VICH/02/031
10 June 2002
Final

VICH STEERING COMMITTEE
10th meeting
9-11 April 2002
Washington DC, USA

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr R. Hill, chairman, opened the meeting by welcoming the participants to Washington, and particularly the new colleagues, K. Grein, J. Jenkins-Showalter and A. Wennberg. He suggested that the 10th SC should be seen as a milestone since the SC had not met over the last 10 months. He thanked all those who have supported the USA after the 11th September 2001 events and reminded the participants that Pfizer had lost several co-workers who had been on one of the planes in New York.
The chairman extended his particular thanks to the Japanese colleagues for the change of rotation in the SC meetings.

The Secretariat introduced Dr Jean-Louis Delforge, Executive Director of IFAH since 1st January 2002.

Dr N. Hirayama, on behalf of the Japanese delegation, announced that in Japan many people had prayed for the dead of the 11th September. He indicated that the Japanese colleagues, who had been organising the 10th SC planned in November 2001, had faced the challenge of cancelling that meeting. He thanked the secretariat and the American and European colleagues for having encouraged the continuation of the VICH work by written procedure. He finally indicated that BSE had appeared in Japan last September and explained that he was representing Dr M. Kurimoto at this meeting because important deliberations taking place on this subject at the Japanese Diet had prevented Dr M. Kurimoto and Dr K. Oishi to attend the SC meeting.

2. Adoption of the agenda

The chairman indicated that item 6.1 should be deleted, as draft GL24 had not been finalised by the EWG.
As no representative of OIE could attend the meeting, it was proposed to delete item 12.3 and replace it by the following item: review of the application of Canada.
The EU asked to add under item 13.3 a discussion on the wording behind the abbreviation "PSUR" in GL29, as follow-up of the 9th SC meeting.
The agenda was adopted without further change.

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3. Overview of the VICH Workplan – introduction to the progress reports

The chairman indicated that this item had been included on the agenda prior to the progress reports in order to introduce this issue at the start of the meeting.
The chairman asked the participants to keep the VICH workplan in mind during the discussions and deliberations, which would take place during the meeting.
The current goal set in the workplan was to end the VICH activities in 2005. Further thought was however required, particularly in view of revisions of existing GLs which might be required at a later stage.
The chairman suggested that SC members should aim at a successful VICH2 conference.
Finally, a number of difficult issues, as seen in the exchange of e-mails prior to the SC meeting would be discussed during the meeting and would require consensus and solutions.

4. Progress reports of Expert Working Groups

4.1. Quality

The SC reviewed the written report prepared by the chairman of the Working Group, Dr H. Makie, and presented by JMAFF.
The EWG is currently reviewing by written procedure the VICH GLs related to ICH GLs Q6A and Q6B dealing with specifications. The topic leader has circulated a third revised draft. FDA has however not yet been able to address this revised draft because of lack of resources and the work could not proceed further.

The EWG is also reviewing VICH GL 3 related to ICH GL Q1A (R) (stability testing of new drug substances and products). The Topic leader is drafting a proposal for revision that would be circulated to the EWG for review by written procedure.
Dr Makie suggested to hold a meeting of the EWG just before the VICH2 conference in order to finalise the discussions and sign-off the drafts.

FDA indicated that it was facing a substantial backlog on new animal drug applications because of a lack of resources and manpower. FDA is currently trying to get more resources through legislation that would provide authority for it to obtain user fees for animal drug applications. This would result in being able to recruit more staff for its review divisions and, as the review people are also the ones working on the VICH guidelines, this would result in having some more manpower that could work on VICH again. However this would take some time even with new resources since the new manpower will have to be trained beforehand and other work involving the development of review schedules would have to be completed.
FDA confirmed its commitment to the VICH process but would have difficulties to provide further expertise before the VICH2 conference, even through written procedures.
FDA added that this situation would also prevail if the SC decided later in this meeting to launch new topics, the CTD being one possible new topic. FDA noted that the CTD was worthwhile but had created a huge resource strain on the Center for Drug Evaluation and Research.

FDA mentioned also that in retrospect they regretted reopening some of the ICH guidelines. ICH experienced difficulties with the early revision of GLs Q1A and Q1B, because this revision had triggered a number of new issues whilst the implementation phase of the first GLs was in process. Based on this experience, ICH is pursuing other ways to deal with guideline revisions by talking about implementation experience rather than reopening all the guidelines.

