VICH: General Principles and Global Outreach

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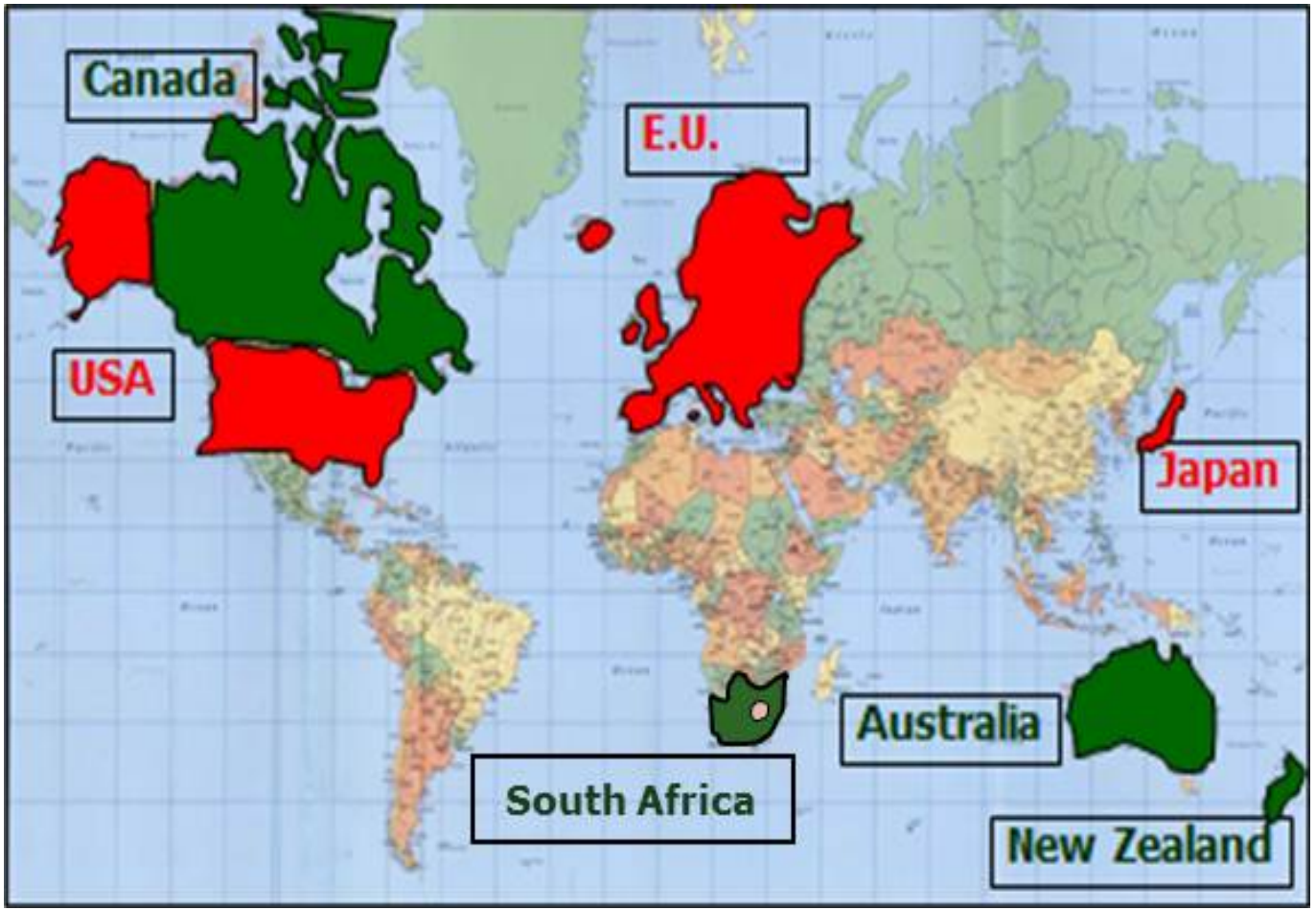
What is VICH?

