VICH/17073
16 January 2018
Final

VICH STEERING COMMITTEE
35th meeting
13, 14 and 16 November 2017
Tokyo, Japan

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr. Kenji Ohara, Director General of the National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries, Japan. He welcomed the participants to Japan full of colourful autumn shades at this time of the year.

The Secretariat indicated that apologies had been received from G. Gowda – AHI. M.-J. Ireland – Canada, A. Sigobodhla – South Africa and C. Du Marchie Sarvaas - HealthforAnimals.

2. Adoption of the agenda

The agenda was adopted with the 1 change: agenda items 7.1.1 and 7.1.3 will be discussed together.

3. VICH Training Implementation

3.1. Pilot training module on bioequivalence GL 52: proposal from industry

The participants briefly reviewed the proposal from AnimalhealthEurope which was circulated with the meeting documents and noted that more time was needed to provide input.
It was therefore agreed that the Secretariat will circulate the document again with a call for comments/proposals to be sent to AnimalhealthEurope by 1st February 2018.

Act: Secretariat/All

3.2 Proposal for further material to be placed on the VICH website

AnimalhealthEurope recalled that the suggested approach is to request the EWGs to develop training material for each future GL, but that the existing GLs would also need to be covered as well. At the last meeting, the FDA notified the Steering Committee that it was no longer able to commit to developing training materials for the Quality GLs due to resources. In view of the expectations of the VOF members, and the need to maintain some momentum in the training strategy, AnimalhealthEurope has therefore prepared an internal action plan to develop training material for the VICH quality GLs over the next few years, and asked the other organisations to contribute to the development of training material as well.

The EU commented that, in the future, it might be able to make material available where this has been developed for EU training purposes, but that it could not make any further commitment for the time being due to resource limitations.
JMAFF explained that budgets would be requested to support the development of training material by an organisation from next fiscal year onwards.
AHI confirmed its willingness to develop material depending on which topic would be considered as a priority by the VOF.
The OIE recommended to set the priorities based on the OIE survey i.e. GLs 1, 2, 9, 17, 27, 52, 39, 40 as well as the 5 PhV GLs.
It was agreed that the Secretariat will circulate an e-mail with the list of priorities and ask the delegations to choose within 3 weeks the topics for which they are able to provide support.

Act: Secretariat/All

3.3 Report from JMAFF on VICH training session held in Brunei and request from ASEAN

JMAFF presented the report on the First VICH Training Seminar in ASEAN and indicated that the participants had posed many basic questions on VICH. The trainers had to highlight fundamental understandings such as the fact that the VICH GLs are not legally binding, that slight amendments can be made by a country etc…
The trainers discovered that the ASEAN contacts were requesting much more information on VICH; it was noted that only 1 country (Thailand) attends regularly the VOF meetings and it is difficult for Thailand to transfer all the correct VICH information to the rest of the ASEAN member countries. As requested by the attendees, JMAFF agreed on the need to organise another session during the next ASEAN meeting in Cambodia in April 2018. Although JMAFF has highlighted at the ASEAN meeting the “beneficiary payment principle” requested by VICH, no confirmation has been yet received from Cambodia.

Due to the resource restrictions within regulatory authorities, and in view of the importance of responding to training requests, Industry volunteered to provide the experts for the next training. However, it was pointed out that it had been agreed by the SC that these trainings should be in principle done by experts from the regulatory bodies, except for a general presentation on VICH which could be done by industry SC members or the Secretariat. Nevertheless the ‘view of an applicant’ to the application of a VICH guideline would be a valuable contribution to the understanding of how a guideline is applied.

The SC agreed to wait until the end of January at the very latest for the response from Cambodia on the financing, but nevertheless decided, as plan B, to recommend using the vacant afternoon to extend the OIE national Focal Points training seminar taking place in next March in Thailand, by one half day for a training session on VICH. The OIE reminded the SC that the OIE would not finance the costs for VICH experts.

Meanwhile the OIE will check the feasibility of a half day meeting for ASEAN members independent from the OIE NFP meeting. Should it be possible, and necessary, the OIE will inform the SC members and Thailand.

