

## PHARMACEUTICAL SECTOR IN INDIA



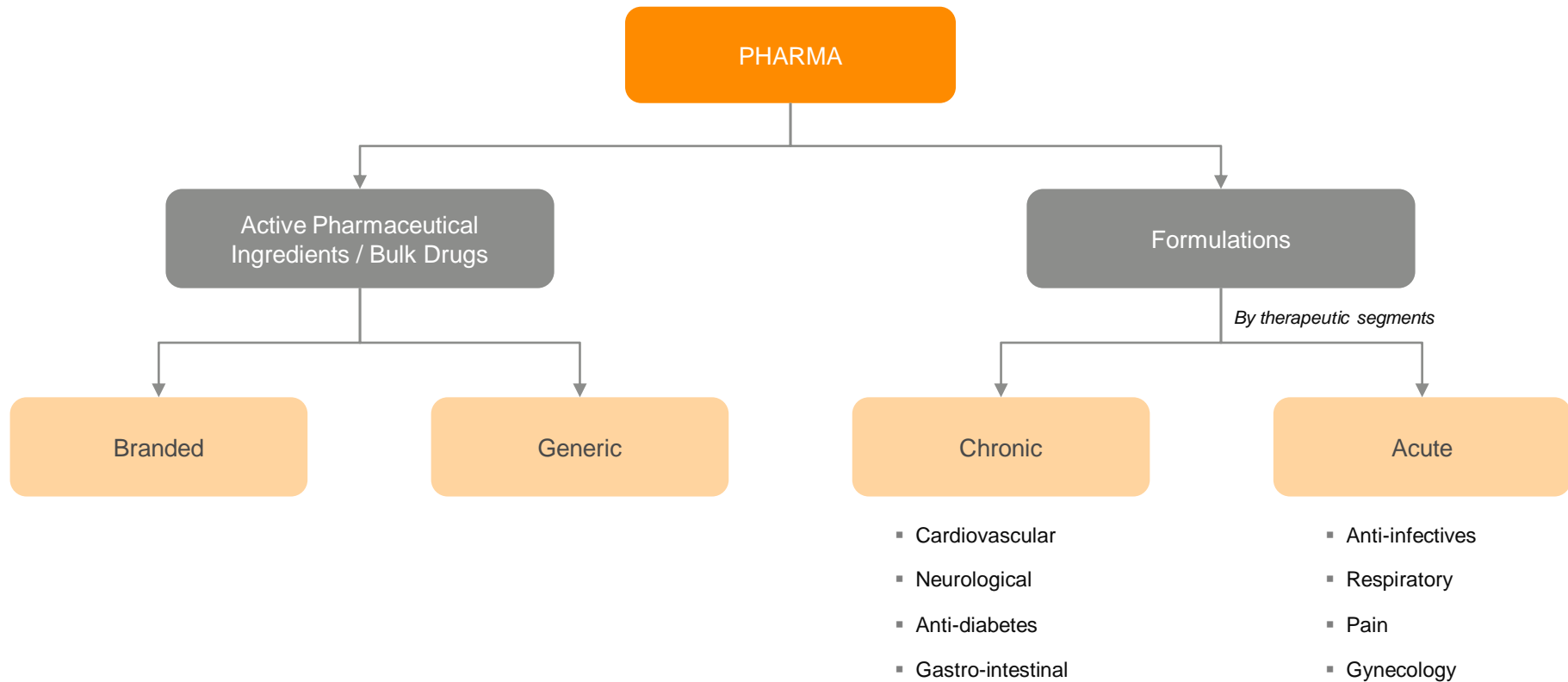
## India Sector Notes

June 2014

01	Sector Overview
02	Competitive Landscape
03	Regulatory Framework
04	Conclusions & Findings
05	Appendix

**\$16.4 billion***Domestic Pharma Market in FY13***\$84.9 billion***Estimated Pharma Market Size in 2020***\$15.6 billion***Pharma Exports in FY13***73%***Share of Indian Companies in the Pharma Market in 2013***60%***Share of Urban Regions in the Domestic Pharma Market in 2013***5%***Pharma FDI as a Share of Total FDI in India in FY14*

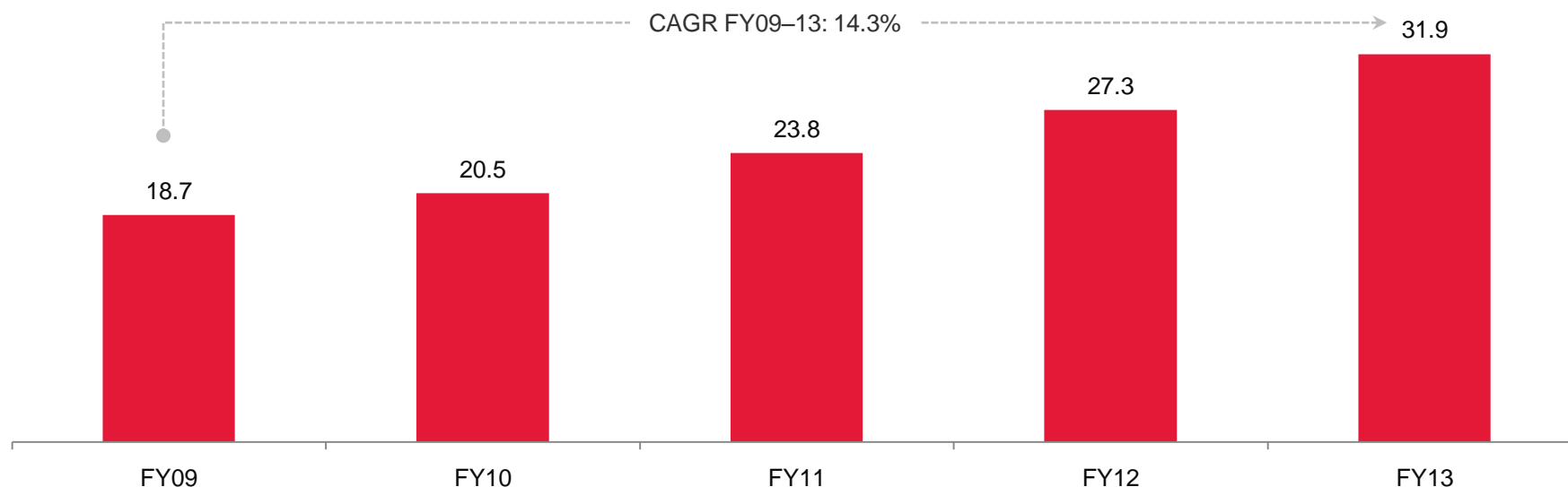
## STRUCTURE OF THE PHARMA SECTOR



Source: Dun & Bradstreet (D&B) report, CII-PwC report, Aranca research

## TOTAL REVENUES\*

(USD billion)



