DRUG REGULATORY AFFAIRS
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June 05th, 2020 | Online Everywhere | Via Cisco Webex |

SPEAKERS

BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

Professor Guido Rasi began his second term as Executive Director of EMA on 16 November 2015. From November 2014 to mid-November 2015, Professor Guido Rasi served as EMA's Principal Adviser in Charge of Strategy.

From November 2011 to November 2014 he was the Executive Director of the European Medicines Agency and a member of its Management Board in the three years prior to this.

He has been elected Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) from 1st October 2019 for a term of 3 years.

He was Director-General of the Italian Medicines Agency from 2008 to 2011 and member of the Management Board from 2004 and 2008.

He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008.

From 2005 to 2008 he was Director of Research at the Institute of Neurobiology and Molecular Medicine of the National Research Council (CNR) in Rome.

From 1990 to 2005 Professor Rasi worked at the Institute for Experimental Medicine of the National Research Council, Italy.

He had a teaching and research experience at the University of California, Berkeley in 1999.

Professor Rasi holds a degree in medicine and surgery, with specialisations in internal medicine, allergology and clinical immunology, from the University of Rome.

From 1978 to 1990, he worked as a physician in hospital, research and private practice. He is author of more than 100 scientific publications.

Prof. Rasi was born in Padova, Italy and is married with two children.

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Christa Wirthumer-Hoche, Dr. techn., Dipl. Ing.

DI Dr. Christa Wirthumer-Hoche studied biochemistry and graduated at the Technical University, Vienna in 1981, she did her doctoral thesis at the Institute for Medical Physiology, graduating in 1983. After joining the Austrian National Institute for Quality Control of Drugs (1983 – 1998), she was the Head of the Licensing Division for medicinal products, in the Unit for Pharmaceutical Affairs at the Austrian Federal Ministry of Health and Women.

Since foundation of the new Austrian Agency 1 January 2006 her position was Head of the Unit for Marketing Authorisation and Lifecycle Management of Medicinal Products, her current position is Head of the Austrian Medicines and Medical Devices Agency at AGES Austrian Agency for Health &Food Safety.

Since 1994 she has been a member in several European Committees and Working Parties, and she is currently appointed Chair of the EMA-Management Board.

She gives lectures at different universities (Vienna, Bonn, Copenhagen)

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Klaus Cichutek is President of the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany, and extra-ordinary Professor of Biochemistry at the Goethe University Frankfurt/Main.

The Paul-Ehrlich-Institut is a research and science driven Medicines Agency (veterinary and human vaccines, human biomedicines) reporting to the German Federal Ministry of Health and providing regulatory services to the European Medicines Agency EMA, EDQM, WHO and others.

Professional career:

1976 to 1984 studies of and Ph.D. in biochemistry
1985 to 1988 postdoctoral scientist at the Molecular Biology and Virus Laboratory, University of California in Berkeley, U.S.A., on fellowships of the DFG (German Research Foundation) and the Univ. of California
1988 to 1994 head, 'Molecular Biology' Research Group, Paul-Ehrlich-Institut, Langen
1994 to 2011 head, Division of Medical Biotechnology, Paul-Ehrlich-Institut, Langen
1999 to 2009 Vice President, Paul-Ehrlich-Institut, Langen
2009 to today President, Paul-Ehrlich-Institut, Langen

Research interests: Retrovirology and gene therapy (> 150 publications).

Early research on oncogenic Harvey sarcoma virus was followed by a characterisation of the apathogenic infection of African green monkeys with SIVagm and of the development of HIV-1 virus variants from a single biological virus clone in patients. In gene therapy, he generated a variety of retro- and lentiviral vectors and vector pseudotypes and he demonstrated the feasibility of cell targeting *in vitro* and *in vivo*.

