VICH/23/071
29 January 2024
Final

VICH STEERING COMMITTEE
42nd meeting
13 – 16 November 2023
Tokyo - Japan

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Tomoaki Shimazaki, Director General of the National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries, Japan.

He welcomed the participants back to Japan again after 4 years and wished everybody a constructive meeting.
The Secretary indicated that apologies had been received from J. Schefferlie (EU), E. Zamora Escribano (EU Commission), D. Murphy (NOAH), L. Nagao (AVBC) and C. du Marchie Sarvaas (HealthforAnimals).

2. Adoption of the agenda

The agenda was adopted with minor changes.

3. VICH Forum new structure

3.1. SC Task Force 2023 - Review of Discussion Document "Criteria to be used for determining whether a VICH member country can change membership category in new VICH structures"

The chairman pointed out that the Task Force (TF) members had fulfilled the mandate within 3 months following the assignment given at the virtual Steering Committee (SC) meeting in last June.
The SC reviewed the draft criteria document presented by the TF and adopted the paragraph 2.a (move from Forum Partner category to Observer category) without further comment.
AnimalhealthEurope recommended not to be too descriptive on the conditions listed in paragraph 2.b (move from Observer category to Standing Member category) in order to enable the SC to evaluate on a case by case basis.
It was further acknowledged that it would be difficult to list specific Guidelines (GLs) that should be implemented.
The SC also exchanged on the exact definition of the implementation of a GL, and agreed that further clarification is needed before agreeing a definition.
It was therefore decided to delete the sentence related to the implementation of GLs.

The participants agreed that up to 3 Forum Partners (FP) delegations composed of maximum 2 persons per country/region, will be allowed to attend a SC meeting. FP should indicate their intention at the previous SC/VF meetings and will be informed 6 months in advance of the decision of the SC.

For the upcoming SC meeting, the participants decided that FP must send their formal request to the VICH Secretariat before next 31st December. The same applies to the FP who will request their acceptance as a VICH Observer at the next SC meeting.

3.2. Adoption of the criteria

The SC adopted the criteria document including a few additional minor changes.
The VF was informed of these criteria at the 16th VF meeting.

3.3. VICH updated structures – any final issue

None

4. VICH 7 Conference

4.1. Review of the draft programme.

The SC reviewed the programme prepared by the EU and AnimalhealthEurope, and agreed on the identification of the organisations which will cover each topic. Each organisation will nominate the speakers shortly.

Act: All

It was proposed to organise a poster session with the EWGs topics, for example during the breaks. The EU supported the principle, but will need to check if this will be possible.

Act: EU

4.2. VICH 7 Conference Communication & Website - Advertisement and invitations

AnimalhealthEurope will develop a communication plan in the near future.

Act: AHE

4.3 Organisational and logistical matters for the Conference

The EU and AnimalhealthEurope provided information at the 16th VF meeting (see slides), including the 3 speaker slots assigned to VF members.

5. VICH Training Implementation

5.1. Update on the development of training material

JVPA reported that a video on GL 59 is nearly finished. JMAFF & JVPA will also develop a new video on GLs 50 & 55.
JMAFF recalled that it had volunteered to develop a general video on VICH, but the project was put on hold during the restructuring phase of VICH, which is now finalised. JMAFF will resume the work shortly.

Act: JMAFF

5.2. Organisation of future training sessions

The chairman recalled that VICH has organised 2 webinars in the past years but the attendance has not been as expected and very few questions were received. The SC recognised that this may not have met the needs of VF members and decided not to pursue this option further.
AnimalhealthEurope believed that the some of the presentations (only those related to VICH topics) made at VF meetings can be utilised on the VICH training web content with the addition of a voice over recording (which can easily be done in Microsoft PowerPoint). This will facilitate reaching the appropriate audiences within the agencies, who are not necessarily the persons attending VF meetings.
Australia pointed out that the presentation with voiceover can be broadly used, also for the training of new staff in the agencies of VICH SC members.

The SC agreed that PowerPoint presentations with voiceover explanations are currently the preferred way forward for the training of VF Partners, although only very few presentations are made available each year.
It was acknowledged that the recording of all presentations that will be made at the VICH 7 Conference would enhance the training page of the VICH Website.

AnimalhealthEurope further pointed out that, although it was not made mandatory, the SC members should continue encouraging the EWGs to develop specific training material on the new and revised GLs.

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

The SC noted that no new material had been uploaded since last year.

