



VICH/11077
17 February 2012
Final

**VICH STEERING COMMITTEE
26th meeting
November 14, 16 & 17, 2011
Tokyo - Japan**

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Masato Sakai, Director General of NVAL of JMAFF. Apologies were received from Dr M. Limolli, FDA.

Dr Sakai welcomed the participants to Tokyo and, on behalf of the whole Japanese delegation, he thanked all the SC members for the strong support that was received after the terrible earthquake and the subsequent tsunami damage on 11 March.

2. Adoption of the agenda

Dr Sakai suggested interchanging the sequence of items 4 & 5 of the agenda. He also proposed to start the meeting on 17 November in the morning with items 9.1 and 9.3 of the agenda as Dr Oishi & Ogata will be able to attend the meeting at that time. The SC agreed.

3. Preparation of the contact meeting on Wider International Harmonisation

3.1. Review of the objectives

The aim of this session was to enable SC members to prepare the contact meeting on Wider International Harmonisation by sharing their thoughts and opinions in order to ensure a constructive and positive contact meeting.

Dr Sakai suggested discussing all matters in agenda points 3.1 and 3.4 to 3.6 together because these represent a single discussion. He thanked OIE for the preparation of a graphic introducing the subject.

OIE recalled that at the 25th SC Meeting it was agreed to "organise a one day informal contact meeting with selected non-VICH transitional countries/regions just before the 26th VICH SC meeting in Tokyo, in order to initiate the dialogue and achieve a better understanding of the needs and expectations of the selected countries/regions".

OIE explained that the graphic is structured in 2 parts, the first part relevant for the creation of a Forum covering the objectives, the members, the conditions of membership and the frequency of meetings.

OIE further recommended that the VICH secretary should act as the secretariat of the Forum.

The SC reviewed and debated several questions.

Would the SC be satisfied with an Outreach Forum including SC members or should the SC invite specific countries to become new observers to the SC? In this case ANZ recommended that new regions/countries becoming an Observer should meet the same expectations as those imposed on the existing Observers.

The SC acknowledged that the criteria that will be set for the selection of suitable countries to become an observer are critical and that these candidate countries should have a minimum regulatory system in place as well as the willingness to adopt VICH GLs. If the criteria are applied strictly, the number of candidates is expected to be limited.

The SC also recognised that precise criteria must be presented to the Contact meeting.

OIE pointed out that the proposal was based on the assumption of setting up a separate Forum and recommending a stepwise approach with a first step of establishing the conditions for membership in the Forum.

For the Forum the SC acknowledged that only the structure should be defined at this stage and that the final criteria for participation in the Forum should be set after the Contact meeting in order to take note beforehand of the wishes and expectations of the countries participating in the Contact meeting.

OIE questioned if a country which is a member of a regional organisation included in the Forum would be allowed to become a direct member of the Forum as well. It was also decided to postpone the decision until after the contact meeting.

JMAFF confirmed that it supported the graphic presentation proposed by OIE but had made some additional proposals, in particular that VICH and OIE should share the responsibilities for the Forum.

After a thorough discussion the SC nevertheless confirmed that the Forum was a VICH initiative with the support of OIE, which could eventually co-chair the Forum. The SC discussed the criteria for membership.

The SC acknowledged that the regulatory framework in place can be less developed than those existing in VICH countries; for example when resources are scarce, countries may adopt what is approved in (a) VICH country/ies.

The SC agreed on the following four criteria for membership of the Forum which should be presented during the Contact Meeting:

- (i) regulation for marketing authorization in place,
- (ii) willingness to accept and work towards implementation of GLs,
- (iii) paying for participation (travel costs, accommodation and translation if needed),
- (iv) regular participation.

AHI recommended adding industry representation in the conditions for membership, but after discussion it was agreed to leave this possibility open for the time being. The SC noted in particular that industry would be represented in any case through SC members who will attend Forum meetings.

The SC confirmed that OIE will chair the Contact meeting. OIE will explain that VICH has not finished the reflection yet and present the 4 membership criteria.

3.2 Review of the agenda of the meeting

The participants reviewed the agenda and agreed on the structure of the discussion in section 3 of the agenda.

The SC expected that during the question sessions the discussion will be opened for the 11 countries and 3 organisations to reply, and SC members will be the audience and can add questions.

