PHARMACEUTICALS

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EXECUTIVE SUMMARY

Leading pharma producer

• Indian pharmaceutical sector accounts for about 2.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms

One of the highest exports

• India accounts for 20 per cent of global exports in generics. In FY15, pharmaceuticals industry of India exported products worth USD15 billion and the exports are expected to reach USD40 billion by 2020

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 is expected to grow to USD26.1 billion by 2016 from USD21 billion in 2015. India’s generics market has immense potential for growth

 Ranked 5th in terms of attracting FDI

• Attracted 5 per cent of the total FDIs into India from April 2000 to September 15
• Cumulative FDI inflows worth USD13.32 billion from April 2000 to September 15

Notes: API - Active Pharmaceutical Ingredient, USFDA - United States Food and Drug Administration, CAGR - Compound Annual Growth Rate
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 and almost half of that of Europe
• Due to lower cost of treatment, India is emerging as a leading destination for medical tourism

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
• 49 per cent of all drug master filings from India is registered in the USA

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
PHARMACEUTICALS

STRUCTURE OF PHARMA SECTOR IN INDIA

Pharmaceuticals

Active Pharmaceutical Ingredients/ Bulk drugs

Generics

Chronic

Acute

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

- Anti-infectives
- Respiratory
- Pain
- Gynaecology

Source: Dun & Bradstreet, 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

**2010-2015**
- Increased patent filings by pharma players
- Likely adoption of newer sales models such as channel management, KAM and CSO
- Leading pharma companies have increased their R&D spending on new cost-effective generic products to strengthen their presence across global markets
- The National Pharmaceutical Pricing Policy, 2012 (NPPP-2012)
- National Health Policy Draft 2015 to increase expenditure in health care sector.
- 2014: 100% 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 and Drugs this will reduce the prices of drugs by 80%
- Leading Indian pharma companies are raising funds aggressively to fund acquisition in domestic as well as international market to increase their product portfolios.

*Source: TechSci Research*

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

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# Pharmaceuticals

**API is the largest segment of the Indian Pharmaceuticals sector**

<table>
<thead>
<tr>
<th>Pharmaceutical Industry</th>
<th>Active Pharmaceutical Ingredients (APIs)</th>
<th>Contract Research and Manufacturing Services (CRAMS)</th>
<th>Formulations</th>
<th>Biosimilars</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>India is expected to be the third largest global generic API merchant market by 2016, with a 7.2 per cent market share</em></td>
<td><em>The Indian pharmaceutical industry accounts for the second largest number of Abbreviated New Drug Applications (ANDAs), is the world’s leader in Drug Master Files (DMFs) applications with the US</em></td>
<td><em>Fragmented market with more than 1,000 players</em></td>
<td><em>Largest exporter of formulations in terms of volume, with 14 per cent market share and 12th in terms of export value</em></td>
<td><em>Biosimilar’s sector is expected to touch USD1.4 billion by 2016 and the sector is expected to grow annually at a rate of 30 per cent in India</em></td>
</tr>
<tr>
<td><em>The government plans to allocate USD70 million for local players to develop biosimilars</em></td>
<td></td>
<td><em>CRAMS industry is estimated to reach USD18 billion in 2018 and expected to witness a strong growth at a CAGR of 18-20 per cent</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Note: OTC - Over The Counter
The Indian pharmaceuticals market increased at a CAGR of 17.46 per cent in 2015 from USD6 billion in 2005 and is expected to expand at a CAGR of 15.92 per cent to USD55 billion by 2020.

By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size.

India’s cost of production is significantly lower than that of the US and almost half of that of Europe. It gives a competitive edge to India over others.

Increase in the size of middle class households coupled with the improvement in medical infrastructure and increase in the penetration of health insurance in the country will also influence in the growth of pharmaceuticals sector.

Revenue of Indian pharmaceutical sector (USD billion)

Source: Department of Pharmaceuticals, PwC, McKinsey, TechSci Research
Notes: F - Forecast, CAGR - Compound Annual Growth Rate
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 supply 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 percent) in the Indian pharma market.

The cardiovascular segment represents 13 percent 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 percent 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 percent to the total drugs consumption.

In FY15, anti-infectives grew at 22 percent, gastrointestinal at 23.4 percent, pain & analgesics at 16.5 percent, cardiovascular at 19.1 percent, anti-diabetic grew at 32.9 percent, respiratory segment grew at 27.8 percent, derma market grew by 19.2 percent and urology by 29.5 percent.

