VICH/05/076
28 December 2005
FINAL

VICH STEERING COMMITTEE
17th meeting
November 1 & 2
Kyoto, Japan

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr Y. Takahashi, chairman, opened the meeting by welcoming the participants to Kyoto on behalf of the JMAFF and JVPA. He thanked JVPA for organising the meeting and reminded the participants that this meeting was a milestone in the VICH activity because it was the last SC meeting of VICH Phase I.
He introduced 2 new participants: Mr R. Clayton, who succeeds Dr S. Zänker as IFAH-Europe coordinator, and Dr K. Sugiura who replaces Dr Sakai as JMAFF representative.
He further introduced Dr B. Rippke, USDA, and Dr M. Holmes, ANZ, who had both already attended the last meeting, as well as Dr H. Makie who represented JMAFF at this meeting.

Dr H. Marion welcomed the participants on behalf of Dr P. Jones, new Executive Director of IFAH, who apologised for not being able to attend this meeting, and conveyed his full support to the VICH process.

2. Adoption of the agenda

The following changes were made to the agenda:
Item 3.4: presentation from OIE
addition of a proposal from the EU on the monitoring of GLs
Item 6.4: addition of the draft response from FDA
Item 7: draft GLs 24 and 42 to be discussed together
Item 8: draft GL 29 to be deleted from the agenda
addition of a discussion on the revision of GL 36
Item 12: addition of a discussion on the selection of a VICH representative at conferences
addition of a proposal from the EU on alternative testing

With these changes, the agenda was adopted.

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

3.1 Review of the discussion paper on the Maintenance of VICH GLs

The EU presented the proposal for a procedure for maintaining VICH GLs, which has been drafted on the basis of the ICH procedure. The EU explained that the first step is to distinguish

major and minor revisions, the latter requiring only an abbreviated procedure, which is however relatively complicated in ICH and where the decision is made by the coordinators only. The EU document proposes a simplified procedure and foresees involvement of the SC in the decision ~~taking~~ making process.
The chairman thanked the EU for this draft proposal.

IFAH-Europe believed that the ICH categorization of possible revisions was too complicated, and suggested just two categories of revisions: major (major amendments, additions or revisions) and minor.
JMAFF warned of the workload and the resources that a systematic revision process might require.
AHI agreed and suggested that each member should review the proposal again in his/her organization, in particular with regard to the systematic review of GLs.
OIE pointed out that the "full VICH revision process" might also include a cost/benefit analysis.

After further discussion it was agreed that all comments should be sent to the EMEA by the end of January 2006. A revised proposal including all the comments will then be circulated for adoption at the 18th SC meeting.

3.2 Decision on the frequency of Steering Committee Meetings

The chairman reminded the participants that at the 16th SC meeting the discussion had concluded that a 1 year interval between meetings might be too long, and 6 months too short. He therefore suggested that the interval should be 9 months with efficient communication and monitoring in-between.
The Secretariat recommended adopting this 9-months interval, but with sufficient flexibility depending on the priorities of the moment.
The EU and JMAFF supported this approach.

JVPA explained that it had been decided to hold 2 meetings per year until end 2006. After that, JVPA recommended holding maximum 2 meetings per year if necessary.

After discussion, it was agreed to hold a SC meeting every 9 months from 2007 on, with flexibility depending on the EWGs activities and progress. The participants recognised that the best timing for the next meeting can only be determined at the end of a SC meeting, when all activities have been reviewed and decisions for the future have been made.

3.3 Communication of the SC between meetings – report since 16th SC meeting

The Secretariat applauded the improvement of the communication since the setting up of the common e-mail address and encouraged all participants to use even more the common address for passing on information from the Regions, such as delays, remarks, comments etc… Formal documents should however be circulated through the Secretariat only.
IFAH-Europe asked that the e-mails subject line should explain what is expected from the SC members (i.e. for action or for information).

3.4 Other issues

3.4.1 Monitoring of GLs

The EU explained that the revision of a Guideline as described in the draft guidance document on maintenance could only be initiated once the need for such review has been identified. No process on how to identify when a GL needs to be changed has yet been discussed. The EU suggested therefore that at each meeting the SC determines which GLs should be reviewed. The task of reviewing could be shared between the regions and each region would have to report at the next meeting.

