

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



VICH and International Harmonisation

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I. VICH

Background, History and Development



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

1980 ies	First talks on harmonisation of veterinary medicines registration around the world at the meetings of the International Technical Consultation on Veterinary Drug Registration (ITCVDR)
1990	Meetings on harmonisation of veterinary biologicals (1992: Ploufragan, France, 1994: Arlington, USA, 1995: Singapore)
1991	Creation of ICH with 1 st conference
1992	7 th ITCVDR conference in Argentina: concept of VICH emerged
1994	OIE ad hoc Group on the Harmonisation of the Regulation of Veterinary Medicines: develops scope, membership and objectives of VICH
April 1996	1 st VICH Steering Committee in the OIE headquarters in Paris, France
Nov. 1999	1 st VICH Public Conference in Brussels, Belgium
Oct. 2002	2 nd VICH Public Conference and 11 th Steering Committee meeting in Tokyo, Japan
May 2005	3 rd VICH Public Conference and 16 th Steering Committee meeting in Washington DC, USA



VICH – the history cont'



June 2008	First reflection on Global Outreach
June 2010	4 th VICH Public Conference , 24 th Steering Committee and plenary exchange on Global Outreach Strategy in the OIE headquarters
November 2011	Contact meeting with selected non-VICH country representatives in Tokyo, Japan
June 2012	1 st VICH Outreach Forum meeting in Brussels, Belgium
February 2013	2 nd VICH Outreach Forum meeting in Auckland, New Zealand
November 2013	3 rd VICH Outreach Forum meeting in Washington DC, USA
June 2014	30 th Steering Committee and 4 th Outreach Forum meetings in Brussels, Belgium
November 2015	5 th VICH Public Conference, 6 th VICH Outreach Forum meeting and 32 nd Steering Committee in Tokyo, Japan



II. VICH

Structure, Role and Objectives

Overview of 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**



- ✓ 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



- ✓ 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



- **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)



- **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

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

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



- 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





- 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



- 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



- 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



III. VICH

Members and participants Requirements and Benefits



- 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



- 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



- 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



- 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



IV. VICH

The 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
- Contribute to the Global One Health approach

- 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
- Increased Product Safety and Consumer Safety



The VICH public website (<http://www.vichsec.org>)

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WHAT IS VICH?

Short Definition
VICH is a bilateral (EU-Japan/USA) programme aimed at harmonising technical requirements for veterinary product registration. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. VICH was officially launched in April 1998. It has 5 main objectives.

[Read more](#)

What is the role of VICH

The role of VICH is to harmonise technical requirements for data necessary for the marketing authorization (also called 'registration') of a veterinary medicine product. This is achieved by developing harmonised guidelines on the studies to be submitted in a marketing authorization application.



VICH Leaflet

Harmonising the global processes for authoring veterinary medicines

[Download](#)

What is VICH Outreach Forum?

The VICH Outreach Forum is a VICH initiative with the main objective of providing a basis for wider international harmonization of registration requirements, improve information exchange and raise awareness of VICH and VICH guidelines with non-VICH countries/regions.

[Read more](#)

Resources

- VICH Information and Administrative Documents
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