### EXECUTIVE SUMMARY

**Leading pharma producer**
- Indian pharmaceutical sector accounts for about 2.4 per cent of the global pharmaceutical industry in value terms & 10 per cent in volume terms

**One of the highest exports**
- India accounts for 20 per cent of global exports in generics. In FY16, India exported pharmaceutical products worth USD16.89 billion, with the number expected to reach USD40 billion by 2020
- Pharma exports in India grew at 9.44 per cent in FY16, registering an amount of US$16.9 billion. The exports are expected to register double digit growth in FY17, with exports growing at 8 per cent in January 2017

**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 USD55 billion

**Rapidly growing healthcare sector**
- Indian healthcare sector, one of the fastest growing sectors, is expected to advance at a CAGR of 17 per cent to reach USD250 billion over 2008–20

**Growing generics market**
- The generics market stood at USD26.1 billion in 2016 from USD21 billion in 2015. India’s generics market has immense potential for growth

**Ranked 4th in terms of attracting FDI**
- Pharmaceutical sector in India attracted 4 per cent of the total FDIs into India, with, cumulative FDI inflows worth USD14.53 billion were made during April 2000 to December 2016

*Notes: API - Active Pharmaceutical Ingredient, USFDA - United States Food and Drug Administration, CAGR - Compound Annual Growth Rate*
PHARMACEUTICALS

Advantage India

Cost efficiency

- Low cost of production and R&D boosts efficiency of Indian pharma companies
- India's cost of production is approximately 60 per cent lower than that of the US & almost half of that of Europe
- Due to lower cost of treatment, India is emerging as a leading destination for medical tourism
- As of February 2017, 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 chemists, especially in rural India, OTC drugs will be readily available

Diversified portfolio

- 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
- 35.7 per cent of all drug master filings from India is registered in the USA in 2015

Policy support

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

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

For updated information, please visit www.ibef.org

MAY 2017
STRUCTURE OF PHARMA SECTOR IN INDIA

Pharmaceuticals

Active Pharmaceutical Ingredients/ Bulk drugs

Formulations

Branded

Generics

Chronic

Acute

- Cardiovascular
- Anti-diabetes
- Gastro-intestinal
- Neurological

- Anti-infectives
- Respiratory
- Pain
- Gynecology

Source: Dun & Bradsheet, TechSci Research
**EVOLUTION OF INDIAN PHARMACEUTICAL SECTOR**

- **1970–90**
  - Indian Patent Act passed in 1970
  - Several domestic companies start operations
  - Development of production infrastructure
  - Export initiatives taken

- **1990–2010**
  - Liberalised market
  - Indian companies increasingly launch operations in foreign countries
  - India a major destination for generic drug manufacture
  - Approval of Patents (Amendment) Act 2005, which led to adoption of product patents in India

- **2010**
  - Increased patent filings by pharma players
  - Likely adoption of newer sales models such as channel management, KAM & CSO
  - The National Pharmaceutical Pricing Policy, 2012 (NPPP-2012)

- **2010-2015**
  - National Health Policy Draft 2015 to increase expenditure in health care sector
  - 2014: 100 per cent FDI allowed in medical device industry. The investment will be routed through automatic route
  - 2013: New Drug Pricing Control Order issued by Directorate of Food & Drugs this will reduce the prices of drugs by 80 per cent.

- **2015**
  - 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 & over 3,000 pharma companies

- **2016**
  - In Union Budget, 2016, FDI increased to 74 per cent in existing pharmaceutical companies

**Source:** TechSci Research

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

For updated information, please visit [www.ibef.org](http://www.ibef.org)
API IS THE LARGEST SEGMENT OF THE INDIAN PHARMACEUTICALS SECTOR

Active Pharmaceutical Ingredients (APIs)
- India has become the 3rd largest global generic API merchant market by 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 USD18 billion in 2018 & expected to witness a strong growth at a CAGR of 18-20 per cent between 2013-2018

Formulations
- Largest exporter of formulations in terms of volume, with 14 per cent market share and 12th in terms of export value
- Domestic market size currently valued at USD11.2 billion
- Double-digit growth expected over the next 5 years

Biosimilars
- Biosimilar’s sector is expected to touch USD1.4 billion by 2016 & the sector is expected to grow annually at a rate of 30 per cent in India
- The government plans to allocate USD70 million for local players to develop Biosimilars
- The domestic market is expected to reach USD 40 billion by 2030

Note: OTC - Over The Counter

For updated information, please visit www.ibef.org
The Indian pharmaceuticals market witnessed growth at a CAGR of 5.64 per cent, during 2011-16, with the market increasing from USD20.95 billion in 2011 to USD27.57 billion in 2016.

