VICH/02/062
21 November 2002
Final

VICH STEERING COMMITTEE
11th meeting
8-9 & 12 October 2002
Tokyo Japan

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr N. Hirayama, chairman, opened the meeting by welcoming the participants to Tokyo, and particularly the Canadian delegation, Dr I. Alexander, representing the Canadian MAH and Ms J. Szkotnicki representing CAHI. The chairman indicated that this meeting was a milestone in the VICH process because the arrival of Canada added a new observer to the VICH process for the first time since the creation of VICH in 1996.

He noted that 5 EWG meetings were being held in conjunction with the SC because of the forthcoming VICH2 conference. Progress reports of these EWGs would therefore be delivered personally by the chairmen "in real time".

Dr N. Hirayama introduced also the following new members to the SC: Dr T. Shimasaki, JMAFF, who is the successor of Dr K. Oishi, Dr L. Beaver, FDA, who is the successor of Dr J Schowalter and Dr D. Morris, NZ regulatory authorities who will replace Dr A. Turner after this meeting.

2. Adoption of the agenda

The EU asked to delete points 9.2 & 9.3 because even if the draft GLs would be signed off today by the EWG, the EU would have to consult with the CVMP before signing off at step 3. The EU also proposed to delete points 10.4 to 10.6 as they concern as well GLs yet to be signed by the EWG and the final GLs for adoption by the SC require review and possibly time to consult with the CVMP before signing off. The SC agreed to maintain these agenda items for the time being and decide later during the meeting if sign-off would be possible, dependent as to whether the changes made by the Safety EWG to the GLs during their ongoing meeting would be substantial or not. The chairman suggested that the adoption at step 6 of these documents be completed via written procedure if necessary.

JMAFF suggested adding under item 7.3 a new topic for Biologicals EWG: testing of vaccine stability concept paper.

The agenda was adopted without further change.

Secretariat : c/o IFAH, rue Defacqz, 1 - B - 1000 Bruxelles (Belgium) - Tel. +32-2-541.01.11, Fax +32-2-541.01.19
e-mail : vich@ifahsec.org - Website : http://vich.eudra.org

3. Introduction of Canada and Camevet

On behalf of the Canadian government, Dr I. Alexander expressed his appreciation of being accepted as an Observer to the SC. He indicated that he represented both the Veterinary Drugs Directorate (VDD) of Health Canada (HC), the Canadian Ministry of Health, and the Veterinary Biologics Section (VBS) of the Canadian Food Inspection Agency (CFIA). He stressed that Veterinary Medicinal Products were currently representing a high priority for the Canadian government. Canada would therefore nominate experts to the following Working Groups:

Ecotoxicity, Biologics Quality Monitoring, Pharmacovigilance, Safety,Target Animal Safety and Antimicrobial Resistance

Ms J. Szkotnicki, president of CAHI, thanked the SC for having accepted Canada as an Observer and presented CAHI, the Canadian Animal Health Institute. She stressed that the agriculture was a very important part of the Canadian economy: with only 30 million inhabitants, Canada was the 1st pork exporter and 3rd beef exporter in the world. It was critical, therefore, for Canada to be a part of international harmonization discussions for animal medications.

Camevet: see item 12.3

4. VICH2 Conference

Dr S. Ohshima explained that the Japanese delegation had given JVPA the important responsibility of managing the secretariat of VICH2. More than 230 persons have registered for the conference and Dr Ohshima thanked the members of the SC for their support in advertising this event worldwide over the past months.

He indicated that some last minute changes had been made in the chairmanships and the speakers. The handout bags will contain a booklet including all documents received from speakers before last 18 September. The presentations received after that date were photocopied on separate sheets. He thanked the companies, which have sponsored this conference and which are listed at the back of the booklet.

The chairman congratulated Dr Ohshima and JVPA for the amount of work achieved over the past weeks and months.

5. Implementation of final VICH Guidelines - Report of implementation in the 3 regions and observer countries

The authorities from Japan reported that the Anthelmintics GLs (VICH GLs 15, 16, 19, 20, 21) had been implemented.

The authorities from the USA reported that these GLs have also been implemented in the USA.

The authorities from the EU reported that these GLs have been implemented in the 15 Member States, as well as the Safety Guidelines 22 & 23.

The authorities from ANZ reported that all these GLs have been implemented as well.

