VICH/05/040
11 August 2005
FINAL

VICH STEERING COMMITTEE
16th meeting
May 24, 25 & 28
Washington DC

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr R. Hill, chairman, opened the meeting by welcoming the participants to Washington DC on behalf of the FDA, USDA and AHI. He presented the apologies for Dr Susanne Zänker, coordinator for IFAH-Europe, who could not attend the meeting, due to a last minute problem. This would have been her last VICH Steering Committee.
Dr R. Hill explained further that Mrs Debbie Morris, representing ANZ and himself, representing USDA, were also participating in their last SC meeting. He introduced Mr Martin Holmes and Dr Byron ~~Ripkee~~Rippke, representing respectively ANZ and USDA.
He finally introduced Dr Catherine Brisson,who will represent Health Canada at the16th and 17th SC meetings in place of Dr I. Alexander.
AHI explained that Dr Sandy Phelan, coordinator, had left her position in AHI and would be replaced in the future. Dr R. Livingston would act both as representative and coordinator for AHI at this meeting.

The chairman thanked AHI for the preparation in work and efforts for the SC and the organisation of VICH3.

2. Adoption of the agenda

The following changes were proposed:
The chairmen of the TAS and Pharmacovigilance EWGs would provide a brief report both days of the SC meeting.
Item 11.1: it was proposed to sign off both draft GLs at step 4
Item 14; USDA proposed to add a report on the "Ploufragan 2" conference
Item 14: the EU proposed to discuss a communication letter to JECFA

The chairman pointed out that this was the second last SC meeting of VICH Phase 1 and whilst VICH would move into ~~phase~~ Phase 2 as from 2006 on, this meeting was the opportunity to define how the next phase of the VICH activities will be structured. The last SC meeting of VICH Phase 1, the 17th, will be held in Japan in next November.

3. VICH3 Conference

* Review of the final programme
AHI presented the final version of the programme and pointed out that no last minute change had occurred.

* Number of participants
160 persons had registered and several on site registrations were foreseen.

* Practical arrangements
AHI explained that the gala dinner at Mount Vernon on the first evening will be the highlight of the social events.

* Last minute questions
AHI suggested that the time management was essential and suggested that the session chairmen should organise brief questions sessions after each presentation as well as a 3 minutes summary at the end of the breakout session.

4. Implementation of the VICH Strategy Phase II 2006-2010

4.1 Monitoring of VICH Guidelines

The EU explained that, in accordance with the new VICH ~~strategy~~ Strategy adopted at the last SC meeting, VICH needed to set up a mechanism for the updating of the adopted VICH GLs. As scientific developments continue their evolution, VICH has to identify which GLs need to be reviewed, then the process through which these should be updated.

A document from ICH has been circulated by the secretariat that addresses the 2nd step, once the necessity to update has been identified. ICH distinguishes between major and minor changes; a major change requires the drafting of a new GL whereas minor changes can be implemented through an abbreviated procedure.
The current VICH 9 step process requires the meeting of an EWG, whilst ICH has improved the efficiency by setting up a "maintenance group".
The EU therefore suggested preparing a discussion paper for the next SC meeting.

During the discussion, the SC recognised that the ICH procedure could serve as a good basis to define a similar VICH procedure and recommended to set up an abbreviated procedure with an essential role for the coordinators.
The EU agreed to prepare, with the secretariat, a discussion paper on the maintenance of VICH GLs for review at the 17th SC meeting.

4.2 Frequency of Steering Committee Meetings and communication issues

The EU started the discussion by highlighting the importance of clear communication channels to be used between the SC meetings. Whilst the frequency of meetings should be reduced, the efficiency of communication should be improved.

The chairman added that the follow-up work of EWGs between the SC meetings should also be improved before reducing the frequency of SC meetings.
During a thorough discussion the SC recognised that it was essential that the EWGs understand clearly their objectives and their tasks, and that stringent, but realistic deadlines should be set for their achievements.

JMAFF voiced its concern whetherthat the SC should continue to meet every 6 months in the 2nd phase Phase of VICH and suggested to reducinge the meetings to once per year after the 18th meeting.

AVCARE believed that the EWGs would in this case lose the momentum of their work.

