VICH/98/085
May, 1999
Final

VICH STEERING COMMITTEE
4th meeting
20 - 22 October 1998
Sanbanchoh Bunchosha
[Sanbanchoh Detached Office (Annex)], Tokyo

Minutes of the meeting

1. Opening of the meeting and chairman's introduction

Dr. Boisseau opened the meeting by welcoming all participants and thanked the Japanese members for hosting the meeting and for the efficient organisation. Dr Ozawa, on behalf of the regional office of OIE for Asia and the Pacific, praised the efforts of VICH members, highlighted the progress achieved, and commented on the importance of VICH for Asian countries and how it fitted with specific regional meetings on veterinary vaccines organised with or by OIE in 1995 and 1997.

Dr. Boisseau reviewed the status of the VICH initiative. On the basis of the progress achieved, and because of the increasing workload in the French Agency, he offered his resignation as the chairman of the SC.

2. Adoption of the agenda

The SC reviewed and adopted the agenda as circulated.

3. Progress reports of Expert Working Groups

A. Existing WGs

1. Quality

The SC reviewed the written report prepared by the chairman of the WG, Dr. Makie. Dr. Makie participated in this part of the meeting and clarified several aspects verbally. One of the issues that the WG has had to deal with was the question of the transfer of topic leadership from an expert representing industry to an expert representing regulatory authorities. This question was to be discussed generically under agenda item 4.5. In the meantime the WG chairman commented that working closely with the secretariat has proven very useful. The SC recognised that the WG and the Secretariat had handled the question appropriately.

Regarding the specific case of GL3, GL4, and GL 5 (stability guidelines), the SC agreed that, even if the comments made were apparently only minor ones, a signed-off step 5 document was not available from the WG, and that therefore these 3 guidelines would not be discussed at this meeting. They should be reconsidered by the SC at the next meeting when a step 5 document would be available.

Regarding the scope of quality guidelines, the SC agreed that the GL on stability of biotechnology/biological products would not apply to conventinal vaccines and allergenic products and that the WG should precisely define the scope of this GL in this regard. The starting point, though, is that the annex of the current ICH guidelines would not cover veterinary vaccines. The EU and Japan expressed concern that this issue was not resolved

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at the last WG meeting and that not all the members had delegated the competent experts to negotiate on this issue. FDA/USDA will provide by December 31, 1998 a letter with comments concerning this document as it relates to veterinary biologicals.

The SC authorised the next meeting of the WG to take place in Tokyo, subject to the above-mentioned letter of FDA/USDA. The next meeting's agenda will concentrate, among other topics, on residual solvents, biotech/biological stability, and finalising GL3, GL4, and GL5.

The EU and the Secretariat congratulated Dr. Makie for the quality of his report and mentioned that this should be the model to be followed by other WG chairmen. The SC reviewed report & requests for clarification by WG particularly on GL1 & GL2 (to be dealt under agenda item 7.)

2. Safety

The FDA apologised for the absence of a written progress report and the lack of progress of this WG. It mentioned, however, that preparatory work had been made for a WG meeting in November in London. Other members said that they had expressed reservations to hold such a meeting in the absence of a discussion document in line with the new mandate of the WG agreed in August 1997. The Japanese delegation said that such a discussion document should be received at least one month (ideally two months) before a WG's meeting in order to be able to prepare adequately for such meeting. The FDA mentioned that it was in the process of assembling contributions from the different regions in order to put together such a document but that all contributions had not yet been received.

The SC agreed to cancel the meeting scheduled for November and agreed that no meeting should be authorised in the absence of a discussion document. The EU questioned whether the SC should not consider the appointment of a new WG chairperson. The FDA committed to ascertain the commitment by the chairperson to progress the work of the WG and notify the Secretariat by November 30. The chairperson will have to provide a discussion document in line with the new mandate of the WG and a meeting date by November 30.

The SC will review the discussion document and proposed meeting date and, on the basis of the outcome of this review, will provide written authorisation of the WG meeting.

3. Ecotoxicity/environment impact assessment

The SC reviewed the written report of the WG chairman. The Secretariat drew particularly the attention of the Committee to the WG chairman's request for guidance as to the contents and scope of phase II guidelines. Two options were available: 1) a minimum approach, just listing a series of exposure and fate studies that may be required or applicable; 2) develop a comprehensive Phase II guidelines which would include not only a list of recommended studies but also interpretative (risk assessment criteria) and perhaps a listing of risk mitigation measures (risk management options).

