EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 May 2010
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Human Medicines Development and Evaluation

Agenda - Workshop on Paediatric Formulations For Assessors in National Regulatory Agencies

31 May 2010, Time: 09:00-16:30, 2A

Chairpersons: Siri Wang and Emilie Desfontaine

Item	Preliminary draft agenda	Initials	Mins
1	Welcome and Conflict of Interest		
2	Introduction		
3	Discussions on topics		

Arrival and Registration / Coffee 08.00–08.45

Morning Session – First Part 09.00–10.40

1. Welcome and Conflict of Interest (5')

Participants will be asked to confirm that they have no conflict of interest in relation to any of the issues, products and applications to be discussed during the meeting.

2. Introduction (5')

A brief introduction of the objectives, topics, and participants of the Workshop will be given by the chairpersons.

3. Discussions on topics

3.1. Paediatric regulation: an update on submissions of paediatric investigation plans (20')

Speaker: Paolo Tomasi

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3.2. Introduction to the work of the PDCO Formulation Working Group: essentials on the paediatric needs with regard to formulations; assessing part D.II of paediatric investigation plans; challenges and difficulties (20')

Speaker: Siri Wang

3.3. Collaboration with other groups and committees such as WHO, FDA and EuPFI (20')

Speakers: Agnès Saint–Raymond, Piotr Kozarewicz and Caroline Le Barbier

3.4. New pharmaceutical form: definition (10')

Speaker: Thomas Girard

3.5. Presentation on preliminary data from paediatric investigation plans submitted to the PDCO Formulation Working Group for assessment: types of requests to and advice from the PDCO Formulation Working Group and PDCO based on proposals and arguments from the applicants (20')

Speakers: Blanca Quijano Ruiz and Caroline Bosc

Coffee Break 10.40–11.00

Morning Session – Second Part 11.00–13.00

3.6. Clinical paediatric issues with dosage forms (30')

- Acceptability/palatability of formulations, size, administration of IV formulations, through feeding tubes, etc.

Speakers: Sara Arenas-Lopez and Tony Nunn

3.7. Formulations for clinical trials in children: possibilities and pitfalls? (20')

Speaker: Robert Ancuceanu

3.8. Excipients: safe or not safe; what do we know? (60' + 10' questions)

- Preservatives (Article 29 example)

Speaker: Piotr Kozarewicz

- Antioxidants
- Colouring agents
- Taste masking agents and co-solvents

Speakers: Caroline Le Barbier and Pedro Franco

- Poorly water soluble substances: challenges, options and limitations for children

Speaker: Ann Marie Kaukonen

Lunch 13.00–14.00

Afternoon Session 14.00–16.30

3.9. Existing guidelines (i.e. regarding quality, formulation and excipients): what do we have; are they relevant for paediatrics? (30')

Speaker: George Wade

3.10. Draft 'Guideline on the Pharmaceutical Development of Medicines for Paediatric Use' (30')

Speaker: Diana Van Riet-Nales

3.11. Completion of the development of a formulation: requirements for compliance check versus requirements for marketing authorisation (30')

Speaker: Caroline Le Barbier and Pedro Franco

3.12. Assessment of a marketing authorisation application (30'):

- Awareness of the paediatric investigation plan recommendation, from a quality point of view
- Issue in relation to generic

Speaker: Pedro Franco

3.13. Conclusions (15')

Speaker: Chairpersons

Departure 16:30