International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VICH/14/053
24 October 2014
Final

VICH STEERING COMMITTEE
30th meeting
23-26 June 2014
Brussels

Minutes of the meeting

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr David Mackay, Head of the Veterinary Medicines Division, European Medicines Agency.
The Secretariat welcomed the VICH Steering Committee to Brussels.
Apologies were received from Mr Duncan Bremner, Animal Medicines Australia.

Welcome by Mr S. Soro, European Commission

Mr Stefano Soro, Head of Unit D6 - Medicinal products - quality, safety & efficacy of the European Commission's Directorate General for Health and Consumer Affairs, welcomed the participants by conveying the support from the European institutions to VICH. He highlighted the importance of existing international standards such as VICH for the EU which is in the process of revising its veterinary legislation.
He congratulated the Steering Committee for the productivity of VICH which has developed more than 50 Guidelines since its creation, with many more under development, facilitating the decision making process of the regulators.
Mr Soro wished all participants a successful meeting.

2. Adoption of the agenda

The agenda was adopted with the addition of item 14.3 – Update on the ICH Safety Brainstorming Group activities by Mr Steven Spanhaak, EFPIA.

3. Finalisation of VICH basic and guidance documents

3.1. Finalisation of the review of the VICH Organisational Charter (VICH/96/002_11)

The SC reviewed and adopted the draft 7 of the revision 11 of the Organisational Charter subject to minor editorial changes.
The SC recognised that some parts of the document still require updating, e.g. the description of the process of the development of guidelines by the EWGs, and this update will be undertaken by the secretariat prior to the 31st SC meeting.

Act: Secretariat

3.2 Finalisation of the review of the "Procedure for publication of VICH Concept Papers" (VICH/11/026-rev 1-dr5) and review of the "Note to prepare a VICH Topic Concept Paper" (VICH/97/037-rev 3-dr3)

The SC reviewed and adopted both draft documents with amendments to the 4th and 5th sentence of the introduction of the "Note to prepare a VICH Topic Concept Paper", as the final versions of the revisions.

3.3. Finalisation of the review of the "VICH procedure for the Expert Working Groups" (VICH/00/151-rev 3-dr6)

The SC reviewed and adopted the draft document as the final version of the revision.

3.4. Finalisation of the review of the "Terms of Reference for the VICH Outreach Forum" (VICH/11/010-rev 1-dr1) and the "Criteria for participation of VICH Outreach Forum members in VICH Expert Working Groups" (VICH/13/041-dr6)

The SC reviewed and adopted both draft documents subject to minor amendments in the 2nd and 4th paragraphs of the "Terms of Reference for the VICH Outreach Forum" as the final versions.
These final versions of items 3.1 to 3.4 will be placed on the VICH public website.

3.5 Other documents

None

4. VICH Outreach Forum

4.1 Preparation for the 4th VICH Outreach Forum meeting

4.1.1 Review of the participants list

The SC noted with satisfaction that 8 VICH Outreach Forum (VOF) countries (Argentina, China, India, Korea, Morocco, Russia, Thailand and Ukraine) and 2 regional organisations (CAMEVET and ASEAN) have confirmed participation with Thailand representing ASEAN. Tanzania will attend for the first time as a guest. Efforts will continue to encourage the countries and organizations not represented at this meeting to participate in future meetings.

4.1.2 Review of the agenda of the meeting

The SC reviewed the draft agenda of the 4th VICH Outreach Forum meeting and approved the presentation prepared by the Secretariat on the report by the SC regarding the issues discussed by the 3rd VOF meeting in Auckland in November 2013.

The SC discussed if industry members from the Outreach countries should be invited as well. The EU pointed out that the Terms of Reference for the VICH Outreach Forum (VICH/11/010) specify that the VOF "…. (is intended to be) comprised of participants from regulatory authorities of non-VICH countries and regions invited by VICH …". Some SC members suggested that the Terms of Reference should reflect the possibility for industry to attend the VOF, but the Terms of Reference adopted previously were not re-opened.

