



VICH/13/026  
24 May 2013  
Final

**VICH STEERING COMMITTEE  
28<sup>th</sup> meeting  
19-21 February 2013  
Washington DC - USA**

**Minutes of the meeting**

**1. Opening of the meeting and chairperson's introduction**

The meeting was chaired by Dr. Bernadette Dunham, Director of the Centre for Veterinary Medicine – FDA. She opened the meeting by welcoming the participants to Washington for the 28<sup>th</sup> VICH SC meeting.

Dr. Dunham acknowledged the tremendous number of accomplishments that the VICH SC has accrued since their first meeting in April 1996. She recognized that during the last 17 years the SC has completed 49 guidelines. Moreover, she stated that the Outreach Forum meetings are further enhancing the SC's strategy to help gain acceptance of these guidelines by other countries to facilitate and accelerate the authorization of veterinary medicinal products.

**2. Adoption of the agenda**

The agenda was adopted with the following changes:

Agenda item 11.3: the words 'E-submission' were deleted and replaced by 'E-file formats'

Agenda item 12.3: 'South African membership application' was added

**3. Preparation for the 2nd Outreach Forum meeting**

**3.1. Review of the agenda of the meeting**

The SC agreed to amend the agenda by moving the "*Topics out of the scope of VICH*" to agenda point 4 which would facilitate the discussion of the OIE survey results.

**3.2 Review of the participants list**

The SC noted that 9 countries (China, Brazil, India, Korea, South Africa, Taiwan, Thailand, Russia and Ukraine) and 2 international organisations (Camevet & WAEMO) would participate in the Forum meeting.

The Secretariat reported that the delegate from SENASA – Argentina had sent a last minute apology. The SC noted that it would be difficult to present the presentation of Argentina without its author, but nevertheless decided to address the questions raised.

The Secretariat therefore prepared a short presentation including only the questions.

OIE indicated that ASEAN is still interested in future long term participation although an ASEAN representative was not able to attend the Forum meeting because of the ongoing restructuring of their veterinary department. IFAH-Europe stated that OIE should encourage ASEAN to re-join the Forum activities as soon as possible.

OIE noted with disappointment that Mexico and Argentina were not able to be represented at the Forum meeting

### **3.3 Review of the Forum participants' needs assessment survey by OIE**

OIE presented the results of the needs assessment survey IFAH-Europe proposed to classify the requests by grouping the VICH topics together rather than by a numerical list of VICH GLs. There were 8 requests for training on Quality and 6 on MRK. OIE agreed to this modification.

It was also noted that Forum members requested clarification on the relationship between VICH and Codex. The SC indicated that this would be addressed during the discussion in the Forum meeting.

OIE reported that it had created a "VICH Outreach Forum" webpage with a link from the tab "Our Scientific Expertise".

### **3.4 Agreement on the opinions/directions from the SC**

The SC approved the presentation from the Secretariat on the "Report by the VICH Steering Committee on issues raised by Forum members during the 1st Outreach Forum meeting".

#### *Observers*

The SC decided that it would be useful to explain the benefits of participating in VICH as an "Observer"; and to acknowledge that the Observer countries are satisfied with their status within the VICH SC. The SC agreed that the Observer countries would present a few slides on this topic.

#### *Participation of Forum members in EWGs*

JMAFF highlighted the need of the SC to respond to the expectations from Forum members. IFAH-Europe recalled that a draft document had been developed that included a proposal for the participation of Forum members in EWGs (Ref.: VICH/10/015 from January 2011). The key criteria for participation were: competence in English, sufficient resources, have sufficient expertise and maintain the confidentiality of the discussions. IFAH-Europe will revise the draft and submit it to SC for review and approval by written procedure.

**Act: IFAH-Europe**

#### *Training*

JMAFF asked if the requests from Forum members concerning training could be addressed by the OIE Collaborating Centres that cover the regulation of veterinary medicines whose experts also participate in OIE Focal Point Training days (which include a topic on VICH). OIE believed that some training could be organised by the OIE Collaborating Centres with the assistance of VICH which has the appropriate expertise.

It was suggested that training sessions could be organised during an additional day in the frame of Forum meetings or during OIE Focal Points for Veterinary Products training

sessions, but OIE questioned if the attendees of both meetings would be the right persons needing training on VICH GLs.

