Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Organización Mundial de Sanidad Animal

VICH general principles and update on Outreach Forum activities; and update of the next upcoming Public Conference

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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

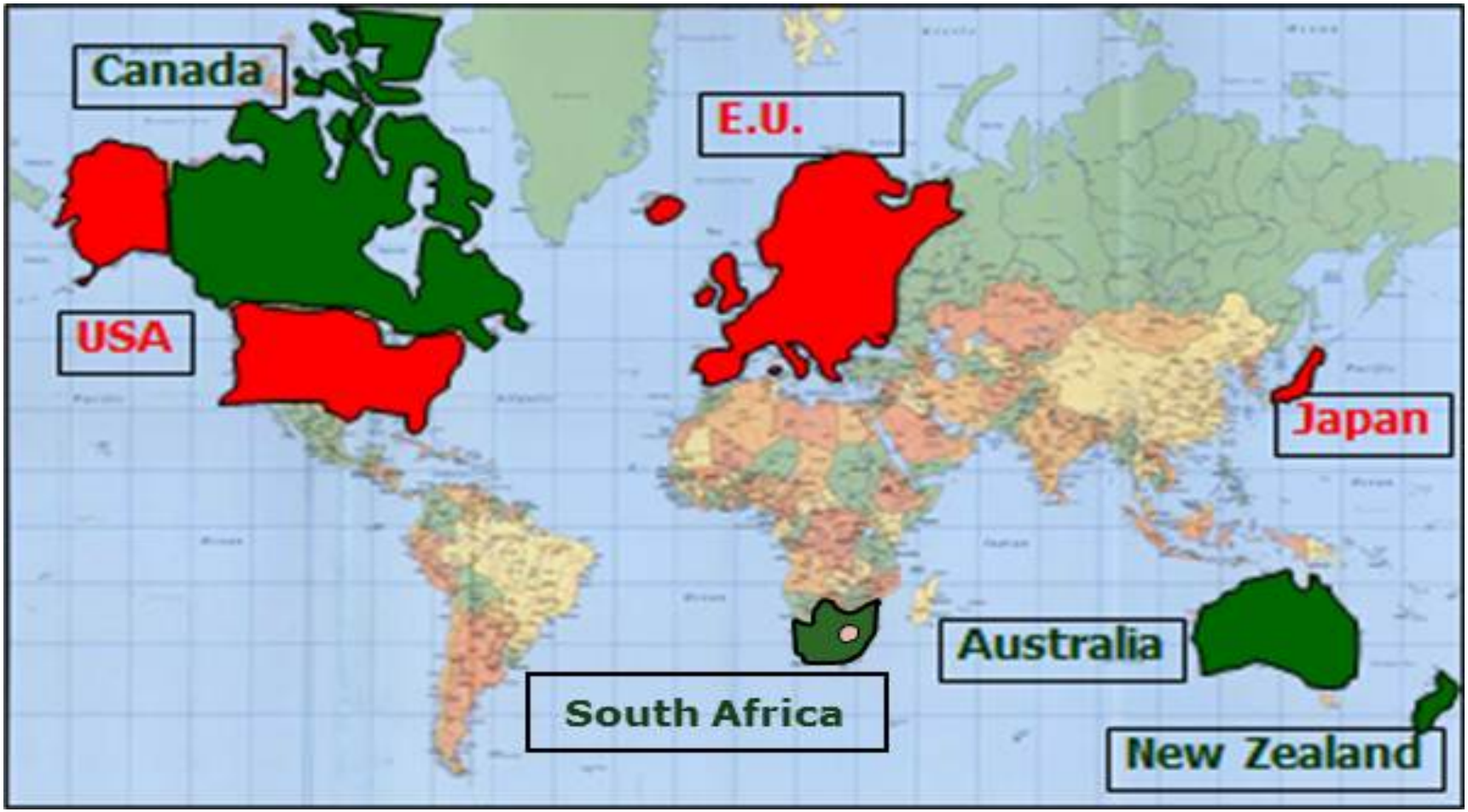
ICH established 1990

VICH established 1996

What does VICH do?

- Encourages global product development approach
- Provides a venue where highly experienced and qualified scientific experts exchange information
- Encourages pooling of regulatory and industry resources
- Provides more regulatory certainty
- Reduces impediments to trade in VMPs and food

VICH Countries and Regions



Participation in VICH

- **Regulatory Authorities**
  - **USA** = FDA and USDA 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

Participation in VICH

- **Industry Representatives**
  - **USA** = AHI
  - **EU** = IFAH Europe
  - **Japan** = JVPA

  - **Australia/New Zealand** = AHA/AGCARM
  - **Canada** = CAHI
  - **South Africa** = SAAHA

The Steering Committee

Status	Country/Region	Number of participants	
		Government	*Industry*
Full members	Japan	3	3
	EU	3	3
	USA	3	3
Observers	Australia / New Zealand	1	1
	Canada	1	1
	South Africa	1	1
Associate member	World Organization for Animal Health (OIE)	2	
Interested Party	Association of Veterinary Biologics Companies (AVBC)	1	
Secretariat	HealthforAnimals		

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, 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
- Active EWGs

Safety | Quality | Biological Quality Monitoring | Bioequivalence

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 if appropriate.

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!

VICH Meetings

33rd SC and 7th VOF June 20-23, 2016 Brussels, Belgium	
34th SC and 8th VOF 27th February -2nd March, 2017 Buenos Aires, Argentina	
34 Steering Committee meetings	Every 9 months
8 VICH Outreach Forum meetings	
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

VICH Meetings

- Next meeting in Tokyo Japan 13rd – 16th November 2017
- 35th VICH SC : main topics
  - Review of progress of EWG
  - Discussion on concept paper :
    - on the revision of GL 22 (safety of residues of VMP)
    - On a GL for safety evaluation of biotechnology-derived biological products
  - Definition of biological products
  - Preparation of the VICH 6th Public conference 6th-7th February 2019 at Cape Town - South Africa
- 9th VOF : main topics :
  - Regional organisation
  - Presentation ad implementation of Pharmacovigilance GLs
  - AMR and GL 27
  - Vaccines : stability, immunogenicity studies

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 that protect public health, animal health and welfare, and the environment - **GLOBALLY**

VICH Outreach Forum (VOF)

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

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

How do VOF countries participate in VICH?

- Participate in the Outreach Forum meetings
- Propose new priority topics for elaboration
- Provide feedback on the relevance of and on the implementation of VICH guidelines in your 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

Benefits of VICH Participation

- VICH offers:
  - 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

For additional information

http://www.vichsec.org/

http://www.oie.int/en/our-scientific-expertise/veterinary-products/vich-outreach-forum/

Thank you for your attention

Organisation mondiale
de la santé animale

World Organisation
for Animal Health

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