



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2014
EMA/785588/2013
Human Medicines Research and Development Support

Preliminary agenda of the pharmacovigilance in the paediatric population workshop

Monday 28 April 2014

Chair: Dirk Mentzer

Item	Preliminary draft agenda	Speaker	Time
1	Introduction	Dirk Mentzer <i>PDCO Chair, DE</i>	09:00 15'
2	Descriptive overview of paediatric versus adult ADRs in EudraVigilance: lessons learned for paediatric pharmacovigilance	Kevin Blake <i>EMA, UK</i>	09:15 15'
3	Feedback from the PRAC on paediatric safety issues	June Raine <i>MHRA, UK</i>	09:30 30'
4	Development of paediatric age group categories of organ maturation: brain, kidney, liver, bone, lung, skin and ear	Janina Karres <i>EMA, UK</i>	10:00 15'
5	Update on Standard EudraVigilance Query Reports	Cosimo Zaccaria <i>EMA, UK</i>	10:15 30'
	Coffee Break		10:45 20'
6	Routine signal detection and statistical tools on paediatrics	Cosimo Zaccaria <i>EMA, UK</i>	11.05 45'
7	List of most frequent paediatric Adverse Drug Reactions in Oncology Discussion	Ralf Herold <i>EMA, UK</i> All	11:50 45'



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8	Update on revision of the guideline for conduct of pharmacovigilance for medicines used by the paediatric population	Dirk Mentzer <i>PDCO Chair, DE</i>	12:35 30'
	Lunch		13:05 85'
9	Strengthening the interaction between PDCO and PRAC Discussion	Benjamin Pelle <i>EMA, UK</i> All	14:30 45'
	Coffee Break		15:15 20'
10	Active pharmacovigilance in the paediatric population: Example of Pharmachild registry Discussion on ways to improve active pharmacovigilance	Nicola Ruperto <i>PRINTO, IT</i> All	15:35 60'
11	A.O.B	All	16:35