

BIOSIMILARS MARKET GLOBAL FORECAST TO 2026







1.1 OBJECTIVES OF THE STUDY

- To define, describe, segment, and forecast the biosimilars market by product, indication, and region
- To forecast the size of the market with respect to five regional segments—North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa
- To provide detailed information regarding the major factors influencing the market growth (drivers, restraints, opportunities, and challenges)
- To strategically analyze micromarkets with respect to individual growth trends, prospects, and contributions to the overall market
- To analyze opportunities in the market for stakeholders and provide details of the competitive landscape for market leaders
- To profile the key players and comprehensively analyze their market shares and core competencies in terms of market developments and growth strategies
- To track and analyze competitive developments such as product launches and approvals, collaborations, partnerships, acquisitions, and expansions in the biosimilars market

1.2 MARKET DEFINITION

Biosimilars are identical to biological drugs in terms of efficacy, safety, and quality. They are the approved forms of original products and can be manufactured and marketed after the patent expiry of original biologics.

1.2.1 INCLUSIONS & EXCLUSIONS OF THE STUDY

TABLE 1 BIOSIMILARS MARKET: INCLUSIONS & EXCLUSIONS

PARTICULAR	INCLUSION	EXCLUSION
Biosimilars	Biosimilar drugs used for medication are included in the scope of the report	Biosimilars used for research and diagnostics are out of scope
Product	Qualitative and quantitative analysis (in terms of USD million) of the products based on active molecules, such as monoclonal antibodies (infliximab, adalimumab, trastuzumab, rituximab, and other monoclonal antibodies), insulin, granulocyte colony-stimulating factor, erythropoietin, recombinant human growth hormone, etanercept, follitropin, teriparatide, interferons, enoxaparin sodium, glucagon, and calcitonin, have been included in the scope of the report	Active molecules for biosimilars under development in the preclinical stages or in the research phase are not considered in the scope of this report





PARTICULAR	INCLUSION	EXCLUSION
Indication	Qualitative and quantitative analysis (in terms of USD million) of various therapeutic indications in which biosimilars are used, such as oncology, blood disorders, chronic diseases, inflammatory and autoimmune diseases, growth hormone deficiency, infectious diseases, and other indications (such as infertility, osteoporosis, and chronic kidney diseases) have been included in the scope of the report.	Therapeutic indications for which biosimilars are in preclinical stages or in the research phase have been excluded from the scope of the report

1.3 MARKET SCOPE

1.3.1 MARKETS COVERED

BIOSIMILARS MARKET



BY PRODUCT

- Monoclonal Antibodies
 - Rituximab
 - Infliximab
 - Adalimumab
- Trastuzumab
- Other Monoclonal Antibodies
- Granulocyte Colonystimulating Factor
- Insulin
- Erythropoietin

- Recombinant Human Growth Hormone
- Etanercept
- Follitropin
- Teriparatide
- Interferons
- Enoxaparin Sodium
- Glucagon
- Calcitonin



BY INDICATION

- Oncology
- Blood Disorders
- Chronic Diseases
- Inflammatory & Autoimmune Diseases
- Growth Hormone Deficiency
- Infectious Diseases
- Other Indications



BY REGION

- North America (US & Canada)
- Europe (UK, Germany, France, Spain, Italy, & Rest of Europe)
- Asia Pacific (China, India, Japan, South Korea, Australia, & Rest of APAC)
- Latin America
- Middle East & Africa

Note: Other indications include infertility, osteoporosis, and chronic kidney diseases.





1.3.2 YEARS CONSIDERED FOR THE STUDY



Note: For market estimates, the calendar year has been considered, whereas, for company profiles, the fiscal year has been considered.

1.4 CURRENCY

- The currency used for this report is the United States Dollar (USD), with the market size indicated in terms of USD million/billion.
- For companies reporting their revenues in USD, the revenues were taken from their annual reports.
- For companies reporting their revenues in other currencies, the average annual currency conversion rate was used for that particular year to convert the value to USD.

1.5 STAKEHOLDERS

- Biopharmaceutical drug (biosimilars and biologics) manufacturers
- Private equity companies and venture capital firms
- Healthcare service providers (hospitals and independent physicians)
- Health insurance payers
- Research and consulting service firms
- Contract research organizations (CROs)
- Contract manufacturing organizations (CMOs)
- Pharmaceutical and medical associations





1.6 LIMITATIONS

- Some of the companies profiled are privately owned, and their revenues are not available in the public domain. Hence, revenues for these companies are not included in the report.
- The list of products included in the "products offered" table is only an indicative list.
- Company developments not reported in the public domain are not included in the report.
- Market values have been rounded off till the second decimal, owing to which there may be a slight difference in numbers.
- For market estimation, products already approved or marketed have been used. Information on products in the clinical phases of development has been used to map the overall market ecosystem for a particular company.

