



VICH STEERING COMMITTEE
41st meeting
14 – 17 November 2022
Washington DC - USA

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Matthew Lucia, Director, Office of New Animal Drug Evaluation, CVM, FDA. He presented the apologies of Dr Steven Solomon, Director, CVM, FDA who was unable to chair the meeting. Dr Lucia welcomed the participants to Washington DC for this first physical meeting after 3 years of virtual interactions.

The Secretary indicated that apologies had been received from C. Bennett (AMA), J. Howe (APHNZ), Z. Zamora Escribano (EU Commission), H. Chee (JVPA), D. Murphy (NOAH) and C. du Marchie Sarvaas (HealthforAnimals).

He confirmed that a delegate from Switzerland has been invited as a guest and will join the meeting once item 3 of the agenda has been finalised.

2. Adoption of the agenda

The agenda was adopted with minor changes.

3. VICH Steering Committee (SC) Task Force (TF) to elaborate proposals for updated VICH structures

3.1. Recommendations towards restructuring based on the Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis

The SC took note of the recommendations prepared by the TF.

AnimalhealthEurope regretted that no reference was made to the BRIC countries (Brazil, Russia, India, and China) of which most should be encouraged to play a role in the new structure. It was also recognised that the SC must define the criteria for Forum-partner countries to become observers.

3.2. Review of draft Discussion Document (DD) and proposals from the TF

As a rapporteur of the TF, JMAFF was honoured to introduce draft 8 of the DD prepared by the TF members to the whole SC participants. The SC reviewed the DD and recognised that an advantage of maintaining a limited SC membership is that it allows the decision making process to be fast & efficient. It is simultaneously aiming for more an inclusive and transparent VICH process acknowledging the 10 years of contribution of the current VOF members since the establishment of the VOF in 2011.

The SC accepted the renaming into “Founding members” (current SC full members), “Standing members” (current observer members) and the new “Visiting delegations” (regular participants

to the SC meeting) which will essentially be the new VICH Forum Observer members. The SC will also accept other VICH Forum on a rotating or temporary basis for sharing experience participating in the SC meeting. Members.

The SC further agreed that World Organisation for Animal Health (WOAH), which plays a key role in the frame of the VICH Outreach Forum (VOF), will remain an associate member, whilst the interested party (AVBC) will become an observer.

The EU supported the document recognising that it is the outcome of an important reflection and represents a significant step forward for VICH.

Regarding the conditions Forum members should meet to be given a status of Observer members (see paragraph starting line 123 in the document), FDA recommended that the listed conditions should be separated by “or” rather than “and”. The SC recognised that the rules should remain flexible as their only objective must be that VOF members show their commitment to VICH.

The SC amended the draft DD into a version 9 that was adopted later in the meeting as the final version. This will remain an internal SC document.

3.3. VICH Structures – next steps

The SC agreed that the VICH Organisational Charter and the VOF Terms of Reference (ToR) document must be updated before the implementation of the new structure.

FDA also proposed a simplified version of the figure from the DD which was shared with the VOF members for discussion/explanation at the 15th VOF meeting.

FDA will provide as soon as possible a first draft proposal for the revision of both documents, the aim being to finalise the proposed changes during a virtual SC meeting in June 2023.

Act: FDA

Once the documents are adopted in June, the SC will create a new Steering Committee Task Force with the mandate to consider other issues related to the VICH restructuring.

Meanwhile, the SC disbanded the current SC TF and thanked its members, Dr Ken Noda (JMAFF) in particular, for the important work that has been achieved over the 9 TF meetings.

3.4. Response to Switzerland

The SC agreed that acceptance of Switzerland as a new observer in the new VICH Forum (VF) would be finalized once the revised structure is completed in next June. It was confirmed that the application provided by Switzerland in November 2020 will remain valid.

Meanwhile, Switzerland was invited as a guest to the VICH SC. The Secretariat will inform the Swiss stakeholders.

