

Herceptin Biosimilar Market Forecasts to 2032 – Global Analysis By Type (Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp) and Other Types), Dosage, Distribution Channel, Application, End User and By Geography

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Abstracts

According to Statistics MRC, the Global Herceptin Biosimilar Market is accounted for \$4.89 billion in 2025 and is expected to reach \$10.66 billion by 2032 growing at a CAGR of 11.77% during the forecast period. A biological medication that closely resembles trastuzumab (Herceptin), the original FDA-approved reference product, is known as a Herceptin biosimilar. Constructed from living cells, it blocks cell development by targeting the HER2 protein in some gastric and breast malignancies. Because biologics are complicated, they cannot be exactly replicated, but thorough testing guarantees that there are no clinically significant variations in potency, safety, or purity. Biosimilars increase patient access to essential cancer treatments by providing similar efficacy and side effect profiles, frequently at a cheaper cost.

Market Dynamics:

Driver:

Patent expiry of herceptin

It cleared the path for other pharmaceutical companies to create and market very identical versions once the patent protection expired. Significant market rivalry was instantly brought about by this flood of biosimilars, which is essential for market growth.

Consequently, increased competition lowers the cost of treatments based on trastuzumab. Reduced costs make these life-saving procedures more accessible and affordable for a larger number of patients worldwide. In the end, the primary facilitator that turns a monopolised market into a competitive environment is patent expiration.

Restraint:

High manufacturing complexity and regulatory challenges

Biosimilars require advanced biotechnological processes, making them difficult to replicate with consistent quality. Regulatory challenges further complicate market entry, as stringent guidelines demand extensive clinical trials to prove biosimilarity. Approval pathways vary across regions, adding additional hurdles for global commercialization. These barriers discourage new entrants and limit competition, slowing market growth. As a result, patients may experience reduced access to affordable alternatives.

Opportunity:

Rising incidence of breast and gastric cancers globally

The need for efficient HER2-targeted treatments, like as trastuzumab, inevitably rises as more people receive diagnoses. Biosimilars of Herceptin provide a vital, less expensive substitute for the pricey original medication. This cost-effectiveness increases patient access to life-saving care, especially in underdeveloped areas where healthcare finances are tight. Since a result, the market for Herceptin biosimilars is expected to develop significantly since the rising illness burden directly affects prescription volume and adoption.

Threat:

Strong brand loyalty and resistance from healthcare providers

Many experts and consumers favour well-known brands because they have faith in the dependability of the products and services. This devotion makes people less inclined to try out newer or different mobility alternatives. Furthermore, medical professionals frequently hesitate to suggest unknown brands out of concern for potential liability or patient unhappiness. Such opposition restricts new businesses' and creative designs' ability to enter the market. As a result, this hinders competition and delays the general development of the market.

Covid-19 Impact

The COVID-19 pandemic presented a mixed impact on the Herceptin biosimilar market. Initially, it caused supply chain disruptions, manufacturing slowdowns, and delays in clinical trials, particularly in early 2020. Reduced hospital visits and shifted healthcare priorities also led to a decline in oncology treatments. However, the pandemic concurrently highlighted the urgent need for cost-effective healthcare solutions. This spurred greater acceptance and adoption of biosimilars, including Herceptin biosimilars, as healthcare systems sought to manage financial burdens and increase access to essential medicines, ultimately accelerating their market penetration in the long term.

The herzuma (trastuzumab-pkrb) segment is expected to be the largest during the forecast period

The herzuma (trastuzumab-pkrb) segment is expected to account for the largest market share during the forecast period, due to intensified competition and driving down costs. As an FDA-approved biosimilar, it offers a proven, equally efficacious, and safe alternative to the reference product. Its widespread availability, particularly in markets like Japan where it has captured substantial share, increases patient access to vital HER2-targeted therapy. This competitive pressure encourages broader adoption of biosimilars, contributing to overall healthcare cost savings. Ultimately, Herzuma's presence fosters a more dynamic and accessible market for trastuzumab biosimilars globally.

The colorectal cancer segment is expected to have the highest CAGR during the forecast period

Over the forecast period, the colorectal cancer segment is predicted to witness the highest growth rate, due to the treatable patient population for trastuzumab. As Herceptin biosimilars offer a more affordable alternative to the originator drug, their use in HER2-positive colorectal cancer makes targeted therapy more accessible. This increased accessibility, coupled with rising colorectal cancer incidence and growing awareness of HER2 status in this indication, drives demand for biosimilars. Furthermore, research and clinical trials exploring trastuzumab's efficacy in other HER2-positive malignancies, including colorectal cancer, contribute to market expansion. Ultimately, the cost-effectiveness and broadened applicability of Herceptin biosimilars in colorectal cancer treatment foster significant market growth.