By 2020, India is likely to be among the top 3 pharmaceutical markets by incremental growth & 6th largest market globally in absolute size.

India’s cost of production is significantly lower than that of the US & 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 & increase in the penetration of health insurance in the country will also influence in the growth of pharmaceuticals sector.

Revenue of Indian pharmaceutical sector (USD billion)

<table>
<thead>
<tr>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
<th>2020F</th>
</tr>
</thead>
<tbody>
<tr>
<td>20.95</td>
<td>22.46</td>
<td>24.52</td>
<td>28.53</td>
<td>29.77</td>
<td>27.57</td>
<td>55</td>
</tr>
</tbody>
</table>

Source: Department of Pharmaceuticals, PwC, McKinsey, TechSci Research
Notes: F - Forecast, CAGR - Compound Annual Growth Rate
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 USD20 billion.

Revenue share of Indian pharmaceutical sub-segments in 2015 (%)

- Generic drugs: 70%
- OTC medicines: 21%
- Patented drugs: 9%

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 5 segments contribute nearly 57 per cent to the total drugs consumption.

**Source:** All Indian Origin Chemists & Distributors, Department of Pharmaceuticals, TechSci Research
Indian pharma companies are capitalising on export opportunities in regulated & semi-regulated markets

In FY16, India exported pharmaceutical products worth USD16.89 billion, with the number expected to reach USD40 billion by 2020

Department of Pharmaceuticals targets to export USD18.02 billion worth of pharmaceuticals in 2016. 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)

Trade data of Indian pharma sector (USD billion)

<table>
<thead>
<tr>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Export</td>
<td>Import</td>
<td>Export</td>
<td>Import</td>
<td>Export</td>
</tr>
<tr>
<td>10.1</td>
<td>3.6</td>
<td>12.6</td>
<td>4.4</td>
<td>14.5</td>
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<tr>
<td>14.9</td>
<td>3.7</td>
<td>16.89</td>
<td>3.7</td>
<td></td>
</tr>
</tbody>
</table>

Source: Department of Commerce India, Department of Pharmaceuticals, India Business News, BMI, TechSci Research
Notes: CAGR - Compound Annual Growth Rate,
*Import - From April 2014 to Dec 2014
* Export – From April 2014 to Dec 2014
Dr Reddy’s accounted for the largest share in the Indian pharma market, with sales of USD2.36 billion during March 2016

Lupin had the 2nd largest share in the Indian pharma market with sales of USD2.09 billion in FY16

Cipla, with a revenue base of USD2.089 billion for March 2016 sales, ranked 3rd in the market

Aurobindo ranked 4th in the market, with a revenue base of USD1.17 billion for March 2015 sales

While these top 4 companies garnering 20 per cent market share, top 10 companies accounted for nearly 39 per cent of the market share in 2015

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Note: The bubbles denote MAT March 2014 sales in USD million

Source: All Indian Origin Chemists & Distributors, Equity Master, BMI, TechSci Research
Notes: Market share is in terms of revenue,
(1) Data is for March 2015
Market share is being calculated on the basis of FY15 revenue
PHARMA GIANTS RAISE THEIR R&D SPENDING

- In FY16, highest expenditure on research & development has been done by Sun Pharma, followed by Dr. Reddy.

- Sun Pharma’s R&D spending is 9.1 per cent of the total sales in the March quarter of FY16, which grew at a rate of 23 per cent YoY, in comparison with March quarter of FY15.

- In FY17, Lupin's R&D spending is expected to be 12-15 per cent of sales, growing from 12 per cent in FY16.

### R&D spending by top six pharma giant FY16 (USD million)

<table>
<thead>
<tr>
<th>Company</th>
<th>FY16 R&amp;D Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun Pharma</td>
<td>352</td>
</tr>
<tr>
<td>Dr Reddy</td>
<td>199</td>
</tr>
<tr>
<td>Lupin</td>
<td>244</td>
</tr>
<tr>
<td>Cipla</td>
<td>164</td>
</tr>
<tr>
<td>Cadila</td>
<td>28</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>102</td>
</tr>
<tr>
<td>Aurbindo</td>
<td>58</td>
</tr>
</tbody>
</table>

**Source:** Company websites TechSci Research

**Notes:**
- R&D - Research and Development
- \(^1\) – Data is up to Dec 2015,
- \(^2\) – Data is up to September 2015,
- \(^3\) - Data is for FY15
NOTABLE TRENDS IN THE INDIAN PHARMACEUTICALS SECTOR … (1/2)

