VICH: General Principles and Global Outreach

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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	HealthforAnimals		

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), 56, 57
	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

Bioequivalence

Combination Products

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.

Status of Guidelines and EWGs

Metabolism and Residue Kinetics

- VICH Guideline 56 Honey - Study design recommendations for residue studies for establishing MRLs and withdrawal periods
  - to measure the residues in honey
  - generate data suitable for establishment of appropriate maximum residue limits
  - justify the withdrawal period for a veterinary drug product
- *Implementation by June 2019*
- *Argentina (VOF) had active involvement in elaboration*

- VICH Guideline 57 Aquatic products
  - Marker residue depletion studies to establish product withdrawal periods in aquatic species
  - *Signed off by SC for implementation by February 2020*

Status of Guidelines and EWGs Quality

- Guideline 58 Stability – Climatic zones III & IV
- 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 to address VOF countries and countries outside VICH regions*
- *6 month public consultation period ended December 2018*

Status of Guidelines and EWGs
Anthelmintics

- Revision of all 9 existing Guidelines
- Address areas of incomplete information, not informative or specific enough, new scientific knowledge especially of development of antiparasitic resistance
- Revisions include study design, methodology, and basis of study conclusions
- Challenging areas for the EWG - adequacy of infection and arithmetic vs geometric means

Status of Guidelines and EWGs

Bioequivalence

- Concept Paper for VICH GL on in-vitro dissolution testing and biowaivers for in-vivo blood bioequivalence determinations
- Reactivation of Bioequivalence EWG
- Establish framework to support development of a Guideline – *what will be the scope of work of the EWG?*
  - Need common definitions and how to do assessments

Status of Guidelines and EWGs
Safety

- Revision of GL 22 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproduction Testing
- Draft Concept Paper
  - Existing two-generation reproduction toxicity study
  - Extended one-generation reproduction toxicity study (EOGRTS)
- Physical meeting adjacent to next SC meeting

Status of Guidelines and EWGs Safety

- Revisions of VICH GLs in light of updates from other organizations (ICH, CODEX, OECD…)
- Guideline 36 Studies to evaluate the safety of residues of veterinary drugs in human foods: General Approach to Establish a Microbiological ADI
  - Changed volume of the human colon in microbiological ADI calculations from 220g to 500ml based on new scientific data from JECFA

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 and revised anthelmintic GLs*
- *Current work on draft GL Harmonization of criteria to waive laboratory animal batch safety testing (LABST) – consistency with TABST GLs*

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

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

My country is NOT a VOF Member – can I contribute to VICH?

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

- **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.

How do VOF countries participate in VICH?

- Participate in the Outreach Forum meetings
- Propose new priority topics for elaboration
  - *EWG on pharmaceutical Combination Products chaired by the People's Republic of China - First topic proposed by a VOF member*
- 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 VOF meetings
- Provide feedback on *SURVEY* on the usefulness of the VICH Outreach Forum and the VICH webpages
- WebEx presentations at VOF meetings

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

“Out of scope” topics

- Discussion paper to address “out of scope” topics that are requested by VOF members in meeting agendas and Guidelines
- Prepare and maintain list of topics with rationale as to why they are out of scope
- Are there other organizations that can address the topics – the OIE, Codex, OECD……?

VICH Training

- ******Any VICH supported training must be in the scope of VICH***
- ***Increasingly difficult to resource in-person training***
- **Visit VICH website training link!!!**
- **Quality Guidelines**
  - **Stability GLs 3(R), 4, 5, 8(R), 10, 11, 18(R), 45(R), 51**
- **Safety Guidelines**
  - **Approval systems for antimicrobials in Japan**
  - **GL 27 Pre-approval info for food-producing animals with respect to AMR**
- **Biologicals Guidelines**
  - **Waiver of Target Animal Batch Safety Testing for inactivated (GL 50) and live (GL 55) vaccines**
- **Pharmacovigilance**
  - **Development of phamacovigilance systems and processes**
  - **How to use pharmacovigilance Guidelines**

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 Meetings

38th SC and 12th VOF November 18 – 21, 2019 Tokyo, Japan *39th SC and 13th VOF November 16 – 19, 2020 Europe*	
37th SC and 11th VOF February 25 – March 1, 2019 South Africa	
37 Steering Committee meetings	*Every 12 months
11 VICH Outreach Forum meetings *Chaired by VICH and the OIE*	
6 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

U.S. FOOD & DRUG ADMINISTRATION

THANK YOU!!!

http://www.vichsec.org/