It was also agreed to prepare the conclusions to present at the end of the Contact meeting.

3.3 Review of the participants list

The SC noted that 11 countries (Argentina, Brazil, China, Korea, Malaysia, Morocco, South Africa, Taipei China, Thailand, Philippines, Ukraine) & 3 international organisations (ASEAN, CAMEVET and UEMOA) will participate in the meeting.

3.4 First review of the VICH global Outreach Strategy

Discussed above

3.5 Agreement on the opinions/directions from the SC

Discussed above

3.6 Expected outcome

Discussed above

5. Review of the Outcome of the Contact meeting on Wider International Harmonisation

5.1. Debriefing and review of the conclusions of the Contact meeting

The SC addressed this agenda item the day after the Contact meeting.

The SC noted the Contact meeting had been successful with fruitful discussions and extensive exchange of information. The SC reviewed the conclusions of the meeting (link), and acknowledged that the expectations of the non-VICH countries/regions were in line with the VICH objectives and that the majority of countries and all regional organizations were willing to become members of the proposed Forum. South Korea, China and Taipei China had indicated their need for further reflection.

With regard to the roles and responsibilities of the regional organisations, the SC noted that UEMOA has the power of regulation, whilst the members of ASEAN and CAMEVET have no decision making power for their region.

The SC noted further that many technical questions were asked, especially regarding existing GLs, and that there was a general request for training. There were also questions regarding the preference for representation of the local industry, whilst it was confirmed that most countries have at least one industry association, except Ukraine.

South Africa and UEMOA asked for information about the conditions to become an Observer to the SC and the SC was reminded that South Africa had already addressed a request to the VICH Secretariat in early 2010.

The SC noted with satisfaction the high degree of interest from all participants in the VICH activities and the expectations for more information & training, as well as for involvement in the elaboration of new GLs.

JMAFF and the EU noted that OIE had invited countries to the Contact meeting that had not been approved by the VICH SC, and expressed concerns that even more countries might attend the Forum in the future.

OIE explained that the Director General of OIE had personally invited additional countries to attend, and pointed out that the future meetings will not be an open Forum but a VICH Forum for which the SC will agree on criteria as well as the Terms of Reference (TORs) which will be implemented and respected.

After an in-depth discussion, the SC agreed unanimously to create a "VICH Outreach Forum" normally composed of the participants in the Contact meeting, but further discussed below. The SC agreed that the objective of the forum is "to provide a basis for wider international harmonisation of registration requirements, improve information exchange and raise awareness of VICH and VICH GLs with non-VICH countries"

Further candidate countries will have to apply in writing and the SC will analyse their application and decide on their participation on a case by case basis.

Stepwise approach

The SC adopted the stepwise approach proposed by OIE:

Step 1: define the participants and criteria e.g. minimum levels of legislation required as regulatory framework and to define and describe the collaboration mechanisms between the Forum, VICH and OIE i.e. agree the Terms of Reference /mandate.

Step 2: define and describe the different roles of VICH, OIE and the Forum.

Number of participants

The SC agreed that in principle one person per country /organisation should participate in Forum meetings, unless a country has a specific regulatory situation requiring the presence of 2 persons i.e. more than one agency involved in veterinary products registration. In this case, the country should inform the SC which will then make a decision on a case by case basis.

Industry participation in the forum

The SC had a lengthy debate on whether the industry associations from the countries participating in the Forum should be invited.

At the end of the discussion, most SC members supported the participation of industry representatives but the EU delegation was not at liberty to make this decision at the current SC meeting as the "graphical" proposal presented by OIE prior to the meeting included only regulatory authorities thus Industry participation had not been discussed beforehand.

The industry representatives did however not express particular concerns because industry would be represented in any case through industry SC members who will attend the Forum meetings and moreover, as the aim of the Forum will be to inform, communicate and train, the primary target of the Forum will be the regulators rather than the industry.

The SC therefore reached the consensus that only regulators will be invited to attend the first meeting in June 2012 in case the EU would not allow the participation of Industry in the Forum, and the SC would decide on industry participation at a later stage.

The EU representatives agreed nevertheless to explain to the EU Commission that the majority of the SC members support the industry participation to the Forum. Should the internal consultations lead to an acceptance of non-VICH countries' industry participation before the next SC meeting, the EU will inform the SC by written procedure through the Secretariat.

