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
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