VICH/17021
17 May 2017
Final

VICH OUTREACH FORUM

8th meeting
28 February & 1st March 2017
Buenos Aires

SUMMARY REPORT

Session 1: Reports and Group Discussions

1. Opening of the meeting and chairperson's introduction

The meeting was jointly chaired by Dr Michael Oehlsen, Director of Policy and Logistics, CVM International Affairs, FDA, and Dr Jean-Pierre Orand, on behalf of OIE.
Dr Orand opened the meeting by welcoming the participants to the 8th VICH Outreach Forum (VOF) meeting in Buenos Aires.

Welcome by Argentina

Dr Zenobi, director of SENASA welcomed the participants to Argentina and expressed his pride that VICH has chosen Buenos Aires for its first meeting in a VOF country.
He recalled that the development of VICH was initiated in Buenos Aires as well, during the 7th ITCDVR which was held in 1992. Indeed, the important discussions which took place at that meeting had 2 immediate outcomes: the first Latin American seminar for the registration of veterinary products, which became CAMEVET in 1999, and the proposal from the representative of the USA to initiate tripartite discussions between the EU, Japan and the USA for the creation of VICH. 25 years later, VICH has returned to Buenos Aires!

2. Report by the SC on issues raised by Outreach Forum members during the 7th VICH Outreach Forum meeting in Brussels in June 2016

The VICH Secretariat reported (link) on the outcome of the discussions that took place at the 33rd VICH Steering Committee (SC) meeting in Brussels on the issues raised by the participants in the 7th VOF meeting. In line with the comments received, the 8th VOF agenda will therefore cover in particular:

- Registration of VMPs in developing countries
- Acceptance of studies conducted according to VICH GLs
- Pharmacovigilance
- Sharing of local strategies on registration of antimicrobials
- Organisation of back to back training with regional meetings: Training with ASEAN on 26 & 27 April in Brunei
- Assessment of premixes for medicated feed
- Sharing of local strategies on AMR in the different countries

- Benefits and challenges of regulatory collaborations for veterinary drug submission in Canada, Australia and NZ
- Presentation VICH GL 54 (Safety- Acute Reference Dose (ARfD))
- Registration requirements for vaccines – Strategies to implement VICH GLs
- Update on VICH topics from the VOF:
    - Development of guidance on stability to address climatic zones III and IV
    - Efficacy studies for combination products
- Updates from VOF members

Regarding the implementation of the VICH training strategy, the Secretariat highlighted the absolute need of support from the beneficiary bodies for the organisation of a local training event.

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

The OIE confirmed (link) its ongoing support to the VOF activities by liaising with Specialist Commissions, for example the Biological Standard Commission (BSC) with which there is a permanent contact on VICH matters. Recently, an information exchange on waiving Target Animal Batch Safety Test (TABST) in live and attenuated vaccines took place. The BSC had contacted the OIE Collaborating Centres in France, Russia, United States of America, Japan, and Ethiopia to solicit their comments and recommendations on this proposal.

In order to achieve greater harmonisation with the OIE Terrestrial Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual) Chapter 1.1.9 and further VICH Guidelines on Extraneous Agents/viruses the OIE Biological Standard Commission took into consideration the comments received from the VICH Biologicals Quality Monitoring Expert Working Group (BQM-EWG) when developing the revised text for Chapter 1.1.9. The BSC will continue this approach for the future revisions to the Terrestrial Manual.

After the 33nd VICH SC & 7th VOF meetings, the OIE sent a letter to all 180 OIE Member Countries with a summary of the meetings, as well as recommendations from the meetings. Invitation letters for the 8th VOF meeting were sent to the Delegates, and copied to the OIE National Focal Points for Veterinary Products and the representatives to VICH.
OIE's objectives are to highlight the VOF activities, remind the OIE position and support the participation of Outreach Forum Countries by underlining the need for sustainability.
OIE has also promoted the VOF activities during the 4th cycle of the OIE Focal Points for Veterinary Products training seminars which has been completed by the European Seminar in Budapest in October 2016.
OIE is also regularly involved in meetings which might be of interest to the VICH.

