VICH/24/065
31 January 2025
Final

VICH STEERING COMMITTEE
43rd meeting
10, 11 & 15 November 2024
EMA/Amsterdam - The Netherlands

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Ivo Claassen, Head of the Veterinary Medicines Division at the European Medicines Agency (EMA). He welcomed the participants to the 43rd meeting of the VICH Steering Committee, which is held for the first time in the EMA's facilities in Amsterdam. He highlighted that, also for the first time, three visiting delegations from the VICH Forum are attending the SC meeting and he specially welcomed the delegates from Botswana, Saudi Arabia and South Korea.

The Secretary indicated that apologies had been received from K. Tuchiya (JVPA) and J. Howe (APHANZ).

2. Adoption of the agenda

The agenda was adopted with two additional items under AOB: AHI will address the topic of VICH Sustainable Funding and AnimalhealthEurope will update the SC on the participation of China.

3. VICH 7 Conference

3.1. SC Review of the final programme & speakers

The SC noted that there were no particular issues that needed to be addressed.

3.2. Any update on logistical matters for the Conference

The EMA indicated that the Conference presentations and discussions will be recorded for further use as VICH training material. The speakers have been informed beforehand.

4. VICH Training Implementation

4.1. Update on the development of training material

JMAFF and JVPA indicated that Japan would unfortunately not be able to provide any additional material this year.
The SC acknowledged however that the training webpage will be upgraded shortly with the VICH 7 Conference and VICH Forum (VF) presentations.

FDA reported that they had surveyed their chairs of EWGs to find out how they felt about the idea of developing training material with each new or revised GL, and the general consensus was not to include this task along with development of a GL.

The EU supported this position.
AnimalhealthEurope suggested giving the EWGs the option to prepare some training material if they volunteered.
FDA continues to support the systematic addition of training material from the VF presentations, also recording the presentations, and recommended waiting to develop specific training material once a GL has been implemented until sufficient experience has been gathered.
FDA agreed to develop a Discussion Document based on the recommendations made at this meeting.

Act: FDA

Meanwhile, the VF members will be asked again about their needs at the forthcoming Forum meeting.

5. VICH Forum

5.1. Preparation of the 17th VICH Forum meeting

5.1.1. VF pre-meeting and meeting setup

WOAH indicated that the VF pre-meeting agenda has been developed based on the experience from the last meeting. The VF meeting agenda had been updated to include a presentation from India.
Regarding the topic of unmet needs, AHI mentioned that an industry perspective paper would be circulated for further information at the VF meeting.

5.1.2. Review of the participants list

The SC reviewed the participants list and noted that 18 delegates representing 12 countries will attend.
WOAH expressed its concern that UEMOA and CAMEVET have not participated anymore since several meetings and will try to understand the reason by contacting the WOAH regional contacts.

5.1.3. Review of the agenda and finalisation of the 17th VF meeting

The SC reviewed the agenda of the meeting.

5.1.4. VF Guidelines implementation tracker

The Secretariat explained that the tracker has been updated with the latest inputs. The missing VF members will be encouraged again to provide their inputs.

Act: Secretariat *(Done)*

5.1.5 Other issues

None

5.2 Discussion of the outcome of the 17th VICH Forum meeting

The SC addressed this agenda item after the 17th VF meeting and thanked L. Le Letty for her outstanding leadership of the VF meeting.

A/ VF pre-meeting

WOAH believed that the expectations from the pre-meeting were unclear. It is furthermore necessary to clarify the timeframe and/or rotation requirements for the pre-meeting chairmanship.
WOAH will therefore suggest a revision of the VF Terms of Reference document for review by the SC.

Act: WOAH

Forum members also requested a clarification of the structure of a Forum network and the level of confidentiality of shared information.
WOAH will prepare a Concept Paper (CP) on the establishment of a VF network for review and approval by the SC before circulating to the VF members.

Act: WOAH

B/ VF meeting

The SC noted that the two breakout sessions had not been structured because no directions or questions had been provided to VF members to guide the discussions.
The group discussions have also shown significant differences in engagement of VF members, some persons being fully involved and others much more passive. It was however acknowledged that some persons hesitate to speak in presence of other colleagues, sometimes also the language barrier may represent a hurdle.
The SC recognised the need to better prepare the next breakout sessions. Moreover, when two sessions are organised, these should not take place on the same day.

