

PHARMACEUTICALS

April 2010

Contents

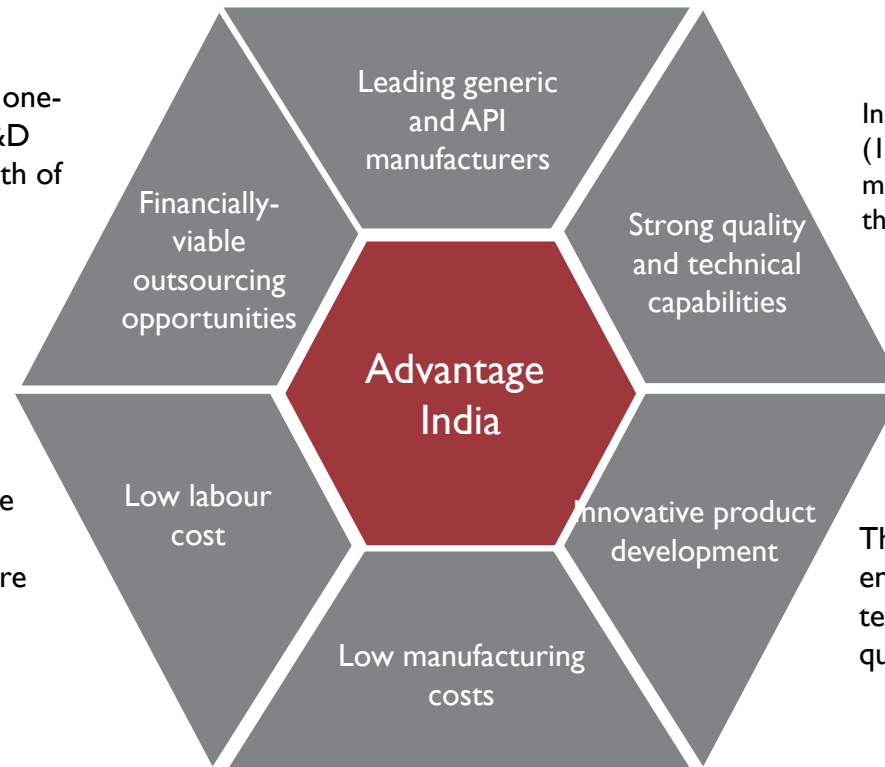
- ❖ **Advantage India**
- ❖ Market overview
- ❖ Industry infrastructure
- ❖ Investments
- ❖ Policy and regulatory framework
- ❖ Opportunities
- ❖ Industry associations

Advantage India

Indian firms produce about 60,000 generic brands across 60 therapeutic categories. India is also among the world's leading five API producers.

Clinical trials in India cost one-tenth of that in the US. R&D costs in India are one-eighth of that in the US.

India produces some of the world's least expensive drugs, since labour costs are 50 to 55 per cent lower than in the West.



India has the highest number (119) of the USFDA-approved manufacturing plants outside the US.

The industry is constantly engaged in upgrading technology to enhance the quality of products.

Indian companies can manufacture pharmaceuticals for less than half the cost in the US.

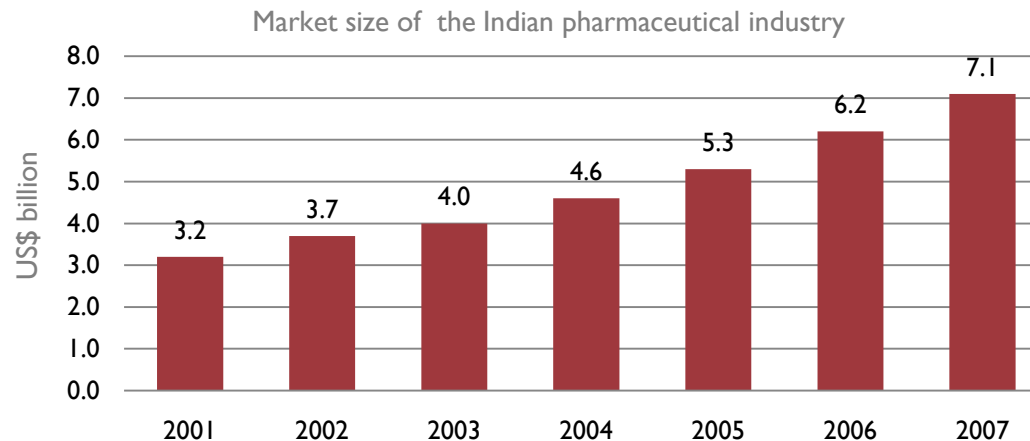
Source: Ernst & Young research USFDA: United States Food and Drug Administration

Contents

- ❖ Advantage India
- ❖ **Market overview**
- ❖ Industry infrastructure
- ❖ Investments
- ❖ Policy and regulatory framework
- ❖ Opportunities
- ❖ Industry associations

