VICH/96/008
July 1996

VICH STEERING COMMITTEE
1st meeting
10 - 11 April 1996
Paris, OIE Headquarters

1. Welcome

Dr. Blancou, Director-General of OIE, opened the meeting by welcoming the participants, and reviewed the objectives and role of OIE in international harmonisation. He praised the work done by the ad hoc group established in 1994 to prepare VICH.

Dr. Boisseau made a more detailed historical review of the background to this 1st VICH Steering Committee (SC) meeting, initiated with the recommendation made at 7th ITCVDR, and followed by the creation of the OIE ad hoc group in charge of the elaboration of the White Paper on the organisation of international harmonization. He emphazised the constructive atmosphere of the ad hoc group which helped in the elaboration of a proper framework for the VICH SC.

Apologies had been received from Mrs. Deuss (MAF, New Zealand). She was replaced by Mr. Hellstrom as representative of the authorities of New Zealand/Australia. FILASA was represented by Mr. Pereira da Silva.

2. Designation of the chairman

The SC unanimously confirmed Dr. Boisseau as chairman of the VICH SC.

3. Adoption of the agenda (VICH/96/001)

FEDESA proposed two amendments to the agenda :

- a discussion on the quantity of work which can reasonably be achieved before taking any decision on the priority topics, as well as on the implementation in the respective regions of the recommendations made by the SC.

- a clear identification/codification of the documents issued by the secretariat.

With these amendments, the agenda was adopted.

4. Organisation of the VICH SC (VICH/96/002)

Led by the chairman, the SC reviewed the document elaborated by the OIE Ad Hoc Group on the organisation of VICH (VICH/96/002). A number of suggestions were made and adopted in relation to the composition of the SC, the further definition of the veterinary pharmaceutical industry, the need for defining the acronyms, the need to stress cost-efficiency, and the need to have a clear cover page for all recommendations with

implementation date and with a list of existing guidelines which are repealed by the VICH recommendation. The EU representative made a specific request for being able to fill their 2 seats at the SC with different individuals depending on the nature of the discussion. This was agreed by the SC.

5. Role of observers (VICH/96/003)

The SC agreed that the observers will have the possibility to participate in the discussions of the SC and send experts to the working groups (WG). However, they will not take part in any vote. They will not be bound by VICH recommendations, but they will be encouraged to take them into account.

For the purpose of simplification, the SC agreed to include the provisions on the role of observers in the organisation document (VICH/96/002) to have a single core document.

6. Role of secretariat held by COMISA

The document (VICH/96/004) outlining the role of the secretariat by COMISA was discussed. A written procedure for the circulation and approval of SC minutes was agreed. With regard to the circulation of documents, the SC agreed that the OIE should take care of the mailing of VICH recommendations at step 4 or higher to its delegates whilst COMISA will circulate the documents to the members and observers of the SC and to the coordinators. The latter will be nominated by each VICH member in order to facilitate the circulation of the information to their respective constituency.

This document will also be suppressed and the agreed provisions on the role of the secretariat will be included in the organisation document (VICH/96/002) to have one single core document.

7. Logo of VICH

COMISA circulated 4 proposals for a VICH letterhead which were discussed by the SC. The Secretariat undertook to provide a final logo taking into account the comments made.

Action : Secretariat

8. VICH work programme

**** identification of priority items***

A general consensus was reached to limit the number of WG to a maximum of 5 at the same time and to choose a selection of both ICH guidelines and de novo veterinary topics in order to achieve results which will be both rapid, tangible and visible to industry and authorities.

Based on the document elaborated by COMISA (VICH/96/005) on the priorities as identified by the EU, the US and Japanese industry, and after a thorough discussion, the SC agreed on 5 top priorities to start in 1996 :

* ICH quality guidelines (Q1A-Stability testing of new drugs and products, Q2A-Validation of analytical methods : definitions and terminology, Q3A-Impurities in new drug substances) and other guidelines related to stability (Q1), validation (Q2) and impurities (Q3) if at ICH step 4 or higher
* ICH safety guidelines (S2A-Genotoxicity : specific aspects of regulatory tests, S5A-Detection of toxicity to reproduction for medicinal products) and other guidelines related to genotoxicity (S2) and reproduction toxicity (S5) if at ICH step 4 or higher
* Good Clinical Practice
* Efficacy requirements for anthelmintics (excluding ectoparasiticides)
* Ecotoxicity/ environmental impact assessment.