FDA suggested organising, together with WOAH, a virtual event taking place in between the VF meetings (a mid-term event) on bioequivalence. The SC highlighted that it would be valuable to ask VF members for their input and to send their questions and expectations prior to the event. There should also be opportunities for questions during the session. WOAH suggested that the WOAH focal points could also be invited to participate in the training. The meeting should be recorded and placed on the web as a new training material. If successful, this could be repeated each year.
The SC approved the proposal.

The EU recalled that two mid-term pre-recorded training sessions on GLs 6/38 and GL 27 had been organised in 2021 & 2022 with a good attendance and were followed up with Q&A session a few weeks later. But the latter had not been much attended and the number of questions submitted beforehand was low. The presentations with voice-over have been placed on the website.

C/ Topics for the 18th VF meeting

The EU and JMAFF highlighted the necessity to better understand which training topics VF members would expect and in which format. VF members should be encouraged to send their questions sufficiently in advance of the next VF meeting.

WOAH mentioned that, as the next VF meeting will be held in the USA, breakout and training sessions with experts could be organised during the VF meeting, on topics such as biologicals or bioequivalence, as a follow up of the mid-term training.
FDA confirmed that US experts could attend the meeting and that Dr. M. Martinez would be available for a training session (without breakout) on bioequivalence.
USDA agreed to lead a training on biologicals explaining the definition of these products, their regulatory requirements and their differences with pharmaceuticals. A more detailed title of the session will be provided in due course. It was suggested that, in preparation for the proposed event, it would be useful to consult VF members on what aspects of biological products they would like to receive training on.

The SC agreed. WOAH and the Secretariat will provide shortly a first draft of the agenda for the 18th VF, for progress by written procedure.

Act: WOAH/Secretariat

Other topics that were suggested by VF members are:
- Novel technology
- Cellular products/regenerative products

- Herbal medicinal products
- Extemporaneous preparations
- Experience in combatting antimicrobial resistance
- Others: autogenous vaccines, premixes containing antimicrobials

6. Reviews of:

6.1 Implementation and interpretation of VICH GLs in the regions

6.1.1 Report from the regulators in the VICH regions

None

6.1.2 Review of the updated VICH GLs implementation tracker

No change was received since last year.

6.1.3 Any input from industry members

AHI recalled that an update regarding the status of implementation in the USA of GLs 50 (TABST inactivated vaccines), 55 (TABST live vaccines) and 59 (LABST) was expected. USDA indicated that a memo has been progressed stepwise and was finalised recently, including the input from AHI. The memo is for signature at congressional level and will be signed shortly.

6.2 Status of consultation for draft GLs at Step 4

6.2.1 Status of Draft VICH Quality GL 61

JMAFF reported that the public consultation phase was delayed because of translation issues but has recently been finalised.

6.2.1 Status of Draft VICH revised Safety GL 22(R1)

JMAFF confirmed that the consultation phase was delayed as well and will end on 7 December.

6.2.1 Status of Draft VICH revised Safety GL 23(R2)

JMAFF confirmed that the consultation phase will also end on 7 December.

7. Review of final VICH Guidelines at step 9

7.1. Proposals for revision of further VICH GLs

7.1.1. VICH GLs which have passed the 5 years of implementation – review of the updated table

The Secretariat recalled that GLs 36, 51 and 56 have been identified for review. The SC decided that none of these GLs needed a revision at this stage.

7.2. Revision of GLs put on hold at the 42nd SC meeting

7.2.1 VICH Safety GL 33

FDA recalled that the proposed revision of GL 33 is minor and recommended to keep it on hold until the revisions of GLs 22 and 23 have been finalised. The SC agreed.

7.2.2 VICH MRK GL 46

FDA confirmed its support for a revision of GL 46 but indicated that it is not in a position to lead this at the moment. No volunteer was identified so far.

