

GUIDANCE ON MARKETING NON-MEDICINAL PRODUCTS

Products presented for the treatment or prevention of disease, or which have that function must be authorised under the Veterinary Medicines Regulations 2013 (as amended) (VMR) before they can be placed on the market. A product can be medicinal “by function” or “by presentation”.

Regulation 2 of the VMR defines a medicinal product as;

“Any substance or combination of substances presented as having properties for treating or preventing disease in animals; or”

“Any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.”

A product that is medicinal by function requires a marketing authorisation. A non-medicinal product cannot make medicinal claims. Nor can it give the impression of being a medicine through the appearance of its packaging. In cases where a product is presented as medicinal, the VMD will require the company to remove the offending words or phrases from its marketing material and, where necessary, change the appearance of the product’s packaging. This will return the product to a non-medicinal status.

The following 3 tables contain information for the marketing of non-medicinal products.

Table A contains examples of words which are normally associated with medicinal products which should be avoided in the marketing of non-medicinal products.

Table B is a list of functions which imply a medicinal effect when attributed to a particular product. If a product possesses the function in question the product may be medicinal by function and would require a marketing authorisation before placing on the UK market.

Table C lists examples of ingredients which are not permitted for use in a non-medicinal product. As a general guide incorporation of an active ingredient contained in an authorised veterinary medicinal product (unless included below an efficacious level) would be likely to cause a product to be medicinal by function.

None of the lists is exhaustive. It is always important to look at the whole presentation of the product to determine whether the words and pictures used make the product appear to be medicinal. In some cases it may even be the placement of a word or phrase alongside text or diagrams that can lead the VMD to consider a word or phrase as unacceptable.

If the ingredient or word you wish to use is not listed in this document we suggest you contact the Enforcement Section via enforcement@vmd.gov.uk for further advice.

Medical conditions are not listed in any of the tables. Specific reference to a condition such as arthritis, cystitis, anaemia, cushing’s, etc... is prohibited. Relating a product to a specific adverse condition or disease could lead the consumer into believing that the product could have an effect on that condition. The only exception is for low sugar feeds which are marketed as suitable for animals said to be prone to conditions such as laminitis. Such products cannot claim to treat, cure or prevent the condition.

Where a condition appears in the product name, the VMD will take a case-by-case approach. Where a product name could be interpreted as a recommendation for its use in the treatment of that condition, the VMD will consider it to be a medicinal claim. In cases involving long-established products, the VMD will ask companies to consider changing the name of the product.

Further information can be found by searching for “Legal controls on veterinary medicines” on gov.uk

A. GENERALLY NOT PERMITTED

| | <u>COMMENT or REASON</u> |
|-----------------------|---|
| Allergy | Medicinal by Presentation |
| Antibodies | Medicinal by Presentation - the supplementation of antibodies has no valid purpose beyond the prevention of disease and is therefore medicinal |
| Boost | Medicinal by Presentation when used in reference to a physiological function or state of health |
| Cures | Medicinal by Presentation |
| Dose / Dosage | Medicinal by Presentation |
| Eradicate / Eliminate | Medicinal by Presentation |
| Heals | Medicinal by Presentation |
| Improve(s) | Medicinal by Presentation (when used relative to a physiological function) |
| Internal Parasites | Medicinal by Presentation |
| Noise phobias | Medicinal by Presentation. This includes claims for fear caused by fireworks, or other sources of loud noise, resulting in pathological distress. |
| Pill | Medicinal by Presentation |
| Prevents | Medicinal by Presentation when used in relation to an adverse condition |
| Promotes | Medicinal by presentation (modification) when used in reference to a health state or physiological function. |
| Prone to <condition> | Medicinal by Presentation when used in relation to a product presented as having an effect on physiological functions associated with an adverse condition. Has been accepted for complete feeds intended for the avoidance of feed related laminitis. This allowance does not apply to feed supplements or products presented for nutritional support of hooves. |
| Protects | Medicinal by Presentation but may be accepted for use in reference to a barrier action such as barrier creams |
| Relieve | Medicinal by Presentation |
| Remedy | Medicinal by Presentation |
| Repairs | Medicinal by Presentation |
| Separation Anxiety | Medicinal by Presentation |
| Strengthens | Medicinal by Presentation when used in relation to a physiological function |
| Therapeutic | Medicinal by Presentation |
| Treat / Treatment | Medicinal by Presentation |
| Wounds | Medicinal by Presentation (Reference to minor wounds has been accepted) |

B. FUNCTIONS THAT CAN IMPLY A MEDICINAL EFFECT

| | <u>COMMENT or REASON</u> |
|-------------------|--|
| Allergen | Medicinal by Presentation |
| Analgesic | Medicinal by Presentation |
| Antacid | Medicinal by Presentation |
| Anthelmintic | Medicinal by Presentation |
| Anti-allergy | Medicinal by Presentation |
| Anti-bacterial | Only Permitted for products used topically for hygiene purposes. |
| Antibiotic | Medicinal by Presentation |
| Anti-coagulant | Medicinal by Presentation |
| Anti-fungal | Only Permitted for products used topically for hygiene purposes. |
| Anti-inflammatory | Medicinal by Presentation |
| Anti-microbial | Medicinal by Presentation |
| Anti-oxidants | Permitted provided the following or similar wording is used; ' <i>contains anti-oxidants to help "mop up" / neutralise free radicals</i> '. Claims to prevent harm caused by Free Radicals or oxidative damage are medicinal by presentation |
| Anti-protozoal | Medicinal by Presentation |
| Anti-pyrotic | Medicinal by Presentation |
| Anti-pruritic | Medicinal by Presentation |
| Anti-septic | Permitted for products used topically for hygiene purposes. Internal action would be considered Medicinal by Function |
| Anti-spasmodic | Medicinal by Presentation |
| Anti-viral | Only Permitted for products used topically for hygiene purposes. |
| Bactericide | Medicinal by Presentation |
| Elixir | Medicinal by Presentation |
| Expectorant | Medicinal by Presentation |
| Fungicide | Medicinal by Presentation |
| Laxative | Medicinal by Presentation |
| Linctus | Medicinal by Presentation |
| Mucolytic | Medicinal by presentation. Reduces viscosity of mucus in the lungs. Mucolytic drugs are often used in conjunction with an expectorant |

