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Veterinary Medicines

## Summary of questions discussed and answers provided on VeDDRA<sup>1</sup> coding at the workshop held on 27 November 2013

This document summarises the questions discussed at the workshop on harmonising the approach to Veterinary Dictionary for Drug Related Affairs (VeDDRA) coding, that was held for regulators and industry at the European Medicines Agency, London on 27 November 2013. Some of the issues will be further considered at the annual VeDDRA sub-group meeting for 2014 and where possible incorporated into the guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.6).

### ***Selection of VeDDRA terms***

1. **When should a more common term be used rather than a more technical term, e.g. 'vomiting' versus 'emesis'?**

The term used by the reporter should be coded using VeDDRA low level terms. The lower level terms 'vomiting' and 'emesis' both code to the preferred term 'emesis'.

2. **When should the terms 'dull' compared with 'dullness' be coded?**

The term closest to that used by the reporter should be used, taking into account which system organ class (SOC) these terms sit under.

3. **When should the term 'unrelated death' be used when coding adverse event reports?**

The low level term 'unrelated death' should be used only when there is clear evidence that the death was not associated with the adverse reaction e.g. road accidents. It should not be used when the owner elected for euthanasia for financial reasons, in which case the 'death by euthanasia' should be used.

4. **What are the criteria for reporting a death as 'sudden death'?**

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<sup>1</sup> Veterinary dictionary for drug related affairs



'Sudden death' should be used when the fatality occurred unexpectedly e.g. without preceding clinical signs.

5. **Should the term 'diabetic ketonuria' be used when ketonuria was triggered by dietary regimen?**

It is advisable to use a low level term which appropriately describes the adverse event. If it is clear that ketonuria resulted from the dietary regime this would not be classified as an adverse reaction to a veterinary medicinal product.

6. **If haemolysis occurred before product administration, should the term 'immune mediated haemolytic anaemia' be coded?**

If the event occurred before administration of the product, the clinical signs should not be coded using VeDDRA.

7. **Coding results from diagnostic tests. How much detail should be coded using VeDDRA E.g. use of term abnormal test result/post-mortem findings or specific necropsy terms?**

There are a limited number of terms relating to diagnostic test results in VeDDRA. Where such a term is reported, it should be coded using the appropriate low level term. If such a term is not available in VeDDRA, 'abnormal test result' should be used for diagnostic test results.

8. **When should 'uncoded sign' be used?**

'Uncoded sign' should ONLY be used when there is no existing VeDDRA term to code the clinical sign observed. Further detail relating to the clinical sign should be explained in the narrative of the adverse event report. Where appropriate a proposal for a new VeDDRA term should be submitted to the VeDDRA sub-group for consideration at their next annual review using the templates available in the call for comments.

### ***Approach to coding***

9. **Should the terms related to the disease which the treatment leading to the adverse event was intended for be coded because it is sometimes difficult to clearly attribute signs to the pre-existing disease and to the adverse event?**

It is important to review the history of the adverse event report thoroughly before coding the clinical signs using VeDDRA. It is preferable not to code signs relating to the disease which the product is intended to treat. If the product is being administered prophylactically (i.e. for prevention of a condition) the VeDDRA term lack of efficacy should be coded but not the clinical signs. However if the report history is unclear and no further information is available from the reporter or if in doubt, the clinical signs observed should also be coded but subsequently taken into account when analysing adverse event data.

10. **Should VeDDRA terms be added again if the event recurs on re-challenge?**

It is preferable to avoid coding the same or similar clinical signs multiple times, unless the low level terms relate to different preferred terms as this may impact on subsequent analysis. Information on signs observed after re-challenge is however useful for determining the causal association with the veterinary medicinal product administered.

**11. Is it appropriate or advantageous to add clinical signs to lack of expected efficacy events?**

If the event clearly relates to lack of expected efficacy, the term 'lack of efficacy' should be used. For any reports resulting in fatalities, 'death' should also be coded. However, if the report describes both clinical signs and lack of expected efficacy or if in doubt, all the terms reported should be coded using VeDDRA.

**12. How should the new pathological/necropsy terms be handled? E.g. does event date = necropsy date? Are there differences in the approach to evaluation of pathological and clinical terms?**

The new 'necropsy terms' (NT) added to VeDDRA in 2013 should be used if described by the reporter. It should be noted that the date of the adverse event refers to when the adverse reaction was observed and not to the date of necropsy. All VeDDRA terms should be evaluated in the same way, regardless of whether they are necropsy terms or clinical signs following the adverse reaction.

## References

1. Committee for Medicinal Products for Veterinary Use (CVMP) (2013) Call for comments on standard lists for EudraVigilance Veterinary (EVVet) (EMA/123352/2004 – Rev.7)  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000173.jsp&mid=WC0b01ac058002dea6](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&mid=WC0b01ac058002dea6)
2. Committee for Medicinal Products for Veterinary Use (CVMP) (2013) Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009-Rev.5)  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000173.jsp&mid=WC0b01ac058002dea6](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&mid=WC0b01ac058002dea6)
3. Committee for Medicinal Products for Veterinary Use (CVMP) (2013) Guidance notes on the use of Veterinary Dictionary for Drug Related Affairs terminology for reporting suspected adverse reactions in animals and humans (EMA/CVMP/PhVWP/288284/2007-Rev.6)  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\\_listing/document\\_listing\\_000173.jsp&mid=WC0b01ac058002dea6](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&mid=WC0b01ac058002dea6)