VICH/13/084
24 February 2014
Final

VICH STEERING COMMITTEE
29th meeting
11-14 November 2013
Auckland – New Zealand

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was held in an observer member country, New Zealand, and chaired by Dr. Shigeyuki NAKAMURA, Director, National Veterinary Assay Laboratory – JMAFF. Normally, meetings are held in VICH Member countries so this venue was a departure from usual practice. He opened the meeting by welcoming the participants to Auckland and thanking the ANZ delegation for organising and hosting this meeting.
The chairman welcomed the delegation of South Africa as a new observer member to the VICH Steering Committee (SC). The Delegation was composed of Government regulators and Industry.

2. Adoption of the agenda

The agenda was adopted with minor changes.

3. Finalisation of VICH basic and guidance documents

3.1. Review of the VICH Organisational Charter (VICH/96/002) and review of the "Terms of Reference for the VICH Outreach Forum" (VICH/11/010)

The SC reviewed the draft versions of both documents and discussed in particular the issues below.

The EU suggested inserting the following new bullet in the "3. Guiding Principle" section: "*The decision making process in VICH should be through consensus of all parties*", as in the SC consensus has been the basis for the decision making. In the discussion it was acknowledged that this addition is not to require unanimous agreement of all participants for the decision making and does not interfere with other parts of the Charter, e.g., voting right of the members. The SC agreed to include the proposal from EU after deletion of the words "of all parties" from the sentence to avoid unnecessary misunderstandings.

The bullet point "*Regular cost/benefit analyses of the VICH process should be performed and communicated*" from the "3. Guiding Principle" section was discussed as this is not actually done in the preparatory stage of the adoption of a topic; in which case it should be deleted.

The EU noted that it is always important to analyse cost/benefit before adopting a topic. After discussion the SC agreed to keep this sentence as it is.

It was suggested to include the provisions for the VICH Outreach Forum (VOF) as the new section 7 of the Organisational Charter, and to suppress the "Terms of Reference for the VICH Outreach Forum" (VICH/11/010) to prevent an overlap of both documents. In the discussion the SC recognized that the VOF is still in a formative stage and may change in terms of members, roles, form of meetings, logistics, etc… The inclusion in the Charter might require frequent revisions. The SC therefore decided not to include the VOF section at this time but in a future revision of the Charter and to maintain the VOF's Terms of Reference (ToR).

Following the proposal of JMAFF the SC agreed to keep the word "Regulatory" in the sixth paragraph of section 5.2.1. Role of the SC, as a regulatory concern sometimes becomes an obstacle for the adoption of a topic.

The SC agreed to change in the second bullet of section 2. "Objective" the word "…. ***registration*** requirements" to "… ***technical*** requirements".

The Secretariat will circulate the revised version prepared considering editorial comments made during the preceding written procedure (VICH/96/002-Revision 11-dr 5) of the Organisational Charter for final approval by written procedure.

Act: Secretariat

3.2 Review of the "Procedure for publication of VICH Concept Papers" (VICH/11/026-rev 1-dr3) and review of the "Note to prepare a VICH Topic Concept Paper" (VICH/97/037)

The SC reviewed the draft versions of both documents and discussed in particular the issues below.

The SC adopted the following amendments to the document VICH/11/026-rev 1-dr3:

- Deletion of the words "*THE PREPARATION AND*" and "*BY VICH AND NON-VICH COUNTRIES* " from the document title to clarify the objective of the document;
- Point "2. Preparation and finalisation of Concept Papers" of the chapter "Process for the elaboration..." was moved to Annex 1 of the document and deletion of the chapter title; the point 1 is kept as a chapter with the title: "Submitting ideas for new VICH topics or guideline revisions";
- Change of the wording "technical registration requirement" in the Background section to "technical requirement" in accordance with the revision of the Organisational Charter (the second bullet of section "2. Objectives").

The SC agreed to keep the document VICH/97/037 at present as a stand-alone document, and to insert in the Introduction of the document the sentence "*A VICH Outreach Forum member can use the same form (CP template) to propose a topic*" to encourage the participation of VOF members in the creation process of concept papers (CP). It was however considered useful to later combine both documents.

