VICH/07/059
8 January 2008
Final

VICH STEERING COMMITTEE
20th meeting
October 17 & 18, 2007
Yokohama, Japan

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr M. Sakai, chairman, opened the meeting by welcoming the participants to Yokohama on behalf of the JMAFF and JVPA. He thanked the JVPA for assisting in the organisation of the meeting.

Dr Sakai introduced Dr H. Sekiguchi, representing JMAFF as coordinator, Mr B. Tully representing AVBC and welcomed back Mrs Debbie Morris from ANZ.

Dr H. Marion presented the apologies from Dr I. Alexander who fell ill just before departing for Japan and indicated that Canada would therefore be represented by CAHI at this meeting.

2. Adoption of the agenda

IFAH proposed to summarise the findings of the IFAH Benchmarking survey under point 3.7. OIE suggested reporting under item 5, and the secretariat amended the point 12 as: Next VICH conference.

Draft 3 of the agenda was adopted without further change.

3. VICH Strategy Phase II

3.1 Review of progress and Implementation

No comment was made on the implementation of the Strategy Phase II.

3.2 Monitoring and Maintenance of VICH Guidelines: implementation of the Guidance Document

The participants reviewed the final version of the guidance document and approved 2 changes in order to align this document with the wording of other documents e.g. the Organisational Charter. The revised document was adopted.

3.3 Review of the Draft Revision 10 of the Organisational Charter

The Secretariat reminded the participants that the role of the coordinators had been updated in the Revision 9 adopted after the 19th SC meeting, and explained the reasons for the 2 proposed amendments to this version.
The Secretariat advocated avoiding any detailed explanations in the Organisational Charter in order to keep this fundamental document flexible. The purpose of VICH Guidance documents is to provide detailed explanations for the implementation of the principles laid down in the Charter. The Charter is comparable to a constitution and the Guidance represents the detailed rules of functioning.
The Steering Committee adopted Revision 10 of the Organisation Charter that will be placed on the VICH public website.

Action: Secretariat *(Done)*

3.4 Future VICH Topics

The Secretariat explained that this item will be on the agenda of each SC meeting to enable a primary discussion on any further proposals.
No further topic was presented.

3.5 Interpretation and Implementation of GLs in the regions

IFAH-Europe reported that companies had encountered problems of interpretation of VICH GL 36 (Safety: Microbiological ADI) in Europe, which raised questions about the fundamental principles of VICH. Indeed, this GL sets a general framework for different studies, of which several are new and do not have protocols in some of the VICH regions. European and US experts have therefore developed protocols, which then have been accepted in one region but not in the other. This had resulted in an increase of the time to market and created a climate of lack of predictability.
IFAH-Europe voiced its concern about this situation as one of the major purposes of VICH is to have the same studies accepted in all regions, but IFAH-Europe was not requesting a review of the GL at this stage.

The EU explained that GL 36 covers an area, different to other VICH GLs, which cannot refer to international guidance, because it currently does not exist. Therefore differences in interpretation are not surprising in this case. The EU explained that the EMEA/CVMP has undertaken efforts in solving the matter and to come to a common understanding of the GL. The EU also clarified that the CVMP was never asked to be involved in protocol developments.

FDA confirmed however that technical discussions were ongoing between FDA and the EU at expert level to solve any differences of understanding.

After further discussion, the SC agreed that it would be premature to undertake a formal revision of GL 36 at this stage, but recommended reviewing the issue of consistent interpretation and implementation at the next SC meeting.

3.6 Proposal for a methodology for the Review of GLs at Step 9

The SC reviewed the methodology proposed by the Secretariat and agreed that the review should proceed in 2 steps. In the first step, the coordinators of the region that had the chair of the EWG that drafted the GL should evaluate if a revision of the GL is necessary, and report to the SC.
In a second step the SC should then decide on the appropriate process for a revision, if necessary.

The SC adopted the final document (VICH/07/039) and requested that the coordinators should report 2 months prior to the 21st SC meeting.

