



**VICH STEERING COMMITTEE**  
**34<sup>th</sup> meeting**  
**27-28 February and 2 March 2017**  
**Buenos Aires, Argentina**

**Minutes of the meeting**

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

The meeting was chaired by Dr. Michael Oehlsen, Director of Policy and Logistics, CVM International Affairs, FDA. He welcomed the participants and presented the apologies from Dr. Steven Solomon, the recently appointed Director of CVM, who was unable to attend this meeting on short notice.

Dr. Enrique Argento welcomed the participants to Argentina on behalf of CAMEVET. He mentioned that CAMEVET and the Argentinian delegation were extremely pleased and honoured that the VICH SC had accepted the invitation to organise these meetings for the first time in an Outreach Forum country.

The Secretariat indicated that apologies had been received from B. Martin - AHI and E. Oishi - JVPA.

**2. Adoption of the agenda**

The agenda was adopted with 3 changes: agenda item 11.1.2 will be discussed prior to item 11.1.1, item 12.1 will be included in item 8.5 and item 12.5.1 will be included in item 8.4.

**3. Report from the ad hoc WG on training implementation**

**3.1. Status report from the ad hoc WG**

FDA recalled that at the last SC meeting it had been acknowledged that the ad hoc WG would not be able to develop further training materials until sources of funding could be identified. Since then, the FDA has not been able to develop additional work due to a reduction of internal resources.

FDA confirmed however that it remained very committed to the implementation of training within VICH and would support alternative options that would be less expensive.

**3.2 Proposal for defining a procedure for the approval of VICH training documents**

The SC reviewed the Discussion Document prepared by IFAH-Europe and took note of the recommendation to give the EWGs the specific task of preparing suitable training materials relevant to each GL. Once the experts will have finalised the drafting of a GL, they could be

asked to prepare a simple Concept Paper detailing what training material would be appropriate in order to achieve a harmonised understanding of the GL.

This could be a reasonably straight forward approach going forward; however, for existing GLs, particularly as some EWGs have been disbanded, new experts would have to be identified who would be able to draft the training material.

The SC agreed that the organisation of face to face training events over several days is very difficult and costly. The SC confirmed that such training events must be specifically requested by the local organisations which will in any case have to provide a major part of the financing. The secretariat will pass the message at the 8<sup>th</sup> VOF meeting.

**Act: Secretariat (Done)**

IFAH-Europe pointed out that the ICH website contains specific training materials for many GLs, using a range of tools, such as presentations and “points to consider”. In addition, ICH works with many external organisations to deliver training events.

The APEC Harmonisation Center has set up an E-learning website to drive the harmonised implementation of ICH GLs through interactive e-training. Each module ends with a quiz to test acquired knowledge. After completion of all the modules of a set the student is awarded a certificate.

The SC agreed, in principle, that the EWGs are best placed for the development of training material, but the EU and FDA stated that they would need to discuss the proposal further with their experts in order to establish whether they would be willing to take on this additional task.

Instead the SC agreed to a proposed pilot exercise in which industry could develop training material to be vetted through an EWG. As such, IFAH-Europe agreed to lead the development of training material for the bioequivalence GL 54 with the bioequivalence EWG.

**Act: IFAH-Europe/Bioeq EWG**

All SC members, including the EU and FDA, agreed to ask their experts to review the material that will be proposed by industry for this pilot. The point was made that the EWG has not been active for some time and consequently some of the experts within the EWG may no longer be able to participate. The draft material should therefore also be circulated to the SC members, in order to ensure that appropriate experts are identified to review the material.

**Act: All**

The SC will review the outcome of this pilot test at the next meeting and decide on a pathway forward.

**Act: Next SC meeting**

Meanwhile, the ad hoc training WG was put on hold until the next steps have been clarified.

The SC discussed if more general training documents on regulatory convergence from recent workshops (New Delhi – November 2016) should also be placed for informational purposes on the VICH website. As these do not focus on specific VICH guidelines, it was proposed to add a section for “topics of general interest”, separate from the specific VICH training materials.

**Act: Secretariat**

JMAFF mentioned that following the request from ASEAN to VICH, they have accepted to provide 2 experts for a training session on TABST and a session on AMR to be held in Brunei on 25 & 26 April back to back with the 4<sup>th</sup> ASEAN National Focal Point for Veterinary Products (ANFPVP) Meeting. JMAFF also pointed out that face to face training is effective and important for propagating the VICH principle and GLs, especially to the regions where internet

environment is still poor. JMAFF will circulate the presentations and asked all SC members to assist in the finalisation of this training material by providing comments and suggestions.

