EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Annual review of the VeDDRA list and associated documents		
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1. Purpose

The Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) is the standard terminology for electronic reporting of adverse events to veterinary medicinal products. This standard terminology enables systematic coding and analysis of reported adverse events and necessitates continuous revision. This task is undertaken annually following a consultation lead by the CVMP Pharmacovigilance Working Party (PhVWP-V), in accordance with their mandate, with the stakeholders/interested parties they deem appropriate, including delegates from the Federation of Veterinarians of Europe (FVE) and European Union (EU) veterinary pharmaceutical industry, in addition to VICH[1] representatives from industry and regulatory partners.

This document describes the steps taken to invite comments from national authorities and interested parties and subsequently update the VeDDRA list and associated documents, used in the electronic reporting of adverse events to veterinary medicinal products in the Union Pharmacovigilance Database, and referred to in VICH guideline GL30 on pharmacovigilance of veterinary medicinal products: controlled list of terms (EMA/CVMP/VICH/647/2001) and VICH GL42 on pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports (AERs) (EMA/CVMP/VICH/355996/2005).

2. Scope

This SOP applies to staff in the Veterinary Pharmacovigilance (V-SR-PHV) service of the Surveillance and Regulatory Support (V-SR) department.

[1] VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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3. Responsibilities

It is the responsibility of the Head of V-SR-PHV to ensure that this procedure is adhered to.

The roles responsible for each step are further detailed under section 9.

4. Changes since last revision

Revised to align with the updated process.

5. Documents needed for this SOP

- Permanent call for comments on the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) standard list for EudraVigilance Veterinary (EVV) (EMA/123352/2004); indicating the deadline for submission of comments to be considered during the annual review
- Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009)
- Non-current Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) low level terms (LLT) and codes (EMA/CVMP/PhVWP/360871/2010)
- Guidance notes on the use of Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) terminology for reporting suspected adverse events in animals and humans (EMA/CVMP/PhVWP/288284/2007)
- Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) dataload friendly file including deprecated terms (EMA/502060/2014)
- VICH GL30 on pharmacovigilance of veterinary medicinal products: controlled list of terms (EMA/CVMP/VICH/647/2001)
- VICH GL42 on pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports (AERs) (EMA/CVMP/VICH/355996/2005)

