VICH/23072
19 January 2024
Final

VICH FORUM

16th Meeting
14 & 15 November 2023
Tokyo - Japan

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 Tomoaki Shimazaki, Director General of the National Veterinary Assay Laboratory, Ministry of Agriculture, Forestry and Fisheries, Japan - JMAFF. Dr Norio Kumagai, CVO of Japan, gave an introductory speech on behalf of the Japanese Minister of Agriculture, Forestry and Fisheries. He highlighted the importance of VICH for Japan to guarantee the safety, efficacy and quality of affordable VMPs.

Dr Le Letty opened the meeting by welcoming the participants to the 16th VICH Forum (VF) in Tokyo and looking forward to fruitful discussions.

2. Report by the SC on issues raised by Forum members during the 15th VICH Forum (VF) virtual meeting in November 2022

The VICH Secretariat presented the report from the SC (link) and pointed out that several concrete suggestions were made at the first VF premeeting in 2022, such as the creation of a VF members' database (available the VF members only webpage), the development of a VICH GLs implementation tracker enabling an overview of the status of implementation in the VF countries, as well as a list of topics for the next meeting.
A second pre-meeting, chaired by Dr Maria Szabó WOAH (HQ), before the 2023 VF session had a successful outcome (see item 4 below).
Other topics suggested at the 15th VOF meeting were:

- Regulatory approach to Generics in order to better understand the regulations on generic products
- The VICH 9 step procedure as a reminder of the process of development and adoption of VICH Guidelines
- Session on the VICH 7 Conference planning with a review of the Conference draft programme
- An explanation of the VICH updated structure facilitating the involvement of VF members in VICH activities
- A brief summary on the activities of the 9 VICH Expert Working Groups

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.
WOAH welcomed the application of Egypt, Rwanda and Saudi Arabia to the VF membership, and detailed further:

- Support provided to VICH by WOAH (update)
- Promotion of VICH and VF activities in connection of the Focal Points seminars
- Activities and meetings with WOAH involvement of potential Interest to VICH
- The strong involvement of WOAH in the organisation and support of the VF pre-meeting

4. Feedback from the VF pre-meeting

The rapporteur (Dr Ayoyi – EAC) reported (link) that open and constructive discussions took place between the 16 participants to the meeting which was chaired by Dr M. Szabó (WOAH).
A number of expectations were listed in particular:

- Training and case studies on VICH Guidelines
- How to use the GLs for product registrations – e.g., bioequivalence, generics, etc.
- Translation of Guidelines into national language
- Information on becoming a member of the Steering Committee
- More information on classification of members at different levels of VICH
- Requirements for the control of VMPs on the market (post-market monitoring, testing, etc.)
- How do quality requirements for human and veterinary products compare in order to achieve regulatory flexibility?
- Minor use, minor species (e.g., camel)

The participants also exchanged broadly on the impact of being a VICH member and discussed a number of regulatory challenges, which are mostly not belong to the scope of VICH. The *primary messages* emphasized by Forum Members were about the benefits of VICH membership on the trade, availability and quality of registered veterinary medicinal products, as well as positive impacts on the veterinary legislation. Throughout the discussion, it became clear that establishing a network within the Forum Members could lead to efficient exchanges of national experience and facilitate Members' ability to assist each other with professional challenges.

Next year's Forum will be chaired by the representative from Botswana with strong support from WOAH. WOAH will prepare the agenda for the November 2024 Forum meeting in collaboration with the WOAH Collaborating Centres ANSES and FDA.

Upon request, 3 volunteers (Brazil, EAC & Ukraine) were identified as speakers at the VICH 7 Conference with the aim to involve Forum Members more actively in the global VICH activities.

5. Information from VICH Forum members

5.1 Presentation of the national system in the United Arab Emirates

Presentation cancelled as the United Arab Emirates, did not attend the meeting.

5.2 Presentation of the national system in Egypt

Dr Salama presented (link) an overview on Veterinary Medicines Regulatory system in Egypt and detailed the mission, responsibilities and goals of the Egyptian Drug Authority – EDA.
She explained the VMP registration system in Egypt and pointed out that since a few months all registration requests are submitted through an automated electronic registration system enabling a better communication between EDA and veterinary pharmaceuticals companies as well as an acceleration of the registration process of VMPs.