After a long discussion, the SC decided that harmonisation of risk management decisions was beyond the scope of the work of VICH. However, the SC recognised that the harmonisation would be purposeless if it would only include a listing of studies. Therefore, the SC concluded that the mandate of the WG is to set a list of studies and the important interpretative criteria necessary to enable a proper phase II risk assessment, but not to consider risk mitigation measures. The SC also concluded that the WG should also review the comments received during the step 4 consultation on phase I draft guidelines.

4. Good Clinical Practices

The SC reviewed the written report of the WG chairman. The report questioned the decision of the SC at its third meeting to restrict the scope of the guidelines to pharmaceuticals. Several members of the SC expressed similar concerns and the issue

was re-discussed. USDA expressed concern that the industry in the US might resist the document since it has not been involved in the early stages of the elaboration of the draft guidelines. After a long discussion on this topic, the SC agreed that the scope of the draft GL is covering all veterinary medicinal products (i.e. veterinary pharmaceuticals, diagnostics, and biologicals). A biological expert from USDA and possibly another one from AHI will be added to the WG for the consultation at step 4 and 5.

5. Efficacy requirements for anthelmintics

The SC reviewed the written report of the WG chairman, and praised his work in achieving considerable progress in the various guidelines. The EU said that the three draft guidelines on caprine, ovine, and bovine anthelmintics are at a fairly advanced stage of elaboration. The SC agreed that the draft GLs should be released for consultation at step 4 prior to the next SC meeting through a written procedure.

The SC authorised the next meeting of the WG to be held in Europe but requested the WG to delay this meeting until April or May 1999 in order, if possible, to take into account the outcome of the consultation on the draft GLs on caprine, ovine, and bovine anthelmintics.

B. Preparatory work of new WGs

6. Biologicals Quality Monitoring

The SC reviewed the written progress report from the WG chairman and benefited from verbal clarifications from Dr Itoh who participated in this section of the meeting. Dr. Itoh explained that the Japanese delegation had taken all the steps necessary to prepare the meeting but that lack of progress in other WGs (not step 2 document) and the absence of discussion documents on two of the three topics have prevented the WG to meet. Several members expressed strong disappointment about the lack of commitment of some topic leaders who blocked progress in this WG.

The SC agreed that the 2 additional discussion documents should be sent to the chairman and to the secretariat by November 30. The chairman will circulate them by mid-December to its WG and to the secretariat with a proposal for a date and location for the meeting.

The SC authorised the meeting to take place in Japan in Q1 1999.

7. Pharmacovigilance

The SC reviewed the progress report from the WG chairman. The FDA explained that the US delegation had taken all the steps necessary to prepare the meeting but that lack of progress in other WGs (no step 2 document) and the absence of discussion documents on one of the two topics have prevented the WG to meet. The FDA said that it will provide the secretariat with the discussion documents and a proposed date and location for the meeting by November 30.

The SC confirmed that, as per the decision taken at the third meeting of the SC regarding the definition of progress in the WGs, it considered that the Quality WG, the Ecotoxicity WG, and the GCP WG have completed their work in relation to their original mandate.

The SC authorised the first meeting of the WG to be held in the US.

4. Review of VICH procedures and functioning of the VICH process

1. Observers

The SC discussed the lack of participation of Latin American observers. The Secretariat also mentioned that it had written and verbally communicated to both industry

and regulatory authorities representatives about the need to get involved in the activities of the SC. The SC agreed that, because of the lack of participation, and in line with the decision taken at the third meeting of the SC, the VICH observer status of Latin American representatives (Mercosur and Filasa) will be withdrawn. The Secretariat would notify the Latin American representatives and amend the charter accordingly.

The SC discussed the participation of Pharmacopoeias experts from the three regions on the WGs. In order to avoid changing the charter and to avoid imbalance in the number of experts between the number of industry experts and government experts, the SC agreed, in accordance with § 5.1.1. of the VICH organisational charter, to grant observer status in relevant specific WGs to representatives from the Pharmacopoeias from the three regions. These observers will not have voting rights and will not sign off on the draft VICH guidelines. The EU mentioned that these Pharmacopoeia experts should participate at their own expenses.

The SC confirmed the participation of a representative of the Canadian government as an expert in the Quality monitoring of Biologicals WG.

2. Role of the chair, including consideration of rotating the chair

The SC agreed on the definition of the role of the chair as discussed at the third meeting of the SC and as laid down in the minutes of that meeting. The organisational charter would be amended accordingly.

The SC discussed at length the pros and cons of rotating the chair vs. maintaining the same chairman. Many members recognised the qualities of Dr. Boisseau and how his chairman skills have benefited the VICH process, and the benefits of continuity and neutrality in maintaining such a permanent chair. By the same token, many members also viewed it as important to rotate the chair for engaging fully the VICH members in the process and for a good balance in respecting the interests of all members. After a long discussion, the SC agreed that Dr. Boisseau would continue to chair the SC meetings until after the first VICH conference. After the conference, the chair will be rotated among the regulatory authorities from the three regions in line with the hosting region. The respective authorities would decide how this chairmanship would be accommodated and filled.

