Bulgarian Association for Drug Information (BADI)

MODULE 2 - 22.11.2024 - Round table Discussion - Hot Regulatory Issues | Online

Topics / Welcome & Opening and Moderator / Prof. Tatyana Benisheva, MU-Sofia, President of BADI and Prof. Dobriyana Sidgimova, Margarita Strokova Phd and Daniela cherneva (Board Members)

13.00 - 13.45 Overview on the new EU Artificial Intelligence (AI) Act andregulatory consequences for healthcare products
Prof. Dr. sc. hum. Folker Spitzenberger

13.45 - 14.30 Regulatory considerations in the development of new drugs'. Would that work? Discussion
Anne Louise Kirkegaard

14.30 - 15.15 Break

15.15 - 16.00 Pharmacovigillance – Update
Dr. Maria Popova, PhD - BDA

16.00 - 16.30 Pharmacovigilance of Biosimilars
Valentin Kopanarov, PhD, MPharm

16.30 - 17.15 Regulatory Frame of Nonregistered Products in Bulgaria Discussion
Rozalina Kulaksazova - BDA

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.

Prof. Dobriana Sidjimova, PhD graduated Sofia University in 1998 with subject Russian Philology with a Master`s degree. In 2001 she defended Master`s degree in Public Relations at the Sofia University. In 2003 she obtained Master`s degree in Health management at the Medical University of Sofia in the Faculty of Public Health. In 2005 she defended a PhD thesis. Her professional experience started as a State Expert in the PR Department of the National Health Insurance Fund. In 2006 she became an Assistant Professor at the Faculty of Public Health in the Medical University of Sofia. Since 2008 she is an Associate Professor in The Faculty Of Public Health, Medical University, Sofia. In 2014 obtain "Health Economics" speciality. Till 14th of May 2015 she was Chairman of Board of Directors of BADI. In 2016 she became Professor at the Faculty of Public Health, MU-Sofia. She is Chief Editor of Health Policy and Management Journal. Prof. D. Sidjimova is Head of Department of Medical Pedagogy, Language and Sport in Medical University of Sofia

Prof. Dr. sc. hum. Folker Spitzenberger, Dipl.-Chem. M.D.R.A. Jahrgang 1970, ist Diplom-Chemiker und promovierte am Institut für Pharmakologie der Universität Heidelberg im Bereich der Molekularbiologie zum Dr. sc. hum. Nach Postdoc-Tätigkeiten an der Medizinischen Fakultät der Universität Dresden und an der Yale University war er von 2002 - 2016 hauptamtlich im Bereich der Begutachtung und Implementierung von Qualitätssicherungssystemen im Bereich Medizinprodukte bei der ZLG, am RKI und bei der Deutschen Akkreditierungsstelle DAkkS tätig. Mit der zusätzlichen Qualifikation als Master of Drug Regulatory Affairs berät er internationale Organisationen wie die WHO und die EU im Bereich QM/QS und Regulatory Affairs. Seit 2016 vertritt Folker Spitzenberger als Professor das Fachgebiet Regulatory Affairs für Medizinprodukte an der Technischen Hochschule Lübeck. Seit 2021 leitet er im Rahmen einer Kooperation zwischen der TH Lübeck und der Fraunhofer-Gesellschaft den Zentralbereich Regulatory Affairs am Fraunhofer IMTE in Lübeck. Folker Spitzenberger, born in 1970, is a graduate chemist and received his PhD in molecular biology from the Institute of Pharmacology at Heidelberg University. After postdoctoral work at the Medical Faculty of the University of Dresden and at Yale University (CT, USA), he worked from 2002 to 2016 in the area of assessment and implementation of quality assurance systems in the field of medical devices at the ZLG, the RKI and the German accreditation body DAkkS. With the additional qualification as a Master of Drug Regulatory Affairs, he advises international organizations such as the WHO and the EU in the field of QM/QA and Regulatory Affairs. In 2016, Folker Spitzenberger joined the University of Applied Sciences Lübeck (TH Lübeck) as Professor for Regulatory Affairs for medical devices. Since 2021 he leads the Regulatory Affairs department at Fraunhofer IMTE in Lübeck as part of a cooperation between the TH Lübeck and the Fraunhofer-Gesellschaft.

