EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

STAMP 4/19 rev.1

Draft

AGENDA

4th Meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) 10 March 2016 (10:00 – 18:00) Conference Centre Albert Borschette (CCAB), Room AB-2D 36 Rue Froissart, 1040 Brussels, Belgium

1. **Opening and adoption of the Agenda**
2. **Endorsement of the minutes of the 3rd STAMP meeting**
3. **Repurposing of established medicines/active substances**

   Background paper - presentation by the UK
4. **Real world evidence data collection** *(registries, health records etc)*

   Background paper - presentation by EMA

   Member State experience - presentation by Italy
5. **Update on European Medicines Agency activities:**
   a. Adaptive Pathways

      Replies from Member States to the questionnaire on adaptive pathway pilot project – presentation by EMA

      Presidency meeting on "Innovation for the benefit of the patient" - presentation by the NL

   b. PRIority MEdicines (PRIME) Scheme, CHMP scientific guidance on Conditional marketing authorisations, CHMP scientific guidance on Accelerated assessment – update by EMA
6. **Compassionate use programmes**

   EMA experience of compassionate use opinions – presentation by EMA

   Industry experience of compassionate use opinions – presentation by EFPIA

7. Personalised medicines

Commission funded research initiatives - presentation by the Commission (RTD)

Background paper - presentation by the Commission (SANTE)

8. Update on other EU initiatives relevant for timely patient access to innovative medicines

a. Conditional Marketing Authorisation Regulation – Commission (SANTE)

b. EU cooperation on Health Technology Assessment – Commission (SANTE)

c. Update on Multistakeholders Workshop and the Network of Competent Authorities on Pricing and Reimbursement of Pharmaceutical Products (CAPR) – Commission (GROW)

d. Publication of the EU Health Program Study on enhanced cross-country coordination in the area of pharmaceutical product pricing – Commission (SANTE)

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