

INDIA – THE PHARMACEUTICAL MARKET WITH FOCUS ON PATIENTS

Tapan Ray

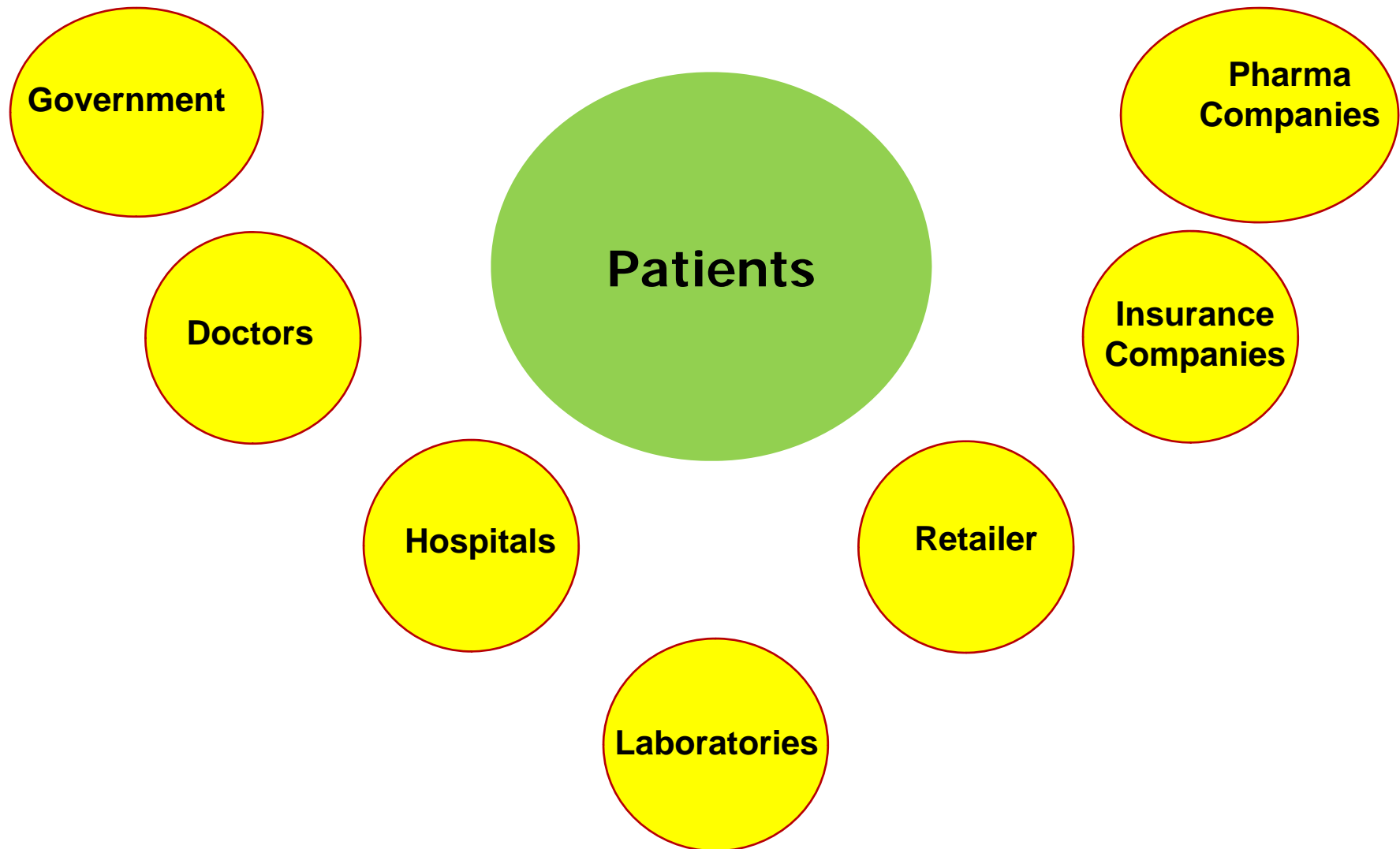
India Chem

October 22, 2008
Mumbai, India

Content

- ❖ Mission and vision of the stakeholders
- ❖ Demographic, Economic & Healthcare Scenario of India
- ❖ Overview of Indian Pharmaceutical Industry
- ❖ Healthcare Policy of India – has it delivered?
- ❖ Improving Access to Healthcare
- ❖ Outsourcing opportunities
- ❖ The New IPR regime – the new paradigm
- ❖ Growth with focus on patients

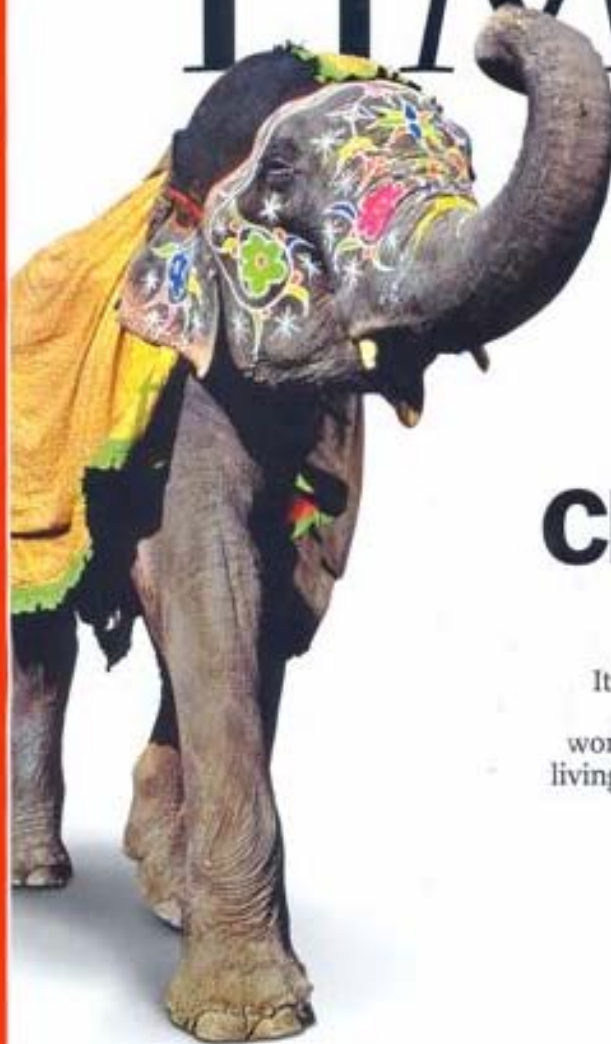
Mission and Vision of Stakeholders: Improving access of safe and effective medicines to.....



