VICH/07/006
25 April 2007
Final

VICH STEERING COMMITTEE
19th meeting
January 24 & 25, 2007
Washington DC, USA

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr S. Sundlof, chairman, opened the meeting by welcoming the participants to Washington on behalf of the FDA/CVM, USDA and AHI. He thanked the AHI for assisting in the organisation of the meeting.

Dr Y. Takahashi read a message from Dr K. Sugiura apologising for not being able to attend this meeting, and conveying his full personal support to VICH and the SC's activities.
Dr Takahashi explained further that Dr K. Suguira and Dr Y. Ishihara were not able to attend because of a recent avian influenza outbreak in Japan.

Dr H. Marion introduced Dr Masaya Kajiwara, representing JVPA replacing of Dr Ando who retired, and welcomed back Dr Ian Alexander from Health Canada, Veterinary Drugs Directorate.

2. Adoption of the agenda

The EU wished to add under point 3.4 a discussion focusing also on the strategy in the medium term for VICH and suggested adding this item to each VICH agenda in the future.
Under point 13, the EU proposed to initiate a reflection about the next VICH conference timing, goals, location, etc…
The EU proposed that the minutes of the previous meeting should not be presented as a full agenda item (12). The EU and FDA urged the Secretariat to provide an annotated agenda such as that provided for Codex meetings. The Secretariat agreed to present, in the agenda of the next SC meeting, another format for the addition of documents that are not for discussion.

Draft 3 of the agenda was adopted without further change.

3. VICH Strategy Phase II

3.1 Approval of the draft Guidance Document on the Monitoring and Maintenance of VICH Guidelines

The EU reminded the participants that many points of the draft document were discussed and approved at the 18th SC meeting and that only a few changes had been made following that discussion.

The SC reviewed the amendments included in the current version.

IFAH (Dr P. Jones) confirmed that the Industry strongly supported this document and commented, however, that the word maintenance should be used for minor changes, rather than calling both major and minor changes revisions.

The EU pointed out that this wording was taken from the Strategy document and the Organisational Charter of VICH and should therefore be kept aligned. ~~The reveiw.~~

The SC adopted the guidance document for implementation by the next SC meeting.

3.2 Expectations from the partners to VICH success in Phase 2 (VICH/IN/06012) + Efficiency of VICH – A Discussion Paper by the Secretariat and Results of the Questionnaire

The Chairman reminded the participants that the SC members had accepted IFAH's proposal at the last meeting to review the effectiveness of the VICH SC.
IFAH thanked all the SC participants for having all replied to the questionnaire circulated by the Secretariat and stated that this participation reflected the interest of the VICH SC.
He presented detailed slides and reviewed and commented on the responses to the questionnaire (*see presentation circulated with meeting documents – ref. VICH/IN/6026*).
Several members congratulated Dr P. Jones for his work and praised SC colleagues for the unanimous response to the questionnaire.

The SC then reviewed the Paper on Efficiency prepared by IFAH and focused in particular on the proposed recommendations. The SC acknowledged that most recommendations were addressed to the SC Coordinators.
After discussion, the SC amended slightly the wording of the recommendation under c) Preparation of Expert working Groups (page 4) and decided to adopt the recommendations presented in the Paper on Efficiency as amended, with the exception of the first one on page 3 of the document (i.e., "reading of SC documents within 5 days should be the goal").

The SC decided to add these 5 recommendations to the bullet points under chapter 5.2.2 of the Organisational Charter on the role of the coordinators.
The Secretariat will amend the Organisational Charter and circulate to the SC for approval.

Action: Secretariat

3.3 Review of the Organisational Charter and Proposal for Publication

The SC acknowledged that the Organisational Charter is already posted on the VICH website, although the version of the document that is there is outdated (Revision 7!).
JMAFF questioned the substitution of the word "implement" for "monitor" in the first bullet under Objectives. The Secretariat will check the correct wording.
The SC agreed that the most recent version of the Organisational Charter (Revision 9), including the addition of the bullet points under 5.2.2, including a few additional minor changes (e.g., up to date names of observer organisations), should be placed on the website as soon as possible.

The Secretariat should further prepare a draft Revision 10 for discussion and adoption by written procedure at a later stage. This draft should include a proposal for revision of the wording “monitoring and maintenance”, and “cost/benefit analysis”, as well as a proposal for revision of the step 9 procedure to reflect the guidance document adopted under point 3.

Action: Secretariat and ALL

Information from OIE

OIE conveyed to the SC its decision to improve its worldwide communication about VICH activities.

OIE confirmed that the information about VICH activities is distributed to all OIE members after each SC meeting. However, OIE does not receive much feedback because the national Chief Veterinary Officers (CVOs) are OIE’s contact points and in most countries these officials do not ordinarily deal with licensing of veterinary medicines.

Dr Bernard Vallat, General Director of OIE, is preparing a 3 level action plan to improve the communication on VICH with OIE members.