6. VICH Forum

6.1. Preparation of the 16th VICH Forum meeting

6.1.1. VF meeting setup - preparation of the VF pre-meeting

The SC confirmed that WOAH will chair the pre-meeting which will focus on the future expectations of VF members.

6.1.2. Review of the participants list

The SC reviewed the participants list for the 16th VF meeting and noted
that 16 participants will attend the meeting, including a new country, Egypt. Rwanda and the UAE are recent new VF members but will not attend this time. It was also noted that Brazil and India were attending again, as well as the East Africa Community (EAC) representing 7 countries.
The participants questioned the reasons for the limited attendance and agreed that China should be encouraged to return to the VF. There has been no further contact with China since Dr Xu retired. WOAH will try, in collaboration with the VICH Secretariat, to identify a new contact.
The delegate of South African Development Community (SADC) will not participate, therefore Zambia will present the Zazibona Veterinary Medicines Regulatory Harmonisation Initiative, built on the SADC initiative for regulatory harmonisation for human medicines.

6.1.3. Review of the agenda and preparation of the 16th meeting

Although the combination products topic was initiated by the VF (China), the SC noted that, considering the current discussions within the EWG, it was difficult to provide useful information to the VF at this stage. It was therefore agreed to delete this topic from the VF agenda.

6.1.4. Presentation of the updated VICH and VF structures

FDA has prepared a short presentation to explain the revised structures to the VF members on behalf of the SC.

6.1.5. VF Guidelines implementation tracker

The Secretariat explained that 7 inputs have been received so far, which enables to have a first overview of the implementation status in the different VF countries. The tracker will also facilitate the decision-making by the SC when a VF Partner will request its acceptance as an observer.
The Secretariat will continue requesting the completion of the tracker by other VF partners.

6.1.6 Other issues

None

6.2 Discussion of the outcome of the 16th VICH Forum meeting

A/ General discussion

The SC addressed this agenda item after the 16th VF meeting and thanked L. Le Letty for her excellent leadership of the VF meeting.
The SC noted that, although the attendance was lower than usual, all VF participants were very satisfied with the setup and the information that had been provided.
The SC noted a certain lack of continuity in the VF participation as for some member countries new persons are regularly delegated to VF meetings.

B/ Feedback from the VF pre-meeting

L. Le Letty confirmed that the pre-meeting had been very fruitful with very active participants. It enabled to build a relationship also for the new participants; 16 persons from 89 countries including one regional organisation attended the meeting.
Upon request, 3 speakers have volunteered to present at the VICH 7 Conference. The participants have discussed the expectations and impact of being a VICH Member and have identified several regulatory challenges. The 17th VF pre-meeting will be chaired by Botswana (Innocent Ravengai).

L. Le Letty reported further that in the premeeting participants have identified the following challenges:

- Guidelines on good regulatory practices (general requirements for registration of a VMP)
- Improvement of regulatory strengthening activities (similar as WHO good regulatory practice)
- Training: case studies on GL, possibility to have zoom sessions, recorded presentations, YouTube, or potentially face-to-face.
- Status of the GL on combination products
- Classification of products/VMPs in general - Proposition for a discussion on the harmonisation of the prescription status
- Assessment of the quality part of VMPs / Flexibility compared to medicinal products for human use
- SME (local) : facilitation for the registration of VMPs
- Minor Use Minor Species
- AMR: how to harmonise the registration of VMPs in order to tackle AMR, pre-registration, post-authorisation, surveillance of the market. Implementation of national action plan on AMR => WOAH/VICH

The SC congratulated WOAH for the organisation and leadership of the very well-structured and successful premeeting, and acknowledged that the participants' expectations have been met.
Then SC took note of the ongoing call for more training but agreed that VICH is confronted with a lack of resources. VICH focuses on the VICH technical GLs whereas the VF Partners expect more information on regulatory matters. It was acknowledged that the delegates to the VF meetings expect training essentially on regulatory aspects rather than on technical GLs, which is more a matter for the technical experts in the agencies.

C/ Topics for the 17th VF meeting

The SC noted that the breakout discussions on generic products had been very active and constructive. As it is not a VICH topic, the SC agreed to upload the presentations on generics to the VF's members only webpage, but not to the public training section.
The SC agreed to keep the same set-up for the 17th VF meeting next year; following the very active inputs into the breakout session, it was considered to possibly organise a second session of breakout discussions.