After discussion, the SC confirmed that a breakout session on Quality would take place at the VICH2 conference, as many GLs have been implemented since VICH 1 and a discussion of this implementation experience would be very beneficial to the audience. Furthermore, any minor repetition of discussion about accomplishments under Quality would not be a serious problem because VICH2 was taking place in Asia and many of the participants would not have attended the VICH 1 meeting.

The SC decided to put on hold the EWG's activities until the 11th SC meeting and asked FDA to report on its manpower availabilities at that meeting.

4.2. Ecotoxicity/environment impact assessment

Dr J. Robinson, chairman of the Working Group reported on the achievements of the EWG through a short presentation. The 4 initial documents have been combined into a single merged draft phase II document, but significant concerns have been raised regarding this draft. FEDESA and AHI in particular have voiced a strong opposition and a joint discussion document has been submitted to the EMEA.
As a next step the expert from ANZ will highlight the most contentious issues by drafting a revised document containing all comments received.
Notwithstanding the complexity of the problems remaining to be solved within the EWG, Dr Robinson stressed nevertheless that the EWG members remained committed to completing the phase II draft GL and proposed to confirm the 7th EWG meeting to be held over 4 days prior to VICH2. A revised timeline with milestones will be available by the end of April and Dr Robinson believed that a face-to-face meeting would be the most efficient way to solve the remaining issues.

AHI thanked all the members of the EWG for the work already achieved and recommended that the October meeting be held.
The EU confirmed that the CVMP ad-hoc group on environmental risk assessment would discuss with FEDESA the contentious issues in the phase II draft during their meeting on 2&3 May 2002.

Following the discussion, the SC encouraged the EWG to resolve the contentious issues as quickly as possible and to hold a meeting in October in Tokyo preceding VICH2 in order to provide a step 3 document to the SC at its 11th meeting.
The SC asked Dr Robinson to inform the members of the EWG and the SC without delay in case insufficient progress would be achieved to meet the fixed deadline for the meeting.

The SC discussed the suggestion from the EU expert for the development of methods for testing the effects of veterinary medicines on dung flies and dung beetles, for which advanced preparatory work has been done in an international expert group.
The SC agreed not to expand the mandate of the EWG in order to include the drafting of such recommendations but that the OECD would be the appropriate body to establish such a guideline as an internationally agreed protocol.

4.3. Safety & Task Force on Microbial Safety

Dr. T. Mulligan, chairman of the Expert Working Group, reported that at the 7th meeting of the Safety Expert Working Group on 5-7 December 2001, the draft GLs on Repeat-dose (90 days) toxicity testing (GL 31), Developmental toxicity testing (GL 32) and General approach to

testing (GL 33) had been signed off at step 2. These draft GLs were presented to the SC for adoption and release for consultation at step 4.

The SC limited the consultation period to 5 months, in order to enable the EWG to review the comments at its 9th meeting in October 2002.

The EWG could not review the draft GL on carcinogenicity testing (GL 28) at step 5 because the consultation period was not ended.
Agreement is still to be sought on the repeat-dose (chronic) toxicity testing (3rd draft of the document) due to different approaches within the regions (6 or 12 months, mandatory or optional…).

The general approach to determine a microbiological ADI is however progressing. The microbial Task Force will meet on 16-19 April 2002 and the document will be submitted for discussion to the 8th EWG meeting.

Dr Mulligan indicated that 3 more meetings of the EWG would be necessary to fulfil its mandate: 8th meeting in August 2002, 9th meeting in October 2002 (Tokyo) and 10th meeting in April 2003.

After discussion, the SC authorised the 8th and 9th meetings of the Safety EWG as proposed. JMAFF however requested that the document prepared by the TF should be circulated to the Safety EWG at least 2 months before the 8th meeting.

Report on the Microbial Safety Task Force (MSTF)

Dr T. Mulligan reported that the Task Force had met on 11-13 December 2001 and had reviewed the research data presented by the FDA. The TF had agreed on the determination of end-points and progress had been made on the development of a general approach to determine a microbiological ADI. The TF drafted recommendations for test protocols, in vitro test systems for determining NOECs and for deriving ADI from in vitro data.
Dr Mulligan expressed regret at what seems to be a misunderstanding between the Task Force and the EU because of the latter's concerns that developments were proceeding very much along the lines of the FDA guidelines published in January 2002 with insufficient note taken of the EU and JECFA approach to setting ADIs. The EU reported that the matter was being addressed and was committed to progressing the work to achieve consensus.