7.3. Proposals from the SC members for a revision of a VICH GL

None

7.4 Proposal for a revision of other VICH GLs in light of an update of other organisations' GLs (ICH, OECD...)

None

8. Update on the topics & scopes of the Expert Working Groups activities - review of the progress reports of Expert Working Groups and decisions on next steps

8.1. Quality EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr T. Ogata, and presented by JMAFF. The Expert Working Group is addressing 3 topics.

a. GL 18 (R2) Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients

The work is finished as the final revised GL has been implemented in April 2024.

b. GL 60: GMP - Good Manufacturing Practice for Active Pharmaceutical Ingredients

JMAFF reported that several comments, which were not raised in the drafting phase, were received during the consultation phase from a subgroup member. Several of these comments are related to the ongoing development of new European legislation.
AnimalhealthEurope highlighted that the EMA scientific advice of November 2023, developed in the context of the above-mentioned EU activity, recommended not to refer to animal welfare nor to the environment. AnimalhealthEurope expressed concern that, if the VICH GL is not consistent with the eventual EU legislation, this could result in international disharmonisation with a potentially negative impact on MRAs.
The EU indicated that the wording of the text proposed in the GL is sufficiently high level, and so remains acceptable. It was further noted that this issue is being discussed within the EWG. It was pointed out that WHO initiatives regarding GMP measures and animal welfare and environment requirements are ongoing.

AHI recommended to provide clear guidance to the experts on the political issues at stake. AnimalhealthEurope suggested adding a Q&A section, or an explanatory section, to the GL, maybe as an additional document without changing the main GL text. Such a separate document would need to be published at the same time as the GL. No final agreement on this was reached as, at this point, it is not clear what information would be contained in such a document. However, the SC agreed that, if the experts consider it is helpful, they should develop an explanatory document for review by the SC.

Act: Quality EWG

c. GL 61 on pharmaceutical development

The SC took note that the public consultation phase is nearly finalised. No further comment was made.

8.2. Biologicals EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr K. Sato, and presented by JMAFF.

a. EV subgroup - Test on the Presence of Extraneous Viruses in veterinary vaccines

JMAFF reported that the subgroup experts are reviewing the first draft of the document at step 1, which is focussing on swine only, and are asking the SC if other animal species should be considered as well before moving the draft GL to step 2.
The SC decided that the focus should remain on swine only in order not to delay the development of the GL. The EWG could already start to consider additional species during the

public consultation period, but this should not delay completion of the work relating to swine vaccines.

AHI considered that the current draft does not explain how this GL would be implemented. Without additional explanations many questions may be raised during the public consultation phase.
The EU indicated that there needs to be clarity that the GL will not represent a list of tests that must be undertaken, but rather a list of tests that can be used to demonstrate the absence of relevant extraneous viruses. Alternative approaches, including scientific justification for not undertaking a test, can also be accepted.
AHI volunteered to develop an additional explanatory text providing clarity on the risk-based approach, which the AHI experts will provide to the EWG before the sign-off of the draft GL at step 2.

Act: AHI

WOAH indicated that the WOAH biologicals committee will provide its own comments during the public consultation phase.

b. BS subgroup - Safety evaluation of biotechnology-derived/biological products

JMAFF reported that the fifth draft of the document is under review by the subgroup experts.

c. BPT subgroup - guidance for the transition to in vitro methods for batch potency tests

The subgroup is discussing the third draft of the document.

8.3. Pharmacovigilance EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr Linda Walter-Grimm and presented by FDA.

Signal Detection/Signal Management Discussion Document (DD)

FDA reported that the EWG is targeting to finish the DD, without a consensus to move further towards developing a Concept Paper for a GL. It was noted that the EWG had expressed interest in publishing this document.
AnimalhealthEurope supported this proposal stressing the fact that it is a rapidly progressing field on which every region in the world is working. Such documents would also be helpful to steer these countries in the same general direction.
Other SC members, while acknowledging that the contents of the document may indeed be of interest to a wider audience, indicated that a decision to make the document widely available should be deferred until the SC has had an opportunity to review the final document. However, there was an “in-principle” agreement that, subject to its final review, the document could be made available in the Forum section of the VICH website.
This was rediscussed under item 14.1 where the SC agreed that once this document is finalised and adopted, it will be placed in the trainings section of the VF webpage.

A discussion took place on the future format of VICH documents that would not be VICH GLs. See item 14.1.

GL 30 and VEDDRA lists of terms

FDA reported that the discussions are ongoing within the EWG.
AnimalhealthEurope highlighted the fact that the timings of the formal implementation of the VEDDRA list of terms by the EU and by FDA are different, FDA could not commit to accelerate the process in the USA.

