VICH/21/084
15 February 2022
Final

VICH STEERING COMMITTEE
40th virtual meeting
15 – 18 November 2021

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Ivo Claassen, Head of the Veterinary Medicines Division at the European Medicines Agency. He welcomed the participants to the 40th meeting of the VICH Steering Committee, which is held "virtually" for the second time. He regretted to be unable once more to welcome the participants to the EMA's facilities in Amsterdam.
Dr Claassen was nevertheless pleased to see all SC members back on screen again. He thanked all participants for their attendance, some very early, others very late in their day.

The Secretary indicated that apologies had been received from J. Preuss – EU.

2. Adoption of the agenda

JMAFF asked to take the discussion of item 8, Update of the VICH structures, under item 5 of the agenda.
The Secretariat mentioned that item 16.3, EuFMD/FAO project for pre-qualification system for veterinary medicines, had been added recently to the agenda. The SC decided to move this topic to agenda item 4.2.
The agenda was adopted with these changes.

3. VICH Training Implementation

AnimalhealthEurope indicated that the VICH training Discussion Document, that was revisited in mid-2021, shows that training presentations are now available for 43% of the VICH guidelines. AnimalhealthEurope called for volunteers to prepare training for the outstanding GLs.
The SC reviewed the ongoing activities and noted that the topics out of the scope of VICH can be addressed by VICH experts by a "white paper" without VICH branding.
At the last SC meeting it had been proposed 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, but this had been rejected by the SC because of the possible additional impact on the resources of the VICH organisations. AnimalhealthEurope believed nevertheless that it is necessary to make the VICH GLs more easily understandable by third parties. The experts remain the best persons to develop at least a first draft of training material, including case studies if appropriate. AnimalhealthEurope will therefore propose amendments to the EWGs and procedure for EWG guidance documents in order to find a wording acceptable by all that will encourage the involvement of the EWG in the development of training material.

Meanwhile, AnimalhealthEurope strongly supported the organisation of another webinar for the VOF members.
The OIE encouraged the development by the experts of training material for new GLs and pointed out that the VOF members regularly ask for translations of the GLs, which is difficult to provide because of the costs.

The OIE suggested to share this Discussion Document with the VOF before the next face to face meeting in order to receive feedback on these issues from the VOF members themselves.
The SC recognised that it would be useful to ask VOF members if case studies would be helpful, and which would be their priorities.

The EU supported the idea of seeking input from the VOF in relation to its needs. In relation to the suggestion that it may be possible to write GLs in a way that makes them more accessible, the EU indicated that current VICH GLs are not difficult to understand for the technical audience at which they are aimed, including persons outside of VICH.
FDA suggested that explanations and case studies would be better placed in training rather than in GLs.
JMAFF believed however that case studies are difficult to develop and may lead to misunderstandings, therefore, the developer should be aware of this when developing such training material.
The VMD indicated that it is in the process of developing online training for a range of regulatory topics and would be keen to liaise with the VICH SC and EWGs to see if these can be adapted (or in future developed) to also be utilised by VICH and VOF members.
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The OIE supported strongly the training on VICH GLs but pointed out that the training sessions for the OIE Focal Points of Veterinary Products may not be the proper audience for the training on VICH GLs.

It was agreed that AnimalhealthEurope will provide suggestions for amendments to the SOPs for the experts and EWGs for review by the SC.

Act: AnimalhealthEurope

4. Review of Discussion Documents for presentation to the VOF

4.1. Autogenous vaccines

AnimalhealthEurope recalled that the VOF members had asked how Autogenous Vaccines are regulated in the VICH countries/regions.
Although the topic is out of the scope of VICH, AnimalhealthEurope had volunteered to circulate a questionnaire to the VICH members and to collate the replies. A simple presentation will be made to the VOF and the material (a PowerPoint presentation and a Word document) placed on the VOF members only website.