The chairman pointed out that according to the Charter, a review should be done on a 3 years basis.
JMAFF agreed that a systematic procedure should be defined.
JVPA requested defining who should be responsible for the monitoring.

After discussion, the SC recognised that further reflection was necessary on this item and asked the EU to draft a discussion document for review at the 18th SC meeting.

3.4.2 Presentation from OIE

OIE reviewed the needs of third countries and presented possible actions to meet these needs (*see presentation attached*).

The chairman thanked OIE for disseminating the VICH GLs throughout the world.
IFAH-Europe stressed that it was critically important for third countries to have access to affordable products, and this required a simple cost-effective regulatory system.
AVCARE pointed out that these are generally generic products, which do not always fall under VICH guidance.

The chairman suggested that OIE should address the VICH activities at its next General Assembly (GA), but the European Commission, which recently became a member of OIE, and also of Codex, requested to be informed of the objective of such a discussion at the GA.

The SC acknowledged that the VICH GLs distributed by OIE reached the CVOs (Chief Veterinary Officers) rather than the Regulatory Authorities, and suggested therefore that OIE should use other mailing lists to reach the right people. Some third counties are indeed in the process of setting up a modern regulatory system.

4. Reporting by the coordinators to the Secretariat

The Secretariat explained that not much information had been received so far.
In the discussions of the reason for this, it became apparent that it was not entirely clear on what exactly update reports were expected from the co-ordinators. The coordinators requested therefore that the Secretariat should circulate a template for reporting, which would already include up-to-date information on the topics, as far as available to the Secretariat, and a reminder of the deadlines for the reports.
It was agreed that the next deadline for the coordinators' reporting will be at the end of February.

5. Update on the implementation of final VICH Guidelines since the 16th SC meeting in the 3 regions and the 2 observer countries

FDA reported that GL 3 R is ready for publication at step 4, hopefully soon, and that GL 38 has been published for implementation.

The EU reported that GL 38 has been implemented since mid-October. The EU is working closely with Industry on the drafting of a technical guidance document in support of this VICH GL, which will probably be published within 3 months. The EU will inform the other SC members.

The EU has also published an update of a comprehensive document on the assessment of MRLs in relationship with the VICH safety GLs.

JMAFF reported that it is a little behind schedule, as GLs 28, 36 & 37 are in the process of being reviewed and will probably be published next month. GLs 6 & 38 are in the preparation phase for publication.

Australia reported that GL 38 will be published in December. The GLs 36 & 37 will be adopted for publication in November.

Canada confirmed the information of the last SC: the Ecotoxicity GLs cannot be published yet because of a necessary revision of the Canadian legislation.
Canada also pointed out that in the consultation phase at step 4, it refers directly to the VICH website for the mandatory translation before publication. Canada depends therefore on the swiftness with which the VICH documents appear on the VICH website. Canada regretted that sometimes the delay had been very long and asked for a prompt follow-up after meetings.
The Secretariat confirmed that the information was always passed rapidly to the relevant person in the European Commission, which is kindly hosting the VICH website free of charge.

IFAH-Europe suggested that the Secretariat should set up a template for the reporting on the implementation that the regions would fill in before the next meeting, for review and questioning at the meeting. The SC agreed to this proposal.

6. Progress Reports of Expert Working Groups

6.1. Quality

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr K. Hamamoto, and presented by the JMAFF.
No particular comments were made during the consultation on GLs 39 & 40 and both GLs were presented for signature at step 6 by the SC.
GL3-R is currently in public consultation in the regions, except in Canada because the GL was not yet posted on the VICH Website. ~~and t~~The public consultation for GLs 10-R & 11-R will soon be initiated in Japan and in the USA; the consultation is finished in the other regions.

The EU explained that the topic leader Dr N. Moeller wanted to finalise the document, but had not received feedback from all the experts. The EU pointed out that the coordinators should ask all experts to communicate to their topic leaders the outcome of the consultations, even if they have no comment to add.

The SC congratulated the EWG for the progress achieved.

