International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VICH/18034
28 September 2018
Final

VICH OUTREACH FORUM

10th meeting
26 and 27 June 2018
Bruges, Belgium

SUMMARY REPORT

Session 1: Reports and Group Discussions

1. Opening of the meeting and chairperson's introduction

The meeting was jointly chaired by Dr Isaura Duarte, Head of the Veterinary Medicines Department at the European Medicines Agency, 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 10th VICH Outreach Forum (VOF) meeting in sunny Bruges. He pointed out that the agenda has been slightly modified to accommodate a WebEx presentation from the USA on Bioequivalence.

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 35th VICH Steering Committee (SC) meeting in Tokyo on the issues raised by the participants in the 9th VOF meeting. In line with the comments received, the 10th VOF agenda will cover in particular:

- An overview of the anthelmintics GLs and a discussion session on issues encountered by VOF members for the implementation of the GLs
- A breakout session on the roles and missions of VICH, Codex and OIE, and in particular on what is in the scope of VICH, and what is not…
- The Regional Mutual Recognition System in Africa and the EAC Experience
- A presentation of VICH GLs 3 & 8 followed by a discussion on medicated premixes and on the needs from VOF members
- A review of the minimum requirements of Pharmacovigilance and how to keep a system simple
- A WebEx session organised by the FDA on Bioequivalence and how to use VICH GL 52
- An overview of the Metabolism and Residue Kinetics GLs

The Secretariat also highlighted again the active role of VOF members' experts in different EWGs' activities.
The VOF participants took note that the draft VICH GL 58 - Stability: Climatic Zones III and IV will be released for a 6 months public consultation period after the SC meeting, and that the SC has signed off draft VICH GL 56 - MRK: Residues in Honey 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.

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. It was noted that the OIE Biological Standards Commission (BSC) has elected a new chairman.
The OIE described the numerous activities of promotion of VICH activities, in particular during the OIE Focal Points for Veterinary Products training seminars.
The OIE also listed the new resolutions adopted in the sector of VMPs by the World Assembly of OIE Delegates during their 86th General Session in May 2018.

4. Mutual recognition system in Africa

Uganda reported (link) that a mutual recognition system in the East African Community (EAC) was created following the workshop for African regulators organised by GALVmed in Cape Town in 2010 and is composed of Burundi, Kenya, Rwanda, Tanzania, Uganda and South Sudan, which just joined. At the 2010 workshop a strong desire was expressed for development of a harmonised registration system for immunological products, for training of regulators in registration of veterinary vaccines and for the establishment of a system of Mutual Recognition.
The EAC Technical Working Group has developed harmonised documents and training on dossier preparation (aimed at vaccine manufacturers), dossier assessment and GMP inspection. The EAC has also held numerous technical workshops.
The EAC has 2 types of Mutual Recognition Procedures (MRP): one for new product applications and one for the expansion of existing Marketing Authorisations, and is progressing well towards an extended MRP. The first product (poultry vaccine, IB H120 strain) was approved under this system on 1st June 2018. The Pan African vaccine center is in charge of the quality assurance of the product.

Responding to questions about the difficulties encountered, Uganda explained that the biggest hurdle was ensuring that national registration fees were received and the issue of common labelling of the products, as official languages in the EAC include English, French and Swahili. The EAC had also to review the technical capabilities of each country. All EAC members are now supporting and are aligned for the fast application process.

The EAC has already a mutual recognition system for human medicines in place and other African communities have shown interest in the EAC process for veterinary medicines, such as SADAC countries where there is also a system in place for human medicines and there are initiatives to establish a system for veterinary medicines.

Uganda explained that the countries participate in the procedure only if they have the vaccines' strain that is used in the product in their country. Uganda confirmed that for veterinary medicines, the VICH GLs are mostly used as the international references. Regarding the capacities of testing sterility, potency etc… the EAC uses the Pan African veterinary vaccines Centre (PANVAC) of the AU in Ethiopia, but Uganda intends to create its own lab.

5. Discussion of individual VICH Outreach Forum member questions – Anthelmintics GLs

The EU gave an overview of (link) the VICH guidelines on Efficacy requirements for Anthelmintics, and covered general considerations, study design and the efficacy calculation methodology and explained that minor use/minor species and resistance are out of scope of the VICH GLs.

6. Tour de table discussion & questions on anthelmintics

To initiate the discussion, the following questions were posed to the VOF members:

1. *Do you assess the efficacy of Anthelmintics in your country?*

Zimbabwe indicated that it does not request local studies for anthelmintics, only for ectoparasiticides and requested information on the recommended number of animals for a clinical control group to evaluate the efficacy of products.

