VICH/03/058
23 January 2004
FINAL

VICH STEERING COMMITTEE
13th meeting
7-8 October 2003
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 USDA, FDA and AHI. He welcomed two new participants, Dr Brigitte Boenisch from IFAH-Europe and Dr Masato Sakai from JMAFF, as well as Dr Annika Wennberg replacing Mr Ph. Brunet, Dr Steve Karli representing USDA and Dr C. Francia replacing Dr Gimeno.

2. Adoption of the agenda

The secretariat apologised for numbering mistakes which had appeared in the draft 3 of the Agenda, circulated shortly before the meeting.
IFAH-Europe explained that according to the strategy and the original objective of VICH, in their view the SC should not only monitor the completion of implementation of the VICH GLs, but also consider reviewing the way VICH GLs may be interpreted in the different regions.
IFAH-Europe therefore suggested adding the following item to the agenda:
"8.2 Regional regulatory agency reports on amendments introduced to harmonised GLs during the implementation phase."
The agenda was adopted without further change.

3. Progress reports of Expert Working Groups

3.1 Ecotoxicity and Environmental Impact Assessment

The chairman, Dr J. Robinson, reported that all outstanding problems had been solved at the 8th EWG meeting and the Phase II GL had been signed-off at step 2. He warmly thanked the members of the EWG, in particular Dr J. Holland, for their commitment to finalise this draft GL.

He considered that the work started in March 1997 had been successfully completed in April 2003 and that the EWG had fulfilled its mandate. He thanked also the members of the SC for their strong support.

He hoped that the full implementation of the Phase II GL would be achieved in the regions by end 2005 at the latest.

The EU reminded the members of the decision made at the 9th SC meeting in June 2001 to transfer the topic leadership at step 5 to the EU. The EU explained that the EU has made preparations for this role such as the setting-up of an expert group on environmental risk assessment supporting the EU expert, Dr Joop de Knecht, and that the EU therefore confirmed its previous proposal.
FDA indicated that this issue had been discussed with the FDA expert who expressed his agreement. AHI and JMAFF confirmed their support ~~to~~ of the EU proposal.

The SC therefore reconfirmed to transfer the topic leadership to the EU.

Dr Robinson indicated that the EWG had not planned any further meeting, and it was hoped that this might not be necessary and no new major issues would be raised during the consultation period.
The SC asked that the topic leader should report to the 14th SC meeting on the comments received and if major issues would have been raised for the SC to decide on the further procedure to finalise the GL.

The SC applauded the achievement of this difficult task and expressed its gratitude to Dr Robinson and to all the experts.

3.2 Safety & Task Force on Microbial Safety

The SC reviewed the written report prepared by the chairman of the Working Group, Dr T. Mulligan, and presented by the FDA. No meeting took place since the last SC as the draft guidelines on Repeat-dose: chronic toxicity and Establishment of a microbiological ADI are still under consultation.

FDA indicated that the next EWG meeting, approved at the last SC meeting, was scheduled for early December, after the end of the consultation period on 15 November in the USA.

The EU expressed its concern that the meeting was planned only 2 weeks after the end of the consultation period and explained that if major comments were received during the public consultation these would not be possible to be considered prior to the meeting, and members might therefore not be able to sign-off, and therefore a further meeting might become necessary.
After discussion, the SC strongly encouraged the EWG to reschedule the 11th meeting to January-February 2004, or to ensure that all issues are addressed at that meeting.

The OIE confirmed that it had released the safety GLs to all OIE members on 8 June for comments before 8 September, together with the general information leaflet on VICH.
OIE had not received any comments, and attributed this to fact that the contact points are the CVOs (Chief Veterinary Officers), who are not directly involved in the registration process. The OIE headquarters have addressed this issue and plans to create within OIE a network of people interested in these particular matters in all regions, in order to stimulate the involvement of third countries in the VICH process, and particularly in the VICH consultations.

3.3 Pharmacovigilance

The chairman, Dr Hill, pointed out that the SC had given a clear mandate to the EWG as the EWG had not yet met to solve outstanding issues. He therefore encouraged the SC members to solve the problems if possible at this meeting. He insisted that each of the experts needed to attend the meeting prepared to outline and discuss the legislative requirements; regulatory authorities may need to provide guidance to assist the group in confirming what is legislation and what is policy.

