EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 May 2014
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Human Medicines Research & Development Support Division

Agenda – EMA paediatric osteoporosis expert meeting

02 June 2014 9.00 – 17.00, Room 2G

Chair: Richard Veselý, Viveca Odlind

Item	Preliminary draft agenda	Time	Speaker
1.	Welcome and introduction	9.00	Richard Veselý
2.	Paediatric osteoporosis – regulatory overview	9.05	Viveca Odlind
3.	Overview of agreed Paediatric Investigation Plans for treatment and prevention of osteoporosis	9.15	Richard Veselý
4.	Discussion I (Similarity of paediatric and adult osteoporosis, extrapolation)	9.30	All
5.	Coffee break	10.00	All
6.	Discussion II (Feasibility of paediatric studies, study design and duration, age of children to be included)	10.15	All
7.	Lunch break	12.00	
8.	Discussion III (Outcome measures, primary and secondary endpoints of the clinical studies)	13.00	All
9.	Coffee break	15.00	All
10.	Discussion IV (Glucocorticoid-induced osteoporosis, Osteogenesis imperfecta – specific considerations)	15.30	All
11.	Conclusions, next steps	16.30	Richard Veselý, Viveca Odlind
12.	End of the meeting	17.00	

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Questions proposed for discussion:

1. Is paediatric osteoporosis sufficiently similar to adult disease to allow extrapolation of efficacy of new medicines? Is PK/PD similar? Are outcome measures used in adults comparable with those in children?
2. Are studies in children feasible? What are the hurdles for paediatric studies? What are the realistic numbers of children available for studies?
3. If controlled studies in children are necessary, what control should be preferably used – placebo or active comparator (which?)?
4. What duration of study is necessary to establish efficacy and safety in children? Is there a difference for treatment studies and for prevention studies?
5. What is the age of children to be studied?
6. Is presence of fractures necessary for inclusion into treatment studies? Should prevention of fractures be studied in treatment studies? What children would be eligible for such treatment?
7. For glucocorticoid-induced osteoporosis what underlying diseases should be studied? Is there difference in treatment effect or can they be pooled together into one study?
8. What dosage of glucocorticoids represents a significant risk for development of GIOP?
9. What are the advantages/disadvantages of using fractures, bone mineral density, imaging techniques and laboratory markers as primary/secondary endpoints for clinical studies in children and what impact the selection of endpoints may have on the feasibility of the study?
10. What are the specificities of studies in osteogenesis imperfecta?