



VICH FORUM 18th Meeting

**11 & 12 November 2025
Indianapolis - The USA**

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 - WOAHC Collaborating Centre, on behalf of the WOAHC, and Dr Matthew Lucia, Director, Office of New Animal Product Evaluation, CVM, US FDA.

Dr Le Letty opened the meeting by welcoming the participants to Indianapolis, in particular the delegates from Kuwait for their first participation in the VICH Forum (VF).

2. Report by the Steering Committee (SC)

The VICH Secretariat presented the report from the SC ([link](#)) and confirmed that the VICH Forum (VF) pre-meeting was chaired again by Botswana by remote with leadership of WOAHC. The VF members discussed in a round table session how VICH GLs are implemented. The participants have clarified the structure of a Forum network and received feedback from the WOAHC Wildlife Group meeting to provide appropriate feedback on challenge identified during the last meeting and explore opportunity for further cooperation. VF members have identified topics to be addressed at the 19th VF meeting.

In the 18th VF meeting, the leader of the VICH Bioequivalence Expert Working Group (EWG) – Dr Marilyn Martinez - will provide a detailed training session on Bioequivalence and Biowaivers.

Regulators from the EU, JMAFF and the USDA will describe the regulatory processes to register biological products in their countries/region and provide an introduction to the breakout group discussions. The aim of this session is to support the implementation of the [WOAHC Resolution 29](#) adopted in May 2025: "Veterinary Vaccines and Vaccination. From science to action – reflections for change".

A brief overview of the activities developed by the 9 VICH EWGs since the last meeting was presented to the VF.

The Secretariat concluded by inviting VF members to nominate experts to the newly formed VICH Global Regulatory Dossier Framework (GRDF) EWG.

3. Report by WOAHC to the Forum members

The WOAH HQ representative presented the report ([link](#)) focusing on the activities of WOAH since the last VF meeting by providing an update on the support provided throughout the year by WOAH and the promotion of VICH and VF activities in connection with the Focal Points' seminars.

The WOAH HQ representative mentioned that the VICH-related objectives are included in the proposed capacity-building activities of [Veterinary Products Focal Points for French-speaking Africa](#), and addressed in the Recommendations for 2025–2028, which are published on the Regional Website. WOAH has in particular encouraged their members to use the VICH GLs for the registration of VMPs and to participate in the VF activities.

The WOAH HQ representative concluded by listing several activities and meetings with WOAH involvement of potential interest to VICH (especially WOAH Biological Standards Commission (BSC) on potential interest subjects in order to achieve much wider harmonisation with VICH Guidelines and WOAH Standards concerning vaccines.

4. Feedback from the VF pre-meeting ([link](#))

The chairman of the VF pre-meeting (Dr Ravengai - Botswana) confirmed that open and constructive discussions took place between the 17 participants to the meeting (including 2 participants connected remotely).

In a round table discussion, the participants exchanged views on benefits of implementing VICH GLs as well as the challenges involved. The cost of compliance to the VICH GLs, especially for SMEs, was highlighted. This was balanced by many positive aspects such as: common rules worldwide for the registration of VMPs, timely access of VMPs, and facilitation of joint assessments. Translations, training and adaptation to the local context generate resources constraints.

The participants reviewed the GLs implementation tracking table and proposed to update the table once per year 2 months before the VICH Forum meeting.

The creation of an active network was agreed with the objective to facilitate the exchange of information, asking questions and receiving feedback from other VF members or from WOAH Collaborating Centers for Veterinary Products (ANSES, FDA, JMAFF).

It was agreed to keep the process simple by using an appropriate IT tool. It was acknowledged that the network will not replace bilateral discussion and that no confidential topics or documentation should be addressed within this network. The draft Concept Note will be adopted by end of 2025.

The VF members received a presentation from the WOAH Wildlife Group meeting and discussed the availability of VMPs to wildlife animals which highlighted the complexity of the challenge and the impact on the One Health aspect. It was recognised that although much quality data is available, safety and efficacy data are very difficult to obtain for wildlife animals. The Chair of the WOAH Wildlife Working group has expressed his interest for further collaboration.

Australia recommended using wildlife products registered for other animal species and explained that in Australia the applicants can apply for a “permit” based on limited quality data, the authorities providing the recommendations for the safety and efficacy parts of the dossier.

Regarding the VF visiting delegations to the 45th VICH SC meeting in 2026, VF members will consult with their leadership and confirm their intention to attend to the VICH secretariat. Current visiting delegations presented their experience to the VF members.