Act: Secretariat

4. VICH Training Implementation

4.1. Format of future training sessions.

JMAFF pointed out that, although the 2 follow up training webinars organised in February 2021 and 2022 required many resources, only very few questions were received from VOF members. JMAFF suggested to evaluate the impacts on the VOF members and if they had the adequate resources for participating in these webinars.

AnimalhealthEurope suggested that it would be more efficient to complete the PowerPoint presentations that are made at the VOF meeting by recording a voice-over, using the record function in the latest versions of Powerpoint, before placing these presentations in the training section of the website.

4.2. Update on the development of training material

The SC agreed that both presentations made at the 15th VOF meeting will be completed by the recording of the presenters' voices before being placed on the website.

It was recalled that VOF members had requested the development of case studies to illustrate the use of VICH Guidelines (GLs). It was agreed to ask the VOF members to identify which GLs would benefit from case studies.

JMAFF and JVPA indicated that they will develop a training material on VICH in general once the new VICH structure will be in place.

Australia and the UK mentioned that they have training material available that could be used by VICH. Both organisations will provide a list of possible items to approve by the SC before placing them on the VICH website.

Act: Australia/UK

JMAFF recalled that VICH also has a YouTube video channel which is a powerful tool for disseminating VICH activities worldwide when used properly, although currently it has a small number of videos with only a few view counts yet. Links to these are available on the VICH website [Training section \(https://vichsec.org/en/training.html\)](https://vichsec.org/en/training.html).

4.3. Update of the documents already placed on the VICH Website

None

5. VICH Outreach Forum

5.1. Preparation of the 15th VICH Outreach Forum meeting

5.1.1. VOF meeting setup - preparation of the VOF pre-meeting

WOAH confirmed that questions were prepared that have been circulated to all the VOF members prior to the meeting. Saudi FDA will lead the meeting.

WOAH explained that the aim is to facilitate an informal open discussion between VOF members only, without the presence of SC members. The main objectives are:

- to prepare the VOF "Plenary" Meeting on 16 November
- to identify the needs and challenges
- to identify what can be improved by WOAH and VICH Secretariat in the future

5.1.2. Review of the participants list

The SC reviewed the participants list for the 15th VOF meeting and noted that half of the participants have travelled to Washington, whilst the other half will connect remotely. The remote connections are mainly in Africa. There will only be Taiwan connecting from Asia because of the broad time zone difference.

5.1.3. Review of the agenda and preparation of the 14th meeting

The Secretariat explained that the agenda had been restructured in October to accommodate as much as possible the members connecting remotely.

The SC acknowledged that it will be difficult to organise a breakout session with the people who will connect remotely. It was therefore agreed not to split the participants for the discussion under agenda item 6.

The SC reviewed and approved the presentation from the SC to the VOF prepared by the Secretariat which included a simplified figure of the new VICH structure.

5.1.4 Other issues

Agenda 16th VOF meeting

The secretariat explained that no draft had been proposed yet because of the possible change of setup of the next meeting.

FDA proposed to increase the focus on VICH activities so that VOF members can get more involved in core VICH work. FDA also suggested to re-explain the 9 step procedure and discuss deeper the ongoing EWG activities.

It was agreed that the VOF meeting should be organised over 2 days with overall the same setup as previously (including a pre-meeting without SC members) but with an equal balance between training activities and other VICH focused information.

The question of the leadership of the pre-meeting was discussed, noting that a rotating leadership might be useful to address the VOF issues.

WOAH and the secretariat will circulate a first draft agenda to the SC in January 2023. To improve the quality of the meeting, it will be essential to receive the input from the VOF members who should suggest topics for next year's discussions.

It was noted that the forum members might not all have the same needs and expectations, some wanting more training, others wishing to be more involved in VICH activities.

5.2 Discussion of the outcome of the 15th VICH Outreach Forum meeting

A/ General discussion

The SC addressed this agenda item after the 15th VOF meeting and thanked L. Le Letty for her first excellent leadership of the meeting.