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 the guidance on stability testing in the climatic zones III and IV will be provided as an annex to the VICH Parent Guideline GL3(R). The stability testing is used to support product expiry and label storage conditions.
The second draft guideline was circulated within the EWG by the topic leader, Mai Huynh (FDA) in last November.

4.2 Efficacy studies GL for combination products

JMAFF explained (link) that following the circulation of the revised version of the Concept Paper in July 2016, several supportive comments were received from VOF members, as well as some minor suggestions, emphasising the main focus. These were reflected in the version that was finalised in February 2017.
The Task Force has finished its work by submitting the CP to the VICH SC, which has, at the 34th SC meeting in Buenos Aires, adopted the CP and decided to establish a new EWG for a General Guideline on Pharmaceutical Combination Products. The topic leader will be Dr. Crystal Groesbeck, FDA, whilst the chairperson needs to be confirmed. The SC has proposed Dr. S. Xu, China, to be the first VOF members who will chair a VICH EWG.
The Secretariat explained that each VICH full and observer member will be asked to nominate 1 expert to the EWG. Moreover, the SC has decided to ask the VOF members if they wish to nominate an expert to this EWG, as had been the case for the Task Force. The VOF experts will have the same rights and obligations as the VICH experts, and will be authorised to sign-off the Guideline at step 2.
The Secretariat will send a specific call for nominations to the VOF members.

5. 1st Group Discussion of individual VICH Outreach Forum members – members' questions

5.1.1 Feedback from good regulatory practice Workshop

IFAH-Europe reported (link) on the experience of the workshop on good regulatory practice – from the South Asian perspective, which was organised in the frame of the 5th Global Animal Health Conference in New Delhi and funded by the BMGF.
The aim of this workshop was to share knowledge and understanding of good regulatory practices and to promote further close cooperation amongst a regional network of regulatory agencies. These objectives were covered through 7 specific sessions covering the different aspects of a regulatory system for veterinary medicinal products.
The next similar event will take place in Nairobi, Kenya, on 12-14 June 2017.

5.1.2 Update of results of survey on priorities

OIE recalled (link) that the results of the survey were presented at the 7th Outreach Forum meeting, which showed that the priority topics requested were for quality, safety and pharmacovigilance related guidelines.

An additional simplified questionnaire was circulated to the European Member Countries in last October during the (4th Cycle) Regional Seminar for OIE National Focal Points for Veterinary Products to obtain answers on their needs in terms of VICH training priorities and to evaluate the level of VICH knowledge. The responses varied but were more divergent between EU and Non-EU countries.

Moreover, Montenegro, Macedonia, Armenia, Uzbekistan and Georgia showed interest to potentially join the VICH Outreach Forum.

5.2 Registration of VMPs in developing countries - acceptance of studies conducted according to VICH GLs

Two 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: Brazil, Morocco, Saudi Arabia
Group 2: Argentina, Thailand, Ukraine & CAMEVET

Argentina introduced the topic (link) by highlighting the differences between developing countries and VICH member countries in the registration requirements of veterinary products. The acceptance of studies conducted according to VICH GLs is highly encouraged, with flexibility to local conditions where necessary. As general models, the VICH guidelines are recognised and recommended by authorities for product development studies required for registration. However specific epidemiological situations, as well as different production systems , may create the need for local studies and sometimes the creation of local guidelines. The language may also be an issue, as translations of technical GLs are difficult.

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

Each of the 2 groups focused their discussions on the differences with VICH member countries and the acceptance of studies conducted according to VICH GLs.

Group 1

The participants in Group 1 reported that:

- As there are not many food producing animals in Saudi Arabia (SAr), Saudi FDA accepts trials from outside of the country, although not field studies
- Vaccines have to be registered in Brazil, but studies from outside are accepted
- However, studies must be made in Brazil for antimicrobials and parasiticides
- Morocco accepts for all products studies done inside or outside of the country

Group 2

The participants in Group 2 explained that (link):

- Most countries accept the VICH GLs, although many are adapted to comply with local regulatory requirements
- Additional studies are often required locally due to regional regulatory requirements
- Even if not mandatory, some countries have issued “formal recommendation” for the use of VICH GLs
- What can be done to help acceptance of GLs
    - Encourage more countries to participate in VOF
    - Education on the similarities between local GL and VICH GL to reduce fears/hesitations
    - More training and communication
    - Cater messaging to different audiences (regulatory policy vs. technical) to attract the attention of regulatory policy makers (i.e. OIE delegates)

The VOF participants also noted that the local industries often have the perception that VICH GLs are complicated and expensive to use; they therefore sometimes refrain from using them, preferring the local GLs which may be as stringent as the VICH GLs.

