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

VICH/20/091
17 December 2020
Final

VICH OUTREACH FORUM

13th Meeting (held virtually)
17 November 2020

SUMMARY REPORT

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by 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 13th VICH Outreach Forum (VOF) which is held for the first time as a virtual meeting due to the special global health circumstances. This meeting will serve as a test case for reflection by the VICH Steering Committee on future formats for communication with VOF members.
He thanked particularly the delegations who have invited many colleagues, confirming the interest for VICH in the VOF countries.

2. Report by the SC on issues raised by Outreach Forum members during the 12th VICH Outreach Forum meeting in Tokyo in November 2019

The VICH Secretariat briefly summarised the report from the SC (link) that was circulated prior to the meeting and addressing the replies from the SC to the issues raised at the 12th VOF meeting. Several topics had to be postponed to the next VOF face to face meeting.
The main features are:

- Provision of a training, partly as video – *see agenda point 5*
- Proposed agenda for the 14th VOF provided well ahead of the meeting in November 2021
- Calculation of withdrawal periods – document circulated to the VOF in September 2020
- Specific topics – update on the regional mutual recognition system in the GCC – see agenda point 4
- Brief summary on the activities of the 9 VICH Expert Working Groups
- Summary of VICH priorities Phase V - 2021 to 2025

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

The OIE briefly summarised the report (link) that was circulated prior to the meeting and focussing on the activities of OIE on VMPs since the last VOF meeting.
The presentation details:

- The support provided by the OIE to the VOF, including the brief summary with the key items to OIE Delegates and the Focal Points of Veterinary Products, parallel invitation letters (in addition to the invitation letter sent by the VICH Secretariat) for this meeting to

the Delegates and Focal points of the VOF countries and the 3 Organisations, ASEAN, CAMEVET and UEMOA

- An update on the OIE Specialist Commission (Biological Standards Commission)
- The promotion of VOF activities in the 6th cycle training seminars for OIE Focal Points of Veterinary Products with a dedicated session to the VICH Outreach Forum and VICH Quality Guidelines. The latest face-to-face meeting took place in Kuala Lumpur from 14 to 16 January 2020 for Asia and Oceania. The OIE expressed its thanks again to the Malaysian Delegation for their warm hospitality. Due to the COVID 19 pandemic the training seminar for the Middle East had to be cancelled at the end of March; however, webinars will be held on 7 - 9 December 2020, and in early February 2021 for Europe, to focus on the main items, to improve access to quality veterinary medicinal products, to follow up the recommendations of the second OIE Global Conference and to provide opportunity for experience sharing.
- A strong cooperation with the HealthforAnimals' Pharmacovigilance expert group and OIE Collaborating Centres on the quality of VMPs and the ways to finalise the manual/document: "*How to set up a Pharmacovigilance system for veterinary medicinal products"* in the OIE Regions, including the VOF Members, by taking in the feedback from the Focal Points from all OIE Regions. VOF members asked for a broad distribution of this document.
- A list of meetings with OIE involvement, which might also be of interest to VICH and VOF members with special focus on the activity of the electronic experts' group on antiparasitic resistance.

The OIE also expressed its satisfaction with the high number of delegates attending this VOF meeting and their notification of the delegations to the OIE HQ. The UEMOA expressed its appreciation of the OIE activities and raised the question concerning the possibility of the translation of VICH Guidelines into French. The OIE expressed the willingness to continue the update of the OIE Website with new translated VICH GLs (French, Russian and Spanish) and invited the native speaker participants to provide further support for that.

4. VOF Topics - Update of regional mutual recognition system in GCC

SFDA explained (link) that the GCC centralised registration is a harmonised system for product registration for GCC countries. It is based on central coordination, common guidelines, and consensus decision making based on individual national assessments of the product dossiers. The goal of the GCC Health Council is to harmonise the registration processes for pharmaceutical manufacturers and their products, also in the veterinary field.
SFDA detailed the current situation for veterinary products, the pathway of GCC Vet products registration, the regulatory time framework, the 2 existing guidelines (*available on the SFDA drug authority English version website*), the assessment criteria and future plans, as well as the advantages, disadvantages and challenges of the GCC harmonisation.

