



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

The objectives of VICH are to:

- Establish and implement harmonised technical requirements for the registration of veterinary medicinal products in the VICH regions, which meet high quality, safety and efficacy standards and minimize the use of test animals and costs of product development.
- Provide a basis for wider international harmonisation of technical requirements.
- Monitor and maintain existing VICH guidelines, taking particular note of the ICH¹ work program and, where necessary, update these VICH guidelines.
- Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following the implementation of VICH guidelines.
- By means of a constructive dialogue between regulatory authorities and industry, provide technical guidance enabling response to significant emerging global issues and science that impact on technical requirements within the VICH regions.

3. Guiding Principles

- The decision-making process in VICH should be through consensus.
- Procedures should ensure the smooth and consistent functioning of the process for preparation, consultation and adoption of guidelines.
- Acceptance of any new topics for harmonisation activities requires a thorough evaluation of the importance and feasibility of the project based on a detailed concept paper and acceptance of all full VICH members. Particular consideration should be given to the adaptation of new ICH¹ guidelines.

¹ ICH – International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use

- Recommendations on guidelines should be based on scientific assessment of existing information. These guidelines should focus on the essential scientific requirements needed to address a topic and should eliminate unnecessary or redundant requirements.
- Regular benefit/cost analyses of the VICH process should be performed and communicated.
- Once adopted, the VICH guidelines replace corresponding regional requirements in principle.
- The VICH process 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.
- An open and transparent consultation process should be maintained for revision of existing guidelines as well as any new draft guideline.
- All parties commit to provide the necessary human and material resources for the proper and timely functioning of VICH and execution of agreed work, subject to the general economic situation. The experts should be chosen both on scientific merits and ability to work within a multicultural team environment as well as on skills in negotiation/finding compromises.
- The wider involvement of non-VICH countries should be encouraged, taking into account that continued efficiency in the operation of VICH should be preserved.

4. General organisation

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 Outreach Forum is a VICH initiative with the main objectives of providing a basis for wider international harmonisation of technical requirements for veterinary medicinal product registration, improving information exchange and raising awareness of VICH and VICH guidelines with non-VICH countries/regions.

5. Steering Committee

5.1. Structure of the SC

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

EU: European Commission – European Medicines Agency

JMAFF: Japanese Ministry of Agriculture, Forestry and Fisheries

USA: US Food & Drug Administration – Center for Veterinary Medicine (CVM) and US Department of Agriculture – Center for Veterinary Biologics (USDA/CVB)

AHI: US Animal Health Institute

AnimalhealthEurope: representing the European Animal Health Industry

JVPA: Japanese Veterinary Products Association

5.1.2. VICH Coordinators

Each SC member appoints a coordinator to act as contact point with the VICH secretariat. The coordinators participate in SC meetings.

5.1.3. Associate member

OIE: World Organisation for Animal Health

The associate member has the opportunity to take part in the discussion of the SC; it does not take part in any formal decision on topics or guidelines, which may be taken, nor will it sign-off any VICH draft/final guidelines.

5.1.4. Observer members (1 delegate per observer member)

Australia: Australian Pesticides and Veterinary Medicines Authority (APVMA)

AMA: Animal Medicines Australia Ltd.

New Zealand: New Zealand Ministry for Primary Industries

AGCARM: Agricultural Chemicals & Animal Remedies Manufacturer's Association of New Zealand

Canada: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian – Centre for Veterinary Biologics (CCVB)

CAHI: Canadian Animal Health Institute

South Africa: Department of Agriculture, Forestry and Fisheries (DAFF) and Department of Health

SAAHA: South African Animal Health Association

Observer members have the opportunity to take part in the discussion of the SC; they do not take part in any formal decision on topics or guidelines, which may be taken and do not sign-off any draft/final guideline.

5.1.5. Interested Parties (1 delegate only per party)

An interested party does not have the right to contribute to the discussions or intervene in the meetings, unless requested by the chair to provide certain information. The interested party is entitled to attend VICH Steering Committee meetings at its own expense.

The interested party is currently:

AVBC: Association of Veterinary Biologics Companies (USA).

5.1.6. Chair of SC meetings

The chair rotates among the 3 full member regions in accordance with the rotation of the location of the SC meetings. The members of the region in charge of the SC meeting have the discretion to choose the most appropriate person for this task.

5.1.7 Secretariat

HealthforAnimals, the global animal medicines association, provides the secretariat for VICH activities.

