#### INDIAN PHARMACEUTICAL MARKET IN A NEW PARADIGM

Tapan Ray
Director General
Organisation of Pharmaceutical Producers of India



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#### Content

- India Today
- Pharmaceutical Industry a snapshot
- Policy and Regulatory Framework
- Key Growth Drivers
- Issues and Concerns

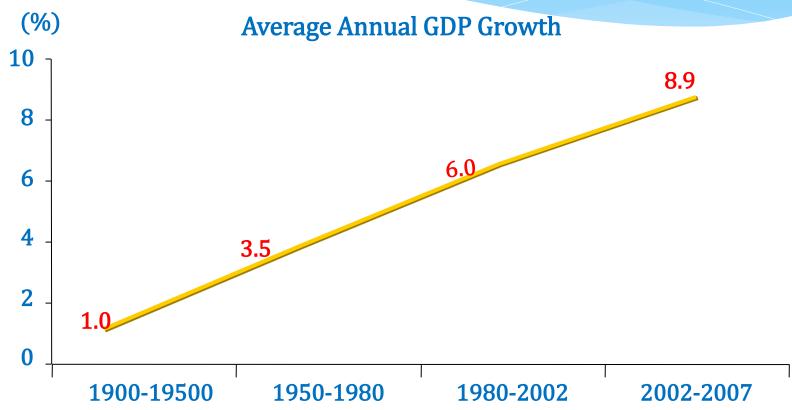


## **India Today**



#### 28 Years of High Growth

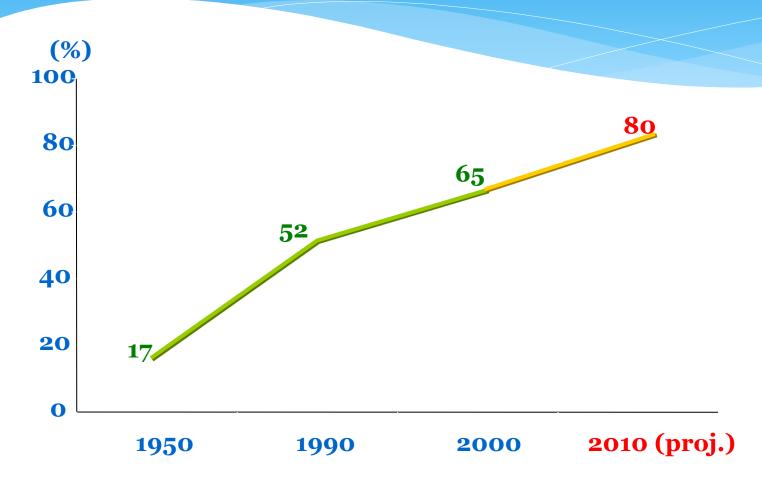
India is the 4<sup>th</sup>
Largest economy
Average Gr. Rate
8.56% during
2004-2009





#### Literacy is Rising



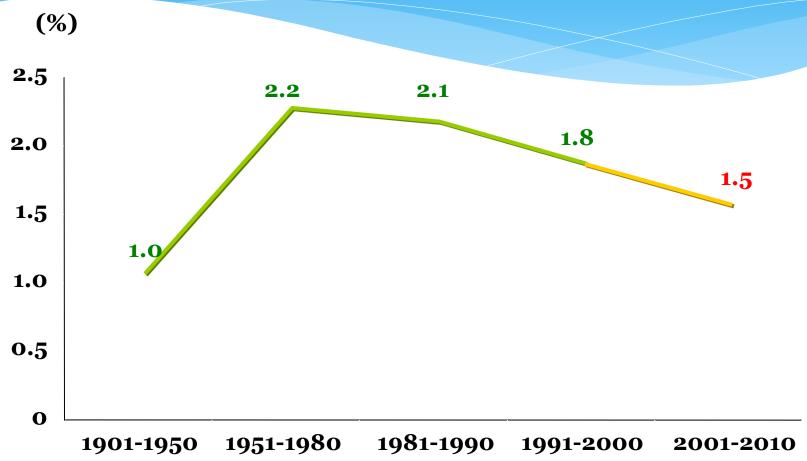


Source: Census of India (2001)





