VICH Impact and future expectations

Programme

June 23, 2010

4:00 – 7:00 PM Registration Open
6:00 PM Welcome Reception

DAY 1 (June 24, 2010)

8:00 AM – 4:00 PM Registration Open

9:00 AM Plenary Session I:

Official Opening Session
Chair: Bernard Vallat, Director of OIE

Introductory Remarks
Martin Terberger, European Commission

09:25 AM VICH – where are we?
- **VICH Phase I and II: strategy and achievements**

Hervé Marion VICH secretariat

9:45 AM Keynote Addresses: The needs and expectations of regulatory authorities outside the VICH regions
Mr. Issoufou Dare (UEMOA) West Africa Region
Representative of the Ministry of Agriculture, People's Republic of China
Dr. Marcos Vinicius de S. Lendro, MAPA, Brazil

10:30 AM Keynote Address: The needs and expectations of a global industry
Mr. Eric Maree (Virbac), IFAH Board president

10:50 AM Questions

11:00 AM Coffee break

11:30 AM – 17:00 PM Workshops and Poster session

Three workshops (two from 'stream 1' and one from 'stream 2') and a poster session will run in parallel; there will be three sessions each of one hour duration, separated by a lunch break and an afternoon tea/coffee break. Each of the nine workshops will be run by a chairperson who will be assisted by a rapporteur. The conclusions of the workshops will be presented to the plenary session on day 2 of the conference.

For more details on the workshops please see the next page.

Workshops Stream 1: Impact of VICH guidelines and future topics

Review and discussion of guidelines adopted, scientific issues, impact of the guidelines locally and globally, new topics, future vision with members of the expert working groups (EWGs).

Session 1: (a) EWG on Safety (toxicology) and EWG on Target Animal Safety (TAS) (Pharmaceuticals); plus: Implementing the "3Rs" (welfare of experimental animals)
(b) EWG on Pharmacovigilance

Session 2: (a) EWG on Metabolism and Residue Kinetics
(b) EWG on Biological quality monitoring and EWG on TAS (Biologicals)

Session 3: (a) EWG on Microbiological ADI (acceptable daily intake of residues)
(b) EWGs on Quality, Efficacy, and Environmental Risk Assessment

Workshops Stream 2: VICH as a global partner

The needs and expectations of regulatory authorities in non-VICH regions; the needs and expectations of industry, VICH outreach, vision for the future.

Session 1: Global environment for veterinary medicines

- OIE Strategy and role in animal health
- Role of CODEX and JECFA
- Role of VICH
- Discussion

Session 2: Plans for VICH Global Outreach

- The results of the OIE/VICH survey
- Needs of non-VICH countries
- Proposal for VICH Global Outreach – new topics from non-VICH countries, information sharing, communication, training, assistance in implementation.
- Discussion

Session 3: Value and Future Vision (VICH Phase III)

- What value does VICH bring (to industry / regulators / animal health / other)?
- What are the future objectives and needs?
- Which aspects of the VICH mandate should be changed to accommodate future needs?
- Which key elements require consideration in the phase III strategy?

Poster session

Session 1: with experts present from:

- - Metabolism and Residue Kinetics
- - Quality
- - Efficacy (anthelmintics)

Session 2: with experts present from:

- - Safety
- - Environmental safety
- - Microbiological ADI

Session 3: with experts present from:

- - Pharmacovigilance
- - Biological Quality Monitoring
- - ECVAM/ICVAM/JCVAM

5:00 PM **Adjourn for the day**

6:00 PM **Gala dinner** ***(Meeting at 6:00 PM at the dinner venue)***

DAY 2 (June 25, 2010)

(7:30 AM – 4:00 PM Day 2 Registration)

08:30 AM **Plenary Session II: Reports from Stream 1 Workshops on "Impact, value, key areas of scientific debate, and future topics"**
Chair: Tadashi Nagata, JVPA

- EWG on Biological topics
- EWG on Microbiological ADI
- EWG on Safety
- EWG on METRES
- EWG on Pharmacovigilance
- EWGs on Quality, Efficacy and EIA

10:00 **Panel discussion**

10:30 AM **Coffee break**

11:00 AM **Plenary Session III: Reports from Stream 2 Workshops**
Chair: Monique Eloit, Deputy Director General OIE

- Session 1 (*rapporteur*)
- Session 2 (*rapporteur*)
- Session 3 (*rapporteur*)
- Summary Presentation from OIE, Patrick Dehaumont, OIE

Panel discussion

12:30 PM **Lunch**

2:00 PM **Plenary Session IV: Benefits and Impact of the VICH Initiative; and spreading the word**
Chair: Bernadette Dunham, FDA
Panel: a member of each VICH region, plus India, China, Brazil, AAHA
Panel discussion with representatives from the regulatory agencies and industry from the participating regions and observer nations and Non-VICH countries; to discuss the benefits and impact of the VICH initiative, and how to spread the word to other countries so that VICH guidelines are recognised, or products authorised in VICH regions.

3:20 PM **Coffee Break**

3:50 PM **Plenary Session V: VICH – The Vision for the Future**
Chair: Barbara Freischem, IFAH Executive Director

The Progress of ICH, Michelle Limoli, FDA

How can VICH be inspired from the evolutions in ICH? Martin Terberger, European Commission

VICH Phase III future opportunities, Ludwig Klostermann, IFAH-Europe

4:50 PM **Conclusion of Conference,** David Mackay, EMEA
5:00 PM **Closure of the Conference**