



## POLICY ON CONSULTATION AT STEP 4

### Objectives:

1. *Transparency: To allow any group or individual to express their views on the draft guidelines, or major revisions to existing guidelines and receive feedback that indicates that their views have been considered.*
2. *Expertise: To support the expertise available to the Expert Working Groups (EWGs) in preparing the final guideline or revision.*

In accordance with the organisational charter of VICH (VICH/96/002), a draft recommendation/guideline once adopted by the Steering Committee (SC), is circulated at step 4 to all interested parties for consultation. This includes draft new guidelines and major revisions to existing guidelines (minor revisions to correct typographical errors or to update administrative details and cross-references do not need to be released for public consultation). Past experience has demonstrated the critical importance of ensuring that a broad range of consultation with all interested parties on VICH guidelines takes place in a timely and transparent manner in the regions. The length of the consultation period is agreed upon by the SC members at step 4. The current public consultation period is 6 months from the date it is published on the VICH website, however this may be extended in particular cases if the VICH SC feels it appropriate.

### Consultation managed by SC active participants

Each of the active participants to VICH, i.e. US, Japan, EU, Australia, New Zealand, Canada and WOA, must define its own consultation/public disclosure methods. For industry this must ensure that not only member companies and, in the EU, national industry associations, are included but also, through the national associations, those small enterprises who may not be affiliated with the regional trade association.

For government parties to VICH the consultation must ensure full public transparency. Government parties must ensure that all appropriate bodies and relevant interested parties are consulted. The European Medicines Agency (EMA) shall ensure proper dissemination of documents to governments of the 27 EU Member States.

For WOA, the consultation should ensure a broad dissemination at world-wide level and coordination of submissions from non-VICH regions.

It is the responsibility of each coordinator supporting each of the six parties to VICH plus observers to disseminate the documents, and to coordinate responses in the consultation process, and channel the comments and inputs received to the chair of the relevant VICH EWGs, with copy to the VICH secretariat – preferably as early as possible.

In case a delay occurs in a region with the public consultation, it is also the responsibility of the coordinator to notify immediately the VICH secretariat, in order to inform the VICH Steering Committee.

SC participants are not required to report back to the EWG on their consultation. However, as a result of their consultation each SC member will bring to the EWG any new relevant information or ideas that they believe should be considered in Step 5 of the guideline process.

### **Worldwide consultation managed by the VICH Secretariat**

The VICH Secretariat will:

- a) post the draft guidelines on the VICH web page within four weeks of Step 3 being completed (i.e. being signed by the SC)
- b) maintain a distribution list so that any organisation or individual that requests it is automatically sent an e-mail when a new guideline at Step 4 is posted on the VICH web page (URL modifier).

The Secretariat will request comments on all guidelines distributed to be sent to the Secretariat.

The Secretariat will send a standard brief acknowledgement to the submitter of each comment within four weeks of receipt stating:

- a) their comments have been received and thanking them,
- b) all comments will be sent to the EWG Chairs,

All comments received by the Secretariat will be sent immediately to the Chair of the EWG.

The EWG Chair will be responsible for sending a copy of each comment received, or a compilation of the comments received, to each member of the EWG. At the same time, they may indicate to EWG members how the comments will be considered. This process may vary depending on the number of comments received and the number of new issues raised.

In case major issues, which have been highlighted during the consultation period, have not been integrated in the final document, the EWG Chair will explain to the proposer the reasons why.

A template (VICH/12/056) is available to the EWG Chair to aid in providing an overview of comments received during the public consultation. The template provides a format for summarizing the comments received and the outcome of consideration of each comment. Comments which are substantive to the content and understanding of the guideline should be included. Comments which correct typographical errors can be incorporated without listing the comment and outcome in the overview.