BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

DRUG REGULATORY AFFAIRS – UPDATE TRAINING COURSE

3 + 1 MODULES | 10 YEARS BADI

SPEAKERS

Module 3 | Regulatory Affairs - Update | Workshop up to the current Bulgarian and EU legislation and procedures of Life Cycle Management and
Working discussion about Challenges in the Reimbursement & HTA policy in Bulgaria

November 27, 2020 | Digital event only

Lyubina Todorova, MD, PhD in pharmacology

Head of Department for Marketing Authorisation of Medicinal Products at Bulgarian Drug Agency since 2010.

Started working at BDA since 2001 and took several different positions including clinical assessor and Head of Department for Control of Blood transfusion system.

Since 2017 has been working as a member of Committee for Orphan Medicinal Products.

Veska Gergova graduated University of Sofia "St. Kliment Ohridski" in 2012 with a Master's degree in Law. In 2017 she obtained Master's degree in Public Health and Health Management from the Medical University of Sofia, Faculty of Public Health. Since 2018 she is a PhD Candidate at the Medical University of Sofia, Faculty of Public Health. Her professional experience started as a Legal Advisor in the Legal Department of Bulgarian Drug Agency. Since September 2019, she is Head of Division "Legal Service, Human Resources and International Cooperation" in Bulgarian Drug Agency. She is interested in Administrative Law and Pharmaceutical Law.

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Manfred Caeser Ph.D.
PhD in Neuroscience/Diploma in Economics

> 20 years of health economics/market access experience
Global Head of Market Access, Pricing and Reimbursement in medium sized global pharmaceutical company.

Principal in NY based management-consulting firm with focus on strategy and execution of market access in EU.

Member of LSCN and consulting in health economics, strategy and execution of market access.

Health economic research and integration of clinical and economic research.

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Dr Brigitte Franke-Bray MD PhD FFPM, IFAPP
Treasurer since September 2018 and member of the ECPM Basel, CH, Advisory Board since November 2018, is an independent consultant with special expertise in Pharmaceutical Medicine.

She worked as a hospital physician in internal medicine, respiratory diseases and allergology in Germany, then joined Ciba-Geigy, Switzerland, in 1985 as a medical expert for asthma/allergy, before she moved to Sandoz in a similar position.

In 1995 she joined Quintiles as the first office head Switzerland and also became head of two German offices. She then worked for a small Swiss company as Medical Director for 3 years. From 2005-2012 she was Director DIA Europe, Middle East, Africa, and, as of 2011, additionally the DIA's Global Training Officer. In 2013 she worked for the Swiss Medicines Regulatory Authority Swissmedic as a Clinical Reviewer in Marketing Authorisation. She then was a globally acting Medical Director at Novartis in Basel, Switzerland, in the Respiratory Franchise before she started her consultancy in Pharmaceutical Medicine.

Dr. Franke-Bray has ample experience in Pharmaceutical Medicine education and training, also through the IMI (EU Commission's Innovative Medicines Initiative) projects PharmaTrain and EUPATI (European Patients' Academy, www.eupati.eu). She was a teacher and examiner at a diploma course at the University of Basel, Switzerland, and is a regular examiner at Basel University's ECPM (European Course in Pharmaceutical Medicine) and also for the board certified physicians' specialisation in Pharmaceutical Medicine, Switzerland.

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Vicki Edwards
VP Pharmacovigilance Excellence & QPPV
Maidenhead, United Kingdom

Qualified as a pharmacist in 1981 and started her career in hospital pharmacy. In 1983 she specialised in Drug Information Services and moved to Kuwait to set up and run the first National Drug Information Centre.
On her return to the UK, Vicki spent the next four years in community pharmacy.
In 1996 Vicki joined GlaxoWellcome and started her career in pharmacovigilance. In 2002 she moved to AstraZeneca UK Ltd as the Drug Safety Manager moving on to become Head of Drug Safety & Medical Information.
Vicki joined Abbott in 2005 as European Qualified Person for Pharmacovigilance (EU QPPV). In 2013 moved to AbbVie as EU QPPV and Head of Affiliate Safety Excellence (ASE) and is now VP, Pharmacovigilance Excellence and QPPV. In this global role, in addition to fulfilling legal responsibilities of QPPV she is responsible for PV obligations for Patient Support Programs, oversight and provision of safety information to Affiliate staff and for the global PV quality management system. Vicki is the Chair of the EFPIA pharmacovigilance Expert Working Group.

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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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ЕВРОПЕЙСКИ СЪЮЗ
ЕВРОПЕЙСКИ
СОЦИАЛЕН ФОНД

ОПЕРАТИВНА ПРОГРАМА
ДОБРО УПРАВЛЕНИЕ

РАБОТНА ДИСКУСИЯ #2 | част от изпълнение на Дейност 3 – „Обмен на добри практики, свързани с подобряване на гражданското участие в процесите на оценки на здравни технологии, ценообразуване, реимбурсиране и контрол на лекарства по лекарско предписание, заплащани с публични/ бюджетни средства в страната”, Проект „Разработване на предложения за подобряване на гражданското участие в процесите на ценообразуване и реимбурсиране на лекарства, формиране и отчитане на публичните/бюджетните средства за здравеопазване в областта на лекарствата”, Процедура номер BG05SFOP001-2.009 - „Повишаване на гражданското участие в процесите на формулиране, изпълнение и мониторинг на политики и законодателство”, Приоритетна ос „Ефективно и професионално управление в партньорство с гражданското общество и бизнеса”, Оперативна програма „Добро управление”, съфинансирана от ЕС чрез ЕСФ