

## **Monitoring and Maintenance of existing VICH Guidelines**

### **1. Background**

In its document on the VICH Strategy Phase II 2006-2010 published on 25 January 2005, the VICH Steering Committee recognized that

- The number of Guidelines adopted by VICH since the start of the process requires now additional focus on maintenance and updating of the VICH Guidelines and a strategy for the second phase programme.

Within the same document the VICH Steering Committee listed under its objectives:

- Establish and implement harmonized regulatory requirements for veterinary medicinal products in the VICH Regions, which meet high quality, safety and efficacy standards and minimize the use of test animals and costs of product development.
- Monitor and maintain existing VICH guidelines, taking particular note of the ICH work program and, where necessary, update these VICH Guidelines.

This document describes the process of for the monitoring and maintenance of existing VICH guidelines.

### **2. "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".

"Major" maintenance topics will be handled under the full 7-step VICH Process similarly as the development of a new guideline. Proposals for "Minor" changes to existing VICH guidelines will be handled through the Abbreviated Maintenance Process.

### **3. Monitoring of existing guidelines**

The systematic monitoring of existing guidelines in order to identify any need to change or update of a guideline is carried out with 3 year intervals starting 3 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

A table comprising all guidelines identifying their review status is considered at each SC meeting and the guidelines due for review are identified. 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 3-yearly systematic review.

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

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

As outlined in section 2, 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 of 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. Whether face-to-face meetings would be necessary or the discussion between the experts could be done by a written procedure depends on the complexity of the matter. The EWG should have their exchange as much as possible by written procedure.

### **4.2. 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 no agreement would be possible 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 maintenance experts, in close liaison with their respective VICH coordinators, are then empowered to deal with the amendment of the respective guideline and the discussions and negotiations with the experts of the other regions. 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.