VICH/11021
16 May 2011
Final

VICH STEERING COMMITTEE
25th meeting
February 23 & 24
Washington DC - USA

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Bernadette Dunham, Director of the Centre for Veterinary Medicine – FDA. She opened the meeting by welcoming the participants to the 25th VICH SC meeting. There were 5 new representatives in attendance. Apologies were received from L. Klostermann, IFAH-Europe, O. Itoh, JVPA and B. Freischem, IFAH.

2. Adoption of the agenda

It was agreed to discuss item 10.3 - Review of the Proposal for public disclosure of VICH Concept papers under item 3.2 - VICH Work Programme and to change the order of EWG reports under point 7 in order to enable the chairmen from FDA to attend the meeting in the morning of the second day.

IFAH-Europe suggested changing the format of the VICH SC press release in order to give more detail to the information that is provided, to avoid leaving open questions and to make other changes that may result in a better likelihood of the press release being accepted by journals.
After discussion it was agreed to provide an improved template for the press release for the next SC meeting.

3. VICH Strategy Phase III

3.1. Review & discussion of the draft Phase III Strategy

The SC reviewed draft 6 of the document. The Secretariat pointed out that this version included the input from the Global Outreach subgroup. As the Phase III Strategy covers the next 5 years, the EU stated that it was hesitant to commit to VICH work that may require additional funds because of the difficult economic situation in the European Union and expected restrictions. The EU suggested that the same caution may apply in the other VICH regions as well. The SC members agreed.

IFAH-Europe had suggested changing the word "biologicals" to immunologicals, as the VICH BQM EWG had so far only addressed issues regarding vaccines, but in the discussion JMAFF suggested that other types of products such as cytokines, DNA-vaccines, diagnostics or sera may also be considered in the future; it was therefore agreed to retain the term "biologicals".

The SC discussed several further suggestions for changes which were included in draft 7 of the document that was subsequently tabled for a final discussion. The SC adopted in principle draft 7 with minor changes but requested that the Secretariat should circulate the next draft (draft 8) for final adoption by written procedure.

Action: Secretariat *(Done)*

The final Phase III Strategy will then be placed on the VICH public website.

3.2 VICH Work Programme

The Secretariat presented the recently updated version and reminded that this Work Programme is used as an internal working document which is available on the "members' area" of the website. It was suggested that this document could, after modification, be placed on the public website, but no decision was made.

Review of the Proposal for public disclosure of VICH Concept Papers (VICH/IN/10/013-dr4)
The SC reviewed the draft proposal prepared by IFAH-Europe and amended by the Global Outreach subgroup. The SC agreed that the objective was to facilitate achieving the wider harmonisation of VICH GLs and to make potential stakeholders worldwide aware of new VICH topics, thus stimulating their interest to provide input in the development/revision of harmonised GLs as appropriate. After a thorough discussion, the SC agreed that only final versions of CPs that are approved by the SC would be published on the VICH and OIE websites. The public will be informed by press releases and input from non VICH countries/regions could be provided to the SC by sending it to OIE or the VICH Secretariat. It was recognised that although the aim was not to request comments, any feedback could influence the mandate and the future work of the EWG.

After the discussion, a new draft was tabled for a final discussion, which the SC adopted in principle. The Secretariat was requested to circulate the final draft for final adoption by written procedure.

Action: Secretariat *(Done)*

3.3 Discussion on how the VICH GLs are implemented

Following the discussion at the last SC meeting, JMAFF provided a clarification in writing for the SC to consider prior to this meeting. IFAH-Europe thanked JMAFF for the written response and acknowledged the points made in the paper.

JMAFF confirmed that in principle a new VICH GL would replace any existing GL, but that in very limited cases both GLs might be maintained in parallel, only when described in the considered Guideline or for a limited transitional period in order to not disturb the ongoing development of new products.

Other regions did not provide any comments. The SC agreed that this topic should be a standing agenda point and that updates should be provided by the SC members at each SC meeting.

Action: Secretariat

3.4 Future VICH Topics

No topic was proposed.

