VICH/99/054
4 June, 1999
Draft 1

VICH STEERING COMMITTEE
5th meeting
18 - 20 May 1999
Rockville, Maryland (USA)

Minutes of the meeting

1. Opening of the meeting and chairman's introduction

Dr. Boisseau opened the meeting by welcoming all participants, in particular new member Dr Tokui (new member for JAVB) and Dr. Holdsworth (new observer for Avcare/Agcarm), and observer Dr. Hill (future new member for USDA) and Dr. Turner (future new observer for ANZ/MAF). He thanked the American members for hosting the meeting and for the efficient organisation.

2. Adoption of the agenda

The SC reviewed and adopted the agenda after adding "common technical documentation" under item 6 of the draft agenda circulated.

3. Progress reports of Expert Working Groups

1. Quality

The SC reviewed the written report prepared by the chairman of the WG, Dr. Makie, and presented by Dr. Hirayama. Dr. Hirayama highlighted the progress by the WG, resulting in the preparation of a total of 10 VICH guidelines. He mentioned the adoption of a revised text of GL 3, GL 4, and GL 5 by the WG at step 5, and the adoption of draft guidelines at step 2 for residual solvents, for stability of premixes, and for stability testing of biological/biotechnological products. With regard to the latter, the SC noted that the WG had been able to satisfactorily resolve the scope of the guidelines as they relate to biological, biotechnological products, and vaccines.

The SC agreed that unless new topics are identified and assigned, and in view of the completion of the original mandate by the WG, the WG could suspend its activities. In order to identify such additional topics, the SC agreed that the Secretariat with the help of the coordinators would monitor the ICH initiative to determine if there are additional topics for the experts to address.

The representatives of the US Pharmacopoeia were invited to present their activities and their relevance to the work of VICH. They thanked the SC for the opportunity to appoint advisors to specific WG (see also para 9.1.).

2. Safety

Dr. Miller, chairperson of the Safety WG was invited to present the progress report of the WG. She reported on the meeting of the WG, which had been held in April in London. She raised five points for which she requested the SC's guidance (see written report).

After discussion on the various points, the SC agreed:

- to modify the mandate of the WG to "determine the complete package" of studies that may be needed to set the ADI.

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- to add a fourth component to the mandate to “recommend modifications to existing protocols necessary to evaluate veterinary medicinals.”
- to encourage the WG to prepare by the end of October 1999 and review a retrospective analysis of the data relied upon to assess both systemic toxicity and developmental toxicity.
- to a proposal from the WG, to have experts review, at a workshop organised by the FDA, the JECFA document on microbiological safety and other relevant scientific information and prepare a recommendation for the WG. This preparatory work will be completed by late September 1999 and will be discussed by the WG in November.
- to recommend that the WG should focus initially on the technical requirements to establish a NOEL; the SC will consider at a later stage whether and how to address the choices of safety factors and the establishment of the ADI.

The SC authorised the next meeting of the WG to take place in conjunction with the VICH conference, conditional on work outlined in the previous 2 paragraphs having been completed by that time. If the meeting can be held in conjunction with, but prior to the VICH conference, the WG meeting would take place in Brussels; if not, then the meeting will be held in Tokyo, in line with the rotation schedule of the WG meetings.

The SC encouraged the WG to include experts on microbiological safety in this meeting.

3. Ecotoxicity/environment impact assessment

The SC reviewed the written report prepared by the chairman of the WG, Dr. Robinson, and presented by AHI.

The SC noted that the consultation period on GL6 (Ecotox phase I) had ended on April 30, 1999. The SC encouraged the WG to resolve any remaining issues on the Phase I document through a written procedure prior to the November SC meeting.

The SC authorised the next meeting of the WG to address Phase II to take place in Brussels immediately preceding the VICH Conference in November 1999. If the Phase I document has not been finalised, it will also be addressed at this meeting.

4. Good Clinical Practice

The SC reviewed the written report prepared by the chairman of the WG, Dr. Cracknell, and presented by Fedesa.

The SC noted that the consultation period on GL9 (GCP) had ended on April 30, 1999. US members mentioned that they could not commit to this deadline as consultation was still on going in their country. Other members expressed disappointment at this situation and said that all members should endeavour to respect the deadlines and the procedures.

