

# **Biosimilar Market in Europe Report by Molecule (Infliximab, Insulin Glargine, Epoetin Alfa, Etanercept, Filgrastim, Somatropin, Rituximab, Follitropin Alfa, Adalimumab), Indication (Auto-Immune Diseases, Blood Disorder, Diabetes, Oncology, Growth Deficiency, Female Infertility), Manufacturing Type (In-house Manufacturing, Contract Manufacturing), and Country 2024-2032**

<https://marketpublishers.com/r/B29479EA1393EN.html>

Date: January 2024

Pages: 138

Price: US\$ 3,699.00 (Single User License)

ID: B29479EA1393EN

## **Abstracts**

The biosimilar market in Europe size reached US\$ 11,849.5 Million in 2023. Looking forward, IMARC Group expects the market to reach US\$ 53,222.9 Million by 2032, exhibiting a growth rate (CAGR) of 17.6% during 2024-2032. The implementation of favorable reimbursement policies to encourage the use of biosimilars, the expansion of production facilities to ensure a consistent supply of the products, and technological advancements are among the key factors driving the market growth.

Biosimilars are biological products designed to have similar safety, efficacy, and therapeutic characteristics as an already approved biological product, known as the reference product. While they aren't identical, due to the complex nature of biological products, they match closely in terms of their function, administration, and intended use. The goal of a biosimilar is to provide an equivalent treatment option that can be marketed at a potentially lower cost once the original product's patent expires. The development of biosimilars undergoes a rigorous process, involving multiple phases of trials to demonstrate their comparability to the reference product. The key focus lies in achieving "biosimilarity" that assures no clinically meaningful differences from the reference product in terms of safety and effectiveness. Therefore, biosimilars play a

significant role in increasing access to life-changing biological treatments by offering cost-effective alternatives.

Europe has one of the highest proportions of elderly people globally. Aging is often associated with an increased prevalence of chronic diseases, many of which require biological treatments. Biosimilars, offering affordable options for biologic drugs, therefore cater to this demographic and the associated increased demand for therapeutics. Along with this, European countries are implementing favorable reimbursement policies to encourage the use of biosimilars. Such policies, for instance in Germany and France, facilitate better access to biosimilars for patients and help to reduce the financial burden on healthcare systems. In addition, the rising manufacturing capacities for biosimilars in Europe are also positively influencing the market. Several biosimilar companies are investing in expanding their production facilities to ensure a consistent supply of these products, which in turn supports market growth. Apart from this, the escalating educational initiatives for healthcare professionals and patients, and measures to incentivize prescription is contributing to the market. Furthermore, innovations in bioprocessing and analytical methods to reduce the time and cost of biosimilar production and development are creating a positive market outlook.

#### Biosimilar Market in Europe Market Trends/Drivers: Patent Expiries and Cost Containment

One of the most prominent market drivers for the biosimilars industry in Europe is the expiry of patents for a host of high-revenue biologic drugs. These patent expiries create lucrative opportunities for biosimilar manufacturers to introduce less costly alternatives in the market, which in turn accelerates the adoption of biosimilars. As European countries grapple with rising healthcare costs, cost containment has become a crucial aspect. In addition, biosimilars typically enter the market at a significantly reduced price compared to their reference biologic, contributing to savings in healthcare expenditure. Several European healthcare systems are encouraging the use of biosimilars as a cost-effective strategy. For instance, government organizations are introducing policies to incentivize the prescription of biosimilars. As a result, cost containment strategies coupled with patent expirations are fostering the growth of the biosimilars market in Europe.

#### Increased Adoption due to Awareness and Acceptance

The growing level of awareness and acceptance of biosimilars among healthcare providers and patients in Europe is positively influencing the market. This can be

supported by the educational initiatives of regulatory bodies and industry groups, which aim to dispel misconceptions about biosimilars and highlight their comparable safety and efficacy to reference biologics. Such initiatives have led to increased trust and wider acceptance of biosimilars. In confluence with this, successful case studies, such as the introduction and usage of biosimilar infliximab in several European countries, have showcased potential cost savings without compromising patient outcomes. This increased acceptance and trust in biosimilars, supported by positive real-world evidence, is a significant driver for the growth of the biosimilars industry in Europe.

