Aranca Research, Global Industry Analysts Report (GIA)

# BIO-PHARMA ACCOUNTS FOR MAJORITY MARKET SHARE AND WITNESSES FASTEST GROWTH IN FY16

- The bio-pharmaceutical segment accounted for largest revenue share of 64 per cent in India biotech industry, during FY16.
- India is becoming a leading destination for clinical trials, contract research & manufacturing activities which is leading to the growth of bio services sector
- In FY16\*, the bio-services & bio-agri segments accounted for 18 per cent & 14 per cent of the biotech industry, respectively
- Serum Institute of India is the largest biopharma company in the country and accounts for approximately 22 per cent of biopharma market
- In May 2017, the Department of Biotechnology held a strategy meet in Delhi to discuss the future scenario of the Biotechnology industry in the country. The meet highlighted the aim of reaching US\$100 billion mark by 2025, research and development of cutting edge technologies and other important aspects.

Market break-up by revenues (FY 16\*)



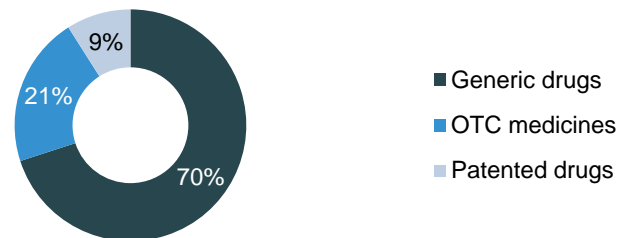
Source: \* Information is as per latest available data

Source: ASSOCHAM, Makeinindia, Aranca Research

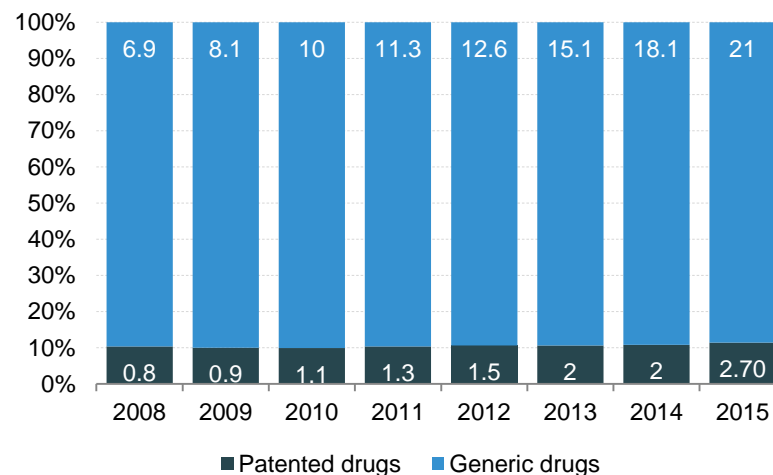
# GENERIC DRUGS FORM THE LARGEST SEGMENT OF INDIAN PHARMA MARKET

- 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

## Revenue share of Indian pharmaceutical sub-segments in 2015



## Share of patented and generic drugs in prescribed drug market (US\$ billion)



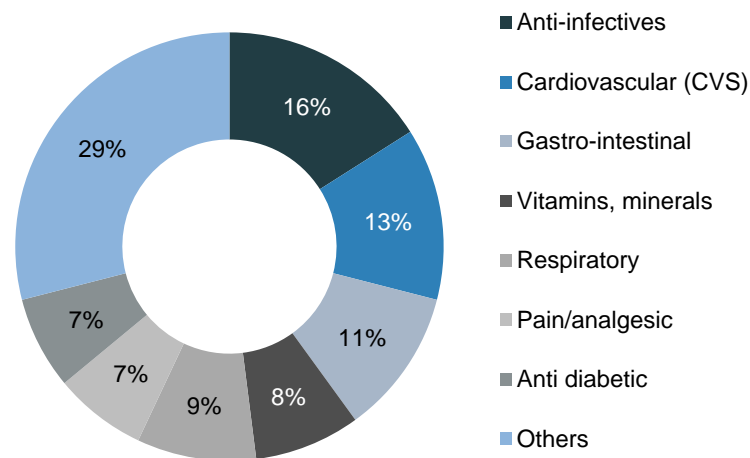
*Note: Figures are as per latest available data*

*Source: Business Monitor International, FCCI Indian Pharma Summit 2014-15*

# ANTI-INFECTIVE DRUGS LEAD THE PHARMA MARKET

- Anti-infective drugs command the largest share (16 per cent) in the Indian pharma market
- The cardiovascular segment represents 13 per cent of the market share; its contribution is likely to rise due to the growing number of cardiac cases in India
- Gastro-intestinal contributes around 11 per cent of the total value of pharma industry in India. With increasing number of research in gastroenterology, segment is going to grow at significant pace in coming years
- Top five segments contribute nearly 57 per cent to the total drugs consumption

Indian pharmaceutical market segments by value (FY15\*)



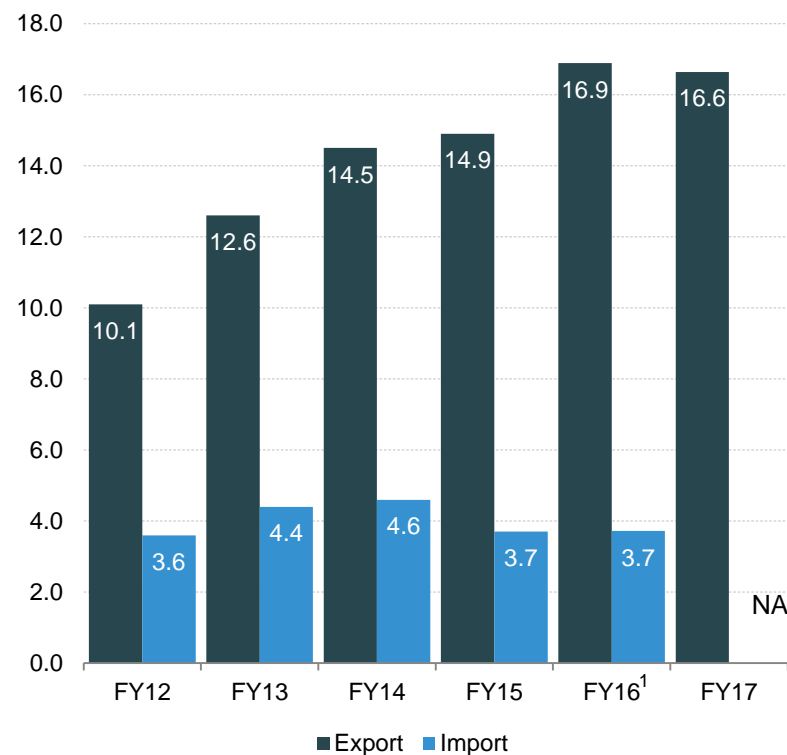
*Note: \*Figures are as per latest available data*

*Source: All Indian Origin Chemists and Distributors, Department of Pharmaceuticals*

# PHARMA EXPORT TO CONTINUE WITNESSING HIGH GROWTH

- Indian pharma companies are capitalising on export opportunities in regulated and semi-regulated markets
- In FY17, India exported pharmaceutical products worth US\$ 16.8 billion, with the number expected to reach US\$ 40 billion by 2020. During April – November 2017, India exported pharmaceutical products worth Rs. 549.56 billion (US\$ 8.49 billion).
- Indian drugs are exported to more than 200 countries in the world, with the US as the key market
- India is the world's largest provider of generic medicines; the country's generic drugs account for 20 per cent of global generic drug exports (in terms of volumes)
- Around 40.6 per cent of India's US\$ 16.8 billion pharmaceutical exports in 2016-17 were to the American continent, followed by a 19.7 per cent to Europe, 19.1 per cent to Africa and 18.8 per cent to Asian countries.

