VICH/97/044 - Rev. 2
Nov. 7, 1997

VICH STEERING COMMITTEE
2nd meeting
20 - 21 August 1997
Paris, OIE Headquarters

Minutes of the meeting

1. Opening of the meeting and chairman's introduction

Dr. Reichard gave a welcoming address on behalf of Dr. J. Blancou, Director General of OIE. He praised the progress of VICH and confirmed the continuous support of OIE to the process. He highlighted that the objectives of VICH are fully compatible with the mandate of OIE and its results will contribute to the objectives of OIE in terms of standardisation and facilitation of trade.

Dr. Boisseau thanked the OIE for the logistical and substantial support. He expressed satisfaction at the progress achieved since the 1st SC meeting. He thanked the members, coordinators, experts and the secretariat for their positive contributions which enabled a smooth start of the process.

An introductory roundtable followed to introduce new representatives from ANZ (Australia/New Zealand) Mr. T. Knox who replaced Ms. Deuss, Dr. Wieda replacing Dr. Verschueren as representative of FEDESA and Dr. Yoshimura who represented JMAFF on behalf of Dr. Makie. Dr. Batalha represented Mr. Deboyser (EU) on the first day.

2. Adoption of the agenda (VICH/97/016 - Rev. 1)

A revised version of the agenda was circulated to the SC. Dr. Boisseau suggested to discuss item 7 as the last part of item 3. The following issues were explicitly added to the agenda : membership of the SC, guidance to the WGs and location of future SC meetings.

With these amendments, the agenda was adopted.

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

The SC reviewed the document VICH/97/032, prepared by the Secretariat and attempting to clarify the issues raised by members in relation to the procedures and the functioning of VICH. These points were the basis for the discussion and for possible amendments to be made to the organisational charter of VICH (VICH/96002).

Scope of VICH (i.e. definition of) "veterinary medicinal products"

The SC agreed that, for the time being, the scope of VICH should be limited to pharmaceuticals, biologicals and medicated premixes and specified as such. The organisational charter will be amended accordingly and the WGs will be given clear guidance.

Secretariat : c/o COMISA, rue Defacqz, 1 - B - 1000 Bruxelles (Belgium) - Tel. +32-2-543.75.67, Fax +32-2-537.00.49

Steering Committee

*** membership of SC**

The SC discussed the possibility of adding additional countries and/or organisations to the VICH SC as observers. Dr. Boisseau suggested that these requests should be transmitted in a written form to the SC through the secretariat for consideration and decision by the SC members. The Secretariat was requested to prepare a discussion document, based on the input from the SC members, on the criteria for the participation of other countries in the VICH as SC observers.

Action : All/Secretariat

With regard to the request from the US Association of Veterinary Biologicals Companies (AVBC), the SC agreed that AVBC could contribute to VICH through the US representatives. The Secretariat was asked to respond to AVBC.

Action : Secretariat

As far as the participation of international organisations as observers is concerned, the SC confirmed that, for the time being, that OIE was fulfilling the role of disseminating the results of VICH, a role played by WHO in ICH.

*** participation of WG chairperson and topic leaders in SC meetings (first part; to be continued under agenda item 5)**

In the absence of any clear consensus and in the light of discussions with several SC members, the WG Chairpersons had been invited to this second SC meeting. The SC recognised the benefits of having chairpersons present to discuss their work but expressed concern about the resource burden this might present for some representatives. The final decision on the issue was postponed to point 5 of the agenda.

*** preparation of agenda**

The SC agreed that the agenda should be prepared by the secretariat in consultation with the chairman and on the basis of written proposals from SC members. The organisational charter will be amended accordingly.

*** location of SC meetings**

Mr. Deboyser explained the ICH concept whose success was due to the fact that the SC and WGs meetings were held at the same time, which enable a good interaction/exchange of information between both.

The SC discussed the advantages of rotating the location of the SC meetings. Several members expressed a strong willingness to rotate SC meetings among the three regions in the near future. After discussion, the SC agreed on the proposal to have the next meeting held in Paris and to reflect at that meeting on the way to proceed afterwards. Specifically the rotation of the location of SC meetings will be considered in the light of the experience gained in the first years of VICH and in the ICH process.

The SC went on reviewing the organisational charter (VICH/96002)

Coordinators

The SC agreed to include as a separate point in the organisational charter (VICH/96/002) the role of coordinators. This role could be played by a SC member or by a separate person, according to the need of the SC member. Coordinators can attend the SC meetings as observers, they receive all documents but cannot be part of any final decision taken by the SC. It was considered that coordinators attend the SC meetings as

observers, and in line with their competence, speak on procedural aspects. However, the SC did not agree on specific additional wording to be added to the charter. The Committee therefore postponed the decision to the next SC meeting. The Secretariat was asked to draft proposed wording for consideration at the next SC meeting.

