EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

STAMP 2/008

AGENDA

2nd Meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) 6 May 2015 (10:00 – 18:00) Centre A. Borschette, Room AB-3B, Rue Froissart 36, 1040 Brussels, Belgium

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

2. **Endorsement of the minutes of the 1st STAMP meeting**

3. **Regulatory tools for early access:**
   a. **Conditional marketing authorisations (CMA)**
   b. **Accelerated assessment**
   c. **Update on EMA's pilot project on Adaptive Pathways**

4. **Update on other EU initiatives relevant for timely patient access to innovative medicines**
   a. **"EU cooperation on HTA – latest developements" -** Tapani Piha, Head of SANTE Unit D3-e-Health and Health Technology Assessment**;** Prof. Finn Børlum Kristensen, Chair, Executive Committee of EUnetHTA
   b. **Information about Network of Competent Authorities on Pricing and Reimbursement of Pharmaceutical Products (CAPR)-** DG GROW Unit I.3

5. **Exchange of experiences from national routes (other than clinical trials) for making available medicines to patients before authorisation: early access schemes, compassionate use etc.**
   - The **UK Early Access to Medicines Scheme** - Presentation by the Medicines and Healthcare products Regulatory Agency (MHRA)

6. **Introduction of Ministry of Health Labour and Welfare of Japan(MHLW)/Pharmaceuticals and Medical Devices Agency (PMDA) and recent updates in Japan -** Mr. Yoshi Sano, PMDA's International Liaison Officer at EMA

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