PharmaSphere

Global Biosimilars Strategy

Regulatory Landscape, Key Drivers, Markets and Trends in 2013

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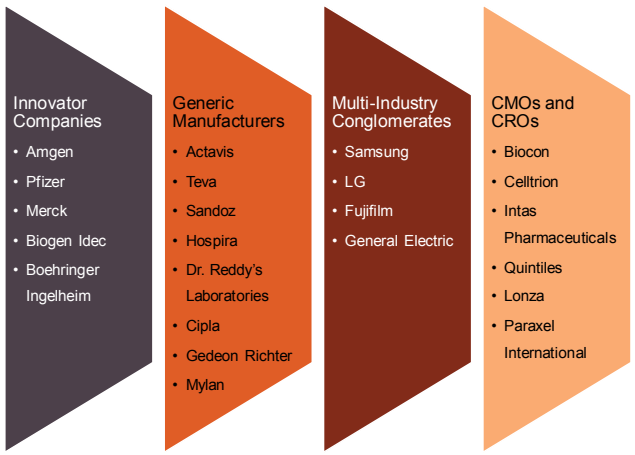
GlobalData

Biosimilars have stated their intention of being here to stay, as recent events show an increasing trend in efforts by companies to enter and/or enhance their position in the biosimilars industry. Indeed, biosimilars are becoming crucial features of governments' plans to reduce healthcare expenditures and increase foreign investment. Various factors, including financial austerity measures due to increasing budget deficits and debt, slowed economic growth in countries such as the US, an increasing aging population and an associated increase in the demand for healthcare in other countries like Japan, are some of the key drivers of initiatives to encourage biosimilars.

Furthermore, the recent intensification of efforts to establish frameworks under which biosimilars can be effectively regulated, by various regulatory bodies including the US Food Drug and Administration (FDA), point to a future influx of biosimilars into significantly untapped markets, as companies continue to actively position themselves strategically. Interestingly, pharmaceutical and biotech companies are not the only ones getting into the biosimilars business, but also Contract Manufacturing Organizations (CMOs) such as Lonza and Celltrion, Contract Research Organizations (CROs) like Quintiles and Paraxel, and multi-industry conglomerates such as Samsung and LG – all companies that fancy a significant payday from being involved in the development and sale of biosimilars.

The figure below shows the various groups of companies currently involved in biosimilars development.

Groups of Companies Currently Involved in Biosimilars Development



Source: GlobalData, Pharma eTrack [Accessed May 2, 2013].

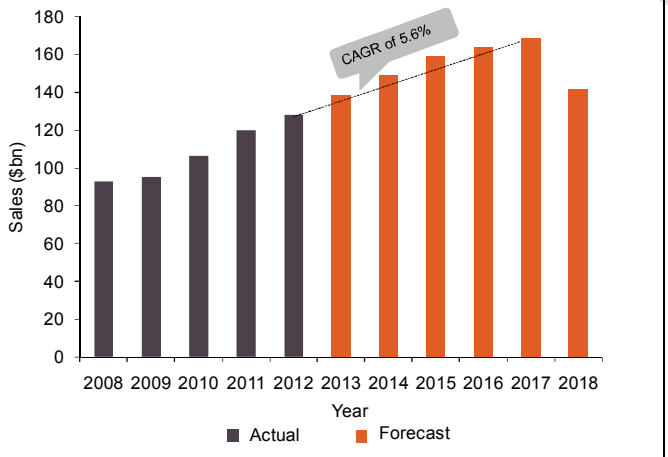
Although biosimilars will deliver some healthcare cost savings, the discount percentages earlier expected have been significantly reduced. Biosimilars are expected to be marketed at between 70% and 80% of the cost of the branded biologic, thereby delivering only a 20%–30% reduction in cost. For instance, Celltrion's recently approved Remsima – a biosimilar to Merck's Remicade (infliximab) – is expected to sell for 70% the price of Remicade in South Korea. This is in sharp contrast to generic small-molecule drugs, some of which sell for up to only 10% of the price of the innovator drug. However, the expensive nature of biologics, some of which sell for as much as hundreds of thousands of dollars for a year's treatment, makes even a 20% price reduction quite significant. In fact, it is estimated that enabling generic options on just the top 12 categories of biologic treatments with expired patents would save the US $67 billion–$108 billion over the first 10 years, and $236 billion–$378 billion over 20 years – an average of about $31 billion a year (Shapiro, 2008). This would significantly aid the government's efforts to stabilize the economy and reduce its budget deficit.