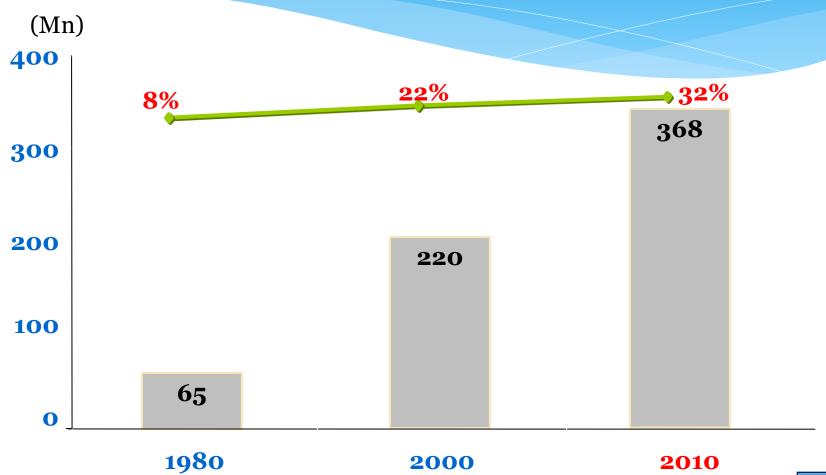
India is the 2<sup>nd</sup> Largest population





### Middle Class: Growing

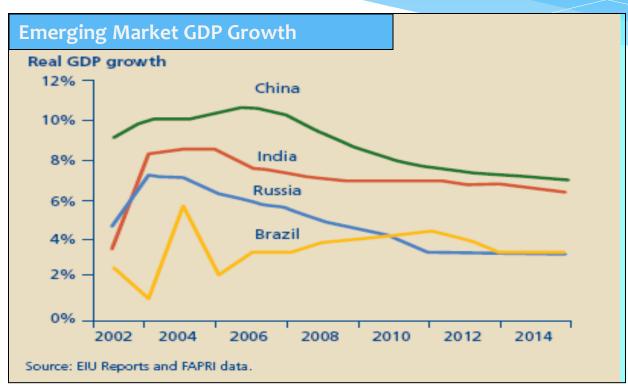






#### India: GDP Growth

India will overtake Japan by 2014



Deloitte: Pharmaceutical Market Entry in India

India growing by 6% + despite the current global recession Indian growth story is still intact



## Key Reforms

India : Growth Trajectory

- 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)\*



<sup>\*</sup> Yet to be implemented

Healthcare Environment and Pharmaceutical Industry

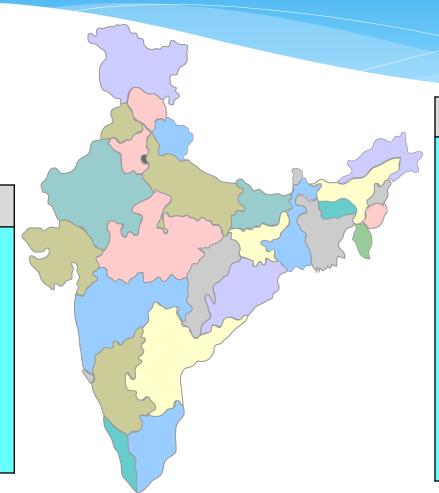


#### India is Changing Fast

Setting 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



#### Government: Changing Role

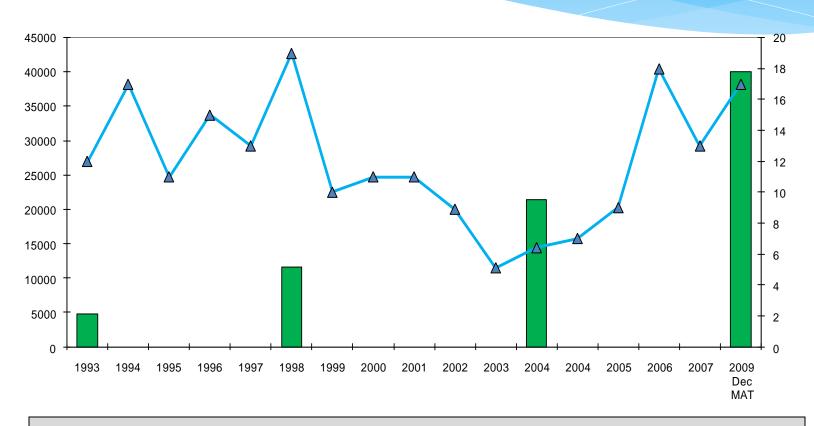
## From Healthcare Provider to Healthcare Facilitator