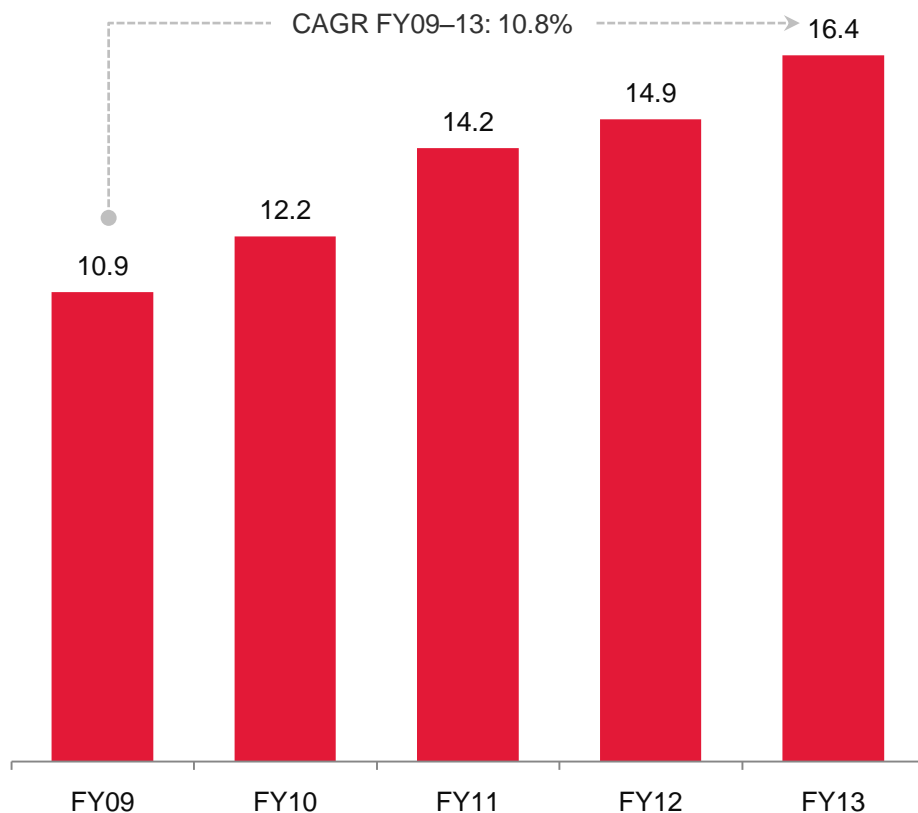
- As per Organisation of Pharmaceutical Producers of India (OPPI), the Indian pharma sector is the third-largest producer in the world in terms of volume and fourteenth in terms of value. The sector accounts for around 1.5% share of the total global pharma production by value.
- The sector expanded at a CAGR of 14.3% during FY09–13 to USD31.9 billion in FY13. Demand from domestic and international markets contributed to the growth of the sector.
- Growth was driven by high quality and competitively priced medicines for domestic and global markets, covering developing and highly regulated markets of the US and the EU.

Source: Directorate General of Commercial Intelligence and Statistics (DGCI&S), Kolkata; D&B report; Aranca analysis

1) \* Includes domestic and exports' revenues 2) 1 USD = 51.020 INR

## DOMESTIC REVENUES

(USD billion)



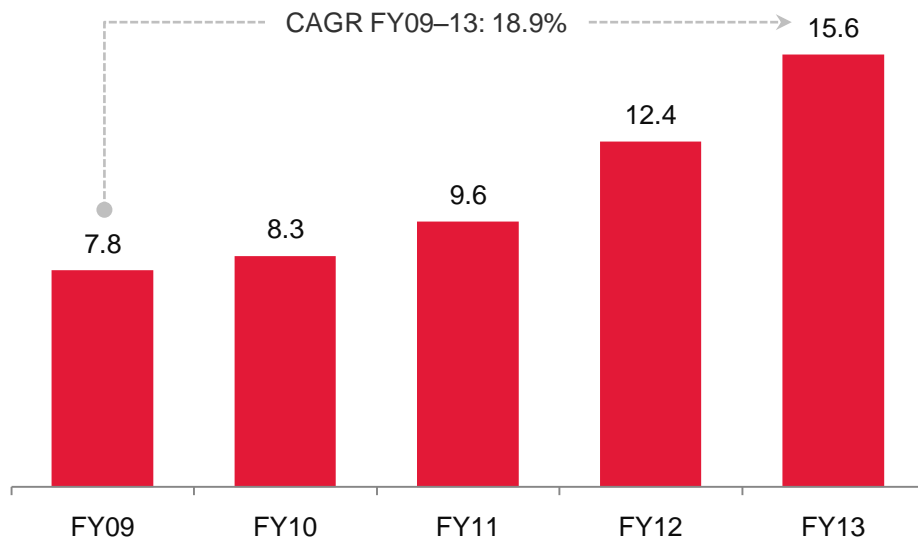
- The domestic pharma market rose at a CAGR of 10.8% during FY09–13, driven by increasing sales of generic medicines, continued growth in chronic therapies, and greater penetration in rural markets.
- Other key factors driving growth include favorable demographics, rising income levels, growing health awareness, increasing incidence of lifestyle diseases, and insurance coverage.

Source: DGCI&S, Kolkata; Department of Pharmaceuticals annual report 2011–12; Centre for Monitoring Indian Economy (CMIE) report; ICRA report

1 USD = 51.020 INR

## EXPORT REVENUES

(USD billion)



## EXPORT REVENUES – BY REGION

Year	Americas	Asia	Europe	Africa	Oceania	Others
FY09	28.8%	21.5%	31.6%	16.9%	1.1%	0.1%
FY10	31.6%	22.8%	27.3%	16.7%	1.5%	0.1%
FY11	32.5%	20.9%	27.0%	18.0%	1.5%	0.1%
FY12	33.6%	20.0%	26.4%	17.9%	1.7%	0.3%
FY13	34.3%	19.8%	25.5%	18.4%	1.6%	0.4%
<b>CAGR (FY09–13)</b>	<b>23.6%</b>	<b>15.9%</b>	<b>12.2%</b>	<b>21.1%</b>	<b>30.0%</b>	<b>71.9%</b>

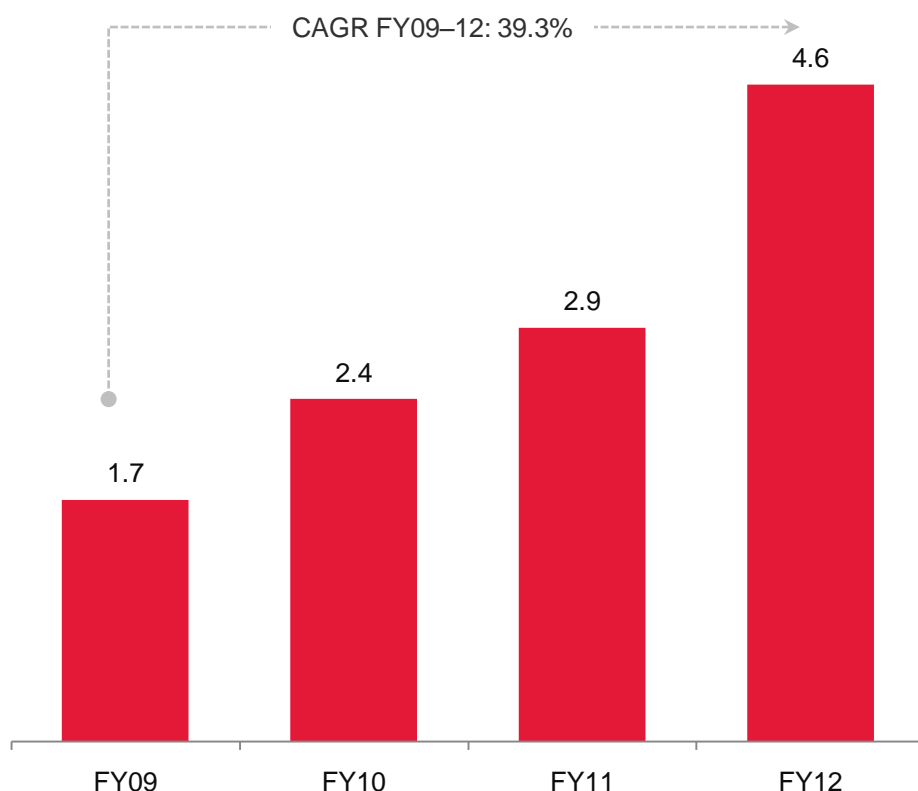
- The exports market performed well, with exports increasing from USD7.8 billion in FY09 to USD15.6 billion in FY13.
- The Americas accounted for ~34% of Indian pharma exports in FY13, followed by Europe (~26%) and Asia (~20%). The US had a ~26% share, making it the single-largest export destination.
- Exports to Africa increased at a CAGR of 21% from FY09 to FY13, contributed mainly by export of anti-malarial and anti-retroviral drugs.
- Europe's share in Indian pharma exports has declined during FY09-13.