3.5 Other issues

No issue was brought up.

4. VICH Global Outreach

4.1. VICH Global Outreach Strategy

OIE summarised the outcome of the Global Outreach subgroup meeting held on 2-3 December 2010 in Paris (**link**).
The EU confirmed its support of the Global Outreach initiative by VICH but believed the proposal that was presented to be too ambitious as it includes many actions and tasks for all SC members. The EU voiced its concern regarding the resources that would be required to implement the proposed actions and the commitments that would be needed in times of budget restrictions, particularly with regard to training programmes that require many efforts and resources to develop and undertake.

JMAFF also confirmed its support to the Global Outreach initiative but suggested that OIE rather than VICH should lead this initiative because non-VICH countries/regions have requested very broad support regarding training and development. JMAFF believed that VICH should only support the technical aspects of the outreach.

FDA pointed out that VICH represented 15 years of successful collaboration between industry and the regulators to develop GLs on harmonisation of technical requirements, but cautioned that the development of regulatory legislation and infrastructures in non-VICH countries/regions may not be an appropriate role for industry to take even in partnership with the regulatory agencies. FDA emphasized that because VICH GLs describe studies that industry must undertake and regulators use to assess product safety, efficacy, and quality, the development of these GLs should be a joint effort between industry and government. The development of overall regulatory programmes and infrastructures within the context of OIE is, however, more appropriately suited to be an effort of government regulatory agencies.

IFAH-Europe noted that the Animal Health industry should first focus on transitional countries (such as China and Brazil) with established regulatory frameworks and not on the developing countries, many of which do not have regulatory programs or standards. Industry's objective is primarily to encourage the establishment of identical technical requirements in transitional countries in order to maintain the same regulatory standards for veterinary medicines.

ANZ recommended that the Global Outreach initiative needs to clarify that its intention is not to impose VICH requirements in the developing countries. The EU recalled that the information from the VICH questionnaire showed that many countries do not have a clear understanding of the scope of VICH GLs. The SC acknowledged that it is not the role of VICH (an industry/government collaboration) to set up a regulatory framework nor to control the implementation of GLs and reiterated that VICH GLs concern data requirements, not the assessment of a dossier.

OIE confirmed its active support of the development of regulatory/legislative frameworks for VMPs in developing countries and agreed that this is not the role of VICH. Moreover, OIE noted that many countries/regions do not have the resources to implement the VICH GLs.

OIE believed that the primary question is if VICH wants to develop or not an outreach approach and favoured providing such an opportunity to all countries/regions that may want to be involved. All of the SC recognised that during the VICH 4 Conference, many countries/regions confused the activities of OIE and those of VICH. Most of the SC agreed that the VICH Global Outreach should start by assisting the countries/regions that could likely utilize the VICH GLs and those would be the countries/regions with a relatively developed regulatory framework.

The EU reminded the SC that the implementation of the GLs and the training will be a very resource demanding exercise. VICH members would have to commit to provide the necessary resources. The EU therefore warned against setting objectives for the Global Outreach that are too ambitious and that could later on not be achieved because of a lack of resources and recommended that the Global Outreach Subgroup should reflect further until the next SC meeting on how best to implement a realistic VICH Global Outreach program.

The EU highlighted the need for improvement of communication as many countries/regions do not clearly understand the role of VICH and VICH Guidelines.

OIE pointed out that there is a clear demand from non-VICH countries/regions for more transparency from VICH. OIE believed therefore that informing non-VICH countries/regions that the SC was reflecting further on its Global Outreach Initiative would convey a negative message from VICH. The OIE therefore suggested that the SC should create a VICH Outreach Group that all countries/regions could join but that this group would implement only very limited actions in the first year.

The EU and JMAFF reiterated however that they could at this point in time not support the creation of such a VICH Outreach Group. IFAH Europe suggested that the Global Outreach Subgroup should review the proposal again in order to ensure that its objectives do not lead to misunderstandings.

The Secretariat reminded the SC that it had previously agreed to improve the openness and transparency of VICH through the Global Outreach Initiative.

