ONLINE-SEMINAR

FORUM

Market Access of Orphan Drugs

Focus the EU4 and the UK

TOPICS

- Evidence generation with small patient groups
- Evaluation of the orphan and paediatric legislation
- Orphan drugs in the German AMNOG procedure
- Value proposition from a health insurance perspective
- Value creation process for a launch in the EU4 and the UK

YOUR SPEAKERS

Dr Dan Dammann
Techniker Krankenkasse, Hamburg, GERMANY

Dr Frauke Naumann-Winter, M.Sc.
- requested -
Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr Yvonne Schmidt
Federal Joint Committee (G-BA), Berlin, GERMANY

Sophie Schmitz
Partners4Access, Hilversum, THE NETHERLANDS

Pietro Sternini
Astellas Gene Therapies, Astellas AG, SWITZERLAND

21 JANUARY 2022 - ONLINE

Aims and objectives

The orphan drug sector is about to change. EU orphan drug and paediatric legislation is under review and the EU HTA is fast approaching - it is time for a thorough update on regulatory and HTA issues.

This course provides the latest on marketing authorisation and market access, as well as practical tips for evidence generation and value creation.

Who should attend?

This course addresses the needs of all who are involved in regulatory affairs or market access with small patient groups or orphan drug status.

It is also recommended for those who address medical affairs and clinical issues related to orphan drugs.

Your benefits

- Experts provide HTA, regulatory body, health insurance and industry perspectives in a single course
- Learn how regulatory affairs and the HTA fit together
- Use of live engagement tools to ensure a sustainable learning effect
- Bringing participants across Europe together

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Dr Dan Dammann
Techniker Krankenkasse, Hamburg, GERMANY

Team Leader Drug Prescription Management

Dr Frauke Naumann-Winter, M.Sc.
- requested -
Bonn, GERMANY

Senior Expert Regulatory Affairs

Dr Yvonne Schmidt
Federal Joint Committee (G-BA), Berlin, GERMANY

Consultant, Pharmaceuticals Department

Sophie Schmitz
Partners4Access, Hilversum, THE NETHERLANDS

Managing Partner

Pietro Sternini
Astellas Gene Therapies, Astellas AG, SWITZERLAND

Market Access & Marketing Lead, EMEA

Your programme 09:00 - 17:00

09:00 Introduction

09:15

The appropriate route to market for your product group - strategic thinking

Sophie Schmitz

10:00 Short break

10:15

Evidence generation with small patient groups

Sophie Schmitz

10:45

Marketing authorisation of orphan drugs in the EU

Dr Frauke Naumann-Winter

- Evaluation of the orphan drug status after initial designation (before and after EC Notice 2016/C 242/03)
- Relevance of register data in marketing authorisation and conditions after approval
- EC joint evaluation of orphan and paediatric legislation

12:00 Lunch break

13:00

Orphan drugs in the German AMNOG procedure

Dr Yvonne Schmidt

- Requirements for the dossier
- Additional benefit and re-evaluation of the additional benefit
- Re-evaluation of the evidence
- Register requirements and conditions ('anwendungsbegleitende Datenerhebung')
- Orphan drugs and the EU HTA: New possibilities?

14:15 Coffee break

14:30

Value proposition of orphan drugs from a health insurance perspective

Dr Dan Dammann

15:30 Short break

15:45

Value creation process in the run-up to a launch in the EU4 and the UK: a manufacturer's perspective

Pietro Sternini

17:00 Seminar end

Market Access of Orphan Drugs

REGISTRATION UNDER

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Yes, I will attend

☐ Market Access of Orphan Drugs

☐ Yes, I agree that FORUM Institut may inform me about events by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Date
Friday, 21 January 2022
Online from 09:00 - 17:00
You may dial in 30 min. before the session

Fee
€ 1,090.00 (+ German VAT)
The fee includes a comprehensive online documentation and a certificate.

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- And you can also ask questions live, using the chat or audio function.

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