VICH/06/019
30 August 2006
FINAL

VICH STEERING COMMITTEE
18th meeting
May 31st & June 1, 2006
London, Europe

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

Dr M. Terberger, chairman, opened the meeting by welcoming the participants to London on behalf of the EU and IFAH-Europe. He thanked the EMEA for organising and hosting the meeting.
He introduced 2 new participants: Dr Y. Ishihara, who replaces Dr T. Shimazaki as coordinator for JMAFF, and Dr R. Berman in replacement of Dr J. Szkotnicki, CAHI, who has sent her apologies for this meeting.

Dr H. Marion indicated that the Secretariat had received apologies from Health Canada. The Secretariat had also received a kind letter of farewell from Dr T. Shimazaki to the Steering Committee, which Dr Marion read to the SC.

Dr P. Jones, Executive Director of IFAH, welcomed the participants on behalf of IFAH.

2. Adoption of the agenda

Draft 5 of the agenda was tabled at the beginning of the meeting. It was adopted without further change.

3. VICH Strategy Phase II

3.1 Review of the draft guidance document on the Monitoring and Maintenance of VICH GLs

The EU reminded the participants that it had presented at the 17th SC meeting a discussion document on the maintenance and the monitoring of VICH GLs, which had been based on the respective ICH document.
The new document presented to the current meeting is based on the previous document and the comments received at the 17th SC meeting, the EU having received no further written comments since then.

The EU highlighted the outstanding decisions which the SC has to take before finalising the document: the need to differentiate major and minor changes, as at the last meeting the SC

had decided that the presented ICH process for major and minor changes was too complicated to apply to VICH.
Also there is a need to define the monitoring procedure determining which GL should be revised and updated.
The SC was reminded that the Organisational Charter states in the 9 step procedure that a monitoring should be done 3 years after the GL has been implemented.

The EU suggested that the review of GLs should be done on a systematic basis with decisions on revision or not on GLs due for such review to be made at each SC meeting.

After discussion, the SC confirmed its responsibility for the decision making on whether a process should be initiated and whether it would be a major or minor change.
For major changes the revision process shall be a full 7 step process.

The SC unanimously agreed that the revision process should be streamlined and should limit required resources by avoiding as much as possible the organisation of full EWG meetings and by shortening timelines.

The SC agreed further that the “Contact Point” for the revision of a GL would be the nominated expert of each region, who will be in charge of initiating the proposals for GL revisions and discussions and negotiations with the other experts. The coordinators would be responsible for the coordination of the input in their region. The sign-off responsibility would lie with the coordinator instead of the expert.
A concept paper detailing the proposed amendments will be requested for each revision proposal. The SC will be the final decision maker for the initiation of a GL revision and approval of a revised GL.

OIE suggested again, as stated in the Organisational Charter, to include a cost/benefit analysis in the review of existing GLs for which this was not done and an impact assessment of the GL after 3 years or more of implementation.

IFAH-Europe raised the issue of the interpretation of VICH GLs in the regions and suggested elaborating also a procedure to resolve such issues.

After discussion, the SC recognised that issues of interpretation may appear even before the 3 years deadline for review and agreed therefore to include in the final document the possibility to amend a GL at any time.

After further discussion, it was agreed that the EU would revise the document in order to include the decisions made. The EU would also highlight any change to the Organisational Charter arising from the guidance document and make a proposal for consideration by the SC.
The Secretariat will circulate the amended document for approval by written procedure.

3.2 Expectations from the partners to VICH success in Phase 2

Dr P. Jones explained that Industry applauded the many achievements reached by VICH since its creation 10 years ago and enthusiastically supported the VICH process. Lately however concerns were frequently raised about the lack of progress during recent years.

The IFAH Board had therefore considered that it would be appropriate for Industry to review the current VICH process and to define Industry's vision for VICH in the next 5 years.