1.7 SUMMARY OF CHANGES

- In the latest edition of the report, the market is segmented by product, indication, and region.
- The new version of the report includes the value chain analysis, ecosystem market map, technology analysis, Porter's five forces analysis, and a region-wise regulatory landscape.
- Market drivers, restraints, opportunities, challenges, and trends have been updated for the biosimilars market. The report also includes the impact of COVID-19 on the biosimilars market.
- The new version of the report includes the company evaluation quadrant for 25 companies operating in the biosimilars market.
- The new version of the report includes the startup/SME company evaluation quadrant for 10 companies operating in the biosimilars market.
- The new version of the report comprises 25 players (15 top players and 10 startups/SMEs), as compared to 20 in the previous version. The report includes the historical revenue analysis of the top five players in the biosimilars market.
- The new edition of the report provides updated financial information in the context of the biosimilars market from 2018 to 2021 for each listed company in a graphical representation.
- The report includes market developments from January 2018 to August 2021.

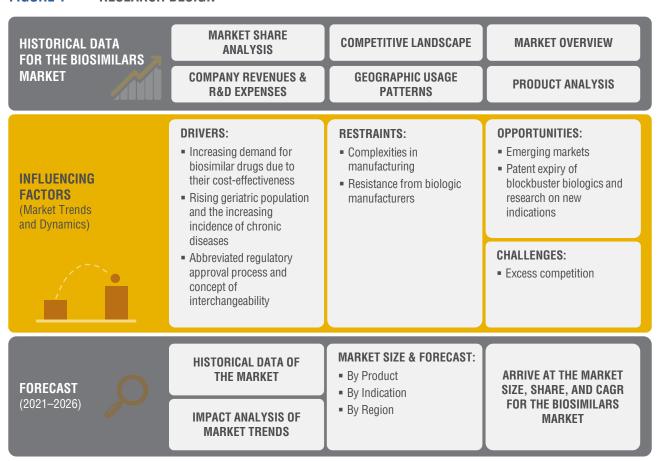




2.1 RESEARCH APPROACH

This market research study involves the extensive use of secondary sources, directories, and databases to identify and collect information useful for this technical, market-oriented, and financial study of the global biosimilars market. Indepth interviews were conducted with various primary respondents, including key industry participants, subject-matter experts (SMEs), C-level executives of key market players, and industry consultants, to obtain and verify critical qualitative and quantitative information and assess market prospects. The biosimilars market size was estimated through various secondary research approaches and triangulated with inputs from primary research. The following figure shows the market research methodology applied in making this report on the global biosimilar market.

FIGURE 1 RESEARCH DESIGN



2.2 SECONDARY DATA

In the secondary research process, information was collected from secondary sources such as annual reports, press releases, investor presentations of companies, white papers, certified publications, articles from recognized authors, gold standard and silver standard websites, directories, and databases.

The secondary sources referred to for this research study included publications from government sources [such as the World Bank, World Health Organization (WHO), and Centers for Disease Control and Prevention (CDC)]; sites like ClinicalTrials.gov and FierceBiotech; MarketsandMarkets analysis; and trade, business, and professional associations.





Secondary research was used to identify and collect information useful for the extensive, technical, market-oriented, and commercial study of this market. It was also used to obtain important information about the top players, market classification and segmentation according to industry trends to the bottom-most level, and key developments related to market and technology perspectives. A database of the key industry leaders was also prepared using secondary research.

FIGURE 2 SECONDARY SOURCES

PARAMETER SOURCE Company Financials Magazines Journals **MARKET SIZE** Press Releases Paid and Public Databases MarketsandMarkets Data Repository Annual Reports & SEC Filings Company Websites **COMPANY REVENUES** Public Databases MarketsandMarkets Data Repository Company Websites Annual Reports **QUALITATIVE INFORMATION** Investor Presentations ■ Press Releases MarketsandMarkets Data Repository

Secondary research involved three major activities:

BACKGROUND STUDY

- Building a basic understanding of the biosimilars market
- Analyzing MarketsandMarkets' data repository, followed by drawing and updating data tables using current information
- Identifying data gaps and key global players in each segment

MARKET UNDERSTANDING

- Identifying stakeholders and key decision-makers in different regions
- Identifying the selection criteria of key decision-makers
- Analyzing the competitive landscape
- Analyzing major global players and their respective product portfolios





- Analyzing the strategies adopted by global players to position their product offerings
- Analyzing markets at the regional/country level

TRENDS

- Identifying and analyzing key products and industry trends to draw notes and include considerations in the final forecasts
- Identifying major drivers, restraints, opportunities, and challenges in the market
- Analyzing the regulatory landscape

2.3 PRIMARY DATA

In the primary research process, various sources were interviewed to obtain the qualitative and quantitative information for this report. Primary sources were mainly industry experts from core & related industries and preferred suppliers, manufacturers, distributors, technology developers, researchers, and organizations related to all segments of this industry's value chain. In-depth interviews were conducted with various primary respondents, including key industry participants, subject-matter experts (SMEs), C-level executives of key market players, and industry consultants, among other experts, to obtain and verify critical qualitative and quantitative information as well as assess prospects.

