VICH/08/030
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VICH STEERING COMMITTEE
21st meeting
July 8 & 9, 2008
Paris, Europe

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired on 8 July by Dr M. Terberger and on 9 July by I. Sacristan Sanchez, both representing the European Commission. Dr M. Terberger opened the meeting by welcoming the participants on behalf of the EU and IFAH-Europe.
He passed the floor to Dr Bernard Vallat, Director General of OIE, who welcomed the participants to the Headquarters of OIE in Paris

B. Vallat confirmed that VICH represents a key activity for the 172 member states of OIE as VICH contributes to the raising of the quality standards of veterinary products in the world, which are critical for the improvement of the global animal health status.
The use of veterinary products plays an important role in the field of food security. OIE is therefore involved in a permanent dialogue with WHO and FAO on the prudent use of veterinary antibiotics worldwide.

The governments of 170 OIE countries have nominated official focal points for receiving the information related to veterinary products. B. Vallat pointed out that OIE regularly sends the VICH information to these official focal points, but is disappointed with the follow-up which is generally insufficient.
B. Vallat therefore proposed that the VICH standards could become OIE recognised standards, and suggested to dialogue further on a cross recognition between OIE and VICH standards.

OIE has recently initiated measures to improve the quality of veterinary products in Africa where more than 50% of the products are counterfeited.
B. Vallat concluded by supporting in principle the co-organisation of the VICH 4 conference between VICH and OIE.

H. Marion presented apologies from Dr P. Holdsworth. He introduced the new SC members and coordinators; Dr Y Endoh, the new SC member representing JMAFF, Dr Ken Noda, the new coordinator for JMAFF, Dr T Komatsu, the new SC member representing JVPA, Dr G. Moulin the new SC member representing the EU (CVMP) and Dr D. Mackay also representing the EU at this meeting.

2. Adoption of the agenda

FDA proposed that topic 9.1 should be changed to “Update on ICH”
The EU recommended that Point 9.5 should be discussed under point 3.
Draft 5 of the agenda was adopted without further change.

3. VICH Strategy Phase II

3.1 Future VICH topics

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

3.2 Other issues

No other issue was raised.

3.3 Proposal to establish a VICH Global Coordination Group

The participants reviewed the proposal to establish a VICH Global Coordination Group to advance the wider international harmonization of registration requirements within VICH prepared by IFAH (P. Jones). The secretariat pointed out that the objective was to enhance the global outreach of VICH GLs by broadly disseminating the VICH information similar to the work of the Global Coordination Group of ICH.

The chairman mentioned other regional cooperation agreements would not have the same level of commitment as VICH and ICH, in which the regions are committed to implement the GLs. The SC needs to consider how far VICH guidelines can be applied in the different non-VICH regions as this depends on their level of development of industry and regulation.
The EU supported the principal objective of the proposal to improve the outreach of VICH but considered there is a need to balance resources, ensure that the needs of the regions are taken into account, and that OIE is fully engaged.
JMAFF agreed and suggested that VICH should discuss the proposal further with OIE, through which much VICH information is disseminated. JMAFF stressed that OIE is playing a pivotal role in spreading the VICH GLs to the OIE members who are not active participants in VICH.

FDA recommended clarifying the resources that would be required, to identify the organisations that would be called to participate in this group and to define how these would be selected.

IFAH Europe highlighted the need to increase the level of the quality of the medicines on local markets, but this should be via mutual recognition of products authorised in compliance with VICH GLs, and not by local re-assessment of dossiers.

OIE confirmed its endeavour to enhance the dissemination of VICH information in order to improve the quality of veterinary medicines in non-VICH regions. The conference organised recently by OIE in Dakar has for the first time brought all the African countries together to discuss Animal Health issues. OIE also highlighted the current difficulty to build a worldwide

efficient network based on the OIE focal points that often lack motivation to disseminate the information which they receive.
OIE therefore strongly supported the proposal from IFAH and suggested analysing the successes and failures of the ICH GCG in order to enable VICH to focus more on capacity building and training.

The EU pointed out that, unlike ICH, VICH has a strong link with the global health organisation, OIE, which should enable VICH to build much more on OIE activities and conferences.

