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Biosimilars Market based on by Material Type (Silicon, Germanium, Transition Metal Oxides, Gold), Industry (Consumer Electronics, Automotive, Aviation, Energy, Medical Devices), Regional Outlook– Global Forecast up to 2032

https://marketpublishers.com/r/B8149010AD20EN.html
Date: March 2024
Pages: 118
Price: US$ 4,500.00 (Single User License)
ID: B8149010AD20EN

Abstracts

A number of significant industry participants place a high priority on the development of biosimilars. By December 2022, 25 biosimilars had been introduced in the US and 40 had received FDA approval. FDA approvals fell off dramatically during the COVID-19 pandemic, but they resumed in 2022 with the approval of seven new biosimilars. No biosimilars were approved in 2022 citing new reference items; the seven biosimilars that were approved in 2022 all referenced products that had previously received approval as biosimilars. In addition, four additional products were introduced in 2022, including the first two biosimilar versions of Lucentis (ranibizumab). Furthermore, the FDA approved Rezvoglar (referring to Lantus (insulin glargine)) and Cimerli (referring to Lucentis (ranibizumab)) as two novel interchangeable biosimilars in 2022. The number of development programs taking part in the FDA's Biosimilar Development Program has increased even if there was a general decrease in approvals between 2020 and 2021. There were about 60–70 biosimilars undergoing pipeline research as of April 2023. (Clinical.gov); in three to four years, half of them will be introduced. Growing biosimilar approvals will provide access to a larger range of treatments and propel market expansion.

Because developing nations sometimes have laxer regulations, biosimilar firms can find substantial development prospects in the Asia Pacific, Latin America (LATAM), and Middle East markets. Their legislative processes, payer views, pricing, affordability, and competitive landscapes are different from those of established markets. Because of their cheap labor and laboratory setup costs as well as their abundance of qualified

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personnel, China and India are viewed as desirable locations for global biosimilar development and manufacturing companies to outsource their research and development (R&D). Important market participants have shown a great deal of interest in this.

Asia Pacific's market is a vibrant and quickly changing sector, driven by a few major firms like Dr. Reddy's Laboratories (India), Celltrion (South Korea), Samsung Bioepis (South Korea), Biocon, and Shanghai Henlius Biotech (China). These businesses have been crucial to the development and implementation of biosimilars in the area, and it is anticipated that they will continue to spur innovation and expansion in the years to come.

Research Methodology:

After secondary research provided a fundamental understanding of the worldwide Biosimilars Market scenario, extensive primary research was carried out. A number of primary interviews were carried out with industry experts from the supply and demand sides, including C- and D-level executives, product managers, and marketing and sales managers of major manufacturers, distributors, and channel partners from tier 1 and tier 2 companies offering Biosimilars Market, as well as personnel from academia, research, and CROs. These interviews were conducted across five major regions: North America, Europe, Asia Pacific, and the Rest of the World (Latin America & the Middle East & Africa). Participants from the supply-side and demand-side participated in about 70% and 30% of the primary interviews, respectively. Through the use of questionnaires, emails, online surveys, in-person interviews, and phone interviews, this main data was gathered. The primary participants share is given below:

The segmentation coverage of the study is provided below.

Biosimilars Market based on Product

Recombinant Non-glycosylated Proteins

Recombinant Glycosylated Proteins

Biosimilars Market based on Application

Oncology

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Blood Disorders

Growth Hormonal Deficiency

Rheumatoid Arthritis

Chronic and Autoimmune Disorders

Others

Biosimilars Market based on Geography

North America

US

Canada

Europe

Germany

UK

France

Italy

Spain

Rest of Europe (RoE)

Asia Pacific (APAC)

China

Japan

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India

Australia

South Korea

Rest of Asia Pacific (RoAPAC)

Latin America (LATAM)

Brazil

Argentina

Rest of South America

Middle East and Africa (MEA)

