



VICH/15/031
11 May 2015
FINAL

VICH OUTREACH FORUM
5th meeting
24-25 February 2015
Washington DC
SUMMARY REPORT

Session 1: Reports and Group Discussion

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, in cooperation with Dr Jean-Pierre Orand, OIE. Dr Dunham welcomed the participants to the 5th VICH Outreach Forum (VOF) meeting in Washington DC.

2. Report by the SC on issues raised by Outreach Forum members during the 4th VICH Outreach Forum meeting in Brussels in June 2014

The VICH Secretariat reported on the outcome ([link](#)) of the discussions that took place at the 30th VICH Steering Committee (SC) meeting in Brussels on the issues raised by the participants in the 4th VOF meeting. The 5th VOF agenda items will therefore provide more time for discussion (2 Breakout sessions) and cover:

- GLP/GCP: requirement and implementation
- Effectiveness studies for anthelmintic drugs
- Pharmacovigilance
- Communication and training
- Updates from VOF members

3. Report by OIE on their activities concerning Veterinary Medicinal Products (VMPs) since the last Forum – Strategy phase IV

OIE reported ([link](#)) that it not only actively disseminates information on VICH to OIE member countries after each VOF and SC meeting, but also promotes VICH and Outreach Forum objectives during OIE focal points trainings. OIE has addressed more than 450 persons in 3 training cycles over the past 5 years.

OIE is also actively involved in the development of the VICH training strategy for the VOF members.

2015 will be the year of important changes in OIE with the election of a new Director General and the adoption of the 6th Strategic Plan. The current draft confirms the necessity for good quality, safe and effective VMPs and the strong support of OIE for the work of VICH.

The participants acknowledged that the circulation of information is very important, and stressed that the invitation to VOF meetings are not always sent to the right persons in the countries. Mexico was mentioned as an example.

4. Report by the VICH ad hoc group on training and communication strategy

FDA reported that the ad hoc group has finalised the VICH training strategy and pointed out that many communication materials are available on the VICH public website, such as the VICH leaflet in 5 different languages and several PowerPoint presentations. The SC will further discuss key issues on the implementation of the training strategy focussing on financing and funding opportunities to support the VICH level 2 training programme.

The participants highlighted the importance of political buy-in. It is often difficult for the technical experts participating in the VOF initiative to convince the political decision makers. It was acknowledged that the existing slide sets represent a good starting point in educating the decision makers, but it is important to identify the right officials to whom the presentations should be sent.

5. Report from SC discussions on the TFs on Concept Papers

5.1 Revision of GL 3(R) on stability to address climatic zones III and IV

IFAH-Europe reported ([link](#)) that the Task Force (TF) is composed of experts from VICH members as well as from Argentina, CAMEVET and Thailand. Within the SC there is support, in principle, for VICH to provide a guidance on how to conduct stability studies for zones III and IV, but there is a consensus to develop a document separate from the existing VICH GL 3(R). The technical requirements will be similar to those in GL 3(R), but the aim is not to change the current GL as the coverage is different.

VICH members will implement the new GL if they have climatic zone III, although the ultimate aim of this GL is to address non-VICH countries' issues.

CAMEVET confirmed that it has a GL very similar to the VICH proposal and will provide its expertise to the EWG.

Thailand explained that ASEAN does not have a GL and is welcomed the VICH initiative.

5.2 Development of guidance on efficacy studies for combination products

JMAFF presented ([link](#)) the status of the development of a discussion document by the Task Force and the results of the survey that was made in the VICH and VOF regions. The survey has provided a global assessment of the needs in these regions.

The objective of the TF is to prioritise the target products and explore the possibility of developing a general guidance document in respect to combination products.

It was noted that, as the SC has decided not to consider combination products containing antimicrobial substances, the TF's scope is limited to the class of anthelmintic products and a general combination GL.

Argentina confirmed its support for the development of a general GL.

China questioned if a combination product will be applied, only after approval of each constituent as new active pharmaceutical ingredients (APIs), because of the difficulty in safety assessment of a new combination without knowing each API's toxicological status. It was pointed out that this is a decision in the hands of the national regulatory authorities.

6. 1st Group Discussion of individual VICH Outreach Forum member questions

3 breakout groups were organised comprising VOF members with SC members. Each team designated a rapporteur and a moderator.

