INDIAN PHARMACEUTICAL INDUSTRY – AN EMERGING SCENARIO

Tapan Ray

July 21, 2008
IIM Ahmedabad, India

CONTENT

- Economic Scenario of India
- Pharmaceutical Industry & Healthcare Scenario
- Policy framework supporting Pharmaceutical Industry
- Access to Medicine
- Issue of Counterfeit Medicine
- IPR Scenario in India & Indian Patents Act 2005
- The Way Forward


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

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

	1990-91	2007-08
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

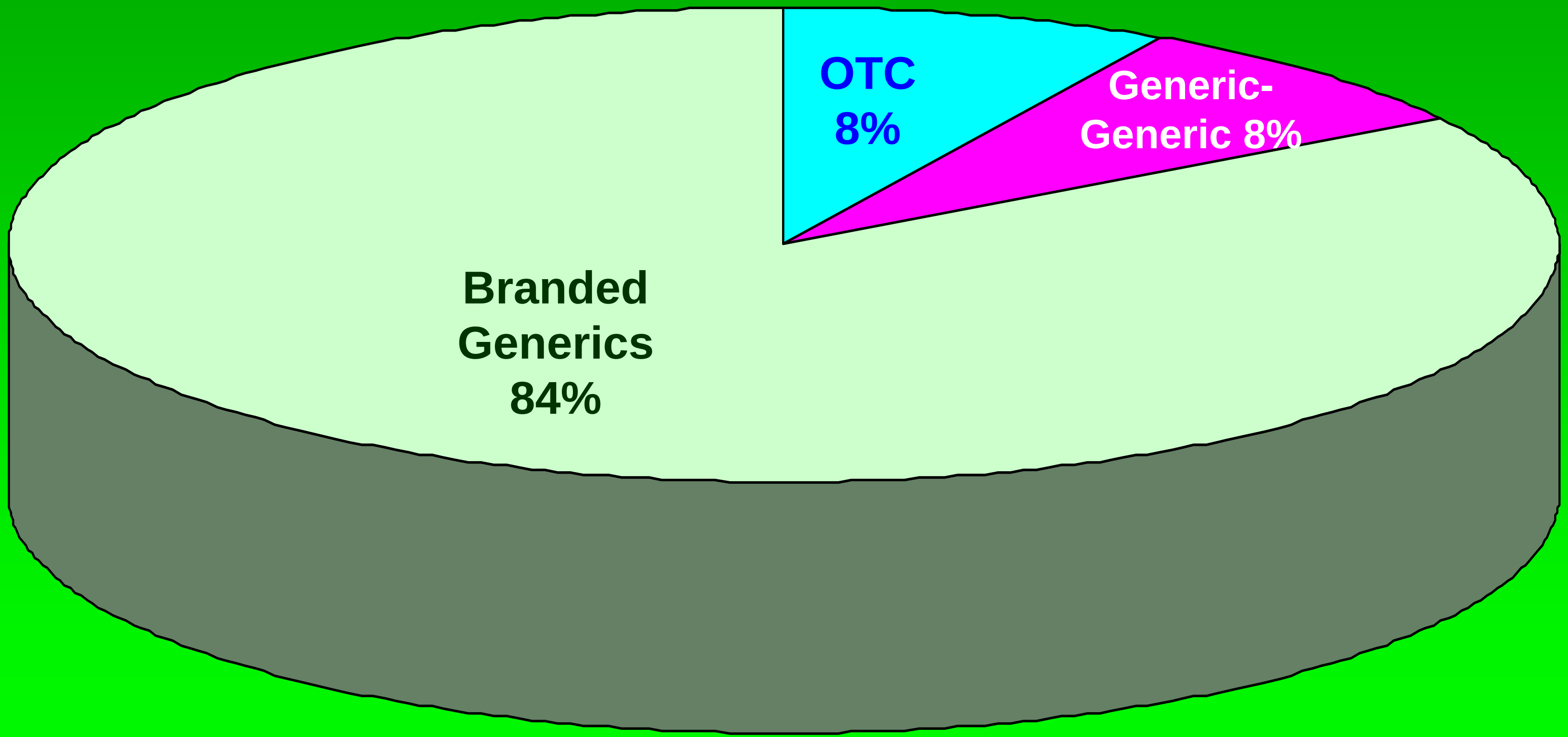
Growing at 6.1%

INDIAN PHARMACEUTICAL INDUSTRY: 2007-2008

- 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

KEY MARKET TYPES - 2007

Market Size US$ 7.5 Billion



Source : IMS Dec 2007

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

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

TOP 10 PHARMACEUTICAL COMPANIES IN INDIA

1. The contribution of the top ten companies has marginally declined from 38% in 2004 to 36% in 2007.

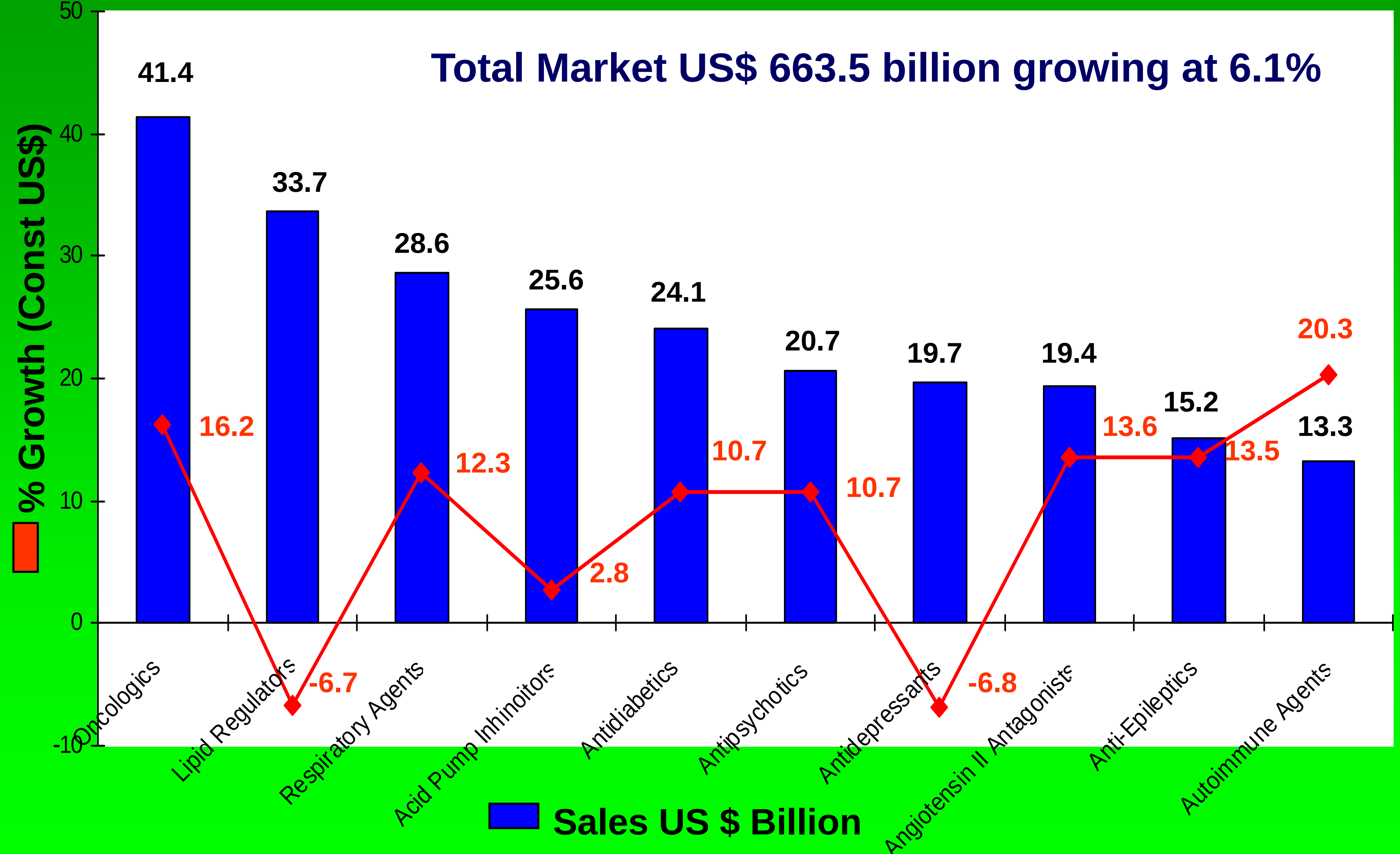
2. The top companies that have maintained their ranking since Dec. '04 MAT are Nicholas Piramal, Zydus Cadila, Sun Pharma, Alkem and Torrent Pharmaceuticals