The EU clarified that the frequency of reporting, introduced by Dr Post as an additional item for discussion in the EWG, was laid down in basic EU legislation and could not be subject to any negotiation. The EU also clarified that the new proposals for amending the legislation contained provisions to review the reporting requirements in light of experience gained in the future, but this piece of legislation is yet to be adopted by the EU Parliament and the Member States of the EU. The FDA, USDA and JMAFFSC members also acknowledged that, equally, the USA and Japanese basic legislations could not be changed easily.

The EU raised concern that the chairman's report and EWG agenda suggested that it was intended to discuss subjects beyond the mandate of the 12th SC, and the frequency of PSUR reporting was now raised as new subject. The EU stressed that the mandate that was given to the EWG (see minutes 12th SC) included the review of section V of GL 24 on data fields, the definition and the setting of international birthdates, and the mechanism for expedited 3rd country reporting. ~~However, it was agreed by the SC that the working group experts should be free to discuss any and all topics necessary to complete the guidelines.~~
The chairman of the EWG, Dr L. Post, confirmed these 3 items of discordance in the EWG still needed the SC's attention.

The SC confirmed to Dr Post that the EWG would have to work by consensus and that the relevant draft documents should be signed either by all "pharmacovigilance experts" or by all "IT experts" depending on the GL.

International birthdates and periodic reporting

The meeting concentrated on identifying the problems related to the subject for consideration by the EWG.

AHI and IFAH-Europe insisted that the International birthdates must be linked to the frequency of Periodic Safety Reporting.

The EU clarified that for any new veterinary medicinal products the choice of the birth date is left to the company, if the EU birth date or the international birth date shall be used for the periodic reporting.
The EU explained that ~~this~~ the issue related to old national products' birthdates would have been raised only very recently in preparatory discussions for the EWG meeting with IFAH-Europe experts. The only advice the EU could provide at present, namely variations of the marketing authorisations requesting changes of the frequency of reporting, was considered not practicable by IFAH Europe considering the large number of products. The discussion was however considered very useful clarifying the issue of concern. The EWG is requested to further develop the possibilities.

The EU recommended that the experts be as open-minded as possible in order to find practical solutions.

Further to the question from SC members as to whether the “data lock point” used in the EU would provide a solution for the problem, the EU explained that the “data lock point” would be a deadline linked to the PSUR closing date. This deadline represents the date when the Market Authorisation Holder can close the reporting file and send the PSUR to the authorities. Every event happening after that deadline can be reported in the next PSUR. This does not influence the frequency of reporting.

The Industry representatives called for a pragmatic approach and recommended synchronising the reporting of PSURs among the regions, until further harmonization on their submission can be achieved.

The EU stressed again that the frequency of reporting was laid down in basic EU legislation and could not be subject to any negotiation. The EU also clarified that the legislation contains provisions to review the legal conditions in light of experience in some time.

It was clarified after long discussion that the term “frequency” as introduced by industry was to be understood as “synchronisation” of PSURs, and therefore the subject was linked to the birth date of a product. AHI clarified, as an intermediate step, that the intervals by which PSURs have to be provided in the different regions could be left intact and modified over time based upon experience.

After an in-depth discussion the authorities of the 3 regions confirmed each that solutions could be found to recognise common international birthdates and agree on synchronised reporting.

The SC members will encourage the experts to find compromise solutions.

Electronic Data fields

Dr Post explained that the EWG would not be able to accept all data elements currently proposed by the EU, because some would be out of scope of GL 24 and should not be discussed at the EWG meeting e.g data fields for clinical trials, literature data, compliance with withdrawal periods and environmental problems and he believed that human adverse events should not be included as a separate field.

The EMEA clarified that that these issues would not be considered as suspected adverse drug reactions but that the EU legislation would require that they would be taken into account in the EU pharmacovigilance system. These fields would not be mandatory to complete but should be foreseen in the data reporting system, as only 1 database for pharmacovigilance reporting would be set up in the EU, the Eudravigilance database, and that it would of course not be obligatory to fill in all the fields that are proposed.

JMAFF and USDA expressed their concern on the suggestion of data fields for which it would not be possible to provide data in Japan or in the USA.

