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Guidance for Industry

Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms

VICH GL30

REVISED DRAFT GUIDANCE

This document is being distributed for comment purposes only

This draft guidance is intended to provide a recommended controlled list of terminology to ensure that terms are used consistently in adverse event reports, as well as to allow comparison between products and across product classes.

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.fda.gov/dockets/ecomments. All comments should be identified with the Docket No. 2002D-0005.

For questions regarding this document, contact Lynn Post, Center for Veterinary Medicine, (HFV-210), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9062, e-mail: lynn.post@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
June 20, 2007

VICH GL30 (PHARMACOVIGILANCE: LIST OF TERMS)
June 2006
For consultation at Step 4

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: CONTROLLED LIST OF TERMS

Recommended for Consultation
at Step 4 of the VICH Process
on June 2006
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 US.

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS
Controlled Lists of Terms
VICH GL 30

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

Use of controlled lists of terms is important to ensure consistency in adverse event reports, as well as to allow for comparison between products and across product classes. The controlled lists of terms should have standardized groupings of terms, and these lists should be of a manageable size but with sufficient detail to allow standardised input and analysis. Industry and government should partner in the development, implementation, and ongoing maintenance necessary to keep the controlled lists of terms up to date and useful. A joint industry and government oversight board would best meet these needs.

An anticipated list of terms would provide a level of discrimination sufficient to record, search and categorize for trending. The management and distribution of the controlled lists of terms should be strictly version controlled.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

II. SCOPE

This document provides guidance for the development and maintenance of the controlled lists of terms recommended to complete the controlled data fields as identified in "Pharmacovigilance of Veterinary Medicinal Products Data Elements for Submission of Adverse Event Reports" (VICH GL42).

III. SPECIFICATIONS

1. The controlled lists of terms as referred to in the data elements in VICH GL42 should be used. An initial draft proposal submitted to the VICH Pharmacovigilance Expert Working Group (EWG) of the controlled lists of terms for use by the proposed Controlled Lists of Terms Working Group is provided in Appendix A.

2. Veterinary Medicinal Dictionary for Drug Regulatory Authorities (VEDDRA) terminology for animal and human adverse events has been agreed by the VICH Pharmacovigilance EWG as a suitable basis for a clinical dictionary to describe adverse clinical manifestations (GL42 B.3.6) for paper or electronic submissions to the regulatory authorities (RA).[1, 2]

3. Product identification data in a separate dictionary is important to allow analysis across veterinary medicinal products (VMPs) and active ingredients. A list of possible data fields includes:

    - Marketing authorization holders (MAH) name
    - Registration identifier
    - Registration country
    - Registered or brand name
    - Package description
    - Dosage form
    - Active ingredient(s)
    - ATCvet code

4. A Controlled Lists of Terms Working Group, reflecting appropriate membership from regional industry and regulatory agencies, should oversee the implementation and maintenance (see Appendix B), within the pharmacovigilance systems, of the controlled lists of terms. The group should be appointed immediately subsequent to the Steering Committee's acceptance of this document. The implementation should be completed within one year of appointing the group.

5. The current version of controlled lists of terms should be accessible to all parties in an electronic format.

6. The Controlled Lists of Terms Working Group should consider existing RA and MAH lists of controlled terms, in particular, lists that are already in operation for the electronic exchange of pharmacovigilance data.

7. The lists of controlled terms should be backward compatible between versions.

8. Terms common to multiple data elements should be consistently defined.

9. Terms within the controlled list of terms should have precise definitions and user guidance.

10. Terms within the VICH-controlled list of terms should be in English.

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[1] VEDDRA List of Clinical Terms for Reporting Suspected Adverse Reactions in Animals to Veterinary Medicinal Products (EMEA/CVMP/413/99, as updated) - http://www.emea.eu.int/pdfs/vet/phvwp/041399en.pdf

[2] VEDDRA - List of Clinical Terms for Reporting Suspected Adverse Reactions in Human Beings to Veterinary Medicinal Products (EMEA/CVMP/891/04, as updated) http://www.emea.eu.int/pdfs/vet/phvwp/089104en.pdf

In case other VICH-controlled lists of terms emerge during the implementation of the electronic standards for transfer of data, these should be developed and managed according to the specifications outlined above.

APPENDIX A

The attached (PDF file) entitled "Lists of Values" contains an initial draft proposal submitted to, but not approved by the VICH Pharmacovigilance EWG, of the controlled lists of terms. (GL30_Appendix A.pdf)

Although the revised draft guidance includes, as Appendix A, a proposed list of terms, FDA prefers the list of terms maintained by the National Cancer Institute's NCI Thesaurus and would like to refer to the NCI Thesaurus in the final guidance. For more information about the NCI Thesaurus, please go to http://www.cancer.gov/cancertopics/terminologyresources/page2. FDA invites comments regarding which list of terms (Appendix A or the NCI Thesaurus) would be the best choice to further the goals set forth in this revised draft guidance. Since Appendix A was included in the revised draft guidance for discussion purposes only, it has not yet been formally considered within the VICH process. FDA expects that the list of terms included in Appendix A will be discussed by a Task Force chosen from the members of the VICH Pharmacovigilance Expert Working Group.

APPENDIX B

PROPOSAL FOR MAINTENANCE OF CONTROLLED LISTS

Recommendations

1. Maintenance & Technical Change Committee

Composed of VICH members – two per region (one from RA and one from Industry)
Meetings – one per year (estimated two per year). The meeting should take place by virtual means, for example, e-mail, e-room, or conference call.

One member acts as secretariat (rotates on a biannual basis).

2. RESOURCES

Updated once per year.
Freely available on regional RA website.

Resources Recommended

Item	Estimated man-hours/year
Member of Maintenance & Technical Change Committee	20
Secretariat	20
Annual update of controlled lists of terms	8
Putting updated version on website	2

On top of this estimate, there will be a once only resource of 35 man-hours (estimated) for development of a specific website.