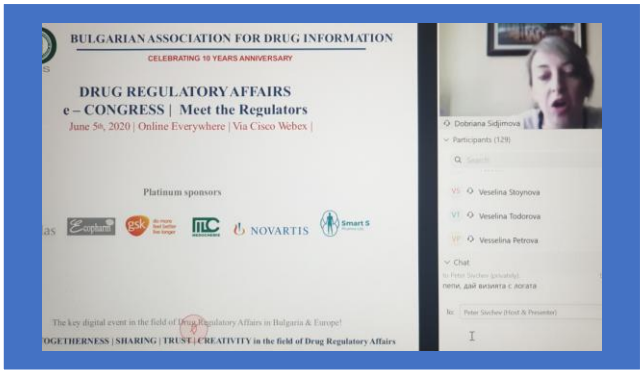
DRUG REGULATORY AFFAIRS e-CONGRESS | MEET THE REGULATORS

10th Anniversary

of Bulgarian Association of Drug information (BADI)

5th of June 2020, Sofia, Bulgaria

On 05 June 2020 BADI, a new IFAPP National Member Association in Bulgaria, held a webinar on the occasion of its 10th anniversary with the title “Meet the Regulators”. Originally the event had been planned to be a face-to-face conference but COVID-19 mandated a different approach.



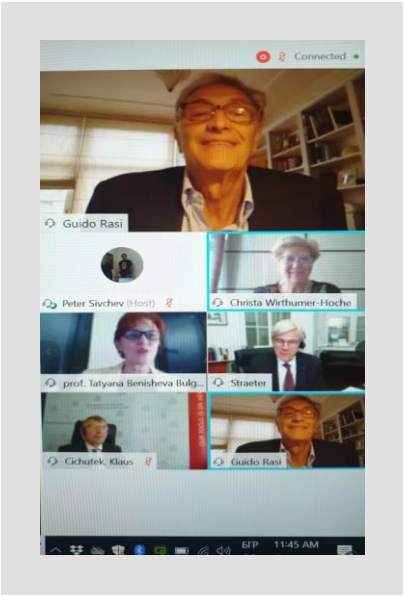
Following an introduction of **Professor Tatyana Benisheva-Dimitrova**, BADI’s President, **Dr Dobriana Sidjimora**, BADI’s Vicepresident, gave a welcome address,also from the Bulgarian Parliament Health Comission

Almost 140 professionals attended the 7-hour webinar. Moderator was Dr Burkhard **Straeter from Germany** introducing a variety of very eminent speakers who talked about very important projects and regulatory updates.

Professor Tatyana Benisheva and four Bulgarian moderators as well as Dr Lybina Todorova, Director at the Marketing Authorisation Department of the Bulgarian Drug Agency and Bulgarian Member of the Committee for Orphan Medicinal Products at the EMA.

Mag Pharm. Bogdan Kirilov, Executive Director of the Bulgarian Drug Agency, talked about the history of the agency and its challenges, in particular since Bulgaria became a member of the European Union in 2007 but also addressed the main learnings in 2020 with regard to COVID-19. His presentation was followed by a talk by..

Professor Guido Rasi, the Executive Director of the European Medicines Agency, EMA, who addressed emerging business models with regard to Health Technology Assessment and payers and the profound transformation of the healthcare landscape and the regulators' changing role to become enablers between science and healthcare systems.

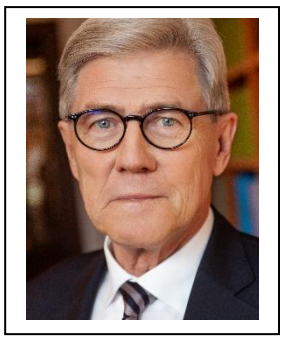


Professor Rasi presented the Strategy of EMA for the next 5 years period where the innovation, digital tools and digital analytics, sustainability of the network and operational excellence , are among them.

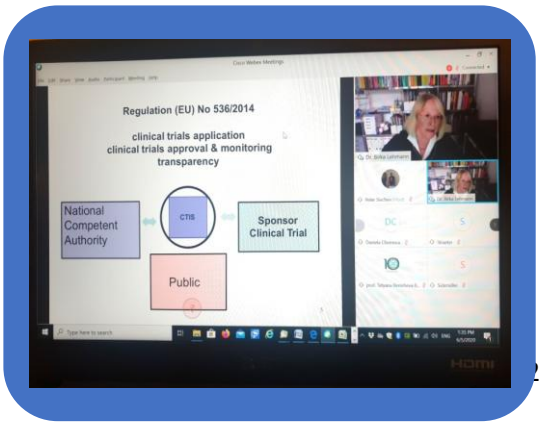
Then **Professor Klaus Cichutek**, President of the Paul Ehrlich Institute (PEI) in Germany talked about the quest for COVID-19 vaccines and therapeutic biomedicines, RNA and DNA vaccines, recombinant protein vaccines as well as vectored vaccines, new vaccine platforms used in candidate COVID-19 vaccines. He also addressed convalescent plasma therapies and "repurposing" as well as symptomatic anti-infectious treatments in COVID-19. The PEI is not only dealing with regulatory procedures but is strongly involved in scientific projects of drug development which is an amazing achievement for a competent authority.