These groups were composed of the following VOF members:

Group 1: Argentina, Thailand, Camevet & China

Group 2: CAMEVET, ASEAN-Thailand, Ukraine & Korea

Topics: TABST & Bioequivalence (BE)

The EU introduced ([link](#)) the topic of waiving of TABST for vaccines and Dr M. Martinez/FDA, chair of the EWG, introduced the progress achieved by the VICH Bioequivalence EWG.

7. Reporting back to plenary on outcome of 1st group discussions

Group 1

The Group 1 reported ([link](#)) that their discussion had mainly focused on the TABST issue for vaccines.

Argentina explained that TABST waiving is not allowed to date, but such a waiving would not only have technical implications (need for expertise), but would also impact the employment (of such a waiver) within the administration.

Thailand will introduce in the near future a new regulation on animal vaccines which will enable a reduction of the animal testing requirements based on the VICH GLs.

In China both laboratory animals' tests and TABST are required.

Regarding study design and analysis considerations pertaining to the assessment of generic products, CAMEVET explained that it has already developed a BE GL based on the current FDA and EU GLs. However, its execution is a challenge because of the difficulty they are encountering with regard to the identification of experts who can perform such BE studies. The new VICH GL is considered as an important step forward.

China will establish a legal definition of generic products in the near future.

In Thailand the BE concept exists only for human drugs.

Group 2

The discussions were very similar regarding TABST.

With regard to BE assessments, Ukraine indicated that there currently are no generic applications within their jurisdiction and that a full dossier for all products is currently required. However, there is legislation in preparation which will distinguish generic and pioneer products. The rollout of this legislation will be facilitated by the availability of the VICH BE GL, but Ukraine expressed concern about the availability of expertise to conduct blood level BE trials.

In Korea generic products are permitted but their evaluation is based upon the same efficacy and safety study requirements as pioneer products. Korea may consider waiving of TABST for inactivated vaccines.

8. 2nd Group Discussion of individual VICH Outreach Forum member questions

These groups were composed of the following VOF members:

Group 1: Argentina, Thailand, Camevet & China

Group 2: CAMEVET, ASEAN-Thailand, Ukraine & Korea

Topic: Application of VICH GLs

CAMEVET detailed ([link](#)) the member countries that frequently use the original or modified VICH GLs and explained the advantages and difficulties of using these VICH GLs.

9. Reporting back to the plenary on the outcome of group discussions

Group 1

In the discussion ([link](#)) it was pointed out that some governments are concerned that the system for adopting VICH GLs is very different from the OIE & CODEX systems in which many countries are represented.

The participants noted that VICH observer countries may, where appropriate, decide not to adopt all elements of a VICH GL, but the VICH philosophy is always followed and GLs are modified only where absolutely necessary. Where the adoption is not 100%, it is important to clearly highlight in the local GL any differences to the VICH GL in order to ensure predictability.

Argentina has no generic product legislation: all products are considered as new products and require a full dossier. However once a molecule was approved, the regulators accept bibliographic references (e.g. pharmacology, toxicology) complemented by local trials.

Thailand has not used VICH GLs until now, but will propose the use of some VICH GLs within the 10 ASEAN countries, at the next ASEAN meeting scheduled to take place in Thailand.

China has approximately 30 national GLs in place for pharmaceuticals, vaccines and herbal medicines. Following the active VOF participation, existing Chinese GLs will be modified to include the VICH GL elements. Several VICH GLs are currently being translated into Chinese, with limited resources and time.

The participants stressed that an adaptation phase is needed to allow local industries to adjust to the new requirements through a gradual process.

Group 2

The 4 VOF members in group 2 have implemented some VICH GLs as a first step, mainly related to pharmaceutical veterinary drugs. As the group 2 countries do not have GLP certification the quality GLs cannot be implemented. The GLP certification from other countries is therefore important for safety studies.

The GCP requirements are not yet compulsory, but nevertheless are already in place in Thailand, Korea and some CAMEVET countries.

CAMEVET has a WG in place to develop specific guidances as well as a specific system for the implementation of these guidances.

All participants agreed that VICH GLs are important for the application of the 3R requirements in addressing reduction of animal testing.

Group discussion conclusion

In conclusion, it was noted that the main driver for countries to start implementing VICH GLs was the participation in the VOF and a better understanding of the VICH process.

It was noted that the VICH GLs apply to applications for new products, and they can in general also apply to extension or variation applications, e.g. to add new

formulations/presentations, new indications, new species (efficacy studies), new food producing target animal species (depletion studies) etc...

The participants also considered important the need to convince the local industry of the importance of VICH GLs.