Post meeting note: the EU has informed the Secretariat and the members of the VICH Steering Committee via e-mail dated 24.01.2012 about its agreement to invite industry representatives to the first VICH Outreach meeting in Brussels in June 2012.

The SC confirmed that the representatives of the regulators in the Forum would indicate which industry organisation to invite from their respective countries but the SC is the body which will invite the participants to the Forum. Only one industry organisation per country will be invited.

SC representation in the Forum

After a brief discussion, the SC agreed that in principle all SC members would attend Forum meetings. Should not all members be able to attend Forum meetings, it was decided that in any case at least 6 SC members, 3 representatives from the regulators and 3 representatives from industry, should attend Forum meetings, as well as the VICH Secretariat.

Criteria for participation in the Forum

OIE presented 4 revised criteria for participating in the Forum and reminded the SC that the aim was to involve further countries/regions in VICH activities.

Some SC members expressed concerns that the Forum would become too large, with many countries willing to participate but other SC members believed that the costs of attendance would restrict the participation to those with a strong motivation.

After further discussion, the SC adopted unanimously the following 4 criteria for participating in the Forum:

- Regulation for marketing authorisation in place
- Willingness to accept and work towards implementation of VICH GLs
- Paying for participation (travel costs, accommodation and translation if needed)
- Regular participation

Countries/regions to be invited to the Forum

The SC acknowledged that the Forum should start with a limited number of countries and could expand at a later stage.

After a thorough discussion, the SC decided to invite the countries and regions which attended the Contact meeting, as well as Russia, India and Mexico, which are countries of importance on the world market. The SC also decided to not re-invite the countries that were invited to the Contact meeting but did not attend, except India and Russia.

Should other countries wish to participate in the Forum, these will be required to send a formal demand to the Secretariat and the SC will decide by written procedure on a case by case basis.

Frequency of meetings

The SC decided that the Forum would meet back-to-back with VICH SC meetings. The first meeting will take place in the margin of the 27th SC meeting in June 2012 in Brussels, and should if possible be held for 1,5 days (Tuesday 26 all day & Wednesday 27 June in the morning), to be confirmed.

Link between Forum, VICH and OIE

After a thorough discussion, the SC agreed that VICH will chair the Forum in collaboration with OIE.

The SC confirmed that the VICH Secretariat will be the secretariat for the Forum and therefore will be responsible for sending the invitations and circulating all necessary documents, as well as for the logistics of Forum meetings.

Training

The SC acknowledged that it is not VICH's role to provide training, as training needs relate primarily to risk assessment and risk management questions, but VICH can provide support to the activities of OIE.

OIE explained that it has started the second phase of the OIE National Focal Points on veterinary products' training, including a session on VICH and VICH GLs. The VICH secretariat has collaborated with OIE for this part of the training programme.

The SC agreed to postpone further decisions until the Forum has met in order to identify more precisely the needs & expectations of the Forum countries; meanwhile VICH will work with OIE on training the Focal Points.

Budget

The chairman pointed out that in the regulators' pre-meeting it was noted that all VICH regions are facing financial difficulties. The EU and the US are suffering major budget cuts whilst Japan has to face the aftermaths from the earthquake and the tsunami. The regulators are therefore expecting support from OIE and industry.

IFAH-Europe confirmed that it will cover the costs of the first Forum meeting taking place in the margin of the SC meeting in Brussels in, June 2012.

The SC recognised the difficult financial situations from authorities and agreed on mutual support.

5.2 Decision on the next steps and agreement on messages for the contact countries

The SC agreed that the secretariat will send a message to the participants to the VICH/OIE Contact Meeting thanking them for attending and informing them of the creation of the VICH Outreach Forum as well as of the date of the first Forum meeting.

Act: Secretariat (Done)

5.3 Request for observer membership from South Africa

During the Contact meeting South Africa had expressed its interest to become an observer to the VICH SC.

The Secretariat reminded the SC that South Africa had applied for VICH membership in early 2010 and that the SC had postponed any decision until after the outcome of the outreach initiative.

In the discussion the EU and JMAFF suggested requesting again more information on their regulatory structure, marketing authorisation procedures etc...

It was agreed that the Secretariat will ask South Africa to provide:

- A short outline of the regulatory framework for the granting of marketing authorisation (regulatory approval) for veterinary medicinal products (pharmaceuticals and vaccines).