The Secretariat will circulate the revised versions of both documents for final approval by written procedure.

Act: Secretariat

3.3. Review of the "SOP on VICH procedure for the Expert Working Groups" (VICH/00/151)

The SC reviewed the draft version of the document (Revision 3 – Draft 4) and discussed in particular the issues below.

The SC considered the number of participants to the EWG and acknowledged that groups of ten to eighteen experts are acceptable.

It was agreed to refer to the "Procedure for publication... (VICH/11/026)" and the "Note to prepare... (VICH/97/037)" in section D-1.

Following a proposal from JMAFF the SC agreed to maintain the numbering in the Section H "Teleconference".

The Secretariat will circulate the revised version of the document for final approval by written procedure.

Act: Secretariat

3.4. Review of the "Criteria for participation of VICH Outreach Forum members in VICH Expert Working Groups" (VICH/13/041)

The SC reviewed the draft version of the document that was proposed and discussed in particular the issues below.

JMAFF pointed out the wording "Proficiency in English" could lead to misunderstanding by the VOF members and discouragement for individuals willing to participate in the EWG.

The secretariat explained that as English is formal language of VICH, the participants need to understand the written text in English and have fundamental abilities to communicate with other experts. The SC therefore agreed to alter the wording to "Ability to participate in the meeting conducted in English".

The SC agreed to change the wording "guideline development process" in the third bullet of the "Background" chapter to "guideline development *or revision* process".

3.5 Other documents

None

4. Preparation for the 3rd VICH Outreach Forum meeting

4.1. Review of the participants list

It was noted that the Secretariat and OIE have done their utmost to encourage all Forum members to participate. A few countries have not replied to the invitations. The appropriate contact details will be re-verified, as contacts can change.

The Chair asked OIE for its support to encourage Forum member countries to participate in future VICH Outreach Forum - VOF meetings.

4.2 Review of the agenda of the meeting

The SC reviewed the agenda and approved the presentation prepared by the Secretariat.

4.3 Review of the proposals from the ad hoc group on Training Strategy

The SC reviewed the proposal for a VICH training strategy prepared by the VICH ad hoc working group on training strategy. The primary mandate of the ad hoc group was to propose a training strategy. Details of the financing and implementation still need to be elaborated.

The ad hoc group recommended a two-pronged approach for the implementation of the training strategy: a first level of intervention during the Outreach Forum meetings and a second level at Outreach Forum member country or regional level.
The first level proposed is high level training such as the introduction to GLs, rather than training on technical details of a specific GL technical details. The SC confirmed that VICH does not have the capacities to train the assessors of dossiers.
For the second level of intervention the development of (a) training course(s) composed of different modules was proposed. The ad hoc group recommended developing these modules with the support of SC members and observers who were encouraged to provide existing material.

For the second level it was proposed that the countries which will request the training should be able to provide the funding, if necessary by requesting support from larger international organisations that have the financial means to advance these activities.

The SC took note that most of the content of the proposed modules is already available but it is spread among various organisations in the world. The existing material should therefore be gathered and updated. However, as very few funding resources are available, VICH should prioritise the needs.

It was recalled that the primary objective of the VOF initiative and the training was to create awareness that the VICH GLs exist and can be used by all countries, thus preventing duplications and repetitions of studies, including those studies that use animals.

The proposal would be presented to the VOF explaining reservations, and discussions with the VOF were expected to bring further focus on the needs and priorities for a training strategy.

4.4 Organisation of the group discussion session

The Outreach Forum meeting will include breakout sessions. The SC decided to organize 3 breakout teams comprising VOF members with SC members. Each team will designate 1 rapporteur and 1 moderator. The topics to discuss could cover implementation of VICH GLs, training, pharmacovigilance, regional GLs and their compatibility with VICH GLs, and other topics that will be proposed by the VOF members.
The groups were agreed as follows:
Group 1: Argentina, CAMEVET, ASEAN & Malaysia

Group 2: Korea & Thailand
Group 3: Ukraine, Russia & China

4.5 Consensus on the opinions/directions from the SC

Covered above.

5. Review of the Outcome of the 3rd VICH Outreach Forum meeting

5.1. Debriefing and review of the conclusions of the Forum meeting

The SC addressed this agenda item the day after the 3rd VICH Outreach Forum meeting.