Research and development
- Indian pharma companies spend 8-11 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 Promotion Council expects pharma exports exceeded USD15 billion in 2015 & reached USD16.89 billion in 2016

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
- 6 leading pharmaceutical companies have formed an alliance ‘LAZOR’ to share their best practices, so as to improve efficiency & reduce operating costs

Expansion by Indian players abroad
- Cipla, the largest supplier of anti-malarial drugs to Africa, sets up a USD32 billion plant in Africa for the production of anti-retroviral & anti-malarial drugs

Source: TechSci Research
Note: R&D - Research and Development
For updated information, please visit www.ibef.org
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 & approval time for new facilities has been drastically reduced

Source: TechSci Research
Note: R&D - Research and Development
For updated information, please visit www.ibef.org
PHARMACEUTICALS

STATES HOSTING KEY PHARMACEUTICAL VENTURES

- **Dholka in Gujarat** houses a major manufacturing facility of Cadila, which spans over 100 acres.
- **Piramal**'s USFDA-approved manufacturing plant in Hyderabad.
- **GlaxoSmithKline** has a major facility at Rajahmundry, Andhra Pradesh.
- **Lupin** has an USFDA-approved plant at Tarapur, Maharashtra. The facility forms the core of Lupin's fermentation capabilities.
- **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.
- **Mandideep in Madhya Pradesh** is the manufacturing hub for Lupin’s cephalosporin & ACE-Inhibitors.
  - Cipla has a formulations manufacturing plant at Indore.
- **Sun Pharma**'s API manufacturing facility at Toansa, Malanpur, Guwahati, Ankleshwar, Panoli, Ahmednagar, Maduramthakam.
- **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.

Source: Company websites

For updated information, please visit www.ibef.org

MAY 2017
PORTER'S FIVE FORCES ANALYSIS

PHARMACEUTICALS
**Competitive Rivalry**
- Growth opportunities for pharma companies are expected to grow in the 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 pharma companies, backed by huge financial muscle

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

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

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**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

**Bargaining Power of Customers**
- 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

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Source: TechSci Research
PHARMACEUTICALS

STRATEGIES ADOPTED
## PHARMACEUTICALS

### STRATEGIES ADOPTED

#### Cost leadership
- Sun Pharma is trying to achieve cost leadership by
  - Vertical Integration: Complex API, which require special skills & technology, are developed & scaled up for both API & dosage forms

#### Differentiation
- Players in the sector are trying to strengthen their position in the market & 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 & pain management drugs from US based drug maker – Mallinckrodt, for USD 203 million.
  - In May 2017, Lupin has launched erectile dysfunction drug named as Cialis. The company has quoted the market worth for USD58.01 million in India. This tablet is available in 20 mg & 10 mg strengths.

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

- Review product portfolio
- Build customer centricity
- Achieve organisational agility
- Create value by JV/M&A
- Strengthen operational capability

Strategies for Success

Source: TechSci Research
Notes: R&D – Research and Development, JV – Joint Venture, M&A – Mergers and Acquisitions

For updated information, please visit www.ibef.org
PHARMACEUTICALS

SECTOR DRIVEN BY CONFLUENCE OF DEMAND, CAPABILITIES AND POLICY

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

Supply-side drivers

• Cost advantage
• Skilled manpower
• India a major manufacturing hub for generics
• In FY16, 546 sites registered at USFDA. India accounts for 22 per cent of overall USFDA approved plants
• Increasing penetration of chemists

Growth drivers

• 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 & research institutes
• Exemptions to drugs manufactured through indigenous R&D from price control under NPPP-2012

Policy Support

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

For updated information, please visit www.ibef.org
PHARMACEUTICALS

### SUPPLY-SIDE DRIVERS OF INDIAN PHARMA SECTOR

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
</table>
| 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 USD200 billion by 2024  
• In October 2016, the government gave a nod to set up the country’s 1st 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 & it is expected to reach USD27.9 billion by 2020 |
| Over-The-Counter (OTC) drugs     | • India’s OTC drugs market is expected to rise at a CAGR of 16.3 per cent to USD6.6 billion over 2008–16 and is further expected to grow on the account of increased penetration of chemists, especially in rural regions |
| Patent Expiry                   | • The total sales value of the drugs with expiring patent in 2015 is USD66 billion and drugs with expiry protection in 2014 valued around USD34 billion |

