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

VICH/15/083
22 December 2015
Final

VICH OUTREACH FORUM

6th meeting
26-27 October 2015
Tokyo

SUMMARY REPORT

Session 1: Reports and Group Discussions

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Minoru Yamamoto, Director General, National Veterinary Assay Laboratory, JMAFF, in cooperation with Dr Jean-Pierre Orand, OIE.
Dr Minoru Yamamoto opened the meeting by welcoming the participants to the 6th VICH Outreach Forum (VOF) meeting in Tokyo.

2. Report by the SC on issues raised by Outreach Forum members during the 5th VICH Outreach Forum meeting in Washington in February 2015

The VICH Secretariat reported on the outcome (link) of the discussions that took place at the 31st VICH Steering Committee (SC) meeting in Washington on the issues raised by the participants in the 5th VOF meeting. The 6th VOF agenda items will therefore provide more time for discussion (2 Breakout sessions) and cover in particular:

- Pharmacovigilance
- Data requirements for "old" products/generics - Bioequivalence
- Application of VICH GLs and acceptance of studies conducted according to VICH GLs AMR : general principles of authorization of antimicrobials - risk assessment of data according to VICH GL 27
- Regulation for aquaculture medicines
- Updates from VOF members

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

OIE confirmed (link) that before each VOF meeting a, letter is sent to OIE Delegates of the Forum Countries in order to reiterate the OIE position on the importance of the VICH Outreach Forum as well as to support the participation by Outreach Forum Countries and underline the need for sustainability.
After each VOF meeting OIE circulates the Summary of the meeting and informs all 180 OIE Member Countries on the recommendations that were made.
As the 3rd training cycle for OIE focal points is finished, OIE is preparing the programme of the 4th cycle in which VICH will remain important topic.

OIE presented its new objective to implement a global database on the use of antimicrobial agents in animals, with the aim to collect baseline information and the different reporting options on antimicrobial sales and use in food producing animals.
OIE summarised the new OIE standards on VMPs adopted during the OIE general session in May 2015.

4. Report from SC discussions on the Task Forces on Concept Papers

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

FDA explained (link) that in February 2015, the Steering Committee mandated the Quality Expert Working Group to develop a guidance on stability testing in the climatic zones III and IV (based on a concept paper submitted by the Task Force). This guidance will be developed as a new VICH GL. New members from China, CAMEVET and Morocco, as well as South Africa were nominated to the EWG.
The speaker highlighted several points to consider for this new GL, in particular that the majority of active substances are also used for human medicinal products and that therefore there are some veterinary medicinal products which were approved first as human medicinal products, that testing at elevated temperature and higher humidity conditions may result in shorter expiry, and that several potential problems that may appear with extrapolation.
Thailand explained that ASEAN does not have a GL on this topic and is therefore welcoming the VICH initiative.

4.2 Efficacy studies GL for combination products

JMAFF recalled (link) that, considering the broadness of the topic, the SC gave the mandate to the Task Force (TF) to elaborate a discussion paper proposing a more focused scope for the development of a VICH GL for efficacy studies for combination products.
VOF experts to the TF were from Argentina, CAMEVET, China, Taiwan and UEMOA.
The TF has categorised the combination products and reviewed the GLs existing in the world.
The TF determined that the main targets for the specific combination products GL are antiparasitic products. The TF recommended that VICH should firstly develop a general GL by extracting appropriate elements from existing EU and US GLs. As a next step, the SC has mandated the TF to develop a Concept Paper addressing the development of a general combination products GL.

5. 1st Group Discussion of individual VICH Outreach Forum member questions

3 breakout groups were organised comprising VOF members with SC members. Each team designated a rapporteur and a moderator.
These groups were composed of the following VOF members:
Group 1: CAMEVET, Singapore, UEMOA, Taiwan
Group 2: Singapore, Korea, Taiwan Tanzania
Group 3: Argentina, Korea, Thailand, UEMOA

5.1: VMP registration in Korea

Korea presented (link) an overview of the regulatory processes as well as the post-marketing surveillance system which is in place in Korea.

5.2 Data requirements for “old” products/generics, bioequivalence

Argentina presented (link) the data requirements for old products/generics and explained that in nearly all CAMEVET countries the veterinary medicines’ registration system is based on the

«new product» concept, meaning that every product, innovative or not, has to undergo the same requirements.

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

Each of the 3 groups focused its discussions on pharmacovigilance and “old” products/generics/bioequivalence.

Group 1

Group 1 reported (link) that the participants had reviewed the different levels of regulation in place in their respective countries/regions and highlighted the main challenges that they are facing.
All participants reported that Pharmacovigilance is considered as a high priority in their respective countries/regions.

