



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

PAED 001

AGENDA

**Meeting with Member States and the European Medicines Agency on
The Paediatric Regulation
19 September 2016 (10:00 – 18:00)
CCAB, meeting room AB-3C
36 Rue Froissart, 1040 Brussels, Belgium**

- 1. Opening and adoption of the Agenda**
- 2. Setting the scene – The Paediatric Report**
- 3. The economic impact of the Paediatric Regulation**
Presentation by technopolis (Peter Varnai)
Questions and Answers
- 4. Experience with the Paediatric Regulation from a public health perspective**
Presentation by EMA based on the draft 10-year report (EMA)
Questions and Answers
- Lunch Break (13:15 – 14:30)*
- 5. Open floor – Exchange of views with Member States regarding their experience**
Tour de table – open floor discussion
- 6. Preview of the public consultation**
Consultation strategy
- 7. Closing remarks**

* * *