

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 and healthcare cost controls:
EU principles and national examples

This seminar addresses the different legal situations and the practical handling of off-label use in Europe

Your speakers

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

Dr Dr Adem Koyuncu
Covington & Burling LLP,
Brussels, Belgium

Peter Solberg
Janssen-Cilag GmbH,
Neuss, Germany

Aims and objectives

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

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

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 minimise 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 - 17.00

> 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

The broader context of off-label use in europe

Peter W.L. Bogaert

- Off-label v. marketing of an unapproved medicine
 - Compassionate use and named patient sales
 - Applicable rules and guidelines
 - Early-access through compassionate use/named patient use?
 - Pharmacy and hospital preparations
- Off-label use and healthcare cost controls
 - National examples (Italy, France, Ireland, etc.)
 - Off-label comparator for pricing decisions
 - EU principles
- The regulatory context
 - Clinical trials, PASS and PAES
 - Real world evidence

> 15.30 Coffee break

> 15.45

Liability for off-label use and Pharmacovigilance issues

Peter W.L. Bogaert

- Who is liable in case of damages?
- Companies' responsibilities vs. doctors' responsibilities
- Applicable product liability rules
- Personal liability risks (e.g. of the QPPV)
- Pharmacovigilance obligations and their interplay with liability laws
- What to do in the event of damage claims?
- Practical examples & recommendations

> 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

☐ Off-Label Use 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. 17 11 210

Date/Venue:

Wednesday, 22 November 2017 in Düsseldorf
8.30 registration; 9.00 - 17.00 seminar
Leonardo Royal Hotel Düsseldorf Königsallee
Graf-Adolf-Platz 8-10 · 40213 Düsseldorf
Tel. +49 211 3848-0 · Fax +49 211 3848-390

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

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