International Structures: VICH

Merton V. Smith, Ph.D., J.D.

Director, International Programs, Center for Veterinary Medicine, FDA and

FDA Representative to the VICH Steering Committee

Presentation Outline

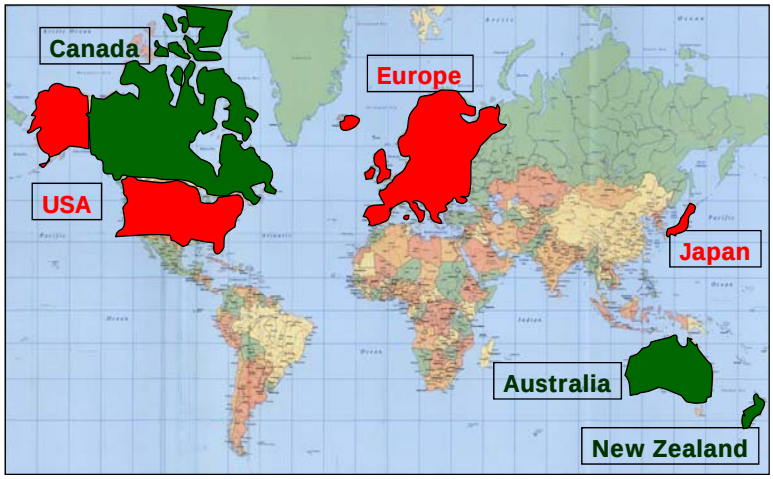
- Introduction to VICH
- VICH Achievements
- VICH Challenges, Issues and Considerations
- VICH Possible Future Work
- Future Opportunities for VICH

What is VICH?

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

International program of cooperation and information exchange with the goal of reaching consensus on the data requirements and study protocols needed to show safety, quality, and efficacy for registration or licensing of veterinary medicinal products

VICH Countries/Regions



Participating in VICH

- **Regulatory Agencies**
  - USA = FDA and APHIS
  - EU = EMA (and European Commission)
  - Japan = MAFF (and NVAL, MHLW and FSC)
  - Australia/New Zealand = APVMA and NZFSA
  - Canada = VDD

Participating in VICH

- **Industry representatives**
  - USA = AHI
  - EU = IFAH Europe
  - Japan = JVPA
  - Australia/New Zealand = AHA/AGCARM
  - Canada = CAHI
- **Other participants**
  - IFAH Global
  - OIE

Building Stronger Infrastructures

- FDA and OIE support building stronger veterinary medicine regulatory infrastructures
- Authorisation of veterinary medicines around the world almost universally follows a similar model that is based in veterinary legislation and regulation
- Premarket demonstration of quality, safety and efficacy
- Supported by appropriate surveillance and controls of quality, safety and efficacy

Building Stronger Infrastructures

- To implement such a regulatory registration/licensing system requires the development of regulatory guidelines that are scientifically sound and based on public health and animal health protection principles
- Generally industry, regulators, and consumer- and animal-protection organizations support this approach

VICH Goals

- Draft guidelines for studies that ensure high product standards of quality, safety, and efficacy that protect public health, animal health and welfare, and the environment
- Implement harmonised regulatory requirements for veterinary medicines in the VICH countries/regions
- Minimize the use of test animals and costs of product development

VICH Goals
(Continued)

- Facilitate and accelerate the authorization of Veterinary Medicinal Products
- Provide a basis for future international harmonisation of registration requirements
- Provide forum for dealing with new, emerging global issues and relevant science

VICH Goals
(Continued)

- Harmonized requirements should replace corresponding national/regional requirements
- Development process is transparent, cost-effective, and open for public comments
- Public conferences (VICH 1-4 Conferences)
- Reduction of costs and time for all stakeholders

VICH Goals
(Continued)

- Unique opportunity for industry to work with regulators on common interests
- Forum where highly experienced and qualified scientific experts exchange information
- Better understanding generally of regulations and related concerns

VICH Goals

(Continued)

- Encourages global product development approach
- Encourages pooling of regulatory resources
- Provides more regulatory certainty
- Reduces impediments to trade in drugs and food

The VICH Process

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	Recommendation for review
→	9 step procedure repeated

Working Groups

• Quality • Safety • Good Clinical Practices • Anthelmintic Efficacy • Ecotoxicity • Biologicals Quality	• Pharmaco/Vaccinovigilance • Antimicrobial Resistance • Target Animal Safety • Metabolism and Residue Kinetics • Bioequivalence

Development of Guidelines

- Finalized and implemented guidelines: **38**
  - already revised: **5**
  - currently under revision: **3**
- Guidelines out for comment and expected to be implemented during the next 2 years: **14**
- Future guidelines under early development or under consideration: **3**

Current Work

- Further develop current draft guidelines and concept papers
  - Pharmaceuticals Quality guidelines
  - Biologicals Quality guidelines
  - implement Pharmacovigilance guidelines
  - develop Acute Reference Dose guideline
  - develop Bioequivalence guideline
  - develop Rabies Vaccine Potency Test guideline

Future Work

- Criteria for the development of VICH priorities
  - significance of the issue
  - benefit to VICH participants and others
  - special challenges

Possible Future Work in VICH

- Good Laboratory Practices
- Good Manufacturing Practices
- Common Technical Document
  - content and format of applications

Possible Future Work in VICH (continued)

- Harmonization of antimicrobial susceptibility testing
- Safety and efficacy requirements for minor species and rare diseases

Challenges/ Opportunities

- Maintaining commitment to VICH by all parties
- Questions concerning new technologies
- Complementary work of JECFA and Codex
- VICH Global Outreach Initiative
- OIE 5th Strategic Plan
- Role of additional countries/regions in the VICH process

Summary

- VICH offers:
  - opportunity to exchange scientific regulatory information of mutual interest
  - transparent process for development of harmonized standards based on principles of sound science and public health and animal health protection
  - practical efficiencies for both regulatory authorities and industry
  - process that will help assure that veterinary medicinal products available to promote livestock and companion animals' health and well-being

VICH Website

http://www.vichsec.org/