A meeting took place at the end of April 2006 between SC Industry representatives and other Industry members. The participants to that meeting unanimously appreciated the unique opportunity VICH represents for Industry to meet with the regulators and the benefit that has resulted from these regular contacts.
They praised in particular the change in regulatory approaches that occurred in some regions following the discussions in VICH.

A number of issues were highlighted in the document prepared by IFAH such as the interval between VICH SC meetings, the representation to VICH at all levels or the preparation of concept papers.

IFAH praised the excellent preparatory work of the Metabolism & Residue Kinetics EWG that should serve as example for future topics, and appreciated also the consistent support since the start of the VICH process from OIE.
The fact that Dr M. Terberger, head of Unit F2 in DG Enterprise and Industry of the European Commission, had agreed to lead this 18th VICH SC meeting was further considered as an encouragement from the hierarchy of the EU Institutions.

The purpose of IFAH's paper was to bring issues to the attention of the SC in order to enable an in-depth debate at the 19th SC meeting in Washington.

The EU asked for clarification on the content of the document and the aim of the initiative, while supporting in principle the initiative.

FDA confirmed its strong support to VICH, although while acknowledging that, at times in the past, the FDA and CVM hierarchy has not been able to make some VICH activities a top priority because of resource contraints, FDA nevertheless pointed out that many experts and resources have been, and continue to be, allocated to VICH, which is a unique forum where FDA can have very valuable discussions with Industry.

JMAFF considered the VICH activities impressive compared to outcomes of other international fora~~ums~~, and supported IFAH's initiative in principal, but requested more specific proposals to be put forward for discussion at the next SC meeting.

OIE supported also the proposal and indicated that there was a growing demand from OIE members to participate in the VICH process. OIE encourages therefore the national veterinary services to take the VMPs into account in their national policies and furthermore supports developing countries to adopt harmonised positions on VMPs.
OIE is further prepared to adopt VICH GLs as International OIE Standards.

The chairman concluded that the concerns raised regarded more the efficiency of the VICH process than the strategy itself, which has been reviewed recently.

It was agreed that IFAH will prepare a discussion paper on the efficiency of VICH for the next SC meeting in Washington.

4. Review of written updates

4.1 From the coordinators

The Secretariat presented the written update report on the actions agreed at the 17th SC meeting circulated before the meeting.
FDA asked the Secretariat to include its report which had not reached the Secretariat.

Following the question from the Secretariat for the timing for future reports, the EU supported that there would be updates between the SC meetings, as this would also serve as reminder for any outstanding actions. The EU suggested circulating also updates from the EWGs on the progress on GLs.
JMAFF supported this proposal and asked the Secretariat to add the dates of reporting by the regions.
It was agreed that an intermediate update report on actions agreed would be circulated half-time between the SC meetings. The EU will assist the Secretariat in setting up a procedure for update reports on the progress on GLs.
Meanwhile, the Secretariat will circulate the revised version of the update report on the actions between SC meetings.

4.2 On the implementation of final VICH Guidelines since the 17th SC meeting

A table on the implementation of VICH GLs has not yet been circulated. The Secretariat will attach the updated table to the minutes.

5. Discussion Paper on Metabolism and Residue Kinetics

5.1. Update on the Experts' activities

The chairman of the EWG, Dr S. Scheid, pointed out that the interim paper had been reviewed at the 17th SC meeting in Kyoto and that the EWG had subsequently met in a face to face meeting to produce the final discussion paper that was circulated before this SC meeting. During the EWG meeting the participants reviewed the current situation in the different regions and sought clarifications on the EWG's mandate.
The chairman explained that the core set of data is very similar in the regions, but that differences exist in the concept to set MRLs or "tolerances", in exposure estimates, in calculations of intake of residues by consumers etc… that can impact on the development of harmonised GLs.
Taking the example of injection site residues, there are several different approaches in the world to this issue, whilst the data are assessed very differently.
The majority of EWG members therefore suggested attempting a single approach, and brought the matter to the attention to the SC although it is not in the mandate of the Group.