The Chairman summed up that the proposal was endorsed in principle but any similar VICH initiative needs to recognise the difference between the human and veterinary sectors and maximise the link with OIE.

Following the suggestion of the Secretariat, the SC decided to create subgroup with the mandate to analyse the possible ways forward for the veterinary area. The subgroup will be composed of one representative from: FDA, JMAFF, EU, AHI, IFAH-Europe, JVPA, OIE and the Secretariat. OIE will lead the subgroup.

The mandate of the subgroup is:

- to prepare a new discussion paper clarifying the general objective to enhance the global outreach of VICH GLs
- to assess the best ways to fulfil this objective taking into account:
    - the links with OIE and the potential to maximise synergies
    - the resources available
    - the regional harmonisation cooperations existing in some non VICH regions
    - the needs of the countries regarding training and capacity building

Action: OIE/Subgroup

FDA pointed out that VICH already has an outreach initiative in terms of input by FDA into CAMEVET meetings and mentioned its intention to participate in a CAMEVET meeting in September 2008. The SC agreed that FDA could represent VICH at that meeting.

4. Review of

4.1 Written updates from the coordinators

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

4.2 Status of consultation for draft GLs at Step 4

The Secretariat asked the regulatory coordinators to inform the SC when the consultation period for GL 45 will be finished in their region.

Action: Regulatory coordinators

5. Review of final VICH Guidelines

5.1. Review of the implementation and interpretation of VICH GLs

Discussed below.

5.2. Interpretation and implementation of the GLs in the regions

Implementation of VICH 36 – report from FDA

FDA explained that the former chairperson of the VICH Safety TF, Dr H. Fernandez, and the EMEA had the perception that differences had appeared in the submissions by industry as well as in the interpretation by regulators between Europe and the USA. Dr Fernandez had therefore invited a group of industry and regulatory scientists to meet at FDA in order to review the text of VICH GL 36 (Safety: microbiological ADI - Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish a microbiological ADI), and to determine whether this GL should be revised and eventually the VICH Safety TF re-convened.
This group that met at FDA concluded that the GL should be reviewed, because science had progressed since the GL had been finalised.
After its review of the report of the group that met at FDA, FDA recommended reconvening the TF, either for an electronic discussion, or for a face-to-face meeting.

The chairman pointed out that the GL is not questioned, but that it is suggested to improve its scientific arguments in order to provide more clarity to stakeholders.

AHI believed that industry had not been sufficiently represented in the meeting. AHI did not support the re-establishment of the TF to review the GL because the suggestions presented by the group would limit the flexibility of the GL and might generate more problems than it would solve.

IFAH-Europe supported AHI's position.

The EU voiced its surprise as the discussion was initiated following concerns raised at the last SC meeting by IFAH-Europe on the interpretation by the EMEA of this GL and industry had requested more guidance to ensure consistent interpretation.

IFAH-Europe appreciated the work achieved by the CVMP to improve the interpretation of the GL and explained that it would prefer that problems were solved by regional discussions, rather than by amending the GL.

However, IFAH-Europe, JVPA and AHI confirmed their support for further scientific discussions on the interpretation of the GL between the adequate experts from industry and the regulators.
JMAFF also supported further discussions.

After a thorough discussion the SC took note of the recommendation of the group of scientists, but recognised that at this stage there was no consensus within the SC to re-open the GL. Therefore, the Chairman proposed that expert discussions allowing participation of all VICH parties could continue mainly focussing on the interpretation of the GL without opening up the GL itself, which was accepted by the SC.

The Chairman pointed out that this discussion did not in any way question the valuable work achieved by VICH Safety EWG and the TF, as well the CVMP and the group of scientists that met at FDA.

5.3. Proposals from the coordinators on the review of final GLs at Step 9

The Secretariat reminded the SC that following the "Methodology for a systematic Review of the VICH Guidelines at step 9" adopted at the 20th SC meeting, each coordinator from the organisation that had chaired the topic of a GL has been asked to recommend to the 21st SC meeting whether it should be reviewed or not.
The SC should at this stage only decide in principle if a GL should be reviewed or not. In case of approval, the next formal step would be the presentation of a Concept Paper for adoption at the 22nd SC meeting, that should suggest if the review would be minor or major, and how the process of revision should be carried out (by the former EWG, a new EWG, the SC....).