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

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).

In terms of value, exports of pharmaceutical products increased at a CAGR of 14 per cent during FY12–15.

US is the largest export market for India.

During FY12-14, imports of pharmaceutical products rose at a CAGR of 13.04 per cent to USD4.6 billion.

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
COMPETITIVE MARKET; TOP FOUR FIRMS ACCOUNT FOR OVER 20 PER CENT MARKET SHARE

* Dr Reddy’s has the largest share (24.45 per cent) in the Indian pharma market, with sales of USD1.66 billion during March 2015

* Lupin has the second largest share of 23.71 per cent in the Indian pharma market with sales of USD1.61 billion.

* Cipla, with a revenue base of USD 1.55 billion for March 2015 sales, ranks third in the market

* Aurobindo ranks fourth in the market, with a revenue base of USD 1.17 billion for March 2015 sales

* While these top four companies garnered 20 per cent market share, top 10 companies comprise nearly 39 per cent of the market share

Market share, revenue, growth rates of leading companies (%), FY15

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, Market share is being calculated on the basis of FY15 revenue.
PHARMA GIANTS RAISE THEIR R&D SPENDING

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

* By 2020, the Indian healthcare sector is expected to reach USD280 billion from USD70 billion currently

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

<table>
<thead>
<tr>
<th>Company</th>
<th>R&amp;D Spending (USD million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun Pharma</td>
<td>160</td>
</tr>
<tr>
<td>Dr Reddy</td>
<td>145</td>
</tr>
<tr>
<td>Lupin</td>
<td>115</td>
</tr>
<tr>
<td>Cipla</td>
<td>164</td>
</tr>
<tr>
<td>Cadila</td>
<td>28</td>
</tr>
<tr>
<td>Wockhart*</td>
<td>85</td>
</tr>
<tr>
<td>Aurbindo*</td>
<td>58</td>
</tr>
</tbody>
</table>

Source: Company websites TechSci Research
Note:**: For FY15
**: up to September 2015
R&D - Research and Development
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 reached USD15 billion in 2015 and estimated to reach USD18.02 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
- 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 USD32 billion plant in Africa for the production of anti-retroviral and anti-malarial drugs
- Sun Pharma, become the world’s fifth largest company worldwide having 48 manufacturing sites more than 3000 marketed product

Source: TechSci Research
Note: R&D - Research and Development
NOTABLE TRENDS IN THE INDIAN PHARMACEUTICALS SECTOR … (2/2)

**PPP in R&D**
- Indian Government plans to involve the private sector in R&D mainly for sectors such as vaccines, drugs and pharmaceuticals, super computing, solar energy and electronic hardware
- As on January 2016, the total project cost of healthcare infrastructure project is USD151.91 million and there are five healthcare projects under PPP. Green Field Super Specialty Hospital (Bathinda), Green Field Super Specialty Hospital (Mohali), Indira Gandhi Government Medical College Complex (Maharashtra), Nephrology and Dialysis unit at Coronation Hospital (Uttarakhand), Nephrology Dialysis unit at Base Hospital (Uttarakhand)

**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
- Necessary permissions to be taken from the concerned authority before the grant of patents

**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

**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

Source: TechSci Research
Note: R&D - Research and Development
STATES HOSTING KEY PHARMACEUTICAL VENTURES

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

Source: Company websites
## PORTER’S FIVE FORCES ANALYSIS

### 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 pharma companies, backed by huge financial muscle

### 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

### 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

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STRATEGIES ADOPTED

Cost leadership

- Players in the sector are trying to achieve cost leadership in various ways. For example, Sun Pharma is trying to achieve the same 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 differentiate themselves by investing heavily on R&D efforts. For example,
  - In 2015, Lupin opened a research and development centre for inhalation products in Florida, US
  - Sun Pharma is trying to develop technically complex APIs, such as steroids, sex hormones, peptides, carbohydrates and taxanes, which require special skills and technology
  - Dr Reddy’s is investing in technology platforms. It 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

Focus on new markets

- Certain players in the sector are focusing on entering new markets with new opportunities. For example, 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

Source: Company websites, TechSci Research
Note: R&D – Research and Development
PHARMACEUTICALS

LEVERS FOR SUCCESS

- Review product portfolio
- Achieve organisational agility
- Build customer centricity
- 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

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JANUARY 2016
SECTOR DRIVEN BY CONFLUENCE OF DEMAND, CAPABILITIES AND POLICY

