EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM **640**

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: Draft agenda of the 72nd meeting of the Pharmaceutical Committee
26 March 2014, **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: 1.00 pm – 2.30 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA

72nd meeting, 26 March 2014
Centre Albert Borschette, Brussels, **AB-4B**

AGENDA

– Adoption of draft agenda

1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

a) Ongoing Court cases

b) Study on off-label use

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

a) Identification of biological medicinal products - Implementation of Article 102(e) of Directive 2001/83/EC

b) Relation between pharmaceuticals regulatory framework and timely access of medicines to patients: Reflection on difficulties and opportunities

c) Penalties

d) 2015 – 50 years of EU pharmaceutical legislation

e) Update on the implementation of Directive 2011/62/EU (Falsified Medicines Directive)

f) New Regulation on clinical trials, update from the Commission and EMA

g) GMP Guide

3. PHARMACOVIGILANCE

a) Delegated Act on Post authorisation efficacy studies

b) Regulation on fees for Pharmacovigilance and revision of EMA fees

4. LEGISLATIVE ISSUES

Paediatrics: Best practices to promote at national level clinical trial research with children

5. INTERNATIONAL DEVELOPMENTS

a) International Pharmaceutical Regulators Forum (IPRF)

b) Transatlantic Trade and Investment Partnership (TTIP)

c) International Nonproprietary Names (INN) for biosimilar medicinal products