- More information on the status of implementation of existing VICH Guidelines in the country, and intention to implement further existing VICH Guidelines as well as future VICH Guidelines.
- Confirmation that South Africa has the capacities in place, including a sufficient pool of experts to contribute to the existing and future VICH Expert Working Groups, from the regulators side as well as from the animal health industry's side.
- Confirmation that the South African Animal Health Industry Association is prepared to represent the country's animal health industry on VICH.

Act: Secretariat (Done)

It was recalled that when Canada joined VICH it provided a clear action plan with commitment to implement VICH GLs and to provide experts to EWG. Moreover, Canada had adopted 20 GLs in one bulk.

4. VICH Global Outreach Strategy

4.1. Review of the VICH Global Outreach Strategy

After a short discussion the SC recognised that the strategy as it stands (VICH/10/064-draft 5) was a working document which has become outdated. No urgent issue detailed in the strategy needs to be addressed or revised. Therefore, in order to save time and resources the SC decided not to work any further on this document.

4.2. Review of the draft Terms of Reference (ToR) for the VICH Outreach Group

The participants reviewed and amended the revised draft that was presented.

It was noted that Industry participation to the first meeting is pending on the EU decision; in principle the first meeting would take place without industry. Nevertheless the local authorities will be asked to identify which is the most appropriate industry organisation in their country. The SC confirmed that if the EU has received the authorisation before the next SC meeting, the local industry organisations will be invited to attend the first Forum meeting in Brussels.

The SC adopted the final TOR (VICH/11/010-Final); the Secretariat will circulate this document with the message to the participants.

Act: Secretariat (Done)

6. VICH 4 Strategy Phase III

6.1. Update from the regions on how the VICH GLs are implemented – Feedback from IFAH-Europe

The SC reviewed and commented the non-validated feedback on the implementation of VICH GLs and the issues raised by IFAH-Europe.

JVPA expressed its concern that it had not been consulted prior to the circulation of information related to Japan.

In the future IFAH-Europe agreed to submit such information earlier in order to enable a validation in the regions.

JVPA explained that it will publish GLs 6 and 38 as self-regulation guidelines by the end of March 2012.

With regard to the implementation of GL 3R in Japan, JMAFF confirmed that the operating rules will be changed and that the applications for new Active Ingredients will be clearly separated from the others.

JMAFF explained the VICH TAS guidelines include a statement that allows the local regulatory authority's discretion on the usage of the guidelines for the products of local distribution only.

With regard to efficacy studies, JMAFF confirmed that Japan continues to require a local field study for veterinary medicinal products because there are still inconsistencies requiring local clinical trials, which is a decision of each government and out of the scope of VICH.

When the VICH GL is implemented, JMAFF will start accepting applications under the VICH BE GL.

FDA confirmed that the FDA will in the future consistently request the conversion of submitted data (specifically clinical pathology data) to units commonly used in the US.

Regarding specific efficacy field studies, FDA indicated that field conditions climate etc... are different in the USA.

Regarding the different elements required for efficacy studies in the EU and the US IFAH-Europe believed that VICH will have to consider changing the GL if this becomes an issue.

The EU confirmed that the request for submission of pharmacovigilance reports for products registered in the EU that occur outside their frontiers is a legal requirement in the EU, the aim being to get knowledge of issues arising elsewhere. This legal requirement was known to VICH from the outset when the VICH pharmacovigilance guidelines were drafted. When all the electronic systems will be in place, this should become easier to report by industry.

Regarding the different reference lists for the reporting, the SC acknowledged that these issues will be resolved as soon as the Pharmacovigilance data package and the GLs are finalised.

7. Review of

7.1 Written updates from the coordinators

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

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

The SC took note of the report.

8. Review of final VICH Guidelines at step 9

8.1. Proposal for a revision of the 3 Revised VICH GLs implemented in January 2008:

8.1.1 VICH GL 3 (R): Stability 1 - Stability testing of new drug substances and products

8.1.2 VICH GL 10: Impurities Substances – Impurities in new veterinary drug substances

8.1.3 VICH GL 11: Impurities Products – Impurities in new veterinary medical products

Dr Ogata, chairperson of the Quality EWG explained that she had consulted the Quality EWG members for their advice on the draft comment prepared by JMAFF, and no objection had been expressed. The EWG also found that ICH Q1A (corresponding to VICH GL3(R)) has not been revised since 2003. For ICH Q3A and ICH Q3B (corresponding to VICH GL10(R) and VICH GL11(R), respectively, a revision was conducted in June 2006, but the EWG confirmed that the revised part of ICH Q3A is just quoted in VICH GL10(R), and the revised part of ICH Q3B does not exist in VICH GL11(R). The EWG therefore concluded that there is no need to revise VICH GL3(R), 10(R) and GL11(R) at Step 9 for the time being. The SC agreed.