After much discussion most SC members were of the opinion the initial focus of VICH should be limited to transitional countries, such as China and Brazil that have a relatively developed regulatory framework. With consideration of the written joint comments of JMAFF and JVPA as well as the comments of other SC members, most SC members also agreed that no further individual country memberships to the SC should be considered at this time.

FDA mentioned that the ICH Global Coordination Group is composed of representatives from the ICH SC and 5 regional harmonisation groups that are focussed on training (i.e., Gulf Cooperation Countries, Asia-Pacific Economic Cooperation, Association of South East Asian Nations, Pan American Network on Drug Regulatory Harmonization, and Southern African Development Community), and that the ICH Regulatory Forum is additionally composed of eight more countries which can all participate in the Drug Regulatory Forum of the ICH SC meetings (i.e., China, Brazil, Australia, Russia, India, Chinese Taipei, Singapore and South Korea).

It was noted that at the Global Outreach Subgroup meeting, OIE had indicated that in case VICH did not develop a Global Outreach procedure for involving other countries/regions in VICH, OIE would be forced to develop its own GLs, which possibly would result in OIE standards being different compared to VICH standards.

After an in-depth discussion where each member expressed their concerns and expectations, the SC noted that a consensus could not be reached for the immediate adoption of the full Action Plan that was proposed by the Global Outreach Subgroup and the immediate creation of the proposed "VICH Global Outreach Group". The SC nevertheless recognised the need to be pro-active, to transmit a positive and constructive message to, and to initiate a direct dialogue with, other countries/regions that want to be involved in VICH.

The SC therefore decided to progress stepwise starting with the following short term objectives:

- To focus on providing better information and communication to countries/regions not participating in VICH and develop an Information/communication action plan, including elaboration of communication materials.
- To work in close cooperation with OIE and in particular:
  - Strongly support the OIE 5th Strategic Plan
  - Utilize the OIE networks and structures to collect and disseminate information (particularly the OIE network of National Focal Points for Veterinary Products)
- To develop proposals on how to address the needs and expectations of non-VICH countries/regions:
  - Improve information, communication and raising awareness on VICH
  - Consider organising a dialogue among VICH, OIE and certain non-VICH countries/regions, to be identified, to discuss VICH
  - Increase contributions of non-VICH countries/regions in the consultation process of developing VICH GLs and potential involvement in GL development in the future.

The SC agreed to organise a one day informal contact meeting with selected non-VICH transitional countries/regions just before the 26th VICH SC meeting in Tokyo, in order to initiate the dialogue and achieve a better understanding of the needs and expectations of the selected countries/regions. The countries/regions will be invited to attend the meeting at their own expense.
The SC agreed in principle that the invited countries/regions would likely be many of the same countries/regions that are taking part in the ICH Global Coordination Group and the ICH Regulatory Forum; i.e., Brazil, Russia, India and China (BRIC), as well as Chinese Taipei, Singapore (although Singapore may not be included because it does not use many veterinary drugs), South Korea and South Africa.

The Global Outreach Subgroup will work with OIE to identify the countries/regions to be invited and will provide a proposal with the identified countries and regions to the SC by mid-April 2011. The SC will make the final decision by written procedure, and the Secretariat will invite the selected countries/regions to attend the meeting.
{Post-meeting note: the Outreach Subgroup also suggested to invite, APEC, ASEAN, Gulf Cooperation Council (GCC), South African Development Community (SADC) and Pan American Network for Drug Regulatory Harmonization (PANDRH)}.

Action: OIE & VICH Global Outreach Subgroup

The agenda for this meeting will be finalised and approved before the end of June 2011.

The Global Outreach Subgroup also received the mandate to develop further an information/ communication action plan, including the elaboration of communication materials, and proposals on how to improve information, communication and raising awareness on VICH.

Action: VICH Global Outreach Subgroup

The SC agreed to revisit the draft VICH Global Outreach Strategy (ref.: VICH/10/064 currently at draft 6) at the 26th SC meeting after the contact meeting.