Act: OIE

4. VICH 6 Conference

4.1 Review of the draft programme presented by South Africa and the Secretariat

The participants reviewed and amended the draft programme, and an additional session on AMR was suggested.
The OIE and the EU will reflect on if and how to best integrate this topic in the programme.

Act: OIE/EU *(Done)*

The Secretariat will then circulate a draft 7 of the programme for final comments by next 8 December. This draft will be placed on the Conference's website.

Act: Secretariat

4.2 Logistical matters

Because of the high prices that would be charged for the conference facilities during the initial dates, the SC supported the proposal from South Africa to postpone the Conference by 3 weeks to the 25 – 28 February 2019.

5. VICH Outreach Forum

5.1 Preparation for the 9th VICH Outreach Forum meeting

5.1.1 Review of the participants list

The SC reviewed the participants list of the 9th VOF meeting and noted the countries and organisations that will be present or absent. The SC regretted in particular the absence of Russia, Ukraine, India and the UEMOA.
The Secretariat indicated that several last-minute cancellations had been received. Nevertheless, Nigeria will be able to attend, as well as a new delegation from Zimbabwe.

5.1.2 Review of the agenda and preparation of the 9th meeting

The EU confirmed that a draft letter from the VICH regulators to encourage the VOF senior regulators to attend the meetings had been provided by the secretariat. The letter will be finalised to be used for the next VOF meeting.

Act: Regulators

5.2 Discussion of the Outcome of the 9th VICH Outreach Forum meeting

A/ General discussion
The SC addressed this agenda item after the 9th VOF meeting and acknowledged that the breakout sessions and the tour de table discussions had been both very fruitful.
It was however pointed out that some discussion topics requested by the VOF participants for future meetings are not in the scope of VICH such as AMR monitoring plans management.
It was recommended that, ahead of the next meeting, the tour de table session should be prepared by sending the questions to the VOF participants a few weeks prior to the meeting.

B/ Topics for the 10th VOF agenda
The OIE summarised the topics suggested by the participants:

1/ Update on training

2/ AMR
The request for monitoring and surveillance plans is out of the scope of VICH
Ukraine will be asked again to prepare and present a Discussion Document for a new GL on AMR. Existing VICH GLs that address AMR include VICH GL27 and VICH GL36..

3/ MRLs extrapolation

JMAFF pointed out there is a misunderstanding in the VOF about the scope of VICH and the residues and MRLs issues. The request relating to extrapolation of MRLs is out of the scope of VICH, as risk management is not covered by VICH. It was agreed that a few slides explaining the scope of VICH as well as the role of Codex and OIE should be routinely added to the introductory presentation given by the Secretariat at the beginning of each VOF session.

Act: Secretariat

VOF members had also expressed interest in relation to the microbiological ADI (GL 36) and its link to AMR. However, the use of the microbiological ADI relates to the setting of MRLs and as many of the Outreach countries will use Codex MRLs rather than setting their own MRLs, it was agreed that the usefulness of a session on the microbiological ADI may be rather limited. The EU agreed to consider giving a presentation on residues and withdrawal periods more generally, and possibly to incorporate some information on use the microbiological ADI. This presentation could also touch on the limitations of VICH

Act: EU

As interest was expressed in extrapolation of MRLs the EU provided to the VOF several papers on the extrapolations in the EU.
Another angle to approach a residue/MRL training would be to look at how VICH GLs are used in relation to CODEX MRLs and from there go on to describe the VICH standards.

4/ Stability of *medicated premixes*
VICH GLs 3 & 8 cover this request, and should be explained at the next meeting. JVPA agreed to prepare the presentation.

Act: JVPA

AnimalhealthEurope believed that the information contained in GL 8 is very limited. AnimalhealthEurope will therefore draft a CP for a revision of GL 8, by 1st March 2018, to propose additions to the GL which would respond to the request of the VOF members. AnimalhealthEurope will include Zimbabwe in the process.

