

2012 European Medicines Agency/IFAH-Europe Info Day

'THE LATEST DEVELOPMENTS'
IN SCIENTIFIC REVIEW, LEGISLATION AND MARKETING AUTHORISATION PROCEDURES
8-9 March 2012, European Medicines Agency, London

Programme

Thursday 8th March 2012

13:30 Registration open

14:00 Introduction and Welcome

Andreas Pott, EMA

Session I: Scientific Developments

Chair: Rick Clayton, IFAH-Europe

14:10 Antimicrobial resistance activities

- The European Commission's action plan against the rising threats from antimicrobial resistance – a holistic approach
- Review of recent activities, developments and plans of CVMP
- Industry: perspectives for the future

Karin Krauss, European Commission

Karolina Törneke, CVMP

Declan O'Brien, IFAH-Europe

Questions

15:10 Immunologicals

- Review of recent activities, developments and plans

Nikolaus Križ, EMA

Questions

15:40 Tea and Coffee

Session II: Scientific Developments

Chair: David Mackay, EMA

16:10 Latest developments in VICH guidelines

Rick Clayton, IFAH-Europe

Questions

16:40 Pharmacovigilance

- Update on developments (including databases, signal detection, inspections)
- Industry perspective

Jos Olaerts, EMA

Marie-Odile Hendrickx,
Pfizer/IFAH-Europe

Questions

17:20 New technologies and innovative medicines

- Latest thinking on how to manage these
- Industry perspective

David Mackay, EMA

Elanco, IFAH-Europe

Questions

18:00 CVMP Work programme for 2012

- Including reports on the scientific challenges facing the CVMP and the Working Parties of CVMP

Anja Holm, CVMP Chair

Questions

18:30 Cocktail reception, followed by supper at 19:00

Friday 9th March 2012

Session III: EMA Procedural Updates and wider international harmonisation

Chair: Kornelia Grein, EMA

09:00 Progress in electronic submission

- Project update (Including e-application form project)
- Industry perspective

Anne-Christine Lantin, EMA

Corinne-Philippe Reversat,
Merial/IFAH-Europe

Questions

09:45 European Medicines Agency Road map to 2015

- Progress on implementation

Melanie Leivers, EMA

10:00 VICH wider international harmonisation initiative

Brigitte Boenisch, Merial/IFAH-Europe

Questions

10:30 Tea and coffee

Session IV: Future Legislation

Chair: Declan O'Brien, IFAH-Europe

11:00 Update on the review of the legislation

Martinus Nagtzaam, European Commission (TBC)

11:20 Outcome of Packaging and Labelling workshops

- Report from workshops held jointly with CMDv/CVMP/IFAH-Europe/FVE

Jiří Bureš, CMDv/CVMP

Questions

11:45 SPC harmonisation (CVMP/CMDv Task Force)

Kornelia Grein, EMA

Questions

12:15 IFAH Benchmarking Study

Barbara Freischem, IFAH

12:35 Close of the meeting

Rick Clayton/Kornelia Grein