



VICH STEERING COMMITTEE
31st meeting
23-26 February 2015
Washington DC

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Bernadette Dunham, Director of the Center for Veterinary Medicine – FDA. She opened the meeting by welcoming the participants to Washington for the 31st VICH SC meeting.

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_12-dr1)

The SC reviewed the version 12-draft 1 prepared by the secretariat and supported most of the changes proposed. The SC asked the secretariat to simplify chapter 5.2.2. *Role of the Coordinators* as well as to shorten the new chapter 7. *VICH Outreach Forum* in order not to duplicate details described in other documents and to use consistent terminology. The secretariat will circulate a second draft for further electronic discussion, and possibly approval by written procedure within the next months.

Act: Secretariat

3.2 Other documents

None

4. VICH Outreach Forum

4.1 Preparation for the 5th VICH Outreach Forum meeting

4.1.1 Review of the agenda of the meeting

The SC reviewed the draft agenda of the 5th VICH Outreach Forum (VOF) meeting and approved the presentation by the secretariat.

4.1.2 Review of the proposals from the ad hoc group on Training and Communication Strategy

FDA reported that the ad hoc group has finalised the training strategy, including a communication leaflet and PowerPoint presentations providing information on VICH and its guidelines and prepared an updated training strategy. ..

The SC reviewed and adopted the draft 3 of the training strategy (VICH/13/078) including the amendments proposed by the EU as well as the information material which will be made available to the VOF.

The SC took note of the draft key messages document developed by OIE, but agreed not to develop this proposal further as the VICH website already contains sufficient messages and information. The SC concluded that the ad hoc group had accomplished its task and thanked for their achievement.

FDA presented the Concept Paper for the Creation of an Ad Hoc Working Group on Training Implementation recommending that a new ad hoc group be created.

The main objectives of the new group will be: to develop funding opportunities including forging partnerships with outside organisations for the level 2 training; to clarify the logistics of the training programmes; and to establish training material and identify the experts needed to deliver the training. The latter will be essentially managed by the regulators. Considering the high interest for training on quality requirements particular commitment may be expected of the Quality EWG in the initial training stage.

The SC endorsed the CP with the comments submitted by the EU and decided to create an ad hoc group 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, e.g. exploring how to deliver training in practice incl. technical options such as web based training material, videos etc...

The ad hoc group could be chaired by OIE, after confirmation by OIE Headquarters.

The members are:

- J.-P. Orand (OIE)
- B. Walters (FDA)
- A. Sigobodhla (South Africa)
- 1 representative of JMAFF
- 1 representative of JVPA
- 1 representative of the EU (to be confirmed)
- R. Clayton (IFAH-Europe)
- C. du Marchie Servaas (IFAH)
- H. Marion (Secretariat)

OIE will confirm the chair of the ad hoc group and then will circulate a first draft of a "Terms of References – ToR" for the ad-hoc group by the end of March.

Act: OIE

The SC decided that 1 or 2 members of the VOF should also be invited to take part in the ad hoc group.

The SC confirmed that all the information on VICH, such as the VICH general presentation, the explanation document in 5 languages, the presentations of general interest made at the different VOF meetings etc... should be easily accessible on the VICH public website. The

VICH General short presentation made by JMAFF at the OIE NFP training seminar in Tokyo on 3-5 Dec 2014 will also be placed on the website.

Act: Secretariat

4.1.3 Review of the participants list

The SC noted that 6 VICH VOF countries (Argentina, China, Korea, Russia, Thailand and Ukraine) and 2 regional organisations (CAMEVET and ASEAN) have confirmed participation with Thailand representing ASEAN.

The secretariat mentioned that UEMOA, Morocco and Tanzania could not participate at this meeting but had confirmed their strong interest in participating in the VOF. No recent update information has been provided by Brazil, India and Mexico. The Russian representative informed OIE just before the meeting that he could not attend the meeting.

OIE has re-sent specific letters to the relevant countries and will highlight once more, at its next General Assembly, the importance of attending the VOF meetings.

Regarding the participation of Tanzania, the secretariat will clarify if Tanzania will represent the Tanzanian government or the EAC.

Act: Secretariat

4.1.4 Organisation of the group discussion session

The SC proposed the following two discussion groups' memberships:

Group 1: Participants from Argentina, Thailand, CAMEVET & China

Group 2: Participants from CAMEVET, ASEAN-Thailand, Ukraine & Korea

4.1.5 Review of progress of the Task Forces

4.1.5.1 Review of the Concept Paper prepared by the Task Force on the revision of VICH Stability GL 3(R)

IFAH-Europe reported that the TF has worked mainly by electronic exchange.

