

INDIAN PHARMACEUTICAL MARKET IN A NEW PARADIGM

- Win some and... Win some more...

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DHL 10th Life Science & Healthcare Conference & Workshop
21st- 23rd Sept 2010
Dubai

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- ❖ India Today
- ❖ Healthcare Environment
- ❖ Policy and Regulatory Framework
- ❖ Changing Growth Fundamentals
- ❖ Business Outsourcing Opportunities
- ❖ Rising Confidence
- ❖ Advantage India



Temptation of the West

“If you don’t know INDIA, you don’t know the WORLD”

- Andre Malraux

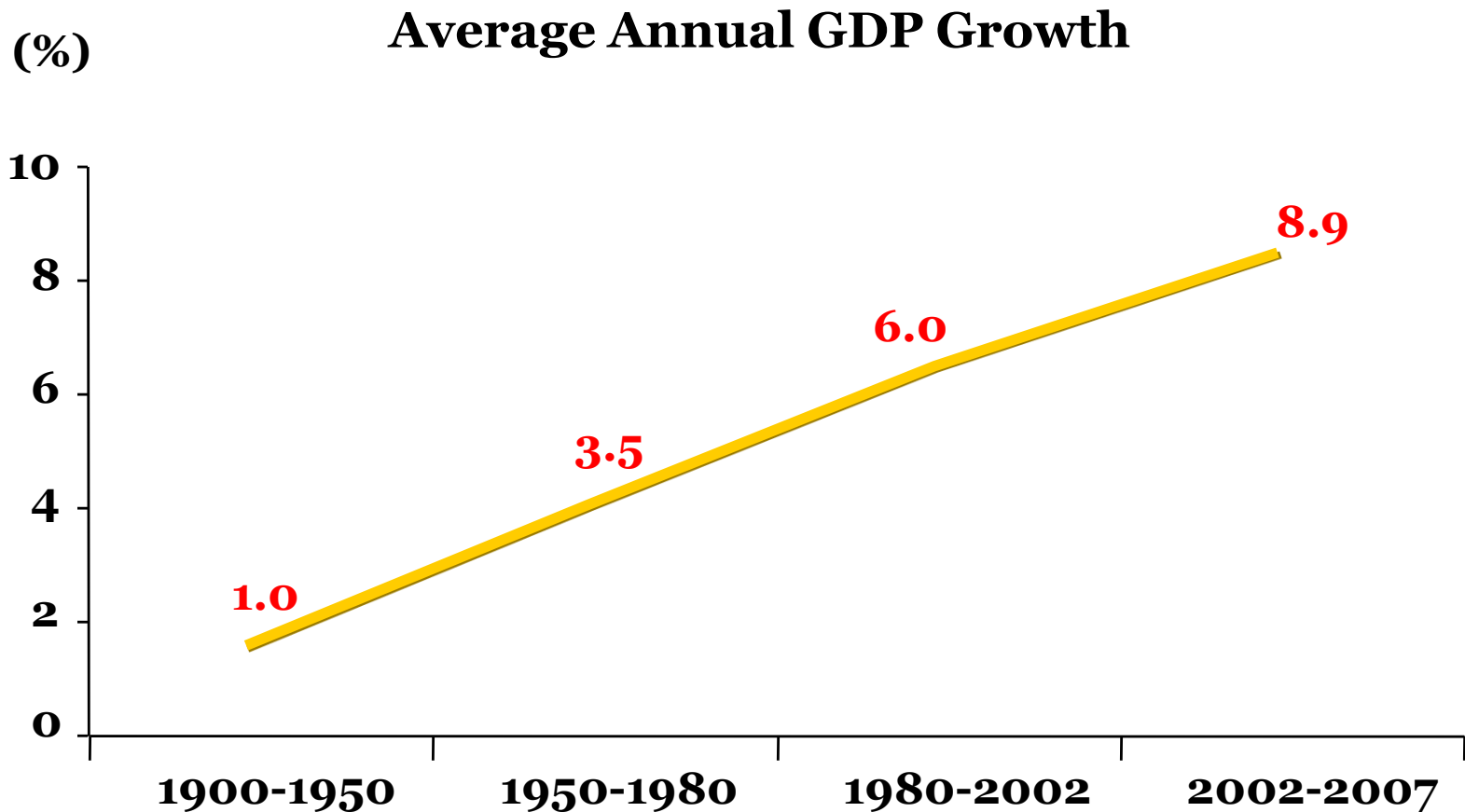


India Today



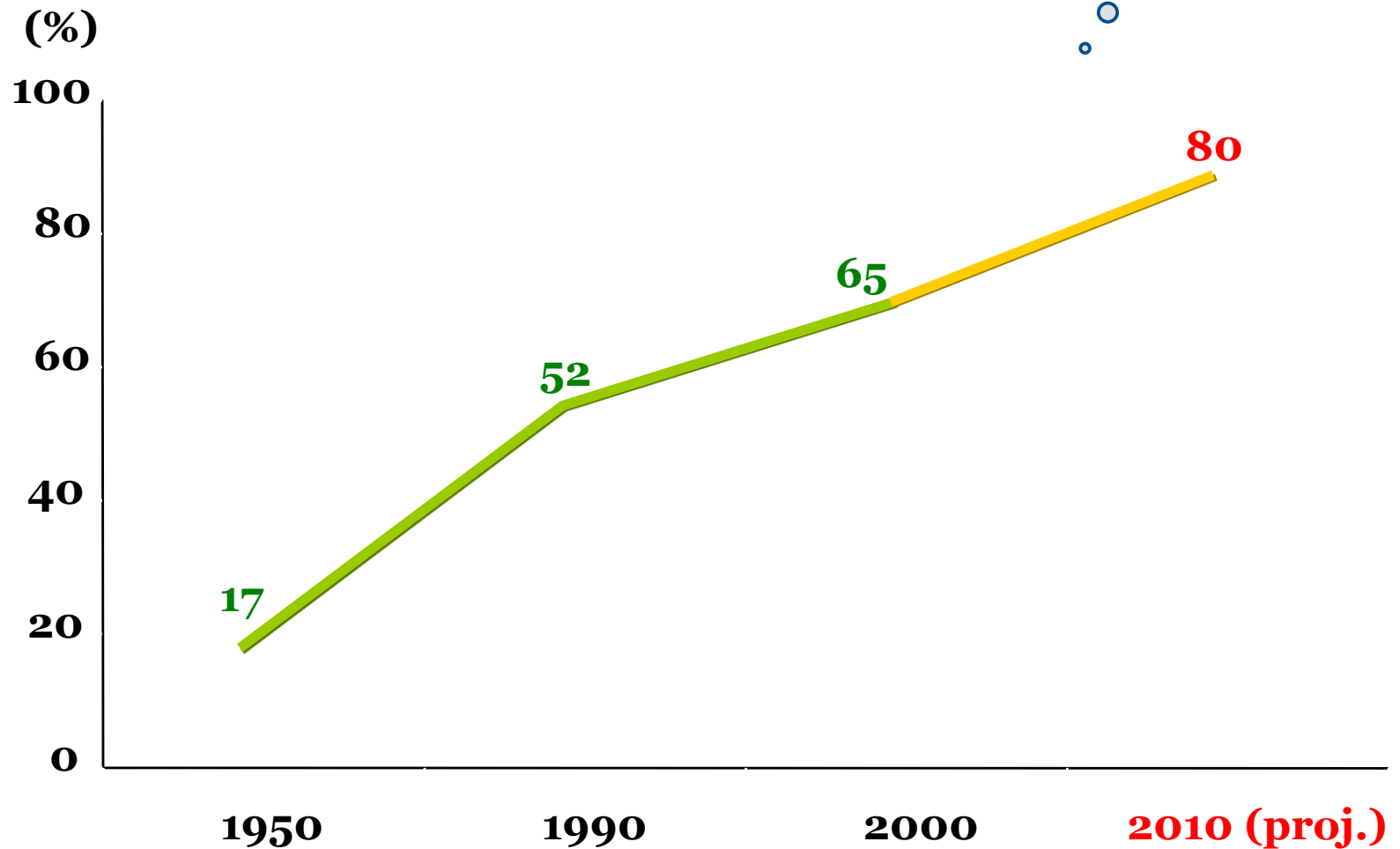
28 Years of High Growth

India is the 4th
Largest
economy



Literacy is Rising

India is the 4th
Largest economy

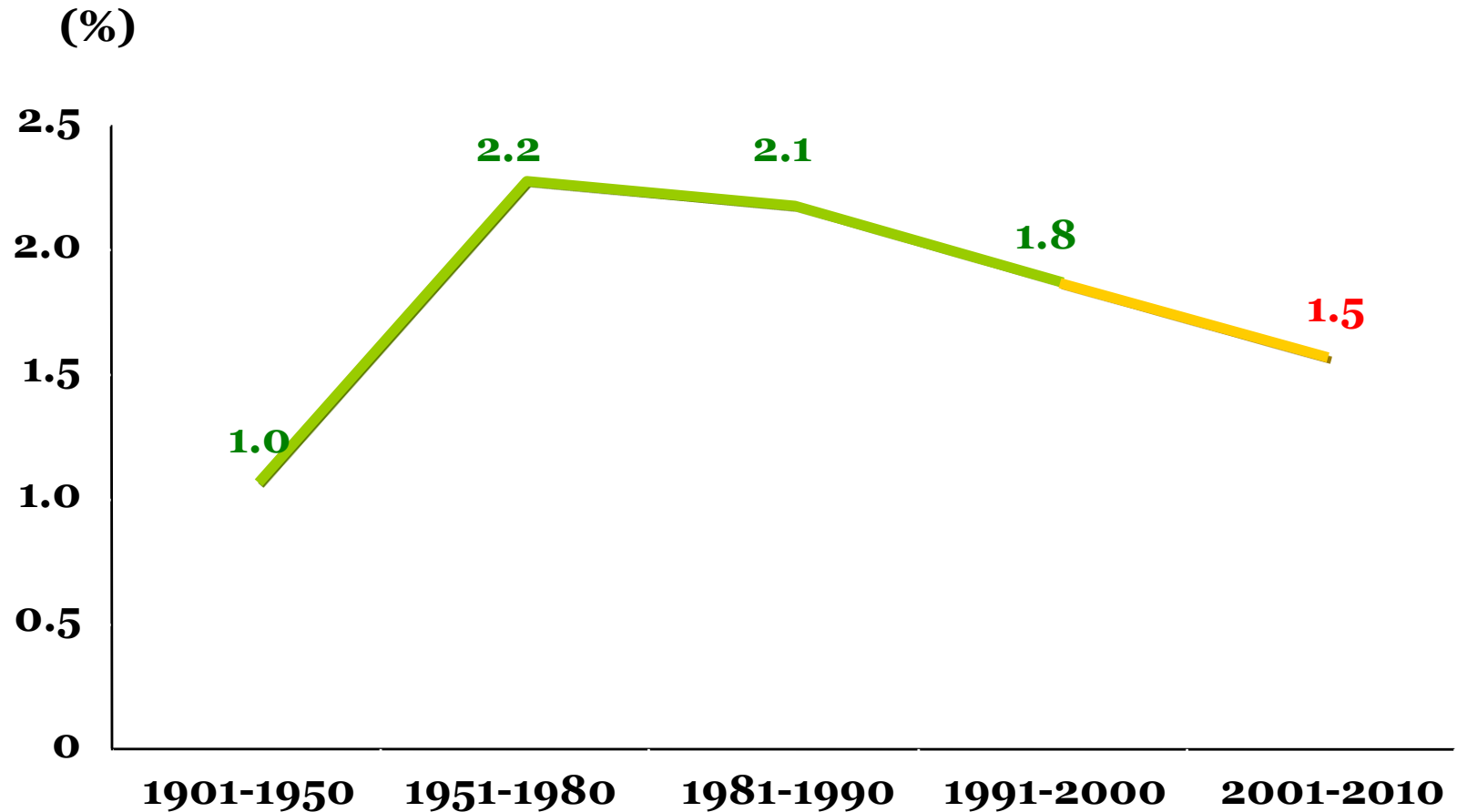


Source: Census of India (2001)



