Bulgarian Association for Drug Information (BADI)

11.45 - 12.20

Registration - Networking experience (coffee and gifts)

12.20 - 12.30

Topics / Welcome & Opening and Moderator

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

Session 1

12.30 - 13.15

Audits and inspections of the PV/QA systems
Teodora Chachevska - Woerwag Pharma Bulgaria EOOD.

13.15 - 14.00

Pharmacovigilance - Update. Signal Management Discussion
Margarita Strokova, MD - PharmaLex Bulgaria

14.00 - 14.30 Coffee break

Session 2

14.30 - 15.00

Attitude of medical doctors to adverse drug reactions reporting in Bulgaria.
Dr. Vili Topalova - AV Consult Bulgaria

15.00 - 15.45

Change of the prescription status
Lyubina Todorova MD, Assoc. Prof. - BDA

15.45 - 16.00 Discussion

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Prof. Tatyana Benisheva - Dimitrova, MD DSc., President of BADI is a medical doctor and professor in the Faculty of Public Health at Medical University, Sofia, Bulgaria. After receiving an EC-CADREAC scholarship she completed master's degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn and later in 2010 a Master degree in "Public Health" at the Medical University of Sofia, Bulgaria.
She was a Director of the "Drug Policy" Department at the Ministry of Health (2000-2005) and has over 10 years of experience at the Bulgarian Drug Agency (BDA). As the first president of the National Council on Prices and Reimbursement of Medicinal Products 2013-2014 (pricing and reimbursement competent authority in Bulgaria) she started an EU-project-OPAC for establishing of electronic database of medicinal product.
As a managing director of consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) she developed drug regulatory activities at the global regulatory database IDRAC of the Thompson Reuters (2006-2012) In 2010 she established a NGO - Bulgarian Association for Drug Information (www.badibg.org) for postgraduate education in the field of medicine and medical devices. Prof. Benisheva was a member of the German society DGRA and Board member of the EAMEA at DIA, and Advisory council at the DIA in Europe. and board member of IFFAP. Since 2023 she is a member of the Ethical Committee for clinical trials at the Ministry of Health in Bulgaria. Her over 25 years of experience in drug regulatory affairs (life cycle management and market access of medicinal product) is complemented by more than 100 publications in the regulatory science field of medicines

Teodora Chachevska - Head of Regulatory Affairs, Quality Assurance and Pharmacovigilance inWoerwag Pharma Bulgaria EOOD.I havemore than 13 years of experiencein the field of Regulatory Affairs. I am experienced in the maintenance and life-cycle of the medicinal products, food supplementsand cosmeticsworldwidewith emphasis on Europe, non-EU countries, CIS,etc.My field of expertise is also extended topharmacovigilance, quality assurance(QA), including wholesale distributionof medicinal productsandfood supplements.The experience in the Regulatory affairs field started for me in 2007at SopharmaADas Expert Regulatory coordination (CMC and administrative) andwas promoted to Manager Regulatory Coordinationthe same year.I joinedWoerwag Pharma GmbH & Co. KG, branch officein 2012as Regulatory Affairs Manager, where later widened my skills and expertise in the field of Pharmacovigilanceand QA. Ideveloped myself by partcipating in different international projects within the Pharmaceutical industry.I have a Master's degree in Chemistry and chemical technologies(2001) fromPlovdiv Universityang hold aSpecialization of Ecologyand Pedagogy.After thatI completeda Master's degree in FinanceatVeliko Tarnovo University (2008)and have a post-graduation Certificate in Pharmacy for non-pharmacists from Medical University Sofia(2009).

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Margarita Strokova, MD has master's degree in Medicine from Medical University, Sofia and Master of Business Administration from New Bulgarian University, Sofia. Joined Pharma Industry in 1997 and has extensive experience in pharmaceutical marketing, scientific communication, Medical Governance and Pharmacovigilance (for products both under clinical trials and marketed). Worked for over 13 years as local person responsible for Pharmacovigilance in GSK Bulgaria and has 3 years experience as Local Country Medical Head. In Feb 2021 joined IQVIA as Associate Manager, Safety Operations Team.

Dr. Vili Topalova, an MD from Bulgaria, specializes in pharmacovigilance and regulatory affairs, currently serving as Medical Director and EU Qualified Person for Pharmacovigilance (QPPV) at AV Consult Pharm since 2018. She has extensive experience managing pharmacovigilance systems, adverse drug reaction reporting, and ensuring compliance with EU regulations. Her work also covers medical device vigilance, cosmetovigilance, and regulatory inspections. In previous roles at Pharmalex Bulgaria and the Bulgarian Drug Agency, she led clinical and non-clinical assessment divisions and provided strategic guidance on pricing and reimbursement of medicinal products. Dr. Topalova is currently pursuing a PhD in drug safety management and is fluent in Bulgarian, Russian, and English.

Lyubina Todorova, MD, PhD in pharmacology
Head of Department for Marketing Authorisation of Medicinal Products at Bulgarian Drug Agency since 2010.
Started working at BDA since 2001 and took several different positions including clinical assessor and Head of Department for Control of Blood transfusion system.
Since 2017 has been working as a member of Committee for Orphan Medicinal Products.