

# PHARMACEUTICAL INDUSTRY

## – CAPTURING EVOLVING MICROTRENDS

**Tapan Ray**

Ernst & Young Health Sciences Meet  
26<sup>th</sup> March, 2009 - Mumbai

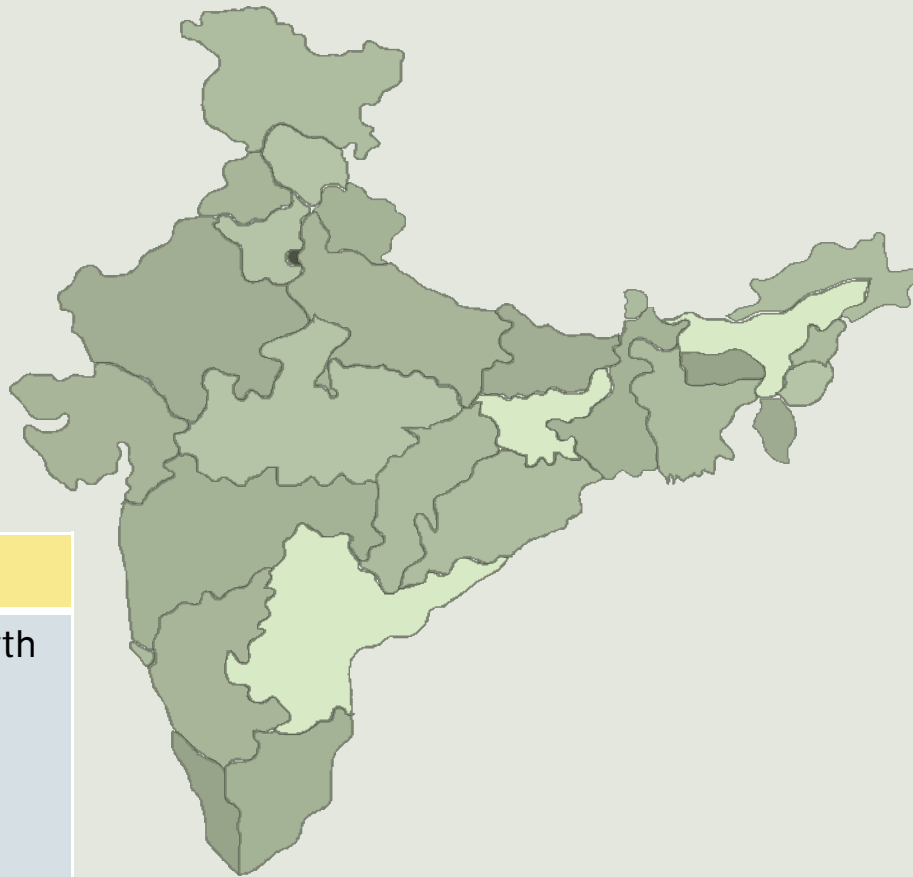


# Content

- ❖ Indian Pharmaceutical Market
- ❖ Global Pharmaceutical Market
- ❖ Indian Healthcare Policy Framework & environment
- ❖ Emerging scenario:
  - Global Pharmaceutical Industry
  - Indian Pharmaceutical Industry
- ❖ Indian Pharmaceutical policy initiatives
- ❖ Evolving micro-trends in Global Pharmaceutical Industry

# 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
- Reasonably proactive
- Significant outsourcing opportunities
- Fast growing markets
- Significant investment in infrastructure creation for industry
- Product patent regime / R&D

# Healthcare Sector remains insulated from global meltdown....



## Pharma

From Rs.20,000 Crs to Rs.34,118 Crs  
forms the core of healthcare



## Insurance

Has grown from Rs.400 Cr (2000)  
to > Rs 700 cr. (2006) growing  
& still growing at 40%



## Hospitals

No.of beds  
~65,500  
Increase in Private Sector



## OTC Market

Today > than Rs 3000 crs. has  
grown at 12-15%



## Medical Tourism

Risen from nothing, is today a \$450 Mn industry.  
Infertility, Cardiac management are big contributors

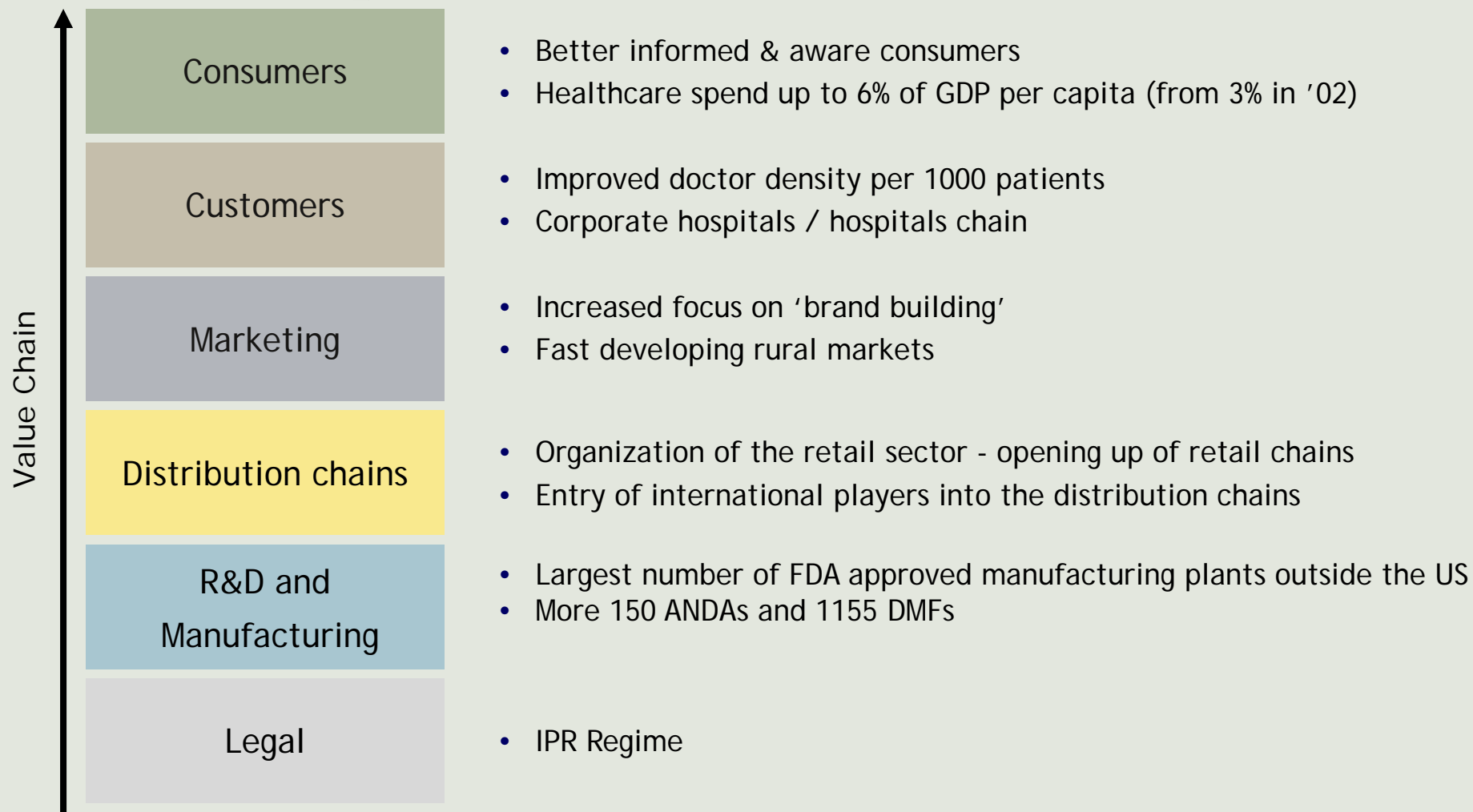


## Medical Devices

Small but maturing market

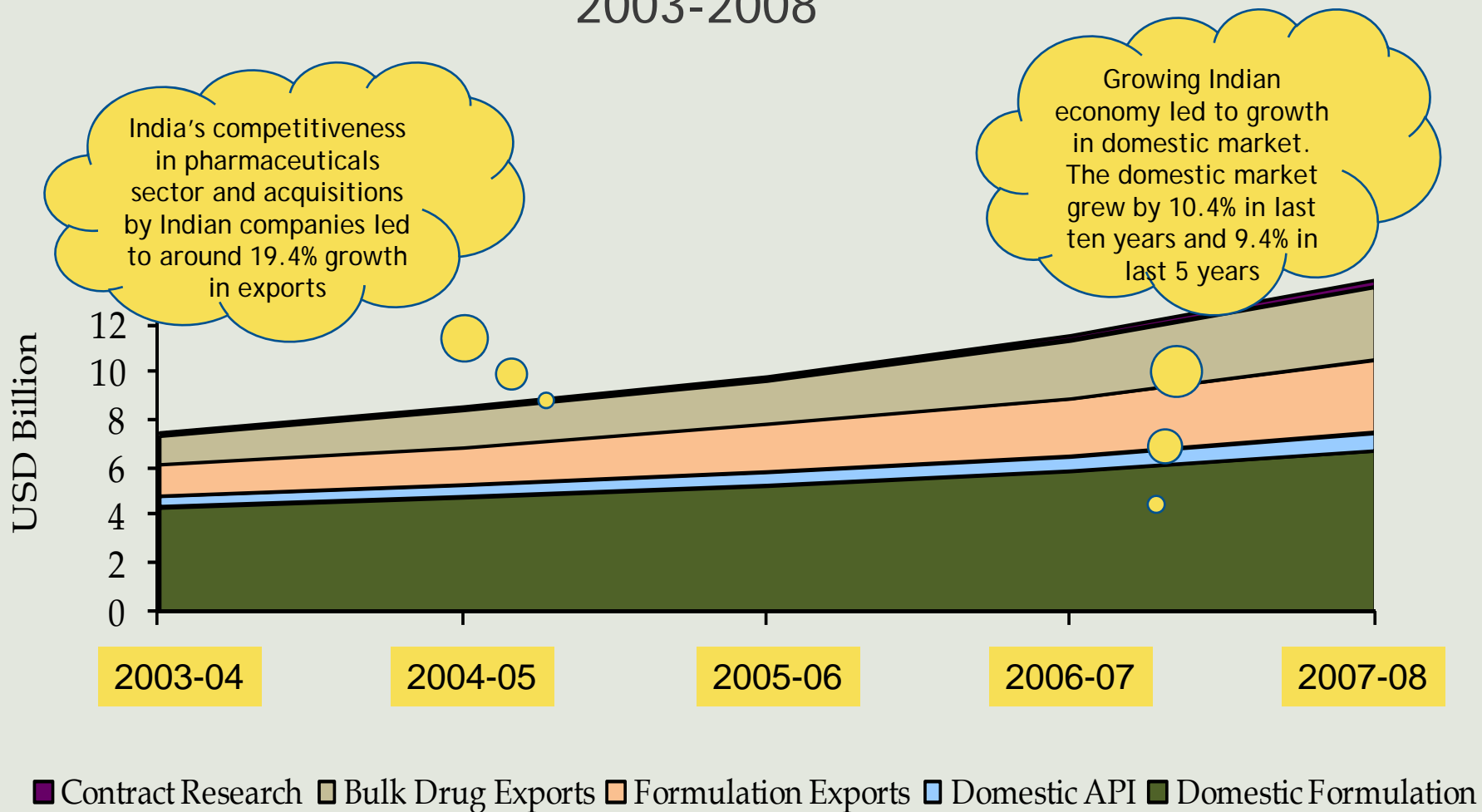


## ...with developments across most components of the value chain during the last decade



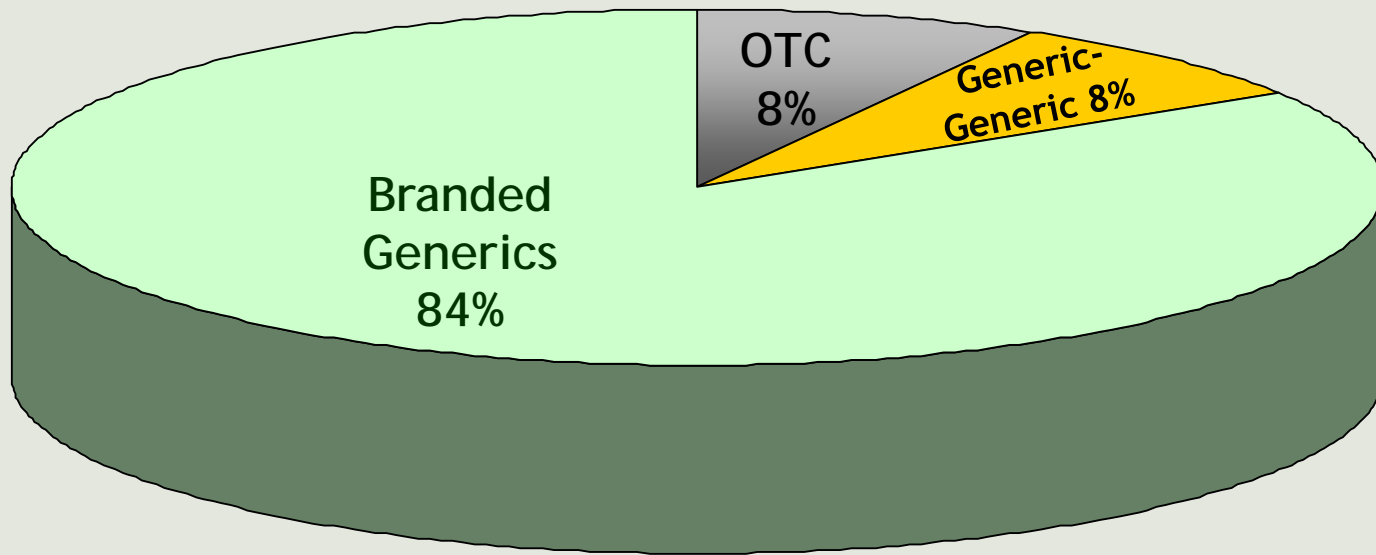
# Indian Pharmaceutical Market

2003-2008



# Key Market Types - 2008

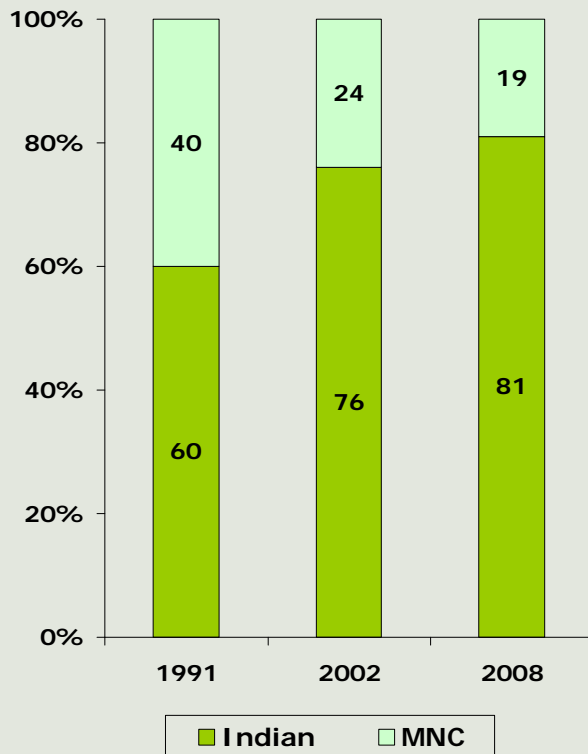
**Market Size US\$ 7.5 Billion**





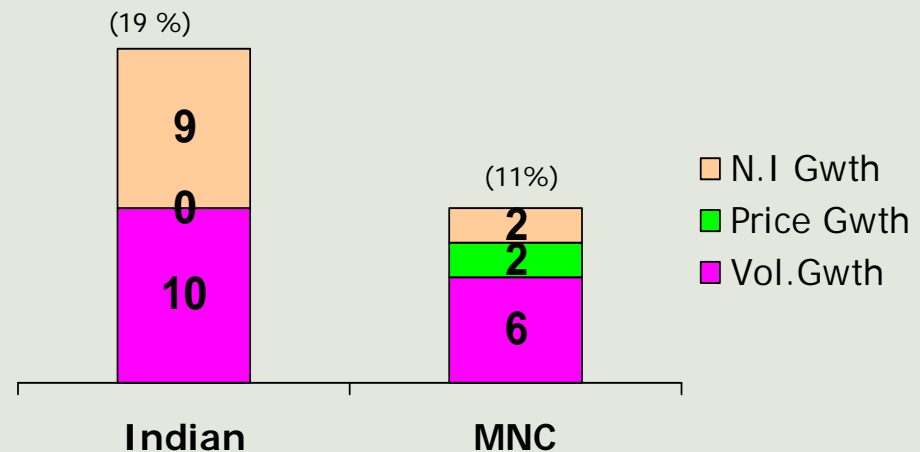
# MNC vs. Indian Companies

High Dominance of Indian companies, MNC contribution to 20%



New Introductions & old products are the major growth drivers for Indian companies

Parameters	Indian	MNC
Product Basket	Large	Selective
New launches	Very High	Very Low
Value/Brand	Low	High
Strategy	Short term; grab the opportunity	Long term; Brand building
Pricing	Primarily low priced products	Premium