SC members proposed that, after the VICH conference, OIE would be an official observer of the SC. JMAFF, on the other hand, said that, in view of the important role of OIE in VICH, it could not support such a proposal.

The EU mentioned that SC meetings in Europe would normally be held in Brussels or in London, and not in Paris as mentioned in the minutes of the third meeting.

3. For information: final notes

* Notes on the format & style of VICH guidelines (VICH/97/061)
* Notes on elaboration of topic concept paper (VICH/97/037)
* Notes on elaboration of VICH discussion document (VICH/97/036)
* Notes on elaboration of topic progress report (VICH/97/038)

The SC took note of the final notes. The Secretariat will amend the notes to include more specific recommendations to the chairpersons/topic leaders.

4. Efficiency of VICH process

ANZ apologised for not having provided a document on a VICH strategy outline proposal. The SC agreed that the task force under the leadership of ANZ would provide a document by December 31, 1998 for consideration at the next SC meeting.

5. Procedure for amending adopted guidelines, in particular with regard to amendments under discussion in relevant ICH

The SC adopted the Secretariat's proposal VICH/98/077 on the procedure to amend adopted VICH guidelines with some modifications.

6. Clarification of step procedures and appointment of regulatory chairperson at Step 5

The SC discussed at length the clarification of the various steps of the VICH procedure on the basis of proposals from Japan and the Secretariat.

The SC agreed that sign-off by the WG experts at step 5 was essential even if there were no or limited comments. The SC agreed that documents at step 5 should be signed off by all experts of the WG but that experts representing industry and SC observers cannot block the adoption of a step 5 document if unanimity is reached by the members of the WG representing the regulatory authorities. Signatures from industry experts and experts from observer regions on the one hand, and experts representing the regulatory authorities from the VICH members in the three regions on the other hand, should be clearly separated on the sign-off sheet. The SC also agreed that step 6 final documents would only be signed by SC representatives of regulatory authorities.

The SC agreed that, in case the topic leader is a representative from industry, at step 5, the topic leader should be a representative from regulatory authorities. In principle, but not necessarily, it will be the regulatory expert from the same region.

The Secretariat will amend the document VICH/98/077 accordingly and circulate it for final approval. The charter will also be modified accordingly.

7. Clarification on definition of "guidelines" and "guidance"

The SC agreed to use the word "guidelines" for all VICH recommendations. VICH SC members retain the right to use alternative wording in the consultation and implementation of the guidelines in their region.

5. Review and adoption of draft guidelines at Step 6

1. GL1 - Validation of analytical procedures: definition and terminology

The SC adopted GL1 as final VICH guideline at step 6. This guideline was transmitted to the VICH members for implementation in the three regions at step 7.

2. GL2 - Validation of analytical procedures: methodology

The SC adopted GL2 as final VICH guideline at step 6. This guideline was transmitted to the VICH members for implementation in the three regions at step 7.

On the occasion of these guidelines (the first ones to be adopted at step 6), the SC discussed the general rule for the implementation date of the VICH guidelines. The SC agreed that the implementation should be simultaneous in the three regions and therefore agreed by the SC, but that the date will be decided on case-by-case basis for each guideline. It was recognised that in some cases, the industry will need more time to adapt to new or modified requirements. For GL1 and GL2, the SC agreed that the GL would enter into force in October 1999.

6. Review and release for consultation of draft guidelines at Step 3

1. GL6 - Environmental impact assessments (EIAs) for veterinary medicinal products: Phase I

The SC agreed, at step 3, to release for consultation GL6. This guideline was transmitted to the VICH members for a six-month consultation period at step 4. Pending confirmation by the EU, Dr. Aldridge (EU) would be the topic leader from step 5 onwards.

The chairman of the WG would remain the topic leader of the future work concerning the elaboration of VICH GLs on the Phase II of the EIA.

2. GL7 - Efficacy requirements for anthelmintics: overall guidelines

The SC agreed, at step 3, to release GL7 for consultation, after some changes were made in the wording and in the title of the draft guideline. This guideline was transmitted to the VICH members for a six-month consultation period at step 4. The FDA also mentioned that some of the introductory phrases in the guidelines should be removed during the consultation process, as those are superfluous and irrelevant in regulatory guidelines. JMAFF commented that comments on the text should be incorporated at the WGs level rather than at SC.

3. GL8 - Stability testing for medicated premixes

The SC agreed, at step 3, to release GL8 for consultation. This guideline was transmitted to the VICH members for a six-month consultation period at step 4.

