

INDIAN PHARMACEUTICAL INDUSTRY – AN EMERGING TRAILBLAZER

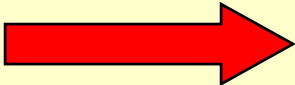
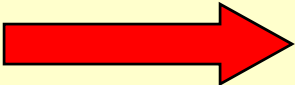
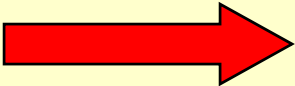
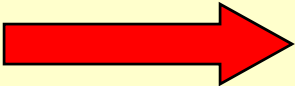

Tapan Ray

**February 6, 2008
IIM – Ahmedabad, India**

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- Advantage India and Affordable Healthcare for all
- Contribution of OPPI

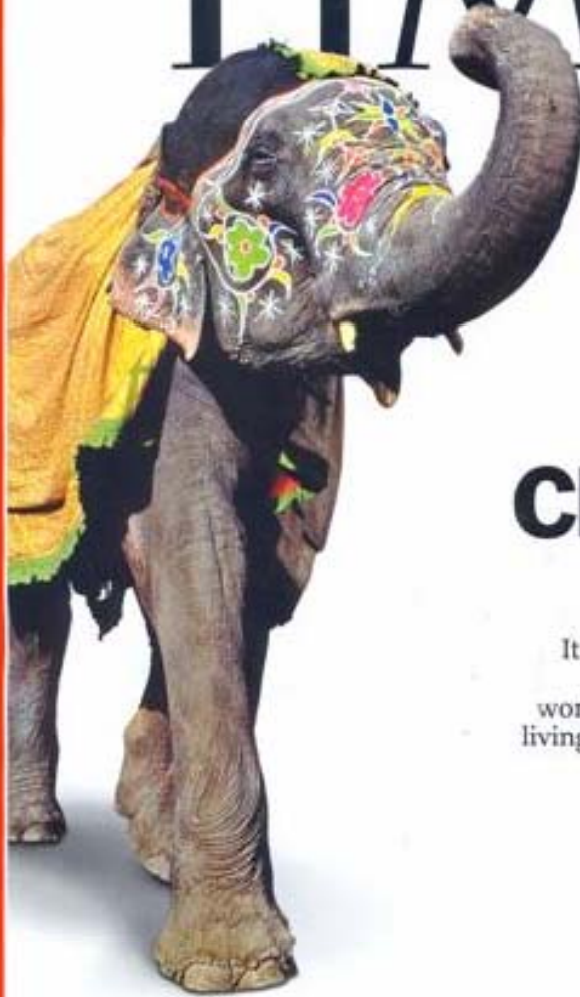
SELECTIVE ECONOMIC INDICATORS

		<u>1990-91</u>	<u>2006-07</u>
Real GDP		USD 48 billion	USD 840.1 billion
GDP Growth		5.3%	9.4%
Forex Reserves		USD 1 billion	USD 220 billion
FDI		USD 0.36 billion	USD 15.7 billion
Inflation		10.3%	< 5%

AUGUST 13, 2007

SPECIAL REPORT: 60 YEARS OF INDEPENDENCE

TIME

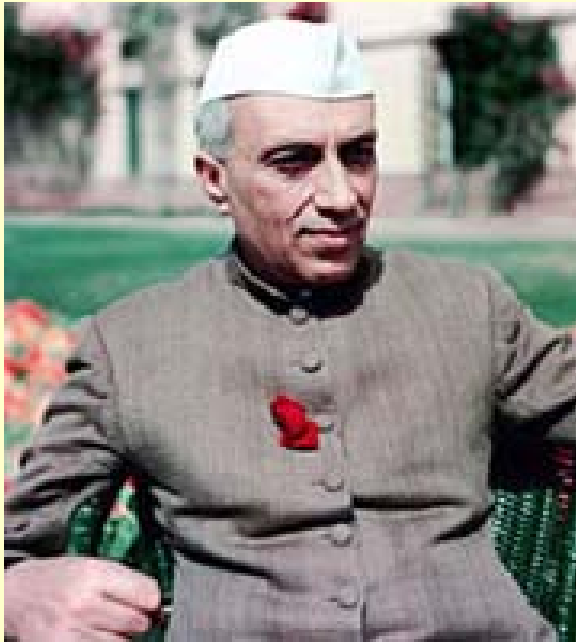


India Charges Ahead

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



JAWAHARLAL NEHRU SAID ON THE EVE OF INDEPENDENCE



“A new star rises A new hope
comes into being”

PHARMA IS POISED

- Government to provide enabling environment for growth
- Improve access to medicines
- Invest in health infrastructure
- Encourage R&D

INDIAN PHARMACEUTICAL INDUSTRY: 2006-2007

- 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

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

INDIAN BIOPHARMA MARKET

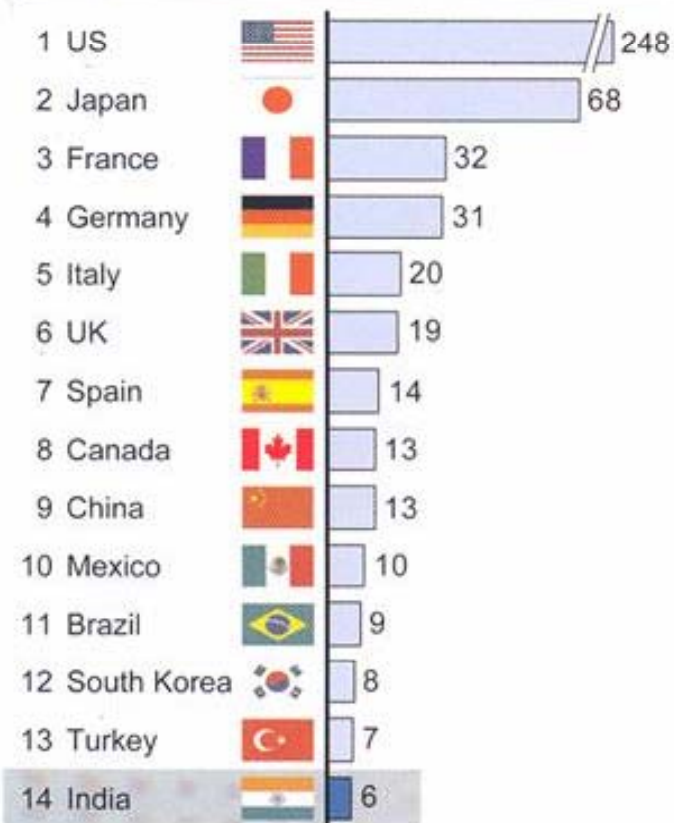
- Biotech Market Size 2 Bn. U.S.\$ - 70% in Biopharma
- 2 types of Products - Recombinant Drugs and Monoclonal Antibodies
- Products - Erythropoietin, Human Insulin, tPA, Filgrastim, Hepatitis B Vaccine, Interferon, Streptokinase, etc.
- India emerging as a major global source of Vaccines
- Biosimilars – Regulatory Issues, a Challenge