Population Growth is Slowing Down

India is the 2nd Largest population

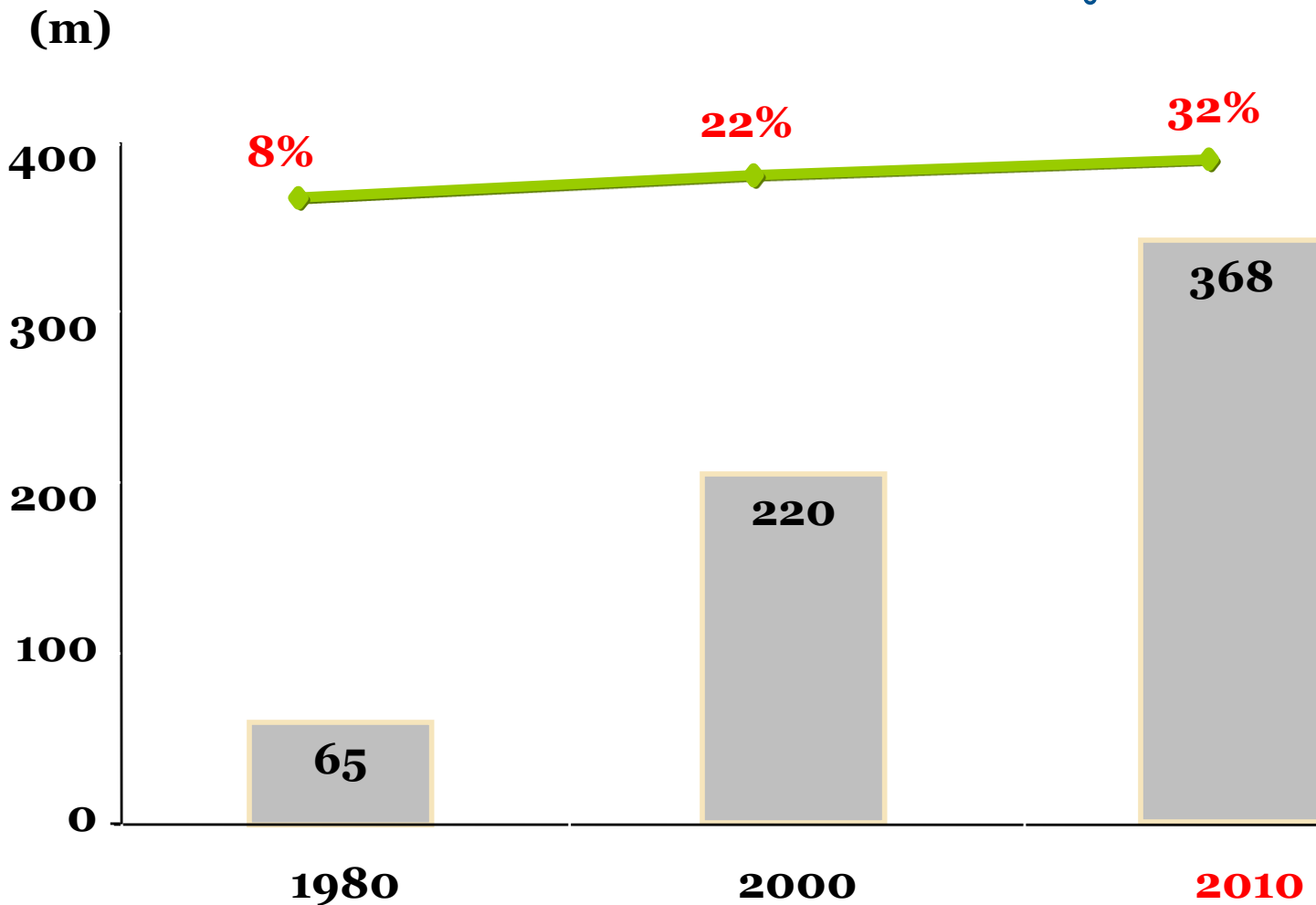


Sources: Monitoring the World Economy, 1990-2000; Census of India (2001)



Growing Middle Class Population

India is the
Largest
consumer base



Source: The Consuming Class, National Council of Applied Economic Research, 2002

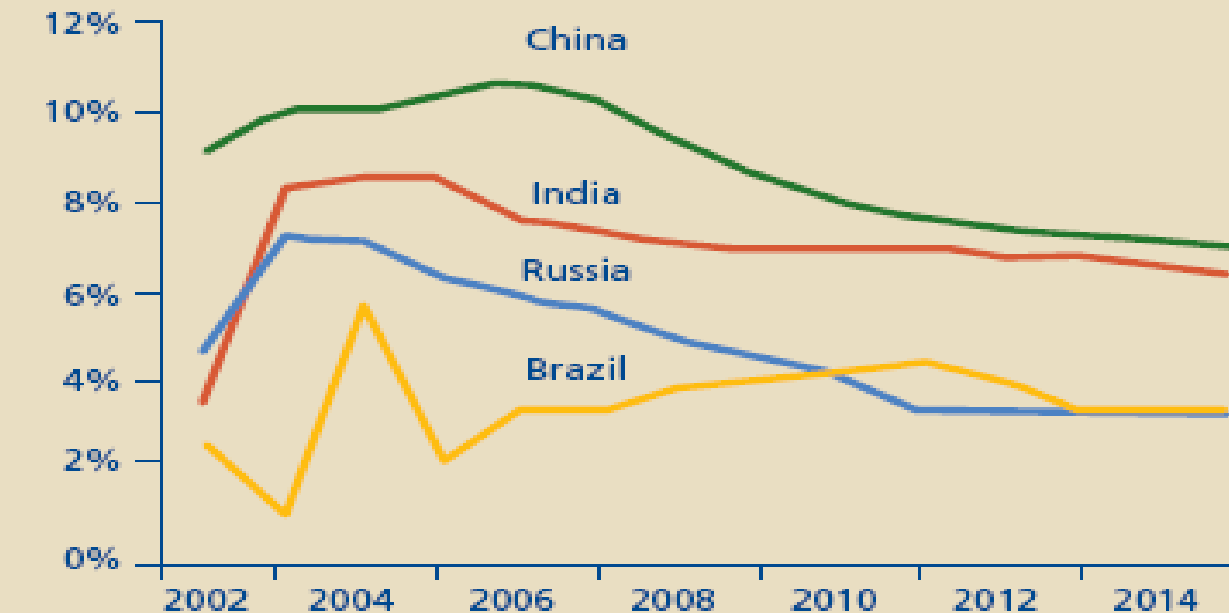


India's GDP Growth

India
will overtake
Japan by 2014

Emerging Market GDP Growth

Real GDP growth



Source: EIU Reports and FAPRI data.

Deloitte : Pharmaceutical Market Entry in India

India growing by 6% + despite the current global recession

Indian growth story is still intact



Key Reforms

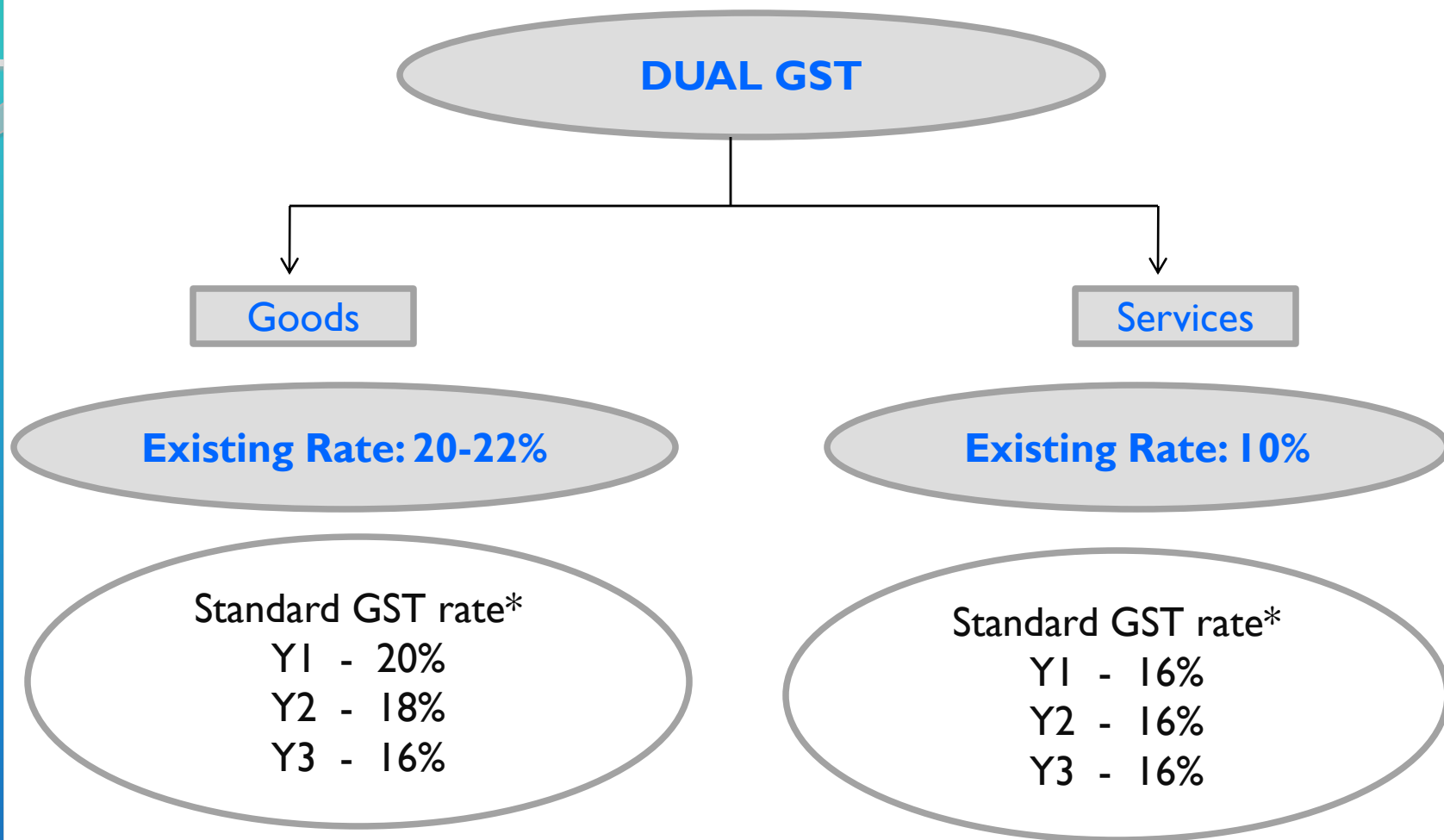
India
will overtake
Japan by 2014

- ❖ Globalization of economy
- ❖ Dismantling 'license' regime
- ❖ Lowering tariffs / taxes
- ❖ Breaking public sector monopolies
- ❖ Indigenous R&D
- ❖ New IPR Regime
- ❖ Goods and Services Tax (GST)*
- ❖ Direct Tax Code (DTC)*

* Yet to be implemented



Proposed DUAL GST Model



* Proposed by the Central Finance Minister on 21st July 2010, yet to be agreed by the States



Proposed Rate Structure

Goods / Services	Levy	Rate in 1 st Year	Rate in 2 nd Year	Rate in 3 rd Year
Goods – Lower Rate	CGST	6%	6%	8%
	SGST	6%	6%	8%
Goods – Standard Rate	CGST	10%	9%	8%
	SGST	10%	9%	8%
Services	CGST	8%	8%	8%
	SGST	8%	8%	8%

* Based on Finance Minister Speech



Taxes in DUAL GST

DUAL GST

Central Taxes -----> CGST

- Central Excise
- Additional Duty of Customs
- Service Tax

Sales Tax -----> SGST

- VAT
- Purchase Tax
- Entertainment Tax
- Luxury Tax
- Lottery Taxes
- State Cesses and Surcharges
- Entry Tax not in lieu of Octroi