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

Source: India Trade Promotion Organization (ITPO)



# Indian Pharmaceutical Industry is doubling every 6 Years





## Indian Pharmaceutical Market is Different

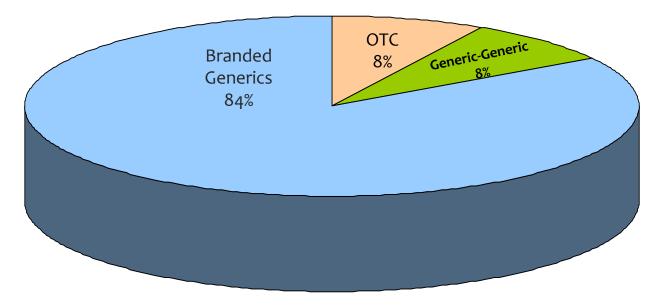


- Highly fragmented
- ❖ Top 50 companies contribute to 85%
- \* Retails Sales (91%) and Institutional Sales (9%)
- 5.5 Million Pharmacies
- Acute therapies (74%) dominate over Chronic Therapies (26%)
- Combination Drug Market (62% of new introductions in 2010)



## Key Market Types

#### Market Size US\$ 11.5 Bn.







# Indian Pharmaceutical Market Top 10 Companies

Top 10 Companies contribute to 42%

Rank	Company	Sales (US \$ Mn.)	M.S. %	% Growth	
	Industry	11466	100	17.5	
1	Abbott (combined)	708	6.17	13.2	
2	Cipla	650	5.67	24	
3	Ranbaxy	545	4.75	14.6	
4	GSK	539	4.71	13.4	
5	Sun Pharma	507	4.43	23.5	
6	Zydus Cadila	442	3.86	13.1	
7	Alkem	370	3.31	20.9	
8	Lupin	373	3.26	24.5	
9	Mankind	361	3.15	29.7	
10	Pfizer + Wyeth	340	2.97	22.3	

Source: AIOCD



# Indian Pharmaceutical Market Top 10 Products

Top 300 brands = 33%, Top 10 brands = 3.68%

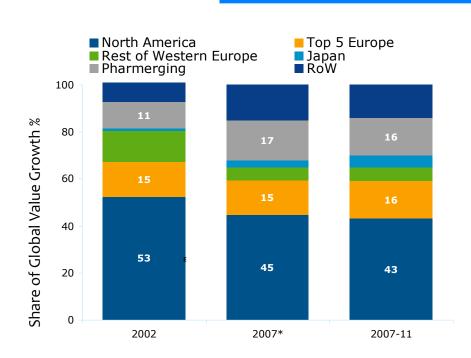
Rank	Products	TG	Company	Value (\$ Mn)	% GR
1	Corex	Cough Preparation	Pfizer	46.37	24.3
2	Phensedyl	Cough Preparation	Piramal Healthcare	44.781	10.8
3	Voveran	NSAID	Novartis	39.29	15.1
4	Augmentin	Amoxy+Clav	GSK	36.44	33.9
5	Human Mixtard 30/70	Insulin	Abbott	36.39	30.9
6	Revital	Nutritional	Ranbaxy	34.88	42.4
7	Dexorange	Haematinic	Franco Indian	32.39	25.7
8	Zifi	Cephalosporin	FDC	32.01	25.1
9	Monocef	Cephalosporin	Aristo	31.82	29.2
10	Becosule	Nutritional	Pfizer	31.50	29.3

Source: IMS 1 USD = 45.29 INR



## Contribution of Emerging Markets will be as much as top 5 Europe by 2011

#### **Contribution to Global Growth (US\$)**



Mature Markets CAGR 2007-11			
USA	4-7%		
Canada	6-9%		
Japan	2-5%		
Germany	3-6%		
France	2-5%		
Italy	3-6%		
UK	4-7%		
Spain	5-8%		