Current committee and board memberships (selection):

- European "Heads of Medicines Agencies" (HMA Management Group chair; 02/2014 to 02/2018),
- "WHO Expert Committee on Biological Standardization" (ECBS) (elected chair in 2016-19),
- "WHO Product Development for Vaccines Advisory Committee" (PD-VAC),
- ICMRA member ("International Coalition of Medicines Regulatory Authorities"),
- founding member of the German Center for Infection Research DZIF,
- Loewe Centre for Cell and Gene Therapy Frankfurt/Main,
- Board member of the German Working Group of Departmental Research Institutes (AG Ressortforschung),
- reviewer of research proposals for the Federal Ministry of Education and Research, the German Research Foundation DFG, Fraunhofer, Helmholtz Association and the European Commission.

Bogdan Kirilov

Executive Director of the Bulgarian Drug Agency from August 2018

Deputy Executive Director of the Bulgarian Drug Agency from November 2017 to August 2018.

Master degree in Pharmacy from Faculty of Pharmacy, Medical University, Sofia.

Master degree in Public Health from Faculty of Public Health Medical University, Sofia.

PhD candidate in Medical University, Varna.

Eight years' experience in Pharmaceutical industry in different positions

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Prof. Dr. rer. nat. Barbara Sickmüller is a pharmacist. She studied and obtained her doctorate at the Philipps University in Marburg - Germany (1967-1974).

From 1977 she worked as a scientific executive at the Association of the German Pharmaceutical Industry (BPI) and took over the section "Drug Safety" of BPI in 1979. 1984/1985 she had a sabbatical year in the USA with training into US drug legislation. From 1988 she was appointed as head of the department "Medical affairs" and from 1997 Director of the Medicines and Pharmacy Division of BPI. In 2000 she was appointed as Deputy Director General of BPI.

Since 1987 until 2011 she gave yearly lectures in the department of Pharmacy, University of Marburg, and was appointed honorary Professor of the University of Marburg/Lahn (Januar 2000). In addition she gave lectures for the Master of Drug Regulatory Affairs at the University in Bonn. She had further teaching assignments at the Universities of Frankfurt and Heidelberg on Pharmacovigilance and clinical trials, and has published numerous publications and book contributions in these regulatory areas.

The German Ministry of Health appointed her as Member of the Advisory Committee on prescription of pharmaceutical products, the Commission on Medicines for Children and Adolescents (KAKJ) and member of the Board of Trustees of the Institute for Quality and Efficiency in Health Care (IQWiG) and a member of the Board of Trustees of the German Agency for Health Technology Assessment (HTA) at DIMDI.

She was member of several Working Groups of the Council for International Organizations of Medical Sciences (CIOMS) and the International Conference on the Harmonization of Marketing Authorization Requirements (ICH) in the areas of pharmacovigilance and clinical trials.

Since March 2012 she has retired and is now active as Senior Scientific Advisor for BPI.

In July 2014 she was appointed President of the German Association for Regulatory Affairs (DGRA) and in October 2014 member of the university council of the University of Applied Sciences of Central Hesse (THM) in Gießen.

Dr. Birka Lehmann
Senior Expert Drug Regulatory Affairs

Career
Head of Executive Department EU and International Affairs of the Federal Institute for Drugs and Medical Devices (BfArM) since October 2011 till March 2016.
Study of Human Medicines at the Free University Berlin (MD, PhD) and training at the Kinderklinik Norderney.
My working experience includes 9 years preclinical assessment in the division 'Pharmacology and Toxicology' of Federal Health Office. I served as head of unit 'Decentralised Procedure' (1996-2002) Federal Institute for Drugs and Medical Devices and as deputy head of EU Division (2000-2002) and supported the Committee Human Medicines Products of the European Medicines Agency (EMA) as expert.
From 2002 – 2006 I joined the European Commission, Directorate-General Enterprise and Industry as expert on secondment to in the unit 'Pharmaceuticals' responsible for inter alia Marketing Authorisation and implementation of Clinical Trials Directive.
From September 2006 till October 2011 I was head of the division 3 Marketing Authorisation procedure at the BfArM. Since 2007 I was member of the Paediatric Committee at the European Medicines Agency till end of 2015.
Lecturer:
Friedrich-Wilhelm-University Bonn (Master of Drug Regulatory Affairs) since 1999

