



**VICH STEERING COMMITTEE**  
**37<sup>th</sup> meeting**  
**25, 26 February and 1<sup>st</sup> March 2019**  
**Cape Town, South Africa**

**Minutes of the meeting**

**1. Opening of the meeting and chairperson's introduction**

The meeting was chaired by Dr Matthew Lucia, Director, Office of New Animal Drug Evaluation, CVM, FDA. He welcomed the participants to Cape Town and noted apologies from K. Tuchiya – JVPA and B. Rippe – USDA; G. Gowda - AHI is replaced by C. Lowney.

**2. Adoption of the agenda**

The agenda was adopted with the 4 following changes: agenda item 10.1, 11, 12.3 and 15.2 will be discussed before the VOF meeting.

**3. VICH 6 Conference**

**3.1. Review of the final programme & speakers**

The participants reviewed the final programme and took note of the latest changes.

**3.2. Messages for the VOF members**

None

**3.3. Update on logistical matters for the Conference**

E. Schay provided the latest details on the Conference's events and indicated that about 130 participants would attend.

**4. VICH Training Implementation**

**4.1. Update on the development of training materials**

The SC reviewed the updated table on the status of the VICH training materials and agreed the next steps.

Presentations on Quality GLs 3, 4, 5, 8, 10, 11 & 18, as well as 45 & 51 have been prepared by AnimalhealthEurope and circulated for comments. These have now all been finalised and will be uploaded on the website shortly.

AnimalhealthEurope will also shortly circulate presentations on GLs 1 & 2; presentations on GLs 17, 39 & 40 will be drafted in the course of 2019.

The SC agreed to place the following disclaimer at the beginning of each presentation: “*These slides have been provided for training purposes only. The presenter has made every attempt to ensure that they are consistent with relevant VICH guideline(s). As always, the original Guideline(s) should be used as the primary source of information for working with regulators.*”

Presentations on TABST GLs 50 & 55 have been drafted by JMAFF & JVPA and also circulated for comments. The final versions will also be uploaded shortly on the website. JMAFF explained that video training materials have been prepared on MRK GL 57 and these training materials will be circulated for comments. JMAFF also explained that these training materials on the 3 GLs will be presented during the VICH 6 Conference.

FDA indicated that training documents for internal use will be developed in the future, which could be used for VICH, and will be submitted to the SC.

The EU confirmed that it will develop a presentation on GCP GL 9 in the course of 2019 and AHI will draft training material on PhV GLs 24 & 29, as well as on Safety GL 33.

Depending on the timing and the topic, the SC asked the Secretariat to avoid sending too many drafts for review in the same timeframe.

**Act: Secretariat**

The SC recalled that it had been recommended that the EWGs should prepare a set of training slides when finalising each new GL, but the EU and FDA repeated that they could not commit to this exercise. It was therefore suggested that an industry representative could take the lead role in generating the training material.

The SC discussed the intended audience for these presentations and how much detail they should include. The SC recognised the challenge of not repeating the GL in slides, but of rather providing additional explanations.

It was noted that the intention of the training materials was to respond to the VOF members’ needs. The OIE suggested asking VOF members for feedback on the content of these training materials. The SC agreed that this could be done once the first batch has been made available.

#### **4.2 Review of the FAQ document prepared by AnimalhealthEurope**

AnimalhealthEurope presented the draft document based on the information already available on the VICH website, with the addition of obvious questions, and proposed to develop specific topics in separate chapters of the document or in separate documents.

Health Canada and FDA agreed that the questions on Pharmacovigilance are out of scope of a general Q&A, but could be part of a separate Q&A related to pharmacovigilance training materials.

The SC agreed out of scope questions would be excluded from the document.

All SC members were asked to send their comments and suggestions to R. Clayton by the end of April.

**Act: All**

AnimalhealthEurope will then circulate a second draft for adoption by electronic procedure. The document should then be sent to the VOF members, and placed on the VOF website, with a request for further questions and comments.

#### **4.3 Update of the documents already placed on the VICH Website**

R. Clayton explained that a new version of the website will be uploaded within the next few weeks. The access to the training page will be much easier.

There are already a few training presentations available on the current version of the website. The SC authorised the OIE to include on its own website a link to the new VICH website.

## **5. VICH Outreach Forum**

### **5.1 Preparation for the 11<sup>th</sup> VICH Outreach Forum meeting**

#### **5.1.1 Review of the participants list**

The SC reviewed the participants list for the 11<sup>th</sup> VOF meeting and regretted that Dr Xu was not able to participate.

