VICH/04/028
26 July 2004
FINAL

VICH STEERING COMMITTEE
14th meeting
12-13 May 2004
Tokyo

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 Tokyo on behalf of JMAFF and JVPA. He welcomed new participants, Dr F. Caceres representing Camevet as well as Dr H. Makie representing JMAFF.

2. Adoption of the agenda

The agenda was adopted without further change.

3. Progress reports of Expert Working Groups

3.1 Quality

The chairman of the Working Group, Dr K. Hamamoto, was pleased to report that the expert from FDA had resumed the work within the Quality EWG and had provided 2 minor comments on the current draft 4 of GL VQ6A, and no comment on draft 4 of GL VQ6B. The other experts are expected to provide any additional comment by next May 20. Dr K. Hamamoto expected to circulate a final draft of both GLs for sign-off by the EWG at step 2 during the summer ~~and to~~and to present these at step 3 at the 15th SC meeting.

The FDA has also resumed its activities with regard to the revision of VICH GL 3 at step 9 and a proposal may be ready to circulate to experts by early summer this year.

The secretariat suggested that the written procedure should be speeded up in order to enable the SC to sign-off the draft GLs at step 3 by written procedure before the 15th SC meeting.
The chairman supported this proposal and encouraged the Quality EWG to sign-off the step 2 documents by the end of June.
The EU confirmed that this time schedule would allow internal consultation prior to the 15th SC meeting.

The SC expected the EWG to present the proposals for revision of GL VQ6A & VQ6B for sign-off at step 3 during the summer. ~~The SC urged Dr Hamamoto to also aim for sign-off by written procedure of GL 3 (R) by end of June to allow sign-off for consultation at the 15th SC.~~

Canada informed the SC that Mr S. Jones represented Health Canada in the Quality EWG.

3.2 Biologicals Quality Monitoring

The chairman of the Working Group, Dr O. Itoh, reported that no progress has been made at the 8th BQM EWG meeting on the mycoplasma draft GL because the EDQM had encountered unexpected difficulties whilst trying to prepare the low passage lyophilised strains. The EWG had indeed decided to test the strains in all the regions to ensure a common standard before signing-off the draft GL at step 5.

The topic of extraneous virus testing was at a very difficult stage of the discussion within the EWG, because of different approaches in the regions, the EU and US focussing on the starting material (upstream testing), Japan mainly focusing on the final products (downstream testing). The EWG has listed the advantages and disadvantages of both approaches, but has not been able to recommend which method should be preferred. The recommendation could therefore be to include both approaches into the draft GL.

Dr O. Itoh added that the different way how authorities apply these tests on starting materials and products (i.e. upstream or downstream) was also a source of concern and that the EWG may not be able to reach a conclusion.

Mycoplasma testing

The EU explained that the EDQM had encountered more difficulties than initially expected for the preparation of the reference strains, which should be ready in early 2005 only.
The EU believed that the experts mostly agree on the current wording of the draft GL and that strains testing would not induce major changes to the draft text. The EU suggested therefore resuming the work by reopening the public consultation period, with the opportunity to add any comments when the outcome of the testing will be known.

AHI did not support that approach because the draft GL was written with the assumption that low passage lyophilised strains would be used. The work could therefore not be progressed until it was demonstrated that the companies were able to validate the method with reference strains, and to detect low concentrations of mycoplamsa, with their own laboratory techniques. The use of deep frozen strains implies a different approach to the testing.

Dr O. Itoh pointed out that the preparation of the strains and the testing by authorities and companies in the different regions may require at least 2 further years of work.

The EU stressed that it was concerned that time was meanwhile wasted, whereas most experts consider the draft GL acceptable as it stands.

USDA, AHI and JVPA recommended therefore asking the experts for suggestions to change the approach by investigating if valid alternatives could be found to the prerequisite that the strains are made available, and then to proceed with the draft GL as a technical document, leaving the possibility open to incorporate the reference strains in the GL when they will be available and validated.

The SC recommended therefore that the EWG should resume its work by discussing the best way to proceed under the direction of the topic leader and by providing a recommendation to the SC.

In case the EWG would consider that a meeting was needed, the chairman should notify the secretariat, which would seek approval from the SC by written procedure.

Extraneous agents testing
The SC acknowledged that no progress had been achieved and recognised the difficulties of the EWG on this issue.

Dr O. Itoh explained that in his view the methodology as laid down in the current draft GL included both the upstream test and the downstream test approaches.