After a thorough discussion the SC recommended that the EWG should identify the data fields, which would be recommended as obligatory and which would not be obligatory.

The SC expected that all the experts would sign-off the draft GL at the end of the EWG meeting.

Third country reporting
The SC discussed the EU's requirements for expedited third country reporting and it was clarified that such reporting was only required when a same product as authorised in the EU was registered in at least one other region.
USDA pointed out that the definition of "same products" for biologicals was very different than for pharmaceuticals.

The EU clarified that a definition of "same product" had been included in the draft GL 24 and that companies should report within 15 days only when serious and unexpected adverse reactions have occurred outside the EU, and human adverse reactions.
The EU confirmed once more that the 15 days would apply from the moment the Marketing Authorisation Holder's Qualified Person received the information in Europe.

AHI suggested that the experts should include parameters in the GLs to help companies in understanding when and which events they would have to report.

After discussion the SC confirmed the mandate given to the EWG at the 12th SC meeting and decided not to write any further recommendation.

The chairman understood that during the discussions a solid commitment had been given by all the SC members that their experts would strive to reach a consensus on all 3 outstanding issues.

It was agreed that SC participants would brief the experts at the forthcoming EWG of the SC discussions and conclusions.

The SC confirmed the 7th meeting to take place in the USA on October 13-17, 2003.

3.4 Antimicrobial Resistance

The SC reviewed the written report prepared by the chairman of the Working Group, Dr D. Mevius, and presented by the EU.

The EWG has raised the issue of the scope of the GL, asking if it should cover only new active substances or if products containing existing active substances should also be concerned.
The EU stressed that, by experience, for products containing existing substances it will be difficult for Marketing Authorisation Holders to comply with these GLs and that flexibility was needed because otherwise the old products would disappear from the market. Furthermore, it was stressed that there can't be absolute worldwide harmonisation because the resistance situation may differ~~et~~ between and within each region, necessitating different regulatory requirements for similar products.

JMAFF believed that both old and new chemical entities should be considered, but that it is difficult to include a specific wording in the document. JMAFF thought that the GL's current wording provided for sufficient flexibility for the regions.
FDA supported JMAFF's views.

IFAH-Europe confirmed that it was reasonable to apply the GL to new "submissions", but recommended a "double flexibility" for older products with new submissions, because it is difficult for products existing on the market since many years to fulfil the requirements at the moment of the Marketing Authorisation renewals.

The SC confirmed the flexibility of the scope should be decided by each region.

The SC agreed to include in the draft GL several editorial changes regarding references and asked the secretariat to liaise with Dr Mevius to finalise the text.

The EWG had asked for guidance on future work on labelling recommendations on prudent use. After discussion the SC agreed to delete this topic from the EWG's mandate because other bodies (OIE, Codex) were already addressing this issue.

The EU indicated that as the GL had been circulated only a few days before this meeting, it had not received the CVMP opinion and could therefore not sign off the document at this meeting.

The SC confirmed that the EWG had completed its mandate and agreed to disband the EWG.

3.5 Biologicals Quality Monitoring

The SC reviewed the detailed written report on the 8th BQM EWG meeting prepared by the chairman of the Working Group, Dr O. Itoh, and presented by the JMAFF.

JMAFF indicated that the experts had not been able to discuss further the Mycoplasma testing because the 5 reference strains are not yet available.
The EU explained that the EDQM had encountered difficulties with the preparation of the frozen strains and with their production on a large scale.
EDQM hoped to distribute the strains to all authorities by the end of this year.
The authorities from all regions committed to facilitate the importation of the strains.

A new topic leader was designated in the topic of Testing for the presence of extraneous agents, and as a result, JMAFF pointed out that it was embarrassed by the proposal to change the procedure from the orientation the EWG had taken so far during its 7 first meetings.
It was announced that previous discussions in the EWG had focused on technical harmonisation of the test method based on the presumption that there were some differences in the opinions and standpoints concerning the time of testing.

However, due to basic philosophical and regulatory differences between the regions, the extraneous agents WG had concluded that merely a harmonisation of technical tests can take place, but not of the way how authorities apply these tests on starting materials and products (i.e. upstream or downstream).

The EMEA explained the concerns expressed in the letter circulated during the summer, i.e. that to develop a phase I document on how to conduct the test, and to then define the testing requirements in a phase II document as proposed by the EWG is not the best way forward. AHI and IFAH-Europe supported that position.