Growth 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

Demand-side drivers

Supply-side drivers

Policy Support

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

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
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

Medical infrastructure

- Pharma companies have increased spending to tap rural markets and develop better medical infrastructure
- In 2015, Indo-UK healthcare agreed to invest USD1.63 billion to set up hospitals and the first hospital will set up in Punjab
- Hospitals’ market size is expected to increase by USD200 billion by 2024
- 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
- India’s generics drug market accounts for around 70 per cent of the India pharmaceutical industry and it is expected to reach USD27.9 billion by 2020

Scope in generics market

- India’s OTC drugs market is expected to rise at a CAGR of 16.3 per cent to USD6.6 billion over 2008–16
- Increased penetration of chemists, especially in rural regions, would increase the availability of OTC drugs in the country

Over-The-Counter (OTC) drugs

- 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
- The newly available market will be filled by generics, which would provide great opportunity to Indian companies

Patent expiry

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 60 per cent lower than that of the US and almost half of that of Europe
  * 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

Competency

* India has a skilled workforce as well as high managerial and technical competence in comparison to its peers in Asia
* India has the second 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

Relative cost of production with US cost as base as on March 2014

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 and tier-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

**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 and lifestyle changes to boost demand
- Increasing prevalence of lifestyle diseases

Note: RSBY - Rashtriya Swasthya Bima Yojna
Over 2010-15, total healthcare spending is expected to rise at a CAGR of 7.04 per cent to USD91.2 billion

Pharmaceutical sales, as a percentage of total healthcare spending, are expected to increase to 32.88 per cent by 2015 from 25.30 per cent in 2015.

Source: Deloitte, BMI, PWC, TechSci Research

Notes: F - Forecast, 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 19.4 per cent to USD33 by 2016F.

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

Source: BMI, TechSci Research
Notes: F - Forecast, 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 two weeks compared to 12 weeks earlier

Collaborations
- MoUs with USFDA, WHO, Health Canada, etc. to boost growth in the Indian Pharma sector by benefiting from their expertise. In 2015, NIPER (Mohali) signed MoUs with pharmaceutical industry leaders Bharat Biotech, Dr Reddy, Cadila Healthcare, Sun Pharma and Panacea Biotech

Support for technology upgrades and FDIs
- Zero duty for technology upgrades in the pharmaceutical sector through the Export Promotion Capital Goods (EPCG) Scheme
- Permission for 100 per cent Foreign Direct Investment (FDI)
- Government is planning to relax FDI norms in the pharmaceutical sector

Industry infrastructure
- Under the Union Budget 2015-16, government has announced to set up 3 new National Institute of Pharmaceuticals Education and Research in Maharashtra, Rajasthan & Chattisgarh and government is also planning to set up one institute of Science and Education Research in Nagaland & Orissa each.

Pharma Vision 2020
- Pharma Vision 2020 by the government’s Department of Pharmaceuticals aims to make India a major hub for end-to-end drug discovery

Exceptions
- Full exemption from excise duty is being provided for HIV/AIDS drugs and diagnostic kits supplied under National AIDS Control Programme funded by the Global Fund to fight AIDS, TB and Malaria (GFATM)
- The customs duties on the said drugs are also being exempted

Source: Union Budget 2015-16, TechSci Research
For updated information, please visit www.ibef.org
Government expenditure on health increased from USD14 billion in 2008 to USD30.4 billion in 2015.

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

Under Union Budget 2015-16, USD243.86 million has been allocated to set up medical institutions and six more institutions of the stature of AIIMS in J&K, Punjab, Tamil Nadu, Himachal Pradesh and Assam & Bihar.

Rising share of government expenditure (USD billion)

Notes: CAGR - Compound Annual Growth Rate, F - Forecast
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 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.

### RISING EXPENDITURE SHARE BY PRIVATE SECTOR

<table>
<thead>
<tr>
<th>Year</th>
<th>Private Expenditure</th>
<th>Public Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>36</td>
<td>14</td>
</tr>
<tr>
<td>2009</td>
<td>38</td>
<td>16</td>
</tr>
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<td>2010</td>
<td>44.4</td>
<td>20.5</td>
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<tr>
<td>2011</td>
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<td>20.7</td>
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<td>2012</td>
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<td>2013</td>
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<tr>
<td>2015</td>
<td>60.8</td>
<td>30.4</td>
</tr>
<tr>
<td>2016F</td>
<td>80</td>
<td></td>
</tr>
</tbody>
</table>

*Source: Business Monitor International, TechSci Research*

*Note: F - Forecast*
HEALTH INSURANCE PENETRATION EXPECTED TO SURGE

- Penetration of health insurance is expected to more than double by 2020. Around 439.5 million population has been covered by 2014.
- 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.