Moreover the EU pointed out that the SC members would not necessarily be the right persons to dispense training on GLs. The persons requesting training in the Forum countries are in reality the hands-on technical staff rather than the program managers or policy officials. Moreover, IFAH-Europe mentioned that not all Forum member countries are at the same stage of regulatory development.

The SC acknowledged also that the preparation of a training session represents a significant amount of work. It would include developing “artificial” data for case-studies and preparing the training in small hands-on working groups. The problem of resources needs to be addressed.

The EU pointed out that ICH has organised a new training module on Quality and recommended that the SC find out what training materials from ICH are available, as the requirements are similar in VICH.

The SC decided to explain during the Forum meeting that the SC is aware of the training needs and is examining ways of addressing them.

The SC also agreed to set up an ad hoc Working group of SC members and Forum members to develop a strategy defining the priorities for training and the strategy for establishing the resources and funds needed for future VICH trainings of Forum members. The strategy should include: focus on priorities of Forum members (e.g. Quality), seek funding (e.g; under the Food Security banner), and proposals for development of training modules based on a category of GLs.

#### *Translations*

The SC agreed that OIE would present to the Forum a list of translations currently available on the OIE website and propose that when a new translation is available in a country it should be communicated to OIE who will then update the website. Translations were in particularly needed of the GLs identified as most important by Forum members. On the reasons explained at the previous meeting VICH itself is not in the position to translate the GLs; VICH can only refer to 3<sup>rd</sup> party translations, noting the English version is the original language version.

#### *Proposal for new topics*

The SC agreed that the Forum members were to be reminded that they may propose new topics for VICH guidelines for consideration by the SC, provided they have a clear intention to implement the proposed guideline in their country. A Concept Paper should then be prepared by the proposing Forum member in collaboration with a SC member sponsor.

#### *Questions from Argentina*

The Secretariat summarised for the SC the questions asked by the 1<sup>st</sup> Forum participants.

#### *Participation in EWGs*

IFAH-Europe explained that VICH has a draft document on the qualification of experts and that this could be shared with the Forum members.

#### *Definitions from Camevet*

The SC agreed that the regulators from the SC will provide their definitions to Camevet.

### **3.5 Endorsement of revised general document on the role of VICH**

The SC reviewed and endorsed the amendments that were suggested. The Secretariat will ensure that the translations are updated as well.

**Act: Secretariat**

## **4. Review of the Outcome of the 2<sup>nd</sup> Outreach Forum meeting**

### **4.1. Debriefing and review of the conclusions of the Forum meeting**

The SC addressed this agenda item the day after the 2nd Outreach Forum meeting.

#### *Agenda*

The SC noted that the discussions, in general, were very good, but the agenda and the presentations should have been available much earlier.

The presentations from Taipei and South Africa were excellent. The benefit of receiving the presentations beforehand enabled the SC to ask a few precise questions to enhance the discussions during the meeting.

The SC adopted the objective for the next Forum meeting to circulate a draft agenda with the formal invitation by the end of June, and to ask Forum members to complete the agenda by the end of July.

Once the input from Forum members is received, the SC can send a few simple questions, for replies in advance of the meeting, and can also ask certain countries to prepare presentations based on the replies.

USDA encouraged the SC to engage the Forum members when setting up the agenda so that they can become the co-owners of the Forum.

The EU pointed out that not all Forum countries are at the same level of development, and suggested to split the agenda into information sessions and breakout sessions where participants can express themselves much more freely in smaller groups. The English language was also considered to be a hurdle for some participants.

The SC supported this approach.

OIE recommended circulating the conclusions from the SC as soon as possible rather than at the start of the next meeting.

The SC also discussed how to approach the countries that did not attend the Forum meeting. OIE reminded the participants that the criteria for participation in the Forum are defined in the ToRs of the Forum and that there will probably not be many new candidates.

The Secretariat mentioned that VICH has identified a list of all countries which should be invited to each Forum meeting.

The SC agreed that it is not recommended to exclude a country because it does not attend but the programme should be interesting enough to motivate them to attend.

FDA pointed out that the Outreach initiative is still in the early phase with only 3 meetings (a pilot and 2 Forums) being held to date and already the Forum members approach has changed from fears they expressed in Tokyo that VICH would impose on countries the agreed VICH requirements.