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4.1.3 Review of the proposals from the ad hoc group on Training and Communication Strategy

It was recalled that at the last SC meeting there had been strong support for the proposed level 1 and level 2 approach to training, but concerns had been expressed regarding the resources needed for this two level training approach.
The ad hoc group had developed an overall communication proposal, building on available elements and documents that were presented to the SC for discussion. It recommended developing a key messages document supporting a communication strategy that included the existing VICH leaflet, a long and abbreviated VICH general presentation as well as a presentation on the VOF.
The proposal also recommended increasing the VICH media engagement, to broaden the audience of the press release, to renew regularly the content of the website and to consider developing a regular electronic newsletter on VICH.
The SC thanked the ad hoc group and welcomed these concrete proposals but noted that the resources are a key limiting factor to the implementation of these proposals. The proposals on extending communication activities should therefore be considered further as part of an overall strategy.
It was further noted, as explained in the proposed strategy, that communication material in the form of documents and presentations on the role of VICH and VICH GLs at different levels are already available. The US representative urged the meeting to agree the message that should be conveyed to the VOF which needs to balance the high expectations of the VOF members against the reality of what VICH SC can deliver.

The SC reviewed and commented on the “VICH Communication Strategy” draft document. After a thorough discussion, the SC agreed to focus firstly on delivering the key messaging and the communication of the role of VICH in regulatory systems (items 5.a & 5.b of the document), and to reflect on ways to attract funding such as from Public Private Partnerships to develop the material necessary for the second level of training strategy. The SC further agreed to finalise the Training strategy for the next SC meeting with the explained caveats regarding resources.

Regarding the level 2 training, the message to the VOF will be that VICH does not have the resources for the time being to provide specific training material and sessions to VOF members.

4.1.4 Organisation of the group discussion session

The SC decided to split the VOF participants in the 3 following groups:
Group 1: Korea, Thailand & China
Group 2: Ukraine, Russia, Morocco & India
Group 3: Argentina, CAMEVET & Tanzania.
The primary discussion items would be identical for all groups, and the groups should have the opportunity to address other topics as well that would be of specific interest for the countries.

4.1.5 Review of progress of the Task Forces

4.1.5.1 Task Force on the revision of VICH Stability GL 3(R)

The SC reviewed the results of the OIE Survey regarding potential acceptance of a VICH guideline on stability testing for climatic zones III and IV (link), and noted that a majority of respondents with relevant climatic zones indicated willingness to use such a VICH guideline. Furthermore many respondents are prepared to provide input into the VICH activity. The SC therefore considered that the survey provided sufficient assurance that a VICH guideline considering stability for climatic zones III and IV would be used by non-VICH countries. IFAH-Europe reported that the members of the TF are analysing in detail the various comments made and concerns raised by the TF members and will consider the comments received from the OIE survey. The TF will provide proposals in a more detailed concept paper before the 31st SC meeting. The TF was requested to consider in particular the impact that a GL could have on the expiry date of products in different climatic zones.

Act: TF

4.1.5.2 Task Force on VICH Guidance for Efficacy Studies for Combination Drug Products

JMAFF reported that a questionnaire was circulated on April 28, 2014 to collect data on the main/major veterinary combinations in a country/region. Answers from the TF members submitted by the time of this meeting indicated “antiparasitics” is the top combination category, closely followed by “antimicrobials”.

There is already a broad consensus within the TF as well as SC members regarding the needs for the development of a general GL, which should include general considerations for combination products, followed by specific GLs addressing different combinations.
The EU proposed the TF should focus on specific guidance on new developments for combination products. In addition, the EU indicated that they would not support the development of a specific GL for combination products consisting of antimicrobials as regulators do not wish to encourage new developments of the latter except in very particular circumstances (e.g. sulphonamides and trimethoprim) and a VICH guideline on such combination products could be misunderstood as encouragement to third countries for their development. It was considered useful to convey such thinking in a general guidance.
The SC took note that the TF members will continue to analyse relevant guidelines/guidance for combination products already in place in the different regions and that a discussion document will be provided before the 31st SC meeting.

Act: TF

4.1.6 Consensus on the opinions/directions from the SC

Covered above.

4.2 Review of the Outcome of the 4th VICH Outreach Forum meeting

4.2.1 Debriefing and review of the conclusions of the Forum meeting

The SC addressed this agenda item the day after the 4th VICH Outreach Forum meeting by reviewing the conclusions of the meeting (link).
The SC noted with satisfaction that the VOF has developed much faster and better than expected thanks to the active participation and strong commitment of VOF members.
In reviewing the outcome and conclusions from the VOF meeting the SC addressed the follow-up activities in preparation of the next VOF meeting.

