



# **Generic Generic and Branded Generic**

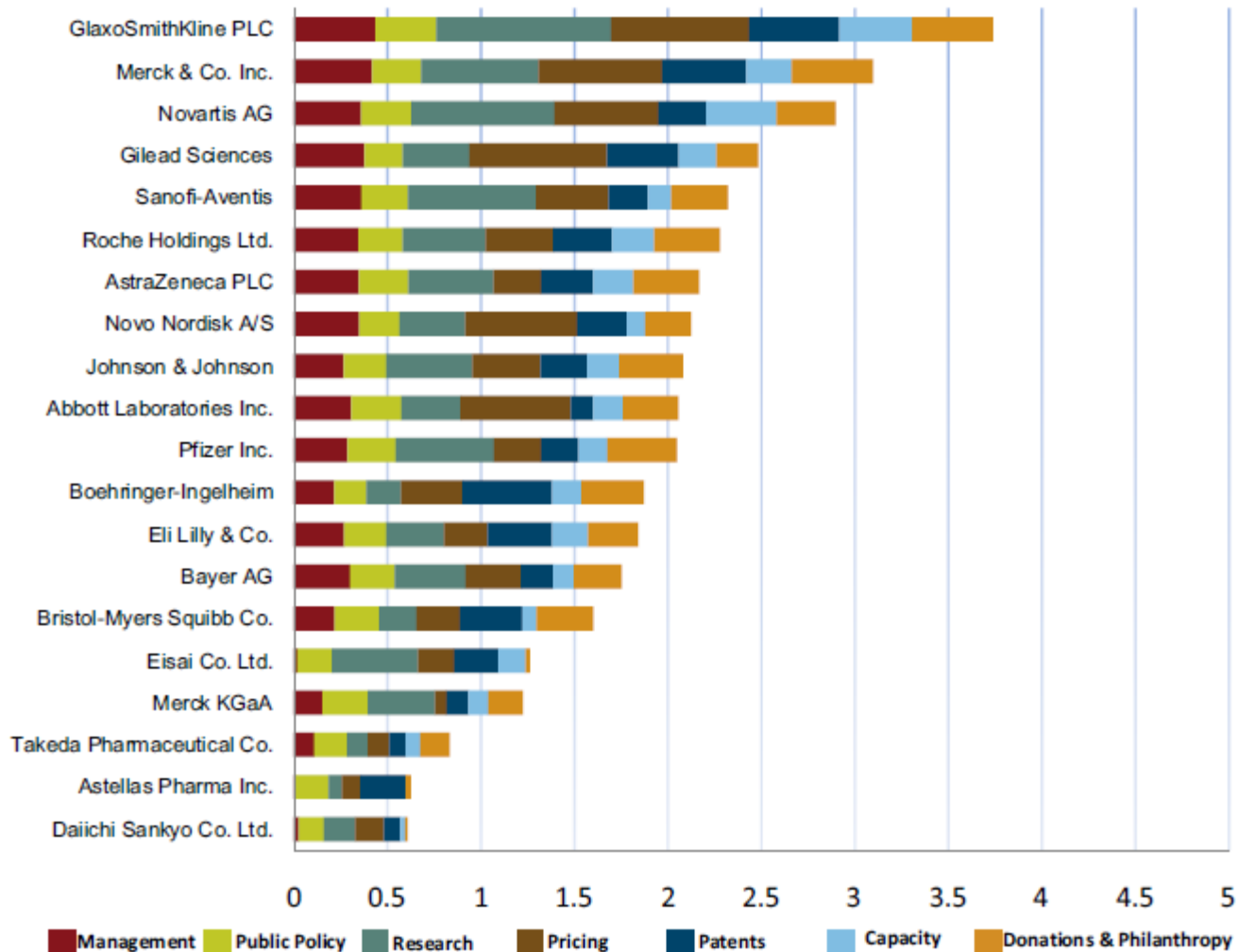
**Kewal Handa**

21<sup>st</sup> September 2012

# R&D spend

Sector	M Euros	% of Sales
Pharmaceutical and Bio technology	70524	15.9
Technical and hardware	64352	8.6
Automobiles	60807	4.1
Software and computer services	26323	9.8
Aerospace and Deffence	15991	4.8
Total	36646	3.4

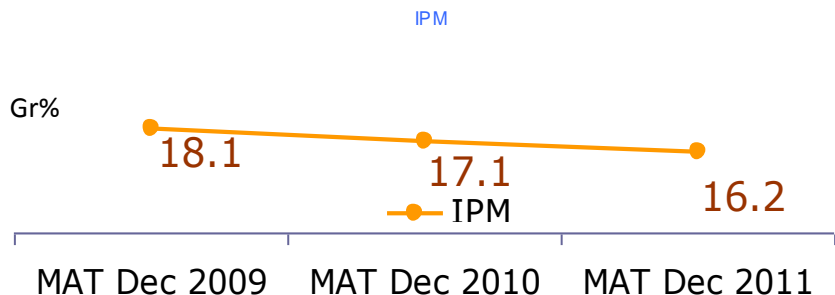
# Access to medicine index 2010 – Ranking of Originator companies