Primary research was conducted to identify segmentation types; industry trends; key players; and key market dynamics such as drivers, restraints, opportunities, challenges, and strategies adopted by key players.

FIGURE 3 KEY DATA FROM PRIMARY SOURCES

ТҮРЕ		PARAMETER	KEY DATA		
	GEOGRAPHIC SPLIT	 Overall market and subsegments in 2020 CAGR of each region in the forecast period (2021–2026) 	 Biosimilars market, by region—North America, Europe, Asia Pacific, Latin America, and the Middle East and Africa 		
	GLOBAL Market Size	 Global market size for 2020 CAGR for the forecast period (2021–2026) 	 Global biosimilars market size Global biosimilars market, by product and indication 		
	MARKET SPLIT	 Insulin, rhGH, G-CSF, interferons, erythropoietin, mAbs, follitropin, etanercept, glucagon, calcitonin, teriparatide, and enoxaparin sodium Oncology, blood disorders, chronic diseases, inflammatory and autoimmune diseases, growth hormone deficiency, infectious diseases, and other indications 	Global biosimilars market By product By indication		





RESEARCH METHOI

2.4 MARKET BREAKDOWN AND DATA TRIANGULATION

After arriving at the overall market size from the market size estimation process explained above, the total market was split into several segments and subsegments. In order to complete the overall market engineering process and arrive at the exact statistics for all segments and subsegments, data triangulation and market breakdown procedures were employed, wherever applicable. The data was triangulated by studying various factors and trends from both the demand and supply sides. Along with this, the market was validated using the bottom-up approach.

FIGURE 4 DATA TRIANGULATION METHODOLOGY



PRIMARY SOURCES

INTERVIEWS WITH PERSONNEL FROM:

SIDE

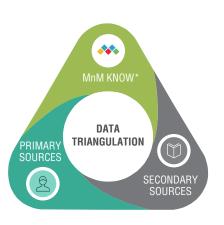
SIDE

PPLY :

- Clinical Laboratories
- Pharmaceutical Companies
- Academic Research Institutes
- CROs
- Independent Consultants

INTERVIEWS WITH:

Biosimilar Providers (Such As Sandoz, Teva Pharmaceutical, Celltrion, Pfizer, Eli Lilly and Company, Biocon, and Dr. Reddy's Laboratories), Suppliers, Importers, Distributors, and Key **Opinion Leaders**



SECONDARY SOURCES

- Annual Reports, Presentations, Websites, Press Releases of Top Players, News Articles, Journals, and Paid Databases
- American Cancer Society
- World Health Organization (WHO)
- GLOBOCAN
- Centers for Disease Control and Prevention (CDC)
- World Bank
- European Medicines Agency (EMA)
- Food and Drug Administration (FDA)
- National Cancer Institute (NCI)
- National Medical Products Administration (NMPA)
- Therapeutic Goods Administration
- National Institutes of Health (NIH)
- International Diabetes Federation

INFORMATION SOURCED

STEP 1

Information gathered related to disease epidemiology: biosimilar products were used during treatments

STEP 2

Information on various percentage splits were gathered from sales VPs. CEOs, and regional managers through primary interviews

STEP 3

Market sizing for biosimilars provided based on MnM analysis

2.5 MARKET ESTIMATION METHODOLOGY

The market size estimates and forecasts provided in this study are derived through a bottom-up approach (revenue share analysis of leading players).

^{*}MnM KNOW stands for MarketsandMarkets' 'Knowledge Asset Management' framework. In this context, it stands for the existing market research knowledge repository of over 5,000 granular markets, our flagship competitive intelligence and market research platform "Knowledge Store", subjectmatter experts, and independent consultants. MnM KNOW acts as an independent source that helps us validate information gathered from primary and secondary sources.





2.5.1 BOTTOM-UP APPROACH

The size of the global biosimilars market was arrived at using the revenue share analysis of leading players in the market. Wherever feasible, the revenue share analysis was employed to arrive at the segmental market sizes by identifying leading players in respective drug categories at the segmental and subsegmental levels.

For this purpose, major players in the market were identified through secondary research, and their revenues from the biosimilars business were determined through insights gathered during primary and secondary research. Secondary research included the study of the annual and financial reports of top market players, while primary research included extensive interviews with key opinion leaders such as CEOs, directors, and marketing executives of key market players.

2.5.2 TOP-DOWN APPROACH

Individual shares of each segment were arrived at by assigning weightages based on the adoption rate of various services and demographic patterns. The regional splits of the overall biosimilars market and its subsegments are based on the adoption or utilization rates of the given service in the respective regions or countries. In countries where reliable and recent data was not available, analogy/benchmarking-based market estimation and forecast techniques were used.