The main discussion topics for the next VF meeting will focus on the accessibility to the market for new products and innovative products, the availability of VMPs and the flexibility of regulatory process and the challenges to address unmet needs, including the approach to Minor Uses Minor Species – MUMS, such as wild species in Africa.
The presentations should explain where flexibility regarding legislation, quality standards and incentives exist to bring products to the market, as well as the principles around MUMS.
One member suggested sharing how a regulator can allow a product authorised in 1 country to be marketed in another country when there is a need. It was highlighted that the routes to market should be explained and the reasons for a non-availability of products in some markets clarified.

The SC considered also that industry should input on how unmet needs are approached and the reasons for requesting, or not, a market authorisation, in particular for MUMS products.
It was noted that the definition of MUMS varies much between the countries/regions.
JMAFF explained that although there is no clear definition of MUMS in Japan, JMAFF will contribute to the debate.
Australia volunteered to present its well-established system for MUMS to the VF.
In conclusion, the SC agreed that the general topic of unmet needs will be addressed by the regulators from the 3 founding members and from Australia, as well as representatives from the industry.

Other topics to be considered at the 17th VF meeting:

- Report on medicated premixes GL
- Biowaivers
- Progress from other EWGs
- The 3 Rs principles
- Industry engagement bringing new products forward

The SC agreed to finalise the agenda for the 17th VF meeting through written communication or at the June virtual SC meeting at the latest. The SC accepted FDA's offer to provide a representative (E. Hart) to support the WOAH efforts in leading the VICH Forum.

7. Reviews of:

7.1 Implementation and interpretation of VICH GLs in the regions

7.1.1 Report from the regulators in the VICH regions

None

7.1.2 Review of the updated VICH GLs implementation tracker

No change was received since last year.
The EU indicated that it would update the tracker as the pharmacovigilance GLs have now been implemented.

Act: EU

7.1.3 Any input from industry members

AHI reported that the draft USDA guidance on the implementation of GLs 50, 55 & 59 has raised issues regarding the feasibility of seeking batch safety testing waivers in the USA. While variation in implementation exists between countries, industry explained that disharmonization negatively affects the adoption of the guidelines and the real-world 3R impacts. Steering committee members reflected on how risk tolerance may effect regional approaches and raised questions about the understanding of the definition VICH guideline 'implementation'. "

USDA confirmed that the US is working with the industry towards implementation, and will not require to review these GLs again. It was proposed that USDA would update the VICH SC on progress at the November 2024 meeting.

AnimalhealthEurope explained that industry is under strong pressure to move forward with the 3Rs. The industry noted the importance of expanding the application of these GLs worldwide in order to benefit fully from these GLs.

The SC recognised the need to define more precisely the "implementation of VICH GLs", as variations seem to exist between the different VICH countries/regions. AHI will develop, with the help of the other industry organisations, a draft Discussion Document aiming to clarify the definition of implementation.

Act: AHI

7.2 Status of consultation for draft GLs at Step 4

7.2.1 Status of Draft VICH Quality GL 60

The 3 VICH Founding members reported that the consultation phase is ongoing and comments should be provided within the set timeline.

8. Review of final VICH Guidelines at step 9

8.1. Proposals for revision of further VICH GLs

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

The Secretariat recalled that only GL55 has been identified for review. The EU, topic leader, reported that the EU experts do not recommend a revision of this GL at this time.
The SC agreed.

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

8.1.2.1 VICH Safety GL 33

Although FDA had suggested minor revisions of GL33 at the last SC meeting, FDA now recommended to put this revision on hold and proceed with the minor revisions after the on-going work on safety GL22 and GL23 has been completed.

8.1.2.2 VICH MRK GL 46

Although FDA had proposed a revision at the last SC meeting, FDA now recommended to put this revision on hold because of the anticipated workload and a current lack of resources to address this topic.

8.1.2.3 VICH MRK GL 47

See item 9.8

8.1.2.4 VICH Stability GL 3

See item 9.9

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

The EU indicated its intention to provide 2 Concept Papers (CP) before the 43rd SC meeting. The first one on the revision of GL 27 (Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance).

Act: EU

The second CP proposed by the EU experts will cover the Environmental Risk Assessment – ERA GLs, following an EU reflection paper considering companion animal products.
FDA also reported a current internal review of ERA GL6 & GL38 to consider if revisions would be necessary.