Thailand will propose the common application in ASEAN of some VICH GLs during the next ASEAN meeting in April.

Overall the application of VICH GLs will enable countries to prevent duplication of studies and save resources.

10. Participation in the VICH process:

10.1 Vaccines in ASEAN

ASEAN presented ([link](#)) the procedure for the Registration of Animal Vaccines in the ASEAN countries. The summary of product characteristics (SPC) is identical and the Marketing Authorisation is valid for all ASEAN countries. The working language is English.

The submission of the complete application and registration documents is done to the ASEAN Secretariat for circulation to 9 member states through their National Focal Points for VMPs. The comments are consolidated by the National Focal Point of the country of application.

10.2 How to comment on a draft VICH GL

China explained ([link](#)) that when a VICH GL is circulated for public comments, it is translated into Chinese and distributed to 10 experts (from regulators, academia and industry) who are familiar with the scientific area, and who are asked to provide their comments within 10 working days. The collected comments are translated into English and sent back as the national comments to the National Focal Point who will send them to the VICH secretariat. China recommended to facilitate and accelerate the development of GLs for vaccines and herbal medicines; to develop more guidelines suitable for the development of combination products; and to enable more experts from VOF countries to participate in EWGs and TFs activities.

SC members noted that in general non-VICH countries do not provide many comments on draft GLs, although OIE encourages the countries to respond.

OIE confirmed that the draft GLs are circulated each time with request for comments, but sometimes the OIE contact is not the proper contact point for VMPs in the country. The language is also often a barrier.

VOF members pointed out that translations are difficult and there is a need for specialists to ensure correct wording.

CAMEVET also sends the draft GLs for comments to its focal points in its member countries.

Session 2: Issues of interest to Outreach Forum members

11. Specific issues

11.1 GLP/GCP: requirement and implementation

JMAFF ([link](#)), the EU ([link](#)) and China ([link](#)) each presented the definition and the requirements for Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) in their country/region.

FDA explained that in the United States, the FDA/CVM employs GLPs and GCPs to ensure the quality of the conduct of the investigational studies as well as the quality of the data submitted by sponsors to CVM for evaluation to determine the safety and effectiveness of new animal drugs. GLPs are required for all safety studies including the bioequivalence studies. GLPs are codified as regulation in 21 CFR Part 58.

There are differences in GLP requirements in different regions of the world. In the United States, a sponsor must certify in the New Animal Drug Application how a submitted safety study complied with the US GLP requirements.

For effectiveness trials, CVM recommends the use of GCPs which are found in Guidance for Industry #85. The effectiveness trials are also subject to broad regulations found in 21 CFR Part 511. GFI # 85 can be found on the FDA website at:

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052417.pdf>.

The purpose of having GLPs and GCPs is to enable CVM's scientific reviewers to have confidence in the data that they are evaluating to make safety and effectiveness decisions. A reviewer reviewing a study report and data from the conduct of a study has to literally be able to reconstruct what occurred during the study based on what is written in the report.

In order to augment the reviewer's level of understanding and confidence in the data that they are reviewing, CVM reviews the submitted studies for data quality. This review is conducted by Consumer Safety Officers. The study is then provided to the scientific reviewer for scientific evaluation. Also, CVM's Office of Surveillance and Compliance has a Bioresearch Monitoring Team that oversees the assignment and conduct of inspections of studies used in support of the evaluation of New Animal Drug Applications. Different types of inspections are conducted depending on the nature of the study. GLP inspections are focused on the laboratory studies whereas Clinical Investigator and Sponsor Monitor studies are focused on clinical studies. More information available at:

<http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/default.htm>

In 2013, FDA conducted a detailed webinar to discuss data quality. The transcript and an extensive question and answer document can be found at:

<http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm348902.htm>.

11.2 Pharmacovigilance

The EU explained ([link](#)) how Pharmacovigilance systems and processes are developed.

The chairperson of the VICH PhV EWG, Dr Margarita Brown, presented ([link](#)) the achievements of VICH Pharmacovigilance harmonisation work.

11.3 Effectiveness studies for anthelmintic drugs

Dr Aimée Philippi-Taylor, leader of the VICH TF on the discussion document on the Anthelmintics GLs, reported that the TF has worked one year on a list of topics, mostly by electronic procedure and that the discussion document is well progressed.