CST will be phased out



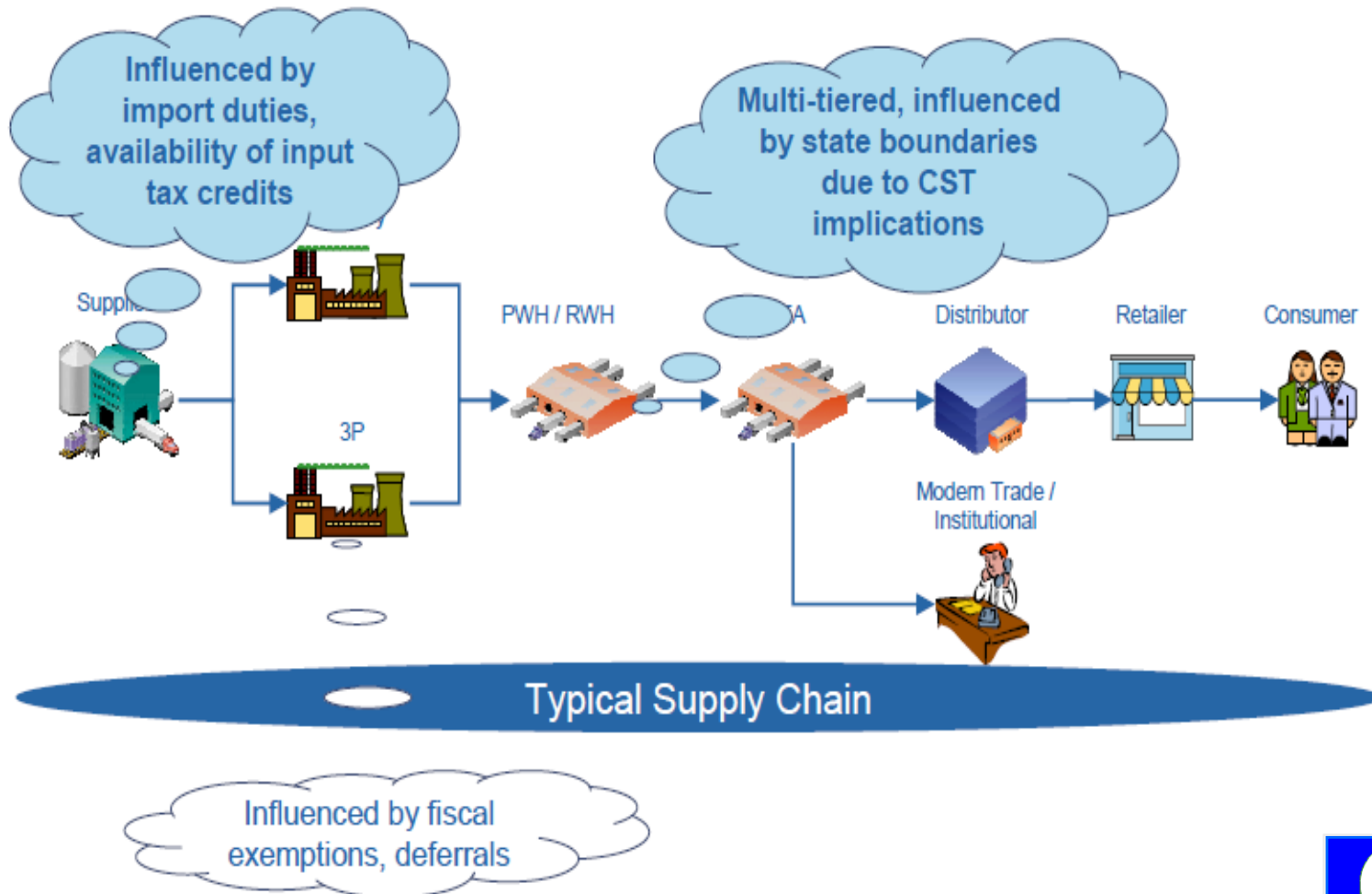
Phasing out of CST

- ❖ Central Sales Tax ('CST') presently levied on interstate sales of goods
- ❖ Present CST rate is 2 percent
- ❖ Input tax credit of CST not available; so this 2 percent is added to cost of procurement
- ❖ Under GST, CST to be replaced by Integrated GST ('IGST')
- ❖ IGST to be applicable on all interstate supplies of goods and services, including stock transfers
- ❖ Central Government to levy IGST, which would be aggregate of CGST and SGST rates
- ❖ Full credit of IGST to be made available



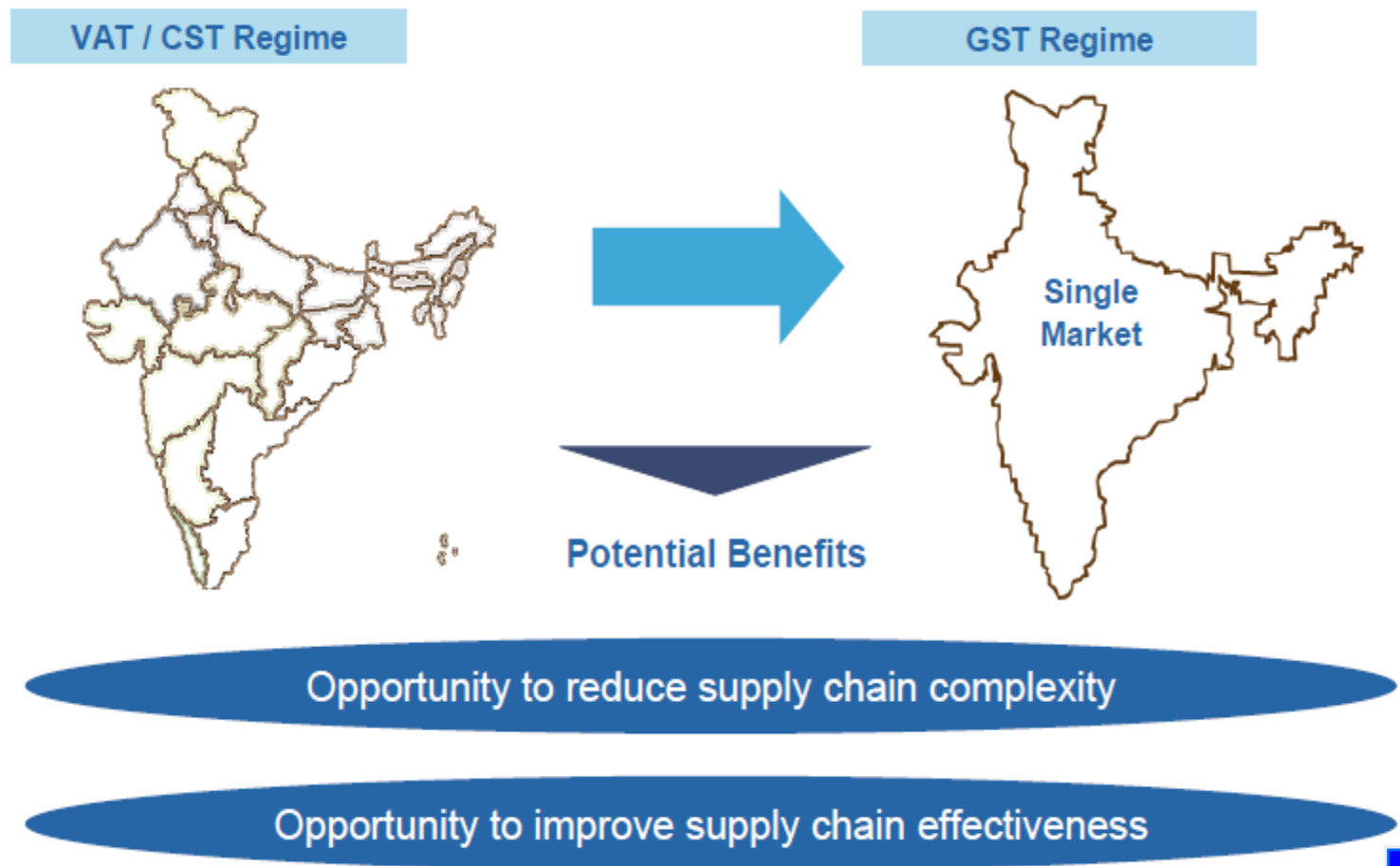
Current Supply Chain Paradigm

Fiscal costs have remained a key determinant of supply chains in India with supplier locations, manufacturing bases and distribution networks engineered to harness fiscal benefits...



Current Supply Chain Paradigm

The proposed introduction of GST, with its intent of creating a unified market from a material flow perspective, is expected to significantly influence supply chain models and networks in India...



Business Impact of GST

Changes in effective tax rates for supplies as well as purchases

Transactions/ Supplies which are currently exempt from tax may become liable to GST and vice-versa

Input taxes which are currently a cost may be eligible as 'credit' in future

Current special tax computation schemes, valuation provisions may be amended/ withdrawn

Supply chain: Tax cost on sourcing/ distribution/ logistics

Finance: Impact on cash flows, project costs

Pricing: Impact on product price, discounts

IT: Invoicing, returns, MIS reports



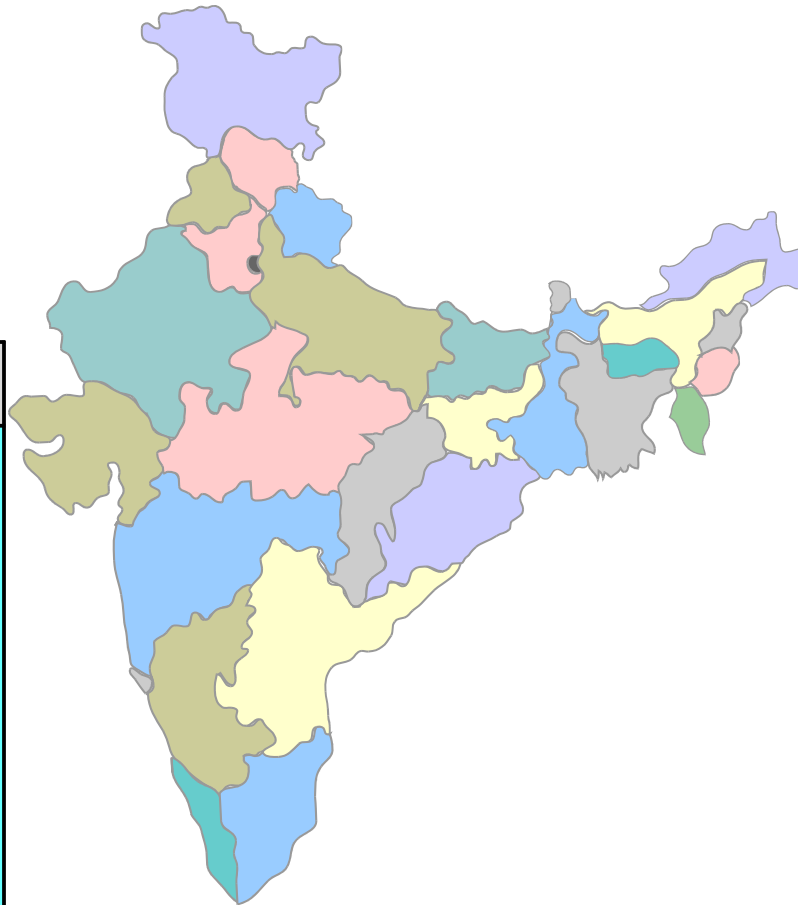
Healthcare Environment and Pharmaceutical Industry



India is Changing Fast setting the pace for growth and stability...