AnimalhealthEurope, AHI & JVPA did not support revising these GLs for the moment, considering that more research is required to understand what the issues would be. Moreover, much progress is being made in the international implementation of VICH guidelines, including the ERA GLs, which are very challenging for some countries. Changing the ERA guidelines now would hamper progress on international harmonisation on this topic. Industry considered it would be more useful to review the scientific information on the issues, particularly in scientific journals, before moving to a revision of these GLs. Additionally, industry raised concern that some efforts have taken more than ten years and stated that an effort could be more efficient with additional work prior to development of the concept paper.
AnimalhealthEurope recommended continuing supporting the implementation of GL6 throughout the world before deciding on revising this GL.
Industry therefore strongly recommended developing a DD before drafting a CP.

The EU and FDA agreed to liaise together on the way forward and to consider the possibility of developing a single CP covering all issues relating to the ERA GLs. JMAFF mentioned that the ERA GLs are used on a voluntary basis in Japan and did not identify any particular subject for discussion, but will take part in any upcoming exchange.

The EU noted the high level of concern that was raised and indicated that, at an EU level, there would be further discussion on the way forward. Nevertheless, at this point, its intention to come forward with a CP ahead of the next SC meeting is unchanged.

The SC agreed that more discussion is required before, as well as at, the next SC meeting on this topic.

AnimalhealthEurope pointed out that the current VICH GLs represent an excellent international guidance for ERA and proposed the regulatory authorities should develop a harmonised technical guidance rather than revising the internationally recognised VICH GLs. This document would not be called a VICH GL, but could be a “harmonised technical document”. The EU did not reject the proposal but believed that this could not be presented as a VICH document.
The SC agreed that this suggestion needs further reflection and discussion as well.

Act: Next SC meeting

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

8.2.1 ICH Q12

AnimalhealthEurope suggested studying ICH Q12 as a potential future VICH topic. ICH Q12 covers the product life cycle and will help to reduce the number of variations when the CMC dossier section is updated.
FDA pointed out that so far only ICH Q7 and Q8 have been addressed, so VICH needs to consider ICH Q9 & Q10 before addressing Q12.
The SC recognised that firstly a CP must be developed for a possible development of the VICH GLs related to ICH Q9 & Q10.
JMAFF also pointed out that VICH needs to carefully consider whether ICH Q9 and Q10 are within the scope.

8.2.2 VICH GLs 1 & 2

The Secretariat mentioned that very recently a message had been received from an external party mentioning that GL ICH Q2(R2) had been recently adopted and asking if VICH had the intention to revise VICH GLs 1 & 2 on validation of analytical procedures.
The SC asked the Secretariat to respond taking note of the suggestion.

Act: Secretariat *(Done)*

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

9.1. Quality EWG

The chair of the Expert Working Group, Dr T. Ogata, reported that the EWG is addressing 3 topics.

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

The revised GL has been signed off at step 6 by the SC in April 2023 for implementation by April 2024.

b. Guideline for Good Manufacturing Practice for Active Pharmaceutical Ingredients

This draft GL60, based on ICH Q7, was signed off by the SC at Step 3 in September 2023 and was released at Step 4 for a 6-months consultation period until 25 March 2024.

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 EWG has developed a draft GL which should shortly be signed off at step 2.

9.2. Biologicals EWG

The chair of the Expert Working Group, Dr K. Sato, reported the progress of the 3 EWG subgroups.

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

The SC had agreed to limit the focus of the first draft to a single animal species, swine. In a first step the experts have collected the current EV procedures carried out in each VICH country/region. A first draft GL is under review by the experts until January.
AHI supported a risk-based approach and pointed out that as a basic principle the number of studies should be minimised as much as possible, reducing the number of experimental animals as well. The GL should not require testing each virus.
The EU supported the AHI comment, highlighting that, in the EU, a risk-based approach is a fundamental aspect of the way extraneous viruses are addressed. Consequently, the EU emphasized the importance of a risk-based approach citing concerns with an approach that seeks to create a list that dictates minimum testing requirements.

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

The topic leader is JVPA. A draft version 2 of the GL for TAS Evaluation for Veterinary Monoclonal Antibody Products was reviewed by the subgroup experts. Following the comments and suggestions received, the topic leader is preparing a draft version 3 for final review by the experts, the target being to provide the step 2 document as soon as possible.

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

The subgroup has finalised its tasks as the 3 GLs have now been adopted at step 7 with ongoing progress reports at step 8.