The SC noted also that CAMEVET will be represented again, as well as ASEAN, UEMOA, India and Russia.

#### **5.1.2 Review of the agenda and preparation of the 11<sup>th</sup> meeting**

The SC took note of the last version of the agenda.

The OIE summarised the issues encountered to finalise the agenda: it had been difficult to obtain the commitments from VOF members as well as SC members to prepare discussion topics and presentations.

The SC decided to create a subgroup to assist OIE in the development of the future VOF agendas (see item 5.3.B).

At the end of the VOF meeting, the chairs will also ask each VOF delegation to propose 1 agenda item of discussion for the next meeting.

#### **5.1.3 Review of the Discussion Document on how to manage “Out of Scope” topics**

AnimalhealthEurope presented the Discussion Document on how to manage out of scope VICH topics as well as the proposed list of out of scope topics.

The SC decided to consider these chapters as 2 different documents: 1) the Discussion Document as a SC guidance document and, 2) the “out of scope” topics’ list as a document to share with the VOF. The SC will approve them separately. Once approved by the SC, the draft “out of scope” topics document will be submitted to the VOF members for their input.

JMAFF expressed concern that this document might discourage VOF members from participating in the meetings and proposed to add a chapter on “meeting topics” as well as to further develop the statement on the background of this document. It was noted that some flexibility exists in relation to the discussion topics at VOF meetings, and that these may address topics that are not strictly within the scope of VICH.

Australia also suggested removing the references to the VOF as this document will be useful for other third parties.

AnimalhealthEurope will circulate shortly a revised version for further comments and approval by electronic procedure. The objective is to present this work at the next VOF meeting in Tokyo.

**Act: AnimalhealthEurope/All**

It was acknowledged that this should be a “living document” to be amended as necessary.

#### **5.1.4 other issues**

FDA suggested asking VOF members in the future to provide feedback in writing on the VOF meeting and to record the presentations from experts in the VOF meetings for training purposes.

OIE mentioned that during the focal point trainings, OIE always provides feedback from VOF meetings, as the audience is not identical.

## **5.2 Procedure for applications for VICH Outreach Forum membership**

The Secretariat explained that VICH does not have a procedure in place, nor information on the website, regarding the criteria for interested countries to become VOF members. So far, when new countries have applied for VOF membership the Secretariat has sent a list of questions, together with the VOF's ToRs, and the SC considered the replies that were received. The Secretariat will develop a simple application form, for SC approval by written procedure, before placing the application form on the public website.

**Act: Secretariat**

Australia will provide a proposal to restructure the ToR document as well.

**Act: Australia**

## **5.3 Discussion of the Outcome of the 11<sup>th</sup> VICH Outreach Forum meeting**

### ***A/ General discussion***

The SC addressed this agenda item after the 11<sup>th</sup> VOF meeting and thanked warmly J.P. Orand (OIE) for all his efforts to prepare the VOF agenda.

The SC noted that all VOF participants were satisfied with the outcome of the meeting and become actively engaged when they can exchange experiences with their colleagues.

Moreover, the delegates who are assessors appreciate the detailed technical explanations.

JMAFF suggested that VOF members could be split into 2 different groups: 1) assessors and, 2) other regulators who are managers rather than assessors.

The SC noted that when VOF members were requested to provide input in advance, many had replied that they cannot commit too early in the process. It was pointed out that the VICH GLs may not always be their highest priority whilst many requested topics that are out of scope of VICH.

The detailed technical presentation on the Guidance on withdrawal period studies (GL 48) had been appreciated and was considered as excellent training material.

VOF members have also shown much interest in the other countries' authorities' activities on regulatory matters.

The WebEx presentation was also appreciated, although some improvement might be required, and is a useful tool to involve VICH experts in VOF meetings when they cannot attend in-person.

### **VOF members specific meeting**

Uganda had suggested creating a separate session where VOF countries can discuss issues between themselves. Such sessions could take place in parallel with the VICH SC meeting but would require an additional meeting room.

AnimalhealthEurope suggested asking VOF members to chair a session of the VOF meeting, or one of the breakout sessions, and to include a specific topic at each VOF meeting that could be used to create training materials.

VOF members must also be prepared to take notes for the reporting from breakout sessions.

An electronic forum would allow VOF members to continue discussing their issues after VOF meetings.

