

Guidance for Industry

Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs) VICH GL29

DRAFT GUIDANCE

This document is being distributed for comment purposes only

This draft guidance is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products (VMP's).

Comments and suggestions regarding this document should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the Docket No. 01D-0501.

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Contains Non-Binding Recommendations

Draft—Not for Implementation

VICH GL29 (PHARMACOVIGILANCE: PSU)

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For consultation at Step 4 - Draft 1

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: MANAGEMENT OF PERIODIC SUMMARY UPDATE REPORTS (PSUs)

Recommended for Consultation
at Step 4 of the VICH Process
on 28 June 2001
by the VICH Steering Committee

THIS GUIDANCE 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.

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Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)

This draft guidance represents the agency's current thinking and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

INTRODUCTION:

The VICH Guidance GL24, Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERs), defines the Periodic Summary Update (PSU).

Based on this definition, using the terminologies as defined in the GL24 document, this document will give guidance related to the scope, timing and contents of the PSU.

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 veterinary medicinal products (VMPs) mainly concerned with the safety and efficacy in animals and the safety in people exposed to these products. 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.

DEFINITIONS:

See VICH GL 24 (guidance may be found on the Internet from the CVM homepage at <http://www.fda.gov/AnimalVeterinary/default.htm>)

TIMING OF REPORTING:

Each VMP should have as an International Birth Date (IBD), the date of the first marketing authorization for the product granted in any country in the VICH region. For administrative convenience, if desired by the Marketing Authorization Holder (MAH), the IBD can be designated as the last day of the same month. The IBD should be the basis for harmonizing MAH periodic reporting dates. To maximize harmonization until regional requirements are made synchronous with the IBD, the Regulatory Authority (RA) in each country where a subsequent registration occurs should discuss with the MAH on an individual product basis the implementation of harmonization of periodic reporting dates with the IBD.

At the present time, the regions cannot agree on a mechanism to harmonize the frequency of Periodic Summary Update reports. As a result, the frequency of report submission to RA is subject to regional regulatory requirements.

CONTENTS:

1. Sender of the PSU and VMP identification

- 1.1 Name and address of the MAH responsible for the VMP detailed in this PSU.
- 1.2 Name and registration number of the VMP used in the country/region for which the PSU is prepared. As the name of the same VMP may be different in the various regions, the other names should be mentioned as well.
- 1.3 Time period covered by PSU (start date and end date).
- 1.4 The PSU should contain AERs from the same VMP. The same VMP is defined as the same active ingredients in the same concentrations in the same formulation originating from the same MAH, being responsible for pharmacovigilance of this/these VMP(s).

2. Individual AERs

Within the respective time period covered, all reports of AEs occurring inside a region should be submitted in the form of a line listing or as an entire report depending on regional requirements. All other AERs should be submitted as part of a global line listing. The PSU reported as a line listing should include the following elements:

- 2.1 AER identification number (VICH GL 24 A.4.1)
- 2.2 Date of first exposure (VICH GL 24 B.2.11)
- 2.3 Use according to label (VICH GL 24 B.2.14)
- 2.4 Date of onset of AE (VICH GL 24 B.3.1)
- 2.5 Species (VICH GL 24 B.1.3)
- 2.6 Number of animals exposed (VICH GL 24 B.1.1)
- 2.7 Minimum Age (VICH GL 24 B.1.9.a)
- 2.8 Maximum Age (VICH GL 24 B.1.9.b)
- 2.9 Age Units (VICH GL 24 B.1.9.c)
- 2.10 Number of animals affected (VICH GL 24 B.1.2)
- 2.11 Died (VICH GL 24 B.3.8.4)
- 2.12 Registered or Brand name (VICH GL 24 B.2.1) for each VMP associated with the AER
- 2.13 Adverse clinical manifestations (VICH GL 24 B.3.5)
- 2.14 MAH assessment (VICH GL 24 B.5.2)
- 2.15 Type of submission (VICH GL 24 A.4.5)
- 2.16 MAH Comment (free text)
- 2.17 Country/region where the AE occurred (VICH GL 24 A.3.1 country of attending veterinarian)

3. Safety and Efficacy Citations

A brief statement assessing the impact of the scientific articles in a bibliographic listing of published scientific articles that pertain to the safety or efficacy of the VMP should be included.

4. Sales Volume

The PSU should address the relationship of sales volume of the VMP related to the number of AERs. These volumes should be presented in such a form as to enable an incidence-calculation (number of AEs per country or region in relation to the sales volume in that country or region). If the VMP is labelled for use in more than one species and the use in one species is unknown or the VMP is provided in a multiple use container, theoretical calculations are sometimes of value but should be treated as arbitrary.

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5. Approved label texts or approved VMP documentation

The approved label text or approved product documentation of the region/country should accompany the PSU.

6. Actions taken for safety reasons

An update should be presented if any significant RA-initiated or MAH-initiated actions have been taken, or are pending for safety reasons during the report period anywhere in the world. The format should be a brief narrative stating the reasons for significant regulatory or MAH action, with documentation appended when appropriate.

7. Narrative review of AERs and an Overall Safety Evaluation

The PSU should include a brief narrative based on the MAH analysis of the AERs presented. This narrative, or separately to the PSU, should include a concise critical analysis and opinion on the risk/benefit profile of the VMP written by a suitably qualified expert for pharmacovigilance. The PSU should include comment on any new important information on the following:

- a. evidence of previously unidentified toxicity or safety concerns
- b. increased frequency of known toxicity or expected AEs
- c. drug interactions
- d. overdose and its treatment
- e. AEs associated with off-label use
- f. human AEs associated with the use of the VMP

The evaluation should indicate in particular whether the safety data remain in line with the cumulative experiences to date and the approved label texts and should specify any future action recommended and the reasons for those recommendations.