4.2. EuFMD/FAO project for a pre-qualification system for veterinary medicines

The Secretariat explained that Kornelia Grein, project leader at the FAO, had contacted VICH to introduce a project that the FAO European Commission for the control of Foot-and-Mouth Disease has recently launched for the development of a feasibility study for a pre-qualification system for veterinary medicines, similar to the WHO established pre-qualification system.
The FAO is asking the VICH SC to inform the VOF members about the project and assist FAO in identifying contact points in countries or regions, that could support the EuFMD in developing prioritization criteria and identify one or two representative(s) of member countries/regions to join a Technical Stakeholder Advisory Group.

The OIE indicated that they had not been involved nor informed of this project, and would like to have more information concerning the objective of such initiative.
The SC agreed to present this request to the VOF and authorise the FAO to use the VOF group mailing list to contact further the VOF members.

5. VICH Outreach Forum

5.1. Review of the participants list

The SC reviewed the participants list for the 14th VOF meeting and noted that some delegations will provide several participants. It was pointed out that Brazil, China and India will participate in this meeting but not Russia.

5.2 Review of the agenda and preparation of the 14th 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 draft agenda for the 15th meeting. Suggestions had already been received from India.

5.3 Other issues

The SC reviewed the presentation from the SC to the VOF prepared by the Secretariat and approved in particular slide 15 on the Update of the VICH structures.

The SC discussed agenda item 8 on the update of the VICH structures – see below.

6. Reviews of:

6.1 Implementation and interpretation of VICH GLs in the regions

The EU mentioned that in the past it had reported delays in the development of the pharmacovigilance database in Europe. The EU was now pleased to confirm that the database will be active in early 2022 which will enable the EU to fully the PhV GLs 35 and 42.

6.2 Status of consultation for draft GLs at Step 4

None

6.3 VICH GLs implementation tracker

The Secretariat indicated that a revised version of the document including the status of GLs 58 & 59 had been circulated prior to the meeting. The update from USA and NZ were still missing. FDA and NZ agreed to provide the information shortly.

Act: FDA/NZ

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 indicated that since the last SC meeting 24 GLs have reached the 5 years' deadline for review. The SC considered each GL highlighted in the revised table. AHI

recognised the current workload and encouraged the SC to prioritise completion of current work prior to embarking on additional efforts.

- *Quality GLs 1 & 2*

The EU indicated that ICH is revising the corresponding GLs, so a revision will be necessary at a later stage.

- *Stability GLs 4 & 5*

No need for revision

- *Ecotox GLs 6 & 38*

No need for revision at this time. The EU did highlight that there is now an OECD guidance document relevant to testing in dung fauna and an update to the VICH GLs could be made to reflect this. The EU further informed the SC that it is developing guidance for testing of aquaculture products and that discussions are also ongoing in relation to environmental impact of companion animal products. The EU indicated that, depending on the outcome of these activities, it may come back to the SC with a CP proposing revision of these VICH GLs.

- *GCP GL 9*

AnimalhealthEurope recommended a revision as this GL has been finalised a long time ago and is very much used by stakeholders.
It was noted that the efficacy experts are currently focussing on the anthelmintics GLs, but the step 2 documents should be ready in the near future. AnimalhealthEurope therefore agreed to prepare a Concept Paper before the next SC meeting.

Act: AHE

- *Stability GL 17*

No need for revision

- *Pharmacovigilance GLs 24, 29, 35 & 42*

These GLs are under review by the EWG.

- *Biologicals GLs 25, 26 & 50*

No need for revision

- *AMR GL 27*

The EU mentioned that some clarifications could be made to the GL and noted that there is additional supporting (non-VICH) guidance in some countries/regions and that consideration could be given to expanding the VICH GL to incorporate some of the information available in these supporting guidance documents.
The EU indicated that it would reflect on the issue further and prepare a Concept Paper if it concludes that a revision of the VICH GL would be appropriate.

Act: EU

- *Safety GLs 31 & 32*

May need a revision as OECD GLs, particularly relating to effects on endocrine parameters, have been updated. To reconsider at a later stage, as the Safety EWG is working on 2 other GLs.

