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# Europe Biosimilars Market Opportunity Outlook 2020

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## Abstracts

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Burgeoning pressure on healthcare system has caused the regulators across the globe to look for suitable therapeutic options. Biologic drugs are commonly used for treatment of various diseases but they are costly and their alternative options are difficult to find. Biosimilars have come forth as new modality having lesser cost with equivalent therapeutic efficacy like biologics. They are introduced in market after patent expiry of biologics and Europe became the first market to allow commercialization of biosimilars. European Commission (EC) passed legislation in 2004 creating approval pathway (Directive 2001/83/EC Directive 2004/27/EC) for biosimilars. European Medicines Agency (EMA) approved first biosimilar in 2006, since then several biosimilars have been introduced in European market owing to applicability in numerous indications and higher cost arbitrage. In this way, European nations are expected to relieve burden from their healthcare system with the help of biosimilars.

Safety and efficacy are main concerns with biosimilars; EMA requires head-to-head comparison for ensuring pharmacological parameters. Ensuring similarity or high similarity in bioanalytical way decreases market winding time. Consequently, clinical trials could be conducted with higher confidence levels to ensure patient safety. Many biosimilars belonging to different categories for different indications has been introduced in past years. They have been able to erode profit margins of biologics in past decades. Wide acceptance could also be observed leading to higher prescription for biosimilars as compared to biologics. This scenario shows that biosimilars developers will have lots of commercialization opportunities in European market.

Biosimilars have been introduced for several disease categories offering myriad of options to the patients. Cancer supportive therapies have large consumer base due to which associated biosimilars are in high demand. Filgrastim and Erythropoietins

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biosimilars are one of the widely used products in European market. These well-established segments have numbers of products as compared to other disease categories. Biosimilar monoclonal antibodies are in high demand as they have high safety and efficacy along with minimized side effects. Their cost is also lesser as compared to biologic monoclonal antibodies. Besides this, biosimilar insulin has also been introduced which have capability to generate significant revenues. Biosimilar insulin has created as new segment due to which more biosimilar products are expected to enter in coming years. In this way, European biosimilars market shows diverse categories and opportunities to venture in newly developed segments.

Extrapolation of biosimilars is allowed after establishing significant comparability with reference biologics. Depending on quality profile they are approved by EMA and biosimilar developers have to submit Risk Management Plan (RMP). This measure ensures that biosimilars entering in European market are harmless. Biosimilar developers from developing countries find it difficult to enter in European market as their fall short of EMA's standards. On the other hand, outsourced biosimilars products showing compliance with EMA's norms are allowed for commercialization. In this way, biosimilar developers from under developing countries find Europe as a suitable market place. Their competitive prices and highly developed manufacturing capabilities have also contributed in growth of European biosimilars market.

"Europe Biosimilars Market Opportunity Outlook 2020" Report Highlight:

Europe Biosimilars Market Outlook

Europe Biosimilars Market Trend Analysis by Country

Introduction of Biosimilars in European Market by Segment

Clinical & Non Clinical Guidelines

Europe Biosimilar Clinical Pipeline by Country, Company, Indication & Phase

Europe Biosimilar Clinical Pipeline: 109 Biosimilars

Clinical Insight of Biosimilars Marketed in Europe

Marketed Biosimilars in Europe: 20 Biosimilars

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# Contents

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# List Of Figures

## LIST OF FIGURES



## COMPANIES MENTIONED

Alvotech, Allergan, Amgen, Biocad, Bio-Ker, BioXpress Therapeutics, Boehringer Ingelheim, Cerbios Pharma, Celltrion, Gedeon Richter, Genentech, Genexine, Glycotope, Harvest Moon Pharmaceuticals, Hospira, Janssen Biotech, LFB

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