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

This questions and discussion session was taken as part of the plenary meeting.

A/ Pharmacovigilance

The first topic for discussion was pharmacovigilance, introduced by the leader of the PhV EWG, Linda Walter-Grimm (link); VOF members were asked to give a brief overview of their country’s pharmacovigilance process.

- *Does your country have a single, centralized pharmacovigilance reporting site?*

- Arg: yes; the reporting form must be filled in only by a vet and submitted to SENASA
- Ukr: yes; is trying to implement a new system according to VICH GLs which have been implemented; but still need to create the electronic system for the website
- SAr: yes; has a centralised PV system for both human & vet products and it is mandatory for the user or the applicant to report; however, for vet products no report has yet been received; SFDA will start an education programme this year.
- Bra: no PhV system implemented yet, but discussions are on-going to create the system according to VICH GLs; it is not yet mandatory to send a report
- Thai: yes; same reports for human and animals, but not mandatory
- Mor: yes; reports have to be sent to authorities but not mandatory; so only very few reports are received as vets report directly to the companies; the Moroccan PhV committee is the same for human and vet products; the Ministry of Health assesses all reports.

– *Is adverse event reporting (AER) mandatory (by regulation) or voluntary?*

Voluntary in all except SA where it is mandatory and in Thai where it is mandatory for new drugs and voluntary for old drugs. In addition:

- Arg: should become mandatory but need more resources for training and development
- CAMEVET: has a WG reflecting on the development of PhV in Latin America

– *How do reporters submit AE reports and to whom? Do they predominantly utilize paper forms, or is there an electronic reporting option (computer form or phone app?)*

- SAr: uses the same electronic system for human and vet products, but the application forms are different so different vocabulary can be used
- Ukr: will be electronic reporting
- Arg: a form is on the website to be filled in by a vet and can be transmitted electronically or by paper
- Mor: paper form only
- Thai: encourages electronic reporting, also for microbial consumption data

– *What challenges does your country experience in either obtaining information or utilizing the information you receive?*

– Thai: problem to identify who must do the report, users or vets; vets sometimes do not report the AER, mixed stakeholders
– Mor: most of the few reports received do not cover the quality, but mostly problems of storage or off label use; plans exist to train the vets to encourage them to declare AER; until now companies have never reported to authorities

– *Future implementation of PhV*

- Ukr: has no legislation yet; notifications will have to come from companies or vets and be sent directly to the agency
- Bra: plans to publish the PhV legislation next year, once the system is set up; reporting will be mandatory
- SAr: has a system in place; the channel is through companies and vets; so far it has not received many reports, but a campaign is planned to inform the stakeholders to report any adverse effect

– *What processes/systems are in place for reviewing and analyzing AE data?*

- Arg: each time a report is received (mortality), samples are taken for pathological investigation, then an onsite inspection takes place to check the batch; sometimes need

to suspend the marketing authorisation, and sometimes the MAH has to recall the product; no systematic approach but on a case by case basis
- Thai: tries to focus on the product, and to gather more information by a close monitoring

  – *Do you have an information sharing platform to communicate adverse event concerns or counterfeiting?*
- Mor: no system in place
- Arg: no platform, but communication through the website
- Ukr: not yet, but is planned
- Bra: no, only communication by paper
- SAr: only for human products
- Thai: no platform, only tracking of the Active Ingredient

  – *Are there opportunities for regional cooperation? If so, how is this being achieved in the area of PhV*
- CAMEVET: discussions ongoing in a WG
- Thai: tries to harmonise in the 10 ASEAN countries; PHV is a hot issue, which Thai tries to drive
- SAr: explained that SFDA has been chosen as the central body for the registration of products for the Arabian gulf countries, and will address the PhV issue
- Ukr: is seeking more global cooperation

  – *Promoting pharmacovigilance – how is this being accomplished?*
- SAr: training of the stakeholders is being developed
- Arg: when an AER is registered, SENASA communicates to the vets' association
- Thai: tries to inform the stakeholders

IFAH-Europe highlighted the importance for the companies to receive the information from the authorities as well, so that they can include the AE information in their PhV databases.