The authorities from Canada reported that they were currently considering implementing a number of the VICH GLs; the VICH Anthelmintics GLs are expected to be implemented without difficulties.

The SC suggested that Canada should present at the next meeting a detailed timeframe for the implementation of the various VICH GLs.

6. Review of the VICH Workplan

The secretariat opened the discussion by explaining that the current version of the Workplan included the suggestions made at the last SC meeting and reminded the participants that the SC had decided to review more thoroughly the Workplan at the 11th SC meeting.

FEDESA suggested broadening the debate to include the aims that were set, the achievements, and the benefits of VICH. FEDESA believed that the SC should also give guidance to EWGs when major problems appear, as is currently the case in some EWGs. For some areas, the SC should probably be ready to recognise that harmonisation is difficult to achieve.

The chairman reminded the participants that the SC had agreed on this Workplan. He believed that although the VICH process is currently facing some problems in a limited number of EWGs, the target set for 2005 should nevertheless be pursued as far as possible. He suggested discussing the way forward in a new Workplan after 2005.

FDA reminded the SC that at the 10th SC meeting it had drawn attention to its internal resources problem. FDA suggested conducting a survey to evaluate the implementation of VICH GLs and present the results publicly at the VICH3 conference to assist in prioritising future VICH work. ICH has conducted such surveys in 1997 and in 2000.

JVPA supported the objective of meeting the targets set for 2005, but stressed that VICH GLs should be practical in order to be implemented easily.

In order to give some guidance to the EWG chairmen, AHI suggested that the SC should set up a process in case the WG was unable to achieve the requested goals.

The chairman supported the proposal, but reminded the participants that within VICH the decisions are not based on majority votes, but rather on consensus. Usually, in case of problems, the chairman of the EWG would propose a way forward which would be considered by the SC. The chairman called upon each member of the SC to play his expected role in the overall consensus building effort. It was common understanding that if attempts to achieve harmonisation on a subject failed, the SC would decide to abandon this issue to allow for progress on a new topic.

JMAFF confirmed that common agreements on the ways forward should be sought.

ANZ indicated that written guidance existed for the EWGs on how to organise the work and draft GLs, but no guidance has been established on how to disband an EWG in case of unsolvable impasse.
ANZ proposed therefore to draft a proposal for the next SC meeting. The SC thanked ANZ for this proposal

7. New topics

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

FEDESA confirmed the concept paper presented at the 10th 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. The adoption of this concept paper has already been postponed at 9th and 10th SC meeting because of FDA resource constraints.

FDA explained that its inability to bring resources to the activities of the Quality EWG had not been solved yet.

JMAFF confirmed its commitment to this review and urged FDA to solve the resource problem without delay.

After discussion, the SC adopted the proposed concept paper subject to written approval and commitment to contribute by FDA. FDA will report to the secretariat by 20 November next in order to confirm the participation of FDA in this review.

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

The SC reviewed the concept paper prepared by the EU. The EU reported that since the last SC meeting it received several useful comments from Japan, which had been incorporated in the concept paper.

The SC confirmed that the issue is important and should be progressed. However, during the discussion, the SC recognised that further resources would be needed to set up a new EWG, whilst none of the other EWG have finalised their tasks yet.

THE SC therefore decided to postpone the discussion to the 12th SC meeting. Meanwhile, the EU will welcome further comments.

The secretariat asked the participants to begin identifying potential experts for this new EWG in order to be prepared to set up the EWG at the 12th SC meeting.

7.3. Review of the concept paper on Tests for stability in Veterinary Vaccines

The SC reviewed the concept paper arising from the proposal of the EWG on Biologicals Quality Monitoring presented by the JMAFF which had only be tabled to the 11th SC meeting.

JMAFF, JAVB and USDA supported the topic, but indicated that new resources might not be required as the existing Biologicals Quality Monitoring EWG may be able to work on this topic. Other members needing time to consult with their experts, the SC agreed to review this topic again at the next SC meeting.

JMAFF indicated that there would also be a concept paper on inactivation testing at the next meeting. The SC asked that the concept paper be circulated well in advance of the next SC meeting. AHI will prepare the concept paper.

8. Progress reports of Expert Working Groups

8.1. Quality

Dr H. Makie, chairman of the Working Group reported that the EWG continued to review by written procedure the VICH GLs related to ICH GLs Q6A and Q6B dealing with specifications. The topic leader had circulated a fourth revised draft.

