

INDIAN PHARMACEUTICAL INDUSTRY – AN EVOLVING SCENARIO

Tapan Ray

August 30, 2008
NMIMS, Mumbai



The Indian Pharmaceutical Market , the Regulatory Thinking, and Challenges facing the Pharma industry

Content

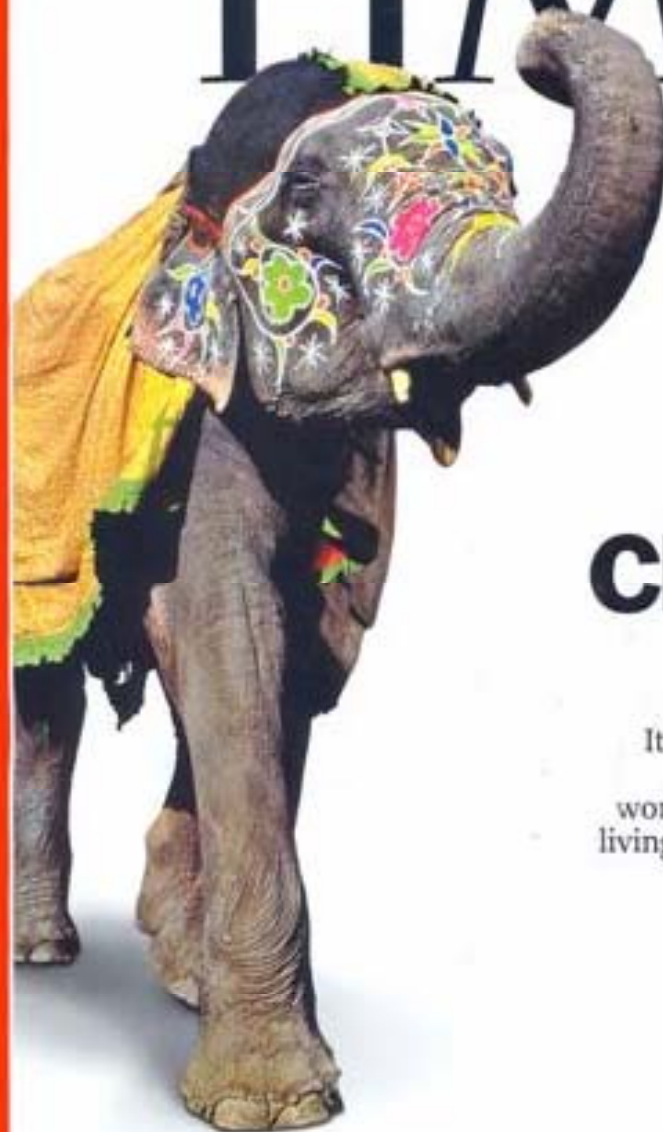
- ❖ Economic and Healthcare Scenario of India
- ❖ National Healthcare Policy of India – has it delivered?
- ❖ IPR Scenario in India & Indian Patents Act 2005
- ❖ Advantage India and the Way Forward

Economic & Healthcare Scenario of India

AUGUST 13, 2007

SPECIAL REPORT: 60 YEARS OF INDEPENDENCE

TIME



India **Charges** **Ahead**

It faces challenges the size
of an elephant, but the
world's largest democracy is
living up to the dreams of 1947



30

Facts About India

Land Area	2% of World Area
Burden of Disease	21% of Global Disease Burden
Population	16% of World's Population
Urban : Rural	28 : 72
Literacy Percentage	65.38%
Poverty Percentage	Below poverty line: 26%
Poverty Line (U.S.\$)	Rural : U.S.\$ 500 Urban : U.S.\$ 900

Source: WHO, India

Selective Economic Indicators

	<u>1990-91</u>	<u>2007-08</u>
Real GDP	US\$ 48 billion	US\$ 1174 billion
GDP Growth	5.3%	8.7%
ForEx Reserv.	US\$ 1 billion	US\$ 290 billion
FDI	US\$ 0.36 billion	US\$ 15.7 billion
Inflation	10.3%	5.5%*

Global Pharmaceutical Market - 2007

Value: US\$ 663.5 billion

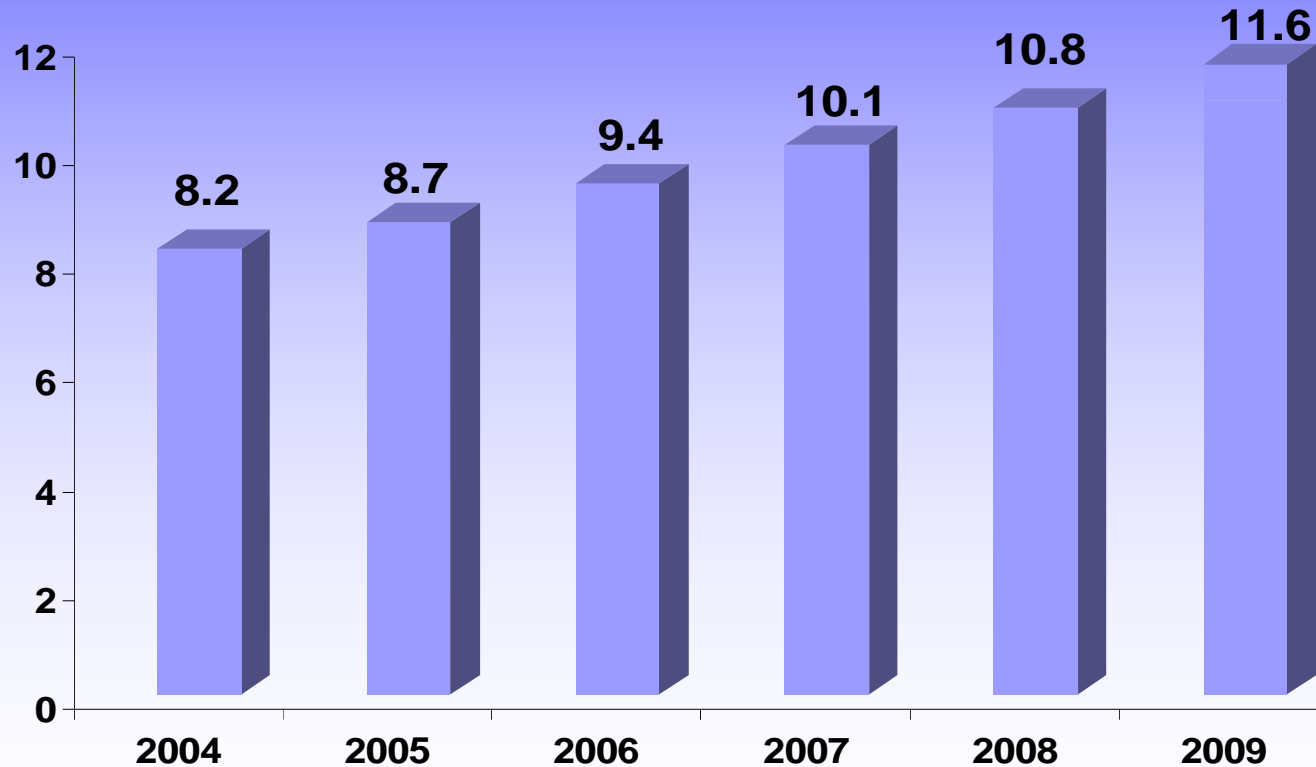
Growing at 6.1%

Indian Pharmaceutical Industry - 2007-08

- ❖ U.S.\$ 8 Bn. Domestic Sales
- ❖ U.S.\$ 5 Bn. Exports
- ❖ Highest number of U.S. FDA approved plants outside U.S.
- ❖ Ranks 4th in Volume & 14th in Value
- ❖ McKinsey projects U.S.\$ 20 Bn. by 2015

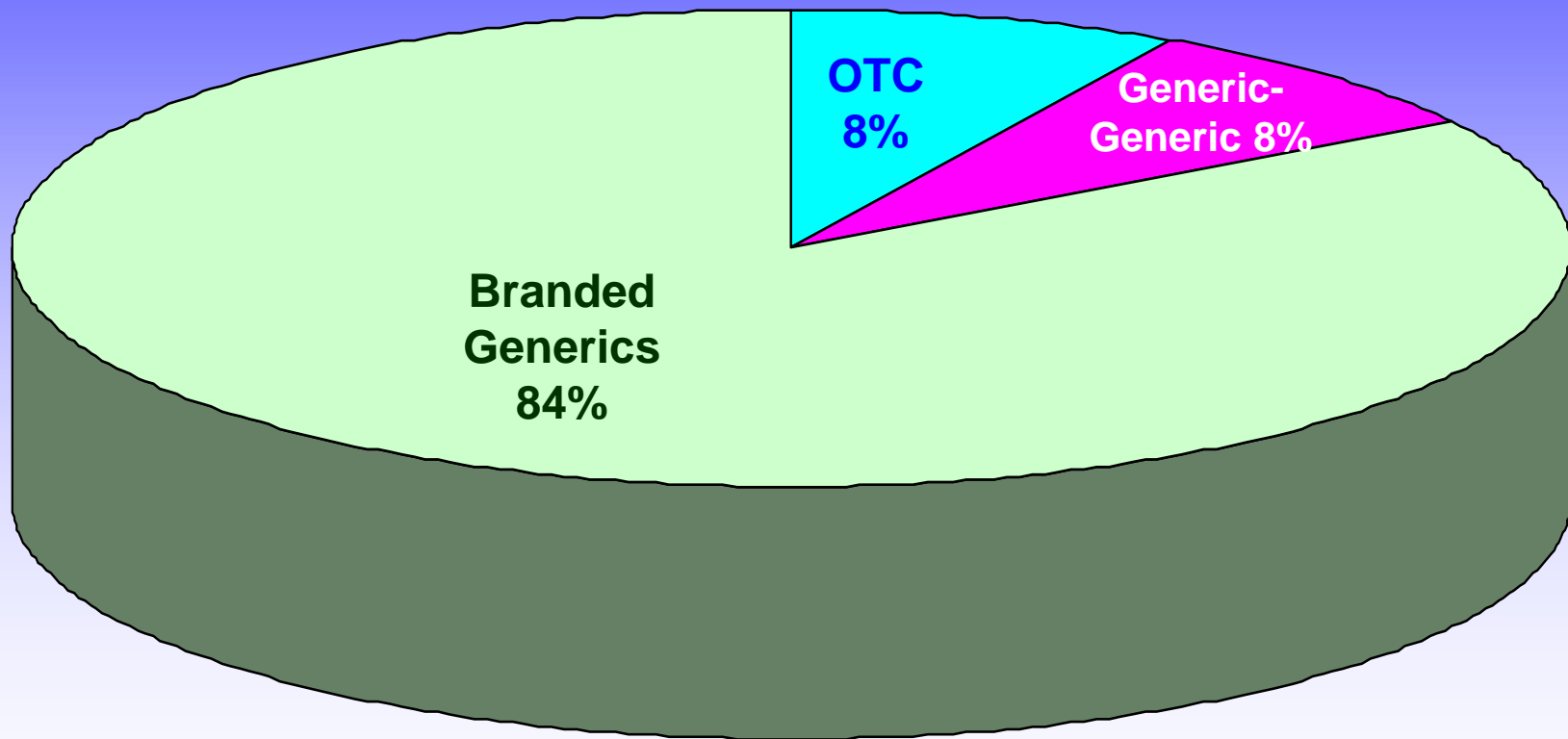
Indian Pharmaceutical Market - USD 11.6 Billion Opportunity

Projected Pharmaceutical Market 2009



Key Market Types - 2007

Market Size US\$ 7.5 Billion



Source : IMS Dec. 2007

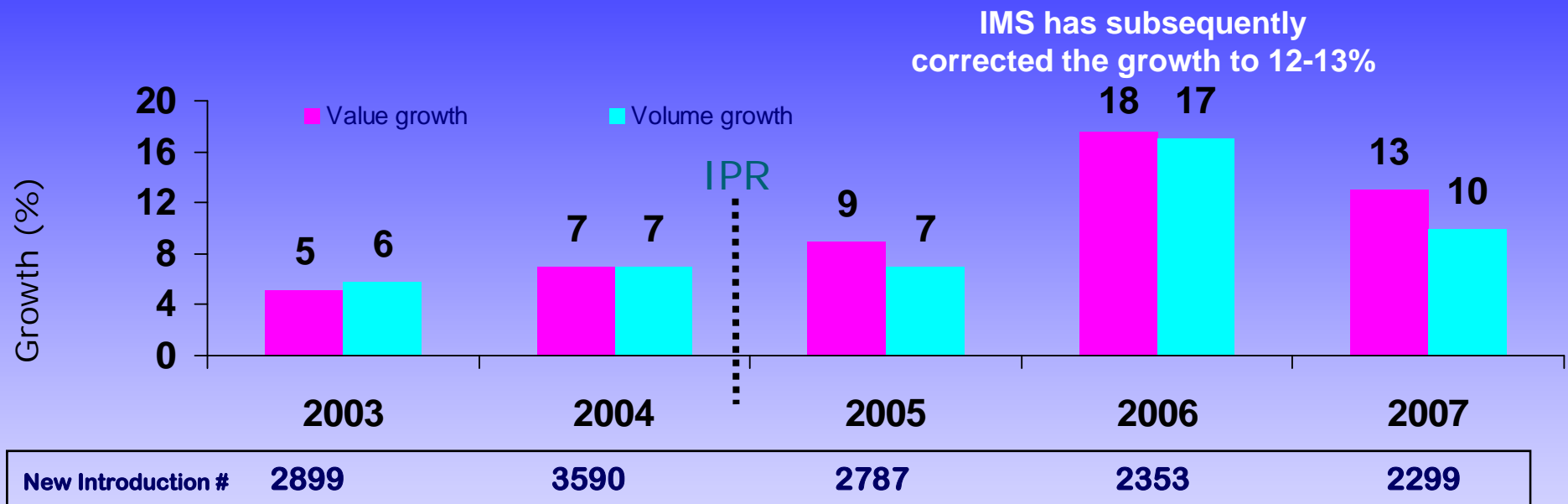
Reliance on Alternative Medicine

Heavy reliance on Indian system of medicine which is more accessible and viewed as 'one with no side effects'

70% of the population is believed to supplement or even replace drugs with traditional medicine



The Retail Market Recorded a Growth of 13% in terms of Value, the Highest Growth Performance witnessed in the Last decade



Increasing contribution to growth from Emerging Markets

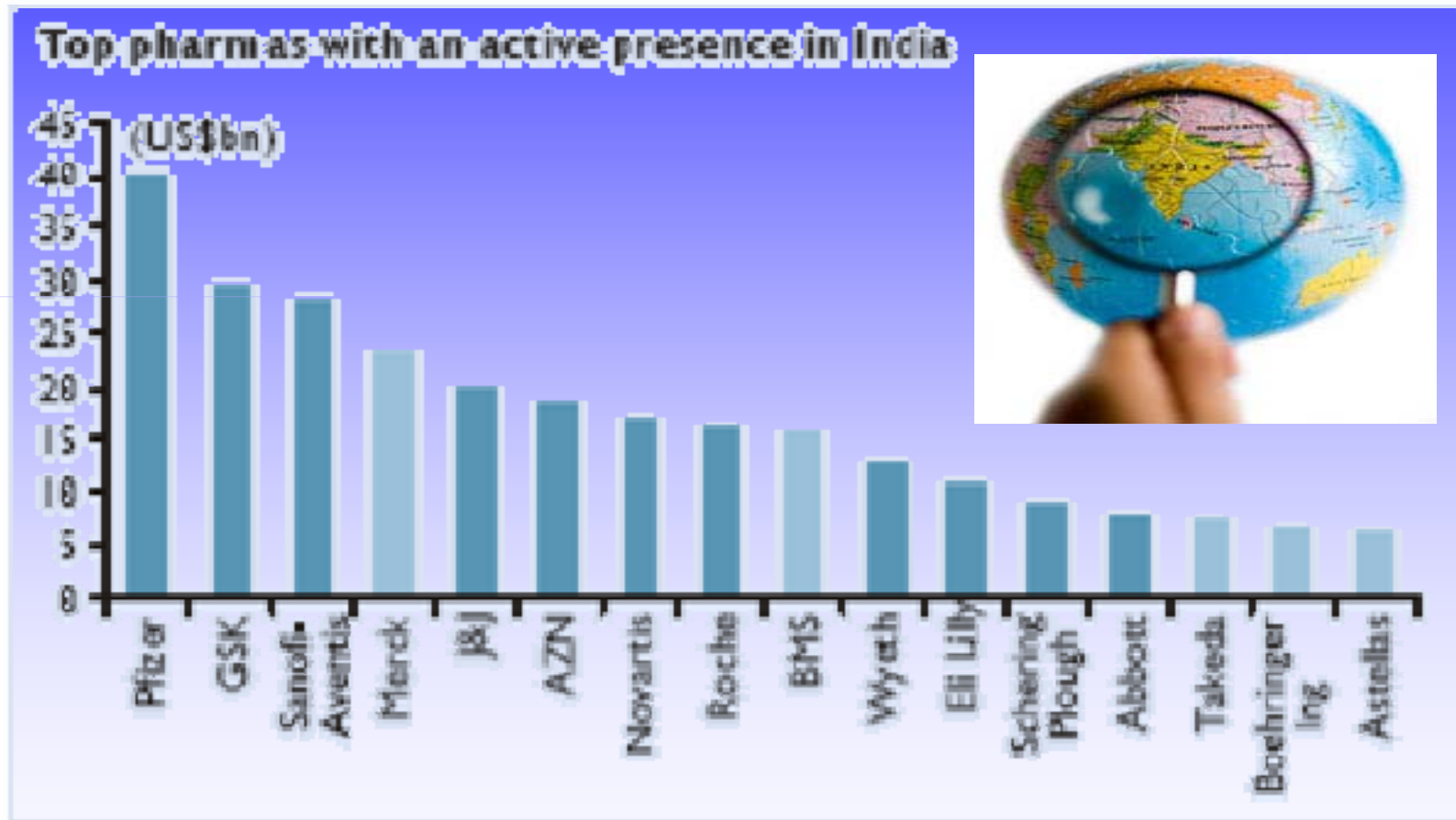
China	12.3%
S.Korea	11.7%
Turkey	11.8%
Russian Fed	21.3%
Greece	11.3%
Brazil	11.3%
Mexico	9.0%

Top 10 Global Pharmaceutical Companies

Rank	Company	Country	Total Revenues (USD Bn.)
1	Johnson & Johnson	USA	53.32
2	Pfizer	USA	48.37
3	Bayer	Germany	44.20
4	GlaxoSmithKline	UK	42.81
5	Novartis	Switzerland	37.02
6	Sanofi-Aventis	France	35.64
7	Hoffman-La Roche	Switzerland	33.54
8	AstraZeneca	UK/Sweden	26.47
9	Merck & Co.	USA	22.63
10	Abbott Laboratories	USA	22.47

Source: Wikipedia – MAT 2007

Post 2005, India an Exciting Market for Big Pharma



Source: CMA Asia-Pacific Markets

Top 10 Pharmaceutical Companies in India

Value – Rs.7.5 Bn.