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



Demography, Economic and Healthcare Scenario of India

Demographics

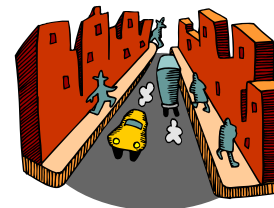


Population: 1.13 billion

Male	Age	Female
15.0%	50- 80+	15.0%
25.1%	30-49	25.8%
59.9%	0-29	59.2%

➡ **Life Expectancy : 64.59 years**

➡ **Birth Rate : 22.69 /1000**



29% : Urban



71% : Rural

➡ **Literacy rate: 59.5%**

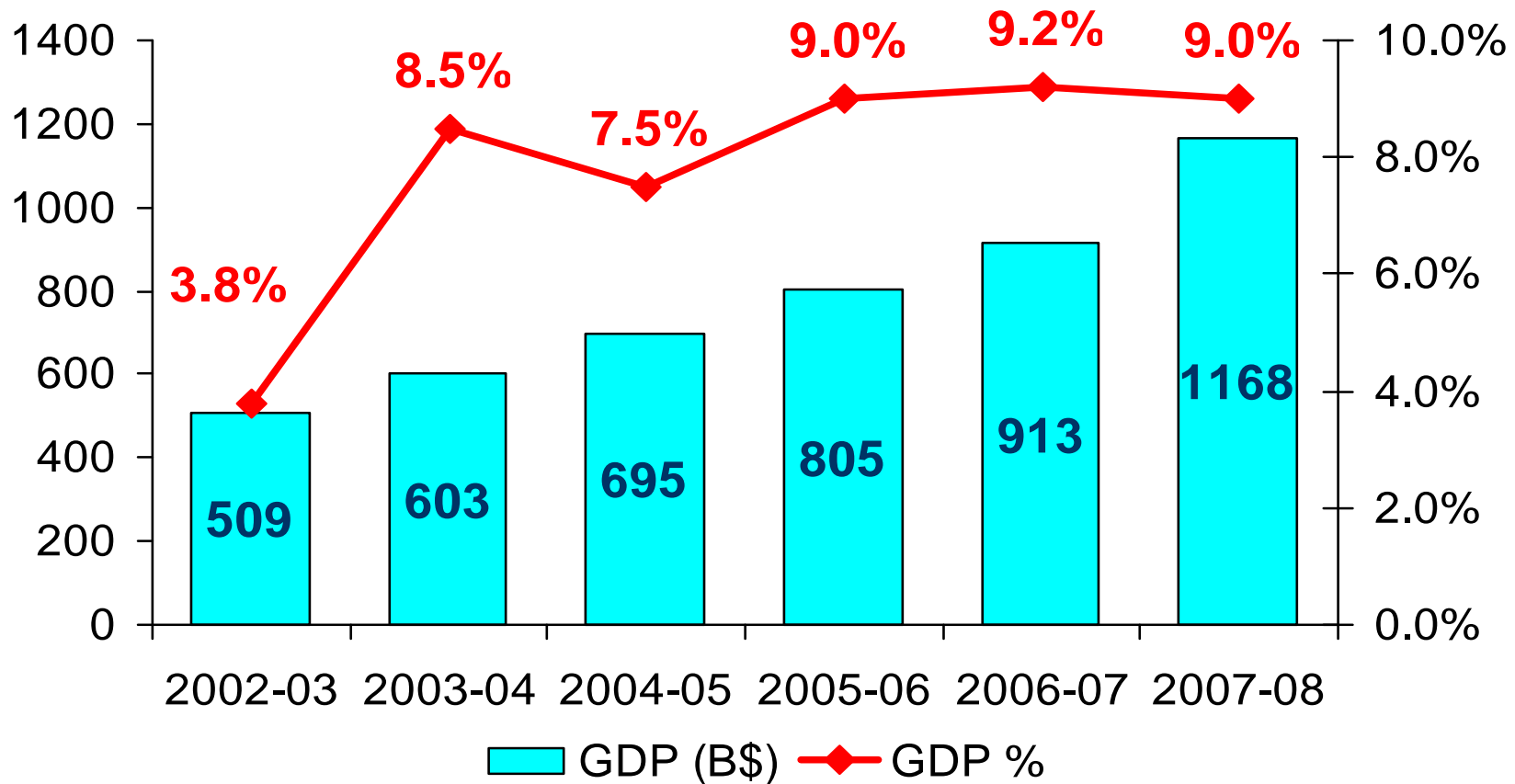
➡ **Business Language: English**

➡ **Yearly addition of 2.46M graduates from 253 universities & 13150 colleges**

Source : CIA – The World Factbook

India : Robust Economic Platform

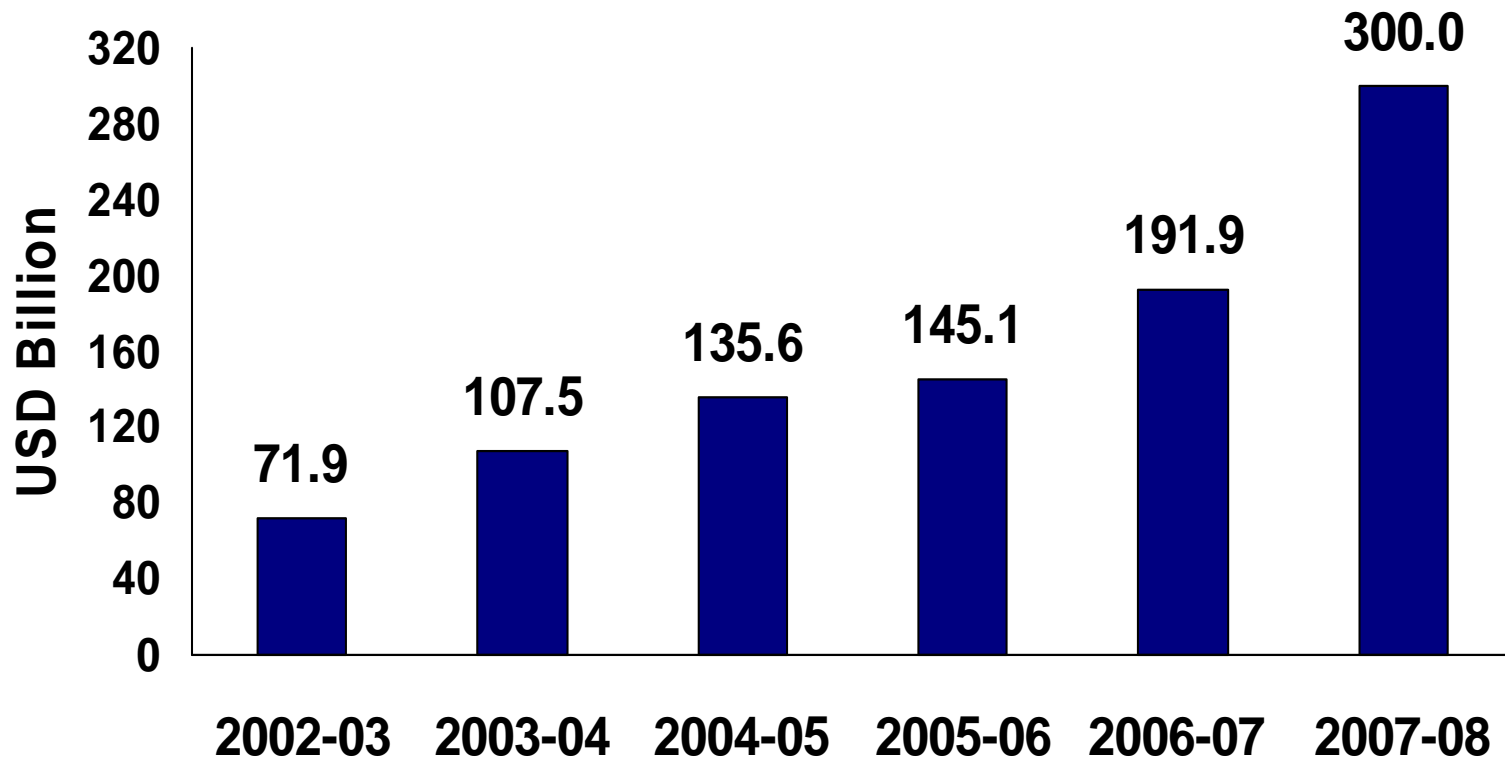
India's GDP



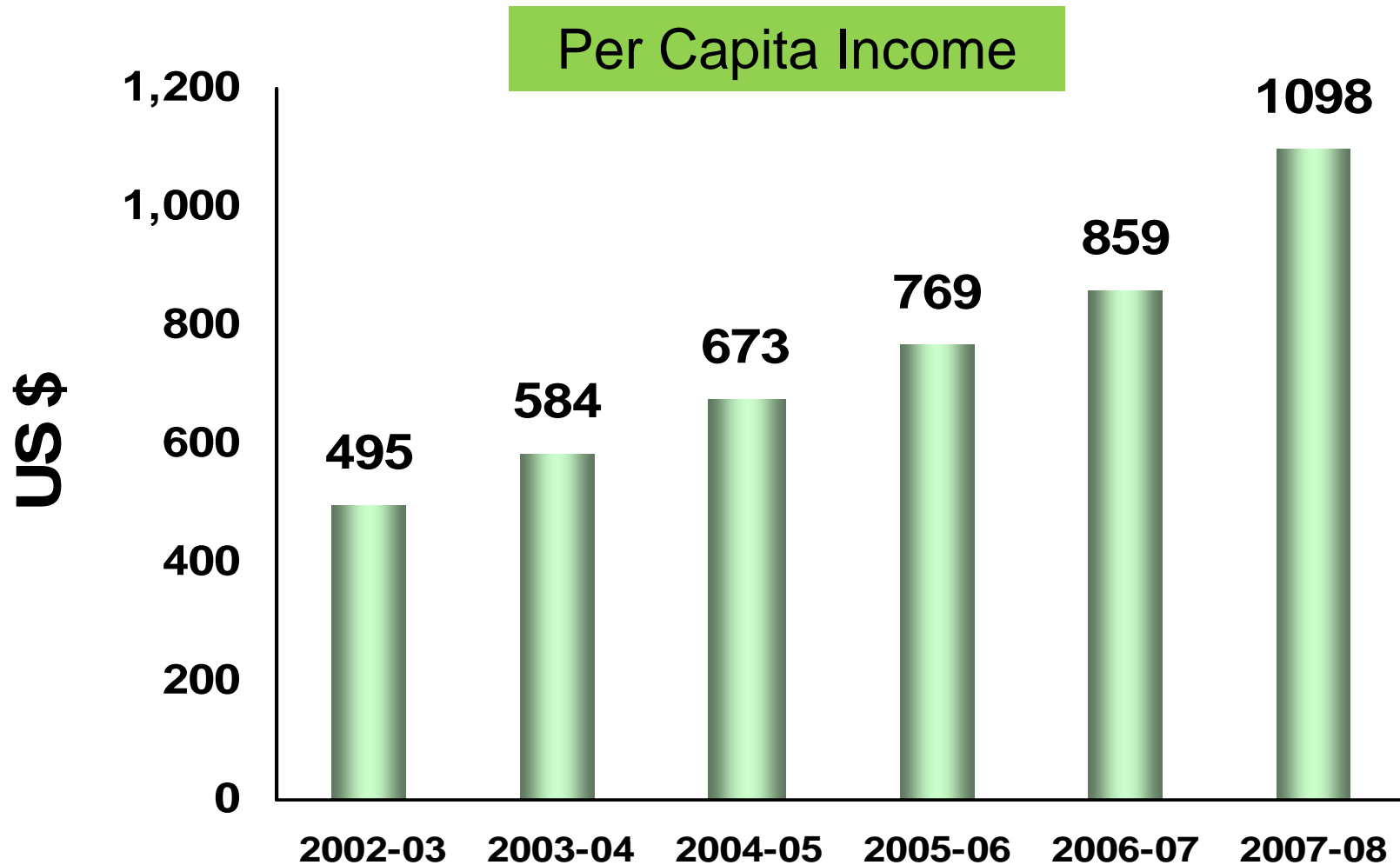
Indian economy is estimated as 4th largest in terms of PPP – USD 5.2 trillion in 2008

