

Europe Biosimilars Market Opportunity Outlook 2020

<https://marketpublishers.com/r/E561A9EEEC9EN.html>

Date: November 2015

Pages: 310

Price: US\$ 2,400.00 (Single User License)

ID: E561A9EEEC9EN

Abstracts

Please note: extra shipping charges are applied when purchasing Hard Copy License depending on the location.

Burgeoning pressure on healthcare system has caused the regulators across the globe to look for suitable therapeutic options. Biologic drugs are commonly used for treatment of various diseases but they are costly and their alternative options are difficult to find. Biosimilars have come forth as new modality having lesser cost with equivalent therapeutic efficacy like biologics. They are introduced in market after patent expiry of biologics and Europe became the first market to allow commercialization of biosimilars. European Commission (EC) passed legislation in 2004 creating approval pathway (Directive 2001/83/EC Directive 2004/27/EC) for biosimilars. European Medicines Agency (EMA) approved first biosimilar in 2006, since then several biosimilars have been introduced in European market owing to applicability in numerous indications and higher cost arbitrage. In this way, European nations are expected to relieve burden from their healthcare system with the help of biosimilars.

Safety and efficacy are main concerns with biosimilars; EMA requires head-to-head comparison for ensuring pharmacological parameters. Ensuring similarity or high similarity in bioanalytical way decreases market winding time. Consequently, clinical trials could be conducted with higher confidence levels to ensure patient safety. Many biosimilars belonging to different categories for different indications has been introduced in past years. They have been able to erode profit margins of biologics in past decades. Wide acceptance could also be observed leading to higher prescription for biosimilars as compared to biologics. This scenario shows that biosimilars developers will have lots of commercialization opportunities in European market.

Biosimilars have been introduced for several disease categories offering myriad of options to the patients. Cancer supportive therapies have large consumer base due to which associated biosimilars are in high demand. Filgrastim and Erythropoietins

biosimilars are one of the widely used products in European market. These well-established segments have numbers of products as compared to other disease categories. Biosimilar monoclonal antibodies are in high demand as they have high safety and efficacy along with minimized side effects. Their cost is also lesser as compared to biologic monoclonal antibodies. Besides this, biosimilar insulin has also been introduced which have capability to generate significant revenues. Biosimilar insulin has created as new segment due to which more biosimilar products are expected to enter in coming years. In this way, European biosimilars market shows diverse categories and opportunities to venture in newly developed segments.

Extrapolation of biosimilars is allowed after establishing significant comparability with reference biologics. Depending on quality profile they are approved by EMA and biosimilar developers have to submit Risk Management Plan (RMP). This measure ensures that biosimilars entering in European market are harmless. Biosimilar developers from developing countries find it difficult to enter in European market as their fall short of EMA's standards. On the other hand, outsourced biosimilars products showing compliance with EMA's norms are allowed for commercialization. In this way, biosimilar developers from under developing countries find Europe as a suitable market place. Their competitive prices and highly developed manufacturing capabilities have also contributed in growth of European biosimilars market.

“Europe Biosimilars Market Opportunity Outlook 2020” Report Highlight:

Europe Biosimilars Market Outlook

Europe Biosimilars Market Trend Analysis by Country

Introduction of Biosimilars in European Market by Segment

Clinical & Non Clinical Guidelines

Europe Biosimilar Clinical Pipeline by Country, Company, Indication & Phase

Europe Biosimilar Clinical Pipeline: 109 Biosimilars

Clinical Insight of Biosimilars Marketed in Europe

Marketed Biosimilars in Europe: 20 Biosimilars

Contents

1. EUROPE BIOSIMILARS MARKET OUTLOOK

- 1.1 Market Overview
- 1.2 Biosimilars in Clinical Trials in Europe

2. EUROPE BIOSIMILARS MARKET TREND ANALYSIS BY COUNTRY

- 2.1 Austria
- 2.2 Belgium
- 2.3 France
- 2.4 Germany
- 2.5 Hungary
- 2.6 Italy
- 2.7 Norway
- 2.8 Poland
- 2.9 Spain
- 2.10 Sweden
- 2.11 Switzerland
- 2.12 UK

