VICH

International Cooperation on the Harmonisation of Technical Rquirements for the Registration of Veterinary Medicinal Products

VICH also on the Web ➔ http://vich.eudra.org

Introduction

The need to harmonise has become obvious in a shrinking world where communication on science and safety issues, international trade, industry consolidation, rising R&D costs, concern about the use of experimental animals, are some of the factors increasingly impacting the development, regulation and use of veterinary medicines.

Harmonisation of technical data requirements should, over time, rationalise the development of new product, - even potentially reduce the R&D costs -, and facilitate their evaluation by registration authorities. This should, in turn, advance the availability of much needed new and innovative medicines of benefit to animal owners and professionals.

With these objectives in mind, VICH was launched in 1996. The purpose of this text is to explain the operating process of VICH and its benefits.

What is VICH?

VICH is an international programme of co-operation between regulatory authorities and the animal health industries of the European Union, Japan, and the United States of America which aims to harmonise technical requirements for veterinary medicinal products registration. Australia and New Zealand participate as active observers.

The full title of VICH is the "International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products". VICH was officially launched in April 1996. The scope of the VICH programme includes both pharmaceutical and biological veterinary medicinal products.

VICH has been established under the auspices of the International Office of Epizootics (OIE), also dubbed the World Organization for Animal Health. The OIE, through its Collaborating Centre for Veterinary Medicinal Products, has recently been made an associate member of the VICH Steering Committee.

The creation of VICH

In the eighties and early nineties, a number of international and harmonisation initiatives have been developed and created to pave the way for the creation of VICH: the harmonisation within the European Community, bilateral discussion between regulatory agencies, the creation of the Codex Committee on veterinary drugs, informal discussions at the International Technical Consultation on Veterinary Drug Registration (ITCVDR), international meetings on veterinary vaccines, and the GHOST (Global Harmonisation of Standards) report by industry.

The concept of VICH has been proposed for the first time for discussion during the 7th ITCVDR held in Buenos Aires, Argentina in 1992. After two resolutions adopted in 1994, respectively by the ITCVDR and by the OIE International Committee, OIE set up an ad hoc group to discuss the scope, membership and objectives of the proposed VICH. In making its proposals for setting up the VICH, the OIE ad hoc group has drawn on the experience of the human pharmaceutical harmonisation initiative and used this International Conference on Harmonisation of Technical

Requirements for Registration of Pharmaceuticals for Human Use (ICH) as a model. As part of the work of this ad hoc group, COMISA, the World Federation of the Animal Health Industry was invited to write a report on interests and priorities of industry. This report was essential to the selection of VICH priority topics. It defined in detail areas of non-harmonisation between the EU, the US and Japan and provided preliminary suggestions for priority topics.

With all the groundbreaking work completed, the Steering Committee of VICH held its first meeting in April 1996 in Paris. At this inaugural meeting, the membership and the working procedures were agreed and a first work programme established.

With respect to food safety standards, the VICH complements the work of Codex and JECFA. Issues related to GLP and GMP which are already the subject of mutual agreements will not normally come within the remit of the VICH.

The objectives of VICH

- 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 will lead to a wider international harmonisation.

- 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.

- Make recommendations on practical ways to achieve harmonisation in technical requirements affecting registration of veterinary products and to implement these recommendations in the three regions. Once adopted the VICH recommendations should 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 and cost-effective manner and should provide an opportunity for public comment on recommendations at the draft stage.

The benefits of VICH

Regulatory Certainty

- Uniform requirements.
- More predictable regulatory environment.
- Advancing the introduction of new innovative medicines to the benefit of animal owners and professionals

Reduced Animal Testing

- Elimination of duplicate testing.
- Encourage and implement the introduction of uniform *in vitro* testing methods.

Removal of Trade Barriers

- Harmonisation facilitates the prevention of potential trade barriers.

Product Safety and consumer confidence

- Transparent and uniform science-based requiementsshould contribute to consumer confidence in food safety.
- Complements work of Codex and JECFA.

Broader Harmonisation

- Stimulates the extension of harmonisation initiatives beyond EU/ Japan/ USA/.
- Participation in VICH promotes regional harmonisation.

Work rationalisation and cost Efficiencies

- Eliminates duplicate testing.
- Rationalisation of product development and potential reduction in R&D expenditure.
- Development of drugs with limited market potential.
- Facilitates the evaluation of new product applications.

