

Quo Vadis, August 5th, 2011

Issue 27/Workshop Drug safety discussed at a scientific roundtable

In late June, the Bulgarian Association for Drug Information (BADI), with the support of the Faculty of Public Health (FPH) and the Pharmaceutical Faculty (FF) at the University of Medicine – city of Sofia, held its second scientific event - a workshop on the topic of "New legislation in the field of pharmacovigilance in the EU - Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use".

The Association was registered in late 2010. Its purpose is related to the training of specialists and the exchange of experience in the field of drug information, particularly in the regulation of medicinal products, medical devices, food, cosmetics, having implications for public health and life.

Professor Dr Tzekomir Vodenicharov welcomed the participants on behalf of the Public Health Department. "As a full-fledged member of the European community Bulgaria increasingly feels the demand for professionally trained specialists to conduct effective health policy and to introduce new pharmaceutical legislation - an integral part of health law and medical practice. The Bulgarian Association for Drug Information (BADI) is a bridge between industry and academy, regulators and industry both at home and abroad." The workshop programme was divided into four sessions, attended by a number of physicians, pharmacists, health managers, etc.

The list of invited guest speakers included Dr. A. Thiele and Dr. N. Peshke from the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM) in Germany. They introduced the forum participants to the new legislation and the pharmacovigilance system in the EU Member states, outlined the role of qualified pharmacovigilance experts and presented the concept of pharmacovigilance inspection, while reviewing in detail the provisions of Article 107 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.



Prof. Vodenicharov congratulates the foreign speakers Mr. A. Thiele and N. Paeschke from the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM) in Bonn, Germany. (28 of June 2011) (publication in Quo Vadis 5th of June)

Participants welcomed with a particular interest the lecture on adverse drug reactions and reporting them - individual reports and spontaneous reports (of suspected unexpected serious adverse reactions in order to regulate the compassionate use of medicines). During the discussion there was a consensus to facilitate the procedure for reporting this kind of adverse drug reactions. Attending specialists from divisions of some foreign pharmaceutical companies operating in Bulgaria shared the experience and achievements on this issue following the country's accession to the European Community

A favorable impression was left with the participation of Bulgarian lecturers partnering in this hard field of practical medicine – studying and combating unwanted drug reactions in Bulgaria, the situation in Bulgaria since 2000 (I. Getov, T. Benisheva, V. Petkova), the experience and initiatives of the Bulgarian Drug Association (BDA) - as part of the harmonization process of the Bulgarian legislation with the EU acquis.

Thus the workshop produced a good training background for the Bulgarian specialists to proceed more smoothly for the implementation of relevant regulations after July 2012.