3. INTRODUCTION OF BIOSIMILARS IN EUROPEAN MARKET BY SEGMENT

- 3.1 Growth Hormones (2006)
- 3.2 Epoetin (2007)
- 3.3 G-CSF (2008)
- 3.4 Monoclonal Antibodies (2013)
- 3.5 Follitropin (2013)
- 3.6 Insulin (2015)

4. EUROPE BIOSIMILARS RISK MANAGEMENT PLANNING & SAFETY REGULATION SCENARIO

5. EUROPE BIOSIMILARS MARKET DYNAMICS

- 5.1 Favorable Parameters
- 5.2 Growth Inhibitors

6. EUROPE BIOSIMILARS MARKET FUTURE OUTLOOK

7. EUROPE BIOSMILARS MARKET REGULATORY FRAMEWORK

8. CLINICAL & NON CLINICAL GUIDELINE FOR DEVELOPMENT OF BIOSIMILARS IN EUROPE

- 8.1 Development of Similar Biological Medicinal Products Containing r-hFSH
- 8.2 Similar Biological Medicinal Products Containing Interferon Beta
- 8.3 Immunogenicity Assessment of Monoclonal Antibodies Intended For In Vivo Clinical Use
- 8.4 Similar Biological Medicinal Products Containing Monoclonal Antibodies
- 8.5 Similar Biological Medicinal Products Containing Recombinant Erythropoietins
- 8.6 Similar Medicinal Products Containing Recombinant Human Soluble Insulin
- 8.7 Similar Medicinal Products Containing Somatropin
- 8.8 Similar Biological Medicinal Products Containing Biotechnology Derived Proteins as Active Substance
- 8.9 Immunogenicity Assessment of Biotechnology-Derived Therapeutic Proteins
- 8.10 Comparability of Biotechnology-Derived Medicinal Products After A Change In The Manufacturing Process

9. EUROPE BIOSIMILAR CLINICAL PIPELINE BY COUNTRY, COMPANY, INDICATION & PHASE

- 9.1 Unknown
- 9.2 Research
- 9.3 Preclinical
- 9.4 Clinical
- 9.5 Phase-I
- 9.6 Phase-II
- 9.7 Phase-III
- 9.8 Preregistration
- 9.9 Registered

10. CLINICAL INSIGHT OF BIOSIMILARS MARKETED IN EUROPE

- 10.1 Epoetin Alfa Biosimilar (Sandoz)
- 10.2 Epoetin Alfa Biosimilar (Wockhardt)
- 10.3 Epoetin Theta Biosimilar (Teva Pharmaceutical)

- 10.4 Epoetin Zeta (Hospira, STADA Arzneimittel)
- 10.5 Filgrastim Biosimilar (CT Arzneimittel)
- 10.6 Filgrastim Biosimilar (Hexal)
- 10.7 Filgrastim Biosimilar (Hospira)
- 10.8 Filgrastim Biosimilar (Ratiopharm/Teva)
- 10.9 Filgrastim Biosimilar (Sandoz)
- 10.10 Follitropin Alfa Biosimilar (Teva)
- 10.11 Infliximab (Janssen Biotech)
- 10.12 Infliximab Biosimilar (Celltrion)
- 10.13 Insulin Biosimilar (Wockhardt)
- 10.14 Insulin Suspension Isophane Biosimilar (Wockhardt)
- 10.15 Insulin/Insulin Suspension Isophane Biosimilar (Wockhardt)
- 10.16 Lipegfilgrastim (Teva Pharmaceutical)
- 10.17 Peginterferon Alfa-2a (Roche)
- 10.18 Peginterferon Alfa-2b (Merck Sharp & Dohme)
- 10.19 Somatropin Biosimilar (Sandoz)
- 10.20 Trastuzumab (Genentech)

11. SUSPENDED & DISCONTINUED BIOSIMILARS CLINICAL INSIGHT

- 11.1 No Development Reported
- 11.2 Discontinued

12. COMPETITIVE LANDSCAPE

- 12.1 Alvotech
- 12.2 Allergan
- 12.3 Amgen
- 12.4 Biocad
- 12.5 Bio-Ker
- 12.6 BioXpress Therapeutics
- 12.7 Boehringer Ingelheim
- 12.8 Cerbios Pharma
- 12.9 Celltrion
- 12.10 Gedeon Richter
- 12.11 Genentech
- 12.12 Genexine
- 12.13 Glycotope
- 12.14 Harvest Moon Pharmaceuticals

