VICH/00/070
8 September 2000
Final

VICH STEERING COMMITTEE
7th meeting
14-15 June 2000
Tokyo, Japan

Minutes of the meeting

1. Opening of the meeting and chairman's introduction

The chairman, Dr N. Hirayama, opened the meeting by welcoming all participants and paying tribute to Dr J. Boisseau who has chaired the Steering Committee since the beginning of VICH and Dr C. Verschueren who has provided the full Secretariat role, and who have left the Steering Committee.

He explained that, according to the organisational charter, as from this meeting on, the chair of VICH is taken by the region where the meeting takes place. This was therefore the start of the second phase of the VICH process, which should monitor permanently the progress of ICH whilst being however veterinary focused.

Dr N. Hirayama reminded the participants that the aim of the harmonisation process is to ensure that the VICH Guidelines should not only be implemented in the 3 regions, but also in most of the 155 OIE countries.

On behalf of the Japanese government, Dr S. Miyajima, Director of administration of JMAFF warmly welcomed the participants to Japan and congratulated them for the amount of work achieved since the beginning of the VICH process. He added that Japan had the first FMD outbreak since 1 century, but that with the support of many countries, in particular the EU, Japan had been able to limit the outbreak.

Dr Y. Ozawa, representative of OIE, also welcomed the participants on behalf of Dr J. Blancou, Director of OIE. Although OIE was not longer chairing the VICH SC, he assured the meeting that OIE would continue to disseminate the VICH information. He added that during the next congress of the Asian veterinary association in Taiwan, the OIE would hold a joint session on harmonisation of veterinary pharmaceuticals and biologicals where progress on the VICH activities will be reported. He wished the participants a successful meeting and hoped that the three regions would continue the harmonisation exercise.

2. Adoption of the agenda

The chairman proposed to discuss item 14. under item 4.3 and the secretariat proposed the following addition to the agenda: GL24 - Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERs).

This addition being agreed, the revised agenda was adopted.

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3. Reorganisation of the VICH secretariat following C. Verschueren's departure

Dr A. Mudd thanked his colleagues from Japan for the warm welcome in Tokyo. He explained that Dr C. Verschueren had moved to the global crop protection association, and that as Vice-President, he would temporarily be Acting Secretary General of COMISA.

He acknowledged the support of the COMISA staff and thanked Dr H. Marion for the hard work achieved over the past weeks. He also thanked Mrs F. Pardo for her commitment. He promised that the minutes and all relevant documents would be circulated within the forthcoming 4 weeks.

The Chairman proposed to write a letter of appreciation, on behalf of the VICH SC, to Dr C. Verschueren for his involvement in VICH and congratulating him for his new appointment.
A proposed draft was adopted and signed by the Chairman.

4. Progress reports of Expert Working Groups

4.1. Quality

Dr H. Makie, chairman of the Working Group, reported that 8 out of 10 Guidelines proposed by the Working Group had already been approved by the Steering Committee. The consultation period for draft Guidelines 17 and 18 had expired at the end of last January and the revised drafts had been signed-off by the Working Group. They were therefore presented at this meeting at step 5.

He explained furthermore that the ICH Quality Guidelines Q1A (Stability Testing of New Drugs and Products), Q3A (Impurities in New Drug Substances) and Q3B (Impurities in New Drug Products) were currently proposed for revision and had been released for consultation at step 2 of ICH. He indicated that some of the technical provisions of these guidelines were under review, but he believed that there was no need for immediate review of the VICH Quality Guidelines. As the VICH Guidelines on stability (GL3, GL4 and GL 5) have only just been implemented and that the VICH Guidelines on impurities in new veterinary drug substances and new veterinary products (GL 10 and 11) are due to be implemented between December 2000 and June 2001, the Steering Committee understood that the industry would not welcome an immediate revision. After discussion, the Steering Committee therefore agreed that, once the revised ICH Quality Guidelines Q1A, Q3A and Q3B have been published, the WG should firstly consider, by written procedure, if the VICH Quality Guidelines needed to be revised at step 9 in the light of the amendments of ICH Guidelines.

