

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 Team 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
Pill	Medicinal by Presentation
Prevents	Medicinal by Presentation when used in relation to an adverse condition
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
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

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>
Acetylcysteine	Medicinal at any level
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
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
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
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 Gulconate	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 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 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
Permethrin	Medicinal by Function
Potassium Bromide	Medicinal by Function
Potassium Iodide	1% Orally or less is not Medicinal by Function
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)