



# BIOTECHNOLOGY

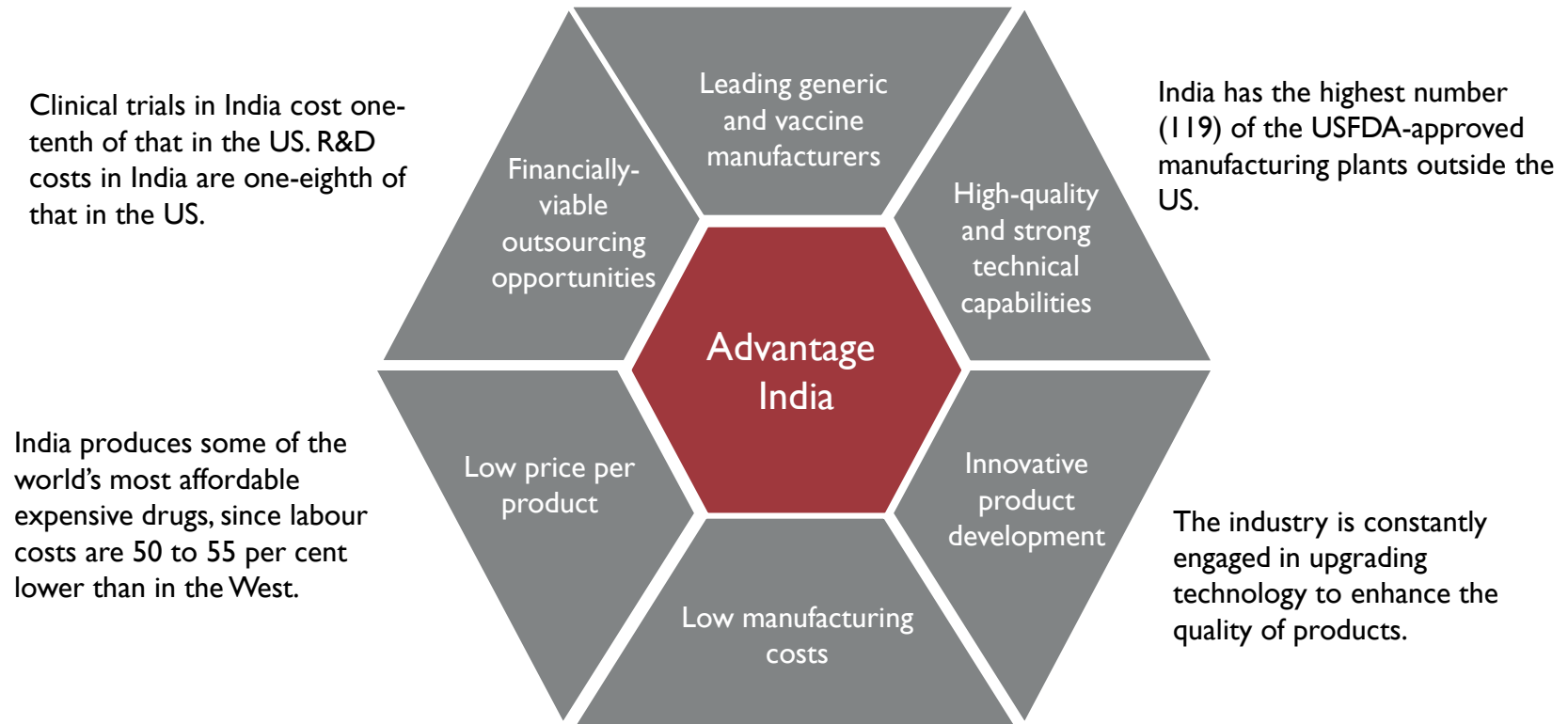
April 2010

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## Advantage India

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



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

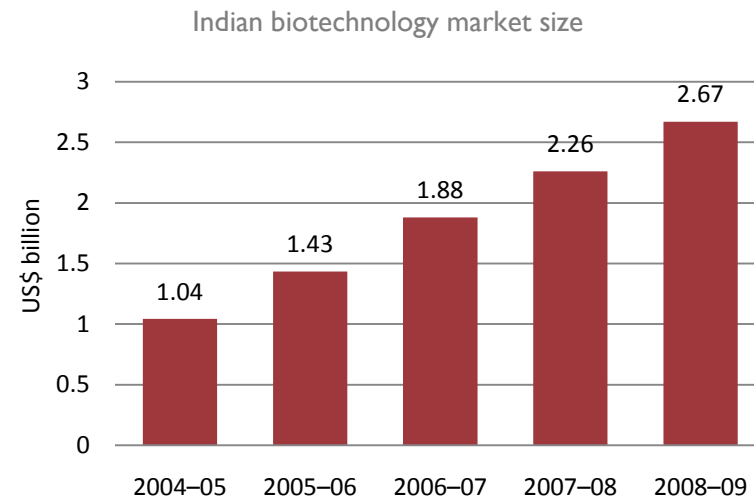
Source: Ernst & Young research  