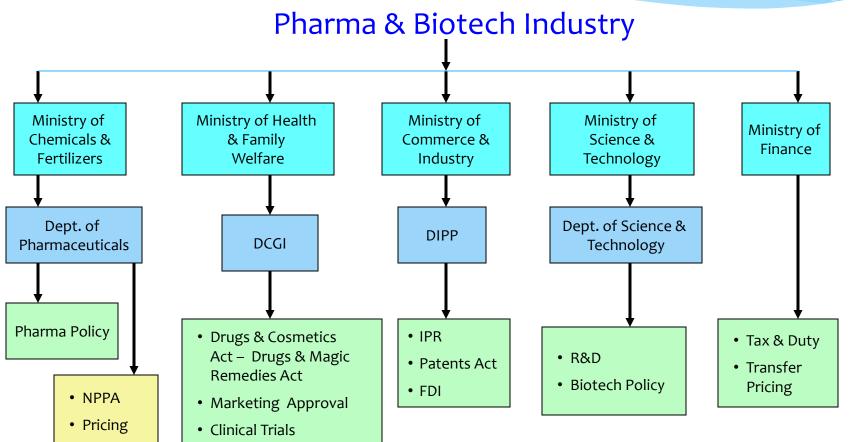
Emerging Markets CAGR 2007-11			
China	13-16%		
Korea	8-11%		
Brazil	9-12%		
Russia	17-20%		
Mexico	6-9%		
India	11-14%		
Turkey	9-12%		



#### Policy and Regulatory Framework



#### Regulatory Structure





## **Key Growth Catalysts and Trends**



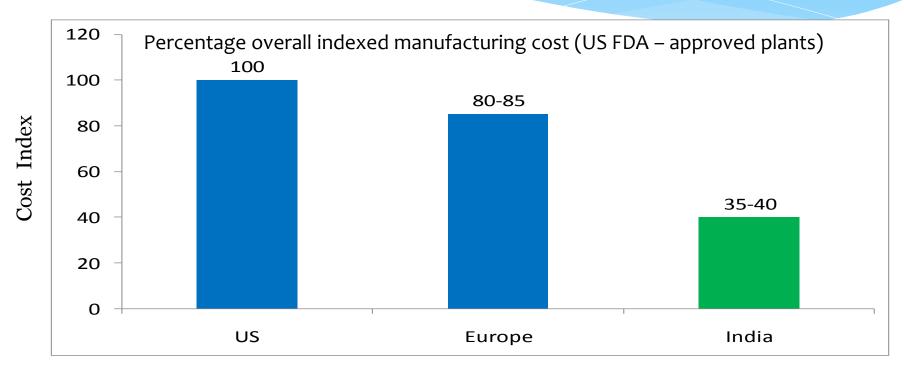
#### Changing Growth Fundamentals

- 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 Million by 2015
- Increasing purchasing potential of the middle class to drive consumption of healthcare services
- Public Healthcare Initiatives NRHM, NUHM
- Increasing Penetration of Medical Insurance



### Cost Arbitrage

India rates higher on cost efficiency as compared to other countries



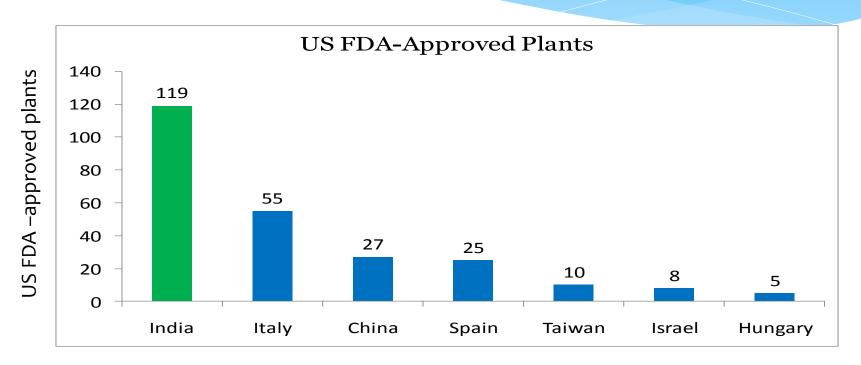
- Over 8,000 manufacturers drives down costs
- Costs of US FDA plants in India are 65 per cent lower than the US and 50 per cent lower than that in Europe.



