EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2010
EMA/572868/2010

Agenda – Expert Group Meeting on Paediatric Heart Failure

Monday 29 November 2010, Time: 09:30-17:00, Room 3C

Chair: Gylfi Oskarsson (GO), Dobromir Penkov (DP)

Invited Experts: Angeles Alonso Garcia (AAG), Teresa Hernández-Sampelayo Matos (THSM), Thomas Paul (TP), Michael Burch (MB), Martial Massin (MM), Brigitte Stiller (BS), Krishna Prasad (KP), Anna Turska-Kmieć (ATK), Anna Kaneva-Nencheva (AKN), Robert Shaddy (RS), Daphne Hsu (DH)

PDCO members: Gylfi Oskarsson (GO), Christoph Male (CM), Michal Odermarsky (MO), Hugo Devlieger (HD)

European Medicines Agency (EMA): Dobromir Penkov (DP), Dominik Schrey (DS)

Item	Preliminary draft agenda	Initials	Mins
09:00-09:30	**Arrival and registration**		
09:30-10:45	**MORNING SESSION – FIRST PART**		
1	Opening of the meeting		
2	Introduction: • Introduction of participants • EU Paediatric Regulation • Objective of the workshop	 DP GO	30
3	Drug classes for paediatric heart failure • currently used drugs, standard of care, and level of evidence • previous PIPs on drugs for paediatric HF • new drug classes in the pipeline • optimal properties of a drug for treatment of paediatric HF • priority list for drugs to be studied for paediatric HF	 MB CM KP	45
10:45-11:00	*Coffee break*		15

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Item	Preliminary draft agenda	Initials	Mins
11:00-12:30	**MORNING SESSION – SECOND PART**		
4	Types of paediatric HF, epidemiology, indications to be studied: • aetiological subtypes (congenital HD, myocarditis, CMP, arrhythmia) • left ventricular failure (high output, low output, high pressure), right ventricular failure (high pressure, high output), biventricular heart failure • acute/post-operative, chronic heart failure • efficacy data from adult population and their extrapolation to older children and from older to younger children for different indications	MM	90
12:30-13:15	*Lunch break*		45
13:15-15:30	**AFTERNOON SESSION – FIRST PART**		
6	Overall development plan – what type of studies are required and feasible? • pharmacokinetic and pharmacodynamic studies • safety studies • efficacy studies	MO	45
7	Study design issues: • choosing the study population (homogeneous population versus generalisability and feasibility) • baseline assessment • comparison groups • defining an optimal (composite) primary endpoint (responsive, clinically relevant, feasible)		90
15:30-15:45	*Coffee break*		15
15:45-17:00	**AFTERNOON SESSION – SECOND PART**		
8	Paediatric Cardiology Network for drug studies: • experience with the North American Paediatric Cardiology Network • steps required for establishment of an European Paediatric Cardiology Network for drug studies • cooperation between networks	RS	45
9	Other issues		30
17:00	**Departure**	--------	----