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# The Future of Biosimilars in Europe: Mapping critical uncertainties and the impact of future events

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## Abstracts

Education is top priority as biosimilar mAbs enter the market

With the recent approval of Celltrion’s Truxima, all eyes are on biosimilar oncology monoclonal antibodies (mAbs). Experts say they’re the next frontier in the European biosimilars market, but warn that they may not achieve widespread uptake unless stakeholders can put doctors’ and patients’ biggest concerns to rest. Just what are those concerns? Who should lead the education initiative? What will it take to close the information gap?

Report Overview

Future of Biosimilars: Europe (2017) offers a step by step walkthrough of key developments in the European biosimilars market, as well as future challenges and opportunities. 11 respected industry experts weigh in on adoption and pending approvals, policy and regulation, the evolving role of payers and patients, and the urgent need for more and better education. You’ll also hear about promising future targets for manufacturers, noteworthy trends, upcoming events, and more.

Report Features

An in-depth look at the state of the European biosimilars market, and the prospects for new entrants.

Insight into the commercial, legal, regulatory, and educational challenges facing biosimilars.

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A clear assessment of the information gaps, including a breakdown of common misperceptions and key concerns for doctors and patients.

Near term challenges and opportunities, including the changing roles of patients and other stakeholders, and future targets for biosimilar developers.

Download now – and gain greater insight into the European biosimilars market.

## Key Benefits

Plan your education strategy: Learn what kind of data and messages are needed to bring reluctant physicians and patients on-side, and which stakeholders are the best messengers.

Understand the changing stakeholder landscape: Discover how the role of patients and payers is evolving, and how each group can help drive biosimilar adoption.

Gain influence: Hear how stakeholder groups influence one another, and how you can use these chains of influence to make sure your message is heard.

Anticipate regulator’s next move: Learn what national policymakers are up to, where the EMA is likely to weigh in (or not), and how data requirements for approvals may change.

Plan ahead: As uptake of biosimilar oncology mAbs increases future target selection will be critical for developers. Find out how your choices will shape the market.

Keep biosimilar adoption trending up. Download this report to find out how.

## Why education needs to be Pharma’s top priority

Biosimilars have come a long way in Europe, but persistent misconceptions threaten to undermine their progress. Clear, accessible explanations of what biosimilars are, how they’re approved, and how they compare to branded medication are essential. Equally important is ensuring that stakeholders all understand key concepts like switching,

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interchangeability, and substitution. Closing the information gap is the only way to ensure that physicians are comfortable prescribing biosimilars and, more importantly, payers are comfortable granting formulary status.

Key Questions Answered by this report

Education is critical, but who should lead the charge and where should they focus their efforts?

Will the push to lower clinical data requirements succeed? What will govern approvals?

How are national policies evolving? Will the EMA issue interchangeability and switching guidelines?

Patients can play a pivotal role. How and when should they be involved in decisions about biosimilars?

Will biosimilar oncology mAbs see widespread uptake? What should developers target next?

For biosimilars to thrive, payers must shift their focus. How do experts expect their role to evolve?

Expert Views

The 11 industry experts we interviewed for this report either have direct experience in the development and/or commercialisation of biosimilars, or are considered experts in the field. To enable them to express candid views, some respondents have chosen to remain anonymous.

Carsten Brockmeyer – CEO, Formycon

Rakesh Dixit – VP R&D, MedImmune

Rüdiger Jankowsky – Managing Director, Cinfa Biotech

Matthew Jones – Chief Commercial Officer, Dyadic International

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Steve Lehrer – CEO, Cipla Biotec

Adam Levysohn – Head of Global Market Access (Biosimilars), Biogen

Carol Lynch – Global Head of Biopharmaceuticals, Sandoz

Grzegorz Orlik – Head of Medical Affairs, Accord Healthcare

Mourad Rezk – Global Head Medical Affairs (Biosimilars), Biogen

Erik Skullerud – Owner & Partner, Element Consulting (former Marketing Director, Amgen)

Account Manager – European Biosimilars Company (anonymous)

4 Key Quotes

“We believe the number one priority in any educational effort is to bring biosimilar science to the patients and the medical community in a simple, understandable way, making them aware of what is possible using modern technology.” Rüdiger Jankowsky – Managing Director, Cinfa Biotech

“Education can rapidly remove a lot of the concerns that physicians, patients, payers and pharmacists have about using biosimilars. It is important to take all stakeholders on this journey.” Carol Lynch – Global Head of Biopharmaceuticals, Sandoz

“Companies will provide information, but when the payers, patient groups and medical societies take ownership, there is more trust in the information. Regulators could take a role, but I think they do quite a good job now with all of the publications that emerge from the EMA and EC [European Commission]. Critically, all of the information that gets published needs to be understandable by the average person.” Carsten Brockmeyer – CEO, Formycon

“I think people can learn from what happened with generics in the 1980s, how they were faced resistance and then eventually got accepted. Now almost 90 percent of drugs prescribed are substituted generic drugs.” Rakesh Dixit – VP R&D, MedImmune

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## Who Would Benefit from This Report?

Managers planning biosimilar development programmes

Market access teams supporting biosimilar market access

Medical affairs teams working to educate and inform stakeholders

HEOR professionals building evidence of biosimilar value

MSL teams demonstrating the safety and efficacy of biosimilars to physicians

Marketing teams driving educational initiatives for physicians and patients

Strategy teams working with regulators to establish clinical data requirements

Competitive intelligence professionals monitoring competitor education initiatives

Post-marketing surveillance teams collecting real world data on clinical and patient biosimilar experience

## Content Highlights

Biosimilars in Europe: current status, key developments

Key insights

Overview

The European biosimilars market continues to evolve across all key areas, from clinical to commercial and beyond

Despite improvements in awareness, information gaps on biosimilars still exist

The biosimilar pipeline continues to advance, with positive clinical data being published for several key pipeline programmes

The European regulatory landscape continues to evolve, but concerns about

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What are the specific challenges in the biosimilar oncology mAbs market?

What are the remaining challenges in the European biosimilars market?

What key future events are experts keeping tabs on?

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FirstWord Reports deliver timely, need-to-know intelligence about your products, your competitors and your markets. Covering biosimilars, market access, medical affairs, sales & marketing, technology and therapy areas, FirstWord Reports provide expert views and intelligence on the challenges facing pharma today.

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