



European Medicines Agency
Veterinary Medicines and Inspections

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<p>COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)</p>
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<p>LIST ON ADDITIONAL CONTROLLED TERMINOLOGY FOR ELECTRONIC SUBMISSION OF REPORTS ON ADVERSE REACTIONS TO VETERINARY MEDICINAL PRODUCTS</p>
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ADDITIONAL CONTROLLED TERMINOLOGY FOR ELECTRONIC SUBMISSION OF REPORTS ON ADVERSE REACTIONS TO VETERINARY MEDICINAL PRODUCTS

1. INTRODUCTION

The CVMP guideline on data elements for the electronic submission of adverse reaction reports related to veterinary medicinal products authorised in the European Economic Area (EEA) including message and transmission specifications (EMEA/CVMP/065/03 in its latest revision) not only sets out the data elements that may be submitted electronically, but for a number of these data elements it specifies that the data should be submitted using controlled terminology or vocabulary.

The guideline EMEA/CVMP/065/03 sets out for which fields controlled terminology is required. For a number of these fields this guideline also defines the acceptable values. For other fields the reference '*under development by the PhVWP*' or '*to be defined*' is made. Of these, the List of Animal species and breeds for electronic reporting (EMEA/CVMP/553/03) was adopted by CVMP and published on the EMEA website (April 2004), to be revised on a regular basis.

The additional controlled terminology is set out in this list - originally developed as a guideline under the same document reference number - with the exception of controlled terminology for necropsy results that remains to be developed. This list is revised on a regular basis.

A. LIST OF HEALTH STATE

1	Good
2	Fair
3	Poor
4	Critical
5	Unknown

B. LIST OF OFF-LABEL USE

1	Unauthorised species/species sub group
2	Unauthorised indication
3	Unauthorised dosage – dose too high
4	Unauthorised dosage – dose too low
5	Unauthorised dosage – administration too frequent
6	Unauthorised dosage – administration not frequent enough
7	Unauthorised dosage – other
8	Unauthorised route of administration
9	Unauthorised storage conditions
10	Expired products
11	Other
12	Multiple

C. LIST OF TEST RESULTS

1	Within normal range
2	Higher than normal range
3	Lower than normal range
4	Other abnormal findings
5	Positive (test parameter present)
6	Negative (test parameter absent)
7	Other result

D. LIST OF EXPOSURE REASON LIST (REASON FOR HUMAN EXPOSURE)

1	Accidental (unintended) exposure	Ingestion
2	Accidental (unintended) exposure	Topical exposure
3	Accidental (unintended) exposure	Injection
4	Accidental (unintended) exposure	Airborne exposure/Inhalation
5	Accidental (unintended) exposure	Immersion
6	Accidental (unintended) exposure	Contact with the treated animal
7	Accidental (unintended) exposure	Ocular exposure
8	Accidental (unintended) exposure	Other accidental exposure
9	Suicidal intent	Ingestion
10	Suicidal intent	Injection
11	Suicidal intent	Inhalation
12	Suicidal intent	Other suicidal intent
13	Other	N/a
14	Unknown	N/a

E. LIST OF LABORATORY TESTS AND OTHER PROCEDURES

	Test type	Test parameter
1	Haematology – red blood cells	Anisocytosis
2	Haematology – red blood cells	Haemoglobin concentration (Hb)
3	Haematology – red blood cells	MCH (Mean corpuscular haemoglobin)
4	Haematology – red blood cells	MCHC (Mean corpuscular haemoglobin concentration)
5	Haematology – red blood cells	MCV (Mean corpuscular volume)
6	Haematology – red blood cells	Methaemoglobinaemia
7	Haematology – red blood cells	Packed cell volume (PCV) = Haematocrit
8	Haematology – red blood cells	Red blood cell count (RBC count)
9	Haematology – red blood cells	Reticulocytes
10	Haematology – red blood cells	Spherocytosis
11	Haematology – white blood cells	Basophil count
12	Haematology – white blood cells	Eosinophil count
13	Haematology – white blood cells	Lymphocyte count
14	Haematology – white blood cells	Monocyte count
15	Haematology – white blood cells	Neutrophil composition
16	Haematology – white blood cells	Neutrophil count
17	Haematology – white blood cells	Total white blood cell count (total WBC count)
18	Haematology – coagulation	Activated partial thromboplastin time
19	Haematology – coagulation	Bleeding time (ear/gum)
20	Haematology – coagulation	Fibrin degradation products
21	Haematology – coagulation	Platelet count (thrombocyte count)
22	Haematology – coagulation	Prothrombin time
23	Haematology – other microscopy	Helminth parasites
24	Haematology – other microscopy	Protozoal parasites
25	Haematology – other microscopy	Rickettsial parasites
26	Haematology – other microscopy	Viral inclusions
27	Haematology – serology	Fibrinogen
28	Haematology – serology	Antiplatelet antibody
29	Haematology – serology	Anti-nuclear antibody (ANA)
30	Haematology – serology	Coombs test
31	Haematology – serology	Specific bacterial antigen
32	Haematology – serology	Specific bacterial antibody
33	Haematology – serology	Specific fungal antigen
34	Haematology – serology	Specific fungal antibody
35	Haematology – serology	Specific rickettsial antigen
36	Haematology – serology	Specific rickettsial antibody
37	Haematology – serology	Specific protozoal antigen
38	Haematology – serology	Specific protozoal antibody
39	Haematology – serology	Specific helminth antigen
40	Haematology – serology	Specific helminth antibody
41	Haematology – serology	Specific viral antigen
42	Haematology – serology	Specific viral antibody
43	Haematology – blood biochemistry	Blood urea nitrogen (BUN)
44	Haematology – blood biochemistry	Creatinine
45	Haematology – blood biochemistry	Total protein (TP)
46	Haematology – blood biochemistry	Albumin