During its final meeting on 16-18 April 2002, the TF will finalise its mandate by recommending in vivo test systems for the determination of NOEL and will propose a draft GL for approval to the safety EWG.

The SC acknowledged that the TF will address, at their April meeting, the issues raised by the EU in February 2002.
Responding to a question raised by a SC representative on how the TF would finalize their draft document, Dr Mulligan stated that if needed, a drafting committee composed of government and industry TF members would be formed to finish the document. The drafting committee would only edit the document agreed upon by the TF representatives at the April meeting. The final document would be circulated to all members of the TF to assure that the agreed upon concepts had not been changed. Once the document is sent to the SWG, any comments would be addressed by the representative to the SWG utilizing members of the TF as experts.

4.4. 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 EWG had reviewed at its 5th meeting the 12 comments received on GL 25 (residual formaldeyde) and GL 26 (residual moisture), but that no major contentious issue has been expressed.
The draft GL 31 (testing of mycoplasma) was signed off at step 2 and forwarded to the SC for adoption and release for consultation at step 4. The EWG suggested establishing a12 month consultation period in order to enable the EDQM (European Directorate for the Quality of Medicines) to prepare and distribute 5 reference strains to the member regions. These strains will furthermore require testing in the 3 regions.
After discussion, the SC agreed to establish a 12 month consultation period and decided to review this timeline at the 11th SC meeting.
The SC thanked the EDQM for the efforts currently undertaken to produce the reference strains

The SC acknowledged the efforts achieved by the EWG after in-depth discussions to reach an agreement on a draft document on the testing for the presence of extraneous agents.

USDA informed the participants that the EWG had finalised a study on the harmonisation of validation and test methods in the 3 regions, which had been published recently in "Biologicals". The SC complimented Dr Itoh and the EWG for their work.

The SC authorised the 6th meeting in Tokyo in October 2002.

4.5. Pharmacovigilance

Dr Keller, chairman of the EWG, reported that the 5th meeting planned for October 2001 and then February 2002, had been rescheduled due to the events of 11th September 2001 and the subsequent reservations of EWG members regarding GL 24 section 4.IV and related issues. The meeting will now take place in the week following the 10th SC meeting. The EWG had failed to reach consensus by written procedure on draft GL 24 (Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)), following the chairman's proposal for a revision of Section IV.4 of the draft GL. He indicated however that, considering the recent comments received from the different members, an agreement would probably be reached at the next meeting.

Dr Keller indicated that the EWG had asked further clarification from the SC with regard to the requirements for AE Reporting, noting that conflicting requirements are currently in place within regions.
After a thorough discussion, the SC strongly recommended to the EWG to seek the best possible compromise and to come to an agreement at its next meeting. In case of failure, the SC would address this issue at the 11th SC meeting.

The EU indicated that the definition of adverse reactions in the EU and adverse events in the draft GL were currently not compatible. Thus, should the GL be adopted in the present form, a declaration of equivalence with respect to EU law would have to be made.
AHI believed that the EWG was near to reaching an agreement on 3rd country reporting, but asked the EWG to clarify the issue of languages of the reports.

The EU stressed that Pharmacovigilance was an essential asset to human and animal health and safety, and that the authorities therefore needed to be informed of any serious adverse events in 3rd countries. A non-assessed or not translated report would not be of any use.
FEDESA and AHI called for pragmatism on this issue, in order to avoid setting requirements which some regions could not implement, stressing that any over interpretation of the requirements set in the GL would not lead to the expected goal either. The SC acknowledged that translation would be needed in certain cases in order that the report could be understood, i.e. when the report would come from a country with another language.
The SC confirmed furthermore that adverse event reporting should ultimately cover all products, new and old.

Dr Keller pointed out that the few comments received on draft GLs 29 and 30 will be reviewed at the 5th EWG meeting next week. The EWG will also initiate a new draft GL on electronic transmission, which will be the last task assigned to the EWG.
He added that as the EPA (Environmental Protection Agency-USA) had declined the suggestion to participate in VICH, no provisions for EPA registered products (ectoparasites) had been included in the VICH pharmacovigilance GLs.