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

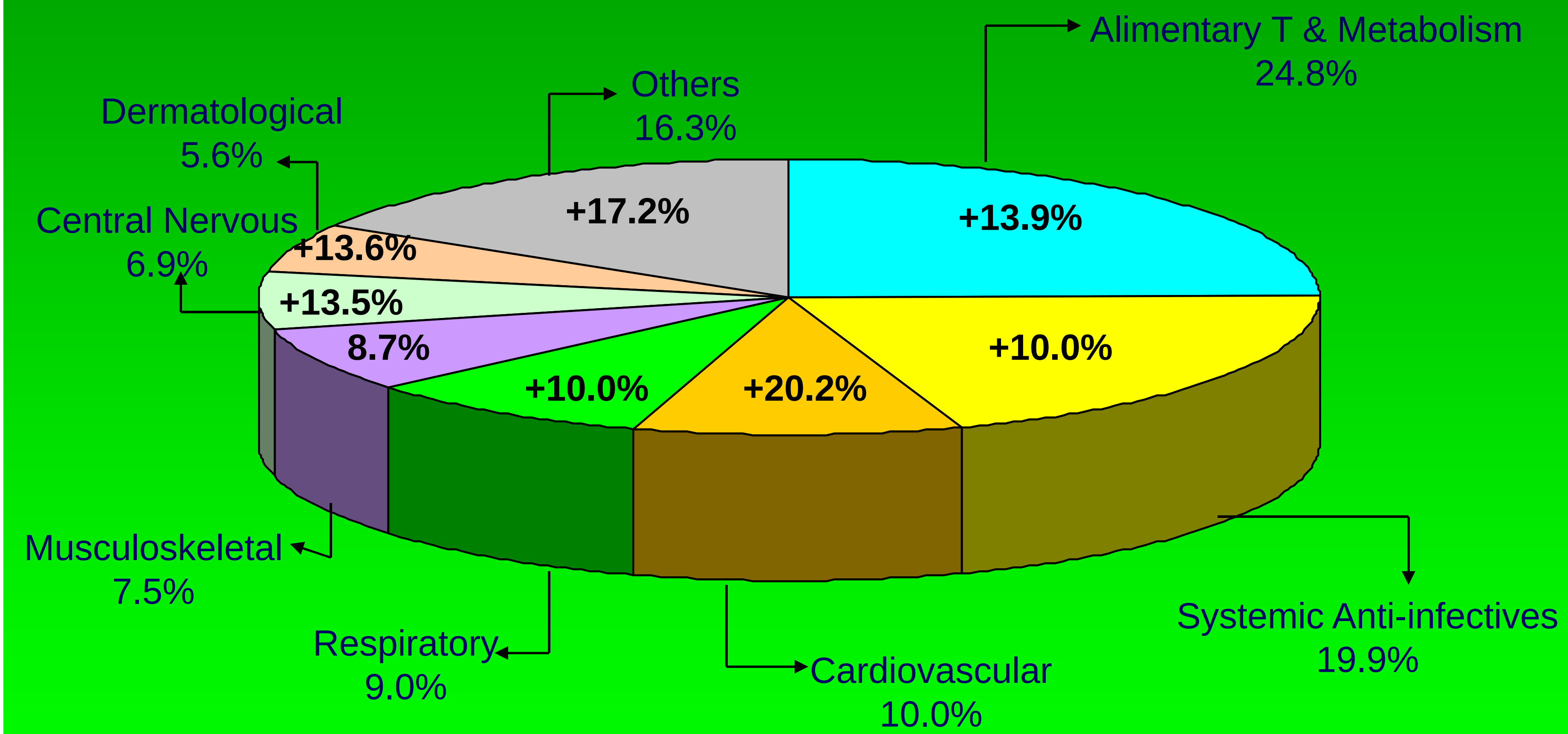
TOP GLOBAL THERAPY AREAS



Source : IMS, December 2007

INDIAN TOP THERAPY AREAS

Key Therapeutic Segments

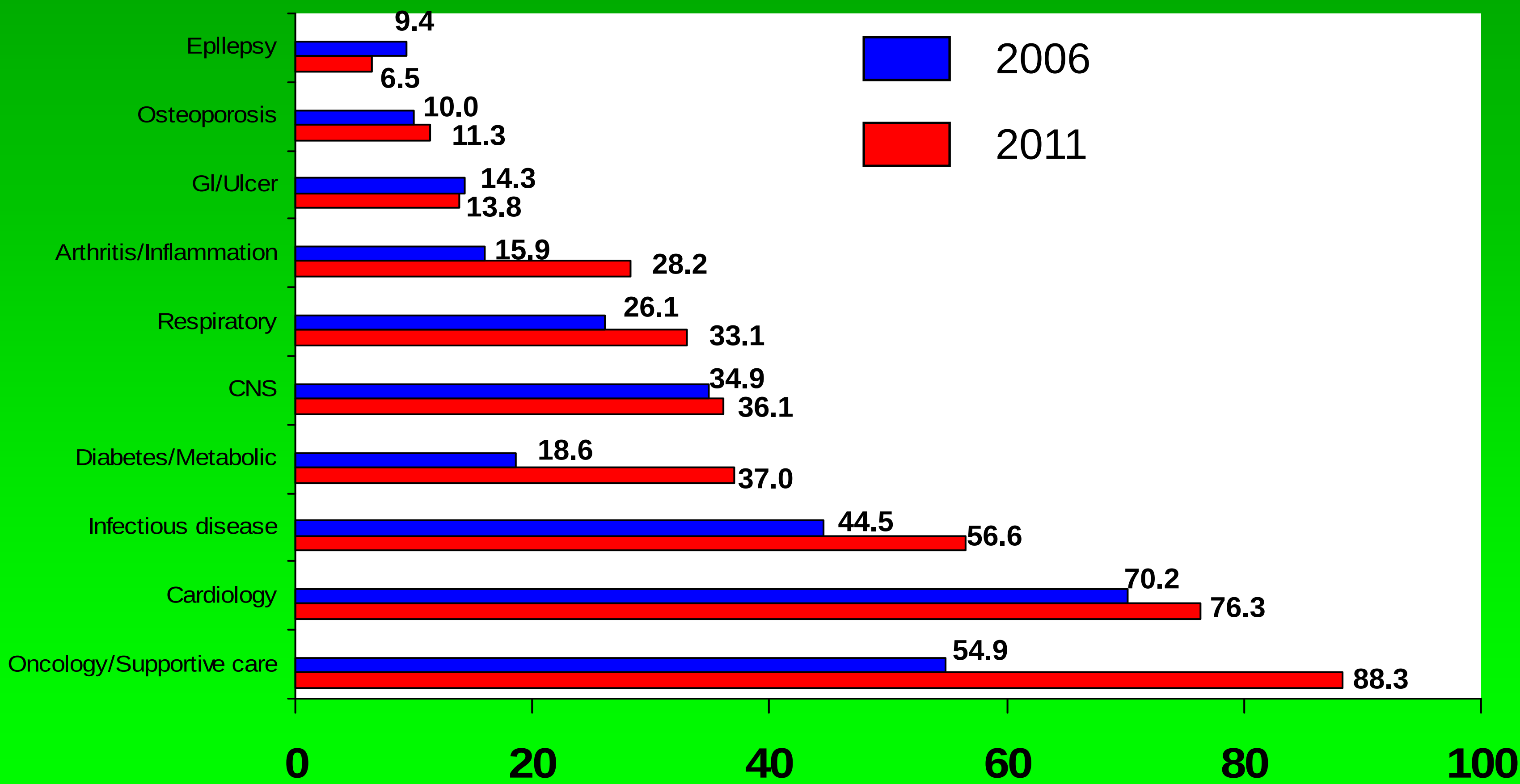


Total Market US$ 7549.2 Mn (Growth 13.4%)
[13th in value and 4th in volume globally]

*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)

Worldwide sales market share			Therapeutic classes	Worldwide sales ranking	
2006	2011	Trend		2006	2011
1.7	**0.9**	↘	**Epllepsy**	**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**

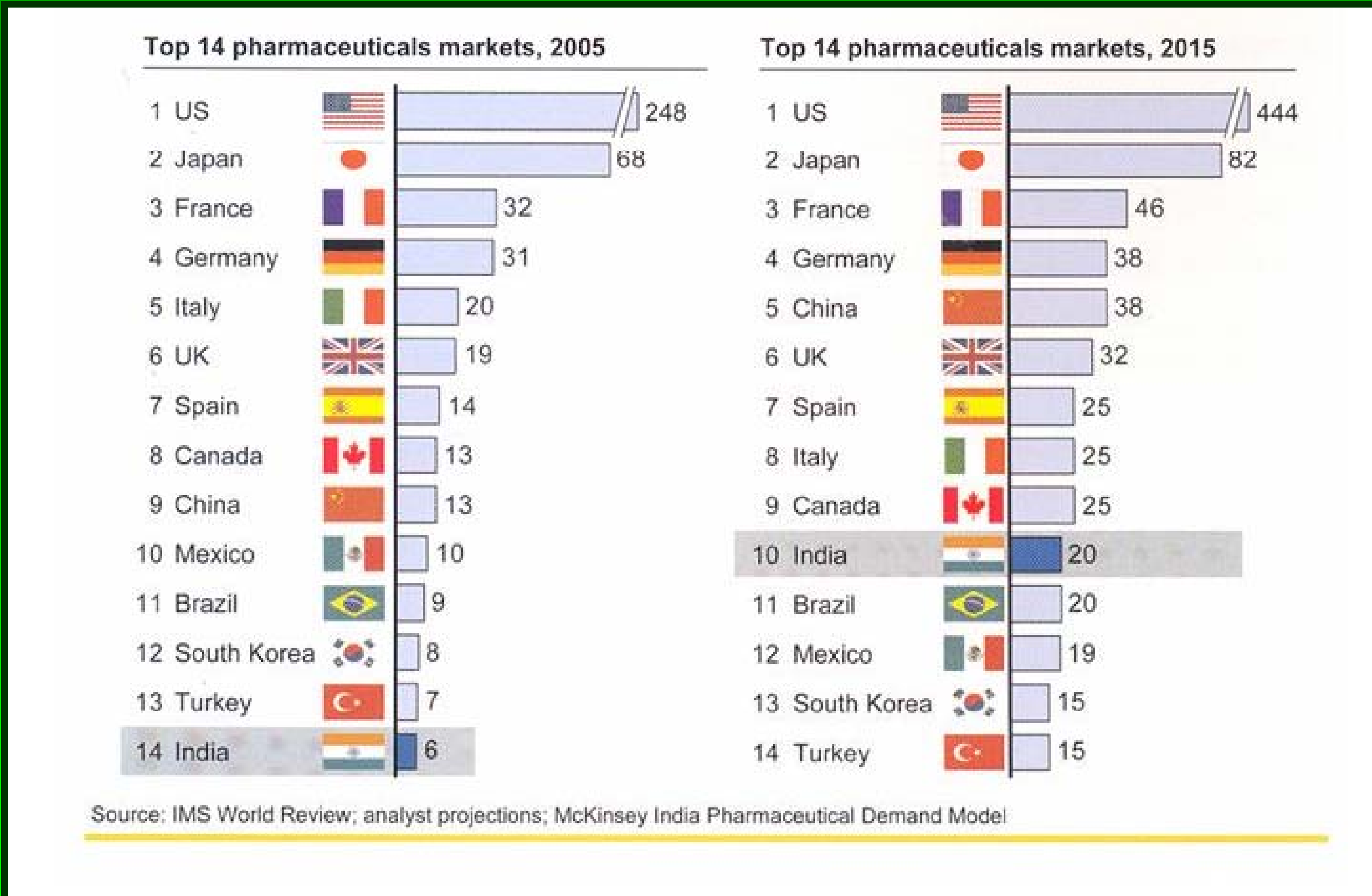
Source: IMS Health, Analyst Reports, Bionest Partners Analysis

MCKINSEY PROJECTION 2015*

- ❖ Domestic Sales to reach U.S.$ 20 Bn.
- ❖ Incremental growth between 2005 – 2015, U.S.$ 14 Bn.
- ❖ Key Drivers for Growth:
  - Robust Economy
  - Increasing Affordability
  - Deeper Penetration of Health Insurance
  - Increase in Organised Retail Chains
  - Shifting Disease Patterns
  - Increase in Healthcare Spend (from present 7% to 13% of average household income)
  - The New IPR Regime

* "Indian Pharma 2015", McKinsey & Co. – August 22, 2007

INDIA IS PROJECTED TO BE THE 10TH LARGEST MARKET BY 2015



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

HEALTH INDICATORS IMPROVED SIGNIFICANTLY

	1950-51	1980-81	2006-07
Birth Rate (per 1000)	40.8	33.9	23.8
Death Rate (per 1000)	25.0	12.5	6.0
Infant Mortality Rate (per 1000 live births)	146.0	110.0	58.0
Life Expectancy (years)	36.7	54.0	65.4

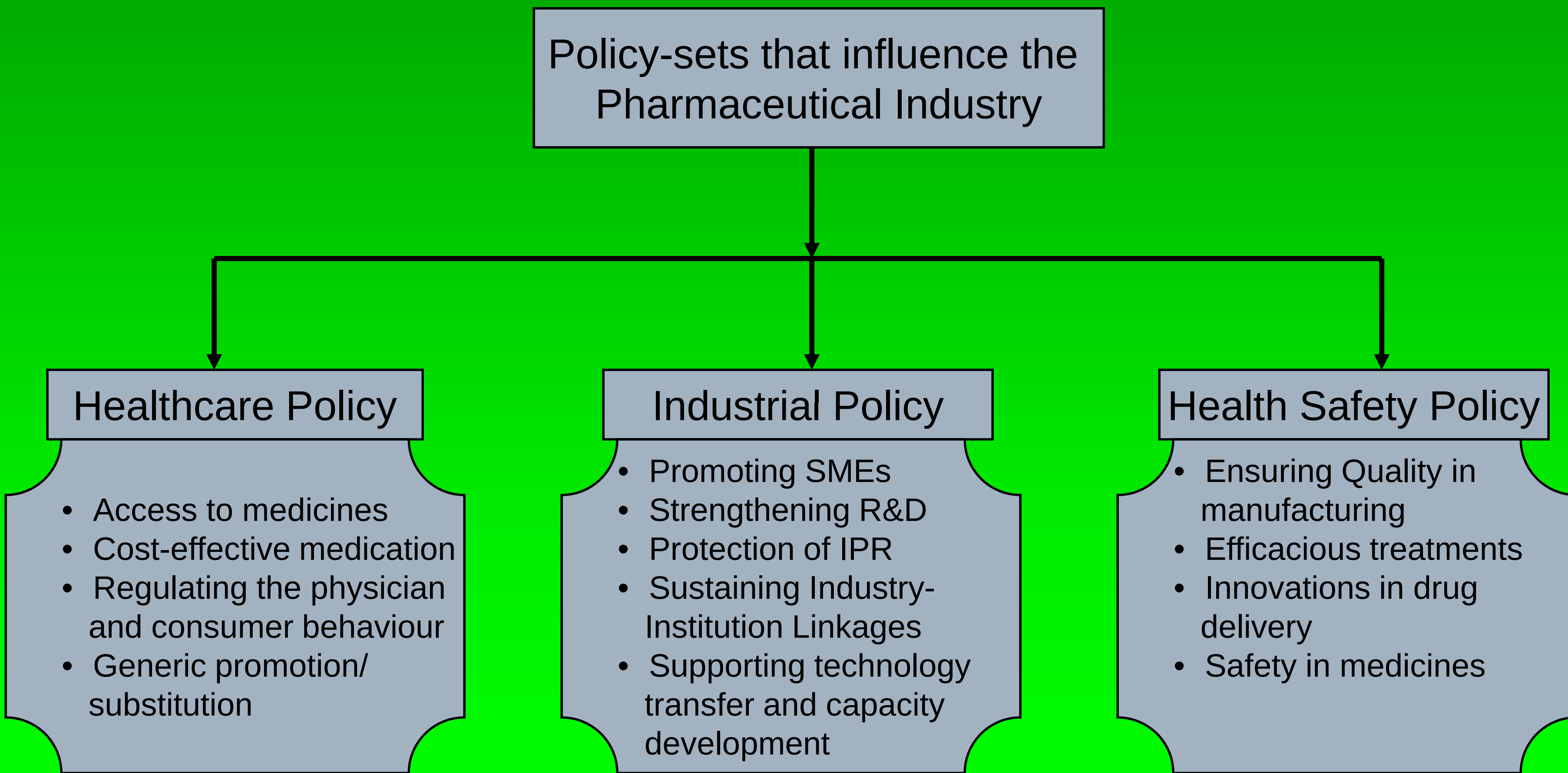
ACHIEVEMENTS THROUGH THE YEARS

Epidemiological Shifts

	1951	1981	2000	2005
Malaria (cases in million)	75	2.7	2.2	0.8
Leprosy (cases per 10,000 population)	38.1	57.3	3.74	1.0
Small Pox (no. of cases)	>44,887	Eradicated	-	-
Guinea Worm (no. of cases)		>39,792	Eradicated	-
Polio		29,709	265	660