Product identification

The experts have proposed to address this new topic in a Discussion Document once the signal detection/signal management paper has been finalised.

The SC agreed in principle.

8.4. Anthelmintics EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr A. Phillippi-Taylor, and presented by FDA.
The SC congratulated and warmly thanked Dr Phillippi-Taylor and the experts for the impressive amount of work that has been achieved.
The SC acknowledged that the allocated task has been finished and decided to disband the Anthelmintics EWG.

8.5. Safety EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr T. Zhou, and presented by FDA.
The SC acknowledged that both revised draft GLs 22 and 23 are in the consultation phase which will be closed soon. The EWG will review the comments received and prepare the GLs for sign-off at step 5 before May 2025.

8.6. Pharmaceutical Combination Product GLs EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr D. Laucks, and presented by FDA.
At the last meeting the SC had acknowledged the proposal from the EWG to revise the scope of the GL and had been asked to reflect whether a final deliverable other than a GL should be considered.
FDA reported that the experts could not reach a consensus on developing a GL or an alternative “Consideration Document (CD)” for publication by VICH, and therefore were seeking advice from the SC.
The SC was informed that there are major differences between the legal requirements from the different VICH members’ legislations with the result that a VICH GL would need to be very high level and, as such, may fail to achieve harmonisation across regions.
Some SC members were nevertheless in favour of developing a GL whilst others considered that it would be more appropriate to develop a Consideration Document providing information on the different approaches in place in different regions.

It was noted that VICH rules allowed for the publication of a “status report” in cases where an EWG is not able to produce a harmonised GL.
FDA expressed support for providing a work product from the EWG and some concern at focusing communication on VICH’s inability to develop a Combination product GL.
It was nevertheless recommended to explain, in a status report, why it had not been possible for the EWG to develop a harmonised GL. The status report could also be used as a vehicle to disseminate information on the approaches taken in different regulatory jurisdictions.

JMAFF expressed its concern that the VF members may be disappointed that VICH could not develop the proposal for this topic that was initiated by a VF member.

The SC accepted that the EWG should discontinue the development of a high-level GL and develop the argumentation in a “status report” that should explain the points to consider and why a VICH GL was not possible.
The SC will review and adopt this document before it is published on the website.

8.7. Bioequivalence EWG

The chair of the Expert Working Group, Dr M. Martinez, recalled (link) that in 2016, the VICH Bioequivalence Expert Working Group (BioEqEWG) completed the in vivo blood level bioequivalence (BE) study GL. That GL did not address the issue of BE study requirements for

additional tablet or capsule strengths within a product line. To resolve this remaining gap, the BioEqEWG was reconvened for the purpose of developing a new GL that would address between-strength biowaivers.
A first draft of this biowaiver GL was circulated among the BioEqEWG members for comment and revision. While agreement was achieved on many of the initial concerns raised (via email exchanges and virtual meetings), several critical questions remained. Therefore, a face-to-face meeting was convened on 8 & 9 November 2024 to discuss and resolve these remaining concerns.
At the conclusion of this face-to-face meeting, a new draft of the between-strength biowaiver guideline was generated without the need to create EWG subgroups as initially planned.
There are nevertheless 3 remaining issues for which there was acceptance in principle, but for which final acceptance depends upon response of VICH member organisations. Therefore e-mail exchanges will continue as needed within the EWG and another virtual meeting will be convened in March 2025.
The aim of the EWG is to provide the final draft at step 2 by early 2026 at the very latest.
The SC warmly thanked Dr Martinez for the progress made under her efficient leadership.

8.8. Metabolism and Residue Kinetics EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr D. Benesch, and presented by the EU.

Revision of GL 49
The EU pointed out that the current version of the GL was implemented in 2016 and that the ongoing review of the GL was focussed on revising Annex 3 only. Over the last year considerable effort was put into revising the Annex, however, in the end, a number of members of the EWG considered that the proposed revisions were too substantial and put too much emphasis on Annex 3.
The EWG held a virtual meeting on 5 November and has agreed to complete the revisions to Annex 3. The EWG will furthermore develop a CP proposing additional changes to the GL if it considers there are other aspects of the guideline that need to be addressed

Revision of GL 47
See item 11.4.