Action : Secretariat

Secretariat

The SC agreed that documents produced by the WGs such as minutes of the meetings or draft guidelines at step 2 should be circulated by the Secretariat to the SC members in a timely fashion. A point will be added to the organisational charter which should give clear guidance to the secretariat on its role in the coordination of the WGs.

Chairman

The chairman proposed to add a point to the organisational charter in order to clarify the role of the chairman of the SC. After discussion on the proposal, the SC decided to postpone any decision until the next meeting and to review this question in the light of the discussion on the location of future SC meetings and evaluation of the ICH concept.

*** procedure for adoption of new topics**

At its first meeting in 1996, the SC decided on its work programme and prioritised the topics identified for 1996, 1997 and 1998.

However, in view of the time elapsed after the preparation of the Comisa document, previously used as concept document for the decisions taken on priority topics in 1996, the SC decided that, in future, all topics to be taken up for active elaboration by the WGs should be put forward with a (new) concept paper.

Proposals for new topics with concept papers should be sent to the Secretariat for circulation to the SC 2 months prior to the meeting in order to give the SC members enough time to prepare for the discussion.

Working Groups

*** location of working group meetings**

After consideration of the advantages and disadvantages of two possible options (no rotation at all or systematic rotation of all WG meetings), the Committee concluded that, for an optimal balance in sharing burden and resources, all WG meetings should rotate, starting with the country chairing the WG. The order of the rotation is to be determined by each WG.

It was noted that some SC members would wish to know the meeting schedules and location well in advance for all WG in order to be in the position to manage their budgetary provisions.

*** participation of technical advisors in working group**

Considering the need to save resources and to ensure efficiency of the WGs it was agreed by the SC to limit the WG participants. The Committee agreed that, as a standard measure, each SC full member and SC observer can nominate one expert per WG (and not for each topic). This expert, if needed and unless otherwise specified by the SC, could receive technical support from one advisor. In the case where the expert wishes to be accompanied by an advisor, the topic leader or chairperson of the WG should be notified. In specific cases, the SC may decide that separate experts may be appointed for

specific topics. In this case, this should be explicitly spelled out. The expenses of Technical Advisors are to be self-funded, as are the ones of experts of WGs.

For the existing WGs, the SC agreed that the present composition of WGs could be maintained, with the exception of the Safety WG (see below). In these WGs where there is more than one expert per region, it should be ensured that only one expert is speaking on a given topic.

*** observers**

The presence of observers at WG meetings was discussed. Whilst the benefit of having observers attending the meeting was recognised from an education point of view, the Committee concluded that it would be more efficient to organise, where needed, training and educational workshops in conjunction with WG meetings.

The Committee re-affirmed that SC observers have the right to appoint experts. The Committee agreed that these experts nominated to working groups by Steering Committee observers have the same status as other experts from SC full members. The Committee noted that voting would not take place in WGs and that any disagreement within working groups would be referred to the Steering Committee for resolution.

Format of documents

The SC reviewed the following draft documents prepared by the Secretariat : format of concept papers (VICH/97/037), format of topic discussion document (VICH/97/036), format of topic progress report (VICH/97/038).

The Committee complimented the Secretariat for taking the initiative to prepare these documents. Overall, the Committee judged that these should be a good starting basis but that the documents needed to be fleshed out in order to be more specific in the guidance given to the experts. The SC members were invited to provide additional comments and proposals to flesh out these documents to the Secretariat by mid-October 1997.

Action : All

The Committee also agreed that an additional guidance document should be developed on the elaboration of VICH guidelines (i.e. structure, format, style, etc.) in order to ensure a certain homogeneity and consistency in the VICH texts. The Secretariat undertook to provide the SC members with a draft based on the ICH guidelines, for comments by mid-October.

Action : Secretariat/All

The SC agreed that all documents relating to procedural aspects or the format of VICH documents should be integrated in or added as Annexes to the Organisational Charter (VICH/96/002).

Codification of VICH topics and documents (VICH/97/034)

The SC agreed that a single numbering should be used, in order to avoid potentially confusing multiple numbering systems. Where necessary a cross reference to the ICH guidelines that served as a basis will be added. A key word will be added next to the number of the guidelines to specify the topic concerned.

In order to ensure that all the key core documents have been received by the SC, the Secretariat undertook to develop a list of the VICH key documents.