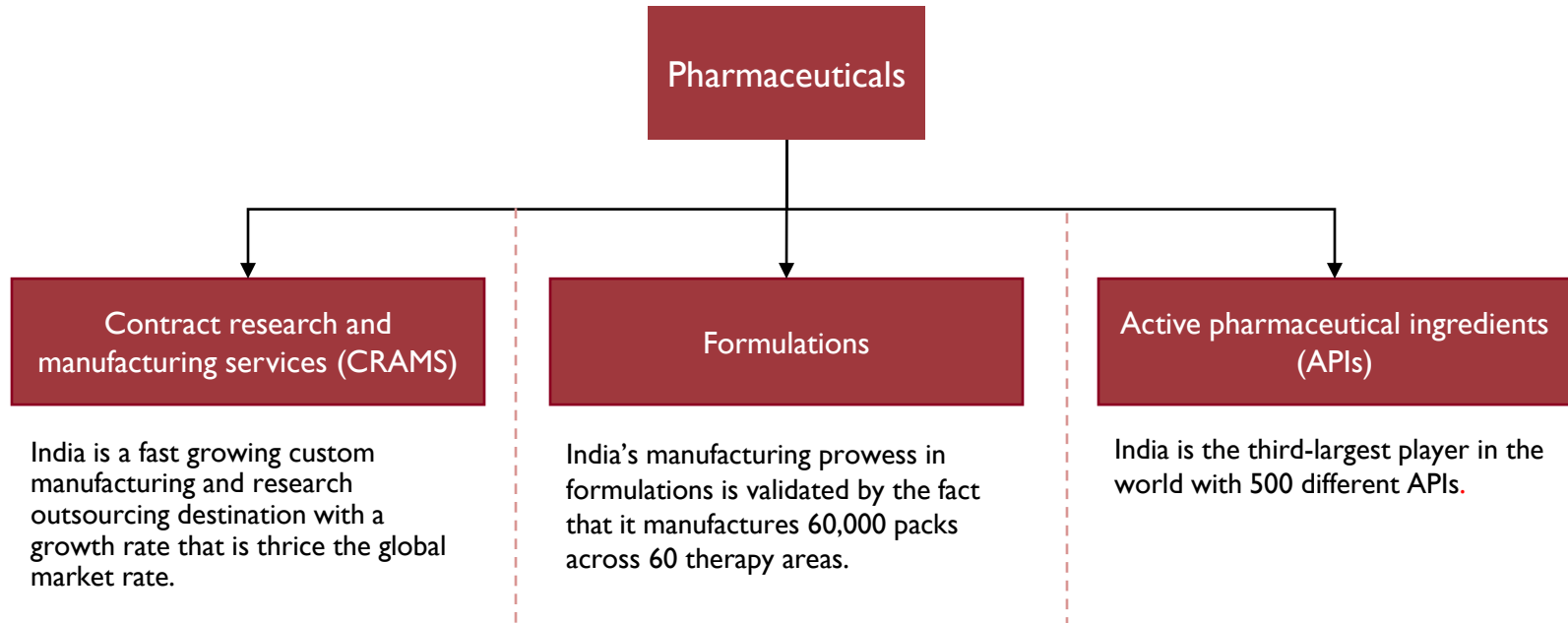
Market overview

- India is among the fastest growing pharmaceutical markets in the world, with its growth rate having nearly doubled between 2001 and 2006.
- It is ranked fourteenth in the world in terms of value, and is the third largest in terms of volume.
- The Indian pharmaceutical market is expected to triple to US\$ 20 billion by 2015 from US\$ 7.1 billion in 2007 at a compound annual growth rate (CAGR) of 12.3 per cent, and establish its niche among the world's leading 10 markets.



