

# Market Access of Biosimilars in Europe

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Biosimilar uptake in Europe, Aut idem and tenders in Germany

## TOPICS

- Biosimilars markets in Europe: Navigating market access barriers
- Demand-side measures to ensure biosimilar uptake in Europe
- Aut idem in Germany - the current rules
- Tenders including Biosimilars in Germany
- Regulatory update Biosimilars - current status of authority guidances

## YOUR SPEAKERS

### **Dr Barthold Deiters**

GWQ ServicePlus AG, GERMANY

### **Dr Christopher Kirsch**

Sandoz Germany

### **Dr Petra Nies**

Federal Joint Committee (G-BA), GERMANY

### **Meike Madelung, MBA**

IQVIA Commercial GmbH & Co.OHG, GERMANY

### **Prof Dr Steven Simoens**

KU LEUVEN, BELGIUM

### **Dr Sabine Vogler**

The Austrian National Public Health Institute

### **Dr Elena Wolff-Holz**

BIOCON, GERMANY

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## Aims and objectives

This training course provides comprehensive insights into the European biosimilars landscape. Participants will gain a deep understanding of current market dynamics, regulatory frameworks, and access strategies across Europe, with a special focus on recent developments in Germany.

By the end of this course, you will be equipped with practical knowledge of regulatory and market access pathways for biosimilars in Europe and know how the new rules in Germany affect your market access and healthcare management.

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## Who should attend?

This training course is aimed at regulatory affairs and market access specialists in the pharmaceutical industry who bring biosimilar products to the market. It is also of value to all those working in health insurance companies dealing with pharmaceuticals in their work.

## YOUR SPEAKERS

### Dr Barthold Deiters

GWQ ServicePlus AG, GERMANY  
Member of Executive Board, Pharmaceuticals

### Dr Christopher Kirsch

Sandoz Germany  
Head Market Access

### Dr Petra Nies

Federal Joint Committee (G-BA), GERMANY  
Head of the Pharmaceuticals Department

### Meike Madelung, MBA

IQVIA Commercial GmbH & Co.OHG, GERMANY  
Senior Consultant EMEA Thought Leadership

### Prof Dr Steven Simoens

KU LEUVEN, BELGIUM  
Senior full professor of health economics; one of the founders of the “Market analysis of biologics and biosimilars following loss of exclusivity” (MABEL) Fund

### Dr Sabine Vogler

The Austrian National Public Health Institute  
Pharmacoeconomics Department Head

### Dr Elena Wolff-Holz

BIOCON, GERMANY  
Chief Medical Officer

## Your programme: 9:00 - 17:00 CE(S)T

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09:00

**Opening address**

09:20

**Key note: Biosimilar markets in Europe: Navigating market access barriers and sustainability challenges**

Prof Dr Steven Simoens

10:10 Short Break

10:20

**The European Biosimilars market: trends, dynamics and opportunity**

Meike Madelung, MBA

- Market development, maturity, and key structural trends
- Drivers and limits of future potential
- Strategic implications for stakeholders

11:10 Coffee break

11:30

**Demand-side measures to ensure biosimilar uptake in Europe and its impact**

Dr Sabine Vogler

- Biosimilar substitution, prescription guidelines and quotas, gainsharing and further measures: Overview of 32 European countries and case studies
- Impact on uptake of biosimilars: Findings from the AUGMENT project

12:20 Lunch break

13:20

**Aut idem in Germany - the rules specified in the Pharmaceuticals Directive (AM-RL) of the Federal Joint Committee (G-BA)**

Dr Petra Nies

14:10 Short break

14:30

**Tender including Biosimilars in Germany**

Dr Barthold Deiters

15:10

**Industrial perspective - adapting to the new rules in Germany**

Dr Christopher Kirsch

15:50 Coffee break

16:10

**Regulatory update Biosimilars - current status of authority guidances**

Dr Elena Wolff-Holz

- Fostering Biosimilars development, the regulatory landscape (Europe, the US and worldwide)

17:00 Seminar end

# Market Access of Biosimilars in Europe

## REGISTRATION UNDER

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## REGISTRATION FORM

Yes, I will attend

- Market Access of Biosimilars in Europe
- Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:  
 email; and/or  telephone.  
I may withdraw my consent at any time.

### Date

28 September 2026 – Online  
09:00-17:00 CE(S)T  
You may dial in 30 min before the session

### Fee

€ 1,290.00 (+ German VAT)  
The fee includes high-quality course material for download, a participation certificate, access to the Learning Space as well as technical support, including a test meeting.

### How our online events work

- Our online events are live and interactive. They can be accessed in the Learning Space, where you will also find the programme, the list of participants and all relevant documents.
- You can access the Learning Space with the same account you use for the customer portal.
- The free pre-meeting helps you resolve any technical issues before the event.
- Continuous support during the online event guarantees that you concentrate entirely on the training.
- We guarantee the highest quality according to ISO 9001 and ISO 21001.

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Position

Company

Street address

Postal Code/City/Country

Tel. No.

Date, Signature

## CANCELLATION POLICY

Our general terms and conditions (as of 01 June 2024) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at [www.forum-institut.com/t&c](http://www.forum-institut.com/t&c)

## YOUR CONTACT



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