



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 June 2017
EMA/CVMP/PhVWP/288284/2007-Rev.10
Committee for Medicinal Products for Veterinary Use

Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans

1. Introduction

The purpose of these notes is to explain the principles of Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) terminology and to provide advice about its use. The aim is to achieve a harmonised approach to the selection of VeDDRA terms.

VeDDRA has a four-level hierarchical structure as follows:

SOC – system organ class

HLT – high level term

PT – preferred term

LLT – low level term

The relationship between the SOC and the LLT is mono-axial i.e. a specific LLT is only available in one specific SOC. In cases where similar LLTs exist in other SOCs, an LLT contains a cross reference to the location of the other terms. In order to achieve medically relevant groupings for analysis of adverse events, the relation between PTs and LLTs covers two different concepts, allowing an LLT to be either a synonym or a sub-classification of a particular PT. For example, the PT 'Anaphylaxis' includes the LLTs 'Anaphylaxis' and 'Anaphylactoid reaction'. In VeDDRA, the terminologies in the SOC and the HLT are plural, with the PT and the LLT being in the singular (unless a particular term would not otherwise make medical sense). In addition, any PT term is available as an LLT too.

The selection of VeDDRA terms to describe an adverse event should be at LLT level, taking care to choose the terms which most closely resemble the clinical signs described by the reporter. Analysis will normally be carried out at PT level. There are a number of situations where there could be more than one choice at LLT level, sometimes with different results at SOC level. Some of the more frequent situations are discussed below. It is not the intention to restrict the choices, but to encourage a standard approach so that the results of analysis will be consistent and valid.

If it is clear that a reported clinical sign occurred before administration of the product, or if it is known that it was due to the disease being treated or another specific cause (e.g. the reporter mentions dietary ketoacidosis) it should not be coded using VeDDRA as this would not be classified as an adverse event related to a veterinary medicinal product. However, if there is any element of doubt the



clinical sign should be coded in the usual way and this situation should subsequently be taken into account when analysing adverse event data.

In general it is preferable to avoid coding the same or similar clinical signs multiple times (e.g. emesis and vomiting) unless the LLTs relate to different PTs as this may impact on subsequent analysis. However there are some PTs e.g. gingival disorder, where multiple LLTs may need to be coded (e.g. gum bruising, gingival hyperplasia, gum pain and gingivitis) resulting in the PT being coded multiple times. Information on signs observed after re-challenge is useful for determining the causal association with the veterinary medicinal product administered.

It should also be noted that the VeDDRA terms list is deliberately kept as a non-exhaustive list where the focus is to cover the most commonly used terms and situations and to learn from practice through the feedback from users as part of the yearly revision exercise. In addition the list is not intended to provide terms that would define a specific disease or syndrome.

2. Death

Death should always be recorded using VeDDRA. There are 8 choices at LLT level, all of which are described as 'Death' at PT level.

SOC	HLT	PT	LLT
Systemic disorders	Death	Death	Death by euthanasia
Systemic disorders	Death	Death	Sudden death
Systemic disorders	Death	Death	Found dead
Systemic disorders	Death	Death	Death
Systemic disorders	Death	Death	Unexplained death
Systemic disorders	Death	Death	Unrelated death
Systemic disorders	Death	Death	Increased mortality rate
Systemic disorders	Death	Death	Increased culls

This means that data extracted at PT level will not identify the relationship between the death and the adverse reaction so the case narrative must include all relevant details, including information as to how death occurred or why euthanasia was carried out if appropriate. The LLT '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 economic reasons, in which case the LLT 'Death by euthanasia' should be used. The LLT 'Sudden death' should be used when the fatality occurred unexpectedly e.g. without preceding clinical signs.

While there may be events involving multiple animals where it is appropriate to add both 'Death' and 'Death by euthanasia', it is important to be aware that the frequency of term selection in individual reports could influence the results of analysis, depending on the level at which analysis is carried out. Although the VICH standard enables the number of animals per VeDDRA term to be specified in individual reports, this has yet to be implemented in Eudravigilance Veterinary (EVVet). In cases where animals are euthanised (slaughtered) in high numbers, the LLT 'Increased culls' should be used.

