VICH/03020
16 June 2003
Final

VICH STEERING COMMITTEE
12th meeting
7-8 May 2003
EMEA, London

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Prof Dr R. Kroker, chairman, opened the meeting by welcoming the participants to London and particularly a new Interested Party, CAMEVET, which represents Authorities and Industry Associations from Latin American countries, and represented at this meeting by Dr E. Gimeno. The chairman also introduced the following new representatives to the VICH Steering Committee (SC): Dr S. Ando, from JVPA, who is the successor of Dr K. Sawada, Dr P. Dehaumont representing OIE, and Dr A. Gautrais from the EC, replacing Dr P. Brunet at this meeting.
Dr Kroker presented the apologies of Dr Ph. Brunet and explained that he had accepted at the last minute to chair this meeting. Dr Kroker called on all the participant's collaboration for a fruitful and successful meeting.

AHI reported the tragic death in an accident of Dr James Derr, AHI expert to the BQM Expert Working Group (EWG). The chairman expressed his sorrow on behalf of the SC and asked AHI to forward the SC's sincere condolence to Dr Derr's family.

2. Adoption of the agenda

The secretariat explained that item 6.3 of the agenda should be deleted because the Ecotoxicity EWG was unable to meet prior to the SC meeting.
The agenda was adopted without further change.

3. Introduction of Camevet

Dr E. Gimeno presented Camevet, representing Authorities and Industry Associations from Latin American countries. He explained that Latin America is an important producer of food of animal origin for the world market. Veterinary Medicinal Products are part of the food chain and their production under strict safety and quality requirements is therefore very important for the Latin American countries. A direct link to VICH is essential for Latin America. Camevet hopes that it will be authorised to collaborate with the EWGs and represent the specificities of the Latin American region.

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4. Progress reports of Expert Working Groups

4.1. 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 US FDA expert had presented a revised version of draft GL 27 - Antimicrobial Resistance to the chairman, explaining that FDA's legal advisers had recommended not to publish for consultation the identical text of the adopted draft GL as done in the other 2 regions. The reason for this is that its introductory part did not reflect FDA's current position. The FDA expert had asked that the EWG should continue its work on basis of the new FDA text proposal.
Dr Mevius had proposed that FDA should publish the VICH draft GL as adopted at step 4 and that FDA should explain in its comments why it wished to eliminate the first three paragraphs of the introduction. The FDA legal counsel did not accept this proposal. The chairman then decided to suspend the 4th meeting of the EWG scheduled on 6-7 March 2003 and to ask the SC for advice on this matter.

Other options proposed to the SC were that the EWG would reconvene, and based on the comments as result of the consultation in the EU and Japan, and the FDA proposal for changes, prepare a new Step 3 document, requiring a second consultation. Alternatively, FDA would publish the amended text of the draft GL and FDA would explain in a preamble its reasons for the changes. The experts from the other regions could then review and comment the changes at the next EWG meeting. The experts would also evaluate whether the 2 other regions would need to republish the draft GL at step 4 or whether the draft GL could proceed to the next step.

The chairman recommended to the SC the second option because FDA amendments concerned mainly the introductory part and stressed that this procedure would prevent any further delay.

During the discussion, the SC acknowledged that the scientific value of the draft GL was confirmed again by the regulators as well as by the industry from all regions.

AHI and IFAH-Europe recommended that FDA should publish in the USA the text as amended by the legal advisors.

AHI stressed that this should be a unique event and not a precedent for further different publications in the regions.

FDA confirmed that the current amended draft GL could be published very soon, probably within the forthcoming 30 days, and that the consultation period could be fairly short (30 days).

The EU and JMAFF confirmed that they would most probably not republish this amended draft GL, as a republication of a draft GL at step 4 would be very confusing, and appeared not to be necessary.

The SC encouraged the EWG to review the comments received after publication in the EU and Japan, as well as the amended text published by FDA including~~.~~ comments to this text, and to propose the way forward for the VICH GL.

The SC recommended that the EWG should hold its 4th meeting in Europe as soon as possible after the end of the USA consultation period.

4.2. Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the Working Group, Dr O. Itoh, and presented by the JMAFF.

GL 34 - test for the detection of Mycoplasma contamination

** Splitting of the GL*

JMAFF reported that at its 7th meeting in Washington D.C., the EWG reviewed the current draft GL 34 on Mycoplasma testing and came to the conclusion that this draft GL could not be split into strain development and requirements as suggested by the VICH secretariat, following IFAH-Europe's proposal.

