VICH/15/081
12 January 2016
Final

VICH STEERING COMMITTEE
32nd meeting
25, 26 & 30 October 2015
Tokyo

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Minoru Yamamoto, Director General, National Veterinary Assay Laboratory, JMAFF. He opened the meeting by welcoming the participants to Tokyo for the 32nd VICH SC meeting.
The SC held a minute of silence in the memory of Dr M. Moroe, former representative of the South African regulators to the VOF, then the SC.

2. Adoption of the agenda

The agenda was adopted with 3 additions: discussion on the training implementation, timing and location of the VICH 6 Conference and composition of the ANZ delegation.

3. Finalisation of VICH basic and guidance documents

3.1. Review of the VICH Organisational Charter (VICH/96/002_12-dr5)

The SC reviewed and discussed the version 12 draft 5 prepared by the secretariat, and adopted the final version after including minor changes for clarification.

3.2 Other documents

None

4. VICH Outreach Forum

4.1 Preparation for the 6th VICH Outreach Forum meeting

4.1.1 Review of the participants list

The SC reviewed the draft agenda of the 6th VICH Outreach Forum (VOF) meeting and approved the presentation by the secretariat.
The SC regretted that neither China, Russia nor India were represented. It was noted that, exceptionally, Argentina will be represented by only the industry representative from CAPROVE due to the late apology from the Argentinian regulator.

4.1.2 Review of the agenda and preparation of the 6th meeting

The SC decided to add a point introducing the VICH Phase 4 Priorities to be presented by JMAFF under specific issues agenda item 10.4, and to include a discussion on the TABST (already addressed at the 5th VOF meeting) in the discussion on application of VICH guidelines.

4.1.3 Other issues

4.1.3.1 Saudi Arabia

IFAH-Europe reported that the Kingdom of Saudi Arabia FDA had expressed interest in becoming a member of the VOF. It was agreed that there is a need to ensure that the SFDA meets the necessary criteria laid down in the Terms of Reference (VICH/11/010).
Post-meeting note: a verbal contact was made during the VICH 5 Conference. The SFDA has immediately sent a written confirmation of interest to the VICH Secretariat, which has returned questions on the regulatory framework to the SFDA. The Secretariat will follow-up.

Act: Secretariat

4.1.3.2 Training implementation WG

FDA recalled that the implementation of the training strategy is part of the VICH Phase IV strategy. At the last meeting the SC had decided to create an Ad Hoc Working Group on Training Implementation that will be composed of 3 subgroups: one subgroup led by industry which will identify sources of funding; one subgroup led by the regulators which will focus on the training programmes and educational materials and a third subgroup, to be established later, to work on technical means and logistics.
OIE indicated that it would not lead this ad hoc group because of lack of resources and the necessity to seek funding.
The SC therefore decided that the 2 subgroups would work independently. It was confirmed that the subgroup on funding is led by industry.
The subgroup on the Training Content and Materials is composed of:
S. Vaughn (FDA)
B. Walters (FDA)
A. Holm (EU)
N. Jarrett (EU)
A. Sigobodhla (South Africa)
P. Reeves (ANZ)
M. Szabo (OIE)
T. Kozasa (JMAFF)
H. Marion (Secretariat)

HealthforAnimals confirmed that discussions on possible funding started during the Global Animal Health Conference last June with the Bill and Melinda Gates Foundation (BMGF). A successful training session on VICH, with 80 participants, was organised in the margin of that Conference. The BMGF is showing strong interest in providing financial support for training on VICH for non-VICH countries, in particular on the Asian and African continents. The BMGF would not want to be involved in developing the content of training sessions.

FDA verbally presented an outline of a draft implementation plan for the Training Content and Materials subgroup with the overall objective to develop training materials on all VICH GLs by the end of 2020. The first steps would be to determine which GLs to prioritise, to identify all existing presentations and to develop a template for the training, based on a 3-day training course for 25 to 30 persons.

