VICH/00/161
31 January 2001
FINAL

VICH STEERING COMMITTEE
8th meeting
20-21 November 2000
Washington, USA

Minutes of the meeting

1. Opening of the meeting and chairman's introduction

Dr S. Thompson, chairperson, welcomed the attendees and thanked Ms S. Phelan for the outstanding preparation of this meeting. Dr Thompson congratulated Dr N. Hirayama for having chaired the 7th SC meeting in Tokyo and having set the high standards for the rotating chairmanship.

Dr Thompson introduced the chairmen of the Expert Working Groups who will present their progress reports to the SC: Dr J. Robinson, for the EWG on Ecotoxicity, Dr T. Mulligan, for the EWG on Safety and Dr W. Keller for the EWG on Pharmacovigilance. Dr Thompson finally introduced the two staff persons from CVM assisting with the meeting, Ms C. Andres and Dr P. Chamberlain, as well as Mr John Thomas attending on behalf of the AVBC (Association of Veterinary Biologics Companies) as a potential interested party.

2. Adoption of the agenda

One item was added to the agenda: *11.6 Participation of Associate Member in working groups*. The agenda was adopted with this 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. The SC noted that there had been no new developments since the last SC meeting. The EWG had achieved its initial mandate and no new task had been requested.

The VICH GLs 1 to 5 are already implemented and VICH GLs 17 and 18 will be implemented at the latest in July 2001.

3.2. Efficacy requirements for Anthelmintics

The SC reviewed the written report prepared by the chairman of the Working Group, Prof J. Vercruysse, and presented by the EU. The SC acknowledged that following the request of its last meeting asking the EWG to adopt the draft GLs 15, 16 and 19 by written procedure, the EWG had expressed the need of a face to face meeting to review and finalise the last 5 drafts guidelines together. The SC agreed to discuss the adoption and release of the Corrigendum to GL7 under agenda item 5.

The final meeting of the EWG will take place on 5-7 January 2001 in Australia.

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3.3. Ecotoxicity/environment impact assessment

Dr J. Robinson, chairman of the Working Group, reported that the last meeting was particularly challenging as strong regional differences of views had been expressed. The aim had been to finalise the decision tree for Phase II. Agreement was reached on the following:

- The minimum dataset requirements for the three branches of Phase II Tier A,
- The criteria to be used in deciding when further testing beyond Phase II Tier A are needed, and on
- The Tier B testing requirements as well as decision making criteria that would prompt more extensive review and/or risk management beyond Tier B.

It was agreed that Phase II Tier C issues should be dealt with on a region-by-region basis. For products at Tier C, the applicant and the regional authority should decide on a case-by-case basis whether to use testing requirements and/or the risk management options. The testing requirements for Phase II should rely on OECD GLs. In the cases where no OECD GLs exist, the industry will explore developing proposals.

Dr Robinson proposed to hold the next meeting in Japan on 15-18 May 2001. He added that a 7th meeting might be necessary because of the difficulty and complexity of this subject.

JMAFF thanked Dr Robinson for leading this EWG and added that extensive discussions would probably take place in the forthcoming meeting. JMAFF believed also that an additional meeting might be necessary to resolve all issues for the Phase II GL. Environmental evaluations are new issues for Japan, and it will probably be difficult to resolve all outstanding questions before the next meeting. Consequently, JMAFF supported the idea to extend the EWG's work programme after the next meeting.

Dr Robinson stressed that it would be very difficult to solve problems by electronic discussions. In this case, face-to-face meetings were necessary.

The EU added that the planned Society of Environmental Toxicology and Chemistry (SETAC) meeting would have to be postponed if no Phase II GL was produced in May.

The SC authorised the 6th meeting of the EWG in Tokyo on 15-18 May 2001. The SC authorised in principle a 7th meeting. The time and location will be confirmed at the next SC meeting.

3.4. Safety & Task Force on Microbial Safety

Dr. T. Mulligan, chairman of the Working Group, reported that at the 5th meeting of the Safety Working Group it was decided to adopt the term "repeat dose studies" to clear up any confusion over the use of the terms chronic and subchronic since opinions differ on the actual length of a chronic vs. a subchronic study. Thus, studies will be referred to as 28-day repeat-dose study, 90-day repeat-dose study, 1-year repeat dose study, etc.