- *Biologicals GL 34*

No need for revision

- *TAS GLs 41, 43 & 44*

No need for revision

- *Bioequivalence GL 52*

No need for revision

- *Electronic File Format GL 53*

No need for revision

The Secretariat will provide an updated version of the GLs status table.

Act: Secretariat

7.1.2. 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. Update of the VICH structures – review of the DD from the VICH SC Task Force

Discussed under agenda item 5.3.

The SC reviewed the draft 4 of the Discussion Document (DD) prepared by the VICH SC Task Force (TF).
JMAFF reported that the TF has reached agreement in many of the points but there remain a few **points to be discussed and decided by the SC.**
JMAFF, which took the lead in developing the discussion document (draft 4), presented an overview of the TF discussions. In the current structure the SC undertakes a management function while the VOF has more of an observer/learning function. It was considered important to maintain a management body that is small enough to function efficiently, while also recognising and encouraging the growing contribution made by VOF members to the activities of VICH. An alternative naming system for categories of members of the SC and VOF was put forward in the discussion document, along with a suggestion to rename the VOF as an Observer Forum. Consideration was also given to the possible attendance at SC meeting of VOF members.

SC members were supportive of a number of the proposals made in the discussion document but there was no consensus to move forward with specific changes at this time, recognising that further discussion is needed, as is input from the VOF.

The chairman highlighted that it will be critical to maintain the central objective of VICH as the harmonisation of technical GLs for the registration of VMPs.

Discussed under agenda item 15.1.

As complete consensus could not be found in the previous discussion, it was agreed to maintain the VICH structure as it is for the time being, to progress the discussions in the TF, and to agree on the first step of the restructuring in next year's face to face meeting.

The SC recognised that a SWOT analysis should be the basis for further in-depth discussions within the SC. For the VOF, at this point in time a questionnaire with a limited number of questions to collect their opinion will be developed.

The SC decided that the VICH SC Task Force should continue its work by running a SWOT analysis with the VICH members. The SWOT analysis will be initiated internally and the TF will consolidate the replies that will be received.

Act: SC TF

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.

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

JMAFF confirmed that the draft revised GL has just been signed off at step 2 by the experts and will be presented to the SC for sign-off at step 3.

b. New guideline for Good Manufacturing Practice for Active Pharmaceutical Ingredients

Following the adoption of Concept Paper for the adoption of ICH Q7 - Good Manufacturing Practice for Active Pharmaceutical Ingredients - a new subgroup of the EWG was created with FDA as the topic leader. The work is progressing according to the schedule and the subgroup is currently reviewing the second draft of the proposed GL. The subgroup will take note of the similar work being conducted by the PIC/S veterinary subgroup.

9.2. Biologicals

The chair of the Expert Working Group, Dr K. Sato, reported that 3 different subgroups are or have been active:

a. BST sub group - Harmonisation of criteria to waive Laboratory Animals Batch Safety testing

VICH GL59 (Biologicals: LABST veterinary vaccines) has been finalised at Step 7 in November 2020 and is now in the process of implementation in Japan and USA.
AnimalhealthEurope recommended that the SC should consider allowing flexibility with different scientific approaches by the applicants, as this is a new scientific area.

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

The EV subgroup held a first meeting in June to discuss the expectations of the subgroup and the guidance. The task that was set for the subgroup is to start collecting the regional test information for swine vaccines that is being used currently. A timeline of 6 months was agreed to gather the requested information. A second meeting was held in August to ensure the progress and address any concerns, and another meeting took place recently. Dr Sato confirmed the work progresses according to the schedule and the collection will be finished by the end of this year.

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

Dr Sato reported that the first draft GL was prepared by the Topic Leader and distributed to the subgroup members for review in April 2021.

