



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 626

PHARMACEUTICAL COMMITTEE
23 October 2013

Subject: Draft agenda of the 71st meeting of the Pharmaceutical Committee
23 October 2013, **10.00 am – 6.00 pm**

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

Welcome coffee: 9.30 am – 10.00 am

Lunch break: 1.00 pm – 2.30 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
71st meeting, 23 October 2013
Centre Albert Borschette, Brussels, **AB-4C**

AGENDA

- Adoption of draft agenda

1. LEGISLATIVE ISSUES

Paediatrics: the Commission report published in June and the 10 year report in 2017

2. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

- a) **Recent Judgments of the European Court of Justice**
- b) **The Judgement of the European Court of Justice on Orphacol**
- c) **Off-label use**
- d) **The Notice to Applicants (NtA) – way forward**

3. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

- a) **Identification of biological medicinal products - Implementation of Article 102(e) of Directive 2010/84/EC-International Nonproprietary Names (INN) for biosimilar medicinal products**
- b) **Legal and regulatory news**
- c) **Update on the implementation of Directive 2011/62/EU (Falsified Medicines Directive)**
- d) **Update on antimicrobial resistance (AMR)**

4. PHARMACOVIGILANCE

- a) **Post-authorisation efficacy studies**
- b) **Additional monitoring and the black symbol**
- c) **Audits of national pharmacovigilance system**

5. INTERNATIONAL DEVELOPMENTS

- a) **International Pharmaceutical Regulators Forum (IPRF)**
- b) **Trade negotiations with the United States**

6. A.O.B

- a) **Questions on marketing of medicinal products containing kava**
- b) **Advertising organic origin of traditional herbal medicinal products**