VICH/18032
28 September 2018
Final

VICH STEERING COMMITTEE
36th meeting
25, 26 and 28 June 2018
Bruges, Belgium

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr. Isaura Duarte, Head of the Veterinary Medicines Department (*ad interim*) at the European Medicines Agency. She welcomed the participants to the nice and sunny city of Bruges in Belgium.

The Secretariat indicated that apologies had been received from I. Abe – JVPA and M. Ross – AGCARM.

2. Adoption of the agenda

The agenda was adopted with 2 changes: agenda item 11.4 to be discussed in item 5, and a topic was added as item 5.1.3 – Invitation of additional countries as observers.

3. VICH 6 Conference

3.1. Review of the draft programme

The participants reviewed the latest draft that was tabled at the meeting and adopted several changes that were proposed in the discussions.

3.2. Presentation of the VICH 6 Website - Advertisement and invitations

South Africa presented the latest iteration of the website, which went active prior to the presentation. The OIE confirmed that it will broadly invite Member Countries to attend the Conference with special focus of active contributions of the representatives of the African Region. It was also proposed to use the contact lists from the GAHC - Global Animal Health Conferences and from GALVmed to ensure that as many people as possible are contacted. There will be a registration fee for participants. VICH SC members and VOF members will receive a discount code, which is connected to an individual member's e-mail address. The SC agreed that VICH 6 speakers will not be required to pay the registration fee.

3.3. Organisational and logistical matters for the Conference

South Africa encouraged all Steering Committee (SC) members to return their accommodations booking form as soon as possible following receipt from the VICH Secretariat.

It was noted that most speakers had been confirmed, and South Africa will ensure confirmation from those who were still unsure.

4. VICH Training Implementation

4.1. Review and approval of the module (including the comments below) on Bioequivalence GL 52 prepared by industry

AnimalhealthEurope explained that comments had been received recently from the EU and FDA, which have been considered in the last draft.
FDA confirmed that a speaker would link into the VICH Outreach Forum (VOF) meeting for a WebEx presentation and would give the presentation incorporating some minor editorial/ formatting changes. The presentation would be recorded and will be placed as training material on the VICH website.

After the VOF meeting, the SC agreed to release the version of the slides that were presented as training material, together with the audio recording if possible.
FDA will provide the material to the Secretariat.

Act: FDA

4.2 Determination of a priority list for further material to be placed on the VICH website – Development of additional training material

AnimalhealthEurope recalled that the priority list was based on the outcome of the OIE survey with the VOF members made in 2015 & 2016; the top priorities had been Quality, Safety and Pharmacovigilance (PhV) Guidelines. AnimalhealthEurope has therefore already drafted presentations for 8 quality GLs.
JMAFF & JVPA have volunteered to develop material on the Metabolism and Residue Kinetics (MRK) GLS 48 & 57 and biologicals GLs 50R & 55, whilst AHI will address the PhV GLs 24 & 29. The SC agreed that the other PhV GLs are not suitable for training material because the first round of training should be limited to the basic GLs.
All draft training material will be shared with the SC members for approval before being placed on the VICH website training section.
Regarding other GLs not included in the current list, AHI volunteered to draft material on food safety and toxicology GLs and the EU agreed to draft a presentation on GL9 on Good Clinical Practices. AnimalhealthEurope noted that FEDESA had produced a GCP booklet in 2001 and perhaps this text can be up-cycled.

It was noted that WHO has much training material available on ICH GLs, especially as Q&As, which could be relevant for VICH guidelines, but this material should be reviewed by VICH experts before being proposed as VICH training material.
The SC therefore agreed that each VICH member organisation responsible for developing training materials would review the WHO material to see if this could be used or adapted.

All SC members will be given the opportunity to comment on draft training materials before these are finalised. As there are quite a number of training presentations under development it was agreed that requests for comments would be staggered.