Dr Makie added that ICH had also produced 2 new Final Guidelines on specifications for new drug substances and products, GL Q6A (Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances) and Q6B (Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products), but these Guidelines were not in the scope of the mandate given to the Working Group. AHI agreed to draft a concept paper based on the new ICH Guidelines Q6A and Q6B.

The chairman, on behalf of the Steering Committee, thanked Dr Makie, the three topic leaders and all the members of the Working Group for the work achieved during the first years of VICH.

4.2. Efficacy requirements for Anthelmintics

The SC reviewed the written report prepared by the chairman of the Working Group, Prof. Vercruysse and presented by the EU. The SC noted that the consultation period for the draft Guidelines 15 (equine), 16 (swine) and 19 (canine) concluded at the end of May 2000 and that draft Guidelines 20 (feline) and 21 (poultry) would be released for consultation after this meeting and comments expected by the end of December 2000.

The SC acknowledged that a problem concerning acceptance criteria for efficacy thresholds when pooling two trials had occurred with GL 7 (Efficacy of Anthelmintics: general requirements).

After discussion, the SC agreed that the Working Group should identify the items, which needed to be corrected in the Anthelmintics Guidelines and propose a corrigendum accordingly. The chairman of the Working Group should therefore prepare a recommendation to be issued as a corrigendum to the Guideline for review by written procedure and approval by the Working Group. The SC will review this proposal at its next meeting.

Following the proposal of the Working Group chairman, the SC agreed that VICH final Guidelines should be published whenever possible in relevant scientific Journals in order to spread the information as much as possible. However, in order to avoid any misinterpretation, the SC decided that the publication of the VICH Anthelmintics Guidelines shall be postponed until the problems in these Guidelines had been resolved with the approval of the SC. The EU agreed to inform the chairman accordingly.

The SC acknowledged that there seem to be inconsistencies in Guidelines 15, 16 and 19, which must be communicated to the chairman of the Working Group by 30 June 2000. The EU Coordinator will encourage the chairman of the Anthelmintics WG to adopt GL 15, 16 and 19 by written procedure before the meeting of the WG in January (step 5).

The SC confirmed the next meeting of the Working Group in Australia and authorised it to be held in January 2001, and once again acknowledged the hard work done by the Working Group and its chairman.

4.3. Ecotoxicity/environment impact assessment

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

The SC noted that in November 99 the Japanese representatives could not sign off GL 6 on Environmental impact assessments for veterinary medicinal products - phase 1 because of a public consultation period required in Japan, but that this consultation period was over and the draft Guideline had been approved by written procedure.

JMAFF indicated that Ecotoxicity being an issue with significant importance for Japan, it wished to be informed on the content of the phase 2 draft Guideline before implementing the phase 1 Guideline. After discussion, it was agreed to discuss the implementation date for Japan under item 7.1.

After having considered the amount of work that was still outstanding before a proposal for a Phase 2 Guideline could be drafted, the SC recommended that the next meeting of the Working Group be postponed to the end of 2000, in order to leave sufficient time for the preparation of the document. The SC agreed furthermore that a second further meeting may be required to finalise this draft Guideline and therefore authorised the Working Group to hold a further meeting if necessary.

(Items 14.1 and 14.2 were discussed at this stage.)

4.4. Good Clinical Practice

The SC reviewed the written report prepared by the chairman of the Working Group, Dr Cracknell, and presented by FEDESA.

The SC noted that the group had finished its task and thanked Dr Cracknell, Dr Schoenemann and the members of the WG for their contribution to VICH.

4.5. Safety & Task Force on Microbial Safety

The SC reviewed the written report prepared by the chairman of the WG, Dr Mulligan, and presented by FDA. The WG met in April and produced, for the SC's approval, two step 2 documents on reproductive safety and mutagenicity respectively.

The SC noted that membership of the Task Force on Microbial Safety was now complete and that it would hold its first meeting in July 2000 in the USA.