Level 1: information

The aim is to provide more information on Veterinary Medicinal Products (VMPs) in general and on VICH activities in particular to the CVOs and to the OIE regional contact points by:

adopting an OIE document on VICH (completed and distributed 2-3 years ago);

placing a link to the VICH website on the OIE website;

adding to the agenda of the next OIE General Session in May a point about VMPs including a presentation on VICH.

Level 2: training

The aim is to train CVOs with the support of the OIE collaborating centre in Lyon, ~~France~~France,~~)~~ in order to improve their knowledge about OIE procedures and to develop a module on VMPs and VICH;

This training will also include national “focal points” identified by the countries, and coordinated by the OIE regional offices.

Level 3: twinning activities

This is an emerging activity. All OIE collaborating centres and OIE reference labs met together for the first time in December 2006 in Brazil and developed the idea of twinnings to create new collaborative centres in developing countries specialised in VMPs, in particular in West Africa (UENOA) and in South America.

During the discussion, the participants authorised OIE to place a link to VICH on its website.

AHI explained that some companies have commented that several Latin American and Asian countries have implemented some VICH GLs and are reportedly requesting VICH generated data from multinational companies, but not from local companies. Some requirements are also set without always having an overall understanding of the VICH process by the local regulators. AHI therefore suggested that the OIE training should also include information about the VICH process and how to implement VICH Guidelines.

The EU suggested exploring ways of communicating on VICH activities, the GLs and the participants in VICH. The EU believed that some countries outside the VICH regions might not need or might not be ready yet to draft local regulatory requirements for the authorisation of VMPs based on VICH Guidance. They should therefore receive clarifications on the context in

which VICH was developed, in particular pointing out that the VICH regions already had developed regulatory framework for VMPs.

OIE explained that, as part of its training, it would focus on post marketing measures such as border controls, Pharmacovigilance, etc…

IFAH-Europe mentioned the problem of confidentiality of data and patent protection in the developing countries.

After further discussion, the SC agreed in principle to participate in the OIE General Session in May, taking into consideration the limitations that have been expressed.

The Secretariat will then circulate the OIE suggestions and a request for speakers.

Post meeting note: OIE has informed the Secretariat that VICH would be on the Agenda of the OIE General Session in 2008.

3.4 Other issues: VICH strategy

The EU suggested reviewing the VICH strategy as an agenda item of each SC meeting.

IFAH confirmed that the Industry strongly supports the VICH process and highly appreciates the dialogue with the regulators within VICH.

The recent IFAH Benchmarking Survey completed by Industry assesses the impact of regulatory hurdles on bringing VMPs to the market and the costs of the procedure. IFAH needs more time for reflection and will present some ideas for discussion at the next SC meeting.

Action: IFAH

IFAH-Europe confirmed the European Industry's very strong support for VICH and suggested it would identify some future VICH topics.

AHI pointed out that the main objectives of VICH phase 2 are to focus more on the maintenance process but certainly also to progress further. AHI members also strongly support VICH.

AHI mentioned that the TAS GLs are a very good example of a VICH accomplishment that is very useful for the Industry. Government regulators expressed the view that the Industry should be the primary point of initiation for considering new VICH work.

The SC agreed that the VICH Strategy will be a discussion point on future agendas, and asked the Secretariat to include the Phase II Strategy document in the preparatory documents for the next SC meeting

Action: Secretariat

4. Review of written updates

4.1 From the coordinators

The Secretariat briefly presented the written report, and indicated that this report was not for discussion at the SC but aimed to inform SC members on the status of activities a few weeks before the SC meeting, as well as half way between each meeting.

4.2 On the implementation of final VICH Guidelines since the 18th SC meeting

The EU and FDA confirmed that Quality GLs 39 & 40 have been implemented since the last SC meeting.
JMAFF indicated that Environmental Impact Assessment GLs 6 (Phase I) & 38 (Phase II) have not been implemented because they first require a revision of the Japanese legislation. Quality GLs 39 & 40 will be implemented soon in Japan.

ANZ reported that Safety GLs 36 & 37 have been adopted since the last SC meeting and that Quality GLs 39 & 40 will be adopted very soon.
Canada indicated that Quality GLs 39 & 40 are currently under review.

AHI questioned if there were any problems/challenges on the interpretation of GLs in the regions, and requested in particular feedback regarding the implementation of the Environmental impact assessment GLs in the regions.
All SC parties, both Industry and Government, indicated that it would be useful to develop a report on implementation status for future SC meetings. A summary table covering all adopted GLs and all regions should be prepared.

