

India Biosimilar Market Analysis

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Abstracts

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As the number of patent expiries of biologic drugs is increasing, Indian companies are developing biosimilar manufacturing capabilities. Firms are developing their capabilities by either forming partnerships with R&D-intensive firms or outsourcing to upcoming Indian contract research organizations (CROs). Domestic manufacturers have a cost advantage (lower facility and development costs) than peers in developed countries. Moreover, Indian firms seem keen on repeating their successes achieved in developing and commercializing biosimilars. They are increasingly partnering with large multinational corporations for clinical trials, regulatory approval processes in the EU/US, and marketing to physicians as well as consumers.

Launching biosimilar products in India also provides firms with an advantage to develop their post-marketing safety and efficacy data. This is specifically significant for biosimilar products as even minor changes in manufacturing processes may lead to serious health issues. One of the key challenges regarding biosimilar products is immunogenicity. Studies that compare innovator biologics and biosimilars often report differences in aggregate levels, protein concentration, stability, conformational states, and impurity profiles. Nevertheless, the biosimilar market is still nascent to gauge which of these differences is significant in determining the safety and efficacy impacts.

The Indian biosimilar market includes product segments such as insulin, erythropoietin, GCSF, hormones, interferon alpha, thrombolytics, plasma proteins, vaccines, and others. Of these, insulin is the largest segment of the biosimilar market followed by erythropoietin and GCSF. In 2011, there were about 15 epoetin, 8 G-CSF and 4 insulin biosimilars available in the Indian market. The acceptability of biosimilars is higher in the domestic market. Biosimilar substitution is automatic and can take place as soon as a biosimilar is launched.

“India Biosimilar Market Analysis” research report by Kuick research gives detailed insight on various aspects related the biosimilar market in India like Market Overview, Biosimilar Pipeline Analysis, Biosimilar Development Capabilities of Indian Players, detailed insight into recently announce Guidelines for the Development & Marketing of Biosimilar and competitive landscape.

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