Source: BMI, India Biz, TechSci Research  
Note: CAGR - Compound Annual Growth Rate
COST EFFICIENCY AND COMPETENCY CONTINUE TO BE INDIA’S FORTE

Cost efficiency

* 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 & Africa

Competency

* India has a skilled workforce as well as high managerial & 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

<table>
<thead>
<tr>
<th>Country</th>
<th>Cost Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>100</td>
</tr>
<tr>
<td>Germany</td>
<td>93.9</td>
</tr>
<tr>
<td>India</td>
<td>67.2</td>
</tr>
</tbody>
</table>

Source: Deloitte, BMI, Financial Express, TechSci Research
Note: USFDA - United States Food and Drug Administration
# Demand Drivers of Indian Pharma Sector

## Accessibility
- Over USD200 billion to be spent on medical infrastructure in the next decade
- New business models expected to penetrate tier-2 & 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 & preventive medicines to rise
- A skilled workforce as well as high managerial & technical competence
- Surge in medical tourism due to increased patient inflow from other countries

## 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 2017
- By 2017, the government plans to provide free generic medicines to half the population at an estimated cost of USD5.4 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 & lifestyle changes to boost demand
- Increasing prevalence of lifestyle diseases


Note: RSBY - Rashtriya Swasthya Bima Yojna

For updated information, please visit www.ibef.org
During 2010-16, total healthcare spending is expected to increase at a CAGR of 12.70 per cent to USD133 billion in 2016.

Moreover, pharmaceutical sales, as a percentage of total healthcare expenditure, are likely to reach 27 per cent by 2016 from 32.88 per cent in 2015 owing to increased healthcare expenditure on R&D of patented drugs.

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.

Source: Deloitte, BMI, PWC, TechSci Research
Notes: CAGR - Compound Annual Growth Rate
Growing per capita sales of pharmaceuticals in India offers ample opportunities for players in this market.

Per capita sales of pharmaceuticals is expected to expand at a CAGR of 17.6 per cent to USD33 by 2016.

Economic prosperity would improve affordability for generic drugs in the market & improve per capita sales of pharmaceuticals in India.

Per capita sales of pharmaceuticals (USD)

9 9 11 13 14 16 19 23.43 33

Source: BMI, TechSci Research
Notes: CAGR - Compound Annual Growth Rate
**FAVOURABLE POLICY MEASURES SUPPORT GROWTH**

**Reduction in approval time for new facilities**
- Steps taken to reduce approval time for new facilities
- NOC for export licence issued in 2 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 & Panacea Biotech.
- In 2016, Strides Arcolab & US-based Gilead Sciences Inc. entered into a licensing agreement for manufacturing & distributing Gilead Sciences’ cost-efficient TenofovirAlafenamide (TAF) product in order to treat HIV patients in developing economies.

**Support for technology upgrades and FDIs**
- Zero duty for technology upgrades in the pharmaceutical sector through the Export Promotion Capital Goods (EPCG) Scheme
- 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 & open 2 new AIIMS in Jharkhand & Gujarat. In 2016, the government has planned to set up 6 pharma parks at an investment of about USD27 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 & diagnostic kits supplied under National AIDS Control Programme funded by the Global Fund to fight AIDS, TB & Malaria (GFATM)
- The customs duties on the said drugs are also being exempted.

**Source:** Union Budget 2015-16, TechSci Research

**For updated information, please visit** [www.ibef.org](http://www.ibef.org)
Government expenditure on health in the country increased from USD14 billion in 2008 to USD53 billion in 2016.

The expenditure is expected to expand at a CAGR of 18.1 per cent over 2008–16 to USD53 billion.

Under Union Budget 2017-18, new 5000 postgraduate seats were announced by the government, in medicine, to ensure availability of specialist doctors.

Medical technology park in Vishakhapatnam, Andhra Pradesh has already been set up with an investment of USD183.31 million. States like Himachal Pradesh, Gujarat, Telangana & Maharashtra are showing interest for making investments in these parks.

**Rising share of government expenditure (USD billion)**


Notes: CAGR - Compound Annual Growth Rate
The share of private sector spending increased from USD36 billion in 2008 to USD60.8 billion in 2015.

Supported by favourable government policies, the private sector's share is expected to reach USD80 billion by 2016.

With increasing urbanisation & 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 & 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 & drop services for patient by private helicopters & luxurious arrangements for visitors to patient in hospital.