With regard to draft GL 30 – controlled list of terms, the SC reviewed the suggestion of the EWG that VEDDRA be adopted as international nomenclature for reporting.
The EU reminded the participants that MedDRA (Medical Dictionary for Drug Regulatory Authorities) was initially originated in the Medicines Control Agency of the UK and had been further developed by the EMEA Committee for Proprietary Medicines (CPMP) as an EU pharmacovigilance data base system. VEDDRA was then modelled on MedDRA, by the EMEA and donated to the EU. The EWG has proposed that VEDDRA should become the international reference. As the database format for VEDRRA had been developed by the UK competent authorities (VMD-Veterinary medicines Directorate), their agreement to use it as basis for a harmonisation approach within VICH would be needed.

The chairman proposed to sign off the GLs 24, 29 and 30 by written procedure after the EWG meeting. Several members requested that the documents be circulated as soon as possible but requested a discussion at the next SC meeting.

Questions were raised at the last SC meeting on the costs and functioning of MedDRA.
Further to the proposal of Dr Keller, the SC invited representatives of TRW, the company that is responsible for the maintenance and support of MedDRA, to explain the cost implications of such a database.

TRW made a detailed presentation on the maintenance, support and the mode of financing of MedDRA. MedDRA is maintained and distributed through subscriptions from the human pharmaceutical industry. TRW provides the maintenance and support services organisation (MSSO).
In case TRW is chosen, VEDDRA would use the same infrastructure, but the control would be in the hands of VICH. TRW proposed to maintain the VEDDRA database for an annual cost of 12.000$ (Supply of 120 hours of work per year), invoiced by 12 monthly equal invoices, and covering the management of change requested from members, the management of a web-site, the semi-annually production of new versions and their posting on the website, the production of CDs made available to subscribers not having access or outside subscribers.
Additionally, a one-time initial cost of 5000 $ would fund the set-up of a subscriber database, the modification of existing SOPs, establishment of an internet domain name, as well as the design, development, testing and implementation of a VEDDRA basic web site. Further

technical work would be charged 125$ per hour and calls upon an experienced veterinarian consultant would be charged 175 $ per hour. TRW would indicate to VICH when 50% and 75% of the contractually included 120 hours of work have been expended.

FDA confirmed that ICH's experience with MSSO was satisfactory although it had taken many years to set up, as it was a voluntary exercise and at the start only a few companies supported the system.
The EU pointed out that VICH was not a legal entity, so IFAH or another organisation would have to sign a contract and collect the funds.
After discussion, the SC encouraged the EWG to finalise the proposal at its next meeting, and agreed to set up a final agreement at the 11th SC meeting.

The SC also asked the secretariat and IFAH to draft a proposal for financing and for a legal scheme. After the last SC meeting the EU has forwarded a copy of the agreements between IFPMA, ICH and MSSO to IFAH.
IFAH expressed its concern about the future of VEDDRA if VICH would end in 2005. The EU stressed however that the purpose being the establishment of harmonised requirements for the 3 regions, in case VICH was ended, VEDDRA would stay the reporting form, and IFAH could be the legal entity controlling the database.

Dr Keller suggested that the completion of EWG tasks would require at least 2 if not 3 further meetings, but he informed the SC that he would be retiring from FDA this summer and would thus also resign as chairman of the EWG.
FDA indicated that, although no successor could be nominated at this stage, it reserved the opportunity to nominate a new chair, assuming an appropriate person could be identified very soon. If this was not the case, the EU expressed its willingness to nominate a suitable chairman from the EU.
The SC strongly recommended that a new chairman should be nominated without delay.

The SC unanimously expressed its gratitude to Dr Keller for his commitment since the start of the EWG and congratulated him for the amount of work achieved on these difficult issues.

4.6. 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 noted that, although the consultation period on GL 27 (Pre-approval information on Antimicrobial resistance) was finished in autumn 2001 and a meeting had been planned in spring 2002, the EU has asked for a postponement of the meeting until the early summer to allow for consideration of comments received on the draft CVMP guideline on the same subject before finalising the EU comments on GL 27. The chairman was currently trying to reschedule a meeting before the 11th SC meeting in October.

FDA announced that the VICH draft GL had not been published for consultation in the USA yet. It would be published in summer 2002 after a US guidance document on antimicrobial resistance had been published. It was explained that this publication delay was necessary in order to avoid a confusion of the issues. The consultation period would therefore not end before the VICH conference.
FDA confirmed once more its commitment to the VICH process and explained again that it was currently facing a problem of manpower and available expertise.
EU, AHI, FEDESA and JVPA voiced their frustration that FDA was delaying the publication of the VICH draft GL and expressed their concern for the future of the VICH process.

