

# Gauging the Biosimilar Effect: will the Market Boom or Bust?

<https://marketpublishers.com/r/G055CA5D6B6EN.html>

Date: December 2011

Pages: 42

Price: US\$ 895.00 (Single User License)

ID: G055CA5D6B6EN

## Abstracts

It was supposed to be the “epoch of biosimilars”, or drugs that copied existing biologics but had the potential to be more cost-effective. Yet five years later, biosimilars have failed to reach their forecasted potential of \$16.4 billion in sales this year, falling short to just \$235 million in 2010.

The pitfalls—everything from cost and unfavorable US legislation to a lack of interchangeability and physician resistance—have led some in the industry to ring the death knell. Yet according to others, the market remains alluring, predominantly because it represents life-changing medicine and the future of healthcare.

## Scope

## Report Overview

Cast against European and particularly German experiences, *Gauging the Biosimilar Effect: will the market boom or bust?* looks at the current state-of-play for biosimilars. The report, based on 16 industry interviews, examines the drivers and resistors to the still-unproven biosimilars market. The report moves from a general discussion of biosimilars to an explanation why they proved immediately popular in Germany. Market drivers—patent expiry, developing markets and costs savings—are reflected against the roadblocks, including high barriers to entry, lack of substitution, repressive US legislation and the physicians’ reluctance to engage. Finally, the report reviews the responses of both innovator and biosimilar companies, as well as their strategies for future success.

## Highlights

## **Key Report Features**

Comprehensive and up-to-date overview of the biosimilars market

Insight into the resistors and drivers to biosimilar uptake

Strategies on how to improve biosimilar spending

Discussion of how the branded industry should respond to defend market share

## **Purchase Reasons**

### **Key Benefits**

Insight from 16 industry leaders from Europe, the US and Canada

Unique insight into the German biosimilars market

Recommendations of how the industry can move forward

### **Key Questions Asked**

What are the drivers and resistors of biosimilar uptake?

Why was Germany the most successful market for biosimilars

What strategies should biosimilar manufacturers do to increase uptake

How should the branded industry respond?

How will the biosimilars industry evolve and what forces will shape it

### **Who Would Benefit From This Report?**

Executive Management

Sales and Marketing Executives

Pricing and Reimbursement Teams

Medical and Scientific Affairs Professionals

Pharmaceutical Consultants

Strategic Planning Executives

Clinical Development Professionals

Regulatory and Government Affairs Managers

## **Key quotes**

“I think that the biosimilar market will become a part of the landscape where major pharmaceutical companies and biotechnology companies will control that market, and use the biosimilar market as a means to extend the lifecycle of their innovative franchises.”

– Clifford Mintz, Management Consultant

“In the US and other countries where there is much more importance placed on price, and where the private sector insurers are a lot more involved, and where government is now seeking to reduce drug spending, yes, price could very well be the number one determinant of gaining market share for biosimilars in the US market.”

– Ronald Rader, President of the Biotechnology Information Institute

“Unless you have 100% patient interchangeability, you don’t have 100% medication interchangeability. You have acceptable ranges. But an acceptable range for a generic statin is one thing. An acceptable interchangeability rate for rheumatoid arthritis is something else entirely.”

– Peter Pitts, President and Cofounder, Center for Medicine in the Public Interest

## **Expert Views**

Gillian Woollett, Vice President, Avalere Health

Louis-Christian Clauss, Senior Consultant, Hisut SA and Atheln Biomed

Peter Pitts, President and Cofounder, Center for Medicine in the Public Interest

Markus Hauser, Director Strategic Commercial Effectiveness, Biogen Idec

Alex Kanarek, Senior Consultant, BioProcess Technology Consultants Inc.

Sandy Eisen, Chief Medical Officer, Frontline Pharma Consulting

Andrew Bourgoïn, Pharmaceutical Research Analyst, Thomson Reuters

Andrew Merron, Director, Biosimilars Advisory Service & Oncology, Decision Resources

Ronald Rader, President, Biotechnology Information Institute

Steven Grossman, Consultant, Public Policy and FDA

Magdalena Leszczyniecka, Founder and CEO, STC Biologics Inc.

Kristie Kuhl, Senior Vice President, Makovsky & Co.

Clifford Mintz, Management Consultant

Dimitrios Papadopoulos, Commercial Executive in the Pharmaceutical Industry

Regina Au, Strategic Marketing Consultant, BioMarketing Insight

Michael Castagna, Executive Director, Immunoscience Division, Bristol-Myers Squibb

## Contents

### **EXECUTIVE SUMMARY**

### **BIOLOGICS**

The Biologics Market  
Patent Landscape  
Innovation comes at a cost

### **BIOSIMILARS**

Terminology  
Regulatory Overview

### **THE BIOSIMILARS MARKET**

This is not a generics market  
EU's biosimilars market  
Biosimilar uptake in the EU  
Initial uptake was rapid in Germany  
Reference Pricing System  
Reimbursement system  
Pre-defined quotas

### **MARKET DRIVERS AND RESISTORS**

Market Drivers  
Cost savings  
Patent expiry  
Fierce competition  
Growth of developing markets  
Expanding uses of drugs  
Market Resistors  
High barriers to entry  
Cost  
Technical challenges  
Clinical challenges  
Lack of substitution and interchangeability

- Substitution
- Interchangeability
- Wholesale switching
- Therapeutic substitution
- Unfavorable biosimilars laws in the US
  - Period of market exclusivity
  - Data sharing
- Reluctant physicians
  - Switching
  - Lack of physician and patient education
  - Outright opposition to biosimilars
  - Lack of incentives
  - Patient and public misperception
- Assignment of the International Nonproprietary Name (INN)

## **RESPONSE FROM INNOVATOR COMPANIES**

- Reduce the price of the innovator drug
- Form a biosimilars division
- Partner with a biosimilars company
- Rely on their resources
  - Develop innovative second-generation drugs

## **RESPONSE FROM BIOSIMILARS COMPANIES**

- Make a capital investment
- Develop competitive marketing strategies
  - Early entry strategies
  - Direct marketing
  - Emerging markets
  - Choice of target
- Form partnerships
- Have a legal strategy in place

## **MARKET OUTLOOK**

## **SUMMARY**

## **ACKNOWLEDGEMENTS**

## I would like to order

Product name: Gauging the Biosimilar Effect: will the Market Boom or Bust?

Product link: <https://marketpublishers.com/r/G055CA5D6B6EN.html>

Price: US\$ 895.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

[info@marketpublishers.com](mailto:info@marketpublishers.com)

## Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/G055CA5D6B6EN.html>