AHI stressed that difficulties had appeared in the EWG when the experts had tried to integrate 2 different production ways in a single document. AHI submitted a proposal to develop one guideline for extraneous agent testing where well characterised ingredients of biological origin have been used and a second guideline where they have not. Much of this work has already been done by the EWG and can be captured with this approach using 2 separate documents. IFAH-Europe and JVPA supported also this approach.

JMAFF confirmed that it could not support the proposal to advance the topic of Master Seeds as suggested by the AHI because JMAFF was concerned that this proposal would be directly linked to a modification of Japanese regulations about the time of testing.

JVPA pointed out that the phase I would solve the technical issues and the phase II the regulatory issues
JMAFF thought that it would be very difficult to harmonise these regulatory issues as each region had currently different systems in place that all enabled the production of excellent products.

The SC recognised that through this approach VICH would limit itself to strictly technical matters, rather than harmonising the regulatory approaches.

JMAFF explained that it would be very difficult to set up two different GLs at this time because it would consequently lead to a modification of Japanese regulations surpassing technical harmonisation. JMAFF proposed therefore to progress the work by going back to the efforts and results achieved in the past seven EWG meetings and limiting the task to technical harmonisation of the test methods. In addition, technical harmonisation of test methods may be useful for a future review of Japanese regulations.

Recognising the work already undertaken by the EWG during 7 meetings it was agreed that the EWG be asked to prepare a proposal what can be pulled out from their achievements with the objective to forward a work product to the SC. Meanwhile no 9th EWG meeting was yet agreed.

3.6 Target Animal Safety

The SC reviewed the written report prepared by the chairman of the Working Group, Dr T. Nagata, and presented by the JVPA.

JVPA explained that the TAS EWG was preparing 3 draft GLs: one on pharmaceuticals, one on live and inactivated vaccines and one on reversion/increase of virulence. The 6th TAS meeting was postponed and not rescheduled so far. No major progress had been made since the last meeting because FDA had not yet provided its comments on the draft documents.

FDA indicated that the GL on TAS for pharmaceuticals was a priority and that the comments would be circulated end of October or early November. JMAFF confirmed that the draft documents would be ready very soon thereafter.

JVPA suggested that the EWG meeting could take place 2 months later, in December or January and proposed to limit the discussions to the draft documents on pharmaceuticals and reversion/increase of virulence, which could be progressed at the following meeting.

As the EWG could not agree on the TAS GL for live and inactivated vaccines, the EU had proposed in a letter to convene an ad hoc meeting with additional specialised experts in order to address key issues yet to be solved before further progress can be made. USDA supported this proposal.

JMAFF recommended limiting their scope to the difficult issue of overdose testing.

IFAH-Europe and Canada proposed to split the EWG into pharmaceuticals and biologicals EWGs. The EU supported this approach, but JMAFF preferred to keep one EWG with two subgroups.

After a thorough discussion, the SC confirmed that one single EWG meeting should take place in total for one week duration. The sessions on pharmaceuticals and biologicals issues would follow one after the other starting with the session on pharmaceuticals. The EWG meeting, which would divide its time between the 3 topics, as for example 2 days on the pharmaceutical topic, 1 day on reversion/increase of virulence, and the last 2 days on the live and inactivated vaccines, with additional experts to address the overdose safety tests issue ~~and other key issues proposed~~. Sufficient time should be allocated to this issue in order to enable the progress of the draft document.

The SC agreed that the ad hoc additional experts nominated by the regions could attend the session on TAS on live and inactivated vaccines at the next EWG meeting, but it was clarified that this was for this occasion only. Nevertheless, in case that the overdose tests issue could not be solved at the forthcoming EWG meeting, the EU offered to organise a separate special ad hoc meeting in 2004.

To ensure no uncertainties remain with regard to the next meeting, it was agreed that the TAS EWG chairman should lay out a detailed plan for the next meeting including what will be needed from whom by when in order to secure the future progress.

The SC recommended that the TAS EWG should hold its 6th meeting in spring 2004, if possible in March.