The working group rejected the proposal of using a 28-day repeat dose study for the initial selection of the most sensitive species due to insufficient data to support doing so, although all members were in favour of the proposal. They are now considering the use of two 6-month repeat dose studies in two different species (rodent and non-rodent) to fulfil the requirement for a long-term study.

The working group decided that neurotoxicity testing would be incorporated into protocols for repeat-dose studies as opposed to having a separate study for neurotoxicity testing.

For developmental toxicity studies, both the rat and the rabbit will be used. The rat study will be required first. If a NOEL for developmental toxicity cannot be established in the rat, testing in the rabbit will be required. If a NOEL is established in the rat, the rabbit study will not be required.

Proposed goals for the 6th meeting include review of the comments received in the consultation period on GL22 (reproduction) and GL23 (genotoxicity), final draft of the carcinogenicity guidelines, second draft of the repeat dose studies guideline, 5th draft of the guideline on general approach to testing, draft of developmental toxicity guideline, topic papers on length of long-term repeat-dose studies and on approach to developmental toxicity testing.

Step 2 guidelines are scheduled to be signed-off by the EWG as follows:

- 6th meeting: carcinogenicity and general approach to testing
- 7th meeting: repeat dose studies and developmental toxicity
- 9th meeting: microbial safety (this GL developed by the TF will be reviewed by the EWG at its 8th meeting)

Concerns were expressed over the large number of EWG meetings necessary to fulfil these tasks. After discussion, the SC however agreed that the multiple issues in discussion and the number of problems to be solved required several meetings.

Dr Mulligan proposed that the 6th meeting of the EWG be held in conjunction with the International Congress of Toxicology, 8-12 July 2001 in Australia, since a majority of the members of the SWG also plan to attend this meeting.

The EU explained that according to the recently revised EU budget appropriation, in future only meetings held in the 3 regions could be covered by the EU budget. The SC discussed this issue thoroughly and finally decided to amend the organisational charter in order to limit future meetings of EWGs to take place within the 3 regions only.

The SC authorised the 6th meeting of the EWG to be held in the Europe in July 2001. The SC recommended that the EWG should try to schedule further meetings at 4 to 5 month intervals in order to fulfil its tasks prior to the VICH2 conference scheduled in October 2002.

Report on the Microbial Safety Task Force (TF)

Dr Mulligan reported that the task force held its first meeting in July 2000. It reviewed its mandate and identified the tasks to be addressed. The task force focused on basic science issues with a view to what was available and what was needed to address microbial safety. Several tasks and topic papers were assigned during that meeting for review at the 2nd meeting including:

1) a literature review of the consequences of changes in intestinal microflora populations,
2) a literature review of bile acid metabolism,
3) concept paper on the meaning of "increased resistance" and implications thereof,
4) concept paper on binding kinetics
5) investigation into the sampling approaches and use of faecal samples for testing and analysis purposes,
6) literature review on inherent variability of human bacterial populations and in numbers/percentage of resistant bacteria,
7) analysis of the FDA results using statistical procedures in microbial safety studies and
8) a concept paper on other models used to evaluate microbial safety.

Dr Mulligan anticipated that the TF would need 3 additional meetings spaced 6 to 9 months apart in order to fulfil its mandate. A draft guideline should be ready for review at the 8th EWG meeting. The EWG also hopes to continue to utilise the expertise from the TF when needed for further guideline development.

Japan expressed concerns over the number of meetings planned for the TF since the original plan was for only one single meeting. It appears now that the TF is operating like an additional working group although the VICH charter only allows 6 operating working groups.

After discussion the SC authorised the TF to hold one but extended more meeting in May 2001 in Brussels. This would be the final meeting of the TF. The TF would then draft a recommendation, which will be forwarded to the EWG for review at their next meeting.

