

2014 European Medicines Agency/IFAH-Europe Info Day

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

13-14 March 2014, European Medicines Agency (EMA), London

Programme

Thursday 13th March 2014

13:30 Registration open

14:00 Introduction and welcome

David Mackay, Head of
Veterinary Medicines (EMA)

Session I: Scientific Developments

Chair: Rick Clayton, IFAH-Europe

14:10 **CVMP work plan for 2014** (30')
Highlights and potential implications for new applications
and developments

Anja Holm, CVMP

14:40 **Pharmacovigilance** -Vision and needs for the future

- Industry perspective (20')

Karen Quine (CEVA/IFAH-
Europe)

- EMA view (20')

Jos Olaerts (EMA)

15:20 Questions (20')

15:40 Tea and Coffee (30')

Session II: Scientific Developments

Chair: Kornelia Grein, EMA

16:10 **Consumer safety issues**
- Upcoming actions for the implementation of the MRL
regulation (10')

Martinus Nagtzaam (European
Commission)

- Approach for injection site residues (10')

CVMP speaker

16:30 **Demonstration of efficacy for veterinary medicines
containing antimicrobials** (30')
Key developments and outcome of focus group

CVMP speaker

17:00 **Update on guidance on user safety** (10')

Nicholas Jarrett (EMA)

17:10 Questions (20')

17:30 Cocktail reception, followed by supper at 18:30

Friday 14th March 2014

Session III: EU Procedural Updates

Chair: David Mackay, EMA

09:00 **Clarification of MUMS Policy** (20')

EMA/CVMP

09:20 **Industry feedback on MUMS Policy** (20')

Alexander Böttner (MSD/IFAH-
Europe)

09:40	Packaging and labelling (20')	CVMP speaker
	QRD template, opportunities for reduced label text and multi-lingual labels, recent examples	
10:00	Pre-submission phase and guidance for novel products (30')	Fia Westerholm, Nikolaus Križ (EMA)
	incl. Innovation Task Force, scientific advice, updates on pre-submission guidance	
10:30	Trends in veterinary medicines (10')	David Mackay (EMA)
10:40	Questions (20')	
11:00	Tea and Coffee (30')	
Session IV: Procedural updates - Variations		Chair: Declan O'Brien, IFAH-Europe
11:30	Variations and progress on worksharing (20')	Melanie Leivers (EMA) and CMDv comments
11:50	Variation guidelines (20')	Rose-Marie Molina (Merial/IFAH-Europe)
	Impact on administrative burden and fees	
12:10	EMA IT strategy (20')	David Mackay (EMA)
	An update	
12:30	Update on Agency move (10')	Agneta Brandt (EMA)
12:40	Questions (20')	
13:00	Close of the meeting	Rick Clayton/Kornelia Grein