



**VICH OUTREACH FORUM**  
**12<sup>th</sup> meeting**  
**19 and 20 November 2019**  
**Tokyo, Japan**

**SUMMARY REPORT**

**Session 1: Reports and Group Discussions**

**1. Opening of the meeting and chairperson's introduction**

The meeting was jointly chaired by Kenji Ohara, Director General of the National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries, Japan, and Dr Jean-Pierre Orand, Director of the French agency for veterinary medicinal products - OIE collaborating centre, on behalf of OIE.

Dr Ohara opened the meeting by welcoming the participants to the 12<sup>th</sup> VICH Outreach Forum (VOF) meeting in this nice venue in the outskirts of Tokyo.

Dr Orand recalled that the first contact meeting with the Outreach countries had taken place in Tokyo in November 2011.

**2. Report by the SC on issues raised by Outreach Forum members during the 11<sup>th</sup> 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 37<sup>th</sup> VICH Steering Committee (SC) meeting in Cape Town on the issues raised by the participants in the 11<sup>th</sup> VOF meeting. In line with the comments received, the 12<sup>th</sup> VOF agenda will cover in particular:

- An overview of VICH GCP GL 9, followed by a breakout session and an open discussion on questions on issues and opportunities in VOF countries related to GCP
- An introduction by SC members on opportunities and difficulties on sharing assessment reports, followed by a group discussion on sharing assessment reports & exchange of experience
- Presentation by AnimalhealthEurope of the VICH document on the scope of VICH and a discussion on topics of interest for VOF members
- The regional mutual recognition system in Latin America presented by CAMEVET
- Medicated premixes
- Criteria for calculation of withdrawal periods
- Update on review of Anthelmintic guidelines
- Biologicals quality (GLs 25 & 34)

The Secretariat also gave an overview of the activities currently ongoing in the 8 active VICH Expert Working Groups.

The Secretariat recalled that the interval between the VOF/ VICH SC meetings will be extended to a 12 months cycle from 2020 onwards; the next meeting is scheduled to take place at the EMA in Amsterdam in November next year.

### **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 promotion of VOF activities, and pointed out that many meetings with OIE involvement are of potential interest to the VICH activities.

OIE ensures the liaison with the OIE specialist commissions, primarily with the Biological Standards Commission and provides regularly information on VICH and VOF to OIE Member Countries.

Regarding the quality of veterinary products, the OIE is examining the potential for a global information and alert system of Substandard and Falsified (SF) veterinary products.

OIE is currently reflecting on what role(s), if any, OIE should play in defining the minimum requirements for a pharmacovigilance system for veterinary medicinal products. The subject is included into the 6<sup>th</sup> Cycle Training Seminars for Focal Points of Veterinary Products in strong collaboration with HealthforAnimals and OIE Collaborating Centres who actively participated in the first seminar in Africa and will be participating in upcoming seminars in other Regions. The document "How to set up a pharmacovigilance system for veterinary medicinal products" was well received, especially among those OIE Member Countries which currently lack fully functioning pharmacovigilance legislation and systems. The seminar would also offer opportunities to the OIE Focal Points to provide comments/suggestions for further improvements for this document.

### **4. Feedback on the results of the OIE survey**

OIE presented the outcome of the survey of VOF members expectations that was launched after the last meeting ([link](#)).

The most beneficial, positive aspects are the harmonisation of technical requirements, regulatory discussion and breakout group discussions, networking with other regulators, opportunities to improve information, share knowledge, and awareness of VICH guidelines, capacity building... The least helpful aspects are logistical and organisational aspects such as the time allocated to certain topics is very short, the VOF does not have allocated time to meet on its own, weak interconnection between developed and advanced regulatory agencies, VICH is rather too rigid, agenda and documents should be circulated before the VICH meeting, language barriers, gaps between the different countries...

The main expectations are the development of international standardised guidelines, trainings and exchange of experiences, using the technical assistance for making the regulatory system better, continuation of VICH openness and collaboration, the participation of VOF experts in guideline development.

OIE also highlighted more general issues related to the organisation of VICH as well as a list of positive impacts and benefits from VOF meetings.

The feedback from the 11<sup>th</sup> VOF meeting was generally positive and several considerations for future meetings were expressed.

OIE presented a list of topics that have been suggested for future VOF meetings.