MCKINSEY PROJECTION 2015*

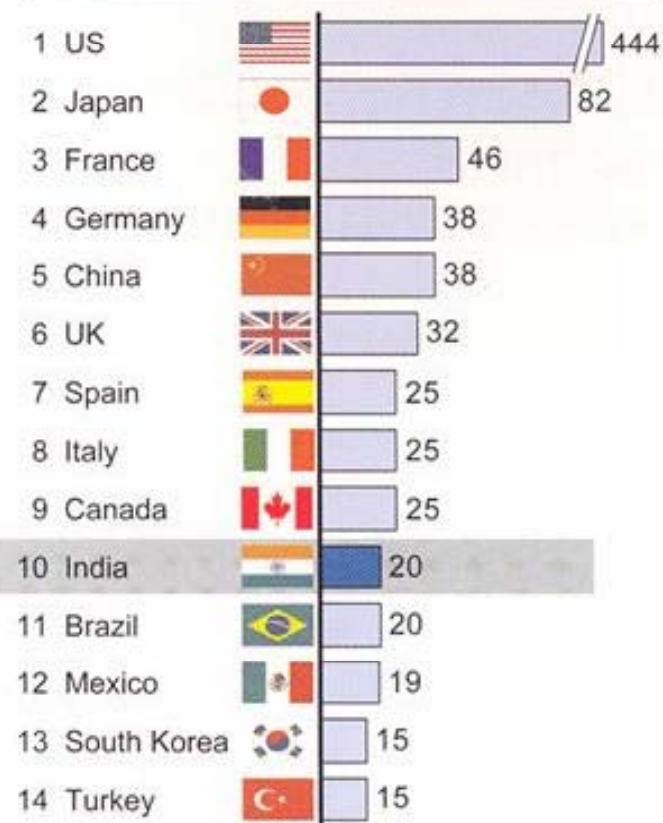
- Domestic Sales to reach U.S.\$ 20 Bn.
- Incremental growth between 2005 – 2015, 14 Bn. U.S.\$
- Key Drivers for Growth:
 - Robust Economy
 - Increasing Affordability
 - Deeper Penetration of Health Insurance
 - Increase in Organised Retail Chains
 - Shifting Disease Patterns
 - Increase in Healthcare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

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

Top 14 pharmaceuticals markets, 2005



Top 14 pharmaceuticals markets, 2015



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

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

CONTRIBUTION FROM PHARMA INDUSTRY HAS IMPROVED HEALTH INDICATORS 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

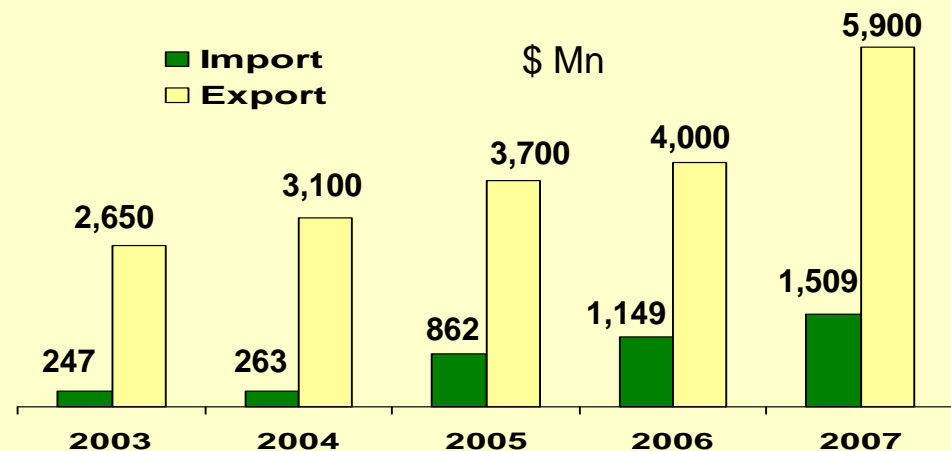
Epidemiological Shifts

	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	-	-
Guineaworm (no. of cases)		>39,792	Eradicated	-
Polio		29,709	265	660

Source: Ministry of Health & Family Welfare

INDIAN PHARMA INDUSTRY ... A TRULY SHINING EXAMPLE OF GLOBAL SUCCESS

- Amongst the top 15 countries in consumption value: fourth largest country in the world production volume.
- Though India's pharmaceutical market is just 1% of the global pharmaceutical industry in value, it accounts for 8.5% of global pharmaceutical production in the generics space, Indian firms account for 22% of global production.
- Net foreign exchange earner.



Source: The Financial Express, February 26, 2007;
U.S. International Trade Commission May 2007

MEDICINES

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

* 60% towards taxes and trade margins

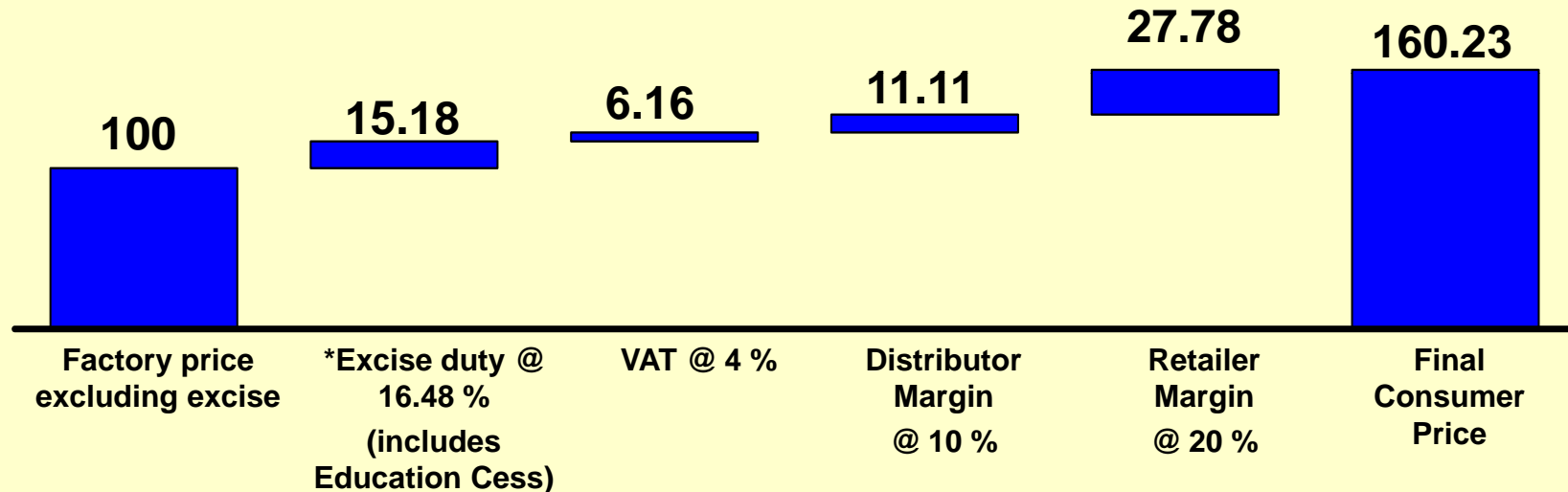
15% of Total Household Cost for Individuals

HOW EXPENSIVE ARE MEDICINES?

Per day treatment cost for common ailment	Rs.	Average cost of common goods & services of daily consumption (one time)	Rs.
Asthma	0.45	Public telephone call	1.00
Angina (chest pain)	0.55	Banana	1.50
Diabetes	0.70	Egg	2.00
Common Allergy	0.75	Newspaper	2.00
Common Headache	1.00	Inland letter	2.50
Amoebiasis	1.10	Cup of Tea	3.00
Diarrhoea	1.20	Bus fare (minimum)	4.00
Anti-ulcer	1.40	Suburban train ticket (return)	8.00
Common Cold	1.50	Milk (half litre)	9.00
Arthritis	1.50	Thali meal	25.00
Blood Pressure	1.75		

HIGH TRANSACTION COSTS INFLATE THE FINAL PRICE

Final consumer price with trade margins added



* Note: Abatement 42.5%

Need to review ancillary costs such as import duties and margins to trade

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	30
2002	30 drugs proposed	Under review

THIS ENLIGHTENED POLICY RESULTED IN

- India emerging as a global powerhouse in Pharmaceuticals with a robust domestic industry.
- According to McKinsey latest report released on August 22, 2007, India's pharma turnover is expected to treble to 20 Bn. U.S.\$ by 2015.
- Intense competition has resulted in medicine prices falling to lowest in the world (lower than even neighboring countries like Pakistan, Indonesia, etc.).