It was agreed that training will have to be requested by a country or a region and that the individual programmes will have to be set up with a flexible approach, in order to take account of the level of development of the country's regulatory structure.
Post-meeting note: The draft plan (VICH/15/088) was circulated to the SC immediately after the meeting for comment by the end of November.

Act: All

The SC decided that a first test training session should be organised in summer 2016 considering that the BMGF intends to finance a first training session before the end of the year 2016.

4.2 Review of the Outcome of the 6th VICH Outreach Forum meeting

The SC addressed this agenda item after the 6th VOF meeting and noted that Singapore had participated for the first time.
The SC regretted that the representatives from Brazil had travelled to Japan and attended the VICH Conference but not the VOF meeting as they had misunderstood the invitation. The SC expressed its hope that Russia would be represented again at the next meeting.
It was confirmed that, for the next meeting, the VOF members wished to maintain the current structure of the agenda, which had allowed successful discussions in 2 different breakout sessions.

The SC identified the following topics for discussion at the 7th VOF meeting:
Breakout sessions:

- Discussions on the expectations regarding the training strategy implementation, and how to address the needs in the different VOF countries
- Group discussion on the application of VICH GLs with feedback on challenges from VOF members

OIE and the secretariat will ask the VOF members to review and discuss the topics in advance with the experts in their countries in order to encourage more practical debates.

Specific issues suggested by VOF members for possible presentation/discussion

- Pharmacovigilance and the need for an adequate system
- GL 27 & AMR, the management of Risk Assessment: putting policies in place at registration level to implement AMR control
- Functioning of the OIE database
- Experience of VICH members on the implementation of the Anthelmintics GLs and the issue of parasiticides' resistance (FDA will prepare a presentation)

Act: FDA

- Efficacy of vaccines (OIE to liaise with China in order to better understand what is sought)

Act: OIE

- Generics registration
- Results of the survey from HealthforAnimals on VICH GLs awareness
- Presentation by new participants of their regulatory framework (OIE will ask Singapore and Saudi Arabia – if they participate)

IFAH-Europe recommended that the SC should remain flexible regarding the demands from VOF members on topics to be addressed at VOF meetings.
It was agreed that OIE and the secretariat will circulate a first draft agenda very soon to the SC for comment, and to the VOF members.

Act: OIE/Secretariat

Following a request from the ASEAN representative, the SC agreed in principle to contribute to the next ASEAN meeting in April 2016. The secretariat will ask for clarification on what is expected.

Act: Secretariat

5. Review of the VICH 5 Conference programme and any comment

The SC supported last minute changes made to Session 7 and agreed to add a short presentation from JMAFF on combination products.
The SC noted with satisfaction that 193 participants from 23 countries had registered.

6. Review and adoption of the draft Priorities-Phase IV

The SC adopted the draft 4 of the document with 2 minor changes.

7. Reviews of:

7.1 The implementation and interpretation of VICH GLs in the regions

7.1.1 Report from the regulators

The EU explained that although all GLs are usually implemented on time, it will not be possible to fully implement GLs 30, 35 and 42 by the formal implementation date because ofresource issues associated with updating the EU database on adverse events reporting (Eudravigilance). The delay could exceed 1 year.

JMAFF confirmed that GLs 23 R, 48 R & 49 R have been implemented on time, but Japan has to delay the implementation of the PhV GLs because Japan needs a new budget. The delay could be of 1 or several years.
JMAFF will provide more information at the next SC meeting.

Act: JMAFF

FDA reported that GLs 24 & 29 have not been fully implemented yet; bioequivalence GL 52 will be published shortly.

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

South Africa reported that the members of a national policy Task Force (representing the 2 ministries and the industry) have been appointed in order to consider together how to implement all VICH GLs.

Australia confirmed that it will adopt as much VICH GLs as possible, with the exception of the MRKs GLs which must be considered separately because of local legal issues.

