

#143

Guidance for Industry

Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms

VICH GL30

Submit comments on this guidance at any time. Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All written comments should be identified with the Docket No. FDA-2002-D-0268 (formerly Docket No. 2002D-0005).

For further information regarding this document, contact the Division of Veterinary Product Safety (HFV-240), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, Email: CVMAESupport@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/cm123602.htm> or <http://www.regulations.gov>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
October 2014**

Contains Non-Binding Recommendations

VICH GL30 (PHARMACOVIGILANCE: LIST OF TERMS)

June 2010

For Implementation at Step 7

PHARMACOVIGILANCE OF
VETERINARY MEDICINAL PRODUCTS:
CONTROLLED LIST OF TERMS



Recommended for Implementation
at Step 7 of the VICH Process
by the VICH Steering Committee
in June 2010
for implementation by December 2015

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 is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: Controlled Lists of Terms¹

This guidance represents the Food and Drug Administration's (FDA or Agency) 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 using the contact information on the title page of this guidance.

I. INTRODUCTION

To assess the safety and efficacy of veterinary medicinal products, the use of controlled lists of terms is important in order to assure consistency, as well as to provide for comparison between products and across product classes. The data fields that warrant controlled lists of terms have been identified in FDA's Guidance for Industry (GFI) #188, "Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine [(CVM)]" (FDACVM GFI#188) available on the FDA website at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM213153.pdf>.

Regulatory authorities (RA) and industry have partnered in the development of the lists and of an appropriate maintenance procedure (through the ad-hoc Controlled Lists of Terms Implementation Task Force from June 2008 to February 2009). The lists have been developed by making use of existing lists from RA and industry.

The controlled lists of terms provide a level of discrimination appropriate to record, search and categorize for trending. The lists have recommended groupings of terms of a manageable size but with sufficient detail to provide for uniform input and analysis. The controlled lists are accessible via the FDA website at <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportProblem/ucm212682.htm>. For the data fields that use controlled lists of terms, user systems can, to facilitate reporting or inputting, use a subset of terms listed in this guidance that are considered relevant to the region and to the products involved. However, when receiving reports electronically that are compliant with the relevant VICH guidances, all systems should be capable of importing and storing the full report, including all terms and codes, without loss of information.

¹ This title harmonizes this guidance, to the extent consistent with FDA regulations, with the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidance document, "Pharmacovigilance of Veterinary Medicinal Products Controlled Lists of Terms" (VICH GL30), but identifies it as having some FDA-specific applications.

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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 on the controlled lists of terms critical to completing the controlled data fields as identified in FDACVM GFI#188. This document includes also an appropriate maintenance procedure to keep the lists of terms up to date.

III. SPECIFICATIONS

III.1. List of Terms (see Annex A)

The lists should be updated in line with the maintenance procedure described in section III.2.

The controlled lists of terms as referred to in the data elements in FDACVM GFI#188 should be used for submission of adverse event reports. The lists include:

- a. Reporter Categories (FDACVM GFI#188 A.3.1.1 and A.3.2.1)**
- b. RA Identifier Codes (FDACVM GFI#188 A.4.1)**
- c. Type of Submission (FDACVM GFI#188 A.4.4.1)**
- d. Type of Information in Report (FDACVM GFI#188 A.4.4.3)**
- e. Attending Veterinarian's Health Status Assessment (FDACVM GFI#188 B.1.2.1)**
- f. Species (FDACVM GFI#188 B.1.3)**

The species list contains the predominant species or general collection of species terms that are being observed in adverse event reports by regulators and industry. The list accommodates data entry of commonly known terms and therefore does not follow taxonomy.

- g. Breeds (FDACVM GFI#188 B.1.4)**

The breed list contains commonly reported subspecies/breeds for the species identified in the Species list but also includes the special circumstances of:

- “other”: to provide for submission data for breeds that have not yet been included (e.g., “other rodent (other)”).

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- “unspecified”: to provide for identification of breed if the “general” breed could be identified but not the specific one (e.g., “Pointing dog – German (unspecified)” if it was not identified whether it was a shorthair or wire haired German pointing dog).
- “mixed”: to provide for the submission of cases that include a mix of different breeds for which it was not possible and/or not useful to identify the specific breeds of the group, e.g., “Mixed (cattle)”.

h. Gender (FDACVM GFI#188 B.1.5)

i. Reproductive Status (FDACVM GFI#188 B.1.6)

j. Female Physiological Status (FDACVM GFI#188 B.1.7)

k. Precision Categories (FDACVM GFI#188 B.1.8.1 and B.1.9.1)

l. RA Assessment (FDACVM GFI#188 B.2.1.6)

m. Route of Exposure (FDACVM GFI#188 B.2.1.7)

The VICH list that has been developed by the Controlled Lists of Terms Implementation Task Force is a comprehensive list that includes routes of exposure specific to veterinary medicinal products. At this stage however, in an interim phase, it is agreed to use a less detailed list that is in operation by the FDA.