Trade data of Indian pharma sector (US\$ billion)



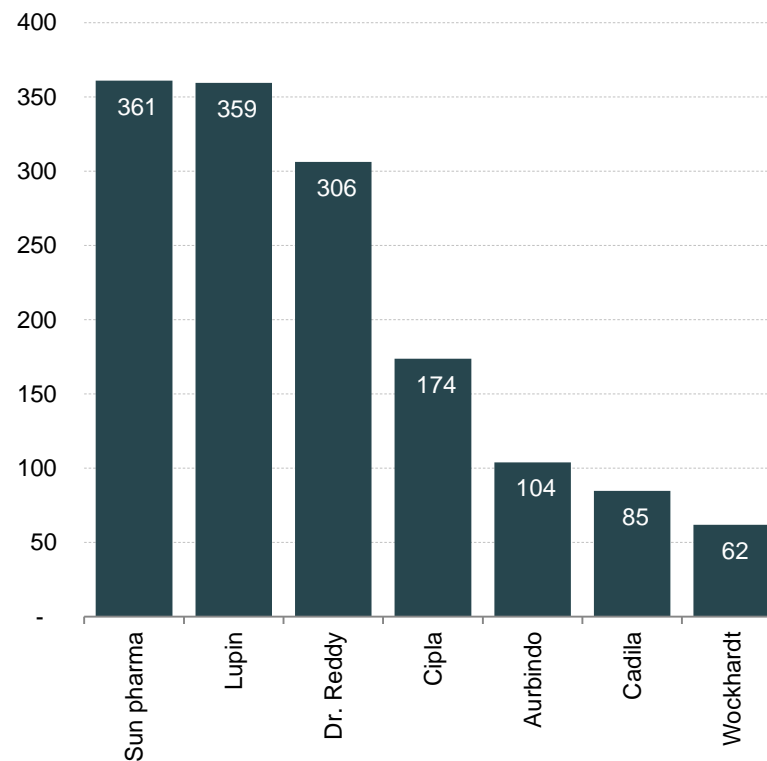
*Note: CAGR - Compound Annual Growth Rate, 1 – Import from April 2015-December 2015.*

*Source: Department of Commerce India, Department of Pharmaceuticals, India Business News, BMI*

# PHARMA GIANTS RAISE THEIR R&D SPENDING

- In FY17, highest expenditure on research and development has been done by Sun Pharma, followed by Lupin
- Sun Pharma's R&D spending is 7.6 per cent of the total sales in the FY17, which grew at a CAGR of 38.3 per cent from FY11 to FY17.
- Sun Pharma's R&D plan includes developing more products through expanded R&D team for global markets, focussing on more complex products across multiple dosage forms and investments in speciality pipeline
- Lupin's R&D spending was 13.5 per cent of sales in FY17, with major thrust on oral solids (45 per cent of R&D spend)

R&D spending by top six pharma companies FY17 (US\$ million)



*Note: R&D - Research and Development 1 – Data is up to Dec 2015, 2 – Data is up to September 2015, 3 - Data is for FY15*

*Source: Company websites*

# Porter's Five Forces Framework Analysis

## Threat of Substitutes ●

- Threat to substitute products is low; however, homeopathy and Ayurvedic medicines can act as substitute

## Bargaining Power of Suppliers ●

- Difficult-to-manufacture APIs such as steroids, sex hormones and peptides give bargaining power to suppliers. However, generic APIs do not have much of that power

## Competitive Rivalry ●

- Growth opportunities for pharma companies are expected to grow in next few years, with many drugs going off-patent in the US and other countries, thus increasing competition
- Indian pharma companies will face competition from big companies, backed by huge financial muscle

## Bargaining Power of Buyers ●

- Generic drugs offer a cost-effective alternative to drugs innovators and significant savings to customers
- Biosimilars offer significant cost saving for insurance companies in India

## Threat of New Entrants ●

- Strict government regulations thwart entry of new players
- Difficult to survive because of high gestation period

- Positive Impact
- Neutral Impact
- Negative Impact

Source: Aranca Research

# RECENT TRENDS AND STRATEGIES



# NOTABLE TRENDS IN THE INDIAN PHARMACEUTICALS SECTOR ... (1/2)

## 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.

*Notes: R&D - Research and Development*

*Source: Aranca Research*

# NOTABLE TRENDS IN THE INDIAN PHARMACEUTICALS SECTOR ... (2/2)

## 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, organise 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

*Notes: R&D - Research and Development*

*Source: Aranca Research*

# NOTABLE TRENDS IN THE INDIAN BIOTECH SECTOR

## Remarkable global positioning

- India is among the top 12 biotech destinations in the world
- India ranks 2nd in Asia, after China
- India is the world's largest producer of recombinant Hepatitis B vaccine

## Pharma companies focusing on biotech

- Ranbaxy, Cadila Healthcare, Lupin, Wockhardt & Dr Reddy's are among the major Indian pharmaceutical companies operating in the bio-pharma segment

## Global companies setting up base

- US based DiabetOmics Inc., medical diagnostic company has raised US\$ 4 million from Ventureast & US\$1 million from KI Varaprasad Reddy for driving manufacturing & commercialisation activities in India.

## Biosimilars and molecular diagnostic remain strongholds

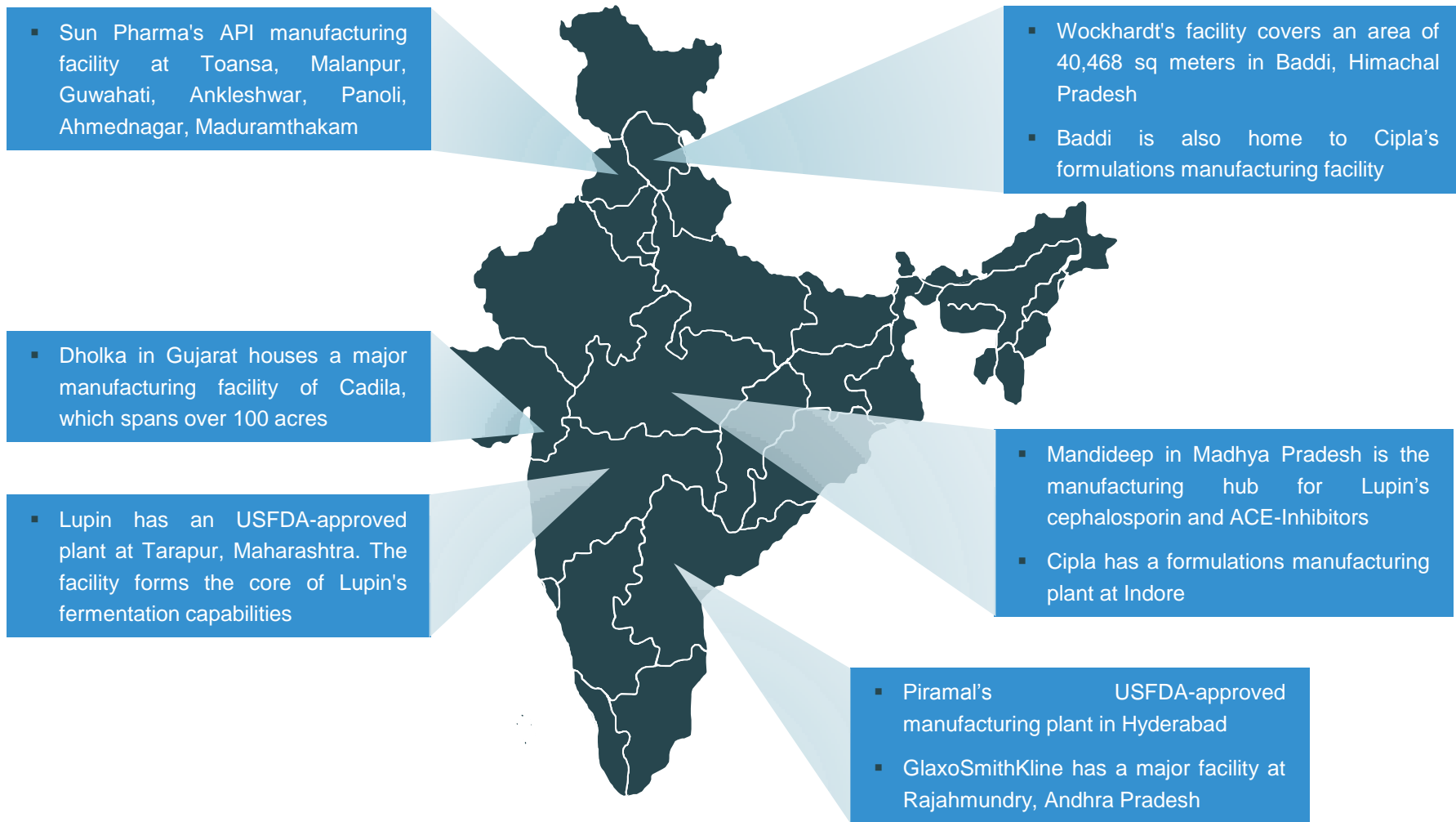
- Growth in the sector is anticipated to come from the country's strong position in biosimilars & molecular diagnostics as well as personalised medicine (where export & domestic trends look promising). In 2016, development of biosimilars has been speeding up via Glycosylation Control Technology.

