



VICH OUTREACH FORUM
7th meeting
21-22 June 2016
Brussels

SUMMARY REPORT

Session 1: Reports and Group Discussions

1. Opening of the meeting and chairperson's introduction

The meeting was jointly chaired by Dr David Mackay, Head of the Veterinary Medicines Division, European Medicines Agency, and Dr Jean-Pierre Orand, on behalf of OIE.

Dr David Mackay opened the meeting by welcoming the participants to the 7th VICH Outreach Forum (VOF) meeting in Brussels.

He noted that the record attendance to this meeting showed the growing interest from VOF countries in VICH activities.

2. Report by the SC on issues raised by Outreach Forum members during the 6th VICH Outreach Forum meeting in Tokyo in October 2015

The VICH Secretariat reported on the outcome of the discussions that took place at the 32nd VICH Steering Committee (SC) meeting in Tokyo on the issues raised by the participants in the 6th VOF meeting. In line with the comments received, the 7th VOF agenda will therefore provide more time for discussion (2 Breakout sessions) of topics and cover in particular:

- Implementation of the VICH training strategy
- Application of VICH GLs and acceptance of studies conducted according to VICH GLs - feedback on general approach to the use of VICH GLs
- New VICH topics:
 - o Development of guidance on stability to address climatic zones III and IV
 - o Efficacy studies for combination products
- Antimicrobial Resistance - AMR: actions taken by VICH SC members and observers related to AMR management for registration of VMPs – Veterinary Medicinal Products
- Experience from members with anthelmintics and parasiticides resistance
- Pharmacovigilance
- Updates from VOF members

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

The OIE reported ([link](#)) that at the last OIE General Session in May 2016, 3 recommendations were adopted: one for the production and quality of vaccines, one to approve two diagnostic

kits and one to recommend the OIE to compile and consolidate all its action on AMR within an OIE Strategy on antimicrobial resistance.

The OIE national focal points for VMPs trainings have continued with cycle IV in Uganda and Senegal (for English and French speaking African countries, respectively) and in Japan (for the Asia-Pacific region). This cycle will be concluded in the European region.

The OIE is also developing further its database on the surveillance, by products and classes of products, of the use of antimicrobials in animals in order to monitor the evolution of use. The OIE encourages each National Member Country to develop its own database. It can then be used as a tool to monitor the effectiveness of the OIE AMR strategy. Countries should provide as much detail as possible so that the OIE can develop recommendations for the reduction of usage if necessary.

The EU highlighted that surveillance of use of antimicrobials in Europe has been standardised through the progressive implementation of the ESVAC standardised methodology and database. The data required is currently limited to the volumes of sales at the package level. This allows analysis of total sales and sales categorised by antimicrobial class, pharmaceutical form and route of administration. Work has now started to develop systems to collect data on actual use of antimicrobials per target animal species.

India asked if the OIE and WHO plan to organise AMR seminars together. OIE replied that meetings are organised with WHO to ensure that both organisations have a coordinated One Health approach.

4. Report from SC discussions on proposed new topics for the VOF

4.1 Development of guidance on stability to address climatic zones III and IV

FDA reported ([link](#)) that discussions on the new stability testing guideline in climatic zones III and IV are ongoing in the VICH Quality EWG, which comprises also new experts from China, CAMEVET and Morocco, as well as South Africa.

The Quality EWG received informal comments from different regulators prior to the circulation of a draft guideline. Costa Rica suggested establishing a guideline for in-use stability for multi-dose injectable products but this concept is not within the scope of the current draft stability guideline.

4.2 Efficacy studies GL for combination products

JMAFF presented ([link](#)) the current draft Concept Paper created by the Task force (TF) the development of a general combination guideline and explained that the main focus of the GL will be on efficacy and, in particular, justification of the combination. Safety topics, if addressed, should only be addressed at a high level. The SC asked the VOF members to provide comments and suggestions to the draft Concept Paper by 1st December 2016 at the very latest, in order to enable the EWG to provide a revised CP before the next SC and VOF meetings scheduled in February.