Training
During the discussion, it appeared clearly that outside of the VICH regions there is an important need for more explanations on what is VICH and what are the VICH GLs. Several proposals were made by VOF members, in particular invitations from ASEAN and CAMEVET for SC members to participate in regional meetings.

Status of VICH GLs
VOF members raised questions on how VICH GLs can be used in countries outside VICH regions. It was recognised that clearer explanations should be provided that VICH GLs are not legislation but only technical requirements, which do not have to be integrated into national legislations, and that the approach for implementation is up to the countries.
Several VOF members have nevertheless suggested that GLs should be integrated in the OIE Manuals as OIE standards.

How to integrate the GLs at national level
VOF members requested to share experience on the implementation of the GLs, either as full GLs or as adapted GLs.

Communication
The VOF requested clarification on the VICH communication strategy. The SC agreed that more reflection was required at VICH SC level.

Active participation of VOF members in VICH activities
The VOF welcomed the draft Concept Paper from China for a VICH GL on combination products. A Task Force including VOF participants will be created to drive the topic further.
Several VOF members showed strong interest in the proposed review of VICH GL 3 on stability to cover climatic zones III & IV, as a GL on stability is needed in these regions.
A TF will also be created.
The VOF applauded the fact that Argentina has already an expert in the Metabolism and Residue Kinetics EWG on honey. It was seen as a confirmation that the VOF members are being integrated into the VICH activities,

Preparation of the 4th VOF meeting
Requests have been made for training on the implementation of VICH GLs on bioequivalence, on the rules to develop a Concept Paper and how VOF members can participate in EWGs.
The SC took good note of the important request for a better communication on understanding VICH, on the implementation and the use of VICH GLs, highlighting the fact that GLs are not legal but just provide guidance on technical requirements.

The SC confirmed that the breakout format into smaller groups had been a very fruitful exercise which enabled delegates to speak freely about their needs and concerns. Breakout groups will be organised again in future VOF meetings.
The ad hoc working group on training strategy will review the outcome of the breakout groups and will highlight the main topics for further discussion.

Act: ad hoc group

5.2 Review of the requests and topics raised by the Forum participants

Implementation of VICH GLs
The SC recognised that the implementation of the VICH GLs is a key issue for the VOF and agreed that an information document on the implementation of the VICH GLs should be prepared to be used for the VICH and OIE website. The EU agreed to draft the document, supported by IFAH Europe, to be finalised in coordination with the Outreach sub-group and to be sent to the VOF well in advance of the next meeting.

Act: EU/ IFAH Europe/Subgroup

Following the request from VOF members, OIE noted the need to also explain the role of the OIE Manuals as international standards. OIE will reflect further on the status of VICH GLs without integrating them into the OIE standards' documents. This reflection will be integrated into the document on implementation of VICH GLs.

Act: OIE

Follow-up with VOF members
OIE will write to the VOF participants to encourage them to provide ideas for topics to be addressed at the next meeting. The OIE website will be updated in coordination with VICH to ensure that both websites are aligned.

Act: OIE

Improvement of communication strategy

At the next VOF meeting high level communication will be necessary on VICH work and on what are VICH GLs. It was noted that many existing presentations about VICH are available. These should be reviewed and a new agreed VICH presentation should be developed, eventually to be placed on the new VICH website.

IFAH Europe proposed that a short document on the VICH communication strategy should be developed for discussion at the next SC meeting.

The VICH website will become an essential communication tool with the VOF members. It was recalled that many VOF members stated that they were the only individuals informed about VICH in their country and therefore needed active support to spread the message through presentations and other tools.
The SC therefore agreed that the ad hoc working group on training strategy will consider the improvement of the communication tools within the first level of the training strategy. Existing material will primarily be used. The ad hoc working group on training will develop a draft recommendation document on the VICH communication strategy.

Act: Subgroup

Agenda

OIE will circulate in January a draft agenda for the 4th VOF meeting.