9.3. 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.

GL 30
The proposed changes to the VICH GL 30 code lists have been finalised and the revisions posted on the VICH website as an updated Excel sheet (version number 3).

Signal detection/signal Management Discussion Document
The work on this draft DD is ongoing with the objective to provide a final document in 2024.
AnimalhealthEurope acknowledged that this is a working document, collecting experience in a new developing field, and therefore recommended to further develop the section on signal management as experience is gained.
FDA indicated that this document would not be developed as a GL but will remain a DD for the foreseeable future.

Revision of GLs 24 & 29
The experts have agreed that both GLs are still valid as they are and therefore paused the work to revise these GLs.

9.4. 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 EWG has deployed many efforts to incorporate the large number of comments received in the consultation period. The work is now mostly completed and the step 5 documents should be available soon.

FDA mentioned that the large number of comments has resulted in questioning the process to respond to comments in general.
The secretariat indicated that the intent is to respond to the substantial comments only, not the minor/grammatical ones. The VICH policy document on the consultation at step 4 has last been revised in February 2019 (VICH/00/154-rev 3). When the final GL is published, an overview of the comments received with the replies from the EWGs, is also published on the VICH website.

The SC recognised that further guidance should be given to the EWGs on the expectations regarding the responses to the comments; and also how to address out of scope comments.
FDA will review the policy document and draft a proposal for additional guidance, for review by the SC by written procedure.

Act: FDA

The SC congratulated again Dr Phillippi-Taylor and the experts, and noted that an enormous amount of work has been achieved by the EWG for the revision of these 9 GLs.

9.5. Safety EWG

The chair of the Expert Working Group, Dr T. Zhou, reported that the experts had met last week in person to review both GLs 22 & 23. This meeting was critical for the progress, and had been well prepared by a virtual meeting in last August.

GL 22
The EWG agreed that the 2 generation reproduction tox study remains the default, the extended one generation study being an option. The experts agreed on the language to clarify the GL.
The last minor comments should be provided by the end of November so that the revised GL can be signed-off at step 2 before end December.

GL 23
The experts have made extensive edits in order to improve the accuracy and readability of the draft GL. They have also added references to other documents to improve the clarity of the document. Further comments need to be provided on the last version agreed; only minor comments are expected and a sign-off at step 2 is expected by end March 2024.

Dr Zhou questioned what the SC expects from the EWG regarding training material on the GLs. AnimalhealthEurope confirmed that there is an ongoing request to EWGs to make a recommendation for what training material might be suitable for these particular guidelines and if possible, to consider providing training material. This could be in the format of a short static PowerPoint presentation summarising the GL and its key points or, preferably more explanations can be provided by adding a soundtrack with comments to the slides. The training material can also be a discussion document, a Q/A document, a case study or a video.

The SC congratulated Dr Zhou for her efforts and commitment to drive these draft GLs forward, and thanked Dr Zhou and the experts for the significant progress achieved during the last days.

9.6. 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. A draft document is being reviewed by the experts in order to identify which areas are clear, and which need to be clarified further. AHI recalled that this effort started from a request by a forum member and questioned whether a guidance was the best route for providing the forum with the information they needed. The EWG is therefore asked to reflect on the recommendations specific to combination products and brainstorm whether a final deliverable other than a guidance would be better suited to provide the requested education. The SC asked the EWG to discuss further and provide a recommendation to the SC, for further discussion at the next SC meeting.

Act: EWG

Meanwhile it was agreed not to include this topic in the 16th VF agenda.

9.7. Bioequivalence EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr M. Martinez, and presented by FDA.
As the dissolution GL that has been drafted overlapped much with CMC, there has been a shift within the EWG to develop a biowaivers GL, which was the initial objective that had been requested by the SC.
A draft biowaiver GL has been circulated to the experts for review and comments by the end of November. The in vitro dissolution data needed to support biowaivers are included in this draft GL.
Further discussion is now necessary within the EWG.
It was questioned whether FDA would present a CP for a further GL focusing on in vitro dissolution and CMC.
FDA will not develop a CP for the time being, but the SC acknowledged that any other SC member could present a new CP.

9.8. Metabolism and Residue Kinetics EWG

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

Revision of GL 49
The new proposal of GL 49 with the corrected and combined annex 3 will be ready shortly for final feedback from the experts. The chair hoped that any further comments will be minor and that the revised GL 49 should be ready for sign off for public consultation at step 4 before the 43rd SC meeting.