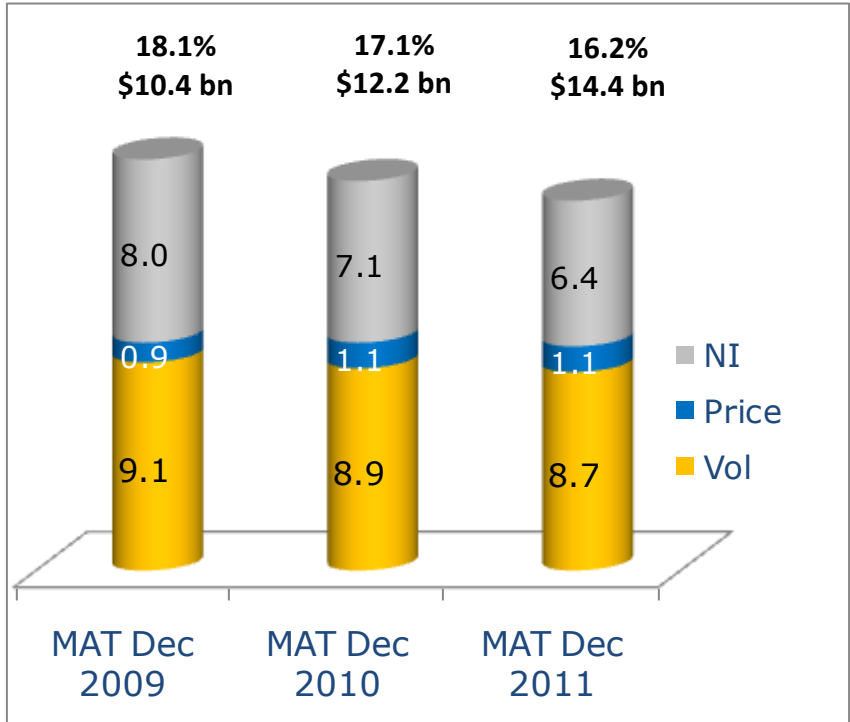
# Access to medicine index 2010 – Ranking of Generic companies

	High	Access to Medicine Management	Public Policy and Market Influence	R&D for Index Diseases	Equitable Pricing, Manufacturing & Distribution	Patents and Licensing	Capability Advancement in Product Development & Distribution	Product Donations & Philanthropy	Overall Ranking
	Medium								
	Low								
	No evidence found								
Ranbaxy Laboratories Limited	High	High	Medium	High	High	High	Low	Medium	1
Cipla Limited	Medium	Medium	Medium	Medium	Medium	High	High	High	2
Dr. Reddy's	High	High	High	Medium	Low	Low	Medium	Medium	3
Mylan Inc.	Low	Low	High	High	Low	Low	No evidence found	Low	4
Sun Pharmaceuticals	Low	Low	No evidence found	No evidence found	Low	Low	High	No evidence found	5
Teva Pharmaceuticals Ltd	Low	Medium	No evidence found	No evidence found	No evidence found	Low	No evidence found	Low	6

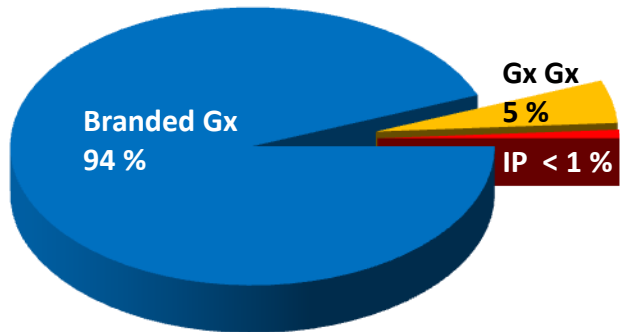
# Indian Pharma Market growing at 16%



## Growth driven by volume and NIs



## Branded generics dominate



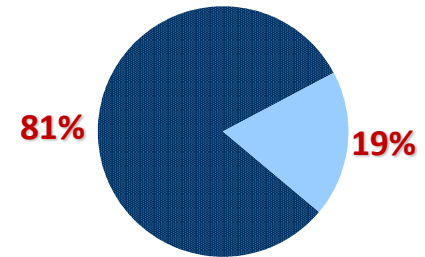
	Globally	Earlier	Now
Branded Gx		20%	50%
IP Products		80%	50%