**Act: All**

JMAFF mentioned further that the planned session in Brunei will cover 1,5 days, and therefore proposed to add other topics of training such as AMR monitoring, antimicrobial usage and control of AMR.

The SC agreed.

*Post meeting note: the training was finally reduced to a half day due to the tight scheduling of the ANFPVP meeting. The attendees requested to receive a VICH training also at the next meeting in Cambodia in April 2018. JMAFF replied that it could be possible, provided the cost is covered by the ASEAN Member States.*

### **3.3 Proposal for defining a procedure for the approval of VICH training documents**

The SC reviewed the document presented by the EU.

Although it was recognised that the proposal diverged from the previous discussion, it would nevertheless cover the availability of ad hoc material that would be provided from sources other than the EWGs.

If it will be decided that the EWG should develop training material, the working process should be identical to the process used for the development of the GLs.

The EU recommended that any materials that had not been thoroughly reviewed by all VICH delegations should include a disclaimer stating this to be the case.

The SC supported the document presented by the EU and agreed that it should become a VICH guidance document.

Regarding timelines for approval of documents by the SC, it was decided that no response within a specific timeline for a proposed document should be considered a silent approval (implied consent). If necessary, SC members can request an extension of the proposed timeline for review.

The SC confirmed that the meeting in Brunei will serve as a trial for the development of VICH training material, which could be further used as an electronic training material.

### **3.4 Proposal for a training module on quality**

The SC took note that FDA would not be able to commit to the further development of the module as explained previously at the 33<sup>rd</sup> SC meeting.

## **4. VICH Outreach Forum**

### **4.1 Preparation for the 8<sup>th</sup> VICH Outreach Forum meeting**

#### **4.1.1 Review of the participants list**

The SC reviewed the participants list of the 8<sup>th</sup> VOF meeting and noted the key countries and organisations that will be present and absent.

The Secretariat indicated that a new person from Morocco and a new delegation from Nigeria was expected (Nigeria *in fine* did not attend).

#### **4.1.2 Review of the agenda and preparation of the 8<sup>th</sup> meeting**

The SC reviewed the agenda and agreed to change the setup of the second breakout session by organising the discussion in a single group. The first breakout session would remain split as two groups.

## **4.2 Review of the Outcome of the 8<sup>th</sup> VICH Outreach Forum meeting**

The SC addressed this agenda item after the 8<sup>th</sup> VOF meeting and regretted that only 6 countries and 1 regional association were able to attend.

### ***A/ Set-up of the discussion sessions***

Two different approaches were discussed:

1. on Day 1, the usual breakout in small groups with the definition of discussion topics and subsequent report back to the plenary;
2. and on Day 2, the discussion continued in the plenary with introductory presentations followed by a tour de table reply round for each set of questions.

The final discussion at the end of this meeting showed that there is no clear preference for option 1 or option 2: some delegates prefer 1 because of a more direct communication with the other VOF members, but they need to report to the plenary, and some information may get lost.

It was suggested that more time be given to the groups to prepare their reports with a summary provided on 1-2 slides.

The SC noted that in option 2 the information exchange is complete and comprehensive, but the dialogue and exchange is difficult to maintain between the VOF members; it may become even more difficult if 12 delegations are attending the session.

It was acknowledged that option 2 necessitates more expertise to drive the discussion and may require a professional facilitator, as was the case at the New Delhi conference in November 2016.

It was nevertheless agreed that the discussion in larger groups is useful; it may be helpful to provide the questions 1-2 weeks ahead of the meeting and to allocate more time to facilitate discussion between the individual VOF members.

The SC recognised also that some individuals may be more comfortable in smaller group discussions.

In conclusion, the SC decided to maintain both options for the discussions at the next VOF, but VOF members will be asked in advance to prepare the replies to the questions.

### ***B/ Topics for the 9<sup>th</sup> VOF agenda***

OIE summarised the topics suggested by the participants:

#### *1/ Regional organisation and collaborating systems*

- Presentation by CAMEVET, GCC, ASEAN, West African Economic and Monetary Union (WAMEU), SADC
- Collaboration between observers or VICH SC
- Then small group discussion how collaborations could be developed, what are the pros and cons, ...

