

# Global Pharmaceutical and Biotechnology Outlook 2014 - India Pharma

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## Abstracts

Indian companies are taking center stage in Complex Generics at US and EU markets. In Bio-similars, Indian companies will have perhaps the largest basket aimed at Emerging Countries in 2014-16 and later for Developed countries. Though few but is the beginning of NCE/mAb development by Indian companies is a sign of Indian Generics moving up in the chain. The uncertainty of clinical and regulatory pathways in the US helps Asian biopharma and biotech companies to be in forefront in developing and marketing biosimilars. Biopharma/ biotech companies in India, S. Korea, China may have significant advantages of low-cost manufacturing, colossal markets, and healthy government support over potential peers from other regions. The cost barriers in the biosimilar market lead regulated marketed giants to tie up with Asian companies to gain access to these advantages and hedging their bets through a joint-venture strategy. Though reimbursement remains a concern as no countries provide full reimbursement – patient pay total cost out-of-pocket in India; with well defined regulatory pathways, we believe Indian biopharma companies keep leveraging their strength of low cost manufacturing along with skilled workforce which would support them to gain global recognition.

Factories at India continue to have lion's share of US Generics market, despite a couple of plants at India facing scrutiny from US FDA. India has 526 USFDA units in which 403 intimations of violation (Form 483) of its manufacturing norms to Indian plants in the period from 2011 to Nov 2013. It is to be noted that one fourth of FDA inspection outside the US conducted in India. But Indian plants have received very less Import alerts/Warning letters by FDA which indicates strong quality consciousness of Indian Drug Manufacturers. Only 21 warning letters have been issued to Indian companies which is far less than other Ex-US countries (Mexico: 74%; Canada and British: 30% - Import alert).

With a robust outlook, companies continue to invest in sales force to target more doctors and more focus per brand. The implementation of quality norms with vigor has helped companies with better quality perception to charge high prices. Every company has invested in increasing the sales force to capture the market that has consolidated at the tail end. With tiny companies getting out of business importance of branding has increased drastically. Thus, all companies are trying to increase focus per brand. Policy makers in India to start the process of strict audit of marketing practices followed by pharma companies in India.

Our outlook 2014 on India Pharma covers overall business and market growth for Indian companies, ParaIV filing, NCE pipeline and biosimilar and NDDS development.

### Key Topics Covered

1. Uniform Code on Sales and Marketing Practices in India
2. Issuance of warning letters to Indian facilities by USFDA: not a concern
3. Biosimilar perspective for Indian market
4. New drug discovery development in India
5. Biocon: Sits comfortable with its near and long term contributory products
6. Cadila Healthcare: NCE, Transdermal, Biosimilars and Complex generics launches thru 2016 – Eventful time ahead
7. Cipla: Major change in business model
8. Dr. Reddy's Lab: Focus on Complex formulations and Biogenerics to intensify
9. Glenmark: US business, NCE and ParaIV will show significant growth
10. IPCA: Fine chemicals to formulation –Global leadership in select products
11. Lupin: US and Japan Business –Key for long term growth
12. Natco: Leveraging chemistry, formulation and IP strength – For Us and India Markets
13. Panacea Biotec: Financial trouble mounting, Acceptance of WHO prequalification and formulation business will revive the company
14. Shasun: On path to become fully integrated Pharma company
15. Shilpa Medicare: A leader in Oncology API, Expanding into Non-Onco, peptides and complex formulations
16. Sun Pharma: Strong Management Team - Absolute and Comparative Advantage

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Gifting Policy Changed

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