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The Future of Biosimilars: mapping critical uncertainties and the impact of future events

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Abstracts

The Future of Biosimilars: Mapping Critical Uncertainties and the Impact of Future Events offers timely insight into the critical biosimilar market issues, and how they could shape the continued evolution of the sector. Key insight is provided to questions such as:

With multiple new clinical trials focusing on mAbs, and 14 new biosimilar approvals worldwide, since the beginning of 2013, what do experts predict for the biosimilars market in 2014 and beyond?

How will the pending outcomes of several high profile intellectual property and data sharing lawsuits in India, the US and South Korea impact and shape future market dynamics?

Which companies are more likely to be the first to market in the EU and US with biosimilar mAbs, erythropoietin and insulin, and what uptake rates are expected?

Do experts believe that the biosimilars market can become profitable and sustainable, or is the market likely to crumble under the weight of its own expectations?

The biosimilar market remains filled with opportunity, but only for those companies that can navigate the complex maze of regulations, clinical development requirements, policies, originator company defensive tactics and physician scepticism. The markets immediate future, however, lies in the balance. From pricing and naming issues, to legal challenges and questions about its profitability, The Future of Biosimilars: Mapping Critical Uncertainties and the Impact of Future Events provides analysis and expert insight into where the market is headed.

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Critical stakeholder insight

Based on in-depth telephone interviews and a 50 question survey with biosimilar experts from the US, Europe, Canada and Argentina, FirstView's The Future of Biosimilars: Mapping Critical Uncertainties and the Impact of Future Events lays out the current state of play within the biosimilars market and identifies some key inflection points for the future. Widely researched and filled with expert insight, the report offers the quickest and most up-to-date access to recent and future events in the biosimilars market, including battles being waged over policy, regulatory, intellectual property and commercialisation, and how uncertainties could affect market evolution.

A report for the whole industry

The biosimilars market is evolving quickly, making The Future of Biosimilars: Mapping Critical Uncertainties and the Impact of Future Events a must-read reference not only for those working in biosimilars competitive intelligence, brand strategy, business development and licensing, but also brand forecasting, market research and financial analytics.

Key benefits, features and insights

The biosimilars market is evolving and requires constant updates to keep abreast of changes. In this report, the industry – and particularly those in competitive intelligence, brand strategy, business development, licensing, partnering and alliances – will:

Gain access to the latest developments and expert views on future trends across a range of topics, from competitive strategy, clinical development, IP, policy and pricing

Understand the key issues, such as country-level policy changes in relation to biosimilar naming, interchangeability and automatic substitution

Learn about the key dynamics governing the biologic and biosimilar landscape;

Identify which companies will be first-to-market and where biosimilar approvals and clinical trials stand

Understand what needs to be done, according to a consensus of experts, to

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drive biosimilar use, particularly in Europe

Gain insight into intensifying legal and defensive tactics concerning intellectual property, data sharing and biosimilarity claims

Key Features

Overview of key biologic brands, including analysis of development programmes by reference molecule, therapy area and drug class

Insight into future market evolution, with a focus on first-to-market dynamics, lifecycle and portfolio management, partnerships and collaborations, pricing and payer strategies and profitability

Breakdown of offensive and defensive strategies aimed at shaping biosimilar market entry and market uptake

Key findings from regulatory and policy issues, including indication extrapolation and naming

Analysis of other potential issues, such as clinical trial results, M&A and authorised biosimilars

Key Insights

Which companies are most likely to launch biosimilar mAbs in Europe and the US, and what benefits would be conferred by first-to-market status

In depth coverage of the key clinical, regulatory, legal, policy and commercial issues;

How biosimilar and originator pricing dynamics could negatively impact the market's long-term sustainability

What effect key originator lifecycle management tactics are having on biosimilar uptake and pipelines

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Expert Views

Incisive Questions. Expert Answers. Critical Insights.

This report examines key future events in the biosimilars market. It includes data from extensive secondary research plus the most prominent insights gained from in-depth telephone interviews with 12 biosimilar experts, questionnaires completed by 22 industry experts vetted for their biosimilar market knowledge, discussions with commercial, legal and financial experts, and biosimilar conference proceedings.

Lead Research Analyst

Duncan Emerton, PhD, Senior Director, Syndicated Insights & Analysis, FirstWord

Experts Interviewed

Paul Calvo: Director, Sterne Kessler Goldstein Fox

Sandy Eisen: Chief Medical Officer (CMO), Frontline Pharma Consulting Ltd. (previously CMO, Teva Pharmaceuticals Europe)

Gopalan Narayanan: Managing Director at Biologicals Advice Limited (former Expert Medical Assessor, MHRA)

Eduardo Spitzer: R&D Biotechnology & Biologics Manager; Laboratorio Elea

Juan Vergez: Global Brand Manager & Global Biosimilars Business Intelligence, Merck

Patrick Vink: Senior Vice-President, General Manager International Business, Cubist Pharmaceuticals (previously Senior Vice-President, Head Global institutional at Mylan, and Global Head Biopharmaceuticals at Sandoz)

Peter Wittner: Senior Consultant; InterPharm Consultancy (former Managing Director of Ranbaxy UK)

European Expert: Competitive Intelligence Manager, European Biotech company (anonymity requested)

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European Expert: Biosimilar Brand Manager, European generics company (anonymity requested)

US Expert: biosimilars market commentator, formerly involved with sales and marketing for a US biotech company (anonymity requested).

About FirstView

FirstView is a new line of FirstWord reports that aim to provide clients with data, expert opinion and insight on critical market shaping issues and changes in the pharma industry's operating environment. With leading market research capabilities and expertise, a 1-million strong online physician community, FirstView's insights and analysis are 'must read' for industry professionals seeking to understand future pharma market dynamics.

FirstView is headed by Dr Duncan Emerton, Senior Director, Syndicated Insights & Analytics, FirstWord. Duncan has over 15 years' experience in the pharmaceutical industry. He started out in the pharmaceutical industry as a Clinical Research Associate, supporting clinical R&D efforts and several pharma and biotech companies. Roles in clinical project management, sales, marketing and scientific support followed. After leaving Pfizer in 2003, Duncan joined Datamonitor Healthcare. There he worked mainly in strategic consulting roles, with his way final role being that of Director and Biosimilars Practice Lead for Datamonitor Healthcare's Consulting business.

Duncan is an acknowledged expert in the field of biosimilars. He is a regular presenter and chair at biosimilar-focused conferences, and has contributed several articles on biosimilars. Duncan's views on biologics lifecycle management and biosimilars were published in Pharmaceutical Lifecycle Management: Making the Most Out of Each and Every Brand. He has also contributed articles on the potential profitability of biosimilars, myth-busting for biosimilars and key dynamics of the EU biosimilars market.

Duncan holds a BSc(Hons) in Medical Biochemistry from the University of Surrey and a PhD in Microbiology from the University of Kent.

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