Morocco asked if efficacy testing is mandatory in the EU, and the EU confirmed that it is.

Argentina explained that all products, generics and NCE (New Chemical Entities), are assessed, mostly based on VICH or CAMEVET GLs but questioned the need for at least one local study as this means repeating studies.
The EU pointed out that although studies performed according to VICH GLs are recognised internationally, national/regional conditions may mean that a study performed in one country/region is not relevant to the conditions in a second country/region. However, the requirement for a local study can be waived if there is adequate justification (eg, if the conditions are sufficiently similar to those in the country where a study has already been performed).

Brazil confirmed that local clinical trials are mandatory, as the country is very large. Brazil is in the process of revising its requirements for registration of anthelmintics and is using the VICH GLs as a basis for the new legislation under development. Brazil mentioned that hemoparasites are particular to Latin America as they exist nowhere else.

Australia indicated that different clinical trials may not be needed in “similar” regions, but the acceptance of the extrapolation from one region to another is a case by case decision and will depend on the assessor. All VICH GLs indicate that deviations are acceptable with appropriate justification, depending however on the assessor’s final opinion.

Thailand does not apply local GLs or VICH GLs for marketing authorisations, only for post marketing surveillance.

Taiwan has local GLs for efficacy, but these are different from the VICH GLs.

In *Korea* it is not mandatory to use VICH GLs as Korea has national GLs to test the efficacy of drugs, which are different from the VICH GLs.

In *Nigeria* the authorities consider that veterinary drug registrations should comply with the VICH GLs. Nigeria is however not able to require clinical trials for pharmaceutical products before registration because of a lack of resources, so the companies may submit the results of trials done in other countries.
No trials are requested for vaccines either because of the number of animals that would be required for the tests.

The authorities are however concerned to maintain the efficacy of antibiotics in the country and have therefore decided not to register new antibiotic products for livestock production.

2. *Do you apply VICH GLs for the assessment of Anthelmintics?*

Brazil will include the GLs in its new legislation, with slight amendments required by the legal advisors, although the technical basis of the GLs will not be changed.

Argentina applies strictly the GLs for the registration of NCEs but is more flexible for generic products. Local trials may not be necessary for pets because pets are similar around the world so repetitions of studies are unnecessary.

3. *Do you have local guidance in your country in addition to VICH Anthelmintics GLs?*

Korea uses lower numbers of parasites in control groups, and only 4 animals per control group.

Taiwan requests 10 animals for each group of clinical trials, except for poultry where 20 are requested.

In *Ukraine* the applicant must demonstrate the efficacy for new molecules, new combinations and new formulae; VICH GLs or any other GL can be used. If it is demonstrated that the product has a well-established use in another country, the application can be based on literature only. The marketing authorisation holder needs to prove that there is a product already authorised in another region.

Morocco does not have a specific approach for anthelmintics, which are considered as any other drug.

Thailand has specific post marketing assessments of resistance, but mainly for antimicrobials, which are a priority for the moment.

7. Specific issues

- **Medicated Premixes GL 3 + 8**

JVPA presented (link) the background and the current status of the VICH Quality GLs and explained the relation between VICH GL3 and VICH GL8.

- **Medicated Premixes and VICH**

AnimalhealthEurope explained (link) that the objective of developing new guidance would be to provide more technical information on the studies required to demonstrate the quality and stability of medicated premixes, to supplement GL8.
The VICH Steering Committee has created a subgroup to review the current premix regulations in the VICH regions and to propose the scope of further guidance on medicated premixes. A decision on further work will be taken at the next Steering Committee meeting.
AnimalhealthEurope asked VOF members to provide their questions and suggestions to the SC subgroup.

Zimbabwe pointed out that developing countries are facing many challenges, in particular specific stability issues of medicated feed, although these are outside of the scope of VICH.

Thailand confirmed that this topic is important for Asia, because this continent uses high concentrations of premixes in feed compared to the EU, Japan and the USA resulting in high levels of active substance administration, although regulators are trying to reduce the concentration.

Saudi Arabia asked why medicated feed are separated from premixes. AnimalhealthEurope replied that in many countries/regions these are covered by different jurisdictions and different legislation.

The SC will provide more information to the VOF members at the next meeting once the subgroup will have defined the scope of any guidance that could be developed.