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 had met 3 times and 2 draft GLs had been produced on moisture (GL25) and on formaldehyde (GL26) and 2 other guidelines (mycoplasma and extraneous virus) were in an advanced stage. After the last SC meeting, the EWG met in July 2000. The EWG requested guidance from the SC on the 3 following issues:

1) Is the scope of the Guidelines limited to new vaccines only, or are diagnostic kits and sera to be included?
2) Is extraneous agents detection testing limited to extraneous virus detection in live viral vaccines?
3) Can the results of the joint testing of the formaldehyde and residual moisture be published in a scientific journal?

Regarding the scope of the Guidelines, the concept paper provides for new vaccines. The approach is different in each region. Several members thought that limiting the scope to new vaccines would enable the WG progress rapidly in solving the issues. However other members believed that this limitation might postpone the harmonisation process and that the concept paper should be revised. The SC agreed finally that the SC members from regulatory authorities in the 3 regions should comment on the scope of the guidelines during the consultation period.

The SC agreed that the EWG would start with the extraneous agents detection in live viral vaccines. However, the EWG will be encouraged to broaden its scope.

The SC authorised the publication of the results of the joint testing of the formaldehyde and residual moisture be published in a scientific journal.

The SC authorised the 4th meeting of the EWG to take place in Tokyo, but requested that the meeting proposed from 28 May to 1 June 2001 should be postponed for 1 or 2 months in order to enable the experts to review all comments received on GL25 and GL26 by the 31 May 2001 deadline.

3.6. Pharmacovigilance

Dr W. Keller, chairman of the Working Group, reported that several tasks assigned to the WG had been completed and the draft GL (GL24) on the management of adverse reactions was in the consultation process. The deadline for comments was 31 December 2000. No comments had been received so far.

At its 7th meeting, the SC had requested that inconsistencies should be eliminated from this GL, but the specific inconsistencies were not identified. ANZ agreed to provide Dr Keller with a tabulated list of inconsistencies.

Dr Keller indicated that the EWG needed guidance from the SC on the details that the periodic safety update module (PSU) should include, as this was not originally specified in the terms of reference of the EWG. The EWG could finish these tasks during its next meeting, although a 5th meeting might be necessary. Depending on the level of information required, additional expertise might also be needed.

The chairperson reminded Dr Keller that the original tasks of this group included veterinary pharmacovigilance and electronic standards for the transfer of information.

Dr Keller commented that, adverse reactions that were high priority should be reported immediately, and those that were low priority should be reported in the PSU.

The representatives from industry stated that the quantitative data should be reported in a simple harmonised format. The system should be practical and affordable.

The SC agreed that the EWG will deal with Periodic Safety Update but recommended that it should be kept simple. The SC agreed to review the EWG mandate as it relates to periodic safety update and asked the EWG to report back to the SC on the scope of the PSU.

On Adverse Drug Reporting, Dr Keller stressed the complexity of capturing data in a computer database. He asked for advice on which details needed to be captured in a database and on what standard reporting format should be developed. The SC, not having the necessary expertise, suggested the EWG to make a recommendation to the SC. It was however agreed that VICH should not follow the detailed ICH model. Things needed to be kept practical and affordable.

On the development of an internationally acceptable terminology database, the EWG requested feedback on how it was going to be funded. The MEDDRA database developed by ICH is very complex and expensive, and funded by the human pharmaceutical industry. Dr P. Jones indicated that the EMEA had developed a VEDDRA dictionary modelled on MEDDRA, which was regularly updated. It appeared that such a dictionary needed to be updated on a regular basis and that there were important financial implications. The workload required for the maintenance, updating, translation and dissemination of the latest version is tremendous and would need to be subcontracted. The industry stressed that without more information it could not commit to funding such a database at this time. It was nevertheless unanimously agreed that an efficient international electronic exchange of information required such a terminology database.

It was finally agreed that the EWG should develop a paper on the scope of work and cost estimate for the internationally acceptable terminology database, addressing in particular the fact that this will be an ongoing project, and report to the SC well in advance (1 month) of its 9th meeting.