YESTERDAY

- Slow rate of growth
- Bureaucratic
- Protected
- Small markets
- Under-developed infrastructure
- No Product Patent

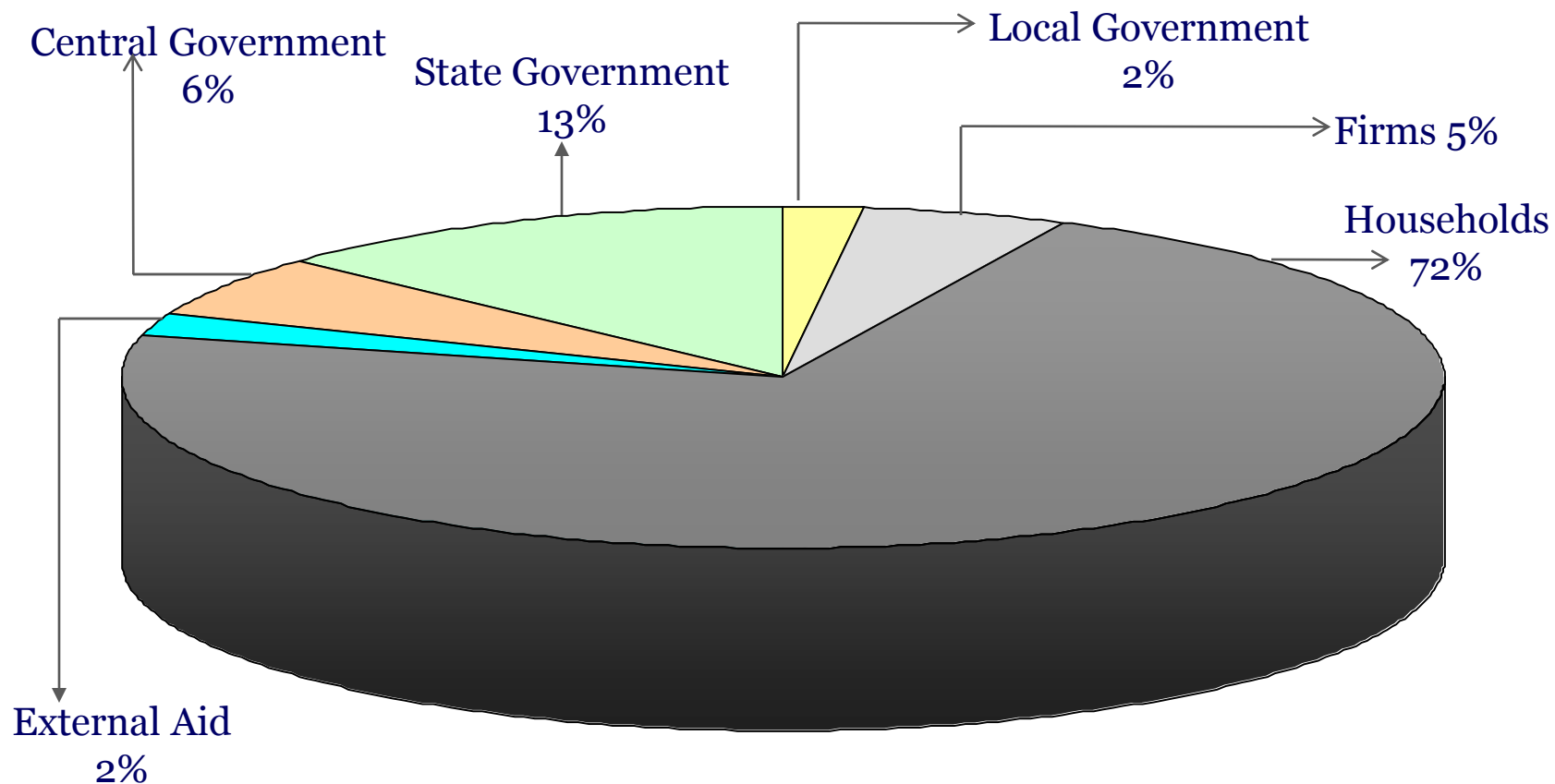


TODAY

- One of the fastest growing world economies
- Less impacted by financial meltdown
- Significant outsourcing opportunities
- Fast growing markets
- Significant investment in infrastructure creation for industry
- Product patent regime / R&D



Proportion of Health Expenditure by Financing Source



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



Government : Changing Role

From Healthcare Provider to Healthcare Facilitator

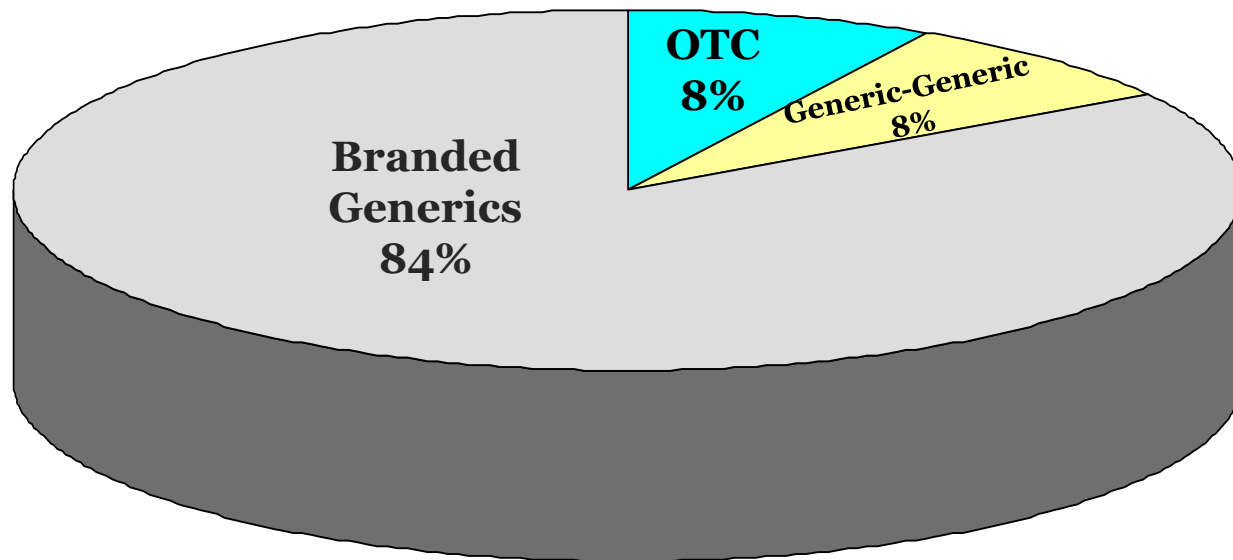
	2002	2012
Private Healthcare Spending (U.S.\$ Bn.)	14.8	33.6

Source: India Trade Promotion Organization (ITPO)



Key Market Types

Market Size US\$ 8.9 Bn.



Source : IMS Feb. 2010



Key Players

Leading Indian players by sales (US\$ million)

Company	Sales in US\$Mn.	Year end
Cipla	1,033.46	March 2009
Ranbaxy	951.03	December 2008
Dr Reddy's	866.44	March 2009
Sun Pharma	805.51	March 2009
Lupin	603.99	March 2009
Aurobindo	582.27	March 2009
Piramal	483.10	March 2009
Cadila	354.02	March 2009
Matrix	310.06	March 2009
Wockhardt	309.68	December 2009

Leading foreign players by sales (US\$ million)

Company	Sales in US\$Mn.	Year end
GSK Pharma	346.94	December 2008
Aventis Pharma	207.37	December 2008
Abbott India	158.53	November 2009
Pfizer	147.31	November 2009
Novartis India	125.11	March 2009
Merck	98.56	December 2009
Wyeth	79.64	March 2009
AstraZeneca	73.91	December 2008
Solvay Pharma	50.36	December 2009
Fulford India	38.61	December 2008

Sources: Company websites, annual reports

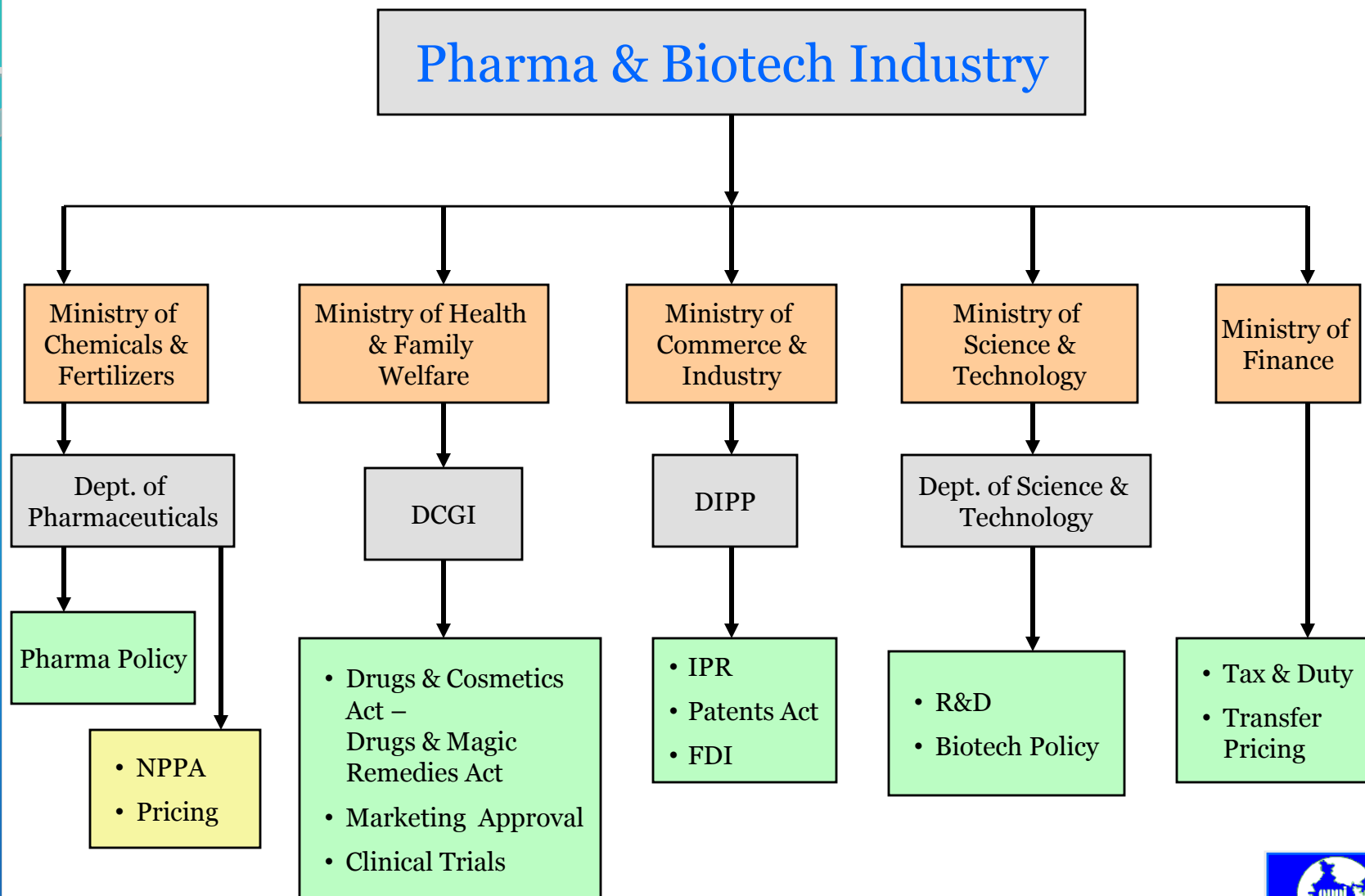
Note: All revenues were reported in INR.



