EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products

Medicinal products – authorisations, European Medicines Agency

PHARM 615

PHARMACEUTICAL COMMITTEE 27 March 2013

Subjec	<u>t</u> : Draft agenda of the 70 th meeting of the Pharmaceutical Committee 27 March 2013, 10.00 am – 6.00 pm
enue: Cent	re 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