Action : Secretariat

Modification of organisational charter (VICH/97/002)

Because of lack of time, the proposed addenda and amendments to the VICH organisational charter could not be reviewed by the Committee. It was agreed to use a written procedure for approving these changes on the basis of a proposal to be submitted by the Secretariat as soon as possible. The issues on the definition and role of the chairman and of the coordinators were postponed to the next meetings when a general discussion will take place on the organisation of VICH and the way it should proceed in the future.

4. Progress reports of Expert Working Groups on selected topics and feedback from topic leaders and chairpersons

Dr. Boisseau welcomed the chairpersons and congratulated them on behalf of the SC for the work done with their respective WGs.

ICH Quality guidelines (see written report by Y. Takahashi/JMAFF)

In the absence of Dr. Takahashi, the SC members reviewed the written report of the WG meeting.

As a general rule, the Committee recommended that the WGs dealing with ICH Quality guidelines should take a flexible approach and, where appropriate, modify the ICH guidelines to take into account the specificities of veterinary medicinal products. A specific recommendation to the WG was drafted to that effect.

Stability

With regard to the development of a guideline on the stability testing requirements for medicated premixes, the SC agreed that a separate guidance document should be prepared, instead of an annex to Q1A. The SC agreed that the topic leader on stability testing should remain the same. However, if needed, for these specific guidelines, the expert could be accompanied by a technical advisor. It was emphasised that the remaining issues (essentially the minimum duration of real-time stability studies at submission) of the guideline ICH Q1A should be resolved and the guideline be forwarded as soon as possible for adoption to the SC. The extended mandate to deal as well with medicated premixes should not hold up the progress of this guideline.

The SC recommended that the WG should also evaluate the ICH guidelines on biologicals/biotechnology products (Q5C) and those on impurities : residual solvents (Q3C). If necessary, additional expertise could be added to the group through technical advisors.

On photostability testing (Q1B) and stability testing for new dosage forms (Q1C), two ICH guidelines which have reached ICH-step 4, the SC agreed that these could be discussed but only after evaluation of their relevance and preparation of a discussion paper by the topic leader. The Secretariat undertook to send these ICH guidelines to the WG.

Action : Secretariat

Analytical validation

The SC followed the recommendation by the WG and adopted at step 3 to be released for consultation the first draft VICH guidelines, VICH GL1 : Validation of analytical procedures: definition and terminology and VICH GL2 : Validation of analytical procedures: methodology. These two draft guidelines were developed on the basis of the ICH guidelines Q2A and Q2B.

Impurities

The Committee agreed with the FDA proposal to apply to the guidelines on impurities the general recommendation calling for flexibility in the elaboration of guidelines. The EU expressed reservations to the positions expressed by the majority of WG members in relation to impurities in the drug substance.

The SC recommended that the WG try to finalise a step 2 document at the next WGmeeting on theICH guidelines on Impurities in new drug substances (Q3A) and on impurities (Q3B).

ICH Safety guidelines (see written report by M. Miller/US FDA)

Dr. Miller presented the problems faced by the group when reviewing the ICH guidelines and requested guidance from the Committee on a number of issues. In essence, it had appeared during the discussions of the WG that the ICH guidelines were drawn up with a different objective (setting toxicological end-points for target patients) than what should be required for guidelines for veterinary products (setting ADI for veterinary drug residue levels). In view of this, the appropriateness of the experts in the WG was also questioned.

After discussion, the SC modified and confirmed the mandate of the WG which should focus towards defining food safety requirements. Mr Sargent mentioned that in view of the refocused activities of the WG, ANZ might wish to send an expert. The SC members agreed that the WG expertise should be reviewed and reconfirmed.

Action : Secretariat/SC members

As human food safety issues are dealt with in Japan by the Japanese Ministry of Health, Dr. Yoshimura kindly accepted to explain the activities of VICH.

Action : Dr. Yoshimura

It was noted that wherever appropriate, the ICH guidelines on safety should be taken into consideration.

Ecotoxicity/environment impact assessment (see written report by J. Robinson/AHI)

Dr. Robinson reported on the 1st meeting of the WG which reviewed the current regulatory requirements and identified a set of issues to be harmonised. The 2nd meeting scheduled on 1-3 September 1997 should be used to discuss unresolved issues and to agree on a decision tree for VMPs (Phase I). The SC agreed that Phase I and II would be forwarded as two separate guidelines to the SC.

The SC recommended that the WG finalise the Phase I decision tree as a Step 2 document by the end of 1997. The draft of Phase II should be completed by the 3rd meeting of the WG in 1998.

