VICH/22069
24 January 2023
Final

VICH OUTREACH FORUM

15th Meeting
16 November 2022
Washington DC - USA

SUMMARY REPORT

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Laetitia Le Letty, Head of the European and international affairs at the French agency for veterinary medicinal products - WOAH collaborating centre, on behalf of the WOAH.
Dr Le Letty opened the meeting by welcoming the participants to the 15th VICH Outreach Forum (VOF), taking place as a physical meeting again, and thanked those who were able to participate, either in Washington, or remotely.

2. Report by the SC on issues raised by Outreach Forum members during the 14th VICH Outreach Forum virtual meeting in November 2021

The VICH Secretariat briefly summarised the report from the SC (link) that was circulated prior to the meeting and addressing the follow up from the SC to the discussions held at the 14th VOF meeting.
The main features are:

- As requested, the VOF meeting agenda was circulated in January 2022
- The proposed agenda for the 15th VOF was also provided in advance of this meeting
- A pre-meeting for VOF members chaired by SFDA with the support of WOAH-HQ, with the main objectives to identify the needs and challenges as well as what can be improved in the future
- Specific topic for discussion – Stability of vaccines
- AnimalhealthEurope will take the VOF members through the previous and updated versions of VICH Guideline 8 helping to better understand the use of this GL
- FDA will present an update on the review of Anthelmintic guidelines
- Brief summary on the activities of the 9 VICH Expert Working Groups
- Ongoing update of the VICH structures with the aim of improving and facilitating further involvement of VOF members in VICH activities – the VOF will become the "VICH Forum"
- Confirmation that VICH 7 Public Conference will take place in Amsterdam in November 2024 in conjunction with the 17th VOF and 43rd SC meetings.

3. Report by WOAH on their activities concerning Veterinary Medicinal Products (VMPs) since the last Forum

The WOAH briefly summarised the report (link) focussing on the activities of WOAH on VMPs since the last VOF meeting.

The presentation details:

- WOAH 7th Strategic Plan 2021-2025
- Support provided to VICH by WOAH (update)
- Promotion of VICH and VOF activities in connection of the Focal Points seminars, CODEX and Quadripartite alliance
- Activities and meetings with WOAH involvement of potential Interest to VICH

4. VOF Topics – Stability of vaccines

USDA took the participants (link) through the background, the historical practices and the current policy in the USA with regard to the stability of veterinary biological products. USDA listed the stability criteria and detailed the Stability Study Requirements currently in place.
The EU detailed (link) the approach to the stability of vaccines in place in Europe and pointed out that GL 3 (Stability testing of new drug substances and products) does not cover the specific identities of biologicals, as it is more pharmaceutical orientated, so that the assessors are mostly following GL 17 (Stability testing of new biotechnological/biological products).
JMAFF highlighted (link) the points to consider regarding the stability of vaccines in Japan and indicated that Japan does not have any supplemental GL specifically for vaccines. It was suggested that VICH could develop a supplemental GL for vaccines.

Uganda questioned how to handle applications for imported biological products (for example manufactured and licensed in the USA) which only provide information on potency. USDA confirmed that the importing country can request any additional data needed on stability.

Zimbabwe mentioned that the regulators can assess a number of other parameters of the registered products, not only the potency. Moreover authorities from third countries can also consult other countries' assessment reports when these are publicly available.

USDA indicated that other characteristics of the product, for example chemical or physical tests, shelf life etc…, can be assessed in case a problem appears with the use of a biological product in the field.

It was questioned if the stability testing is also mandatory for vaccines packed in multidose bottles. USDA replied that it is mandatory for new products, but the data may also be requested for older products.
In the EU the applicant needs also to provide data on the shelf life for multidose products.

Sindan reported that Brazil is in the process of harmonising the requirements for the stability of biological products with the GL. A consultation period with stakeholders is ongoing and should be finalised in 2023.

5. Discussions in breakout groups

Not applied

6. Reporting back to plenary on outcome of group discussions

Not applied

7. Information from Outreach Forum members

7.1 Presentation of the Veterinary Zazibona SADC work sharing (harmonisation) initiative

Dr Makoni explained (link) that the Zazibona is a collaboration in assessments and GMP inspections for medicines registrations; it was built on the SADC - Southern African Development Community Collaborative Medicines Registration Initiative on regulatory harmonisation of human medicines which started 2013 and continued in 2017 with the joint GALVMED/OIE Workshop's recommendations for veterinary medicinal products https://rr-africa.woah.org/wp-content/uploads/2000/11/recommandations.pdf
The work sharing platform within SADC Member States aims to conduct joint:
- Assessments of Dossiers for VMPs
- GMP inspections of Manufacturers of VMPs
- Pharmacovigilance activities of VMPs
- Other: collaborate to curb circulation of SFs

The member countries are Botswana, Namibia, Malawi, South Africa, Tanzania, Zambia and Zimbabwe.