5.2. Review of the final Discussion Paper

Dr S. Scheid presented the summary conclusions agreed by the experts and believed that progress in the harmonisation of the studies themselves was a first step to the global harmonisation of procedures.
He stressed that there had been general agreement between the experts that the GLs should apply to the most common food producing species, cattle, pig, poultry as well as bees/honey & fish, and should be easily applicable to corresponding related species.
The experts endorsed also the primary topics proposed by the SC at the 17th meeting, confirming that there are currently no harmonised GLs in these 5 areas. Other topics raised in the discussion paper were discussed but not considered to be within the scope of the EWG's mandate.
During the discussion AHI believed that the 5 topics did not represent a real impediment to international trade and suggested to broaden the mandate to other more controversial issues, and include derivation of MRLs and concept for consideration of residues at the injection site, as the expertise is available in the EWG.
The EU pointed out that the objective of VICH is not to duplicate work with other organisations such as Codex, who has the responsibility for setting MRLs at international level. Regarding the residues at injection site issue, the EU noted that attempts had been made over several years to come to an international agreement, which did however fail, and recommended to discuss possible extensions of the mandate only when the EWG has progressed on the current topics.
ANZ supported AHI's suggestion to consider injection site residues within the EWG's mandate and requested further that sheep being a major species in ANZ be taken into account by the EWG at this stage.

~~S~~ Dr Scheid commented that sheep could be included as main species.

After further discussion, the SC agreed to review the mandate at a later stage. Meanwhile it was recognised that the discussion on MRLs at the injection site is related to the risk assessment concept of considering acute reference dose or not and is in any case not within the scope of this EWG, but could be dealt with by the Safety EWG.
IFAH proposed to prepare a discussion document on the acute reference dose concept to consider further this issue at the next SC meeting in order to decide if the Safety EWG should be reactivated to deal with the issue of MRLs at the injection site. This was agreed by the SC.

The SC formally approved the establishment of the EWG on Metabolism and Residue Kinetics and confirmed that the EWG should consider the 5 proposed priority topics.

Dr S. Scheid added that the discussions were progressing within the EWG to nominate a topic leader and co-leader for each of the 5 topics; the SC agreed to approve the nominations by written procedure as soon as Dr Scheid circulates a formal recommendation. (*Post meeting note: Done*)

The SC confirmed the timetable proposed by the EWG being 12 to 18 months for the release of draft GLs at step 4 for consultation. The SC encouraged the EWG to achieve as much work as possible by written procedure and agreed in principle for one full meeting of the EWG to finalise the draft GLs at step 3 and another meeting to review the draft GLs at step 5, after the consultation. The EWG will have to present the SC with a formal request for each of these 2 meetings.

The chairman thanked Dr Scheid and the experts on behalf of the SC for the amount of work already achieved in drafting the final discussion document.

6. Progress Reports of Expert Working Groups

6.1. Quality

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr K. Hamamoto and presented by JMAFF.
No major progress has been achieved since the 17th SC meeting because GLs 3R, 10R and 11R are still under public consultation in Japan and in other regions.
JMAFF confirmed that Dr K. Hamamoto's endeavour was to progress the work as fast as possible

The SC supported Dr K. Hamamoto's efforts in progressing the finalisation of the draft GLs in close collaboration with the topic leaders.

6.2. Pharmacovigilance

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr L. Post, and presented by the FDA.
GLs 24 (Management of Adverse Event Reports (AERs))& 42 (Data Elements for Submission of Adverse Events Reports) were signed off for consultation by the EWG in London at its 9th meeting last year and subsequently by the 17th SC meeting; these GLs will require a review for changes after the consultation.
GL 29 (Management of Periodic Summary Update Reports (PSUs)) was signed off by the EWG in Tokyo at its 10th meeting earlier this month.
GL 30 (Controlled list of terms) was also signed off in Tokyo for a second consultation although the list of terms was not finalised and the EWG suggested setting up a special subgroup to finalise the list of terms.

