VICH
and International Harmonisation

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VICH Secretariat
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Background, History and Development
What is VICH?

**VICH = International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products**

- International tripartite cooperation programme
- US-JAPAN-EU (+ AUS/NZ + Canada + South Africa as observers)
- Discussion Forum for Regulatory Authorities and Industry – A unique set-up of public and private sector expertise sharing
VICH - the regions

- **VICH Members**: Committed to implement VICH Guidelines
- **VICH Observers**: Voluntarily implement VICH Guidelines

OIE (World Organisation for Animal Health): Associate Member
IFAH (International Federation for Animal Health): Secretariat
**VICH – the history**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tr>
<td>1980ies</td>
<td>First talks on harmonisation of veterinary medicines registration around the world at the meetings of the International Technical Consultation on Veterinary Drug Registration (ITCVDR)</td>
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<td>1991</td>
<td>Creation of ICH with 1\textsuperscript{st} conference</td>
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<td>1992</td>
<td>7\textsuperscript{th} ITCVDR conference in Argentina: concept of VICH emerged</td>
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<td>1994</td>
<td>OIE ad hoc Group on the Harmonisation of the Regulation of Veterinary Medicines: develops scope, membership and objectives of VICH</td>
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<td>April 1996</td>
<td>1\textsuperscript{st} VICH Steering Committee in the OIE headquarters in Paris, France</td>
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<td>Nov. 1999</td>
<td>1\textsuperscript{st} VICH Public Conference in Brussels, Belgium</td>
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<td>Oct. 2002</td>
<td>2\textsuperscript{nd} VICH Public Conference and 11\textsuperscript{th} Steering Committee meeting in Tokyo, Japan</td>
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<td>May 2005</td>
<td>3\textsuperscript{rd} VICH Public Conference and 16\textsuperscript{th} Steering Committee meeting in Washington DC, USA</td>
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<td>Date</td>
<td>Event Description</td>
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<tr>
<td>June 2008</td>
<td>First reflection on Global Outreach</td>
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<td>June 2010</td>
<td>4th VICH Public Conference, 24th Steering Committee and plenary exchange on Global Outreach Strategy in the OIE headquarters</td>
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<td>November 2011</td>
<td>Contact meeting with selected non-VICH country representatives in Tokyo, Japan</td>
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<td>June 2012</td>
<td>1st VICH Outreach Forum meeting in Brussels, Belgium</td>
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<td>February 2013</td>
<td>2nd VICH Outreach Forum meeting in Auckland, New Zealand</td>
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<td>November 2013</td>
<td>3rd VICH Outreach Forum meeting in Washington DC, USA</td>
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<td>June 2014</td>
<td>30th Steering Committee and 4th Outreach Forum meetings in Brussels, Belgium</td>
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<td>October 2015</td>
<td>5th VICH Public Conference, 6th VICH Outreach Forum meeting and 32nd Steering Committee in Tokyo, Japan</td>
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II. VICH

Structure, Role and Objectives
Overview of the VICH structure
What is the role of VICH?

• VICH’s role is to harmonise technical requirements for data necessary for the marketing authorisation (also called registration) of a veterinary medicinal product.

• Development, implementation and maintenance of VICH Guidelines in the VICH regions:
  - Guidelines relating to studies (study design and testing strategy) to support product authorisation
  - Quality, safety and efficacy (including bioequivalence)
  - Pharmacovigilance Guidelines (post-marketing safety monitoring)
It is NOT the role of VICH to:

- Provide guidance to establish regulatory systems and regulations for marketing authorisations for Veterinary Medicinal Products
- Decide which studies are necessary to obtain a marketing authorisation
- Assess data or provide guidance on the assessment approach
- Grant marketing authorisations
- Establish safety standards

These are typically the roles of national competent authorities and governments!
How do the roles of VICH, OIE and Codex differ?

- **VICH** develops harmonised data requirements, i.e. standards of the scientific studies on quality, safety and efficacy that are required to obtain a marketing authorisation for a veterinary medicinal product.

  > **VICH Guidelines**

- **OIE** sets international standards for animal health and welfare, including laboratory animals, adopted by its 180 Member Countries.