The SC noted that all VOF participants were satisfied with the setup and the information that had been provided.

WOAH reported that in the discussion on the stability of vaccines, VOF members had suggested to develop a supplemental GL for vaccines. VOF members had also recognized that the terms related to biologicals, biologics and biopharmaceuticals are sometimes used in a confusing manner. JMAFF mentioned that VICH has already finalised in May 2018 a related internal guidance document entitled "Definition of Biologics" (VICH/17/060-Final) which should be used for further discussion in the future SC/VF meetings.

VOF members also highlighted the importance of having harmonised dossier formats for the different countries.

B/ Feedback from the VOF pre-meeting

L. Le Letty confirmed that the pre-meeting had been very successful and the participants had welcomed the opportunity to discuss between themselves. It was suggested that this format should be repeated, probably with more time allocated to this meeting, an improved format and a more detailed agenda.

The dissemination of the VICH documents by WOAHA was considered as essential and VOF members asked for support (from industry?) to translate these documents.

The VICH training sessions, such as for withdrawal periods, should be complemented with case studies whenever possible.

L. Le Letty indicate that the topics requested by the VOF members for the next VOF meeting included: Autogenous vaccines (but a paper is already available on the website at: <https://vichsec.org/en/outreach-forum/outreach-membres-documents.html>), pharmaceutical combination products, Antimicrobials, Parasitocides, Generics, Withdrawal periods and Residues.

VOF members recommended the creation of a database accessible to VOF members with the names and e-mail addresses of all VOF members. The SC agreed.

Act: Secretariat

The development of the GLs implementation tracker to follow the members' progress was strongly supported. The secretariat will circulate a GLs implementation tracker to be completed by the VOF members.

Act: Secretariat

The VOF members proposed to create a welcome pack for the new participants. JVPA and JMAFF confirmed that they will prepare a general training on VICH after the restructuring of VICH. Meanwhile, the VICH general presentation will be completed with slides providing a guided tour of the VICH website.

Act: Secretariat

Regarding the withdrawal periods, the secretariat pointed out that a detailed 12-page information paper (<https://vichsec.org/en/training/module-2.html>) has been added to the website to complement the presentations made in 2019.

The EU pointed out that for authorities, the data submitted by applicants is often considered to be confidential and so cannot be used to show as examples. It was acknowledged that industry might be able to develop a demonstration package.

The SC noted that it may not be necessary for SC members to attend VOF training sessions, where experts and assessors from countries would probably be more useful.

FDA pointed however out that if the SC and VOF meetings were run in parallel, the new VICH observers would have to choose which meeting to attend. Moreover, WOAHA would not be able to attend both meetings in parallel.

It was highlighted that for some GLs the VOF members have requested a demo of practical examples. WOAHA mentioned that the questionnaire from 2016 on the needs of VOF members had been very helpful to set priorities.

It was also suggested that the questions posed by external stakeholders to the VICH secretariat should be captured and used for training purposes when the replies were provided by VICH experts.

JMAFF supported the view of the EU and expressed its concern that practical training with technical case studies may not be in the scope of what VICH is able to achieve, because practical training might interfere with the decision of each authority for the approval of VMPs.

C/ Topics for the 16th VOF meeting

The SC decided that the next meeting would not utilise a hybrid option, in light of the difficulties for VOF members from other time zones to attend, and the poor feedback received during the 15th meeting from VOF members who were connected virtually.

The SC recognised that the approach to generics is a complicated topic; the 3 VICH regions will explain how these products are regulated for each. JMAFF will take the lead on the presentation with the support of the EU and FDA.

As several VOF members already regulate generic products, it was also suggested to ask a VOF country to explain how they address this topic.

