VICH/01/046
14 September 2001
FINAL

VICH STEERING COMMITTEE
9th meeting
27-28 June 2001
London, U.K.

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr Ph. Brunet, chairman, opened the meeting by welcoming the attendees and asked the delegates to introduce themselves.

2. Adoption of the agenda

The FDA indicated it would propose a new topic under agenda item 7.

JMAFF proposed that item 5.8 should be removed from the agenda because the EU had not signed off GL 24 at step 5. After discussion and explanation from the EU, it was agreed to maintain this item on the agenda.

The agenda was adopted without further change.

3. Progress reports of Expert Working Groups

3.1. Quality

The SC reviewed the written report prepared by the chairman of the Working Group, Dr H. Makie, and presented by JMAFF. Following the request of the SC, the EWG has started the review of ICH GLs Q6A and Q6B dealing with specifications by written procedure.

VICH GL 3 on stability testing of new drug substances and products is also being reviewed. A proposal for amendment will be drafted and presented to the SC.

FEDESA mentioned that the ICH GL Q6B does not indicate clearly that it should be applied to new products. JMAFF replied that it should be applied to new biotechnological/biological products, as it is the case for the other VICH GLs. The EU indicated that in the EU, the GL should be applied at the 5 year renewal. Several participants requested this to be made clear. After discussion it was agreed to discuss this item under 6.2.

3.2. Efficacy requirements for Anthelmintics

Prof. J. Vercruysse, chairman of the Working Group reported on the achievements of the EWG. As all the draft Guidelines on anthelmintics have been finalised by the EWG at step 5, the EWG has now fulfilled its mandate. Through a short presentation, Prof. Vercruysse reminded the participants of the tasks which were required and achieved. He explained which problems had been encountered during the discussions and how solutions were found. He stated that Helminths are a worldwide problem and that no alternatives to chemicals (vaccines) are expected for some

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time. The implementation of the last GLs in 2002 will represent a major enhancement for regional agencies and the animal health industry.

In conclusion, the EWG considered that there was no need for other GLs on this subject. There might however be a need to update the anthelmintics GLs every 2 years by written procedure. The members of the EWG wished also to publish in Veterinary Parasitology, under their name, the remaining GLs, once adopted, as it had been the case for the first set of GLs.

The EWG finally suggested that ectoparasiticides should be the logical continuation of the EWG's task, beginning with ectoparasiticides for canines.

The SC unanimously congratulated Prof. J. Vercruysse and the members of the EWG for the tremendous amount of work achieved.

After discussion, the SC recognised that although there was interest in the proposed new topic i.e. efficacy requirements for ectoparasiticides, many technical and regulatory differences between the regions would make discussions on this subject very difficult. JMAFF mentioned that this topic should not be adopted and the EWG should stop its activity because only very few of its members were experts in this topic. Furthermore, VICH needed to concentrate on more important topics. In any case, a concept paper needed to be presented to the SC before any formal decision could be made.

The SC recognised that it was important to make as much publicity as possible for these GLs, and therefore agreed that the new GLs should be published on behalf of VICH. The SC requested to review the paper before publication.

3.3. Ecotoxicity/environment impact assessment

The SC reviewed the written report prepared by the chairman of the Working Group, Dr J. Robinson, and presented by Dr C. Long, the EU's expert on the EWG, who was present for this section of the meeting. Prior to the 6th meeting held in Tokyo on 15-18 May 2001, the documents discussed at the previous meeting had been considerably revised and circulated to the members of the EWG. The goal of the meeting had been to finalise the key elements of the phase 2 decision trees for aquatic animals, intensively reared terrestrial animals and pasture reared terrestrial animals. The EWG was however not able to finalise the wording because of the number of details included in the 3 documents. The 3 documents will be merged in one and duplications will be removed. A very strict timeline was set for the revision of the documents. The aim being that the EWG agrees upon and signs off the Phase 2 draft GL at step 2 by written procedure before the 10th SC meeting, so that if adopted by the SC, the draft GL will be released for consultation in December 2001. The EWG would amend and adopt the draft GL at step 5 at its 7th and final meeting, in October 2002, prior to the 12th SC meeting and VICH 2.

