



## Methodology for a systematic review of VICH Guidelines at step 9

### I. Introduction

The VICH Steering Committee requires that the systematic monitoring of existing guidelines should be carried out every 5 years in order to identify any need to change or update of a guideline.

This document describes the methodology for the monitoring and maintenance of existing VICH guidelines, and combines and replaces the following 2 documents:

- (a) "Methodology for a systematic Review of the VICH Guidelines at step 9" (VICH/07/039-final)".
- (b) "Monitoring and Maintenance of existing VICH Guidelines" (VICH/IN/05/017-FIN-Rev).

### II. Review methodology

#### A. Status Updates

The secretariat will circulate an updated table 6 months before each VICH SC meeting to reflect the current status of all the VICH GLs.

The list of the VICH guidelines is detailed in the document VICH/99/036 – Status of VICH Guidelines and Work plan, which is updated whenever required. The last version of this document is published the Members Area of the VICH Website.

#### B. Methodology

In order to facilitate the overview of the table, the status of the GLs is highlighted by the following colour code in the status column of the table:

**Red: GL for consideration at the forthcoming SC meeting**

*Yellow:* ongoing – the topic is under consideration for revision or is currently under revision

*White:* GL adopted less than 5 years ago or GL revised less than 5 years ago or has been reviewed with no need for further action

The updated table will be sent to the VICH SC 6 months before each VICH SC meeting. The delegation that led the topic for the initial development of the GLs that are flagged in red should come to the meeting with a proposal on the way forward for each GL.

Each delegation should consult internally on the need for revisions to each of these GLs and should come to the meeting with a view on whether each GL needs or does not need to be revised.

At each SC meeting the SC will decide on the way forward and, if relevant, ask the region which led the topic for the initial development of the GL to collect the formal comments from the other regions and provide a final proposal for the next step for the review of the GL considered.

### **III. Process**

#### **A. "Major" and "Minor" harmonization activities**

Different processes for changes and updates to existing guidelines apply depending on the type of such changes, i.e. whether they are considered as "major" and "minor" harmonization activities.

A "major" topic concerns major amendments to a guideline, its extension and addition of further aspects or revision due to new scientific knowledge or regulatory requirements. Other changes are considered as "minor". The SC will decide whether a proposed revision is major or minor.

"Major" maintenance topics will be handled under the full 7-step VICH Procedure as for the development of a new guideline. Proposals for "Minor" changes to existing VICH guidelines will be handled through the Abbreviated Maintenance Procedure (see section C.b).

#### **B. Monitoring of existing guidelines**

The systematic monitoring of existing guidelines in order to identify any need to change or update a guideline is carried out with 5 year intervals starting 5 years after the implementation of a guideline. The review considers in particular the following aspects:

- consistency of interpretation,
- need for further clarification and guidance,
- need for consideration of new scientific knowledge
- review of ICH guidelines whether these require adaptation of VICH guidelines

As outlined in section A, the Secretariat will circulate prior to, and present at each Steering Committee meeting an updated table. In principle, the delegation which had the initial topic leadership of a GL is responsible for the review the GL. Should this however not be possible, the SC determines who will be responsible for the review and act as rapporteur to the SC. The rapporteur presents the outcome of its review and recommendation to the SC.

Concept papers for the proposed maintenance work detailing the issues for amendment will be required for both major and minor harmonisation activities. For major changes, this should include an impact analysis. The concept papers may be presented to the SC once a first feedback has been received as to the likely necessity for changes to the guideline.

If a SC member wishes to propose that a VICH guideline is amended, which may arise in particular if inconsistencies in interpretation would occur, such a proposal can be presented to the SC at any time without awaiting the 5-yearly systematic review.

#### **C. Process for changes to guidelines**

##### **a. Maintenance Process for major changes to guidelines**

As outlined in section A, for all major changes to GLs the full 7-step VICH process is required. Therefore, once a proposed topic for the amendment or update of an existing GL has been agreed by the SC on the basis of a concept paper, an EWG will be assigned with this task.

Depending on the GL this EWG may be an existing EWG or a new one to be established. If a new EWG is required, this may in practice often be the re-establishing of a previous EWG that had completed their original mandate. However, in such a case, new nominations of experts and topic leader would be necessary.

Reference:

- The VICH procedure regarding the operations of EWGs (VICH/00/151)
- Guidance for Members of VICH Expert Working Groups (VICH/00/150).

#### **b. Abbreviated Maintenance Process for minor changes to guidelines**

Minor changes to VICH guidelines are carried out through an abbreviated process. The procedure is intended to provide results quickly and efficiently using the minimum amount of resources consistent with the achievement of a scientifically valid result. As far as possible, such abbreviated maintenance work should be completed via a written procedure with recourse to meetings only in exceptional cases.

The concept papers with a proposal for a minor amendment of a VICH guideline can be considered and approved by the SC in a written process. If agreement is not achieved by a written procedure, the matter would be referred to the next SC meeting.

Once the VICH SC has approved a proposal for a minor amendment of a guideline, based on the concept paper, each VICH partner nominates an expert for the work. These experts should appoint a topic leader to lead and manage the group (normally from the region that had the initial topic leadership of a GL), These experts, in close liaison with their VICH coordinators, are then empowered to deal with the amendment of the guideline. The draft amended guideline is signed-off by the coordinators prior to the sign-off by the SC. The sign-off is normally by written procedure.

Consistent with previous amendments to VICH GLs, minor changes of VICH GLs due to scientific or regulatory reasons should be subject for public consultation, which can normally be shortened, as appropriate. In case of changes due to editorial or procedural reasons, these updates would be undertaken without public consultation.

#### **D. Timelines**

The timelines necessary for the process for changes to VICH GLs should be identical than the timelines required in the following guidance documents:

- Note to prepare a VICH Topic Concept Paper (VICH/97/037)
- VICH procedure for the Expert Working Groups (VICH/00/151)