Act: All

4.3 Report from the VICH Workshop - 5th AESAN NFPVPs meeting – Cambodia

R. Clayton recalled that ASEAN had provided the request for a VICH workshop just 1 month before the meeting date, which was too late for a coordinated response and organisation from VICH SC. Moreover, no funding was made available by ASEAN. HealthforAnimals had therefore

agreed to send a representative to the ASEAN workshop for a basic introduction to VICH and a discussion on how to organise future training events.
The SC reviewed the report of the workshop and acknowledged the importance of the introduction to VICH, as it appears that few workshop participants had received much information on VICH beforehand.
R. Clayton explained that the questions in the brainstorming session (and listed in his report) had enabled all participants to express their views and concerns. It was agreed that these could become the basis for a Q&A document on the VICH website.
JMAFF recommended to include the introduction to VICH in all training material on VICH GLs.
Regarding the 9 questions that the participants posed during the session on pharmacovigilance (also listed in the training report), it was suggested that these, along with appropriate replies, could also be developed into a useful Q&A training document for inclusion on the VICH website.
AnimalhealthEurope will follow up with the SC.

Act: AnimalhealthEurope

4.4 VICH website update

R. Clayton recalled that the current website had been designed 5 years ago, and therefore required refreshing and updating.
The SC reviewed the new features and design, and thanked HealthforAnimals for having also translated the website into French & Spanish.
R. Clayton agreed to circulate a link to the staging site.

Act: R. Clayton

5. VICH Outreach Forum

5.1 Preparation for the 10th VICH Outreach Forum meeting

5.1.1 Review of the participants list

The SC reviewed the participants list of the 10th VOF meeting and noted that several countries such as Argentina, Mexico or Russia had not sent a representative. CAMEVET had indicated that the Brazil representatives would also represent CAMEVET at this meeting.

5.1.2 Review of the agenda and preparation of the 10th meeting

The SC decided to reorganise the agenda of the VOF meeting in order to accommodate the WebEx presentation on the Bioequivalence GL by FDA on Wednesday afternoon, and to cancel the update on the combination products GL Expert Working Group (EWG) activities because of the absence of Dr Xu.

JMAFF suggested some changes to the Terms of Reference (TORs) for the VOF, but OIE recommended to focus the debate on the scope of VICH (VOF agenda point 8 - Scope and missions of VICH & the VOF).
It was agreed that although the VOF discussions should address VICH matters only, the scope of the discussions in the VOF meetings can be more flexible to include the broader regulatory context in which the VICH guidelines are used.

5.1.3 Invitation as observers

AnimalhealthEurope suggested to invite the BRIC countries, the largest growing market economies as guests to a SC meeting. The SC discussed the intentions, goals and implications of such an invite, and the signal it sends, and recognised that further reflection is needed to clarify medium to long-term expectations of the SC.

AnimalhealthEurope suggested inviting Brazil and the People's Republic of China as guests of a future SC meeting to provide them with the opportunity for an in-depth conversation with the SC on their future intentions regarding the VICH GLs

Meanwhile, the SC agreed to first invite Russia formally to report at the next VOF meeting on the evolution of their regulatory framework to align it with the international requirements.

Act: Secretariat

The Secretariat indicated that Zambia had just made a formal request to become a VOF member and has been asked to provide the usual information on the status of the local regulatory framework.
Moreover, in the frame of the VOF meeting, the CVO of Taiwan has asked orally to become a SC observer member. The Secretariat recommended this request is provided in writing.

5.2 Discussion of the Outcome of the 10th VICH Outreach Forum meeting

A/ General discussion

The SC addressed this agenda item after the 10th VOF meeting and noted that all VOF participants had actively contributed to the different discussions.
The OIE summarised the outcome of the discussions:

1/ VOF expectations

- EWG to report to VOF

A point raised by the VOF was that they should be given more information on ongoing work of EWGs. The EWG progress reports could be provided but it was recognised that these are very brief and cannot be delivered without additional explanations on the ongoing work.
The SC agreed that a very brief update on the ongoing activities of each EWG could be provided in a couple of bullet points. The SC member which has the leadership of the EWG should provide the bullet points to the Secretariat prior to each VOF meeting.
The FDA supported this proposal but warned that the EWG chairs & members would need more guidance on what is expected.

Act: All

Based on discussion, VICH SC members brainstormed additional actions to further engage VOF members:

- Report on the proposed international forum of regulators of VMPs
- Rotation system for chairing sub-sections of the meetings

The SC agreed to propose this initiative to the VOF members; the OIE will ask for volunteers when circulating the first draft agenda.

Act: OIE

- Invite VOF country to present their local regulatory system

As the new members do not have the information from the other members, it could be suggested to periodically repeat these presentations.

