



## **Terms of Reference for the VICH Forum**

The VICH Organisational Charter states in its objectives that as well as establishing and implementing harmonised technical requirements for registration of veterinary medicinal products in the VICH regions, the programme should “work towards providing a basis for wider international harmonisation of technical requirements”.

VICH continues to reiterate this objective of wider international harmonisation in its strategic priorities (e.g. Strategy for Phase V: 2021-2025), and has initiated a set of activities aimed at the wider dissemination and acceptance of VICH guidelines and co-operation on a more global level, including:

1. Establishment of the VICH Outreach Forum and its conversion to the VICH Forum, with two main objectives:
  - a. to provide a basis for wider international harmonization of registration requirements
  - b. to improve information exchange and raise awareness of VICH and VICH guidelines with countries/regions which are not currently included in VICH activities.
2. VICH Training Strategy, including development of training materials and participation in regional training events.
3. Dissemination of information through an upgraded website, and through the WOAHA website.

The VICH Forum is chaired by either the rotating SC chairperson in collaboration with WOAHA, recognising WOAHA’s membership in VICH as well as its broader mandate. VICH Forum meetings bring together Observers and Forum Partners with Steering Committee Founding and Standing Members. Observers and Forum Partners may meet in pre-meetings prior to VICH Forum Meetings for broader discussion of regulatory challenges which may or may not be within the scope of VICH. VICH Forum pre-meetings are chaired by Observers or Forum Partners on a voluntary, rotating basis with support from WOAHA. The VICH Forum will meet in the margins of the VICH Steering Committee meetings, which take place every 12 months typically at a location in one of the VICH member countries/regions.

Topics that will be addressed at the VICH Forum will include:

- How to participate in VICH, including submitting comments on concept papers and draft guidelines
- Discussing practical issues related to VICH guidelines arising in the participants’ countries/regions and providing feedback to the Forum
- Collaborating and sharing of translations of guidelines
- Providing feedback on acceptance of existing guidelines
- Detailed review of selected topics covered by VICH guidelines

Concept papers and draft guidelines for consultation will be distributed to other countries and regions through WOAHA and the VICH website.

The VICH Steering Committee supports the participation of VICH Forum members in VICH activities

and will consider requests for involvement in guideline development by Observers and Forum Partners.

In light of the discussions at the Forum meetings the VICH Steering Committee will review other questions arising and may add or amend tasks and roles or composition of the Forum.

The VICH Forum membership is composed of Observers and Forum Partners.

The conditions for Forum Partners are:

- A regulatory framework for the marketing authorisation of veterinary medicinal products is in place and operational in the country or a regional organization related to a regulation of veterinary medicinal products;
- Willingness to work towards accepting and implementing VICH guidelines;
- Willingness to self-fund own costs for participation (travel costs, accommodation and translation, if needed);
- Regular participation in the VICH Forum meetings;

The conditions for Observers are:

- Willingness to regularly participate in the Forum meetings
- Willingness to assist with the running of the Forum and training on VICH guidelines
- Confirmation that the applicant has the financial and human capacity to observe VICH SC meetings at its own cost
- Confirmation that the applicants has the capacity to conduct all online and in-person VICH matters in the English language or to provide all necessary translations at their own cost
- Confirmation that the applicant has a commitment to VICH such as through one or more of the following:
  - A history of volunteering for leadership roles within the Forum, or
  - A history of providing experts to EWG discussions, or
  - Implementation of a number of VICH guidelines, or
  - Participation in a majority of VOF meetings over the last 5 years

An observer may lose its position if the conditions at the time of approval are not maintained.

Moreover, a national competent authority is encouraged to invite its local industry association to also participate in VICH Forum meetings.

Forum Partners may request to participate as Observers if they meet the above conditions. The SC will discuss any Observer requests to confirm such participation.

VICH Observers should attend VICH Steering Committee meetings on a regular basis. VICH Forum Partners may attend VICH Steering Committee meetings on a temporary or rotating basis. They do not contribute to the Steering Committee discussions or intervene in the meetings unless requested by the chair to provide information.

Other relevant documents include:

- The VICH Organisational Charter
- The VICH Forum – topics that are out of scope