India : Robust Economic Platform

India's Forex Reserve are in Excess of Foreign Debt

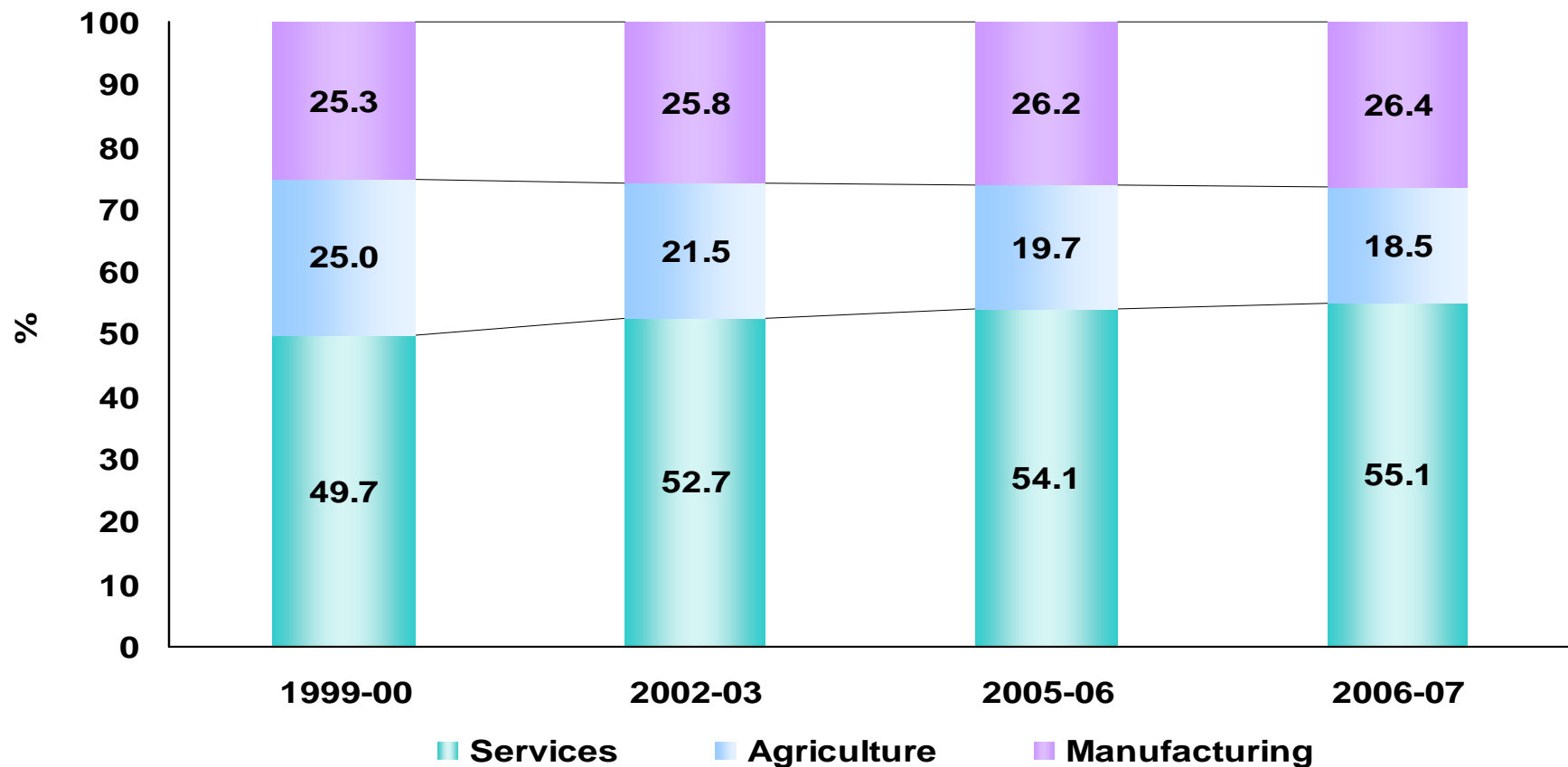


India : Robust Economic Platform

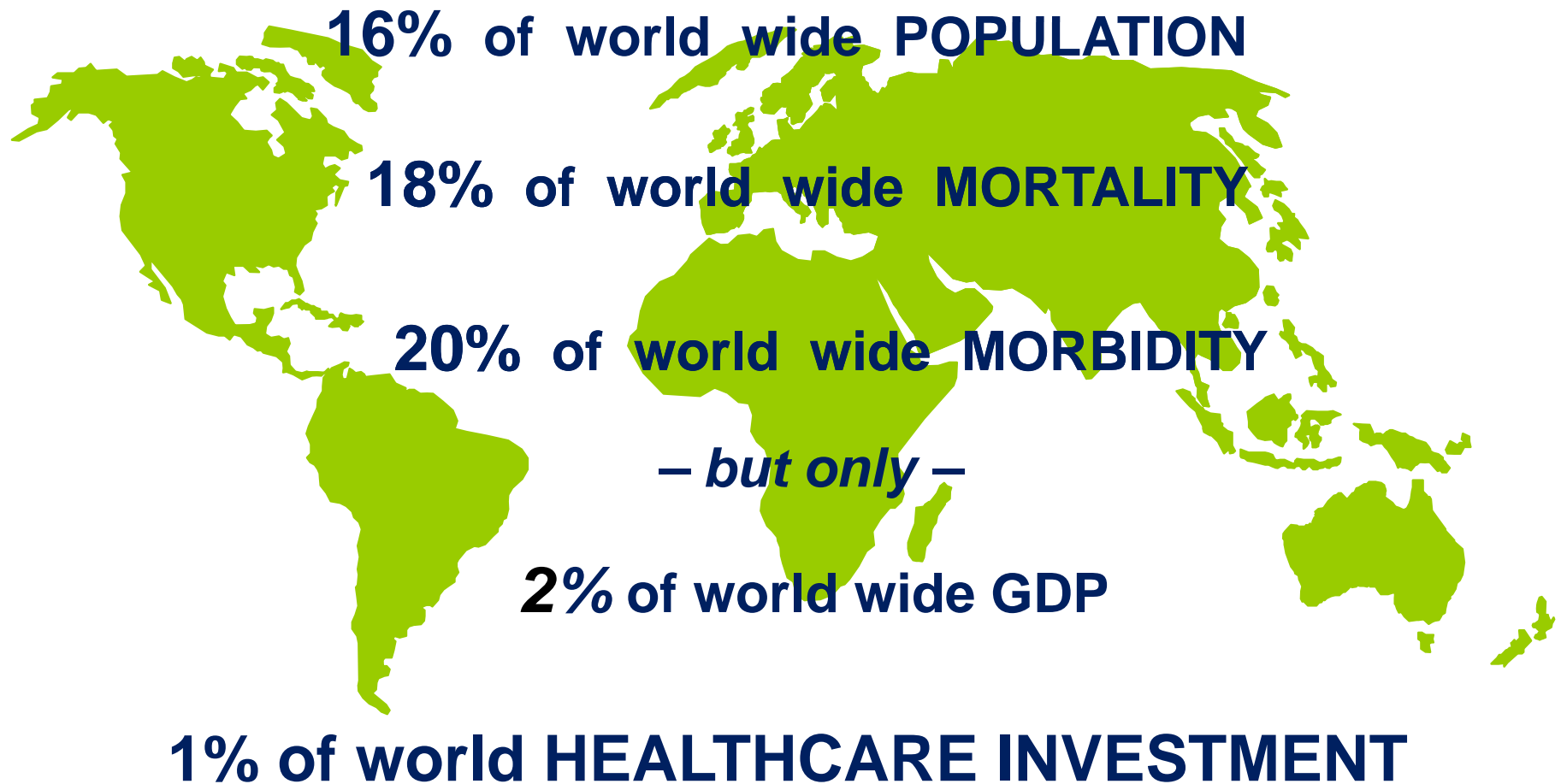


India : Robust Economic Platform

Contribution of Services - increased from 49% to 55 %



Healthcare : High Population / Low Investment



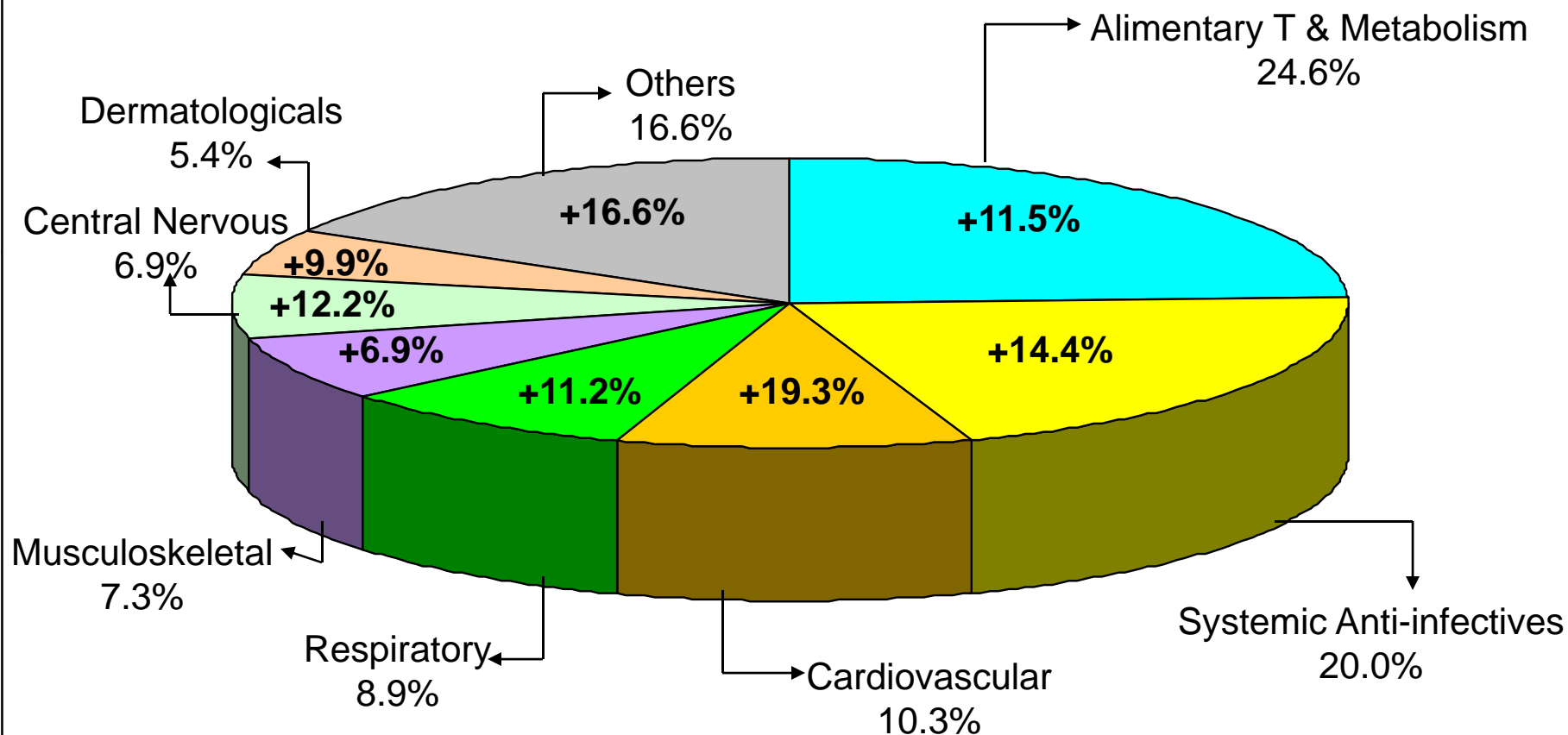
Pharmaceutical Industry - An Overview



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

Pharmaceutical Market

Key Therapeutic Segments



Acute Therapies over 70% of Market (35% in U.S.A.)

Total Market US\$ 7549.2 Mn (Growth 13.4%)

[13th in value and 4th in volume globally]

Source : IMS SSA July 2008

Pharmaceutical Market

Strengths

- ❖ Patent Protection from Jan. 2005
- ❖ Increasing affordability : Middle class of 150 M*
- ❖ Technical expertise : Highest (100+) number of US FDA approved plants outside USA
- ❖ Cost Competitiveness
- ❖ Low cost of C R&D

* Annual Income >\$ 5000

Pharmaceutical Market

Issues

- ❖ 50,000+ Brands - 60 therapeutic segments (dispersed)
- ❖ No Reimbursement & Negligible Medical Insurance
- ❖ Govt. planning to increase span of cost based price control – 100% of market currently under Price Regulation
- ❖ No medical facilities in rural areas (future opportunities)

Reliance on Alternative Medicine

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

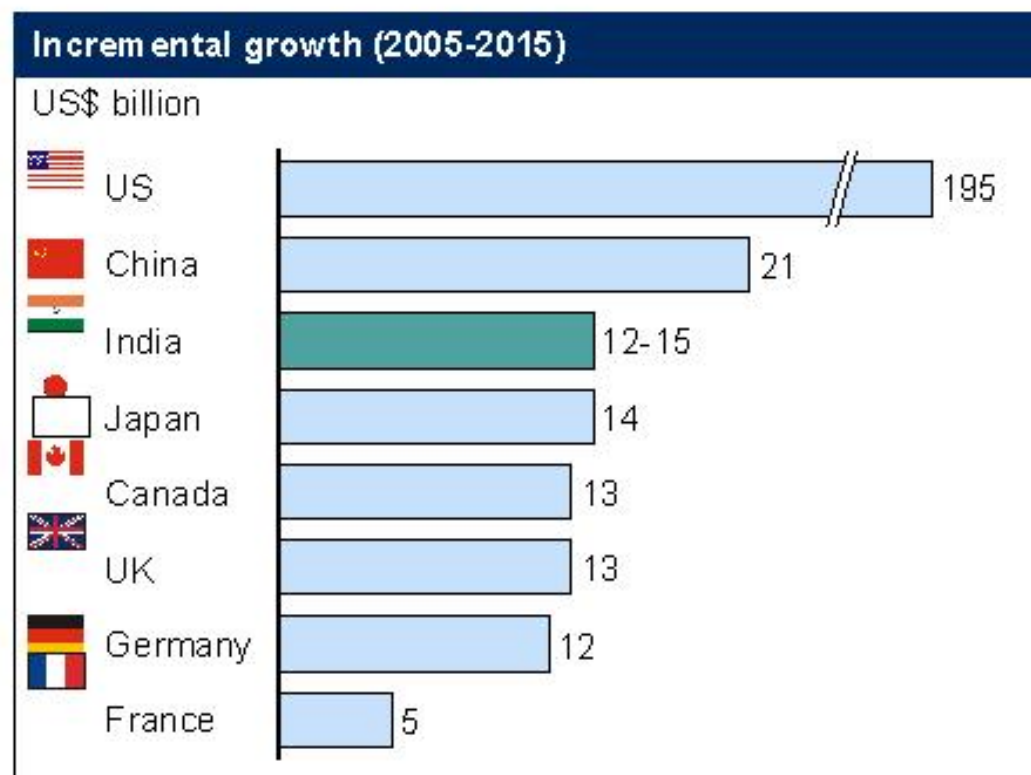
70% of the population is believed to supplement or even replace drugs with traditional medicine.



Source : NCAER – The Indian Middle Class

McKinsey Prognosis: India to be the Third Largest Growing Market

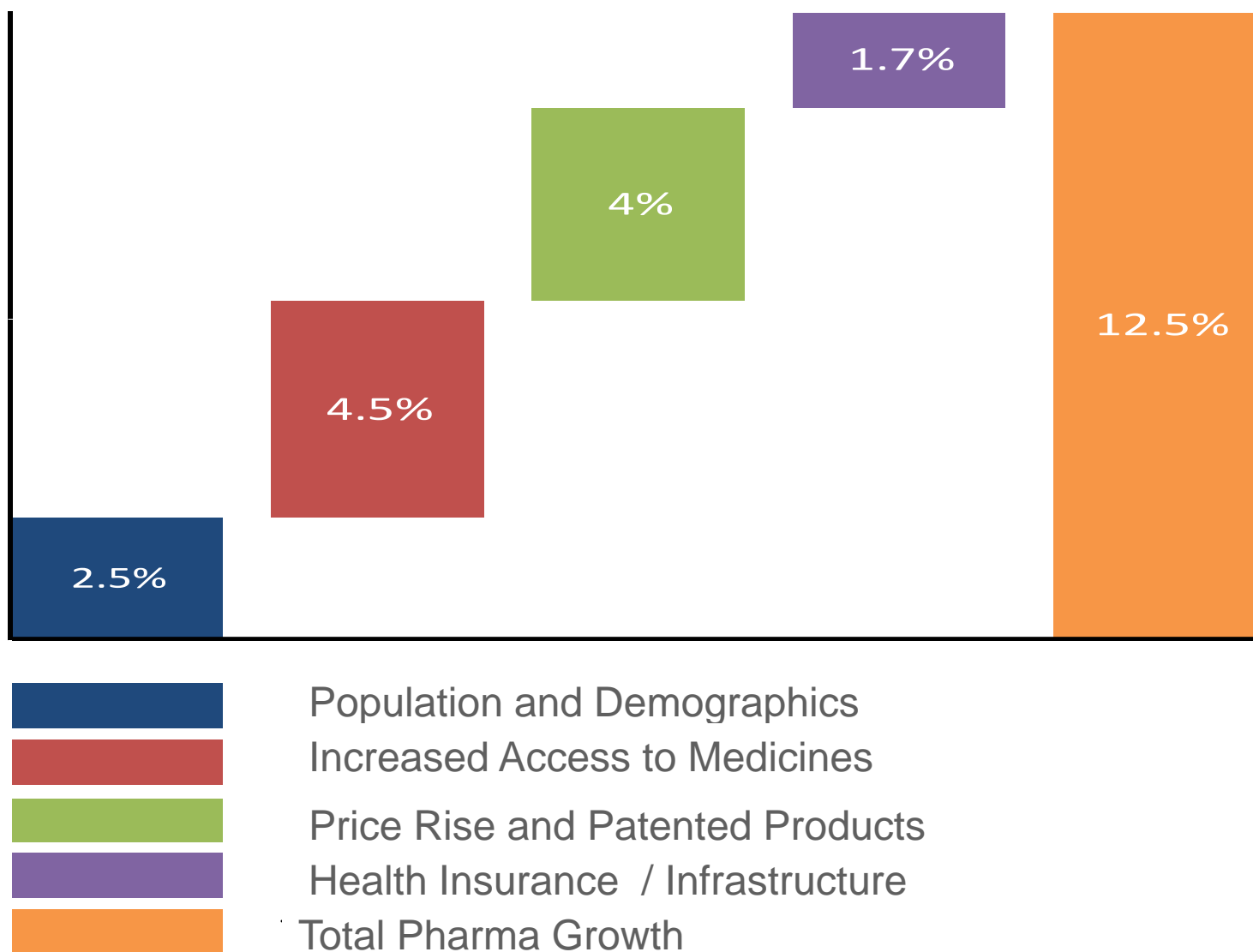
INDIA WILL BE AMONG THE HIGHEST GROWTH MARKETS IN THE WORLD



Source: Datamonitor projections; McKinsey analysis

McKinsey & Company

Key Growth Drivers



Source: OPPI-Yes Bank Vision 2015, Sept. 2008

Top 50 Products

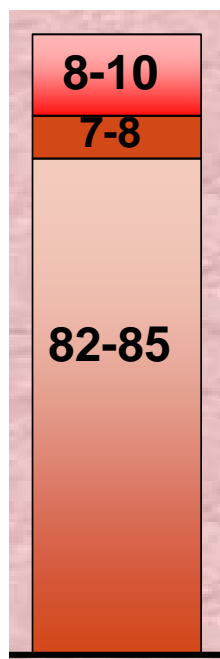
Market segments

Per cent

100% = US\$ 8.0 B

OTC
Generic-
Generics

Branded
Generics

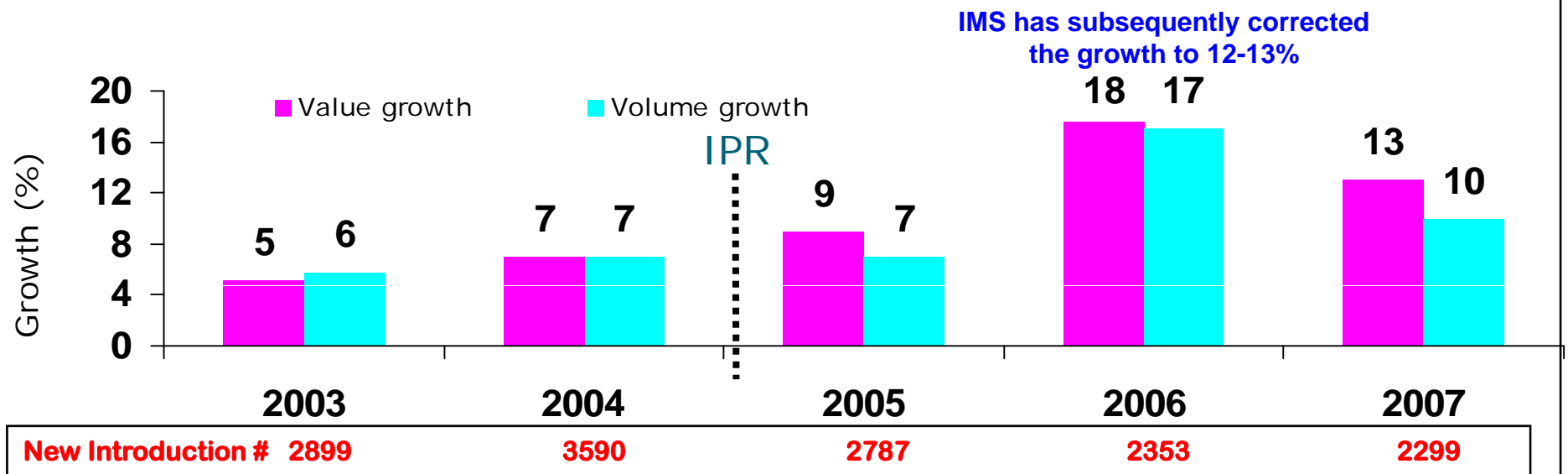


2007

RANK	PRODUCTS	Description	Company	M\$	Gr %
	TOTAL MARKET			8,121.4	13.68
1	VOVERAN	NSAID	Novartis	35.7	13.50
2	COREX	Cough Syrup	Pfizer	35.7	7.30
3	HUMAN MIXTARD30/70	Insulin	Abbott	29.9	13.50
4	TAXIM	Cefotaxim	Alkem	28.5	12.23
5	LIV-52	Ayurvedic	Himalay Drug	27.9	4.61
6	PHENSEDYL COUGH	Cough Syrup	Nicholas Piramal	27.0	0.87
7	AUGMENTIN	Amoxy+Clav	GSK	27.0	11.21
8	ZIFI	Cefixime	FDC	26.4	22.91
9	MOX	Amoxy	Ranbaxy	25.7	22.73
10	DEXORANGE	Iron	Franco Indian	24.3	11.31
11	BECOSULES	Vitamins	Pfizer	23.8	4.06
12	ASTHALIN	Asthma Prep	Cipla	23.2	4.45
13	TAXIM-O	Cefixime	Alkem	22.3	25.94
14	MONOCEF	Ceftriaxone	Aristo Pharma	21.8	7.98
15	COMBIFLAM	Analgesic	Sanofi Aventis	21.0	1.81
16	REVITAL	Vitamins	Ranbaxy	20.1	24.15
17	NISE	Nimusulide	Dr Reddy's	20.0	-4.76
18	SEROFLO	Asthma Prep	Cipla	19.8	17.15
19	CIFRAN	Cipro	Ranbaxy	19.8	-6.56
20	SPORIDEX	Cephalexin	Ranbaxy	19.5	-2.68
21	CARDACE	Ramipril	Sanofi Aventis	19.4	13.23
22	DIGENE	Antacid	Abbott	18.7	13.58
23	CALPOL	Paracetamol	GSK	18.5	6.20
24	BETADINE	Antiseptic	Win Medicare	18.2	9.04
25	OMEZ	Omeprazole	Dr Reddy's	18.1	6.41