Act: OIE

Task Forces
VOF members will be invited to participate in both the TF on the revision of VICH GL 3 – Stability and the TF to develop a Discussion Document for a VICH GL for efficacy studies for combination products; the number will be limited to one expert per region (LA, Asia & Africa) with a maximum of 3 experts. It was considered essential to maintain the balance between industry and regulators' experts.
The Secretariat will explain to the VOF members that a TF is not an EWG and that its role is not to develop a GL, but in this case to further develop CPs. The Secretariat will also highlight the need for proper expertise on the topic as well as a good understanding of English; the experts must also be committed to the task.
In the long term, it was acknowledged that the number of VOF experts can vary in the TFs depending on the topics that will be addressed.

5.3 Proposals for Training Strategy

The ad hoc working group on training strategy will develop the process for the training strategy, which will probably not be finalised for the next meeting.
The Secretariat will invite ASEAN and CAMEVET to designate a representative to the ad hoc working group on training strategy.

Act: Secretariat

5.4 Decision on the next steps and items for the agenda of the 4th Forum meeting

Discussed above.
It was agreed that another SC member (i.e. JMAFF) and another observer member (i.e. Canada) should prepare presentations similar to the ones presented by FDA and ANZ at the 3rd VOF meeting which were considered as very useful by VOF participants. The topic on TABST waiver should be included in the presentations.

6. VICH Strategy Phase III

6.1 Review of the implementation and interpretation of VICH GLs in the regions

6.1.1 Report from the regulators

The EU confirmed that all VICH GLs have been implemented within the required timelines.
JMAFF reported that all VICH GLs are implemented as scheduled, except the VICH Ecotoxicity Phase I (VICH GL 6) and Phase II (VICH GL 38) because of the need to modify the Japanese national legislation. These GLs have meanwhile been placed on the JVPA website in order to make them available to the industry and the public.
FDA reported that no problems of implementation or interpretation of VICH GLs have been encountered so far.

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

Australia is in the process of revising all GLs thus taking the opportunity to implement the VICH GLs that had not been implemented previously. Only the Pharmacovigilance GLs will have a flexible implementation date.
New Zealand has implemented all VICH GLs so far and is reviewing the cost of implementation.
Canada has implemented all VICH GLs, except VICH GL 50 (Biologicals: TABST) because in Canada waivers are allocated on a case by case basis based on the current GMP legislation on vaccines. Canada will develop a policy document explaining the interpretation of this GL.
South Africa, being a new observer of VICH, has not considered specific implementations yet; a national VICH Committee composed of industry and regulators has just been proposed in South Africa. The Committee is envisaged to create an implementation policy.

6.1.3 Any input from industry members

AHI commended FDA for publishing all VICH GLs in accordance with the VICH timelines.

6.2. Industry vision for pharmacovigilance harmonisation

Industry indicated that many comments had been received from its members in response to the draft CP for the revision of VICH GL 42.
Industry pointed out that despite the development of VICH pharmacovigilance GLs, full harmonisation has not been achieved at a global level because companies still have to maintain 2 differing reporting systems.

The industry SC members supported the revision to GL42 as outlined in the CP. However industry did not support the timing of the revision, preferring to postpone revisions until after the GLs have been implemented. The industry wishes to take a much more strategic approach regarding pharmacovigilance, and will recommend the 'immediate' implementation of these GLs with a deadline that will be clearly defined because it is a very important topic within the VOF and at the global level. The aim is to have one single efficient pharmacovigilance system available worldwide.
However, as soon as possible after implementation, a revision process of the 5 VICH pharmacovigilance GLs should be initiated in a logical order, starting with GL 24 (in order to clarify and agree the definitions), followed by GLs 42, 30 and 35.
Concerns were raised by the EU as to the proposal for a fundamental review of the pharmacovigilance system. The matter was further addressed under 12.2.

6.3. Other issues

No point was raised.

7. Review of

7.1 Written updates from the coordinators

The SC took note of the report and thanked the coordinators for their work.

7.2 Review of the written status of consultation for draft GLs at Step 4

The SC took note of the report.

8. Review of final VICH Guidelines at step 9

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

None presented

8.2. Proposals for revision of further VICH GLs

None presented

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

9.1. Quality

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr. T. Ogata, and presented by JMAFF and acknowledged that the EWG has no further work to undertake for the time being.

