



**EUROPEAN COMMISSION**  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation  
**Medicines: policy, authorisation and monitoring**

PHARM 784\_v3

**PHARMACEUTICAL COMMITTEE**  
**17 December 2019**

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**Subject: Agenda of the 85<sup>th</sup> meeting of the Pharmaceutical Committee**  
**17 December 2019**

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

**Welcome coffee: 9:30 am – 10.00 am**

**PHARMACEUTICAL COMMITTEE**  
**DRAFT AGENDA**  
**10:00h – 18:00h**

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. Pharmaceuticals in the environment

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

7. Update on enhancing oversight of the global manufacturing and supply chain of Active Pharmaceutical Ingredients
8. Update on the ICH Q12 guideline
  
9. A.O.B.

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