VICH Steering Committee
Fundamental to the existence of the VICH is the Steering Committee which is empowered to drive the harmonisation process. The key tasks of the Steering Committee are:

- Select the topics to be worked upon, on the basis of proposal by its members
- Appoint the working groups' chairs and topic leaders
- Release for consultation the draft guidelines prepared by expert working groups
- Adopt the final guidelines
- Adopt and modify the operating rules and procedures of VICH

The Steering Committee is composed of two delegates of the regulatory authorities and two delegates of representative industry associations from the three regions. Australia/New Zealand has observer status with one delegate representing government authorities and one delegate representing industry associations from the two countries

The Steering Committee meets twice a year on a rotational basis in participating member countries. Its meetings are held in English, but members can bring their interpreters if necessary.

VICH Steering Committee Structure *(number of seats) TABLEAU ??*

Chair:	Provided by hosting country
Secretariat:	COMISA
Full members:	
European Union	European Commission (1), EMEA (1)
Japanese government	JMAFF (2)
US government	FDA/CVM (1), USDA/CVB (1)
European Industry Association	FEDESA (2)
US Industry Association	AHI (2)
Japanese Industry Associations	JVPA (1), JAVB (1)
Observers: Australia/New Zealand	NRA(Aus)/MAF/ERMA (NZ)(1), Avcare/AGCARM(1)
Associate member	OIE Collaborating Centre for Veterinary Drugs

The role of OIE

VICH was established under the auspices of OIE, but is not subject to OIE rules for the adoption of its recommendations. The OIE has hosted and chaired the Steering Committee during the first phase of VICH (1996-99). The OIE will act as a body for the dissemination of VICH guidelines to its 153 member governments, both for consultation and for information. While these guidelines are being developed to harmonise requirements in three VICH regions (EU, Japan, and USA), other countries are encouraged to adopt them, but are not bound to do so.

The role of Coordinators

Each SC member will appoint a **coordinator** to act as contact point with their constituency and with the VICH secretariat. Co-ordinators 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. The Coordinators serve also on behalf of their respective parties as a functional liaison between working group experts and the Steering Committee and the Secretariat.

Expert Working Groups and Topic Leaders

Under the oversight of the Steering Committee, **expert working groups** have been created to address the priority topics selected by the Steering Committee. The working groups are responsible for elaborating draft recommendations for the priority topics determined by the Steering Committee. Membership of the working groups is decided by the Steering Committee; however, each full member and observer of the Committee have the right to appoint one expert per topic to the group. The Committee can appoint additional members as advisors from other regions to the working group based on their expertise.

For each new topic, the Steering Committee can assign the work to an already existing group or create a new working group to address this topic. In the case where multiple topics are grouped within one working group, a **chairperson** provides overall direction to the group, with leadership for individual topic areas provided by **topic leaders** within the group. In the case where only one topic is assigned to a group, the topic leader is responsible for managing the working group process.

The various topics are currently being addressed by the following Working Groups:

- Quality (related to stability, validation, impurities),
- Safety (related to consumer safety),
- Good Clinical Practice,
- Efficacy requirements for anthelmintics,
- Ecotoxicity/environmental impact assessment,
- Pharmacovigilance, and
- Biologicals quality monitoring.

The VICH Secretariat

COMISA provides the secretariat for VICH activities. In particular, the Secretariat prepares and circulates all relevant documents (agenda, minutes, conclusions of meetings, relevant correspondence) for the Steering Committee. The Secretariat furthermore publishes press releases adopted at the end of each meeting as well as recommendations adopted by the Steering Committee. It maintains the VICH web site up-to-date.

As a permanent point of a contact, the Secretariat, together with the co-ordinators, provides information, clarification, and proposed solutions to advance the work of VICH.

The VICH Guidelines

The main “end-product” of the VICH work is a scientific consensus regarding regulatory requirements, expressed in the form of a guideline. All VICH guidelines, both final (step 7) and at draft stage (step 4) can be downloaded from the VICH web-site: http://vich.eudra.org, or obtained from the secretariat.

The VICH step process

The development of VICH Guidelines follows a well-sequenced multi-step process:

Step 1: The Steering Committee defines a priority item from a concept paper prepared by a member and appoints a working group if needed. A topic leader is given a mandate to draft a recommendation.

Step 2: A recommendation is drafted and agreed by the working group.

Step 3: The draft is submitted to the Steering Committee for approval.

Step 4: Following adoption by the Steering Committee, the draft recommendation is circulated for consultation.

Step 5: The working group takes comments into consideration in preparing a revised draft. The topic leader must be a representative of a regulatory authority at this stage.

