

Commercialisation of Biosimilars: Multifunctional teamwork for success

<https://marketpublishers.com/r/C4D41FFEBA3EN.html>

Date: October 2017

Pages: 0

Price: US\$ 2,245.00 (Single User License)

ID: C4D41FFEBA3EN

Abstracts

Commercialisation of Biosimilars

From bench to bedside, biosimilars continue to dominate boardroom discussions around the world. But after all the talking, what's the secret to success in this high stakes market? Against a backdrop of ever increasing competition and great expectations, the most effective and lucrative commercial strategies for biosimilars are emerging. Is it a case of 'business as usual' or do experts believe companies need to choose 'a road less travelled'? Commercialisation of Biosimilars: Team Tactics & Strategies Across the Product Lifecycle reveals what you need to know, and what you need to avoid.

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2. What you will learn from the report
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1. Reasons to buy this report

Operating in a biosimilar world means that companies need to find new and innovative ways to differentiate themselves versus the competition; conversations have moved from clinical differentiation to commercial differentiation. So when it comes to commercial differentiation, is it just about being the cheapest product on the pharmacy shelf? Not so, say experts. While price gives you the 'ticket to the game', it will only take you so far. So what are the options? Experts suggest that the way forward is a hybrid

approach, where the best bits of innovative drug and generic drug commercialisation are blended in order to forge a new path.

This report will enable you to:

Get up-to-speed on the current biosimilars landscape including opportunities, investment drivers, regulatory and policy developments, and the key factors influencing the market.

Define team roles and responsibilities across spectrum biosimilar asset's lifecycle, including technical and manufacturing, clinical and regulatory, medical affairs, commercial and legal.

Set out timings and key stages for commercial strategy development and implementation including guidance on when to involve specific functions.

Formulate a plan of attack for data, key performance indicators and pre- versus post-approval activities and responsibilities.

Build a strategy for global and local implementation success, considering who takes the lead and the five critical elements not to be ignored.

Look ahead to potential future strategy development and implementation challenges facing biosimilars as the market matures, and discover longer term ideas to boost success rates.

2. Research Methodology and Objectives

This report draws on the views and experience of experts directly involved in developing biosimilars and bringing them to market. It provides a valuable perspective on this growth area and offers the benefit of lessons learned, pitfalls to avoid, plus ideas on how to proceed.

The insights presented are based on detailed interviews carried out between 8 August 2017 and 3 October 2017 with 9 biosimilar-focused professionals.

Caroline Boulliat, Head of Biosimilar, Business Unit Director, Amgen
(UK/Ireland)

Rakesh Dixit, VP R&D, MedImmune (AstraZeneca)

Dr. Rüdiger Jankowsky, Managing Director, Cinfa Biotech

Steven Lehrer, Managing Director, SBLehrer LLC

Grzegorz Orlik, MD, Head of Medical Affairs, Biosimilars and Generics (Europe), Accord Healthcare

Erik Skullerud, Owner & Managing Partner, Element Consulting

VP Medical, Global Biotech Company (anonymous)

Pricing & Reimbursement Strategy Manager, Top 10 Pharma Company (anonymous)

Account Manager, European Biosimilars Company (anonymous)

Key questions explored in this report include:

When should a biosimilar commercial strategy be formulated and who should be involved?

Who should define the strategic vision at each stage in the biosimilar lifecycle?

What is the importance of steering committees?

What role do specific internal teams play, and when are they most critical?

What are the key differences between the pre- and post-approval phases for commercial strategy development and implementation?

How should global tactics be adapted to fit local markets; what market-specific tactics are needed?

What influences decision-making at each stage of commercial strategy development?

How do experts see biosimilars commercial strategies and market tactics evolving?

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A summary of the current biosimilars pipeline

Key regulatory and policy developments in the biosimilars market

Key drivers and resistors, and their influence on the commercial landscape for biosimilars

Timing and defining the commercial strategy for biosimilars

Key insights

Biosimilar companies need to 'begin with the end in mind' when it comes to developing the commercial strategy for biosimilar brands and portfolios

Defining the commercial strategy for a biosimilar requires a multi-stakeholder, cross-functional approach

Commercial teams have an important role in commercial strategy development, but other functions provide much needed expertise and insight

External steering committees and advisory boards are used, but their level of involvement will decline as the market matures

Team roles and responsibilities during commercial strategy development and implementation

Key insights

Multiple teams are involved in developing, supporting and implementing the commercial strategy for biosimilars

Technical and manufacturing teams give life to biosimilar programmes and play a key role in driving future commercial strategy

Clinical and regulatory teams are responsible for the accumulation of positive clinical experience for a biosimilar, but visibility within certain organisations could be an issue

Medical affairs plays a critical role in shaping biosimilar commercial strategy via communication, education and key stakeholder management

Legal teams provide much needed visibility on a biosimilar company's freedom to operate, without which commercial strategy would be unable to evolve

Commercial teams form the sharp end of the spear in relation to commercial strategy, owning both development and implementation across multiple countries

Biosimilar companies are advised to develop strong relationships with patient advocacy and support groups in order to understand what levels of support will be needed

Comparing and contrasting pre- and post-approval activities

Key insights

Commercial strategy for a biosimilar brand and/or portfolio must build from five critical elements

In the early stages of product development, global teams tend to take the lead on developing product and portfolio commercial strategy

Local teams take more ownership over commercial strategy implementation as a biosimilar gets closer to being launched, with global teams supporting where needed

Global brand/portfolio tactics must be adapted to fit the local market in order for a biosimilar's commercial strategy to be relevant in all markets

Key future challenges in relation to optimal strategy development and implementation for biosimilars

Key insights

As the biosimilar market matures, commercial strategies will evolve to focus more on education, embrace innovation and put price front and centre of decision making

To support more effective collaboration, global and local affiliate teams need to focus on communication, education and sharing best practice

A successful commercial strategy will be supported by robust market understanding and selection, flexible pricing, differentiation, product quality and effective stakeholder management

Concluding remarks

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