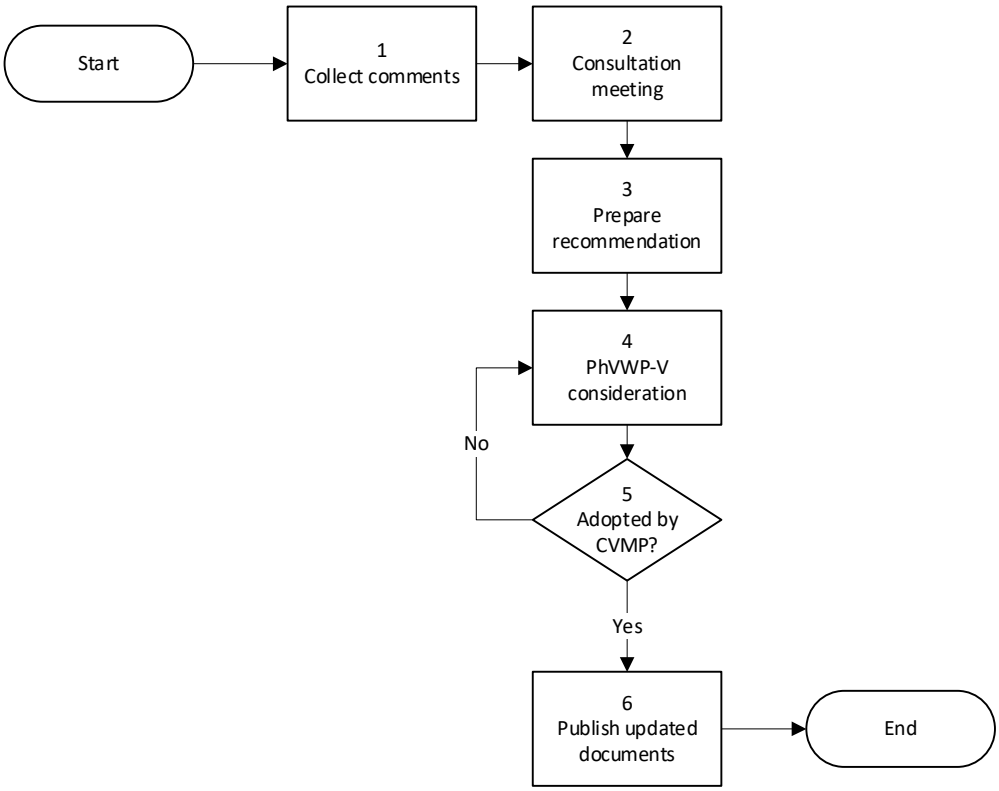
6. Related documents

- Toolkit – Checklist for annual VeDDRA review process (EMA/268702/2017)

7. Definitions

Call for comments	A document inviting submission of comments on the VeDDRA list
CVMP	Committee for Veterinary Medicinal Products
DREAM	Records management system at EMA
EMA	European Medicines Agency
ICT systems	Information and communication systems, here specifically the Union Pharmacovigilance Database and SPOR systems (ie. RMS, the referentials management system)
PC	Procedure Coordinator (in V-SR-PHV)
PhVWP-V	CVMP Pharmacovigilance Working Party
SL	Scientific Lead in V-SR-PHV
VeDDRA	Veterinary Dictionary for Drug Regulatory Affairs
VeDDRA consultation meeting	Dedicated consultation meeting organised by the CVMP Pharmacovigilance Working Party in liaison with stakeholders/interested parties consisting of nominated PhVWP-V experts, representatives from the Federation of Veterinarians of Europe (FVE), EU pharmaceutical industry and VICH partners
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
V-SR	Surveillance and Regulatory Support department in Veterinary Medicines division
V-SR-PHV	Veterinary Pharmacovigilance service in V-SR

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1	Collect and collate comments received by the annual deadline for submission, as specified in Call for Comments, and circulate to the VeDDRA consultation meeting participants.	SL
2	Facilitate the review and proposal of revisions to the VeDDRA list and associated documents at the VeDDRA consultation meeting. Prepare (updated) list of changes, if applicable.	SL
3	Following the consultation meeting, update the proposed revision of the VeDDRA list and associated documents, including the proposed list of changes for that year. Circulate the updated list to the VeDDRA consultation meeting participants.	SL PC
4	Circulate the updated VeDDRA list and associated documents to PhVWP-V for agreement. NB: The final agreed VeDDRA document(s) may be identical to the recommendations from the VeDDRA consultation meeting or may contain additional amendments agreed by PhVWP-V in consultation with international regulatory counterparts.	SL
5	Arrange for adoption of the updated VeDDRA list and associated documents by CVMP. *If adopted, go to step 6* *If not adopted, go to step 4* NB: The final adopted VeDDRA document(s) may be identical to the documents agreed by PhVWP-V or may contain additional amendments introduced by CVMP before adoption. Before the CVMP adopts the list, and if the list has been amended following step 4 above, then CVMP may decide to consult other regulatory partners, e.g. in case of major changes.	SL
6	Arrange for publication of updated VeDDRA list and associated documents in the pharmacovigilance area for veterinary medicines on the EMA public website (see *section 10* for location). Send the updated VeDDRA list to the VICH secretariat for publication on the VICH website. Arrange for implementation in relevant ICT systems by 1 October.	PC PC PC

10. Records

The adopted VeDDRA list and associated documents (including Call for comments, Excel®-versions and list of changes, guidance notes if applicable) are available on the EMA public website under https://www.ema.europa.eu/en/veterinary-regulatory-overview/post-authorisation-veterinary-medicines/pharmacovigilance-veterinary-medicines/eudravigilance-veterinary#veterinary-dictionary-for-drug-regulatory-activities-veddra-11398.

The electronic archive of the comments received and the versions of the VeDDRA list and associated documents, as well as related correspondence, shall be maintained in the relevant folders in DREAM: Cabinets/03. Pharmacovigilance/PhV - Veterinary/Pharmacovigilance guidance/VeDDRA.