Biosimilars in India and potential impact in the global biopharmaceuticals Market

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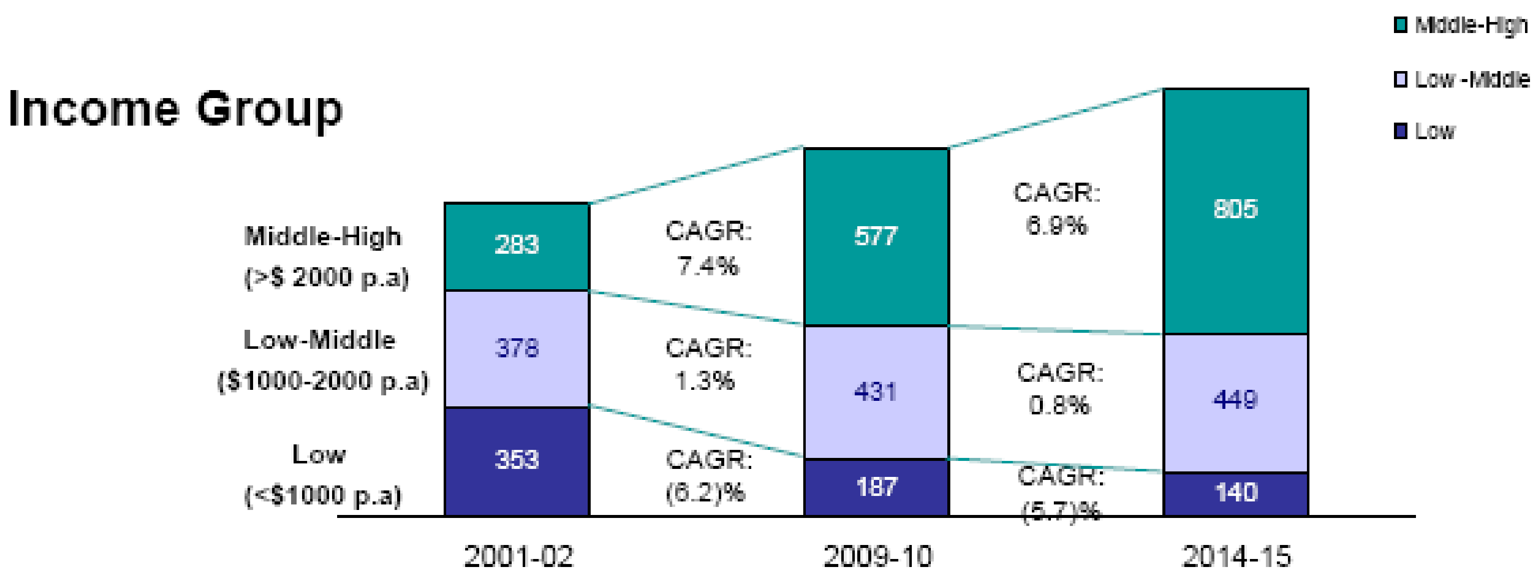
Rising incomes in India are increasing healthcare demand

Disposable income and the (slow) spread of health insurance will emerge as important demand enablers by increasing affordability

Population (Mn) by Annual Income Level



Source: 2008 – Deloitte consulting "The right spice "- Biopharma ceutical market entry into India

