



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

PHARM 607

PHARMACEUTICAL COMMITTEE
22 October 2012

Subject: Draft agenda of the 69th meeting of the Pharmaceutical Committee
22 October 2012, **10.00 am – 6.00 pm**

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

Welcome coffee: 9.30 am – 10.00 am

Lunch break: 1.00 pm – 2.30 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
69th meeting, 22 October 2012
Centre Albert Borschette, Brussels, AB-0A

AGENDA

- Adoption of draft agenda (**PHARM 607**)

1. LEGISLATIVE ISSUES

- a) **Hospital exemption for ATMPs (implementation of Art 28(2) of Regulation 1394/2007): update on feedback received by the Commission**
 - For information
- b) **Request for information by the European Parliament on the possibility in the Member States to advertise organic origin of herbal medicinal products**
 - For information and feedback from Member States
- c) **Status of old marketing authorisations: oligotherapy**
 - For information and possible follow-up
- d) **Legal and Regulatory news**
 - For information

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

- a) **Shortages of medicinal products due to quality or manufacturing issues**
 - For information / discussion
- b) **Enforcement of pharmacovigilance obligations**
 - For information / discussion
- c) **Implementation of the new rules on importation of active substances**
 - For information / discussion
- d) **Joint Action 'Facilitating collaboration among the Member States for the effective operation of the pharmacovigilance system in the EU' : state of play and next steps**
 - For information / discussion
- e) **Presentation from France: new framework in France for regulating off-label use**
 - For information / discussion

3. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

- a) **Recent judgments of the European Court of Justice**
 - For information

4. A.O.B.

- a) **Health claims on botanicals: feedback from the expert group meeting on the position paper of the legal framework for botanicals with health claims**
 - For information

- b) **E-health network and interoperability**
 - For information

- c) **Medicinal products for human use which contain the active substance “methylphenidate**
 - Request for information