Action: Secretariat

CAHI reported that Canada has a coordination committee for the implementation of GLs and that the past chairman of the VICH Environmental Impact Assessment EWG is the industry representative on this committee covering the implementation of Environmental Impact Assessment GLs in Canada.
The EU explained that for the Environmental Impact Assessment GLs, the EU has drafted an supporting guidance document, as announced at the time of adoption of the phase II guideline, that had been circulated for public comments; the EMEA is currently working on the finalisation of this document, which aims to fill the gaps where the VICH GL indicates that a global harmonisation was not possible; i.e. the calculations for soil exposure, etc…

After discussion, the SC agreed that the next meeting agenda should include a point on the interpretation and implementation. It was recognised that the main role on reporting would fall on industry, but also regulators may be in position to indicate any difficulties in the implementation. The SC highlighted the importance of this issue for the monitoring & maintenance.
IFAH-Europe suggested adding a column to table VICH/99036 to indicate the date of the release for consultation in each region.
The EU supported this proposal and stressed the importance of information on delays in one region, especially during the consultation process where EWGs chairs and topic leaders need to plan their further work. Information on delays (I.e. For publication or for implementation) should be circulated spontaneously without awaiting the request for formal reporting.

Action: Secretariat

5. Progress Reports of Expert Working Groups

5.1. Quality

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr Hamamoto and presented by JMAFF.

Although there were some delays because one expert's signature was missing until just before the SC meeting, JMAFF reported that the GLs 3R, 10R & 11R were ready for adoption at step 6.

The SC applauded the excellent progress made by the Quality EWG and congratulated the Chairman and the experts for the work they had diligently achieved.

5.2. Pharmacovigilance

The Chairman, Dr L. Post, reported that the EWG had overcome many obstacles in recent years, but a number of difficult issues had not been resolved yet. He specifically pointed out that a common electronic standard that will underlie the VICH Electronic Standard for Transfer of Data (GL35) had not been officially adopted by all regions.

He also requested that all pharmacovigilance guidelines (GL 24, 29, 30, 35 and 42) should be considered as a set, as they would have an impact on each other, and consistency should be assured. He identified a couple of examples of potential inconsistencies. Furthermore, the need for adoption of all guidelines as a package ~~w~~could be a legal requirement in the USA.

GL29
Dr Post reported that some of the experts believed that significant changes may have to be made to this GL and that this GL therefore may have to go back to a step 4 consultation. The Secretariat pointed out that this GL had been signed off at step 6 and circulated for implementation at step 7; the VICH process did not allow going backwards to step 4 again.

During an in-depth discussion on this GL, Dr. Post and the SC acknowledged that there was not clear agreement concerning the need to republish this GL for consultation at step 4 and all recommended that the textual language of GL29 not be altered from that signed off at step 6, if at all possible. Furthermore, the SC instructed Dr. Post to inform them if members of the EWG determined that there was a need to alter the text of GL 29 to make it compatible with other Pharmacovigilance GLs.
The SC agreed that, should the EWG identify during future discussions that GL29 needed to be changed, the EWG should request a formal revision procedure at step 9, in accordance with the VICH Organisational Charter.
The SC decided unanimously that the agreements concerning the language in GL 29 that were made previously (as initiated by the March 2004 meeting in Ottawa and agreed to at the 15th SC meeting) should not be altered and agreed that each SC member will remind their experts that no change to the agreed critical text passages of GL 29 should be considered.
The SC recognised that some additions to improve the text to ensure consistency in terminology between the various Pharmacovigilance GLs may be necessary through the step 9 procedure.

Action: All SC members

GL 24 and 42
Dr Post confirmed that comments had been received which will be discussed at the next EWG meeting. Several SC members regretted however that these GLs had not been published yet for consultation in all regions.

Dr Post suggested that if no electronic standard could be agreed for GL 35 then it would not make much sense to implement GLs 24 and 42.

In the discussion, the SC recognised that, ~~GLs 24, 29, 35 and 42 are linked and that the EWG should review them together, because a change to the text of one GL might affect another one.~~
~~These GLs should also be published together for consultation at step 4. Should~~ should the next EWG meeting conclude that ~~also~~ GL 29 needed revision, the latter would be published under a step 9 revision procedure.

GL 35
Dr Post confirmed that HL7 was identified as the main technical issue in this GL. He indicated that if the regions all can agree on a single VICH electronic standard then there should be no further major obstacle and all pharmacovigilance GLs could be progressed. If no agreement on an agreed standard could be reached there would be the option of "mapping" each schema within a region to the other schemas. This would however be an undesirable option, and would require a lot of work for all regions.

The EU clarified that the issue of agreeing on an electronic standard is not a technical issue within the authority of an EWG expert, and requires consideration at a higher level first. The Issue is being addressed within VICH and ICH. The EU indicated that although the EU has an advanced EudraVigilance system, in the ICH discussions agreement has already been achieved that electronic international technical standards will be determined through a consortium of Standard Development Organisations (SDOs) ~~-~~including HL7, CEN and ISO standards. The EU suggested that it would be also for VICH an agreement could be found. AHI stressed that it would be very costly for Industry to invest in 2 or more different electronic standards.

JMAFF indicated that Japan had not decided yet if it would support the HL7 standard, but JMAFF will do its utmost to clarify this issue as soon as possible.