8.9. Medicated premixes

The chair of the Expert Working Group, Prof. E. De Ridder, noted that the SC had just signed the draft GL off at step 3 for a 6-month public consultation period at step 4 (see agenda point 9.1).
Prof. De Ridder reported that meanwhile, the experts are considering the necessity and possibility of developing further guidance on other related topics.
There is in particular broad support between the experts to create further guidance on:
- Analytical method validation, focusing on additional points on top of VICH GL39 and GL1 and GL2 including sampling methodology
- Homogeneity and segregation studies
- Stability requirements for medicated premixes, including pelleting/extrusion stability

The EWG will develop a new Concept Paper for a first review at the next virtual SC meeting in June 2025.
The SC thanked Prof. De Ridder for the progress achieved so far by the EWG.

In conclusion, the chairman thanked all EWGs for their work and congratulated the experts for the progress achieved over the last year.

REMINDER: General issue

The Secretariat reminded the EWG leaders and the coordinators that it is of utmost importance that all delegations keep their expert lists up to date and immediately inform the Secretariat of any change to keep the group e-mail addresses reliable.

Act: All

9. Adoption at Step 3 and release of Guidelines at Step 4

9.1. Draft VICH GL 8(R) – (Stability Premixes): Stability testing for medicated premixes

The SC adopted the draft revised GL 8 at Step 3. This guideline was transmitted to the VICH and VF members for a 6-month public consultation at Step 4.

10. Adoption at Step 6 and release of Guidelines at Step 7

None

11. Concept Papers/Discussion Documents

11.1. Status of the draft Concept Paper for the revision of VICH GL34: Biologicals: Testing for the Detection of Mycoplasma Contamination

The EU indicated that a meeting was held recently with USDA and that the EU will develop a revised CP for review by the SC.
AHI and AnimalhealthEurope explained that their experts do not see a need and or the benefits of revising this GL and would therefore welcome additional information to clarify the potential need.
AnimalhealthEurope also pointed out that the Biologicals EWG is already addressing 3 topics spread between its subgroups.
The EU will provide the revised CP, which will make the case for upgrading GL 34 in line with amendments that are to be made to the parallel chapter of the European Pharmacopoeia.

Act: EU

11.2 Draft Concept Paper for a Global Regulatory Dossier Framework for pharmaceutical Veterinary Medicinal Products

The chair of the SC Task Force, Prof. E. De Ridder, thanked the SC organisations for their input and their support. The aim of the proposed GL is to develop a single global format for regulatory dossiers. Industry will mostly benefit from the GL but regulators will also benefit from more compliance and opportunities for joint assessments.
At this stage the intention is only to propose a global regulatory framework, not to address the implementation.
The SC reviewed the CP prepared by the TF and adopted the CP with one change. The SC decided that this topic will be addressed by a new Global Regulatory Dossier Framework for pharmaceutical VMPs EWG. The EWG leader will be AnimalhealthEurope.
The Secretariat will ask the SC members to nominate the experts for the subgroup before next 15 December.

Act: Secretariat *(Done)*

11.3 Draft Concept Paper for the revision of VICH GL 6 (Ecotox)

The SC reviewed the CP presented by the EU.
The EU explained that this GL is over 20 years old and does not consider substances coming from non-food producing animals.
However, over the past years reports have been published regarding the detection of residues in the environment, including through urban wastewater, of substances used as pets'

ectoparasiticides which can be toxic for animal species living in the environment. The EU therefore suggested revising GL 6 to integrate the review of substances used in pets only, where appropriate.

FDA noted the proposal but will need more time to review the CP, in particular because the jurisdictions related to this topic are split between FDA and EPA.
JVPA expressed reservations about revising the guideline and also requested additional time to review how the revisions may align with existing laws and their practical implementation possibility.

The SC therefore agreed that additional comments must be sent to the EU by end April 2025.The feedback received can then be discussed by the SC at the June virtual meeting.