Zimbabwe confirmed that some countries have agreed that industry can use the CTD format in dossiers coming from India or European countries. These dossiers are easily converted into the CTD format and the regulators have benefitted from several training sessions regarding the technical requirements. WOAH congratulated Zimbabwe for the progress made, how implemented the recommendations into practice.

7.2 Presentation of the EAC mutual recognition system initiative

Dr Ayoyi detailed (link) the Mutual Recognition Procedure put in place by the East African Community countries. The MRP initiative provides for the adoption of a common mechanism to ensure safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines. This harmonisation is applied to requirements, procedures and standards, so that they are the same across regions/countries, representing a clear advantage for both industry and regulatory bodies that agree to cooperate.

WOAH encouraged the EAC to continue using the good regulatory practices from WHO and to operate within the nine principles of good regulatory practices (GRP) outlined by WHO.
The EAC confirmed that if an application is rejected, the authority asks the company to comply with the WHO GRP.

7.3 Presentation of the national system in Botswana

Dr Ravengai presented (link) the general evolution of medicines regulation in the country and pointed out that the Botswana Medicines Regulatory Authority – BoMRA was created in 2018 and the Veterinary officers recruited in 2019. He then detailed the national regulatory framework for VMPs as well as the legal background for the registration requirements.

AnimalhealthEurope pointed out that both Zazibona and Botswana are accepting the (human pharma) CTD format for registration dossiers. Industry does not have an issue in using this format which regulators are getting familiar with.

7.4 Presentation of the national system in Zambia

Dr Ndambasia gave on overview (link) of the regulatory system for VMPs in Zambia and indicated that regulation of VMPs for Marketing Authorisation is relatively recent.
The GLs in place to grant marketing authorisation are completed by guidances referring to VICH GLs as well as WAAVP and SADC GLs.

Dr Ndambasia confirmed that a new legislation will also enable the companies to use electronic submissions.
He confirmed that the legislation required companies to submit their dossiers through a local technical representative.
South Africa and WOAH congratulated the regulators from Zambia for the progress achieved over the past years.

Session 2: Issues of interest to Outreach Forum members

8. Specific issues

8.1 Stability of Medicated Premixes

The chair of the VICH Medicated Premixes EWG presented (link) an overview of the content of GL 8 - Stability testing for medicated premixes and gave an insight on the revisions currently under discussion in the EWG. Outstanding issues still under discussion are

- Inclusion of all medicated premixes or “new substances and VMP”
- Liquid premixes
- Stability testing conditions
- In use stability
- Packaging material

As a next step, the EWG may address:

- Additional considerations on analytical method validation and sampling methodology
- Additional guidance on homogeneity and segregation!
- Additional guidance on pelleting/extrusion stability?
- New suggestions
    - Concurrent use of veterinary medicated premixes
    - Mixability/dissolution of liquid medicated premixes in the intended matrix

It was asked which is the scope of products covered by this GL.
AnimalhealthEurope confirmed that each country has its own legislation and defines which substances are covered by this GL. For example, in the EU the coccidiostats are not covered, but these are authorised in other countries around the world.

9. VICH Anthelmintics GLs

The chair of the VICH Anthelmintics EWG presented (link) a summary of the revisions that have been made in the 9 VICH anthelmintics GLs. These draft revised GLs have been circulated during 6 months for a public consultation period that has just ended. The EWG will consider carefully each comment received and will prepare a final draft of the 9 revised GLs for approval by the VICH SC and implementation in the course of 2023.
Ukraine asked if the EWG has considered including provisions related to the possibility of resistance.
FDA replied that these GLs address only the efficacy of anthelmintics, and the experts did not address the resistance issue.

Session 3: Discussions and conclusions

10. Feedback from the VOF pre-meeting

Saudi Arabia reported that this pre-meeting enabled an open discussion on the needs of VOF members who attended physically as well as remotely.