Source : Stockist Secondary Audit, Dec 08 MAT

Fig. in ( ) indicate value growth

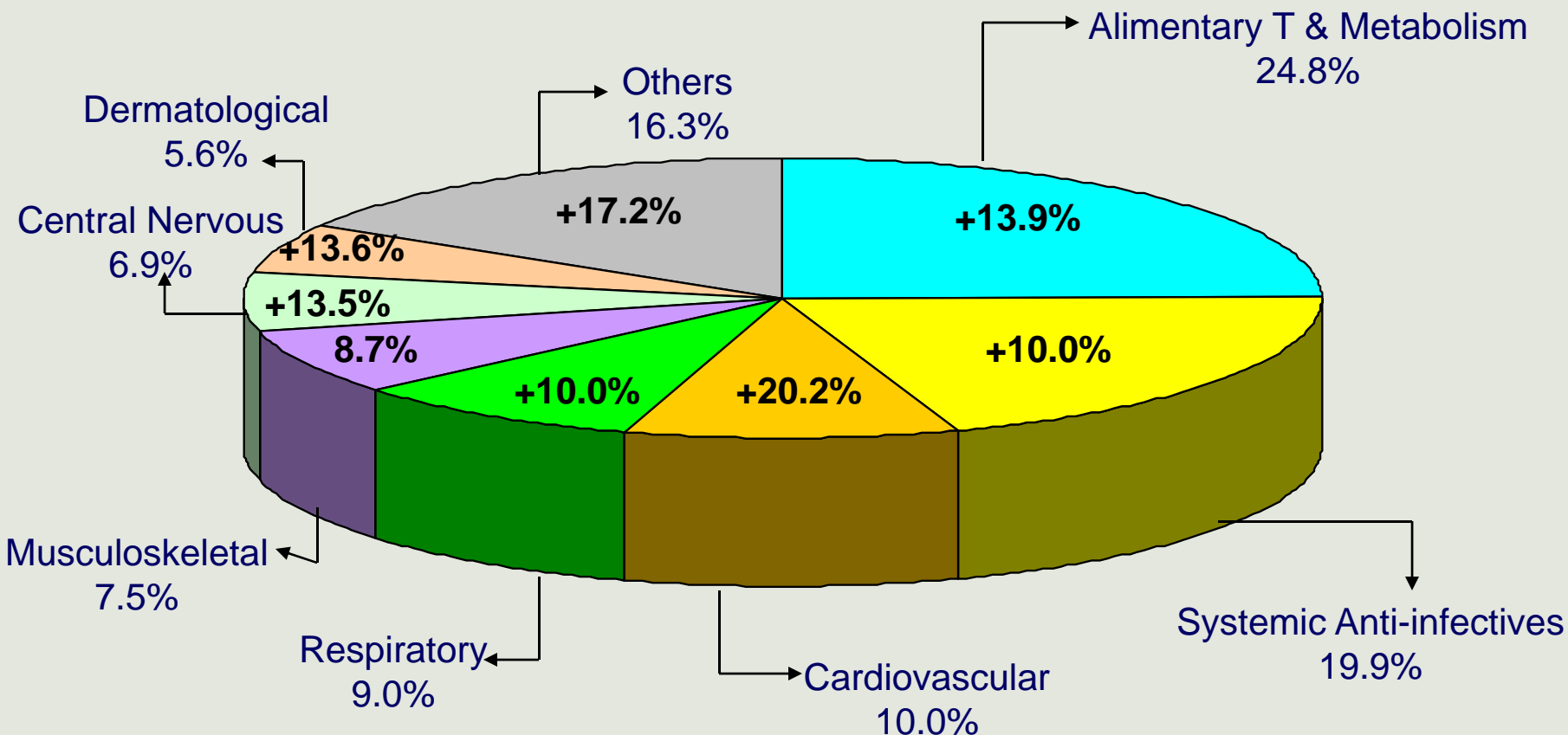


# Top 10 Products

Rank	Products	TG	Company	Value (US\$ Mn)	%GR
1	Corex	Cough Preparation	Pfizer	36.9	16.8
2	Voveran	NSAID	Novartis	33.6	8.2
3	Phensedyl Cough	Cough Preparation	Piramal	29.6	19.0
4	Human Mixtard 30/70	Insulin	Abbott	27.8	3.6
5	LIV 52	Ayurvedic	Himalaya	27.2	5.8
6	Zifi	Cephalosporin	FDC	26.3	21.9
7	Taxim	Cephalosporin	Alkem	26.2	3.1
8	Augmentin	Amoxy+Calv	GSK	25.7	5.8
9	Mox	Amoxycillin	Ranbaxy	25.3	22.4
10	Dexorange	Haematinic	Franco Indian	24.8	17.2

# Indian Top Therapy Areas

## Key Therapeutic Segments



**Total Market US\$ 7549.2 Mn (Growth 13.4%)**  
**[13<sup>th</sup> in value and 4<sup>th</sup> in volume globally]**

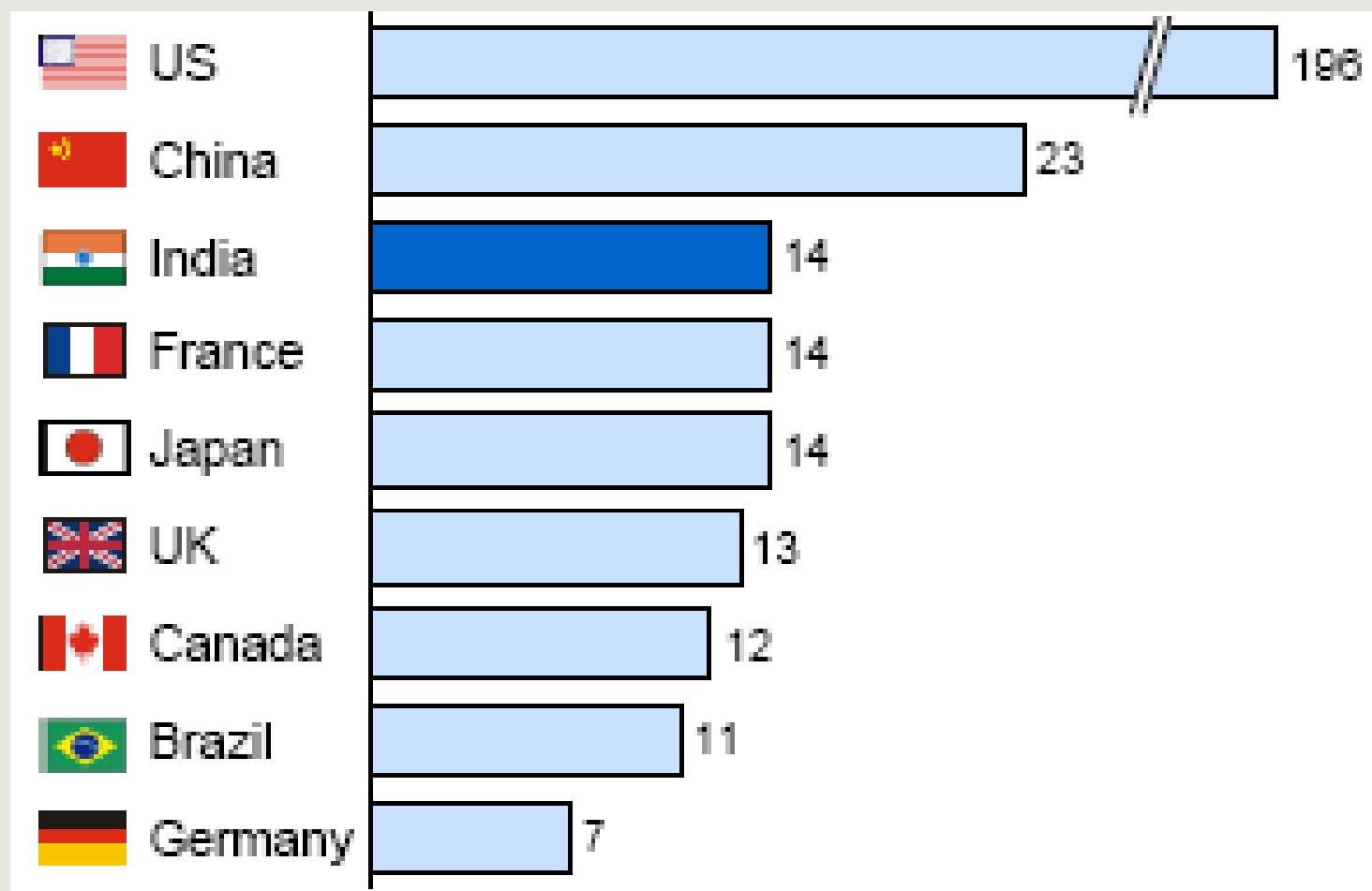
\*Annual Income >\$ 5000

Source: IMS Dec. 2008

# INDIAN GROWTH STORY



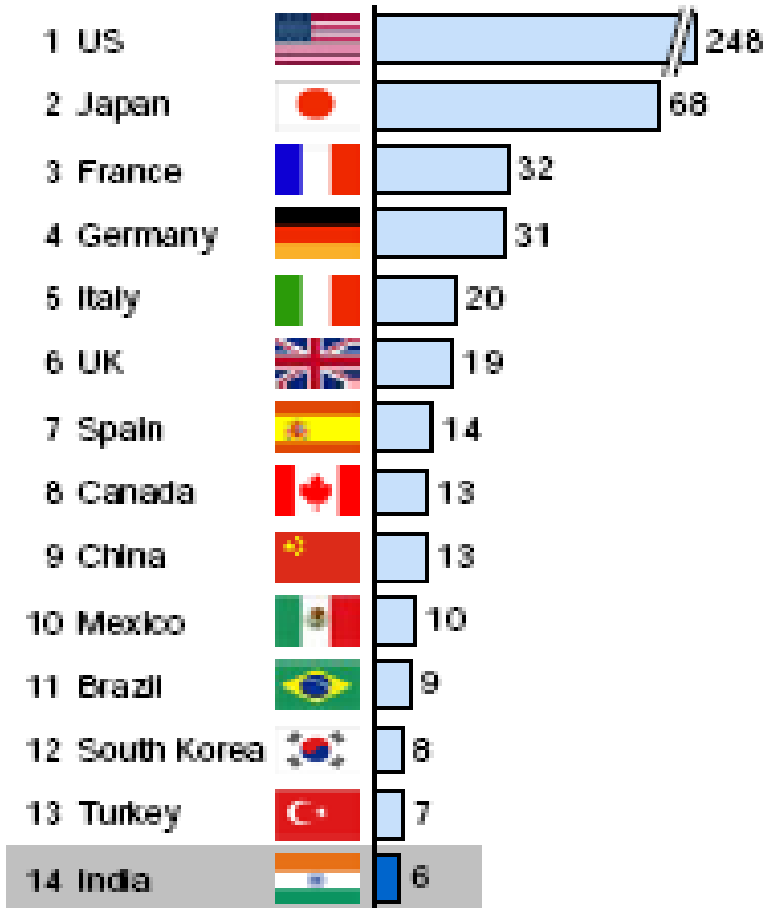
## By absolute growth, India will be among the top 5 markets globally during 2005 to 2015



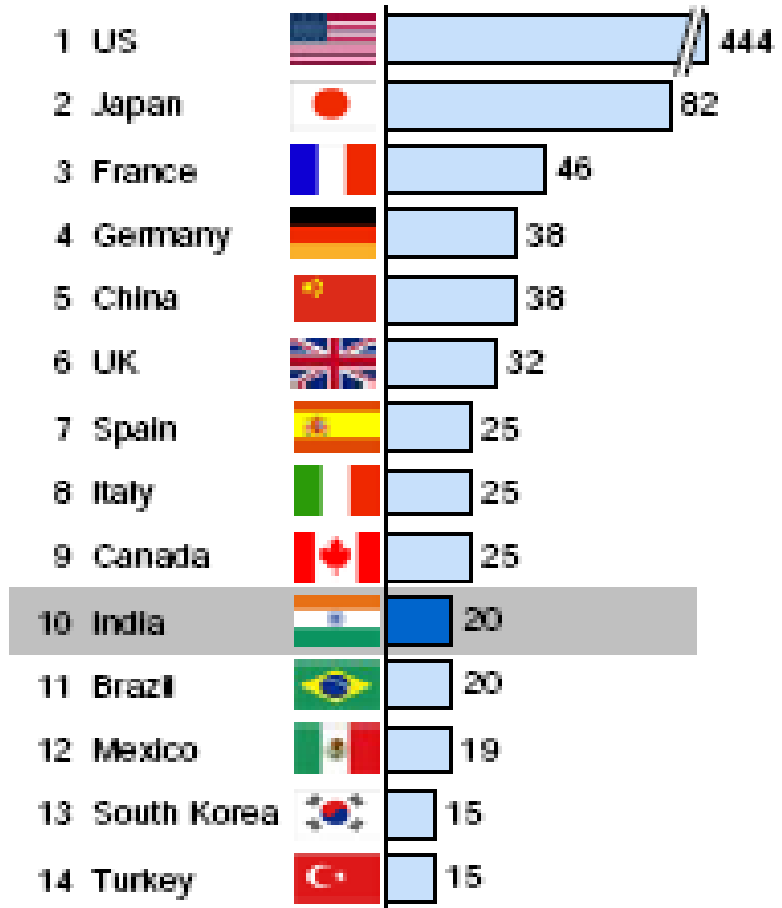
Source: IMS World Review; analyst projections; McKinsey India Pharmaceutical Demand Model

# Top Pharmaceutical Markets

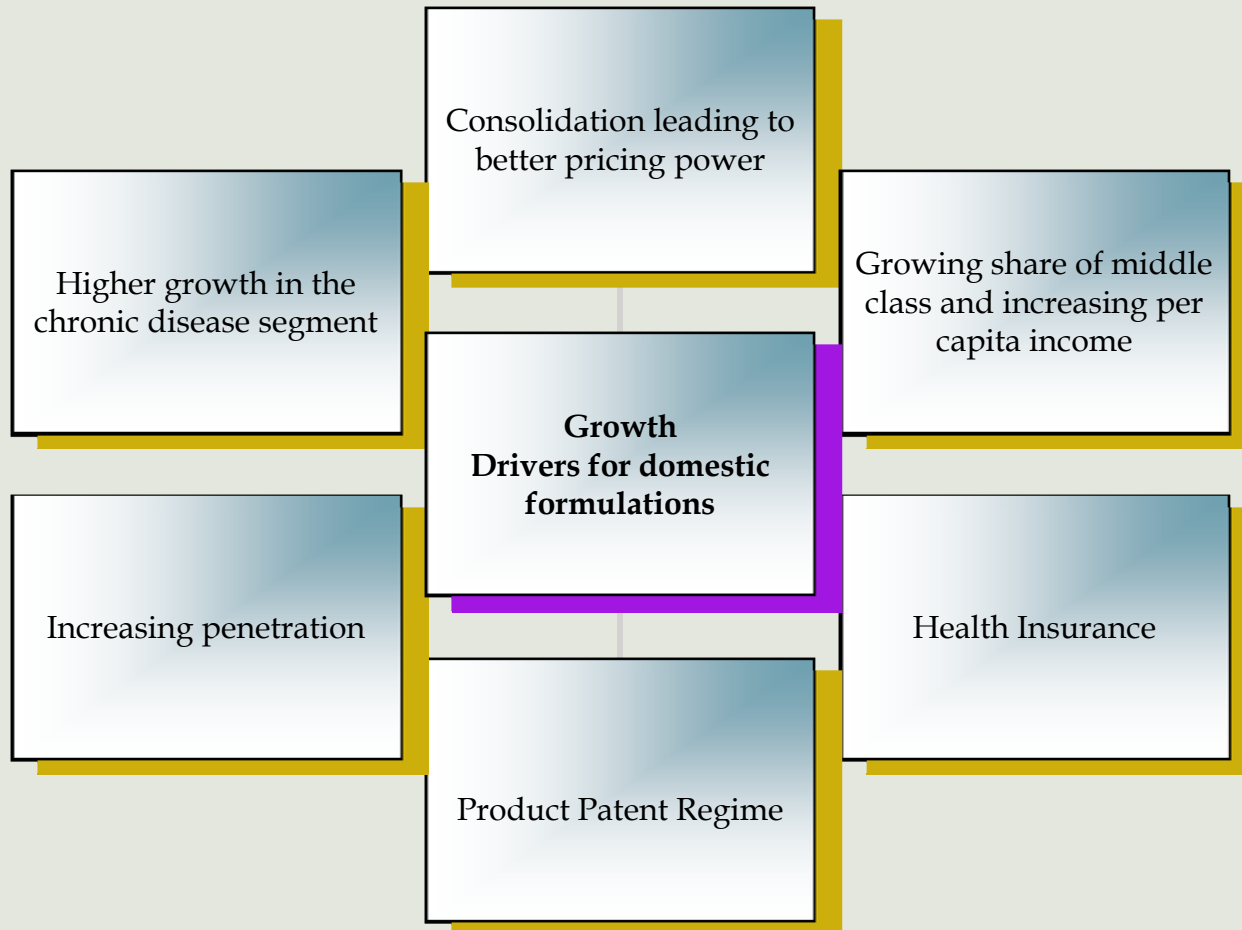
Top 14 pharmaceuticals markets, 2005



Top 14 pharmaceuticals markets, 2015



# Key Growth Drivers



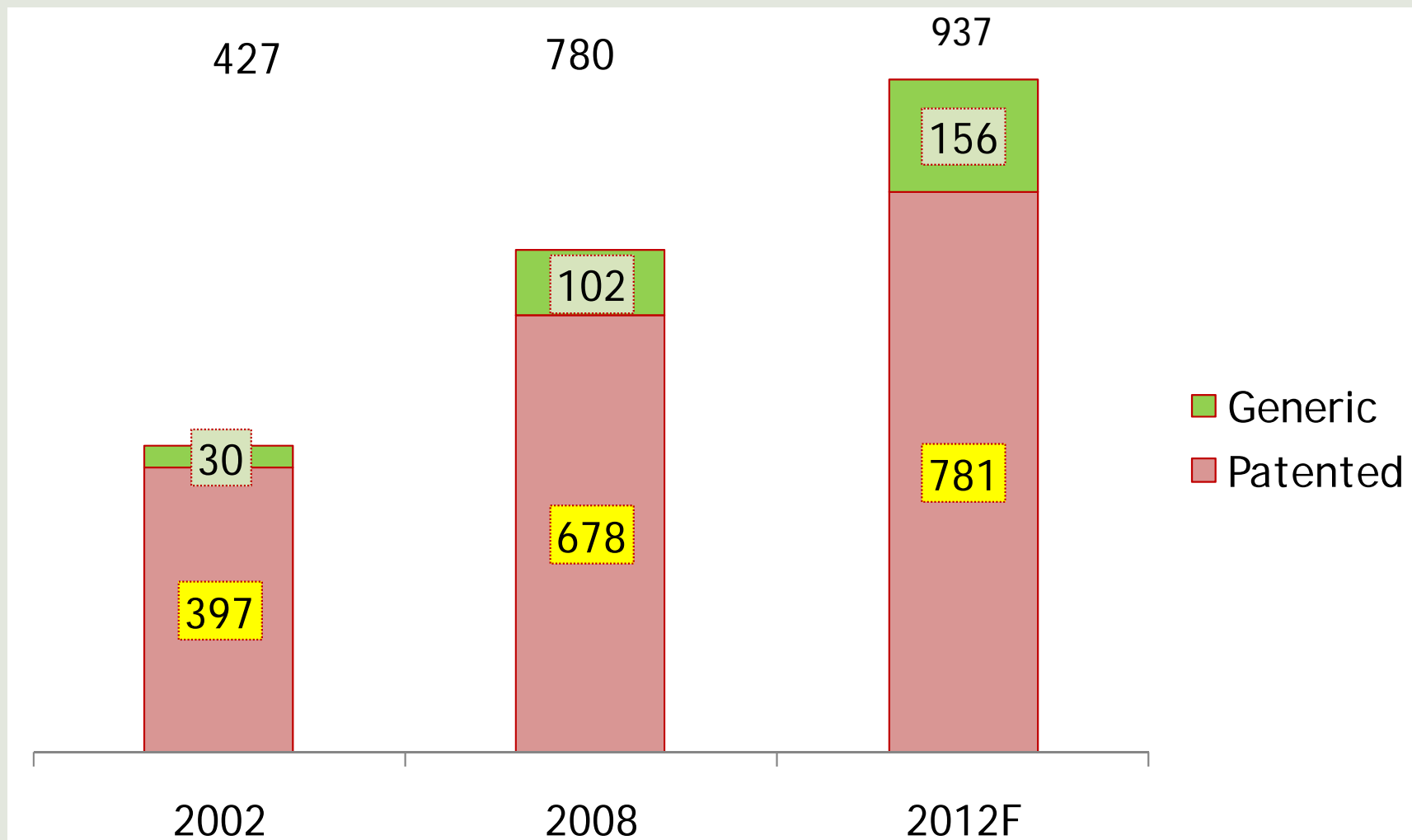
# Global Pharmaceutical Market 2008

Value: US\$ 780 billion

Growing at 4.5%

# Global Pharmaceutical Market

(USD Bn.)