3.7 Quality

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

FDA confirmed that, as committed to at the 12th SC meeting, it will resume its involvement in the EWG in spring 2004, hopefully in April, with priority given to the revision of ICH GLs Q6A and Q6B.
The EU referred to the letter from the EMEA on Q6A & Q6B, for which work had progressed between all partners except FDA. The GLs are ready for release for consultation provided FDA gives its input.
The EU urged the EWG to progress these GLs (Q6A & Q6B and the revision of the VICH GLs 11 & 12) in spring 2004; otherwise the EMEA's CVMP (Committee for Veterinary Medicinal Products) would have to develop specific EU GLs for the time until VICH GLs would be available.

FDA informed the SC that it had initiated an agency-wide initiative on quality: "GMP for 21st century", for human and veterinary products because human and veterinary products are based on the same quality requirements.
FDA plans to continue to work within ICH and would like discuss the possibility of other VICH partners taking part in these discussions.

The EU indicated that no such discussion was taking place between the human and the veterinary fields in the EU. However, the GMP GLs currently adopted in the EU apply to both human and veterinary products,

FDA recommended that the Quality EWG should monitor closely the ICH activity and try to participate as observer. AHI reported however that there has not been a favourable response from ICH, because the ICH WG would become very large, which would slow its work.

After discussion, the SC agreed that as FDA resumes its involvement in the work of the EWG, the EWG should try to proceed by written procedure.
If a meeting should be required in spring 2004, the chair should inform the SC as soon as possible.

The SC expected the EWG to present the proposals for revision of Q6A & Q6B for sign-off at step 3 at the 14th SC meeting.

4. Review of VICH Workplan 2000-2005

The chairman reminded the members that the Safety and Ecotoxicity EWGs had nearly finished their tasks and that the Antimicrobial Resistance EWG had just been disbanded.
The secretariat explained that the proposed amendments included the changes that had been made at the last meeting as well as several suggestions from the secretariat to update the document. The secretariat stressed that the Workplan was a "living document" which was amended at each meeting.

JMAFF proposed to delete reference to the years 2006 and further from the table of the schedule in Part II 3). JMAFF also informed the SC that it had decided to withdraw the Concept paper on Tests for stability in Veterinary Vaccines from Part II 2) a).

After discussion the SC agreed to delete the "Part II) 2) b) other topics", because it was most probable that the proposed topics would not be achieved by end of 2005.
The SC confirmed that the updated Workplan should be placed on the website and updated when necessary.

5. VICH Phase II: 2006-2010

The secretariat explained that the proposed draft document was presented in 2 parts in order to separate the Strategy from the Workplan itself; the latter being a document that was being reviewed at each SC meeting. The secretariat confirmed that both documents included the suggestions that had been received from the SC members.

5.1 Review of the proposed strategy and Workplan

The European Commission informed the SC that the EU would continue supporting VICH until 2005, but for the time thereafter only a scheme dealing with maintenance work on guidelines could be supported. The European Commission stated that it was currently not in a position to engage in a discussion about VICH after 2005, because of upcoming elections in the EU (new Parliament and a new Commission) in 2004 implying also new budget discussions.
The European Commission also expressed reservations about the continuation of VICH with its current format, particularly considering the slow progress during the last years and lack of commitment and resources. The globalisation of industry with multinational companies represented in all regions and observer countries was also indicated as a reason for a need to review the structure and working methods. Nevertheless, the EU confirmed that it would be committed to participate in maintenance activities beyond 2005, with a more streamlined and representative structure and increased efficiency of the process.

Other SC members confirmed their wish to continue the VICH process involving both the development of new guidelines beside maintenance work.

The chairman pointed out that all the suggestions received by secretariat implied that the current work should be speeded up. He believed that the vision for the future would come out of that work.

He agreed however that the situation had changed since the start of VICH. This was why the secretariat had anticipated this fact and separated the Strategy from the Workplan.

ANZ supported the setting up of a Workplan as otherwise it would be difficult to organise the maintenance work.
ANZ believed that although the members could not always agree on regulatory issues, VICH had progressed well on technical matters and mutual understanding.

On behalf of the Industry members, AHI proposed to create a small SC Working Group to review Workplan and the topics for the future.

Canada confirmed that it would commit the necessary resources for future VICH activities. The benefits to the industry on the short term would also benefit the regulators over the longer term.

