

Sathguru Management Consultants

Life Science Advisory Group

Fostering Innovation | Leveraging Opportunities | Driving Growth

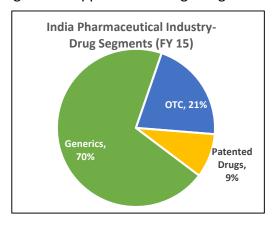


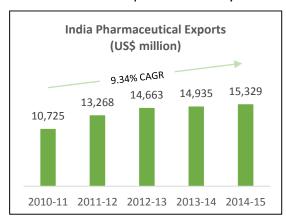
Pharma – Industry Briefing March 2016

www.sathguru.com lifesciences@sathguru.com Size of the Indian pharmaceutical industry is anticipated to reach US\$55 bn by 2020 from US\$30 bn in 2015 at 13% CAGR. Anti-infectives, CVS and GI drugs dominate the market, and anti-diabetic, respiratory and urology segments are growing in excess of 25% y-o-y.

Continued International Expansion Will Drive Growth in Mid-Term

India is the largest supplier of generic drugs in the world and exports have been the major driver of growth for Indian pharmaceutical industry. US and Europe remain largest markets of focus but there is rising interest in key emerging markets such as LATAM, Russia & CIS, South Africa and MENA. There is significant appetite for inorganic growth and robust outbound acquisition activity is anticipated.





Domestic market expected to continue expanding, especially in chronic and lifestyle diseases

The domestic pharma market was close to US\$15 bn in 2015 and recorded growth of 12%. Double digit growth is expected to continue primarily due to increasing incidence of chronic diseases, demand for contemporary therapies to manage them, greater penetration of diagnostics and expanding healthcare access.

Key Industry Trends

Complex **Formulations**

- Required to expand small molecule generic portfolios into higher value and leaner competition products
- Need to build capabilities in alternative delivery forms and formulation platforms
- Growing focus on in-house development, in-licensing technologies and acquiring companies for complex injectables, controlled release dosage forms and inhalation platforms

Peptides and **Biosimilars**

- Peptides and increasingly critical to long term sustenance of generic companies owing to their accelerated uptake globally
- Indian biosimilar sector expected to grow at ~30% • Limited risk appetite and CAGR with several Indian firms investing in pipelines, particularly for onco-mAbs
- Key development and regulatory challenges remain in the evolving ecosystem, globally and in India

Novel Drugs and Proprietary Portfolio

- Biosimilars Overall limited engagement from Indian pharma in novel discovery development - very few companies with concerted investments
 - general preferences is for progressively incremental innovation engagement
 - Several companies making near term investments in lower risk re-formulated and re-purposed assets



Technology and Innovation Adoption Scenario

Factors propelling the innovation ecosystem

Hurdles remaining

Dearth of VC capital with appetite for product development risk

Most large companies apprehensive of shouldering risk of novel product development

Lack of experience in innovation advancement across the ecosystem

available for technology derisking in Comprehensive ventures efforts to nurture

Non-dilutive

funding

Larger companies now making moderate investments to enhance portfolios

Growth Drivers, Challenges and Outlook

Growth Drivers

innovation

across the ecosystem

engagement

- Increased healthcare access and purchasing power
- Increased pharma penetration into tier 2,3 cities and rural areas
- Global drug pricing pressures and India's low cost manufacturing advantage
- Portfolio strength of domestic manufactures to drive export into emerging markets
- Global, sustained vaccine leadership of domestic manufacturers and emerging biologics capabilities
- Evolving opportunity in peptides and biosimilars

Challenges

- Quality issues and increasing US FDA scrutiny
- Complex regulatory mechanism, with persistent need for regulatory efficiency and transparency
- Nascent innovation eco-system and reliance on generics
- Limited VC participation and dearth of risk capital to fund product development
- Increasing dependence of domestic manufacturers on intermediate and bulk imports from Asian countries threatening local manufacturing and limiting quality control

Increased healthcare access, improved medical infrastructure, higher insurance penetration and purchasing power are expected to drive the domestic market forward. Overall, the industry has most ingredients required to sustain double digit growth for several years to come, provided it has uncanny emphasis on quality and is supported by robust regulatory and export policies. Finally, incentivizing new drug discovery and development, and further nurturing the innovation eco-system will be critical to empower the industry with sustained competitive advantage and to empower India to deal with burgeoning burden of disease.





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