Branded Biologics Sales Will Grow through 2017

The growing dependence on biologics to provide significant benefits in the effective treatment of chronic diseases such as rheumatoid arthritis, psoriasis, cancer, Crohn's Disease and similar conditions has resulted in the continued increase in sales, generating over $128 billion in 2012 alone. This trend is expected to continue in the short term, growing by a Compound Annual Growth Rate (CAGR) of about 5.6% to reach over $168 billion by 2017. Afterwards, patent expirations and the existence of clearer regulatory frameworks for biosimilars will result in an upsurge of biosimilars in key biologics markets such as the US, having an adverse effect on global branded biologic sales. Furthermore, the uptake of biosimilars is also expected to increase in other markets outside the US as physicians and other stakeholders get more comfortable with their substitution – capturing market share from branded biologics.

The figure below shows the historical sales of branded biologics from 2008–2012 and forecast to 2018.

Historical Sales of Branded Biologics, 2008–2012 and Forecast to 2018



Source: GlobalData, Pharma eTrack [Accessed May 13, 2013].

Industry Challenges Result in Caution by Potential Entrants and Current Players

The biosimilars business is not for the faint-hearted, as various challenges are currently facing the development and commercialization of biosimilars. One of these is the uncertainty regarding the regulatory and legislative structures available for the review, regulation, and substitution of biosimilars in certain markets, particularly the US. Furthermore, the development of biosimilars involves greater investment than is required for the development of chemical-based generics. Biosimilars potentially pose a greater risk to patient safety than chemical-based generics, primarily due to issues regarding immunogenicity. Therefore, they are currently required to undergo non-clinical, clinical, and post-marketing surveillance – the same requirements for obtaining approval for novel biologics. In addition to potentially resulting in increased review times, the need for other capital-intensive steps like clinical testing, as well as the complex manufacturing processes required, significantly increases the financial muscle needed to participate in biosimilar development.

Furthermore, companies currently active in the field of biologics are establishing various barriers, including patents protecting their manufacturing techniques, to prevent or at least slow the entry of biosimilars into the market. Indeed, companies such as Amgen, Genentech (now part of Roche), Pfizer, J&J, and AbbVie are not ready to surrender market share, bearing in mind the substantial sales being generated by blockbuster drugs such as Humira (adalimumab), Rituxan (rituximab), Enbrel (etanercept), Herceptin (trastuzumab), and Remicade (infliximab). In June 2011, Merck licensed biosimilar etanercept from Hanwha Biologics in a deal worth about $720m over 12 years. However, Amgen's announcement of a new Enbrel patent in the US in November 2011 forced Merck to halt the development of the Enbrel biosimilar. Similarly, AbbVie has stated that it intends to aggressively defend about 200 patents on Humira to prevent the approval of biosimilar versions, noting that competitors will experience a difficult time trying to enter into the market.

Consequently, many potential entrants are exercising caution in advancing their biosimilars programs. In October 2012, Teva halted Phase III clinical trials of a biosimilar to Roche's Rituxan (rituximab), while Samsung also stopped its studies on the same drug. Roche does not anticipate that a rituximab biosimilar will appear on the market before 2016, three years later than its initial expectation of 2013 – when Rituxan's patents expire in Europe – adding that the timelines for biosimilars are "moving out".

Deals Emerging as a Vital Means of Entry into Biosimilars

The noteworthy challenges and risks associated with the development of biosimilars, particularly in the current regulatory and economic climate, has led many companies to embrace strategic deals as a way to enter and/or strengthen their presence in the global biosimilars industry. Most of these deals are collaborations and licensing agreements targeted at enabling companies to pool their resources and capabilities, share the risks involved, and consequently, to improve their chances of success.

Despite the company's past unsuccessful attempts to develop biosimilars, Merck entered into a joint venture (JV) with Samsung Bioepis – itself a JV formed by Samsung and Biogen Idec – in February 2013 to develop and commercialize multiple pre-specified and undisclosed biosimilar products. Pfenex also signed a partnership agreement with Strides Arcolab's Agila Biotech unit – acquired by Mylan in February 2013 – in a deal that seems to be focused on tapping into the significantly untapped South Asian and South-East Asian biosimilars markets. Other deals include Viropro and Oncobiologics' partnership to manufacture six monoclonal antibodies (mAbs) that are being developed by Oncobiologics, and Dr. Reddy's Laboratories' agreement with Merck Serono to co-develop a portfolio of biosimilar compounds in oncology.