Source: DGCI&amp;S, Kolkata; CMIE report; India Ratings &amp; Research (Ind-Ra) report, Aranca analysis

1 USD = 51.020 INR

## IMPORTS

(USD billion)



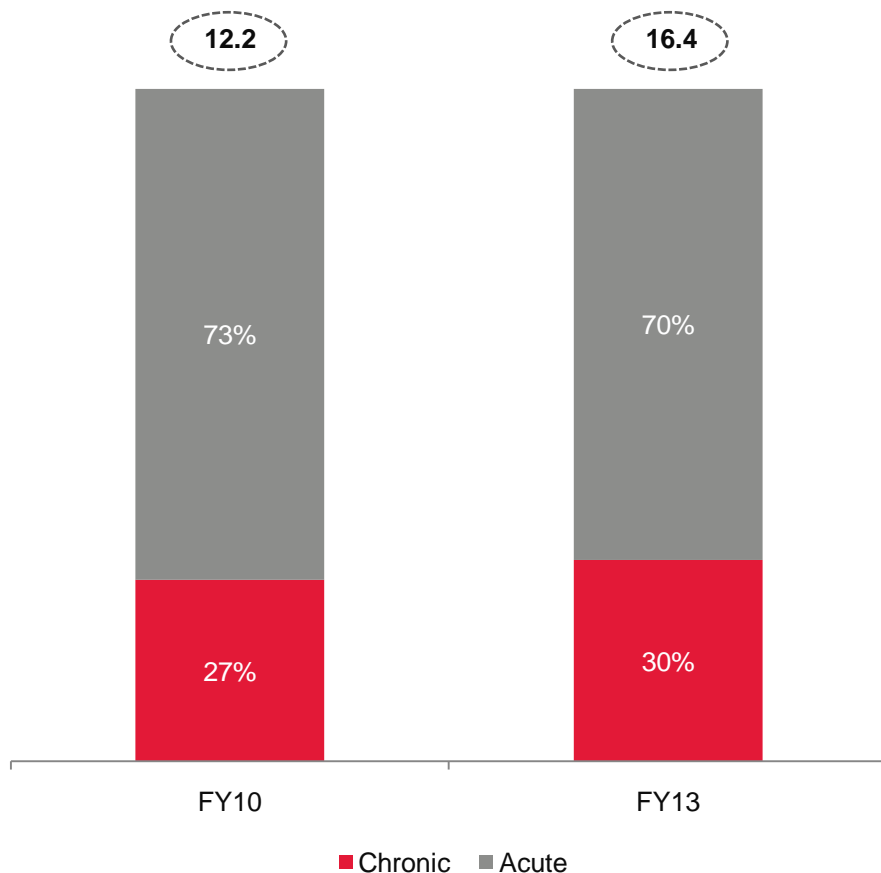
- Active pharmaceutical ingredients (APIs) and intermediates worth USD4.6 billion were imported in FY12.
- The sector has been mainly importing from China as it provides low-cost products which help the Indian formulation manufacturers to mitigate rising production cost and increasing pressure on margins.
- China has overtaken India as the main source of APIs for other countries as well due to planned and sustained support from its government in terms of infrastructure, subsidies, cheap power, transportation, dedicated capacities in voluminous manufacturing, effluent treatment facilities, industry-friendly labor laws, etc.

Source: DGCI&S, Kolkata; Department of Pharmaceuticals annual report 2011–12; Business Standard; The Economic Times; Aranca analysis



## CONTRIBUTION – BY THERAPEUTIC AREAS

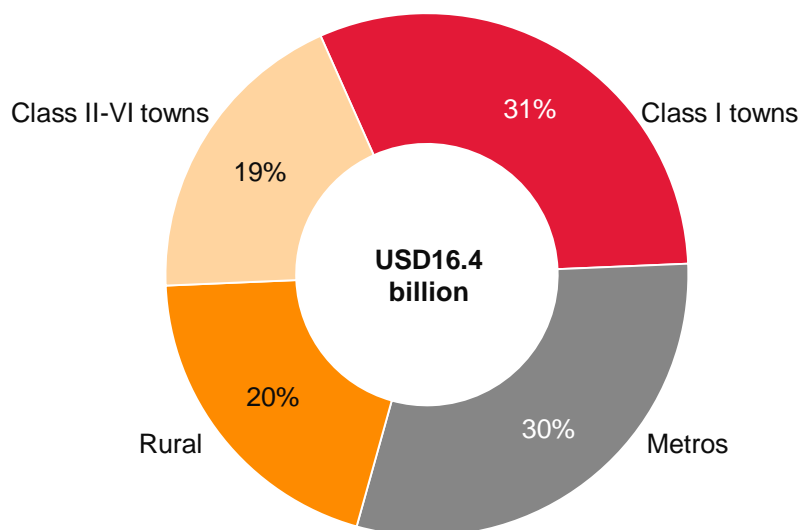
(% share)



- Chronic therapies have been rapidly growing in the market for the past four years at a rate of 14%, faster than the acute therapies which grew at 9.6% in FY13.
- Growth in chronic therapies reflects the changing disease profile of Indians. Lifestyle ailments, such as cardiac problems or diabetes, are rising sharply, thus entailing lifelong treatment.
- As per IMS Health, chronic therapies are estimated to comprise over 50% of the market by 2020, with cardiovascular and anti-diabetic therapies taking the lead. Therapies like anti-cancer are also expected to add to the momentum.

Source: CII-PwC report, Express Pharma, IMS Health, Aranca analysis

### CONTRIBUTION – BY TOWN CLASS (2013)



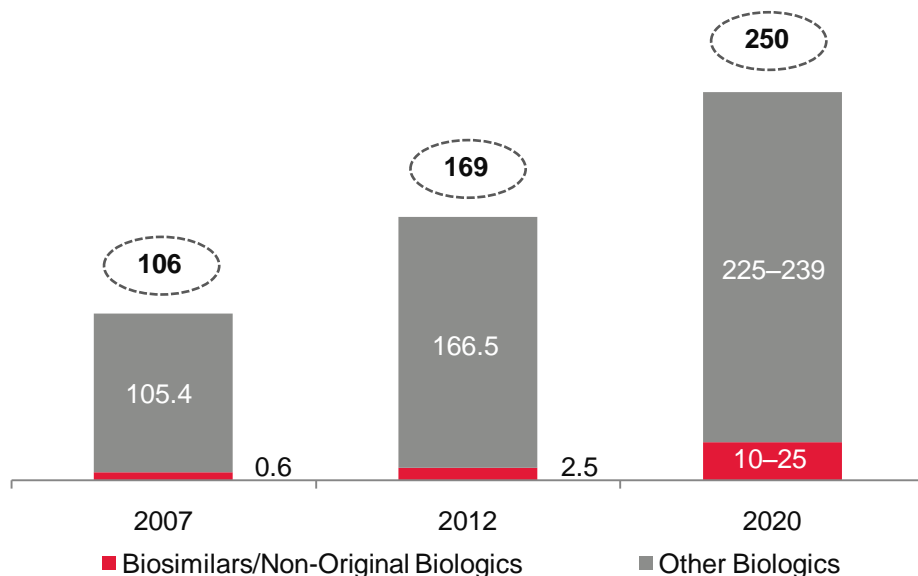
Town-class	Annual Growth in 2013
Metros	8%
Class I towns	10%
Class II - VI towns	10%
Rural	14%

- Urban regions (metros and Class I towns) contributed ~60% to the Indian pharma sales, while the extra-urban regions (Class II to VI towns and rural) contributed ~40% in 2013.
- Higher contribution and growth in lower town classes has led to an expansion in the Indian pharma market.
- Growth in the Indian pharma market was mainly driven by Class I towns and rural areas, which grew 10% and 14% annually, respectively.
- Growth has been driven by increased access to healthcare, improved infrastructure, and greater penetration of pharma companies into Class I towns and rural areas.

