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

VICH/24/066
17 January 2024
Final

VICH FORUM

17th Meeting
11 & 12 November 2024
EMA/Amsterdam - The Netherlands

SUMMARY REPORT

1. Opening of the meeting and chairperson's introduction

The meeting was chaired by Dr Laetitia Le Letty, Head of the European and international affairs at the French agency for veterinary medicinal products - WOAH Collaborating Centre, on behalf of the WOAH and Dr Ivo Claassen, Head of the Veterinary Medicines Division at the European Medicines Agency.
Dr Le Letty opened the meeting by welcoming in particular the delegates from Rwanda and the UAE for their first participation, as well as all the other the participants to the 17th VICH Forum (VF) in Amsterdam.

2. Report by the Steering Committee (SC) on issues raised by Forum members during the 16th VICH Forum (VF) meeting in November 2023

The VICH Secretariat presented the report from the SC (link) and pointed out that following the success of last year's VF pre-meeting with VF members only, chaired by WOAH, a new meeting has taken place this year chaired by Botswana. The participants discussed the strengthening of the Forum network, the benefits of implementing VICH GLs as well as several challenges not in the scope of VICH (see item 4 below).

From the topics suggested by VF members at the 16th meeting, the regulatory approach to unmet medical needs will represent the main discussion subject, including in breakout sessions, during the 17th meeting. VF members will hear the experience from EU, Japan, USA & Industry as well as Canada and Australia in order to better understand how decisions are made for unmet medical needs.
The UK will present a self-assessment tool for veterinary medicines regulators under development and Botswana & Rwanda will provide their first feedback on the use of the tool.

A brief overview of the activities developed by the 9 VICH Expert Working Groups since the last meeting was presented to the VF.
The Secretariat concluded by highlighting that 3 VF members (Brazil, EAC, Ukraine) will be speakers at the VICH 7 Conference.

3. Report by WOAH to the Forum members

The representative of WOAH HQ summarised the report (link) focusing on the activities of WOAH since the last VF meeting by detailing the support provided by WOAH to the VF and VICH.

WOAH further explained how it promotes the VICH and VF activities in connection <ith the Focal Points' seminars; WOAH also listed the activities and meetings with WOAH involvement of potential interest to VICH.
WOAH concluded by thanking for their collaboration the WOAH Collaborating Centers represented in the VICH SC (ANSES, FDA and NVAL) and the WOAH members who are also VF members as well as the VICH Secretariat and the WOAH AMR and Veterinary Products Department.

4.Q & A

Skipped

5. Feedback from the VF pre-meeting

The chairman of the VF pre-meeting (Dr Ravengai - Botswana) confirmed that open and constructive discussions took place between the 18 participants to the meeting.
A reminder was made regarding the objective of being a member of the VF
The participants recommended to update the Terms of Reference to clarify the objectives of the pre-meeting, the rules including the duration of the mandate for the chairmanship and the network to be developed.

Act: WOAH

The participants encouraged the creation of a VF living network with the forum members based on the database published on the VICH website and suggested to also include the WOAH focal points for VMPs who are under the responsibility of the Delegates of Members. A Concept Paper will be developed for the establishment of a VF network and the involvement of the WOAH collaborating centres. Saudi Arabia proposed to clearly define the mandate of the network, and define the confidentiality level of the information.

Act: WOAH

It was confirmed that the objectives of the pre-meeting are to share success stories and experiences, ask questions, develop cooperation among VF members, discuss the implementation of guidelines. The VF members were encouraged to complete and update whenever necessary the GLs implementation tracking table.
A major discussion point was related to the definition of implementation; VF members suggested further exchange with VICH SC member countries on their approach to implementation.
AnimalhealthEurope pointed out that a VICH guidance document (VICH/14/013-fin) on the implementation of VICH GLs is available on the website (link).

It was also acknowledged that the language barrier remains a major challenge. The translation of the VICH GLs into the national languages, with the help of experts having the adequate lingual and scientific expertise was considered as a useful support.