Dr Keller finally stated that at the last meeting a number of individuals were missing and that he felt that a lack of continuity had developed within the EWG. He stated that it was important all SC members should have representation at every meeting. Dr Jones clarified that contrary to what was reported in the EWG minutes, the EU was represented at that meeting by Dr Kamphuis.

The SC authorised the next meeting of the EWG to be held in April or May 2001 in the USA.

3.7. 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 the issues dealt with by the EWG are very controversial and that it had difficulty in reaching consensus on several aspects: animal studies, categorisation of antimicrobials, and how much detail was requested in the GL. Should the EWG produce a general GL or should each test be considered in detail in the GL? The EWG reached the conclusion that it would be better to have a guideline on the overall package (rather than detailed tests) from which the regulatory authorities could draw conclusions. Based on this initial information and potentially the categorisation of the product, additional studies, such as animal studies, may be requested. On the subject of whether animal studies should be requested, the EWG was not able to reach consensus, as no in-vivo models exist. The chairman felt that consensus on this issue would be difficult to achieve at the next EWG meeting.

The issue of prudent use recommendations in labelling has yet to be discussed; however, the EWG recommended that this subject be addressed in a separate guideline.

The SC agreed that at its next meeting the EWG should finalise at Step 2 a draft guideline on the general components of the safety package and prepare a draft GL on prudent use labelling

recommendations. The discussion on the animal testing requirements and the categorisation issue should be postponed to a further meeting.

The SC authorised the 3rd meeting of the EWG to take place on 9-10 May 2001 in Tokyo.

3.8. Target Animal Safety (TAS)

The SC reviewed the written report prepared by the chairman of the Working Group, Dr T. Nagata, and presented by JVPA. The SC acknowledged that the EWG had just held its 1st meeting the previous week in Tokyo. 14 experts had participated in this meeting. Each region gave an overview of the current requirements for registration. The WG agreed on the final concept paper on the TAS for pharmaceuticals. The EWG also agreed to prepare a guideline in the format requested by SC. There was agreement to give consideration to documents prepared by JAVP and a guidance document prepared by FDA and to produce a draft guideline comprising points raised in both documents. Each region was to take back home the outstanding issues and come back with its own proposal at the next meeting.

The EWG gave consideration to the proposal from JAVB on TAS for biologicals, revised by FEDESA and some modifications were made. JAVB thanked FEDESA and USDA for their help to draft the concept paper. The EWG suggested that the biological batch release safety studies should be an issue for the BQMWG. The SC decided to discuss this item under 8.1.

The SC authorised the 2nd meeting of the EWG to take place in May 2001 in Europe

Finally the EWG requested that the names of the experts should not appear on the VICH website in order to prevent targeting by animal rights activists. The SC unanimously agreed to this request. Additionally, it was agreed to discuss this topic further under 12 as a general policy.

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

4.1. GL25 – Testing of residual formaldehyde

The SC received the text of GL25 as a proposed guideline at Step 3. The SC agreed that the deadline for comments on this GL is 31 May 2001. This guideline was transmitted to the VICH members for a 6 months public consultation period at Step 4 until 31 May 2001.

4.2. GL26 – Testing of residual moisture

The SC received the text of GL26 as a proposed guideline at Step 3. The SC agreed that the deadline for comments on this GL is 31 May 2001. This guideline was transmitted to the VICH members for a 6 months public consultation period at Step 4 until 31 May 2001.

5. Adoption and release of Corrigendum to GL7 – Efficacy of Anthelmintics: General Requirements

The SC adopted Corrigendum to GL7 and agreed on an immediate implementation date.

This corrigendum was transmitted to the VICH members for implementation at the same time as GL7 in December 2000 at the latest June 2001 in the three regions at Step 7.

The corrigendum being adopted, the SC authorised the publication of the VICH anthelmintic Guidelines together with the corrigendum.

6. Implementation of final VICH Guidelines

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

The representatives of the authorities from the EU, Japan and the USA indicated that they had nothing new to report since the 7th SC meeting.

The representative of the authorities from Australia/New Zealand reminded the SC that ANZ considered itself under a similar obligation to report to the SC. She indicated that GL 6, GL 17 and GL 18 will be implemented by May 2001. All the other Guidelines have been implemented as in the VICH member regions.

