

# 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

# Off-Label Use in Europe

## 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

# Off-Label Use in Europe

Registration under  
[formacion@qualitecfarma.com](mailto:formacion@qualitecfarma.com) or  
Telf.: +34 91 372 83 99

## 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: +34 91 372 83 99**

**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 accommodations:

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.

**Pablo García**

Conference Manager

Tel. +34 91 372 83 99

[formacion@qualitecfarma.com](mailto:formacion@qualitecfarma.com)

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