The following topics were proposed for the 19th VF pre-meeting:

- VMD self-assessment tool: presentation of the progress made in those countries that used the self-assessment tool and had made some proposal for improvement of the tool.
- Autogenous vaccines: WOAHA is finalizing a document that will be published next year and proposed to present the document at the next pre-meeting. The document also focusses on reduction of AMR.
- Feedback from the forum network
- Feedback on the tracking table on the implementation of VICH GLs

The VF members discussed the challenging areas they plan to propose for the next VF meeting.

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

5. Bioequivalence and Biowaivers

The leader of the VICH Bioequivalence EWG, Dr Marilyn Martinez, gave a detailed introduction ([link](#)) to Bioequivalence (BE) and Biowaivers from a scientific perspective. She addressed questions raised as points of interest by the VICH forum members, for example: what is bioequivalence or why it is necessary to limit BE evaluations to a single reference product when evaluating generic formulations etc... illustrated by many practical examples and demonstrations.

She concluded by indicating that a draft VICH Biowaiver Guideline should soon be ready for public consultation.

6. Presentation of the national system in Kuwait

Dr Talal Alenezi gave an overview ([link](#)) of the Veterinary Pharmaceuticals Registration system in Kuwait. He presented the regulatory background and showed some key data regarding the registration of VMPs.

He listed key challenges due to the relatively small size of the local veterinary medicines market and noted that the veterinary pharmaceutical registration field is still in the development phase for both companies and regulatory authorities. Stakeholders are continuing to build experience, technical capacity, and understanding of veterinary-specific requirements. Moreover, guidelines, classification criteria, and review procedures are being refined as the system matures.

He concluded by confirming that continuous efforts are underway in Kuwait to align national practices with GCC and VICH guidelines while strengthening institutional expertise.

Session 3: Focus on Bioequivalence & Biological Products

7. VICH Bioequivalence GL

In this second session, the leader of the VICH Bioequivalence EWG, Dr Marilyn Martinez, explained ([link](#)) how to establish treatment BE based on blood level profiles and why statistics are needed for BE study design and analysis.

She pointed out that the VICH Bioequivalence GL52 requires that BE must be tested in each major target animal species included on the product label.

Applying again a very practical approach, Dr Martinez guided the audience through examples of basic statistics used in the determination of product BE, as well as how to analyse the results from a 2-treatment, 2-period, 2-sequence crossover trial design.

Both presentations were welcomed by the participants and were deemed useful for all parties. These presentations have been recorded and are available on the training page of the VICH website for dissemination within the VF members authorities, at: <https://vichsec.org/training/module-3-efficacy/>.

8. Bioequivalence Q&A

None.

9. Presentations for group discussion: Biological products

Presentations on the regulatory processes to register biological products

➤ *EU overview*

The EU gave a general overview ([link](#)) of the registration process for biological VMPs and explained that in the EU, the term 'biologicals' encompasses both 'immunological' and 'biological other than immunological' VMPs. Legal definitions apply, and dossier requirements vary depending on the product classification.

The EU has one set of common rules although there are different authorisation routes i.e. the centralised procedure (via the EMA) and decentralised & national procedures (via EU Member States). The definitions of immunological veterinary medicinal products, biological veterinary medicinal products and biological substances are different with also different registration dossier requirements.

The EU concluded by describing the regulatory tools that are available for the applicants.

➤ *Regulatory processes in Japan*

JMAFF described ([link](#)) the Law Hierarchy of Pharmaceutical Affairs in Japan and the Japanese Pharmaceuticals Act (Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices).

JMAFF explained the types of approval and licence for marketing VMPs in Japan and detailed the appendixes required for the application for marketing approval as well as the data required for the application approval for Veterinary Biological Products.

JMAFF concluded with an explanatory flow chart from application to approval of VMPs for food producing animals.

➤ *Regulation of Veterinary Biologics in the United States*

The USDA explained ([link](#)) that the US Veterinary Biologics Program implements the provisions of the Virus-Serum-Toxin Act (VSTA) to ensure that the veterinary biologics available for the diagnosis, prevention and treatment of animal diseases are pure, safe, potent and effective.

In the USA veterinary biologics are all viruses, serums, toxins, or analogous products which are intended for use in the treatment of animals and which act primarily through the immune system or immune response.

USDA described the different licence types that are available in the US and listed the requirements for a US veterinary biologics product permit.

USDA concluded by mentioning that there is regulatory flexibility for emerging diseases, the USDA's mission being to ensure licensed products are pure, safe, potent and effective.