In conclusion, the SC noted that the WG had been requested to provide the Secretariat with the step 5 GL by August 31 but recognised that the consultation on the step 4 draft GL might not be completed by this deadline.

Nevertheless, the SC reiterated the goal to reach step 6 during the November SC meeting.

The SC decided to authorise the next meeting of the WG, if such meeting would be needed; the chairman and the topic leader would have to determine whether such meeting would be needed or not. The SC assessed that this would probably not be the case but that it would depend on the extent of the comments to be received, particularly on the biologicals side. The SC decided that the location of the meeting would depend on the timing of such meeting. If the meeting can be held in conjunction with, but prior to the VICH conference, the WG meeting would take place in Brussels; if not, then the meeting will be held in Tokyo, in line with the rotation schedule of the WG meetings.

5. Efficacy requirements for anthelmintics

The SC reviewed the written report prepared by the chairman of the WG, Prof. Vercruysse, and presented by the EU.

The SC noted that the consultation period on GL 7 (anthelmintics: general requirements) had ended on April 30, 1999. US members mentioned their concerns on some issues in this guideline. The Secretariat proposed that these comments be sent as soon as possible to the WG chairman and to the Secretariat; the Secretariat and the EU would liase with the WG chairman and endeavour that these comments be taken into account by the WG at their next meeting. Other members expressed disappointment at this situation and said that all members should endeavour to respect the deadlines and the procedures, and that much better briefing and communication between the expert and the SC member and co-ordinator needed to take place in order to avoid major scientific issues being raised at the SC level, and at such late stage in the process.

The SC strongly encouraged industry to comment on step 5 documents even if governments have not officially published documents for public review.

The SC recommended the WG to provide a step 5 draft GL on the general requirements (GL7) by the end of August.

The SC noted that the consultation period on GL 12, 13, and 14 (bovine, ovine, and caprine anthelmintics) would end on August 31, 1999, and that the WG meeting is scheduled for mid-August. For reasons of efficiency, the SC therefore recommended that the WG evaluate comments received on GL12, GL13, and GL14. The SC agreed that VICH members could be encouraged to provide comments on those by the end of July, so that the WG could assess those during their August meeting, but that the WG could not issue a step 5 document on GL12, 13, and 14 before some time after the official deadline of the end of the consultation period (end of August).

As a result of those agreed arrangements, the SC expected that draft texts at step 5 for GL 7, GL 12, GL 13, and GL 14 would be ready for adoption at the next SC meeting in November.

The SC encouraged the WG that the anthelmintics GL for anthelmintics for poultry and for companion animals would be available as step 2 documents in Q1 2000.

The SC confirmed the authorisation of the next meeting of the WG in August in Ghent prior to the WAAVP meeting.

6. Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the WG, Dr. Itoh, and presented by Dr. Hirayama. Dr. Hirayama highlighted the progress by the WG, which looked at testing requirements for mycoplasma, moisture, sterility, and extraneous agents testing. Regarding the latter, Dr. Hirayama mentioned that the group's intention is to concentrate only on live viruses in live viral vaccines for mammalians. He concluded by stressing the need for all parties to respect the deadlines for the assignments agreed by the WG, and which, in this particular case, relate to comparative testing investigations of critical importance to elaborate sound harmonised guidelines.

The SC authorised the next meeting of the WG to take place in Brussels in conjunction with, but prior to the VICH conference.

The SC encouraged the WG topic leaders to complete their assigned tasks by the assigned deadline (as per the WG workplan) in preparation for the November meeting.

7. Pharmacovigilance

Dr. Keller, chairman of the Pharmacovigilance WG was invited to present the progress report of the WG. He reported on the meeting of the WG, which had been held in April in Rockville. He raised several points of his written report for which he requested the SC's guidance (see written report).

After discussion on the various points, the SC agreed:

- to the recommendation to limit the scope of the mandate to pharmaceuticals and biologicals, excluding ectoparasiticides.
- that the WG should work to harmonise the format of the Adverse Event reporting form of periodic reports. Regulatory actions and dissemination of product information should be at the discretion of the regulatory agency.
- that the WG should define "responsible individual" and "recordable complaint."
- that the IT subgroup would be asked to focus their efforts on developing recommendations regarding the underlying technical issues of electronic transmission rather than a common security standard.

