EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, 19 December 2007

PHARM 560

PHARMACEUTICAL COMMITTEE

10th December 2007

63rd meeting

Meeting Report

The Pharmaceutical Committee held its 63rd meeting on 10 December 2007, 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 outcome on the different topics on the agenda. It will be complemented by the publication of the summary record of the meeting.

Ø **Revision of the EU system of pharmacovigilance**

The Commission presented the draft pharmacovigilance legislative proposals, which are undergoing public consultation until 1 February 2008. The legislative proposals were discussed by the Committee members.

Ø **Communication on the future of the single market in pharmaceuticals for human use**

The Commission presented the outcome of the public consultation on the Communication which should be adopted by the Commission in October 2008. The Communication will provide an opportunity to outline the challenges ahead of the EU single market in pharmaceuticals and set out a vision for the future of the sector by proposing concrete deliverables for the Commission and Member States over the next few years.

Ø **State of play of a possible legal proposal for a Commission Directive on excipients**

The Commission presented the impact assessment for the Directive on GMP for certain excipients used in the manufacture of medicinal products for human use. Preliminary results suggests that there is no indication that a continuation of present policies would present a considerable risk to patients and thus the least costly option based on the principles of risk assessment and management should be preferred compared to a specific legislation.

Ø **Transposition of Community Legislation by the Member States**

The Commission updated the Committee on the transposition of Directives 2004/24/EC, 2004/27/EC and 2005/28/EC and the state of related infringement procedures.

Ø **Implementation of Regulation (EC) No 1901/2006 on medicinal products for paediatric use**

The Commission and EMEA updated the Committee on the progress of the implementation of the paediatric regulation. The Paediatric Committee met for the first time in July 2007 in line with the legal provisions and has now become fully operational. Member States were reminded of their reporting obligations pursuant to Articles 39 and 49 of the Regulation.

Ø **International Aspects**

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

- The EU-US Workshop on administrative simplification, which took place on 28 November 2007 with the aim of identifying opportunities for administrative simplification through transatlantic cooperation.
- The latest ICH activities and particularly international standard setting with CEN/ISO.
- Principles and Elements for National Legislation against Counterfeit Medical Products finalised and agreed by WHO Impact on the meeting, which took place on 10-13 December in Lisbon.
- Following intensive negotiations between DG ENTR and Australian authorities, exchange of Canadian Assessment Reports with Australia has started. Amendment to the GMP annex of the MRA with Australia is currently being prepared.

Ø **The following items were discussed under A.O.B.**

- The legal status of radiopharmaceuticals in the Member States. Member States were invited to report on this specific situation.
- A Progress report on the preparation of "Draft Guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No. 726/2004" was given by the Commission.
- EP Declaration 0061/2006 on Pharmaceutical Active Substances – an oral report on inspection practices of active substance manufacturers and experience by Member States was given by the Commission.
- The EMEA updated Member States on the state of play of "Enlargement of the mandatory scope of the centralised procedure in 2008: Scientific aspects and working definitions for the mandatory scope of the centralised procedure".

Ø **Better Regulation of Pharmaceuticals: Review of the Variations Regulations**

During the afternoon session a joint meeting of the Pharmaceutical Committee (Human) and the Veterinary Pharmaceutical Committee dealt specifically with the revision of the Variations Regulations. The Commission presented the draft legal proposal on the comitology part of the revision of the Variations Regulations, which is subject to public consultation until 4 January 2008. The draft legal proposal is built as a single regulatory text covering, in conjunction with a 'co-decision' level amendment to Directive 83/2001/EC, changes to all marketing authorisations (centralised, decentralised/mutual recognition, purely national). Major issues discussed were: « Do and Tell » Procedure, Worksharing, Type IB by default, Grouping of variations and ICH aspects.

Further discussions will take place after finalisation of the public consultation, based on the revised text, in the Standing Committee on Medicinal Products for Human Use.