IFAH-Europe suggested that the coordinator of the region which is leading the topic should attend EWG meetings when necessary in order to inform immediately the SC if delays and problems occur.

The chairman stressed the importance of the guidance documents, which will be reviewed later on the agenda.

It was therefore suggested to set the frequency of meetings on an ad hoc basis, depending on the workload and the progress expected from the EWGs.

Most members recognised that a yearly frequency of SC meetings would be inadequate, at present but probably also for the future. It was proposed to continue to hold 2 meetings per year until the end of 2006 (19th SC meeting). It was further recommended to hold in the future SC meetings approximately every 9 months, depending on the workload.

The SC agreed to discuss this item again at the 17th SC meeting in November 2005 in Japan with the objective to make a decision on the future frequency of SC meetings, and in particular the efficiency of holding a SC meeting every 9 months.

5. Communication between the SC and EWGs

The secretariat reported that the Quality EWG had recently cancelled its meeting planned in Washington DC without informing AHI or the secretariat, which demonstrated an evident lack of communication between the EWGs and the secretariat and/or the SC.
The secretariat added that rules existed in the different guidance documents and these needed certainly to be reminded and reinforced.

During an in-depth discussion where all the participants expressed their views, it was recognised that only efficient procedures could ensure that everybody knows what is happening and enable the right choice of priorities.
It was therefore decided to reinforce the role of the regional coordinators who should become the active link between the EWGs and the SC.
It was suggested in particular that the coordinator of the region/member of the chair of an EWG should act as “liaison” between the EWG and SC by updating the SC periodically of the progress achieved in and between meetings, and informing immediately the latter of problems arising, of delays occurring etc…
The SC would then be able to react in a timely fashion and avoid unnecessary delays and unproductive meetings of EWGs.
All chairmen of EWGs will be asked to include the coordinators in all communication within the EWG.

It was also agreed to avoid unnecessary formalities by enabling the coordinators to write directly to the SC through a special e-mail address that the secretariat proposed to set up. Moreover all SC members were encouraged to also use that address:
VICHSC@IFAH.BE

Official matters such as GLs, agendas, minutes etc…. would still pass through the secretariat with an official numbering.

Several members pointed out once more that the number of SC meetings could be reduced only after the efficiency of communication has been improved.
The impetus of the SC on the EWGs' activities should not be underestimated.

5.1. Meeting with the VICH Topic Leaders

Considering that only 2 EWGs were meeting simultaneously to the SC, the SC agreed not to develop this item further.

6. Review of VICH Guidance and Policy Documents

6.1. Note to prepare a VICH Topic Concept Paper

The SC reviewed and amended the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the revised document (VICH/97/037-Revision 2-draft 3), subject to the further editorial changes agreed by the SC.

6.2. Guidance for ~~SC~~ the Steering Committee on the Appointment of Experts and Chairpersons/~~topic~~ Topic ~~leaders~~ Leaders to ~~EWGs~~Expert Working Groups

The SC reviewed the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the document (VICH/00/152-Revision 1-Draft 1).

6.3. SOP on VICH Procedure for the Expert Working Groups

The SC reviewed and amended the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the revised document (VICH/00/151-Rev 1- draft 4**)**, subject to the further editorial changes agreed by the SC.

6.4. Policy for Disbanding Expert Working Groups

The SC reviewed the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the document (VICH/00/153-Rev 1-draft 2).

6.5. Policy on Consultation at Step 4

The SC reviewed ~~and~~ the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the document (VICH/00/154-Rev 1-draft 2), subject to the further changes agreed by the SC.

6.6. Notes on the ~~format~~ Format and Style of VICH Guidelines

The SC reviewed the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the document (VICH/97/061-Revision 1-draft 2).

6.7. Guidance for Members of VICH Expert Working Groups

The SC reviewed the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the document (VICH/00/150-Revision 1 – Draft 1).

6.8. Policy on Appreciation ~~Shown to~~and Recognition of the Chairs and Expert Working Group Members

The SC reviewed the draft, which had been circulated by the secretariat in preparation of the SC meeting.

The SC adopted the document (VICH/00/155-Revision 1 – draft 2).

In accordance with this document, the SC reminded the secretariat to disband the Safety and Ecotoxicity EWGs at the end of 2005.

