



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 April 2011
EMA/97974/2011
Human Medicines Development and Evaluation

Agenda - Expert Meeting on Clinical Investigation of New Drugs for the Treatment of Chronic Hepatitis C in the Paediatric Population

Monday 4 April 2011, 09:30-15:15, Room 3A

Chair: Ian Weller (IW)

External experts: Stefan Wirth (SW), Giorgina Mieli-Vergani (GMV), Deirdre Kelly (DK), Florence Lacaille (FL), Jose Luis Calleja (JLC), Lawrence Serfaty (LS), Filip Josephson (FJ), Nathalie Morgensztejn (NM), Luis Mendao (LM)

Paediatric Committee (PDCO): Daniel Brasseur (DB), Johannes Taminiau (JT), Maria Jesus Fernandez Cortizo (MFC) by TC, Marianne Orholm (MO), Sylvie Benchetrit (SB)

European Medicines Agency (EMA): Sophie Olivier (SO), Nathalie Seigneuret (NS), Rachel Turner (RT)

Food and Drug Administration (FDA): Linda Lewis (LL) by TC

Item	Agenda	Initials	Time Slots
	Arrival and registration/coffee		09:00 - 09:30
1	Welcome – Introduction Declaration of conflict of interest	IW	09:30 - 09:40
2	Draft EMA Guidelines – Paediatric Studies	FJ	09:40 - 09:50
3	ESPGHAN recommendations (November 2009)	SW	09:50 - 10:00
4	Recent Decisions on PIP applications	SO	10:00 - 10:15
5	Problem Statement and Initial Discussion	Panel	10:15 - 10:45
	<i>Coffee Break</i>		<i>10:45 - 11:00</i>
6	List of questions	SO	11:00 - 11:15
7	Panel Discussion	Panel	11:15 - 12:45
	<i>Lunch Break</i>		<i>12:45 - 13:30</i>
8	Consensus	Panel	13:30 - 15:00
9	Wrap-up	IW	15:00 - 15:15