6.2. Target Animal Safety

Reversion to virulence (GL 41)

The chairman of the EWG, Dr T. Nagata, reported that not much progress had been made since last meeting for the Reversion to virulence GL, although many e-mail exchanges had taken place.
The proposal of the EWG at the meeting in Washington to reduce the number of passages to 5 was made with the reservation of the EU expert Dr M. Moos subject to the review of the proposal by the CVMP, which has in the meantime taken place. In Europe 6 passages are required including the first set of animals inoculated. Following consultation of the CVMP, the EU could not agree to reduce the passages from 6 to 5 groups of animals, but suggested a compromise to the EWG to maintain 6 passages for pathogens with a high risk of reversion to virulence and to reduce to 5 passages for pathogens which are unlikely to revert. The EU explained that the inability to accept the reduction to 5 passages would be due to the fact that the data available in the dossiers do not allow the assessment on the impact of such a reduction, but such data may be available to industry.

IFAH-Europe, having noted that the EU's decision not to fully accept 5 passages was based on a lack of data, and not on data indicating that reducing the number of passages was a problem, suggested that the other four regions where 5 passages are used should provide the EU with data on the use of 5 passages, indicating the pathogens that had been tested and the results obtained. The EU should then consider whether this is sufficient evidence to allow it to accept harmonisation to 5 passages for all pathogens.

The SC supported this approach and requested Dr Nagata to ask the EWG members to provide this data.

Dr Nagata reported that the EWG is currently reviewing the EU proposal and request for data, and indicted that he planned to resolve this issue in a face-to-face meeting in order to finalise this GL.

TAS for live and inactivated vaccines
The text is still being improved for clarity. One issue remains pending: the EWG will probably have to drop the definition of the size of the batch; other minor issues should also be solved in the face to face meeting and Dr Nagata hoped to finalise this GL the next meeting.

TAS GL for pharmaceuticals
No final solution was found since the last meeting on the 10x dose issue. There was a general consensus that if FDA could not suggest an acceptable position that would be agreeable to all, the EWG likely would drop its efforts to reach agreement on this GL. The EWG is expecting a reply from FDA to the letter from AHI.
FDA shared with the SC the draft language for the GL covering the 10x dose issue that it was planning to send to the AHI with its response letter. The EU Commission and Dr. Nagata indicated that the FDA's draft language would likely be well received by the EWG

Dr Nagata asked to hold the 9th EWG meeting in next March in Europe.

The EU pointed out that at the last SC meeting it was agreed that the EWG would sign off the draft GLs by written procedure and that another meeting aimed at finalising the documents at step 5, would only be held after the consultation.
Dr Nagata replied that too many issues needed to be solved for the 3 GLs; a face-to-face meeting would be more efficient and would accelerate the procedure.

The EU did not support this meeting as long as most issues were not solved by written procedure. FDA, JMAFF and Canada supported the EU approach.
JVPA pointed out that the experts' responses to the e-mail discussion were not sufficient.
The EU indicated that the coordinators had the responsibility to ensure that the experts send their comments within the requested deadlines.

Dr Nagata asked therefore the SC members to encourage their experts to respond in a timely manner.

After discussion, the SC requested that the EWG should continue the discussion by written procedure, and only if the issues cannot be solved, the EWG should report to the SC and request a face-to-face meeting.

6.3. Biologicals Quality Monitoring

Mycoplasma testing

The chairman of the EWG, Dr S. Nakamura, reported that for the mycoplasma detection tests, the reference strains have not been distributed yet. Meanwhile a revised protocol has been proposed but the experts would like to use the strains for the validation of the protocol.
JVPA asked the EU to inform the SC on the latest status of the strains.

The EU explained that here have been further delays in the production of the reference strains. At the last SC meeting the deadline of July 2005 had been given. Although the strains have been produced in time, 2 strains did not comply with the criteria that had been set. Consequently, the EDQM decided not to send out these strains, but to produce new strains which will however not be available before June 2006.

JVPA questioned if successful mass production could be guaranteed or if VICH should envisage alternative solutions.
The EU replied that the EDQM was confident that the quality problems could be solved. Nevertheless the issue of mass production should be addressed as well as the practicalities of shipping these strains.
The EU will follow this up internally and will update the SC.

AHI believed that it was very useful to test the strains before using them, but questioned if the SC still wished to proceed with this project, considering the timelines.

Extraneous agent detection testing

As for the extraneous agent detection test, JMAFF had asked, at the 15th SC meeting, for a delay in order to review the feasibility of the seed lot system to be introduced in Japan. Japan has to create new legislation and the project by JVPA has started in 2005 with a 3 year schedule; the seed lot system could be introduced by March 2008.
JMAFF requested to resume the discussion on this issue from 2008.