UEMOA asked how the GCC approaches the mutual recognition when there are differences between the dossiers from the EU and the USA. SFDA explained that when a product is presented that has been registered in the EU and the USA, most countries re-evaluate only a part of the dossiers.

The EU commented that, in its own experience with a mutual recognition system, the availability of common standards and guidelines has been critical in minimising disagreements between member states. The EU has also in place a coordination group for mutual recognition, comprising one representative from each EU member state, which seeks to address different views that arise in procedures. If it is not possible to solve issues in the coordination group, it is possible to trigger an arbitration procedure run by the EMA's CVMP.

Zimbabwe asked if the GCC is able to meet the timelines that are set. SFDA confirmed that the aim is to strictly respect these timelines; the clock is of course stopped when questions are sent to the company.
Zimbabwe questioned how many applications are reviewed. SFDA has received about 250 new applications in the year 2020. This would set the expectation for the incoming GCC centralised system.

SFDA wished to receive more information about the timelines in the VICH countries. The EU explained that for applications processed by the EMA, the standard timeline is 210 days from start of assessment to finalisation of opinion. During this procedure, the clock may be stopped after 120 days and the applicant is given the opportunity to address questions raised by assessors. Once the applicant's responses to the list of questions is received, the clock is restarted and runs to completion at Day 210, with the possibility of a further clock stop at Day 180 if there are remaining outstanding issues.
JMAFF questioned why the GCC only considers (slide 12) products registered by the EMA and the USDA and why products registered by FDA and JMAFF are excluded?
SFDA explained that the GCC Health Council will review this list in the near future.

Morocco asked if, when a product is already registered in the EU or the USA, and the GCC does not evaluate all the dossier, as GCC is able to get copies of the EU or USA assessment reports. SFDA explained that in this case the dossier is reviewed more strategically, focussing on key areas of interest, as the EU and US assessment reports are either provided by the company, or available on the EMA website (EU assessments only).

5. Information about training recording and follow-up webinar

The EU expressed its regrets that it was not possible to host the VOF in Amsterdam this year; different means of training were therefore developed. The proposed solution could represent a positive step towards new developments of VOF training sessions.
4 presentation's on VICH GL 27 application, prepared by the VICH members regulatory authorities, have been placed on the VOF website (link), all with audio voice-over explanations which hopefully make the slides easier to understand.
The EU confirmed that the organisation of a 1.5 hours follow-up webinar is planned provisionally on Tuesday 9 February 2021. The EU asked however to receive the questions in writing beforehand in order to enable the experts to prepare their replies.
Questions should be sent in writing to the VICH secretariat by Friday 22 January 2021 at the latest.

Act: All

A Q/A paper based on this session will also be prepared for further use by the VOF members.

The OIE mentioned that if this new approach to training is successful, the VICH SC will reflect on this and other ways to address the VOF training requirements in the future.

6. Discussion on the draft agenda for the 14th VOF

The OIE took the participants through the draft agenda that was circulated before the meeting.
The OIE expected that it will be possible to hold the face-to-face meeting in Amsterdam in November 2021, as currently scheduled.
As discussed at the 12th VOF meeting, a pre-meeting will take place on the first morning for exchanges between VOF members only, with a representative of the OIE. It will be followed by a training session by VICH experts, without the presence of the SC members. The 2nd day's set up will then be similar to the previous VOF meetings.

JMAFF pointed out that under agenda item 5, there is specific reference to GL17, which is aimed at harmonizing stability testing of biotech-products such as cytokines, monoclonal antibodies, growth factors and vaccines component which consist of well-characterized proteins and peptides, and asked if VOF members are interested in these novel therapeutic products.
HealthforAnimals asked if VOF members would be interested in the topic of digital platforms, with a discussion on their advantages & disadvantages, as these are much more used since the COVID-19 crisis.
The OIE suggested that it could be a discussion in the pre-meeting, as well as in item 4 of the part 2 of the 14th VOF meeting, based also on the experience from the webinar training session provided this year and the follow-up session in February 2021.

