



VICH OUTREACH FORUM
11th meeting
25 and 26 February 2019
Cape Town, South Africa

SUMMARY REPORT

Session 1: Reports and Group Discussions

1. Opening of the meeting and chairperson's introduction

The meeting was jointly chaired by Dr. Mathews Lucia, Director of the Office of New Animal Drug Evaluation, CVM FDA and Dr Jean-Pierre Orand, Director of the French agency for veterinary medicinal products - OIE collaborating centre, on behalf of the OIE.

Dr Orand opened the meeting by welcoming the participants to the 11th VICH Outreach Forum (VOF) meeting in Cape Town. He mentioned that the agenda has been slightly modified to accommodate a WebEx presentation from the FDA on Pharmacovigilance.

He regretted that the VICH Secretariat had not received much input from VOF members for the meeting's agenda and encouraged all participants to participate actively in the development of the agenda for the next VOF meeting.

At the end of this VOF meeting, each VOF member will be asked to propose 1 topic/issue for discussion at the next meeting, and to volunteer to preparing a presentation if possible.

2. Report by the SC on issues raised by Outreach Forum members during the 9th VICH Outreach Forum meeting in Tokyo in November 2017

The VICH Secretariat reported ([link](#)) on the outcome of the discussions that took place at the 36th VICH Steering Committee (SC) meeting in Bruges on the issues raised by the participants in the 10th VOF meeting. In line with the comments received, the 11th VOF agenda will cover in particular:

- An overview of VICH GL 48, followed by a breakout session and an open discussion on the withdrawal period studies and the issues encountered by VOF members for the implementation of GL 48
- An introduction by Industry on the practical aspects of the implementation of the Pharmacovigilance
- A presentation of VICH GL 30 and vocabularies, followed by a tour de table and questions on pharmacovigilance
- The building of a Regional Mutual Recognition System in the GCC
- A presentation of VICH GLs 3R training material and a discussion on the VICH Quality GLs
- Presentations of the regulatory systems in India & Russia
- The expectations of VOF members regarding the EWGs activities
- Examples of new topics raised by VOF members and participation in EWG activities

The Secretariat also presented a brief overview of the status of activity in the different VICH EWGs.

The VOF participants took note that the SC has signed off draft VICH GL 57 - MRK: Residues in aquatic species, for implementation in the VICH countries & regions.

The Secretariat confirmed that the interval between the VOF/ VICH SC meetings will be extended to a 12 month cycle from 2020 onwards, and that the future meetings will take place each year in November.

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

The OIE reported ([link](#)) on its activities on VMPs, in particular on the strong support provided by OIE to the VICH activities. OIE highlighted the importance of the dialogue between the OIE Biological Standards Commission (BSC) and the VICH Steering Committee in order to ensure proper harmonisation between the OIE Standards and future VICH guidelines related to vaccines.

OIE indicated that the 5th cycle of training seminars is completed and the 6th cycle will start in Ethiopia in July and in Togo in October.

The promotion of VOF activity topics include the prudent and responsible use of antiparasitics, minimum requirements' for PhV systems including vaccines, the identification of actions that can be done with the World Customs Organisation and relevant stakeholders in order to fight against substandard and falsified VMPs.

Nigeria asked if OIE will extend the training to the persons responsible for VMPs, but OIE replied that it cannot change its internal rules, and encouraged the national authorities to address this aspect.

4. Discussion of individual VICH Outreach Forum member questions – questions

Guidance on withdrawal period studies

The EU gave an overview of ([link](#)) the VICH Guidance on withdrawal period studies and explained that the development of the VICH GLs had been a pioneering work since hardly any national GLs existed at the time.

The harmonised GLs represent therefore the consolidation of the knowledge of the VICH experts, very widely accepted, including by CODEX.

The GLs reflect only data requirements, not the regional approach; without knowing how the generated data are handled, it is difficult to agree the study design.

5. Continued in Breakout Groups: *Withdrawal Period studies* :

- Discussion on withdrawal period topics

VOF members:

Group A: CAMEVET, India, Russia, Ukraine, Kingdom of Saudi Arabia

Group B: Singapore, Taiwan, Thailand, Zimbabwe, Kingdom of Saudi Arabia

Group C: Morocco, Nigeria, Uganda, UEMOA

Questions for discussion

1. How are withdrawal periods (WP) established for your local market?
2. Do you use withdrawal periods established elsewhere?
3. Do you use VICH GL48?