JVPA stressed in particular the implications for the VICH2 conference.
The EU highlighted the negative message that would be received by the chairman of the EWG and the experts.
JMAFF encouraged the FDA to shorten the consultation period.

After a very long and in-depth discussion, the SC agreed to further extend the consultation period until 31 December 2002, but to review the situation at the 11th SC meeting. The SC requested that FDA should keep the SC informed on the progress made.
The SC decided furthermore that the chairman and the secretariat should send a letter to the FDA expressing the SC's concerns and encouraging the FDA to publish the draft GL without further delay.

4.7. 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.

Pharmaceuticals

JVPA explained that the EWG discussed at its 3rd meeting held in February 2002 the guidance document for pharmaceuticals prepared by FDA. Agreement was reached on most technical issues. The draft GL is intended to be signed-off at next EWG meeting scheduled for October 2002 in Tokyo, pending further discussion and final review of the document.

Further to the request from the EWG, the SC confirmed that the EWG should include in their task the issue of safety for mastitis products.
FDA reported that an internal discussion was ongoing between the division of production drugs and therapeutic drugs on the number of animals to include in the test groups. The difference of opinion is quite entrenched thus the issue might not be resolved before Spring 2003. FDA indicated that it will investigate other ways to solve the issue as soon as possible and asked for suggestions. AHI offered its help to FDA by organising opportunities such as a side FDA-AHI discussion on this subject..
After discussion, the SC recommended that the EWG should move ahead with the next meeting as scheduled and resolve all outstanding issues to finalise the draft GL, but exclude the issue of number of animals until an agreement is reached within FDA.

Biologicals

JAVB reported that the discussion on the guidance document for biologicals had just started and further discussion on specific issues would be needed. The EWG agreed that fundamental differences exist between the 3 regions in the requirements for safety evaluation of biologicals. Furthermore, as USA and Japanese vaccine manufacturers have no need to export to the other parts of the world they do not necessarily wish to meet worldwide standards.
The EWG suggested therefore that the VICH GL should leave the option to comply with existing regional regulations only.
The EWG requested guidance from the SC on the inclusion of the spread of vaccine strain in the GL, as it is relevant to the reversion to virulence test, and whether the GL should refer to the definition of batch release titre.
After a thorough discussion, the SC confirmed that both subjects should be addressed. The spread of vaccine strain is included in the concept paper of the TAS EWG, and should be handled by the TAS EWG,.

The SC confirmed however that the batch release safety test was a mandate of the BQM EWG.
The SC encouraged the EWG to achieve progress on the biologicals issues at its next meeting.

The SC appreciated the progress achieved by the EWG, and expressed its thanks and congratulations to the experts.

The SC authorised the 4th meeting to take place on 7-9 October 2002 in Tokyo.

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

The SC acknowledged the importance for the safety WG to receive the comments on VICH GL 31 - Safety of residues of Veterinary Drugs in Human Food –Repeat Dose (90 days) Toxicity testing, VICH GL 32 - Safety of residues of Veterinary Drugs in Human Food – Developmental Toxicity testing and VICH GL 33 - Safety of residues of Veterinary Drugs in Human Food –General Approach of testing, before the VICH 2 conference and agreed therefore to commit to a 5 month consultation period. The EU raised the issue that due to the internal consultation process involving specialised working parties, the CVMP and 15 member states, the 5 month consultation period might be too long to allow input for the October meeting, and may consider in Europe an even shortened time, than was confirmed by the SC.

5.1. GL 31 - Safety of residues of Veterinary Drugs in Human Food – Repeat Dose (90 days) Toxicity testing

The Steering Committee received the text of GL 31 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 5-month public consultation at Step 4.

The Steering Committee agreed that the deadline to submit comments on the guidelines is 15 September 2002.

5.2. GL 32 - Safety of residues of Veterinary Drugs in Human Food – Developmental Toxicity testing

The Steering Committee received the text of GL 32 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 5-month public consultation at Step 4.

The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 15 September 2002.

5.3. GL 33 - Safety of residues of Veterinary Drugs in Human Food – General Approach of testing

The Steering Committee received the text of GL 33 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 5-month public consultation at Step 4.

The EU indicated that the annex to the EU directive laying down the testing requirements for veterinary medicinal products would need to be modified before implementation of this

guideline, which does not foresee an acute toxicity test as part of the safety data, and is however currently required in the EU. The modification will only require a procedure involving committees of the Commission and EU member states, without reference to the full legislative procedure. The implementation period may nevertheless be longer in the EU.