Source: Taking wings, Ernst & Young 2009

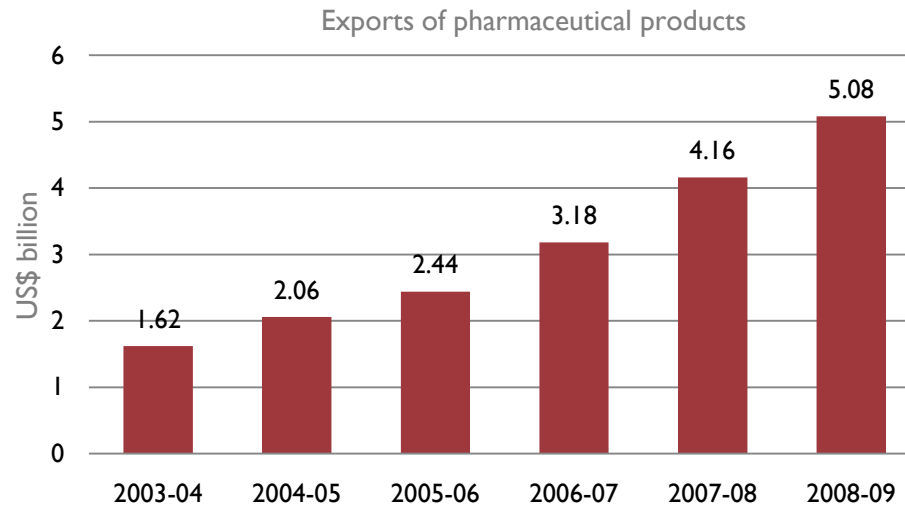
Market segments



Source: Ernst & Young analysis

Exports

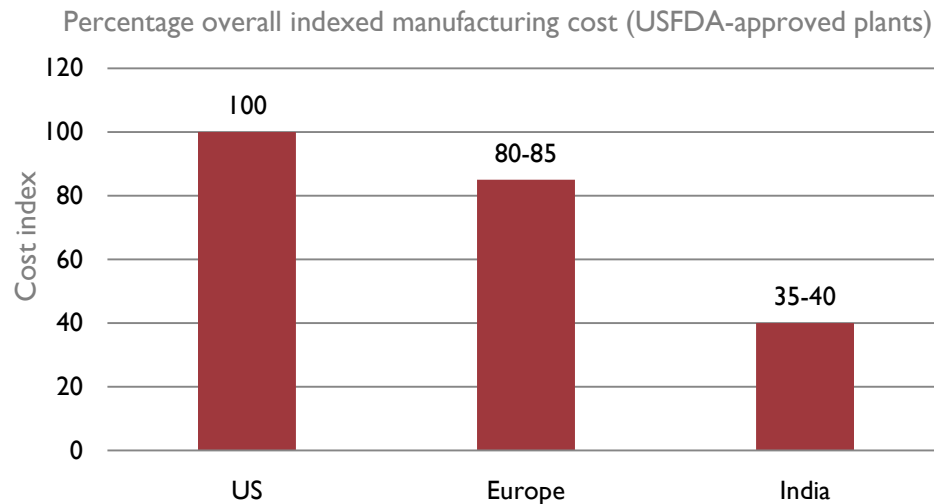
The exports of drugs, pharmaceuticals and fine chemicals have increased from US\$ 7.24 billion in 2007–08 to US\$ 9.35 billion in 2008–09, while the exports for pharmaceutical products were recorded at about 5 billion in 2008–09. Formulation drugs are expected to outperform the bulk drugs in the exports segment.



Sources: Ministry of Commerce and Industry, Government of India; Ernst & Young analysis; “Pharma exports up by 29% in 2008–09, Anand Sharma addresses Indo-Africa Pharma Business Meet,” Ministry of Commerce and Industry press release, http://commerce.nic.in/pressrelease/pressrelease_detail.asp?id=2478, September 25, 2009 Note: HS code 30 used for the above analysis

Growth drivers — cost efficiency

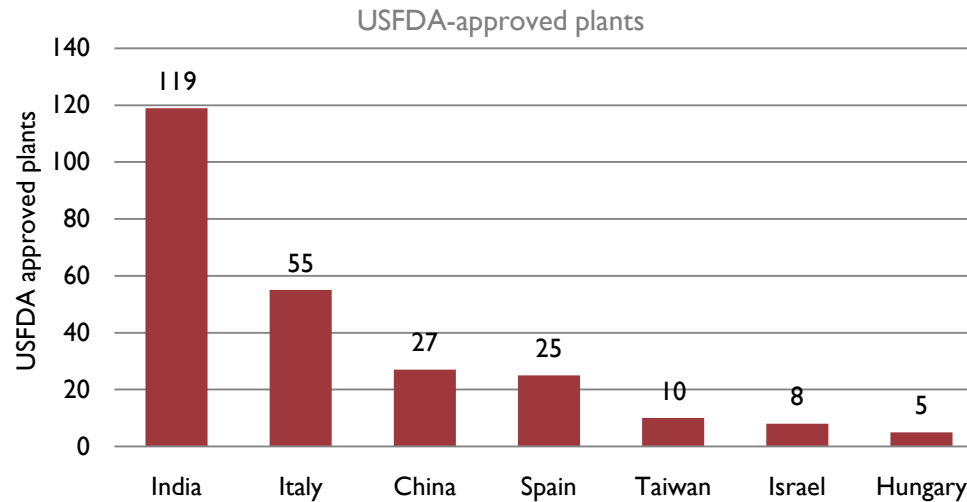
India rates higher on cost efficiency as compared to other countries.



- The Indian market is highly fragmented with about 8,000 manufacturers. This high competition has driven Indian companies to reduce costs across the life cycle of a product.
- This is visibly reflected in the manufacturing costs of USFDA plants in India, wherein the costs are 65 per cent lower than the US and 50 per cent lower than that in Europe.

Source: Taking wings, Ernst & Young 2009

Growth drivers — technical capability



- India has 119 USFDA-approved plants in addition to 84 UK MHRA-approved plants.
- Many of these plants also have approvals from countries such as Canada, Australia, Germany and South Africa.
- These approved sites aptly demonstrate the ability of Indian companies to deliver quality products worldwide and act as a platform for CRAM players.

Source: Taking wings, Ernst & Young 2009 UK MHRA: United Kingdom's Medicines and Healthcare products Regulatory Agency

Growth drivers — government support

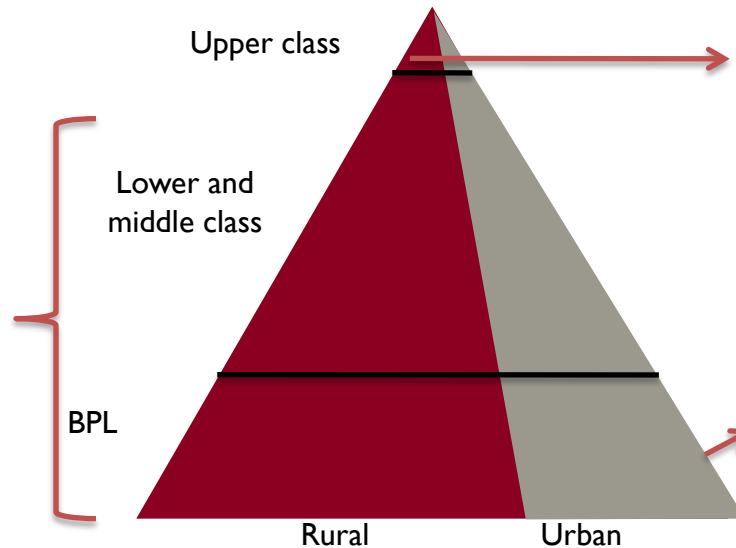
Objective	Key initiatives undertaken
Promote Indian drug discovery platforms	The Government of India is embarking on a major multi-billion dollar initiative with 50 per cent public funding through a public-private partnership model to harness India’s innovation capability. The vision is to catapult India into one of the top five pharma innovation hubs by 2020, targeting to achieve a global niche with one out of every five to ten drugs discovered worldwide by 2020 originating from India.
Collaborations between industry, academia and the government	The government is promoting collaboration among industry, academia and government through various programmes such as New Millennium Indian Technology Leadership (NMITLI) and Drugs and Pharmaceuticals Research Program (DPRP).
Focus on specialised pharmaceutical education	The government has set up seven National Institutes of Pharmaceutical Education and Research (NIPERs) as institutes of ‘national importance’ to achieve excellence in pharmaceutical sciences and technologies, education and training.