IFAH-Europe pointed out that on the human side, the regional organisations are ahead of the vet side. In Africa, for example, a pan-African human pharma regulatory system is already being developed

It was suggested to identify a speaker who could present the situation on the human side at the next VOF.

**Act: IFAH-Europe**

## 2/ AMR

- GL27 (request from Argentina)
- Presentation proposed by Ukraine: discussion document for a new GL on AMR
- Presentation by OIE of the global data base on use of AM (request from Thailand)
- Alternative to AM (request from Thailand)

JMAFF agreed to prepare a topic on surveillance connected to efficacy, as AMR leads to reduced efficacy of products.

It was noted that VOF members are asking for presentations explaining how a GL is used rather than explaining the GL itself, so JMAFF may also explain how GL 27 is used in Japan.

**Act: JMAFF**

## 3/ Acute Reference Dose

- Different approach on management of injection site residues

The SC acknowledged that the VICH regions do not have a harmonised approach for dealing with injection site residues and consequently it is difficult to see what guidance it can offer on this topic. The relevance of the VICH acute reference dose GL for the evaluation of injection site residues is linked to the approach taken for consumer exposure modelling, and there is not currently a harmonised approach to consumer modelling across the VICH regions.

It was therefore agreed to postpone this topic.

## 4/ Pharmacovigilance

- Global electronic systems (request from several VOF countries including Thailand and Ukraine)
- Sharing the PhV data ...

VOF members are at different stages of implementing pharmacovigilance programs. It was noted that some VOF members are asking for a global database, whereas the VICH recommendations are still far from this objective.

The chair of the PhV EWG suggested exploring the needs of the VOF countries.

The SC agreed this discussion would take place at the next SC meeting and be a discussion topic for the VICH 6 Conference.

**Act: next SC meeting**

## 5/ Vaccines

- Different ways from VICH SC member to register vaccines (request from SFDA)
- Vaccines stability (request from Morocco & BRA)
- Immunogenicity studies (request from Brazil)
- Proposal to come from Argentina ...

The EU suggested to limit the discussions to topics where specific VICH GLs already exist; VICH has so far developed 7 GLs on biologicals.

JMAFF proposed to present the VICH approach to safety studies for vaccines: the 3Rs and reduction of animal testing.

USDA agreed to prepare a presentation on the general approach to the regulation of vaccines.

**Act: JMAFF/USDA**

## 6/ General

JMAFF also proposed to report on the outcome of the training session in Brunei.

**Act: JMAFF**

## C/ Attendance

Except for Argentina and Brazil, no other country from Latin America attended, even though the meeting was organised in their region. It was acknowledged that all efforts deployed by CAMEVET to bring Mexico to the table had been fruitless so far. Uruguay, initially interested, had not followed up either.

The delegate from Nigeria who had been very enthusiastic to join the VOF, encountered a last-minute problem and was unable to travel.

South Africa explained that for some regulators the invitations were received too late for budget preparation.

The SC therefore asked the Secretariat to send simultaneously the invitations for the 3 next VOF meetings concurrently, as the dates have already been fixed.

**Act: Secretariat**

The SC regretted the absence of 3 of the 4 BRIC countries, and asked OIE to increase the contact with these countries to encourage their attendance.

OIE replied that after all VICH meetings (SC and VOF) a summary letter and an invitation letter (for VOF Countries) are regularly sent to the CVOs and OIE focal points. Moreover, the OIE French collaborating centre distributes the information through the local "attachés agricoles" in the French embassies.

It was suggested that a letter signed by the regulators from the 3 VICH members be sent by VICH to the heads of agencies of the BRIC countries (except Brazil).

JMAFF and FDA will submit their ideas to their respective management.

**Act: FDA/JMAFF**

## **5. Preparation of the VICH 6 Conference**

The SC received the presentation made by South Africa (link) and reviewed the first draft of the programme that was proposed.

It was agreed that the Conference should highlight the advantages of a regional harmonisation process.

South Africa noted several proposed amendments and asked all SC members to provide further input and proposals, with copy to the Secretariat, by Wednesday 31<sup>st</sup> May.

**Act: All**

South Africa will circulate a revised/updated draft before the summer break for further discussion.