## Growth in Genetically Modified crops

- According to International Service for the Acquisition of Agri-Biotech Applications, India has the 4th largest area covered under genetically modified crops
- In India, 11.57 million hectares of area is covered under genetically modified crops which is majorly dominated by Bt cotton.
- The bio agriculture industry in India can reach US\$ 34-37 billion size by 2025.

Source: Ministry of External Affairs, Accenture, Aranca Research

# STATES HOSTING KEY PHARMACEUTICAL VENTURES



Source: Company websites

# 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
- Companies like Dr Reddy's, Cipla and Wockhardt are planning their expansions in US\$ 100 billion China market in 2018.

## 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 Laboratories.

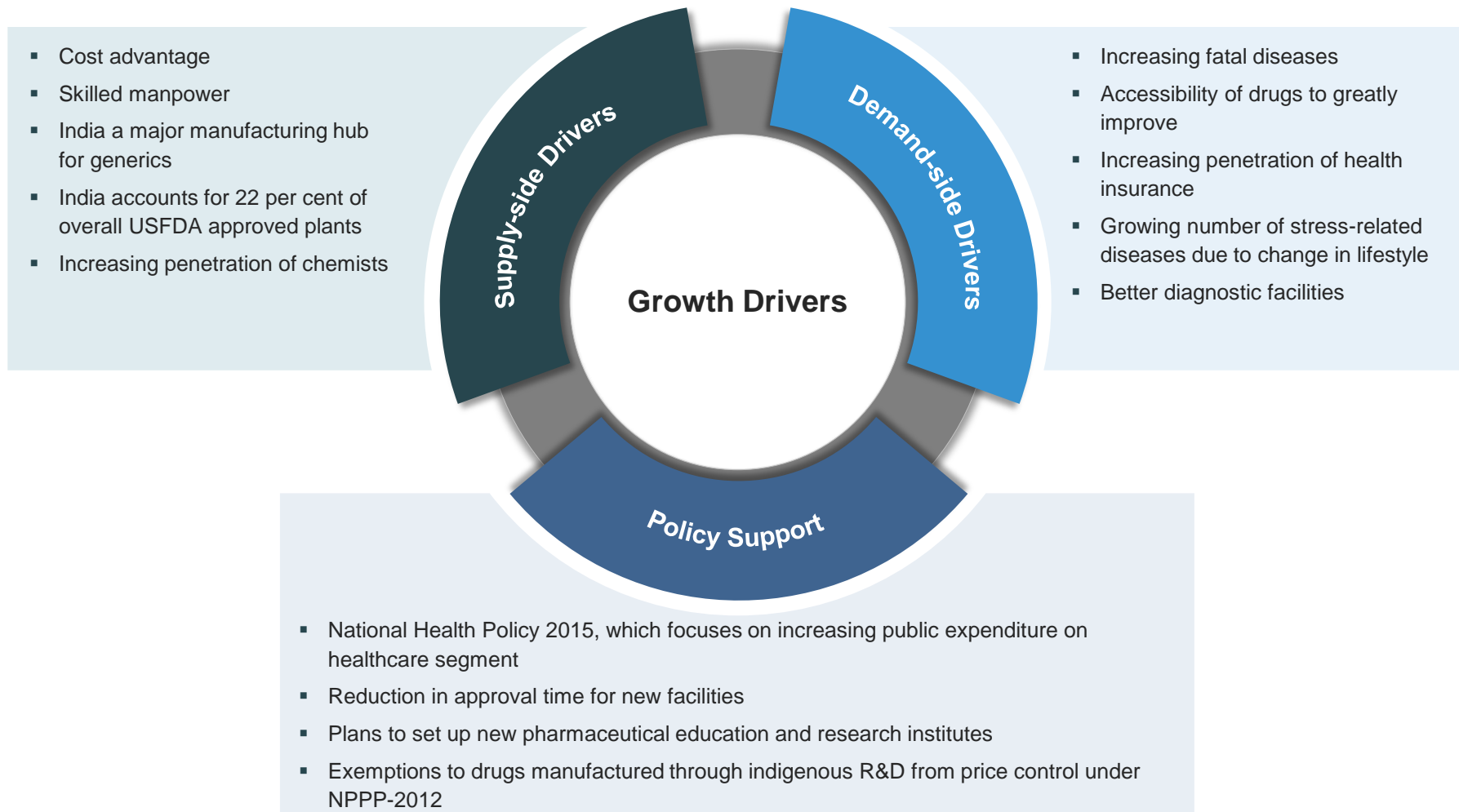
*Notes: R&D – Research and Development*

*Source: Company websites, Ministry of External Affairs, RBI*

# GROWTH DRIVERS



# SUPPLY-SIDE DRIVERS OF INDIAN PHARMA SECTOR



**Notes:** BPL - Below Poverty Line, USFDA - United States Food and Drug Administration, NPPP-2012--The National Pharmaceutical Pricing Policy, 2012

**Source:** Pharmaceutical Export Promotion Council

# SUPPLY-SIDE DRIVERS OF INDIAN PHARMA SECTOR

## Launch of patented drugs

- Following the introduction of product patents, several multinational companies are expected to launch patented drugs in India
- Growth in the number of lifestyle diseases in India could boost the sale of drugs in this segment
- High Court allowing to export patent drugs, to foreign players in the Indian market.

## Medical infrastructure

- Pharma companies have increased spending to tap rural markets and develop better medical infrastructure
- Hospitals' market size is expected to increase by US\$ 200 billion by 2024
- In October 2016, the government gave a nod to set up the country's first medical devices manufacturing park in Chennai

## Scope in generics market

- India's generic drugs account for 20 per cent of global exports in terms of volume, making it country the largest provider of generic medicines globally. The generics drug market accounts for around 70 per cent of the India pharmaceutical industry and it is expected to reach US\$ 27.9 billion by 2020

## Over-The-Counter (OTC) drugs

- India's OTC drugs market is expected to have grown at a CAGR of 16.3 per cent to US\$ 6.6 billion over 2008–16 and is further expected to grow on the account of increased penetration of chemists, especially in rural regions. Indian OTC market is expected to grow at a CAGR of 9 per cent from 2016-26 to cross Rs 44,115 crore (US\$ 6.81 billion).

## Patent Expiry

- About 120 drugs are expected to go off-patent over the next 10 years; with expected worldwide revenue between US\$ 80 to 250 billion

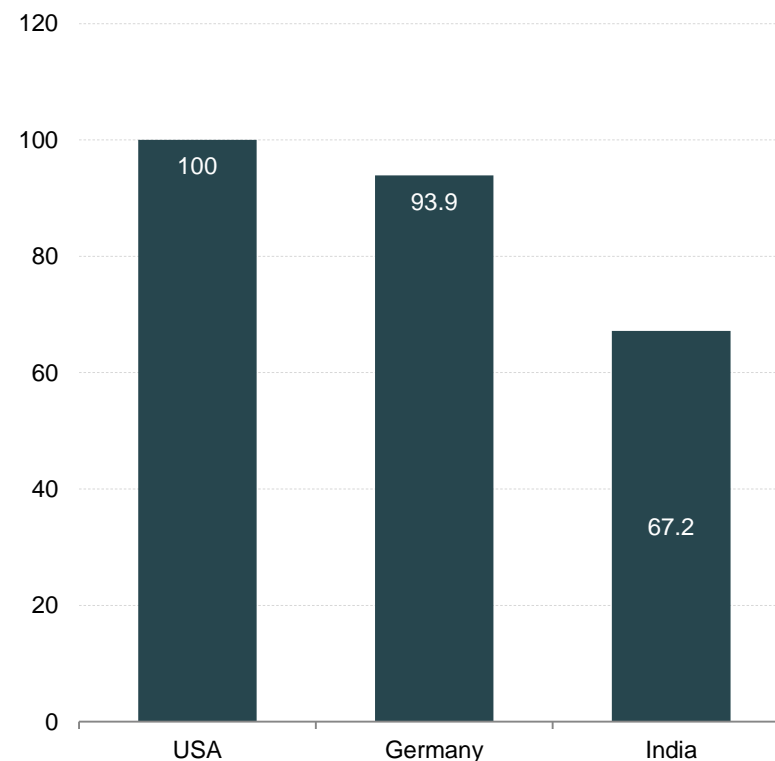
*Notes: CAGR - Compound Annual Growth Rate*

