Discussion on variations in drug regulation in Medicus Forum

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On 9 March, 2011, Sofia hosted a workshop on the topic of "Drug Regulatory Challenges - authorization - focus variations, under Council Regulation (EC) №1234." The event was organized by the Bulgarian Association for Drug Information (BADI) with the support of the Medical University in Sofia.

Special guest speakers at the forum were Mrs. Janse-de Hoog, Chairperson of the Coordination Group of the European Medicines Agency, and Mrs. Susanne Winterscheid, Chairperson of the Variation Subgroup to the Coordination Group and Project Manager in the German Agency of Medicines BfArM. The list of lecturers included also Bulgarian experts in the field of drug regulation.

Official guests to the forum were Mrs. Desislava Atanasova, Chairperson of the Parliamentary Committee on Health, Mr. Svetlan Stoev, Administrative Secretary of the Ministry of Foreign Affairs, Professor Dr Tzekomir Vodenicharov from the Faculty of Public Health with the Medical University in Sofia, Associate Professor Nikolay Lambov, Dean of Pharmaceutical Faculty with the Medical University in Sofia.

The event was opened by Professor Genka Tashkova Petrova, Deputy Rector of the Medical University in Sofia, who stressed that the forum offers a good starting point establish cooperation between NGOs, pharmaceutical companies and Bulgarian lawmakers.

Mrs. Desislava Atanasova, Chairperson of the Parliamentary Committee on Health, welcomed the participants and expressed readiness to launch cooperation with the Bulgarian Association for Drug Information (BADI).

The workshop has sought, as its main purpose, to provide a platform for presentation and discussion of new variation aspects envisaged in Council Regulation (EC) №1234, which became effective in the EU in January 2010. The topic is highly relevant, since Bulgaria’s Health Ministry has the task to draft by May 8, 2011 an ordinance implementing the current drug variations as set forth in the Law on Medicinal Products in Human Medicine (LMPHM).

In her introductory presentation Professor Genka Tashkova Petrova stressed on the dynamic development of legislation in the field of drugs regulation. Every five years there is a new regulation drafted in this area. The continuous improvement in drug regulation is associated primarily with the tendency for harmonization of the requirements and procedures with respect to drug variations in the EU countries, she said.

Regulation (EC) № 1234 applies to products approved via mutual recognition, decentralized or centralized procedure. Several groups of medicinal products have been left beyond the scope of the document - homeopathic medicinal products and traditional

herbal medicinal products. This enactment does not affect the transfer of rights between authorization holders.

The agenda of the workshop included also detailed presentations and in-depth discussions on different variation procedures - type IA, type IB and type II, enacted by Regulation № 1234. Participants were informed that the European regulator is tenfold busier with variations than with approval of new authorizations. It is noteworthy that in recent years there has been an increasing rate of type II variations, which are characterized by significant changes in drug content, possibly associated with quality changes.

Participants in the workshop were introduced to the new provisions of Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending

Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products, with whose requirements the EU member states should harmonize their national legislations by January 20, 2011. The purpose of this document is that any future products of valid market authorization, including for national markets only, to be subject to identical criteria for evaluation and approval regardless of their original authorization procedure.

The discussion also spread to amendments in the Bulgarian law, in particular the latest version of the Law on Medicinal Products in Human Medicine (LMPHM) dated February 8, 2011.

The tasks of the Coordination Group of the European Medicines Agency were presented by Mrs. Janse-de Hoog. She presented in detail the specifics of the mutual recognition procedures and the decentralized procedure. The focus in the presentations of Mrs. Susanne Winterscheid, was placed on the peculiarities of variations and their grouping.