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

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Guidance for Industry

Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms

VICH GL30

DRAFT GUIDANCE

This document is being distributed for comment purposes only

This draft guidance addresses the process for developing a controlled list of terminology in order to assure that terms are used consistently in adverse event reports, and to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. 02D-0005.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: CONTROLLED LIST OF TERMS

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.

Pharmacovigilance of Veterinary Medicinal Products:
Controlled List of Terms

This draft guidance represents the agency's current thinking and does not create or confer any rights for or on any person and does not operate to bind FDA or the public.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 the applicable statutes and regulations.

INTRODUCTION:

Use of a controlled list of terminology is important in order to assure that terms are used consistently, as well as to allow comparison between products and across product classes. The controlled lists of terms should have standardized groupings of terms, and these lists should be limited to a manageable size, taking into account the practical realities of the animal health industry and meaningful trending parameters. Moreover, industry and government should partner together in the development, implementation, and ongoing maintenance necessary to keep an adverse event terminology up to date and useful. A joint industry and government oversight board could best meet these needs.

SCOPE:

This guidance will be limited to terminology describing veterinary medicinal products (VMPs), animals, clinical signs, and associated body systems and organs for reporting an adverse event associated with the use of a VMP.

RECOMMENDATIONS:

The controlled lists of terms should be of sufficient size to allow a reasonable sorting of reports by standardized grouping of terms, yet should not be of such size and complexity as to make it difficult to manage or use. An anticipated limit of terms would provide a level of granularity sufficient to record, search and categorize for trending.

The management of the controlled lists of terms should be of a structure and have processes to guarantee the viability of the controlled lists of terms through stringent change control and distribution processes.

A viable funding model should be developed that should ensure accessibility and implementation by even the smallest Marketing Authorization Holder (MAH) and all Regulatory Authority (RA).

BACKGROUND:

The possibility of developing VICH Pharmacovigilance controlled lists of terms is a task that is beyond the resources of our working group[1]. We are clearly directed in our charge to explore existing dictionaries for applicability. Several dictionaries currently exist that might have application to the Veterinary Pharmacovigilance System, for example, MedDRA[2], SnoMED[3], and VEDDRA[4]. VEDDRA

[1] Working Group (VICH Expert Working Group) - A group of individuals with recognized technical expertise appointed by the VICH to develop draft recommendations within their field for the purpose of harmonizing regulatory requirements within the EU, USA and Japan for veterinary medicinal products. The VICH Pharmacovigilance Working Group developed this guidance.

[2] MedDRA (Medical Dictionary for Drug Regulatory Activities)- Standard terminology developed as a clinically-validated medical terminology for regulatory authorities and

has been developed for a veterinary application and is targeted for pharmacovigilance. It is the current selection of the EMEA[5] as indicated in their guidance document. While VEDDRA shows the greatest promise, there are several issues that should be resolved for it to meet the recommendations.

The administrative process and maintenance procedures for VEDDRA are not yet fully defined. This in itself should be viewed as a positive opportunity. It allows for consideration and negotiations of all interested parties which should be strongly encouraged. While it has not been heavily used, it does provide an adequate number of terms and organization, sufficient to establish a base from which to further develop it within the guidances of Pharmacovigilance rather than attempting to adapt a controlled list of terms organized for other purposes.

RECOMMENDATIONS:

1) Implement the use of VEDDRA as the basis for post-approval clinical pharmacovigilance data. Submissions to RA of Adverse clinical manifestations (GL24 B.3.5) should use the "preferred term(s)" from VEDDRA in English for paper documents or numeric codes for electronic documents.

2) Create a Maintenance and Technical Change Committee reflecting VICH representation. This committee should control the modification of the controlled lists of terms after the nominated changes have been reviewed. Controlling the modifications to a very deliberately limited number should minimize the overhead costs associated with changes, distribution and maintenance. It should not be so restrictive however as to render the listing ineffective. Numeric codes for the preferred terms in the controlled list of terms should be developed and implemented in order to facilitate electronic submission.

3) The controlled lists of terms should be distributed to all parties via website(s).

4) In the interest of promoting wide use, it is essential that the cost be kept to a minimum and shared among all parties.

5) In order to minimize maintenance, a test program of defined duration should be conducted to ensure an adequate number of terms prior to widespread distribution.

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the regulated pharmaceutical industry under the auspices of ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use).

[3] SNOMED (Systematized Nomenclature of Medicine)- Developed under the auspices of the College of American Pathologists it is a standard, comprehensive, multiaxial, controlled terminology created for the indexing of the entire medical record.

[4] VEDDRA (Veterinary Medicinal Dictionary for Drug Regulatory Authorities)- The list of clinical terms/terminology for suspect adverse reactions to veterinary medicines in animals proposed for regulatory use in the European Union and published by EMEA for comment. If accepted for international use by VICH it will ultimately be the veterinary equivalent of MedDRA.

[5] EMEA (The European Agency for the Evaluation of Medicinal Products, Veterinary Medicines and Inspections) - The European Commission Agency within the Enterprise Directorate General that is responsible for centralized approval and monitoring of human and veterinary drugs.

6) The following categories of controlled lists of terms as referred to in GL 24 should be developed and managed:
   a) A.3.3 Primary reporter category
   b) A.4.2 AER submission status
   c) A.4.5 Type of submission
   d) B.1.3 Species (combining US, EU, Japanese existing lists)
   e) B.1.4 Breed (combining US, EU, Japanese existing lists)
   f) B.1.5 Production type
   g) B.1.6 Sex
   h) B.1.8.c Exact, Approximate, Unknown Weight
   i) B.1.9.d Exact, Approximate, Unknown Age
   j) B.2.8 Route of Exposure
   k) B.2.10 Interval of Administration
   l) B.2.13 Who administered the VMP
   m) B.2.14 Use according to label
   n) B.3.6 Treatment of AE
   o) B.3.7 Relevant medical history
   p) B.4.1 Previous exposure to the primarily suspect VMP(s)
   q) B.4.2 Previous AE with the primarily suspect VMP(s)
   r) B.4.3 Did AE abate after stopping the primarily suspect VMP(s)
   s) B.4.4 Did AE reappear after re-introduction of the primarily suspect VMP(s)
   t) B.5.1 Attending Veterinarian's assessment
   u) B.5.2 MAH assessment