4. Is there other guidance that you use in relation to setting withdrawal periods?
5. Are there particular reasons for not using VICH GL48?

6. Reporting back to the plenary

Group A

The participants reported that:

India: has MRLs in place by Min of Health; for the withdrawal period legislation is still being worked upon

Ukraine: the EU MRLs are being followed, the withdrawal times are based on the VICH GLs

Saudi FDA: follows the EU MRLs, local MRLs can also be submitted

South Africa: follows the EU MRLs, withdrawal periods are based on local studies and according to VICH guidelines.

Russia: follows national MRLs; withdrawal period and studies are based on VICH guidelines.

Regarding difficulties faced by the different countries

Ukraine: the MRLs are set by the Min of Health and the WP by the Min of Agriculture; the process of setting up of local MRLs is still being developed.

Russia: the MRLs are set by Min of Health and the WP by Min of Agriculture but there is no process to set up a new MRL.

Saudi FDA: As the issues are being dealt by different ministries, it needs to be synchronized, better alignment is required.

South Africa: A good aligned committee, from different ministries, which works towards solving all the issues.

India: there is no veterinary Drug Authority as such, the drug regulatory authority is Min of Health which seeks technical expertise/ comments on all the veterinary products (drugs/vaccines) from the Dept of Animal Husbandry, Min of Agriculture.

Group B

Thailand: accepts VICH GLs, will accept EMEA, US FDA & Australia approved SPC; for new drug will review

Zimbabwe: uses EMEA WP and document but for generic with shortened WP, will ask for new data: using VICH GL since 2016

Singapore: the Min of Health is responsible for with WP

Taiwan: uses VICH GLs but with different animal species; accepts EMEA and FDA data, has an aquatic GL

Saudi FDA: relies on EU data and concern about lack of harmonized WP; has also special species e.g. Camel. Companies have analysis on which species approved, in which country and the ADI in that country.

Concerns exist when a product is a supplement vs a drug

Group C

UEMOA: reference to VICH GLs and WP established by international organisations

Nigeria: is in the process of developing GLs for generating residue data and establishing WPs as a pre-requisite for issuing marketing authorisations; currently refer to WP stated by applicant for imported products;

Morocco: MRL Decree published in 2018 (list of MRLs for active ingredients); adopted EU MRLs for trade reasons; can also refer to CODEX MRLs; for establishing WPs statistical or alternative approach; for imported products statistical approach (EMA GL), for local products alternative approach acceptable

Uganda: have WP GLs developed in 2007 (under review); applicants submit data generated in line with GLs for MA application; have generic applications submitting with different WPs than originating company (do not always have access to those data) => will look to authorised WPs of innovator products in other regions; EMA and CODEX MRLs used as reference

Special cases

WP for combination products: important to use the final formulation, typically analysis of both substances, however, the basis for the WP establishment is the substance with the longest depletion

Minor species: VICH recommendation is to conduct residue studies for each intended species; extrapolation out of VICH scope – not proposed within that context

Homeopathic products: active substances considered as not requiring an MRL - for Europe active compounds assumed to be safe if below a certain dilution

Injection sites: Have all EU products generated residue data to reflect the specific requirements for injectable products?

Yes, for new applications, which need to take into account new EU GLs.

No retrospective application of guidance to old products.

7. Discussion of individual VICH Outreach Forum member questions – Pharmacovigilance

7.1 Introduction by Industry: to present practical aspects from industry perspective, template ...

AnimalhealthEurope presented ([link](#)) practical aspects on how to address the Pharmacovigilance.

7.2 VICH GL 30

FDA explained ([link](#)) that the VICH GL30 pharmacovigilance data standards are vocabulary lists that pharmacovigilance end-users/reviewers use every day. FDA explained that the GL 30 vocabularies help to develop user friendly PV forms and how to capture data

8. Tour de table: open discussion & questions on pharmacovigilance

Nigeria asked for clarification on the role of OIE in the PhV => OIE is involved in the SC and supports the establishment of the VICH GLs; the technical requirements are set by VICH. OIE assists in the establishment of regulatory capabilities in the member countries.