Act: All/June SC meeting

11.4. Draft Concept Paper for the revision of VICH GL 47

The SC reviewed the CP presented by FDA who explained that the experts from FDA and JMAFF have prepared together the draft CP which is being reviewed by the EWG.
The proposal is to revise the entire GL and in particular the section on in vitro testing for which much scientific progress has been achieved in recent years.
The SC acknowledged that the experts will need more time to review the document and agreed that comments should be provided to FDA by mid-March 2025 for a review of the revised CP at the June virtual meeting

Act: All/June SC meeting

11.5 Status of the draft Concept Paper for the revision of VICH GL 27

The EU explained that the CVMP has reviewed this GL which is 20 years old and has identified sections that should be revised. The EU pointed out that the VICH Phase 5 work plan also focusses on the reduction of antimicrobial resistance.
The EU will circulate shortly a draft CP for all to comment by mid-May 2025.The feedback received can then be discussed by the SC at the June virtual meeting.

Act: All/June SC meeting

12. Outcome of the VICH 7 public Conference

The SC applauded the successful outcome of the VICH 7 Conference and warmly thanked the staff from AnimalhealthEurope and the EMA for the smooth and perfect organisation of the events.
The SC noted that the feedback from the participants has been very positive; the speakers have very well covered the current status and addressed the potential future developments within VICH.
Lessons retained from the Conference

- ✓ Need to give moderators more responsibility to ensure a better coordination of speakers in same sessions and preventing too much overlap.
- ✓ The presentations could be made available before the conference – they have been uploaded on the VICH website immediately after the Conference.
- ✓ The timing allocated to questions has all been fully used
- ✓ Need to encourage more industry participants to attend
- ✓ Need to encourage more participation from Africa
- ✓ Need to reach out to more VF members to attend the conference and to be speakers or moderators
- ✓ Need to understand in particular from VF members which topics they want to address in the next conference

- ✓ The outcome of several discussions showed that there is a demand to VICH to produce alternative documents, such as reflection papers, that are not GLs on new topics in order to steer the future on new technologies, of which some were addressed at the conference.
- ✓ Suggestion to address again ICH Quality GLs 9 & 10 by reactivating the draft CP

It was suggested to organise more regional/local events on VICH between the Conferences, although it might require SC members and experts to travel. It was acknowledged that industry experts' costs could be funded much easier than regulatory experts.
Smaller VICH events could be addressed as training sessions for VF members.
WOAH is routinely raising awareness about VICH during the WOAH regional conference and encouraged SC and VF members to participate in these meetings.

Feedback
The SC recognised the need to receive feedback from the Conference participants on the content and quality in order to better understand the expectations and future needs. The Secretariat will organize a short survey with the participants.

Act: Secretariat *(Done)*

Frequency
It was questioned if a VICH Conference should be organised each 3 years, but the SC decided that the timeframe of 4 to 5 years should be maintained in order to have sufficient progress to update the audience on new GLs and experts' experiences on new scientific topics, and to allow rotation of the host organisation.

VICH 8 Conference
JMAFF pointed out that the next VICH Conference will be held in Japan and requested that the SC must identify the topics to be addressed sufficiently in advance.
It was suggested to invite more speakers outside of VICH, as had been the case for the VICH 6 Conference in South Africa.
JMAFF noted that for non-native English speakers who will participate to the Public Conference, language will be a hurdle to be overcome. For example, the presentations will have to be provided at an early stage in order to allocate sufficient time for understanding and discussion.

13. Other issues

13.1. Sign-off of draft GLs by EWG subgroup experts

The Secretariat explained that since the creation of specific topic subgroups in the Quality and Biologicals EWGs, these subgroup experts are the ones signing off the draft GLs at step 2 and step 5, rather than the "full EWG" nominated experts who are mostly not the topic experts.
AHI agreed that the experts who have created a GL should be the ones signing-off the documents.
The Secretariat confirmed that although the "main EWG experts" may not be as such active anymore, they are still all copied on all mails and documents exchanged by the subgroups.
JMAFF confirmed that the chair of the Biologicals EWG remains involved in the activities of the subgroups, but recognised that the EWG members may not have the time and the expertise to "oversee" the subgroups.
It was questioned why these subgroups have been created, rather than new EWGs. The Secretariat explained that these subgroups had been formed in order not to increase the number of main EWGs, although the required topic expertise is different.

The Secretariat will revise the EWG guidance documents providing for subgroups to be authorised to sign-off the draft GLs. The SC will review and adopt the revised documents at the June 2025 virtual meeting.