GL 35 (Electronic Standards for Transfer of Data) was not signed off yet as the experts are seeking guidance from the SC on the common electronic standard which could be either FDA's HL 7 or the EMEA Eudravigilance standard.
ICH, on its side, will consider this issue of interoperability of electronic systems in the near future.
FDA stressed that if HL7 is not adopted as a common electronic standard, FDA will be able to adapt the information received in another standard.
FDA reported further that it had agreed recently to work together with USDA and AHI in order to reach a consensus on the controlled list of terms before the next EWG meeting.

The EWG requested a final meeting to take place before the next SC meeting in order to finalise GL 35, review the comments received for GLs 24 & 42 and agree on the final of GLs 24 and 42.
JMAFF and Australia indicated that the consultation will be achieved ASAP.

After discussion the SC agreed to postpone any decision on the interoperability of electronic systems to the next SC meeting, after ICH has clarified the issue.

Regarding the controlled list of terms for GL 30, the SC agreed to set up a special Task Force (TF), which would deliver a list within a year. This TF will later become responsible for the maintenance of the Pharmacovigilance (PhV) terminology.
The SC unanimously agreed that the membership will be mainly from the EWG members to be complemented possibly by additional experts and that the TF should work essentially by electronic procedure. Any meeting would have to take place in the frame of the last PhV EWG only.

The Secretariat requested that the chairman of the EWG should send the list of members of the TF to the Secretariat for circulation to the SC, as well as any formal request for a full meeting of this TF.

The SC supported in principle another meeting of the EWG, the 11th and final, to take place before the end of 2006, but requested the chairman of the EWG to provide a formal demand to the SC through the Secretariat when a date will be fixed.

6.3. Target Animal Safety

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr T. Nagata, and presented by the JVPA.
Regarding GL 41 on the reversion to virulence, the updated version of the report shows that progress was made recently as the issue of the number of passages has been resolved.
In accordance with the Organisational Charter a representative of the regulatory authorities has to be topic leader at step 5, and the EWG recommends that Dr M. Moos should become this topic's leader.

For the TAS GL for pharmaceuticals, CVM has proposed a revised text on the 10X dose issue, which would enable the EWG to sign off the draft GL at step 3.

With regard to the draft GL for live and inactivated vaccines, JVPA reported that the EWG was unable to make progress by written procedure. Dr T. Nagata requested a final face-to-face meeting in fall 2006 to solve the issues of batch size as well as the definitions of pilot batch and working batch.

The SC agreed Dr Moos to be topic leader for draft GL 41.

The SC discussed thoroughly the EWG's request for a final meeting.
JVPA, IFAH-Europe, AHI and USDA felt that, following the reports of their own experts, this meeting would enable completion of the work on the remaining issues.

The EU requested that the SC should receive a detailed list of the issues to be solved before authorising formally the meeting. JMAFF supported the EU's request.

The SC therefore supported in principle a final meeting of the EWG but required a detailed list of issues that would be solved before authorising formally the meeting.

6.4. Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr S. Nakamura, and presented by JMAFF.
This EWG is progressing 2 topics: mycoplasma and extraneous agents testing.
JMAFF pointed out that in Japan the new standard establishing the seed lot system will be finalised by March 2008 and that the progress is on schedule. JMAFF is working closely with JVPA to prepare the implementation.
Regarding draft GL 34, Mycoplasma testing, Dr S. Nakamura wrote his report before the EU update report on the testing so he did not take into account the EU proposal.
GL 34 cannot be finalised until the testing has been done, as agreed by the SC several meetings ago.
The EWG is seeking guidance on which direction the testing should be developed.

The EU reported that the reference strains are now ready and
once the European Pharmacopoeia will have formally adopted the strains in its Commission meeting at the end of June, they can be made available. The recipients are asked to organise the shipping of the strains during the month of July. Requests should be addressed to the EDQM, but the EU coordinator offered assistance, if required.

