

2009 EMEA/ IFAH-Europe Info Day

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

12-13 March 2009, EMEA, London

Programme

Thursday 12th March 2009

13:30 Registration open

14:00 Introduction and Welcome

Thomas Lönngren, EMEA

Session I: Scientific Developments

Chair: Kornelia Grein, EMEA

14:10 **An analysis of the changes to Annex I and their impact**

- Title I: Part 1 (Summary) and Part 2 (Pharmaceutical Quality)
- Title I: Part 3 (Safety and residue tests) and Part 4 (Clinical) and Title III (Specific marketing authorisations)
- Title II (Immunologicals) and Title IV (particular products – immunologicals)

Wilhelm Schlumbohm,
CVMP
Ray Harding, Cyton

Nikolaus Križ, EMEA

15:10 Discussion

15:30 **Review of main conclusions from recent scientific discussions:**

- Oncology guideline for cats and dogs
- PK/PD modelling

Barbara Cyrus, EMEA
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15:55 **Tea and Coffee**

16:15 **Biologicals** - Developments in scientific requirements and procedures

Jean-Claude Rouby,
IWP Chair

16:40 **ERA Requirements** - Clarification of requirements and procedures

Alex Tait,
ERA WP Vice Chair

17:05 Discussion

17:25 **VICH:** an update on developments following the 22nd Steering Committee meeting in February 2009

Kornelia Grein, EMEA

17:45 Close of the session by the chairman

18:00 **Cocktail reception, followed by supper at 18:30, EMEA canteen**

Friday 13th March 2009

Session II: EMEA Bulletin board and procedures

Chair: David Mackay, EMEA

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| 09:00 | Review of priorities for CVMP and its working parties for 2009, including plans for interactions with stakeholders | Anja Holm, CVMP Vice Chair |
| 09:30 | Update on the Centralised Procedure <ul style="list-style-type: none"> Renewals and sunset clause: practical tips for compliance E-presentations | Melanie Leivers, EMEA |
| 09:45 | Survey of the centralized procedure <ul style="list-style-type: none"> Industry perspective EMEA perspective | Sylvie Meillerais, IFAH-Europe
Veronica Picciafuoco, EMEA |
| 10:10 | MRL Regulation – where we are now | Isaura Duarte, EMEA |

10:30 [Tea and coffee](#)

Session III: Legislation Developments

Chair: Declan O'Brien, IFAH-Europe

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| 10:50 | Variations Regulation <ul style="list-style-type: none"> Are we on the right track Implementation proposal for the variation Regulation | Jacques Cuvelier, IFAH-Europe Variations Task Force
Melanie Leivers, EMEA |
| 11:20 | Discussion | |
| 11:30 | Pharmacovigilance: how should the current challenge be met? <ul style="list-style-type: none"> Update on Volume 9B Detailed description of pharmacovigilance Streamlining PSURs | Fia Westerholm, EMEA |
| 11:50 | Pharmacovigilance: industry perspective on how the veterinary chapter should be reviewed | Bob Cornez, IFAH-Europe Pharmacovigilance Working Group |
| 12:10 | Questions | |
| 12:20 | The 2010 Review: IFAH-Europe proposals for optimising veterinary medicines legislation | Rick Clayton, IFAH-Europe |
| 12:40 | Questions | |
| 12:50 | Close of the meeting | Declan O'Brien and David Mackay |