PHARMACEUTICAL PRICES IN SELECT COUNTRIES

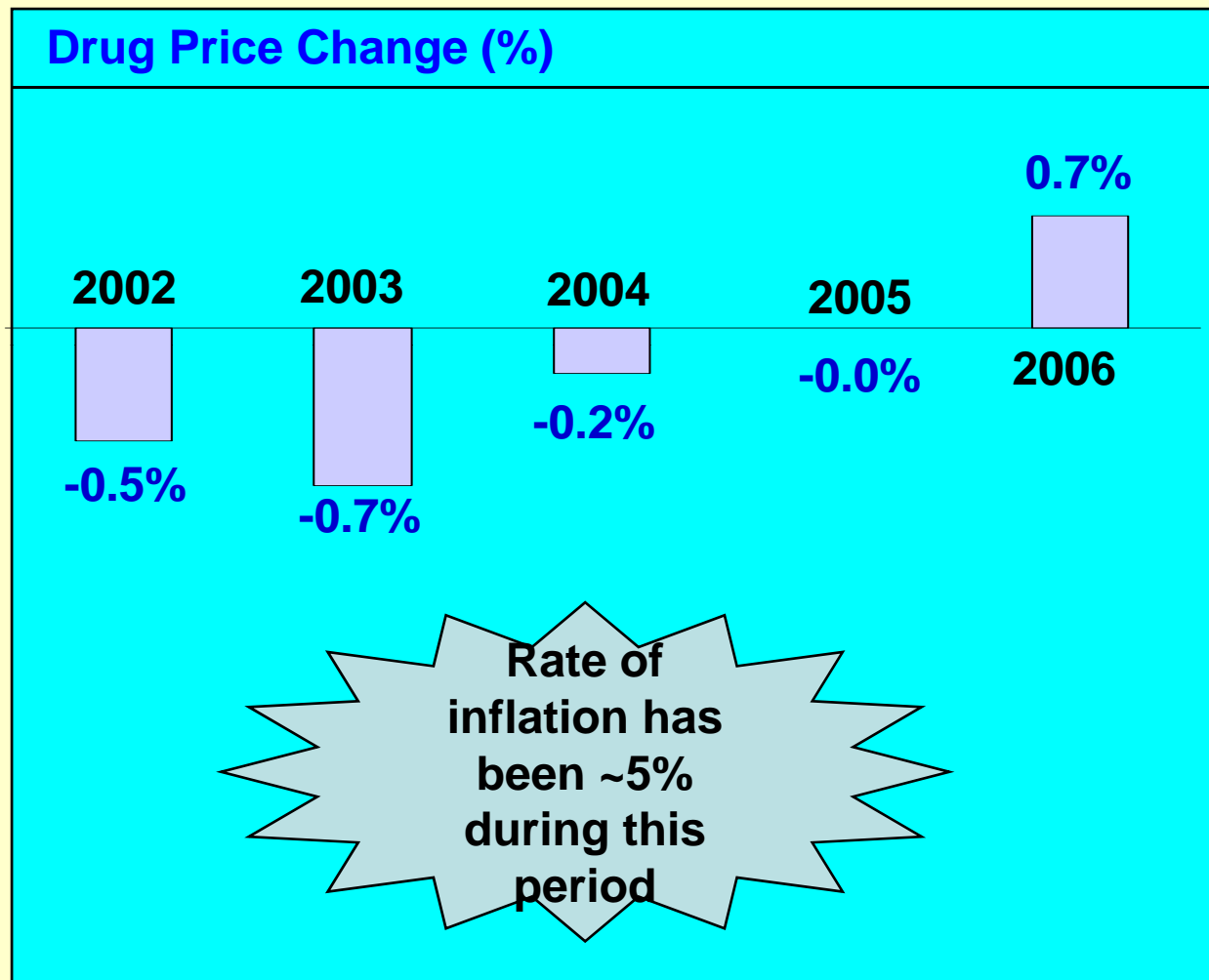
	Drugs, Dosage form and Strength	Pack	Prices in India (INR)	Prices in Pakistan (INR)	Prices in Indonesia (INR)	Prices in USA (INR)	Prices in UK (INR)
I. ANTI-INFECTIVES							
1	Ciprofloxacin – HCL 500 mg tabs	10's	29.00	423.86	393.00	2352.35	1185.70
2	Norfloxacin 400 mg tabs	10's	20.70	168.71	130.63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

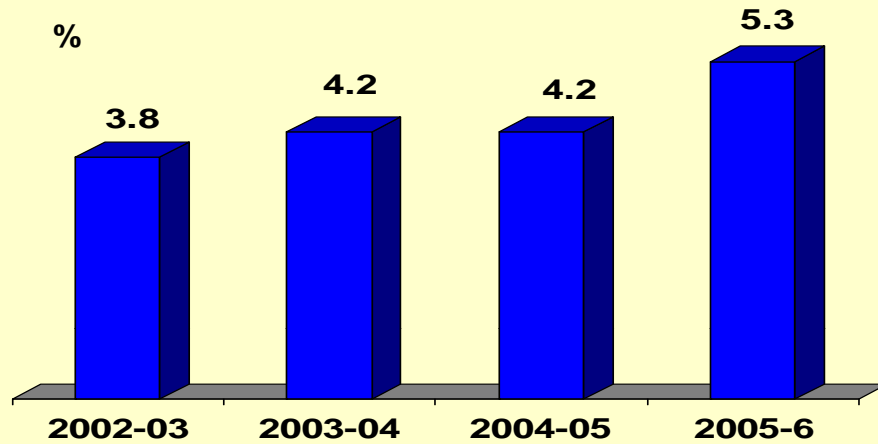
... AND REAL PRICES HAVE FURTHER DECLINED YEAR ON YEAR



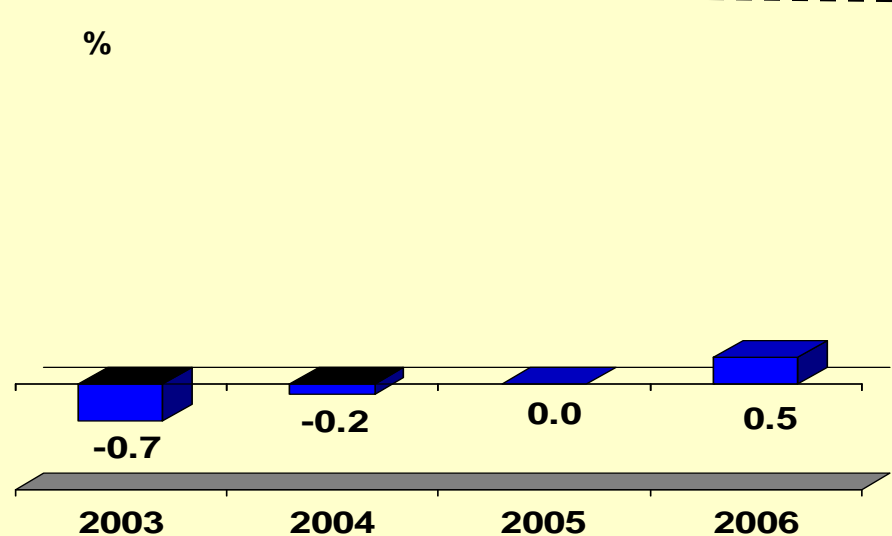
- Nearly 5% price decline in each year in real terms over last 5 years
- Prices of 539 formulations reduced over the last 2-3 years

