EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, 11 December 2006

PHARM 541

PHARMACEUTICAL COMMITTEE
61st Meeting
5th December 2006

Meeting Report

The Pharmaceutical Committee held its 61st meeting on the 5 December 2006, 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.

- **Better Regulation of Pharmaceuticals: revision of the Variations Regulations**

  The Committee supported the general approach and objectives of the initiative. Members identified a number of relevant issues to be taken in consideration at next phases by the Commission. An open public consultation will take place in 2007 on the basis of a draft Regulation proposal.

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

  The Commission provided an update on the transposition of Directives 2004/24/EC, 2004/27/EC and 2005/28/EC.

- **Medicinal gases**

  The Commission stressed to the Committee that gases fulfilling the definition of medicinal product need to be made subject to the pharmaceutical acquis. Following the invitation from the Commission to report any difficulties, some Member States raised practical problems in this regard.

- **Clinical Trials Directive**

  The Committee endorsed the working priorities identified concerning the implementation of the Clinical Trials Directive and supported the orientation for the Ad Hoc on the Implementation of the Clinical Trials Directive to focus on these priorities.

- **Pharmacovigilance**

  The Commission presented the Committee with a summary of the results of its public consultation launched in March 2006 entitled an Assessment of the Community System of Pharmacovigilance. The Committee welcomed the thorough analysis that had been conducted and noted the findings.

- **Paediatrics**

  The Commission informed the Committee about the joint DG Enterprise and Industry and EMEA implementation plan for the paediatric regulation. The Committee noted the DG Enterprise and Industry and EMEA commitment to implement the paediatric regulation as quickly as possible with top priority being put on establishment of the paediatric committee together with development of implementing guidelines.

- **Study on Distribution Channels (Counterfeit Medicines; Safe Medicines in Parallel Trade)**

  The Commission presented the objectives and methodology of these studies intended to address public health issues in relation to distribution channels. The collaboration of Member States was sought and this was noted.

- **Pharmaceutical Forum**

  The Committee heard an update on the Pharmaceutical Forum held on 29 September and the Progress Report it adopted and the outline of the upcoming actions in the three Working Groups on: Information to Patients, Relative Effectiveness and Pricing and Reimbursement. The next Pharmaceutical Forum is likely to be held at the end of June 2007.

- **International Aspects**

  The Commission informed the Committee on different activities ongoing at international level as follows:

  - **MRAs – GMP Annex:** the Commission agreed with Member States on a way forward for further steps towards inclusion of new Member States under the MRAs GMP Annex.
  - **ICH:** the Committee was updated on the state of play of the different topics stemming from the Steering Committee meeting in October 2006. The important implications of the move to working with standards development organisations (including HL7/CEN and ISO) for the development of international electronic standards applicable to the regulation of medicinal products for human use was highlighted.
  - **Regulatory Dialogues with India and Russia:** the Committee was informed of the activities initiated in 2006. The main issues for the EU concern GMP and IPR enforcement. For India the main issue relates to marketing of Ayurveda products.
  - **WHO International Medical Products Task Force**.

- **Upcoming activities**

  The Commission informed the Committee on future activities, in the areas of:
  - Commission Report on Information to Patients.
  - Commission Report on Traditional Herbal Medicinal Products.
  - Commission guidelines in the area of orphan medicinal products.
  - Penalties Regulation.
  - Directive on excipients.