



VICH/13/086
28 January 2014

**VICH OUTREACH FORUM
3rd meeting
12-13 November 2013
Auckland – New Zealand**

SUMMARY REPORT

Session 1: Reports and discussion

1/ Opening of the meeting and chairperson's introduction

The meeting was exceptionally held in a VICH observer member country, New Zealand, and chaired by Dr. Shigeyuki NAKAMURA, Director, National Veterinary Assay Laboratory – JMAFF, in cooperation with Dr Jean-Pierre Orand, OIE. These meetings have normally been held in VICH Member countries so the venue of this meeting was a departure from usual practice.

2/ Report by the SC on issues raised by Forum members during the 2nd VICH Outreach Forum (VOF) meeting in Washington DC in February 2013

The VICH Secretariat reported on the outcome ([link](#)) of the discussions that took place at the VICH Steering Committee meeting in Washington DC on the issues raised by the participants in the 2nd VOF meeting.

3/ Report by OIE

OIE presented an overview ([link](#)) of the OIE activities on VMPs since the 2nd (VOF) meeting. OIE has funded the translation of 3 GLs into Spanish, with technical assessment by CAMEVET. OIE confirmed its commitment to support the VICH activities.

4/ Report by the subgroup on training and discussion

The participants took note of the proposal ([link](#)) for a VICH training strategy prepared for the VICH Steering Committee (SC) by the VICH ad hoc working group on training strategy.

5/ Link between legal Framework of VMP and VICH GLs

The VOF members were informed how VICH GLs are implemented in the USA ([link](#)) and in Australia ([link](#)).

6/ Group discussion of individual VICH Outreach Forum 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, CAMEVET, ASEAN & Malaysia

Group 2: Korea & Thailand

Group 3: Ukraine, Russia & China

7/ Reporting back to the plenary on the outcome of group discussions

[Group 1 link](#)

CAMEVET and ASEAN presented their perspectives on the implementation of VICH GLs. It was pointed out that there is a strong need for VICH to communicate to non-VICH countries in order to enable them to understand how VICH GLs can be implemented by these countries. Several VOF members confirmed their fear that they would have to implement all VICH GLs as a package. The need to clarify the difference between “regulatory system” and regulations/legislation was recognised.

The SC confirmed again that non-VICH countries have no commitment to implement VICH GLs; they can implement them completely or adapt them to fit local requirements.

Moreover, Australia explained that VICH observer members are expected but not obliged to adopt the GLs as in particular circumstances the regulators may decide that they require slight adjustments to local conditions (e.g. covering aspects lacking in VICH GLs such as topical products, climatic zones III/IV). Australia attempts adoption of VICH GLs “to the fullest extent possible”..

Argentina highlighted the fact that the GLs have been set up for VICH countries/region and may need adaptations for non-VICH countries as some specific situations might not be addressed in the GLs.

It was proposed to develop a feedback mechanism to the SC to explain how GLs have been adapted in VOF countries and for which reasons.

[Group 2 link](#)

Thailand & Korea mentioned that their regulatory standards are very similar to VICH; however use of antibiotics as growth promoters or for prevention purposes is prohibited.

Currently ASEAN is developing the harmonisation of registration requirements for animal vaccines but both countries recommended an extension to VMPs (Veterinary Medicinal Products) by using the VICH GLs, with a strong need for capacity building and training.

It was pointed out that in both countries VMPs could be obtained without prescription previously, but both countries have recently or will soon introduce prescription requirements. The EU indicated however that the governance of VMPs is out of the scope of VICH.

[Group 3 link](#)

Ukraine, Russia and China highlighted the very important need for VOF countries’ regulators to understand how VICH GLs could be integrated into the national regulatory system before being able to use them nationally.

It was stressed again that VICH GLs are technical, not legal requirements whilst the need for more communication by VICH was also highlighted once more.

Several VOF members encouraged again OIE to include the VICH GLs in the OIE manuals but OIE explained again that this is not the most appropriate manner to spread VICH GLs as these GLs may not meet the needs of all countries and the process would furthermore require the formal approval by all OIE 178 OIE member countries.

Moreover, the approval process that is necessary when VICH GLs need to be updated is much simpler within VICH than in OIE.