The participants acknowledged the existence of a fast track registration system, mainly a document assessment except for the Safety assessment, within a 4 months' timeline for priority products already registered in a reference country.
The participants took note of the list of VICH GLs already partly or totally implemented in Egypt.
It was finally noted that the vaccines are not in the scope of the EDA, as they are registered by the Ministry of Agriculture.

5.3 Presentation of the Veterinary Zazibona SADC work sharing (harmonisation) initiative

Dr Ravengai explained (link) that the Zazibona Initiative is a veterinary medicines regulatory harmonisation initiative, based on the SADC initiative for regulatory harmonisation for human medicines which started 2013.
The initiative is aimed at enabling joint:

- Assessments of Dossiers for VMPs
- GMP inspections of Manufacturers of VMPs
- Pharmacovigilance activities of VMPs, &
- Any other collaboration e.g., to curb circulation of VMPs

There is no regulatory obligation, as it is a memorandum of understanding between the member countries which are Botswana, Malawi, Namibia, South Africa, Tanzania, Zambia & Zimbabwe.
He highlighted the objectives of the Zazibona veterinary medicines initiative and explained that after a period of limited activity in 2022, the Veterinary Medicines Regulatory Harmonisation Initiative is being revived with the aim to continue with the project based on the founding principles. He called for a re-engaging of industry for the submission "Expression of Interest" for which selected products will be identified to be assessed under the scheme.

Industry asked for a clarification of the re-engaging request. Dr Ravengai explained that it is asked to the companies to confirm again that the initial 8 products that had been put forward previously for submission, and mentioned that these would now be accepted.
Companies will receive a formal reply by the end of Q1/24.

SAAHA thanked Botswana and confirmed the strong support from industry.

Australia mentioned that the development of a collaboration with Canada and New Zealand has been very challenging, much time was required to learn working with different systems, but has become very rewarding once established.

6. Topic of interest

6.1 Guidelines implementation tracker

The Secretariat presented the consolidated VF guidelines' implementation tracker and thanked the 7 countries/organisations who have replied so far: Argentina, Egypt, Republic of Korea, Mexico, Saudi Arabia, UEMOA and Zimbabwe. The aim is to get an overview of the status and evolution in the VF member countries/regions.
The Secretariat explained that the tracker is intended to be a living document which each VF member can update when changes to the GLs status are made, and asked the VF members which have not replied yet, to provide their tracker table ASAP.
A new call will be circulated to the VF together with the current consolidated tracker table.

Act: Secretariat

VF members asked if there is a need to implement an “official translation” of a GL. The secretariat confirmed that VICH has no official translated documents, the working language of VICH being English only. All GLs are available for free and anyone is welcome to translate them as needed.
A few translations in Spanish, Russian and French can be downloaded from the WOAH website (https://www.woah.org/en/what-we-offer/veterinary-products/vich-outreach-forum/).
Brazil and Ukraine confirmed that some VICH GLs have been translated in the local languages.

7. Regulatory approach to generics

JMAFF took the participants (link) through general considerations and regulation systems applicable to generic products in Japan.
JMAFF pointed out that there is no clear definition of “Generics” in Japan, neither in VICH, and that Biologicals including vaccines and biotechnological/biological VMPs are out of the scope of the presentation.
JMAFF demonstrated that VMPs with a demonstrated bioequivalence with already approved VMPs are considered to be “Generics” and concluded with an overview of a dossier for “Generics” in Japan.

Korea and Botswana questioned why Japan requires an additional residue confirmation test for VMPs for food-producing animals. JMAFF replied that there is a need to check that the withdrawal period for the “Generic” does not exceed MRL established for the original product. It is not sufficient to measure the blood residue level; the regulator needs to evaluate the residues in tissues to ensure that the concentration does not exceed the required levels.
The information in the dossier must be the same and the study must show that the product is truly equivalent, the blood concentration is tested in accordance with GL 52.
When this is proven the generic can be authorised.

Botswana asked if a product approved in another jurisdiction can be used as reference product. JMAFF only accepts a reference product registered in Japan, not a product approved outside of Japan. Studies can be done in other markets but only with reference products that are approved in Japan.

The EU presented (link) the approach to generics in Europe and detailed the background of the EU legislation, the types of application and the conditions and dossier requirements for a generic application.
The EU explained that a reference product is a product that has been approved with a complete set of quality, safety and efficacy data. If this product is not authorised in the EU, a company may use it as a reference product, but only for specific studies.