**Act: SA**

## **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 Information from the EU on the delay of implementation of PhV GLs 35 & 42**

At the last SC meeting, the EU had reported difficulties in implementing Pharmacovigilance GL 35 and partly GL 42, due to resource issues relating to development of the required IT systems. The EU stated that resource had now been identified and it is hopeful that these GLs will be implemented in the EU by the end of 2018.

##### **6.1.1.2 Report from other regions**

JMAFF reported that the implementation of GL 52 is on schedule. Japan has increased its efforts to implement the Pharmacovigilance GLs, but has had some difficulty with the translation of the documents that has subsequently created further delays. Japan hopes to implement these GLs before November 2017.

FDA reported that the implementation of GL 54 has been delayed, but the implementation process has begun.

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

Australia reported that the project to adopt the remaining GLs (biologicals' and PhV GLs) has been reactivated. The aim is to adopt all VICH GLs within the next 12 to 18 months, but there may be points of difference with the Australian versions which will be highlighted on the agency's website.

New Zealand has focussed on the review of its internal processes so the VICH GLs' adoption was put on hold. New Zealand hopes to revisit the implementation of VICH GLs in the near future.

South Africa is reviewing the comments received on the VICH GLs in the first phase of adoption. The second phase will cover the efficacy and PhV GLs.

Canada has also delayed the implementation of the PhV GLs, but processes are being put in place for implementation of these GLs.

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

None

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

The SC took note of the written report on the status of comments for GL 56.

FDA confirmed that the consultation has started on 5 January and all comments are expected by 6 March.

## **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**

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. The SC took note of the GLs highlighted in red that are due for review and acknowledged that the GLs highlighted in blue should be addressed as well.

The SC asked that the date of the last review should be added in the last column of the table together with the region/country that was the topic leader (*with the help of a student*).

**Act: Secretariat**

The Secretariat reminded the participants that the VICH process is very flexible so that, besides the systematic monitoring of the VICH GLs, the VICH process provides that any

delegation may at any time present a formal proposal (usually a Concept Paper) to the SC recommending the review of a GL.

The Secretariat was confident that the past has shown that when there is an urgent need to review a GL because of difficulties that appear in the implementation phase, or because of a scientific evolution, there is a rapid consensus to revise the document.

The SC reviewed the document prepared by the Secretariat "Revised Methodology for a systematic Review of the VICH Guidelines at step 9" (VICH/17/007) and agreed that this should become a VICH guidance document, replacing the document "Methodology for a systematic Review of the VICH Guidelines at step 9" (VICH/07/039-Final) which was deemed obsolete and should be removed from the list of VICH guidance documents.

FDA suggested incorporating the document from 2005 "Monitoring and Maintenance of existing VICH Guidelines" (VICH/IN/05/017-FIN-Rev) into the new document as a unique guidance document.

The Secretariat will prepare a proposal for adoption at the next meeting.

**Act: Secretariat**

**- EU recommendations on need for revision of 6 Quality VICH GLs**

The SC took note of the document prepared by the EU and agreed that none of the 6 Quality VICH guidelines required revision/updates at the current time for scientific or regulatory reasons. Furthermore, it was noted that the guidelines are more or less equivalent to ICH guidelines and that it was desirable not to deviate from that similarity unless there are sufficient reasons to do so.

**- EU recommendations on need for revision of VICH Safety GLs: GL33, GL37 and GL28**

The SC reviewed the document prepared by the EU, which identified aspects of each of these guidelines that could be further discussed by the EWG, with a view to determining whether revisions are needed. However, the point was made that the Safety EWG has already several topics in discussion. Overall, the SC considered that there is not a pressing need to revise these GLs at this stage. As always, if a delegation considers that a revision is needed, it is free to come forward with a Concept Paper (CP) detailing the scope of the proposed revision.

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

The EU mentioned that JECFA has produced a draft GL on acute reference dose which has been published for consultation, and recommended to consider the review of VICH GL 54 once the JECFA GL has been finalised. The SC agreed.

**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.

The second draft of the GL on "Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV" is currently being reviewed by the EWG and the work is progressing well. A teleconference is planned in March 2017, to enable the experts to reach a rapid agreement.



## 8.2. Electronic Standards Implementation – Pharmacovigilance

The chair of the Expert Working Group, Dr. Linda Walter-Grimm (replacing Dr. M. Brown who retired recently) reported the following main topics:

- The procedure in annex of GL 30 has been placed on the VICH website;
- The first major GL 30 vocabulary changes have also been placed on the website, and FDA CVM will implement these changes shortly;
- The standardised technology xml messages are under discussion;
- the EWG is monitoring the work of ICH on its harmonised products dictionary and will evaluate if VICH could benefit from these changes;
- After 2 rounds of comments on the industry paper on disharmonisation, the EWG has collated the outcome on an excel sheet.

