Seminar

FORUM

The Eurasian Economic Union (EAEU) – Changes in Regulatory Affairs, PV & Distribution

Topics

- Changes you will face when registering drugs in the EAEU region
- Pharmaceutical activities regulated by the Eurasian Economic Commission
- National versus EAEU legislation – What is binding in which context?
- How to use this transitional period?

January 2016: A single, binding legislation for marketing authorisation in Russia, Kazakhstan, Belarus, Armenia & the Kyrgyz Republic

Your speakers

Dr Raimond Lozda
Director, FMS Baltic Ltd.,
Riga, LATVIA

Dr Edelgard Rehak
Dr Edelgard Rehak
Consulting, GERMANY

28 January 2016 in Frankfurt

The Eurasian Economic Union (EAEU)

Aims and objectives

Starting January 2016, common regulations set by the Eurasian Economic Union for the registration of medicinal products will come into force.

The aim of the seminar is to give you a qualified overview of the expected changes in legislation, the possible impact on registration strategies in EAEU member states and how your business might be improved.

You will not only learn about the EAEU mutual recognition procedure, but also receive in-depth knowledge on further changes affecting pharmacovigilance and distribution.

Who should attend?

This seminar is aimed at regulatory affairs managers, as well as all pharmaceutical employees dealing with pharmacovigilance and/or distribution in EAEU countries (Russia, Kazakhstan, Belarus, Armenia and the Kyrgyz Republic).

All registered participants are welcome to send their qualified questions to the speakers prior to the seminar.

Your speakers

Dr Raimond Lozda

Director, FMS Baltic Ltd., Riga, LATVIA

Dr Lozda has intensive experience in regulatory affairs. From 1995 till 2002 he worked for Sanofi-Synthelabo representative office in Belarus and Baltic States.

Since 2002 he is working as an independent consultant covering assistance for MA applications in Russia, Ukraine, Belarus and Baltic States.

Dr Edelgard Rehak

Dr Edelgard Rehak Consulting, GERMANY

She is an expert for registrations in Russia and in Central and Eastern Europe. From 2011 to 2014 she worked as Regulatory Director at Sanofi and Medical Director at Zentiva based in Moscow, and prior to that from 2006 to 2009 as Head Regulatory and QA for Novartis based in Kiev, Ukraine.

She has a broad range of experience in bioequivalence and toxicological trials in Russia. Until 2006 she worked in various functions in product development (Gx and biosimilars) and clinical research at Sandoz/HEXAL, Germany.

Your programme 9.00 - 17.00

> 9.00

Development of a common pharmaceutical market within the EAEU

- EAEU scope and aims
- EAEU members: Russia, Kazakhstan, Belarus, Armenia and the Kyrgyz Republic
- Role of the Eurasian Economic Commission (EEC)
- EAEU's impact on the pharmaceutical market

> 10.15 Coffee break

> 10.30

A look at the changes in legislation for medicinal products as of January 2016

- Harmonising legislation for medicinal products within the EAEU
- National vs. EAEU legislation
- Pharmaceutical activities not regulated by the EEC
- Transitional period for the harmonisation

> 12.00 Lunch

> 13.15

Changes affecting pharmacovigilance, distribution and the responsible person

- Responsible person - Still necessary in each country
- Pharmacovigilance duties - Need to be harmonised?
- Cross-border distribution - Simplified?

> 14.45 Coffee break

> 15.00

Marketing authorisation of medicinal products - mutual recognition procedure in place!

- The legal basis for procedures and the different types
- Dossier requirements
- The responsible authorities
- Interaction with European committees (CMDh, EMA)?

> 17.00 End of the seminar

Registration recommended 30 days in advance

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

Registration Form

Yes, I will attend the seminar
☐ The Eurasian Economic Union (EAEU)

☐ I am interested in receiving more information on FORUM events and agree that this information be sent to me by e-mail.

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 01 236**

- **Internet:**
www.forum-institut.com

- **Date/Venue:**
Thursday, 28 January 2016 in Frankfurt
8.30 registration; 9.00 - 17.00 seminar
Steigenberger Airport Hotel
Unterschweinstiege 16 · 60549 Frankfurt
Tel. +49 69 6975-0 · Fax +49 69 6975-2505

- **Fee:**
€ 1090.00 (+ 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

Our general terms and conditions apply (as of 1 December 2011) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.com/t&c