Source: ‘Taking wings’, Ernst & Young report 2009

Growth drivers — increasing expenditure on health

- Healthcare expenditure in India is expected to contribute 6.1 per cent of GDP in 2012.
- With the healthcare expenditure in the country expected to increase by 15 per cent per annum, the sector is poised to employ around nine million people.
- The large population base and improving healthcare awareness, in particular, are expected to result in higher expenditure on healthcare.

- The National Rural Health Mission was initiated in 2005 to address the healthcare needs (access and affordability) of the population 'below the poverty line' (BPL), as well as the lower and middle classes in rural India.



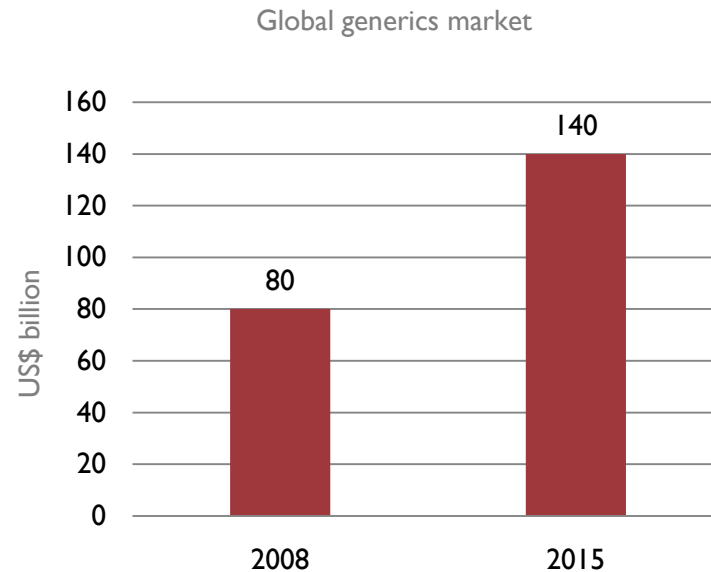
- This section of society (rural and urban) is well equipped to finance its healthcare needs due to higher incomes and access to insurance.

- The National Urban Health Mission intends to address the healthcare needs of the slum dwellers in urban India.

Source: HEAL report, Ernst & Young 2009

Key trends — growing global demand for generics

- Globally, the generics segment is expected to grow to about US\$ 140 billion by 2015.
- Healthcare reforms and cost-saving initiatives, along with US\$150 billion worth of brands going off-patent in the next five years, would continue to drive this growth.



Sources: “Teva investor presentation,” Investor Relations, Teva Pharmaceuticals Industries website, www.tevapharm.com, accessed January 28, 2010; Ernst & Young research

Key trends — launch of patented molecules

- The advent of the product patent regime in 2005 has instilled confidence in the intellectual property regime with many patented drug launches over the last two to three years.
- Global innovators have secured 302 drug patents from the Indian patent office until October 2008, and the number of patents is expected to grow in the next few years.
- While pharmaceutical MNCs already present in India are further consolidating their presence through acquisitions, many MNCs have staged a re-entry post 2005. The share of pharmaceutical MNCs in the domestic pharmaceutical market is estimated to increase to 35 per cent by 2015 from 25 per cent in 2008.

Source: Ernst & Young research

Company	Product	Launch date
Pfizer	Caduet	February 2006
Pfizer	Genotropin	March 2006
Pfizer	Champix	March 2008
GSK	Arixtra	March 2008
GSK	Boostrix	January 2008
GSK	Infranrix	January 2008
GSK	Tykerb	May 2008
Roche	Tamiflu	April 2006
Roche	Tarceva	April 2006
Roche	Pegasys	May 2006
Sanofi Aventis	Aprovel (Avalide)	July 2006
Sanofi Aventis	Stilnox (Ambien)	January 2007
Novartis	Lucentis	November 2008
MSD	Gardasil	October 2008
Abraxis	Abraxane	July 2008

Note: This is an indicative list.

Key trends — rural market opportunities

- The robust consumption in the rural economy is expected to be the key growth driver for the Indian market.
- The untapped Indian rural market accounts for 45 per cent of India's total GDP.
- Rural India accounts for more than 70 per cent of all Indian households and close to two-fifth of the total consumption pie.
- A large number of companies are organising their efforts to derive a major portion of their overall sales from this untapped market.