4.2. Review of the proposal for Criteria for participation of non-VICH countries to VICH Expert Working Groups

Postponed to the 26th SC meeting

4.3 Action Plan

Postponed to the 26th SC meeting

4.4 Future mandate for the VICH Global Outreach Subgroup

See 4.1

4.5 Consequences arising from VICH Global Outreach strategy (e.g. Review Organisational Charter, Working parties procedures document, etc…)

Postponed to the 26th SC meeting

5. Review of

5.1 Written updates from the coordinators

The SC took note of the report and thanked the coordinators for their work.

5.2 Review of the written status of consultation for draft GLs at Step 4

The SC took note of the report.

6. Review of final VICH Guidelines at step 9

6.1. Proposal for a revision of VICH GL 23 – Safety Genotoxicity - Studies to evaluate the safety of residues of veterinary drug in human food: Genotoxicity testing

FDA reported that OECD has now completed its GL on genotoxicity testing by adopting the in vitro mammalian micronucleus assay and proposed therefore that the VICH Safety EWG be given the mandate to revise VICH GL 23 accordingly, by written procedure.
The SC agreed and noted that this should not represent a major revision of the GL.
The SC recognised that the experts in the VICH Safety EWG may need to call upon expertise from genotoxicity experts in their organisation or that the comments may need to be submitted through the coordinators, but decided that there was no need to formally nominate any additional experts to the Safety EWG.

Action: Safety EWG

6.2 Review of other VICH Guidelines

No other revision was proposed.

7. Progress Reports of Expert Working Groups and decisions on next steps

7.1. Quality

The SC reviewed the written report prepared by the chair of the EWG, Dr T. Ogata and presented by JMAFF. The revised VICH GL 18 (Quality: Impurities: residual solvents in new veterinary medicinal products, active substances and excipients) is still at step 5 and comments have not been received from all EWG members yet. The comments from FDA on the amendment proposed by the Topic Leader are expected shortly. The first draft of the new GL on statistical evaluation of stability data based on the ICH GL Q1E (Evaluation of stability data) has been reviewed by all the experts and is being progressed at step 2.

7.2. Pharmacovigilance- Electronic Standards Implementation

Dr M. Brown, chair of the EWG, recalled that the mandate of the group is to finalise GL 35 and to create VICH implementation technical documents for GL35 which will be in line with ISO 27953-1 Health Informatics, pharmacovigilance and individual case safety reports (see presentation – **link**).
The EWG has identified and corrected the numbering inconsistencies in GL42 and has made changes to all references throughout the document and in the associated lists, charts, and tables in GL30 and draft GL35.

Dr Brown listed further tasks to be achieved by the EWG and presented a tentative time schedule for their fulfilment, with a teleconference at the end of April and a proposed face to face meeting combined with a workshop in November 2011.
In the discussion, Dr Brown clarified that the plan was to have a workshop type training with IT experts beyond EWG members at this occasion, besides the EWG meeting. The SC advised that only an EWG meeting with business and IT members should be held, and no training. Whether training should be organised in the future would need to be considered by the SC at a later time. Dr Brown pointed out that not all VICH members have nominated their IT expert yet.

Dr Brown mentioned also that a second face to face meeting would be necessary at a later stage. Dr Brown believed that some sections of the step by step guide need to be improved and that the EWG should develop a good communication with one single message in all VICH regions. The EWG will also have to develop explanations for the technical document.

The SC recommended that the EWG should progress stepwise, by finalising the GLs before considering training of the IT experts.
The EU questioned whether the proposed timelines were too ambitious and requested that the meeting should only take place once all possible tasks have been achieved by electronic discussion.

The SC recommended that the action plan and timelines presented to the SC should be proposed to the EWG in order to enable the experts to plan their resources and agree on the availabilities. The SC decided to authorise the face to face meeting at a later stage, subject to a written progress report from Dr Brown to the SC.