Act: AnimalhealthEurope

5/ Parasiticides
The Steering Committee was reminded that current VICH GLs only cover anthelmintics, and not ectoparasiticides. Furthermore, in the USA the latter are not regulated by the FDA but by EPA, and as EPA has no involvement with VICH it would not be possible to commit to apply a VICH GL on ectoparasiticides in the USA.
The SC therefore decided that this topic would not be appropriate for discussion at the VOF at the present time.

In relation to the scope of VICH/VOF activities, the OIE recalled that when the VOF was established, the aim was not only to outreach but also to consider new topics for GLs. It was therefore agreed to request at the next meeting an open discussion on what new topics VOF members would expect from VICH; this could be a breakout session on the expectations from the VOF members. The OIE made also the remark that during the VOF discussion on new topics no VICH SC member made any comment on the fact that certain topics are out of the scope. The OIE encouraged the VICH SC members to make their views clear to the VOF members during discussions on topics for the next session so that VOF members fully understand the feasibility to have proposed topics on the VOF meeting agenda.

It was further suggested to start future VOF meetings with information on the scope of VICH in order to prevent misunderstandings and to additionally dispatch the basics on VICH with

each agenda. During the VOF meetings, areas not directly within the scope of VICH but still sensible to be covered based on a strong information need by the VOF members could be gathered under a session titled “Other topics out of scope of VICH”.

6/ Mutual recognition
It was suggested to request a presentation on the plans/experience with regional harmonisation by Saudi Arabia and by Uganda. The OIE will address this topic in December at the local Focal Points’ meeting

Act: OIE

7/ Combination GL
The Secretariat indicated that Dr Xu has agreed to explain the EWG’s activity at the next VOF.

8/ Pharmacovigilance
AnimalhealthEurope pointed out that some of the VICH GLs (3 of the existing 5) were written for the establishment of a harmonised electronic adverse drug event (ADE) reporting system for message exchange between well-established regulatory agencies and marketing authorization holders and may not be suited for broader international use. In fact, most VOF countries are just starting to set up PhV and are not ready for electronic systems yet.
It was acknowledged that VICH tends to present what VICH countries do, which is often quite complex, whereas VOF countries receive very differently the PhV messages i.e. from farmers more than from vets, and their questions are relatively basic relating to how to set up and run a simple system. One goal might be to show how ADE messages from the public can be captured in a way that could facilitate electronic exchange at some point in the future as PV programs grow.

The SC agreed to keep the PhV topic on the agenda, but with a presentation on the basics rather than the complex systems, also suggesting objectives and solutions on how VOF countries could move forward toward eventually implementing VICH guidelines.
AnimalhealthEurope will prepare a simple presentation based on previous presentations.

Act: AnimalhealthEurope

The Chair of the ESI-EWG recommended consideration of a change in approach at the Outreach Forum meeting, including a break-out session to provide countries with one-on-one time with PV experts (industry and regulatory), in order address the wide scope of PV questions received. PV questions varied significantly depending on the stage of development of PV within each respective country.
AnimalhealthEurope also agreed to develop a CP for a basic GL on PhV, adapted to the needs of VOF members for PhV, describing minimum requirements only.

Act: AnimalhealthEurope

As a more general remark in relation to future VOF meetings AnimalhealthEurope suggested that in going forward it would be useful for SC to add the objectives we are trying to achieve in presenting on a given topic to the VOF agenda.

C/ Attendance
It was noted that Ukraine had not attended, nor UEMOA, which had been a very active participant until recently. The OIE will contact UEMOA to encourage them to attend again.

Act: OIE

6. Reviews of:

6.1 The implementation and interpretation of VICH GLs in the regions

6.1.1 Report from the regulators

6.1.1.1 Update from the EU & Japan on the delay of implementation of PhV GLs

The EU confirmed its intention to implement the PhV GLs by the end of 2018 or in early 2019. However, the EU also highlighted the fact that the move of the EMA to another location will have an impact on the Agency's resources, and the possibility that this might impact on development of the relevant database cannot be ruled out.

JMAFF confirmed that Japan will implement GLs 24 and 29 in December 2017 at the latest, and the 3 other PhV GLs as soon as possible; JMAFF will provide further information at the next SC meeting.