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

Step 7: A final recommendation and proposed implementation date are circulated to the relevant regulatory authorities.

Step 8: Steering Committee members report back on the implementation progress in their regions.

Step 9: Recommendations may be revised at the request of a member to take into account new scientific evidence.

At the time of publication of this brochure excellent progress had already been achieved: five guidelines had been finalised and released at the end of 1998 and in mid 1999, and another 14 had been released for consultation. The updated list of guidelines is annexed to this brochure as a separate sheet.

The First public VICH conference (VICH1) is taking place in mid-November 1999 in Brussels. It marks the completion of the first phase of harmonisation of regulatory requirements among the VICH regions. The public conference serves to disseminate the results of VICH and enables public information and debate on its on-going activities.

Final Guidelines

- Validation of analytical procedures : Definition and Terminology <../pdf/gl01_st7.pdf>
  VICH GL1 (Validation definitions) October 1998 For implementation at Step 7 in October 1999

- Validation of analytical procedures : Methodology <../pdf/gl02_st7.pdf>
  VICH GL2 (Validation methods) October 1998 For implementation at Step 7 in October 1999

- Stability testing of new drugs substances and products <../pdf/gl03_st7.pdf>
  VICH GL3 (Stability drugs) May 1999 For implementation at Step 7 in May 2000

- Stability Testing :Requirements for New Dosage Forms <../pdf/gl04_st7.pdf>
  Annex to the VICH guidelines on Stability Testing for New Drugs and Products
  VICH GL4 (Stability products) May 1999 For implementation at Step 7 in May 2000

- Stability Testing :Photostability Testing of New Drug Substances and Products <../pdf/gl05_st7.pdf>
  VICH GL5 (Photostability) May 1999 For implementation at Step 7 in May 2000

Draft guidelines

- Environmental Impact Assessment (EIAs) for veterinary medicinal products (VMPs) - Phase I <../pdf/gl06_st4.pdf>VICH GL6 (Ecotoxicity - Phase 1) October 1998 For consultation at Step 4 - Draft1

- Efficacy of Anthelmintics: General Requirements <../pdf/gl07_st4.pdf>VICH GL7 (Anthelmintics General) October 1998 For consultation at Step 4 - Draft 1

- Stability Testing for Medicated Premixes <../pdf/gl08_st4.pdf>
  <../pdf/gl07_st3.pdf>VICH GL8 (Stability premixes) October 1998 For consultation at Step 4 - Draft 1

- Good Clinical Practices <../pdf/gl09_st4.pdf>VICH GL9 (GCP Pharma) October 1998 For consultation at Step 4 - Draft 1

- Impurities in New Drug Subtances <../pdf/gl10_st4.pdf>VICH GL10 (Impurities New Subtances) October 1998 For consultation at Step 4 - Draft 1

- Impurities in New Veterinary Medicinal products <../pdf/gl11_st4.pdf>VICH GL11 (Impurities New VMPs) October 1998 For consultation at Step 4 - Draft 1

- Efficacy of Anthelmintics : Specific Recommendations for Bovines <../pdf/gl12_st4.pdf>VICH GL12 (Anthelmintics : Bovines) February 1999 For consultation at Step 4 - Draft 1

- Efficacy of Anthelmintics : Specific Recommendations for Ovines <../pdf/gl13_st4.pdf>VICH

GL13 (Anthelmintics : Ovines) February 1999 For consultation at Step 4 - Draft 1

- Efficacy of Anthelmintics : Specific Recommendations for Caprines <../pdf/gl14_st4.pdf>VICH GL14 (Anthelmintics : Caprines) February 1999 For consultation at Step 4 - Draft 1

- Efficacy of Anthelmintics : Specific Recommendations for Equines <../pdf/gl14_st4.pdf>VICH GL15 (Anthelmintics : Equines) For consultation at Step 4 - Draft 1

- Efficacy of Anthelmintics : Specific Recommendations for Swine <../pdf/gl14_st4.pdf>VICH GL16 (Anthelmintics : Swine) For consultation at Step 4 - Draft 1

- Stability testing of biotechnological/biological veterinary medicinal products <../pdf/GL17_ST4.pdf>
  VICH GL17 (Stability: biotechnologicals/biologicals) July 1999 For consultation at Step 4 - Draft 1

- Impurities: Residual Solvents <../pdf/GL18_ST4.pdf>
  VICH GL18 (Impurities: Residual Solvents) July 1999 For consultation at Step 4 - Draft 1