- **VICH** = International Cooperation on Harmonization of **Technical Requirements** for Registration of Veterinary Medicinal Products (VMPs)
- 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
- ICH established 1990
- VICH established 1996

VICH Countries and Regions



The Steering Committee

Status	Country/Region	Number of participants	
		Government	*Industry*
Full members	Japan	3	3
	EU	3	3
	USA	3	3
Observers	Australia	1	1
	New Zealand	1	1
	Canada	1	1
	South Africa	1	1
Associate member	World Organization for Animal Health (the OIE)	1	
Interested Party	Association of Veterinary Biologics Companies (AVBC)	1	
Secretariat	AnimalHealthEurope		

Overview of VICH Structure

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

VICH Guidelines

Category		Guideline numbers
Pharmaceuticals	Quality	1, 2, 3, 4, 5, 8, 10, 11, 17, 18(R)*, 39, 40, 45, 51
	Efficacy	7, 12, 13, 14, 15, 16, 19, 20, 21
	Environmental Safety	6, 38
	Metabolism and Residue	46, 47, 48(R), 49(R)
	Toxicology	22, 23, 28, 31, 32, 33, 37, 54
	Target Animal Safety	43
	Antimicrobial Safety	27, 36
Biologicals	Quality	34, 25, 26
	Target Animal Safety	41, 44, 50(R), 55
	Bioequivalence	52
General	GCP	9
	Electronic File Format	53
Pharmacovigilance	Pharmacovigilance	24, 29, 30, 35, 42

Expert Working Groups (EWG)

- The SC establishes an EWG with a specific mandate
- Current active EWGs

Safety | Quality | Biological Quality Monitoring | Anthelmintics

ESI (Pharmacovigilance) | Metabolism & Residue Kinetics

- Participants for each EWG

Country/Region	Number*	
	Government	Industry
Japan	1	1
EU	1	1
USA	1	1
Observers	1	

*Each member and observer may send one additional advisor when required.
Experts from VOF countries may also be appointed.

What is NOT the role of VICH?

- Provide guidance to establish regulatory systems and regulations for marketing authorisations
- Decide which studies are necessary to obtain a marketing authorisation
- Assess data or provide guidance on the assessment approach
- Grant marketing authorisations
- Establish safety standards

These are typically the roles of national competent authorities and governments!

Work done by VICH must be within the scope of VICH.

VICH Global Outreach Strategy

- Provide basis for wider international harmonization of technical registration requirements
- Improve information exchange
- Raise awareness of VICH and use of VICH Guidelines with non-VICH countries / regions
- Minimize the use of test animals (which promotes animal welfare) and costs of product development
- Ensure high product standards of quality, safety, and efficacy to protect public health, animal health and welfare, and the environment - **GLOBALLY**

Members of the VOF

- Nigeria
- Uganda
- Zimbabwe
- Tanzania
- Argentina
- Brazil
- People's Republic of China
- Republic of Korea
- Saudi Arabia
- India
- Mexico
- Philippines
- Russia
- Taiwan
- Thailand
- WAEMO/UEMOA
- CAMEVET
- ASEAN

Impact of VOF Members in VICH

VOF members report that technical requirements set in the GLs are increasingly gaining importance for the registration of VMPs

- New EWG to develop general guideline on pharmaceutical Combination Products
  - EWG chaired by the People's Republic of China (VOF)
    - *First topic proposed by a VOF member

- Draft guidance on stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV (hot and dry/humid conditions) – first GL to *specifically address VOF countries and countries outside VICH regions*

Impact of VOF Members in VICH

- VICH GL56: Study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods
  - Argentina (VOF) had active involvement in elaboration
  - 6 month public consultation period ended July 2017
  - Assessing comments in order to revise draft GL

- Pharmacovigilance – Electronic Standards Implementations – *request from VOF for agenda item on global electronic system at November 2017 Outreach Forum meeting*

What if the GLs don't fit exactly the situation in my country?