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

9.1. Quality

The chairperson of the Expert Working Group, Dr T. Ogata reported that GL 18 has been released for implementation in June 2012.

The draft GL 50 was signed off by the experts at step 2 on 5 November and sent to the SC for adoption at step 3.

9.2. Pharmacovigilance- Electronic Standards Implementation

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

The SC acknowledged that the work of the EWG is progressing very well and noted the proposed revised timelines.

FDA indicated that FDA is working with the contractors on changes of electronic codes; the contractors are paid directly by CVM.

The EU asked if draft GL 35 has been launched for public consultation.

JMAFF explained that the public consultation on draft GL 35 has not started yet in Japan, because the ISO standard is only in preparation; Japan has to confirm the content of the ISO standard before public consultation of GL35 and JMAFF wants to be sure that the ISO standard is the one that will be put into effect.

The EU confirmed that with regard to GL 30 the EMA will continue to invite VICH partners to attend VEDDRA meetings for updates of the lists; the EMA also updates the terms of reference on the website.

The EU recommended that all organisations should download the updates and use the most recent lists.

The SC took note that GL 42 also needs slight updates, only possible when draft GL 35 is finalised.

The SC approved these changes in principle.

The EU voiced its concern that the work on GL 35 should strictly follow the timelines that were set.

The EU pointed out that it was unusual for an EWG to request the authorisation for 2 planned meetings, in Spring & November 2012. Also, if a further meeting would become necessary it should be held at a venue according to the rotation rules for VICH meetings.

After discussion, the SC authorised the meeting scheduled for spring 2012 meeting, and encouraged the EWG to achieve further work electronically.

If a further meeting is needed in 2012, the SC will consider the request at its next meeting in June.

The chairman thanked Dr Brown and the experts for the hard work achieved so far with many teleconferences addressing many technical issues.

9.3. Biologicals Quality Monitoring

Dr K. Oishi, chairman of the Expert Working Group, reported that the EWG held its 9th meeting in Strasbourg in Sept 2011. The previous face to face meeting had taken place 8 years ago. The experts reviewed the 3 following topics:

a. Mycoplasma contamination testing

Dr Oishi reminded the SC that GL 34 has already been signed off at step 4 in 2002, with a public consultation. The use of reference strains had been agreed, but a discussion had taken place on which reference strains should be used; it was finally agreed to use the European reference strains, which should then become the world wide reference.

Collaborative studies were done in all the regions to validate the methodology and the reference strains. The development of the reference strains and these studies took 7 to 8 years because of various issues that were encountered.

Early last year these studies were completed and EDQM compiled the results, based on which the topic leader Dr Hyde has drafted a new document. The revised GL was reviewed at the last meeting, and signed off at step 2.

Dr Oishi asked therefore the SC to sign this draft GL off at step 3.

The EU expressed its surprise that the draft GL was presented at step 3 instead of step 6, recalling that at its 24th meeting the SC had encouraged the regions to re-open the public consultation that had been interrupted during the 2002 consultation.

The EU therefore questioned why it was not possible to finalise the draft GL at step 5, and why the experts requested another public consultation.

USDA explained that until the last EWG meeting it was not clear which issues would arise when the GL would be implemented. The experts do not expect many comments, which could probably be solved by electronic procedure. USDA therefore recommended to proceed with an abbreviated consultation.

Dr Oishi explained that the experts had compared both drafts, and agreed that the biggest difference was that the reference strains **MUST** be used. Operational details on how to use these strains were also modified. He confirmed that the first part of the text is not different, but the second part contains these relevant differences.

USDA confirmed that science has progressed and revisions are needed.

The EU acknowledged that the commitment to finalise the GL as soon as possible has been expressed.