The SC supported Dr Makie's proposal to progress Q6A & Q6B further by written procedure for finalisation in spring 2003. The SC asked the EWG to finalise the draft GL before mid-March 2003 in order to enable the SC to review the draft at the 12th SC meeting.

Dr Makie added that the revision of VICH GL 3 (stability testing of new drug substances and products) related to ICH GL Q1A (R) has made no progress, as the FDA's expert/topic leader has not yet been able to address the revised draft.

FEDESA offered to act as topic leader for GL 3 for as long as Dr Bersley of the FDA cannot work on the subject in order to allow for some progress by written procedure by the time until the FDA would be able to re-engage.

The EU pointed out that the delays of the work on the quality GLs would cause gaps between ICH and VICH GLs, as VICH would under the current situation not be in the position to follow ICH in updating GLs.

FDA again stated that it was unable to allocate any resources to these topics of the Quality EWG before Spring 2004 and therefore could not offer its attention to reviewing and commenting on or revising these GLs.

In response to FDA's inability to dedicate resources to the current work of the Quality EWG at this time, AHI, FEDESA and JVPA pointed out that the VICH Quality GLs were the most useful in a global registration perspective as they were used daily both by the animal health industry and by the regulators. They furthermore strongly voiced their concern about the backlog of FDA on the VICH Quality topics. This situation could lead to a disadvantage of the veterinary industry compared to the human industry. Many in the animal health industry are part of multinational companies, using the same manufacturing sites as the human industry.
.
JMAFF also encouraged FDA to allocate the needed resources to the Quality EWG.

The representative of FDA promised to bring forward the strong concerns expressed in the SC and confirmed that FDA still wished to keep the topic leadership after step 5.

JMAFF informed the SC that, because of Dr Makie's new priorities within JMAFF, a new chairman for the Quality EWG will be proposed.

The SC warmly congratulated Dr Makie for his excellent leadership and outstanding work achieved at the head of the Quality EWG.

The SC agreed to address the different issues again at the next meeting.

8.2. Pharmacovigilance

Dr L. Post, chairman of the EWG, reported that at the 5th EWG meeting in April 2002 GL 24 - Management of Adverse Event Reports was signed off at step 5. This followed the SC asking the EWG to find the best compromise possible on the issue of 3rd country reporting. The EU, however, was of the opinion that the discussion on section V of GL 24 should be reopened to include additional fields regarding reporting specifications. Dr Post explained that GL 24 represented the scope and GL 35 - Electronic Standards for Transfer of Data - represented the technical explanations on how the reporting will be done. He also reported that the EWG at their ongoing meeting had considered the electronic standards for transfer of data but did not make any progress on the matter, as all proposals from the EU regulatory experts for re-consideration of requirements had been rejected by the other members of the EWG and the chairman, as they would not be consistent with the requirements of GL 24. The requests from the EU would require re-opening GL 24, but this was not supported by the remaining EWG members and the chairman. He therefore proposed to progress further the development of details for the electronic transfer of data and then reopen GL 24 at a later date.

Dr Post reported also that no agreement had yet been reached on GL 29 - Management of PSURs - because industry and the authorities could not agree on an international birthday and the ways of reporting.

The EWG has signed off GL30 - Controlled list of Terms - and had unanimously agreed to take VEDDRA as the controlled list of terms for VICH. The EWG recommended however a separate VEDDRA WG in charge of reviewing proposed revisions to the dictionary. The authorities of the 3 regions had agreed to share their lists of active ingredients and products.

The EU confirmed that it offered to allow use of VEDDRA worldwide, but expressed its doubts about the usefulness of a separate WG to oversee the revision process.
The secretariat confirmed that it had met with the VMD (Veterinary Medicines Directorate - UK) to discuss the possibilities of managing the VEDDRA database on a worldwide basis. A proposal has been issued by the VMD. The secretariat will not pursue this matter further until progress is achieved by the EWG.

The EU confirmed that it could not accept the current version of section V of GL 24, which identifies the data elements required in the reporting of Adverse Events. When this section was developed, the EU did not believe that adequate consideration was given regarding the way this would be applied in electronic reporting and the resources that would be needed. The EU is currently developing a system of electronic reporting that is nearly finalised for the human products. The EU added that it was convinced that a more elaborated electronic reporting system, as developed in the EU, would benefit all regions. Certainly the EU itself needed a very detailed and precise reporting system to allow for detection and analysis of signals in an automated fashion. One of the main reasons for the development of such a system is that the EU needs to communicate in a coordinated way between the EMEA and 15 different regulatory authorities in EU Member States, and 10 further countries would be joining soon, all with limited resources for this kind of activities.