The overall size of the biosimilars market was used in the top-down approach to estimate the sizes of other individual submarkets (mentioned in the market segmentation—by product and indication) through percentage splits from secondary and primary research.

For calculating specific market segments, the most appropriate, immediate parent market size was used for implementing the top-down approach. The bottom-up approach was also implemented (wherever applicable) for data extracted from secondary research to validate the market segment revenues obtained.

FIGURE 5 TOP-DOWN APPROACH

- Global biosimilars market (USD million)
- Percentage splits applied to derive the biosimilars market, by product and indication
- Percentage splits applied to derive the market size for each region (North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa)
- Further splits were applied to arrive at the size of each subsegment and country
- ▼ Total biosimilars market: USD ~12 billion
- Validation of estimation via primary research







2.6 RESEARCH ASSUMPTIONS

PARAMETER	ASSUMPTION	IMPACT
COVID-19	COVID-19 is assumed to have a positive impact on the biosimilars market	COVID-19 has increased the spending on healthcare by governments and end users
GOVERNMENT R&D SPENDING PATTERNS	Current R&D spending patterns will prevail in major countries and regions during the forecast period	This will lead to increasing growth opportunities for market players in emerging countries
EXCHANGE RATES	Dollar fluctuations will not affect the market to a significant extent	Steady exchange rates will stabilize the prices of biosimilars provided in the market
COMPANY FINANCIALS	Revenues of private companies acquired from paid databases were assumed to be in-line with actual company financials	The revenues of companies are of high importance for estimating the size of the parent market and its subsegments
MARKET GROWTH	The exchange rate is assumed to be the same as that of 2020 for the forecast period	The exchange rates are of high importance when estimating the market size of the parent market and its subsegments
ECONOMY	A positive economic climate will continue globally till the end of 2026	This will result in positive spending on R&D activities

2.7 LIMITATIONS

- Market sizes and CAGRs for biosimilars are not provided for regions and countries where they are yet to be approved.
- Company developments not reported in the public domain are not included in the report.
- Some companies in this market are privately owned, and their revenues are not available in the public domain.
- The market size for 2020 is given for some products that were approved in 2020 but not launched until February 2021.



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Chronic Diseases to Drive Market Growth

8.3.6 Rest of Asia Pacific

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10.1 Major Players

(Business Overview, Products Offered, Recent Developments, and MnM View (Key strengths/Right to Win, Strategic Choices Made, and Weaknesses and Competitive Threats))*

- 10.1.1 NOVARTIS AG
- 10.1.2 PFIZER INC.
- 10.1.3 DR. REDDY'S LABORATORIES LTD.
- 10.1.4 AMGEN INC.
- 10.1.5 ELI LILLY AND COMPANY
- 10.1.6 TEVA PHARMACEUTICAL INDUSTRIES LTD.
- 10.1.7 FRESENIUS SE & CO. KGAA
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- 10.1.10 GEDEON RICHTER PLC
- 10.1.11 CELLTRION
- 10.1.12 SAMSUNG BIOLOGICS
- 10.1.13 COHERUS BIOSCIENCES
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- 10.1.15 VIATRIS
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(For complete list of tables and figures, pl see Appendix of this Report Brochure)

READ MORE

^{*}Details on Business Overview, Products Offered, Recent Developments, and MnM View (Key strengths/Right to Win, Strategic Choices Made, and Weaknesses and Competitive Threats) might not be captured in case of unlisted companies.



SAMPLE PAGES





1 EXECUTIVE SUMMARY

Biosimilars are approved forms of original innovator products that are manufactured and marketed after the patent expiry of innovator biologics. Biosimilars are functionally identical to the reference products but not at the molecular level. The biosimilars market is projected to reach XX billion by 2026 from USD XX billion in 2021, at a CAGR of XX%. The rising incidence of chronic diseases and the increasing demand for biosimilars due to their cost-effectiveness are expected to drive the growth of this market. However, a complex manufacturing process for biosimilars coupled with market resistance from established innovator companies is expected to restrain the growth of this market during the forecast period.

FIGURE 1 BIOSIMILARS MARKET, BY REGION, 2021 VS. 2026 (USD MILLION)



Source: Central Drugs Standard Control Organization (CDSCO), GLOBOCAN, International Diabetes Federation, National Center for Biotechnology Information, National Cancer Institute (NCI), United States Food and Drug Administration, Therapeutic Goods Administration, Health Canada, Generics and Biosimilars Initiative, Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis

Based on region, the biosimilars market is segmented into North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa. In 2020, Europe accounted for the largest share of XX% of the biosimilars market. The patent expiry of biologic products and the launch of new biosimilars, the rising incidence of chronic disorders, the emergence of new market participants, and greater acceptance and market penetration of biosimilars are expected to drive the growth of the biosimilars market in the region.