The EU asked industry on their experience with the installation of the software by the company PVWORKS, which has mapped the different lists currently in operation in the US and Europe for most of the multinational companies in relation to GL 35 and GL30 on the controlled list of terms, as this could have an impact on the extent of harmonisation needed. Industry was not in the position to answer the questions but would investigate the matter. The EU would draft questions regarding industry's experience of the mapping done by PVWORKS, to be sent out by the VICH secretariat.

GL 30
Dr Post believed that the TF on the Controlled List of Terms mandated by the SC at its 18th meeting could not meet before the EWG had completed GL 42. Moreover, the TF would probably need several meetings to agree on the list of terms and may need to work on a long term basis to maintain the dictionaries. Dr. Post was asked to take the lead in organizing this TF and the SC would decide who would be on the TF.
The SC agreed that the members of the TF on the Controlled List of Terms would be nominated by each region, as it is normal practice by the VICH. It was suggested that it might be useful~~k~~ that each region would nominate 2 experts: one Pharmacovigilance expert and one IT expert if considered appropriate. In order to set up the group quickly the SC agreed to submit nominations within the forthcoming weeks.

Action: All SC members

Depending on when the consultation on GL 30 will be finalised in all regions, Dr Post will propose to the SC a date for the TF's first meeting. ~~All members would to send their comments to the draft GL as soon as available to the TF.~~
The SC recommended strongly that the TF should work as much as possible by electronic procedure.

EWG activity
Dr Post regretted that he did not always receive sufficient feedback from the experts in the requested timeframes and that several reminders were often needed.
In order to ensure efficient co-operation prior to the next meeting the SC encouraged Dr Post, as well as all EWG chairmen to inform the SC when there would be a lack of reactivity from the experts. The SC confirmed that whenever necessary, it is the role of the coordinators and SC members to remind the experts of their responsibilities.
The Secretariat explained that in the near future a specific e-mail address will be set up for each EWG, which will contain the individual addresses of each expert, as well as those of the coordinators. It will enable all of them to receive the mails sent to that specific address.
The SC recommended that Dr Post should use this address as soon as it is available to enable the coordinators to follow the day-to-day work of the Pharmacovigilance EWG.

Dr Post mentioned that, based on the replies he had received from some experts, it will be difficult to organise a last meeting of the EWG before the 20th SC meeting in October.
The SC however requested firmly that the EWG must meet in September in order to give sufficient time to the SC to review the documents from the EWG meeting.
SC members agreed to inform their experts immediately of the need to meet in September.
(*Post meeting note: on 26 January Dr Post asked the experts to confirm their available dates for September*)

The SC requested Dr Post to make thorough preparations by electronic procedure leading up to the planned September EWG meeting in order to ensure that the group can finalise their work.

After further discussion, the SC adopted the following specific actions and deadlines:

- The EWG will meet in September 2007;
- SC members will inform and encourage all experts to meet in September;
- Dr Post will prepare an action plan for the EWG's activities in preparation of the September meeting;
- This action plan should be reviewed by the EWG in February by written procedure for presentation to the SC by March 1st at the latest;
- SC members will inform their experts that the previously agreed text of GL 29 should not be altered;
- If necessary, to ensure consistency with the other pharmacovigilance guidelines, the EWG may propose amendments to the text of GL 29, through the step 9 revision procedure, for public consultation at step 4 ~~together with GLs 24 & 42~~;
- The Secretariat will rapidly set up a specific address for the Pharmacovigilance EWG;
- SC members/coordinators will send their nomination(s) for expert(s) of the TF on GL 30 to L Post.

5.3. Target Animal Safety

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr L. Nagata, and presented by the JVPA.
GL 41 on the reversion to virulence has been circulated to the experts for sign-off at step 5 by the EWG.
JVPA pointed out that there seemed to be slight differences in interpretation between the chairman and the topic leader. Indeed, JMAFF had proposed several comments to which the EU had responded, and as a result JMAFF decided to withdraw these comments and considered therefore the issue as settled. However, the topic leader believed that the EU expert's comment on JMAFF's comments was not reflected in the latest draft. The chairman believed that these comments were included and informed the topic leader who did not reply until now. The chairman nevertheless hopes that the draft GL will soon be signed at step 5.

The SC has signed off GL43 TAS for pharmaceuticals at step 4 and each region is in the process of finalising the public consultation before next June 10. As soon as the consultation is finished the EWG will revise the document.

Draft 14 of the TAS GL for live and inactivated vaccines was submitted to the experts in September and the chairman is receiving various comments. However the chairman has recently received comments from the topic leader on draft 13, which was very surprising.
JVPA pointed out that the chairman feels that there are limitations in proceeding through electronic discussion and believes therefore that it may now be necessary to hold a face-to-face meeting very soon.

The EU supported a face-to-face meeting as it appears difficult to progress by written procedure, with the objective to finalise the drafting of both TAS GL for live and inactivated vaccines and to resolve the last issues for GL 41.
In some EWGs the written procedure is constructive, whereas others are faced with unsolvable problems and therefore need to meet.