The EU mentioned that some comments provided had not been taken into account in the CP. The SC reviewed the CP prepared by the TF and agreed that the VICH Quality EWG should continue the work initiated by the TF. The EWG should seek good representation from the VOF regions, with active involvement from Asia, Africa and Latin America, in particular those with warmer climatic zones. OIE was asked to provide, where possible, more details from the survey on the topic that was conducted last year.

The EWG should focus on developing a basic guidance for conducting stability studies for climatic zones III and IV, which will be a stand-alone GL and not a revision of VICH GL 3(R) itself. The EWG will take into account the considerations included in the discussion from the TF and in existing guidance, and keep the new guidance simple, with a step-wise approach for later further development, if appropriate.

The SC reviewed and amended the presentation prepared by IFAH-Europe for the VOF.

After the VOF meeting, the SC adopted the mandate for the EWG (VICH/15/035) and agreed that the FDA will be the topic leader for this guidance.

The secretariat will ask the VOF countries/regions to identify experts to complete the Quality EWG for this topic: 1 expert from Asia, 1 expert from Africa and 1 expert from Latin America. It was hoped that Australia and South Africa could contribute to the work.

Act: Secretariat

4.1.5.2 Review of the Concept Paper prepared by the Task Force on VICH Guidance for Efficacy Studies for Combination Drug Products

The SC reviewed the progress report prepared by the TF, in particular the list of combination products existing in the world, and noted that the main target combination products are anti-parasitics.

The SC recognised the need for a general combination GL as a first step, but asked the TF to continue to work on a Discussion Document, including a global catalogue of major combination products, for presentation at the 32nd SC meeting, as per the mandate of the TF. Meanwhile, the SC encouraged UEMOA and ANZ to provide input into the TF.

4.1.6 Consensus on the opinions/directions from the SC

Covered above.

4.2 Review of the Outcome of the 5th VICH Outreach Forum meeting

4.2.1 Debriefing and review of the conclusions of the Forum meeting

The SC addressed this agenda item the day after the 5th VOF meeting by reviewing the conclusions of the meeting and noted with satisfaction that there has been much progress in the recognition of VICH technical standards in the VOF countries/regions. China in particular confirmed that they have already adopted several GLs based on VICH standards.

There is a clear recognition by the VOF participants of the importance of VICH GLs, but the message must also be conveyed to the higher level of decision makers in the countries in order to obtain political support.

The SC also recognised the importance of the future attendance of representatives from Brazil, India and Mexico, and that a personal outreach to senior decision makers in VOF countries may be useful. FDA proposed to build on its contacts in Brazil and Mexico to encourage VOF attendance.

Act: FDA

It was pointed out again that there seems to be expectations in the VOF countries that VICH would have similar structure and adoption process as Codex and JECFA, with which work VOF countries are more familiar, and that the understanding of the difference between the activities of the different organisations needs to be emphasized.

OIE highlighted its dedicated webpage on the VOF, which points out the importance of having legislation in place for the authorisation and control of veterinary medicinal products and provides links to the VICH website.

It was noted that some VOF participants had indicated that the best way to get support from their hierarchy to attend VOF meetings is to have the CVO of their country receive the invitation to VOF meetings.

The SC acknowledged that more ASEAN countries may wish to participate in the 6th VOF meeting in Tokyo and agreed that the attendance of ASEAN members that are not direct VOF members should be encouraged on this occasion.

The secretariat will therefore send a formal invitation to the ASEAN secretariat for senior representatives of its member countries.

Act: Secretariat

The SC discussed the suggestion from VOF members to invite industry representatives from the VOF countries to attend the meetings. It was noted that industry could bring the support of more regional companies and encourage the support of the VOF process at the political level in some countries.

The SC recognised that in some Asian countries there is a close working relationship between industry and regulators, and therefore agreed to suggest to the VOF members that they invite a representative of their industry to the next VOF meeting.

The EU expressed some reservations during the SC meeting regarding industry attendance but committed to review the position.

[Post meeting note: the EU confirmed that it supports participation of industry associations from the countries attending VICH Outreach Forum meetings. Industry participation at those meetings should be beneficial regarding transparency and should improve awareness of VICH and VICH guidelines in the VOF countries.]