Rank	Company	Market Share	Gain/Loss Market Share (%)	Value Growth (%)
1	Cipla	5.2	0.1	16
2	Ranbaxy	4.9	-0.2	10
3	GlaxoSmithKline	4.8	-0.3	6
4	Nicholas Piramal	3.8	-0.5	0
5	Zydus Cadila	3.6	0.2	19
6	Sun Pharma	3.3	0.1	17
7	Alkem	3.2	0.2	21
8	Lupin Labs.	2.6	0.3	26
9	Pfizer	2.5	-0.1	9
10	Dr. Reddy's Labs.	2.3	0.0	13

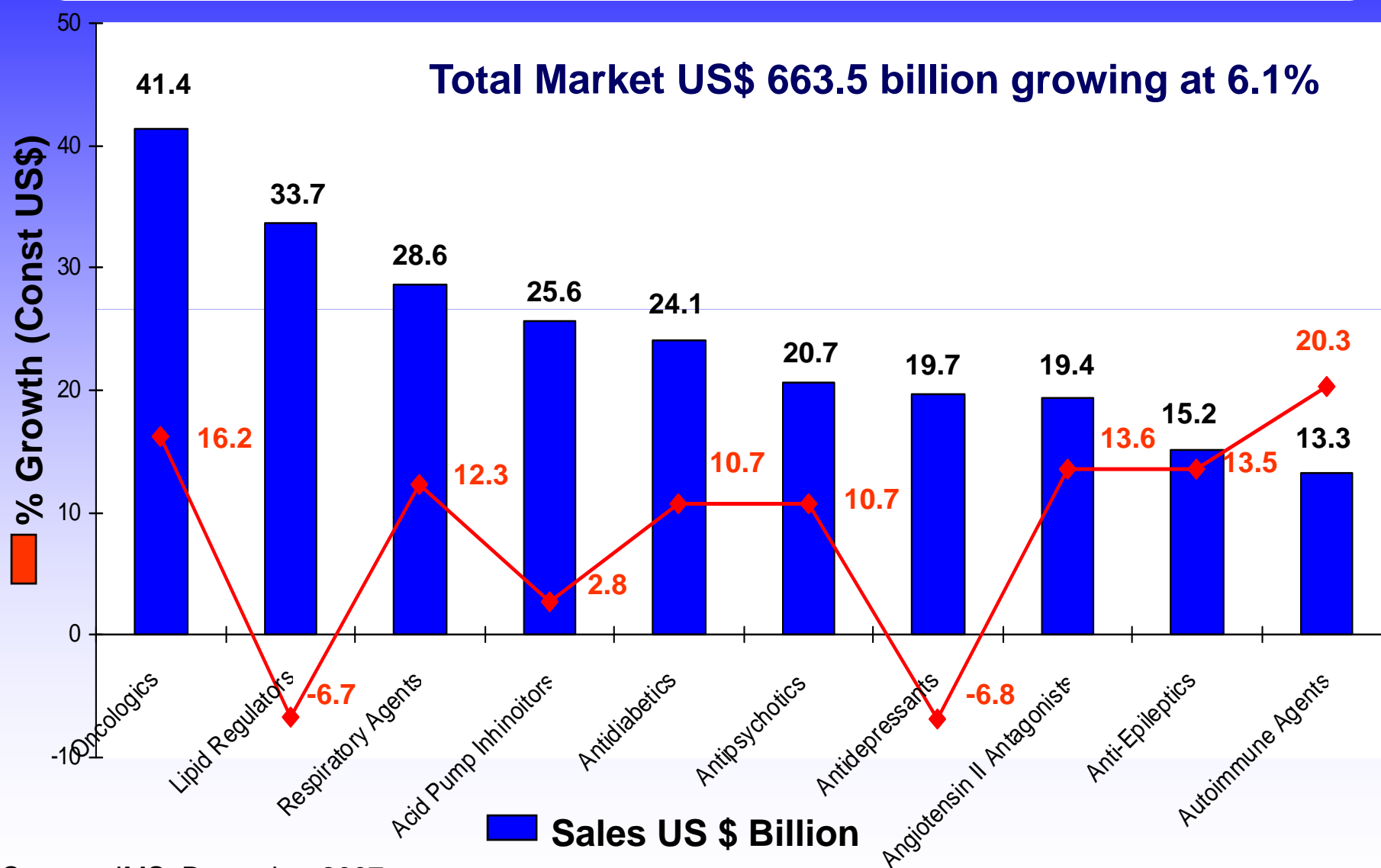
Source : IMS Dec. 2007

Top 10 Products

Rank	Products	Description	Company	M\$	Gr %
TOTAL MARKET				7,549.2	13.38
1	COREX	Cough Syrup	Pfizer	33.4	1.21
2	VOVERAN	NSAID	Novartis	32.9	8.72
3	HUMAN MIXTARD 30/70	Insulin	Abbott	28.3	24.50
4	LIV 52	Ayurvedic	Himalaya Drug	27.4	17.30
5	TAXIM	Cefotaxim	Alkem	27.2	9.47
6	PHENSEDYL COUGH	Cough Syrup	Nicholas Piramal	26.4	-11.70
7	AUGMENTIN	Amoxy+Clav	GSK	25.7	14.72
8	BECOSULES	Vitamins	Pfizer	24.1	7.02
9	ZIFI	Cefixime	FDC	23.1	18.82
10	DEXORANGE	Iron	Franco Indian	22.5	10.66

Source : IMS Dec. 2007

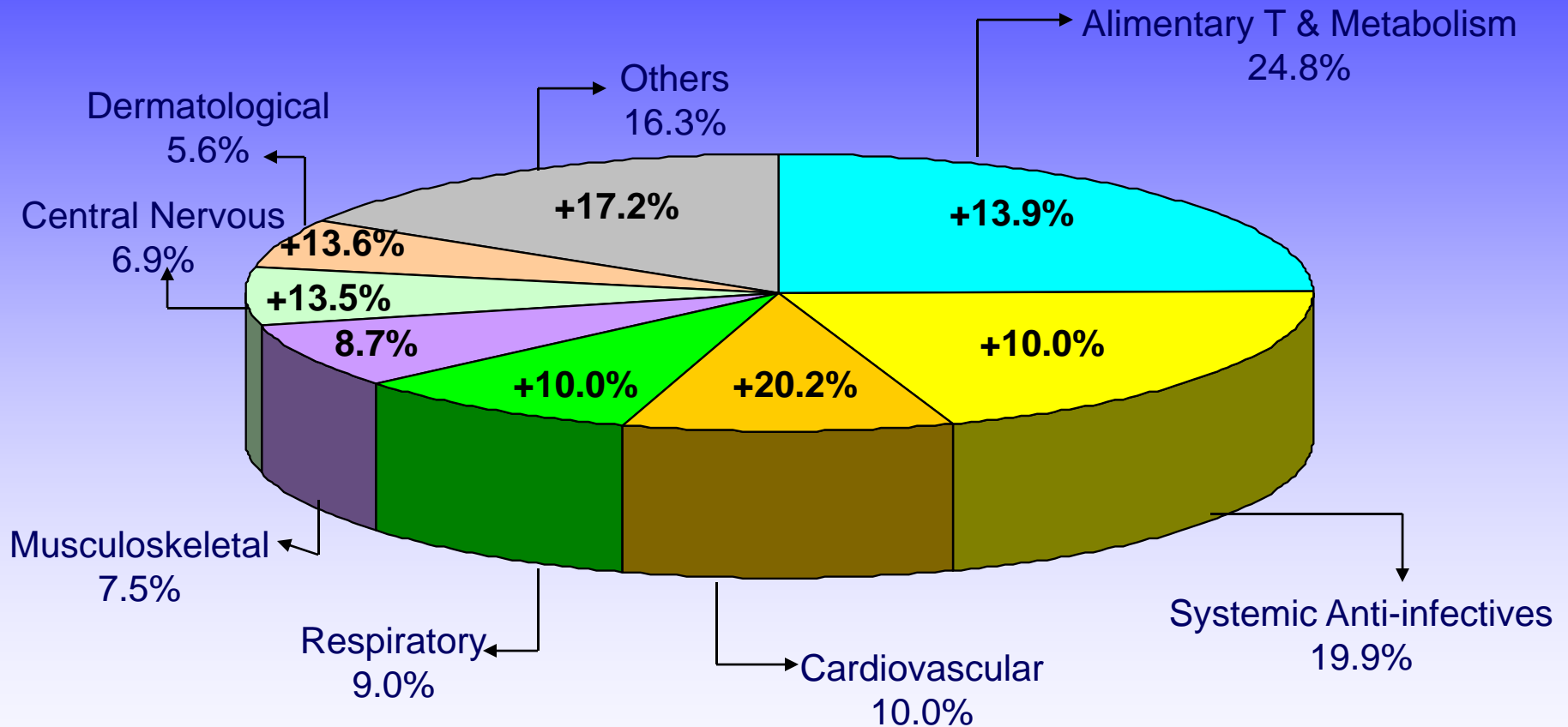
Top Global Therapy Areas



Source : IMS, December 2007

Indian Top Therapy Areas

Key Therapeutic Segments

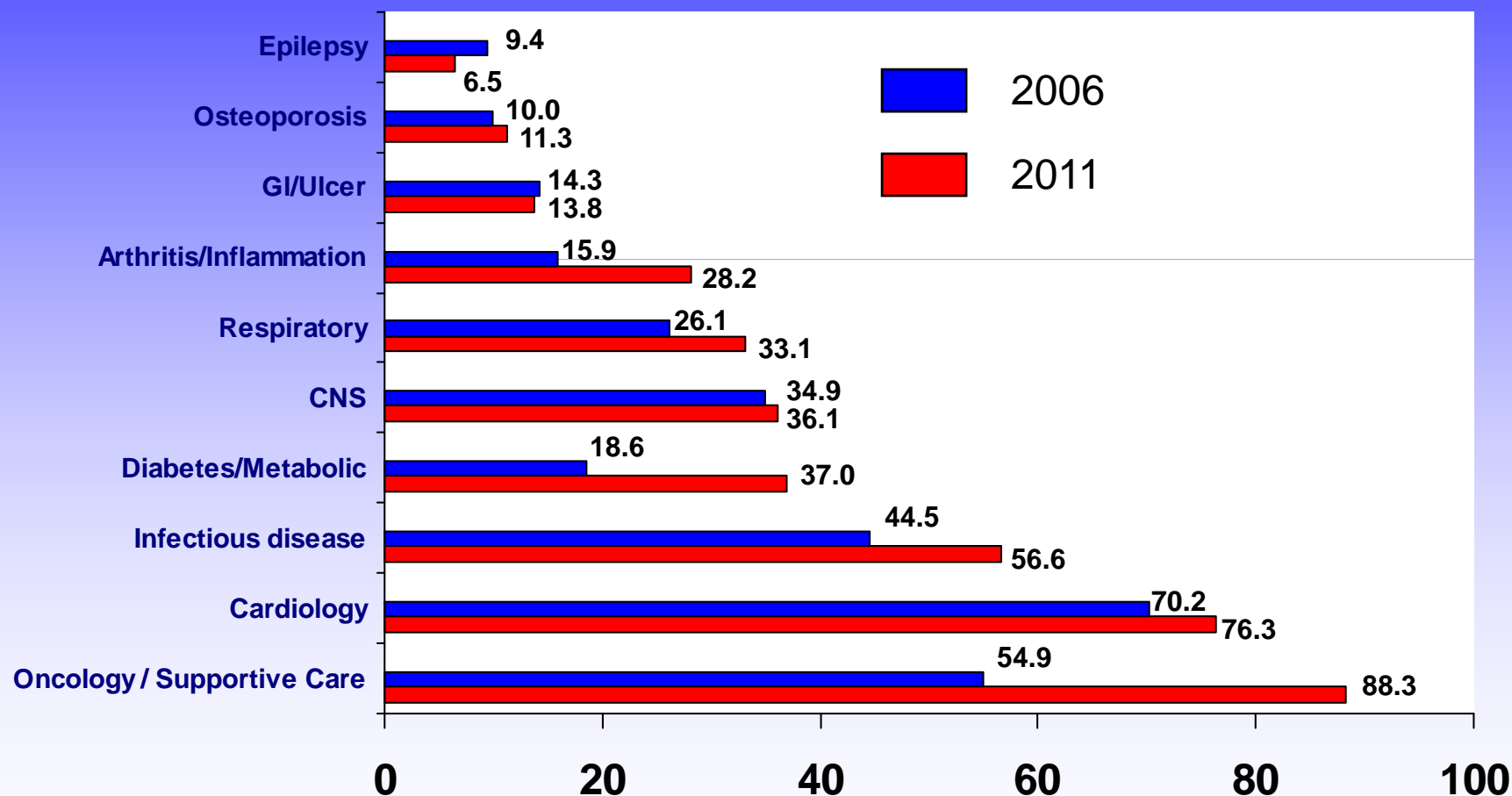


Total Market US\$ 7549.2 Mn (Growth 13.4%)
[13th in value and 4th in volume globally]

*Annual Income >\$ 5000

Source: IMS Dec. 2007

Top 10 Worldwide Therapeutic Classes in Turnover Terms (2006 vs. 2011)












Including supportive care: blood factor sales excluding kidney dysfunction anemia related sales

Source: IMS Health, Analyst Reports, Bionest Partners Analysis

Top 10 Worldwide Therapeutic Classes in Turnover Terms (2006 vs. 2011)

contd..

Worldwide Sales Market Share			Therapeutic Classes	Worldwide Sales Ranking	
2006	2011	Trend		2006	2011
1.7	0.9		Epilepsy	10	10
1.8	1.6		Osteoporosis	9	9
2.6	2.0		GI/Ulcer	8	8
2.9	4.0		Arthritis/Inflammation	7	7
4.8	4.7		Respiratory	5	6
6.4	5.1		CNS	4	5
3.4	5.3		Diabetes/Metabolic	6	4
8.1	8.1		Infectious Disease	3	3
12.8	10.9		Cardiology	1	2
9.5	11.1		Oncology/Supportive Care	2	1

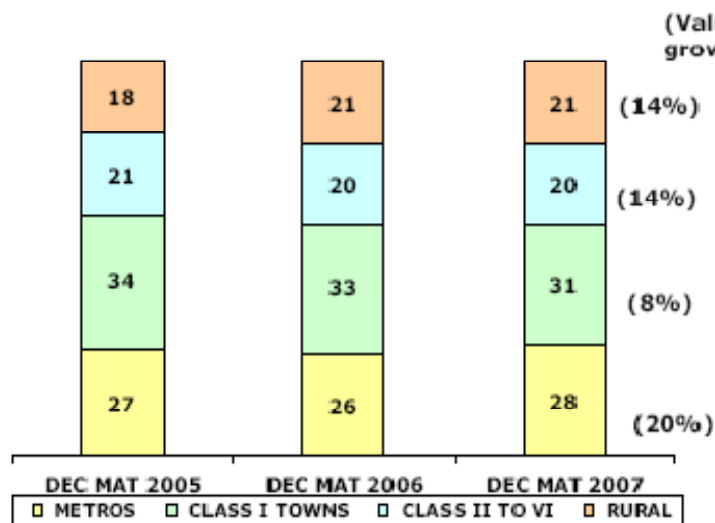
Source: IMS Health, Analyst Reports, Bionest Partners Analysis

Rural Market Opportunities

Market Access - Rural markets

As the chasm between India's cities and villages narrows, we believe that the next wave of growth for pharma would also come from rural markets

% Value Contribution



Total market :USD 6.9 bn, value growth 13%

Opportunities in urban are changing

- Market becoming more cluttered and fragmented - 45% market consists of products launched before 1995; these matured products need to look at strategies to extend their lifecycle
- Changing lifestyles are making the market more prone to Specialty therapy opportunities

New opportunities in rural market opening

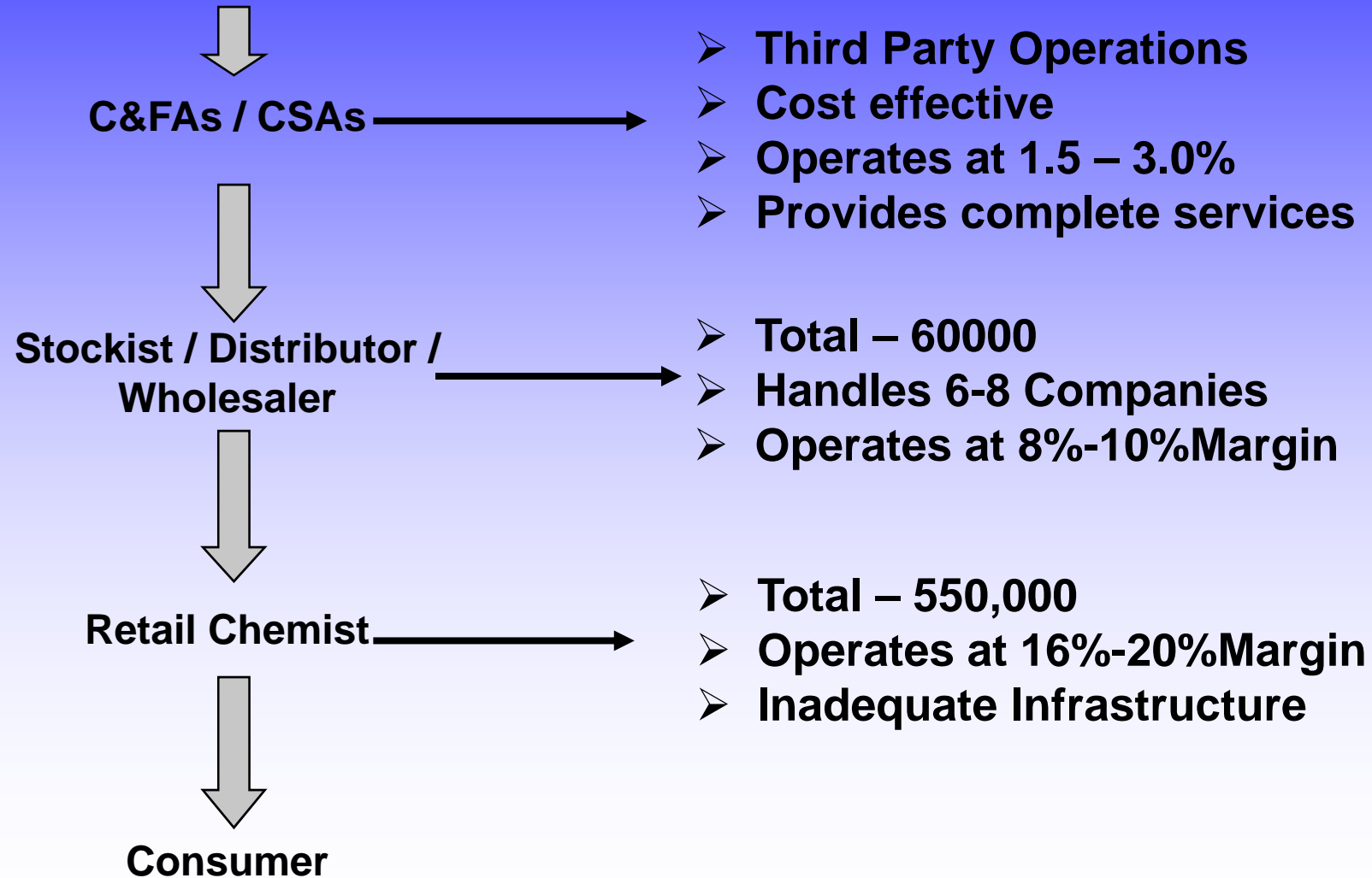
- 47 out of 50 top pharma companies have recorded growths of more than 20% across rural
- Identification of the 'right' portfolio, distribution and access strategy would lead to a new wave of growth

