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- Advantage India
- Market overview and trends
- Growth drivers
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- Useful information

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Advantage India

Cost Efficiency
- Low cost of production and R&D boosts efficiency of Indian pharma companies
- Comparative cost advantage enhances Indian pharma exports

Economic Drivers
- Economic prosperity to improve affordability of drugs
- Increasing penetration of health insurance

Diversified Portfolio
- Accounts for over 10 per cent of global pharmaceutical production
- Over 60,000 generic brands across 60 therapeutic categories
- Manufactures more than 400 different APIs

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

Market size: USD35.9 billion

Source: BMI, Aranca Research
2016 revenue forecasts are estimates of BMI, United States Food and Drug Association (USFDA), BMI stands for Business Monitor International, API stands for Active Pharmaceutical Ingredients

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Evolution of the Indian pharmaceutical sector

Before 1970
- Market dominated by foreign companies, with little domestic participation

1970-1990
- Indian Patent Act passed in 1970
- Several domestic companies start operations
- Development of production infrastructure
- Export initiatives taken

1990-2005
- Liberalised market
- Domestic players expand aggressively
- Increased propensity for R&D

2005 onwards
- Indian companies increasingly launch operations in foreign countries
- India a major destination for generic drug manufacture
- Higher spending on R&D due to the introduction of product patents

For updated information, please visit www.ibef.org
API is the largest segment of the Indian pharmaceuticals industry

Pharmaceutical industry

- Active pharmaceutical ingredients (APIs)
  - USD8.7 billion export market as of 2010
  - India is expected to supplant Italy as the second largest producer of APIs globally

- Contract research and manufacturing services (CRAMS)
  - Fragmented market with more than 1000 players
  - From USD2.5 billion in 2009, industry analysts expect market size to surge above USD7 billion by end - 2012

- Formulations
  - Domestic market size is currently valued at about USD10 billion; the segment is set for double-digit growth over the next five years
  - Consists of prescription and OTC drugs

- Biosimilars
  - From USD200 million in 2008, revenues are set to jump to USD550-600 million by 2012-13
  - The government plans to allocate USD70 million for local players to develop biosimilars

Source: BMI, Datamonitor, Various industry estimates, Aranca Research
Note: OTC - Over The Counter
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MARKET OVERVIEW AND TRENDS

The Indian pharmaceuticals industry sales stood at USD 15.6 billion during 2011.

It is forecasted to double in five years, reaching USD 35.9 billion by 2016.

Revenue of Indian pharmaceuticals industry (USD billion)

- **2008**: 9.7
- **2009**: 11.2
- **2010**: 13.8
- **2011**: 15.6
- **2012F**: 17.4
- **2013F**: 20.8
- **2014F**: 25.0
- **2015F**: 30.0
- **2016F**: 35.9

**CAGR**: 17.8%

**Source**: BMI, Aranca Research

Note: F stands for Forecasts
Fast growth to continue in both domestic, export segments ... (2/2)

- Pharma exports from India are forecasted to increase more than two folds over the next five years.

- The trade surplus in the pharma sector is likely to expand to USD16.5 billion by 2016.

Trade data of Indian pharma industry (USD billion)

<table>
<thead>
<tr>
<th>Year</th>
<th>Exports</th>
<th>Net exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>4.9</td>
<td>4.1</td>
</tr>
<tr>
<td>2009</td>
<td>4.9</td>
<td>3.9</td>
</tr>
<tr>
<td>2010</td>
<td>6.0</td>
<td>5.1</td>
</tr>
<tr>
<td>2011</td>
<td>7.0</td>
<td>6.1</td>
</tr>
<tr>
<td>2012F</td>
<td>8.0</td>
<td>7.0</td>
</tr>
<tr>
<td>2013F</td>
<td>9.8</td>
<td>8.6</td>
</tr>
<tr>
<td>2014F</td>
<td>12.0</td>
<td>10.7</td>
</tr>
<tr>
<td>2015F</td>
<td>14.7</td>
<td>13.3</td>
</tr>
<tr>
<td>2016F</td>
<td>18.2</td>
<td>16.5</td>
</tr>
</tbody>
</table>

Source: BMI, Aranca Research
Note: F stands for Forecasts

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Alimentary drugs lead the market; India is third in Asia-Pacific ... (1/2)

- Alimentary drugs command the largest share (over 13 per cent) in the Indian pharma market.

- The cardiovascular segment represents 10 per cent of the market share; its contribution is likely to rise due to the growing number of cardiac cases in India.