Dr Post added that the FDA and JMAFF were satisfied with the current version of GL 24 and that the USA did not want to reopen the debate. He insisted that the EWG had no further recommendation until this issue had been resolved.

In a lengthy and thorough discussion, the SC evaluated all possible options for moving GL 24 forward. No agreement was however reached on this GL and the SC asked the EWG to look at further options and report back the next day.

On the second day of meeting Dr Post reported that, despite every effort to seek resolution, the EWG had not been able to make any progress on the development of details for the electronic transfer of data and to reach a consensus on GL24. Therefore, the EWG had adjourned its work.

The chairman reminded the participants that the role of the SC is to solve any political issues, as each representative had a mandate from his region.

Although several members suggested strongly deleting section V of GL 24 in order to move forward, the EU and FDA opposed this deletion.

The EU delegation expressed their disappointment that the EWG again did reject all EU proposals for improvement of the reporting requirements. The EU concerns regarding the possibilities to make progress on the guideline on data transfer specifications re-considering certain sections of GL 24 had been raised before, and the EU SC members had only agreed to the Tokyo EWG meeting under the provision that the group would consider their concerns.

FEDESA urged the EU and FDA to revise their approach in order to save the work achieved so far.

Following a further discussion where no solution could be found, the SC agreed to discuss this issue again on the last day of the SC meeting, after VICH2.

8.3. Antimicrobial resistance

The chairman of the Working Group, Dr D. Mevius, reported that no progress had been made since the last meeting. There was a first delay because the EU had postponed their approval until the adoption of the CVMP Guidelines. No further progress was possible because FDA had not yet opened the public consultation period in the USA.

He reminded the participants that he had already expressed his frustration in a letter from May 2002 that had been circulated to the SC.
He therefore asked the SC for guidance on how to progress the EWG's task and proposed if necessary either to change the mandate or to create another EWG.

FDA explained that its internal legal counsel had recommended in order to avoid any confusion not to publish the VICH GL before the pending CVM GL. As the CVM GL had just been published prior to this SC meeting, FDA confirmed that the VICH GL will be published very soon, for a 30 day comment period. The comments will therefore be available before the end of the year. According to the FDA, GL27 and the draft FDA guidance were not contradictory.

FEDESA understood the frustration of the experts and suggested to consider disbanding the EWG if no progress could be achieved. Other members however did not support this proposal because the subject is of worldwide importance and few consistent data is currently available for the Risk Managers.

Dr Mevius reminded the participants that the original mandate of the EWG was to establish a set of data requirements for the assessment of antimicrobial resistance for new products. The EWG therefore had developed a guidance document only, leaving the qualitative Risk Assessment criteria, believing that those would be determined by another GL or determined through each regions' own policies. This VICH guidance document should of course be accepted in all the regions.

The EU, JMAFF, JVPA, Canada and ANZ expressed also their strong support for the continuation of the original work and Canada confirmed that it would nominate an expert to the EWG.

After a thorough discussion, the SC unanimously agreed that the EWG should continue to develop a GL for an international set of data requirements to evaluate the risks, but that the guidance on Risk Assessment would not be included in the mandate.

The SC authorised the 4th meeting of the EWG to take place in March (before 15 March) 2003 in Europe

8.4 Safety & Task Force on Microbial Safety

Before inviting the chairman of the EWG to the SC meeting, the SC discussed the potential problem raised by the chronic toxicity and microbiological safety draft GLs.

The chronic toxicity GL could not be signed at step 2 by the EWG because there could not be agreement on the number of species necessary to address chronic exposure. Japan and Australia insist on two studies, which are required by their national legislation, while the remaining regions are satisfied with one depending on the outcome of the 90-day studies. Although the experts of EU, FDA, NZ and Japan could agree to add a footnote indicating that Japan and Australia could require testing 2 animal species, AHI and FEDESA did object to such a footnote. AHI and FEDESA considered that a footnote enabling regions (Japan & Australia) to add a second species did not achieve harmonisation and proposed eliminating the footnote.

JMAFF explained that Japanese legislation required 2 species for chronic testing for all toxic products because there was not sufficient scientific data to recommend only 1 specie.