- *The SC identified the following topics for discussion at the 5th VOF meeting:*
  - *Update on task force activities*

Update on the TF on the revision of VICH Stability GL 3(R) to address climatic zones III and IV and on the TF on VICH guidance for efficacy studies for combination products

- *GCP/GLP*

Questions regarding implementation of GCP and GLP requirements have been raised by several VOF countries. Whilst it is recognised that GLP does not fall under the remit of VICH and the questions are of more regulatory nature, it was considered useful to provide presentations on both GCP and GLP addressing how the requirements are implemented in different VICH member and observer countries/ regions.

- *Pharmacovigilance*

IFAH-Europe pointed out that several VOF members had expressed concerns regarding the complicated setup of a developed pharmacovigilance system. IFAH-Europe therefore proposed to draft a presentation explaining how VOF countries could start the implementation of pharmacovigilance without needing to develop electronic reporting systems in a first step. The EU pointed out that their presentation on pharmacovigilance at the 3rd VOF meeting focussed on this issue and recommended to start with a simpler system suitable for the needs of the country. It was agreed that the existing presentation will be used as basis for the future presentation(s), which will be prepared jointly by IFAH-Europe and the EU. The SC will review and approve the draft presentation(s), which will be circulated to the VOF members in advance of the next VOF meeting in order to encourage further questions and explanations.

Act: IFAH-Europe/EU

- *Implementation of VICH GLs by VOF countries*
  - Relationship between local existing GLs and VICH GLs particularly when VICH GLs are more demanding than existing GLs
  - Further discussion on how VICH GL can be applied in different regions based on experience gained to date

From numerous discussions and contributions during the VOF meeting, and in particular the session on the link between legal framework of veterinary medicinal products (VMPs) regulation and VICH guidelines as well as the break-out group discussions it became apparent that the implementation of VICH guidelines by VOF countries will continue to be a major discussion item. The SC recognised the challenges that the introduction of VICH GLs represents for VOF countries, in particular for those that have local GLs in place.

It was considered important to emphasize that VICH GLs are technical requirements. They do not fit with the objectives and structure of primary legislation (such as legally binding acts or ministerial ordinances) but non-binding notices or memorandums, which needs to be understood by the VOF members. It was also recognised that adequate time needs to be allowed for local industry to adapt to new requirements. It was stressed that one of the aims of the Outreach process is also to encourage acceptance of studies performed according to VICH guidelines in other regions in order to avoid repetition of animal studies thereby both promoting animal welfare and saving resources for industry. VOF members were informed that they can implement progressively the VICH GLs when the necessary resources are available.

The SC further agreed that VICH and VOF could start “mapping” the technical GLs that exist in VOF countries and related VICH GLs. Focus should be given to those that are different from VICH requirements and where the implementation of VICH GLs pose difficulties in order to understand better the differences and the hurdles for the implementation of VICH GLs.

VOF members will therefore be asked to provide before the next SC/VOF meeting as much information as possible on GLs that are currently applied in their countries. VOF members will also be encouraged to provide examples of specific challenges encountered with local GLs when implementing VICH GLs.
Industry SC members will further provide examples of difficulties to achieve acceptance of studies based on VICH requirements because of the diverging requirements of local GLs.

OIE strongly supported this approach and pointed out that the OIE collaborating centres are investing much effort to support the objective of the OIE 5th strategic plan aiming at the development of an effective system forVMPs registration and control in all its member countries.
In this context, OIE recommended that SC members should highlight to their OIE permanent Delegates the importance of OIE's support to VICH in the next OIE strategic plan.

The SC agreed that at the 5th VOF meeting the topic with the different elements will be discussed again. The most suitable format appears to be group discussions which should be preceded by introductory presentations aimed to identify the critical elements and focus the discussions.

Act: All

- *Waiving TABST*

The SC noted that several VOF countries already apply VICH GL 50 and agreed that further discussion would be useful. The EU will introduce the topic with a presentation on TABST similar to the one given at the 3rd VOF meeting.
VOF members will be asked to present their views, achievements or intentions regarding TABST in their country.

- *Format of the small group sessions*

The SC recognised that more time should be allocated to group discussion, as they are particularly fruitful and appreciated by VOF members. It was agreed that for the next meeting several shorter group discussions will be organised for discussing specific single topics introduced before, with changing composition of the different groups. Less time will be allocated to presentations.
The secretariat and OIE will change the structure of the VOF agenda accordingly.