The EU will inform the SC if the situation in the EU changes with regard to the current conditions of implementation of Phase I guidelines for Ecotoxicity.

6.2. Review of the status paper on how the VICH Quality GLs are applied in the different regions

FEDESA reported that at its 7th meeting, the SC had asked to investigate how the VICH Quality Guidelines were implemented in all regions. FEDESA thanked the US authorities and industry, which replied to the questionnaire, as well as the EU, which has addressed the questionnaire to all EU Member States. FEDESA is awaiting the remainder of replies before consolidating the responses.

The issue is to find out if the quality guidelines (Guidelines 1, 2, 3, 4, 5, 8, 10, 11, 17 and 18) are applied to new products only or also to renewals of existing products?

The EU explained that all quality Guidelines are applied to new entities in the EU Member States and the EMEA. There have been differences in interpretation of the questionnaire form sent out by FEDESA in the different Member States on what is new. The CVMP in turn believes that these guidelines on quality should be applied to existing products when they come up for renewal each five years, but finalisation of this still has to be discussed within CVMP.

JMAFF explained that Japan has a system of re-examination of the applications. If a different applicant makes an application for a product, it is treated like a new drug. After 6 years have expired it is considered an old product. More detailed information will be provided to FEDESA.

The USA explained that the VICH Guidelines would apply to new products or to new sponsors of an already approved chemical entity or when an existing product is changed, e.g., new indication or new dosage form.

The SC expressed its concerns about guidelines not being equally applied in the different regions. The SC asked the EU to supply additional information before the next meeting.

FEDESA will review and consolidate the answers to the questionnaire, with the help of the EU and input from SC members, before the next SC meeting (end April 2001).

7. VICH Strategy and Work Programme

7.1. Adoption and prioritisation of the list of potential future topics

The secretariat presented the revised document and explained the changes that had been incorporated in the new version, following the comments received from the SC members. After a thorough discussion on the list of potential future topics (chap II.2), the SC agreed to add the following sentence before the list: “The following list should be considered as a proposal which was set up in November 2000. The SC can amend this list at any time in particular by adding further new topics to the list.” The SC decided also to remove any prioritisation to the proposed topics and adopted the list as it was presented.

The SC agreed that each proposed item would need the development of a concept paper before consideration as a new VICH topic.

7.2. Adoption of the timeframe

JMAFF reminded the participants that when the timeframe was originally discussed, the SC had felt that the objective of 2010 was too long. JMAFF therefore proposed that a deadline should be set for 2005. Other members considered however that it was difficult to set a deadline and that 2005 was ambitious considering the number of the priority topics, which had been set.

After discussion the SC agreed to revise some of the wording in the introduction of the document, in order to indicate that the goal is to complete work by 2005. The SC agreed however to review the work plan on a regular basis to evaluate, if necessary, the need to extend the date of completion goal.

The OIE recalled its role in the dissemination of VICH documents to promote consultation and communication that result in wider international awareness of VICH guidelines. The OIE indicated that VICH currently elaborates criteria and requires acceptance and implementation by its member countries. To alleviate these remarks, the SC agreed to add the words “within the 3 regions” to the document.

The SC adopted the work plan including all the changes.

The secretariat reminded the participants that the work plan included a proposed schedule for meetings of the SC and the Working Groups and will encourage the chairmen and topic leaders to organise future meetings of the EWG in compliance with this schedule whenever possible.

8. New topics

8.1. Review of the concept paper on Target Animal Safety for biological products

JAVB presented the concept paper and explained that the suggestions from FEDESA had been incorporated.

After discussion, the SC agreed that the batch release tests should be removed from the concept paper and added to the list of priority topics in the Work Plan for future work by the Biologicals Quality Monitoring WG.

The SC approved the concept paper as amended.

8.2. Review of the concept paper on Q6A and Q6B quality guidelines

AHI reported that it had reviewed the ICH GLs Q6A and Q6B. AHI recommended that the Quality WG should review these 2 ICH GLs by written procedure to determine if the corresponding VICH Guidelines should be revised.

