VICH: General Principles and Update on Global Outreach Initiative

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Presentation Outline

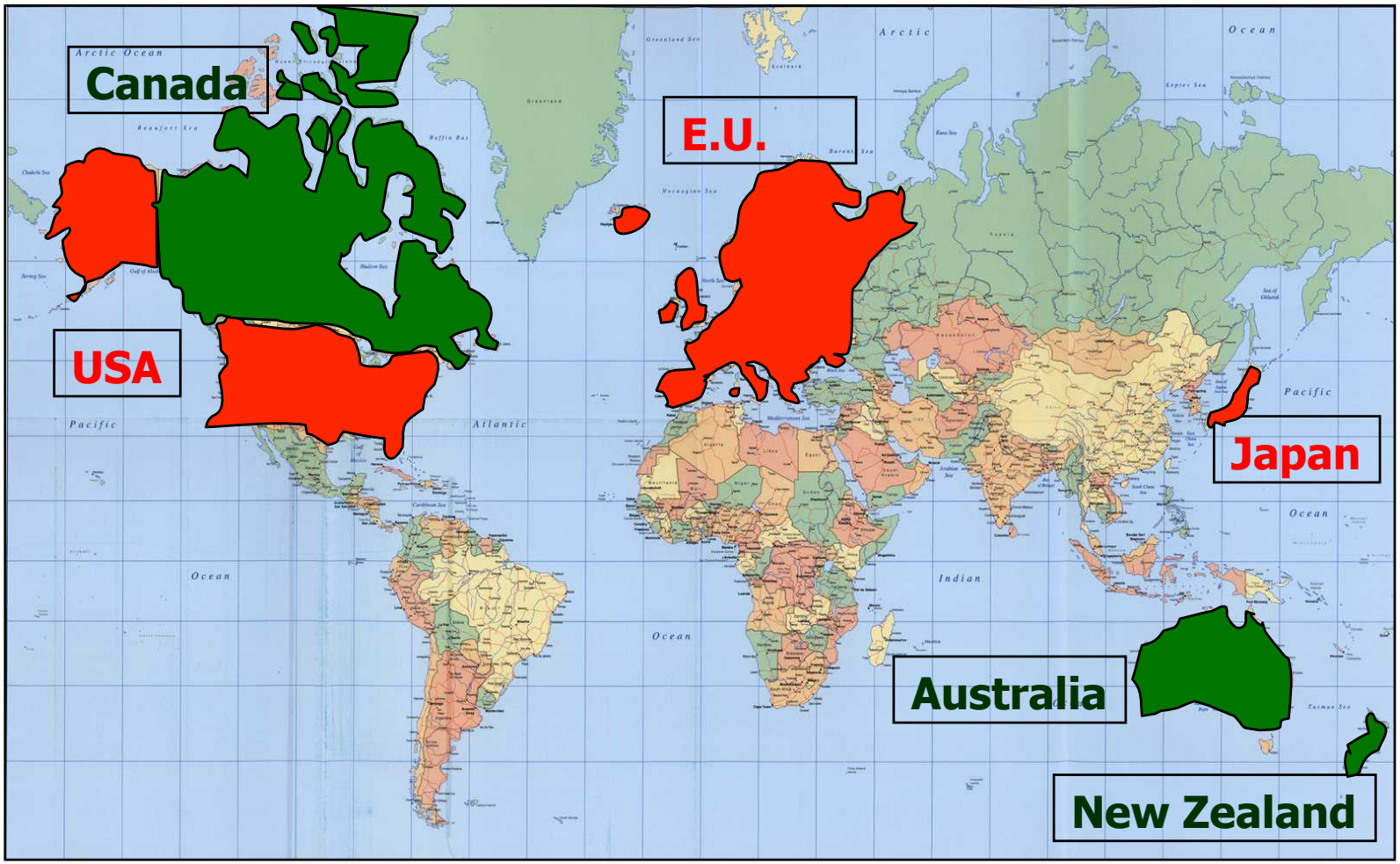
- Introduction to VICH
- Achievements
- Challenges and other Considerations
- Future Work
- Global Outreach Initiative

What is VICH?