  - Standards on animal health are:
    - Recognised by WTO
    - References for international trades
    - Used by trading countries to:
      - Set up their national animal health policies
      - Protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers.

  > **OIE normative documents**
How do the roles of VICH, OIE and Codex differ?

- **OIE** also supports its Member Countries in improving the legal framework and resources capacity of national Veterinary Services and setting standards on animal production food safety.

- The **Codex Alimentarius Commission** develops, on international level, food safety standards, guidelines and related texts (recognised by WTO as references for international trade) such as:
  - Codes of practice under the Joint FAO/WHO Food Standards Programme to protect consumers and ensure fair practices in the food trade.
  - Maximum residue limits (MRLs) for residues from veterinary drugs in foodstuffs from animal origin under the Joint FAO/WHO Expert Committee of Food Additives (JECFA).

→ **Codex food safety standards**
VICH Objectives and Guiding Principles

✓ Establish and implement harmonised requirements for veterinary medicines in the VICH regions, which

  • Meet high standards of Quality, Safety & Efficacy to protect public health, animal health & welfare and the environment
  • Minimise the use of test animals and costs of product development

✓ Provide a basis for wider international harmonisation of technical requirements

✓ Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following implementation

✓ Provide technical guidance enabling response to significant emerging global issues and science of relevance
VICH 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

✓ New topics for development of guidelines are agreed following evaluation of importance and feasibility of project; requires acceptance of all full VICH members

✓ Harmonised requirements should replace corresponding regional requirements

✓ Transparent and cost-effective procedures, open for public comments
  
  • Consultation by all regulatory authorities in VICH
  • Consultation procedure by dissemination to OIE Member Countries through OIE
  • VICH public website
VICH Members

• European Union
  • European Commission (EC) - European Medicines Agency (EMA)
  • International Federation for Animal Health – Europe (IFAH-Europe)

• United States
  • Food and Drug Administration/Center for Veterinary Medicine (FDA-CVM)
  • US Department of Agriculture/Animal Plant Health Inspection Service - Center for Veterinary Biologics (USDA – CVB)
  • Animal Health Institute (AHI)

• Japan
  • Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF)
  • Japan Veterinary Products Association (JVPA)
VICH Observers

• Australia/New Zealand –
  —Australian Pesticides and Veterinary Medicines Authority (APVMA)/New Zealand Ministry for Primary Industries
  —Animal Medicines Australia Ltd (AMA)/AGCARM/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand

• Canada
  —Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Centre for Veterinary Biologics Section (CCVB)
  —CAHI - Canadian Animal Health Institute

• Republic of South Africa
  • Department of Agriculture, Forestry and Fisheries (DAFF) and Department of Health (DH)
  • South African Animal Health Association (SAAHA)
Also participating in VICH
Associate Member/Interested Party

• **Associate Member**
  — World Organisation for Animal Health (OIE)

• **Interested Party**
  — AVBC: Association of Veterinary Biologics Companies (USA)
The VICH Steering Committee

- Regulatory Representatives from:
  - EU → EMA + EC
  - JAPAN → JMAFF
  - USA → FDA-CVM + USDA-CVB
  - ANZ → APVMA + NZMPI
  - Canada → HC-VDD + CCVB
  - South Africa → DAFF + DH

- Representatives from Industry Associations:
  - AHI, JVPA, IFAH-Europe, AMA, AGCARM, CAHI, SAAHA

- OIE - Associate Member

- Secretariat: IFAH Global
The VICH Steering Committee

✓ Is the decision making body of VICH and drives the process
✓ Is composed of senior representatives of the member and observer organisations (2 delegates and 1 coordinator for each organisation)
✓ Meets every 8 to 9 months alternatively in the 3 member regions
✓ Determines the priority items based on concept papers prepared by its members
The VICH Steering Committee

- Sets up the appropriate Expert Working Groups (EWGs) and appoints topic leaders and EWG chairpersons;
- Considers and resolves issues raised by the EWGs;
- Approves the draft Guidelines issued by EWGs before release for public consultation;
- Is responsible for a programme of monitoring maintenance and review of guidelines;
- Approves (ONLY the regulatory authorities from the EU, Japan and the USA) the final Guidelines for implementation in the member regions.
The VICH Expert Working Groups

