

# The Future of Biosimilars in the USA: Mapping critical uncertainties and the impact of future events

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## Abstracts

### The Future of Biosimilars in the USA

Can pharma resolve the litigation frenzy hampering biosimilars' market entry in the US? Is too much focus on legal wrangling stifling healthy competition and innovation? And, as the arguments rage, is the patient being forgotten? This report looks at recent progress on biosimilars penetration in the US market, reviews the key events of the last year, and prompts new thinking to push the ongoing debate forward towards more sustainable solutions.

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The Future of BiosThe executive summary, taken directly from the report, presents key findings from the research

Research objectives and methodologies employed to produce the report

Detailed report contents

Key themes covered in the report

What you will learn from the report

### Executive Summary

This report examines the critical issues shaping the future of the rapidly evolving and

highly dynamic United States (US) biosimilars market, in light of key events that have occurred during the last 12 months. FirstWord's research and analysis for this report identified the following key findings:

Progress and investment in the biosimilar pipeline is being made, but litigation continues as a key defence tactic used by originator companies to protect their market share and delay the entry of biosimilars. The anticipated high legal fees may act as a barrier for entry for smaller biosimilar companies, at least initially, and therefore may potentially influence early market dynamics.

Patients and physicians continue to be the key stakeholders requiring further education to increase their familiarity and confidence with biosimilars. Physicians and HCPs have gaps in knowledge in terms of concepts surrounding interchangeability and extrapolation of indications. A key strategy will be the presentation of clinical and real-world data demonstrating biosimilar safety and efficacy from trusted sources such as physician peers or the FDA.

Reimbursement policies and lack of payment coverage are some of the most immediate issues contributing to the bottleneck of biosimilar uptake today. There are specific concerns with policies that may disincentivise the use of biosimilars, such as the grouping of biosimilars that share the same reference product under the same payment code, the lack of commercial payer coverage, and the possibility for rebate manipulation by originator companies.

Commercially, price is unlikely to be the only differentiator between different biosimilars and other biological products such as biobetters and non-originator biologics in the US market. Price is still important, although differentiators providing additional patient value such as the quality of product, a reliable supply chain, and patient support services communicated through marketing campaigns are also critical considerations.

In the longer term, it is difficult to predict how the US biosimilars market will evolve and which market segments may be targeted next, as companies may make selections based on patent expiry and/or their therapeutic area of expertise. Regardless, the development of biologics is a complex endeavour and therefore finding the right combination of skills, knowledge, and expertise is crucial for biosimilar success, which may entail cultivation of in-house or external partnerships.

Creation of a sustainable biosimilar market that enables healthy competition and predicted cost-savings to be realised requires a multi-faceted approach that keeps

patients at the forefront. Progress in reimbursement policy, payer engagement, and the education of healthcare professionals and patients are all needed to foster an environment which incentivises the use of biosimilars. The US biosimilars market is just beginning to evolve towards maturity but there are steps that can be taken today to ensure that it reaches its full potential – and that cost-savings continue – in the long-term.

These findings are discussed in relation to the industry literature and interviews with 8 experts.

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## Research Methodology and Objectives

Much has already been said on the specific issues and huge potential of biosimilars - so this report sparks the debate by offering food for thought. Aimed at market players in the thick of this fast-moving area, it includes a critical assessment of the key developments in the US over the last 12 months and provides insight into how those closest to the action believe the complex issues could be resolved.

Analysis is based on detailed interviews carried out between June and August 2017 with 8 biosimilar-focused professionals within the pharmaceutical industry.

Richard Markus, Vice President, Global Development, Amgen, US

Juliana Reed, Senior Vice President, Government Affairs, Coherus Biosciences, US

Peter Goldschmidt, President and Head of North America, Sandoz, US

Jay Chatfield, Senior Manager, Market Access Strategy and Strategic Alliances, Orexigen Therapeutics Inc., US

Kiran Mazumdar-Shaw, Chairman and Managing Director (CMD), Biocon, India

Chrys Kokino, Head of Commercial Global Biologics, Mylan, US

Cheryl Schwartz, General Manager, US Biosimilars, Pfizer, US

Anonymous expert, with extensive regulatory and medical affairs experience with a large pharmaceutical company

Key questions explored in this report include

How have the key events of the last 12 months impacted the biosimilars market in the US?

Which critical issues and challenges are cause for most concern and why?

How is the commercialisation of biosimilars in the US progressing?

Where are bottlenecks and what are the factors behind them?

What must happen for the US biosimilars market to achieve sustainable and long-term return on investment for drug manufacturers?

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In the midst of fierce debate, high profile legal confrontations and vastly differing levels of understanding (and acceptance) of biosimilars across the US healthcare sector, there are lots of voices vying to be heard and a lack of clarity about the way forward. One of the key questions this report raises is how patient interests could be better served amongst all of this. The US biosimilars agenda clearly needs to move beyond financial

rows and the 'patent dance' and look at creating more sustainable long-term strategies. This can then pave the way for healthy competition, achieving greater value from drug budgets, and, ultimately, better patient access.

This report will enable you to

Understand in more detail the differing perspectives of originator drug companies, biosimilars manufacturers and other stakeholders.

Prioritise the most crucial issues and challenges in the biosimilars sector, including the multiple barriers to market entry.

Take stock of the key developments over the last 12 months and the impact they have had thus far.

Form new ideas to tackle issues such as interchangeability, litigation, physician understanding and patient education.

Enter the debate on the future of biosimilars and how the market can evolve to take advantage of its vastly untapped opportunities.

## About FirstWord

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