

Steering Committee

(Chairperson rotates among the three full member regions, in accordance to the location of the meeting)



Paris, June 2010

Introduction

VICH consists of a Steering Committee (SC) responsible for decisions and governance of the process and Expert Working Groups (EWG) responsible for technical input. The VICH Steering Committee is the driver of the harmonisation process.

The Steering Committee is the only structure that is empowered to take decisions such as selecting topics, releasing draft guidelines for consultation and adopting final guidelines for implementation in the three regions. The SC is also responsible for the organisational charter of VICH and for establishing the VICH Strategy and Work Programme. The VICH Steering Committee meets every 9 months; the location of meetings alternates between Japan, the EU and the US.

Steering Committee Composition

Members: B. Livingston and M. Mc Gowan (AHI), M. Terberger and G. Moulin (EU), L. Klostermann and B. Boenisch (IFAH-Europe), T. Komatsu and M. Kajiwara (JVPA),

Y. Endo and K. Ikeda (JMAFF), M. V. Smith and B. E. Rippe (US FDA)

Coordinators: B. Livingston (AHI), K. Grein (EU), R. Clayton (IFAH-Europe), K. Noda (JMAFF), O. Itoh (JVPA), M. Limoli (FDA/USDA), W. Hughes (AU/NZ)

Observers: D. Morris (APVMA/ACVM), P. Holdsworth (Animal Health Alliance/AGCARM), I. Alexander (Health Canada), J. Szkotnicki (CAHI)

OIE: P. Dehaumont

Secretariat: B. Freischem and H. Marion (IFAH)



VICH Coordinators

Each SC member appoints a coordinator to act as contact point with the VICH secretariat. The coordinators can actively participate in SC meetings but have no voting rights.

Observer members

(1 delegate per observer member)

Australia, New Zealand and Canada, from both the regulatory authorities and the industry associations, are observers to VICH. Observer members participate in SC meetings and have the opportunity to take part in the discussion, but they do not take part in any vote and do not sign-off any draft or final guideline.

Observer members

(1 delegate per observer member)

An interested party can request to attend the VICH SC meetings, but has no right to contribute to the discussions or intervene, unless requested by the chair to provide certain information. The interested party is currently the Association of Veterinary Biologics Companies (USA).

The role of the OIE

OIE provides support to VICH and encourages its member countries to take into consideration the VICH results. OIE indeed considers that the International harmonisation process of pre and post marketing authorisation of veterinary medicines is a necessity for animal health, public health and facilitation of international trade, and that VICH is one of the necessary tools to achieve these aims. In order to provide OIE member countries with full information about the trilateral harmonisation efforts between the USA, Japan and the EU, OIE circulates relevant VICH documents to OIE member countries for comments and circulates final VICH Guidelines.

The role of the Steering Committee

- ❖ Perform an analysis of existing gaps where the development of VICH guidelines could produce a benefit for all members (consideration of any new topic requires a concept paper containing an adequate feasibility assessment);
- ❖ Determine the working procedures;
- ❖ Determine the priority items based on concept papers prepared by its members;
- ❖ Set up the appropriate Expert Working Groups (EWGs) and appoint topic leaders and EWG chairpersons;
- ❖ Consider and resolve issues raised by the Expert Working Groups;
- ❖ Approve the draft recommendations issued by EWGs before release for world-wide consultation and subsequently for approval by the regulatory authorities of the EU, Japan and the USA;
- ❖ Take responsibility for monitoring the maintenance and review of Guidelines;
- ❖ Agree assignments at the end of the SC meeting recorded on an actions table with deadlines.

New topics

The Steering Committee defines a priority item from a detailed concept paper sponsored by one of its members; establishes an appropriate EWG, if needed and designates a chairperson. A topic leader in charge of drafting a Guideline is appointed and given a clear mandate to do the expected work.

The SC members and coordinators ensure that each expert is properly briefed and has a clear mandate enabling him/her to meet the expected outcome in the timeframe defined by the SC, in accordance with established VICH guidance; and ensure that each topic leader has the required competence and interpersonal skills to lead an EWG and achieve its objectives.