It was noted that only India, attending for the first time had expressed fears of having requirements 'being imposed', and it was therefore suggested to ask India to present their

approach to regulation of vet medicines at the next Forum meeting, as other countries have done.

It is also not clear yet to all Forum countries that the “adoption” of GLs means only that they are advisory and are not obligatory or mandatory.

#### *Pharmacovigilance GLs*

It was noted that some Forum members had expressed an interest in training on pharmacovigilance GLs. It should be explained that the pharmacovigilance systems in VICH member countries are a facet of a mature regulatory system resulting from years of development and investment. Pharmacovigilance is not a first priority when establishing a new regulatory system. The control of the quality of products circulating in the market is a first priority.

The EU suggested therefore preparing a presentation on the PhV GLs for the next Forum meeting, explaining the principles on a higher level without too many technical details and suggesting what is feasible for the Forum countries.

FDA pointed out that in regions, such as Africa and Latin America, the authorities are fighting with counterfeit products, and suggested that PhV may be useful for identifying these products

Following some discussions on what PhV can deliver, the SC considered that for identification and control of counterfeit products the PhV would not be suitable and possibly OIE would be able to provide assistance to countries to tackle this problem.

OIE noted that the Forum members have different levels of implementation, and that the BRIC countries may be ready to develop a PhV system similar to the one being adopted in the VICH regions whereas the other countries probably need a program that is more similar to a rapid alert system than a PhV program.

Moreover if some countries are ready to set up such a PhV system, it is not the role of VICH to implement one but rather the role of their national government. It was agreed that OIE can assist in setting up a solid regulatory system that could include an appropriate level of PhV.

#### *VICH Outreach subgroup*

In order to prepare the agenda and assist the secretariat in the organisation of the Forum meetings, the SC decided to revive the VICH ad hoc Outreach Subgroup which will work by electronic procedure only:

The members are:

Chair: OIE – J.-P. Orand  
IFAH-Europe : B. Boenisch  
EU: K. Grein  
JVPA: O. Itoh  
JMAFF: K. Noda  
AHI: M. McGowan  
US FDA: M. Smith + S. Vaughn  
ANZ : A. Bryce  
VICH Secretariat: H. Marion

#### *Training*

The SC confirmed that the members of the ad hoc working group on training strategy, which will also work by electronic procedure only, are:

Chair: FDA - S. Vaughn

JMAFF: S. Iwamoto  
OIE: J.-P. Orand and S. Munstermann  
FDA: M. Smith  
EU: K. Grein  
ANZ: tbd  
IFAH-Europe: R.A. Clayton  
IFAH: B. Freischem  
VICH Secretariat: H. Marion  
*Forum members:*  
Y. Kosenko (Ukraine)  
M. Moroe (South Africa)  
Camevet: tbd

#### *Participation in Forum activities*

OIE pointed out that it had invested many resources to convince the Forum countries to attend the meetings and asked that all SC members reach out and encourage the countries, and the industry in the countries, as well as the regional organizations such as ASEAN, to attend regularly the Forum meetings.

JMAFF recalled that South Africa had asked to have a document explaining how to develop a Concept Paper and pointed out that an internal document exists. JMAFF therefore recommended creating a password protected “Forum members only page” in the VICH website, making this kind of internal documents available to the Forum members. This would not only be useful to maintain the confidentiality of internal documents, but it would also be a tool encouraging the Forum members to develop a “sense of belongingness” to VICH.

It was noted that China clearly expressed its intention to propose the development of a guideline for “combined products”. In the Forum meeting the SC explained the need to develop a Concept Paper and FDA volunteered to assist China in preparing a Concept Paper for this topic.

#### **4.2 Review of the requests and topics raised by the Forum participants**

Discussed above

#### **4.3 Decision on the next steps and items for the agenda of the 3<sup>rd</sup> Forum meeting**

Discussed above

### **5. VICH Strategy Phase III**

#### **5.1. Update from the regions on how the VICH GLs are implemented**

IFAH-Europe recalled that this is a standing agenda item because it is the second element in the current VICH Strategy.

IFAH-Europe therefore suggested developing a method to seek feedback on how the GLs are implemented in the different regions. It would be sufficient for each region to report every two years. Consequently each region could take a turn on successive SC meetings. IFAH-Europe had reported on this subject at the last meeting. It was proposed to ask the regulators from

the regions to report regularly on how the GLs are implemented, however, the initial intention had been to receive feedback from industry.

