



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

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

PHARM 751

**PHARMACEUTICAL COMMITTEE**  
**23 October 2018**

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**Subject:** Draft agenda of the 81<sup>st</sup> meeting of the Pharmaceutical Committee  
23 October 2018

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Venue: Centre Albert Borschette, 36, rue Froissart, Brussels, meeting room **AB-2D**.

**Welcome coffee: 9.30 am – 10.00 am**

**PHARMACEUTICAL COMMITTEE**  
**DRAFT AGENDA**  
**10:00h – 13:00h**  
81<sup>st</sup> meeting, 23 October 2018  
Centre Albert Borschette, Brussels, **AB-2D**

**AGENDA**

- Adoption of draft agenda

**1. INTERPRETATION OF PHARMACEUTICAL LEGISLATION**

- i. Update on Court cases

**Action to be taken:** For information

**2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION**

- i. Feedback from the 8th meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)

**Action to be taken:** For information

- ii. Members States' reports on the audits of their pharmacovigilance systems

**Action to be taken:** For information

**3. LEGISLATIVE ISSUES**

- i. Update on the state-of-play of the evaluation of the orphan and paediatric regulations

**Action to be taken:** For information

- ii. Commission's Report on Product Information Leaflets and related activities

**Action to be taken:** For information

- iii. Evaluation of the legislation on blood tissue and cells

**Action to be taken:** For information

- iv. Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use

**Action to be taken:** For information

#### 4. AOB

- i. Shortages of medicinal products

**Action to be taken:** For information

- ii. Follow up to the questionnaire on safety measures

**Action to be taken:** For information

- iii. ICH Q12 public consultation

**Action to be taken:** For information

- iv. Note on the handling of duplicate marketing authorisation applications: the case of duplicates of biologicals/Public consultation

**Action to be taken:** For information

- v. Austrian Presidency proposal to present to the next meeting of the committee the work of the Health Ministries directors responsible for pharmaceutical policy platform. In particular they will present their work on proposals for concrete measures to address the disparity in access between Member States

**Action to be taken:** For information

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