

VICH/19/091 4 February 2020 FINAL

#### VICH STEERING COMMITTEE 38<sup>th</sup> meeting 18 – 21 November 2019 Tokyo, Japan

# Minutes of the meeting

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

The meeting was chaired by Dr Kenji Ohara, Director General of the National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries, Japan. He welcomed the participants to Japan full of colourful autumn shades at this time of the year.

The Secretary indicated that apologies had been received from I. Abe – JVPA, A. Sigobodhla – South Africa and C. Du Marchie Sarvaas - HealthforAnimals.

# 2. Adoption of the agenda

The agenda was adopted with the following changes: item 7.1.2 will be discussed in item 8.1, item 13.3 in 8.2 and item 13.1 in 8.5. Moreover items 13.4 & 13.5 will be discussed together, whilst item 16.1 will be deleted. Finally, the draft CP from FDA for the adoption of ICH GL Q7 was added as agenda item 13.6.

# 3. VICH Training Implementation

# 3.1. Update on the development of training materials

The SC reviewed the updated table on the status of the VICH training materials and AnimalhealthEurope confirmed that materials on GLs 1, 2, 39 and 40 will be provided to complete the quality section. A presentation on GCP GL 9 will be made at the 12<sup>th</sup> VOF and this may be used as a basis for developing training material on that GL. AnimalhealthEurope will also provide to VOF members copies of the re-printed booklet "An investigator's handbook" developed many years ago. This booklet, based on VICH GL 9, is intended as support for persons who are responsible for running clinical trials.

JVPA explained that it will integrate the comments received into the Video on GLs 50 & 55, which will then be placed on the website.

AHI will prepare a presentation on adverse events, hopefully in the format of a video story. AHI proposed to provide case studies such as those that have been prepared for the OIE 6<sup>th</sup> cycle focal points' training.

JVPA hoped to be able to develop another training video on VICH in general, based on the VICH general PowerPoint presentation, which the SC supported.

### 3.2 Update of the documents already placed on the VICH Website

The SC took note that the website already contains training material covering 18 GLs but it is necessary to develop further material over the next years.

# 4. Review of Discussion Documents for presentation to the VOF 4.1. Review of the

- Draft Guidance on how to manage "Out of Scope" topics (VICH/19/077-dr3) AnimalhealthEurope presented the draft 3 of the document which includes the comments received from SC members.

This document will be submitted to the VOF members for their comments.

#### - List of VICH "Out of Scope" topics (VICH/19/078-dr3)

AnimalhealthEurope recalled that the SC had adopted this list of topics, detailing also the reasons for the out of scope and where VOF members can request more information. This list should be maintained as a "living document" updated after each VOF meeting. This document will also be submitted to the VOF members.

#### Post VOF meeting note

JMAFF pointed out that the "out of scope table" has been interpreted as a negative message by some VOF members, and proposed to improve the table by providing more detailed sources of information (contact details of VICH members and others) which VOF members can consult. VOF members have asked many questions on where to find information.

It was also noted that the "out of scope" wording may have given the false impression that these issues are not considered important by VICH members, which is not the case. The SC agreed that the language should be changed to "not for harmonisation by VICH". AnimalhealthEurope suggested to use the VetMedWorld website to house information that is important, but not in the scope of VICH. The OIE website is also an important source of information for VOF members.

JMAFF agreed to provide a proposal for the improvement of both documents.

#### Act: JMAFF

Post meeting note: AnimalhealthEurope has already provided a first input to the documents.

#### 4.2. Review of the Discussion Document from the subgroup on medicated premixes

AnimalhealthEurope acknowledged that the draft had been circulated too late for SC members to review and provide comments. The document will nevertheless be introduced to the VOF members, clarifying which topics may be in the scope of this proposed GL. VOF members will be reminded that the VICH GL8 on Stability testing for medicated premixes is applicable. In order to avoid the development of expectations that may not be met, the SC agreed that it should be clear that, at this stage, a discussion document is being developed and that the SC has not yet agreed a Concept Paper for the development of a GL. It is also important to include a wording explaining that the GL will establish the technical requirements for the suitability of the product as a medicated premix (to prepare medicated feed), not for the registration of a medicated feedingstuff.