Indian pharmaceutical market segments by value (2010E)

- Alimentary/metabolism (13%)
- Cardiovascular (10%)
- Respiratory (9%)
- Central Nervous System (6%)
- Oncology (3%)
- Other therapeutic purposes (59%)

Source: Datamonitor, Aranca Research
Japan accounts for over 50 per cent of pharmaceutical sales in Asia-Pacific, followed by China which is a distant second with 19 per cent.

India, with a little over 10 per cent market share, ranks third by market size.

Market share by value in Asia-Pacific (2010)

Source: Datamonitor, Aranca Research
→ Cipla has the largest share (5.2 per cent) in the Indian pharma market with revenues of USD643 million during the year ending January 2011

→ During January 2011-January 2012, Sun Pharma posted the highest growth in revenue among the major players

→ Ranbaxy, with a revenue base of USD559 million, ranks fourth in the market

→ The top four firms account for less than one-fifth of the market share

Source: BMI, Aranca Research
Market share is in terms of revenue

The bubbles denote revenue earned during Jan 11-Jan 12 in USD million
Notable trends in the Indian pharmaceuticals sector

Research and development
- Indian pharma companies spend 2 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

Clinical trials
- Due to its cost advantage, India is increasingly becoming a hub for clinical trials. Clinical trials market is estimated to be worth USD485 million in 2010 and is projected to grow at 17 per cent CAGR over 2009-15

Export revenue
- The pharmaceutical export market in India is thriving due to strong presence in the generic space

Joint ventures
- Several multinational companies are collaborating with Indian pharma firms to develop new drugs
- Pfizer partnered with Aurobindo Pharma to develop generic medicines

Product patents
- The introduction of product patents in India in 2005 has boosted the discovery of new drugs
- India has reiterated its commitment to IP protection following the introduction of product patents
States hosting key pharmaceutical ventures

**Dholka** in Gujarat is home to the major manufacturing facility of **Cadila**. The facility is spread over an area of hundred acres.

**Ranbaxy’s** API manufacturing facility at Toansa, Punjab.

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

**Cipla** has a formulations manufacturing plant at Indore.

**Lupin** has an USFDA approved plant at Tarapur in Maharashtra. The facility forms the core of Lupin’s fermentation capabilities.

**Mandideep** in Madhya Pradesh is the hub of **Lupin’s** cephalosporin and ACE-Inhibitors manufacturing. **Cipla** has a formulations manufacturing plant at Indore.

**Piramal’s** USFDA approved manufacturing plant in Hyderabad.

**Glaxo SmithKline** has a major facility at Rajahmundry, Andhra Pradesh.

Source: Company websites

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Sector driven by confluence of demand, capabilities and policy

**Demand-side drivers**
- Accessibility of drugs to greatly improve
- Increasing penetration of health insurance
- Growing number of stress-related diseases due to change in lifestyle

**Supply-side drivers**
- Cost advantage
- India a major hub for the manufacture of generics
- Over 120 USFDA-approved facilities

**Policy support**
- Reduction in approval time for new facilities
- Focus on specialised pharma education
- Improved accessibility for BPL people

Notes: BPL means Below Poverty Line
Supply-side drivers of Indian pharma industry

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 related diseases in India could boost the sale of drugs in this segment

Scope in generics market
- Due to its cost advantage, India has emerged as a major producer of generic drugs with several companies focussing on this sector
- With an expected market size of USD26.1 billion in 2016 vis-à-vis USD11.3 billion in 2011, there is immense potential for growth in India’s generic market

Medical infrastructure
- Pharma companies have increased spending to tap rural markets and develop better medical infrastructure
- Hospitals’ market share is expected to increase from 13.1 per cent in 2009 to 26 per cent in 2020

OTC drugs
- Increased penetration of chemists, especially in the rural parts of India would make OTC drugs easily available
Competency and cost efficiency continue to be India’s forte … (1/2)

→ India has over 120 USFDA-approved and 84 UK MHRA-approved manufacturing facilities

→ These facilities significantly support the companies involved in CRAMS

Number of USFDA-approved facilities in different countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hungary</td>
<td>5</td>
</tr>
<tr>
<td>Israel</td>
<td>8</td>
</tr>
<tr>
<td>Taiwan</td>
<td>10</td>
</tr>
<tr>
<td>Spain</td>
<td>25</td>
</tr>
<tr>
<td>China</td>
<td>27</td>
</tr>
<tr>
<td>Italy</td>
<td>55</td>
</tr>
<tr>
<td>India</td>
<td>120</td>
</tr>
</tbody>
</table>

Notes: USFDA is United States Food and Drug Administration
CRAMS is Contract Research and Medical Services

Source: BMI, Aranca Research
The manufacturing cost of Indian pharma companies is up to 65 per cent lower than that of US firms and almost half of that of European manufacturers.