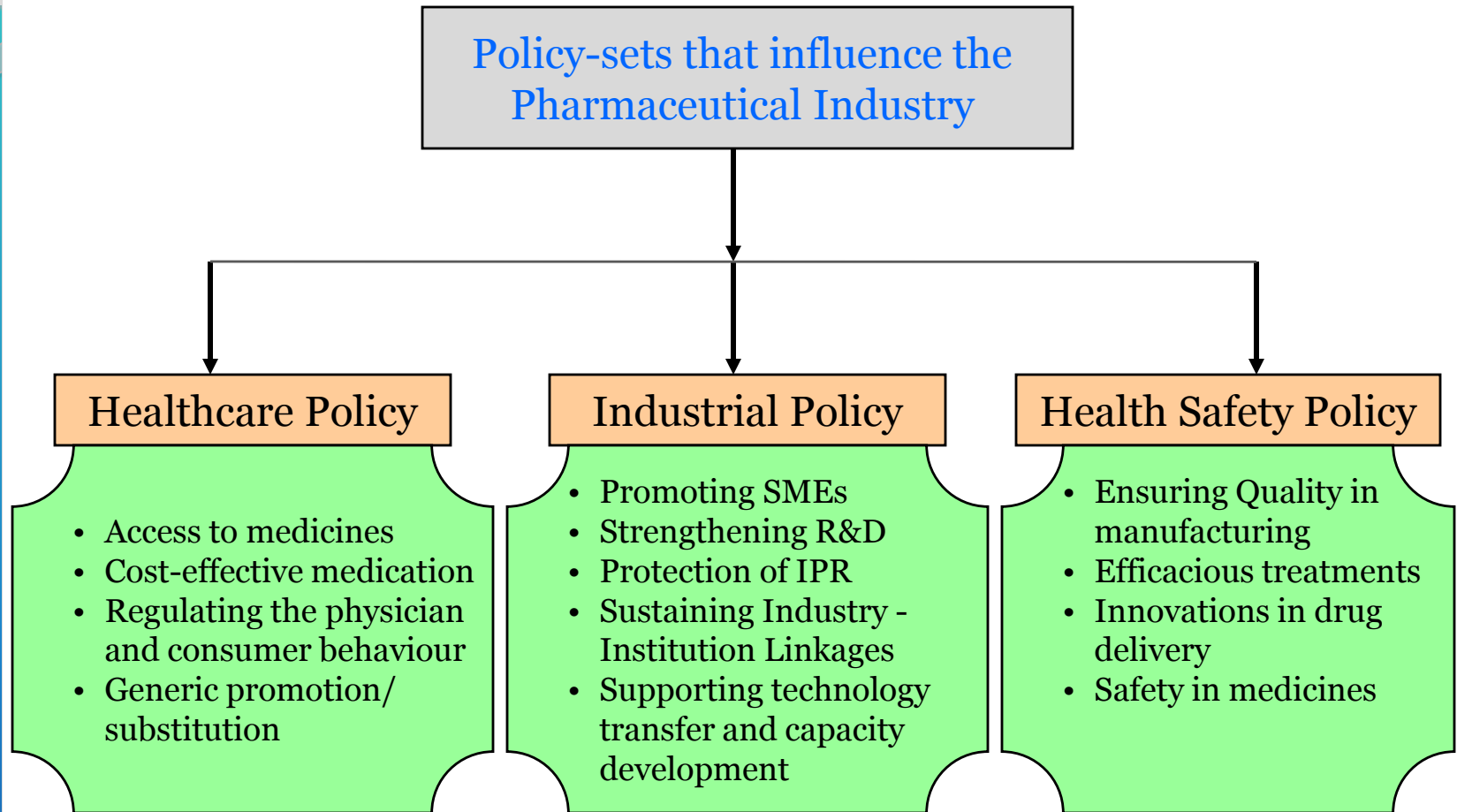
Policy and Regulatory Framework



Regulatory Structure



Policy Framework - Indian Pharmaceutical Industry



Changing Growth Fundamentals



Changing Growth Fundamentals

- ❖ Private sector healthcare driving access.
- ❖ Medical Tourism led to investment spurt in the private healthcare services.
- ❖ Accelerated investment from the private sector in healthcare facilities across tier-I and tier-II cities.
- ❖ Estimated one million beds would be added by 2010 taking the total beds available in the country to over two million.**



Changing Growth Fundamentals

- ❖ Estimated US\$ 69.7 Bn. to be invested by private sector in healthcare infrastructure by 2012
- ❖ Number of patients visiting Indian hospitals is expected to rise by 30 per cent to 22 Mn. by 2015
- ❖ High purchasing potential of the middle class to drive consumption of healthcare services, including pharmaceuticals
- ❖ Increasing Penetration of Medical Insurance

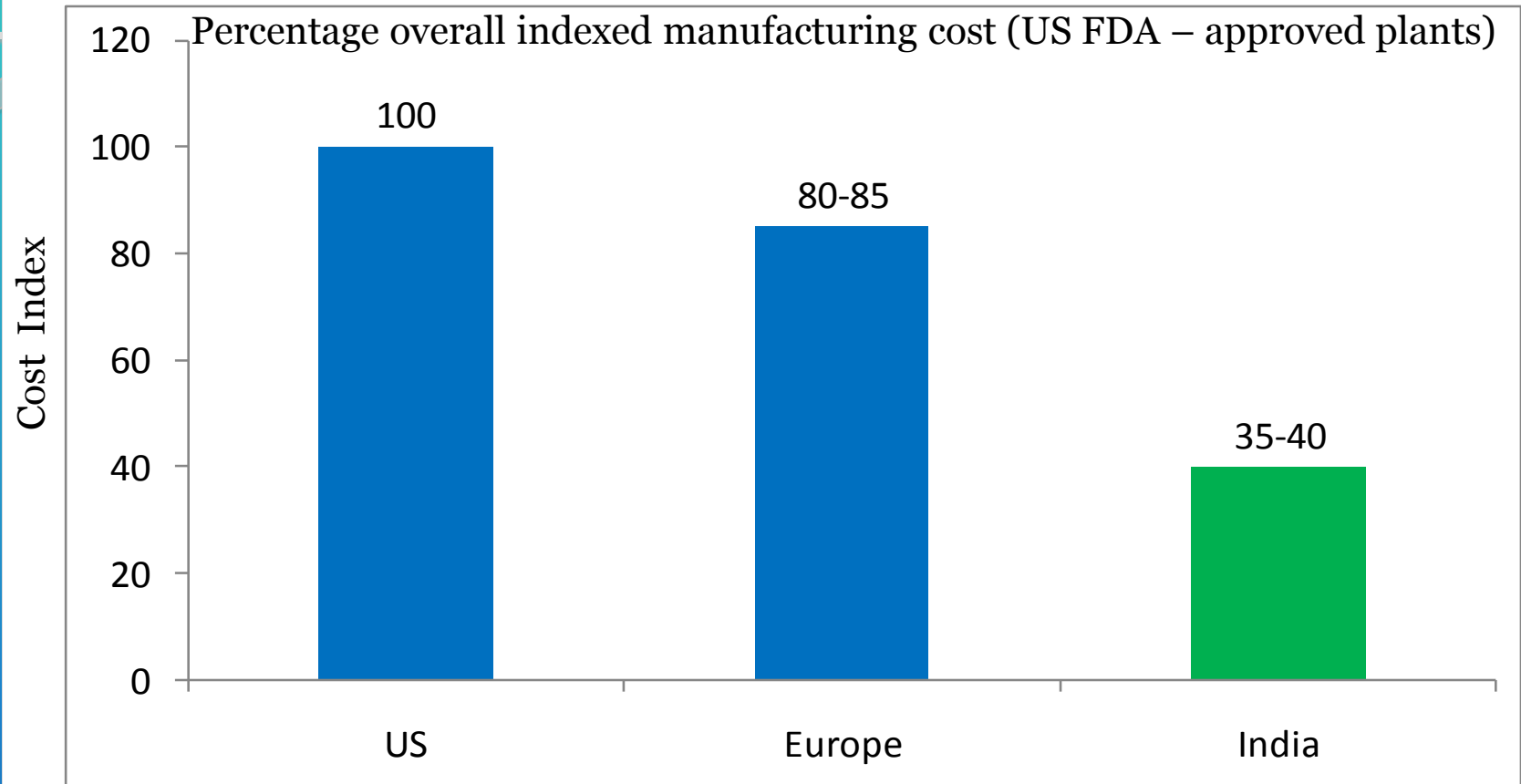


Key Growth Catalysts and Trends



Cost Arbitrage

India rates higher on cost efficiency as compared to other countries.

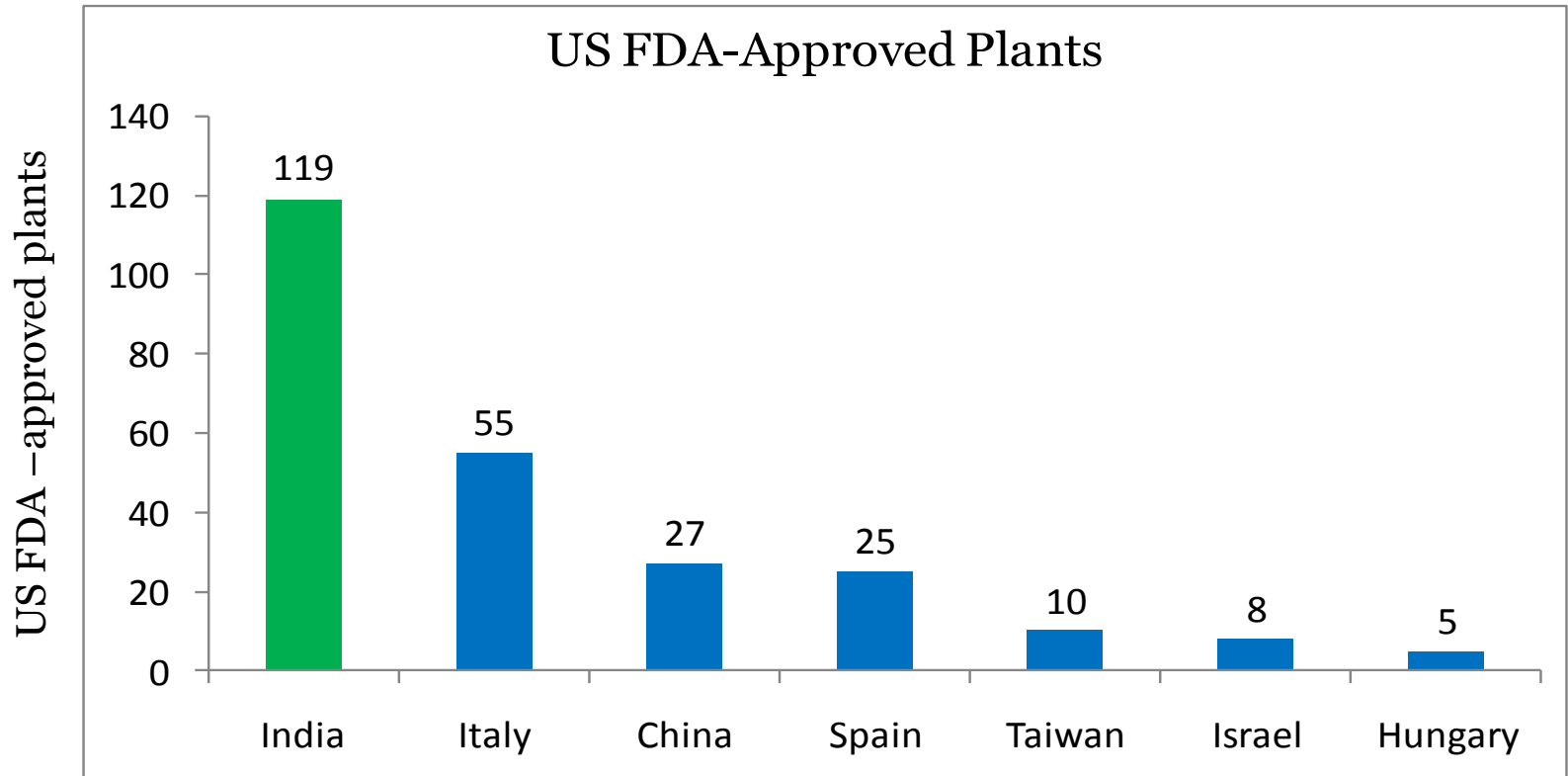


- Over 8,000 manufacturers drives down costs
- Costs of US FDA plants in India are 65 per cent lower than the US and 50 per cent lower than that in Europe.

Source: Taking Wings, OPPI - Ernst & Young 2009



Technical Capability



- ❖ 119 USFDA and 84 UK MHRA approved plants.
- ❖ Many plants approved by Canada, Australia, Germany and South Africa.
- ❖ These could also act as a platform for CRAM business.

Source: United Kingdom's Medicines and Healthcare products Regulatory Agency



Government Support

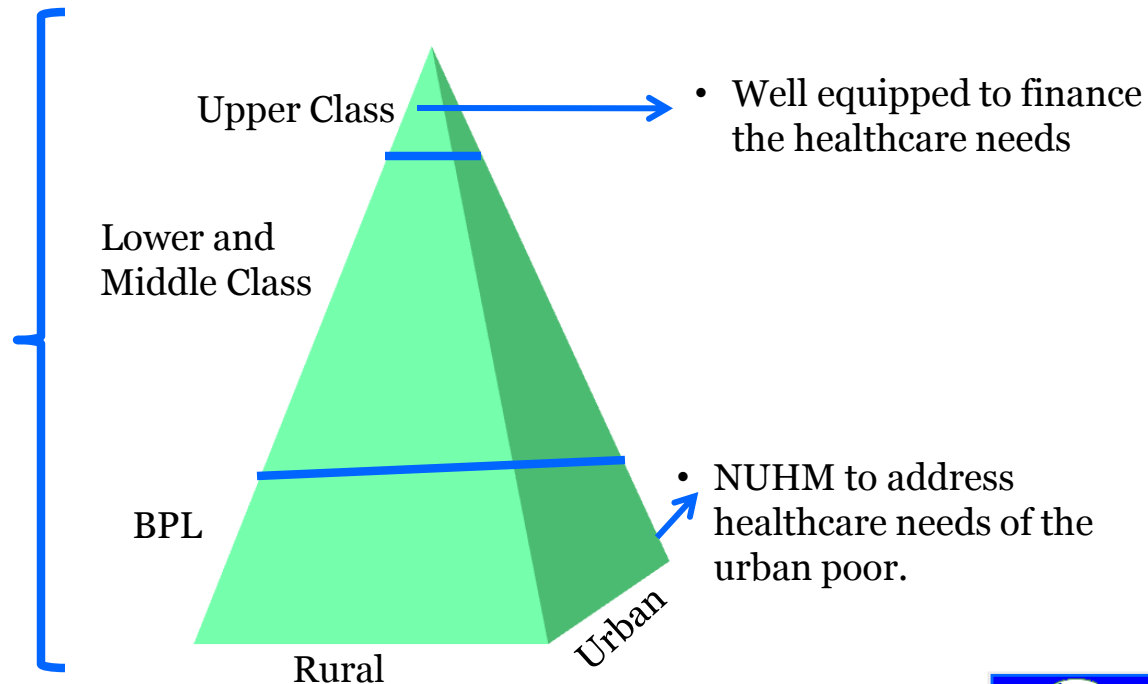
Objective	Key Initiatives Undertaken
Promote Indian drug discovery platforms	A multi-billion initiatives with 50% PPP model to catapult India into one of the top five pharma innovation hubs by 2020
Collaboration between industry, academia and the Government	<ul style="list-style-type: none">❖ New Millennium Indian Technology Leadership (NMITLI)❖ Drugs and Pharmaceuticals Research Program ((DPRP)
Focus on specialized pharmaceutical education	<p>Seven National Institute of Pharmaceutical Education and Research (NIPERs) as centers of excellence in Pharmaceutical:</p> <ul style="list-style-type: none">❖ Sciences and Technologies❖ Education and Training



Increasing Expenditure on Health

- ❖ Healthcare expenditure to contribute 6.1% of GDP in 2012
- ❖ With increase by 15 % per annum, the sector to employ around 9 MM people.

