EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Annual review of VeDDRA list to be used in EudraVigilance Veterinary		
Status: **PUBLIC**		Document no.: SOP/V/4019
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Signature: on file	Signature: on file	Supersedes: SOP/V/4019 (22-JUN-11)
Date: 13-MAY-15	Date: 12-MAY-15	TrackWise record no.: 4062

1. Purpose

This document describes the steps taken to invite comments from national competent authorities and interested parties and to subsequently update the Combined VeDDRA[1] list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (VMPs) used in the electronic reporting of adverse events to VMPs via EudraVigilance Veterinary (EVVet). The list shall be reviewed and updated annually.

2. Scope

This standard operating procedure (SOP) applies to the CVMP Pharmacovigilance Working Party secretariat being part of the Veterinary Medicines department (PhVWP-V secretariat), CVMP, CVMP Pharmacovigilance Working Party (PhVWP-V) and the VeDDRA Sub-Group (Sub-Group).

The target groups for the call for comments are the Member States national competent authorities and interested parties.

3. Responsibilities

It is the responsibility of the Head of the Animal and Public Health service to ensure that this procedure is adhered to.

[1] Veterinary Dictionary for Drug Regulatory Activities

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It is the responsibility of the pharmacovigilance scientific administrator (PhV SA) to initiate the call for comments, collect, collate and circulate the comments, arrange for required meetings and publish the outcome.

The roles responsible for each step are further detailed under *section 9*. The overall estimated time frame for this procedure is half a year.

4. Changes since last revision

- Exclusion of the List of species and breeds for electronic reporting of adverse reactions in veterinary pharmacovigilance (EMA/CVMP/553/2003) and List of additional controlled terminology for electronic submission of reports on adverse reactions to veterinary medicinal products (EMA/CVMP/556/04) from the scope of the annual review; Proposals for amendments to these lists are taken forward via the Consultative Group on Veterinary Pharmacovigilance Systems (formerly known as the EudraVigilance Veterinary Joint Implementation Group);
- Changes reflecting the restructuring of the division and the rebranding of the Agency;
- Update of deadline for submission of comments on VeDDRA;
- Inclusion of agreed deadline for implementation of the revised list in EudraVigilance Veterinary;
- Update of location of electronic archive for documents in DREAM.

5. Documents needed for this SOP

This SOP applies to the Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009) for use in EudraVigilance Veterinary.

The SOP applies to the following documents related to the VeDDRA review:

- Permanent call for comments on VeDDRA for EudraVigilance Veterinary (EMA/123352/2004);
- Non-current VeDDRA low level terms (LLT) and codes (EMA/360871/2010).

