

Global Biosimilars Market – Products, Applications and Regulations

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Abstracts

Report Synopsis

Due to the COVID-19 Pandemic, telehealth and tele-detailing (also called remoter detailing or web calls) have set forth that allow a biosimilars companies' commercialization branch to have a wide range with less few reps. Also, the fluidity of the labor market is another new dynamic allowing for a greater diversity of commercialization build-out models. These new dynamics greatly change how companies should be building models of commercialization that also has vast implications for potential BD partnerships. The solution to 'build versus buy' is no longer driven by the size, scale, and cost of a sales force leading to outdated product P&L's. However, a hybrid solution that a partial build plus skilled, experienced contractors plus CSO for sales reps will be the optimal solution. This hybrid model could allow for greater biosimilar uptake and more efficient uptake.

Global market for Biosimilars is dominated by Oncology, estimated at US\$5.4 billion (38.6% share) in 2020, which is anticipated to post the slowest CAGR of 29% between 2020 and 2026 and reach a projected US\$24.8 billion by 2026.

Research Findings & Coverage

Global Biosimilars market is analyzed in this report with respect to key product types and major therapeutic areas

The study exclusively analyzes the market for each product type and therapeutic area of Biosimilars by all major geographic regions/countries globally



mAbs - All the Rage in Biosimilars' New Wave

Patent Expirations of Major Biologics Leads Way for Biosimilars

Role of Biosimilars in Continuous Manufacturing (CM) Development and Innovation

Availability of Biosimilar May Affect Biologic Drug Pricing

Key business trends focusing on product innovations/developments, M&As, JVs and other recent industry developments

Major companies profiled – 36

The industry guide includes the contact details for 155 companies

Product Outline

The report analyzes the market for the following key product types of Biosimilars:

Monoclonal Antibodies (mAB)

Erythropoietin (EPO)

Granulocyte Colony-Stimulating Factor (G-CSF)

Insulin

Others (includes Interferons, Follitropins, Recombinant Proteins etc.)

Therapeutic areas of Biosimilars analyzed in this study comprise the following:

Oncology

Autoimmune Disorders

Blood Disorders



Growth Hormone Deficiency

Others (includes Chronic Diseases, Infectious Diseases, Cardiovascular Disorders etc.)

Analysis Period, Units and Growth Rates

The report reviews, analyzes and projects the global Biosimilars market for the period 2017-2026 in terms of US\$ and the compound annual growth rates (CAGRs) projected from 2019 through 2026

Geographic Coverage

North America (The United States, Canada and Mexico)

Europe (Germany, the United Kingdom, France, Spain, Italy and Rest of Europe)

Asia-Pacific (China, India, Japan, South Korea and Rest of Asia-Pacific)

Rest of World (Brazil, Israel and Other Rest of World)



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AXXO GmbH (Germany)

BIOCAD (Russia)

Biogen, Inc. (The United States)

Bioton S.A. (Poland)

C.H. Boehringer Sohn AG & Co., KG. (Germany)

Coherus Biosciences (The United States)

Creative BioMart (The United States)

Dong-A Socio Group (South Korea)

Dr. Reddy's Laboratories Ltd. (India)

Eli Lilly and Company (The United States)

Genor Biopharma Co., Ltd. (China)

Hetero Drugs Limited (India)

Insud Pharma SL (Spain)

mAbxience SA (Spain)

Intas Pharmaceuticals Ltd. (India)

Kashiv Biosciences LLC (The United States)

LG Chem (South Korea)

Lupin Limited (India)

Mylan, Inc (The United States)

Nippon Kayaku Co., Ltd. (Japan)

Pfizer, Inc. (The United States)

Reliance Life Sciences Pvt. Ltd. (India)

Sandoz International GmbH (Germany)

Shanghai Henlius Biotech, Inc. (China)

STADA Arzneimittel AG (Germany)

Teva Pharmaceutical Industries Limited (Israel)

Wockhardt Limited (India)

6. KEY BUSINESS AND PRODUCT TRENDS



AbbVie Inc and Frontier Collaborate on Novel Therapies and E3 Degraders Eli Lilly and UHG Collaborate on Bamlanivimab (LY-CoV555) Antibody Study Merck Receives FDA Review Acceptance for KEYTRUDA® (pembrolizumab) Plus Chemotherapy

