



17 December 2010
EMA/234804/2010

Final Agenda - Expert Meeting on Neonatal and Paediatric Sepsis

8 June 2010, Time: 09:00-16:30, Room 2G

Chairs: Paolo Rossi (PR), Radu Botgros (RB)

Invited experts: Paolo Rossi (PR), Hugo Devlieger(HD), Jean-Pierre Aboulker(JPA), Irja Lutsar(IL), Francesca Rocchi(FR), Marianne Orholm(MAO), Francesca Calò Carducci (FCC), Shane Tibby(ST), Ursula Trafojer(UT), Simon Nadel(SN), Paolo Manzoni(PM), Sara Arenas-Lopez(SAL), Uwe Ewald(UE), Christoph Härtel (CH) (Responses to list of questions contributions from: Adolf Valls-i-Soler, Erik Normann, Susanna Esposito)

European Medicines Agency: Paolo Tomasi(PT), Ralf Herold (RH), Ralph Bax(RBA), Eric Pelfrene (EP), Emma Sala Soriano(ES),

US FDA: via teleconference - Tom Smith and Lily Mulugeta

Item	Preliminary draft agenda	Initials	Mins
08.00 – 09.00	<i>Arrival and Registration / Coffee</i>		
09.00 – 10.30	<i>Morning Session – First Part</i>		
	1. Welcome of participants and declaration of any conflict of interest	RB	5
	2. Introduction	RB	5
	3. Discussions on topics:		
	3.1 Update from the previous meeting: presentation of the remaining discussion topics and of the expert's answers to the proposed list of questions	RB	30
	3.2 Neonatal organ failure scores –contribution from the Expert Working Group on Neonates	HD	25
	3.3 Paediatric organ failure scores – contribution from the Expert Working Group on the rest of the paediatric population	ST	25
10:30 – 11:00	<i>Coffee Break</i>		
	3.4 Age range for inclusion in clinical trials	PR	15
	3.5 Inclusion criteria: optimal timeframe for enrolment, biomarkers for population selection	PR	20



Item	Preliminary draft agenda	Initials	Mins
	3.6 Primary endpoints – particularities for different age groups (neonates) and for different mechanisms of action of the investigational drug (antibiotics)	PR	30
	3.7 The standard of care in severe sepsis	RB	45
13:00 – 14:00	<i>Lunch</i>		
	3.8 Early onset sepsis: clinical and biochemical criteria for diagnosis	PR	60
	3.9 AOB	RB	60
	3.11 Final discussions and conclusions	RB	30
16:30	<i>Departure</i>		