

Europe Biosimilars Market & Pipeline Insight

<https://marketpublishers.com/r/E9D3CEB2C88EN.html>

Date: October 2014

Pages: 360

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

ID: E9D3CEB2C88EN

Abstracts

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

Biosimilars have emerged as one of the most promising segment of the European pharmaceutical industry in recent years. The biosimilars segment has been experiencing a steady growth driven by patent expiration of blockbuster drugs, amenable regulatory framework, economic incentives along with favorable pricing and reimbursement policies adopted across multiple markets in Europe. The current biosimilars market is highly fragmented in nature due to their accessibility in various therapeutic categories. The European biosimilars market is divided into various categories: Granulocyte-colony stimulating factor (G-CSF or GCSF), erythropoiesis-stimulating agents (ESAs) and somatropin biosimilars, Insulin, mAbs and follitropin. The present market fragmentation is driven by the availability of particular biosimilar products which were introduced over a decade ago. These products created niche among them and resulted in inclination toward a particular segments over a period of time.

One of the most promising factors responsible for the development of biosimilars market is the patent expiration of reference drugs. The European biosimilars market is experiencing tremendous growth as blockbuster biologic drugs are going off-patent. The entry of new biosimilars due to patent expiry into various therapeutic indications has created a new category for the biosimilars. For instance, Ely Lilly and Boehringer Ingelheim have already got marketing authorization of their biosimilar insulin in June'2014 even as the current diabetes drug (Lantus) marketed by Sanofi will go off patent in February'2015.

The competitive pricing and reimbursement policies adopted by country specific regulators are also promoting the introduction of biosimilars in European market. The newly introduced biosimilars are approximately 20-30% cheaper and hence results in

high level of acceptability among patients and physicians in comparison to originator molecule. The benefits of using the biosimilars include reimbursement provided by many governments which further decreases the financial burden from the patients as result of which they do not revert to originator molecules.

Currently there are 18 biosimilars available in European market and more than 90 are in multiple phases of development in clinical pipeline. Majority of the available biosimilars are approved for the treatment of indication like Cancer, Kidney Failure and Anemia.

Approved Biosimilars in Europe:

Abseamed (epoetin alfa), Bemfola (follitropin alfa), Binocrit (epoetin alfa), Biograstim (filgrastim), Epoetin Alfa Hexal (epoetin alfa), Filgrastim Hexal (filgrastim), Grastofil (filgrastim), Inflectra (infliximab), Nivestim (filgrastim), Omnitrope (somatropin), Ovaleap (follitropin alfa), Ratiograstim (filgrastim), Remsima (infliximab), Retacrit (epoetin zeta), Silapo (epoetin zeta), Tevagrastim (filgrastim), Zarzio (filgrastim), Wepox (epoetin alfa)

“Europe Biosimilars Market & Pipeline Insight” Report Highlight:

Biosimilars Market Overview & Trend Analysis by Country

Biosimilars Introduction Timeline in Europe

Biosimilars Development & Market Authorization Guidelines

Biosimilars Clinical Pipeline by Phase, Indication, Company & Country

Marketed Biosimilars Clinical Insight by Phase, Indication, Company & Country

Europe Biosimilars Pipeline: 93 Biosimilars

Marketed Biosimilars: 18 Biosimilars (17 Approved by EMA & 1 in Ukraine)

Contents

1. EUROPE BIOSIMILARS MARKET OVERVIEW

- 1.1 Current Market Scenario
- 1.2 Biosimilars Clinical Pipeline Overview

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. BIOSIMILARS INTRODUCTION TIMELINE IN EUROPE

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

4. EUROPE BIOSIMILARS RISK MANAGEMENT PLANNING & SAFETY REGULATION SCENARIO

5. EUROPE BIOSIMILARS MARKET DYNAMICS

- 5.1 Favorable Market Parameters
 - 5.1.1 Bolar Provisions Supporting Biosimilars Development
 - 5.1.2 Patent Expiry to Tap European Biosimilars Markets

- 5.1.3 Reimbursement Policies
- 5.1.4 Increasing Level of Investments
- 5.1.5 Manufacturing Capabilities
- 5.1.6 R&D Expertise
- 5.2 Market Growth Challenges

6. FUTURE PROSPECTUS OF BIOSIMILARS IN EUROPE

7. REGULATORY & APPROVAL AUTHORITIES: EMA & CHMP

8. BIOSIMILARS DEVELOPMENT & MARKET AUTHORIZATION GUIDELINES

- 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 BIOSIMILARS CLINICAL PIPELINE BY PHASE, INDICATION, COMPANY & COUNTRY

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

10. MARKETED BIOSIMILARS CLINICAL INSIGHT BY PHASE, INDICATION, COMPANY & COUNTRY

11. NO DEVELOPMENT REPORTED IN BIOSIMILARS CLINICAL PIPELINE

11.1 No Development Reported

11.2 Discontinued

12. COMPETITIVE LANDSCAPE

12.1 Apotex

12.2 Celltrion Healthcare

12.3 Hexal

12.4 Hospira

12.5 Finox Biotech

12.6 Medice Arzneimittel P?tter

12.7 Sandoz

12.8 Stada Arzneimittel

12.9 Teva Pharma

List Of Figures

LIST OF FIGURES

- Figure 1-1: Europe – Biosimilars Market Opportunity (US\$ Million), 2014-2020
- Figure 1-2: Factors Responsible for Growth of Biosimilars Market in Europe
- Figure 1-3: Europe Biosimilar Pipeline by Phase (%), 2014
- Figure 1-4: Europe Biosimilar Pipeline by Phase (Number), 2014
- Figure 1-5: No Development Reported in Biosimilar Pipeline by Phase (%), 2014
- Figure 1-6: No Development Reported in Biosimilar Pipeline by Phase (Number), 2014
- Figure 1-7: Suspended Biosimilar Pipeline by Phase (%), 2014
- Figure 1-8: Suspended Biosimilar Pipeline by Phase (%), 2014
- Figure 3-1 Biosimilar Product Approval Timeline in Europe
- Figure 3-2: Europe Biosimilars Market Emerging Segment
- Figure 3-3: Approved Biosimilars by Segment
- Figure 3-4: HGH Biosimilars Approved & Available in European Market
- Figure 3-5: EPO Biosimilars Approved & Available in European Market
- Figure 3-6: G-CSF Biosimilars Approved & Available in European Market
- Figure 3-7: mAbs Biosimilars Approved & Available in European Market
- Figure 3-8: Follitropin Biosimilars Approved & Available in European Market
- Figure 3-9: Insulin Biosimilars Approved & Available in European Market
- Figure 4-1: Safety Evaluation of Biosimilars after Marketing Approval in Europe
- 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: Drivers for Success in European Biosimilars Market
- Figure 5-5: Market Growth Challenges
- Figure 7-1: Regulatory Timeline for the Approval of Biosimilars
- Figure 7-2: Schematic Overview of Biosimilar Approval in EU
- Figure 7-3: Biosimilars Development Process

I would like to order

Product name: Europe Biosimilars Market & Pipeline Insight

Product link: <https://marketpublishers.com/r/E9D3CEB2C88EN.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/E9D3CEB2C88EN.html>