A list of questions with main discussion topics prepared by WOAH was shared prior to the meeting.
In general the participants suggested that this meeting should be longer (a full day?) and more structured with a detailed agenda. WOAH reflected that due to the fact that this was the first opportunity to explore the challenges and needs in an informal way, no agenda was prepared and only some basic questions were put forward. An agenda will be prepared for the next meeting including an open question on the nomination and duration of the chairmanship.

It was suggested to receive an overview of the VICH GLs in place.

The participants recommended the development of a database including the details of all VOF members (names and e-mails) accessible on the VOF members only webpage.

It was also suggested to set up a database indicating if the VOF countries are following the VICH GLs or their own GLs.
The Secretariat confirmed that a VICH GLs implementation tracker will be circulated shortly to all VOF members
Regarding the VICH GLs, the participants highlighted the challenge of the language barrier and, when translations are available, the lack of quality of some documents.

The participants also took note of the lack of feedback from the training sessions organised by VICH, but highlighted again the important need for training which is very important for VOF members, also on non-VICH topics.
The virtual training sessions have shown important challenges such as the time differences, the difficulties to log in or the lack of proper IT resources in some countries.
The participants confirmed the importance of the summary reports from WOAH and their broad dissemination to all countries.

The proposed topics for the next meeting are:

- Combo products
- Antimicrobials
- Antiparasitics
- Generics
- Withdrawal periods
- Residues

Dr L. Le Letty thanked the VOF participants for the constructive outcome of this first formal VOF pre-meeting.

11. Feedback on the meeting from Outreach Forum members: requests for next meeting and open discussion

Uganda voiced its appreciation for the webinars and online training sessions that have been organised with the VICH experts, but expressed some concerns regarding the ways to implement and apply the lessons learned.
The demonstration of case studies with “mentor authority’s’ experts would be very beneficial.
To ensure the continuity of the active VOF membership, Uganda explained that the delegates to the VOF have to report back to their organisations and have to provide a summary report which is disseminated in the organisation, and if relevant, identify action points for specific internal departments.

Uganda also proposed to make available to all on the VICH website a welcome package for new participants explaining what is available on the VICH website and where.

The EU pointed out the difficulties to organise practical training, which ideally would be in the format of an assessment training but this is impossible because of the confidentiality of data. Moreover, the VICH GLs are focussed on technical requirements only, and do not provide an assessment guide. The assessment can be different from one jurisdiction to another.

UEMOA confirmed that a pre-meeting brings an added value to the VOF meeting and suggested to discuss how the VOF members can remain active between VOF meetings.
The participants acknowledged that the needs are different between the regions.
UEMOA agreed that the VOF pre-meeting must be well prepared in advance with clear agenda topics, addressed by whom, and who will chair the meeting.

Zimbabwe confirmed the need for case study presentations by VICH to bridge gaps on specific topics.
For the review of the VICH Anthelmintic GLs, VOF members would like to receive examples that they can use to benchmark their own regulations and provide guidance to the staff in their own organisations.

It was pointed out that examples on the concepts would be easy to explain within the VOF members' agencies.
Zimbabwe believed that the GLs only explain the technical requirements, not the science that was used to define the requirements. It is therefore difficult for VOF members to understand the hidden concepts. Scientific explanations in the format of examples would be immensely helpful to all, the request being to explain the concepts only, not the full GLs.

AnimalhealthEurope recommended that the VOF members should reflect on what kind of examples they expect and for which GL. Examples on which training is needed on which GLs would be very helpful for the VICH members.
It would also help to identify the immediate needs before each meeting.

AVPMA and VMD have developed additional training material which will be made available on the training section of the website.

SINDAN reported that the Brazilian MAPA is in the process of adopting the VICH GLs and will participate more in the VOF and VICH in the near future.

Ukraine explained again the necessity of translations of VICH GLs into the local languages and requested as much as possible support from VICH industry members.

The VOF participants also appreciated the use of the Mentimeter tool for questioning during the last part of the meeting (link).

12. Conclusions and next steps

The Secretariat thanked again all participants for their attendance, in person or remotely, especially those located in other time zones.
Dr Le Letty confirmed that the organisation of the pre-meeting has been particularly appreciated by the participants in the meeting, and the SC will support further the organisation of VOF pre-meeting before the main session.
The first draft of the agenda for the 16th VOF meeting will be provided in next January.
She hoped to see all VOF members in person next year in Japan.

