VICH/16032
29 September 2016
Final

VICH STEERING COMMITTEE
33rd meeting
20, 21 & 23 June 2016
Brussels

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr David Mackay, Head of the Veterinary Medicines Division, European Medicines Agency.
The Secretariat welcomed the VICH Steering Committee to Brussels and indicated that apologies had been received from B. Martin - AHI and M. Wright - AMA.

Welcome by Mr S. Soro, European Commission

Mr Stefano Soro, Head of Unit E5 – Animal nutrition, Veterinary medicines of the European Commission's Directorate General for Health and Consumer Affairs, welcomed the participants by conveying the support from the European institutions to VICH. He mentioned that VICH has now been active for 20 years and has become a reference in the world. The growing interest of third countries in the activities of the VICH Outreach Forum (VOF) shows the importance of the VICH Guidelines in the international environment. The Guidelines are increasingly recognised in all parts of the world.
Mr Soro wished all participants a successful 33rd VICH Steering Committee meeting.

2. Adoption of the agenda

The agenda was adopted with 1 modification: item 13.1 will be covered in item 9.5.
It was also agreed that item 13.4 will be addressed early in the meeting.

3. Report from the ad hoc WG on training implementation

3.1. Status report from the ad hoc WG

FDA presented a timeline with the status of the tasks but highlighted that the intended timelines for further development of materials will not be met as, in the absence of funding, development of materials cannot be prioritised.
The WG has prioritised between the VICH GLs and agreed that the quality topic would be the first priority.

IFAH-Europe explained that industry is trying to address the funding issue and has developed a strategy on training as an aid to developing regulatory competence with the Bill and Melinda Gates Foundation (BMGF). The BMGF has funded last year the GAHC Conference on

regulatory convergence while a pre-GAHC Conference workshop on VICH was funded by the US Department of Agriculture.
The BMGF's focus is on the promotion of animal husbandry as a means of alleviating poverty and the importance of having a system for registration of veterinary medicinal products as a key component of promoting animal health in sustainable husbandry systems. It cannot fund further VICH training as this is too narrow and their first priority must be to promote the establishment of basic regulatory systems and market control in developing economies.

3.2 Proposal for a training module on quality

FDA presented a proposal for a training module on quality and explained that the WG proposes this programme as a template for all future programmes that VICH may develop.
The SC thanked FDA for leading the work in the ad hoc WG, and agreed that timelines will have to be realistically adapted to the availability of funds.
It was nevertheless agreed that in order to keep the momentum, the ad hoc group will aim to complete the proposed work plan relating to development of training materials on quality guidelines within the 2 next years.
The EU mentioned that it is also developing training materials for EU regulators. While the focus of these materials will not always be appropriate for VICH specific training, it is hoped that, in time, it will be possible to make relevant materials available to experts outside the EU Regulatory Network. However, progress is slow and it is likely to be several years before a significant amount of training material could be made available. It was further noted that training materials from ICH could be used as a basis, but would need review and adaptation by experts.
FDA welcomed additional comments and suggestions from SC members to finalise the quality module.

Act: All

4. VICH Outreach Forum

4.1 Preparation for the 7th VICH Outreach Forum meeting

4.1.1 Review of the participants list

The SC reviewed the participants list of the 7th VOF meeting and applauded the participation of 23 delegates from 12 countries and 3 international organisations (ASEAN, CAMEVET and UEMOA), including the two new VOF members – Saudi Arabia and Uganda.
The SC appreciated in particular the presence of representatives from the 4 BRIC countries.

4.1.2 Review of the agenda and preparation of the 7th meeting

The SC reviewed the agenda and acknowledged that training would be the main expectation from VOF members. The SC however decided not to present the draft modules on quality which were not yet considered to be sufficiently developed for wider exposure.
It was noted that the current trend is to develop web based training, often including video material, but FDA mentioned that feedback indicated that technical issues often prevent reliable internet access in certain less developed regions. Views would be sought from VOF members as to the best ways of delivering training.
It was suggested to ask the regional organisations for support and facilitation of training at their level.

The highest priority topic for training is quality, which is being addressed by FDA and the ad hoc group. It was suggested that another region should develop the next training topic which is pharmacovigilance.

