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Global & USA BioSimilar Market Analysis to 2021; BioBetters, Erythropoietin (EPO), Human Growth Hormone (HGH), Granulocyte Colony-Stimulating Factor (G-CSF), Anti-Tumor Necrosis Factor (Anti-TNF), Monoclonal Antibodies (MAbs), Insulins, Interferons, Product Pipelines, Trends, Key Players, Regulations and Strategic Outlook.

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Abstracts

"Biosimilars are highly-similar versions of biological drugs that are indicated for cancer, kidney disorders and a wide range of autoimmune diseases. Originator biologics are the most expensive drugs in the pharmaceutical industry and many of them cost nearly $100,000 per patient per year. These expensive biologics impose a heavy financial burden on patients and healthcare systems, limiting easy access and optimal care. Patent protection for some of the biologics has already expired and many more are to lose patent rights between now and 2020. This has given an opportunity to biotechnology companies to develop and market biosimilars with a cost benefit of about 20% to 30%.

In order to gain a slice of the $190 billion worth of biologic’s market, many biotechnology companies have ventured into the biosimilar sector bringing out less-expensive copies of reference biologics. Biosimilars have been in the E.U. market since 2006 and less-regulated markets such as China, India, and South Korea have a number of biosimilars in their domestic markets. After a long delay, finally, the FDA took a historic decision to approve the first biosimilar Zarxio from Sandoz on March 6, 2015. The coming years will witness the flooding of large number of biosimilars into the U.S., which happens to be the largest market for biopharmaceuticals.

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This report provides a comprehensive overview of the size of biosimilars' market, the segmentation of the market, key players and the vast potential of therapies that are in clinical trials. On total, about 44 biosimilars are available in the global market and currently the E.U. is the major market with 19 approved biosimilars in use. A significant number of biosimilars are available in the markets of China, India, South Korea and Latin America. Biosimilars from these emerging countries are approved by a less-stringent approval pathway and therefore, the commercialization of their products is mostly confined to the domestic markets. The report describes how the long-awaited FDA approval of Zarxio from Sandoz (biosimilar for Amgen's Neupogen) in March 2015 is to transform the otherwise nascent market. The report includes:

An overview of biosimilars that includes differences between biologics; biosimilars and generics, definition of biosimilars by different agencies, barriers in developing biosimilars, cost of developing biosimilars.

A summary of regulatory pathways in various geographic regions.

Development of biosimilars in Europe, China, India, South Korea, Latin America and the sudden spurt in the development of biosimilars in the U.S.

A list of biosimilar developers in different geographic locations.

An overview of biobetters that includes regulatory considerations, differences between biosimilars and biobetters, various biobetters that are in developmental stages, and the companies with the largest biobetter pipeline.

An overview of approved biosimilars in the E.U., U.S., India, South Korea and Latin America.

The market impact of biosimilars on their reference biologics such as Epogen, Humira, Remicade, Neupogen, Neulasta, Enbrel, Rituxan, Herceptin, Avastin and Lantus through 2021.

The top ten biologics on the focus of biosimilar developers.

The five major classes of biologics and their biosimilar counterparts.

The current landscape of originators of biosimilars.

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Global market for biologics by region, through 2021.

Global market for biologics by indication, through 2021.

Global market for biologics by drug class, through 2021.

Global market for biosimilars by region, through 2021.

Global market for biosimilars by indication, through 2021.

Global market for biosimilars by drug class, through 2021.

Profiles of 95 biosimilar developers, their products in the market and their product pipeline.

A newsletter in the appendix gives the latest news of biosimilar sector as of February 2015.

1.3 Key Questions Answered in This Report

How do biologics, biosimilars and generics vary from each other?

What are the different quality, safety and efficacy assessment tests for biosimilars?

How much is being spent for developing a biosimilar molecule?

How many years does a biosimilar take to reach the commercial market?

How do regulatory pathways differ from region to region?

What is the need for biosimilars?

What are the different platforms for the development of biosimilars?

What is the success rate in the development of a biosimilar when compared to a biologic and generic?

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What are the most attractive target biologics for the development of biosimilars?

How many biosimilars are being developed for Avastin, Enbrel, Herceptin, Humira, Neulasta, and Rituxan, and what are they?

How many biosimilar MAbs are being developed and what are they?

How much can the U.S. save by the introduction of biosimilars, through 2024?

Which companies are involved in developing biosimilar MAbs in South Korea?

Who are the Indian players active in Indian biosimilar industry?

What are the biosimilar drugs being developed by the Indian biosimilar developers?

Name the biosimilars approved in the E.U., India, South Korea and Latin America?

What is the current utilization rate of biosimilars in the E.U. countries?

The biosimilars approved for use in Germany, Netherlands, U.K., South Korea, Japan, Latin America and India?

How far the markets of Epogen, Humira, Remicade, Neupogen, Neulasta, Enbrel, Rituxan, Herceptin, Avastin and Lantus will be affected by the entry of biosimilar counterparts?

What are the top ten biologics that have become the focus of biosimilar developers?

What are the five major classes of biologics that have attracted the attention of biosimilar developers and what are their current market shares?

What are the top ten biologic drugs from 2009 to 2014?

Which biologic drugs dominated the U.S. market, between 2010 and 2014?

How much is the Medicare Part B spending on biologics in the U.S.?

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What are the top-eight biologic drugs in the E.U. market?

How many biologics maintain absolute dominance in the German market?

What is the average cost of a biologic drug in the U.S.?

How did the market for biosimilars perform between 2007 and 2014?

How small is the market for biosimilars, when compared to that of biologics?

What favorable signs are there in the industry to hope for an accelerated growth for biosimilars?

What is the projected global and regional market for biosimilars from 2014 to 2021?

What is the projected market for biosimilars by major drug classes from 2014 to 2021?

Who are the market leaders in the biosimilar sector?

What was the market for biosimilars in the major E.U. countries between 2007 and 2013?

How much is the competition between biologics and biosimilars in the German market between 2007 and 2020?

What is the potential market for biosimilars in the U.S., through 2020?

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