Source: Ministry of Health & Family Welfare

POLICY FRAMEWORK SUPPORTING PHARMACEUTICAL INDUSTRY



Source: EXIM Research

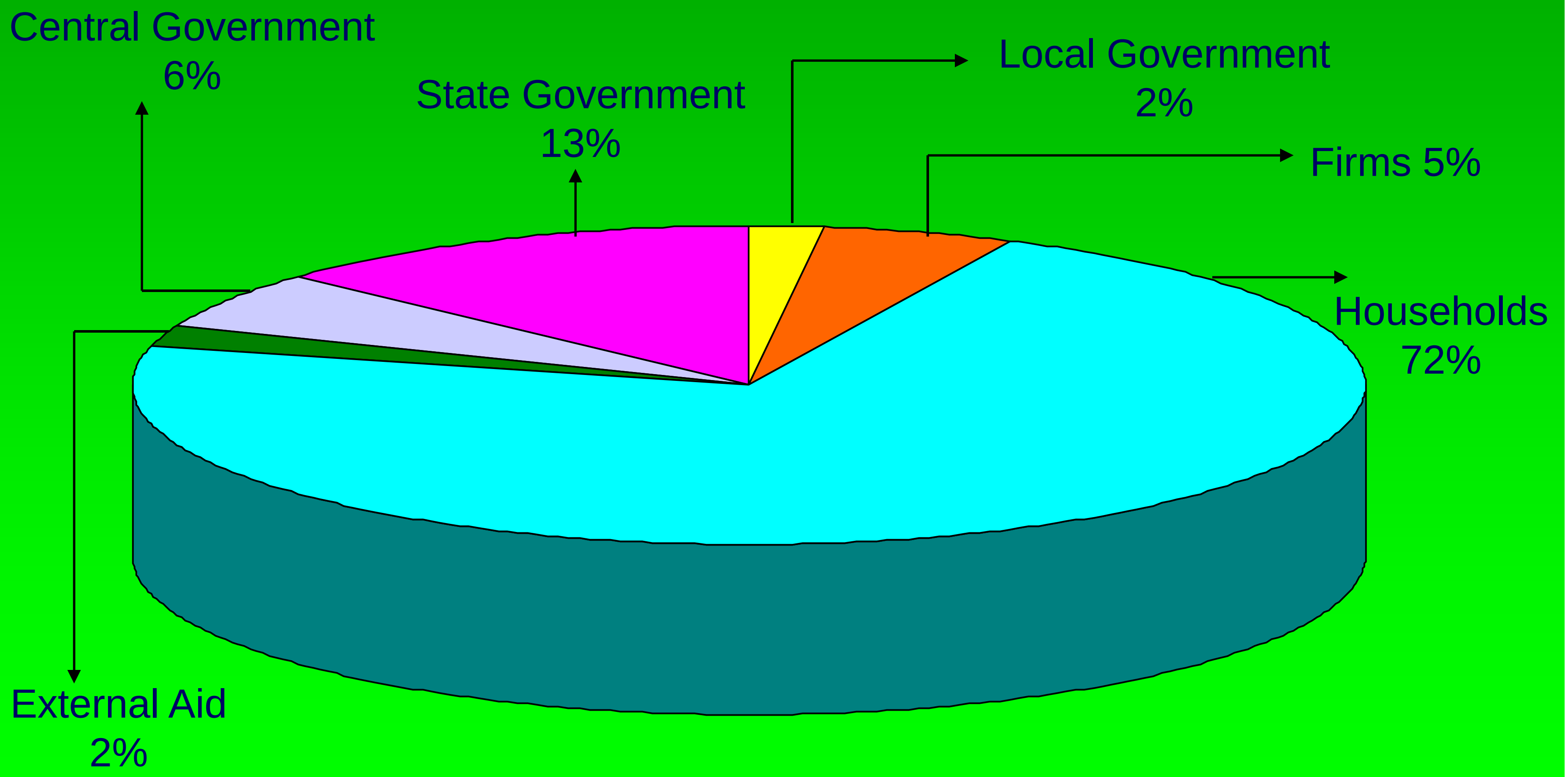
INDIA’S HEALTHCARE CONTEXT IS UNIQUE

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 : 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**

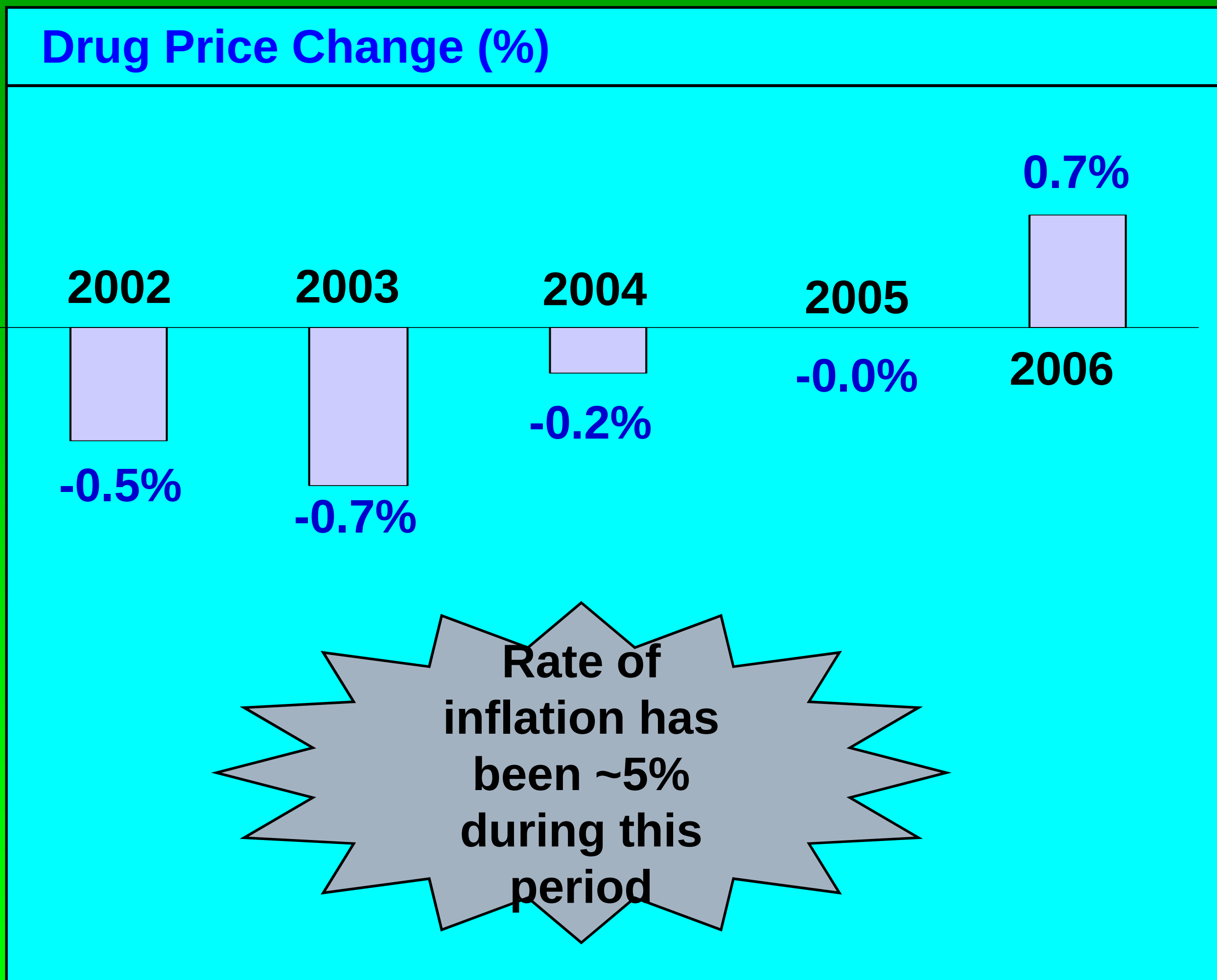
. . . More than 10 brands in each Molecule

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

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

Source : IMS ORG data

REAL PRICES HAVE FURTHER DECLINED YEAR ON YEAR

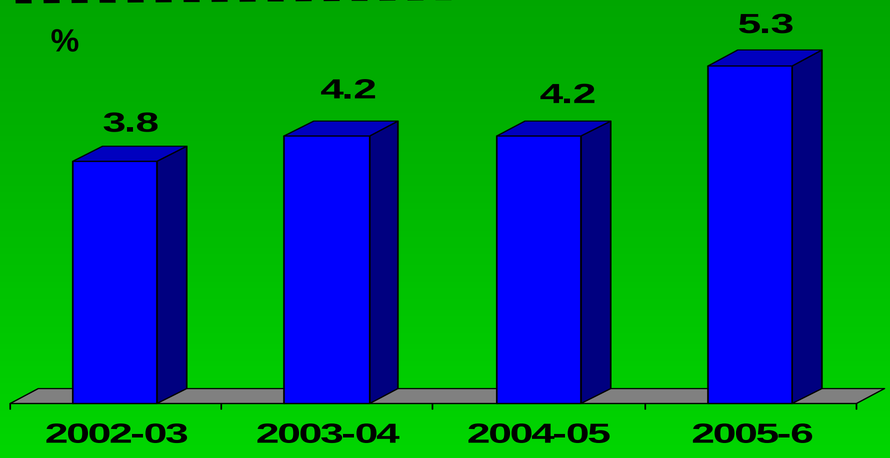


- Nearly 5% price decline in each year in real terms over last 5 years
- Prices of 539 formulations reduced over the last 2-3 years

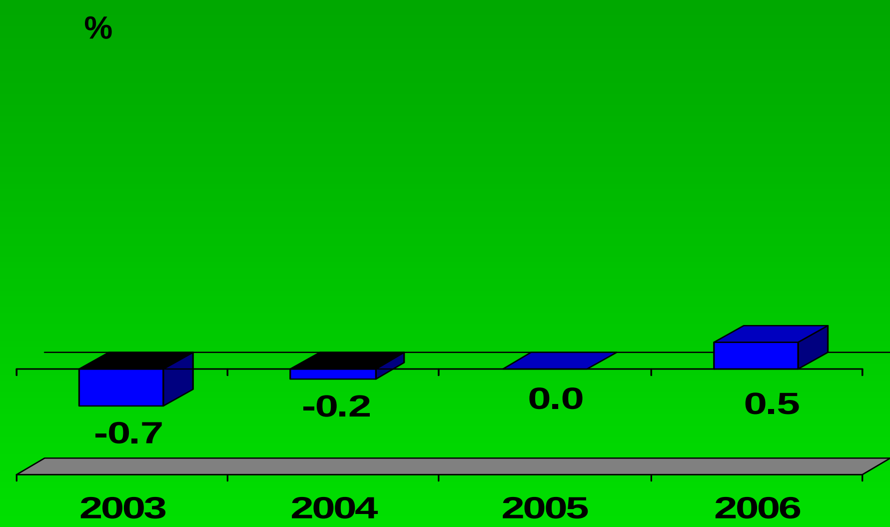
Source : IMS ORG data, OPPI

PHARMA INDUSTRY HAS ACTED VERY RESPONSIBLY ON DRUG PRICES

INFLATION RATE AT (CONSUMER PRICE)



DRUG PRICE CHANGE (WEIGHTED AVERAGE)



PERCENTAGE NUMBER OF PACKS WHOSE PRICES REMAIN STABLE

	APL	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR
2003-04	96.91	97.72	97.27	96.89	97.65	97.32	97.74	97.47	98.38	95.87	97.87	97.11
2004-05	97.38	97.24	98.2	98.85	96.5	97.9	96.39	95.03	97.16	98.47	96.2	97.73
2005-06	95.38	96.46	96.62	96.05	51.16	49.17	82.21	93.09	97.9	98.22	97.85	97.64
2006-07	99.52	99.20	99.41	99.31	99.37	99.51	99.23	100	99.02	98.81	99.18	99.81
2007-08	98.99	99.65	99.48									