JVPA mentioned also that the chairman was faced with long delays for replies from some experts.
IFAH-Europe pointed out that the chairman is asking SC members to encourage their experts to respect the deadlines.
The SC agreed to remind the experts that they should reply within the set deadlines.

FDA explained that it had not yet published GL 43 but that it was under legal review within FDA and publication was expected soon.

Health Canada suggested strongly that when the feedback does not come from experts, the chairman should ask the Secretariat to report to the relevant SC member, preferably the coordinator.
The Secretariat mentioned again that a specific e-mail address for each EWG, including the coordinators, would be set up very soon. This will enable the coordinators to stay updated on all deadlines to ensure their experts complete their tasks on time.

The SC supported in principle a meeting of the EWG to take place in Europe and asked the chairman to confirm the dates in due time.

Action: TAS Chairman

5.4. Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr S. Shimazaki, and presented by the JMAFF.
JMAFF reported that Dr Shimazaki recently replaced the previous chairman, Dr Nakamura.

The draft GL on testing for extraneous agents is at step 2 and further discussion has been put on hold until March 2008, when Japan will have introduced the seed lot system. JAMFF confirmed that the implementation is on schedule, and that the standards of specifications and test methods have already been prepared. The authorities will determine the kind of seedlot system to use by March 2008 and plan to fully implement the system by 2011.

Regarding draft GL 34 on mycoplasma testing, JMAFF explained that the regions were instructed to conduct the tests according to the protocol prepared by the EU. It had been understood at the last SC meeting that the EU would provide the protocol rapidly in order to enable a face-to-face meeting of the experts in Japan.

The EU explained that it had been delayed because of lack of available resources, but confirmed that as soon as draft 1 is available the experts should meet to discuss the protocol as well as other testing issues.
The EU will provide the exact timelines and status within the next few weeks.

Action: EU

Regarding the shipping of the strains, JVPA indicated that the strains had not been sent yet and warned that some regional offices may not be able to receive these strains because they do not have adequate security systems.
Everyone was reminded that at the last SC meeting, the EU had asked the recipients to organise their shipment and had circulated the necessary information.

Following the question from the EU to SC members whether reference strains would have been ordered from EDQM it became apparent that, although both JMAFF and USDA had contacted the EU during the summer 2006 to enquire about the shipping process, no region had asked for the strains so far. The EU offered to circulate the information again after this SC meeting on the details for obtaining reference strains and contact details at EDQM.
The EU will also discuss the issue of security of transport and storage with the EDQM and will circulate any relevant information about security requirements.

Action: EU

ANZ indicated that as an Observer member, it strongly supports all VICH GLs. ANZ will however not implement this one because of stringent security requirements for the entry of such strains into ANZ.

The SC supported in principle a meeting of the EWG to take place in Japan once the protocol is provided and the shipping issues solved and asked the chairman to confirm the dates in due time.

5.5. Metabolism and Residue Kinetics

The EU reminded the participants that at the last SC meeting 5 topics had been approved, 5 topic leaders were designated within the EWG, and the work has started on each topic.
The time point in the EWG's work plan to deliver the first drafts on the 5 topics is 1st March 2007. The discussion within the EWG will take place during the summer and the revised documents should be circulated to the experts before the 20th SC meeting in October where an oral report will be delivered.
The EU and the Chairman of the EWG were very optimistic that the initial deadlines will be met.
The EU confirmed that for the purpose of this EWG's work, sheep are considered as a major species.

The SC applauded the activity of the EWG and the strong leadership of the Chairman.

5.6. Proposal for the re-establishment of the Safety EWG

AHI explained that the Metabolism & Residue Kinetics (MRK) EWG will have to consider residues at the injection site and to establish residue kinetics.
The majority of MRK EWG members has asked the SC to reconvene the safety EWG to establish a GL for the elaboration of an Acute Reference Dose (ARD) for VMPs. Several years ago Codex had started to address this issue but the work was stopped.
AHI hoped that the establishment of a VICH GL would encourage Codex to address this issue again.

IFAH-Europe and ANZ supported the proposal.
The EU believed that it should not be the former Safety EWG that should be reconvened because these experts working on guideline to set up an ARD should have a more pharmacological background and questioned if this task should rather not be in the mandate of Codex (CCRVDF) or JECFA.
AHI explained that JECFA meets only for 10 days and typically does not have the time to address these kinds of issues. When the JECFA experts group is disbanded, it does not work between meetings. Codex might be an appropriate venue, but it has not considered this topic to be a high priority.

JMAFF confirmed its interest in having this topic addressed by VICH. However policies involving ADIs and MRLs do not come under the authority of JMAFF, but are under the responsibility of the Food Safety Commission and the Ministry of Health, Labour, and Welfare.
JMAFF indicated that these Japanese agencies had expressed the opinion that, rather than VICH, the CCRVDF ~~of Codex~~ should develop this topic.

AHI pointed out that neither Codex nor JECFA have ever developed such GLs, whereas VICH has the best expertise to address this topic.