- Pharmacovigilance (PhV)
AnimalhealthEurope presented (link) an overview of the 5 existing pharmacovigilance GLs and explained how these pharmacovigilance GLs should be used. AnimalhealthEurope also listed the replies to 10 common questions posed on these GLs.
It is important to understand that non-VICH countries can save resources when they align on these VICH international standards.

Zimbabwe reported that it is in the process of adopting VICH GLs 24, 29 & 30 and that the process will be facilitated now that the reporting forms have been clarified by the presentation.

Taiwan asked if the Adverse Event reports are shared with non-VICH countries. AnimalhealthEurope replied that the GLs require reporting to the VICH countries but many other countries are already requesting these summary reports.

8. Discussion on scope & missions of VICH & the VOF

- **The role of Codex**

OIE introduced (link) the structure of the organisation and explained its mission and role in the context the zoonotic threat. OIE then described the Codex Alimentarius which is a collection of food standards, guidelines and codes of practice developed by the Codex Alimentarius Commission.

- **VOF, ToRs Missions of VICH**

JMAFF presented the role & mission of VICH and highlighted also what is not the role of VICH, in particular to provide guidance to establish regulatory systems and regulations for marketing authorisations, to make final decision on which studies are necessary to obtain a marketing authorisation etc… which are typically the roles of national competent authorities and governments.

9. Discussion on scope & missions in breakout groups
3 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 A: Taiwan, Argentina, Morocco, Thailand
Group B: Brazil, Nigeria, Korea, Zimbabwe
Group C: Brazil, Uganda, Ukraine, Kingdom of Saudi Arabia

The issues for discussion were:

- VOF members' expectations
  - From VOF meetings

- From EWG participation
  - Recommendations for future meetings
  - Ideas for how “out of VICH scope” topics could be addressed

The outcome of these discussions is reported under point 12, below.

10. VICH 6 Conference

South Africa encouraged all VOF members to return their accommodation booking form to the VICH Secretariat (Sophie) as soon as possible following receipt from the VICH Secretariat.
South Africa presented (link) the logistical information for the registration to the VICH 6 Public Conference and stressed the need to book very early.
The Conference webpage is: www.vich6.co.za

Session 2: Issues of interest to Outreach Forum members

11. Specific issues

11.1 Metabolism and Residue Kinetics

The EU gave an overview (link) of the 4 original VICH Metabolism & Residue Kinetics (MRK) GLs as well as the 2 more specialised ones on residues in honey and aquatic species. The presentation was ended with several questions to the participants on the local standards and withdrawal periods in the VOF countries.

Brazil confirmed that the VICH MRK GLs are used in the country; legal questions may pose some problems because these GLs are not transposed as an official regulation.

In *Nigeria* there is no need to label withdrawal periods for honey, and the marker residues may not be the same as in VICH countries, as environmental conditions may influence the choice of marker residue.

Saudi Arabia confirmed the use of the MRK GLs but questioned why there is a big difference in the withdrawal periods, for example of ivermectin in meat which is 6 days in Europe and 14 days in the USA for the same product.
The EU explained that the VICH GLs provide harmonised data requirements and provide information on the studies to be undertaken. However, there is not a harmonised approach to the assessment of the resulting data. In the EU and the USA, authorities use different assumptions and models to evaluate the data and consequently the resulting withdrawal periods may be different.

Thailand explained that some molecules can still be used without withdrawal periods although they have high residues in tissues such as kidney and asked if the VICH GLs address this.
The EU responded that the guidelines do make provisions for such cases as they indicate that, if there is the intention to market a product in a region where tissues other than muscle, fat, liver and kidney are routinely eaten, then it is appropriate to sample these tissues. The relevant Competent Authority can then take these data into account when setting withdrawal periods and so ensure that consumer exposure remains below the Acceptable Daily Intake.

Argentina explained that most Latin American countries use Codex MRLs or other countries’ MRLs when Codex MRLs are not available, so GLs 46 & 47 are not used in Argentina. The Latin American countries use a CAMEVET GL for residue depletion studies, which is identical to VICH GL 48, with some small additions to address some topical products with a local use.

The CAMEVET GL on analytical methods also slightly differs from VICH GL 49. The Honey GL is used with EMA references.

Nigeria uses sometimes the MRK GLs, essentially for antimicrobials used in food animals.

The EU then showed an additional slide on GL 36 (on the microbiological ADI) and explained that at the last VOF meeting, interest was expressed in relation to the link between withdrawal periods, the microbiological ADI and antimicrobial resistance. The main concerns relating to antimicrobial resistance and veterinary medicines relate to resistance development in treated animals and transfer of that resistance to humans (via food or direct contact).

