

VMGN No.23



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

VETERINARY MEDICINES
- DO YOU NEED A
MARKETING AUTHORISATION?



INVESTOR IN PEOPLE



Contents

1.

Introduction

- 1.1 Background
- 1.2 Definition of a Medicinal Product

2.

Medicinal by Presentation

- 2.1 Medicinal Words and Phrases
- 2.2 Diseases and Adverse Conditions
- 2.3 Articles in Journals/Magazines
- 2.4 Customer Testimonials
- 2.5 Websites
- 2.6 False and Misleading Claims

3.

Medicinal by Function

4.

Specific Topics

- 4.1 Vitamins and Minerals
- 4.2 Feeding Stuffs Intended for a Particular Nutritional Purpose
- 4.3 Nutraceuticals
- 4.4 Insecticides and Repellents
- 4.5 Shampoos
- 4.6 Cosmetic Products
- 4.7 Teat and Udder Products
- 4.8 Antiseptics
- 4.9 Disinfectants
- 4.10 Herbal Products
- 4.11 Homeopathic Products
- 4.12 Colostrum
- 4.13 Diagnostic Tools (Testing Kits)

5.

Other Legislation

6.

Contact

Annex A

Annex B



1. Introduction

1.1 Background

The Veterinary Medicines Directorate (VMD) is the body responsible for the granting of marketing authorisations for veterinary medicinal products in the United Kingdom. Products which are presented for the treatment or prevention of disease in animals or which have that function, must be authorised under the terms of the current Veterinary Medicines Regulations (the 'Regulations') before they can be sold or supplied legally in the United Kingdom.

This booklet explains what causes a product to come within the definitions of a veterinary medicinal product and under what circumstances a product needs a marketing authorisation. It explains the terms "medicinal by presentation" and "medicinal by function" and outlines the various ways in which a product can be medicinal. A product which is not medicinal by function and for which no medicinal claims are made can be marketed without a marketing authorisation.

If you would like specific guidance about your products please contact the Enforcement Team (See section 7 for contact details). General information is also available on our website www.vmd.gov.uk. Please note however that while we can give guidance, only the courts can give a definitive interpretation of the legislation.

This booklet only offers guidance and is not definitive. It is ultimately the responsibility of the person or company marketing a product, to do so in accordance with the legislation. *Failure to comply with the Regulations is an offence punishable by a maximum penalty on summary conviction of a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or both, or on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.*

1.2 Definition of a Medicinal Product

The Veterinary Medicines Regulations define a "Veterinary 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.



2. Medicinal by Presentation

A product falling within the first part of the definition of a medicinal product is said to be medicinal by presentation. European Court of Justice case law demonstrates that a product is medicinal by presentation if the person responsible for placing the product on the market, or the manufacturer, or a connected third party, expressly indicates or recommends the product for treating or preventing disease. This may be by way of product labels, leaflets, advertisements or even oral recommendations, or by other forms of literature relating to the product issued before, during or after the sale.

In the absence of express indications or recommendations such as those described above, a product is also medicinal by presentation if it gives the averagely well-informed person the impression that the product treats or prevents disease.

All products which are medicinal by presentation must have a marketing authorisation before they can be placed on the market.

2.1 Medicinal words and phrases

Claims to treat or prevent disease are considered to be medicinal claims and would cause a product to be medicinal by presentation. Certain words are considered medicinal as they are normally associated with authorised medicinal products. Annex A contains a guidance list of frequently encountered words and phrases, and the VMD's position regarding their suitability for use in the promotion of non-medicinal products. It is important to note that **this is not an exhaustive list**, and it would be necessary to look at the whole presentation of the product to determine whether the words used make the product appear medicinal. The most up to date information can be found on our website www.vmd.gov.uk.

2.2 Diseases and adverse conditions

Reference, expressed or implied, to the treatment or prevention of a specific disease or adverse condition or to improving the condition of the animal treated may be considered a medicinal claim. Such a reference, for example, to the treatment or prevention of *scours*, *mastitis*, *colic*, *footrot*, *laminitis*, *eczema*, and also to *stress* related to nervous conditions such as hyperactivity, or any other condition which is not the normal state of a healthy animal, would usually amount to a medicinal claim.