Regarding the way forward the SC agreed that all should provide comments to the SC WG on the DD by 1<sup>st</sup> February 2020.

#### <u>Act</u>: All

The WG, composed of AnimalhealthEurope, FDA, EU, JMAFF, AHI and South Africa, will aim to finalise the DD by mid-February, for approval by the SC by mid-March.

#### Act: WG/SC

In March a VICH TF will be created including VOF members. This TF will have the objective to finish the draft CP by end June in time for SC approval by electronic procedure before end September.

#### Act: TF/SC

In order to keep the momentum, the SC agreed that the TF should be transformed into an EWG as soon as the CP has been adopted.

The SC acknowledged that the minimum objective is that the CP is adopted and the EWG set up by the next SC meeting. If the work progresses more rapidly the EWG may have already started its work by the next SC meeting.

In order to facilitate the discussion, it was agreed that all documents should be shared with all SC members at each step of the process.

### 4.3. Review and adoption of the VOF Application Form (VICH/19/068-dr3)

The Secretariat presented the draft application form and noted that it would be preferable not to include the mandatory signature of the OIE Delegate, since this might delay the process of internal discussion before application. Nevertheless, the Secretary and OIE will add appropriate wording in order to ensure that appropriate communication takes place between the parties within a country, as this exchange is highly recommendable as part of the process.

Act: Secretary/OIE (Done)

### 5. VICH Outreach Forum

#### 5.1. Review of the outcome of the VOF survey

The SC thanked OIE for having run the VOF survey and provided the detailed compilation of comments received. The SC acknowledged that most VOF members had highlighted the positive impact and listed the benefits of VOF meetings. Furthermore, most topics that were proposed for future meetings are in the scope of VICH.

The SC took note of the main highlights of the survey:

- The importance of the training by experts on the technical GLs
- The request for longer time for discussions in VOF meetings
- The difficulty of some countries to attend VOF meetings, and the issues raised by travelling to other continents
- The need to receive the final VOF agenda 3 months prior to the meetings
- The proposal for a pre-VOF meeting of VOF members without SC members, where they can share their topics & concerns
- The recommendation to organise regional VICH training sessions with experts in the frame of other local sessions (CAMEVET, ASEAN...), which would facilitate the attendance of the relevant experts from VOF countries

The SC recognised the definite value to extend the VOF meetings by facilitating a separate session without the SC. Such sessions would however require proper structuring and leadership. It was noted that, at this meeting, JVPA already provided a meeting room for VOF members before the formal 12<sup>th</sup> VOF meeting.

It was noted that the participation of VICH experts in trainings requires a preparation sufficiently in advance of the meetings as well as specific funding. Moreover, it is difficult to ask VICH

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experts to deliver their presentations in a format that can be taken back to the VOF countries for further use by VOF members.

# 5.2 Preparation for the 12<sup>th</sup> VICH Outreach Forum meeting

# 5.2.1 Review of the participants list

The SC reviewed the participants list for the 12<sup>th</sup> VOF meeting and regretted that ASEAN & UEMOA were not able to participate.

The SC noted also that India and Russia will be represented at a high level again.

# 5.2.2 Review of the agenda and preparation of the 12<sup>th</sup> meeting

The SC took note of the last version of the agenda.

OIE pointed out that once again it had been difficult to obtain the commitments from VOF members as well as SC members to prepare the agenda points and discussions.

### 5.2.3 Other issues

The participants reviewed the presentation prepared by the Secretariat on behalf of the SC.

### 5.3 Discussion of the Outcome of the 12<sup>th</sup> VICH Outreach Forum meeting

#### A/ General discussion

The SC addressed this agenda item after the 12<sup>th</sup> VOF meeting and thanked again warmly J.P. Orand (OIE) for all his efforts to prepare the VOF agenda.

The SC noted that all VOF participants were satisfied with the format as well as the outcome of the meeting, and have been actively engaged when they can exchange experiences with their colleagues.