7.1.3 Any input from industry members

None

7.2 Written updates from the coordinators

The SC took note of the report.

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

None

8. Review of final VICH Guidelines at step 9

8.1. Proposals for revision of further VICH GLs

8.1.1. Review of the status of the revision of all VICH GLs

The SC reviewed the table presented by the secretariat and acknowledged that the resources required for a regular systematic review of all GLs would be substantial. It was noted that, in practice, when an issue arises with a GL this is picked up quickly by industry and regulators, which bring the issue to the attention of the SC. It was agreed that, in future, topic leaders would be asked to review new GLs after 5 years, with a view to highlighting any areas that might need updating. The SC asked the secretariat to keep the list of reviews updated and to flag at each SC meetings the GLs which have passed the 5 years of implementation.

8.1.2. Review VICH GLs

No suggestion for a review was made.

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 noted that new experts who will address the topic of climatic zones III & IV have been nominated recently, including experts from the VOF countries.
The topic leader is Dr Mai Huynh – FDA.

9.2. Electronic Standards Implementation – Pharmacovigilance

Dr M. Brown, chair of the Expert Working Group, reported that the ESI EWG held a teleconference in September and agreed to proceed with the routine maintenance of GL 30, the revisions of GLs 35 & 42, as well as GLs 24 & 29. The EWG has reviewed the document from industry and concluded that disharmonisation is the main obstacle to implementation of the GLs; some issues cannot be solved at this stage because legislative barriers.
The EWG also decided to address specific topics in smaller subgroups.

The SC thanked Dr Brown and the experts for the work achieved and confirmed the mandate given at the 31st SC meeting to proceed with the routine maintenance of the GL 30 vocabulary list, with the review of industry's paper on the impact of disharmonisation, with the finalisation of the validation procedures document and with the discussion on the creation and use of a harmonized xml message to be sent as acknowledgement for received submissions from industry.

However, the SC concluded that it had not given the EWG a mandate to revise GLs 24 & 29. In order to prevent possible confusion the SC adopted the document “Mandate for the VICH ESI EWG” (Ref.: VICH/15/085-final)

The SC recommended strongly that the work should progress in a manner that allows all member of the EWG to participate fully.
The SC also encouraged the EWG to ensure that, if additional experts are invited to participate in a meeting, they should represent the knowhow and the needs from all VICH regions.

9.3. Biologicals Quality Monitoring

Dr K. Oishi, chair of the Expert Working Group, confirmed that during the 10th EWG meeting, which took place simultaneously to the SC meeting, progress was made on the 3 following topics.

a. Harmonisation of criteria to waive Target Animal Batch Safety Testing for live vaccines for veterinary use
The EWG has signed off at step 2 the draft GL 55 for TABST for live vaccines. In order to align the text of both GLs for live and inactivated vaccines, the EWG recommended to review simultaneously GL 50 in order to introduce editorial changes and to align the number of consecutive batches recommended in order to waive TABST.

The SC agreed that GL 50 should be revised at step 9 and asked the EWG to provide an amended draft ASAP to the SC. The SC will then sign the revision of GL 50 off at step 3 by written procedure and publish both draft GLs together at step 4 for a 6 months consultation period.
Meanwhile the SC signed off GL55 at step 3 during the meeting.

b. Harmonisation of criteria to waive Batch Safety Testing for veterinary vaccines: Laboratory Animal Batch Safety Testing (LABST)
Dr Oishi considered that the appropriate expertise was available in the EWG and recommended that the SC should give the mandate to the EWG to proceed with the development of the GL based on the Concept Paper submitted by the EU in 2013 (Ref.: VICH/IN/13001), including the collection of the data. Although the CP was originally an EU document it was modified and agreed by the EWG and so was presented to the SC as a CP from the EWG. He pointed out that the 2 existing TABST GLs may serve as basis but that some criteria used might be different.
The EWG expected that the draft GL could be signed off during a face to face meeting in early 2018.