SOURCE : ECONOMIC SURVEY, ORG-IMS AUDIT

Data instability due to system change-ORG-IMS

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

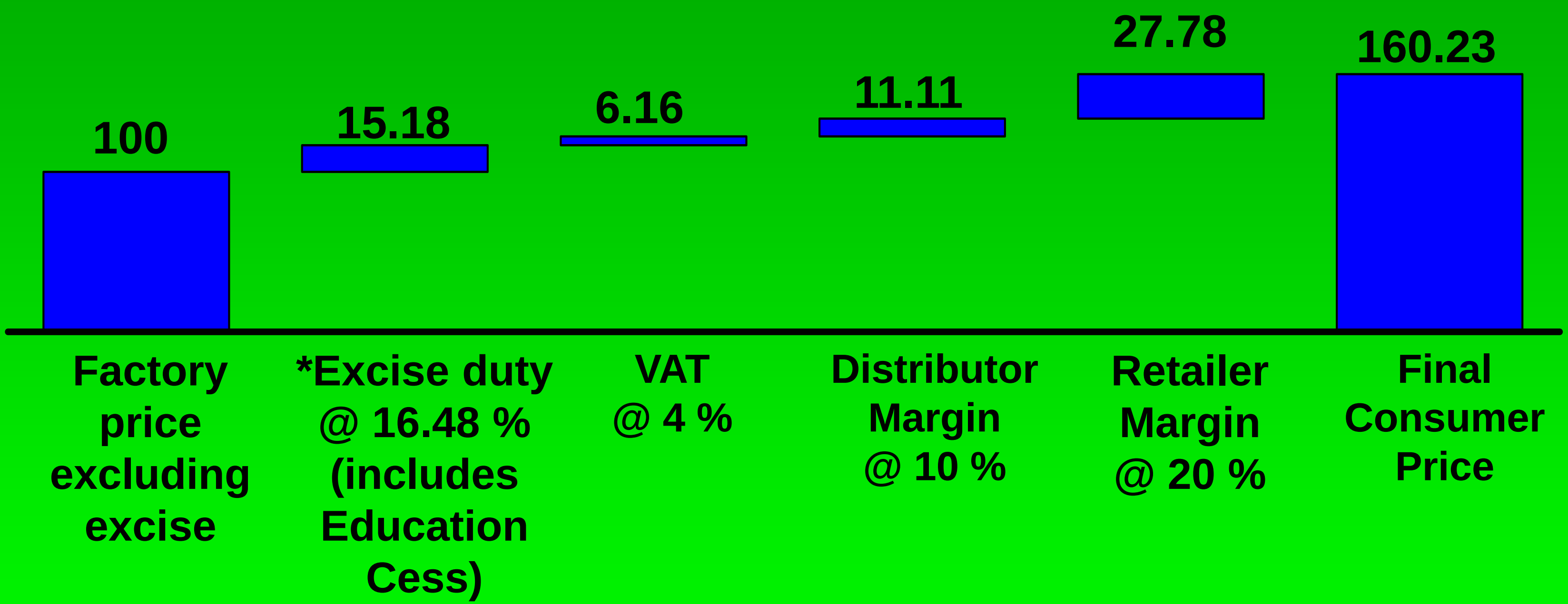
Source: ORG-IMS

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

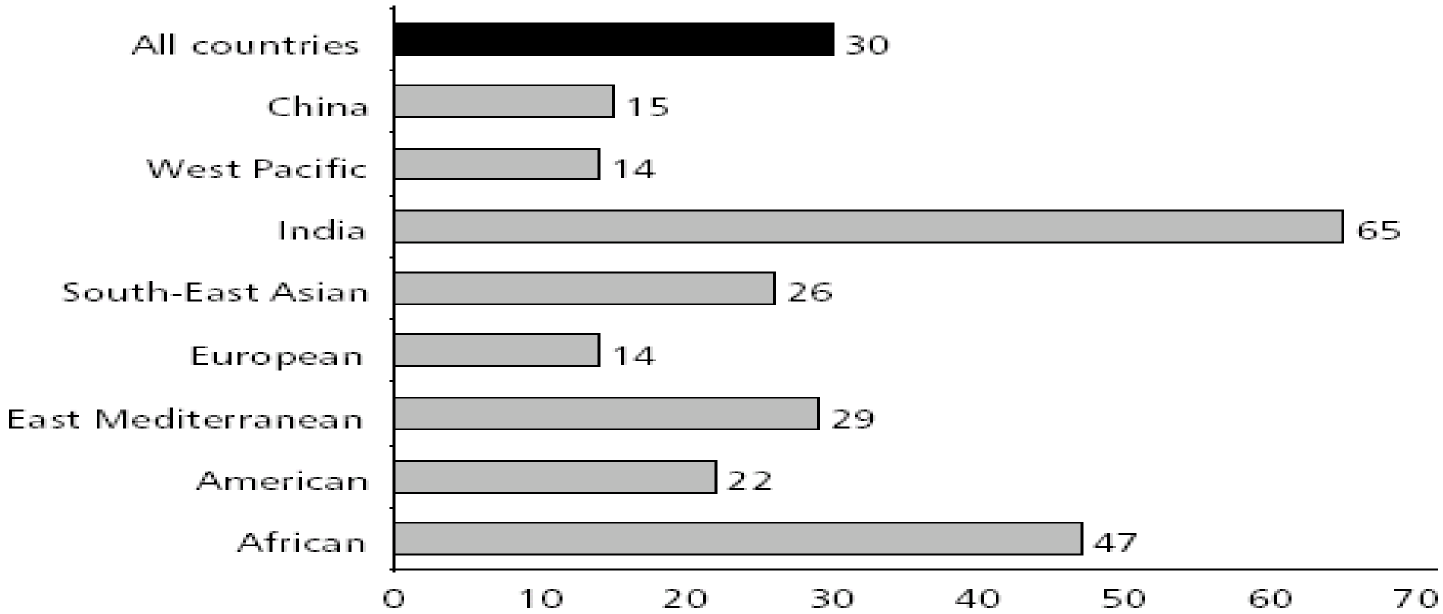
Source: ORG-IMS/NPPA

HIGH TRANSACTION COSTS INFLATE THE FINAL PRICE



THE REAL ISSUE IS ACCESS

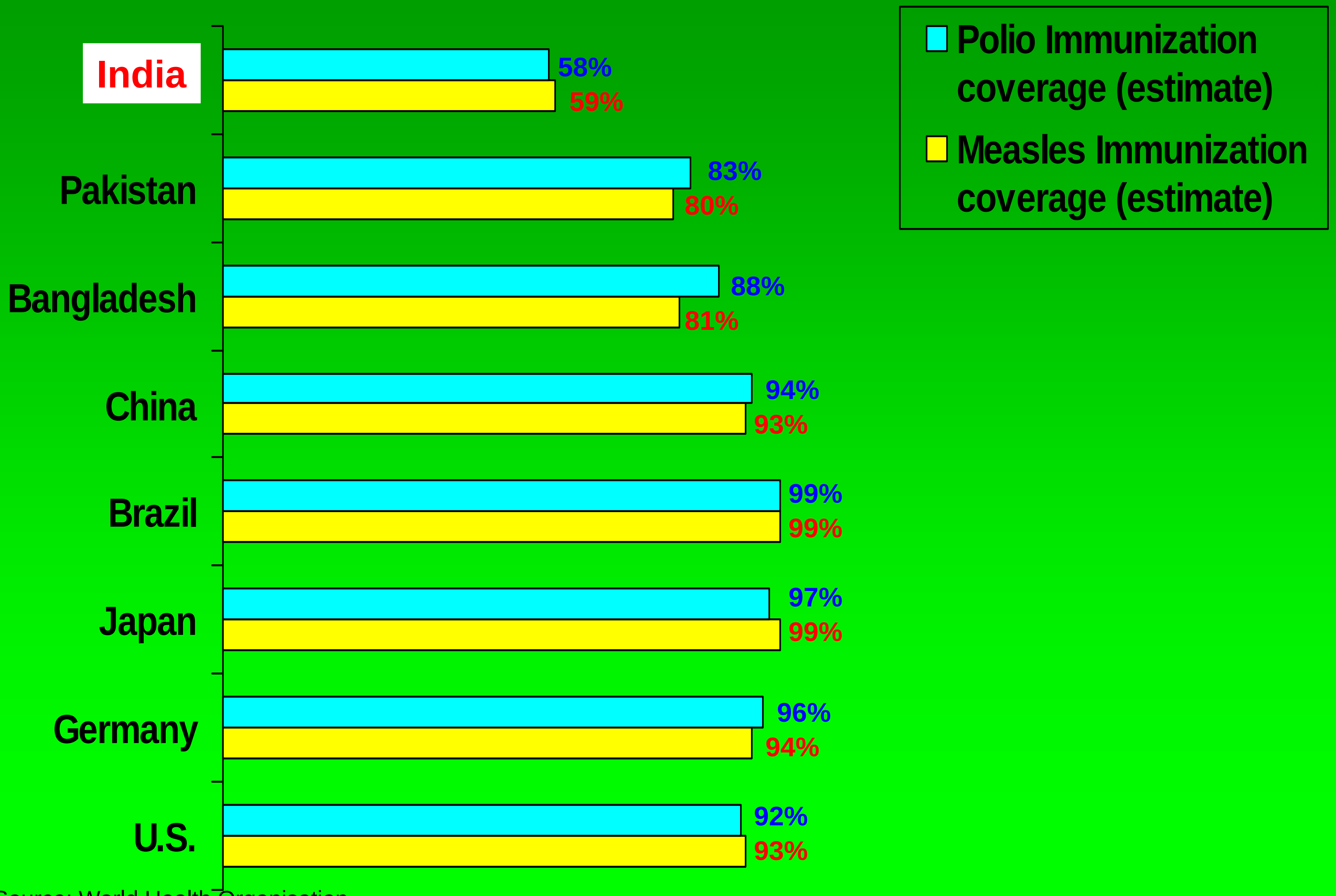
Percentage of WHO regions lacking access to essential medicines



650 Mn. Indians have no access to Essential Medicines

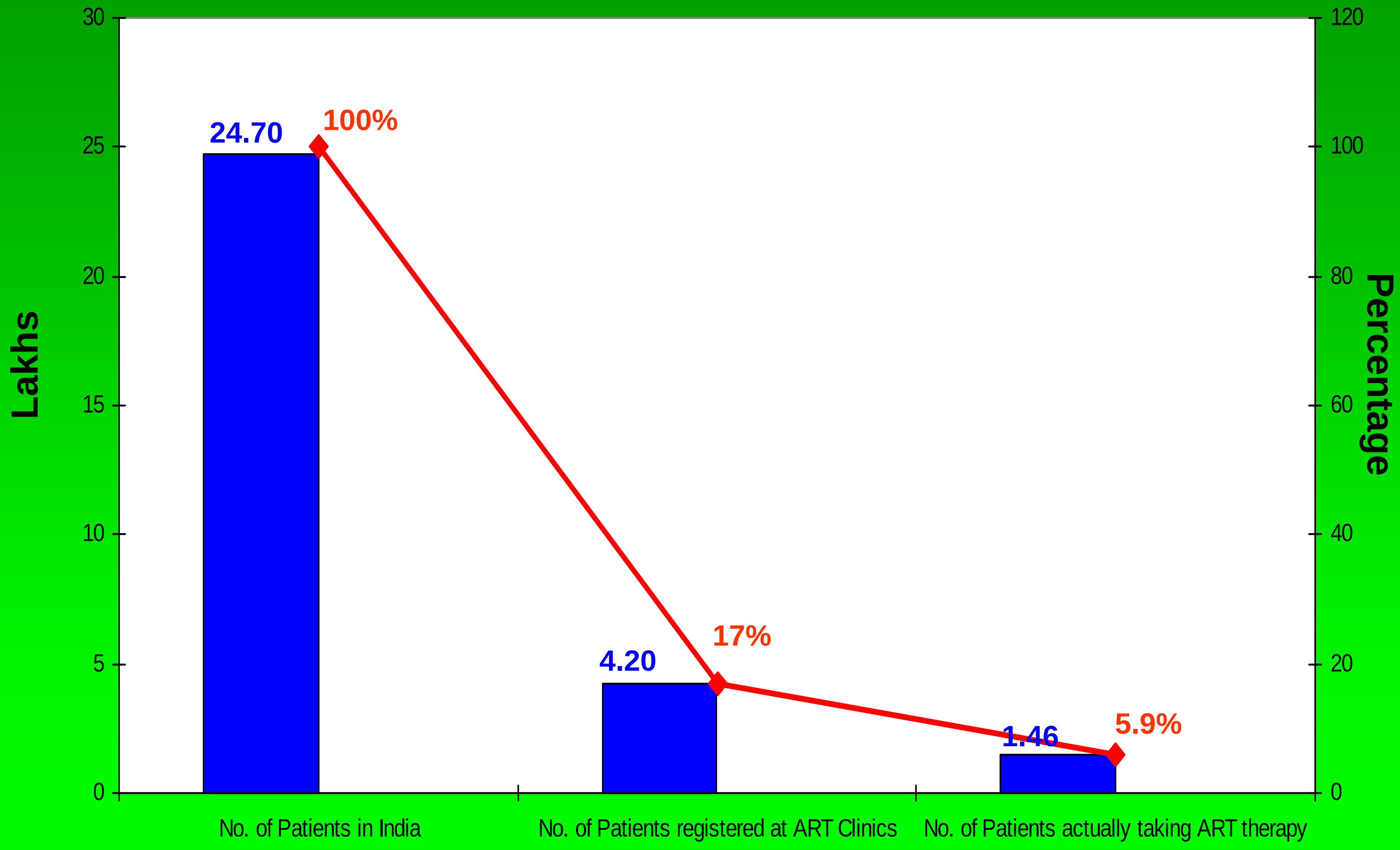
350 Mn. people having access are largely clustered around urban centers where health care facilities exist