Action: Coordinators

3.7 Other issues: report from the IFAH Benchmarking study

IFAH (Dr P. Jones) pointed out that although the AH industry is small compared to the human pharmaceutical industry, it has an essential role in the maintenance of animal health and public health. The Benchmarking study was therefore an essential exercise for the future availability of Veterinary Medicinal Products. (*see presentation*)

The SC acknowledged the growth of defensive R&D and the increase of overall costs of placing products on the market.

The SC also recognised the fact that the general public has become more risk averse and the need of regulators to respond to the public's concerns. Risk communication is therefore a major topic for the future through which the public should be clearly informed on the benefits and the risks of each situation.

4. Review of written updates

4.1 From the coordinators

The Secretariat briefly presented the written report and encouraged all coordinators to respond in the future, even by confirming that there is nothing to report on their behalf.

The IFAH Europe coordinator suggested adding requests in the table for reports on the coordinators new responsibilities that have been added in the Version 9 of the Organisational Charter.
The Secretariat will complete the report table accordingly before the next request for reporting to the coordinators.

Action: Secretariat

4.2 On the implementation of final VICH Guidelines since the 19th SC meeting

The EU reported that since the 19th SC meeting the only new GL for implementation was GL29 (PSURs) and that this GL had been implemented in the EU.

JMAFF explained that the implementation of GLs 6 and 38 (EIA) had been delayed because the current Japanese pharmaceutical law does not permit the inclusion of the environmental impact concept. In Japan, the same pharmaceutical law under the responsibility of the Ministry of Health, Labour and Welfare covers the human and veterinary drugs.

The inclusion of the environmental impact concept requires an amendment to the Japanese pharmaceutical law, which has not yet been planned.
For the moment, these GLs will therefore be sent to the AH industry by JVPA, for voluntary implementation.
GLs 39 & 40 are also behind schedule, but will be implemented shortly.

FDA reported that GL29 had not been implemented yet, because FDA intends to implement all Pharmacovigilance GLs as a package.

Canada reported that GLs 39 & 40 will be implemented by the end of this year and that the revised Quality GLs (3R, 10R & 11R) will be implemented in 2008.
Canada will implement GL 29 in conjunction with the other pharmacovigilance GLs .

ANZ indicated that in both countries several GLs are still in the public consultation process. The two EIA GLs have been adopted in both countries, but the environmental assessments are under the responsibility of a different ministry and problems are similar to Japan.

4.3 Review of status of consultation of draft GLs at step 4

JMAFF reported that the consultation for GL 43 has been finalised and no particular comment was made.

5. Report from the 17th CCRVDF meeting

See item 6.6

Report from OIE
OIE reported on the follow up of the topics presented at the 19th SC meeting.
The distribution of the VICH information to OIE membership was done after the last SC meeting through the Chief Veterinary Officers (CVOs) and the OIE focal points.

Regarding the training activities, OIE confirmed that it was in the process of setting up training models through the collaborating centers that will be put in place in early 2008. A first training programme will be launched in Asia on medicated feedstuffs.

OIE pointed out that the “twinning” project aimed to strengthen the roles of the OIE collaborating centres. Twinning activities will start in West Africa within a few weeks. The objectives are to reinforce the role of veterinary medicines and to set up a network of labs to control Veterinary Medicinal Products in this part of Africa.

OIE will further organise a pan African conference on Veterinary Medicinal Products in March 2008, including the participation of 53 African countries. This conference aims to review the current situation in Africa and to strengthen the cooperation between African countries as well as with other regions.
OIE is convinced that such conferences will encourage the harmonisation at worldwide level, thus improving the quality of Veterinary Medicinal Products.

6. Progress Reports of Expert Working Groups

6.1. Quality

Dr K. Hamamoto, chairman of the Quality EWG confirmed that the GLs 3R, 10R & 11R had been released at step 7 for implementation in the regions.

The first draft of the GL on Bracketing and Matrixing (VQ1D) was finalised by the experts in September. All comments were minor. The draft was however not completely signed off at step 2 because of communication errors.
Most comments on the draft GL had been received at the end of September, except the Canadian expert's comment.
Canada apologised for the problems of communication, and explained that the Canadian expert's comments will be sent shortly. Canada confirmed its intention to sign the GL off at step 2.

The chairman hoped that the draft GL would be delivered at step 2 within the next weeks.

6.2. Pharmacovigilance

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr L. Post, and presented by FDA.