USFDA: United States Food and Drug Administration

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## Market overview

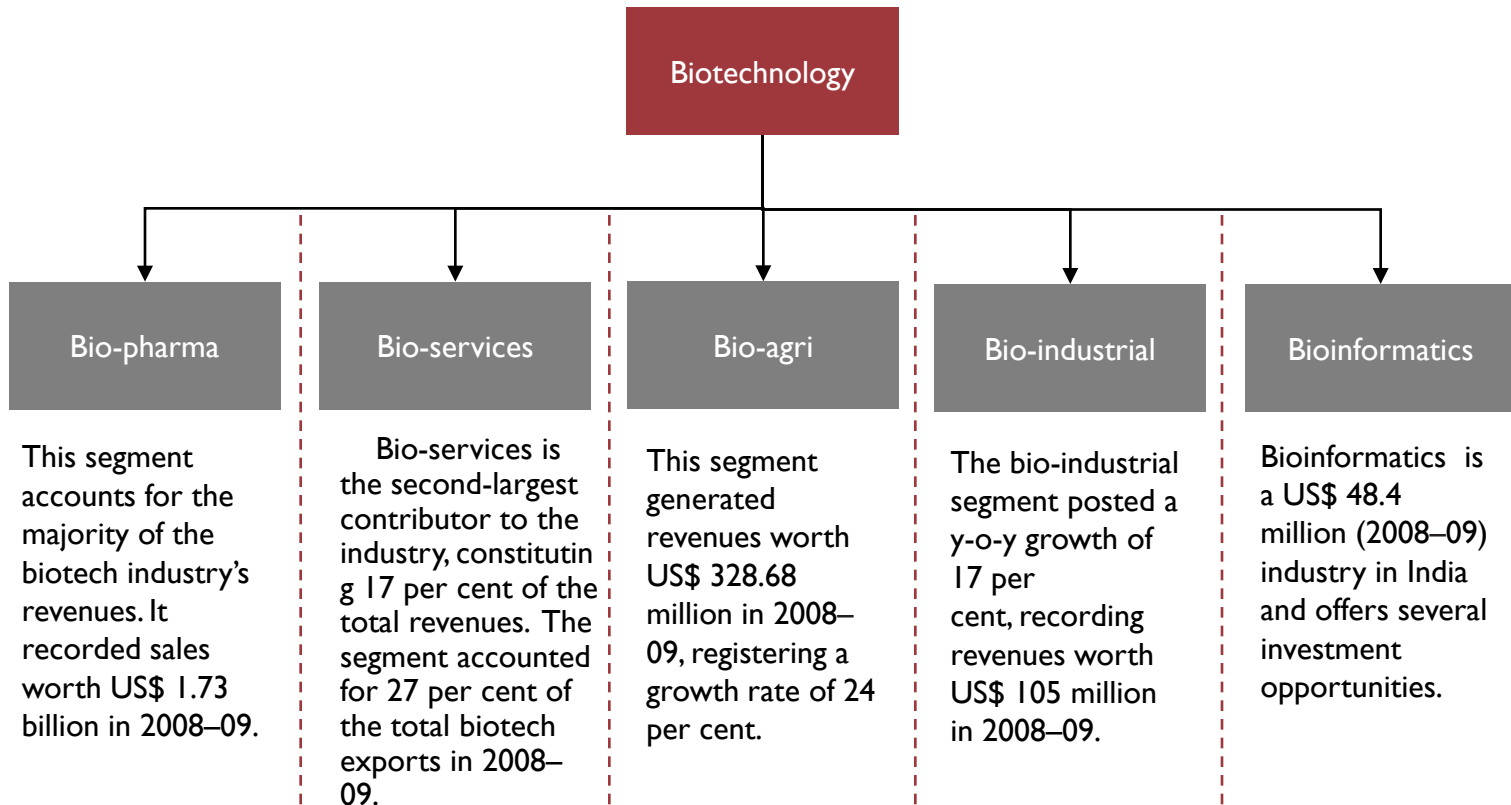
- In 2008–09, the industry recorded revenues worth US\$ 2.67 billion (INR 121.37 billion), registering a y-o-y growth of 18 per cent (in value) from 2007–08.