References to the *nutritional maintenance of a healthy animal* / *healthy digestive system* / *healthy respiratory system* would not normally be regarded as medicinal claims.

The notes which follow are brief guidelines on particular points of difficulty. Please remember that these are just guidelines and are not to be treated as a definitive account of the requirements.



2.3 Articles in journals/magazines

Articles placed in journals/magazines by those persons responsible for the sale or supply of unauthorised veterinary products may not make medicinal claims. Editorials or readers' letters which make medicinal claims are not acceptable if they have been placed in the journal by, or on behalf of, those persons marketing the product.

2.4 Customer testimonials

If customer testimonials are used in connection with the marketing of a product and which report results containing medicinal claims, the claims will be taken to be those of that company marketing the product.

2.5 Websites

Websites are considered in the same way as any other form of advertising and must not make medicinal claims for products that do not hold marketing authorisations. Should a website incorporate a chat room or forum this must abide by the same rules as any other part of the website. UK based websites advertising non UK authorised veterinary medicinal products, intended for sale and administration outside the UK, must clearly indicate that the products will not be sold to UK customers. Overseas-based websites are generally considered to be outside of our control unless they are found to be targeting the UK market, for example by pricing in sterling or quoting UK delivery charges.

2.6 False & Misleading Claims

If a claim made for an unauthorised veterinary product is thought to be misleading or false but does not imply a medicinal effect, this would fall outside our remit. False advertising claims are the responsibility of local Trading Standards Officers under the Trade Descriptions Act 1968.

3. Medicinal by Function

A product is considered medicinal by function if it possesses properties for treating or preventing disease in animals or if it may be administered to animals with a view to restoring, correcting or modifying a physiological function.

All products which are medicinal by function must have a marketing authorisation before they can be placed on the market.

In order to establish whether a product has a medicinal function, the VMD will ask for its complete formulation, listing quantities of all ingredients. This information is treated in confidence. Products can also be considered medicinal due to their route of administration. For example a vitamin supplement administered in an injectable form would be considered medicinal. If the formulation of the product causes it to be considered medicinal by function, the company is required to apply for, and have granted, a marketing authorisation under the terms of the Regulations, before it can legally sell or supply the product in the United Kingdom.



Some ingredients may cause a product to be medicinal by function, either by their presence in the product at any level or by their presence above a certain concentration. However certain ingredients may fall under different areas of legislation depending on the quantity present and how they are administered. Annex B contains a list of ingredients and their suitability for use in non-medicinal veterinary products, **this is not an exhaustive list** and further details can be found on our website, www.vmd.gov.uk.

4. Specific topics

4.1 Vitamins and Minerals

A product which has not been authorised as a veterinary medicinal product in the United Kingdom should not, by its recommended rate of use, cause the overall level of any vitamin or mineral administered to an animal to go above what is generally considered to be its normal dietary requirement. Otherwise the product would be considered a deficiency treatment and as such would require authorisation. The vitamin and mineral levels stated in the Feeding Stuffs Regulations 2005 are considered to be the normal dietary requirement. A product containing vitamins or minerals in excess of these levels would be considered medicinal. A product which claims to correct a vitamin or mineral deficiency, or whose formula indicates that purpose, would be considered medicinal.

4.2 Feeding Stuffs Intended for a Particular Nutritional Purposes

The Feeding Stuffs Regulations 2005 (SI 2005/3281) set out a list of adverse conditions that require a particular diet. It may be possible to refer to one of these adverse conditions in connection with a product, if that product is being marketed as a dietetic feed in accordance with the labelling requirements of the above regulations. For further information you should contact the Food Standards Agency animal feeding stuffs helpline on 0207 276 8407.

The Feeding Stuffs Regulations 2005 are enforced by local Trading Standards Officers. Your local Trading Standards Office (contact your local council for details) will be able to provide individual advice on these Regulations.