The NRHM initiated in 2005 for BPL and the lower and middle income people in rural India.

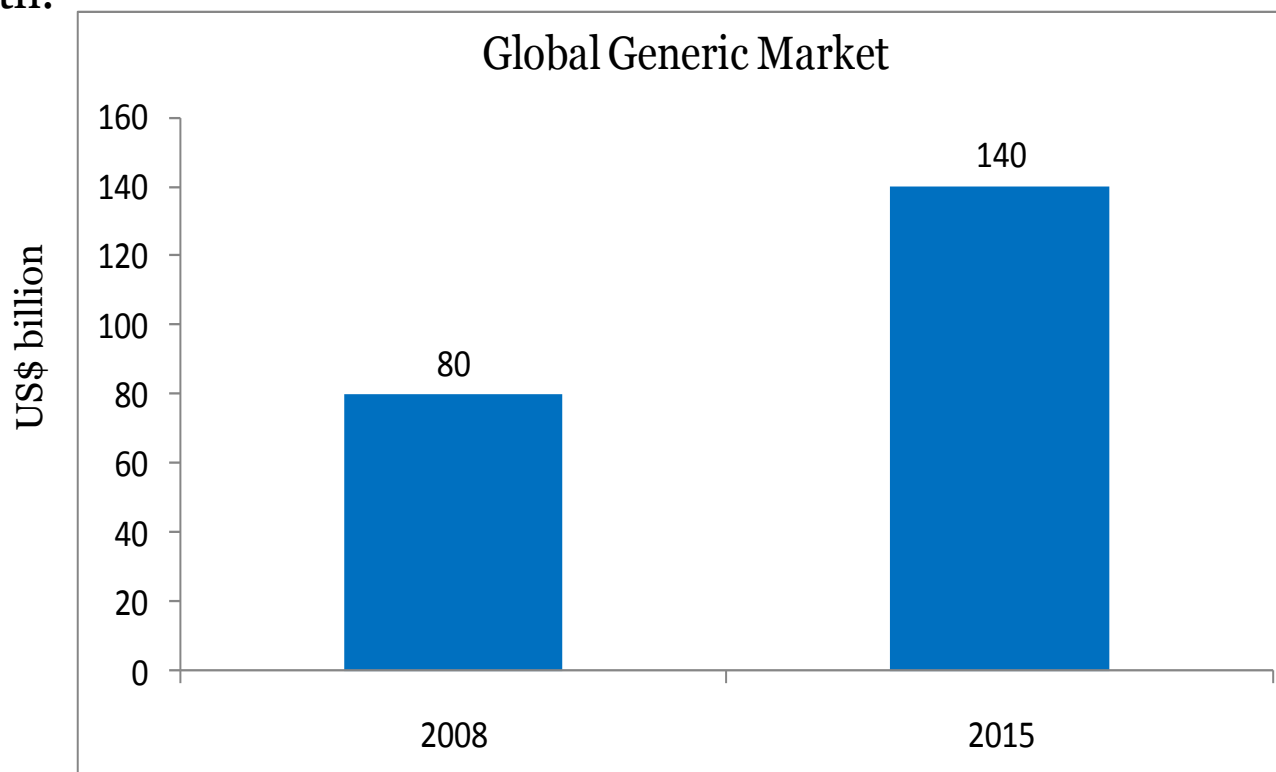


Source: HEAL Report, 2009



Growing Global Demand for Generics

- ❖ Global generics to grow to about US\$ 140 billion by 2015.
- ❖ Healthcare reforms, cost-saving initiatives, along with US\$ 150 billion worth of brands going off-patent in next 5 years, would drive this growth.



Sources: "Teva investor presentation," Investor Relations, Teva Pharmaceuticals Industries website, www.tevapharm.com, as on January 28, 2010



Growing Rural Markets

Rural Initiatives

- ❖ The robust consumption in the rural economy
- ❖ Untapped rural markets accounts for 45% of GDP
- ❖ Rural India accounts 70% of Indian households and two-fifth of total consumption pie
- ❖ Novartis with 'Arogya Parivar' covers 25 million people in more than 18,000 villages
- ❖ GSK, sanofi-aventis and others strengthened its focus on rural penetration and have initiated a pilot project in Uttar Pradesh



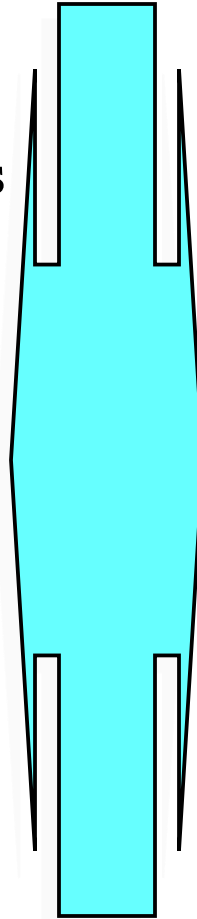
Business Outsourcing Opportunities



Twin Opportunity

Product Market

- ❖ Significant unmet needs
- ❖ 20 Bn. USD by 2015
- ❖ One of the Top 10 markets by 2015
- ❖ Top 3 in growth opportunity



Service Provider

- ❖ Resources
- ❖ Competence
- ❖ Cost Arbitrage
- ❖ Experience
- ❖ Young population
- ❖ Growing economy
- ❖ Pharmaceutical expertise
- ❖ Democratic set up
- ❖ IP Protection



R&D

– Indian Pharma Companies

Innovation
through R&D is
the life blood of
Pharma Industry

Company	NCE Pipeline	Key Therapeutic Area
Biocon	Preclinical – 2 Phase II – 2 Phase III – 1	Inflammatory Diseases, Oncology, Diabetes
Piramal Healthcare	13 Compounds in Clinical Trials	Oncology, Infectious Diseases, Diabetes, Inflammatory Diseases,
Glenmark	Discovery – 4 Preclinical – 5 Phase I – 1 Phase II – 3	Metabolic Disorders, Dermatology, Inflammatory Diseases
Ranbaxy	Preclinical – 4-6 Molecules Phase II – 1	Metabolic Diseases, Infectious Diseases, Respiratory Diseases, Oncology
Suven Life Sciences	Discovery – 2 Preclinical – 4 Phase I – 1	Neurodegenerative Diseases, Obesity, Diabetes, Inflammatory Diseases

Source: March 23, 2009, Financial Express



R&D

– Indian Pharma Companies

Innovation
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Pharma Industry

Company	NCE Pipeline	Key Therapeutic Area
Dr Reddy's Lab	Pre-clinical – 1 Phase II – 2 Phase III – 1	Metabolic Disorders, Cardiac, Oncology
Advinus	Pre-clinical – 3	Diabetes, Cardiac, Lipid Disorders
Wockhardt	Preclinical – 10 Phase II – 1	Infectious Diseases,
Lupin	Discovery – 2 Pre-clinical – 1	Migraine, Psoriasis, T.B.
Sun Pharma	Discovery – 2 NDDS – 1	Allergy, Muscle Relaxant,, Inflammatory Diseases, Pain Management

Source: March 23, 2009, Financial Express



R&D

– Indian Pharma Companies

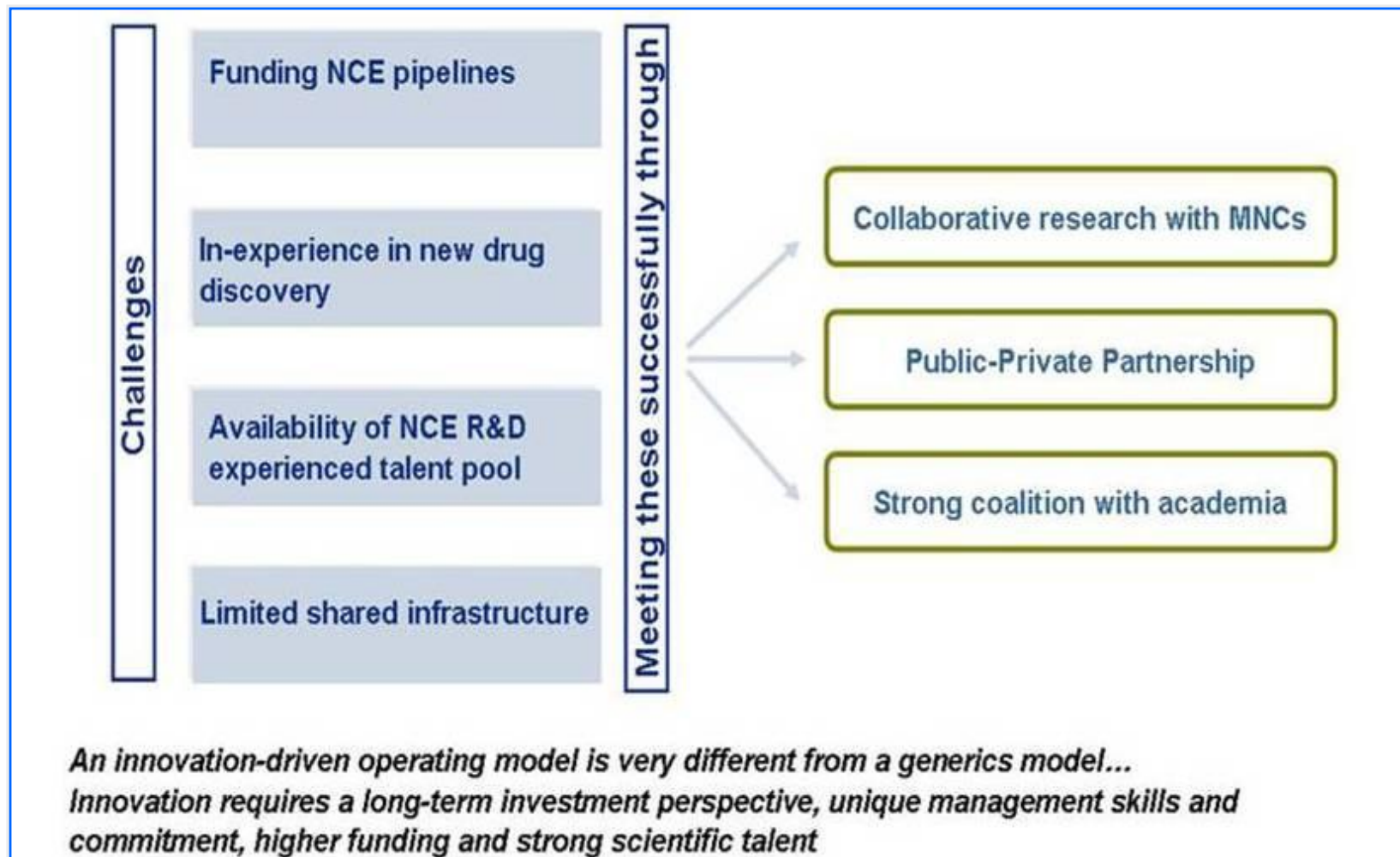
Innovation
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Pharma Industry

