

2016 European Medicines Agency/IFAH-Europe Info Day

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

17-18 March 2016, European Medicines Agency (EMA), London

Programme

Thursday 17th March 2016

13:30 Registration open

14:00 Introduction and welcome David Mackay, Head of Veterinary Medicines Division (EMA)

Session I: Scientific Developments

Chair: Rick Clayton (IFAH-Europe)

14:10 **CVMP work plan for 2016** Anja Holm (Chair CVMP)
Highlights and potential implications for new applications and developments (20')

14:30 **CVMP activities regarding antimicrobials** Helen Jukes (Chair CVMP Antimicrobials WP)
Ongoing and recent activities (30')

15:00 **Workshop on data requirements for vaccines March 2015 – Impact on availability**
- Conclusions of workshop and follow-up actions (20') Faye Ioannou (EMA)
- Reflections from Industry (20') David John (IFAH-Europe)

15:40 Questions (20')

16:00 Tea and Coffee (30')

Session II: Scientific Developments

Chair: Isaura Duarte (EMA)

16:30 **Pharmacovigilance and signal management**
- Experience and trend for future (30') Peter Ekström (Chair CVMP Pharmacovigilance WP)
- Industry viewpoint (15') Jaume Colomer (IFAH-Europe)

17:15 **VICH update**
- Update on VICH activities (15') Nick Jarrett (EMA)
- Update on work on biologicals (10') Esther Werner (Chair CVMP Immunologicals WP)

17:40 Questions (20')

18:00 Cocktail reception at The Pearson Room Restaurant, followed by supper at 18:45

Friday 18th March 2016

Session III: EU Procedural Updates

Chair: David Mackay (EMA)

09:00 **EMA procedural updates** (15')

- Pre-authorisation procedures
- Post-authorisation procedures

Fia Westerholm (EMA)
Melanie Leivers (EMA)

09:15 Questions (10')

09:25 **E-submissions update** (15')

- Update on developments
- E-application form
- Progress on harmonization with MSs
- Industry viewpoint (points from the floor) (10')

Dorota Stark (EMA)

09:50 Questions (5')

09:55 **Development of veterinary novel therapies: Update** (10')

Minna Leppanen (EMA)

10:05 **Stakeholders liaison – update on EMA policy** (15')

Melanie Carr (EMA)

10:20 Questions (10')

10:30 **Tea and Coffee** (30')

Session IV: The wider perspective / Regulatory Policy

Chair: Roxane Feller (IFAH-Europe)

11:00 **Update on the revision of the veterinary legislation** (20')

Stefano Soro (European Commission)

11:20 Questions (10')

11:30 **IFAH-Europe Global Benchmarking Study - Highlights of 2015 report for Europe** (30')

Rick Clayton (IFAH-Europe)

12:00 Questions (10')

12:10 **EU Network Strategy**

- Vision for veterinary medicines (20')
- Industry viewpoint (10')

David Mackay (EMA)
Roxane Feller (IFAH-Europe)

12:40 Questions (10')

12:50 Close of the meeting (5')

Roxane Feller/David Mackay