*Source: BMI, India Biz, Nicholas Hall & Company*

# COST EFFICIENCY AND COMPETENCY CONTINUE TO BE INDIA'S FORTE

- India's cost of production is nearly 33 per cent lower than that of the US
  - Labour costs are 50–55 per cent cheaper than in Western countries
  - The cost of setting up a production plant in India is 40 per cent lower than in Western countries
- Cost-efficiency continues to create opportunities for Indian companies in emerging markets and Africa
- India has a skilled workforce as well as high managerial and technical competence in comparison to its peers in Asia
- India has the 2nd largest number of USFDA-approved manufacturing plants outside the US
- India has 2,633 FDA-approved drug products
- India has over 546 USFDA-approved company sites, the highest number outside the US

Manufacturing Cost Index by Country, 2016



*Note: USFDA - United States Food and Drug Administration*

*Source: Deloitte, BMI, Financial Express*

# DEMAND DRIVERS OF INDIAN PHARMA SECTOR

## Accessibility

- Over US\$ 200 billion to be spent on medical infrastructure in the next decade
- New business models expected to penetrate tier-2 and 3 cities
- Over 160,000 hospital beds expected to be added each year in the next decade
- India's generic drugs account for 20 per cent of global exports in terms of volume, making the country the largest provider of generic medicines globally

## Acceptability

- Rising levels of education to increase acceptability of pharmaceuticals
- Patients to show greater propensity to self-medicate, boosting the OTC market
- Acceptance of biologics and preventive medicines to rise
- A skilled workforce as well as high managerial and technical competence
- Surge in medical tourism due to increased patient inflow from other countries

## Demand drivers

## Affordability

- Rising income could drive 73 million households to the middle class over the next 10 years
- Over 650 million people expected to be covered by health insurance by 2020
- Government-sponsored programmes set to provide health benefits to over 380 million BPL people by the end of 2017
- The government plans to provide free generic medicines to half the population at an estimated cost of US\$ 5.4 billion

## Epidemiological factors

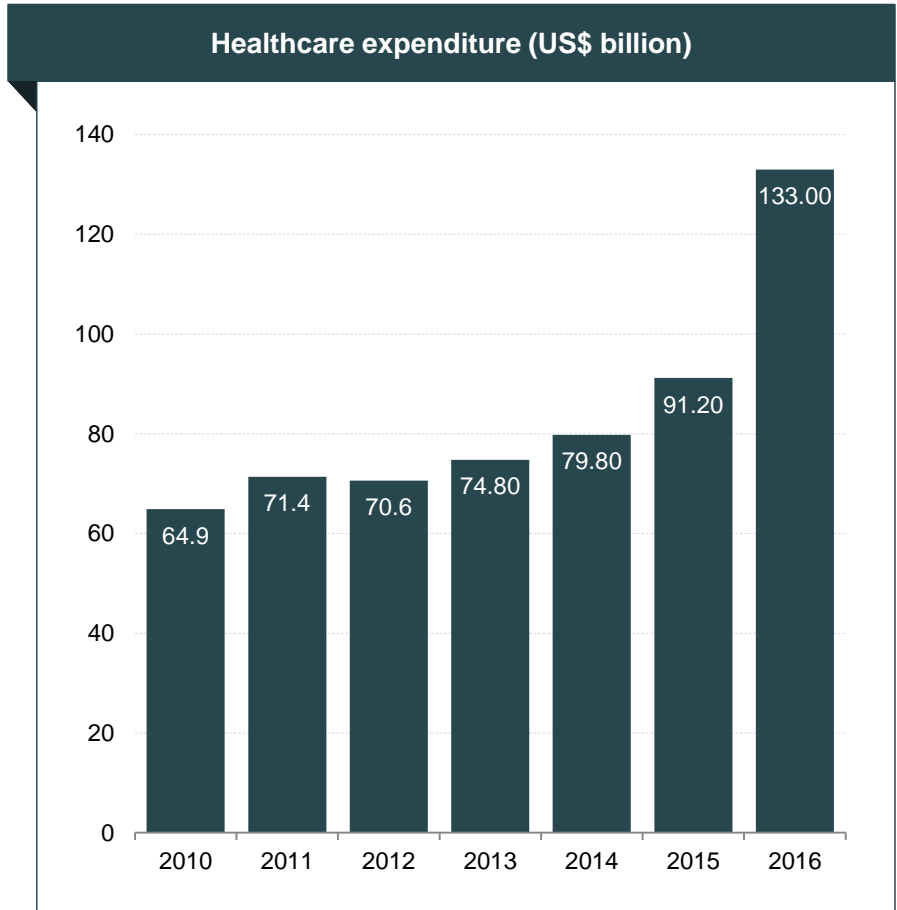
- Patient pool expected to increase over 20 per cent in the next 10 years, mainly due to rise in population
- New diseases and lifestyle changes to boost demand
- Increasing prevalence of lifestyle diseases

**Note:** RSBY - Rashtriya Swasthya Bima Yojna

**Source:** ICRA Report on Indian Pharmaceutical Sector, Pharmaceutical Industry: Developments in India- Deloitte, Mckinsey Pharma Report 2020

# ANTICIPATED STEEP GROWTH IN EXPENDITURE ON PHARMACEUTICALS

- During 2010-16, total healthcare spending is estimated to have increased at a CAGR of 12.70 per cent to US\$ 133 billion in 2016.
- In May 2017, Hyderabad-based pharmaceutical firm Hetero Drugs Ltd. launched a velpatasvir and sofosbuvir combination drug for the treatment of Hepatitis-C in India, after getting full compliance from the regulatory authorities.



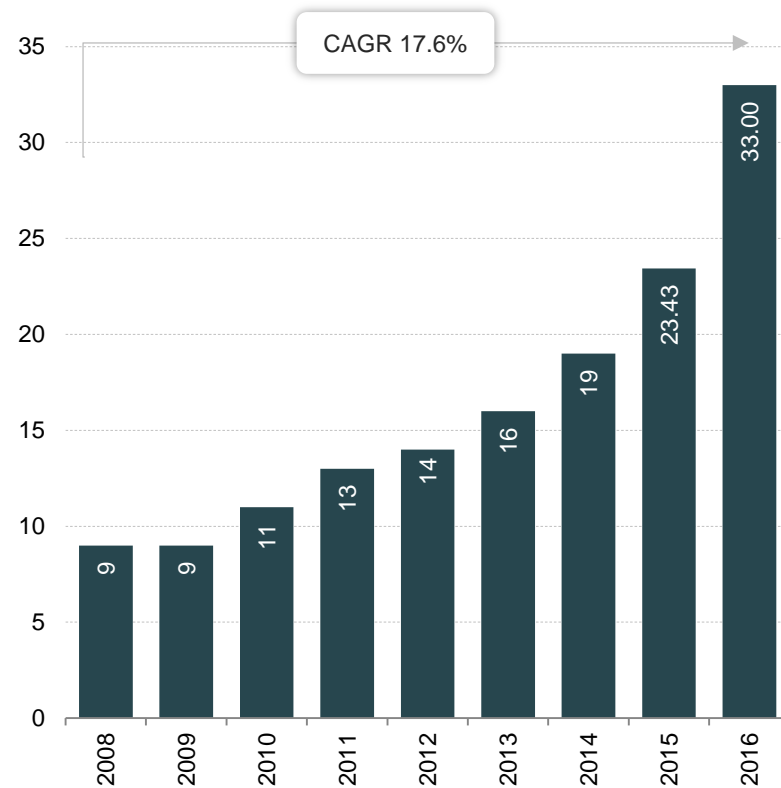
*Note: CAGR - Compound Annual Growth Rate*

*Source: Deloitte, BMI, PWC*

# GROWING PER CAPITA SALES OF PHARMACEUTICALS

- Growing per capita sales of pharmaceuticals in India offers ample opportunities for players in this market
- Per capita sales of pharmaceuticals expanded at a CAGR of 17.6 per cent to US\$ 33 in 2016
- Economic prosperity would improve affordability for generic drugs in the market and improve per capita sales of pharmaceuticals in India

Per capita sales of pharmaceuticals (US\$ )