Population with health cover* (In Million)

<table>
<thead>
<tr>
<th>Year</th>
<th>Govt Sponsored</th>
<th>Non Govt Group Cover</th>
<th>Individual cover</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011-12</td>
<td>20.6</td>
<td>30</td>
<td>131.2</td>
</tr>
<tr>
<td>2012-13</td>
<td>23.6</td>
<td>34.3</td>
<td>149.4</td>
</tr>
<tr>
<td>2013-14</td>
<td>27.3</td>
<td>33.7</td>
<td>155.3</td>
</tr>
</tbody>
</table>

*Figures mentioned are as per latest data available.

Source: IRDA, Mckinsey estimates, TechSci Research, World Bank
Notes: RSBY - Rashtriya Swasthya Bima Yojna, ESIC - Employees State Insurance Corporation;
NATIONAL PHARMA POLICY TO BRING GREATER TRANSPARENCY

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 and efficacy

National Pharma Pricing Policy 2012

- 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

Market-based pricing
Price control of formulations only

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

* Pharma, healthcare and biotech have witnessed significant increases in M&A activities over the years; over the last three years, pharmaceuticals segment has accounted for more than 70 per cent of M&A deals

* In the first nine months of 2015, mergers and acquisitions deals in pharmaceuticals sector has reached USD1.7 billion in India

<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>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>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>April, 2011</td>
<td>Sun Pharma</td>
<td>Merck</td>
<td>NA</td>
<td>Marketing</td>
</tr>
<tr>
<td>September, 2010</td>
<td>Piramal</td>
<td>Abbot</td>
<td>3,720</td>
<td>Business buyout</td>
</tr>
<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
### 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>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>
</tr>
<tr>
<td>July, 2011</td>
<td>Ranbaxy</td>
<td>Gilead Sciences Inc</td>
<td>NA</td>
<td>Licensing agreement</td>
</tr>
<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>
<td>NA</td>
<td>Exclusive marketing</td>
</tr>
<tr>
<td>March, 2013</td>
<td>Unichem Laboratories</td>
<td>Mylan</td>
<td>30</td>
<td>Acquisition</td>
</tr>
<tr>
<td>October, 2012</td>
<td>SMS Pharmaceuticals</td>
<td>Mylan</td>
<td>33</td>
<td>Acquisition of manufacturing unit</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>February, 2012</td>
<td>Jubilant Biosys</td>
<td>Mnemosyne Pharmaceuticals Inc</td>
<td>NA</td>
<td>Drug development</td>
</tr>
<tr>
<td>January, 2011</td>
<td>Zydus Cadila Healthcare</td>
<td>Bayer</td>
<td>NA</td>
<td>Marketing arrangement</td>
</tr>
<tr>
<td>December, 2012</td>
<td>Claris Lifesciences</td>
<td>Otsuka Pharmaceutical</td>
<td>250</td>
<td>JV</td>
</tr>
<tr>
<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
**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

### High-end drugs
- Due to increasing population and income levels, demand for high-end drugs is expected to rise
- Demand for high-end drugs could reached USD7.5 billion in 2015
- 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 USD8 billion in 2015, up from USD3.8 billion in 2012 has a 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 and other countries.

Share of patented and generic drugs in prescribed drug market (USD billion)

<table>
<thead>
<tr>
<th>Year</th>
<th>Patented drugs</th>
<th>Generic drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>0.8</td>
<td>6.9</td>
</tr>
<tr>
<td>2009</td>
<td>0.9</td>
<td>8.1</td>
</tr>
<tr>
<td>2010</td>
<td>1.1</td>
<td>10</td>
</tr>
<tr>
<td>2011</td>
<td>1.3</td>
<td>11.3</td>
</tr>
<tr>
<td>2012</td>
<td>1.5</td>
<td>12.6</td>
</tr>
<tr>
<td>2013</td>
<td>1.8</td>
<td>15.1</td>
</tr>
<tr>
<td>2014</td>
<td>2.2</td>
<td>18.1</td>
</tr>
<tr>
<td>2015</td>
<td>2.7</td>
<td>21</td>
</tr>
</tbody>
</table>

Source: BMI, TechSci Research
Note: F - Forecast

For updated information, please visit www.ibef.org
Sun Pharma was set up in 1983, with a compact manufacturing facility for tablets and capsules.