See also section 23 Lack of efficacy for coding death in events following the use of euthanasia products.

3. Anaphylaxis

The clinical signs of anaphylaxis can vary according to the species and, in less severe cases, some of the signs are not obviously part of the syndrome, so it is sometimes a matter of opinion as to whether the reaction was anaphylaxis. If the reporter has described it as such, it should be recorded as anaphylaxis. There are 5 terms at LLT level, all of which are described as 'Anaphylaxis' at PT level. Therefore, from the point of view of analysis, the choice of LLT term will make no difference.

SOC	HLT	PT	LLT
Immune system disorders	Allergic conditions	Anaphylaxis	Anaphylaxis
Immune system disorders	Allergic conditions	Anaphylaxis	Anaphylactic shock
Immune system disorders	Allergic conditions	Anaphylaxis	Anaphylactoid reaction
Immune system disorders	Allergic conditions	Anaphylaxis	Anaphylactic-type reaction
Immune system disorders	Allergic conditions	Anaphylaxis	Generalised allergic reaction NOS ¹

If there is an association in the time between product administration and onset of the reaction (usually starting within a few hours after administration) and some, or all, of the classic signs of anaphylaxis are present, the reaction should be recorded as anaphylaxis. All the reported clinical signs should also be listed at LLT level. The clinical signs of anaphylaxis in individual species are listed below.

Species	Clinical signs
Dog	Excitement, urticaria, pruritus, angioedema, vomiting, defecation, dyspnoea, collapse, convulsions.
Cat	Pruritus, angioedema, salivation, vomiting, dyspnoea, incoordination, collapse.
Horse	Shivering, sweating, incoordination, coughing, dyspnoea, diarrhoea, colic, collapse.
Cow and sheep	Urticaria, restlessness, pruritus, angioedema, defecation, urination, coughing, dyspnoea, cyanosis, bloat, collapse.
Pig	Dyspnoea, cyanosis, pruritus, collapse.

Difficulties arise when the reaction is not clearly anaphylaxis, but some of the clinical signs and the time between administration of the product and onset of the reaction indicate that it might be. Any reaction starting within a few hours after administration which is accompanied by signs of circulatory disturbance, such as pale mucous membranes, lethargy or weakness, change in heart rate, tachypnoea or dyspnoea, should be recorded as anaphylaxis, in addition to listing the clinical signs. If the attending veterinarian has reported a reaction as anaphylaxis, it should be recorded as such.

'Vagal shock' is an LLT term which maps to 'circulatory shock' at PT level. It is advised that 'Vagal shock' should only be coded if specifically mentioned by the original reporter. Marketing authorisation holders (MAHs) and National competent authorities (NCAs) should not code this term based on an interpretation of case narratives describing collapse-type events within seconds following product administration. 'Circulatory shock' or 'Circulatory collapse' is more appropriate terms to code these

¹ NOS = Not otherwise specified

types of events. It is also important to differentiate between these events and those of suspected anaphylaxis as described above.

4. Local reactions

Adverse reactions which occur at the application, injection or implantation site should be described using LLT terms selected from the appropriate HLT under SOC 'Application site disorders'. This distinguishes them from non-specific local reactions which may be more difficult to assess for causality. For example:

SOC	HLT	PT	LLT
Application site disorders	Injection site reactions	Injection site hair change	Injection site alopecia
Skin and appendages disorders	Hair follicle and sebaceous gland disorders	Alopecia	Alopecia local

5. Sarcoma

The LLT term 'Injection site sarcoma' should be used to describe sarcomas at injection sites. Other LLT terms used to describe sarcomas should be avoided because of the differences at PT level which would exclude them from analysis. For example:

SOC	HLT	PT	LLT
Application site disorders	Injection site reactions	Injection site sarcoma	Injection site sarcoma
Application site disorders	Application site reactions	Application site sarcoma	Application site sarcoma
Skin and appendages disorders	Skin and appendages neoplasms	Skin and/or appendage neoplasm NOS	Skin sarcoma NOS
Skin and appendages disorders	Skin and appendages neoplasms	Skin fibrosarcoma	Skin fibrosarcoma

6. Dullness, lethargy, sleepiness, drowsiness, depression and malaise

Reporters often describe an animal which is ill in non-specific terms. The clinical signs which are reported should be viewed in the context of the overall reaction and it is important to be aware of the SOC in which an individual LLT is located. An exact match at LLT level could exaggerate the seriousness of the reaction. For example, dullness is frequently used to describe a mild, transient post-vaccinal reaction, but at LLT level the term is located in the SOC 'Neurological disorders' which does not reflect the true nature of the reaction. In this case it is important to record any additional reported clinical signs which give a more accurate picture of the overall reaction. If dullness is the only clinical sign which is reported, it may be necessary to obtain more details from the reporter.

Similarly, although the terms sleepiness and drowsiness may be used interchangeably by reporters in cases where there is either neurological impairment or general lethargy, from the overall picture of the report, it should be possible to select the most appropriate term from the list in the following table:

SOC	HLT	PT	LLT
Neurological disorders	Impaired consciousness	Impaired consciousness	Dullness
Neurological disorders	Impaired consciousness	Somnolence	Sleepiness – neurological disorder
Neurological disorders	Mental impairment	Cognitive disorder NOS	Drowsiness – neurological disorder
Systemic disorders	General signs or symptoms	Lethargy	Lethargy (see also Central nervous system depression in ‘Neurological’)
Systemic disorders	General signs or symptoms	Lethargy	Depression
Systemic disorders	General signs or symptoms	Lethargy	Dull
Systemic disorders	General signs or symptoms	Lethargy	Drowsiness – systemic disorder
Systemic disorders	General signs or symptoms	Lethargy	Sleepiness – systemic disorder
Systemic disorders	General signs or symptoms	Malaise	Malaise
Systemic disorders	General signs or symptoms	Malaise	Off colour

7. Head tilt, balance problems and ataxia

Head tilt may be reported in association with adverse reactions which did not result from the administration of a product into the ear. The choice of this term at LLT level can be difficult as it may be due to either inner ear or neurological causes. The usual default would be to select the term ‘Head tilt – ear disorder’ but in situations where the overall picture is one of a neurological disturbance, the alternative ‘Head tilt – neurological disorder’ should be selected. Conversely, balance problems may be vestibular in origin, so when they are reported in association with a possible ear disorder, a term from the SOC ‘Ear and labyrinth disorders’ should be included with terms from the SOC ‘Neurological disorders’.

SOC	HLT	PT	LLT
Ear and labyrinth disorders	Internal ear disorders	Internal ear disorder	Head tilt – ear disorder
Ear and labyrinth disorders	Internal ear disorders	Internal ear disorder	Internal ear disorder
Ear and labyrinth disorders	Internal ear disorders	Internal ear disorder	Tumbling circling disease (see also ataxia in ‘Neurological’)

SOC	HLT	PT	LLT
Ear and labyrinth disorders	Internal ear disorders	Internal ear disorder	Vestibular disorder NOS
Neurological disorders	Central nervous system disorders	Central nervous system disorder NOS	Head tilt – neurological disorder
Neurological disorders	Coordination and balance signs	Ataxia	Balance impaired
Neurological disorders	Coordination and balance signs	Ataxia	Balance problem
Neurological disorders	Coordination and balance signs	Ataxia	Equilibrium disorder
Neurological disorders	Coordination and balance signs	Ataxia	Lack of coordination (see also 'Ear' – vestibular disorder)

8. Pain and discomfort

Animals are sometimes reported as being in pain or showing signs of pain when touched. This could reflect a systemic condition, in which case the choice of one of the following LLT terms in the SOC 'Systemic disorders' would be appropriate. However, an exaggerated response could be a sign of a different syndrome. A separate PT exists for cases where discomfort, as opposed to overt pain, is reported.