Morocco asked to discuss the in-use stability of animal medicines and stability in drinking water. OIE suggested that this topic could be merged with the current item 5, by expanding the point to cover stability testing more generally.
AHI mentioned that it is in discussion with USDA on this topic and could provide more information within a few months if the discussions with USDA are progressed.

AHI proposed a topic aimed at comparing regulatory frameworks relating to Good Manufacturing and Distribution practices applicable in different regions. AHI has developed a "translation guide" (https://ahi.org/wp-content/uploads/Global-Regulatory-Frameworks-comparison-spread-sheet-1-23-20.pdf) to identify where to find the same information in the different systems: the PIC/S, the US cell 9 Code of Federal Regulations and the EU requirements. This document contains much information, but the VOF could receive a high-level presentation of elements of interest to the VOF members. CAMEVET agreed that this would be useful. The SC will discuss this proposal further.

CAMEVET proposed to address at the next meeting the topic of extrapolation of withdrawal periods to minor species.

Nigeria proposed to address the topics of validation of computer systems and pharmacovigilance.

The VOF agreed overall on the draft agenda proposed.
OIE asked all members to provide further contributions for presentations in the course of next few months.

Act: All

7. AOB

- *Congress*

Yuri Kosenko reported that Ukraine will host the 15th Congress of the European Association of Veterinary Pharmacology and Toxicology from 4 to 7 July 2022. As the chair of the organizing committee, he invited all VOF members to take part in this congress, especially in relation to the regulatory section.

- *Update on the "Out of scope topics" document*

AnimalhealthEurope recalled that this document lists the topics that were raised by the VOF members but are not in the scope of VICH.
The updated list and guidance document will be shortly uploaded on the VOF members website.

- *Pharmacovigilance*

UEMOA asked if VICH & OIE would support the African countries to develop a basic pharmacovigilance system. It is indeed an important issue for UEMOA countries which need the basis of the experience from other countries. The OIE reported that the subject was included and discussed in the frame of 6th Cycle OIE Focal Points Training Seminars for Veterinary Products for English Speaking Africa in Ethiopia and French Speaking Africa in Togo in 2019. It was evident that a regional approach is proposed, based on the outcome of the survey conducted before the seminar. At the 6th cycle of Training Seminars, a practical session was dedicated to Pharmacovigilance with some case studies. The manual/document "*How to set up a pharmacovigilance system for veterinary medicinal products"* (described in point 3 above) was included and presented in the 6th Cycle Training Seminars. As a follow up, the OIE HQ had invited the Focal Points to provide their comments to the manual. The consolidated comments were provided to HealthforAnimals for further consideration and will be made available after the upcoming webinar as well, and taken into consideration for the final version which will be published.
Nigeria indicated that they are also in the process of setting up a pharmacovigilance system with the support of the UK VMD.
UEMOA pointed out that it is nevertheless not easy to develop such a system with 8 countries and would appreciate further support. The OIE HQ representative assured that this will be a further subject of the representative of Africa and the OIE HQ representative will provide further support as much as she can.
India questioned how many countries had adopted the OIE document on Pharmacovigilance. The OIE pointed out that this is an information document which is not for formal national adoption.
The GCC indicated that they have not developed yet a regional GL on Pharmacovigilance.

AnimalhealthEurope mentioned that the manual is available to all through OIE; it is also translated in French and Arabic, and will also be translated into Russian.
The OIE indicated that it aims to publish a consolidated version, taking into account the OIE Members comments (via the Focal Points of Veterinary Products) in cooperation with HealthforAnimals by end 2021.

- *Report on the calculation of withdrawal periods*

AnimalhealthEurope mentioned that the document was circulated to the VOF in September and a discussion on the calculation of withdrawal periods is also planned at the 14th VOF meeting.
It was acknowledged that further exchange on this topic 1 year after the circulation of the document will be useful to VOF members.

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

The **14th VICH Outreach Forum** meeting will be held in November 2021 in the offices of the EMA in Amsterdam - the Netherlands

9. Conclusion

The Secretariat thanked all participants throughout the different regions for their participation in this virtual meeting, which, for some people, took place at a very late or very early hour of the day.
Dr Ivo Claassen, Head of the Veterinary Medicines Department at the European Medicines Agency, congratulated the participants for this highly successful meeting and hoped to be able to host all VOF members in Amsterdam in next November.