- More in-depth treatment of specific topics, more profound discussions

The SC agreed that at least 1 specific topic could be addressed in depth per forum.
The topics for the 11th VOF will be anthelmintics to be addressed with similar level of detail as provided for the Bioequivalence GL training slides.

- Prior exchange of presentations with specific questions to allow VOF members to prepare
- Updates of implementation by VOF members with more focus as well on difficulties encountered with implementation, exchange of experience
- Suggestion to allow side-meetings with countries united in a common interest and/or workshops with experts (as happens in CAMEVET)
- Invite local industry to VOF meetings in order to get more support

The SC agreed that outreach members can invite their industry as long as there would be 1 industry for 1 regulatory representative and that this should be reflected in the TORs.
The Secretariat mentioned however that industry from VOF countries has been invited 2 times in the past without much reaction.

AHI suggested that VOF members could have a "WG meeting" on their own in parallel to the SC meeting, then report their outcome to the SC.
They could also hold a teleconference between the VOF meetings.

AnimalhealthEurope proposed more training programmes that can be delivered by WebEx meetings should be developed, which can be regionally focussed because of time differences.
The presentation on Bioequivalence was considered as an excellent example.
It was however pointed out that the VOF participants have different levels of development and all persons attending the VOF are not always the technical staff in the specific area.

2/ EWG participation

- Expectations to express the situation in their own country, problems faced in the countries, to seek solutions and to standardise them
- Circulation of the draft GLs to local experts (authority and industry); organisation of a meeting to discuss content

The OIE proposed to organise a breakout session on the topic of participation in EWGs.
For example, a VOF country could only be included in an EWG if it has adequate expertise in a particular domain. For the rest, the public consultation is more appropriate and should be highlighted.

- Eager to participate in a TF on medicated pre-mixes

The SC agreed that this topic would be included in the document to be prepared (see item 3 below), which will be keeping track of "out of scope" requests received, together with an explanation as to why the SC intends to move forward cautiously (see below).

- Have Q&As appended to GLs for further explanation

It had been proposed previously that the EWGs should provide some training documents when finalising a new GL, but not all VICH members could commit resources for additional work. So Q&As will be provided whenever possible.

- Interest in more participation in EWGs but need to use WebEx to save resources

3/ Ideas for how "out of VICH scope" topics could be addressed

It was agreed that the SC needs to explain to the VOF members why "out of VICH scope" topics cannot be taken forward within VICH. It was agreed that a running document detailing this information should be created. This could include advice where those topics have been discussed in the past and what other organisations might be qualified to take them forward (e.g. OIE …).
AnimalhealthEurope believed that in relation to many topics, the goal of many VOF members is not to develop a GL, but just to understand how the topic is regulated in VICH regions.
The EU pointed out that the legislation in place in different VICH regions differs and this impacts on what can be addressed by VICH and mentioned that it could not implement VICH GLs for products that are not regulated as veterinary drugs in the EU.
FDA recommended to explain to the VOF that some topics cannot be harmonised because of different regulatory requirements in the VICH countries and suggested to define the "out of scope topics" as all topics that are not technical requirements.
AnimalhealthEurope agreed to draft a first document listing what is out of scope, explaining why, and suggesting where these topics could possibly be discussed.

Act: AnimalhealthEurope

4/ Proposals for new GLs:

- Homeopathics, complements, supplements, probiotics – first applications being submitted to counteract AMR, GL would be useful
- Autogenous vaccines: Quality, Safety & Efficacy
- More and more innovative products being submitted, appropriate guidance not existing locally, so VOF members would appreciate help
- Abridged GLs for "grey" areas, emerging issues (e.g. GMP, antiparasitics, medicated feed)

The SC agreed that complements, supplements, probiotics etc. are not supported for harmonisation by VICH members for different reasons. The 'out of scope' paper will explain that these topics are not in the remit of VICH and that it is not the role of VICH to provide information or training on these. If possible, the paper will point to other sources of information & training that are available.
The VOF members will be reminded that when a new topic is proposed, the VICH procedure requires a Concept Paper, which must then be adopted by the SC before any GL can be developed.