Until a few years ago there had been regular brief update reports of the regulators describing how the GLs are implemented at each SC meeting, and it was agreed that the Secretariat will place this item on the agenda in the same manner that it had been done previously. In respect to analysis of any industry analysis, IFAH-Europe proposed preparing such analysis with a rotation of the regions.

**Act: Secretariat**

## **5.2. Other issues**

No point was raised.

## **6. Review of**

### **6.1 Written updates from the coordinators**

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

### **6.2 Review of the written status of consultation for draft GLs at Step 4**

The SC took note of the report.

## **7. Review of final VICH Guidelines at step 9**

### **7.1. Proposal for a revision of other VICH GLs in light of an update of other organisation's GLs (ICH, OECD...)**

The EU explained that regarding the 3Rs principles for the reduction of animal testing, the VICH GL 22 – Reproduction Toxicity Testing refers to the OECD 2 generation reproduction toxicity study (OECD 416). OECD has now developed an extended 1 generation reproduction toxicity study GL (OECD 443), which is already accepted in the EU for the evaluation of food additives, and the use for evaluation for other substances (e.g. chemicals, pesticides) is being discussed.

In the discussion it was recommended to review what has been done in ICH with regard to this OECD GL. The SC supported a proposal from the EU to prepare a discussion document on this topic for review at the next SC meeting.

**Act: EU**

## **8. Progress Reports of Expert Working Groups and decisions on next steps**

### **8.1. Quality**

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr. T. Ogata, that was presented by JMAFF and acknowledged that the EWG was working exclusively by electronic procedure.

The SC noted that after the public consultation period no change had been made by the experts to VICH draft GL 51- Stability.

## 8.2. Electronic Standards Implementation – Pharmacovigilance -

The chair of the Expert Working Group, Dr. M. Brown, reported that draft GL 35 and its two technical documents were finalised, but the EWG had decided to sign the 3 documents separately.

Dr. Brown explained that so far, GL 35, which is the “foundation document”, has been signed off by all experts.

The *step by step document*, which is the “blue-print” for implementation, describes how the system should be assembled so that it works throughout the regions. It is not completely finalised and consequently it has not yet been signed off by all experts.

CVM is currently testing the step by step document procedures to ensure that the proposed assembled system works correctly and will complete the document with the remaining details. Discussion on the details will continue by teleconference and by e-mail.

The aim of the *validation document* is to ensure that the procedures are correct. Some regional requirements currently differ and each region will review its electronic systems to identify the specific differences.

The SC complimented Dr. Brown and the EWG for the difficult task that was achieved with the development of these documents, recalling that many challenges needed to be addressed when this work was first started. The SC also noted with satisfaction that all regions had been able to sign the final GL.

IFAH-Europe indicated that its expert would sign the final version of both technical documents once the final versions are available.

The EU reminded the SC that the EU could not sign off the validation document: the EU accepts reports on the premise that all adverse events should be logged even if not all details are available. The strict implementation of the VICH GL and the validation document would result in rejecting of reports which are not fully complete. This is however not compatible with the EU legislative requirements which aims to ensure that all suspected adverse events are reported, even those cases where the data are not entirely complete, e.g. where it is not possible to identify exactly which strength or which presentation was used of a certain product. The above situation with incomplete reports happens frequently; the reports are considered in the EU still valid information. Rejecting these reports would reduce the power of surveillance significantly and undermine the purpose of a pharmacovigilance system. An email from the EU expert to the EWG explaining in detail the reasons of the EU for not being able to sign the validation guideline was circulated by the secretariat to the SC.

There was discussion about whether all three documents could be published on the VICH website, since they had not been signed. It was thought there was a precedent for publishing documents with regional differences, and perhaps the validation procedures document could be addressed in this manner when the documents have been finalized.

Dr Brown and the EU would liaise in order to prepare a text explaining the disagreement for publishing the validation document on the VICH website.

Dr. Brown pointed out that the evolution of IT and the electronic systems used in PhV was very fast and that many things had changed since the year 2007 when GL 42 was first signed off. The SC agreed that the EWG should prepare a CP recommending a revision of GL 42 to update the IT issues.