The SC had a lengthy discussion on the chairman's proposal to relocate the next meeting of the Safety Working Group from the USA to New Zealand. Although the SC acknowledged the need to demonstrate appreciation for the work done by the ANZ experts of the Working Group, the SC noted that some members had budgetary constraints for the travel expenses of their experts and could therefore not authorise such a change in the location. Furthermore the organisational charter did not provide for meetings outside the 3 member regions unless a special event was taking place simultaneously.

The SC therefore confirmed that the next meeting of the Working Group should take place in the USA on 14-17 November 2000, as authorised in November 1999 and in accordance with the rules and principles laid down in the organisational charter.

The SC agreed however that the venue of the following (6^{th}) meeting of the Working Group could be open to discussion at the next SC meeting.

The chairman thanked Dr Mulligan for having stimulated the Working Group's achievements and enabled the production of 2 draft Guidelines.

4.6. Biologicals Quality Monitoring

Dr O. Itoh, chairman, presented a detailed report on the activities of the Working Group. He confirmed that the text of the draft Guidelines on the testing for residual moisture and for residual formaldehyde were nearly finalised, pending results of comparative trials. He added that the draft Guideline on mycoplasma detection and extraneous agent testing had already been outlined. Hopefully step 2 GL for formaldehyde and moisture should be signed at the next WG meeting to take place in the USA from 11 to 14 July 2000.

The SC took note of the difficulties, which may be posed by the draft Guidelines setting different thresholds that would be in contradiction with existing regulatory requirements and pharmacopoeias in the different regions. The regulatory members of the SC from the EU and USA undertook to address this problem with the members of the WG.

The SC asked the Working Group to check that no contradictions with the OIE manual of standards appear in the Guidelines.

The EU requested an extension of the period of consultation for these draft Guidelines due to the above-mentioned need to harmonise the regulatory requirements. The SC decided to postpone a decision on extension to its next meeting, when the draft will be available.

4.7. Pharmacovigilance

The SC reviewed the written report prepared by the chairman of the Working Group, Dr Keller, and presented by FDA.

The SC noted that the Pharmacovigilance Working Group had achieved major progress and had provided a proposal for a draft Guideline on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports.

The SC acknowledged that some inconsistencies had appeared in this draft, particularly on the scope of the GL, and decided to discuss this issue under item 5.5.

The SC decided to discuss the authorisation of the next meeting of Pharmacovigilance Working Group at the November SC meeting.

4.8. 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 SC confirmed that the mandate of the Working Group was to develop a Guideline on pre-approval studies for pharmaceutical products in pigs, poultry and cattle, and to work on requirements concerning the inclusion of prudent use principles in label recommendations. Growth Promoters were not in the scope of this mandate.

The SC noted that the WG needed to gather as much data as possible before going further.

The SC authorised the Working Group to hold its next meeting on 12 and 13 October 2000 in the USA.

5. Release of guidelines at step 4

5.1. GL20 - Efficacy of Anthelmintics: specific recommendations for feline

The Steering Committee received the text of GL 20 as a proposed guideline at Step 3. This Guideline had been signed-off by written procedure by the SC except for the US FDA and AHI because of inconsistencies between the different Anthelmintics GL. After discussion, both agreed to sign-off GL 20 as a draft Guideline at step 3, but with the provision that the US representatives would provide additional comments to the chairman of the WG to eliminate inconsistencies with GL 7 before 30 June 2000.

This guideline was transmitted to the VICH members for a 6 months public consultation period at Step 4 until 31 December 2000.

5.2. GL21 - Efficacy of Anthelmintics: specific recommendations for poultry

The Steering Committee received the text of GL 21 as a proposed guideline at Step 3. This Guideline had been signed-off by written procedure by the SC except for the US FDA and AHI because of inconsistencies between the different Anthelmintics GL. After discussion, both agreed to sign-off GL 21 as a draft Guideline at step 3, but with the provision that the US representatives would provide additional comments to the chairman of the WG to eliminate inconsistencies with GL 7 before 30 June 2000.

This guideline was transmitted to the VICH members for a 6 months public consultation period at Step 4 until 31 December 2000.

5.3. GL22 - Safety studies for veterinary drug residues in human food: reproduction studies

The SC received the text of GL 22 as a proposed Guideline at step 3. The SC reviewed this Guideline and agreed to delete two sentences in paragraph 2.4 on page 4.

