EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 715

PHARMACEUTICAL COMMITTEE
18 October 2016

Subject: Draft agenda of the 77th meeting of the Pharmaceutical Committee
18 October 2016, **10.00 am – 6.00 pm**

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

Welcome coffee: 9.30 am – 10.00 am

Lunch break: 12.30 pm – 2.00 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
77th meeting, 18 October 2016
Centre Albert Borschette, Brussels, **AB-OC**

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. Good Manufacturing Practice (GMP) guidelines for Advance Therapy Medicinal Products (ATMPs)

ii. Implementation of the Clinical Trials Regulation

iii. Implementation of the Falsified Medicines Directive – update on the common logo for online pharmacies

iv. Feedback from the 5th meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)

v. Information on the Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States

3. PHARMACOVIGILANCE

i. Report on the Pharmacovigilance activities of the Member States and EMA

ii. Members States' reports on the audits of their pharmacovigilance systems

4. LEGISLATIVE ISSUES

i. Paediatrics: Feedback from the meeting with Member States on 19/09

5. INTERNATIONAL DEVELOPMENTS

i. Transatlantic Trade and Investment Partnership (TTIP)

6. AOB

i. Strengthening EU cooperation on HTA (HTA inception impact assessment)