The SC adopted the Concept Paper and asked the EWG to proceed with the work. The SC acknowledged the request for face to face meeting but noted that it was too early to authorise this meeting. The EWG will submit a formal request once the work would be sufficiently progressed.

c. Extraneous agents testing for Biologicals extraneous viruses testing
It was noted that this topic had previously been discontinued twice but that all SC members were willing to re-open the discussion.
The EWG suggested to draft 3 different GLs and estimated that a draft GL on topic 1 (description of use of cell culture for the detection of extraneous agents) may be finalised at step 2 by written procedure in early 2016.

The SC agreed that the topic leader from the EU will provide one or two new Concept Papers covering topics 2 and 3 (i.e. list of extraneous agents and general principles for detection of extraneous agents and defining the testing of seeds and materials of animal origin) for approval by the SC.
The SC congratulated Dr Oishi and the experts for the work achieved.

9.4. Metabolism and Residue Kinetics EWG

The SC noted 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 a further revised version of the document is being reviewed by the experts and a draft GL could be signed off at step 2 in early 2016.

b. Draft GL on Aquatic products
Some difficult issues remain to be addressed by the experts and a draft GL may be signed off at step 2 in mid-2016.

9.5. Safety EWG

a) Revision of VICH GL 23 (Safety - genotoxicity)
The chair of the Expert Working Group, Dr K. Greenlees, reported that the experts have started to review the issues but a consensus has not yet been reached on the tiered approach to genotoxicity testing, as recommended by EFSA. Additional data is being collected and the EU experts will provide a consolidated document reviewing the inputs.

b) VICH GL 54 on the determination of an acute reference dose for residues
The public consultation period for the draft GL ended in August 2015 and the experts are reviewing the comments received. A step 5 document should be available in mid-2016

c) Review of the reports from the EU and JMAFF regarding the analysis of data on the revision of VICH GL 22
Dr Greenlees explained that a proposal has been made to consider revising GL 22 to allow for inclusion of the extended 1-generation reproduction study (EOGRTS) as an alternative to the 2 generation study but that, at the moment, there was not a feeling that the EOGRTS can be accepted as a default alternative to the 2 generation test.
The EU recalled that it had previously given an update on its review of the 2 generation study; the final paper had now been made available to the SC (VICH/IN/15019). The EU paper concludes that the 2 generation study is very unlikely to result in a more appropriate NOEL than the EOGRTS. The EU also reminded the SC that JMAFF had previously presented its report regarding the analysis of data on the revision of VICH GL22 (VICH/IN/15029), in which it had highlighted some concerns.
The EU, JMAFF and FDA agreed that further scientific discussion of the issues is needed and therefore proposed that the EWG should analyse the issue and consider how the EOGRTS might be integrated into GL 22 (VICH/IN/15027).

The SC noted the need to include reproductive toxicity specialists in the discussions.
The SC mandated the safety EWG to provide, to the 34th SC meeting, a Concept Paper for a revision or not of the VICH GL 22 by including extended 1-generation reproduction study, and decided that additional advisors on reproductive toxicity should be added to the EWG.

The secretariat will circulate call for advisors.

Act: Secretariat

The SC thanked Dr Greenlees and the EWG for the progress achieved so far.

9.6. Bioequivalence EWG

The chair of the Expert Working Group, Dr M. Martinez, presented the achievements and challenges encountered in the development of VICH GL 52 and explained that the EWG had recognised that the implementation of the GL should maintain flexibility to allow, within some jurisdictions, for less stringent requirements on when a study is to be submitted to support product marketing solely within that specific region. Therefore, in these situations, the term "To be internationally acceptable" was used.
The SC thanked warmly Dr Martinez and the experts for the finalisation of this GL in a short period.

IFAH-Europe recalled that at the 24th SC meeting related topics such as in vitro dissolution testing and biowaivers were excluded from the scope of the GL and it was agreed that new Concept Papers should be submitted in case these topics should be addressed.

