



24 June 2023
EMA/CVMP/PhVWP/218994/2023
Committee for Veterinary Medicinal Products

List of changes to combined VeDDRA list of clinical terms

For reporting suspected adverse events in animal and humans to veterinary medicinal products for 2023

Change number	Current System Organ Class (SOC) Term	Current SOC Key	New SOC Term	New SOC Key	Current High Level Term (HLT)	Current HLT Key	New HLT Term	New HLT Key	Current Preferred Term (PT)	Current PT Key	New PT Term	New PT Key	Current Low Level Term (LLT)	Current LLT Key	New LLT	New LLT Key	Current Term Type ¹	New Term Type ¹	Action ²
1	Application site disorders	1			Application site reactions	1					Application site skin slough	3045			Application site skin slough	3046		C	A

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2	Application site disorders	1			Application site reactions	1			Application site self-trauma	18	Application site reaction NOS	16	Licking at application site	1973			A		M
3	Application site disorders	1			Application site reactions	1					Application site purulent discharge	3047			Application site purulent discharge	3048		C	A
4	Application site disorders	1			Application site reactions	1					Application site purulent discharge	3047			Application site pus	3049		C	A
5	Application site disorders	1			Application site reactions	1					Application site discharge NOS	3050			Application site discharge	3051		C	A
6	Application site disorders	1			Injection site reactions	3			Injection site pain	56	Injection site reaction NOS	59	Licking at injection site	2752			A		M
7	Application site disorders	1			Injection site reactions	3			Injection site self-trauma	61					Biting at injection site	3052		A	A

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8	Application site disorders	1			Injection site reactions	3			Injection site self-trauma	61					Chewing at injection site	3053		A	A
9	Application site disorders	1			Injection site reactions	3					Injection site discharge NOS	3054			Injection site discharge NOS	3056		C	A
10	Application site disorders	1			Injection site reactions	3					Injection site cyst	3055			Injection site cyst	3057		C	A
11	Behavioural disorders	2					Bird behavioural disorders	3058			Pecking	3059			Pecking	3060		A	A
12	Behavioural disorders	2			Other behavioural disorders	6			Anxiety	70					Easily startled	3061		C	A
13	Behavioural disorders	2			Other behavioural disorders	6			Anxiety	70					Fear/fearful	3062		C	A

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14	Behavioural disorders	2			Other behavioural disorders	6			Anxiety	70					Nervous	3063		C	A
15	Behavioural disorders	2			Other behavioural disorders	6			Behavioural disorder NOS	71					Disinterested	3064		C	A
16	Cardio-vascular system disorders	4			Circulatory disorders	24			Peripheral vascular disorder	833					Telangiectasia	3065		C	A
17	Digestive tract disorders	5			Other digestive tract disorders	35			Digestive tract disorder NOS	187					Not defecating	3066		C	A
18	Behavioural disorders	2			Other behavioural disorders	6					Behavioural disorder NOS	71			Aerophagia	3068		C	A
19	Digestive tract disorders	5			Other digestive tract disorders	35			Diarrhoea	186					Soft stool	3069	C		A

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20	Digestive tract disorders	5			Other digestive tract disorders	35			Digestive tract haemorrhage NOS	188	Haematochezia	1163	Blood in faeces NOS	1081	Blood in faeces		C		M
21	Digestive tract disorders	5			Other digestive tract disorders	35			Gastroenteritis	194					Gastrointestinal irritation	3070		C	A
22	Digestive tract disorders	5			Other digestive tract disorders	35			Haematochezia	1163					Bloody stool	3071		C	A
23	Digestive tract disorders	5			Pancreas disorders	37			Pancreatitis	880					Acute pancreatitis	3072		C	A
24	Digestive tract disorders	5			Pancreas disorders	37			Pancreatitis	880			Pancreatitis	1891	Pancreatitis NOS		C		M
25	Digestive tract disorders	5			Stomach disorders	38			Emesis	211					Vomiting foam	3073		C	A

