BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PRELIMINARY PROGRAM

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

Date: June 5, 2020

Venue: Online Meeting | Via Cysco Webbex

Timing: 8:45 am - 3:30 pm CET (Central European Time)

Moderators 1-2 Sessions: Prof. Tatyana Benisheva, Medical University - Sofia, President of BADI, Prof. Dr. Barbara Sickmüller, Prof. Burkhard Sträter, Sträter Lawyers, Dr. Christa Wirthumer-Hoche;

Working language: English		
TIME	**TOPICS**	**SPEAKERS**
08:45 - 9:00 CET	**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 CET	**SESSION 1 (25-30 min. for every presentation + 5-10 min. for Discussion**	
	Regulatory update - Challenges at the Bulgarian Drug Agency	Bogdan Kirilov, Executive Director of Bulgarian Drug Agency (BDA)
	EMA Relocation Challenges and EMA Future Strategies	Prof. Guido Rasi, Executive Director of European Medical Agency (EMA)
	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	Discussion	
10:45 - 11:00 CET	**Break (15 min.)**	
11:00 - 13:00 CET	**SESSION 2 (25 min. for every presentation + 5-10 min. for Discussion)**	
11:00 -11:30	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	PhV - Update and Challenges	Prof. Dr. Barbara Sickmüller, President of German Association for Drug Information (DGRA) e.V.
12:00 - 12:30	The EU System of Regulatory data protection	Prof. Burkhard Sträter, Sträter Lawyers, Health legislation in Germany and the European Union
12:30 -13:00	Clinical trials regulation - update	Dr. Birka Lehmann, Senior Expert Drug Regulatory Affiars, Lehrbeauftragte der Universität Bonn
13:00 - 13:15 CET	**Lunch Break (15 min.)**	
13:15 - 15:15 CET	**SESSION 3 (25 min. of every presentation + 5-10 min. for Discussion)**	
13:15 - 13:45	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)
13:45 - 14:15	The UNICOM Project - benefits from ISO IDMP/SPOR for health care professionals and patients	Peter Bachman, Federal Institute for Drug and Medical Devices (BfARM)
14:45 - 15:15	The future of HTA in Europe	Sophie Werkö, Manager of International Relations at Swedish Agency for Health Technology Assessment and Assessment od Social Serveces (SBU)
14:15 - 14:45	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
15:15 - 15:30	Closing Remarks	
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