Revision of GL 47

The experts expressed mixed views on whether there is a need for a review and additional guidance to address the issues but committed to considering a Concept Paper. A topic leader from FDA has agreed to develop a CP that would be shared with the EWG and be ready for review by the SC before the 43rd SC meeting

9.9. Medicated premixes

The chair of the Expert Working Group, Prof. 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.
The main issue raised last year has been resolved by replacing the word “new” by “existing”.

An additional two questions remained: the mixability requirements for liquid premixes, which was not supported by the experts and liquid premixes proposed for concurrent use, which will require further discussion on the need for stability requirements for suspensions.
A new virtual meeting is planned in April with the aim to sign-off a step 2 document in May and that the public consultation period would be finalised before by the next SC meeting.

Prof. De Ridder reported further that the EWG continued the assessment on the necessity and possibility to develop further guidance on other related topics with potentially a major impact on the quality of medicated premixes and their suitability to manufacture medicated feed.
There is wide 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
- Sampling methodology
- Homogeneity and segregation studies
- Stability requirements for medicated premixes, including pelleting/extrusion stability

Prof. De Ridder finally confirmed that there is no proposal anymore from the EWG to revise VICH GL 3.

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

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

None

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

None

12. Concept papers/Discussion Documents

12.1 Review of the recommendation from the Discussion Group on a Mandate for a Task Force to create a Concept Paper for a Global Regulatory Dossier Framework for Veterinary Medicinal Products

AnimalhealthEurope reported that the Discussion Group (DG) had concluded unanimously that this topic was in the scope of VICH and consequently developed a proposal for a “Mandate for a

VICH SC Task Force charged with writing a Concept Paper for the development of a Global Regulatory Dossier Framework (GRDF)".
The first focus will be on pharmaceuticals, providing a modular skeleton that can accommodate the dossiers parts currently submitted in the different regions.
The DG recommended to not include the implementation phase which would need a separate TF to consider.
The DG proposed a 6 months' timeframe to develop the CP.
AnimalhealthEurope thanked the participants of the DG for their constructive inputs.

The SC adopted the proposed mandate and decided to create a new TF composed of SC delegations, and Forum Partners will be invited to participate at a later stage.
AnimalhealthEurope will be the topic leader.
The Secretariat will ask SC members to nominate up to 2 representatives for each SC organisation before next 15 December.

Act: Secretariat *(Done)*

12.2. Review of the revised Concept Paper on principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals

The SC reviewed the revised CP presented by AnimalhealthEurope. The SC noted that AnimalhealthEurope had provided a response to the 4 questions posed by JMAFF and that modifications have also been made to the CP following JMAFF's questions.
JMAFF confirmed that the responses received have addressed the questions that were posed. The last concern was that 3 months may be too short for the subgroup to establish recommendations. AnimalhealthEurope agreed to review the proposed timelines.

JVPA supported the recommendation to move batch potency test from in vivo to in vitro, but pointed out that some tests can only be done in vivo; some specific vaccines still would need in vivo tests.
AnimalhealthEurope confirmed that the GL will not make in vitro testing mandatory, but if in vitro is chosen, this GL will serve as a guidance. If in vivo is preferred or required by the regulators for a particular vaccine, then the GL will not be applicable.
The SC acknowledged that the title of the CP has been changed to "principles for technical guidance...".

The SC adopted the CP and decided that this topic shall be addressed by a new Batch Potency Tests subgroup of the Biologicals EWG. The subgroup's Topic 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)*

The SC further agreed to disband the Animal Batch Safety Test subgroup which has finalised its task.

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

The SC reviewed the draft CP presented by the EU and noted that it had been circulated only shortly before the meeting.
The EU explained that GL 34 was implemented in 2014, but that some guidance documents describing the methods for testing for mycoplasma contamination, on which the guideline is based, have meanwhile been revised, for example in the European Pharmacopoeia.

The SC recognised the possible need to review GL 34 to take the changes into account, but noted that more time is needed for the different regions' experts to review the proposed CP and provide comments in writing.
It was agreed that all SC members should provide their inputs to the EU before the end of February 2024.

Act: All

The EU will then provide a second draft of the CP for further review by written procedure.

Act: EU

13. Any other issue

13.1 Coordination of the timing of VeDDRA updates

AnimalhealthEurope and AHI explained that some countries have not updated their systems to the latest version of VeDDRA, with the consequence that some AER are rejected by their system.
There is an urgent need for a harmonised approach to prevent further rejections.

