



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 725

PHARMACEUTICAL COMMITTEE
27 March 2017

Subject: Draft agenda of the 78th meeting of the Pharmaceutical Committee
27 March 2017, **10.00 am – 6.00 pm**

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

Welcome coffee: 9.30 am – 10.00 am

Lunch break: 12.30 pm – 2.00 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
78th meeting, 27 March 2017
Centre Albert Borschette, Brussels, **AB-4D**

AGENDA

- Adoption of draft agenda

1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

- i.** Update on Court cases
- ii.** Legal and Regulatory news

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

- i.** ATMPs for discussion
 - (a)** Presentation of initiatives to optimise the regulatory framework for ATMPs
 - (b)** Draft Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal
- ii.** Feedback from the 6th meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)

3. PHARMACOVIGILANCE

- i.** Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action

- ii. Report on use of additional monitoring list – experience of Member States

4. LEGISLATIVE ISSUES

- i. Paediatrics: Feedback from the public consultation
- ii. Results of the public consultation on the concept of “similar medicinal product” in the context of the orphan legislation
- iii. Report from the Commission on Summary of Product Characteristics and Package Leaflet

5. INTERNATIONAL DEVELOPMENTS

- i. Transatlantic Trade and Investment Partnership (TTIP)

6. AOB

- i. Update on the initiative to strengthen EU cooperation on HTA
- ii. Shortages of medicines
- iii. Questionnaire on the national law implementing article 85c of Directive 2001/83/EC
- iv. The Implementation of the Clinical Trials Regulation