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Biosimilar Market Report by Molecule (Infliximab, Insulin Glargine, Epoetin Alfa, Etanercept, Filgrastim, Somatropin, Rituximab, Follitropin Alfa, Adalimumab, Pegfilgrastim, Trastuzumab, Bevacizumab, and Others), Indication (Auto-Immune Diseases, Blood Disorders, Diabetes, Oncology, Growth Deficiency, Female Infertility, and Others), Manufacturing Type (In-house Manufacturing, Contract Manufacturing), and Region 2024-2032

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Abstracts

The global biosimilar market size reached US$ 21.2 Billion in 2023. Looking forward, IMARC Group expects the market to reach US$ 164.5 Billion by 2032, exhibiting a growth rate (CAGR) of 25.1% during 2024-2032. The upcoming expiry of patents on blockbuster biologic drugs, growing awareness about the efficacy and cost-effectiveness of biosimilars, rising prevalence of chronic diseases worldwide, and continual advancements in biopharmaceutical manufacturing technologies are some of the major factors propelling the market.

Biosimilars are biological products that are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product. They are developed to have the same mechanism of action, route of administration, dosage form, and strength as the original product. While they are not identical to their reference products due to their complex nature and production methods, they maintain comparable safety, purity, and potency. These biologic drugs offer a more affordable alternative to high-cost reference biologics, creating competition, and making treatment more accessible for patients. Their introduction in the market is subject to rigorous

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testing and stringent regulatory scrutiny to ensure therapeutic equivalence and patient safety. In recent years, biosimilars have gained immense traction biosimilars in different therapeutic areas such as oncology, diabetes, and autoimmune diseases.

One of the key factors driving the market is the upcoming expiry of patents for several blockbuster biologics, which has opened the field for biosimilars, creating ample opportunities for market expansion. As biosimilars are less expensive alternatives to costly biologic therapies, they offer significant potential for healthcare cost savings, making them appealing for healthcare systems and patients. This, coupled with the rising global burden of chronic diseases including cancer, diabetes, and autoimmune disorders, where biologics play a crucial role in management, is also augmenting the product demand. In addition to this, various regulatory bodies such as the FDA and EMA have streamlined the approval pathways for biosimilars, encouraging their development and market entry. Moreover, the rapid globalization of biosimilar companies looking to expand their footprint to unexplored markets. Besides this, continual innovations in biopharmaceutical manufacturing technologies have made it feasible to produce biosimilars with high efficacy and safety, further driving the market growth.

Biosimilar Market Trends/Drivers:
Upcoming Patent Expiry of Blockbuster Drugs

The expiry of patents on branded biologics is one of the key factors driving the growth of the market. Biologics are often protected by robust patent portfolios that prevent the entry of competing products for extended periods. However, once these patents expire, it opens the door for companies to develop and market comparable, more affordable alternatives. Over the next few years, multiple blockbuster biologics with billions in annual sales are set to lose patent protection. The end of these patent protections, therefore, represents a massive opportunity for manufacturers to bring their alternatives to market and gain a substantial market share, catalyzing the market growth.

Cost-Effectiveness

Biosimilars are less expensive to produce than their reference biologics, mainly due to reduced research and development (R&D) costs, as manufacturers do not need to repeat all the original clinical trials that were done for the reference product. Therefore, biosimilars can be priced significantly lower, offering an affordable alternative to often costly biologic therapies. This cost-effectiveness is particularly appealing for healthcare systems striving to manage increasing healthcare costs and for patients who may

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struggle with the high cost of biologic therapies. Furthermore, in emerging markets where biologic therapies may have previously been unaffordable, biosimilars can facilitate easier access to essential treatments.

Increase in Prevalence of Chronic Diseases

The prevalence of chronic diseases such as cancer, autoimmune disorders, and diabetes is on the rise worldwide. These conditions typically require long-term treatment with biologics, fueling the demand for these drugs. As biosimilars offer similar efficacy and safety profiles to the original biologics but at a lower cost, their use in the treatment of these chronic diseases is increasingly becoming the preferred choice. For instance, the rising incidences of diseases, including rheumatoid arthritis and psoriasis, which are managed with biologic drugs like tumor necrosis factor inhibitors, presents a large market for biosimilars of these drugs. As the global burden of chronic diseases continues to grow, it is anticipated that the product demand will similarly increase, propelling the market growth.