Action: Dr Brown

JMAFF highlighted the particular difficulties for the Japanese experts to participate in EWGs' teleconferences and suggested that EWGs should not plan too many teleconferences in the decision making procedure. JMAFF asked Dr Brown to strictly comply with the procedures for EWG teleconferences detailed in point H of the SOP on VICH Procedures for the EWGs (ref: VICH/00/151-rev2 –Final).
The secretariat will re-circulate the SOP to all EWG Chairmen.

Action: Secretariat

7.3. Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chair, Dr K. Oishi, and presented by JMAFF, including the following topics:

a. Mycoplasma contamination testing
JMAFF explained that the 9th meeting of the EWG initially planned in November 2010 was postponed because of additional comments from USDA. USDA pointed out that when this topic was initiated in 2001, the new technologies were not available yet. Now, with the progress in analytical methodology that has taken place since the first drafting of the GL, USDA recommended inclusion of the PCR technology. USDA mentioned also that a significant part of the references strains' titres had been very low after shipment to USA and their concern is that they cannot be utilised. Therefore more flexibility in their use is required to allow reference to cross-calibrated local standards. Also the cost for obtaining the EDQM strains was raised as an issue by USDA.

JMAFF however did not agree to entirely change the methodology at this stage of the process because much work has been achieved with the EDQM strains, and suggesting adopting the GL in its current version, then changing to the new technology through the step 9 procedure. JMAFF considered that the problem with growth of frozen strains experienced by USDA could be due to shipment, and should be easily solved as JMAFF did not encounter such problems.
The SC reached a consensus that the PCR would be mentioned in the introductory section of the GL as a potential alternative method, to be cross validated against EDQM golden standard.
The SC considered therefore that enough progress had been achieved to enable the EWG to meet and to adopt the draft GL.

b. Extraneous agents testing for Biologicals
JMAFF reported that no progress has been achieved recently.
A timetable for the next steps will be established at the 9th EWG meeting. IFAH-Europe reported that the topic leader has already prepared an updated document for discussion at the next EWG meeting.

c. Harmonisation of the Target Animal Batch Safety Test for immunological veterinary medicinal products
The EU topic leader confirmed that good progress has been made by electronic procedure. Two points were raised during the electronic discussions:

- Preconditions that allow waiving batch safety testing are quality assurance processes for manufacturing and pharmacovigilance. However, there is not yet agreement on

how these preconditions should be phrased in the GL. As there is no GMP GL in VICH, there may be differences between the regions.

- As the current scope is restricted to target animals and inactivated vaccines, the GL would only be applicable in regions where the batch safety test is carried out in the target animals. The GL has no effect in countries/regions where the batch safety test is done on laboratory animals.

IFAH-Europe therefore suggested expanding the scope to laboratory animals and live vaccines, but JMAFF considered that large parts of the draft document would need to be rewritten. The EU clarified that they could support the wider scope, as had been proposed in the draft concept paper. However, considering that a wider scope would not be acceptable by all VICH partners, the EU proposed to revert to the restricted scope agreed by the SC.

The SC therefore agreed to maintain the current scope and consider any expansion as a future step.

d. Letter from PETA

JMAFF recalled that the VICH Secretariat had asked the chairman that the Biologicals Quality Monitoring EWG should consider the letter from PETA at its next meeting.
The chairman believed however that the VICH Secretariat should deal with such matters.

After discussion, the SC recommended that the Secretariat should respond to such letters in a much abbreviated fashion, so that further letters from PETA are not stimulated, and inform the relevant EWG in case such a letter contains a specific reference to an EWG. If necessary the SC can agree a more complete response at the next SC meeting.

7.4. Metabolism and Residue Kinetics EWG

The SC reviewed the written report prepared by the chairman of the EWG, Dr. S. Scheid, and presented by the EU. The four draft MRK GLs have been presented to the SC for sign-off at step 6. The SC congratulated the EWG and the chairman for the important work that was successfully finalised.

The EWG proposed further topics to be developed, i.e. (1) residues from treatment of fish, (2) residues in honey from treatment of honey bees, and (3) studies to address metabolism and residue kinetics of biopharmaceuticals in food producing animals. The EU, being careful to start new work due to resource considerations, recommended that the EWG could prepare Concept Papers addressing these proposed topics.