➤ *The SC identified the following topics for discussion at the 6th VOF meeting:*

○ *VICH topics*

The SC noted that VOF members had suggested review of the following topics:

- High level discussion on the objectives of the GL 27 (AMR)
- Setting up of an Aquaculture medicines dossier with different requirements - to extend beyond the MRK GL in fish; it was acknowledged that JMAFF has evaluated many aquatic medicines (including anaesthetics) for fish and JMAFF agreed to introduce this topic.
- Bioequivalence and generics
- Implementation of GL on TABST waiver in the 3 VICH regions
- TABST
 - Issue in Korea with GMP on seed lots
 - Presentation to ASEAN countries who have not participated in the past VOF meetings

○ Possibility of a GL on Herbal medicines

The SC considered the latter as a challenging topic; for some herbal veterinary medicines evaluations have been carried out in the EU) regarding residues/MRLs, but there are no specific GLs for authorisation of veterinary herbal medicines.

○ VICH training strategy

It was agreed to follow the strategy proposed by the training task force, and to introduce training modules at two levels (1: high level and 2: more detailed).

The SC noted again the importance of circulating the presentations from SC members in advance of the meeting or providing hand-out documents at the meeting to maximize its training efficiency.

○ Vaccines

China has requested more information on technical standards for vaccines; the secretariat will ask the delegate from China to clarify this request.

Act: Secretariat

Although the SC recognised that VICH should communicate with the VOF members why some topics (agrochemicals, probiotics etc...) are not in the scope of VICH, it was recognised that an additional value of the VOF to its members was the possibility to explore some regulatory topics.

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

Covered above

4.2.3 Decision on the next steps and items for the agenda of the 6th Forum meeting

Covered above

5. VICH Strategy

5.1. Review of the Phase IV strategy

The EU recalled that the subgroup has attempted to re-organise the document in different steps and provide more clarity.

The SC agreed to rename the document as “VICH priorities”.

JMAFF proposed to change some definitions in the draft strategy e.g., “Biologicals” in “2. The scope of VICH” to “Biologics” which includes a broader range of products manufactured in or extracted from biological resources, rather than the current wording “biologicals” limited to classical vaccine and serological products. Several members supported this idea in principle but the SC recognised that the definitions required further discussion and agreed that the perimeter of a bullet point in the strategy/priorities document should be broad because it is very difficult to summarise all novel technologies.

It was pointed out the SC should not exclude other technologies such as “nano technology” as a target in the new strategy and therefore proposed to use a wording “novel technology” regarding section 4 and it was pointed out that the strategy it is open for another round of comments and suggestions.

The SC concluded that the scope (section 2) will remain as drafted mentioning “biologicals (vaccines and other biological products)”. Under priorities (section 4) general considerations regarding development of guidance for novel therapies will be mentioned as well as general considerations regarding pharmacovigilance.

SC members were requested to review the second draft and send comments to K. Grein by 15 April. A third draft will be provided at the end of April as a final draft for adoption at the 32nd SC meeting.

Act: AI/EU

5.2. Review of the report by JMAFF on the survey and needs assessment for guidelines for veterinary biological/biotech products

The SC reviewed the report on the survey prepared by JMAFF and noted that 7 VICH members out of 9 supported to address both ICH GLs S6 & Q5A. JMAFF pointed out the “Priorities-Phase 4” document should include a message to clarify how to rend the next five years’ renewed and attractive for all.

JMAFF agreed to develop a discussion document on the definition of “biologics” generally being used by the regulatory authorities, industries and academia for review at the next meeting.

Act: JMAFF

6. Reviews of:

6.1 The implementation and interpretation of VICH GLs in the regions

6.1.1 Report from the regulators

JMAFF reported that VICH GLs 23(R), 48(R) & 49(R) will be implemented as soon as they have been translated.

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

South Africa reported that since the 30th SC meeting, parts of the national legislation has been changed to enable the implementation of some VICH GLs. 7 GLs (9, 27, 33, 48, 49 & the PhV GLs) are currently being considered for a formal adoption, although they are already being used. GL 52 will also be considered once finalised.

6.1.3 Any input from industry members

None

6.2 Written updates from the coordinators

The SC took note of the report.

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

The SC noted that GL 54 has just recently been signed-off for public consultation and was circulated to members.

7. Review of final VICH Guidelines at step 9

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

None presented

7.2. Proposals for revision of further VICH GLs

7.2.1. Discussion of the recommended frequency of review

The SC reviewed the proposal presented by the secretariat and agreed that a systematic review of the need to revise a GL should be done every 5 years following its adoption.

7.2.2. Review of the list proposed by the secretariat

The SC reviewed the list proposed by the secretariat and requested that the secretariat should provide a general status of the review of all GLs before the next meeting. A column will also be added to the general GLs table (VICH/99/036) indicating the date and the number of the review.

Act: Secretariat

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

8.1. Quality

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

The SC noted that the Quality EWG did not have any recent activity.