Topics to be covered at the 16th VOF meeting:

- Pharmaceutical combination products
- Generics
- GL implementation tracking table
- The VICH 9 step procedure
- Session on the VICH 7 Conference planning

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

The EU mentioned that in the past it had reported delays in the development of the pharmacovigilance (PhV) database in Europe. The EU was now pleased to confirm that the database is active since January 2022 and so the EU is now fully implementing the PhV GLs 35 and 42.

VMD confirmed that UK has implemented all VICH GLs.

6.1.2 Review of the updated VICH GLs implementation tracker

South Africa provided an updated version of the tracker confirming that the Pharmacovigilance GLs have been implemented.

AnimalhealthEurope proposed to ask VOF members to complete this tracker as well, which would provide an insight on the progress in individual VOF member countries.

The secretariat prepared a new blank Excel sheet which was shared at the VOF meeting and will be sent to the VOF members shortly. A reminder will also be sent in next September.

Act: Secretariat

6.1.3 Any input from industry members

None

6.2 Status of consultation for draft GLs at Step 4

6.2.1 Status of Draft VICH Quality GL 18 R2

The EU recalled that the aim of the revision was to align the VICH GL with the update of the ICH GL. The EWG is currently reviewing the comments received during the consultation period and it is hoped that a final draft will be provided to the EWG for their approval at step 5 before the end of the year.

6.2.2 Status of 9 Draft revised VICH Anthelmintics GLs

JMAFF indicated that the public consultation period will finish shortly; it had been delayed because of the need to translate the 9 documents.

FDA confirmed that the EWG will review the comments as soon as all have been received and progress the 9 draft revised GLs to step 5 of the process.

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 12 GLs have been identified for consideration and that the SC members leading the different topics had provided their advice to the SC before the meeting.

➤ Safety GL 33

FDA will propose minor revisions to update the references to other GLs and will provide a revised draft document.

Act: FDA

➤ MRK GL 46

FDA recommended a substantial revision to incorporate parameters for aquaculture as well as additional minor revisions. FDA will provide a Concept Paper (CP) to the SC.

Act: FDA

➤ MRK GL 47

The topic leader from AHI did not recommend a revision, but suggested that the MRK EWG should consider whether a revision of the GL would be appropriate. The SC gave the EWG the mandate to provide a recommendation if updates to GL 47 will be necessary.

Act: MRK EWG

➤ Stability GL 3

AnimalhealthEurope reported that the medicated premixes EWG had proposed a revision of GL 3, which in its title refers to "...NEW drug substances and products", aiming to delete the reference to "New...", as this GL is also used when addressing existing products.

FDA did not support the proposal, mentioning that additional references to "new" drug substances and products are within the guideline which would also require revision and making this change would bring it out of alignment with the ICH stability GL. JMAFF pointed out that at present the EWG is not mandated to change GL 3 and considered that in the case of substances that are not new, the GL is sufficiently flexible to be used in any case for the decision making process of each regulatory authority.

It was proposed to add a section to the text of the GL explaining that in the case of premixes it could also be used for products other than "new" products. The SC mandated the Medicated Premixes EWG to discuss this issue further and to provide a proposal to the SC. It was agreed that this can be done by written procedure.

Act: Medicated Premixes EWG

7.1.2. GLs proposed for revision at the 40th SC meeting

7.1.2.1 Status of the Concept Paper from the EU for the revision of Antimicrobial Resistance GL 27 – Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance

The EU reiterated its view that there is scope for revising this GL but considered that it is not an immediate priority. The EU indicated that it intends to come back to this topic but it will not be in the next year.

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

None proposed.

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

None proposed.

8. Progress Reports of Expert Working Groups and decisions on next steps

8.1. Quality

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

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

The consultation period is finished and the EWG is currently reviewing the comments received.

b. Guideline for Good Manufacturing Practice for Active Pharmaceutical Ingredients

Following the adoption of the Concept Paper proposing development of a VICH version of ICH GL Q7, the subgroup of the EWG has been able to discuss several drafts of the new proposed GL. The fifth draft of the document is under consideration.

c. New GL for pharmaceutical development

Following the adoption of the Concept Paper proposing the development of a VICH version of ICH GL Q8, the new subgroup has discussed a first draft of the document. The draft 2 should be ready for sign-off at step 2 in the near future.