The EU explained that EU experts had suggested to review entirely the microbiological safety draft GL at step 2 because this GL does not take into account the long EU experience in establishing microbiological ADIs. Dr. L. Mulligan, chairman of the Safety EWG, reported that GL 28, and GLs 31, 32 and 33, had been signed off at step 5 for adoption by the SC.

The experts could still not agree on the draft GLs on Repeat-Dose (chronic) Toxicity Testing and General Approach to Establish a Microbiological ADI. Both GLs were continuing to pose problems.

Repeat- Dose (chronic) Toxicity Testing

Dr Mulligan explained that the technical discussion that took place at the EWG meeting had not solved the problem as to whether 1 or 2 species should be required for chronic testing.

JMAFF thanked Dr Mulligan for his efforts to reach an agreement. JMAFF proposed to release the draft GL with the footnote (2 species would be required in Japan and Australia), which will be of importance because it would show that Japan and Australia are out of phase with the other regions and could help to solve the problem politically. JMAFF insisted that this GL was highly important for the safety file of veterinary products.

FEDESA believed that one of the aims of VICH is to minimise the use of animals and reduce the cost of placing VMPs on the market. If this GL were to be signed off with the footnote, the European industry in complying with the requirements would use more test animals and incur higher costs for drug development. This would be entirely in contradiction with the aims of VICH. Consumers would furthermore not understand why 2 species would be required in some regions and only 1 specie in all the others. FEDESA, therefore, proposed to adopt the GL without a footnote, knowing that Japan and Australia would not be able to implement the GL at this stage but could implement the GL at a later stage.

After a thorough discussion, the SC was still not able to reach a consensus. Australia offered to do more work on the scientific evaluation and to try to broaden the database of substances with both 90-day and chronic toxicity studies to compare their No Effect Level data. The SC agreed to re-address the matter at its next meeting in light of any new data.

General Approach to Establish a Microbiological ADI

Dr Mulligan explained that this document was originally proposed as a draft GL by the TF on microbiological safety to the EWG. The CVMP had objected to the GL. One issue was the inclusion of a formula in the GL that did not contain safety factors. The EWG at their 8th meeting reviewed the draft GL and included a statement in the GL which indicated that in the case of insufficient data a safety factor may be required. The inclusion of this statement did not remove the CVMP's objection. At the 9th Safety EWG meeting, comments of the CVMP, which were expressed by the EU experts, indicated disagreement with the pathway approach proposed in the GL and suggested that the GL should be limited to the actual mandate given to the TF to consider the data requirements for microbial safety assessment only and not comprise the additional formulas for the establishment of the microbiological ADI.The pathway approach, using mostly existing data and information, allows the sponsor of a new antibiotic to evaluate if the determination of a microbiological ADI is required. If both the formula and the pathway approach were removed from the GL, the essence of the GL would be lost. Although the TF felt that it had addressed the CVMP's concerns, no agreement could be reached in the EWG meeting. He believed that this was due to a lack of direct communication between microbiological experts.

Dr Mulligan therefore proposed to hold a special meeting of a core group of microbiological (intestinal flora) experts in January 2003 to be held in London in order to allow attendance of more experts from the CVMP. He thought that an agreement could be reached at such a meeting where a full discussion of the outstanding issues could be achieved. The special meeting would discuss 1) a harmonised approach to determine the need for a microbiological ADI, 2) data requirements and suggested test systems to use when a microbiological ADI was needed and 3) whether suggested approaches to derive an ADI from test system data should be included in the guideline.

The EU confirmed their comments restricting the GL to the TF mandate to provide guidance on the data requirements only, and not to include guidance on the assessment on these data

and a method for the determination of the microbiological ADI. Dr Mulligan replied that the TF felt that after recommending *in vitro* models that might be utilised to determine Microbiological ADIs, it would be useful to also recommend how an ADI might be derived from these test systems. Dr Mulligan stressed that he did not support the omission of the ADI from the GL what could only be the last resort in the attempts to salvaging the GL if no solution would be possible at all. The EU committed that the special meeting would consider whether a harmonised approach for establishing a microbiological ADI could be found and not to restrict the discussions to data requirements, which was a fall back position only, as Dr Mulligan had pointed out.

The SC thanked Dr Mulligan for the work achieved by the EWG and his endeavour to find a solution to the outstanding issues.