The major players in the biosimilars market are Pfizer (US), Sandoz International GmbH (Germany), Teva Pharmaceutical Industries Ltd. (Israel), Amgen (US), Biocon (India), Dr. Reddy's Laboratories Ltd. (India), Eli Lilly and Company (US), Celltrion (South Korea), and Samsung Biologics (South Korea).





PREMIUM INSIGHTS 2

2.1 **BIOSIMILARS MARKET OVERVIEW**

FIGURE 2 RISING INCIDENCE OF CHRONIC DISEASES TO DRIVE MARKET GROWTH



Europe accounted for the largest share of 38.4% of the biosimilars market in 2020. The rising incidence of chronic diseases. patient expiry of biologic products, and the launch of new biosimilars are the key factors driving market growth.





CAGR of

The global biosimilars market is projected to reach USD 44,729.6 million by 2026 from USD 15,551.8 million 23.5% in 2021, at a CAGR of 23.5%.



Market growth can be attributed to the increasing demand for biosimilar drugs due to their costeffectiveness and the rising incidence of chronic diseases.



The Asia Pacific market is estimated to grow at the highest CAGR owing to the increasing incidence of chronic and infectious diseases and low healthcare budgets.



Product launches & approvals and regional partnerships were some of the widely adopted growth strategies by market players.



Emerging markets are expected to offer lucrative growth opportunities for market players during the forecast period.

Source: Central Drugs Standard Control Organization (CDSCO), GLOBOCAN, International Diabetes Federation (IDF), National Center for Biotechnology Information (NCBI), National Cancer Institute (NCI), United States Food and Drug Administration (US FDA), Therapeutic Goods Administration (TGA), Health Canada, Generics and Biosimilars Initiative (GaBI), Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis





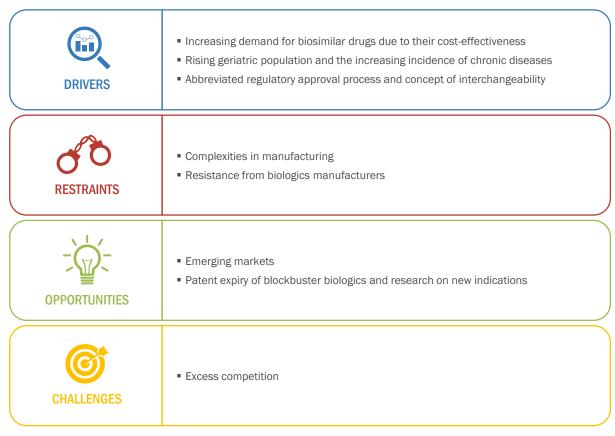
3 MARKET OVERVIEW

3.1 INTRODUCTION

Biosimilars are used to treat various disorders, such as cancer, hematopoietic anemia, rheumatoid disorders, and diabetes mellitus. Factors such as the increasing demand for biosimilar drugs due to their cost-effectiveness and the rising incidence of chronic diseases such as cancer, diabetes, and rheumatoid arthritis, are expected to drive the growth of the global biosimilars market during the forecast period. Moreover, the development of biosimilars for new indications in therapeutic areas of bone health, cardiovascular diseases, nephrology, ophthalmology, and hematology and the patent expiry of biologic drugs are expected to offer significant growth opportunities to market players in the coming years.

3.2 MARKET DYNAMICS

FIGURE 3 BIOSIMILARS MARKET: DRIVERS, RESTRAINTS, OPPORTUNITIES, & CHALLENGES



Source: Expert Interviews and MarketsandMarkets Analysis





4 BIOSIMILARS MARKET, BY PRODUCT

KEY FINDINGS

- The monoclonal antibodies segment accounted for the largest share of the biosimilars market in 2020. This segment is projected to reach USD XX million by 2026 from USD XX million in 2021, at a CAGR of XX% during the forecast period.
- Wide applications of monoclonal antibodies in the treatment of cancer, autoimmune disorders, rheumatoid arthritis, multiple sclerosis, macular degeneration, and osteoporosis to drive market growth.
- Among monoclonal antibodies, adalimumab is expected to witness the highest CAGR of XX% during the forecast period.
- The biosimilars market for insulin is projected to reach USD XX million by 2026 from USD XX million in 2021, at a CAGR of XX%. The rising incidence of diabetes, cost-effectiveness of biosimilars, and the presence of many biosimilar versions of insulin are expected to drive the growth of the biosimilars market for insulin.
- The biosimilars market for granulocyte colony-stimulating factor is projected to register a CAGR of XX% during the forecast period.





4.1 MONOCLONAL ANTIBODIES

This segment is projected to reach USD XX million by 2026 from USD XX million in 2021, at a CAGR of XX% during the forecast period. This segment includes infliximab, rituximab, adalimumab, trastuzumab, and other monoclonal antibodies. The low prices of biosimilar monoclonal antibodies compared to the reference drugs and their wide use in the treatment of cancer, autoimmune disorders, and osteoporosis will drive market growth. They are also used in indications such as rheumatoid arthritis, multiple sclerosis, and macular degeneration.