7. Reporting of the coordinators to the secretariat

The secretariat reminded the participants that at the 15$6^{th}$ SC meeting it had been suggested to set up a procedure for a regular reporting of activities by the coordinators. The EU had proposed an example for a simple table for follow-up of actions that could be completed on a regular basis.

During the discussion, the SC recognised the necessity for a pragmatic approach that would allow an easy flow of information.

The SC agreed that the secretariat could circulate ~~a~~ regularly (at least each 2 months) a table updated with the information received from the coordinators.
The SC also recommended once more that the coordinators should use as much as possible the common e-mail address to provide each other and the secretariat with relevant updates regarding the work of the EWGs and SC.
The secretariat will propose a format of table with the help of the EU.

8. Update on the implementation of final VICH Guidelines since the 15th SC meeting in the 3 regions and the 2 observer countries

The EU reported that VICH GL 36 (Safety - Microbiological ADI) had been implemented. GL 37 (Safety - Repeat dose chronic toxicity) had also been implemented.

FDA reported also VICH GLs 36 and 37 ~~(Safety – Repeat dose chronic toxicity)~~ haved ~~been~~ implemented

USDA reported that no new GL was implemented.

JMAFF reported GL 27 has been implemented in February and that GLs 36 & 37 are being prepared for implementation.

ANZ reported that GLS 36 & 37 haved been implemented in NZ and would be implemented in Australia very soon.

Canada reported that GL 28 (Safety – Carcinogenicity) was being translated before publication.

9. VICH Workplan 2006-2010

The SC reviewed the new draft document presented by the secretariat and highlighted the complexity of the proposed lay-out.

After discussion, the SC agreed that the work planWorkplan should be placed on the VICH Website together with the progress status of GLs and this page will be called "Guidelines and workplanWorkplan".
Part 1 of the work planWorkplan will appear as the full text and part 2 will appear as the table currently on the web Web that shall be updated regularly.
The new VICH Strategy will also be placed on the public websiteWebsite.

The current internal table (document VICH/96/036) will be updated by the secretariat before and after each meeting and circulated to the SC. It shall include the status of progress of documents at stage 1 as well as all potential future topics.

It was further suggested to place the Concept papers Papers on the websiteWebsite.
After a thorough discussion it was however agreed that Concept papers Papers should be published only when the SC will have adopted them formally.

10. Progress reports of Expert Working Groups

10.1 Quality

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr K. Hamamoto, and presented by the JMAFF.
For GLs 39 & 40 the consultation period should have ended in January, but FDA did not publish these GLs yet; comments had been received from all other regions.
FDA informed the participants that the GLs had been published very recently and that the consultation period would be finished at the end of June.

JMAFF reported further that the all members of the EWG had commented on GL 3(R) and that Dr Bensley will propose very soon the final draft for sign-off at step 2 by written procedure.

For the revision of GLs 10 & 11, the topic leader Dr Moeller had reviewed the documents which had only been very recently signed off the step 2 by all the experts. The EWG nevertheless submitted during the current meeting both draft GLs to the SC at step 3 with the signatures of all the experts.

JMAFF pointed out that overall much progress was achieved and expressed its appreciation to the topic leaders and the experts.

With regard to the lack of communication between the EWG and secretariat concerning the cancellation of the EWG meeting, JMAFF explained that, although the SC had approved a face-to-face meeting of the experts, it appeared in last February that excellent progress had been made through written procedure and that it was therefore decided not to hold the EWG meeting.
JMAFF expressed its regrets that the secretariat had not been informed.

The SC received the draft GLs 10 & 11. After discussion, the SC agreed to sign them off and to publish them for consultation at step 4

Health Canada explained that a legal opinion on the human equivalent of GL 39 in Canada had been asked in the human field, so the consultation was not finalised yet.

JMAFF indicated that for the moment the EWG did not require a specific meeting, as it planned to progress through written procedure.
After discussion, the SC agreed in principle to an EWG meeting if in the future this would become necessary. However, before such a meeting would be held, approval should be requested from the SC sufficiently in advance by written procedure.

10.2. Target Animal Safety
The chairman of the Expert Working Group, Dr T. Nagata, met twice with the SC during the 3 days' discussions in the EWG and presented detailed explanations on the outstanding issues to the SC.
The SC discussed thoroughly each problem, agreed the conclusions and made the recommendations described below.