Source: Stockist Secondary Audit, Dec MAT 2007

ORG | ims

Distribution Chain

Manufacturing Locations



Regulatory Environment

Drugs & Cosmetics Act 1940 / Rules

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

Essential Commodities Act, 1955

DPCO, 1995

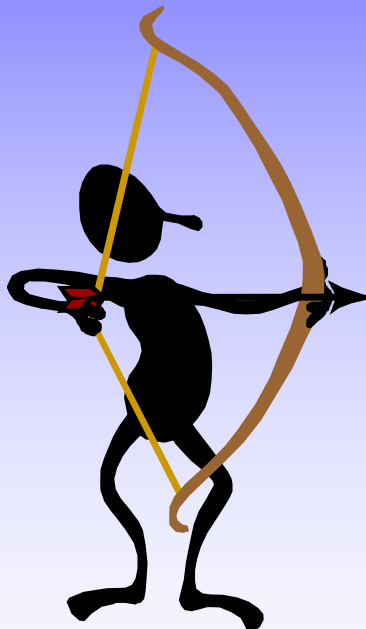
C. Excise

Customs

Transfer Pricing Regulations

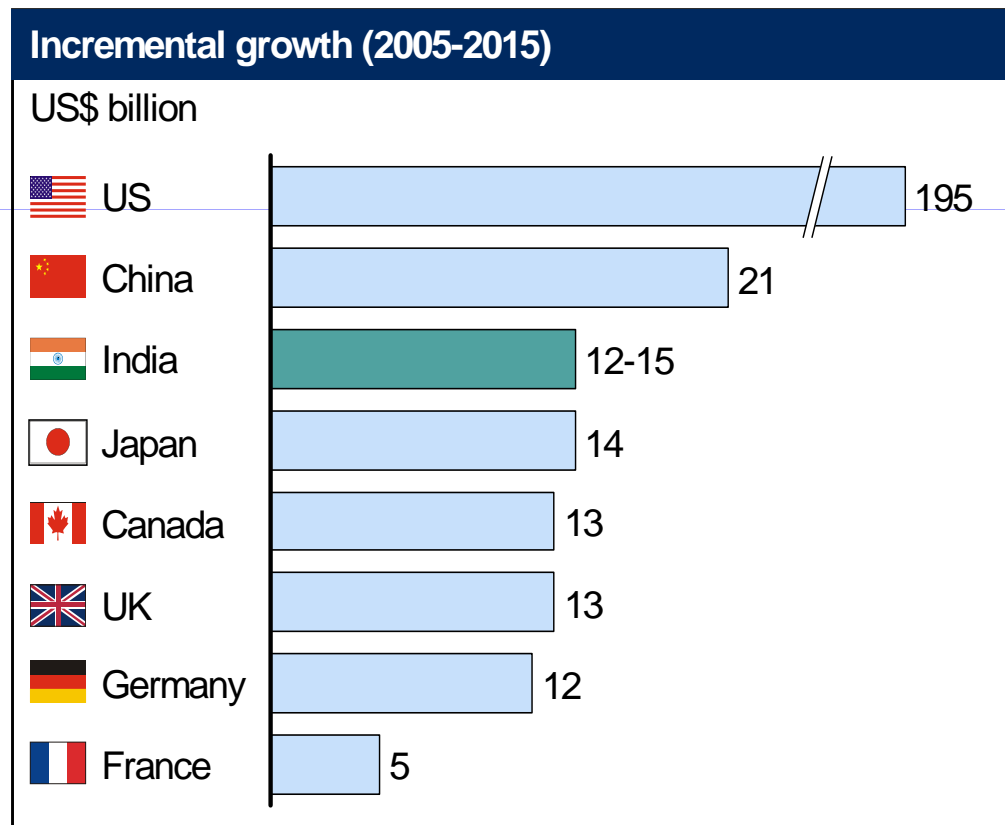
Patents' Regulations

Various VAT regulations



McKinsey Prognosis: India to be Third Largest Growing Market

INDIA WILL BE AMONG THE HIGHEST GROWTH MARKETS IN THE WORLD



McKinsey Prognosis for Growth Drivers

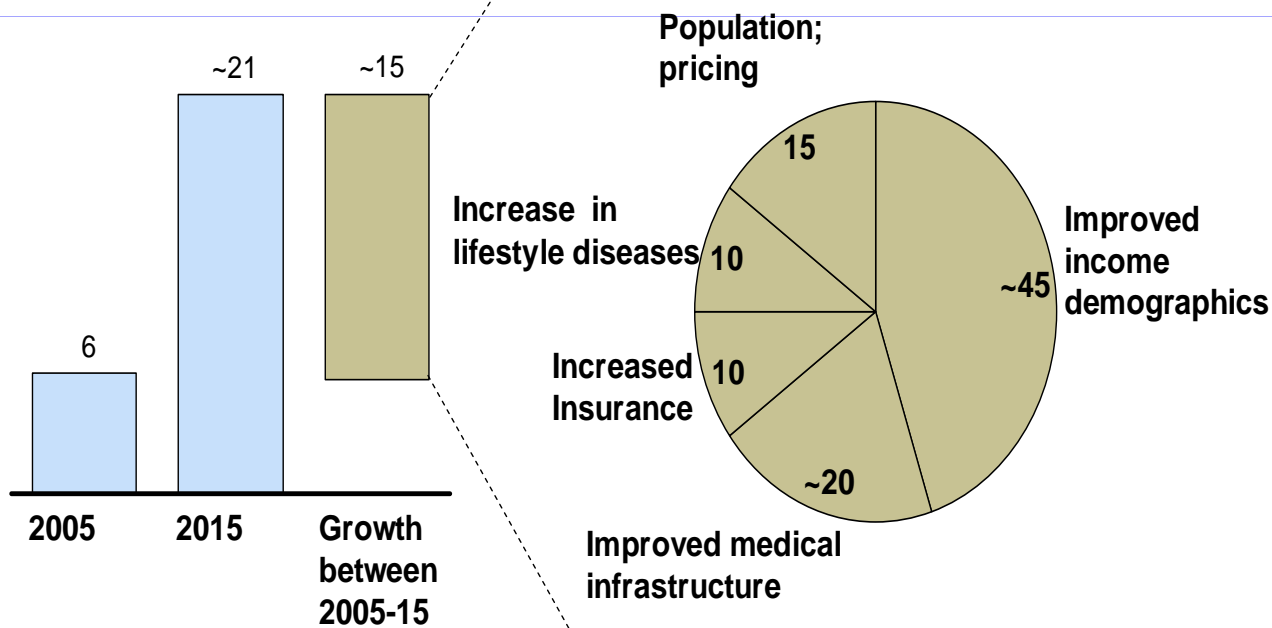
SHIFT IN INCOME DEMOGRAPHICS WILL ACCOUNT FOR NEARLY HALF OF MARKET GROWTH

US\$ billion

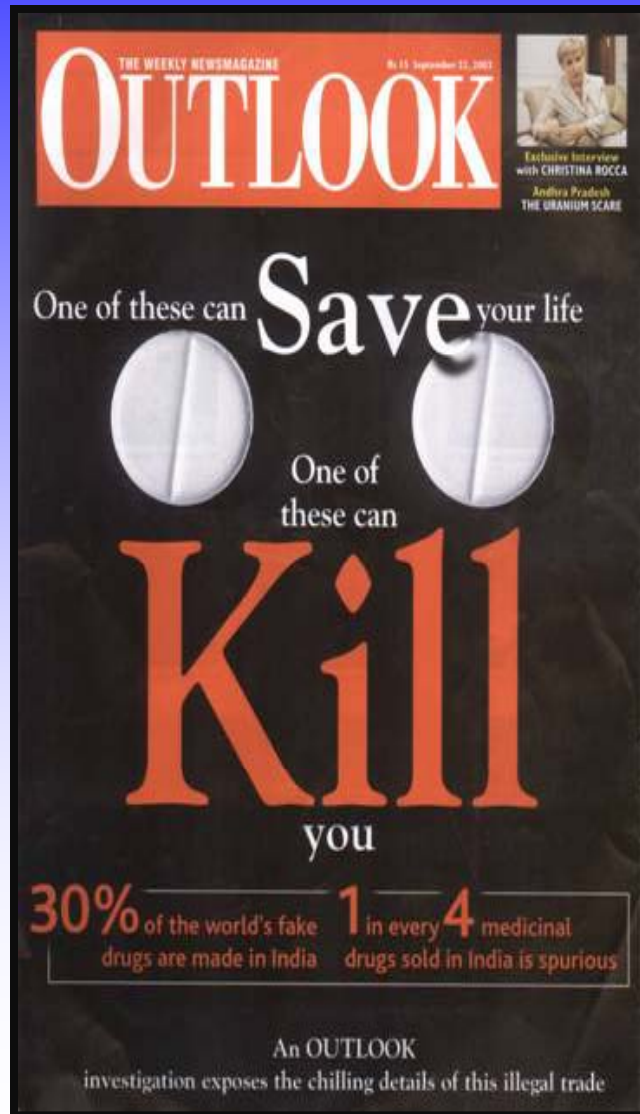
Market growth, 2005-2015

Sources of growth

Per cent



Counterfeit Drugs – A Menace

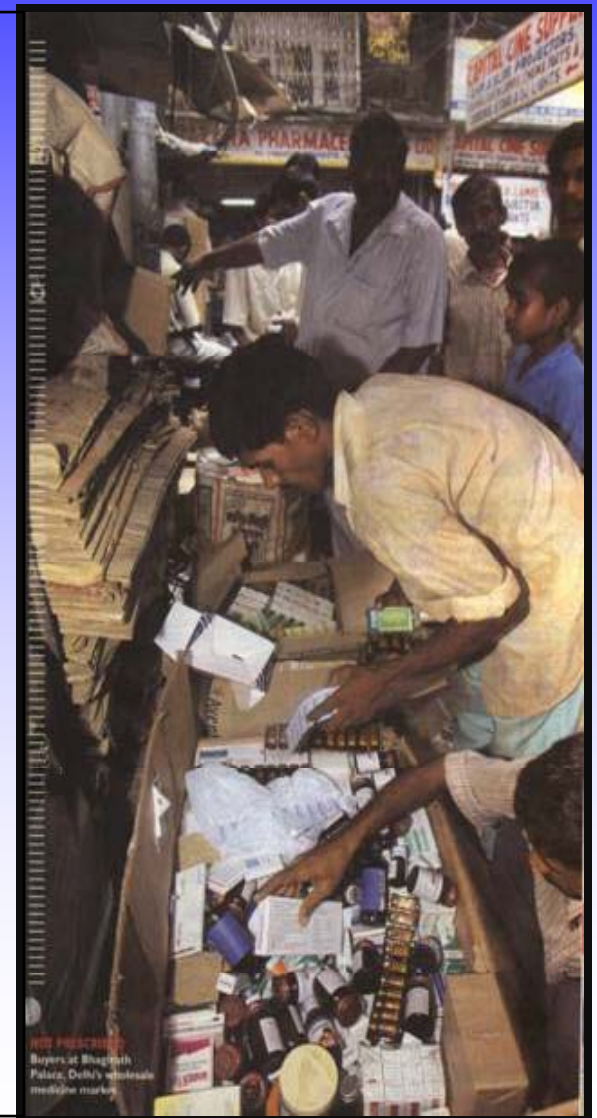


Making or selling spurious drugs is not a criminal offence in India

Anti-counterfeiting measures not used due to high cost

Some popular brands have 12-15 copies in the market

Most common fakes includes anti-viral, antibiotics and life-saving drugs



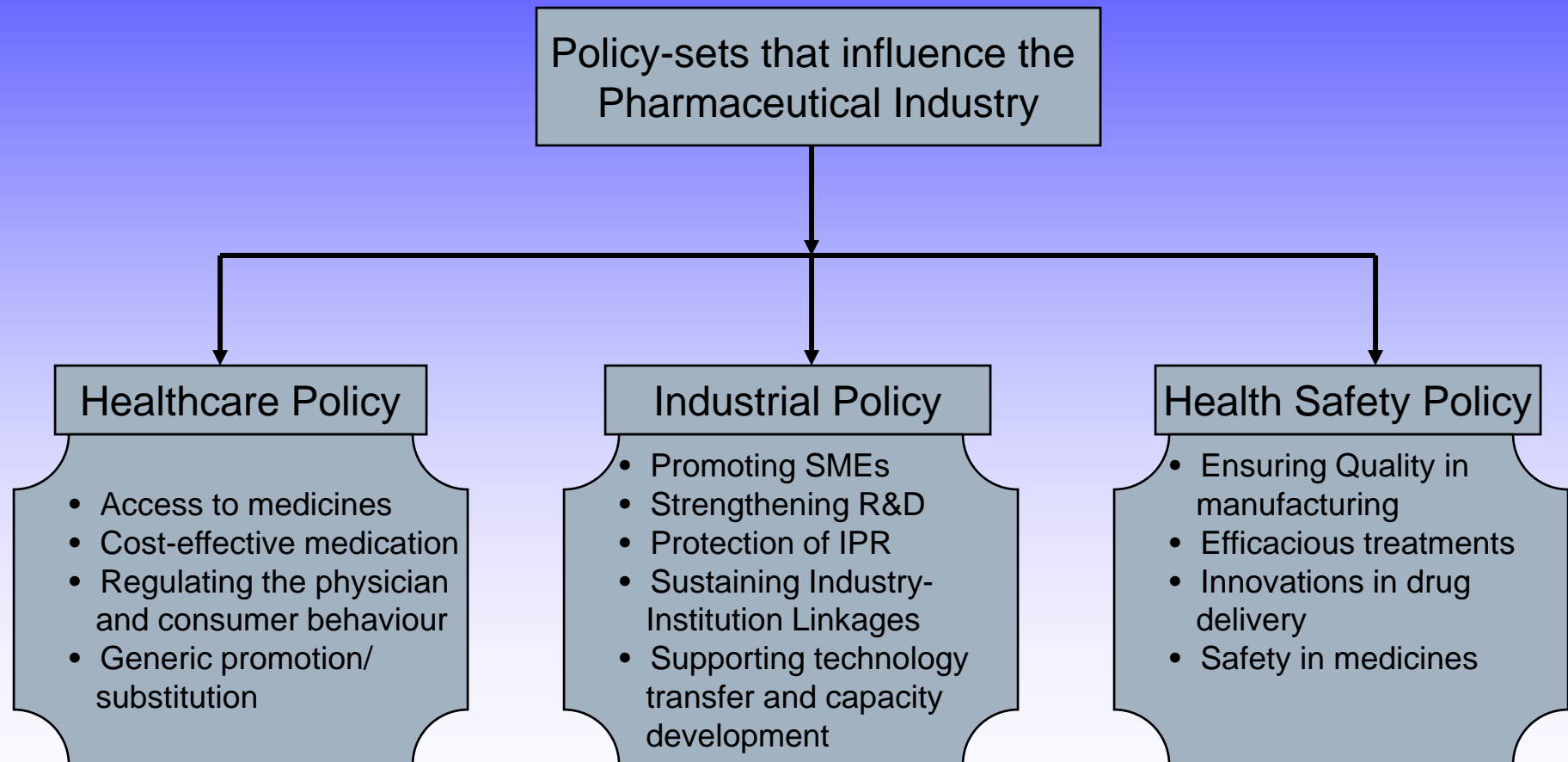
Spurious Drugs are a Serious Problem and Combating Them Requires Investment

Spurious drugs are a serious issue . . .

- Major public health hazard since leading brands attract counterfeit and spurious products
- Passage of Bill No. LIV of 10th may, 2005 in the Parliament is an utmost priority

National Healthcare Policy of India – has it delivered?

Policy Framework Supporting Pharmaceutical Industry



Total Expenditure on Health as a % of GDP

Country	Public Sector	Private Sector	Total
India	1.2	3.6	4.8
Sri Lanka	1.6	1.9	3.5
China	2.0	3.6	5.6
Japan	6.4	1.5	7.9
Switzerland	6.7	4.8	11.5
USA	6.8	8.4	15.2
UK	6.9	1.1	8.0
France	7.7	2.4	10.1

Source: World Health Report, 2006, WHO

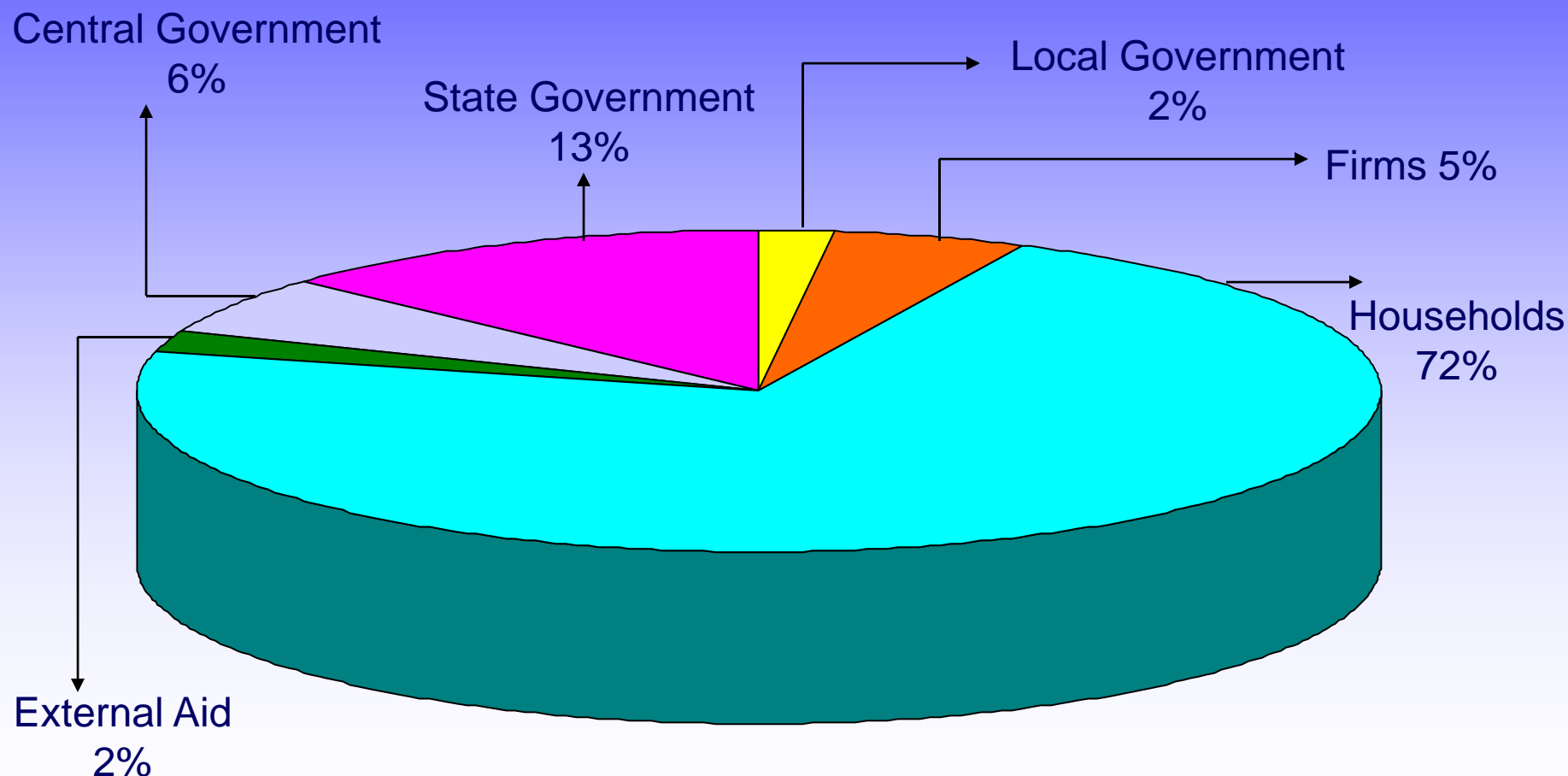
India's Healthcare Context is Unique

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%		

India : 80% out of pocket payment and 20% from others

Sources of Financing Healthcare Services in India

Proportion of Health Expenditure by Financing Source



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

Medicines

Doctor's Fees	9%
Medicines	15%*
Diagnostic Investigations & Pathological Tests	24%
Hospitalization	17%
Transport	20%
Miscellaneous	8%
Others	7%

* 60% towards taxes and trade margins

15% of Total Household Cost for Individuals

Source: National Survey of Health, 2003

The Indian Pharma Market is Extremely Competitive

Large number of Companies in the Industry...