The SC supported that the EWG should prepare a Concept Paper on topics (1) and (2) for review at the SC's next meeting. It was confirmed that the request for a Concept Paper should not be understood as a commitment from the SC that the work should be undertaken. The SC will have to also consider whether sufficient resources will be available to fulfil this additional task. The SC agreed further that the EWG should work by electronic procedure only to develop the Concept Papers.

Regarding honey, it was pointed out that Codex is already addressing this topic. The SC therefore recommended that the EWG should consider the ongoing work at CCRVDF.

Concerning residue studies with biopharmaceuticals the SC acknowledged that the development of a Concept Paper was premature. It was decided that the VICH members will review this suggestion within their respective organisations and provide their positions at the next SC meeting.

Action: All SC members

7.5. Microbiological ADI EWG

Dr S. Pineiro, chair of the EWG, reported (see presentation – **link**) that the EWG had met in Tokyo in January 2011 and had successfully signed-off and approved the draft revised GL 36 at step 2. The revision of the GL has been done in the form of a new Appendix D.

The SC congratulated Dr Pineiro and the EWG for the excellent work achieved.

Later in the discussion (see point 7.6) the SC gave the Microbiological ADI EWG the mandate to consider the topic of microbiological endpoints by electronic procedure only, in support to the work of the Safety EWG which is developing a GL for determining Acute Reference Doses.

7.6. Safety EWG

The chair of the EWG, Dr. K. Greenlees, reported that the EWG met in October 2010 in Washington DC (see presentation – **link**). The draft GL resulting from the discussion has been circulated to the members of the EWG for comment and Dr Greenlees is currently collating comments and preparing a revised draft of the document.

Dr Greenlees pointed out that questions were raised by several members of the EWG concerning the narrow scope of work given to the EWG and what its impact would be on the draft GL. The EWG produced a discussion paper on this issue, which collated the different viewpoints of the members of the EWG on extending the scope. IFAH Europe expressed its concern that the EWG had continuously questioned the scope, which was intentionally kept narrow by the SC after its long and difficult discussions on the original concept paper.

Dr Greenlees indicated that the EWG would focus its work on the scope as provided previously by the SC. The EWG's goal is to reach consensus by the summer 2011 on the draft document and forward that draft to the SC for sign-off at step 3 and public consultation. Dr Greenlees mentioned that the web based e-room (Google Gmail account) enabling real-time commenting and editing of the draft document had been abandoned at last October's meeting.

The EU recognised the importance of the possible toxicity of substances for acute exposure on the human gut microflora and presented a proposal to revise the mandate of the EWG by including the microbiological endpoints in the current mandate. The SC noted that this is a very technical issue and supported the proposal from the EU.

Dr Greenlees pointed out that the Safety EWG may need additional expertise on microbiological endpoints. FDA proposed therefore that this specific topic should be passed for further consideration to the Microbiological ADI EWG which has the proper expertise. After consultation with Dr Pineiro and Dr Greenlees the SC agreed that the Microbiological ADI EWG should support the Safety EWG on this specific topic by electronic procedure only.

7.7. Bioequivalence EWG

The representative of GADA joined the meeting.
Dr M. Martinez, chair of the EWG, reported (see presentation – **link**) that the EWG had been established in November 2010 and that the EWG had already gathered a sound scientific

understanding as to what is needed to demonstrate bioequivalence from a technical point of view. A first draft of a bioequivalence GL to establish a platform for discussing scientific and statistical principles, protocol considerations and regulatory issues had been circulated. Questions have however been raised in relation to data interpretation.

Dr Martinez submitted three questions from the EWG to the SC
a) The EWG suggested developing an appendix where important statistical and scientific points are summarised.
After discussion, the SC supported the development of an appendix but recommended to keep it simple and short, reminding that the mandate of the EWG was to develop a basic bioequivalence GL.

b) Since the resulting VICH bioequivalence GL will present stricter criteria than those of several jurisdictions, the EWG would like to include a table summarizing regional differences in bioequivalence *requirements. Is the SC comfortable with the inclusion of a preface that summarizes the international differences (contrasted against the VICH BE GL)?*
The chair reminded the SC that at its last meeting it had reached the consensus that the basic BE GL should describe when blood level bioequivalence should be applied and that it should not detail when blood level bioequivalence does not apply.