9.2. Electronic Standards Implementation – Pharmacovigilance

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr. M. Brown, and presented by FDA.
The technical documents were updated to reflect amendments resulting from any identified gaps, lack of clarity, or functionality issues. The updated documents were circulated to the ESI EWG members in August 2013 for final comment.
FDA has meanwhile developed a solid experience in implementing the pharmacovigilance GLs and considered that these GLs will need modifications and improvements. FDA has therefore developed the CP for the revision of GL 42.
The EWG has already reviewed the CP and requested guidance from the SC on the way forward.

Industry mentioned that its vision for a global harmonised PhV system will require in-depth discussions on fundamental issues.

9.3. Biologicals Quality Monitoring

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

a. Testing for Harmonisation of the Target Animal Batch Safety Test for immunological veterinary medicinal products for live vaccines
The first draft of the document has been completed and circulated to the experts. It was noted that not all experts have yet commented and a reminder for submitting comments would be sent. The second round of comments from the experts should be finalised by the end of 2013.

b. Extraneous agents testing for Biologicals Extraneous viruses testing

The EWG will wait to initiate the drafting of the document until the work of the EU CVMP Immunological WP is completed. The EU confirmed that work is progressing and it is hoped that a proposal will be available in the near future.
The SC confirmed the authorisation for the EWG to hold a face to face meeting as soon as the work from the EU is available.

9.4. 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.

New GL on residues in fish
The topic leader is currently reviewing the comments to draft 1 received from the experts.

New GL on residues in honey
A first draft document has been circulated to the subgroup of experts/advisors in October, who are currently providing their comments.

Amendment to GL 48
The SC acknowledged that the preparatory work has shown that the task was more complicated than originally thought.
The topic leader has provided a proposal and noted that the revision of the GL can only be finalised in a face to face meeting which has already been agreed in principle by the SC.

The SC confirmed the authorisation to hold the face to face meeting in June 2014 in the EU to review the 2 new draft guidelines under consideration and finalise the revision of GL 48.
As the EWG is composed of the core group and the experts specialised in fish and in honey, the EU will organise the meeting in sequential sessions of the different topics to enable the specialised experts to attend only their part of the meeting.

The SC congratulated Dr Scheid and the experts for their efficiency in addressing the different topics.

- **Feedback from the CCRVDF regarding residues in honey**

It was confirmed that the CCRVDF will not discuss the related technical study design issues further, as explained comprehensively in the report from the MRK EWG chair.
Furthermore, it was recalled that the SC had supported the MRK EWG addressing this issue rather than a separate EWG, in order to build on the experience of the experts, together with additional special advisors. Moreover members of the EWG can consult external experts in each region if necessary.

9.5. Safety EWG

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

a) Revision of VICH GL 23 (Safety - genotoxicity)
A new draft will be circulated to the experts before end of 2013; a draft revised GL should be ready for signature at step 5 in Q1 of 2014.

b) GL on the determination of an acute reference dose for residues
A revised draft should be available by the end of 2013 as well; a step 2 document should be ready for signature by mid-2014.

The SC agreed that the ongoing revision should be finalised before further work for the safety EWG is requested.

9.6. Bioequivalence EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr. M. Martinez, and presented by FDA.
The SC noted that VICH draft GL 52 is ready for signature at step 3 and congratulated Dr Martinez and the experts for their ongoing efforts and the work achieved.

9.7. Electronic File Format EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr M. Colmorgen, and presented by IFAH Europe.

The SC noted that a draft 4 of the document has been circulated recently and that all experts have agreed to the draft. The signature procedure at step 2 is ongoing and will be ready shortly for sign-off by written procedure at step 3 by the SC.

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

10.1. Draft VICH GL 52 – Bioequivalence: Blood Level Bioequivalence Study

The SC adopted the draft GL 52 at Step 3. This guideline was transmitted to the VICH members for a 6 months public consultation at Step 4 until May 31st, 2014.

