EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Pharmaceuticals
Head of Unit

PHARM 597

PHARMACEUTICAL COMMITTEE

5 October 2011

67th meeting

Meeting Report

The Pharmaceutical Committee held its 67th meeting on 5 October 2011, in Brussels, chaired by Patricia Brunko, Head of Unit SANCO D3 - 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 gave a short presentation of the state of play. Discussions focussed mainly on the approval process.

- **Hospital exemption for ATMPs (implementation of Art 28(2) of Regulation (EC) 1394/2007 on advanced therapies): impact on products legally on the market and on new ATMPs**

  Member States were invited to inform the Commission before 2 December 2011 on: how many ATMP products are legally on their market; which of those products are prepared on a routine basis and which fall under the hospital exemption, as well as the criteria applied for the latter.

- **Amendment to Commission Regulation (EC) No 658/2007 concerning financial penalties in order to incorporate the Paediatric Regulation**

  The Commission provided the Committee with an oral update report as regards the planned amendment to the scope of Regulation (EC) No 658/2007 in order to incorporate infringements of the Paediatric Regulation as well as the modifications due to the new pharmacovigilance legislation. Those amendments should be adopted in 2012.

- **Implementation of the new pharmacovigilance legislation**

  The Commission provided an update on the state of play with respect to implementing measures, public consultation and transitional arrangements. The new legislation will become applicable as from July 2012.

- **European Court of Justice judgments**

  The Commission called the Committee's attention to recent rulings and to the Court's conclusions concerning advertising provisions for medicinal products:

  - Case C-249/09, judgment of 5 May 2011, "Novo Nordisk"
  - Case C-316/09, judgment of 5 May 2011, "MSD"

- **Joint meeting on borderline cases between medical devices and medicinal products**

The Commission reported on the outcome of a meeting between pharmaceuticals' and medical devices' authorities on borderline issues, held on 10 March 2011. This meeting was dedicated to the sharing of expertise between experts of the two fields on the qualification of some specific products and on emerging nanotechnology-based products. The Commission emphasized the importance of developing a strong cooperation between the medical device and the pharmaceutical sectors, to enhance both the functioning of the internal market and the protection of public health.

- **Antimicrobial resistance**

The Commission gave an update on the latest developments in the field. A Communication from the Commission is being prepared and a five-year strategy is planned to be presented on 18 November 2011, European Antibiotic Awareness Day.

- **International Aspects**

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

- negotiations on a EU-Singapore Free Trade Agreement;
- Japan-EU bilateral meeting held on 27 September 2011 in Brussels;
- the International Conference on Harmonization of Technical Requirements for Registration of Medicinal Products for Human Use 'ICH' (EU, USA, Japan) with respect to its future developments.

- **Amended proposals on information to patients on prescription-only medicines**
  - The Commission provided information on the main axes of the amended proposals: (COM(2011) 632 final and COM(2011) 633 final).

- **Tobacco control : status of electronic and herbal cigarettes**
  - The Commission gave a short presentation on the process in view of the revision of the Tobacco Products Directive (Directive 2001/37/EC). Participants were asked to submit feedback on national regulations regarding, in particular, electronic cigarettes.

- **Falsified medicines**
  - The Commission gave a short presentation on the next steps and informed that it plans to set up an expert group as regards the delegated act on safety features.

- **Negative opinion issued by EMA on 'Celecoxib'**
  - The Commission drew the attention of the MS to the opinion of the CHMP issued under Art. 5 (3) of Regulation (EC) No 726/2004, concluding on the negative benefit-risk of the use of celecoxib for the concerned indication[1] and invited them to take any actions that may be appropriate to inform prescribers in relation to this opinion.

- **Updates from Member States**
  - Sweden provided an update on the upcoming first meeting for the project *Make the Baltic Sea Region a Lead in Sustainable Development for Pharmaceuticals*, staged by The Swedish Medical Products Agency in Stockholm on 17-18 Oct. 2011.
  - The UK provided an update on a case of malicious tampering of *Nurofen plus* packages detected on its territory in August 2011.
  - France provided an update on the national legislative proposal aiming at strengthening safety in the area of medicines.

[1] EMA, Assessment Report for Celecoxib for the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis, as an adjunct to surgery and further endoscopic surveillance, ref. EMA/416998/2011, 26 May 2011.