GL27 (information with respect to potential antimicrobial resistance development) is relevant for minimising resistance development in the treated animal. On the other hand, GL 36 is not relevant for minimising risk of transfer of resistance from treated animals to humans. GL 36 relates to microbiological effects that occur in humans as a result of exposure to residues (as opposed to exposure to resistant organisms). The withdrawal period should be sufficient to ensure that residue levels are too low to have relevant microbiological effects in consumers but this does not tell us anything about the risk of transfer of resistant organisms.

11.2 Bioequivalence – how to use VICH GL 52

FDA gave by WebEx an extensive training presentation (link) on the VICH bioequivalence GL 52.

Zimbabwe asked if there exists a database of highly soluble, highly permeable APIs for medicinal products. FDA replied that this is out of the scope of VICH, but nevertheless explained that in formulations for human medicines, BE studies are required for highly soluble APIs. For a veterinary product the sponsor must choose the reference product with a reference formulation. It must be a veterinary product registered using a full data package.

Zimbabwe asked how to find out the time when a reference product was first registered. FDA explained that sometimes the reference is a “market leader” or “old product” which existed before the registration legislation was put in place. For these products FDA will ask the sponsor to provide the information on these old products to ensure they meet the current modern standards.

Thailand asked if GLP standards are required for blood level study; the reply was yes.

Saudi Arabia asked if blood level BE or additional studies are required from the applicant for NCEs. FDA explained that a NCE cannot be copied for a period of time, so a BE test for a generic product would not be accepted until the patent or the market exclusivity period of the original product is over..
AnimalhealthEurope pointed out that the BE GL can also be applied to bridge between the development of a NCE formulation used in the trials and the final formulation for registration.

Nigeria questioned if it is possible that a product does not have an expiry date. FDA replied no, only a test product, packaged solely for use in clinical trials, would have a manufacturing date without an expiry date.

Session 3: Discussions and conclusions

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

In this session the breakout groups identified under point 9 reported back to the plenary meeting.

Group A:

Group A reported that the VOF provides a good opportunity to deep dive into topics with the perspective of authorities and the perspective of industry. Participants can take back knowledge and ideas to improve the systems in their own countries.
VICH can help to build public confidence; but need to get the buy-in of local industry.
Also VOF members have a high interest in medicated feed and autogenous vaccines (topics for which no ICH GLs exist); quality of raw materials; definition of medicated premix and medicated feed.
Need to continue the education on pharmacovigilance with broader reach; VICH organisations need to help with this topic.

VOF members expectations:

- EWGs to report to VOF;
- Invite VOF country to present their local regulatory system
- PHV: information on how to encourage reporting and run systems; content and structure of annual reports; example EMA; OIE role?

From EWG and Task Force participation?

- Yes we have expectations to express the situation in our own country including specific species and breed information
- Circulation of the draft guideline to local experts (authority and industry); organisation of a discussion of content; clarification of unclear text; submission of comments to VICH
- Eager to participate in a Task Force on medicated premixes

Recommendations for topics for future meetings

- How to establish a withdrawal period
- Premixes and medicated feed (separately)
- Autogenous vaccines; Quality, Safety & Efficacy
- Invite local industry to VOF
- Reporting from EWG chairs at the VOF meetings
- Reports from countries on their local licencing systems
- Case study on authority annual report on adverse events (pharmacovigilance)
- PhV: How companies practically report to the government; how to submit specific species and breed information
- System for updating viral strains in vaccines

Ideas for how "out of VICH scope" topics could be addressed

- Report from VICH to VOF on why some topics cannot be taken forward within VICH
- Still useful to discuss these topics at VOF, for important background and to understand the different approaches and the different perspectives
- Is the topic appropriate to be addressed by an OIE National Focal Point training seminar; such as medicated feed and annual reports on pharmacovigilance?
- Create an international forum of regulators to discuss regulatory cooperation?

