

POLICY FOR DISBANDING EXPERT WORKING GROUPS

Objective:

Clarity of procedure: To enable members of working groups to understand when their VICH services have concluded and when the activities of the Expert Working Group cease.

Currently the Expert Working Groups (EWG) are convened by the Topic Leader/Chairperson as mandated by the Steering Committee (SC) to draft guidelines on the basis of the original concept paper, and a detailed discussion document prepared by the chairperson.

The EWGs progress their work according to the various steps detailed in the organisational charter of VICH (VICH/96/002) ending at Step 7 when a final guideline and proposed implementation date are circulated to the relevant regulatory authorities.

Currently two further actions are possible: Step 8 requires SC members to report back on implementation progress in the three regions and Step 9 provides for the guideline to be revised at the request of a SC member to take account of new scientific evidence. At step 9, the SC will designate the appropriate EWG or a topic leader as the reviewer.

The EWG shall remain in existence until the second meeting of the SC after the final implementation date, i.e. implementation achieved in all regions. This leaves a period of approximately 12 months to allow full application of the guideline in the three regions – a sufficient period of time to identify any issues that may need to be referred back to the EWG for resolution.

If no issues have been raised during this 'second' SC meeting the EWG may be formally disbanded. The VICH Secretariat will then communicate in writing (letter, fax or e-mail) to each member of the EWG notifying them that their EWG is disbanded and thanking them for their participation in the VICH process, in accordance with the policy on appreciation to EWGs (VICH/00/155).

However, in case the SC foresees that in a medium term (1 to 2 years) it may ask the EWG for guidance on a new topic (topic laid down in the work plan, review of a relevant revised ICH Guideline....), the EWG should not be disbanded. In this case it would stay temporarily (1 to 2 years) inactive, i.e. without specific assignment. Members of the EWG shall be informed by the VICH secretariat of this status and the timeframe involved.

If an EWG cannot reach agreement, the SC should consider publishing the main outcomes in a status report document. In such cases a document should be prepared by the EWG

including the points on which an agreement could not be reached. The SC may decide thereafter to disband immediately the EWG.

The VICH Secretariat communication to the EWG members should initiate the process to implement the “Policy on Appreciation and Recognition of the Chairs and Expert Working Group Members” (*VICH/00/155*).