



NOTE TO PREPARE A VICH TOPIC CONCEPT PAPER

Introduction

In order to propose and select a new topic in the VICH process, or to propose a revision of an existing guideline, a concept paper should be prepared. This will be submitted to the VICH Steering Committee (SC) for concurrence prior to the development of any guideline. A concept paper should be developed by the member of the SC who wishes to propose a specific topic.

A VICH Outreach Forum member can use the same concept paper template to propose a topic to the SC.

Purpose

A concept paper is a document which serves to guide the SC in the selection of a topic where harmonisation of technical registration requirements of veterinary medicinal products by elaboration of guidelines or a revision of existing guidelines may be beneficial.

Outline

A concept paper should outline the proposed content of the guideline and explain the differences in requirements between the regions, if existing (comparison of existing requirements in the regions can be laid out in a tabulated format). The impact of these differences on regulators and the industry should be assessed. A proposal for an action plan should be developed. This should include the need for a new Expert Working Group or proposal for coverage by an existing EWG, the specific expertise proposed, the number of meetings needed (time frame), and the various phases if appropriate.

The SC should review the concept paper, with the assistance of regional expertise, and ensure that:

- Existing requirements in each country/region are clarified at the outset;
- There is no crossover with the work of other international committees such as Codex, OECD, etc.
- The document does not contain confidential information, as the document will subsequently be published.

Submitting ideas for new VICH topics or guideline revisions

Any member of the VICH SC or the VICH Outreach Forum may submit ideas for new topics or for proposed revisions to existing guidelines by sending a proposal to the VICH Secretariat for discussion at the next VICH SC meeting and Outreach Forum meeting. To allow a proposal to be adequately discussed it should be submitted in the form of an informal discussion paper (giving a good description of the topic and the need for harmonisation) or a formal concept paper, which has a defined structure (see template below).

Timelines*

Work flow plan	Month
• SC “1”: SC is informed and agrees that a CP will be drafted	0
• CP draft 1 to be submitted to secretariat by month 3	+3
• CP draft 1 immediately circulated to SC/VOF for comment by the SC/VOF within 3 months	+6
• CP draft 2 submitted by the author to the secretariat within 1 month	+7
• CP draft 2 immediately circulated to SC/VOF for final comment/approval by the SC/VOF within 3 months	+10
• Any final comments received at month 10 to be compiled and shared with SC 6 weeks before the SC meeting (4 weeks absolute minimum)	+10.5 to 11
• SC “2”: Outstanding issues discussed at SC and decisions taken	+12

* The timelines recommended in this document must be seen as guidance, but should be respected as much as possible.

Concept Paper Template for proposing the elaboration of a new guideline

- **Introduction**
- **Problem statement, including references to existing technical and legislative requirements in the different regions**
- **Impact for public health, animal health and animal welfare**
- **Anticipated benefit to:**
 - **Industry and Other Interested Parties**
 - **Regulatory Authorities**
- **Discussion**
- **Recommendation (action plan, issues to be addressed, mandate, etc.)**
- **Timetable**
- **Milestones**
- **Impact assessment for Industry**
- **Impact assessment for Regulatory Authorities**
- **References to literature, existing relevant international guidelines or standards (e.g. ICH, OECD, CODEX, JECFA,...).**

Note: suggested number of pages: 2-4