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

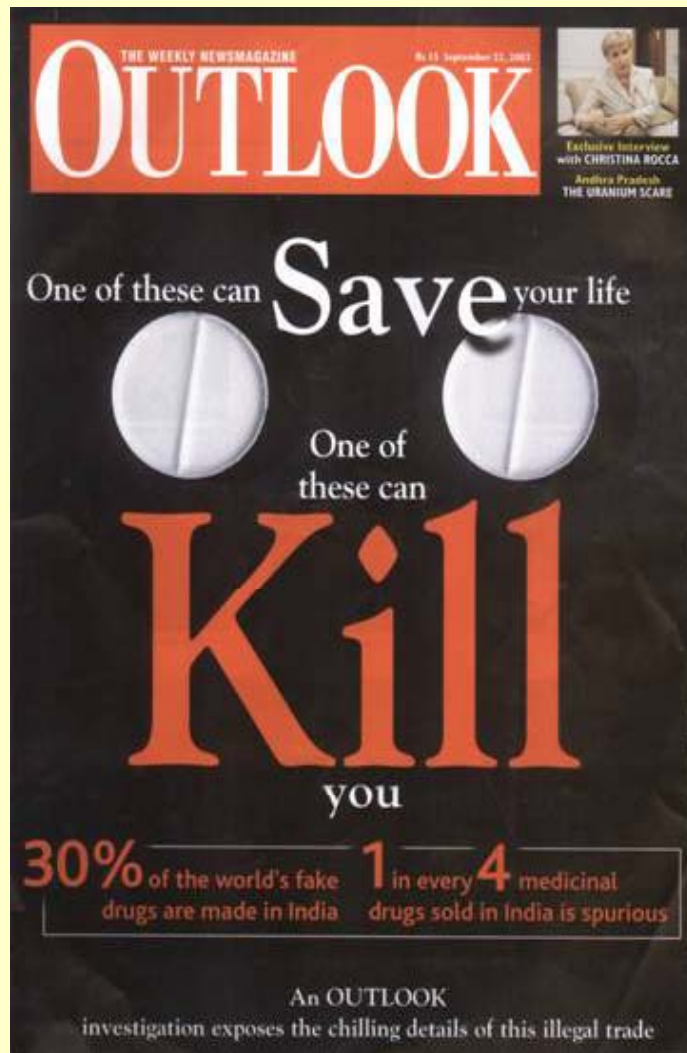
REVERSAL OF POSITIVE TREND

- The positive trend of phase-wise decontrol is now being reversed and 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 8 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 MENACE



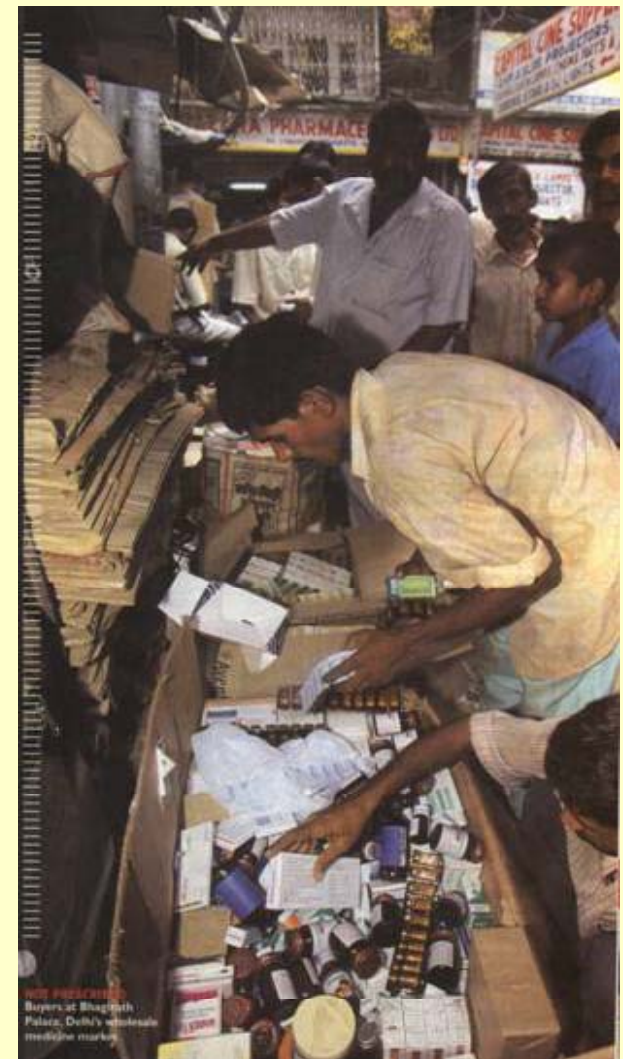
Making or selling spurious drugs is not a criminal offence in India

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-virals, 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**

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**

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





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.	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

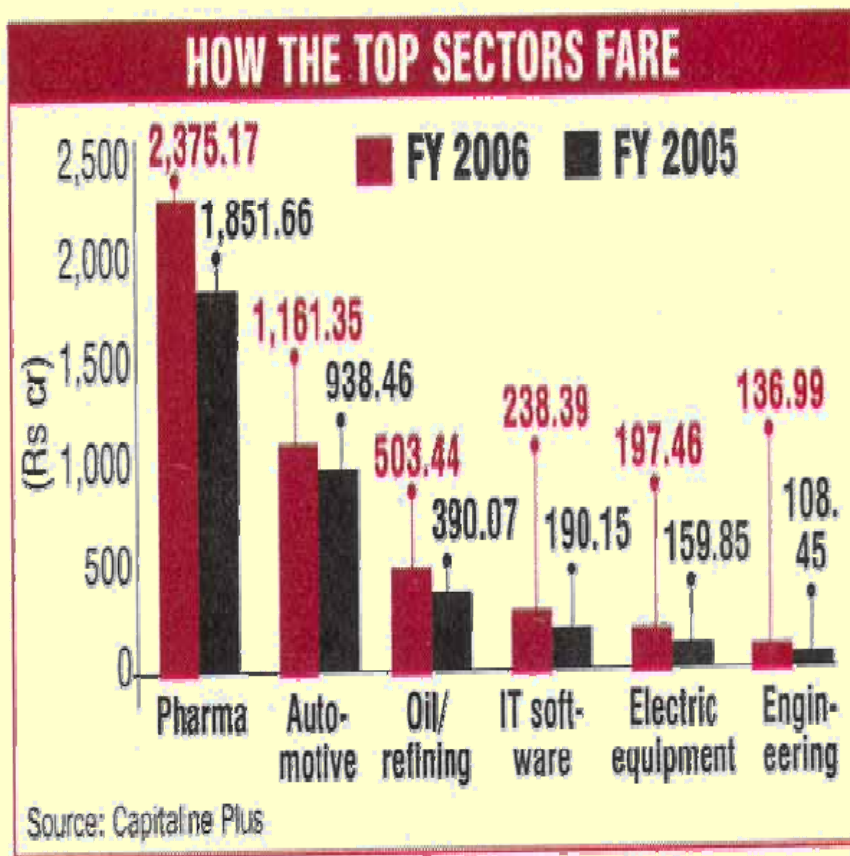
R&D DEDICATED TO DISEASES OF DEVELOPING WORLD

- ASTRAZENECA – Bangalore Research Institute
- LILLY – not-for-profit Public Private Partnership for T.B. in Seattle
- NOVARTIS – Institute for Tropical Diseases, Singapore
- GSK – Diseases of the Developing World, Discovery Centre, Tres Cantos (Spain)