Ukraine: asked if it would be possible to set up a database, same for all products, and same for all countries, maybe under the umbrella of OIE => regions such as the EU already progress towards a unique EU database

For the moment many different databases exist which are difficult to interconnect. In the EU the objective is to achieve a regional database which must also comply with international standards.

FDA hopes to be able to share some elements of its database that could become available to a global database.

FDA highlighted the importance of facilitating the access, communicating, educating and providing feedback to the reporters.

Common questions are for example: clarifying who can send reports, and to whom. Should reporting an Adverse Events (AE) be a legal requirement for consumers/veterinarians. What

periodicity is used for periodic summary update reports (with aggregate analyses). A deadline of 15 days to report a serious AE, is the timeline adequate?
Is an Excel spreadsheet sufficient? It is indeed as a first step

In future focal points meeting OIE will describe what is PhV and the GLs, but a global database will not be a feasible solution because it would require many resources; the work must be first done at the local level. Countries must evaluate what they can develop with their own resources.

9. Mutual recognition & national regulatory systems

9.1 GCC – Gulf Cooperation Council

Saudi Arabia is the only country which has the resources to cover a full review of products; the GCC registration council therefore bases the products' approvals on Saudi evaluations. The law of Veterinary Pharmaceuticals for the GCC, and their executive guidelines of mutual recognition (MR), are based on the Saudi Arabia legislation, and Saudi Arabia provides the necessary support to the other GCC countries.

The adoption of the GCC legislation has been very challenging and took 3 to 4 years to be finalised.

Saudi Arabia confirmed that the MR covers not only marketing authorisations, but also inspections and, in the future, pharmacovigilance. Most Gulf countries do not have the resources to do full dossiers reviews. The GCC registration council meets every 2 months to discuss the evaluation reports from the different countries.

Most GCC electronic systems are shared between human and veterinary departments, although they are separate human and vet sections in each system. Only the pharmacovigilance will be totally separated.

Until now the MR systems was shared essentially on the human side, in the Golf Health Council, but the GCC registration council has acknowledged the difference between AH and HH products. A specific vet meeting will therefore take place shortly and the sharing of veterinary dossiers should start within the next month.

The MR will also include veterinary vaccines and the Saudi lab has sufficient capacity to do the evaluations for the whole GCC region. Saudi Arabia will present the first GCC MR experience and the number of files registered to the next VOF meeting.

An active industry association is also being developed.

Saudi Arabia highlighted the importance of MR which, on the human side, has already improved the GCC region's product availability, product quality and safety, GMP and manufacturing resources, as well as the track and trace issue. It will also facilitate the future development of Pharmacovigilance in the region.

It was questioned if in the GCC there are restriction in the number of veterinary active antimicrobial substances per product. Saudi Arabia replied that there are no rules, the scientific experts review the files submitted by the companies and make their decisions to accept or reject the files.

Regarding the timelines for registration Saudi Arabia indicated that stringent timelines have been defined and meetings take place every 2 months.

Industry stressed that companies are strongly supporting such regional MR systems because they would not be able to afford to submit dossiers in all countries. MR enables companies to make products available in markets which would be too small individually. It is important to ensure that smaller countries receive assurances on GMP certification, as they do not have the capacity to visit all manufacturing sites.

9.2 Russia

The VGNKI presented ([link](#)) the Russian regulatory system, which is under the responsibility of the Federal Service for Veterinary and Phytosanitary Surveillance in the Russian Federation's Ministry of Agriculture. The VGNKI is legally authorised for the scientific expertise of risk/benefit ratio, quality, GMP inspections and certification of veterinary medicines. The VGNKI is the OIE Collaborating Centre for Food Safety, Diagnosis and Control of Animal Diseases in Eastern Europe and Central Asia, and also a member of the EAEU Pharmacopoeia Committee and of the State Pharmacopoeia Council of the Ministry of Health of the Russian Federation.

Within the next months a MR system will be put in place in the EAEU (Eurasian Economical Union), which will be similar to the one in the EU.