IFAH-Europe stressed that the basic aim of VICH is to harmonise technical requirements, and regional differences should not persist in VICH guidelines unless truly unavoidable. In addition the scope of VICH does not normally include how to interpret the data. For these reasons the table should be left out.
JMAFF mentioned that the VICH guideline should be developed on the basis of scientific discussions; it would nevertheless be needed to include some diversity in the description of a putative Bioequivalence guideline to reach an agreement for countries/regions under different generic drug approval regulations.
After a thorough discussion, the SC agreed that the EWG should progress in a stepwise approach, the first target being to prepare a GL based on the scientific criteria for demonstrating bioequivalence. The questions relating to the different interpretations in different jurisdictions should be addressed only in a second phase if necessary, with a new mandate and a new Concept Paper.

c) However, many jurisdictions are legally constrained from accepting generic drug bioequivalence studies performed with a reference medicinal product obtained from outside that jurisdiction, even if the reference formulation is identical across jurisdictions. Therefore, in this case, the VICH GLs may not minimize the number of generic bioequivalence studies needed to support global generic product marketability.

The SC considered that these issues were related to data interpretation, which is not under the remit of VICH, but fall to the judgment of the regulatory authorities in the VICH countries/regions.

Procedure of the EWG
The SC reviewed the next steps presented by Dr Martinez and considered that the recommended timelines were too short. The SC requested Dr Martinez to review these timelines with the experts at the forthcoming EWG meeting in order to expand the time for comments and electronic discussion of all the proposals that will be made.

With regard to the strategy for the activities after the EWG meeting, Dr Martinez suggested that the elaboration of different parts of the documents should be allocated to subgroups of experts, working by electronic discussion or teleconference if necessary. Dr Martinez confirmed that all the experts will have the opportunity to review all the documents and provide comments.
JVPA and JMAFF nevertheless strongly recommended that teleconferences should only be held when the entire EWG is available.
At the end of this topic the representative of GADA left the meeting.

8. Adoption at Step 3 and release of Guidelines at Step 4

8.1. Draft Revised GL 36(R) (Safety) – Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI

The SC endorsed the text of GL 36(R) as a proposed GL at Step 3. This GL was transmitted to the VICH members for a 6-month public consultation at Step 4, until August 31st, 2011.

9. Adoption at Step 6 and release of Guidelines at Step 7

9.1 Draft GL 46 (MRK) – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Metabolism Study to determine the Quantity and Identify the Nature of Residues

The SC adopted GL 46 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2012.

9.2 Draft GL 47 (MRK) – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Laboratory Animal Comparative Metabolism Studies

The SC adopted GL 47 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2012.

9.3 Draft GL 48 (MRK) – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods

The SC adopted GL 48 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2012.

9.4 Draft GL 49 (MRK) – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Validation of Analytical Methods used in Residue Depletion Studies

The SC adopted GL 49 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2012.

10. Concept papers/Discussion papers

10.1. Review of the recommendation from the TF with regard to the Concept Paper from IFAH Europe for a VICH GL on potency test of rabies vaccines

The Secretariat reminded the SC that the TF has the mandate to develop a discussion document for review by the SC, with particular focus on the scope of a possible GL and how this would fit within the remit of OIE or VICH.

The EU, who had been asked at the 24th SC meeting to liaise with the appointed TF chair from OIE, reported that the work had not progressed since the last SC meeting. The contact with the OIE representative, Dr Fooks, has now been established and misunderstandings clarified. The work will be initiated shortly.

10.2 Review of the Concept paper from IFAH Europe for a revision of VICH GL 3(R) to consider climate zones III and IVb

IFAH Europe explained that since VICH GL 3(R) is specific for climatic Zones I and II, there is currently no GL or common approach for addressing the stability testing requirements of Zones III and IV. As a result authorities in the individual countries/regions of Zones III and IV apply their own criteria. IFAH Europe therefore suggested to update the current GL and to harmonise the global stability requirements.

