



## **Discussion Document**

### **Criteria to become a VICH Steering Committee Member**

#### **Introduction**

The VICH Organisational Charter (VICH/96/002) lists the full members and observer members to the Steering Committee (SC), but does not define the criteria that should be requested from new countries who would wish to become a member of the VICH SC.

However, since the creation of the VICH Outreach Forum (VOF), several VOF member countries have inquired about the conditions to become an observer or full VICH SC member. At its 36<sup>th</sup> meeting in June 2018, the SC has therefore decided to define these criteria.

#### **VICH Organisational Charter**

Article 4 of the Charter states that the SC is responsible for decisions and governance of the process.

Article 5.2 of the Charter defines the role of the SC whilst article 9 requires that at the end of the 9-step procedure the VICH members implement the VICH Guidelines within the requested timeframe (steps 7 & 8).

Article 5.1.4 of the Charter indicates that “*Observer members have the opportunity to take part in the discussion of the SC; they do not take part in any formal decision on topics or guidelines, which may be taken and do not sign-off any draft/final guideline*”.

#### **VICH current Membership**

##### *VICH Full members*

From the different articles of the Organisational Charter, it is clear that the VICH founding members have considered that the initial full member countries/regions (the EU, Japan and the USA) are able to comply with all the Charter's requirements, having a solid and developed regulatory system in place. The SC full members' regulators and industry participants represent the national/regional regulatory authorities and national/regional recognised industry

associations. The regulators and industry representatives participate to SC meetings on a 1 to 1 basis.

The organisations currently represented on the SC have the capacity to support the financial burden of VICH (by sending their delegates to VICH meetings, nominating experts to all VICH EWGs, supporting the work of their delegates and experts to progress the VICH activities, organising and supporting locally SC and EWG meetings on a regular basis....). The regulatory bodies have the authority to implement all VICH GLs.

#### *VICH observer members*

The Organisational Charter provides that VICH observer member countries are also represented on the SC on a 1 to 1 basis by 1 representative from the regulatory authorities and 1 representative from the local industry association.

### **Criteria for membership**

#### *Past experience*

The Charter does currently not provide detailed criteria to become a VICH SC member. However, there is past experience which can be used as a reference. After the founding of VICH, when Canada requested to join the SC as an observer member, Canada provided a clear action plan with commitment to implement a majority of VICH GLs and to provide experts to the different VICH EWG.

When later on South Africa requested to join the SC as an observer, the SC via the Secretariat asked South Africa to provide the following information:

- A short outline of the regulatory framework for the granting of marketing authorisations (regulatory approval) for veterinary medicinal products (pharmaceuticals and vaccines).
- More information on the status of implementation of existing VICH Guidelines in the country, and intention to implement further existing as well as future VICH Guidelines.
- Confirmation that South Africa has the capacities in place, including a sufficient pool of experts to contribute to the existing and future VICH Expert Working Groups, from the regulators side as well as from the animal health industry's side.
- Confirmation that the South African Animal Health Industry Association is prepared to represent the country's animal health industry on VICH.

With this information and commitment, the SC welcomed both Canada and South Africa as VICH observer members.

#### *Future membership requests*

##### **1/ Observer membership**

It is likely that most future SC membership requests will come from current (or future) VOF member countries.

The requirements to become a VOF member are detailed in VICH guidance document VICH/11/010 - Terms of Reference for the VICH Outreach Forum.

If a VOF member country requests to join the VICH SC, it would normally be expected that in a first step this request is for VICH SC observer membership. A full membership can be considered in a second step.

It is suggested to ask the candidate country to respond in writing to the Secretariat on each of the 4 questions detailed above, as well as to provide a detailed action and time plan demonstrating the commitment to implement the existing VICH GLs.

Main issues for consideration of the application should be:

- 1/ the financial and human capacity of both regulators and industry to participate in VICH SC activities, and the commitment to do so;
- 2/ the existence of a well-established and broadly representative local industry association;
- 3/ the capacity to deal with all VICH matters in the English language or to provide all necessary translations at their own costs.
- 4/ a functioning and adequately resourced regulatory system for the marketing authorisation and market control of veterinary medicinal products.

## 2/ Full membership

Although expected to remain exceptional, the VICH SC should have the capacity to consider requests for full membership on an ad hoc basis, as for example in the case of the UK, which, having been a member of VICH through the EU, would fully comply with all VICH regulatory requirements after the Brexit.

The country's financial and regulatory capacity to address all VICH requirements should nevertheless be considered.

In addition to the points for consideration for VOF membership, full membership should require a long-term commitment to:

- Attend all SC meetings (regulators and industry)
- Participate in the VICH activities and work program, such as internal and public consultations on working drafts and final draft guidelines (regulators and industry)
- Provide experts to EWGs (regulators and industry)
- Host SC meetings in rotation (local industry association)
- Implement all VICH GLs (article 9 of the Organisational Charter)