FDA confirmed that the following critical progress was made at the last EWG meeting: draft GLs 24 and 42 were signed off at step 5 and GL 29, which had been signed off previously by SC, was reviewed again by the EWG but no revisions were required.

FDA further stated that the EWG also reached consensus on both draft GL 30 and GL 35, but that these GLs probably should not be moved ahead in the step process by the SC without further work being completed. Specifically, FDA mentioned that draft GL 30 needed to have a Controlled List of Terms (CLT) developed to give it context and that draft GL 35 cannot be completed until there is international consensus on an appropriate electronic standard (e.g., HL 7). As they are currently written, FDA described draft GL 30 and draft GL 35 as position papers and stated that they do not represent substantive VICH guidance documents in that they do not provide much practical use to regulators or industry in their present state.

Draft GLs 30 and 35 have been signed off by the EWG at step 3, but the SC must determine the appropriate time for their publication based on completion of a CLT and agreement on an international electronic standard.

The SC recognised the excellent preparations that were undertaken by the chairman and others in the EWG through electronic procedure before the meeting and congratulated the chairman and the experts for the very significant progress that was accomplished during its 11th Pharmacovigilance EWG meeting in September 2007, after a prolonged period of difficult negotiations.

Discussion on GL 24 & GL 42

The SC discussed thoroughly the addition to GL 24 of the sentence related to “similar biologicals” and decided to delete this sentence before signing off the final GL.
The SC agreed to adopt this GL but to delay its implementation until draft GLs 30 and 35 are ready. However the SC decided that the Regulatory Authorities may consider implementation at an earlier stage as they deem appropriate*.*

The SC discussed also in depth several points of GL 42 and agreed to very minor changes, recognizing that the EWG had reviewed and discussed extensively the specific data elements as well as the examples contained in GL 42. The SC decided that GL 42 could not be implemented until the CLT and the Electronic Standards have been determined. The SC recognised that Appendix 2 of GL 42 (diagram of the scheme for the data elements in IT format) which is a reproduction of the data elements in another format, may still need to be amended and finalised by the EWG. This Annex will be made available to the SC as soon as possible.
The SC agreed to adopt also this GL but to delay its implementation until draft GLs 30 and 35 are ready.

Discussion on GL 30 & GL 35
The participants reviewed draft GLs 30 and 35 and discussed thoroughly the present status of both documents.
Several SC members consulted their experts during the SC meeting in order to avoid any misunderstanding of the objectives of the EWG and the decisions expected from the SC.
The SC agreed that these documents were not ready for public consultation yet. Draft GL 30 will be final only when the CLT is completed, i.e. after the Task Force (TF) has achieved its work.

The EU mentioned that discussions on HL7 as a common Electronic Standard are still ongoing in the EU where any legal standard has to be based on the ISO or CEN European standards. HL7 will therefore have to become an ISO (or CEN) standard to comply with EU legislation, and this is explained in the text of draft GL35.

The SC agreed therefore that GL 35 was still a position paper and could not be adopted either.
The SC will continue to monitor the evolution of HL7 in ICH and review the status of draft GL 35 at the next SC meeting again.

Action: Next SC meeting

Discussion on the CLT Task Force
Several members questioned whether or not the proposed large number of experts was actually needed to accomplish the work of the TF. It was reminded that the SC had agreed to nominate to the TF a maximum of 2 experts representing each member, and that this number was based on the understanding that the TF would work by electronic procedure only.
As the chairman of the TF (Dr C. Ibrahim) has requested a face-to-face meeting, it was suggested in that case to limit the number of experts (criteria: good size of group to allow progress, necessary expertise to take decisions, balance regulators/industry). The chairperson should submit with the request for the meeting a proposed list of participating experts to be confirmed by the SC.

IFAH Europe and FDA recommended defining clearly the objectives of a face-to-face meeting.

The EU suggested that the TF should achieve its objectives within a limited timeframe with approval by the EWG before July 2008.

After discussion, the SC agreed that the TF should finalise its work by July 2008 and hold only one face-to-face meeting probably in early 2008.