AnimalhealthEurope encouraged the EWG to monitor the activity of the PIC/S veterinary group which is also working on international guidance on GMP.

8.2. Biologicals

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

JMAFF reported that 3 different subgroups are or have been active:

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

At the 38th SC meeting a compromise had been reached asking the EWG to first focus on swine vaccines only and, as an initial step, to collect the current EV procedures carried out in each region. This has been done and the experts will provide their comments and proposals.

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

The second draft of the GL has been circulated within the EWG and comments from experts are expected. A step 2 document should be available next year.

c. BST subgroup: Harmonization of Criteria to Waive Animal Batch Safety Testing

The subgroup is not active anymore as the GLs are in the implementation phase. The subgroup would be reactivated if questions would be raised during this phase.

8.3. Pharmacovigilance

The chair of the Expert Working Group, Dr Linda Walter-Grimm, reported that the EWG has held 4 teleconferences since December 2021 and addressed in particular the following issues:

- Proceed with routine maintenance of the VICH GL30 vocabulary lists (focusing primarily on species/breed lists)
- Clarifying edits to VICH GL 35 and GL 42 were proposed by EMA and Japan as those regions worked through implementation.

- Develop a discussion paper describing veterinary pharmacovigilance signal detection and signal management practices currently utilized in several regions
- Discuss and propose the minor revisions to VICH GL24 and GL29 as outlined in the Concept Paper

GL 30

The proposed changes to the VICH GL 30 code lists have been finalized and the revisions submitted as an updated Excel sheet (excel document version number 5).

Signal detection/signal Management Discussion Document

Dr Walter-Grimm confirmed that the subgroup of advisors will finalize the DD shortly, which will then be reviewed by the full EWG.

Revision of GLs 24 & 29

The experts (both industry and regulatory representatives) have agreed that both documents are still of value for now as written. The experts have agreed that they need more experience with piloting existing signal detection/signal management systems prior to proposing and substantive revisions to these guidelines.

Updates to GLs 35 & 42

Clarifying edits to both VICH GL35 and GL 42 were agreed upon and revised documents are being circulated for signatures.

The SC thanked Dr Walter-Grimm and the experts for addressing this wide scope of topics and their ongoing commitment.

8.5. Safety EWG

The chair of the Expert Working Group, Dr T. Zhou, reported that little progress has been made since last year partly due to the lack of responsiveness of many new experts who have joined the EWG recently and need time to get familiar with the 2 topics under discussion.

AnimalhealthEurope recommended that the SC members should encourage their experts to respond in a timely manner to Dr Zhou's messages. The experts must also be asked not to reopen discussions that have been closed previously.

Act: SC members

The EU pointed out that the discussions had been ongoing in the EWG for several years and therefore encouraged the experts to rapidly finalize the work on these GLs, especially GL 22.

JMAFF recalled that at the 38th SC meeting in Tokyo the SC had recognised that these topics are difficult to progress by electronic procedure and had therefore agreed that a physical meeting would be helpful. A face to face meeting had been authorised simultaneously to the 39th SC meeting but had been postponed.

The SC reconfirmed the authorisation to hold a physical meeting, probably in November 2023 in Tokyo in parallel to the next SC meeting, with the aim to progress the discussions sufficiently for a rapid signature of draft GLs at step 2 after the meeting. It was agreed that a draft version of the GL should be circulated to EWG members ahead of the physical meeting in order to allow experts to fully prepare.

Dr Zhou confirmed that the EWG will hold 1 or 2 virtual meetings during the next months, in order to prepare adequately the physical meeting.

The SC thanked Dr Zhou for her efforts and her commitment to drive these difficult topics forward.

