Subject: Agenda of the 85th meeting of the Pharmaceutical Committee
17 December 2019

Venue: Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room AB-4C

Welcome coffee: 9:30 am – 10.00 am
1. Adoption of the draft Agenda

2. Adoption of the summary record of the last meeting (Pharm 782) and high level summary of working method and priorities of the Committee (Pharm 783)

**ENSURING ACCESS AND AFFORDABILITY WHILE ADDRESSING SHORTAGES, UNMET NEEDS**

3. Evaluation of orphan & paediatrics regulations

4. Development of antimicrobials: how to address market failures

5. Challenges in access to medicines: updates from the EU/OECD project on pharmaceuticals

**SUSTAINABLE INNOVATION**

6. ATMPs – Hospital exemption

7. Pharmaceuticals in the environment

**ENSURING SECURITY AND OVERSIGHT OF THE GLOBAL MANUFACTURING SUPPLY CHAIN**

8. Update on enhancing oversight of the global manufacturing and supply chain of Active Pharmaceutical Ingredients

9. Update on the ICH Q12 guideline

10. A.O.B.

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