



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PROGRAM

DRUG REGULATORY AFFAIRS e - CONGRESS | MEET THE REGULATORS | 10 YEARS BADI

Date: June 5th, 2020

Venue: Online Meeting | Via Cysco Webex

Timing: 8:45 AM - 3:30 PM | Consider (UTC+02:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna

BG Timing: 9:45 AM - 4:30 PM |

Moderators Sessions I - II: Prof. Tatyana Benisheva, President of BADI | Prof. Dr. Barbara Sickmüller | Prof. Burkhard Sträter, Sträter Lawyers | Dr. Christa Wirthumer-Hoche | Daniela Cherneva, Member of Management Board, BADI |

Moderators Session III: Prof. Tatyana Benisheva, Medical University - Sofia, President of BADI | Lyubina Todorova, Department "Marketing Authorisation of Medicinal Products", BDA | Todor Darakchiev, Head of Division "Medical Devices" in Department "Market supervision and Inspections", BDA | Prof. Guenka Petrova, Head of the Department of Organization and Economics of Pharmacy, Medical University - Sofia |

Working language: English		
TIME	TOPICS	SPEAKERS
08:45 - 9:00 AM	Welcome Speeches	
	Welcome and Opening of the Drug Regulatory Affairs e - Congress and introduction to Sessions	Prof. Tatyana Benisheva, MU - Sofia, President of Bulgarian Association for Drug Information
	Welcome Speeches	Dr. Daniela Daritkova, Chairperson, Healthcare Committee, National Assembly of the Republic of Bulgaria; Bogdan Kirilov, MScPharm, Executive Director, BDA; Dobrijana Sidgimova - Vice President of Bulgarian Association for Drug Information; Prof. Dr. Barbara Sickmueller - Senior Scientific Advisor, Bundesverband der Pharmazeutischen Industrie e. V (BPI), President of German Association for Drug Information DGRA e.V.;
9:00 - 10:45 AM	SESSION I (25-30 min. for every presentation, incl. 5 min. discussion)	
9:00 - 9:30 AM	Regulatory update - Challenges at the Bulgarian Drug Agency	Bogdan Kirilov, Executive Director of Bulgarian Drug Agency (BDA)
9:30 - 10:00 AM	EMA Relocation Challenges and EMA Future Strategies	Prof. Guido Rasi, Executive Director of European Medical Agency (EMA)
10:00 - 10:30 AM	The quest for Covid-19 vaccines and therapeutic biomedicines: the regulatory approach	Prof. Klaus Cichutek, PhD, President of Paul Ehrlich Institute (PEI)
10:30 - 10:45 AM	Discussion	
10:45 - 11:00 AM	Break	
11:00 AM - 1:00 PM	SESSION II (25 min. for every presentation, incl. 5 min. discussion)	
11:00 - 11:30 AM	Drug Shortages - is COVID 19 worsening the situation	Dr. Christa Wirthumer-Hoche, Chair of Management Board of European Medicines Agency (EMA); Head of the Austrian Medicines and Medical Device Agency at AGES - Austrian Agency for Health & Food Safety (AGES)
11:30 - 12:00 AM	PhV - Update and Challenges	Prof. Dr. Barbara Sickmüller, President of German Association for Drug Information (DGRA) e.V.
12:00 - 12:30 PM	The EU System of Regulatory data protection	Prof. Burkhard Sträter Sträter Lawyers, Health legislation in Germany and the European Union
12:30 - 1:00 PM	Clinical trials regulation - update	Dr. Birka Lehmann, Senior Expert Drug Regulatory Affairs, Lehrbeauftragte der Universität Bonn
Discussions after each presentation		
1:00 - 1:15 PM	Lunch Break	
1:15 - 3:15 PM	SESSION III (25 min. for every presentation, incl. 5 min. discussion)	
1:15 - 1:45 PM	EDQM's contributions for the protection of public health in the COVID-19 pandemic	Susanne Keitel, Director of European Directorate for the Quality of Medicines (EDQM)
1:45 - 2:15 PM	The UNICOM Project - benefits from ISO IDMP/SPOR for health care professionals and patients	Peter Bachman, Federal Institute for Drug and Medical Devices (BfARM)
2:15 - 2:45 PM	The future of HTA in Europe	Sophie Werkö, Manager of International Relations at Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU)
2:45 - 3:15 PM	Aspects of the new EU regulatory framework for medical devices and IVD - Lessons learned by the COVID-19 pandemic	Prof. Dr. Folker Spitzenberger Centre for Regulatory Affairs in Biomedical Sciences - CRABS Technische Hochschule Lübeck University of Applied Sciences
3:15 - 3:30 PM	Closing Remarks	Prof. Valentina Petkova, Vice-Rector for Science and Accreditation of MU-Sofia