4.2 Review of the Outcome of the 7th VICH Outreach Forum meeting

The SC addressed this agenda item after the 7th VOF meeting and noted that the participation was excellent, with very active and lively discussions. It was nevertheless recognised that VICH needs to maintain momentum by identifying relevant, new topics for the VOF as there is a risk that further discussion on the current topics will not bring additional benefits at the present time. The breakout sessions showed once again their value as they enabled all attendees to express their opinion.
The SC confirmed the urgent need to progress with identifying a practical way of delivering the requested training in order to maintain the current high level of interest from VOF members.

1/ Training strategy and priorities - Back to back training on OIE regional meeting (needs to be confirmed by the OIE Director General)
ASEAN will invite representatives of VICH SC to attend a training session back-to-back with their regional ASEAN meeting in 2017 in Brunei. An official invitation shall be sent by the ASEAN secretariat.
IFAH-Europe encouraged the SC to clearly understand the expectations (regulatory convergence, mutual recognition…) so that VICH does not disappoint VOF members.
IFAH-Europe recommended to commit to develop the necessary training modules and to discuss with OIE how to ensure that the training within this Forum is complementary to the training that OIE provides to its National Focal Points for veterinary medicinal products.
Although the work in the ad hoc WG continues, resources clearly need to be urgently secured.
HealthforAnimals confirmed that, once the proposed training session has been defined at a sufficient level of detail, resources will be found for this event.

JMAFF explained that the participants to a back-to-back meeting with OIE would be the National Focal Points for VMPs who are not always assessors but managers or policy makers so the training should not be at a too technical level.
OIE confirmed that the delegates who register for these seminars are not necessarily familiar with VICH, as often they come from the Ministries of Agriculture (supporting the CVOs) and not from the Ministries of Health (MoH) whilst it is often the MoH that is responsible for authorisation of both human and veterinary medicines. Moreover, the veterinary staff in MoH are often very limited and poorly trained in veterinary aspects, so the technical parts of training must be adapted accordingly.
OIE confirmed its support of mutual recognition of assessments by applying them to a region so that countries do not systematically repeat the assessments; Thailand is already pushing for a mutual recognition system in ASEAN.

The Chairman agreed that the VOF members must be sufficiently aware of the relevance of VICH GLs, and how they can be applied in the assessment of a dossier in the local registration process. A training on VICH GLs, without an explanation on how they fit in the overall registration process would not meet the objectives.
FDA pointed out that there is a broad difference of knowledge between the countries; the presentations at the VICH Conference in Tokyo and the Workshop in Tanzania were very high level.
The SC agreed to ask ASEAN for a draft agenda for a back-to-back meeting including learning objectives, areas to be covered and timing. Once the level of expectations is clear,

the ad hoc WG will assess how best to develop the required training material and the SC will determine which persons are best suited to deliver such a training.
In summing up, SC agreed that OIE will ask ASEAN, through Thailand, to submit as soon as possible a formal request to VICH including a draft agenda indicating the expected topics and duration of the training, and will inform the Secretariat of progress.

Act: OIE

2/ Use increased international interest as stimulus
This will be addressed in the training programme.

3/ Get engagement also from the Ministries of Health
OIE clarified that each country decides independently which persons attend which meetings and OIE is therefore unable to control exactly who attends each Focal Point meeting. As OIE must respect its internal procedures (contact with focal points and CVOs only), the SC agreed that the VICH Secretariat would forward the OIE invitations to the VOF contact points as well for information.

Act: Secretariat

4/ Development of electronic training aids
The Secretariat confirmed that all available training material is placed on the VICH website. The SC noted that a considerable amount of general material is available elsewhere but not focussing specifically on VICH GLs.
It was agreed that it is necessary to put in place a system for quality assurance of training material before it is placed on the VICH public website. The EU will draft a proposal for a procedure for approval of VICH training documents.

Act: EU

5/ Application of VICH GLs and acceptance of studies
OIE confirmed that all available translations of VICH GLs can be placed on the OIE website. All members were once more asked to provide any available translation.

Act: All

6/ Topics for the 8th VOF agenda
OIE indicated that it will send a call for topics and for volunteers for presentations when circulating the first draft agenda. In preparing for the agenda of the next meeting, the outcome of a recent OIE survey on training requirements will be taken into account, together with the feedback received from the current VOF meeting.

The Secretariat encouraged all SC members to provide suggestions for topics and volunteers for presentations at the 8th VOF meeting and to liaise with VOF members to identify suitable topics, as appropriate.

Act: All

The SC requested that the future participants' lists should include the first names of VOF attendees, e-mail addresses, as well as SC members.

