EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 615

PHARMACEUTICAL COMMITTEE
27 March 2013

Subject: Draft agenda of the 70th meeting of the Pharmaceutical Committee
27 March 2013, **10.00 am – 6.00 pm**

Venue: Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room **AB-0B**.

Welcome coffee: 9.30 am – 10.00 am

Lunch break: 1.00 pm – 2.30 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
70th meeting, 27 March 2013
Centre Albert Borschette, Brussels, AB-0B

AGENDA

– Adoption of draft agenda **(PHARM 615)**

1. PREPARATION OF DELEGATED ACT ON POST-AUTHORISATION EFFICACY STUDIES

2. LEGISLATIVE ISSUES

a) Medicinal products and the environment

Information from the Commission on:

- Proposal from the Commission to include three medicinal substances on the list of priority substances of the Water Framework Directive

- Preparation of the Commission report on the risks of environmental effects of medicinal products and on-going preparatory study

b) Report on the use of -omic technologies in the development of personalised medicines

– For information

3. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

a) Legal and Regulatory news

b) Enforcement of pharmacovigilance obligations

c) Implementation of the 'Falsified medicines Directive'

– Transposition by Member States

– Incoming rules on importation of active substances for medicinal products for human use

4. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

a) Recent Judgments of the European Court of Justice

b) Feedback of the MS on off-label use

– For information

c) Classification of medicinal products

5. INTERNATIONAL DEVELOPMENTS

a) International developments

Information from the Commission on

- Reform of ICH and the Regulators Forum
- International Generic Drug Regulators Pilot (IGDRP)
- Launch of Free Trade Agreement negotiations between the EU and the United States

6. A.O.B.

a) Request of Ukraine of having a GMP Mutual Recognition Agreement with the EU

b) Public consultation on the ATMP's regulation