**Act: PhV EWG**



Regarding the implementation of GL 35, the EU mentioned that the other Pharmacovigilance GLs are still with an open implementation date and recommended not to set an implementation date until all the PhV GLs are ready to be put in place. Dr. Brown explained that the 2 technical documents should be finalised by next June, then the industry will need at least a year to move into the new reporting system.

After discussion, the SC agreed to sign off the draft GL 35, but to wait to determine the implementation date until the next SC meeting.

**Act: next SC meeting**

### **8.3. Biologicals Quality Monitoring**

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr. K. Oishi, and presented by JMAFF.

#### *a. Mycoplasma contamination testing*

The SC took note that the VICH GL 34 was presented for final sign-off by the SC and acknowledged that the topic leader has deployed much effort to reach a consensus between the experts for signature of VICH GL 34 which has been developed over the past 10 years.

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

VICH GL 50 was also presented to the SC for final sign-off.

The SC considered the 2 questions posed by the EWG regarding the comments received during the public consultation period and agreed for PETA's comment that it had been "Noted by the VICH Steering Committee. Matter to be considered by the local regulatory authorities" The SC also agreed for ICAPPP's comment that "The proposed change has been discussed by the VICH Steering Committee and the scope will be extended in the future. This sentence has been removed to avoid updating the Guideline in the future".

#### *c. Extraneous agents testing for Biologicals*

The experts have resumed the work on this topic during the year 2012. Following the receipt of fundamental comments from the EU the EWG will need at least a further 6 months to progress enough to hold the next face to face meeting, probably in the second half of this year.

### **8.4. Metabolism and Residue Kinetics EWG**

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

#### *New GL for fish*

Additional experts were nominated to the EWG and a Topic Leader and 2 Co-topic Leaders have been appointed. A first draft GL should be circulated among the experts shortly.

#### *Amendment to GL 48*

The discussions among the experts have shown that the proposal for a revised text to the GL in respect to the study design for a zero day withdrawal period for milk raises more complications than foreseen.

What has appeared to be a small issue that could be solved as a minor change to the GL will probably need a consultation at step 4 of the 9 step revision procedure.

#### *Request for a meeting in Q3*

The SC agreed in principle for a meeting of the EWG to take place in Europe during the autumn of 2013 pending the progress made and the draft agenda that will be presented by the chairman to the SC.

### **8.5. Safety EWG**

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

#### *a) Revision of VICH GL 23*

The expert EWG has incorporated language into the guidance on the inclusion of a new mammalian cell micronucleus test based on OECD TG478, the OECD Guideline for Testing of Chemicals.

The revised draft GL is currently in the public consultation procedure at step 4, which should end during this coming April. The EWG does not expect many comments.

At the last SC meeting, the EU had reported it was reflecting on the need to further revise the testing strategy for genotoxicity testing, in line with an EFSA GL, which might have an influence on the international level.

The SC confirmed that the EU should address the comments based on the EFSA guideline to the EWG at this point in time, and recognised that in case the EWG adopts the EFSA proposal, a new consultation on the revised draft GL will be needed.

**Act: EU**

#### *b) GL on the determination of an acute reference dose for residues*

The EWG is currently considering revising the title of the GL to “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)”.

A new version of the draft has been circulated and the chairman anticipates that the draft GL should be available at the end of this year.

The EWG considered how to address acute toxicity to the barrier of the gut microflora and recommended that guidance on this subject is contained in the VICH Microbiological ADI GL.

### **8.6. Bioequivalence EWG**

The chair of the EWG, Dr. M. Martinez, reported that the EWG has extended the projected timelines for completion because of the high number of differences between the regions and the need for extended discussions to find a common agreement.

Several parts of the initial document (i.e., sample size analysis, sequential analysis) have become supplemental materials, which will be signed off and placed on the VICH website together with the GL.

Dr. Martinez confirmed that the EWG experts are energetically engaged to find a consensus and that the current revision is very close to the final step 3 version. She mentioned that part

of the delay resulted from having some new experts replace outgoing experts, noting that there is not always a clear understanding of why previous compromises were made.

JMAFF explained that the 2 supplemental documents would take more time to be reviewed by the experts of Japan, and suggested therefore that the GL be signed off as soon as possible whilst the 2 supplemental documents could be signed off together at a later stage.