NOTE: The Feeding Stuffs Regulations 2005 apply in England only, separate but parallel legislation is in force in Scotland, Wales and Northern Ireland.

4.3 Nutraceutical

Nutraceutical products are subject to the general definition of veterinary medicinal products. They are considered to be medicinal if presentational claims are made or if they contain certain herbal ingredients that exert a pharmacological effect on the target animal. In such cases, a marketing authorisation is required in the usual way (see Veterinary Medicines Guidance Notes 2 and 5 available on request from the VMD or on the VMD website: www.vmd.gov.uk).



4.4 Insecticides and Repellents

Any product applied to animals containing substances that kill insects, such as pyrethrins or organophosphorus compounds, is medicinal by function and therefore must have a marketing authorisation. Products containing a repellent, such as diethyltoluamide (DEET) or ethylhexanediol, without any form of insecticidal activity may be marketed without a marketing authorisation provided they claim only to repel insects. However, it should be noted that as from April 2002 products claiming to control by repelling or attracting came under the control of the Health and Safety Executive as part of the Biocidal Products Regulations (SI 2001/880). The marketing of such products are subject to the criteria as set out in the Regulations. For further information you should contact the Health and Safety Executive, Biocides & Pesticides Assessment Unit on 0151 951 3535.

Products applied only to housing and/or bedding fall within the scope of the Biocides legislation and would not be considered veterinary medicinal products. For further information contact the Biocides Information Section on the above number or www.hse.gov.uk.

4.5 Shampoos

A shampoo for animals will be considered medicinal if it contains an insecticide or is presented as an insecticidal shampoo. However, a medicated shampoo which claims for the control or prevention of dandruff or scurf is not considered medicinal. Reference to skin conditions such as seborrhoea and dermatitis should not be made in connection with an unauthorised shampoo.

4.6 Cosmetic Products

There are no specific regulations for cosmetic products for animals; they are subject to the general definition of veterinary medicines. Products that do not make specific medicinal claims and are used for cosmetic purposes only, such as colouring shampoos and hoof oils are not normally considered to be veterinary medicines.

4.7 Teat and Udder Products

Products applied to teats and udders are subject to the general definition of veterinary medicinal products. Teat dips are considered to be medicinal by presentation since they are used as aids for the prevention of mastitis. Thus, any product presented specifically as a teat dip applied to teats immediately after milking requires a marketing authorisation. Products applied to teats and udders which contain more than 0.3% iodine or chlorhexidine gluconate are considered medicinal by function. However, products other than teat dips which do not contain medicinal ingredients and make no medicinal claims, such as udder washes for use before milking, may be marketed without a marketing authorisation, although they may fall within the scope of the Biocidal Products Regulation (SI 2001/880).



4.8 Antiseptics

A product labelled as an antiseptic would indicate that the product may be used to treat or prevent disease and therefore would be regarded as medicinal by presentation.

A product applied to intact skin may claim to have antifungal or antibacterial properties without requiring a marketing authorisation.

4.9 Disinfectants

A product labelled as a *disinfectant* and which does not claim to treat or prevent disease would not be considered medicinal by presentation. However, it should be noted that only disinfectants approved under the Diseases of Animals (Approved Disinfectants) Order 1978 (as amended) (SI 1978/32) can be used for cleansing and disinfection procedures carried out under Orders made under the Animal Health Act 1981.

DEFRA has an approval scheme for disinfectants for use against notifiable diseases or for statutory cleansing and disinfection of markets, animal transport, etc. To obtain approval, disinfectants are tested at the Veterinary Laboratories Agency and the Institute for Animal Health. The manufacturer is charged a fee for this service. The list of approved disinfectants is set out in the Diseases of Animals (Approved Disinfectants) Order 1978 (as amended) (SI 1978/32). However, it should be noted that veterinary hygiene biocidal products are one of the product types covered by the Biocidal Products Regulations (SI 2001/880). For further information you should contact the Health and Safety Executive, Biocides and Pesticides Assessment Unit on 0151 951 3535.