Group B

Group B reported that participants expected more in-depth technical discussions, although the information provided offers a great introduction to subjects

- How to use the GLs? Training
- In depth discussion on a topic, i.e. how to assess based on science, how to compile information for submission
- Bioequivalence, medicated feeds – real problems being faced in the countries
- Level of detail on anthelmintics was a good start, could have been more even detailed; more lasting learning effect

More and more innovative products are being submitted, appropriate guidance does not exist locally, expect help from VOF

Legal framework to ensure Quality, Safety, Efficacy is very important – Nigeria: emphasis is on human medicines mainly; VOF meetings can help to reinforce importance of veterinary specific GLs and adoption of VICH GLs locally

VOF members' roles

- Presenting problems faced in the countries to seek solutions and standardise them
- To be able to understand the GLs, to train the national assessors and to disseminate the information
- Move from an era without GLs at all to an era with GLs in place, information received at VOF facilitates getting there
- Understand, anticipate, comply with VICH GLs – all is connected, e.g. residues in exported food from treated animals
- Adoption of existing GLs will allow national competent authorities to focus on other priorities, e.g. enforcement in the field

Need for further guidance on:

- Homeopathics, complementary medicines, supplements
  - Emphasis on quality, safety, biomarkers
  - Must not neglect the fact that these are areas which are becoming more important as alternatives to antibiotics
- GL on probiotics – first applications being submitted as alternatives to antibiotics, GL would be useful
- Have Q&As appended to GLs for further explanation
- Abridged GLs for "grey" areas, emerging issues (e.g. GMP, antiparasitics, medicated feed)

Recommendations for future meetings

- More in-depth treatment of specific topics, understand from scientific background why GLs request certain data
  - Proposal to prepare locally with assessors what topics would be of particular interest and what the hurdles encountered are
  - Case studies would be very useful, could be proposed by the VOF member countries
- Review the existing, anticipate the future, work in groups
- VOF members to move to the next level of involvement, e.g. to participate in working groups alongside with VICH experts; OIE to play a role in bringing international experts together in working groups?
- Rotation system for chairing sub-sections of the meetings
- Prior exchange of presentations to ensure expected objectives are met

Ideas for how "out of VICH scope" topics could be addressed

- Medicated premix and medicated feed: impact is the same; both have medicinal ingredients; there should be abridged GLs to identify and describe aspects common to both; liaise with newly established feed harmonisation initiative
- Medicated additive is inside scope as opposed to non-medicated additives, same for coccidiostats

Questions for discussion
Homeopathics /supplements – why out of scope?
- Zimbabwe – usefulness of complementary medicines
- Brazil – vet meds regulations should be separated from human medicine
- US – supplements, complements – no specific regulation for it currently
- South Africa – similar situation as in US, start to see problems in the field since industry grows quickly (e.g. high levels of actives included in feed with strong claims); inadequate legal framework;
- Canada – since last year Health Canada has established a "Low Risk Program" for veterinary 'health' products (VHPs) in the absence of suitable regulation covering this product category (which are not medicines). VHPs are low risk animal health products in final dosage form (such as vitamins, minerals and traditional 'medicines'). (low risk products – acceptable substance list reviewed by Health Canada; 1100 products notified, 100 of which for food producing animals; topical, oral products only) (see https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-health-products.html
- Nigeria – imported homeopathic products; if VICH criteria were available, could be used (focus on safety/toxicological aspects)
- France - copied regulatory concepts from human side; start having problems with certain herbal medicines/oil (quality, pesticide residues, but no MRLs); increase in use of those products

Group C:
Group C reported that the expectations from VOF members are:
- Exchange of experience
- How we can harmonise the decision making for similar issues
- Share the practices for implementing the GLs in the same manner
- EWGs: VOF members want to participate with their experts from VOF countries; meetings should be held by teleconferences because of the problem of resources
- Some VOF countries have more acute problems with parasiticides and biologicals
- The local experts should determine if GLs are not applicable to some countries

Recommendations for future meetings
- Participants would like to receive feedback from each VOF members regarding the outcome in their countries; they should provide reports to the next meeting
- Worries were expressed that the 12 months' meeting schedule may prolong the meeting time on site
- The meetings could be spread between the VOF countries
- There seems to be no VOF country that uses the Environmental GLs
- Need for clarification of the responsibilities of the different agencies
- Common difficulties between countries, should organise joint meetings to solve the problems together

New topics

Guidance on the use of herbal products

13. Conclusions and next steps

A tour de table confirmed that the VOF members unanimously expressed their satisfaction for the quality and the level of information received during the meeting; they requested that the same format should be retained for the future meetings. The WebEx training presentation was also considered as very useful.
There was also a general request for more in depth information on certain topics. The OIE strongly encouraged again all VOF members to better prepare the meetings and provide requests from their countries on specific agenda items to be shared as soon as the first draft of the new agenda will be circulated in September. The OIE regretted that VOF members mostly do not provide much feedback on the agenda when requested.
The OIE suggested that the questions should be circulated for internal discussions by VOF members in advance of the meetings.