The SC commended Dr. Martinez and the other members of the EWG and noted that all the partners have supported the proposed approach. The SC confirmed that the supplemental documents will describe, with examples, how to implement some items described in the GL.

After discussion the SC decided that these supplemental documents should be published for consultation at step 4 together with the draft GL, if possible before the next SC meeting.

## **9. Adoption at Step 3 and release of Guidelines at Step 4**

None presented

## **10. Adoption at Step 6 and release of Guidelines at Step 7**

### **10.1. Draft GL 34 (Biologicals: Mycoplasma) – Test for the detection of Mycoplasma contamination**

The SC adopted GL 34 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2014.

The compilation of comments received with their consideration by the EWG/SC were endorsed by the SC and will be published on the VICH website.

**Act: Secretariat**

### **10.2. Draft GL 35 (Pharmacovigilance: ESTD) – Pharmacovigilance: Electronic Standards for Transfer of Data**

The SC adopted GL 35 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by a date to be determined at a later stage.

### **10.3. 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 GL 50 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2014.

The compilation of comments received with their consideration by the EWG/SC were endorsed by the SC and will be published on the VICH website.

**Act: Secretariat**

### **10.4. Draft GL 51 (Quality: Stability data) – Statistical evaluation of stability data**

The SC adopted GL 51 as final VICH GL at Step 6. This GL was transmitted to the VICH members for implementation in the three regions at Step 7.

The SC agreed that the GL will enter into force by February 2014.

The compilation of comments received with their consideration by the EWG/SC were endorsed by the SC and will be published on the VICH website.

**Act: Secretariat**

## **11. Concept papers/Discussion papers**

### **11.1. Discussion on the next steps regarding the Concept Paper from IFAH-Europe for a VICH GL on potency test of rabies vaccines**

IFAH-Europe reminded the SC that at the last meeting it was decided that a subgroup of the Task Force experts should meet in the frame of the next BQM EWG meeting, because the Japanese experts had not been able to participate in previous TF teleconferences.

However, the meeting of the BQM EWG did not take place as planned.

IFAH-Europe proposed at this point in time not to pursue this topic further because the window of opportunity for harmonisation of *in vitro* methods has passed, and recommended to disband the TF and to thank the experts for the work achieved.

VICH should nevertheless keep the useful information that has been gathered so far in case in the future it would be decided to revive this topic.

USDA agreed that the time has indeed passed and mentioned that there is still a desire from regulators in the regions to develop activities regarding potency test of rabies vaccines e.g. *in vitro* test without using laboratory animals (Japanese Method), in particular with OIE.

OIE reported that the rabies vaccines chapter in the OIE Terrestrial Code is being revised and comments from the countries have been included in a second draft of the revision, which could be adopted at the next OIE general session in May 2013.

The SC agreed, on the reasons explained, to disband the TF and to thank the experts for the work achieved

### **11.2 Concept Paper for a VICH GL on harmonisation of criteria to waive batch safety testing for vaccines for veterinary use: abnormal toxicity testing**

The SC reviewed the Concept Paper on the VICH approach for harmonisation of criteria to waive batch safety testing for vaccines for veterinary use regarding the implementation and extension of GL 50, which had been prepared by the EU.

The EU reported that following the discussion at the last SC meeting on the next step for the extension of GL50 and the scientific data available that could be considered for this topic, no further recommendation was given on the order of the steps and the EU based the proposal on its own experience considering that waiving abnormal toxicity would have the highest impact on reducing animal testing.

The EU therefore recommended in the CP to the SC that the BQM EWG should initiate a GL on harmonisation of criteria to waive batch safety testing for vaccines for the abnormal toxicity testing (testing in laboratory animals).

The EWG should work essentially by electronic procedure.

JVPA and USDA questioned the reason for dealing first with abnormal toxicity testing rather than harmonisation of criteria to waive TABST for live vaccines.

The EU recalled that the SC had not given a precise direction at the last meeting and rather left this to the EU, and the EU has made the proposal with the highest impact on the 3Rs.

JMAFF explained that the EWG has experience with animal batch safety testing of inactivated vaccines and would therefore prefer that VICH extends this topic to live vaccines first.

The EU pointed out that no CP was prepared to address the live vaccines topic, but JMAFF considered that in this case a new specific CP was not really required as the principles addressed for inactivated vaccines can be applied to live vaccines.