The SC acknowledged that VICH needs to regularly repeat basic information about VICH for the benefit of newcomers to the VOF.

The OIE summarised the VOF members' expectations:

- To express the problems faced in their own countries, to discuss solutions and seek standardised approaches
- More in-depth treatment of specific topics, more debate and interaction: presentations of case studies, information on the scientific background underlying why GLs request certain data
- Preference for Breakout Groups
- Circulation of the draft guidelines to local experts (authority and industry) and organisation of a TC via OIE to discuss the content

#### Survey of VOF members expectations

A subgroup composed of OIE, FDA and AnimalhealthEurope will develop a questionnaire for VOF members including questions on pre and post VOF activities.

The survey should identify what went well, what did not, how the efficiency of the VOF meetings can be improved and what are the needs and expectations of VOF members.

The survey will be run before the next VOF meeting.

**Act: OIE/FDA/AnimalhealthEurope**

#### ***B/ Proposed topics for the 12<sup>th</sup> VOF agenda***

- Process validation - API and finished products (JMAFF pointed out that some countries have several authorities related to validation process and a different authority than the VOF member may be responsible)
- Medicated premixes
- Biologicals: quality for vaccines (especially stability)
- GLs on anthelmintics (more detailed presentation)
- How to assess withdrawal periods
- GCP (the EU will provide a presentation)
- AMR and VICH GL 29
- Guidance of validation in quality GLs
- Autogenous vaccines
- Herbal medicines
- Discussion Document on out of scope topics

#### Timelines for development of the VOF agenda:

- First draft agenda: April
- Proposal for speakers: June
- TC if needed: July
- Final agenda to send with invitation: September

A subgroup composed of OIE, AnimalhealthEurope, SAAHA and Saudi FDA (Maher ALJASER) will hold a teleconference to finetune the agenda if necessary.

**Act: Subgroup**

#### ***C/ Attendance***

The SC noted the VOF had been attended by 22 VOF members from 13 countries, but regretted that Dr Xu (People's Republic of China) had once more not been able to travel.

## **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**

JMAFF confirmed that PhV GLs 24 & 28 were implemented in Japan in June. GLs 35 & 42 require the creation of a database; a specific budget should be made available in next April. JVPA added that it is closely collaborating with JMAFF in order to make the database available as soon as possible.

The EU recalled that at the last meeting it had foreseen that PhV GLs 35 and 42 would be fully implemented by the end of 2019. This likely implementation time has however now been put back to end of 2020 or early 2021.

#### **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**

After unexpected delays, South Africa confirmed that work towards implementation of the PhV GLs and Ecotox GLs will resume at the start of the new fiscal year.

The publication of all VICH GLs is up to date in Canada, except for the PhV GLs for which the database requires an update of the Agency's IT system.

Australia confirmed that most GLs have been implemented and Australia tries to participate in most EWGs.

New Zealand indicated that it does not have sufficient resources to nominate experts to all EWGs.

Canada proposed that VICH should develop a simple tracker spreadsheet detailing the status of implementation of the VICH GLs in the member and observer countries/regions, as is done in ICH.

The SC agreed that in a first step this should be only an internal tool for use by SC members.

The Secretariat will circulate an Excel sheet for all to complete before the next SC meeting. This document can then be updated before each SC meeting.

**Act: Secretariat**

FDA proposed that in a second step the SC should ask the VOF countries, if they would be interested in contributing to such a document as well. This will be a discussion topic for the 12<sup>th</sup> VOF meeting.

#### **6.1.3 Any input from industry members**

AnimalhealthEurope commented that so far not all regions have yet implemented the TABST GLs.

#### **6.2 Status of consultation for draft GLs at Step 4**

FDA reported that it had to delay the public consultation for draft Stability GL 58, but that consultation will be closed shortly.

### **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**

None

### **7.1.2 VICH Quality GL 18(R) on Residual Solvents – Update on the progress of the ICH GL**

The EU reported that the available information indicates that revised ICH GL Q3C is due to be released for public consultation in March and adopted in Q3 of this year. Once this has been done work to update the VICH GL can resume.

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

HealthforAnimals will launch a global survey with the industry and the results of this survey will be provided at the next SC meeting.

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

#### **7.2.1 Decision on the value of 500ml for the volume of the human colon in the microbiological ADI calculations in VICH GL 36 - Safety: microbiological ADI**

The SC decided to change the value for the volume from the human colon in the microbiological ADI calculations in VICH GL 36 to 500mL instead of 220g in line with the new scientific data provided by JECFA.