With this modification, the SC adopted GL 22 as proposed Guideline at step 3.

This guideline was transmitted to the VICH members for a 6 months public consultation period at Step 4 until 31 December 2000.

5.4. GL23 - Safety studies for veterinary drug residues in human food: genotoxicity studies

The SC received the text of GL 23 as proposed Guideline at step 3. The SC reviewed this Guideline and acknowledged that the glossary would be added by the Working Group at a later stage. After discussion, the SC, considering that other Guidelines had been adopted without

glossary, adopted GL 23 as proposed Guideline at step 3, but requested that the glossary should be circulated before 30 June 2000.

This guideline was transmitted to the VICH members for a 6 months public consultation period at Step 4 until 31 December 2000.

5.5. GL24 – Pharmacovigilance of veterinary medicinal products: Management of Adverse Event Reports

The SC received the text of GL 24 as a proposed Guideline at step 3. The SC reviewed this Guideline and considered possible inconsistencies, which have been identified in the text.

After discussion, the SC agreed that the WG experts should explain these apparent inconsistencies and ensure that, if necessary, these are eliminated during the consultation period. The SC adopted GL 24 as proposed Guideline at step 3.

This Guideline was transmitted to the VICH members for a 6 months public consultation period at Step 4 until 31 December 2000.

6. Review and adoption of guidelines at Step 6

6.1. GL17 - Stability testing of new biotechnological/ biological veterinary medicinal products

The SC agreed that the scope of this Guideline was with new products and active substances, and decided to rename this Guideline as follows: *Stability testing of new biotechnological/ biological veterinary medicinal products.*

With this change the SC adopted GL 17 as final VICH guideline at Step 6. The SC noted that the CVMP had not agreed on this Guideline yet and that the EU would therefore defer the sign-off of this Guideline until the CVMP had agreed to such at its June meeting.

This Guideline will be transmitted to the VICH members for implementation in the three regions at Step 7 as soon as the EU delegation has signed off this Guideline. The SC agreed that the Guideline would be implemented by July 2001.

6.2. GL18 - Impurities: residual solvents in new veterinary medicinal products, active substances and excipients

The SC agreed that the scope of this Guideline was with new products, active substances and excipients, and decided to rename this Guideline as follows: *Impurities: residual solvents in new veterinary medicinal products, active substances and excipients*.

With this change, the SC adopted GL18 as final VICH guideline at Step 6. The SC noted that the CVMP had not agreed on this Guideline yet and that the EU would therefore defer the sign-off of this Guideline until the CVMP had agreed to such at its June meeting.

This guideline will be transmitted to the VICH members for implementation in the three regions at Step 7 as soon as the EU delegation has signed off this Guideline. The SC agreed that the Guideline would be implemented by July 2001.

The SC discussed the need for defining the scope of the Quality Guidelines. The SC accepted the proposal from FEDESA to prepare a status paper, for discussion at the next SC meeting, on how and to which products the VICH Quality Guidelines are applied in the different regions.

7. Release of guidelines at Step 7 and decision on implementation date

7.1. GL6 - Environmental impact assessments (EIAs) for veterinary medicinal product (VMPs) Phase 1

The SC had adopted GL 6 as final VICH Guideline at Step 6 by written procedure prior to this meeting. The Japanese delegation pointed out that environmental toxicity was not included in the Japanese pharmaceutical act and therefore suggested postponing the implementation of this Guideline until the adoption of the Phase 2 Guideline. The Japanese delegation considered that it would be useful for them to know the content of the latter before implementing Phase 1.

The other delegations stressed however that this Phase 1 Guideline needed to be implemented as soon as possible because it was expected to replace local requirements in their regions.

After a lengthy discussion, the SC decided that in this particular case an exception to the general rule of simultaneous adoption in the three regions was acceptable.

The SC therefore agreed that VICH GL 6 would be implemented before July 2001 in the US and the EU. However implementation in Japan will be deferred until the Phase 2 guideline has been completed and adopted.

