

Europe Biosimilars Market Forecast to 2030 - Regional Analysis By Disease Indication (Cancer, Diabetes, Autoimmune Disease, and Other Disease Indication), Route of Administration (Intravenous, Subcutaneous, and Others), Drug Class (Granulocyte Colony-Stimulating Factor, Insulin, TNF Blockers and Monoclonal Antibodies, and Others), Distribution Channel (Hospital Pharmacies, Compounding Pharmacies, Retail Pharmacies, and Online Pharmacies), and Region

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## Report description:

The Europe biosimilars market is expected to grow from US\$ 10,344.86 million in 2022 to US\$ 1,15,125.91 million by 2030; it is estimated to grow at a CAGR of 35.1% from 2022 to 2030.

The report highlights trends prevailing in the market and factors driving the market growth. The market growth is attributed to the increasing prevalence of chronic diseases and rising approvals of biosimilars. Additionally, collaborations for biosimilars and clinical trials is likely to emerge as a significant trend in the market during the forecast period. However, high cost involvement and complexities in biosimilar product manufacturing hinders market growth during the forecast period 2022-2030.

Collaborations for Biosimilars and Clinical Trials Drives the Europe Biosimilars Market

Joint ventures and other collaboration models will help biosimilar medicine manufacturers maintain a competitive edge over rivals in the market in the coming years.

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By collaborating with other companies planning to research, launch, and market biosimilar drugs, biosimilar manufacturers can develop their products rapidly and launch products effectively in a way that overcomes patent risks and gains clinician and patient confidence in the product. Product development can be expedited by gaining local and foreign expertise, development platform access, and research and clinical trial funding.

Collaborating with a bigger biopharmaceutical manufacturer allows access to established manufacturing facilities. The collaboration can be done for outsourcing activities such as cell line development, biologics and biosimilar manufacturing, process scaling, and any required technology transfer.

There are long-term benefits from collaborations. They can make it easy to tender for future biosimilar production projects within the country and offer early and efficient product development and market penetration. In a sizeable market such as Europe, which has significant country-level diversity in healthcare policies and market dynamics, access to local knowledge obtained through such collaborations can also prove invaluable.

The immense potential of the biosimilars market has led to many recent, high-profile collaborations. A few instances are given below:

In June 2023, Samsung Biologics announced a strategic partnership with Pfizer for the long-term commercial manufacturing of Pfizer's multi-product portfolio. The agreement aims that Samsung Biologics will offer Pfizer additional capacity for large-scale manufacturing of a multi-product biosimilar portfolio encompassing oncology, inflammation, and immunology.

In May 2023, Sandoz, a Novartis division, announced a biosimilar collaboration with Evotec Biologics. The agreement covers developing and manufacturing multiple biosimilar medicines intended for rapid development and the subsequent manufacturing of multiple biosimilars. The development of biosimilars at the Evotec Biologics facility will ramp up under the collaboration in the next 12-18 months.

Thus, collaborations of manufacturers for biosimilar production and clinical trials will be the key trend in the biosimilar market during the forecast period.

Patent Expiry of Blockbuster Biologics Offers Lucrative Market Opportunity

Biologicals represent promising new therapies for previously incurable diseases and are becoming highly important in the pharmaceuticals market. However, patents for originator biologicals are expected to expire in the coming years.

Estimated patent and exclusivity expiry dates for best-selling biologicals are given in the following table .

Biologicals Expiry Month & Years

Avastin January 2022

Cyramza May 2023

Adcetris August 2023

Abthrax

☐ October 2024

Gazyva/Gazyvaro November 2024

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Darzalex∏May 2026

Ocrevus April 2027

Emgality September 2028

Hemlibra February 2028

Llumetri

March 2028

Imfinzi∏September 2028

Mylotarg

☐ April 2028

Imfinzi

September 2028

Mylotarg April 2028

Sylvant∏uly 2034

Source: Generics and Biosimilars Initiative (GaBI) Journal

The patent expiration and other intellectual property rights for originator biologicals will create a need to introduce new biosimilars in the future. As a result, competition among market players will surge in the industry in the coming years. Thus, the patent expiry of blockbuster biologics is expected to create lucrative opportunities for the biosimilar market during the forecast period.

Germany holds largest market share for the Europe biosimilars market from 2022-2030. Biosimilars introduce competition and increase the affordability of biologics, which ultimately deliver savings and value-added services to support patient care and the healthcare community. Healthcare professionals can treat more patients with high-quality biologics while reducing spending. For example, in Germany, according to Sandoz, the number of daily therapeutic doses of an anti-TNF medicine increased by 29% (from 17.18 to 22.18 million) after introducing biosimilars in 2022.

Germany has achieved acceptance of biosimilars with payers, providers, and patients as an integral part of appropriate medicine use. There is full reimbursement from a price set by the company, including immediate patient access to biosimilars. The structure of hospital tendering by multiple buying groups and separate hospital chains allows for competition among manufacturers to be maintained in Germany. For instance, in November 2018, the German Health Ministry introduced a draft bill on safety in the supply of pharmaceuticals. The Gesetz fur Mehr Sicherheit in der Arzneimittelversor-gung (GSAV) bill aims to provide a legal framework for the automatic substitution of biosimilars by pharmacists in Germany.

Due to the huge potential for cost savings, the German Health Ministry introduced a new law to increase the adoption of biosimilars. As few European Union (EU) countries allow pharmacist substitution of biosimilars, this would represent a significant change in practice, particularly for Germany. Additionally, in Germany, a law passed in 2019 foresees the automatic substitution of biosimilars in pharmacies beginning in 2022, provided the Federal Joint Committee (the highest decision-making body of the self-governance of health insurers and providers) has determined the interchangeability of the medicines in question, and the prescribing physician has not explicitly excluded it. Therefore, with the growing government initiatives for adopting biosimilars in

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Germany, the market is expected to grow.

Various organic and inorganic strategies are adopted by companies in the Europe biosimilars market. The organic strategies mainly include product launches and product approvals. Further, inorganic growth strategies witnessed in the market are acquisitions, collaborations, and partnerships. These growth strategies allow the market players to expand their businesses and enhance their geographic presence, thereby contributing to the overall market growth. Further, acquisition and partnership strategies help the market players strengthen their customer base and expand their product portfolios. A few of the significant developments by key players in the Europe biosimilars market are listed below.

International Diabetes Federation, European Medicine Agency, Centers for Disease Control and Prevention, Chinese Clinical Oncology, National Comprehensive Care Network are a few of the major primary and secondary sources referred to while preparing the report on the Europe biosimilars market.

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