JMAFF asked the EU and USDA to reconfirm to JMAFF in writing (e-mail) whether they require Extraneous agent detection testing on the final product

The EWG chairman felt confident that for the extraneous agent testing an agreement on the GL will be reached. For mycoplasma testing the delay may be an issue.

JVPA suggested that if the deadlines were too long, the SC should review its position and enquire if new technologies would not be usable.
USDA agreed with the previous speakers and supported the exploration of alternatives if these are available.

The EU recommended to give EDQM a last delay until the next SC meeting and to review the situation at that time.
The SC supported this approach.

6.4. Pharmacovigilance

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr L. Post, and presented by the FDA.
At the 9th meeting of the EWG that took place in early October, the experts adopted GL 24, as well as its previous section V that is now GL 42.
GL 29 could not be adopted because JMAFF has to check the Japanese law.
Progress was not made on GLs 30 & 35 because of lack of time.
FDA indicated that the chairman intended to advance the discussions by written procedure, before making a formal request for the next meeting, in order to identify clearly the subjects to be discussed at the meeting.

The SC congratulated the chairman and the experts for the significant progress achieved.

JMAFF, which participated in this meeting, questioned if the teleconference exchange between several SC members that took place before the EWG meeting should be considered as a normal VICH procedure.
FDA replied that the intention was not to exclude the other parties but was necessary to expeditiously move ahead some points of contention between the U.S. and the EU. The FDA and EU representatives apologised for not keeping the JMAFF more informed about these discussions

The EU added that there had been only very little time for the exchange before the EWG meeting and that it would have been extremely difficult to organise a teleconference simultaneously in the 3 regions. The intention of the teleconference was to solve legal and regulatory issues and dissent between EU and the USA prior to the EWG meeting, as had been requested by the SC.

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

7.1 Preliminary Discussion

GL 24 and 42
The Secretariat reminded the participants that GL 24 had now been signed-off 3 times by the EWG at step 2 and had already been published once for consultation in some VICH regions in 2001.
GL 42 was included in GL 24 during the previous consultation periods: however it was now a new GL. The Secretariat recommended therefore that at least GL 42 should be published for consultation at step 4.
Considering the changes made to the documents, the SC agreed to publish GLs 24 and 42 at step 4 for a short consultation period of 3 months.

GL 36
The Secretariat explained that the chairman of the EWG, Dr L. Mulligan, had discovered that one sentence, which had been part of the consultation and adopted by the EWG, had disappeared in the step 5 document.

After discussion it was agreed to ask Dr Mulligan to provide the explanation in writing and that the SC would proceed with a revision procedure at step 9 by written procedure.

7.2 GL 24 (Pharmacovigilance) – Pharmacovigilance of Veterinary Medicinal Products – Management of Adverse Event Reports

The Steering Committee endorsed the text of GL 24 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 guideline is February 1, 2006.

7.3 GL 42 (Pharmacovigilance) – Pharmacovigilance of Veterinary Medicinal Products – Data Elements for Submission of Adverse Event Reports

The Steering Committee endorsed the text of GL 42 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 guideline is February 1, 2006.

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

8.1 Revision at Step 9

8.1.1 GL 39 (Quality – Specifications) - Test Procedures and Acceptance Criteria for new Veterinary Drug Substances and New Medicinal Products: Chemical Substances

The Steering Committee adopted GL 39 as a 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 November 2006.

8.1.2. GL 40 (Quality – Specifications) - Test Procedures and Acceptance Criteria for new Biotechnological/Biological Veterinary Medicinal Products

The Steering Committee adopted GL 40 as a 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 November 2006.

9. Discussion paper on Metabolism and Residue Kinetics

9.1 Update on the Experts' activities

The EU explained that, as requested at the 16th SC meeting, the chairman of the EWG has circulated a first discussion paper to the experts and has received a reply from all. The

chairman has then prepared an interim discussion paper including all the comments provided by the experts.

9.2 Review of the Interim Discussion Paper

The EU presented the interim discussion paper, which includes a first list of 5 potential priority topics, as well as other potential topics that have further been proposed by the experts. The EU recommended therefore that another round of discussion should take place by written procedure in order to prepare an agreement on the priority topics. A face-to-face meeting should then take place in spring 2006 prior to the next SC meeting.

The SC reviewed the interim discussion paper, in particular the potential priority topics, and congratulated the Experts for the work already achieved.

