

INDIAN PHARMACEUTICAL INDUSTRY IN THE NEW PARADIGM

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- ❖ India Today
- ❖ Healthcare and Regulatory Environment
- ❖ Pharmaceutical/Biotech Industry
- ❖ R&D
- ❖ Outsourcing Opportunities
- ❖ Drivers and Barriers
- ❖ Advantage India



Temptation of the West

“If you don’t know INDIA, you don’t know the WORLD”

- Andre Malraux



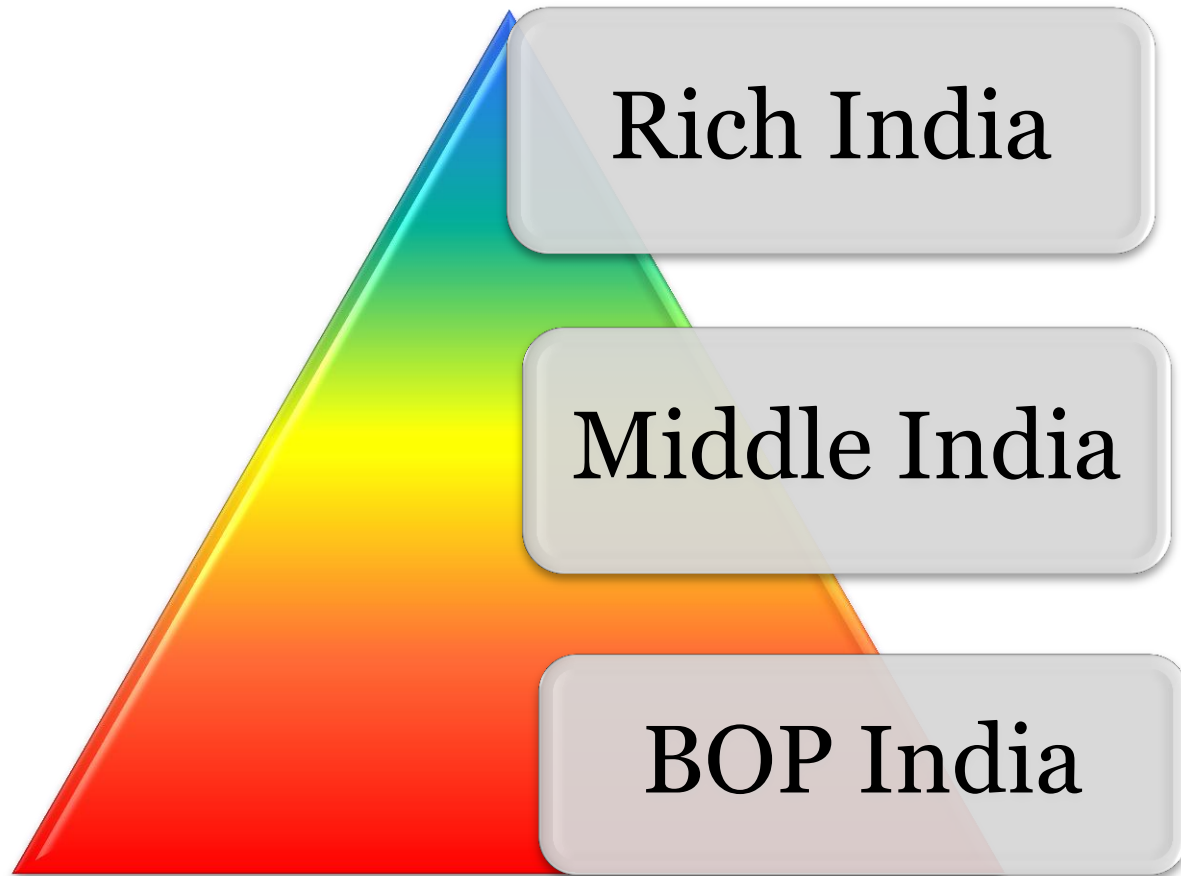
India Today



The Wise Elephant



India Market Pyramid



Opportunities in Each Tier

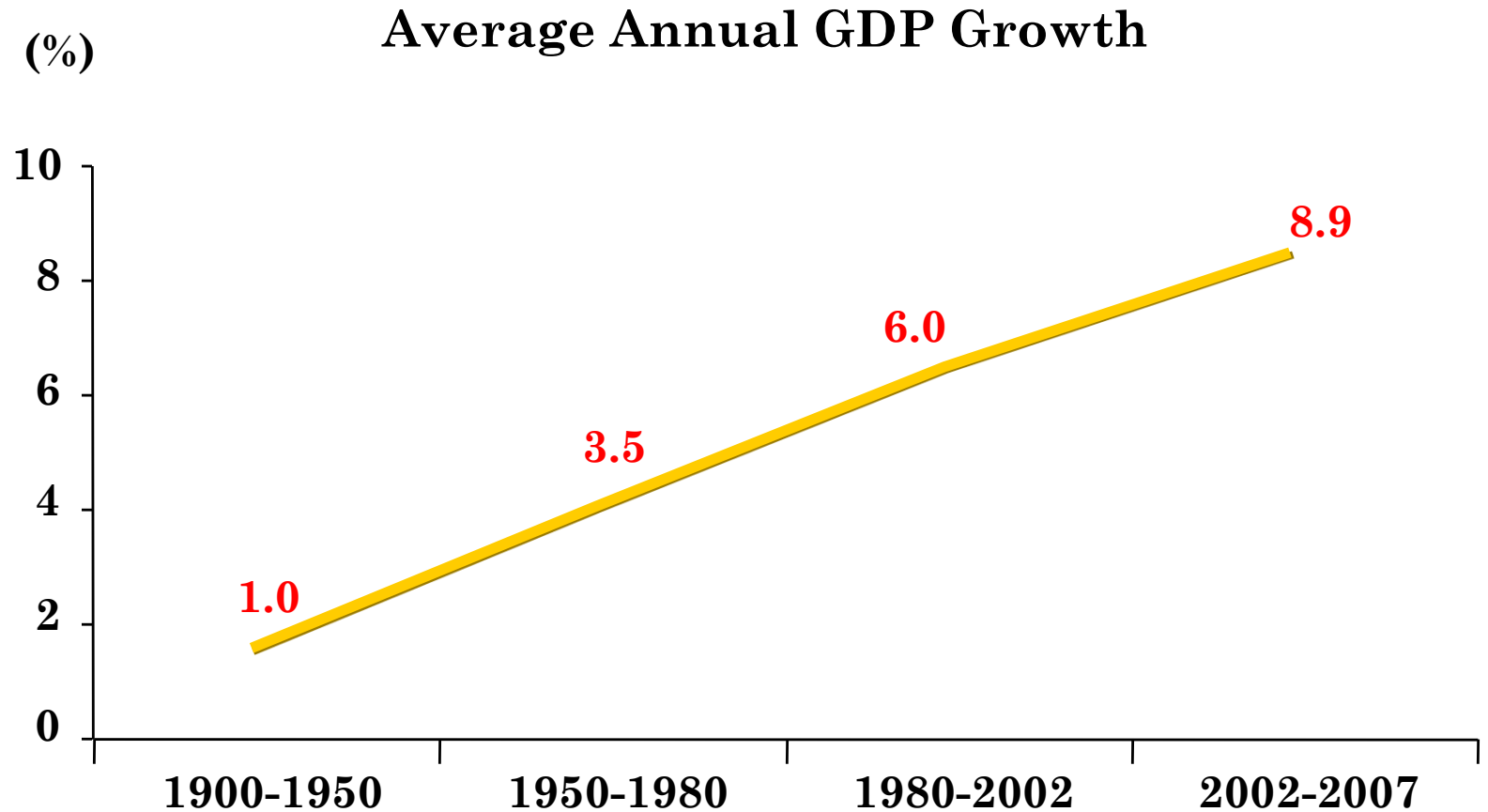
Income Percentile	Population (MM)	% of Income	GDP per capita (\$)
Class (Top 10%)	109	34.1	1,878
Mass (Next 30 %)	368	36.1	662
BOP (Last 60%)	653	29.7	265

Source: Rama Bijapurkar, We are like that only



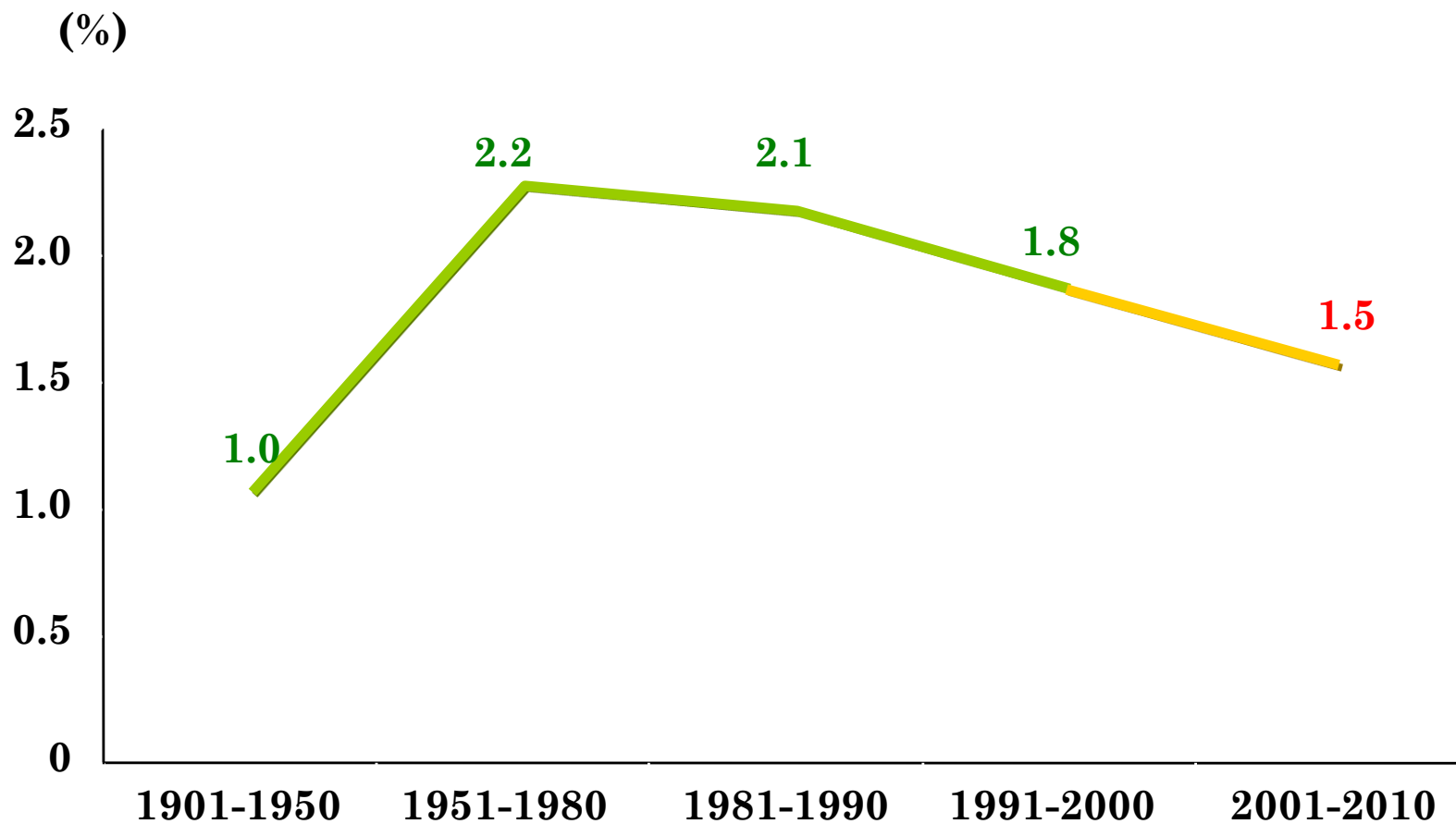
28 Years of High Growth

India is the 4th
Largest
economy



Population Growth is Slowing Down

India is the 2nd
Largest
population

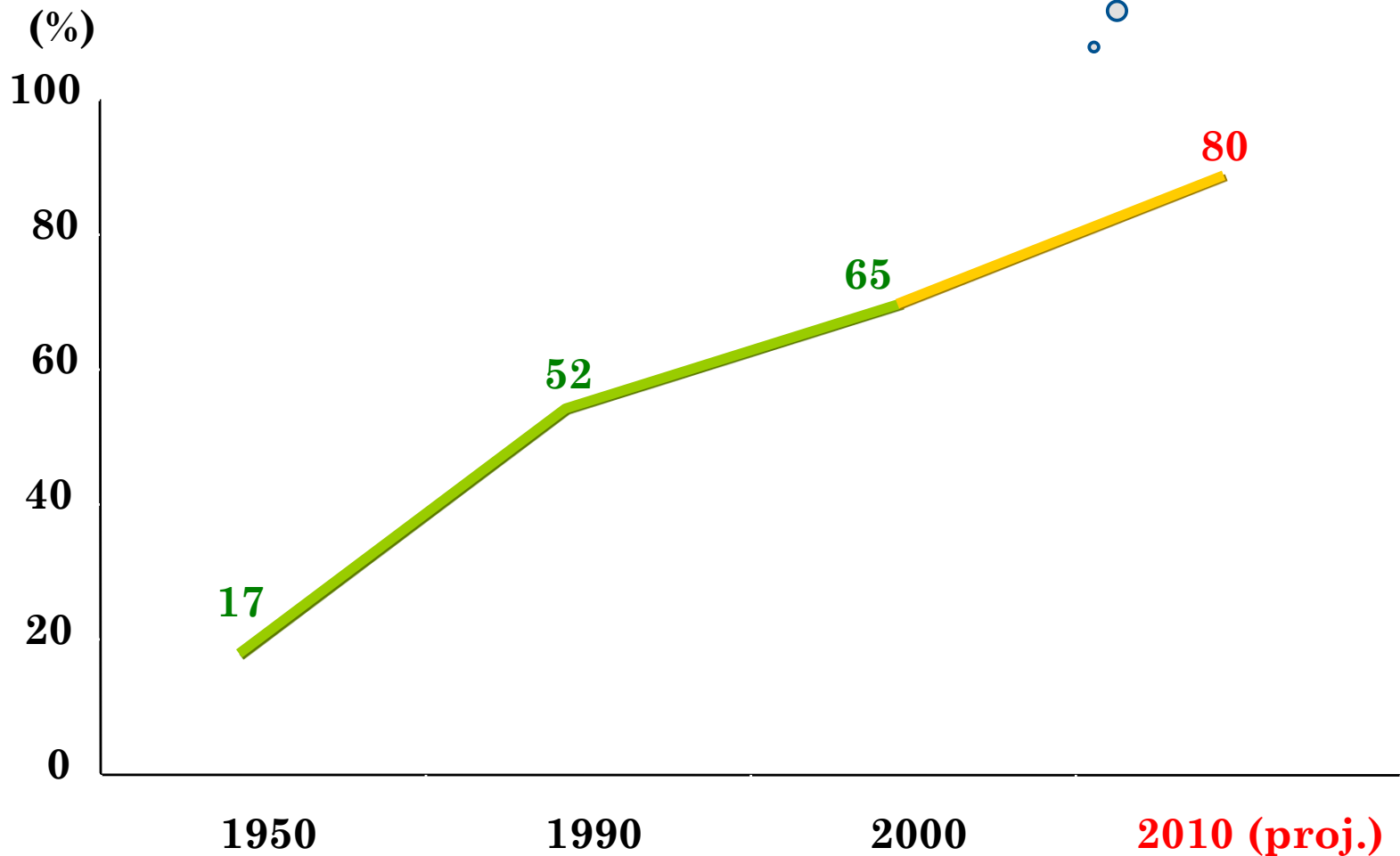


Sources: 1900-1990: Angus Maddison (1995), Monitoring the World Economy, 1990-2000: Census of India (2001)



