



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 June 2010  
EMA/404170/2010

## Final Agenda – Experts Meeting on Gastroenterology and Rheumatology

Monday 28 June 2010, Time: 10.00-16.00, Room 1B

**Chair:** Johannes Taminau (JT), Richard Vesely (RV)

**Invited experts:** Hankje Escher (HE), Annamaria Staiano (AS), Frank Ruetteme (FR), Nicolino Ruperto (NR), Alberto Martini (AM), Nico Wulffraat (NW), Dirk Mentzer (DM), Daniel Brasseur (DB)

**European Medicines Agency (EMA):** Agnès Saint-Raymond (ASR), Paolo Tomasi (PT), Edith La Mache (ELM)

**Minutes:** Emma Sala Soriano (ESS)

Item	Preliminary draft agenda	Initials	Mins
<b>09.30-10.00</b>	<b>Arrival and Registration</b>		
<b>10.00-11.20</b>	<b>MORNING SESSION – FIRST PART</b>		
	1. Opening of the meeting		5
	2. Opening remarks – what is expected from the meeting	JT	5
	3. Overview of experts' answers to EMA questions	RV	15
	4. Overview of PIPs in paediatric gastroenterology	RV	5
	5. Discussion		50
11.20-11.35	<i>Coffee break</i>		
<b>11.35-12.40</b>	<b>MORNING SESSION – SECOND PART</b>		
	6. PRINTO experience with trials in paediatric rheumatology	NR	20
	7. Experience with IBD trials in children	HE/AS/FR	15
	8. Discussion		30
12.40-13.30	<i>Lunch break</i>		



Item	Preliminary draft agenda	Initials	Mins
<b>13.30-14.50</b>	<b>AFTERNOON SESSION – FIRST PART</b>		
	9. Pharmacovigilance – general issues and focus on gastroenterology	DM	5
	10. Paediatric rheumatology patient registry (PharmaChild project)	NW	15
	11. IBD patient registries in children	HE/AS/FR	20
	12. Discussion		40
14.50-15.05	<i>Coffee Break</i>		
<b>15.05-16.00</b>	<b>AFTERNOON SESSION – SECOND PART</b>		
	13. Final discussions on outcome of the meeting		25
	14. Conclusions, final remarks and future steps		30
<b>16.00</b>	<b>Departure</b>		