Source: Ernst & Young research

Rural initiatives

- Rural initiative of Novartis: Arogya Parivar covers 25 million people in more than 18,000 villages. Through this novel 'for-profit' program, the company aims to create health awareness among rural masses as opposed to the traditional pharma marketing approach. The company has divided its field operations into 170 independent cells, each covering a radius of about 35 km. Every cell is managed by a supervisor with the assistance of health educators. As of end 2009, the company estimated to operationalise 500 cells.
- GSK has also strengthened its focus on rural penetration and has initiated a pilot project in Uttar Pradesh.

Key players

Leading Indian players by sales (US\$ million)

Company name	Sales in US\$ million	Year end
Cipla	1,033.46	March 2009
Ranbaxy Lab	951.03	December 2008
Dr Reddy's Labs	866.44	March 2009
Sun Pharma	805.51	March 2009
Lupin Ltd	603.99	March 2009
Aurobindo Pharma	582.27	March 2009
Piramal Health	483.10	March 2009
Cadila Health	354.02	March 2009
Matrix Labs	310.06	March 2009
Wockhardt	309.68	December 2009

Sources: Company websites, annual reports; Ernst & Young research

Note: All revenues were reported in INR.

Leading foreign players by sales (US\$ million)

Company name	Sales in US\$ million	Year end
GlaxoSmithKline Pharma	346.94	December 2008
Aventis Pharma	207.37	December 2008
Abbott India	158.53	November 2009
Pfizer	147.31	November 2008
Novartis India	125.11	March 2009
Merck	98.56	December 2009
Wyeth	79.64	March 2009
AstraZeneca Pharma	73.91	December 2008
Solvay Pharma	50.36	December 2009
Fulford (India)	38.61	December 2008

Contents

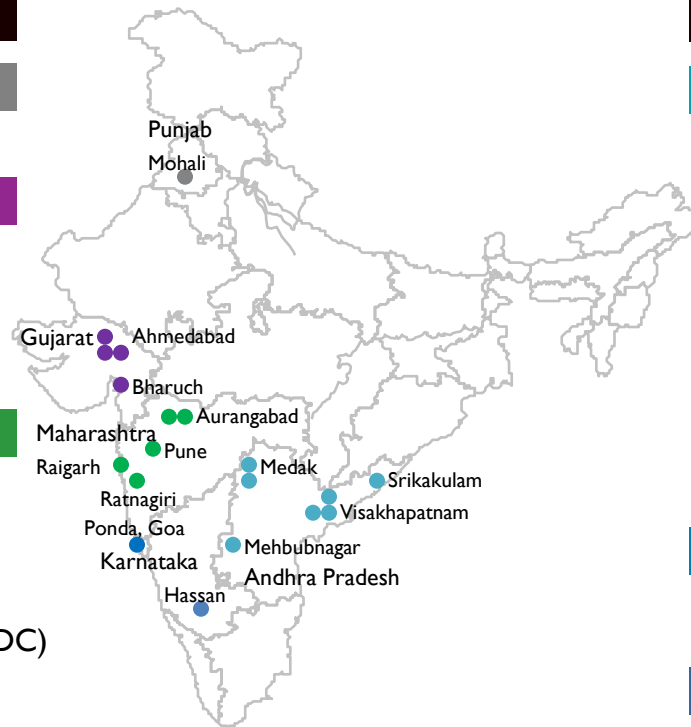
- ❖ Advantage India
- ❖ Market overview
- ❖ **Industry infrastructure**
- ❖ Investments
- ❖ Policy and regulatory framework
- ❖ Opportunities
- ❖ Industry associations

Industry infrastructure — SEZs ... (1/2)

- There are 19 dedicated SEZs in various stages of development.
- The functional pharma SEZs in India include Jawaharlal Nehru Pharma City (JNPC) at Visakhapatnam (Andhra Pradesh), PHARMEZ (Gujarat) developed by Zydus infrastructure and PhaEZ park (Gujarat) developed by Cadila Pharma.

Industry infrastructure — SEZs ... (2/2)

Location of pharma SEZs in India



Pharma SEZ developers

Punjab

- Ranbaxy Laboratories Ltd

Gujarat

- Zydus Finance Ltd
- CPL Infrastructure Pvt Ltd
- Dishman Infrastructure Ltd
- J.B. SEZ Pvt Ltd

Maharashtra

- Serum Institute of India Ltd
- Wockhardt Infrastructure Development Ltd
- Maharashtra Industrial Development Corporation (MIDC)
- Ajanta Pharma Ltd
- Navi Mumbai SEZ Pvt Ltd (Kalamboli Pharmaceutical division)

Pharma SEZ developers

Andhra Pradesh

- Divi's Laboratories Ltd
- Ramky Pharma City (India) Ltd
- Hetero Infrastructure SEZ Ltd
- Andhra Pradesh Industrial Infrastructure Corporation Ltd (APIIC)
- Dr Reddy's Laboratories Ltd
- Deccan Infrastructure and Land Holdings Ltd
- Dr Reddy's Laboratories Ltd

Karnataka

- Karnataka Industrial Areas Development Board

Goa

- Meditab Specialities Pvt Ltd

Source: Ernst & Young research

Contents

- ❖ Advantage India
- ❖ Market overview
- ❖ Industry infrastructure
- ❖ **Investments**
- ❖ Policy and regulatory framework
- ❖ Opportunities
- ❖ Industry associations

Investments ... (1/2)