Literacy is Rising

India is the 4th
Largest
economy

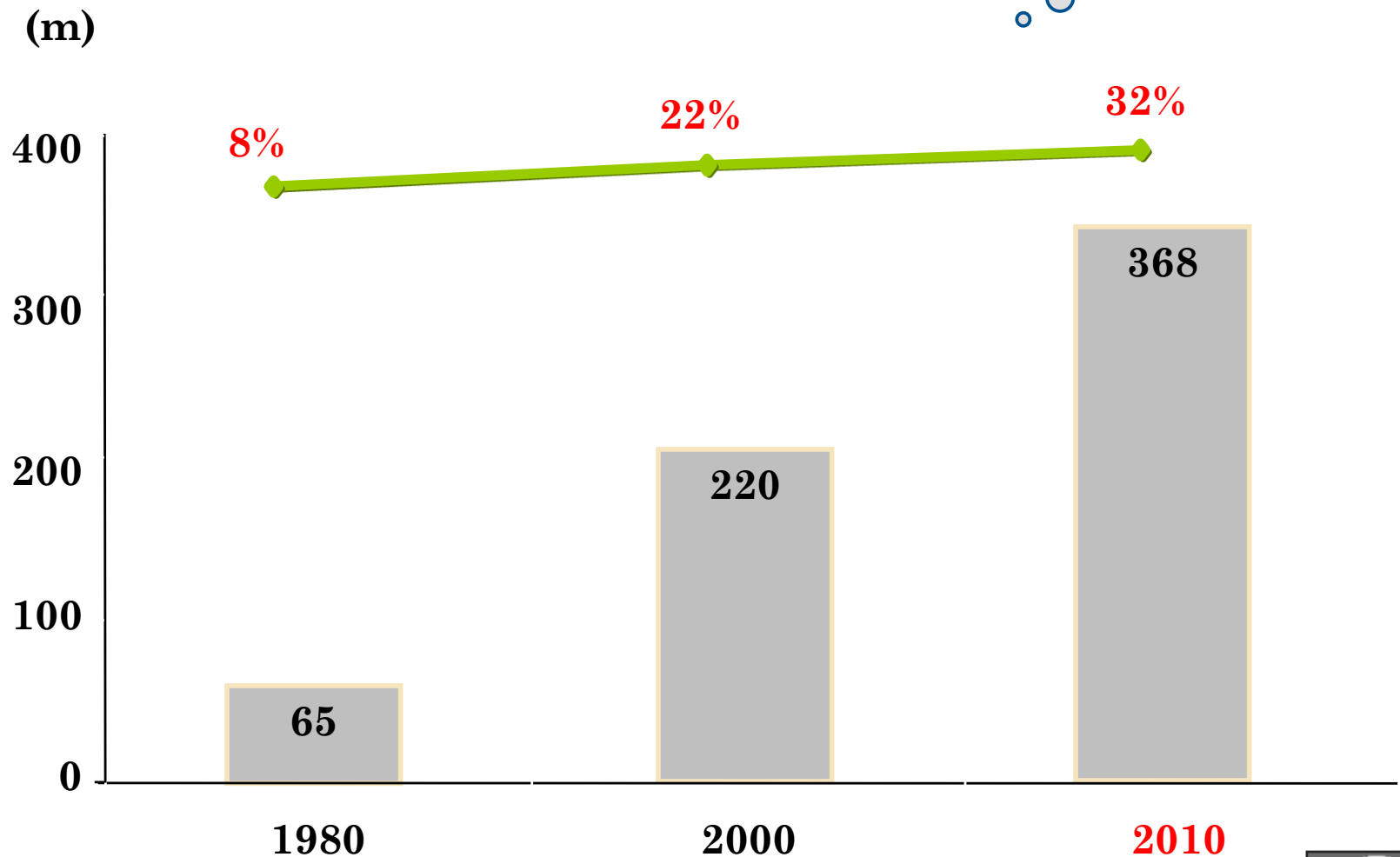


Source: Census of India (2001)



Growing Middle Class Population

India is the
Largest
consumer
base

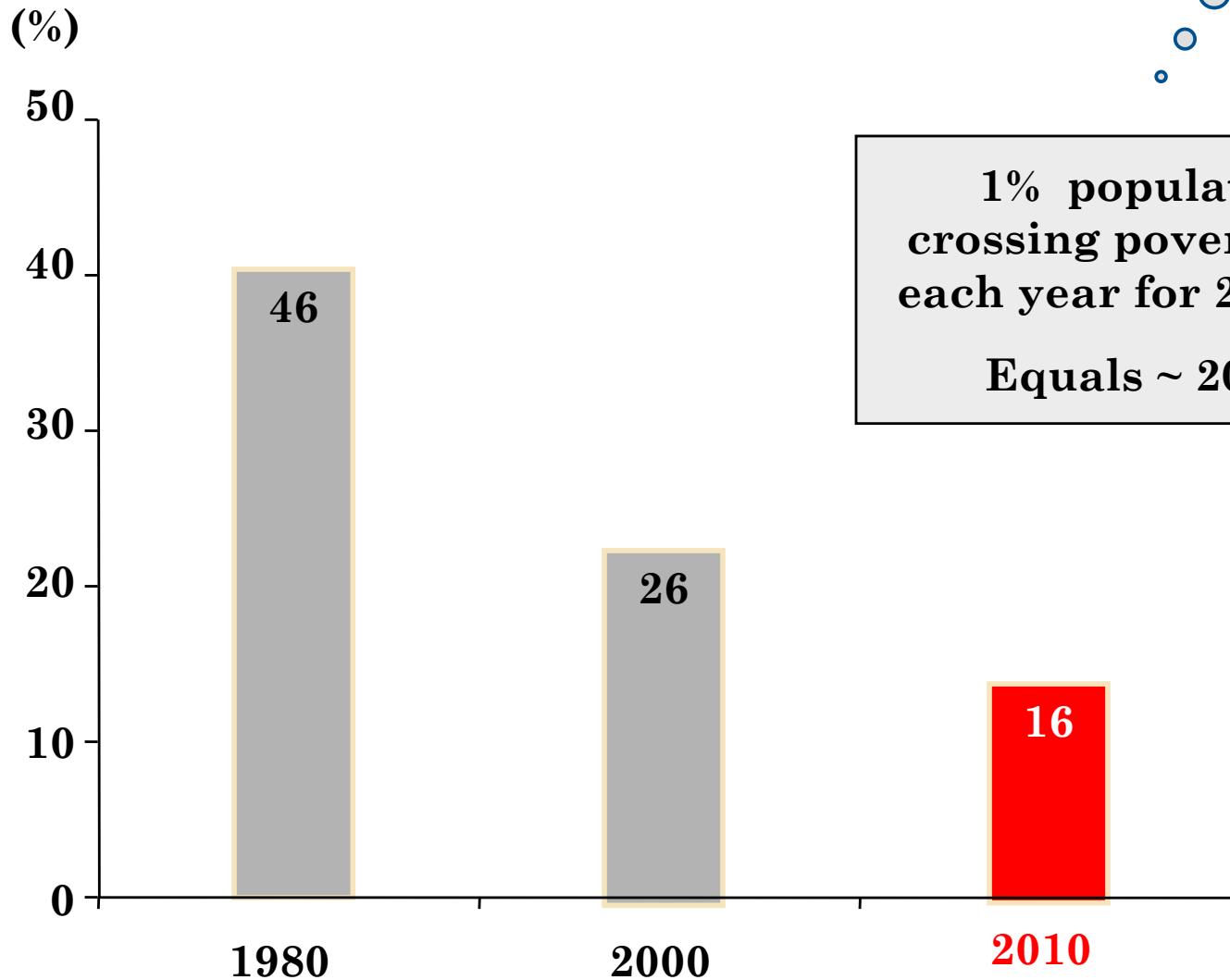


Source: The Consuming Class, National Council of Applied Economic Research, 2002



Poverty is Declining

India is the 4th
Largest
economy

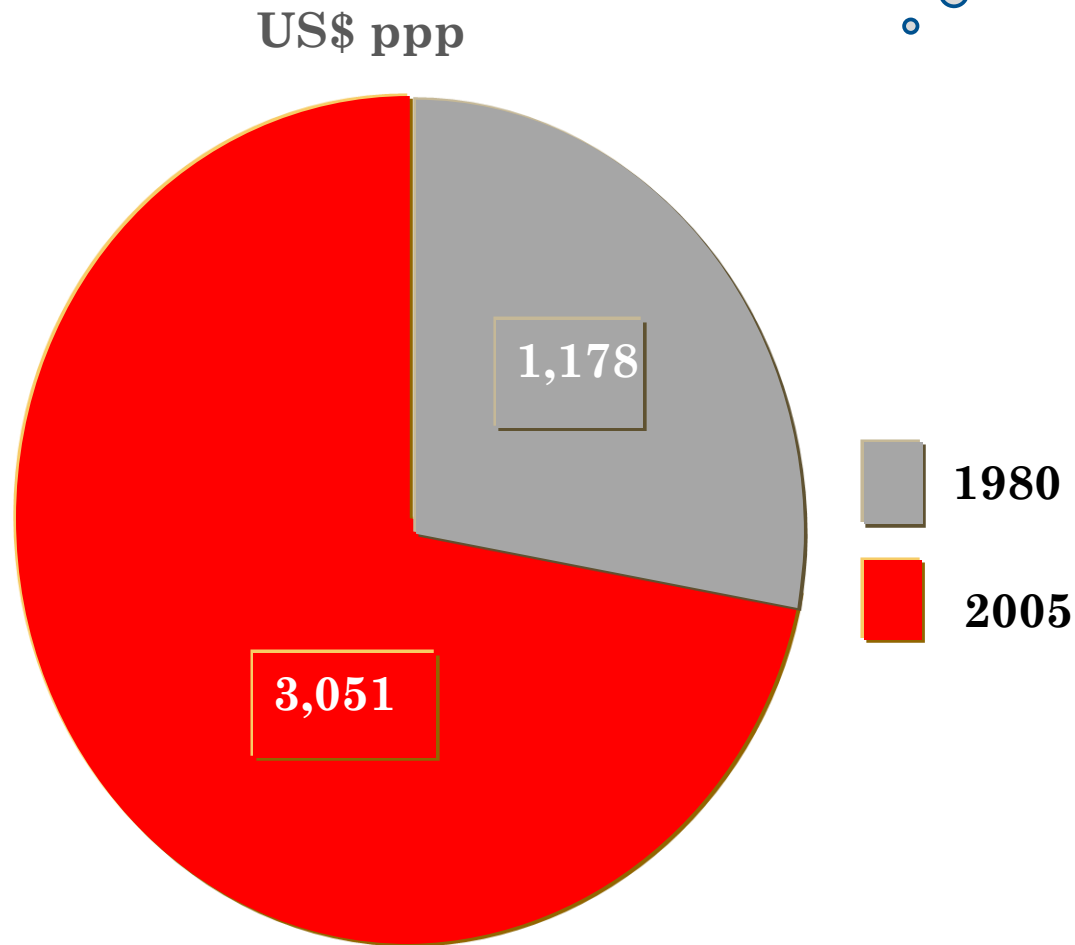


**1% population
crossing poverty line
each year for 25 years
Equals ~ 200m**



Per Capita Income Gains

India
will overtake
Japan by 2014

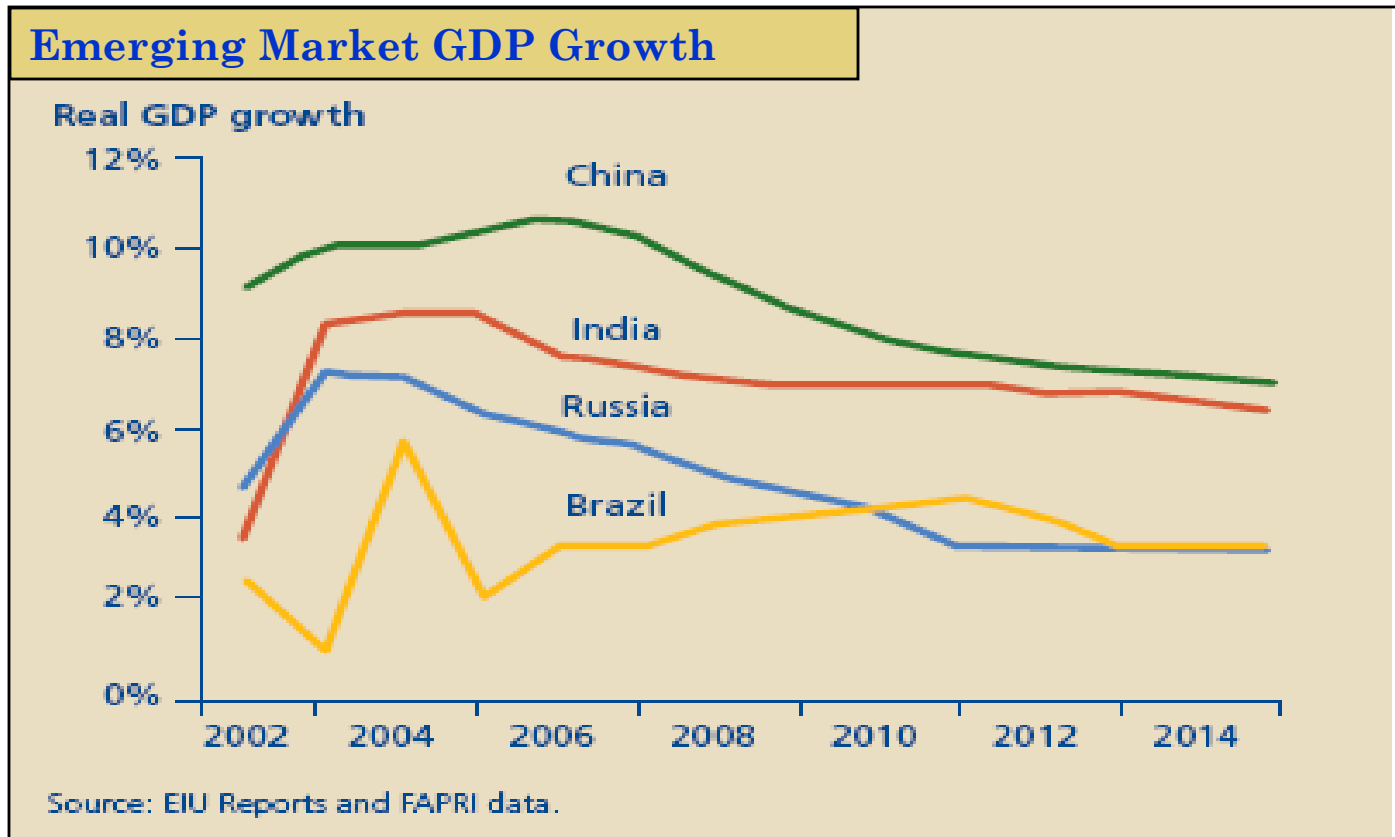


Source: World Bank



India's GDP Growth

India
will overtake
Japan by 2014



Deloitte : Pharmaceutical Market Entry in India

India growing by 6% + despite the current global recession

Indian growth story is still intact



Key Reforms

India
will overtake
Japan by 2014

- ❖ Globalization of economy
- ❖ Dismantling 'license' regime
- ❖ Lowering tariffs / taxes
- ❖ Breaking public sector monopolies
- ❖ Indigenous R&D
- ❖ New IPR Regime



India is Changing Fast

setting the pace for growth and stability...