In the discussion, VOF members expressed their appreciation of the separate meeting for VOF members that had been organised prior to the VOF meeting. China, CAMEVET, Saudi Arabia and Taiwan had attended the meeting, which in the future will need to be more structured with an agenda listing topics for discussion as well as a leadership. This meeting was seen as an unique opportunity to share experience on local registration processes and harmonisation initiatives. OIE offered its assistance for this meeting, considering that OIE has a special role in providing support to the VOF.

## 5. Discussion of individual VICH Outreach Forum member questions

*Good Clinical Practice: An introduction to GL9 and how to implement it*

The EU gave a high-level summary ([link](#)) of VICH GL 9, including the history of the VICH GL, the description of what is GCP, the benefits and the key elements of GCP, as well as the approach to assessment of GCP.

The EU pointed out in conclusion that from a regulatory point of view it is one of the most important guidelines. It facilitates the review of clinical studies because of the standardisation of terminology, formats and structure of the study documentation and allows for transparency of procedures, giving assessors confidence in the results. It will however not compensate for poorly designed studies!

AnimalhealthEurope presented the "Investigator's Handbook on Good Clinical Practice" ([link](#)). This handbook is aimed at anyone involved in the implementation of clinical studies, particularly at clinical investigators, and should be read in conjunction with VICH GCP GL9.

Copies of the handbook were distributed at the meeting, and can be obtained by contacting AnimalhealthEurope.

The pdf version of the handbook will be placed on the VICH website.

AnimalhealthEurope also confirmed that the document is freely available for translation into local languages.

## 6. Continued in Breakout Groups:

*- Discussion on Good Clinical Practice*

VOF members:

Group A: India, Korea, Russia, Taiwan, Thailand, Kingdom of Saudi Arabia

Group B: CAMEVET, China, Korea, Thailand, Ukraine, Kingdom of Saudi Arabia, Zimbabwe,

*Questions for discussion*

1. What quality standard do you require for field studies?  
Do you require studies conducted in accordance with VICH GL9? Are there alternative (local) standards that you can apply?
2. Do you accept GCP studies conducted in other regions/countries?  
If not, why not?
3. What are some of the common issues/problems encountered with field studies?  
Are they to do with the conduct and/or the reporting of the study?  
Are they to do with study design?

## 7. Reporting back to the plenary

### Group A

*The participants reported that:*

- *Question 1*
  - Saudi: GL9, local studies can have a different standard
  - Thailand: looks for GCP, but accepts GCP standards applicable in the country where the study was done (including VICH GL9)
  - Russia: uses a local standard, very similar to GL9,
  - S. Korea: local GLs on number of animals and assessment criteria
  - Taiwan: follows GL9, but for biologicals will request the clinical trial protocol for review, and require a local field trial
  - India: has a local GL, similar to GL9; has a mechanism to review the protocol and protocol must be prior approved
- *Question 2*
  - S. Korea: Clinical studies must be done in S. Korea
  - All other countries accept clinical studies from other countries (except biologicals)

- Taiwan: for biological products clinical studies have to be done in Taiwan
  - Saudi: may need local study in local species (eg, camel)
  - India: in general, will accept foreign studies, unless there are issues with the protocol, or insufficiency of the data, or need local target species
  - What reason would you reject a study? If no GCP
- *Question 3*
    - Saudi/Thailand: how the sample is done is wrong; sample too small
    - Poor study design; poor endpoint, endpoint definition is wrong,
    - Russia: group size too small and insufficient demonstration of efficacy
    - Korea: lack of potency for vaccines
    - Taiwan: confidence level is insufficient
    - India: companies mis-represent their data, e.g. adding another species, lack of data on the environmental residues and effects on non-target species,
    - Thailand: disease not present in Thailand for the product
    - Saudi: sometimes insufficient information submitted, and we have to ask for everything

### Group B

- *Field studies*
  - CAMEVET Countries: some use VICH GL (one of the most used GL)
  - Zimbabwe: Local GL (ask for study protocol)
  - Ukraine: no local GL, so far following VICH GL (with minimum changes ex. number of animals)
  - Saudi: divided into legislation and guidance (Ethical standards serving as a national legislation & Guidance for Reg. by SFDA) + differences exist btw local and foreign standards
  - China: GCP implemented 3 years ago with key elements being adopted from the VICH GL. (pk. standards are incl. in the GL)
  - Thai: follows the VICH GL.
- *Challenges*
  - Implementation of local GCP
  - Validation of studies
  - lack of details in VICH GL, eg. conditions and how animals are maintained
  - Ethical approval
  - Control of sample size

Several VOF members explained that it is challenging to follow the VICH GL, but recognised that it would be even more challenging to develop locally approved GLs.

