

NOTE TO PREPARE A VICH TOPIC CONCEPT PAPER

Introduction

In order to propose and select a new topic in the VICH process, a concept paper should be prepared. This will be submitted to the VICH 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.

Purpose

A concept paper is a document which serves to guide the SC in the selection of a topic where harmonization of registration requirements of veterinary medicinal products by elaboration of 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.

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