The chairman stressed the commitment of the VICH members to transparency and communication to each other of delays

The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 15 September 2002.

5.4. GL 34 – Test for the detection of Mycoplasma contamination

The Steering Committee received the text of GL 34 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 12-month public consultation at Step 4.

The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 15 April 2003.

The SC confirmed that the consultation period would be reviewed at the next SC meeting pending the availability of the EDQM reference strains.

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

The EU indicated that the European Pharmacopoeia had started to revise the European monographs. However the implementation would have to be delayed if the revision was not finalised on the implementation date.

The SC agreed to review this item at the next meeting.

6.2. GL25 – Testing of Residual Formaldehyde

The Steering Committee adopted GL 25 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 by May 2003.

6.3. GL26 – Testing of residual moisture

The Steering Committee adopted GL 26 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 by May 2003.

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7. Review of VICH workplan

7.1. Achievements, delays, priorities

The SC reviewed the status of each of the activities of the VICH EWGs based on the discussions under item 4, and the status reports of the various guidelines. Their status is as follows:
Quality: delays from original timeline, work is pending at present
Ecotoxicity: it is yet unsure when the task will be achieved; more information will be available at the 11th SC meeting
Safety: further 3 meetings planned, work is ongoing
BQM: at least 2 more years work ahead, but new topics might be added
Pharmacovigilance: pending the progress of the next meeting, it might end its task early 2003
Antimicrobial Resistance: while delays occurred in finalisation of GL, work is ongoing
TAS: active until at least 2004
The chairman summarised that 6 EWGs are currently active and one (Quality WG) has pending status at present.

The SC discussed whether the document VICH Strategy and Work Programme 2000-2005 should be revised.
The SC decided not to amend the work programme at this meeting, but asked the secretariat to update the relevant sections, particularly chapter 2.1 on the VICH Guidelines.
At this occasion FEDESA expressed their disappointment regarding the lack of commitment and achievement during last year and the foreseeable further delays in the forthcoming months due to the expressed resource problems at some agencies. FEDESA reminded the regulatory authorities of the purpose of VICH i.e. to accelerate and increase efficiency of licensing procedures for the benefit of all participating parties. These comments were supported by AHI.
After discussion, the SC however agreed that overall much progress had been achieved since the start of the VICH process and recognised the need for a more in depth discussion on the Workplan.

The SC decided to discuss the Workplan thoroughly at the start of the 11th SC meeting.

7.2. Feasibility of establishing topics on which no regional GL has been issued before

The SC recognized that the need for regions to develop their own GLs prior to VICH Guidelines was delaying some parts of the VICH process.
The SC agreed to debate this issue at the 11th SC meeting.

8. Implementation of final VICH Guidelines

Report of implementation in the 3 regions and observer countries

The authorities from ANZ reported that all VICH GLs will be implemented by mid-2002.

The authorities from the EU confirmed all implementation deadlines have been met and that by mid-2002 all GLs will be implemented

The authorities from Japan confirmed that all GLs have been implemented

The authorities from the USA reported that all GLs have been implemented

9. Need for revision of VICH Guidelines at step 9

The EU reported that technical issues had been raised whilst implementing the Anthelmintics General Approach GLs in the EU

No other SC member commented on this issue. The EU therefore agreed to add further information on this issue if relevant at the 11th SC meeting

10. VICH2 conference

10.1. Review of the revised draft programme and confirmation of speakers

The SC reviewed and discussed the VICH2 draft programme. Speakers and chairs were confirmed and a new draft produced.

SC members were requested to send any final comments to the secretariat before 30 April 2002.

10.2 Guidance to the EWG chairpersons for the report of the breakout sessions

Following the experience of VICH1, it seemed useful that chairmen of the EWG should receive guidance on the way to conduct the breakout sessions most efficiently and effectively

The SC reviewed the expected content of the discussions in each breakout session and the information that was expected to circulate between the participants and the members of the EWG.

After discussion, the SC agreed that the breakout session should be chaired by members of SC, who will have the responsibility for the relevant breakout session. The chair of EWG would act as speaker and both would decide between themselves who will report to the plenary session.

The SC agreed on the members to chair the individual breakout sessions (see revised draft of programme).

10.3. Organisational matters: poster session etc…..

The SC discussed this proposal from the secretariat and decided that a poster session would not be necessary.

JVPA informed the SC that the deadline for providing the documents included in the handouts of VICH2 was 15 July 2002, but after discussion, it was agreed that this deadline could be extended to15 August at the latest. Documents should be sent to Dr S. Ohshima.