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

None presented

12. Concept papers/Discussion papers

12.1. Review of the draft Concept Paper from FDA for the revision of VICH Anthelmintics GLs

FDA recommended that the VICH Anthelmintics GLs are revised because some scientific issues have been raised by FDA experts that would necessitate a review of the current text of the GLs.
The SC debated the need for such a review. Whilst industry recognised that the scientific discussions regarding the issues raised in the draft CP (VICH/IN/13015) are ongoing, industry pointed out that these are not all resolved yet and believed therefore that the current GLs are in line with the actual established scientific knowledge.
The regulators recommended however to initiate a review of the GLs to update several scientific issues to reflect the current knowledge.

The SC decided to create a Task Force (TF) with experts who will review the science regarding the issues raised in the draft CP. The mandate of the TF will be to:

- Consider the topics outlined in the draft CP through in-depth discussions regarding the current state of scientific knowledge and the current experience gained from the evaluation of anthelmintic animal drugs. This should result in a comprehensive discussion document elucidating the various scientific opinions and arguments.
- Recommend to the VICH SC as to whether an EWG to revise the VICH Anthelmintic Guidelines should be convened after there has been a full discussion by the TF of the issues and the related science. The points to be addressed must be defined.

The TF will consist of one scientific expert representing each individual VICH member and observer. A SC member should also participate in the TF instead of a scientific expert, as was experienced in the Bioequivalence TF, in order to provide clear guidance to the TF on the output of the SC discussions.
Although it was considered useful that the TF might meet face to face at some point in time, the SC decided that the TF will start working by electronic procedure only.
FDA will chair the TF.
The secretariat will circulate a call for experts to the TF.

Act: Secretariat

It was suggested to organise a scientific expert workshop outside of VICH to provide a forum for scientific discussion of the issues, with a view to closing the gap in the understanding of "current knowledge" between regulators and industry, before the formation of an EWG could be considered. The SC agreed that a workshop outside VICH with the aim to provide input/direction to VICH was not appropriate. Therefore such a workshop would have to be organized by one or more interested parties separately. The SC agreed that the current draft CP should stay within the frame of VICH in order to limit the discussions to the scientific aspects of the GLs only. It was nevertheless acknowledged that VICH experts could call upon outside expertise on an individual basis if deemed necessary.

12.2 Review of the Concept Paper from the ESI EWG for the revision of VICH GL42

The SC supported the proposal to revise GL 42 - Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Events Reports (AERs), but debated if the timing was appropriate. Industry confirmed its vision for a strategic approach regarding pharmacovigilance expressed under agenda item 6.2 and its recommendation to initiate a revision process of the 5 VICH pharmacovigilance GLs as soon as possible but in a logical order, starting with GL 24.
The EU raised concerns regarding the opening of the principles for the pharmacovigilance system at this stage or in the near future, but supported the revision of GL 42, as proposed by the FDA with the support of the ESI EWG.
The SC recognised that the fundament for a harmonised implemented pharmacovigilance system is available through VICH, but there is a need for improved harmonisation of the system.
Industry, at the global level, will therefore prepare a discussion document including the vision and the issues that were raised, for consideration by the SC at its 30th meeting in June 2014.

Act: Industry

The SC discussed the implementation date of Pharmacovigilance GLs 24, 30, 35 and 42. Most SC members considered that 2 years would be appropriate. JMAFF explained however that Japan could not promise the implementation of these GLs within 2 years, but would

nevertheless support the proposal for 2 years with the provision that it will not be the obligatory date for Japan.
The SC agreed to implement the Pharmacovigilance GLs 24, 30, 35 and 42 within 2 years, by 31st December 2015.
The secretariat will circulate the final GLs for implementation.

Act: Secretariat

The SC noted that the EWG still needs more time to finalise the technical documents that are annexed to GL 35 and agreed that these documents should also be published in December 2015 together with GL 35.
The SC will therefore formally adopt these documents as well and expects to be able to sign them off at the 30th SC meeting that will take place in June 2014.

12.3. Review of the Concept Paper from IFAH-Europe for the revision of VICH Stability GL 3(R)

The SC recognised the need to address the stability testing of new drug substances and products in countries in climatic zones III & IV. Concerns were expressed that these zones are out of the scope of VICH. It was questioned if these countries would support and use this VICH GL, and if OIE would mandate VICH to develop this GL. It was furthermore pointed out that the extrapolation proposed in the CP is an entirely new approach that needs further consideration. This GL may also have impacts on stability testing protocols in VICH countries and result in a shorter shelf life than currently the case. Detailed comments addressing *inter alia* the points above had been prepared by the EU.
The SC noted with satisfaction that after circulation of the CP to the VOF, comments had been received from CAMEVET and the Thai FDA.

