



Current Regulatory Challenges Regarding Pharmaceuticals

Topics

- Marketing authorisation procedures two years after EU accession
- Patient information for medicinal products in the EU
- Medicines for children in the EU – experience with the new paediatric legislation
- Variations – the upcoming new legislation

Key note speakers

Dr. Emil Hristov

Executive Director,
Bulgarian Drug Agency, Bulgaria

Prof. Dr. Johannes Löwer

President of the Paul-Ehrlich-Institut, Germany;
Acting Director of the Federal Institute for Drugs
and Medical Devices (BfArM), Germany

Current Regulatory Challenges Regarding Pharmaceuticals

Who should attend?

This international conference will be of interest to managing directors and co-workers of the pharmaceutical industry, especially from the following departments:

- Marketing authorisation
- Clinical trials & medical affairs

Opening address

Minister of Health, Eugeni Jelev

Ministry of Health

Rector, Prof. Vanyo Mitev

Medical University - Sofia

Dean, Prof. Nikolai Lambov

Faculty of Pharmacy, Medical University - Sofia

Dean, Prof. Tzekomir Vodenicharov

Faculty of Public Health, Medical University - Sofia

Dr. Emil Hristov

Executive Director, Bulgarian Drug Agency

Speakers

Assoc. Prof. Dr. Ivanka Atanasova

Director of Marketing Authorisation Department, BDA
Bulgarian member of the CMDh

Prof. Dr. Daniel Brasseur

Federal Agency for Medicines and Medicinal Products, Belgium,
Chairman of the PDCO at the EMEA

Dr. Borislav Borisov

Former director of the BDA, Bulgaria

Tzvetomir Deliyski

Head of Division Validation and procedure administration, Department Marketing Authorisation of Medicinal Products, BDA,
Bulgarian representative at EudraPharm, Eudratrack CTS, eCTD and alternative delegate in the CMD(h) and PIM

Deyan Denev

Executive Director, Association of the Research-based Manufacturers in Bulgaria

Assoc. Prof. Dr. Tatyana Benisheva-Dimitrova, MDRA,

Faculty of Public Health, Medical University - Sofia

Truus Janse-de Hoog

Medicines Evaluation Board, The Netherlands,
Chair of the CMD(h)

Dr. Susanne Keitel

Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), France

Assoc. Prof. Dr. Dobri Konstantinov

Bulgarian representative in the Paediatric Committee (PDCO)

Mag. Pharm. Rozalina Kulaksazova

Head of Division Medicinal Information and International relations, Department Pharmacovigilance and Medicinal Information, BDA,

Bulgarian representative in the working group on quality review of documents (QRD)

Prof. Dr. Johannes Löwer

President of the Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines, Germany

Acting Director of the Federal Institute for Drugs and Medical Devices (BfArM), Germany

Prof. Guenka Petrova, DSc

Vice-rector of the Medical University - Sofia

Prof. Dr. Dimiter Terziivanov

University Hospital, "St. Ivan Rilski", Sofia
Head of Clinic of Clinical Pharmacology and Pharmacokinetics, Bulgarian CHMP member

Svetlana Zaharieva

Head of Division Quality Assessment, Department Marketing Authorisation of Medicinal Products, BDA,
Bulgarian representative in the Quality Working Party

N.N.

Association of Bulgarian Pharmaceutical Manufacturers

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Time table

> 8.45 a.m.

Opening address

- from the Ministry of Health –
Minister of Health, Eugeni Jelev
- from the Medical University –
Rector, Prof. Vanyo Mitev,
Dean, Prof. Nikolai Lambov, Faculty of Pharmacy
Dean, Prof. Tzecomir Vodenicharov, Faculty of Public Health,
- from the Bulgarian Drug Agency
Executive Director, Dr. Emil Hristov

Session 1:

Marketing authorisation procedures two years after the accession – experiences of 2008

Chair: Dr. Daniel Brasseur

Co-Chair: Prof. Dr. Dimiter Terziivanov

> 9.15 a.m.

- MA procedures two years after accession
Tzvetomir Deliyiski

> 9.45 a.m.

- The network of The Heads of Medicines Agencies after EU enlargement
Marketing authorisation in the enlarged EU,
new responsibilities within the CHMP in the enlarged EU
Prof. Dr. Johannes Löwer

> 10.30 a.m.

- The MRP/DCP experience in the EU
Truus Janse-de Hoog

11.15 - 11.30 a.m. coffee break

Session 2:

Patient information for medicinal products in the EU

Chair: Truus Janse-de Hoog

Co-Chair: Assoc. Prof. Dr. Ivanka Atanasova

> 11.30 a.m.

- The package leaflet – regulatory update
Truus Janse-de Hoog
User testing; Braille requirements

> 12.00 a.m.

- QRD templates – implementation in Bulgaria
Mag. Pharm. Rozalina Kulaksazova

> 12.30 a.m.

- Additional requirements for marketing authorisations in the EU
Dr. Borislav Borisov
User testing; environmental risk assessment

1.00 – 2.00 p.m. lunch

Session 3:

Medicines for children in the EU

Chair: Dr. Susanne Keitel,

Co-Chair: Assoc. Prof. Dr. Dobri Konstantinov

> 2.00 p.m.

- Experience with the new paediatric legislation
Prof. Dr. Daniel Brasseur

Development of medicinal products for paediatric use – a one-year experience with the PDCO

> 2.45 p.m.

- Medicines for children in the EU – the Bulgarian point of view

Assoc. Prof. Dr. Dobri Konstantinov

> 3.15 p.m.

- Summary of sessions 1 - 3: Challenges for applicants/ marketing authorisation holders

Prof. Guenka Petrova; Assoc. DSc.;

Assoc. Prof. Dr. Tatyana Benisheva-Dimitrova, MDRA

3.45 p.m. coffee break

Session 4:

Variations in the EU

Chair, Prof. Guenka Petrova, DSc.

Co-Chair: Deyan Denev

> 4.00 p.m.

- The new EU variation regulation
Dr. Susanne Keitel

> 4.30 p.m.

- The industrial point of view

N.N., Association of Bulgarian Pharmaceutical Manufacturers

> 5.15 p.m.

- Quality-related variations
Svetlana Zaharieva

> 5.45 p.m.

- Discussion, closing remarks

> 6.00 p.m.

- End of conference

Registration

registration@forum-institut.com or

Fax +49 6221 500-555

Registration Form

- Yes, I attend the conference
"Current Regulatory Challenges Regarding Pharmaceuticals"
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I agree, that this information is transmitted to me via E-Mail.

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How to Register

Information:

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Conference-No. 08 11 900 I

Date/Venue:

Friday, 28 November 2008, 8.45 am – 6.00 pm
University Hospital St.Ekaterina
Hall Maxima, Penzo Slaveikov Str. 52,
Sofia, Bulgaria
<http://www.uhsek.com>

Fee:

€ 150,-. The fee includes course documentation as well as
mid-session refreshments and lunch.

Hotel Accommodation:

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Information



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