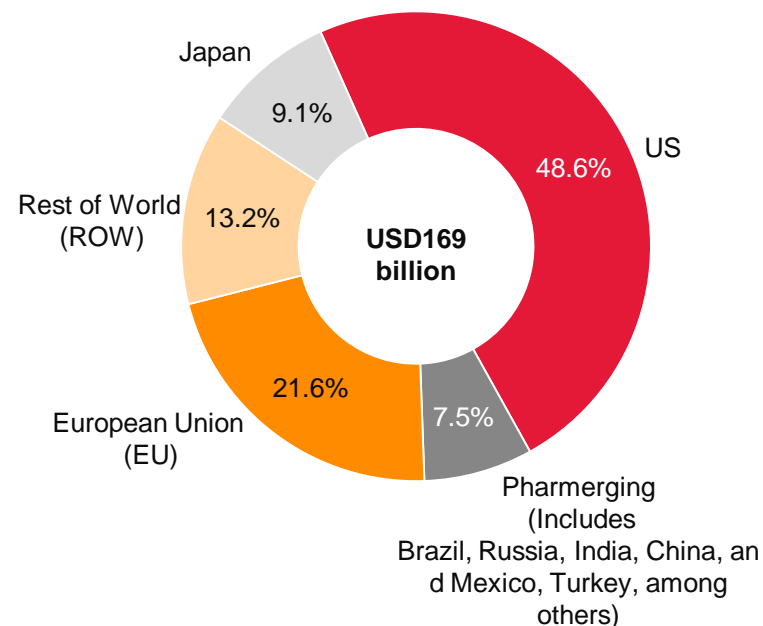
Source: CII-PwC report, Business Standard, Aranca analysis

## GLOBAL BIOLOGICS SPENDING

(USD billion)



## BIOLOGICS – SHARE OF SALES BY REGION (2012)



- According to IMS Health forecasts, the global biologics market is estimated to grow to USD250 billion by 2020 from USD169 billion in 2012.
- Biosimilars and non-original biologics would represent 4–10% (USD10–25 billion) of the market by 2020, depending on the number of new biosimilars introduced, especially in the US.
- The global biologics market is largely driven by mature markets. The US constituted approximately 49%, while the European Union (EU) accounted for approximately 22% of the market in 2012.
- The pharmerging markets accounted for only approximately 8% share.

Source: IMS Health, MIDAS, MAT Dec 2012; Aranca analysis

## INCREASED INVESTMENTS BY MNCs

- The Indian pharma market is one of the fastest-growing markets in the world. This has led to increased investments by MNCs to gain a larger market share.
- It is estimated that MNCs would hold 35% of the Indian pharma market share by 2017 compared with 28% in 2009.
- MNCs have grown in the Indian market mainly due to implementation of India-focused strategies.
- MNCs compete with domestic players through launch of patented drugs at relatively low price points than those in other global markets.

## GENERIC DRUG MARKET

- The global generic drug market is poised to grow amid expiration of drug patents. The share of generic drug market is projected to grow from 25.3% in 2011 to 35.2% by 2016.
- As per forecasts, in the US, rights for USD80 billion worth of patented drugs would expire during 2012–15.
- Indian drug makers have been aggressive in launching patented drugs on the expiry date of patents.
- Indian companies are believed to increase their activities in the pharma sector to benefit from the expiration of patents and growth of the global generic drug market.

## DOWNTURN IN NEW PRODUCT LAUNCHES

- In recent times, the number of new product launches and their contribution have reduced.
- Contribution from new product launches was 4.1% in 2013 vis-à-vis 6.3% in 2010. Furthermore, the number of new products launched was low at 1,700 in 2012 compared with 1,900 in 2010.
- Maximum number of new product launches were in anti-infectives (468), analgesics (435), and gastro therapies (389).

## FOCUS ON RURAL INDIA

- Almost 70% of India's population resides in the rural areas and this population accounts for 40% of the total pharma consumption.
- To benefit from the untapped rural demand, MNCs and domestic players are increasingly focusing their activities in rural India.
- Pharma companies are adopting differential pricing and marketing strategies to derive opportunity from the potential rural demand.
- They are also implementing new distribution strategies to address the issue of inaccessibility faced by the rural population.

Source: CII-PwC report, Express Pharma, Aranca research

## BIOSIMILARS BY INDIAN COMPANIES

Company	Biosimilars
Dr. Reddy's Laboratories	Grafeel, Reditux, and Cresp
Biocon	Eripro, Biomab, Nufil, Myokinase, and Insugen
Reliance Life Sciences	ReliPoietin, ReliGrast, ReliFeron, and MIREl
Shantha Biotech	Shanferon, Shankinase, and Shanpoietin
Intas Biopharmaceuticals	Neukine, Neupeg, Intalfa, and Epofit
Wockhardt	Biovac-B, Wepox, and Wosulin
Ranbaxy	G-CSF (filgrastim) and BOW015
Lupin	Etanercept
Zydus Cadila	Albumeon, Matergam P, Zyrop, Tetagam P, and Ovidac

*Source: Company websites, Nature Biotechnology, Biosimilar News*



## KEY GROWTH ENGINES

### ↑ Changing disease profile and favorable demographics

- Change in patient demographics and increased lifestyle-related ailments are likely to boost demand for quality and affordable drugs.
- Indian population's lifestyle has changed over the years due to socio-economic factors and growing urbanization. This has led an increase in lifestyle-related ailments such as obesity, heart disease, stroke, cancer, and diabetes.
- India is estimated to have a patient pool of 20% by 2020 due to ~1.3% population growth per year and increased disease burden.

### ↑ Rapid urbanization

- The Indian pharma sector is poised to benefit from increased contribution from metros and Class I towns, mainly due to growing urbanization and economic development.
- According to McKinsey and BNP Paribas's estimates, India's urbanization is projected to accelerate at a rate and scale comparable only to China, reaching 40% by 2030.
- Rapid urbanization would lead to growth in India's medical infrastructure, thereby enabling companies to reach inaccessible and untapped markets.

### ↑ Increasing health insurance coverage

- Increased penetration of health insurance in India is likely to solve the affordability issue in the Indian pharma sector, thereby boosting demand.
- As of 2013, only 30% of population in India had health insurance coverage; the remaining 70% paid for healthcare expenses from their own savings.
- Health insurance penetration is estimated to reach ~45% by 2020.



## KEY GROWTH INHIBITORS

### ↓ Drug price control

- The Indian government increased the number of drugs under price control from 74 to 348 in 2013, thereby adversely impacting retail price of drugs.
- The move is said to have far-reaching implications on branded pharma manufacturers with patented products rather than generics manufacturers which are mostly domestic companies already selling products at relatively low prices.

### ↓ Growing concern regarding clinical trials

- Clinical trials play a vital role in drug development. India accounts for less than 2% of global clinical trials.
- Growth in the number of clinical trials in India has been low primarily due to regulatory uncertainty with regard to the conduct of clinical trials.
- Unethical practices, delay in approvals, corruption, etc., have led pharma companies to shift their focus from India to other geographies like Malaysia and East European countries like Poland for clinical trials.