*Note: CAGR - Compound Annual Growth Rate*

*Source: BMI*

# FAVOURABLE POLICY MEASURES SUPPORT GROWTH (1/2)

Reduction in approval time for new facilities	<ul style="list-style-type: none"><li>▪ Steps taken to reduce approval time for new facilities</li><li>▪ NOC for export licence issued in two weeks compared to 12 weeks earlier</li></ul>
Collaborations	<ul style="list-style-type: none"><li>▪ 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.</li><li>▪ In 2016, Strides Arcolab and US-based Gilead Sciences Inc. entered into a licensing agreement for manufacturing and distributing Gilead Sciences' cost-efficient TenofovirAlafenamide (TAF) product in order to treat HIV patients in developing economies</li></ul>
Support for technology upgrades and FDIs	<ul style="list-style-type: none"><li>▪ Government is planning to relax FDI norms in the pharmaceutical sector</li><li>▪ 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</li></ul>
Industry infrastructure	<ul style="list-style-type: none"><li>▪ 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</li></ul>
Pharma Vision 2020	<ul style="list-style-type: none"><li>▪ Pharma Vision 2020 by the government's Department of Pharmaceuticals aims to make India a major hub for end-to-end drug discovery</li></ul>
Exceptions	<ul style="list-style-type: none"><li>▪ 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)</li><li>▪ The customs duties on the said drugs are also being exempted</li></ul>

Source: Union Budget 2015-16

# FAVOURABLE POLICY MEASURES SUPPORT GROWTH (2/2)

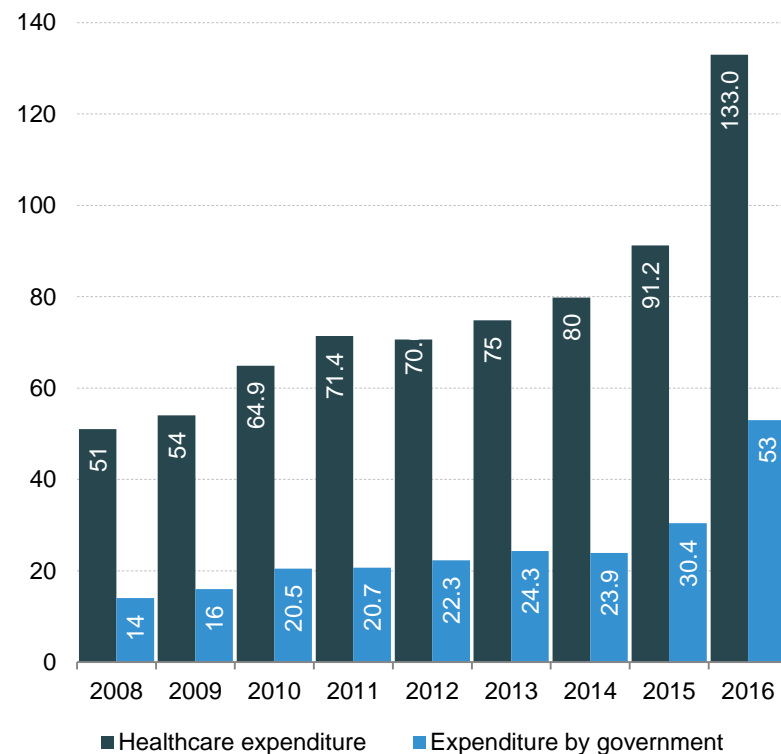
Bulk Drug Parks	<ul style="list-style-type: none"><li>Government of India is planning to set up mega bulk drug parks in order to reduce industry's dependency on raw material imports.</li></ul>
OTC drugs	<ul style="list-style-type: none"><li>A new category of over the counter (OTC) drugs has been given in-principle approval. The category includes muscle relaxants, decongestants, anti-inflammatory drugs, antacids, external preparations for skin and hormonal contraceptives.</li></ul>
Online Pharmacies	<ul style="list-style-type: none"><li>Government of India is planning to set up an electronic platform to regulate online pharmacies under a new policy</li></ul>
National Biopharma Mission	<ul style="list-style-type: none"><li>The Industry – Academia mission was launched in June 2017 to boost development of biopharmaceuticals in India.</li></ul>
Union Budget 2018-19	<ul style="list-style-type: none"><li>The allocation to the Ministry of Health and Family Welfare has increased by 11.5 per cent to Rs 52,800 crore (US\$ 8.16 billion).</li><li>The National Health Protection Scheme is largest government funded healthcare programme in the world, which is expected to benefit 100 million poor families in the country by providing a cover of up to Rs 5 lakh (US\$ 7,723.2) per family per year for secondary and tertiary care hospitalisation.</li><li>The government has allocated Rs 1,200 crore (US\$ 185.36 million) towards the National Health Policy 2017 under which 150,000 health and wellness centres, will provide healthcare closer to homes of the people.</li><li>The increased expenditure on healthcare is expected to benefit the pharmaceutical sector as well</li></ul>

Source: Evermit

# GOVERNMENT EXPENDITURE IN THE PHARMA SECTOR ON AN UPTREND

- Government expenditure on health in the country increased from US\$ 14 billion in 2008 to US\$ 53 billion in 2016.
- The expenditure expanded at a CAGR of 18.1 per cent over 2008–16 to reach US\$ 53 billion.
- Under Union Budget 2017-18, new 5,000 postgraduate seats in medical colleges were announced by the government, to ensure availability of specialist doctors.
- Medical technology park in Vishakhapatnam, Andhra Pradesh has already been set up with an investment of US\$ 183.31 million. States like Himachal Pradesh, Gujarat, Telangana and Maharashtra are showing interest for making investments in these parks.
- German technical services provider TUV Rheinland's Indian subsidiary has partnered with Andhra Pradesh MedTech Zone (AMTZ) to create an infrastructure for Electro-Magnetic Interference (EMI/EMC) at an investment of US\$ 12.64 million over a course of four to five years.

Rising share of government expenditure (US\$ billion)



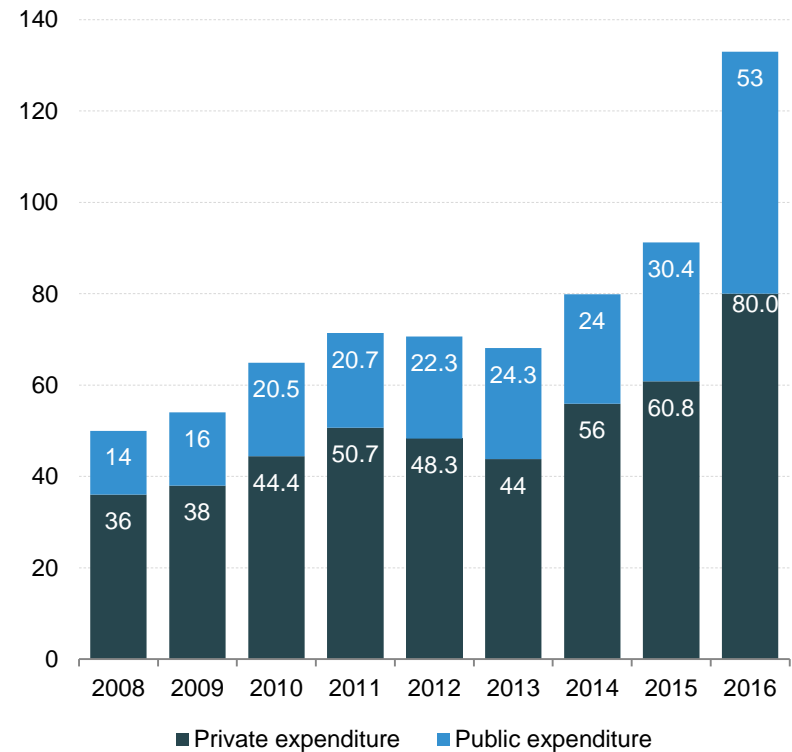
Note: CAGR - Compound Annual Growth Rate

Source: Business Monitor International, Union Budget 2015-16

# RISING EXPENDITURE SHARE BY PRIVATE SECTOR

- The share of private sector spending increased from US\$ 36 billion in 2008 to US\$ 80 billion in 2016
- Supported by favourable government policies, the private sector's share is expected to reach US\$ 80 billion by 2016
- With increasing urbanisation and problems related to modern-day living in urban settings, currently, about 50 per cent of spending on in-patient beds is for lifestyle diseases; this has increased the demand for specialised care
- To standardise the quality of service delivery, control cost and enhance patient engagement, healthcare providers are focusing on the technological aspect of healthcare delivery
- Digital Health Knowledge Resources, Electronic Medical Record, Mobile Healthcare, Electronic Health Record, Hospital Information System and PRACTO are some of the technologies gaining wide acceptance in the sector
- A new trend is emerging as luxury offerings in healthcare sector. More than essential requirements, healthcare providers are making offerings of luxurious services. For example: pick and drop services for patient by private helicopters and luxurious arrangements for visitors to patient in hospital

Public and private expenditure on healthcare (US\$ billion)



Source: Business Monitor International

# STRONG POLICY SUPPORT CRUCIAL TO THE SECTOR'S DEVELOPMENT

## Programme for SC/ST and Rural Population

- Training & demonstration programme in various biotechnology based activities were undertaken to empower the population resulting in socioeconomic upliftment

## Biotechnology Based Programme for Women

- Programme on application of biotechnology for women was done to provide employment, skill development, awareness generation, health improvement & socio-economic upliftment of the women population

## Single-window clearance

- As per NBDS, a proposal has been made to set up the National Biotechnology Regulatory Authority (NBRA) to provide a single-window clearance mechanism for all bio-safety products to create efficiencies & streamline the drug approval process

## Biotechnology Industry Research Assistance Council

- BIRAC has been established to promote research & innovation capabilities in India's biotech industry. The council will provide funding to biotech companies for technology & product development.
- BIRAC under Small Business Innovation Research Initiative (SBIRI) scheme supports innovations in biotechnology.

