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Biosimilars- Market Insight, Competitive Landscape and Market Forecast- 2027

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Abstracts

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Biosimilars Market By Product Class (Monoclonal Antibodies, Recombinant Hormone/Proteins, Anti-Inflammatory Agents, Immunomodulators, And Others), By Manufacturing Type (In-House And Outsourced/Contract), By Application (Autoimmune Diseases, Blood Disorders, Oncology, Infectious Diseases, And Others), by geography, is projected to expand at a significant CAGR till 2026 owing to the growing prevalence of various chronic disorders such as autoimmune disorders, cancers, among others and increasing demand for biosimilar drugs owing to their cost-effectiveness

The global biosimilars market was valued at USD 15.02 billion in 2020, growing at a CAGR of 21.54% during the forecast period from 2021 to 2026, in order to reach USD 48.00 billion by 2026. The escalating demand for biosimilars is primarily attributed to the rising burden of various chronic disorders such as diabetes, arthritis, cancers, among others across the globe. Moreover, an increase in demand for cost-effective biosimilar drugs by the patients is also anticipated to boost the market for biosimilars. Also, patent expiry of successful and blockbuster biologics in the forthcoming years and increasing R&D investments and product launches, among others is further expected to augment the global biosimilars market.

Biosimilars Market Dynamics:

The market for biosimilars is gaining momentum at present owing to the growing cases of various chronic disorders such as autoimmune inflammatory disorders (Rheumatoid Arthritis, Inflammatory Bowel Diseases, and more), diabetes, cancer, and others among the worldwide population. For instance, according to the data published by the World

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Health Organization (WHO) in the year 2021, approximately 14 million people were suffering from rheumatoid arthritis in the world in 2019.

In addition, according to the statistics published by GLOBOCAN in the year 2020, a total of 19,292,789 new cases of cancer were reported worldwide in the same year. Thus, the rising burden of various chronic disorders is likely to surge the demand for biosimilars in the forthcoming years. Biologics are the key components of many therapeutic regimens in cancer treatment. However, the high cost of biologic-based drugs limits the accessibility of cancer treatment for many patients especially in developing countries where healthcare resources are limited. Biosimilars with biological activity comparable to their corresponding reference biologic drugs are often cost-effective and provide enhanced treatment accessibility for the target population.

Furthermore, the rise in patent expiry of various blockbuster biologics in the upcoming years is also expected to raise the market for biosimilars during the forecasted period. For instance, Avastin (Bevacizumab), a monoclonal antibody drug developed by Roche for the treatment of various cancers such as breast cancer, cervical cancer, colorectal cancer, and others lost its market exclusivity in the US in the year 2019 which opened the way for biosimilar players. For instance, in June 2019, Pfizer received the US FDA approval for its oncology biosimilar, ZIRABEV™ (BEVACIZUMAB-BVZR). Also, in July 2019, Amgen and Allergan plc (now a part of Abbvie Inc.) launched MVASI™ (bevacizumab-awwb), a biosimilar to Avastin® (bevacizumab) in the US market.

Moreover, rising product approvals of the biosimilars are also anticipated to boost the market for biosimilars during the forecasted period. For instance, on September 17, 2021, FDA approved the Byooviz (ranibizumab-nuna) as the first biosimilar to Lucentis (ranibizumab injection) developed by Samsung Bioepis for the treatment of several eye diseases and conditions, including neovascular (wet) age-related macular degeneration (nAMD).

Also, rising government initiatives and investments in educating prescribers, pharmacists, and consumers on the benefits of using biosimilar medicines will contribute to the biosimilars market growth.

Thus, all the aforementioned factors are expected to augment the global market for biosimilars during the forecasted period.

However, the high-cost involvement and complexities in manufacturing are likely to impede the market for biosimilars.

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Also, the unprecedented COVID-19 pandemic has had a substantial impact on the biologics market. This is because the pandemic had imposed a great challenge to the pharmaceutical manufacturers focused on developing biosimilars. Moreover, the reduction in the approval of non-COVID drugs and therapeutics during the pandemic is projected to delay the product approval process as well as launches, thus stagnating the market growth. Also, postponement of most of the clinical trials to minimize the infection transmission among the participants and to combat the pandemic situation led to the slow pace in research and development activities of the pipeline products. Furthermore, the implementation of logistical restrictions across the globe resulted in disruption in the supply chain of raw materials, and others which had an impact on biosimilar production. However, owing to the launch of vaccines and mass vaccination drive in different regions of the world, the biosimilar market is expected to regain normalcy in the post-pandemic period as all the facilities are expected to work normally.