Group 2
The participants in Group 2 reviewed (link) the status of Pharmacovigilance in their respective countries.
Bioequivalence was also briefly discussed and the participants requested more training on this topic.

Group 3
Group 3 also discussed (link) the topics of Pharmacovigilance and Bioequivalence.

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

These groups were composed of the following VOF members:
Group 1: Singapore, Thailand, Argentina, CAMEVET, Tanzania
Group 2: Korea, Taiwan, UEMOA

7.1 Topic 1: waiving of TABST

JMAFF reminded (link) the audience that a Target Animal Batch Safety Test (TABST) is a safety test in target animals which is performed as a routine final product batch test for all immunological veterinary medicinal products (IVMPs) or a specific product group such as inactivated viral vaccines. JMAFF confirmed that the aim of the waiving Target Animal Batch Safety tests is to minimise animal testing in accordance with the 3Rs principle, and explained briefly the content of VICH GL 50.

8-9. Reporting back to the plenary on the outcome of group discussions

Both groups focused their discussions on the application of VICH GLs in general and the implementation of GL50 on TABST in particular.

Group 1:
The participants in Group 1 reported (link) on their discussions regarding the application of VICH GLs and acceptance of studies conducted according to VICH GLs.
The importance of a general awareness by all interested parties, as well as of proper training was highlighted. It was acknowledged that adequate legislation should be in place in all countries, but that legislation should remain top level without including technical details.
The status of waiving of TABST in the different countries/regions was also reviewed.

Group 2:
Group 2 also discussed (link) the status of TABST and the general approach on use of VICH guidelines. The participants agreed on the importance of efficiently reaching out and sharing information on the VICH GLs.

Session 2: Issues of interest to Outreach Forum members

10. Specific issues

10.1 AMR: general principles of authorization of antimicrobials - risk assessment of data according to VICH GL 27

The EU presented (link) relevant issues considered as part of the efficacy assessment for antimicrobials in the EU, as well as prudent use principles.
It was noted that new legislation currently under development may require the development of a list of substances reserved to human treatment.

FDA explained (link) the possible public health impact resulting from the use of antimicrobials in food-producing animals and detailed the FDA Guidance for Industry #152 - Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern. FDA confirmed that this guidance is applied for each new application, for old as well as for new drugs.

In the subsequent discussion it was pointed out that in many African countries' access to veterinarians is very limited, meaning that decisions on what antibiotics to use and how to use the available products are rarely overseen by professionals, thus removing a key part of the controls available in Japan, the USA and Europe.

The EU mentioned that many EU Member States provide a guidance to their vets regarding the class of substances to choose for each animal disease.

The representative of the Food Safety Commission Japan (FSCJ) explained (link) that, under the framework of risk analysis, the FSCJ is responsible for the science based Risk Assessment of antimicrobial-resistant bacteria selected by antimicrobial use in food producing animals. The Assessment Guideline is based on Codex, VICH, and OIE guidelines and aims to assess the potential and degree of effect on human health of antimicrobial-resistant bacteria, which may be selected by antimicrobial use in food animals.

10.2 Aquaculture Medicines:

- Regulation for aquaculture medicines

JMAFF described (link) the status of the aquaculture in Japan, the regulation in place for aquaculture medicines, mainly vaccines and antimicrobials, and the procedure for the use of aquatic drugs.
In case of an outbreak of a disease on a farm, the farmer consults the local government and, in case there is a need for antimicrobial treatment, the disease is recommended to be identified before a treatment can be applied.
All medicinal products administered to fish must be approved.
Only inactivated vaccines can be approved for fish, and each vaccine must have a registration number.
A certificate for the use of vaccine must be presented to purchase the vaccine from a dealer; this certificate is issued following the farmer's request.

Antimicrobials, anthelmintics and antiseptics are approved by taxonomical order of the target species, vitamins and anesthetics are approved for all species of fish, but vaccines are approved by genus or species. Autogenous vaccines are not authorised in Japan.
Human food shall not contain any antimicrobial residues unless a MRL has been set, and food shall not contain more than the uniform limit (0.01ppm) for veterinary medicines other than antimicrobials unless a different MRL has been set in Japan.

- Experience from VOF members

Thailand explained (link) the registration procedure in place for aquatic products and confirmed that most registered products are antimicrobials, as well as one anaesthetic.

CAMEVET explained that they are developing a GL for aquatic products. Chile has much experience and is a leading country on this topic, although the number of products is relatively small.