The TF will update the draft reflecting the discussions and comments received during the current meeting and Secretariat will circulate the draft CP shortly with a formal call for comments.

Act: TF and Secretariat (Done)

JMAFF pointed out that the general GL will cover the general factors that should be considered with respect to all combination products. The point was made that there is no intention to develop guidance relating to combinations of antimicrobials as such guidance could be seen to be inconsistent with the aim of encouraging prudent use of antimicrobials.

If additional, specific, requirements are needed, the EWG will develop GLs for more specific types of products at a later stage.

JMAFF thanked again China for having submitted the topic initially to VICH.

5. 1st Group Discussion of individual VICH Outreach Forum member – VOF members training strategy needs and ideas for organisation

Three breakout groups were organised comprising both VOF members and SC members.

Each team designated a rapporteur and a moderator.

These groups were composed of the following VOF members:

Group 1: Uganda, UEMOA, Morocco, Saudi Arabia

Group 2: China, Korea, Thailand, Malaysia, ASEAN

Group 3: Argentina, CAMEVET, Brazil, India, Russia, Ukraine

5.1 Implementation of training strategy

FDA explained that the VICH ad hoc WG on training implementation is developing a template for training modules, starting with the topic of quality. No precise timing can yet be provided for the implementation of this module because funding needs to be available and secured beforehand.

5.2 Results of survey on priorities

The OIE presented the results ([link](#)) of the survey on the acceptance of VICH GLs in Member Countries that was circulated by the OIE to the countries as well as by HealthforAnimals to industry associations.. The results of the survey priorities showed that the guidelines of most interest are the Quality, Safety and Pharmacovigilance Guidelines (GLs). The OIE showed the extent of acceptance of the VICH GLs in the VOF countries.

It was noted that there has been significant progress regarding awareness of VICH GLs, as studies are now widely accepted when conducted according to VICH GLs, despite progress still being needed for formal adoption of VICH GLs in many countries.

China noted that the results shown in the industry survey do not reflect the current situation in China. The replies may have been provided by local companies which have misunderstood the background of the survey conducted by Industry.

China will provide an official input to the survey from the regulators' side because the country accepts VICH Guidelines (GLs) and local GLs are no longer used.

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

Each of the 3 groups focused their discussions on the VOF members' needs in terms of training and ideas for how this could be delivered.

Group 1

Group 1 emphasised the following issues:

- training modules to be proposed as regional training
- climate for drug assessment
- issue of language of the training
- mock-up for training programmes = sharing assessment reports
- onsite training

- identifying the right people for training and assessment of the outcome of the training
- cost and fees – possibility to use UN development programmes
- different training levels: for beginners etc...

Group 2

The participants in Group 2 highlighted the following topics

- Needs and ideas for training
- ASEAN works with the OIE on training sessions
- ASEAN still does not yet have the official green light from all its members
- Online training can be valuable but some ASEAN countries have difficulties with IT access (Laos, Cambodia)
- Countries are not always aware of each other's trainings
- Joint training with industry
- Target audience needs to be defined
- Need for support from donors funding
- Trainings are currently funded by OIE, FAO & WHO

Group 3

Group 3 ([link](#)) discussed the following:

- Grouping of the trainings for quality, safety and efficacy
- As quality concerns are universal, this should be the initial focus
- Training of the trainers
- Language issues
- Regulators and industry must participate together at all levels.
- Flexibility to accommodate regional requirements and priorities is crucial
- Country legal framework must be considered
- Potential benefit in offering different levels of electronic training prior to specific trainings
- Quality assurance of training modules before use, preferably by an international organisation
- Regional priorities are crucial
- In CAMEVET all the fees are paid by industry only

7. 2nd Group Discussion of individual VICH Outreach Forum member questions

These groups were composed of the same VOF members as in 5.