There are no established MRL in Russia or the Russian MRLs are lower than in other countries; VGNKI can implement the statistical approach for the establishment of WP but this approach is not widely used. Russia also takes into account the Codex MRLs.

Regarding the absence of GMP compliance from Russian inspectors, Russia indicated that it is possible to present the decision from Russian regulatory authorities to conduct the inspection for GMP compliance in registration dossier at the time of the application for a registration, but in case of refusal to confirm the GMP certificate, the registration of the medicinal product will be denied. The GMP requirement and procedures are the same for human and vet medicines.

Preselected antibiotics may not be used for prophylaxis, but can be used for surgery as it is not considered as a prophylactic usage.

Russia has a state register of all products authorised in Russia, and consumers can consult the products' leaflets.

9.3 India

India explained ([link](#)) that the Central Drugs Standard Control Organisation (CDSCO) from the national Ministry of Health and Family Welfare is responsible for the registration of veterinary products at the Central Level. Another authority EIC (Export Inspection Council) is dealing with exportations, and yet another department provides the certificates for exports of Active Ingredients.

For imported products India always requires approval dossier from the country of origin and companies must provide all the study data.

Vaccines produced by the national public sector must go through the same approvals process than the private sector.

In emergency cases, India has a system to enable urgent importation of vaccines.

10. Specific issues - Group Discussion of individual VICH Outreach Forum member questions – *Participation in Expert Working Groups:*

10.1 Expectations of VOF members along with the range of opportunities to contribute to guideline development

FDA presented ([link](#)) the background to become an Expert Working Group (EWG) member and explained the opportunities for VOF members to nominate an Expert to the EWGs. FDA further encouraged strongly VOF member countries to submit comments to draft Guidelines when these are circulated for public consultation at Step 4. It was reminded that the Secretariat sends specifically all draft GLs at step 4, as well as the final GLs at step 7, to all VOF members.

10.2 Example of taking new topics raised by VOF members and its participation in EWG: combination EWG

As an example of the close involvement of VOF members in the VICH process, JMAFF explained ([link](#)) how the SC & VOF members welcomed the Concept Paper for “Efficacy studies for combination drug products” presented by the Peoples Republic of China at the 3rd VOF meeting in November 2013. It was considered as an important topic where guidance is currently lacking.

The SC decided to create a task force (TF), including 4 VOF members, chaired by JMAFF with the mandate to elaborate a discussion paper proposing a more focused scope for the development of a VICH GL for combination products.

The TF narrowed the focus of the CP which was adopted by the SC in February 2017, enabling the creation of the EWG for a General Guideline on Pharmaceutical Combination Products, chaired by the PR China; Argentina has also nominated an expert.

JMAFF confirmed that VICH will not consider combination products containing antimicrobial substances because VICH does not encourage the future development of combination of these substances. Countries remain nevertheless free to approve new combinations of antimicrobials if they wish to do so.

OIE reminded the participants that the international standards such as OIE or FAO recommend that a clinical diagnose is made before administration.

As prerequisites to become an expert, the individual must have the required expertise in the specific field, be prepared to allocated time to the work of the EWG, participate actively in the work by electronic procedures and in teleconferences, and, if necessary, participate in EWG meetings funded by their organisation.

When invited to nominate an expert, VOF members must send an e-mail to the secretariat with the details of the proposed expert and a short CV to confirm that the nominee has the required expertise.

Each VICH organisation has the right to nominate only 1 expert, as well as an advisor in cases decided by the SC.

Session 2: Issues of interest to Outreach Forum members

11. Specific issues

11.1 VICH Quality GLs

FDA gave an overview of the different VICH Quality GLs and explained that VICH is in the process of developing training presentations to explain these GLs. These presentations will be posted in the VOF section of the VICH website. FDA highlighted the disclaimer that will be included at the beginning of each presentation.

India suggested that VICH should develop a guidance for feed additives. AnimalhealthEurope replied that a CP on medicated premixes is currently being developed by the SC. In a first

phase the scope will be defined in a Discussion Document, then the VOF members will be involved, probably at the next VOF meeting in Tokyo.

11.2 Introducing GL3R (Stability testing) training material

AnimalhealthEurope presented ([link](#)) the training material which has been developed for VICH GL3 - Stability Testing of New Veterinary Drug Substances and Medicinal Products.