The SC authorised the special meeting to take place at the EMEA in London in January 2003.

The SC also authorised the 10th meeting of the EWG to take place in March 2003 in Europe.

8.5. Target Animal Safety

Pharmaceuticals

Dr T. Nagata, chairman of the Working Group, reported that the draft document on Pharmaceuticals had been finalised, but could not be moved forward until spring 2003, because of the lack of available resources in FDA and therefore non-participation at the recent EWG meeting.
FDA confirmed that a number of issues had been raised by its legal and policy staff concerning the existing draft document and that CVM would be committing resources to address these issues as from next February.

Following the EU's concern, the SC had decided to exclude production drugs (feed additives) from the draft GL. In the EU and Japan production drugs (feed additives) fall under different legislation in their region/country and are not within the scope of VICH.
FEDESA suggested to revise the concept paper in order to define the products which should be in the scope of the GL and to agree on the definitions. This would give clear guidance to the EWG and avoid further misunderstandings.
FDA indicated that such a revision would not obviate its need to address the legal and policy issues mentioned above. JMAFF pointed out that its exclusion from the scope of GL would be enough to define it.

Biologicals

Dr Nagata reported that fundamental differences on how to evaluate the Target Animal Safety still existed between regions, but the EWG was progressing at its ongoing meeting. A way had been found to include all the issues in one document currently under discussion.

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

The SC authorised the 5th meeting to take place on 7-9 March 2003 in Europe.

8.6. Biologicals Quality Monitoring

Before inviting the chairman of the EWG, the SC acknowledged that not all reference strains were available for distribution yet. AHI and JAVB asked to extend the consultation period until the strains were available.

After discussion, the SC asked Dr Itoh to inform the Secretariat by mid February on the availability of the strains and progress of the testing, and whether an extension would be needed. The SC would approve an extension by written procedure and decide the duration of the extension at the 12th meeting in May.

Dr O. Itoh, chairman of the EWG explained that the reference strains for draft GL 34 - Tests for the Detection of Mycoplasma contamination comments, were difficult to produce. EDQM had however indicated today that 3 of the 5 strains had passed the feasibility test, and would be distributed to the regions very soon. Dr P. Castle had agreed to run the test worldwide with a uniform testing format. He had promised that the 2 last strains would be produced in time to meet the consultation period.

Dr Itoh reported that great progress had been achieved on the extraneaous agents document, as the EWG was able to identify more clearly what were the relevant issues by focussing primarily on the methodology and the technology. Agreement on this draft GL could be reached fairly quickly.

2 further topics were proposed at the EWG, the first one regarding stability, the other the confirmatory testing of inactivation testing (AHI offered to be the topic leader).

Dr Itoh requested that if a change occurred in the membership of an EWG, the secretariat should immediately inform the chairmen of the EWG

The SC thanked Dr Itoh for his commitment and the EDQM for the great efforts and progress in the production of the reference strains.

FEDESA raised the issue of the scope of the GLs, asking if they covered only “new products”, as usually written, or do they require testing of existing products against new strains.

Dr Itoh confirmed that the mycoplamsa GL covered new products, however in some regions a new GL would have to include the evaluation of the master cells impacting therefore on the existing products. He confirmed that this issue was discussed within the EWG.
Dr Itoh promised to update the secretariat on the status of the reference strains.

The EU asked if the extraneous virus testing should be carried out on the raw material or the finished product. Dr Itoh explained that no clear progress had been achieved yet, although the EWG had already agreed on the master cell and the master seed virus.

The chairman mentioned that this issue had been raised at the 9th SC in London where it had been suggested to develop a “hybrid GL” = some tests could be done on master seeds and some tests could be done on final product. Dr Itoh replied that the EWG would try to reach an agreement on this matter. The final GL could be a hybrid type, or tests could be made in the upstream product or in the final product only.

With regard to the new topic on “Tests for stability in Veterinary Vaccines” Dr Itoh explained that it might require new expertise to the EWG. 2 or 4 meetings should be enough to reach a consensus.

The SC authorised the 7th meeting to take place in Washington in March 2003 and the 8th meeting to take place in Europe (Strasbourg) in September 2003.

8.7. Ecotoxicity/environmental impact assessment

Dr J. Robinson, chairman of the EWG, reported that at the current 7th meeting much progress had been achieved towards harmonisation of the phase II GL.

