12 June 2025
EMA/CVMP/123352/2004 – Rev.15
Committee for Veterinary Medicinal Products

Call for comments on the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) standard list

Permanent call for comments on:

VeDDRA: Clinical terminology specifically developed for the electronic reporting of suspected adverse reactions (adverse events) in animals and humans to veterinary medicinal products.

Introduction

The Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) terminology for electronic reporting of adverse events to veterinary medicines allows systematic coding and analysis of reported adverse events. The use of the terminology necessitates continuous revision. This task is undertaken annually by consultation which involves the CVMP Pharmacovigilance Working Party (PhVWP-V), delegates from veterinary pharmaceutical industry and VICH partners.

Call for comments and timeline for annual revision

The VeDDRA standard list shall be revised annually considering the comments received during the consultation and in line with the principles outlined in this document. The aim is to make the revised terminology available by October of each year.

Proposals for consideration at the annual VeDDRA consultation should be submitted, using the template for submission of comments, to VEDDRAComments@ema.europa.eu by **14 February of each year**.

All proposals for VeDDRA should be substantiated by brief background text in the 'comments' column in the template. For example, including the number of adverse event reports received requiring a clinical sign that is not yet part of the VeDDRA list or for a new clinical syndrome etc.

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Principles underlying the VeDDRA standard list

In preparing comments for consideration for revision of the VeDDRA list it would be greatly appreciated if the following principles underlying the VeDDRA terminology were respected.

- VeDDRA has a four-level hierarchical structure, SOC – System Organ Class being the highest, followed by HLT – High Level Term, PT – Preferred Term and LLT – Low Level Term.
- The relation between SOC and LLT is mono-axial i.e. a specific LLT will only be available in one specific SOC. Where similar LLTs exist in other SOCs, an LLT may contain a cross-reference to the location of the other terms.
- To achieve medically relevant groupings for analysis of adverse events, the relation between PTs and LLTs covers two different concepts, allowing an LLT to be either a synonym or a sub-classification of a particular PT (Example: PT 'Anaphylaxis' includes the LLTs 'Anaphylaxis' and 'Anaphylactoid reaction').
- The convention is that SOC and HLT terminology should be plural, with PT and LLT being singular unless it does not make medical sense (Example - SOC: Cardio-vascular system disorders, HLT: Cardiac/heart disorders, PT and LLT: Cardiac disorder NOS).
- Any PT term must be available as LLT too.
- The use of 'NOS – not otherwise specified' should be limited to the minimum and ideally restricted to PT and LLT-level.
- Ideally VeDDRA should only contain terms that have actually been reported as adverse events.

Further details regarding the use of VeDDRA terminology are provided in the guidance notes available on the European Medicines Agency website.