Sources: ABLE-Biospectrum industry survey, June 2009; Ernst & Young analysis

Conversion rate: US\$ 1 = INR 48

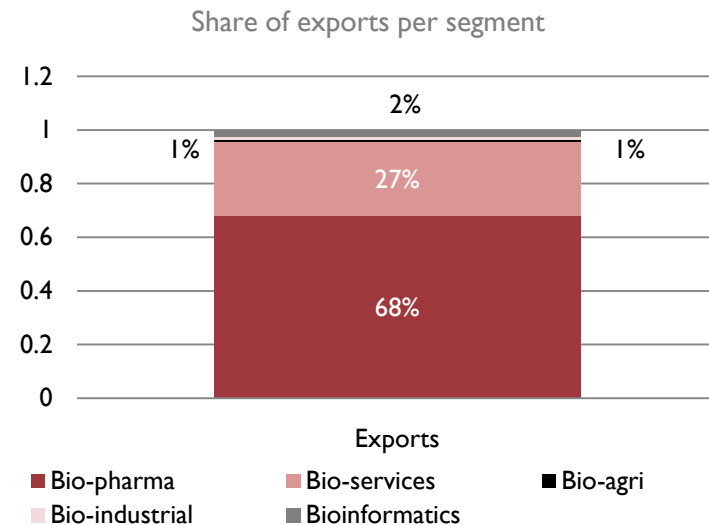
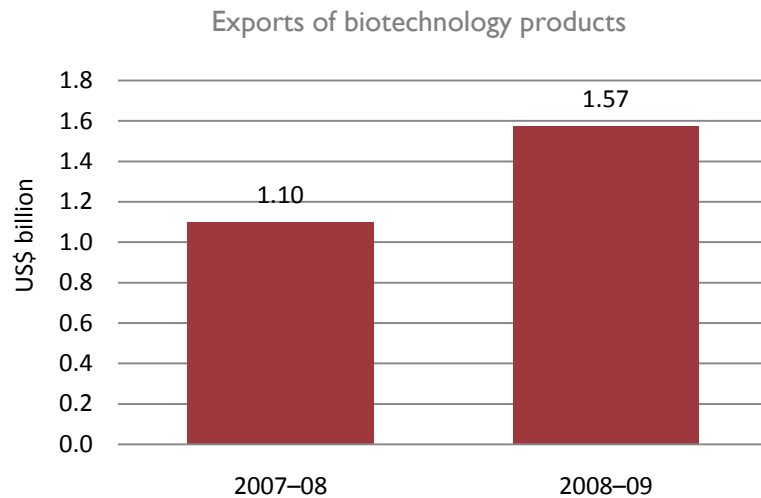
# Market segments



Sources: ABLE-Biospectrum industry survey, June 2009; Ernst & Young analysis  
Conversion rate: US\$ 1 = INR 48

# Exports

- Revenues from biotech exports have been valued at US\$ 1.57 billion in 2008–09, constituting 59 per cent of the total biotech industry revenues.



Sources: ABLE-Biospectrum industry survey, June 2009; Ernst & Young analysis  
Conversion rate: US\$ 1 = INR 48

## Domestic demand

### Specialised treatment

- There has been a gradual shift in the disease profile afflicting the Indian population. An increasing number of lifestyle-related diseases are being reported, which has led to the demand for various kinds of specialised treatments.