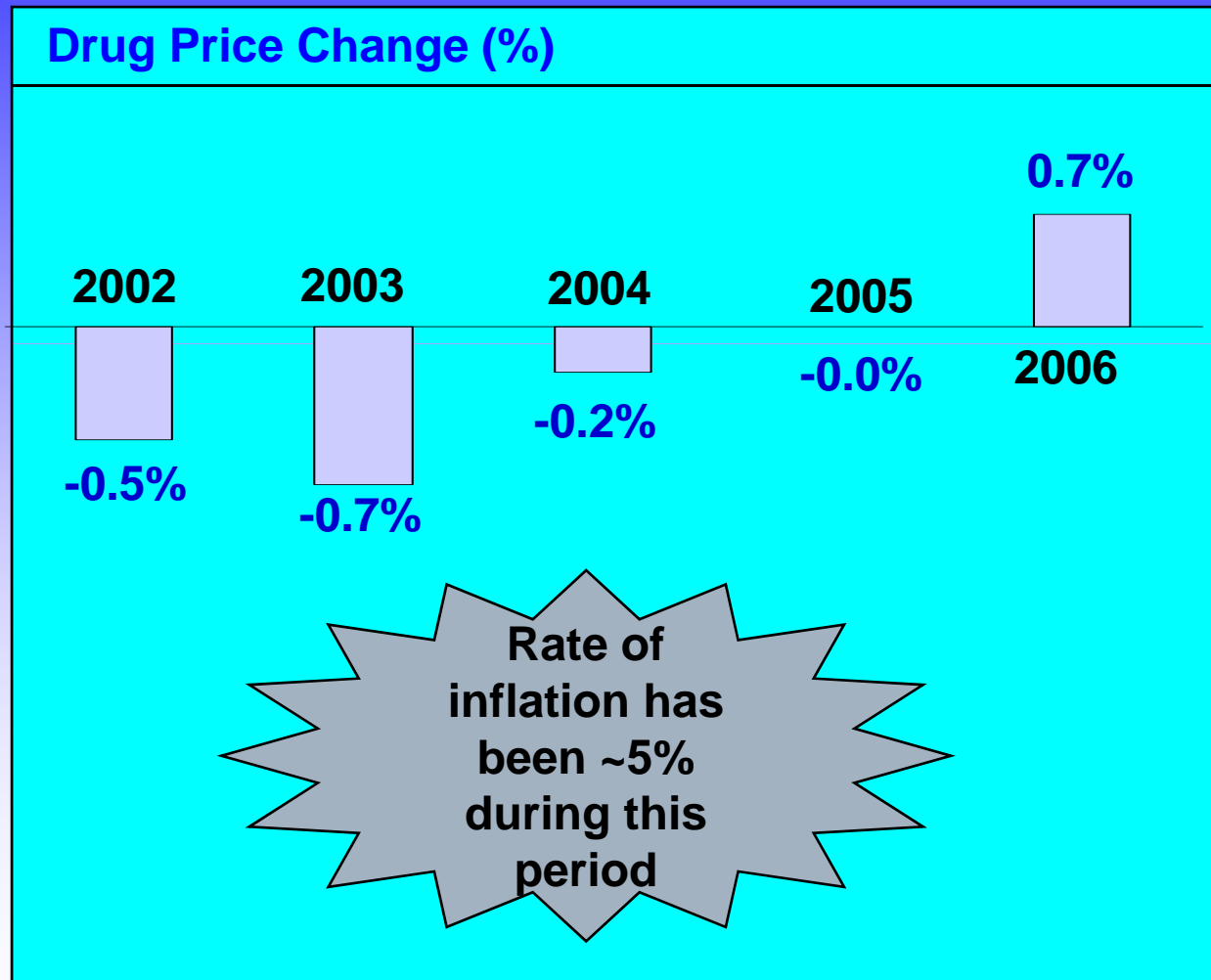
- **10,000+ listed and unlisted companies in the market**
- **Highly Fragmented Market**
 - Top 10 companies account for < 40% of the market
 - 250+ companies account for 70% share
- **Mix of companies: of MNC and Indian companies; national and regional companies**

... More than 10 brands in each Molecule

Molecule	Number of Brands
Ciprofloxacin	101
Gatifloxacin	67
Cetirizine	83
Diclofenac	67
Rabeprazole	49
Atenelol	49
Glimeperide	40

■ **Intense competition – ensures prices are low**

Real Prices have declined Year on Year



- Nearly 5% price decline in each year in real terms over last 5 years

- Prices of 539 formulations reduced over the last 2-3 years

Price Control Trend

In the past 30 years, successive Governments have reduced the span of price control on medicines

DPCO Year	No. of Drugs under Price Control	Percentage of Controlled Market
1970	All	100
1979	347	90
1987	143	70
1995	74	20
2002	30 drugs proposed	Under review

Source: ORG-IMS

Current Price Regulation

Nature of Price Regulation	Percentage of Controlled Market
Cost based Price Control	20
Price Monitoring with annual price increase ceiling of 10%	80
Total	100

Source: ORG-IMS/NPPA

Pharmaceutical Prices in Selected Countries

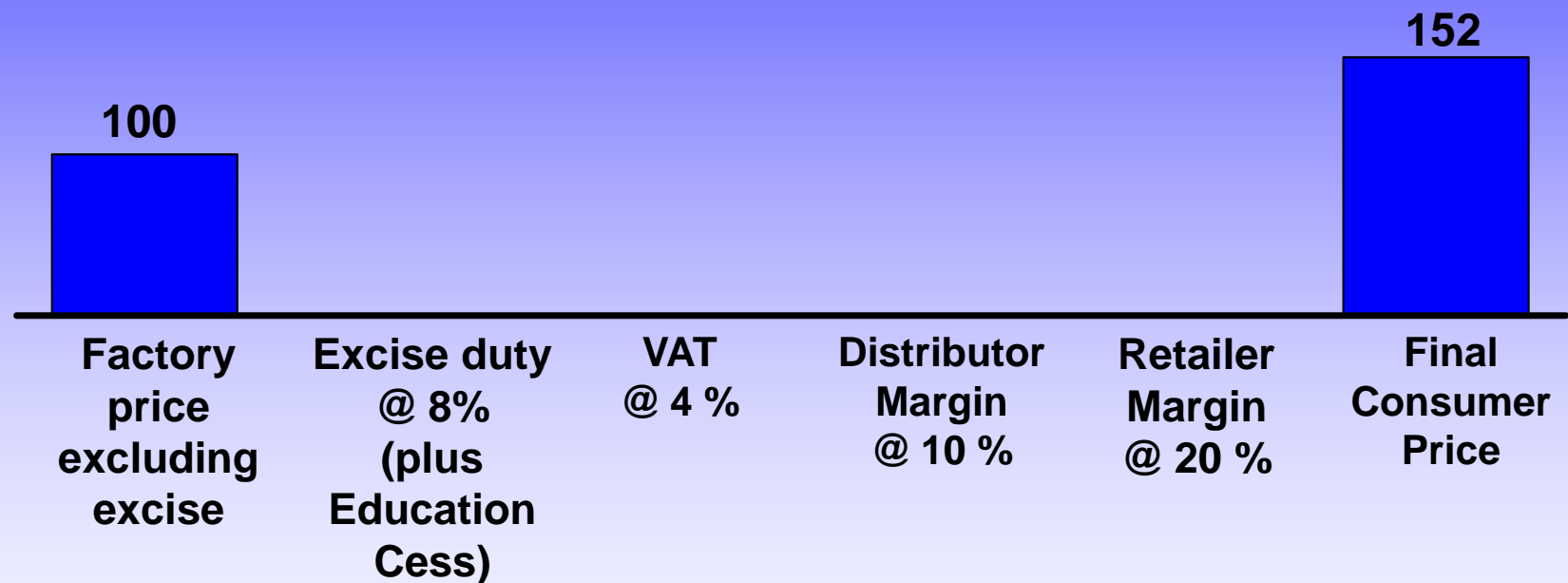
	Drugs, Dosage Form and Strength	Pack	Prices in India (INR)	Prices in Pakistan (INR)	Prices in Indonesia (INR)	Prices in USA (INR)	Prices in UK (INR)
I. ANTI-INFECTIVES							
1.	Ciprofloxacin – HCL 500 mg tabs	10's	29.00	423.86	393.00	2352.35	1185.70
2.	Norfloxacin 400 mg tabs	10's	20.70	168.71	130.63	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

Pharmaceutical Prices in Selected 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)
II. NSAIDs							
1.	Diclofenac Sodium 50 mg. tabs	10's	3.50	84.71	59.75	674.77	60.96
III. ANTI-ULCERANTS							
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 Cost



Regulatory Monitoring Increasing Pressures

Drug overpriced? Soon you can call 24-hour helpline

Rupali Mukherjee | TNN

New Delhi: There's good news for consumers. If you have been overcharged while buying a drug or cannot find a particular drug in the market, you will soon be able to call a 24x7 helpline and register a complaint. It will help consumers to seek information on essential drugs and their prices, and also to locate a cheaper generic version if an expensive one (sold by the brand name) has been prescribed.

The helpline will be run by a consumer organization, VOICE, and will initially be funded by the government. A toll-free number that can be accessed from anywhere in the country is set to be introduced soon. It will also offer consumers information about the prices of scheduled drugs which are under government control.

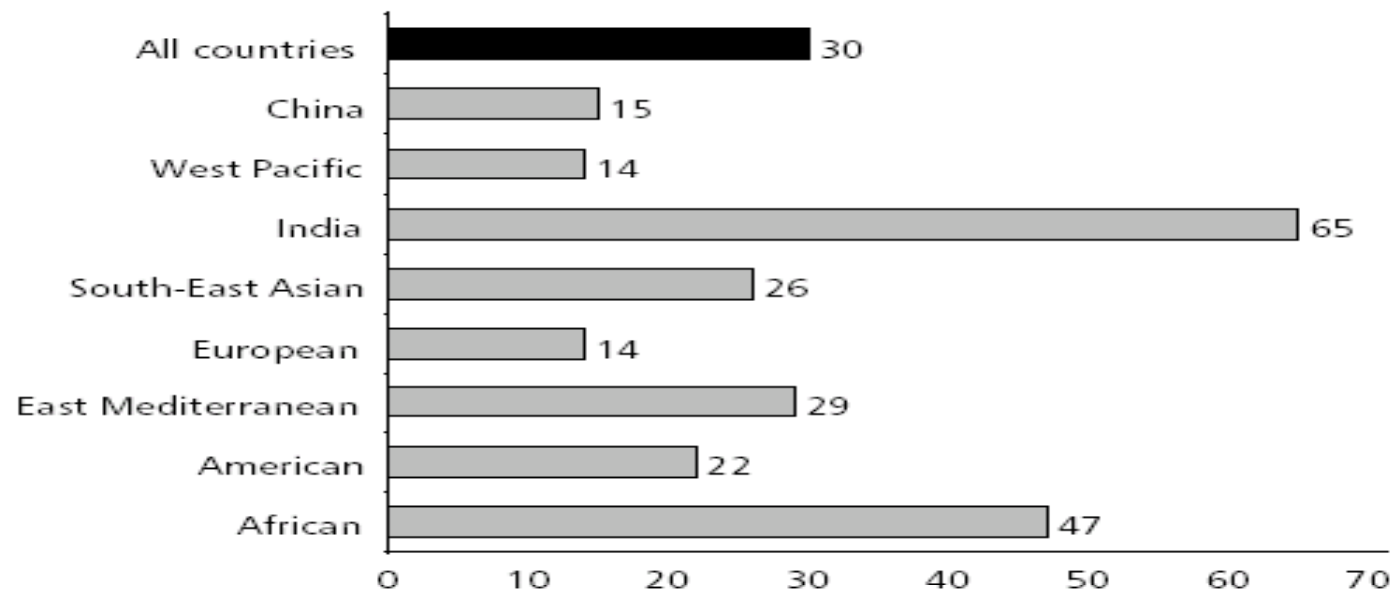
In another move to benefit 'aam admi', the government has decided to promote the sale of non-branded generic drugs (cheaper versions of branded medicines) by setting up drug stores in each district. They will be run by NGOs and sell drugs at reduced prices.

The 24-hour toll-free number can be reached from anywhere in the country and will relay the prices of scheduled drugs under govt control



Access to Modern Medicine – A Challenge

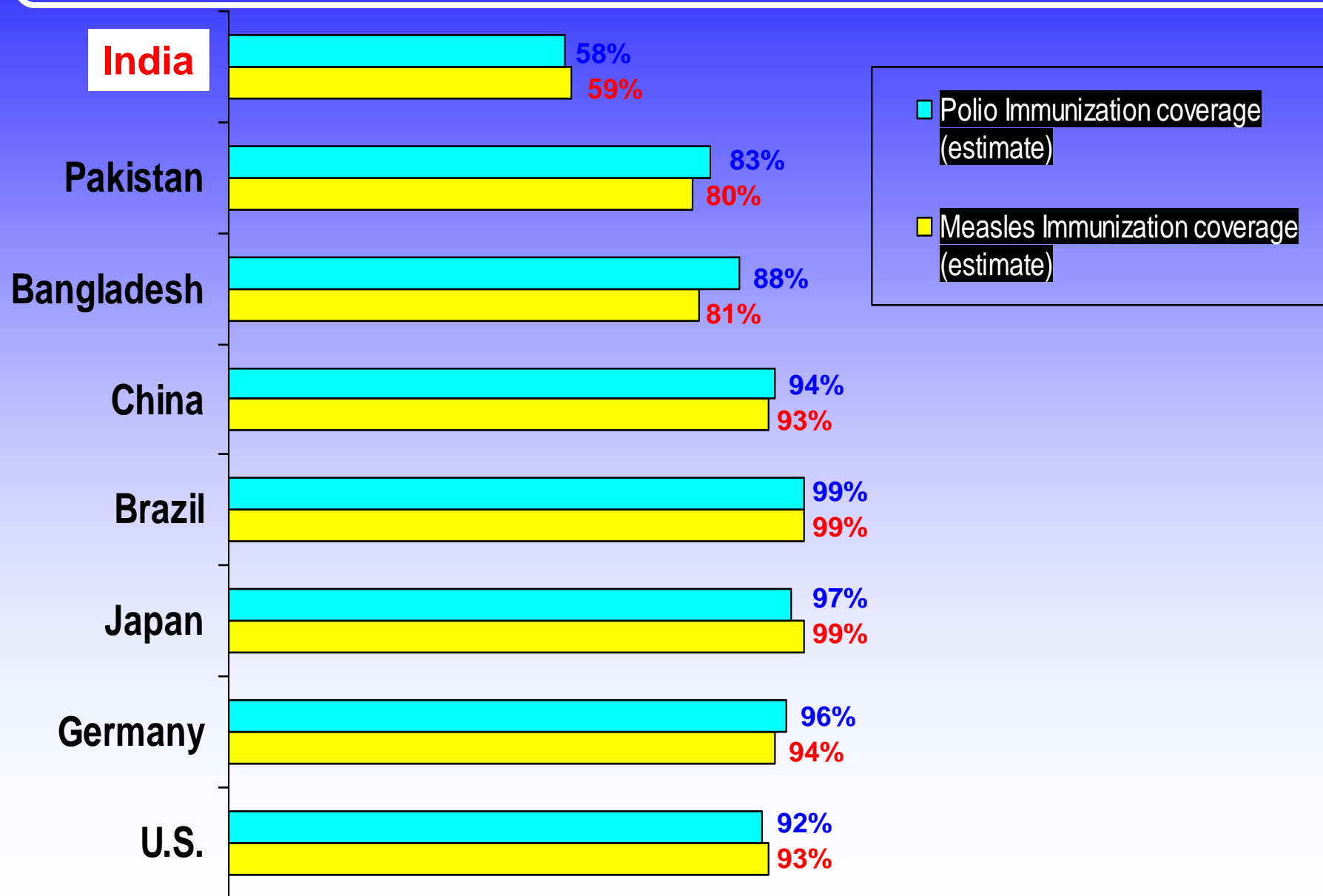
Percentage of WHO regions lacking access to essential medicines



650 Mn. Indians have no access to Essential Medicines

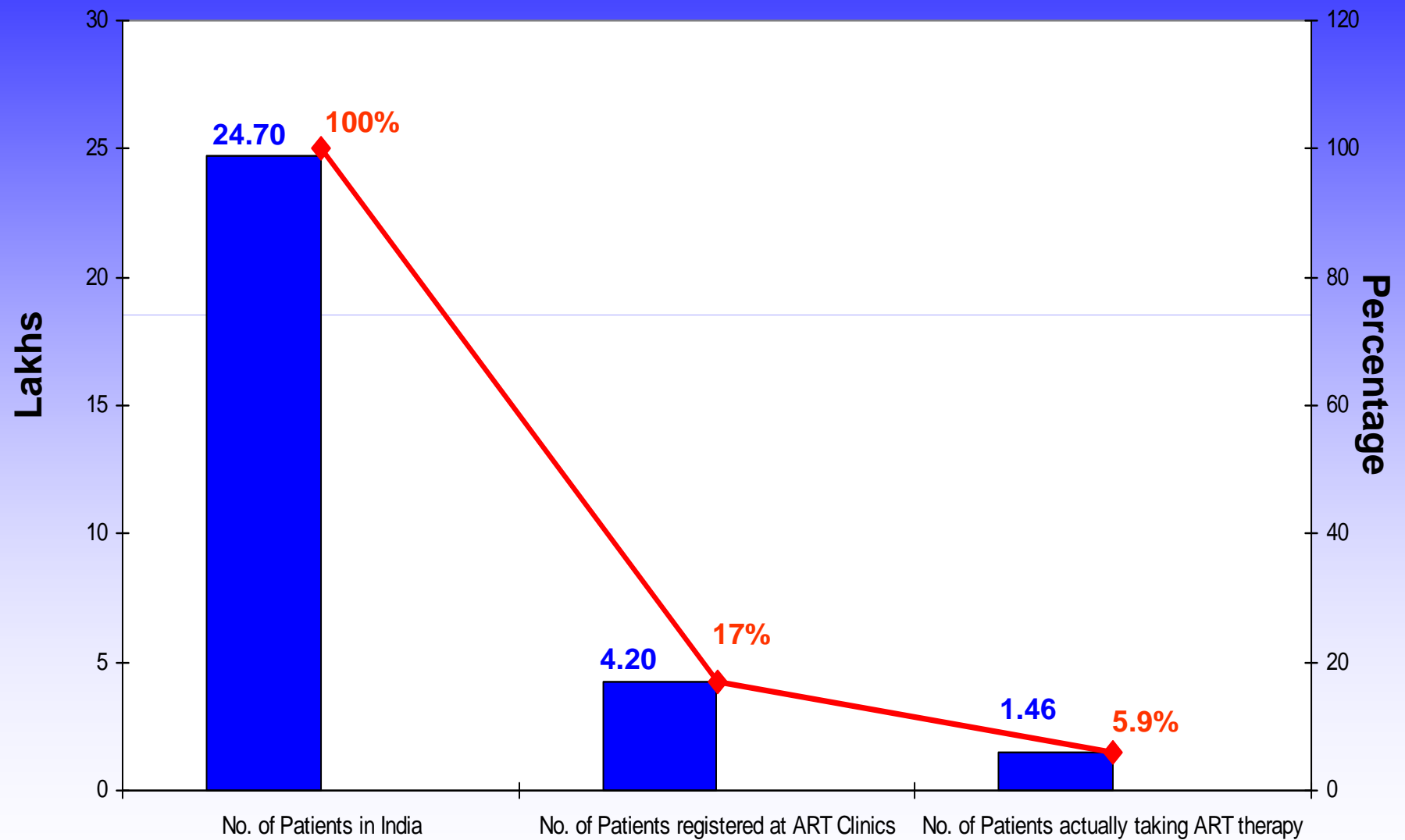
350 Mn. people having access are largely clustered around urban centers where health care facilities exist.

