EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, 25 May 2007

PHARM 554

PHARMACEUTICAL COMMITTEE
62nd Meeting
21 st May 2007

Meeting Report

The Pharmaceutical Committee held its 62nd meeting on the 21 May 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.

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

  The Commission presented results of the consultation on its strategy paper, which expressed an overall support for all five key proposed items. The outcome of the consultation will be taken forward in the preparation of draft legal texts, which will be subject to public consultation in the course of 2007.

- **Directive on excipients**

  The Commission informed about preparation of a Directive on GMP for certain excipients used in the manufacture of medicinal products for human use. The commission is currently consulting on possible impacts of different policy options via online questionnaires.

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

  The Commission representative provided an update on the transposition of Directives 2004/24/EC, 2004/27/EC and 2005/28/EC as well as reminded the Committee of the duty of Member States to fully transpose these pieces of legislation and notify the transposition measures to the Commission.

- **Optional Scope of the centralised procedure**

  The committee provided final comments and endorsed the draft guidance on Article 3(2) of Regulation (EC) No 726/2004, which will be incorporated to the Notice to Applicants.

- **Names of medicinal products**

  The Commission highlighted 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 Art. 1(20) of Directive 2001/83/EC.

- **Enlargement of the mandatory scope of the centralised procedure**

  The EMEA representatives presented a draft document on the key scientific aspects and working definitions for the new therapeutic areas for which the centralised procedure will become mandatory with effect from 20 May 2008.

- **Paediatrics**

  The Commission and EMEA updated the Committee on the progress of implementation for the paediatric regulation.

- **Implementation of Pharmaceutical Review**

  Final revisions of draft guidance documents [Guidance on significant clinical benefit in comparison to existing therapies of a new indication in order to benefit from an extended marketing protection and Guidance on new therapeutic indication for a well-established substance] were endorsed by the Committee with some minor comments, which will be implemented. These documents will be incorporated to the Notice to Applicants.

- **Publication of information on clinical trials**

  The Committee was consulted on the recommendations stemming from the Draft Guideline on the data fields of the EudraCT database to be included in the EudraPharm database, specifically focusing on the scope of information to be provided and on the inclusion of medicinal products with and without marketing authorisation.

- **Study on Distribution Channels**

  The consultation of Member States and stakeholders on the study on distribution channels has been closed. The Commission will contact experts nominated by Member States to discuss policy options during the second half 2007. Results will be available by the end of 2007 for the part on Parallel Trade and in 2008 on Counterfeit Medicines.

- **International Aspects**

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

  - **EU-US Workshop on administrative simplification:** The Committee was informed about preparation of the Workshop, which will take place on 28 November 2007 and should identify opportunities for administrative simplification through transatlantic cooperation**.**
  - **ICH:** The Committee was reminded of the important move to work towards elevating certain ICH guidelines to CEN/ISO standards, and was encouraged to follow the development of these standards carefully.

- **Upcoming activities**

  The Commission informed the Committee about

  - Impact assessment following publication of “Strategy to strengthen and rationalise the EU system of pharmacovigilance”.
  - Public consultation on the draft Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products (until 30 June 2007).
  - Report on the traditional herbal medicinal products, which will be released for public consultation shortly.
  - Preparation of a Communication on the future of the single market in pharmaceuticals for human use.