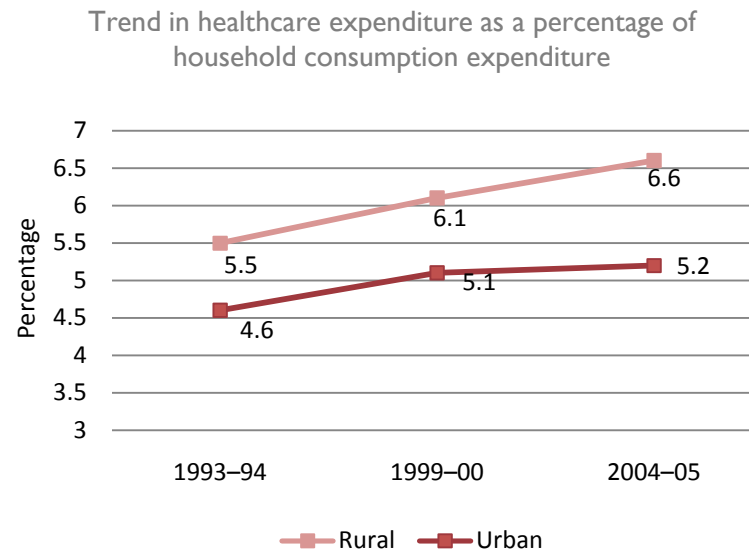
### Preventive healthcare

- Demographic changes have led to an increase in demand for vaccines, both for geriatrics and pediatrics.

Source: Ernst & Young research

## Growth drivers - increased expenditure on drugs and devices

- Healthcare expenditure, as a percentage of GDP, has been recorded at 1.37 per cent for 2008–09, with the growth being driven primarily by the rise in private expenditure.



Source: Ernst & Young research

## Growth drivers - government support

### New facilities

- The Department of Biotechnology (DBT) has set up 35 facilities between 2002 and 2007 to produce and supply biologicals, reagents, culture collections and laboratory animals to scientists, industries and students at a nominal cost.

### Regulatory

- According to the National Biotechnology Development Strategy (NBDS), there is a positive inclination to set up a centralised National Biotechnology Regulatory Authority to provide a single window clearance mechanism for all biosafety clearances for products.

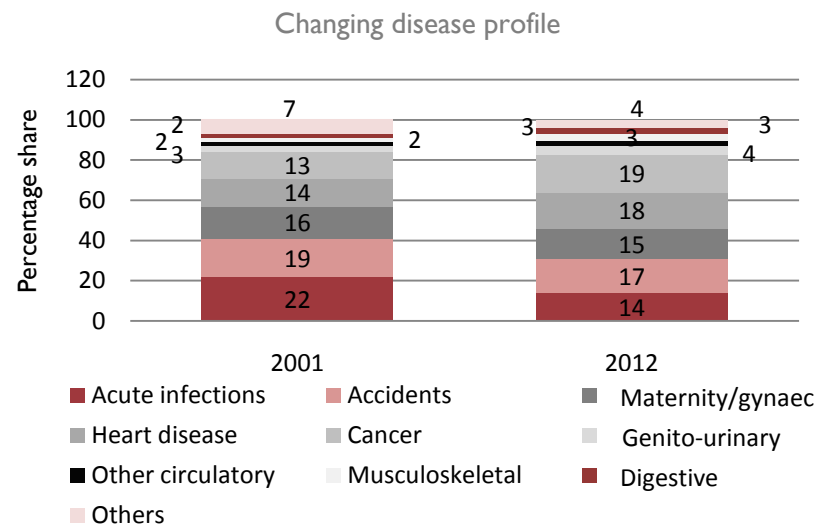
### International collaborations

- There are various international collaborations with different countries in the offing, which are directed at enabling an effective transition of knowledge. To achieve this, India has partnered with Denmark, Finland, France, the UK, the US, Switzerland and the Netherlands.

Source: Ernst & Young research

## Growth drivers - rising incidence of chronic diseases

- Lifestyle diseases are set to assume a greater share of the healthcare market.
- Lifestyle diseases such as cardiac diseases and diabetes require biotechnology products for treatment, thereby increasing the revenues of biotech companies.



Source: Fortis Healthcare Limited annual report 2008-09

## Key trends - pharma companies are focussing on biotech

- The increasing pressure on multinational companies due to the declining R&D productivity, rising genericisation and fewer and smaller blockbuster drugs has led the industry to focus on exploring new markets and products to strengthen its top-line momentum.
- The major Indian pharmaceutical companies that have entered the bio-pharma segment include Ranbaxy, Cadila Healthcare, Lupin, Wockhardt and Dr Reddy's.