4.10 Herbal Products

Herbal products are subject to the general definition of veterinary medicinal products. They are considered to be medicinal if presentational claims are made or if they contain certain herbal ingredients that exert a pharmacological effect on the target animal. For example, a product containing either pyrethrum, pyrethrins or alkaloids, such as digoxin from *Digitalis* sp., would be considered medicinal by function. In such cases, a marketing authorisation is required in the usual way (see Veterinary Medicines Guidance Notes 2 and 5 available on request from the VMD or on the VMD website: www.vmd.gov.uk).

4.11 Homeopathic Remedies

A simplified registration scheme has been implemented for homeopathic remedies for non-food producing animals which are placed on the market without medicinal claims and where there is sufficient dilution to guarantee safety of the product. Further details of the registration scheme can be found in Veterinary Medicines Guidance Note 9 (available from the VMD or www.vmd.gov.uk). All new homeopathic veterinary remedies to be placed on the market must either be registered under the scheme or have a full marketing authorisation. A marketing authorisation for a homeopathic product that was on the market prior to 1 January 1994 is optional, provided no medicinal claims are made. Homeopathic products are legally bound into UK law by the Veterinary Medicines Regulations.



4.12 Diagnostic Tools (Testing Kits) and Medical Devices

Any substance, or combination of substances administered to animals with a view to making a medical diagnosis, would fall within the definition of a veterinary medicinal product and would therefore require a marketing authorisation before it could be legally marketed in the UK. However, the withdrawal of fluid/tissue for diagnostic purposes and laboratory diagnostic tests is not considered medicinal.

4.13 Colostrum

Colostrum, or colostrum based products that contain pure colostrum are not required to hold a marketing authorisation provided that no reference is made to immunoglobulin, antibodies or immunity. Manufactured colostrum, including that from cows that have been treated to ensure the colostrum will contain particular antibodies, must be authorised in the normal manner.

5. Other Legislation

If a product does not fall within the definition of a veterinary medicinal product care should be taken to ensure that it meets the requirements of any legislation which might be relevant, such as:-

- The Food and Environment Protection Act 1985 as amended.
- The Control of Pesticides Regulations (SI 1986/1510) as amended.
- The Biocides Product Regulations (SI 2001/880) as amended.



6. Contact

For further information regarding unauthorised products contact:

The Enforcement Team

VETERINARY MEDICINES DIRECTORATE
Woodham Lane, New Haw
Addlestone, Surrey
KT15 3LS

Tel: 01932 338308

Fax: 01932 336618

Email: postmaster@vmd.defra.gsi.gov.uk

For further information regarding authorised products contact:

Licensing Administration Branch

VETERINARY MEDICINES DIRECTORATE
Woodham Lane, New Haw
Addlestone, Surrey
KT15 3LS

Tel: 01932 338452

Fax: 01932 336618

Email: postmaster@vmd.defra.gsi.gov.uk

Whilst the Veterinary Medicines Directorate will be happy to assist with the enquiries about any matters discussed in this booklet, you are reminded that it is ultimately the responsibility of the person or company marketing a product to ensure that such marketing complies with the regulations.

Copies of any national Regulations or Directives mentioned in this booklet are available from the 'Stationery Office Limited' or at <http://www.tso.co.uk>. Alternatively the OPSI website has access to Directives and Statutory Instruments at <http://www.opsi.gov.uk/legislation/index.htm>. A charge may be made for these publications.