MANY CHILDREN NOT GETTING PRIMARY VACCINATION



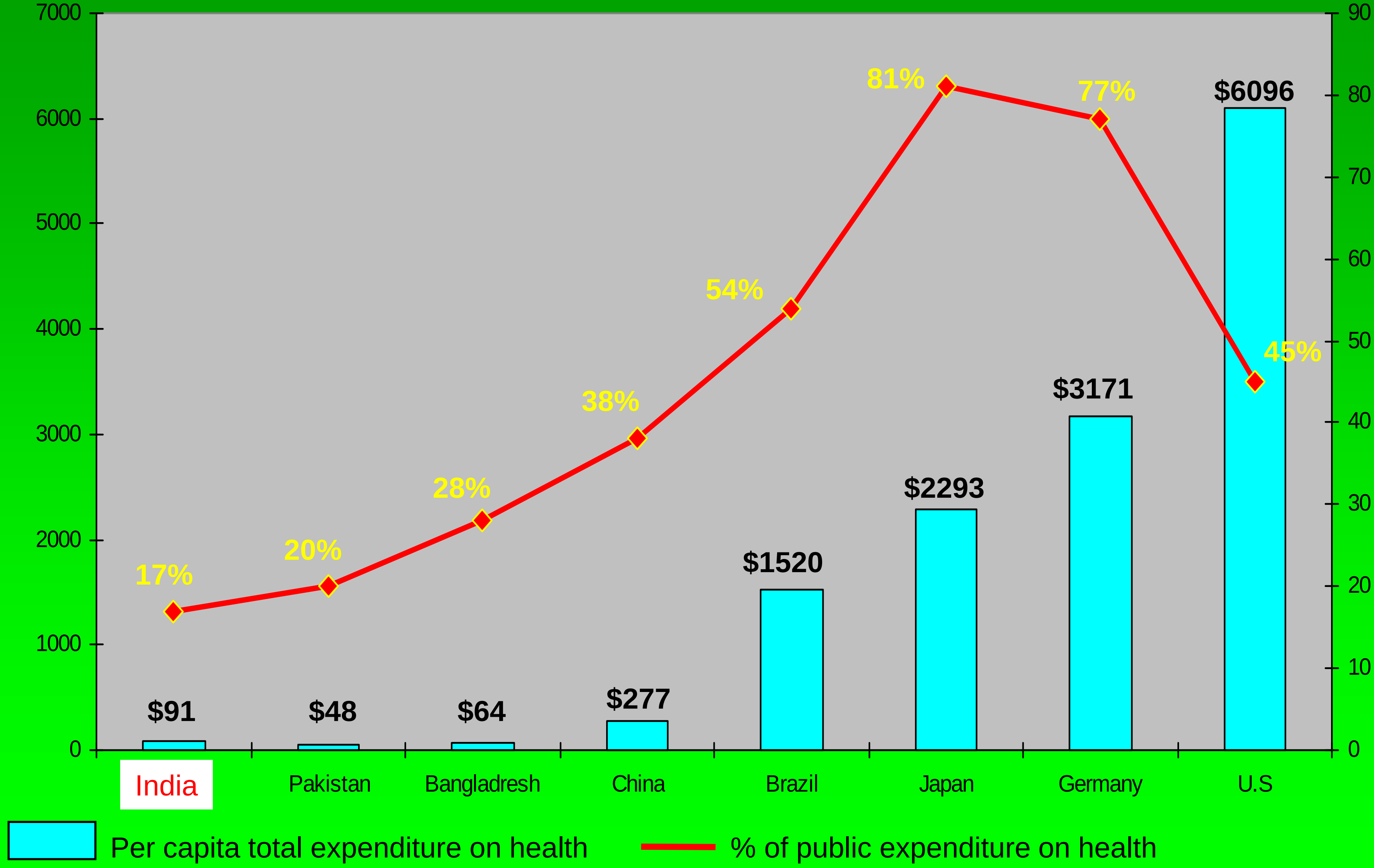
Source: World Health Organisation

HIV PATIENTS: ACCESS TO MEDICINE



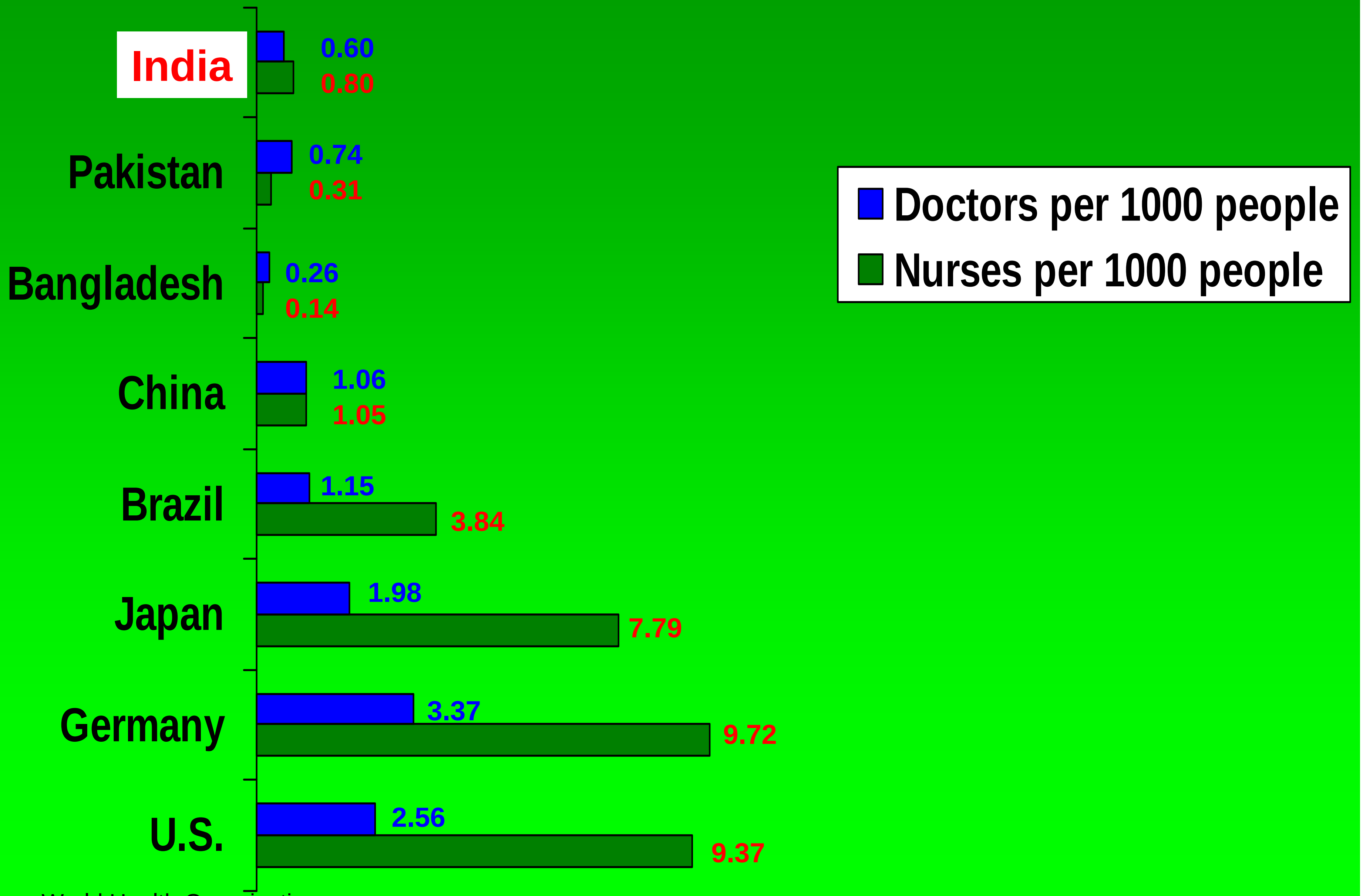
Source: NACO, INDIA

INDIA SPENDS RELATIVELY LITTLE ON HEALTHCARE



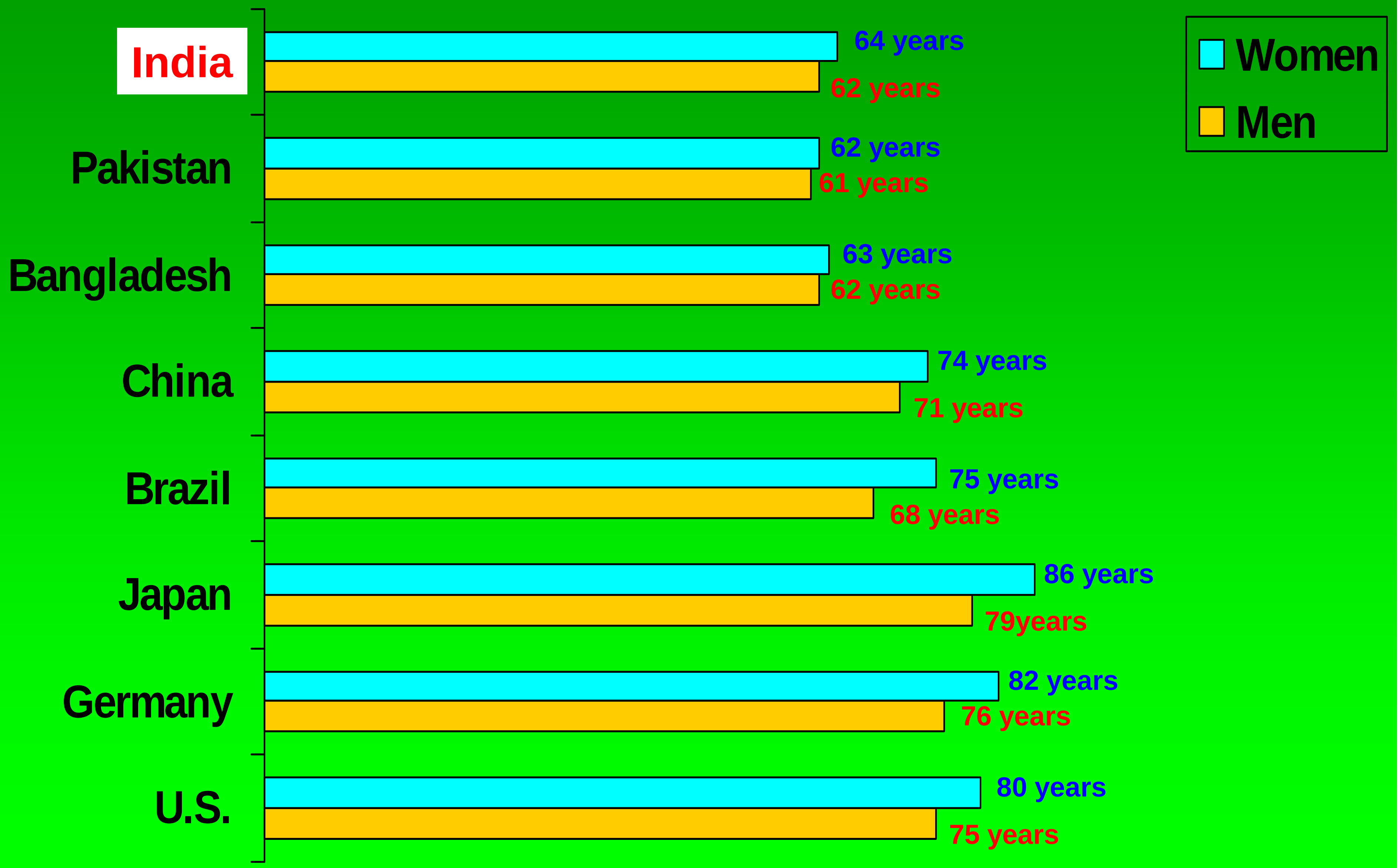
Source: World Health Organisation

SHORTAGE OF DOCTORS AND NURSES IN INDIA



Source: World Health Organisation

LIFE EXPECTANCY IN INDIA



Source: World Health Organisation

ACCESS TO INNOVATIVE MEDICINES

350 Mn. access to medicines

150 Mn. – Formal

200 Mn. – Largely above Poverty line

Pharma Industry role is restricted to this sector

650 Mn. (no access to medicines)

300 Mn.

Above Poverty line

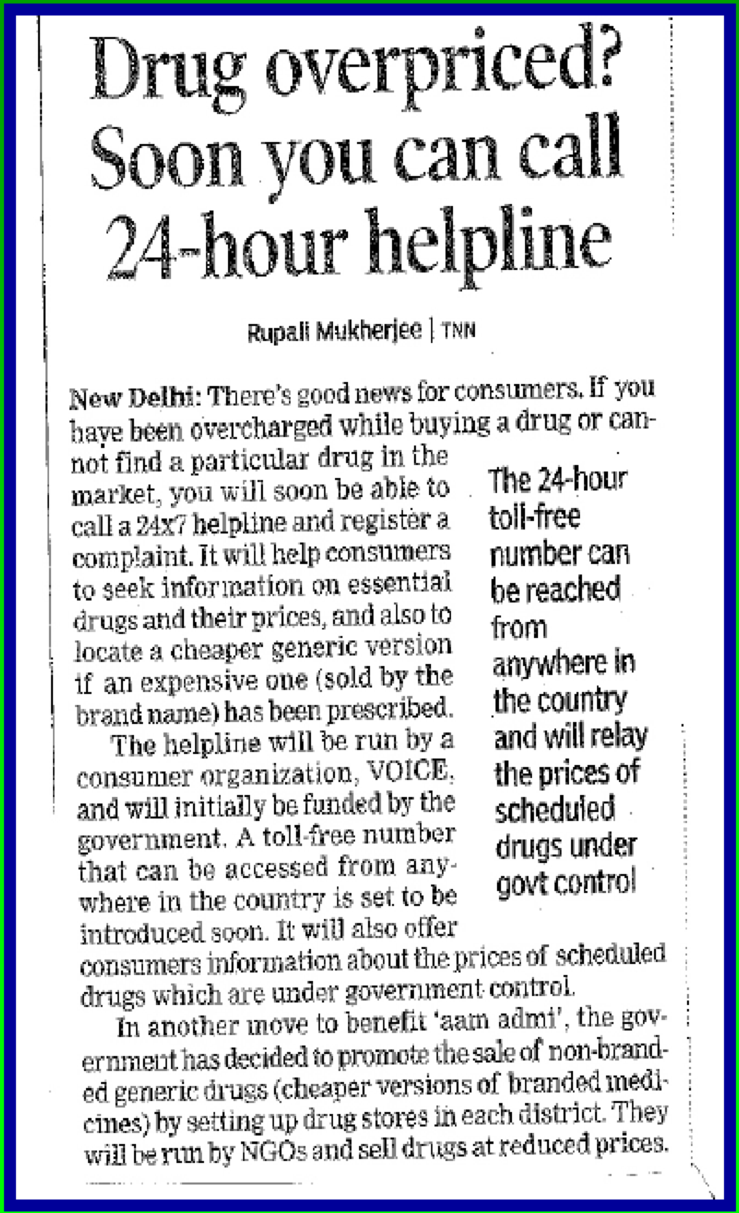
350 Mn.