- Nine deals were completed in 2009.
- Lupin Ltd completed the acquisition of US rights for Antara® (Fenofibrate Capsules 43 mg and 130 mg). Lupin acquired the product from Oscient Pharmaceuticals on September 25, 2009, while Antara recorded net sales of US\$ 70 million for 2008. Lupin paid US\$ 38.61 million for the product and related assets inclusive of inventory.*

Cumulative FDI inflows	
Period: April 2000 to January 2010	
Sector	Amount of FDI inflows (US\$ million)
Drugs and pharmaceuticals	1,656.2

Source: "Fact Sheet On Foreign Direct Investment (FDI)", Department of Industrial Policy and Promotion, www.dipp.nic.in, accessed January 29, 2009

M&A scenario — details		
Period: January 1, 2009 to November 30, 2009		
Deal type	No of deals	Deal value (US\$ million)
Inbound	5	42.8
Outbound	3	8.7
Domestic	1	-

Sources: Bloomberg, accessed December 4, 2009; Ernst & Young analysis

*"Lupin Expands Branded Play Announces Acquisition of US Rights to ANTARA," Lupin Limited Press release, www.lupinworld.com, September 29, 2009

Investments ... (2/2)

Deal summary				
Deal type	Acquirer	Target	Announced total value (US\$ million)	Announcement date
Outbound	Lupin Ltd	US rights for Antara's Fenofibrate capsules	38.6	September 2009
Inbound	Perkinelmer Inc	Prenatal and newborn screening laboratory	N/A	September 2009
Inbound	Schering-Plough Corp	Fulford India Ltd	8.4	July 2009
Outbound	Lupin Ltd	Allernaze	N/A	June 2009
Outbound	Wanbury Ltd	Cantabria Pharma SL	N/A	June 09
Domestic	Ranbaxy Laboratories Ltd	Certain Assets	N/A	May 2009
Outbound	Lupin Ltd	Mutlicare Pharmaceuticals	N/A	March 09
Inbound	Haw Par Corp Ltd	Haw Par Elder Health Care Ltd	0.3	February 2009
Outbound	Piramal Healthcare Ltd	Rxelite Holdings Inc	4.2	January 2009

Source: "Transactions," Bloomberg, accessed December 4, 2009 N/A: Not available

Contents

- ❖ Advantage India
- ❖ Market overview
- ❖ Industry infrastructure
- ❖ Investments
- ❖ **Policy and regulatory framework**
- ❖ Opportunities
- ❖ Industry associations

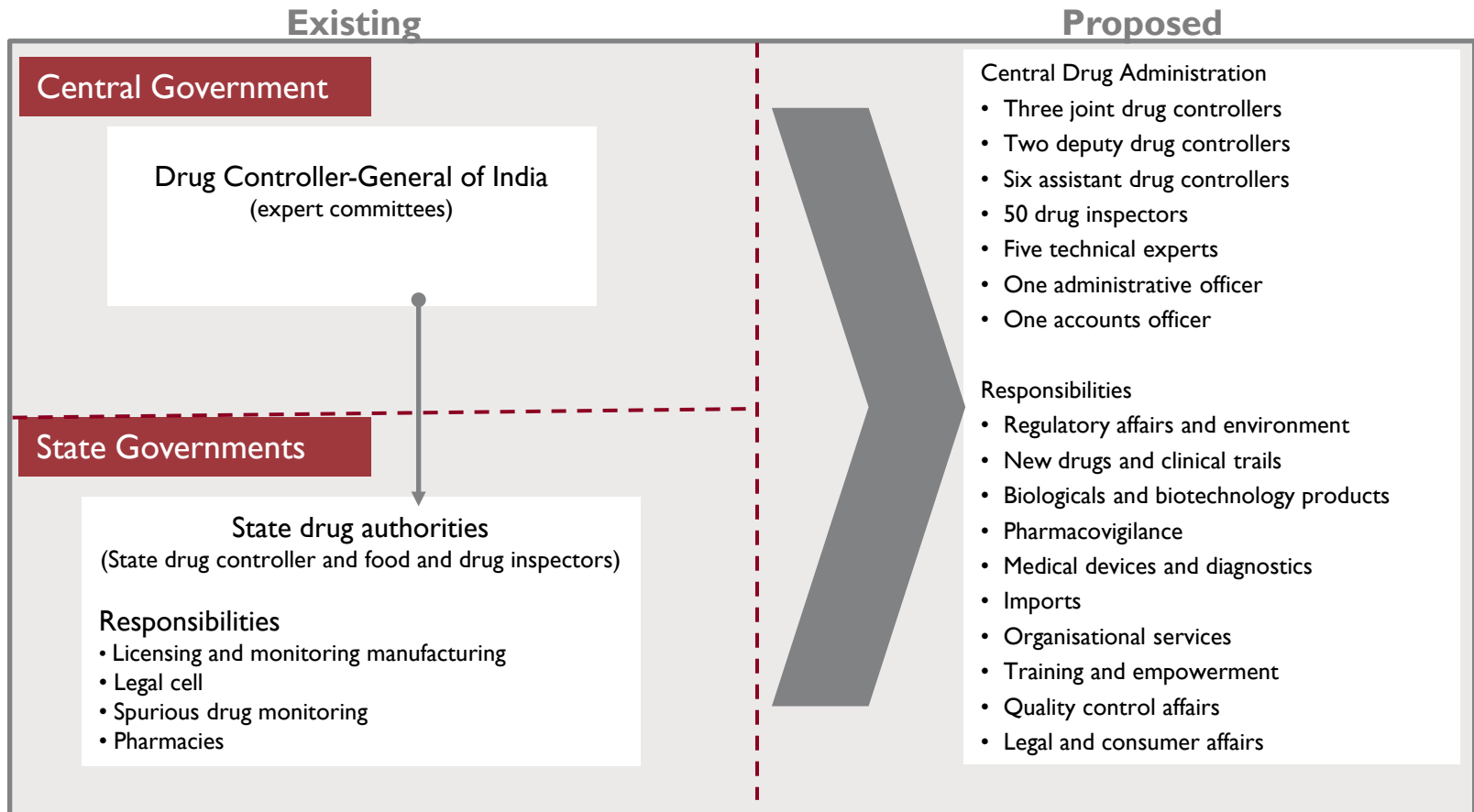
Policy and regulatory framework ... (1/4)