Biologics
Draft GL 41 – Reversion to virulence
JMAFF, JVPA and AHI confirmed that they required that GL included a statement recommending its use for the registration of locally used products, but that different standards could apply to the latter at the discretion of the local authorities.
Other SC members objected that this would not be in line with the basic principles of VICH.
The SC recognised however that most biologicals, which are developed, are marketed in one region only, very few having a global destination. After a thorough discussion the SC confirmed the agreement of the 15th SC meeting that at local level deviations from the VICH GLs could be allowed. These considerations apply also to the Draft GL on TAS for live and inactivated vaccines and the one on TAS for Pharmaceuticals, which include similar restrictions of their scope.

Dr Nagata indicated that the EWG would complete the sign-off at step 2 by written procedure before the end of next July.

Draft GL on TAS for live and inactivated vaccines
The SC agreed that the issue of fibrosarcoma in cats should not be covered in the GL and recommended therefore that the EWG should sign-off the current version of the draft GL~~. Dr Nagata indicated that 3 experts had agreed to review the literature on the fibrosarcoma in cats during the consultation period and to provide comments, if required, during the consultation.~~ without doing any additional work on the fibrosarcoma in cats.

The EWG will also sign-off the GL at step 2 by written procedure before the end of next July.

For both Biological draft GLs, the SC agreed that if these were delivered signed-off by the mid-summer to the secretariat, the SC would sign them off and release them at step 4 by written procedure. Otherwise they will be signed-off at the 17th SC meeting

TAS for Pharmaceuticals
Dr Nagata reported that most issues relating to the draft GL had been solved, except the dosage testing.
He explained that in preparation of the EWG meeting, ~~all regions had supported through a written questionnaire, the 3x or 5x dose testing in the target animal~~ cases were identified, through a written questionnaire in all regions, where 5x dose had provided additional information in predicting future adverse drug events, and the EWG had agreed on the 5x dose testing.
In the current meeting however, the FDA expert indicated that 10x dose testing may be required in some instances. All other experts however did not agree to imposing a 10x dose testing and considered that this point was essential and could not be compromised. The EWG had debated this issue at length and finally considered writing a special position paper explaining that the 5x dose testing was largely sufficient and that this position paper would to be submitted to FDA.

After a long discussion, the SC opposed the drafting of such a paper because FDA was the only member of the EWG to take the position that 10x dose testing should be recommended and therefore the burden should be on FDA to explain its position.

In the light of the concluding remarks of the VICH3 Conference by Dr S. Sundlof, Director of the CVM, who stated that he would personally ensure that the issues relating to the TAS GLs are resolved adequately, the SC agreed that AHI would write to the CVM within the next month, asking CVM to reconsider its position.
AHI hoped the issue to be resolved within a 60 to 90 days period.
The SC asked to be copied on all follow-ups and that the EWG members should be informed as well.

As the biologicals draft GLs will be signed-off by written procedure, and as the outstanding issue of the pharmaceuticals draft GL could also be resolved by written procedure, the SC agreed not to authorise another meeting of the TAS EWG before the end of the consultation periods of the draft GLs.
The SC will therefore consider another meeting at the 17th SC meeting.

~~The EU and IFAH-Europe asked JVPA to remind the chairman of the EWG that at the 13th SC meeting it had been agreed that, for a matter of clarity in the tasks, the experts on Biologicals and those on pharmaceuticals should meet separately in order to avoid any confusion in the debates.~~
~~JVPA confirmed that in the TAS EWG meetings, first the experts of one of the topics meet for a certain time period, then the experts change and the other topic is considered.~~
~~JVPA will nevertheless clarify this situation with the chairman.~~

10.3 Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr S. Nakamura, and presented by JMAFF.
JMAFF indicated that the chair of the EWG had now been passed from Dr. O. Itoh to Dr Nakamura who will make the presentation at the VICH3 Conference.

JMAFF reported that no further meeting of the EWG had taken place since the last SC meeting.
However for the mycoplasma testing, the EDQM had confirmed that it would provide the test strains in July 2005.
It was recommended that the regional studies should be made before the 9th meeting of the EWG could be held.
The EU added that the experts should exchange sufficient information on the testing by written procedure prior to the organisation of any meeting.
The SC supported these proposals.