The SC requested that this face-to-face meeting should be prepared with extreme care in order to assure its efficiency, and agreed that the attendance should be limited for the full meeting. Participation can be extended for the electronic discussions.
The SC will review the agenda before authorizing the meeting and will set the list of experts that will be permitted to attend this meeting.

Action: SC

The SC agreed to discuss later on by written procedure if a second meeting would be necessary.

The SC confirmed the objectives of the TF detailed in Appendix A of draft GL 30. The TF should develop the CLT, based on the existing lists (VEDDRA etc…) ensuring that all lists existing in the regions are available.
The SC requested the chairman of the TF to provide the SC with a detailed report on the work already achieved when requesting the face-to-face meeting.

In accordance with the rules of VICH, the TF will report to the EWG, which will endorse the work of the TF and report to the SC. The CLT will be implemented following the approval of the SC.

The SC acknowledged that future maintenance work of the CLT will be necessary, but estimated that it would not represent a major task and that it was too early to discuss the suggestions made in the Addendum to the 11th Pharmacovigilance EWG meeting report.
The SC will discuss this issue again at a later stage.

The SC agreed also to review at the 21st SC meeting, the organisations that would be authorised to make the lists available to the public.

Action: Next SC meeting

The SC applauded again the efforts and accomplishments of the EWG, endorsed the workplan of the TF detailed in the Annex of draft GL 30, and encouraged the TF to proceed with its work.

6.3. Target Animal Safety

Dr L. Nagata, chairman of the Expert Working Group, confirmed that GL 41 has been signed off for implementation at step 7 in the regions and that GL 43 had been released for consultation at step 4 for comment by the end of June 2007. Comments have been received from Europe and from the US. In Japan, the consultation ended in September and no comments were made.

The EWG will consolidate and review the comments received, and requested a face to face meeting in Japan in 2008.

At the EWG meeting that was held in last June in Paris, the experts on biologicals reviewed the outstanding issues regarding draft GL 44 (live and inactivated vaccines). Most issues were solved and the SC has released the draft GL for comments by February 2008.

The chairman requested SC endorsement of a face-to-face meeting in spring 2008 in order to review the comments received for both GL 43 and GL 44.
JMAFF recommended holding the next EWG after the experts' electronic discussion on public comments about both GL43 and GL44.

The EU supported this meeting but requested that it should be well prepared by electronic procedure.
AHI and IFAH Europe also supported a meeting in Q2 2008 and encouraged the experts to achieve as much as possible before the meeting.

The SC approved in principle a face-to-face meeting of the EWG in Q2 2008 under the condition that the work is properly prepared by electronic procedure. This meeting should be the last one of the TAS EWG.

Dr Nagata will confirm the dates for the meeting in due time.

Action: TAS Chairman

6.4. Biologicals Quality Monitoring

Dr T. Shimazaki, chairman of the Expert Working Group, informed the participants that regarding GL 34 (Mycoplasma detection) the EU had recently circulated a report indicating that the Working Parties of EDQM and CVMP were reviewing the mycoplasma testing protocol, which will be submitted to the BQM EWG in early November.
The EDQM is ready to distribute the reference strains, but the regions need access to the protocol to determine how many vials of strains are required for the tests.

After having received the protocol, the BQM EWG will review the comments on the EU protocol with the protocol submitted by USDA.

The EU confirmed that the internal consultation in the EU had been finalised and that the draft protocol for Mycoplasma detection will therefore be circulated before the end of October.
The EU pointed out that the draft protocol from USDA represented a different approach from the EDQM and could re-launch a discussion on the former methodology for mycoplasma detection. The aim for the testing would need to be confirmation of the draft VICH GL.

USDA explained that its protocol was put forward because of the absence of any other protocol at that time. USDA confirmed its willingness to discuss the EU draft protocol, to clarify the feasibility of using the EU protocol

Dr Shimazaki reported further that the discussion on the Extraneous Agents draft GL will be continued after the introduction of a seed lot system in Japan. The standard of a seed lot system is being prepared by JMAFF, and will be published for public consultation shortly. This standard should be finalised by March 2008.

The SC congratulated the chairman and the EWG, for its commitment to this long and complicated process.

Dr Shimazaki requested to hold the next meeting of the EWG in Strasbourg, but recognised that all assumptions for a successful meeting were not complete.

