



**EUROPEAN COMMISSION**  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

**PHARM 677**

**PHARMACEUTICAL COMMITTEE**  
**17 March 2015**

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**Subject:** Draft agenda of the 74<sup>th</sup> meeting of the Pharmaceutical Committee  
17 March 2015, **10.00 am – 6.00 pm**

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Venue: Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room **AB-4A**.

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

**Lunch break: 1.00 pm – 2.30 pm**

**PHARMACEUTICAL COMMITTEE**  
**DRAFT AGENDA**  
74<sup>th</sup> meeting, 17 March 2015  
Centre Albert Borschette, Brussels, **AB-4A**

**AGENDA**

- Adoption of draft agenda
  
- 1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION**
  - a) Update on the study of off-label use**
  - b) Ongoing Cases**
  - c) Legal and Regulatory News (New pieces of legislation, COM guidelines)**
  - d) The use of registries in the context of marketing authorisations: experiences and legal framework**
  
- 2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION**
  - a) Written procedure of Standing Committee – Scientific accelerated procedure**
  - b) Feedback from the 1<sup>st</sup> meeting of the Commission Expert Group on “Safe and Timely Access to Medicines for Patients”**
  - c) Clinical Trials Regulation: update on the implementation**
  - d) Falsified Medicines Directive: update on the implementation**
  - e) Falsified Medicines Directive: update on the common logo for online pharmacies**
  - f) Forthcoming activities on orphan medicinal products**
  - g) Update on activities regarding advanced-therapy medicinal products (ATMPs)**
  
- 3. PHARMACOVIGILANCE**
  - a) Report on the performance of pharmacovigilance tasks by the Member States**
  - b) Reports of Member States pharmacovigilance audits**
  
- 4. INTERNATIONAL DEVELOPMENTS**
  - a) International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)**
  - b) Update on the Transatlantic Trade and Investment Partnership (TTIP)**

**5. AOB**

- a) Presentation of the joint procurement agreement for medical counter-measures**
- b) 50 years of EU pharmaceutical legislation: communication activities and events**