Specialties	2001	2008	Comments
R&D Exp. as a % of sales	1.4%	9.9% ↑	7 times
R&D Exp. in absolute terms	55	660 ↑	12 times

Source: Ernst & Young Analysis of top 25 pharmaceutical companies operating in India



R&D : Addressing the Challenges

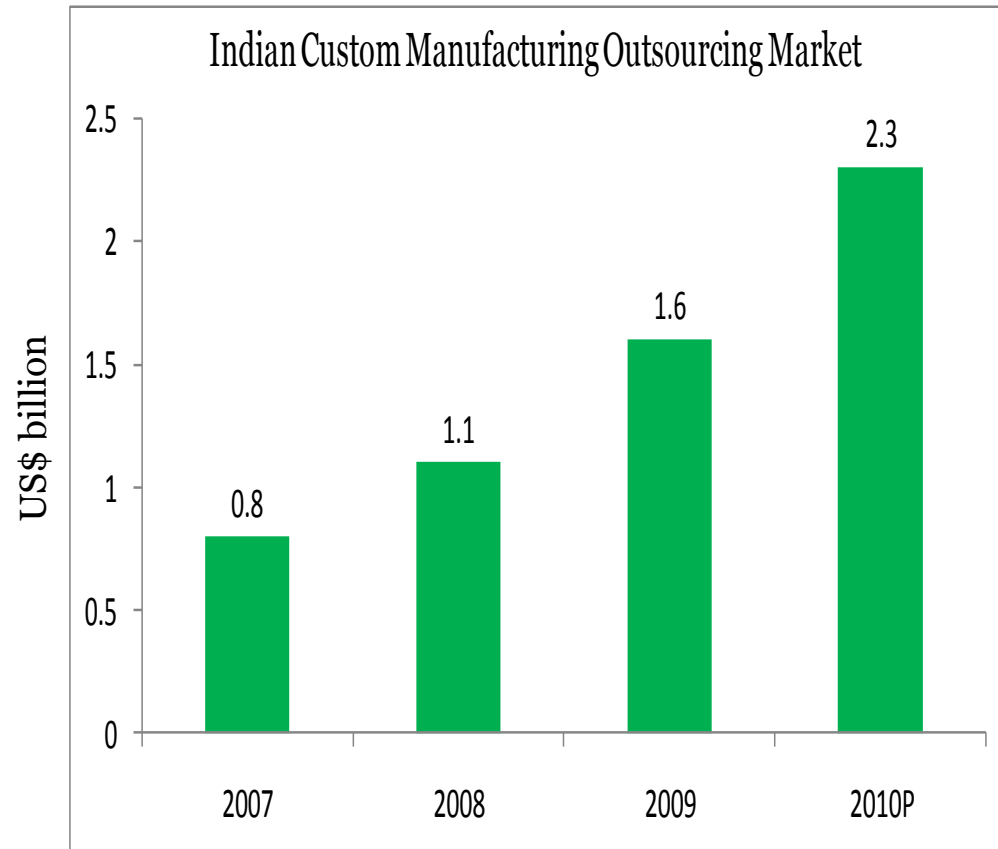


Source: Pharma Summit Report 2009



Contract Manufacturing

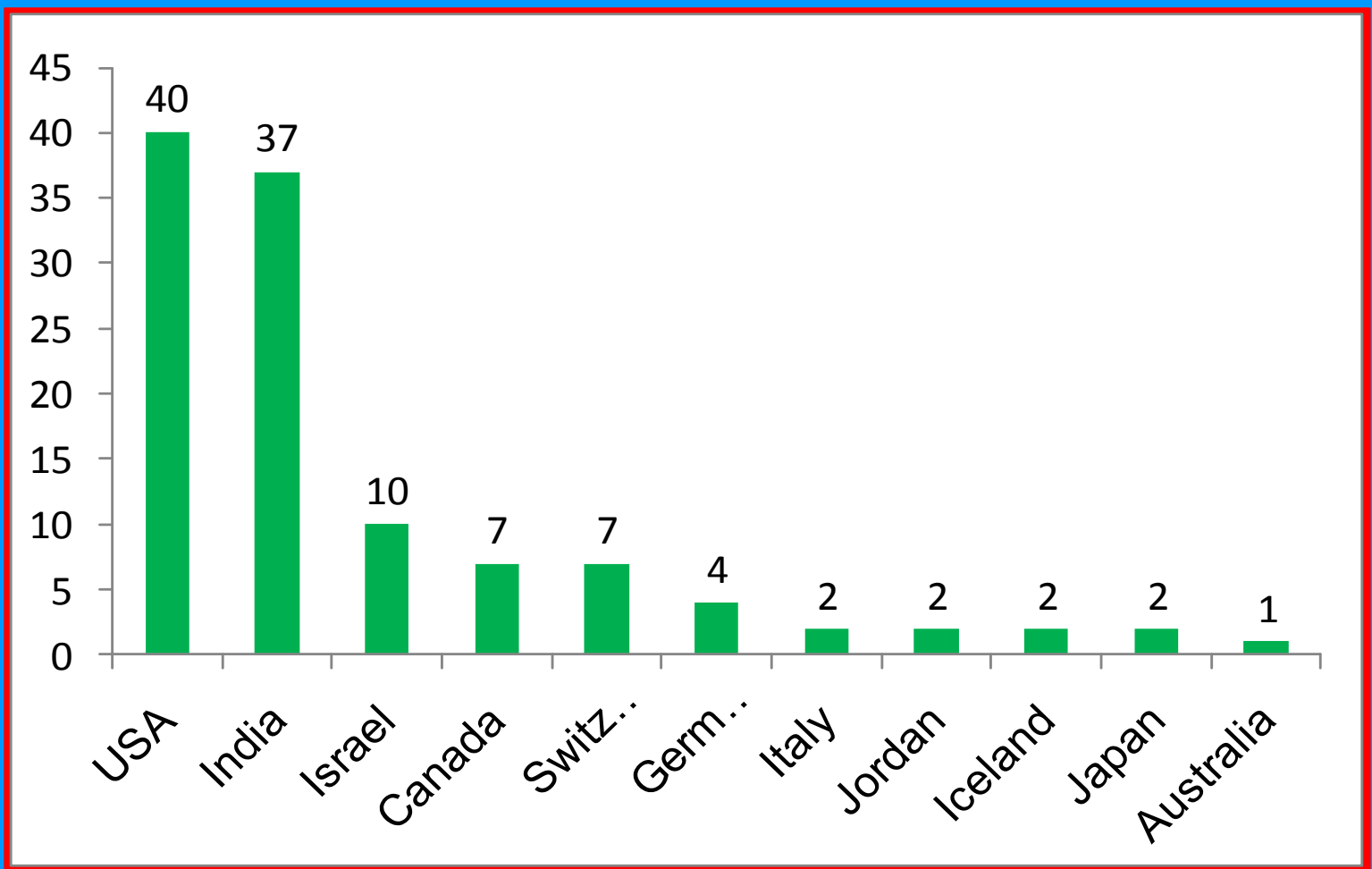
- ❖ Pharmaceutical manufacturing outsourcing market is valued at US\$ 1.1 billion in 2008, and growing at thrice the global market rate.
- ❖ India's share of the outsourcing market is to grow from 2.8% in 2007 to 5.5% in 2010.
- ❖ APIs/intermediate outsourcing is 64% of total outsourcing