#### Biosimilar Market in Europe Industry Segmentation:

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

#### Breakup by Country:

- Italy
- Germany
- United Kingdom
- France
- Spain
- Rest of Europe

Italy exhibits a clear dominance, accounting for the largest biosimilar market share in Europe

The report has also provided a comprehensive analysis of all the major regional markets, which includes Italy, Germany, France, the United Kingdom, Spain, and the rest of Europe. According to the report, Italy accounted for the largest market share.

The biosimilar market in Italy is driven by the rising prevalence of chronic diseases in the country, such as autoimmune disorders, cancer, and diabetes, which has led to an increased demand for cost-effective treatment options. Biosimilars offer significant cost savings compared to their originator counterparts, making them a compelling choice for healthcare providers and patients alike. Along with this, the Italian government is implementing policies and incentives to encourage the adoption of biosimilars, recognizing their potential to improve patient access to essential therapies while reducing healthcare expenditures. The country's well-established regulatory framework

and robust guidelines for biosimilar approval have instilled confidence in these products, further fostering their acceptance and utilization in the Italian market. Additionally, collaborations between biosimilar manufacturers and Italian healthcare organizations have played a crucial role in driving market growth, as they work together to raise awareness, educate stakeholders, and establish best practices for biosimilar integration into the healthcare system.

#### Breakup by Molecule:

Infliximab  
Insulin Glargine  
Epoetin Alfa  
Etanercept  
Filgrastim  
Somatropin  
Rituximab  
Follitropin Alfa  
Adalimumab

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, and adalimumab.

In the Europe biosimilar market, Infliximab has emerged as a prominent product with significant market drivers. Infliximab, a monoclonal antibody used to treat various autoimmune diseases, has witnessed growing demand due to its efficacy and cost-effectiveness. Along with this, the rising prevalence of chronic conditions, such as rheumatoid arthritis, Crohn's disease, and psoriasis, has propelled the demand for Infliximab biosimilars in recent years. Additionally, the expiry of patents on originator biologic products has opened opportunities for biosimilar manufacturers to enter the market, further intensifying competition. Furthermore, healthcare systems in Europe's cost-containment measures and the emphasis on providing access to affordable treatments have fueled the adoption of Infliximab biosimilars.

On the contrary, insulin glargine, a long-acting insulin analog, is widely used to manage diabetes, a chronic condition affecting a substantial population in Europe. The increasing prevalence of diabetes, coupled with the growing need for cost-effective treatment options, has fueled the demand for insulin glargine biosimilars. As the patents for originator insulin products have expired, it has created an opportunity for biosimilar

manufacturers to enter the market and offer more affordable alternatives. In addition, the rising pressure on healthcare systems to optimize expenditure on diabetes care has also accelerated the adoption of insulin glargine biosimilars. These factors, along with the Europe Medicines Agency's stringent regulatory framework for biosimilars, contribute to the market's growth, positioning insulin glargine biosimilars as key drivers in the expanding landscape of biosimilar utilization in Europe.

Breakup by Indication:

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

A detailed breakup and analysis of the market based on the indication has also been provided in the report. This includes auto-immune diseases, blood disorder, diabetes, oncology, growth deficiency, and female infertility.

In the region, the indication for auto-immune diseases has emerged as a significant driver for growth. Auto-immune diseases, encompassing a wide range of conditions like rheumatoid arthritis, psoriasis, and inflammatory bowel disease, affect a substantial number of patients across the region. In confluence with this, the growing prevalence of these chronic disorders has driven the demand for cost-effective and accessible treatment options. Biosimilars, as comparable alternatives to originator biologics, offer the potential for significant cost savings, making them an attractive choice for healthcare systems aiming to manage expenditure while ensuring quality care for patients. Moreover, the expiry of patents on several originator biologics has created opportunities for biosimilar developers to enter the market, fostering competition and promoting innovation. As regulatory agencies in Europe, such as the European Medicines Agency, continue to establish robust guidelines for biosimilar approval, the confidence in the safety and efficacy of these products grows, further supporting their adoption.

