

2008 EMEA/ IFAH-Europe Info Day

'BALANCING THE BENEFITS AND RISKS OF VETERINARY MEDICINAL PRODUCTS'

13-14 March 2008, EMEA, London

Programme

Thursday 13th March 2008

13:45	Registration	
14:00	Introduction and Welcome	David Mackay (EMEA)
Session I: The benefit:risk assessment		
	<u>Chair:</u> David Mackay, Head of Vet. Unit and Inspections, EMEA Background and status of the CVMP Benefit:Risk Guideline	David Mackay
14:15	The industry reaction to the benefit:risk guideline	Neil Craven (Pfizer)
14:45	How to do a robust benefit:risk assessment • Including a response to industry's initial comments	Gérard Moulin (Chairman of the CVMP)
15:15	Discussion	
15:45	Tea and Coffee	
Session II: Outcome of recent discussions on new safety guidelines		
16:15	User safety guideline: conclusions of the December focus group meeting	Kevin Woodward (Schering-Plough), Johan Schefferlie (CVMP)
16:45	Discussion	
17:00	Environmental Risk Assessment • ERA Technical Guidance Document: conclusions of the January focus group meeting on developing a common understanding on its use and interpretation • Requirements for ERA under Dir 2001/82/EC, as amended. Development of guidance for all applications, including for generics, variations, renewals and extensions	Joop De Knecht (Chairman of the ERA WP), Leo van Leemput (Janssen) Kornelia Grein (EMEA)
17:30	Discussion	
18:00	Close of the session by the chairman	
18:15	Cocktail reception, followed by supper at 18:45, EMEA canteen	

Friday 14th March 2008

Session III: Update on Pharmacovigilance

Chair: Kornelia Grein, EMEA

09:00	Perspective of the veterinary practitioner	Jan Vaarten (FVE)
09:20	Progress with pharmacovigilance • Volume 9: status and content (what is changing) • Status of EudraVigilance Veterinary • Signal detection and related possible regulatory actions • Feedback from the December workshop on detailed description of Pharmacovigilance system and Pharmacovigilance inspections	Cornelia Ibrahim (Chairperson, CVMP Pharmacovigilance WP) and Fia Westerholm (EMEA)
09:50	Industry perspective on the future of veterinary pharmacovigilance , including follow-up to the December workshop	Bob Cornez (Alpharma)
10:10	Discussion	
10:30	Tea and coffee	

Session IV: Referrals

Chair: Jill Ashley-Smith, EMEA

10:50	Initial results from industry survey (article 33 referrals)	Sylvie Meillerais (IFAH-Europe)
11:05	Recent experience of referrals at CVMP	Gabriel Beechinor (IMB, and CVMP)
11:20	Recent experience of referrals at CMD(v)	Esther Werner (Chairperson, CMD-v)
11:35	Questions	

Session V: EMEA Bulletin board

Chair: Melanie Leivers, EMEA

11:45	EMEA/CVMP activities • Medicines availability • CVMP response to IFAH-Europe Benchmarking	David Mackay
12:00	E-presentations – update	Melanie Leivers
12:15	EMEA Cooperation agreement with FDA	Kornelia Grein
12:30	Questions and answers session to Vet Unit senior management and CVMP Chairman following a list of key points on CP functioning presented by industry	David Mackay, Kornelia Grein, Jill Ashley-Smith, Gérard Moulin, Melanie Leivers
13:00	Close of the meeting	David Mackay



European Medicines Agency
Veterinary Medicines and Inspections



REGISTRATION FORM

2008 EMEA/IFAH-Europe Info Day

London, 13-14 March 2008

Venue: EMEA, 7 Westferry Circus, Canary Wharf, London E14 4 HB

***Deadline for registration:
Monday 25 February 2008***

*The official registration confirmation will only be sent to the participants
who have duly completed this registration form.*

Name: First Name:
Title Company/Agency:
Address:
Postal code: City:
Country:
Phone: Fax:
Email: VAT (essential):

- ☐ will attend the EMEA/IFAH-Europe Info Day on 13-14 March 2008*
☐ will attend the cocktail reception and supper in the evening of 13 March 2008*

**tick as appropriate*

FOR INDUSTRY ONLY

REGISTRATION FEE: € 300,00 / person

(The registration fee covers documentation, coffee breaks, cocktail reception, supper and administrative charges;
the cancellation fee is Euro 30,00 / person after 25 February 2008)

Payments by cheque are not accepted

- ☐ I will pay by bank transfer to Fortis Bank - IBAN code BE73 0014 4916 6660 (Account n° 001-4491666-60) - Agence Louise, Avenue Louise 200 -1050 Bruxelles
(all costs borne by the payer)
Please include reference "EMEA/IFAH-Europe Info Day" and complete name

- ☐ By credit card: Amex ☐ Visa ☐ MasterCard ☐

Card number: Expiry Date: (MM/YY):

Cardholder's name Mr/Mrs/Ms:

Please return this form to *Marie-Hélène Delvaux, Secretary, Technical Department*
by e-mail (techsec@ifahsec.org) or by fax (+32 2 537 00 49)
before Monday 25 February 2008