YESTERDAY

- Slow rate of growth
- Bureaucratic
- Protected
- Small markets
- Under-developed infrastructure
- No Product Patent



TODAY

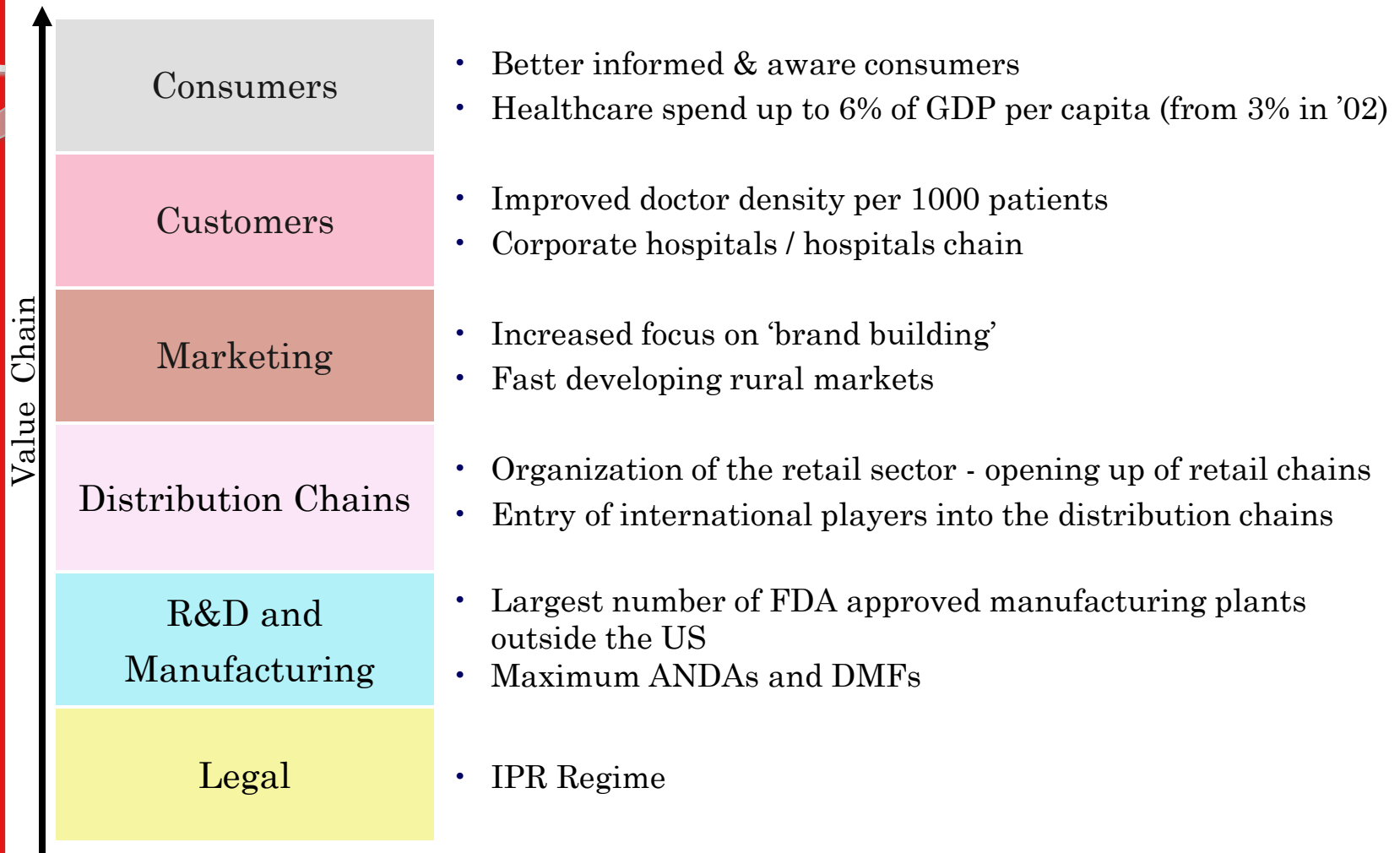
- One of the fastest growing world economies
- Less impacted by financial meltdown
- Significant outsourcing opportunities
- Fast growing markets
- Significant investment in infrastructure creation for industry
- Product patent regime / R&D



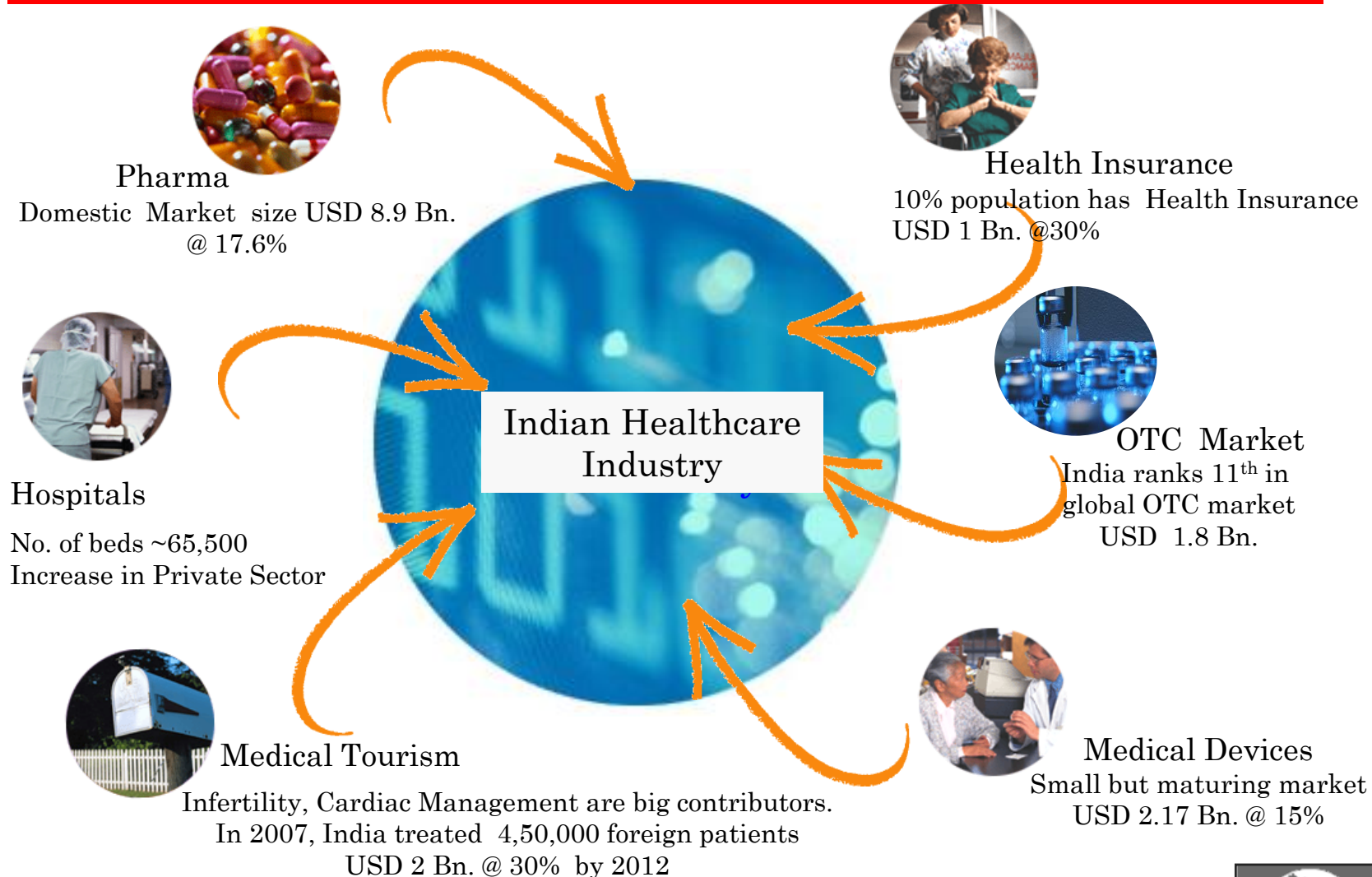
Healthcare and Regulatory Environment



Developments Across the Value Chain



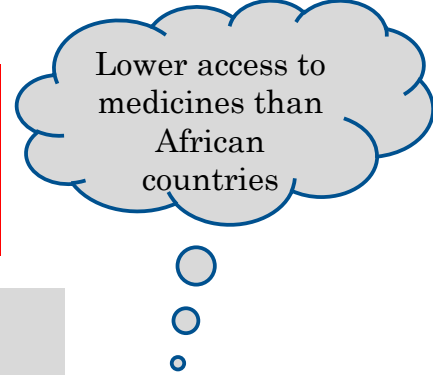
Healthcare Sector Insulated From Global Meltdown....



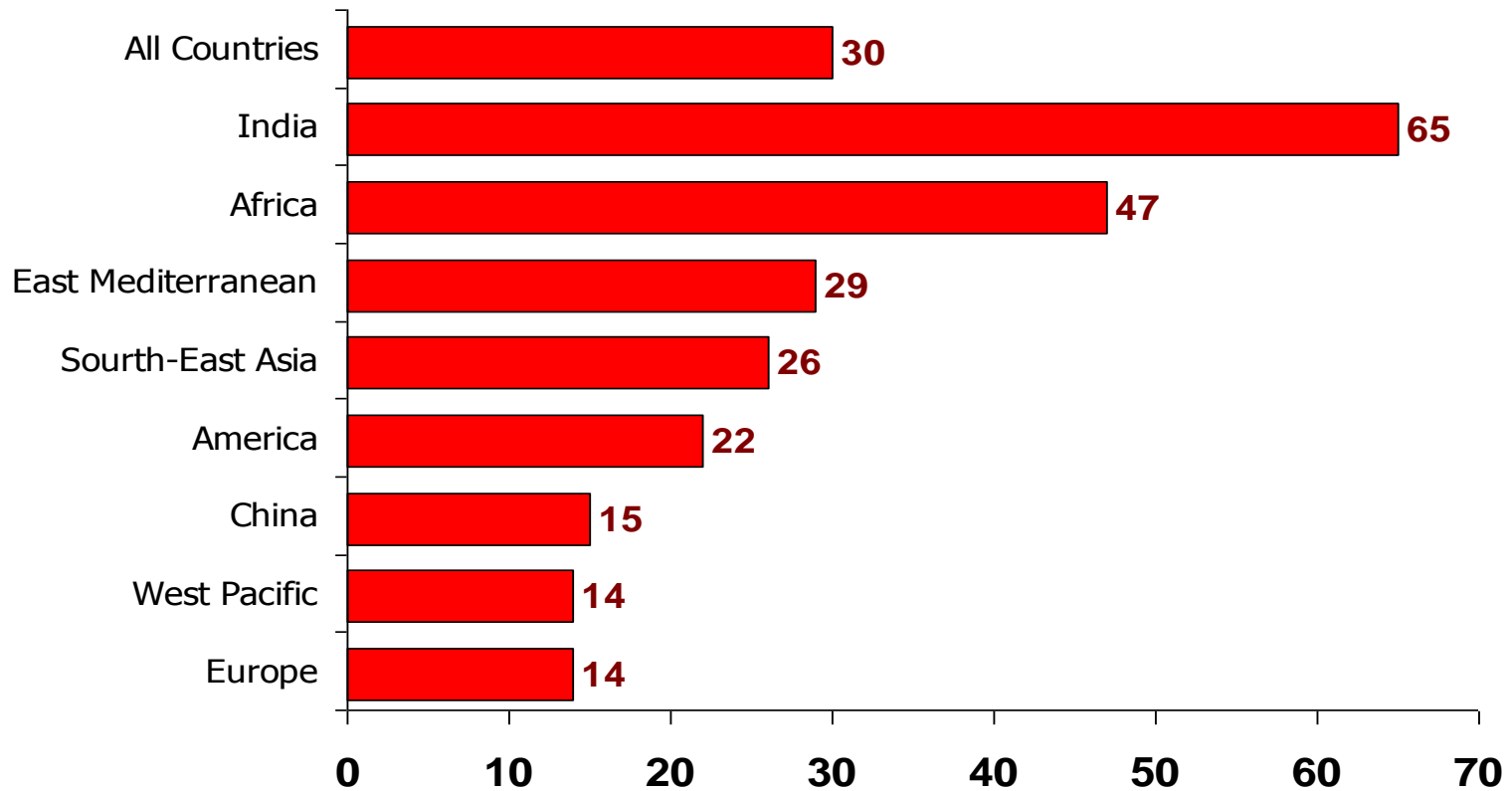
Source: ORG IMS Intelligence, various data sources, IBEF



Access to Healthcare



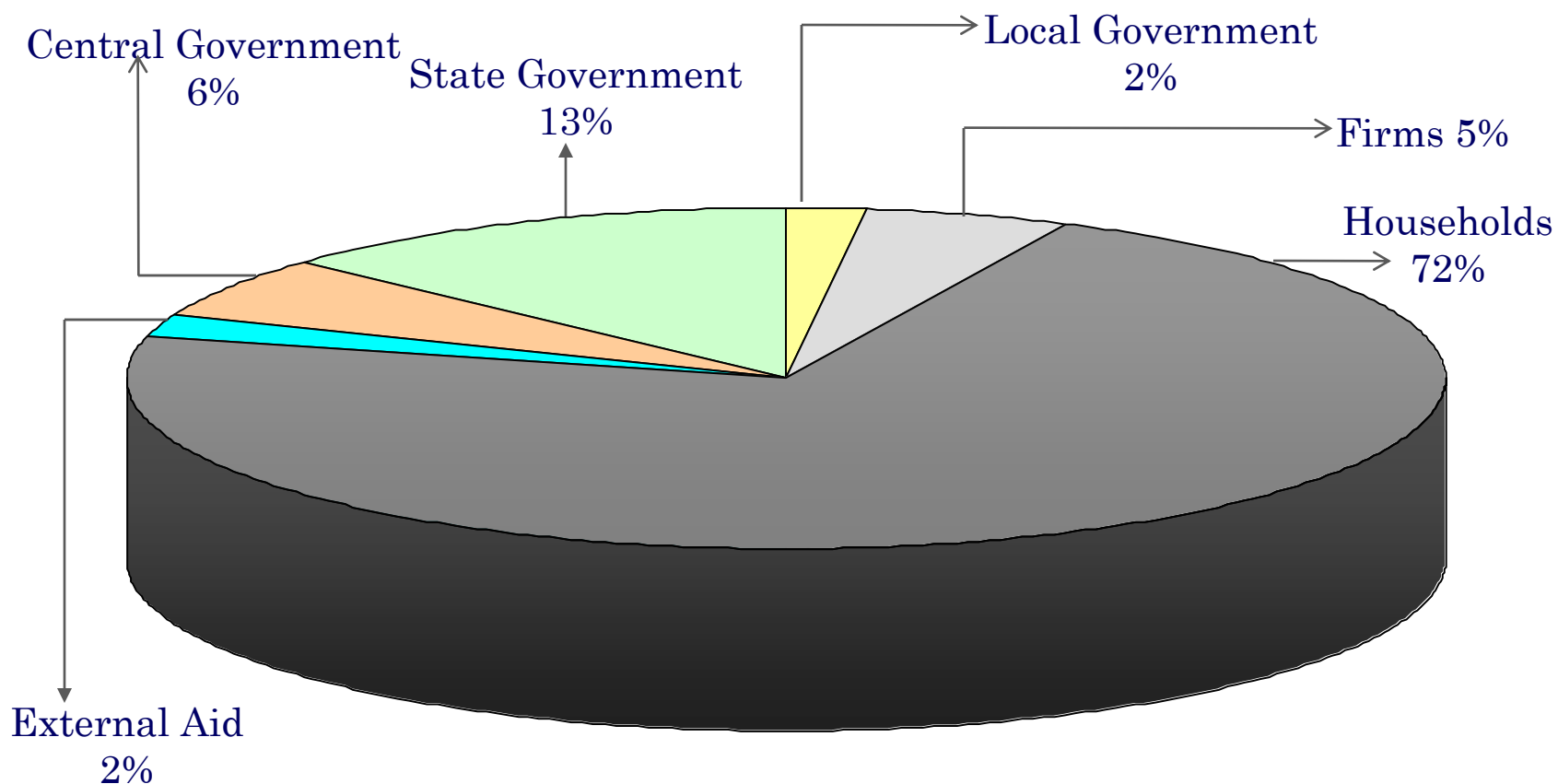
Percentage of WHO regions lacking access to essential medicines



Source: Diseases of Poverty and the 10/90 Gap,
International Policy Network, November 2004



Proportion of Health Expenditure by Financing Source



Source: National Health Accounts – 2001-02, MoHFW, GoI



Government: Changing Role

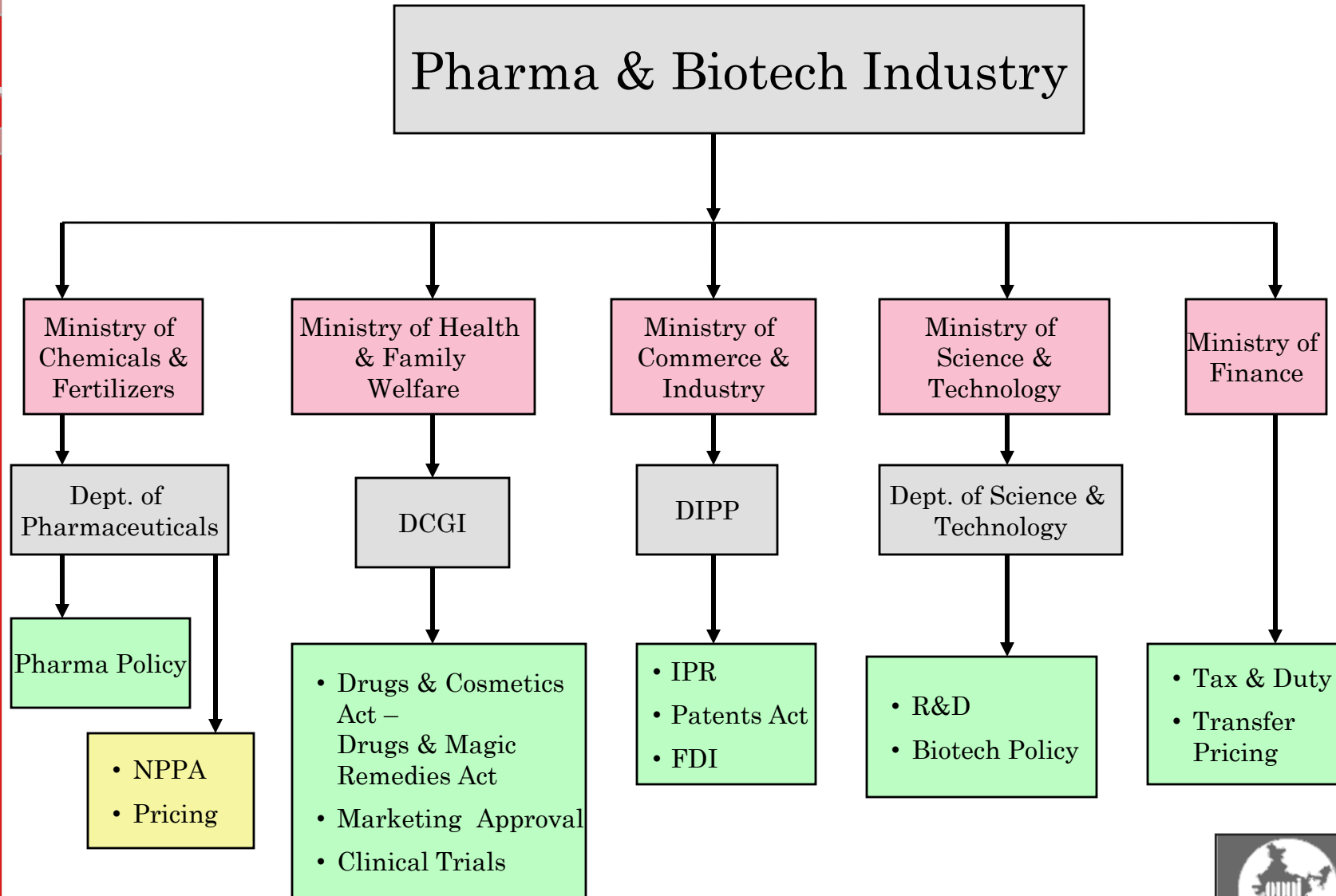
From Healthcare Provider to Healthcare Facilitator