On the contrary, blood disorders, including anemia, thrombocytopenia, and various hematologic malignancies, affect a considerable number of patients in the region. The escalating prevalence of these conditions, coupled with the rising demand for cost-effective and efficient treatments, has stimulated the adoption of biosimilars as viable

alternatives to originator biologics. Biosimilars offer the potential for substantial cost savings, making them an attractive option for healthcare providers and systems striving to manage their budgets effectively. In addition, as patents for several originator biologics used in the treatment of blood disorders have expired or are nearing expiration, it has paved the way for biosimilar manufacturers to enter the market and introduce competitive products. Moreover, the growing confidence in the safety and efficacy of biosimilars, supported by the stringent regulatory framework established by agencies, has further boosted their acceptance and utilization.

Breakup by Manufacturing Type:

In-house Manufacturing

Contract Manufacturing

The report has provided a detailed breakup and analysis of the market based on the manufacturing type. This includes in-house manufacturing and contract manufacturing.

In-house manufacturing refers to the practice of biosimilar companies producing their products internally rather than outsourcing the manufacturing process. This trend has been fueled by several factors. Additionally, in-house manufacturing allows for better control over the entire production process, ensuring higher quality standards and reducing the risk of supply chain disruptions. In addition, it offers greater flexibility in responding to market demands and regulatory changes, enabling companies to adapt quickly to emerging opportunities and challenges. Apart from this, it often results in cost efficiencies, as it eliminates the need for third-party involvement and reduces transportation and logistics expenses. In confluence with this, companies can protect their intellectual property and maintain a competitive edge by safeguarding their manufacturing know-how. As biosimilar competition intensifies, in-house manufacturing provides companies with a means to differentiate their products and establish themselves as reliable and competent players in the European biosimilar market.

On the other hand, the utilization of contract manufacturing has emerged as a compelling market driver. Contract manufacturing involves biosimilar companies outsourcing the production of their products to specialized manufacturing facilities. This trend has been fueled by several key factors. Moreover, contract manufacturing offers cost advantages, allowing companies to leverage the expertise and economies of scale of established manufacturing facilities without significant capital investments. This enables them to focus on research, development, and commercialization aspects, ultimately expediting time-to-market for their biosimilars. Additionally, access to contract



manufacturing facilities with cutting-edge technologies and regulatory compliance expertise ensures high-quality production, meeting the stringent standards required by regulatory authorities. Moreover, contract manufacturing allows biosimilar companies to maintain flexibility in their operations, scaling production up or down as market demands fluctuate.

#### Competitive Landscape:

The key players in the market are investing significantly in research and development to identify suitable reference biologics and develop biosimilar versions. This involved conducting pre-clinical and clinical studies to demonstrate similarity in efficacy, safety, and quality with the originator biologics. Along with this, the rising utilization of pricing and marketing initiatives to gain market share and compete with originator biologics effectively is significantly supporting the market. In addition, companies are managing their supply chains to ensure a consistent and reliable supply of biosimilar products to meet market demand, such as establishing partnerships with contract manufacturing organizations and distribution networks. Thus, it is positively influencing the market. With increasing competition in the biosimilar market, manufacturers are employing cost-effective pricing, and value-added services, and developing a strong brand reputation. Furthermore, negotiating reimbursement and formulary inclusion to ensure widespread adoption is contributing to the market.

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

Novartis  
Pfizer  
Teva  
Celltrion  
Merck Sharp & Dohme  
Samsung Bioepis  
Eli Lilly  
Accord Healthcare Ltd.  
Amgen  
Boehringer Ingelheim  
Hexal Ag  
Apotex  
Stada Arzneimittel Ag  
Ratiopharm

Mylan

### Key Questions Answered in This Report

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



## Contents

### 1 PREFACE

### 2 SCOPE AND METHODOLOGY

- 2.1 Objectives of the Study
- 2.2 Stakeholders
- 2.3 Data Sources
  - 2.3.1 Primary Sources
  - 2.3.2 Secondary Sources
- 2.4 Market Estimation
  - 2.4.1 Bottom-Up Approach
  - 2.4.2 Top-Down Approach
- 2.5 Forecasting Methodology

### 3 EXECUTIVE SUMMARY

### 4 EUROPE BIOSIMILARS MARKET – INTRODUCTION

- 4.1 Overview
- 4.2 WHO and EMA Terminology on Biosimilars
- 4.3 Biosimilars and Generics
- 4.4 Biosimilars and Branded Biological Products