Source: Taking Wings, OPPI - Ernst & Young 2009

#### **Technical Capability**

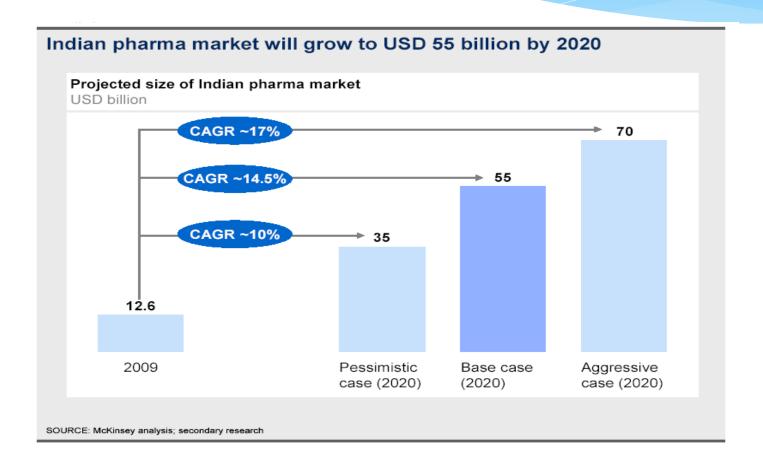




- ❖ 119 USFDA and 84 UK MHRA approved plants.
- Many plants approved by Canada, Australia, Germany and South Africa.