The SC agreed that the change is considered a minor revision for which public consultation is not needed. (see also agenda item 10.1)

#### **7.2.2. Proposals for a revision of other VICH GLs**

None

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

### **8.1. Quality**

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

JMAFF confirmed that GL 58 (Stability - Climatic zones III & IV) had been released for a 6-month public consultation period until 31<sup>st</sup> December 2018. The EWG is now waiting to receive the comments on the draft from the regulatory authorities of all VICH members before finalising the document.

As indicated under agenda point 7.1, the SC agreed that the revision of VICH GL 18 remains on hold until the Revision 7 version of the ICH GL Q3C is finalised.

### **8.2. Electronic Standards Implementation – Pharmacovigilance**

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr Linda Walter-Grimm, and presented by FDA.

The EWG has received a document from industry on a vision for the global harmonisation of PhV, and the experts are providing their comments.

AnimalhealthEurope pointed out that this document is limited to a vision; it does not go into detailed recommendations on how to reach the goal.

The harmonised acknowledgement message has been put on hold but progress continues in the development of the global product dictionary.

The review of GL 30 should also be put on hold until next year due to lack of resources.

FDA reported that there had been a high turnover of experts in the EWG and many new experts having been nominated recently.  
AnimalhealthEurope will nominate a new IT advisor.

The EU confirmed that new legislation relating to the regulation of veterinary medicinal products in the EU was recently published. The legislation is due to become effective in January 2022 and work is currently ongoing to develop the measures and requirements necessary for implementation of the new legislation. While this will include work on PhV, it is not expected that the new legislation will have a significant impact regarding the EU's ability to implement the VICH PhV GLs. The EU will update the SC as the work in the EU develops.

**Act: EU**

### **8.3. Biologicals Quality Monitoring**

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

#### *a. Harmonisation of criteria to waive Batch Safety Testing for veterinary vaccines: Laboratory Animal Batch Safety Testing (LABST)*

This 3<sup>rd</sup> draft of the GL, including all the comments received on the previous version, has been prepared and circulated.

JMAFF explained that the USDA has proposed significant changes to the 3<sup>rd</sup> draft of the GL, including the change of "required number of batches", "the use of combined vaccines derived safety data for fallout products" and the inclusion of "criteria of maximum antigen contents". Should these suggestions be included in the final LABST GL, the TABST GLs 50 & 55 would require major revision as well.

The chairman of the EWG proposed as a compromise to finalise the LABST GL now, without these major revisions, then develop a CP to review all 3 TABST GLs at a later stage.

FDA confirmed that the USDA, not present, supports this proposal. The SC consequently decided that the immediate task of the EWG is to finalise the LABST GL, maintaining as much consistency as possible with the TABST GLs. Consideration of the need for amendments to these GLs can take place subsequently.

#### *b. Extraneous virus (EV) testing for Biologicals*

The SC reviewed the expanded version of the CP presented by JMAFF.

The EU informed the SC that its experts still have reservations on the revised proposal as the EU could not implement a GL that sets out a set of mandatory tests for extraneous viruses. This is because the EU system allows the applicant to choose the tests to be performed (and indeed the applicant can argue that there is no need to test for certain viruses), as long as the tests are demonstrated to be fit for purpose. The EU further considered that, if the tests are presented as optional, it is unlikely that the tests would be implemented in the EU as companies would choose to continue using existing tests with which they have experience and expertise.

JMAFF believed that the EU and JMAFF are considering the same things from different perspectives, not so far apart, and suggested asking the EWG whether a new approach would be scientifically relevant and feasible.

FDA confirmed that USDA supported the JMAFF CP and agreed to move the process forward. JVPA also showed strong support to the JMAFF CP and asked the EU to clarify the point to be solved further.

After additional discussion, the SC recommended that the EU and JMAFF should hold bilateral discussions during the SC meeting period.



