The Future of Biosimilars 2016

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Objectives

The first two editions of The Future of Biosimilars – published in May 20141 and June 20152 – provided a qualitative and semi-quantitative analysis of the key future milestones and events within the biosimilars market, and how they could potentially drive the evolution of the market. With much progress in the biosimilars market having been made since June 2015, and many of the previously identified uncertainties having either been resolved, refined or replaced, FirstWord believes that a follow-up analysis of the critical issues that face the future evolution of the biosimilars market is required.

As such, this FirstWord Dossier Advisory report provides a comprehensive, qualitative review of some of the key milestones, critical issues and remaining uncertainties that still exist in the biosimilars market.

The information for this report was gathered from multiple sources, including primary research from in-depth telephone interviews with physicians, patient representatives and biosimilar-focused professionals from the pharmaceutical industry.

The report was supported by secondary research which focused on areas such as regulation, clinical development and pipeline activity, commercialisation, international and national policy, legal, and key stakeholder dynamics. Information was obtained from publicly available sources of information and from previously published FirstWord reports and analysis, most notably FirstWord's Biosimilar Index.3 During the course of the research, three key issues were addressed:

- What have been the most important events in the biosimilars market since the publication of the last report (June 2015), what are the potential implications of these events, and how could these events help predict future market evolution?
- What is the current status of the biosimilars market, both in terms of key stakeholder perceptions, pipeline activity, key opportunities and challenges, and remaining uncertainties?
- What key events are biosimilar experts monitoring, and what predictions are being made about these events as they relate to the future of the biosimilars market?

Methodology

This report is based upon credible secondary sources and first-hand insights from 12 physicians, legal professionals, industry stakeholders and patient representatives, all of which either have direct experience in the development and/or commercialisation of biosimilars or are considered experts in their respective fields.

Secondary research was conducted to map key dynamics within the biosimilars market, to understand some of the remaining uncertainties that exist in the market and to understand what critical events are expected to happen over the next 12-18 months. Additional insights were gained from the author’s experience in the biosimilars market and from other FirstWord reports on biosimilars, as well as leading business intelligence providers in the biosimilars market.

For the primary research, each respondent gave an in-depth telephone interview which was based on a semi-structured discussion guide. While many of the comments provided in this report are directly attributable to the experts interviewed for this report, some comments have been anonymised to ensure requested confidentiality.
The commercial story is beginning to unfold, with investments in infrastructure, portfolios and partnerships focused on driving biosimilar adoption

With discussions on regulatory and clinical issues becoming more academic, as opposed to market shaping, commercialisation of biosimilars has become a key area of debate; making money from biosimilars, delivering cost savings to health services and improving patient access have become critically important at this stage of the market’s evolution. To support commercialisation efforts, companies are investing in various areas of the business to provide a competitive edge, both near-term and longer-term, versus branded and biosimilar companies.

Several companies have made announcements in recent months regarding investments in infrastructure, particularly manufacturing capacity, in order to meet the expected demand for biosimilars in the future. In May 2016, Celltrion announced that it would be investing $275 million to increase its current 140,000-liter capacity to 310,000 liters by 2019. The company will double the capacity of its first plant by 2018 and build a third plant that will have a 120,000-liter capacity by 2019. The new facilities will enter commercial operations in 2019 and 2021, respectively. In June 2016, Pfizer and Novartis announced aggressive expansion plans for its manufacturing capacity. Pfizer said that it would be investing $350 million in the development of a state-of-the-art biotechnology centre in China, with Novartis committing to investing $1 billion by 2020 to increase its manufacturing presence in Europe.

There have also been significant amounts of pipeline investment and prioritisation activity in recent months, either by moving internal programmes forward, or by engaging in licensing deals or establishing joint ventures. In October 2015, US biosimilars developer Oncobiologics announced that it had secured $31 million in financing to develop its currently biosimilars portfolio, which includes adalimumab and bevacizumab biosimilar programmes. The company followed this up in November 2015 by announcing that it had expanded its portfolio to include several more biosimilar programmes, including biosimilars targeting Prolia/Xgeva (denosumab; Amgen), Erbitux (cetuximab; Eli Lilly/Merck Group), Actemra/RoActemra (tocilizumab; Roche), Simponi (golimumab; Janssen Biotech/Merck & Co.) and


What could be the impact of national and local initiatives on biosimilar adoption rates?

In April 2016, it was announced that NHS England plans to rationalise the approach to medicines evaluation through the creation of four regional medicines optimisation committees. The committees will work together to ensure medicine evaluation are carried out once and that the output is shared across the NHS. Currently, new medicines or indications of existing medicines, which are not evaluated by NICE, are evaluated many times across the NHS by local area prescribing committees. A workshop to discuss how these committees could be implemented was held in the same month, the results of which were published in May 2016. Experts involved with the UK market suggest that these medicines optimisation committees could provide guidance on how best to implement biosimilars at the national level.

“Regional medicines optimisation committees, which sit underneath NHS England, are being set up in the UK. These committees could provide more of a steer on prescribing initiatives, formularies, and all sorts of medicines optimisation issues. Biosimilars could become an issue which these committees focus on. It’s not totally clear what’s going to happen, but more benchmarking, more comparative work, more information on how biosimilars are performing, could support future uptake. These committees may well provide some of the joined-up thinking we need around driving biosimilar adoption, and some support around the quality of prescribing and uptake of drugs in general. That might be where we start to see a bit more visibility and pressure in relation to biosimilar uptake.”

James Kent – Clinical Lead Pharmacist, Southend on Sea, UK

Other changes in the UK include the Cancer Drugs Fund (CDF) now being controlled by NICE. For the first time, NICE will issue draft guidance on new cancer drugs, or significant new licence indications, before they have received marketing approval in the UK. Any drug that receives a positive draft recommendation would then be funded from the point of licence. With several oncology mAbs being developed for the UK market, and some already being reviewed by the EMA, it raises the possibility that NICE’s control of the CDF could have a positive impact on biosimilars in the future. Experts are unsure, however, suggesting that the main focus will be on innovative therapies.

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340 Regional medicines optimisation committees set to change the way medicines are evaluated within the NHS (April 2016). Retrieved from https://www.wellards.co.uk/whats-new/regional-medicines-optimisation-committees-set-to-change-the-way-medicines-are-evaluated-within-the-nhs


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