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| Pesticide | Medicinal by presentation - Implies a killing effect |
| Therapy | Medicinal by Presentation |
| Treatment | Medicinal by Presentation |
| Worming | A claim for action, effect or results relating to internal parasites is considered medicinal by presentation. This includes oblique references to internal parasites such as calling them “unwanted visitors” |

C. EXAMPLES OF MEDICINAL INGREDIENTS

Note; In some cases a medicinal level is stated

| <u>ENTRY NAME</u> | <u>COMMENT or REASON</u> |
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| Acetylcysteine | Medicinal at any level |
| Adelmidrol | Medicinal by Function. |
| Adenosylmethionine (aka SAME) | There are references to its use in the treatment of depression, liver disorders and osteoarthritis It is considered Medicinal by Function for these indications |
| Attapulgate | Medicinal by function when orally administered. |
| Belladonna | Medicinal by Function |
| Benzalkonium Chloride | More than 0.02% in topical products is considered Medicinal by Function |
| Benzoyl Peroxide | Medicinal by function |
| Bismuth Sub Carbonate | Products for oral administration containing this ingredient are Medicinal by Function |
| Bloodroot (Sanguinaria canadensis) | Medicinal by Function |
| Bronopol | Permitted in leave-on and rinse off topical products at levels up to 0.1% |
| Boric Acid | Products require warning “Do not use on damaged skin” and levels must be below the limit set for cosmetics. (5% max in talc, 0.5% max in oral hygiene products and 3% maximum in other products) |
| Camphor | Topical limit of 4% without claims, medicinal at greater levels |
| Cannabidiol (CBD) | Medicinal by function. Also, Cannabigerol (CBG) as it metabolises into CBD. |
| Capsaicin | 0.012% or more in cream is classified Medicinal by Function active as a topical analgesic |
| Cetylpyridinium Chloride | Is an antiseptic However, in-drinking water a concentration of 0.0012% in an oral hygiene product for cats/dogs, is not considered to be Medicinal by Function |
| Chlorhexidine Gluconate | For hygiene purposes, up to 0.3% when applied to broken skin and up to 4% when applied to intact skin. Concentrations exceeding these limits |

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| | are considered medicinal by function. |
| Chlorophene (2 benzyl 4 chlorophenol) | Preservative. 0.2% permitted level in cosmetics. Above 0.2% is considered Medicinal by Function |
| Clotrimazole | Used for healing dermatological conditions and infections - Medicinal by Function |
| Copper Naphthenate | Used for the treatment of ringworm in cattle - Medicinal by Function |
| Cypermethrin | Is an ectoparasiticide and is considered to be Medicinal by Function |
| Diazolidinyl Urea | In topical preparations below 0.5% this is not considered to be Medicinal by Function |
| Dibenzoyl Peroxide | Over 2.5% is considered to be Medicinal by Function |
| Dichlorophen | Considered cosmetic (not Medicinal by Function) if levels are less than 0.5% |
| Diflubenzuron | Medicinal by Function |
| DMDM hydantoin | In topical preparations below 0.6% this is not considered to be Medicinal by Function |
| Ephedrine | Medicinal by Function. A known precursor chemical for Methamphetamine |
| Foxglove (Digitalis) | Medicinal by Function |
| Guanidinopropionic Acid | Medicinal by Function |
| Hydrogen Peroxide | Used as antiseptic, disinfectant and deodorant At up to 6% to cleanse wounds/ulcers Not medicinal by function when presented in dilute concentrations and applied to intact skin |
| Iodine | If a product contains more than 0.3% iodine, it is considered Medicinal by Function |
| Iodoform | Less than 10% is not Medicinal by Function |
| Ketaconazole | 1% or less is not Medicinal by Function |
| Lactic Acid | 5% or less is acceptable when applied topically |
| Methoprene | Medicinal at any level - A growth regulation hormone often used as an insecticidal water treatment to prevent larva developing into pupa |
| Methyl salicylate (wintergreen) | Above 0.25% is considered Medicinal by Function |
| N-Acetylcysteine | Medicinal by Function |
| Palmitoylethanolamide | Medicinal by Function. Has anti-inflammatory and antinociceptive properties. |
| Permethrin | Medicinal by Function |
| Potassium Bromide | Medicinal by Function |
| Potassium Iodide | 1% Orally or less is not Medicinal by Function |

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| Pyrethrins | Medicinal by Function |
| Pyrethrum | Medicinal by Function |
| Resmethrin | Pyrethroid. Medicinal by Function. |
| Thymol | Thymol at any concentration in a product intended for use on bees or in their hives should be considered Medicinal by Function |
| Willow Bark | Medicinal by Function. (Natural Aspirin equivalent) |