Biosimilar Market Segmentation:
IMARC Group provides an analysis of the key trends in each segment of the global biosimilar market report, along with forecasts at the global and regional levels from 2024-2032. Our report has categorized the market based on molecule, indication and manufacturing type.

Breakup by Molecule:

Infliximab
Insulin Glargine
Epoetin Alfa
Etanercept
Filgrastim
Somatropin
Rituximab
Follitropin Alfa
Adalimumab
Pegfilgrastim
Trastuzumab
Bevacizumab
Others

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Infliximab represents the largest market segment

The report has provided a detailed breakup and analysis of the market based on the molecule. This includes Infliximab, Insulin Glargine, Epoetin Alfa, Etanercept, Filgrastim, Somatropin, Rituximab, Follitropin Alfa, Adalimumab, Pegfilgrastim, Trastuzumab, Bevacizumab, and others. According to the report, infliximab accounted for the majority of the share in the market.

Infliximab, a monoclonal antibody, is used for the treatment of several chronic conditions such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, plaque psoriasis, and ulcerative colitis. A high prevalence of these conditions worldwide has augmented the demand for effective treatments. Moreover, the wide range of indications leads to a large patient population that could potentially benefit from infliximab.

The original reference product, Remicade, has been on the market for a long time, with a well-established efficacy and safety profile. Once its patent expired, the entry of infliximab biosimilars offered a more cost-effective treatment option for these chronic conditions. Furthermore, the relatively earlier patent expiry of Remicade compared to other biologics has significantly contributed to its widespread popularity. Besides this, the manufacturing process and formulation for monoclonal antibodies such as infliximab are now well-established, facilitating the development and production of biosimilars, thereby propelling the segment growth.

Breakup by Indication:

Auto-Immune Diseases
Blood Disorder
Diabetes
Oncology
Growth Deficiency
Female Infertility
Others

Auto-immune diseases dominate the market

The report has provided a detailed breakup and analysis of the market based on the indication. This includes auto-immune diseases, blood disorders, diabetes, oncology, growth deficiency, female infertility, and others. According to the report, auto-immune

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diseases represented the largest segment.

Autoimmune diseases include conditions such as rheumatoid arthritis, psoriasis, and inflammatory bowel disease, which are prevalent worldwide, affecting millions of people. This high prevalence results in a substantial increase in the demand for effective treatments. These diseases are typically chronic, requiring long-term treatment, leading to a consistent demand for the associated therapies. Over the years, biologics have revolutionized the treatment of numerous autoimmune diseases, offering improved control and prognosis. Many of these biologics have now lost or are losing patent protection, opening the way for biosimilars. Additionally, the original biologics used to treat autoimmune diseases can be expensive, placing a financial burden on healthcare systems and patients. Since biosimilars offer a more affordable alternative, they are becoming the preferred choice for patients and healthcare professionals. Furthermore, the increasing acceptance of biosimilars among physicians, patients, and healthcare systems for treating autoimmune diseases owing to their similar efficacy and safety profiles to the reference biologics is fueling the growth of this segment.

Breakup by Manufacturing Type:

In-house Manufacturing
Contract Manufacturing

In-house manufacturing accounts for the majority of the market share

The report has provided a detailed breakup and analysis of the market based on the manufacturing type. This includes in-house and contract manufacturing. According to the report, in-house manufacturing represented the largest segment.

In-house manufacturing allows complete control over the product quality, which is essential for biosimilars. Given the complexity of biologics and the strict regulations surrounding their manufacture, companies usually prefer to handle production themselves to ensure high standards are met. Moreover, biologic manufacturing processes often involve proprietary methods and technologies. In-house production helps protect these trade secrets, making it the preferred choice of manufacturing type. While the initial setup cost may be high, maintaining production in-house can significantly reduce costs per unit over time. Also, in-house manufacturing enables companies to minimize the risk of supply chain disruptions, ensuring a consistent supply of their products while facilitating flexibility and agility in production, including making adjustments or adaptations to the product or process as needed.

