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Commercialisation of Biosimilars: strategies for market penetration

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Abstracts

Times, they are a-changin'—at least for the American biological product market.

With five major biological products worth a collective US$35 billion in annual sales now facing imminent patent expiration, the market is poised to develop and commericialise biosimilars. With the new abbreviated regulatory pathway now in place in the US, the race is on to develop strategies that will ensure the rapid acceptance of biosimilars.

And some of those approaches will come directly from the European experience. While their lessons have been slow in coming, the EU is ahead of the US in market development and currently leads the world in biosimilar sales. Although the European experience differs markedly from the anticipated evolution of biosimilars in the US, there are lessons to be learned.

In Commercialisation of Biosimilars: strategies for market penetration, FirstWord expertly examines the European experience and what it means for other developed markets. Based on expert opinions from the top commentators in the field, the report offers insight into how European biosimilar markets have evolved, includes up to the minute US case studies and which strategies have proven effective—and why.

Key Report Features of Commercialisation of Biosimilars: strategies for market penetration include:

- Up to date analysis of the European model and commentary on why uptake varies by market

- A look at which products are now in advanced development

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Case studies contrasting the US experience of somatropin and enoxaparin

Strategies to improve market penetration

Key Benefits

The biosimilar market in the US is poised to take advantage of major biologicals going off patent.

Through Commercialisation of Biosimilars: strategies for market penetration, you will:

Understand the differences in the US experiences with somatropin and enoxaparin biosimilars

Gain insight from experts on potential issues regarding interchangeability, in both regulation and in practice

Gain knowledge of how to design strategies to influence key opinion leaders

Understand why biosimilar acceptance is slower than most new generic drugs

Commercialisation of Biosimilars: strategies for market penetration answers key questions:

How much cross over in practice will be seen between the European and American markets?

What specific strategies will work in kick starting the acceptance of biosimilars in the US?

What are the potential advantages and disadvantages of alternative US biosimilar approval pathways?

How can the industry best educate decision makers on biosimilars' value, efficacy and safety?

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What lessons can be gleaned from US experiences to date?

Key quotes

“When it comes to long term treatments I think that doctors are more reluctant to use biosimilars because immunogenicity concerns have been highlighted by the biotechnology industry. They want to see more evidence on their long term safety.” Steinar Madsen, Medical Director, Norwegian Medicines Agency, Norway

“In a market like the US, you really will need these dual strategies where you need to have a pretty well thought out market access strategy, working with payers, while the sales and marketing tactics, will look a little bit different from what we're used to with traditional innovative products. It's not differentiating on the product profile but it's really establishing biosimilarity.” Sophie Opdyke, VP Commercial Development, Pfizer Biosimilars

“For a biosimilar to come in there and think they're only going to compete on price, I think it's going to be a challenge for them, to say the least. I think we got too used to the analogy of how generics work in the US now and we forget all the early days. It takes a lot of trust building in these early years (of product safety and efficacy), to get people to an understanding to use such products. That's important.” Virginia Acha, Director Regulatory Affairs, Amgen, UK

Content Highlights

As the nascent US biosimilars industry prepares to commercialise, lessons can be learned from the European experience. In this report, you will discover:

The importance of utilising different strategies to enhance market penetration

How development pathway options for drugs targeting multiple diseases will offer the best chance of comprehensive marketing approvals

The anticipated differences in uptake between biosimilar insulin and antibodies indicated for oncology

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