Act: JMAFF

6.1.1.2 Report from other regions

None

6.1.2 Update from the regulators of observer countries on the implementation of VICH GLs

South Africa reported that the 5 PhV GLs will be discussed together in the course of next year as per the overall implementation plan in South Africa.

Australia and New Zealand confirmed that the GLs are frequently used and incorporated where possible in the respective national legislations. Both Australia and New Zealand reported issues with the PV GL implementation.

Canada uses most GLs and is very active on the EWGs.

6.1.3 Any input from industry members

None

6.2 Status of consultation for draft GLs at Step 4

None for consultation at the moment.

7. Review of final VICH Guidelines at step 9

7.1. Proposals for revision of further VICH GLs

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

The Secretariat explained that the GLs status table (VICH/17/006) circulated prior to the meeting has been improved following the remarks made at the last meeting. 4 GLs (18, 46, 47 & 49) were highlighted in red reaching the 5-year timepoint for considering the need for a review (see item 7.1.3).
The SC asked the Secretariat to circulate a new table, 6 months before each SC meeting.

Act: Secretariat

The Secretariat will add to the table a column indicating the date of the last consideration of each GL.

Act: Secretariat

7.1.2 Review of the revised guidance document "Revised Methodology for a systematic Review of the VICH Guidelines at step 9"

The SC approved the finalised document which will be incorporated to the VICH internal guidance documents.
Simultaneously, the documents "Methodology for a systematic Review of the VICH Guidelines at step 9" (VICH/07/039-final)" and "Monitoring and Maintenance of existing VICH Guidelines" (VICH/IN/05/017-FIN-Rev) will be deleted from the guidance documents.

7.1.3. Proposals from the EU for a revision of VICH Quality GL 18(R) and VICH Safety GL 46 & GL 47

GL 18(R)
The EU presented a discussion document explaining that ICH has revised the corresponding GL, and proposing to update the VICH GL to bring it into line with the parallel ICH GL.

The SC agreed that the EU discussion document can serve as a Concept Paper for this work. The SC therefore gave the mandate to the quality EWG to review this CP in order to provide further recommendations. The EU accepted in principle to take the topic lead within the EWG.

GLs 46 & 47
The EU indicated that, in the view of its experts, GLs 46 & 47 do not need to be revised yet. The SC agreed.

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

None

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

8.1. Quality

The chair of the Expert Working Group, Dr T. Dr Ogata, reported that final draft of the new stability testing guideline for climatic zones III and IV should soon be ready for signature at step 2 by the experts. The GL will be an annex to the parent stability guideline, "Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL3 (R))" and addresses the recommendations on what should be submitted regarding the stability data package for a new veterinary drug substance and medicinal product for registration applications submitted within the regions in climatic zones III and IV.

The SC highlighted the importance of these climatic zones for the VOF members and expressed its appreciation to the chair and experts for the advancement of this topic.

8.2. Electronic Standards Implementation – Pharmacovigilance

The chair of the Expert Working Group, Dr Linda Walter-Grimm mentioned several membership changes since the EWG was formed.
A draft concept paper to address areas of disharmonisation in veterinary pharmacovigilance was developed following the ESI EWG meeting of June 2017. The draft has been circulated within the EWG for a first round of comments and is under discussion.

Discussions on the electronic acknowledgement message also continue.

The development of global product dictionaries and IDMP standards is progressing in ICH and VICH experts are monitoring the future developments. It was noted that the standards are relatively complex, so VICH may need to consider a simpler approach. The development of a harmonized global product dictionary remains a long-term goal for VICH as well. AnimalhealthEurope highlighted the difficulties for smaller companies to implement such complex requirements.

It was reminded that AnimalhealthEurope had been asked to update the vision document from 2010, which is ongoing and should focus on the basic requirements of pharmacovigilance systems globally, as well as compatibility of simple and complex systems. AnimalhealthEurope is also reviewing the 12 areas of disharmonisation in order to link them to the specific parts of the PhV GLs. The Chair mentioned that both AHI and AnimalhealthEurope had provided comments on linking the 12 issues to the relevant parts of the PhV GLs as part of the discussion documents circulated prior to the last Steering Committee meeting.