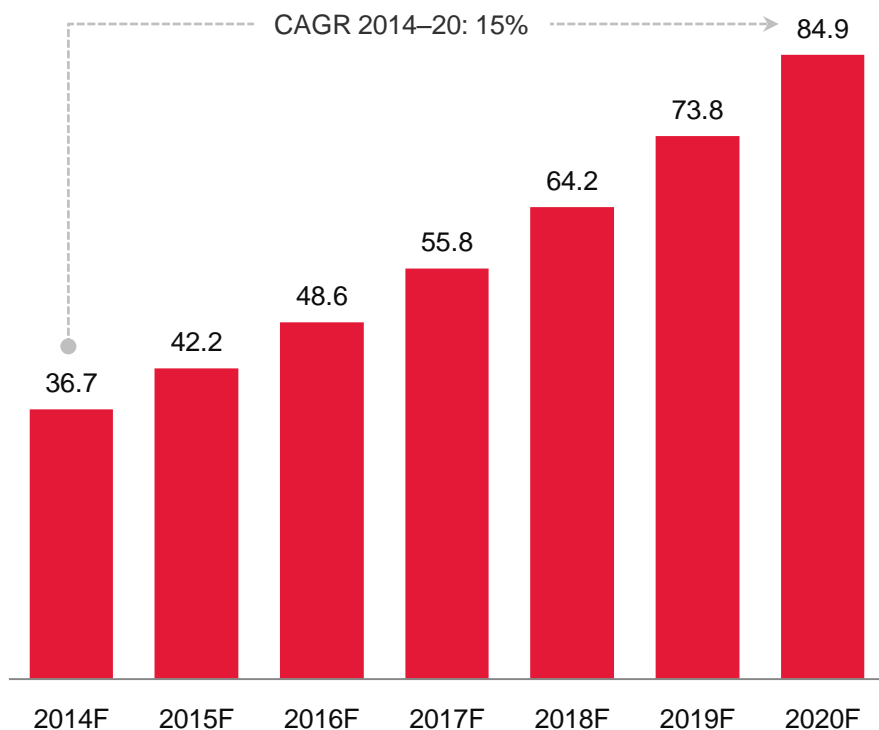
### ↓ Fragmented supply chain

- The Indian pharma market is highly fragmented in manufacturing as well as distribution. This has led to several inefficiencies in the sector.
- Fragmented supply chain leads to ineffective inventory management systems, resulting in high inventory holding costs, thereby increasing operating costs.
- On the distribution front, dominance of small chemists leads to lack of economies of scale and consumers having to pay high prices.

Source: Sun Pharma Annual Report 2013, PwC, McKinsey & Company, Deloitte, Aranca research

## OUTLOOK FOR THE INDIAN PHARMA SECTOR\*

(USD billion)



Source: Express Pharma, India Ratings &amp; Research (Ind-Ra) report, Aranca analysis

- As per the Department of Pharmaceuticals, the Indian pharma market is estimated to expand at a CAGR of 15% to USD84.9 billion by 2020.
- The sector's healthy growth momentum would be driven by:
  - Consistent growth in incidence of lifestyle chronic ailments.
  - A large number of drug patents expiring, which would open up huge generic opportunities, leading to newer brands being launched in the domestic market.
- As per India Ratings & Research, pharma exports would overtake domestic sales in FY15.
  - Exports to the US are expected to continue to grow in the medium term backed by the largest number of United States Food & Drug Administration (USFDA)-approved facilities outside the US as well as the largest share of drug approvals over the last few years.
  - Approvals from the World Health Organization (WHO) and European regulators are also strong, providing added visibility for exports.

\* Includes domestic and exports' revenues

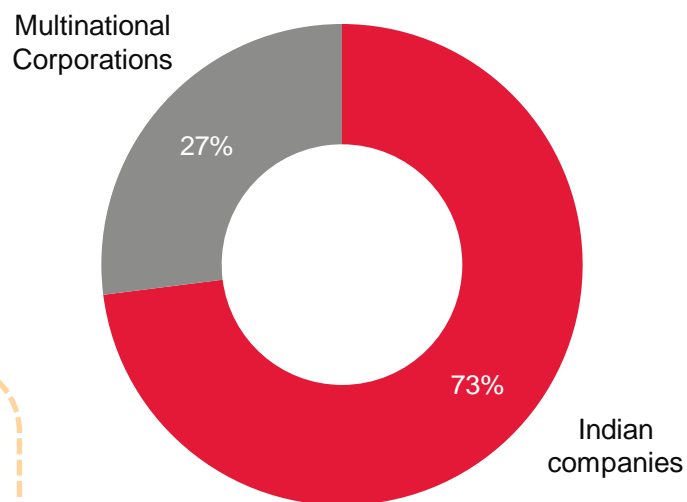
01	Sector Overview
02	Competitive Landscape
03	Regulatory Framework
04	Conclusions & Findings
05	Appendix



## KEY PLAYERS IN THE INDIAN PHARMA SECTOR

**Key International Players**

Abbott Laboratories  
GlaxoSmithKline  
Pfizer

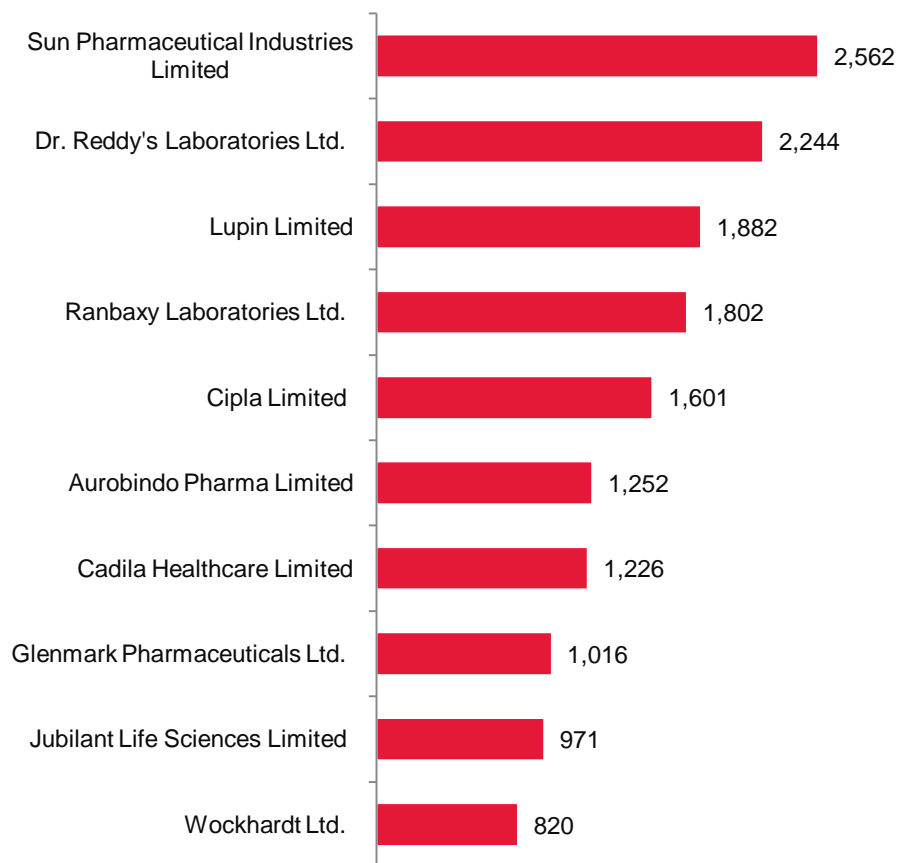
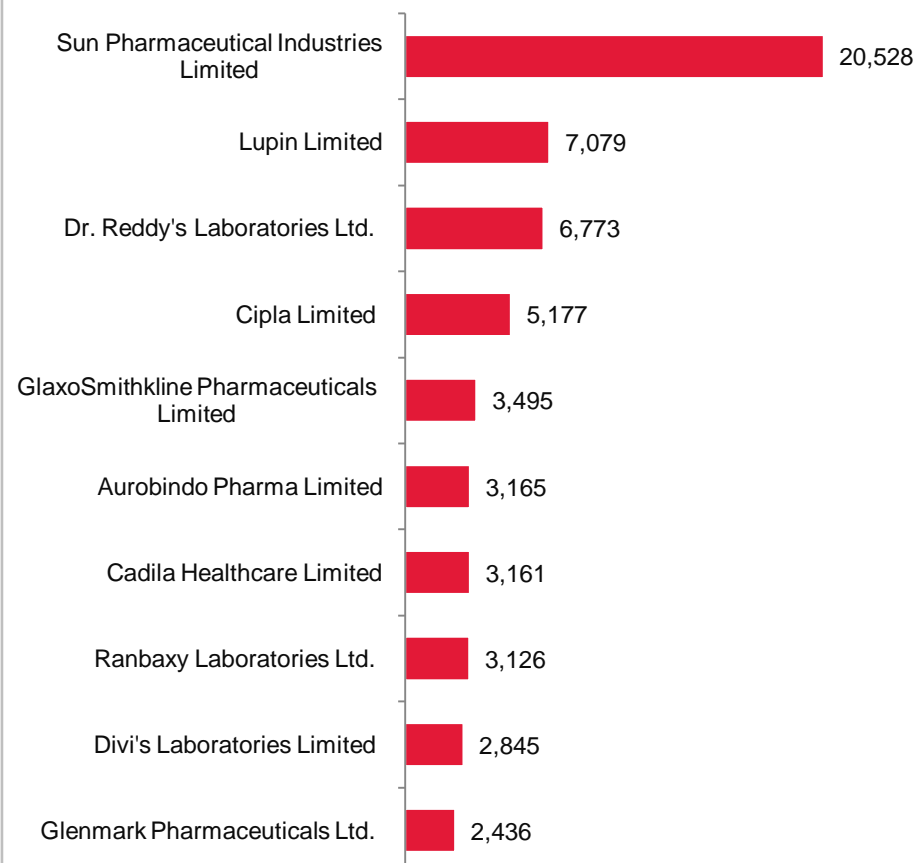
**Market share for 2013****Key Domestic Players**