8.4. Anthelmintics EWG

The chair of the Expert Working Group, Dr A. Phillippi-Taylor, reported that the 9 revised GLs had been released for public consultation in May until 1st November, except in Japan where the consultation will end shortly. The EWG will consider thoroughly the comments received and provide the revised draft GLs for signature at step 5 within the next months.

AnimalhealthEurope asked if there were any major comments that might delay the process, but Dr Phillippi-Taylor believed that many comments may be out of the scope of the revision.

The SC applauded Dr Phillippi-Taylor and the experts for the enormous work that has been achieved so far.

8.6. Pharmaceutical Combination Product GLs EWG

The chair of the Expert Working Group, Dr D. Laucks, explained that the EWG is recommending to modify the scope of the proposed GL from a merger of the existing EMA and FDA/CVM documents to the generation of a novel harmonized GL.

The SC supported the creation of a new general GL and accepted the proposal from the EWG to create an outline of the GL in a first step and draft a text for the justification and effectiveness sections.

The SC confirmed that the EWG should start with a GL general enough to encompass any pharmaceutical combination product, and should not address issues of particular relevance to antimicrobial combinations. The SC had already agreed that VICH should not deliver wrong messages such as recommending the development of antimicrobial combination products, which would be in contradiction with the principle of prudent use of antimicrobials. The scope of the proposed GL, as outlined in the chair's report, was supported.

8.7. Bioequivalence EWG

The chair of the Expert Working Group, Dr M. Martinez, reported that the work had progressed well but the experts are still trying to define a dissolution guidance acceptable to all.

The responses received from the minutes of the meeting held in September 21 were summarized and recirculated. The original draft dissolution GL was divided into 7 subsections and members of the EWG selected the subsections on which they were willing to collaborate. The results of these collaborations were submitted back at the end of September 22.

Dr Martinez will collate these into a single revised *in vitro* dissolution guideline and recirculate to the EWG for comments. Depending upon the nature of the comments received, virtual meetings (with the individual subgroups or with the entire EWG) may be needed. That will probably not occur until late 2023 or early 2024.

The SC thanked Dr Martinez and the experts for addressing this difficult task.

8.8. Metabolism and Residue Kinetics EWG

The SC reviewed the written report prepared by the new chair of the Expert Working Group, Dr K. Schmidt, and presented by the EU.

The EU confirmed that the EWG's only task is to prepare a revision of GL 49 to address technical issues highlighted by external stakeholders. A new momentum was given to the work in February 22 with the circulation of a draft revised GL. The topic leader received several comments from the experts, some of which are outside of the current mandate of the EWG.

The experts will continue to work towards a consensus on the necessary/possible changes to VICH GL 49.

As some topics are out of the scope of the current revision, the EWG will develop at a later stage a new CP to address these.

The SC encouraged the EWG to finalise the revision at step 2 of annex 3 as soon as possible.

8.9. Medicated premixes

The chair of the Expert Working Group, Dr E. De Ridder, reported that the work is progressing well as the experts are now considering a third version of the proposed revision of VICH GL 8.

Comments are expected by mid-January and a virtual meeting will be organised in February to align on a final draft. The step 2 document is expected to be submitted to the SC in spring 2023.

The EWG will also prepare, before the 42nd SC meeting in Tokyo, an assessment on the necessity and possibility to develop further guidance on other topics with potentially a major impact on the quality of medicated premixes and their suitability to manufacture medicated feed.

The EU pointed out that medicated feeding stuff does not fall within the scope of legislation on veterinary medicinal products in the EU. In line with this, the EU will only be able to support development of VICH guidance that does not stray beyond the scope of its VMP legislation.

Dr De Ridder explained that the intended scope of the proposal is to provide guidance only on the medicated pre-mixes that can be potentially used to prepare medicated feeding stuff or liquid medicated premixes. Dr De Ridder thanked the members of the EWG, especially the Japanese delegates, for their efficiency and their commitment.