The VF members confirmed that their overall expectations are related to more harmonisation, more convergence, more work sharing considering the limited resources available etc…
The main challenges that were discussed cover:

- Novel technologies
- Cellular products/regenerative products
- Herbal medicinal products
- Experience in combatting AMR
- Bioequivalence studies including post-marketing surveillance
- Biological GLs

- Fixed combination products, in particular the principles of combination products

The regulation of Autogenous Vaccines was raised by VF members, but it was recalled that this topic has been addressed at the 14th VOF meeting in November 2021; the presentation remains available on the website (link). The WOAH representative mentioned that WOAH is working on a reflection paper on autogenous vaccines with their Collaborating Centres of Veterinary Products to address Recommendation 8 of the Second Global Conference on AMR : *"…explore the opportunity to develop standards or guidelines related to autogenous vaccines and other alternatives to antimicrobials, including guidance for quality, safety and efficacy, as tools to reduce the need to use antimicrobials".*

The approach to generics was mentioned; this topic was addressed at the 16th VF meeting last year and the presentations are also available on the website (link: EU – Japan - USA).
The regulation of premixes containing antimicrobials was also mentioned, but it was acknowledged that the revised VICH GL8 - *Stability testing for Medicated Premixes* has been signed off by the SC at step 4 of the VICH process and will be circulated for a 6 month public consultation period.

In conclusion, the chairman pointed out that the pre-meeting session is much appreciated and considered very useful by the VF members, and should therefore be continued at each VF meeting.

6. Self-Assessment tool for veterinary medicines regulators

VMD presented (link) the Self-Assessment tool which is being developed and has been tested by Botswana and Rwanda in a pilot study.
The aims of the tool are to establish clear roles and functions for regulators, to measure and improve regulatory service delivery, to evaluate the structure and functions of regulatory bodies and to then to ensure improvements in regulatory performance are tracked over time.
VMD took the participants through the features of the tool and the steps to complete the assessment. The tool is currently available in English language only, but the French version is under development. The Spanish version will be developed later.
WOAH informed the participants that the tool will be presented during the next Focal Point Seminars of Veterinary Products for French Speaking Africa in Tunis (21-23 January 2025).

Botswana described (link) the anticipated benefit of the pilot Self-Assessment for a new National Regulatory Authority (NRA) such as BoMRA. This tool presents an opportunity to understand what makes a fully functional VMP NRA and will represent an excellent support for justifying and motivating adequate resources for start-up NRAs or those intending to review and enhance their capacity.
Botswana pointed out that some terminology used leaves room for multiple or different interpretations and recommended simplifying the tool to avoid misunderstanding of requirements or the required evidence as well as enabling the copy of some text (the required evidence) and speed capturing of the submissions and responses of the NRA input.

Rwanda FDA reported (link) its experience using the pilot tool and praised its simple use with a user friendly well-organised approach to the different regulatory functions, allowing for a step-by-step assessment of various regulatory services. Rwanda highlighted the challenges and provided recommendations for improvements in order to ensure that resources are allocated adequately and the staff can fully utilise all tool features reducing the time necessary to understand and complete the questionnaires.
It was acknowledged that the tool should be continually improved based on user feedback.

Saudi Arabia questioned how the proposed tool can be used to foster harmonisation. VMD explained that the tool separates the regulatory functions so that an outsider can immediately understand the country's exact situation and the confidence level of the administration.

WOAH confirmed that this tool is in the pilot phase with the support of WOAH. It was understood that VMD has developed the tool for self-assessment application, and it is being refined using feedback gathered from NRAs participating in the pilot; any output from tool application is owned by the participating NRA. Once the tool will be finalised, WOAH might host the tool if it is adopted by the WOAH General Session in light of the WOAH Performance of Veterinary Services (PVS) Process.