With regard to extraneous agents testing, JMAFF reminded the participants that at the 15~~6~~th SC meeting it had indicated that Japan would introduce the seed lot system, but as the process would be slow, JMAFF had asked for a suspension of the discussions for 1 year. JMAFF therefore expected to be able to present a report at the 17th SC meeting.

The SC confirmed that this topic would be re-discussed at the 17th SC meeting.

JMAFF indicated that the EWG required a meeting in fall 2005 to progress the mycoplasma testing draft GL.
The SC agreed in principle but required that the testing in the regions have been progressed beforehand and that the issues for discussion have been clearly defined.
At that moment, the EWG should require approval from the SC by written procedure.

10.4 Pharmacovigilance
The chairman of the Expert Working Group, Dr L. Post, met twice with the SC during the 2 days' discussions in the EWG and reviewed the ongoing progress and unsolved issues.

On the first day, Dr Post reported that the experts had agreed on the definition of the international birth date and on the frequency of reporting.
However, for the PSURs Japan would prefer the GL to be applicable only to products issued after the VICH GL is adopted, whereas the Industry wished to harmonise the requirements for older products also.
JMAFF explained the Japanese legislation currently required a new PSUR for new indication, new animal species, active ingredient etc…

With regard to the expedited reporting of AERs, the experts reached an agreement on a definition of "same" products and another definition for "similar" products

The SC expressed its appreciation for the breakthrough in these difficult issues.

On the second day, Dr Post reported that with regard to section V and the appendixes of draft GL 24 (Management of AERs) the experts had decided to place the data reporting requirements in a separate GL. The EWG will therefore sign off the revised of GL 24 containing the general definitions at step 5 again by written procedure after the meeting.

The EWG will however need 3 further days of discussion to review the contents of the data requirements (data fields).

Concerning the standard list of terms, Dr Post reported that Veddra had been accepted unanimously as reference.

Regarding the Japanese issue with the PSU reporting, Dr Post pointed out that the EWG did not consider this as a major problem and was confident that a solution would be found.

JMAFF asked Dr Post for clarifications regarding the route of AERs between different regions. He confirmed that the MAHs would have to inform their counterparts in other regions, and not directly the authorities of other regions. Only in the region of the Adverse Event will the MAH have to inform the authorities.
In other regions, the relevant MAH will have to report the Adverse Event only if the products are considered as "same" products.

The EU asked if progress had been achieved with GL 29 (Management of PSURs) as well as GL 35 (Electronic Standards for Transfer of Data), taking into account the split of GL 24.
Dr Post replied that the EWG's main concern had been to solve all the policy issues. GLs 29; 30 & 35 would be discussed again at the next meeting.

The SC praised the chairman and the experts for the breakthrough in the task of this EWG and recognised that the presence and advice of Dr P. Jones had been essential in guiding the EWG towards consensus.

The SC reviewed thoroughly the progress achieved by the EWG and discussed the possible approval of the next PhV EWG meeting.
The SC agreed that the EWG could clarify and find agreement through electronic discussion before meeting again, on points which are still under debate, such as the revised GL 24, but recognised also that the experts should meet again in the near future in order to build on the breakthroughs achieved and keep the momentum of the group.

After an in-depth discussion, the SC asked the experts to prepare thoroughly the next meeting and approved the 9th meeting to take place in Europe as soon as possible, and sufficiently in time before the 17th SC meeting in order to enable the SC to review the report of that meeting and consider the points which the SC will be asked to address.

The SC also strongly recommended that the EWG should invite Dr P. Jones to attend the meeting again, as well as other SC members whenever possible.

The SC also asked EWG to provide without delay a detailed report on the current 8th meeting identifying clearly what was agreed and which are the outstanding issues to be solved at the next meeting.

11. Adoption at ~~step~~ Step 3 and release of guidelines for consultation at ~~step~~ Step 4

11.1 Revision at Step 9

GL 10 **-** *(Impurities New Substances) – Impurities in New Veterinary Drug Substances*

The Steering Committee received the text of GL 10 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 3-month public consultation at Step 4. The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 1st September 2005.