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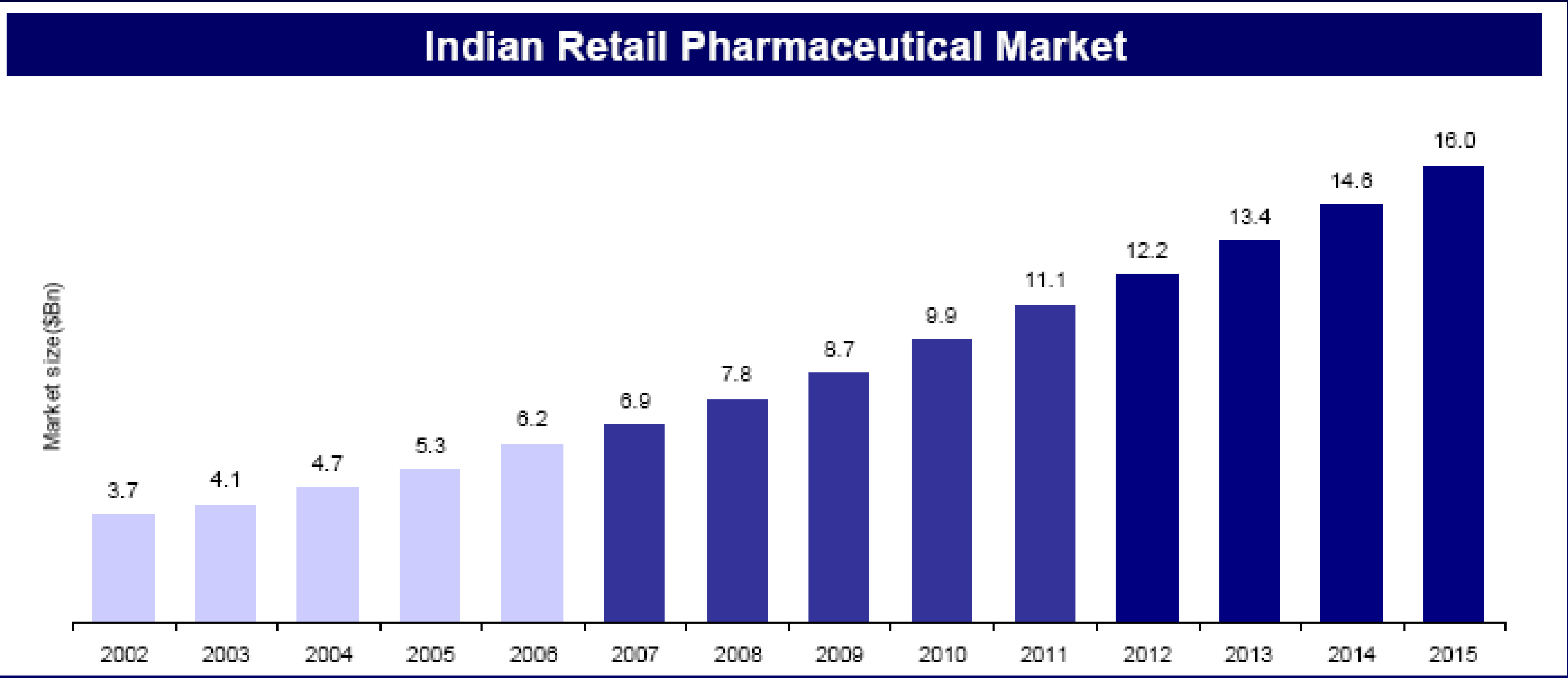
India is a large future pharma market among the top 10 in the world



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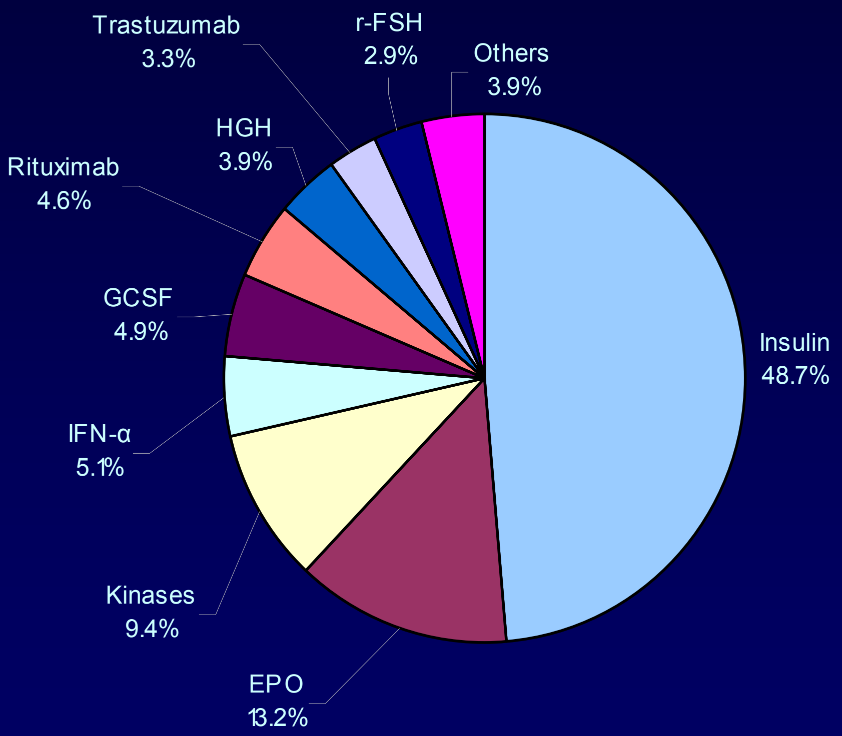
India: Biopharmaceutical Market