The EU recommended that when discussing the disharmonisation issues, the EWG should precisely identify which topic in which GL would potentially need to be reviewed.

The SC agreed that the EWG should develop a CP outlining the scope of the areas that would require changes, and in which GL, and which solutions could be proposed.

The EWG should also provide an impact analysis for the proposed changes.

IFAH-Europe indicated that Industry has proposed solutions for 11 of the disharmonisation areas; only 1 area (the seriousness criteria) will require more discussions. In the same document, industry has already provided some impact analysis.

## 8.3. Biologicals Quality Monitoring

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

### *a. Harmonisation of criteria to waive Target Animal Batch Safety Testing for live vaccines for veterinary use*

Comments have been received on both revised VICH GL50 (TABST inactivated vaccines) and draft VICH GL55 (TABST live vaccines) which have been circulated to the EWG following the end of the public consultation. Both GLs are under final discussion and the experts should sign-off shortly both GLs at step 5.

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

The first draft document was circulated by the EU topic leader in the week prior to the SC meeting.

### *c. Extraneous agents testing for Biologicals extraneous viruses testing*

JMAFF explained that following approval of the CP at the last SC, the topic leader has provided a first draft for 2 GLs (GL on general principles for detection of extraneous viruses in veterinary vaccines and defining the testing of seeds and materials of animal origin, and GL on a list of extraneous viruses that need to be covered). Comments from EWG members have yet to be circulated. In relation to the GL on the use of cell cultures for the detection of extraneous viruses, as agreed, the EU had provided a shortened version of the GL. All parties, except the EU, agreed that the level of detail in the new draft GL was insufficient and had expressed a preference to go back to the more detailed original version as a starting point. There was therefore disagreement within the EWG on which version to use as the starting point for further development of the GL.

IFAH-Europe recalled that the previous, more detailed GL had been well advanced and that most members of the EWG considered that there were only a relatively small number of points that still needed to be resolved.

The participants reviewed the response provided by the EU, and took note of the EU's willingness to move forward and to seek a compromise. The EU acknowledged that the GL may need to be more detailed but did however not want to go back to the previous version of the draft GL. The EU suggested an extension to the timeline in order to allow its experts to further reflect on the additional detail that could be included in the draft GL.

IFAH-Europe, as the topic leader, expressed its strong concerns regarding the argumentation detailed in the reply from the EU, as well as the proposal to extend the timeline, considering that the topic has already been discussed for numerous years.

As an alternative, IFAH-Europe was considering whether it should take back the rapporteur role in order to prepare a new draft GL.

The EU agreed under the condition that the topic leader will not re-develop the previous more detailed draft of the GL.

JMAFF and USDA stressed that the EWG members need to understand which issues are not acceptable to the EU in the initial longer version of the draft GL.

The EU reminded the SC that it had provided written comments on the detailed GL in 2012. However, in order to clarify the situation, the EU agreed to ask its experts to look again at its previous comments with a view to clarifying its concerns over the previous more detailed version of the GL.

**Act: EU**

#### **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 acknowledged that draft GL 56 - MRK: Residues in Honey is in the public consultation procedure at step 4.

*b. Draft GL on Aquatic products*

The topic leader has initiated a last round of consultation on the most recent draft. This document should then be circulated for final comments and adoption at Step 2 to the MRK EWG.

*c. Potential revision of GL 49*

Several comments have been received from stakeholders, highlighting difficulties encountered in reproducing the results in annex 3 of the GL. The Chair of the EWG therefore provided a CP proposing to review the annex of the GL while also taking the opportunity to update any other aspects of the GL, as needed. Other delegations supported the correction of the annex, but noted that "general review" was too vague and therefore could not be supported without more details of what might be changed.

IFAH-Europe indicated that the scope of any revisions need to be identified in the CP. While it supported the need to update the GL to address issues raised by stakeholders, it was not comfortable with the idea that any aspect of the GL could be revised. The SC therefore agreed that the EWG should only be given a mandate to revise those parts of the GL that have caused difficulties for stakeholders. If, during its review, the EWG identifies other areas

of the GL that are also in need of revision, then it can present a further CP to the SC detailing the scope of the additional revisions proposed.