13. Confirmation date and venue of the next VICH Outreach Forum meetings

- The **16th VICH Outreach Forum** meeting will be held on 14 & 15 November 2023 in Japan
- The **17th VICH Outreach Forum** meeting will be held in November 2024 in Amsterdam, together with the VICH 7 public Conference.

15th VICH Outreach Forum meeting
Participants

1/ Forum members

ARGENTINA – SENASA	Luisina GARCIA SAINZ (*Remotely*)
BRAZIL – SINDAN	Luiz MONTEIRO (*Remotely*)
BOTSWANA – BoMRA	Innocent RAVENGAI (*Remotely)*
BURKINA FASO – UEMOA	Emmanuel COUACY-HYMANN
MEXICO – SENASICA	Maria Elena GONZALEZ RUIZ (*Remotely*)
MOROCCO – ONSSA	Sami DARKAOUI (*Remotely*)
MOROCCO – ONSSA	Hasnae BENALLA (*Remotely*)
MOROCCO – ONSSA	Younes EL WAHLI (*Remotely*)
NIGERIA – NAFDAC	Bukar USMAN (*Remotely*)
SAUDI ARABIA – Saudi Food & Drug Authority	Manar ALMEHAIJEEN
SAUDI ARABIA – Saudi Food & Drug Authority	Bandar ALHAMMAD
SAUDI ARABIA – Saudi Food & Drug Authority	Mohammed ALSHANQITI
SAUDI ARABIA – Saudi Food & Drug Authority	Walid ALHOMAYIN
TAIWAN – BAPHIQ	Ying-Kai CHANG (*Remotely*)
TAIWAN – BAPHIQ	Cheng-Jou CHAN (*Remotely*)
TAIWAN – BAPHIQ	Ying-Ping MA (*Remotely*)
TANZANIE – EAC	Adelaide AYOYI
TOGO – UEMOA	Aklesso PERE (*Remotely*)
UGANDA – National Drug Authority	Josephine NANYANZI
UGANDA – National Drug Authority	Pamela ABWOYO
UKRANIA – SCIVP	Yuriy KOSENKO
UKRANIA – SCIVP	Andrii OSTAPIUK
ZAMBIA Medicines Regulatory Authority	Daniel NDAMBASIA
Medicines Control Authority of ZIMBABWE	Zivanai MAKONI (*Remotely*)

2 / VICH Steering Committee

Members and (C) Coordinators

STEERING COMMITTEE (C) coordinators

AHI (ZOETIS)	C. LOWNEY
AHI (BI)	E. NORTON
AHI	R. CUMBERBATCH (C)
CVMP / CGB-MEB	J. SCHEFFERLIE
EU (EMA)	N. JARRETT (C)
ANIMALHEALTHEUROPE (BI)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)

JMAFF	K. EGUCHI
JMAFF	K. NODA
JMAFF	J. OHMORI (C)
JVPA (Nisseiken Co.)	K. TUCHIYA
JVPA	K. OISHI (C)
US (FDA)	M. LUCIA
US (USDA APHIS)	M. PAGALA
US (FDA/CVM)	B. ROBINSON (C)

OBSERVERS

Australia (APVMA)	D. SIBANDA
Canada (Health Canada)	M. BASSI
Canada (CAHI)	C. FILEJSKI
New Zealand (MPI)	K. BOOTH
South Africa (SAAHA)	M. CHURCHILL
South Africa (SAHPRA)	A. SIGOBODHLA (*Remotely*)

INTERESTED PARTY

AVBC	G. DOWELL

WOAH

WOAH	L. LE LETTY (*Chair*)
WOAH	M. SZABO

VICH

HealthforAnimals	H. MARION (*Secretary*)

GUESTS / INFORMAL OBSERVERS

VMD	G. CLARKE
Canada (Health Canada)	E. TATONE
Swissmedic (Switzerland)	N. WALSER
US FDA	E. HART
US FDA	L. ALVAREZ (*Remotely)*
US FDA	A. PHILLIPPI-TAYLOR (*16/11*)
US FDA	O. CERIC (*16/11*)

APOLOGIES

EU (EUROPEAN COMMISSION)	E. ZAMORA ESCRIBANO
JVPA (NIPPON ZENYAKU KOGYO CO.)	H. CHEE
Australia (AMA)	C. BENNETT
HealthforAnimals	C. DU MARCHIE SARVAAS
NOAH	D. MURPHY
New Zealand (APHNZ)	J. HOWE