UAE

Turkey

Saudi Arabia

South Africa

Rest of Middle East & Africa

The market is divided into two segments based on the product: glycosylated and recombinant non-glycosylated proteins. The highest revenue share of 54.9% was generated by the recombinant non-glycosylated proteins category in 2022. This can be attributed to the growing number of regulatory approvals for biosimilars by different governments. For example, the U.S. Food and Drug Administration has already approved biosimilars for the reference product Humira (adalimumab), which is a significant medication that helps treat rheumatoid arthritis (RA), under the names Yuflyma (adalimumab-aaty) and Idacio (adalimumab-aacf), in May 2023 and December 2022, respectively. Furthermore, the growing incidence of long-term illnesses like

diabetes may propel the market expansion in this particular sector.

The International Diabetes Federation's Atlas 2021 states that 537 million adults worldwide have diabetes, whereas the American Heart Association's data shows that the age-adjusted prevalence rate of cardiovascular disease was 7354.1 per 100,000 individuals in 2020. Over the course of the projection period, the recombinant glycosylated proteins segment is anticipated to rise at the quickest CAGR of 14.9%. Since the patents on biologics like erythropoietin (EPO), Humira, and Neulasta are about to expire, a number of companies are vying to enter the biosimilars market, which has the potential to dramatically accelerate market growth by providing patients with better access to medicines. Additionally, as a result of technological developments in the recombinant glycosylated proteins market, a number of therapeutics, including soluble receptors and modified proteins, have emerged. These developments have the potential to further propel the market's expansion.

The market has been divided into segments based on applications, including blood disorders caused by growth hormone deficiency, rheumatoid arthritis, cancer, and chronic and autoimmune disorders. Because autoimmune diseases are becoming more common and well-known, the chronic and autoimmune disorders category had the highest revenue share in 2022—roughly 21.6%. According to the National Institute of Environmental Health Sciences, autoimmune illnesses affect over 24 million people in the United States. Over the course of the forecast period, the oncology application category is anticipated to rise at the quickest CAGR of 17.0%.

Globally rising cancer cases are anticipated to be the main factor driving market expansion. As per the data disclosed by the World Cancer Research Fund International, over 18.1 million individuals were afflicted with cancer in 2020. The creation of biosimilars for cancer treatment can offer patients in low- and middle-income nations—where cancer patient mortality rates are higher—affordable therapeutic alternatives. Improving the availability of reasonably priced care can help the market grow even more.

Due to the existence of significant companies and a robust regulatory environment for biosimilars, North America dominated the market in 2022 with the biggest revenue share of 40.4%. Furthermore, biosimilars are reasonably accessible in the area. The U.S. Generic Biosimilars Saving Report 2021 states that there have been 20 biosimilars introduced and 31 approved in the country, adding up to around 10 million therapy days. The price of the 20 biosimilars that were introduced in the United States is 30% less than that of the biologics, which has led to a decrease in the cost of both biosimilars and

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biologics. It is anticipated that this cost reduction will give biosimilars in this area even more momentum.

Over the course of the projection period, Asia Pacific is anticipated to develop at the fastest CAGR of 18.4%. Important companies including Pfizer Inc., Celltrion, Biocon, and Dr. Reddy's Laboratories have made it easier for biosimilars to be developed and sold in this area. For example, Dr. Reddy's Laboratories introduced a biosimilar of Roche's Avastin in India in August 2019, making it easier to treat a variety of tumors. Biosimilars are predicted to rise rapidly in this region due to similar market developments and rising health care costs. The World Bank data, which was collected in April 2023, indicates that China's health expenditures as a percentage of GDP climbed from 4.98% in 2015 to 5.59% in 2020.

This report illustrates the most vital attributes of the Biosimilars Market, which are driving and providing opportunities.

This research gives an in-depth analysis of the Biosimilars Market growth on the basis of several segments in the market.

This report presents the predictions of the past and present trends of the Biosimilars Market.

This study also presents the competitive analysis, such as key strategies and capabilities of major players of the Biosimilars Market.

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