SOC	HLT	PT	LLT
Systemic disorders	General signs or symptoms	General pain	General pain (see other SOC's for specific pain)
Systemic disorders	General signs or symptoms	General pain	Pain NOS
Systemic disorders	General signs or symptoms	Localised pain NOS	Localised pain NOS (see other SOC's for specific pain)
Systemic disorders	General signs or symptoms	Discomfort NOS	Discomfort NOS
Systemic disorders	General signs or symptoms	Discomfort NOS	Uncomfortable
Neurological disorders	Sensory abnormalities	Hyperaesthesia	Hypersensitivity to pain

9. Distress

Distress is a term often used by reporters to describe an animal which is not behaving normally, yet the reaction is rarely associated with a behavioural disorder. In VeDDRA the term is located in this SOC, so in cases in which it is the only reported sign and the overall picture is not clear, it may be

necessary to seek advice from the Qualified Person for Pharmacovigilance (QPPV) or the NCA in order to achieve consistency in the recording of this term.

SOC	HLT	PT	LLT
Behavioural disorders	Other behavioural disorders	Anxiety	Distress

10. Collapse

There are three LLT terms available in VeDDRA to describe collapse, each of which is located in a different SOC (see below). It is important to ensure that the choice of term at LLT level is appropriate in the context of the overall reaction. None of the LLT terms describing collapse are located in the SOC 'Immune system disorders', yet this clinical sign is often reported in association with anaphylaxis (see section 3).

SOC	HLT	PT	LLT
Cardio-vascular system	Circulatory disorders	Circulatory shock	Circulatory collapse (see also 'Neurological' and 'Systemic disorders')
Neurological disorders	Impaired consciousness	Loss of consciousness	Collapse (see also 'Cardio-vascular' and 'Systemic disorders')
Systemic disorders	General signs or symptoms	Collapse NOS	Collapse NOS (see also 'Cardio-vascular' and 'Neurological disorders')

11. Reduced urination

Failure to urinate may be due to either a physiological or anatomical problem within the urinary tract itself or else a more psychological or behavioural response (e.g. to distress or fear). A complete absence of urination should be coded as 'Anuria' unless there is evidence of behavioural dysfunction in which case the term 'Not urinating' can be selected.

Note also the terms in the PTs 'Dysuria' and 'Stranguria' which represent difficulty or pain in urinating respectively. Although the LLT 'Pollakiuria' describes abnormally frequent attempts at urination it appears in the 'Dysuria' PT due to the low volume of urine produced on each attempt.

SOC	HLT	PT	LLT
Behavioural disorders	Other behavioural disorders	Inappropriate urination	Not urinating
Renal and urinary disorders	Renal disorders	Anuria	Anuria
Renal and urinary disorders	Urinary tract disorders	Dysuria	Difficulty in micturition
Renal and urinary disorders	Urinary tract disorders	Dysuria	Pollakiuria
Renal and urinary disorders	Urinary tract disorders	Stranguria	Painful urination

12. Recumbency, prostration and self-auscultation position

Recumbency can be the result of several different types of adverse reaction and the term is located in the SOC 'Systemic disorders', under the PT 'Recumbency'. Some abnormal postures relating to recumbent animals can also be found as LLTs within this PT, including 'Prostration' (a specific body position where the animal is lying completely flat out) and 'Self-auscultation position' (when the animal's neck is bent so that the head lies against the chest).

In situations where the reason for recumbency could be neurological, it would be advisable to select at least one other LLT term from the SOC 'Neurological disorders' (see examples below) in order to capture this information.