Source: Taking Wings, OPPI - Ernst & Young Research 2009 , P: Projected



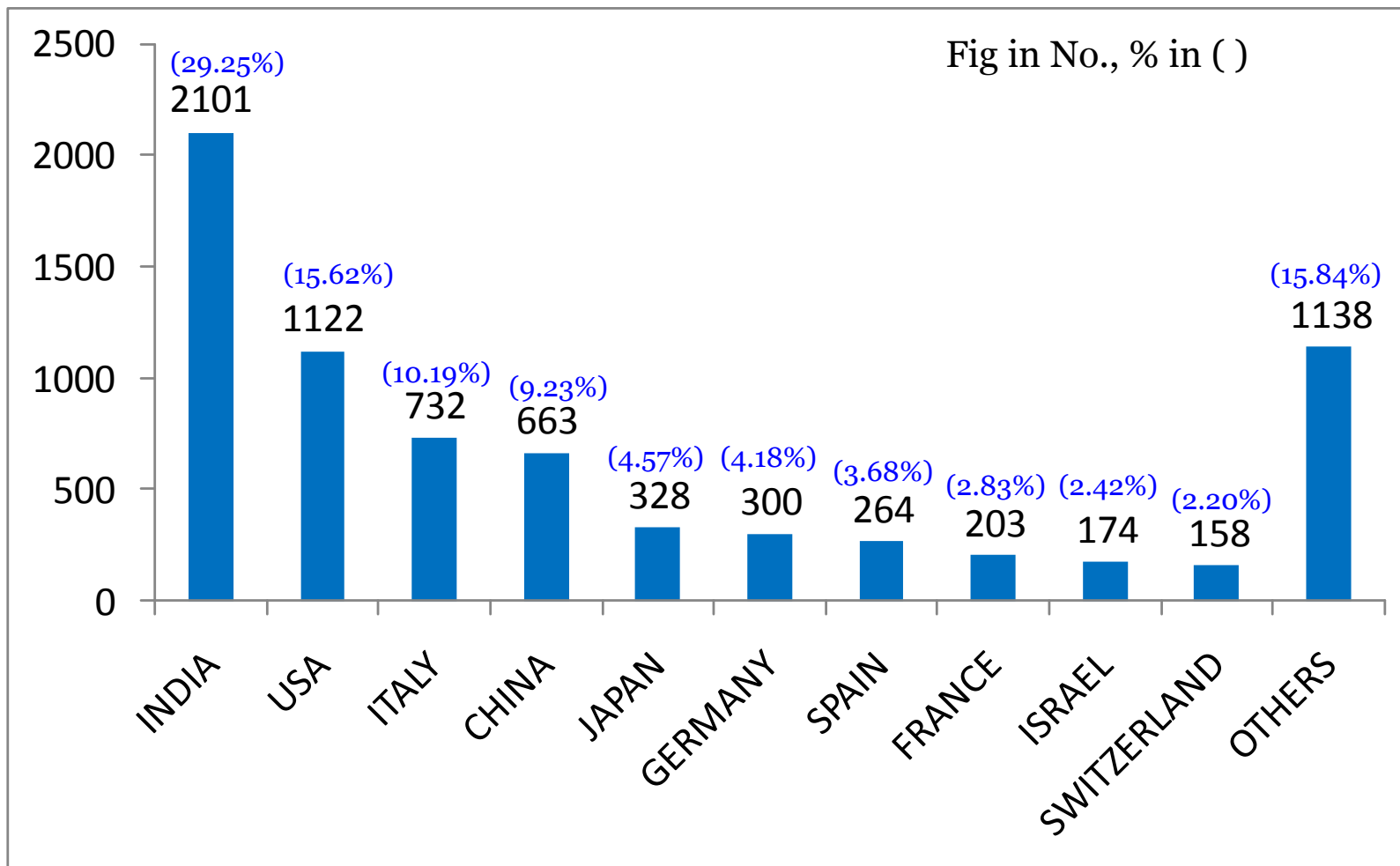
Country-wise ANDAs



Source: Pharma Matters-Movers and Shakers – Oct-Dec 2008



Global DMF with U.S. FDA



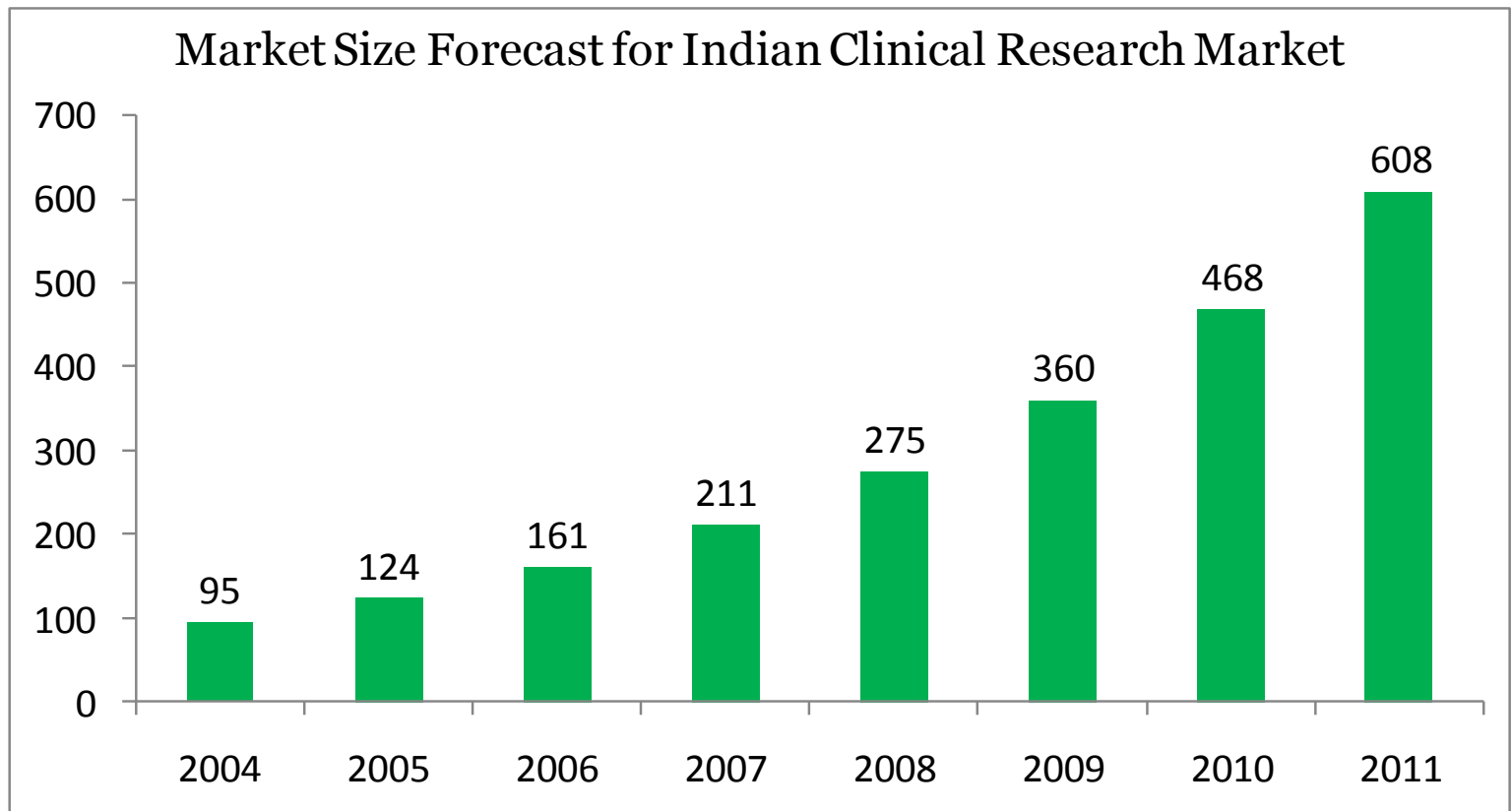
Updated to September 2009

Source: Pharmexcil Research on CDER US-FDA data base



Clinical Research

Clinical trials market in India, currently valued at about US\$ 250–275 million, is expected to grow at a CAGR of 30 per cent over the next few years, at nearly double the global average.

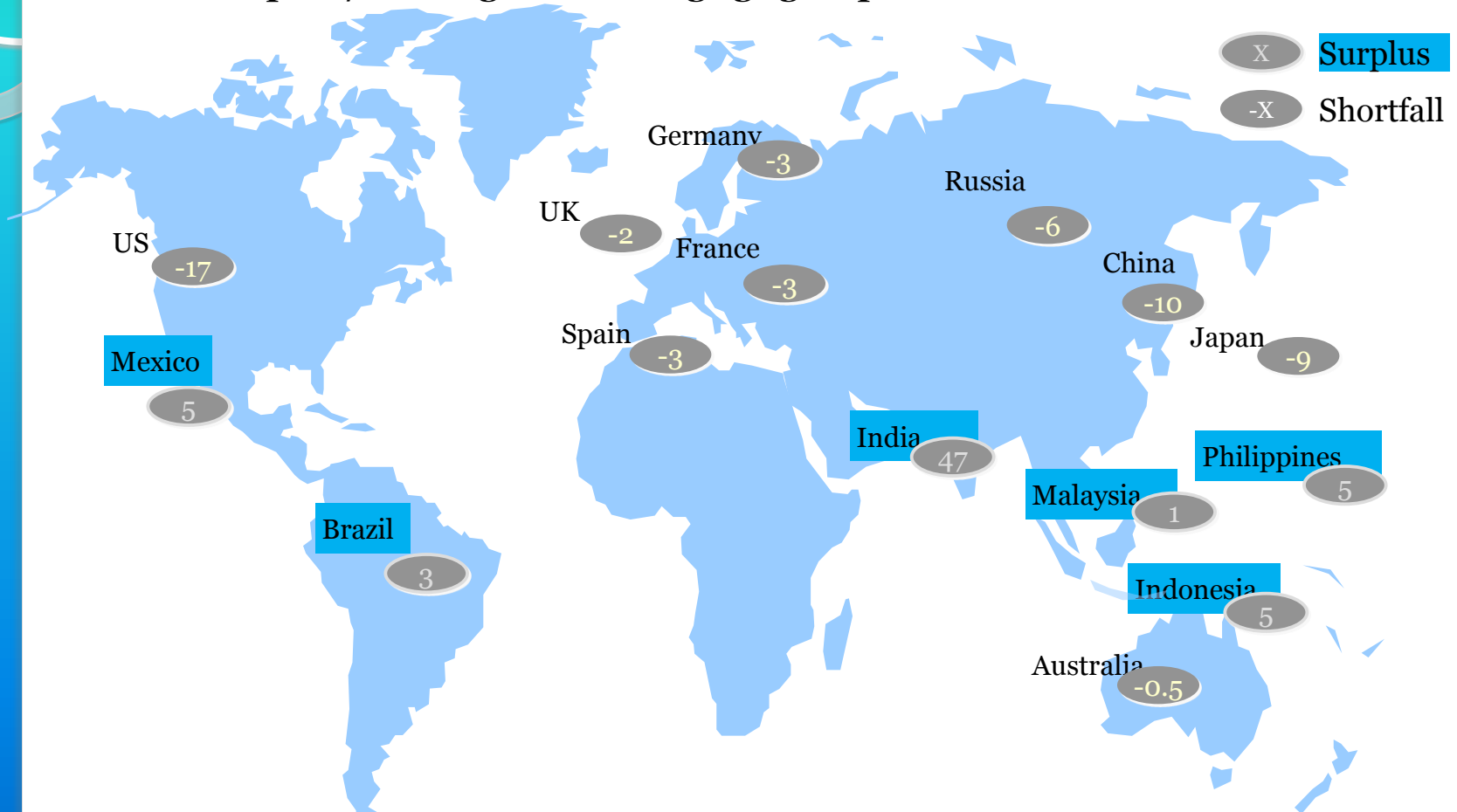


Sources: *The glorious metamorphosis*, Ernst & Young Research 2009



Global Availability of Human Resources by 2020

Potential surplus / shortage in working age group across the world (2020) in millions



Notes: Working population is defined at the 15 – 59 years age group. Ratio of working population to total population is assumed to be constant. Labour numbers are based on assumptions of interventions by respective governments.

Source: US Census Bureau. BCG. 2002.



Rising Confidence of Global Pharma Companies in the Indian Market

Patented molecule launches in India after enactment of Product Patent Regime in 2005

Innovators treading a cautious path and awaiting further clarity on several issues:

- ❖ RDP
- ❖ Patentability
- ❖ Patent Enforcement
- ❖ CL

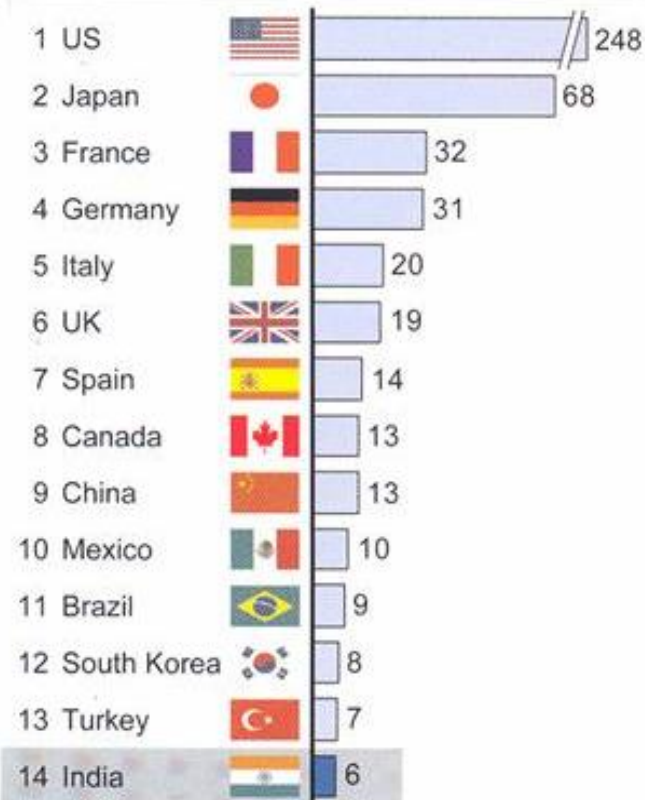
Product	Company	Therapeutic category	Launch date
VFend	Pfizer	Systemic Anti-Fungal	Feb 2005
Viagra	Pfizer	Erectile Dysfunction	Dec 2005
Lyrica	Pfizer	Neuropathic	Jan 2006
Caduet	Pfizer	Cardiovascular	Feb 2006
Carvedilol	GSK	Cardiovascular	Mar 2006
Avastin	Roche	Various cancers	Apr 2006
Tarceva	Roche	Lung Cancer	Apr 2006
Tamiflu	Roche	Bird flu	Apr 2006
Pegasys	Roche	Hepatitis C	May 2006
Macugen	Pfizer	Wet Age-Related Macular Degeneration	Jun 2006
Avalide	Sanofi Aventis	Cardiovascular	Jul 2006
Lucentis	Novartis	Wet Age-Related Macular Degeneration	Nov 2006
Ambien	Sanofi Aventis	Insomnia	Jan 2007
Champix	Pfizer	Smoke cessation	Feb 2008
Tykerb	GSK	Breast Cancer	May 2008
Abraxane	Abraxis	Breast Cancer	Jul 2008
Januvia	Merck	Diabetes	Jul 2008

Source: OPPI - Ernst & Young Research

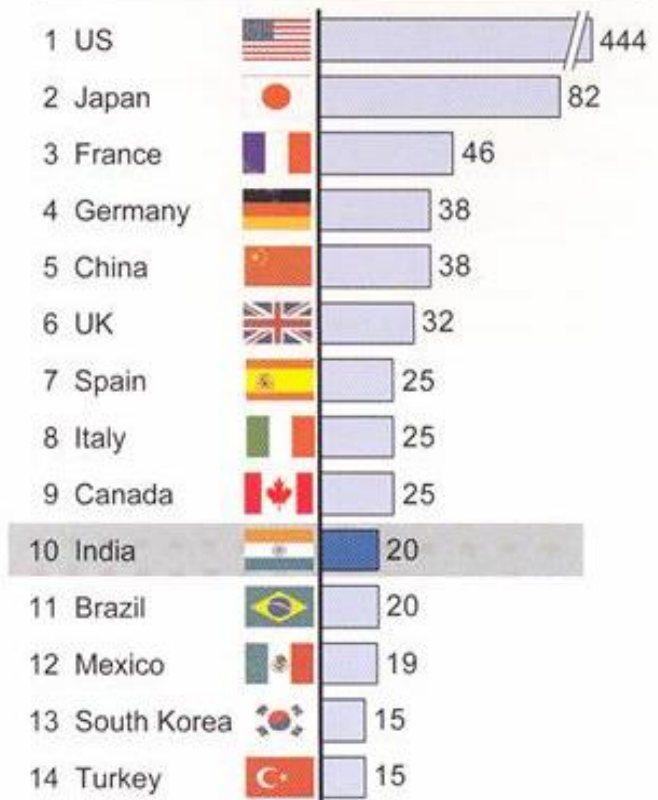


India to be in Top 10 ...

Top 14 pharmaceuticals markets, 2005



Top 14 pharmaceuticals markets, 2015



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



India Poised

- *Win some and... Win some more...*





Thank You