AHI indicated that it could not support a draft GL specifying only the methodology of testing and not including the regulatory aspects.
USDA added that some SC members had acknowledged that a GL on technical harmonisation would not be adequate without regulatory harmonisation, which had led to the previous proposal for a 2 phase approach.

AHI stressed that it did nevertheless not support the fact that the methodology would be included in one GL and the regulatory requirements in another.
AHI, IFAH-Europe and JVPA pointed out that the aim of VICH GLs is not to add more regulatory burdens on the Industry.

JMAFF indicated that an agreement on the testing methodology would enable the different regions to use their existing regulations. As the regions have different regulatory systems currently in place, it may be very difficult to find a compromise with the regulatory aspects at this stage.

IFAH-Europe proposed to include all the different regulatory requirements in the GL and to mention that discussions were ongoing, leaving the option to review the GLs in the future.

JVPA questioned if the topic of Extraneous agents should not be suspended for the time being.

The chairman concluded that the discussions had not led to an agreement on this topic and that the SC would encourage the EWG to continue the beneficial discussions through electronic procedures.

3.3. Target Animal Safety
The chairman of the Working Group, Dr T. Nagata, reported that EWG has progressed in the discussions of the 3 draft GLs: the reversion to virulence GL, the TAS GL for live and inactivated vaccines and the general TAS GL for pharmaceuticals.
At the 6th EWG meeting in March additional experts were invited to address the unresolved ~~overdose~~ issues regarding the TAS for live and inactivated vaccines, of which the main one was the overdose testing.

Dr T. Nagata confirmed that a general consensus was achieved on the draft 4 of the reversion to virulence document, which will become a step 2 draft GL during the next EWG meeting.

The EWG reviewed the 7 outstanding issues regarding the TAS for live and inactivated vaccines and a new draft 8 of the document was produced. It proposed a number of drastic changes from the existing requirements for all regions and especially additional regulatory burdens to local companies in the USA. The chairman stressed that the EWG may need 1 or 2 further meetings to overcome the outstanding difficulties.

Dr T. Nagata confirmed that FDA had prepared a revised draft 14 of the document on the TAS for pharmaceuticals and that the EWG expected to reach a step 2 document at its next meeting.

The SC expected to receive the step 2 draft GLs on the reversion to virulence and the TAS for pharmaceuticals draft GLs at the next SC meeting.

The SC authorised the 7th meeting to take place on September 21-24, 2004 in Japan and recommended that the documents should be sent to the secretariat immediately after the meeting for circulation to the SC.

JMAFF pointed out once more the delays required for the translations and requested strongly that the SC and EWGs should circulate all documents sufficiently in advance of the meetings.

3.4 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 FDA. At its last meeting the EWG reviewed the comments received on GLs 36 (General approach to establish a microbiological ADI) and 37 (Repeat-dose chronic toxicity testing). An appendix was added to GL 36 and in GL 37 the list of tissues to be examined at necropsy was amended. Consequently, the EWG believed that the additional tissues should also be included in GL 28 (Carcinogenicity testing) and therefore proposed to the SC to revise this GL by adding an appropriate text. The EWG asked the SC for advice on the proper formal procedure for this revision.

The EWG finally presented to the SC changes to all other Safety GLs (GL 22: Reproduction testing, GL 23: Genotoxicity testing, GL 31: Repeat-dose (90 days) toxicity testing, GL 32: Developmental toxicity testing, GL 33: General approach to testing), but the suggested changes are merely editorial, in order to improve the consistency between all the Safety GLs. The amendments have been highlighted in the documents circulated to the SC.

The chairman thanked Dr T. Mulligan and the experts for the efforts achieved and indicated that the SC will review GL 28 under item 6 of the agenda.

After discussion, the SC agreed that the editorial changes to the Safety GLs mentioned above did not require a revision with public consultation, and adopted the revised versions presented by the EWG.
The secretariat was requested to circulate the revised final versions before the end of May to the SC, for re-publication in the regions. The cover page shall highlight the fact that it is a revised version with editorial changes, and include a specific numbering. This version shall also be posted on the VICH web site.

After discussion, it was also agreed not to determine a specific timeline for publication, but that the regions will publish the revised version as soon as practical, taking into consideration the time for translation.
The SC asked the secretariat to record this new procedure for future usage with other GLs.

3.5 Pharmacovigilance

Dr I. Alexander reported that Health Canada had organised a regulatory forum on veterinary pharmacovigilance in March where the regulatory authorities in VICH met in order to search for a way forward and get the EWG out of the current impasse. Unfortunately JMAFF was not able to attend.