The topics for discussion were:

- o What more can be done to help with acceptance of VICH GLs by more countries?
- o Feedback on general approach on use of VICH GLs

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

Group 1:

The participants in Group 1 addressed the following issues

- Usefulness of the OIE survey, but incompleteness of the information
- Application of GLs is done per country
- Importance of industry involvement at all levels of training
- Language issues
- What can be done in the countries to help with the acceptance of studies based on the VICH GLs

- The OIE information on VICH activities does not always reach the right people as the veterinary focal point may not be the right person
- The OIE has to follow the official communication paths decided by the OIE member countries
- VICH has no restriction in communication

Group 2:

Group 2 addressed the following issues

- Identify and address blockages in the countries to the uptake VICH GLs; in many VOF countries this is a key issue
- What can be done to promote the uptake of the GLs
- Training facilitated by being held back-to-back with regional meetings (e.g. OIE)
- Need to understand more clearly how GLs are implemented
- Training on categorisation of different types of products containing antimicrobials would be helpful as countries may classify products differently and have different regulatory systems for different types of products (e.g. pre-mixes as medicines; medicated feed as foodstuffs; different approaches to growth promoters, where allowed)
- OIE stressed however that VICH GLs concern only premixes as these are a recognised pharmaceutical form of a medicine
- VOF countries are also concerned by how to control use of medicated feed in a responsible way so training might need to involve trainers from other disciplines such as animal foodstuffs
- A need was recognised to provide training in how VICH GLs support the authorisation of veterinary antimicrobials in line with the principles of responsible use
- Training in the application of VICH GL with respect to generics products would be important (e.g. quality, blood level bioequivalence)

Group 3:

Group 3 ([link](#)) addressed the following topics:

- All VOF countries are ready to use VICH GLs, but there are differences in priorities between countries
- There was a mis-conception that VICH GLs are relevant only for new products, whereas there are often many generics on the local markets of VOF countries.
- Regional experience is very helpful for VOF countries
- Factors influencing the acceptance of VICH GL
- Topics of interest: Residues, safety and efficacy, AMR
- Possible conflict with existing local GLs
- In Brazil VICH GLs are accepted for new products, but not for generics

IFAH-Europe pointed out that many VOF countries already accept studies based on VICH GLs, but it would be helpful that these countries inform industry beforehand i.e. indicate the acceptance on their websites.

9. Registration systems in

- *Saudi Arabia*

Saudi FDA reported ([link](#)) on their Veterinary Pharmaceutical Legislations and Marketing Authorization Application (MAA) system, and pointed out that only 15% of VMPs are produced locally.

The local importance of the Gulf Council Countries (GCC) in the development of veterinary legislation was highlighted.

The participants recommended that Saudi Arabia should encourage the GCC to become a formal member of the VOF.

- *Uganda*

The representative of the National Drug Authority (NDA) described the registration system in [Uganda](#) and explained that the veterinary division has only 8 vet staff experts. All human and veterinary products' registration activities are under a common organisation which has a small veterinary unit.

Session 2: Issues of interest to Outreach Forum members

10. Specific issues

10.1 Pharmacovigilance

IFAH-Europe presented ([link](#)) the principles of Pharmacovigilance, and explained how a basic Pharmacovigilance system should be developed and implemented.

It was noted that a very similar presentation is already available in the training material on the VICH website' VOF members only page.

10.2 AMR: Actions taken by SC members and observers related to AMR management for registration of VMPs

The EU summarised ([link](#)) the problem of antimicrobial resistance (AMR) and detailed the current CVMP strategy and vision statement on antimicrobials. The aim of the measures being to balance the need for antibiotics to remain available in the interests of animal and human health with the risks to man from AMR arising as a result of the use of antibiotics in animals.