This guideline was transmitted to the VICH members for implementation at Step 7.

7.2. GL9 - Good Clinical Practice

The SC having adopted GL 9 as final VICH guideline at Step 6 by written procedure prior to this meeting, the SC agreed that the Guideline would be implemented by July 2001.

This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.

8. Report of implementation of final guidelines by VICH members (step 8)

GL3 - Stability testing of new drug substances and products

The representatives of the Authorities of the three regions confirmed that this Guideline has been implemented before May 2000 in their region.

GL4 - Stability testing for new dosage forms

The representatives of the Authorities of the three regions confirmed that this Guideline has been implemented before May 2000 in their region.

GL5 - Stability testing: photostability testing of new drug substances and products

The representatives of the Authorities of the three regions confirmed that this Guideline has been implemented before May 2000 in their region.

9. New topics

** Target animal Safety: review of concept paper and establishment of WG*

The SC reviewed the concept paper on target animal safety, which has been prepared by JVPA and circulated prior to the meeting. On behalf of JVPA, Dr T. Nagata explained the background of this concept paper and reminded the participants that the current requirements vary broadly from one region to another. He added that the aim was to establish a single Guideline that can be applied to different animal species and different product formulations, without having to

produce any specific Guidelines. The scope of this Guideline would furthermore not include non-target animal safety.

He stressed that, once established and applied in all regions, the Guideline would avoid unnecessary test duplication minimising therefore the global use of test animals.

The SC approved the 2-phase approach proposed by JVPA, the WG concentrating firstly on the pharmaceutical products and later on the biological products, the range of expertise being different. The SC however agreed that both pharmaceutical and biological experts would benefit from collaborating and participating in the WG meetings from the early beginning on.

JAVB therefore offered to draft the concept paper on Target Animal Safety for biological products before the first meeting of the WG. The SC accepted JAVB's offer and furthermore encouraged that experts from both fields should attend the first meeting of the WG.

After discussion, the SC approved in principle the proposed concept paper. JVPA confirmed that comments were still welcomed, with copy to the VICH secretariat, until 15 July 2000. JVPA proposed that the WG should hold its first meeting in October 2000 with the aim of preparing a draft step 2 document for pharmaceuticals. JVPA indicated that 1 year would probably be necessary to finalise this step 2 document and a further year to finalise a step 2 document for biologicals.

In order to enable JVPA to prepare the first meeting of the Target Animal Safety WG, the SC agreed to nominate the experts to this WG as soon as possible and before 15 July 2000.

The SC finally authorised the WG to hold its first meeting in October 2000 in Japan.

10. Outline of regulation system of veterinary medicinal products in Japan

On behalf of JMAFF, Dr H. Makie outlined the regulatory system for veterinary medicinal products currently applicable in Japan.

Following the chairman's proposal, the SC agreed that a review of the regulatory requirements in the host region is appropriate to familiarise members with the different systems and should be undertaken by the host regulatory authority when the SC meets in that region.

11. Discussion on the proposed VICH Strategy and Work Programme

The secretariat explained the changes included in draft 2 of the document, following the comments received from the SC during the 6th SC meeting.

The SC reviewed this document and agreed on several minor changes to be included in the document. The SC agreed furthermore to replace the word SC *members* by SC *participants* in order to include the VICH coordinators and observers.

The SC questioned the secretariat on COMISA's commitment to continue to absorb the cost of the VICH secretariat. The secretariat replied that, as a matter of good management procedure, the COMISA Board posed the question of the funding of the VICH secretariat each year when reviewing the association's budget, but the Board had so far agreed each year to continue the current arrangements.

The SC discussed in depth the chapter "II) 2) Potential future topics to be considered by the SC" and, as no consensus could be reached at this meeting, agreed that each region would review the list of potential priority topics and send their comments to the secretariat before 20 September 2000. This list of potential future topics will be finalised at the 8th SC meeting.

The SC discussed also the timeframe to be applied to the VICH process and decided that it would be set at the next meeting, once the revised list of potential future topics would be agreed.

The SC adopted the rest of the document provided that the requested changes are made by the secretariat.