The EU requested clarification, as to whether the splitting of GL 34 would be discussed by the SC, as it had been requested by the EU further to the proposal from IFAH-Europe for decision by the SC by written procedure.

IFAH-Europe explained that its aim had been to encourage potential progress of the EWG for this GL and to accelerate the progress of the draft GL. The EWG had however dismissed the proposal.

No further discussion on the subject took place and the SC therefore agreed with the EWG proposal not to split the draft GL.

** Extension of the consultation period*

JMAFF reported that the EWG asked the SC for guidance on this issue.
The EU updated the SC on the production of the reference strains by the EDQM and explained that the feasibility studies had been done. The EU estimated however that 2 to 2,5 years would still be needed until these strains were available and testing had been done in the regions and proposed therefore that the consultation of the draft GL be discontinued until this stage.

AHI proposed to revisit the status of this topic at each SC meeting, and to set up a new consultation period once the strains are available in all regions.

After discussion, the SC decided to discontinue the current consultation at step 4 until the strains are available and to determine a new consultation period at that stage. The EWG would be requested to review at their next meeting, if there would be any other possibility for progressing of the GL. The SC will continue reviewing the matter at each SC.

Extraneous virus testing

JMAFF reported that the draft was still under discussion at step 2. The EWG agreed to prepare a full description of "the examination method on the intermediate product and final product", taking into account the Japanese minimum requirements, and to review the list of viruses to be tested for.
A new draft document will be produced before the 8th EWG meeting.

The SC confirmed the 8th meeting to take place in Europe (Strasbourg) in September 2003.

4.3. Target Animal Safety

The SC reviewed the written report prepared by the chairman of the Working Group, Dr T. Nagata, and presented by JVPA and JAVB.

Pharmaceuticals

JVPA reported that at its 5th meeting the EWG had reviewed the comments from FDA and a revised text of the draft GL will be circulated to the EWG in July.
The EWG intended to reach an agreement at the 6th meeting and produce a step3 document.

JVPA added that Dr Nagata requested the guidance of the SC on the possible invitation to the EWG of the US EPA, as it regulates the insecticides.
After discussion, the SC recommended not to involve the US EPA, in accordance with the scope of VICH defined in the VICH Workplan.

FDA expressed its satisfaction that the EWG had accepted to review the general approaches to designing the studies and hoped that progress will be achieved at the next meeting.
The chairman thanked the FDA for its co-operation.

Biologicals

JVPA explained that the EWG had felt that the harmonisation of safety tests from the 3 regions was difficult, and had therefore agreed to set up an ad hoc group that will collect the data available, and evaluate them in order to justify the necessity of the overdose safety tests.
The SC approved the initiative of an ad hoc group provided it will communicate by written procedure/teleconferences only and will report to the EWG by early July.

The SC noted that the experts had proposed that the sections on reproductive safety test and field safety test would be included within the vaccines draft GL. A separate draft GL had been prepared to handle the reversion to virulence GL.
The EWG will discuss if the drafts are acceptable and the experts will discuss the acceptability in each region.

The SC authorised the 6th meeting to take place on 9-12 September 2003 in the USA.

4.4 Safety & Task Force on Microbial Safety

The chairman of the Working Group, Dr T. Mulligan, reported that excellent progress had been achieved at the 2 meetings held since the last SC meeting in Tokyo.

Special meeting in London

The special 3-day meeting which was held in January 2003 enabled a core group of microbiological (intestinal flora) experts to review the Task Force document (draft 13) on the General Approach to Establish a Microbiological ADI and to address the issues of disagreement raised by the CVMP.
After thorough discussions all contentious issues were resolved and all the participants present signed the draft 15 of the document.

10th Safety EWG meeting

T. Mulligan reported that at the meeting held in Brussels on 28-30 April the experts reviewed two draft documents, Microbial Safety and Repeat-Dose (chronic) Toxicity, at step 2. The experts finalised the Microbiological ADI draft document prepared by the core group at the London meeting and signed it at step 3.

The Repeat-Dose (chronic) safety document, although relatively short, was difficult to finalise as the experts raised many issues such as, 1) the need for chronic studies to address the concerns for chronic exposure, 2) the length of chronic studies, 3) the default species for chronic studies, and 4) the number of chronic studies and the selection of animal species. The experts agreed that there would be a need for at least one 12-month chronic study and the default rodent species would be the rat and the default non-rodent specie would be the dog. The mouse would be used only in special circumstances.

