

## 2010 European Medicines Agency/IFAH-Europe Info Day

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

11-12 March 2010, European Medicines Agency ('The Agency'), London

### Programme

#### Thursday 11th March 2010

13:30 Registration open

14:00 Introduction and Welcome

Thomas Lönngren  
(European Medicines Agency)

#### Session I: Scientific Developments

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')

Karolina Törneke  
(Läkemedelsverket)

Valerie Thomas (Chair IFAH-  
Europe Anti-infectives WP)

Questions (10')

15:00 **Feedback from Working Parties of CVMP and recent focus group meetings**

- Workshop on Medicines for bees (20')
- CVMP **Efficacy WP** (10')
- Joint CVMP/CHMP **Quality WP** (10')
- CVMP **Immunologicals WP** (10')

Kornelia Grein (The Agency)

Barbara Cyrus (The Agency)

Teresa Potter (The Agency)

Nik Križ (The Agency)

Questions (10')

16:00 **Tea and Coffee (30')**

#### Session II: Scientific Developments

Chair: Kornelia Grein (European  
Medicines Agency)

16:30 **Feedback from Working Parties of CVMP and recent focus group meetings (contd.)**

- Fate of VMPs in Manure (20')
- Feedback on operation of the "Technical Guidance Document" (20')

Joop de Knecht (RIVM, chair  
CVMP ERA WP)

Chris van den Eede (Alpharma,  
Chair IFAH-Europe Environmental  
Safety WP)

Questions (10')

17:20 **Referrals**

- Referrals survey 2008
- CVMP view on referrals

Yara Antonissen (IFAH-Europe)

Ruth Kearsley (VMD)

17:50 Questions

18:00 **Cocktail reception, followed by supper at 18:30**

**Friday 12<sup>th</sup> March 2010**

**Session III: Procedural Updates from the European Medicines Agency**

Chair: David Mackay (European Medicines Agency)

09:00 **Progress in electronic submission (20')**

Erik Waterdrinker (Virbac)

Including e-application form project

09:20 **Pharmacovigilance (30')**

- Volume 9B
- Inspections

Fia Westerholm (The Agency)

Fergus Sweeney (The Agency)

09:50 **Agency interaction with other regions (15')**

David Mackay

- confidentiality agreements,
- joint discussions
- exchanges of info

10:05 **Volume 6B (10')**

Karin Krauss (European Commission) (tbc)

**New vet unit structure (10')**

Kornelia Grein (The Agency)

10:35 [Tea and coffee](#)

**Session IV: Legislation Developments**

Chair: Declan O'Brien (IFAH-Europe)

11:00 **Implementation of the new variations regulation (20')**

Melanie Leivers (The Agency)  
Sylvie Meillerais (IFAH-Europe)

11:20 Questions (10')

11:30 **Implementation of the new MRL regulation (20')**

Isaura Duarte (The Agency)

12:00 Questions (10')

12:10 Close of the meeting

Rick Clayton (IFAH-Europe)

David Mackay (The Agency)