SOC	HLT	PT	LLT
Systemic disorders	General signs or symptoms	Recumbency	Lateral recumbency
Systemic disorders	General signs or symptoms	Recumbency	Recumbency
Systemic disorders	General signs or symptoms	Recumbency	Unable to rise
Systemic disorders	General signs or symptoms	Recumbency	Prostration
Systemic disorders	General signs or symptoms	Recumbency	Self-auscultation position
Systemic disorders	General signs or symptoms	Recumbency	Abnormal posture
Neurological disorders	Paralytic and paretic disorders	Paralysis	Hind limb paralysis
Neurological disorders	Paralytic and paretic disorders	Paresis	Paresis
Neurological disorders	Coordination and balance signs	Ataxia	Unable to stand

13. Reluctance to move

Non-specific changes in an animal's behaviour, such as inertia, are difficult to record accurately if other clinical signs are not reported. There are a number of choices at LLT level (see below). In cases where the situation is unclear and few details are reported it would be advisable to select a term in the PT 'Lethargy' in order to indicate the generalised systemic nature of the reaction. This could be important in a situation where an animal is showing some signs of mobility but not the full range of movement. In such cases a single term from the SOC 'Musculoskeletal disorders' or the SOC 'Neurological disorders' may not be an accurate description of the reaction.

SOC	HLT	PT	LLT
Systemic disorders	General signs or symptoms	Lethargy	Reluctant to move

SOC	HLT	PT	LLT
Musculoskeletal disorders	Musculoskeletal disorders	Musculoskeletal disorder NOS	Limb weakness
Neurological disorders	Coordination and balance signs	Ataxia	Walking difficulty

14. Anorexia

Anorexia in humans may be a symptom of a psychological disturbance, in which case the LLT 'Eating disorder NOS' in the SOC 'Psychological disorders' should be used. This term should be used only for human reports.

SOC	HLT	PT	LLT
Psychological disorders	Eating disorders	Eating disorder NOS	Eating disorder NOS (see Systemic for anorexia etc)

Anorexia is frequently used by reporters to describe loss of appetite as a clinical sign in many different types of adverse reaction in animals and humans. In this situation a term from the PT 'Anorexia' in the SOC 'Systemic disorders' should be selected (see examples below).

SOC	HLT	PT	LLT
Systemic disorders	General signs or symptoms	Anorexia	Anorexia
Systemic disorders	General signs or symptoms	Anorexia	Decreased appetite

15. Hyperactivity

In animals, hyperactivity is regarded as a behavioural disorder in VeDDRA. This term should be used only for animal reports.

SOC	HLT	PT	LLT
Behavioural disorders	Other behavioural disorders	Hyperactivity	Hyperactivity

Hyperactivity may also be reported in a human as a symptom of abnormal behaviour, in which case the LLT 'Hyperactive' in the SOC 'Psychological disorders' should be used. This term should be used only for human reports.

SOC	HLT	PT	LLT
Psychological disorders	Personality and mood disorders	Abnormal behaviour	Hyperactive

16. Foaming at the mouth

There are two LLT terms available in VeDDRA to describe the drooling of non-bloody fluid from the mouth of an animal which is often described by reporters as 'foaming at the mouth'. An additional term exists to describe incidents when bloody foam is seen in both the mouth and nose.

SOC	HLT	PT	LLT
Digestive tract disorders	Oral cavity disorders	Hypersalivation	Foaming at the mouth
Respiratory tract disorders	Respiratory tract disorders	Foam in respiratory tract	Foam in the mouth
Respiratory tract disorders	Respiratory tract disorders	Foam in respiratory tract	Bloody foam in mouth and nose

As the terms are located in different SOCs, their selection at LLT level could be critical in ensuring that the clinical syndrome described by the reporter is recorded correctly. It is advisable to include additional LLT terms from the relevant SOCs whenever possible so that the adverse reaction is characterised accurately. It should also be remembered that 'foaming at the mouth' can be associated with neurological disorders such as muscle tremors, convulsions and tetany, although in these cases it is unlikely to be the sole clinical sign which is reported.

17. Induced vomiting

Vomiting may be induced in order to treat a condition. In such cases it would not be appropriate to record vomiting as a clinical sign involved in the adverse reaction if an emetic had been administered.