**Source:** Business Monitor International, TechSci Research
HEALTH INSURANCE PENETRATION EXPECTED TO SURGE

* Increasing penetration of health insurance is likely to be driven by government-sponsored initiatives such as RSBY and ESIC

* Government-sponsored programmes expected to provide coverage to nearly 380 million people by 2020

* Private insurance coverage would increase nearly 15 per cent annually till 2020

* In FY15, 27 per cent of the total population has been covered under government sponsored health insurance schemes

* From March to November 2015, gross direct premium income for health insurance segment reached USD2.58 billion. Private sector accounted for 36.3 percent of the total gross direct premium income (March to November 2015)

* Increase in private sector insurance would play an important role in affordability for high cost
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

• 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 & efficacy

National Pharma Pricing Policy 2012

- 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

Market-based pricing

Price control of formulations only

Source: National Pharmaceuticals Pricing Policy 2012
PHARMACEUTICALS

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

- Pharma, healthcare & biotech have witnessed significant increases in M&A activities over the years.
- Over the last 3 years, pharmaceuticals segment has accounted for more than 70 per cent of M&A deals

<table>
<thead>
<tr>
<th>Date announced</th>
<th>Indian company</th>
<th>Foreign company</th>
<th>Value (USD million)</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2017</td>
<td>Piramal</td>
<td>Mallinckrodt</td>
<td>170</td>
<td>Specialty products</td>
</tr>
<tr>
<td>July 2016</td>
<td>Continental Hospitals Ltd.</td>
<td>HH Healthcare Berhad</td>
<td>192.84</td>
<td>73.4% Stake</td>
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<tr>
<td>February 2016</td>
<td>Cipla</td>
<td>InvaGen Pharmaceuticals Inc. and Exelan Pharmaceuticals Inc.</td>
<td>550</td>
<td>100% Stake</td>
</tr>
<tr>
<td>November 2015</td>
<td>Famy Care Ltd</td>
<td>Mylan Inc – Mylan Laboratories Limited</td>
<td>750</td>
<td>100% Stake</td>
</tr>
<tr>
<td>October 2015</td>
<td>Nitin Lifesciences</td>
<td>Recipharm</td>
<td>109.8</td>
<td>75% stakes in equity</td>
</tr>
<tr>
<td>July 2015</td>
<td>Lupin</td>
<td>Temmler</td>
<td>Not disclosed</td>
<td>Acquisition</td>
</tr>
<tr>
<td>May 2015</td>
<td>Cadila Healthcare</td>
<td>Claris Lifesciences</td>
<td>556.8</td>
<td>To be acquired</td>
</tr>
<tr>
<td>July 2015</td>
<td>Lupin</td>
<td>Gavis &amp; Novel Laboratories</td>
<td>880</td>
<td>Acquisition</td>
</tr>
<tr>
<td>April 2014</td>
<td>Sun Pharma</td>
<td>Ranbaxy</td>
<td>320</td>
<td>Acquisition</td>
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<tr>
<td>November, 2014</td>
<td>Curatio Healthcare</td>
<td>Sequoia Capital</td>
<td>15.8</td>
<td>Acquisition</td>
</tr>
<tr>
<td>July, 2013</td>
<td>Cipla</td>
<td>Cipla Medpro</td>
<td>512</td>
<td>Acquisition</td>
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<tr>
<td>January, 2013</td>
<td>GlaxoSmithkline Consumer</td>
<td>GlaxoSmithkline Plc.</td>
<td>1,088</td>
<td>Acquisition</td>
</tr>
<tr>
<td>September, 2011</td>
<td>Natco Pharma</td>
<td>Litha</td>
<td>NA</td>
<td>JV</td>
</tr>
<tr>
<td>May, 2010</td>
<td>Glenmark</td>
<td>Sanofi</td>
<td>615</td>
<td>JV</td>
</tr>
<tr>
<td>March, 2011</td>
<td>Dr Reddy’s</td>
<td>Iso Ray</td>
<td>NA</td>
<td>Licensing rights</td>
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<tr>
<td>April, 2011</td>
<td>Sun Pharma</td>
<td>Merck</td>
<td>NA</td>
<td>Marketing</td>
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<tr>
<td>September, 2010</td>
<td>Piramal</td>
<td>Abbot</td>
<td>3,720</td>
<td>Business buyout</td>
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<tr>
<td>December, 2012</td>
<td>Shantha Biotech</td>
<td>Sanofi Aventis</td>
<td>783</td>
<td>Acquisition</td>
</tr>
</tbody>
</table>

Source: BMI, TechSci Research
Note: JV - Joint Venture
For updated information, please visit www.ibef.org
## INVESTMENTS, JVs INFUSING SUPERIOR CAPABILITIES IN INDIAN FIRMS … (2/2)