The EU and JMAFF had therefore a thorough discussion and provided the following joint statement to the SC:

*As agreed earlier this week JMAFF & EU have discussed the extraneous viruses (EV) topic further. As previously indicated, the main EU concern was the possibility that the proposal was suggesting a move towards development of a standard set of tests that would become requirements across the VICH regions, which is something the EU would not be able to sign up to.*

*However, JMAFF has explained its intention that, if the work goes forward, the tests would be presented as sufficient condition - i.e. a regulatory authority would accept that the listed test systems are appropriate for detection of the identified viruses; and alternative tests would be equally acceptable, provided they are scientifically justified (as is also the case for other VICH GLs). In other words, JMAFF has no intention of establishing a "global EV testing standard" to be followed by the marketing authorization holders.*

*The EU delegation further insisted it is important to highlight that the EU feels that there are significant limitations to the level of harmonisation that would be likely to come out of the proposed work as it seems unlikely that EU companies would choose to move away from the use of established tests with which they already have expertise. So while EU is happy to discuss the topic further and to seek to involve an EU expert, it is not clear that the system would be widely applied in the EU. For that, JMAFF pointed out that the proposed approach would not be inconsistent with the current EU approach, and that there would therefore be no need to move away from the established tests after the adoption of new EV-GL.*

*We further clarified that the main task of the EWG would be to review the groupings presented in the concept paper, to comment/amend these and comment on the feasibility and/or scientific relevancies of the groupings. Depending on the outcome, future work might include developing similar groupings for additional species.*

*With the above clarification the project seems more acceptable to the EU delegation but the EU still needs to discuss it with EU experts to be more definite. So as a next step we propose:*

*- EU to further discuss the project with its experts with a view to providing revised text for the 'recommendation' section of the draft concept paper, clarifying the scope of the proposed work.*

*The EU delegation will need to discuss with its experts and then put the issue to its scientific committee. The EU will do its best to provide feedback to the SC in the next 3 to 4 months.*

*EU and JMAFF delegation*

AnimalhealthEurope indicated that, as the EU concerns relate partly to the question of whether the European industry would implement the proposed GL, it would be appropriate for a discussion to take place between EU and AnimalhealthEurope experts. The EU agreed and will seek to arrange these discussions in the coming months and to feed back to the SC within 3 months.

. **Act: EU**

#### **8.4. Metabolism and Residue Kinetics EWG**

The chair of the Expert Working Group, Dr S. Scheid, confirmed the following:

*a. VICH GL 56 on Honey*

GL 56 (MRK – Residues in Honey) is adopted for implementation at step 7 by June 2019.

*b. Draft GL 57 on Aquatic products*

GL 57 (MRK - Residues in Fish) is signed-off by the SC during this meeting for implementation at step 7.

*c. Revision of GL 49*

The topic leader is developing a proposal for a revision; only some examples in the annex need to be corrected.

### **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)*

Following the comments from the experts on a modified proposal (based on the interaction of the chair with individual members) circulated previously, a revised draft has been provided to the EWG for consideration and comment.

#### *b) Revision of VICH GL 22*

The task of the EWG is to consider if a consensus can be reached on a CP for the revision of the existing guideline through adoption of one or more of the new extended or modified one generation reproduction study protocols as a replacement for the existing multi-generation reproduction study.

FDA indicated that K. Greenlees has requested the authorisation to hold a face to face meeting of the EWG, if the EWG members consider that this would significantly facilitate progress. AnimalhealthEurope supported the request as the EWG seems to have gone as far as possible with electronic discussions on the very difficult issues it is addressing.

JMAFF requested that the EWG should identify clearly the issues to solve before holding the meeting.

FDA confirmed that the EWG will provide a more detailed document for review by the SC if the EWG members express their support for a physical meeting.

The SC agreed that the EWG chair could ask EWG members if they would support a physical meeting. If the group expresses its support, then clarification of the objectives and a proposed date will be provided to the SC. The SC will give the final authorisation for a face to face meeting, by written procedure, once the date is determined.

### **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.

The SC noted that work on the revision of the GLs is progressing well and the adequacy of infection issue has been clarified for most parasites. The issue of the arithmetic vs geometric means has been discussed in December and the comments from the experts are expected by the end of February. This is proving to be a particularly difficult aspect of the guidance on which to reach consensus.

FDA indicated that it has submitted an abstract on the statistical adequacy of an infection to be presented at the World Association for the Advancement of Veterinary Parasitology (WAAVP) conference which will be held in July 2019. This is unrelated to the work of the EWG.

### **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 topic leader, Dr Groesbeck.

FDA pointed out that the participation in the EWG activities has improved and the topic leader hopes to be able to provide a first draft document for the 38<sup>th</sup> SC meeting.

A teleconference is planned in March and the advisors have been invited to participate as well.