Source : IMS SSA Jun 2008

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%

Source : SSA, Retail Store Audit

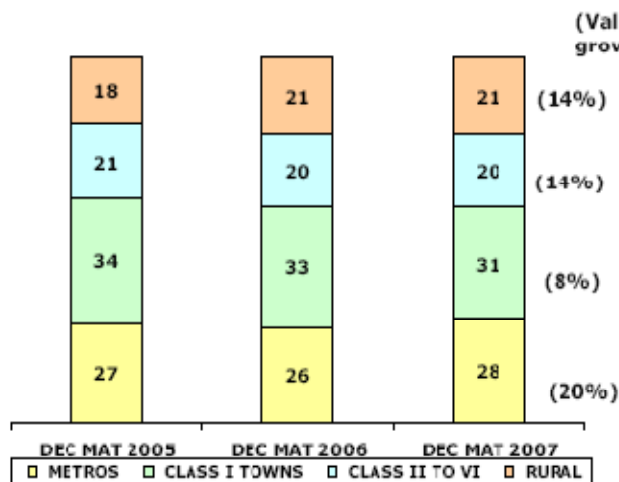
Source: IMS Health, MIDAS, MAT Dec 2007

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

Regulatory Environment

Drugs & Cosmetics Act 1940 / Rules

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

Essential Commodities Act, 1955

DPCO, 1995

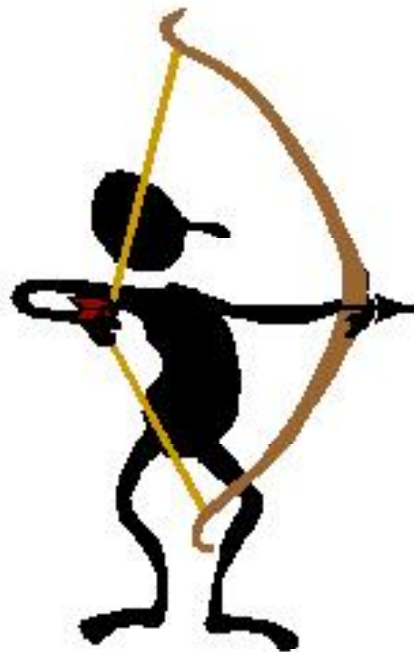
C. Excise

Customs

Transfer Pricing Regulations

Patents' Regulations

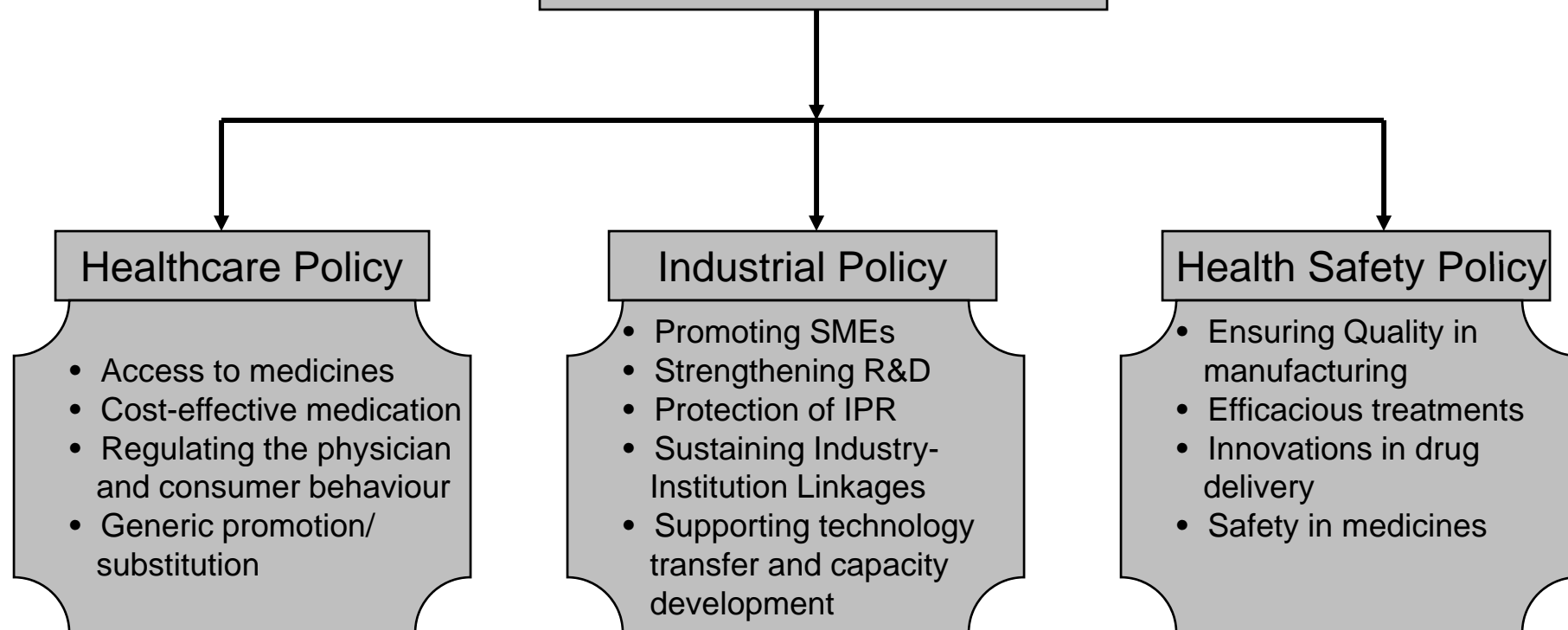
Various VAT regulations



Healthcare Policy of India – has it delivered?

Policy Framework Supporting Pharmaceutical Industry

Policy-sets that influence the Pharmaceutical Industry



Source: EXIM Research

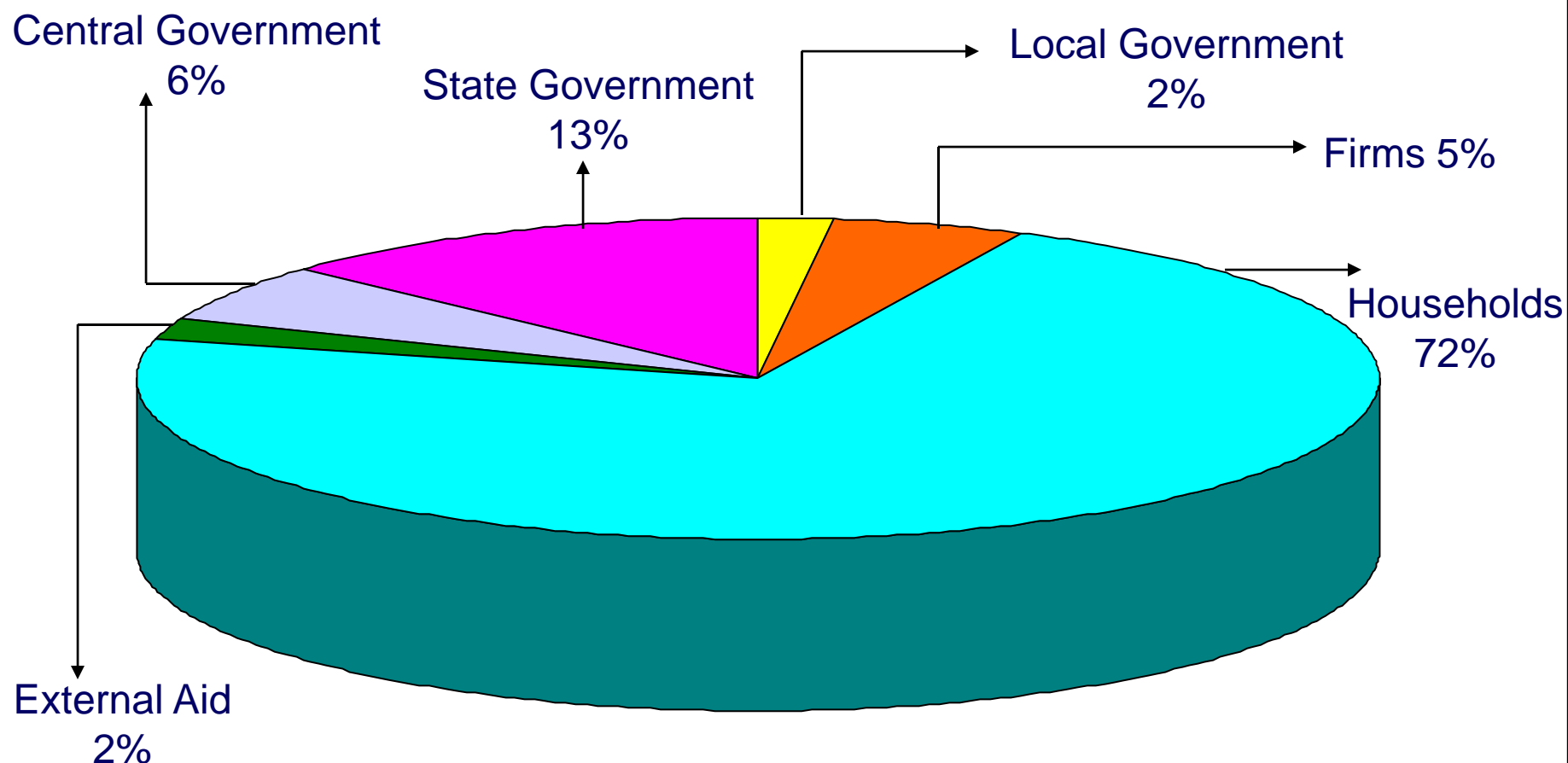
India's Healthcare Context is Unique

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 : 72% out of pocket payment and 28% 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

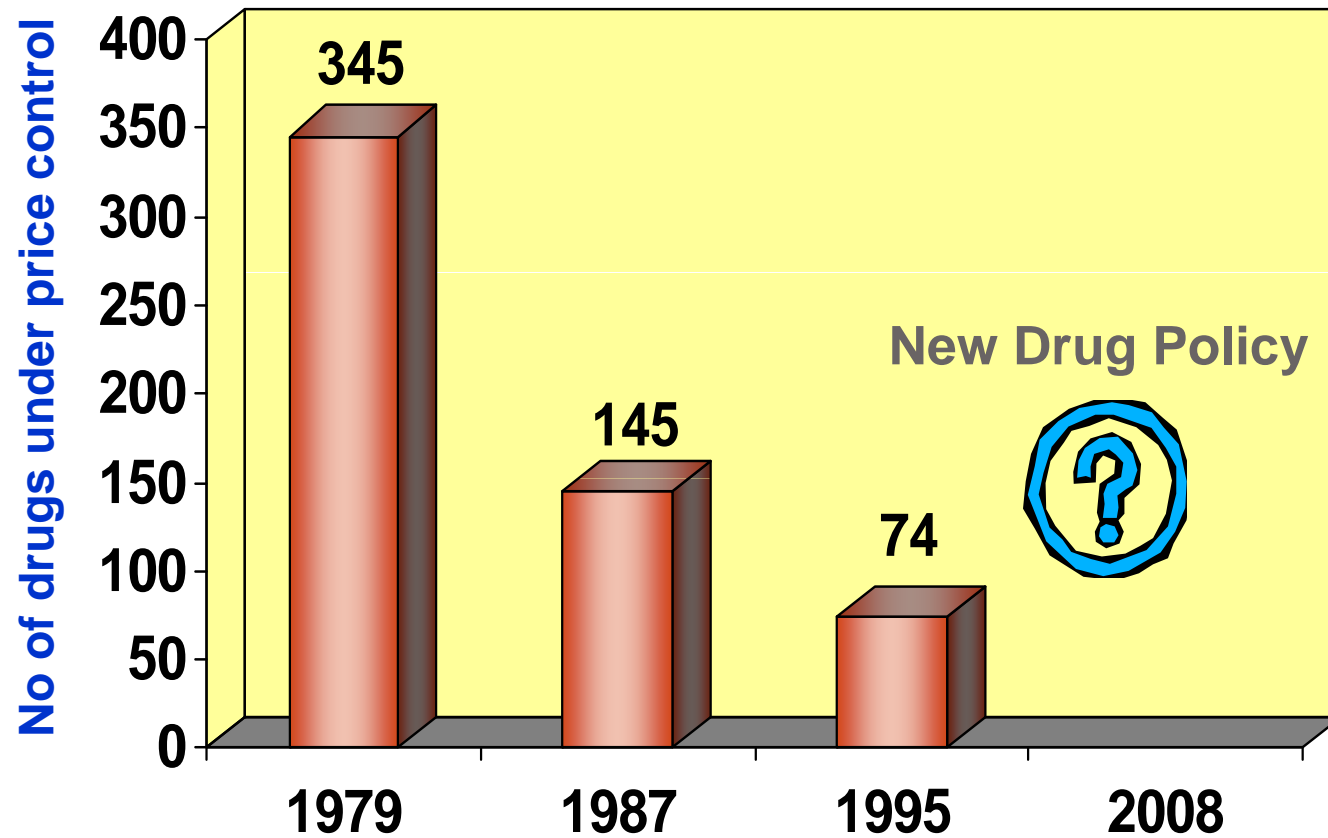
Doctor's Fees	9%
Medicines	15%*
Diagnostic Investigations & Pathological Tests	24%
Hospitalization	17%
Transport	20%
Miscellaneous	8%
Others	7%