It set up its first API plant at Panoli in 1995.

It has 48 manufacturing facilities across five continents and employs more than 30,000 people as on FY16*.

Nearly 72 per cent of its sales come from international markets.

Its revenues increased from USD932 million in FY09 to USD 4.5 billion in FY15, at a CAGR of 30.13 per cent.

In March 2015, Sun Pharma completed the acquisition of Ranbaxy Laboratories Ltd to become the fifth largest global specialty pharma company, No 1 pharma company in India, and ensure a strong positioning in emerging markets.

**Sun Pharma net sales (USD million)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales (USD million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY09</td>
<td>932</td>
</tr>
<tr>
<td>FY10</td>
<td>847</td>
</tr>
<tr>
<td>FY11</td>
<td>1256</td>
</tr>
<tr>
<td>FY12</td>
<td>1672</td>
</tr>
<tr>
<td>FY13</td>
<td>2067</td>
</tr>
<tr>
<td>FY14</td>
<td>2655</td>
</tr>
<tr>
<td>FY15</td>
<td>4526</td>
</tr>
<tr>
<td>FY16*</td>
<td>2182.9</td>
</tr>
</tbody>
</table>

**Source:** Sun Pharma website, TechSci Research

Note:*Up to September 2015, CAGR - Compound Annual Growth Rate
PHARMACEUTICALS

SUN PHARMA: LEVERAGING ITS GENERICS MARKET CAPABILITIES … (2/2)

- Revenue base of USD2.18 billion for FY16*
- Generated net profit of USD260 million for FY16*
- Over half the sales from North America
- Strong presence in generics market
- Among top five Indian pharma companies
- Focus on R&D
- 256 approved products and 391 filed for approval
- Acquisitions across the globe
- 48 manufacturing sites worldwide
- Organic growth phase
- All-India operations begin

- Commenced operations in Calcutta 1983
- Nationwide marketing operations rolled out 1987
- Built the first API plant 1995
- First international acquisition: niche brand in the US 2004
- Acquired controlling stake in Caraco 2012
- Acquired controlling stake in Ranbaxy 2015
- 30,000 employees across the globe
- 256 approved products and 391 filed for approval
- Source: Sun Pharma website
  Note: * up to September 2015

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

Its revenues increased from USD1.5 million in FY09 to USD2.4 million in FY15, at a CAGR of 8.79% per cent.

Global generics comprised over 81 per cent of its revenue mix in FY15.

Dr Reddy’s is investing heavily on R&D to differentiate itself in the market. In FY 14-15 Dr Reddy’s spend around 11.8% of sales on R&D.

**Dr Reddy’s net sales (USD million)**

<table>
<thead>
<tr>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>FY15</th>
<th>FY16*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1479</td>
<td>1480</td>
<td>1626</td>
<td>2016</td>
<td>2141</td>
<td>2193</td>
<td>2452</td>
<td>1269</td>
</tr>
</tbody>
</table>

Source: Dr Reddy’s website, Notes: FY16* (April to September 2015) CAGR - Compound Annual Growth Rate, *CAGR is mentioned in INR terms, R&D – Research and Development.
Among top three Indian pharma companies

Integrated business spanning three segments- PSAI, GG and PP

Net profit generated in FY16* is USD220 million

Among the leaders in supply of generic APIs globally

Revenue base of about USD1.2 billion for FY16*

Four technology development centres

23 manufacturing sites worldwide

Over 25 billion units in generics capacities

Fastest Indian company to cross USD2 billion revenues

First company in Asia-pacific outside of Japan to list on NYSE

Net profit generated in FY16* is USD220 million

20,000+ associates worldwide

Dr Reddy’s is planning to expand its portfolio by acquiring various companies with deal size worth USD 1 billion.

Acquires UCB’S India selected portfolio worth USD 132 million

During the 2015 Dr Reddy’s

Dr Reddy’s Research Foundation established, Drug Discovery begins

Listed on BSE; commenced production of its first API

First company in Asia-pacific outside of Japan to list on NYSE

2015

1993

1986

1984

Source: Dr Reddy’s website, Annual Report

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

* Half year ended September 2015

JANUARY 2016
Lupin is a renowned pharma player producing a wide range of quality, affordable generic and branded formulations and APIs.

It is one of the world’s largest manufacturers of TB drugs and has significant market share in the cardiovascular, diabetology, asthma, paediatrics, CNS, Anti-infectives and NSAIDS therapy segments.