Many Children not getting Primary Vaccination



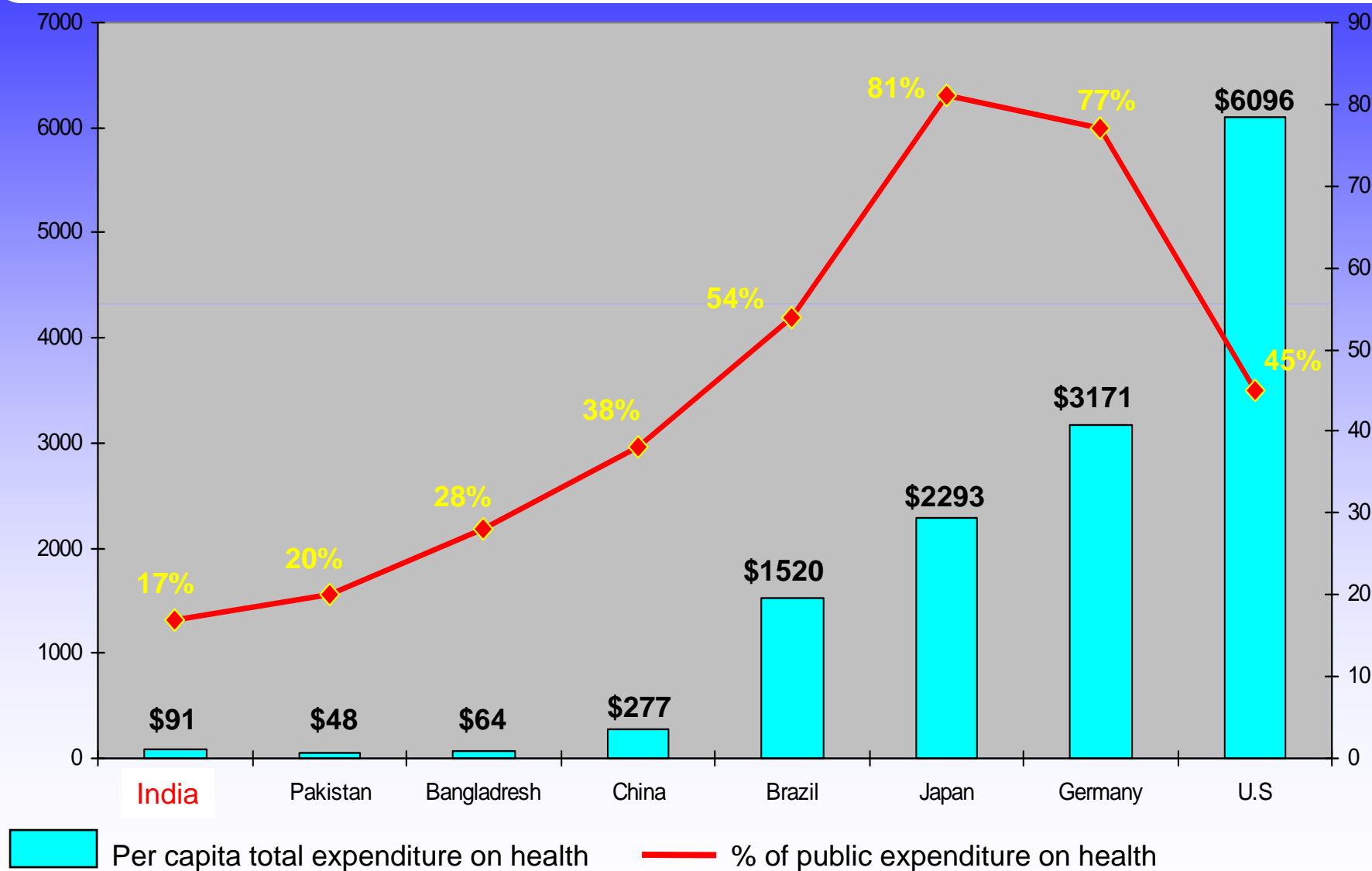
Source: World Health Organisation

HIV Patients: Access to ART



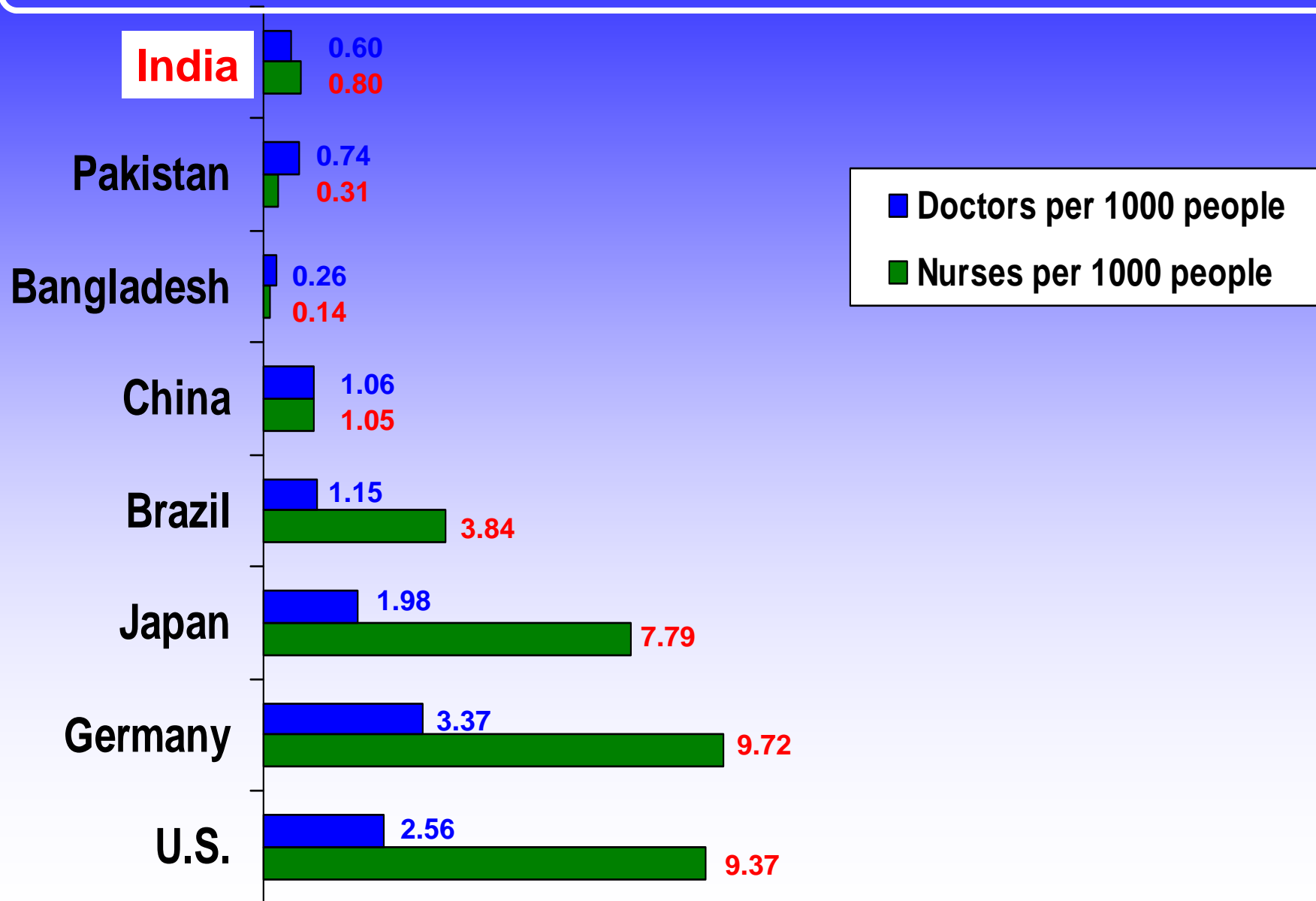
Source: NACO, INDIA

India Spends Relatively little on Healthcare



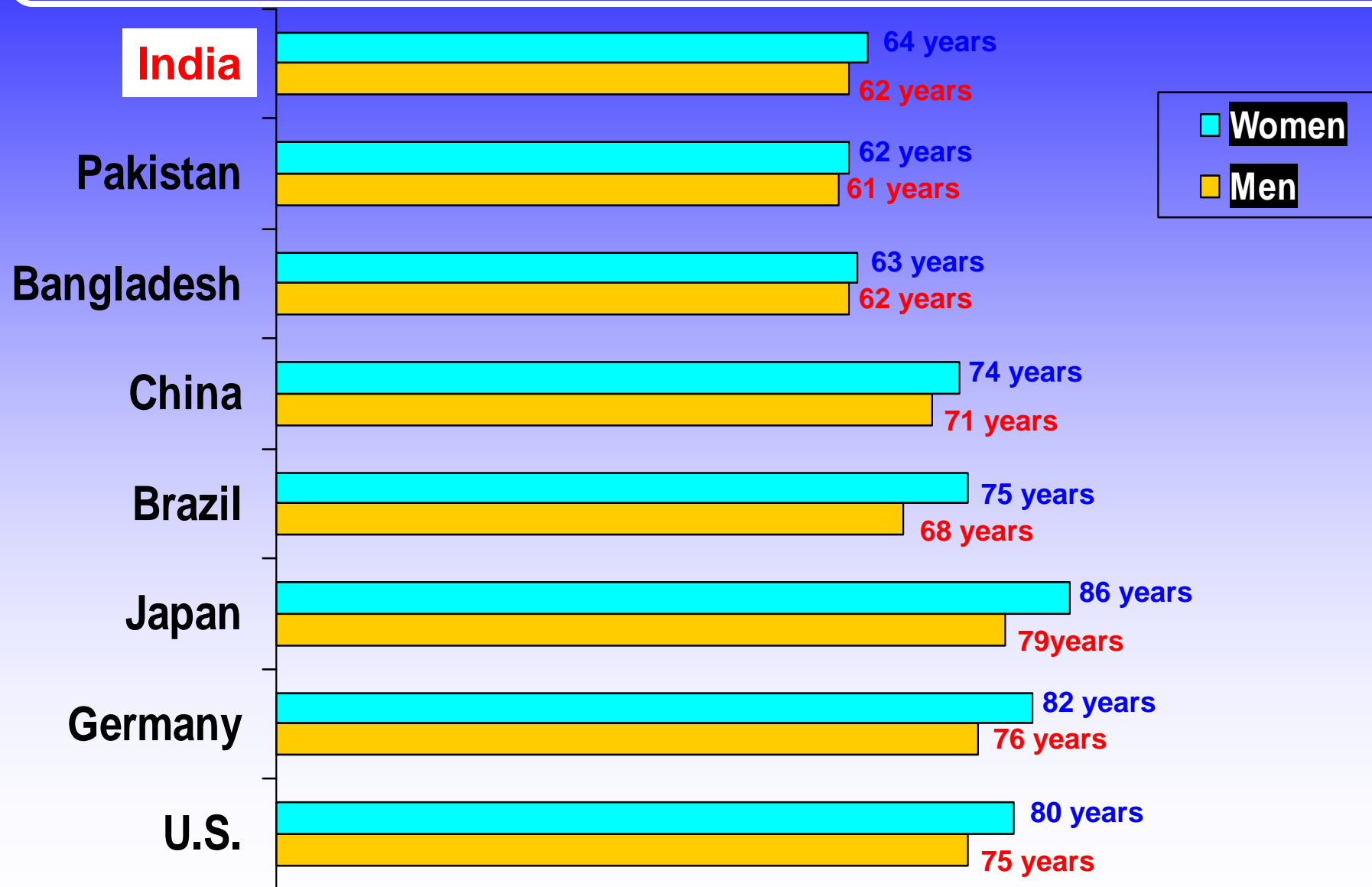
Source: World Health Organisation

Shortage of Doctors & Nurses in India



Source: World Health Organisation

Life Expectancy in India



Source: World Health Organisation

How to Improve Access to Modern Medicines

- ❖ Robust Healthcare Infrastructure
- ❖ Improved Healthcare System and Delivery
- ❖ Introducing a sound Healthcare Financing Model for all

Promote Health Insurance

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

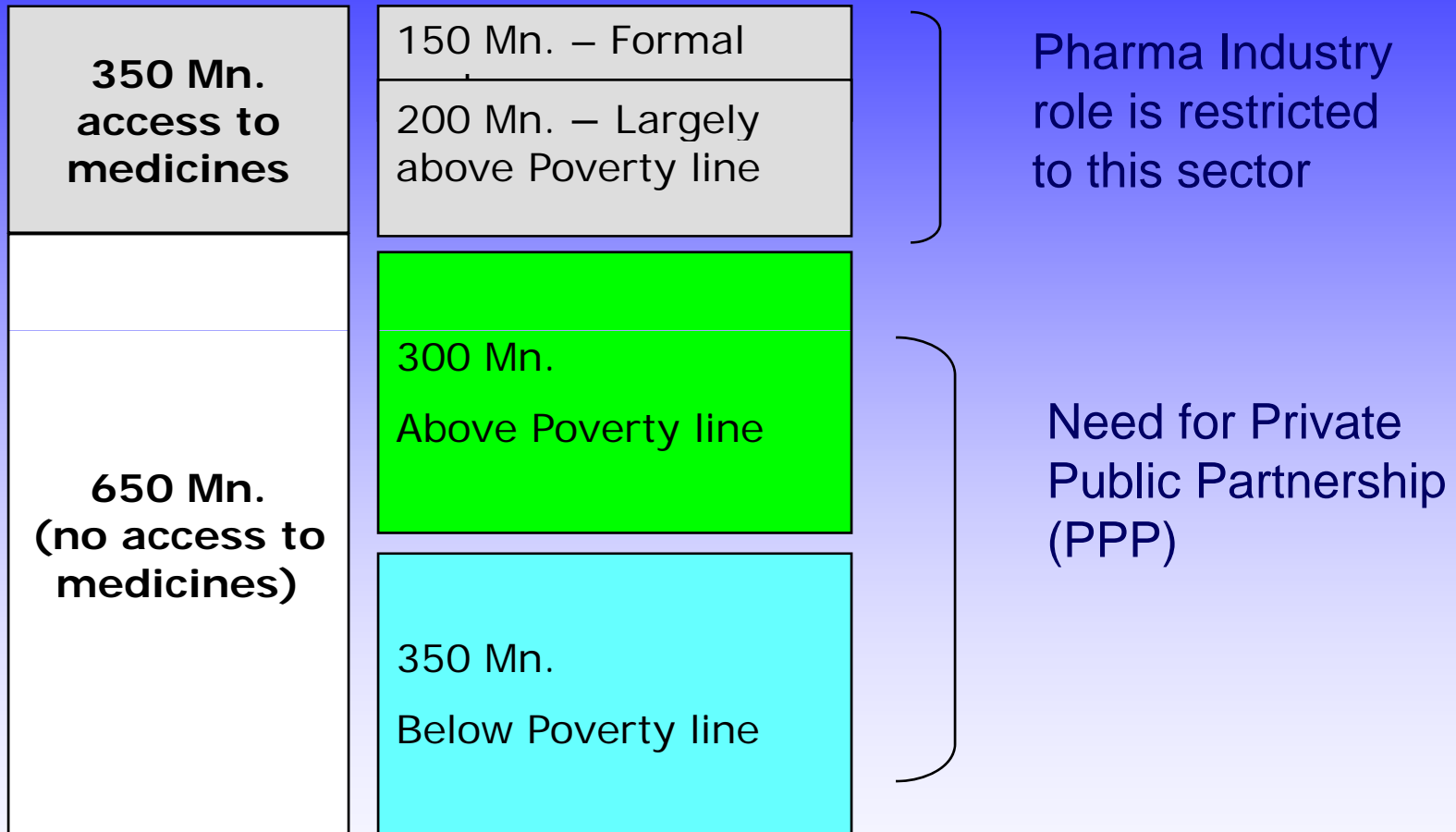
Recent Healthcare Infrastructure Initiative in India

- ❖ National Rural Health Mission to upgrade PHCs, recruit doctors, nurses, paramedical staff and train community health workers
- ❖ Budget : Rs.12,000 crores