Act: Secretariat

5. Discussion on the location and date of the VICH 6 Conference

The SC received a formal invitation from the industry and regulators' representations of South Africa to organise the 6th VICH Conference in Cape Town – South Africa in Spring of 2019 or 2021, with the support of the US delegation which would retain the leadership of the VICH events.

The SC thanked South Africa and accepted in principle the invitation to hold the VICH events on the African continent, subject to final confirmation by the EU delegation.

Act: EU

The SC decided that the Conference should ideally take place in February 2019, in conjunction with the 37th SC meeting.

6. Discussion on the location and date of the 34th SC meeting

It was recalled that CAMEVET had invited VICH to organise the 34th SC and the 8th VOF meetings in Buenos Aires, Argentina, from 27 February to 2 March 2017. The USA delegation has agreed to support the organisation and retain the leadership of these meetings.
The SC unanimously welcomed the invitation and thanked CAMEVET for this proposal.

7. Reviews of:

7.1 The implementation and interpretation of VICH GLs in the regions

7.1.1 Report from the regulators

7.1.1.1 Report from JMAFF on the delay of implementation of Pharmacovigilance GLs in Japan

JMAFF confirmed that JMAFF is in the process of finalising the implementation of the Pharmacovigilance GLs in Japan which should be completed by the end of March 2017.

7.1.1.2 Report from other regions

The EU reported some difficulties to implement Pharmacovigilance GL 35 and partly GL 42, due to resource issues relating to development of the necessary IT capacity. The EU will update the SC at the next SC meeting.

Act: EU

The EU has agreed with the stakeholders to implement Electronic File Format GL 53 on a step by step basis.
JMAFF reported that the implementation of GL 53 has been made on schedule.

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

South Africa reported that the members of the national policy Task Force (representing the 2 relevant Ministries and the Industry) have been appointed. Two meetings have already taken place and 8 WGs are reviewing whether any of the 54 VICH GLs will require amendments to existing local rules. Most VICH GLs will probably be adopted and published on the authorities' website this fall. The next meeting of the TF is scheduled for September.

Australia reported problems establishing the database for VICH pharmacovigilance GLs, due to a lack of resources, which slows down the implementation of these GLs.

7.1.3 Any input from industry members

None

7.2 Written updates from the coordinators

The SC questioned the remaining usefulness of this specific document, providing an update with respect to the Action Table established after each SC meeting, and decided to discontinue this report.
In future, the Secretariat will re-send the Action Table with the first draft agenda of the following SC meeting, and add a specific column in which members can indicate the status of the actions at that time.

Act: Secretariat

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

The SC took note of the report.
USDA confirmed that the consultation for revised GL 50 and GL 55 will finish in mid-August.
The consultation in the EU will end on 1st August.
NZ will finish the consultation shortly.
Australia indicated that no consultation has been launched because the legislation does not provide for batch testing after approval; it is therefore unsure if Australia can implement these GLs.

8. Review of final VICH Guidelines at step 9

8.1. Proposals for revision of further VICH GLs

8.1.1. Update from the Secretariat on the VICH GLs which have passed the 5 years of implementation

The Secretariat explained that the table circulated prior to the meeting was based on the general GLs table with an additional column highlighting the current status of review for each GL. For each GL in chapter 1/ Draft and adopted GLs, the last column (date of last review) indicates either the status of revision (ongoing) or the date of the last revision; in this case the GL is reclassified in chapter 2/ VICH revised GLs at step 9.
If the corresponding block of a GL in the last column is in grey, the GL has been reviewed and no further action was required. If the block is in red, the GL is eligible for the 5 years' review.

The Secretariat will circulate the table again together with the detailed explanations. The table will include the GLs to be reviewed in 2017 and indicate which region had the topic leadership for each GL to be revised. The latter will be expected to collect comments from the regions.
The Secretariat will further update the procedure for review of final GLs.

Act: Secretariat

8.1.2. Review of VICH GLs

FDA has received questions from analytical chemists about the interpretation of language in MRK GL 49 and suggested therefore to consider the need for a revision of the GL.
The EU confirmed that the EWG Chair is aware of the issue that has been raised, but indicated that it is difficult to address as the EWG member with the most relevant expertise has left the group, so the EWG would need input from a new expert.
The EU agreed to provide a short Concept Paper (CP) clarifying the concern that has been raised and any action that would be needed to address this, in order to enable the SC to make a formal decision on whether to instigate revision of the guideline at the next meeting.