* 60% towards taxes and trade margins

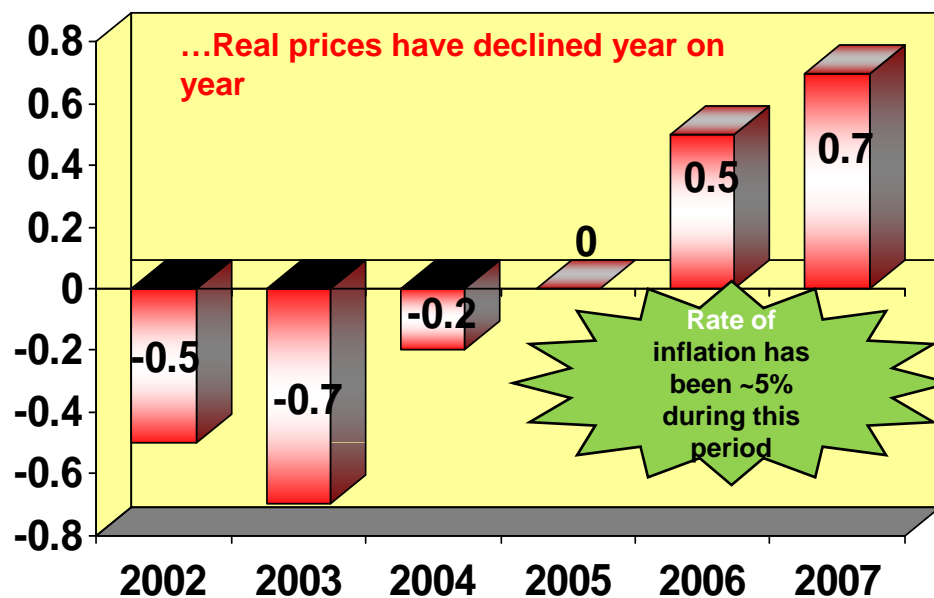
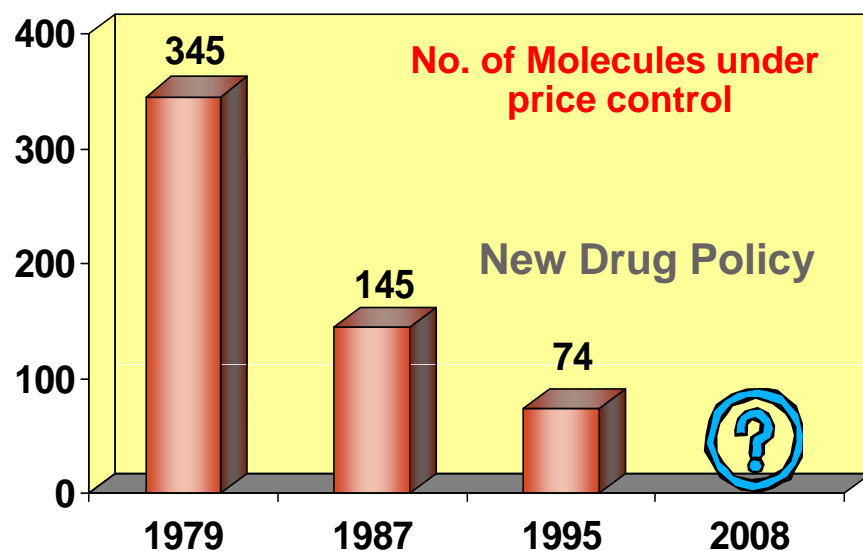
15% of Total Household Cost for Individuals

Source: National Survey of Health, 2003

Declining Price Control?



Decontrol has not resulted Increase in Prices



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

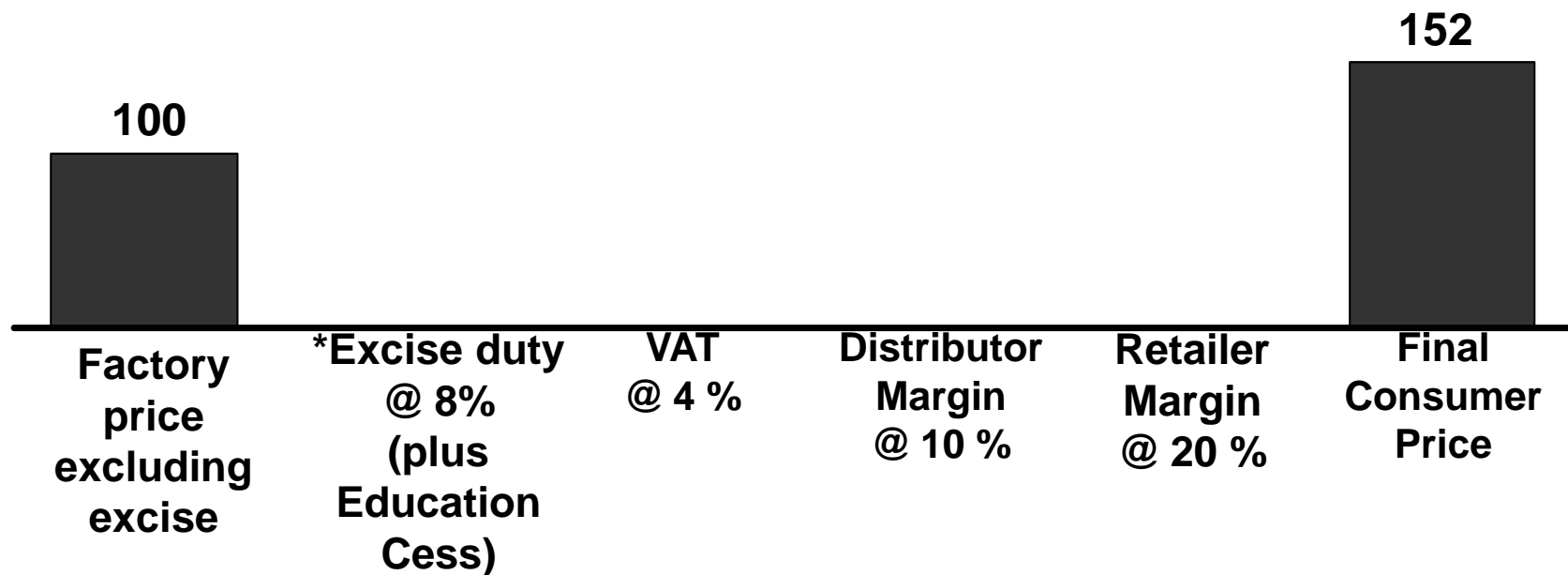
	Drugs, Dosage Form and Strength	Pack	Prices in India (INR)	Prices in Pakistan (INR)	Prices in Indonesia (INR)	Prices in USA (INR)	Prices in UK (INR)
I. ANTI-INFECTIVES							
1.	Ciprofloxacin – HCL 500 mg tabs	10's	29.00	423.86	393.00	2352.35	1185.70
2.	Norfloxacin 400 mg tabs	10's	20.70	168.71	130.63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

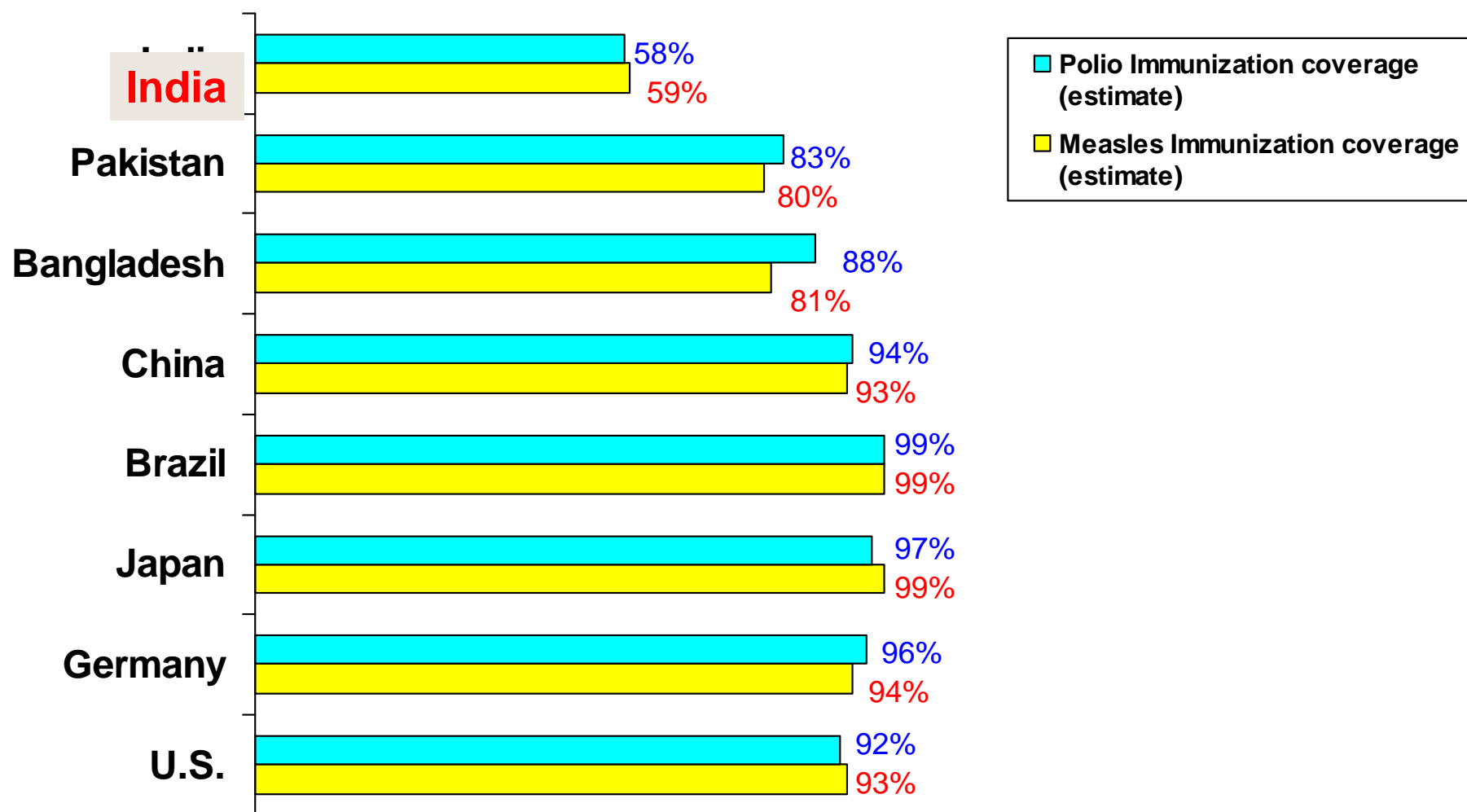
contd...