The subgroup had a virtual meeting in October, as USDA proposed to reduce the scope further. Dr Sato, EWG Chair, recommended to keep the original scope, and recalled that the scope that had initially been proposed included all biologicals, but was then narrowed down to monoclonal

antibodies only. Although a majority of the experts supported the original scope as stated in the Concept paper, but an agreement could not be reached, and a further discussion was proposed

At the present SC meeting, USDA recommended to reduce the scope further because it may be difficult to address all monoclonal antibodies in a single GL.
AHI agreed that a further reduction of the scope would enable this topic to be progressed more efficiently.
There was some discussion relating to the possibility for applicants to submit data that do not comply with VICH GLs. In relation to this the EU indicated that in Europe the existence of a guidance does not prevent an applicant from proposing alternative approaches if these are properly justified.
AnimalhealthEurope supported the initial narrowed scope but agreed that the EWG should discuss further and review the different proposals.
JMAFF pointed out that the aim of this new GL is to supplement the existing TAS GLs 43 & 44 by addressing topics that were not included in these GLs. USDA agreed that they need additional information on the ways to fully implement these two existing GLs in the US.
JMAFF further advised that it is totally a decision of RA how it would utilize the finalised VICH GL in the country.

The SC recognised that a consensus could not be reached and asked the EWG to continue the discussions and use wording in the future GL that will allow a flexible approach to the new requirements (alternative approaches can be justified).

9.3. Pharmacovigilance

The chair of the Expert Working Group, Dr Linda Walter-Grimm, reported that the EWG has held 4 teleconferences since December 2020 and addressed in particular the following issues:

- Develop a discussion paper describing veterinary pharmacovigilance signal detection and signal management practices currently utilized in several regions. A subgroup of advisors was formed to assist with drafting the initial document, and this group met separately during the latter half of 2021.
- Proceed with routine maintenance of the VICH GL30 vocabulary lists (focusing primarily on species/breed lists)
- Discuss and propose the minor revisions to VICH GL24 and GL29 as outlined in the Concept Paper submitted to Steering in October 2019.
- Review proposals for minor revisions/corrections to existing VICH GL 42 and VICH GL 35.

The SC thanked Dr Walter-Grimm and the experts for addressing this wide scope of topics and their ongoing commitment.
Several SC members pointed out that the number of topics may have become too large and difficult to manage by the EWG, and suggested to set limited goals for the next months.
The SC noted that the science related to Pharmacovigilance is progressing fast and therefore mandated the EWG to first finish the revisions to the existing GLs, in particular the revisions of GLs 24 & 29 which have been under discussion since many years. The EWG should also finalise the revisions of GLs 35 & 42, and afterwards address the signal detection and signal management topic.

9.4. Safety EWG

The chair of the Expert Working Group, Dr C. Long, reported that the experts, who had intended to meet in a physical meeting just before the COVID crisis, were able to hold recently 2 virtual

sessions to progress the discussions on the 2 revisions of GLs under consideration by the EWG.

a. GL22, Extended One Generation Reproduction Study (EOGRTS):

The experts confirmed their support to revise the GL to include the EOGRTS as an option. As the EOGRTS has been published as part of the OECD 443 for some time now, it was proposed that a new literature search be performed to see how it has been implemented in practice. The aim is to address the veterinary medicines safety, but also to limit, if possible, to a one generation safety testing in order to reduce the number of animals used.
The UK commented that there had been reports of epigenetic changes that only become evident after the second generation and asked if this is something the EWG had discussed.
The EU pointed out that the Concept Paper for the current review was focussed on the 3R argumentation; recommending to use another generation testing would not comply with the initial objective.
AHI mentioned that the discussion has been ongoing for several years so that many new experts have joined the EWG over time. Nevertheless, all experts agreed to consult the literature again. Some experts have suggested including developmental neurotoxicity and immunogenicity cohorts as a default , but that would not meet the intention to reduce the number of animals used.
The SC agreed that the EWG should continue its task by consulting the literature and continuing the discussion.

b. GL23, Tiered Approach Genotoxicity:

The experts agreed that at a minimum, GL23 needs to be revised to reference recent OECD genotoxicity guidance. As before, several experts, who are in full support of the tiered approach, did not feel that any *in vivo* testing is necessary if both *in vitro* tests are negative, while others believe that even in those situations, at least one *in vivo* test should be performed as a confirmation of the negative *in vitro* tests.
While it appears that not all experts are ready to revise GL23 to incorporate the tiered approach as previously discussed, experts who support the tiered approach did confirm that if the GL was revised to incorporate two *in vitro* tests plus a minimum of one in vivo test (which could be performed as part of a repeat dose tox study), they would support it.

The SC acknowledged that several issues still need to be resolved, but noted that the EWG had made considerable progress during the virtual meetings. The SC therefore encouraged the experts to continue the discussion by electronic procedure and agreed that a virtual meeting of the EWG should take place again before the summer 2022.
The SC thanked Dr Long for her efforts and her commitment to drive these difficult topics forward.

9.5. Anthelmintics EWG

The chair of the Expert Working Group, Dr A. Phillippi-Taylor, reported that a virtual meeting took place in last August which enabled the experts to progress significantly the different topics under discussion. After the meeting, Dr Phillippi-Taylor has circulated the documents including the proposed revisions and has received feedback from all experts. The editorial proposals for change are now being finetuned for a final incorporation into the revised GLs.

Regarding the question of addressing new topics that were not in the original mandate of the EWG, the SC confirmed that these would need to be considered in a second step with a new Concept Paper, once the revised GLs have been finalised.

The Secretariat will contact Dr Phillippi-Taylor to explain the procedure for submitting the draft revised GLs to the SC.

Act: Secretariat

The SC applauded the fact that, after several years of work, the EWG is now close to agreeing the proposals in draft 2 documents and thanked Dr Phillippi-Taylor and the experts for their constructive discussions.

9.6. Pharmaceutical Combination Product GLs EWG

The co-chair of the Expert Working Group, Dr D. Laucks, reported that unfortunately not much progress was made since the last SC meeting. Many experts have changed and the overall approach to the topic may have changed as well.
Dr Laucks therefore proposed to hold a virtual meeting of the EWG early next year to define a workplan for 2022 with a clear scope of the objectives, for approval by the SC.
The SC agreed.

The Secretariat indicated that the co-chair of the EWG, Dr S. Xu, had recently addressed a letter to the SC explaining his wish to resign from the co-chair position of the EWG, because of the lack of resources.
The SC accepted the resignation and asked the Secretariat to send a letter of thanks to Dr Xu on behalf of VICH and the SC.

Act: Secretariat

The SC nominated Dr Laucks as chairman of the Combination Product GLs EWG.

9.7. Bioequivalence EWG

The chair of the Expert Working Group, Dr M. Martinez, reported that the work had progressed well. The critical questions document has been completed and a first draft in vitro dissolution GL is under discussion. A virtual meeting of the EWG, held at the end of September, enabled the experts to progress the discussions.
The experts agreed that the topics of Biowaivers and Dissolution tests should be separated.
The critical areas for the dissolution GL have been identified and it was agreed that subgroups of experts would review the different sections of the document to address topics such as what is dissolution, which data should be required etc...
Dr Martinez pointed out that this will represent an international effort and the EWG will establish a timing for the different activities.

AHI suggested nominating additional advisers, if necessary, in order to ensure that the adequate expertise, particularly in the area of CMC, is available in the EWG. Dr Martinez fully agreed that the proper expertise is essential for the success of the work.
AnimalhealthEurope supported the way forward.
JMAFF believed that the GL may become broad, because of the different dosage forms and therefore suggested to start with a limited focus on immediate release oral tablets, which would be the easiest to address.
Dr Martinez agreed that it made sense to start with this limited scope and to possibly consider other types of products in the future. Afterwards, the work on biowaivers will be resumed.
The SC agreed.