- Full VICH Member regulatory authorities (EU, Japan, US) agree by consensus to the final GLs and adopt GLs as they are

- For other countries and regions, it is the preference is to adopt GLs in their entirety, but there can be some flexibility to fit local country situations – adopt all or part of a GL

My country is NOT a VOF Member – can I participate in the process?

- **YES!!! Review and comment on the draft GLs when presented by the OIE during the public consultation period.**

- As regulatory authorities deal with new, emerging and innovative global issues, your comments can help provide more regulatory certainty and improve the science that supports the GLs.

- Draft GL on residues in aquatic species will soon be signed off by the Metabolism and Residue Kinetics EWG and released for 6 months public consultation period

How do VOF countries participate in VICH?

- Participate in the Outreach Forum meetings
- Propose new priority topics for elaboration
- Provide feedback on the relevance and implementation of VICH guidelines in their country and region
- Where relevant, participate in VICH Expert Working Groups
- Submit comments to draft guidelines during the public consultation phase (step 4 of the VICH process)
- Make suggestions for discussion at the VICH Outreach Forum meetings
- Provide feedback on the usefulness of the VICH Outreach Forum and the VICH webpages

How to become a VICH VOF Member

Criteria to participate in the VICH Outreach Forum:

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

Countries or regional organizations that are interested in participating in this initiative should write to the VICH secretariat: sec@vichsec.org

VICH and promotion of Animal Welfare and the 3 R's Concept

- Statement of Principle for VICH – Alternatives to animal testing (VICH 07/038-Final; 18/09/2007)
- International harmonization reduces the need to repeat studies thereby minimizing the use of test animals
- Harmonization of criteria to waive target animal batch safety testing for inactivated (GL50R) and live (GL 55) vaccines will be implemented in the regions by May 2018 and are available on the VICH website
- Current work on *draft* GL Harmonization of criteria to waive laboratory animal batch safety testing

VICH Training

- ******Any VICH supported training must be in the scope of VICH***
- ***Increasingly difficult to resource in-person training***

- VICH Steering Committee considering options for developing and delivering training on the Guidelines (materials for self-learning)
  - Bioequivalence EWG currently reviewing a pilot training module on GL52

- ASEAN training in Brunei April 2017 / 7 countries attended

- Global Animal Health Conferences in Tanzania and India focusing on regulatory convergence - funded by the Bill and Melinda Gates Foundation

- Steering Committee considering redesign of VICH website to include section on training and resource library with references to other relevant organizations i.e. the OIE, WHO, FAO, ICH, CODEX, JECFA….

VICH GL 27 on AMR

- Guidance on preapproval information for registration of new VMPs for food producing animals with respect to antimicrobial resistance - Implemented December 2004

- Outlines the types of studies and data recommended to characterize potential resistance development as it might occur in the food producing animal under the proposed conditions of use of the product

- Pathogen load studies, eco-toxicity studies, the process of risk assessment, the establishment of Acceptable Daily Intakes (ADIs), and consideration of residues of antimicrobial agents are not included in the guidance.

VICH Meetings

36th and 10th VOF June 25-28, 2018 Bruges, Brussels	
35rd SC and 9th VOF November 13-16, 2017 Tokyo, Japan	
35 Steering Committee meetings	Every 9 months
9 VICH Outreach Forum meetings *Chaired by VICH and the OIE*	
5 VICH Public Conferences	Every 5 years
Expert Working Groups work through e-mails, teleconferences and face-to-face meetings to progress their work	Ad hoc and ongoing

37th Steering Committee, 11th Outreach Forum, 6th VICH Public Conference

- February 24 – March 1, 2019 in Cape Town, South Africa – a VICH Observer Member country
- First time a VICH Public Conference will be held outside of one of the 3 regions and first in Africa
- Public Conference will focus on the global outreach activities as well as the current work of the EWGs
  - Hope to attract regulators and industry from the continent

U.S. FOOD & DRUG ADMINISTRATION

THANK YOU!!!

http://www.vichsec.org/

*Hope to see you in Cape Town in 2019.