8.2. Electronic Standards Implementation – Pharmacovigilance

Dr M. Brown, chair of the Expert Working Group, reported that the first technical document supporting the implementation of GL35, the Step-by-Step Document for Electronic Transmission Specifications, has been signed by all ESI EWG members. The second technical document, the Validation Procedures, has been revised and she hoped that the revised version could be signed by all experts. Personnel changes also necessitate the designation of new ESI EWG members before any work can proceed.

Dr Brown asked the SC to authorise a meeting of the ESI EWG with several topics of discussion, in particular the routine maintenance of the GL 30 vocabulary list, the review of industry's paper on the impact of disharmonisation and the finalisation of the validation procedures document. The ESI EWG would also discuss the creation and use of a harmonized xml message to be sent as acknowledgement for received submissions from industry.

The SC supported that the ESI EWG would work on the topics proposed and congratulated Dr Brown and the experts on their excellent work.

Discussion Document from Industry on the revision of VICH Pharmacovigilance GLs

The SC acknowledged the importance of this very technical Discussion Document and noted that the 12 areas of disharmonisation raised are very valid, and show that elements in the PhV documents are already outdated because PhV is a fast evolving topic. However, it was also recognised that some elements of disharmonised implementation may possibly be overcome through consensus interpretation of the existing GLs and technical documents. Industry pointed out that some issues will require the political commitment from senior officials and governments because of the need to adapt national systems. The EU mentioned that the EU legislation was in the process of revision, but others noted that the issues raised in the document would probably not be impacted by this revision.

The SC discussed the request for an EWG meeting and decided that a face-to-face meeting should be prepared properly beforehand by electronic discussion between the experts. The EWG was authorised to hold a teleconference if necessary. Once the preparatory work has been completed, the EWG will have to make a formal request to the SC for a face-to-face meeting. Meanwhile, the EWG should report back on the progress of the review of the technical issues at the next SC meeting.

8.3. 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. Harmonisation of criteria to waive Target Animal Batch Safety Testing for veterinary live vaccines

The SC noted that the EWG is very near to an agreement on the draft GL with only a few outstanding issues remaining. The chair requested to hold a face-to-face meeting to overcome the last obstacles to reach an agreement.

The SC supported the proposal that the experts should start discussing the development of GL on Laboratory Animals BST (LABST).

b. Extraneous agents testing for Biologicals extraneous viruses testing

As no further progress was achieved.

The SC discussed the EWG proposal for a face-to-face meeting to be held in the margins of the VICH 5 Conference in Tokyo, but considered that the meeting should only be convened when beside the (TA)BST guidelines also extraneous agents testing could be discussed. The EU informed that it is planned to present an outline of the EU approach for the meeting in October, and would confirm readiness in 2 months' time.

The SC reconfirmed in principle a face-to-face meeting to be held in October and will take a final decision following confirmation by the EU for being able to present the proposal in time to the EWG,

The SC confirmed that during this meeting the EWG should also address the topics of TABST for live vaccines and LABST, and encouraged the EWG to advance the issues by electronic discussion prior to the meeting.

Act: EU

8.4. 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.

The SC acknowledged that the EWG has reviewed by electronic procedure several drafts of both GLs on residues in fish and in honey and congratulated Dr Scheid and the experts for the good progress made so far.

8.5. 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 begun to address the issue for the second revision for the removal of the mandatory character of the in-vivo micronucleus test in consistency with the 3Rs goals of VICH, following the finalisation of the first revision.

b) VICH GL 54 on the determination of an acute reference dose for residues

This GL has just been published with a comment period that closes on 15 August 2015. If possible the experts will address the comments and finalise the GL before the next SC meeting.

Dr K. Greenlees mentioned that he had been contacted by the JECFA secretariat (WHO), who indicated interest in the acute reference dose. JECFA might want to use the GL in assessments and monographs.

The SC expressed its appreciation to Dr Greenlees and the experts for the amount of work achieved so far.

8.6. Bioequivalence EWG

The chair of the Expert Working Group, Dr M. Martinez, reported that the draft GL is very close to completion. The consultation period was finalised in June 2014. By 1st January 2015, the chair received all EWG considerations of proposed responses to comments received during the consultation period. Based upon EWG input, there remained 5 outstanding issues. Two were readily resolved by simple wordsmithing. Three necessitated additional discussions. These legal issues that should be resolved in the near future.

JMAFF expressed its appreciation that the specific requests for Japan were taken into account by the experts.

8.7. 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.

VICH GL 53 (*Electronic exchange of documents: File format requirements*) was adopted recently by the SC for implementation.

The SC congratulated Dr Colmorgen and the experts for the work that was finalised in a short timeframe.