Cost efficiency continues to create opportunities for Indian companies in emerging markets and Africa.

**Relative cost of production with US cost as base**

- **India**: 40
- **Europe**: 85
- **US**: 100

*Source: BMI, Aranca Research*
Demand drivers of Indian pharma industry

**Accessibility**
- Over USD200 billion to be spent on medical infrastructure in the next decade
- New business models expected to penetrate tier-2 and 3 cities
- Over 160,000 hospital beds expected to be added each year in the next decade

**Acceptability**
- Rising levels of education to increase the acceptability of pharmaceuticals
- Patients to show greater propensity to self-medicate, boosting the OTC market
- Acceptance of biologics and preventive medicines to rise
- Vaccine market could grow 20 per cent per year in the next decade

**Affordability**
- Rising income could drive 73 million households to the middle class over the next ten 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 also plans to provide free generic medicines to half the population at an estimated cost of USD 5.4 billion

**Epidemiological factors**
- Patient pool expected to increase over 20 per cent in the next ten years mainly due to a rise in population
- Newer diseases and changes in lifestyle to boost demand

*Source: McKinsey pharma report 2020, Aranca Research*
Anticipated steep growth in expenditure on pharmaceuticals

→ From 18.9 per cent of healthcare expenditure in 2008, pharmaceuticals sales is likely to increase to 27 per cent of total spending on healthcare by 2016.

Pharmaceutical sales as a per cent of healthcare expenditure

*Source: BMI, Aranca Research
Notes: F - Forecast*
Growing per capita sales of pharmaceuticals in India offers ample opportunities for players in this market.

Per capita sales of pharmaceuticals (USD billion)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>8.1</td>
<td>9.3</td>
<td>11.3</td>
<td>12.6</td>
<td>13.9</td>
<td>16.3</td>
<td>19.3</td>
<td>22.9</td>
<td>27.1</td>
</tr>
</tbody>
</table>

CAGR: 16.3%

Source: BMI, Aranca Research
Pharmaceuticals MARCH 2013

Favourable policy measures support growth

Reduction in approval time for new facilities
- Steps taken to reduce approval time for new facilities
- NOC for export license issued in two weeks compared to 12 weeks earlier

Collaborations
- MOUs with USFDA, WHO, Health Canada, etc. to boost growth of the Indian Pharma sector by benefiting from their expertise

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 pharmaceuticals sector

Industry infrastructure
- Government of India plans to set up a USD640 million VC fund to boost drug discovery and strengthen the pharma infrastructure

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

Notes: NOC - No objection certificate; VC - Venture Capital
MOU - Memorandum of Understanding

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Government-led initiatives aim at better availability of drugs ... (1/2)

→ Government spending on healthcare expanded at a CAGR of 18 per cent during 2005-09

→ Increased government expenditure on healthcare could create an over USD4.5 billion market for pharmaceuticals in the next few years

Government spending on healthcare (USD billion)

Source: Mckinsey estimates, Aranca Research

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Government-led initiatives aim at better availability of drugs ... (2/2)

→ Penetration of health insurance is expected to more than double by 2020

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

Note: RSBY stands for Rashtriya Swastha Bima Yojna, ESIC stands for Employees State Insurance Corporation

Population covered by health insurance (in million)

- 2010
  - Government-sponsored Insurance: 265
  - Private Insurance: 35

- 2020F
  - Government-sponsored Insurance: 525
  - Private Insurance: 130

Source: Mckinsey estimates, Aranca Research
Cost based pricing is complicated and time consuming in comparison to market based pricing. Market based pricing is expected to create greater transparency in pricing information would be available in public domain.

Essentiality of drugs is determined by inclusion of the drug in the National List of Essential Medicines (NEDL).

Promote rational use of medicines based on cost, safety and efficacy.

Only finished medicines are to be considered essential which would prevent price control of APIs which are not necessarily used for essential drugs.

National Pharma Policy to bring greater transparency in pricing of essential drugs.
In recent years, several foreign players have made acquisitions in India to get a foothold in the country’s pharma market and leverage on the technical and cost efficiency of Indian companies.

Increasing number of companies are forming JVs to benefit from research and development; large firms from developed markets are venturing with Indian majors to develop new medicines.