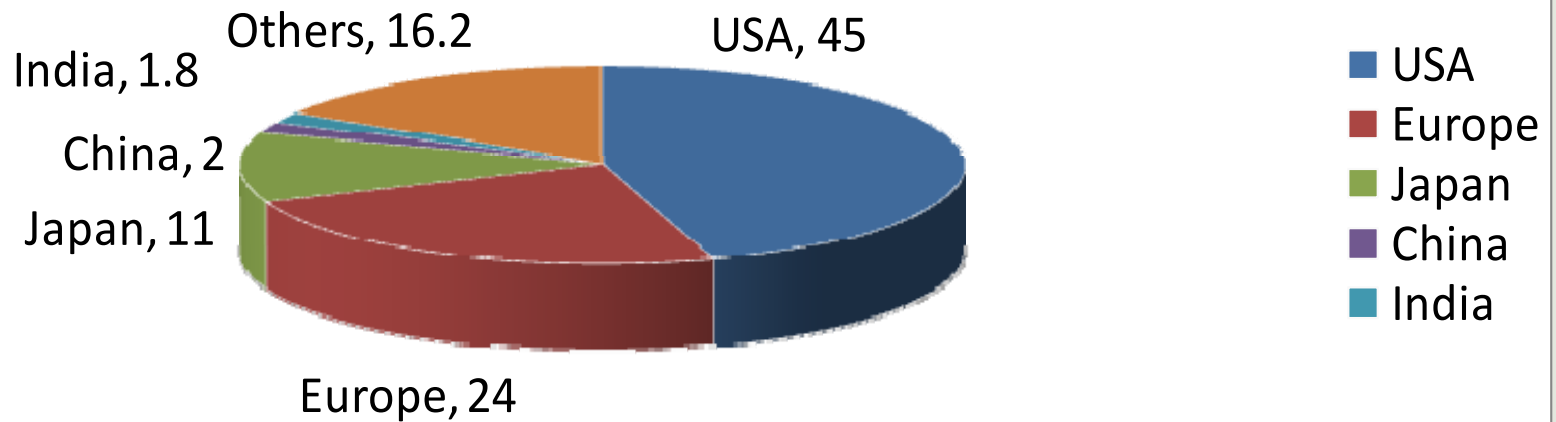


Source: IMS



# Global Pharmaceutical Market

## Top Players in Pharma Market



# Global Pharma - Top 10

Rank	Company	Pharma Sales 2007 (\$ million)	% Change	Pharma sales as % of total sales
1	Pfizer	44,424	-1.5	91.8
2	GlaxoSmithKline	38,501	4.0	84.7
3	Sanofi-Aventis	38,452	7.9	100.0
4	Novartis	31,194	9.3	78.4
5	Roche	30,686	15.4	79.7
6	AstraZeneca	29,559	11.6	100.0
7	Johnson & Johnson	24,866	6.9	40.7
8	Merck & Co	20,102	-1.3	83.1
9	Wyeth	18,662	10.5	83.3
10	Lilly	17,638	19.0	94.7

# Global Pharma - Top 10 Products

Sales US\$ (Bn.)

S. No.	Brand	Company	Sales
1.	Lipitor	Pfizer	13.35
2.	Plavix	BMS	9.40
3.	Enbrel	Wyeth	7.66
4.	Advair	GSK	7.65
5.	Remicade	J&J	6.20
6.	Diovan	Novartis	5.74
7.	Rituxam	Roche	5.48
8.	Nexium	AstraZeneca	5.20
9.	Avastin	Roche	4.82
10.	Ablify	BMS	4.75

Source: Knol-BETA-Global Market Research

# Key Global Acquisitions-Is it working?

Year	Target Company	Bidder	Value	Country
2008	Mentor Corporation	Johnson & Johnson	1100	USA
2008	ImClone Systems Inc	Eli Lilly & Co.	5867	USA
2008	Bristol Myers Squibb (Egyptian mature Products Pharma Buss	GlaxoSmithKline Plc.	210	Egypt
2008	Nektar Therapeutics	Novartis AG	115	USA
2008	Q-MED AB	Ivytan AB	473	Sweden
2008	AZ Tika	GlaxoSmithKline Plc.	215	Sweden
2008	Omrix Biopharmaceuticals Inc	Johnson & Johnson	348	USA
2008	Dow Pharmaceutical Sciences, Inc.	Valeant Pharmaceuticals International	285	USA
2008	Radi Medical Systems AB	St. Jude Medical Inc	250	Sweden
2008	MediGuide Inc.	St. Jude Medical Inc.	283	Israel
2009	Curidium Medica Plc.	Avacta Group Plc	7	U.K.
2009	Wyeth	Pfizer Inc.	66176	USA
2009	Genentech Inc.	Roche Holdings Ltd.	43249	USA
2009	Ovation Pharmaceuticals, Inc.	H. Lundbeck A/S	900	USA
2009	PharmaNet Development Group, Inc	JLL Partners	244	USA
2009	Arana Therapeutics Ltd.	Cephalon International Holdings, Inc.	206.7	AU
2009	Insmmed Incorporated - Biologics Platform - Assets	Merck & Co., Inc.	130	USA

**US \$ Mn.**

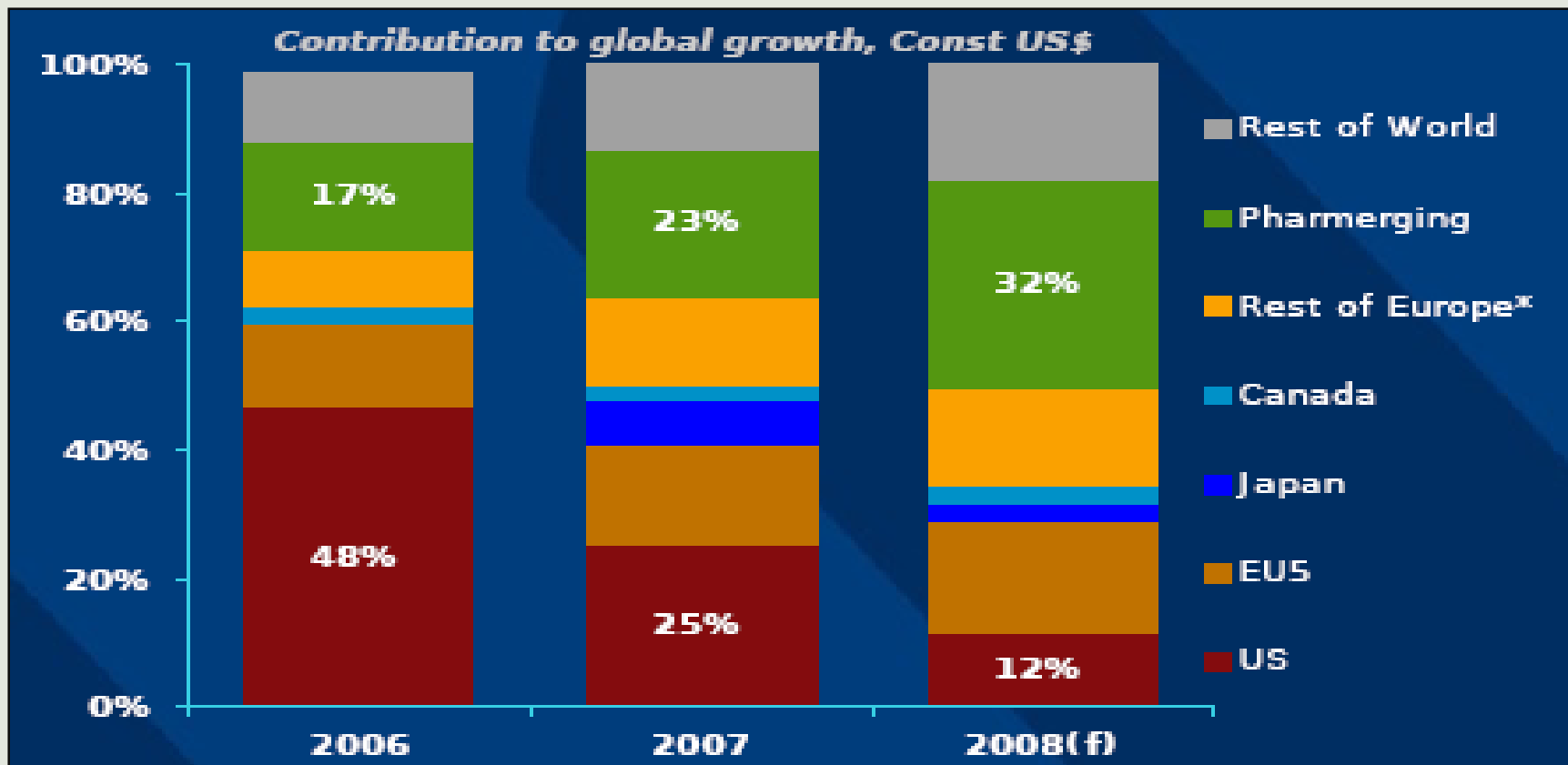
## Fundamental Shift of Global Pharma

### New Reality

- Lower growth in developed market

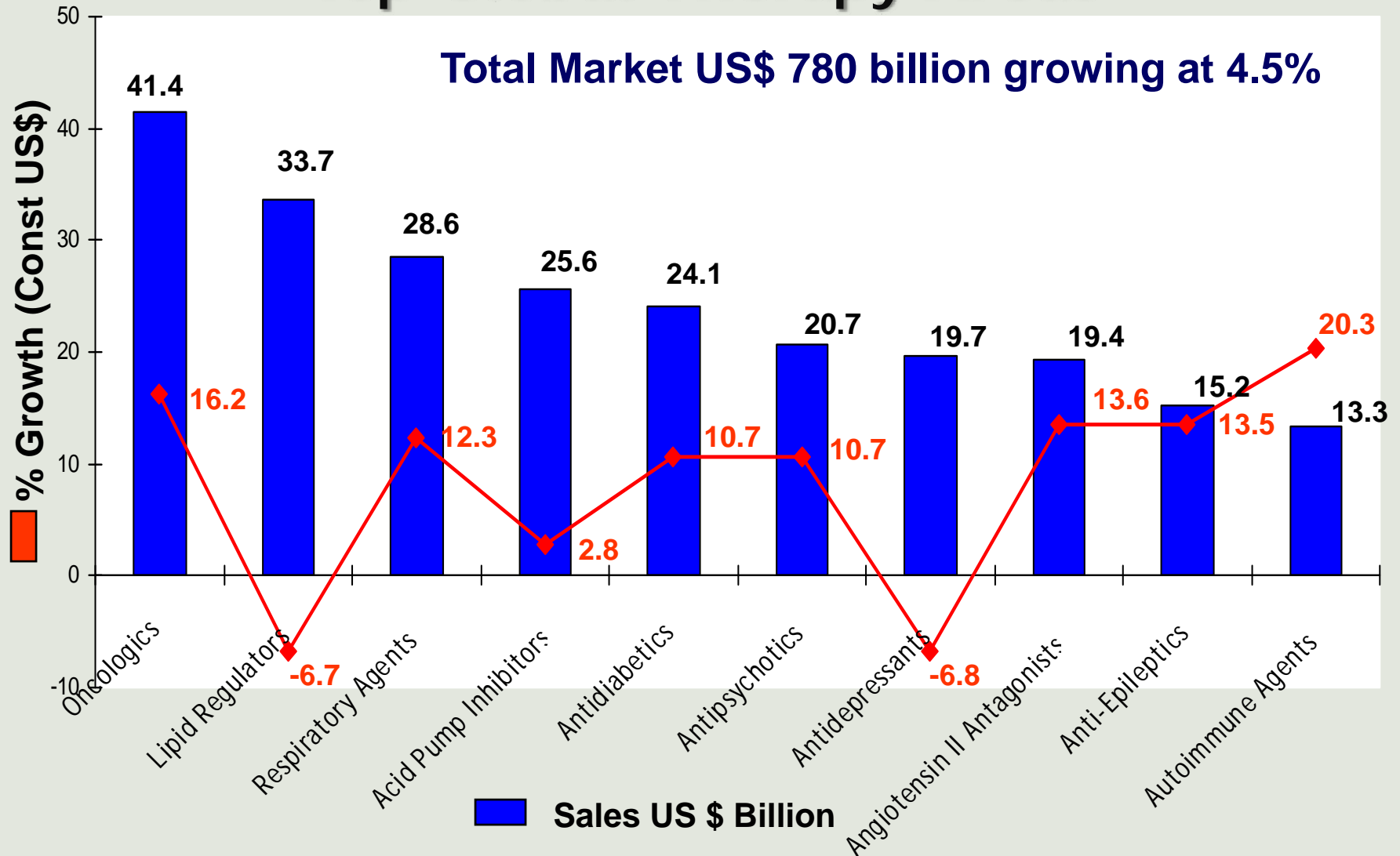
### New Opportunities

- Robust growth in “pharmerging” market



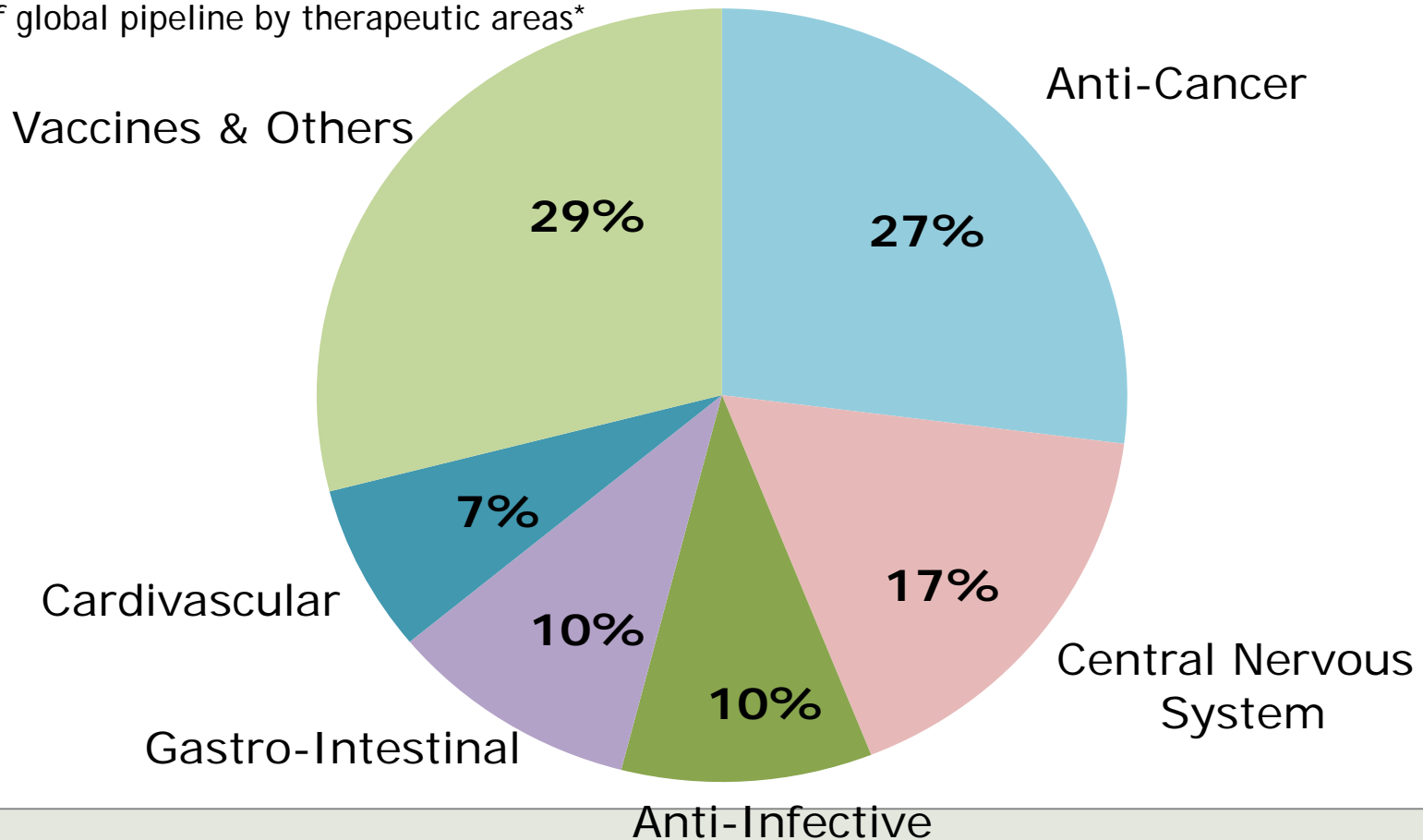
# Top Global Therapy Areas

**Total Market US\$ 780 billion growing at 4.5%**



# Global Pipeline for Patented Product is concentrated in in five TAs

Share of global pipeline by therapeutic areas\*



\*excluding pre-clinical

# Policy Framework -Indian Pharmaceutical Industry

Policy-sets that influence the  
Pharmaceutical Industry

## Healthcare Policy

- Access to medicines
- Cost-effective medication
- Regulating the physician and consumer behaviour
- Generic promotion/substitution

