



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 660

PHARMACEUTICAL COMMITTEE
22 October 2014

Subject: Draft agenda of the 73rd meeting of the Pharmaceutical Committee
22 October 2014, **10.00 am – 6.00 pm**

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

Welcome coffee: 9.30 am – 10.00 am

Lunch break: 1.00 pm – 2.30 pm

PHARMACEUTICAL COMMITTEE
DRAFT AGENDA
73rd meeting, 22 October 2014
Centre Albert Borschette, Brussels, **AB-4A**

AGENDA

- Adoption of draft agenda

- 1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION**
 - a) **Ongoing Court cases**
 - b) **Legal and regulatory news (New pieces of legislation, COM guidelines)**

- 2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION**
 - a) **Relation between pharmaceuticals regulatory framework and timely access of patients to medicines: Reflection on difficulties and opportunities – Follow up from the 72nd meeting and next steps**
 - b) **50 years of pharmaceutical legislation in 2015**
 - c) **State of play of the preparations for the application of the Clinical Trials Regulation**
 - d) **Summary of comments to study on availability of medicines for human use**

- 3. PHARMACEUTICALS IN THE ENVIRONMENT**
 - Strategic approach to pollution of water by pharmaceutical substances: feedback from EU workshop 11/09/2014**

- 4. PHARMACOVIGILANCE**
 - a) **Report on the performance of pharmacovigilance tasks by the Member States**
 - b) **Update on Reports of Member States pharmacovigilance audits**

- 5. LEGISLATIVE ISSUES**
 - Paediatrics: “Road to 2017”**

- 6. INTERNATIONAL DEVELOPMENTS**
 - a) **Update on multilateral collaborations:**

- i. International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)**
- ii. International Pharmaceutical Regulators Forum (IPRF)**
- iii. International Coalition of Medical Regulatory Authorities (ICMRA)**
- b) Update on bilateral negotiations, notably the Transatlantic Trade and Investment Partnership (TTIP)**
- c) Biological Qualifier**

7. AOB

- a) Update on antimicrobial resistance (AMR) - World Health Organisation input**
- b) Adoption of legal proposal on veterinary medicines (for info)**
- c) Update on the study of off-label use**
- d) Move from DG Health and Consumers to DG Internal Market, Industry, Entrepreneurship and SMEs**
- e) Update on the common logo for on-line pharmacies**
- f) New voting rules in Committees**