5.2. Roles

5.2.1. Role of the SC

The SC:

- determines the working procedures;
- determines the priority topics for developing guidelines based on concept papers prepared by its members, also taking recommendations from the VICH Outreach Forum into consideration;
- sets up the appropriate Expert Working Groups (EWGs) and appoints topic leaders and EWG chairpersons;
- provides direction on issues raised by the EWGs in the development of guidelines;
- approves the draft guidelines prepared by EWGs before release for world-wide consultation and subsequently for approval by the regulatory authorities of the EU, Japan and the USA;
- implements a procedure for monitoring, maintenance and review of guidelines;
- agrees assignments at the SC meetings and, on request of the Secretariat, provides updates on the status of these actions between SC meetings.

As the VICH guidelines catalogue grows the additional focus on maintenance activities requires SC reconsideration of the need for and the methodology of the EWGs as well as the consultation

requirements. Revision of guidelines should not be treated in the same way as new topics as there is an established VICH commitment to the topic.

Outside the review process for existing guidelines the SC has the function to review the progress of ICH and investigate the applicability to the VICH process; although it is recognised that there are further considerations in the VICH process.

The SC regularly requests information on the cost / benefit of the VICH process from all of those investing resources, including the benefits achieved from completing new guidelines.

The SC requires regular updates from any active EWG identifying progress and addressing any issues for resolution. Any regulatory or technical concerns need to be identified early in the process and resolved by the SC; if they cannot be resolved, the mandate of the EWG needs to be revised to cover only those areas that can be agreed on.

All parties will actively seek to achieve agreed VICH schedules for deliverables.

Consideration of any new topic requires a concept paper containing an adequate feasibility assessment. As new topics are initiated, the SC should set achievable targets for the completion of work.

5.2.2. Role of the coordinators

The coordinators appointed by each SC member are responsible for:

- communication between members of their delegation, ensuring in particular that, prior to the SC meetings the relevant documents are distributed in a timely fashion and reviewed, the key issues discussed, the positions and perspectives agreed, and that the requested inputs are provided to the SC;
- ensuring that each expert of their delegation 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 procedural guidance;
- the monitoring of the progress of ICH and alerting the SC of relevant developments applicable to VICH;

Moreover, the coordinator from the delegation who appoints the chairperson of the EWG is responsible for the communication and follow-up of all relevant matters with the EWG chair (in particular the feedback from SC meetings) and the other SC members from the same delegation.

Each region may define a more specific role of the coordinator within the region.

5.2.3. Role of the Secretariat

5.2.3.1 General Tasks

The Secretariat tasks include:

- to prepare and circulate for SC meetings, in coordination with the chairman, the updated documents to SC delegates, coordinators and interested parties;
- to circulate the agenda, minutes and conclusions of meetings to SC delegates (the draft minutes are circulated within 3 weeks of the meeting with a written procedure for comments/approval);
- to circulate the agenda, minutes and conclusions of VICH Outreach Forum meetings to SC delegates and VICH Outreach Forum members (the draft minutes are circulated within 4 weeks of the meeting with a written procedure for comments/approval);
- to circulate to the SC delegates, coordinators and interested parties the minutes of EWG meetings and draft guidelines at step 2 and step 5;
- to circulate the adopted draft guidelines at step 4 for consultation in the regions and inform the SC of the start and completion of the consultation in the regions;
- to circulate the adopted guidelines at step 7 for implementation in the regions as well as the date of implementation in the regions;

- to circulate to the SC delegates, coordinators and interested parties other relevant information pertaining to the activities of VICH, in particular the activities of the EWGs;
- to publish the outcomes of each meeting;
- to update the VICH website regularly;
- to notify the SC regularly about the possible need of updating a GL every 5 years.

5.2.3.2 Timelines for meeting documents

- 4 months prior to the meetings of the SC and the VOF the VICH Secretariat sends out a reminder to coordinators, EWG Chairs, and VICH SC members, observers and VOF members to submit updates/papers etc to the VICH Secretariat no later than 10 weeks prior to the SC and VOF meetings. A follow up reminder is sent 3 weeks after the first reminder.
- The VICH Secretariat sends out the draft agendas and papers 2 months prior to the SC and VOF meetings.
- Papers covering new topics/areas of work submitted after the above deadline to the VICH Secretariat will not be included on the agenda, unless there are exceptional circumstances.

5.2.4 Role of OIE

OIE provides support to VICH and encourages its Member Countries to take into consideration the VICH guidelines. OIE indeed considers that the international harmonisation of technical requirements for 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 harmonisation efforts between the USA, Japan and the EU, OIE circulates VICH draft guidelines and other relevant VICH documents to OIE Member Countries for comments and circulates final VICH guidelines.

OIE co-chairs the VICH Outreach Forum in collaboration with the chair of the VICH SC.

5.3. SC meetings

5.3.1. Frequency

Up to twice a year.