The SC thanked Dr Martinez and the experts for the ongoing progress of the discussions.

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 annex 3 of GL 49, to address some technical questions highlighted by external stakeholders (mainly clarification around the acceptance criteria and some issues around example calculations using the method in annex 3).
Dr S. Scheid believed that a revision of the core GL is not necessary for the time being.
The SC encouraged the EWG to finalise the revision at step 2 of annex 3 as soon as possible.

9.9. Medicated premixes

The chair of the Expert Working Group, Dr E. De Ridder, explained that the EWG's mandate covered 2 topics. The first topic is the revision of the VICH GL 8 on Stability testing for medicated premixes to include specific requirements that are not addressed in the current GL. All experts have now delivered their comments on a first draft revision of the GL and the EWG aims to provide a step 2 document by end May 2022.

A second separate task will be the development of 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 experts have all expressed their preference on which topics they want to work.
The EWG will reflect in 2022 on what should be covered for each topic and if the topic should be dealt with as a second revision of GL8 or as an additional guideline.
A concept paper defining the further work to complete GL 8 should be ready for review by the 41st Steering Committee meeting.
The SC thanked Dr De Ridder and the experts for the swift progress achieved.

In conclusion, the chairman thanked all EWGs for their work and congratulated the experts for keeping the momentum of the work of VICH in the difficult COVID-19 environments.

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 up to date.

Act: All

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

10.1 Draft VICH GL 18(R2) – (Quality) - Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision 2)

The SC took note that the signatures of the EWG at step 2 had been received just before the SC meeting.
AHI indicated that 2 additional weeks will be necessary for a final review and approval by the industry experts.
The SC therefore agreed that once the Secretariat has received all SC signatures at step 3, this guideline will be transmitted to the VICH and VOF members for a 6-month public consultation at Step 4.

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

None

12. Review of the Outcome of the 14th VOF meeting

The SC noted more than 70 participants, including the SC members, had attended the meeting. The SC acknowledged that virtual meetings are not really suitable to generate discussions during VOF meetings. The VOF members provided only very few comments and questions. Nor was any feedback received on the proposed webinar and training.

Regarding the topic of autogenous vaccines, AnimalhealthEurope explained that the initial aim was to give VOF members the opportunity to present their own approaches to autogenous vaccines but only Thailand and Singapore seem to develop autogenous vaccines regulation. No feedback was received from the other delegates.
Thailand and Singapore have proposed to present their policy on autogenous vaccines among ASEAN countries at a future VOF meeting.
AnimalhealthEurope suggested to organise during 2022 a webinar dedicated to this topic, but the SC felt that a webinar would pose difficulties because of different time zones and languages.
The EU reminded the SC that the topic of autogenous vaccines is not a VICH topic as there are no relevant GLs, and consequently VICH should only offer to the VOF members the opportunity to discuss the topic but should take care to avoid giving the impression that VICH can offer training on this topic.

15th VOF agenda
The Secretariat and the OIE will consult with Thailand if they wish to include the autogenous vaccines topic in their presentation planned under agenda item 10.1 of the 15th VOF meeting.

The SC considered 2 of the topics requested by India:
1. Discussion on standardizing formats and status of the progression of Harmonizing veterinary drugs
2. Digitalization of the data and internationally approved protocols for harmonization
It was suggested to have a discussion on electronic submission of dossiers under agenda item 9.
FDA indicated that they would also propose an additional topic for the agenda in the new year.

The SC agreed that OIE and the Secretariat will provide a revised draft of the VOF 15 agenda in the course of February 2022.

Act: OIE/Secretariat

13. Concept papers/Discussion Documents

13.1 Proposal from FDA for a Concept Paper to adopt ICH Q8, Q9 & Q10

FDA explained that following the comments received and the concerns expressed, a consensus has been reached to limit the scope of the revised CP to ICH Q8 – Pharmaceutical development; ICH Q9 & Q10 are postponed to a later stage.