### 5 EUROPE BIOSIMILARS MARKET

- 5.1 Market Overview
- 5.2 Historical and Current Market Trends
- 5.3 Impact of COVID-19
- 5.4 Market Breakup by Country
- 5.5 Market Breakup by Molecule
- 5.6 Market Breakup by Indication
- 5.7 Market Breakup by Manufacturing Type
- 5.8 Patent Landscape
- 5.9 Market Forecast

## **6 MARKET BREAKUP BY COUNTRY**

### 6.1 Italy

- 6.1.1 Market Performance
- 6.1.2 Key Players and Biosimilars
- 6.1.3 Market Forecast

### 6.2 Germany

- 6.2.1 Market Performance
- 6.2.2 Key Players and Biosimilars
- 6.2.3 Market Forecast

### 6.3 France

- 6.3.1 Market Performance
- 6.3.2 Key Players and Biosimilars
- 6.3.3 Market Forecast

### 6.4 United Kingdom

- 6.4.1 Market Performance
- 6.4.2 Key Players and Biosimilars
- 6.4.3 Market Forecast

### 6.5 Spain

- 6.5.1 Market Performance
- 6.5.2 Key Players and Biosimilars
- 6.5.3 Market Forecast

### 6.6 Rest of Europe

- 6.6.1 Market Performance
- 6.6.2 Market Forecast

## **7 MARKET BREAKUP BY MOLECULE**

- 7.1 Infliximab
- 7.2 Insulin Glargine
- 7.3 Epoetin Alfa
- 7.4 Etanercept
- 7.5 Filgrastim
- 7.6 Somatropin
- 7.7 Rituximab
- 7.8 Follitropin Alfa
- 7.9 Adalimumab

## **8 MARKET BREAKUP BY MANUFACTURING TYPE**

## 8.1 In-house Manufacturing

8.1.1 Market Trends

8.1.2 Market Forecast

## 8.2 Contract Manufacturing

8.2.1 Market Trends

8.2.2 Market Forecast

## **9 MARKET BREAKUP BY INDICATION**

9.1 Auto-Immune Diseases

9.2 Blood Disorder

9.3 Diabetes

9.4 Oncology

9.5 Growth Deficiency

9.6 Female Infertility

## **10 EUROPEAN BIOSIMILAR MARKET: SWOT ANALYSIS**

10.1 Overview

10.2 Strengths

10.3 Weaknesses

10.4 Opportunities

10.5 Threats

## **11 EUROPEAN BIOSIMILAR MARKET: VALUE CHAIN ANALYSIS**

11.1 Characterizing the Existing Innovator Drug

11.2 Research and Development

11.2.1 Characterization of Biosimilars

11.2.2 Developing a Unique Cell Line

11.3 Product Development

11.3.1 Pre-Testing

11.3.2 Intermediary Clinical Testing (PK/PD)

11.3.3 Confirmatory Clinical Phase-III

11.4 Final Product Formulation

11.5 Marketing and Distribution

## **12 PORTER'S FIVE FORCES ANALYSIS**

- 12.1 Overview
- 12.2 Bargaining Power of Buyers
- 12.3 Bargaining Power of Suppliers
- 12.4 Degree of Competition
- 12.5 Threat of New Entrants
- 12.6 Threat of Substitutes

## **13 PRICE ANALYSIS**

- 13.1 Key Price Indicators
- 13.2 Price Trends

## **14 REQUIREMENTS FOR SETTING UP A GENERIC DRUG MANUFACTURING PLANT**

- 14.1 Manufacturing Process
- 14.2 Raw Material Requirements
- 14.3 Raw Material Pictures
- 14.4 Land and Construction Requirements
- 14.5 Machinery and Infrastructure Requirements
- 14.6 Machinery Pictures
- 14.7 Plant Layout
- 14.8 Packaging Requirements
- 14.9 Utility Requirements
- 14.10 Manpower Requirements