DEVELOPING NEW DRUGS IS EXTREMELY RESOURCE INTENSIVE

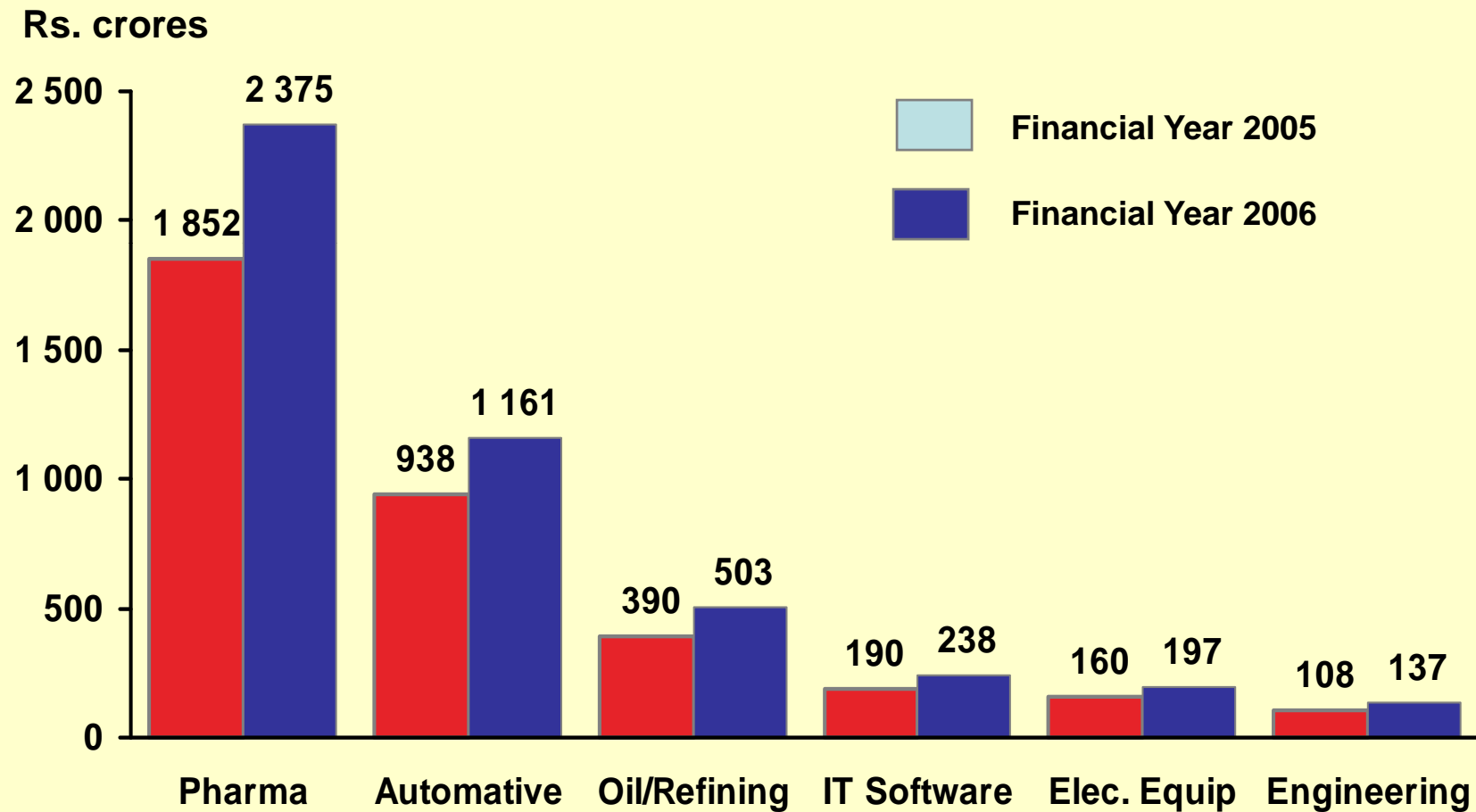
Pharma is already a large spender on R&D . . .

. . . But bringing a drug to market requires massive resources



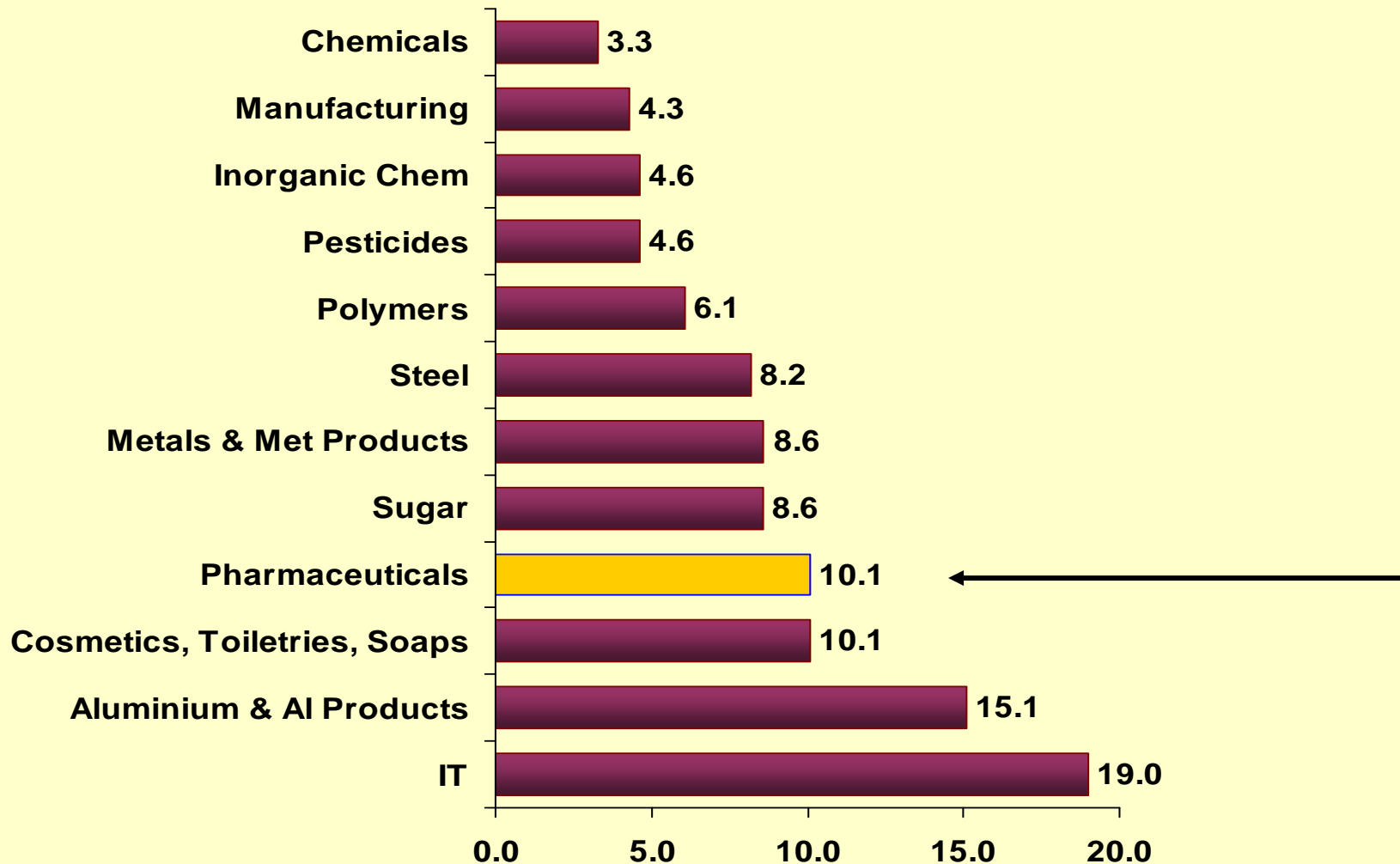
- It costs over USD 800 mn on average to take a new drug to the market
- 5 of every 5,000 compounds are tested on humans
- One out of every 5 drugs that enters trials makes it to the market
- It takes an average of 12 years for a new drug to reach the market

