

Early Access Programmes for Pharmaceuticals in Europe

Topics

- Conditional approval
- Compassionate use and off-label use
- Named patient programme and expanded access programme
- French ATU - Best practice?
- Early access for orphans
- EMA's PRIME scheme

Accelerated market access - Which programmes and methods fit? Get the latest information here!

Your speakers

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myTomorrows, Amsterdam,
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Sascha Glanemann
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Early Access Programmes for Pharmaceuticals in Europe

Aims and objectives

The EMA's PRIME (PRiority MEDicines) scheme is the latest attempt to accelerate access for innovative drugs to the European market. This seminar addresses not only this programme, but also provides you with a thorough understanding of the various programmes and methods currently facilitating pharmaceuticals' market access.

After attending this seminar, you will have a core set of ideas on how to speed up market access for your products and know for exactly which programmes your product is eligible.

Who should attend?

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

Especially those dealing with market access strategies within Europe will benefit from this course.

Limited number of attendees

This seminar is restricted to 20 participants. This limitation, a feature of all FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

Your speakers



CEO & Founder

Ronald Brus MD
myTomorrows, Amsterdam,
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Consultant

**Dr. Marie-Geneviève
Champion**
Ecker + Ecker GmbH,
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Head of Market Access & Primary Care

Sascha Glanemann
Teva GmbH, Berlin,
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Secretary General

**Dr. Alexander Natz,
LL.M.**
EUCOPE - European Confe-
deration of Pharmaceutical
Entrepreneurs, Brüssel,
BELGIUM

Which programmes and methods fit?

Your programme 9.00 - 17.00

> 9.00

Early access under the existing EU legal framework

Dr. Alexander Natz

- The regulatory framework for early access
 - Conditional approval
 - Compassionate use programme
 - Off-label use
 - Decisions of the European Court of Justice - The "Polish Case"

> 10.15

Compassionate use in Germany and France: ATU as a best practice?

Dr. Marie-Geneviève Campion

- Regulatory requirements and eligible medicinal products
- ATU in France: nominative ATU versus cohort ATU
- ATU - A successful scheme for early access in Europe?

> 11.15 Coffee break

> 11.30

Early access programmes for orphan drugs - lessons learnt

Sascha Glanemann

- Success factors for early access
- Useful programmes in the EU

> 12.30 Lunch

> 14.00

Drugs in development - Expanded access programmes

Ronald Brus

- Making new, innovative medical treatments available - Options in Europe
- Individual imports - The challenges in practice

> 15.00 Coffee break

> 15.30

Liability and legal challenges of the various access programmes

Dr. Alexander Natz

- Pharmacovigilance and patient information
- Off-label use vs. compassionate use
- Impact on national HTA submissions and regulatory data protection

> 16.15

European pilot programmes to fasten market access in Europe - Current status 2016/2017

Dr. Alexander Natz

- PRIME vs. adaptive pathways: Which programme is applicable?
- Specific programmes for orphan medicinal products (MoCA)
- Overview on national programmes
- HTA coordination vs parallel scientific advice

> 16.45 Final discussion

> 17.00 Seminar end

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

Registration Form

Yes, I will attend the seminar
☐ Early Access Programmes
for Pharmaceuticals 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. 16 02 236

Internet:
www.forum-institut.com

Date/Venue:
Wednesday, 17 February 2016 in Cologne
8.30 registration; 9.00-17.00 seminar
Köln Marriott Hotel
Johannisstraße 76-80 · 50668 Köln
Tel. +49 221 94222-0 · Fax +49 221 94222-777

Fee:
€ 990.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as mid-session 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 Course No.

Any Further Questions?



Please feel free to contact me if you have any questions.

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Cancellation Policy

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