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Biosimilar Defensive Plays - Assessing the options

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Abstracts

Although biological therapeutics have developed into an increasingly valuable segment of the pharmaceutical market, the commercial impact of biosimilar products has, to date, been fairly insignificant. However, that’s set to change.

Five of the world’s best-selling innovator drugs, with collective sales of $35 billion in 2012, will shortly lose patent protection, making them vulnerable to biosimilar competition. Developers of biosimilars will also benefit from the recent establishment of an abbreviated regulatory pathway for the approval of biosimilars in the United States.

With the biosimilar market on the brink of expansion, FirstWord Dossier has recognised the need for robust guidance on defensive strategies, focusing on two main areas: delaying approval of competing biosimilars; and sustaining product revenues in the face of the competitive challenge.

In creating this unique report, FirstWord sought expert opinions on factors that have influenced decisions to date and how these will impact further developments.

Biosimilar Defensive Plays - assessing the options is an essential resource for biotechnology executives who need to understand the challenges and opportunities presented by biosimilars.

Key Benefits

> Generic defence strategies are well documented, but many of these are either less relevant or inapplicable to biosimilars. With Biosimilar Defensive Plays - assessing the options, you will learn which generic defence strategies are effective against biosimilars, and which contexts call for specific biosimilar defence strategies. You’ll also be informed about how different strategies may

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be appropriate according to interchangeability status, orphan drug status, and whether the product is a paediatric therapy. This insightful report brings you completely up to date with the biosimilar competitive landscape, and gives you the information you need to strengthen your brand and sustain revenues against an emerging threat. Specific topics addressed include:

State-by-state variations of biosimilar legislation in the U.S. market

The pronounced difference in the uptake of the two main biosimilar products in Europe

Non-patent approaches, e.g., exclusivity, lobbying, citizen petition, and interchangeability

Which marketing and pricing strategies can be adapted from the branded drug market

Technological leadership through the development of biobetters

Key Quotes

“On the production side, process patents and the technology they cover could be core to the production of a particular biosimilar and they could well expire well after he actual product use patent, so that’s been an interesting lesson learnt.” Steven Flatman, head of R&D Biosimilars, Lonza Biologics

“Companies have used their market strength and relationships with key stakeholders to present a negative perception about biosimilars. They especially stressed data on the poor quality of copy biological products produced in Southeast Asia, and used this to imply that biosimilars approved in the EU would be of poor and variable quality.” Paul Greenland, vice president, Biologics, Hospiram

“The very firm, thick, black lines between being an originator company and a generic company are getting much thinner and fainter, and we are just going to see people coming to the market with a range of products competing in a different way.” Warwick Smith, director-general, British Generic Manufacturers Association

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Biosimilar Defensive Plays - assessing the options is designed to answer your strategic and tactical questions, such as:

How can I sustain market exclusivity without a valid patent?

Why are some biotechnology companies partnering with biosimilar companies?

What does the new U.S. regulatory pathway for biosimilars mean for developers of these products?

What tactics can we employ to delay market entry of biosimilars?

How can we build brand loyalty for our branded biologic in a more crowded marketplace?

Expert Views Include:

John Ansell, director, John Ansell Consultancy

Sandy Eisen, chief medical officer, Frontline Pharma Consulting

Steven Flatman, head, R&D Biosimilars, Lonza Biologics

Paul Greenland, vice president, biologics, Hospira

A portfolio development PM for autoimmune diseases within a German-based pharmaceutical company

Diem Nguyen, general manager, biosimilars business unit, Pfizer

Warwick Smith, director-general, British Generic Manufacturers Association

Report Highlights

Up-to-date summary of biosimilar product development and sales

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Insights into why biosimilars have had limited commercial impact to date, and how that will change

A look at seven major companies in particular need of defensive strategies

Tactics for delaying or preventing approval of biosimilars-with real-world examples

Defensive sales, marketing, pricing, and drug development strategies

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