IFAH-Europe did not support the need for a public consultation, urged therefore that it should be shortened and recommended that no lengthy delays should take place in the regions between the sign-off and the start of the consultation period.

JMAFF and USDA recommended starting a shortened 3 months consultation ASAP.

The SC therefore agreed to sign off draft GL 34 at step 3 for a 3 months consultation at step 4, until 29 February 2012.

b. Harmonisation of the Target Animal Batch Safety Test for immunological veterinary medicinal products

Dr Oishi reported that at the Strasbourg meeting the EWG reviewed and agreed draft 4 of the TABST draft GL for inactivated vaccines.

The scope of the draft GL is limited to safety tests of inactivated vaccines, and the EWG proposed to extend the scope to include the abnormal toxicity test and live vaccines. The EWG recommended that the SC should consider this proposal.

JMAFF explained that a Concept Paper (CP) should be reviewed at the next SC meeting and suggested to expand the scope with a scientific rationale, and to include the need for retrospective analysis in the CP.

The SC agreed to the EWG proposal. The EU will prepare the CP, which would be for a new GL, not an extension of GL 50. The SC confirmed that draft GL50 be finalised with the current scope and a new guideline be prepared on the extended scope. The EU reminded the SC that some of these issues had been addressed in the initial CP and asked SC members to convey the request from JMAFF to the experts so that they can send any scientific data available to the EU coordinator/topic leader.

Act: All/EU

The SC agreed to sign-off of the draft GL at step 3 for a 6 months consultation at step 4 and confirmed that the EU should remain the topic leader; the EU confirmed that Dr Halder would be available for the completion of the GL.

c. Extraneous agents testing for Biologicals

Dr Oishi confirmed that Japan has introduced the seed lot system, and is now ready for harmonisation of extraneous agents testing.

The EWG has therefore restarted the discussion on the existing draft GL, and reviewed the future direction of the GL.

The EWG suggested creating a separate GL for other starting materials i.e. bovine serum testing. The topics proposed for other GLs would initially be vaccines for mammals, and later for poultry etc...

The EU believed that it will be difficult to identify all areas for harmonisation in extraneous agents testing.

USDA agreed to start with classical methods, and asked if the EWG had started considering how to cover PCR testing.

Dr Oishi explained that the EWG had agreed that as a first step, the basic methods are addressed in this GL. The equivalent testing can then be adapted in each region.

It was suggested to add to the GL a sentence covering the new technologies which were not included in this GL.

The SC authorised in principle the 10th meeting of the EWG, to be confirmed on request of the EWG chairman.

9.4. Metabolism and Residue Kinetics EWG

The SC reviewed the written report prepared by the chairman of the Expert Working Group, S. Scheid, and presented by the EU.

The 4 major GLs are in the implementation phase but the SC had requested the EWG to prepare a Concept Paper on MRK GLs for fish and honey bees.

See further discussion under item 12.2.

The EU pointed out that industry had recently encountered difficulties in a region with implementation of GL48, specifically the interpretation of the study design and time points to obtain a 0-day milk withdrawal period. The EWG has discussed in-depth the 0-day withdrawal time and reached a consensus wording, but the GL may not be clear enough to ensure unambiguous interpretation. Dr Scheid therefore suggested reconvening the EWG by electronic discussion to clarify the wording and eventually propose a minor revision of GL 48.

In the discussion the SC noted that a clarification would likely not represent a major revision, thus it is expected that no public consultation would be needed for final decision by the SC once the revision is available.

The SC therefore agreed that the EWG should revise GL 48 by electronic procedure.

9.5. Microbiological ADI EWG

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

The consultation for draft revised GL 36 is finished in all regions and the EWG members are reviewing the comments that were received.

The EWG will sign the draft revised GL at step 5 by written procedure.

The SC agreed that the sign-off at step 6 will also be addressed by written procedure.

9.6. Safety EWG

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

FDA mentioned that the experts are currently reviewing draft 4 of the Acute Reference Dose GL and the chairman expects that this draft could be signed off by the end of 2011.

Following the recommendations from the Microbiological ADI EWG, the EWG noted that both acute and chronic toxicity to the human gastrointestinal microflora are addressed in VICH Guideline 36 and the Safety EWG should cross-refer to that guideline.

The SC had also tasked the Safety EWG with a revision of VICH Guideline 23, Safety, Genotoxicity, Revision 1. FDA confirmed that the work is progressing and no particular issue was raised. The draft GL will probably be circulated for signature by written procedure.

