VICH/20/090
29 January 2021
Final

VICH STEERING COMMITTEE
39th virtual meeting
16 – 19 November 2020

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 Department at the European Medicines Agency. He welcomed the participants to the 39th meeting of the VICH Steering Committee, which is held "virtually" because of the current exceptional circumstances generated by the global pandemic. He would have indeed preferred to welcome the participants in the EMA's new facilities in Amsterdam. He nevertheless hoped to be able to host the 40th SC meeting in November next year.
Dr Claassen pointed out that the SC is facing the challenge to fulfil the annual meeting in the limit of only 3 sessions of 2 hours teleconference, because of the broad time differences, and he warmly thanked the members who have agreed to participate either very early or very late in their day.

The Secretary indicated that apologies had been received from R. Cumberbatch – AHI.

2. Adoption of the agenda

The agenda was adopted without change.

3. VICH Priorities Phase V

The Secretariat indicated that the draft 9 of the document is presented for final adoption.
The OIE suggested to add at the end of the 7th bullet point of chapter 3, a reference to the global One Health approach and the protection of the environment. It was however pointed out that the latter is already in place at the end of the first bullet point.
The SC therefore agreed to complete the first bullet point with a reference to the One Health principles.
The SC adopted the final version of the VICH priorities Phase V which will be placed on the VICH website.

Act: Secretariat

4. VICH Training Implementation

The participants reviewed the updated report circulated by AnimalhealthEurope prior to the meeting. It was acknowledged that good progress had been made; all modules now include at least some training material whilst the module on quality has been very well populated.

AnimalhealthEurope called upon further volunteers to provide training material for the GLs which have not yet been addressed (highlighted in yellow in Annex 2).
The participants noted that the training sessions provided in the VOF meetings represent an excellent training material for the website as well.
JVPA recalled that a draft video on GL 57 had been presented at the 38th SC. This video has been finalised with the input received from the SC members and will be provided shortly for upload on the VICH website.
Moreover, the Japanese delegation is developing further material which will be provided in due course.

AnimalhealthEurope suggested to include in the mandate of each EWG the requirement to provide training material on each new GL as soon as it is at step 5 of the process.
The EU supported the approach on the understanding that it would be the EWG that takes on this responsibility rather than specifically the topic lead. FDA considered that the EWG might not always have the proper persons to develop training material and that the EWGs should first be focused on harmonization of GLs, and therefore was reluctant to add this mandate to the EWGs.
JMAFF questioned if this was indeed feasible and recommended to consult with the leaders of the EWGs before including this requirement in the mandates. JMAFF however agreed that the experts are mostly the best persons to develop at least a first draft of the material. AHI agreed.
AnimalhealthEurope believed that not only the topic leader, but any expert in the EWG could develop this material. Moreover, the experts from each delegation can also rely on their expert colleagues in their countries & regions.
AnimalhealthEurope will provide a Discussion Document with proposals for the next steps.

Act: AnimalhealthEurope

5. Review of Discussion Documents for presentation to the VOF

5.1. Review of the Discussion Document on how to manage "Out of Scope" topics

The SC reviewed the latest suggestions for amendments which had been circulated after the first part of the SC meeting and supported the proposed changes.
The SC acknowledged that the document provides sufficient flexibility to address "outside of the scope" topics in VOF meetings when the 3 VICH regions' regulators are able provide information on their local guidance.
The SC adopted the internal guidance document.

AnimalhealthEurope recalled that the list of VICH "Out of Scope" topics had been thoroughly discussed in the 12th VOF meeting last year and that much feedback had been received from VOF members. Their proposals are included in the current draft, with the reformatting of table 1 as suggested by JMAFF.
JMAFF confirmed that each VICH country/region had the opportunity to partially provide the link to their own material on these topics.
JMAFF insisted that a professional association (such as WAAVP in the "Ectoparasiticides" topic) should not be placed in "Country/Region/Organisation" but in the "website and/or contact" column, as the aim is to clarify which guidance is adopted in each member country/region as national/regional guidance.
AnimalhealthEurope recommended to adopt this document with a reformatting of the table layout and the addition of a reference to the Withdrawal Periods material that was circulated to the VOF.
The SC adopted this document (list of VICH "Out of Scope" topics) as well.
The Secretariat will circulate the finalised documents, and place both documents on the website.