The SC endorsed the proposal. The secretariat will ask the chairman of the Quality Working Group, Dr Makie, to initiate the review of these GLs by written procedure.

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

A written document prepared by FDA and USDA was circulated.

10. Communication

10.1. VICH2 conference (Venue & date, Outline of the Programme)

Japan indicated that it was willing to host the VICH2 conference. The other regions warmly supported this suggestion. FEDESA offered its full support to assist Japan with the preparation of VICH2.

The SC discussed the outline prepared by the secretariat. The SC agreed that VICH2 would take place in October 2002 in Tokyo.

The SC agreed that the plenary session should include a discussion item on the future direction of VICH.

The SC asked the secretariat to recirculate the assessment of VICH1 in order to review the comments and proposals expressed after the conference as a source of suggestions for possible improvements.

The SC proposed to include a session on the costs and benefits of the VICH process and how it has affected the veterinary medicine's availability.

The SC decided to discuss the outline of the program proposed by Japan at the next SC meeting and agreed that a SC meeting should take place together with the VICH2 conference in Tokyo. The planning of the rotation of future SC meetings will therefore be revised at the next meeting.

10.2. Review of VICH Communication

The EU reported that the SETAC (Society of Environmental Toxicology and Chemistry) was planning a workshop on the environmental impact of veterinary medicinal products in order to review the VICH guideline on Phase II Ecotoxicity/Environmental assessment. The EMEA had been asked to co-sponsor the workshop. The plan is to hold the workshop during the 6-month comment period for the Phase II document. The EU confirmed that the date of the workshop would not be set until the Phase II document is released. The comments generated at this workshop will be reviewed as any other comments received during a consultation period.

The EU stressed that the EMEA would not support this workshop if it took place before the Phase II document was released for consultation.

Concern was expressed that a worldwide review of this very specific area of environmental concern may result in requiring the working group to address new issues or questions that are not relevant and will only serve to delay the completion of the document. The SC agreed however that all comments were welcomed and that the VICH should not act as a "closed forum".

The SC supported the proposal provided that the workshop is held during the consultation period of the Phase II GL.

10.3. Report from OIE on its activities as Associate Member of VICH

Dr Röstel representing OIE referred to Dr Blancou’s letter of October 2000 reiterating OIE's commitment in the VICH activities and suggesting, to improve awareness of VICH, among others, to include an hyperlink to VICH on the OIE website. It will however be the new Director of OIE, beginning his term on 1 January 2001 who will comment on the role of OIE as an associate member in VICH, probably after the meeting of the OIE International Committee in May 2001.

JMAFF was of the opinion that the role of OIE defined in the Organisational charter was sufficient, unless OIE would like to express other roles.

The representative of OIE confirmed that from the very beginning OIE has disseminated the draft and final Guidelines. Comments have been received and sent to the VICH secretariat. To the concerns expressed by SC members on the dissemination of VICH information by OIE, the representative of OIE explained that the documents are sent to the official delegate of OIE who then must redirect them to the appropriate channels within his country The OIE will investigate the possibility to send the VICH information in the future in parallel to the relevant national authority responsible for veterinary drug registration.

The EU stated that some developing countries are "reinventing the wheel" when setting up new regulatory agencies. In these cases, the VICH GLs could be very helpful to them. VICH should communicate as much as possible to them.

The SC endorsed the OIE proposals to improve communication and asked the secretariat to answer Dr Blancou's letter.

11. Review of VICH procedures and functioning of the VICH process

11.1. Clarification of VICH step procedure

The secretariat highlighted the changes included in the new version of the draft document. The SC adopted the draft 2 as the final version of this document.

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

The secretariat highlighted the changes included in the new version of the draft document. The FDA stressed that any revision to an existing guideline would need to go through a consultation process, unless the changes were editorial only.

After discussion, the SC adopted the draft 2 as the final version of this document, including the following new wording: “such as for minor editorial changes”

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

The representative of AVBC was not present during the discussion of this item.