The SC systematically evaluated the proposals for reviews of certain GLs provided beforehand by the relevant coordinators. The review concerned 9 Anthelmintics guidelines (GL7, GLs 12-21), 7 Quality GLs (GLs 1, 2, 4, 5, 8,17 and 18), GL9 on GCP, GL6 on Ecotoxicity: EIA-phase I, 6 Safety GLs (GLs 22, 23, 28,32, 32 and 33) and 2 Biologicals GLs (GLs 25 and 26).

Anthelmintics GLs
The EU believed it would be useful to add additional guidance to GL 7, in particular to clarify requirements for generic products. However, after discussion, the SC noted that no particular problems have been reported on the existing GLs by the regions, and decided not to review any Anthelmintics GL at this stage.

Quality GLs
JMAFF recommended proceeding with a minor change to Quality GL 18 (Impurities: residual solvents) only in order to include the update of the "ICH GL (Impurities: Guideline for residual solvents) and add reference to additional solvents.
The SC agreed that JMAFF should prepare a Concept Paper to be presented before the next SC meeting.

Action: JMAFF

Safety GLs
FDA suggested reconvening the EWG in order to analyse in general the latest scientific evolution regarding safety issues and adding the referencing to the minimisation of animal testing (VICH 3Rs policy) to the VICH safety GLs.

Discussion on specific guidelines:
GL 22 (Reproduction studies)
The discussion showed that most SC members felt that it was too early to review the details of this GL as no general consensus has yet been reached within the scientific community.
Although AHI and the EU supported FDA's proposal to draft a Concept Paper, the SC concluded, after further discussion, not to review GL 22 at this stage. However, the SC agreed to continue the review of further developments of science in this field.

GL 23 (Genotoxicity studies)
The EU recommended opening the Safety EWG to revise the GL to include the in vitro micronucleus assay. FDA agreed with the EU but noted its opinion that this work could be accomplished electronically rather than through physical meetings. After discussion, the SC approved the preparation of a Concept Paper by FDA for the review of GL 23, which will be considered at the next SC meeting.

JMAFF pointed out that the revised ICH GL was still at step 3 of the ICH procedure, and encouraged FDA to monitor closely the outcome of the discussions in ICH whilst drafting the VICH Concept Paper.

Action: FDA

GL 28 (Carcinogenicity testing)
The SC did not support the drafting of a Concept paper for the time being.

GL 33 (General approach to testing)
The SC recognised the need to include reference to the VICH policy of adopting testing standards and protocols that minimise the use of animals to the extent possible (3Rs policy) in the General Approach GL, that the adopted wording of the VICH public statement should be used as the basis for the amendment and therefore encouraged FDA to provide a Concept Paper as soon as possible. The SC agreed that the review should be a minor change procedure that could be done by written agreement.
FDA will provide the Concept Paper by the end of October.

Action: FDA

No other GLs were proposed for revision or update.

5.4. Decision on timing and organisation for Review of final GLs at Step 9

Decided above.

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 Hamamoto, and presented by JMAFF.
The SC acknowledged that GL 45 (Bracketing and Matrixing Designs for Stability Testing) is currently under consultation until August 2008. The EWG has currently no other active topic.

6.2. Pharmacovigilance

6.2.1. Pharmacovigilance EWG

The FDA reminded the SC of the report on the last meeting of the Pharmacovigilance EWG held in September 2007 prepared by the chairman of the EWG, Dr L. Post. The SC recollected that at the 11th meeting of the Pharmacovigilance EWG last year many issues

were solved. It was reminded that GLs 24 and 29 are at step 7, whilst draft GL 30 will only be complete when the appendix with the Controlled List of Terms (CLT) is added. Draft GL 35 is also incomplete and considered as a position paper only until a final decision is made on the use of HL7 as the electronic standard of the governments that are participating in VICH.

The SC noted that there will be a need to convene the EWG again when all the missing information is available in order to finalise the 5 GLs. These can then be implemented by the regions as a package.