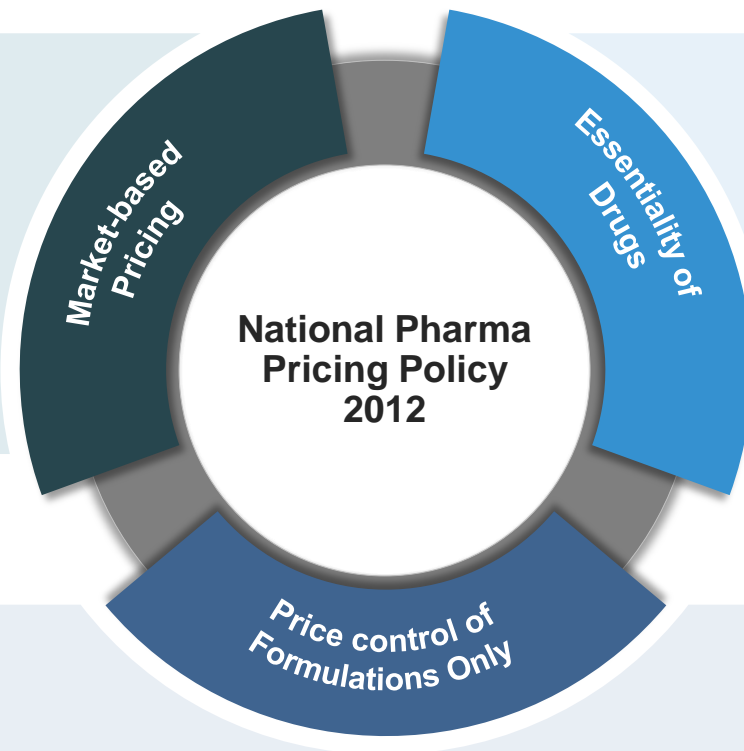
## State Policy Support

- The Andhra Pradesh government in 2015 formulated a new policy which covers the benefits for the following categories: Incubation Centres, Biotech manufacturing industries, Life Science Park, Life Science Knowledge Centre, Research & Development Centres.
- The Tamil Nadu government announced a biotech policy in 2014 which aims to encourage new companies to operate in Tamil Nadu, thereby increasing the R&D & manufacturing activities in the sector
- The Biotechnology Policy of Gujarat established in 2015, promises to provide financial incentives of up to US\$3.81 million & capital assistance of up to US\$7.63 million would be given to biotechnology parks & biotechnology companies.

*Note: BIRAC - Biotechnology Industry Research Assistance Council*

*Source: "Biotechnology facilities," Department of Biotechnology, Aranca Research*

# NATIONAL PHARMA POLICY TO BRING GREATER TRANSPARENCY



- Cost-based pricing is complicated and time-consuming than market-based pricing
- Market-based pricing is expected to create greater transparency in pricing information and would be available in public domain
- Prices of NLEM drugs linked to WPI

- Essentiality of drugs is determined by including the drug in National List of Essential Medicines (NLEM) (348 drugs at present)
- Promote rational use of medicines based on cost, safety and efficacy

- The regulation of prices of drugs on the basis of regulating the prices of formulations only
- Only finished medicines are to be considered essential which would prevent price control of APIs, which are not necessarily used for essential drugs

Source: National Pharmaceuticals Pricing Policy 2012; WPI – Wholesale Price Index

# INVESTMENTS, JVs INFUSING SUPERIOR CAPABILITIES IN INDIAN FIRMS ... (1/2)

- Indian Drugs & Pharmaceuticals sector has received cumulative FDI worth US\$ 15.59 billion between April 2000 – December 2017.
- Companies in Indian drug and pharmaceuticals industry are expected to invest Rs 82 billion (US\$ 1.27 billion) between FY16-18.
- Pharma, healthcare and biotech have witnessed significant increases in M&A activities over the years. PE-VC investments in Indian pharmaceutical sector increased 38 per cent in the first half of 2017.
- Over the last three years, pharmaceuticals segment has accounted for more than 70 per cent of M&A deals

Date Announced	Indian company	Foreign company	Value (US\$ million)	Type
December 2017	Unichem Laboratories	Torrent Pharma	NA	Acquisition
March, 2017	Sun Pharma	Thallion Pharmaceuticals	19.77	Acquisition
January, 2017	Zyodus Cadila	Zoetis	NA	Acquisition
February 2017	Piramal	Mallinckrodt	170	Specialty products
July 2016	Continental Hospitals Ltd.	HH Healthcare Berhad	192.84	73.4% Stake
February 2016	Cipla	InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc.	550	100% Stake
November 2015	Famy Care Ltd	Mylan Inc – Mylan Laboratories Limited	750	100% Stake
October 2015	Nitin Lifesciences	Recipharm	109.8	75% stakes in equity
July 2015	Lupin	Temmler	Not disclosed	Acquisition
May 2015	Cadila Healthcare	Claris Lifesciences	556.8	To be acquired
July 2015	Lupin	Gavis and Novel Laboratories	880	Acquisition
April 2014	Sun Pharma	Ranbaxy	320	Acquisition
November, 2014	Curatio Healthcare	Sequoia Capital	15.8	Acquisition
July, 2013	Cipla	Cipla Medpro	512	Acquisition
January, 2013	GlaxoSmithkLine Consumer	GlaxoSmithkLine Plc.	1,088	Acquisition
September, 2011	Natco Pharma	Litha	NA	JV
May, 2010	Glenmark	Sanofi	615	JV
March, 2011	Dr Reddy's	Iso Ray	NA	Licensing rights
April, 2011	Sun Pharma	Merck	NA	Marketing
September, 2010	Piramal	Abbot	3,720	Business buyout

Note: JV - Joint Venture

Source: BMI, Business Standard

# INVESTMENTS, JVs INFUSING SUPERIOR CAPABILITIES IN INDIAN FIRMS ... (2/2)

Date Announced	Indian company	Foreign company	Value (US\$ million)	Type
December, 2014	Panacea Biotec Ltd	Apotex Inc	NA	JV
August, 2012	Strides Arcolab Ltd	Gilead Sciences Inc	NA	Licensing agreement
July, 2011	Ranbaxy	Gilead Sciences Inc	NA	Licensing agreement
August, 2013	Jubilant Biosys	Endo Pharmaceuticals	NA	Drug development
October, 2012	Piramal Healthcare Ltd	Fujifilm Diosynth Biotechnologies	NA	Drug development
March, 2009	Biocon	Bristol-Myers Squibb	NA	Exclusive marketing
March, 2013	Unichem Laboratories	Mylan	30	Acquisition
October, 2012	SMS Pharmaceuticals	Mylan	33	Acquisition of manufacturing unit
March, 2012	Biocon	Abbott Laboratories	NA	Contract research
September, 2012	Agila Specialties	Mylan, A Canonsburg	1,850	Acquisition
February, 2012	Jubilant Biosys	Mnemosyne Pharmaceuticals Inc	NA	Drug development
January, 2011	Zydus Cadila Healthcare	Bayer	NA	Marketing arrangement
December, 2012	Claris Lifesciences	Otsuka Pharmaceutical	250	JV
November, 2012	Zydus Cadila Healthcare	Abbot Laboratories	NA	Licensing agreement
July, 2011	Lupin	Eli Lilly	NA	Marketing arrangement

*Note: JV - Joint Venture, ADC - Antibody Drug Conjugates*

*Source: ICRA Research on Indian Pharmaceutical Sector, India Ratings Research Outlook on Indian Pharmaceutical, BMI*

# OPPORTUNITIES



# OPPORTUNITIES ABOUND IN CLINICAL TRIALS AND HIGH-END DRUGS

## Clinical trials market

- India is among the leaders in the clinical trial market
- Due to a genetically diverse population and availability of skilled doctors, India has the potential to attract huge investments to its clinical trial market
- From 2009 to 2015, 3043 clinical trial has been carried out in India.
- As of June 2017, the Clinical Trials Registry – India had 8,950 trials registered.