The table below shows a breakdown of some deals in the biosimilars industry.

Overview of Biosimilars Deals Analyzed in this Report					
Deal Category	**Completion Date**	**Acquirer/ Licensor**	**Target/Partner**	**Value**	**Strategic Significance**
Partnership	16-Apr-13	Pfenex, Inc.	Agila Biotech	Undisclosed	The deal positions both companies to tap into the significantly untapped South Asian and South-East Asian biosimilars markets. However, the uncertainty surrounding Agila's future may hinder the JV.
	25-Feb-13	Viropro, Inc.	Oncobiologics	Undisclosed	Oncobiologics can leverage Viropro's bio-manufacturing capabilities and network, while Viropro will benefit significantly from royalties.
	20-Feb-13	Samsung Bioepis	Merck	Undisclosed	The JV reaffirms Merck's focus on biosimilars despite earlier failures and its attempt to plug the revenue gap resulting from patent expirations. Also, Samsung Bioepis can leverage the R&D, financial, and manufacturing capabilities of Samsung and Biogen Idec.
	6-Jun-12	Dr. Reddy's Laboratories	Merck Serono	Undisclosed	Merck Serono's biopharmaceutical capabilities and Dr. Reddy's expertise in generics and presence in emerging markets can be leveraged. Furthermore, this signifies Merck Serono's search for alternative sources of revenues due to increasing competitive pressure on the sales of its current products.
Licensing Agreement	18-Jul-12	Synthon, Inc.	Amgen, Actavis	Undisclosed	Watson and Amgen can leverage their combined R&D, manufacturing, and distribution expertise in successfully developing and commercializing trastuzumab. Synthon stands to gain an upfront payment, and potential milestone and royalty payments, from the deal.
Source: GlobalData, Pharma eTrack [Accessed April 24, 2013].					

US Biosimilars Regulatory Framework Gradually Evolves

In February 2012, the FDA issued three draft guidances on biosimilar product development in the US. This is a big step forward for the market as the US remains the largest pharmaceuticals market, including biologics; therefore, being able to obtain approval to market biosimilars in the US holds considerable benefit. However, the draft guidelines have been received with mixed feelings, particularly among companies seeking to pursue the development of biosimilars in the US. On the one hand, the guidelines emphasize a totality of evidence approach, the use of analytics and focused clinical trials to document biosimilarity, and use of ex-US reference products, and allows extrapolation across indications that share the same mechanism.

On the other hand, there are areas of uncertainty and risks. These include the absence of an interchangeability guidance, a lack of clarification on naming biosimilars – something that is quite clear in the European Medicines Agency's (EMA) guidelines – and a requirement to provide a full dossier to the originator of a biologic. Consequently, there are fears that the FDA's guidances may, in fact, slow the entry of biosimilars into the US market.

Governments Aim to Utilize Biosimilars Development to Foster Macroeconomic Development

Emerging markets, including China, India, Brazil and Mexico, have developed their own regulatory pathways to manage the approval of biosimilars. However, they have generally established lower barriers to entry in terms of clinical trial requirements and regulatory control, thereby enabling domestic companies to easily enter the market, while also potentially providing a lower-cost entry point for international players. Some of these governments are actually entering into deals to drive the growth of their biosimilars industry. In April 2011, the Brazilian Ministry of Health (Ministério da Saúde) entered into an agreement with PharmaPraxis to manufacture a biosimilar to Humira.

Furthermore, the governments of South-East Asian countries like South Korea have launched various initiatives targeted at boosting the biosimilars market and thereby, sustaining their domestic industry. For instance, the South Korean government has been setting up bio-clusters, some of them matching the quality standards of advanced economies, to foster biopharmaceutical manufacturing and establish the country as a leading biosimilars market. In February 2011, the government pledged to promote the biosimilars industry and revealed plans to provide financial and institutional support to the industry as well as aim to capture 22% of the global biosimilars market by 2020. Also, it anticipates the creation of about 120,000 new jobs by its biosimilars industry.

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2 Introduction

2.1 Report Scope

This report is an essential source of information and analysis on the global biosimilars industry. Using detailed company data, financial analysis, corporate strategy, and market trends analysis, GlobalData provides in-depth analysis of the current and future growth drivers of the biosimilars industry. The report discusses the various regulatory frameworks under which biosimilars are currently reviewed and regulated. Furthermore, it discusses the key factors shaping and driving the biosimilars business, and provides insights on the competitive landscape and emerging strategies expected to significantly influence the market positions of companies currently involved in the development and commercialization of biosimilars.