8.3. Biologicals Quality Monitoring

The chair of the Expert Working Group, Dr K. Sato, JMAFF reported the following:

a. Harmonisation of criteria to waive Target Animal Batch Safety Testing for live vaccines for veterinary use
GLs 50 & 55 have been finalised in May and should be implemented by May 2018; both are already implemented in the USA and will be implemented in Japan before the end of 2017. The SC expressed its appreciation for the finalisation of these GLs.

b. Harmonisation of criteria to waive Batch Safety Testing for veterinary vaccines: Laboratory Animal Batch Safety Testing (LABST)
This draft GL will be very similar to the 2 TABST GLs. A first draft has been circulated within the EWG early this year and comments were received from the experts. The topic leader Dr Halder is now preparing a second draft to be circulated before the end November.

c. Extraneous virus testing for Biologicals
The EWG has been working on 3 distinct GLs but there has been a lack of consensus on the first GL “cell-based methods for testing virus seeds, cell seeds and other starting materials of animal origin for the presence of extraneous viruses”.

The EU recalled that at the last SC meeting it had agreed to provide further explanation for its objections to a previous, detailed version of the above-mentioned “cell-based methods” GL. A document was subsequently provided explaining that the EU no longer accepts the concept of a general test (13 July 2017, EMA/CVMP/404064/2017). Following circulation of that document regulatory and industry experts from the EU met to discuss possibilities for moving the topic forward. However, as described in the EU joint regulator-industry document (9 Nov 2017, EMA/689747/2017), the conclusion of the experts was that, until additional experience has been gained following changes introduced in the EU in relation to extraneous virus testing, it would not be appropriate to move forward with the topic at a VICH level.

Recognizing the EU concern, JMAFF pointed out the EU experts have suggested that any test must be demonstrated to be fit for purpose, and the provision of such a demonstration turns the tests into “specific tests”. On the other hand, other SC members believe that general tests are still of value, as they aim to detect a range of viruses in a single testing operation to save costs and human resources for routine testing work.

In view of the difficulties being experienced in relation to progressing the current draft GLs JMAFF submitted a proposal for an alternative approach (on 3 November - VICH/IN/17036). JMAFF explained that this involved grouping several tests which share a common cell type and detection method, into a single category, with a view to limiting the total amount of testing required).
This proposal was welcomed by several SC members, but there was agreement that more time was needed to properly review the proposal and provide written comments.

It was decided that all SC members should review the 2 documents (i.e. the EU joint regulator-industry document and the new JMAFF proposal) within their respective organisations and provide written comments on both documents by Thursday 1st March 2018 at the latest. All members can then review these comments in time for a discussion on the 2 documents at the 36th SC meeting in June.

Act: All

Meanwhile, no action was given to the EWG on this topic.

8.4. Metabolism and Residue Kinetics EWG

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

a. Draft GL on Honey

The SC noted that draft GL 56 - MRK: Residues in Honey public consultation procedure at step 4 has ended in July and that the EWG is working on the comments received. The EWG will respond to each comment and amend the draft GL as necessary.

b. Draft GL on Aquatic products

The draft GL 57 is currently under signature at step 2 and should be presented at step 3 in the very near future.

c. Potential revision of GL 49

The SC confirmed the agreement from the last meeting i.e. that the review of the GL must be limited to addressing specific issues raised by stakeholders and in particular the example calculation given in annex 3. If any other corrections are proposed, these must be clearly identified in an updated CP and approved by the SC.
Each expert was authorised to nominate 1 advisor. So far, the Secretariat had only received a nomination from the EU. Canada and FDA indicated that they would nominate an advisor as well.
Pamela Boner was announced as the new topic leader from AHI.

8.5. Safety EWG

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

a) Revision of VICH GL 23 (Safety - genotoxicity)

The SC noted that proposed options were shared within the EWG, the results have been consolidated, and a revised proposal has been circulated for comments. It is hoped that the EWG will be able to reach an agreement by the end of November in order to start the work on the actual revision of the GL by the middle of next year.

b) Revision of VICH GL 22

The SC noted that the experts would agree to develop a CP to revise GL 22 based on the inclusion of both the EOGRTS and the existing 2-generation study as options without preference.
The SC requested the CP to be provided by next 15 March, so that it can be circulated for SC comments, and then the CP and the comments can be ready for review at the next SC meeting.

