

16 November 2010
EMA/719882/2010

Agenda – Paediatric – Rheumatology Expert Group Meeting

Wednesday 17 November 2010, Time: 10.00-16.00, Room 2G

Chair: Dirk Mentzer (DM), Richard Vesely (RV)

Invited experts: Tadej Avcin (TA), Michael Beresford (MB), Fabrizio De Benedetti (FDB), Pavla Dolezalova (PD), Ivan Foeldvari (IF), Alberto Martini (AM), Nicolino Ruperto (NR), Pierre Quartier (PQ), Patricia Woo (PW), Nico Wulfraat (NW), Stefan Hagelberg (SH), Taunton Southwood (TS), Hermine Brunner (HB), Carol Wallace (CW)

FDA Members: Sarah Okada, Nikolay Nikolov

CHMP Members: Heelan Bridget (HB), Nils Feltelius (NF)

PDCO Members: Daniel Brasseur (DB), Dirk Mentzer (DM), Johannes Taminiau (JT), Francesca Rocchi (FR), Agnes Gyurasics (AG), Matthew Thatcher (MT)

European Medicines Agency (EMA): Agnès Saint-Raymond (ASR), Paolo Tomasi (PT), Emma Sala Soriano (ESS), Edith La Mache (ELM), Michael Berntgen (MB), Antonio Addis (AA), Radhouane Cherif (CR), Thomas Castelnovo (TC), Beate Schmidt (BS).

Item	Preliminary draft agenda	Initials	Mins
09.00-10.00	Arrival and Registration		
10.00-11.00	MORNING SESSION – FIRST PART		
	1. Opening	ASR, PT	5
	2. Conclusions of previous expert meeting in December 20009 – follow-up	RV	10
	3. Update on rheumatology PIPs	RV	5
	4. Answers from experts to EMA questions 1 st part	RV	20
	5. Discussion		20
11.00- 11.15	<i>Coffee break</i>		15

Item	Preliminary draft agenda	Initials	Mins
11.15- 12.30	MORNING SESSION – SECOND PART		
	6. ACR treatment guidelines for JIA	NR	10
	7.Discussion		20
	8. Answers from experts to EMA questions -2 nd part	RV	10
	9.Why infliximab was not authorised for JIA? – what can be learned	NR	10
	10. Pharmacokinetics of tocilizumab	FDB	5
	11.Discussion		20
12.30- 13.00	<i>Lunch break</i>		30
13.00-14.30	AFTERNOON SESSION – FIRST PART		
	12. Answers from experts to EMA questions – 3 rd part.	RV	15
	13. Extrapolation – systematic approach	ASR	10
	14. Pharmacovigilance – ideas for future	DM	5
	15. Discussion		60
14.30- 14.45	<i>Coffee Break</i>		15
14.45- 16.00	AFTERNOON SESSION – SECOND PART		
	16. PharmaChild – Registry for children treated with biologics - update	NW	10
	17. Final discussions on outcome of the meeting		50
	18. Conclusions, final remarks and future steps	ASR	15
16.00	Departure	-----	----