## **15 COMPETITIVE LANDSCAPE**

- 15.1 Market Structure
- 15.2 Key Players
- 15.3 Profiles of Key Players
  - 15.3.1 Novartis
  - 15.3.2 Pfizer
  - 15.3.3 Teva
  - 15.3.4 Celltrion
  - 15.3.5 Merck Sharp & Dohme
  - 15.3.6 Samsung Bioepis
  - 15.3.7 Eli Lilly

- 15.3.8 Accord Healthcare Ltd.
- 15.3.9 Amgen
- 15.3.10 Boehringer Ingelheim
- 15.3.11 Hexal Ag
- 15.3.12 Apotex
- 15.3.13 Stada Arzneimittel Ag
- 15.3.14 Ratiopharm
- 15.3.15 Mylan

## List Of Tables

### LIST OF TABLES

- Table 1: Europe: Sales and Patent Expiry of Blockbuster Biological Drugs (in Million US\$)
- Table 2: Biosimilar vs. Innovators Drug Development
- Table 3: Biosimilar vs. Biologics Manufacturing
- Table 4: Europe: Biosimilar Market: Key Industry Highlights, 2023 and 2032
- Table 5: Europe: Biosimilar Market: Patent Landscape
- Table 6: Europe: Biosimilar Market: Price Comparison Between Biosimilar and Originator Drugs
- Table 7: Europe: Biosimilar Market Forecast: Breakup by Region (in Million US\$), 2024-2032
- Table 8: Europe: Biosimilar Market: Key Players and Biosimilars
- Table 9: Italy: Biosimilar Market: Key Players and Biosimilars
- Table 10: Germany: Biosimilar Market: Key Players and Biosimilars
- Table 11: France: Biosimilar Market: Key Players and Biosimilars
- Table 12: United Kingdom: Biosimilar Market: Key Players and Biosimilars
- Table 13: Spain: Biosimilar Market: Key Players and Biosimilars
- Table 14: Europe: Rituximab: Brand & Biosimilar Market Overview
- Table 15: Europe: Infliximab: Brand & Biosimilar Market Overview
- Table 16: Europe: Insulin Glargine: Brand & Biosimilar Market Overview
- Table 17: Europe: Epoetin Alfa: Brand & Biosimilar Market Overview
- Table 18: Europe: Filgrastim: Brand & Biosimilar Market Overview
- Table 19: Europe: Somatropin: Brand & Biosimilar Market Overview
- Table 20: Europe: Etanercept: Brand & Biosimilar Market Overview
- Table 21: Europe: Follitropin Alfa: Brand & Biosimilar Market Overview
- Table 22: Europe: Biosimilar Market Forecast: Breakup by Manufacturing Type (in Million US\$), 2024-2032
- Table 23: Europe: Biosimilar Market Forecast: Breakup by Indication (in Million US\$), 2024-2032
- Table 24: Biosimilar Manufacturing Plant: Raw Material Requirements
- Table 25: Biosimilar Manufacturing Plant: Land and Construction Requirements
- Table 26: Biosimilar Manufacturing Plant: Machinery Requirements
- Table 27: Biosimilar Manufacturing Plant: Manpower Requirements
- Table 28: Europe: Biosimilar Market: Competitive Structure
- Table 29: Europe: Biosimilar Market: Key Players

## List Of Figures

### LIST OF FIGURES

Figure 1: Europe: Biosimilar Market: Sales Value (in Million US\$), 2018-2023

Figure 2: Europe: Biosimilar Market: Breakup by Molecule (in %), 2023

Figure 3: Europe: Biosimilar Market: Breakup by Manufacturing Type (in %), 2023

Figure 4: Europe: Biosimilar Market: Breakup by Indication (in %), 2023

Figure 5: Europe: Biosimilar Market: Breakup by Country (in %), 2023

Figure 6: Europe: Biosimilar Market Forecast: Sales Value (in Million US\$), 2024-2032

Figure 7: Italy: Biosimilar Market: Sales Value (in Million US\$), 2018-2023

Figure 8: Italy: Biosimilar Market Forecast: Sales Value (in Million US\$), 2024-2032

Figure 9: Germany: Biosimilar Market: Sales Value (in Million US\$), 2018-2023

Figure 10: Germany: Biosimilar Market Forecast: Sales Value (in Million US\$), 2024-2032