1997

Priority topics for this year are Pharmacovigilance, target animal safety, testing methods for extraneous agents in veterinary biologicals. Among these topics, the SC decided that Pharmacovigilance should be the first topic to be dealt with in 1997. However, a clear mandate should be defined for the pharmacovigilance WG before starting the work. Meanwhile, in order to minimize discrepancies and divergent developments in the different regions, each party agreed to circulate on a regular basis information on the development of each pharmacovigilance system. Dr. Makie presented the post-marketing surveillance scheme elaborated in Japan.

1998

Work should start on priority topics design of metabolism and residue kinetics studies, sub-chronic and chronic-toxicity testing requirements, elaboration/calculation of withdrawal periods.

The detailed work programme (VICH/96/006) is annexed. This work programme is to be reviewed at each SC meeting in light of the progress achieved, the resources available, and the evaluation of the needs of the VICH members.

**** appointment of topic leaders and chairmen***

The SC agreed that one topic leader will be responsible for each topic. He/she will normally chair the specific WG and therefore be accountable to the SC with respect to the mandate and time frame given by the SC. He/she will also be responsible for preparing a discussion document on the topic prior to the first WG meeting. In some working groups, several topics will be handled together. Each topic will have a topic leader. In addition, a chairperson will be elected for the whole working group. This chairperson will be appointed by the SC and will be accountable to the SC with respect to the mandate and time frame given by the SC.

After detailed discussion, it was decided to share the topic leaderships/chairmanships as follows :

The EU will be topic leader/chairperson for the working group on the efficacy requirements for anthelmintics.

AHI will be topic leader/chairperson for the working group on ecotoxicity/environmental impact assessment.

FEDESA will be topic leader/chairman for the working group on Good Clinical Practice

The Japanese MAFF will chair the WG which will evaluate the ICH quality guidelines. Within the WG, the US FDA will be topic leader for the guidelines on stability testing, the EU will be topic leader for the guidelines on impurities and AHI will be topic leader for the guidelines on analytical validation.

The US FDA will chair the WG which will evaluate the ICH safety guidelines. Within the WG, the EU will be topic leader for the guidelines on genotocixity and FEDESA will be topic leader for the guidelines on reproduction toxicity.

**** setting up of WG***

The SC agreed to follow a written procedure for the setting up of the WG. The names of the experts should be communicated to the secretariat by the end of May. Proposals on dates of meeting and location should be forwarded to the secretariat by the WG topic leaders/chairpersons by the end of June. The SC will approve these proposals through a written procedure. The SC also agreed that no working group meeting would be held before the appropriate dicussion documents drafted by topic leaders were available to all WG members.

Action : All

9. VICH SC meetings in 1996 and 1997

The SC agreed to schedule its next meeting for the end of 1996 or early 1997 depending on the progress made on the different topics.

10. Adoption of the minutes of the SC meeting

Acccording to the decision to approve the minutes of the SC meeting through a written procedure, the SC members are invited to forward their comments on this VICH/96/008 document by the end of May.

Action : All

11. Adoption of the press release

The SC reviewed and approved the press release (annexed as VICH/96/007).

12. Any other business

* The SC agreed that the documents should be circulated to all members of the SC and to the coordinators which will be appointed by the US, the EU and Japan. No coordinator needs to be appointed for the observers. The name of the coordinators should be communicated by the end of June.

Action : All

All the points having been covered, Dr. Boisseau adjourned the meeting by thanking the participants for their constructive input which had facilitated the consensus of the group. He particularly thanked Dr. Blancou for the hospitality offered by the OIE in welcoming the VICH SC, and Dr. Verschueren for the preparatory work carried out by COMISA.

Dr. Blancou closed the meeting by recognising the collaborative spirit and the quality of expertise of the participants which had helped to achieve progress, and offered the OIE collaboration on specific issues relating to biologicals through its newly created group.