	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

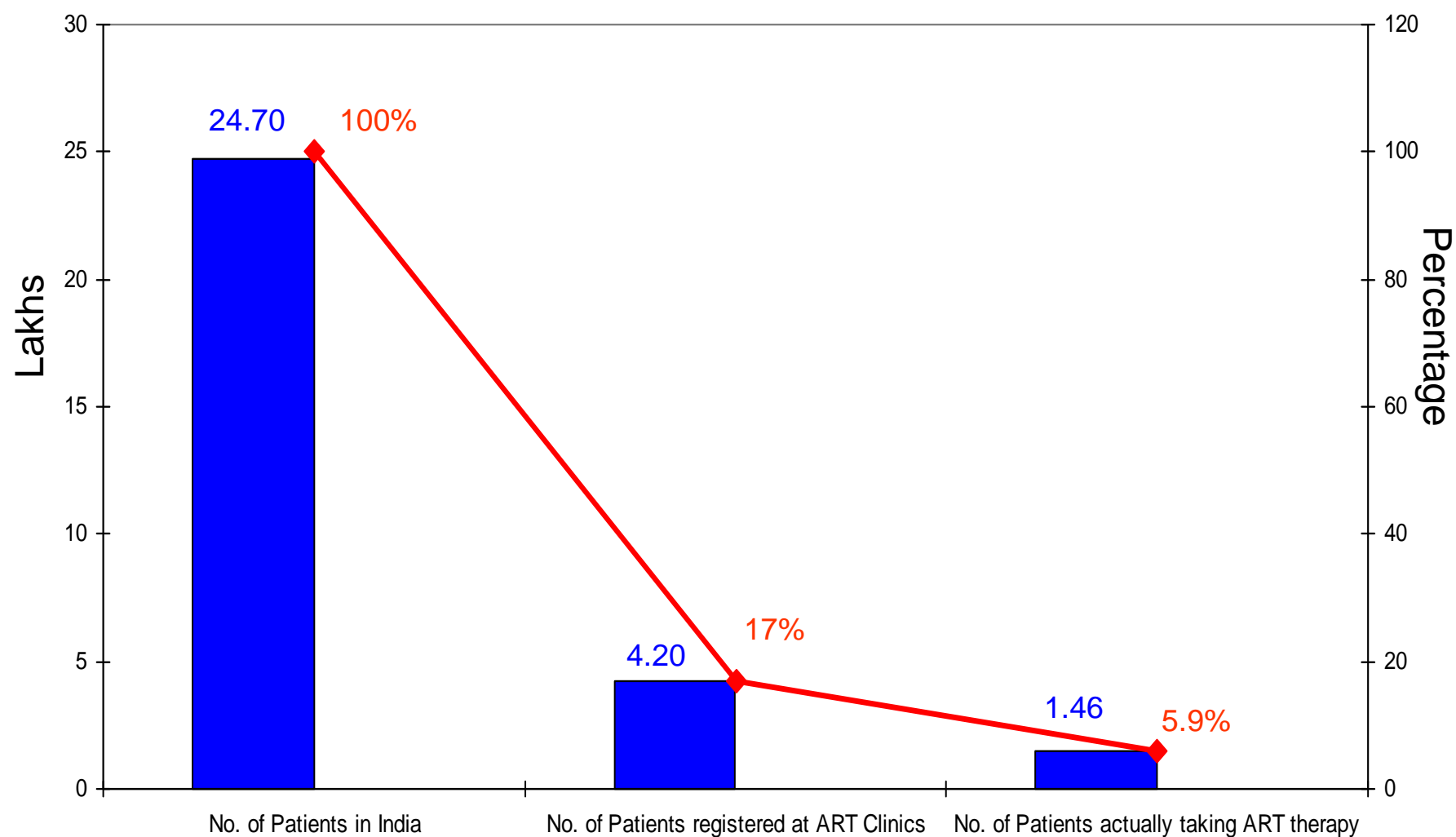


Despite being free Many Children not getting Primary Vaccination



Source: World Health Organisation

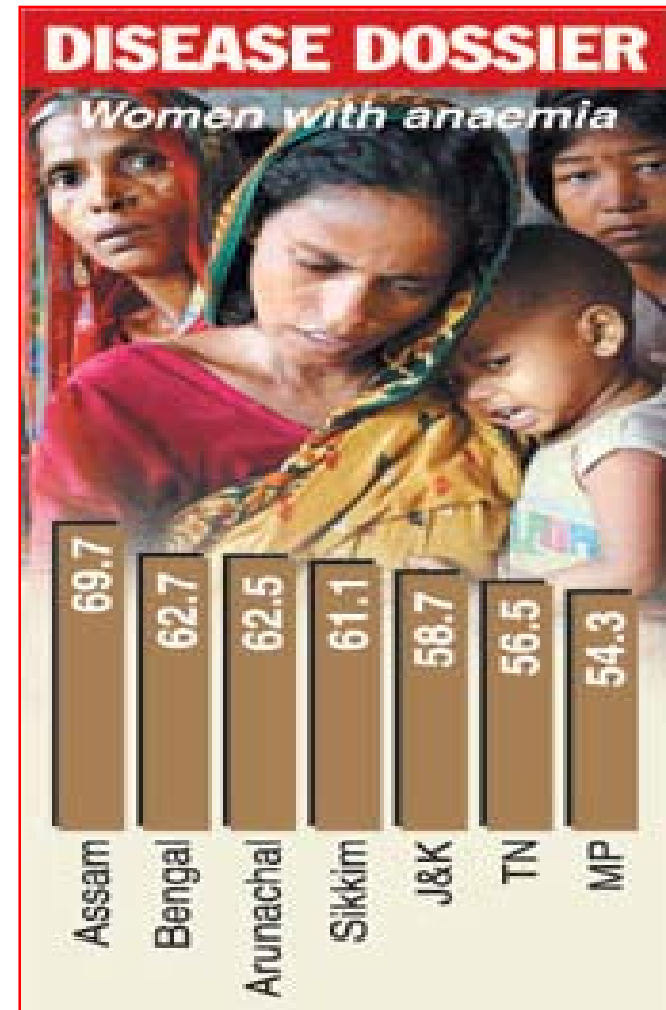
Despite being free to HIV Patients - Poor Access to ART



Source: NACO, INDIA

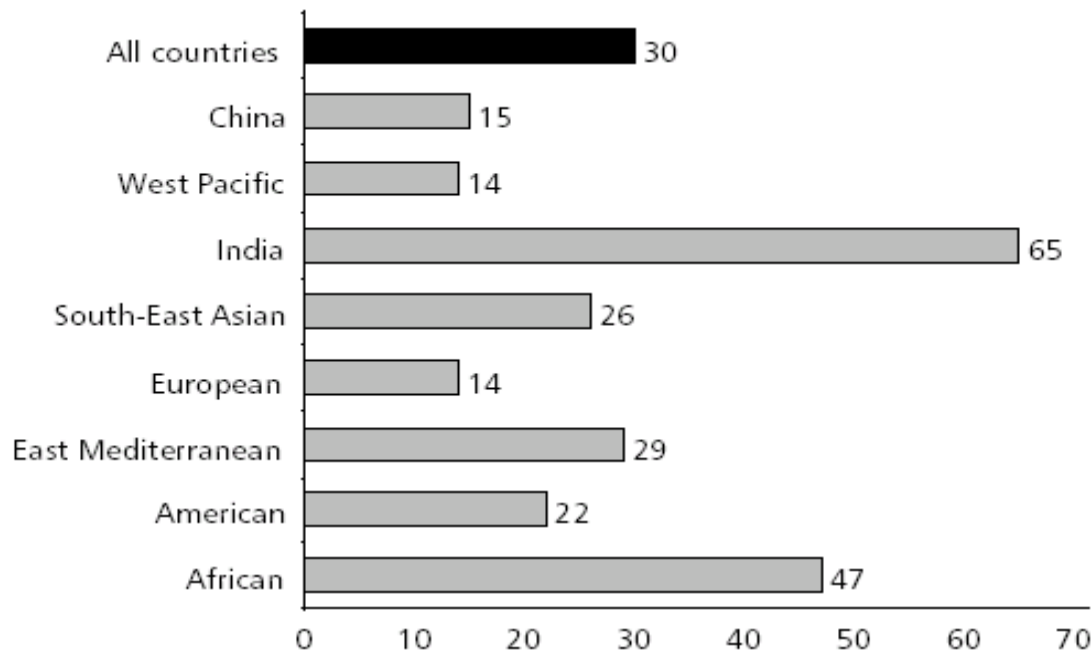
The Cost of Iron Supplements are Rupee One only

- ❖ Neglected anaemia problem lowers productivity of nations
- ❖ 200 million Indian women and more than 80% of children have iron deficiency anaemia.
- ❖ Lack of rural availability for delivery failure even though the costs are extremely low
- ❖ It is a shame that the situation has not improved since independence.



Access to Modern Medicine – A Challenge

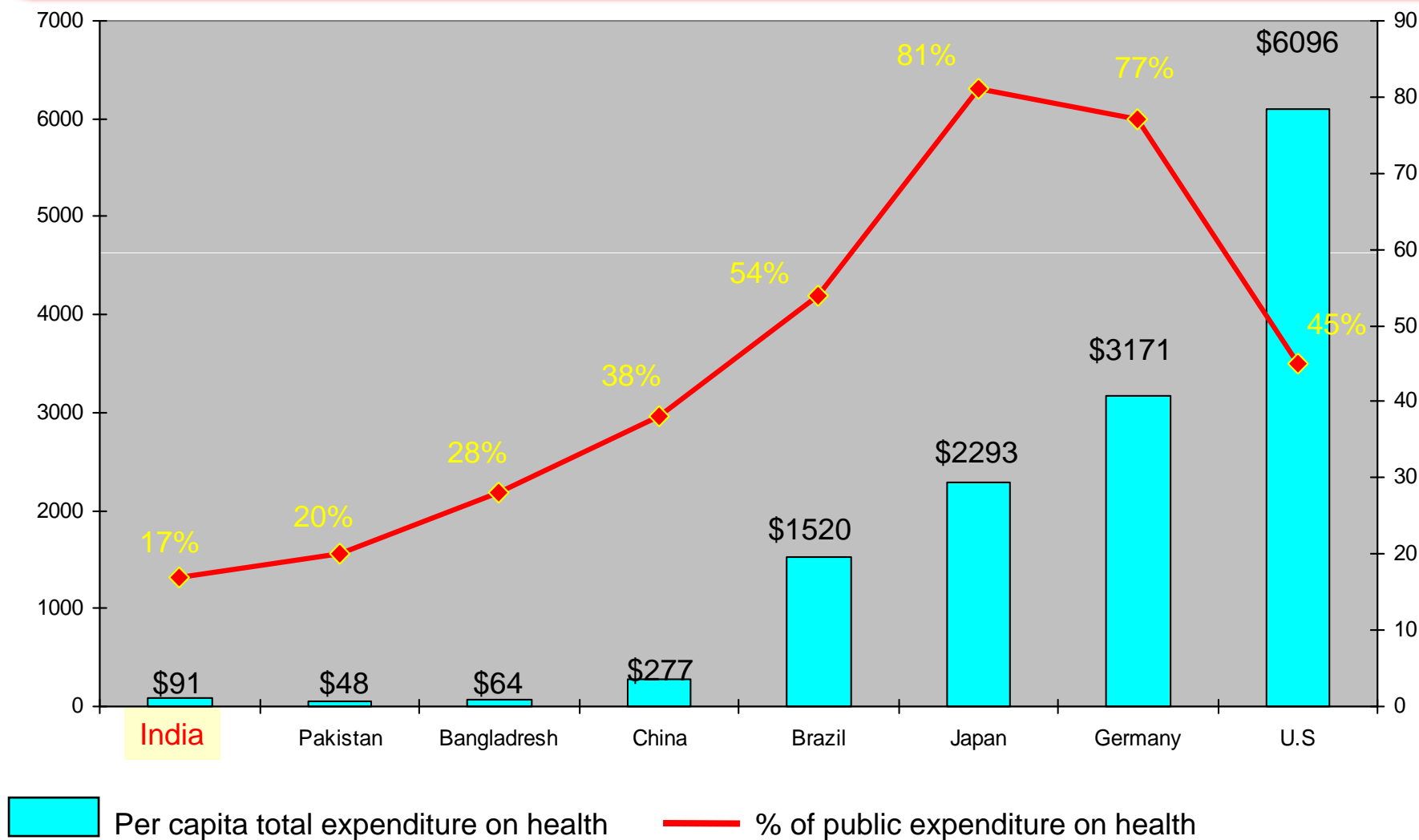
Percentage of WHO regions lacking access to essential medicines



- This 350 mn. people are largely clustered around urban centres where health care facilities exist