Sun Pharma  
Lupin Limited  
Cipla  
Ranbaxy  
Dr. Reddy's  
GlaxoSmithKline

- Currently, Abbott Laboratories leads the market in therapies with a 6.5% share.
- With Sun Pharma's acquiring Ranbaxy in 2014, market share of Indian companies is forecasted to increase to 77% from the current 73%.
- The combined entity is estimated to replace Abbott Laboratories' market share by holding a combined market share of ~9.3%.

Source: Company websites, The Economic Times, Aranca analysis, PwC report

## TOP 10 PHARMA COMPANIES (2013–14)

**By LTM Revenue (USD million)****By Market Cap (USD million)**

Source: CapitalIQ, Aranca analysis

Note: 1) LTM stands for Last twelve months 2) Market Cap as on 29<sup>th</sup> May, 2014 3) Above ranking includes companies listed on BSE only

01	Sector Overview
02	Competitive Landscape
03	Regulatory Framework
04	Conclusions & Findings
05	Appendix

Particulars	Description	Implications
<b>National Pharmaceutical Pricing Policy (NPPP) 2012</b>	<ul style="list-style-type: none"> <li>■ The Indian government introduced NPPP in 2012 to regulate the prices of 348 essential drugs, based on their strengths and dosages.</li> <li>■ Manufacturers are allowed to sell these drugs on or below the ceiling price fixed by the government.</li> <li>■ The policy is applicable to imported drugs as well.</li> </ul>	<ul style="list-style-type: none"> <li>■ Implementation of NPPP resulted in decline of profit margins for products under regulation from 20% to 16% and 10% to 8% for retailers and stockists, respectively, during 2012–13.</li> <li>■ The policy has resulted in significant uncertainty among stockists on whether to continue with the business amid low profits and margin reduction.</li> </ul>
<b>Foreign Direct Investment (FDI) policy</b>	<ul style="list-style-type: none"> <li>■ In 2001, 100% FDI was allowed through the automatic approval route in the pharma sector.</li> <li>■ Post November 2011, 100% FDI is allowed in Greenfield projects through the automatic route, while 100% FDI is allowed in Brownfield projects with the approval of the Foreign Investment Promotion Board (FIPB).</li> </ul>	<ul style="list-style-type: none"> <li>■ As per the Department of Industrial Policy &amp; Promotion (DIPP), the pharma sector attracted cumulative FDI investments of approximately USD11.6 billion between April 2000 and February 2014.</li> </ul>
<b>Medical Council of India (MCI) guidelines on sales and marketing practices</b>	<ul style="list-style-type: none"> <li>■ MCI guidelines were issued to ensure transparency in sales and prevent unethical practices of some doctors.</li> <li>■ MCI aimed to stop medical professionals from prescribing drugs in exchange of bribe from drug manufacturers.</li> </ul>	<ul style="list-style-type: none"> <li>■ Tax authorities use the Central Board of Direct Taxes (CBDT) circular based on MCI guidelines to decide on permissible sales and marketing expenses.</li> </ul>

Source: Sun Pharma annual report 2013, PwC report, Aranca research

Particulars	Description	Implications
<b>Department of Pharmaceuticals (DoP) uniform code on sales and marketing</b>	<ul style="list-style-type: none"> <li>■ In 2011, DoP laid down a code of marketing practices for the pharma sector to streamline marketing efforts.</li> <li>■ The DoP code lays down guidelines for exaggerated claims; audiovisual promotions; activities of medical representatives; and provision of samples, gifts, hospitality, and sponsorships by pharma companies.</li> </ul>	<ul style="list-style-type: none"> <li>■ The adoption of DoP code is voluntary. However, in recent times, the pharma sector has agreed to enforce the code.</li> <li>■ DoP would review its implementation and after a set interval of time if it is discovered that the code has not been implemented by pharma associations or companies, it would consider making it a statutory code.</li> </ul>
<b>Compulsory licensing</b>	<ul style="list-style-type: none"> <li>■ India has adopted compulsory licensing on the following grounds under Section 84 of the Indian Patent Act: (1) the drug did not meet reasonable requirements of the citizens, (2) the drug was not reasonably priced, and (3) the patent was not locally manufactured.</li> </ul>	<ul style="list-style-type: none"> <li>■ The imposition of this regulation paved way for production of low-cost generic medicines of the branded patent drugs. Thus, costly, branded life saving drugs are available at a cheaper rates to the Indian population.</li> <li>■ The regulation affects the brand value of branded drugs manufactured by MNCs, and thus has been opposed by them.</li> </ul>
<b>Clinical trial regulations</b>	<ul style="list-style-type: none"> <li>■ As per new regulations introduced in 2013, all clinical trials need to be approved by a government committee and at least half of each trial needs to be run in a government-run hospital.</li> <li>■ Pharma companies need to have the videotaped consent of each test subject.</li> </ul>	<ul style="list-style-type: none"> <li>■ Stringent regulations increase the duration of the approval process; hence, the number of clinical trials has dropped to 19 in 2013 from 500 in 2011.</li> <li>■ It also has projected India as a less favorable option to conduct clinical trials.</li> </ul>