IFAH pointed to the issue of the global availability of VMPs for food producing animals, and stressed that the development of VMPs for food producing animals should be facilitated.

IFAH-Europe reminded the SC members that the aim is not to set ARDs but to give guidance on how to set an ARD.
FDA supported this approach and indicated that such a GL would assist JECFA in making their assessments.

JMAFF believed that if the aim of the EWG is to give guidance on how to determine the ARD, the Food Safety Commission and the Japanese Ministry of Health, Labour, and Welfare would probably support this approach. JMAFF agreed to share this information with that Ministry as soon as possible.

AHI suggested that when VICH has a draft GL, it should ask JECFA for comments.

The EU proposed to proceed as with the MRK EWG, i.e. that a new Safety EWG should develop a more detailed concept paper before the SC formally decided on further activities of an EWG.

JMAFF and JVPA suggested asking the CCRVDF and JECFA to support the work within a VICH EWG.

JMAFF requested that the concept paper should clarify that VICH would only address the establishment of ARDs and should confirm the intention to share information with regional and international organisations involved in the Risk Assessment of VMPs, especially JECFA and Codex. The EU supported that the concept paper would need changing, and shared in principle the concerns of JMAFF.

JMAFF would then support this topic, although the Japanese Ministry of Health, Labour, and Welfare would also need to give its approval and to nominate an expert.

After further discussion the SC agreed that AHI would send a revised concept paper to JMAFF as soon as possible. The EU indicated that they would send written comments. Once JMAFF has commented, the revised paper will be circulated to the SC for approval.

Action: AHI/JMAFF

JMAFF could not commit to a precise deadline for the formal comments.

Nevertheless, the SC agreed that, depending on the formal reply from Japan, a new Safety EWG should be convened and chaired by the FDA.
The FDA then will circulate criteria for the appointment of the experts.

Action: FDA

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

6.1

No GL was submitted to the SC

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

7.1. GL 3R (Quality) – Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)

The Steering Committee adopted GL 3R as final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.
The Steering Committee agreed that the Guideline will enter into force by January 2008.

7.2. GL 10R (Quality) – Impurities in New Veterinary Drug Substances (Revision)

The Steering Committee adopted GL 10R as final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.
The Steering Committee agreed that the Guideline will enter into force by January 2008.

7.3. GL 11R (Quality) – Impurities in New Veterinary Medicinal Products (Revision)

The Steering Committee adopted GL 11 as final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.
The Steering Committee agreed that the Guideline will enter into force by January 2008.

8. Discussion papers

8.1. Update on ICH's experience with the Common Technical Document

FDA reported that in all 3 ICH regions timetables have been set up in order to implement the CTD by October 2008. By the end of next year an evaluation on the implementation of electronic documents should therefore be available. In the USA, the electronic-CTD is a combination of HL7 and other electronic systems.

The SC agreed to monitor this topic at the next SC meeting again.

8.2. Electronic Submission of Dossiers

The EU pointed out that veterinary medicines need a different approach than the human medicines. The EMEA has set up a specific veterinary technical group on electronic submission that is separate from the human medicines' group. This group includes stakeholders and is mandated to agree on electronic standards appropriate for the veterinary sector
This group recognised that there is a need for a much reduced version on the veterinary side and is currently reviewing which tools would be useful and appropriate for the animal health industry.

8.3. IFAH-Europe presentation on a Review of the Potential Benefits and Potential Downsides of E-submissions

The SC reviewed the document provided by IFAH-Europe presenting some of the benefits and drawbacks of electronic submissions.
IFAH-Europe insisted that very clear objectives should be set within a framework for the receipt of electronic documents by the Authorities and that specific solutions should be found for the veterinary sector, which will have no impact on the structure of the documentation. The Industry will be flexible on the choice of the electronic format.

IFAH-Europe pointed out that on the human medicines' side there had been no prior discussion of life-cycle management of an electronic dossier. Moreover, paper documents can be easily updated by inserting for example a new page that is renumbered whereas in

electronic versions an inserted page will move all the numbers on the pages that follow the inserted page.Legally, companies may be obliged to retain paper versions. Many companies would most probably continue to rely on paper versions for their archives, as CD-roms deteriorate over time (10 years). Therefore Industry is concerned that it would have to set up two documents management and tracking systems: a paper and an electronic one, which will be very costly.

The EU reiterated that it is working on this topic with the Industry and asked the SC whether it should become a topic for VICH.
IFAH-Europe confirmed that the global Industry is interested in electronic submissions because things are already moving in the human field and have now also started in the veterinary sector.
IFAH-Europe therefore agreed to prepare a concept paper for the next meeting, which will include information on what is happening in other regions.

Action: IFAH-Europe

ANZ pointed out that since January 1st, Australia requires that the complete label of a product is made available to the regulators in a pdf version. Paper versions are not accepted anymore because these are tedious to manipulate whilst the pdf programme enables regulators to easily compare the old and new versions of labels.