Recent Healthcare Financing Initiative in India

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

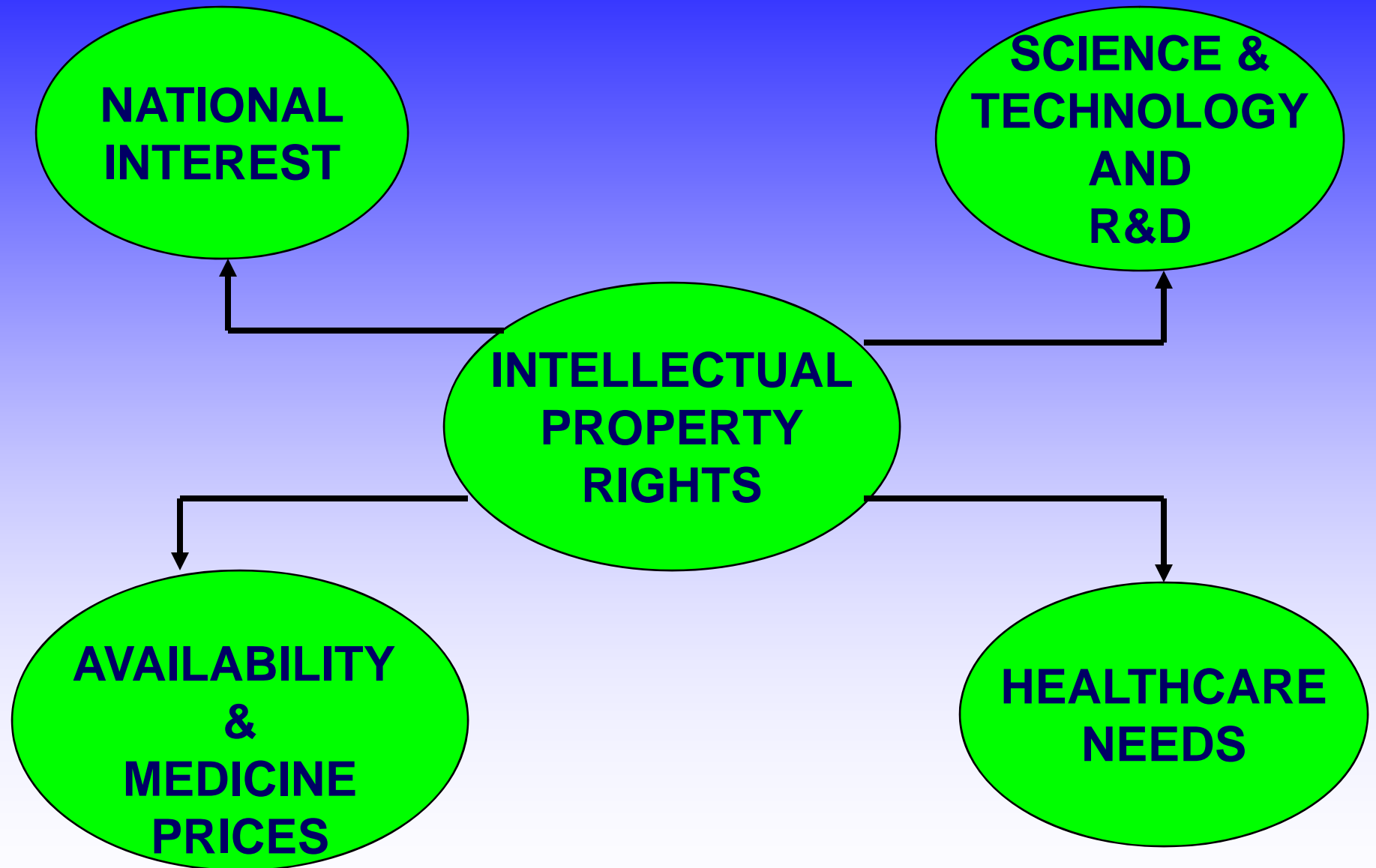
Access to Innovative Medicines



Formal Sector: Those employed with the Public or Private Sector

Patenting Landscape in India

Ideal IPR Policy



Patents in India : Historical Perspective

1911

Indian
Patents and
Design Act

Product
Patents

1970

Indian
Parliament
enacted the
Patents Act

Process
Patents

1999

First
Amendment to
the Patents Act

EMR and
Mailbox
provided

2002

Second
Amendment
to the
Patents Act

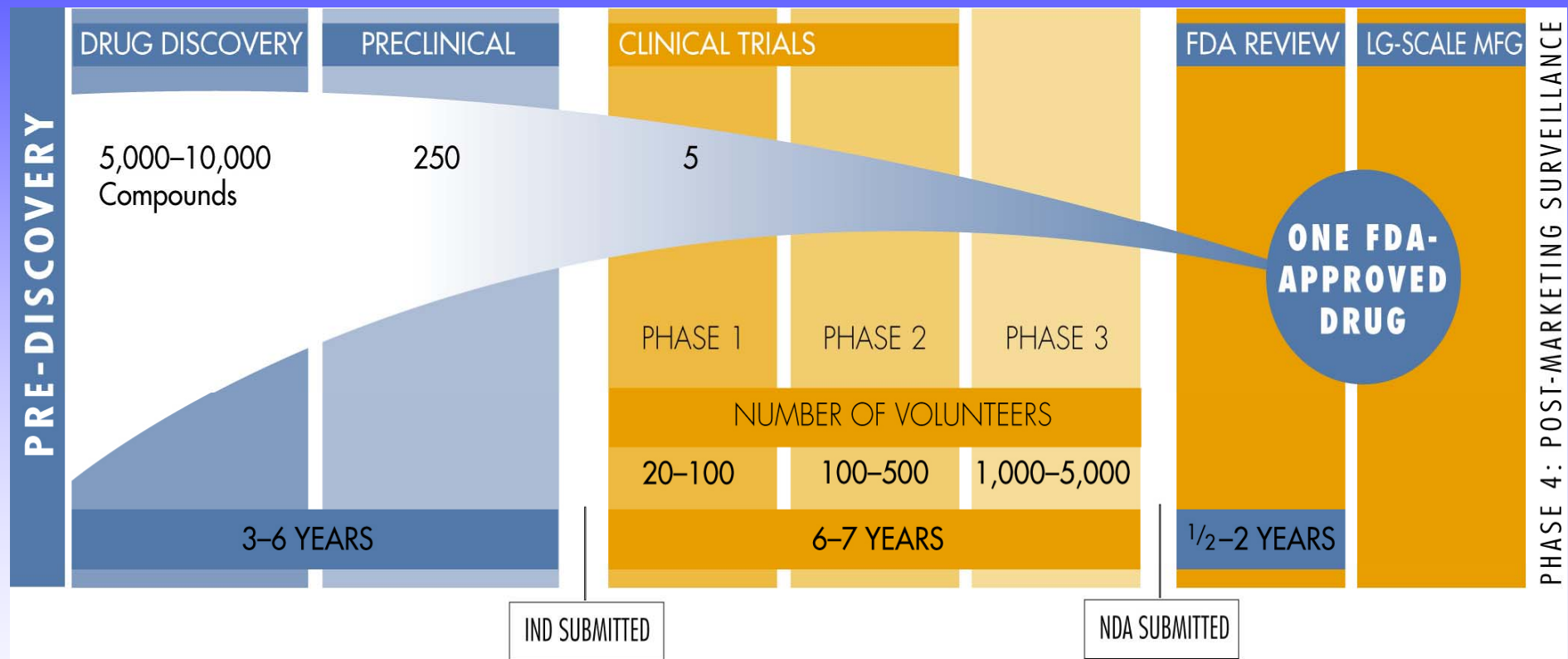
Patent term
extended to
20 years

2004

Patents
Ordinance
passed on
December
26, 2004

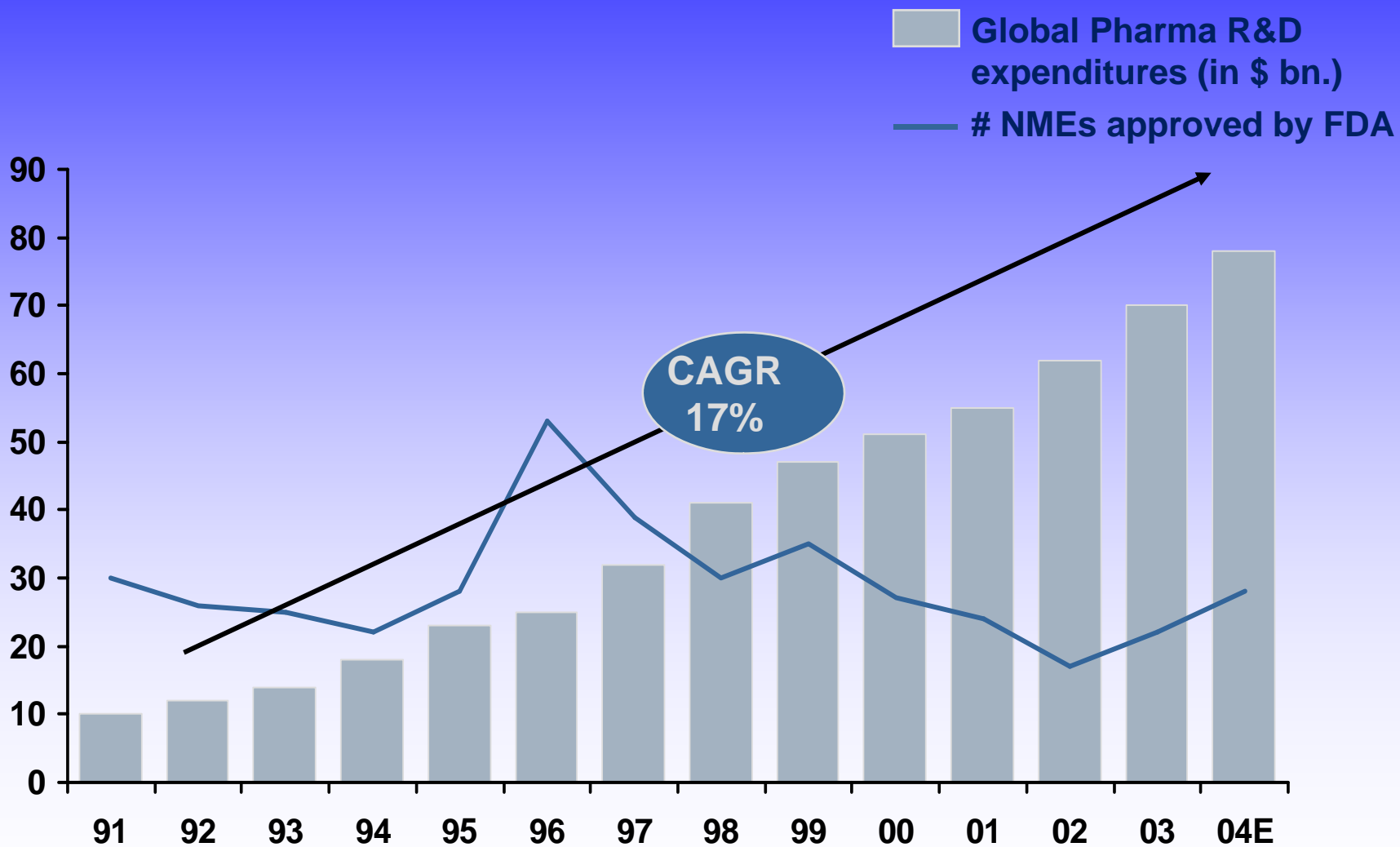
In technical
compliance with
the commitment
made under the
WTO Agreement

R&D Process – Long, Costly & Complex



Source: Pharma - Profile 2008 – Pharma Industry

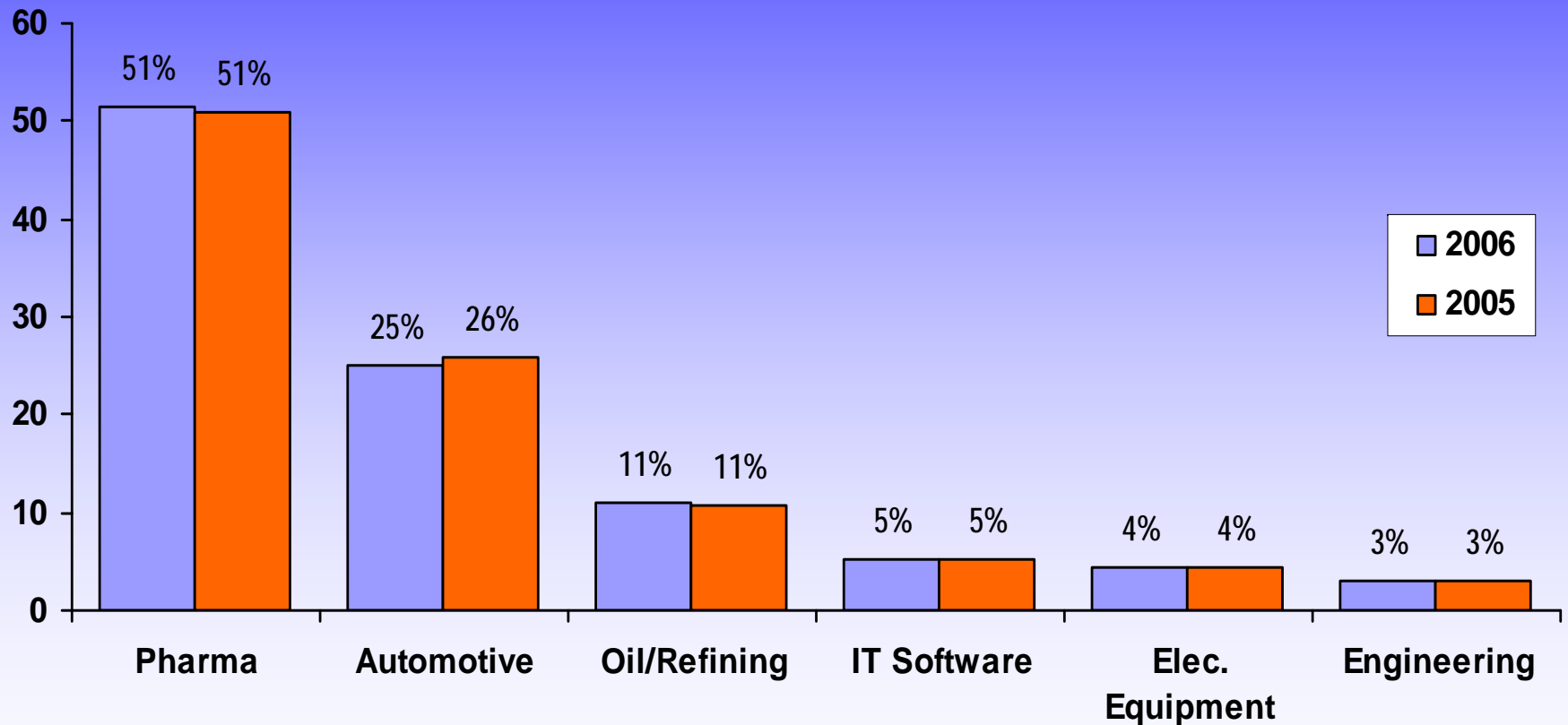
India Spends More to get Less



Source: FDA CDER & CBER; Evaluate

Indian Industry – R&D Spend

R & D Spend: How Top Sectors Fare

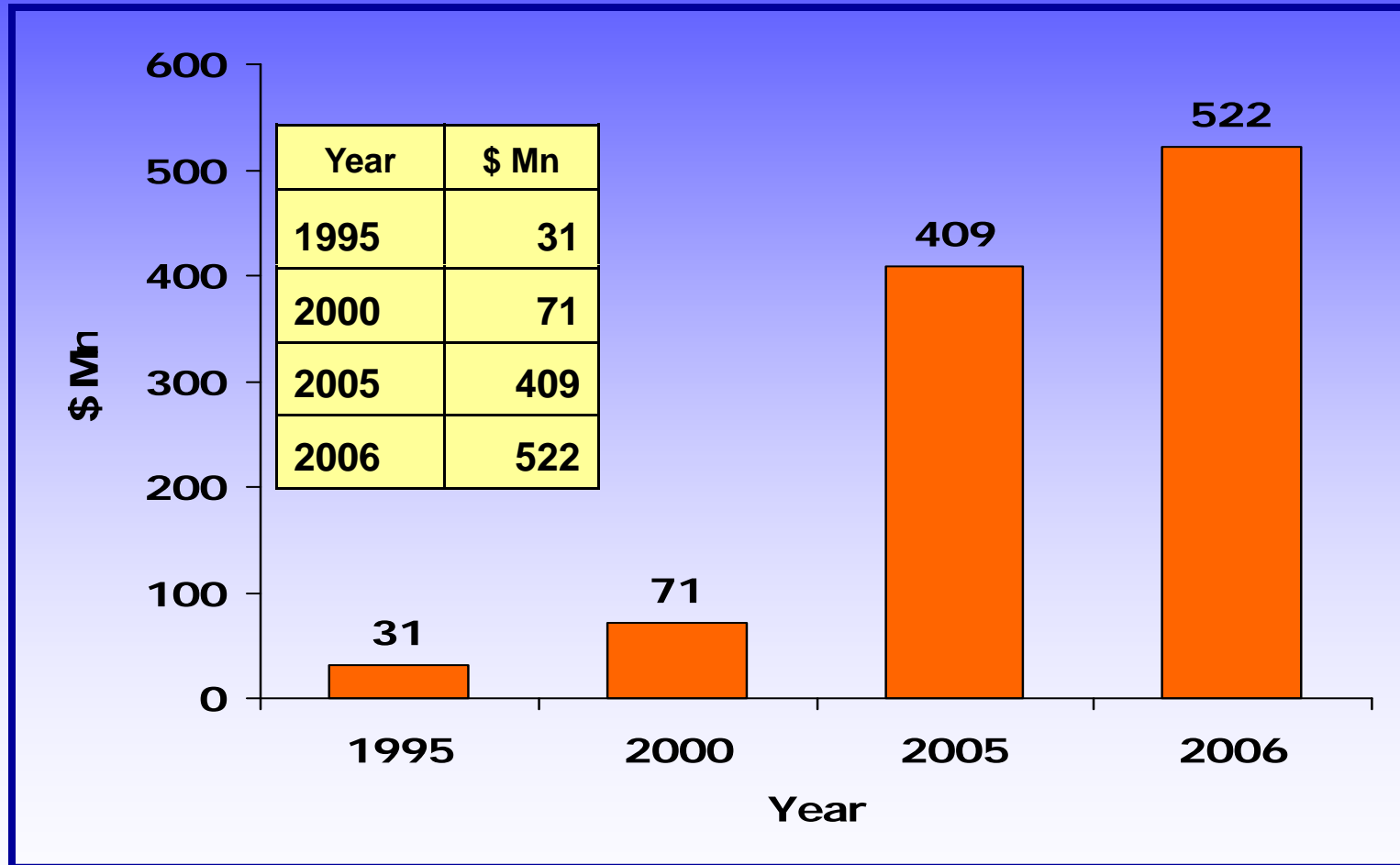


Source: Capitaline Plus

Pharma Spends More Than All Industries Put Together

Indian Pharmaceutical Industry

R & D Spend - Pharmaceuticals

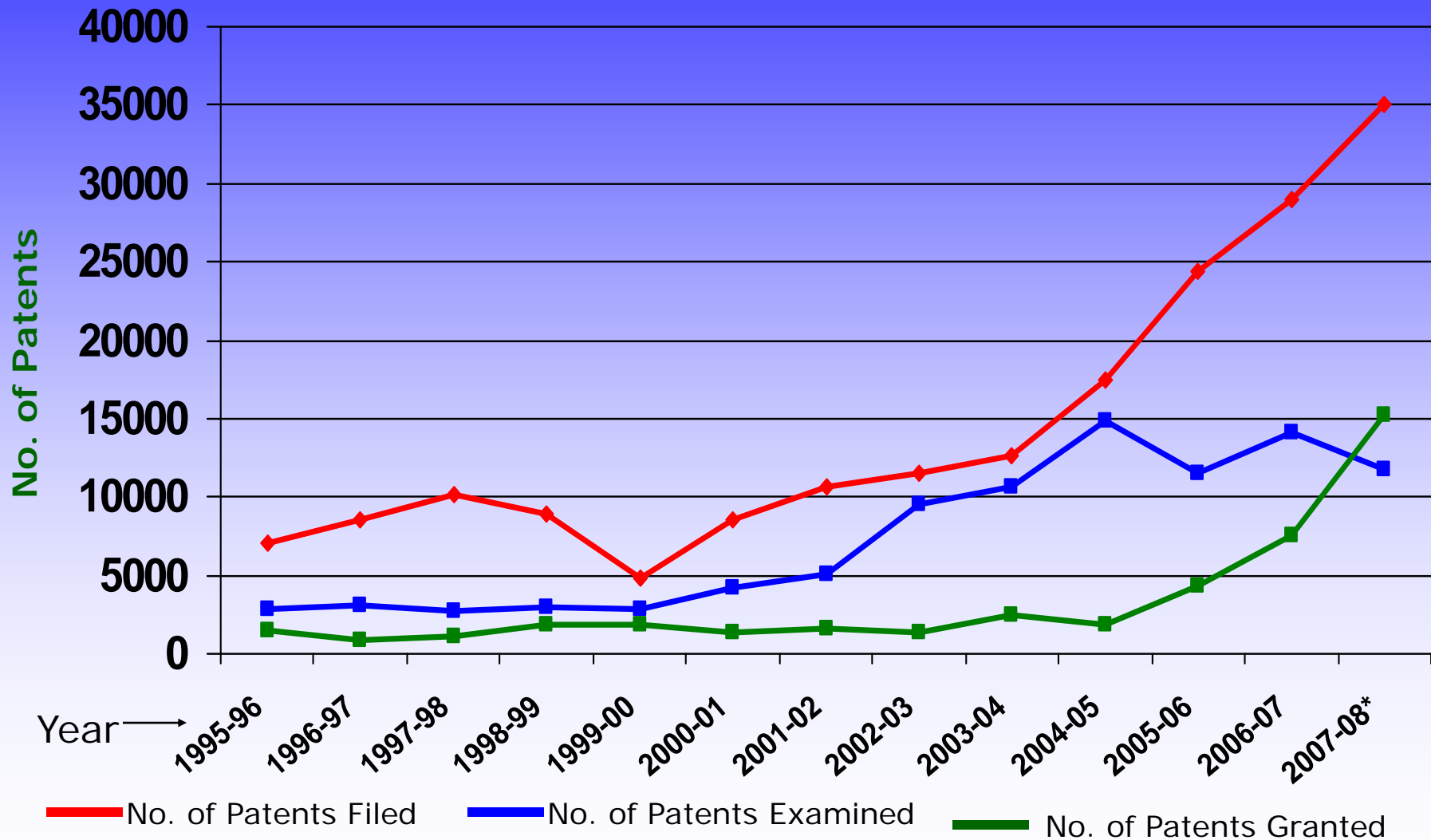


@ Constant \$ (1 = INR 40)