10. Introduction to the discussions - [instructions](#)

Dr Le Letty presented the following questions prepared in advance by the 3 speakers for the breakout sessions:

1. What are the biggest challenges your agency encounters in relation to regulation of vaccines and other immunologicals?
2. Adverse events of vaccines and quality control post licensing in response to adverse events: do you have a regulatory system in place and how do you handle the detection of adverse events (including accidental injection) and quality control?
3. The promotion of the installation of vaccines needed for disease control in one's own country: how to develop them? how to import and distribute vaccines in VICH Forum countries. Any challenges?
4. Are there any incentives (both in terms of data and finances) and flexibilities in requirements for the developers and manufacturers of veterinary vaccines?
5. How to confirm the efficacy of vaccines, in cases where confirmation of efficacy is needed against the current infectious field strain? How do regulators check, review and address this issue?
6. Which classes of biological (non-immunological) products did your agency authorise so far (e.g. peptides, proteins, monoclonal antibodies, phages, cell-based products...) and what is your experience from assessing such product(s)? Were there any challenges you did not encounter when assessing non-biologicals?
7. Do you have specialised legislation (or part thereof) dealing with novel/advanced therapies and/or biologicals? If yes, how do the requirements differ from the 'conventional' veterinary medicinal products?

11. Discussion session in breakout groups

- *Discussion in 3 groups of VF members:*

Group 1: Brazil, Republic of Korea, Saudi Arabia, Kuwait,

Group 2: EAC, Egypt, Kuwait, Ukraine – DPSS, Ukraine - SCIVP

Group 3: Republic of Korea, Rwanda, Ukraine – SCIVP, Saudi Arabia

12. Reporting back to plenary on outcome of the group discussions Breakout

The participants reported that:

Group 1

Q1 The Republic of Korea and Brazil indicated that training of regulators and of inspectors would be necessary to analyse the safety for new technologies in new dossiers and to inspect the manufacturing facilities.

Saudi Arabia and Kuwait do not accept new vaccines if the virus was not isolated in the country and need training for new experts.

Q2 For most participants Pharmacovigilance and adverse events of vaccines is a new concept.

Q3 & Q4 some countries have national biosafety policies. Where vaccines cannot be imported, Korea has a fast-track procedure for the dossier for imported vaccines and Brazil prioritised the assessment of the dossier of the product concerned.

Q5 All participants recognised that Pharmacovigilance is a useful tool.

Companies need to change the composition of a vaccine if a new virus strain appears. All participants are aware of the importance of the 3Rs in the efficacy tests but meet challenges on the ways to implement this approach.

The efficacy is confirmed through potency testing.

Q6 Regulators are sometimes unsure if the pharmaceutical or the biological pathway should be used for new products (ex: stem cells). This is usually addressed on a case-by-case basis.

The safety of products for pets or for production animals may be addressed differently. However, the high costs of the development of new products can much limit their development at the local level.

Q7 None of the countries has specific legislation to facilitate the process for novel products. Sometimes a fast-track is used for new technologies.

Group 2

Q1 The participants mentioned as a major challenge the different regulatory systems between regions.

Most national laws were tailored for new chemical products and are sometimes not applicable to vaccines.

Most agencies have a limited number of staff for the assessment procedure, and lack of technical expertise for new technologies.

Q2 Most local systems depend on the adverse events reported by the vets. Most countries do not have a developed Pharmacovigilance monitoring system. Moreover, the relatively small size of the markets and the high risk for manufacturing novel products limit the availability of these products.

Q4 As an incentive some countries have a data protection period for new biological products, others have a fast-track for the assessment of new products.

Most participants apply a flexible approach for products already authorised in other countries with recognised regulatory systems.

Q5 Most countries rely on the clinical trials from the companies because they have limited local testing facilities for bio products.

Q6 Most countries use the same pathways for both.

Q7 Most countries do not have specific legislation for novel/advanced therapies.

Group 3

Q1 The participants discussed the shifting of strains and localisation of vaccines production sites in the countries.

Rwanda requires a common format for all dossiers.

Q2 Saudi Arabia has adapted rules for human products to vet products.

In Korea a product is reassessed after 6 years.

Rwanda has a new website with a reporting form for AERs.

Q3 Saudi Arabia has a national programme to upscale the production facilities

Korea has a fast-track procedure for the dossier for imported vaccines.

Q4 In Rwanda the government encourages the development of local production sites especially for cattle vaccines and research development can be funded for universities.

Q5 In Saudi Arabia it is done by the government

The Republic of Korea reviews data from other countries but the field trials must be repeated in the Republic of Korea.

Rwanda accepts data from countries located in the vicinity.

Q6 Saudi Arabia and Rwanda do not have registered products for Companion Animals, whilst the Republic of Korea has registered 1 product for CA.

Q7 None of the participating countries has specific legislation for novel/advanced therapies.

Session 4: Discussions and conclusions

13. 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 particularly appreciated the opportunities for discussions and interactions between VF members and SC regulators. The participating Members also expressed some proposals for the training sessions for the next meeting in November 2026. The final topics will be decided at a later stage to take into account the whole VICH Forum's needs and common interests, reflecting the current situation and also the result of the survey which was conducted in 2019.