4. GL9 - Good Clinical Practices

The SC agreed, at step 3, to release GL9 for consultation, after modifying the title of the guidelines since the guidelines would cover both pharmaceutical and biological products as per the decision of the SC. This guideline was transmitted to the VICH members for a six-month consultation period at step 4. (see also related decision under 3.A.4.)

The SC agreed that Dr. Schoenemann (US FDA) would be the topic leader from step 5 onwards.

5. GL10 - Impurities in new veterinary drug substances

The SC agreed, at step 3, to release GL10 for consultation. This guideline was transmitted to the VICH members for a six-month consultation period at step 4.

The Secretariat expressed some concern that international guidelines such as VICH guidelines would mention words such as ”regional requirements”, in that this might legitimise separate or additional specific regional requirements over and above the agreed international consensus, and hence overshadow the benefit and purpose of international harmonisation.

6. GL11 - Impurities in new VMPs

The SC agreed, at step 3, to release GL11 for consultation. This GL was transmitted to the VICH members for a six-month consultation period at step 4.

7. Proposed new topics for discussion under VICH

The FDA introduced its proposal to have VICH looking at pre-approval studies and registration requirements for antimicrobials. The SC recognised that this would be within

the mandate of VICH. The SC agreed that criteria for the specific registration requirements pertaining to the potential risk of development of resistance for new antimicrobial products could be subject of future work of VICH. The FDA volunteered to prepare a concept paper with the help of the EU (by March 1, 1999) for consideration at the next SC meeting.

Several members insisted on the need to clearly define the scope of the issue. Several members also mentioned that this issue would benefit from some discussion at the VICH conference.

8. First VICH Conference 1999

The SC reviewed the discussion document with the draft programme outline prepared by the Secretariat. The SC reaffirmed its decision made at the 3rd SC meeting to hold the first VICH conference. The conference will take place in Brussels in week 46 of 1999.

VICH members will provide estimates of number of participants and other comments on VICH/98/083 to the Secretariat by Nov. 30, 1998. The FDA and Japan mentioned that budgetary constraints would prevent from having all experts at conference unless WG meetings are scheduled around the conference. The SC agreed that if WGs have to meet around the time of the conference they should preferably meet in Brussels shortly before the conference, so that all experts could attend the conference.

The Secretariat, with the help of the VICH co-ordinators and WG chairpersons, will prepare an updated and more detailed version of the programme for adoption at the next meeting. It was agreed that after the opening speeches of a more political nature, the following papers by representatives from different regions should address specific issues. The SC agreed that a first announcement should be prepared for release in early 1998.

The SC agreed that fees should be waived for SC members and speakers, and that government representatives should be charged a lower fee than other participants. The SC also agreed that the purpose of the conference is not to earn money, but that, if there would be a profit, it should be transferred to the Secretariat to cover future operational expenditure of VICH, in line with the practice in ICH.

The SC agreed that it would be essential to have proceedings of the conference.

9. Communication

**** Publication of a VICH brochure***

The SC recognised that, with VICH web site, the need for a VICH brochure was less compelling. However, with the first conference coming, several members thought that a brochure does have some added value to the web site.

**** VICH web site***

The Secretariat mentioned that the web site (http:\\vich.eudra.org) had just been launched and he thanked the European Commission for its technical collaboration in the development of this web site. The Secretariat invited all the members to check the site and to notify the Secretariat of any comments, changes and corrections. The Secretariat committed to update the site regularly. Members were asked to provide their web sites addresses and to check the legality of putting direct links between the VICH web site and the members web sites.

**** Dissemination of draft documents to interested parties/authorities***

The Steering Committee agreed that the responsibility for sharing and distributing relevant VICH documents to interested parties and other regulatory authorities rests entirely with the VICH members, and in particular with the co-ordinators, within each region.

The SC reaffirmed that the VICH Secretariat is responsible for publishing VICH guidelines and that the Secretariat should seek to obtain a copyright for the publication of final VICH guidelines. The Secretariat should be generous in granting copyrights to parties requesting publication of guidelines, yet requesting acknowledgement of the source.

10. Any other business

None

11. Date(s) and venue of next meeting(s)

To be held on May Tuesday 18 (morning) - Thursday 20 (noon), 1999 in the Washington DC area, USA.

12. Adoption of press release

The SC adopted the press release drafted by the Secretariat, with some changes.

Dr. Boisseau closed the meeting by thanking the Japanese delegation for hosting the meeting and for the effective organisation. He also thanked all the members, in particular the co-ordinators for their active involvement and the Secretariat for its efficient support. The Japanese delegation thanked all the participants and expressed satisfaction on how successful the first meeting held under the new rotation scheme went.