Dr **Christa Wirthumer-Hoche**, Chair of EMA's Management Board and Head of the Austrian Medicines & Medical Devices Agency, spoke about drug shortages as a global problem rising in Europe, their economic causes and corporate reasons like market changes, mergers, production and supply chain problems and the lower manufacturing costs in China and India but also the inherent Quality problems. There is now a joint HMA/EMA Task Force on the availability of authorised medicines (TF-AAM) established in 2016, also now because of the global impact of COVID-19. Production sites will be brought back to Europe in upcoming years.

Professor Barbara Sickmüller, formerly with the German Pharmaceutical Industry Association, BPI, and President of the German Society of Regulatory Affairs, DGRA, followed with an update on pharmacovigilance (PhV) and its challenges with a new legislation since 2012 and one single database, EudraVigilance. She also talked about ICSRs, individual case safety reports, and EVDAS, the EudraVigilance Data Analysis System with new PhV signal detection requirements. Marketing Authorisation Holders have had access since 2017.



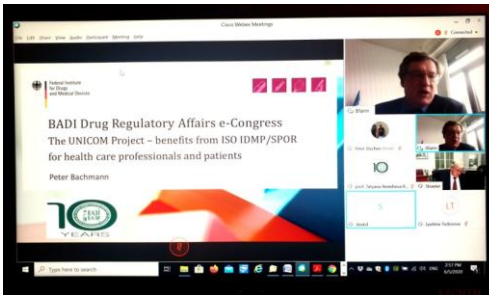
Dr Burkhart Straeter then discussed the EU system of Regulatory Data Protection. He presented the topic of Intellectual Property in the field of medicines with the focus on a Global Marketing Authorisation and Protection Certificate.



Dr Straeter's presentation was followed by a talk by **Dr Birka Lehmann**, formerly Head of the Executive Department EU and International Affairs of the Federal Institute for Drugs and Medical Devices, BfArM, who presented the new Clinical Trial

Regulation 536/2014 and the Clinical Trials Information System CTIS as well as the Clinical Trials Facilitation and Coordination Group, the voluntary harmonisation procedure (VHP) plus participation, EudraLex Vol 10 clinical trial guidelines, and the Guideline for GCP E6 (R2)**Dr Susanne Keitel**, Exec Director at the European Directorate for the Quality of Medicines & HealthCare, EDQM, then talked about EDQM's contributions for the protection of public health in the CoVID-19 pandemic and the role of EDQM, being a member of the Council of Europe (47 EU and non-EU members plus observers.

Dr Peter Bachmann, Deputy-Head European Union and International Affairs at the German Federal Institute for drugs and Medical Devices (BfArM) and Chair of the Coordination Group for Mutual Recognition and Decentralised Procedures (human) and, amongst other functions, also a member of the Scientific Coordination Board of the EMA, presented the UNICOM project. UNICOM is about improved patient safety and better healthcare for all. This European Commission supported Innovation Action focuses on implementing the International Organization for Standardization (ISO) suite of **IDMP** (**Id**entification of **M**edicinal and pharmaceutical **P**roducts) standards. Work will involve further development, testing, implementation and diffusion of these standards for regulatory purposes, global PhV, advancing cross-border digital health services, particularly ePrescription.



Dr Sophie Werkoe, Manager International Relations & Patient Engagement at the Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU, and Chair of the Board of the International Network of Agencies for HTA, INAHTA, founded in 1993, explained this network and the global HTA bodies, the EU legislation proposed for HTA after 2020, the trust and capacity building between HTA bodies as well as their joint tools and joint works.

The last presentation was given by Professor Folker Spitzenberger from the Technische Hochschule Luebeck in Germany who spoke about the EU regulatory framework for medical devices and IVDs (in-vitro diagnostics) and the lessons learned from the COVID-19 pandemic and the postponement of Regulation (EU)2017/745 from May 2020 to May 2021 given the unprecedented magnitude of the COVID-19 pandemic and that therefore not all the EU member states could be expected to implement it in time.

The conference was concluded by Valentina Petkova, Member of the Management Board of BADI.

All presentations are available on the website of the organisation www.badibg.org and have open access