Act: Secretariat/OIE

As in some countries registration of VMPs has not the same importance as human products' registration, it was suggested to reach out to more senior staff and invite them to attend a part or the entire VOF meeting in order to highlight the importance of VMPs.
After a thorough discussion the SC however acknowledged that the objective of VOF meetings was not to address policy issues but, as defined in the TORs (VICH/11/010), to focus on technical and practical topics related to the registration of VMPs.
The SC recognised also the importance of the continuity of the VOF and of the dialogue with representatives from VOF countries/organisations who have the knowledge and understanding of the technical discussion points, and who are then able to influence the senior decision makers in their country.
The VICH 5 public conference will provide the opportunity to highlight more publically the importance of the activities within the VOF and to address policy makers.

- *Bioequivalence*

The SC agreed to discuss the topic of bioequivalence again at the next VOF meeting, and the need for such studies in legal frameworks for registration of VMPs that have special provisions

for ‘generic’ applications. Any discussion would need to include a full explanation of the underlying concepts behind the approach to generics in VICH regions.

- *Other actions and other considerations*
  - *VICH Phase IV*

The SC agreed that the reflection on the VICH Phase IV strategy should include a discussion on what more VICH can do to minimise the risk of development of antimicrobial resistance arising as a result of the authorisation of veterinary antibiotics; a guidance could act as an orientation for VOF members when considering new requests for authorisation of antibiotics.

  - *Translation of GLs*

VICH and VOF members will be reminded to supply OIE with any translation of VICH GLs that are available in their countries/regions.

  - *Support of VICH by OIE*

The SC recommended that OIE should find ways to increase the visibility of the support that OIE provides to the use of VICH GLs by its member countries.

  - *Link between ICH and VICH*

Considering several interventions indicating that ICH guidelines are used for veterinary medicines in some VOF countries the SC will consider putting a presentation onto the OIE Website explaining the relationship between ICH and VICH, and the application of ICH guidelines for veterinary products.
Furthermore presentation material should be developed explaining the relationship between ICH and VICH guidelines and why veterinary-specific guidance and adaptation of ICH GLs is required.

- *Tanzania*

IFAH-Europe reminded the participants that the Tanzanian FDA had been invited to participate as a guest because of the probable organisation of the next Global Animal Health Conference in Tanzania although they are not a member of the VOF.
As the Tanzanian delegate highlighted the important harmonisation activities in the human field of the East African Community (EAC), the SC agreed in principle to invite the EAC to become a member of the VOF, pending the approval of the EU which will require internal consultation and possibly consultation of EU Member States. The EU aims to provide the conclusions of the consultation at the latest at the end of October. It was also recognised that information on the regulatory systems for veterinary medicines in EAC is not available and such information will be helpful in assisting the EAC in deciding who might be the most appropriate representative to send to the VOF.

Act: EU

IFAH-Europe will ask Tanzania to provide information focussing on the EAC’s regulatory activities in the veterinary field.

Act: IFAH-Europe

4.2.2 Review of the requests and topics raised by the Forum participants

Covered above

4.2.3 Proposals for Training Strategy

The VOF members had confirmed that the Forum is the most suitable venue for information and exchanges within the scope of the level 1 of the training strategy. It was highlighted that the communication strategy should take into account the need for direct presentations to the decision makers on legislation in the countries' relevant ministries who are not necessarily the persons participating in the VOF activities.
The SC agreed that the ad hoc subgroup on training will convene again by teleconference to revise the draft training strategy document discussed at the 29th SC meeting (VICH/13/078) in order to update the level 1 proposals in line with the most recent developments. The level 2 proposals can remain as a strategic goal.
The ad hoc subgroup will also review and update the draft VICH Communication Strategy document (VICH/14/042) for review and adoption at the next SC meeting taking into account the comments and proposals expressed during the discussion.

Act: Ad hoc subgroup on Training

The SC will need to adopt the communication strategy and discuss whether the document as such will be made publically available. The strategy will need to be realistic in terms of deliverables. The SC further proposed that a new Working Group for the implementation of the communication strategy should be created during the next meeting.
It will be important that the next draft VICH Phase IV Strategy is aligned with the proposed revised text of both the Training and Communication strategies.

4.2.4 Decision on the next steps and items for the agenda of the 5th Forum meeting

Covered above

5. VICH Strategy

5.1. Any issue on Phase III strategy

The SC considered that a systematic review of success and achievements of the Phase III strategy was not required, but recognised the considerable progress that has been made in the new area of global outreach.