Samsung Bioepis and Biogen File U.S FDA Acceptance of SB11 Biosimilar

EMA Approves Roche's Xofluza® Biosimilar

Genor's New Drug Application for GB242 Infliximab Biosimilar is Under Review by NMPA

NeuClone Discloses it's Stelara® Biosimilar Candidate Clinical Trials

FDA Approval for Anti-IL-4R? Monoclonal Antibody

Pfizer's NYVEPRIA™ Biosimilar Receives FDA Approval

Biocon Ltd Establishes Biosimilar Plant in India

Boehringer Acquires Northern Biologics, Inc

Biocon Ltd. and Mylan N.V Unveils Fulphila® Biosimilar

mAbxience Establishes New Biosimilar Antibody Plant in Argentina

CHMP Recommends RUXIENCE™ Biosimilar

FDA Approval for ABP 798, a Biosimilar Candidate to Rituxan®

Amgen Receives FDA Approval for its AVSOLA™ (Infliximab-axxq) Biosimilar Antibody

3SBio, Inc and Verseau Agree on Monoclonal Antibody Development - VTX-0811

Boehringer Ingelheim Discloses GioTag Study Results

Dr. Reddy's Lab Unveils Versavo® Biosimilar

Allergan and Gedeon Receive FDA Approval for VRAYLAR® Drug Use

Samsung Bioepis Signs Biosimilars Development and Marketing Agreement with C-Bridge Capital

Biosimilar Association of Samsung Bioepis and 3SBio

Kashiv Pharma Renamed as KashivBioSciences Post Acquiring Adello Biologics

Intas Unveils New Pegylated G-CSF Biosimilar in Europe

Japanese Release of Trastuzumab and Agalsidase Beta Biosimilar

Epoetin Alfa and Pegfilgrastim Biosimilars Now Accessible In the US at Considerable Concession

Biosimilars of Insulin Glargine Introduced in South Korea and the UK

CNDA Accepted Review of Adalimumab Biosimilar

Filgrastim Biosimilar Application Submitted to the US FDA

European Commercial Release of Amgevita and Imraldi

MHLW of Japan Received Approval Application for Dual Darbepoetin Alfa Copy Biologics

Evaluation of Adalimumab Biosimilar SB5 by USFDA

Acceptance of Approval Application by CFDA for Adalimumab Biosimilar



Review Acceptance for MabionCD20 by EMA and Rituxan Expanded the Therapeutic Range

Dr Reddy's Introduces Hervycta, A Trastuzumab Biosimilar in India

Apotex Influence Canadian Biosimilar Market

Resubmission of Marketing Approval of Biosimilar Rituximab to FDA by Celltrion

Refusal of Trastuzumab and Rituximab Biosimilars Approval Applications by FDA

Rejection of Rituximab and Trastuzumab of Celltrion/Teva by FDA

Amgen and Allergan Authorize ABP 980 Biosimilar

OntruzantTrastuzumab Biosimilar Released in the UK

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AXXO GmbH (Germany)

BIOCAD (Russia)

Bioton S.A. (Poland)

C.H. Boehringer Sohn AG & Co., KG. (Germany)

F. Hoffmann-La Roche Ltd (Switzerland)

Fresenius Kabi AG (Germany)

Insud Pharma SL (Spain)

mAbxience SA (Spain)

Sandoz International GmbH (Germany)

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Apotex, Inc. (Canada)

Biogen, Inc. (The United States)

Coherus BioSciences (The United States)

Creative Biomart, Inc. (The United States)

Eli Lilly and Company (The United States)

Kashiv Biosciences LLC (The United States)

Mylan, Inc (The United States)

Pfizer, Inc. (The United States)

Probiomed S.A. De C.V (Mexico)

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Celltrion, Inc. (South Korea)

Dong-A Socio Group (South Korea)

Dr. Reddy's Laboratories Ltd. (India)

Genor Biopharma Co., Ltd. (China)

Hetero Drugs Limited (India)

Intas Pharmaceuticals Ltd (India)

LG Chem (South Korea)

Lupin Limited (India)

Nippon Kayaku Co., Ltd. (Japan)

Reliance Life Sciences Pvt., Ltd. (India)

Samsung Biologics Co., Ltd. (South Korea)

Shanghai Henlius Biotech, Inc. (China)

Wockhardt Limited (India)

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