FDA indicated that the chairman will not be able to participate, so that the topic leader will lead the meeting.

The members will encourage all their experts to provide additional support to the topic leader. AHI recommended that the SC should identify ways to support the chair and topic lead. An example was proposed to ask a volunteer from industry to assist in taking notes.

The SC took note of the timelines for the achievement of the first draft GL and noted that the proposed deadline of August 2019 for the step 2 signature might be too ambitious.

The Secretariat reminded SC members that the Organisational Charter provides that in each EWG, each expert may (but is not required to) be assisted by an advisor; the Secretariat must be informed.

### **8.8. Bioequivalence EWG**

The SC reviewed the CP on biowaivers presented by AnimalhealthEurope.

FDA considered that the proposal is still too broad and that the document should be fine-tuned in order to define, while working on biowaivers, what will be acceptable for *in vitro* dissolution. There was discussion on whether to separate biowaivers from dissolution.

The EU supported the proposal in principle, but requested clarification of the exact scope of the task that will be expected from the EWG.

AnimalhealthEurope took note of the comments and reminded the SC of its decision during the previous meeting to move forward with biowaivers. AnimalhealthEurope recommended to ask the EWG to move forward as soon as possible with biowaivers. Adding *in vitro* dissolution as an additional topic would be acceptable.

FDA proposed that, before the end of May, it would take on the task of revising the CP, which will specify that, as a first step the EWG will develop a foundation document that will establish relevant definitions and clarify the exact scope of the GL to be developed.

The revised draft CP will be circulated to the SC for electronic approval by the end of June.

**Act: FDA (Done)**

This document will then be submitted to the EWG for the development of a CP to be provided to the SC sufficiently in advance of the next meeting in November. The CP will need to include a request to prioritize the work and recommendations on the scope of the expected GL.

**Act: EWG**

Meanwhile, the SC agreed to re-activate the EWG. FDA confirmed that it will continue to lead the EWG.

The Secretariat will circulate a call for (re)nomination of experts as well as advisors if the delegation wishes to do so.

**Act: Secretariat**

#### **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**

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

### **9.1. ....**

None

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

### **10.1. Draft VICH GL 57 – MRK: Residues in Fish – Studies to evaluate the Metabolism and Residue Kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species**

The SC adopted GL 57 as a final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2020.

### **10.2. Revised VICH GL 36 (R2) – Safety: microbiological ADI - Studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to establish a microbiological ADI**

As agreed under 7.2.1, the SC adopted GL 36 (R2) as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the revised GL will enter into force by August 2019.

## **11. Review of the first draft Priorities - Phase V**

The Secretariat presented a first draft for the Phase V priorities, which will cover the period from 2021 to 2025. The final document must therefore be adopted at the latest at the 39<sup>th</sup> SC meeting in 2020.

OIE will provide a suggestion to include the issues of AMR, and the usage of alternatives to Antibiotics such as vaccines etc.

**Act: OIE**

AHI suggested clarifying the role VICH plays in efforts to combat the spread of antimicrobial resistant bacteria.

**Act: AHI**

HealthforAnimals proposed to include the reference to alternatives to the need to use antibiotics rather than using the phrase, "Alternative to Antibiotics" to describe VMPs like vaccinations. HealthforAnimals will provide a proposal.

**Act: HealthforAnimals**

All SC members were asked to provide further comments and suggestions to the Secretariat by next 30 April. A version 2 of the draft document will be circulated for discussion at the 38<sup>th</sup> SC meeting.

**Act: All**

## **12. Concept papers/Discussion Documents**

### **12.1 Review of the Concept Paper from the Safety EWG on the revision of VICH GL 22**

Covered under 8.5.

### **12.2 Revised Concept Paper from JMAFF on a Guideline for Safety Evaluation of Biotechnology-derived/Biological products**

JMAFF, having received no further comment, clarified that this document is the same as that reviewed at the 36<sup>th</sup> SC meeting and proposed to identify the most important topics to be addressed, in light of finalising the CP by 2020. JMAFF therefore considers it has received silent approval from the members.

The EU agreed to move forward with the restricted scope and timelines as proposed. The EU indicated that it may have some minor editorial comments on the CP, which it will provide to JMAFF.

**Act: EU**

Several SC members including the USA and Canada supported the choice to start with monoclonal antibodies.

The SC agreed to adopt the CP at the next SC meeting, with a clear mandate for the EWG to start the work in early 2020!