5.2. Outline of Phase IV strategy

The SC agreed to start working on the strategy for Phase IV with the aim to have a first draft available at the 31st SC meeting and adopting the new strategy at the 32nd meeting in October 2015.
The Secretariat suggested deleting from the new strategy all the paragraphs that are copied from the Organisational Charter and to limit the strategy document to the explanation of the strategy itself.
The SC confirmed that the main objectives of VICH are to continue establishing new GLs and maintaining existing GLs, and that the wider harmonisation of technical requirements will remain a key strategic goal of VICH.
The SC agreed that the VICH Phase IV strategy should include a discussion on what more VICH can do to minimise the risk of antimicrobial resistance arising as a result of the authorisation of veterinary antibiotics.
The SC agreed that the new strategy should remain high level and to set up a VICH ad hoc Strategy Subgroup with the following membership:

IFAH-Europe: R. Clayton

EU: K. Grein
JMAFF: K. Noda
USDA: B. Rippke
ANZ: A. Bryce
S. Africa: A. Sigobodhla
OIE

IFAH-Europe offered to draft a first proposal. The subgroup will work by electronic exchange and prepare a first proposal for the Phase IV strategy before the next SC meeting.

Act: Strategy Subgroup

The SC acknowledged that it had been difficult to progress biological topics covering classical vaccines in phase III but agreed to continue to include biological VMPs in the next strategy and explore ways to accelerate this process in the future.
It was confirmed that VICH should keep the long-standing practice of taking maximum opportunity to benefit from ICH guidelines and using ICH experience in the development of the VICH guidelines. Comparing the ICH and VICH GLs highlighted major differences in the category of "Multidisciplinary" including common technical document (CTD), and Biotechnological/biological products (Biotech-products) GLs. The SC agreed that the CTD is not appropriate for the next term strategy because of the heavy burden to industry.

JMAFF proposed (link) to define the scope of VICH biotech- product GLs and to review the ICH guidelines for biotech-products (Q5A(R1), Q5B, Q5D, Q5E and S6(R1)), assessing which would be useful to adapt to the veterinary field.

It was agreed that JMAFF will circulate a questionnaire to the SC for each regulatory and industry delegation to identify the needs for GLs for biotech VMPs. The results will be presented to the next SC meeting.

Act: JMAFF/All

6. Reviews of:

6.1 The implementation and interpretation of VICH GLs in the regions

6.1.1 Report from the regulators

No delays in implementation of guidelines were reported. Japan pointed out that they have successfully implemented this year the biologicals guidelines: GL 34 - Testing for the detection of Mycoplasma contamination and GL 50 - Harmonisation of criteria to waive TABST for inactivated vaccines.

6.1.2 Report from the regulators of observer countries on implementation of VICH GLs

Australia has now formally adopted 14 VICH GLs that had not been adopted so far. In some cases there may be minor differences with the original VICH GL.
South Africa reported that both authorities responsible for the registration of veterinary medicines are discussing the process of implementing VICH GLs. Possibly this would require that parts of the legislation may have to be changed.
Canada explained that the CVB is not in a position to adopt VICH GL 50 - Criteria to waive TABST for inactivated vaccines - for the time being.

6.1.3 Any input from industry members

None

6.2 Written updates from the coordinators

The SC took note of the report.

6.3 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 organisations' GLs (ICH, OECD...)

None presented

7.2. Proposals for revision of further VICH GLs

None presented
The secretariat will provide before the next meeting a list of further GLs to be reviewed 3 years or more after implementation.

Act: Secretariat

Based on this document, the SC agreed to discuss at the next meeting the recommended frequency of review as a frequency of 3 years seems to be rather short for certain GLs.

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, and presented by JMAFF.
The EWG itself did not have any activity since the last SC meeting, but most experts are members of the TF on the revision of VICH Stability GL 3(R) (see item 4.1.5.1).
The SC confirmed that the Quality EWG should not be disbanded in view of the upcoming work.

8.2. Electronic Standards Implementation – Pharmacovigilance

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr. M. Brown, and presented by FDA.
The SC noted that no particular issue was raised.

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. Harmonisation of criteria to waive Target Animal Batch Safety Testing for veterinary live vaccines
The topic leader has circulated the 2nd draft for consultation in the EWG. The main issue is the comparison between inactivated and live vaccines according to the difference in the nature of

the ingredients. The EWG is seeking agreement on the number of batches required before waiver and intends to finalise the document by electronic discussion.

b. Extraneous agents testing for Biologicals extraneous viruses testing
The discussions are still ongoing within the EU (CVMP and its Immunologicals Working Party) and the EU confirmed its objective to present a proposal before the next SC. The SC confirmed the authorisation for the EWG to hold a meeting as soon as possible in early 2015.