The EU explained that a new topic leader/analytical expert will need to be identified as the initial topic leader is no longer part of the group.

AHI agreed to nominate a new topic leader.

**Act: AHI**

The SC decided that each expert will be authorised to call upon 1 advisor; the SC member must report the name of the advisor to the Secretariat in order to keep the list up to date.

**Act: All**

The Secretariat reminded the participants that the advisors are not authorised to sign-off the documents.

It was noted that several delegations could not accept the open statement in the CP “the opportunity should be taken for a general review and update of the GL to reflect consistent and up-to-date analytical practice” as it was not transparent what would be changed. It was agreed that provided the rejection of this statement was recorded, then there is no need to amend the CP to remove it.

The review of the GL must be limited to addressing specific issues raised by the stakeholders and in particular the example calculation given in annex 3. If any other corrections are proposed, they must be clearly identified in an updated CP first and approved by the SC.

### **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 acknowledged that the EWG is close to an agreement on the proposed revision.

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

FDA explained that discussions are progressing well and the EWG will provide a CP with a recommendation to the SC. A key question remains whether to approach the harmonised requirement to provide reproduction toxicity data (1) based on the results of a multi-generation (two-generation) study, with an option to use a one-generation study if justified, or (2) whether to start with the requirement of the one-generation study, with an option of requiring a multi-generation assay if needed.

### **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 took note of the 3 topic groups for revision as well as the revised workplan that was proposed.

The SC reviewed the proposed draft agenda and confirmed the authorisation of a face to face meeting, to be organised in July 2017. The SC recommended that the EWG should extend the meeting to 3 days.

The SC authorised the experts to invite 1 or more statisticians to the meeting as advisors; the SC members must report the name of the advisor to the Secretariat.

**Act: All**

### **8.7. Bioequivalence EWG**

No report was expected from this EWG which is waiting for its next task. It was recalled that under item 3.2 the SC had agreed that the industry member of the EWG will develop training material as pilot for the new approach to developing training materials described in the training discussion document from IFAH-Europe. The SC has decided previously that the EWG should remain dormant until the topic of biowaivers is revived, but FDA asked if the EWG should be disbanded, IFAH-Europe however recommended that the EWG be maintained for the time being so it can review the training material prepared by industry, but agreed that the group could be disbanded once the training material pilot was complete. The SC agreed and will review the future of this EWG at the next 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. Progress Reports of the Task Forces and decision on next steps**

##### **11.1 Task Force for the development of a General Combination GL**

###### **11.1.1 Feedback from VOF members on the Draft Concept Paper for a General Combination products guideline**

JMAFF reported that comments have been received from Nigeria & Argentina.

###### **11.1.2 Progress report of the Task Force**

The SC reviewed the progress report prepared by the TF and acknowledged that the comments, mostly minor, have been summarised in the last version of the CP. IFAH-Europe proposed to add a sentence in order to clarify that, although the GL will not address issues of particular relevance to combinations of antimicrobials (as there is a desire to avoid encouraging antimicrobial combinations that could be inconsistent with prudent use principles), this does not preclude future innovations or combinations of an antibiotic with another substance that are consistent with prudent use.

The SC supported the proposal and adopted the CP, and asked JMAFF to circulate the final version.

**Act: JMAFF**

The SC decided to create a new EWG for combination product GLs and agreed that the chairman should be Dr. Xu from China, as suggested at the last SC meeting. However, because of China's absence at the current VOF meeting, the SC asked the Secretariat to write formally to China to ask him to accept the leadership of the new EWG.

**Act: Secretariat**

The Secretariat will send a call for experts to the SC and members of the VOF.

**Act: Secretariat**

The SC nominated Dr. Crystal Groesbeck (FDA) as topic leader for the general GL on pharmaceutical combination products.

The SC acknowledged that the objective of the EWG will be to provide a step 2 document in February 2019.

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

### **12.1 Recommendation from the Safety EWG on a revision or not of the VICH GL 22 by including extended 1-generation reproduction study**

Covered under 8.5.

### **12.2 Discussion on the next steps in the global approach to demonstrate Bioequivalence**

Covered under 8.7

### **12.3 Discussion Document on the definition of “biologics” generally being used by the regulatory authorities, etc... (VICH/IN/17013) & Taxonomy of “Biologics”**

JMAFF recalled that at the 33<sup>rd</sup> SC meeting, they had presented a background document with a taxonomy table, and had received several comments to the taxonomy proposed. The SC reviewed and adopted the updated taxonomy table per the comments received. The Secretariat will formalise the document under the VICH heading with number version 2.