  – *VICH members were asked if systems are in place to prevent counterfeiting?*
- The leader of the PhV EWG believed that some AER may indicate counterfeiting issues and there is a special code for this in VEDDRA. But these reportings tend however more towards criminal investigations.
- Australia explained that identified counterfeited products are considered as a consumer protection issue
- South Africa confirmed that when a counterfeited product is reported, the law enforcement does an inquiry.
- The EU indicated that there is no formal system to report counterfeited product as it depends on the channel through which the information is received. But when there is a detection of a counterfeit product, there is a rapid alert system between the EU Member States to coordinate the required actions.

B/ Local strategies on registration of antimicrobials

The second discussion topic covered the local strategies on the registration of antimicrobials (AM), introduced by the EU (link). VOF participants were asked to reflect on the following questions:

- *Are MRLs (or equivalent) set locally or are standards set by external countries/bodies (eg Codex Alimentarius) used?*
- *If MRLs (or equivalent) are set locally, is impact on GI flora taken into account?*

- *Is VICH GL36 used?*
- *Is VICH GL27 used as a basis for considering the potential for development of resistance in the target animal?*

- Arg: does not set MRLs, and relies on international bodies, if no Codex MRL, then the FDA or EU MRL will be considered; does not use VICH GLs, but plans to start this year the evaluation of GL 27 by experts to initiate the implementation
- SAr: uses Codex as standard, but no VICH GLs, because there is no control on AM usage in the field; would need the support from Min of Agriculture
- Bra: uses Codex as standard, but no VICH GLs
- Mor: is already using GL 36 for assessment of all vet products and will implement GL 27 soon; also uses Codex or EU MRLs,
- Ukr: MRLs are under the responsibility of the Ministry of Health, which uses Codex or EU MRLs; is working on the implementation of both VICH GLs; will set up the future legislation to prevent multicombination products including several ABs, as is the case now
- Thai: uses Codex MRLs.

- *In your country, are any of the above used to guide the risk assessment of antimicrobial resistance to public health?*
- *If not, is other guidance used?*

- Arg: is using OIE Chapter 6

- *Are antimicrobial products evaluated for effectiveness against specific microorganisms/strains?*
- *Are the specific microorganisms/strains listed in the product information?*
- *Is the dosing regimen established based on data?*
- *Does use of antimicrobials require a prescription from a veterinarian?*
- *Does product information recommend laboratory diagnosis/susceptibility testing?*
- *Is prudent use advice routinely included in product information?*
- *Do you follow particular guidance on prudent use?*

- Arg: does not evaluate effectiveness by local clinical trials unless it is a new vet drug; for old products efficacy can be supported with bibliographic data; Microorganisms are listed on the label, dose regimen are also based on bibliographic data; the prescription by a vet only is compulsory and authorities recommend often diagnostic test; prudent use recommendations are broadcasted through communications from authorities, vets etc…; a new legislation will be put in place from 2019 onwards banning the use of premixes except the medicated feed prepared on farm, as well as AM growth promotors
- Bra: evaluates effectiveness during the regulatory process; specific microorganisms are listed on the label; established dosage regimens are based on data; prescription not mandatory but legislation is in preparation; no recommendation for laboratory diagnosis/susceptibility testing; no guidance on prudent use, but it is included in the product info
- Mor: effectiveness is based on data; previously all products had a large spectrum but now regulators ask for precise data on microorganisms' susceptibility; all are on prescription only; no prudent use guidance yet
- SAr: asks for efficacy test when different microorganisms are on the same label; usually the specific microorganisms are not listed; the dosage regimens are published; no prescription yet, but it will be put in place; no prudent use guidance yet
- Ukr: evaluates effectiveness for new molecules, or new combinations of old molecules; the specific microorganisms are listed; the dosage regimens are based on data; no prescription, also not in human, but new legislation is in preparation; lab susceptibility

tests are required in big farms; no prudent use guidance but ABs are only used for treatment, banned for preventive use; prudent use GLs will be developed in the future
- Thai: has implemented good practice; implements international standards from Codex and OIE on AMR; has a new regulation to control AMR to be implemented this year: no use of combination products, unless after a lab diagnose; prescription is compulsory; there is a national 5 years action plan to contain AMR with the aim to decrease AM usage by 30% by 2021; requirement for lab tests before using Amoxicillin and Colistin in feed.