Figure 11: France: Biosimilar Market: Sales Value (in Million US\$), 2018-2023

Figure 12: France: Biosimilar Market Forecast: Sales Value (in Million US\$), 2024-2032

Figure 13: United Kingdom: Biosimilar Market: Sales Value (in Million US\$), 2018-2023

Figure 14: United Kingdom: Biosimilar Market Forecast: Sales Value (in Million US\$), 2024-2032

Figure 15: Spain: Biosimilar Market: Sales Value (in Million US\$), 2018-2023

Figure 16: Spain: Biosimilar Market Forecast: Sales Value (in Million US\$), 2024-2032

Figure 17: Rest of Europe: Biosimilar Market: Sales Value (in Million US\$), 2018-2023

Figure 18: Rest of Europe: Biosimilar Market Forecast: Sales Value (in Million US\$), 2024-2032

Figure 19: Europe: Rituximab Biosimilar Market: Sales Value (in Million US\$), 2017

Figure 20: Europe: Infliximab Biosimilar Market: Sales Value (in Million US\$), 2015 - 2017

Figure 21: Europe: Insulin Glargine Biosimilar Market: Sales Value (in Million US\$), 2016 & 2017

Figure 22: Europe: Epoetin Alfa Biosimilar Market: Sales Value (in Million US\$), 2014 - 2017

Figure 23: Europe: Filgrastim Biosimilar Market: Sales Value (in Million US\$), 2014 - 2017

Figure 24: Europe: Somatropin Biosimilar Market: Sales Value (in Million US\$), 2014 - 2017

Figure 25: Europe: Etanercept Biosimilar Market: Sales Value (in Million US\$), 2016 & 2017

Figure 26: Europe: Follitropin Alfa Biosimilar Market: Sales Value (in Million US\$), 2015



- 2017

Figure 27: Europe: Adalimumab Biosimilar Market: Sales Value (in Million US\$), 2018

Figure 28: Europe: Biosimilar Market (In-House Manufacturing): Sales Value (in Million US\$), 2018 & 2023

Figure 29: Europe: Biosimilar Market Forecast (In-House Manufacturing): Sales Value (in Million US\$), 2024-2032

Figure 30: Europe: Biosimilar Market (Contract Manufacturing): Sales Value (in Million US\$), 2018 & 2023

Figure 31: Europe: Biosimilar Market Forecast (Contract Manufacturing): Sales Value (in Million US\$), 2024-2032

Figure 32: Europe: Biosimilar Market (Autoimmune Diseases): Sales Value (in Million US\$), 2018 & 2023

Figure 33: Europe: Biosimilar Market Forecast (Autoimmune Diseases): Sales Value (in Million US\$), 2024-2032

Figure 34: Europe: Biosimilar Market (Blood Disorders): Sales Value (in Million US\$), 2018 & 2023

Figure 35: Europe: Biosimilar Market Forecast (Blood Disorders): Sales Value (in Million US\$), 2024-2032

Figure 36: Europe: Biosimilar Market (Diabetes): Sales Value (in Million US\$), 2018 & 2023

Figure 37: Europe: Biosimilar Market Forecast (Diabetes): Sales Value (in Million US\$), 2024-2032

Figure 38: Europe: Biosimilar Market (Oncology): Sales Value (in Million US\$), 2018 & 2023

Figure 39: Europe: Biosimilar Market Forecast (Oncology): Sales Value (in Million US\$), 2024-2032

Figure 40: Europe: Biosimilar Market (Growth Deficiency): Sales Value (in Million US\$), 2018 & 2023

Figure 41: Europe: Biosimilar Market Forecast (Growth Deficiency): Sales Value (in Million US\$), 2024-2032

Figure 42: Europe: Biosimilar Market (Female Infertility): Sales Value (in Million US\$), 2018 & 2023

Figure 43: Europe: Biosimilar Market Forecast (Female Infertility): Sales Value (in Million US\$), 2024-2032

Figure 44: Europe: Biosimilar Industry: SWOT Analysis

Figure 45: Europe: Biosimilar Industry: Value Chain Analysis

Figure 46: Europe: Biosimilar Industry: Porter's Five Forces Analysis

Figure 47: Biosimilar Manufacturing: Detailed Process Flow

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