Region with largest share:

During the forecast period, the Asia Pacific region is expected to hold the largest market share due to rising incidence of HER2-positive cancers and expanding healthcare access. Local manufacturing capabilities in countries like India and China, along with streamlined regulatory pathways, have enabled faster product launches and greater market penetration. Cost-effective biosimilar alternatives are increasingly accessible to middle-income populations, supported by favorable regulations and reduced production costs. Growing awareness among healthcare professionals and patients, combined with the region's large population base, positions Asia Pacific as the most dynamic and rapidly expanding market for Herceptin biosimilars in the coming years.

Region with highest CAGR:

Over the forecast period, the North America region is anticipated to exhibit the highest CAGR, owing to a high prevalence of breast cancer, robust healthcare infrastructure, and well-established regulatory frameworks for biosimilar approvals. The early adoption of biosimilars, supported by strong payer incentives and physician familiarity, has accelerated market growth. Major pharmaceutical companies actively conduct biosimilar research, and the U.S. FDA's streamlined approval process further supports commercialization. The region benefits from comprehensive insurance coverage and mature reimbursement systems, ensuring broad patient access. However, the market faces increasing pricing pressures, competition from alternative HER2 therapies, and ongoing formulary negotiations.

Key players in the market

Some of the key players profiled in the Herceptin Biosimilar Market include Amgen Inc., Celltrion Healthcare Co., Ltd., Pfizer Inc., Samsung Bioepis Co., Ltd., Biocon Biologics Limited, Viatrix Inc., Teva Pharmaceutical Industries Ltd., Shanghai Henlius Biotech, Inc., Merck & Co., Inc., Stada Arzneimittel AG, Accord Healthcare Ltd., BIOCAD, AryoGen Pharmed Co., Ltd., Prestige BioPharma Limited, EirGenix Inc., Apotex Inc. and Gedeon Richter Plc.

Key Developments:

In November 2024, Celltrion acquired Swiss-based iQone Healthcare for approximately 30 billion KRW. This strategic move aims to enhance Celltrion's European distribution and commercialization capabilities, particularly for biosimilars like Herzuma, by

leveraging iQone's established regional market presence.

In December 2023, Pfizer and Roche (via Genentech) reached a confidential settlement resolving U.S. patent litigation over trastuzumab. This agreement cleared a key legal hurdle, enabling Pfizer to proceed with the future launch of its Herceptin biosimilar.

In June 2023, Celltrion expanded its partnership with Rani Therapeutics to supply CT-P17, its adalimumab biosimilar, for development in Rani's oral biologics platform. This collaboration reflects Celltrion's commitment to innovative drug delivery and global pipeline growth, aiming to transform injectable treatments into convenient oral alternatives.

Types Covered:

Ogivri (trastuzumab-dkst)

Herzuma (trastuzumab-pkrb)

Ontruzant (trastuzumab-dttb)

Trazimera (trastuzumab-qyyp)

Kanjinti (trastuzumab-anns)

HERCESSI (trastuzumab-strf)

Other Types

Dosages Covered:

150mg/single-dose vial

420mg/multidose vial

Distribution Channels Covered:

Hospital Pharmacies

Retail Pharmacies

Online Pharmacies

Direct Tender

Other Distribution Channels

Applications Covered:

Breast Cancer

Gastric Cancer

Colorectal Cancer

Leukemia

Lymphoma

Other Applications

End Users Covered:

Oncology Centers

Specialty Clinics

Other End Users

Regions Covered:

North America

US

Canada

Mexico

Europe

Germany

UK

Italy

France

Spain

Rest of Europe

Asia Pacific

Japan

China

India

Australia

New Zealand

South Korea

Rest of Asia Pacific

South America

Argentina

Brazil

Chile

Rest of South America

Middle East & Africa

Saudi Arabia

UAE

Qatar

South Africa

Rest of Middle East & Africa

What our report offers:

- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2024, 2025, 2026, 2028, and 2032
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market estimations
- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

Free Customization Offerings:

All the customers of this report will be entitled to receive one of the following free customization options:

Company Profiling

Comprehensive profiling of additional market players (up to 3)

SWOT Analysis of key players (up to 3)

Regional Segmentation

Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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Note: Tables for North America, Europe, APAC, South America, and Middle East & Africa Regions are also represented in the same manner as above.

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