Dr Martinez suggested that it would be appropriate to address next in vitro dissolution testing - both for oral dosage form as well as parenteral form.
IFAH-Europe agreed to provide to the SC a Concept Paper formally proposing this work and including a work plan.

Act: IFAH-Europe

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

The SC adopted the draft GL 55 at Step 3. This guideline will be transmitted to the VICH members for a 6 months public consultation at Step 4. The SC delayed the publication in order to enable the publication of this draft GL together with the revised VICH GL 50 at step 9, once adopted at step 3 by the SC.

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 Review of the revised Discussion Document to be prepared by the Task Force on the revision of VICH Anthelmintics GLs

Dr A. Phillippi-Taylor, leader of the TF, reported that the members of the TF have considered potential topics for revision and classified these as topics for revision, not for revision, or as topics for which no consensus was reached.
The SC reviewed the Discussion Document and congratulated Dr Phillippi-Taylor and the experts for the quality of the document that was developed.
The SC confirmed that the document represents a useful basis for the work of the EWG.

The SC decided to create an Anthelmintics EWG, chaired by FDA, to consider the topics referenced in the Discussion Document. The SC detailed the mandate of the EWG in the document "Mandate for the VICH Anthelmintics EWG" (Ref.: VICH/15/084-final).

The EWG will initially work by electronic procedure, but may request a face-to-face meeting at a later date if needed.
The Secretariat will circulate a call for Experts.

Act: Secretariat

12.2 Review of the revised Discussion Document prepared by the Task Force on VICH Guidance for Efficacy Studies for Combination Drug Products

The SC reviewed the extensive documents prepared by the TF and congratulated Dr K. Noda and the TF for the excellent summary that was collected.

The SC confirmed that the topic of the combination of antimicrobials shall not be addressed. FDA believed that, if a specific GL is to be developed on the topic combination of antiparasitic substances, this should be addressed by the Anthelmintics EWG.
The SC decided that the first topic to address should be a general GL, and recognised the need of a Concept Paper to clarify the mandate of an EWG, and in particular which expertise will be required i.e. safety, toxicity etc…

The SC decided to rename the "TF for the development of a general combination GL" and mandated the TF to develop by electronic procedure a Concept Paper addressing the development of a general combination GL, for review at the next SC meeting. This CP will have to clarify the scope and address the justification of combinations as well as safety, efficacy and residues issues.

It was agreed that the composition of the TF will be flexible in order to include in the electronic discussion any expert which a SC would deems appropriate; moreover the SC members themselves should be included in the electronic discussion.

Act: TF

13. Concept papers/Discussion papers

13.1 Review of the reports from the EU and JMAFF regarding the analysis of data on the revision of VICH GL 22

Covered under 9.5.

13.2 Review of the Discussion Document from JMAFF on the definition of "biologics" generally being used by the regulatory authorities, etc...

JMAFF recalled that following the survey results on the needs for biological/biotechnological product guidelines, the SC had supported possible conversions of corresponding ICH GLs to VICH GLs, under the condition that an appropriate Concept Paper will be proposed and supported by the SC.

Separately, the SC recognized that the definitions for such products required further discussion; JMAFF was therefore asked to develop a discussion document.

The SC reviewed the Discussion Document prepared by JMAFF and took note of the Taxonomy of Biologics created by JMAFF. It was acknowledged that the Taxonomy could be discussed separately from GLs, e.g. including a glossary on the VICH website.

The EU pointed out that these definitions would not be legally binding, but this could be overcome by adding some explanatory remarks such as "taxonomy" is independent of any regulatory framework of the authority.

The SC decided that each member should consult their experts in view of a further discussion at the next SC meeting.

