



**EUROPEAN COMMISSION**  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 599

**PHARMACEUTICAL COMMITTEE**  
**28 March 2012**

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**Subject:** Draft agenda of the 68<sup>th</sup> meeting of the Pharmaceutical Committee  
(28 March 2012): **10.00 am – 5.00 pm**

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Venue: Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room **AB-1B**.

**Welcome coffee: 9.30 am – 10.00 am**

**PHARMACEUTICAL COMMITTEE**  
**DRAFT AGENDA**  
68<sup>th</sup> meeting, 28 March 2012  
Centre Albert Borschette, Brussels, AB-1B

**AGENDA**

- Adoption of draft agenda (**PHARM 599**)

**1. LEGISLATIVE ISSUES**

- a) **Hospital exemption for ATMPs (implementation of Art 28(2) of the ATMP regulation): update on feedback received by the Commission**
  - For information

**2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION**

- a) **Pharmacovigilance legislation**
  - State of play of ongoing preparatory work
- b) **Directive on Falsified medicines**
  - Transposition and implementation, state of play
- c) **Paediatrics Regulation**
  - Lessons learnt after five years of application

**3. INTERPRETATION OF PHARMACEUTICAL LEGISLATION**

- a) **Recent judgments of the European Court of Justice**
  - For information
- b) **Interpretation of the legislation on biosimilars**
  - For discussion

**4. REGULATORY ISSUES**

- a) **Comparators in the context of marketing authorisation**
  - For discussion

**5. INTERNATIONAL**

- a) **Reform of ICH and international collaboration on generics**

**6. A.O.B.**