Veterinary Products: VICH Initiatives

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Presentation Outline

- Introduction to CVM and to VICH
- VICH Achievements
- VICH Challenges, Issues and Considerations
- VICH Possible Future Work
- Future Opportunities for VICH
CVM’s Core Responsibilities

- New Animal Drug Review
- Animal Generic Drug Review
- Post-approval monitoring of animal drugs and feeds, and marketed animal devices
- Animal Feed Protection/Safety
- Compliance related actions
- Research to support regulatory decision-making
CVM’s Total Staff is 472
Some CVM Challenges

- Animal and plant biotechnology including genetic engineering and cloning
- Bovine Spongiform Encephalopathy (BSE) spread through the feed supply
- Antimicrobial resistance from the use of veterinary drugs
CVM International Activities

• Chairs Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

• Leads U.S. Delegations to:
  – Codex Task Force on Antimicrobial Resistance
  – Electronic Working Group on Animal Feeding
  – CCRVDF

• Provides scientists to FAO/WHO Joint Expert Committee on Food Additives (JECFA)

• Serves on VICH Steering Committee and most VICH Expert Working Groups
CVM International Activities (Continued)

• Carries out capacity building projects
  – Animal drug workshops
  – Support for OIE outreach about VICH guides and strengthening regulatory infrastructures
  – Support of WHO plan to harmonize antimicrobial resistance monitoring
  – Dissemination of aquaculture proper drug use information
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.
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

<table>
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<tr>
<th>Industry representatives</th>
<th>Other participants</th>
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<td>USA = AHI</td>
<td>IFAH Global</td>
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<td>EU = IFAH Europe</td>
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• 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 proof of quality, safety and efficacy

• Supported by appropriate controls of quality, safety and efficacy
Building Stronger Infrastructures

• In order to implement such a regulatory registration/licensing system requires the development of regulatory guidelines that are scientifically sound and rational.

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

- Finalized and implemented guidelines: 38
  - already revised: 5
  - currently under revision: 3

- Guidelines out for comment, or out for comment soon, 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
• Harmonization of antimicrobial susceptibility testing

• Safety and efficacy requirements for minor species and rare diseases

• Alternatives to animal testing
Challenges/Opportunities

- Maintain 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
Increased Need for Veterinary Medicinal Products

- Global population reached 6 billion people in 1999 and 6.9 billion in 2010 and is estimated to reach 7.6 billion by 2020 and 9.1 billion by 2050
- Increased desire for animal protein from the developing world
- FAO estimates that by 2050 there will be a need to double current meat production worldwide to meet demand
Increased Need for Veterinary Medicinal Products (continued)

- Require safety of residues for protection of the consumer
- Increased importance of companion animals worldwide
- Increased importance of animal welfare worldwide
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/