VICH/IN/09007
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VICH International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

*Tokyo, 7 January 2009*
*JMAFF*

# Concept Paper that Requests to Revise GL18

## IMPURITIES: RESIDUAL SOLVENTS IN NEW MEDICINAL PRODUCTS, ACTIVE SUBSTANCES AND EXCIPIENTS

## Introduction

The Quality Expert Working Group (QEWG) has a mandate to evaluate the relevance or applicability of ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) quality guidelines of Q1 (stability), Q2 (analytical validation), Q3 (impurities) and other quality topics in accordance with the VICH work program. The procedure for elaboration of VICH quality guidelines was that the VICH guidelines should be developed on the basis of the corresponding ICH guidelines and changes of the text should be made only in cases where necessary or justified for veterinary medicinal products. The new guidelines could be formulated for specific areas of veterinary medicinal products where corresponding ICH guidelines not exist.

Particularly, the guideline for residual solvents of ICH (Q3C) has been revised three times from September 2002 to November 2005. Therefore, we propose in the SC meeting that the VICH GL18 which corresponds to the ICH GL Q3C should be revised as soon as possible.

## Problem statement

When some kinds of organic solvents are contained within a veterinary medicine, a very noxious effect on administered animals is well known in general. In order to guarantee the safety of veterinary medicine, it is important that the GL 18 will be revised according to revise of the ICH Q3C. The last revision of the ICH Q3C was made about three years ago; therefore, we think that a revise of the VICH GL 18 should be started soon by the QEWG.

## Objectives

The overall aim of this concept paper is to make a revision of the VICH GL 18 according to the revision of the ICH Q3C (R3). As regards revision of the GL 18, it is a main examination matter to consider containing permissible daily exposure values of some organic solvents, for example, Tetrahydrofuran (THF) and N-Methylpyrrolidone (NMP). The topic leader for revised VICH GL 18 would be the expert of EMEA same as the last time.

## Recommendation (action plan, timetable)

| Proposed Action | Timing |
|---|---|
| 1. This concept paper should be discussed at VICH SC 22nd meeting, with a view to agreeing the next steps and the timing. | February 2009 |
| 2. Next step would be the making a draft of revised VICH GL 18 by the topic leader. | July 2009 |
| 3. The draft of revised GL 18 in step 2 would be agreed by the QEWG members. | February 2010 |

## References to literature, existing relevant international guidelines or standards

ICH harmonised tripartite guideline: Impurities: Guideline for residual solvents Q3C (R3), Parent guideline dated 17 July 1997 (Revised PDE for the THF and NMP dated 12 September 2002 and 28 October 2002 incorporated in November 2005)