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26	Digestive tract disorders	5			Stomach disorders	38			Retching	217					Dry heaving	3074		C	A
27	Endocrine system disorders	7			Adrenal gland disorders	45			Hypoadrenocorticism	237					Addisonian crisis	3075		C	A
28	Endocrine system disorders	7			Adrenal gland disorders	45					Adrenal necrosis	3076			Adrenal necrosis	3077		C	A
29	Endocrine system disorders	7			Thyroid gland disorders	51			Thyroiditis	867	Thyroiditis		Thyroiditis	1839	Thyroiditis		C		M
30	Immune system disorders	10			Autoimmune disorders	70					Immune mediated encephalitis	3078			Immune mediated encephalitis	3079		C	A
31	Immune system disorders	10			Autoimmune disorders	70					Immune mediated meningitis	3080			Immune mediated meningitis	3081		C	A

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32	Immune system disorders	10			Autoimmune disorders	70					Immune mediated myelitis	3082			Immune mediated myelitis	3083		C	A	
33	Immune system disorders	10			Autoimmune disorders	70					Immune mediated polymyositis	3084			Immune mediated polymyositis	3085		C	A	
34	Immune system disorders	10			Bursal disorders	71					Bursa of Fabricius lymphocyte depletion	3086			Bursa of Fabricius lymphocyte depletion	3087		A	A	
35	Investigation	34			Red blood cell investigations	249					Elevated haemoglobin	3088			Elevated haemoglobin	3089		C	A	
36	Investigations	34			Hepatobiliary investigations	258			Elevated liver enzymes	1052			Elevated liver enzymes	1942	Elevated liver enzymes NOS			C		M
37	Investigations	34			Hepatobiliary investigations	258			Low liver enzymes	1115			Low liver enzymes	2689	Low liver enzymes NOS			C		M

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38	Investigations	34			Investigations NOS	259			Elevated serum alkaline phosphatase (SAP)	1100	Elevated serum alkaline phosphatase (ALP)		Elevated serum alkaline phosphatase (SAP)	2055	Elevated serum alkaline phosphatase (ALP)		C		M
39	Investigations	34			Investigations NOS	259			Low serum alkaline phosphatase (SAP)	1116	Low serum alkaline phosphatase (ALP)		Low serum alkaline phosphatase (SAP)	2690	Low serum alkaline phosphatase (ALP)		C		M
40	Investigations	34			Red blood cell investigations	249			Disorder of red blood cell NOS	745					Decreased mean corpuscular haemoglobin concentration (MCHC)	3090		C	A
41	Investigations	34			Red blood cell investigations	249			Disorder of red blood cell NOS	745					Elevated mean corpuscular haemoglobin concentration (MCHC)	3091		C	A
42	Investigations	34			Renal and urinary investigations	262					Porphyrinuria	3092			Porphyrinuria	3093		C	A
43	Investigations	34			Renal and urinary investigations	262			Urine abnormalities NOS	907					Abnormal urine cortisol:creatinine ratio (UCCR)	3094		C	A

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44	Mammary gland disorders	11			Mammary gland disorders	74					Mammary gland enlargement	3095			Mammary hypertrophy	3096		C	A
45	Mammary gland disorders	11			Mammary gland disorders	74					Mammary gland enlargement	3095			Mammary gland enlargement	3097		C	A
46	Mammary gland disorders	11			Milk production disorders	76					High somatic cell count	3098			High somatic cell count	3099		A	A
47	Application site disorders	1	Medication and product use errors	20	Injection site reactions	3	Administration errors and issues	3020	Puncture wound	1108	Needlestick injury		Puncture wound	2672	Needlestick injury			C	M
48	Medication and product use errors	20			Device use issues	3023			Device use issues NOS	3031					Accidental device injury	3100		C	A
49	Musculoskeletal disorders	13			Jaw disorders	87			Jaw disorder	368					Clenched jaw	3101		C	A