Brazil expressed their satisfaction of the outcome of the meeting and confirmed that the Brazilian regulatory requirements are in line with general approaches. VICH GLs are increasingly used and Brazil is currently implementing VICH GL 9. The presentations on bioequivalence are particularly important as Brazil is in the process of improving the legislation of generic medicines.

Rwanda appreciated the discussions in both the pre-meeting and meeting. Rwanda is already using some VICH GLs and is keen to improve the knowledge on the use of the VICH GLs.

Kuwait has very much appreciated the meeting and would like to receive more information on how to implement VICH GLs and how to adapt the local GLs considering the VICH GLs.

EAC-MRP confirmed that the VF meetings are providing very useful training sessions and appreciated particularly the training on bioequivalence. The representative would appreciate receiving additional training on the implementation of the Safety GLs as well as their practical usage.

It would be useful to develop more expert training on VICH GLs in the EAC.

Egypt also highly appreciated training on bioequivalence as the country is in the process of introducing the request for bioequivalence studies.

The Republic of Korea thanked the USA delegation for the excellent hosting of the meeting and explained that the ministry is planning to expand the internal organisation responsible for the registration of vet products.

Saudi Arabia highlighted the importance of this annual meeting and interaction between colleagues from regulators and industry from the different regions of the world. Saudi FDA recognises the importance of being a SC observer and will request observer membership in the SC.

Ukraine highlighted the high level of discussion on the registration of biological products and appreciated the very useful and detailed presentations on bioequivalence, which is highly important in the registration process of generic products.

Botswana and Uganda attended the meeting online and were not able to express their conclusions.

14. 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 thanked again Botswana for having chaired efficiently the pre-meeting, although virtually.

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

- The **19th VICH Forum** meeting will be held on 17 & 18 November 2026 in Japan, in Tsukuba-city, Ibaraki prefecture, (Narita is the closest airport)
- The **20th VICH Forum** meeting will be held in November 2027 in Europe

18th VICH Forum meeting Participants

1/ Forum members

BOTSWANA – BoMRA	Innocent RAVENGAI (<i>remotely</i>)
BRAZIL – SINDAN	Luiz MONTEIRO
BRAZIL – Ministry of Agriculture & Livestock	Leandro BARBIERI
EGYPT – Egyptian Drug Authority	Samah SALAMA
KENYA – EAC MRP	Adelaide AYOYI
KUWAIT – Ministry of Health	Talal AL ENEZI
MOROCCO – ONSSA	Hasnae BENALLA (<i>remotely-part</i>)
MEXICO – SENASICA	Lorena REYES GUERRA
REPUBLIC OF KOREA – APQA	Hee YI
REPUBLIC OF KOREA – APQA	Sung-Won PARK
REPUBLIC OF KOREA – APQA	YangHo JANG
REPUBLIC OF KOREA – APQA	YunHi KIM
RWANDA – Rwanda Food and Drug Authority	Olivier MURERAMANZI
RWANDA – Rwanda Food and Drug Authority	Felix TUYISENGE
SAUDI ARABIA – Saudi Food & Drug Authority	Bandar ALHAMMAD
TANZANIA – Ministry of Livestock and Fisheries	Benezeth Lutege MALINDA (<i>remotely</i>)
UGANDA – National Drug Authority	Pamella ABWOYO (<i>remotely</i>)
UGANDA – National Drug Authority	Josephine NANYANZI (<i>remotely</i>)
UKRAINE - CVO	Volodymyr KUSTUROV (<i>remotely</i>)
UKRAINE – SCIVP	Yuriy KOSENKO
UKRAINE – SCIVP	Volodymyr STYBEL
UKRAINE – DPSS	Oleh OSIIAN
ZAMBIA - ZAMRA	Daniel NDAMBASIA (<i>remotely-part</i>)

2 / VICH Steering Committee

Members and (C) Coordinators

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JMAFF
JVPA (Nisseiken Co.)
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US (USDA CVM)
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STANDING MEMBERS

Australia (APVMA)
Canada (Health Canada)
Canada (CAHI)
New Zealand (MPI)
South Africa (SAAHA)
South Africa (SAHPRA)
VMD

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SWISSMEDIC
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Canada (Health Canada)
Canada (Health Canada)
US (FDA/CVM)
US (FDA/CVM)
APQA (Republic of Korea)
APQA (Republic of Korea)
VMD

WOAH

WOAH Collaborating Center
WOAH

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APOLOGIES

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EU (EUROPEAN COMMISSION)
JVPA (NIPPON ZENYAKU KOGYO CO.)
Australia (AMA)
New Zealand (APHANZ)
NOAH

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