<table>
<thead>
<tr>
<th>Indian company</th>
<th>Foreign Company</th>
<th>Value (USD million)</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo</td>
<td>OJSC DIOD</td>
<td>NA</td>
<td>JV</td>
</tr>
<tr>
<td>Dosh Pharmaceuticals</td>
<td>Sanofi</td>
<td>NA</td>
<td>Acquisition (animal health div.)</td>
</tr>
<tr>
<td>GlaxoSmithkline Consumer</td>
<td>GlaxoSmithkline Plc.</td>
<td>1088</td>
<td>Acquisition</td>
</tr>
<tr>
<td>Natco Pharma</td>
<td>Litha</td>
<td>NA</td>
<td>JV</td>
</tr>
<tr>
<td>Glenmark</td>
<td>Sanofi</td>
<td>615</td>
<td>JV</td>
</tr>
<tr>
<td>Dr. Reddys</td>
<td>Iso Ray</td>
<td>NA</td>
<td>Licensing rights</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>Merck</td>
<td>NA</td>
<td>Marketing</td>
</tr>
<tr>
<td>Piramal</td>
<td>Abbot</td>
<td>3720</td>
<td>Business buyout</td>
</tr>
<tr>
<td>Orchid Chemicals</td>
<td>Hospira</td>
<td>400</td>
<td>Business buyout</td>
</tr>
<tr>
<td>Aurobindo Pharma</td>
<td>Pfizer</td>
<td>Not disclosed</td>
<td>Generic development and supply</td>
</tr>
<tr>
<td>Shantha Biotech</td>
<td>Sanofi Aventis</td>
<td>783</td>
<td>Acquisition</td>
</tr>
<tr>
<td>Ranbaxy Labs</td>
<td>Daiichi Sankyo</td>
<td>4600</td>
<td>Acquisition</td>
</tr>
<tr>
<td>Dabur Pharma</td>
<td>Fresenius Kabi</td>
<td>219</td>
<td>Acquisition</td>
</tr>
</tbody>
</table>

Notes: JV is joint venture.

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Opportunities abound in clinical trials and high-end drugs

<table>
<thead>
<tr>
<th>Clinical trials market</th>
<th>High-end drugs</th>
<th>Penetration in rural market</th>
</tr>
</thead>
<tbody>
<tr>
<td>• According to various studies, India is among the leaders in the clinical trial market</td>
<td>• Due to increasing population and income levels, demand for high-end drugs is expected to rise</td>
<td>• With 70 per cent of India’s population residing in rural areas, there are immense opportunities for pharma companies to tap this market</td>
</tr>
<tr>
<td>• Due to a genetically-diverse population and availability of skilled doctors, India has the potential to attract huge investments to its clinical trial market</td>
<td>• Demand for high-end drugs could reach USD8 billion by 2015</td>
<td>• Demand for generic medicines in rural markets has grown sharply. Various companies investing in the distribution network in rural areas</td>
</tr>
<tr>
<td></td>
<td>• Growing demand could open up the market for the production of high-end drugs in India</td>
<td></td>
</tr>
</tbody>
</table>

*Source: BMI, Aranca Research*
Drug sales to more than double by 2015 across segments … (1/2)

→ The share of generic drugs is expected to continue to increase; it could represent about 90 per cent of the prescription drug market by 2016

→ Due to their competence in generic drugs, growth in this market offers a great opportunity for Indian firms

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

Source: BMI, Aranca Research
Notes: F - Forecast
Drug sales to more than double by 2015 across segments ... (2/2)

→ The OTC market is forecasted to be worth USD6.6 billion by 2016

→ The inclusion of various other drugs and cosmetics under the OTC market may provide a further boost to this sector

OTC drug market (USD billion)

<table>
<thead>
<tr>
<th>Year</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>2.0</td>
</tr>
<tr>
<td>2009</td>
<td>2.2</td>
</tr>
<tr>
<td>2010</td>
<td>2.7</td>
</tr>
<tr>
<td>2011</td>
<td>3.0</td>
</tr>
<tr>
<td>2012F</td>
<td>3.3</td>
</tr>
<tr>
<td>2013F</td>
<td>3.9</td>
</tr>
<tr>
<td>2014F</td>
<td>4.7</td>
</tr>
<tr>
<td>2015F</td>
<td>5.5</td>
</tr>
<tr>
<td>2016F</td>
<td>6.6</td>
</tr>
</tbody>
</table>

Source: BMI, Aranca Research
Pharmaceuticals

MARCH 2013

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Industry Associations

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www.idma-assn.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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