B/ Proposed topics for the 11th VOF agenda

- Guidance on withdrawal period studies
- Safety GLs
- Premixes and medicated feed – Update on discussions at SC
- PhV: Practical aspects from industry perspective. Additionally, VOF members are interested in templates and further explanation of GLs
- System for updating viral strains in vaccines
- GL on anthelmintics (more detailed presentation)

Regarding the system for updating viral strains in vaccines, it was noted that this would need to be a presentation by region and USDA proposed not to take up the topic.
The main topic for the 11th VOF will be the Anthelmintics' GLs, using the same model as the Bioequivalence GL. Moreover, the SC decided that Pharmacovigilance should be discussed in depth as well. Withdrawal periods will be covered if the chairman of the EWG, Dr S. Scheid, attends the VICH 6 Conference.
AnimalhealthEurope will address the Quality topic and will circulate the draft training documents beforehand (see agenda point 4.2).

C/ Attendance

The SC noted the VOF had been attended by 14 VOF members from 11 countries, but regretted that Dr Xu (People's Republic of China) had 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

The EU recalled that the full implementation of the PhV GLs 35 and 42 in the EU was delayed pending development of the database. Progress on the development of the pharmacovigilance database is underway and it is hoped that the EU will be able to fully implement the guidelines by the end of 2019. However, the EU also highlighted that the move of the EMA to another location will have an impact on the Agency's resources, and that this might impact the development of the relevant database.

JMAFF confirmed that GLs 24 and 29 were implemented in Japan. JMAFF is doing its utmost to implement the 3 other PhV GLs as soon as possible and 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 explained that the PhV and Ecotox GLs have not been implemented yet, but discussions are ongoing with industry to decide which of the GLs will be implemented.

6.1.3 Any input from industry members

None

6.2 Status of consultation for draft GLs at Step 4

The SC took note that FDA needed an extension of the consultation period for GL 57 until the end of November.

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 mentioned that a column indicating the date of the last consideration of each GL has been added to the table. No GL is due to be reviewed at this time.

7.1.2 VICH Quality GL 18(R) on Residual Solvents - Proposal from the EU in relation to ongoing and future work

In view of the ongoing work in ICH, the EU proposed that the work on VICH GL 18 (2) is put on hold until the Revision 7 version of the ICH GL Q3C is finalised. The SC agreed.

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

None proposed.

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

7.2.1 Letter from WHO on the JECFA Guidance document for the establishment of Acute Reference Dose (ARfD) & consideration of the need to revise VICH GL 36 - Safety: microbiological ADI

The SC reviewed the letter from JECFA and noted that JECFA considered that a colon volume of 500 ml for the establishment of an ARfD would be more appropriate than the current value of 220 ml recommended in VICH GL 36.
It was noted that GL 36 already has sufficiently flexible wording to allow applicants to use a different colon volume, with justification, and a revision of GL 36 is not absolutely necessary.

Several other SC members indicated that they did not consider that a general review of the GL is needed. They recommended to only consider if the current value of 220 ml should remain in the GL or be changed to 500 ml.
The SC agreed that all SC members will ask their experts if they would support a change of the colon volume to 500 ml or not, for a final decision at the next SC meeting. A more general review of the GL was not supported at this time.

Act: All

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) will be signed-off for public consultation at step 4 during the meeting.
As indicated under agenda point 7.1, the SC agreed that the revision of VICH GL 18 is put on hold until the Revision 7 version of the ICH GL Q3C is finalised.

8.2. Electronic Standards Implementation – Pharmacovigilance

The chair of the Expert Working Group, Dr Linda Walter-Grimm, confirmed that the working group continued developing a draft Concept Paper (CP) (via teleconference and email circulation) to address the remaining areas of disharmonisation in veterinary pharmacovigilance. A new draft has been circulated, the challenge being the current process of legislation revision that is ongoing in the EU. One of the recommendations of the EWG will be to propose some short-term changes via a minor revision of VICH GL24 and to redefine expedited reporting broadly. Dr Linda Walter-Grimm pointed out that discussions need to continue regarding a long-term vision for harmonisation as pharmacovigilance evolves and regions incorporate additional tools such as signal detection.
She mentioned that the Canadian version of an electronic acknowledgement message (“ACK”), which serves as a “receipt” for an electronic adverse event message, was circulated for comment and only minor differences were identified with the EU acknowledgement messages; a consensus on the best approach should be reached in the EWG during Q4 2018.
Progress continues in the development of the global product dictionary using IDMP standards for human and veterinary medicinal products, and a list of data elements will be reviewed by the EWG in the near future.