IFAH-Europe mentioned that it supports this strategy with the main objective to promote responsible use of antibiotics. IFAH-Europe also actively supports the collection of sales data as well as the objective of authorities to move towards collection of data on actual use per species. The recent establishment by the EMA of standardised units of measurement, such as Daily Define Dose for Animals, is supported as it allows generation of more comparable data. Even better will be when this data can be linked to the total biomass treated per species as collecting data only on volumes/tonnage can be misleading due to the differences in animal and human populations, and differences in specific activity of different types of antimicrobial.

JMAFF described ([link](#)) the actions taken related to risk management of AMR for livestock. These measures cover both antimicrobial medicinal products and feed additives. JMAFF has just started monitoring AMR in companion animals, at a reduced level only.

The Food Safety Commission (FSC) of the MAFF conducts risk assessments based on scientific findings in line with the assessment guideline for AMR established by the FSC. JMAFF highlighted the importance of the Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM) which has monitored antimicrobial resistant bacteria since 1999 (http://www.maff.go.jp/nval/yakuzai/pdf/jvarm_report_2012_2013.pdf).

South Africa detailed ([link](#)) the background to the AMR strategy in South Africa and explained that the South African AMR initiative started in October 2014 at a summit which brought together key stakeholders from government, laboratory services, clinician societies, civil societies and regulatory bodies. All the stakeholders have signed a commitment to support the South African AMR Strategy Framework. An implementation plan has recently been approved and published in February 2016.

10.2 Anthelmintics and parasiticides resistance - experience from members

FDA explained ([link](#)) the recent history of antiparasitic resistance and responsible use of parasiticides in the USA, and pointed out that this is a global issue for grazing livestock. Internal parasitism has a large impact on livestock owners throughout the world. FDA recommended a change in the way veterinarians and animal producers view parasites, from parasite elimination to parasite control and responsible use of parasiticides.

Session 3: Discussions and conclusions

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

It was confirmed that the VOF members wished to maintain the current structure of the agenda highlighting the very useful discussions in two different breakout sessions.

The VOF participants identified the following topics for discussion at the 8th VOF meeting:

Breakout sessions:

- Group discussion on AMR: relevant GLs and how they can be applied for AMR
- Sharing local strategies on AMR in the different countries
- AMR and Harmonisation of standards, implementation strategies, good practices
- Sharing information and experience on Pharmacovigilance
- Sharing recommendation for VOF countries on training, exchange of knowledge and results for training
- Acceptability of VICH GLs
- Sharing of info on the application of VICH GLs and acceptance of studies conducted to VICH standards in VOF countries

Training strategy and priorities:

- Organisation of back to back training with regional meetings – need to clarify expectations (contents, level of training) directed to needs (basic, proficient, advanced)
- Use increased international interest on regulation of veterinary medicines as a stimulus for training and update on VICH GLs
- Develop electronic training aids
- Both regulators and industry need training
- Train the trainer approach
- Quality assurance of training material & outcome measurement
- Priority for training on the topic of Quality

Specific issues

- Bioequivalence
- Presentation from VICH members explaining the relevance of existing VICH GLs for the assessment of generics and existing old products
- Use of VICH GLs for the assessment of premix substances
- Pharmacovigilance
- Promote translation of existing VICH GLs
- Clarify relevance of existing VICH GLs to generic products and to medicated pre-mixes
- Explain how to ensure an appropriate infrastructure within which VICH GLs can be applied (e.g. GMP)
- VICH secretariat to review communication channels to complement the official channels of the OIE

Act: Secretariat

- CAMEVET will bring items for agenda after their next meeting in November

Act: CAMEVET

- Morocco will provide topics as well

Act: Morocco

12. Conclusions and next steps

The VOF participants appreciated the selection of topics that were discussed, the quality of the presentations made and the opportunity provided by the breakout sessions for open discussions and exchange of information.

It was pointed out that in many VOF countries the Ministries of Agriculture (which are the primary OIE contacts) and of Health (often responsible for the registration of VMPs) both need to be engaged in the VOF activities.