As an example of a topic under discussion within the TF, comparison of geometric means in anthelmintic studies may not be universally the best approach for all studies. The current GLs may be too prescriptive by generally recommending the use of geometric means for all anthelmintic studies. It was acknowledged that work of the TF is highly technical and scientific,

and that many issues will remain that need to be addressed which will be detailed in the final version of the discussion document.

Session 3: Discussions and conclusions

12. Feedback on the meeting from Outreach Forum members and open discussion

The extension of the group discussion sessions was highly appreciated by all participants.

Topics proposed for the next VOF meeting were:

- Bioequivalence and requirements for generics
- Apiculture products and VICH MRK GL for honey
- Aquaculture products and VICH MRK GL for fish
- The Anthelmintics GLs discussion document
- Herbal medicines and phyto products
- Review of AMR GL 27
- Practical approaches to GCP
- Implementation of the GL on TABST requirements in the 3 VICH regions
- VICH training strategy/Breakout session on VICH training strategy and modules 1 & 2

All VOF members recommended inclusion of industry participants from the VOF countries. ASEAN indicated that, because of their invitation to attend the VICH 5 Conference, many ASEAN member states will probably wish to send delegates to the 6th VOF meeting in Tokyo.

The secretariat informed that all the presentations made at the VOF meeting were immediately uploaded to the VOF section of the VICH members' only website.

13. Conclusions and next steps

All VOF participants appreciated the presentations and the open discussions which improved their understanding of the VICH process.

The breakout sessions enabled fruitful discussions with very useful reporting sessions.

The SC members were impressed by the number of VICH GLs that have already been adopted by many VOF countries.

The SC will discuss the participation of more ASEAN countries in the 6th VOF and the ways to move the training strategy forward, and determine the topics for the next VOF meeting and breakout sessions recognising the possibilities within the scope of VICH and need to allocate adequate time for fruitful discussions.

13. Update on the preparation of the 5th VICH public Conference in Tokyo

The participants took note of the draft programme for the 5th VICH public conference that will take place on 28 & 29 October in Tokyo, in conjunction with the 32nd VICH SC meeting and the 6th VOF meeting.

14. Confirmation date and venue of 6th VICH Outreach Forum meeting

The 6th VICH Outreach Forum meeting will be held in Tokyo, Japan on 26 & 27 October 2015.

5th VICH Outreach Forum meeting Participants

1/ Forum members

ARGENTINA - SENASA	L. SBORDI
CAMEVET (Argentina)	E.J. ARGENTO
CAMEVET (Argentina)	C. FRANCIA
CHINA – Institute of Vet. Drug Control	S.X. XU
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	S-J. JOH
THAILAND – Department of Livestock Development	S. JAROENPOJ (also representing ASEAN)
THAILAND – Department of Livestock Development	T. RODSOM
UKRAINE – State Scientific Research Control Institute of VMPs	Y. KOSENKO

No reply (reminder sent)

BRAZIL – Ministry of Agriculture, Livestock and Food Supply	L.C. SCHAPER
CHINA – Veterinaria Bureau, MOA	Ch. XIANG
GOVERNMENT OF INDIA – CDSCO	P.B.N. PRASAD
INDIA – Ministry of Agriculture	R. SING RANA
INDIA – Ministry of Health & Family Welfare	P.B.N. PRASAD
MALAYSIA – DVS	Z. BINTI ABDULLAH
MEXICO – SENASICA	O.F. HERNANDEZ
THAI FDA	P. LUSANANDANA
THAI FDA	J. TORON

Apologies

MOROCCO – ONSSA	A. GRINI
PHILIPPINES – ASEAN Bureau of Animal Industry	M. ABENES
Plant Quarantine Agency	J-H. HUR
RUSSIA - VGNKI	A. PANIN
TANZANIA FOOD AND DRUGS AUTHORITY	A.M. KHEA
TAIWAN – Council of Agriculture	Y-F. LIU
WAEMO/UEMOA (Burkina Faso)	S. DIALLO

2 / Steering Committee (C) coordinators

Members

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AHI (ZOETIS)	M. J. MCGOWAN
AHI	K. KLAUS (C)
EU (EUROPEAN COMMISSION (DG SANCO))	M. SPAGNUOLO-WEAVER
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Australia/New Zealand (MPI)	W. HUGHES
Australia/New Zealand (APVMA)	P. REEVES
Canada (Health Canada)	M-J. IRELAND
Canada (CAHI)	J. SZKOTNICKI
South Africa (DAFF)	A. SIGOBODHLA
South Africa (SAAHA – BAYER)	E. SCHAY

INTERESTED PARTY

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