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

None

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

None

11. Concept papers/Discussion Documents

11.1 Draft CP from AnimalhealthEurope on the implementation of *in-vitro* methods to replace animal batch potency tests in veterinary immunologicals

The SC reviewed the draft 2 of the CP presented that had been circulated by AnimalhealthEurope at the end of July 22.

JMAFF requested clarification on the objectives of the CP, as JMAFF would only support a recommendation aimed at setting the technical requirements on *in-vitro* batch potency tests for registration. JMAFF would not support a proposal replacing testing by *in vitro* testing, as this would influence the individual national policies, which is not in the scope of VICH.

The EU confirmed that its understanding is that the GL would provide guidance on the how to achieve regulatory acceptance but would not impose which type of test should or should not be accepted.

It was suggested to limit the scope of the CP to specific vaccine products but the SC decided to develop a more general GL without narrowing the scope, each country/region would then have the ability to apply the GL to specific products.

JMAFF pointed out that the aim of VICH is not to propose replacements, but to facilitate the harmonisation of technical requirements. JMAFF therefore suggested to change the words “CP....to replace” in the title by “CP on technical requirements for in vitro methods for batch potency...”

The EU added that the CP could be on the acceptance of *in vitro* methods.

AnimalhealthEurope recalled that the aim is to lay out the steps to reach the fundamental goal of the 3Rs and supported the change of the wording of the title.

AnimalhealthEurope will liaise with JMAFF and the AnimalhealthEurope experts to refine the wording of the CP, aiming to keep the focus on technical requirements and will discuss the development of an annex to address specific products such as rabies vaccines.

A revised version of the CP will be circulated for adoption by electronic procedure.

Act: AnimalhealthEurope

11.2. Review of the Discussion Document from AnimalhealthEurope for a Global Regulatory Dossier Framework for Veterinary Medicinal Products

The SC reviewed the Discussion Document presented by AnimalhealthEurope and took note that the DD had been updated following the comments received after the 40th SC meeting.

JMAFF questioned if this topic would be in the scope of VICH, as it might require administrative changes of procedures in some countries.

AnimalhealthEurope pointed out that the aim is not to modify the registration procedures but only to agree on a global format to structure the information in different harmonised sections so as to facilitate the cooperation between the countries and regions. The objective would not be to define data requirements but to clarify how the data is technically organised in the dossier, in which sequence etc. It would provide clarity to authorities and industry when considering the dossiers at the international level.

AnimalhealthEurope confirmed that the aim of this first document is only to open a discussion on this topic.

It was noted that there was a demand from the VOF members and that several VOF countries already accept parts of a dossier in the CTD format.

The SC agreed that a Task Force will be necessary to develop a CP clarifying the framework of what could to be harmonised. In a first step however, the SC decided to limit the initial discussion to the development of a mandate for a TF in an electronic discussion group of

experts. Once this mandate has been adopted by the SC, a TF will be created to develop the CP.

AnimalhealthEurope will lead the discussion group with the aim to submit a mandate for the TF to the SC before the SC's next virtual meeting in June 23.

The Secretariat will circulate a call for experts to the discussion group.

Act: Secretariat

12. VICH 7 Conference

12.1 Proposal from the EU and AnimalhealthEurope

AnimalhealthEurope and the EU explained that no formal reply had been received from Saudi FDA before the SC meeting, and therefore confirmed the proposal of Amsterdam for the Conference location in November 2024.

The SC supported the location and timing.

In the margin of the VOF meeting it was proposed to SFDA to host a VICH special event (training or other) in the future, after the VICH 7 Conference. It was noted that additional events separate from SC meetings may pose travel difficulties for some members.

12.2. Conference expected objectives & audience

The SC took note that, as laid down in article 8 of the Organisational Charter, the aim of the VICH communication is to provide public information and opportunities for feedback on its work for all parties. The organisation of open and transparent VICH public conferences meets this aim.

As usual, VICH members will communicate broadly to encourage experts and interested parties to attend the Conference.