The SC denied the request from USP for observer status to this WG.

The SC authorised a meeting of the ADR/DT subgroup only, to take place in Brussels in conjunction with, but prior to the VICH conference.

As a general rule applying to all WG meetings in November, the SC recommended that, if WG needed to meet for longer than two days, they should not hesitate to schedule meetings starting or during the week-end (Saturday and Sunday).

4. VICH 1 Conference

**** Proposed programme***

The Secretariat introduced the draft programme of the general and breakout sessions. After discussion on several aspects of the programme, the SC agreed to the general concepts of the programme of VICH 1, i.e.

- to maintain the overall structure of the programme, including the parallel breakout sessions as proposed.
- to remove the breakout session on antimicrobial resistance and decide to mention the subject as part of a general presentation on future work.
- to restructure the second part of the general session with one speaker from industry, one speaker representing veterinarians, one speaker representing a regulatory authority (Australia), and one speaker from WTO on trade.
- the general nature of introductory speeches by senior politicians in the first general session.
- to have a paper in the general session (by the VICH secretariat), outlining the history, the objectives, the process, the results achieved, and the strategic plan.

The Secretariat mention that it will draft a final programme and circulate to the SC membership with a one week review deadline, and that it will also follow up with SC members and WG chairpersons to get the names of the speakers.

The SC agreed the fee structure proposed by Fedesa with a fee waiver for SC members and speakers.

The SC agreed to the protocol for the distribution of invitations to the VICH 1, as prepared by the Secretariat.

Fedesa clarified some logistical aspects for the conference and stressed that members wishing to have a booth in the halls of the conference centre needed to let Fedesa and the Secretariat know before the end of July.

The SC also agreed that all members should ensure that the conference is highly publicised and that, for that matter, stronger and more inventive marketing efforts are needed from all members. As an example, the SC agreed that all members should mention the conference in their upcoming presentations and mailings.

5. Discussion on the proposed VICH Strategy

Dr. Knox presented the proposed strategy he had developed with the help of Drs Thompson, Jones, and Verschueren. The SC praised Dr. Knox for his initiative and discussed at length the document. Dr. Knox agreed to integrate the comments made by SC members and to issue a revised document before his new assignment. The SC endorsed the plan, agreed to remove the last part of the document on the working plan and requested the Secretariat to develop a more elaborate working plan.

6. New topics

The SC reviewed several potential new topics based on two new concept papers (on minor species prepared by the EU, and on specific requirements for antimicrobials prepared by the US FDA), on an additional suggestion by AHI on CTD, and on the original working plan agreed in 1996.

The SC reviewed the concept paper prepared by the FDA on the requirements for antimicrobials, with a special focus on the evaluation of the human health impact of antimicrobial resistance. The SC considered taking new work in this area and endorsed the future formation of an expert WG on this topic. However, formation of the WG will be delayed until December to allow for the collection of additional relevant information.

On the EU proposal to consider requirements for minor species as a new VICH topic, the SC recognised the value of the topic, but decided to postpone any decision on initiating VICH work on it, contingent on prioritisation of additional/new topics at the next SC meeting.

On the AHI proposal to consider the ICH topic CTD (Common Technical Documentation), the SC recognised the value of the topic, but decided to postpone any decision on initiating VICH work on it, contingent on prioritisation of additional/new topics at the next SC meeting, and preferably also the availability of a concept paper.

In conclusion the SC agreed to the proposal of the Secretariat to consider these issues as part of a proposed working plan to be prepared by the Secretariat (see para. 5.).

7. Review and adoption of guidelines at Step 6

1. GL3 – Stability testing of new drug substances and products

After modifying the title and paragraph four of the core text, the SC adopted GL 3 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 GL would enter into force in May 2000.

2. GL4 – Stability testing of new drug substance

After modifying the title, the SC adopted GL 4 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 GL would enter into force in May 2000.

3. GL5 – Stability testing: photostability testing of new drug substances and products

After modifying the title, the SC adopted GL 5 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 GL would enter into force in May 2000.

