

VICH: General Principles, Global Outreach and the 6th Public Conference

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The Steering Committee

Status	Country/Region	Number of participants	
		<i>Regulatory authority</i>	<i>Industry</i>
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		

How are VICH Guidelines developed?

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



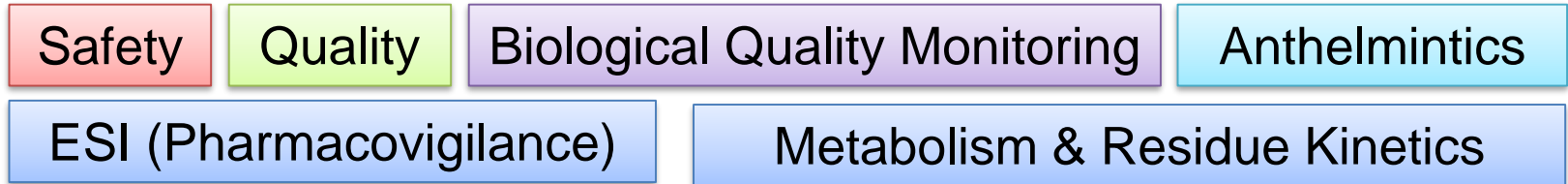
9 step procedure repeated

Expert Working Groups (EWG)



- The SC establishes an EWG with a specific mandate

- Current active EWGs **Bioequivalence** **Combination Products**



- 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.

Which Guidelines are available?



Category		Guideline numbers
Pharmaceuticals	Quality	1, 2, 3, 4, 5, 8, 10, 11, 17, 18(R)*, 39, 40, 45, 51, 58
	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

What is the most recently adopted VICH Guideline?

- Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV
- Adopted as final **Guideline 58** at November 2019 Steering Committee meeting
- Implementation by November 2020
- *First guideline to specifically address VOF countries and countries outside VICH regions*

Why does VICH have a 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***

Who are the VOF Members?

- 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 do VOF countries participate in VICH?

- Participate in the Outreach Forum meetings
- Respond to survey to improve VOF meetings and participation
- Propose new priority topics for elaboration
 - *EWG on pharmaceutical Combination Products co-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](#))
- *39th SC and 13th VOF November 16 – 19, 2020 Amsterdam*

Why become a VOF Member?

- How to participate in VICH, including submitting comments on concept papers and draft guidelines
- Discuss practical issues related to VICH guidelines arising in the participants' countries/regions and provide feedback to the Forum
- Detailed review of selected topics covered by VICH guidelines
- Use of presentations for training subordinates back home
- Network with other regulatory and industry colleagues
- Pre-VOF meetings attended only by VOF members

How to become a VICH VOF Member

Criteria to participate in the VICH Outreach Forum:

- Regulatory framework for marketing authorization regulations in place and operation in country
- Willingness to work towards accepting and implementing the Guidelines
- Self financing participation in meetings
- Regular attendance at meetings
- *National Competent authority encouraged to invite local industry association to also participate

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

Which topics were covered at the 12th VICH Outreach Forum meeting?

- Input on VOF meeting topics from VOF, SC, the OIE
 - Group discussion on Good Clinical Practice and intro to GL9
 - Opportunities and challenges of sharing assessment reports
 - Topics not for harmonization by VICH and how to handle those topics
 - Biological quality guidelines 25 and 34
 - Update on revision of 9 existing Anthelmintics guidelines
 - Mutual Recognition systems
 - ASEAN
 - CAMEVET (Latin America)
- Survey of VOF members (expectations, considerations for future VOF meetings, topics for future meetings)

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.

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 guidelines and adopt them as they are
- For other countries and regions, it is **the preference is to adopt guidelines in their entirety**, but there can be some flexibility to fit local country situations – option to adopt all or part of a guideline

What are some highlights of the 6th VICH Public Conference?

- Held in Cape Town, South Africa, February 2019
- Theme was “*Unlocking Africa’s Potential*”
- Goal to increase global access to safe, effective, high quality animal medicines
- Presentations by regulators, industry, the OIE, the World Bank, and the Bill and Melinda Gates Foundation
- Attended by 127 participants from 28 countries
- Next Public Conference in 2023

THANK YOU!!!

<http://www.vichsec.org/>