Act: EWG

8.6. Anthelmintics EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr A. Phillippi-Taylor, and presented by the FDA.
A face to face meeting was held in July which enabled the experts to agree on a number of revisions. Several topics still need to be addressed by the EWG.
Nevertheless, the experts will review the GLs with the incorporated revisions by December for further discussion and agreement on the draft revisions in the course of 2018. The final versions of the revised GLs could be ready for sign-off by mid-2019.
The SC thanked the chair and the experts for the ongoing work.

8.7. Combination product GLs EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr S. Xu, and in his absence presented by the FDA.
The EWG has merged the US and EU GLs, which were circulated to the experts with some additional discussion questions and a request to populate the document with other questions to be considered in the development of the GL. It was noted that limited comments had been received so far from EWG members which may be partially due to early technology/communications problems. These problems had since been resolved and the EWG hoped to receive more feedback from members.
The next round of discussion should take place in April - May 2018.

8.8. Bioequivalence EWG

No report was expected from this EWG which had completed its work.
FDA recalled that at the last meeting the SC had envisaged to disband this EWG, but AnimalhealthEurope believed that, as there is now a guidance for biowaivers in the major regions, a global harmonisation effort (ie a VICH GL) should be put in place.

Several SC members considered however that, despite the existence of guidance for biowaivers in the major regions, more scientific background is needed, so it is difficult for the time being to set a timeline for harmonisation discussions.
It was therefore agreed to maintain the EWG until completion of the training module and to discuss this topic again at the next SC meeting.

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

None presented

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

None presented

11. Concept papers/Discussion Documents

11.1 Review of the Concept Paper from the Safety EWG on the revision of VICH GL 22

Covered under 8.5.

11.2 Revised preliminary Concept Paper from JMAFF on a Guideline for Safety Evaluation of Biotechnology-derived/Biological products

JMAFF provided a new version of the document including the comments that were received, highlighted in blue.
The new table 1 shows examples of selection of items from ICH GL S6(R1), that may be needed or not for a VICH GL. The new tables 3 and 4 show the scope of the VICH GLs for bio-products already in place, i.e., GLs 17 and 40 (Stability testing and Test procedure /acceptance criteria, respectively) which may be used as reference when discussing the scope of a new guideline.

The SC agreed that any work on this topic should start with a narrow scope such as monoclonal antibodies and be expanded gradually.
It was decided that all SC members should provide further written comments to JMAFF by Thursday 1st March 2018. JMAFF will then prepare a revised CP by including the comments received, and completing the "Recommendation and Timetable" section for review and further discussion at the 36th SC meeting in June.

Act: All/JMAFF

11.3 Potential VICH topics

None proposed.

12. Other issues

12.1 Internal guidance document on the "Definition of Biologics" & Comments received

JMAFF recalled that the SC had clearly stated that this is an informal and internal VICH document not relating to any regulatory framework of any region, and explained that the last document dated 21 September is a consolidation of previous discussions, which do not need to be precisely discussed again.
It was noted that in the USA, biologics are regulated by USDA and drugs by FDA. The definition included in this draft document is from the human part of FDA, and should be deleted.
The EU indicated that the EMA definitions included in the appendix should be updated and indicated that it would forward the more relevant definitions to JMAFF.
JMAFF will therefore prepare a draft 2 of the document including the last comments received for circulation and approval within 4 weeks.

Act: JMAFF/All

If no further comments are provided the draft 2 will be finalised and included in the VICH guidance documents (and not made public).

12.2 Discussion Document on the VICH Steering Committee (SC) Meeting Frequency

NZ presented a discussion document on the frequency of VICH SC meetings and explained that there was a case for moving to a 12-month meeting cycle, which would reduce the overall costs for the different delegations and give delegates the opportunity to better prepare and

attend meetings without necessarily losing efficiency. A number of regulator delegations indicated that their initial impressions were that the proposal could be supported.