To assess the number of studies and the selection of animal specie, the experts collected 90-day and chronic data from 46 compounds. T. Mulligan explained that those represented an enormous amount of data. As it was the first time that such data was collected, the experts lacked the time to assess all the data in depth as to class of compound, type of studies and accuracy of estimated NOELs etc. Therefore, the regions could not use the data to reach unified decisive conclusions.

However, a surface review of the data suggested that, 1) the most sensitive animal species in the 90-days study was not always the most sensitive one in the chronic study, 2) on the average the NOEL from a chronic study was only about 3-fold lower than that estimated from 90-day studies, and 3) often the NOEL from chronic exposure was the same as that seen from 90-day studies. For a limited number of compounds, the NOEL estimated following chronic exposure was found to be lower than that estimated from 90 day studies by more than 10-fold.

Future issues for the Microbial Safety GL after step 4 are the unknown comments that may come from the public and the derivation of the MIC value included in the formula to determine an ADI.

Future issues for the Chronic Toxicity GL is the list of tissues for histopathological examination and the scientific justification needed for determining the appropriate species for testing.

T. Mulligan added that the EWG would also need to review the carcinogenicity and the repeat-dose 90-days GLs for consistency in the list of tissues for histopathological examination with the chronic toxicity GL and review the 6 previously finalised safety GLs for consistency based on the current final drafts.

The Safety EWG proposed an in-depth review, including statistical evaluation, of the 90-day and chronic data collected on the 46 compounds. They also recommended that regular meetings would take place between sponsors and regulatory authorities in order to plan the minimum toxicology program necessary to address human food safety concerns. T. Mulligan believed that the sponsors have a lot of data (ADME, class history etc.), which the regulatory bodies could use to aid ~~decision~~ decision-making during this process.

The SC acknowledged that the animal species for the tests could not yet be determined for the various classes of compounds since the EWG did not have the time to study the 46 compounds in detail.

The SC recognised that on the long term the positive impact of these GLs will cover both the regulatory assessment and the applications in the 3 regions.

On behalf of SC, the chairman thanked the EWG for their efficiency and T. Mulligan for his strong personal commitment in the process.

The SC authorised the 11th and final meeting to take place in December 2003 in the USA.

4.5. Pharmacovigilance

The SC reviewed the written progress report of the EU and the FDA on their discussions regarding the requirements for adverse event reporting for Veterinary Medicinal Products. The meeting was held following the SC's request to the EMEA and FDA to find solutions to the impasses reached in several areas at the last EWG meeting.

FDA reported that at a special meeting between FDA and the EMEA, which took place in Washington on March 10, both parties recognised the need to reopen section V of GL 24 in order to take account of the EU reporting system by adding more data fields and use more structured entry fields. The FDA had requested that clinical and necroscopy data be added to the VEDDRA dictionary and use of lower level terms for coding purposes while keeping the narrative as a possible reporting field. The main question for the FDA concerned the number of fields to be added. FDA stressed that flexibility was needed to move forward.

JMAFF informed the SC that it supported this agreement between the EU and FDA, but to clearly define the task required by this agreement.

AHI and IFAH-Europe congratulated both parties for the agreement, but pointed out that the experts will have all to be very flexible at the next meeting in order to reach a positive outcome.

AHI stressed that the experts would have to evaluate carefully all proposed fields as some may be useful in human medicine, but without value for veterinary products.

AVCARE/AGCARM and CAHI supported this view.

AHI requested also re-consideration of other issues such as International birth dates and the expedited third country reporting.

The EU explained that much of the very important information was reported in full "narrative" text in the other regions. The EU believed however that it is essential to have such information in structured text fields, which enables to set up a structured database and to detect trends. The EU believes a harmonised system would benefit all the regions and partners involved. Regulators would agree to provide industry with access to specific data from a structured system.
FDA agreed to add structured fields but insisted on leaving some place for free text.

The SC agreed that the aim was to set up a really well functioning Pharmacovigilance system.

The EU requested clarification regarding the issue of the international birth date as it would be practice in the EU to accept the determination of the birth date of a product based on an international birth date, even outside the EU.