7. India's Regulatory Procedure for Manufacturing, Import, and New Drug Approvals

Dr A. Sharma and Dr Shankar presented (link) an overview of India's regulatory procedures for manufacturing, import and new drug approvals.
They gave an overview of Indian regulatory procedures and described the roles of the different agencies involved in the approval process of VMPs and veterinary vaccines, as well as the process for granting permission for their import.
It was noted that the regulatory standards are regularly updated since the first central founding act for drugs and cosmetics was passed in 1940.
A flowchart of the regulatory approval process clarified the Indian regulatory procedures in place.
The participants applauded the fact that animal testing was deleted from the monographs of the Indian pharmacopoeia, which mentions in vitro batch releases only.

Session 3: Group discussions

8. Introduction

The chairperson pointed out that the topic of unmet needs was a request from the 17th VF meeting last year.

9. Presentations on unmet needs

- *EU approach to unmet needs*

The EU explained (link) that the EU allows acceptance of dossiers not meeting all standard requirements of quality, safety and efficacy in exceptional cases and listed the requirements for the marketing authorisation under exceptional circumstances.
A marketing authorisation may also be granted for a limited market (previously called Minor Use Minor Species, MUMS) in the absence of comprehensive safety and/or efficacy data.
The EU also described in detail the "cascade" prescription procedure in place which provides a decision tree allowing veterinarians to prescribe authorised products "off-label" when an authorised product for the desired indication is not available.
In conclusion, the EU has a thorough, complex, regulatory system for the authorisation of veterinary medicines, but measures are in place to support (prospective) applicants, promote availability, support innovation and technology, and encourage compliance.
The EU also strongly supports international cooperation and exchange of information between regulatory agencies.

- *FDA Approach to unmet needs*

The FDA described (link) the MUMS Act of 2004 which aims to bring products to market for minor species and uncommon diseases in major species. This conditional approval is valid for 1 year and can be renewed up to 4 more years for a total of 5 years during which the company has collected sufficient data for a full approval application to FDA.
In 2018, the conditional approval was expanded beyond MUMS drugs in order to incentivize development of drugs for use in major species that address serious or life-threatening conditions or an unmet animal or human health need and where demonstrating effectiveness would require complex or particularly difficult studies.

Priority Zoonotic Animal Drug (PZAD) designation offers flexibilities in review processes for drugs that address zoonotic outbreaks whilst FDA provides for certain fee waivers as an incentive to encourage drug development, including Minor Use or Minor Species indications.
In the USA the Animal and Veterinary Innovation Agenda (AVIA) sets a vision for the future of animal and veterinary innovation in the US.
FDA highlighted the need for regulatory flexibility and mentioned recent risk-based decisions that were made based on the review of safety and quality information.

- *Regulatory approach to unmet needs in Japan*

JMAFF explained (link) that in Japan the approach to unmet needs differs from the EU and the USA as the law does not provide for such provisions; these are generally considered scientifically on a case by case basis which requires regulatory flexibility.
JMAFF detailed the data required for the different applications and explained how regulatory flexibility can be applied.
JMAFF used the example of the acceleration of development of African Swine Fever (ASF) vaccination through public-private/international cooperation with the objective to strengthen the epidemic control measures in response to the domestic outbreak of ASF. the aim was to prevent the spread of CSF (Classical Swine Fever), reduce the economic damage through early eradication and to provide a stable supply of pork.

- *Unmet needs – view from industry*

AHI introduced (link) a background document from industry "*Innovation in Veterinary Health: Understanding the Path to Address Unmet Medical Needs and Ways to Support It*" focussing on key aspects of the developers' decision-making process when pursuing the development of new veterinary medicinal products for MUMS or limited markets. The document also provided the industry viewpoint on best regulatory practices, relevant to each decision point, that support investment in un-met needs.
AHI presented the key points that should be considered to address the unmet needs issue.

Q & A session
Brazil asked about the criteria used to determine that animal species are minor.
FDA explained that it is based on the calculation oof the number of animals in the country. These numbers are reviewed every 5 years. In relation to how substantial evidence of effectiveness is demonstrated, FDA focussed on the thresholds to demonstrate that the product is efficient.
The EU pointed out that major and minor species are defined in the EU Regulation 2019/6 (article 4, definition 29) and that guidelines are published on where data requirements can be reduced for limited market products. It was also added that considering the small numbers of animals that are considered compared to other species, industry requires regulatory certainty to understand which data are requested by the regulators.