The SC reviewed each paragraph of the draft document prepared by the secretariat and agreed on a number of changes.

After discussion the SC agreed to the following principles:

- Accreditations to attend SC meetings shall be granted to Interested Parties (IP) on a permanent basis. However, the accreditation would be withdrawn if they failed to attend 2 consecutive SC meetings.
- The IP will have to provide a copy of its constitution to the secretariat.
- The SC could decide to grant an accreditation to an IP by written procedure, providing the request is made in writing to the secretariat at least 3 months before the SC meeting.
- The IP will have to sign a confidentiality agreement
- The IP will receive SC meeting documents.

The secretariat will circulate the revised document to the SC for final adoption by written procedure.

The SC decided to accept the AVBC as Interested Party provided that the AVBC complies with the requirements and produces the requested documents.

11.4. Costs and benefits assessment derived from VICH activities

The EU reported that no new element had been registered since the last SC meeting. After discussion, the SC agreed that it might be premature to discuss this item. The industry's representatives highlighted the difficulty to define clear figures for this evaluation.

The SC could not agree if this item should be included in the VICH2 programme but will reconsider it again at its 10th SC meeting in fall 2001.

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

The FDA indicated that a few suggestions had been received since the last SC meeting. It appeared difficult to set up a glossary applicable to all VICH guidelines until the definition of "new" was agreed to by the SC. Once the definition of "new" is approved, the FDA suggested that the glossary of ICH GL Q7A should be considered by the VICH SC.

JMAFF explained that there were some words, which are commonly used in the VICH process, but are sometimes misunderstood and misused. These words must first be identified. JMAFF offered to submit a list of these words.

After discussion, the FDA, with the help of FEDESA, agreed to collect and review the terms which need to be defined at SC level. A draft proposal taking into consideration the suggestions received will be circulated well in advance of the next SC meeting.

In the meantime, FEDESA will come up with a definition of "new" and volunteered to draft a concept paper on ICH Q7A for discussion at the next meeting.

The SC members agreed to send their suggestions on terms to be defined to FDA before the end of January 2001. The FDA will circulate a proposal before the end of March 2001 to the SC for discussion at its meeting in June.

11.6. Participation of the Associate Member in WG

The Secretariat explained that OIE had requested to participate in the EWG on Antimicrobial resistance, shortly before its last meeting. Given that the Organisational charter provided that additional experts from other regions may be appointed to working groups but at its 5th meeting, the SC had decided that the associate member may not appoint experts to working groups, the Secretariat had requested a decision by written procedure. However, no consensus was reached.

Some SC members requested that OIE should define its role in VICH before deciding on OIE's participation in WGs.

The representative of OIE reported that the OIE guidelines on Prudent Use of antimicrobials were close to finalisation. A copy would be provided to the SC when available for circulation to the EWG. She requested that the decision be based on what is in the best interest of the guideline and moving the process forward.

After a thorough discussion, the SC agreed to allow a representative of the OIE to attend the antimicrobial resistance working group meeting as an observer. The SC decided to address this issue again after a response was received from OIE defining the role of OIE in VICH. The secretariat will inform the OIE and the EWG chair.

12. VICH process efficiency

12.1. Guidance document on the establishment of Working Groups and the appointment of experts and chairs by SC members

The SC reviewed briefly the draft document prepared by Dr A. Turner assisted by the secretariat. A few editorial changes were included in the document. No major concern being expressed, the SC decided that the revised version would be circulated by the secretariat in December. Further detailed comments will be sent to the secretariat before the end of January 2001. The SC agreed that the document would be approved by written procedure.

12.2. Guidance document for WG members

The SC reviewed briefly the draft document prepared by Dr A. Turner assisted by the secretariat. A few editorial changes were included in the document. No major concern being expressed, the SC decided that the revised version would be circulated by the secretariat in December. Further detailed comments will be sent to the secretariat before the end of January 2001. The SC agreed that the document would be approved by written procedure.