The SC noted the need for new representatives from USDA, AHI, Australia and New Zealand.

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 Target Animal Batch Safety Testing for live vaccines for veterinary use
GLs 50 & 55 have been implemented in the USA and Japan.

b. Harmonisation of criteria to waive Batch Safety Testing for veterinary vaccines: Laboratory Animal Batch Safety Testing (LABST)
This 3rd draft of the GL, including all the comments received on the previous version, is being prepared and will be circulated within a few months.

c. Extraneous virus testing for Biologicals
JMAFF thanked the EU for the detailed comments (VICH/IN/18/002) to the JMAFF proposals that were presented at the last SC meeting and addressed the 3 following topics raised by the EU (see JMAFF written response VICH/IN/18/006).
Firstly, JMAFF considered that it was able address the concerns of the EU and reduce the scale of the task which will be required, by using a matrix to identify a shortlist of matched cell lines and known viruses.
Secondly, nothing would prevent the EU from using its own methodology. The SC could also ask the EWG to investigate the feasibility of wide testing methodologies by dividing the viruses in several common testing groups based on the EU classification.
Thirdly, JMAFF proposed to limit in the first stage the scope of the feasibility investigation to 3 major animal species: canine, bovine and porcine. Detection methods for emerging viruses such as HoBi and Seneca Valley viruses should also be discussed simultaneously.
JMAFF did not believe that the risk assessment approach that will be applicable in the EU could be extrapolated globally as virus contamination sometimes occurs beyond human knowledge and imagination.
USDA and the AVBC supported the proposal from JMAFF to widen the testing methodologies.

The EU thanked JMAFF for its work but indicated that it can still not support the proposed activity because the proposal is not consistent with the approach that the EU has committed itself to implement and cannot support the development of different approaches.

The SC nevertheless agreed that JMAFF would develop a CP to find a point of compromise for review at the next SC meeting.

Act: JMAFF

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. VICH GL 56 on Honey
GL 56 (MRK - Honey) will be signed-off by the SC for implementation at step 7 during this meeting.

b. Draft GL on Aquatic products
The consultation period for draft GL 57 has been prolonged until November 2018 in the USA.

c. Revision of GL 49
AHI has the topic leadership for the revision process of GL 49 which has been initiated beginning 2018 and the topic leader, Pamela Boner, is currently working on a revised version of the GL.

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 expert working group has collected and collated data on experience with the existing genetic toxicology battery as it may relate to the proposed tiered approach.
The SC acknowledged that the chairman has continued to collect comments from the experts on a modified proposal that had been circulated. A revised draft will be provided to the EWG for further consideration.

b) Revision of VICH GL 22
A CP is being developed which the members of the EWG could adopt for submission to the SC.

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 is progressing well although the experts have provided many comments & suggestions for revisions that are out of scope of the mandate given for the existing revisions. It is expected that progress will be achieved throughout the next months and that the revisions should be completed by the end of 2019.
The EWG is facing issues regarding the use of geometric means versus arithmetic means, because there is not enough expertise in statistics available within the current EWG membership. The EWG is therefore suggesting that each expert be accompanied by a statistical expert for the next teleconference of the EWG. The SC agreed.
The EU acknowledged that as the source of some of the “out of scope” comments, it will reflect further on whether there are issues that it considers should be addressed and that are not identified in the existing mandate. If necessary it will make a specific proposal for additional topics for the EWG to cover and bring this to the SC.

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 SC took note that the EWG is progressing well as a first draft document has already been circulated and commented upon, and a further revised complete draft will be circulated to the EWG during the summer.
FDA confirmed that the experts from the VOF countries are participating actively in the EWG activities.

8.8. Bioequivalence EWG

No report was expected from this EWG which had completed its work and FDA proposed to disband the EWG as had been previously agreed one the bioequivalence training was complete.
AnimalhealthEurope explained however that the hiatus is caused by the need for one delegation to re-assure itself of the underlying science on in vitro dissolution testing, and that industry strongly supports keeping the EWG active in order to address this topic of Biowaivers. Australia and South Africa also supported progressing on biowaivers.

FDA supported the development and consideration of a concept paper on the topic of Biowaivers, but stated that further research on *in-vitro* dissolution was required before taking a decision.
The SC agreed that AnimalhealthEurope, in close collaboration with Australia and South Africa, will develop a Concept Paper on biowaivers for review at the next meeting.
Meanwhile the SC decided to maintain the EWG.