OIE stressed that it would be very concerned if VICH would only maintain the existing GLs. OIE recommended that the VICH system should evolve in a new way. A Task Force could try to determine the real needs of the international harmonisation process. OIE strongly believes that VICH is essential for the developing countries and that the whole life of VMPs should be harmonised, including post-marketing aspects, which are very important.

OIE insisted that international medicines harmonisation was an essential asset for the defence and maintenance of public and animal health.

The chairman pointed out that VICH was the only forum where industry and regulators exchanged their ideas and that such discussions were taking place in no other group in the world.

IFAH Europe confirmed its clear commitment to VICH, which is still a young process and can be improved. The globalisation of the Animal Health Industry is a fact of society. VICH is the only forum where topics on harmonisation can be addressed. It is therefore important to

continue and forge the future for veterinary products, although the strategy and mechanisms need to be reviewed.

USDA confirmed its support for a plan covering VICH activities after 2005 and indicated that the necessary resources will be available.
FDA indicated that its priority is mainly on dossier reviews for marketing authorisations and the industry should clearly indicate its priorities.

JMAFF confirmed the proposal already announced in the position paper to progress efficiently the future actions of VICH.

After an in-depth discussion, the SC agreed to set up a Task Force of maximum 4 persons, chaired by OIE and assisted by the secretariat, with the mandate to evaluate the demands, the expectations, the resources needed, the risks and the possible obstacles, as well as to review new ways of working. The Task Force should draw up a proposal for the remodelling of the future of VICH.

The Task Force will be composed of 1 representative of the observers, of AHI, of the EU and of Japan.
The observers will be represented by D. Morris (ANZ), AHI by M. McGowan, the EU by A. Wennberg and Japan by S. Tokiyoshi.

OIE thanked the SC for their confidence and proposed to circulate very soon a questionnaire to all SC members addressing the general harmonisation issues.

6. Adoption at step 3 and release of guidelines at step 4

GL 38 *(Ecotoxicity Phase II) – Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II*

The Steering Committee received the text of GL 38 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-month public consultation at Step 4.

The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 15 April 2004.

7. Adoption at step 6 and release of guidelines for implementation at step 7

GL 27 *- (Antimicrobial resistance) – Pre-approval information for registration of new veterinary medicinal products for food-producing animals with respect to antimicrobial resistance*

As the EWG had met only recently, the document had been circulated shortly before the SC meeting.

The SC reviewed the draft document and proposed a few minor amendments. The secretariat will confirm the amendments with Dr Mevius and circulate the revised document for adoption by written procedure before December 15, 2003.

The SC agreed that the implementation date would be December 15, 2004.

8. Update on the implementation of final VICH Guidelines since the 12th SC meeting in the 3 regions and the 2 observer countries

8.1 Implementations

The EU reported that since the last meeting VICH GLs 28, 31 & 33 have been implemented in Europe as from October 2003, whereas GL 32 will be implemented at a later date because the EU legislation needs to be changed.

FDA reported that VICH GLs 28, 31, 32 & 33 had been implemented in the USA.

USDA confirmed that the VICH GL 26 was published this week.

Japan reported that VICH GLs 28, 31, 32 & 33 have been implemented, as well as VICH GLs 25 & 26 since July 29, 2003.

ANZ reported that VICH GLs 28, 31, 32 & 33 were implemented in August 2003 in New Zealand and in October 2003 in Australia.

Canada confirmed that, as explained in 12th SC meeting, the implementation of 27 VICH Gls, including VICH GLs 28, 31, 32 & 33, was taking place this fall. The process took additional time, as the guidelines must also be posted in French in Canada.

8.2 Regional regulatory agency reports on amendments introduced to harmonised GLs during the implementation phase

IFAH-Europe explained that the first goal of the proposed new Workplan was not only to complete, but also to monitor the implementation of the VICH GLs. It might be also useful to monitor how the GLs are implemented in practice and check if there are divergent interpretations, which would have forced regional authorities to amend slightly the published text, and this should be brought to the attention of the SC.

The SC clarified that VICH guidelines cannot be amended, unless a step 9 procedure would be initiated. After discussion, the SC agreed that the Task Force should consider this issue.

9. New topics

The chairman reminded the participants that the Ecotoxicity, Antimicrobial Resistance and Safety EWGs had finished their tasks, or were nearing the end of their mandate.