On behalf of all the regulators, USDA thanked Health Canada for having organised the meeting and pointed out that the regulators are convinced that harmonisation of pharmacovigilance is necessary, and that pharmacovigilance for veterinary medicines will progress anyway in all regions. Consensus is therefore necessary in VICH.

FDA mentioned that at the 13th SC meeting in Washington, no written recommendations had been given to the EWG, which created misunderstandings throughout the 7th EWG meeting, leading the discussions to an impasse.
FDA therefore recommended strongly that the SC should enable the EWG to progress by giving clear guidance before any further meeting.

The secretariat pointed out that no report from the last EWG meeting, or progress report from the EWG chair had been received.

The chairman reminded that all EWG chairmen are required to provide regular reports to the SC. FDA will remind this to Dr Post.

The SC reviewed the Position Paper prepared by the regulatory authorities at the Ottawa meeting and discussed the technical issues for which proposals for solutions had been made. It was recognised that this was the last chance to find a way forward for the harmonisation of pharmacovigilance guidelines.

AHI commented that most of the key issues are clearly identified in the document: the international birth dates, synchronisation and frequency of periodic reporting, the definition of similar/same product for expedited third country reporting and timing, the data fields in the documents for electronic reporting, the common dictionary. AHI stressed that industry can be flexible on these topics. However, the total final set of pharmacovigilance guidance documents must represent improvement over current global pharmacovigilance reporting systems and not merely a compilation of regional requirements or global adoption of a single region's requirements.

IFAH-Europe wondered if the SC members had had sufficient time to review the proposals in the document. ~~AHI, IFAH-Europe and JVPA called for sufficient flexibility in future discussions.~~

The EU explained that the European legislation has a number of provisions, which are written in a very strict format. Consequently, flexibility was only possible on the interpretation of the legislation. Some issues put forward by the EU are therefore strictly legal constraints which

have maybe not been understood by all EWG members. AHI, IFAH Europe and JVPA called for sufficient flexibility in future discussions. Otherwise, there is little chance for success.

FDA, JMAFF and Health Canada confirmed their flexible approaches to the different issues.

After a thorough discussion, the SC agreed that clarification by the SC on these issues raised needs to be achieved before a further meeting of the EWG is authorised and decided to review and approve the proposed position paper before sending it to the EWG.
The discussion, comment and revision of the paper will be done by written procedure.

Comments should be sent to Dr I. Alexander by next June 15, with a copy to the Secretariat, which will distribute all comments to the SC members.
Health Canada will draft a revised document, including different options if necessary, by mid-July.
Health Canada will take into account the legislation in all regions and evaluate if the proposed comments comply with the different legal requirements. The EU requested that the other regulatory authorities be consulted to ensure that the proposals would comply with the regional legislation.

The deadline for the 2nd ~~d~~ round of comments on the revised document is September 15, in order to include those in the preparatory documents for the next SC meeting.
Whether the EWG should be asked to meet again or to close the topic would be decided at the 15th SC meeting.

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3.6 Ecotoxicity and Environmental Impact Assessment

The SC reviewed the report prepared by the topic leader, Dr J. de Knecht, and the chairman, Dr J. Robinson and presented by the EU.
The consultation period ended in most regions in mid-April, but as in the USA the draft GL was published later, the consultation period will run until the end of May.
Most comments already available are of important nature, but not new and have appeared in previous discussions within the EWG.

The EU pointed out that it was unlikely that all issues could be solved by written procedure, as an ultimate solution has to be found by the experts. The EU proposed therefore that the EWG should hold a final meeting in July, in order to provide the SC with the final document well in advance of the October meeting.

IFAH-Europe supported the view that some issues can only be resolved through a meeting.

JMAFF expressed its concern of not having seen yet the comments received by the EU.
The EU replied that the comments received from the public consultation in the EU needed to be reviewed. The final EU comments will be circulated to the SC shortly. Most of the comments received so far seem to be in line with previous discussions and indicate that further debate is needed to find an acceptable wording.

The EU confirmed that the Topic Leader and the chairman would be able to send the revised document to the experts sufficiently in time prior to the EWG meeting.

The SC authorised the 10th and final meeting to take place on September 6-10, 2004 in the USA *(date agreed after the SC meeting).*

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

GL 36 *- (Safety) – Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish a microbiological ADI*

The SC adopted GL 36 as final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the guidelines will enter into force by May 2005.

GL 37 *- (Safety) – Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose chronic toxicity testing*

The SC adopted GL 37 as final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the guidelines will enter into force by May 2005.

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

The EU, Japan and the USA confirmed that no change had occurred since the last meeting as all the GLs had been published.