Act: EU

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

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.
The SC acknowledged that the discussions on the new stability testing guideline in climatic zones III and IV are ongoing and thanked the chairman and the topic leader for the excellent progress of the work.

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 SC confirmed its expectation of an in depth discussion at the next SC meeting on the areas of disharmonisation presented by the EWG.

The SC noted that the USA has proposed that the ISO 3166 Country Code list will be replaced with the GENC Country Code list, which would require an update of the wording in GLs 30, 35 and 42.
The EU indicated that it still needs to establish whether it can support this change.

Regarding the maintenance committee and procedures for VICH GL 30 - Controlled list of terms, the SC noted that the EWG has defined a revised procedure for an annual update of the lists.
The SC adopted the procedure proposed by the EWG in document VICH/IN/16010, subject to additional publication.

The SC asked FDA to thank Dr Brown for her excellent leadership.

9.3. Biologicals Quality Monitoring

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

a. Harmonisation of criteria to waive Target Animal Batch Safety Testing for live vaccines for veterinary use
Both draft revised VICH GL50 (TABST inactivated vaccines) and draft VICH GL55 (TABST live vaccines) have been released at Step 4 for a 6-months consultation period until 1st August 2016.

b. Harmonisation of criteria to waive Batch Safety Testing for veterinary vaccines: Laboratory Animal Batch Safety Testing (LABST)
As requested by the SC, a GL to waive LABST is in development based on the 2 TABST GLs. The EU recalled that members of the BQM EWG had indicated that they would collect information in their region on numbers of batches that have passed and failed LABST. SC members were asked to remind their BQM EWG experts of this.

c. Extraneous agents testing for Biologicals extraneous viruses testing
It was recalled that the EWG is currently developing a draft GL on the description of use of cell culture for the detection of extraneous agents (topic 1 - use of cell cultures for the detection of extraneous viruses in master seed viruses, master cell seeds and other starting materials of animal origin for mammalian veterinary virus vaccines) of which IFAH-Europe is the topic leader.

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.

a. Draft GL on Honey
The SC acknowledged that the draft GL 56 - MRK: Residues in Honey is ready for sign off by the experts at step 2.

b. Draft GL on Aquatic products
A new version was circulated to the EWG and the deadline for comments is end July. The GL should therefore be ready for sign off at step 2 in the near future.

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 the FDA.

a) Revision of VICH GL 23 (Safety - genotoxicity)
The SC acknowledged that the EWG has collected and collated data on experience with the existing genetic toxicology battery as it may relate to the proposed tiered approach. A report summarising this effort is being developed by a sub-group to be shared with the full EWG for additional discussion.

b) VICH GL 54 on the determination of an acute reference dose for residues
The final draft is ready for approval by the EWG.
The SC noted that JECFA (the FAO/WHO Joint Expert Committee on Food Additives) is also developing a draft ARfD guideline, which was discussed at the JECFA meeting in November of 2015, and further reviewed at the beginning of June 2016. The VICH draft was available at the JECFA discussions, and JECFA has shared a version of its draft with the VICH EWG members.
The SC was informed that the 2 drafts differ in the level of detail provided and, of particular note, the JECFA draft GL addresses the establishment of an ARfD based on microbiological effects on the human intestinal flora, an issue not addressed in the draft VICH GL. The SC acknowledged that the EWG may need to update the draft GL once JECFA has finished its work.

c) Review of the reports from the EU and JMAFF regarding the analysis of data on the revision of VICH GL 22
The EWG has made progress but discussions are still ongoing, as experts yet need to clarify if the extended 1-generation or the 2-generation study should be the default reproduction toxicity study recommended.

A proposal has been circulated for comment from the EWG members by the end of June. It was noted that there would be a slight delay providing EU comments as these need to be endorsed at the July CVMP meeting.
It was recalled that at the 32nd SC meeting it had been agreed that the recommendation from EWG would only be provided at 34th SC meeting.

9.6. Bioequivalence EWG

No report from the EWG which is waiting for its next task.

9.7. Anthelmintics EWG

The chair of the Expert Working Group, Dr. A. Phillippi-Taylor, reported that the EWG has been formed and has established its work plan.
The EWG requested the authorisation for a face to face meeting in 2017, avoiding the period of March to early June, as preferred by Japan.
The SC recognised the need for a face to face discussion and authorised the meeting in principle, subject to the provision of more details on the suggested time and location.