8.4. Metabolism and Residue Kinetics EWG

The SC noted the written report prepared by the chair of the Expert Working Group, Dr. S. Scheid, prior to the EWG meeting held the week before the SC meeting and the oral update report from the EWG meeting presented by the EU.
The SC congratulated the experts for the excellent progress made at the recent EWG meeting.

Amendment to GL 48
GL 48 (*Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods)* has been revised to include an amendment covering the "zero" day withdrawal period in milk. The revised draft has been circulated to the experts for approval. A formal sign-off by the EWG will be initiated.
The SC decided that the revisions made can be considered as minor changes and a public consultation on the amendments is not necessary. The GL will be signed-off by the SC at step 6 for implementation at step 7 with an adequate communication regarding the amendments made.
Moreover, a small amendment on GLP requirements has been made to GL 49 (*Guidelines for the Validation of Analytical Methods used in Residue Depletion Studies)* which will also require a sign-off procedure by the EWG and SC as a minor revision at step 6 by the SC.

New GL on residues in fish and in honey
The SC noted that excellent expertise was provided for the development of both draft GLs allowing fast progress. Revised versions of both GLs will be circulated to the experts during the summer. Finalisation and sign-off at step 2 of the GLs is expected to be achieved by electronic procedure.

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 (Safety - genotoxicity)
The sign off by the experts of the final draft at step 5 is expected by 1st August.
The EU confirmed that review of the mandatory character of the *in-vivo* micronucleus test should be done after the sign-off of the GL in a next revision, in accordance with the step by step procedure decided at the 27th SC meeting.
It was noted that the revision of the ICH genotoxicity GL is not finalised yet; the EU will recirculate to the EWG the previous proposal for further revision of the testing strategy for genotoxicity testing, and will take consideration of the ongoing ICH revision.

Act: EU

The SC confirmed the mandate of the EWG to proceed with this revision as soon as the GL has been signed off.

b) GL on the determination of an acute reference dose for residues
It is expected that the EWG will provide to the SC by the end of 2014 the final draft of the GL signed off at step 2.

8.6. Bioequivalence EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr. M. Martinez, and presented by FDA.
Only 3 comments were received during the consultation period of the draft GL 52 on Bioequivalence. The EWG is reviewing the comments and the revised draft GL is planned to be signed-off at step 5 before the end of this year.

8.7. Electronic File Format EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr M. Colmorgen, and presented by IFAH Europe.
The public consultation on draft GL 53 (*Electronic exchange of documents: File format requirements*) will end shortly. So far no major issues have been raised and it is expected that the experts will sign the Draft GL off at step 5 by the end of this year.
As from the step 5 onwards, the topic leader must be a representative of a regulatory authority. The SC decided that the EU will become the topic leader.

The SC thanked all EWG chairs for their excellent work, their ongoing commitment and the progress achieved on all topics.

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

None presented

11. Progress Reports of the Task Forces and decision on next steps

11.1 Task Force on the revision of VICH Anthelmintics GLs

FDA explained that the TF has started to work electronically on the items listed in the Concept Paper and has differentiated issues easy to resolve versus more difficult topics.
The TF might need a face to face meeting in spring 2015 to review and discuss these topics in depth. Once the TF has achieved its mandate the SC must decide whether an EWG will be needed to continue the task, as the mandate of a TF is limited in time.
The secretariat reminded the participants that in principle the TF's mandate is limited in time and that the decision to follow up with an EWG has to be made by the SC.
IFAH-Europe expressed its reservations that the leader of the TF is already drawing conclusions on the outcome, which is not appropriate at this stage of the process. However, it was clarified that the TF had been set up to address the concerns raised by industry that further scientific discussions were required to refine the concept paper before an EWG could be established and the mandate for the group be defined.

The SC approved in principle a face to face meeting in early 2015 after the TF has provided a detailed Discussion Document. The final decision will be made at the 31st SC meeting.

Act: TF

11.2 Task Force on the revision of VICH Stability GL 3(R)

Covered under item 4.1.5.1.

11.3 Task Force on VICH Guidance for Efficacy Studies for Combination Drug Products

Covered under item 4.1.5.2.