FDA indicated that in the document "Summary of key points" (VICH/IN/01/065) specific tests are recommended in many areas, but some boxes are left blank because of the EWG agreed that only finalised OECD GLs will be recommended in the VICH GL. In case no OECD GL exists, the applicant will have to seek regulatory guidance.

JMAFF highlighted the fact that there is currently no GL on environment in the Japanese legislation. The VICH GLs will therefore have an impact on the human medicines and pesticide sectors.

The SC acknowledged that the EWG had agreed that the SETAC workshop initially scheduled in October 2001 at the EMEA, should be postponed until the draft GL has reached the consultation phase.

The SC agreed that the topic leadership would be transferred at step 5 if possible to the EU, otherwise to the FDA.

The SC confirmed the authorisation of the 7th meeting of the EWG and agreed that it should take place in Tokyo, prior to VICH2 in October 2002.

3.4. Safety & Task Force on Microbial Safety

Dr. T. Mulligan, chairman of the Expert Working Group, thanked the SC for the opportunity to report on the progress of the EWG and the Task Force. He reported that at the 6th meeting of the Safety Expert Working Group in London on 21-23 May 2001 the comments on the draft GLs on reproduction studies (GL 22) and genotoxicity studies (GL 23) were reviewed and discussed. These draft GLs were presented to the SC for signoff at step 6.

The EWG also adopted the draft GL on carcinogenicity testing (GL 28) at step 2.

The EWG proposed to hold 4 further meetings to complete the further draft GLs which are still under discussion (Repeat-dose 90 days toxicity testing, repeat-dose chronic toxicity testing, developmental toxicity testing, general approach to testing, microbial safety).

JMAFF requested that at the 7th meeting of the Safety WG in Tokyo, the general approach GL should be sign off at step 2, in order to finalise all safety GLs as soon as possible

The SC thanked Dr T. Mulligan for the progress already achieved by the EWG. After a thorough discussion, the SC authorised 3 further meetings of the EWG, the 7th meeting to take place in Tokyo on 2-4 October 2001, the 8th to be determined (March 2002), and 9th (last meeting) to take place in Tokyo prior to VICH 2.

Report on the Microbial Safety Task Force (TF)

Dr T. Mulligan reported that the task force held a 5-day meeting in Brussels on 14-18 May 2001 and reviewed the existing data and the different possible models for the determination of the microbiological ADI. He reminded the participants that the aim of the TF is to address the concern of adverse reaction of antimicrobial drug residues in human food on the human gut flora and recommend testing methods to identify and measure these effects. The task force therefore views the human gut as any other target system of VMPs. The TF will present a draft GL for the safety EWG.

Dr Mulligan indicated that the TF needed 2 additional 3-day meetings to achieve its objective. One meeting to review and outline protocols for in vitro studies and another to outline protocols for in vivo studies and review the data obtained from the FDA in vivo contract study.

The SC complimented the members of the TF for their work. After discussion, the SC agreed that the TF needed 2 further meetings and authorised the 3rd meeting to take place in Tokyo on 9-11 October 2001 and the 4th meeting in the USA in March 2002.

3.5. Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the Working Group, Dr O. Itoh, and presented by JMAFF. The SC noted that the working group would review the comments on GL 25 (Testing of residual formaldehyde) and GL 26 (Testing of residual moisture) at its next meeting and that the preparation of the draft GL on the testing for the presence of Mycoplasma was progressing.

The EU pointed out that comments received on GL 25 at step 4 following the consultation in the EU meant that significant changes would likely have to be made to this GL.

JMAFF indicated that the EWG requested advice from the SC on the requirements on tests for the presence of extraneous agents, as the approach for live vaccines was quite different between Japan and the USA and EU. The 2 latter produce mostly vaccines on SPF cells whereas in Japan, live vaccines are produced from primary cells. Therefore in the USA and the EU the

seed virus, seed cells and medium are tested before the final product is produced, whereas in Japan, each final product is tested, as well as in some cases the initial product.

After a thorough discussion, the SC recommended that the EWG should consider a possible hybrid approach indicating in which cases extraneous virus testing should be conducted on seed and starting materials, and in which final product testing would be necessary. For example, if primary cells are utilized, more rigorous final product testing may be necessary. Whereas, where starting materials are tested and production methods controlled, little or no final product testing may be necessary. The EWG should ensure that the authorities in all regions would recognise the results of the tests, whatever approach is required.