TABLE 1 BIOSIMILARS MARKET FOR MONOCLONAL ANTIBODIES, BY TYPE, 2019–2026 (USD MILLION)

Туре	2019	2020	2021	2026	CAGR (2021-2026)
Infliximab	XX	XX	XX	XX	XX%
Trastuzumab	XX	XX	XX	XX	XX%
Rituximab	XX	XX	XX	XX	XX%
Adalimumab	XX	XX	XX	XX	XX%
Other Monoclonal Antibodies	XX	XX	XX	XX	XX%
Total	XX	XX	XX	XX	XX%

Source: Central Drugs Standard Control Organization (CDSCO), GLOBOCAN, International Diabetes Federation (IDF), National Center for Biotechnology Information (NCBI), National Cancer Institute (NCI), United States Food and Drug Administration (US FDA), Therapeutic Goods Administration (TGA), Health Canada, Generics and Biosimilars Initiative (GaBI), Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis

TABLE 2 BIOSIMILARS MARKET FOR MONOCLONAL ANTIBODIES, BY REGION, 2019–2026 (USD MILLION)

Region	2019	2020	2021	2026	CAGR (2021-2026)
Europe	XX	XX	XX	XX	XX%
Asia Pacific	XX	XX	XX	XX	XX%
North America	XX	XX	XX	XX	XX%
Latin America	XX	XX	XX	XX	XX%
Middle East and Africa	XX	XX	XX	XX	XX%
Total	XX	XX	XX	ХХ	XX%

Source: Central Drugs Standard Control Organisation (CDSCO), GLOBOCAN, International Diabetes Federation (IDF), National Center for Biotechnology Information (NCBI), National Cancer Institute (NCI), United States Food and Drug Administration (US FDA), Therapeutic Goods Administration (TGA), Health Canada, Generics and Biosimilars Initiative (GaBI), Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis





5 BIOSIMILARS MARKET, BY REGION

5.1 INTRODUCTION

In this report, the biosimilars market is segmented into North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa. These regional markets are further studied based on country. Europe accounted for the largest share of XX% of the global biosimilars market in 2020. Factors such as the patent expiry of biologic products and the launch of new biosimilars, rising incidence of chronic disorders, country-level laws to promote the uptake of biosimilars, and the emergence of new market participants will propel market growth.

The market in the Asia Pacific is expected to register the highest CAGR of XX% in the global biosimilars market during the forecast period. The increasing incidence of chronic and infectious diseases and low healthcare budgets are driving the growth of this market.

5.2 EUROPE

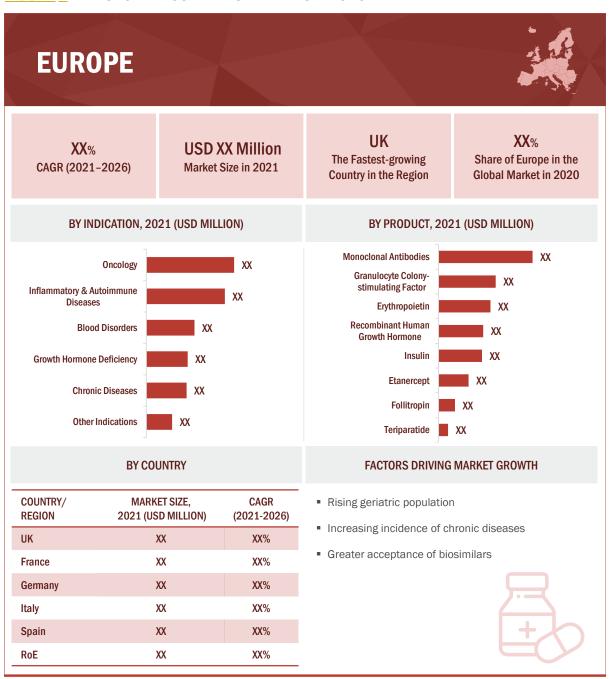
Europe is the largest market for biosimilars owing to several factors, such as the impending patent expiry of biologic products and the launch of new biosimilars, the rising incidence of chronic disorders, and the emergence of new players. The rising geriatric population and the subsequent increase in the incidence of age-related disorders and chronic disorders are also expected to drive market growth. Europe was also among the first regions to enter the biosimilars business by approving the first biosimilar way back in 2006. Being an early entrant in the market, stakeholders had more time to evaluate the effectiveness and clinical safety and efficacy of biosimilars, leading to greater acceptance as compared to any other region.

Europe has been at the forefront for biosimilar approvals with XX authorized biosimilars, of which XX have been approved, and XX biosimilar approvals were withdrawn after approval by the EMA. The list of biosimilars currently approved by the EMA consists of XX filgrastim/pegfilgrastim biosimilars, XX adalimumab biosimilars, XX bevacizumab biosimilars, XX trastuzumab biosimilars, XX rituximab biosimilars, and XX insulin analog biosimilars.