VICH Steering Committee

- Expert Working Groups
  - Metabolism and Residue Kinetics EWG
  - Quality EWG
  - Bioequivalence EWG
  - Safety EWG
  - Electronic File Format EWG
  - Biologicals EWG
  - ESI – Electronic Standards Implementation EWG

Secretariat (IFAH)

OIE
The VICH Expert Working Groups

- Membership decided by the Steering Committee (SC)
- Composed of a limited number of members
- Each SC 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
- Additional experts from non-VICH regions can be appointed by the SC
III. VICH

Members and participants Requirements and Benefits
Rights and obligations of VICH Members

• Members have pledged to implement all finalised VICH Guidelines

• Members participate in Steering Committee meetings and in Expert Working Group meetings

• Members consult with stakeholders concerning draft and final VICH guidelines

• Members are permitted to sign-off of guidelines (in final steps regulators only)

• Members chair Steering Committee meetings and Expert Working Group meetings
Rights and obligations of VICH Observers

• Observers have made no pledges regarding the implementation of VICH Guidelines but they are encouraged to use them

• Observers participate in Steering Committee meetings and in Expert Working Group meetings

• Observers consult with stakeholders concerning draft and final VICH guidelines
Benefits of VICH to participants

• Acceptance of multilaterally agreed guidelines for studies undertaken to ensure product quality, safety and efficacy as well as to protect public health, animal health and welfare and the environment

• Use of harmonised technical guidelines for veterinary medicines in the countries/regions participating in VICH

• Minimisation of the use of test animals and costs of product development
Benefits of VICH to participants - cont’

• Facilitation and acceleration the authorisation of Veterinary Medicinal Products in the countries/regions participating in VICH

• Provision a basis for future international harmonisation of registration guidelines

• Participation in a forum dealing with new, emerging global issues and relevant science
Benefits of VICH to participants - cont’

• Sharing information with others through public conferences (VICH Public Conferences I-IV)

• Reduction of costs and time for developing new product and bringing them on the market*

  * For example, cost/benefit study showing savings from implementing VICH stability testing guidelines

• Provides all participants with a better understanding of the content and implementation of guidelines and regulations
Benefits of VICH to participants - cont’

• Participation in a global product development approach
• Increase of pooling and leveraging of regulatory resources
• Assurance of more regulatory certainty in that results from studies carried out in accordance with VICH guidelines are recognised
• Reduction of impediments to trade in veterinary medicines and food
Potential Benefits of VICH to Other Countries or Regions

• Countries and regions currently not part of VICH can profit of many of the benefits as experienced by current VICH participants

• Those benefits will depend greatly on the nature of the veterinary medicines regulatory system that exists in each country or region
The VICH Outreach Forum

- Composed of participants from 14 countries and 3 regional organisations that have expressed an interest in the work of VICH
- Countries: Argentina, Brazil, China, India, Korea, Morocco, Malaysia, Mexico, South Africa*, Thailand, Taiwan, Philippines, Russia & Ukraine
- Regional organisations: ASEAN, CAMEVET & UEMOA

* Has become a VICH Observer in 2013
The VICH Outreach Forum

• First met in June 2012

• Meets every 9 – 10 months (in the frame of SC meetings), chaired by VICH in collaboration with OIE

• Objectives are:
  ✓ To provide a basis for wider international harmonisation of registration requirements,
  ✓ To improve information exchange and
  ✓ To raise awareness of VICH and VICH guidelines with non-VICH countries/regions
IV. VICH

The Guidelines
and their development process
The VICH Process

• Thorough selection of topics by SC based on assessment of benefits and feasibility for harmonisation and resources requirements

• Work mandated by the SC to Expert Working Groups

• Elaboration and adoption of guidelines in a 9-step procedure

• Taking particular note of ICH guidelines taking account of veterinary specific needs

• Consequent need for maintaining and updating existing guidelines on a regular basis
The VICH Process

- Programme runs in cost-effective and transparent way
- Expert Working Groups work through emails, teleconferences and face-to-face meetings to progress their work
- Steering Committee
  - Monitors progress of Expert Working Groups and provides support and direction
  - Monitors implementation of Guidelines in the VICH regions
Development of a VICH Guideline: The 9 step procedure