The group discussions were of high quality.

OIE presented the following proposal for improvements:

- Future premeeting, SFDA will lead the preparation and chair the next stand-alone meeting of the VOF in Amsterdam prior to the 13<sup>th</sup> VOF
- The formal invitation and the agenda must be available 3 months before the meeting, and the documents 1 month before
- Training videos are preferred
- Preparation in advance of the agenda for the following meeting i.e. the 14<sup>th</sup> agenda to be validated at the 13<sup>th</sup> meeting
- A template to describe the expectation of VOF members when they propose a topic: list of questions and concerns... would help VICH SC to prepare the presentations

# *B/* Proposed topics for the 13<sup>th</sup> VOF agenda

For Group discussion :

• Criteria for the standardization of withdrawal period

The EU pointed out that such criteria do not exist at a VICH level, so presentations represent the views of individual regions/countries (as provided at this VOF meeting); alternatively, a training session might be considered.

FDA suggested to stimulate a discussion on what VOF members are doing and can compare between themselves

- Stability of medicated premixes (for 2021? ...)
- Pharmaceutical Equivalence (data statistical analysis)

This would also be a training session

#### For specific issues:

- AMR:
  - general principles of authorization of antimicrobials, approach to authorisation of VMPs containing combinations of antimicrobials

Industry could provide experts to support discussion

• Process Validation for sterile products (manufacturing process)

#### C/ Further topics for future group discussions

- Guideline & Implementation of autogenous vaccines
- New products (VMPs with formulas similar to innovators with expired patent), reviewing New Category of veterinary products
- · Creation of a new category of VMPs with official formulas-pharmacopeia
- Registration of herbal veterinary products
- Environment safety
- Evaluation of metabolism and residue kinetics of VMPs
- Assessment of veterinary biological products:
- o Quality,
- Safety (target animal safety for veterinary live and inactivated vaccines, target animal safety, examination of live vaccines in target animals for examination for absence of reversion to virulence)
- Stability of vaccines
- Pharmacovigilance of veterinary products
- Stability studies in use (for sterile products or those that must be diluted or reconstituted)
- Antimicrobial Resistance

#### D/ Further topics for future specific issues

- Impurities
- Residue Marker Depletion studies
- Veterinary biological products, GL39, veterinary vaccines in the Middle East
- Stability of medicated premixes GL8
- Creation of a new category of VMPs with official formulas-pharmacopeia
- · Generics and established withdrawal periods

The SC noted that several of these topics are just a request for information rather than a request for a detailed training

AnimalhealthEurope will collect information on the regulation of autogenous vaccines from the regions and provide a summary document to the VOF.

Act: AHE

On withdrawal periods, AnimalhealthEurope will provide a document explaining how the 3 regions calculate their WPs.

#### Act: AHE

It was suggested that the VOF members should discuss more between themselves in advance, then address their questions to the SC.

The SC noted the need to differentiate what can be provided as information, what could become a training video or a webinar, and what can be presented at VOF meetings.

OIE will provide a first draft agenda to be circulated to the SC with the minutes of the VOF meeting, requiring first comments and additional topics as well as volunteers to lead some topics.

#### Act: OIE (Done)

AHI and AnimalhealthEurope would be able to provide a facilitator to support the VOF members during their private meeting.

Depending on the topics that will be requested, the EU and FDA indicated that they could provide experts to develop specific topics at the next VOF meeting.

### 6. Reviews of:

# 6.1 The implementation and interpretation of VICH GLs in the regions

### 6.1.1 Report from the regulators

# 6.1.1.1 Update from the EU & Japan on the delay of implementation of PhV GLs

JMAFF has started the specification designing of the database for PhV GLs 35 & 42, which will be completed in 2020 enabling the implementation of the 3 remaining Pharmacovigilance GLs

The EU indicated that the likely implementation time for PhV GLs 35 and 42 has been pushed back to early 2021.