Regarding HL7, the Chairman explained that the EU legislation couldn't accept any standard that is not recognised by the International Standardisation Organisation - ISO or by CEN. The European Commission is therefore not in a position to commit to the HL7 standards, unless these would become ISO or CEN standards.
The European Commission is nevertheless open to developments within ISO for ICH as well as for VICH.
ISO will only adopt a new standard if a maintenance organisation is chosen.
He pointed out that resources would be needed to maintain the standards for the veterinary side. There needs to be clarity in how the veterinary side of any lists of terms would work in practice i.e. whether vet terms would be 'added to' or separate from ICH terms.
He further stated that the resource implications for both industry and regulators need to be considered because it is important the SC does not adopt a formal position which it is unable to sustain

JMAFF reported that a Working Group on HL7 took place in Japan last September and its conclusions are expected soon. JMAFF were content to support HL7, provided the efficiency and the cost effectiveness of HL7 are maintained. JMAFF pointed out that because the present Japanese system is compatible neither with HL7 nor CEN, the introduction of a new system, as long as it is low cost, would be acceptable.

ANZ explained that it did not perceive any benefit in moving to HL7 and was therefore not inclined to allocate resources for a move to HL7.

In conclusion, FDA, JMAFF and Canada supported HL7, whilst ANZ, the EU and IFAH Europe questioned the cost of the change of standard to HL7.

The Chairman suggested receiving a report from ISO at the next SC meeting.

6.2.2. Pharmacovigilance Task Force

Dr Cornelia Ibrahim, Chairman of the CLT Task Force, reported that the TF meeting that took place recently had been very productive (*see presentation-link*), the TF's aim being to complete GL 42 with the lists of terms.
The TF reviewed the status of electronic reporting of Adverse Events (AE) in the different VICH regions.

The TF must develop 8 different lists with a VICH code for each list. The official language is English (N.B.: the ISO lists for human and veterinary products in parallel are in American English).
Further management and maintenance of the lists were not discussed.

The leaderships for the drafting of the lists are the following:

Species and breed list:	EU
Regulatory authority identifier codes	US
Explanation for off label use	Japan
Route of exposure	EU
Dosage form	Canada
Units of value for dose	US
Strength unit	US
VeDDRA	EU (it was already agreed in GL 30 that VeDDRA would be used by all regions)

The list of species and breeds is not strictly linked to zoological definitions. Regarding the list of routes of exposure, mapping to ISO lists is foreseen. The human and animal terms VeDDRA lists will be merged into one list and it will be indicated if the term refers to animal health, human health or to both.

The TF recommended that all VICH partners would in future be involved in the updating process of VeDDRA by the EMEA, and that they could participate at a VeDDRA sub-group meeting in autumn 2008.

The TF also agreed to set up definitions of further terms in GL42 that are not part of GL30 and identified the timelines for the fulfilment of its tasks.
In order to enable the TF to finalise the different lists, C. Ibrahim requested the extension of the deadline for the completion of the lists and authorisation of the SC for a second and final meeting to take place on 19-23 January 2009 in Japan.

C. Ibrahim mentioned that once the TF had completed its task, it could be disbanded. However, she pointed out that in the future a more technical oriented group on PhV issues would be necessary to maintain these lists properly. Indeed, in the context of the HL7 initiative and the ISO lists, such a technical group of VICH could ensure that the veterinary part is taken into account. Furthermore VICH would facilitate the involvement of all the regions in the discussions.
This group could finally also be proactive in the implementation phase of GL 35.

C. Ibrahim confirmed that, following the request of the PhV EWG, the TF will have to provide a recommendation on the maintenance of the PhV CLT at its final meeting.

The EU explained that the VeDDRA sub-group meets once per year following a yearly public consultation and invited the VICH regions to take part in this process.

The SC approved the extension of the timeline and a second face-to-face meeting of the CLT TF to take place on 19-23 January in Japan.

Regarding the development of a technical group, the SC agreed to review, at its 22nd meeting, the recommendation on the maintenance (including resource implications and costs) which will be provided by the TF.

Action: TF/Next SC meeting

The SC thanked C. Ibrahim and the TF members for the excellent progress achieved at its first meeting.