Anne-Louise Kirkegaard is a seasoned Regulatory Affairs expert with over 25 years of experience in the life sciences industry. Currently, she serves as the Director of Regulatory Affairs and Principal Pharma Consultant at Pharma IT in Copenhagen. Throughout her career, she has held various leadership roles, including Director of Regulatory Affairs at FluoGuide A/S and VP of Regulatory Affairs at Cyxone AB. Her expertise encompasses regulatory strategic and operational support for startup biotech companies, where she has successfully managed teams and led projects that have advanced drug development and market access. Anne-Louise holds a Master of Drug Regulatory Affairs from the University of Bonn and an

MSc in Pharmacy from the Royal Danish School of Pharmacy. Her academic background is complemented by her extensive practical experience, including significant positions at Novozymes, Galenica AB, and LEO Pharma A/S. Her work has focused on regulatory compliance and pharmacovigilance, ensuring that companies navigate complex regulatory landscapes effectively to bring innovative therapies to market.

Maria Popova, MD, PhD / Dr. Maria Popova is head of "Pharmacovigilance and Clinical trials" Department in the Bulgarian Drug Agency. Maria Popova is medical doctor graduated Medical Academy Sofia. She has specialty on pharmacology and theses: "Drug utilization and pharmacoeconomics of the national pattern of prescribing antibiotics". She was member of the first and second National Positive Medicine List's Committee. Dr Popova has additional experience in the field advertising of medicines and is current vice chair of the Expert Council on Medicine's Advertising. Representative of Bulgaria within the CHMP Pharmacovigilance Working Party since 2005. Representative of Bulgaria in the Pharmacovigilance Risk Assessment Committee (PRAC) since July 2012.
In July 2014 is appointed as chair of the new national Committee for Risk Assessment in Pharmacovigilance to the executive director of the Bulgarian Drug Agency. The last three years Dr Popova is assessors of PSURs when Bulgaria is appointed as Lead Member State in PSUSA procedures.

Valentin Kopanarov, PhD, MPharm
Valentin Kopanarov holds a Master of Science in Pharmacy from the Medical University in Sofia, Bulgaria. Building on a three-year foundation as a pharmacist, he has more than eight years of pharmacovigilance experience, both with clinical trials and with marketed products. His therapeutic expertise spans nervous system, digestive system, dermatology, hematology, infectious/parasitic diseases, oncology and rare diseases. Valentin joined a leading global contract research organization in 2012 as a Drug Safety Specialist. Through a series of increased levels of responsibility including the roles of Senior Safety Specialist, Principal Safety Specialist, Manager Pharmacovigilance, Senior Manager Pharmacovigilance, Valentin assumed his current role of Associate Director Pharmacovigilance in Aug 2018.

Rosalina Kulaksazova graduated from the Faculty of Pharmacy, Medical Academy in Sofia with a Master thesis. She obtained a speciality in Clinical Pharmacy as a post-graduate study.

In 1987 after a competition, Rozalina Kulaksazova joint the Pharmaceutical Dosage Forms Section at the Chemical Pharmaceutical Research Institute in Sofia as a research associate and worked in the field of parenteral dosage forms. In 1999 Rozalina Kulaksazova joint the Bulgarian Drug Agency where currently she holds the position of Director of Drug Information and Non-interventional Studies Department. Her main responsibilities are focused on product information of centrally authorised medicinal products and related issues, and evaluation of post authorisation studies. Currently Rozalina Kulaksazova is a member of the Committee for Advanced Therapies (CAT) at the European Medicines Agency. As a member of CAT she has been involved in the ATMPs classification procedure. Rozalina Kulaksazova has been invited to deliver presentations in her field at different international regulatory and professional forums – in London, Berlin, Shanghai, etc. Her professional interests also include regulatory affairs in the fiels of medicinal products, use of real world data in decision making, advanced therapy medicinal products, etc.