Act: Secretary

5.2. Update on the reports to VOF on calculation of WP and on autogenous vaccines

AnimalhealthEurope thanked the regulatory members from the SC for having provided an overview of the situation in the VICH regions & countries. The document on the calculation of withdrawal times has been compiled by AnimalhealthEurope with the support of an external consultant and has been circulated to the VOF in September. A further document is in preparation for a publication in a scientific journal.

For the document on autogenous vaccines, AnimalhealthEurope will have to prepare the work internally and did not have the time to develop it yet.

6. VICH Outreach Forum

6.1. Review of the participants list

The SC reviewed the participants list for the 13th VOF meeting and noted that some delegations will provide many participants: 8 for Malaysia, 8 for Singapore 8 for UEMOA and 12 for Korea. Furthermore, Brazil (MAPA and SINDAN), India as well as Mexico will participate as well. The SC nevertheless regretted that Thailand had not replied to the invitation this time.

6.2 Review of the agenda and preparation of the 13th meeting

The SC took note of the last version of the agenda and noted that the VOF will also have the opportunity to finalise the agenda for the 14th meeting.
OIE pointed out that little input had been received from VOF and SC members to prepare the agenda points and discussions.
The material for the training session had been made available on the website and a follow-up webinar is provisionally scheduled on Tuesday 9 February 2021. The VOF members will be asked to send their questions beforehand to the VICH Secretariat.
AnimalhealthEurope suggested to ask the VOF members to provide feedback on the document on WP, in order to clarify if such a document on an “out of scope” topic is sufficient or if the VOF members would like more discussion at the 14th VOF meeting.

The SC noted the value of this virtual meeting which enables to reach much more persons in the VOF countries than in face-to-face meetings. The usefulness of annual face-to-face meetings was nevertheless considered as essential to develop constructive contacts and networking opportunities.
AnimalhealthEurope recommended however that VICH should organise follow up virtual meetings on a regular basis between the annual face-to-face VOF meetings to maintain interest.
Meanwhile, the follow up webinar organised by the EU will represent a first step before the 14th VOF in 2021.

Regarding the agenda for the 14th VOF meeting, AnimalhealthEurope will ask the EWG on medicated premixes to prepare a presentation for that meeting.

6.3 Timing of VOF meetings

The EU presented its proposal for amendments to the standard timings of SC and VOF meetings and explained that this could increase the efficiency of the meetings by reducing the meeting time for the SC, which has not always needed the full session 4 of its meeting during the past years.

AnimalhealthEurope suggested to remain with the proposal 1 until more experience has been gathered in the 1 meeting per year format.
The OIE believed that more time was needed to reflect on the EU proposal and also to ask the opinion of the VOF members. The OIE pointed out that the 14th VOF meeting agenda had been built on the basis of the current meeting setup, also compatible with the proposal 1, and therefore also suggested to remain with the proposal 1 for the time being.
The EU asked all SC members to provide further input on this document by next 15 December.

Act: All

A final decision should be made before end of March in order to organise properly the next meetings in November 2021.

7. Reviews of:

7.1 The implementation and interpretation of VICH GLs in the regions

The EU reported that following delays in its development, the pharmacovigilance database will be ready before the end of 2021 so that the PhV GLs 35 and 42 should be implemented by end 2021.

JMAFF confirmed that the PhV GLs 30, 35 and 42 have been implemented in Japan on last 12 November.

7.2 Status of consultation for draft GLs at Step 4

None

7.3 VICH GLs implementation tracker

The Secretariat indicated that a final complete version of the document including the status in all VICH member and observer countries, has just been placed on the website.
Clarifications were requested in order to explain why specific GLs had not been implemented in some Observer countries, and also in the USA.
The USA, Canada, South Africa and New Zealand will provide additional information to the Secretariat.

Act: FDA/HC/SAHPRA/MPI

The Secretariat recalled that as next step, the SC had suggested to ask the VOF members if they would be interested in completing this tracker as well. It was agreed to add this topic to the agenda of the 14th VOF meeting next year.

