LATEST IN MEDICATION SAFETY PRESENTED IN FIRST MODULE OF DRUG REGULATORY AFFAIRS TRAINING COURSE 2022

Unprecedented transparency of all PRAC decisions during the pandemic

Over 90 regulatory experts participated in the first module of this year's DRUG REGULATORY AFFAIRS TRAINING COURSE. The event took place on October 7, 2022, in a completely online format and presented some of the most current and hot topics in the sector in the field of drug safety. Speakers were well-established names in the pharmaceutical regulations in Bulgaria and Germany:

- Prof. Dr. Barbara Sickmueller, Senior Scientific Advisor, Bundesverband der Pharmazeutischen Industrie e. V (BPI), President of German Association for Drug Information DGRA e.V. - Safety communication;
- Dr. med. Renald Hennig, SCRATCH Pharmacovigilance GmbH & Co. KG - PV Signal management for pharmaceutical companies;
- Dr. Jan Schaefer, Federal Institute for Drugs and Medical Devices (BfArM) - PASS – update;
- Maria Popova, MD | BDA | BG member of PRAC - EMA committee - PRAC activities – update;
- Konstantin Kachulev, Mpharm - Clinical Trial Safety;
- Valentin Kopanarov, Mpharm - Pharmacovigilance inspections & audits - online challenges;
- Margarita Strokova, MD, Pharmalex - Pharmacovigilance audit;
- Yordanka Ralinska, August research - Pharmacovigilance outsourcing – challenges and solutions;

Active discussions are provoked by each of the presented topics. It became clear from **Prof. Barbara Sickmüller's** report that ePL (Electronic product information) is the future in the industry, and that a special electronic portal has been created in Germany through which every patient or healthcare worker could immediately find the latest product information for the relevant pharmaceutical product. The information on the portal in question (https://www.gebrauchsinformation4-0.de/) is updated by the respective PRG at the time an update is registered, giving everyone the option to use the most up-to-date information. In Bulgaria, the latest approved information about the pharmaceutical product, leaflet or summary of the product is published on the BDA website. The complex topic of PV Signal management, presented by **Dr. Renald Hennig**, also attracted exceptional interest, in which the statistical methods for registration and analysis of data from received signals for adverse drug reactions were presented.

Dr. M. Popova - director of the "Pharmaceutical Safety Monitoring and Clinical Trials" Directorate and representative of Bulgaria in the Drug Safety Committee (PRAC) at the EMA, presented the current news about the PRAC and summarized the enormous work of the committee during the Covid-19 pandemic. Key to the activity of the PRAC during the pandemic were the unprecedented transparency of all decisions, the enormous help of the EMA and the national competent authorities such as the sending of adverse drug reactions (ADRs) in short terms, the teams evaluating the reports, etc. and the fight against the infodemic. The pandemic is proving to be an example of international collaboration, given the continued

cooperation with the US Food and Drug Agency (FDA) and competent authorities of Israel, Canada, Japan and others. One of the priority directions in the work of the PRAC for 2023 was also indicated - pregnancy and breastfeeding, which will be the subject of discussion in the next Drug Safety Module, which will be held on November 4, 2022, live at the Forum Hotel, Sofia . The presentations from the first module of the DRUG REGULATORY AFFAIRS TRAINING COURSE 2022 are now published on the closed page of www.badibg.org , accessible only to BADI members 2022. The modular training continues with a second module on November 4, 2022, which will be held in person in the Central Hall of the Hotel Forum Sofia, and a third module, which will take place on December 2, 2022, in a fully online format, where, in general, all issues of drug regulation are discussed. Registration form and program at www.badibg.org