EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 688

PHARMACEUTICAL COMMITTEE
21 October 2015

Subject: Draft agenda of the 75th meeting of the Pharmaceutical Committee
21 October 2015, **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: 1.00 pm – 2.30 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
75th meeting, 21 October 2015
Centre Albert Borschette, Brussels, **AB-4D**

AGENDA

– Adoption of draft agenda

1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

a) Court cases

b) Legal and Regulatory News

c) Variations and the use of the Article 57 database

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

a) Written procedure of Standing Committee – Scientific accelerated procedure

b) Review of the 2003 Communication on orphan medicinal product

c) Specific GMP guidelines for Advanced Therapy Medicinal Products (ATMPs)

d) Feedback from the 2nd meeting of the Commission Expert Group on "Safe and Timely Access to Medicines for Patients" (STAMP)

e) Clinical Trials Regulation: update on the implementation

f) Falsified Medicines Directive: update on the implementation

3. PHARMACOVIGILANCE

a) Report on the performance of pharmacovigilance tasks by the Member States and the European Medicines Agency

b) Reports of Member States pharmacovigilance audits

4. LEGISLATIVE ISSUES

a) Paediatrics

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

6. AOB

a) Summary of comments to the study reports on the Patient Information Leaflet (PIL) and the Summary of Product Characteristics (SmPC)

b) Biosimilars: World Health Organisation (WHO) Biological Qualifier