In respect to third country reporting the EU reminded the SC of the EU legal requirements~~,~~ and of t~~T~~heir interpretation, that had been agreed in the past that the deadline for the expedited reporting of adverse events having occurred in third countries is understood to be calculated from the day of the receipt of the information by the pharmacovigilance person of the MAH in the EU.

AHI believed that there was a basic difference between the regions on the ways of collecting and utilising Pharmacovigilance data.

Canada indicated it expected progress to be achieved on this topic by agreeing on the minimal information common in all regions and on the minimal number of fields required.

After a thorough discussion, the SC acknowledged that increased harmonisation is needed between the regions on how Pharmacovigilance data is collected and utilised, and agreed that the experts should reopen the discussion on the pharmacovigilance draft Guidelines (GL 24 - Management of Adverse Event Reports (AERs); GL 29 - Management of Periodic Summary Update Reports (PSURs); GL 30 - Controlled list of Terms; GL 35 - Electronic Standards for Transfer of Data).

The SC strongly encouraged the experts to reach an agreement at the next EWG meeting and determined the following guidance to the EWG:

> *"After discussion, the SC agreed that the entire Pharmacovigilance EWG should meet again as soon as possible.*
>
> *The SC agreed that the EWG should fulfil the following 3 tasks:*
> *a) Evaluate the proposed new data fields for their relevance and importance for veterinary medicinal products, understanding that the EWG should carefully evaluate each field;*
> *b) Establish criteria for an international birth date for purposes of periodic reporting among the regions;*
> *c) Develop a better mechanism for expedited third country reporting.*
>
> *The SC understood that flexibility from all the parties was a condition for fruitful progress on these Guidelines. Each party agreed to instruct their experts on the importance of working together to reach agreement on these issues."*

The chairman thanked everyone for their motivation to reach an agreement on this topic and recommended that clear guidance should be given individually to each expert by the relevant SC member.

IFAH-Europe stressed that this guidance was a very important tool for communication with EWGs and should be taken as a precedent in case such problems should occur again.

The SC authorised the 7th meeting to take place in the USA and requested that the EWG should meet at the earliest possible date, and certainly before the summer break.

4.6. Ecotoxicity/environmental impact assessment

AHI reported that the EWG had been obliged to postpone its 8th meeting because of travel restrictions of the experts.
During the SC meeting the secretariat received a message from the chairman of the EWG confirming that the 8th meeting would take place on 25-28 July in Bilthoven, The Netherlands, Europe.
The SC confirmed the authorisation of the meeting.

4.7. Quality

The SC reviewed the written report prepared by the chairman of the Working Group, Dr H. Makie, and presented by JMAFF.

JMAFF confirmed that draft modified texts have been circulated electronically within the EWG, but that comments from FDA are expected at the earliest by spring 2004.

JMAFF announced that Dr H. Makie has been replaced by Dr K. Hamamoto as expert for the Quality topics and chairperson of the EWG.

The Chairman asked JMAFF to convey to Dr H. Makie the SC's warmest thanks for his personal commitment and the excellent work achieved.

FDA informed the SC that ICH was currently drafting a new quality GL on GMPs, which may influence the existing GLs.
FDA confirmed that it would reengage its efforts on the Quality EWG in Spring 2004.

The EU transmitted the disappointment of the CVMP that no progress can be achieved.

The SC agreed in principle to reactivate the Quality EWG in early 2004 and decided to review the status at the 13th meeting.

5. Update on VICH objectives

5.1 Review of VICH Workplan

The secretariat presented the revised version of the VICH Workplan (VICH/99/108-Rev.1-Draft 2) and reminded the participants that the SC had agreed that not more than 6 EWGs should be active at any time. Currently there are 6 active, altough 2 are near to finalisation. The secretariat stressed that it was not reasonable to believe that the future topics listed in Part II.II.2.b would be finalised by end of 2005.

After discussion, the SC agreed to reactivate the Quality EWG as soon as possible before creating new EWGs.

FDA questioned whether the term “liaison” used in the heading of part II.I.2 would be correct in respect to the relationship between VICH and OECD. Eventually the SC agreed that the heading and text could remain unchanged. In this context the EU reported that further to the SC’s decision of the 10th meeting the 2 Ecotoxicity phase II test guidelines for dung flies and dung beetles are being presented to OECD for development as OECD GL. The decision of the OECD is yet outstanding.

IFAH-Europe proposed to add a paragraph on how to develop good concept papers defining the requirements in the different regions and identifying the problems which the EWG have to resolve.