## Industrial Policy

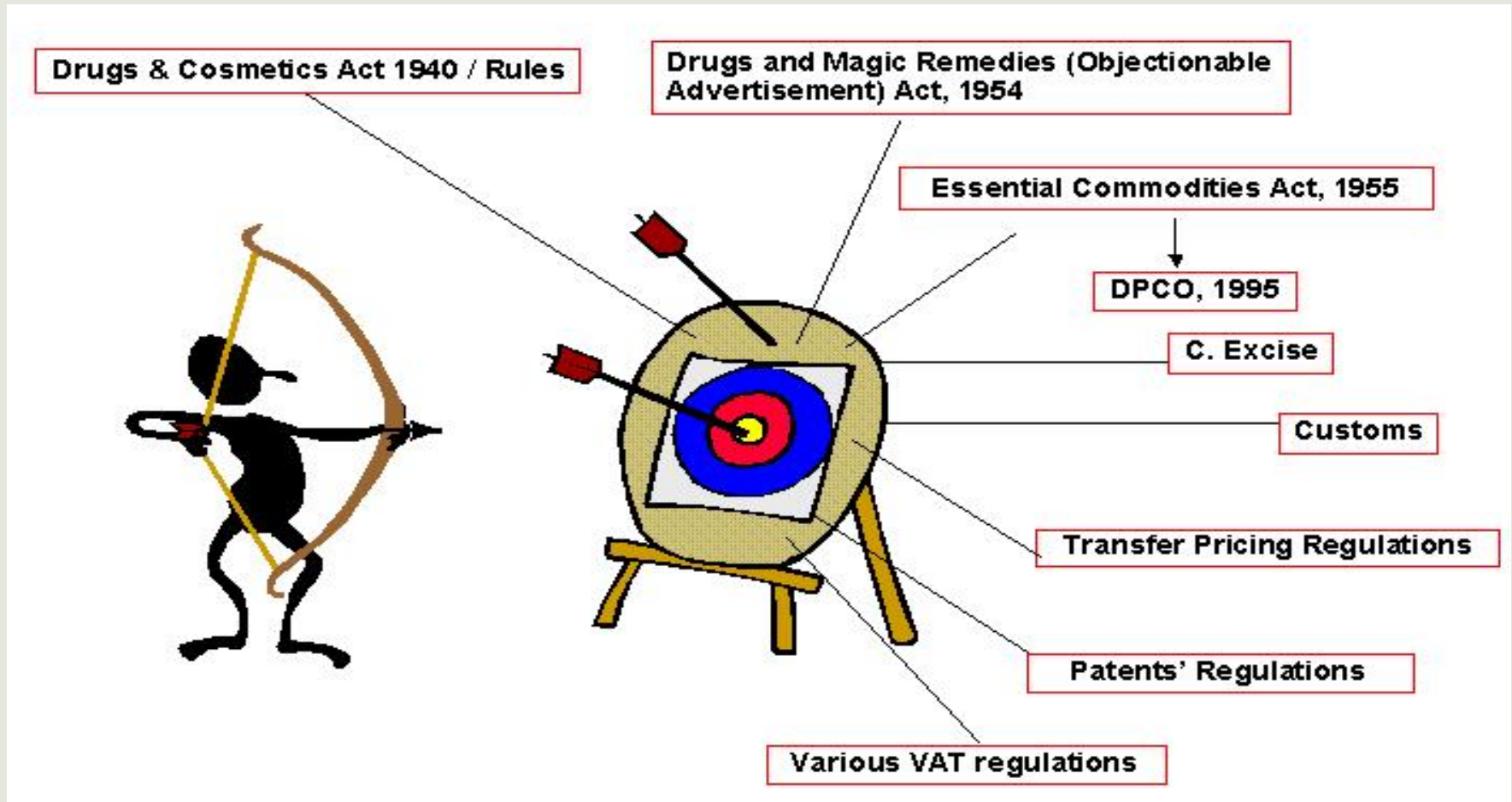
- Promoting SMEs
- Strengthening R&D
- Protection of IPR
- Sustaining Industry-Institution Linkages
- Supporting technology transfer and capacity development

## Health Safety Policy

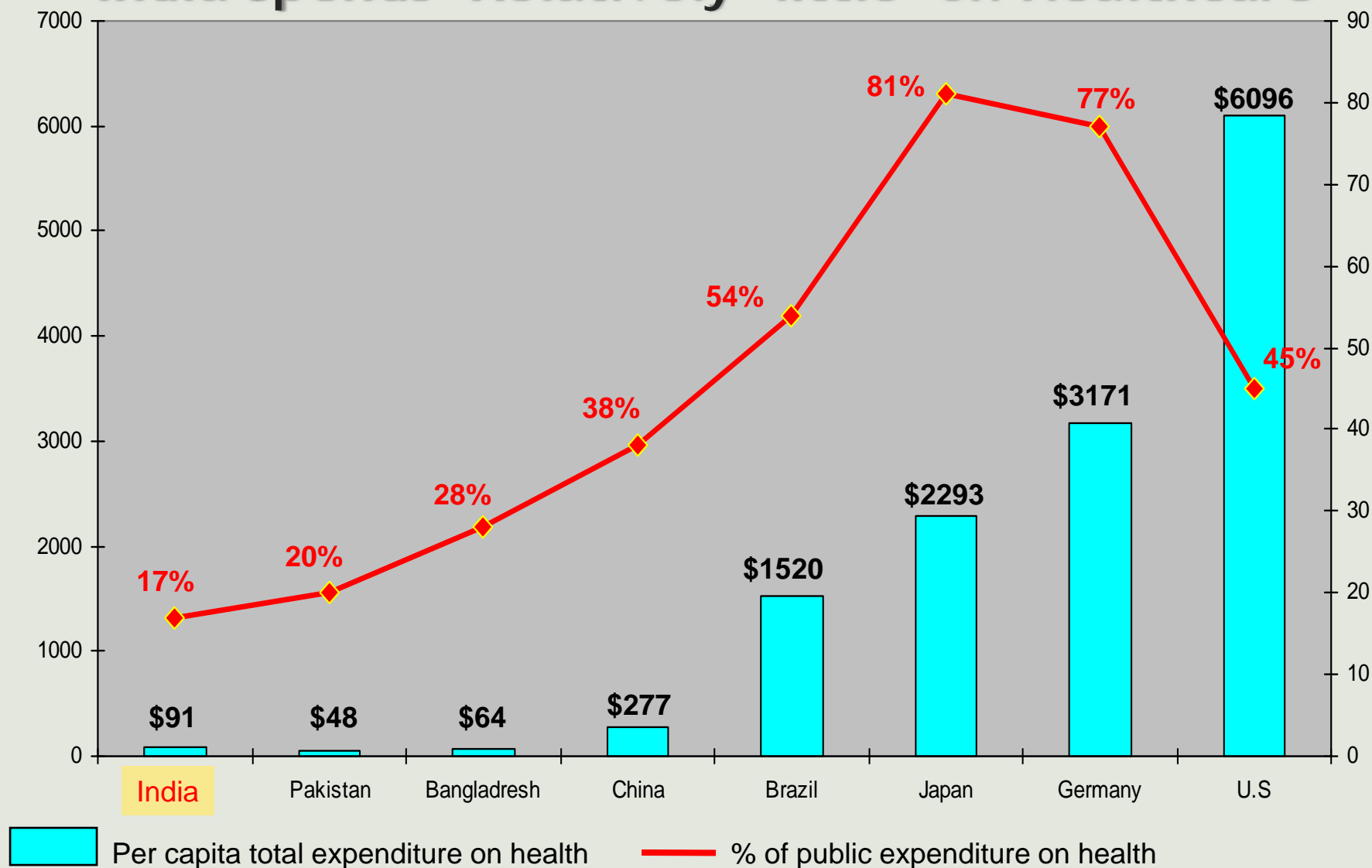
- Ensuring Quality in manufacturing
- Efficacious treatments
- Innovations in drug delivery
- Safety in medicines



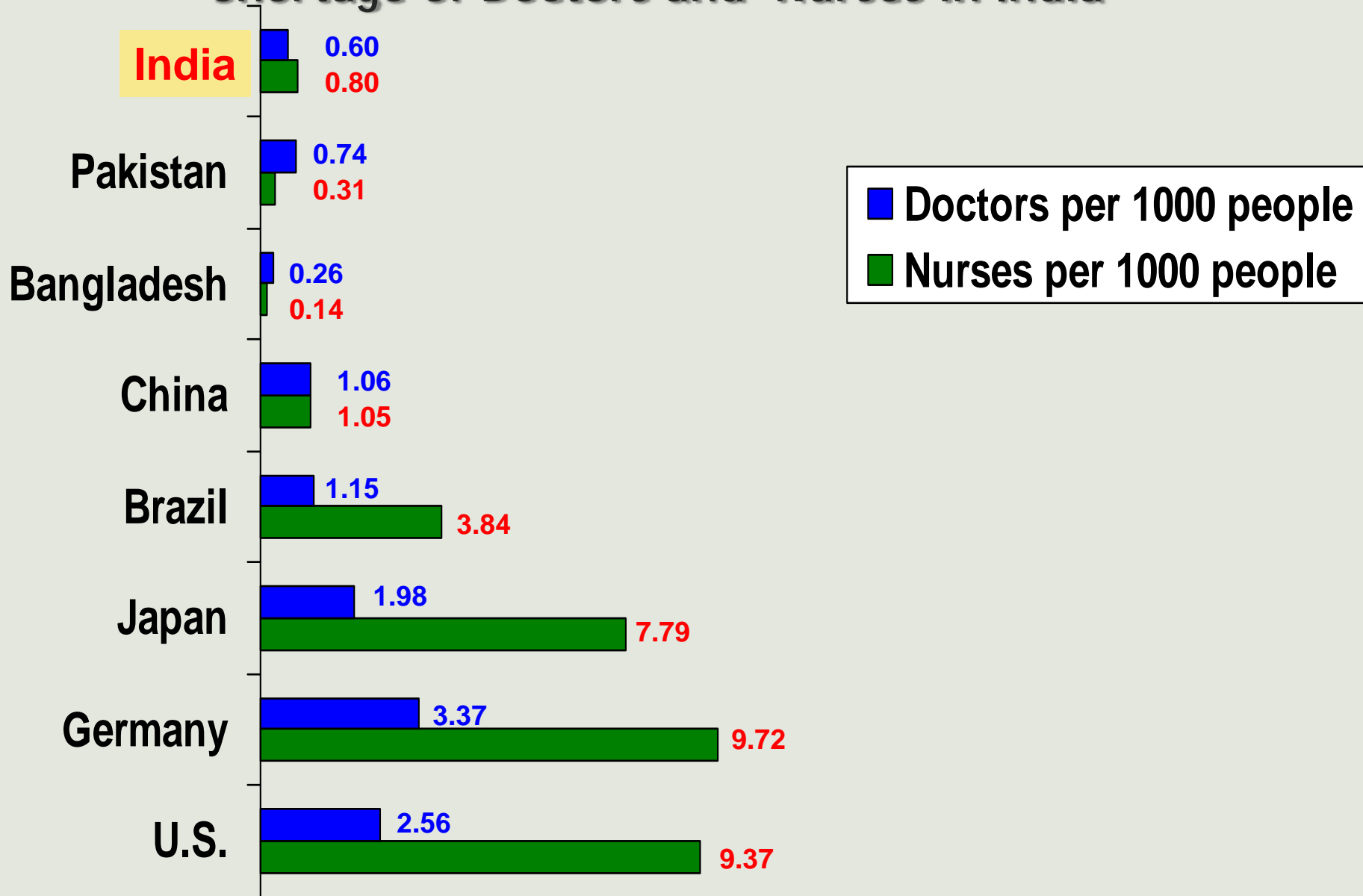
# Healthcare Environment -Regulatory



# India Spends Relatively little on Healthcare



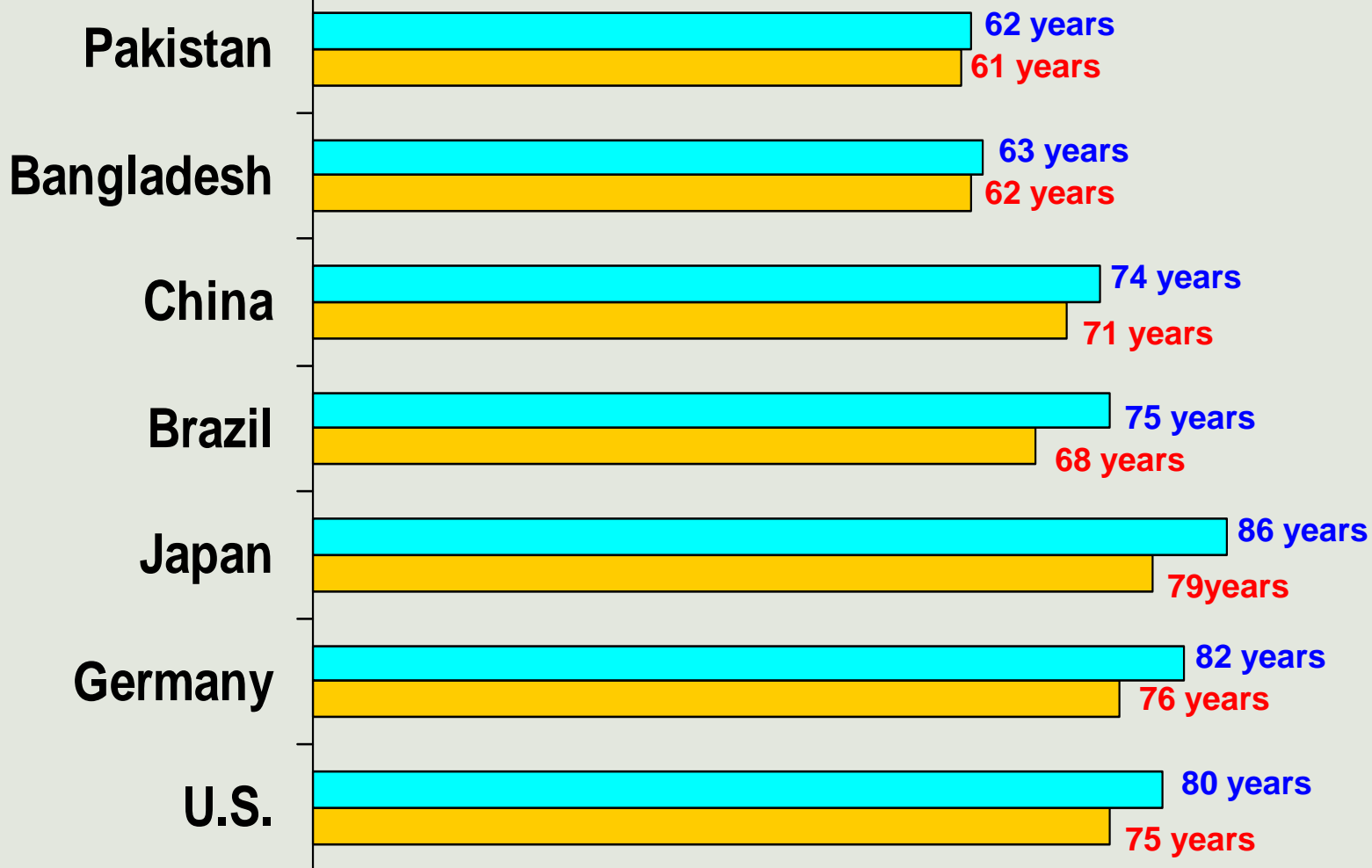
## Shortage of Doctors and Nurses in India



