EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

STAMP 3/13

AGENDA

3rd Meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) 20 October 2015 (10:00 – 18:00) Centre A. Borschette, Room AB-4D, Rue Froissart 36, 1040 Brussels, Belgium

1. **Opening and adoption of the Agenda**

2. **Endorsement of the minutes of the 2nd STAMP meeting**

3. **Regulatory tools for early access:**

   a. **Conditional marketing authorisations (CMA)**

   - Revised CHMP guidelines and summary of comments received during public consultation-Presentation by the European Medicines Agency (EMA)
   - Discussion on legal aspects related to CMA

   b. **Accelerated assessment**

   - Revised CHMP guidelines and summary of comments received during public consultation - Presentation by EMA
   - New scheme to support development of innovative medicines for unmet needs -Presentation by EMA and detailed discussion

   c. **Adaptive Pathways**

   - Comprehensive discussion on policy related issues on the basis of current experience from the EMA's pilot project**.** Presentation by EMA and detailed discussion
   - EMA's proposal for strategy on registries- Presentation by EMA and discussion
   - "Prescrire" position paper on adaptive pathways- Presentation by Ms Teresa Leonardo Alves International Policy Advisor, Prescrire

   d. **Cross-cutting issues for all tools**

   - A holistic approach and communication about all regulatory tools
   - Possible HTA aspects that could be addressed in the regulatory tools for early access under discussion

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

   a. IMI projects- Presentation by Ms Nathalie Seigneuret-Senior Scientific Project Manager, IMI

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