## **8. Discussion of individual VICH Outreach Forum member questions – Opportunities and difficulties on sharing assessment reports**

### Introduction by ASEAN/Can/NZ & Australia

Canada, Australia and New Zealand presented ([link](#)) the opportunities and challenges of sharing regulatory assessment reports between regulators from 2 or more countries.

The usefulness of regulatory assessment reports to inform decision making is dependent on several factors such as the type of assessment e.g. hazard assessments, risk assessments, the differences in governing legislation and policies, the regional differences, and, last but not least, the ability to share information in confidence.

The main opportunities are to advance international collaboration, delivering regulatory decisions sooner, supporting faster access to multiple markets and reducing administrative burden for industry by harmonising data requirements and complying with international standards.

In response to a question on how to manage the dossiers, it was noted that 95% of what regulators ask companies are similar and only slight regional differences between countries exist, and these differences do not prevent the working together.

In the sharing of the work, the countries decide together who will review which part in depth whilst other countries will peer review their report.

## 9. Group discussion on sharing assessment reports

### Group A ([link](#))

Saudi Arabia reported that it had formal joint assessments within Gulf Cooperation Council countries (GCC) whereas the other countries have different levels of assessment report sharing.

### Group B ([link](#))

- CAMEVET: some countries do it. Mutual recognition for national products depending on economic and political agreement between countries.
- Ukraine: no joint assessment.
- China: internal joint system for 20-30 years, with experts from human medicine side (academia + industry) - some budget limitation
- SADC: well-established for humans but not yet for vet. 6-7 countries serving as active members by doing the assessment and sharing it with the rest of the 16 countries.

The participants acknowledged that to exchange their dossiers the countries must have confidence in each other's assessors.

## 10. Group Discussion of individual VICH Outreach Forum member questions – *VICH Out of scope topics:*

### *- Presentation of the VICH document on the scope of VICH discussion on VOF topics*

AnimalhealthEurope explained ([link](#)) that the SC has formalised the “out of scope” issue in 2 documents (Draft Guidance on how to manage VICH “Out of scope” topics (VICH/19/077-dr 3) & Draft List of VICH “Out of Scope” topics (VICH/19/078-dr 3)) that were circulated to the VOF for consultation prior to the meeting.

The objectives are to highlight the role of VICH, to enable a common understanding on topics which could be discussed at VOF meetings, for VOF members to receive some direction on potential ways to handle “out of VICH scope” topics and also to obtain any feedback VOF members may have on the two draft documents.

### *- Discussion*

Zimbabwe believed that diagnostics and autogenous vaccines should be in the scope of VICH as these will become more important in the future. VICH should support the Quality, Safety and Efficacy of all veterinary medicines, including vaccines.

India questioned why complements & supplements are out of scope. AnimalhealthEurope and FDA explained that the definitions of VMPs as well as medicated feed are different in the VICH countries, which have distinct legislations. For example, medicated feed is not a VMP in the EU. As a result the EU authorities responsible for the evaluations of VMPs have no mandate to develop guidance on medicated feed and so cannot support development of VICH guidance on this topic. Similar difficulties may exist for other VICH regulators in relation to other topics.

Zimbabwe considered nevertheless that medicated feed should be considered as VMPs. VOF members are confronted daily with the challenge of registering such products, and VICH should support VOF members in this area.

The OIE highlighted the fact that some products are considered as VMPs but have not automatically to be authorised or registered (such as autogenous vaccines, medicated feeds...). The OIE reminded the participants that VICH deals only with the technical requirements, the criteria for the registration of a product, not the registration procedure itself. So veterinary medicinal products which have not to be registered, do not enter in the scope of VICH. VICH does not address Risk Management issues, such as the management of risks of cross contamination in medicated feed. VICH members & observers have their own legislations that apply to these topics.

Saudi Arabia pointed out that medicated feeds do not represent a challenge for all VOF members, and that premixes and medicated feed are addressed differently.

Ukraine mentioned that the establishment of different MRLs lead to different withdrawal periods for a same product

The EU pointed out that VICH does not establish MRLs or withdrawal periods, but provides only guidance on the studies that are required; these studies need however to be assessed and the assessments performed in different regions may result in different conclusions. Each authority will make its own independent decision on the values to establish and whether to authorise or not the product and these decisions can be different between countries.

OIE asked all VOF members to send to the VICH secretariat their comments and proposals for improvements of the documents.