	2002	2012
Private Healthcare Spending (U.S.\$ Bn.)	14.8	33.6

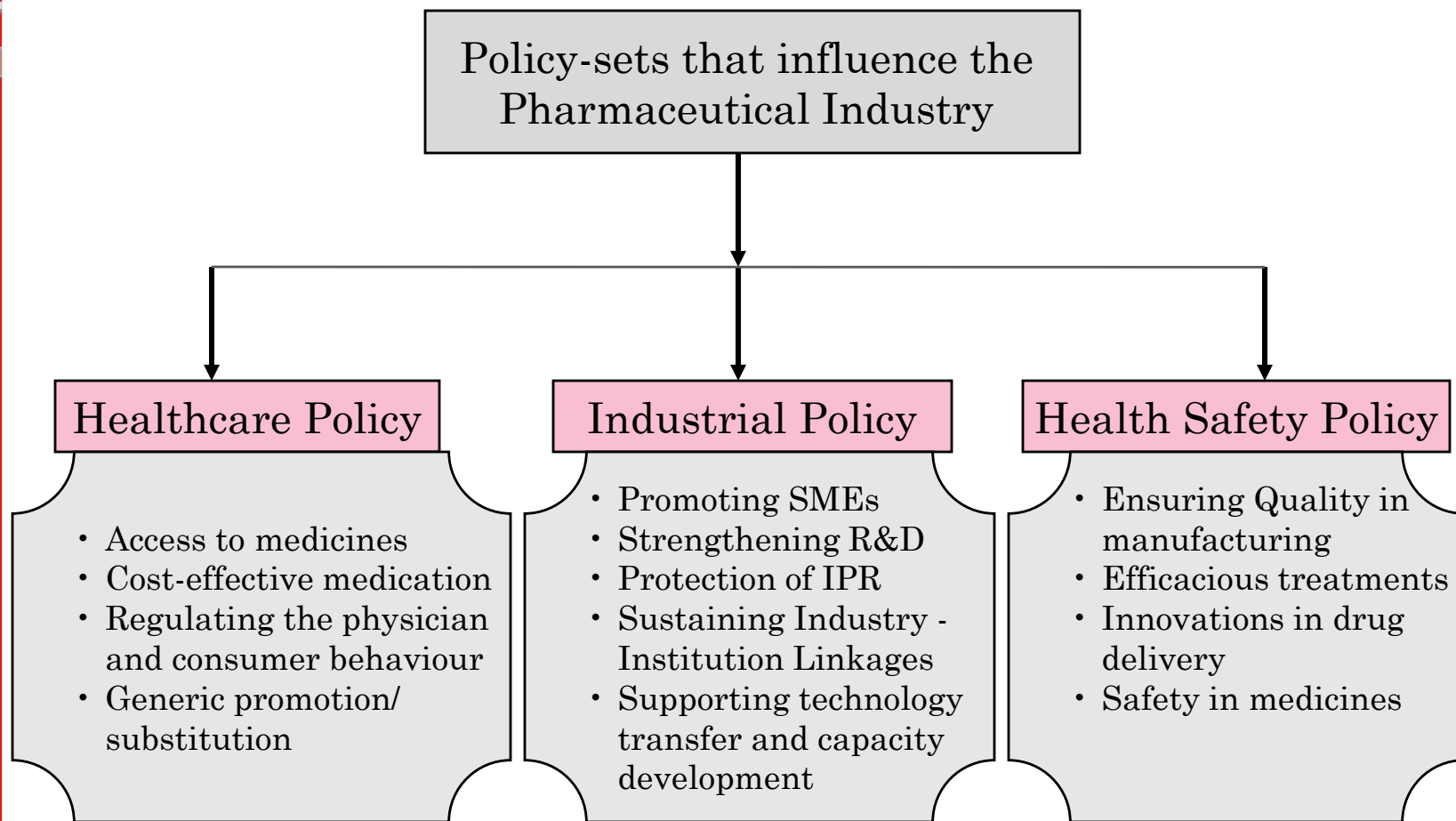
Source: India Trade Promotion Organization (ITPO)



Regulatory Structure



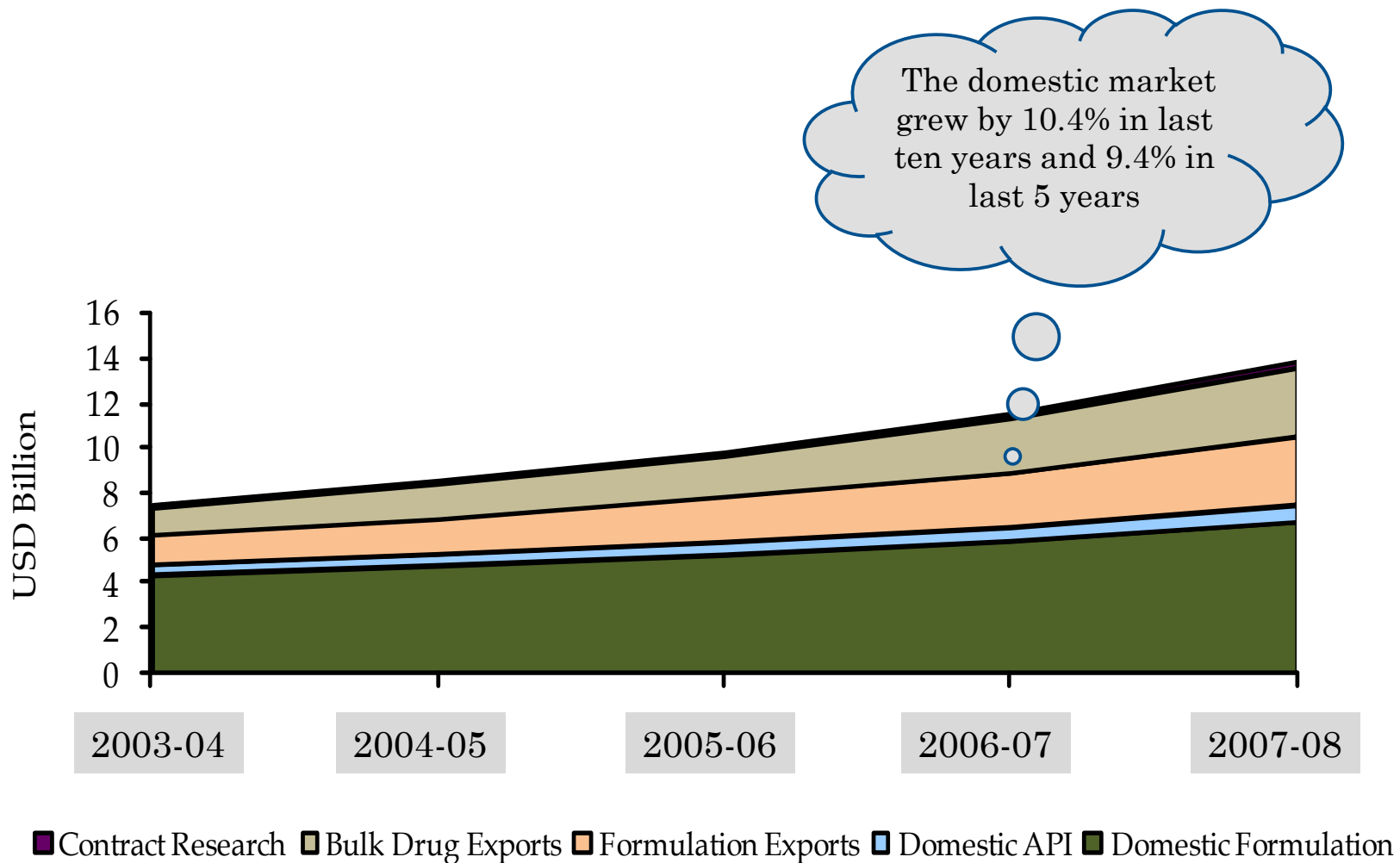
Policy Framework - Indian Pharmaceutical Industry



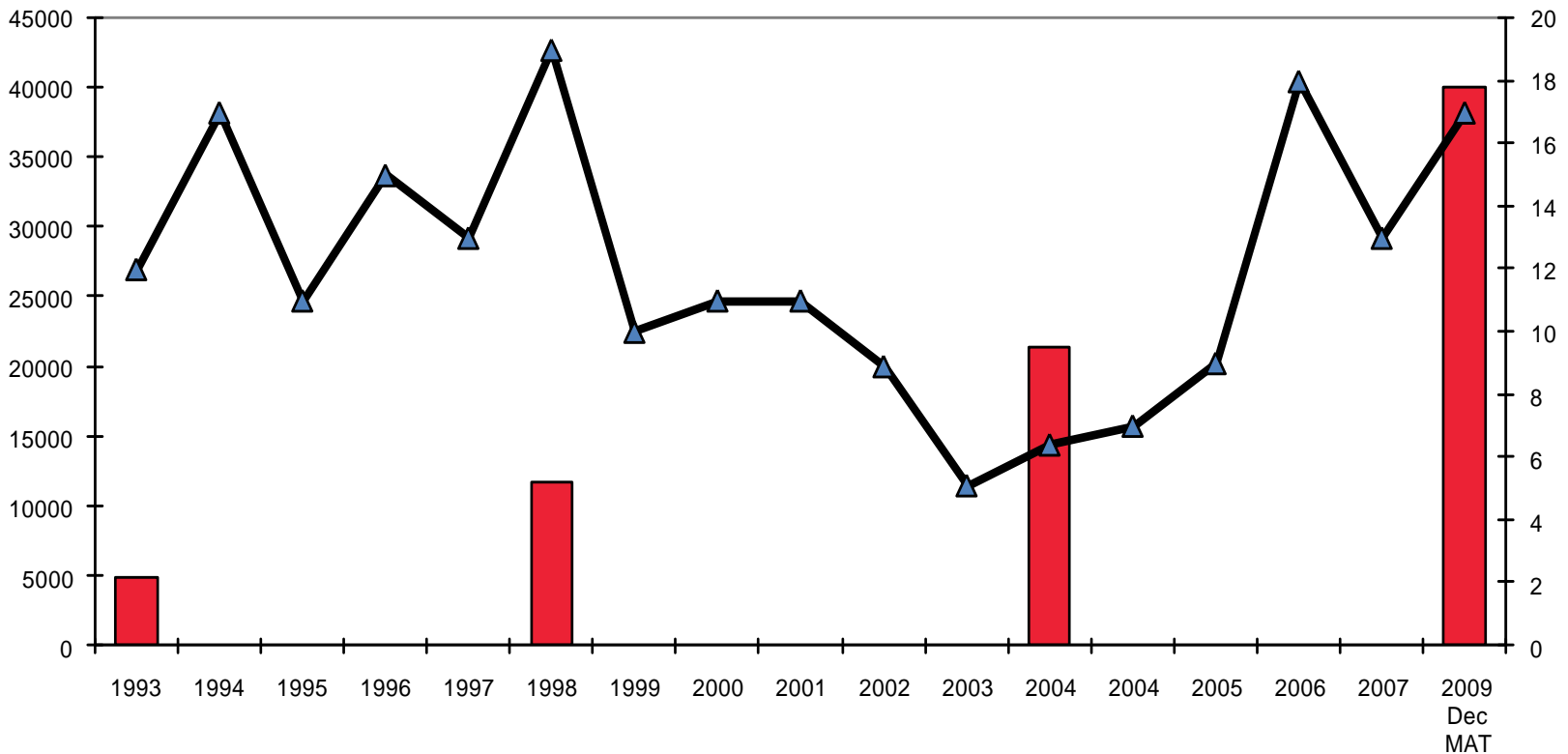
Pharmaceutical Industry



Indian Pharmaceutical Market



Indian Pharmaceutical Industry is doubling every 6 years...



Total retail market size: US \$ 8.9 bn; >23,000 companies; over 60,000 Brands

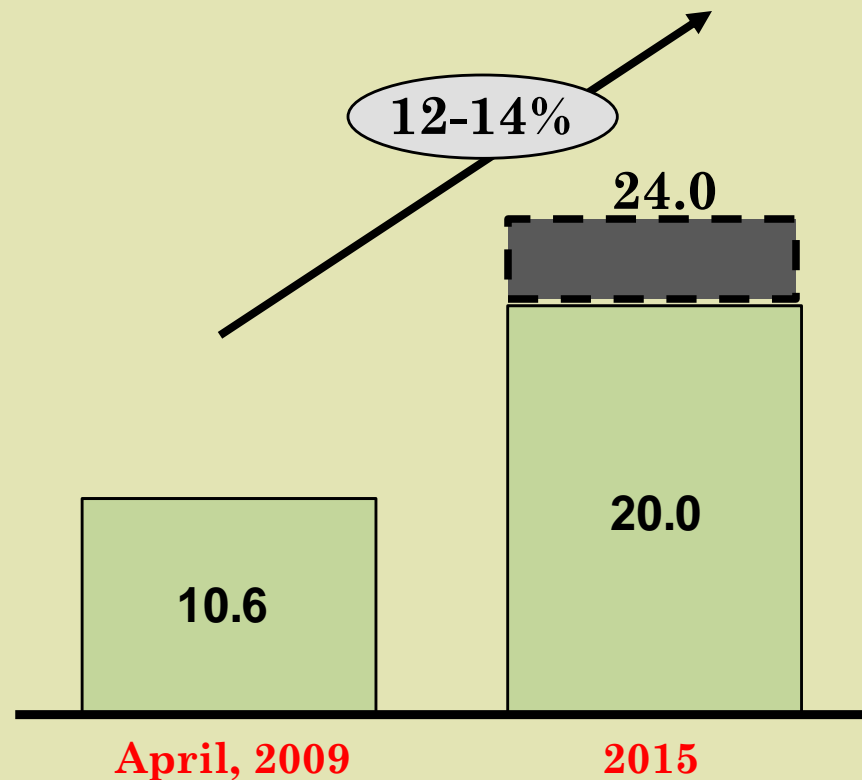


India Pharma Market

Will maintain
healthy growth
momentum

Growth enablers

- ❖ Income growth
- ❖ Growth in medical infrastructure
- ❖ Rising prevalence of chronic diseases
- ❖ Aggressive market creation
- ❖ Rise in insurance coverage

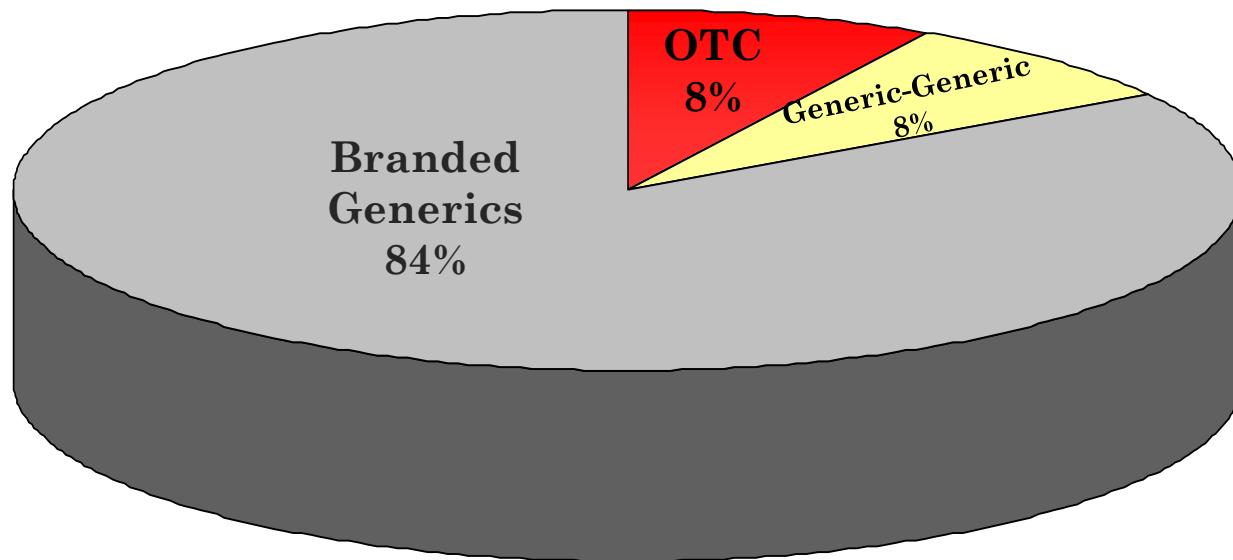


US\$ billion



Key Market Types

Market Size US\$ 8.9 Bn.