The EU raised concern regarding the direction of the ongoing discussions by email exchange on the testing protocol, as it appeared that the current proposal for a protocol would not reflect the step 4 document of the GL, but attempted that the work would go back to step 2 (drafting) rather than move on to step 5 (study of comments). If the SC would confirm that the objective of the testing of the reference strains is to verify GL34 and demonstrate its suitability rather than to restart the debate of the concept of the mycoplasma testing, the EU experts/EDQM were willing to propose a protocol for testing.

The SC recommended therefore that the strains have to be validated in the frame of the existing GL to represent the practical implementation of the GL that has been developed.

During the discussion JMAFF reminded the participants that GL 34 had been released for public consultation, but then the process was disrupted because the strains were not available. Now that the strains will be delivered and tested, JMAFF suggested restarting the public consultation, whilst the protocol will be agreed by the EWG, and the testing based on the protocol will be finished.

USDA pointed out that the strains are different from those initially planned (frozen strains) and therefore the EWG should ensure that the strains fit with the GL; the GL should however not be re-discussed at step 2.

The intention of the distribution of the protocol was not to go back and question the agreements in the GL.

After an in-depth discussion where each member expressed his opinion, the SC agreed that the EWG should urgently progress the work on both the protocol and the testing. If felt necessary, the EWG should request a full meeting to the SC. The EU was requested to draft a protocol.

The SC acknowledged that the testing of the strains would take about 1 year.
The consultation should start again only when the testing has been completed. The GL will be reviewed after the consultation period.

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

7.1 GL 30 (Pharmacovigilance of Veterinary Medicinal Products - Controlled List of Terms)

The Steering Committee received the text of GL 30 as a proposed guideline at Step 3. This guideline was transmitted to the VICH members for a 6-month public consultation at Step 4.

The Steering Committee agreed that the deadline for members to submit comments on the guideline is December 1, 2006.
*(Post-meeting note: As the document was circulated only in late June to the SC, the deadline for comments is **December 31**, 2006)*

7.2 GL 43 (Target Animal Safety for Pharmaceuticals)

As the GL had not yet been signed off at step 3 by all members of the EWG, the sign- off of GL 43 by VICH SC members was postponed for a written procedure at a later stage.

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

8.1. GL 29 (Pharmacovigilance of Veterinary Medicinal Products - Management of PSUs)

The participants recognised that the wording of this GL may require updating because it has been on hold for some time. After discussion, it was agreed to adopt this GL in its current version, subject of three more editorial changes (correction of title on cover page, change of "adverse effect" to "adverse events" in first paragraph, addition of the abbreviation "(AER)" after "Adverse Event reporting" in III. Definitions), and to amend it by the maintenance procedure at a later stage when all Pharmacovigilance GLs have been finalised, if considered necessary.

The Steering Committee therefore adopted GL 29 as final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation in the three regions at Step 7.
The Steering Committee agreed that the Guideline will enter into force by June 2007.

8.2. GL 41 (Target Animal Safety - Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence)

As the GL had not yet been signed off at step 3 by all experts of the EWG, the sign off GL 43 by VICH SC members was postponed for a written procedure at a later stage.

9. Update on ICH's experience on the CTD

FDA presented a report on the benefits and challenges of the electronic CTD in the human pharmaceutical and biological area (*see presentation attached*).

Three colleagues from the human sector of the EMEA (Hilde Boone, George Wade and Jean-Marc Vidal), also involved in ICH, shared the EMEA experience on the implementation of the CTD in Europe
During the discussion, the SC recognised that for the moment the electronic submission and the CTD are both a very expensive exercise and therefore agreed that the animal health sector should keep these issues on hold until remaining complicated issues have been resolved in ICH . The CTD shall nevertheless remain a potential topic for VICH and the SC will review ICH developments at future meetings.

The chairman thanked the colleagues from the FDA and EMEA on behalf of the SC for their useful explanations.