The SC approved in principle a face-to-face meeting of the EWG to be held in Strasbourg and asked the chairman to confirm the request in writing in due time.

Action: BQM Chairman

6.5. Metabolism and Residue Kinetics EWG

Dr S. Scheid, chairman of the Expert Working Group, reported that the EWG, which just met, had reached fundamental consensus on 4 of the 5 topics that were identified.
Regarding Topic 1 and 3 (total residues studies in target animal species and marker residue depletion studies) clarifications are still needed on the exact approach related to the sampling of specific regional tissues representing edible offal. The proposal put forth by industry is to expand the total residue study and generate residue data not only for the 4 core tissues (liver, kidney, muscle, fat) but for other additional (regional) tissues such as small intestine, gizzard, heart that are requested in Japan. These data would allow an MRL to be established. However, only one of these tissues would need to be selected/included in the marker residue study (i.e. the tissue with the highest residues or the slowest depletion rate). This proposal is currently under discussion.

The EWG agreed that total residues studies were not necessary in bees, and probably neither in fish. The experts agreed that sampling of 500 gram of sample tissue at the injection site would be acceptable in all regions. Agreement on the additional ring-shaped surrounding sample, as practised in the EU, was not reached yet. Feedback on the acceptability of this approach is pending.

There was consensus that one globally residue and metabolism study of each type would usually be an acceptable and sufficient basis for decision making. Japan indicated that they would waive a previous formal requirement for a residue study under local (Japanes) conditions. Some regional circumstances in Australia were discussed (e.g., extreme climate) and may need to be reflected in the study design (Australia and possibly other countries will provide examples and proposals for appropriate wording).

Regarding Topic 2 (comparative metabolism), the experts agreed that a minimum number of tissues would not need to be specified for the comparison. Metabolites to be considered are only those defined as >10% of residue or >100 µg/kg.
A proposal to encourage and allow use of in-vitro studies to demonstrate comparative metabolism was broadly welcomed and supported by the EWG. Feedback as to the extent to which this approach will be acceptable in all regions is pending.

For Topic 3 (residue depletion studies with the aim to establish withdrawal time), the experts agreed on the four core tissues. Industry proposed to include one additional edible offal tissues in this study (see discussion above). For this purpose, the tissue with the slowest depletion rate identified in the total residue study can be selected. Japan will provide feedback on the acceptability of this approach. The experts agreed also on the number of animals to be used and some principles for the allocation of slaughter time points. It was agreed that under

certain conditions a single time point approach to support “zero” withdrawal periods would be acceptable. This approach would apply to substance where residues are at steady state or are in depletion phase at the earliest possible sampling time (i.e. “zero”) already.

On Topic 4, (validation requirements for analytical methods), the experts agreed on a common set of validation criteria, similar to those used currently by Codex.

Topic 5 (scientific model assumptions) is regarded as the most difficult topic to solve, as it requires statistical methods and assumptions to be used. Some assumptions could generate difficult situations such as the acceptance of residue studies in one region, and their rejection in another region.
Examples from the milk industry have shown that studies could be rejected only because of the use of different statistical methods.
Some possibly relevant differences linked to in the statistical programs were discussed (e.g., approaches to deal with “left censored data”) but the EWG felt that additional examples including other parameters would be useful before a final conclusion can be reached. Industry agreed to provide additional examples.

The following options were discussed:

Short-term
The region agree to accept each others programs for the time being or develop a recommendation for a uniform (integrated) program for the calculation of tissue/milk withdrawal times based on the already existing programs. Any harmonized algorithm should however allow the necessary flexibility in the selection of the desired level of consumer protection in the different regions (e.g., 99/95 or 95/95 confidence limits).

Long term
Explore new statistical procedures for calculation of withdrawal times including data censoring techniques, Monte Carlo simulations, etc, with the intent of developing entirely new and more appropriate methodologies for this process *(*will probably require an extended mandate).

The EWG will discuss this topic further and, if necessary, will ask the SC to create a sub group of statistics experts.

S. Scheid pointed out that regarding the Acute Reference Dose, the EWG recognised the necessity of residue assessment, and was expecting guidance and decisions from the SC.

The SC congratulated the EWG for the work achieved with diligence so far.

