2015 European Medicines Agency / IFAH-Europe Info Day

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

12-13 March 2015, European Medicines Agency (EMA), London

Programme

Thursday 12th March 2015		
13:30	*Registration open*	
14:00	Introduction and welcome	Andreas Pott; Deputy Executive Director (EMA)
Session I: Scientific Developments		Chair: Rick Clayton (IFAH-Europe)
14:10	**CVMP work plan for 2015** (30') Highlights and potential implications for new applications and developments	Anja Holm (CVMP)
14:40	**Update from the CVMP Immunologicals Working Party** – recent developments (20')	Esther Werner (CVMP)
15:00	**Update from the CVMP Environmental Risk Assessment Working Party** - assessment of VMPs containing persistent, bioaccumulative and toxic substances (15')	Boris Kolar (CVMP)
15:15	Questions (20')	
15:35	Tea and Coffee (30')	
Session II: Scientific Developments		Chair: Kornelia Grein (EMA)
16:05	**EMA advice on impact of the use of antibiotics in animals on public and animal health** (25') Potential impact on the authorisation of antimicrobials	Helen Jukes (CVMP)
16:30	**Innovation in veterinary medicines** (including antibiotics) - reflections from industry (25')	Erik de Ridder (Elanco/IFAH-Europe)
16:55	**Novel therapies** (30') ITF, scientific advice and new Ad Hoc group on Veterinary Novel Therapies (ADVENT)	Fia Westerholm (EMA)
17:25	Questions (35')	
18:00	Cocktail reception at Rocket Restaurant & Bar, followed by supper at 18:45	

Friday 13th March 2015

Session III: EU Procedural Updates		Chair: Melanie Leivers (EMA)
09:00	**MUMS policy – short update** (10') - Clarification of MUMS Policy - Industry viewpoint (5')	Kornelia Grein (EMA) Ludwig Klostermann (Bayer/IFAH-Europe)
09:15	Questions (5')	
09:20	**E-submissions Roadmap** (15') - Update on progress along the road - Where are we on the map? - Progress on harmonization with MSs - Industry viewpoint (points from the floor) (10')	Anne-Christine Lantin (EMA)
09:45	Questions (5')	
09:50	**Active Substance Master File** (10') Update of guidance, worksharing	Isabel Diaz (EMA)
10:00	**Pharmacovigilance** (40') Establishing a signal detection process - Experience to date with new procedures - Industry viewpoint	Jos Olaerts (EMA) Karen Quine (Ceva/IFAH-Europe)
10:40	Questions (20')	
11:00	Tea and Coffee (30')	
Session IV: Procedural updates and organisation		Chair: Roxane Feller (IFAH-Europe)
11:30	**Variations** (30') - Update/progress with worksharing - Outcome of joint stakeholder discussions to date - Progress of joint CMDv/industry task force	Melanie Leivers (EMA) Gavin Hall (VMD/CMDv) Kevin Yount (Bayer/IFAH-Europe)
12:00	Questions (15')	
12:15	**EMA reorganisation** (15') Update on structure and internal organisation	Kornelia Grein (EMA)
12:30	**EMA communication strategy** (15') Vision for veterinary medicines	Marie-Agnes Heine (EMA)
12:45	Close of the meeting (5')	Rick Clayton/Kornelia Grein