# Features & Complexities of Indian Pharma Market

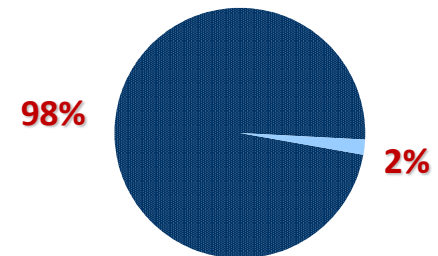
Key Emerging Pharma Market USD 23B by 2014

(15%+ growth rate projected)

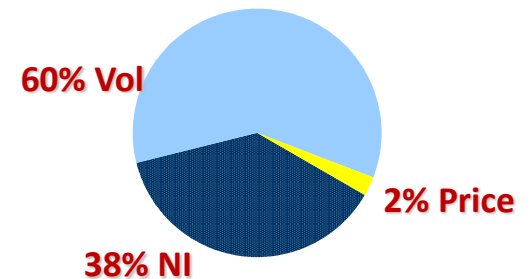
Local companies - dominating presence



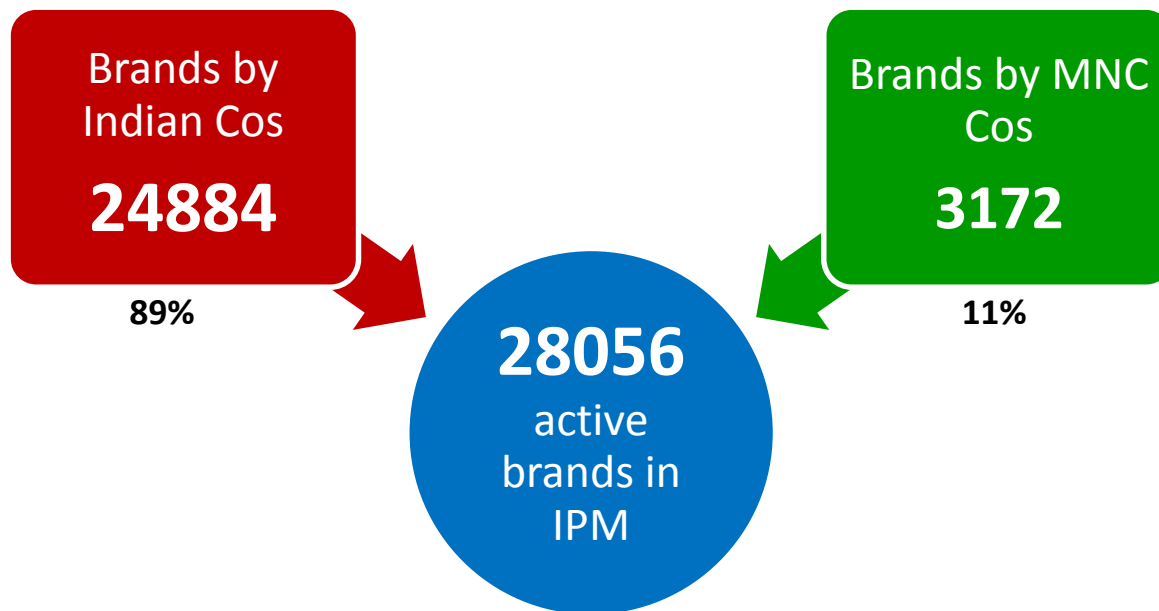
Branded Gx – lion’s share in the space



Market driven by Volume & New Introductions



# Brands Classification



TA	Indian	MNC	Total
GI	3059	284	3343
Pain	2936	303	3239
AI	2849	380	3229
Respi	2238	256	2494
VMS	2000	275	2275

TA	Indian	MNC	Total
Cardiac	1974	285	2259
Derma	1895	321	2216
CNS	1562	231	1793
Gynaec	1397	172	1569
Othrs	4974	665	5639

# Generic Products in US

- Contains same ingredients as innovative drugs
- Is bio equivalent to patented drugs
- Is identical in strength dosage form and route of administration
- Requires efficacy and safety data for approval



# Branded Generic Products in India

- Generics of original products not patented in India
- First approval based on US and Europe approvals
- Subsequent approvals need to have only pharmacokinetic bio equivalents
- For products above 4 years no regulatory requirements

# Generic Generic drugs

- Government aggressively pushing for generic generic drugs to provide larger access
  - Tamil Nadu, Kerela, AP, Rajasthan: Jan Aushadi program
- “Prescribe generic drugs” is what government doctors are told (TOI Bangalore)
- “In many cases generic drugs do not provide the desired effect in the expected time which branded ones do” (Down to earth)