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

9.1. Draft VICH GL 58 - Stability: Climatic Zones III and IV - Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV

The SC adopted the draft GL 58 at Step 3. This guideline was transmitted to the VICH and VOF members for a 6-month public consultation at Step 4.

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

10.1. Draft VICH GL 56 - MRK: Residues in Honey - Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Species: Study Design Recommendations for Residue Studies in Honey for establishing MRLs and Withdrawal Periods

The SC adopted GL 56 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 GL will enter into force by June 2019.

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

JMAFF recalled it stated that guidance for Biotechnology products represents a high strategic importance in the VICH Phase 4 2015 - 2020 priorities.
The SC reviewed the new version of the CP (complete version 1.0) including the comments that were received and proposed extended timelines in order to facilitate further reflection within the VICH organisations. JMAFF thanked AnimalhealthEurope for its supportive comment indicating that JMAFF's approach is in line with the EMA's Q&A on quality and safety for monoclonal antibody products published in Dec. 2017.
JMAFF indicated that once the CP is adopted the task could be allocated to the current safety EWG, although it probably does not have entirely the adequate expertise, or a new EWG could be created.
All SC members were asked to provide feedback from their organisations to JMAFF by end of November 2018.

Act: All

If JMAFF has received useful feedback sufficiently in advance of the next SC meeting, JMAFF will be pleased to provide the revised CP (version 1.1) for review and discussion at the meeting.

Act: JMAFF

AnimalhealthEurope supported progressing the CP, and the narrow focus on Target Animal Safety on monoclonal antibodies, although it regretted that efficacy would not be included in the first stage.
The EU indicated that it was willing to discuss the CP again as proposed but, at this stage, it could not provide any guarantee that will be in a position to endorse the revised CP in 2019.

11.3 Concept Paper for a VICH guideline providing guidance on the establishment and running of a basic pharmacovigilance system

AnimalhealthEurope explained that it accepted the position of the FDA which considered that this topic was not within the mandate of VICH and it has withdrawn the CP. AnimalhealthEurope

will now work with OIE to develop alternative appropriate support for VOF members on setting up a basic pharmacovigilance system.

11.4 Discussion Document on the need for further guidance around medicated premixes

This topic was addressed together with agenda point 5.
AnimalhealthEurope recalled that at the 9th VOF meeting there had been a request from VOF members for more guidance on medicated premixes and creation of a Task Force to define the scope of any potential work on medicated premixes was subsequently proposed.
The EU explained the EU regulations for medicated premixes, medicated feed and feed additives fall under different regulatory frameworks, with only medicated premixes falling within the scope of the veterinary medicines' legislation. As only the EU veterinary medicines regulators are represented within VICH, the EU was unable to support any VICH activities related to medicated feedstuffs.
The OIE highlighted that medicated feed is very important in particular for some regions (ASEAN) and sectors (fish farming); the OIE gets many questions on the issue in the focal points' meetings.

AnimalhealthEurope confirmed that the scope would be limited to medicated premixes only and indicated that the current VICH GL8 does not give sufficient guidance to guarantee the quality of these medicated premixes. The initial role of the TF would be to define exactly the scope of the guidance.
The SC agreed that in light of the concerns raised by the EU, it would not be appropriate to set up a task force at this stage but that a subgroup of the SC should first develop a discussion paper, in electronic discussion, to better consider the possible scope of any guidance that could be developed. Several VOF members (i.e. Zimbabwe, Thailand and Saudi Arabia) had expressed interest in participating in the task force when it was assembled.
Members of the subgroup will be AnimalhealthEurope (leader), FDA, the EU and JMAFF.

Act: Subgroup

It was agreed that, if a decision is made to set up the TF, VOF members could be invited to become members of the TF.

11.5 Potential VICH topics

The SC noted that many ICH quality GLs are applied to veterinary medicinal products because of the absence of specific veterinary GLs. Some of these ICH GLs might be adaptable to the veterinary pharmaceutical field.
AnimalhealthEurope will reflect further and provide a Discussion Document before the next SC.

Act: AnimalhealthEurope

12. Other issues

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

The SC reviewed the revised version of the Discussion Document including all of the comments received by New Zealand and discussed the potential impact of the timelines proposed in the document.
The EU explained that the constraints of internal consultation procedures will require some flexibility.
The SC therefore agreed that these timelines should be seen as guidance but should be respected as much as possible.