The SC requested that the secretariat reports at each meeting the number of hits received on the VICH web site since the previous meeting.

The SC agreed that the Secretariat should write to OIE reminding it of its obligation as an Associate Member of VICH and requesting an update of their activities in this respect, particularly as far as dissemination of VICH information and guidelines are concerned.

12. Review of VICH procedures and functioning of the VICH process (based on VICH/96/002-Rev. 4- Jan. 2000)

12.1. Steering Committee: observers

The chairman noted that this subject was raised for the first time when the World Veterinary Association (WVA) had asked to be admitted as observer to the SC. Other bodies had forwarded the same request since. The chairman stressed that transparency was an important issue for VICH and that in order not to give the impression to be a closed body, the VICH SC should rapidly find ways to open the attendance to the SC meetings.

Proposals from the different regions for amending the organisational charter had been forwarded prior to the meeting. After a lengthy discussion, the SC agreed in principle to amend the organisational charter immediately in order to enable new attendance to the next SC meeting.

A further thorough discussion followed on the choice of the wording. Following the secretariat's proposal, the SC unanimously agreed that the word "observers" should be kept with the current definition because it implies many rights to the concerned parties i.e. Australia/New Zealand. The SC therefore decided to define a new class of affiliation to VICH called "Interested Parties". The SC also decided to change immediately the organisational charter accordingly and agreed on a definition of "interested parties" under 5.1.5 of the charter.

The SC agreed furthermore that such organisations would have to apply in writing, and if successful will be allowed to attend at, but not participate in SC meetings. Applications will be considered by the SC at their plenary on a case-by-case basis. Exceptionally, for the 8th SC meeting, written applications received from organisations that had applied in the past will be considered by written procedure.

The secretariat agreed to develop some general guidance as to acceptance criteria to become an "Interested Party" with input from the SC by 15 July. The draft paper will be discussed at the next SC meeting.

The SC further agreed to delete "and observers" under "7. Procedures Step 5" in the organisational charter.

The US delegation proposed to open the experts Working Groups membership to Interested Parties accepted by the SC. After discussion, it was however agreed that, in order not to imbalance the current representation in the Working Groups, such Interested Parties could not nominate experts to participate in Working Groups and did therefore not take any action on this US recommendation. The SC requested nevertheless the US to prepare a position paper for consideration at a future SC meeting. The US delegation agreed to pursue a solution in order to enable US Interested Parties to provide input to the VICH process prior to VICH WG meetings.

The SC finally agreed to further discuss the specific transparency issue at the next meeting.

12.2. VICH process efficiency assessment: results of questionnaire

Dr A. Turner summarised the conclusions and recommendations put forward following the results of the survey. The SC agreed that further guidance and policy documents should be established to implement these recommendations.

The SC therefore requested the secretariat, in collaboration with Dr Turner, to prepare the three following documents:

- A guidance document for the SC on the establishment of Working Groups and the appointment of experts and chairs by SC members
- A guidance document for WG members
- An expanded SOP on VICH procedures regarding the operations of the WGs

The SC agreed furthermore that the representatives of each region would draft, before 30 September 2000, a paper on the three following policy issues: policy for disbanding working groups, policy on consultation at step 4, and policy on how appreciation can be shown to the chairs and WG members for their work and how they can communicate with the SC members.

The secretariat will produce a consolidated draft for discussion at the next SC meeting.

The chairman thanked Dr A. Turner, on behalf of the SC, for her hard work and the enthusiasm she had shown to set up such extensive recommendations.

12.3. Costs and benefits assessment derived from VICH activities: review of the paper prepared by the EU

The EU presented the discussion paper, which was circulated at the meeting. He noted that so far it was difficult to assess the exact costs and benefits of the VICH process for authorities and industry.

It was questioned if at this stage it was not too early to make a proper evaluation of the VICH process, as most Guidelines had only been implemented recently and their potential benefits could not yet be quantified.

After discussion, the SC decided to postpone the decision on further work on this proposal until the next meeting.

The SC however agreed to provide feedback on draft document to Dr. Jones by 31 July 2000.

