



# Bulgarian Association for Drug Information (BADI)

## DRUG REGULATORY AFFAIRS - update | Training Course | 3 modules

PROGRAM MODULE 2 - 03.11.2023

Round Table Discussion - Hot Regulatory Issues | In person event

Venue: Forum Hotel Sofia, 41 Tsar Boris III Blvd./on the corner with "Sofiiski geroi" str.



**8.30 - 09.00**                      **Registration**

**Topics / Welcome & Opening and Moderator / Assos. Prof. Lyubina Todorova (BDA) & Prof. Tatyana Benisheva, MU-Sofia, President of BADI**

**Session 1**                      **Discuss the new upcoming pharmaceutical legislation**

**09.00 - 10.30**

**1. Subject Matter, Scope And Definitions;**

Prof. Tatyana Benisheva, MU-Sofia, President of BADI, Ekaterina Genova, MD

**2. General Provisions And Rules On Applications;**

Prof. Tatyana Benisheva, MU-Sofia, President of BADI

**3. Incentives For The Development Of 'Priority Antimicrobials';**

Margarita Strokova, MD

**4. Post-Marketing Authorisation Measures.**

Margarita Strokova, MD, Romyana Sharenkova

**10.30 - 11.00**

**Coffee break**

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**11.00 - 12.30**

**5. Pre-Authorisation Regulatory Support;**

Radoslava Naydenova – Tunel, Romyana Sharenkova

**6. Orphan Medicinal Products;**

Delinna Gigova, Prof. Tatyana Benisheva, MU-Sofia, President of BADI

**7. Paediatric Medicinal Products;**

Prof. Tatyana Benisheva, MU-Sofia, President of BADI, Margarita Strokova, MD

**8. Pharmacovigilance;**

Margarita Strokova, MD

**12.30 - 14.00**

**Lunch break**

**Session 2**

**14.00 – 15:00**

**9. Regulatory Sandbox;**

Radoslava Naydenova – Tunel, Ekaterina Genova, MD

**10. Availability and Security of Supply of Medicinal Products.**

Radoslava Naydenova – Tunel, Ekaterina Genova, MD

Prof. Tatyana Benisheva, MU-Sofia, President of BADI

**Discussion**

**Contacts:**

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