The EU indicated again that GL 32 will be implemented at a later date.

ANZ and Canada confirmed that the situation had not changed.

6. New topics

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

The SC reviewed the concept paper prepared by IFAH-Europe.

IFAH-Europe explained that the aim is to amend the VICH GLs in accordance with the ICH GLs. It would require only minor changes and could possibly be dealt with by written procedure by the Quality EWG.

Dr H. Makie, as former chairman of the Quality EWG, explained that the topic leader is not member of the EWG anymore. The EU confirmed that the new expert, Dr N. Möller, would also accept to be the topic leader.

The SC agreed that the EWG should proceed with the revision of both GLs.

6.2. 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 this topic had been discussed by the SC for many meetings and recommended therefore either creating a new EWG at this meeting and starting the work, or withdrawaing this topic definitely from the agenda.

AHI indicated however that industry representatives needed further discussion to align their position, and suggested to postpone the decision one more time in order to finalise the discussions.

JMAFF raised several technical questions, such as necessity of additional residue test and the issue of residue at the injection site, and indicated that JMAFF needed to coordinate the topic with Japanese Food Safety Commission and Ministry of Health, Labour and Welfare.

The EU explained that the concept paper does not propose that the GL would define how to assess the residue data, but to agree on the tests that should be carried out. The concept paper does not propose either to define how to calculate MRLs, but only to establish an instrument enabling to provide the data.

After an in-depth discussion, the SC recognised that the current concept paper is 2 years old and therefore needs to be revised again, and that a number of practical issues to be addressed as well.

The chairman pointed out the difficulty of this topic and recommended that the EWG should receive a very clear mandate on the task to achieve.

The SC therefore decided that each organisation should consult its experts again, and that further comments should be sent to Dr K. Grein, by September 30, 2004 at the very latest, if possible earlier in order to allow sufficient time for review.

The issue will be subject for discussion and final decision at the next SC meeting, based on a revised concept paper prepared by the EU. *(SC members should however note that, with that deadline set, the revised paper will be circulated only very shortly before the 15th SC meeting).*

6.3. Proposal to modify GL 28

The chairman pointed out that the revision of VICH GL 28 had been agreed under agenda item 3.3, but the procedure needed to be defined. He therefore proposed to initiate a step 9 revision procedure as for step 4, for a public consultation, in order to allow for comments. This consultation should however be limited to the new additional text only, not the whole GL.

IFAH-Europe suggested that the consultation period should be shortened compared to the usual procedure, as it is done in the EU for similar revision procedures of CVMP GLs.

After discussion, the SC decided to release the revised GL for a 2 months consultation period until July 25, and asked the secretariat to add an explanatory note explaining the purpose of the proposed revision, and confirming that the new requirements would not apply retrospectively to existing studies.

The SC asked the secretariat to record this new procedure for future usage with other GLs.

The chairman encouraged the Safety EWG to sign-off rapidly the draft GL at step 5 after the consultation period in order to enable the SC to adopt draft revised GL 28 at step 6 by written procedure before the 15th SC meeting.

7. Review of VICH Workplan 2000-2005

The secretariat presented the revised version of the document (revision 1-draft 5) and highlighted the main changes decided at the 13th SC meeting

The chairman pointed out that the Workplan needed to be updated frequently in order to reflect the latest situation of VICH activities.

The SC reviewed the current document and included several amendments.

The SC discussed thoroughly if under "Guidelines-ongoing work-step 1", the topic of extraneous virus test methods should be maintained and finally agreed that the discussion should continue until the next SC meeting.

8. VICH Phase II: 2006-2010

8.1 Feedback from the 1st VICH Task Force meeting

Dr P. Dehaumont, chairman of the TF, presented the methodology of the TF's work and the conclusions reached so far (see presentation attached).

The SC reviewed and commented the proposal for a strategy presented by the TF. Written comments have been circulated by the EU following consultation within the EU

The participants congratulated OIE and the members of the TF for the work achieved so far.

IFAH-Europe understood that in the future the focus will very much be focussed on maintenance, but requested that it should also be open for harmonisation of future topics, such as e.g. new technologies, provided a clear "business plan" is submitted to the SC for approval.

The EU stressed that it is important to maintain all the work which has been achieved since the creation of VICH.
The EU indicated that it would support the future activities as outlined in the TF document, when the issue of the industry representation at European level would be solved. ~~The EU believed indeed that the industry representation in the EU needed toi be independent~~The EU confirmed that in their view industry representation needed to be regionally independent.
IFAH-Europe confirmed that this issue ~~as~~ is being addressed at this very moment.