10. Potential New Topics

10.1 Review of the Proposed concept paper on harmonisation of MIC Breakpoints

IFAH-Europe explained that as discussions with the regulatory authorities in the EU were still ongoing, IFAH-Europe will prepare a revised concept paper for review at the 19th SC meeting in Washington.

10.2 Review of the Discussion Paper on Alternative Tests to Animal Testing

The EU presented the Discussion Paper that had been drafted following the SC's agreement at the 17th SC meeting to prepare such a document aimed for the VICH to set up guidance for alternative testing methods or appropriate testing strategies aimed to reduce animal testing; the end objective being the reduction of animal testing. The EU reminded the participants that although several EWGs had already included in their work on developing GLs on the data requirements for the registration of veterinary medicinal products guidance to reduce the number of animal tests, the EU believed that it would be nevertheless important to provide more comprehensive guidance to the industry on the use and acceptance of alternative tests and/or approaches for the reduction of animal tests for registration dossiers.
The EU has received several contributions following the call for comments at the last SC meeting.

VICH's aim should however not be the development of new validated tests but rather the compilation of the validated tests that are already available and to provide guidance to use these and on the testing strategy regarding for example the number of species tested.
The EU suggested further that the mandate of all EWG should include the possibilities for refinement, reduction and replacement of animal testing.
During the maintenance of existing VICH GLs updates may also be required to include alternative approaches that could be used.

The chairman recommended focussing on the 4 points proposed by the EU as main points of activity.

IFAH-Europe suggested the topic should also cover the identification of barriers to regulatory acceptance, and recommendations for addressing these barriers. IFAH-Europe also reported that a European partnership between the European Commission and 7 chemical/pharma industry associations had been formed with similar objectives.

FDA indicated that in the USA alternative testing issues are presently addressed through an interagency coordination of 34 US agencies, for which the activities are described on the following website: *http://iccvam.niehs.nih.gov/home.htm*

JMAFF supported that VICH provides guidance on reduction of animal testing and would support to create an EWG. JMAFF pointed out that the scope of its activities would be limited by the Japanese existing animal welfare legislation, and requested therefore that if any VICH EWG is established for dealing with alternative testing issues, it should receive a very clear and precise mandate.

JVPA reported that in Japan a new body, the JaCVARM (Japanese Centre for the Validation of Alternative Methods), had been created in November 2005 under the responsibility of the National Institute of Health Science. Its activities cover not only the fields of pharmaceuticals, but also of agricultural pesticides and cosmetics. JVPA supported in principle to create a specific EWG and the update of existing GLs.

AHI expressed interest in the topic and supported the detailed comments provided by IFAH Europe.

The EU clarified that the aim was not to develop new guidelines on alternative testing other than those currently existing and being developed by regional and international bodies, but rather to identify the existing test guidelines and to indicate which tests can be used.
The EWG mandate would be to compile a list of existing alternative tests and to agree on common validated tests, thus clarifying a sometimes confused situation.

FDA confirmed that it supported the principle ~~that~~ of a thorough review to assure that alternatives to animal testing are well considered when VICH guidance are developed and that it would support further discussion by the SC about how this goal can best be accomplished. It, however, at this time was not sure that creating a new EWG was necessary to achieve this goal.

The chairman concluded that this is a topic about which the public is very sensitive and that the VICH parties view with great importance.
He recommended that the SC members should continue further bilateral discussion in order to enable the preparation of a paper reflecting the common level of scope.
The participants agreed to discuss the issues further with the EU before the next SC meeting. If the FDA would support the topic, the EU would prepare an updated discussion paper for the 19th SC meeting.

10.3. EU Proposal on Electronic Submission of Dossiers

The EU explained that some companies were asking to submit the quality part of the registration dossier in electronic format, as do their "human" counterparts, when the substances were identical.
The EU therefore requested advice from the SC on the level of interest for further work on electronic submission.