- 12.15 Hospira
- 12.16 Janssen Biotech
- 12.17 LFB Biotechnologies
- 12.18 Mabion
- 12.19 mAbxience
- 12.20 Merck
- 12.21 Momenta Pharmaceuticals
- 12.22 Novartis
- 12.23 Perosphere
- 12.24 Pfizer
- 12.25 Reliance Life Sciences
- 12.26 Roche
- 12.27 R-Pharm
- 12.28 Samsung Bioepis
- 12.29 Sanofi
- 12.30 Teva Pharmaceutical
- 12.31 Wockhardt

List Of Figures

LIST OF FIGURES

- Figure 1-1: Europe - Biosimilars Market Opportunity (US\$ Million), 2015-2020
- Figure 1-2: Europe - Biosimilars Market Favorable Parameters
- Figure 1-3: Europe - Biosimilar Pipeline by Phase (%)
- Figure 1-4: Europe - Biosimilar Pipeline by Phase (Number)
- Figure 1-5: Europe - No Development Reported in Biosimilar Pipeline by Phase (%)
- Figure 1-6: Europe - No Development Reported in Biosimilar Pipeline by Phase (Number)
- Figure 1-7: Europe - Suspended Biosimilar Pipeline by Phase (%)
- Figure 1-8: Europe - Suspended Biosimilar Pipeline by Phase (%)
- Figure 3-1 Europe - Biosimilar Product Approval Timeline
- Figure 3-2: Europe - Biosimilars Market Emerging Segment
- Figure 3-3: Europe - Approved Biosimilars by Segment
- Figure 3-4: Europe - HGH Biosimilars Approved & Available in Market
- Figure 3-5: Europe - EPO Biosimilars Approved & Available in Market
- Figure 3-6: Europe - G-CSF Biosimilars Approved & Available in Market
- Figure 3-7: Europe - mAbs Biosimilars Approved & Available in Market
- Figure 3-8: Europe - Follitropin Biosimilars Approved & Available in Market
- Figure 3-9: Europe - Insulin Biosimilars Approved & Available in Market
- Figure 4-1: Europe - Safety Evaluation of Biosimilars after Marketing Approval
- Figure 4-2: Risk Management of Biosimilars
- Figure 4-3: Overview of Demonstrating Biosimilarity
- Figure 5-1: Bolar Provision for the Development of Biosimilars in Europe
- Figure 5-2: Effects of Reimbursement Policies on Healthcare System
- Figure 5-3: Available Biosimilars in Market by Company & Segment
- Figure 5-4: Europe - Drivers for Success in European Biosimilars Market
- Figure 5-5: Europe - Market Growth Challenges
- Figure 7-1: Europe - Regulatory Timeline for the Approval of Biosimilars
- Figure 7-2: European Union - Schematic Overview of Biosimilar Approval
- Figure 7-3: Biosimilars Development Process

COMPANIES MENTIONED

Alvotech, Allergan, Amgen, Biocad, Bio-Ker, BioXpress Therapeutics, Boehringer Ingelheim, Cerbios Pharma, Celltrion, Gedeon Richter, Genentech, Genexine, Glycotope, Harvest Moon Pharmaceuticals, Hospira, Janssen Biotech, LFB

Biotechnologies, Mabion, mAbxience, Merck, Momenta Pharmaceuticals, Novartis, Perosphere, Pfizer, Reliance Life Sciences, Roche, R-Pharm, Samsung Bioepis, Sanofi, Teva Pharmaceutical, Wockhardt

I would like to order

Product name: Europe Biosimilars Market Opportunity Outlook 2020

Product link: <https://marketpublishers.com/r/E561A9EEEC9EN.html>

Price: US\$ 2,400.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/E561A9EEEC9EN.html>

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:
Last name:
Email:
Company:
Address:
City:
Zip code:
Country:
Tel:
Fax:
Your message:

****All fields are required**

Customer signature _____

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms & Conditions at <https://marketpublishers.com/docs/terms.html>

To place an order via fax simply print this form, fill in the information below and fax the completed form to +44 20 7900 3970