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

Its revenues increased from USD822.5 million in FY09 to USD2.1 billion in FY15, at a CAGR of 16.8 per cent.

Advanced market formulations comprised nearly 48 per cent of its revenues in FY15.

Specialty generic player across the globe, including emerging markets.

Lupin is third largest drug manufacturer in India by sales.
PHARMACEUTICALS

LUPIN: ON A HIGH GROWTH PATH … (2/2)

- Revenues stood at USD 1024 million in FY16*
- Net profit earned in FY16* is USD 153 million
- Global leadership in anti-TB segments
- 14th largest global generic pharma company
- Third largest Indian pharma company
- Entered in anti-diabetes drug market in India
- 12 Manufacturing Facilities
- Diversifying into different business segments
- 18434 permanent employees
- Expanding India operations
- 730 Products filled in Rest of the World
- Focus on R&D

- Commenced business in 1968
- Commissioned a formulations plant and R&D centre at Aurangabad in 1980
- JV in Thailand – Lupin Chemicals (Thailand) established in 1989
- Acquires GAVIS Pharmaceutics LLS for USD 880 million in 2015
- Acquires Medquimica for an undisclosed amount in 2015

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 and 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 and 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 sixth-largest player in South Africa.

Its revenues increased from USD1.11 billion in FY09 to USD1.88 billion in FY15, at a CAGR of 9.7 per cent.

It is the first company to develop drug for the treatment of H1N1 flu.

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

Cipla net sales (USD million)

Source: Cipla website, Cipla brochure, Cipla corporate profile
Notes: CAGR - Compound Annual Growth Rate, FY16*: Up to September 2015
API - Active Pharmaceutical Ingredient, OTC - Over The Counter
CIPLA: MAKING HEALTHCARE ACCESSIBLE … (2/2)

- Cipla established to make India self-sufficient in healthcare (1935)
- Pioneered inhalation therapy to manufacture MDI (1978)
- Launched Dferiprone, world’s first oral iron chelator (1994)
- Pioneered access to HIV. ARVs made available at less than a dollar (2001)
- Made cancer treatment affordable with breakthrough in reducing cost of cancer drugs (2012)
- Increased its R & D expenses and patent filing (2015)

- Revenue base of about USD1.05 billion in FY16*
- Net profit generated USD179.7 million in FY16*
- Global presence in over 170 countries
- One of the world’s largest generic drug companies
- Second largest Indian pharma company

- Manufactured first Indian API in 1960
- 34 internationally approved facilities
- World’s largest ARV manufacturer
- Over 2,000 products in 65 therapeutic categories
- 53 per cent of total income from oversees sales
- In 2015, Cipla is planning to launch ‘Efavirenz’ a drug against HIV infection
- Over 10,000 product registrations globally
- R & D expense 6.2 per cent and more than 200 formulation development projects

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
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Fax: 91 40 23704804
E-mail: info@bdmai.org
www.bdmai.org
GLOSSARY

* **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

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JANUARY 2016
## Exchange Rates

### Exchange rates (Fiscal Year)

<table>
<thead>
<tr>
<th>Year</th>
<th>INR equivalent of one USD</th>
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</thead>
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<td>44.81</td>
</tr>
<tr>
<td>2005–06</td>
<td>44.14</td>
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<tr>
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<td>45.14</td>
</tr>
<tr>
<td>2007–08</td>
<td>40.27</td>
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<tr>
<td>2008–09</td>
<td>46.14</td>
</tr>
<tr>
<td>2009–10</td>
<td>47.42</td>
</tr>
<tr>
<td>2010–11</td>
<td>45.62</td>
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<tr>
<td>2011–12</td>
<td>46.88</td>
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<td>54.31</td>
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<td>2013–14</td>
<td>60.28</td>
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<tr>
<td>2014–15</td>
<td>61.06</td>
</tr>
<tr>
<td>2015-16(Expected)</td>
<td>61.06</td>
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### Exchange rates (Calendar Year)

<table>
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<th>Year</th>
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</thead>
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<td>43.98</td>
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<tr>
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<td>45.72</td>
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<td>53.46</td>
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<td>2013</td>
<td>58.44</td>
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<tr>
<td>2014</td>
<td>61.03</td>
</tr>
<tr>
<td>2015(Expected)</td>
<td>63.72</td>
</tr>
</tbody>
</table>

Source: Reserve bank of India, Average for the year

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