The start had been difficult as the initial document was composed of 140 pages which had now been reduced to 8 pages; only 3 of the initial 21 issues were yet to be resolved.
He expressed the EWG’s sincere thanks to Dr J. Holland who had compiled the initial document and summarised the 21 contentious issues. The EWG still needed to address how to calculate the expected environmental concentrations; it would probably require one further meeting.

Dr Robinson added that the difficult issues had been solved through trust and mutual confidence between experts.
The SC warmly congratulated Dr Robinson for his leadership and the successes of his EWG over the past few days.

After the end of the EWG meeting, the SC acknowledged the excellent progress made by the EWG at its 7th meeting although a few outstanding issues still needed to be resolved.

The SC authorised an 8th meeting of the EWG to take place in Europe in March 2003, but stated that this would be the last meeting of the EWG to develop a step 2 phase II document.

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

No draft GL was reviewed

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

The Steering Committee once again requested that the EWGs provide the GLs according to the timeframe outlined by the SC and to provide a version where revisions are highlighted for ease of review.

10.1. GL 28 - Studies to evaluate the safety of residues of Veterinary Drugs in Human Food – Carcinogenicity Testing

The Steering Committee adopted GL 28 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 October 2003.

10.2. GL 31 - Studies to evaluate the safety of residues of Veterinary Drugs in Human Food – Repeat-Dose (90 days) Toxicity Testing

The SC reviewed GL31 which had just been signed off at step 5 by the Safety EWG and noted that a few editorial changes would be needed before circulation.

The Steering Committee nevertheless adopted GL 31 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 October 2003.

10.3. GL 32 - Studies to evaluate the safety of residues of Veterinary Drugs in Human Food – Developmental Toxicity Testing

The SC reviewed GL32 which had just been signed off at step 5 by the Safety EWG. The EU indicated that it would need to change the current EU legislation (Annex to Directive 2001/82/EC) to implement GL 32, and therefore requested a longer timeframe for implementation than in the other regions.

The Steering Committee adopted GL 32 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 October 2003, with the exception of the EU implementing this GL at a later date.

10.4. GL 33 - Studies to evaluate the safety of residues of Veterinary Drugs in Human Food – General Approach to testing

The SC reviewed GL33 which had just been signed off at step 5 by the Safety EWG and noted that a few editorial changes would be needed before circulation.

The Steering Committee adopted GL 33 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 October 2003.

11. Review of the VICH2 conference

11.1. Observations

The SC reviewed the VICH2 conference and discussed the outcome of the breakout sessions. Dr Ohshima reported that 197 participants of the 239 registered attended the Conference. The SC congratulated Dr Ohshima for the outstanding organisation of the Conference, which went along without any major problem. The breakout sessions were perfectly timed. The only issue of concern was the late input of the texts by the speakers.

As organiser of VICH1, FEDESA congratulated particularly Dr Ohshima for the very well organised Conference and excellent timings. FEDESA pointed out that it had encountered the same problems with the speakers' written inputs.

Dr Ohshima announced that Japan would try to produce the proceedings of the Conference on a CD.

On behalf of OIE, Dr J. Pearson commented that he was impressed with the quality of organisation of the meeting and the accomplishments of VICH over the past years. He reminded the SC that the OIE had encouraged the VICH to keep the harmonisation process as science based as possible. He added that Dr Vallat, Director General of OIE, had confirmed that OIE would work towards submitting the results of VICH to the OIE International Committee, maybe in 2005. To accomplish this goal, the VICH results should be acceptable to all 162-Member Countries. Dr Pearson indicated that if the GLs were submitted to the International Committee, they would first need to be translated into French and in Spanish, the other OIE official languages.

The secretariat confirmed that Dr Duhaumont, the successor of Dr Boisseau as the head of the OIE Collaborating Center for Veterinary Drugs, had committed to continue the support offered to VICH by the Center. Dr Pearson agreed that OIE would circulate the VICH draft GLs for comment and final GLs for information.

The SC acknowledged that many comments were expressed in the breakout sessions. After discussion, the SC agreed that each EWG should summarise and follow-up on the comments which have been made in these sessions, and report to the SC. The secretariat will write to the chairmen of the EWGs.

The participants to the SC agreed to send their assessment of the VICH2 Conference to the secretariat before 15 December 2002. The secretariat will compile the comments received in a document to be discussed at the next SC meeting.