- *Is antimicrobial use allowed for growth promotion (GP) purposes in your country*

- Arg: GP banned
- SAr: GP banned
- Bra: GP allowed but some substances are banned
- Mor: will be banned in July 2017
- Ukr: GP banned
- Thai: GP banned in 2016; has established the monitoring of AM usage in human and vets together with prudent use in order to know what the usages are; using also OIE GLs to monitor the usage in animals

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

Not relevant

9. Registration systems in

9.1 Argentina

Argentina explained (link) that the registration system is based on regulations which require a lengthy administrative process to be established, amended or withdrawn. Although recommendations are not a current tool, the Regulatory Authorities are trying to promote recommendations such as VICH GLs through informal ways. It is currently being assessed how to formally recommend those valuable tools.
For registration purposes, all Vet products are considered as new products, so bioequivalence does not fit into the current registration system.

9.2 Nigeria

In the absence of the Nigerian delegate, this topic was postponed.

9.3 Benefits and challenges of regulatory collaborations for veterinary drug submission in Canada, Australia and NZ

Health Canada provided a summary (link) of a pilot “joint review” of a veterinary drug submission between the regulatory authorities of Australia, Canada and New Zealand.
In April 2016, Health Canada’s Veterinary Drugs Directorate, New Zealand Ministry for Primary Industries and Australian Pesticides and Veterinary Medicines Authority simultaneously approved a veterinary drug for use in sheep (Metacam by Boehringer Ingelheim), which was a first ever “joint review” of a veterinary drug submission. The evaluation of the veterinary drug submission was shared by the regulatory authorities. Health Canada identified the key foundational elements that supported this initiative and shared lessons, benefits and challenges learned from the exercise.

CAHI explained (link) how the trilateral assessment of Metacam for use in sheep enabled the best use of company human and financial resources, and how, with limited sales in 2 of the 3 countries, it would provide animal welfare improvements and benefits to producers.

CAHI highlighted that by jointly reviewing the submission and sharing expertise, the workload for each regulatory agency was reduced as they only had 1 data module each to assess. The 3 authorities used the Australian Boehringer Ingelheim submission and Boehringer Ingelheim Australia was the project lead and main contact. The VICH process provided an opportunity for the regulators to meet and discuss together the application and assessment processes.

The participants acknowledged the development of greater understanding of commonalities and differences in review approaches of all 3 regulators, the very strong trust building exercise and the facilitation of access to a new drug for sheep industry, a minor species in Canada. It was discussed how to quantify the benefits to companies and regulators.

The participants were informed that joint reviews are also done between Australia and New Zealand for pesticide products in ANZ, and that Canada and the USA are having a bilateral review of 12 dossiers for veterinary products.

Session 2: Issues of interest to Outreach Forum members

10. Specific issues

10.1 Assessment of premix for medicated feed - regulation in New Zealand

New Zealand described (link) the veterinary medicine and animal feed regulatory requirements in the country and explained how medicated animal feeds are managed versus animal feeds, as their risk profiles are different.

10.2 Strategic plans for the control of AMR

Argentina explained (link) that a joint resolution between the Ministry of Health and the Ministry of Agroindustry (and SENASA) has created the Argentine Strategy for the Control of Antimicrobial Resistance, establishing the national policies for the control of AMR.
A program of surveillance of AMR in animal health has been set up and involves taking faecal samples at the slaughterhouse in pigs, poultry and cattle.
The results of resistance testing will be analysed in a central database with the aim to improve knowledge on AMR phenotypes and to evaluate the impact that mitigation actions have on the prevalence of AMR.