AHI pointed out that it had drafted a preparatory document 2 years ago, which took into account the characteristics of the veterinary sector. Compared to the "human" sector, the structure of the Industry is different, the number of applications in the 3 regions is different etc… AHI suggested nevertheless continuing to monitor the evolution on the "human" side and recommended that the Industry should produce an assessment on the number of applications and an estimate of the costs considered necessary to harmonise this topic. Having also worked closely with FDA on this topic, AHI agreed to prepare for the next meeting a short statement from its electronic submission working group.

IFAH-Europe warned of the high set-up costs and the need to develop solutions specific for and proportionate to the veterinary sector. Due to the diverse range in size of veterinary companies it was important to allow choice, and it will be necessary to keep the paper option for the foreseeable future.

After further discussion, it was agreed that for the next SC meeting the Regulators will review the developments on the "human" side and the Industry will provide, together with the Regulators, a cost benefit analysis.
It will then be decided if a discussion document, including an estimation of the cost and the expected timeframe, should be drafted.

10.4. Applicability of ICH Quality Initiatives (Q8, Q9 and Q10) to Veterinary Medicines

The EU explained that it had added this topic to the agenda because it believed that the ICH initiative on quality issue could be interesting for the veterinary industry.
The EU therefore suggested that these 3 new ICH GLs could be reviewed by the Quality EWG.

IFAH-Europe confirmed its support on the long term because these GLs are very general and do not require additional data.
However IFAH-Europe stressed ~~strongly~~ the general principle ~~aiming at~~of keeping a strong differentiation between the human and the veterinary sectors and that in no case an ICH GL should be "copied & pasted" to VICH unless a thorough review has been done.
Furthermore ICH Q8 is referring to the design space area concept, which is not yet well understood and may have a limited applicability in the veterinary sector because the volumes produced are generally small. IFAH-Europe recommended therefore waiting until more experience was gathered on the human side.

JMAFF and FDA supported the initiative and FDA suggested reporting the evolution on the human side at the next SC meeting.

Dr P. Jones recommended that the Animal Health industry should consider carefully the implications of these “human” guidelines because the “human” pharmaceutical industry has embraced them very enthusiastically. Their benefits became apparent only after detailed consideration by the “human” industry.

After further discussion it was agreed that at the next SC meeting the Regulators from the 3 regions will report on the experience and perception of concept on the human side in their region and indicate their views of the impact on the veterinary side.
Industry will clarify its opinion on the applicability of these GLs to the veterinary sector and the foreseen impact of VICH GLs.
FDA will report also on the progress from the 2 forthcoming ICH meetings.

11. Update of the VICH Work Plan

The SC reviewed the document prepared by the Secretariat. The Secretariat will update the document and circulate it after the meeting.

12. VICH Web site

The Secretariat reported that because of a reorganisation of the European Institution’s IT systems, the EU would not be able to host the VICH website at “vich.eudra.org” after the end of 2006.
IFAH has consequently agreed to take over the hosting and management of the VICH site and has asked the EU to transfer to IFAH the ownership of the “vich.org” domain name, which the EU had bought at the creation of VICH.

There has however been a delay in the transfer for technical reasons. As the current site was frozen at the end of last February and is in urgent need of updating after this SC meeting, the Secretariat will set up a temporary site on the IFAH homepage under “ifahsec.org/VICH”, until the address vich.org is available.

Automatic transfers will be put in place and the SC will be informed of the evolution.

13. Any other business

On behalf of the SC the chairman thanked the EMEA for the perfect organisation and hosting of this SC meeting.

14. Dates and venue of next meetings

- The 19th SC meeting will take place on January 24 & 25, 2007 in Washington DC - USA
- The 20th SC meeting will take place on October 17 & 18, 2007 in Japan

15. Adoption of the press release on the 18th SC meeting

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

VICH STEERING COMMITTEE

18th meeting

May 31st & June 1, 2006
London, Europe

Chair: Dr Martin Terberger, European Commission

LIST OF PARTICIPANTS

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