EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

STAMP 1/001 rev.2

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-3A, Rue Froissart 36, 1040 Brussels, Belgium

1. **Opening and adoption of the agenda**
   - *Opening remarks by **Dr A. RYS**, European Commission, **Director of Health systems and products***

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 voluntary basis:
   - *Presentation by the Federal Agency for Medicines and Health products- **Belgium***
   - *Presentation by the Ministry of Health **France***
   - *Presentation by the **Spanish Agency of Medicines and Medical Devices***

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)

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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-*presentation by the researchers of the study*

   b. FDA Breakthrough therapy designation program- *presentation by the FDA Europe Office*

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

   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.

      - Presentation of the study "Minds open" -*by the* ***Netherlands*** *National Institute for Public Health and the Environment*

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