9.1. Review of the concept paper on the revision of VICH GLs 10 & 11 at Step 9

The SC recognised that it was difficult to discuss this concept paper considering the previous discussion on the work of the Quality EWG.

The SC recommended that, as soon as it would resume its activities, the EWG should also review other ICH GLs and, if relevant, propose concept papers to the SC for the revision of corresponding VICH GLs.

The SC agreed to review the concept paper at the 14th SC meeting again.

9.2. Review of the revised concept paper on Metabolism and Residue Kinetics

The SC reviewed the concept paper prepared by the EU.

The EU indicated that FDA had asked to include the issue Pharmacokinetics & residue kinetics in the concept paper.

The EU suggested creating a new EWG at this meeting.

FDA indicated that it could not support a new EWG because of the current lack of resources.

JMAFF reported that a Food Safety Commission was established in July 2003 in Japan and was responsible for risk evaluation. JMAFF explained that in Japan, this Food Safety Commission may be responsible for the issue of ADI, the Ministry of Health, Labour and Welfare may be responsible for establishing MRLs, and JMAFF may be responsible for establishing the withdrawal periods. JMAFF therefore considered that, since the collaboration between these three parties was unclear, it was difficult to establish a new EWG.

After discussion, the SC agreed therefore to reconsider the concept paper at the next meeting.

The EU, supported by the chairman, pointed out that the management of this proposal was not a highlight of an efficient work in the VICH SC. This topic was on the list since 4 years and had been suddenly challenged over the past few months. Meanwhile the EU had allocated a lot of resources to this proposal.

The chairman therefore recommended that for the future the SC should carefully evaluate a proposal before adding it on the topic list.

9.3. Concept paper on Tests for Stability in veterinary vaccines

Considering the current status of the BQM EWG, JMAFF decided to withdraw the concept paper; JMAFF may propose this concept paper again at a later stage.

9.4. Review of the revised concept paper for Sterility for Veterinary Medicinal Products

ANZ indicated that, with regard to the comments received, mainly that the work is already taken care of by the Pharmacopoeias of these 3 regions ANZ withdraw the proposed concept paper.

10. Review of VICH Documents

10.1 Review of the Organisational Charter of VICH

The secretariat presented the proposed revisions and asked for comments from the SC.

The SC reviewed and adopted the proposed changes one by one.

The European Commission pointed out that although it cannot decide on how the Industry should be represented, it considers that the replacement of FEDESA by IFAH-Europe had not been made with the consent of the European Commission.

The SC adopted the new version (VICH/96/002 Rev. 7-Final) of the Organisational charter and asked the secretariat to place this version on the VICH website.

10.2 Review of the Notes on the Format and Style of VICH Topic Concept Papers

IFAH-Europe reminded the participants that the SC had agreed to review the old concept paper and set up a template for the elaboration of a new GL.

The SC reviewed the template proposed by IFAH-Europe and adopted the new Note with minor amendments.

11. Preliminary exchange of ideas on the VICH3 conference

The SC reviewed possible dates proposed by the USA representatives and agreed that VICH3 would take place either in the week of April 11, 2005 or during the first week of May 2005.

The conference will be organised in Washington DC.

The SC will discuss the agenda and organisational matters at the 14th SC meeting.

12. Any other business

None

13. Dates and venue of next meetings

- The 14th SC meeting will take place on 12-13 May 2004 in Japan (Tokyo)
- The 15th SC meeting will take place on 20-21 October 2004 in Europe (London or Berlin)

14. Adoption of the press release

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

VICH STEERING COMMITTEE

13th meeting

7-8 October 2003
Washington DC, USA

Chair: Dr R. Hill, USDA APHIS

LIST OF PARTICIPANTS

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HEALTH Canada	I. ALEXANDER
CAHI	J. SZKOTNICKI

INTERESTED PARTY

AVBC	J. THOMAS
CAMEVET	C. FRANCIA

OIE

OIE	P. DEHAUMONT

INVITED

AHI	J. ROBINSON
USDA APHIS CVB	S. KARLI

VICH SECRETARIAT

IFAH	H. MARION
IFAH	J.-L. DELFORGE

APOLOGIES

JVPA	S. OHSHIMA (C)