Below Poverty line

Need of these patients are primarily for essential medicines

Formal Sector: Those employed with the Public or Private Sector

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

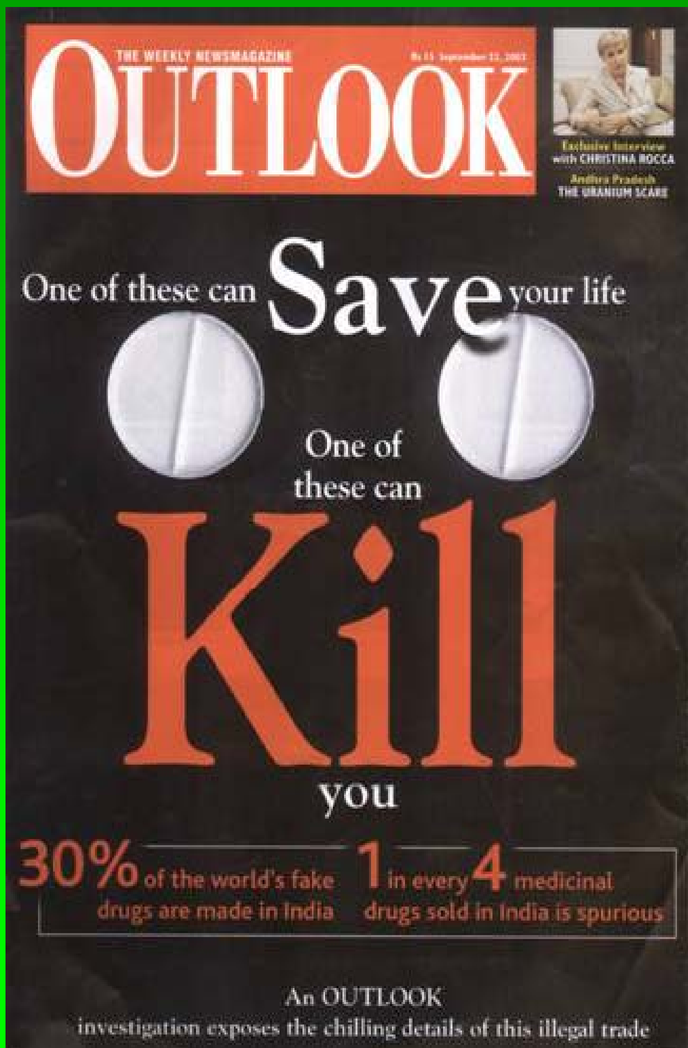
REVERSAL OF POSITIVE TREND

- The positive trend of phase-wise decontrol is now being reversed
- The National Pharmaceutical Policy proposes to bring all the 354 drugs in the National List of Essential Medicines, in addition to current 74 drugs under price control

CURRENT ACTIONS ON PRICE CONTROL

- 10% cap on price increase per year retrospectively for decontrolled products.
- Ceiling prices announced for 23 formulations which were outside price control.
- MAPE for imported formulations reduced from 50% to 35% in some cases.
- Price check at entry point on decontrolled drugs planned.

COUNTERFEIT DRUGS – A MENACE



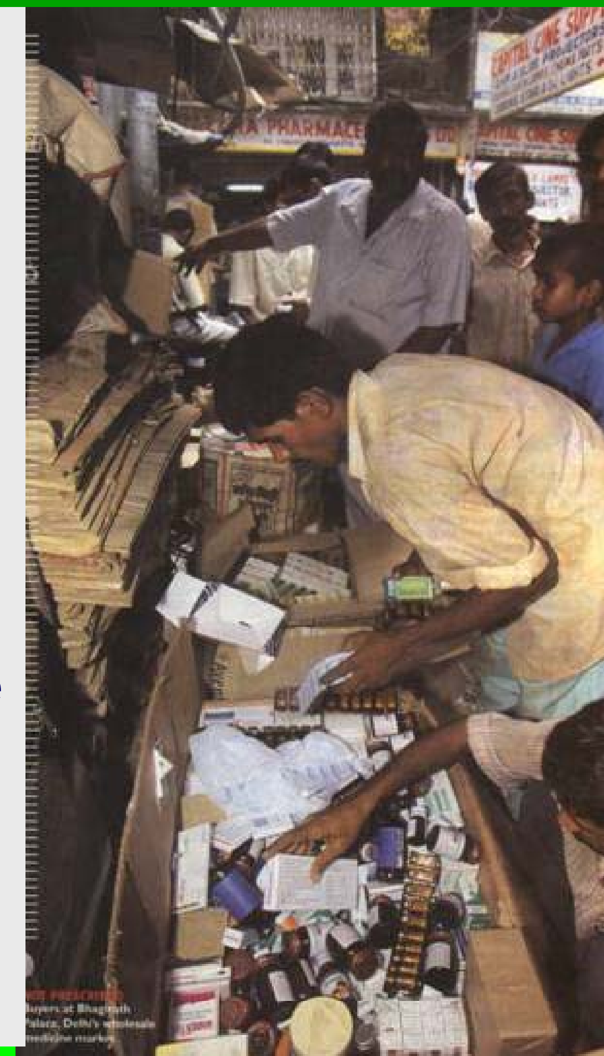
Making or selling spurious drugs is not a criminal offence in India

Anti-counterfeiting measures not used due to high cost

Quantification of Spurious Drugs required

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 10^{th} may, 2005 in the Parliament is an utmost priority

But there is little incentive to control this . . .

- No specific allowances for differentiation in packaging/tamper proof packs
- Packaging innovations are given standard MAPE markups
- Low margin on products under price control leads to low investment on them

A S I A

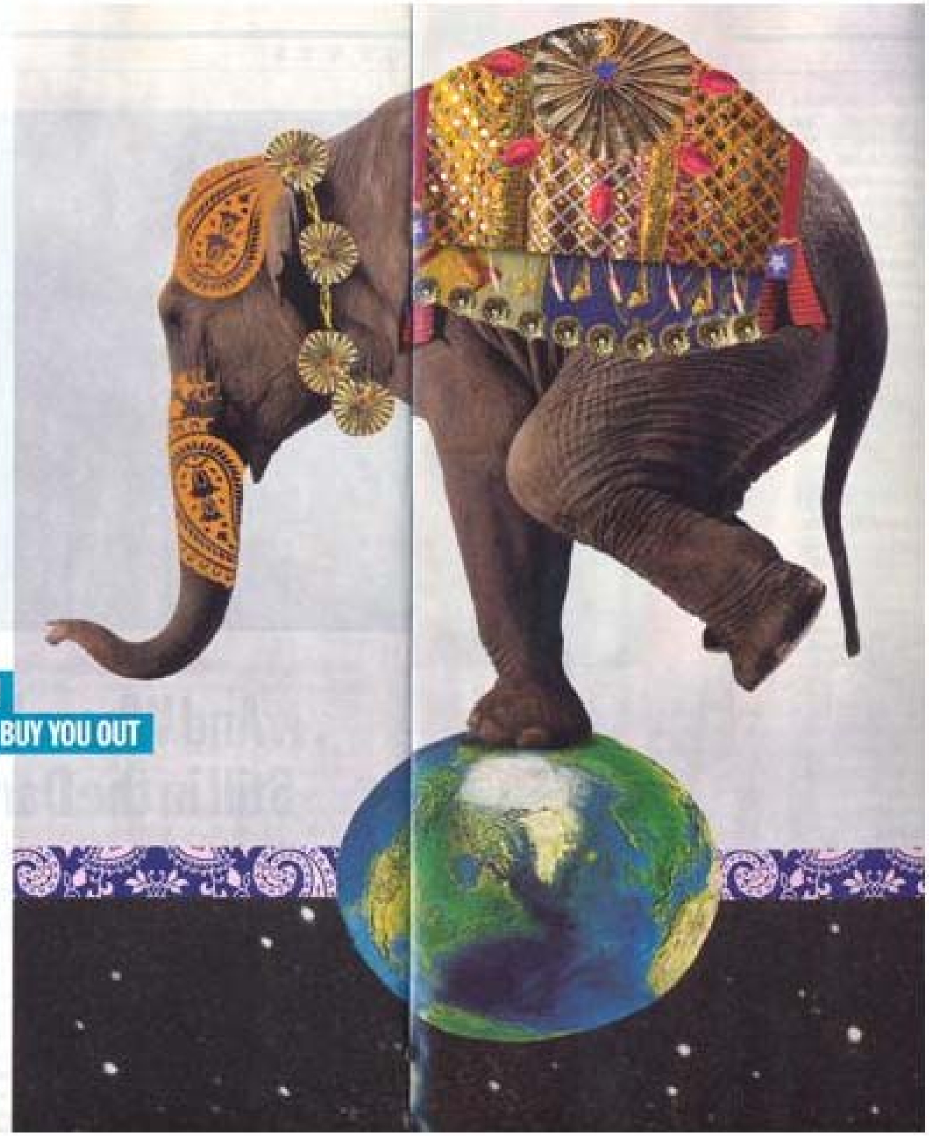
INDIA TAKES ON THE WORLD

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

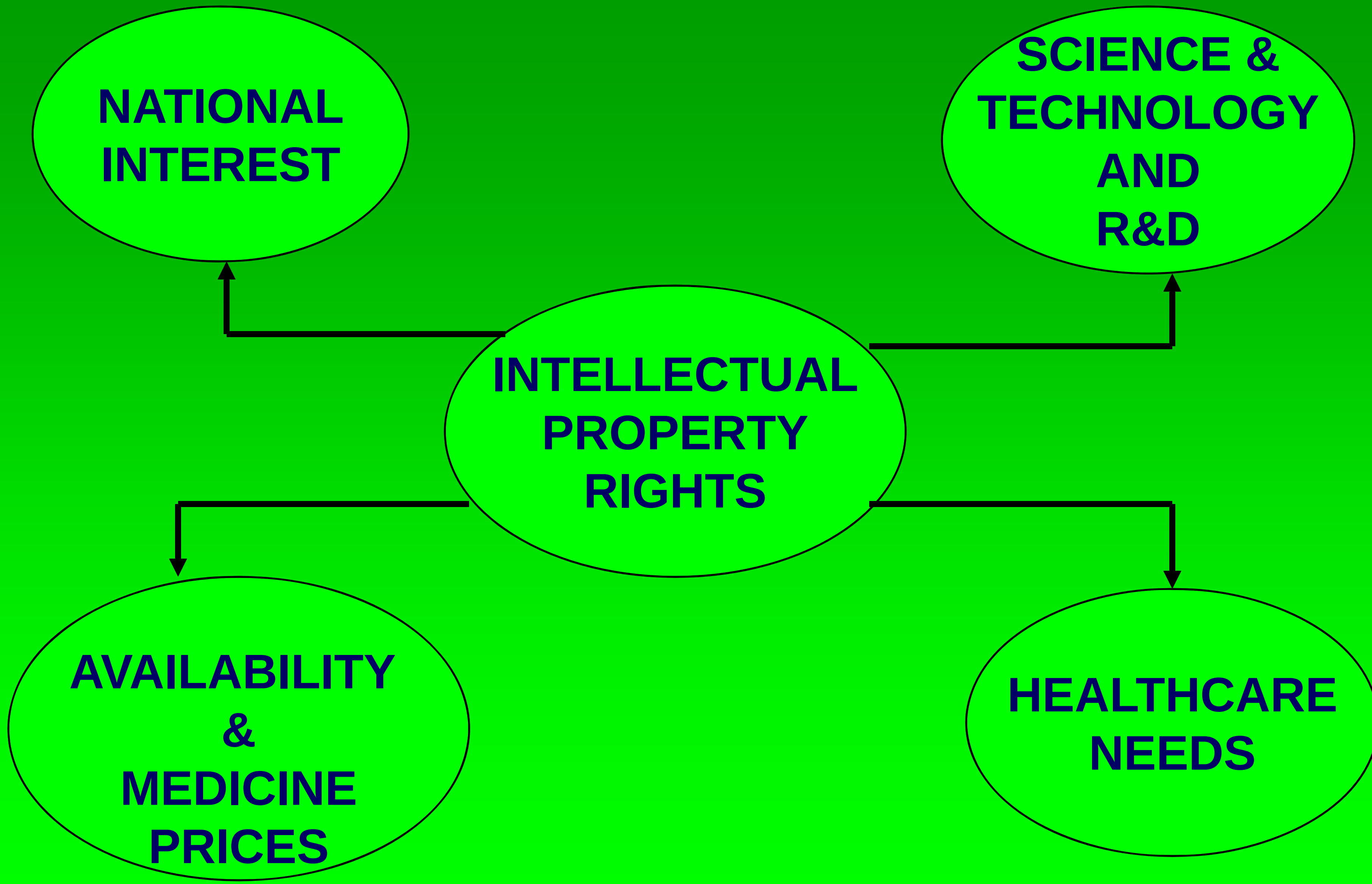
contd…

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

Sr. No.	Acquirer	Target	Sum ($ Mn.)
7.	Strides Arcolab	Strides Latina	16.00
8.	Wockhardt	Epharma Negma	13.30 265.00
9.	Jubiliant	Trinity	12.30
10	Zydus Cadila	French Formulation Unit of Apharma	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

