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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

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PHARM 571

PHARMACEUTICAL COMMITTEE

16th March 2009
65th meeting

Meeting Report

The Pharmaceutical Committee held its 65th meeting on 16 March 2009, in Brussels, chaired by Martin Terberger, Head of Unit ENTR/F/2-Pharmaceuticals.

This meeting report intends to provide for public information a brief summary of the different topics on the agenda. It will be complemented by the publication of the summary record of the meeting.

Ø **Names of medicinal products: implementation of Art. 1(20) of Directive 2001/83/EC**

The Commission recalled the discussion on this topic held at the 62nd meeting in May 2007 and reiterated the fact that national rules on naming of medicinal products should not run counter to the provision provided by the pharmaceutical acquis for a generic product authorised via the centralised procedure to have a single name, chosen by the applicant in accordance with the possibilities of Article 1(20) of Directive 2001/83/EC.

Ø **Issues arising in the context of the authorisation of non-prescription medicinal products through the centralised procedure**

Following the first authorisation of an OTC product in the centralised procedure and at the same time, the first switch to non-prescription status (for a new strength), the Commission presented its interpretation of the legislation with regard to the possibility for the same medicinal product to have a dual status in the same Members State; the circumstances under which central and national marketing authorisations can/cannot co-exist and how to address a potential conflict between central and national marketing authorisations.

Ø **European Court of Justice judgment on the mutual recognition procedure (C-452/06 Synthon)**

In its ruling of 16 October 2008 European court of Justice delivered its judgment in the above mentioned case. The Commission called the Committee attention to this important ruling and to the court's conclusions.

Ø **Issues arising in the context of the marketing authorisation procedure under the generic and well established legal bases**

The Commission called the attention of the Pharmaceutical Committee to several issues of application of the pharmaceutical acquis in the areas of generic and well established use applications. The Commission emphasised a need for common approach throughout the Community in order to ensure respect of the objectives of the legislation in terms of reward to innovation and generic access, as well as to safeguard the good functioning of the European network of authorities.

Ø **Implementation of Regulation (EC) No 1901/2006 (Paediatric Regulation) – Conditions for the granting of the reward foreseen in Article 36**

The Commission representative called the Committee attention to a problem related to the requirement to proof the authorisation of a medicinal product in all Member States as a precondition for the extension of the Supplementary Protection Certificate. The Commission stressed the need, in this context, for Member States to respect the 30-days deadline of Directive 2001/83/EC to grant marketing authorisation after completion of a mutual recognition or decentralised procedure.

Ø **Implementation of Pharmaceutical Legislation**

The Commission informed participants about a number of recently adopted guidelines and presented main conclusions of Communication from the Commission to the Council and the European Parliament concerning the Report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products.

Ø **Pharmaceutical package and Pharmaceutical Forum**

The Commission updated the participants on the ongoing legislative procedures and conclusions of Pharmaceutical Forum.

Ø **International Aspects**

The Commission informed the Committee on the following activities ongoing at international level:

- Implementation of Transatlantic Administrative Simplification Action Plan as a follow up of the EU-US Workshop;
- The latest ICH activities with an emphasis on international standard setting with CEN/ISO;
- IMPACT resolution on Principles and Elements for National Legislation against Counterfeit Medical Products will not be endorsed by World Health Assembly in May 2009;
- Negotiations with Israel on Agreement on conformity assessment and acceptance of industrial products.

Ø **Supply shortage of radiopharmaceuticals**

Strategies to respond to the shortages in radioisotopes in the medium and long term were outlined.