After a thorough discussion, the SC recognised that it had committed to address the topic of the live vaccines, and agreed that no specific CP was necessary. Moreover, most BQM experts having addressed the topic of inactivated vaccines would be competent for the topic of live vaccines.

The SC therefore agreed that the BQM EWG should start the development of a new VICH GL on the harmonisation of criteria to waive TABST for live vaccines using VICH GL 50 as a blueprint for the drafting of the new document.

The SC confirmed that the composition of the EWG would not change and that the EU would remain the Topic Leader for this new topic.

### **11.3. Review of the Concept Paper on Electronic file formats presented by the TF**

IFAH-Europe recalled that when reviewing the discussion document at the last meeting, the SC had agreed to set up a Task Force to develop a Concept Paper covering electronic file formats.

IFAH-Europe emphasised that this GL would just cover the issue of converting a word document into a pdf document for the electronic exchange of documents.

JMAFF asked what would be the “other parameters” referred to in the CP.

IFAH-Europe replied that this will concern the small details for pdf documents such as fonts, hyperlinks in the document, sizes of fonts etc...

The SC adopted the CP and decided to create an Electronic File Format (EFF) EWG that will be chaired by IFAH Europe.

The Secretariat will call for the nomination of 1 expert, and if desired, 1 advisor per SC member.

**Act: Secretariat**

### **11.4. Review of the Concept Paper for a VICH guideline on residue studies in honey**

The EU explained that in previous SC meetings reservations were expressed for the development of this topic because the CCRVDF was reviewing this topic as well.

The CCRVDF has now agreed that the development of a technical guideline on residue studies in honey falls within the remit of VICH.

The SC agreed that there is no overlap or duplication of work between CCRVDF and VICH on this subject.

The EU recommended this topic to be handled by the MRK EWG, and that SC members should indicate if they wish to nominate an additional advisor or a new expert for this topic. Recognising that several jurisdictions have nominated advisors to the EWG members for the fish guideline, it would need to be ensured that only 1 comment is sent per jurisdiction, and in

case of a face to face meeting only 1 representative per jurisdiction presents the position on the topic.

The initial work will be done by electronic procedure and an outline of the GL should be ready by mid October.

The SC noted that there will be a need for additional experts or advisors, such as residue chemistry experts and apiculture experts, and considered if a new EWG should be created, or if this topic should be handled by the MRK EWG.

After a thorough discussion, the SC agreed that in order to make best use of the considerable experience of the MRK EWG and to ensure consistency within the MRK guidelines this group of experts will be a subgroup of the MRK EWG, with a separate e-mail address, in order not to include unnecessarily all MRK experts.

The EU will be the topic leader.

The Secretariat will ask all SC members if they wish to nominate additional advisors.

**Act: Secretariat**

The SC further considered the request from Argentina to take part in the development of this topic and agreed the participation of Argentina provided it could nominate an expert with adequate expertise and fluency in English. The Secretariat will send Argentina the CP with the documents explaining the requirements for the experts.

**Act: Secretariat**

## **11.5 Other VICH topics**

### *11.5.1 Report on the ICH initiative to form a Pre-safety Group*

IFAH-Europe explained that ICH has created a pre-Safety WG to review specific Safety issues and gave a presentation explaining the background and key principles behind this initiative.

The SC recommended that IFAH-Europe should continue to monitor the work of this ICH WG.

IFAH-Europe proposed that a representative of the EMA is invited to the 30<sup>th</sup> SC meeting in Europe in June 2014 to provide an update on the activities of this WG.

**Act: IFAH-Europe**

### *11.5.2. Climatic zones discussion in the Outreach Forum*

A revision of the stability guideline to include climatic zones 3 and 4 would be of direct relevance to several Forum members. IFAH-Europe will update the CP drafted several years ago.

**Act: IFAH-Europe**

## **12. Other issues**

### **12.1. Proposal from JVPA to organise the 5th VICH Public Conference in Japan the frame of the 32nd VICH SC meeting in fall 2015**

JVPA proposed to organise the 5<sup>th</sup> VICH public Conference in Tokyo in fall 2015, in conjunction with the 32<sup>nd</sup> VICH SC meeting.

The SC agreed in principle and asked JVPA to provide a more precise proposal at the next SC meeting.