The EU has provided comments to the IFAH Europe proposal in writing, recommending addressing several technical issues and impact considerations beforehand. JVPA questioned whether the revised GL would be optional or if the implementation would be mandatory in all VICH countries/regions and recommended to elaborate further on the impact of the GL once it would be implemented.
JMAFF noted that it is necessary to confirm that the reasoning by which the corresponding ICH GL-Q1F had been withdrawn does not interfere with the current revision of VICH -3(R).

After a brief discussion, the SC agreed to postpone any decision until more progress has been achieved on the VICH Outreach strategy.

10.3 Review of the Proposal for public disclosure of VICH Concept papers

Considered under point 3.2

11. Any other business

11.1 Proposal from IFAH Europe for a revision of the VICH Guidance document on the "Policy on Consultation at step 4"

IFAH Europe explained that the VICH Policy on Consultation at Step 4 (ref: VICH/00/154) did not refer to the revision of existing GLs. The SC therefore adopted the proposed amendments to this guidance document. The Secretariat will circulate the revised document.

Action: Secretariat

11.2 Presentation by Dr Makie

JMAFF reported that Dr Makie will provide a presentation on VICH at a forthcoming OIE Workshop.
JMAFF recommended that OIE should disseminate VICH information whenever there is an opportunity to do so in its activities.

11.3 Grouped e-mail address

JMAFF requested clarification on the functioning and the scope of grouped e-mail addresses.
The Secretariat recognised that some IT problems had occurred during the last months of 2010, but that these were now solved.
The Secretariat explained that, in addition to the e-mails of all relevant experts, the grouped e-mail addresses for the EWGs also contained the e-mails of the SC coordinators as well as of the Secretariat.

12. Dates and venue of next meetings

- The 26th SC meeting will take place in Tokyo, Japan, from Tuesday 15 to Thursday 17 November 2011.
- The 27th SC meeting will take place in Brussels, Belgium from Tuesday 26 to Thursday 28 June 2012

13. Adoption of the Press Release for the 25th SC meeting

The SC members reviewed and adopted the press release proposed by the Secretariat.

VICH STEERING COMMITTEE

25th meeting

February 23 & 24, 2011
Washington DC, USA

Chair: B. DUNHAM (FDA)

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI	R. LIVINGSTON
AHI (BAYER)	B. MARTIN
AHI (PFIZER)	M. J. MCGOWAN
EUROPEAN COMMISSION (DG SANCO)	K. KRAUSS
EMA	K. GREIN (C)
EMA-CVMP	A. HOLM
IFAH-Europe (MERIAL)	B. BOENISCH
IFAH-Europe	R. CLAYTON (C)
JMAFF	M. SAKAI (for K. IKEDA)
JMAFF	Y. ENDO
JMAFF	K. NODA (C)
JVPA (KYORITSU SEIYAKU CO.)	M. KAJIWARA
JVPA (DS PHARMA ANIMAL HEALTH Co.)	T. KOMATSU
FDA	M. SMITH
FDA/USDA	M. LIMOLI (C)
USDA APHIS	B.E. RIPPKE

OBSERVERS

HEALTH Canada	M-J. IRELAND
CAHI	J. SZKOTNICKI
NZMAF	D. MORRIS
ANIMAL HEALTH ALLIANCE (AU)	P. HOLDSWORTH

INTERESTED PARTY

AVBC	J. THOMAS

OIE

OIE	J-P. ORAND
OIE	C. LAMBERT

VICH SECRETARIAT

IFAH	H. MARION

APOLOGY

IFAH-Europe (BAYER)	L. KLOSTERMANN
IFAH	B. FREISCHEM
JVPA	O. ITOH (C)

INVITED

AHI	S. VELUVOLU (C)
APVMD	A. BRYCE
GADA (*part - Bioequivalence discussion only*)	S. BATLINER