11.2. Update of the VICH Workplan

After discussion, no further change was proposed. The secretariat will circulate the updated Workplan for review at the next SC meeting.

11.3. Adoption of the Press Release for VICH2

see item 14.

11.4. Forecast for VICH3

The US delegation confirmed that the VICH3 Conference would take place in USA. After discussion, the SC agreed that the Conference should take place in Spring 2005.

12. Any other business

12.1. Report from Ecotoxicity EWG

included in item 8.7

12.2. Pharmacovigilance

The discussion on the pharmacovigilance EWG (see item 8.2) was continued on the last day of the SC meeting as follows:

The SC acknowledged that no further progress towards harmonisation had been made at the VICH2 breakout session. Several members expressed their concern on the negative comments towards the authorities, which had been expressed in the breakout session. The SC discussed once more the different possible ways forward.

The EU and FDA confirmed their opposition to the deletion of section V of GL 24 and proposed to find a common understanding on how the electronic reporting system should work.

As the main divergences are due to differences in approach between the FDA and the EU, the SC strongly encouraged the EU and FDA to start discussions without delay toward possible solutions for this issue and to inform the secretariat in writing on the progress achieved. The SC expected the EWG to provide a recommended solution at the 12th SC meeting at the latest.

Meanwhile, the SC agreed to put the Pharmacovigilance EWG on hold until the 12th SC meeting and asked the secretariat to inform the chairman of the EWG.

12.3. Camevet

Apologies have been received from Camevet.

The SC expressed its concern that Camevet, the new Interested Party, had not attended the 11th SC meeting and asked the secretariat to remind Camevet of the rules applying to Interested Parties.

13. Dates and venue of next meetings

- The 12th SC meeting will take place on 7-8 May 2003 in Europe (London).
- The 13th SC meeting will take place on 7-8 October 2003 in USA (Washington).

14. Adoption of the press release

The SC reviewed the 2 separate press releases for VICH2 and the 11th SC meeting prepared by the secretariat and decided to merge both texts into 1 document, which was adopted.

The chairman closed the meeting by thanking the SC participants for their constructive support over the past 2,5 days of meeting.

On behalf of the SC he bid farewell to Dr A. Turner and expressed the gratitude of the SC for the amount of work that Dr Turner has achieved since joining VICH at the 5th SC meeting in May 1999.

VICH STEERING COMMITTEE

11th meeting

8-9 & 12 October 2002
Tokyo, Japan.

Chair: Dr N. Hirayama, JMAFF

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI	K. MCCLURE
AHI (PFIZER)	M. J. MCGOWAN
AHI	S. PHELAN (C)
EUROPEAN COMMISSION (ENTERPRISE)	P. BRUNET represented by A. WENNBERG
EMEA	K. GREIN (C)
EMEA-CVMP (BgVV)	R. KROKER
FEDESA (BAYER)	L. KLOSTERMANN
FEDESA (INTERVET)	J. WIEDA
FEDESA	S. ZÄNKER (C)
JAPAN MAFF	M. KURIMOTO
JAPAN MAFF	T. SHIMAZAKI (C)
JAPAN MAFF	Y. TAKAHASHI
JVPA (MEIJI SEIKA KAISHA)	K. SAWADA
JVPA	S. OHSHIMA (C) (part)
JAVB (KIKUCHI RESEARCH CENTER)	S. TOKIYOSHI
USDA APHIS CVB	R. HILL
US FDA	M. SMITH
US FDA	L. BEAVER (C)

OBSERVERS

AVCARE/AGCARM	P. HOLDSWORTH
ANZ (NRA)	A. TURNER
CANADA	I. ALEXANDER
CAHI	J. SZKOTNICKI

INTERESTED PARTY

AVBC	J. THOMAS

ASSOCIATE MEMBER

OIE	J. PEARSON (Part)

INVITED

ANZ	D. MORRIS
US FDA	S. SUNDLOF (Part)
US FDA	T. MULLIGAN (Part)
US FDA	L. POST (Part)
AHI (PHARMACIA)	J. ROBINSON (Part)

EU	D. MEVIUS (Part)
JMAFF	O. ITOH (Part)
JMAFF	H. MAKIE (Part)
JVPA (MERIAL)	T. NAGATA (Part)

VICH SECRETARIAT

IFAH	H. MARION
IFAH	J.-L. DELFORGE

APOLOGIES

OIE	B. VALLAT
CAMEVET	C. FRANCIA