

Early Access and Managed Entry Agreements in Europe

Topics

Market access possibilities
in France, Germany, Spain,
UK, Ireland and the EU

- Early access and accelerated access programmes at the EU level
- Unmet medical need: compassionate use and off-label use
- Market access via managed entry agreements
- Possibilities at a national level in France, Germany, Spain, the UK and Ireland
- Pricing: reimbursement in early access programmes

Your speakers

Dr Alexander Natz, LL.M
– Chair –
EUCOPE
Brussels, BELGIUM

Dr Dr Marie
Geneviève Plaud
Ecker + Ecker GmbH
Hamburg, GERMANY

Alexander Wilke MBA, LL.M.
Institute for market/patient
access & medical economics
I.f.G.V. Huglfing, GERMANY

Francisco Aránega
Faus & Moliner
Barcelona, SPAIN

Christian Hill
MAP BioPharma Limited
Cambridge, GREAT BRITAIN

Early Access and Managed Entry Agreements in Europe

Aims and objectives

This seminar provides you with a detailed overview of early access possibilities in the EU in general as well as in Germany, the UK, Ireland, Spain and France in particular.

After having attended the seminar, you will be aware of the available options for, and the arising challenges of, bringing your pharmaceuticals to the European market as fast as possible.

Specifically, topics such as eligibility to the various programmes, data requirements and reimbursement options will be discussed in order to acquire a deep understanding of how patients could benefit from your products at the earliest possible.

Who should attend

This seminar addresses the needs of pharmaceutical industry employees in medical affairs, market access and healthcare management.

Those dealing with market access strategies within Europe will especially benefit from this seminar.

Your benefits

- Local experts with detailed knowledge of the Spanish, UK, Irish, French and German markets
- Combination of early access, compassionate use and managed entry agreements comprehensively explained
- Focus on access and reimbursement strategies

Your chair



Dr Alexander Natz, LL.M.
EUCOPE – European
Confederation of
Pharmaceutical
Entrepreneurs
Brussels, BELGIUM

Secretary General

Your speakers



Francisco Aránega
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Affairs



Dr Dr Marie
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Senior Consultant



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Scientific Director and CEO

Your programme 09:00 – 17:00

09:00

Early access and accelerated access programmes in the EU and beyond

Dr Alexander Natz

- EU early access programmes
- Accelerated access possibilities: conditional approval, PRIME and adaptive pathways
- Possibilities beyond EU borders

10:00

Early access, compassionate use and off-label use in Europe: a legal perspective

Francisco Aránega, Dr Alexander Natz

- Unmet medical need and the consequences for market entry
- Legal framework, hurdles and possibilities

11:00 Coffee break

11:15

Managed entry agreements in Europe – facilitating the early access of products?

Alexander Wilke

- Introduction to scientific-based contracting
- Early market access and reimbursement via managed entry agreements
- Overview of the possibilities and challenges in the EU

12:15 Lunch

13:30

Practical cases:

Early access, compassionate use and off-label use at a national level

Christian Hill, Marie Geneviève Plaud, Francisco Aránega

- Overview of the possibilities and challenges in the EU
- Germany
- France
- The UK and Ireland
- Spain

15:30 Coffee break

16:00

Pricing – what to keep in mind when deciding for early or accelerated access

Christian Hill

- Reimbursement for early access products
- Named patient programme – paid access or free of charge?
- Price anchor through early access
- Examples: How the ATU can impact on the AMNOG procedure in Germany and in other countries

17:00 End of seminar

Registration under
service@forum-institut.com or
Fax +49 6221 500-555

Registration Form

Yes, I will attend the Seminar

☐ Early Access and Managed Entry
Agreements in Europe

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to register

Registration: +49 6221 500-500
Conference-No. 18 02 234

Internet:
www.forum-institut.com

Date/Venue:
19 February 2018 in Frankfurt
Steigenberger Airport Hotel
Unterschweinstiege 16 · 60549 Frankfurt
Tel. +49 69 6975-0 · Fax +49 69 6975-2505

Fee:
€ 1,090.00 (+ German VAT)
The fee includes course documentation (incl. free
download) as well as midsession refreshments,
lunch and certificate.
Invoice and confirmation will be forwarded to you.

Hotel accommodation:
A limited number of rooms have been reserved at
the hotel and are subject to availability. Please book
at least six weeks prior to the seminar to obtain
a hotel room at the discounted rate. All bookings
should be made directly with the hotel quoting
Forum-Institut and the Seminar-No.

Any Further Questions?



I am gladly at your disposal should
you have any further questions
about the seminar.

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Cancellation Policy

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