The SC agreed that a more detailed impact assessment including resource implications should be done, and that a TF should develop, for review at the next SC meeting, the draft CP in more detail.
The mandate of the TF is:

- To elaborate more in-depth the existing Concept Paper (draft 3), addressing the various areas of concern and reflection raised in the comments received, including identification of the full impact of the proposed work.
- The goal is to gather all elements required for the VICH SC to assess whether the topic and proposed work plan are feasible with a high probability of a successful outcome, so that a decision to form an EWG to work on the topic or not could be taken.

The TF will be chaired by IFAH Europe and work mainly by electronic procedure. It should comprise scientific experts from VOF countries in climatic zones III/IV, such as CAMEVET or the Thai FDA.
The secretariat will circulate a call for experts from the SC members and the VOF members.

Act: Secretariat

OIE agreed to survey its members before the next SC meeting asking them if they would support and use the revised GL. OIE stipulated that it is preferable to conduct a survey on several topics and OIE asked VICH SC members to propose other related topics for this survey. IFAH Europe agreed to provide further topics for questions such as VICH communication strategy issues. OIE will circulate a draft questionnaire based on IFAH Europe's proposal to the SC for approval beforehand and will conduct the survey.

Act: IFAH Europe/OIE

12.4. Review of the Discussion Document from the EU on the revision of VICH GL 22

The EU explained that VICH GL 22 – Reproduction Toxicity Testing - refers to the OECD 2 generation reproduction toxicity study (OECD 416). This test requires a large number of test animals which are analysed for a limited set of endpoints. OECD has now developed an extended 1 generation reproduction toxicity study GL (OECD 443), which is already accepted in the EU for the evaluation of food additives, and the use for evaluation for other substances (e.g. chemicals, pesticides) is being discussed. Testing according to OECD 443 requires a reduced number of animals compared to testing according to OECD 416.
The EU emphasized the necessity to evaluate the regulatory consequences of introducing OECD 443 as an alternative to OECD 416 in GL 22 and proposed a review of publicly available evaluations of veterinary medicines to estimate the potential impact of conducting reproductive toxicity tests according to OECD 443 on the final safety assessment. JMAFF expressed also its concern and offered to review similar assessments done independently in Japan, and to report to the 30th SC meeting. Other SC members were encouraged to review the consequences as well on a voluntary basis.

The SC agreed that the EU and JMAFF will in a first step review publicly available evaluations of veterinary medicines to establish the proportion of substances for which reproductive toxicity provides the basis for setting the overall NOEL and to consider, for these substances, whether the 1 generation reproduction toxicity study would have been likely to detect critical effects noted in the second generation.

Act: EU/JMAFF/All

The SC will analyse the conclusions of this review at the next meeting and decide on the steps forward.

Act: next meeting

12.5. Review of the Draft Concept Paper from China on the Need to Develop a VICH Guidance for Efficacy Studies for Combination Drug Products

The SC applauded China for providing the draft CP, with the support of FDA, and noted that it was China's first active involvement in the VICH outreach process as well as the first concrete proposal for a VICH topic from a VOF member.

The SC agreed that the CP addresses an important topic of relevance to VICH, although the proposed scope was considered to be too broad.
The SC noted the need for a more focussed scope and to assess the impact, the feasibility, the timelines etc…
The SC agreed to create a TF chaired by JMAFF with the mandate to develop a discussion document proposing a more focussed scope for the development of a VICH GL for efficacy studies for combination products. It should include a proposal for an overall strategy on how to approach combination products in general and/or detailing the different therapeutical classes in which combination products are available (anthelmintics, antibiotics…), proposing a prioritisation of the topics, evaluating the feasibility and the resources that would be available to provide an adequate basis for the development of future GLs on combination products.
The TF should also review which classes of combination products are available in the different regions/countries and what regional/national GLs are available for these products.