6.3. Target Animal Safety

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr Nagata, and presented by JVPA, and acknowledged that the EWG has finalised GLs 43 & 44 at step 5 at the end of June.
The SC thanked Dr Nagata and the EWG members for the efficient fulfilment of their task.

The Secretariat confirmed that, in accordance with the VICH guidance, the EWG was not immediately disbanded, but kept dormant for a period of 2 years in case a problem arises during the implementation phase of the GL.

6.4. Biologicals Quality Monitoring

The SC reviewed the written report prepared by the chairman of the Expert Working Group, Dr Shimazaki, and presented by JMAFF.
The SC noted with sadness that Dr P. Castle had passed away recently and paid tribute to his most valuable input to the VICH process as an efficient and committed topic leader.

Regarding mycoplasma testing, the SC acknowledged the need for an agreement on the protocol, before the strains can be tested and the EWG reconvened (meeting previously proposed to be hosted by EDQM in Strasbourg. The EU will liaise with EDQM to confirm that meeting is held at EDQM).
As no comments have been received by the EWG so far, the SC decided that final comments on the protocol should be provided to EDQM and the EWG within 2 months, i.e. by early September.
The SC approved the face-to-face EWG meeting but requested that it should be held after receiving the comments.

Most delegations expressed their support for the protocol. Canada would re-circulate their comments so far sent only to EDQM. USDA stated that they would in principle accept the protocol but need to review the protocol in detail and would provide comments within the deadline.

Action: BQM EWG

6.5. Metabolism and Residue Kinetics EWG

Dr S. Scheid, chairman of the Expert Working Group, detailed the progress achieved by the EWG since its last meeting (*see presentation - link*).
Four of the five topic guidelines (Studies to identify the nature and quantity of residues; Comparative metabolism studies in laboratory species; studies to determine the depletion of residues; Analytical method validation) are nearly ready for sign off for consultation. Dr. Scheid listed the issues that are still under discussion for topics 1 to 4. He reassured the SC that most are in the process of being clarified and resolved.

Topic guideline 5 (statistical methods for the determination of withdrawal periods) has still important unresolved issues in particular the issue of residues at the injection site. He

stressed that topic 5 would be difficult to progress without new input. He regretted that no final conclusion was in reach, and therefore proposed to suspend the topic for the moment, in order to enable the EWG to concentrate on topics 1 to 4.
The 4 draft GLs could be signed-off by the EWG and submitted to the SC by Q4 of 2008 in order to enable a rapid release for public consultation.

The SC agreed with the proposal and that the four GLs should be advanced to the formal consultation step and that work on the fifth should be suspended pending finalisation of the others.

The SC complimented the chairman and the EWG for the excellent progress made since the last SC meeting.

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

AHI presented the revised proposal and reminded the participants that the aim was to reconvene the Safety EWG with the mandate to identify the tools to determine an Acute Reference Dose (ARfD), considering that there is a need to define standardised reference protocols for ARfD especially since JECFA has used the ARfD rather than the ADI.

The EU appreciated that all direct references to injection site residue and residue control had been eliminated from the proposal but stressed that concerns about the document still remain; the document still contains references to the work of JECFA/CCRVDF, i.e. implying the use of the acute reference dose for injection site assessment. Furthermore, as no other need for the guideline has been identified, again agreement would imply acceptance of the approach for injection site assessment.
However, the EU would at present not support the approach as was described in detail in the recently published CVMP document on injections site assessment, which discusses the role of ARfD, for consultation. The EU proposed to delay any decision until after the end of the consultation procedure on the CVMP document on injection site residues. Moreover, no Concept Paper is available in order to identify the scope and impact assessment of the intended work.

IFAH Europe, FDA, JMAFF and JVPA supported the document revised by AHI and encouraged the SC to endorse this document as a Concept Paper (CP) or to develop a CP.

The EU believed however that if the current document was transformed into a CP limited to ARfD, it would need to clarify in which cases the ARfD should be used in the future.

AHI explained that the toxicologists understood very clearly the suggested mandate: to develop a methodology for setting an ARfD.

The Chairman suggested separating the drafting of the CP from the decision of re-establishing the EWG and to make the final decision on the base of the CP.