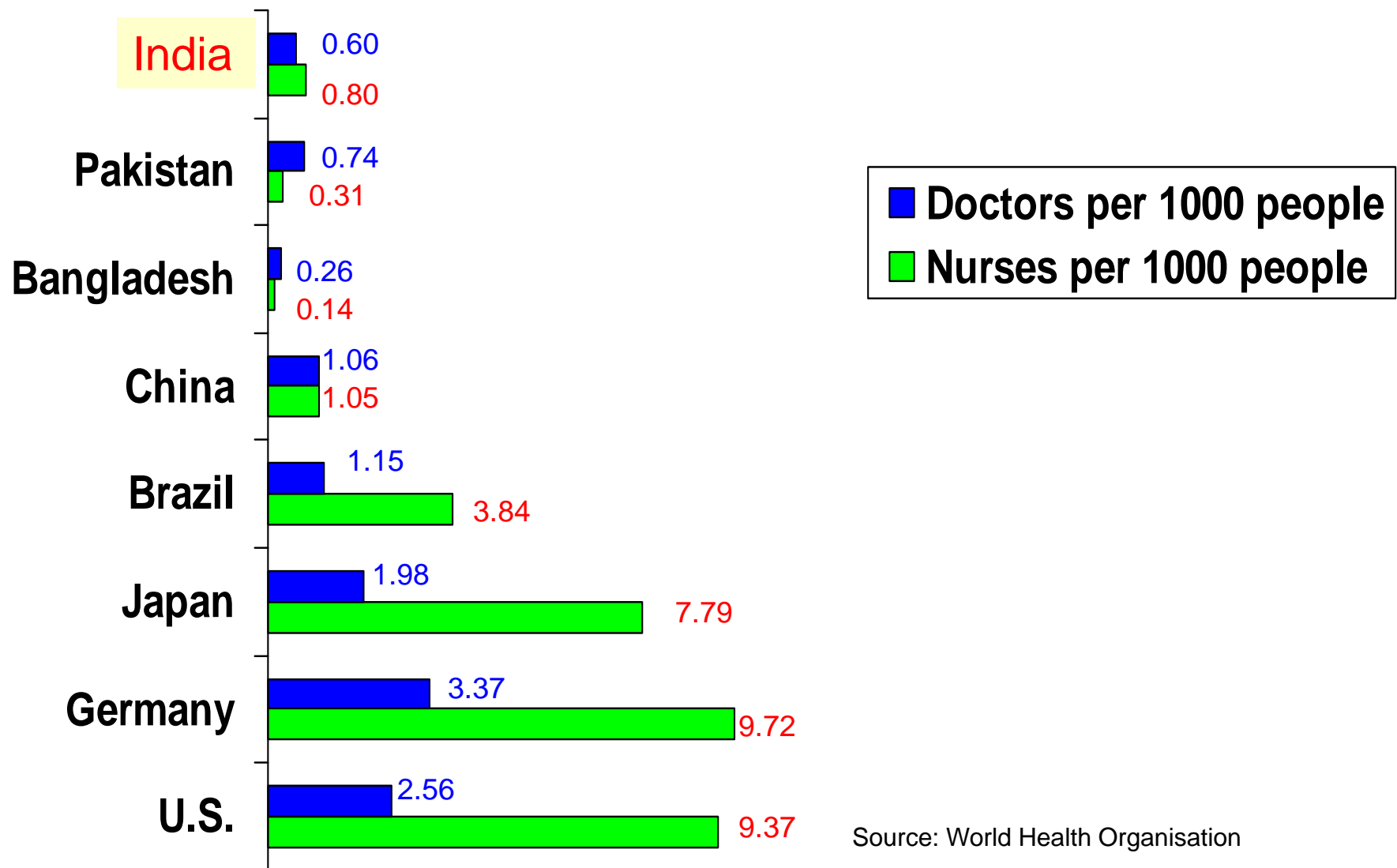
Source: Network,
November 2004

India Spends Relatively Less on Healthcare

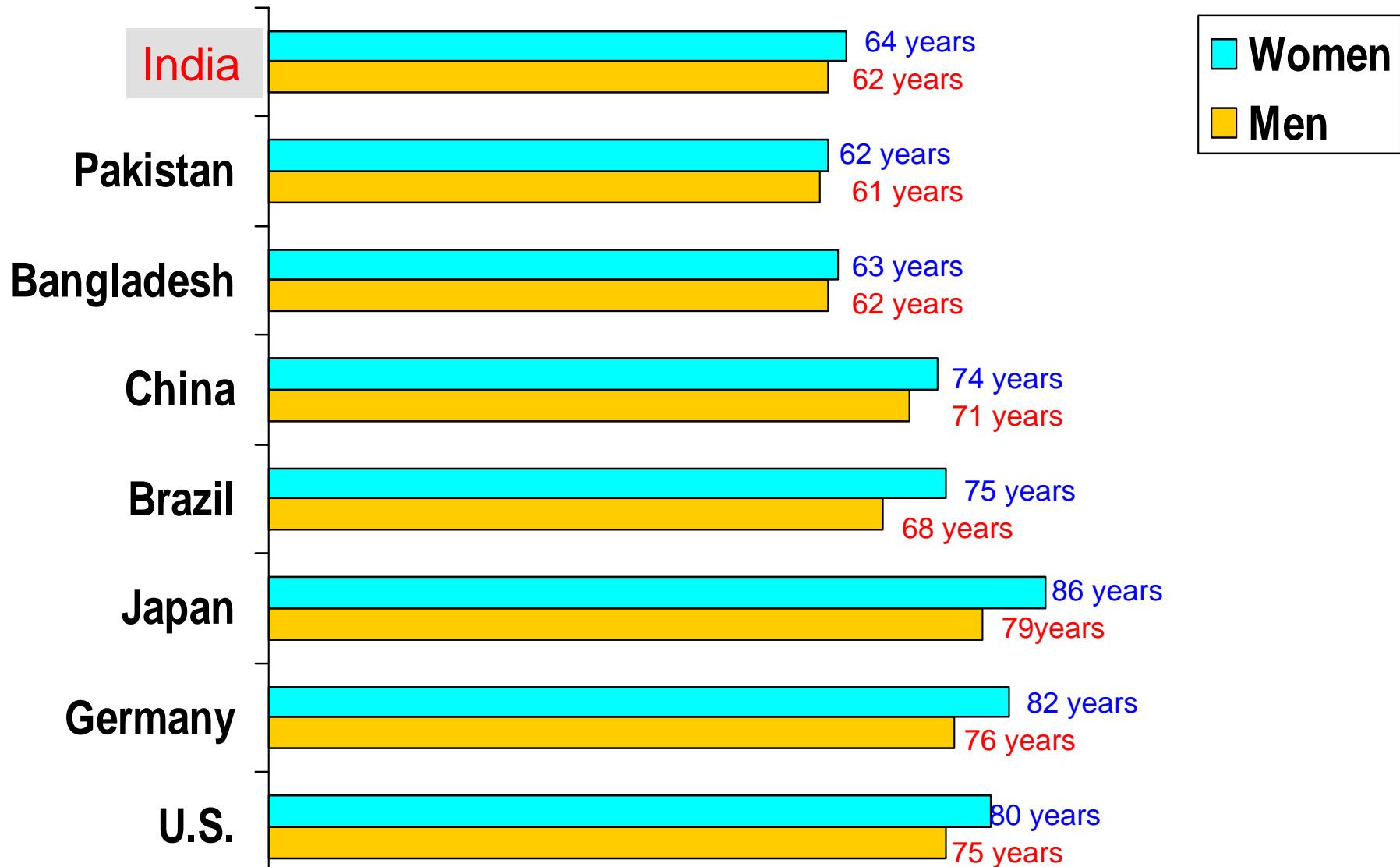


Source: World Health Organisation

Shortage of Doctors and Nurses in India



Life Expectancy in India



Source: World Health Organisation

Access to Healthcare – Key Barriers

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

AND

JUST NOT PRICE

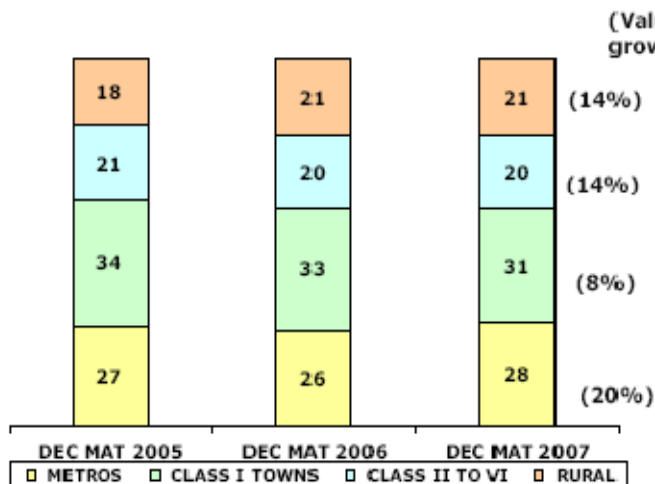
Improving Access to Healthcare

Improving Access to Healthcare Rural Market Penetration

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

Improving Access to Healthcare Government Plans Drug Stores in all Districts

- ❖ Retail network of drug stores across the country
- ❖ In public private partnership
- ❖ Would sell 350 essential medicines
- ❖ At half the rate of its branded substitute
- ❖ Project to be launched in 15 states in first phase
- ❖ Ultimate aim – at least one such store in every district of the country

Source : Economic Times Sept 17, 2008

Separate Pricing from Access

- ❖ Progressive Pricing Policy which is free from price control to enable investment in R&D.
- ❖ Make medicines affordable to those who cannot afford.
- ❖ If kerosene, fuel and agriculture can be subsidized for poor,
why not medicines?
- ❖ Government and industry should work in PPP model.

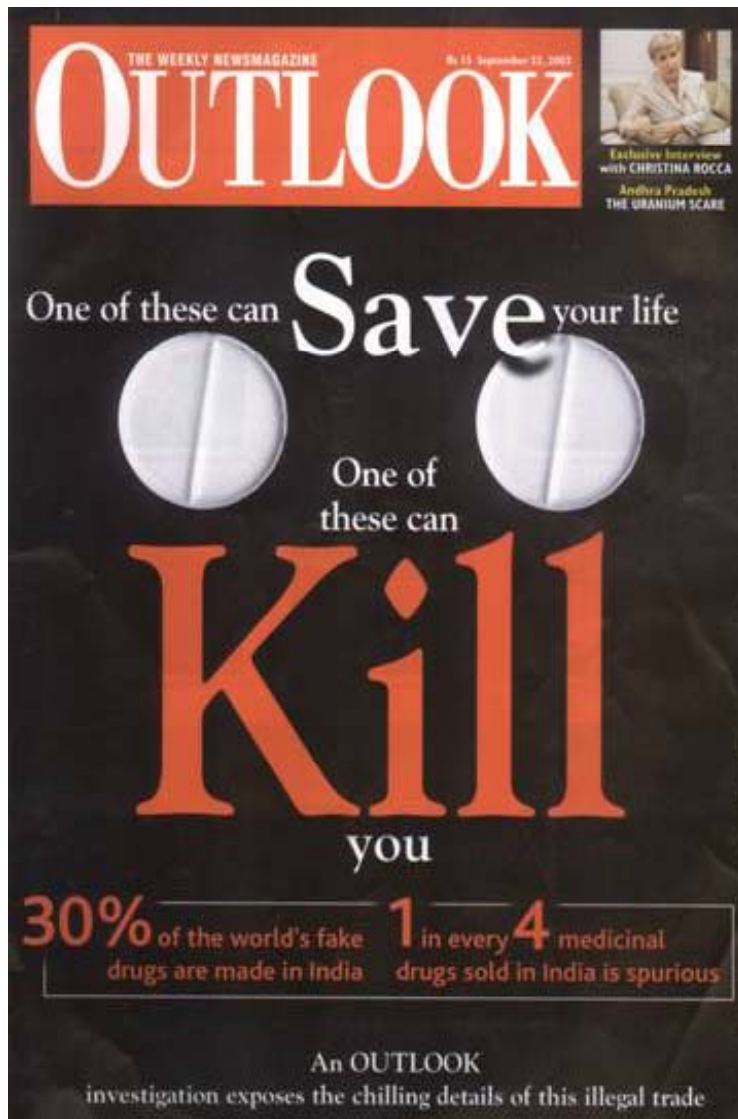
Improving Access to Healthcare

- ❖ Requires 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

Counterfeit Drugs



Centre for Medicines (NY) has estimated that global counterfeit drug sales will reach US \$ 75 Bn. by 2010

Current estimates indicate 0.5% - 30% (of the US \$ 7.5 Bn. Indian pharma market) prevalence rates for spurious and fake drugs in India – WHO pegs the estimate at 3%

Good Quality and Safe Healthcare

Achieved good progress with:

- ❖ Implementation of Schedule 'M'
- ❖ 100+ US FDA approved Plants
- ❖ Revision of Indian Pharmacopeia
- ❖ Central Drug Authority proposal
- ❖ Elimination of irrational FDC

What is further needed:

- ❖ Pharmacovigilence
- ❖ Transportation and storage guidelines and
- ❖ Data Protection to encourage conduct of trials which will help in handling AE

Some Policy Initiatives

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”**
- ❖ **Creation of Pharmaceutical Department within Ministry of Chemicals & Fertilizers**



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 (Government , Private Insurance & Medical Community)
<ul style="list-style-type: none">• Rashtriya Swasthiya Bima Yojana (RSBY) for families below BPL	<ul style="list-style-type: none">• Tata Steel invited Dr. Shetty for similar scheme at Jamshedpur	
<ul style="list-style-type: none">• Niramaya by Ministry of Social Justice & Empowerment for BPL families		

Wall Street Journal – October 20, 2008

Beijing Plans Health Care For Everyone

By MEI FONG and JASON LEOW

BEIJING -- China has unveiled an ambitious plan to achieve universal health care. The plan, released for public debate last week, lays out in broad strokes plans to introduce greater health-care funding and control prices. The current system leaves out much of the population and forces the rest to pay heavy out-of-pocket expenses. Overhauling China's health-care system has global significance, given the country's demographic heft, its frequent role as epicenter of infectious diseases and its growing importance in health innovations ranging from organ donation to the use of traditional Chinese medicine.

"What happens in China is a major driver in the dynamics of global health," said medical journal Lancet.

The overall goal of the plan is to cover 90% of the population within two years and achieve universal health care by 2020.

One major point in the draft is to return to the nonprofit motive for national health care. This was dismantled in the 1980s as China cut public services, especially in the countryside.

Today, public hospitals receive little government funding and are pressed to operate like businesses. The peddling of experimental, costly drugs and treatments has become rampant.

contd...

Beijing Plans Health Care For Everyone

contd...

Out-of-pocket payments constituted more than 60% of health spending at the end of the 1990s in China, a significantly larger percentage than in developed countries, according to the World Health Organization.

The draft proposal was crafted in a year-long process of consultations with groups such as the World Health Organization, the World Bank, management consultancy McKinsey & Co. and a few Chinese university-based public health experts.

According to the plan, all revenue raised by public hospitals will have to be funneled to state coffers. The government aims to set pricing standards for medical services, according to the plan, reflecting broad nationalization of the health-care system.

The proposal has drawn heavy criticism. The current draft "is also hard for experts to understand," said Gordon Liu, an economist at the Guanghua School of Management at Peking University. Robert Pollard, director of Synovate Healthcare, a Beijing-based medical consultancy, said the plan doesn't give sufficient details on funding and implementation.

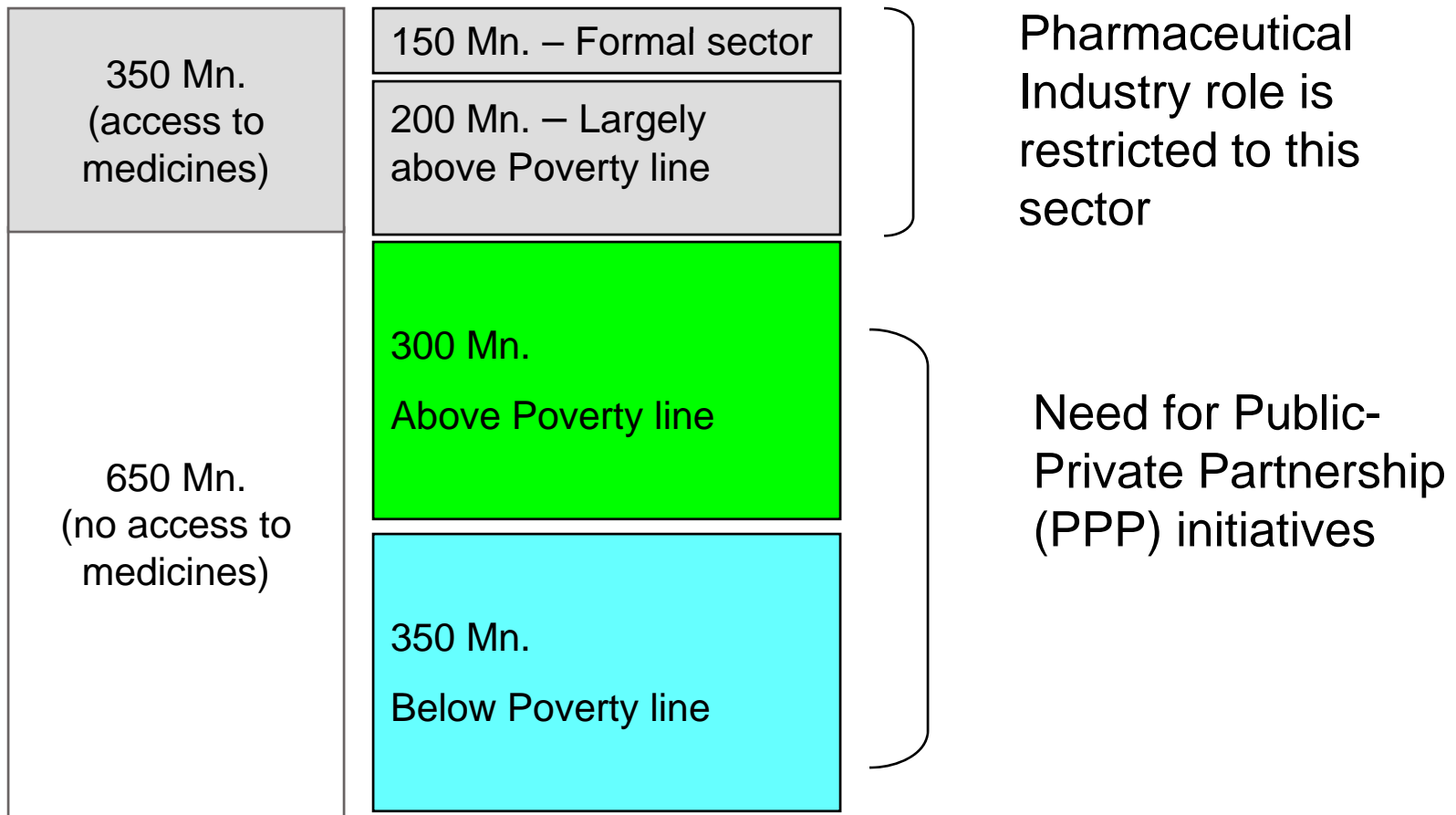
The plan doesn't address how the government would pay for its nationalization program if hospitals are restrained from earning more and tax collection mechanisms remain weak.