PHARMA IS THE LARGEST SPENDER ON R&D



Source: Capitaline Plus

...BUT MEDIAN IN PROFITABILITY COMPARED TO OTHER INDUSTRIES



Pharmaceuticals is comparable to many other industries except IT

MNCs FOCUS ON DEVELOPING COUNTRIES DISEASES

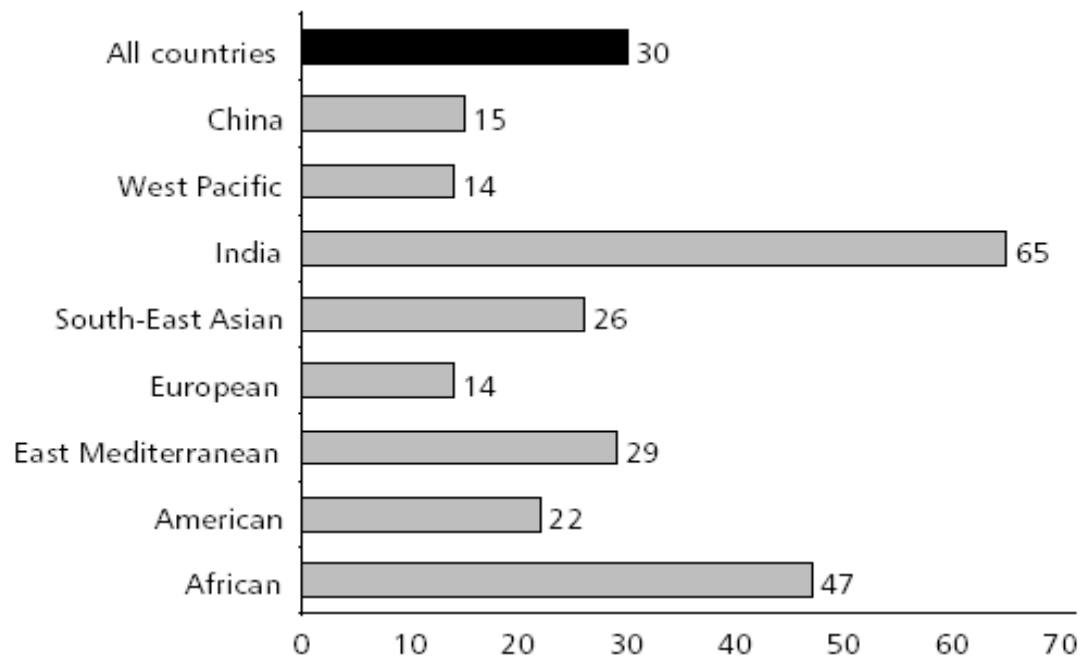
Disease	Companies
TUBERCULOSIS	AstraZeneca, Bayer, GSK, Lupin, J&J, Novartis, Otsuka, Pfizer, Sanofi-Aventis, Crucell
MALARIA	BMS, GSK, Novartis, Pfizer, Ranbaxy, Sanofi-Aventis, Sigma Tau, Crucell
SLEEPING SICKNESS (African Trypanosomiasis)	Bayer, Sanofi Aventis
SHISTOSOMIASIS	Pfizer
KALA AZAR (Leishmaniasis)	Zentaris, GSK
DENGUE	Novartis, GSK, Sanofi Aventis
RIVER BLINDESS (Onchoceriasis)	Wyeth

IMPLEMENT TRIPS COMPLIANT IPR

- Encourage FDI, Technology Transfer
- Stimulate R & D
- Allow Incremental Innovation
- Provide Data Exclusivity
- Drop Pre-grant Opposition