## Life Expectancy in India

**India**

**Women**  
**Men**

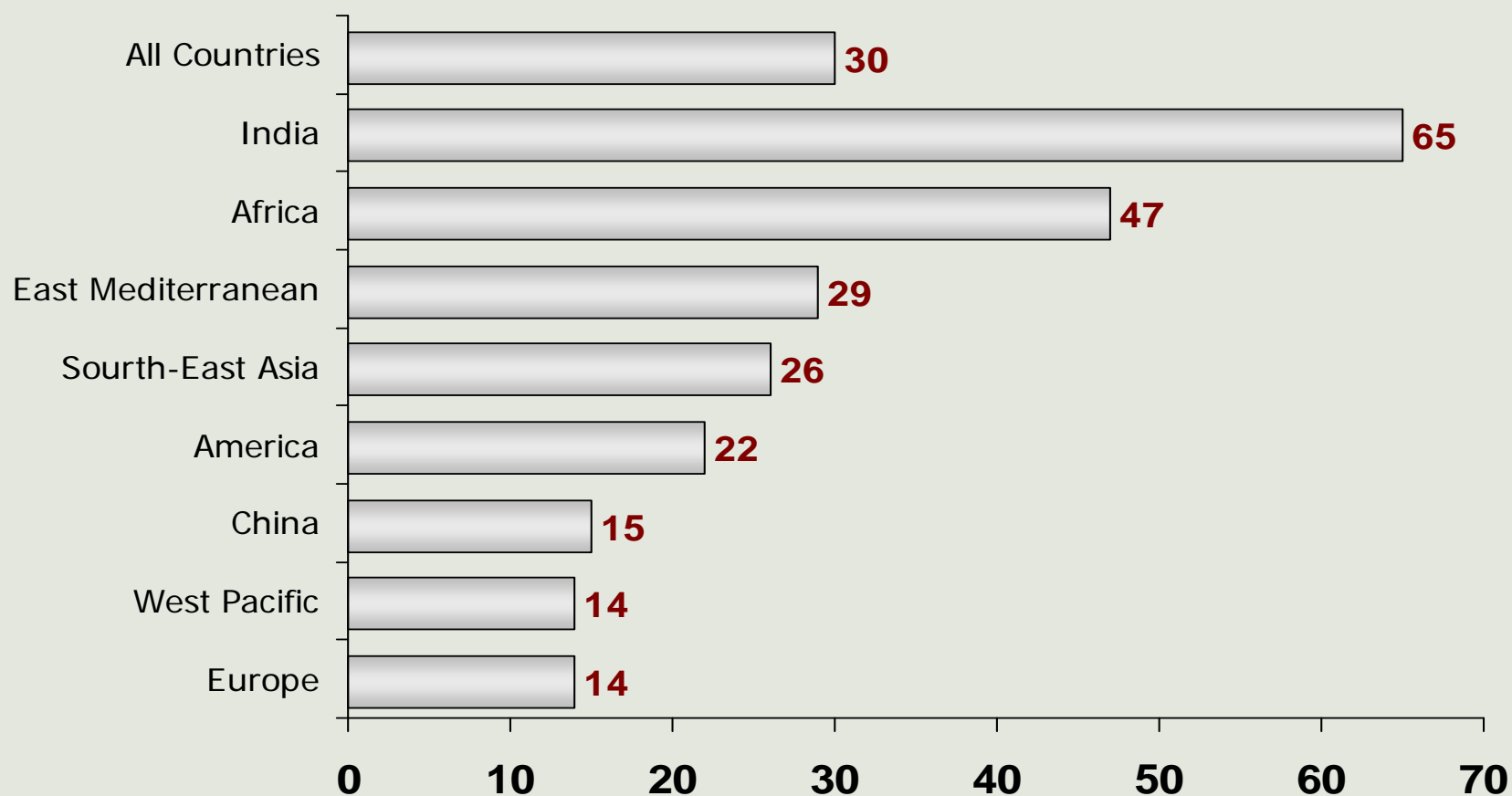


# Healthcare Environment

## Access to Healthcare

Lower access to medicines than African countries

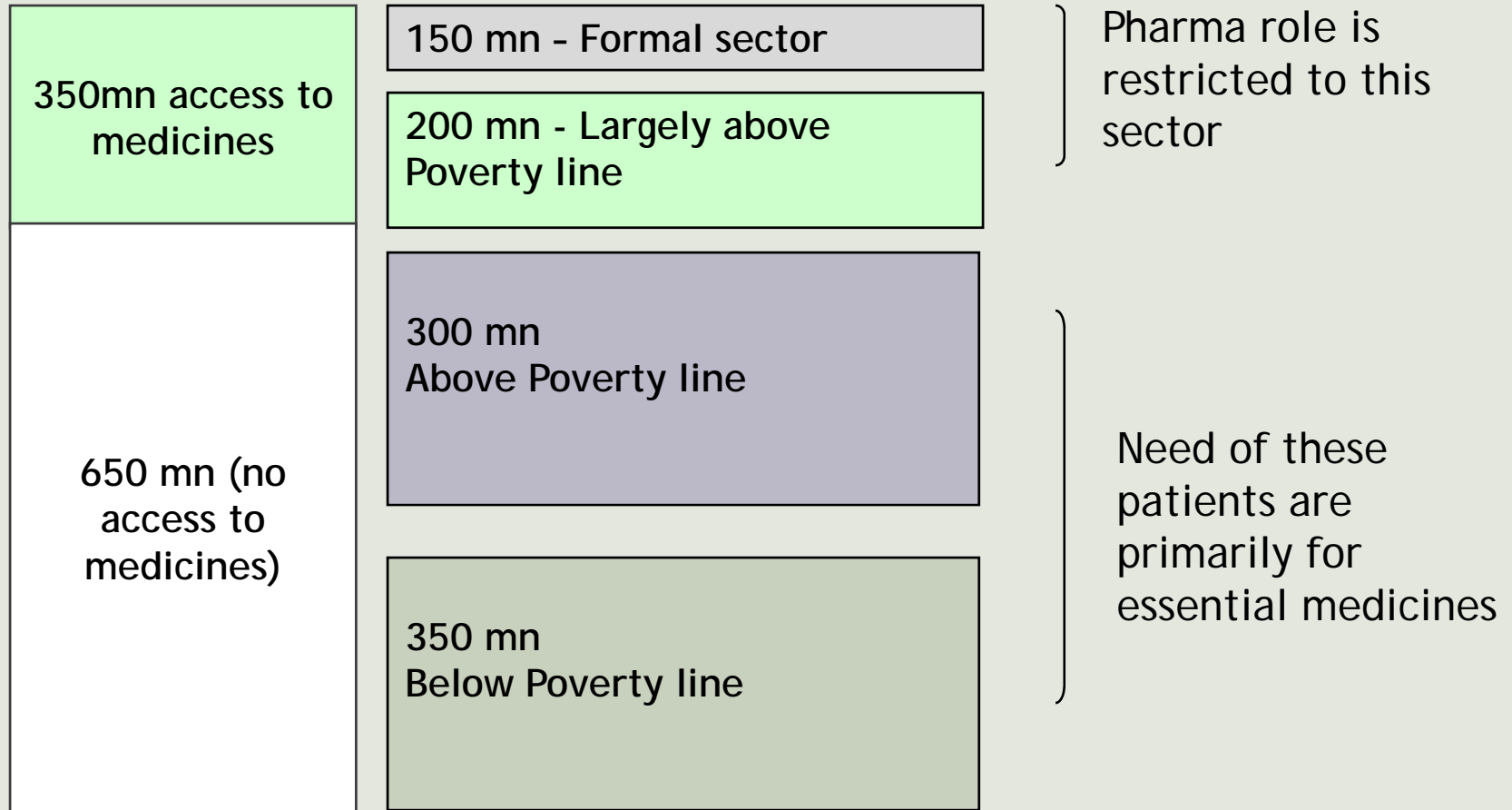
### Percentage of WHO regions lacking access to essential medicines



# Healthcare Environment

## Access to Healthcare

Majority have no access to medicines



Formal Sector: Those employed with the public or private sector



# Healthcare Environment

## Affordable Prices

80% out of pocket payment

Countries	Govt. Payment	Out of pocket payment	Insurance	Others
United States	44.3%	13.7%	35.8%	4.9%
Japan	80%	20%	-	-
Australia	71%	16%	7%	5%
France	77.5%	20.5%	2%	
Germany	75.1%	11%	13.9%	
Canada	72%	17%	11%	
UK	81%	3%	16%	
Spain	72%	20.5%	7.5%	
Italy	73.7%	26.3%		

# Medicine V/s. Commodity Prices

Per day treatment cost for common ailment	Rs.	Average cost of common goods & services of daily consumption (one time)	Rs.
Common headache	1.00	Cup of tea	5.00
Common allergy	0.75	Thali meal	30.00
Common cold	1.50	Milk (half litre)	12.00
Gas trouble (antacid)	3.00	Egg	2.50
Asthma	0.45	Banana	2.00
Diarrhoea	1.20	Suburban train ticket (return)	8.00
Amoebiasis	1.10	Bus fare (minimum)	3.00
Diabetes	0.70	Inland letter	2.50
Blood pressure	1.75	Newspaper	2.00
Angina (chest pain)	0.55	Public telephone call	1.00
Arthritis	1.50		



# Affordable Prices

More affordable than in neighbouring countries

More affordable than nearby countries

	Drugs, Dosage form and Strength	Pack	Prices in India (INR)	Prices in Pakistan (INR)	Prices in Indonesia (INR)	Prices in USA (INR)	Prices in UK (INR)
I. ANTI-INFECTIVES							
1	Ciprofloxacin - HCL 500 mg tabs	10's	29.00	423.86	393.00	2352.35	1185.70
2	Norfloxacin 400 mg tabs	10's	20.70	168.71	130.63	1843.66	304.78
3	Ofloxacin 200 mg tabs	10's	40.00	249.30	204.34	1973.79	818.30
4	Cefpodoxime Proxetil 200 mg tabs	6's	114.00	357.32	264.00	1576.58	773.21

# Affordable Prices

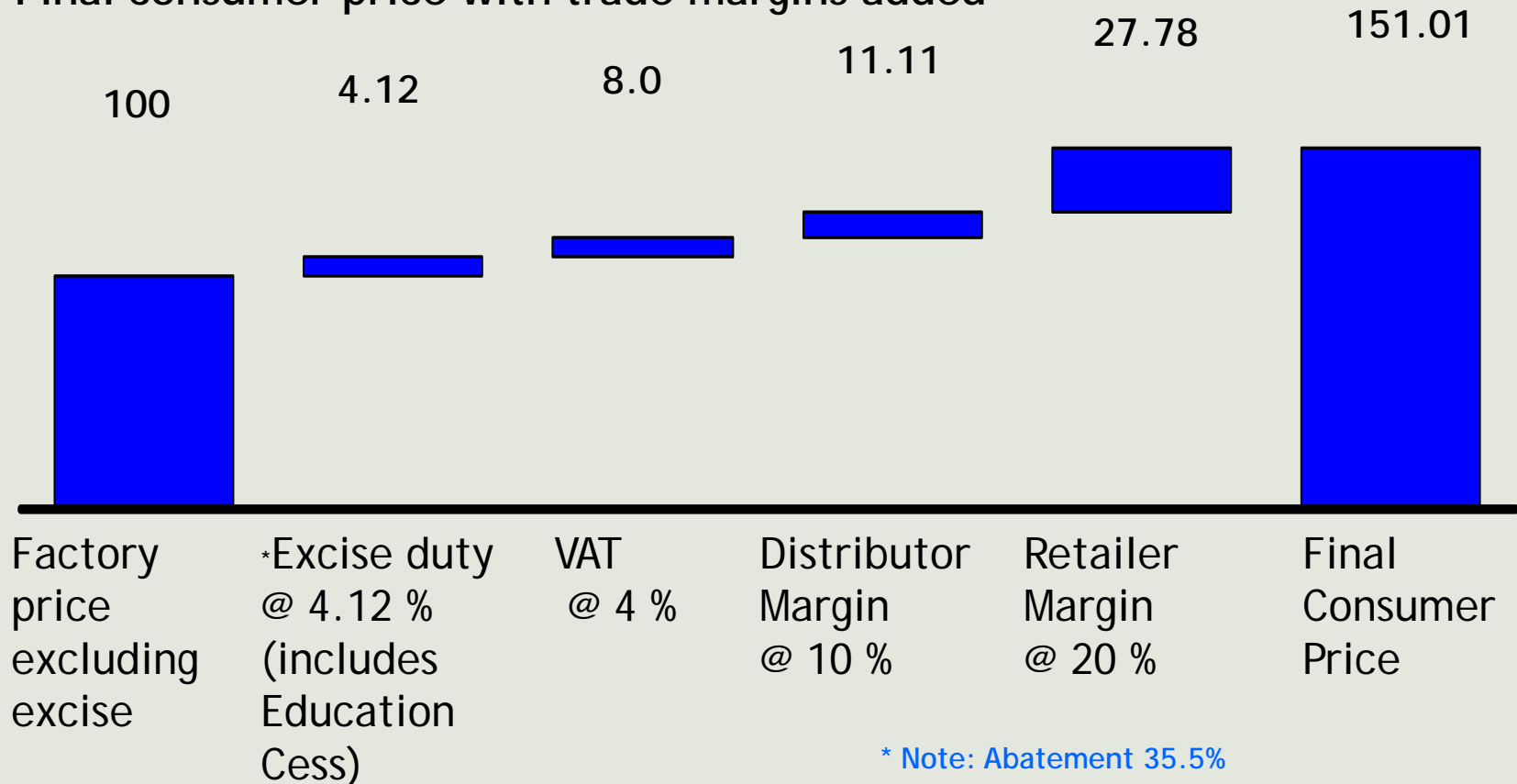
More affordable than in neighbouring countries

contd...

	Drugs, Dosage form and Strength	Pack	Prices in India (INR)	Prices in Pakistan (INR)	Prices in Indonesia (INR)	Prices in USA (INR)	Prices in UK (INR)
<b>II. NSAIDS</b>							
1	Diclofenac Sodium 50 mg tabs	10's	3.50	84.71	59.75	674.77	60.96
<b>III. ANTI-ULCERANTS</b>							
1	Ranitidine 150 mg tabs	10's	6.02	74.09	178.35	863.59	247.16
2	Omeprazole 30 mg Caps	10's	22.50	578.00	290.75	2047.50	870.91
3	Lansoprazole 30 mg Caps	10's	39.00	684.90	226.15	1909.64	708.08

# High Transaction Costs Inflate the Final Price

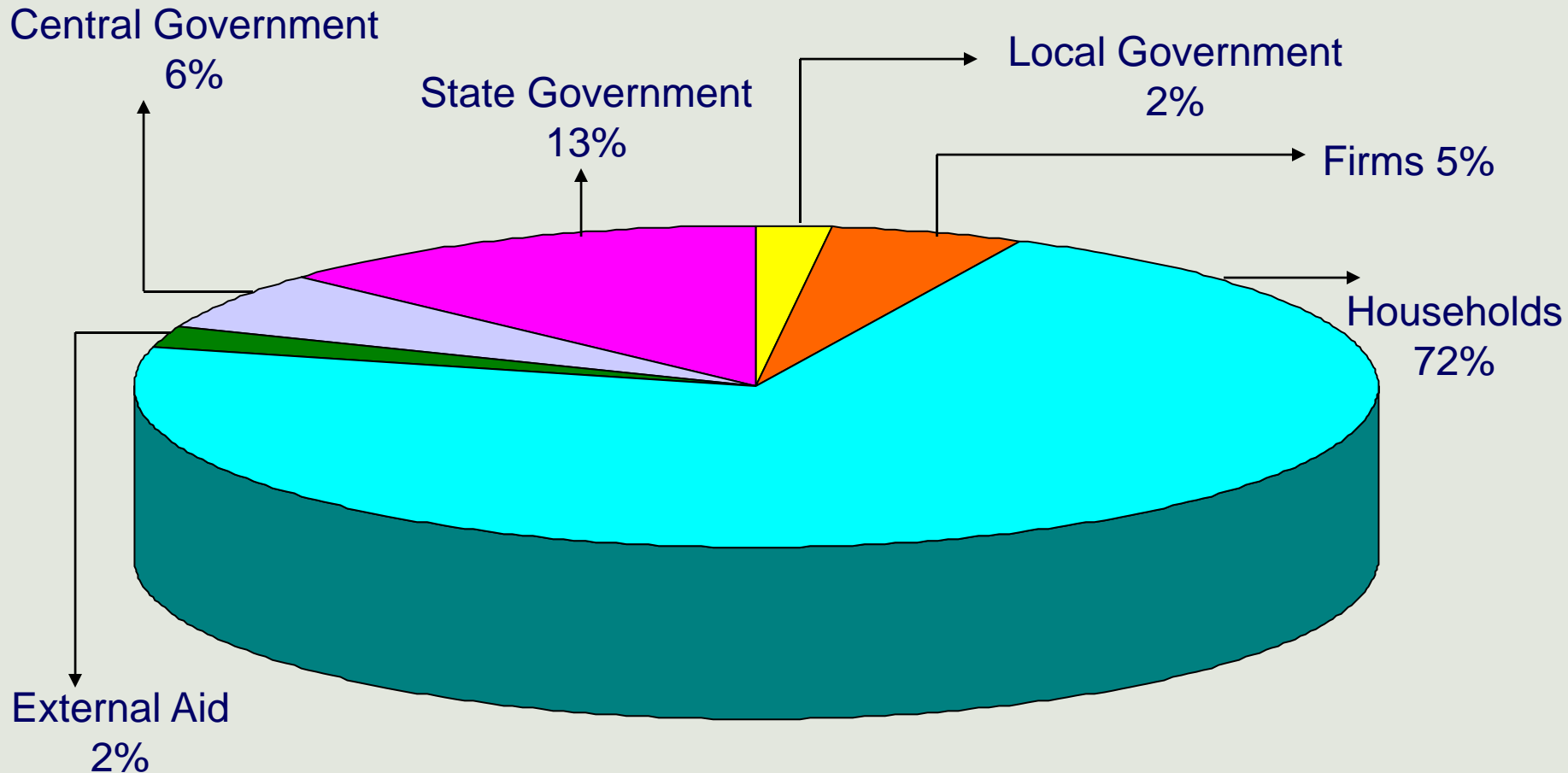
Final consumer price with trade margins added



Customs duty borne by manufacturer is not reflected

# Source of Financing Healthcare Services in India

## Proportion of Health Expenditure by Financing Source



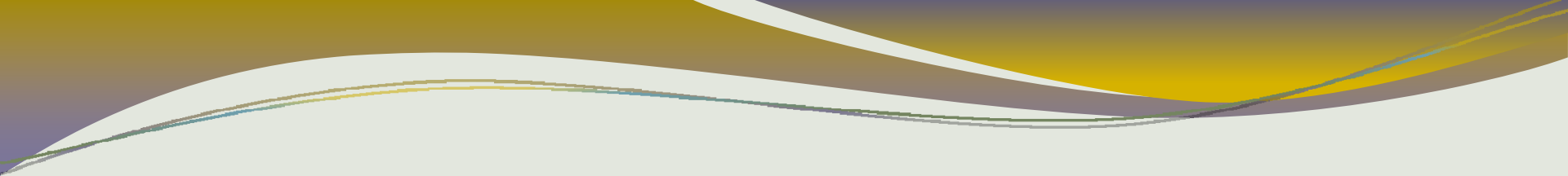
Source: National Health Accounts – 2001-02, MoHFW, GoI

# Recent Healthcare Financing Initiatives

Public	Private	Public Private Partnership
<ul style="list-style-type: none"><li>• Rajiv Gandhi Shilpi Swasthiya Bhima Yojana (RGSSBY) for weavers run by Textile Ministry</li></ul>	<ul style="list-style-type: none"><li>• Karnataka Yeshavini Co-operative Farmers' Health Insurance Scheme run by Dr. Devi Shetty without any insurance tie-up</li></ul>	<ul style="list-style-type: none"><li>• Rajiv Aarogyasri by the Government of AP for BPL population (Government , Private Insurance &amp; Medical Community)</li></ul>
<ul style="list-style-type: none"><li>• Rashtriya Swasthiya Bima Yojana (RSBY) for families below BPL</li></ul>	<ul style="list-style-type: none"><li>• Tata Steel invited Dr. Shetty for similar scheme at Jamshedpur</li></ul>	
<ul style="list-style-type: none"><li>• Niramaya by Ministry of Social Justice &amp; Empowerment for BPL families</li></ul>		

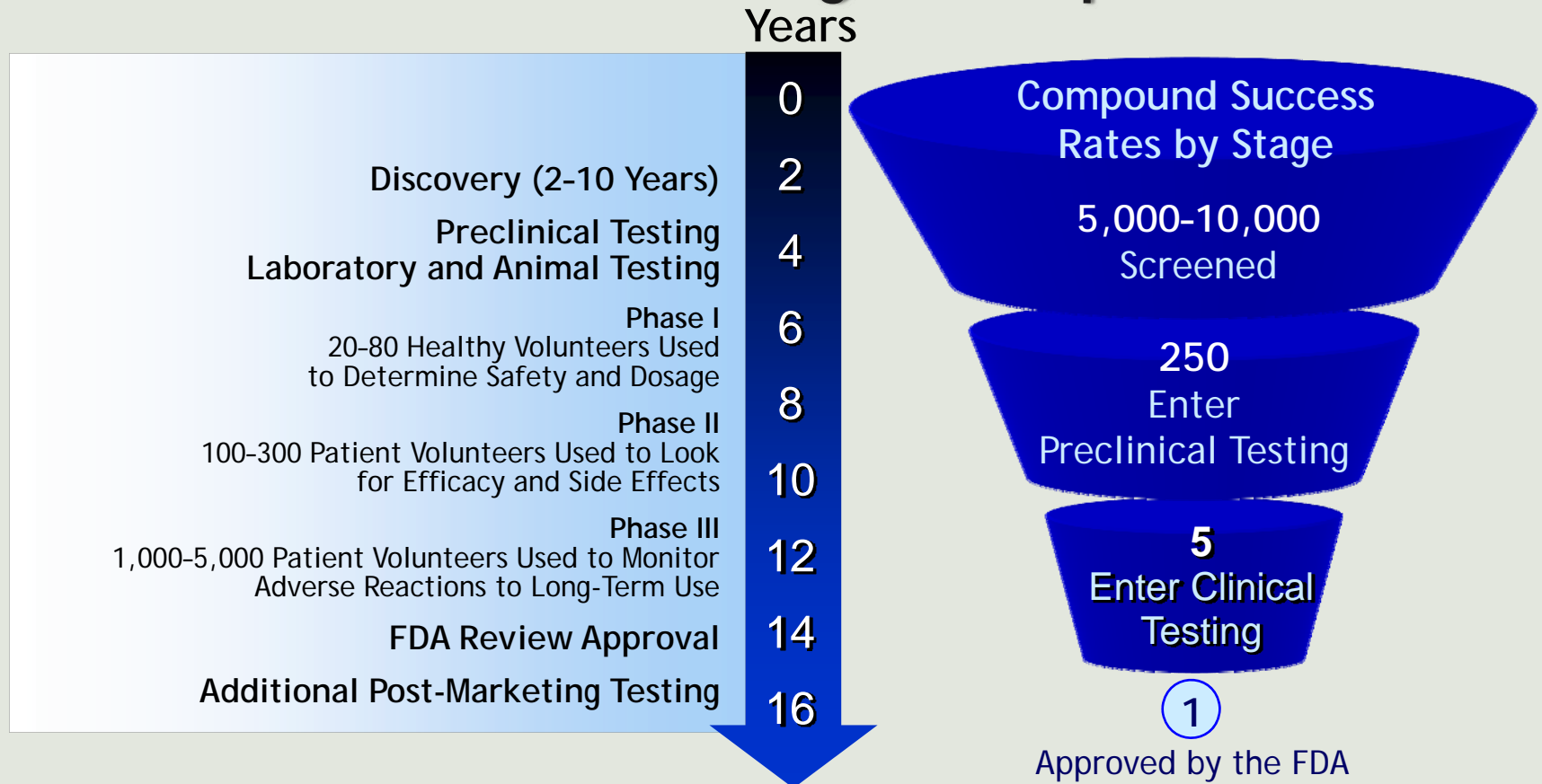
# Global Pharmaceutical Industry - Emerging Scenario

- ❖ Growth slowing down
- ❖ Research pipeline is gradually getting dry
- ❖ US \$ 47 Bn going for patent
- ❖ Penetration of Generics
- ❖ Reduction in Drug approval from US FDA
- ❖ High new Drug development costs



Innovation through R&D  
is the life blood  
of the Pharmaceutical Industry  
to meet the unmet needs of  
ailing patients.