- The main drug regulatory body in India is the Central Drug Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare.
- CDSCO is presided over by the Drug Controller-General of India (DCGI), who is incharge of approval of licences for drugs at both the central and state levels.
- India introduced the product patent regime, in accordance with the Trade-Related Aspects of the Intellectual Property Rights (TRIPS) agreement, in January 2005, with an amendment to the Patent Act.
- FDI, up to 100 per cent is permitted through the automatic route in drugs and pharmaceuticals.

Policy and regulatory framework ... (2/4)

- FDI in licensable drugs and pharmaceuticals manufactured by recombinant DNA technology and specific cell/tissue targeted formulations, FDI requires prior government approval.
- The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and controlling the prices of 74 bulk drugs and formulations under the Essential Commodities Act.
- The Department of Pharmaceuticals was formed on July 2, 2008, under the Ministry of Chemicals and Fertilisers with the objective to give a heightened focus and thrust on the development of the pharmaceutical sector in the country and to regulate various complex issues related to the pricing and availability of medicines at affordable prices, R&D, protection of intellectual property rights and international commitments related to the pharmaceutical sector.

Policy and regulatory framework ... (3/4)



Policy and regulatory framework ... (4/4)

Budget measures

- There has been an increase in weighted reduction from 150 to 200 per cent on expenditure incurred on in-house R&D activities and from 125 to 175 per cent on activities outsourced to specific institutions.
- There has been a partial roll-back in excise duty from 8 to 10 per cent (to impact raw material costs).

Policy measures

- DCGI has made the registration of all clinical trials compulsory for trials initiated after June 15, 2009. Earlier, the registration of clinical trials by various institutions and companies was voluntary.
- The DCGI has discontinued the issuance of the WHO-GMP certificate for both pharmaceutical products and plant audits.
- The government has issued the draft version of Drugs and Cosmetics (4th Amendment) Rules, 2009, which provides for the product licences for narcotic drugs and psychotropic substances to be issued by the Central Licensing Approval Authority (CLAA), which were earlier issued by SLAs.

Source: India Budget 2010, Ernst & Young; Note: WHO – World Health Organisation, GMP – Good manufacturing practice

Contents

- ❖ Advantage India
- ❖ Market overview
- ❖ Industry infrastructure
- ❖ Investments
- ❖ Policy and regulatory framework
- ❖ **Opportunities**
- ❖ Industry associations

Opportunities — new chemical entities (NCEs)

- Indian pharmaceutical companies are ascending the value chain with a focus on innovation.
- The level of investments in R&D capabilities and infrastructure has been enhanced by both the industry and the government.
- Dr Reddy's Laboratories' NCE Balaglitazone is India's first indigenously-developed molecule to enter the Phase III trial.
- The growing R&D pipeline of Indian companies presents significant in-licensing opportunities for global companies.

Number of molecules in various stages of drug development pipeline of key Indian companies				
	Discovery/pre-clinical phase	Phases		
		I	II	III
Ranbaxy	6	0	1	0
Dr Reddy's	1	1	0	1
Glenmark	6	2	3	0
Zydus Cadila	4	3	2	0
Piramal Healthcare	10	3	4	0
Lupin	4	1	2	1
Sun	3	0	1	0

Indian pharmaceutical R&D expenditure		
Specifics	2001	2008
R&D expenditure as a percentage of sales	1.4	9.9
R&D expenditure in absolute terms (US\$ mn)	55	660