The Workplan should also define the way the dialogue between the SC and EWGs can be improved: template and procedures exist and should be included.

IFAH-Europe agreed to draft a proposal.

After discussion, the SC agreed that the secretariat would include the changes discussed and update the Work programme for discussion at the 13th SC meeting.

Presentation from OIE
OIE explained that it was responsible for world wide animal health, but has also developed activities in new fields such as public health and food safety, in close collaboration with Codex and FAO. The importance of animal welfare was also increasing and veterinary medicines are very important tools.

All OIE members have been asked to review these subjects in preparation of next year’s new strategic plan for the years 2005-2010. It will be an important element for animal health, public health and the trade of animals.

OIE expressed its satisfaction with the development of VICH which was created under the auspices of OIE. The SC has shown again that difficult agreements can be reached by consensus.

OIE confirmed that it would continue to play its role as support to VICH by assisting all VICH members in their work and by broadening the spectrum of distribution of VICH GLs.
OIE will need tools to harmonise the registration of veterinary products, and OIE considers that VICH can provide these tools for international harmonisation of the regulatory aspects for veterinary products.

The chairman thanked OIE for this clear statement.

5.2 VICH after 2005

The secretariat proposed to start the discussion on the future of VICH after 2005. A new draft document will be needed to start formal discussions at the 13th SC meeting.
The secretariat repeated that the current work will probably not be finished in 2005 and the SC has to define sufficiently in advance what will be the next steps.

The secretariat proposed to draft a wish list and define the resources available in the future.

IFAH-Europe suggested carefully reviewing the objectives for the next 5 years, concentrating on the benefits and defining what may be achievable.

JMAFF insisted on the questions of resources and costs and believed that it would be very difficult to continue the VICH process with the same scheme.
JMAFF confirmed that it would continue to participate actively in VICH. JMAFF suggested however that as much work as possible should be completed until 2005 and recognised that there would be some work to finish after 2005.

After discussion, the SC agreed that VICH would obviously need maintenance tasks including step 9 procedures as well as the development of new topics after 2005.

All participants agreed to send their proposals in writing to the secretariat before the end of June.
The secretariat will then draft a proposal for a new VICH after 2005 for discussion at the 13th SC meeting.

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

6.1 GL 36 - Studies to evaluate the safety of residues of Veterinary Drugs in Human Food – General Approach to establish a microbiological ADI

The Steering Committee received the text of GL 36 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-months public consultation at Step 4. The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 15 November 2003.

6.2 GL 37 - Studies to evaluate the safety of residues of Veterinary Drugs in Human Food –Repeat-dose Chronic Testing

The Steering Committee received the text of GL 37 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-months public consultation at Step 4. The Steering Committee agreed that the deadline for members to submit comments on the guidelines is 15 November 2003. A written procedure for signature for the EU SC members to allow for consultation of the CVMP was agreed.

7. Implementation of final VICH Guidelines

7.1 Report of implementation in the 3 regions and observer countries since the last SC meeting

The authorities from ANZ reported that GL 25 - Testing of residual Formaldehyde and GL 26 - Testing of residual Moisture have been implemented in both Australia and New Zealand.

The authorities from the EU confirmed all the Member States would have implemented both GLs on biologicals.

The authorities from Japan confirmed that all both biological GLs would be implemented this month.

The authorities from the USA reported that both biologicals GLs would be put in place in formal regulations. These GLs have been cleared for publication, but a slight delay could occur because of a final review by the authorities.

7.2 Presentation of the timeframe for implementation of the GLs in Canada

Canada reported that it would implement 27 of the 29 GLs, but these documents needed to be all translated into French before publication.

GL 9 - GCPs will be implemented at a later stage, because it may require a regulatory change in Canada.

GL 6 - Ecotoxicity phase 1 will also be implemented later, because Canada is in the process of developing specific Canadian regulations on environmental assessments for human and veterinary drugs.

The VICH GLs will therefore be under consultation together with the proposed Canadian regulations.

8. New topics

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

FDA confirmed that resources would be allocated to this topic in early 2004.
The SC agreed to review the concept paper at the 13th SC meeting again.

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

The SC reviewed the concept paper prepared by the EU.
FDA expressed its concerns with the suggested protocol and asked if the GL would cover only the methodologies or would also include determination of the ADI.