Botswana asked how compounded medicines are regulated, as they compete with registered medicines, undermine the authorisation process and have negative effects on the markets.
FDA pointed out that compounding is a complicated issue as not all compounding should be disregarded; sometimes compounding is useful to facilitate the product's administration. In many areas however it hinders the development of new products.
JMAFF mentioned that compounding does not represent a mix of registered products, which would be better described as the combination of registered products.
In the EU the preparation of "extemporaneous" products by pharmacists are not regulated at the national level and not at the centralised level. The "cascade" rules permit extemporaneous preparation only where no other solution is possible (Regulation 2019/6, articles 112(1)(c), 113(1)(d) and 114(1)(d)).

Saudi Arabia questioned which tests should be conducted to extrapolate products authorised in other countries to camels.
JMAFF explained that in Japan the veterinarians have the freedom to decide on the extra label use or the use of human products. These are exempted from clinical tests for animals, which does not facilitate innovation of veterinary medicines.
The EU mentioned that the extrapolation of MRLs to camels was recently discussed at Codex.
AQHE warned of the disincentive generated by generic products authorised in a local market without any specific label requirements and a lack of control of the usage of the product.

10. First discussion session in breakout groups

- Discussion in 3 groups of VF members:

Group 1: Egypt, Saudi Arabia, Singapore, Taiwan,
Group 2: Botswana, Brazil, India, Ukraine
Group 3: EAC, Kenya, Rwanda, South Korea

11. Reporting back from the breakout session 1

Skipped

12. Presentations for group discussion 2

- *Canada*

Health Canada explained (link) that to address unmet needs, a regulated access to unapproved veterinary drug exists in Canada, referred to as the Emergency Drug Release program (EDR).
This regulated pathway to access unapproved products allows veterinarians greater access to product, including those for minor use, minor species It improves oversight of products being brought into the Canadian market, helps to encourage authorized product use first and ensures food safety. It also gives the regulator additional information on product use.
Manufacturers must also ensure that the requesting veterinarian has sufficient information to submit an EDR request and must verify that the amount of drug being requested can be accessed.
An example of the benefit of receiving additional data through this pathway is with the use of sedative products on wildlife for which clinical trials are not possible. This information was released publicly so that a company could use it to help support a regulatory submission.

- *Australia*

The Australian Pesticides and Veterinary Medicines Authority explained (link) that a veterinary chemical product to legally be manufactured, imported, supplied, sold or used in Australia,

must be registered or permitted by the APVMA. To address unmet needs, special permits, or import consents, can be delivered to legalise off-label use of a registered product or use of an unregistered product for a limited time period.

13. Second discussion session in breakout groups

Second discussion in 3 groups of VF members

14. Reporting back to plenary on outcome of the 2 sessions of group discussions

Group 1

The participants reported (link) that they had shared their experience and questions on the following topics:

- Regulatory Predictability
- Public Private Partnerships
- Sharing of Unmet Needs
- Responsibility for Product Availability by the holders of the marketing authorisation
- Compounding
- Permits and current systems to address unmet need
- Liabilities and Use of Unauthorized Product

Group 2

The participants detailed (link) their exchanges regarding the approaches to unmet needs available in their countries as well as in the VICH member countries.
It was noted that the cascade system is critical to address unmet needs in the EU whilst in Japan veterinarians have an important flexibility regarding the usage of unregistered products.
Japan mentioned that the digital label is considered as an advantage in the availability of medicinal products.
The challenges highlighted by the participants of this group were about the compounding products (products that are not authorised as medicinal products but used as veterinary medicinal products), products available for wildlife animals and communication on the availability of veterinary medicinal products.

Group 3

The participants reviewed (link) the possibilities to use products for unmet needs and MUMS in the different jurisdictions and acknowledged that all approvals granted remain conditional. It was noted that the definition of minor species varies depending on the regions and countries i.e. in some African countries, pets are considered as a minor species
The participants also reviewed the data required during registration and noted the challenges that can be met such as the lack of veterinary medicines, the authorised medicines that are not marketed, and the extrapolation of the MRLs.