# New Product Development is Risky, Time-consuming and Expensive

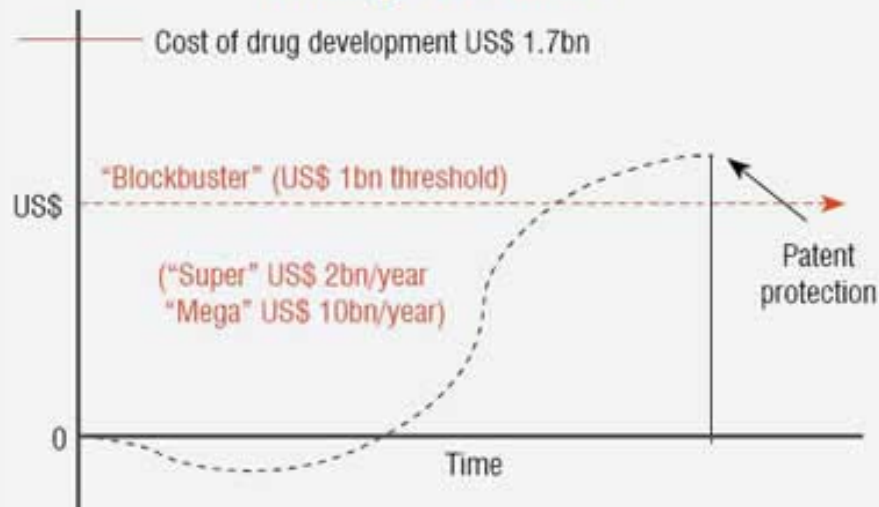


***Cost to Develop New Biotech Products Is Estimated to Average \$1.2 – 1.7 Bn***

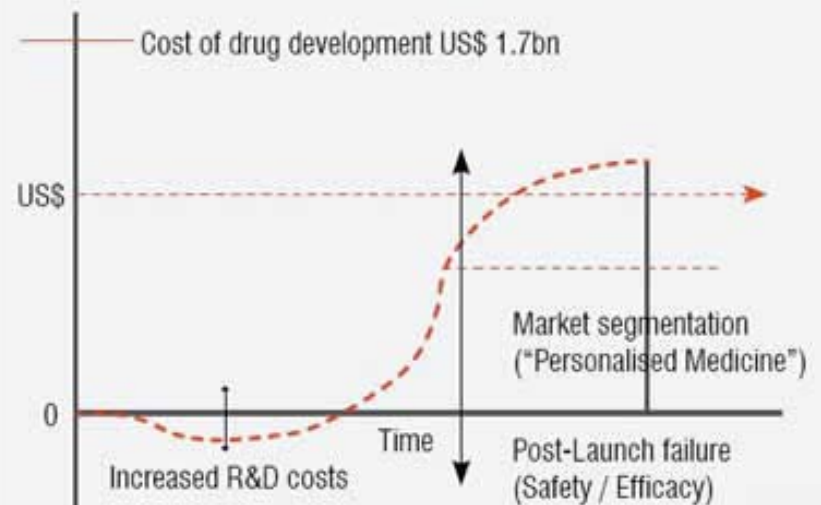


# R & D And Challenges

## Defining a "Blockbuster"



## Challenges



# High Dependence On Blockbuster Drugs

Company	Product Name	Therapeutic Class	Global Turnover (€ Bn)	% Product Share of Company Turnover (Global)
Pfizer	Lipitor (atorvastatin calcium)	Cardiovascular System	9.25	30
GSK	Seretide/Advair (fluticasone + salmeterol)	Respiratory System	5.11	18
Johnson & Johnson	Risperdal (risperidone)	Nervous System	6.23	35
Sanofi-Aventis	Clopidogrel (clopidogrel)	Blood & Blood Forming organs	2.42	9
Hoffmann-La Roche	Herceptin (trastuzumab)	Antineoplastic and Immunomodulating agent	2.95	13
Nycomed	Pantoprazole (pantoprazole)	Alimenatry Tract & Metabolism	1.68	55
Wyeth	Enbrel (etanercept)	Antineoplastic and Immunomodulating agent	1.49	13
Johnson & Johnson	Eprex (epoetin alfa)	Blood & Blood Forming Organs	1.64	9
Eli Lilly	Zyperxa (olanzapine)	Nervous System	3.47	27
Novartis	Glivec (imatinib)	Antineoplastic and Immunomodulating agent	2.23	13
Total/Average			36.47	19

# R & D

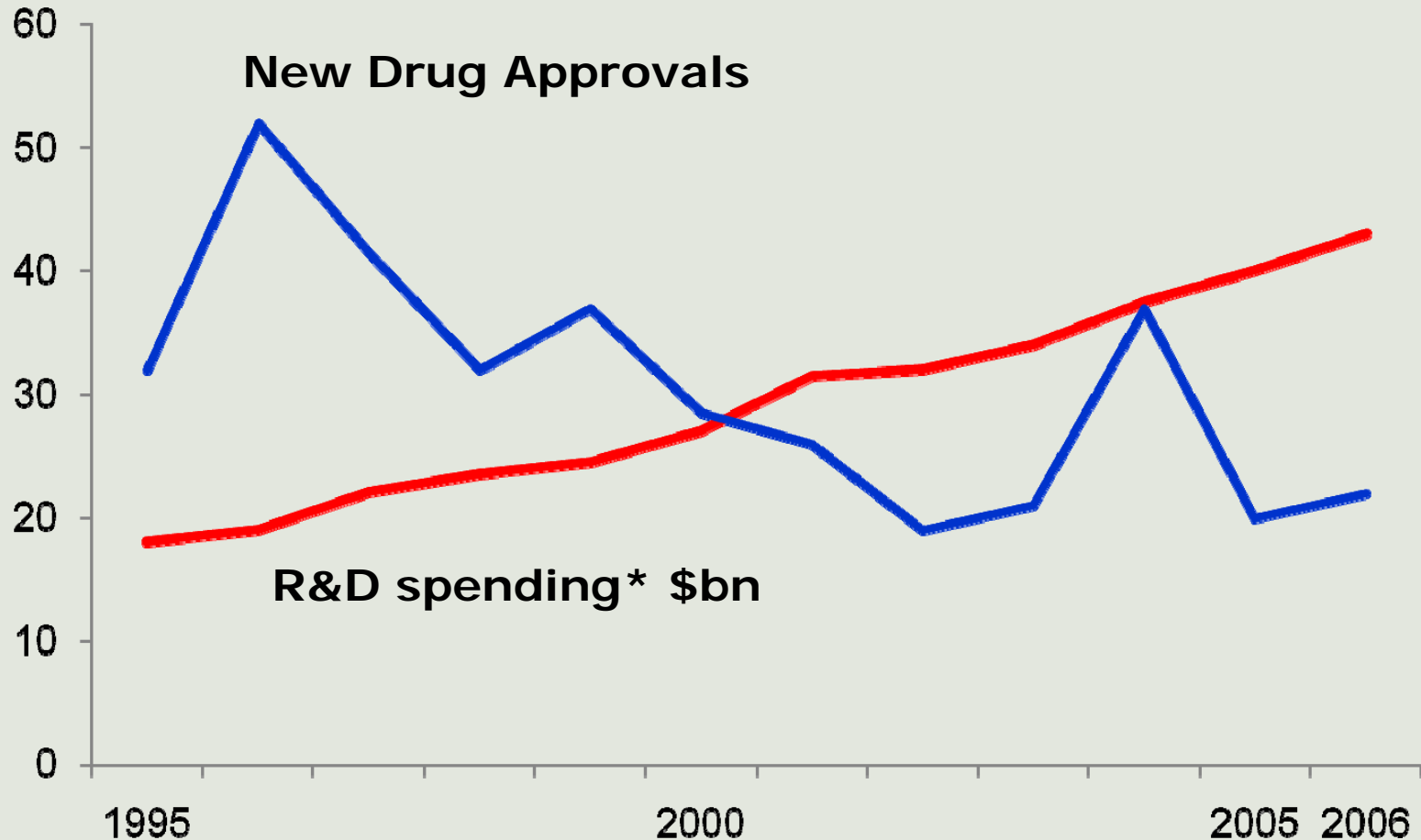
## - Key Challenge

A drug may be withdrawn even after achieving Blockbuster status on various issues like:

- ❖ Vioxx (MSD) – U.S.\$ 2.5 Bn/Yr – Super Blockbuster – was pulled from the market on safety issues
- ❖ Subsequently led to U.S.\$ 5 Bn settlement of legal proceedings from patients
- ❖ The stock value of MSD came down from U.S.\$ 44 / share to U.S.\$ 28 /share immediately post-withdrawal

# R&D Pipeline Running Dry

North American Pharmaceutical Firms\*



\*Pharmaceutical Research & Manufacturers of America Companies only



# Prevention is on the Rise

- ❖ Focus on R&D on preventive vaccines and immunization
- ❖ Opportunity for Indian vaccines manufacturers

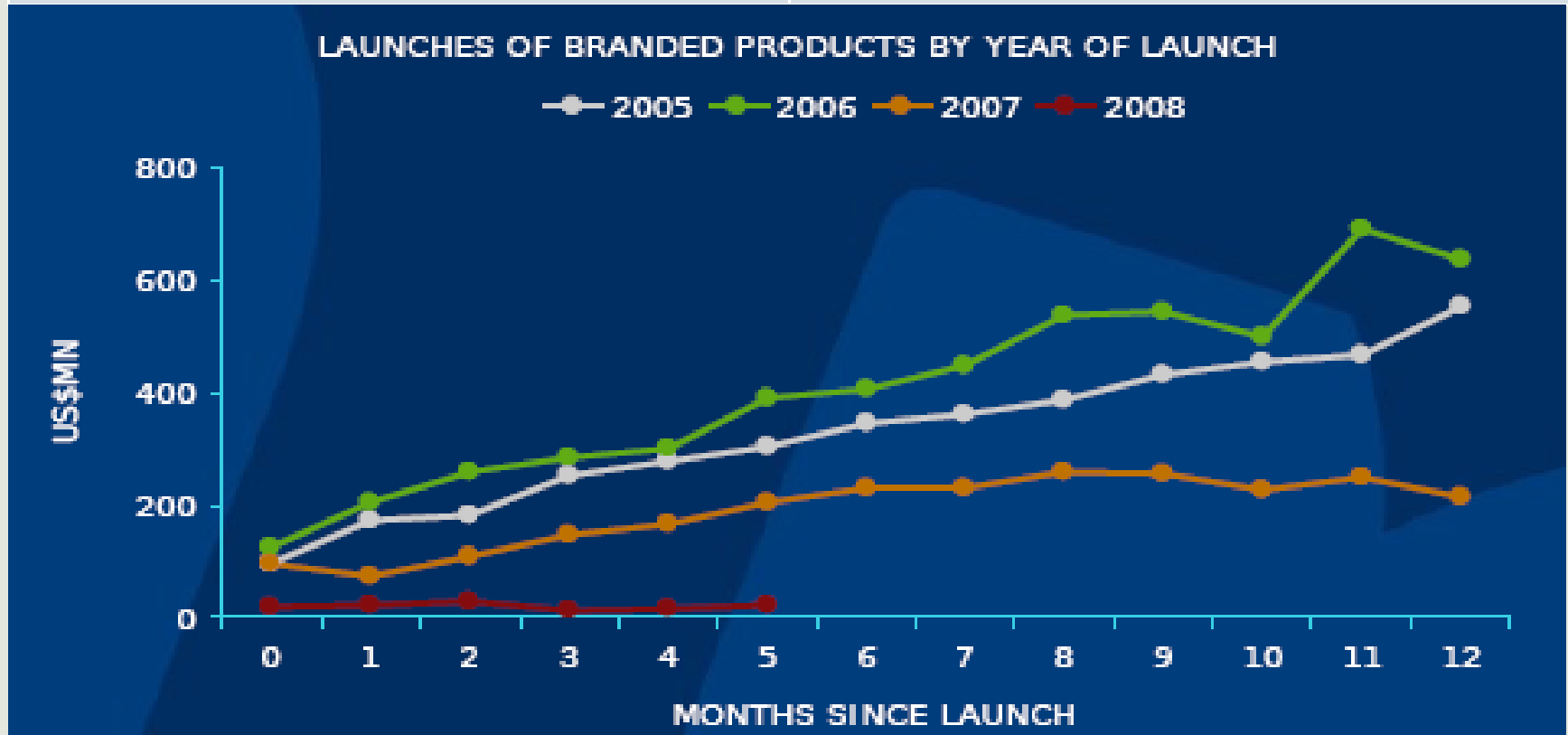
# Less Contribution From New Launches

## New Reality

- Less growth contribution from innovation

## New Opportunities

- Steady increases in the number of Phase I and II products



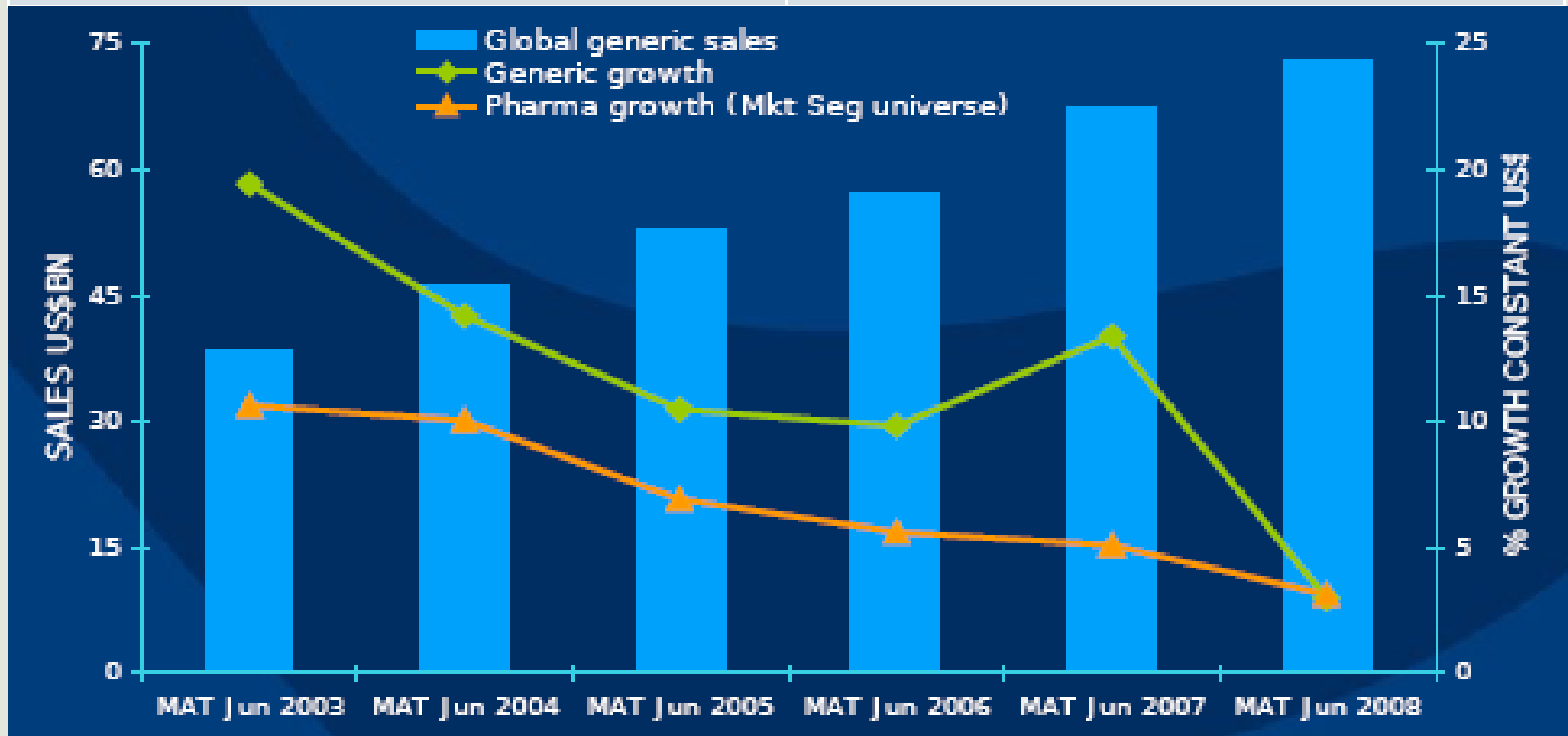
# Growing Generics Market : An Attraction

