EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 February 2014
EMA/500544/2012
Veterinary Medicines

Workshop: harmonising the approach to VeDDRA[1] coding

27 November 2013, 12.00-15.00, Room 2D, European Medicines Agency, London

Chair: G. Davis (Chair of VeDDRA sub-group)

Workshop objective(s): To gain hands on experience using VeDDRA to code adverse event reports and to strengthen the harmonised approach for use of VeDDRA coding terminology

Item			Duration	Time
1.	Welcome and objectives of workshop incl. health and safety announcement	Chair/M. Leivers (European Medicines Agency)	5 mins	1200-1205
2.	Introduction: Best practices in VeDDRA coding (EMA/711996/2013)	Presentation (Chair)	15 mins	1205-1220
3.	Overview of process for VeDDRA revision (EMA/717828/2013)	Presentation (R. Gopal; EMA)	5 mins	1220-1225
4.	Case studies Introduction (EMA/489659/2013) Case studies and suggested answers (EMA/476984/2013) Participants will be allocated to groups of 5-6 people. Each group will work through 4-6 case studies. Groups will be assigned different case studies. Facilitators will be available to provide guidance/prompting as required.	Group-work (All)	65 mins	1225-1330
5.	*Break*		20 mins	1330-1350

[1] Veterinary dictionary for drug related affairs

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Item			Duration	Time
6.	Round up from case studies Facilitators will report on selected case study examples or issues arising during the group discussions	Plenary discussion (Facilitators)	30 mins	1350-1420
7.	Discussion/question and answer session based on topics submitted in advance (EMA/702567/2013; EMA/804163/2013)	Plenary discussion (All)	35 mins	1420-1455
8.	Summary and close	Chair	5 mins	1455-1500

Documents for information:

- 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)
- Non-current VeDDRA low level terms (LLT) and codes (EMA/360871/2010-Rev.1)
- 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)
- Call for comments on standard lists for EudraVigilance Veterinary (EVVet) (EMA/123352/2004 – Rev.7)
- Standard operating procedure for annual review of standard lists to be used in EudraVigilance Veterinary (SOP/V/4019)
- List of participants (EMA/631896/2013-Rev.1)
- Health and safety presentation (EMA/714088/2013)