9.7. Bioequivalence EWG

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

FDA reported that the EWG held its first meeting in March 2011 and different subgroups were set up to progress the work. FDA pointed out that some of the initial timelines were extended but the EWG nevertheless requested to hold a 2nd meeting on 5-7 June 2012 in Brussels. Noting the delays, the EU stressed that all experts needed to have sufficient time to comment on all aspects of the draft GL.

With regard to the publication of an article that was initially planned, FDA confirmed that the proposal had been dropped. In the discussion, the SC confirmed that the differences in the jurisdictions should be addressed at a later stage. The SC believed that any other work (publication) could only be done on an individual basis, although the SC would not support any such initiative from any VICH expert. A scientific paper highlighting the regional differences would not be an appropriate message from any VICH participant.

The SC authorised in principle the EWG to hold its 2nd meeting in June 2012.

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

10.1. Draft GL 34 (Biologicals) - Mycoplasma - Test for the detection of Mycoplasma contamination

The SC adopted the draft GL 34 at Step 3. This guideline was transmitted to the VICH members for a 3 months public consultation at Step 4, until February 29, 2012.

10.2. Draft GL 50 (Biologicals): TABST - Harmonization of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use

The SC adopted the draft GL 50 at Step 3. This guideline was transmitted to the VICH members for a 6 months public consultation at Step 4, until May 31, 2012.

10.3. Draft GL 51 (Quality) - Statistical evaluation of stability data

The SC adopted the draft GL 51 at Step 3. This guideline was transmitted to the VICH members for a 6 months public consultation at Step 4, until May 31, 2012.

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

None presented

12. Concept papers/Discussion papers

12.1. Review of the recommendation from the TF on potency test of rabies vaccines

IFAH Europe reported that a recommendation has been received from the chairman of the TF, Dr A. Fooks, but JMAFF had not been fully involved in the discussions that took place.

The EU reminded the SC that the main question to the TF was: should a GL be drafted by OIE, VICH or both and added that not all experts received the e-mails that were circulated. JMAFF confirmed that their experts were not involved in the 2 teleconferences that took place and did not receive the minutes of the meetings. JMAFF requested Dr Fooks to make proper

contact with all TF members by using the group e-mail address of the TF and to reflect all members' comments in the work.

OIE mentioned that an OIE expert group will start a review of the OIE GL on rabies, mainly to review the quality rather than potency, in which Dr Fooks will participate.

The SC evaluated if the TF should continue the discussion and noted that the recommendation from Dr Fooks exceeds the mandate that was set, the aim being to prevent duplication of work between the VICH regions.

The EU recalled that the aim expressed within the Concept Paper was to clarify the situation in the regions, not yet to develop a VICH GL.

IFAH Europe recommended strongly that, if the TF continues, a SC member should be member of the TF to ensure a full understanding of the mandate and a proper compliance with VICH procedures. IFAH-Europe stressed that its vision was for inter-regional acceptance of each of the in-vitro methods being developed in each region and not a VICH GL restricted to one in-vitro test. Thus the purpose of a future VICH EWG would be to ensure there is comprehensive communication and understanding between the regions on the local work being done, to facilitate inter-regional acceptance of any new in-vitro tests that are developed.

After discussion, the SC agreed that the TF should continue to work in order to understand what is currently done in the 3 regions and to provide a report to the next SC meeting. The SC agreed that Dr B. Rippe will be a member of the TF, representing the SC.

The mandate of the TF is to compile the situation in the regions of the world regarding the potency testing, and to make a recommendation for whom should develop a guideline (OIE, VICH or "joint"). This should include clarification on the issues that OIE will address i.e. if OIE will cover the issues developed in the VICH CP. The SC requested the TF to provide a revised CP to the next SC meeting. The Secretariat will contact Dr Fooks.

Act: Secretariat

12.2 Review of the draft Concept Paper on Residue Studies in Fish and Honey

The SC reviewed the Concept Paper presented by the EU.

JMAFF recommended that Dr Scheid should collect information about the work of CCRVDF on honey, and review any possible duplication before the next SC meeting.

The SC therefore agreed to postpone any decision on honey until the CCRVDF will progress its work and pending a more focussed CP on the subject eliminating any duplication with the CCRVDF ongoing work.

