

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')
- Environmental Risk Assessment: the mutual journey (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 12th 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 **European Medicines Agency Road map to 2015 (20')**

[David Mackay](#)

- Agency interaction with other regions
- confidentiality agreements, joint discussions, exchanges of info

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

[Karin Krauss](#) (European Commission) (tbc)

10:20 Questions (15')

10:35 [Tea and coffee](#)

Session IV: Legislation Developments

Chair: Declan O'Brien (IFAH-Europe)

11:10 **Implementation of the new variations regulation (20')**

[Melanie Leivers](#) (The Agency)
[Sylvie Meillerais](#) (IFAH-Europe)

11:30 Questions (10')

11:40 **Implementation of the new MRL regulation (20')**

[Isaura Duarte](#) (The Agency)

12:00 Questions (10')

12:10 **New vet unit structure (10')**

[Kornelia Grein](#) (The Agency)

12:20 - Close of the meeting

[Rick Clayton](#) (IFAH-Europe)

12:30