

23 May 2011
EMA/123284/2011

Agenda – EMA/EFPIA Info Day 2011

23 May 2011 – room 2A

Morning session: 9.00-13.00

Time	Co-Chairs: <i>Daniel Brasseur, Sue Forda</i>		
9.00	Welcome and general introduction	Andreas Pott, EMA Christine-Lise Julou, EFPIA	10 min
9.10	EMA report to the European Commission	Agnès Saint Raymond Florian Schmidt	30 min EMA/EC: 20 min Q&A: 10 min
9.40	EMA survey on all existing paediatric uses of medicinal products	Radu Botgros	30 min EMA: 20 min Q&A: 10 min

Q&A session: Daniel Brasseur (EMA/PDCO), Sue Forda (Eli Lilly), Agnès Saint Raymond (EMA), Florian Schmidt (EC), Radu Botgros (EMA)

10.10	Coffee Break		30 min
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	Co-Chairs: <i>Isabelle Stöckert, Dirk Mentzer</i>		
10.40	EFPIA survey results	Judith Creba Craig Johnson Angelika Joos Paolo Tomasi Agnès Saint Raymond	140 min EFPIA: 70 min EMA: 30 min Q&A: 40 min

Q&A session: Isabelle Stöckert (Bayer HealthCare), Dirk Mentzer (EMA/PDCO), Judith Creba (Novartis Pharma), Craig Johnson (Eli Lilly), Angelika Joos (Merck Sharp & Dome), Paolo Tomasi (EMA), Agnès Saint Raymond (EMA), Alban Dhanani (EMA/CMDh), Sophie Olivier (EMA), Peter Karolyi (EMA), Irmgard Eichler (EMA), Ralf Herold (EMA), Anne-Sophie Henry Eude (EMA), Konstantina Makrogianneli (EMA)

13.00	Lunch Break		60 min
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Afternoon session: 14.00-17.10

	Co-Chairs: <i>Eric Abadie, Gesa Pellier</i>		
14.00	Indications/Conditions	Ralph Bax (Cancelled)	30 min EMA: 20 min Q&A: 10 min
14.30	One PIP or multiple PIPs?	Magda Tovar Gomis	30 min EMA: 20 min Q&A: 10 min
15.00	Formulations	Caroline Le Barbier Isabel Esteve Garcia	30 min EMA: 20 min Q&A: 10 min
15.30	Compliance Check (including validation)	Peter Karolyi Ali Harrison	45 min EMA: 15 min EFPIA: 15 min Q&A: 15 min
16.15	Experience on article 46 of Paediatric Regulation	Gaëlle Andriantafika Michel Stoffel	40 min EMA: 15 min EFPIA: 15 min Q&A: 10 min
16.55	Conclusions	Agnès Saint Raymond Christine-Lise Julou	15 min

Q&A session: Eric Abadie (EMA/CHMP), Gesa Pellier (Novartis Pharma), Daniel Brasseur (EMA/PDCO) Ralph Bax (EMA), Magda Tovar Gomis (EMA), Thomas Girard (EMA), Caroline Le Barbier (EMA), Emilie Desfontaines (EMA), Siri Wang (EMA/PDCO), Peter Karolyi (EMA), Gaëlle Andriantafika (EMA), Paolo Tomasi (EMA), Agnès Saint Raymond (EMA), Alban Dhanani (EMA/CMDh), Sue Forda (Eli Lilly), Victoria Kitcatt (Pfizer), Karen Miller (GlaxoSmithKline) , Ali Harrison (AstraZeneca), Tom Sam (Merck Sharp & Dome), Michel Stoffel (GlaxoSmithKline Biologicals)