18. Panting, stridor and rale

'Panting' describes a fast and shallow open mouthed breathing pattern observed commonly, but not exclusively, in dogs in response to both physiological and psychological disturbances. Since VeDDRA terms can only appear under one SOC, if it is considered that a report of panting indicates some form of anxiety, this should be coded separately.

'Stridor' is an abnormal, high-pitched sound produced by turbulent airflow through a partially obstructed airway within the upper respiratory tract. Its aetiology is therefore quite different from 'Rale', an abnormal rattling sound from within the chest and can be either bronchial or tracheal. This is reflected in their coding where cross referencing has also been provided.

SOC	HLT	PT	LLT
Respiratory tract disorders	Bronchial and lung disorders	Tachypnoea	Panting
Respiratory tract disorders	Bronchial and lung disorders	Rale	Bronchial rale
Respiratory tract disorders	Bronchial and lung disorders	Rale	Harsh lung sounds
Respiratory tract disorders	Bronchial and lung disorders	Rale	Increased lung sounds

SOC	HLT	PT	LLT
Respiratory tract disorders	Tracheal and laryngeal disorders	Tracheal and laryngeal disorder NOS	Tracheal rales
Respiratory tract disorders	Respiratory tract disorders	Respiratory tract disorder NOS	Stridor (Upper respiratory; for lower respiratory see also Bronchial rale)

19. Embolism and thromboembolism

Since emboli are generally formed in the heart, this LLT is found under the PT 'Cardiac embolism'. Conversely where emboli lodge in the lung this is recorded under the SOC 'Respiratory tract disorders'.

SOC	HLT	PT	LLT
Cardio-vascular system disorders	Cardiac/heart disorders	Cardiac embolism	Cardiac embolism
Cardio-vascular system disorders	Cardiac/heart disorders	Cardiac embolism	Embolism
Respiratory tract disorders	Bronchial and lung disorders	Pulmonary thromboembolism	Pulmonary thromboembolism

20. Metastatic neoplasia and secondary malignancy

Secondary malignancies are cancers caused by treatment with radiation or chemotherapy. They are unrelated to the first cancer that was treated and may occur months or even years after initial treatment. They should not, therefore, be confused with metastatic tumours which are related to the primary tumour and are the result of local, haematogenous or lymphatic spread of malignant cells from the primary tumour. Consequently these terms are coded differently.

SOC	HLT	PT	LLT
Systemic disorders	Neoplasia NOS	Metastatic neoplasia	Metastatic neoplasia
Systemic disorders	Neoplasia NOS	Metastatic neoplasia	Metastatic tumour
Systemic disorders	Neoplasia NOS	Neoplasia NOS	Secondary malignancy

21. Prolonged anaesthesia, premature anaesthesia recovery and rough recovery

Although 'prolonged anaesthesia' and 'premature anaesthesia recovery' might on the face of it be considered simply the opposite of each other they are located in quite different SOCs, as indicated below. A separate PT exists for 'Rough recovery' and therefore this should also be coded when applicable.

SOC	HLT	PT	LLT
Neurological disorders	Impaired consciousness	Sedation	Prolonged anaesthesia
Systemic disorders	General signs or symptoms	Premature anaesthesia recovery	Premature anaesthesia recovery
Systemic disorders	General signs or symptoms	Rough recovery	Rough recovery

22. Abnormal test results and necropsy terms

The principles of VeDDRA terminology were established to describe clinical signs or other easily detectable clinical information. However, as the availability of diagnostic equipment and services to veterinary practices continues to develop, there are an increasing number of previously uncoded terms related to test results which appear to be required. More common terms that clearly belong to a particular SOC have been assigned their own PT in the respective area, but in order to prevent creating an overly unwieldy system some of the less common terms can be found under the PT 'Abnormal test result' and these are listed in the following table. If the appropriate term is not available in VeDDRA, the LLT 'Abnormal test result' should be selected and details of the test should be provided in the narrative.