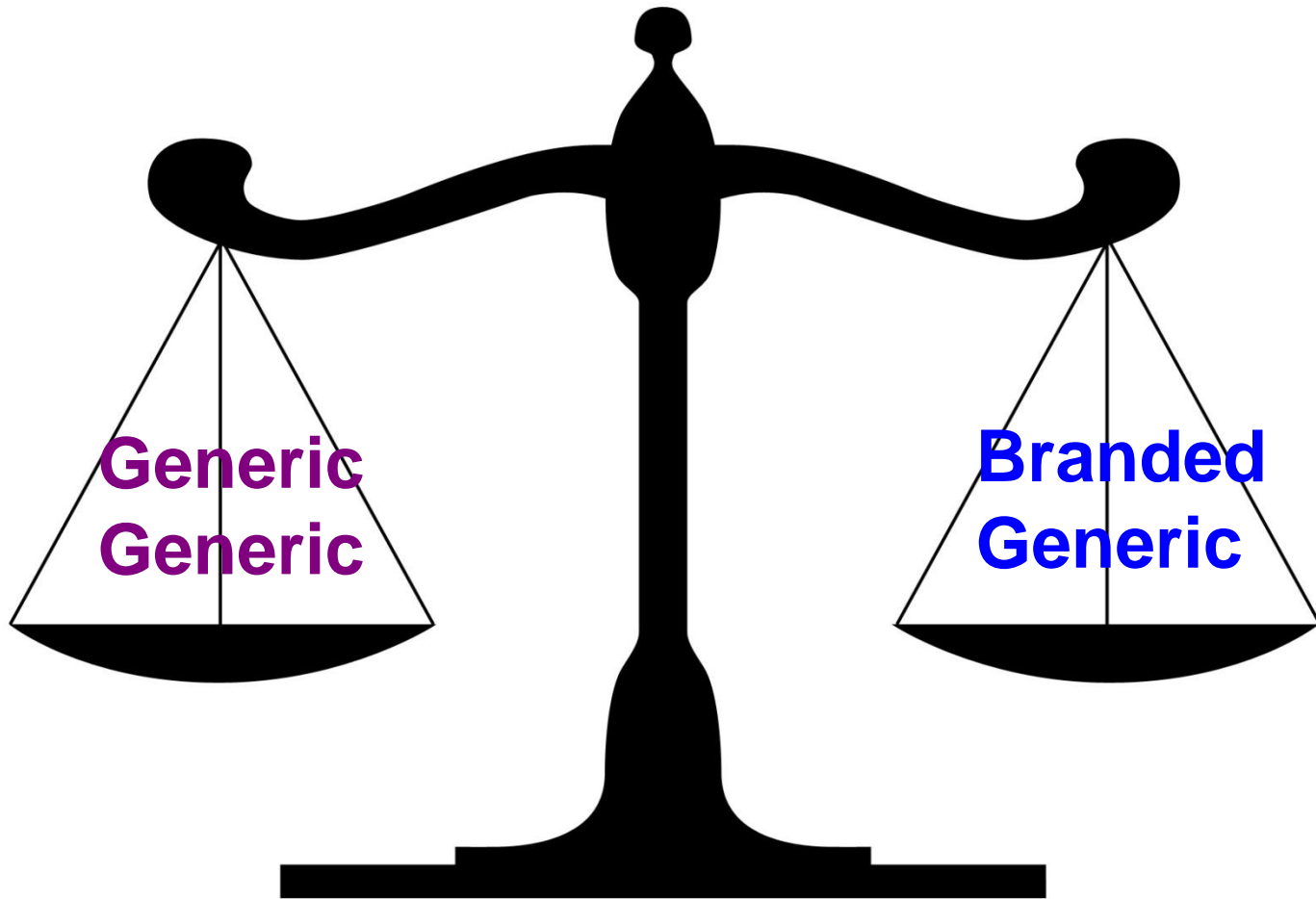
# Risks to patients with Generic Generic drugs

- Many single ingredient medicines have differences in formulations and drug delivery system that could have varied impact on the patient
- Active ingredients may be different having impact on absorption
- Active ingredients may be the same but the therapeutic equivalence may not exist
- Most of the products do not have data to prove similar efficacy and safety against originals or other generics
- Substitution is common, chemist making choice not based on patients need but on higher margin

# Case for Branded Generics

- Branded manufacturer is more at risk for not adhering to quality
- Responsible for monitoring and reporting adverse impact
- Patient under the hands of knowledgeable share holder
- Doctor is aware of the patients condition and is best suited to prescribe the drug
- Builds trust and confidence amongst patients

# Strike a balance



# Need for a holistic approach

- Strengthen regulations for generic generics and branded generics based on US FDA
- Discourage generic generics combinations
- Expand healthcare insurance
- Strengthen counterfeit measures
- Stringent requirements for generic generic formulation procurement in drugs having narrow therapeutic equivalents

“ Reducing the price of molecules through supply of low cost generics is palliative not a cure to country’s ills”

Thank you