### Global companies setting up base

- Lonza is planning to set up a manufacturing base in India at an investment of US\$ 150 million in Hyderabad. The investment outlay has been planned over two phases:
  - Phase I (from 2011 to 2013) will include the development of R&D labs for more than 100 resources.
  - Phase II (from 2014 to 2015) will include the expansion of manufacturing capabilities and the provision for increasing R&D lab capacity for biologics with additional 200 resources.

Source: Ernst & Young research

## Key players

- The leading ten companies (in terms of revenues) accounted for 39 per cent of the total industry revenues in 2008–09.
- MNCs such as Novo Nordisk and Novozymes feature among the leading 10 biotech companies.
- Of the top 20 companies, 19 of them generated revenues worth US\$ 20 million in 2008–09.
- The leading 30 home-grown companies contributed revenues worth US\$ 1.31 billion, accounting for 57 per cent of the total revenues of the industry in 2008–09.
- Serum Institute of India and Biocon are the two leading players in the industry.

Leading 10 companies (2008–09)		
Company	Revenue (US\$ mn) 2008–09	Per cent change since 2007–08
Serum Institute of India	245.08	12.87
Biocon	200.71	4.04
Panacea Biotec	131.37	-11.98
Rasi Seeds	82.63	28.07
Nuziveedu Seeds	80.07	24.69
Novo Nordisk	72.60	26.92
Siro Clinpharm	61.60	—
Novozymes South Asia	55.00	11.11
Shantha Biotech	54.34	64.67
Jubilant	53.24	52.20

Sources: ABLE-Biospectrum industry survey, June 2009; Ernst & Young analysis  
Conversion rate: US\$ 1= INR 48

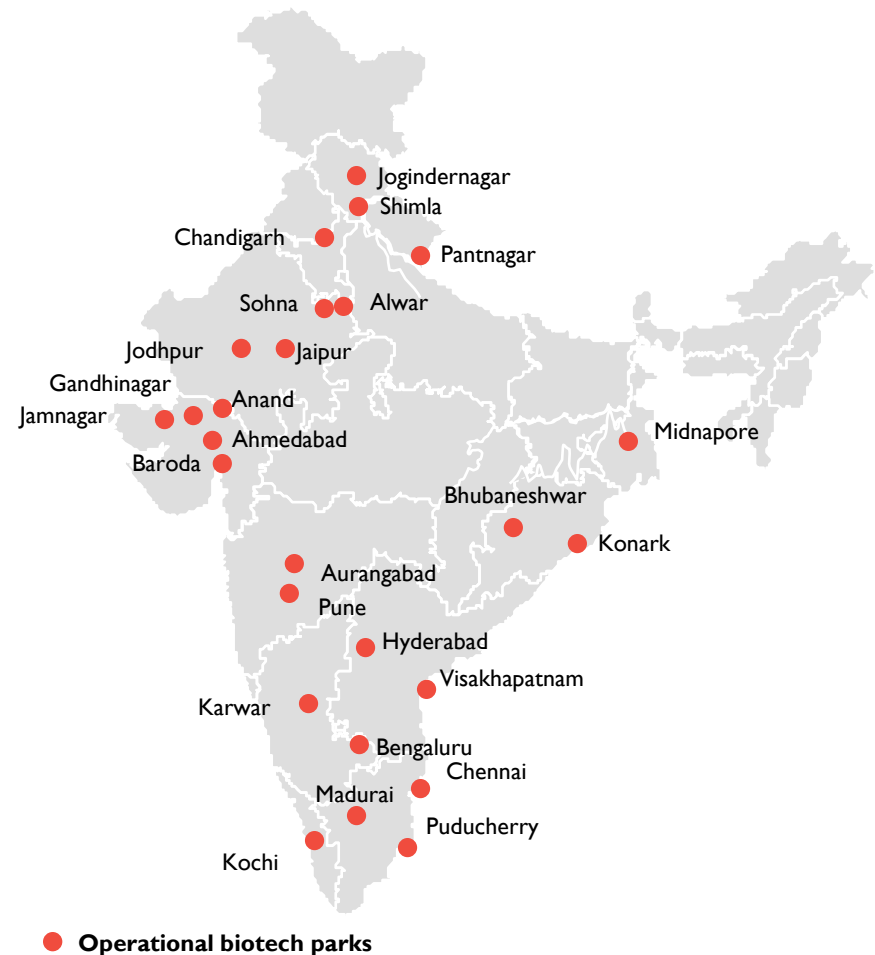
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## Industry infrastructure ... (1/2)