Session 3: Discussions and conclusions

12. Feedback on the meeting from Outreach Forum members and requests for next meeting

The VOF members unanimously expressed their satisfaction for the quality and the level of information received during the meeting. VOF members were asked to propose topics to be developed at the next meeting.

India confirmed that important points were highlighted during this very fruitful meeting and asked to discuss the medicated feed additives at the next VOF meeting; the chair replied that this topic is however not in the scope of VICH.

Thailand has learned much about the VICH GLs which will be useful in the regulators' daily work. Thailand will provide an update on VICH at the next ASEAN meeting.

Russia has been particularly interested in the presentation on residue studies, and suggested receiving more information on Bioequivalence and the opportunities to change the studies in live animals to in vitro studies.

Singapore found the exchange of experience with other VOF members very fruitful and confirmed its intention to attend regularly the VOF meetings. Singapore will provide at the next meeting a presentation on the harmonisation of vaccines' regulation in ASEAN.

Taiwan explained that the adverse events are still reported locally on paper and suggested discussing the topic of herbal medicines at the next meeting.

Uganda has appreciated receiving the information on withdrawal periods and on the combination products GL, and suggested receiving more information on the draft stability GL for climatic zones III & IV, as well as on the topic of medicated premixes. In future meetings, Uganda recommended to allocate more time to VOF members to share each other's experience, and discuss how to improve their regulatory systems.

Saudi Arabia has been particularly interested in the sharing of the evaluation reports between countries, and suggested that ASEAN and CAMVET should provide more information on their experiences at the next meeting. Saudi Arabia will provide an update on the GCC activities.

Zimbabwe has been particularly interested in the discussion on withdrawal periods and GL 48, and suggested receiving a presentation on the capacity building of regulatory officers, as well as some guidance on processes for drug validation.

CAMEVET has learned much about PhV processes and will provide later on proposals from CAMEVET countries on their need & expectations from the next meeting.

Ukraine has also appreciated the discussion on PhV and recommended that VICH should develop not only technical requirements for clinical testing of Anthelmintics, but also for other products such as ABs. Ukraine will also provide proposals for further topics.

Nigeria recommended discussing the topic of combination products, essentially antimicrobials, and receiving criteria to assess combined formulations

UEMOA suggested receiving recommendations on how to handle files proposing the combination of 4, 5 or even 6 antimicrobial products. UEMOA will present its mutual recognition system at the next meeting.

Morocco proposed to discuss the topic of quality & stability for vaccines as well as of autogenous vaccines.

13. Conclusions and next steps

The Chairs confirmed that at the next meeting, the SC will clarify what is in the scope and what is outside of scope of VICH.

The Chairs informed the VOF members that the SC will shortly launch a survey with all VOF members regarding about organisation of meetings, the list of requests for further information and the proposed topics for future presentations.

OIE encouraged once more strongly the VOF members to provide more presentations for VOF meeting and to interact more between meetings.

OIE will circulate very soon a request for topics and presentations from VOF members to be included in the 12th VOF meeting's agenda

1 VOF member (Saudi Arabia) will participate, with OIE and 3 SC members, in the development of the next VOF agenda.

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

- The **12th VICH Outreach Forum** meeting will be held on 19 & 20 November 2019 in Tokyo, Japan.
- The **13th VICH Outreach Forum** meeting will be held on 17 & 18 November 2020 in Europe – location TBD.