<table>
<thead>
<tr>
<th>Date announced</th>
<th>Indian company</th>
<th>Foreign company</th>
<th>Value (USD million)</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>March, 2017</td>
<td>Sun Pharma</td>
<td>Thallion Pharmaceuticals</td>
<td>19.77</td>
<td>Acquisition</td>
</tr>
<tr>
<td>January, 2017</td>
<td>Zydus Cadila</td>
<td>Zoetis</td>
<td>NA</td>
<td>Acquisition</td>
</tr>
<tr>
<td>December, 2014</td>
<td>Panacea Biotec Ltd</td>
<td>Apotex Inc</td>
<td>NA</td>
<td>JV</td>
</tr>
<tr>
<td>August, 2012</td>
<td>Strides Arcolab Ltd</td>
<td>Gilead Sciences Inc</td>
<td>NA</td>
<td>Licensing agreement</td>
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<td>July, 2011</td>
<td>Ranbaxy</td>
<td>Gilead Sciences Inc</td>
<td>NA</td>
<td>Licensing agreement</td>
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<tr>
<td>August, 2013</td>
<td>Jubilant Biosys</td>
<td>Endo Pharmaceuticals</td>
<td>NA</td>
<td>Drug development</td>
</tr>
<tr>
<td>October, 2012</td>
<td>Piramal Healthcare Ltd</td>
<td>Fujifilm Diosynth Biotechnologies</td>
<td>NA</td>
<td>Drug development</td>
</tr>
<tr>
<td>March, 2009</td>
<td>Biocon</td>
<td>Bristol-Myers Squibb</td>
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<td>Exclusive marketing</td>
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<tr>
<td>March, 2013</td>
<td>Unichem Laboratories</td>
<td>Mylan</td>
<td>30</td>
<td>Acquisition</td>
</tr>
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<td>October, 2012</td>
<td>SMS Pharmaceuticals</td>
<td>Mylan</td>
<td>33</td>
<td>Acquisition of manufacturing unit</td>
</tr>
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<td>March, 2012</td>
<td>Biocon</td>
<td>Abbott Laboratories</td>
<td>NA</td>
<td>Contract research</td>
</tr>
<tr>
<td>September, 2012</td>
<td>Agila Specialties</td>
<td>Mylan, A Canonsburg</td>
<td>1,850</td>
<td>Acquisition</td>
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<td>February, 2012</td>
<td>Jubilant Biosys</td>
<td>Mnemosyne Pharmaceuticals Inc</td>
<td>NA</td>
<td>Drug development</td>
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<td>January, 2011</td>
<td>Zydus Cadila Healthcare</td>
<td>Bayer</td>
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<td>Marketing arrangement</td>
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<tr>
<td>December, 2012</td>
<td>Claris Lifesciences</td>
<td>Otsuka Pharmaceutical</td>
<td>250</td>
<td>JV</td>
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<td>November, 2012</td>
<td>Zydus Cadila Healthcare</td>
<td>Abbot Laboratories</td>
<td>NA</td>
<td>Licensing agreement</td>
</tr>
<tr>
<td>July, 2011</td>
<td>Lupin</td>
<td>Eli Lilly</td>
<td>NA</td>
<td>Marketing arrangement</td>
</tr>
</tbody>
</table>

**Source:** ICRA Research on Indian Pharmaceutical Sector, India Ratings Research Outlook on Indian Pharmaceutical, BMI, TechSci Research  
Notes: JV - Joint Venture, ADC - Antibody Drug Conjugates
### 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, 3,043 clinical trials have been carried out in India

### High-end drugs
- Due to increasing population & income levels, demand for high-end drugs is expected to rise
- Demand for high-end drugs would reach USD7.5 billion in 2016
- 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 & Manufacturing Services industry (CRAMS) – estimated at USD8 billion in 2015, is expected to reach huge potential for investments
- The market has more than 1,000 players

*Source: BMI, TechSci Research*
The share of generic drugs is expected to continue increasing; it could represent about 85 per cent of the prescription drug market by 2016.

Domestic generic drug market is expected to reach USD27.9 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 & other countries.

Domestic generic drug market has reached USD26.1 billion in 2016.

In April 2017, Jubilant Life Sciences received a final approval from the US health regulator for olmesartan medoxomil tablets, which is used for the treatment of hypertension. The approved product is a generic version of Benicar of Daiichi Sankyo.