Based on the report given, the SC agreed on the programme proposed by the WG for the finalisation of Phase I and the extension of the work programme until 1998.

Good Clinical Practice (see written report by V. Cracknell/FEDESA)

Dr. Cracknell reported on the progress of the WG and on the future prospects. A 2nd meeting of the WG will be held in September 1997 to discuss any comments received from the experts on the draft guidelines. A revised version of the draft guidelines should be ready as VICH step 2 draft guidelines by the end of year.

Dr. Cracknell asked the SC for guidance on the way to address the issue of protocol review prior to the conduct of trials which is tackled very differently in the 3 regions.

Dr. Thompson and industry raised the question of the mutual acceptance of foreign data and the need for the VICH to encourage this acceptance, perhaps in the GCP document. The SC did not agree on any recommendation and decided to discuss this issue at a later stage.

The SC recommended that the WG adopts a step 2 recommendation for GCP by the end of 1997.

The SC and the WG should investigate how the acceptance of foreign data in all regions could be supported.

Efficacy requirements for anthelmintics (see written report by J. Vercruysse/EU)

Prof. Vercruysse presented the development of the WG work. He expressed concern on the lack of support received from some experts. The SC recommended that each member should stimulate its experts to contribute to the work of the WG.

The finalisation of the guidelines on general principles for anthelmintics will depend on the advancement of the discussions on data analysis, which seems to be the key point of discussion left to be resolved. As far as specific species guidelines are concerned, a lot of consensus had already been reached for ruminants and, horses on the basis of WAAVP guidelines, and these guidelines could be finalised at the 2nd meeting.

In the draft guidelines on general principles, it was suggested to delete the recommendation on combination products since this is a regulatory policy issue best dealt with at the regional level. It was also proposed to delete the recommendation on reference laboratories. The SC agreed on these two proposals.

The SC recommended that the WG should endeavour to finalise the document on the general requirements for anthelmintics at its September meeting, adopt this document as a step 2 VICH guideline and, if possible, finalise draft guidelines on ruminants and horses.

Authorisation of WG meetings

Based on the reports provided, the SC authorised the meetings as follows :

- Quality WG meeting : September 29-30, 1997 in London, UK
- Ecotoxicity WG meeting : September 1-3, 1997 in London, UK.
- GCP WG meeting : last quarter of 1997. The US FDA offered to host the meeting. The SC agreed on the principle of having the meeting and decided that it would be held in the US. Information on the exact date will be communicated to the SC in writing.
- Anthelmintics WG meeting : September 28 - 30, 1997, Bethesda, Maryland.

The 2nd meeting of the Safety WG will be the subject of a future written authorisation procedure on the basis of a request to be provided by the chairperson of the WG.

Recommendations to WGs

The SC reviewed and endorsed the recommendations drafted by the Secretariat for the Quality WG and the Safety WG. The SC agreed that such guidance should be given to all WGs. The Committee agreed to use a written procedure for the approval of these recommendations.

5. Finalisation of discussion on the participation of topic leaders and/or chairpersons in the SC meetings

The SC agreed that a clear mandate should be given to the WGs toprovide a comprehensive written progress report, indicating among others the progress made, the issues resolved, the issues unresolved and the issues on which advice of the SC is requested. This progress report should be circulated by the Secretariat well in advance of the SC meeting in order to enable the SC to take proper decisions. As a general rule, the SC felt that the presence of the chairpersons was not necessary. If however, for specific reasons, a SC member was of the opinion that the presence of a WG chairperson was needed, he/she should notify the Secretariat prior to the meeting.

6. New priority topics and confirmation of work programme for 1998 (VICH/96/006)

The SC reviewed the concept papers received for pharmacovigilance & biologicals testing and the proposals to create two new WGs to address these topics.

The Japanese representative raised concern on the creation of an additional working group while the existing ones had not finalised their work and referred to the minutes of the first SC meeting. Dr. Boisseau clarified that the limitation to 5 groups had been decided for the initial phase only, and that the work programme was to be reviewed anyway, in the light of the progress achieved.

After a general discussion, the SC concluded that VICH should not be limited by a specific number of WGs or topics, but that the creation or elimination of WGs should be decided on the basis of the needs of the members, whilst taking due consideration to the limitation in resources available.