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

None presented

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

None presented

12. Progress Reports of the Task Forces and decision on next steps

12.1 Task Force for the development of a General Combination GL

12.1.1 Progress report of the Task Force

The SC reviewed the progress report prepared by the TF and congratulated Dr K. Noda for the extensive work that was achieved so far.

12.1.2 Draft Concept Paper for a General Combination Products GL

The SC reviewed the draft Concept Paper and agreed that the main focus of the GL should be on efficacy and, in particular, justification of the combination. Safety topics, if addressed, should only be addressed at a high level. It was noted that a broader scope would require several areas of expertise and could delay progress.
In order to finalise the draft CP at next SC in February, JMAFF recommended to ask the VOF countries to review the draft document and provide comments by 1st December. This would enable the TF to provide an updated version of the CP in time for the February SC meeting. TF Chair will prepare the updated draft CP reflecting discussions and comments provided at the present SC and VOF meetings. The Secretariat will send the document to the VOF members for comments by 1st December at the very latest.

Act: TF/Secretariat *(Done)*

It was nevertheless agreed that in case only few comments were received from the VOF by December, the deadline should be extended in order to gain good responses from VOF

members. The timeline would in this case be extended and the adoption of the CP postponed to a later date.
JMAFF suggested proposing to China to chair the new EWG, with support from JMAFF. The Secretariat confirmed that the Organisational Charter did not prevent a member of the VOF to chair an EWG, but a member from the regulatory authorities of the SC (full) members must become the topic leader after step 4. JMAFF indicated that current SC participants are not in a position to be topic leader for the development of this guideline and appealed SC members to find an appropriate person from a SC country/region for this role.
The SC proposed the chairmanship to China at the VOF meeting. China indicated needing a preliminary internal discussion and more information on chairmanship before being able to reply. China will respond to the SC next year.

13. Concept papers/Discussion papers

13.1 Status of the progress of the Concept Paper for a revision or not of the VICH GL 22 by including extended 1-generation reproduction study

Covered under 9.5.

13.2 Concept Paper on the need to elaborate on the next steps in the global approach to demonstrate Bioequivalence

The SC reviewed the draft Concept Paper presented by IFAH-Europe and the comments provided by the EU, and noted that different regions accept *in vitro* dissolution testing and biowaivers to differing extents, which could have an important impact on companies.
FDA believed as well that the underlying scientific issues need to be resolved before VICH could address this issue.
JMAFF would also support the topic once scientific evidence is available.
IFAH-Europe pointed out that companies are sometimes hindered by the lack of guidance for biowaivers; a common set of waivers would enable companies to identify when specific tests must be fulfilled.

The SC decided to keep this item on the list of VICH priority topics, and agreed that meanwhile SC members from authorities and industry will consider how to further establish the scientific basis.

Act: All

13.3 Concept Paper for two VICH Biologicals Guidelines

Following the request at the 32nd SC meeting for a proposal to develop two further GLs on Extraneous Agents (EA) testing of veterinary vaccines, the EU presented a Concept Paper for two further GLs: (1) general principles for detection of EA in veterinary vaccines and defining the testing of seeds and materials of animal origin, (2) a list of EA that need to be covered.
The SC reviewed the CP and noted that for the moment each region is handling these issues differently.
The SC agreed that the scope should be limited to extraneous viral agents (VA), based on a long history of consideration by VICH, and that the wording of “EA” should be substituted by “VA” from this moment onwards in order to focus on the right target for the potential GL. The general principle proposed in the CP is to first conduct a risk assessment to identify those agents for which testing is not required, then consider those agents for which testing would be needed and the appropriate test to apply.

JVPA noted that the USA have a different legal framework than Japan as they have currently different approaches to VA detection.
USDA believed that addressing emerging agents for which standardised testing procedures do not yet exist will be a challenge but confirmed that the USA can accept the principles behind the approach proposed for this GL.

The SC acknowledged that a number of challenges will have to be addressed in developing these guidelines. The list of viruses to be addressed should be global rather than regional and harmonised principles will be required to decide in which circumstances testing would not be necessary for agents appearing on this list, the intention being to provide the basis for a harmonised global approach which is lacking at the moment.

The SC approved the proposed CP and agreed that the EU will be topic leader for both proposed topics whilst IFAH-Europe will retain the topic leadership of the current draft GL on viral agent testing on cell lines.
The SC confirmed that the required expertise is already present in the current EWG and supported the proposed timeline for a first draft GL to be circulated at the end of January 2017.