IFAH-Europe suggested that the validation of analytical methods should be limited to residue study methods (i.e. not surveillance methods) and also pointed out that most of the issues included in topic 5 (*withdrawal periods/withdrawal period estimation*) are already included in topic 3 (*substance specific residue depletion studies*)
The EU clarified that topic 5 suggested that a statistical method should be elaborated to calculate the withdrawal period which is a mathematical approach.

With regard to “other potential topics”, IFAH-Europe proposed that the import and export considerations should not be included in the scope of the EWG’s task.
ANZ believed however that this item should be maintained within the scope at this stage.
The chairman pointed out that this is indeed an interim report and recommended that the SC should not limit the scope before the face-to-face meeting, but only give its opinion to the EWG.
JVPA, JMAFF, the EU and FDA supported this approach.

After a thorough discussion the SC endorsed in principle the interim discussion paper and supported the continued discussion by the EWG on the 5 proposed priority topics, within the concept paper endorsed by the SC and with the exception of "(…. *diverging opinions about the control methods*)” in topic 4 “Analytical methods”.

The SC encouraged the experts to continue the discussion by written procedure to refine the paper before holding a face-to-face meeting.
The SC authorised the 1st meeting of the EWG to take place in spring 2006 in Europe, in order to enable the chairman to deliver the final discussion paper by April 15 at the latest.

The chairman asked the SC members to explain the discussion that took place at the SC meeting to their experts.

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. Potential New Topics

11.1 Review of the Proposed concept paper on harmonisation of MIC Breakpoints

IFAH-Europe presented the concept paper and stressed the special interest of the industry for harmonisation in this field. Indeed, although most known GLs were set up by the US NCCLS, now called CLSI, different bodies and different regions (FDA, Vetcast, European Member States…..) are beginning to define breakpoints, with risk that different values are used. Sometimes the situation is even complicated by the fact that substances have breakpoints defined in human use.
This does not facilitate the marketing of products for the Industry because different breakpoints require the establishment of different dosages in different parts of the world. This has further cost implication for resistance monitoring.
The Industry wished therefore to avoid the current situation in the human field, where different breakpoints have been established for the same substances in different countries, as well as clinical breakpoints that are different from microbiological breakpoints. This is already posing important problems for the use of antimicrobial products in humans.

AHI added that its experts had collaborated with IFAH-Europe to establish the concept paper.

The EU supported the topic in principle, but requested to review some issues such as whether the different aspects of harmonisation of MIC breakpoints and criteria for establishing the breakpoints could be dealt within one GL, and also the potential need to involve in the EWG other organisations that are also dealing with this issue.
JMAFF also supported the topic in principle.

JVPA supported also the revised concept paper and expected that this topic would not require an excessive workload, as it could be finalised within 3 meetings of an EWG.

FDA explained that it was not prepared for the moment to support this VICH topic because of the potential consequences on human products and the possible involvement of other agencies that are under the responsibility of the same US Ministry (such as the CDC).
FDA indicated further that there was a potential conflict between CLSI methods and what FDA could request from both human and veterinary products.
Although FDA believed that breakpoints may be very useful to track resistance, the CVM had not yet identified how these breakpoints would be used for determining or describing drug efficiency. FDA expressed its belief that there is no scientific consensus on the relationship that can be made between microbiological breakpoints and clinical breakpoints.
FDA will make a final decision in the near future.

AHI suggested receiving further guidance from FDA, the EU and JMAFF in order to prepare a revised concept paper, including the feasibility of the harmonisation, before the next SC meeting.
After further discussion, it was agreed that the representatives of the Authorities would provide further comments to IFAH-Europe by the end of 2005. IFAH-Europe will prepare a revised concept paper for review at the next SC meeting.

11.2 VICH Common Technical Document

AHI presented a summary of the replies received after circulation of a questionnaire (see attachment).

AHI explained that there was a consensus not to start this topic *de novo* but to build on the ICH experience.
AHI recognised that further clarification was needed on what exactly was meant by "CTD": including Biologicals/Pharmaceuticals; referring to electronic/paper documents…

IFAH-Europe, JMAFF, JVPA and FDA believed that, although the topic is important, it is too early to set up a working group on this topic.
It was suggested that Industry should provide a more detailed analysis on what would be the benefits of a CTD.
IFAH-Europe stressed that ICH had put enormous resources in the CTD without having established the benefits. ~~Furthermore, if in the future submissions of dossiers would be made electronically, the CTD would not be necessary anymore.~~

After discussion, it was agreed that more information was needed from ICH's experience with the CTD, and that VICH should plan how to handle this topic in the future.

