2011 European Medicines Agency / IFAH-Europe Info Day

'THE LATEST DEVELOPMENTS'
IN SCIENTIFIC REVIEW, LEGISLATION AND MARKETING AUTHORISATION PROCEDURES

10-11 March 2011, European Medicines Agency, London

Programme

Thursday 10th March 2011		
13:30	*Registration open*	
14:00	Introduction and Welcome	Andreas Pott (Acting Executive Director, European Medicines Agency)
Session I: Scientific Developments part 1		Chair: Rick Clayton (IFAH-Europe)
14:10	**Antimicrobial resistance activities** • Review of recent activities, developments and plans (20') • View of industry: perspectives for the future (20') Questions (10')	Karolina Törneke (Läkemedelsverket) Valerie Thomas (Chair IFAH-Europe Anti-infectives WP)
15:00	**The revised Bioequivalence guideline** • The key changes and scientific issues (20') • The approach taken by generic companies (10') Questions (10')	Marianne Bobey (Vice-chair IFAH-Europe Bioequivalence WP) Inge Sandberg (EGGVP)
15:40	Tea and Coffee (30')	
Session II: Scientific Developments part 2		Chair: Kornelia Grein (European Medicines Agency)
16:10	**Feedback from Environmental Risk Assessment focus group meetings** • Fate of VMPs in Manure and PBT guidelines (20') • Environmental Risk Assessment: the journey continues (20') Questions (10')	Alex Tait (VMD, co-chair CVMP ERA WP) Chris van den Eede (Chair IFAH-Europe Environmental Safety WP)
17:00	**CVMP work plan for 2011** Updates on latest developments from CVMP Working Parties, plans for focus group meetings (30') Questions (10')	Anja Holm (Chair, CVMP)
17:40	End of session	
18:00	Cocktail reception, followed by supper at 18:30	

Friday 11th March 2011

Session III:	**Procedural Updates from the European Medicines Agency**	Chair: David Mackay (European Medicines Agency)
09:00	E-submission of MA application dossiers Update from the Agency (20')	Barbara Cyrus (European Medicines Agency)
09:20	EMA interaction with other regions, including confidentiality agreements (20')	Emer Cooke (European Medicines Agency)
09:40	EMA transparency policy - big changes foreseen (20')	Nick Jarret (European Medicines Agency)
10:00	Scientific advice, including joint scientific advice with FDA (20')	Karen Quigley (European Medicines Agency)
10:20	Updated Post-authorisation guidance (10')	Ann-Christine Lantin (European Medicines Agency)
10:30	Questions (20')	
10:50	Tea and coffee (30')	
Session IV: Legislation Developments		Chair: Declan O'Brien (IFAH-Europe)
11:20	The Evaluation of the EMA – the recommendations going forward (20')	David Mackay (European Medicines Agency)
11:40	CVMP reflections regarding the Commission consultation on better regulation – review of the veterinary legislation (20')	Kornelia Grein (European Medicines Agency)
12:00	Questions (15')	
12:15	Review of the veterinary medicines legislation – what will be the impact? (30')	Rick Clayton (IFAH-Europe)
12:45	Questions (10')	
12:55	Close of the meeting	