- The biotechnology-related infrastructure has evolved from traditional clusters to specialised industrial infrastructure such as biotech or science parks.
- States such as Andhra Pradesh, Maharashtra, Tamil Nadu and Kerala have been early movers in establishing world-class biotech parks and clusters.
- Investors such as TCG and Alexandria have significantly contributed in establishing biotechnology-related infrastructure in the country.

Source: Ernst & Young research



## Industry infrastructure ... (2/2)

- Currently, there are about 26 operational parks in the country.

Details of key biotechnology parks		
Parks	City	Area (in acres)
Shapoorji Pallonji Biotech Park	Hyderabad	300
ICICI Knowledge Park	Hyderabad	200
International Biotech Park	Pune	103
Lucknow Biotech Park	Lucknow	20
Golden Jubilee Biotech Park	Chennai	8
Ticel Bio Park	Chennai	5

## Enabling research infrastructure

- The country has more than 450 institutes/colleges and departments imparting education in life sciences.
- More than 25,000 pharmacy students graduate from these institutes every year.

Key research institutes in India
• Central Drug Research Institute (CDRI), Lucknow
• National Institute of Pharmaceutical Education and Research (NIPER), Mohali
• Indian Institute of Chemical Technology (IICT), Hyderabad
• Centre for Cellular & Molecular Biology (CCMB), Hyderabad
• Indian Institute of Chemical Biology (IICB), Kolkata
• Indian Toxicology Research Institute (ITRI), Lucknow
• Institute of Genomics and Integrative Biology (IGIB), New Delhi
• Institute of Microbial Technology (IMTECH), Chandigarh
• National Chemical Laboratory (NCL), Pune
• National Centre for Biological Sciences (NCBS), Bengaluru
• Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Bengaluru
• Indian Institute of Science (IISc), Bengaluru
• National Institute of Immunology (NII), New Delhi

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## Investments ... (1/2)

- Six deals were completed in 2009.
- Merck KGaA acquired Bangalore Genei (India) Pvt Ltd (BGIP) through its wholly-owned subsidiary in India, Merck Specialities Pvt Ltd, from the Sanmar Group.

M&A scenario — details		
Period: January 1, 2009 to November 30, 2009		
Deal type	No of deals	Deal value (US\$ million)
Inbound	5	8.8
Outbound	1	—

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

Note: Deal still pending

Cumulative FDI inflows	
Period: April 2000 to January 2010	
Sector	Amount of FDI inflows (US\$ million)
Drugs and pharmaceuticals	1,656.24

Source: "Fact Sheet on Foreign Direct Investment (FDI)," Department of Industrial Policy and Promotion website, [www.dipp.nic.in](http://www.dipp.nic.in), accessed April 29, 2010

## Investments ... (2/2)

Deal summary					
Deal type	Acquirer	Acquirer's country	Target name	Target country	Announcement date
Inbound	Millipore Corp	United States	Millipore India Pvt Ltd	India	November 23, 2009
Inbound	Merck KGaA	Germany	Bangalore Genei India Pvt Ltd	India	October 13, 2009
Inbound	Lonza Group AG-REG	Switzerland	Preclinical Cell and Molecular Biology Assets	India	October 13, 2009
Inbound	Du Pont (E I) De Nemours	United States	Cotton Germplasm	India	June 26, 2009
Inbound	Du Pont (E I) De Nemours	United States	Cotton Seed Business	India	June 26, 2009

