Workshop for OIE National Focal Points on Veterinary Products
Casablanca, Morocco, 6-8 December 2011

VICH
Structure and Organisation

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What is VICH?

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

- International tripartite cooperation programme
- Brings together Regulatory Authorities and Industry
The VICH Regions

VICH Structure and organisation
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tr>
<td>1991</td>
<td>Creation of ICH with 1st conference</td>
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<td>1992</td>
<td>7th ITCVDR conference in Argentina: concept of VICH</td>
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<td>1994</td>
<td>OIE ad hoc group: scope, membership and objectives of VICH</td>
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<td>10-11 April 1996</td>
<td>1st VICH Steering Committee in the OIE Offices in Paris – <em>VICH takes up work</em></td>
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<td>Nov. 1999</td>
<td>1st VICH Public Conference in Brussels (Europe)</td>
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<td>Oct. 2002</td>
<td>2nd VICH Public Conference and 11th Steering Committee meeting in Tokyo (Japan)</td>
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<td>Oct. 2004</td>
<td>Adoption of the VICH Strategy for 2006-2010</td>
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<td>May 2005</td>
<td>3rd VICH Public Conference and 16th Steering Committee meeting in Washington DC (USA)</td>
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<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 Offices in Paris (Europe)</td>
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Establish and implement harmonized regulatory requirements for 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

- VICH Guidelines

Monitor and maintain existing VICH guidelines, taking particular note of the ICH work program and, where necessary, update these VICH Guidelines

- VICH revised Guidelines

* But not necessarily the highest possible
VICH Objectives

- 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 regulatory requirements within the VICH regions.
VICH Objectives

- Greater harmonisation of requirements for veterinary product registration
  - Reduced/eliminate need for duplicate testing
  - More efficient use of human, animal and material resources while safeguarding quality, safety & efficacy
  - Reduction of unnecessary delays in global product development
  - Provide a basis for wider international harmonisation of registration requirements

⇒ VICH Outreach – Forum agreed
Members of VICH SC

- Regulatory Representatives from:
  - EU ➔ EMA + European Commission
  - JAPAN ➔ JMAFF
  - USA ➔ FDA-CVM + USDA-CVB
  - ANZ ➔ AVPMA + NZFSA
  - Canada ➔ HC-VDD + CFIA-VBS

- Representatives from Regional Industry Associations:
  - AHI, JVPA, IFAH-Europe, Animal Health Alliance, AGCARM, CAHI

- OIE - Associate Member

- Secretariat: IFAH

VICH Structure and organisation
Role of VICH/OIE/Codex

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

  ⇒ **VICH Guidelines**

- **OIE** develops health standards for international trade in animals and animal products that member countries can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers

  ⇒ **OIE normative documents**

- **OIE** also improves the legal framework and resources of national Veterinary Services
Role of VICH/OIE/Codex

- **Codex Alimentarius**, the Joint FAO/WHO Food Standards Programme develops international **food safety standards**, such as
  - Codes of practice, Guidelines
  - Maximum residue limits (MRLs) for residues of veterinary drugs in foodstuffs of animal origin:
    proposed by the Joint FAO/WHO Expert Committee of Food Additives (JECFA),
    recommended by the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF),
    adopted by the Codex Alimentarius Commission (CAC)

⇒ **Codex food safety standards**
The VICH Process

- The **VICH Steering Committee** drives the process: selects topics, releases draft guidelines for consultation, and adopts final guidelines for implementation.

- **VICH Expert Working Groups** bring together the specific expertise for guideline development.

- **Transparent guideline development** through the VICH 9-step process, public website and conferences.

- **Commitment:** VICH members have committed to implement VICH guidelines in their veterinary product regulatory processes, VICH observers voluntarily do so.
The VICH Process

- Thorough selection of topics by the Steering Committee: assessment of benefit to human and animal health through greater harmonisation, and resource management
- Work mandated by Steering Committee to Expert Working Groups
- Elaboration and adoption of guidelines in a 9-step procedure
- Follows closely ICH, taking account of specific veterinary needs
- Consequent need for maintaining and updating existing GLs on a regular basis
The VICH Process

VICH Steering Committee

Expert Working Groups

- Quality EWG
- Bioequivalence EWG
- Safety EWG
- Biologicals EWG
- MRK* EWG
- Microbiological ADI EWG
- ESI† EWG

* Metabolism and Residue kinetics
† Electronic Standards Implementation
The VICH process: 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 review draft Guideline

**Step 4**
Public consultation in the regions

**Step 5**
EWG to review comments

**Step 6**
SC to adopt final Guideline

**Step 7-8**
Implementation of Guideline

**Step 9**
Recommendation for review

9 step procedure
The VICH Process

- Programme runs in cost-effective & transparent manner
  - All participants pay their own way
  - Industry associations host events & meetings