6.6. Proposal for the re-establishment of the Safety EWG

AHI presented the revised Concept Paper and indicated that the numerous comments received after the last SC meeting have been included in the new draft.
The injection site issue is complex and has already been addressed by Codex and JECFA; but their guidances refer however to post approval procedures.
AHI therefore believed that VICH is the appropriate organisation to address the Acute Reference Dose (ARfD) at the injection site in the pre-approval phase.

FDA mentioned that the new Codex WG on Risk Management plans to address the issue of residues at the injection site and had agreed at its last meeting in September 2007 to work on this issue in coordination with VICH (see Codex report included in VICH/IN/07010).

The EU pointed out that in the different VICH regions, different ministries are responsible for the control of residues (in the EU it is DG Sanco), and expressed its concern about the latest version of the Concept Paper and the final objective of a VICH GL.

IFAH Europe believed that the objective of VICH is to set scientific rules for the determination of the data requirements for an ARfD and not to address Risk Management issues such as the control of residues.
Codex and JECFA have called for cooperation with VICH on the scientific basis of the determination of an ARfD, whereas the Risk Management responsibilities are under the authority of Codex and the post approval compliance control authorities in the different regions.

AHI stated that the setting of pre approval guidance is in the mandate of VICH. The Risk Management aspect must be left to other bodies. The residue at the injection site represents an important international issue that can limit trade.

The EU acknowledged that a VICH GL would be helpful in assisting JECFA for the determination of a methodology for setting ARfDs, as mentioned by the JECFA Secretariat at the last CCRVDF meeting.
The EU therefore suggested clarifying in the Concept Paper that the VICH EWG mandate would be focused on the harmonisation of the data requirements for the setting of an Acute Reference Dose, without interfering with the Risk Management by the local authorities.
The EU confirmed that under these conditions it would support the re-establishment of the Safety EWG, although the EU did not consider this topic as a high priority.

FDA believed also that a VICH GL would assist Codex and JECFA, and supported the revision of the Concept Paper as well as the re-establishment of the Safety EWG.

JMAFF recognised that the residue at the injection site is an important issue, and confirmed that it would support the re-establishment of the Safety EWG under the condition that an adequate clarification of the Concept Paper is achieved as mentioned above.
In Japan, this topic is under the responsibility of the Food Safety Commission and the Ministry of Health, Labour and Welfare (MHLW), which has yet to reach a consensus, but the determination of the ARfD to evaluate the amount of residues at the injection site would facilitate the discussions.
JMAFF confirmed that the experts for the new Safety EWG have already been nominated.

Currently Canada does not use the ARfD model, but supported the re-establishment of the Safety EWG and will nominate an expert.
ANZ also supported the re-establishment of the Safety EWG.

The chairman concluded that the SC had not raised fundamental objections to the development of this topic under the condition that the scope and the objectives of the VICH GL would be clarified in the Concept Paper.

JMAFF mentioned that it would need to consult with the Food Safety Commission and the MHLW on a new draft Concept Paper before adopting the final version.

The SC requested therefore that AHI should revise the Concept Paper, in close consultation with the EU and JMAFF, in order to produce a new draft sufficiently in advance of the next SC meeting. The new draft should comprise clear suggestions for the objectives of the EWG's task, the objective to be achieved by a GL, the estimated timelines, the number of meetings etc…

Action: AHI

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

No Guidelines were at this step in the process and therefore no document was submitted.

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

8.1. GL 24 (Pharmacovigilance: AERs) – Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERs)

The Steering Committee adopted GL 24 as final VICH guideline at Step 6, subject to the changes agreed. This guideline was transmitted to the VICH members for implementation at step 7 in the regions to be determined pending adoption of VICH Guideline 30 (Controlled List of Terms) and VICH Guideline 35 (Electronic Standards for Transfer of Data).
However the SC agreed that Regulatory Authorities may consider implementation at an earlier stage as appropriate*.*

8.2. GL 42 (Pharmacovigilance: AERs) – Pharmacovigilance: Data Elements for Submission of Adverse Event Reports

The Steering Committee adopted GL 42 as final VICH guideline at Step 6, subject to the changes agreed. This guideline was transmitted to the VICH members for implementation at step 7 in the regions to be determined pending adoption of VICH Guideline 30 (Controlled List of Terms) and VICH Guideline 35 (Electronic Standards for Transfer of Data).