ANNEX A

Frequently encountered words and phrases

Allergy / Allergen	Allergy is an adverse condition. Allergen is a substance that causes an allergy. Where appropriate, food intolerance should be used in place of allergy because whilst an allergy is an adverse condition, food intolerance is considered to be a nutritional problem.
Analgesic	Medicinal by presentation.
Antacid	Medicinal by presentation.
Anthelmintic	Anthelmintics are wormers. All wormers require a marketing authorisation.
Anti-allergy	Medicinal by presentation.
Anti-allogenic	Not medicinal by presentation.
Anti-bacterial	Not medicinal by presentation.
Anti-biotic	Medicinal by presentation.
Antibodies	The supplementation of antibodies has no valid purpose beyond the prevention of disease and is therefore medicinal.
Anti-coagulant	Medicinal by presentation.
Anti-fungal	Not medicinal by presentation.
Anti-inflammatory	Medicinal by presentation.
Anti-microbial	Medicinal by presentation.
Anti-oxidants	It is acceptable to state that a product contains anti-oxidants and that they help "mop up" / neutralise free radicals (excess or otherwise). However to associate anti-oxidant activity with adverse conditions or effects such as claiming to 'neutralise damage' or 'harmful free radicals' would constitute a medicinal claim.
Anti-protozoal	Medicinal by presentation.
Anti-pyrotic	Medicinal by presentation.
Anti-pruritic	Medicinal by presentation.
Anti-septic	Medicinal by presentation.
Anti-spasmodic	Medicinal by presentation.
Anti-viral	Medicinal by presentation.
Bactericide	Medicinal by presentation.
Boost	Medicinal by presentation, in relation to a physiological function.
Bute	Reference to Bute should be further qualified by brackets stating "This is not Phenylbutazone".
Combat the effects of aging	Should be replaced with 'helps maintain vitality in the older <species>.'
Cures	Medicinal by presentation.
Dose / Dosage	Medicinal by presentation.
Dressings (Wound)	Are considered a medical device if presented as a sterile barrier to protect wounds. If impregnated with a medicinal substance or presented as having an action on the wound outside of the above then it may be considered as a medicinal product.
Elixir	Medicinal by presentation.
Eradicate / Eliminate	Medicinal by presentation.
Expectorant	Medicinal by Presentation.
Free Radicals	Referring to damage caused by free radicals or "damaging free radicals" is a medicinal claim. Phrases such as "Mopping up free radicals" or "Targeting free radicals" are not medicinal by presentation. (See Anti-oxidants for more detail)



Fungicide / Fungicidal	Medicinal by presentation.
Heals	Medicinal by presentation.
Herbal Wormers	Any product claiming to be a 'Herbal wormer', or comparing itself to the action of a wormer, is considered to be making a medicinal claim as all wormers must be authorised as veterinary medicines.
Herbiotic	Medicinal by presentation.
Hypoallergenic	Not medicinal by presentation.
Improve(s)	Medicinal by presentation, in relation to a physiological function.
Keratolytic / Keratoplastic	Not medicinal by presentation.
Laxative	Medicinal by presentation.
Linctus	Medicinal by presentation.
Medicated Shampoo	Not medicinal by presentation.
Nutraceutical	Not medicinal by presentation.
Ointment	May only be used to describe a barrier cream.
Pesticide	Medicinal by presentation.
Pill	Medicinal by presentation.
Prescription diet	Comparison to a prescription diet is not medicinal by presentation.
Prevents	Medicinal by presentation.
Protects	Only acceptable in reference to a barrier action such as barrier creams.
Relieve	Medicinal by presentation.
Remedy	Medicinal by presentation. Common usage in relation to herbal & homoeopathic products means this is addressed on a case by case basis.
Repairs	Medicinal by presentation.
Solves	Medicinal by presentation when further qualified by an adverse condition eg. "Solves Laminitis".
Strengthens	Medicinal by presentation in relation to a physiological function or anatomical system.
Treat / Treatment	Medicinal by presentation.
Wounds	Medicinal by presentation. "Minor wounds or minor cuts and abrasions" is acceptable.



