EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA
Head of Unit

PHARM 598

PHARMACEUTICAL COMMITTEE - HUMAN

5 October 2011

67th meeting

SUMMARY RECORD

The Pharmaceutical Committee held its 67th meeting on 5 October 2011, in Brussels, chaired by Patricia Brunko, Head of Unit SANCO D3 - *Pharmaceuticals*[1].

AGENDA

- The draft agenda of the 67th meeting **(PHARM 589)** was adopted with additional items under A.O.B.

1. LEGISLATIVE ISSUES

- **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

[1] Additional information: as of 1 January 2012, Unit SANCO D5 - *Medicinal products – authorisations, EMA*

infringements of the Paediatric Regulation as well as the modifications due to the new pharmacovigilance legislation. Those amendments should be adopted in 2012.

- **Amended proposals on information to patients on prescription-only medicines**

The Commission provided information on the two main axes of revision of the legislative proposals: put a stronger emphasis on patients' needs ('pull' approach) and closing the gaps in the area of Pharmacovigilance which have been identified through the 'stress test' based on the Mediator example.

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

- **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.

- **Falsified medicines**

The Commission gave a short presentation on the next steps as regards the delegated act on safety features.

3. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

- **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"

Both preliminary rulings relate to EU legislation on advertising of medicinal products as provided in Title VIII of Directive 2001/83/EC. In particular, they concern the correct interpretation of Articles 87 and 88 of the Directive.

- **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 legal status 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.

4. UPCOMING INITIATIVES

- **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.

5. INTERNATIONAL

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 within the framework of the confidentiality arrangement between the two parties. This arrangement will expire in February 2012 and the decision on the continuation (form and duration) of this arrangement will be taken once the new Executive Director of EMA is in place (expected in November 2011). As regards the Mutual Recognition Agreement between the EU and Japan on Good Manufacturing Practice, the EU side stressed the importance of Japan recognizing the new Member States.
- 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. The EU will present proposals on the restructuring of ICH at the next ICH meeting in Sevilla 5-10 November 2011

6. A.O.B.

- **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.

- **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 indication2 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.
    - One important aspect announced for discussion is how environmental control can be incorporated in the EU manufacturing regulations within the framework of good manufacturing practice (GMP). In this respect, the

[2] 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.

Commission stressed that EU pharmaceutical legislation addresses quality, safety and efficacy of products. Incorporation of environmental standards in GMP could therefore be legally questionable.

- The Commission informed the Committee that a limited number of pharmaceutical substances could be listed in the new proposal of the Water Framework directive.

- 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.
    - Major aspects are: transparency of relations between the industry and health professionals, declaration of conflict of interests of experts and national agency, visits of industry representatives, notably in hospitals. The proposal was adopted by the National Assembly, next stage is the vote in the Senate.