

## **GUIDANCE FOR MEMBERS OF VICH EXPERT WORKING GROUPS**

Thank you for agreeing to participate actively in the VICH process. You have been appointed by your region to be an expert member of a VICH Expert Working Group (EWG). VICH values highly the contribution of EWG members, and appreciates that often their contribution is in their own time. The EWGs are the cornerstone of the VICH process. Your expertise is therefore highly appreciated by the Steering Committee (SC) and will be an important contribution towards the development of international guidelines.

This document is intended to assist members of VICH working groups to contribute and to make the best use of everyone's time. The comments in this document are not obligatory, but they are based on suggestions from previous EWG participants on what works and what doesn't.

You have also received a document "SOP on VICH procedure for the EWGs" (VICH/00/151). This document outlines the rules that you must follow and explains roles and processes. If you have not already done so, it is suggested you read that document before you read this one. You may also contact your regional coordinator for further details.

Before going any further you might moreover find it useful to look at the VICH web-site on <http://www.vichsec.org> where you will find a lot of general information regarding the VICH process, the VICH structure, the topics discussed in VICH and the composition of the current EWGs, who is who in VICH, press releases as well as the list of all final and draft Guidelines already published.

### **What is VICH?**

This is covered in "SOP on VICH procedure for the EWGs" (VICH/00/151). If you have any questions, we suggest you ask your VICH regional coordinator. The role of the coordinator is also explained in this document. Make sure you understand the nine-step guideline process and the role of the EWG within those steps.

### **Scope of the guidelines**

Your EWG will receive the concept paper that has been agreed by the SC. Sometime EWGs members have felt that the scoping paper gives them insufficient guidance on matters such as the boundaries of the guidelines, timeframes for guideline production and what feedback the SC wants.

Please make sure you discuss all these matters at your first EWG meeting. If the EWG feels that it needs more guidance, it is important that your Topic Leader/Chairperson asks the Steering Committee for extra guidance as soon as possible.

### **Roles of EWG members**

The majority of EWG members consider they have three roles, ie.

- to be a topic expert,
- to represent the views of their sponsoring organisations,
- to communicate outcomes of the EWG back to their sponsoring organisations.

As your principle role is as an expert, you need to bring that expertise to the table and be prepared to consider different views when justified by the science. Your sponsoring organisation must give you that amount of flexibility needed in international discussions and decision-making process. You must nevertheless be aware of your sponsoring organisation's views and recommendations. The VICH process will only work if experts have the flexibility to consider and support different ideas.

### **The commitment required by EWG members**

VICH EWG membership requires a high level of commitment. Please ensure that you have established clearly what time commitment will be required of you.

The most significant reason limiting EWG members' contribution in the past has been the pressure of non-VICH work. Many experts have indicated that it had prevented them from contributing fully. If you do not feel you have the time, or do not fully understand the commitment required, please talk to your coordinator.

If you also think it unlikely that you will be able to contribute for the whole of the process, please also discuss this with your coordinator.

### **Creation of a work plan with clear goals and timeframes**

The production of a work plan is part of good management. VICH procedures require a draft plan to be produced before the first meeting by the Topic Leader/Chairperson. The plan should specify the planned outputs, key actions and a proposed timetable and schedule of meetings. This plan should be agreed by all EWG members at or before the first meeting and reviewed at each meeting.

It is important that each group sticks to its work plan. Make sure you can achieve what it says, before it is agreed. If unforeseen problems arise, your Topic Leader/Chairperson will need to send an amended plan to the SC.

You may also be asked to contribute to a discussion paper that the Topic leader/Chairperson should produce for the first meeting. This document provides a summary of the regulatory requirements for VICH regions, and outlines the issues for discussion by the EWG.

## **What to do at the first meeting**

At the first meeting, the Topic Leader/Chairperson needs to establish:

- agreement on the principles contained in the discussion document prepared by the topic leader
- agreed timeframes for the distribution of papers prior to meetings (this is important as late papers can create problems for those who need to consult broadly, or who may need papers translated)
- that members are familiar with the VICH processes that relate to guideline production and consultation
- that sufficient expertise is available within the group to complete the work (if not, the Topic Leader/Chairperson can approach the SC to seek additional expertise)
- that the mandate for the EWG is sufficiently clear, and in particular what it is planned to include/not include within the guideline (if not, seek more guidance from the SC)
- that between EWG meetings experts exchange as much information as possible by e-mail/fax and/or establish an e-mail discussion site (previous groups have indicated that they would have made better progress if electronic exchange had been used more)
- the length of each meeting. Previous EWG members have commented that meetings are sometimes too short to allow adequate discussion on all aspects, especially for important, difficult or controversial topics.