### **12.3 Review of the Discussion Document from the subgroup on the need for further guidance around medicated premixes and compilation of comments**

AnimalhealthEurope recalled that at the last SC meeting it had been decided that the scope of any guidance on this topic would be limited to medicated premixes and recommended to focus on the technical requirements only, not on risk management issues such as labelling.

AnimalhealthEurope has received many comments including from Zimbabwe.

The SC reviewed the document prepared by AnimalhealthEurope proposing to set up a Task Force to define exactly the scope of the guidance and develop a CP; in the CP it can then be proposed to set up an EWG.

The TF will need to understand the exact requests from VOF members and agree on the scope and the basic definitions.

The EU recalled that, at the last VOF meeting, the VOF members had voiced a desire for guidance with a broader scope than what is suggested in the DD and noted that the scope of what VICH can provide may not entirely satisfy the VOF.

The SC agreed to first create a Working Group composed of AnimalhealthEurope, FDA, the EU, JMAFF, AHI and South Africa with the aim to clarify the DD and provide a new version of the DD sufficiently in advance of the next SC meeting.

The aim will be to create at the next SC meeting the TF to develop a CP proposing an EWG and development of a GL.

**Act: Working Group**

### **12.4 Review of the Discussion Document on which ICH GLs might be adaptable to the veterinary pharmaceutical field**

This topic was postponed

### **12.5 Potential VICH topics**

This topic was postponed

## **13. Outcome of the VICH 6 Conference**

The SC warmly congratulated the South African delegation and AHI for organising a successful Public Conference, as well as the memorable social event. The SC also thanked the OIE for its involvement in the invitations and support of many African regulators.

The appraisal from VOF members, especially the delegates from the African continent, has also been very positive, indicating in particular that the discussions on harmonisation, collaboration, exchange of experience had been extremely useful to them.

South Africa pointed out that there had been strong expectations from African regulators to share experience and receive support from developed countries.

AnimalhealthEurope noted the significant progress in knowledge and acceptance of VICH standards since the 4<sup>th</sup> VICH Conference in 2010 in Paris.

AHI and SAAHA will develop a “lessons learned” document for review by the SC.

**Act: AHI/SAAHA**

### Participation

127 participants from 28 countries attended the conference including 64 regulators from around the world. There were 75 delegates from Africa with 49 persons from South Africa.

AHI recalled that many individual contacts and personal letters had been necessary to remind African regulators to attend. Human resources and funds are the main causes of the limitation in African regulatory agencies’ participation.

### Videos

The SC also thanked JVPA and JMAFF for the development of the excellent training videos that were presented.

It was confirmed that the TABST training video can be placed on the VICH website, but the video on GL 57 needs to be approved by the SC member beforehand. JVPA will circulate the scenario of the video for comments.

As funds are still available for further training videos as well as for minor revision of the finalised ones, JMAFF & JVPA will ask the SC for suggestions on new topics and further improvement.

**Act: JMAFF/JVPA**

### Topics

The SC noted the overall high quality of the presentations. AHI noted a concern of a sponsor that the future 1-year cycle of SC meetings would slow down the VICH process. The expectations from third countries for sharing experience and best practices are high and the promotion of regulatory convergence through individual organisations should be encouraged. Meanwhile harmonisation initiatives through organisations such as the SADAC, GCC or UEMOA may accelerate the process.

The SC agreed that each organisation will reflect further on the challenges that were expressed at the Conference and on the future direction of VICH. The primary function of VICH is to develop technical guidance, but another key objective is to disseminate the information through the global outreach, although the two should be kept separate.

## **14. Other issues**

### **14.1 Proposal for a review of the VICH Guidance document - Meeting Efficiencies and Initiatives**

The EU and the OIE had provided additional minor suggestions, which have been detailed in the of the revision 1 of the document.

The SC accepted the proposed changes and acknowledged that the 1-year cycle will require more involvement of the coordinators as well as the Secretariat to ensure that the timelines for actions are met and the issues driven forward.

The SC agreed to hold the meetings in November from 2020 onwards, although it was acknowledged that some flexibility will be needed.

### **14.2 Proposal for a review of the VICH Organisational Charter**

The Secretariat explained that following the adoption of version 15 of the Organisational Charter, the OIE had proposed several additions to the document. The aim of these proposals

was to clarify the OIE VICH-related activities undertaken in the past and to be done in the future.