Korea asked if a standard application can be compared with a long acting formulation with additional residue studies. This is not possible because the bioequivalence equivalence study would be impossible.
Brazil asked if when the generic product has the same route of administration, the EU accepts the withdrawal period without any additional study. The EU replied that this is possible if the applicant demonstrates that the generic product’s composition is identical to the reference product.
Ukraine asked if a generic application can be accepted if the reference product is not marketed anymore, but only generic products. The EU explained that it is not possible to authorise a generic based on another generic.

The US however accepted that if a reference product is not on the market anymore a generic of the original can serve as the reference product.

US FDA gave an overview (link) of the US FDA regulatory process for the approval of generic animal drugs and explained that the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988 provides FDA the statutory authority to approve abbreviated new animal drug applications (ANADAs) for a generic copy of an approved off-patent reference listed new animal drug.
FDA took the participants through the allowable and not allowed differences between a generic and a reference product under a Suitability Petition (SP), which is a type of citizen petition requesting FDA to approve a specific change in the generic product from the reference product.
FDA pointed out that although the terminology differs, the actions and approaches for the approval of animal generic products are very similar between the 3 regions.
Regarding the exclusivity protection rules, in the USA the first animal pioneer drug approval is granted 5 years exclusivity, otherwise known as “marketing exclusivity”. Three years of marketing exclusivity can be granted for additional claims to an existing approval or for a new approval that includes an active pharmaceutical ingredient that was previously approved.
JMAFF explained that in Japan a generic application can only be approved 6 years after the authorisation of the pioneer product. In the EU the period is10 years.

Botswana questioned why all authorities require approved reference products from their own jurisdiction only, whilst the African/Asian/third countries accept reference applications made in third countries; most countries are benchmarking on the US or EU countries.
Most VICH countries’ authorities require that they perform the initial evaluation of the safety and efficacy of the reference products. The bioequivalence studies can nevertheless be conducted outside of the country. It was noted that for the assessment of the data, the regulators need access to the original dossier.
The EU pointed out that the aim of the VICH GLs is to harmonise the technical requirements, but not the regulatory assessments which are done by the relevant competent authority.

8. Discussions in breakout groups

- Discussion in 3 groups

VF members:
Group 1: Taiwan, Botswana, India
Group 2: Korea, Egypt, Ukraine
Group 3: SFDA, Brazil, EAC

9. Reporting back to plenary on outcome of group discussions

Group 1
The participants described (link) the approach to generic products in their countries and detailed the lessons learned in the discussions.

Group 2
The participants also described (link) the approach to generic products in their respective countries and noted that in Japan & the USA there is systematically a need for additional residue studies (for food producing animals), whilst in the EU these are only required for locally administered products.

In USA and the EU the extrapolation of the BE to minor species is only accepted on appropriate justification.

Group 3
The participants described (link) also the approach to generic products in their respective countries and pointed out that each country and region is its own ecosystem. Much discussion took place on the FDA phased review process.

General discussion
The SFDA explained that in Saudi Arabia 70 % of the VMPs are administered to farm animals, of which 20% are in small farms. So far there is no requirement for bioequivalence data in Saudi Arabia, but by end 2024, applicants will have to demonstrate bioequivalence and submit bioequivalence data to Saudi FDA for the registration of generics.
However, in the whole Middle East, there exist currently no recognised study centres to conduct bioequivalence studies in animals, so Saudi FDA questioned how to solve this issue.
The SC members recommended to accept studies conducted outside of the country as long as the GLP standards are met and the data is shown to be reliable.
This may be appropriate for international companies having submitted their applications in different countries, but the local companies will not have a solution.
In some cases, in vitro studies could replace in vivo studies, but these are not available yet.
Moreover, bioequivalence studies may not be required in each case.
AnimalhealthEurope suggested to start by doing the studies in the pharmacological departments of the universities which have the adequate resources. This had been the way the studies were started in the EU.
JMAFF mentioned that the OECD has adopted GLP standards, thus may be able to provide an adequate lab as well.

Session 3: Issues of interest to VICH Forum members

10. Specific issues

10.1 Updated VICH structures

US FDA detailed (link) on behalf of the SC, the updated structures of VICH and explained that the new setup will provide more opportunities for Forum Partners to be involved in VICH.
Forum Partners may consider attending a SC meeting on a temporary basis or becoming an Observer to VICH if the country meets the conditions that have been set.

11. Specific issues - continued

11.1 The VICH 9 Step procedure

The secretariat explained (link) that the elaboration and adoption of VICH guidelines follow a 9-step procedure which is defined in the VICH Organisational Charter (https://www.vichsec.org/en/library/organisational-documents-priorities-strategy-and-charter.html) and took the participants through the details of the procedure.

