

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 (30')

- Referrals survey 2008
- CVMP view on referrals

Yara Antonissen (IFAH-Europe)

Ruth Kearsley (VMD)

Questions (10')

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 (The Agency)

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

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

Karin Krauss (European Commission)

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)

Questions (10')

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

Isaura Duarte (The Agency)

Questions (10')

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

Kornelia Grein (The Agency)

12:20 Close of the meeting (10')

Rick Clayton (IFAH-Europe)

12:30 [End of meeting](#)