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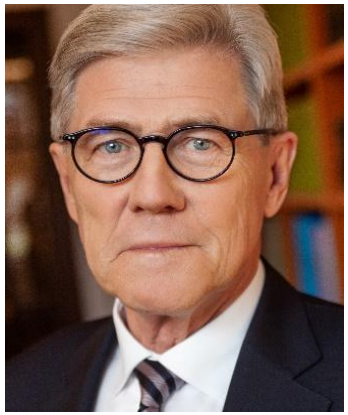

Prof. Burkhard Sträter is born 1950 in Werl (Westphalia).
University: 1969-1974 Study of law in Marburg, Münster and Berlin; 1974 1st state law examinations; 1977 2nd state law examinations.

Professional career:

1977 Judge at the Local Court of Berlin-Tiergarten
- criminal matters -
1978 Legal advisor in the senate administration of justice, Berlin
- public law -
1979 Judge at the Regional Court of Berlin
- civil matters –
1980 Judge at the Administrative Court of Berlin;
1981 Government director; Head of section for Matters of Law and General Policy of the Federal Health Agency;
1985-1997 Lawyer in Aachen, intermittently in Brussels;
since 1997 Lawyer in Bonn;

Teaching activities:

1980-1984 Lecturer at the Administrative Academy of Berlin
-public law –
1981-1985 Practical training of law students - Court of Appeal in Berlin - public law - Since 1985 Advanced training of scientists from the pharmaceutical industry on regulatory, pharmaceutical law and social law issues associated with the development, manufacture, marketing authorization and marketing of medicinal products and medical devices. Advanced and further training of practice-based and hospital physicians on questions of medical and social law and of officinal and hospital pharmacists on questions of medicinal product and pharmacy law.
Corresponding publications in pertinent scientific journals. Since 1999 Lecturer at the University of Bonn. Opinions heard on many occasions as expert in the Health Committee of the German Bundestag on amendments to the German Drug Act (AMG).

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Prof. Dr. Folker Spitzenberger, PhD (Molecular Biology), Chemist (Diploma), Drug Regulatory Affairs (Master, MDRA), Fachhochschule Lübeck, University of Applied Sciences, Focus area of clinical/scientific work. Drug and medical device regulatory affairs, standardization, quality management, conformity, assessment, accreditation, laboratory medicine, in vitro diagnostic medical devices ; Experience in international projects. Since 2005 until present experience as consultant, scientific expert, advisor for WHO, EU, PTB and other organizations in numerous international projects related to regulatory affairs, quality assurance, quality management, biosafety/biosecurity, accreditation/certification and standardization of medical/health laboratories.

Membership of Scientific Societies /Relevant Professional Bodies

1. ISO TC 212: „Clinical laboratory testing and in vitro diagnostic test systems“
2. CEN TC 140 „Clinical laboratory testing and in vitro diagnostic test systems“
3. German Standards Committee DIN NAMed „Quality Management in medical laboratories“ with the following functions: 1. Member and Chair of the German delegation; 2. Chairman of CEN TC 140 WG 3; 3. Chairman of the German standards committee. Member of the Scientific Board of DIW-MTA e. V.

Training and Education: International work experience as senior scientist, quality assessor and quality expert for all kinds of quality systems related to the: In vitro diagnostic medical devices (IVDMD) sector including branches as accreditation and designation (German Accreditation Body DAkkS; Central Authority of the Laender for health protection regarding medicinal products and medical devices ZLG); Certification and GMP (International projects for WHO, EU and others); risk assessment and vigilance (Paul-Ehrlich-Institute PEI); Disease control and prevention (Robert Koch-Institute RKI).

Numerous publications and projects in the field of quality assurance/quality management,
Standardization and regulatory affairs related to the IVDMD sector.