Biopharmaceuticals : Therapeutic protein Molecules

Molecule	2006 USD (MM)
Insulin	79.1
EPO	21.5
Strepto/Urokinases	15.3
Interferon	8.3
GCSF	8.1
Rituximab	7.4
HGH	6.4
Trastuzumab	5.3
r-FSH	4.7
Others	6.4
Total	162.6



Source: IMS, Industry

The role of patent laws in the development of biosimilar molecules in India

Changes in patent laws and other regulations will likely generate India-specific innovations

	Before 1970	1970-2005	2005 Onwards
Patent laws	▪ Recognized product patents ▪ Patent term-20 years	▪ Excluded product patent coverage ▪ Limited process patent to 7 years	▪ Recognized product patents ▪ Data exclusivity not guaranteed
Pricing and Royalty	▪ Royalty rates of around 10-15% ▪ No price ceilings	▪ Royalty rates reduced to 4% ▪ Price ceilings on most drugs in the market	▪ Royalty of 5% on local sales ▪ Reduction in the number of drugs under price ceilings
Regulatory	▪ Drug Price Control Order (DPCO) ▪ Drugs & Cosmetics Act	▪ Excise duty levy ▪ Phase I clinical trials to be conducted in India only when foreign trial data is available	▪ VAT implementation ▪ Dual VAT/GST system ▪ MRP based levy ▪ Concurrent trials possible

..Patent laws allowed Indian companies to develop & market several generics and biosimilars invented before 1995 in a derisked model .

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Leading Indian Biosimilar Players

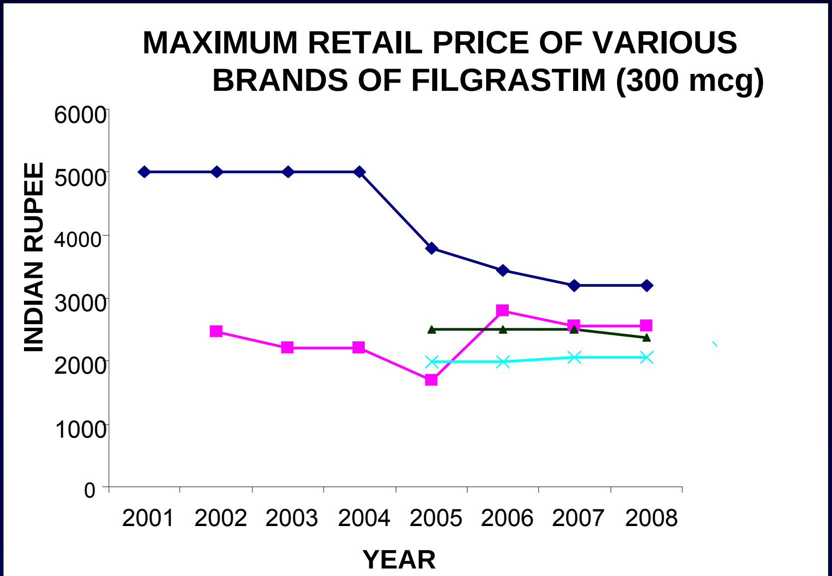
Products / Company	G-CSF	α Inter feron	EPO	Insulin	mAb	Rec. Vaccines	IL-2	Strepto kinase
Shantha		MS	MS			MS		MS
Wockhardt			MS	MS		MS		
Biocon	MS		S	MS				MS
Dr.Reddys	MS				MS			
Intas	MS		MS					
Ranbaxy/Zenotech	MS		S				MS	
RBPL	MS	MS	MS					