GlobalData's *PharmaSphere: Global Biosimilars Strategy – Regulatory Landscape, Key Drivers, Markets and Trends in 2013 Report* provides strategic analysis of the global biosimilars industry. It discusses key market trends, regulatory requirements in various markets, recent deals activity and trends, as well as describes the operations strategy of these companies. Furthermore, it includes a geographical segmentation of various markets including the EU and US, as well as emerging markets such as India – providing in-depth analysis of these markets' regulatory framework, key domestic players and their biosimilar pipelines, and strategic outlook.

Throughout the report, GlobalData's analysts provide you with expert insight, expanding on each strategy and factor discussed, with the aim of providing you with the tools needed for making informed business decisions.

Key Questions Answered

- What are the drivers of the global biosimilars industry?
- Who are the top players involved in the development of biosimilars in the developed markets of Europe and the US, as well as in emerging markets, including India and China?
- What are the major barriers to entry into the biosimilars industry?
- What specific strategies are companies utilizing to combat some of the challenges currently facing the development of the global biosimilars industry?
- What is the current state of biosimilars regulation in the EU, US, Japan, India, China, and South Korea?

Key Benefits

This report will enable you to:

- Understand the frameworks under which biosimilars are currently being reviewed and regulated across various developed and emerging markets
- Identify the key domestic players in various biosimilar markets, including South Korea, Japan and emerging markets such as India and China
- Understand the key drivers and trends in the global biosimilars industry
- Analyze and track the strategies that companies are using to enter and/or strengthen their position in the rapidly evolving biosimilars industry, as well as efforts being made by innovator companies like Amgen to protect their market position
- Use this information as an independent source for your due diligence and transaction strategy

Companies covered: Actavis, Amgen, Biocon, Celltrion, Cipla, Dr. Reddy's, Gedeon Richter, Hospira, JCR Pharmaceuticals, Kyowa Hakko Kirin, LG Life Sciences, Merck, Oncobiologics, Pfenex, Pfizer, Ranbaxy, Reliance Life Sciences, Samsung Bioepis, Sandoz, Shandong Kexing Bioproducts, Stada Arzneimittel, Strides Arcolab, Synthon, Teva, Viropro, 3SBio.

If there is a specific company you would like GlobalData to cover and include in our next report, kindly contact GlobalData's Industry Dynamics Team directly and we will make every attempt to add it to our coverage.

2.2 Upcoming Related Reports

Report titles are subject to change:

- GlobalData (2013). Contract Research Organizations Benchmark Report, June 2013
- GlobalData (2013). Benchmarking Top 10 Domestic Players in India, June 2013
- GlobalData (2013). Benchmarking Top 10 Domestic Players in the BRICS Markets, July 2013
- GlobalData (2013). Early-Stage Biotech Funding and Strategy, August 2013

2.3 Recently Published Reports

- GlobalData (2013). PharmaSphere: Early-Stage Technology Transfer Collaborations, April 2013, GDHC003PSR
- GlobalData (2013). PharmaSphere: Global Generics Strategy – Key Drivers, Markets and Trends in 2013, March 2013, GDHC001PSR
- GlobalData (2013). PharmaLeaders: Generic Manufacturers Benchmark Report – Financial Benchmarking & Competitive Analysis of the leading players in 2013, March 2013, GDHC001PLR
- GlobalData (2013). PharmaLeaders: Innovative Mid-Cap Biotechnology Benchmark Report – Financial Benchmarking, Pipeline Assessment & Competitive Analysis of Innovative Biotechs' Biotech Strategy 2012 – Licensing, Collaboration, and M&A Trends, January 2013, GDHC001SAC
- GlobalData (2012). Biotech Strategy 2012 – Licensing, Collaboration, and M&A Trends, November 2012, GDHC0001MAL
- GlobalData (2012). Pharmaceutical Leaders 2012 – Key Trends, Emerging Strategies and Financial Analysis of Top Performers, July 2012, GDHC0001BR

14.5 About the Industry Dynamics Team

GlobalData's Industry Dynamics Team specializes in tracking and analyzing the pharmaceutical healthcare industry and all its sectors globally. GlobalData's Pharma eTrack database provides insightful analytical reports covering market, trends, companies, pipelines, diseases, technologies, and real-time updates of key global events impacting the industry.

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GlobalData has offices in New York, Boston, London, India, and Singapore.

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