12.3. SOP on VICH procedures regarding the operations of the WGs

The SC reviewed briefly the draft document prepared by Dr A. Turner assisted by the secretariat. A few editorial changes were included in the document. No major concern being expressed, the SC decided that the revised version would be circulated by the secretariat in December. Further detailed comments will be sent to the secretariat before the end of January 2001. The SC agreed that the document would be approved by written procedure.

12.4. Policy for disbanding working groups

The SC reviewed the draft document prepared by the secretariat with the input from members of the SC. A few editorial changes were included in the document. No major concern being expressed, the SC decided that the revised version would be circulated by the secretariat in December. Further detailed comments will be sent to the secretariat before the end of January 2001. The SC agreed that the document would be approved by written procedure.

12.5. Policy on consultation at step 4

The SC reviewed the draft document prepared by the secretariat with the input from members of the SC. A few editorial changes were included in the document. No major concern being expressed, the SC decided that the revised version would be circulated by the secretariat in December. Further detailed comments will be sent to the secretariat before the end of January 2001. The SC agreed that the document would be approved by written procedure.

12.6. Policy on how appreciation can be shown to the chairs and WG members for their work and how they can communicate with the SC members

The SC reviewed the draft document prepared by the secretariat with the input from members of the SC. A few editorial changes were included in the document. No major concern being expressed, the SC decided that the revised version would be circulated by the secretariat in December. Further detailed comments will be sent to the secretariat before the end of January 2001. The SC agreed that the document would be approved by written procedure.

13. Any other business

Concerns were expressed about persons possibly being targeted by animal rights activists and subjected to harassment or personal danger, because their names appeared on the VICH website. However, not posting names was counter to the purpose of transparency. The SC decided therefore that the names of the Experts of the TAS WG will be removed from the VICH website. The SC agreed that the secretariat will raise the issue with the chairmen of the various WGs who would decide whether or not the names of their experts should be posted.

Dates and venue of next meetings

The 9th VICH SC meeting was scheduled on 27-28 June 2001 in London.

The 10th VICH SC meeting was scheduled at the end of November 2001 in Tokyo, Japan.

Considering that the SC requested written reports from WGs at least 2 weeks prior to SC meeting, the secretariat will circulate the schedule included in the workplan to the chairmen of the WGs and ask them to schedule future meetings taking into account the SC meeting dates.

15. Adoption of the press release

The secretariat circulated the draft press release to the SC members for an approval by written procedure.

VICH STEERING COMMITTEE
8th meeting

20-21 November 2000
Washington, USA

Chair: Dr. Sharon Thompson, US FDA

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI	R. A. CARNEVALE
AHI (PFIZER)	M. J. MCGOWAN
AHI	S. PHELAN (C)
EUROPEAN COMMISSION (ENTERPRISE)	P. BRUNET
EMEA	P. JONES (C)
EMEA-CVMP (BgVV)	R. KROKER
FEDESA (BAYER)	L. KLOSTERMANN
FEDESA (INTERVET)	J. WIEDA
FEDESA	S. ZÄNKER (C)
JAPAN MAFF	S. MIYAJIMA
JAPAN MAFF	N. HIRAYAMA
JAPAN MAFF	K. OISHI (C)
JVPA (MEIJI SEIKA KAISHA)	K. SAWADA
JAVB (KYOTO BIKEN)	T. TOKUI
USDA APHIS CVB	R. HILL
US FDA	S. THOMPSON
US FDA	R. LIVINGSTON (C)

OBSERVERS

AVCARE/AGCARM	P. HOLDSWORTH
ANZ (NRA)	A. TURNER

ASSOCIATE MEMBER

OIE	B. RÖSTEL

INTERESTED PARTY

AVBC	J. THOMAS

INVITED

EUROPEAN COMMISSION (ENTERPRISE)	J. WEISSENBERGER
AHI	K. MCCLURE
AHI (P&U)	J. ROBINSON (part time)
FDA	W. KELLER (part time)
FDA	T. MULLIGAN (part time)

VICH SECRETARIAT

COMISA	H. MARION
COMISA	A. MUDD
COMISA	F. PARDO

APOLOGISED

JVPA	S. OHSHIMA (C)

SUPPORT SECRETARIAT

US FDA	C. ANDRES
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