Source: BMI, TechSci Research
Note: F - Forecast
SUN PHARMA: LEVERAGING ITS GENERICS MARKET CAPABILITIES … (1/2)

- Sun Pharma was set up in 1983, with a compact manufacturing facility for tablets & capsules
- It set up its 1st API plant at Panoli in 1995
- It has 48 manufacturing facilities across 5 continents & 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 USD932 million in FY09 to USD 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, & ensure a strong positioning in emerging markets
- The company reported net profit of USD 335.8 million for the period July 2016 - September 2016
- As of October 2016, the company acquired 100 per cent equity in the US-based eye care specialist ‘Ocular Technologies Sarl’ for USD 40 million

Source: Sun Pharma website, TechSci Research
CAGR - Compound Annual Growth Rate

Sun Pharma net sales (USD million)
SUN PHARMA: LEVERAGING ITS GENERICS MARKET CAPABILITIES … (2/2)

- Revenue base of USD4.2 billion for FY16
- Generated net profit of USD825 million for FY16
- Over half the sales from North America
- Strong presence in generics market
- Among top 5 Indian pharma companies

Key Milestones:

- 1983: Commenced operations in Calcutta
- 1987: Nationwide marketing operations rolled out
- 1995: Built the first API plant
- 2004: 1st international acquisition: niche brand in the US
- 2012: Acquired controlling stake in Taro & full control on Caraco
- 2015: Acquired controlling stake in Ranbaxy
- 2016: Distribution agreement with AstraZeneca
- 2015: Acquisition of Insite Vision
- 2015: Acquisition of GSK’s Opiates Business
- 30,000 employees across the globe
- Organic growth phase
- Focus on R&D
- All-India operations begin
- 48 manufacturing sites worldwide
- In 2015, acquisition of Insite Vision
- 256 approved products & 391 filed for approval
- Acquisitions across the globe
- In 2016, Sun Pharma entered into Japan & acquired 14 brands from Novartis

Source: Sun Pharma website

For updated information, please visit www.ibef.org
DR REDDY’S: PROVIDING AFFORDABLE AND INNOVATIVE HEALTHCARE … (1/2)

- 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 3 segments: Pharmaceutical Services & 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 increased from USD1.5 billion in FY09 to USD2.4 billion in FY16, at a CAGR of 6.84 per cent over FY09-16
- Dr Reddy’s is investing heavily on R&D to differentiate itself in the market. In FY15 - 16 Dr Reddy’s spent around 13.8 per cent of sales on R&D

Dr Reddy’s net sales (USD million)

Source: Dr Reddy’s website, Notes: FY16* (April to September 2015)
CAGR - Compound Annual Growth Rate, R&D – Research and Development
In 2015, Aurigene, subsidiary of Dr Reddy’s announced collaboration with Curis.

- Fastest Indian company to cross USD2 billion revenues
- Over 25 billion units in generics capacities
- 1st company in Asia-Pacific outside of Japan to list on NYSE
- 4 technology development centres
- 20,000+ associates worldwide
- In 2016, three New Drug Applications (NDAs) DFD-01, DFD-09 & DFN-11 were approved by the FDA & 2 products are commercially available in the US market for the treatment of migraine & psoriasis.

Dr Reddy’s Laboratories incorporated in Hyderabad in 1984
Listed on BSE; commenced production of its 1st API in 1986
Dr Reddy’s Research Foundation established, Drug Discovery begins in 1993
Acquires UCB’S India selected portfolio worth USD 132 million in 2015
During 2015 Dr Reddy’s is planning to expand its portfolio by acquiring various companies with deal size worth USD 1 billion.

Notes: PSAI - Pharmaceutical Services and Active Ingredients, GG - Global Generics, PP - Proprietary Products, JV - Joint Venture

Source: Dr Reddy’s website, Annual Report

For updated information, please visit www.ibef.org
Lupin is a renowned pharma player producing a wide range of quality, affordable generic & branded formulations & APIs.

Lupin is the 7th largest generic pharmaceutical company globally in terms of market capitalization.

Its revenues increased from USD822.5 million in FY09 to USD2.1 billion in FY16, at a CAGR of 14.3 per cent during FY09-16.

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 & osteoarthritis.

In February 2017, Lupin has received the final approval from USFDA to market potassium sulfate, sodium sulfate & magnesium sulfate oral solutions, which are used to treat a form of cancer.