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Dr. Peter Bachmann

Head of Unit 'International Liaison Office and Conferences', Executive Department 'European Union and International Affairs', Federal Institute for Drugs and Medical Devices (BfArM)

Peter Bachmann has studied biology and chemistry and has a Doctorate of Natural Sciences (Pharmaceutical Biology) from the University of Wuerzburg (Germany). Following a JSPS postdoctoral fellowship at Kyoto University (Japan) and a DFG Fellowship at the Institute of Food Research in Norwich/UK, he has worked at the Institute of Pharmaceutical Biology at the Technical University Braunschweig/Germany, until he joint in 1999 the Federal Institute for Drugs and Medical Devices (BfArM, Germany), Department of ‚Drug Approval'. Following positions as Head of Subunit ‚Variations' (2000-2002), Head of Unit „Mutual Recognition Procedures" (2002 -2005), Senior Expert for 'Drug Regulatory Affairs' in the Executive Department 'European and International Affairs' (2005-2011), and Head of Unit 'Coordination Group' (2011-2017), he holds currently the positions as Head 'International Liaison Office and Conferences' and as Deputy-Head of the Executive Department 'European Union and International Affairs'. He was the German representative to the MRFG (2002 – 2005), the German CMDh Member (2005 – 2011), the elected Chair of the CMDh (2011–2017), and a member of the International Generic Drug Regulators Programme (IGDRP) Steering Committee (2012-2017). Currently he is acting as the German NtA Member (since 2002), a Member of the European Union Network Data Board and the European Union IDMP/SPOR Task Force (since 2018), a Member of the HMA WG 'Better Use of Medicines' (incl the ePI Task Force, a Member of the International Pharmaceutical Regulators Programme (IPRP) Management Committee (since 2018), the European Lead of the ICH IGDG (Informal Generic Discussion Group) and as a member of different other European and International AdHoc Working Parties. He is a lecturer for 'Drug Regulatory Affairs' at the Universities of Bonn, Duisburg-Essen, Basel and Copenhagen, a honorary member of the 'Middle-European Society for Regulatory Affairs' (MEGRA), a honorary life-time TOPRA-member, a former member and Vice-Chair of the DIA Advisory Committee Europe (2007 – 2013), DIA Board of Directors (2013 – 2016) and is currently serving at the DIA Council of Regulators and the TOPRA Advisory Committee.

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Susanne Keitel is a licensed pharmacist with a Ph.D. in pharmaceutical technology. Following ten years in the pharmaceutical industry, she held variatious senior positions at the Federal Institute for Drugs and Medical Devices (BfArM), Germany. Since October 2007, Susanne Keitel has held the post of Director of the European Directorate for the Quality of Medicine & HealthCare (EDQM), Council of Europe in Strasbourg.

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Dr. Sophie Werkö has an MSc in Business Administration and a PhD from the University of Stockholm. She has a longstanding engagement with HTA and started in HTA as Project Director at The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU). In 2012 she was appointed Manager of International Relations at SBU, responsible for coordinating SBU's international work and in 2015 she also became Manager for Patient Engagement at SBU. She publishes frequently in scientific journals and acts as reviewer and associated editor in several journals.

As Chair of the International Network of Agencies for Health Technology Assessment (INAHTA), she has an important role of leading the global network of publicly funded HTA agencies. She is also a member of the steering committee of the Health Technology Assessment International (HTAi) subgroup on Patient and Citizens Involvement since 2007 and the co-chair of the HTAi subgroup on Patient Issues: Methods and Impact Working Group together with Dr Sophie Staniszewska. She has participated in the work of the European network for Health Technology Assessment (EUnetHTA) since 2009 and represents Sweden in the EU HTA Network (HTAN).

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Prof. Tatyana Benisheva - Dimitrova, DSc., President of BADI is a professor in the Faculty of Public Health at Medical University, Sofia. 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 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 activities at the global regulatory database IDRAC of the Thompson Reuters (2006-2012). She was involved like an expert in the project of the European Commission - PLAC assignment medicinal product pricing in Serbia, in 2016. Prof. Benisheva is member of DIA and DGRA and Board member of the EAMEA, Advisory council at the DIA in Europe, since 2017. Her 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.

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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.

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Prof. Genka Petrova is Head of the Department of Organization and Economics of Pharmacy, two terms Deputy Rector of Medical University - Sofia and winner of the ISPOR Award for Outstanding Achievements in the Development of the Organization. Prof. Petrova works in the field of pharmacoeconomics and pharmaceutical legislation, with over 600 publications, of which over 150 journal impact factor, 10 international projects, including 2 of programs Horizon 2020 and Erasmus plus - 2 over the last five years.