**Act: Secretariat**

The SC confirmed that “this document is informal and internal, not relating to any regulatory framework of any region” and that it will remain an internal document that can evolve over time.

### **12.4 Draft Concept Paper on the Guideline for safety evaluation of biotechnology-derived/Biological products**

JMAFF reminded the participants that since the 30<sup>th</sup> SC meeting in June 2014, the SC has been discussing the development of VICH Biotechnology-derived/Biological products GLs (Bio-tech GLs).

The SC reviewed a preliminary draft of a CP prepared by JMAFF in which it proposed development of a GL for the safety evaluation of biotechnology-derived/biological products, which could take not of the ICH GL Bio-tech GL S6 (R1) “Preclinical safety evaluation of Bio-tech pharmaceuticals”, but which would be adapted to the needs of the veterinary field. JMAFF acknowledged that the scope of the preliminary draft is too wide and that, if a GL is to be developed, the scope should be much narrower.

The EU and AHI also recommended clarity needs to be provided in relation to what is meant by the term ‘safety’ (consumer safety, target animal safety, environmental safety, user safety). This should help to prevent any confusion and enable the VICH members to properly identify the appropriate subject matter experts.

USDA explained that there would be an overlap with FDA in the USA for many products that are considered pharmaceuticals.

JVPA confirmed its support for a new VICH GL as new legislation was recently established in Japan that covers biotechnology derived products including regenerative medicinal products.

The SC agreed that JMAFF should further develop the CP, but start with the type of products of which the SC members have some experience regarding the safety evaluation, e.g. monoclonal antibody products.

All members should send further comments to JMAFF by 31<sup>st</sup> May.

**Act: All**

JMAFF will then develop a new version of the preliminary CP before next SC meeting for further discussion.

**Act: JMAFF**

## **12.5 Other VICH topics**

### **12.5.1. Draft Concept Paper for the review of VICH GL49 (MRK: Method used in Residue Depletion Studies)**

Covered under item 8.4

## **14. Other issues**

None

## **15. Any other business**

None

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

- The 35<sup>th</sup> SC meeting will take place in Tokyo – Japan from 13 to 16 November 2017
- The 36<sup>th</sup> SC meeting will take place in Belgium - Europe from 25 to 28 June 2018 - location TBD
- The 37<sup>th</sup> SC meeting will take place in Cape Town – South Africa from 3 to 8 February 2019

## **17. Adoption of the Press Release on the 34<sup>th</sup> SC meeting**

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

## VICH STEERING COMMITTEE

### 34<sup>th</sup> meeting

27 - 28 February & 2 March 2017  
Buenos Aires (Argentina)

Chair: M. Oehlsen (FDA/CVM)

### LIST OF PARTICIPANTS

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

AHI (ZOETIS)	M. J. MCGOWAN
AHI	K. KLAUS (C)
EU (EUROPEAN COMMISSION)	N. JOSEPH
EU (EMA-CVMP)	D. MURPHY
EU (EMA)	N. JARRETT (C)
IFAH-Europe (MERIAL)	B. BOENISCH
IFAH-Europe (ELANCO)	E. DE RIDDER
IFAH-Europe	R. CLAYTON (C)
JMAFF	Y. ENDO
JMAFF	K. NODA
JMAFF	T. KOZASA (C)
JVPA (NIPPON ZENYAKU KOGYO CO.)	I. ABE
JVPA	H. MAKIE (C)
US (FDA)	B. WALTERS
US (USDA APHIS)	B.E. RIPPKE
US (FDA)	B. ROBINSON (C)

#### **OBSERVERS**

Australia (APVMA)	M. O'MULLANE
Australia (AMA)	B. STAPLEY
Canada (Health Canada)	M-J. IRELAND
Canada (CAHI)	J. SZKOTNICKI
New Zealand (MPI)	W. HUGHES
New Zealand (AGCARM)	M. ROSS
South Africa (DAFF)	A. SIGOBODHLA
South Africa (SAAHA – BAYER)	E. SCHAY

#### **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**

AHI (BAYER)	B. MARTIN
JVPA (KYOTO BIKEN LABORATORIES)	E. OISHI