#### 6.1.1.2 Report from other regions

None

#### 6.1.2 Review of the VICH GLs implementation tracker

The SC took note of the table prepared by the Secretariat and asked Australia, South Africa and New Zealand to provide their inputs as well.

### <u>Act</u>: Aus/ZA/NZ

The SC decided that this table can be shared with the VOF, but should remain an internal document, not for the public website.

The SC also agreed not to ask VOF members to complete this table for the moment.

#### 6.1.3 Any input from industry members

None

#### 6.2 Status of consultation for draft GLs at Step 4

The SC acknowledged that GL 59 is in the public consultation phase in the VICH countries & regions until April 2020.

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

#### 7.1. Proposals for revision of further VICH GLs

# 7.1.1. Update from the Secretariat on the VICH GLs which have passed the 5 years of implementation – review of the updated table

The Secretariat indicated that since the last SC meeting only GL 51 has reached the 5 years' point.

The SC considered that this GL remains in line with the corresponding ICH GL and does therefore not need to be reviewed at this time.

# 7.1.2 VICH Quality GL 18(R) on Residual Solvents – Update on the progress of the ICH GL Q3C

Discussed under item 8.1

# 7.1.3. Proposals from the SC members for a revision of a VICH GL

None proposed

# 7.2. Proposal for a revision of other VICH GLs in light of an update of other organisations' GLs (ICH, OECD...)

### 7.2.1 Proposals for a revision of other VICH GLs

None proposed

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

#### 8.1. Quality

The chair of the Expert Working Group, Dr T. Ogata, confirmed that draft GL 58 (Stability - Climatic zones III & IV) has been signed off by the experts at step 5 and is now presented to the SC for signature at step 6.

#### VICH Quality GL 18(R) on Residual Solvents

The EU recalled that the SC had agreed that this GL should be updated to make parallel updates to those made to the ICH GL Q3C (R5, R6 & R8).

The revision 7 of the ICH GL has been published recently, but it covers only partly the required revisions. The additional revisions will be included in the ongoing revision 8 of this GL. The SC therefore agreed to maintain the revision on hold and to start the work in VICH once the revision 8 of ICH Q3C GLs has been finalised, which is expected in May 2020.

JMAFF indicated that it is likely that ICH might launch the revision 9 as soon as the R8 has been published. The SC nevertheless decided to start the revision of VICH GL 18 based on ICH Q3C R8, as this topic covers also the safety issue of pharmaceutical products.

# 8.2. Electronic Standards Implementation – Pharmacovigilance

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr Linda Walter-Grimm, and presented by FDA.

Then SC took note that the EWG has held 4 teleconferences since early 2019 and has developed a draft CP for minor revisions of GLs 24 & 29 in order to provide additional clarity in specific areas so that the GLs are clearer and better understood.

The EWG is also proposing to develop a new GL for signal detection/signal management, which may require new expertise, either in a subgroup of the current EWG or in a new EWG.

The SC supported the request that Australia and New Zealand should nominate experts to this EWG.

# Act: Aus/NZ

#### Concept Paper on the Revision of VICH Pharmacovigilance GLs 24 & 29

The SC adopted the CP proposed by the EWG, pending the deletion of the chapter "Recommendations for future guidelines". The secretariat will finalise the CP which will be placed on the public website.

Act: Secretary

#### Signal detection/signal management

The SC agreed that the EWG should develop a more detailed Discussion Document on the signal detection & management topic and decided that this topic should be handled by specific advisors to the EWG.

Act: EWG

The Secretariat will circulate a call for advisors.

Act: Secretary (Done)

The SC decided to change the name of the ESI EWG back to the former Pharmacovigilance EWG.

### 8.3. Biologicals Quality Monitoring

The chair of the Expert Working Group, Dr K. Sato, reported that:

# a. Harmonisation of criteria to waive Batch Safety Testing for veterinary vaccines: Laboratory Animal Batch Safety Testing (LABST)

The draft GL has been released for public consultation at step 4 until April 2020. Dr Sato indicated that the final draft 4 had been developed with wording similar to the wording in GLs 50 (R) & 55 in order to maintain consistency between the different GLs.