GL 11 - *(Impurities New VMPs) – Impurities in New Veterinary Medicinal Products*
The Steering Committee received the text of GL 11 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 3-month public consultation at Step 4. The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 1st September 2005.

12. New topics (pending revised Workplan)

12.1. Review of the ~~concept~~ Concept ~~paper~~ Paper on Metabolism and Residue Kinetics (EU)

The EU reminded the participants that following the discussions in the 15th SC meeting, comments had been taken into account and a questionnaire had been circulated. All SC members have responded and have clearly supported taking up a new topic on Metabolism and Residue Kinetics and to consider data requirements regarding~~,~~ residue kinetics, metabolism and depletion studies.
Further issues, such as withdrawal periods, have not been unanimously supported and should therefore be left to the EWGs consideration at a later stage.

OIE pointed out that this topic was of enormous importance and recommended ~~to~~ sharing~~e~~ information with JECFA and Codex. Moreover OIE recalled that during the last session of the CCRVDF in 2004, it had emphasized the need to strengthen cooperation between Codex and VICH whenever it is possible.

AHI supported this approach and believed that the SC should be closely involved in the launch of this particular topic.

After a thorough discussion, the SC recognised the need to define very precisely the scope and the timelines.
The SC therefore agreed to establish a new EWG, and confirmed that it would be chaired by Dr Stephan Scheid from the EU.

The initial mandate of the EWG on ~~metabolism~~ Metabolism and ~~residue~~ Residue ~~kinetics~~ Kinetics will be to develop a discussion paper, which shall define clearly the scope of the EWGs mandate. On the basis of this discussion paper, the SC will make a final decision on any GL to be developed.
It was further accepted that experts, but not the chairman, might be different for the drafting of the discussion paper and the consequent scientific work.

The SC decided that the EWG should start its activities by written procedure. ~~The~~ The SC agreed that a face-to-face meeting would be useful, and should, if possible, take place before the November SC meeting. However, it was recognised that this may be difficult to arrange and may have to be delayed.
The SC members were asked to send the name and contact details of their expert to the ~~Secretariat~~ secretariat without delay.
The secretariat will send the "welcome pack" of guidance documents to all experts and copy the SC.

The SC requested the EWG to deliver an interim discussion paper 1 month (30 September 2005) before the 17th SC meeting and a final discussion paper 1 month (31 March 2006) before the 18th SC meeting in spring 2006.

12.2. Proposed Concept Paper on harmonisation of MIC Breakpoints

IFAH-Europe presented the information background paper circulated prior to the SC meeting and explained that the NCCLS standards had been a worldwide basis until recently.
However there was now a risk that different breakpoints would be set in the regions. Moreover some regions were considering setting microbiological breakpoints and clinical breakpoints, which would lead to different dosages in the regions according to different breakpoints for a same substance. This would strongly jeopardise any further research in this area.
By harmonising MIC breakpoints, regulators would benefit from comparable breakpoints.
IFAH-Europe added that it might be necessary to include external parties such as Vetcast, CLSI… in the discussion, either as full EWG members or as external experts.
This topic would require a new VICH EWG.

JMAFF pointed out that principles were established to set breakpoints for the human medical area, and these would only need to be adapted. JMAFF believed that there were currently no big differences between regions.
IFAH-Europe stressed that different bodies were now establishing different breakpoints.

The EU suggested that further information be provided to allow a decision, as to whether there would be a need for harmonisation.

AHI, AVCARE, the EU, JVPA and CAHI supported the preparation of a Concept Paper.

IFAH-Europe therefore agreed to prepare a detailed Concept Paper for review, discussion and decision at the 17th SC meeting.
The SC members were asked to provide IFAH-Europe with information on the current situation in the regions by next July 15.

The SC will review the Concept Paper at the 17th SC meeting in Japan.

12.3. Other: Concept Paper on CTD

AHI indicated that a proposed Concept Paper on the CTD had been discussed at the 10th VICH SC meeting, but that at the time the SC had agreed to first monitor the progress ICH would achieve on this topic.
Now, three years later, AHI suggested to review the positive and negative outcomes of the implementation in ICH, and therefore proposed to prepare an updated VICH Concept ~~paper~~ Paper taking into account the status in ICH.
However, before taking the topic any further AHI wished to know if the SC was interested in this proposal.