The SC authorised the 5th meeting of the EWG to take place in Strasbourg on 15 October 2001. The meeting will be hosted by the EPC.

3.6. Pharmacovigilance

The SC reviewed the written report prepared by the chairman of the Working Group, Dr. W. Keller, and presented by the FDA. FDA explained that a number of questions on the different draft GLs were raised during the EWG meeting.

*General issues:

The SC noted that a majority of the experts in the EWG had not agreed to replace the word "biologicals" by "veterinary prophylactics". The SC therefore agreed to keep the wording "biologicals".

The SC agreed that the IT experts and the Adverse Event reporting experts should sign off on different GLs separately.

The SC noted that industry experts had raised concerns about confidential information being released, and agreed that the regulations in each country regarding the inadvertent release of confidential information should be followed.

After a thorough discussion on the timeframes of reporting, the SC agreed that this issue depended on the Law of each region. VICH could therefore only recommend that regional authorities should change their legislation if necessary. The chairman added that, as the current general revision of the EU legislation would take 3 to 4 years, no additional changes were foreseen at this stage. The SC did agree that harmonization of these timeframes, even if long-term, was desirable.

* GL 24 (Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs))

The SC noted that the EU had raised some concerns about the draft and had therefore not signed it off at step 5 (see detailed discussion under agenda item 5.8).

The SC reaffirmed the decision taken at the 8th meeting not to include in AERs the use of human drugs in animals.

* GL 29 (Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs))

*(*see detailed discussion under agenda item 4.3.*)*.

* GL 30 (Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms)

The SC noted that the EWG recommended using the VEDDRA database for the setting up of a standard international terminology database.

The EMEA indicated that the annual cost of maintenance of the VEDDRA database was 12.000 $ + an initial start up cost of 5.000 $.

The chairman raised the question on who would sign a maintenance contract for VICH that has no legal entity. He added that on human side the contract had been signed with IFPMA on behalf of ICH.

The secretariat indicated that IFAH could consider the contractual aspects and eventually sign such a contract. Support will be requested from the IFAH Board.

The chairman explained furthermore that, as it was difficult to ask the governments to pay for a new system, the human sector had therefore developed a system of fees, paid by industry only, to make the system function. The FDA added that they would be willing to contribute funding to support the system.

FDA and the chairman agreed to send documentation to IFAH on how the problems were solved in the human sector.

The SC agreed that decisions will be taken at the next meeting once the needs and the costs will be clearly identified. The SC asked the EWG to elaborate more details on the budgets required (initial costs, translation costs, maintenance costs.) together with TRW and inform the secretariat before the next SC meeting.

After considering the costs related to an EWG meeting for the Japanese delegation, the SC authorised the next meeting to take place either in Brussels or in London, unless the EWG has a specific reason to meet in Barcelona and requested the meeting to take place in October 2001, prior to the 10th SC meeting.

3.7. Antimicrobial resistance

Dr D. Mevius, chairman of the EWG, reported that the first draft GL (GL 27) on pre-approval studies had been signed off at step 2. He described the data requirements suggested in the draft GL and explained that it focuses on food producing animals but requests information that can be used to assess the potential impact on human health.

Several members of the SC stressed that, although they agreed on the content of draft GL 27 and would sign it off at step 3, this draft GL needed to be reorganised after the consultation period to make it clearer to the reader. There are difficulties in interpreting mandatory and optional sections of the GL, as all GLs are only advisory to the industry.. Dr Mevius indicated that EWG was now seeking guidance from the SC on how to achieve its mandate on the prudent use issue.

During an in-depth discussion the SC considered that many prudent use Guidelines had already been developed in regions and world-wide (OIE, WHO, IFAH…) and that the primary aim of VICH was to facilitate a harmonised approach of registration dossiers. The SC therefore agreed that the label should include some recommendations or general statements on prudent use, but not detailed prudent use GLs.

The SC requested the EWG to propose a list of general statements to be included on the label and define a list of essential information that should be included on the SPC (Summary Products Characteristics)/Package Insert which should help veterinarians to make the essential choice of antimicrobial substances. The proposal will be discussed at the next SC meeting.

The SC authorised the 4th meeting of the EWG to take place in March 2002 in Europe and encouraged the EWG to finalise its task during that meeting.