ANNEX B

Medicinal and borderline Ingredients

Adenosylmethionine (aka SAME)	There are references to the use of stable salts of this material in the treatment of depression, liver disorders and osteoarthritis. It is therefore medicinal by function when presented for this purpose.
Antibodies	The supplementation of antibodies has no valid purpose beyond the prevention of disease and is therefore medicinal.
Belladonna	Medicinal by function.
Benzalkonium Chloride	More than 0.02% in topical products is medicinal by function.
Benzoyl Peroxide	Medicinal by function if included as the active ingredient.
Bismuth Sub Carbonate	Medicinal by function when given orally.
Borage Oil	Medicinal by function.
Bronopol	Not medicinal by function at levels up to 0.1%.
Calamine	May be medicinal by function according to the level present.
Calcium salts (including Chloride and Propionate)	When intended to be given orally to cattle so as to give a calcium level of more than 45g per cow, is medicinal by function.
Capsaicin	At a level of 0.012% or greater in topical creams is considered medicinal by function.
Cetrimide	Medicinal by function at levels greater than 0.1%.
Chlorhexidine Gluconate	Medicinal by function at levels above 0.3%.
Chlorophene	Medicinal by function at levels above 0.2%.
Copper naphthenate	Medicinal by function.
Copper salts (including Sulphate)	When used topically, if the in-use concentration gives a level of copper exceeding 0.5% then it is medicinal by function.
Cypermethrin	Is an ectoparasiticide and is medicinal by function.
Diazolidinyl urea (CAS No 78491-02-8)	In topical preparations below 0.5% this is not considered to be medicinal by function.
Dibenzoyl Peroxide	Medicinal by function at levels greater than 2.5%.
Dichlorophen	For topical application it is not considered medicinal by function if levels are less than 0.5%. Products must have a label that it contains dichlorophen. For products intended for oral application, irrespective of the level, it is medicinal by function.
Diflubenzuron	Medicinal by function.
DMDM hydantoin (CAS No 6440-58-0)	In topical preparations below 0.6% this is not medicinal by function.
Ephedrine	Medicinal by function. Banned for use in competition animals.
Eye drops	Medicinal by function due to route of administration.
Fenticlor	Topical not medicinal by function at levels of 0.02% or less
Formaldehyde	A level of 0.2% in a topical shampoo is not medicinal by function.
Foxglove (Digitalis)	Medicinal by function.
Geranium oil	A level of 0.05% in a topical formulation is not medicinal by function.
Glutaraldehyde	Up to 1% Glutaraldehyde in a preparation intended for application to hooves is not medicinal by function.



Grapefruit seed extract (diphenol hydroxybenzene)	A level of up to 0.5% is not medicinal by function.
Guanidinopropionic acid	Medicinal by function.
Hexidine	Levels of 0.1% or more are medicinal by function.
Injections	Medicinal by function due to route of administration.
Imidurea	A level of no more than 0.5% is not medicinal by function.
Iodine	A level of no more than 0.3% is not medicinal by function.
Iodoform	A level of no more than 10% is not medicinal by function.
Ispaghula (pysllium)	Medicinal by function.
Kaolin	For internal use in liquid formulations, levels of no more than 5% are not medicinal by function.
Ketaconazole	Levels of 1% or less are not medicinal by function.
Lactic Acid	When applied topically, levels of 5% or less are not medicinal by function.
Malachite Green	Banned from use in food producing species including farmed fish.
Methoprene	Medicinal by function.
Methyl nicotinate	Levels of 0.1% or less are not medicinal by function.
Methyl salicylate (wintergreen)	Levels of 0.2% or less are not medicinal by function.
N-Acetylcysteine	Medicinal by function.
Nicotine	Topical – Medicinal by function.
Oxyquinole	Levels of 0.2% or less are not medicinal by function.
Parabens	Levels of 0.25% or less are not medicinal by function.
Permethrin	Medicinal by function.
Potassium Bromide	Medicinal by function.
Potassium Iodide	Levels of 1% or less are not medicinal by function.
Povidone Iodine	Up to 3% is allowed without being medicinal by function.
Pyrethrins	Medicinal by function.
Pyrethrum	Medicinal by function.
Resmethrin	Medicinal by function.
Scullcap	Medicinal by function.
Sulphur	Levels of 5% or less are not medicinal by function.
Thymol	Thymol at any concentration in a product intended for use on bees or in their hives is considered medicinal by function
Undecylenic Acid	Levels of 2% or less in a topical product are not medicinal by function.
Willow Bark	Medicinal by function when given orally.
Zinc oxide	Levels of 5% or less in a topical product are not medicinal by function.
Zinc salts (including chloride and sulphate)	When applied to hooves, if the in-use concentration gives a level of zinc exceeding 2.0% then it is medicinal by function.