The TF will be composed of experts nominated by the SC members, SC members as appropriate and VOF members, and will work by electronic procedure only.

The secretariat will circulate a call for experts from SC and VOF members.

Act: Secretariat

12.6 Other VICH topics

None

13. Other issues

13.1. Preparation of the 5th VICH public Conference in Japan the frame of the 32nd VICH SC meeting in fall 2015

The SC reviewed the outline of the programme for the 5th VICH public conference proposed by JVPA and agreed that the Conference will take place in Tokyo on 28 & 29 October 2015. The SC took note that this will be the first VICH public Conference organised since the creation of the VOF. The SC therefore considered it was essential to include the activities of the VOF and the members of the VOF as an integral part of the 5th VICH Public Conference.

It was further suggested that OIE could consider organising a regional event shortly before or immediately after the VICH public Conference, in order to increase attendance. OIE promised to explore suitable possibilities in consultation with the OIE Headquarters as well as the OIE Asia-Pacific Regional Representation.

JVPA and the secretariat will provide a draft programme for the Conference for electronic discussion at the next SC meeting.

Act: JVPA/Secretariat

14. Any other business

14.1. New version of the VICH website

The SC reviewed the new proposed VICH website online presented by IFAH-Europe. The SC enthusiastically supported the upgraded lay-out and remarked that the changes were a great improvement on the current website.
The SC took note that the documents for consultation will be available through a specific button on the homepage.
It was acknowledged that the new system will also be readable from tablets and smartphones.

The SC decided to create a specific secured webpage for the VOF members.

The SC agreed that as from the 29th SC onwards the final agenda and final minutes of SC meetings will be made available on the public website. The Organisational Charter, the VICH strategy, the VICH SOPs and internal guidance documents as well as the final Concept Papers will also be made publically available.
Discussion documents will be considered on a case by case basis.
The SC thanked IFAH-Europe and IFAH for the development of this new VICH communication tool.

15. Dates and venue of next meetings

- The 30th SC meeting will take place in Brussels, Europe on 23 to 26 June 2014.
- The 31st SC meeting will take place in Washington DC, USA on 23 – 26 February 2015.
- The 32nd SC meeting will take place in Tokyo, Japan on 25, 26, 27 & 30 October 2015.

16. Adoption of the Press Release on the 29th SC meeting

The SC members reviewed and adopted the press release as proposed by the secretariat.

VICH STEERING COMMITTEE

29th meeting

November 11, 12 & 14, 2013
Auckland (NZ)

Chair: S. NAKAMURA (JMAFF)

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI (BAYER)	R. CARNEVALE (for B. MARTIN)
AHI (ZOETIS)	M. J. MCGOWAN
AHI	S. VELUVOLU (C)
EU (EUROPEAN COMMISSION (DG SANCO))	K. KRAUSS
EU (EMA)	K. GREIN (C)
EU (EMA-CVMP)	A. HOLM
IFAH-Europe (MERIAL)	B. BOENISCH
IFAH-Europe	R. CLAYTON (C)
IFAH-Europe (BAYER)	L. KLOSTERMANN
JMAFF	T. KOZASA (C)
JMAFF	Y. ENDO
JMAFF	K. NODA
JVPA	O. ITOH (C)
JVPA (KYOTO BIKEN LABORATORIES)	E. OISHI
JVPA (DS PHARMA ANIMAL HEALTH CO.)	T. KOMATSU
US (FDA)	M. SMITH
US (USDA APHIS)	B.E. RIPPKE
US (FDA)	S. VAUGHN (C)

OBSERVERS

Australia/New Zealand (APVMA)	A. BRYCE
Australia/New Zealand (MPI)	D. MORRIS
Australia/New Zealand (MPI)	W. HUGHES
Animal Health Alliance (AU)	D. BREMNER
CAHI	J. SZKOTNICKI
Canada (Health Canada)	M-J. IRELAND
South Africa (DAFF)	M. MOROE-RULASHE
South Africa (SAAHA – BAYER)	E. SCHAY

INTERESTED PARTY

AVBC	J. THOMAS

OIE

OIE	J-P. ORAND
OIE	S. MÜNSTERMANN

VICH SECRETARIAT

IFAH	H. MARION