- **Step 1**
  - Concept paper to propose issue
  - Review by SC
  - Appointment of Topic Leader/Chairman

- **Step 2**
  - EWG to produce draft Guideline

- **Step 3**
  - SC to approve draft Guideline for consultation

- **Step 4**
  - Public consultation in the regions

- **Step 5**
  - EWG to review comments and finalise Guideline

- **Step 6**
  - SC to adopt final Guideline

- **Step 7-8**
  - Implementation of Guideline

- **Step 9**
  - Recommendation for review
  - 9 step procedure
Development of a VICH Guideline

Step 1

- Concept paper to propose issue
- Review by SC
- Appointment of Topic Leader/Chairman

• The SC defines a priority item from a detailed concept paper sponsored by one of its members

• The SC 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
Development of a VICH Guideline

Step 1

- Concept paper to propose issue
- Review by SC
- Appointment of Topic Leader/Chairman

- The SC ensures 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 procedural guidance.

- The SC ensures that each topic leader has the required competence and interpersonal skills to lead an EWG and achieve its objectives.

- Internal VICH Guidance documents – work procedures.
Step 2  EWG to produce draft Guideline

• The appropriate EWG elaborates a draft guideline, and submits it to the Secretariat with the signatures of all experts
Development of a VICH Guideline - cont’

Step 3 SC to review and approve draft Guideline

• The draft guideline is submitted to the SC for approving its release for consultation
Step 4 Public consultation in the regions

• Following approval by the SC, the draft guideline is circulated to all interested parties for consultation, applying an appropriate consultation period (normally 6 months).

• World wide public consultation through OIE members and VICH website

• EVERYBODY can comment
Development of a VICH Guideline - cont’

Step 5  EWG to review comments and finalise guideline

• The EWG reviews the comments and provides feedback on the use of the comments (VICH Website)
• 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.
Development of a VICH Guideline - cont’

Step 6  SC to adopt final Guideline

• The revised draft guideline is submitted to the SC for approval

• Only the representatives from the regulatory authorities sign off the final VICH guideline
Development of a VICH Guideline - cont’

Step 7-8 Implementation of Guideline

• Once approved by the SC, the final guideline and a proposed date for its implementation (usually 1 year) are circulated to the regulatory authorities represented in the SC

• The VICH Guideline is available for all on the VICH public website
Step 9 Recommendation for review

- Science is not cast in stone...
- Regular maintenance and review of VICH final guidelines
- In principle after 3 years
- Discussion Document considered by the SC
- Formal Concept Paper if need to review
## Existing VICH Guidelines - Summary

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<td>General</td>
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<td>GLs 34, 25 &amp; 26</td>
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<td>Quality</td>
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<td>Safety</td>
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Final and draft Guidelines available on:

www.vichsec.org
V. VICH

The Achievements
Achievements

- Confidence building and close collaboration between the participants since 1996!
  - Considerable improvements of harmonization of data requirements between regions, thus
    - Reduction of animal testing
    - Reduction of costs
  - Better understanding of regulations and concerns in the other regions
  - Unique discussion forum between acknowledged worldwide scientific experts from both the Regulatory agencies and the Animal Health companies
Achievements

- All decisions in the SC and the EWGs are made by consensus.
- Unique opportunity for regulators and industry to discuss topics openly enabling a pooling of expertise to jointly draft guidelines on regulatory data requirements.
- Opportunity to update regional standards.
- Acceleration of Veterinary Medicinal product development for Livestock & Companion Animals.
- Increase availability of Veterinary Medicines.
Achievements

• Increased uniformity of regulatory process and technical requirements for VICH members and observers, and OIE Members

• Global product development approach

• Increased Product Safety and Consumer Safety

• Contribute to the Global One Health approach
Achievements

- Reduction of animal-based tests – commitment to the “3 R” (Reduce – Refine – Replace)
- Reduction in number of animals used (Safety)
- Regulatory Agencies implement in the 5 regions ➔ Official publication – change of regulatory requirements/legislation
- Availability of the best global scientific expertise
The VICH public website
(http://www.vichsec.org)