3.8. Target Animal Safety

The SC reviewed the written report prepared by the chairman of the Working Group, Dr T. Nagata, and presented by JVPA and JAVB. JVPA explained that the discussion on general pharmaceutical drugs has been completed and that at its next meeting the EWG will have to agree on the number of animals to be used.

JAVB added that for biological products, the EWG had agreed that the discussion about the number of animals would depend on the decision made for pharmaceutical products.

FEDESA thanked the EWG for the amount of work achieved and requested that working documents should be released sufficiently in time so that the experts of each region can prepare themselves and ensure that progress is achieved at the EWG meetings.

The secretariat will remind the chairpersons of EWGs that the SC had requested that EWG documents should be circulated 2 months prior to the meetings to facilitate translation and regional review.

The SC confirmed that the EWG should continue to discuss the veterinary pharmaceuticals issues, but that nevertheless all the experts should receive all the EWG documents in order to enable the experts on veterinary biologicals to include in their work the decisions reached for pharmaceuticals

The SC authorised the 3rd meeting of the EWG to take place in the USA. However, if possible, the EWG should meet according to the Workplan in order to enable the members of the SC to review the documents sufficiently in advance of the 10th SC meeting.

The secretariat will remind the chairpersons of all EWGs to try meet the timeframes set in the VICH Workplan for all future meetings.

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

4.1. Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance

The Steering Committee received the text of GL 27 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-month public consultation at Step 4.

The Steering Committee agreed that the deadline to submit comments on the guideline is 31 December 2001.

FDA insisted that the EWG should address the issue of the reorganisation of the format of the document during the consultation period.

4.2. Safety guidelines on carcinogenicity

The Steering Committee received the text of GL 28 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-month public consultation at Step 4.

The Steering Committee agreed that the deadline to submit comments on the guideline is 31 December 2001.

Whilst having signed off the GL at step 4, the EU indicated that the CVMP retained the right to propose changes during the consultation period, which must be considered by the EWG at the end of the consultation.

4.3. Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)

The Steering Committee received the text of GL 29 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-month public consultation at Step 4.

The Steering Committee agreed that the deadline to submit comments on the guideline is 31 December 2001.

During the discussion, a difference of interpretation appeared between the USA and the EU. In the latter pharmacovigilance legislation requires periodic safety update reports, whereas in the USA the PSUs are periodic summary update reports, thus including also the reporting of lack of efficacy. The EU delegates were able to confirm during the meeting that in the ICH GL the "S" in the context of PSUs stands for "Safety".

The FDA will consider whether they would agree to change the current terminology from "summary" to "safety" reports. The FDA delegate noted that this terminology has also been used in GL 24 and no objection had been raised previously either during the consultation period or during the EWG meeting. The SC agreed to solve this issue at the 10th SC meeting and inform the EWG before the end of the consultation period.

4.4. Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms

The Steering Committee received the text of GL 30 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-month public consultation at Step 4.

The Steering Committee agreed that the deadline to submit comments on the guideline is 31 December 2001.

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

5.1. GL15 - Efficacy of anthelmintics: specific recommendations for equines

The Steering Committee adopted GL 15 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 Steering Committee agreed that the guideline will enter into force in July 2002.

The FDA indicated that for publication in the USA it would change some mandatory language of all of the anthelmintics GLs in order to ensure consistency with the previously published ones.

5.2. GL16 - Efficacy of anthelmintics: specific recommendations for porcines

The Steering Committee adopted GL 16 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 Steering Committee agreed that the guidelines will enter into force in July 2002.

5.3. GL19 - Efficacy of anthelmintics: specific recommendations for canines

The Steering Committee adopted GL 19 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 Steering Committee agreed that the guidelines will enter into force in July 2002.

5.4. GL20 - Efficacy of anthelmintics: specific recommendations for felines

The Steering Committee adopted GL 20 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 Steering Committee agreed that the guidelines will enter into force in July 2002.

5.5. GL21 - Efficacy of anthelmintics: specific recommendations for poultry

The Steering Committee adopted GL 21 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 Steering Committee agreed that the guidelines will enter into force in July 2002.

