European Medicines Agency
Veterinary Medicines and Inspections

Europe IFAH
Representing the European Animal Health Industry

2009 EMEA/IFAH-Europe Info Day

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

12-13 March 2009, EMEA, London

Programme

Thursday 12th March 2008		
13:30	*Registration open*	
14:00	Introduction and Welcome	David Mackay, EMEA
Session I:	**Scientific Developments**	Chair: Kornelia Grein, EMEA
14:10	**An analysis of the changes to Annex 1 and their impact**	Ray Harding, Cyton confirmed
14:40	**An analysis of the changes to Annex 1 and their impact:** CVMP perspective	CVMP
15:10	Discussion	
15:30	**Review of main conclusions from recent scientific discussions**:	
	• Oncology guideline for cats and dogs	CVMP
	• PK/PD modelling	CVMP
15:55	Tea and Coffee	
16:15	**Biologicals** - Developments in scientific requirements and procedures	IWP Chair person
16:40	**ERA Requirements** - Clarification of requirements and procedures	ERA WP Chair or Vice Chair
17:05	Discussion	
17:25	**VICH**: an update on developments following the 22nd Steering Committee meeting in February 2009	Kornelia Grein, EMEA
17:45	Close of the session by the chairman	
18:00	Cocktail reception, followed by supper at 18:30, EMEA canteen	

Friday 13th March 2008

Session II:	**EMEA Bulletin board and procedures**	Chair: David Mackay, EMEA
09:00	**Review of priorities for CVMP and its working parties for 2009,** including plans for interactions with stakeholders	CVMP Chairperson
09:30	**Update on the Centralised Procedure** • Renewals and sunset clause: practical tips for compliance • E-presentations	Melanie Leivers, EMEA
09:45	**Survey of the centralized procedure** • Industry perspective • EMEA perspective	Sylvie Meillerais, IFAH-Europe EMEA
10:10	**MRL Regulation – where we are now**	EU Commission or EMEA Secretariat
10:30	Tea and coffee	
Session III:	**Legislation Developments**	Chair: Declan O'Brien, IFAH-Europe
10:50	**Variations Regulation** • Are we on the right track • Implementation proposal for the variation Regulation	IFAH-Europe Variations Task Force Melanie Leivers, EMEA
11:20	Discussion	
11:30	**Pharmacovigilance**: how should the current challenge be met? • Update on Volume 9B • Detailed description of pharmacovigilance • Streamlining PSURs	CVMP Pharmacovigilance Working Party
11:50	**Pharmacovigilance**: industry perspective on how the veterinary chapter should be reviewed	IFAH-Europe Pharmacovigilance Working Group
12:10	Questions	
12:20	**The 2010 Review**: IFAH-Europe proposals for optimising veterinary medicines legislation	Rick Clayton, IFAH-Europe
12:40	Questions	
12:50	Close of the meeting	Declan O'Brien and David Mackay