The EU requested again a clarification in advance that injection site residues are not considered, as they already have been addressed by the CCRVDF.

JMAFF expressed the opinion that the ARfD is not only related to the injection site but also to human exposure in case of accidents, as in the crop protection area when people are exposed to high doses of pesticides.

IFAH Europe reminded the participants that the MRK EWG had requested the drafting of a GL on ARfD.
Dr Scheid confirmed that the ARfD could be used for other parts of the assessment, e.g. assessment of acute endpoints, user safety, and acute exposures to residues in food.

After a thorough discussion, the SC acknowledged that the EU would reserve its position in principle depending on the outcome of external and internal consultations in the EU, and agreed that FDA should draft a CP for review at the next SC meeting, in close collaboration with AHI and the EU. FDA indicated they were prepared to take the lead for the drafting but a decision would need to be made later on who should chair a reconvened EWG.

The chairman thanked AHI for drafting the discussion document and thanked FDA for now leading this task.

Action: FDA

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

No document was submitted.

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

8.1. GL43 - Target Animal Safety - Pharmaceuticals: Target Animal Safety for Veterinary Pharmaceutical Products

The Steering Committee adopted GL 43 as a final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation at step 7 in the regions by July 2009.

8.2. GL44 - Target Animal Safety - Biologicals: Target Animal Safety for Veterinary live and inactivated Vaccines

The Steering Committee adopted GL 44 as a final VICH guideline at Step 6. This guideline was transmitted to the VICH members for implementation at step 7 in the regions by July 2009.

9. Concept papers/Discussion papers

9.1. Update on ICH's experience

The SC noted that this topic had been considered throughout the different agenda points, and no further specific discussion was required.

9.2. IFAH-Europe Topic Discussion Document on Electronic Presentation of Regulatory Documents

IFAH-Europe presented the revised proposal circulated prior to the meeting and confirmed that the objective was to set up a simple GL explaining how the regulatory documents should be set up in electronic format. The data requirements i.e. the content of the dossiers, would be out of the scope because it is different between the regions.
The proposal should not impose electronic submissions, but if a region decides to allow electronic submissions, a harmonised GL would be extremely useful.

JMAFF explained that most of its experts are external and still requiring paper dossiers so JMAFF will therefore need more time to move to electronic dossier.
The Japanese government has however agreed in principle on electronic submissions, which are starting to be used on the human side.
JMAFF confirmed its support of the proposal if no timelines for implementation are imposed and electronic submission is not obligatory.

JMAFF raised the issue of authentification of the electronic documents, which are currently converted into the user-friendly format Adobe pdf format in the 3 regions. It may however not be certain that in the long term Adobe will continue to provide this format. The participants acknowledged that this issue could be included in the GL.

The EU believed that the VICH GL should not contain any notion of acceptability or not of electronic submission, but only focus on standards. The EU stressed that at this moment such a GL would be very appropriate to foster a harmonisation of the standards.

AHI, ANZ, FDA, the EU and Canada noted that electronic submissions will become more and more frequent and therefore supported in principle the proposal from IFAH Europe.

IFAH Europe suggested adopting the proposal as a Concept Paper.
FDA and JMAFF considered however that the document required further clarification on the current situation in the regions.

After a thorough discussion, the SC could not agree to the adoption of the current proposal as a CP or the development of a CP.

The SC however supported that IFAH Europe would coordinate input into preparing a more comprehensive concept note outside VICH without actually creating a formal working group to develop this note into a guideline. The note would contain up-to-date information on what is acceptable in different regions. IFAH Europe would therefore essentially become a coordinator to collate information which will help to promote harmonisation. IFAH Europe agreed to take the role of coordinator and each region was asked to nominate a local contact.

The Secretariat was concerned that this procedure is therefore outside the formal scope of the VICH process. However, ultimately, the SC considered that the eventual development of a GL was acceptable in principle but the timing was not yet optimal. The SC would therefore monitor the situation at each meeting and expressed thanks to IFAH Europe for indicating their willingness to continue the monitoring process.

The SC will review any progress at its next meeting.