11.2 VICH 7 Conference

AnimalhealthEurope and the EU presented (link) an overview of the VICH 7 Conference programme that will take place at the EMA in Amsterdam on 13 & 14 November 2024.
The participants applauded the involvement of 3 VF members who have volunteered to be Conference speakers.
The EU provided additional information on the meeting location and events set-up.

Session 4: Discussions and conclusions

12. 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 as to the VICH SC. The VF members welcomed the structure of the meeting as well as the very fruitful breakout sessions, and recommended to repeat this format at each meeting.

Botswana applauded the numerous discussions during a very productive meeting and will attend next year's meeting to ensure a continuity. The veterinary division being a small department for all approvals, Botswana will take back and implement many of the technical lessons learned in the constructive discussions that took place.

Brazil appreciated the outcome of the discussions that took place in particular on the registration of generics which have been very useful and which Brazil will use to change some local procedures.

Saudi Arabia witnessed the harmonised work and the excellent interaction between the regulatory agencies and industry within the VICH countries/regions, their overall aim being to ensure the safety, efficacy and highest possible quality of VMPs.
Saudi Arabia appreciated the sharing of knowledge and the striving for a consensus on many topics and strongly supported the aim of VICH to harmonise the technical requirements for the registration of VMPs.

Ukraine welcomed the exchange of experience between the VICH countries, and will share the information with the local industry. The discussion on generics has been very useful, providing clear requirements for information and procedures.

The representative of *EAC* expressed her satisfaction of being encouraged to be involved in VICH. The discussion of practical topics regarding the registration of generics has raised many challenges and also shown that many countries encounter the same challenges.

Taiwan thanked the SC for the level of information provided over the 2 days.

India also appreciated the high level of interaction between the participants and the easy communication between all participants. The VICH GLs are very helpful to improve the regulatory system in India.

Egypt appreciated the opportunity of learning from the experience of other regulators. Much of the information provided will enable to fill some gaps in the local regulatory systems.

Korea confirmed that the discussion on generics was very important. Korea may develop a local GL for generics in Korea.

The proposed topics for the next meeting are:

- How to facilitate the registration with global experience => learnings from global experience
- Discuss further on how to facilitate the registration for SMEs
- Minor use minor species: what are the requirements to register VMPs for those target species ?

- AMR from regulatory perspective, how to harmonise the requirements for the control of AMR
- Development of GLs for Combination products requirements
- Requirements for post market control of VMPs
- Training on case studies to improve the implementation of GLs
- Training on general parts of GLs

Further suggested topics:

- Organisation of virtual meetings & discussions with VICH experts
- How to include flexibility in the assessments of the quality part of dossiers
- Classification of products, what are Borderline products
- Involvement of WOAH in VICH; how WOAH intends to facilitate the regulation harmonisation

13. 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 accepted to chair the pre-meeting next year and encouraged all VF Partners to provide suggestions for topics to be discussed in the pre-meeting.

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

- The **17th VICH Forum** meeting will be held on 11 & 12 November 2024 in Amsterdam, together with the VICH 7 public conference.
- The **18th VICH Forum** meeting will be held on 11 & 12 November 2025 in the USA – location TBC

16th VICH Forum meeting
Participants

1/ Forum members

BOTSWANA – BoMRA	Innocent RAVENGAI
BOTSWANA – BoMRA	Bathusi KGOSIETSILE
BRAZIL – Ministry of Agriculture and Livestock	Barbara BORGES CORDEIRO
EGYPT – Egyptian Drug Authority	Samah SALAMA
INDIA – Ministry of Fisheries, Animal Husbandry and Dairying	Sharma ANUNA
Republic of KOREA – APQA	HyunOk KU
Republic of KOREA – APQA	Jinju NAH
SAUDI ARABIA – WEQAA	Sultan HUSSAIN ALNAKHLI
SAUDI ARABIA – Saudi Food & Drug Authority	Bandar ALHAMMAD
SAUDI ARABIA – Saudi Food & Drug Authority	Jameel M.B. ALTHIYABI
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UKRAINE – SCIVP	Yuriy KOSENKO
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2 / VICH Steering Committee

Members and (C) Coordinators

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ANIMALHEALTHEUROPE	R. CLAYTON (C)
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JMAFF	S. IWAMOTO
JMAFF	J. OHMORI (C)
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