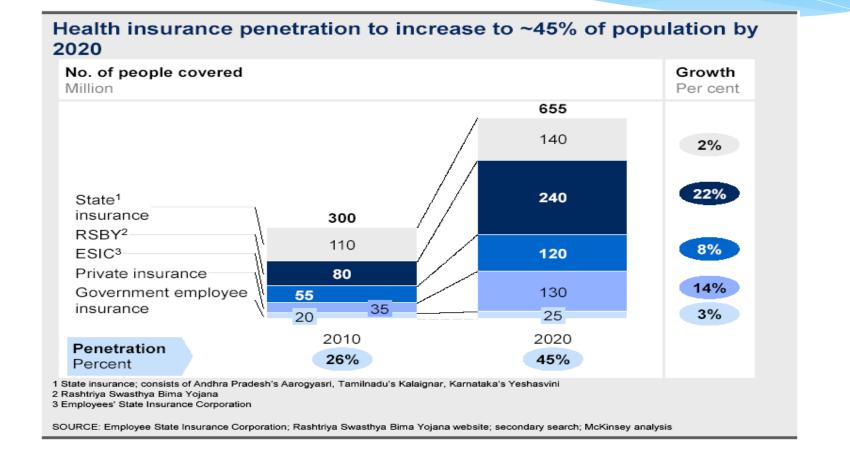


#### Key Indicators for Attractiveness



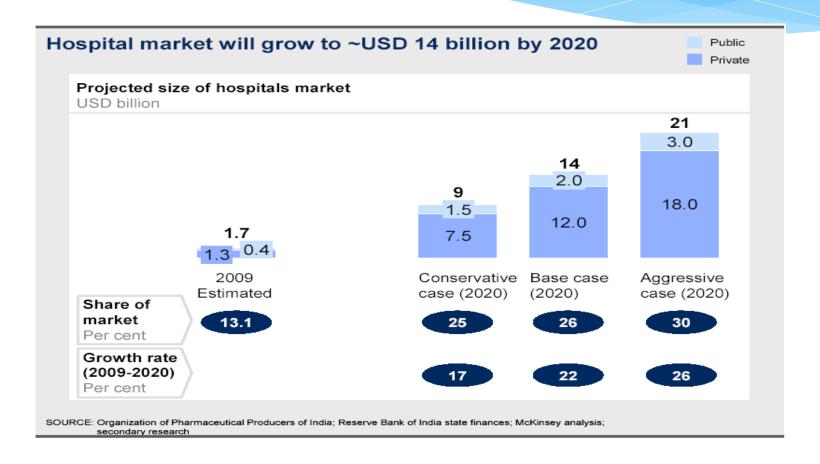


#### Key Indicators for Attractiveness



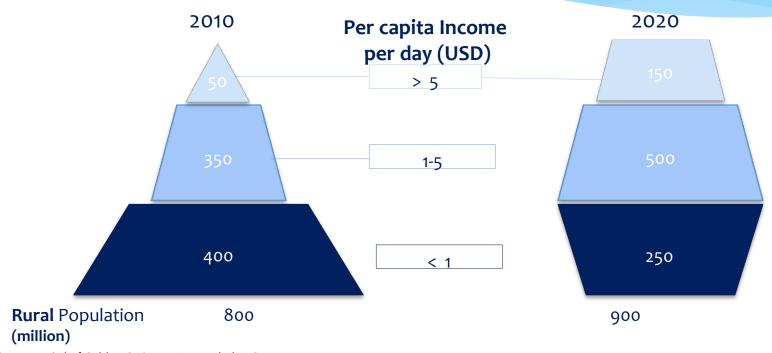


#### Key Indicators for Attractiveness





# Key Indicators for Attractiveness Rural Income







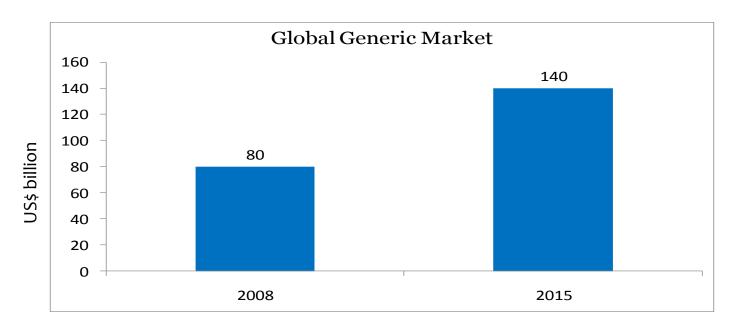
### Government Support

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> <li>New Millennium Indian Technology Leadership (NMITLI)</li> <li>Drugs and Pharmaceuticals Research Program ((DPRP)</li> </ul>
Focus on specialized pharmaceutical education	Seven National Institute of Pharmaceutical Education and Research (NIPERs) as centers of excellence in Pharmaceutical:  Sciences and Technologies  Education and Training



#### 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

#### India Advantage



Over 50% of shortages expected from English-speaking countries

Note: Pakistan, Bangladesh and Vietnam have not been represented for lack of reliable data on productivity and cost of service employees

#### R&D

#### - Indian Pharma Companies

Innovation
through R&D is
the life blood of
the 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

#### R&D

#### - Indian Pharma Companies

Innovation
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contd.

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: Financial Express, March 23, 2009

#### R&D

## - Indian Pharma Companies

R&D spending of 20 pharma companies up by 5% to `2,989 cr. in FY '10

Specialties	2001	2008	Comments
R&D Exp. as a % of sales	1.4%	9.9%	7 times
R&D Exp. in absolute terms (US\$ M)	55	660	12 times