Act: Secretariat/June SC meeting

The SC decided that meanwhile the draft GLs will be signed off by the experts who have developed the documents i.e. the subgroup members.

13.2. Revision of the VICH Policy on Consultation at Step 4

FDA recalled that the Anthelmintics EWG had received several hundreds of comments on the 9 revised GLs and had proposed to clarify which comments which must receive a formal reply versus minor comments.
FDA has therefore added a paragraph to clarify this issue.
The SC agreed and adopted the revised document.

13.3. Update on the VICH guidance translation project from CVM

FDA informed the SC that FDA has initiated a project aiming to translate all CVM VICH GLs in Spanish and French and place them on the CVM website. The Biologicals GLs will also be translated with the support of USDA. FDA will verify the Spanish versions and has asked VDD and ANSES for support to verify the French translations.

FDA will prioritize the guidelines which have not already been translated by WOAH and Canada.
FDA will update the next SC on this project and how many GLs have been translated.
The SC supported this initiative and thanked FDA.

13.4. Update of the VICH website – review of suggestions

HealthforAnimals explained that the current website is based on an old technology, difficult to handle because the website's backend is not flexible. A review has been triggered because of the increasing danger of viruses and hackers' attacks.
The website is now being transferred to a new service provider which will upgrade the website's backend.
The SC recognised that the current website is not very user friendly and needs to be modernised.
HealthforAnimals confirmed that it will fund the upgrade and modernisation of the frontend in Q1-Q2 next year.
FDA recommended creating a central repository to enable document management including electronic signing of the different VICH documents.

HealthforAnimals asked the SC members to provide a wish list for future features of the website to enable a technical discussion with the service provider.
The Secretariat will circulate an e-mail to the SC for reply by the end of January 2025.

Act: Secretariat *(Done)*

13.5. VICH Priorities Phase 6 (2026-2030) – first reflection

The Secretariat pointed out that the current VICH workplan ends in 2025 so a new workplan needs to be adopted at the next SC meeting for the period 2026 to 2030.
The SC acknowledged that most current priorities will remain valid but new features must be considered such as Artificial Intelligence and Big Data.
The Secretariat will update the current document as a Phase 6 first draft for the SC to comment and improve by the end of next February.
A second draft will be developed for review and final approval in November 2025.

Act: Secretariat *(Done)*/**All**

14. Any other business

14.1 Publication of documents which are not GLs

The Chairman recalled that during the discussion (item 8.3 and 8.6) it has been suggested to develop “Consideration” or “Reflection” documents when it was not possible to develop a VICH GL.
It was noted that ICH places many “non Guideline” documents on a special section of its website.
Several members feared that this would create additional work for VICH but it was pointed out that VICH may anyway develop a document which does not become a GL but has a global value. This should be broadly shared in order not to lose the work that has been done.
The Secretariat explained that VICH currently publishes the draft and final GLs, the Concept Papers, the comments received at step 4, the meeting minutes, procedural guidances, public statements and of course numerous training material including presentations from VF meetings and public Conferences.

FDA and AHI recommended discussing such publications on a case by case basis because the two proposals discussed at this SC meeting represent two exceptional cases which are different.
The signal detection/signal management Discussion Document under item 8.3 is a fast moving topic; the EWG is near finalization of the Discussion Document.
The SC agreed that once this document is finalised and adopted, it will be placed in the trainings section of the VF webpage.

The combination products discussion is a special situation where a GL would be too high level to meet its objective, but publishing the output of the work conducted by the EWG would nevertheless be useful for regulators and industry around the world.

JMAFF explained that non-binding documents would of course need to be translated as well and could be supported by Japan, but JMAFF will need to identify how to position such documents.

14.2 Funding of VICH meetings

AHI explained that the VICH meeting costs have increased very much over the past years because of the growth of the SC membership and the creation of the VF (with two more days of meetings), which also continues to grow. As an example, 300 lunches have been financed during this week.
Most meetings are funded by the local industry associations although some regulatory agencies provide support, such as the EMA this week and JMAFF when the meetings are held in Japan.
As the VICH meetings are rotating between the three founding members, the funding has become concerning for the industry associations of the three countries/regions.
AnimalhealthEurope added that VICH is victim of its own success, but industry wants to keep the current format where the socialisation evening events are very important.