General discussion

Industry pointed out that it would be useful for manufacturers to benefit from fast track systems for emergency needs in all countries and regions.
It was suggested that WOAH could represent a central repository for the definition of MUMS in different countries and regions.
Electronic labelling was considered as a progress towards the reduction of the volume of packaging and the ongoing development of an optional electronic labelling by Japan was considered useful to be followed.

Session 4: Discussions and conclusions

15. Feedback on the meeting from Forum members, next steps and open discussion

The VF members unanimously expressed their appreciation to the organisers of the meeting as well to the VICH SC. The VF members applauded in particular the organisation of the premeeting which should be continued.

Egypt appreciated learning from other regulatory systems which enables to identify the gaps in own systems. Egypt is currently drafting a GL on bioequivalence studies of generic Veterinary medicinal products~~on minor uses~~ and is considering incentives which could be provided to companies to take part in the pilot phase. These initiatives are important to improve national regulatory systems.

India considered the exchange between all stakeholders very useful, in particular the sharing of experience from VICH members. India stressed the importance of capacity building and sharing challenges.

Taiwan appreciated the content of the discussions and will share the learnings with the agencies' colleagues.

Rwanda confirmed the importance of meeting delegations from other countries and regions and learning from the experience of colleagues.

Singapore agreed that the exchange of information is of utmost importance and enables to learn much very useful information from other participants.

Saudi Arabia has once more gathered much useful information regarding the implementation of GLs, although would appreciate more clarity on the meaning of GLs' implementation.
Saudi Arabia recommended that VICH should organise again training programmes as well as workshops at regional level with industry.
Saudi Arabia mentioned the strong need for cooperation, harmonisation, regulatory convergence and closer collaboration between regions to conduct the required scientific studies. Industry also needs a harmonised approach to increase predictability.
Saudi Arabia supported the development of a VF members database and recommended VF members to share ideas on the future needs from VF member countries.

Botswana highlighted the importance of the discussions and exchanges that took place over the 2 days and has learned how to chair an international meeting.
Botswana wished to be more involved in EWG activities.

Republic of Korea has also gained much experience in learning from the exchanges that have taken place.

Kenya-EAC considered that the knowledge gathered in these meetings enlightening and enabling to learn much useful information. The discussion on unmet needs has shown that many countries and regions are faced with the same challenges.

Ukraine thanked all the participants for the fruitful exchanges on unmet needs and the approaches to implementation. Ukraine also supported the creation of a VF network.

Brazil agreed that exchanges within the VF help to provide not only possible solutions to the challenges faced by most VF members, but are also important to progress the global harmonisation of technical requirements.

Brazil indicated interest in being a Visiting Delegation to the 44th SC meeting in November 2025.

The proposed topics (also from the pre-meeting) for the next meeting are:

- Bioequivalence
- Experience in combatting antimicrobial resistance
- Regulation of biological products
- Extemporaneous preparations
- Cellular products/regenerative products

Further suggested topics:

- Novel technology,
- Herbal medicinal products
- Global databases of registered products
- How to implement VICH GLs without duplicating efforts
- Regulations on combination products, principle of combination
- Regulations on premixes pharmacovigilance
- Others: autogenous vaccines, premixes containing antimicrobials

16. Conclusions and next steps

Dr Le Letty thanked again all participants for their attendance and confirmed that the discussions in the pre-meeting have been particularly appreciated by the participants. She further thanked Botswana for having chaired efficiently the pre-meeting. She confirmed that a first draft of the 18th VF meeting agenda will be circulated in early 2025.