12. Concept papers/Discussion papers

12.1 Review of the Discussion Document from Industry on the revision of VICH Pharmacovigilance GLs

The SC reviewed the discussion document presented by industry on the future vision on a globally harmonised pharmacovigilance system.
The ESI EWG had proposed to start revising GL 42. Industry however proposes that GL 24 would be more important to revise first because it contains key definitions necessary to establish a single globally harmonised pharmacovigilance system which could improve efficiency for global industry. It is not efficient to revise GL42 until GL24 has been revised, as this may trigger the need for additional changes to GL42.
In a thorough discussion, the SC members welcomed the vision for a strong and harmonised global pharmacovigilance system, with the possibility for a single reporting by industry into a global pharmacovigilance database from which the regulators could draw the reports in any appropriate format and which could also be a tool for countries that do not yet have a pharmacovigilance system in place. The SC recognised however that this will be a long term objective for which further reflection is needed.
Key questions for a reflection on the long term are:

- The funding of a central database (it was recalled that several years ago the SC had considered that even the maintenance of the clinical term database, which has been developed and is maintained by the EU, by a private company would be too expensive);
- The responsibility for the different elements of a central system;
- The need that the responsibility for surveillance of approved products always lies with the marketing authorisation holder;
- The importance of a risk based approach with a strong surveillance on new products and a lighter surveillance for well-characterised products with a history of safe-use, and products which cause only few or minor adverse reactions.

Industry pointed out that in the meantime the current PhV system should be rendered more efficient by addressing a few small critical changes in the current definitions.
The EU stressed that the draft of the new EU veterinary legislation is expected to be published in the near future, which will clarify the EU vision on these issues. The EU is therefore not in a position to commit to a long term vision until after the revised legislation is published. The EU clarified that the legislation is not expected to restrict the ability of the EU to participate in future harmonisation initiatives within VICH.

The SC recognised that the ESI EWG's task is nearing the end, but, as maintenance of the current PhV GLs is required, agreed to keep the EWG in place until further clarity on the next

steps, as well as on the composition and the mandate of any potential new EWG, has been achieved.
It was recognised that the revision of the 5 PhV GLs is a process that will take several years. The SC could not reach a consensus on the PhV GL that should primarily be revised and agreed that further reflection was required by all members before the next SC meeting.

Act: All

Meanwhile Industry will map out more in detail the difficulties it faces with the current non-harmonised system and their impact so that those could be addressed by the regulators even before a guideline revision will be initiated. A new Discussion Document will be prepared for discussion at the next meeting.

Act: Industry

It was further agreed that the vision for a global pharmacovigilance system should also be included in the VICH Phase IV Strategy.

Act: Strategy Subgroup

12.2 Update on the status of the Discussion Document from the EU and JMAFF on the revision of VICH GL 22

At the 29th SC meeting the EU presented a discussion paper proposing the SC should review the suitability of the extended 1 generation reproduction toxicity study instead of the current 2 generation reproduction toxicity study. It had been agreed that "the EU and JMAFF will in a first step review publicly available evaluations of veterinary medicines to establish the proportion of substances for which reproductive toxicity provides the basis for setting the overall NOEL and to consider, for these substances, whether the 1 generation reproduction toxicity study would have been likely to detect critical effects noted in the second generation. The SC will analyse the conclusions of this review and decide on the steps forward."

The EU and JMAFF gave an interim report of the review and analysis carried out so far and confirmed that the review is still ongoing, and more time is needed. Both have reviewed the reproductive toxicity data for a large number of substances for which MRLs and ADIs have been established.
Both the EU and JMAFF expect that reports can be completed before the 31st SC meeting for further discussion.

12.3 Other VICH topics

None

13. Preparation of the VICH 5 Conference

13.1 Review of the draft programme presented by Japan and the Secretariat

The SC reviewed the draft 3 of the programme, developed by JVPA in collaboration with JMAFF and including the comments and amendments received from SC members since the 29th meeting. The SC supported the structure of the agenda and congratulated JVPA for the novel approach.
Further comments and suggestions should be sent to JVPA before the end of July.
All SC members were urgently asked to provide suggestions for speakers, from SC members, EWG members or external keynote speakers as these need to be approached as soon as possible.

As a member of the hosting country of VICH5, JMAFF expressed its appreciation to JVPA-member companies for the effort to gain a sufficient number of participants to the conference, as well as IFAH for their sincere support.

URGENT Act: All

13.2 Organisational and logistical matters for the Conference

Covered above

14. Other issues

14.1 Disbanding of the Microbiological ADI EWG

JMAFF recalled that the VICH policy for disbanding an EWG provides that once the mandate of an EWG is completed the EWG can be disbanded after the 2nd SC meeting following the end of the EWG's task. JMAFF believed that experts should not be kept on mandated lists if their tasks have been fulfilled.
The SC therefore thanked the Microbiological ADI EWG for their work and formally disbanded this EWG. The secretariat will write to the experts.