Source : IMS Feb. 2010



Market Characteristics



Highly
fragmented
industry

- ❖ USD 8.9 Bn. @ GR 17.6%
- ❖ Over 60,000 Rx Brands; 23,000 Companies
- ❖ Top 10 Companies contribute to 38%
- ❖ Top 300 brands contributing to 33%
- ❖ Top 10 brands contributing to 3.6%

Source : IMS February 2010



Top 10 Pharma Companies

Top 35 Companies
contribute to 75%

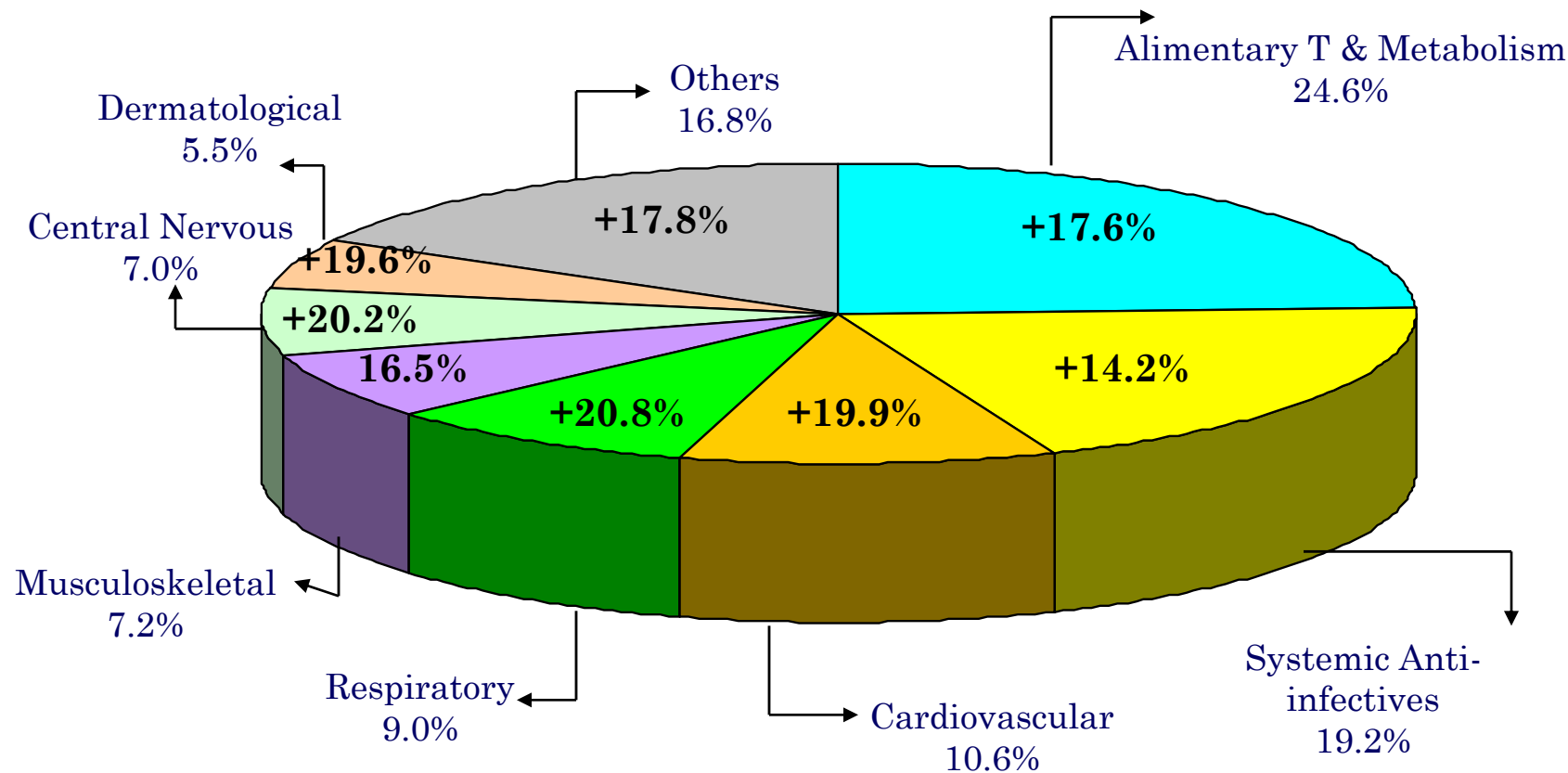
Rank	Company	Sales (USD Mn.)	% M.S.	% Growth	No. of Products
	Market	8939	100.0	17.6	
1	Cipla	482	5.39	18.9	932
2	Ranbaxy	439	4.91	13.0	593
3	GSK	387	4.32	18.2	178
4	Piramal Healthcare	369	4.13	21.4	754
5	Zydus Cadila	334	3.73	22.5	734
6	Sun Pharma	329	3.69	26.0	524
7	Alkem	286	3.20	21.2	657
8	Pfizer	271	3.03	17.3	151
9	Mankind	252	2.82	30.4	456
10	Lupin Labs.	246	2.75	17.9	564

Source: IMS Feb. 2010



Market By Therapy Area

Key Therapeutic Segments



US\$: INR 46

Total Market US\$ 8.9 Bn. (Growth 17.6%)
[13th in value and 4th in volume globally]

*Annual Income >\$ 5000

Source: IMS Feb. 2010



Top 10 Pharma Products

Top 300 brands = 32%,

Top 10 brands = 3.6%

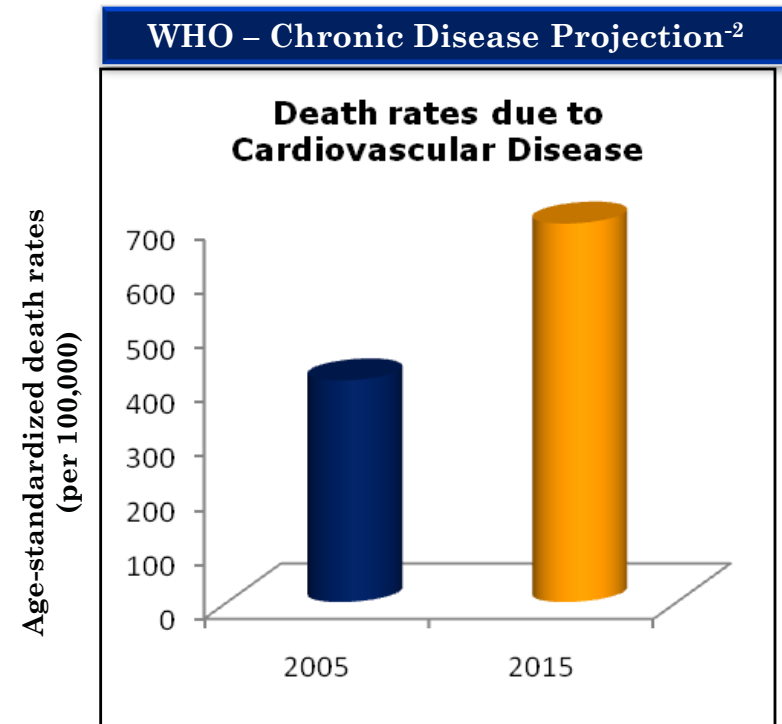
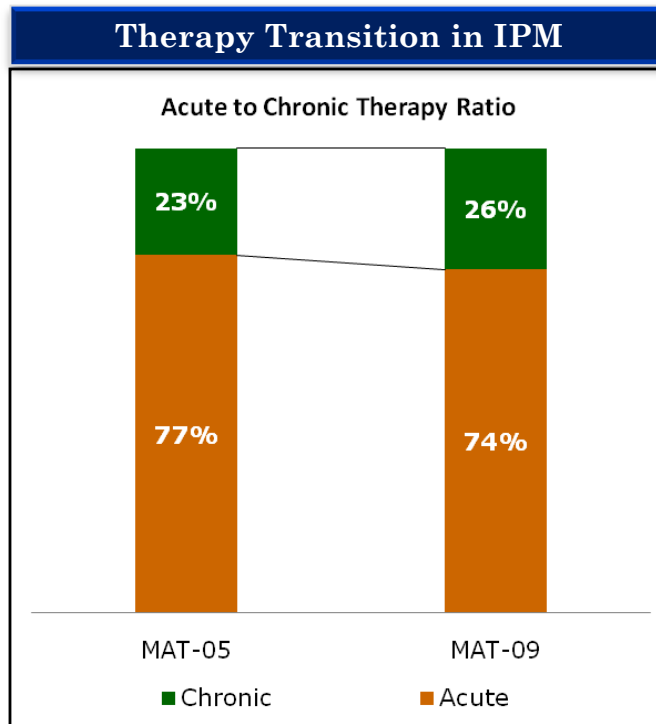
Rank	Products	TG	Company	Value (USD Mn.)	%GR
1	Corex	Cough Preparation	Pfizer	41.02	14.1
2	Phensedyl	Cough Preparation	Piramal Healthcare	37.17	22.6
3	Voveran	NSAID	Novartis	36.73	14.6
4	Augmentin	Amoxy+Clav	GSK	31.63	27.3
5	Human Mixtard 30/70	Insulin	Abbott	30.02	12.4
6	Revital	Nutritional	Ranbaxy	29.39	40.1
7	Zifi	Cephalosporin	FDC	28.43	12.7
8	Monocef	Cephalosporin	Aristo	27.58	23.6
9	Dexorange	Haematinic	Franco Indian	27.49	12.3
10	Taxim	Cephalosporin	Alkem	27.48	7.9

Source: IMS February 2010



Changing Disease Pattern

Increase in life expectancy and rapid urbanization leading to epidemic in chronic diseases



Projected number of Deaths attributed to

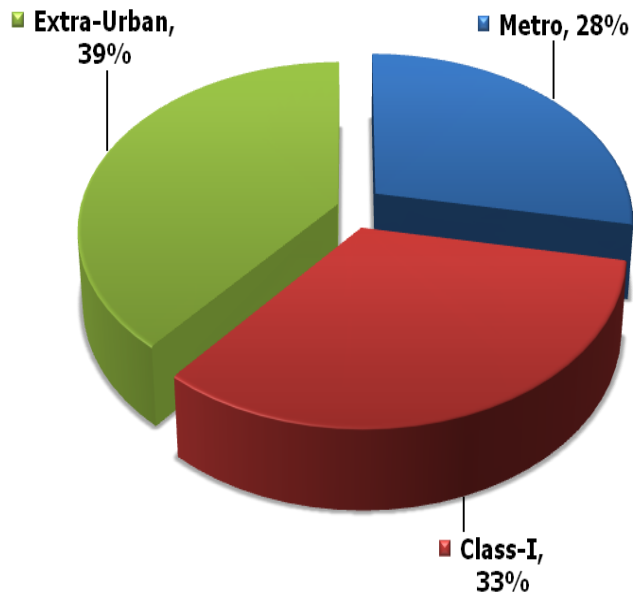
- **Chronic disease 3.78 Mn.** (40.4% to all deaths) in 1999 to **7.63 Mn.** (66.7% of all deaths) in 2020
- Diabetes number up from estimated 19.3 Mn. in 1995 to 57.2 Mn. in 2025



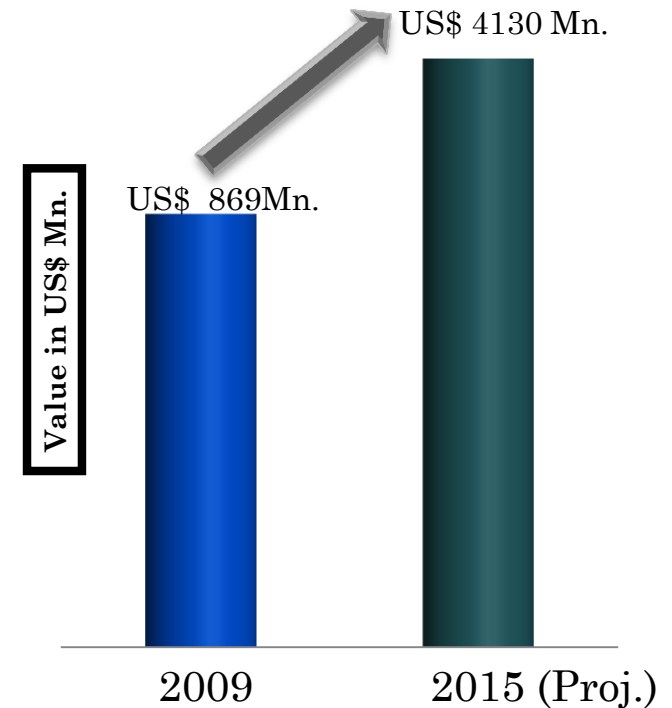
Extra Urban Market

Improved Extra-urban market access would be crucial for the next growth wave

Extra-Urban Market Contribution



Extra-Urban Market Forecast



Source: IMS Plus – March-09 Dataset , IMS Thought Leadership

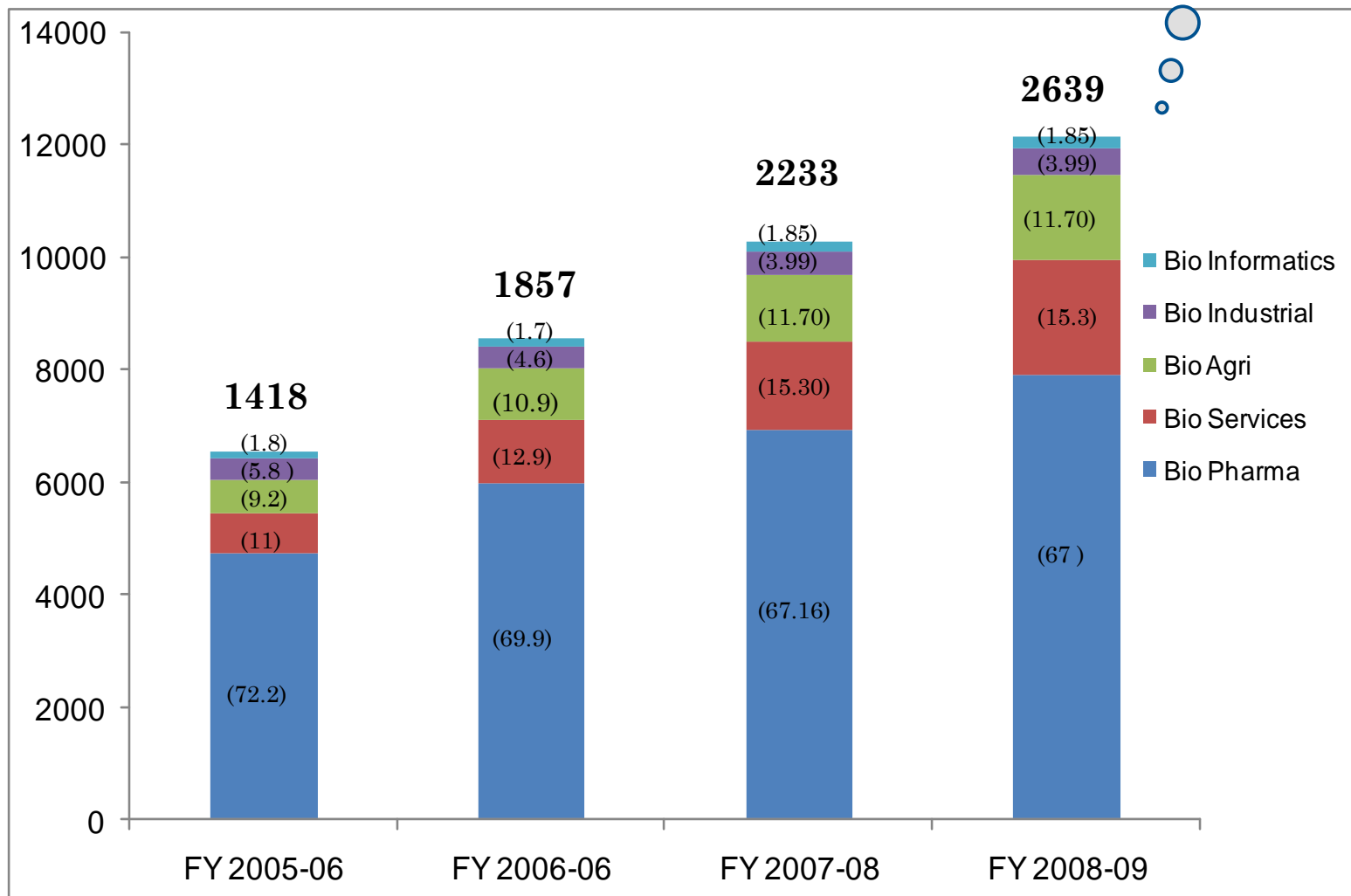


Biotech Industry



Indian Biotech Industry

Biotech growth 18%
Biopharma 67%,
average 14%
growth



USD Mn. (%)

Source: BioSpectrum



Top 10 Indian Biotech Companies

USD Mn.