8.4. Impact of ICH Quality GLs Q 8, 9 & 10

The EU explained that these ICH GLs are fairly new and represent a new concept. They differ from the previous ICH quality GLs, as described in the preparatory meeting document.
ICH Q9 is not finished yet and Q10 is only in the drafting stage; only ICH Q8 has been implemented so far.
Moreover, these ICH GLs are optional, offering flexibility to pharmaceutical companies. The EU therefore recommended that VICH should consider these GLs at a later stage.

IFAH-Europe has also concluded that these GLs may be useful, but should be considered by VICH later on, when experience has been gathered within ICH.

The SC decided to review this topic again at the 21st SC meeting in Europe.

9. Review of Concept / Discussion Papers

9.1 Review of the Proposed concept paper on harmonisation of MIC Breakpoints: IFAH-Europe proposal to withdraw the Concept Paper

IFAH-Europe explained it had reconsidered the concept paper presented at the 17th SC meeting because some issues had changed in the meantime.
IFAH-Europe believed that it is now more appropriate to seek harmonisation through other international bodies, in particular the Clinical and Laboratory Standards Institute through its Veterinary Antimicrobial Susceptibility Testing subcommittee (CLSI VAST).

There has been a major change to the operation of this subcommittee with the withdrawal of US FDA representatives serving as voting subcommittee Members, which now allows

decisions to be viewed as not having to “go through” the US FDA/CVM. Decisions can therefore be made on an international basis.
IFAH-Europe encourages its members to support the CLSI VAST subcommittee by encouraging submission of presentations for quality control and interpretive criteria (i.e. clinical breakpoints).

In the EU the terminology of breakpoints and the differentiation between epidemiological and clinical breakpoints has now been clarified, which is a further reason for IFAH-Europe to reconsider the concept paper.

The SC acknowledged that IFAH-Europe has withdrawn the concept paper.

9.2 Review of the Discussion Paper on Alternative Tests to Animal Testing

The EU reminded the participants that it had presented a discussion paper to the 18th SC meeting and that there was general support. Questions were however raised on how to achieve this goal, by referencing to existing GLs or to available test methods, and how to validate the methods.

Since the last SC meeting, the EU had bilateral discussions with FDA to find a common basis for further discussion at the SC.
The FDA proposed that a general policy statement supporting the 3Rs principles be drafted for consideration, which could be adopted by written procedure.
The EU has revised the discussion paper and presented 5 points for discussion.
The EU indicated that at a recent conference of the European Partnership for Alternative Approaches to Animal Testing between the European Commission and chemical/pharma industry associations the need for agreement also at international level was recognised.

FDA presentation about CVM’s participation in the U.S. Interagency Coordination Committee on the Validation of Alternative Methods (ICCVAM)

Dr Jodie Kulpa-Eddy responsible at USDA’s Animal and Plant Health Inspection Service (APHIS) on policy issues covering animal welfare and horse protection, and newly elected vice-chair of ICCVAM, and Dr Devaraya Jagannath responsible for genetic toxicology at CVM and CVM representative to ICCVAM, presented a description of the structure and activities of the ICCVAM, including the international harmonisation activities of ICCVAM, ECVAM and JaCVAM .(*see presentation attached*).

IFAH-Europe acknowledged that in the USA ICCVAM has set up a list of acceptable methods as has ECVAM in the EU, and recommended that the lists be harmonised as much as possible, by working also in collaboration with JaCVAM in Japan, to show which tests were acceptable in all 3 regions.
FDA indicated that the alternative tests that have been validated by ICCVAM since 2000 are listed on the ICCVAM website.

The SC reviewed the 5 points for discussion in the paper prepared by the EU.
AHI supported having the SC draft a statement that VICH supports the 3Rs rule and encourages the development of international harmonisation in this area. The SC should also give a mandate to the EWG to consider the 3R rule in the development of new VICH GLs.

IFAH-Europe agreed that VICH should act in 3 ways: by issuing this general statement of principle, by enabling access to the information available on the websites in the 3 regions, and

by ensuring that there are ways to check that regional agencies fulfil their legal obligation to use alternative testing.

FDA agreed to having a statement on the VICH website indicating support for the use of alternative tests and urging the submission of such tests for ~~validated~~ validation and ~~harmonised~~ harmonisation by ICCVAM, ECVAM and JaCVAM with linkage to their websites.

The EU pointed out that the 3 centres already cooperate and aim to harmonise tests, but not all the alternative tests are yet mutually recognised by the others. In order to provide assurance to industry that an alternative test would be accepted in all regions, the harmonised and mutually accepted tests need to be identified.
It is indeed not clear that if one test is accepted in 1 region, it is automatically accepted in the other regions. Each individual case still requires a scientific advice.
IFAH-Europe suggested that identifying the tests that are on the 3 lists would be coordinated by ICCVAM.

IFAH-Europe recommended also that the existing VICH GLs should be reviewed, as suggested in point 4 of the EU proposal, through the monitoring and maintenance procedure.