12.3. Outline of the Conference programme

The SC reviewed and supported the proposal provided at the meeting by AnimalhealthEurope.

13. Any other issue

None

14. Any other business

14.1 Farewell Dr Ken NODA

Dr Noda indicated that he would leave JMAFF very soon and therefore step down from the JMAFF delegation after 15 years of participation in the VICH SC. He voiced his greatest appreciation of all the SC members with whom he has worked over the years, highlighting in particular that the long-time interaction with the world's finest and gentlest people has become literally a treasure of his life. He sincerely hoped that VICH will evolve towards a new era, with the new structure for which our TF team members have worked hard for a long time.

The chairman and the secretariat warmly thanked Dr Noda for his outstanding commitment, his ongoing support and his tireless efforts in progressing VICH and wished him all the best for his future activities in his new life.

The SC participants wholeheartedly applauded Dr Noda.

15. Dates and venue of next meetings

- The next SC virtual meeting will take place in June 2023 – provisional date = Wednesday 21 June 2023 – To be confirmed (TBC) by JMAFF
Act: JMAFF
- The 42nd SC meeting will take place from Monday 13 to Thursday 16 November 2023 in Japan. The SC agreed that the VOF meeting will cover 2 days, of which the first half of the first day will be used for a VOF members only premeeting.
- The 43rd SC meeting will take place in Europe, together with the VICH 7 Conference – provisional date = week starting 11 November 2024 - TBC
- The Secretariat will organise a VICH coordinators virtual meeting in February 2023
Act: Secretariat

16. Public statement on the 41st SC meeting

The SC members reviewed and adopted the public statement.

VICH STEERING COMMITTEE

41st meeting

14 to 17 November 2022
Washington, DC

Chair: M. Lucia, FDA CVM

LIST OF PARTICIPANTS

VICH Steering Committee Members and (C) Coordinators

AHI (ZOETIS)	C. LOWNEY
AHI (BI)	E. NORTON
AHI	R. CUMBERBATCH (C)
EU (HEALTH PRODUCTS REGULATORY AUTH)	J. SCHEFFERLIE
EU (EMA)	N. JARRETT (C)
ANIMALHEALTHEUROPE (BI)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)
JMAFF	K. EGUCHI
JMAFF	K. NODA
JMAFF	J. OHMORI (C)
JVPA (Nisseiken Co.)	K. TUCHIYA
JVPA	K. OISHI (C)
US (FDA)	M. LUCIA
US (USDA APHIS)	M. PAGALA
US (FDA/CVM)	B. ROBINSON (C)

OBSERVERS

Australia (APVMA)	D. SIBANDA
Canada (Health Canada)	M. BASSI
Canada (CAHI)	C. FILEJSKI
New Zealand (MPI)	K. BOOTH
South Africa (SAAHA)	M. CHURCHILL
South Africa (SAHPRA)	A. SIGOBODHLA (Remote)
VMD	S. ECKFORD (day 1 only)

INTERESTED PARTY

AVBC	G. DOWELL (not day 1)
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WOAH

WOAH	L. LE LETTY
WOAH	M. SZABO

VICH

HealthforAnimals	H. MARION (<i>Secretary</i>)
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GUESTS

Canada (Health Canada)	E. TATONE
SWISSMEDIC	N. WALSER (part)
US (FDA)	D. LAUCKS
US (FDA)	T. ZHOU
US (FDA)	M. MARTINEZ
US (FDA)	L. WALTER-GRIMM

US (FDA)
VMD

A. PHILIPPI-TAYLOR
G. CLARKE (part)

APOLOGIES

EU (EUROPEAN COMMISSION)
JVPA (NIPPON ZENYAKU KOGYO CO.)
Australia (AMA)
HealthforAnimals
New Zealand (APHNZ)
NOAH

E. ZAMORA ESCRIBANO
H. CHEE
C. BENNETT
C. DU MARCHIE SARVAAS
J. HOWE
D. MURPHY