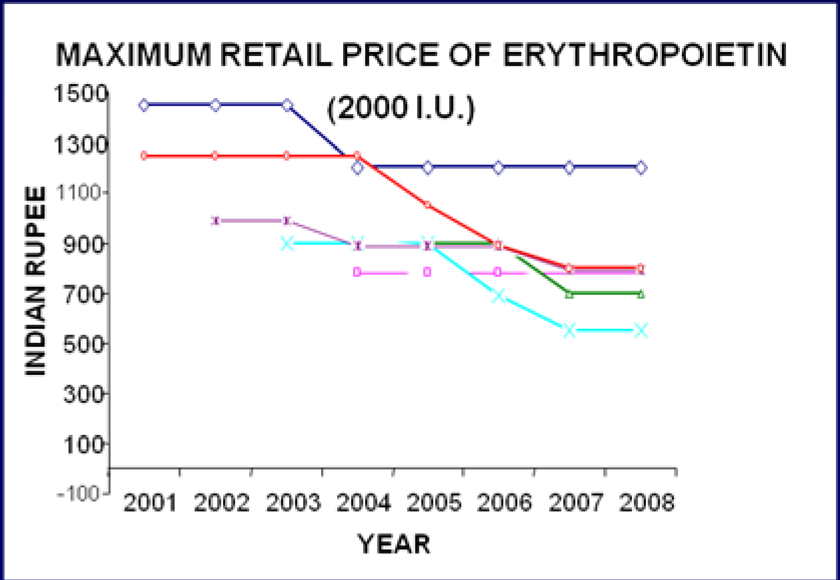
MS : Manufacturing and Sales
S: Sales

Source: BioSpectrum Internal Research

The Indian Biosimilar space is competitive,

Price reduction due to competition





	No. of Biosimilars
Insulin	8
G-CSF	9
PEG-GCSF	1
EPO	12
IFN	7
hGH	4
Streptokinase	3
Rituximab	1

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Future of Indian Biosimilars

- Indian Biosimilars can play a significant role and gain market share around the world.
- There will be a clear advantage of cost of goods in the global market place
- Past quality experience from generics to be leveraged . India has the largest number of US-FDA approved manufacturing facilites outside the United states.
- Additional data specifically mandated by regulations in the EU and other countries would need to be generated.
- Several Indian manufacturers have already started this process…

Indian Biosimilars are here to stay and some of the players will reach global market

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Targetting Regulatory requirements

- CMC: Process & Analytical
- Non-clinical
- Clinical

GMP

- Extensive pharmaceutical experience but limited biopharmaceutical experience for Indian companies

- EU-GMP certified for bulk and fill-finish

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Non-clinical & clinical: gap analysis

- **Non-clinical**
  - More extensive studies
  - Other species
  - Comparative studies

- **Clinical**
  - More extensive studies: PK, PD, efficacy
  - Comparative studies
  - Importance of safety and immunogenicity

Patents

- Increased restrictions within India for next generation products
- Patents on
  - Molecule
  - Process
  - Finished product formulation & presentation

Key advantage

Key advantage to Indian manufacturers compared to EU-based companies:

- Product already in market (cost recovery)
- Possibility of data collection(immunogenecity)

Conclusion

- Indian Biosimilar Industry is poised for growth
  - Natural Selection to Occur over time.
- True Indian Biosimilar product players can play significant role in Europe
  - CoGs advantage will eventually weigh in and help Indian Biosimilars succeed
- Success and Path to Success for US is still to be defined

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Some leading Indian Biopharmaceutitical players …

Biocon, Reliance,Shanta..

..Wockhardt , INTAS , Reddys

Thank you

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