

Off-Label Use in Europe

Topics

- Areas of conflict: medical affairs - sales - pharmacovigilance - legal - insurance
- Advertising vs. information - what is possible?
- Event of damage: consequences and course of action
- Off-label use: tolerated, promoted and reimbursed by health insurance companies?

Special issues in Italy and France: Consequences for EU-wide harmonisation?

Your speakers

Peter W.L. Bogaert
Covington & Burling LLP,
Brussels

Dr Dr Adem Koyuncu
Covington & Burling LLP,
Brussels

Peter Solberg
Janssen-Cilag GmbH,
Neuss, GERMANY

Off-Label Use in Europe

Aims and objectives

This seminar addresses the different legal situations and the handling of off-label use in Europe. The recent course of action in Italy and France and the consequences for the harmonisation will be particularly discussed.

Our experts will provide detailed information on the following areas of conflict: medical affairs, sales, pharmacovigilance, legal and insurance.

After the seminar you will be aware of the difference between advertising, information and pre-approval information for off-label use, how to get knowledge of off-label use and how to handle it. You will know who is liable in cases of damage and how to minimize the risk. Moreover you will understand the regulations for health insurance companies regarding off-label use promotion and reimbursement.

Who should attend?

This seminar will be of benefit to all those working in the pharmaceutical industry who need an in-depth understanding of the current off-label use regulation in Europe and the opportunities and risks of off-label use. Those working in

- Medical Affairs
- Pharmacovigilance
- Marketing/Sales
- Law

will especially profit from the seminar.

Your speakers



Peter W.L. Bogaert
Covington & Burling LLP,
Brussels

Partner, Lawyer



Dr Dr Adem Koyuncu
Covington & Burling LLP,
Brussels

Partner, Lawyer and M.D.;
Licensed to practice in Brussels
and Germany



Peter Solberg
Janssen-Cilag GmbH,
Neuss

Lawyer,
Vice President Legal Affairs & Compliance

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 programme 9.00 - 17.30

> 9.00

Legal Basis

Dr Dr Adem Koyuncu

- Definition off-label use, compassionate use and off-license use
- Applicable EU laws vs. national regulations
- Specific examples & practical relevance
- Responsible persons in pharmaceutical companies

> 10.00 Coffee break

> 10.15

Information about off-label use

Peter Solberg

- How to get knowledge of off-label use
- Practical areas of conflict: medical affairs - sales - pharmacovigilance - legal - insurance
- Acceptance vs. suppression of off-label use
- Overview of advertising rules
- Advertising vs. information - what is possible?
- Pre-approval information about medicines - dos & don'ts
- Competitors' off-label use - how to react?
- Available legal means vs. competitors

> 12.15 Lunch

> 13.15

Compassionate use and named patient use in the EU

Peter W.L. Bogaert

- Applicable rules and guidelines
- Delineation from off-label use
- Early-access through compassionate use/named patient use?

> 14.00

Liability for off-label use

Dr Dr Adem Koyuncu

- Who is liable in case of damages?
- Companies' responsibilities vs. doctors' responsibilities
- Applicable product liability rules
- Personal liability risks (e.g. of QPPV)?
- Event of damage - consequences and courses of action
- Practical examples and recommendations

> 15.00 Coffee break

> 15.15

Off-label use: tolerated, promoted and reimbursed by health insurance companies?

Peter W.L. Bogaert

> 15.45

Special issues in Europe

Peter W.L. Bogaert

- Off-label use as an issue for pharmacovigilance
- Special legal situation in Italy
- Special legal situation in France
- Effects on the EU marketing authorisation system
- Consequences for EU-wide harmonisation?

> 17.00

Discussion

All speakers

> 17.30 End of seminar

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

Registration Form

Yes, I will attend the seminar

☐ Off-Label Use in Europe

☐ 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. 15 11 944

Internet:

www.forum-institut.com

Date/Venue:

Friday, 13 November 2015 in Düsseldorf
8.30 registration; 9.00 - 17.30 seminar
Hilton Düsseldorf Hotel
Georg-Glock-Str. 20 · 40474 Düsseldorf
Tel. +49 211 4377-0 · Fax +49 211 4377-2519

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.

Jessica Jegodka

Conference Manager

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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