VICH/96/002
Revision 6 – November 2000
Final

ORGANISATIONAL CHARTER OF VICH

1. Name of the international body

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

2. Objectives

- To provide a forum for a constructive dialogue between regulatory authorities and the veterinary medicinal products industry on the real and perceived differences in the technical requirements for product registration in the EU, Japan and the USA, with the expectation that such a process may serve as a catalyst for a wider international harmonisation;
- To identify areas where modifications in technical requirements or greater mutual acceptance of research and development procedures could lead to a more economical use of human, animal and material resources, without compromising safety;
- To make recommendations on practical ways to achieve harmonisation in technical requirements affecting registration of veterinary medicinal products (pharmaceuticals, biologicals, medicated premixes) and to implement these recommendations in the three regions. Once adopted, the VICH recommendations will replace corresponding regional requirements. These recommendations should focus on the essential scientific requirements needed to address a topic and should eliminate unnecessary or redundant requirements;
- The VICH should be conducted in a transparent time- and cost-effective manner and should provide the opportunity for public comment on recommendations at the draft stage.

3. General organisation

- VICH activities are carried out under the auspices of the Office International des Epizooties (OIE)
- *A single steering committee (SC)*:
  - determines the working procedures;
  - determines the priority items based on concept papers prepared by its members;
  - sets up the appropriate working groups and appoints topic leaders and WG chairpersons;
  - approves the draft recommendations issued by working groups before release for world-wide consultation and subsequently for approval by the competent authorities of the EU, Japan and the USA.
- *Task-oriented working groups (WG)*:
  - elaborate draft recommendations for the priority items determined by the SC;
  - submit these draft recommendations and the revised draft recommendations to the SC.
- *Open communication* organised in an appropriate flexible way including:
  - broad consultations referred to in the procedure of elaboration of a recommendation;

Secretariat : c/o COMISA, rue Defacqz, 1 - B - 1000 Bruxelles (Belgium) - Tel. +32-2-541.01.11, Fax +32-2-541.01.19
e-mail : vich@comisa.org - Website : http://vich.eudra.org

- meetings, conferences, press briefings and releases. The scope, size, location of these meetings will be decided on a case by case basis by the SC.

4. Steering Committee

4.1. SC structure

4.1.1. Full members (up to 2 delegates per member)

- European Union
- Japanese government
- US government
- FEDESA
- JVPA/JAVB
- AHI

4.1.2. VICH Coordinators

Each SC member will appoint a coordinator to act as contact point with the VICH secretariat and ensure that VICH documents are distributed to the appropriate persons within the area of their responsibility and that the requested input is provided in a timely fashion. This position might be filled by a SC member or by a separate person.

If the co-ordinator is not a member of the SC, he/she will be sent the same correspondence and documents as those sent out to SC members. The co-ordinators will be invited to actively participate at SC meetings. The co-ordinators have no voting rights, and where there is a contentious issue to be debated and agreed upon, the full members of the SC are the spokespersons.

More specific definition of additional roles for the co-ordinator within the region may be defined by each VICH member.

4.1.3. Associate member

- OIE

The associate member will have the opportunity to take part in the discussion of the SC; it will not take part in any vote, which may be taken, nor will it sign-off on any VICH (draft) recommendations.

4.1.4. Observers (1 delegate per observer)

- Australia - New Zealand represented by Australia National Registration Authority and New Zealand MAF Regulatory Authority - Agricultural Compounds Unit
- Veterinary Pharmaceutical Industry of Australia, New Zealand represented by AVCARE/AGCARM

Observers will have the opportunity to take part in the discussion of the SC; they will not take part in any vote, which may be taken.

4.1.5. Interested parties (1 delegate only per party)

An organisation shall make a request in writing to the secretariat to seek accreditation as such party in VICH. The SC will consider the application and provide a decision to the applicant via the secretariat.

An interested party has no right to contribute to the discussions or intervene in the meetings as such in any way, unless requested by the chair to provide certain information. The accredited interested party will be entitled to attend VICH Steering Committee meetings at its own expenses.

4.1.6. Chair of SC meetings

During the initial phase, Mr Boisseau has been asked to chair the SC on behalf of OIE.

After the initial phase, completed after the VICH1 conference, the chair will rotate among the three regions in accordance with the rotation of the location. The members of the region in charge of the SC meeting have the discretion to choose the most appropriate person for this task.

4.1.7. Secretariat

COMISA will provide the secretariat for VICH activities.

Secretariat tasks will include:

- to prepare and circulate for SC meetings, in coordination with the chairman, the updated documents to SC members and observers and to VICH coordinators
- to circulate the agenda, minutes and conclusions of meetings to SC members (the draft minutes will be circulated within 2 weeks of the meeting with a written procedure for comments/approval)
- to circulate to the SC members and observers the minutes of WG meetings and draft WG recommendations at step 2
- to circulate to the SC members, coordinators and observers other relevant information pertaining to the activities of the WG
- to publish the press release adopted at the end of each meeting
- to publish recommendations adopted by the SC.