OIE nevertheless recognises the VICH GLs as international standards and refers regularly to VICH and the VOF initiative. Furthermore the VICH and OIE websites are closely aligned. The objective of making the VICH GLs available to more countries has been achieved via the VOF initiative. OIE strongly supports the VICH activities.

The Group also recommended that whenever possible the same person should be the OIE Focal Point for Veterinary Products and the contact for VICH Outreach Forum matters.

8/ Updates from Outreach Forum members

8.1 Thailand

Thailand presented ([link](#)) an update on Activities on Veterinary Drugs Control.

The difference between modern and traditional medicine was highlighted in the discussion: modern medicine requires a scientific review of the products, also based on VICH GLs, whereas traditional medicines are based on the use of herbs with experienced therapeutical effects, which are compounded in tablets or powder as “traditional medicines”.

8.2 South Africa

South Africa presented ([link](#)) a review of the Control of Veterinary Drugs in South Africa.

Regarding GMP requirements, South Africa has an internal inspection service that allocates GMP certificates, and accepts also certificates from other governments, the aim being to have one single standard within the country.

Session 2: Issues of interest to Outreach Forum members

9/ Specific issues

9.1 Pharmacovigilance: Experience with development of Pharmacovigilance systems and processes (from the view point of government and industry)

The presentation from the EU ([link](#)) addressed the experience with the development of pharmacovigilance systems and processes whilst IFAH Europe ([link](#)) developed the industry view on pharmacovigilance highlighting the need for global harmonisation of pharmacovigilance legislation.

9.1 Target Animal Batch Safety Testing – VICH activities

The EU explained the background for the changes allowing to waive batch safety testing for veterinary vaccines and the current VICH activities on establishing harmonised criteria for waiving Target Animal Batch Safety Testing; VICH has already adopted a GL for inactivated vaccines and the Biologicals Quality Monitoring EWG is currently developing a similar GL for live vaccines.

China indicated that TABST requirements considering the VICH guideline will be put in place at the national level. ASEAN and Thailand stated that they accept the waiving of TABST based on the supportive documentation received from Market Authorisation Holders in line

with the VICH guideline. CAMEVET has no guideline on TABST yet, Argentina works on implementation of GL50.

OIE explained that they included the possibility of waiving TABST when updating certain parts of the vaccine chapters; however, implementation takes 2 – 3 years.

10/ Participation in the VICH process

10-1. Development of Concept Papers (Combination products)

China presented ([link](#)) a proposal for a Concept Paper - CP for a VICH guideline on Combination Products.

The SC members as well as the VOF members welcomed the proposal confirming that it is an important topic where guidance is currently lacking.

It was noted that the scope of this topic is very broad and could lead to several GLs.

It was acknowledged that it would be useful to identify the different combinations available in order to reach agreement on which GLs should be developed.

The SC will reflect further on the topic and report back to the VOF.

Post meeting note:

The SC decided to create a task force - TF chaired by JMAFF with the mandate to develop a discussion document proposing a more focused scope for the development of a VICH GL for efficacy studies for combination products. It should include a proposal for an overall strategy on how to approach combination products in general and/or detailing the different therapeutical classes in which combination products are available (anthelmintics, antibiotics...), proposing a prioritisation of the topics, evaluating the feasibility and the resources that would be available to drive these topics forward.

The TF should also review which classes of combination products are available in the different regions/countries and which are the regional/national GLs available for these products.

The TF will be composed of SC and VOF members, and will work by electronic procedure only.

10-2. Participation to Expert Working Groups (Honey /Residue)

Argentina explained the reasons ([link](#)) for volunteering to participate in the new MRK (Metabolism and Residue Kinetics) EWG subgroup on honey and described the benefits for Argentina to be involved in the development of this new GL.

The VOF applauded the formal participation of one of its members in a VICH EWG.

10-3. Active involvement in commenting on a Concept Paper (Presentation of revision GL3 R)

IFAH Europe explained ([link](#)) that it had proposed to revise VICH GL 3 (R) Guideline on Stability Testing because the current GL addresses stability requirements for climatic zones I and II, but there is currently no “common” document or common consensus covering climatic zones III and IV.

The draft CP has been circulated to the VICH SC and VOF members, and comments were provided by CAMEVET and Thai FDA.