| |
|---|
| 11th VICH Outreach Forum meeting Participants |
|---|

1/ Forum members

| | |
|--|---|
| <p>DOMINICAN REPUBLIC – CAMEVET</p> <p>INDIA – Ministry of Agriculture</p> <p>MOROCCO – ONSSA</p> <p>NIGERIA – NAFDAC</p> <p>NIGERIA – NAFDAC</p> <p>RUSSIA –VGNKI</p> <p>SAUDI ARABIA – Saudi Food & Drug Authority</p> <p>SAUDI ARABIA – Saudi Food & Drug Authority</p> <p>SAUDI ARABIA – Saudi Food & Drug Authority</p> <p>SAUDI ARABIA – Saudi Food & Drug Authority</p> <p>SAUDI ARABIA – Saudi Food & Drug Authority</p> <p>SINGAPORE – Agri-Food & Veterinary Authority</p> <p>TAIWAN – Council of Agriculture</p> <p>THAILAND – Department of Livestock Development</p> <p>THAILAND – Food and Drug Administration</p> <p>UGANDA – National Drug Authority</p> <p>UGANDA – National Drug Authority</p> <p>UKRANIA – SCIVP</p> <p>ZIMBABWE - Medicines Control Authority</p> <p>WAEMO/UEMOA</p> <p>WAEMO/UEMOA</p> <p>WAEMO/UEMOA</p> | <p>Virginia Devi QUINONES PUIG</p> <p>Lipi SAIRIWAL</p> <p>Hasnae BENALLA</p> <p>Yunus SADIQ</p> <p>Josef ASIKPO</p> <p>Polina LOBOVA</p> <p>Hend I. ALFINTOUKH</p> <p>Maher ALJASER</p> <p>Sultan M. ALOTAIBI</p> <p>Mazin Saadi K. FARHA</p> <p>Taha M. RAMZI</p> <p>Taoqi HUANGFU</p> <p>Ying-Ping MA</p> <p>Natthapong SUPIMON</p> <p>Chaiporn PUMKAM</p> <p>Noel AINEPLAN</p> <p>Josephine NANYANZI</p> <p>Yuriy KOSENKO</p> <p>Zivanai MAKONI</p> <p>Moumouni ABSI</p> <p>Komlan AKODA</p> <p>Maimouna SANOGO</p> |
|--|---|

Apologies

| | |
|--|--|
| <p>ARGENTINA – CAPROVE</p> <p>PEOPLES REPUBLIC OF CHINA – Institute of Vet. Drug Control</p> | <p>Carlos FRANCIA</p> <p>Shixin XU</p> |
|--|--|

Cancellations

| | |
|------------------------|-------------------------------|
| <p>UKRANIA – SCIVP</p> | <p>Ihor KOTSYUMBAS</p> |
|------------------------|-------------------------------|

2 / VICH Steering Committee

Members and (C) Coordinators

STEERING COMMITTEE (C) coordinators

AHI (ZOETIS)

AHI (ZOETIS)

AHI

EU (EUROPEAN COMMISSION)

EU (EMA)

EU (EMA)

EU (BVL) – *Guest*

ANIMALHEALTHEUROPE (BOEHR. INGELHEIM)

ANIMALHEALTHEUROPE (ELANCO)

ANIMALHEALTHEUROPE

JMAFF

JMAFF

JMAFF

JVPA (NIPPON ZENYAKU KOGYO CO.)

JVPA

US (FDA)

US (USDA APHIS)

US (FDA)

OBSERVERS

Australia (APVMA)

Australia (AMA)

Canada (Health Canada)

Canada (CAHI)

New Zealand (MPI)

New Zealand (AGCARM)

South Africa (SAHPRA)

South Africa (SAAHA – BAYER)

South Africa (SAAHA) – *Guest*

INTERESTED PARTY

AVBC

OIE

OIE

OIE

VICH SECRETARIAT

HealthforAnimals

HealthforAnimals

APOLOGIES

JVPA (Nisseiken Co.)

M. J. MCGOWAN

C. LOWNEY (for G. GOWDA / Boehringer
Ingelheim)

R. CUMBERBATCH (C)

J-N. PREUSS

D. MURPHY

N. JARRETT (C)

S. SCHEID (Chair of the MRK EWG)

B. BOENISCH

E. DE RIDDER

R. CLAYTON (C)

K. EGUCHI

K. NODA

J. OHMORI (C)

I. ABE

K. OISHI (C)

B. WALTERS

B.E. RIPPKKE (by webex)

B. ROBINSON (C)

A. NORDEN (for C. PARKER)

C. BENNETT

M-J. IRELAND

J. SZKOTNICKI

W. HUGHES

M. ROSS

A. SIGOBODHLA

E. SCHAY

M. CHURCHILL

J. THOMAS

J-P. ORAND

M. SZABO

H. MARION

C. DU MARCHIE SARVAAS

K. TUCHIYA