13.4 Discussion Document from JMAFF on the definition of "biologics"

JMAFF explained that the background of the document rests on the fact that different terminology is used in different regions, sometimes to mean essentially the same thing.
The objective is therefore to clarify the meaning of relevant terms and so avoid confusion when developing the next VICH Biologicals GLs.
JMAFF proposed to manage the update of the taxonomy table as science will advance.

The SC thanked JMAFF for the work that was developed and agreed that this document will remain an internal document.
JMAFF will produce an updated version including the comments received for further review at the next SC meeting with a potential discussion at the 8th VOF meeting as well.

Act: JMAFF

13.5 Other VICH topics

JMAFF recommended the development of a new GL for the Safety of biological/ biotechnological products based on the ICH S6 R1 revised GL. JMAFF is developing a CP that will be presented to the next SC meeting.
It was pointed out that ICH S6 R1 focuses on substances extracted from biotechnological processes, but JMAFF will propose to include an extended scope of topics on safety of biological/biotechnological products.
IFAH-Europe recommended to discuss the proposal with experts at an early stage before presenting the CP to the next SC meeting.

14. Other issues

14.1 Discrepancies with GL 9 – Good Clinical Practice

A clinical investigator had written to the VICH secretariat to point out a discrepancy in GL9 related to defining those situations in which it was appropriate to break the blinding of a clinical trial. AHI explained that this person has recently had an in-depth discussion with a member of the SC and has retracted the request for the GL to be amended.

14.2 Request for separate observer status Australia – New Zealand

Australia and New Zealand explained that they had so far a joint observer status, but there is now locally unanimous support from industry and regulators for separate observer status in VICH.
The Secretariat confirmed that there is no procedural hindrance; there will only be a need to update the Organisational Charter.
The SC approved the separate observer status for Australia and New Zealand. The Secretariat will update the Charter.

Act: Secretariat

15. Any other business

15.1 Update on the ICH reform

The SC received presentations made by Pär Tellner, Director Regulatory Affairs (EFPIA) – ICH Coordinator and Lenita Lindström-Gommers, Directorate General for Health and Food Safety (European Commission) – Chair of the ICH Assembly. ICH had undergone a substantial process of change resulting in the creation of an independent not-for-profit legal body based in Switzerland. The change arose as a result of the need to respond to public pressure for the organisation to be seen to establish guidelines in consultation with, but independently from, the pharmaceutical industry and to ensure that ICH is perceived as an 'open' organisation open to the global community.
Comparing ICH and VICH, the SC recognised that some challenges are common, but that the small scale of the veterinary domain and the consequent lower overall level of resources available mean that it would not be appropriate at the present time to seek to follow the ICH model. The SC noted that VICH has addressed the need for involvement of non-VICH countries in VICH activities through the VOF which is more adapted to the needs of the international veterinary community.

The SC therefore agreed that there is no urgent need for a reform of VICH, although the SC must continue to reflect on the future evolution of VICH in the context of the increased global awareness of VICH and the need to meet reasonable expectations of the public in terms of impartiality in the creation of guidelines.
The SC was surprised by the lack of emphasis placed on the One Health concept within the revised framework for ICH as this is considered such a fundamental building block in the veterinary domain.

15.2 Tribute to T. Komatsu, A. Holm and M. Smith

On behalf of the SC, the Secretariat awarded a certificate and a souvenir plate to T. Komatsu, A. Holm and M. Smith in acknowledgement of their commitment to VICH for many years. The JVPA, EU and FDA delegations received the acknowledgment on behalf of all 3 former SC members, respectively.

15.3 Organisation of the VICH 6 Conference

Considering the date of 2019, the SC agreed that a first draft programme should be discussed at the 34th SC meeting for a finalisation at the 35th SC meeting in Tokyo in November 2017. All members were asked to reflect on the topics that should be covered.

Act: All

16. Dates and venue of next meetings

- The 34th SC meeting will take place in Buenos Aires - Argentina from 27 February to 2 March 2017 hosted by CAMEVET and AHI
- The 35th SC meeting will take place in Tokyo – Japan from 13 to 16 November 2017

17. Adoption of the Press Release on the 33rd SC meeting

The SC members reviewed and adopted the press release drafted by the Secretariat.

VICH STEERING COMMITTEE

33rd meeting

20, 21 & 23 June 2016
Brussels (Belgium)

Chair: D. Mackay (EMA)

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

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