As more preparatory work is required to develop further the CP the SC has decided to create a TF chaired by IFAH Europe that will work mainly by electronic procedure. It should comprise scientific experts from VOF countries in climatic zones III/IV, such as Camevet or Thai FDA.

The secretariat will circulate a call for volunteers from the SC countries/regions and from the VOF members.

Meanwhile OIE will launch a survey with all OIE member countries to obtain an overview of their support that VICH defines the conditions for stability testing for climatic zones III and IV. The results of the survey will be presented at the next SC & VOF meetings.

11/ Communication around VICH

IFAH Europe presented an outline of the new VICH website that should be activated in Q1 of 2014. The new website will contain pages dedicated to the VOF.

Session 3: Conclusions

12/ Feedback on the meeting from Forum members and open discussion

Training

ASEAN confirmed the important need of its member countries to fully understand the VICH GLs and recommended that a general introduction to VICH GLs should be given at future ASEAN meetings. An upcoming opportunity for that would be in May 2014 in Singapore. Thailand supported ASEAN's approach and believed that the ASEAN harmonisation rules should be similar to those of VICH. Indonesia, Philippines and Thailand being currently the countries in the lead of veterinary vaccines' harmonisation, Thailand suggested that training on harmonisation of vaccines registration as well as bioequivalence should be provided at the next VOF meeting.

CAMEVET will recommend to its Executive Board that a VICH SC member is invited to give a presentation on VICH and the work in the VOF at the next CAMEVET meeting to be held in 2014 in Canada.

Argentina suggested VICH communication as a topic for the next VOF meeting and recommended implementation of a feedback process for VOF members as part of which they would be requested how they implement the VICH GLs and adapt them when necessary. Ukraine supported the modular approaches for training and suggested the approach should be tested in one or two countries.

Ukraine and Russia suggested a training on bioequivalence should be organised at the next VOF meeting.

The participants discussed the exact meaning of "training" within the VOF and recognised that the participants in VOF meetings represent the management level of the regulators and not the countries' technical review experts, who require different levels in training.

OIE agreed that technical training should be focused on OIE focal points and national assessors.

VICH has no GL on GLP and these requirements are established by the national legislations; Thailand suggested that VICH countries should provide information on how they have implemented GLP and GCP requirements.

China questioned how VOF members could receive a feedback on the outcome of comments sent to VICH during the consultation periods at step 4. China also emphasized the need for clarification of the VICH rules and SOPs that are available on the VICH website because what is there now is not always easy to understand for external parties.

The secretariat explained that VICH has defined precise rules for the handling by EWGs of comments at step 4. The individual comments and the way they have been addressed by the EWG are now formally published on the VICH public website.

The secretariat will provide detailed explanations at the next VOF meeting.

The VOF members confirmed that the presentation given on the pharmacovigilance GLs was an excellent example of how to approach the need for a global harmonisation.

Korea pointed out that not all VOF regulators have the capacity and the capabilities to implement fully the VICH GLs.

Malaysia recommended that VICH should provide training for assessors who are involved in the registration process.

Regarding the possible adaptation of VICH GLs at the local level, SC members stressed that VICH GLs should normally be implemented to the fullest extent possible as the ultimate objective is to develop a globally harmonised standards.

VICH GLs can be implemented in full, or slightly amended with additions when the GL does not cover local specificities or remains silent on certain points.

It was pointed out that a company can deviate from a GL in the data requirements and assessment on the basis of scientific justifications to be explained, which can be accepted by the authorities if considered appropriate.

It was agreed to discuss this item further at the next meeting.

13/ Conclusions and Next steps

Breakout sessions

All participants agreed that the breakout session was very effective in eliciting input from all participants and should be repeated at the next VOF meeting. All VOF members should send as soon as possible proposals to the secretariat for discussion topics in the next breakout sessions.

Training

This topic will require more discussion; recommendations and suggestions were made by several VOF members.

Misunderstandings about the implementation requirements were highlighted and the SC will provide further explanations at the next meeting.

Strategy for communication on VICH

Communication on the work of VICH and on VICH GLs was considered as an important topic for the breakout sessions of the next meeting.

Participation of VOF members in VICH work

It was noted with satisfaction that VOF members are starting to actively participate in VICH activities: CAMEVET and Thai FDA have provided comments on the draft CP on the revision of GL 3R, China has provided a draft CP, Argentina is a member of the MRK EWG on honey and the VOF members will be asked to nominate experts to 2 VICH Task Forces.