FDA will provide more information at the 18th SC meeting, and the possibility of inviting an EMEA expert to explain the 'human' CTD experience to the SC should be investigated.

12. Any other business

12.1 Biologicals Conference in 2006

USDA indicated that it did not have specific details on this conference, but will circulate more information in writing as soon as available.

12.2 Reporting of VICH activities to the CCRVDF

The EU explained that the agenda of the next CCRVDF meeting in May 2006 will include a report from OIE on VICH activities.
The EU recommended making VICH more visible and suggested that either SC members could present the report on a rotational basis, or, if the SC would opt for the continuation of OIE reporting, that OIE should draft the report with input from the SC members.

The OIE supported strongly the idea of making VICH more visible as well as the common preparation of the report, but believed that VICH could not be directly represented in the CCRVDF.

After discussion it was agreed that the report prepared by OIE on VICH will be shared with the SC beforehand, with the support of the secretariat.
OIE will circulate a draft report for comments at least 1 month before the CCRVDF deadline for reports, and re-circulate the final document 1 week before that deadline.

12.3 FAO/WHO reply to our letter VICH/05/052 on GLs on safety requirements for VMPs

The Secretariat reminded the participants that, with the help of the EU, a letter to JECFA had been drafted following the decision made at the last SC.
The reply from JECFA included an invitation for VICH to attend a workshop on the development of guidance on maximum levels of pesticide and veterinary drugs, organised by the RIVM in the Netherlands on 7-10 November next.

As the deadline to confirm the name of the representative had been very short, the Secretariat had asked the AHI expert, Dr Nappier, to represent VICH at that meeting.
This invitation had however highlighted the fact that the Secretariat needed an established guidance for replying to invitations sent to VICH.

The EU, FDA and JMAFF believed that normally the chairman of an EWG or the topic leader should represent VICH, and the SC should be consulted. The VICH representative should, independent of his/her affiliation, represent the VICH position, not the position of his/her affiliation. In the case of the topic Metabolism and Residue Kinetics, it was considered difficult to present the VICH position, as the topic was in an early stage of development.

The SC approved the representation by Dr Nappier, although it was regretted that time had been too short for a consultation within the SC. The SC asked AHI to inform Dr Nappier that he should refrain from presenting any personal/AHI views, but that if required, he should clearly present VICH and limit any further explanation to the mandate of the EWG. Also the work of the VICH Safety EWG and the safety guidelines should be presented. He was asked to report back to the SC.

After discussion, the SC agreed that for future invitations, the Secretariat should circulate the received invitation with the suggestion of designating the relevant Topic leader who should in principle always represent VICH and report back to VICH SC.
In future the Secretariat shall also brief the representative on what is expected from him/her.
The SC recognised also that in some cases, depending on the content of the meeting, the VICH representative could be a SC member.

12.4 Alternative tests to animal testing

The EU explained that alternative testing methods are available for some parts of a dossier. However, often companies did not use alternative testing methods because there is no harmonised guidance ensuring their acceptance. The EU suggested therefore that VICH could set up guidance for alternative testing methods or strategies to reduce animal testing; the end objective being the reduction of animal testing.
The aim would not necessarily be to develop new guidelines but rather to identify validated tests that exist and to provide guidance on the use of alternative testing methods.

IFAH-Europe, AHI, JMAFF, JVPA, FDA, ANZ and Canada supported this proposal.

It was therefore agreed that the EU will prepare a discussion paper for review at the next SC meeting.
The EU requested that by end of January 2006, members should inform the EU on which guidelines already exist in the different regions.

13. Dates and venue of next meetings

- The 18th SC meeting will take place on May 31st & June 1st 2006 in Europe
- The 19th SC meeting will take place in Washington DC in Dec 2006 or January 2007
  AHI will propose some possible dates to Secretariat in the near future.

16. Adoption of the press release on the 17th SC meeting

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

VICH STEERING COMMITTEE

17th meeting

November 1 & 2, 2005
Kyoto, Japan

Chair: Dr Y. TAKAHASHI, JAPAN MAFF

LIST OF PARTICIPANTS

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