It was noted that the timeline periods between the SC and the EWGs are very different but that, considering the reduction of SC meetings, all should encourage the EWGs to improve their efficiency, and the possibility of more in-person meetings was raised. Alternatively, more use of IT technology may be helpful.
The SC decided that the new 12 months cycle of SC meetings will start in late 2020 and that the SC meetings will take place in late September or October each year.
The Secretariat will add the final version of the document to the VICH procedural guidance documents on the VICH website.

Act: Secretariat

13. Any other business

13.1 Possible participation of the UK in the VICH SC after the Brexit

The Secretariat explained that the VMD had very recently sent a formal e-mail requesting full membership of VICH after the Brexit has taken place.
The EU pointed out that a formal decision cannot be taken now as the UK is currently a member of the EU and will still be at the time of the next SC meeting. It is also not clear yet if specific arrangements will be put in place between the EU and the UK, and the nature of those arrangements after March 2019. A final decision should therefore be postponed to the next SC meeting when hopefully more information will be available regarding the exact terms of the Brexit.
OIE will also inform its HQ.

Act: OIE

The SC asked the Secretariat to respond to the VMD indicating that no objection had been expressed in principle, but that the SC will wait for clarification on the exact position of the UK regulatory policy at the time of the Brexit and the future participation of the UK in the EU regulatory framework.

Act: Secretariat *(Done)*

New Zealand noted that the VICH Organisational Charter does not detail any procedure or criteria for becoming a VICH SC member or observer and suggested that the SC should establish these criteria.
AnimalhealthEurope recalled that the criteria to become a full member are that the country/ region must have implemented all VICH GLs and commit to implement all future VICH GLs, and the authorities and industry must be members of the VICH SC.
The SC acknowledged that some criteria to become a SC member have been detailed in the minutes from the 27th SC meeting in June 2012 but adoption of specific criteria for becoming a VICH SC member has not taken place. The SC asked the Secretariat to develop a first draft of criteria to be reviewed at the next SC meeting.

Act: Secretariat

13.2 Discussion on objectives

The EU noted that many discussions at SC relate to VOF and many topics fall outside the remit of VICH and recommended to initiate an in-depth discussion on VICH objectives at the next SC meeting.

14. Dates and venue of next meetings

- The 37th SC meeting will take place in Cape Town, South Africa, from 24 February to 1st March 2019, in conjunction with the VICH 6 Public Conference
- The 38th SC meeting will take place in November 2019 in Japan – Date TBC

15. Adoption of the Press Release on the 36th SC meeting

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

VICH STEERING COMMITTEE **36th meeting**

25, 26 & 28 June 2018
Bruges, Belgium

Chair: I. DUARTE, EMA

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI (ZOETIS)	M. J. MCGOWAN
AHI (BOEHRINGER INGELHEIM)	G. GOWDA
AHI	R. CUMBERBATCH (C)
EU (EUROPEAN COMMISSION)	J-N. PREUSS
EU (EMA-CVMP)	D. MURPHY
EU (EMA)	N. JARRETT (C)
EU (EMA) – *Guest*	I. CLAASSEN (only 28/6)
ANIMALHEALTHEUROPE (BOEHR. INGELHEIM)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)
JMAFF	Y. ENDO
JMAFF	K. NODA
JMAFF	T. KOZASA (C)
JVPA (Nisseiken Co.)	K. TUCHIYA
JVPA	H. MAKIE (C)
US (FDA)	B. WALTERS
US (USDA APHIS)	B.E. RIPPKE
US (FDA)	B. ROBINSON (C)
US (FDA) – *Guest*	L. WALTER-GRIMM

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 (MPI) - *Guest*	A. KINSELLA
South Africa (DAFF)	A. SIGOBODHLA
South Africa (SAAHA – BAYER)	E. SCHAY

INTERESTED PARTY

AVBC	J. THOMAS

OIE

OIE	J-P. ORAND
OIE	M. SZABO

VICH SECRETARIAT

HealthforAnimals	H. MARION
HealthforAnimals	C. DU MARCHIE SARVAAS

APOLOGIES

JVPA (NIPPON ZENYAKU KOGYO CO.)	I. ABE
New Zealand (AGCARM)	M. ROSS