



Bulgarian Association for Drug Information (BADI)

June 06, 2024 | Pharmaceutical Legislation – Program

ANNUAL CONFERENCE



Venue: University Hospital "St. Ekaterina" | Aula "Prof. Dr. Alexandar Chirkov", Sofia
Address: 52A Pencho Slaveikov blvd Sofia, Bulgaria



Working language: English/ Format: in person

- **New European
Pharmaceutical Legislation**
- **CP, DP, MRP Worksharing**
- **CTIS**
- **MDR**
- **EU-CTR**
- **IDMP**
- **EU Act AL**
- **UNICOM**

with

Prof. Tatyana Benisheva, DSci
(Medical University – Sofia)

Margarita Strokova, MD
(Pharmalex)

Prof. Dr. Barbara Sickmueller
(BPI Advisor)

Dr. Christa Wirthumer-Hoche
*(ex EMA Management Board,
AGES Agency)*

Dr. Daniela Cherneva
(Medochemie Ltd.)

Radoslava Naydenova – Tunel
(Pharmalex)

Hristina Tarpomanova
(BDA)

Prof. Dr. Folker Spitzenberger
(Technische Hochschule Luebeck)

Ekaterina Genova, MD
(RISE advice Ltd.)

Dr. Birka Lehmann
(IFAPP Member)

16 Hubcha Str., Office 2, Krasno Selo, 1618 Sofia, Bulgaria
Tel.: +359 2 955 85 86; Mobile: +359 889 919 655;
e-mail: office@badibg.org; <http://badibg.org/>



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The Program on June 06th 2024

- 08:15 - 08:45 AM** **Registration & Welcome coffee**
Main moderators: Prof. Tatyana Benisheva, DSci (Medical University – Sofia)
- 08:45 - 09:15 AM** **Welcome and introduction to sessions.**
Welcome speeches
- *Prof. Dobriana Sidjimova, MU – Sofia*
Moderation - Prof. Tatyana Benisheva, Margarita Strokova, MD (Pharmalex)
- 09:15 - 10:00 AM** **New European Pharmaceutical Legislation – Proposed changes by the EU - Parliament.**
- *Prof. Dr. Barbara Sickmueller (BPI Advisor)*
- 10:00 - 10:45 AM** **New European Pharmaceutical Legislation - Focus on Drug Shortages, including Orphans & Paediatrics.**
- *Dr. Christa Wirthumer-Hoche (ex EMA Management Board, AGES Agency)*
- 10:45 - 11:00 AM** **Discussion**
- 11:00 – 11:30 AM** **Coffee break**
- 11:30 – 12:15 AM** *Moderation – Dr. Daniela Cherneva (Medochemie Ltd.) and Dr. Christa Wirthumer Hoche (ex EMA Management Board, AGES Agency)*
CP, MRP, DP. Worksharing–Variations; Legislative background and challenges
- *Radoslava Naydenova – Tunel (Pharmalex)*
- 12:15 - 12:45 PM** **The UNICOM project – highlights from the final conference.**
Brussels 25- 26.04.2024. Implementation of the ISO suite of IDMP standards in EU Member States drug databases – facilitating safer identification of medicines, improving patient safety and supporting better healthcare for all.
- *Hristina Tarpomanova (BDA)*



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12:45 - 13:30 PM ***Lunch break***

13:30 -14:15 PM *Moderation - Prof. Dr. Barbara Sickmueller (BPI Advisor) and Prof. Tatyana Benisheva (Medical University – Sofia)*

Overview on the new EU AI Act and regulatory consequences for healthcare products

- *Prof. Dr. Folker Spitzenberger (Technische Hochschule Luebeck)*

14:15 – 15.00 PM **Challenges of new MDR for the stakeholders**

- *Ekaterina Genova, MD (RISE advice Ltd.)*

15:00 - 16:00 PM **EU-CTR - transition period;**

New approaches e.g. decentralized clinical trials; CTIS-Transitional process

- *Dr. Birka Lehmann (IFAPP Member)*

EU-CTR – Clinical Trials Information System; Comments

- *Prof. Tatyana Benisheva (Medical University – Sofia)*

16.00 - 16:15 PM ***Discussion & Closing speech***