## New Reality

- Generics volume penetration increases

## New Opportunities

- Potential source of funding for innovation

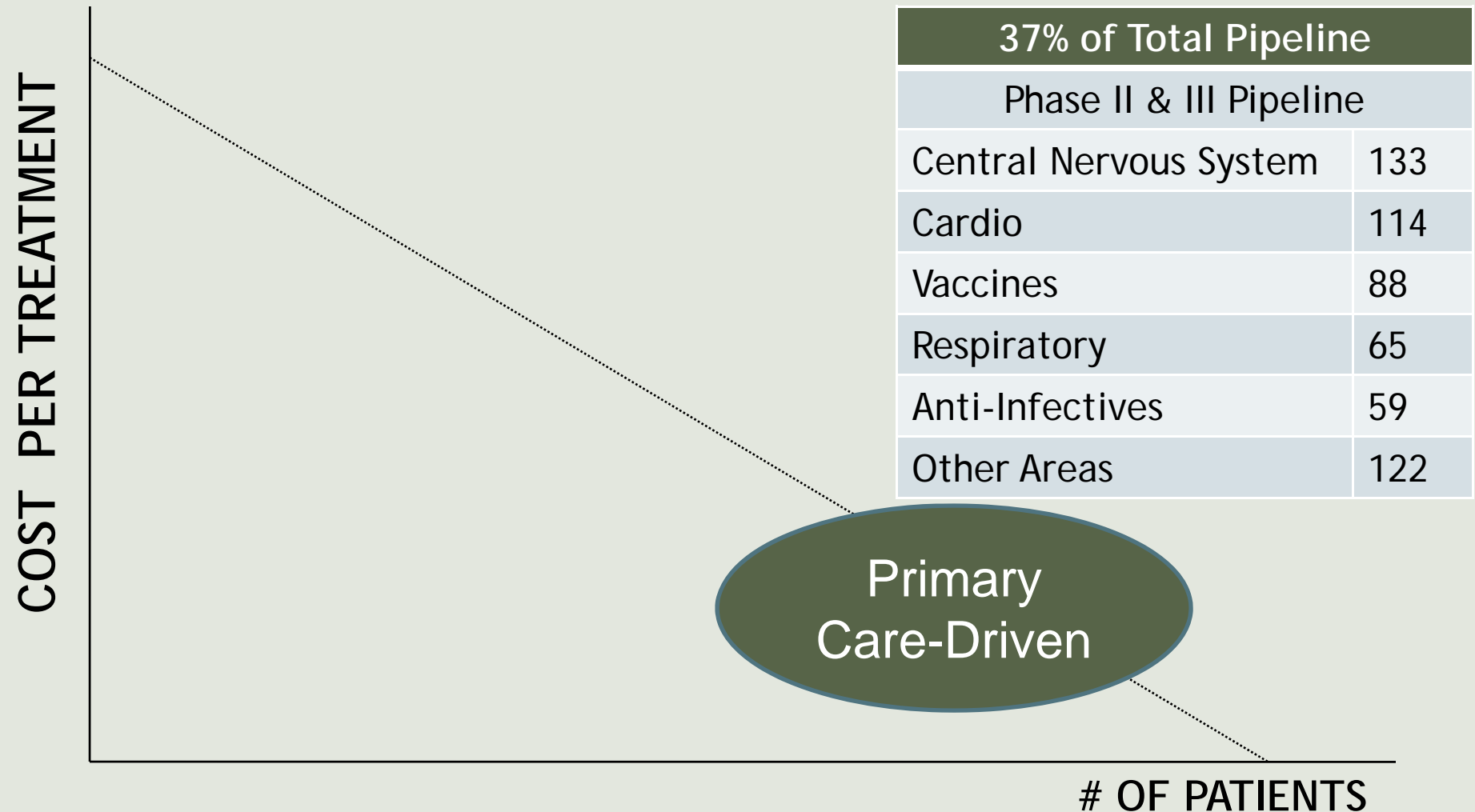


# Looking Ahead...

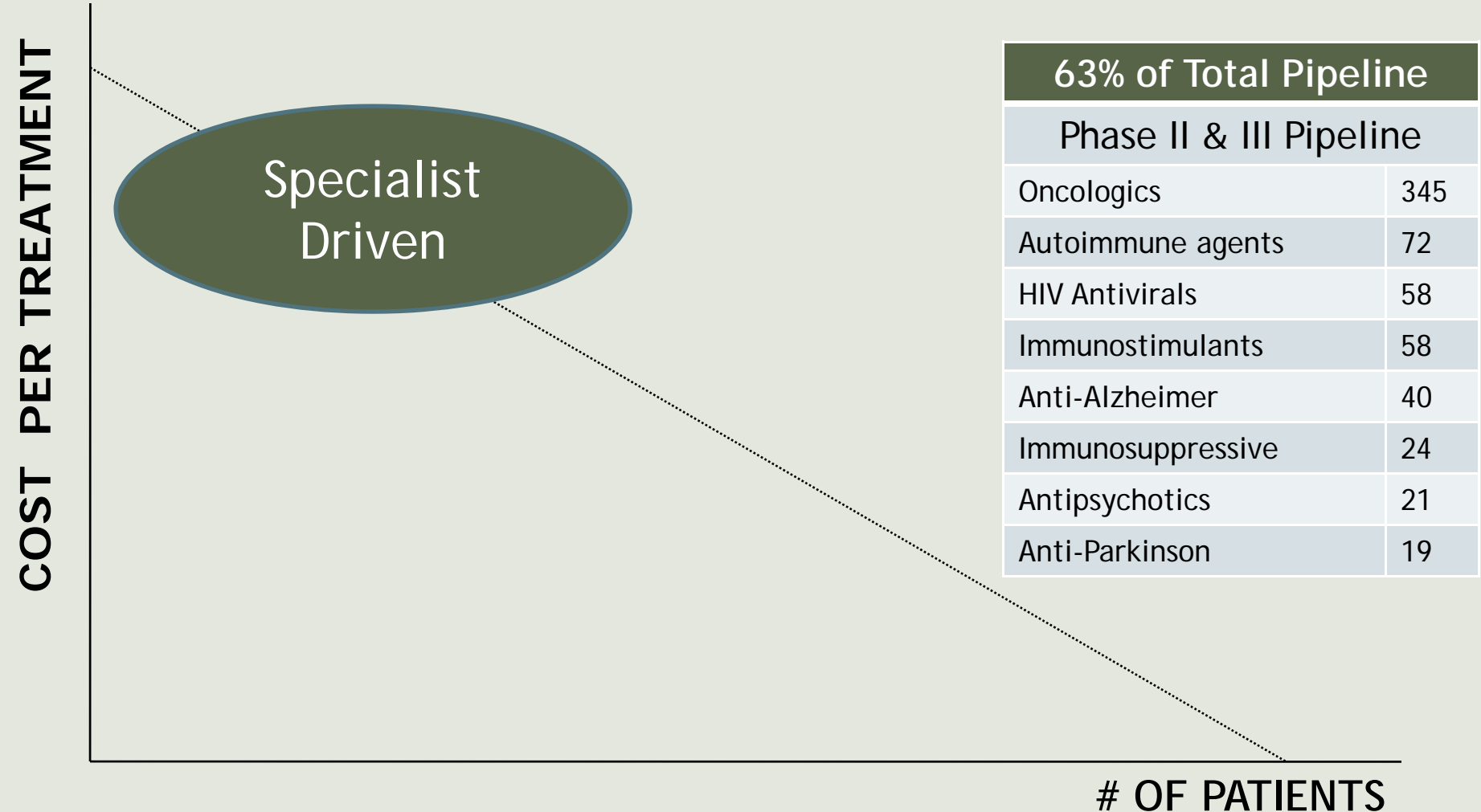
- ❖ **Growth opportunities exist**  
but not where they used to be
- ❖ **Business models need adjusting**  
to account for the shifts in growth and achieve  
operational improvement
- ❖ **A new wave of innovation approaches**  
... with implications on all health care systems



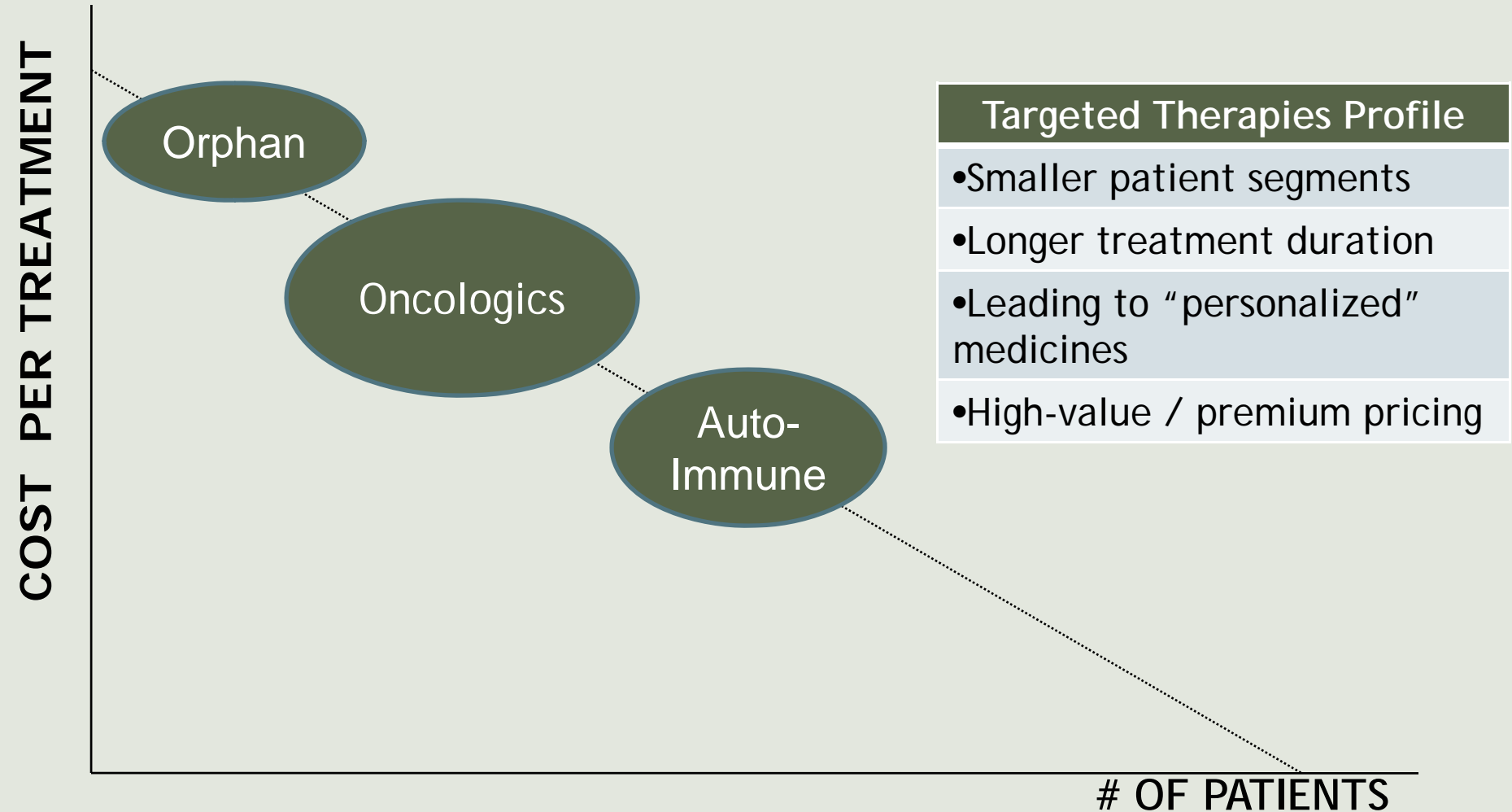
# Portfolio of Late Stage Development



# Portfolio of Late Stage Development



# Portfolio for Targeted Therapies

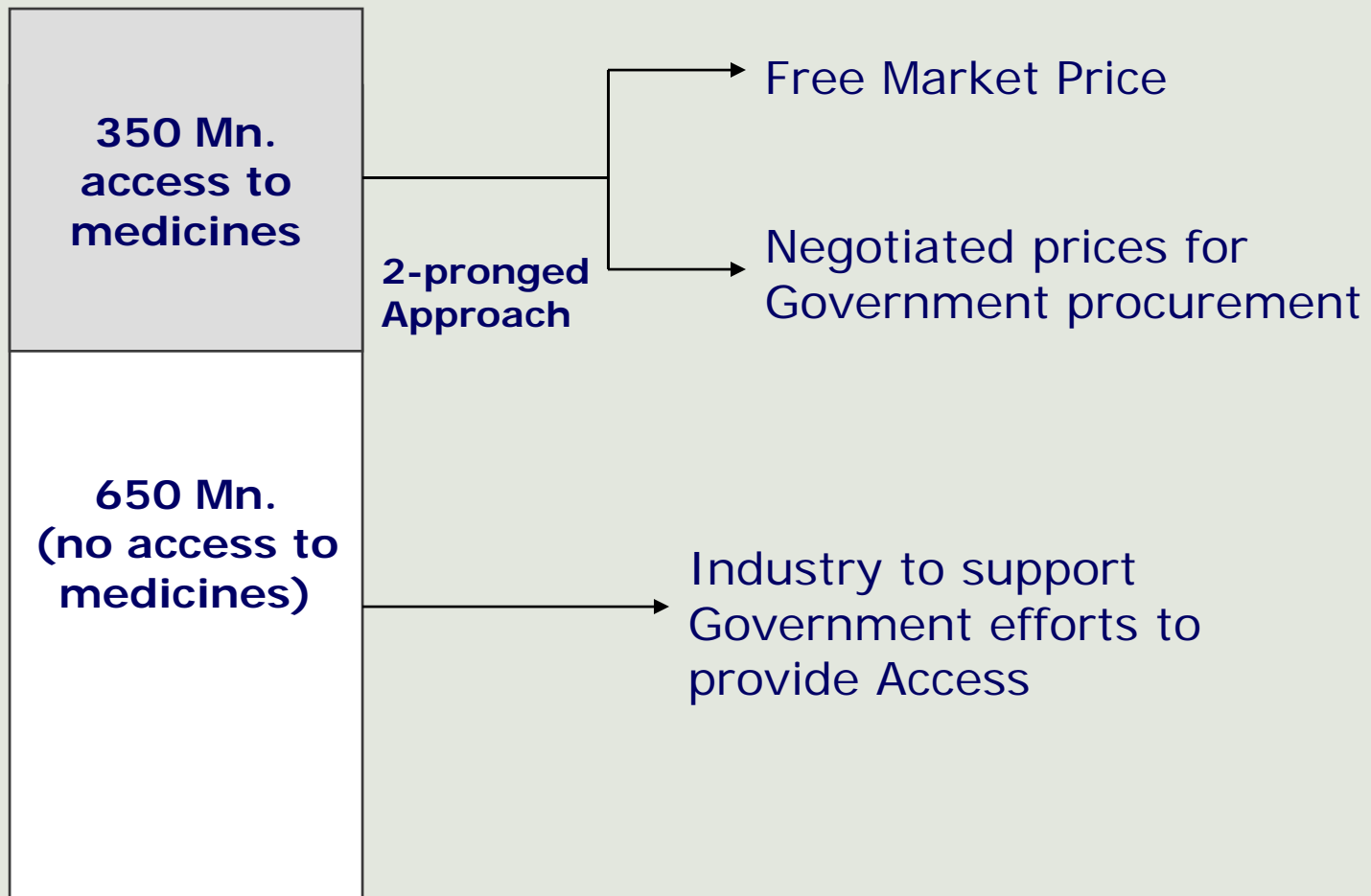


# Indian Pharmaceutical Industry - The Way Ahead



# The Way Ahead...

## Ensuring Access in Control-free Pricing Regime



# Key Growth Driver :Health Insurance

- ❖ Hasten reforms to attract players
- ❖ Mandatory insurance in organised sector
- ❖ Health insurance for farmers, labourers

## **Key Growth Driver : Increase in Health Awareness and Disposable Income**

- ❖ Increasing disposable income and awareness will drive the growth
- ❖ 150 million strong middle class have higher healthcare expectations
- ❖ 35 - 45 million Indians are estimated to be able to afford the best medicines

# Government :Changing Role

From Healthcare Provider To Healthcare Facilitator

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

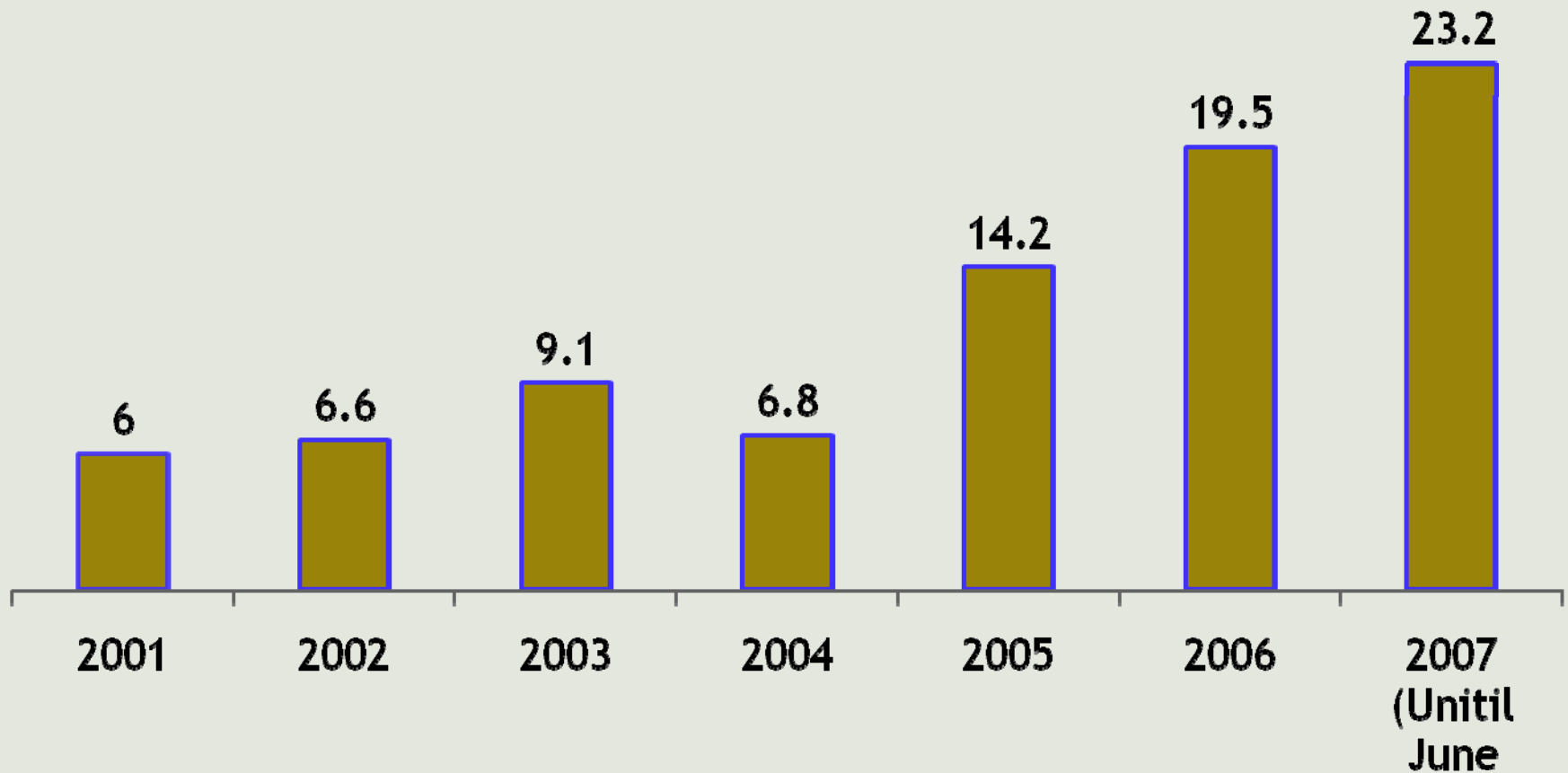
Source: India Trade Promotion Organisation (ITPO)