FIGURE 4 EUROPE: BIOSIMILARS MARKET SNAPSHOT



Source: Central Drugs Standard Control Organization (CDSCO), GLOBOCAN, International Diabetes Federation (IDF), National Center for Biotechnology Information (NCBI), National Cancer Institute (NCI), United States Food and Drug Administration (US FDA), Therapeutic Goods Administration (TGA), Health Canada, Generics and Biosimilars Initiative (GaBI), Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis





TABLE 3 EUROPE: BIOSIMILARS MARKET, BY COUNTRY, 2019–2026 (USD MILLION)

Country/Region	2019	2020	2021	2026	CAGR (2021-2026)
UK	XX	XX	XX	XX	XX%
France	XX	XX	XX	XX	XX%
Germany	XX	XX	XX	XX	XX%
Italy	XX	XX	XX	XX	XX%
Spain	XX	XX	XX	XX	XX%
RoE	XX	XX	XX	XX	XX%
Total	XX	XX	XX	XX	XX%

Source: Central Drugs Standard Control Organization (CDSCO), GLOBOCAN, International Diabetes Federation (IDF), National Center for Biotechnology Information (NCBI), National Cancer Institute (NCI), United States Food and Drug Administration (US FDA), Therapeutic Goods Administration (TGA), Health Canada, Generics and Biosimilars Initiative (GaBI), Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis

TABLE 4 EUROPE: BIOSIMILARS MARKET, BY PRODUCT, 2019–2026 (USD MILLION)

Product	2019	2020	2021	2026	CAGR (2021-2026)
Monoclonal Antibodies	XX	XX	XX	XX	XX%
Granulocyte Colony-stimulating Factor	XX	XX	XX	XX	XX%
Erythropoietin	XX	XX	XX	XX	XX%
Recombinant Human Growth Hormone	XX	XX	XX	XX	XX%
Insulin	XX	XX	XX	XX	XX%
Etanercept	XX	XX	XX	XX	XX%
Follitropin	XX	XX	XX	XX	XX%
Teriparatide	XX	XX	XX	XX	XX%
Interferons	XX	XX	XX	XX	XX%
Glucagon	XX	XX	XX	XX	XX%
Calcitonin	XX	XX	XX	XX	XX%
Enoxaparin Sodium	XX	XX	XX	XX	XX%
Total	XX	XX	XX	XX	XX%

Source: Central Drugs Standard Control Organization (CDSCO), GLOBOCAN, International Diabetes Federation (IDF), National Center for Biotechnology Information (NCBI), National Cancer Institute (NCI), United States Food and Drug Administration (US FDA), Therapeutic Goods Administration (TGA), Health Canada, Generics and Biosimilars Initiative (GaBI), Annual Reports, SEC Filings, Press Releases, Investor Presentations, Expert Interviews, and MarketsandMarkets Analysis





6 COMPETITIVE LANDSCAPE

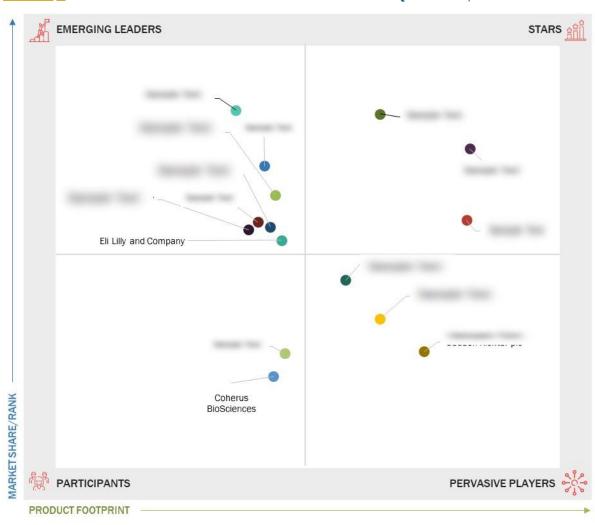
6.1 INTRODUCTION

The competitive landscape includes the analysis of the key growth strategies adopted by major players between January 2018 and August 2021. Players in the global biosimilars market have employed various strategies to expand their global footprint and increase their market shares. The key strategies adopted by the major players in the biosimilars market include geographical expansions (especially in terms of facilities for development and manufacturing), product launches and approvals, agreements, acquisitions, and partnerships.

Prominent players in the biosimilars market include Amgen, Inc. (US), Eli Lilly and Company (US), Teva Pharmaceutical Industries Ltd. (Israel), Fresenius SE & Co. KGaA (Germany), Dr. Reddy's Laboratories Ltd. (India), Novartis AG (Switzerland), STADA Arzneimittel (Germany), Boehringer Ingelheim (Germany), Pfizer Inc. (US), Gedeon Richter plc (Hungary), Celltrion (South Korea), Samsung Biologics (South Korea), and Coherus BioSciences (US).