#### b. Extraneous virus (EV) testing for Biologicals

<u>Concept Paper for a VICH guideline on Test on the Presence of Extraneous Viruses in</u> veterinary viral vaccines

Good progress has been achieved since the review of the last version of the draft CP presented by JMAFF at the last SC meeting, and as a result the SC was able to adopt the CP. The SC further agreed that the EWG should focus on a single animal species in a first phase. JMAFF proposed swine as the first species to be considered, mainly because of the important issue of African Swine Fever in Eurasia and Seneca Valley virus in the United States. The SC supported the timetable detailed in the CP i.e. regional information collection in 2020/2021, GL development in 2022 and a first draft GL presented to the SC in 2023. The SC accepted the proposal to focus on swine pending the agreement from JVPA. JVPA will confirm in early 2020.

Act: JVPA (Done)

Post meeting note: JVPA has considered this matter in January 2020 and agreed to start with swine.

#### c. Structure of the EWG

The SC decided that additional advisors will be needed, different from those who were involved in the batch safety testing topic. The SC also agreed that in this case, the topic leader will be allowed to sign off the documents.

The Secretariat will circulate a table asking all members to clarify again who are the current experts and who are the advisors for the BST (as well as the advisors for the Biotechnological topic – see item 13.2).

SC members will also be asked to nominate advisors for the EV topic. The mailing list for this topic will be composed of the EWG designated experts together with the advisors designated for the EV topic.

<u>Act</u>: Secretary (Done)

#### 8.4. Metabolism and Residue Kinetics EWG

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

The SC noted that GL 57 has now been adopted in the regions and that the revision of GL 49 to clarify issues around the annex 3 is ongoing. A draft proposal should be available in 2020.

# 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 the FDA.

See also 13.1

*a) Revision of VICH GL 23 (R) (Safety - genotoxicity)* The experts have continued to provide comments but have not reached agreement yet.

#### b) Revision of VICH GL 22

The CP having been approved recently by the SC, the EWG will need to hold a face to face meeting as soon as possible to develop a draft proposal for the revision of the GL. The SC agreed that the EWG should decide the date and location of this meeting which had already been approved, and inform the SC.

Act: EWG

#### 8.6. Anthelmintics EWG

The SC reviewed the written report prepared by the chair of the Expert Working Group, Dr A. Phillippi-Taylor, and presented by the FDA.

Good progress has been achieved as the EWG has reached agreement on many issues. However, some major topics are still under discussion, in particular the use of geometric versus arithmetic means for statistical comparisons for which the EWG tends to be divided almost equally with a slight majority for the use of geometric means.

FDA will provide in December a possible compromise proposal with additional options, different to the current 2, for the EWG to consider.

In case still no progress can be made, the EWG will request a face to face meeting.

Should this be the case, the SC authorised in principle a face to face meeting to take place before the summer 2020, in a location to be determined by the experts.

#### 8.7. Combination product GLs EWG

The chair of the Expert Working Group, Dr S. Xu, reported that in early 2019 the EWG has decided to refocus the scope of the GL and to develop a list of "must haves" to be included in the GL.

Based on this list, the EWG will submit a revised draft Concept Paper to the SC, including a new scope with revised milestones and timelines.

#### Act: EWG

The SC thanked Dr Xu and the experts for the excellent progress already achieved. Dr Xu highlighted the important amount of work produced by the topic leader, Dr Crystal Groesbeck, and recommended that she should take over the leadership of the EWG.

After discussion with Dr Xu, the SC agreed that Dr Xu will remain the chairman of the EWG, and nominated Dr Groesbeck as co-chair of the EWG.

#### 8.8. Bioequivalence EWG

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

FDA recalled that the revised draft CP was approved by the SC in September and the EWG reconvened with the mandate to first develop an *in vitro* dissolution GL, then GLs on Biowaivers.

The EWG has started to work with a first round of discussion on the critical questions, which should be concluded by next January, following which the EWG will start the development of an in vitro dissolution GL.

The SC thanked FDA for the progress already achieved.