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

The Steering Committee adopted GL 22 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 EU pointed out that as this was a final GL, it could not be signed off by the EU at this meeting because of the need of final adoption of the CVMP, which was anticipated at the July 2001 meeting, after which signatures could be provided *(Post-meeting note: Done).*

The Japanese delegation indicated its preference to wait until the general approach GL will be adopted before implementing other safety GLs. During the discussion it was reminded that the SC had requested the safety EWG to draft these 2 GLs first because they were based on ICH GLs. All safety GLs might be adopted at the VICH 2 and implemented 1 year later.

The Steering Committee therefore agreed that the guidelines will enter into force in July 2002 in the EU and the USA, and that no implementation date was set for Japan, Japan implementing the General Approach GL at the same time.

The chairman expressed his disappointment that a common implementation date for the three regions was not agreed to and that this was contrary to the spirit of VICH.

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

The Steering Committee adopted GL 23 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 EU pointed out that as this was a final GL, it could not be signed off by the EU at this meeting because of the need of final adoption of the CVMP, which was anticipated at the July 2001 meeting, after which signatures could be provided *(Post-meeting note: Done).*

The Japanese delegation indicated its preference to wait until the general approach GL will be adopted before implementing other safety GLs. During the discussion it was reminded that the SC had requested the safety EWG to draft these 2 GLs first because they were ICH topics. All safety GLs might only be adopted at the VICH 2 and implemented 1 year later.

The Steering Committee therefore agreed that the guidelines will enter into force in July 2002 in the EU and the USA, and that no implementation date was set for Japan, Japan implementing the General Approach GL at the same time.

5.8. GL24 - Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)

The EU reported that some difficulties had been identified only after the conclusion of the consultation period in chapter IV.4. these issues are related to the submission of AERs that contradict with EU legislation. The current version indeed does not provide provision for reports for AER from third countries, as required by EU law. There are currently different deadlines for the

provision of reports by the person responsible for pharmacovigilance reporting to the authorities in the three regions (e.g. 15 days in the EU and 30 days in Japan).

Although the SC considered at length a proposal for a revision of this chapter presented by the EU, no consensus could be reached. The SC therefore decided to send this draft GL back to the EWG for reconsideration of chapter IV.4 only. A revised draft including a clause allowing reference to be made in the GL to third country reporting, whilst accommodating at the same time the different deadlines should be presented by the EWG to the 10th SC meeting.

The chairman added that EU law required since 1999 the reporting of adverse drug reactions related to environmental safety. The SC agreed that this issue should not be addressed by VICH and would therefore not be part of the VICH GLs on pharmacovigilance.

The SC agreed on the following amendments of the draft GL:

Chapter III.2: "…." to be replaced by "…an AE may be considered to be an adverse reaction…."

Chapter III.3 § 2: add the word "large to "….managed and treated as a large group…."

6. Implementation of final VICH Guidelines

6.1. Report of implementation in the 3 regions and observer countries

The authorities from the USA reported that all documents were implemented on schedule,.

The authorities from Japan reported that in Japan GLs 7, 8, 14, 15 and 18 were published on 31 May this year.

The authorities from the EU reported that all GLs had been implemented on time, except Ecotoxicity-Phase 1, which has been implemented in centralised procedure since 1 July 2000, but some Member States have not implemented it in the decentralised procedure. This should be resolved by 1 July 2001. Some Member States have yet to confirm the implementation of quality GLs.

The authorities of ANZ reported that all GLs will be implemented by the requested deadline.

6.2. Implementation and scope of VICH Quality GLs

Referring to the survey, FEDESA reported that the timing of implementation of the Quality Gls seemed to be respected in all regions.

Differences of interpretations existed with regard of the scope. The USA US apply the GLs to new products and supplemental applications. Japan applies the GLs to new substances and products which have not been previously approved, and to those for which the re-examination is not finished.

ANZ applies the GLs to new products only.

In the EU, a consensus has been reached between the different agencies that all GLs are applied to new products, except quality GLs where the latest requirements are taken into account at the renewal date, even if no pharmacovigilance or safety concerns exist.

There is therefore a different scope of implementation of the GLs in the 3 areas.

The representatives of the authorities confirmed furthermore that when an application for a product is made for the first time in a region, it will be considered as new, even if it has been registered in another region.

7. New topics

7.1. Review of the concept paper on Good Manufacturing Practice for active pharmaceutical ingredients Q7A

FEDESA presented the concept paper and explained that the existing Quality EWG would have to meet again to achieve the task.