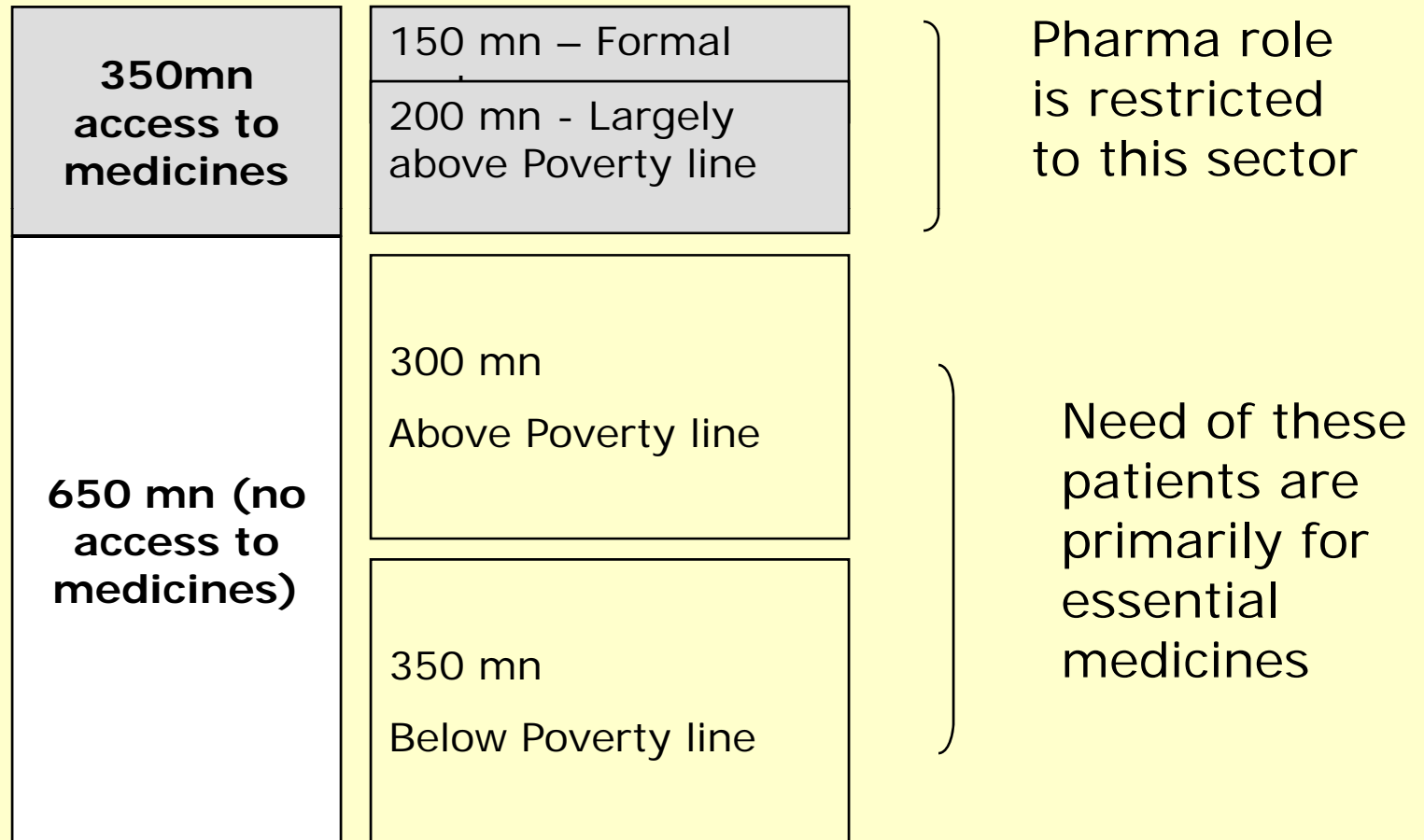
ACCESS TO ALL MEDICINES PROVES TO BE A CHALLENGE

Percentage of WHO regions lacking access to essential medicines



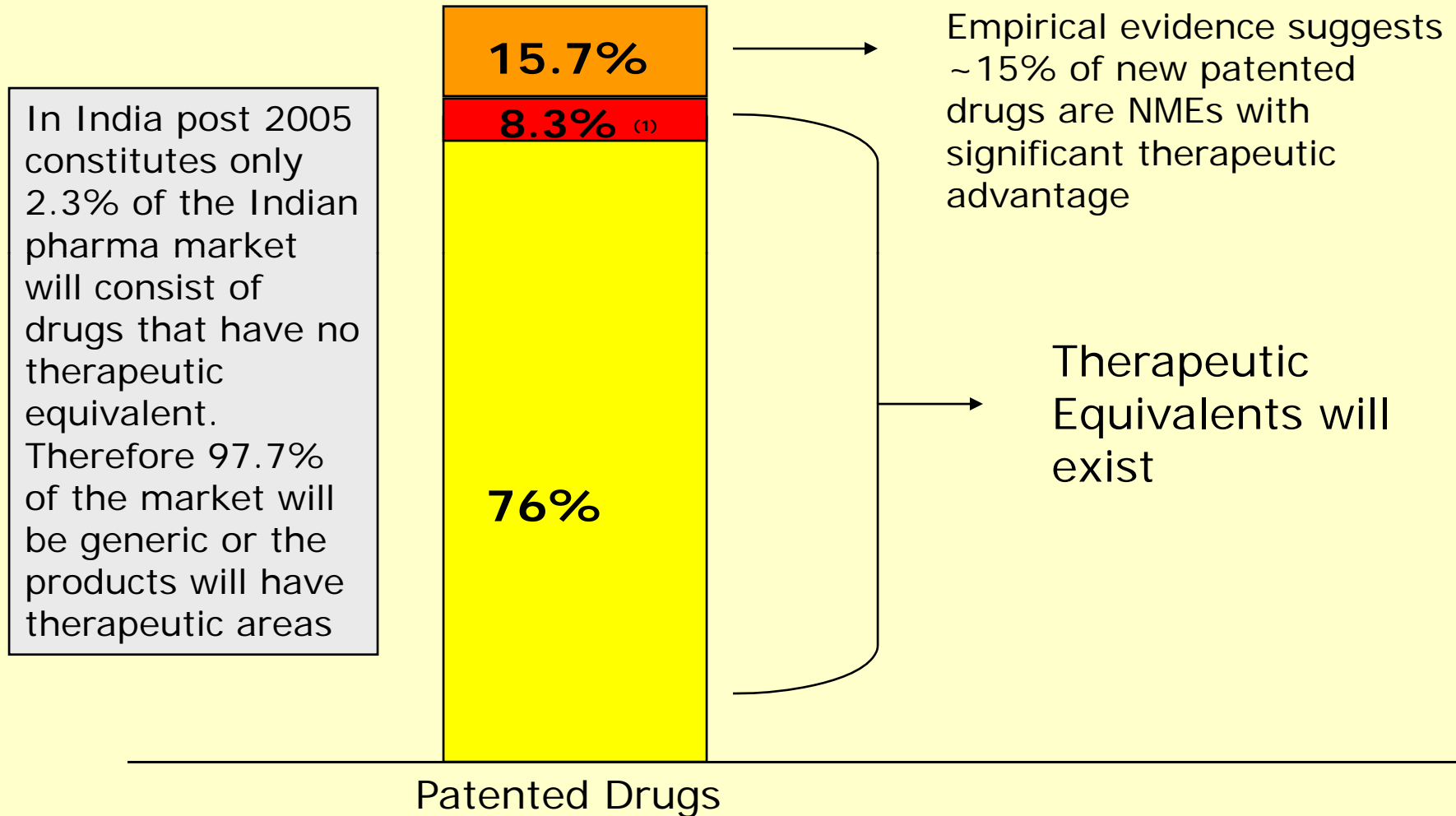
- Therefore this exercise can at best address issues within 35% of the Indian population that can access medicines
- This 350 mn. people are largely clustered around urban centres where health care facilities exist

