VICH GL 29 (PHARMACOVIGILANCE)

June 2006

For implementation at Step 7 - Final

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS – MANAGEMENT OF PERIODIC SUMMARY UPDATE REPORTS

Recommended at Step 7 of the VICH Process

by the VICH Steering Committee in June 2006

for implementation by June 2007

This Guideline has been developed by the appropriate VICH Expert Working Group and is subject to consultation by the parties, in accordance with the VICH Process. At Step 7 of the Process the final draft will be recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS
Management of Periodic Summary Update Reports (PSUs)

I. INTRODUCTION

Pharmacovigilance of veterinary medicinal products (VMP) is important to guarantee the continued safety and efficacy of VMPs in use. The objective of this guidance document is to standardise the data for submission in a Periodic Summary Update (PSU). A consistent set of data will contribute to a harmonised approach for the detection and investigation of adverse events (AE) for VMPs and thus help to increase public and animal health. Based on definitions and terminologies defined in the GL 24 document, this document will give guidance related to the scope, timing and contents of the PSU.

II. SCOPE

The scope of pharmacovigilance in this VICH document is defined as the management of the detection and investigation of the clinical effects of marketed VMPs concerned with the safety and efficacy in animals and the safety in people exposed to these products. This document defines all items submitted in the PSU concerning AERs. While pharmacovigilance in its broadest sense may entail a wide range of activities, this document deals with the spontaneous reporting system for the identification of possible adverse events following the use of marketed VMPs. An RA may request additional information for the VMP(s) based on special circumstances.

III. DEFINITIONS

Refer to GL 24 Management of Adverse Event Report (AER) for definitions.

IV. TIMING OF REPORTING

Each VMP should have an International Birth Date (IBD) as defined in GL 24. The IBD can be designated as the last day of the same month for administrative convenience, if desired by the MAH. The IBD is the basis for harmonizing MAH periodic reporting dates.

The requirements for frequency of reporting are subject to local regulatory needs and the time that a VMP has been authorized may influence such requirements. In the early years of commercialization of a product authorization and market introduction will vary in different countries, and it is during this period that frequency of reporting and the harmonization of such frequency is important.

Therefore it is recommended, when and where required, that preparations of PSUs for all regulatory authorities would be submitted every 6 months for the first two years after the first marketing approval in a VICH region based on the IBD or as per regional requirement if legislated requirements is greater than 6 months.

The various parties to VICH have expressed a good faith commitment to revisit in the future the issue of frequency of PSU reporting in order to consider the possibility of decreasing such frequency to a 12-

month period following authorization on condition that a product has been commercialized in one VICH region for a minimum of two years without significant efficacy or safety concerns associated with the use of the product having been identified.

After the first two years of marketing following the IBD, PSUs should be required no more frequently than yearly for the next 4 years of marketing in any VICH region. Beyond the sixth year of marketing, PSUs should be submitted no more frequently than every 3 years.

V. CONTENTS

1. Name and address of the MAH responsible for the VMP detailed in the PSU.

2. The PSU will clearly identify the VMP(s).

3. Time period covered by the PSU (start date and end date).

4. The PSU will contain AERs for the VMP(s) identified in V.2 and AERs for same and similar pharmaceutical VMP(s) or same biological VMP(s).

5. All data elements for the AERs submitted in the PSU are described in GL 42. Until electronic submission (GL 35) has been implemented by the RA, a subset of GL 42 may be submitted as a line listing of AERs.

6. A bibliographic listing of scientific articles that address AEs found in a widely accepted search engine published during the time period of the PSU that pertains to the VMP(s) identified in V.2., and a brief statement assessing the relevance of these articles to the VMP(s). Additionally, a bibliographic listing of the studies that address AEs and the MAH has sponsored for the VMP(s) identified in V.2. should be included.

7. The PSU must address the relationship of sales volume of the VMP(s) identified in V.2. to the number of AERs. Sales volume by country should be provided.

8. For the same and similar VMP(s), an update should be presented if there are RA-mandated or MAH-initiated regulatory actions (e.g. changes to the VMP(s), changes to labeling, and market suspensions) that have been taken, or are pending for safety and effectiveness reasons during the reporting period. The format should be a brief narrative stating the reasons for the action(s), with documentation appended when appropriate.

9. The PSU should include a concise critical analysis and opinion on the risk/benefit profile of the VMP(s) identified in V.2. Comment on important developments for the following:

    a. Evidence of previously unidentified concerns
    b. Changes in frequency of AEs
    c. Drug interactions
    d. Human AEs

    The evaluation should indicate whether the data remain in line with the cumulative experiences to date and the approved labels, including proposed actions.