Source: Taking wings, Ernst & Young research 2009

Opportunities — contract manufacturing

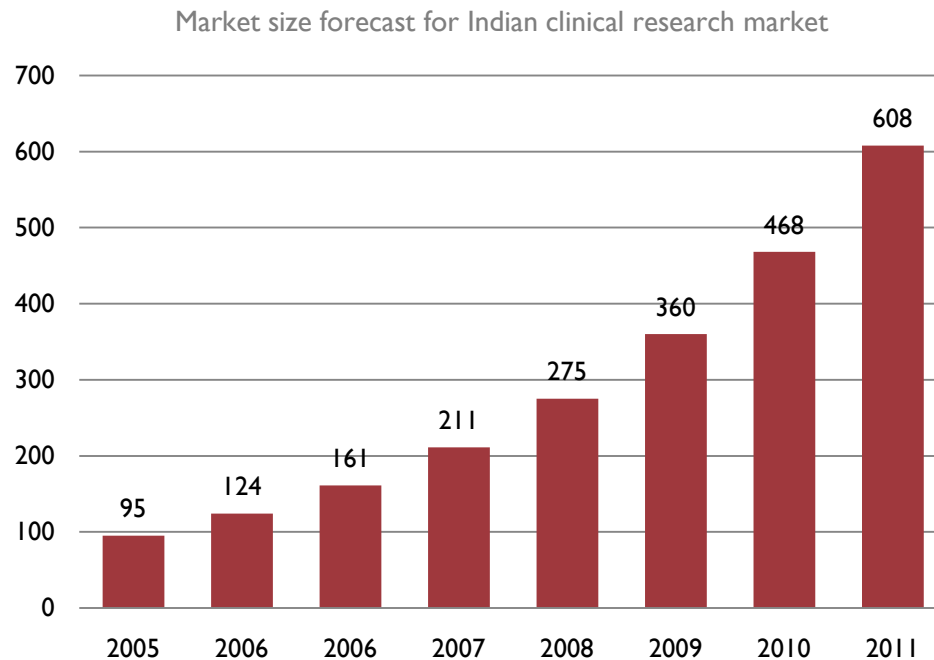
- The Indian pharmaceutical manufacturing outsourcing market is valued at US\$ 1.1 billion in 2008, and the segment is growing at thrice the global market rate.
- India's share of the outsourcing market is estimated to grow from 2.8 per cent in 2007 to 5.5 per cent in 2010.
- APIs/intermediate outsourcing is more prevalent in India than formulation outsourcing; 64 per cent of total outsourcing is in the area of APIs/intermediates.
- The market is estimated to grow to US\$ 1 billion by 2010.
- By 2010, the demand for contract manufacturing of formulations is likely to be between US\$ 210 million and US\$ 300 million. The demand for APIs and intermediate is expected to be in the range of US\$ 600 million and US\$ 700 million by 2010.



Sources: Taking wings, Ernst & Young research 2009
P: Projected

Opportunities — clinical research

- The clinical trials market in India, currently valued at about US\$ 250–275 million, is expected to grow at a CAGR of 30 per cent over the next few years, at nearly double the global average.

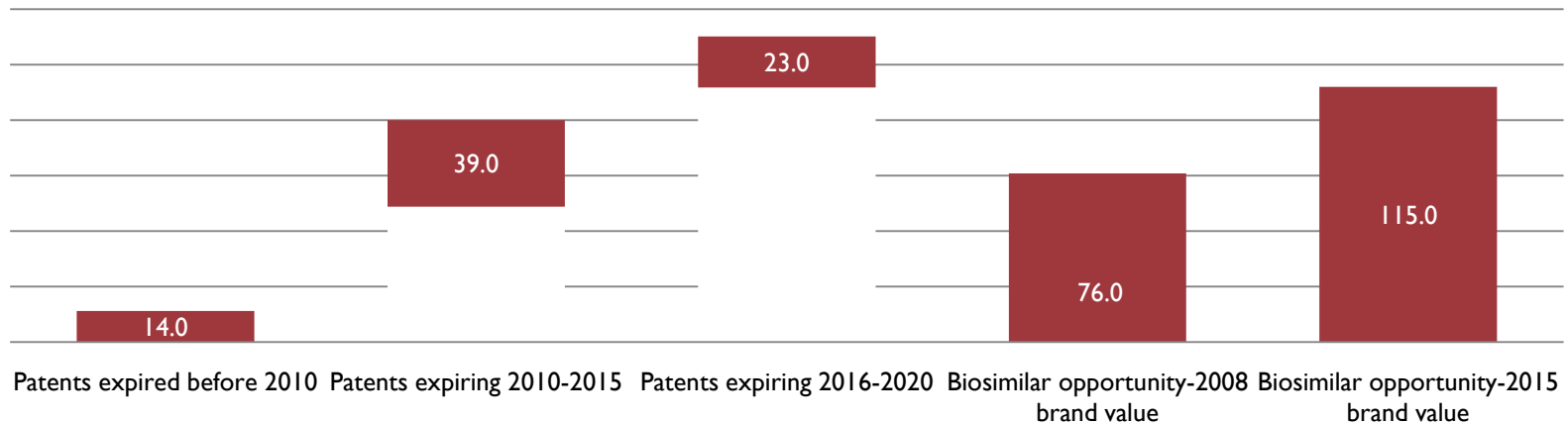


Sources: The glorious metamorphosis, Ernst & Young research 2009

Opportunities — bio-similars

- The increasing use of biologics in disease areas such as cancer, auto-immune and orphan diseases, in addition to healthcare cost containment, has driven the growth of bio-similars.
- Companies in this space include Reliance Biopharma, Shantha Biotech, Panacea Biotec, Wockhardt, Dr Reddy's, Biocon, Intas Biopharmaceuticals and Avesthagen. Glenmark and Cipla are targeting new product launches in 2010.

Future opportunity in biosimilars (US\$ billion)



Sources: "Teva investor presentation," Investor Relations, www.tevapharm.com, accessed January 28, 2010; Ernst & Young research

Contents

- ❖ Advantage India
- ❖ Market overview
- ❖ Industry infrastructure
- ❖ Investments
- ❖ Policy and regulatory framework
- ❖ Opportunities
- ❖ **Industry associations**

Industry associations

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E-mail: ipacentre@ipapharma.org

<http://www.ipapharma.org>

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Note

Wherever applicable, numbers in the report have been rounded off to their nearest whole number.

Conversion rate used: US\$ 1 = INR 48

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