IDEAL IPR POLICY FOR INDIA

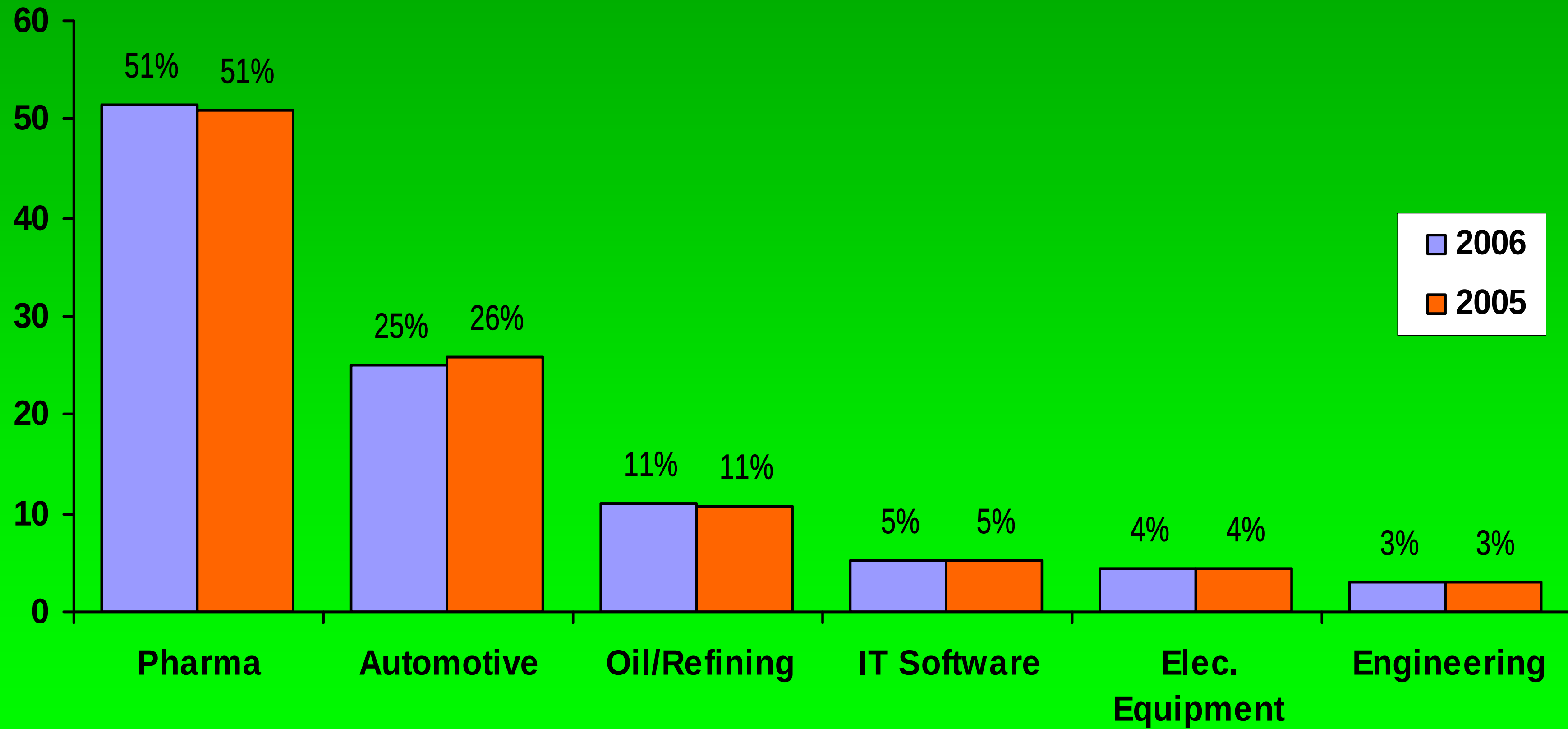


PATENTS IN INDIA – HISTORICAL PERSPECTIVE

1911	1970	1999	2002	2004
Indian Patents and Design Act	Indian Parliament enacted the Patents Act	First Amendment to the Patents Act	Second Amendment to the Patents Act	Patents Ordinance passed on December 26, 2004
Product Patents	Process Patents	EMR and Mailbox provided	Patent term extended to 20 years	In technical compliance with the commitment made under the WTO Agreement

INDIAN INDUSTRY–R&D SPEND

R & D Spend: How Top Sectors Fare

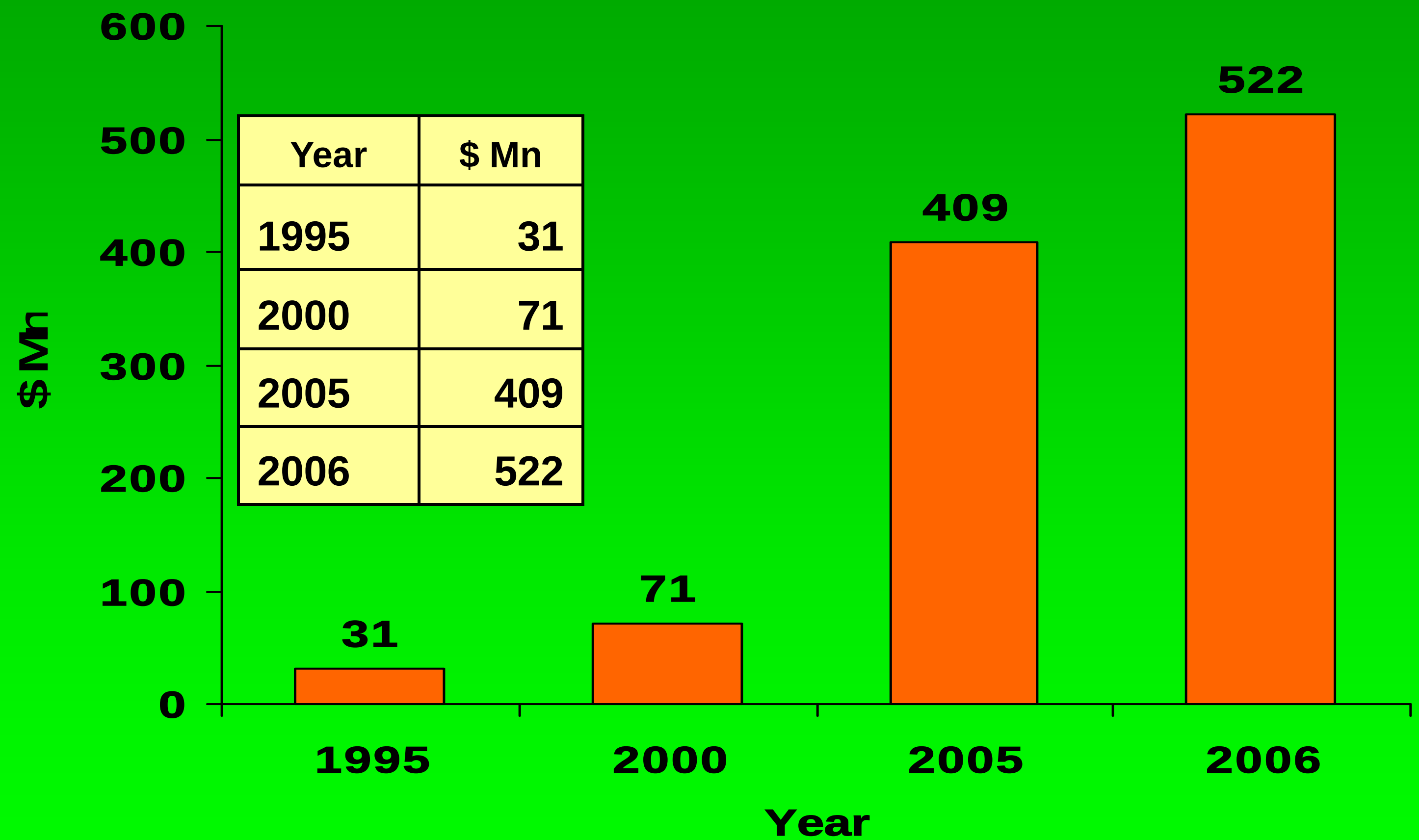


Source: Capitaline Plus

Pharma Spends More Than All Industries Put Together

INDIAN PHARMACEUTICAL INDUSTRY

R & D Spend - Pharmaceuticals



Year	$ Mn
1995	31
2000	71
2005	409
2006	522

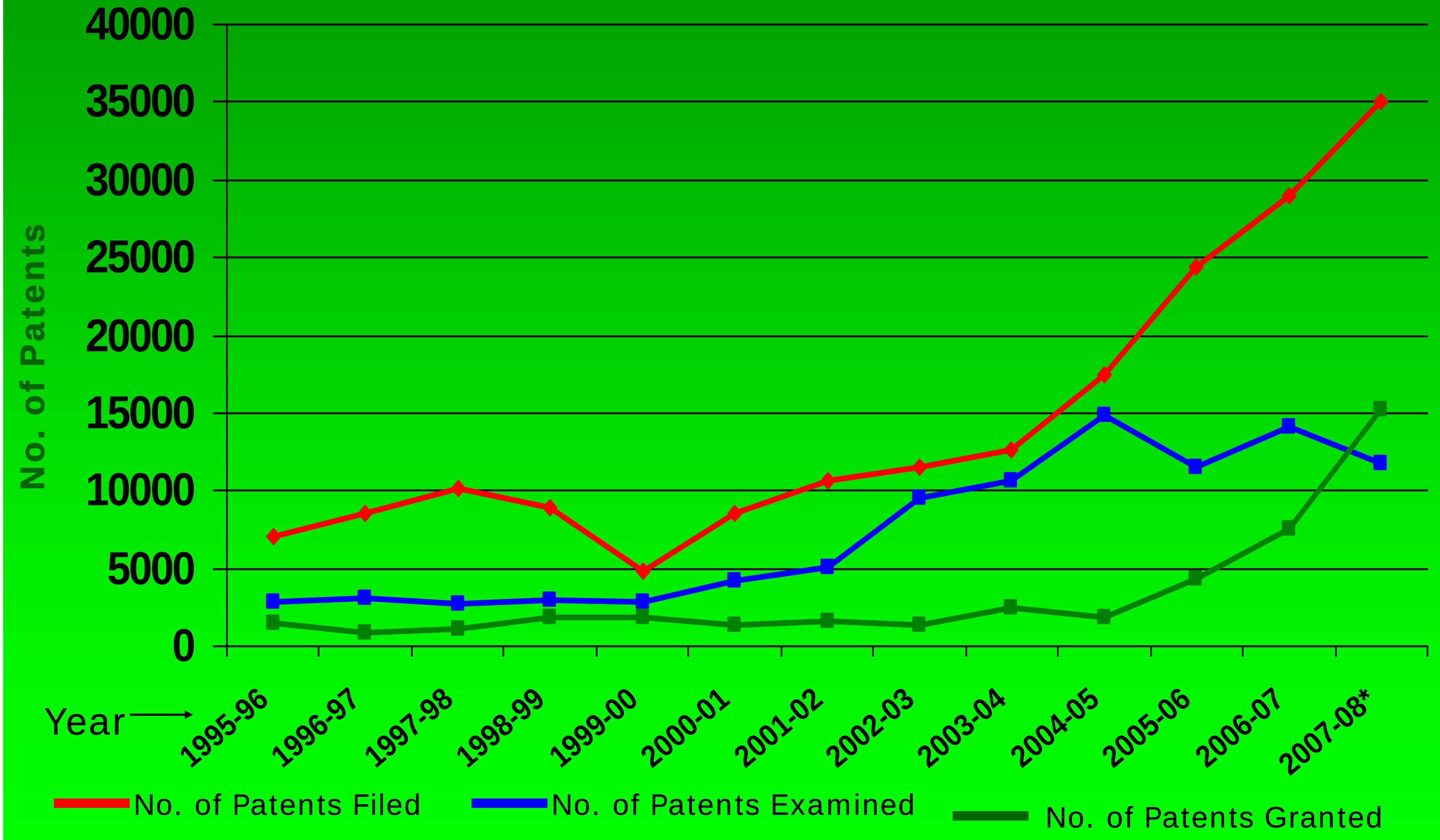
Almost 10% of 2006 Trade Sales

@ Constant $ (1 = INR 40)