#### **REMINDER:** General issue

As the group e-mail addresses are managed by the Secretariat, it is of utmost importance that all delegations keep their expert lists up to date and immediately inform the Secretariat of any change.

<u>Act</u>: All

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

9.1. .....

None

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

# 10.1. VICH GL58 (Quality) – Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV

The SC adopted GL 58 as a 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 November 2020.

### 11. Review of the draft Priorities - Phase V

The SC reviewed the consolidated draft 4 of the document and agreed to add an amendment proposed by AnimalhealthEurope, saved as draft 5, which the Secretariat will circulate.

Act: Secretary (Done)

JMAFF presented an example of evaluation of the phase IV achievements and asked the other delegations to complete this form as well by end February 2020.

<u>Act</u>: All

The phase V draft should then be updated in the light of the phase IV achievements' evaluations. A teleconference could be organised in next July to discuss further amendments to the phase V document, if needed.

The final proposals should be sent to the Secretariat by 1<sup>st</sup> September 2020 so that a final draft can be provided 2 months prior to the next meeting.

Act: All

JMAFF suggested that the current evaluation document for phase IV could become a "living document" that would be updated through the phase V.

#### 12. Organisation of the VICH activities between yearly meetings

The SC reviewed the efficiency guidance document prepared by the Secretariat, which is based on the initial guidance document adopted at the last SC meeting. The importance of the timelines was highlighted again. It was confirmed that these should be updated at the next SC meeting, in the light of the first year of functioning.

The SC adopted the proposed document, with the following changes: the final agenda of the VOF should be circulated 3 months prior to the meeting, and a new bullet point was added in the 2<sup>nd</sup> chapter: Presentations and documents for the VOF will be provided 1 month prior to the VOF meeting.

### 13. Concept papers/Discussion Documents

# 13.1 Update on the progress from the Safety EWG on the revision of VICH GL 22: Final Concept Paper for the Revision of VICH GL 22

Covered under 8.5.

# 13.2 Revised Concept Paper from JMAFF on a Guideline for Safety Evaluation of Biotechnology-derived/Biological products

The SC reviewed the last version of the document that was circulated by JMAFF, including the minor amendments proposed by the EU. The SC adopted the CP and agreed that the first GL will cover the target animal safety (not the human food safety) evaluation of veterinary medicinal products containing monoclonal antibodies.

The SC decided to change the name of the Biologicals Quality Monitoring EWG to Biologicals EWG and agreed that this topic will be addressed by a subgroup of this EWG (Fig.1).

USA, Canada and Australia indicated that they will nominate experts from both the pharmaceutical and biological authorities. The Secretariat will call for additional advisors to the EWG.

Act: Secretary (Done)

The SC agreed that JVPA will nominate the topic leader.

Act: JVPA (Done)

Biologicals- EWG Chair (Dr. Kota SATO) (+Adviser)	
BST subgroup	Bio-products Safety subgroup
(DST@VICISEC.OFg)	(BS@vichsec.org)
<ul> <li>Topic Leader</li> </ul>	<ul> <li>Topic Leader</li> </ul>
EU	JVPA
<ul> <li>Expert</li> </ul>	<ul> <li>Expert</li> </ul>
(+Adviser)	(+Adviser)
	(BST@vichsec.org) • Topic Leader EU • Expert

Fig.1 New Structure of the Biologicals EWG (former BQM EWG)

# 13.3 Review of the Concept Paper from the ESI EWG on the Revision of VICH Pharmacovigilance GLs 24 & 29

Covered under 8.2

# 13.4 Review of the Discussion Document on which ICH GLs might be adaptable to the veterinary pharmaceutical field

Covered under 13.5

# 13.5 Review of the survey by AnimalhealthEurope on potential future VICH Topics and revisions of VICH GLs

AnimalhealthEurope recalled that industry had run a survey with its members to identify potential new topics for VICH. Very good response was received and several pages of comments have been collated, including about 18 suggestions for new topics. AnimalhealthEurope will consult further and seek consensus within industry in order to provide better considered proposals at the next SC meeting. These may include additional suggestions for the VICH phase V.