The EU thought that for the moment it might be too early to impose new quality requirements.

JMAFF pointed out that ICH had now completed its task and that the CTD was used since 2 years in the human medical field. JMAFF recommended not to require a too heavy workload for VICH.

FDA mentioned that as ICH was already updating this document, VICH could also review these updates.

IFAH-Europe indicated that in its view the harmonisation of the technical part of the dossier would be the first priority.

After further discussion, the SC agreed that AHI would present an update at the 17th SC meeting.
In order to have a clear view of each member's position, AHI will circulate a questionnaire to all members, with request for a reply within 3 weeks.

13. VICH3 Conference

13.1 Debriefing

On behalf of the SC, AHI paid tribute to the preparatory work achieved by Sandy Phelan before she left her position.
AHI informed the participants that Mr P. Lichtinger had forwarded his appreciation to the SC for being invited to speak at the Conference and apologised for not attending the meeting further.
Many company representatives had confirmed that the Conference had been conducted smoothly and had congratulated the SC and the VICH organisation.

The SC assessed the overall organisation of the Conference and confirmed that the logistical organisation had been outstanding.
The only downside had been the lack of reactivity of the attendance in the Q&A sessions. One reason may be that most topics presented concerned GLs that were already implemented.
It was therefore recommended that in future Conferences the breakout sessions should concentrate more on scientific arguments and reasoning rather than on the GLs themselves.
It was also proposed to include a session for the discussion of potential new topics.

14. Any other business

14.1 Letter to JECFA

The EU pointed out that Codex & JECFA were 2 other important bodies active in the field of international harmonisation. The EU proposed that the secretariat should write a letter to JECFA informing on the internationally agreed data requirements regarding safety data for veterinary drugs and the approach to set a microbiological ADI and submitting the set of safety guidelines with a recommendation to use these in the JECFA work and not duplicating efforts.

A copy of the correspondence should be sent to the Codex secretariat.

After a brief discussion, the SC supported the proposal in order to prevent duplication of work and especially because JECFA is confronted with resources problem.

The secretariat will draft a letter to JECFA, with the support of the EU, highlighting the existence of the VICH GLs, in particular VICH GLs 22, 23, 28, 31, 33 and 37, as well as 36 – Safety: Microbiological endpoint testing: ADI, which JECFA could use for establishing microbiological ADIs.
The letter will also explain that VICH has initiated further harmonisation work on Metabolism and Residue Kinetics.

14.2 Biologics conference in 2006 (Ploufragan 2)
IAB's request for sponsoring this international meeting on Biologics

USDA explained that the first meeting on harmonisation of Biologics took place in 1992 and that there is now a demand for an update 15 years later.
It is known that VICH is addressing BQM issues (extraneous agent etc...) and the International Veterinary Biologicals Society (IVBS) had asked if VICH would want to be involved in the meeting.

After discussion, the SC requested further clarifications on the aims and objectives of the meeting, as well on the expected involvement of VICH in the conference.
The SC will review a written proposal at the 17th SC meeting.

14.3 Outline of regulatory system in Japan
As a matter of information only, JMAFF explained that a new legislation had been implemented in last April in Japan and presented a document including tables, which have been created by the National Assay Laboratory in order to highlight the specific implemented changes.

JMAFF pointed out in particular that a new paragraph of this legislation enables a company to obtain a marketing authorisation even if the company has no manufacturing facilities in Japan; the MAH is also authorised to consign the manufacturing to a third party.

15. Dates and venue of next meetings

- The 17th SC meeting will take place on November 1-2, 2005 in Japan; location tbd
- The 18th SC meeting will take place in May 2006 in Europe; date tbd

16. Adoption of the press release on the 16th SC meeting and the 3rd VICH Public Conference

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

VICH STEERING COMMITTEE
16th meeting

May 24, 25 & 28, 2005
Washington DC, USA

Chair: Dr R. HILL, USDA

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI	R. LIVINGSTON
AHI (PFIZER)	M. J. MCGOWAN
AHI	X. (C) represented by R. LIVINGSTON
EUROPEAN COMMISSION (DG ENTERPRISE)	A. GAUTRAIS
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