## High-end drugs

- Due to increasing population and income levels, demand for high-end drugs is expected to rise
- Growing demand could open up the market for production of high-end drugs in India

## Penetration in rural market

- With 70 per cent of India's population residing in rural areas, pharma companies have immense opportunities to tap this market
- Demand for generic medicines in rural markets has seen a sharp growth. Various companies are investing in the distribution network in rural areas

## CRAMS

- The Contract Research and Manufacturing Services industry (CRAMS) – estimated at US\$ 9.3 billion in 2014, is expected to reach US\$ 19 billion by 2018.
- The market has more than 1,000 players

Source: BMI

# OPPORTUNITIES FOR INNOVATION IN AGRICULTURE/HEALTHCARE

## Vaccines

- Vaccines & recombinant therapeutics are the sectors driving the biotechnology industry's growth in India
- Newer prominent therapies such as monoclonal antibodies products, stem cell therapies are expected to pick up pace in the foreseeing future
- In 2015, Bharat Biotech launched 'Rotavac' vaccine in India, three doses of the vaccine can prevent the Rotavirus diarrhea in infants.
- Indian pharmaceutical firms supply 80 per cent of the anti retroviral drugs to fight AIDS globally
- In October 2016, Sun Pharmaceutical Industries Ltd & International Centre for Genetic Engineering & Biotechnology (ICGEB) signed a pact to develop vaccine for all four serotypes of dengue virus.

## Bioactive therapeutic proteins

- Protein & antibody production & fabrication of diagnostic protein chips are promising areas for investment
- Stem cell research, cell engineering & cell-based therapeutics are other areas, where India can cash its expertise

## Agriculture sector

- Hybrid seeds, including GM seeds, represent new business opportunities in India based on yield improvement
- Growing at an annual growth rate of 10-15 per cent, the Indian hybrid seed industry is estimated at US\$1.93 billion in FY16, wherein Bt cotton is leading the market accounting for 45 per cent share India hybrid seed industry.

## Intellectual Property

- Using the patent system as a mechanism to control drug pricing forestalls making the difficult decisions about necessary investment in the healthcare system, but does not deal with the underlying issues.

Source: India Law Offices, Aranca search

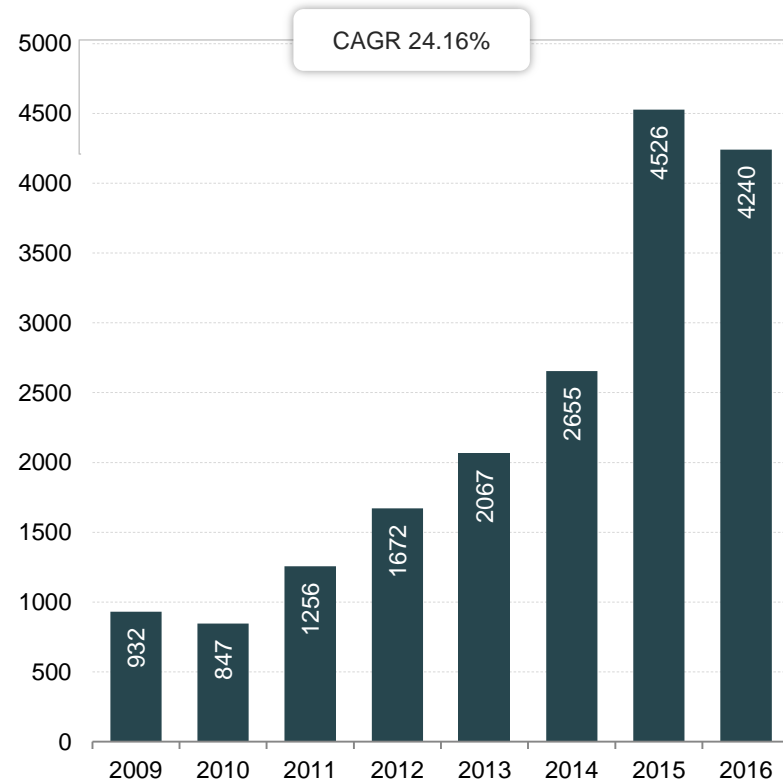
# SUCCESS STORIES



# SUN PHARMA: LEVERAGING ITS GENERICS MARKET CAPABILITIES

- Sun Pharma was set up in 1983, with a compact manufacturing facility for tablets and capsules
- It set up its 1st API plant at Panoli in 1995
- It has 48 manufacturing facilities across 5 continents and employs more than 30,000 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 July 2016 - 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 6,653.23 crore (US\$ 1.03 billion) in the third quarter of FY18.

Sun Pharma net sales (US\$ million)



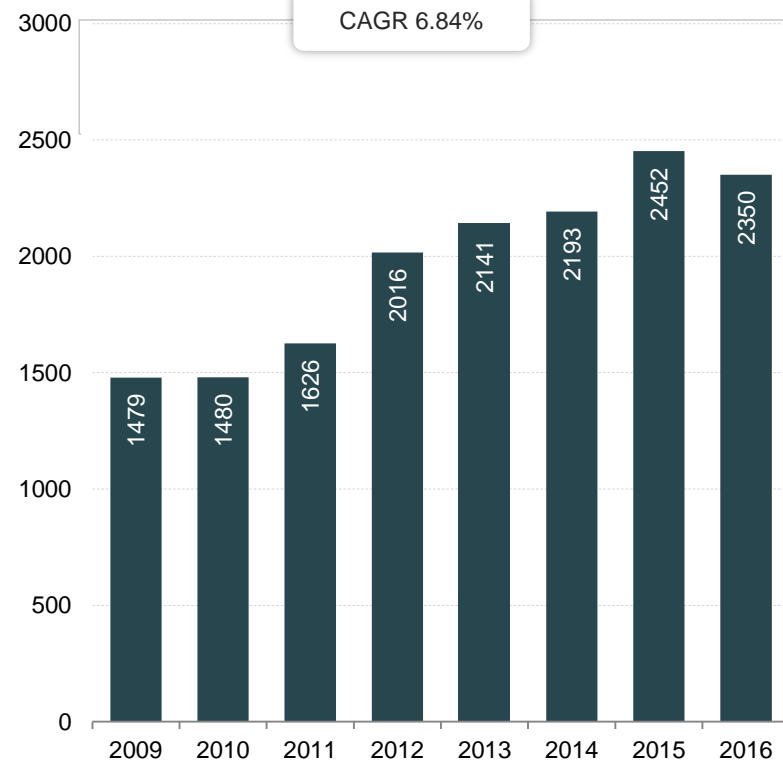
*Note: Compound Annual Growth Rate*

*Source: Sun Pharma website*

# DR REDDY'S: PROVIDING AFFORDABLE AND INNOVATIVE HEALTHCARE

- Dr Reddy's began as an API manufacturer in 1984, producing high-quality APIs for the Indian domestic market.
- It has presence in almost all therapeutic segments.
- It has an integrated business model in three segments: Pharmaceutical Services and Active Ingredients (PSAI), Global generics and Proprietary products.
- Dr Reddy's has access to numerous emerging markets through partnerships with GlaxoSmithKline (GSK).
- Its product offering spans the entire value chain, from process development of APIs to submission of the finished dosage dossier to regulatory agencies.
- The company's revenues reached Rs 3,806 crore (US\$ 587.89 million) in the third quarter of 2017-18.
- Dr Reddy's is investing heavily on R&D to differentiate itself in the market. In FY17 Dr Reddy's spent around 13.9 per cent of sales on R&D.