So far, the draft has drawn a large number of comments -- more than 12,000 -- on the state planning commission's Web site.

-Kersten Zhang contributed to this article.

The Way Forward

Advantage India



Formal Sector: Those employed with the Public or Private Sector

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

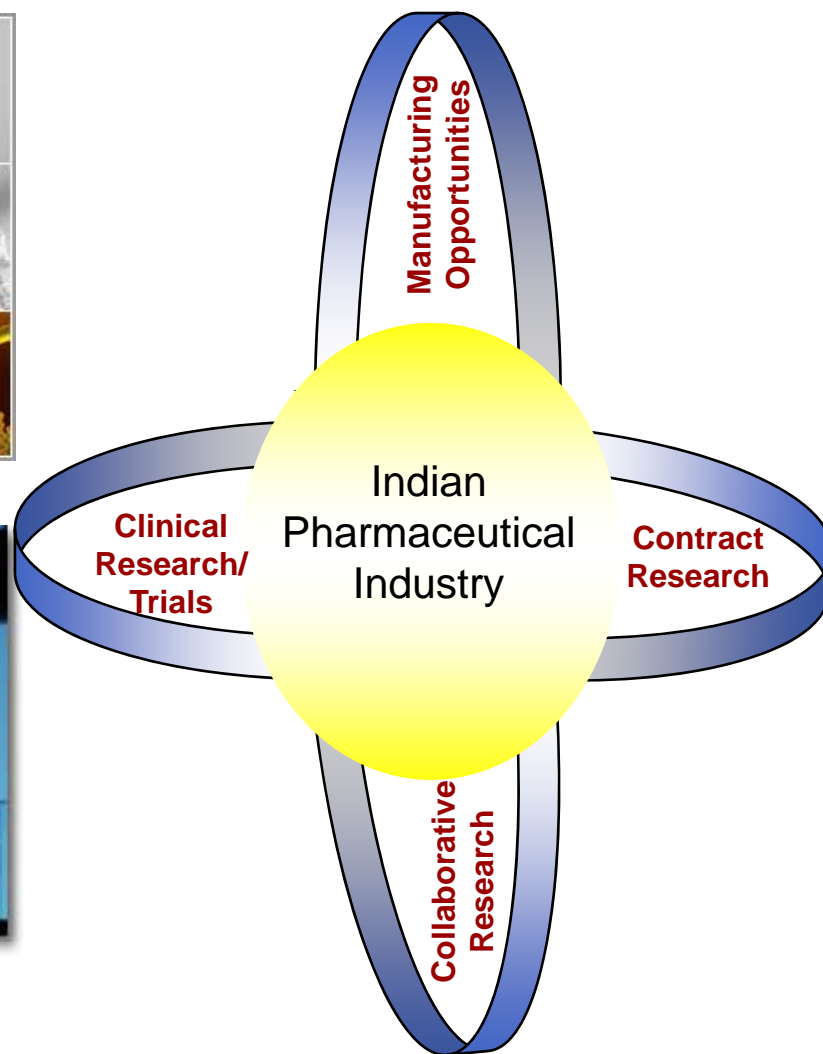
- ❖ Increasing disposable income and awareness will drive the growth
- ❖ 150 million strong middle class have higher healthcare expectations
- ❖ 35 – 45 million Indians are estimated to be able to afford the best medicines

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

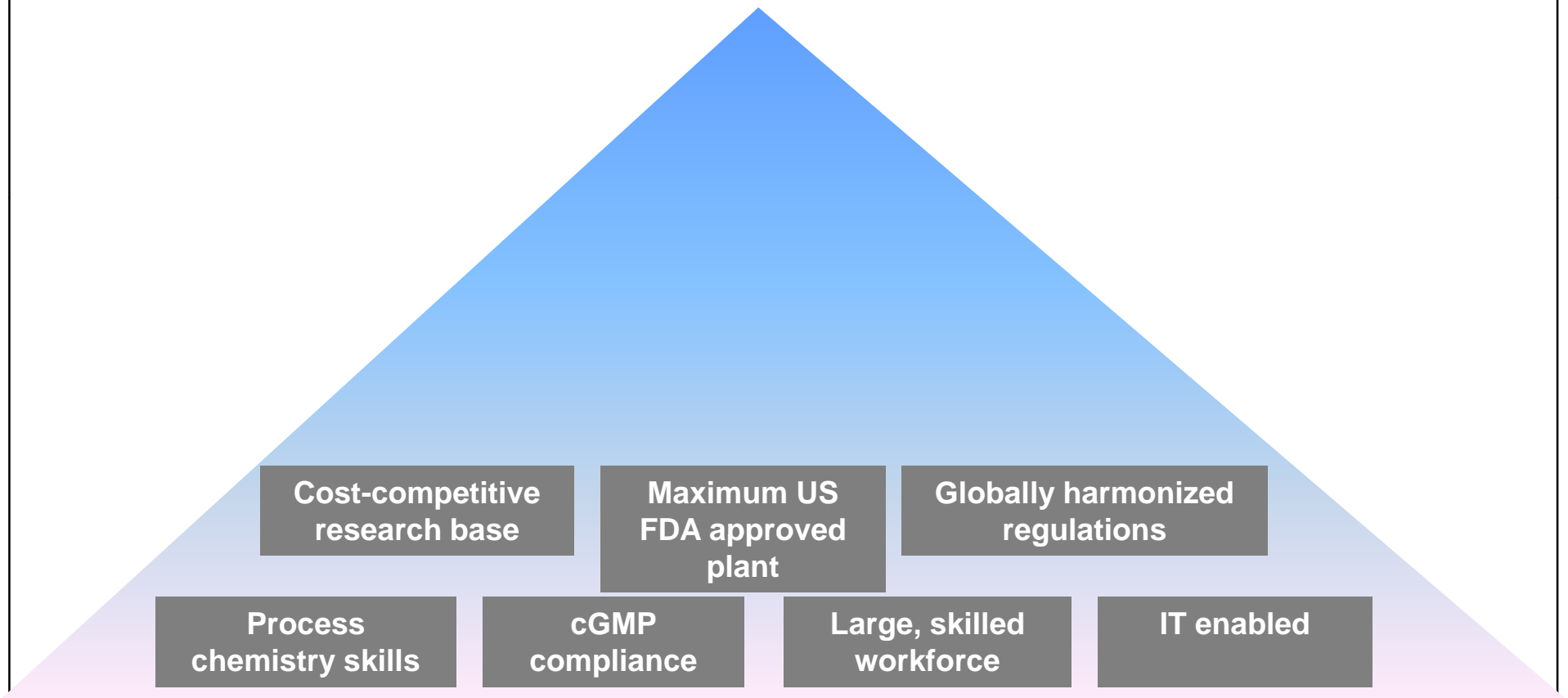
	2002	2012
Private Healthcare Spending (U.S.\$ Bn.)	14.8	33.6

Source: India Trade Promotion Organisation (ITPO)

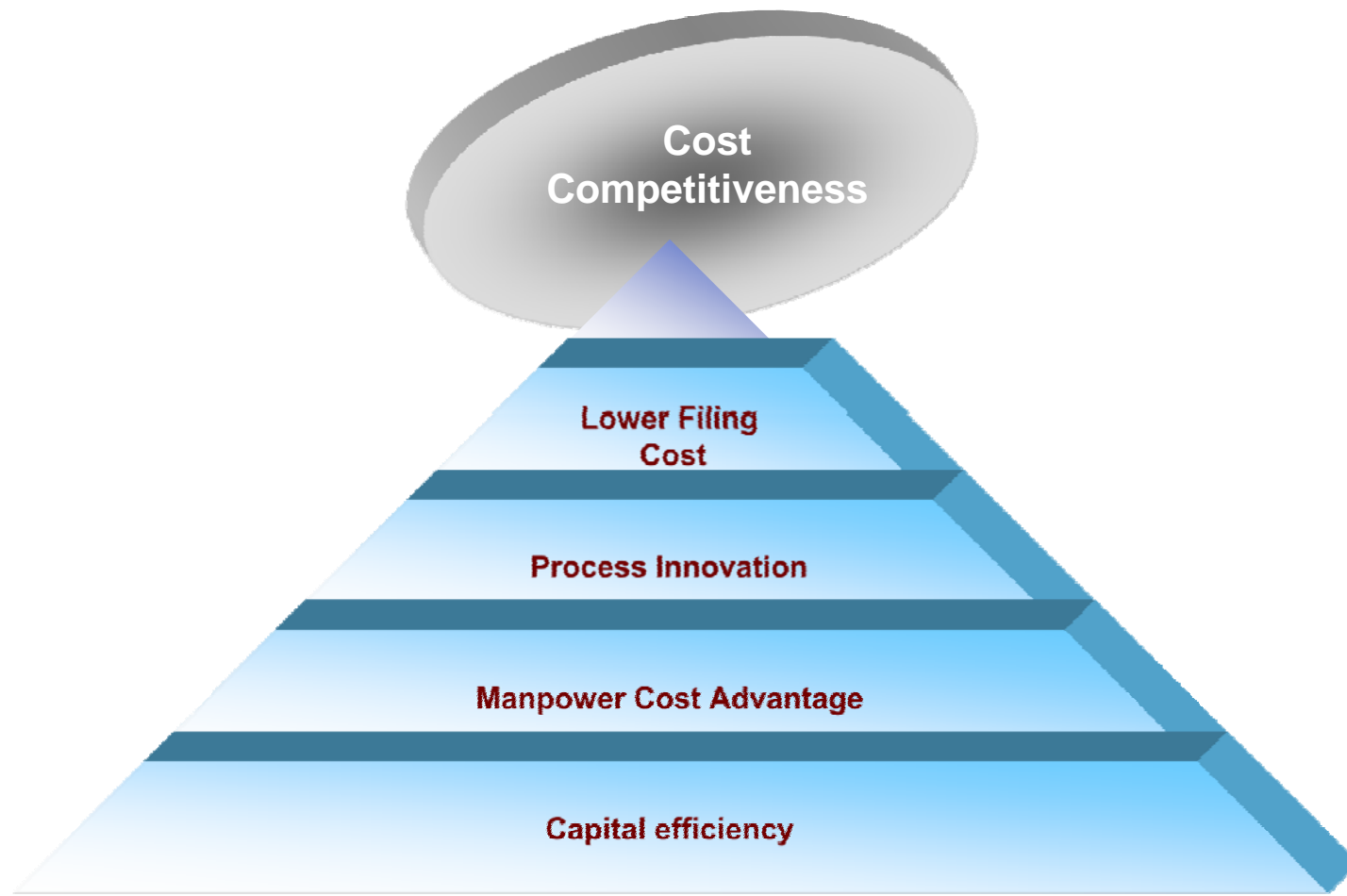
Key Opportunities Segments



Outsourcing Opportunities



Cost-Competitiveness – A Key Advantage



Innovation harnessed through In-licensing

R&D licensing deals by Indian companies

Indian Firm	Partner	Molecule
Dr Reddy's	Novo Nordisk	DRF 2593 (Diabetes)
	Novartis	DRF 4158 (Diabetes)
	Novo Nordisk	DRF 2725 (Diabetes)
Ranbaxy	Bayer	Cipro XR (NDDS)
	Schwarz	RBx 2258 (BPH)
Torrent	Novartis	Age Breaker (Diabetic)
Glenmark	Forest (For North America)	GRC 3886 (Asthma/COPD)
	Tejin (For Japan)	GRC 3886 (Asthma/COPD)

Source: Citigroup Research

New IPR Regime - A New Paradigm

Patents Act - Issues

- ❖ Provides Patent protection for all products patented after 1-1-1995
- ❖ Tighten the loose knots:
 - ▶ Enforcement of Product patent
 - ▶ Scope of Patentability restrictive
 - ▶ Data protection not provided
 - ▶ Too many triggers for Compulsory licensing
 - Can be issued if there is a failure to issue voluntary license within 6 months
 - Supply should be predominantly for domestic use vs. Predominant purpose of license should be for domestic use
 - ▶ Pre-grant / Post Grant opposition permitted
 - Scope restricted – Patentability / Exposure
 - Formal hearing permitted

New IPR Regime - The Benefits to Patients

Newer Therapies ...

Innovations can shorten hospital stays for Patients!

- ❖ Unmet medical needs
- ❖ Reduced overall treatment costs
- ❖ Shortened or eliminate hospital stay
- ❖ Increased compliance
- ❖ Reduced side effects
- ❖ Increased productivity and less absenteeism

Newer Therapies

Need for Strong Patents in Patient's Interest

- ❖ Better efficacy, compliance & reduced side effects
- ❖ Any innovation that fulfils medical need deserves patent
- ❖ Patent Law should protect all innovation
- ❖ Grant of patent should not be long drawn process
- ❖ Compulsory license only for calamities & emergencies



Journey to health for all is long and challenging
Milestones must be crossed at regular intervals

Holistic & Patient–Centric Approach
will lead to
Quantum Growth of
Indian Pharmaceutical Market

Thank You