



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 December 2009
EMA/809438/2009
Human Medicines Development and Evaluation

Paediatric rheumatology expert group meeting, London 4 December 2009

Chair: Dirk Mentzer, Richard Vesely

7 Westferry Circus, Canary Wharf, London E14 4HB

EMA 4th floor, Conference Room 4C

Aim:

To discuss various aspects of development, clinical use and pharmacovigilance of medicines for juvenile idiopathic arthritis and other paediatric rheumatic diseases.

09:00 – 09:05 Welcome, introduction, house-keeping (A.Saint-Raymond, Dirk Mentzer, Richard Vesely)

09:05 – 09:15 Overview of PIPs in paediatric rheumatology (Richard Vesely, Emma Sala Soriano)

Clinical trials in JIA

09:15 – 09:30 Overview of the expert responses to EMA questions (Richard Vesely)

Classification of JIA for clinical trials

- Systemic JIA
- Age groups for different JIA subtypes to be studied
- What can be extrapolated from adult studies?
- Extrapolation of efficacy within same (anti-TNF) class,
- Outcome measures,
- Uveitis

09:30 – 09:45 Design of paediatric rheumatology studies – time to move to active comparator? (Nicola Ruperto)

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09:45 – 10:45 Discussion

10:45 – 11:00 Coffee break

11:00 – 11:20 Outcome predictors – should we request biomarker and genetic studies during drug development? (Patricia Woo)

SLE and other paediatric rheumatic diseases

11:20 – 11:30 Overview of expert responses to EMEA questions (Richard Vesely)

11:30 – 12:00 Discussion

EMA guidelines for drug development in JIA

12:00 – 12:10 Creation and amendment of EMA guidelines (Marion Haberkamp)

12:10 – 12:30 Discussion

12.30 – 13.15 Lunch

Patient follow-up, registry and pharmacovigilance

13:15 – 13:25 Pharmacovigilance - introduction (Dirk Mentzer)

13:25 – 13:35 Role of EMA in patient registries (Jan Petracek)

13:35 – 13:55 Proposal for European registry of paediatric rheumatology patients treated with biologics (Nico Wulffraat)

13:55 – 14:10 Proposal for European registry for paediatric rheumatology patients treated with methotrexate (Nicola Ruperto)

14:10 -14:30 US observational registry – view from FDA (Jeffrey Siegel)

Biologics in paediatric gastroenterology

14:30 – 14:50 Overlapping issues with paediatric rheumatology and gastroenterology (Salvatore Cucchiara)

14:50 – 15:10 Coffee break

Discussion to all topics

15:10 – 16:20 Discussion
Plan for next activities (Richard Vesely)

Conclusion of the meeting

16:20 – 16:30 Summary and concluding remarks
(Agnes Saint-Raymond, Dirk Mentzer, Richard Vesely)