Act: All

13.3 Other VICH topics

None

14. Outcome of the VICH 5 Conference

The SC took note that 189 persons registered from the six continents have attended, which was considered to be a very satisfactory outcome for this first Public Conference since the SC established the VICH Outreach Forum in 2012, looking back on 5 years of active commitment by the VOF members.

The SC applauded JVPA, Dr Itoh & Dr Makie for the perfect organisation of this epoch-making 5th Public Conference in the history of VICH.

There was however not much participation from non-VICH, non-VOF countries. OIE encouraged the SC to stimulate more involvement of these countries for the next VICH Public Conference.

The secretariat confirmed that all the presentations will be placed on a special section of the VICH website

15. Other issues

15.1 ANZ

ANZ explained that the Australian and New Zealander delegations would probably request separate observer status in the future. ANZ will inform the secretariat before the next SC meeting.

16. Any other business

16.1 Location of the VICH 6 Conference

The VICH 6 Conference should in principle take place in the USA in 4 to 5 years, but it was proposed to organise the next VICH public Conference outside of the VICH regions, and to reflect on which region(s) should be considered, knowing that India, Latin America and Africa are regions with growing interest.
The secretariat stressed the importance of having reliable organisers located in the country where the Conference takes place.
JVPA highlighted the necessity of financial contribution from member companies and HealthforAnimals, and that budgets need to be planned at least 3 years in advance.
South Africa volunteered to organise the VICH 6 Conference in Cape Town.

The SC supported the proposal in principle, taking into account that the USA delegation needed to reflect further.
The problem of the date should be also discussed: in 2020 the VICH SC and VOF meetings should in principle take place in June (in Europe). Perhaps the VICH 6 Conference could be moved forward to November 2019 with the 38th VICH SC meeting.
The SC therefore agreed that this topic should be discussed thoroughly at the next SC meeting in June 2016 for a final decision (concerning the date and the location) by the end of 2016 at the latest.

Act: All

16.2 Tribute to K. Grein, O. Itoh and L. Klostermann

On behalf of the SC, the Secretariat awarded a certificate and a souvenir plate to K. Grein and L. Klostermann in acknowledgement of their commitment to VICH for many years. The EU and IFAH-Europe delegations received the acknowledgment on behalf of both persons.
The acknowledgment to O. Itoh was handed out in person during the Conference dinner.

16.3 Farewell from A. Holm and T. Komatsu

A. Holm and T. Komatsu announced that this was their last participation in a VICH SC meeting. The SC warmly thanked A. Holm and T. Komatsu for their strong commitment and their active contributions to VICH over the past several years.

16.4 ICH reform

FDA proposed to review the ICH reform at the next SC meeting. IFAH-Europe will identify a speaker from ICH.

Act: IFAH-Europe

17. Dates and venue of next meetings

- The 33rd SC meeting will take place in Brussels, Belgium on 20 to 23 June 2016
- The date and location of the 34th SC meeting are still to be confirmed.

The Secretariat has received a formal invitation from Argentina to meet in Buenos Aires 27 Feb to 2nd March 2017 - location tbd

18. Adoption of the Press Release on the 32nd SC meeting

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

VICH STEERING COMMITTEE

32nd meeting

25, 26 & 30 October 2015
Tokyo (Japan)

Chair: M. Yamamoto (JMAFF)

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI (BAYER)	B. MARTIN
AHI (ZOETIS)	M. J. MCGOWAN
AHI	K. KLAUS (C)
EU (EUROPEAN COMMISSION)	N. JOSEPH
EU (EMA-CVMP)	A. HOLM
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IFAH-Europe (MERIAL)	B. BOENISCH
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US (FDA)	M. SMITH
US (USDA APHIS)	B.E. RIPPKE
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OBSERVERS

Australia/New Zealand (MPI)	W. HUGHES
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Canada (Health Canada)	M-J. IRELAND
Canada (CAHI)	J. SZKOTNICKI
South Africa (DAFF)	A. SIGOBODHLA
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AVBC	J. THOMAS

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