



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

1st EMEA Workshop on European Paediatric Network

AGENDA

16 February 2009, 9.00-16.30

7, Westferry Circus, Canary Wharf, London E14 4HB
EMEA, Conference Room 2A

~ Registration + Coffee ~
08.00 - 09.00

Chairpersons:

Dr Agnès Saint Raymond - Dr Gerard Pons

1. MORNING SESSION	09.00 – 12.30 (3h 30')
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- 1.1 *Welcome (10')*
Dr Thomas Lönngren - Executive Director - EMEA
- 1.2 *Introduction of participants (40')*
- 1.3 *EU Paediatric Regulation and the objectives of the EMEA European network (15')*
Dr Irmgard Eichler - Scientific Advice, Paediatric Medicines and Orphan Drugs Sector - EMEA
- 1.4 *The role of the Paediatric Committee and short history of previous activities (15')*
Dr Paolo Rossi, PDCO member
- 1.5 *Overview of PIPs reviewed and studies proposed per therapeutic area (10')*
Dr Ralf Herold - Scientific Advice, Paediatric Medicines and Orphan Drugs Sector – EMEA
- 1.6 *Questions and answers (20')*

~ Coffee Break ~
10:50 - 11:10

- 1.7 *Proposal for the organisation and structure of the EMEA network (15')*
Ms Elin Haf Davies - Scientific Advice, Paediatric Medicines and Orphan Drugs Sector - EMEA
- 1.8 *Proposals for quality standards and recognition criteria - Experience from existing networks (45')*
Prof David Edwards, MCRN
Dr Carlo Giaquinto, Fondazione PENTA Onlus
Prof Adriana Ceci, PDCO member, TEDDY NoE
- 1.9 *Questions and answers (20')*

~ Lunch Break ~
12:30 - 13:30

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- 2.1** *After the scene-setting presentations of the morning sessions the Break-out Groups will brainstorm, discuss and define (90'):*
- *Quality standards*
 - *Recognition criteria to be fulfilled by networks involved in the European network*
 - *Structure and operational model for the European network*
 - *Communication strategy*

Group 1 (Room 4B):

- *Structure and operational model for the European network*
 - *Communication strategy*
- Chair: Dr Paolo Rossi, PDCO member
Rapporteur: Dr Paolo Tomasi, EMEA

Group 2 (Room 4C):

- *Quality standards*
 - *Recognition criteria to be fulfilled by networks involved in the European network*
- Chair: Dr Christoph Male, PDCO member
Rapporteur: Dr Ralf Herold, EMEA

~ Coffee Break ~

15:00 - 15:20

- 2.2** *Reports from the break-out groups (30')*
Dr Paolo Tomasi - Scientific Advice, Paediatric Medicines and Orphan Drugs Sector – EMEA
Dr Ralf Herold- Scientific Advice, Paediatric Medicines and Orphan Drugs Sector – EMEA
- 2.3** *Open forum discussion (30')*
- 2.4** *Conclusions and next steps (10')*
Dr Agnès Saint Raymond - Scientific Advice, Paediatric Medicines and Orphan Drugs Sector - EMEA