OIE Conference on Veterinary Medicinal Products in the Middle East

Damascus, Syria, 2-4 December 2009

International Approach for Veterinary Medicinal Products: VICH

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Overview

Regulatory Infrastructure and the role of VICH

- Regulation of veterinary medicines – need for, advantages and costs of regulation; basic framework
- Role of VICH in the regulation of veterinary medicines
- Success of VICH and relevance to the Middle East
Regulatory Infrastructure – a must!

• Authorisation, embedded in veterinary legislation
  – Proof of quality, safety and efficacy, added requirements for vaccines (underpinned by OIE terrestrial code)
  – Complemented by control of quality, safety and efficacy

• Based on reasoned, scientifically sound, regulatory guidelines

• Industry welcomes and supports good regulation of medicines in a framework of scientifically based guidelines

• Advantages for governments, society, and industry
  — Acceptance of and customer confidence in veterinary medicines
  — A transparent scientifically based environment with clear rules
## Legislative framework regulating veterinary medicines (VMs)

### Authorisation of VMs
- Pre-marketing requirements for quality, safety & efficacy
- Dossier submission
- Application evaluation
- Authorisation decision – approval / non-approval

### Control of VMs
- Pre-authorisation
  - GMP inspection of manufacturer
- Post-authorisation
  - GMP-inspection of manufacturer
  - Inspections for other obligations e.g. pharmacovigilance

Random quality control of
**Regulation of Veterinary Medicines – role of VICH**

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VICH introduction

VICH is a trilateral (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 1996, with the support of OIE.

The acronym “VICH” is based on the acronym of the corresponding initiative for human medicines – ICH, the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use.
VICH regions

Canada
USA
Europe
Japan
Australia
New Zealand
VICH objectives

- 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.

- Provide a basis for wider **international harmonization** of registration requirements.

- **Monitor, maintain, and, where necessary, update** existing VICH guidelines.

- Ensure efficient processes for maintaining and monitoring **consistent interpretation of data requirements** after implementation of VICH guidelines.

- Provide **technical guidance enabling response to** significant emerging global issues and science that impact on regulatory requirements within the VICH regions by means of a constructive dialogue between regulatory authorities and industry.
VICH structure and process

- **The program:** a trilateral (EU-Japan-USA) programme involving regulators and industry aimed at harmonising technical requirements for veterinary product registration; Australia/New Zealand and Canada are observers.

- **The Driver:** The **Steering Committee** with representatives from all parties of the VICH regions and observer countries

- **The Process:** the 9-step procedure

- **The Framework:** the official **Organisational Charter**

- **The Workers:** the **Expert Working Groups (EWGs)**; made up of members from all VICH parties and observers
VICH topics

- Quality
- Safety
- Ecotoxicity
- Good Clinical Practice (GCP)
- Anthelmintics
- Pharmacovigilance
- Biologicals quality monitoring
- Antimicrobial resistance
- Target Animal Safety
- Metabolism and Residue Kinetics
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<th>Step</th>
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| 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 | Official consultation in three regions                               |
| Step 5 | EWG to review comments                                               |
| Step 6 | SC to adopt final Guideline                                          |
| Step 7-8 | Implementation of Guideline                                        |
| Step 9 | Monitoring, maintenance & recommendation for review                  |
VICH – what can it do and not do?

VICH does:

• harmonize test requirements for the authorisation of veterinary medicines;
• ensure that test requirements are based on the current state of science;
• reduce need to repeat studies – full VICH partners commit to accepting studies performed to VICH GLs, observers voluntarily accept;
• support animal welfare by wider study acceptance and reducing need for test animals.

VICH does not:

• provide a legislative structure for regulatory system for veterinary medicines;
• harmonize the interpretation of test results;
• guarantee authorisation, even if all tests are done in accordance with VICH GLs;
• harmonize all areas of testing veterinary medicines – only where there is an agreed need of regulators and industry of VICH regions and observers.
VICH - has it worked?

Yes

• An excellent forum for continuing dialogue and collaboration between research based animal health industry and regulatory bodies around the world

• 3 public conferences building confidence into VICH held since the start, the 4th comes to the OIE headquarters, Paris, 24–25 June 2010

• Regular meetings between assessors working towards a consensual approach to assessment and scientific evaluation of regulatory submissions

• Over 40 guidelines finalised on a broad range of topics covering quality, safety & efficacy

• Overwhelming agreement that VICH has helped to streamline the approval of veterinary medicines in participating countries
Does VICH have relevance for the Middle East?

- YES – very definitely! – if only to encourage the legal sector
- Implementing VICH guidelines
  - can help align regulatory systems in the Middle East to global systems for approving veterinary drugs
  - will provide access for assessors to the latest scientific thinking on dossier evaluation
  - can provide a platform for regional regulatory harmonization
- Adopting pharmacovigilance principles will provide detailed and valuable post authorisation information on safety of medicines
- VICH is evaluating the needs of non-VICH countries and considering possibilities for involving new regions the focus of the VICH 4 conference; come and bring your ideas!
Further Information

On IFAH @ http://www.ifahsec.org
On VICH @ http://www.vichsec.org,

including the
VICH 4 conference
24-25 June 2010,
OIE headquarters at
12, rue de prony
Paris

Thank you for your attention