In order to enable the SC to clarify its position at the next meeting, the SC members were requested to bring examples where cost benefits of the VICH process could be quantified to the next SC meeting.

12.4. Clarification of VICH step procedure

The SC discussed briefly the comments received by the secretariat since the last meeting.

The SC requested the secretariat to produce a second draft document based on the different proposals before the next meeting.

12.5. General glossary of terms used in the VICH Guidelines: review of the draft proposal prepared by FDA

The FDA questioned whether it would be useful and possible to produce a general glossary as glossaries are attached to several Guidelines.

It was reminded that the aim was to draft a glossary on general terms used in the SC and in the Working Groups.

In order to clarify the situation, the SC agreed that the regions would send a copy of the material available in the different regions to the FDA, which will produce a proposal before the next meeting.

12.6. Note on the proposal for revision of a VICH GL at step 9

The SC discussed briefly the comments received by the secretariat since the last meeting.

The SC requested the secretariat to produce a second draft document based on the different proposals before the next meeting.

12.7. Communication means from secretariat to VICH members

Following a proposal from the secretariat, the SC agreed to adopt the electronic system as the usual mean of communication between the secretariat and the SC members, maintaining a suitable identification system for VICH documents.

Communication by fax will of course be continued for documents, which cannot be circulated electronically.

13. VICH1 conference

13.1. Assessment of the conference

The SC approved the document assessing the VICH1 conference as well as the financial report presented by FEDESA. FEDESA indicated that it had supported the loss, as initially planned.

The chairman thanked once more, on behalf of the SC, FEDESA, the European Commission and EMEA for the outstanding organisation of VICH1.

The SC agreed to decide at the next meeting where and when VICH2 conference should be held.

13.2. Publication of the VICH1 proceedings

The SC agreed that the CD-Rom with the proceedings of VICH1 conference could be placed on the VICH Web-site when the European Commission will have produced the paper version of the proceedings, which is expected to be soon.

14. Environmental Impact Risk Assessment

14.1. New Scientist article

The EU reported that the letter to the" New Scientist "approved by the SC had been sent and that no other article had appeared in the journal. The EU will follow up as to whether there has been any response from the New Scientist.

He noted that there had probably been insufficient consultation within EU member states and relevant authorities on this issue and that some officials had not been made aware of the adopted Phase 1 Guideline. The FDA added that there had been no reaction on this Guideline in the US.

The SC acknowledged that a broader publicity through consultation, which would be refined as a result of actions under 12.2 (VICH process efficiency assessment), was necessary in future to avoid a repeat of such an incident.

14.2. Proposal from the Cranfield University – Project on environmental risk assessment of Veterinary medicines in Sludge and Slurries

The SC agreed that this proposal was not in the scope of the VICH activities. The secretariat will write a letter, in collaboration with the EU, to inform the Cranfield University accordingly.

After discussion, the SC agreed that in the future such issues need not to be brought before the SC. The secretariat on its own initiative will prepare a reply to such proposals in collaboration with the concerned region.

15. Any other business

Following a request from FEDESA, the SC agreed that the EU Coordinator would encourage the chairman of the Anthelmintics WG to adopt GL 15, 16 and 19 by written procedure before the meeting of the WG in January 2001 (step 5).

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

Following a proposal from the secretariat in order to facilitate the organisation of SC meetings, the SC agreed that in the future the dates of the 2 meetings following the current meeting would be set.

The SC decided that 8th meeting of the SC will take place in Washington on 20-21 November 2000 and the 9th meeting will take place in Europe on 30-31 May 2001.

17. Adoption of press release

The Steering Committee adopted the press release after having incorporated comments from its members.

Dr S. Miyajima thanked the SC, on behalf of the Japanese delegation, for the successful meeting. The SC unanimously congratulated Dr N. Hirayama for his outstanding chairmanship of the first rotating meeting and thanked the Japanese delegation for their warm welcome in Tokyo.

VICH STEERING COMMITTEE
7th meeting

14-15 June 2000
Tokyo, Japan

Chair: Dr. Norio Hirayama, JMAFF

LIST OF PARTICIPANTS

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