



Criteria to be used for determining whether a VICH member country can change membership category in the new VICH structures

1. Background

In June 2023 the Steering Committee (SC) adopted a mandate for a Task Force (TF) to elaborate criteria to be used for determining if a VICH member country can change membership category. At the same virtual meeting the SC adopted the revised VICH Organisational Charter and the VICH Outreach Forum (VOF) Terms of Reference (ToR) which is updated to reflect the changes in structure.

According to the new structure, VICH is made up of the SC and the VICH Forum (VF), as shown in figure 1. The membership categories within the SC are:

- Founding members
- Standing members
- Associate members

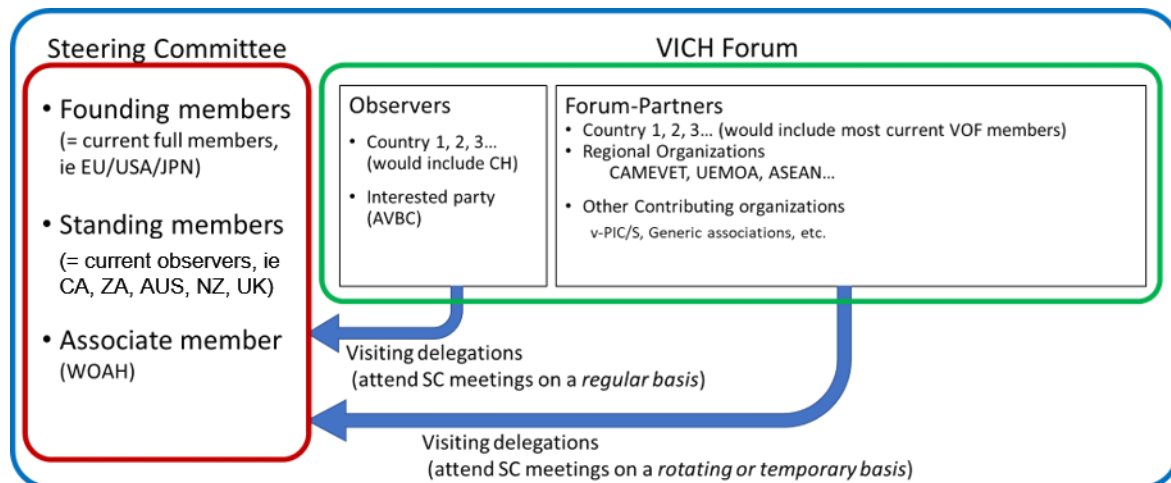
The membership categories within the VICH Forum are:

- Observers, consisting of observer member countries and the Interested Party, the Association of Veterinary Biologics Companies (AVBC)
- Forum Partners, consisting of member countries, regional organisations and other contributing organisations (which could, in future, include organisations like PIC/S and generics associations).

Following the former TF which has provided information on the roles, rights and obligations associated with the different membership categories and sets out where different countries/organisations currently sit within the new structure, current TF aims to provide the criteria on how or if countries might progress from one membership category to another, to make VICH more inclusive and transparent. Information relating to the basis on which VF Partners will attend SC meetings as Visiting Delegations also needs to be elaborated upon.

As movement of member organisations (ie *WOAH, AVBC or Other Contributing organisations*) between membership categories is not expected, the TF is not required to address this topic.

Figure 1. The structure of VICH, as agreed in November 2022



2. Mandate and Discussion points of the Task Force

1) The criteria to be satisfied in order to allow countries to move

a. from the Forum-Partners category to the Observers category

The conditions to be Observers are shown below.

- Willingness to regularly participate in 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 applicant 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 at the discretion of the Steering Committee if the conditions at the time of approval are not maintained.

b. from the Observers category to the Standing members category

Major difference between Observer and Standing member is the "Full implementation of VICH-GL", which is optional for Observers but recommended for Standing members, as mentioned in the Table 2 of the Discussion Document to elaborate proposals for updated VICH structures.

The conditions to be standing members are shown below.

- Criteria to become a VICH Steering Committee Member (VICH/19/007):
 - Regulatory system: A short outline of the regulatory framework in the applicant country for the granting of marketing authorisations (regulatory approval) for veterinary medicinal products pharmaceuticals and vaccines. A functioning and adequately resourced regulatory system for the

marketing authorisation and market control of veterinary medicinal products is a pre-requisite to participate in the VICH Steering Committee (SC).

- A commitment to implement the VICH Guidelines to the fullest extent possible, including:
 - ✧ confirmation on the status of implementation of existing VICH Guidelines in the country
 - ✧ an action plan to implement the remaining VICH Guidelines wherever possible.
- Local Industry Association: Confirmation that the applicant country has a well-established and broadly representative local Industry Association that is prepared to represent the country's animal health industry on VICH.
- Resources: Confirmation that the applicant country has the financial and human capacity of both regulators and industry to participate in VICH SC activities, particularly the Steering Committee meetings, but also Expert Working Groups as desired, at its own cost.

Language: 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.

2) The process by which the SC will reach its decisions on which Forum-Partners will attend upcoming SC meetings as Visiting delegations.

- FPs attend upcoming SC meetings on a Temporary basis.
- As a general rule, up to 3 FP delegations (one or two persons per country/region) will be able to attend SC meetings as visiting delegations per meeting.
- In the run up to a VICH/Forum meeting FPs will be informed that, at the upcoming meeting, the SC will ask if there are FPs that would be interested to attend the next SC meeting as visiting delegations in an observational capacity, 6 months in advance so that FPs can consult with their organizations.
- The secretariat will communicate the SC decision to the FPs concerned.
- Selected Forum Partners will receive a copy of the VICH Charter and list of expectations for participation in the SC meeting (e.g., observer with no speaking role unless requested, one participant, etc.)