Act: OIE

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 indicated that since the last SC meeting only GL 48 has reached the 5 years' point. The SC considered that this GL does not need to be reviewed at this time.

8.1.2 VICH Quality GL 18(R) on Residual Solvents – Update on the progress of the ICH GL Q3C

JMAFF explained that the ICH Q3C GL is still under revision and in the public consultation phase. JMAFF therefore proposed that the VICH Quality EWG should resume its work once this GL has been reviewed and finalised by ICH.
The SC agreed.

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

None proposed

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

None proposed

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

9.1. Quality

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr T. Ogata, and presented by JMAFF.
JMAFF confirmed that GL 58 (Stability - Climatic zones III & IV) has been signed off last year and is being implemented in November 2020.

Regarding the revision of GL 18, JMAFF explained that, as discussed under point 8.1.2, the Quality EWG will resume its work once the ICH Q3C GL has been reviewed and finalised by ICH.

9.2. Biologicals

The chair of the Expert Working Group, Dr K. Sato, reported that the EWG is now progressing the topics through 3 different subgroups:

a. The BST sub group - Harmonisation of criteria to waive Laboratory Animals Batch Safety testing
The subgroup has finalised the LABST GL 59 at step 5 in October. The final GL has been signed by the SC at step 6 last week and has subsequently been circulated for implementation in November 2021.

b. the EV subgroup - Test on the Presence of Extraneous Viruses in veterinary vaccines
Following the CP adopted last year, the subgroup will focus firstly on a single animal species, swine, and, as a first step, plans to collect precise information on the current EV procedures carried out in each region.
Following the proposal from the EWG, the SC supported the nomination of USDA as the topic leader.

c. BS subgroup: Safety evaluation of biotechnology-derived/biological products
This subgroup is composed of 15 experts and, as agreed by the SC, has set a high-level timeline to develop a GL based on the CP from JMAFF focusing on target animal safety (not human food safety) evaluation of veterinary medicinal products containing monoclonal antibodies. In a first step, the JVPA topic leader will provide a preliminary draft GL by March 2021. The EWG should then review the document and start the discussion, with the aim to complete the Step 2 GL by November 2022.

9.3. Pharmacovigilance

The chair of the Expert Working Group, Dr Linda Walter-Grimm, reported that the EWG has held 4 teleconferences since December 2019 and addressed in particular the following issues:

- A minor revision of GLs 24 & 29
- The routine maintenance of the GL 30 vocabulary list; 3 lists were provided for proposed breed changes.
- The scope of a Discussion Document for signal detection and signal management practices was discussed with the support of the additional EWG advisors. This topic is progressing faster than expected and several specific meetings are scheduled.
- The EWG will continue to focus on the GL 30 maintenance procedure
- Within the EWG, the EU raised the possibility of a minor revision of GLs 35 & 42.

The SC congratulated Dr Walter-Grimm and the experts for their ongoing activity and the large amount of work that is being achieved.

9.4. Safety EWG

The chair of the Expert Working Group, Dr K. Greenlees, reported that the EWG continues to address the revisions of GL 22 & 23(R). Some concerns have however been raised by some experts on the revisions that are proposed for both GLs.
The EU pointed out that both revisions are linked to the progress of 3Rs related issues and believed that the alternatives that are currently proposed do not provide a lower level of assurance regarding safety, and have the potential to result in additional, valuable information. The EU therefore recommended strongly to move both revisions forward.

JMAFF believed that these revisions are very challenging because there is a will to harmonise the acceptable safety level between the regions rather than the purely technical level. JMAFF therefore suggested that the discussion on GL 23 should be temporarily (e.g. for 5 years) suspended until there is a significant progress in AI technology for *in silico* analysis for toxicity evaluation. JMAFF also proposed to focus the EWG resources on the discussions on GL22.
After discussion, the SC decided that the EWG should continue the work on both GLs, focussing the efforts on GL 22, but without dropping the progress of GL 23.
Moreover, the SC recommended that the EWG should enhance the discussions by holding a virtual meeting as soon as possible.