As all documents will be translated in Japanese, a 1 page abstract would be sufficient for the handouts.

The JVPA secretariat will communicate with the SC through the VICH secretariat on further organisational matters until VICH2.

EMEA, USDA, FEDESA and JVPA confirmed that they would like to set up a stand at the conference. Other members were required to contact Dr Oshima in case further stands were needed.

The secretariat reminded the participants that a CD-Rom had been produced for VICH1. The SC relied on the secretariat to evaluate if this CD-Rom could be used, or if it was possible to produce a new version.

10.4. Communication on VICH2 in the regions and Worldwide (update of the VICH1 leaflet)

The secretariat presented a revised version of the leaflet, which had been produced for VICH1 and stressed that no fundamental change was proposed.

ANZ suggested adding the Interested Parties to the footnote.

SC members should send suggestions for amendments to the leaflet to the secretariat before 30 May 2002.

JVPA stressed that Japan is committed to the success of VICH2, which will be the first major conference on Animal Health Products in Japan, and that Japanese colleagues expected to receive a maximum support from other SC members in order to draw as many participants as possible to VICH2.

11. New topics

In introducing the subject the chairman reminded the SC on the situation summarised before, that 6 EWGs are currently active and one would have pending status at present. In accordance with the workplan of the VICH therefore, with 6 groups still active, no more groups could be initiated at this time. The Steering Committee was also reminded that in the workplan of the VICH a finalisation point of 2005 for the whole process was identified in earlier SC meetings, but with the slowdown having been observed during this Committee meeting, that date might have to be reviewed since it may well be impossible to complete all the activities and assignments and also the new topics that are waiting in the wings by 2005.

The SC nevertheless reviewed the proposals for new topics

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

FEDESA confirmed the concept paper presented at the 9th SC meeting suggesting to include the ICH GL Q7A on GMPs for active ingredients in the VICH work programme. The Quality EWG would have to address the specific veterinary issues.

After discussion, the SC decided however that this topic did not have a high priority for the time being. Furthermore, the current lack of resources of the Quality EWG (see item 4.1) applies here as well. Consequently FEDESA proposed to delete this item from the list of potential topics.

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

FEDESA confirmed the concept paper presented at the 9th SC meeting proposing to review VICH GLs 10 and 11 following the amendments to the ICH GLs Q3A and Q3B. The Quality EWG could review this topic through written procedure.

Considering the current lack of resources of the Quality EWG (see item 4.1), the SC agreed to review this topic again at the next SC meeting.

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

AHI presented the revised concept paper and reported that in ICH progress was being achieved on the Common Technical Document. AHI proposed therefore to adopt this topic in VICH.

FDA explained that this topic had required a lot of work and resources within ICH, where compromises had to be reached because of numerous regional differences. Each region had to set up its own regional document, explaining to industry how to publish in CTD format. ICH had to create implementation WGs as well as a CTD coordination group chaired by industry.

The EU pointed out that although in the EU the quality parts in the veterinary and in the human dossiers are similar, much work would be required to harmonise the other parts. Many problems would probably appear because the classification of products (as Veterinary Medicinal Products or not) is different between the regions, and therefore more information was needed beforehand.

After discussion, the SC recognised the fact that the first step of this topic would require the reactivation of the Quality EWG, which is currently not possible (see above).

The SC agreed to review this topic when discussing the VICH Workplan at the 11th SC meeting.

11.4. Review of the concept paper on the Efficacy of Mastitis Products

FDA, which had raised this proposal at the last SC meeting, reported that meanwhile, following internal discussions within FDA, it had been decided not to produce a concept paper on this topic for the time being because of resources problems and in order to let the subject mature further in the international arena.

The EU supported the FDA and commented that this subject, which is also not in the VICH Work Programme, was not a priority.

The SC therefore unanimously agreed that this topic would not be discussed within VICH for the time being.

11.5. Review of the concept paper on Metabolism and Residue Kinetics

The SC reviewed the concept paper prepared by the EU.

The EU added that many differences exist between regions and considered therefore that this very important topic should be harmonised. After discussion, it was agreed to harmonize the technical requirements but proposed to leave out the MRL and calculation of ADI.

JMAFF informed the SC that work had been done on this issue in Japan and asked the EU to include it in the concept paper.

After discussion, the SC agreed to review this topic when discussing the VICH Workplan at the 11th SC meeting.