VICH = International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal 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 the 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 (NVAL), MHLW and FSC
  - Australia/New Zealand = APVMA and NZFSA
  - Canada = VDD
  - South Africa = DAFF and Department of Health

Participating in VICH

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

VICH Guidelines

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

VICH Goals

- Encourage global product development approach
- Provide a venue where highly experienced and qualified scientific experts exchange information
- Encourage pooling of regulatory resources
- Provide more regulatory certainty
- Reduce impediments to trade in drugs and food

VICH Outcomes

- Harmonized requirements should replace corresponding national/regional requirements
- Development process is transparent, cost-effective, and open for public comments
- Reduction of costs and time for all stakeholders
- Public conferences (VICH 1-4 Conferences)
  - 5th Public Conference Tokyo October 28 – 29, 2015

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

Current active VICH Expert WGs

- Quality
- Safety
- Bioequivalence
- Electronic File Format
- Biologicals Quality Monitoring
- Metabolism and Residue Kinetics (MRK)
- Electronic Standards Implementation (ESI - Pharmacovigilance)

Development of Guidelines

- Finalized and implemented guidelines: **51**
  - already revised: **7**
  - currently under revision: **3**

- Guidelines out for comment, or out for comment soon, and expected to be implemented during the next 2 years: 2

Recently adopted Guidelines at 28th SC meeting 2013

- VICH GL 34 Biologicals: Test for the detection of Mycoplasma contamination
- VICH GL 35 Pharmacovigilance: Electronic Standards for Transfer of Data
- VICH GL 50 Biologicals: Harmonization of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use
- VICH GL 51 Quality: Statistical evaluation of stability data

Recently completed for implementation at 29th VICH SC meeting 2013

- VICH GL 24 Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)
- VICH GL 30 Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms
- VICH GL 35 Pharmacovigilance: Electronic Standards for Transfer of Data
- VICH GL 42 Pharmacovigilance: Data elements for submission of Adverse Events Reports

Current VICH Work

- 2 biologicals quality guidelines (ongoing)
- Implementation pharmacovigilance guidelines (ongoing)
- Acute Reference Dose guideline (ongoing)
- Electronic File Format for e-submissions guideline (ongoing)
- Metabolism and Residue Kinetics in fish guideline
- Metabolism and Residue Kinetics in honey guideline
- Combination products

Possible Future Work in VICH

- Safety and efficacy requirements for minor species and rare diseases
- Extension of Target Animal Batch Safety Testing (TABST) guideline
- Revision of anthelmintics guidelines
- Revision of Safety guidelines

30th VICH SC meeting

- June 23 – 26, 2014 Brussels

- 4th VICH Outreach Forum meeting

Challenges and Opportunities

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

Veterinary Medicine Industry in 1996 and Today

- In 1996, VICH participating countries/region = 90% of the veterinary medicine global market
- In 2011, VICH participating countries/region = 70% of the veterinary medicine global market
- Increase in international movement of animals, people, and foods derived from animals

VICH Global Outreach Initiative

- November 2011 Contact Meeting on Wider International Harmonization: VICH Steering Committee, 11 countries, and 3 Regional Organizations
- The VICH Steering Committee agreed to form the "**Outreach Forum**" to be held before each future VICH Steering Committee meeting

Objectives of Global Outreach Initiative

- Provide basis for wider international harmonization of registration requirements
- Improve information exchange
- Raise awareness of VICH and VICH guidelines with non-VICH countries and regions

VICH Global Outreach Forum

- Criteria to participate in the VICH Outreach Forum:
  - Marketing authorization regulations must exist
  - Willingness to accept and work towards the implementation of VICH Guidelines
  - Self-financing participation in meetings
  - Commitment to regular attendance at meetings

VICH Global Outreach Forum

- Translation and sharing of translated Guidelines
- Need for training for Forum members
  - VICH Guidelines
  - VMPs regulatory systems
  - Strategic Training Working Group (ad hoc working group) – develop training strategy

Strategic Training Working Group (Ad hoc)

- Mission – promote better understanding of VICH GLs and their utilization to facilitate wider harmonization of registration requirements globally
- Objectives:
  - Discuss elements of training necessary
  - Explore options for delivery of training
  - Identify training opportunities

Scope of VICH training strategy for Forum members

- Address challenges faced by Forum members with respect to the application of VICH GLs
- Assist regulatory authorities with all aspects dealing with the technical requirements for registration of VMPs
  - General requirements
  - Pre-approval (quality, safety, and efficacy)
  - Post-approval (pharmacovigilance)

VICH Training Strategy for Forum Members

29th VICH SC and 3rd VICH Outreach Forum meeting Auckland, NZ November 2013

Implementation Working Group

- Two pronged approach

1. During Outreach Forum meeting

2. At Outreach Forum member country or region level

Benefits of VICH Participation

- opportunity to exchange scientific regulatory information of mutual interest
- forum for dealing with new, emerging global issues and relevant science
- 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/