Almost 10% of 2006 Trade Sales

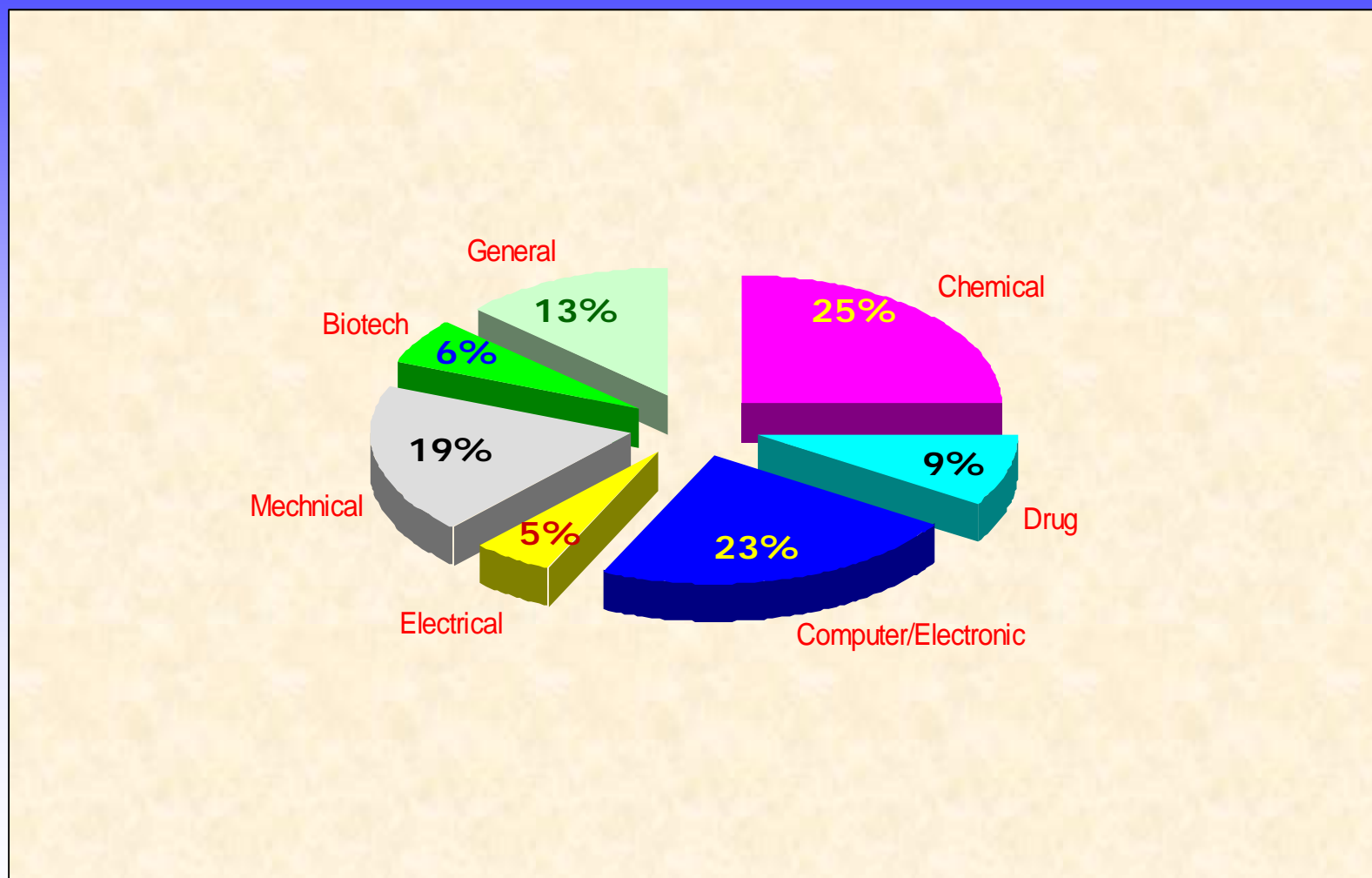
Source: IDMA

Patent Filing Trends at the IPO (From 1995-96 to 2007-08*)



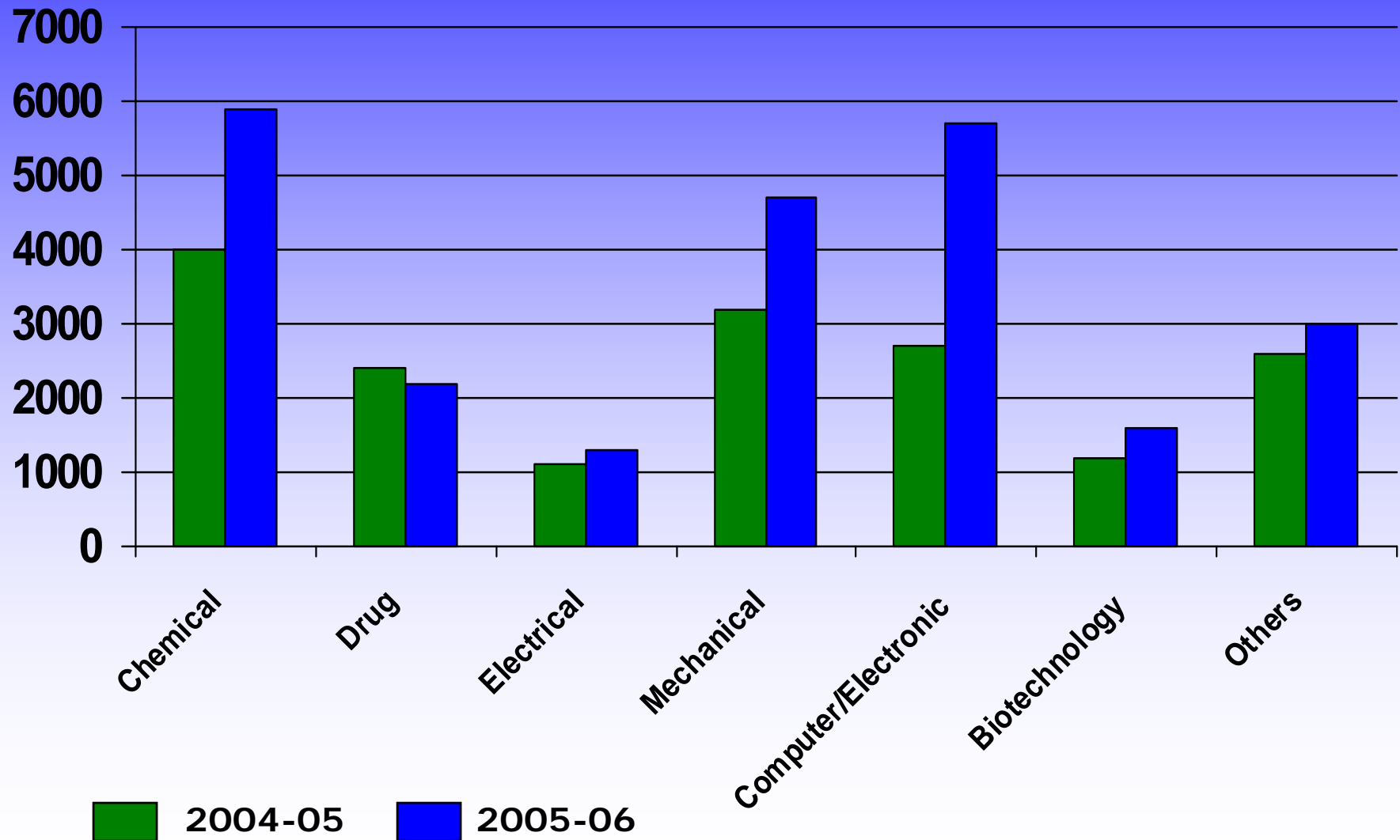
2007-08* provisional figures Source: IPO

Domain-wise Breakdown of Patent Applications Filed at the IPO (2005-06)



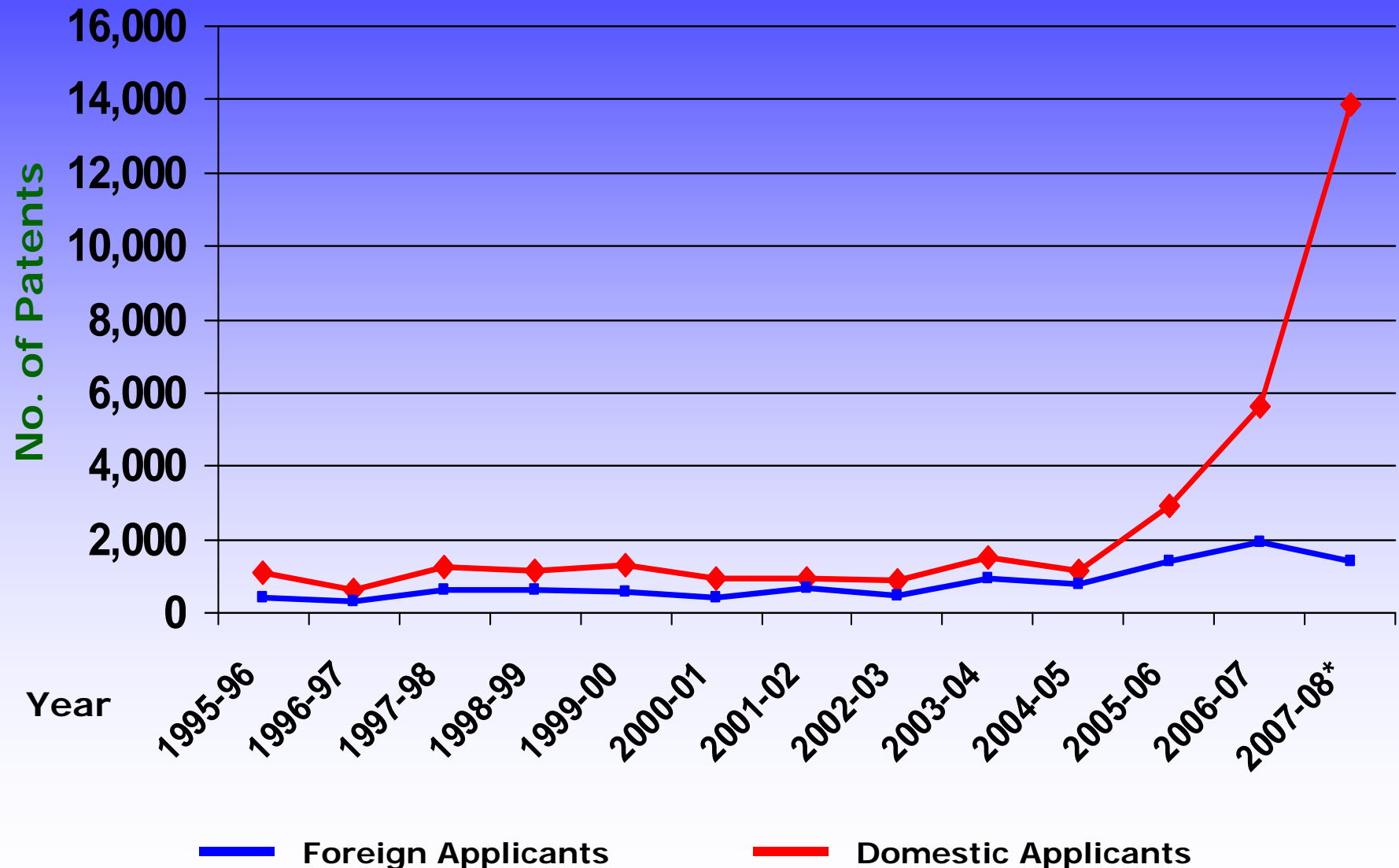
Source: 2005-06 Annual Report, IPO

Growth of Patent Applications Filing in Different Domains (from 2004-05 to 2005-06)



Source: 2005-06 Annual Report, IPO

Trend of Patent Applications filed by Domestic Applicants & Foreign Applicants at the IPO



2007-08* provisional figures

Source: IPO

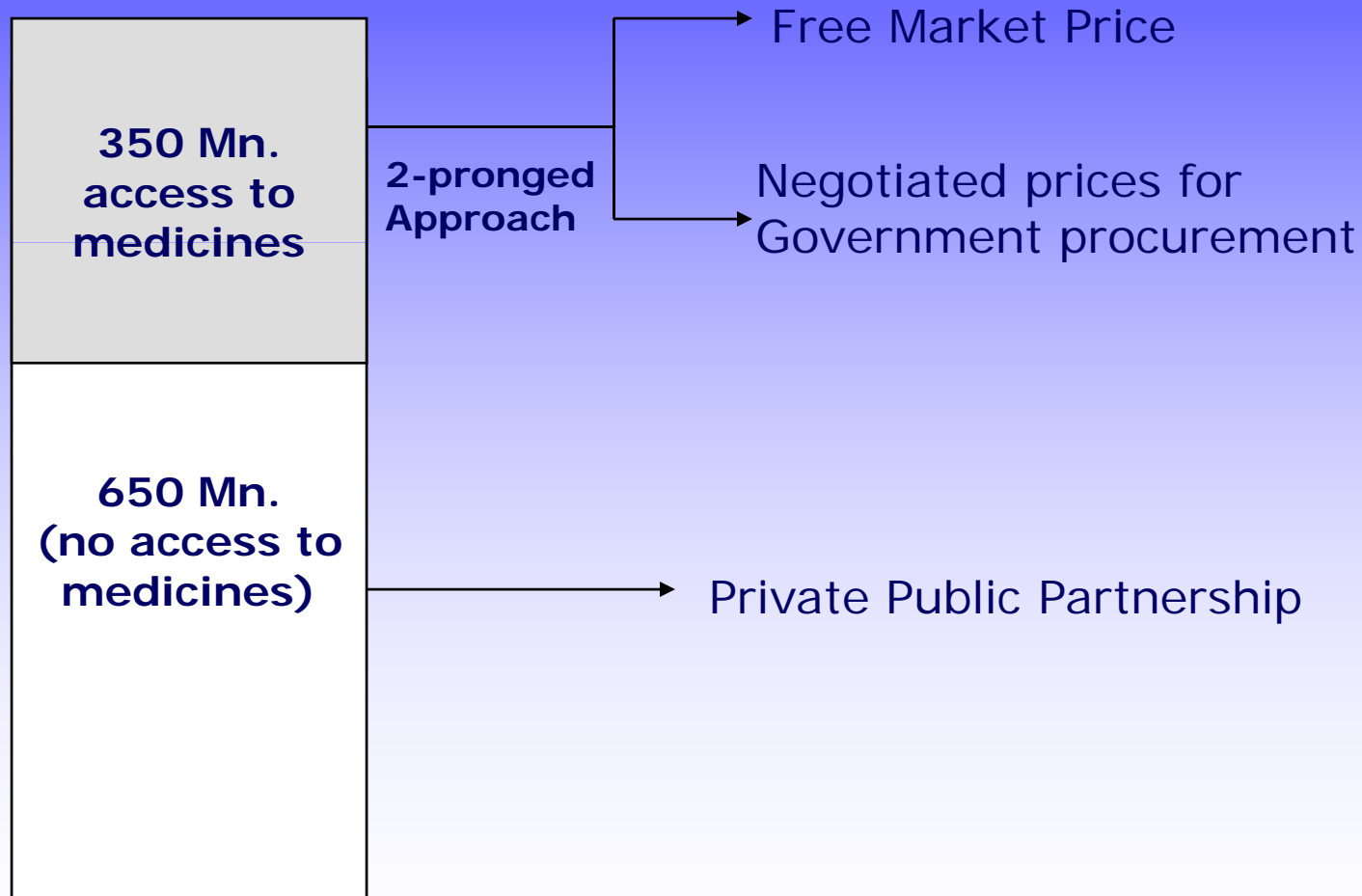
Indian Patent Law – Areas of Concern

- ❖ Definition of Patentability
- ❖ Data Protection
- ❖ Scope of Compulsory Licensing
- ❖ Pre-Grant Opposition
- ❖ Enforcement of Patent Act

The Way Ahead...

Ensuring Access in Control

Free Pricing Regime



Advantage India and the Way Forward

Advantage India

- ❖ An abundance of English speaking scientific and technological brainpower
- ❖ Large and diverse drug naive patient base for conducting international clinical trials
- ❖ Strong base of bulk drug manufacture (400 APIs)
- ❖ 15-16% R&D scientists in U.S. Pharmaceutical Industry are of Indian origin – hence strong networking.