It was confirmed that the GL states that the revision of the VeDDRA list does not require the revision of the GL.
The EU supported to harmonise the approach and explained that the EMA is required to work with the latest or last latest version of VeDDRA. The EU is required to update the system annually on 1st October.
FDA has implemented V 18. The move to V 18 was difficult because of issues of IT resources. FDA has already begun the process to update to V 19 of the list. In general, FDA aims to implement by early January, but cannot commit to a set deadline. FDA noted that additional steps are required for VeDDRA updates including reconciling vocabulary terms to include those for medication errors and product defects, and noted that their system accepts up to four versions in backwards compatibility.
JMAFF stated that they understood some country/regions may not be able to easily move to the latest VeDDRA version on specific date due to financial and IT issues. JMAFF also indicated their availability for moving to the latest version on 1st January as proposed in the document.

AnimalhealthEurope and AHI pointed out that industry needs to be informed of any delays in order to prevent rejections of its AERs notifications. The best practice could be that when a regulator is not able to upgrade the system, industry should be informed as early as possible. Industry follows the date of upgrading by the EMA, so other regulators should notify industry when they encounter delays in their own upgrading. The VICH SC agreed to refer this topic to the pharmacovigilance EWG.

Act: PhV EWG

14. Any other business

14.1 VICH website

AnimalhealthEurope explained that the content management system and the background software of the VICH website is based on old technology and must therefore be updated within the next 1-2 years.
This will be an expensive process, but will also provide the opportunity to update/improve other parts of the website.
It was suggested to improve the display and functionalities, as well as to provide a means to comment on documents on the website itself, as well as to sign-off the required documents.
It was further suggested to provide more space/volume to post videos and voice overs, to include web analytics to understand if the GLs are consulted, downloaded etc… and to improve the accessibility of documents.

AnimalhealthEurope will circulate an e-mail for all to provide further input within the next few months, including suggestions for how the development of additional functionalities might be funded.

Act: AHE

15. Dates and venue of next meetings

- The next SC virtual meeting will take place Monday 24 June 2024. Should there be no topic for discussion by the SC, the meeting will be cancelled.
- The 43rd SC meeting will take place in Amsterdam, together with the VICH 7 Conference from 10 to 15 November 2024
- The 44th SC meeting will take place from 10 to 13 November 2025 in the USA – location TBC
- The Secretariat will organise a VICH coordinators virtual meeting in the week starting 5 February 2024

Act: Secretariat

16. Public statement on the 42nd SC meeting

The SC members reviewed and adopted the public statement.

VICH STEERING COMMITTEE

42nd meeting

13 to 16 November 2023
Tokyo

Chair: T. Shimazaki, JMAFF

LIST OF PARTICIPANTS

VICH Steering Committee Members and (C) Coordinators

AHI (ZOETIS)	C. LOWNEY
AHI (Boehringer Ingelheim)	E. NORTON
AHI	R. CUMBERBATCH (C)
EU (EMA)	N. JARRETT (C)
ANIMALHEALTHEUROPE (Boehringer Ingelheim)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)
JMAFF	K. EGUCHI
JMAFF	S. IWAMOTO
JMAFF	J. OHMORI (C)
JVPA (Nisseiken Co.)	K. TUCHIYA
JVPA (NIPPON ZENYAKU KOGYO CO.)	H. CHEE
JVPA	K. OISHI (C)
US (FDA)	M. LUCIA
US (USDA APHIS)	G. SRINIVAS
US (FDA/CVM)	B. ROBINSON (C)

STANDING MEMBERS

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

OBSERVERS

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

WOAH

WOAH	L. LE LETTY
WOAH	M. SZABO

VICH

HealthforAnimals	H. MARION (*Secretary*)

ADDITIONAL PARTICIPANT

Canada (Health Canada)	X. LI

GUESTS

US (FDA)	T. ZHOU
US (FDA)	E. HART
JMAFF	T. OGATA
JMAFF	K. SATO

APOLOGIES

EU (HEALTH PRODUCTS REGULATORY AUTH)	J. SCHEFFERLIE
EU (EUROPEAN COMMISSION)	E. ZAMORA ESCRIBANO
HealthforAnimals	C. DU MARCHIE SARVAAS
NOAH	D. MURPHY
AVBC	L. NAGAO