

The World Market for Biosimilars and the Potential for US Follow-on Biologics

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Abstracts

Biosimilars, or generic biologic drugs, are marketed around the world but still restricted in the U.S. This may soon change, and Kalorama Information has released this timely study of the market in Europe and other areas in the world and the possibility of a U.S. Market in the near future. As part of its research, this Kalormaa Information report provides the following

- Current market size and forecasts for biogenerics in Europe and Rest of World Markets

- Review of Marketed Biological Drugs with Expired Patents

- Review of Marketed Biological Drugs with Active Patents

- Profiles of the Major Competitors in biogenerics

- Discussion of FDA and EMEA regulatory activity

- Pending U.S. Legislation and Projections for US Markets

- Coverage of Patent Trends, Pricing Trends, Healthcare Spending, IP and ohter Relevant Issues and Trends

For purposes of study, Kalorama has focused on the market for products which have lost patent in key markets. Projections were made based on the progress that is occurring within the generic arena in terms of capabilities, capital, interest, and

development of biopharmaceuticals.

Kalorama has identified the biopharmaceuticals that have lost patent protection and are likely to be the first products that will be attempted by generic companies. Some of these products are relatively simple in structure (by biotech complexity) such as the insulins and human growth hormones, while others are extremely difficult to process.

There are a number of biopharmaceuticals that are identified as potential targets for generic development. Many of these biopharmaceutical patents have expired. Many of these products sport manufacturer sales of over \$10 billion, presenting a ripe opportunity for generic manufacturers. However, because many of these products demonstrate sales of over \$1 billion per year, it is anticipated that there will be considerable resistance from the biotech innovator companies in allowing generic capitalization and consequently approvals.

The information and analysis presented in this report are based on an extensive survey of senior management in the biogeneric drug industry. Background information was obtained from a comprehensive search of published literature and reports obtained from various government, business, medical trade, and international journals.

Key information from published literature was used to conduct interviews with over 42 industry executives and product managers to validate and obtain expert opinion on current and future trends in the psychotherapeutic industry. Interviews were also used to confirm and/or adjust market size, as well as in formulating market projections.

All market data pertains to the world market at the manufacturers' level. Data are expressed in current U.S. dollars. The geographic scope of the study is worldwide with particular emphasis on the United States and Europe.

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Cangene Corporation

Dr. Reddy's Laboratories Limited

Dragon Pharmaceuticals, Inc.

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Hospira, Inc.

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Microbix Biosystems, Inc.

Momenta Pharmaceuticals Inc

Phage Biotechnology Corp

Ranbaxy Laboratories Limited

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