Source: Bloomberg, accessed December 4, 2009

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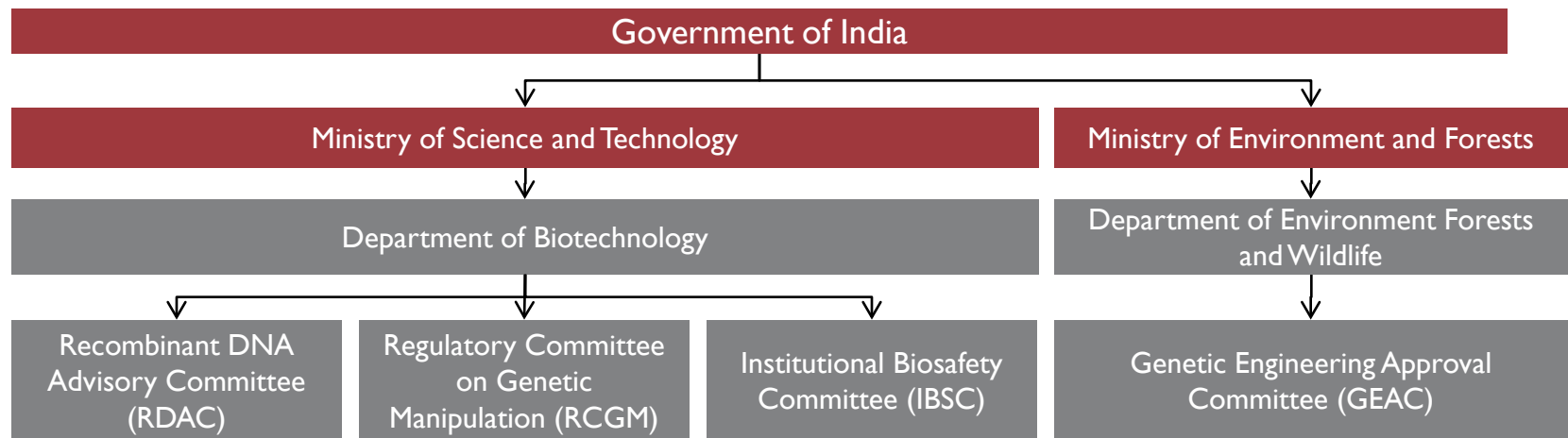
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## Policy and regulatory framework ... (1/2)

- DBT is the primary regulatory body under the Ministry of Science and Technology (MoST).
- The entities involved in industry regulation are the Recombinant DNA Advisory Committee (RDAC), Review Committee on Genetic Manipulation (RCGM), Institutional Biosafety Committee (IBSC), Genetic Engineering Approval Committee (GEAC).
- The NBDS, approved in 2007, envisages setting up a single National Biotechnology Regulatory Agency (NBRA), and is awaiting approval.

Source: "Policy and rules," Department of Biotechnology website, <http://www.dbtindia.nic.in/>, accessed January 18, 2010

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



Source: "Policy and rules," Department of Biotechnology website, <http://www.dbtindia.nic.in/>, accessed January 18, 2010

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## Opportunities — product segments

### Oncology

- In India, the current oncology market is about US\$ 225 million and is expected to reach US\$ 850 million by 2012, growing at a compound annual growth rate (CAGR) of nearly 30 per cent.
- Companies such as Dabur, Biocon, Dr Reddy's, Intas, Roche, Cipla and Sun Pharmaceuticals have a significant market presence in the Indian oncology market.

### Insulin

- Novo Nordisk, Eli Lilly, Biocon and Shantha Biotech are the leading players in this segment, while Ranbaxy, Sun Pharma and Glenmark are among the new players.
- Companies are targeting to develop drugs with a non-invasive insulin delivery technology.

<sup>1</sup>Source: "Cancer drug market to touch \$48b in 2008," The Times of India, www.timesofindia.indiatimes.com, accessed January 18, 2010

## Opportunities

- Companies prefer to outsource the manufacturing of biologics rather than investing in a facility, since the cost of investing in a new manufacturing facility is high.
- The growth in the biosimilars market is driven by an increasing use of biologics in disease areas such as cancer, auto-immune and orphan diseases and cost containment.
- Companies in this segment 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.

Segment	Potential (2010)
Bio-pharmaceuticals	US\$ 2 billion
Bio-services (outsourced research services)	US\$ 1 billion

Source: Ernst & Young research

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## Industry associations

### **Association of Biotechnology Led Enterprises (ABLE)**

# 123/C, 16th Main Road, 5th Cross, 4th Block

Near Sony World Showroom/Headstart School

Koramangala, Bangalore – 560034

Phone: 9-80-416368534, 25633853

E-mail: [info@ableindia.org](mailto:info@ableindia.org)

## Note

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

Conversion rate used: US\$ 1 = INR 48

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