The European Agency for the Evaluation of Medicinal Products

EMEA/CVMP/423/01-FINAL

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

APPLICATION OF THE VICH GUIDELINE ON RESIDUAL SOLVENTS TO VETERINARY MEDICINAL PRODUCTS CONTAINING EXISTING ACTIVE SUBSTANCES

DISCUSSION IN THE QUALITY WORKING PARTY (QWP)	APRIL 2001
ADOPTION BY CVMP	MAY 2001
DATE FOR COMING INTO EFFECT	WITH IMMEDIATE EFFECT

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Introduction

At the Quality Working Party's meeting with Interested Parties in October 2000, Industry was made aware that via the 2001 Supplement of the European Pharmacopoeia, in theory the ICH guideline on limits for residual solvents would apply to already authorised veterinary medicinal products[1] as from 1st January 2001. The CVMP has adopted the following measured approach to the implementation of the residual solvents guideline to existing veterinary medicines. The phased-in implementation of the VICH residual solvents guideline to existing veterinary medicines, is to be in accordance with the decision tree indicated in this document.

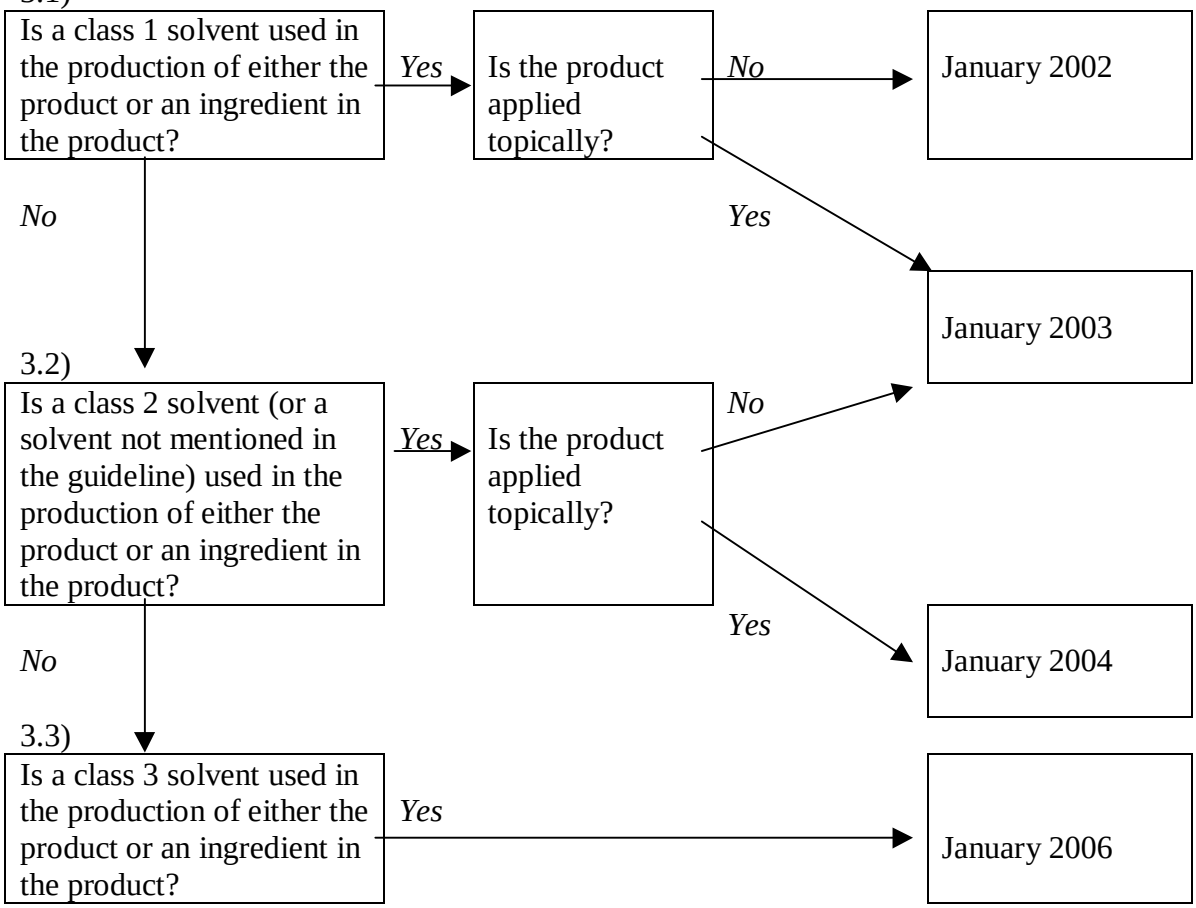
Procedure

In accordance with the decision reached by CPMP in March 1999, the appropriate regulatory action (i.e. no action, type I variation submission, type II variation submission) will be determined using the decision trees for class 1 and class 2 solvents which were issued in July 1999 and are available on the website: http://heads.medagencies.org/mrfg/sops/residual.pdf.

[1] As the ICH guideline is implemented via the Ph.Eur monograph on substances for pharmaceutical use, it is only veterinary medicinal products which contain exclusively Ph.Eur ingredients which were required to comply with the ICH guideline from 1st January 2001.

Marketing Authorisation Type	**Timeline**
1) **New Marketing Authorisation applications for veterinary medicines with a new active substance**	June 2001[2]
2) **New Marketing Authorisation applications for veterinary medicines with an existing active substance**	January 2002

3)
Existing Marketing Authorisations for veterinary medicines



[2] This date has already been agreed by the CVMP