9. Proposal for a categorisation of VICH GLs

AHI explained that, considering the increase of the number of VICH GLs, it could be appropriate to list all VICH GLs in a way different than the current chronological order displayed on the VICH public website.
AHI therefore suggested that the simplest way would be to group the GLs according to the EWG that generated them.

The participants discussed thoroughly the suggestion presented by AHI and adopted a final categorisation (VICH/07/061).

The SC decided that the numbering system for VICH guidelines will remain chronological and that on the VICH Public Website, the Guidelines will be made available both chronologically

and by category.

Action: Secretariat *(Done)*

10. Concept papers/Discussion papers

10.1. Update on ICH's experience with the Common Technical Document

FDA presented an update on what is being implemented in ICH with regard to electronic submission and transmission of information.

The SC agreed to monitor this topic further at the next SC meeting.

10.2. IFAH-Europe Concept Paper on Electronic Presentation of Regulatory Documents

IFAH-Europe presented the draft concept paper circulated prior to the meeting and indicated that the comments received from the regions after the first circulation had all been very positive and most have been included in the current version of the document.

The SC recognised the need to keep the electronic presentation of regulatory documents simple and affordable for the limited resources of the veterinary sector.

FDA highlighted the important costs generated on the human side because of the appearance of some problems, many of which have not all been solved yet. In particular, no cost-benefit analysis was done beforehand.
The veterinary sector will most certainly move towards electronic submission, but should wait until the major problems are solved on the human side and must ensure that future systems are kept proportional to the needs and resources of the veterinary sector.

The EU confirmed its support of this topic and a concept of harmonised approach between the 3 regions, but this concept should be simple with a pragmatic approach.
The EU mentioned that the HMAs (Heads of Member States' Medical Agencies) had decided to render e-submissions possible in the veterinary sector by the end of 2009, and discussions had started between the EMEA, the Member States and the Industry.

IFAH Europe pointed out that the Industry would therefore need harmonisation in order to avoid unilateral developments in the Member States and the different regions.
IFAH Europe has used the term of electronic presentations in its document, to avoid pre-conceptions of the meaning of the term "E-submissions".

The SC reconfirmed that the veterinary sector did not intend to move towards the CTD.

During the discussion, the SC recognised that the smaller companies in the veterinary sector would only be able to allocate a very limited budget to electronic presentations and therefore agreed that electronic presentations should be rendered possible, but not mandatory.
The SC decided that the objective of this topic would be to set minimum standards that have to be at least achieved to submit in an electronic format.

The SC supported the proposal of IFAH Europe that the coordinators should liaise in order to collect the information existing in the regions and to develop a project discussion document outlining a way forward.

IFAH Europe will present the project discussion document for discussion at the next SC meeting.

Action: IFAH Europe

10.3 Proposal for a Concept Paper of VICH Bioequivalence Guideline for the Registration of Animal Products

AHI explained that bioequivalence is an important topic for the extension of products as well as for the marketing of generic products, pharmaceuticals as well as biologicals.
AHI proposed that the first step would be to review the legislation and whatcurrently exists in the regions.
A concept paper for a VICH bioequivalence GL could be drafted thereafter with the assistance of the regions.

FDA supported the proposal and mentioned that a bioequivalence GL has existed in the USA for many years. FDA also expressed a desire VICH take care to assure that the generic industry be appropriately represented in VICH when this topic is dealt with. The European Commission agreed.
The EU supported also the proposal and explained that the European bioequivalence GL was currently under revision, and that the revised guideline would very likely be closer to the FDA GL than the current one.

OIE pointed out that bioequivalence was a global issue and that most OIE Member States would benefit from a VICH bioequivalence GL.

After discussion, the SC agreed that the regions will assist AHI in drafting a Concept Paper that will be discussed at the next SC meeting.