5.3.2. Location

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

5.3.3. Agenda

The agenda is drafted by the Secretariat in collaboration with the SC chair, on the basis of written proposals from the SC members.

5.3.4. Working language

English.

5.4. Funding

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

6. Expert Working Groups

6.1. Structure

6.1.1. Membership

- To be decided by the SC;
- Limited number of members;
- Each SC full member and observer member has the right to appoint 1 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 must be notified of this;
- Additional experts from other regions can be appointed by the SC;
- Unless otherwise decided by the SC, no external observers are allowed in the EWG meeting.

6.1.2. Topic leaders/EWGs chairperson

- Appointed by the SC, on the basis of expertise and geographical balance.
- The chairperson is accountable to the SC with respect to the mandate and time frame given by the SC.
- 1 topic leader is responsible for each topic. He/She is responsible for preparing the appropriate discussion documents for the EWG meetings.
- When several topics are related to each other, these will be addressed by 1 EWG chaired by 1 chairperson. In this instance, each topic is still under the leadership and responsibility of a topic leader.
- At step 5 of the procedure the topic leader must be a representative of the regulatory authorities.

6.1.3. EWG secretariat

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

6.2. Role of EWGs

- Elaborate recommendations and draft guidelines based on a concept paper adopted by the SC for the priority items determined by the SC.
- Report regularly on progress and issues for resolution to the SC.
- Submit these recommendations and draft guidelines to the SC.
- The EWGs will work towards harmonisation of technical requirements by way of consensus in accordance with the procedural guidance (VICH/00/151).
- EWGs developing guidelines involving animal experimentation have a specific responsibility to consider animal welfare, and particularly the possibilities for Replacement, Refinement and Reduction of animal testing (3 Rs) by encouraging the use of validated alternative methods in order to reduce the number of animals used for product development and registration.
- Particular attention should be paid to:
 - Any issues that are likely to be difficult to resolve should be brought to the attention of the SC.
 - Concentrating efforts on what can be achieved within the time provided.
- The SC members should ensure that the members of the EWGs are aware of and apply the existing guidance relating to their work in EWGs.
 - When choosing experts, SC members should take into account the principles laid down in the “Guidance for the Steering Committee on the appointment of experts and Chairpersons/ Topic leaders to Working Groups” (VICH/00/152).

- The SC members should ensure that when an EWG is created or experts are nominated the experts have the appropriate specific knowledge as stated in the “Guidance for members of VICH Working Groups” (VICH/00/150).
 - The SC should ensure that at all times the guidance laid down in the “Policy on Appreciation Shown to the Chairs and Working Group Members” (VICH/00/155) is implemented properly.
- If an EWG cannot reach agreement, the SC should consider publishing the main outcomes in a “status report” document. In such cases a document should be prepared by the EWG including the points on which an agreement could and could not be reached.

6.3. EWG meetings

6.3.1. Frequency

To be decided by the SC on a proposal of the EWG chairperson. Consideration should be given to using as much as possible alternative communication technologies to progress the work between full meetings.

6.3.2. Location

All EWG meetings are rotated among the 3 regions, starting in general with the region which holds the chair of the EWG. For cost-efficiency reasons, the SC could authorise EWG meetings to deviate from the regular rotation scheme among the 3 regions (for example, if most of the EWG experts are going to be present together on the occasion of a particular scientific conference or meeting).

6.3.3. Minutes

The chairperson of the EWG ensures that minutes of the meetings are produced in a timely fashion and sent immediately thereafter to the Secretariat for circulation to the SC members.

6.3.4. Working language

English.

6.3.5. Authorisation procedure

Each face to face meeting has to be authorised by the SC. This is done at SC meetings or by a written procedure.

6.4. Funding

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

7. VICH Outreach Forum

VICH has re-iterated its objective of wider international harmonisation in the priorities for the years 2016-2020 set out in its Priorities for Phase 4: 2016-2020. VICH progresses its objective of wider international harmonisation of technical requirements, which is aimed at the wider dissemination and acceptance of VICH guidelines and co-operation on a more global level, through the VICH Outreach Forum implemented in June 2012. The VICH Outreach Forum meets on decision of the SC.

7.1. Membership and role

The structure, functioning and role of the VICH Outreach Forum are detailed in the “Terms of Reference for the VICH Outreach Forum” (Ref.: VICH/11/010).

7.2. VICH Outreach Forum meetings

7.2.1. Frequency and location

The VICH Outreach Forum meets in the margins of VICH SC meetings.

7.2.2. Working language

English.

7.3. Funding

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

8. Communication

The aim of VICH communication is to provide public information and opportunities for feedback on its work for all parties on:

- VICH guidelines,
- VICH process and procedures,
- General information regarding conferences.