Dr Greenlees indicated that he would leave the EWG after this meeting, and the SC warmly thanked him for his constructive and ongoing efforts during many years to progress these very difficult technical topics within the EWG.
Dr Charli Long (FDA) was welcomed as the new chair of the EWG.

9.5. Anthelmintics EWG

The chair of the Expert Working Group, Dr A. Phillippi-Taylor, reported that all experts have actively provided feedback when requested, although delays have occurred in receiving and collating feedback, due to COVID-19 crisis as well as to the complexity of the issues.
Good progress has nevertheless been achieved and Dr Phillippi-Taylor circulated 8 documents in October with final proposed revisions of the different topics; additional comments are expected by end January 21.
The experts also agreed unanimously on a framework for a solution to the arithmetic/geometric means discussion.

The agreed revisions will be incorporated into the GLs by April 21 and it is expected to have the revised draft GLs ready for the next step in the VICH process by October 21.
The SC thanked Dr Phillippi-Taylor for the amount of work already achieved and the ambitious agenda ahead.

9.6. Combination product GLs EWG

The new co-chair of the Expert Working Group, Dr D. Laucks, recalled that initially the EWG has collated the GLs existing in the EU and the US, but it appeared that some parts would be very difficult to harmonise between the jurisdictions. The agencies are indeed using different approaches in relation to the efficacy requirements for these products. So instead of seeking a harmonisation of the existing guidelines, the experts decided to identify the areas of agreement and those where there are major differences. A new GL needs to be acceptable and meet the requirements of the different regions so the EWG will propose a revised scope of the CP.
The draft revised CP should be circulated to the EWG by the end of December and will be submitted to the SC for approval once agreement is reached.
JMAFF, which had been involved in the drafting of the first CP, requested that the new CP clearly highlights the differences with the original proposal.
The SC thanked Dr Laucks for taking over the co-chair and for the progress achieved by the experts.

Act: EWG

Dr Laucks confirmed that Dr Xu remains closely involved in all the steps of the discussions.

9.7. Bioequivalence EWG

The chair of the Expert Working Group, Dr M. Martinez, recalled that the revised draft CP was approved by the SC in September 2019 and the EWG reconvened with the mandate to first refine the list of critical questions that needs to be addressed in developing an *in vitro* dissolution GL that would be acceptable for all regions, then develop an *in vitro* dissolution GL, and finally develop a VICH policy covering biowaivers for solid oral dosage forms.
As a first step the experts agreed last February on the points to be debated in addition to those listed in the approved CP.
Dr Martinez is currently collating the comments on the critical questions which will be shared with the EWG in early 21. She will provide a framework for a “dissolution GL” before the summer 2021.
Dr Martinez pointed out that it is essential that the EWG agrees on the *in vitro* dissolution studies before discussing the biowaivers.
AnimalhealthEurope voiced its support for this stepwise approach and will provide further proposals once the first steps will be completed.
The SC thanked Dr Martinez for the progress already achieved.

9.8. Metabolism and Residue Kinetics EWG

The chair of the Expert Working Group, Dr S. Scheid, reported that the only current task of the EWG is the revision of GL 49, focusing mostly on the need for clarification around annex 3 of the GL. A revised annex 3 including the comments has been developed by the topic leader, Dr Boner.
A draft of the revised GL, including proposed changes for the validation, is currently in development and should be submitted soon to the experts for discussion.

9.9. Medicated premixes

The chair of the Expert Working Group, Dr E. De Ridder, reported that the Task Force, including a VOF member (Morocco), has very efficiently finalised the CP, which the SC has adopted by written procedure.
The EWG experts have been recently confirmed and the EWG will address the issues of the 4 sections of the CP in smaller working groups.
The aim is that the EWG provides a step 3 document by the 40th SC meeting next November.

REMINDER: General issue
As the group e-mail addresses are managed by the Secretariat, it is of utmost importance that all delegations keep their expert lists up to date and immediately inform the Secretariat of any change.