**Act: All**

These will be “living documents” that will be updated regularly and placed on the VICH website.

## **11. Mutual recognition & national regulatory systems**

### **11.1 Regional mutual recognition system in Latin America**

CAMEVET explained ([link](#)) that the Americas Committee for Veterinary Drugs is a public-private technical entity created within the framework of the Regional Commission for the Americas and the Regional Representation of the World Organization for Animal Health (OIE).

Its purpose is to facilitate the harmonisation of standards, registries and controls of veterinary drugs among member countries.

It brings together representatives of the regulatory authorities and industry of the countries of the American continent. The CAMEVET guidances are non-mandatory; the countries that make up CAMEVET have a legal framework based on laws and decrees dictated by national authorities. Modifying these legal frameworks necessitates passing a new law through congress or issuing a Presidential Decree.

Moreover, CAMEVET has developed and agreed on a set of rules and recommendations that do not completely overlap all the VICH guidelines.

So far, within 25 work sessions, 32 documents have been approved and further documents are under review.

CAMEVET proposed to work more closely with VICH to expand the implementation of harmonised technical documents by selecting the most important VICH guidelines for the countries of the American region and arrange them in order of priority.

CAMEVET suggested further to translate selected VICH GLs into Spanish and Portuguese and to provide to VICH a list of harmonised documents within CAMEVET to assess the possibility of considering them as drafts for the development of guidances that eventually could become VICH GLs and form part of the OIE Standards.

Ukraine recommended to place the translated VICH GLs on the VICH website, but the Secretary explained that the website can only host the official documents in English. VICH does not have “official” translations because the translated documents cannot be approved by the VICH experts (the task would be tremendous).

However, links to other websites can be included. For example, many translations of VICH GLs are available on the OIE website at:

<https://www.oie.int/scientific-expertise/veterinary-products/vich-outreach-forum/>

It was noted that CAMEVET is the only other international forum where industry and regulators come together to develop guidances.

## **Session 2: Issues of interest to Outreach Forum members**

### **12. Specific issues**

#### **12.1 Medicated premixes**

AnimalhealthEurope introduced ([link](#)) the discussion ongoing in the SC on medicated premixes for the potential development of a VICH GL. AnimalhealthEurope presented the potential scope of the discussion and pointed out that feed additives (types and form defined by local/regional legislation) and medicated feed (feed containing medicated premixes) will be out of the scope of the GL. AnimalhealthEurope also detailed the proposed timeline and the process established by the SC to move forward. In the course of 2020, a Task Force will be created, composed of SC and VOF experts, with the mandate to develop a Concept Paper for adoption by the SC before the creation on an EWG.

The VOF considered this GL important and encouraged the SC to progress rapidly.

#### **12.2 Criteria for calculation of withdrawal periods**

FDA ([link](#)), the EU ([link](#)) and JMAFF ([link](#)) each provided an overview of their approach for the calculation and the determination of withdrawal periods. The withdrawal period is the interval between the last administration of a veterinary medicinal product to a food producing animal and the timepoint at which the animal can be slaughtered so that the tissues can be taken for human consumption, or milk can be taken for human consumption. The aim of the withdrawal is to protect public health and it is calculated so that the level of residues in the food commodity is below the MRL.

The participants took note that the MRL represents the tolerance limit of residues in the food product of animal origin.

China indicated that it plans to set MRLs for offal in order to ensure consumer safety, and questioned if food from potentially diseased animals is taken into consideration as the withdrawal periods are determined in healthy animals.

JMAFF confirmed that in Japan MRLs are set for liver, kidney as well as other tissues such as small intestine, with large confidence limits in order to ensure that the sick animals are also included in that limit.

Zimbabwe mentioned that in some African countries the withdrawal periods are determined for specific substances and not for products, mainly for generic products.

Ukraine asked if VICH countries request additional residue studies for generic products. The EU replied that it depends on the product: for a locally administered product, depletion of residues from the injection site may not be the same than for the reference product so additional studies may be needed as a demonstration of blood level bioequivalence may not be sufficient to ensure that the withdrawal period established for the reference product can safely be applied to the generic product.

JMAFF explained that in Japan and the USA there is a requirement for a bioequivalence test; if the products are equivalent, the withdrawal period is expected to be similar.

It was noted that bioequivalence considers the absorption, not the depletion of the substance.

Regarding the 0 day withdrawal period, the EU mentioned that VICH GL48 gives examples of timelines between 3 & 12 hours.