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



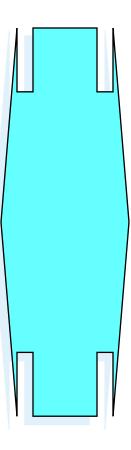
## Business Outsourcing Opportunities



#### 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



Source: McKinsey / BCG

## 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

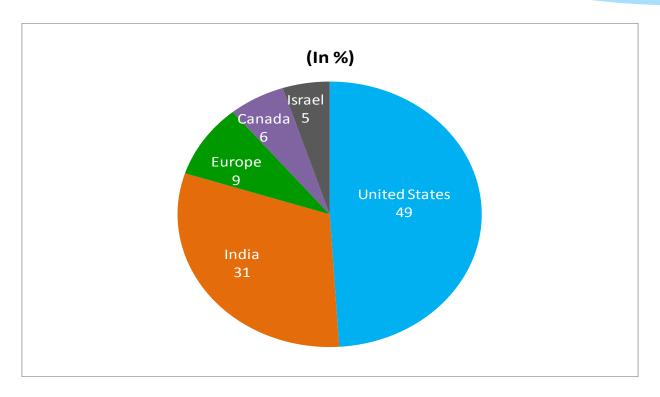






# Country-wise ANDA Approvals 2008 & 2009

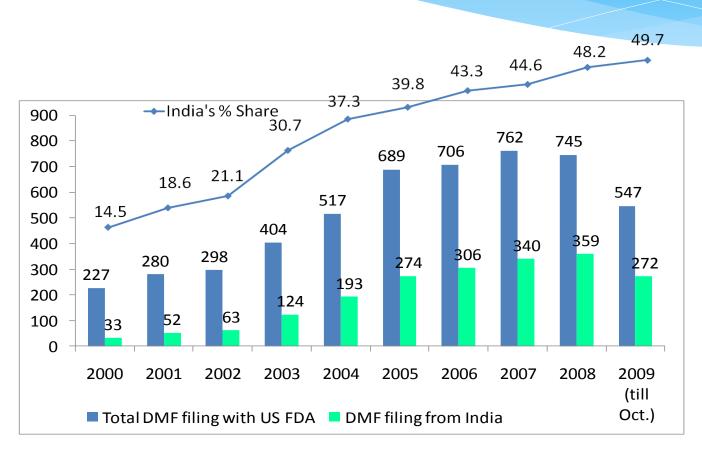
142 ANDAs, 34% of total in 2010

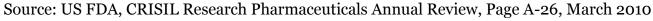


Source: US FDA, CRISIL Research Pharmaceuticals Annual Review, Page A-16 ,  $\,$  Mar 2010 Issue



#### DMF Filing (Global v/s. India)

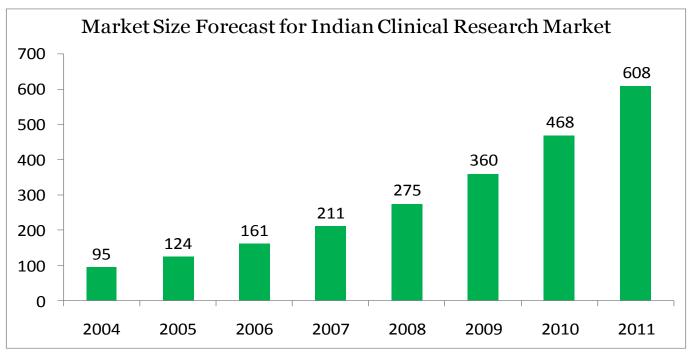






#### Clinical Research

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



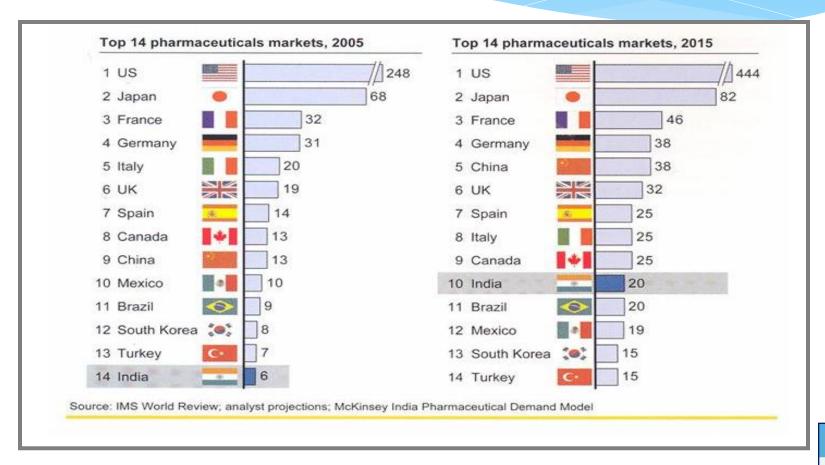
#### **Issues & Concerns**

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

- RDP
- Patentability
- Patent Enforcement
- CL
- Drug Price Control



### India to be in Top 10...





# Thank You