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. Review of the Outcome of the 13th VOF meeting

The SC noted with satisfaction that the meeting had been very successful, with more than 90 participants, including the SC members. Some delegations were large and came together in single meeting rooms. The BRIC countries were all in attendance as well as 2 regional organisations, CAMEVET and UEMOA.
The participants were very interested in the presentation from SFDA on the GCC showing that a mutual recognition procedure is feasible at a regional level.
Much discussion took place on the 14th VOF meeting agenda, which the VOF members accepted in principle.
Regarding the proposal from HealthforAnimals for a discussion on the advantages of digital platforms, OIE suggested to ask the VOF members to address this topic in the VOF pre-meeting, then feedback to the VOF plenary.
HealthforAnimals pointed out that the current pandemic is showing that digital platforms are efficient and successful. The digital media could therefore be used more intensively by VICH, for example by organising a “virtual” SC as well as VOF meeting halfway between annual plenary meetings.

The SC agreed that the Q/A session scheduled for February 2021 will be the only virtual meeting of the VOF to take place before November 2021, where the outcome of this session will be reviewed by the VOF and the SC, and a plan can be laid out for the period 2021 - 22.
Meanwhile AnimalhealthEurope will provide a Discussion Document on the future possibilities of training for the VOF.

Act: AnimalhealthEurope

Agenda part I item 2 & 3: training sessions

The SC took note of the proposal from CAMEVET to discuss more in depth the topic of Withdrawal Periods and extrapolation to minor species. The EU pointed out that the EU experts would not be able to provide much more information than what has been explained in the WP document that was circulated, and therefore suggested to extend the topic of Environmental Risk Assessment using both planned afternoon sessions, as more time would be very useful to cover this topic. The SC agreed.

Agenda Part II item 5: group discussion - stability of vaccines
JMAFF had pointed out at the VOF meeting that GL17 focuses on stability testing of biotech-products such as cytokines, monoclonal antibodies, growth factors and vaccines components which consist of well-characterized proteins and peptides, and asked if VOF members were interested in these novel therapeutic products; no clear reply was received from VOF members.
The OIE recalled that Morocco had asked to discuss in-use stability in the use of animal medicines and stability in drinking water, but the SC did not consider this as an alternative.
Some members suggested to separate the detailed training session from plenary meetings by providing training essentially online, through presentations with voice-over, and focus more the VOF face-to-face meetings on Q/A sessions and discussions. The OIE believed however that VOF members tend to request the training sessions in face-to-face meetings as well.
JMAFF suggested to combine next year's face-to-face meeting with an electronic meeting, but it was pointed out that the VOF members are spread over many time zones and would have difficulties following a whole day's meeting online.
The SC agreed to reflect further during the year 2021 and make decisions at the 40th SC meeting, after the 14th VOF.

Act: All

Topics for future meetings
Pharmacovigilance was again requested as a topic of interest
AHI had proposed to address the global regulatory approach on GMP and distribution topics although VICH does not have a GL addressing this topic.
AHI had briefly presented a comparison document (Global Regulatory Frameworks comparison spread sheet) which has the aim to provide to regulators familiar with the legislation in 1 region, a framework to understand where to find the same regulatory framework in other regions, in particular when products are imported. It is an information document covering only the biological products.
This document is available on the AHI website, and will be shared with the VOF. A link to the document will be included in the VOF minutes and AnimalhealthEurope will place a link on the vetmed.world website.

Act: Secretariat

Conclusion
The OIE will provide a revised version of the agenda, and call for further volunteers to address the different topics.

Act: OIE

13. Organisation of the VICH activities between yearly meetings

The Secretariat noted that after the first year of functioning, the overall efficiency of VICH has been maintained, although the COVID-19 crisis has generated many disturbances.
He pointed out that the timelines which have been recommended for the distribution of documents in preparation of the meetings remain sometimes difficult to meet, for many practical reasons. These timelines had been defined as a guidance.
Nevertheless, the most important documents have been distributed on time, and overall, the timelines which had been set at the last SC meeting have been met.

The Secretariat explained that the coordinators' 2 virtual meetings had been key in the progress of the issues, in particular in the testing of the feasibility of VICH "virtual" meetings and the common organisation of the November 2020 meetings under these very special circumstances. He therefore strongly recommended to maintain the principle of 2 coordinators' teleconferences between the SC meetings.
The SC supported this proposal.

