Conference

FORUM

# ExpertFORUM Labelling

Nationally, within the EU & globally

## Topics

- Medication errors and off-label use
- Safety information management and educational material
- Online product information and safety data features
- Labelling management and working with QRD templates
- Global labelling challenges

## Your speakers

**Dr Petra Bettauer**

Mylan Healthcare GmbH, Hannover, GERMANY

**Dr Claudia-Carolin Keil**

Biotest Pharma GmbH, Dreieich, GERMANY

**Jan MacDonald**

MHRA, London, GREAT BRITAIN

**Dr Thomas Grüger**

Senior Expert Pharmacovigilance, Bonn, GERMANY

**Dr Benjamin Keserü**

Boehringer Ingelheim GmbH, Ingelheim, GERMANY

**Dr Patrick Salmon**

HPRA, Dublin, IRELAND

**Horst Kastrup**

MEDA Pharma GmbH & Co. KG, Bad Homburg, GERMANY

**Dr Dr Adem Koyuncu**

Covington & Burling LLP, Brussels, BELGIUM

31 May – 1 June 2017 in Frankfurt

# ExpertFORUM Labelling: nationally, within the EU & globally

## Aims and objectives

This conference will give you a thorough update on labelling challenges and duties at a national, EU and global level.

One focus of the meeting will be on safety management, including the prevention of medication errors, off-label use, implementation of PRAC decisions and much more. Topics such as online product information, the required anti-counterfeit features, etc. will also be addressed in detail.

After having attended this conference, you will be knowledgeable about labelling duties for 2017/2018 and will have received practical tips for your business operations at the national, EU and global level.

## Participants

This conference will benefit anyone working in the field of product information, such as SmPCs, package leaflets, CCDS and online drug information, and anyone who would like to have a detailed update on regulatory requirements and options in this field.

Members of the following departments will particularly benefit from this conference:

- Regulatory affairs and labelling
- Medical affairs
- Pharmacovigilance

## Chair day one

### Dr Dr Adem Koyuncu

**Covington & Burling LLP, Brussels, BELGIUM**

Partner - Lawyer and medical doctor

## Your speakers

### Dr Petra Bettauer

**Mylan Healthcare GmbH, Hannover, GERMANY**

Head Regulatory Affairs/Information officer packaging material

### Dr Thomas Grüger

**Senior Expert Pharmacovigilance, Bonn, GERMANY**

### Horst Kastrup

**MEDA Pharma GmbH & Co. KG, Bad Homburg, GERMANY**

Senior Regulatory Advisor

### Dr Claudia-Carolin Keil

**Biotest Pharma GmbH, Dreieich, GERMANY**

Director Labelling, Corporate Regulatory Affairs

### Dr Benjamin Keserü

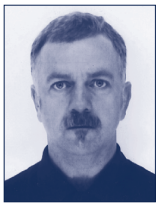
**Boehringer Ingelheim GmbH, Ingelheim, GERMANY**

Head Global Labeling Team 1

### Jan MacDonald

**Medicines and Healthcare Products Regulatory Agency (MHRA), London, GREAT BRITAIN**

Group Manager Access & Information for Medicines & Standards



### Dr Patrick Salmon

**Health Products Regulatory Authority, Dublin, IRELAND**

Senior Medical Assessor,
CHMP alternate member, Chair of the ad hoc group on the SmPC Guideline and member of the SmPC Advisory Group

# Your programme

## 31 May 2017 from 09.00 - 17.00

09.00

### Avoiding medication errors – labelling duties 2017

*Dr Thomas Grüger*

- Requirements according to the good practice guide on risk minimisation and prevention of medication errors
  - Naming and INN
  - Labelling that ensures safe and appropriate use of the product; Usage of the QRD templates

10.15 Coffee break

10.30

### Off-label use: liability aspects, medication errors and advertising issues in the EU

*Dr Dr Adem Koyuncu*

- Applicable laws in the EU with regard to off-label use – EU law vs national peculiarities
- Knowledge of off-label use and its impact on liability risks
- Medication errors due to imprecise labelling?
- Advertising vs information about off-label use? Trends in the EU and the USA

11.30

### Safety issues: from PRAC decision to label change – the regulatory framework

*Dr Patrick Salmon*

- Experience with PRAC decisions and the consequential label changes
- Safety issues and the SmPC: current problems

12.30 Lunch

13.45

### Safety information management in practice

*Dr Benjamin Keserü*

- Labelling process: end 2 end
- Changes in labelling due to safety aspects

14.45

### Educational material – still a solely national topic?

*Dr Thomas Grüger*

- Regulatory framework in the EU
- Challenges and opportunities for MAHs and NCAs

15.30 Coffee break

16.00

### Global labelling challenges

*Dr Benjamin Keserü*

- Labelling beyond national borders: how to work with a CCDS in a global environment

## 1 June 2017 from 09.00 - 15.30

09.00

### Outer package: the anti-counterfeit features – your important duties!

*Horst Kastrup*

- Unique identifier and tamper-evident closure
- EU requirements and expected national peculiarities
- The worldwide calendar for anti-counterfeit labelling elements

10.15 Coffee break

10.30

### Online product information and the use of QR codes

*Jan MacDonald*

- Acceptance of online product information
- QR codes in the labelling texts/at the outer package from a regulator point of view
- What the future holds

11.15

### Safety data features and the QR code in the context of product information

*Dr Claudia-Carolin Keil*

- Additional usage to inform patients and doctors on product characteristics

12.00

### Update from the QRD group – a delegate's perspective

*Jan MacDonald*

- How the QRD operates
- Topics discussed and work in progress

12.30 Lunch

13.45

### Labelling management in the product life cycle

*Dr Claudia-Carolin Keil*

- How to deal with the new QRD templates

14.30

### Labelling of generic products

*Dr Petra Bettauer*

15.30 End of conference

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

## Registration Form

Yes, I will attend the conference

☐ **ExpertFORUM Labelling:**
**nationally, within the EU & globally**
31 May – 1 June 2017 in Frankfurt

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 05 233

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

- **Date/Venue:**
31 May – 1 June 2017 in Frankfurt
1st day: 08.30 registration, 09.00 -17.00 conference
2nd day: 09.00 -15.30 conference

QGREENHOTEL by Meliá
Katharinenkreisel · 60486 Frankfurt
Tel. +49 69 70730-0 · Fax+49 69 70730-333

- **Fee:**
€ 1,890.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as midsession 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 conference to obtain a hotel room at the discounted rate. All bookings should be made directly with the hotel quoting Forum-Institut and the conference-No.

## Any further questions?

I am gladly at your disposal should you have any further questions about the conference.

**Dr. Henriette Wolf-Klein**
Head of department Healthcare
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## Cancellation Policy

Our general terms and conditions apply (as of 01.01.2016) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.de/agb_en