	Test type	Test parameter
47	Haematology – blood biochemistry	Total serum bilirubin
48	Haematology – blood biochemistry	Direct bilirubin
49	Haematology – blood biochemistry	Bile acids
50	Haematology – blood biochemistry	Triglycerides
51	Haematology – blood biochemistry	Cholesterol
52	Haematology – blood biochemistry	Glucose
53	Haematology – blood biochemistry	Ammonia
54	Haematology – blood biochemistry	Calcium
55	Haematology – blood biochemistry	Phosphorus
56	Haematology – blood biochemistry	Magnesium
57	Haematology – blood biochemistry	Iron
58	Haematology – blood biochemistry	Sodium
59	Haematology – blood biochemistry	Potassium
60	Haematology – blood biochemistry	Chloride
61	Haematology – blood biochemistry	Copper
62	Haematology – blood biochemistry	Selenium
63	Haematology – blood biochemistry	Other trace element
64	Haematology – blood biochemistry	Alanine aminotransferase (ALT)=SGPT
65	Haematology – blood biochemistry	Aspartate aminotransferase (AST)=SGOT
66	Haematology – blood biochemistry	Serum Alkaline phosphatase (SAP, ALP, ALKP)
67	Haematology – blood biochemistry	Amylase
68	Haematology – blood biochemistry	Lipase
69	Haematology – blood biochemistry	Creatine kinase (CK, CPK)
70	Haematology – blood biochemistry	Lactate dehydrogenase (LD, LDH)
71	Haematology – blood biochemistry	Gamma-glutamyltranspeptidase (GGT)
72	Haematology – blood biochemistry	Total carbon dioxide (TCO ₂ , HCO ₃)
73	Haematology – blood biochemistry	Cyanocobalamine (Vitamine B 12)
74	Haematology – blood biochemistry	Other vitamin quantification
75	Haematology – blood biochemistry	Thyroxine (T4)
76	Haematology – blood biochemistry	Cortisol
77	Haematology – blood biochemistry	Insulin
78	Haematology – blood biochemistry	Fructosamine
79	Haematology – blood biochemistry	Adrenocorticotrophic hormone (ACTH) stimulation test
80	Haematology – blood biochemistry	Dexamethasone suppression test
81	Haematology – blood biochemistry	Gonadotropin releasing hormone (GnRH) stimulation test
82	Haematology – blood biochemistry	Thyrotropin releasing hormone (TRH) stimulation test
83	Haematology – blood biochemistry	Thyrotropin (TSH) stimulation
84	Haematology – blood biochemistry	Trypsin-like immunoreactivity (TLI) test
85	Haematology – blood biochemistry	Glutathione peroxidase (GSHpx)
86	Other microscopy	Protozoal infection
87	Other microscopy	Rickettsial infection
88	Other microscopy	Bacterial infection
89	Other microscopy	Viral infection
90	Other microscopy	Helminth infection

	Test type	Test parameter
91	Other microscopy	Other parasite infection
92 ¹	Urinalysis	Isosthenuria
93	Urinalysis	Urine transparency
94	Urinalysis	Urine colour
95	Urinalysis	Urine specific gravity (SG = relative density)
96	Urinalysis	Urinary pH
97	Urinalysis	Urinary protein
98	Urinalysis	Urinary glucose
99	Urinalysis	Urinary ketones
100	Urinalysis	Urinary bilirubin
101	Urinalysis	Urinary blood pigment (dipstick)
102	Urinalysis	Urinary haemoglobin
103	Urinalysis	Urinary myoglobin
104	Urinalysis	Red blood cells in urine
105	Urinalysis	White blood cells in urine
106	Urinalysis	Urinary casts
107	Urinalysis	Urinary bacteria
108	Urinalysis	Urinary crystals
109	Faecal analysis	Faecal bacterial antigen
110	Faecal analysis	Faecal bacterial culture
111	Faecal analysis	Faecal virus antigen
112	Faecal analysis	Faecal fungal culture
113	Faecal analysis	Faecal egg count
114	Faecal analysis	Faecal larval count
115	Faecal analysis	Faecal culture NOS
116	Tissue analysis	Puncture
117	Tissue analysis	Aspiration biopsy
118	Tissue analysis	Biopsy
119	Tissue analysis	Swab
120	Tissue analysis	Other tissue analysis
121	Tissue analysis	Skin analysis
122	Tissue analysis	Skin analysis – dermatophytes
123	Tissue analysis	Skin analysis – ear mites
124	Tissue analysis	Skin analysis – mites
125	Tissue analysis	Skin analysis – bacteria culture
126	Tissue analysis	Skin analysis – fleas
127	Other Body fluid analysis	Cerebrospinal fluid (Liquor) analysis
128	Other Body fluid analysis	Cerebrospinal fluid (Liquor) – bacterial culture
129	Other Body fluid analysis	Cerebrospinal fluid (Liquor) – virus antigen
130	Other Body fluid analysis	Sputum – bacterial culture
131	Other Body fluid analysis	Sputum – fungal culture
132	Other Body fluid analysis	Sputum – virus antigen
133	Other Body fluid analysis	Bronchoalveolar lavage – bacterial culture
134	Other Body fluid analysis	Bronchoalveolar lavage – fungal culture
135	Other Body fluid analysis	Bronchoalveolar lavage – virus antigen
136	Other Body fluid analysis	Synovial fluid – bacterial culture

¹ The test parameter Isosthenuria of test type Urinalysis was made non-current in the 2006 revision.

	Test type	Test parameter
137	Other Body fluid analysis	Other body fluid analysis NOS
138	Imaging	Radiography
139	Imaging	Nuclear magnetic resonance
140	Imaging	Ultrasound