This interim phase should end when the relevant International Route of Exposure list becomes available. This list is being developed in the frame of “*ISO prEN 11239 Health informatics — Identification of Medicinal Products — Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration*”. When the relevant ISO list contains the specific “veterinary” routes of exposure that are included in the VICH Route of Exposure list, the Maintenance Committee (see III.2.2) should verify and decide whether to replace the interim FDA list with the relevant ISO list.

n. Units of Presentation (FDACVM GFI#188 B.2.1.7.1.1.1, B.2.1.7.1.2.1 and B.2.2.1.2.1)

o. Units of Measurement (FDACVM GFI#188 B.1.9.2.1, B.1.9.3.1, B.2.1.7.1.1.1, B.2.1.7.1.2.1, B.2.1.7.1.3.1.1, B.2.2.1.1.1, B.2.2.1.2.1 and B.3.5.1.1)

p. Dosage Forms (FDACVM GFI#188 B.2.2.2)

The VICH list that has been developed by the Controlled Lists of Terms Implementation Task Force is a comprehensive list that includes dosage forms specific to veterinary medicinal products. At this stage however, in an interim phase, it is agreed to use a less detailed list that is in operation by the FDA.

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This interim phase should end when the relevant International Dosage Forms list becomes available. This list is being developed in the frame of “*ISO prEN 11239 Health informatics — Identification of Medicinal Products — Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration*”. When the relevant ISO list contains the specific “veterinary” dosage forms that are included in the VICH Dosage Forms list, the Maintenance Committee (see III.2.2) should verify and decide whether to replace the interim FDA list with the relevant ISO list.

q. Administrators of the VMP (FDACVM GFI#188 B.2.4)

r. Off-Label Use Coding System (FDACVM GFI#188 B.2.5.1)

The explanation for off-label use and its corresponding codes can be obtained by sequentially answering 9 questions about the species, route of administration, overdose, underdose, treatment regimen, indications, storage conditions, expiration and “any other”.

s. VeDDRA Terms (FDACVM GFI#188 B.3.2)

The Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) is the clinical dictionary to describe adverse clinical manifestations (FDACVM GFI#188 B.3.2 Adverse Clinical Manifestations). The list, as well as the full explanation and Guidance Notes on the Use of VeDDRA Terminology for Reporting Adverse Events in Animals, can be downloaded from the European Medicines Agency (EMA) Website:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&mid=WC0b01ac058002dea6.

t. Exposure and Onset Time (FDACVM GFI#188 B.3.4)

u. Attending Veterinarian’s Causality Assessment (FDACVM GFI#188 B.5.1.)

v. Document Types (FDACVM GFI#188 B.7.1.1)

w. Dose Denominator Qualifiers (FDACVM GFI#188 B.2.1.7.1.2.1)

x. Accuracy of No. of Animals (FDACVM GFI#188 B.3.2.1.1)

Lists Specific to FDACVM June 2013 Revision

aa. Attached Document Name (FDACVM GFI#188 B.7.1)

bb. ICSR Observation Locator Codes (FDACVM GFI#188 NA)

cc. Explanation for Linkage (FDACVM GFI#188 B.6.1.1)

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- A.36 ISO 3-Character Country Codes (FDACVM GFI#188 A.1, A.2.1, A.3.1, A.3.2, A.4.1, and B.2.1.2)**
- A.20 ATCvet Code – Information Only (FDACVM GFI#188 B.2.1.3)**
- A.35 US States & Territory Codes (US Only) (FDACVM GFI#188 A.1, A.2.1, A.3.1, and A.3.2)**
- A.5 Domestic and Foreign Report Categories (US Only) (FDACVM GFI#188 B.8.2.6)**
- A.26 Profile Identifier Code Vocabulary (US Only) (FDACVM GFI#188 B.8.2.7)**
- A.34 Report Identifier (US Only) (FDACVM GFI#188 B.8.2.5)**
- A.29 List of Package Types (US Only) (FDACVM GFI#188 B.2.6.3.1 and B.2.6.4.1)**
- A.42 National Drug Codes System (US Only) (FDACVM GFI#188 B.2.1.1)**
- A.38 Substance Registration System Active Ingredient Codes (US Only) (FDACVM GFI#188 B.2.2.1.3)**
- A.28 ORA District Field Offices (US Only) (FDACVM GFI#188 B.2.6.5)**
- A.43 FDA CVM Internal Product Problem/Medication Error Terms (US Only) (FDACVM GFI#188 B.3.2)**
- A.44 FDA CVM Internal Adverse Event Terms (US Only) (FDACVM GFI#188 B.3.2)**
- A.18 List of Manufacturer Site Identifiers (US Only) (FDACVM GFI#188 B.2.6.1.1)**

III.2. Maintenance

III.2.1. General Requirements

The lists should be periodically reviewed. Revisions of the lists do not require the revision of the guidance titled “Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data” (GFI#214), FDACVM GFI#188, or this guidance.

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The procedure for the yearly maintenance of VeDDRA is published on the EMA Website (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&mid=WC0b01ac058002dea6). The representatives of all VICH regions are formally invited to participate in the yearly meeting for the revision of VeDDRA.

FDACVM-specific lists may be revised independently by FDA CVM as needed.