The VOF meetings are a unique opportunity for VOF countries to exchange experience between themselves, as well as to benefit from the broad experience of VICH member countries and regions.

The OIE once more strongly encouraged VOF members to provide information from their countries to be shared well in advance of the next meeting, as well as to propose topics for discussion and presentations as soon as the first draft of the agenda will be circulated in next September.

13. Confirmation date and venue of 8th and 9th VICH Outreach Forum meetings

- The **8th VICH Outreach Forum** meeting will be held on 28 February and 1st March 2017 in Buenos Aires, Argentina.
- The **9th VICH Outreach Forum** meeting will be held on 14 and 15 November 2017 in Tokyo.

7th VICH Outreach Forum meeting Participants

1/ Forum members

ARGENTINA – CAPROVE	Carlos FRANCIA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Suzana BRESSLAU
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Barbara CORDEIRO
CAMEVET (Argentina)	Enrique ARGENTO
CHINA – Institute of Vet. Drug Control	Zhongze FENG
CHINA – Institute of Vet. Drug Control	Shixin XU
INDIA – Ministry of Agriculture	A. PRASAD
MALAYSIA – Department of Veterinary Services	Marzuki BIN ZAKARIA
MOROCCO – ONSSA	Amina ELGHAFKI
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Seong-Joon JOH
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Jihyun SON
RUSSIA – FSFI VGNKI	Igor KRAMARENKO
RUSSIA – FSFI VGNKI	Sergei BURLAKOV
RUSSIA – FSFI VGNKI	Yaroslav FEDOSOV
RUSSIA – FSFI VGNKI	Stanislav KRASULIN
SAUDI ARABIA – Saudi Food & Drug Authority	Maher ALJASER
SAUDI ARABIA – Saudi Food & Drug Authority	Taha RAMZI
THAILAND – Department of Livestock Development	Sasi JAROENPOJ
THAILAND – Department of Livestock Development	Thanabadee RODSOM
UGANDA – National Drug Authority	Noel AINEPLAN
UKRAINE – State Scientific Research Control Institute of VMPS	Yuriy KOSENKO
WAEMO/UEMOA (Burkina Faso)	Maimouna SANOGO
WAEMO/UEMOA (Burkina Faso)	Kouadjo Théodore DOMAGNI

Apologies

ARGENTINA - SENASA	Laura SBORDI
PHILIPPINES – ASEAN Bureau of Animal Industry	Maria ABENES
UKRAINE – State Scientific Research Control Institute of VMPS	Ihor KOTSYUMBAS

Speakers

US FDA	Mai HUYNH
US FDA	Aimee PHILLIPPI-TAYLOR

2 / VICH Steering Committee

Members and (C) Coordinators

AHI (ZOETIS)	Michael MCGOWAN
AHI	Kelly KLAUS (C)
EU (EMA)	David MACKAY (<i>Chairperson</i>)
EU (EUROPEAN COMMISSION)	Noel JOSEPH
EU (EMA-CVMP)	David MURPHY
EU (EMA)	Nicholas JARRETT (C)

IFAH-Europe (MERIAL)
IFAH-Europe (ELANCO)
IFAH-Europe
JMAFF
JMAFF
JMAFF
JVPA (KYOTO BIKEN LABORATORIES)
JVPA (NIPPON ZENYAKU KOGYO CO.)
JVPA
US (FDA)
US (USDA APHIS)
US (FDA)

OBSERVERS

Australia/New Zealand (MPI)
Australia/New Zealand (APVMA)
Canada (Health Canada)
Canada (CAHI)
South Africa (DAFF)
South Africa (SAAHA – BAYER)

INTERESTED PARTY

AVBC

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VICH SECRETARIAT

HealthforAnimals
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APOLOGIES

Australia/New Zealand (AMA)
AHI (BAYER)

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Bruce MARTIN

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