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VICH GL30 on pharmacovigilance of veterinary medicinal products: controlled list of terms

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VICH GL30 (PHARMACOVIGILANCE: LIST OF TERMS)
June 2010
For implementation at Step 7 - Final

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: CONTROLLED LIST OF TERMS

Adopted at Step 7 of the VICH Process
by the VICH Steering Committee
in June 2010
for implementation by 31st December 2015

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 allow comparison between products and across product classes. The data fields that require controlled lists of terms have been identified in VICH GL42 "Data Elements for Submission of Adverse Event Reports".

Regulatory authorities and industry have partnered in the development of the lists and a 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 regulatory authorities (RA) and industry.

The controlled lists of terms provide a level of discrimination sufficient to record, search and categorize for trending. The lists have standardized groupings of terms, of a manageable size but with sufficient detail to allow standardised input and analysis. The controlled lists are made accessible via the VICH Secretariat Website (http://www.vichsec.org/) and RA websites.

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 GL30 that are considered relevant to the region and to the products involved. However, when receiving reports electronically, that are compliant with the relevant VICH guidelines, all systems must be capable of importing and storing the full report, including all standard terms and codes, without loss of information.

II. SCOPE

This document provides guidance on the controlled lists of terms required to complete the controlled data fields as identified in GL 42. This document includes also the maintenance procedure to keep the lists of terms up to date.

III. SPECIFICATIONS

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

The lists will 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 GL 42 must be used for submission of adverse event reports. The lists are:

a. **Reporter Categories (GL42 A.3.1.1 and A.3.2.1)**

b. **RA (Regulatory Authorities) Identifier Codes (GL42 A.4.1)**

c. **Type of Submission (GL42 A.4.4.1)**

d. **Type of Information in Report (GL42 A.4.4.3)**

e. **Attending Veterinarian's Health Status Assessment (GL42 B.1.2.1)**

f. **Species. (GL42 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 (GL42 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 allow submission data for breeds that have not yet been included (e.g. "other rodent (other)").
    - "unspecified": to allow 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 allow 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 (GL42 B.1.5)

i. Reproductive Status (GL42 B.1.6)

j. Female Physiological Status (GL42 B.1.7)

k. Precision Categories (GL42 B.1.8.1 and B.1.9.1)

l. RA Assessment (GL42 B.2.1.6)

m. Route of Exposure (GL42 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 that are 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 that 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 to replace the interim FDA list by the relevant ISO list.

n. Units of Presentation (GL42 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 (GL42 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 (GL42 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 that are 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 dosage form list becomes available that 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 to replace the interim FDA list by the relevant ISO list.

q. Administrators of VMP (GL42 B.2.4)

r. Off-Label Use Coding System (GL42 B.2.5.1)

The explanation for off-label use and its corresponding codes are obtained by using a coding system that is based on sequentially answering a maximum of 8 questions related to the approved conditions for target species, route of administration, dose level, treatment regimen, indications, storage conditions, expiration and "any other". The file presents the possible outcomes to the questions and the corresponding codes. Code 120 for "various" should be used when an adverse event report contains a group of animals with different out of label conditions observed for different animals in the group.

s. VeDDRA Terms (GL42 B.3.2)

VeDDRA terminology for animal and human adverse events is the clinical dictionary to describe adverse clinical manifestations (GL 42). The list as well as the full explanation and a Guidance Notes on the Use of VeDDRA Terminology for Reporting adverse events in Animals can be downloaded from the EMA Website: http://www.ema.europa.eu/.

t. Exposure and Onset Time (GL42 B.3.4)

u. Attending Veterinarian's Causality Assessment (GL42 B.5.1.)

v. Document Types (GL42 B.7.1.1)

w. Dose Denominator Qualifiers (GL42 B.2.1.7.1.2.1)

x. Accuracy of No. of Animals (GL42 B.3.2.1.1)

III.2. Maintenance

III.2.1. General Requirements

The lists are periodically reviewed. The revisions of the lists do not require the revision of GL24, GL30, GL35 and GL42.

The procedure for the yearly maintenance of VeDDRA is published on the EMA Website (http://www.ema.europa.eu/). The representatives of all VICH regions are formally invited to participate in the yearly meeting for the revision of VeDDRA.

III.2.2 Maintenance Committee

The maintenance of the controlled List of Terms will 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 may be considered if needed. Ad-hoc meetings may be considered in addition, if urgent matters arise. The preparatory work will take place for each individual list by the lead regions (see Annex B). Implementation of the changes to the lists must be done within realistic time frames.

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

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

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

The revised lists will replace the Annexed lists of GL30 and will be submitted for publication on the VICH Website within 30 days of finalisation.

Annex A. Standard Lists

ANNEX B - GL 30 – CONTROLLED LISTS OF TERMS MAINTENANCE

WORKSHARING – LEAD REGIONS

	LIST	GL 42 REFERENCE	LEAD REGION
a.	Reporter Categories	A.3.1.1 and A.3.2.1	USA (FDA/CVM)
b.	RA (Regulatory Authorities) 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 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)