



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 702

PHARMACEUTICAL COMMITTEE
28 April 2016

Subject: Draft agenda of the 76th meeting of the Pharmaceutical Committee
28 April 2016, **10.00 am – 6.00 pm**

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

Welcome coffee: 9.30 am – 10.00 am

Lunch break: 12.30 pm – 2.00 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
76th meeting, 28 April 2016
Centre Albert Borschette, Brussels, **AB-4B**

AGENDA

- Adoption of draft agenda

1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

- i. Update on Court cases
- ii. Legal and Regulatory news
- iii. Update on the study of off-label use

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

- i. GMP Guidelines specific to ATMPs
- ii. Review of the regulatory framework on orphan medicinal products
- iii. Implementation of the Clinical Trials Regulation
- iv. Implementation of the Falsified Medicines Directive
- v. Feedback from the 3rd meeting of the Commission Expert Group on "Safe and Timely Access to Medicines for Patients"

3. PHARMACOVIGILANCE

- i. Update on pharmacovigilance related reports

4. LEGISLATIVE ISSUES

- i. Update on the preparation of the Commission report on the Paediatric Regulation

5. INTERNATIONAL DEVELOPMENTS

a) Update on multilateral collaborations:

- i.** The reform of the International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- ii.** International Pharmaceutical Regulators Forum (IPRF)

b) Update on bilateral negotiations

- i.** Regulatory cooperation: China and India
- ii.** Agreements on Conformity Assessment and Acceptance of industrial products (ACAA) / Mutual Recognition Agreements: recent developments with Swiss, Japan, Australia and Israel
- iii.** Transatlantic Trade and Investment Partnership

6. AOB