17. Confirmation date and venue of the next VICH Forum meetings

- The **18th VICH Forum** meeting will be held on 11 & 12 November 2025 in Indianapolis, USA
- The **19th VICH Forum** meeting will be held on 17 & 18 November 2026 in Japan, in Tsukuba-city, Ibaraki prefecture, close to the Narita airport

17th VICH Forum meeting
Participants

1/ Forum members

BOTSWANA – BoMRA	Innocent RAVENGAI
BRAZIL – Ministry of Agriculture and Livestock	Barbara BORGES CORDEIRO
EGYPT – Egyptian Drug Authority	Samah SALAMA
INDIA – Ministry of Fisheries, Animal Husbandry and Dairying	Aruna SHARMA
INDIA – Ministry of Health & Family Welfare	Gouri SHANKAR
KENYA – EAC	Adelaide OGUTU
Republic of KOREA – APQA	Hee YI
Republic of KOREA – APQA	JinJu NAH
RWANDA – Rwanda Food and Drug Authority	Geofrey KARASANYI
RWANDA – Rwanda Food and Drug Authority	Doreen INGABIRE
SAUDI ARABIA – Saudi Food & Drug Authority	Bandar ALHAMMAD
SAUDI ARABIA – Saudi Food & Drug Authority	Mohammed ALSHANQITI
SINGAPORE – National Parks Board of Singapore	Chris KHOO
TAIWAN (ROC) – APHIA	Tsai-Lu LIN
TAIWAN (ROC) – APHIA	Yu-Hsien CHEN
UNITED ARAB EMIRATES – Ministry of Climate change and Environment	Kaltham ALI KAYAF
UKRAINE – SCIVP	Yuriy KOSENKO
UKRAINE – DPSS	Oleg OSIIAN

2 / VICH Steering Committee

Members and (C) Coordinators

STEERING COMMITTEE (C) coordinators

AHI (ZOETIS)	Carrie LOWNEY
AHI (BI)	Elizabeth NORTON
AHI	Rachel CUMBERBATCH (C)
EU (EUROPEAN COMMISSION)	Eva ZAMORA ESCRIBANO
EU (EMA)	Ivo CLAASSEN (*Chairperson*)
EU (EMA)	Nick JARRETT (C)
EU (MEB)	Johan SCHEFFERLIE
ANIMALHEALTHEUROPE (BI)	Brigitte BOENISCH
ANIMALHEALTHEUROPE (ELANCO)	Erik DE RIDDER
ANIMALHEALTHEUROPE	Rick CLAYTON (C)
JMAFF	Kaoru EGUCHI
JMAFF	Shoko IWAMOTO
JMAFF	Mariko OCHIAI (C)

JVPA (NIPPON ZENYAKU KOGYO CO.)	HueyShy CHEE
JVPA	Koji OISHI (C)
US (FDA/CVM)	Matthew LUCIA
US (USDA CVB)	Geetha SRINIVAS
US (FDA/CVM)	Brandi ROBINSON (C)

STANDING MEMBERS

Australia (APVMA)	Donald SIBANDA
Australia (AMA)	Charmian BENNETT
Canada (Health Canada)	Marilena BASSI
Canada (CAHI)	Catherine FILEJSKI
New Zealand (MPI)	Karen BOOTH
South Africa (SAAHA)	Margaret CHURCHILL
South Africa (SAHPRA)	Alice SIGOBODHLA
NOAH	Donal MURPHY
VMD	Suzanne ECKFORD (part)
VMD	Gillian CLARKE (part)
VMD	Noel JOSEPH (part)

OBSERVERS

SWISSMEDIC	Nina WALSER
SCIENCEINDUSTRIES (Zoetis, Switzerland)	Yolanda KÄSER

INTERESTED PARTIES

AVBC	Lee NAGAO

WOAH

WOAH	Laetitia LE LETTY
WOAH	Maria SZABO
WOAH (ANMV)	Franck FOURES

VICH

HealthforAnimals	Hervé MARION (*Secretary*)
HealthforAnimals	Carel DU MARCHIE SARVAAS

GUESTS

Australia (APVMA)	Maria TRAINER
Canada (Health Canada)	Jennifer GEDULD
Canada (Health Canada)	Elise TATONE
US (FDA/CVM)	Ellen HART

APOLOGIES

JVPA (Nisseiken Co.)	Kotaro TUCHIYA
New Zealand (APHNZ)	Jeff HOWE