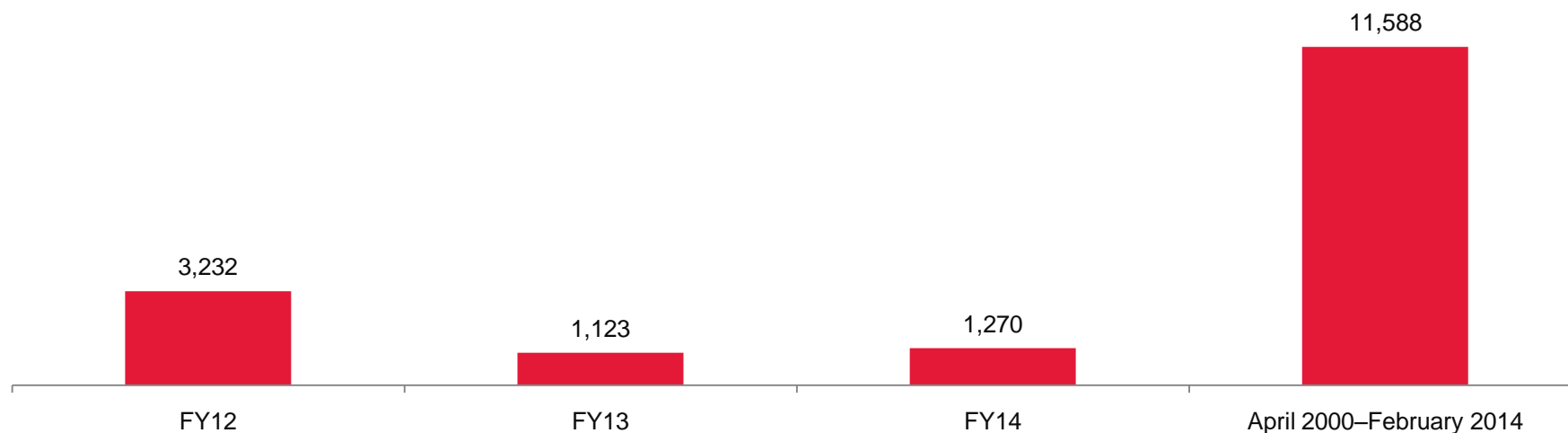
Source: Ernst & Young report, PwC report, The Pharma Letter, Aranca research

Particulars	Description	Implications
<b>Biosimilar Guidelines</b>	<ul style="list-style-type: none"> <li>■ The “Guidelines on Similar Biologics” prepared by Central Drugs Standard Control Organization and Department of Biotechnology in 2012 laid down the regulatory pathway for a biologic claiming to be similar to an already authorized reference biologic.</li> <li>■ The guidelines address the regulatory pathway regarding manufacturing process and quality aspects for similar biologics.</li> <li>■ These guidelines also address the pre-market regulatory requirements including comparability exercise for quality, preclinical and clinical studies, and post-market regulatory requirements for similar biologics.</li> </ul>	<ul style="list-style-type: none"> <li>■ The new guideline creates a pathway for local and international companies to invest in biosimilar development with manufacturing in India.</li> <li>■ The introduction of a similar biologic or biosimilar into the market would result in significant reduction in costs.</li> <li>■ This introduction would also help address local patients’ access to expensive drugs.</li> </ul>

Source: Biosimilar News, BioSpectrum Asia, Aranca research

## FDI INFLOWS

(USD million)



- Cumulative FDI inflows from April 2000 to February 2014 stood at USD11.6 billion.
- FDI inflows into the sector dropped from USD3.2 billion in FY12 to USD1.1 billion in FY13, a 65% year-on-year (YoY) drop.
- FDI inflows increased 13% YoY to USD1.3 billion in FY14.

Source: Department of Industrial Policy & Promotion (DIPP), Aranca analysis

Note: Data for FY14 is from April 2013 to February 2014



2014

Acquires

**RANBAXY**  
 Trusted medicines. Healthier lives

The combined entity would be India's largest pharma company and world's fifth largest generic drugs maker

**USD3.2 billion**


2014

Acquires



The acquisition helps Lupin expand into the Latin American market and build its global specialty business

**NA**


2013

Acquires



The transaction would strengthen Torrent's position in the women healthcare, pain management and vitamins/nutrition segments

**USD321.6 million**
**Cipla**

Acquires



The deal with Medpro would help Cipla to strengthen its African operations

**USD512 million**


2013

Acquires



The acquisition would strengthen Mylan's global injectables platform and create a global injectables leader

**USD1.75 billion**


Vivimed

Acquires



Finoso would become Vivimed's research and development unit to support innovators, generics and licensing efforts

**USD2.8 million**


2013

Acquires



With Indchem's excellent customer service and technical support, IMCD would be able to further strengthen its presence in the Indian market

**NA**

Source: Company websites, Grant Thornton, Business Standard, Thomson Banker, Aranca research

Note: Only key deals for 2013 & 2014 mentioned



01	Sector Overview
02	Competitive Landscape
03	Regulatory Framework
04	Conclusions & Findings
05	Appendix

## INDIA'S COMPETITIVE EDGE

**Robust Generics Pipeline**

- Indian companies have continued to invest significant resources in the development of a robust pipeline of generic drugs.
- During 2009–12, the USFDA approved 2,720 abbreviated new drug applications (ANDAs); of which, Indian companies received approval for 872 (32% of total approvals) ANDAs. This share has increased to 40% in 2013 as India grabbed 110 out of 290 ANDAs approved by the USFDA.