The SC decided to proceed with a residue studies GL in fish by the MRK EWG. Concerns were expressed by some SC members whether the specific expertise / change of experts would be necessary as fish metabolism may require other expertise than some members of the current MRK EWG.

After discussion, the SC confirmed that Dr Scheid would remain the chairman of the EWG and decided that each delegation could, if they wish, replace their expert, or nominate a specific advisor to the current MRK experts (change advisor or nominate a new advisor, if no previous advisor) and inform the Secretariat by the end of the year.

Act: All

The SC agreed that the number of experts in the current EWG should not be expanded, but any advisors may be changed.

The Secretariat reminded that only the official experts may sign-off the draft GLs, and asked all delegations who have nominated advisors to clarify who will be the expert and who will be the advisor.

Act: All

12.3 Other VICH topics

12.3.1 e-submissions

IFAH Europe asked the SC to consider e-submissions again as a future VICH topic because the situation on electronic submissions has evolved and suggested developing a simple VICH GL covering only the format of the individual files themselves (such as a pdf file, the file size, the use of hyperlinks etc..).

The objective was to avoid companies having to convert a study report into several different electronic versions to satisfy different regions.

IFAH Europe believed that this would be useful for companies who want to present a study report in more than 1 region. IFAH-Europe is not proposing a GL to harmonise how the data is submitted electronically (i.e. the electronic technical protocol for the electronic “envelope”).

AHI mentioned that FDA has established rules for e-submissions and in the US 15% of dossier submissions are delivered electronically and it would not be possible to change the FDA rules.

The EU also has a guideline for e-submissions and the many applications that are nowadays submitted electronically.

JMAFF reported however that in Japan there is no possibility for the time being to submit dossiers electronically. JMAFF could therefore not support this topic for the moment.

The SC consequently agreed to postpone this topic and to continue exchanging information.

13. Other issues

None

14. Any other business

14.1 Letter from PETA

The Secretariat reported that another letter had been received from PETA before the SC meeting. The SC noted that the tone of the letter was not appropriate and confirmed the recommendation from the 25th SC meeting that the Secretariat should reply to such letters only in an abbreviated fashion indicating that all information is available on the VICH public website.

14.2. JVPA representation

JVPA informed the SC that Dr M. Kajiwara will retire on 31st March 2012, after having represented JVPA on the SC since the 19th meeting in January 2007. The chairman thanked Dr Kajiwara on behalf of the SC for his active involvement and commitment to VICH.

15. Dates and venue of next meetings

- The 27th SC meeting will take place in Brussels, Belgium on 25, 27 & 28 June 2012; the VICH Outreach Forum will take place on 26& 27 June in the morning.
- The 28th SC meeting will take place in Washington DC, USA from 18 to 21 February 2013.

16. Adoption of the Press Release on the 26th SC meeting

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

VICH STEERING COMMITTEE

26th meeting

November 14, 16 & 17, 2011
Tokyo, Japan

Chair: M. SAKAI (JMAFF)

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI (BAYER)	B. MARTIN
AHI (PFIZER)	M. J. MCGOWAN
AHI	S. VELUVOLU (C)
EUROPEAN COMMISSION (DG SANCO)	K. KRAUSS
EMA	K. GREIN (C)
EMA-CVMP	A. HOLM
IFAH-Europe (MERIAL)	B. BOENISCH
IFAH-Europe	R. CLAYTON (C)
IFAH-Europe (BAYER)	L. KLOSTERMANN
JMAFF	K. IKEDA
JMAFF	Y. ENDO
JMAFF	K. NODA (C)
JVPA	O. ITOH (C)
JVPA (KYORITSUSEIYAKU CO.)	M. KAJIWARA
JVPA (DS PHARMA ANIMAL HEALTH CO.)	T. KOMATSU
US FDA	M. SMITH
USDA APHIS	B.E. RIPPKÉ

OBSERVERS

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

INTERESTED PARTY

AVBC	J. THOMAS
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OIE

OIE	J-P. ORAND
OIE	C. LAMBERT
OIE	S. MÜNSTERMANN

VICH SECRETARIAT

IFAH	H. MARION
IFAH	B. FREISCHEM

GUEST

JMAFF	H. MAKIE (part)
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APOLOGY

US FDA	M. LIMOLI (C)
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