13th VICH Outreach Forum meeting
Participants

1/ Forum participants *(registered)*

ARGENTINA – CAMEVET	Virginia DEVI QUINONES PUIG
ARGENTINA – CAMEVET	Javier CARRACEDO
ARGENTINA – CAPROVE	Patricia MILLARES
ARGENTINA – SENASA	Federico LUNA
ARGENTINA – SENASA	Luisina GARCIA SAINZ
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Isabela Maria ALVES DE AVILA
BRAZIL – Ministry of Agriculture, Livestock and Food Supply	Marcos Vinicius DE SANTANA LEANDRO Jr.
BRAZIL – SINDAN	Luiz MONTEIRO
BRAZIL – SINDAN	Emilio SALANI
BRUNEI – Dept. of Agriculture & Agrifood	?
CHINA (PR) – Institute of Vet. Drug Control	Shixin XU
CHINA (PR) – Institute of Vet. Drug Control	Gu JIANHUA
INDIA – Ministry of Fisheries, Animal Husbandry & Dairying	Upamanyu BASU
INDIA – Ministry of Fisheries, Animal Husbandry & Dairying	Lipi SAIRIWAL
MALAYSIA – Dept of Vet. Services	Nor Natasha bt MOHD SOFIAN
MALAYSIA – Dept of Vet. Services	Azlan BIN ENJAH
MALAYSIA – Dept of Vet. Services	Rachel FONG
MALAYSIA – Dept of Vet. Services	Ani bt YARDI
MALAYSIA – Dept of Vet. Services	Alifah bt ISMAIL
MALAYSIA – Dept of Vet. Services	Rohaya bt MOHD ALI
MALAYSIA – Dept of Vet. Services	Sarah DADANG
MALAYSIA – Dept of Vet. Services	Norlizan BIN MOHD NOOR
MEXICO – CANIFARMA	Alexandra LUNA ORTA
MEXICO – SENASICA	Maria Elena GONZALEZ RUIZ
MOROCCO – ONSSA	Hasnae BENALLA
NIGERIA – NAFDAC	Bukar USMAN
NIGERIA – NAFDAC	Olaniran ALABI
NIGERIA – NAFDAC	Mwapu NDAHI
NIGERIA – NAFDAC	Yunus SADIQ
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Moon HER
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Ok-Mi JEONG
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Hae-chul PARK
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Hee YI
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Byung-suk JEON
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Yangho JANG
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Ji-Yeon KIM
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Yong-Sang KIM
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Na Le PAK
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Eutteum SONG
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Yong HAN
REPUBLIC OF KOREA – Animal and Plant Quarantine Agency	Seong Mi LEE
RUSSIA –VGNKI	Vasilina GRITSIUK

RUSSIA – VGNKI	Anna BABUSHKINA
SAUDI ARABIA – Saudi Food & Drug Authority	Walid A. AL-HOMAYIN
SAUDI ARABIA – Saudi Food & Drug Authority	Saeed M. AL-SHAHRANI
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SINGAPORE – Agri-Food & Veterinary Authority	Juline CHUA
SINGAPORE – Agri-Food & Veterinary Authority	Wai Kwan WONG
SINGAPORE – Agri-Food & Veterinary Authority	Alwyn TAN
SINGAPORE – Agri-Food & Veterinary Authority	Xinyu TOH
SINGAPORE – Agri-Food & Veterinary Authority	Taoqi HUANGFU
SINGAPORE – Agri-Food & Veterinary Authority	Fu Xian HENG
SINGAPORE – Agri-Food & Veterinary Authority	Tze Hoong CHUA
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UGANDA – National Drug Authority	Josephine NANYANZI
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WAEMO/UEMOA	Komlan AKODA
WAEMO/UEMOA	Maimouna SANOGO - SIDIBE
WAEMO/UEMOA	Moumouni ABSI
WAEMO/UEMOA	Assiongbon TÊKO-AGBO
WAEMO/UEMOA	Nafissatou TRAWARE
WAEMO/UEMOA	Yao POTCHOO
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