**How to consult at step 4 and how comments should be considered** VICH procedures indicate how consultation at step 4 should be conducted (see document VICH/00/154). You need to discuss within the EWG how you will consider the comments received. You will need to ensure that:

- all EWG members see all comments submitted
- the comments will be considered by the whole group
- there is sufficient time to consider all comments
- the comments received can trigger a serious reconsideration of the Step 4 document if justified. (This means that EWG members must be open to change)

You will also need to discuss with your coordinator what consultation processes are required within your region and your role in that consultation process.

## **Reaching consensus and alternative methods of developing guidelines**

EWGs are encouraged to use best endeavours to negotiate harmonised guidelines. Flexibility in interpretation should be reserved for use when other consensus building measures have failed.

Difficulties in reaching consensus on particular matters in the guidelines are usually related to different legislation in the 3 regions of VICH – Europe, Japan and the United-States, but

language and cultural differences can be significant. Lack of scientific data can be a limiting factor, as can lack of flexibility shown by experts to change their position. Making the guidelines sufficiently flexible to allow for a broad range of interpretations often provides a solution, but too much flexibility will mitigate against the advantages of a single international guideline and result in a guideline commanding little respect or adherence.

There are a number of techniques used by different EWG to produce guidelines ie.

- start with an existing regional guideline and adapt it
- adapt an ICH guideline
- amalgamate existing guidelines
- develop a new guideline.

Where a group has difficulty in reaching consensus, resolution can usually be achieved by negotiation and adopting different parts of the guideline from different VICH members, but only in very exceptional circumstances. However sometimes EWGs may need to generate new data, undertake a literature search or go back to basics and work forward from key principles. If the difficulties involved are extensive, the SC should be consulted.

### **Consideration for those whose first language is not English**

While the official language for VICH is English, EWG members need to be sensitive to the needs of those whose first language is not English. This includes ensuring papers are sent in sufficient time for translation and effective meeting management (eg. ensuring only one speaker at one time, and effective summarising by the Topic leader/Chairperson).

### **Expert Working group meeting arrangements**

Sufficient sizes of meeting rooms and moderate accommodation cost venues have been concerns for previous groups. In planning meetings, Topic Leader/Chairpersons need to give attention to:

- the physical facilities
- the need for close moderate cost accommodation
- sufficient length of the meeting to allow adequate time for proper discussion, particularly of contentious issues
- non English speaking members.

### **Additional guidance for Topic Leaders**

You have been appointed topic leader on a specific VICH topic. This means that, as such, you have responsibilities to address, with the specific EWG (composition annexed), the non-harmonisation issues of the topic under consideration and attempt to resolve these issues by producing proposals for harmonised requirements. You will then be expected to present these proposals to the VICH SC.

The VICH procedure regarding the operations of EWGs approved by the VICH SC is attached (VICH/00/151). This foresees an authorisation procedure for each EWG meeting in order to consistently monitor the objective of cost-efficiency of the VICH proceedings. For this authorisation by the SC, the SC needs to receive from you a short discussion document in which the issues to be discussed, the meeting schedule, and possibly first proposals, should be outlined. You should send a copy of this document as well to all the experts of your EWG, and to the chairperson of the EWG if you are not the chairperson yourself. This document will facilitate the task of the Steering Committee in authorising the meetings of your EWG.

In case several topics are discussed under one EWG, it is the Chairperson of the EWG who should communicate the meetings schedule.

### **Additional guidance for Chairpersons**

You have been appointed chairperson of a specific VICH expert WG. This means that, as such, you have responsibilities to organise and coordinate the activities of the EWG.

The VICH procedure regarding the operations of EWGs approved by the VICH SC is attached (VICH/00/151). This procedure foresees an authorisation procedure for each EWG meeting in order to consistently monitor the objective of cost-efficiency of the VICH proceedings. For this authorisation by the SC, the SC members need to receive from you a short discussion document in which the issues to be discussed, the meeting schedule, and possibly first proposals, should be outlined. You should send a copy of this document to all the experts of your WG. This document will facilitate the task of the Steering Committee in authorising the meetings of your EWG.

In case several topics are discussed under your working group, it is you, as the Chairperson of the EWG, who should communicate the meeting schedule.