Rank 2008	Company	2008-09	2007-08	2006-07	2005-06	2004-05	% Change over 2007-08
1.	Serum Institute of India	24.22	21.46	20.67	15.28	10.98	12.87
2.	Biocon	19.83	19.07	18.46	14.98	14.37	4.04
3.	Panacea Biotech	12.98	14.74	15.24	9.52	4.72	-11.98
4.	Rasi Seeds	8.17	6.37	7.24	6.71	1.89	28.07
5.	Nuziveedu Seeds	7.91	6.35	4.91	1.37	-	24.69
6.	Novo Nordisk	7.17	5.65	4.82	3.80	3.04	26.92
7.	Siro Clinpharm	6.09	-	-	-	-	-
8.	Novozymes South Asia	5.43	4.89	2.17	1.80	1.50	11.11
9.	Shantha Biotech	5.37	3.26	2.50	1.78	1.46	64.67
10.	Jubilant	5.26	3.46	-	-	-	52.20

Source: BioSpectrum



R&D



R&D Trends

Innovation
through R&D is
the life blood of
Pharma Industry

- ❖ Move from process to basic research
- ❖ Exploit human resource pool
- ❖ Tie up with MNCs for collaboration or out licensing
- ❖ Recent times – NCEs and NDDS
- ❖ Leverage cost advantage
- ❖ The Government in the 11th year plan estimates industrial R&D spend to be 5% of turnover



R&D

– Indian Pharma Companies

Innovation
through R&D is
the life blood of
Pharma
Industry

Company	NCE Pipeline	Key Therapeutic Area
Biocon	Preclinical – 2 Phase II – 2 Phase III – 1	Inflammatory Diseases, Oncology, Diabetes
Piramal Healthcare	13 Compounds in Clinical Trials	Oncology, Infectious Diseases, Diabetes, Inflammatory Diseases,
Glenmark	Discovery – 4 Preclinical – 5 Phase I – 1 Phase II – 3	Metabolic Disorders, Dermatology, Inflammatory Diseases
Ranbaxy	Preclinical – 4-6 Molecules Phase II – 1	Metabolic Diseases, Infectious Diseases, Respiratory Diseases, Oncology
Suven Life Sciences	Discovery – 2 Preclinical – 4 Phase I – 1	Neurodegenerative Diseases, Obesity, Diabetes, Inflammatory Diseases

Source: March 23, 2009, Financial Express



R&D

– Indian Pharma Companies

Innovation
through R&D is
the life blood of
Pharma
Industry

Company	NCE Pipeline	Key Therapeutic Area
Dr Reddy's Lab	Pre-clinical – 1 Phase II – 2 Phase III – 1	Metabolic Disorders, Cardiac, Oncology
Advinus	Pre-clinical – 3	Diabetes, Cardiac, Lipid Disorders
Wockhardt	Preclinical – 10 Phase II – 1	Infectious Diseases,
Lupin	Discovery – 2 Pre-clinical – 1	Migraine, Psoriasis, T.B.
Sun Pharma	Discovery – 2 NDDS – 1	Allergy, Muscle Relaxant,, Inflammatory Diseases, Pain Management



R & D Spend by Indian Pharma Companies

Innovation through R&D is the life blood of Pharma Industry

	FY 2009		
Company	Sales USD Mn.	R&D USD Mn.	As % of Sales
Ranbaxy Laboratories	161.00	9.03	5.6
Dr. Reddy's Laboratories	157.26	8.36	5.3
Cipla	115.16	5.12	4.4
Sun Pharmaceuticals	95.11	6.74	7.1
Lupin	84.75	4.84	5.7
Wockhardt	76.99	1.12	1.4
Piramal Health Care	72.06	1.85	2.6
Cadila Health Care	64.40	3.44	5.3
Aurobindo Pharma	55.72	2.45	4.4
Matrix Laboratories	49.99	4.65	9.3
Total	932.44	47.60	5.1

Source: Prowess
Business World February 8, 2010



Clinical Trials

Far low operating cost

Phase Study	US (\$. Mn)	India
I	20	< 50%
II	50	< 60%
III	100	< 60%

Hiring investigators, nurses, computer staff and recruiting patients (50% of US cost)



R&D

– Indian Pharma Companies

Innovation
through R&D is
the life blood of
Pharma
Industry

Specialities	2001	2008	Comments
R&D Exp. as a % of sales	1.4%	9.9% ↑	7 times
R&D Exp. in absolute terms	55	660 ↑	12 times

Source: Ernst & Young analysis of top 25 pharmaceutical companies operating in India



Indian Players Building Global Assets

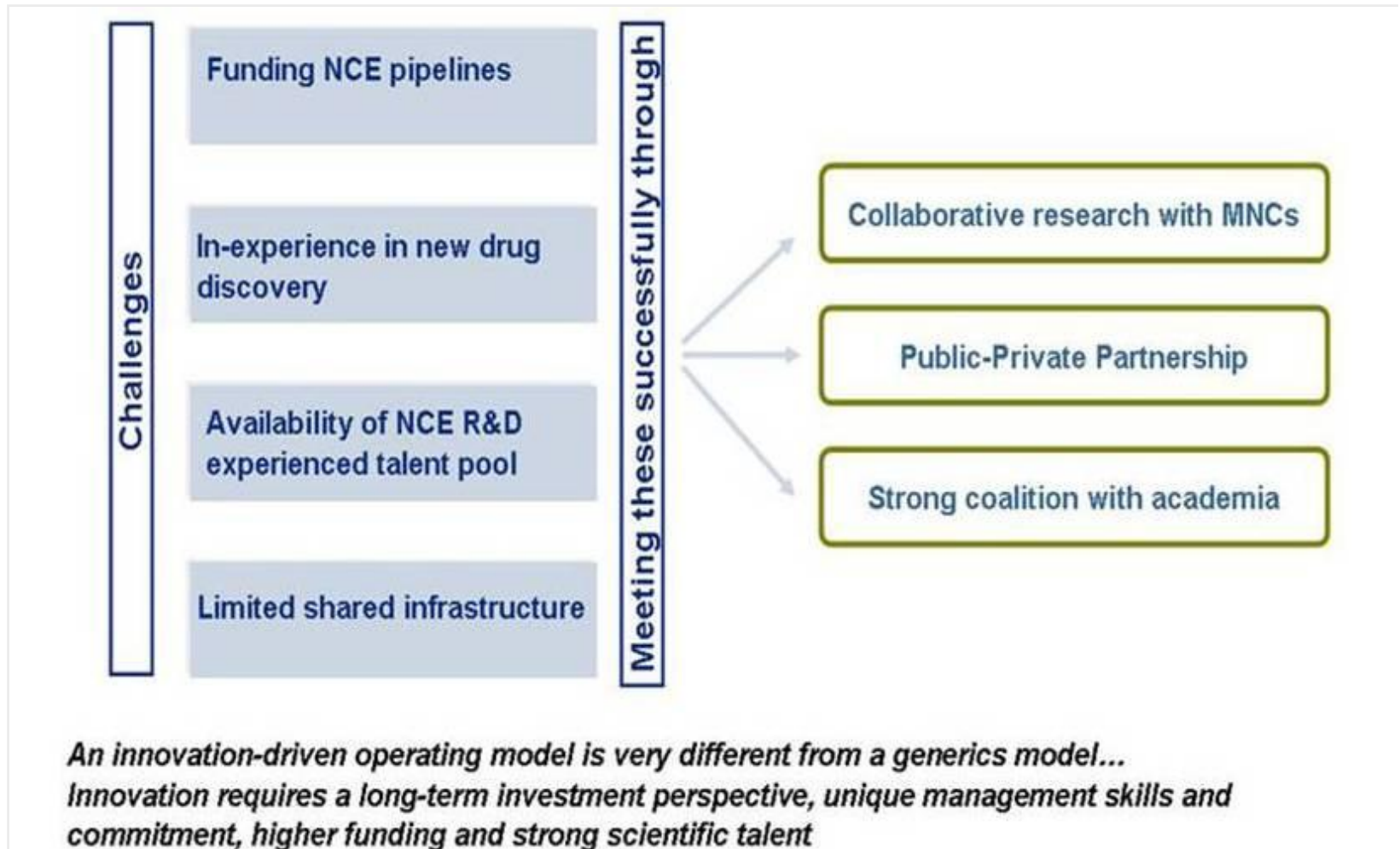
Innovation through R&D is the life blood of Pharma Industry

Indian Player	Acquisitions / Expansion	Geographies
Biocon	30% stake in IATRICa	US
	Nobex Corporation	US
Dishman	Carbogen and Amcis	Switzerland
Jubilant	Target Research Associates	US
Kemwell	Pfizer's Site in Uppsala	Sweden
Piramal Healthcare Ltd.	Avecia Ltd.	Billingham, UK
		Torcan (Canada)
	Pfizer's facility in Morpeth	Grangemouth (Scotland)
		Morpeth, UK
Shasun	Rhodia (Pharmaceutical custom synthesis business)	France