The SC reviewed the proposed wording and suggested the OIE to develop separate SOP for propagation of VICH-info to the OIE members, since these detailed procedures are not suitable to the organizational charter.

Several modifications to the proposals have been included in draft 3 of revision 16.

The Secretariat will circulate this draft 3 of version 16 for a final review and approval within 4 weeks of the circulation.

**Act: Secretariat**

### **14.3 e-mail from ICAPPP**

The SC took note of the questions received during the meeting from the International Council on Animal Protection Programs (ICAPPP) and agreed the reply message that was proposed by the Secretariat.

This reply was sent immediately to ICAPPP.

## **15. Any other business**

### **15.1 Update on the status of the UK in the VICH SC after the Brexit**

As the situation regarding the Brexit and the future status of the UK in the EU was still unclear at the time of this meeting, the SC did not discuss this issue further.

### **15.2 Review of the draft Discussion Document on the criteria to become a VICH SC member**

The Secretariat explained that recently oral or written questions on the criteria to become a SC member had been received from Brazil, Russia, Saudi Arabia & Taiwan. As VICH has no formal explanatory document available about membership criteria, the SC had asked the Secretariat to develop a simple document that should be placed on the public website to be available to potential candidate countries.

The proposal has been drafted based on the criteria that were applied for the countries which had joined the SC most recently, i.e. Canada and South Africa.

The SC confirmed that, amongst other criteria, a country applying to become a VICH observer must have a well-established and broadly representative local Industry Association in order to maintain joint representation of both the regulatory and the industry organisations.

It was also agreed that the position of observer member will be a pre-requisite to become a full member, as well as the requirement to attend several SC meetings as an observer before becoming full member.

The document should not include statements addressing a situation of individual countries. Regional balance and stability in national status should be carefully considered for full membership.

The SC reviewed and amended the document. The Secretariat will circulate the draft 3 for further comments and approval by written procedure before the end of April.

**Act: Secretariat/All**

The final document will then be placed on the public website. JMAFF recommended that the document should not be stand-alone document but an appendix to the Organisational Charter since it is a fundamental criterion of VICH itself.

## **16. Dates and venue of next meetings**

- The 38<sup>th</sup> SC meeting will take place from Monday 18 to Thursday 21 November 2019 at Forest Inn Showa Kan - Japan
- The 39<sup>th</sup> SC meeting will take place from Monday 16 to Thursday 19 November 2020 in Europe – Location TBC

## **15. Adoption of the Press Release on the 37<sup>th</sup> SC meeting**

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



## VICH STEERING COMMITTEE

37<sup>th</sup> meeting

24, 25 February & 1 March 2019  
Cape Town, South Africa

Chair: M. LUCIA, US FDA / CVM

### LIST OF PARTICIPANTS

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#### **STEERING COMMITTEE (C) coordinators**

AHI (ZOETIS)	M. J. MCGOWAN
AHI (ZOETIS)	C. LOWNEY (for G. GOWDA)
AHI	R. CUMBERBATCH (C)
EU (EUROPEAN COMMISSION)	J-N. PREUSS
EU (EMA)	D. MURPHY
EU (EMA)	N. JARRETT (C)
EU (BVL) – <i>Guest</i>	S. SCHEID (Chair of the MRK EWG)
AnimalhealthEurope (BOEHR. INGELHEIM)	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
JVPA	K. OISHI (C)
US (FDA)	B. WALTERS
US (FDA)	B. ROBINSON (C)

#### **OBSERVERS**

Australia (APVMA)	A. NORDEN (for C. PARKER)
Australia (AMA)	C. BENNETT
Canada (Health Canada)	M-J. IRELAND
Canada (CAHI)	J. SZKOTNICKI
New Zealand (MPI)	W. HUGHES
New Zealand (AGCARM)	M. ROSS
South Africa (SAHPRA)	A. SIGOBODHLA
South Africa (SAAHA – BAYER)	E. SCHAY
South Africa (SAAHA) – <i>Guest</i>	M. CHURCHILL

#### **INTERESTED PARTY**

AVBC	J. THOMAS
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#### **OIE**

OIE	J-P. ORAND
OIE	M. SZABO

#### **VICH SECRETARIAT**

HealthforAnimals	H. MARION
HealthforAnimals	C. DU MARCHIE SARVAAS

#### **APOLOGIES**

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JVPA (Nisseiken Co.)	K. TUCHIYA