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50	Musculoskeletal disorders	13			Metabolic bone disorders	88					Osteoporosis	3102			Osteoporosis	3103		C	A
51	Musculoskeletal disorders	13			Musculoskeletal disorders	90			Musculoskeletal disorder NOS	640					Spinal pain NOS	3104		C	A
52	Neoplasia	2913			Nervous system neoplasms	100			Nervous system neoplasm	406					Brain tumour	3105		C	A
53	Neurological disorders	14			Convulsions and epilepsy	97			Convulsion	397					Post ictal state	3106		C	A
54	Neurological disorders	14			Impaired consciousness	99			Impaired consciousness	663					Obtunded	3108		C	A
55	Neurological disorders	14			Mental impairment	217			Disorientation	401					Dazed	3109		C	A

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56	Neurological disorders	14			Central nervous system disorders	94			Head tremor	1183					Head twitching	3110		C	A
57	Other event	33			Other event	243					Parent-offspring event	3111			Parent-offspring event	3112		A	A
58	Other event	33			Other event	243					Parent-offspring event	3111			Father and offspring event	3113		A	A
59	Other event	33			Other event	243					Parent-offspring event	3111			Mother and offspring event	3114		A	A
60	Other event	33			Other event	243					Parent-offspring event	3111			Offspring only event	3115		A	A
61	Renal and urinary disorders	15			Urinary bladder disorders	109			Urinary incontinence	436					Involuntary urination	3116		C	A

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62	Respiratory tract disorders	17			Tracheal and laryngeal disorders	137					Upper respiratory sounds	3117			Stertor	3118		C	A
63	Respiratory tract disorders	17			Tracheal and laryngeal disorders	137					Upper respiratory sounds	3117			Upper respiratory sounds	3119		C	A
64	Respiratory tract disorders	17			Bronchial and lung disorders	132			Atelectasis	991					Bronchiectasis	3120		C	A
65	Respiratory tract disorders	17			Bronchial and lung disorders	132					Lung nodule NOS	3121			Lung nodule NOS	3122		C	A
66	Respiratory tract disorders	17			Respiratory tract disorders	138			Cough	532					Cough, hacking	3123		C	A
67	Skin and appendages disorders	18					Bird skin disorders	3124			Feather loss	3125			Feather loss	3126		A	A

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68	Skin and appendages disorders	18			Epidermal and dermal disorders	237			Dermal thickening	564					Skin induration	3127		C	A
69	Skin and appendages disorders	18			Epidermal and dermal disorders	237			Desquamation	568			Skin slough	943	Generalised skin slough		C		M
70	Skin and appendages disorders	18			Epidermal and dermal disorders	237			Desquamation	568					Local skin slough	3128		C	A
71	Skin and appendages disorders	18			Epidermal and dermal disorders	237			Erythema	570					Local erythema	3129		C	A
72	Systemic disorders	19			General signs or symptoms	154			Abnormal posture NOS	644					Abnormal tail posture	3107		A	A
73	Systemic disorders	19			General signs or symptoms	154			Polydipsia	339					Increased drinking	3130		C	A

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74	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614			Lack of efficacy (bacteria) - Anaplasma NOS	2991	Lack of efficacy (bacteria) - Anaplasma	2990	A		M, D (re-map to 2990)
75	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614			Lack of efficacy (bacteria) - Borrelia NOS	2992	Lack of efficacy (bacteria) - Borrelia	3013	A		M, D (re-map to 3013)
76	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614					Lack of efficacy (bacteria) - Actinobacillus pleuropneumoniae (APP)	3131		A	A
77	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614					Lack of efficacy (bacteria) - Erysipelothrix rhusiopathiae	3132		A	A
78	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614					Lack of efficacy (bacteria) - Rickettsia	3133		A	A
79	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614					Lack of efficacy (protozoa) - Cytauxzoon felis	3134		A	A

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80	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614					Lack of efficacy (virus) - rabies (low titre)	3135		A	A
81	Systemic disorders	19			Lack of efficacy	155			Lack of efficacy	614					Lack of efficacy (virus) - Arterivirus (for PRRS)	3136		A	A
82	Systemic disorders	19			Systemic disorders NOS	158			Generalised congestion NOS	3067					Generalised congestion NOS	3137		C	A
83	Systemic disorders	19			Systemic disorders NOS	158					Organ atrophy NOS	3138			Organ atrophy NOS	3139		C	A

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