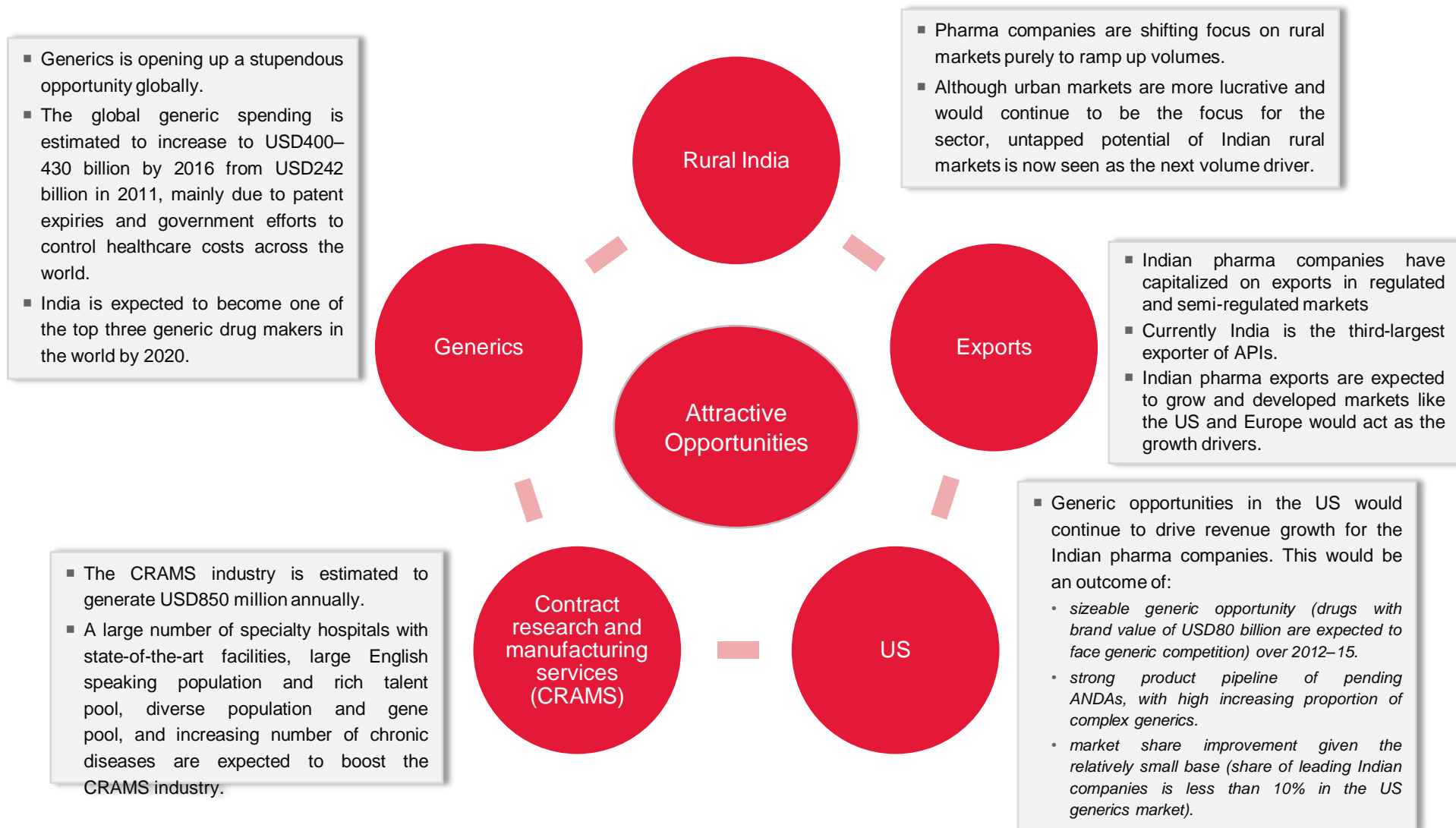
**Low-cost Manufacturing Base**

- The cost of establishing a USFDA-approved plant in India is up to 50% lower than in developed countries. As a result, India currently has the highest number of USFDA-approved plants outside the US. As on March 31, 2014, 523 Indian facilities were registered with the USFDA, which is the highest number for any country outside the US.
- Production costs in India are on an average 40–70% lower than in developed countries due to local equipment sourcing, tax incentives, and focus on process innovation.

**Cost-efficient Talent Pool**

- Labor costs in India are 60–70% lower than in developed countries due to the availability of a large pool of highly qualified personnel specializing in chemistry and process reengineering skills.
- India is an attractive destination for outsourcing of pharma products and services.

Source: Zephyr Peacock India report, India Ratings & Research report, Aranca research



Source: Express Pharma, Aranca research

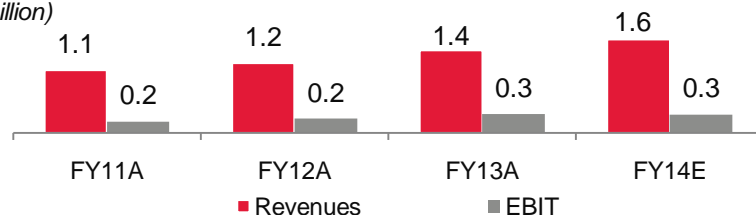
01	Sector Overview
02	Competitive Landscape
03	Regulatory Framework
04	Conclusions & Findings
05	Appendix

## KEY COMPANY FACTS

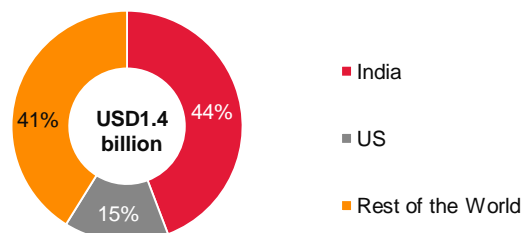
Incorporation date	1935
Headquarters	Mumbai, India
Employee Headcount	26,000
Market Cap (As on May 29, 2014)	USD5,177 million
Presence	Over 170 countries
Website	www.cipla.com

## FINANCIAL PERFORMANCE

(USD billion)



Revenue Mix by Geography – FY13



## KEY DIFFERENTIATING STRATEGIES

- Company Strategy:** Cipla introduced a transformation program called “Jaagruti” to:
  - Streamline business processes in order to reduce exposure to risks in low-value markets. In line with this objective, the company enters into alliances with global pharma companies having strong presence in its target markets.
  - Reduce cost component in product manufacturing while maintaining highest regulatory standards, and quality and safety requirements. In line with this, Cipla recently launched ‘Procurement Effectiveness Effort’ to obtain best-in-class raw materials for product development and to realize cost saving.
- Target markets:** Cipla aims to strengthen its market share in domestic market through increased focus on central nervous system (CNS), oncology, dermatology, and gastroenterology therapies. Additionally, the company plans to implement several new business models to tap opportunities in its key priority markets, including South Africa, the US, Europe, and Australia.

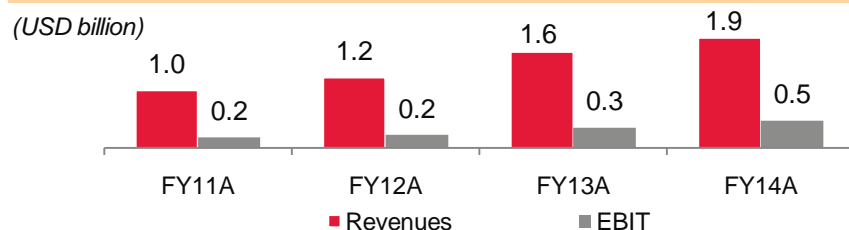
Source: Cipla website, Annual Report 2012–13, Capital IQ

Note: 1) Financials for fiscal years ended March 31 2) A: Actual, E: Estimate 3) 1 USD = 58.928 INR (as on 29<sup>th</sup> May, 2014)

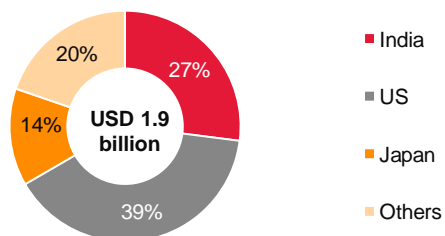
## KEY COMPANY FACTS

Incorporation date	1968
Headquarters	Mumbai, India
Employee Headcount	12,710
Market Cap (As on May 29, 2014)	USD7,079 million
Presence	Global
Website	www.lupinworld.com

## FINANCIAL PERFORMANCE



Revenue Mix by Geography – FY14



Source: Lupin website, Annual Report 2012–13, Capital IQ

## KEY DIFFERENTIATING STRATEGIES

- Competitive advantage:** Lupin positions itself in the global pharma market by leveraging opportunities in new markets, new therapies, new businesses, and product mix. This has enabled the company to gain competitive advantage over peers with singular focus market.
- Focus on innovative offerings:** Lupin strives to offer innovative products through R&D investments. The company's capacity to invest in innovations and ability to remain invested for a long period of time differentiates it from competitors.
- Tapping opportunities through alliances:** Lupin is committed to in-licensing products and entering into strategic alliances with leading global pharma companies. Through this, the company aims to expand its product portfolio as well as tap the unaddressed demand.
- Creation of sales force:** Lupin is committed to create and develop a specialty product marketing and sales team with talented and experienced professionals. This would enable the company to cater to the complex needs of niche markets.
- Leveraging geographic reach:** Lupin has combined the benefits of its nationwide presence with a short mind-to-market cycle, enabling the company to operate locally as well as benefit from local opportunities in global markets.

Note: 1) Financials for fiscal years ended March 31 2) A: Actual 3) 1 USD = 58.928 INR (as on 29<sup>th</sup> May, 2014)

## IMPORTANT NOTES

- Pharma is the short form for pharmaceutical.
- Figures may not add up to the total due to rounding off to the nearest whole number.
- FY refers to fiscal year from April to March.
- CAGR refers to compounded annual growth rate.
- API/ Bulk drug is an active constituent with medicinal properties, which acts as basic raw material for formulations.
- Formulations are specific dosage forms of a bulk drug or a combination of bulk drugs.
- A branded drug is a medication sold by a pharma company under a trademark-protected name.
- A generic drug is a pharma product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.
- Biosimilars are those biologics that are non-original copies of innovative brands and that have been approved for marketing via a dedicated regulatory pathway, such as those created in the EU, U.S., and Japan.
- Non-original biologics (NOBs) are those copies of innovative brands that have not been approved through such a dedicated pathway. Typically, they are introduced in emerging markets.



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