Increase in Health Awareness and Disposable Income – Key Drivers for Future Growth

- ❖ 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

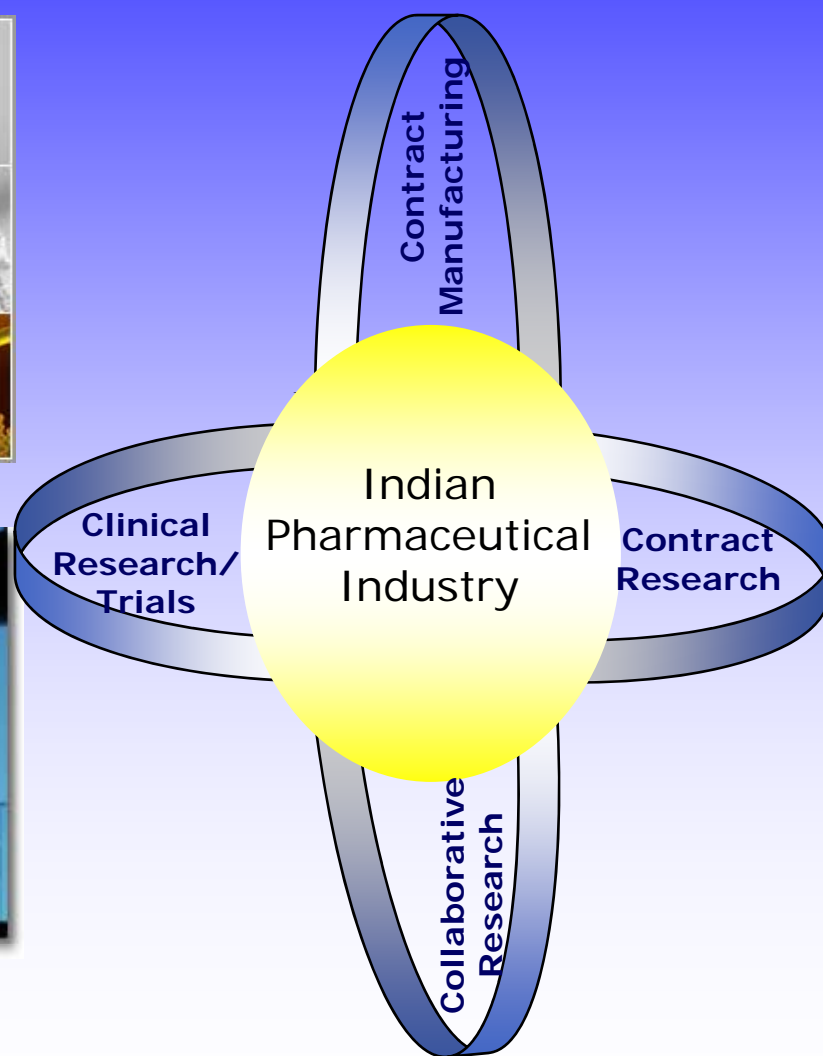
Increase in Health Awareness and Disposable Income – Key Drivers for Future Growth

- **Government changing its role from Healthcare Provider to Healthcare Facilitator**

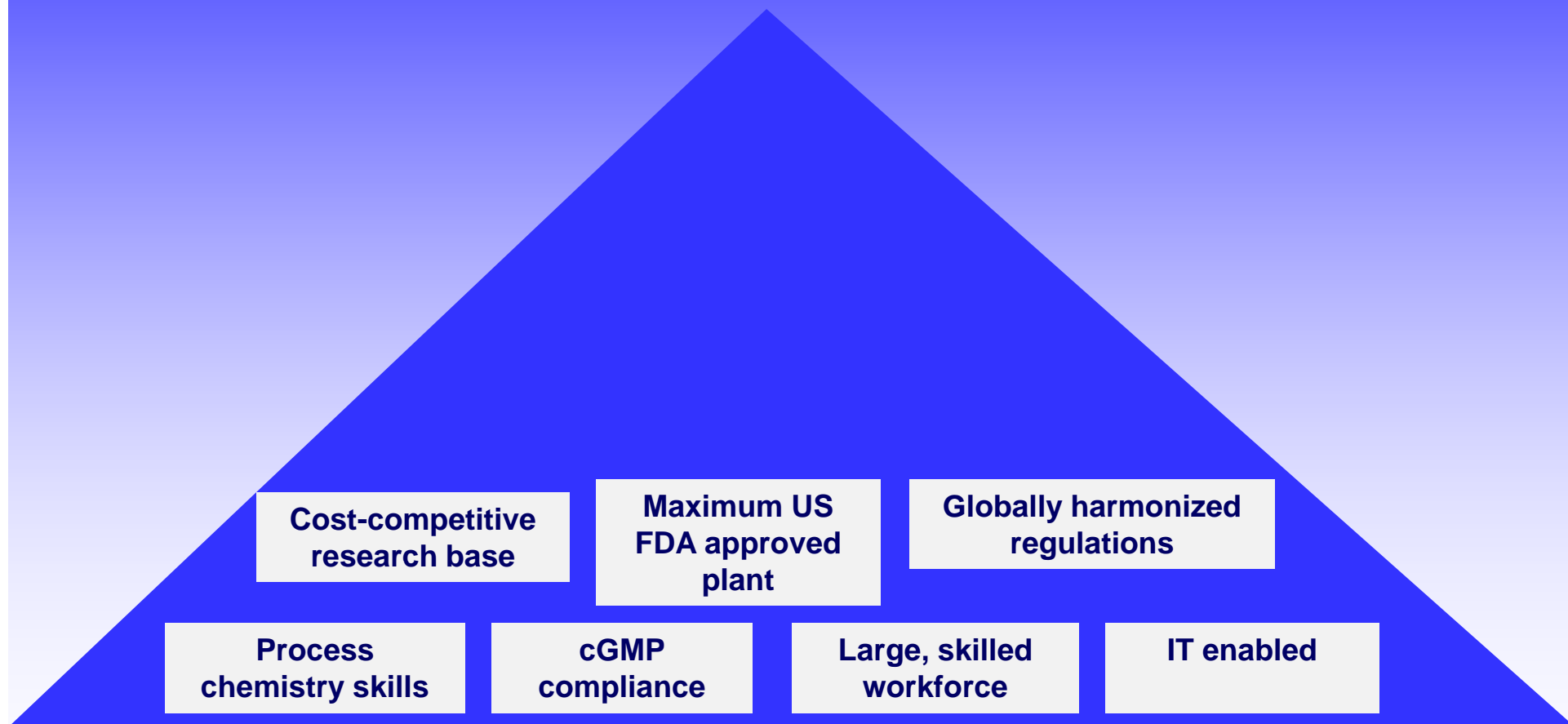
	2002	2012
Private Healthcare Spending (U.S.\$ Bn.)	14.8	33.6

Source: India Trade Promotion Organisation (ITPO)

Key Opportunity Segments

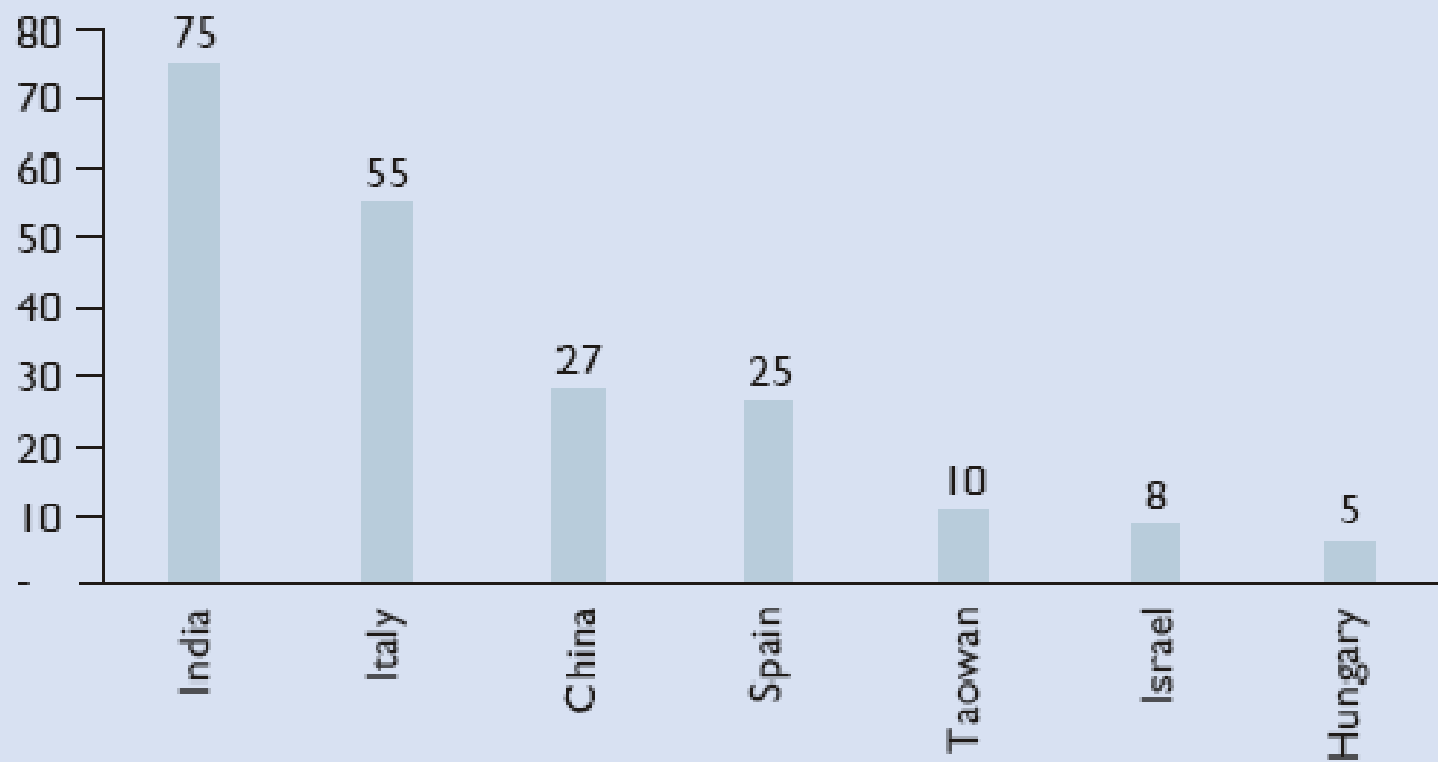


Outsourcing Opportunities



Significant capacity expansion by Indian companies

India has the most US FDA-approved mfg. sites outside the US



Source: US FDA

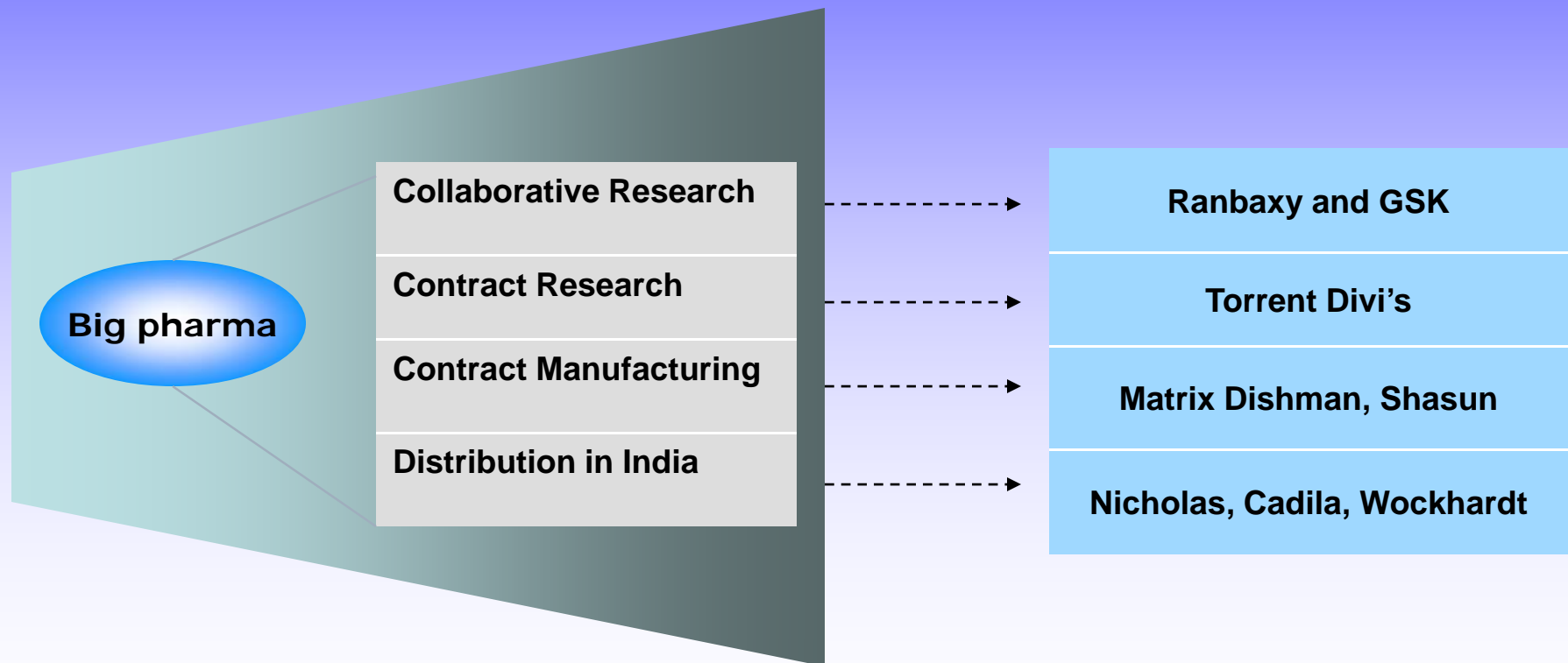
Cost-Competitiveness

– A Key Advantage



Outsourcing and Off-shoring Opportunities Abound

Big pharma partnering with Indian pharma



Policy Initiatives

- ❖ The patent (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
- ❖ Creation of Export Promotion Council “Pharmexcil”



ASIA

INDIA TAKES ON THE WORLD

**BIG COMPANIES BEWARE: THAT ELEPHANT IN THE ROOM
MAY BE AN INDIAN COMPETITOR LOOKING TO BUY YOU OUT**

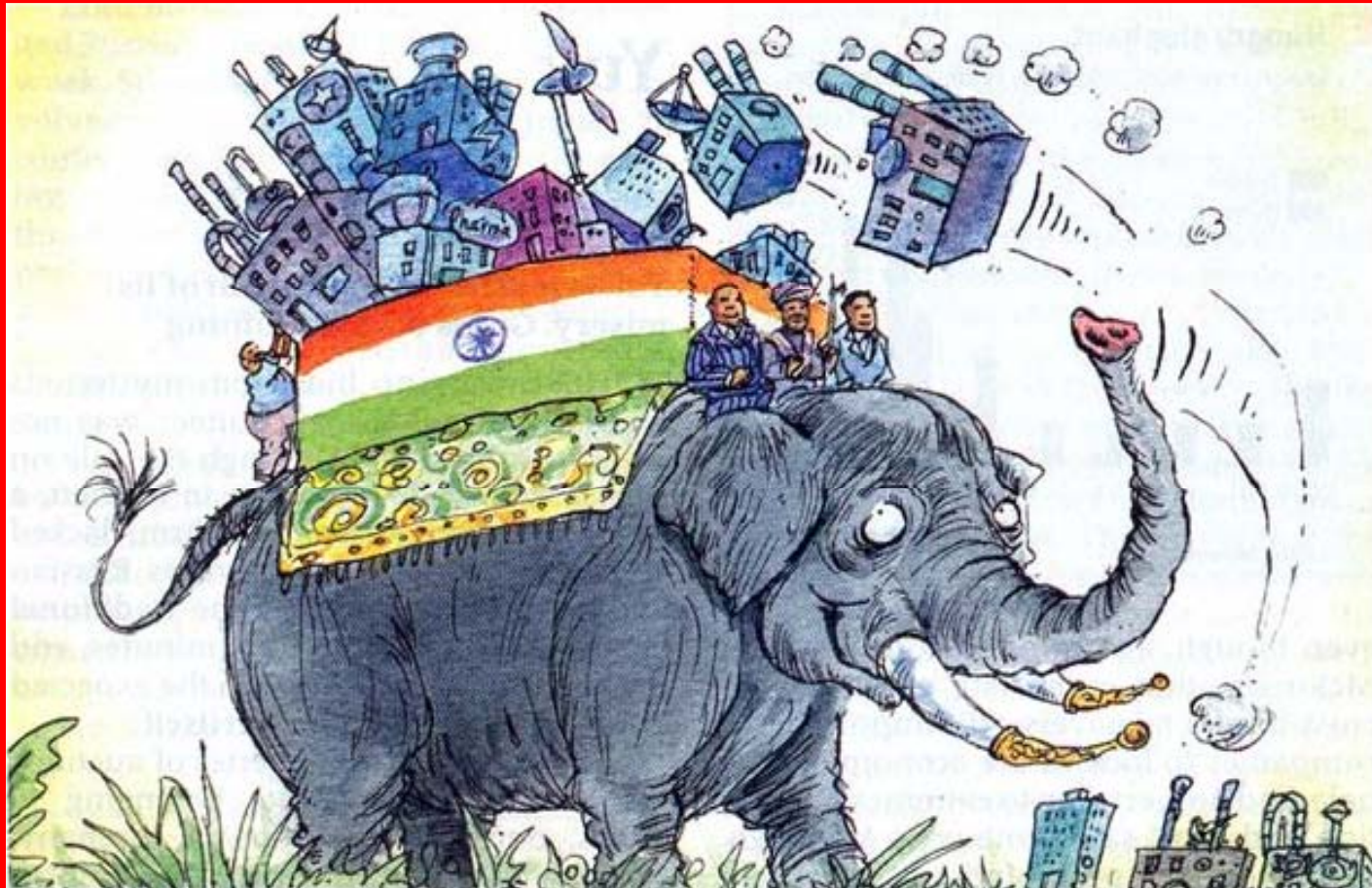
WORLD
ECONOMIC
FORUM

By **SIMON ROBINSON** BOMBAY

YOU HAVE PROBABLY NEVER HEARD of Essel Propack but there's a fair chance you have squeezed one of its products. The Bombay company is the largest manufacturer of laminated tubes in the world. Most toothpaste these days is packaged in such tubes and one-third of global supply comes from Essel Propack's 20 factories in 13 countries across Africa, Asia, Europe, and North and South America. The company also churns out tubes for cosmetics, pharmaceutical creams, hair-care products and food. It may not be the sexiest industry, but the business is growing fast and



Time Magazine – November 2006



India's acquisitive companies

Marauding maharajahs

The Economist March 31st 2007

Pharma on a Shopping Spree – 2005-07

Sr. No.	Acquirer	Target	Sum (\$ Mn.)
1.	Matrix Labs.	DocPharma	263.00
2.	Ranbaxy	RPG Aventis Efarmes Sa Terapia	80.00 18.00 324.00
3.	Dr. Reddy's	Roche's Mexican API Unit Tirgenesis Betapharm	59.00 11.00 572.00
4.	Torrent	Heumann	30.00
5.	Hikal	Marsing Psi Supply	5.90 16.50
6.	Nicholas Piramal	Avecia Pharma Pfizer's Manufacturing Unit in U.K.	16.25 50.00

Pharma on a Shopping Spree – 2005-07

contd...

Sr. No.	Acquirer	Target	Sum (\$ Mn.)
7.	Strides Arcolab	Strides Latina	16.00
8.	Wockhardt	Epharma Negma	13.30 265.00
9.	Jubilant	Trinity	12.30
10	Zydus Cadila	French Formulation Unit of A Pharma	9.41
11.	Glenmark	Labs Kilinger	5.20
12.	Dishman	Synprotec	3.48
13.	Sun	Taro	454.00
14.	Zydus Cadila	Nikkho, Brazil	26.00
Total:			2250.34



India is Emerging as a Preferred Destination for Life Sciences, but China....

Globally aligned industry

- Patent regime
- Relationships and presence in other countries

Strong domestic market

- Companies with a long-term stake
- Generating resources for growth

High quality resources

- Skilled manpower
- Companies looking to invest in long-term growth avenues

India emerging as the preferred destination for . . .

- New Drug Discovery Research
- Manufacturing
- Research Services (Clinical Research, Bio-Informatics, Synthetic and Medicinal Chemistry etc.)

China fast catching up, and already beating India on pharma manufacturing

Thank You