EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

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

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 to EudraVigilance Veterinary (EVVet) allows systematic coding and analysis of reported adverse events. The use of the terminology necessitates continuous revision. This task is undertaken annually by the VeDDRA sub-group of the CVMP Pharmacovigilance Working Party (PhVWP-V) which includes delegates from veterinary pharmaceutical industry and also involves VICH partners.

Call for comments and timeline for annual revision

The VeDDRA standard list for EVVet shall be revised on an annual basis. The VeDDRA sub-group shall meet each year to revise the terminology in the light of comments received and in line with the principles outlined overleaf. The aim is to make a revised terminology available by September / October of each year.

Comments for consideration at the annual meeting of the VeDDRA sub-group should be received by **1 March of each year**, to be submitted by e-mail to **veddra@ema.europa.eu**, using the template for submission of comments.

It would facilitate the sub-group's consideration of proposals for VeDDRA by making best use of the 'comments' column in the template to include brief background text in support of your proposal. 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Principles underlying the VeDDRA standard list for EVVet

In preparing comments for consideration by the VeDDRA sub-group it would greatly facilitate the work of the group if the 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.
- In order 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 in 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 (EMA/CVMP/PhVWP/288284/2007) available on the European Medicines Agency website via the following hyperlink: http://www.ema.europa.eu/Regulatory/Veterinary Medicines/Pharmacovigilance/Eudravigilance.