Biosimilars Market Segment Analysis:

Biosimilars Market by By Product Class (Monoclonal Antibodies, Recombinant Hormone/Proteins, Anti-Inflammatory Agents, Immunomodulators, and Others), By Manufacturing Type (In-House and Outsourced/Contract), By Application (Autoimmune Diseases, Blood Disorders, Oncology, Infectious Diseases, and Others), and By Geography (North America, Europe, Asia-Pacific, and Rest of the World).

In the biosimilars product class segment, the monoclonal antibodies are anticipated to hold a significant market during the forecasted period. This is because monoclonal antibodies (mAbs) based biosimilar are increasingly used for a broad category of disorders including oncology, immunology, and others.

Moreover, rising company investments to ameliorate the production of mAbs biosimilars are also expected to propel the segmental market of the global biosimilars market. For instance, in the year 2020, the laboratory mAbxience, a part of Insud Pharma, inaugurated a new biosimilar monoclonal antibody plant in Gar?n, Buenos Aires (Argentina). These drugs are used in the treatment of oncological and autoimmune diseases such as rheumatoid arthritis.

In addition, shifting manufacturers' focus towards developing of mAbs biosimilars will also contribute to the segmental market growth in the upcoming years. For instance, Shanghai Biomabs Pharmaceutical Co., Ltd. commenced a clinical trial to evaluate the efficacy and safety of cmab807 treatment compared with Prolia® in Chinese

postmenopausal women with osteoporosis at high risk of fracture in the year 2021 which is expected to complete by the year 2023.

Thus, all the above-mentioned factors are likely to spur the mAbs biosimilar market during the forecasted period.

North America is expected to dominate the overall Biosimilars Market:

Among all the regions, North America is expected to hold a major share in the overall biosimilars market during the forecasted period. This domination is owing to the rising burden of the population in the region suffering from various chronic disorders, and the presence of an effective reimbursement scenario for biosimilars in the region. Moreover, the presence of key market players such as Pfizer, Amgen, Eli Lilly, among others active in developing biosimilars is also expected to increase the market for biosimilars in the region.

For instance, in the US, as per the Crohn's and Colitis Foundation 2018 data, approximately 1.6 and 3.1 million Americans suffer from Inflammatory Bowel Disease (IBD) in the same year. In addition, as per the stats revealed by the National Diabetes Statistics Report 2020, about 34.2 million Americans were suffering from diabetes in the same year. Therefore, the rising target population in the region is expected to bolster the demand for biosimilars thereby propelling the market for biosimilars in the country.

Also, in July 2018, the US FDA released the Biosimilars Action Plan to promote and enhance the development of biosimilars, potentially reducing the costs for patients and payors. Thus, such initiatives by the government organizations in the region will contribute to the market growth of biosimilars.

Furthermore, strategic business activities by the key players such as collaboration, acquisitions for market expansion, and product approvals & launches will also drive the market for biosimilars in the region.

For instance, on September 30, 2020, Shanghai Henlius Biotech, Inc. entered into a collaboration with Accord Healthcare Inc. (Accord US), according to which Henlius will grant an exclusive license to Accord US to develop and commercialize HLX02 (trastuzumab biosimilar in the United States of America and Canada.

Also, on December 17, 2020, Amgen received the US FDA approval for RIABNI™ (rituximab-arrx), a biosimilar to Rituxan® (rituximab), for the treatment of adult patients

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with Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis), and Microscopic Polyangiitis (MPA).

Additionally, the APAC region has future potential for the biosimilars market. This is due to the presence of major regional players such as Dr. Reddy’s Laboratories Ltd., Biocon Limited, Fujifilm Kyowa Kirin Biologics Co., Ltd., among others in the region. Moreover, rising approvals of biosimilars in different countries of the APAC region will further contribute to the regional biosimilars market in the forthcoming years, For instance, on June 29, 2020, Fujifilm Kyowa Kirin Biologics received manufacturing and marketing approval (MMA) in Japan for Adalimumab Biosimilar which is the first approved adalimumab biosimilar in Japan to AbbVie Inc's Humira®. Also, on July 20, 2021, Sorrento Therapeutics’ partner Mabpharm Ltd received approval of its New Drug Application for its infliximab biobetter antibody in China. Moreover, the rising population suffering from chronic diseases and government initiatives to raise awareness regarding biosimilars, among others will also propel the biosimilar market in the region in the upcoming years.