In March 2017, Lupin received an approval from United States Food & 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.
LUPIN: ON A HIGH GROWTH PATH … (2/2)

Revenues stood at USD 2093.1 million in FY16

Net profit earned in FY16 is USD346.9 million

Global leadership in anti-TB segments

7th largest global generic pharma company in 2016

3rd largest Indian pharma company

In 2015, Acquires GAVIS to Expand US Generic Business

In 2015, Received awards recognition for the following categories: Best Investor Relations, Risk Management Firm, ICAI for Excellence in Finance Report

12 Manufacturing Facilities

Entered in anti-diabetes drug market in India

18434 permanent employees

730 Products filled in Rest of the World

around 20 per cent Lupin’s revenue came from acquisitions in FY16

Expanding India operations

Focus on R&D

Diversifying into different business segments

1968 Commenced business

1980 Commissioned a formulations plant & R&D centre at Aurangabad

1989 JV in Thailand – Lupin Chemicals (Thailand) established

2015 Acquires GAVIS Pharmaceuticals LLS for USD 880 million.

2016 Acquires Medquimica for an undisclosed amount.

Notes: ANDAS - Abbreviated New Drug Application, DMFs - Drug Master Files, * - As of Half Year Ended September 2015

Source: Lupin website, Annual Report

For updated information, please visit www.ibef.org
Established in 1935, Cipla has over 34 state-of-the-art manufacturing units. Cipla’s R&D division focuses on new product development & new drug delivery systems across a range of therapies.

- It is one of the few companies producing medicines for rare diseases such as Idiopathic Pulmonary Fibrosis, Pulmonary Arterial Hypertension, Thalassaemia & Multiple Sclerosis.

- Cipla outperformed other global pharma majors by offering patented anti-AIDS drugs at affordable prices.

- It has presence in over 170 countries, with an employee strength of over 20,000; moreover, it is the 6th largest player in South Africa.

- Its revenues increased from USD1.11 billion in FY09 to USD2.04 billion in FY16, at a CAGR of 9.52 per cent over FY09-16.

- It is the 1st company to develop drug for the treatment of H1N1 flu.

- Cipla entered into an agreement to acquire two US based pharmaceutical companies, InvaGen Pharmaceuticals Inc., and Exelan Pharmaceuticals Inc., for USD500 million.

Source: Cipla website, Cipla brochure, Cipla corporate profile
Notes: CAGR - Compound Annual Growth Rate, API - Active Pharmaceutical Ingredient, OTC - Over The Counter
CIPLA: MAKING HEALTHCARE ACCESSIBLE … (2/2)

Revenue base of about USD2.04 billion in FY16
Net profit generated USD239.4 million in FY16
Global presence in over 170 countries
One of the world’s largest generic drug companies
2nd largest Indian pharma company

Pioneered inhalation therapy to manufacture MDI
Launched Deferiprone, world’s 1st oral iron chelator
Manufactured 1st Indian API in 1960

In 2016, receives Establishment Inspection Report (EIR) from the US for its Indore Facility
World’s largest ARV manufacturer
Over 2,000 products in 65 therapeutic categories
Cipla’s biotech subsidiary in South Africa has announced to invest USD0.1 billion into biotech manufacturing facility in 2016
34 internationally approved facilities
Pioneered access to HIV, ARVs made available at less than a dollar
Made cancer treatment affordable with breakthrough in reducing cost of cancer drugs
Increased its R & D expenses and patent filing
BioQ Pharma & Cipla Enter into an Agreement to Commercialize BioQ’s Ropivacaine Infusion System in India

53 per cent of total income from oversees sales
Over 10,000 product registrations globally
R & D expense 6.2 per cent & more than 200 formulation development projects
In 2015, Cipla is planning to launch ‘Efavirenz’ a drug against HIV infection

Source: Cipla website, Annual Report
Note: FY16* (Up to September 2015)
Notes: MDI - Metered Dose Inhaler, ARV - Anti-retroviral

For updated information, please visit www.ibef.org
PHARMACEUTICALS

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Fax: 91 40 23704804
E-mail: info@bdmai.org
www.bdmai.org
**CRAMS**: Contract Research and Manufacturing Services

**API**: Active Pharmaceutical Ingredients

**FDI**: Foreign Direct Investment

**GOI**: Government of India

**INR**: Indian Rupee

**USD**: 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

For updated information, please visit [www.ibef.org](http://www.ibef.org)
## Exchange Rates

### Exchange rates (Fiscal Year)

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<th>Year</th>
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<td>2015–16</td>
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<td>2016-2017E</td>
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### Exchange rates (Calendar Year)

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<td>2016 (Expected)</td>
<td>67.22</td>
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Source: Reserve bank of India, Average for the year
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