Source : Ernst & Young Research and Analysis



New Drug Discovery and Biopharmaceuticals



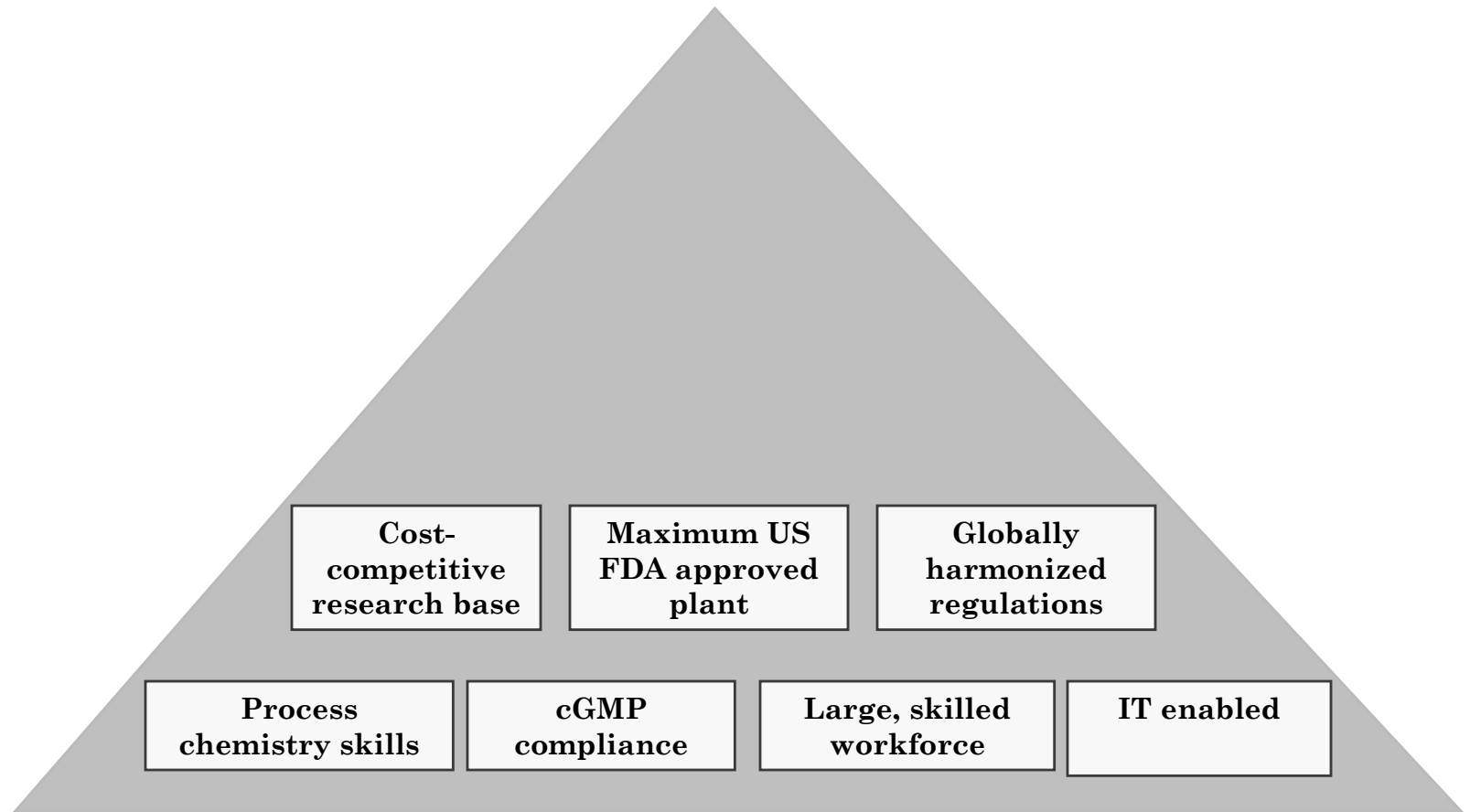
Source: Pharma Summit Report 2009



Outsourcing Opportunities

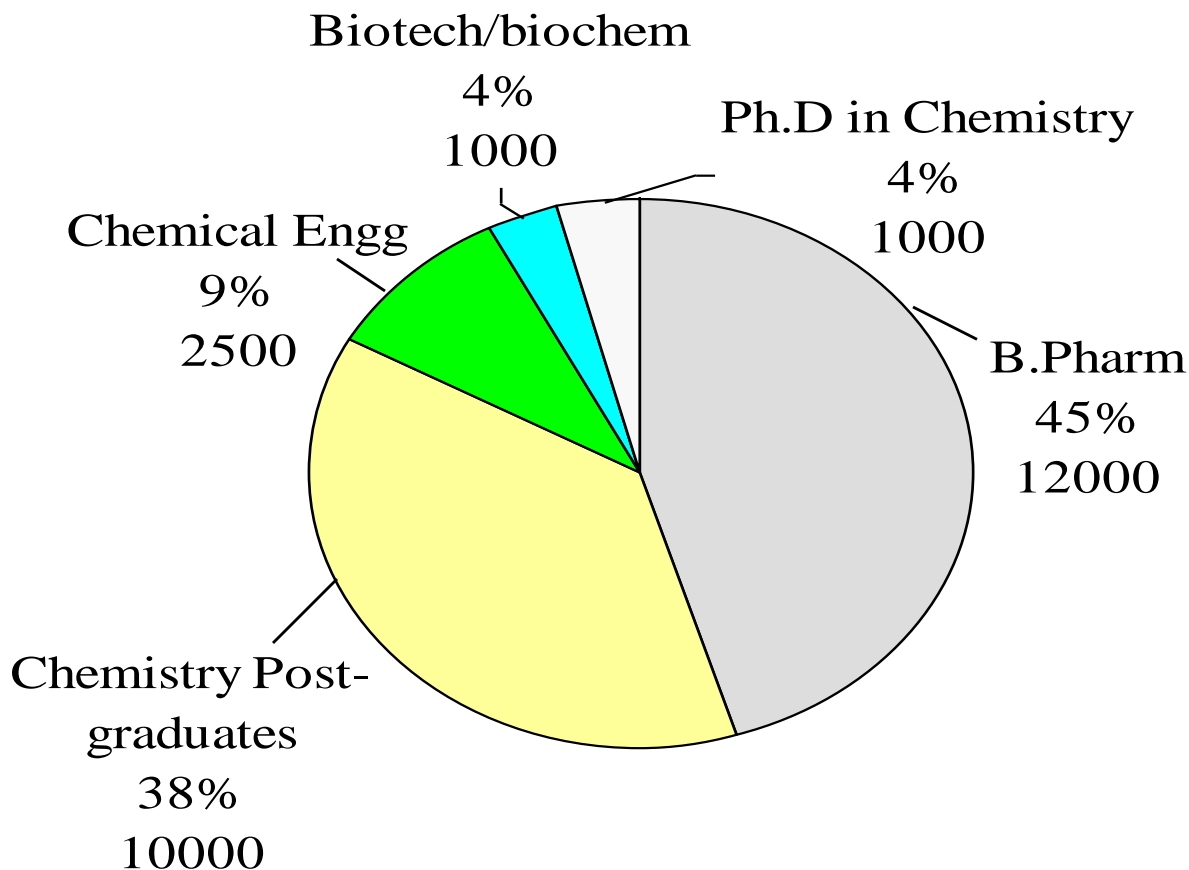


Outsourcing Opportunities



Highly Skilled Manpower

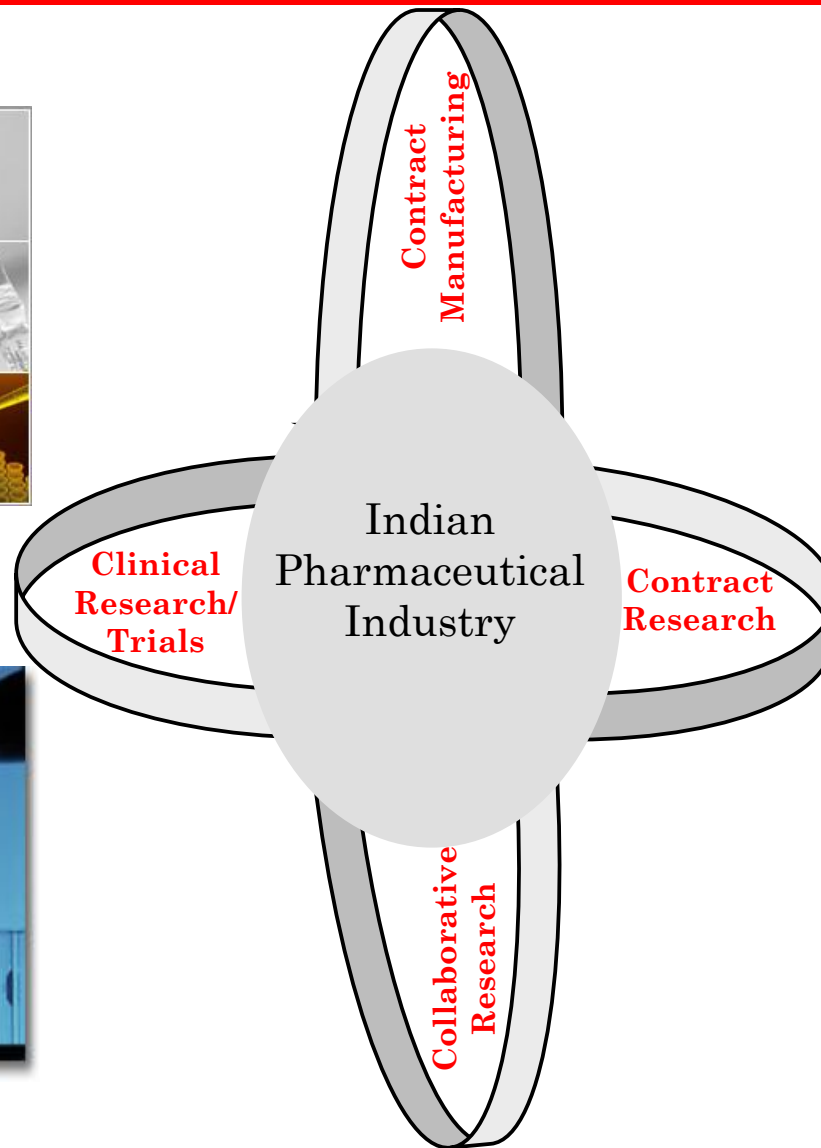
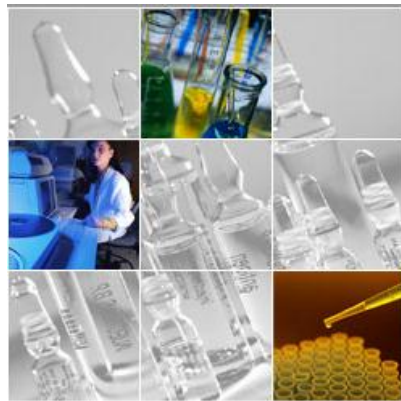
Annual Graduates



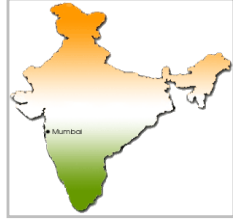
Source: Grant Thornton



Key Opportunity Segments

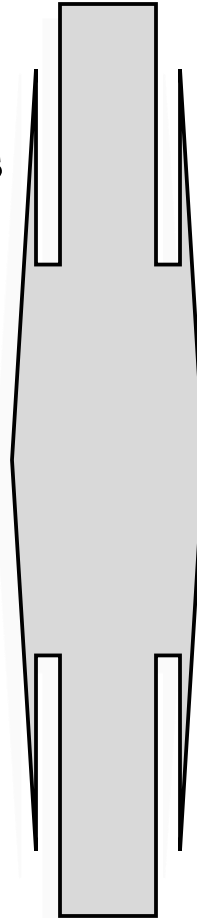


INDIA....The Twin Opportunity



India as a Market

- ❖ Significant unmet needs
- ❖ 20 Bn. USD by 2015
- ❖ One of the Top 10 markets by 2015
- ❖ Top 3 in growth opportunity



India as a Service Provider

- ❖ Resources
- ❖ Competence
- ❖ Cost Arbitrage
- ❖ Experience
- ❖ Young population
- ❖ Growing economy
- ❖ Pharmaceutical expertise
- ❖ Democratic set up
- ❖ IP Protection



India Well-Positioned for New Opportunities

Clinical research

- Most common and important diseases
- Large pool of treatment-naïve patients
- Rapid patient recruitment

Genomic research

- Many isolated populations, varied lifestyles, genetic endowments and numbers
- Large endogamous families for disease linked gene analyses
- Availability of DNA samples from closely and distantly-related sufferers of a disease



Regulatory Requirements

For all 'New drugs'

- ❖ Clinical trial approval
- ❖ Import license
- ❖ Export license
- ❖ Safety reporting
- ❖ Annual report

Regulatory body	Approval	Time
Drug controller general of India (DCGI)	Regulatory approval for study conduct in India	12 weeks
Ethics Committees	Ethics committee approval for study initiation	4-6 weeks (parallel)
Directorate general of foreign trade (DGFT)	Permission to import test supplies	2 weeks
TOTAL	Initiation of clinical trial in India	14 weeks

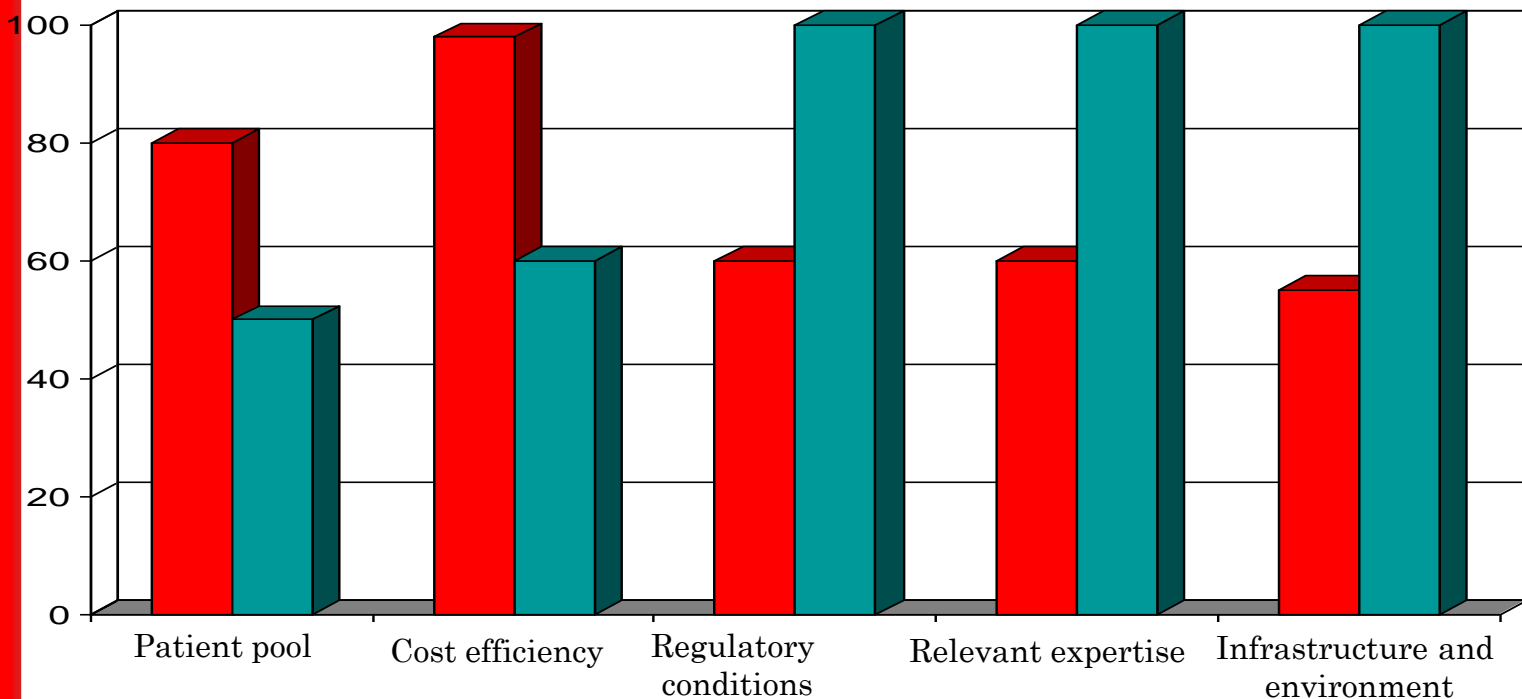


Overall Country Attractiveness Index *alternative clinical trial destinations*

India
tops
the list

■ India (O.C.A.I – 5.58)

■ USA (O.C.A.I – 6.88)



scale 1-10

Source: PharmaExec.



Drivers & Barriers



Drivers & Barriers

Will maintain
healthy growth
momentum

DRIVERS

- Income Growth
- Expanding Healthcare Infrastructure
- Increasing Health Awareness
- 368 Mn. strong Middle Class
- 90 Mn. estimated to be able to afford the best medicines
- Penetration of Health Insurance

BARRIERS

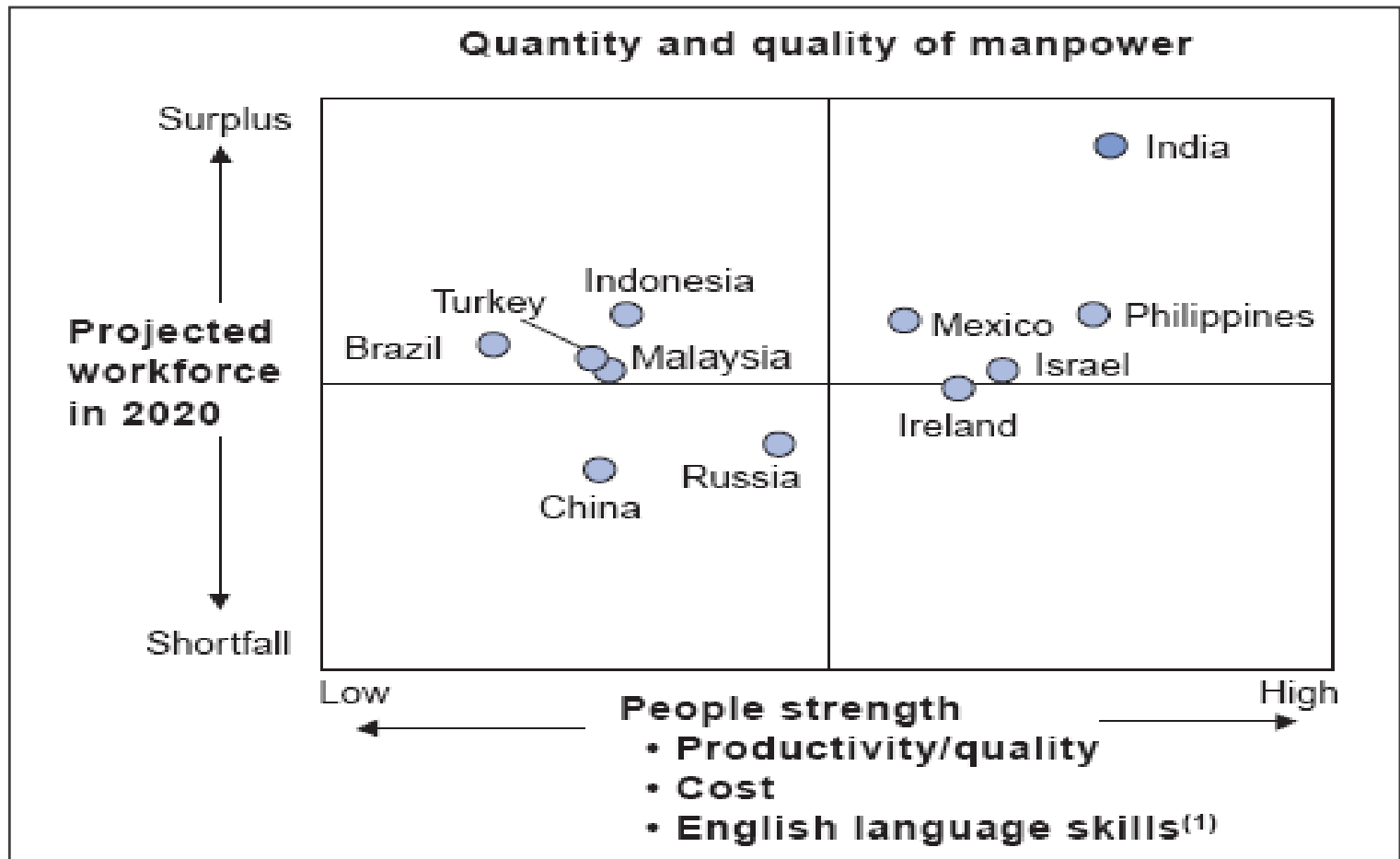
- DPCO
- IPR related issues
- Access to Modern Medicines
- Long pending Regulatory Reform



Advantage India



Advantage India



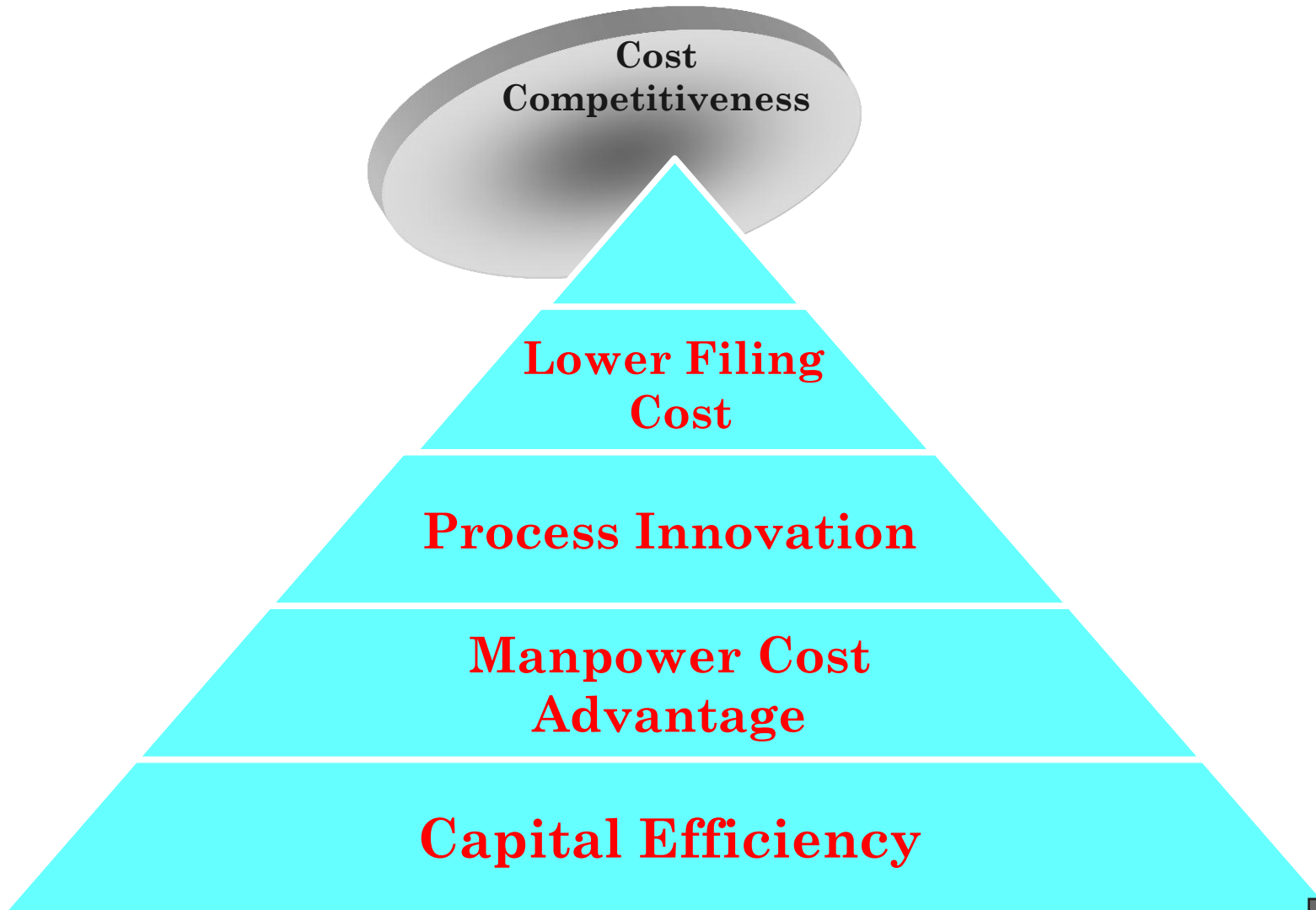
(1) Over 50% of shortages expected from English-speaking countries