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Daniela Cherneva graduated from Sofia University "St. Kliment Ohridski" in 2008 with a Bachelor's degree in Russian philology. In 2011 she graduated from New Bulgarian University in Sofia with Master's degree in International Business and in June 2015 she obtained a Master's degree in Public Health and Healthcare Management from the Faculty of Public Health of the Medical University in Sofia. Starting from March 2017 Daniela is a PhD Student in the Faculty of Public Health, Medical University in Sofia. She has more than 10 years of experience in the Regulatory Affairs, currently in the position of Regulatory Affairs Manager in Medochemie Ltd. Bulgaria.

During her professional life she gained broad experience not only in Regulatory Affairs, but also in pricing and reimbursement, market access, pharmacovigilance, life-cycle product management, etc. Daniela has more than 16 publications and conference participations in the field of Regulatory Affairs and is a member of the Bulgarian Association for Drug Information (BADI) and the International Society for Pharmacoeconomic and Outcome Research (ISPOR)

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Prof. Valentina Petkova, DSc, PhD, MPharm., MPH is Vice-Rector for Science and Accreditation of MU-Sofia since 2016. She is Chair of the Counil of medical Science. During the period 2012–2016 she was Deputy Dean for Academic Affairs for students studying in English at the Faculty Pharmacy, MU-Sofia. In 2015 she obtained the scientific degree of Doctor of Science after defending a dissertation on "Theoretical and applied aspects of the concept of" Pharmaceutical Care "in some specific groups of patients." In 2000 she successfully defended her PhD thesis on the topic ”Study of the chronic patient’s level of compliance” Master of Public Health and Health Management - PHC, MU-Sofia. She has acquired specialties in hospital pharmacy, clinical pharmacy, organization and economics of pharmaceutical production, organization and economics of pharmacy and distribution practice. Master in Marketing and Management at the Technical University, Sofia. Master of Pharmacy at the Faculty of Pharmacy, MU-Sofia. She has more than 200 publication in Bulgarian and foreign scientific journals, 10 books and manuals and more than 75 participations in scientific meetings. She has specialized in Germany (1998), Italy (1999, 2000) and the Netherlands (2006) in the sphere of Biostatistics, Epidemiology, Pharmacoepidemiology, Management and decision making in healthcare, and Pharmaceutical care.

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Dr. Lyubina Todorova, BDA

Lyubina Todorova, MD is a Head of Department for Marketing Authorisation of Medicinal Products at Bulgarian Drug Agency since 2010. Shed has more than 15 years experience in pharmaceutical regulatory affairs. She has been working at BDA since 2001 and took several different positions including clinical assessors and Head of Department for Control of Blood transfusion system. Her background is human medicine and has specializations in internal medicine and hematology. She was Bulgarian representative at CAT and CMDh 5 years ago and in 2017 was nominated as a member of Committee for Orphan Medicinal Products.

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M. Pharm. Todor Darakchiev is a Head of Division "Trade control and supervision" in Department "Market supervision and Inspections" at the Bulgarian Drug Agency (BDA). He has been working in the field of medical devices regulation for more than 18 years after going to work for BDA in 1999. During his career in BDA he gained regulatory experience as a chief expert for issuing of marketing authorizations of medical devices (till 2006) and a chief inspector for medical devices and medicinal products (since 2007). Todor Darakchiev is a member of working groups for medical devices (MDEG and Borderline & Classification) at the European Commission, DG SANCO since 2008. During the same period he participated in the meetings of the Competent Authorities for Medical Devices as a BDA representative. In the period 2005 – 2017 attended at several workshops for medical devices organized by TAIEX. In the beginning of Bulgarian membership in EU he was a member of a working group responsible for transposition of the European legislation for medical devices. In 2011 – 2012 Darakchiev participated in an interdepartmental project ''Creation of digital database of medical devices payed with public resources" as a coordinator.