The Japanese delegation expressed a reservation and was granted a grace period of time until the end of September to express its final opinion on this issue. For the working group on Biologicals, the Japanese delegation mentioned that JAVB (the Japanese Association of Veterinary Biologicals) was prepared to take part in the activities of the SC and WGs on Biologicals under the coordination of JVPA. As a consequence, the Committee agreed provisionally - pending approval or otherwise by the Japanese delegation - to create two new WGs on the respective topics. The mandate and responsibilities for the different WGs were identified as follows :

Pharmacovigilance WG - Chairperson : FDA

- Veterinary pharmacovigilance framework and terminology- Topic leader : EU
- Electronic standards for the transfer of information - Topic leader : AHI

Quality monitoring of Biological products WG - Chairperson : Japan (pending approval by JMAFF)

- Extraneous agents - Topic leader : Fedesa
- mycoplasma - Topic leader : US APHIS
- moisture and formaldehyde - Topic leader : AHI

Regarding the number of experts required for each WG, the SC did not object to the proposals made respectively by the two US government representatives, i.e. :

- For the WG on Pharmacovigilance
  - 1 expert on veterinary pharmacovigilance framework and terminology (the US government will delegate two experts to the WG, one from FDA, and one from the USDA)
  - 1 expert on Electronic standards for the transfer of information

- For the WG on Quality monitoring of biologicals products
  - 1 expert for the first two topics (extraneous agents and mycoplasma)
  - 1 expert for the third topic (moisture and formaldehyde)

In addition each expert may be accompanied by an advisor to cover a specific area of expertise.

7. Communication/publication on VICH

Conferences

Official VICH public conferences

Mr. Deboyser shared his experience of ICH and the benefits of organising conferences to communicate the progress made. The idea to link the conference with international meetings such as ITCVDR, CCRVDF or OIE meetings which will ensure a larger attendance of people was put forward.

After discussion, the SC reached consensus on the principle of holding a VICH conference in late 1998 or in early 1999. The SC members should provide their input to the Secretariat on the format, programme, hosting organisation, etc. These operational/ organisational aspects will be considered by an ad hoc group, consisting of the Chairman, the Secretariat and the coordinators with written contribution of Dr. Yoshimura. The ad hoc group will make a set of proposals to the SC in order for the SC to take an informed decision at its 3rd meeting.

Action : All/Ad hoc group

ITCVDR 1998

The next ITCVDR will be held in June 23 - 26, 1998 in Yogyakarta, Indonesia where a specific session will be devoted to international harmonisation, including VICH activities.

Participation of SC and WG members in other conferences

The SC agreed on the following policy with respect to participation at conferences other than official VICH meetings : public dissemination of information on VICH activities should be encouraged. However, SC members or WG experts should be reminded that VICH WG and SC meetings are the only recognised platforms for the development of VICH guidelines and policies.

Publications

Dr. Jones presented the proposal put forward by Prof. Valverde-Lopez to have an issue of European Pharmaceutical Law Notebooks dedicated to VICH. The SC members agreed to this proposal with the understanding that dissemination of information on VICH activities would not be limited to this publication.

The SC agreed on the need to have a standard VICH document officially adopted by the SC for distribution to external contacts. The COMISA briefing document on VICH may serve as a starting point for such a document. The Secretariat was requested to investigate the costs of producing such a brochure. This will be discussed at the next meeting.

Action : Secretariat

Mr. Deboyser put forward the idea to have a VICH Web site and undertook to investigate the possibilities. Other SC members strongly endorsed this idea. Mr. Deboyser volunteered to develop a tentative VICH web site by the next meeting.

Action : Mr. Deboyser

Dr. Boisseau indicated the possibilities of OIE for publications on VICH and in particular drew the attention of the SC to the fact that OIE has a world wide web site, which may as well be used for VICH publications.

Contacts with press

The SC agreed that the rules adopted for the publications should be adopted for contacts with the press, i.e. the SC reaffirmed that only the secretariat provides the official communication following SC meetings.

8. Any other business

The SC discussed the time frame for the consultation period when a document has reached step 4 for approval. The EU proposed a 6-month period after release of the draft guideline. The SC members agreed to provide the Secretariat with proposals by the end of September.

Action : All

9. Date(s) of next meeting(s)

The 3rd meeting of the VICH SC was scheduled for February 24-26, 1998 at the OIE headquarters, Paris. To ensure that enough time will be allocated to the topics to be covered by the agenda, the SC agreed to extend the meeting to 2 ½ days.

Note of the Secretariat *: Since the meeting, several discussions led to a new agreed date : February 26-27, 1998.*

10. Adoption of press release

With some corrections and after some general comments on its format and style, the attached press release was adopted by the SC.

Closure

All the points of the agenda having been covered, Dr. Boisseau closed meeting by thanking the SC members, the Secretariat and the OIE.