ACCESS TO PATENTED MEDICINES



Formal Sector: Those employed with the public or private sector

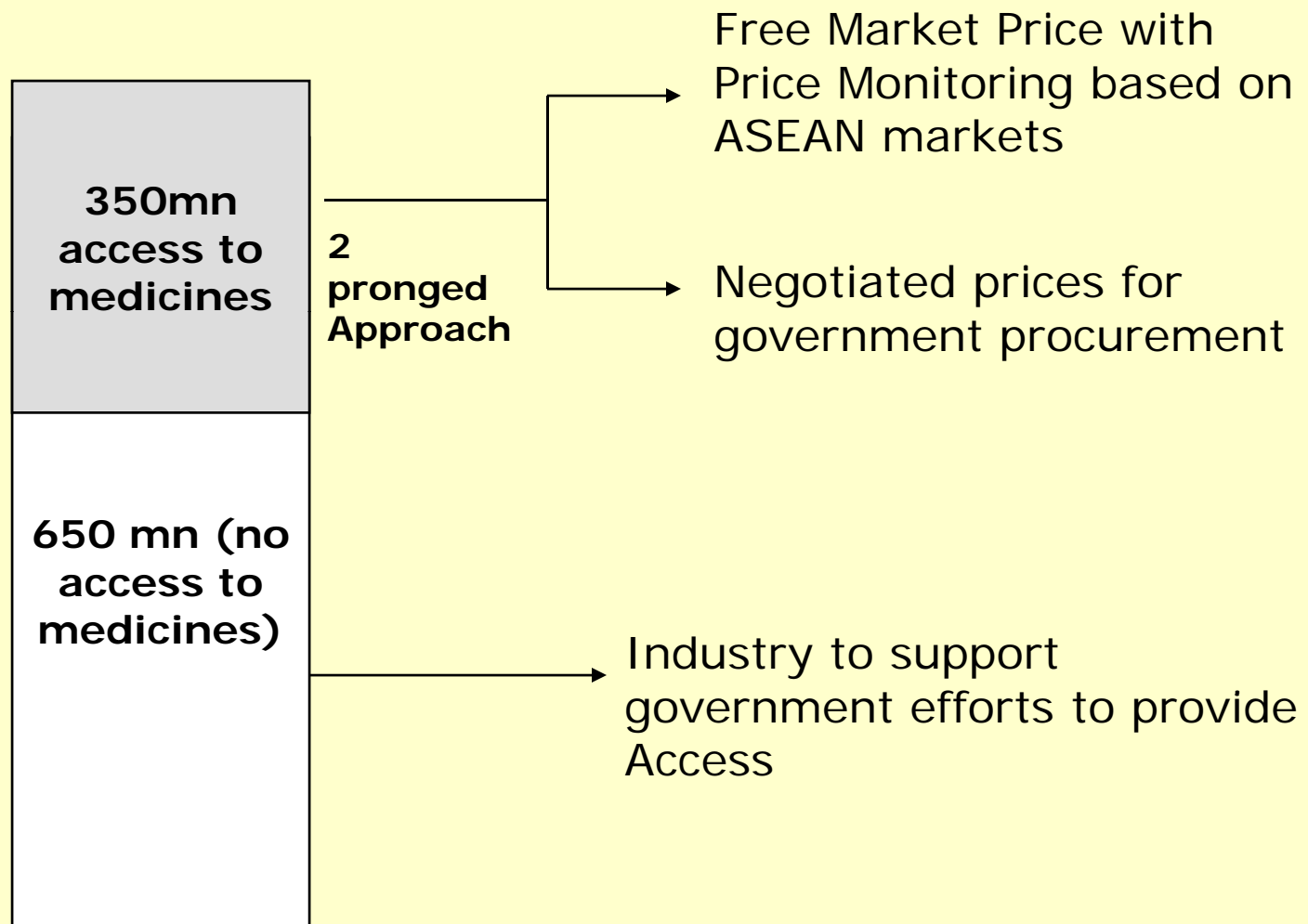
~85% OF ALL PATENTED MEDICINES WILL HAVE A THERAPEUTIC EQUIVALENT



(1) Includes new salt, new formulations, new combinations, new manufacturer or patents for new indications

Source: Lu and Comanor (1998), OPPI, FDA, BCG Analysis

ENSURING ACCESS IN PRICE MONITORING REGIME



GOVERNMENT / INDUSTRY ARE PARTNERS

- Provide medicine at affordable prices
- Supports Government objective to ensure prices do not increase unreasonably
- Instead of cost-based price control recommends price monitoring

HEALTH INSURANCE

- 80% in India pay from their pocket
- Expand Health Insurance
 - Rashtriya Swasthya Bima Yojana for BPL
 - Yashaswini Scheme of Government of Karnataka
 - Arogya Raksha Yojana for rural families
- Policies for specific diseases

STRENGTHENING OF DRUG REGULATORY SYSTEM

OPPI supports formation of
Central Drugs Authority of India

RESPONSIBLE SELF MEDICATION

- Move certain molecules out of Schedule H so that they can be sold OTC
- Remove population restriction in Schedule K

INDIA IS EMERGING AS A PREFERRED DESTINATION FOR LIFE SCIENCES, BUT CHINA IS A THREAT

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

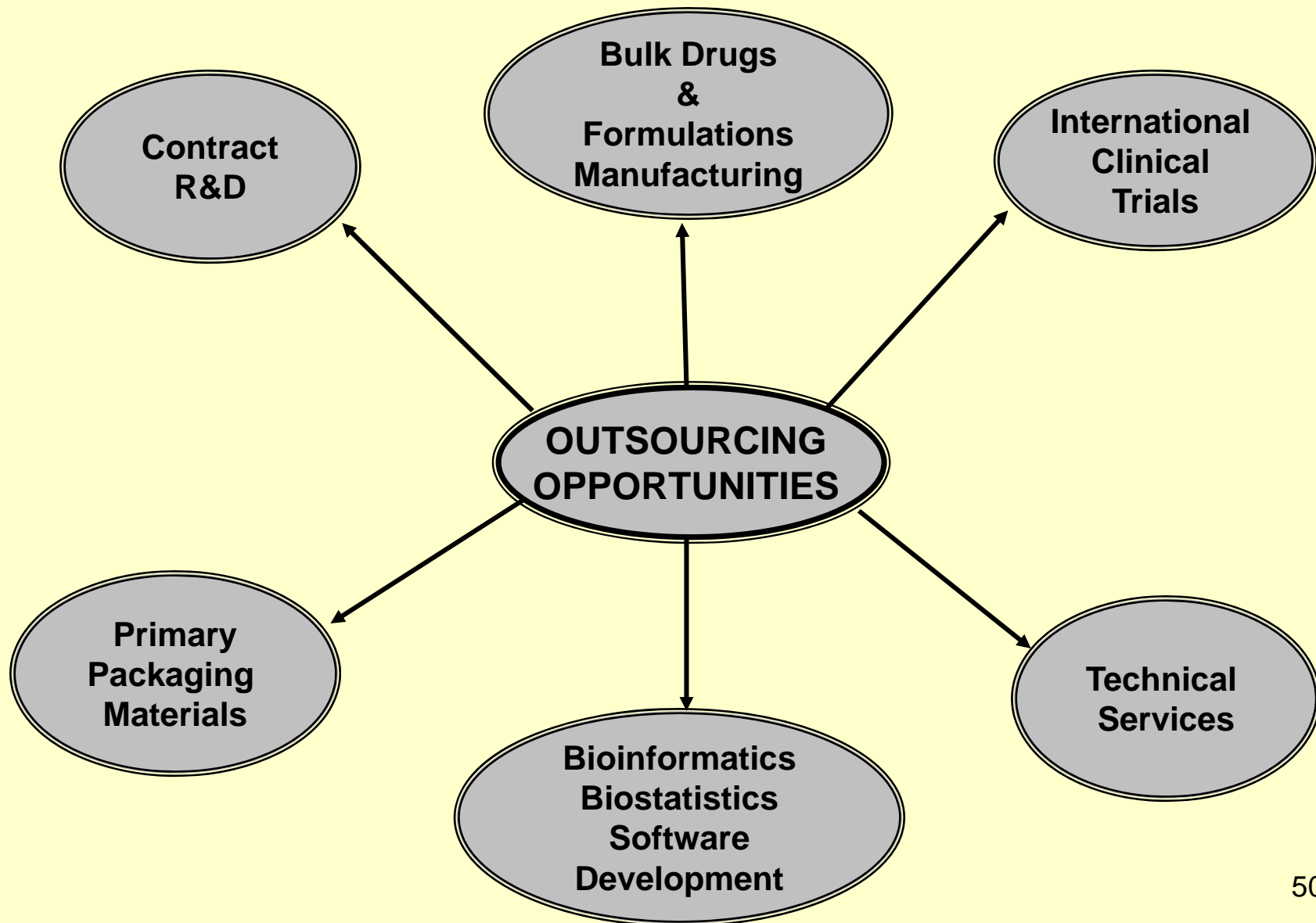
ADVANTAGE INDIA

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

ADVANTAGE INDIA

- World class entrepreneurial skills
- Cost effectiveness (Intellectual Capital per Dollar)
- Well developed ancilliary industry
- Highest no. of U.S. FDA approved manufacturing facilities outside U.S.A.
- Demographic dividend

OUTSOURCING OPPORTUNITIES



AFFORDABLE HEALTHCARE FOR ALL

- Expand Health Insurance
- Reduce transaction costs (duties, taxes, trade margin, etc.)
- Focus on prevention: immunisation, vaccination, sanitation, hygiene, clean drinking water, nutrition, etc.
- Public Private Partnership for Anti-cancer & HIV/AIDS Drugs
- Responsible Self Medication (OTC)
- Increase healthcare budget from 0.9% of GDP to 5% to 7%

CONTRIBUTIONS MADE BY OPPI

- Product Patent
- Schedule M
- Schedule Y
- R&D Incentives
- CSR
- OPPI Code of Pharmaceutical Marketing Practices 2007

INDIAN PHARMA INDUSTRY

An Emerging Trailblazer with
Government providing an
Enabling Environment