During the discussion FDA, the EU and AHI supported the proposal, but JMAFF expressed its objections to VICH dealing with GMPs. The SC recognised that VICH already had 6 active EWGs.

The chairman proposed to discuss this topic again at the next SC meeting.

7.2. Proposal for revision of VICH GLs 10 & 11 at Step 9

FEDESA presented the concept paper and reported that VICH Quality GLs 10 and 11 are based on ICH GLs which have been recently amended. FEDESA proposed to consider only the parts which have been amended in ICH. The existing Quality EWG could achieve the task by written procedure. The EU could agree to the revision of these GLs provided that no change to the impurities thresholds were proposed in the revision.

During the discussion it appeared that the ICH revised GLs were not yet adopted. The SC therefore decided to review the concept paper again at next meeting.

7.3. Review of the revised concept paper on the Common Technical Document

AHI presented the concept paper and indicated that there was interest from industry to harmonise the CTD. The ICH CTD will become mandatory in the EU, Japan, USA and Canada in July 2003. AHI added that this topic would probably require a new EWG, with several sub groups.

After discussion, the SC decided that it was too early to launch this topic, considering that other topics have a higher priority. AHI agreed to provide an update at the next SC meeting.

The SC asked the secretariat to circulate the concept papers as soon as received and not to wait until all meeting documents are ready for circulation.

FDA indicated that it will prepare a concept paper on the efficacy of mastitis products before the next SC meeting.

The EU announced that it will draft a concept paper on Metabolism and Residue kinetics.

8. VICH2: Review of the draft outline programme for VICH2 conference

JVPA presented the current status of the preparation of VICH2 and asked for guidance and clarification on a number of issues.

The SC unanimously complimented JVPA for the preliminary organisation plan. The SC reviewed the plan and proposed a number of amendments and clarifications. The main suggestions are: provide sufficient time for discussion in 8 EWG breakout sessions where VICH2 is an opportunity for hearing comments from outside the 4 regions, focus on active EWGs, modulate their time according to the volume of issues discussed, provide a poster session for dormant EWGs and finalised GLs, provide sufficient time for summarising – prolong day 2 until 18.00 hrs…

The SC asked the secretariat to inform the chairpersons of active EWGs that Japan has made provision for meetings of EWGs before the VICH2 conference in Tokyo.

The SC agreed that a special session on fluoroquinolones was not appropriate and suggested to extend this session to all antimicrobials and ecotoxicity issues.

The SC confirmed that a proper communication and a wide dissemination of information was an important asset to the success of the conference. The SC therefore supported the plan to circulate the first announcement by mid-September 2001 and to provide sufficient publicity to the learned societies and the scientific press. The coordinators will ensure circulation of the announcement in the VICH regions and OIE to its members.

The SC agreed to send further comments to JVPA, with a copy to the secretariat, before the end of July 2001. JVPA will circulate a new draft programme in early September for approval within 2 weeks time.

The VICH website and OIE website will announce the VICH2 conference in the very near future.

9. Outline of regulation system of veterinary medicinal products in the EU

On behalf of the EU, Dr P. Jones outlined the different regulatory systems for the approval of VMPs currently applicable in the EU. Copies of the slides were distributed.

10. Communication

10.1. SETAC/EMEA Workshop on environmental toxicity

The EU explained that the workshop had been postponed because the Ecotoxicity Phase 2 GL had not yet reached the consultation period. The EU believes that this workshop may still prove to be suitable for wide consultation after adoption at step 2 of the Ecotoxicity Phase 2 GL, but the final decision rests with the SC if the conference is sponsored jointly with a regional party to VICH e.g. the EMEA.

10.2. VICH website: names of EWG experts

The secretariat explained that following the SC's request to the chairpersons of the EWG, very diverging replies had been received. In some EWGs, no consensus had been reached at all. The secretariat therefore proposed that names of experts should no longer appear on the VICH website.

The SC supported this proposal and agreed that, if the names of experts were requested, the website should refer to the coordinators who will be able to evaluate the requests received.

11. Review of procedures and functioning of the VICH process

11.1. Guidance for the Acceptance of Interested Parties in VICH Steering Committee meetings

The secretariat reported that given the comments and requests for further discussion received from the EU and Mr J. Boisseau, on behalf of OIE, it had not been possible to sign off this document by written procedure. The secretariat requested also clear guidance from the SC on which documents could be circulated to IPs.