The EU summarised (link) the CVMP strategy on antimicrobials 2016-2020 and detailed the current measures to reduce the need to use antimicrobials in animals. The EU pointed out that the CVMP's vision is the availability of effective antimicrobial medicines for the treatment of important infectious diseases of animals with, at the same time, minimum risks to animals or humans arising from their use. The CVMP has developed recommendations to reduce antimicrobial use in food-producing animals as well as measures to reduce the need to use antimicrobials in animal husbandry in the EU.
The CVMP will continue to work with the EU network agencies, international regulatory bodies and with its stakeholders to ensure harmonisation of regulatory frameworks and that a One Health approach is taken to the control of AMR.
The key messages are: Reduce, Refine, and Re-think.
The EU confirmed that the use of alternatives to antimicrobials is also considered in the frame of this strategy.

10.3 VICH GL 54

FDA explained (link) that the recently implemented GL 54 (General approach to establish an Acute Reference Dose - ARfD) addresses the nature and types of data that can be useful in determining a toxicological acute reference dose (ARfD) for residues of veterinary drugs, the studies that may generate such data, and how the ARfD may be calculated based on these data.
FDA also pointed out that this GL does not address when an ARfD would or would not be appropriate to address the concerns of a national or regional regulatory authority, the evaluation of specific pharmacological or toxicological adverse effects that may lead to the determination of an ARfD or routes of human exposure to veterinary drugs other than the oral route.
FDA then detailed the stepwise approach recommended by the GL to set an ARfD.

10.4 Registration requirements for vaccines – Strategies to implement VICH GLs

JMAFF described (link) the dossier requirements for veterinary vaccines in Japan and the strategies developed to implement the VICH GLs. VICH has developed at least 6 GLs exclusively for vaccines, whilst the Good Clinical Practices (GCP) and pharmacovigilance GLs also cover vaccines.
JMAFF pointed out that additional guidelines (e.g. quality) can be applied for veterinary vaccines and recommended that each VOF country should evaluate which VICH GL could improve the registration of vaccines in their country.

10.5 Introduction to VICH 6

The VICH Conference will take place on 6 & 7 February 2019 in Cape Town – South Africa. The participants received the presentation made by South Africa (link) and reviewed the first draft of the programme that was proposed. South Africa will circulate a revised/updated draft before the summer.

Session 3: Discussions and conclusions

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

The breakout sessions had been organised either in small groups and subsequent reporting back to the plenary, or a continued discussion in the plenary meeting with introductory presentations. The VOF members did not establish a clear preference for one system, as each had advantages and disadvantages, and different topics may be better suited to one or the other system. For the small groups' discussion, it was suggested that more time be given to the groups to prepare their reports with a summary provided on 1-2 slides.

The VOF participants identified the following topics for discussion at the 9th VOF meeting:
Breakout sessions' discussions

- Experience from VOF countries with vaccines' registration
- Discussion on the benefits of international cooperation on regulatory requirements

AMR

- Monitoring of Antimicrobials consumption
- Presentation from OIE of the global data base on use of Antimicrobials OIE and report on the first round of information collection
- Alternatives to Antimicrobials
- Implementation of GL27

- Ukraine will propose a Discussion Document for a new GL on on good clinical practices for usage of Antimicrobials

Act: Ukraine

Regional collaborating systems
- Presentation by regional organisations - CAMEVET, GCC, ASEAN, West African Economic and Monetary Union (WAMEU), SADC
- Mutual cooperation systems between VICH members
- More group discussion how collaborations could be developed, what are the pros and cons, …

Vaccines
- Different ways VICH members register vaccines
- Vaccines stability
- Immunogenicity studies

Pharmacovigilance
- Global electronic system and database for the collection of AERs
- Sharing the PhV data

Acute Reference dose
- More explanation on difference between withdrawal times - Different approach on management of injection site residues

Other topics
- Presentation by SAr on the new centralised regulatory process for the 6 Gulf Cooperation Council countries (GCC)

12. Conclusions and next steps

The OIE once more strongly encouraged VOF members to provide information from their countries on specific agenda items 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.

It was noted again that both approaches for the breakout sessions were appreciated: small groups are easier for a constructive dialogue, whilst discussions in plenary enable to receive responses from all VOF members and to share experience more broadly.
The participants recognised that technical topics may be more adequate for exchanges in a plenary discussion, whilst more general topics generate better discussions in smaller groups. Both approaches will therefore be maintained for the next VOF meeting.