JVPA asked whether ICH Q8 addresses the quality of product development of pharmaceuticals as well as biologicals and other products. JVPA suggested to limit in a first step the focus of the new VICH GL to pharmaceuticals only.
The SC agreed and mandated the Quality EWG to initiate the work on pharmaceuticals only. In case extensions to other product categories would be recommended, a new CP would have to be developed.

The SC decided that FDA will be the topic leader and that a new subgroup of experts will be created within the Quality EWG.
The Secretariat will circulate a call for nominations. It was noted that SC members may nominate their current VICH quality expert or new experts.

Act: Secretariat

13.2 Discussion Document from HealthforAnimals for a Global Regulatory Dossier Framework for Veterinary Medicinal Products

AnimalhealthEurope explained that the aim of the DD is to initiate explorative talks for a high-level approach to a common global regulatory dossier. VOF members in all regions are indeed increasingly demanding a common global approach to a dossier structure.
The DD suggests a discussion on a modular format of the dossier content that could be applicable in all VICH and VOF countries/regions. The aim is not to detail the contents of the modules themselves, with the risk to increase the regulatory requirements, but rather to harmonise the setup of the modules ("skeleton format") so that in different countries/regions the stakeholders can easily find a specific component of the dossier. Nor is the aim to develop a Common Technical Document or to harmonise the different regulatory systems.
AnimalhealthEurope pointed out that this Veterinary Dossier Framework would enable a better global harmonisation of the dossiers, facilitate a global follow up of dossiers for companies and foster the global availability of products.
The proposal does not suggest modifying any existing electronic submission platform.

The SC thanked AnimalhealthEurope for initiating this reflection and acknowledged that the aim of the DD is not to initiate work on a new VICH GL, but to start explorative discussions on this topic.
The SC members supported to continue the discussion on this topic but requested more time to analyse the DD and reflect further internally. Several SC members pointed out that such guidance might require the change of the legislation in some countries.
It was noted that in a next step, a Task Force might be needed to progress the topic further. Meanwhile, the SC was asked to provide additional feedback to AnimalhealthEurope.

Act: All

AnimalhealthEurope will include the comments received in a revised document to be provided in time for the 41st SC meeting, where this topic will be placed on the agenda again for further discussion.

Act: AnimalhealthEurope

14. Outline of the VICH 7 Conference

The Secretariat explained that in the cycle of the VICH public Conferences, it would be the turn of Europe to host the next VICH public event. The next time the SC/VOF meetings will take place in Europe would be for the 43rd SC and 17th VOF meetings in 2024.
The SC decided in principle that the VICH 7 Conference will take place in 2024. In order to ensure a timely organisation, further reflection and decisions will have to be made at the 41st SC meeting next year.
It was suggested that the VICH 7 Conference may be the opportunity to attract more non VICH countries' participants and could therefore be held outside of the VICH regions, in a VOF country, as it had been the case for the VICH 6 in an Observer country.
AnimalhealthEurope and the EU will provide a proposal before the next meeting.

Act: AnimalhealthEurope/EU

15. Restructuring of VICH

15.1 Agreement on the next steps

See agenda item 8.

15.2 Reply to Switzerland (CH)

The SC reviewed the draft proposal circulated by the Secretariat and commented prior to the meeting. A number of further modifications were discussed before agreement was reached.
It was finally agreed to invite CH to the 41st SC meeting in person provided CH would be excluded from sensitive agenda, e.g., restructuring related items. .
The letter was amended accordingly.
Post-meeting note: the letter was further fine-tuned after the meeting and adopted by written procedure.
The Secretariat will send the letter to the Swiss representatives composed of Swissmedic, the IVI and Scienceindustries.

Act: Secretariat *(Done)*

16. Any other business

16.1 Change of VICH leadership region

The Secretariat pointed out that the EU had assumed the leadership of VICH for 2 successive years, a first in the VICH history, and therefore suggested to pass the leadership to the USA at the end of this meeting.
FDA and the SC agreed.