Industry will share over the next months some ideas to overcome this hurdle and ask for feedback from SC members.

Act: Industry

14.3 VICH membership

The SC discussed VICH membership.

14.4 VF membership

AnimalhealthEurope indicated that industry has been able to reestablish contact with the Chinese regulatory body, who apologised for not being able to attend this year and expressed interest to attend the VF again next year.
Meanwhile, industry is planning to organise a workshop on VICH in China with the Chinese regulatory body.

14.5 SC Visiting Delegations

The 3 visiting delegations thanked the SC for the opportunity to attend this meeting.
The delegate from Botswana has appreciated the insight into the VICH decision-making process and the positive dialog between VICH members to overcome the issues.
The Republic of Korea delegates have understood better the process of development of VICH GLs and will share the lessons learned with their colleagues.
The Saudi Arabia delegates considered that it had been very useful to follow the SC activity from the inside and understand the positive impact on the VF.

Korea and Saudi Arabia mentioned that their organisations would request to become observers to the VICH SC.
Botswana will request again to be a Visiting Delegation at the next SC meeting.

The Secretariat confirmed that an e-mail will be sent again to all VF members asking for candidates as Visiting Delegation to the 44th SC meeting in November 2025.

Act: Secretariat *(Done)*

15. Dates and venue of next meetings

- The next SC virtual meeting will take place Monday 16 June 2025.
- The 44th SC meeting will take place from 10 to 13 November 2025 in Indianapolis, USA.
- The 45th SC meeting will take place from 16 to 19 November 2026 in Japan, in Tsukuba-city, Ibaraki prefecture, close to the Narita airport.
- The next VICH coordinators virtual meeting will take place on Tuesday 4 February 2025.

16. Public statement on the 43rd SC meeting

The SC members reviewed and adopted the public statement.

VICH STEERING COMMITTEE

43rd meeting

10, 11 & 15 November 2024
Amsterdam

Chair: I. Claassen, EMA

LIST OF PARTICIPANTS

VICH Steering Committee Members and (C) Coordinators

AHI (ZOETIS)	C. LOWNEY
AHI (BI)	E. NORTON
AHI	R. CUMBERBATCH (C)
EU (EUROPEAN COMMISSION)	E. ZAMORA ESCRIBANO
EU (EMA)	N. JARRETT (C)
EU (MEB)	J. SCHEFFERLIE
ANIMALHEALTHEUROPE (BI)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)
JMAFF	K. EGUCHI
JMAFF	S. IWAMOTO
JMAFF	M. OCHIAI (C)
JVPA (NIPPON ZENYAKU KOGYO CO.)	H. CHEE
JVPA	K. OISHI (C)
US (FDA/CVM)	M. LUCIA
US (USDA CVM)	G. SRINIVAS
US (FDA/CVM)	B. ROBINSON (C)

STANDING MEMBERS

Australia (APVMA)	D. SIBANDA
Australia (AMA)	C. BENNETT
Canada (Health Canada)	M. BASSI
Canada (CAHI)	C. FILEJSKI
New Zealand (MPI)	K. BOOTH
South Africa (SAAHA)	M. CHURCHILL
South Africa (SAHPRA)	A. SIGOBODHLA
VMD	S. ECKFORD (part)
VMD	G. CLARKE (part)
NOAH	D. MURPHY

INTERESTED PARTIES

AVBC	L. NAGAO

OBSERVERS

SWISSMEDIC	N. WALSER
SCIENCEINDUSTRIES (Zoetis, Switzerland)	Y. KÄSER

GUESTS

Australia (APVMA)	M.A. TRAINER
Canada (Health Canada)	E. TATONE
Canada (Health Canada)	J. GEDULD
US (FDA/CVM)	E. HART

VISITING DELEGATIONS

Botswana	I. RAVENGAI
Republic of Korea	J. NAH
Republic of Korea	H. YI
Saudi FDA	B. ALHAMMAD
Saudi FDA	M. ALSHANQITI

WOAH

WOAH	L. LE LETTY
WOAH	M. SZABO

VICH

HealthforAnimals	H. MARION (*Secretary*)
HealthforAnimals	C. DU MARCHIE SARVAAS

APOLOGIES

JVPA (Nisseiken Co.)	K. TUCHIYA
New Zealand (APHNZ)	J. HOWE