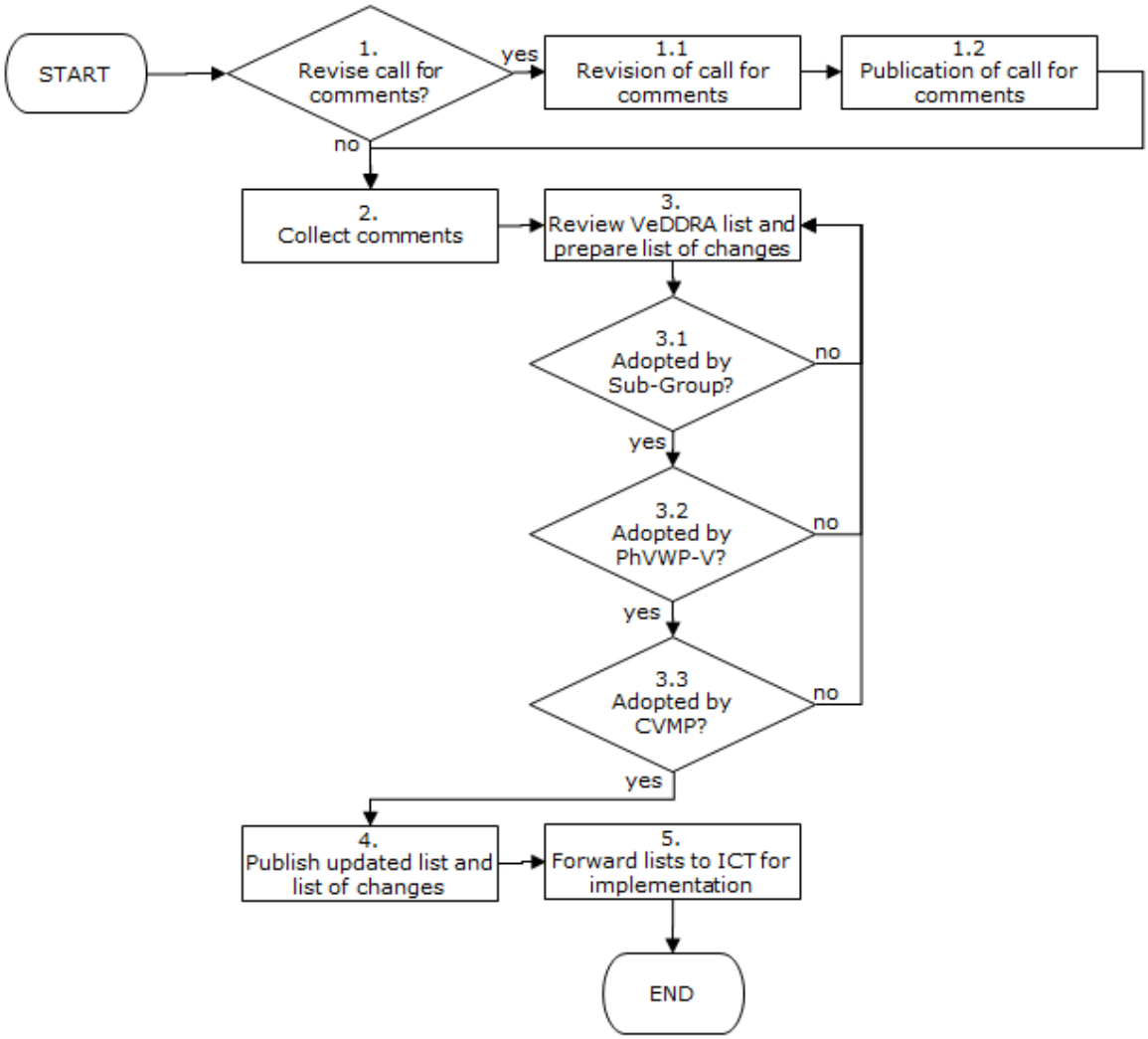
6. Related documents

- ATCvet: The Anatomical Therapeutic Chemical classification system for veterinary medicinal products, for the classification of substances intended for therapeutic use; developed and maintained by the WHO Collaborating Centre for Drug Statistics Methodology (www.whocc.no);
- The “Standard Terms on Pharmaceutical Dosage Forms, Routes of Administration and Containers”, as published by the Council of Europe, is used for the description of the pharmaceutical dosage forms.

7. Definitions

Call for comments	A document inviting submission of comments on the VeDDRA list used for EVVet
CVMP	Committee for Medicinal Products for Veterinary Use
EVVet	EudraVigilance Veterinary - The European data processing network and database management system for pharmacovigilance of veterinary medicinal products in the European Economic Area (EEA)
PhVWP-V	CVMP Pharmacovigilance Working Party
PhV SA	Scientific administrator in veterinary pharmacovigilance
VeDDRA	Veterinary Dictionary for Drug Regulatory Affairs
VeDDRA Sub-Group	Working group consisting of nominated experts from the CVMP Pharmacovigilance Working Party, representatives from the pharmaceutical industry and VICH partners

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



9. Procedure

Step	Action	Responsibility
1.0	Check whether call for comments needs revision. *If yes, go to step 1.1* *If no, go to step 2.0*	PhV SA
1.1	Revise 'Call for comments'.	PhV SA
1.2	Publish revised 'Call for comments' in the pharmacovigilance area (EVVet subheading) for veterinary medicines on the EMA public website. Proceed to 2.0	PhV SA
2.0	Collect and collate comments received by annual deadline, 1 March (of each year), as specified in call for comments, and circulate to the VeDDRA sub-group, copying the PhVWP-V.	PhV SA
3.0	*VeDDRA Sub-Group reviews and proposes revisions to the VeDDRA list at VeDDRA sub-group meeting.* Prepare list of changes and update non-current VeDDRA LLTs and codes list, if applicable.	PhV SA
3.1	*VeDDRA Sub-Group considers adoption of updated list (during meeting or by written procedure, as appropriate).* Did the VeDDRA Sub-Group adopt a (revised) list? If yes, go to 3.2 If no, go to 3.0	
3.2	*PhVWP-V considers adoption of proposals from VeDDRA sub-group.* Did PhVWP-V adopt the proposals? If yes, go to 3.3 If no, go to 3.0	
3.3	*CVMP considers adoption of proposals from PhVWP-V.* Did CVMP adopt the proposals? If yes, go to 4.0 If no, go to 3.0	
4.0	Publish updated lists (including excel-versions, list of changes and non-current VeDDRA LLTs and codes, if applicable) in the pharmacovigilance area (EVVet subheading) for veterinary medicines on the EMA public website.	PhV SA
5.0	Forward updated lists (including list of changes) to ICT for implementation in EVVet by 1 October.	PhV SA

10. Records

The adopted lists (including excel-versions and list of changes, if applicable) are available on the EMA public website under http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002dea6&jsenabled=true.

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