

Early Access Programmes & Compassionate Use in the EU

Topics

Your early access possibilities in Germany, the UK, Spain and France

- Early access in the EU legal framework
- Compassionate use in France – ATU as best practice?
- Early access in the UK – the early access to medicines scheme
- Early access possibilities in Spain
- The German compassionate use programme – lessons learnt

Your speakers

Dr Marc Christian Bauer
TSRO Bio GmbH,
Zug, SWITZERLAND

Dr Dr Marie-Geneviève Campion
Ecker + Ecker GmbH,
Hamburg, GERMANY

Jordi Faus
Faus & Moliner,
Barcelona, SPAIN

Dr Alexander Natz
– Chair –
EUCOPE,
Brussels, BELGIUM

Dr Daniel O'Connor
MHRA,
London, UNITED KINGDOM

Early Access Programmes & Compassionate Use in the EU

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, 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 or healthcare management.

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

Your chair



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

Secretary General

Your speakers



Dr Marc Christian Bauer
TSRO Bio GmbH,
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Vice President, Head of Legal and
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Dr Daniel O'Connor
MHRA, Medicines &
Healthcare products
Regulatory Agency,
London, GREAT BRITAIN

Expert Medical Assessor, specialist areas
rare diseases, oncology, histopathology &
EAMS

Your programme 09.00 – 17.00

09.00

Early access in the EU legal framework

Dr Alexander Natz

- The regulatory framework
 - Conditional approvals
 - Compassionate use programmes
 - Off-label use
 - Single importation/named patient programmes
- EMA's adaptive pathways – a new concept for early patient access?
- European Commission pilot programmes to speed up market access in Europe

10.00

Early access possibilities in Spain

Jordi Faus

- Compassionate use and Off-label use
- Access prior to the completion of P&R Spanish procedures
- Practical tips and future developments

11.00 Coffee break

11.15

Compassionate use in France – ATU as best practice?

Dr Dr Marie-Geneviève Campion

- Regulatory requirements and eligible medicinal products
- Nominative ATU vs cohort ATU
- ATU – a successful scheme for early access in Europe?
- Consequences for the German AMNOG procedure

12.15 Lunch

13.30

Case study: Drugs in the German compassionate use programme

Dr Marc Christian Bauer

14.30

Early access in the UK – the Early Access to Medicines Scheme (EAMS)

Dr Daniel O'Connor

- Overview and experience of the UK's EAMS
- Impact of government's accelerated access review and task force
- Early patient access and the potential to generate real-world data

15.30 Coffee break

15.45

Round table: Best practice examples

- Reimbursed early access?
- Eligibility criteria
- Data requirements
- When to approach the agencies

16.30

Liability risks in the context of early access activities

Dr Alexander Natz

17.00 End of seminar

Registration under
service@forum-institut.com or
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Registration Form

Yes, I will attend the Seminar

☐ Early Access Programmes &
Compassionate Use in the EU

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. 17 02 235

Internet:

www.forum-institut.com

Date/Venue:

20 February 2017 in Düsseldorf

Meliá Düsseldorf

Inselstr. 2 · 40479 Düsseldorf

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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.

Dr Henriette Wolf-Klein

Pharma & Healthcare

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Cancellation Policy

Our general terms and conditions apply (as of 1. January 2016) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.de/agb_en