Action: IFAH Europe, VICH coordinators

9.3 Review of the Proposal for the Establishment of an Expert Working Group to Elaborate the Requirements to Demonstrate Bioequivalence

AHI presented the proposal as a Concept Paper for discussion and approval by the SC, and explained that the aim is to define minimal standards for the determination of the Bioequivalence (BE) of products.
AHI pointed out that BE relates to variations of products as well as generic products, and that BE studies should ensure that the initial studies have been taken into account.
A GL on BE would benefit the VICH regions, but also, through OIE, developing countries wishing to raise their standards of veterinary medicines.

The EU raised several questions regarding the aim of the GL:

- the need for a GL was not well substantiated, the proposed GL would differ in terms of content and purpose from normal VICH GLs;
- input from the generics industry is considered essential on this topic;
- the need for a definition of BE was questioned as well;
- the level of disharmony between the regions and the current situation on the human side.

The EU did not consider that the document fulfilled the requirements of a CP and reminded the participants that the VICH guidance on the drafting of a CP requires to determine if harmonisation is really needed, to evaluate the timelines as well as resources that would be required, and also to make an impact assessment of the GL.
The EU stressed that in the past some EWG had not received a mandate that was sufficiently clarified at the start of the topic, which had lead to difficulties later in developing harmonised GLs and led to the preparation of rules for CPs.

The Secretariat will place the VICH guidance document on CPs available on the Members area website.

Action: Secretariat

AHI believed however that a timeline would be difficult to establish, considering the need to create an EWG and get its feedback in order to refine the scope and the objectives of the GL.

JMAFF felt also that the proposed document lacked clarity regarding the scope, output and timeline of the topic. JMAFF expressed nevertheless that the establishment of an EWG focusing on “blood level BE studies” would be acceptable, but requested that the work should be proceeded carefully taking into consideration the opinion of the generics industry.

IFAH Europe recalled for the MRK EWG, the SC had asked the chairman to lead a discussion group before the formal creation of the EWG. The EU agreed that as in the case of the MRK EWG, the experts should be asked to refine the scope before the formal set up of the EWG.

FDA confirmed that for many years it has had a guidance on BE since many years which has been revised several times. FDA also noted that it was aware of efforts in Australia and in Canada to develop or revise BE guidance.
The EU informed the SC that a revised EU Guidance is nearly finalised and will be very similar to the FDA one.

After further discussion, the SC accepted the offer of FDA to coordinate the preparation of a detailed CP, with the help of the regions, before the next SC meeting.

Action: FDA

9.4 EU proposal for the Harmonisation of the Target Animal Batch Safety Test for immunological veterinary medicinal products

The EU introduced the discussion paper for developing the Target Animal Batch Safety Test (TABST) guideline to harmonise the TABST with the aim to reduce animal testing. The EU explained that recent scientific data showed that TABSTs are of very limited scientific benefit because they are mostly done on a small number of animals. The scientific rational for a routine use of the TABST is questioned at a time where all manufacturers work within the GMP frame and where seed lots are used.

The aim of a GL would not be to eliminate this test for all products, because it will still be necessary to test each batch of live vaccines, as well as new products being registered.
The GL would only consider the final batch safety test, not the efficiency test, or the final inactivation test.
The EU therefore proposed to prepare a Concept Paper for review at the next SC meeting.
IFAH Europe, USDA and JMAFF supported the proposal to develop a concept paper. The US Biologicals Association proposed and the SC agreed that the CP will need to consider whether or not the non-target animal safety test should also be considered within the harmonisation process.
After discussion, the SC supported the proposal. The SC considered that the BQM EWG could take on the future work on this topic.

Action: EU

Other issues
IFAH Europe recommended that CPs should be circulated well in advance of the SC meetings for consultation by written procedure. In this way time would not be spent at SC meetings criticising the papers but rather on deciding whether or not to proceed with development of a guideline. The EU requested that the VICH procedure be reviewed at the next meeting to ensure that timely processing of items is actually possible. IFAH Europe endorsed this review and pointed out that industry expectations from VICH are high and if the process fails to deliver then their continued involvement would be put in question.

The EU also suggested that the Secretariat should include a short note on each agenda point clarifying what is expected from the meeting.