14. Concept papers/Discussion Documents

14.1 Concept Paper for the adoption of ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients

The SC reviewed the draft 2 of the Concept Paper (CP) presented by the FDA and noted that benefit of this guideline would be to harmonise expectations during GMP inspections of facilities that manufacture APIs.
FDA pointed out that the simple adoption of ICH Q7 would be insufficient, as several aspects differ in the veterinary field, and therefore proposed to create a subgroup within the Quality EWG with the aim to develop a veterinary specific GL based on ICH Q7 including a discussion of the scope which would allow harmonization. AnimalhealthEurope supported the CP in principle, provided that ectoparasiticides and clinical trial material were excluded from the scope. JVPA also agreed that clinical trial materials should be excluded.

Some members suggested to look at the PIC/s GLs on GMP for APIs.
The SC therefore agreed that the EWG subgroup should identify the areas that can be addressed by this GL.
The SC adopted the CP and agreed to create a subgroup in the Quality EWG; FDA will be the topic leader.
The Secretariat will circulate a call for experts for this subgroup.

Act: Secretariat

14.2 Proposal for a Concept Paper to adopt ICH Q8, Q9 & Q10

The SC reviewed the CP presented by FDA suggesting that these 3 GLs should be addressed as a single package by the Quality EWG.
AnimalhealthEurope supported developing specific GLs for the veterinary field as currently the regulators in the different regions are applying the ICH GLs to vet products, although there are major differences such as the size of the batches or the frequency of production.
The EU supported the CP but questioned whether they would be applicable for biologicals or only for pharmaceuticals.
JMAFF mentioned that Q8 relates to the CTD which is not addressed by VICH. Moreover, JMAFF and JVPA considered that Q9 & Q10 are supplementing ICH Q7, of which the scope for VICH has not been determined yet, and therefore suggested to delay the adoption of this CP until Q7 has reached Step 3 of the VICH process.
It was agreed that all members should send further comments on the CP to FDA by end January 2021; FDA will then provide a revised draft of the CP by end February 2021.

Act: All/FDA

14.3 Update on Industry future topics

The SC took note of the updated document that was circulated. AnimalhealthEurope acknowledged that the GMP quality topics have now been addressed by FDA.
Industry would consider additional topics, but needs to take also into consideration the current workload of the different EWGs. The prioritisation of further topics will be discussed internally

and formal CPs will be provided to the SC if industry wishes that a new topic is addressed in VICH.

15. Membership applications

15.1 the UK

The Secretariat confirmed that the UK regulators (VMD) and industry (NOAH) had been invited and were participating as “silent guests” in this meeting.
As soon as the Brexit transitional period has ended on 1st January 2021, the SC will welcome the UK as new Observer Member in VICH.
The UK indicated its wish to nominate experts to several EWG meetings early next year.

15.1 Brazil

The Secretariat reported that a first informal contact had been made very recently by the regulatory authorities (MAPA) in Brazil on the requirements to become a VICH Observer member. Questions have been clarified and discussions will be ongoing in Brazil.

16. Any other business

16.1 Procedure for GL sign-off - proposal to drop hard copies of signature sheets submitted by post

The Secretariat explained that the requirement to collect paper copies of all signatures for draft and final GLs from the experts and the SC members dated from the first steps of the VICH process.
As, in the light of the current technology, it is commonly accepted that signed documents in PDF format provided by e-mail have the same legal validity as the signatures delivered on hard copies sent by ordinary mail, he recommended that the SC should waive the requirement for hard copies and authorise the Secretariat to collect the necessary signatures in electronic format only.
The SC agreed.

17. Dates and venue of next meetings

- The 40th SC meeting will take place from Monday 15 to Thursday 18 November 2021 in the offices of the EMA in Amsterdam
- The 41st SC meeting will take place in November 2022 in the USA

VICH STEERING COMMITTEE

39th meeting

16 to 19 November 2020
Virtual Meeting

Chair: I. Claassen, EMA

LIST OF PARTICIPANTS

STEERING COMMITTEE MEMBERS & (C) coordinators

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