Source: IDMA

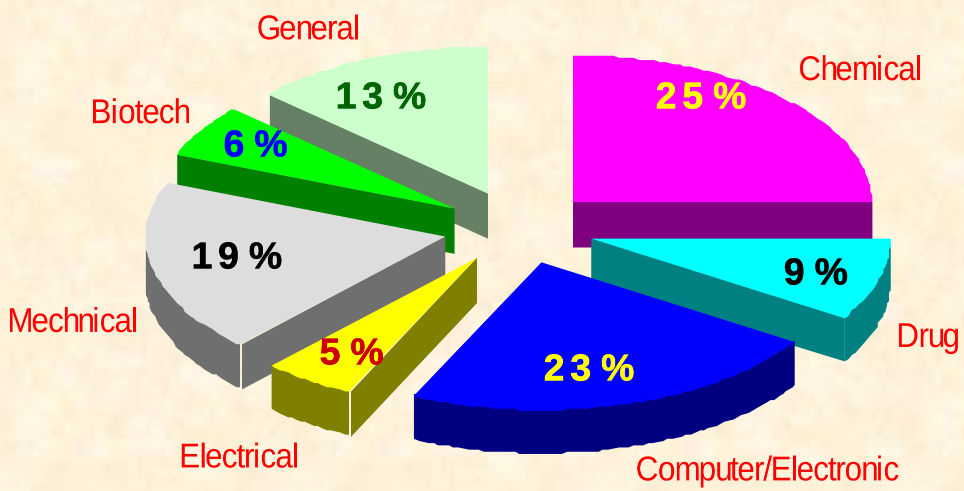
PATENTING LANDSCAPE IN INDIA

PATENTS FILING TRENDS AT THE IPO (FROM 1995-96 TO 2007-08*)



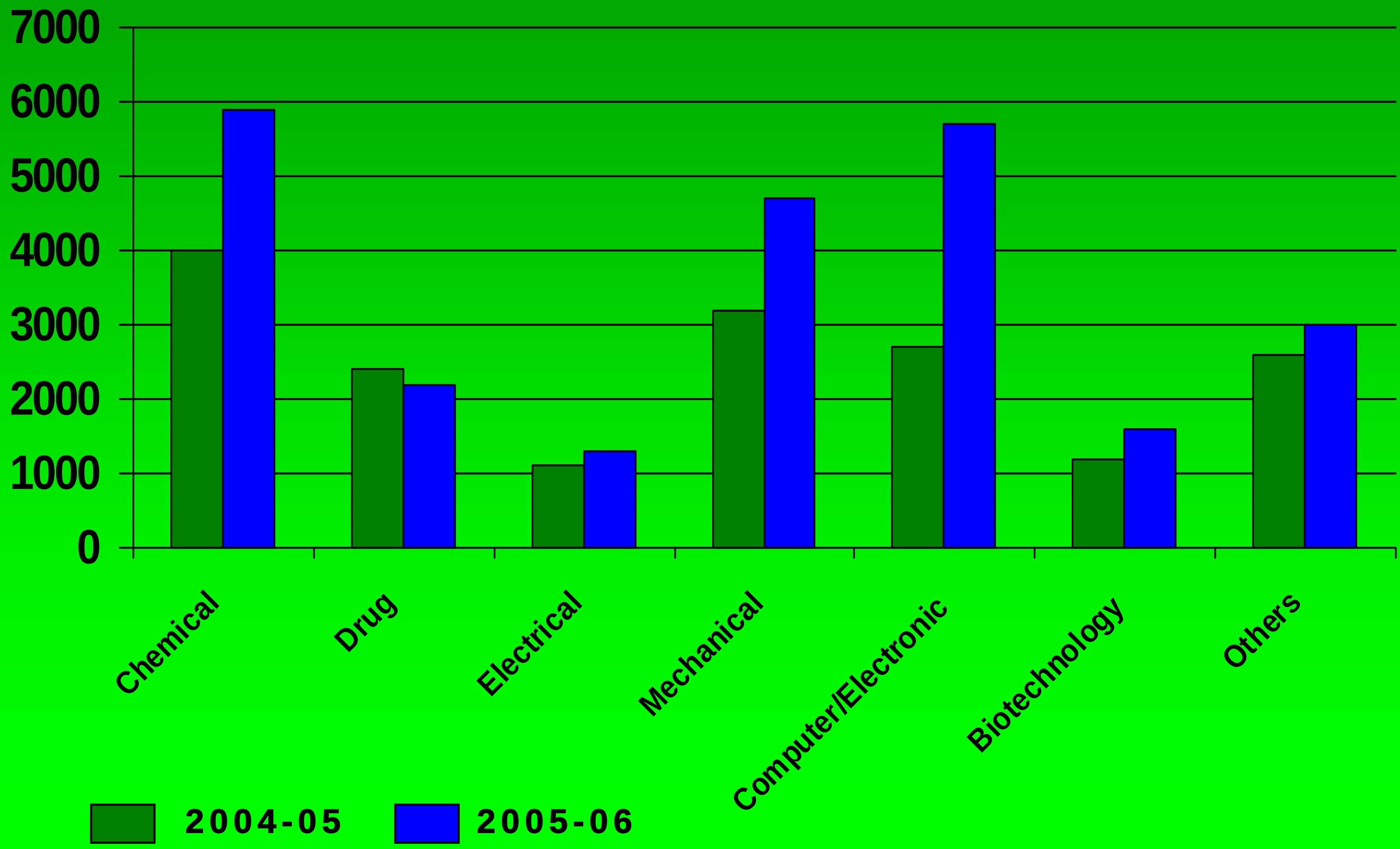
2007-08* provisional figures Source: IPO

DOMAIN-WISE BREAKDOWN OF PATENT APPLICATIONS FILED AT THE IPO (2005-06)



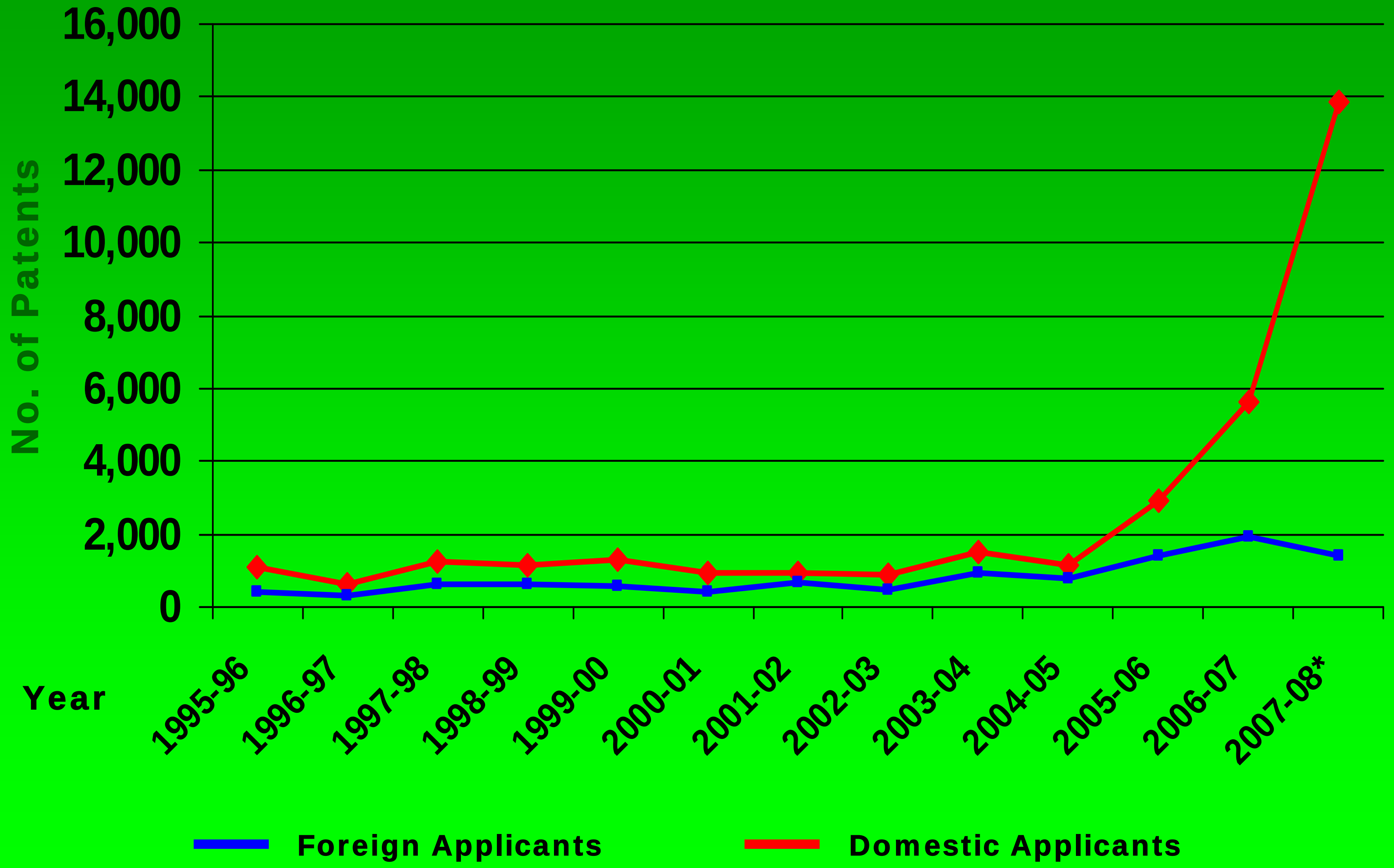
Source: 2005-06 Annual Report, IPO

GROWTH OF PATENT APPLICATIONS FILLING IN DIFFERENT DOMAINS (FROM 2004-05 TO 2005-06)



Source: 2005-06 Annual Report, IPO

TREND OF PATENT APPLICATIONS GRANTED 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…

350 Mn. access to medicines

2-pronged Approach

- Free Market Price
- Negotiated prices for Government procurement

650 Mn. (no access to medicines)

- Industry to support Government efforts to provide Access

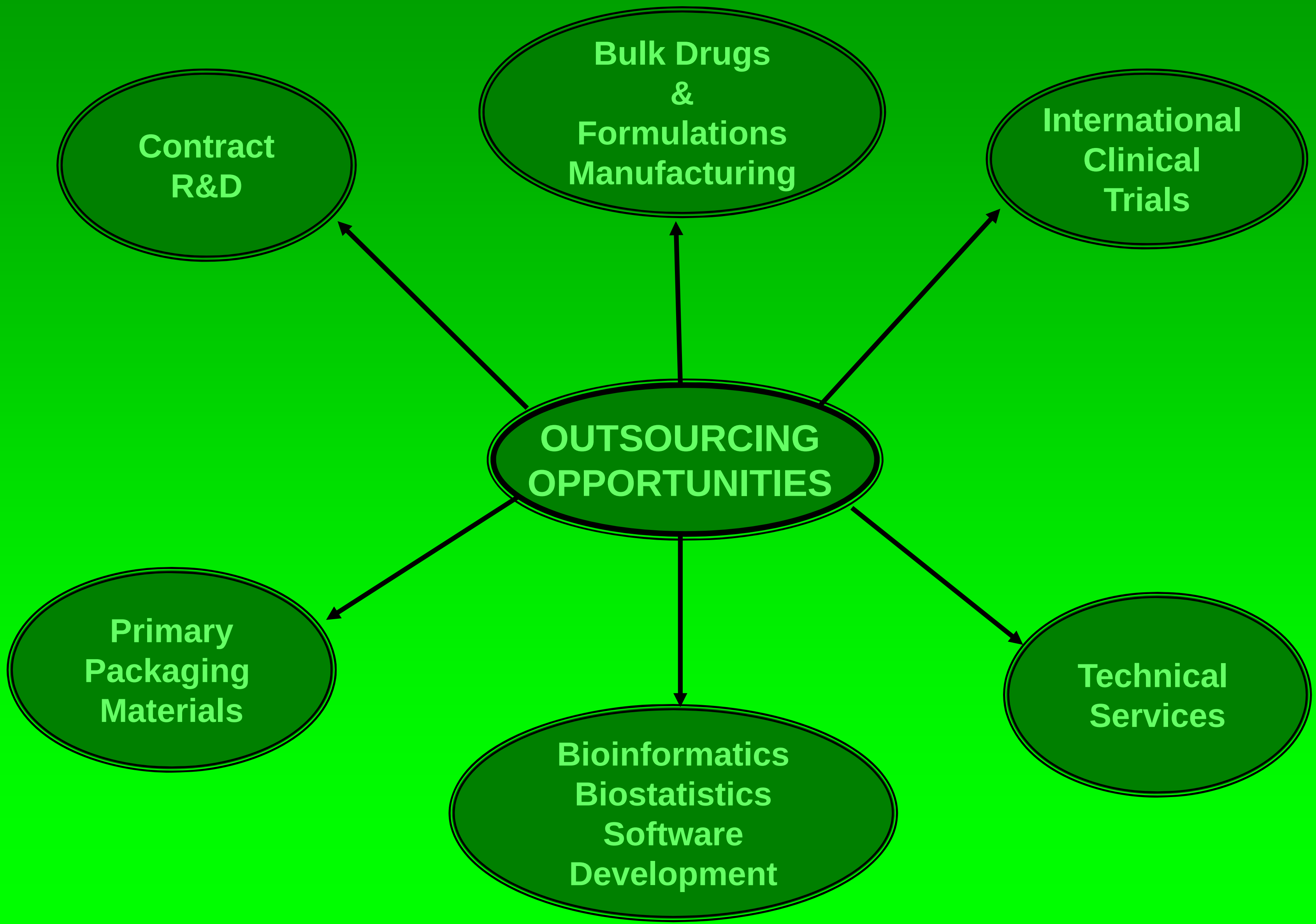
PROMOTE HEALTH INSURANCE

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

ADVANTAGE INDIA

- An abundance of English speaking scientific and technological brainpower
- Large and diverse drug naïve 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.

OUTSOURCING OPPORTUNITIES



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