SOC	HLT	PT	LLT
Systemic disorders	General signs or symptoms	Abnormal test result	Abnormal necropsy finding
Systemic disorders	General signs or symptoms	Abnormal test result	Abnormal radiograph finding
Systemic disorders	General signs or symptoms	Abnormal test result	Abnormal test result
Systemic disorders	General signs or symptoms	Abnormal test result	Abnormal ultrasound finding
Systemic disorders	General signs or symptoms	Abnormal test result	Decreased cholesterol (total)
Systemic disorders	General signs or symptoms	Abnormal test result	Elevated cholesterol (total)
Systemic disorders	General signs or symptoms	Abnormal test result	Elevated C-reactive protein

SOC	HLT	PT	LLT
Systemic disorders	General signs or symptoms	Abnormal test result	Elevated fibrinogen level
Systemic disorders	General signs or symptoms	Abnormal test result	Elevated lactic acid dehydrogenase (LDH)
Systemic disorders	General signs or symptoms	Abnormal test result	Elevated SAP
Systemic disorders	General signs or symptoms	Abnormal test result	Low fibrinogen level

In addition to these terms, in the case where a post mortem examination has been done, the pathological findings of the necropsy report may also be found under each relevant PT as an LLT with the prefix 'NT' to signify that it is a necropsy term. For example in the case of cholangitis, as shown below:

SOC	HLT	PT	LLT
Hepato-biliary disorders	Gall bladder and bile duct disorders	Cholangitis	NT - chronic cholangitis
Hepato-biliary disorders	Gall bladder and bile duct disorders	Cholangitis	NT - suppurative cholangitis

23. Lack of efficacy

If the reported adverse event clearly relates solely to lack of expected efficacy, the term 'lack of efficacy' should be used in isolation without any of the observed signs indicative of the lack of efficacy. For any reports resulting in fatalities, 'death' should also be coded. The term 'uncoded sign' should never be used to code for the disease being treated.

If the report describes clinical signs relating to both safety and lack of expected efficacy or if there is any doubt as to what type of case it is (e.g. if clinical signs appear to have worsened following treatment) it should be submitted as one combined report with all signs being coded including 'Lack of efficacy'.

In order to provide further coding detail for combination antiparasitic products and some multivalent vaccines which carry multiple indications, an exception has been made. Additional LLTs have been created, all situated within the PT 'Lack of efficacy'.

SOC	HLT	PT	LLT
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy (distemper virus)
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy (ectoparasites)
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy (endoparasites)
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy (heartworm)
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy (myxomatosis)

SOC	HLT	PT	LLT
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy (parvovirus)
Systemic disorders	Lack of efficacy	Lack of efficacy	Lack of efficacy (rabbit haemorrhagic disease (RHD))

In order to keep the right balance between the amount of detail and “workability” of the list, it is not intended to further elaborate the VeDDRA list with similar detail being added to the ‘Lack of efficacy’ unless sufficient need is identified for other diseases protected by multivalent vaccines.

Lack of expected efficacy following the use of euthanasia products should be coded using only the VeDDRA low level terms ‘lack of efficacy’ and ‘unrelated death’ (as the death was unrelated to the adverse event ‘lack of efficacy’). No other clinical signs observed should be coded using VeDDRA. In all cases, however, such reports are considered serious adverse events and should be reported accordingly.

24. Uncoded sign

The LLT ‘Uncoded sign’ should ONLY be used when there is no existing VeDDRA term to code the clinical sign(s) 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.

25. Product problems and medication errors

There are currently three LLT terms which map to the PT ‘Product problem’: ‘medication error’, ‘counterfeit product’ and ‘Product problem’.

It is recommended that ‘counterfeit product’ should only be used on those situations where this is suspected.

‘Product problem’ should be used when an adverse event is reported in relation to a quality defect or manufacturing error.

‘Medication error’ should be coded in those cases where an adverse event is reported which is related to errors in prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

26. Decubitus and decubitus ulceration

The LLT term ‘decubitus’ which maps to the PT term ‘recumbency’ describes the body position of the animal. Ulceration (or decubitus ulceration as it is sometimes referred) due to prolonged recumbency should be coded using the term ‘skin ulceration’.