Note: Pakistan, Bangladesh and Vietnam have not been represented for lack of reliable data on productivity and cost of service employees

Source: World Competitiveness Yearbook 2001; Britannica Yearbook; Literature search; BCG analysis



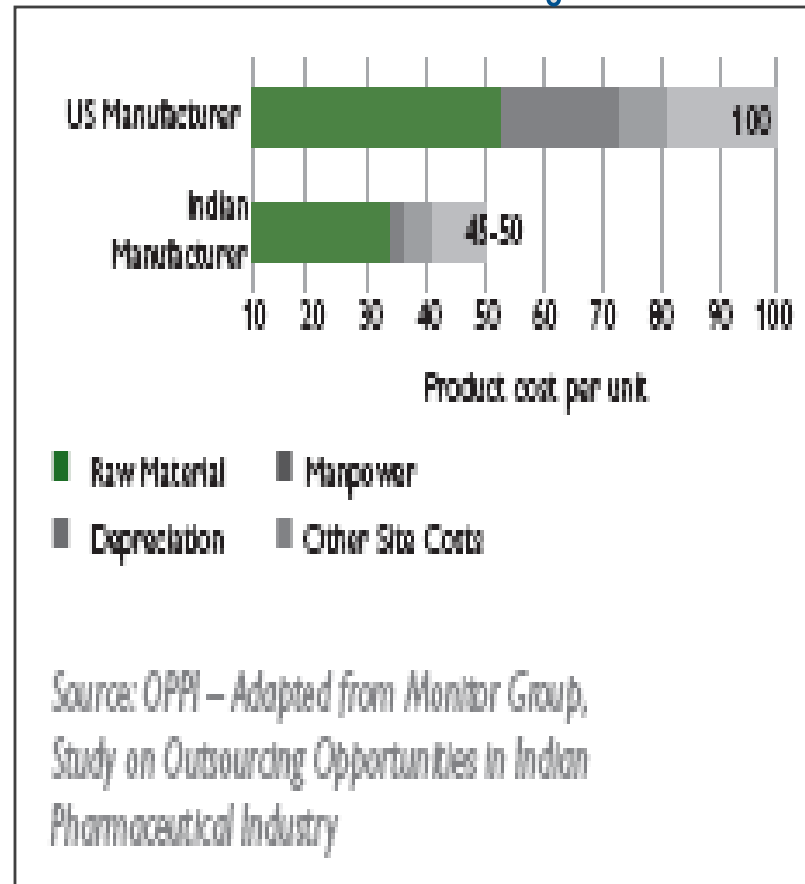
Cost-Competitiveness



Significant Cost Arbitrage

Production cost in
India 50% lower
than US

- ❖ FDA approved plans can be constructed in India for 30 % to 50 % lower cost
- ❖ Higher utilization of equipment due to improved process
- ❖ 85% to 90% manpower cost savings
- ❖ Labor costs 10% to 15% of US cost
- ❖ Increased efficiency contributes to low labor costs per unit

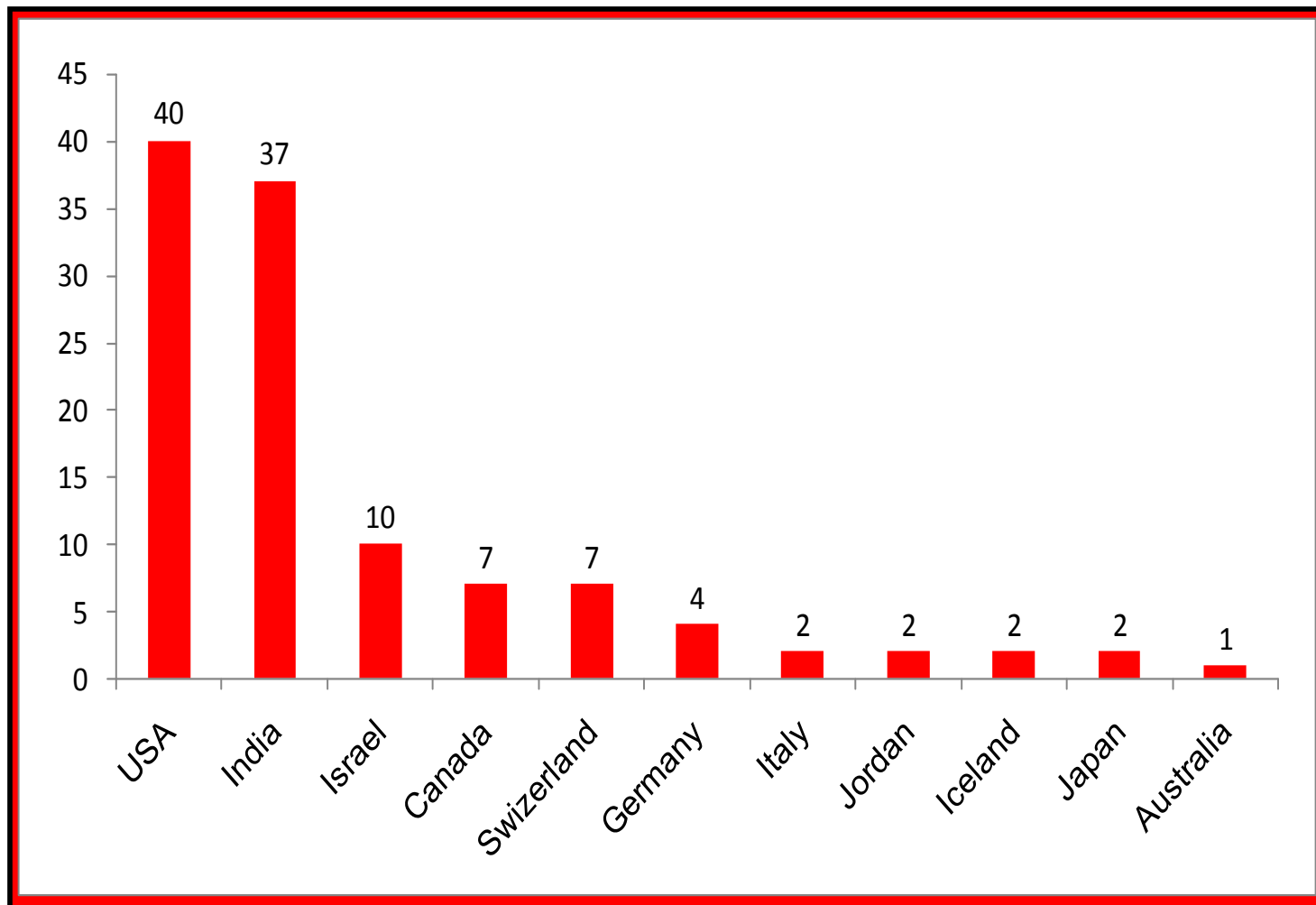


Manufacturing

- ❖ Development/ Pre-clinical Support for NCEs
- ❖ APIs/Intermediates of Patented Drugs
- ❖ Mature APIs/ Intermediates/ Finished Forms
- ❖ Finished Forms for Generic Players
- ❖ Emerging Biopharma Capabilities



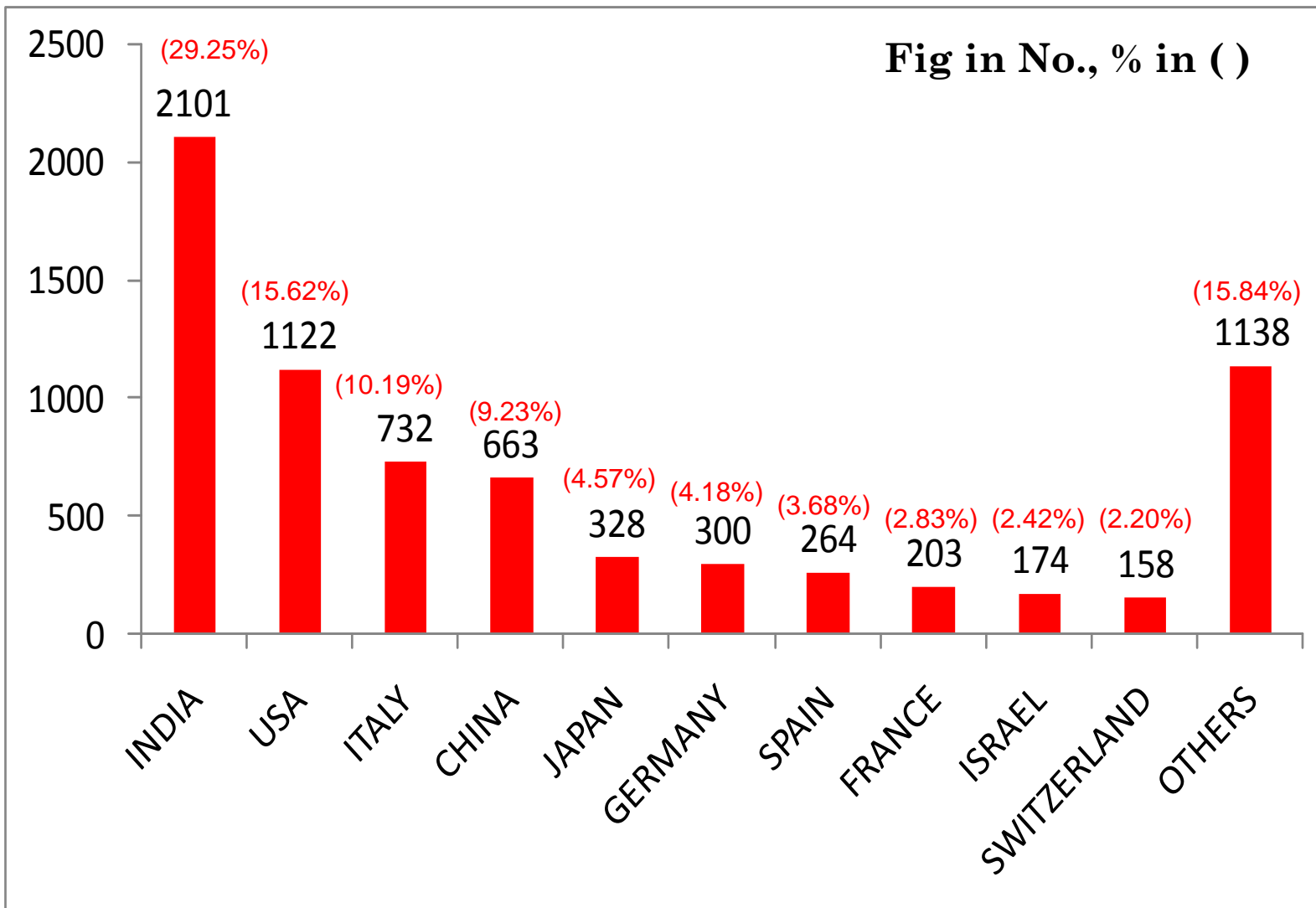
Country-wise ANDAs



Source: Pharma Matters-Movers and Shakers – Oct-Dec 2008



Global DMF with U.S. FDA



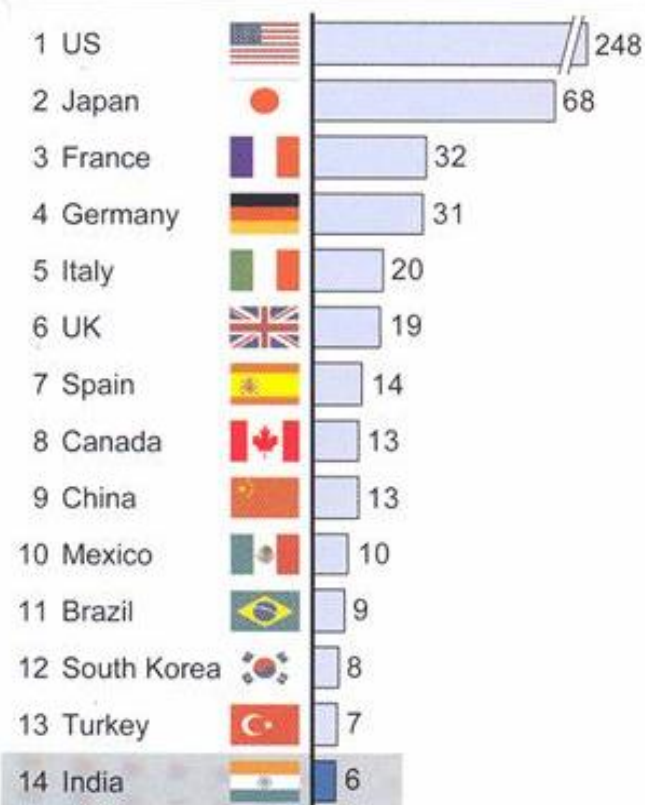
Updated to September 2009

Source: Pharmexcil research on CDER US-FDA data base

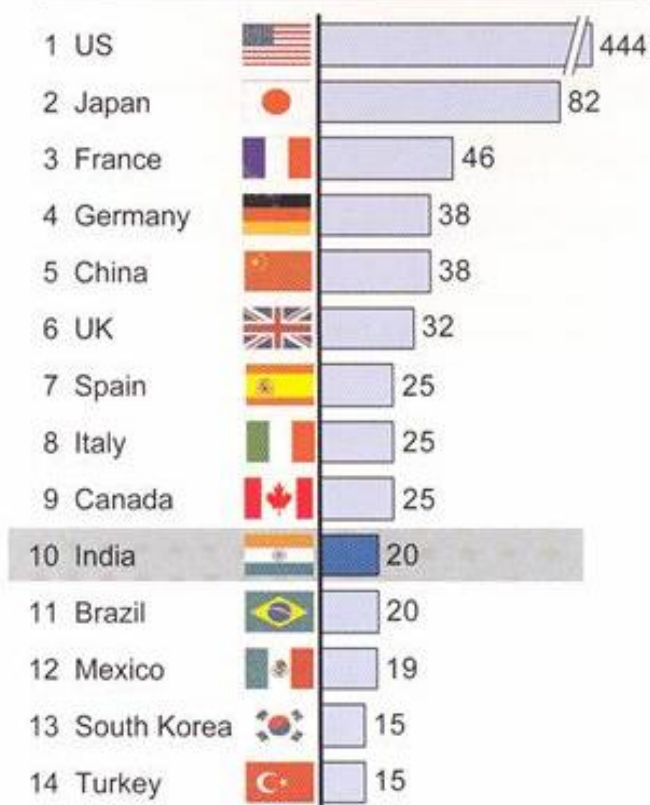


India to be in Top 10

Top 14 pharmaceuticals markets, 2005



Top 14 pharmaceuticals markets, 2015



Source: IMS World Review; analyst projections; McKinsey India Pharmaceutical Demand Model



India Poised

India lives in the growing optimism in the hearts of its people.....

... the world is now looking at this optimistic, pulsating, dynamic and democratic new India as a future economic global superpower...





Thank You