Act: Secretariat *(Done)*

14.2 Proposal to give Chairs of EWG's access to the "members only" page of the VICH website

FDA pointed out that all the VICH internal guidance documents are displayed on the VICH members' only website, and suggested therefore that the chairs of EWGs receive access to this part of the website for practical reasons.
The SC agreed.
The secretariat will inform the chairs and provide access.

Act: Secretariat *(Done)*

14.3 Update on the ICH Safety Brainstorming Group activities

The SC took note with interest of the presentation (link) from Mr Stefan Spanhaak, EFPIA, regarding the status of the proposed ICH Safety Topic Recommendation Working Group.
Mr. Spanhaak explained that this WG was not yet established, due to an internal issue in one of the ICH parties.
Regarding the introduction of alternative testing Mr. Spanhaak indicated that for genotoxicity testing ICH, as VICH, considers the OECD testing methods. The outcome is not based on a single test but on a battery of tests.

15. Any other business

15.1 New version of the VICH website

Mr. Clayton explained that so far the existing content of the old VICH website has been transferred into the new website with some reorganisation. A new VOF section has been created which will contain all the documents and presentations made at VOF meetings.

At the 29th SC meeting several suggestions were made for additional features and the list has been kept, but funds are currently not available for further developments.
Mr. Clayton asked all to provide further suggestions for improvements to the secretariat.

Act: All

The SC recognised the importance of the VICH website as a tool for training and communication and congratulated IFAH and Mr. Clayton for the development of this new website.

15.2 Location of next SC meeting

After the 29th SC meeting, CAMEVET had extended an invitation, with the support of FDA, to hold the 31st VICH SC meeting in February 2015 in Buenos Aires, Argentina, instead of Washington DC, USA.
The SC recognised the strategic opportunity that this relocation would represent to encourage CAMEVET to implement the VICH GLs.
However, after having consulted the VOF members and having discussed the possibility thoroughly, the SC agreed to maintain the initial plan and to hold the 31st SC meeting in Washington DC; several SC members highlighted that they have to seek formal approval and the budget for travel up to 2 years in advance when meeting schedules or locations deviate from the usual VICH schedule.
The SC nevertheless would welcome the opportunity for holding a future meeting in Argentina when the rotation schedule will again foresee a meeting on the American continent, i.e. for the 34th SC meeting in February 2017.
JMAFF stressed it is supporting the idea behind the meeting held in Argentina, although the issues are timing and process, and appreciated that the FDA had kindly provided an appropriate solution on this matter. JMAFF hoped that the SC's decision would not discourage the Argentinian colleagues to actively participating in the VOF activities.
The secretariat will inform CAMEVET.

Act: Secretariat *(Done)*

It was agreed that in the future, proper notice of such deviations from the usual VICH meeting schedule should be given sufficiently in advance (2 years) to allow members to make the necessary arrangements.

16. Dates and venue of next meetings

- The 31st SC meeting will take place in Washington DC, USA on 23 – 26 February 2015.
- The 32nd SC meeting will take place in Tokyo, Japan on 25, 26, 27 & 30 October 2015.

17. Adoption of the Press Release on the 30th SC meeting

The SC members reviewed and adopted the press release drafted by the secretariat.

VICH STEERING COMMITTEE

30th meeting

23, 24 & 26 June 2014
Brussels (Belgium)

Chair: D. MACKAY (EU)

LIST OF PARTICIPANTS

STEERING COMMITTEE (C) coordinators

AHI (BAYER)	B. MARTIN
AHI (ZOETIS)	M. J. MCGOWAN
AHI	K. KLAUS (C)
EU (EUROPEAN COMMISSION (DG SANCO))	M. NAGTZAAM
EU (EMA-CVMP)	A. HOLM
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IFAH-Europe (BAYER)	L. KLOSTERMANN
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JMAFF	Y. ENDO
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OBSERVERS

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Australia/New Zealand (MPI)	D. MORRIS
Canada (Health Canada)	M-J. IRELAND
Canada (CAHI)	J. SZKOTNICKI
South Africa (DAFF)	A. SIGOBODHLA
South Africa (SAAHA – BAYER)	E. SCHAY

INTERESTED PARTY

AVBC	J. THOMAS

OIE

OIE	J-P. ORAND
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IFAH	H. MARION
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APOLOGIES

Australia/New Zealand (AMA)	D. BREMNER