Ukraine considered that the different presentations had just the right length, with 3-4 different topics addressed.

Zimbabwe highlighted the need to further discussion on the interpretation of some GLs, and the science behind these GLs and the practical details, as for example for the electronic reporting forms in PhV. In depth explanations are very useful for the VOF members.
Zimbabwe also proposed to give the chair of certain sections of the VOF meeting to VOF countries' representatives.
Zimbabwe finally proposed that VICH should keep a record of out of scope issues/topics which have been raised but cannot be addresses for reasons to be explained.

Thailand suggested receiving more information on medicated feed and autogenous vaccines for which ICH does not have any reference; these topics are indeed important to veterinary practitioners.

AnimalhealthEurope suggested receiving at the next VOF meeting a report on the outcome of the workshop on international cooperation of regulators of veterinary medicines and the progress that was made.

The EU highlighted the fact that there are limitations and/or restrictions on what VICH can provide to the VOF members, because either the topics are outside of the VICH scope, or because there are legal hurdles in some VICH member countries/regions that prevent that country/region from supporting development of a guideline, or because VICH members have different approaches to an issue and it is considered not feasible to harmonise the approach to that particular issue.

14. Confirmation date and venue of the 11th VICH Outreach Forum meeting

- The **11th VICH Outreach Forum** meeting will be held on 25 & 26 February 2019 in Cape Town, South Africa.

10th VICH Outreach Forum meeting
Participants

1/ Forum members

ARGENTINA – CAPROVE	Carlos FRANCIA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Vivian PALMEIRA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Barbara Agate BORGES CORDEIRO
MOROCCO – ONSSA	Benalla HASNAE
NIGERIA – NAFDAC	Yunus SADIQ
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Hae-Chul PARK
SAUDI ARABIA – Saudi Food & Drug Authority	Mohammed Aosman ALARIFI
TAIWAN – Council of Agriculture	Tai-Hwa SHIH
TAIWAN – Council of Agriculture	Cheng-Jou CHAN
THAILAND – Department of Livestock Development	Sasi JAROENPOJ
UGANDA – National Drug Authority	Noel AINEPLAN
UKRANIA – SCIVP	Yuriy KOSENKO
Medicines Control Authority of ZIMBABWE	Zivanai MAKONI

Apologies

PEOPLES REPUBLIC of CHINA – Institute of Vet. Drug Control	Shixin XU
NIGERIA – NAFDAC	Joseph ASIKPO
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Yong Sang KIM

2 / VICH Steering Committee

Members and (C) Coordinators

STEERING COMMITTEE (C) coordinators

AHI (ZOETIS)	M. J. MCGOWAN
AHI (BOEHRINGER INGELHEIM)	G. GOWDA
AHI	R. CUMBERBATCH (C)
EU (EUROPEAN COMMISSION)	J-N. PREUSS
EU (EMA-CVMP)	D. MURPHY
EU (EMA)	N. JARRETT (C)
EU (EMA)	I. DUARTE (*Chairperson 36th SC*)
ANIMALHEALTHEUROPE (BOEHR. INGELHEIM)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)
JMAFF	Y. ENDO
JMAFF	K. NODA
JMAFF	T. KOZASA (C)
JVPA (Nisseiken Co.)	K. TUCHIYA
JVPA	H. MAKIE (C)
US (FDA)	B. WALTERS
US (USDA APHIS)	B.E. RIPPKE

US (FDA)	B. ROBINSON (C)

OBSERVERS

Australia (APVMA)	A. NORDEN (for C. PARKER)
Australia (AMA)	C. BENNETT
Canada (Health Canada)	M-J. IRELAND
Canada (CAHI)	J. SZKOTNICKI
New Zealand (MPI)	W. HUGHES
South Africa (DAFF)	A. SIGOBODHLA
South Africa (SAAHA – BAYER)	E. SCHAY

INTERESTED PARTY

AVBC	J. THOMAS

OIE

OIE	J-P. ORAND
OIE	M. SZABO

VICH SECRETARIAT

HealthforAnimals	H. MARION
HealthforAnimals	C. DU MARCHIE SARVAAS

GUESTS

EU (EMA)	I. CLAASSEN (only 28/6)
New Zealand (MPI)	A. KINSELLA
US (FDA)	L. WALTER-GRIMM

APOLOGIES

JVPA (NIPPON ZENYAKU KOGYO CO.)	I. ABE
New Zealand (AGCARM)	M. ROSS