#### **12.3 Update on review of Anthelmintic guidelines**

FDA provided an update ([link](#)) on the current progress in the Anthelmintic EWG and explained that the goals of the ongoing review of the Anthelmintic GLs are to improve consistency across regulatory authorities by harmonising technical requirements for effectiveness data, to minimise the number of studies i.e. the number of animals as well as to address new scientific issues.

The topics for revision are limited to the selected topics detailed in the preparatory Discussion Document.

FDA confirmed that for the moment all proposed revisions are in a draft format only, as some topics still require discussion. FDA warned that it could take more than 2 further years to finalise any revision in the format of a revised GL.

### **13. Biologicals quality (GLs 25 & 34)**

USDA provided an insight ([link](#)) into the Quality Guidelines for Biologics: GL 25 – Testing of Residual Formaldehyde implemented adopted in April 2002 and GL 34 – Testing for the Detection of Mycoplasma Contamination adopted in February 2013.

## **Session 3: Discussions and conclusions**

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

The VOF members unanimously expressed their appreciation to the organisers of the meeting as well as to the VICH SC. The VOF members confirmed that the structure of this meeting was adequate and that similar breakout sessions should be organised at the next meeting, with a similar timing for the different topics.

*Saudi Arabia* proposed for the next meeting to develop the topic of batch release testing & detection of mycoplasma, and recommended that VOF countries should explain how they evaluate Withdrawal Periods.

*The Peoples Republic of China* appreciated the platform provided by the VOF for exchanging information at the global level and believed that VOF countries are able to build on the experience shared by the VICH countries.

*Korea* proposed to expand on mutual recognition systems at the next meeting.

*Taiwan* questioned if a simplified procedure exists in some countries to register vet medicines derived from a human product, as currently in many countries, veterinarians may use human products for off-label use for animals.

*Zimbabwe* thanked VICH for the quality of the information received.

*India* confirmed the usefulness of focussing on specific topics such as the harmonisation of assessment reports, and suggested to develop further the methods for the calculation of withdrawal periods.

*Ukraine* recalled the enormous progress made by the VOF since its first contact meeting in 2011 also in Tokyo, and proposed that VICH should develop a methodology to make joint assessments of registration dossiers. The next meeting should address the requirements for pharmaceutical equivalence in the registration of generic products.

*CAMEVET* also suggested to address at next meeting the topics of bioequivalence and the validation of stability studies for products that have to be diluted.

*Thailand* appreciated the opportunity of learning from the experience of other regulators and suggested to receive an insight on the progress of the EWG on Combination Products, as well as more information on medicated premixes, medicated feed and how to control autogenous vaccines.

## 15. Conclusions and next steps

OIE thanked again all participants for the replies provided to the survey and the proposals for the improvement of VOF meetings.

The organisation of the pre-meeting has been particularly appreciated by the participants in the meeting, and the SC will support the organisation of a similar session before the next VOF meeting in Amsterdam.

Saudi Arabia accepted to take the lead of this session, with the support of AnimalhealthEurope.

The OIE headquarter proposed also to offer its support for preparing the pre-meeting.

### Agenda & documents

OIE confirmed that the draft agenda for the next meeting will be sent at an early stage, in the first weeks of 2020, and asked all VOF members to reply to the request for topics & presentations to be made at the next meeting. Inputs from VOF members to present their particular issues will be very much appreciated.

The final agenda for the 13<sup>th</sup> VOF meeting will be made available 3 months before the meeting. It was agreed that the meeting documents will be placed on the VOF website 1 month prior to the meeting.

It was also proposed to develop, at the end of the 13<sup>th</sup> VOF meeting next year, a first draft agenda for the 14<sup>th</sup> VOF meeting to take place in 2021 for discussion during the pre-meeting.

### Training

AHI proposed that an expert could provide a presentation on ADI - Acceptable Daily Intake, but the presentation would be made available before the 13<sup>th</sup> VOF meeting for VOF members to review and prepare their feedback & questions to share with the speaker during the session at the VOF meeting.

The VOF members supported this proposal.

VOF members noted however that although many topics can be easily understood through presentations, other topics may be more complicated and would require a video or even hands on training.

It was noted also that specific VOF seminars can be organised in the frame of other regional meetings. This has already been done with ASEAN; CAMEVET will try to allocate one day of its annual session to VICH topics.