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Breakup by Region:

Europe
Germany
France
Italy
Spain
United Kingdom
Rest of Europe
United States
Japan
India
South Korea
Others

Europe exhibits a clear dominance in the market

The report has also provided a comprehensive analysis of all the major regional markets, which include Europe (Germany, France, Italy, Spain, the United Kingdom, and Rest of Europe); the United States, Japan, India, South Korea, and Others. According to the report, Europe accounted for the largest market share.

Europe held the biggest share in the market since the region has a supportive regulatory environment, allowing several biosimilars to enter the European market well before other regions. This early start enabled Europe to gain a significant share of the market. Furthermore, the European Medicines Agency (EMA) has been a forerunner in creating a clear and supportive regulatory framework for the approval of biosimilars since 2005, earlier than many other regions. This early framework encouraged the development and marketing of biosimilars in the region. Various European countries have nationalized healthcare systems focused on cost-containment. Since biosimilars offer comparable clinical results to original biologics but at lower costs, they have become an attractive option in these settings. In addition to this, Europe has a high prevalence of diseases treated with biologics, such as autoimmune conditions and cancers. This high demand is supporting the growth of the market in the region. Apart from this, the increasing awareness and acceptance of biosimilars among healthcare professionals and patients in Europe has fueled their uptake, contributing to the market growth.

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Competitive Landscape:
The market is experiencing a rise in strategic initiatives by key players aimed at capturing a larger share of the market. Companies are investing heavily in research and development (R&D) activities to introduce new biosimilars and improve their manufacturing processes. Numerous vendors are entering into strategic alliances, partnerships, and licensing deals to leverage the expertise of other companies and speed up the development, production, and marketing of their biosimilars. Besides this, several industry players are seeking regulatory approval for their biosimilars in new geographic markets to expand their global footprint. To build trust and confidence in their biosimilars, the leading manufacturers are conducting post-marketing surveillance studies to confirm the long-term safety and efficacy of their products. We also expect the market to witness a surge in product innovations, launch of new patient support programs, and rise in mergers and acquisitions (M&As) among key players to drive healthy competition within the domain during the forecast period.

The report has provided a comprehensive analysis of the competitive landscape in the market. Detailed profiles of all major companies have also been provided. Some of the key players in the market include:

Sandoz International GmbH
Pfizer Inc.
Teva Pharmaceutical Industries Limited
Celltrion Inc.
Biocon Limited
Samsung Biologics
Amgen, Inc.
Dr. Reddy's Laboratories Limited
Stada Arzneimittel Ag

Recent Developments:
In Jan 2023, Amgen Inc. announced that AMJEVITA (adalimumab-atto), a biosimilar to Humira (adalimumab), is now available in the United States. AMJEVITA was the first biosimilar to Humira approved by the U.S. Food and Drug Administration (FDA), in 2016.
In October 2022, Biocon Biologics Ltd., a subsidiary of Biocon Ltd., announced that it has entered into a strategic out-licensing agreement with Japanese pharmaceuticals company Yoshindo Inc. Under the terms of this deal, Yoshindo will get exclusive commercialization rights in the Japanese market for two of the company’s pipeline biosimilar assets, bUstekinumab and bDenosumab.

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In June 2020, Pfizer Inc. received the approval from the United States (U.S.) Food and Drug Administration (FDA) for NYVEPRIA (pegfilgrastim-apgf), a biosimilar to Neulasta (pegfilgrastim). This biosimilar is indicated to lower the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Key Questions Answered in This Report

1. What was the size of the global biosimilar market in 2023?
2. What is the expected growth rate of the global biosimilar market during 2024-2032?
3. What are the key factors driving the global biosimilar market?
4. What has been the impact of COVID-19 on the global biosimilar market?
5. What is the breakup of the global biosimilar market based on the molecule?
6. What is the breakup of the global biosimilar market based on the indication?
7. What is the breakup of the global biosimilar market based on the manufacturing type?
8. What are the key regions in the global biosimilar market?
9. Who are the key companies/players in the global biosimilar market?

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