13. Confirmation date and venue of 9th,10th and 11th VICH Outreach Forum meetings

- The **9th VICH Outreach Forum** meeting will be held on 14 and 15 November 2017 in Tokyo.
- The **10th VICH Outreach Forum** meeting will be held on 26 & 27 June 2018 in Belgium.
- The **11th VICH Outreach Forum** meeting will be held on 5 & 6 February 2019 in Cape Town, South Africa.

8th VICH Outreach Forum meeting
Participants

1/ Forum members

ARGENTINA – CAPROVE	Carlos FRANCIA
ARGENTINA - SENASA	Laura SBORDI
ARGENTINA - SENASA	Federico LUNA
ARGENTINA - SENASA	Carlos Roberto ZENOBI
ARGENTINA – SENASA	Cristina FRANCO
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Pauline MARTINS DA CUNHA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Barbara Agate BORGES CORDEIRO
CAMEVET (Argentina)	Enrique ARGENTO
MALAYSIA – Department of Veterinary Services	Isa KAMARUDIN
MOROCCO – ONSSA	Elaounia KABDI
SAUDI ARABIA – Saudi Food & Drug Authority	Maher ALJASER
SAUDI ARABIA – Saudi Food & Drug Authority	Mohammed AL-ARIFI
THAILAND – Department of Livestock Development	Porjai RATTANAPANADDA
UKRAINE – State Scientific Research Control Institute of VMPs	Yuriy. KOSENKO
UKRAINE – State Scientific Research Control Institute of VMPs	V. MUZYKA

Speaker

US (FDA)	Linda WALTER-GRIMM

Apologies

AGRI-FOOD & VETERINARY AUTHORITY OF SINGAPORE	Chee Wee LIM
AGRI-FOOD & VETERINARY AUTHORITY OF SINGAPORE	Wai Kwan WONG
CHINA – Institute of Vet. Drug Control	Shixin XU
NIGERIA – NAFDAC	Bukar Ali USMAN
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Jihyun SON
TAIWAN – Council of Agriculture	Cheng-Jou CHAN
TAIWAN – Council of Agriculture	Tsung-Fa HSIEH
UGANDA – National Drug Authority	Noel AINEPLAN

2 / VICH Steering Committee

Members and (C) Coordinators

AHI (ZOETIS)	Michael MCGOWAN
AHI	Kelly KLAUS (C)
EU (EUROPEAN COMMISSION)	Noel JOSEPH
EU (EMA-CVMP)	David MURPHY
EU (EMA)	Nicholas JARRETT (C)
IFAH-Europe (MERIAL)	Brigitte BOENISCH
IFAH-Europe (ELANCO)	Erik DE RIDDER
IFAH-Europe	Rick CLAYTON (C)
JMAFF	Yuko ENDO
JMAFF	Ken NODA
JMAFF	Takashi KOZASA (C)
JVPA (NIPPON ZENYAKU KOGYO CO.)	Izumi ABE
JVPA	Hirotaka MAKIE (C)
US (FDA)	Bettye WALTERS
US (USDA APHIS)	Byron RIPPKE
US (FDA)	Brandi ROBINSON (C)
US (FDA)	Michael OEHLSEN (*Chairperson 34th SC*)

OBSERVERS

Australia (AMA)	Benjamin STAPLEY
Australia (APVMA)	Matthew O'MULLANE
Canada (Health Canada)	Mary Jane IRELAND
Canada (CAHI)	Jean SZKOTNICKI
New Zealand (MPI)	Warren HUGHES
New Zealand (AGCARM)	Mark ROSS
South Africa (DAFF)	Alice SIGOBODHLA
South Africa (SAAHA – BAYER)	Ernest SCHAY

INTERESTED PARTY

AVBC	John THOMAS

OIE

OIE	Jean-Pierre ORAND
OIE	Maria SZABO

VICH SECRETARIAT

HealthforAnimals	Hervé MARION
HealthforAnimals	Carel DU MARCHIE SARVAAS

APOLOGIES

AHI (BAYER)	Bruce MARTIN
JVPA (KYOTO BIKEN LABORATORIES)	Eiji OISHI