ANZ insisted that the maintenance was very important and that the linkage with ICH should be much stronger in the future. ANZ supported the TFs proposal to achieve a more detailed analysis before launching a new topic.

AHI stated that it did not want to exclude biologicals from the VICH topics, and wished that new topics should also be brought forward, especially when gaps have been identified.

JVPA and the industry associations from the Observers supported this view.

AHI believed that the industry associations represented in VICH SC should identify the new topics requiring harmonisation, but encouraged also the regulatory authorities to bring forward new topics, as they have a very broad and unique overview of the regulatory status.

JMAFF stressed the importance of the future maintenance and recommended that it should be thoughtfully organised. JMAFF accepted new topics as long as resource issues and benefits are evaluated beforehand.

FDA stressed the need of a proper Cost/Benefit analysis to be done before launching any new topic, in order to identify properly the resource requirements and improve the efficiency of the VICH process.

USDA pointed out that reduction of development costs and the reduction of animal use were important factors of the Cost/Benefit analysis, however it may be difficult to justify a positive Cost/Benefit. USDA believed that VICH is an extraordinary organisation, with representatives from all over the world, and that the future activities should not be limited to maintenance, but VICH should continue to be a visionary organisation, as before.

The SC discussed the timeframe for initiating revision procedures for GLs and agreed that this period should be flexible; GLs should be evaluated as to whether there would be a need for revision.

The industry representatives insisted on the need for a predictable and stable regulatory framework.

The SC recognised that following the discussion, the TF should integrate the comments received and prepare a draft strategy paper for discussion and approval at the 15th SC meeting.

It was agreed that all comments should be sent to the secretariat in writing by mid-June. OIE will prepare a revised document for discussion by the TF.

The SC authorised the TF to meet on July 19-20 in Paris in order to prepare a more structured strategy proposal for the next SC meeting.

The SC agreed also that any comment on the part I of the current VICH Strategy and Work programme 2000-2005 should also be sent by June 15 to the secretariat for review by the TF.

9. VICH 3 conference

9.1 Review of the draft outline proposal for a programme

The SC reviewed the draft programme presented by AHI and chose the proposed option B with a plenary session at the beginning of the conference.

The secretariat reminded the participants that keynote speakers had made important contributions to VICH1 and VICH2.

IFAH-Europe and the EU proposed that, as in VICH2, a member of SC from the region of the chair of the EWG, should chair the breakout sessions and a speaker present the work, who should be either the EWG chair or the topic leader.

The SC confirmed that this set up should be repeated with the modification that the SC member does not necessarily have to come from the region chairing the EWG and AHI requested receiving the names of volunteers from the SC to chair these sessions as soon as possible.

The SC agreed to add keynote contributions to the programme and that members should send proposals for such speakers to AHI without delay.

AHI will circulate a 2nd draft of the programme to the SC within 2 weeks and welcomed comments to be communicated, with copy to the secretariat, within 2 weeks thereafter.

9.2 Organisational matters

After a thorough discussion it was decided that the SC would meet before the VICH 3 conference and would also hold a short session after the conference, on the Saturday morning.

The SC confirmed that the registration fees would be the following:
500 USD for industry association members,
750 USD for non- members of industry association,
200 USD for regulatory authorities,
free for SC and EWG members, and speakers.

After discussion, the SC agreed that it was more efficient for EWGs to meet earlier than VICH3 in order to enable the SC to adopt proposed draft GLs.

The Experts would nevertheless be encouraged to participate in the VICH3 conference.

9.3. Communication on the VICH3 conference

AHI indicated that the first announcement of VICH3, including the draft agenda, would be available for circulation by the Coordinators and OIE during the summer.

The final programme with the registration forms will be circulated later in the year.

10. Any other business

Dr A. Wennberg indicated that, as she was returning to the national administration in Sweden, this was her last VICH SC meeting and she would in the future not act as representative of the European Commission.

She thanked her colleagues from the SC for their fruitful collaboration and for the constructive work together.

On behalf of the SC, the chairman thanked Dr A. Wennberg for her input into the activities of VICH.

11. Dates and venue of next meetings

- The 15th SC meeting will take place on 19-20 October 2004 in Berlin (Europe)
- The 16th SC meeting will take place on 24-25 and 28 May 2005 in Washington DC (USA)

12. Adoption of the press release

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

VICH STEERING COMMITTEE - 14th meeting

12-13 May 2004
Tokyo, Japan

Chair: Y. Takahashi, JAPAN MAFF

LIST OF PARTICIPANTS

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