16.2 Brooklands New Media publication on VICH

The Secretariat summarised the content of the information received from Brooklands New Media.
The SC noted that this is a private commercial initiative which VICH cannot endorse nor support.
The Secretariat will nevertheless review the documents received to ensure accuracy and will alert the SC in case of a major issue.

16.3 Farewell Dr Izumi ABE

The Secretariat indicated that Dr Abe will step down from the JVPA delegation after 5 years of participation in the VICH SC.
On behalf of all the members of the SC, the Secretariat warmly thanked Dr Abe for his ongoing commitment and his constructive participation in the progress of VICH, and wished him all the best for his future activities. Dr Abe not being in attendance for the last part of this SC meeting, JVPA will forward him the farewell wishes from the SC.

17. Next meetings

17.1 6th VICH coordinators meeting

The Secretariat confirmed that the next coordinators meeting is scheduled to take place on Tuesday 25 January 2022.

17.2 Planning SC Teleconference meeting

The Secretariat suggested to plan a SC virtual session in early 2022. In order to accommodate the Japanese delegation, the SC decided that this virtual meeting should take place in June 2022.
The coordinators will propose a meeting date.

Act: Coordinators

17.3 Dates and venue of next meetings

- The 41st SC meeting will take place from Monday 14 to Thursday 17 November 2022 in the USA in the Washington DC area.

The SC agreed that in case there should still be a concern about the situation next year, a definite decision on holding a face to face or converting the SC meeting into a virtual meeting again will have to be made before 1st August 2022.

- The 42nd SC meeting will take place in November 2023 in Japan

VICH STEERING COMMITTEE

40th meeting

15 to 19 November 2021
Virtual meeting

Chair: I. **CLAASSEN**, EMA

LIST OF PARTICIPANTS

VICH Steering Committee Members and (C) Coordinators

AHI (ZOETIS)	C. LOWNEY
AHI (BI)	E. NORTON
AHI	R. CUMBERBATCH (C)
EU (HEALTH PRODUCTS REGULATORY AUTH)	D. MURPHY
EU (EMA)	N. JARRETT (C)
EU (EMA)	I. CLAASSEN - *Chairperson*
ANIMALHEALTHEUROPE (BI)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)
JMAFF	K. EGUCHI
JMAFF	K. NODA
JMAFF	J. OHMORI (C)
JVPA (NIPPON ZENYAKU KOGYO CO.)	I. ABE (*not on day 3*)
JVPA (Nisseiken Co.)	K. TUCHIYA
JVPA	K. OISHI (C)
US (FDA)	M. LUCIA
US (USDA APHIS)	M. PAGALA (for B.E. RIPPKE)
US (FDA/CVM)	B. ROBINSON (C)

OBSERVERS

Australia (APVMA)	D. SIBANDA
Australia (AMA)	C. BENNETT
Canada (Health Canada)	M-J. IRELAND
Canada (Health Canada)	M. BASSI
Canada (CAHI)	C. FILEJSKI
New Zealand (MPI)	A. KINSELLA
New Zealand (AGCARM)	J. HOWE
South Africa (SAAHA)	M. CHURCHILL
South Africa (SAHPRA)	A. SIGOBODHLA
NOAH	D. MURPHY
VMD	S. ECKFORD

INTERESTED PARTY

AVBC	G. DOWELL

OIE

OIE	J-P. ORAND (*not on day 3*)
OIE	M. SZABO

VICH

HealthforAnimals	H. MARION (*Secretary*)

GUESTS
For the EWGs reports on Day 2:

BVL	S. SCHEID
IVDC	S. XU
JMAFF	K. SATO
US (FDA)	D. LAUCKS
US (FDA)	Ch.M. LONG
US (FDA)	M. MARTINEZ
US (FDA)	L. WALTER-GRIMM

APOLOGIES

EU (EUROPEAN COMMISSION)	J-N. PREUSS
HealthforAnimals	C. DU MARCHIE SARVAAS