III.2.2 Maintenance Committee

The maintenance of the Controlled List of Terms should take place annually in a meeting. In general, this meeting should take place by teleconference, web-conference and/or e-mail exchange. Face-to-face meetings can be considered if warranted. Ad-hoc meetings can be considered if urgent matters arise. The preparatory work should take place for each individual list by the lead regions (see Annex B). Implementation of the changes to the lists should be done within realistic time frames.

The meeting members should discuss and conclude by consensus on the proposals to revise the lists.

Revisions should be maintained consistent at least with the following principles,

- revisions should be made only when justified by rational scientific need,
- revisions should be made with strict version control and backward compatibility, and
- revisions should be consistent with technical requirements.

The revised lists should replace the Annexed Lists of this guidance and should be submitted for publication on the FDA CVM Website within 30 days of finalization.

FDACVM-specific lists may be revised independently by FDA CVM as needed.

ANNEX A - Standard Lists

As these lists are subject to yearly change, we direct you to the FDA CVM website for the most current versions of the lists.

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportProblem/ucm212682.htm>.

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**ANNEX B - GL30 – CONTROLLED LISTS OF TERMS MAINTENANCE
WORKSHARING – LEAD REGIONS**

LIST	GFI #188 REFERENCE	LEAD REGION
a. Reporter Categories	A.3.1.1 and A.3.2.1	USA (FDA/CVM)
b. RA Identifier Codes	A.4.1	USA (FDA/CVM)
c. Type of Submission	A.4.4.1	USA (FDA/CVM)
d. Type of Information in Report	A.4.4.3	USA (FDA/CVM)
e. Attending Veterinarian's Health Status Assessment	B.1.2.1	USA (FDA/CVM)
f. Species	B.1.3	EU (EMA)
g. Breeds	B.1.4	EU (EMA)
h. Gender	B.1.5	USA (FDA/CVM)
i. Reproductive Status	B.1.6	USA (FDA/CVM)
j. Female Physiological Status	B.1.7	USA (FDA/CVM)
k. Precision Categories	B.1.8.1 and B.1.9.1	USA (FDA/CVM)
l. RA Assessment	B.2.1.6	USA (FDA/CVM)
m. Route of Exposure	B.2.1.7	USA (FDA/CVM)
n. Units of Presentation	B.2.1.7.1.1.1 , B.2.1.7.1.2.1 and B.2.2.1.2.1	USA (FDA/CVM)
o. Units of Measurement	B.1.9.2.1, B.1.9.3.1, B.2.1.7.1.1.1, B.2.1.7.1.2.1, B.2.1.7.1.3.1.1, B.2.2.1.1.1, B.2.2.1.2.1 and B.3.5.1.1	USA (FDA/CVM)
p. Dosage Forms	B.2.2.2	CANADA - Veterinary Drugs Directorate
q. Administrators of the VMP	B.2.4	USA (FDA/CVM)
r. Off-Label Use Coding System	B.2.5.1	JAPAN (JMAFF)
s. VeDDRA Terms	B.3.2	EU (EMA)
t. Exposure and Onset Time	B.3.4	USA (FDA/CVM)
u. Attending Veterinarian's Causality Assessment	B.5.1	USA (FDA/CVM)
v. Document Types	B.7.1.1	USA (FDA/CVM)
w. Dose Denominator Qualifiers	B.2.1.7.1.2.1	USA (FDA/CVM)
x. Accuracy of No. of Animals	B.3.2.1.1	USA (FDA/CVM)

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Lists Specific to FDA CVM GFI#188 June 2013 Revision

LIST	GFI #188 REFERENCE	LEAD REGION
aa. Attached Document Name	B.7.1	USA (FDA/CVM)
bb. ICSR Observation Locator Codes	NA	USA (FDA/CVM)
cc. Explanation for Linkage	B.6.1.1	USA (FDA/CVM)
A.36 ISO 3-Character Country Codes	A.1, A.2.1, A.3.1, A.3.2, A.4.1, and B.2.1.2	USA (FDA/CVM)
A.20 ATCvet Code – Information Only	B.2.1.3	USA (FDA/CVM)
A.35 US States & Territory Codes (US Only)	A.1, A.2.1, A.3.1, and A.3.2	USA (FDA/CVM)
A.5 Domestic and Foreign Report Categories (US Only)	B.8.2.6	USA (FDA/CVM)
A.26 Profile Identifier Code Vocabulary (US Only)	B.8.2.7	USA (FDA/CVM)
A.34 Report Identifier (US Only)	B.8.2.5	USA (FDA/CVM)
A.29 List of Package Types (US Only)	B.2.6.3.1 and B.2.6.4.1	USA (FDA/CVM)
A.42 National Drug Codes System (US Only)	B.2.1.1	USA (FDA/CVM)
A.38 Substance Registration System Active Ingredient Codes (US Only)	B.2.2.1.3	USA (FDA/CVM)
A.28 ORA District Field Offices (US Only)	B.2.6.5	USA (FDA/CVM)
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A.18 List of Manufacturer Site Identifiers (US Only)	B.2.6.1.1	USA (FDA/CVM)