# Advantage India

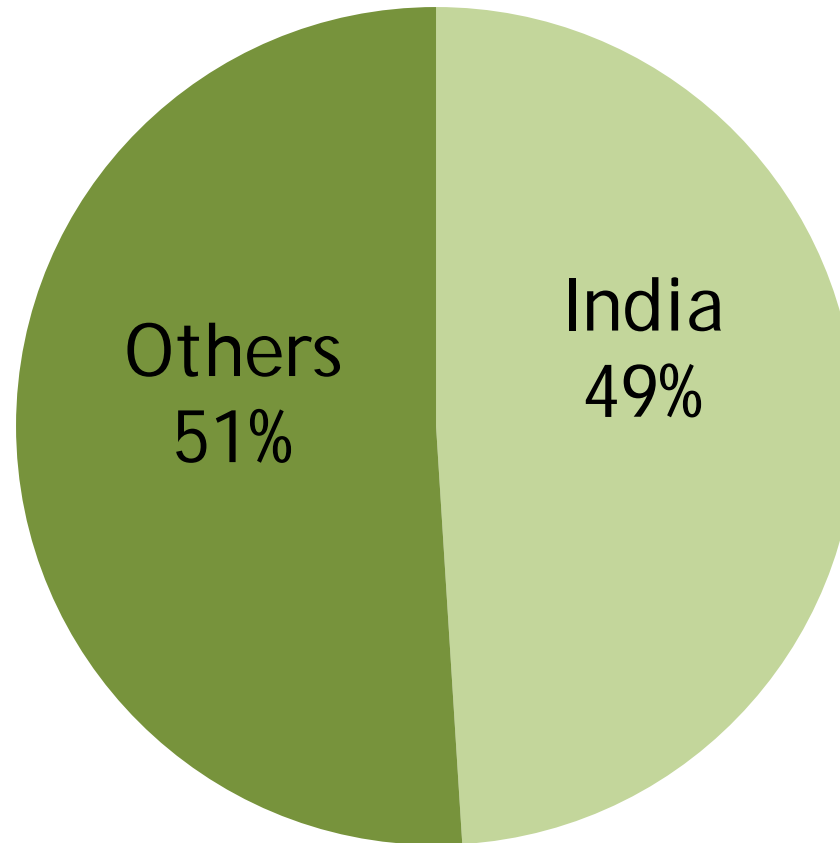


# Indian ANDA Approvals as % of Total

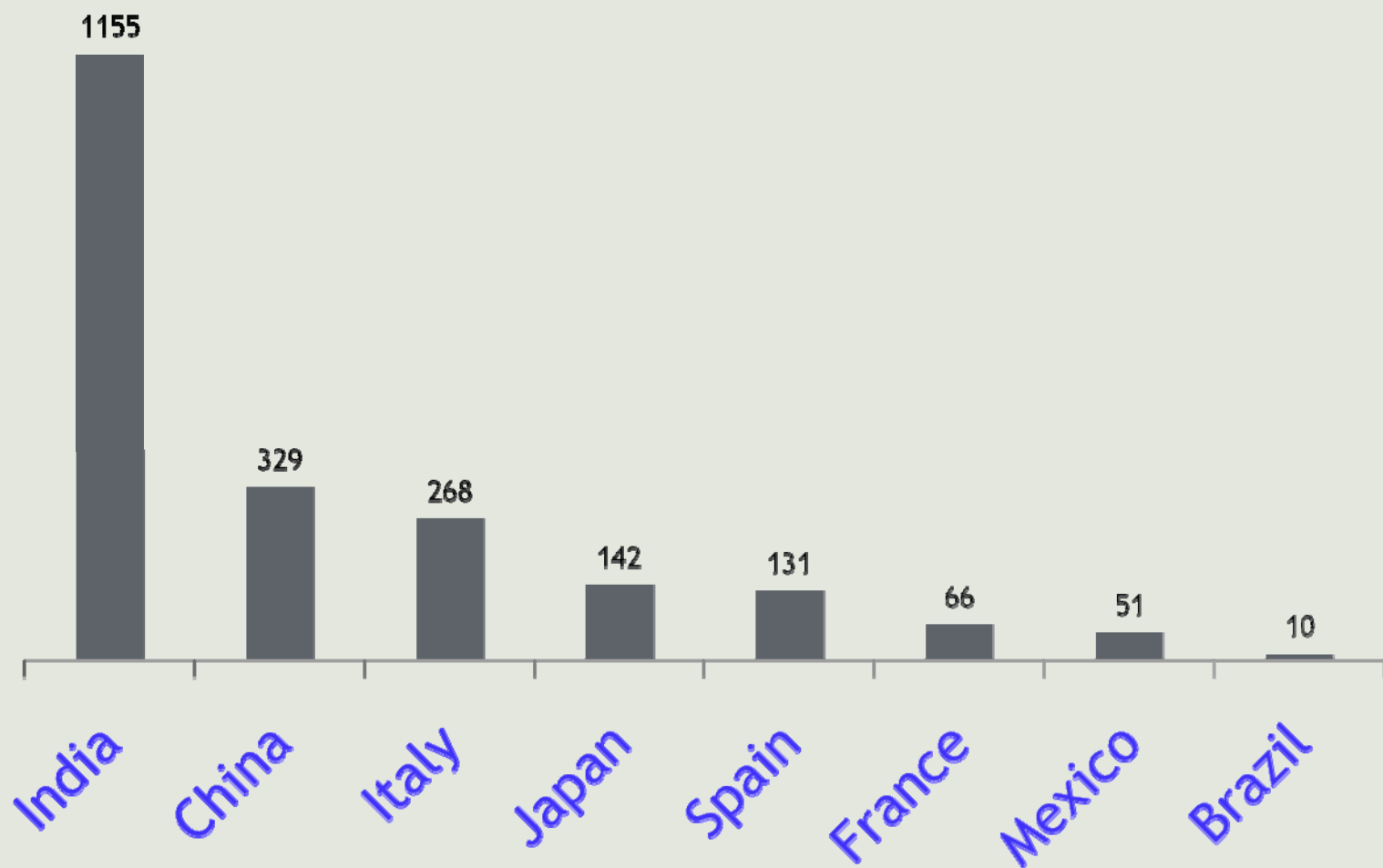


# Indian DMFs vs. Other Countries for 2007

Until June



# Country-wise DMF filings (2000 – June 07)

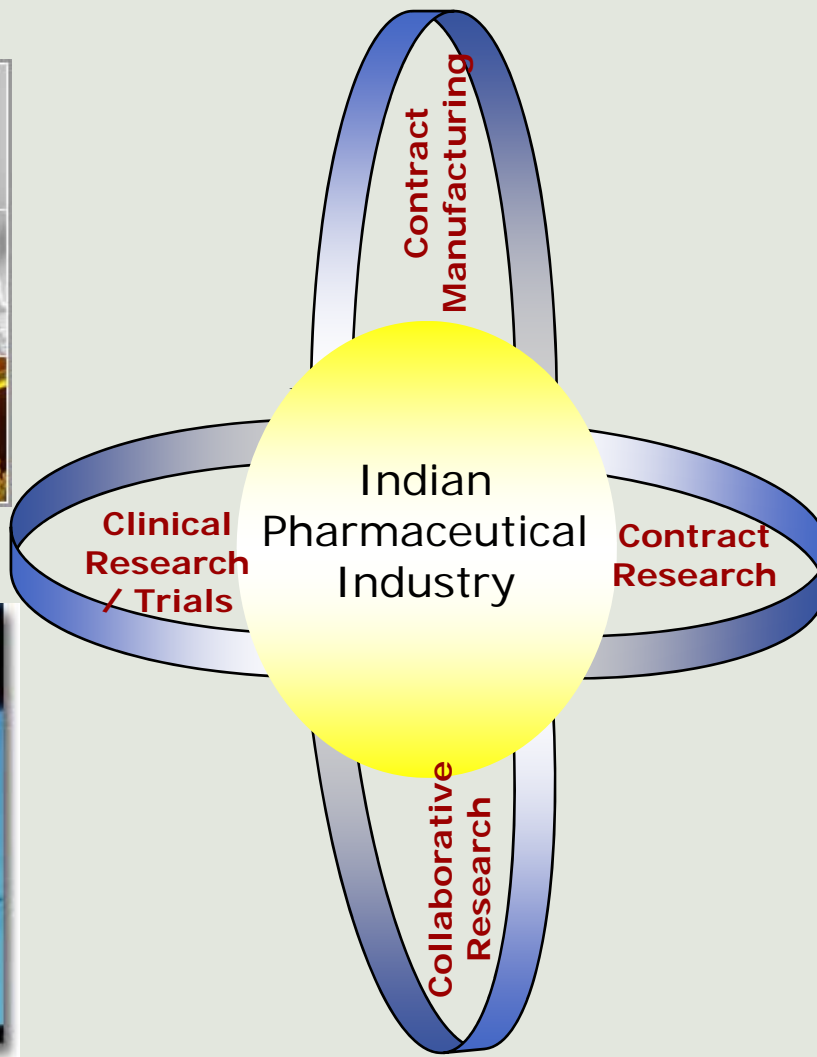


Source: Crisinfac Report Sept 2007

# R&D - Indian Pharmaceutical Companies

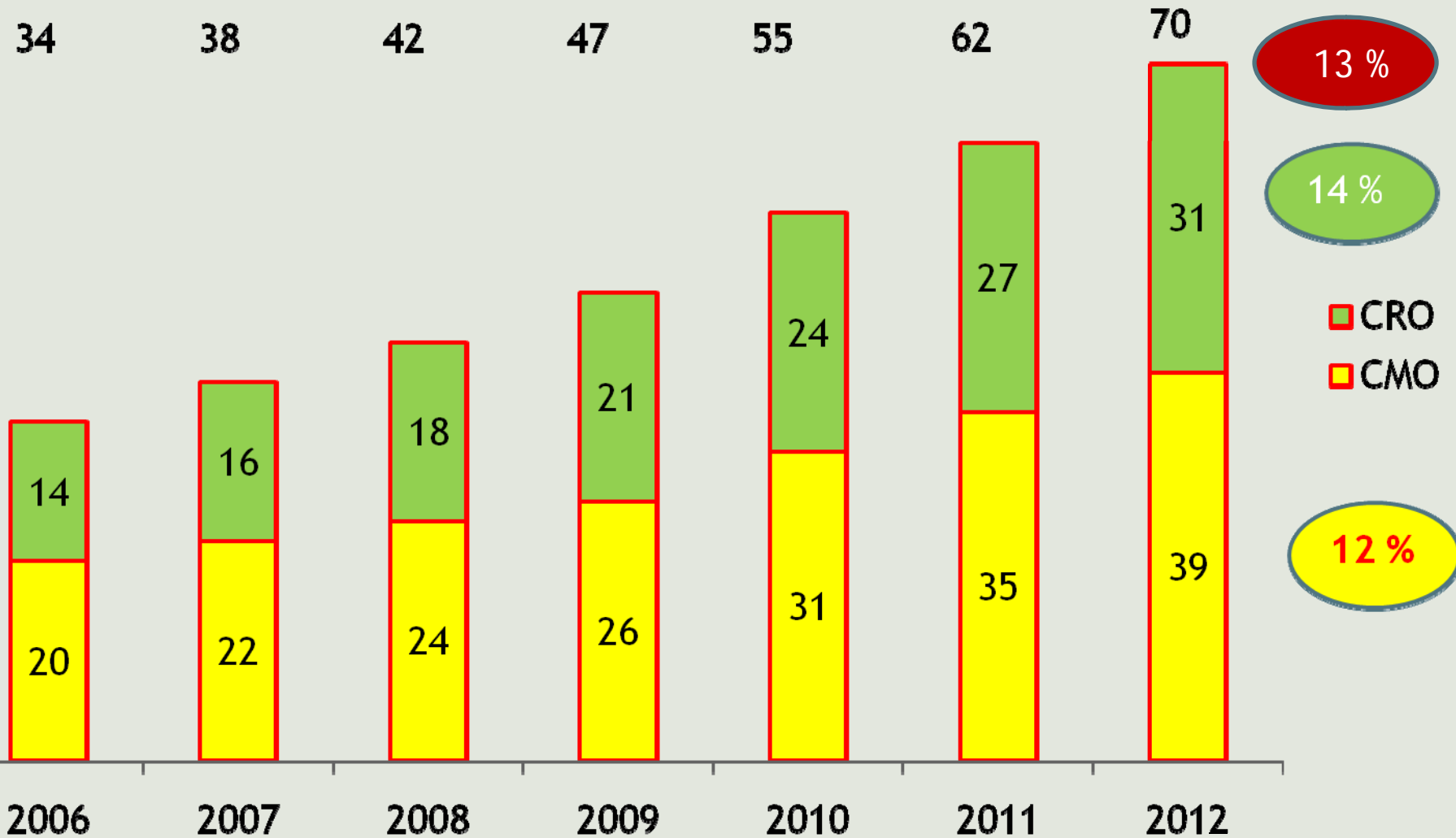
Company	NCE Pipeline	Key Therapeutic Area
Biocon	Preclinical - 2 Phase II - 2 Phase III - 1	Inflammation, Oncology, Diabetes
Piramal Healthcare	13 Compounds in Clinical Trials	Oncology, Infectious Diseases, Diabetes, Inflammation
Glenmark	Discovery - 4 Preclinical - 5 Phase I - 1 Phase II - 3	Metabolic Disorders, Dermatology, Inflammation
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

# Key Opportunity Segments



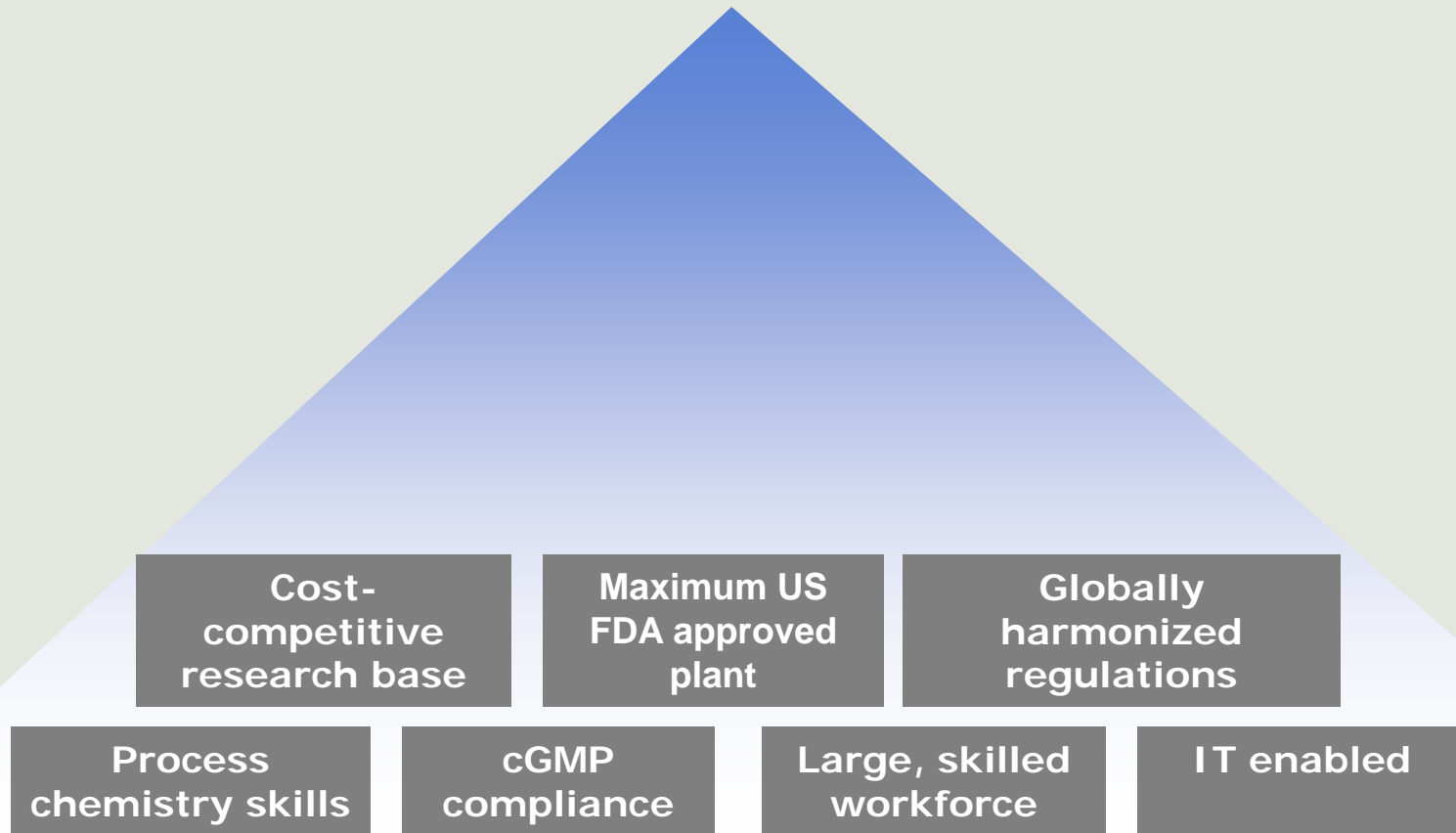
# Global CRAMS Market

USD Bn.



Source: KPMG-CII 2007 India Pharma Report

# Crams Opportunities -India





# Cost-Competitiveness - A Key Advantage



# Policy Initiatives



- ❖ The Patents(Third Amendment) Act, 2005
- ❖ Revision of Schedule Y to permit conduct of phase II-IV clinical trials in India
- ❖ Amendment of Schedule M to make industry compliance to Good Manufacturing Practices
- ❖ Stringent measures for makers of spurious drugs
- ❖ Creation of pharma R&D fund with a total corpus of US\$ 33.3 million
- ❖ Concessional Industrial Package for pharmaceutical manufacturers in certain hilly states
- ❖ Constitution of India Pharmacopoeia Commission

# Global Pharmaceutical Industry

## – Five Micro trends with a potential to become Mega Trends

- ❖ High Risk R&D – reducing risks by spreading business into low risk generic medicines
- ❖ Only Rx Pharmaceuticals – Generics, OTC, Nutrition, Diagnostics, Animal Health etc.
- ❖ Focus on top 10 markets of the world – Focus on emerging markets
- ❖ Disease type focus: Infectious – chronic – preventive (vaccines) – personalized medicines
- ❖ From “Making to Buying” :

**WILL THE BALL GAME BE QUITE DIFFERENT TOMORROW?**