The EWG will not be disbanded in the near future but remain in existence for the next two years.

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

None presented

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

None presented

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

11.1 Review of the progress and timeline for the Discussion Document to be prepared by the Task Force on the revision of VICH Anthelmintics GLs

The SC reviewed the Discussion Document presented by the leader of the TF, Dr A. Phillippi-Taylor, and congratulated her for the quality of the document that was developed.

Dr Phillippi-Taylor reported that the TF has worked for one year on the list of topics related to the anthelmintic GLs, mostly by electronic procedure with 2 teleconferences. She pointed out that the Discussion Document (VICH/IN/15017) was not endorsed by all TF members and should therefore be considered as a working document in progress.

She explained that the use of geometric means to evaluate the effectiveness of the substances may not be universally accepted anymore as the use of arithmetic means has been considered to be a more stringent criterion, so that differences in effectiveness may be measured. The question was raised if the current GLs provide sufficient flexibility for new approaches.

Differences in the opinions of the experts have also arisen on other issues as detailed in the Discussion Document.

The SC acknowledged that the work of the TF is highly technical and scientific, and that for the time being there is no need to reach a consensus on all issues, as long as it is detailed in the final version of the Discussion Document.

Although it was proposed to convene an EWG in order to increase the scientific discussion regarding whether these GLs need to be revised or not, the SC confirmed that the TF should first achieve its mandate by completing the Discussion Document and reporting back to the 32nd SC meeting.

11.2 Review of the Concept Paper prepared by the Task Force on the revision of VICH Stability GL 3(R)

Covered under item 4.1.5.1.

11.3 Review of the Concept Paper prepared by the Task Force on VICH Guidance for Efficacy Studies for Combination Drug Products

Covered under item 4.1.5.2.

12. Concept papers/Discussion papers

12.1 Review of the revised Discussion Document from Industry on the revision of VICH Pharmacovigilance GLs

Covered under item 8.2

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

JMAFF reported that the data publicly available from assessment reports have been reviewed, showing differences between the use of –two generations and –one generation studies. The EU is currently reviewing 160 substances for which ADIs were established and will provide an analysis for the next SC meeting.

K. Greenlees appreciated that this review was very useful and mentioned that the Safety EWG experts are trained critical scientists who will need to analyse the data that will be provided.

The SC noted that the EU and JMAFF will provide a proposal for the way forward before the next SC meeting.

12.3 Other VICH topics

None

13. Preparation of the VICH 5 Conference

13.1 Review of the draft programme and nomination of the speakers

The SC reviewed thoroughly the third draft of the programme developed by JVPA in collaboration with the secretariat, and allocated moderators to each session.

The fourth draft was circulated during the meeting and all moderators were asked to provide concrete proposals for speakers and presentation titles in their respective sessions to the secretariat by the end of March.

Act: Moderators

Sessions 3 and 8 will include a panel discussion.

13.2 Organisational and logistical matters for the Conference

JVPA explained that the 2nd announcement will be published on 16 May which means that the programme must be finalised and the names of the speakers confirmed by the end of April.

A poster session will be provided to all chairs of active EWGs who will work with their respective topic leaders and experts for their preparation.

IFAH-Europe provided JVPA with the VICH 4 poster template.

14. Other issues

14.1 Location of VICH SC meetings in non-VICH countries (invitations by VOF countries)

The Secretariat recalled that at the last meeting Argentina had volunteered to organise the 34th SC meeting which is scheduled to take place in the USA in 2017.

It was agreed to make a final decision at the next SC meeting.

AUS proposed to reduce the frequency of SC meetings and hold SC meetings only once per year, a proposal that had been discussed a few years ago in detail. SC members expressed the view that increased time span between meetings is likely to reduce productivity of VICH and would prolong the time required to prepare guidelines. No changes to the frequency of SC meetings were agreed.

15. Any other business

15.1 Tribute to L. Klostermann

L. Klostermann announced that this was his last participation in a VICH SC meeting. The SC warmly thanked L. Klostermann for his strong commitment and his active contributions to VICH over many years.

16. Dates and venue of next meetings

- The 32nd SC meeting will take place in Tokyo, Japan on 25, 26, 27 & 30 October 2015.
- The 33rd SC meeting will take place in Europe on 20 to 23 June 2016.

17. Adoption of the Press Release on the 31st SC meeting

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

VICH STEERING COMMITTEE

31st meeting

23, 24 & 26 February 2015
Washington D.C. (USA)

Chair: B. DUNHAM (FDA)

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

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AHI (ZOETIS)	M. J. MCGOWAN
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