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The Future of Biosimilars 2016

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Abstracts

Development activity is surging as the focus shifts to commercialisation. How will the market evolve?

The race to commercialise biosimilars is on. What will it take to create a thriving market? Will payers see real cost savings? Will developers make money? What will drive uptake—and what will slow it down?

This must-read report explores how these issues are likely to play out, with first-hand insight from patient groups, physicians, lawyers, and stakeholders from originator and biosimilar companies.

You'll learn about developers' market access strategies, originators' efforts to keep them at bay, key drivers for adoption, and the impact of unresolved regulatory and policy questions. Development is surging, attitudes are improving, and key decisions are imminent. Find out where the market is headed.

"…biosimilars are perfectly poised to come in as part of the solution to the issue of increased pharmaceutical spending."

Christine Simmon – SVP & Executive Director, Biosimilars Council, GPhA

"…there's no one size fits all. You really have to look at the market by channel, by therapy area, by country, and then make the right call about how to commercialise your product depending on those factors."

Carol Lynch – Global Head of Biopharmaceuticals, Sandoz

Understand the Forces Shaping the Biosimilars Market

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Commercialisation: Differentiation may be the key success factor for biosimilars. Discover the strategies manufacturers are using to gain an edge over branded drugs and rival biosimilars.

Regulation: As commercial concerns take centre stage, two important regulatory questions remain unanswered. Find out what they are, and how they'll affect market access.

Litigation: A defining characteristic of the US market, litigation is now on the rise in Europe too. Learn which actions—defensive and offensive—will have the greatest impact.

Adoption: A decade of experience with biosimilars in Europe has revealed the biggest drivers of adoption. Find out what they are, and what countervailing forces may be slowing down uptake.

Plus, a full market analysis: The number of biosimilars programmes has grown by nearly 15% since last year. Get a breakdown of the current landscape by class and by molecule

ANSWERING KEY QUESTIONS

Critical mass: A huge number of biosimilars will be ready for regulatory review in the next 12-18 months. Can regulators keep up? What will it mean for the market if they can't?

No word on interchangeability in the US: What are developers doing to prepare for the (hopefully) imminent release of FDA guidelines? Just how important is an interchangeability designation?

The role of data: How are clinical data requirements for biosimilar applications likely to change? Will analytical data play a bigger role?

Who will switch? How has a decade of experience with biosimilars in Europe shaped attitudes toward switching both treatment-naïve and established patients to biosimilars?

Getting crowded: How will the market handle multiple biosimilars of the same

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reference drugs? What factors will influence key access and reimbursement decisions?

Emerging opportunities: How do regulatory standards in developing economies compare to those in developed ones? How will they affect future opportunities for developers?

Looking ahead: Events in the next 12-18 months could define the decade to come. How will the market evolve? Who will the key players be, and which reference drugs will they target next?

EXPERT CONTRIBUTORS

FirstWord interviewed 12 physicians, legal professionals, industry stakeholders, and patient representatives for this report. All interviewees either have direct experience in the development or commercialisation of biosimilars or are considered experts in their respective fields.

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