12. Review of procedures and functioning of the VICH process

12.1. Policy on consultation at step 4

The secretariat reminded the participants that this document could not be adopted at previous meetings because of the disagreement between the EU and the FDA on the consultation done by the USA through the SPS agreement in parallel to the formal VICH consultation.

After discussion both parties agreed that this issue could not be solved within the VICH SC, but bilaterally, and agreed to adopt the policy paper.

After a final review of the document, the SC agreed to delete the last sentence in order to prevent adding more burdens on the work of the EWG chairmen, and adopted unanimously the Policy Paper. The secretariat will circulate the final version.

12.2. Review of the application from CAMEVET as Interested Party

The secretariat explained that after a request for clarification of the role and the composition of the association, CAMEVET had formally applied as Interested Party. The secretariat had received the constitution.

After a thorough discussion on the roles of Observers and Interested Parties within VICH, and the number of Interested Parties the SC could possibly accept, the SC agreed to accept CAMEVET as an Interested Party to VICH, pending the review by the secretariat of documents received. The SC asked the secretariat to check that the requirements set by the SC are met and to inform CAMEVET of the decision made.

12.3. Review of the application from Canada

The chairman pointed out that VICH had received a request for observership from the Canadian government, but very little guidance was available on the criteria for the acceptance of observers.

The SC reviewed the pros and cons of Canada's membership as observer and agreed that the existence of regional GLs, the strong relationship to the USA and high level of expertise were positive items.

The issue of implementation of existing guidelines would need to be addressed with Canada. It is also not clear if biological products would be covered.

FDA reported on the very fruitful collaboration with Canada within ICH and through other international fora and supported Canada’s candidacy for the observership.

AHI indicated that the Canadian industry association, CAHI, would also be willing to be represented in the membership.

ANZ recalled that the observer status does not set an absolute obligation to adopt the VICH GLs

The chairman proposed to develop a policy document on the admission of observers, but the SC felt that this should be discussed on a case-by-case basis.

After an in-depth discussion, the SC agreed to accept Canada as an observer to VICH. The SC asked the secretariat to inform Canada, to point out that it will have to attend all SC

meetings and to encourage the authorities to implement all VICH GLs as soon as possible (within 2 years). FDA offered to contact Canada and assist them in detailing their plans for VICH observership**.** Canada should discuss with FDA the relevance of attending VICH EWG, depending of the status of achievement of their work.

The SC recommended that Canada should be encouraged to contact the existing observers ANZ to obtain information on the procedure and their experience.

13. Any other business

13.1. Information on the harmonisation work in the Pharmacopoeia Discussion Group (PDG) involving the EP, JP, and USP

The SC decided to postpone the discussion of this item to the next meeting

13.2. Website

AHI pointed out that the homepage of VICH indicated that the last update had been made in October 2001. AHI and EU believed that more frequent updates were necessary. The secretariat replied that several updates had been done since October and that the date of last update of the home page had indeed been overlooked.

The SC asked the secretariat to ensure that all necessary updates were made.

13.3 GL 29 – Pharmacovigilance of Veterinary Medicinal Products: Management of PSUs

The EU mentioned the difference of interpretation of the acronym "PSU" that had appeared at the last meeting between the USA and the EU, for which a solution was still outstanding. In the latter pharmacovigilance legislation requires "periodic safety update reports", whereas in the USA the "PSURs" are "periodic summary update reports", as the term safety would be understood in the USA legislation as not including the reporting of lack of efficacy

The chairman proposed that the SC should give guidance to the EWG to revise the draft GL 29 in such a way that it will be published in EU as "periodic safety update" and in the USA as "periodic summary update", including a footnote mentioning that this wording complies with the laws established in each region and has no influence on the content of the document.

The EU and FDA agreed to this proposal.

14. Dates and venue of next meetings

The SC discussed the necessity of meeting immediately after VICH2, in order to evaluate the conference and agreed to meet on Saturday 12 October in the morning.

- The 11th SC meeting will take place on 8-9 and 12 October 2002 in Tokyo, Japan
- The 12th SC meeting will take place on 7-8 May 2003 in Europe (London).

15. Adoption of the press release

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

VICH STEERING COMMITTEE

10th meeting

9-11 April 2002
Washington DC, USA.

Chair: Dr R. Hill, USDA

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

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INTERESTED PARTY

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INVITED

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US FDA	W. KELLER (part time)
AHI	J. ROBINSON (part time)

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