### Further topics proposed for future VOF meetings

- *Group discussions*
  - manufacturing process validation of sterile products
  - unification of criteria for the standardisation of the calculations for WP
  - pharmaceutical equivalence
  - medicated premixes
  - AMR for combination products in the different SC countries
- *Specific issues*
  - Overview of the different requirements on bioequivalence in the different regions

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

- The 13<sup>th</sup> VICH Outreach Forum meeting will be held on 17 & 18 November 2020 in the offices of the EMA in Amsterdam - the Netherlands
- The 14<sup>th</sup> VICH Outreach Forum meeting will be held in November 2021 in the USA – location TBD

## 12<sup>th</sup> VICH Outreach Forum meeting Participants

### **1/ Forum members**

ARGENTINA – CAMEVET	Virginia DEVI QUINONES PUIG
CHINA (PR) – Institute of Vet. Drug Control	Shixin XU
INDIA – Ministry of Fisheries, Animal Husbandry & Dairying	Malik PRAVEEN
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Byung Suk JEON
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Hyangsim LEE
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	June Hyuk KWON
RUSSIA –VGNKI	Vasilina GRITSIUK
RUSSIA – FSVPS	Anna BABUSHKINA
SAUDI ARABIA – Saudi Food & Drug Authority	Hend I. ALFINTOUKH
SAUDI ARABIA – Saudi Food & Drug Authority	Maher ALJASER
SAUDI ARABIA – Saudi Food & Drug Authority	Abdullah ALDABEEB
SAUDI ARABIA – Saudi Food & Drug Authority	Haitham ALSHBANAT
SAUDI ARABIA – Saudi Food & Drug Authority	Saed Murie ALSHAHRANI
SAUDI ARABIA – MEWA	Ali Mohamed ALDOWERIEJ
TAIWAN – Council of Agriculture	Wen Yuan YANG
THAILAND – Department of Livestock Development	Julaporn SRINHA
THAILAND – Department of Livestock Development	Sasi JAROENPOJ
THAILAND – Food and Drug Administration	Chaiporn PUMKAM
THAILAND – Food and Drug Administration	Supapitch SUPHAP
UKRANIA – SCIVP	Yuriy KOSENKO
Medicines Control Authority of ZIMBABWE	Zivanai MAKONI

### ***Apologies***

ARGENTINA – CAPROVE  
 BRUNEI – Dept. of Agriculture and Agrifood  
 UGANDA – Ministry of Agriculture, Livestock and Food Supply  
 WAEMO/UEMOA

### ***Cancellations***

MOROCCO – ONSSA  
 Hasnae BENALLA

## **2 / VICH Steering Committee**

### **Members and (C) Coordinators**

#### **STEERING COMMITTEE (C) coordinators**

AHI (ZOETIS)	M. J. MCGOWAN
AHI (BI)	E. NORTON
AHI	R. CUMBERBATCH (C)
EU (EUROPEAN COMMISSION)	J-N. PREUSS
EU (HEALTH PRODUCTS REGULATORY AUTH)	D. MURPHY
EU (EMA)	N. JARRETT (C)
ANIMALHEALTHEUROPE (BI)	B. BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	E. DE RIDDER
ANIMALHEALTHEUROPE	R. CLAYTON (C)
JMAFF	K. OHARA ( <i>Chairperson</i> )
JMAFF	K. EGUCHI
JMAFF	K. NODA
JMAFF	J. OHMORI (C)
JVPA (Nisseiken Co.)	K. TUCHIYA
JVPA	K. OISHI (C)
US (FDA)	B. WALTERS
US (USDA APHIS)	B.E. RIPPKE
US (FDA/CVM)	B. ROBINSON (C)

#### **OBSERVERS**

Australia (APVMA)	A. NORDEN
Australia (AMA)	C. BENNETT
Canada (Health Canada)	M-J. IRELAND
Canada (CAHI)	C. FILEJSKI
New Zealand (MPI)	W. HUGHES
New Zealand (AGCARM)	J. QUAY
South Africa (SAAHA)	M. CHURCHILL

#### **INTERESTED PARTY**

AVBC	G. DOWELL
------	-----------

#### **OIE**

OIE	J-P. ORAND
OIE	M. SZABO

#### **VICH**

HealthforAnimals	H. MARION
------------------	-----------

#### **APOLOGIES**

HealthforAnimals	C. DU MARCHIE SARVAAS
JVPA (NIPPON ZENYAKU KOGYO CO.)	I. ABE
South Africa (SAHPRA)	A. SIGOBODHLA

#### **GUESTS**

New Zealand (MPI)	A. KINSELLA
US (FDA/CVM)	M. LUCIA