AHI and IFAH-Europe expressed the same concerns. The EU clarified that the concept paper was intended to cover only the data requirements, and not the data assessment.

Following earlier discussions on the Workplan, the SC agreed that the EU should revise the concept paper in order to narrow down the scope of the topic.

The EU welcomed comments in writing by the end June in order to include them in the revised document.
The SC will review the new draft at the 13th SC meeting.

8.3. 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.
JMAFF explained that since last SC meeting the proposal had been revised because questions about the studies needed for specifications had been raised at the last BQM EWG meeting.

JMAFF believed that this GL could be developed based on GLs 3 and 17, but that ICH GLs Q6A & Q6B should be considered separately.

The EU suggested that more information should be included in the paper on the current different requirements in the different regions, in order to define more precisely the needs and requirements for harmonisation and in order to be able to judge if a GL is needed.

After discussion, the SC agreed that the current work ongoing in the BQM EWG had a higher priority and should thus be achieved before adding a new topic.

The SC decided to review an improved concept paper at the 13th SC meeting. Written comments should be submitted by the end of June to JMAFF in order to include them in the revised document.

8.4. Review of the concept paper on Tests for Sterility for Veterinary Medicinal Products

The SC reviewed the concept paper prepared by ANZ.
ANZ proposed that the BQM EWG could also address this topic. ANZ explained that ICH had recently approved a GL on this topic, which should not be very different for Veterinary medicinal products. A VICH GL would ensure that no discrepancy exists between human and veterinary products.

ANZ believed that the draft GL could be approved in a short term by written procedure by the BQM WG.
EU stated that due to the late receipt of the document no consultation had been possible and no comments could be made, and requested referring the discussion to the 13th SC meeting.

IFAH-Europe believed that this topic might also require the expertise of the Quality EWG.
AHI suggested that this topic would need a face-to-face meeting between the experts.

ANZ asked the SC to provide written comments before the end of June.

After discussion, the SC agreed to review the concept paper at the 13th SC meeting.

9. Review of VICH Documents

9.1 Cancellation of EWGs

ANZ presented the draft 2 of the proposed document.
After a short discussion, the SC agreed to disregard the 2nd comment included in draft 2.

The SC approved the revised proposal as final document

9.2 Revised version of the VICH presentation leaflet

The secretariat presented the revised version of the leaflet that had been prepared for the VICH1 conference. The secretariat explained that this leaflet would be used as communication tool when it receives questions on VICH.

After a few minor corrections, the SC approved the revised document.

10. Review of the VICH2 conference

10.1. Assessment by SC members

The SC reviewed the compilation document paper prepared by the secretariat.

After a short discussion, the SC approved the draft as final document. This paper will be used by the USA in the preparation of the VICH3 conference.

JVPA confirmed that a CD-Rom on VICH2 is nearly finalised and will be circulated soon.

10.2. Summaries of Breakout Sessions from chairpersons

The SC reviewed the comments and reports received and acknowledged that these are personal comments from the chairmen and should serve as basis for thoughts on improvements for the VICH3 conference.

10.3. Financial report of VICH2

JVPA presented the financial report of VICH2 to the SC.

11. Any other business

11.1 Benefits of VICH for Industry

AHI referred to the document on the value for the Industry of VICH as well as to the letters written by IFAH to the Commission and by AHI to FDA distributed by IFAH at the start of the SC meeting.
IFAH indicated that it would continue to monitor the benefits of the VICH process for the Industry.

11.~~3~~ 2 Departure of Dr J. Wieda

Dr J. Wieda indicated that, due to his new responsibilities and an increased workload, he would not act as representative of IFAH-Europe in the future.
Dr J. Wieda thanked his colleagues from the SC for their friendship and their fruitful collaboration since 1996. He left reassured that VICH was successful and progressing again.

The chairman thanked J. Wieda on behalf of the SC for his work and input to VICH over 7 years.

11.~~4~~ 3 Organisational charter

The SC asked the Secretariat to prepare an updated draft of the VICH organisational charter to be approved at the 13th SC meeting.

12. Dates and venue of next meetings

The 13th SC meeting will take place on 7-8 October 2003 in the USA (Washington).
The 14th SC meeting will take place on 12-13 May in Japan (Tokyo).

13. Adoption of the press release

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

VICH STEERING COMMITTEE
12th meeting

7-8 May 2003
London, Europe.

Chair: Prof Dr R. Kroker, EU

LIST OF PARTICIPANTS

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