

The new Variations Regulation

Topics

- The new classification system for variations
- The work of the CMD(h)
 - the new best practice guidelines
- National implementation of the new Variations Regulation
- Annual reports, grouping, worksharing
 - lowering the workload of the pharmaceutical industry?

**Coming into force
on 1 January 2010
- be prepared!**

Your speakers

**Assoc. Prof. Tatyana
Benisheva-Dimitrova, MDRA**
Medical University-Sofia, BULGARIA

Assoc. Prof. Dr. Jasmina Mircheva
Bulgarian Drug Agency,
Sofia, BULGARIA

Dr. Maren von Fritschen
PharmaLex GmbH,
Repräsentanz Berlin, GERMANY

Susanne Winterscheid
Federal Institute for Drugs and Medical
Devices (BfArM), Bonn, GERMANY

The new Variations Regulation

Aims and objectives

The Variations Regulation has been approved and will come into force on 1 January 2010.

Operational guidelines are in preparation and will further delineate the concrete requirements, such as:

- Guidelines on the variation procedures
- Guidelines on the details of the various categories of variations

We will inform you at our seminar in detail on the content of the regulation and the upcoming guidelines.

Count on the expertise of our speakers and get prepared to switch from one variations system to another!

Participants

This seminar will be of benefit to everyone working in regulatory affairs in the pharmaceutical industry.

Limited number of attendees

The seminar is restricted to 30 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 speakers

Assoc. Prof. Tatyana Benisheva-Dimitrova, MDRA

**-Chairperson-
Faculty of Public Health,
Medical University-Sofia, BULGARIA**

More than 15 years experience in drug regulatory affairs and consultant of the single-source regulatory data base IDRAC of Thomson Reuters.

Assoc. Prof. Dr. Jasmina Mircheva

**Executive Director,
Bulgarian Drug Agency,
Sofia, BULGARIA**

She becomes director of the institution for a second time as previously she was Head of the National Institute for Medicinal Products from 1995 to 1998. From 1998 to 2005, Dr. Mircheva worked as director for Central and Eastern Europe at the AESGP. After her return to Bulgaria, she was head of the cabinet of two successive health ministers until 13 April 2009.

Dr. Maren von Fritschen

**PharmaLex GmbH,
Repräsentanz Berlin, GERMANY**

Director Regulatory Affairs

Susanne Winterscheid

Federal Institute for Drugs and Medical Devices (BfArM), Bonn, GERMANY

Head of Process Management of
Licensing Department 4,

Ms Winterscheid is leader of the Variation Subgroup of the CMD(h) and CMD(h)-Contact Point "Variations".

Coming into force on 1 January 2010 - be prepared!

Your programme 9.00 - 17.00

> 9.00

Opening address

Assoc. Prof. Dr. Jasmina Mircheva

> 9.20

The new Variations Regulation (1234/2008 EC)

Dr. Maren von Fritschen

- Implementation phase and timelines; Details of the new variation procedures

> 10.15 Coffee break

> 10.30

The new classification system for variations according to the Regulation

Susanne Winterscheid

- Type I a notification or Type I b / Type II variation? Upcoming changes due to the new Variations Regulation
- Simplifications for changes in the Pharmacovigilance System

> 12.00 Lunch

> 13.15

The work of the CMD(h) - the new best practice guidelines

Susanne Winterscheid

- Guidelines on the operation of the procedures: grouping, what is possible? Worksharing of the authorities
- Communities and differences to the EMEA - The new post authorisation guide for the Centralised Procedure

> 14.30

National implementation of the new Variations Regulation in Bulgaria

Assoc. Prof. Tatyana Benisheva-Dimitrova

> 15.00 Coffee break

> 15.30

Preparing for the new Variation System - lowering the workload of the pharmaceutical industry?

Dr. Maren von Fritschen

- From "tell and do" to "do and tell"; Grouping - a good option?
- Annual reports for Type I a Variations - lowering the workload?

> 16.30 Final discussion

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

Registration Form

Yes, I will attend the Seminar

☐ The new Variations Regulation

☐ I am interested in more information about FORUM-Events
and I agree that this information is 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 500-501**

■ **Conference-No. 09 11 220 I**

■ **Date/Venue:**

Friday, 27 November 2009 in Sofia
8.30 registration; 9.00 - 17.00 seminar
Anel Hotel
14 Todor Alexandrov Blvd. · BG 1303 Sofia
Tel. +359 2 9119 900 · Fax +359 2 9119 761

■ **Fee:**

€ 430,00

The fee includes course documentation as well as
mid-session refreshments and lunch. Invoice and
confirmation will be forwarded to you.

Bank details:

Dresdner Bank Heidelberg
Rohrbacher Str. 5-7
D-69115 Heidelberg
IBAN: DE13 6728 0051 0541 1804 00
BIC: DRES DE FF 672

Please quote the invoice number upon payment.

Any Further Questions?



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

Dr. Henriette Wolf-Klein

Department Manager
Tel. +49 6221 500-680
h.wolf-klein@forum-institut.de

Cancellation Policy

Our general terms and conditions apply (as of
19 December 2008) 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

We recommend taking out a seminar cancellation insurance.
More details at www.erv.de