Biosimilars Market Key Players:

Some of the key market players operating in the Biosimilars market include Pfizer Inc., Dr. Reddy’s Laboratories Ltd., Amgen, Inc., Eli Lilly and Company, Novartis AG, Bioeq AG, Fresenius SE & Co. KGaA, STADA Arzneimittel AG, Gedeon Richter PLC, Celltrion Healthcare Co., Ltd., Samsung Bioepis. (Samsung Biologics), Coherus BioSciences, Viatris Inc., Shanghai Henlius Biotech, Inc., Biocon Limited, Biocad, mAbxience, Fujifilm Kyowa Kirin Biologics Co., Ltd., Alvotech, Sanofi, Senju Pharmaceutical Co., Ltd., and others.

Recent Developmental Activities in the Biosimilars Market:

In September 2021, Senju Pharmaceutical Co., Ltd. received approval for the marketing of the ophthalmic VEGF inhibitor “Ranibizumab BS intravitreal injection kit 10 mg/mL ‘Senju’” in Japan.

In June 2021, Teva Pharmaceutical Industries Ltd. and Bioeq AG ('Bioeq') entered into a strategic partnership for the exclusive commercialization of Bioeq's FYB201, a biosimilar candidate to Lucentis® (ranibizumab) in Europe, Canada, Israel, and New Zealand.

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In March 2021, Cipla Limiteds' subsidiary, Cipla Gulf expanded its partnership with Alvotech for the marketing and distribution of four biosimilar medicines in Australia and New Zealand. As part of this strategic alliance, Cipla Gulf will be responsible for the commercialization of patented biosimilars of the biologic medicine brands, Aflibercept (Eylea®), Ustekimumab (Stelara), Denosumab (Prolia, Xgeva®), and Golimumab (Simponi®) developed and manufactured by Alvotech.

Key Takeaways from the Biosimilars Market Report Study

Market size analysis for current market size (2020), and market forecast for 5 years (2021-2026)

The effect of the COVID-19 pandemic on this market is significant. To capture and analyze suitable indicators, our experts are closely watching the Biosimilars market.

Top key product/services/technology developments, merger, acquisition, partnership, joint venture happened for last 3 years

Key companies dominating the Global Biosimilars Market.

Various opportunities available for the other competitor in the Biosimilars Market space.

What are the top-performing segments in 2020? How these segments will perform in 2026.

Which are the top-performing regions and countries in the current market scenario?

Which are the regions and countries where companies should have concentrated on opportunities for Biosimilars market growth in the coming future?

Target Audience who can be benefited from the Biosimilars Market Report Study

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Biosimilars providers

Research organizations and consulting companies

Biosimilars-related organization, association, forum, and other alliances

Government and corporate offices

Start-up companies, venture capitalists, and private equity firms

Distributors and Traders in Biosimilars

Various End-users who want to know more about the Biosimilars Market and the latest technological developments in the Biosimilars market.

Frequently Asked Questions for the Biosimilars Market:

1. What are Biosimilars?

Biosimilar is a biological drug that is similar to, or nearly identical to, an existing FDA-approved reference biologic product. A biosimilar has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.

2. What is the market for Global Biosimilars?

The global biosimilars market was valued at USD 15.02 billion in 2020, growing at a CAGR of 21.54% during the forecast period from 2021 to 2026, in order to reach USD 48.00 billion by 2026.

3. What are the drivers for the Global Biosimilars?

The major factors driving the demand for Biosimilars are the growing prevalence of various chronic disorders such as cancer, diabetes, and others. In addition, the increase in product approvals, rising patent expiry of biologics, and rising government initiatives for raising awareness regarding biosimilars, among others are also expected to augment the global biosimilars market.

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4. What are the key players operating in Global Biosimilars?

Some of the key market players operating in the Biosimilars market include Pfizer Inc., Dr. Reddy's Laboratories Ltd., Amgen, Inc., Eli Lilly and Company, Novartis AG, Bioeq AG, Fresenius SE & Co. KGaA, STADA Arzneimittel AG, Gedeon Richter PLC, Celltrion Healthcare Co., Ltd., Samsung Bioepis. (Samsung Biologics), Coherus BioSciences, Viatris Inc., Shanghai Henlius Biotech, Inc., Biocon Limited, Biocad, mAbxience, Fujifilm Kyowa Kirin Biologics Co., Ltd., Alvotech, Sanofi, Senju Pharmaceutical Co., Ltd., and others.

5. Which region has the highest share in the Biosimilars market?

Among all the regions, North America is expected to hold a major share in the overall biosimilars market during the forecasted period, 2021-2026. This domination is owing to the rising burden of the population in the region suffering from various chronic disorders, and the presence of an effective reimbursement scenario for biosimilars in the region. Moreover, the presence of key market players such as Pfizer, Amgen, Eli Lilly, among others active in developing biosimilars is also expected to increase the market for biosimilars in the region.

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