The SC reviewed the comments and possible amendments to the draft text. After discussion, the several amendments were included and the SC adopted the draft text as VICH policy. The SC confirmed that the IP policy should not be an encouragement to national authorities and organisations to attend VICH SC meetings.

The SC however agreed to revise the text when needed and decided that if necessary, the number of IPs would be limited.

The SC furthermore agreed that, considering the confidentiality agreement required, IPs should receive all meeting documents circulated prior to a SC meeting, unless a SC member indicates clearly to the secretariat that a document should not be circulated.

11.2. Policy on consultation at step 4

The secretariat reported that it had not been possible to sign off this document by written procedure because the EU had expressed concerns on the way the consultation procedure of VICH documents by the USA.

The chairman confirmed that the US has undertaken the circulation of VICH GLs in the Global Consultation through notification under the SPS agreement without prior discussion with the other parties to VICH, which means that a double consultation takes place. The EU has already expressed in writing its concern to the USA through the official SPS channel, but has received no reply. FDA indicated that the consultation is a government wide policy. FDA also noted that additional language has been added to the notifications of VICH guidelines to try to address the EU concerns. FDA had previously been informed that this language had addressed the EU concerns. FDA requested a copy of the letter sent by the EU since it had apparently been sent to a different agency in the US government and FDA had never received a copy. This will facilitate any further discussions on this issue.

No agreement being reached between the 2 parties, the USA and the EU accepted to solve this issue in bilateral discussions.

The SC did not adopt the draft document.

FDA asked why their suggestion reading: *"In case major issues, which have been highlighted during the consultation period, have not been integrated in the final document, the WG Chair will explain to the proposer the reasons why"* had not been addressed. Several members of the SC did not wish to put a further burden on the EWG chairpersons. No consensus being reached, the SC decided to rediscuss this issue at the next meeting.

11.3. OIE definition of its role as Associate Member of VICH

On behalf of OIE, G. Moulin reminded that the association was the initiator of VICH and reiterated its full support to the VICH process. He confirmed OIE's role as an associate member defined in the organisational charter, mainly to disseminate the VICH information and to feedback the comments. He welcomed the VICH decision to enable its participation on specific EWG meetings to share its experience in specific topics.

The charter already provides for OIE to participate in a EWG if OIE has developed a particular expertise.

OIE therefore wishes to be considered as a partner of the harmonisation process and is ready to support VICH and facilitate the discussion.

11.4. Request from CAMEVET to be observer in VICH

The SC reviewed the request from CAMEVET (an organisation of regulatory authorities in Latin America) to be observer in VICH. The request was made by the OIE Regional Representation for Americas acting as office secretariat of CAMEVET.

After discussion, the SC agreed that if the request was coming for the OIE Regional Representation it could not be accepted as OIE is already represented in VICH. The SC requested the secretariat to ask CAMEVET for clarification on the relationship it has with OIE as well as on the composition and the goals of the association. The letter should also explain why CAMEVET could not be accepted as observer.

The SC agreed that, provided it is clear that it is not linked to OIE, the application as an IP will be considered at the next SC meeting.

11.5. General glossary of terms used in the VICH Guidelines

No further interest being shown, the SC decided not to pursue this item any further.

12. Any other business

* The secretariat indicated that the number of delegates attending this meeting had increased at the last moment, causing some logistical problems regarding the social events and meeting facilities.

After discussion, the SC confirmed that the rules of attendance should be respected and that guests should be allowed to participate only in very specific cases. Attendance of additional attendees at the SC should be approved by all SC members in advance of the meeting.

* The SC asked the secretariat to write to the chairman of anthelmintics EWG to thank him for the work achieved and inform him that to launch the ectoparasiticides work would require the presentation of a concept paper to the SC.

13. Dates and venue of next meetings

- The 10th SC meeting will take place on 28-29 November 2001 in Tokyo, Japan
- The 11th SC meeting will take place on 10-11 April 2002 in Washington, USA

14. Adoption of the press release

With minor changes, the SC members adopted the press release as proposed by the secretariat.

VICH STEERING COMMITTEE
9th meeting

27-28 June 2001
London, U.K.

Chair: Mr. Philippe Brunet, EC - DG Entreprise

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators	
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