Action: Secretariat / next SC meeting

The Secretariat reminded the SC that all documents and drafts should in principle be sent to the Secretariat for circulation to the SC 6 to 8 weeks before a SC meeting in order to enable the Japanese delegation to proceed with the translations.

Action: All

9.5 Proposal to establish a VICH Global Coordination Group to advance the wider international harmonization of registration requirements within VICH

Discussed under point 3.

10. VICH 4 Conference

10.1 Proposal from IFAH-Europe and OIE to host the meeting in Paris (France)

The Secretariat explained that following the suggestion made at the 20th SC meeting to organise the VICH 4 Conference in Europe, OIE had accepted in principle to co-organise the event with IFAH Europe.
OIE still needed to confirm that the Conference could be hosted in the headquarters of OIE in Paris during June 2010, linked to an OIE conference on veterinary medicines.
The final date will be communicated as soon as possible.

The SC acknowledged that the Programme will be drafted by IFAH Europe and the EU, in close collaboration with the coordinators from the other regions and the Secretariat.
A first draft programme will be circulated for review in Q4 of 2008.

IFAH Europe and the EU will build on the conclusions and recommendations noted by the SC after the organisation of the VICH3 Conference.

Action: IFAH Europe/EU

The Secretariat and OIE will propose a final date and review all logistical matters.

Action: Secretariat/OIE

10.2. Final decision and date of the conference

Post meeting note: discussions ongoing with OIE.

11. Any other business

11.1 EDQM

The EU explained that no successor had yet been nominated for Dr P. Castle, so for the time being all correspondence should be sent to Dr Susanne Keitel, Director of EDQM.

11.2 Replacement of Mr Martin Holmes (ANZ)

Mr Holmes informed the SC that following normal practice for the Australia/New Zealand regulator representatives to rotate every three years, his place on SC will be taken by Ms Debbie Morris of the New Zealand Food Safety Authority.

Mr Holmes thanked SC members for their friendship and cooperation during the three years he has represented Australia/New Zealand on the SC.

On behalf of the SC, the Chairman thanked Mr Holmes for his commitment to VICH over the past 3 years.

12. Dates and venue of next meetings

- The 22nd SC meeting will take place in Canada from Tuesday 24 to Thursday 26 February 2009, either in Toronto or Montreal.
- The 23rd SC meeting will take place in Japan from Wednesday November 4 to Friday November 6, 2009 in Kobe.

13. Adoption of the Press Release on the 21st SC meeting

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

VICH STEERING COMMITTEE

21st meeting

July 8 & 9, 2008
Paris, France

Chair: M. Terberger, EC

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI	R. LIVINGSTON
AHI (PFIZER)	M. J. MCGOWAN
EUROPEAN COMMISSION (DG ENTERPRISE AND INDUSTRY)	M. TERBERGER (Chair-*part*)
EMEA	K. GREIN (C)
EMEA-CVMP (AFSSA)	G. MOULIN
IFAH-Europe (BAYER)	L. KLOSTERMANN
IFAH-Europe (MERIAL)	B. BOENISCH
IFAH-Europe	R. CLAYTON (C)
JAPAN MAFF	Y. ENDO (for Y. TAKAHASHI)
JAPAN MAFF	K. NODA (C)
JAPAN MAFF	M. SAKAI
JVPA (KYORITSU SEIYAKU CO.)	M. KAJIWARA
JVPA (DAINIPPON TSUMITOMO PHARMA CO.)	T. KOMATSU
USDA APHIS CVB	B.E. RIPPKE
US FDA	M. SMITH
US FDA	L. BEAVER (C)

OBSERVERS

HEALTH Canada	I. ALEXANDER
APVMA	M. HOLMES
CAHI	J. SZKOTNICKI

INTERESTED PARTY

AVBC	J. THOMAS

OIE

OIE	P. DEHAUMONT
	B. VALLAT (part)

INVITED

EC	I. SACRISTAN SANCHEZ (Chair-*part*)
EU	D. MACKAY
AU/NZ	D. MORRIS

VICH SECRETARIAT

IFAH	H. MARION

APOLOGY

JVPA	S. OHSHIMA (C)
ANIMAL HEALTH ALLIANCE/AGCARM	P. HOLDSWORTH