Dr Reddy's net sales (US\$ million)

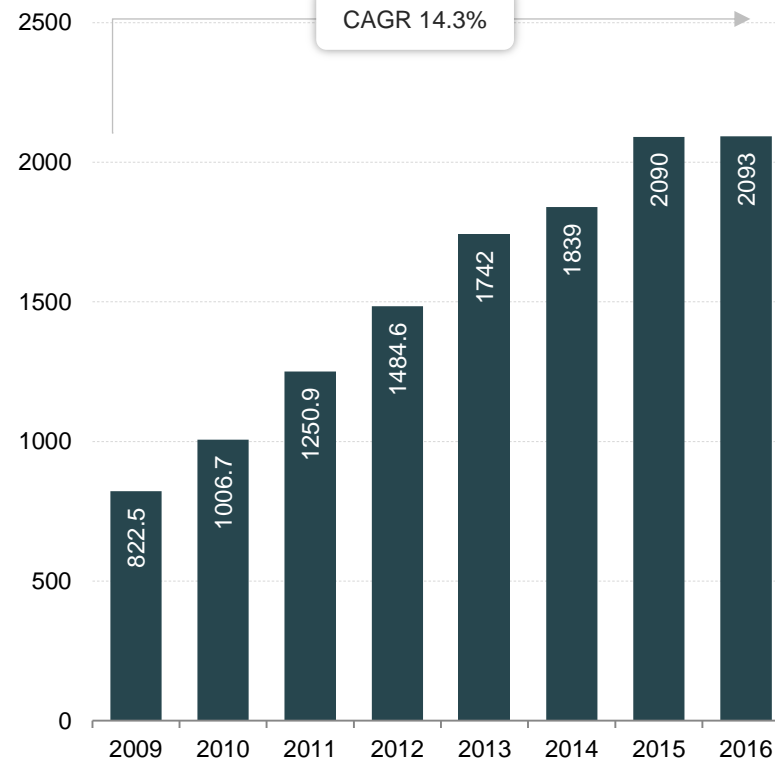


Source: : Dr Reddy's website,

# LUPIN: ON A HIGH GROWTH PATH

- 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
- The company's consolidated income reached Rs 3,900.36 crore (US\$ 602.47 million) in the third quarter of 2017-18.
- 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.

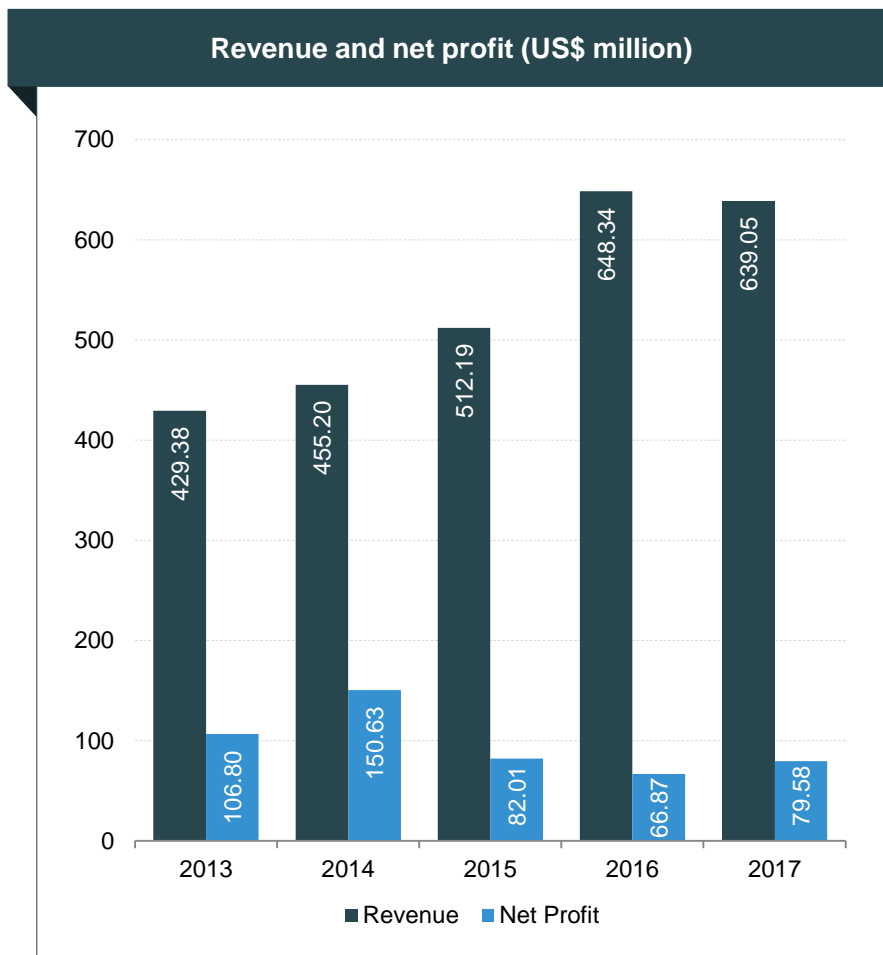
Lupin net sales (US\$ million)



Source: : Lupin website

# BIOCON: AN EARLY MOVER IN THE GLOBAL BIOTECH MARKET

- Biocon is a premier biopharmaceutical company which manufactures generic active pharmaceutical ingredients (APIs).
- It's business model spans the entire drug value chain, from pre-clinical discovery to clinical development and through to commercialisation.
- The company is among the world's largest producers of statins & immunosuppressant's which are used in organ transplants.
- Its total revenue stood at US\$ 633.11 million in FY17 as compared to US\$ 537.04 million in FY16. Consolidated revenues of the company reached Rs 1,057.9 crore (US\$ 163.41) in the third quarter of 2017-18.
- Biocon has two subsidiaries Syngene and Clinigene.
  - Syngene provides contract research and manufacturing services in pharmaceuticals and biotechnology sector and employs over 2,500 research scientists.
  - Clinigene offers clinical trials and studies for novel/generic molecules.
- Biocon and its subsidiaries together employ approximately 4,500 personnel.
- In December 2017, Biocon and Mylan's proposed biosimilar trastuzumab got approval from Brazilian regulatory agency ANVISA, through their partner Libbs Farmaceutica (Libbs).



Source: : Company website, Annual Reports, News Articles

# USEFUL INFORMATION



## The Indian Pharmaceutical Association

Address: Kalina, Santacruz (E),  
Mumbai – 400 098  
Phone: 91-22-2667 1072  
Fax: 91 22 2667 0744  
E-mail: [ipacentre@ipapharma.org](mailto:ipacentre@ipapharma.org)  
[www.ipapharma.org](http://www.ipapharma.org)

## Organisation of Pharmaceutical Producers of India

Address: Peninsula Chambers, Ground Floor,  
Ganpatrao Kadam Marg, Lower Parel,  
Mumbai – 400 013  
Phone: 9122 24918123, 24912486, 66627007  
Fax: 9122 24915168  
E-mail: [indiaoppi@vsnl.com](mailto:indiaoppi@vsnl.com)  
[www.indiaoppi.com](http://www.indiaoppi.com)

## Indian Drug Manufacturers' Association

Address: 102-B, Poonam Chambers, Dr A.B. Road  
Worli, Mumbai – 400 018  
Phone: 91-22-2494 4624/2497 4308  
Fax: 9122 24950723  
E-mail: [idma1@idmaindia.com](mailto:idma1@idmaindia.com)  
[www.idma-assn.org](http://www.idma-assn.org)

## Bulk Drug Manufacturers Association

Address: C-25, Industrial Estate, Sanath Nagar  
Hyderabad – 500018  
Phone: 91 40 23703910/23706718  
Fax: 91 40 23704804  
E-mail: [info@bdmai.org](mailto:info@bdmai.org)  
[www.bdmai.org](http://www.bdmai.org)

- CRAMS: Contract Research and Manufacturing Services
- API: Active Pharmaceutical Ingredients
- FDI: Foreign Direct Investment
- GOI: Government of India
- INR: Indian Rupee
- US\$ : US Dollar
- BPL: Below Poverty Line
- RSBY: Rashtriya Swastha Bima Yojna
- ESIC: Employees State Insurance Corporation
- Wherever applicable, numbers have been rounded off to the nearest whole number

# EXCHANGE RATES

## Exchange Rates (Fiscal Year)

Year	INR Equivalent of one US\$
2004–05	44.81
2005–06	44.14
2006–07	45.14
2007–08	40.27
2008–09	46.14
2009–10	47.42
2010–11	45.62
2011–12	46.88
2012–13	54.31
2013–14	60.28
2014-15	61.06
2015-16	65.46
2016-17	67.09
Q1 2017-18	64.46
Q2 2017-18	64.29

## Exchange Rates (Calendar Year)

Year	INR Equivalent of one US\$
2005	43.98
2006	45.18
2007	41.34
2008	43.62
2009	48.42
2010	45.72
2011	46.85
2012	53.46
2013	58.44
2014	61.03
2015	64.15
2016	67.21
H1 2017	65.73

Source: Reserve bank of India, Average for the year

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