EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Pharmaceuticals
Head of Unit

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PHARM 587

PHARMACEUTICAL COMMITTEE

14th February 2011

66th meeting

Meeting Report

The Pharmaceutical Committee held its 66th meeting on 14 February 2011, in Brussels, chaired by Patricia Brunko, Head of Unit SANCO C8 - 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.

- **State of play and exchange of views on the review of the clinical trials directive 2001/20/EC**

  The Commission has scheduled adoption of a legislative proposal for a revision of the 'Clinical Trials Directive' 2001/20/EC for 2012. A public consultation on a concept paper on the revision of the 'Clinical Trials Directive' has been launched on 9 February 2011. The Commission presented for discussion a preliminary appraisal, on the basis of the current state of the impact assessment, of options to address some of the key concerns of the Clinical Trials Directive.

- **Review of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency**

  The Commission informed participants about the preparation of a legal proposal to amend the 'Fees Regulation'[1] enabling EMA to charge fees for pharmacovigilance activities as foreseen in the new pharmacovigilance legislation[2], which will become applicable in July 2012.

- **Implementation of the new pharmacovigilance legislation**

  As a delay of 18 months is foreseen before the legislation becomes applicable, it is important that the implementing elements necessary for the proper application of the legislation are put in place by July 2012. In order to respect the hierarchy of norms, the Commission representatives emphasised that priority needs to be given to the implementing acts specified in the legislation, more specifically Article 87a of the Regulation and Article 108 of the

[1] Council Regulation (EC) No 297/95
[2] Directive 2010/84/EU and Regulation (EU) No 1235/2010 of 15 December, OJ L 348 of 31.12.2010.

Directive. In this context the Commission representative informed participants about the new procedures for the development and adoption of delegated and implementing acts.

- **Implementation of Pharmaceutical Legislation**

  The following implementation issues were addressed by the Committee:

  - Extension of 'Variations Regulation'[3] to 'purely national' products;
  - Revision of Annex 14 on good manufacturing practices for Medicinal Products derived from Human Blood or Plasma;
  - Exchange of views on the application of the 'Herbal Directive' 2004/24/EC;
  - Use of the EudraCT database.

- **European Court of Justice judgments**

  The Commission called the Committee's attention to recent rulings and to the court's conclusions:

  - Rulings of 28 October 2010 (Case C-350/08, "Commission v. Lithuania") and of 22 December 2010 (Case C-385/08, judgment, "Commission v. Poland);
  - Ruling of 22 April 2010 (Case C-62/09, "ABPI").

- **International Aspects**

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

  - Exploratory task force in the area of combination products;
  - The latest ICH guidelines and developments with an emphasis on international outreach efforts;
  - Exchanges under confidentiality arrangements with the USA, Japan and Canada;
  - Regulatory dialogue with India, China and Russia.

[3] Commission Regulation (EC) No 1234/2008