EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

STAMP 1/001

DRAFT AGENDA

1st Meeting of the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) 27 January 2015 (10:00 – 18:00) Centre A. Borschette, Room AB-0C, Rue Froissart 36, BE-1040 Brussels, Belgium

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

2. **Scope and operation of the STAMP**

3. **Member States proposals for areas to be considered by the STAMP**

4. **Exchange of experiences from national routes (other than clinical trials) for making available medicines to patients before authorisation:** early access schemes, compassionate use etc.
   Member States to present on a volunteer basis

5. **EMA's pilot project on Adaptive Licensing:**
   a. Short presentation of the aims, principles and timelines of the pilot project
   b. Update on stage I of the project: the criteria for the selection of projects and information on selected cases
   c. Update on next steps of (stage II: in-depth discussion on selected cases)

6. **Regulatory tools for early access:**
   a. Results from the Escher project 'Improving the EU system for the marketing authorisation of medicines'[1] with regard to the use of conditional marketing authorisation for oncology medicines.

[1] http://escher.tipharma.com/fileadmin/media-archive/escher/Reports/Escher_report_IA.pdf

b. Experience with conditional marketing authorisations (CMA), with authorisation under exceptional circumstances and accelerate assessment- *European Medicines Agency*

c. FDA Breakthrough therapy designation

d. Member States' experience on results from the use of early access tools (conditional marketing authorisation, authorisation under exceptional circumstances, accelerated assessment) in terms of real time gains and availability of medicinal products to patients: problems, opportunities and lessons learnt.

7. Discussion and prioritisation of possibilities for more effective use of existing early access regulatory tools –work plan for next meetings

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