Agenda and future topics for next meeting

Several proposals were made for future VOF topics: bioequivalence, generics, GCP...

All VOF members were asked to send further proposals for topics to the secretariat

The first draft of the agenda for the VOF next meeting will be circulated in January 2014.

14/ Presentation of the 5th VICH public Conference in Japan

The participants took note that the [5th VICH public conference](#) will take place in Tokyo on 28 & 29 October 2015 in conjunction with the 32nd VICH SC meeting and the 6th VOF meeting.

15/ Confirmation date and venue of 4th VICH Outreach Forum meeting

The 4th VICH Outreach Forum meeting will be held in Brussels (Europe) on 24 & 25 June 2014.

3rd VICH Outreach Forum meeting Participants
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1 / Forum members

NEW ZEALAND – AGCARM	J. QUAY <i>(13 November only)</i>
NEW ZEALAND – AGCARM	G. PETERS <i>(12 November only)</i>
ARGENTINA - SENASA	L. SBORDI
CAMEVET (Argentina)	E.J. ARGENTO
CHINA – Institute of Vet. Drug Control	SH. XU
CHINA – Veterinarian Bureau	CH. XIANG
MALAYSIA – DVS	Z. BINTI ABDULLAH
PHILIPPINES – Bureau of Animal Industry	M. ABENES
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	S-J. JOH
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	J-H. HUR
RUSSIA - VGNKI	A. PANIN
THAILAND – Department of Livestock Development	S. JAROENPOJ
THAI FDA	P. LUSANANDANA
THAI FDA	J. TORON
UKRAINE – State Scientific Research Control Institute of VMPS	Y. KOSENKO

Apologies

ARGENTINA – CAPROVE	C. FRANCIA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	L.C. SCHAPER.
BRAZIL – Sindan	R. PINTOS DOS SANTOS <i>(no reply)</i>
BRAZIL – Sindan	E. SALANI <i>(no reply)</i>
INDIA – Ministry of Agriculture	R. SING RANA <i>(no reply)</i>
MEXICO – CANIFARMA	J.A. PEREZ LEYTON <i>(no reply)</i>
MEXICO – SENASICA	M.L. MOLINA NAVA <i>(no reply)</i>
MEXICO – SENASICA	G.P. PENA FLORES <i>(no reply)</i>
MOROCCO – ONSSA	A. GRINI <i>(no reply)</i>
MOROCCO – ONSSA	K. ID SIDI YAHIA <i>(no reply)</i>
SOUTH AFRICA - National Department of Health	A. SIGOBODHLA
TAIWAN – Council of Agriculture	Y-F. LIU

UKRAINE – State Scientific Research Control
Institute of VMPs

WAEMO/UEMOA (Burkina Faso)

WAEMO/UEMOA (Burkina Faso)

I. KOTSYUMBAS

A.S. SONHAYE

S. DIALLO (*no reply*)

2 / Steering Committee (C) coordinators

Members

AHI (USA)

AHI (USA)

EU (European Commission)

EU (European Medicines Agency)

EU (Danish Health and Medicines Authority)

IFAH-Europe (MERIAL)

IFAH-Europe

IFAH-Europe (BAYER)

JMAFF (Japan)

JMAFF (Japan)

JMAFF (Japan)

JMAFF (Japan)

JVPA (Japan)

JVPA (Kyoto Biken Laboratories) (Japan)

JVPA (DS Pharma Animal Health Co.)
(Japan)

USA (FDA)

USA - AHI (ZOETIS)

USDA (USA APHIS)

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R. CARNEVALE (for B. MARTIN)

S. VELUVOLU (C)

K. KRAUSS

K. GREIN (C)

A. HOLM

B. BOENISCH

R. CLAYTON (C)

L. KLOSTERMANN

S. NAKAMURA (*Chair 29th VICH SC*)

Y. ENDO

K. NODA (C)

T. KOZASA

O. ITOH (C)

E. OISHI

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M. SMITH

M. MCGOWAN

B. RIPPKÉ

S. VAUGHN (C)

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ANIMAL HEALTH ALLIANCE (Australia)

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