10.3 Herbal medicines: approach for registration - Experience from members

Canada presented (link) Health Canada's Approach to Low Risk Veterinary Health Products such as vitamins, minerals, homeopathics, probiotics and herbal products.
In order to guarantee the safety and the quality of these products, a voluntary option of simplified registration for Low-Risk Veterinary Health Products, the Interim Notification Pilot Program, was set up in 2012 covering a limited list of admissible substances, only for cats, dogs and horses. A database is managed by a third party.
For the post marketing surveillance, AERs are gathered by the third party and Health Canada has access to this information, but it is not a Pharmacovigilance approach as such.
For human products there are regulations for herbal medicines, and developed monographs, but no resources are available to develop these for the veterinary side.

South Africa presented (link) a regulatory overview of complementary medicines in South Africa. It is required to evaluate and check the quality, safety and efficacy of these complementary medicines, quality and safety being a mandatory requirement.

10.4 Priorities for VICH in the next 5 Years

JMAFF reported (link) that the SC has adopted the priorities for the VICH activities over the next 5 years (2016 – 2020). One of the main objectives of VICH over the next years is to reach out to the world and contribute to the One Health approach by increasingly collaborating with the non-VICH countries and regions.

Session 3: Discussions and conclusions

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

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

The VOF participants identified the following topics for discussion at the 7th VOF meeting:
Breakout sessions:

- Discussions on the expectations regarding the training strategy implementation, and how to address the needs in the different VOF countries

- Group discussion on the application of VICH GLs with feedback on challenges from VOF members

Specific issues

- Pharmacovigilance
- GL 27 & AMR: Risk Management based on Risk Assessment: how to implement a policy at registration level to implement an AMR policy
- Functioning of the OIE database
- Experience of VICH members on the implementation of the Anthelmintics GLs and the issue of parasiticides' resistance
- Efficacy of vaccines
- Generics registration
- Results of the survey from HealthforAnimals on VICH GLs' awareness
- Presentation by new participants of their regulatory framework

12. Conclusions and next steps

All VOF participants appreciated the presentations and the open discussions which improved their understanding of the VICH process.
OIE strongly encouraged VOF members to provide information from their countries to be shared well in advance of the next meeting.
VOF members were further asked to propose topics for discussion and presentations when the first draft of the agenda will be circulated, before the end of 2015.

13. Confirmation date and venue of 7th VICH Outreach Forum meeting

The 7th VICH Outreach Forum meeting will be held in Brussels, Europe on 21 & 22 June 2016.

6th VICH Outreach Forum meeting
Participants

1/ Forum members

AGRI-FOOD & VETERINARY AUTHORITY OF SINGAPORE	C.W. LIM
AGRI-FOOD & VETERINARY AUTHORITY OF SINGAPORE	W.K. WONG
ARGENTINA – CAPROVE	C. FRANCIA
CAMEVET (Argentina)	E.J. ARGENTO
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	J. SON
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	H-C. PARK
TAIWAN – Council of Agriculture	Ch-J. CHAN
TAIWAN – Council of Agriculture	T-F. HSIEH
TANZANIA FOOD AND DRUGS AUTHORITY	A.M. KHEA
THAILAND – Department of Livestock Development	S. JAROENPOJ
THAILAND – Department of Livestock Development	T. RODSOM
WAEMO/UEMOA (Burkina Faso)	S. DIALLO
WAEMO/UEMOA (Burkina Faso)	K.T. DOMAGNI

No reply (reminder sent on 1 October)

BRAZIL – SINDAN	E. SALANI
CHINA – Veterinaria Bureau, MOA	Ch. XIANG
CHINA – CVDA	Z. JIANHONG
INDIA – Ministry of Agriculture	R. SING RANA
MEXICO – INFARVET	A. LUNA ORTA
MEXICO – SENASICA	M. MOLINA NAVA
RUSSIA - VGNKI	I. KRAMARENKO
THAI FDA	P. LUSANANDANA
THAI FDA	J. TORON
UKRAINE – State Scientific Research Control Institute of VMPs	Y. KOSENKO

Apologies

ARGENTINA - SENASA	L. SBORDI

BRAZIL – Ministry of Agriculture, Livestock and Food Supply	L.C. SCHAPER (*No-show*)
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	G. MAIA MENDES (*No-show*)
CHINA – Institute of Vet. Drug Control	SH. XU
MALAYSIA – DVS	A.B. NGAH HAMID
MOROCCO – ONSSA	A. GRINI
PHILIPPINES – ASEAN Bureau of Animal Industry	M. ABENES

External Speakers

JAPAN – Food Safety Commission	H. OKURA
JAPAN – JMAFF	M. HIKI
US FDA	M. BROWN
US FDA	H. HARBOTTLE
US FDA	M. HUYNH
US FDA	M. MARTINEZ

2 / Steering Committee (C) coordinators

Members

AHI (BAYER)	B. MARTIN
AHI (ZOETIS)	M. J. MCGOWAN
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