Action: AHI

11. Formal presentation of the new VICH Web site

The Secretariat presented the new layout of the VICH website and proposed to develop further the site's Members Area.
The SC agreed that a copy of all documents circulated to the SC by the Secretariat will be placed on the Members Area, as well as all relevant SC internal guidance documents. This part of the site would progressively become the on-line archive of the SC, available to all SC members.
As all new documents will be made available on the Members Area, the SC further agreed that in the future the Secretariat would not anymore circulate paper copies of the SC meeting's preparatory documents.

12. Next VICH Conference

The Secretariat reminded the participants that at the 19th SC meeting it had been agreed in principle to organise a VICH 4 conference and it had been suggested that an Observer country could host this Conference.
Canada and ANZ indicated however that they would not be able to organise such a Conference.

As, in accordance with the rotation principle, VICH 4 would then be hosted by Europe, IFAH Europe suggested organising the Conference in coordination with OIE. It was recommended that the Conference could be linked with the OIE Annual General Assembly, in the frame of the OIE training programme.

IFAH Europe and OIE will discuss this further, and present a proposal to the 21st SC meeting in Paris.

Action: IFAH Europe/OIE

13. Any other business

13.1 Organisation of SC meetings in Observer countries

The Secretariat mentioned that at the last SC meeting it had been proposed to hold a SC in an observer country, in case one of these countries wished to host the SC.
CAHI offered to host the 22nd SC meeting in Canada.

The SC discussed the principle of meeting in an observer country, which had been previously refused to EWGs, and agreed that after 10 years of functioning of VICH, the SC should pay the courtesy to the observer countries who have very actively participated the VICH process since the start.

The SC therefore agreed in principle to hold the 22nd SC meeting in Canada during the last week of February 2009.

13.2 Format of the minutes

IFAH (P. Jones) explained that members of the SC has requested that the minutes should reflect only the conclusions of the meetings' discussions, rather than capturing the entire process which leads to the conclusions, in order to reduce the volume of the minutes.
Other members had confirmed their satisfaction with the current presentation of the minutes.

The Secretariat indicated that the minutes were written in the same format since the start of the VICH process, with the objective of transcribing as faithfully as possible the SC meetings' decision making process.

After discussion, most SC members recommended that the format of the minutes should not be altered, but be preserved as the records of the discussions taking place at SC meetings.

14. Dates and venue of next meetings

- The 21st SC meeting will take place on July 8 & 9, 2008 in Paris, hosted by OIE
- The 22nd SC meeting will take place in Canada during the last week of February 2009

15. Adoption of the Press Release on the 20th SC meeting

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

VICH STEERING COMMITTEE

20th meeting

October 17 & 18, 2007
Yokohama, Japan

Chair: Dr M. Sakai, JMAFF

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI	R. LIVINGSTON
AHI (PFIZER)	M. J. MCGOWAN
EUROPEAN COMMISSION (DG ENTERPRISE AND INDUSTRY)	A. GAUTRAIS
EMEA	K. GREIN (C)
EMEA-CVMP (BVL)	R. KROKER
IFAH-Europe (BAYER)	L. KLOSTERMANN
IFAH-Europe (MERIAL)	B. BOENISCH
IFAH-Europe	R. CLAYTON (C)
JAPAN MAFF	Y. TAKAHASHI
JAPAN MAFF	H. SEKIGUCHI (C)
JAPAN MAFF	M. SAKAI (Chair)
JVPA	M. KAJIWARA
JVPA	S. OHSHIMA (C)
JVPA (CHEMO-SERO-THERAPEUTIC RESEARCH INSTITUTE)	S. TOKIYOSHI
USDA APHIS CVB	B.E. RIPPKE
US FDA	M. SMITH
US FDA	L. BEAVER (C)

OBSERVERS

THE ALLIANCE/AGCARM	P. HOLDSWORTH
APVMA/NZFSA	M. HOLMES
CAHI	J. SZKOTNICKI

INTERESTED PARTY

AVBC	R. TULLY (for J. THOMAS)

OIE

OIE	P. DEHAUMONT

INVITED

Austrilia/New Zealand	D. MORRIS
EU (BVL)	S. SCHEID (part)
JMAFF	K. HAMAMOTO (part)
JMAFF	T. SHIMAZAKI (part)

VICH SECRETARIAT

IFAH	P. JONES
IFAH	H. MARION

APOLOGY
HEALTH Canada I. ALEXANDER