After further discussion, the SC supported the 5 proposals from the EU and agreed that VICH will write to ICCVAM, ECCVAM and JECVAM to ask their authorisation to place a link to their websites on the VICH Homepage.

The Secretariat will draft an outline for a letter with help of the EU, for circulation to the SC. It will also include a reference to the 3Rs under item 6., EWGs, in the Organisational Charter. The Secretariat would also draft, based on input from the EU, a policy statement for approval by the SC by written procedure.

Action: Secretariat

9.3. Draft Concept Paper on Bracketing and Matrixing Designs for Stability Testing of new Drug Substances and Products

IFAH-Europe explained that VICH GL 3 R includes a proposal to consider bracketing and matrixing. An ICH GL exists that could be used as basis to establish a VICH GL.
IFAH-Europe therefore proposed that the Quality EWG should review the ICH GL and evaluate its applicability to VMPs.

The EU believed that this GL would complement the existing VICH GL 3R on stability testing.

FDA questioned how much added value this would bring for the Industry. IFAH-Europe replied that the aim was to provide a specific guidance applicable to VMPs.

JMAFF supported the proposal and indicated that the Quality EWG could review this topic by electronic discussion, with no face-to-face meeting.

The SC mandated the Quality EWG to review the ICH GL by written procedure and evaluate the applicability to VMPs.
The SC nominated IFAH Europe as the topic leader.

10. Update of the VICH Work Plan

The SC reviewed the document prepared by the Secretariat. The Secretariat will update the document and circulate it after the meeting.

11. VICH Web site

The Secretariat presented a proposal for an update of the layout of the VICH website.

The Secretariat suggested establishing specific e-mail addresses for each EWG, which would be managed directly by the Secretariat. One single address will be used to write to each EWG. This address will be linked to a list including all experts of the EWG as well as the SC Coordinators and any Member who would like to receive the mails of a specific EWG. The lists will be managed by the Secretariat and any change of address of an Expert or a Member will have to be communicated directly to the Secretariat.

To enable an easy access to this address, as well as to enable the SC to check permanently the composition of the lists linked to the addresses, the Secretariat suggested adding a button to the VICH homepage giving access to a new, non-public page of the VICH website. This page will require a login and a password, and will be restricted to SC members only.
The EWG lists displayed on this page will include the individual e-mails addresses and the telephone numbers of each expert. This special page will also host the minutes of meetings, and in the future could be expanded to other SC meeting documents or discussion documents.

The SC approved the Secretariat's suggestions.
The Secretariat will circulate a draft of the new web layout for comments and approval.

Action: Secretariat

12. Any other business

a) Next VICH conference

The EU suggested that after having organised 3 VICH conferences in the first phase of VICH, the SC should evaluate if further conferences should be organised in the phase II of VICH and if confirmed, which goals should be achieved before such a conference could take place and to determine the possible time and objectives of such conferences.

AHI mentioned that the conferences under VICH phase 1 were expensive to organise.

IFAH recommended organising a further conference only when sufficient new information was available to form the basis of the conference and informed the participants that at the end of this year, IFAH will organise a global AH scientific conference that will include a session reporting on VICH activities.

The SC agreed that 2 more years would be needed to finalise sufficient new information, so that a VICH 4 conference should not be organised before 2010.

The SC recognised that during the last conference there had been a lack of interactive sessions.

FDA suggested the possibility of organising a conference in an observer country.
CAHI indicated that it would be difficult for Canada to organise a VICH conference, but agreed to host a SC meeting at any time.
A similar proposal to provide a meeting place for the SC was received from the AHA representative from Australia.
The OIE also offered to host a SC meeting.

The SC agreed to discuss this matter further at the next SC meeting.

b) Interpretation of GLs

FDA noted that under point 3, the SC had agreed to continue the discussion on the interpretation of the implementation of VICH GLs at the next meeting.
After discussion, it was agreed that all SC members should review the implemented GLs and 2 months before the next SC meeting, they should inform the Secretariat of any particular issue in order to place these specific items on the agenda of the next meeting.

c) e-mail addresses
The Secretariat informed the SC that the Secretariat's address would be changed to vich@vichsec.org and that all new VICH e-mail addresses would use the new domain name …. @vichsec.org

13. Dates and venue of next meetings

Considering that the interval between two SC meetings has been expanded to 9 months and that the number of items for discussion is growing, the SC agreed that the next meeting would be a "2 day" meeting with the pre-meetings the day before.

- The 20th SC meeting will take place on October (16,)17 & 18, 2007 in Japan
- The 21st SC meeting will take place on July (8,) 9 & 10, 2008 in Paris, hosted by OIE

14. Adoption of the press release on the 19th SC meeting

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

VICH STEERING COMMITTEE

19th meeting

January 24 & 25
Washington DC, USA

Chair: Dr S. SUNDLOF, FDA/CVM

LIST OF PARTICIPANTS

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