This section includes an in-depth analysis of the key developments adopted by major players in the biosimilars market during the study period. These developments are curated based on their overall impact on the market.

FIGURE 5 BIOSIMILARS MARKET: COMPANY EVALUATION QUADRANT, 2020



Source: Annual Reports, SEC Filings, Expert Interviews, and MarketsandMarkets Analysis





7 COMPANY PROFILES

7.1 MAJOR PLAYERS

7.1.1 NOVARTIS AG

7.1.1.1 Business overview

Novartis AG operates through two global business divisions—Innovative Medicines and Sandoz. Sandoz is involved in the business of generic pharmaceuticals and biosimilars. Sandoz is organized globally into three franchises or segments, namely, Retail Generics, Anti-infectives, and Biopharmaceuticals.

In the Biopharmaceuticals segment, Sandoz develops, manufactures, and markets protein and other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies. Key therapeutic areas include oncology, immunology, and endocrinology.

The company has operations in North America, Europe, Oceania, and East Asia. Some of the major countries include the US, Canada, Germany, Switzerland, China, Japan, Australia, and New Zealand.

TABLE 5 NOVARTIS AG: BUSINESS OVERVIEW

NOVARTIS AG	
Founded	1996
Country	Switzerland
City	Basel, Basel-Stadt
Ownership	Public
No. of Employees	XX
R&D Expenditure (2020)	USD XX Billion

Source: Company Website and Annual Reports



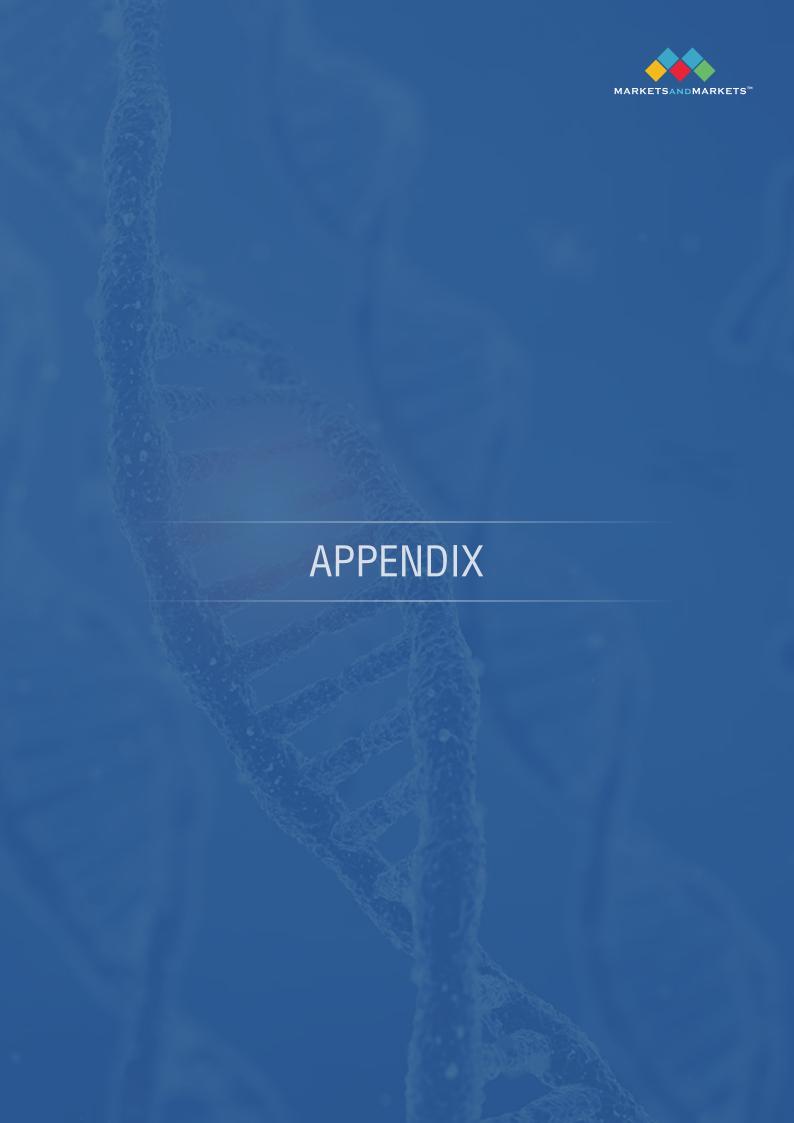


FIGURE 6 SANDOZ: COMPANY SNAPSHOT (2020)



Note: Information for the Recent Financials, Geographic Revenue Mix, and Business Revenue Mix has been provided for the Sandoz division of the company.

Source: Company Website and Annual Reports





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