The following methodology should be utilised:

- The VICH public website is the reference point for all past/current activities and will in particular provide detailed and updated information about VICH activities. It should stimulate the interest of website visitors by developing “active” headings such as Frequently Asked Questions or “What is new?”
- The VICH SC issues a press release after each SC meeting highlighting major outcomes;
- VICH SC communication with other international organisations (e.g. ICH, WHO, Codex or OECD);
- VICH SC communication and consultation within the respective regions: the comments received during the public consultation of draft guidelines by the SC members from the Regulatory Authorities and VICH Secretariat are published together with the comments on their consideration in the finalisation of the guideline;
- OIE ensures broad dissemination of information and coordination of submissions from non-VICH regions;
- VICH public conferences: the SC is responsible for organisation of conferences to promote and progress the objectives of VICH;
- VICH regions may organise meetings for e.g. consultation, technical discussion to progress VICH objectives with full cooperation of the parties within the region.

9. Decision-Making Process and Procedures

Prior to the launch of a new topic, the SC ensures that the pre-requisites laid down in the VICH Priorities have been fulfilled.

The SC may then decide to launch the following 9-step procedure:

| Step | Timeline* |
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| <i>Step 1:</i> The SC: <ul style="list-style-type: none">- defines a priority item from a detailed concept paper prepared by one of its members;- designates the topic to an EWG or establishes a new EWG, as appropriate, and appoints an EWG topic leader and/or chairperson. The EWG chair/topic leader in charge of drafting the | |

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| <p>guideline is given a clear mandate to carry out the expected work;</p> <ul style="list-style-type: none"> - ensures that each topic leader has the required competence and interpersonal skills to lead an EWG and achieve its objectives. | |
| <p><i>Step 2:</i> The appropriate EWG elaborates a draft guideline, and submits it to the Secretariat with the signatures of all experts.</p> | <p>The EWG Chair sets a 4 week deadline for signatures of all experts.</p> <p>The EWG Chair submits draft guideline to secretariat within one week of receiving all signatures.</p> |
| <p><i>Step 3:</i> The draft guideline is submitted to the SC for approving its release for consultation.</p> | <p>The VICH Secretariat within one week of receiving draft guideline submits to SC members.</p> <p>VICH Secretariat sets a 4 week deadline for SC members to sign-off for release.</p> |
| <p><i>Step 4:</i> Once adopted by the SC, the draft guideline is published for consultation, applying an appropriate consultation period (normally 6 months). The regulatory coordinators should inform the VICH secretariat of the dates and if the consultation process in their region is delayed.</p> | <p>The VICH Secretariat within one week of receiving approval by SC will publish the draft guideline for consultation.</p> |
| <p><i>Step 5:</i> The comments received are directed to the EWG for consideration. At this step, the topic leader must be a representative of a regulatory authority. The EWG prepares a revised draft and submits it to the Secretariat with the signatures of all experts. The signatures of industry experts are clearly separated from those of experts representing regulatory authorities.</p> | <p>The EWG Chair sets a 4 week deadline for signatures of all experts.</p> <p>The EWG Chair submits draft guideline to secretariat within one week of receiving all signatures.</p> |
| <p><i>Step 6:</i> The revised draft guideline is submitted to the SC for approval.</p> | <p>VICH Secretariat within one week of receiving draft guideline submits to SC members.</p> <p>The VICH Secretariat sets a 4 week deadline for SC members to sign-off for release.</p> |
| <p><i>Step 7:</i> Once approved by the SC, the final guideline and a proposed date for its implementation are circulated to the regulatory authorities represented in the SC.</p> | <p>The VICH Secretariat within two weeks of receiving approval of SC members will circulate the final guideline and proposed date of implementation to SC regulatory authorities.</p> |

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

Step 9: Monitoring, maintenance and review of guidelines:

- The necessity to review adopted guidelines should be determined, at least every 5 years following the implementation in order to take account of new developments. The Secretariat will notify the SC of the 5 years deadlines.
- Any SC member may propose to review an adopted guideline at any time and inform the VICH Secretariat in due time prior the next SC meeting. Such proposal should be accompanied by an abbreviated concept paper detailing the rationale and the background for review.
- If the SC acknowledges the need for a review of the adopted guideline, the SC will designate the appropriate EWG or a topic leader as the reviewer.
- The SC decides on the appropriate step at which the revision procedure shall start.

** The Steering Committee has agreed that the timelines recommended above should be seen as guidance, but should be respected as much as possible. Nevertheless, where a delegation will not be able to comply with the proposed timelines, it should circulate a message to the SC and Secretariat providing information on when it expects to be able to provide the relevant document.*