### Act: AnimalhealthEurope

# 13.6 Draft Discussion Document for the adoption of ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients

FDA apologised for having circulated the document only shortly before the meeting and understood that no decision can be made at this stage.

The ICH Q7 GMP GL for APIs was implemented by ICH in 2001. FDA CVM uses it because there is much overlap between APIs for human and for vet pharmaceutical products.

The SC agreed that all will send comments on the DD to FDA by end February 2020.

FDA will provide a first draft CP by end April.

This draft CP will be circulated to the SC for further comments by end June.

Act: All

Act: FDA

Act: All

FDA will provide a draft 2 of the CP by 1<sup>st</sup> September for further discussion at the next meeting. <u>Act</u>: FDA

#### 14. Other issues

14.1 None

#### 15. VICH 6 Conference

#### 15.1. Any additional feedback from the Conference

AHI will provide a "lessons learned" list of topics from the organisation of the VICH Conference. These are intended to be recommendations for the next Conference organisers, and should be a living document to be regularly updated.

<u>Act</u>: AHI

#### 15.2 Date of the 7<sup>th</sup> Conference

The SC reviewed the possible location and date of the next VICH 7 Conference. It was pointed out that following the cycle, the next Conference should take place in Europe, in principle in 2023. It was questioned if it could take place in a VOF country.

#### 16. Any other business

#### 16.1 South Africa

South Africa explained that the Department of Agriculture, Forestry and Fisheries (DAFF) from the Ministry of Agriculture would like to nominate an additional delegate to the SC delegation. The SC welcomed this proposal, considering the importance of the registration of veterinary medicinal products by this department.

#### 17. Dates and venue of next meetings

- The 39<sup>th</sup> SC meeting will take place from Monday 16 to Thursday 19 November 2020 in the offices of the EMA in Amsterdam
- The 40<sup>th</sup> SC meeting will take place in November 2021 in the USA

### 18. Adoption of the Press Release on the 38<sup>th</sup> SC meeting

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

#### VICH STEERING COMMITTEE

38<sup>th</sup> meeting

18 to 21 November 2019 Tokyo, Japan

LIST OF PARTICIPANTS

Chair: K. OHARA, JMAFF

#### STEERING COMMITTEE MEMBERS & (C) coordinators

AHI (ZOETIS) AHI (BOEHR. INGELHEIM) AHI EU (EUROPEAN COMMISSION) EU (EMA) EU (EMA) AnimalhealthEurope (BOEHR. INGELHEIM) AnimalhealthEurope (ELANCO) AnimalhealthEurope JMAFF **JMAFF** JMAFF JVPA (Nisseiken Co.) JVPA US (FDA) US (FDA) US (USDA APHIS) US (FDA) - Guest

#### **OBSERVERS**

Australia (APVMA) Australia (AMA) Canada (Health Canada) Canada (CAHI) New Zealand (MPI) New Zealand (MPI) – *Guest* New Zealand (AGCARM) South Africa (SAAHA)

# INTERESTED PARTY

AVBC

# OIE OIE

OIE

#### VICH SECRETARIAT

HealthforAnimals

#### **APOLOGIES**

HealthforAnimals JVPA (NIPPON ZENYAKU KOGYO CO.) South Africa (SAHPRA) M. J. MCGOWAN C. LOWNEY R. CUMBERBATCH (C) J-N. PREUSS D. MURPHY N. JARRETT (C) **B. BOENISCH** E. DE RIDDER R. CLAYTON (C) K. EGUCHI K. NODA J. OHMORI (C) K. TUCHIYA K. OISHI (C) **B. WALTERS** B. ROBINSON (C) **B.E. RIPPKE** M. LUCIA

A. NORDEN C. BENNETT M-J. IRELAND C. FILEJSKI W. HUGHES A. KINSELLA J. QUAY M. CHURCHILL

#### G. DOWELL

J-P. ORAND M. SZABO

H. MARION

C. DU MARCHIE SARVAAS I. ABE A. SIGOBODHLA