- Regulators and OIE ensure wide circulation of draft GLs for a 6-months consultation period

- Expert Working Groups meet regularly to progress their work

- Steering Committee meets at regular intervals
  - Monitors and supports Expert Working Groups
  - Monitors implementation in the Regions
The VICH language is English

- All meetings are run in English, whether Steering Committee or Expert Working Groups (translation is organised at own cost – currently for Japan)

- All documents (drafts and final) are written in English only

- VICH members may translate the documents in their national language at their own cost
The VICH Process

- The Steering Committee meets regularly,
  - Every 8 to 9 months, adjusted to need
  - Rotation between the 3 regions (EU – USA - Japan)
  - A representative from the regulators from the host region chairs the meeting
  - Monitors and supports the Expert Working Groups
  - Monitors implementation of Guidelines in the regions

- Expert Working Groups also meet regularly to progress their topics, subject to Steering Committee approval
VICH Guidelines

- VICH guidelines provide harmonised guidance that describes the data to be provided in an application dossier for a marketing authorisation for a veterinary medicinal product.
- VICH also establishes guidelines on the pharmacovigilance for veterinary medicinal products, i.e. the requirements for their post-marketing safety monitoring.
- VICH does not normally develop guidance on how to carry out the assessment of the data or on the assessment approach.
- Assessments are done by the regulatory authorities of the VICH countries and regions.
15 years of confidence building and collaboration!

- Considerable improvements of harmonization of data requirements between participating regions, thus
  - Reduction of animal testing
  - Reduction of costs
- Better understanding of regulations and concerns in the other regions
- Unique discussion forum between acknowledged scientific experts from Regulatory Authorities and Animal Health Companies
- **New:** VICH Outreach Forum to better involve non-member countries, 1st meeting in June 2012, Brussels
Achievements [2]

- Decisions in the SC and the EWGs 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
- Global product development approach
- Accelerate Veterinary Medicinal product development for Livestock & Companion Animals
- Increased uniformity of regulatory process and technical requirements
- Increase availability of Veterinary Medicines
- Increased Product Safety and Consumer Safety
Achievements [3]

- 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
- Excellent scientific expertise
- VICH guidelines on data requirements for registration of veterinary medicines (more details follow)
  ➔ 47 finalised VICH Guidelines (of which 6 revised)
  ➔ 10 new VICH Guidelines under development
Achievements [4]

- 47 finalised guidelines (GLs):
  - Implemented: 42
  - For implementation in 2012: 5
- New GLs under consultation/discussion: 10
- Revised GLs at step 9
  - Implemented: 6
  - Under review: 1
- Detailed list of GLs available on the website
New GLs under discussion/consultation:

- 3 Pharmacovigilance GLs
- 1/2 Biological GLs
- 1 Safety GL
- 1 Bioequivalence GL
- 1 Metabolism & Residue Kinetics

Final GL under Revision:

- 1 Quality GL
The VICH website

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

VICH GUIDELINES

Documents in consultation

- Residual Solvents in new Veterinary Medicinal Products, Active Substances and Excipients (Revision at step 9)
- Draft revised VICH GL18 (Quality-Impurities) - Released at step 4 for a 6-month public consultation period until October 31, 2010
- Testing for the detection of mycoplasma contamination
  VICH GL 34 (Biologics - Mycoplasma) - Released at step 4 for a 3-month public consultation until February 29, 2012
- Electronic Standards for Transfer of Data
  VICH GL35 (Pharmacovigilance) - Released at step 4 for a 6-month public consultation period until March 15, 2011
- Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI
  VICH GL36(R) (Safety) - February 2011 - Released at step 4 for a 6-month public consultation period until August 31, 2011
- Harmonization of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use
  VICH GL 50 (Biologics - TABST) - Released at step 4 for a 6-month public consultation until May 31, 2012
- Statistical evaluation of stability data
  VICH GL 51 (Quality) - Released at step 4 for a 6-month public consultation until May 31, 2012

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The VICH website

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Conclusions

- Much has been achieved over 15 years of activity, but much lies still ahead
- Consensus and mutual understanding are the keys to the success of VICH’s development
- The Experts are the pillars of the VICH work
- VICH has the potential to eliminate duplications, to reduce timelines and to ensure a more efficient usage of available human material and animal resources, whilst safeguarding the quality, safety and efficiency of products
- The Wider International Harmonisation will enable to extend international harmonisation of regulatory requirements to further countries/regions
Final and draft Guidelines available on:

http://www.vichsec.org