4.1.8. Role of OIE

VICH activities are conducted under the auspices of OIE.

During the initial phase, Mr Boisseau has been asked to chair the SC on behalf of OIE. After the initial phase, completed after the VICH1 conference, OIE is made an associate member of the SC (see 4.1.3 Associate member).

In order to provide OIE Delegates with full information about the trilateral harmonisation efforts between the USA, Japan and the EU, OIE will circulate relevant VICH documents to OIE Delegates for comments and circulate final VICH recommendations.

4.2. SC meetings

4.2.1. Frequency

Twice a year.

4.2.2. Location

Rotates among the three regions (EU, Japan, USA), unless otherwise decided.

4.2.3. Agenda

The agenda will be elaborated by the secretariat in concurrence with the chairman, on the basis of written proposals from the SC members.

4.2.4. Working language

English.

4.3. Funding

Each member bears his/her own travel and accommodation expenses.

5. Working Groups

5.1. Structure

5.1.1. Membership

- To be decided by the SC;
- Limited number of members;
- Each SC full member and observer has the right to appoint one expert;
- If necessary, and unless otherwise specified by the SC, each expert may be accompanied by one advisor. The chairperson, the topic leaders and the secretariat should be notified of this.
- Additional experts from other regions could be appointed by the SC. In order to respect the geographical balance, only one expert or advisor per member should speak on a given topic.
- Unless otherwise decided by the SC, no observers are allowed in the WG meeting.

5.1.2. Topic leaders/WGs chairperson

- Appointed by the SC, on the basis of expertise and geographical balance.
- One topic leader will be responsible for each topic. He/She will normally chair the specific WG and therefore be accountable to the SC with respect to the mandate and time frame given by the SC. He/She will also be responsible for preparing the appropriate discussion documents for the WG meetings.
- In the case where several topics are related to each other, it may be cost-efficient to group them into one group chaired by one chairperson. This chairperson will be appointed by the SC and will be accountable to the SC with respect to the mandate and time frame given by the SC. In this instance, each topic will still be under the leadership and responsibility of the topic leader.

5.1.3. WG secretariat

- Taken in charge by the chairperson and/or topic leader who may delegate this task to secretarial staff

5.2. WG meetings

5.2.1. Frequency

To be decided by the SC on proposal of the topic leader/WG chairperson.

5.2.2. Location

All WG meetings are to be rotated among the three regions, starting in general with the region which holds the chair of the WG. For cost-efficiency reasons, the SC could authorise (see 5.2.5.) WG meetings to deviate from the regular rotation scheme among the three regions, if most of the WG experts are going to be present together on the occasion of a particular scientific conference or meeting.

5.2.3. Minutes

The chairperson of the WG will ensure that minutes of the meetings are produced in a timely fashion and sent immediately thereafter to the secretariat for circulation to the SC members.

5.2.4. Working language

English.

5.2.5. Authorisation procedure

Each meeting has to be authorised by the SC. This is done at SC meetings or by a written (sign-off) procedure.

5.3. Funding

Each member bears his/her own travel and accommodation expenses.

6. Communication

- Objective: To provide public information on the work being undertaken by all appropriate ways.
- In case of organisation of VICH open conferences:
  - Location and programme determined by the SC;
  - Logistically organised by the host region pharmaceutical association;
  - Meeting funded mainly by registration fees.
- Press briefings and releases after each SC meeting.
- Regional meetings and publicity of VICH may be undertaken with full cooperation of the parties within the region.

7. Procedures

It is proposed to work according to a 9-step procedure.

Step 1: The SC: • defines a priority item from a concept paper prepared by one of its members;

- establishes an appropriate WG, if needed. A topic leader in charge of drafting a recommendation is appointed and given a clear mandate to do the expected work;

Step 2: The appropriate WG elaborates a draft recommendation, and submits it to the Secretariat with the signatures of all experts.

Step 3: The draft recommendation is submitted to the SC for approving its release for consultation.

Step 4: Once adopted by the SC, the draft recommendation is circulated to all interested parties for consultation.

Step 5: The comments received are directed to the WG for consideration. At this step, the topic leader must be a representative of a regulatory authority. The WG prepares a revised draft and submits it to the Secretariat with the signature of all experts. The signatures of industry experts should be clearly separated from those of experts representing regulatory authorities.

Step 6: The revised draft recommendation is submitted to the SC for approval.

Step 7: Once approved by the SC, the final recommendation and a proposed date for its implementation are circulated to the regulatory authorities represented in the SC.

Step 8: The SC members report to the SC on the implementation of the recommendations in their respective regions.

Step 9: Upon request of a SC member, a recommendation could be revised in order to take account of new scientific information.