8. Review of draft guidelines at Step 3 (pending progress of WGs)

The SC reviewed four draft guidelines prepared respectively by the Quality WG and by the Anthelmintics WG. These were:

- GL 15 Efficacy of anthelmintics: specific recommendations for equine
- GL 16 Efficacy of anthelmintics: specific recommendations for swine
- GL 17 Stability testing for biotechnological/biological products
- GL 18 Stability testing for residual solvents

US members expressed their reservations about the requirements concerning the number of dose-confirmation studies in GL 15 and GL 16, a similar concern as the one expressed on GL 7. Other members said that much better briefing and communication between the expert and the SC member and co-ordinator needed to take place in order to avoid major scientific issues being raised at the SC level.

As a result, the SC decided to refer the GLs 15 and 16 back to the WG to resolve the issue of the number of studies required to confirm efficacy, in conjunction with the review of the comments on GL 7, in order to ensure that consistent requirements are applied throughout the anthelmintics guidelines.

The SC agreed to a request by the EU to postpone until June 30 the release for consultation of GL17 and GL18 at step 3, the time needed by the EU to obtain clearance by the EU CVMP. The other parties signed off on the guidelines at step 3.

9. Review of VICH procedures and functioning of the VICH process (based on VICH/96/002)

1. Steering Committee: observers

The SC took note of the reactions from regulatory and industry observers from Latin America to the decision taken at the last SC meeting, as well as of the secretariat response.

The SC reviewed the letter from the World Veterinary Association (WVA) expressing interest in the activities of VICH, and agreed that, because of lack of direct involvement in the regulatory process, observer status would not be extended to WVA.

The SC reiterated the position that the Pharmacopoeias from the three regions may participate as observers in relevant WGs in relation to the quality of veterinary medicinal products, which, with the current status of VICH would mean the Quality WG and the Biologicals Quality Monitoring WG.

2. Steering Committee: membership

The SC took note of the changes of persons notified by several members and observers of the SC.

3. Chairmanship after VICH 1

The SC reaffirmed that after VICH 1, the chair will rotate among the three regions in accordance with the rotation of the location and that the members of the region in charge of the SC meeting have the discretion to choose the most appropriate person for the task.

4. Role of OIE

The SC members expressed their appreciation for the efforts by and contribution of OIE in the initiation of the VICH process.

The SC agreed that a special status (associate member of SC) would be offered to OIE. The SC agreed that the associate member will have the opportunity to take part in the discussions of the SC; it will not take part in any vote which may be taken, nor will it sign-off on any VICH (draft) recommendations. The official charter would be amended accordingly. In this offer, OIE will be asked to clarify its contribution to the VICH process.

5. Overall efficiency of VICH process **(VICH/IN/98/156, VICH//99/036)**

The SC congratulated the secretariat for the summary tables put together on the status of VICH guidelines and on the schedule of VICH WG meetings. The SC agreed that these tables should be put on the VICH web page.

After some discussion on the past experience and as a preparation for the future discussions on the VICH working plan, the SC agreed that all VICH members should review their internal procedures and reflect on how to increase efficiencies within the system.

10. Communication

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

After some discussion, the SC agreed that a VICH brochure in addition to and based on the existing web site information would be useful. The SC also agreed that an official VICH brochure would be preferable over members publishing their own brochure. The SC directed the Secretariat with assistance from EMEA and FEDESA to produce a VICH brochure based on the current web site, the ANZ VICH brochure and Dr. Thompson's publication in advance of the VICH conference (September 1999). The SC agreed that the cost of the publication would be shared among the VICH members.

**** Publication of VICH guidelines***

The Secretariat reported that it was still due to investigate the details for publishing VICH guidelines utilising copyright protection and report to the SC in November. The EMEA offered its assistance in this process.

The SC requested that the Secretariat report on the number of hits to the VICH web site.

11. Any other business

None.

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

The SC agreed the dates of its next meeting: November 15-16, 1999 in Brussels in conjunction with the VICH conference, with November 19 in reserve if additional time or an additional meeting is needed.

13. Adoption of press release

The SC adopted two press releases: one in the classical style, with the detailed achievements of the SC meeting, aimed at the technical and trade press, and a second one, drafted by the ANZ guest, publicizing the VICH 1 conference and aimed at a more general audience.

VICH STEERING COMMITTEE
5th meeting

18 – 20 May 1999
Rockville, Maryland
USA

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

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