**Act: JVPA**

## **12.2. Report by IFAH and OIE on the status of the UNEP negotiations on a global legally binding treaty on the release of mercury in the environment – issue of vaccines containing Thiomersal as preservative**

IFAH reported that the latest draft text from the UN environmental programme negotiations on a global binding treaty on the release of mercury in the environment does not include vaccines and excludes Thiomersal in vaccines from the reach of the future treaty.

The treaty, which should be signed in fall 2013 in Minamata, Japan (as “the Minamata Treaty”), will concern only the substances that will be placed in the treaty’s annex.

It was suggested that VICH should draft a general statement, similar to the 3Rs statement, welcoming the research into alternatives to Thiomersal in vaccines, or stating at least that no alternatives will exist in the near future.

After discussion, the SC decided that as this topic concerns a particular substance and not data requirements for the registration of Veterinary Medicinal Products, it is not in the remit of VICH to express a position on it.

Due to specific circumstances surrounding mercury in Japan, JVPA mentioned that it has voluntarily initiated a survey, based on a 3 year funding programme, to determine which veterinary products are concerned and what volume they represent.

## **12.3. South Africa**

Just before the SC meeting the Secretariat received a letter from the Ministry of Agriculture, Forestry and Fisheries of the Republic of South Africa that addressed all the questions posed by the SC in November 2011, and applied for Observer status in VICH.

The South African Animal Health Association (SAAHA), the veterinary medicine industry association of South Africa, has confirmed its support.

FDA mentioned that it had taken several months for the Ministries of Health and Agriculture to agree.

JMAFF voiced also its concern regarding the delay of decision making process.

The SC acknowledged the application for observership of South Africa. A general question was raised and has to be addressed concerning the balance between South Africa's regulators and industry side. The EU emphasised the need for checking the application as well as to consult its Member States. This will be initiated by the European Commission and the result will be communicated possibly by the end of June.

The Secretariat will therefore acknowledge receipt to South Africa explaining that the SC has welcomed the application and that it is in the process of formal approval within the members’ organisations.

**Act: Secretariat**

## **13. Any other business**

### **13.1. Proposal to upgrade the VICH website**

The VICH website is hosted by the IFAH secretariat. At the last SC IFAH-Europe proposed that the website should be upgraded in view of the increased traffic to the site that will be generated by the Outreach activities, and in view of the importance of effective communication tools. IFAH-Europe presented a mock up for the visual design of a new VICH public homepage that was being considered.

The VICH secretariat and IFAH-Europe will select and work with a web-designer and will provide a functional “dummy” version of an upgraded website for SC members to review and comment.

**Act: IFAH-Europe**

### **13.2. Review of the Organisational Charter**

Following the decision made at the last meeting to replace the wording “harmonisation of regulatory requirements” by “harmonisation of technical requirements”, the SC noted that only 2 locations need to be amended in the Charter.

The SC also approved the addition of South Africa in the list of Observers, after final approval by the SC, as well as a few minor changes.

The SC agreed to place the revised Charter on the Forum’s webpage.

### **14. Dates and venue of next meetings**

- The 29<sup>th</sup> SC meeting will take place in Auckland, New Zealand on 11 to 14 November 2013. The meeting will be chaired by Japan.
- The 30<sup>th</sup> SC meeting will take place in Brussels, Europe on 23 to 27 June 2014.

### **15. Adoption of the Press Release on the 28<sup>th</sup> SC meeting**

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



## VICH STEERING COMMITTEE

28<sup>th</sup> meeting

February 19, 20 & 21, 2013  
Washington D.C. (USA)

Chair: B. DUNHAM (CVM/FDA)

### LIST OF PARTICIPANTS

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#### ***STEERING COMMITTEE (C) coordinators***

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

#### ***OBSERVERS***

Australia/New Zealand (APVMA)	A. BRYCE
Australia/New Zealand (MPI)	D. MORRIS
Animal Health Alliance (AU)	P. HOLDSWORTH
CAHI	J. SZKOTNICKI
Canada (Health Canada)	M-J. IRELAND

#### ***INTERESTED PARTY***

AVBC	J. THOMAS
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#### ***OIE***

OIE	J-P. ORAND
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#### ***VICH SECRETARIAT***

IFAH	B. FREISCHEM
IFAH	H. MARION

#### ***GUEST***

OIE	S. MÜNSTERMANN
FDA	M. OEHLSEN