The industry representatives expressed their concern that momentum might be lost and the process become even slower, especially within the EWGs, which generally deliver material in time for SC meetings. Industry would nevertheless support the move to a 12 months cycle under the condition that the efficiency of VICH is improved.
It was acknowledged that a 12 months cycle could be implemented after 2020 only.

JMAFF pointed out that the cycle of VOF meetings would be extended as well, with the threat of VOF members losing interest. To compensate, JMAFF recommended to organise at least 1 training each year between VOF meetings. The OIE believed that a reduction of the number of meetings may be a good opportunity to request a better involvement of VOF members.

It was also recognised that an extension of the meeting cycle would require a much tighter follow up of activities by the Secretariat.
There was a suggestion that a 6-monthly virtual meeting of the VICH coordinators might provide a mechanism for keeping the momentum and improving efficiency.

NZ agreed to take the lead in developing a document on potential efficiency gains, for consideration by the SC. It was agreed that coordinators should provide reflections on this topic to NZ by 31st January 2018. NZ will then circulate a document on the topic by 1st March, making concrete proposals for the way forward, with an impact assessment of both the 9 and 12 months cycles, and an impact assessment of the VOF activities.
All delegations should provide comments on the document by the 31st March.
Following this NZ will provide a draft 2 by mid-April for review and discussion at the 36th SC meeting in June.

Act: All/NZ

13. Any other business

13.1 Upgrade of the VICH Website

AnimalhealthEurope explained (link) that the current website was set up 5 years ago and that updating and modernisation is necessary.
The VOF has now ongoing activities and the training documents and training materials provided by the EWGs could be brought to the front. The website will also be translated into French and Spanish, except the GLs, although some translations exist.

AnimalhealthEurope suggested to create a FAQs page and to enable VICH to receive questions submitted via the website. Additionally, a global resource center on regulatory convergence will be created, as a separate project from the VICH website, but which would refer back to the VICH website, as well as to the OIE website, where some translated VICH GLs are placed.

JMAFF expressed its concern that authorising third parties to pose questions on GLs through the new website will require many VICH experts to be permanently available for replies, as VICH has now nearly 60 GLs. The EU and FDA also expressed concern over resources.
The SC agreed to set up the necessary framework on the new website, but not to make the relevant page publicly available for the time being.
It was nevertheless agreed that retrospective questions will be placed in the FAQ section.

13.2. Change of the Organisational Charter

The Secretariat will amend the charter to integrate the change of name from IFAH-Europe to AnimalhealthEurope.

Act: Secretariat

13.3. Animal Welfare

With regard to alternative methods to animal testing in the regulation of veterinary medicinal products, AnimalhealthEurope reminded the SC that a CP had previously been proposed by the EU in 2006 to the 18th VICH SC on the 3R principles. 2 elements in relation to alternative methods have not been followed up since: i.e. establishing a compilation of existing validated alternative approaches to animal testing, and establishing a mechanism by which the compilation of validated alternative approaches to animal testing is kept up-to-date. AnimalhealthEurope proposed to invite to the 36th SC meeting in Bruges a representative of the EURL ECVAM to update the SC on the status of their work in this field with a focus on regulatory acceptance of alternative methods to animal testing.
The SC agreed.

14. Dates and venue of next meetings

- The 36th SC meeting will take place in Bruges, Belgium - Europe from 25 to 28 June 2018
- The 37th SC meeting will take place in Cape Town – South Africa from 24 February to 1st March 2019

15. Adoption of the Press Release on the 35th SC meeting

The SC members reviewed and adopted the Press Release drafted by the Secretariat.

VICH STEERING COMMITTEE

35th meeting

13,14 & 16 November 2017
Tokyo, Japan

Chair: K. OHARA, JMAFF

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

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AHI	R. CUMBERBATCH (C)
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EU (EMA-CVMP)	D. MURPHY
EU (EMA)	N. JARRETT (C)
ANIMALHEALTHEUROPE (BOEHR. INGELHEIM)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
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