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Biosimilars: Regulatory Outlook

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Abstracts

Biosimilars offer a chance to improve access to, and reduce spending on, life-saving biologic therapies. But could regulators do more to support the market? While experts believe significant regulatory progress has been made in recent years, clarity is distinctly lacking on certain issues, such as interchangeability and naming.

FirstWord's Biosimilars: Regulatory Outlook provides insight and opinion on why. This 64 page report gives in-depth and candid views on what eight industry and biosimilar experts see as the areas that require the most attention within biosimilar regulation.

You'll discover expert concerns and views on critical, market-shaping issues, and understand how they see biosimilar regulations evolving in the future in areas such as indication extrapolation, interchangeability, naming, terminology and the amount and type of clinical data needed to support regulatory approvals.

"The EMA has set the tone when it comes to biosimilar regulation. A pathway that, quite rightly, is seen as the gold standard pathway around the world." EU Biosimilars Expert.

Answering key questions

Get answers to key questions about the regulation of biosimilars, and how the area is set to evolve:

> Approval timelines: The European Medicines Agency (EMA) takes – on average – 18 months to review a biosimilars application, while the U.S. Food and Drug Administration (FDA) took just ten months to approve Sandoz's Zarxio (filgrastim-sndz); is this EMA's timeline fixed, or can FDA-like improvements be made?

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Analytical vs. Clinical? Will the FDA's focus on analytics continue to have an influence on global biosimilar regulations, or will agencies continue to adopt a more clinically focused approach like the EMA?

Naming: The FDA, EMA and World Health Organization (WHO) all have different proposals for naming conventions – what are the merits of each and how will this influence market dynamics?

Interchangeability: What's needed to demonstrate that a biosimilar is interchangeable? What will be the burden of proof? And will there be any commercial advantage? How this plays out in the future could ultimately come down to cost savings.

Extrapolation of indications: An area of fierce and continuing debate, with regulators taking differing views on the same product: will a consensus view emerge?

Emerging markets: Achieving wider patient access has led to a thriving "non-comparable biologics" market in certain emerging markets; will these markets continue to focus on patient access or align themselves with western regulatory models to gain wider access?

Top takeaways

Different paths to a common goal: Understand how differing regulators are approaching biosimilar regulation and know how this could impact product development strategies.

What's in a name? Confusion in naming conventions in the U.S. and Europe are compounded by a further proposal from the WHO. Understand the significance of this and how it might impact the industry.

Interchangeability: While the FDA has a clear remit to approve biosimilars as interchangeable, it has yet to publish guidance. In contrast, European countries make their own decisions on interchangeability and substitution, with the EMA having no remit in this area. The impact of switching to biosimilars can be significant, as demonstrated by developments in Denmark and Norway with biosimilar infliximab, but will it be the case in other markets?

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Extrapolation across indications: While the scientific principles off indication extrapolation are accepted by most of the leading regulatory agencies, it’s the application that sometimes differs. These differences of opinion create uncertainty for industry and have significant commercial implications.

It’s not just about the U.S. and Europe: Get an international perspective by knowing how biosimilar regulation is evolving in other markets, including Australia, Japan and Canada, and evaluate the progress in developing robust biosimilar regulations in markets such as India, South Korea and Brazil.

Key issues explored

Will biosimilars ever be approved without clinical trial data to support the application, or will regulators always need some form of clinical data to satisfy any residual uncertainty?

Non-comparable biologics have found favour in certain emerging markets and patient needs are being met; could these markets move to meet the more stringent standards of the EU and U.S. and be considered biosimilars, or will ensuring patient access always be the number one priority?

Are regulators supporting the industry in achieving biosimilar approvals, or could they do more?

Is it now easier or more difficult to get approval for biosimilars, and does this vary by class of product and type of molecule?

What are the key differences in regulatory approaches around the world, and how are they impacting regulatory and clinical strategies?

A report based on expert US and EU industry knowledge

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Other experts interviewed for the purposes of this report – who requested anonymity due to the content of their comments – include a biosimilars expert working for a European biotech company, the global head of biologic strategy at a leading European biotech company, the global strategy and commercial lead for a US based biosimilars company, and industry experts from EU and US pharma companies. Emailed comments to specific questions were also received from a spokesperson at Germany's Paul Ehrlich Institute, one of Europe's leading regulatory bodies.

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