



Veterinary  
Medicines  
Directorate

## **VETERINARY MEDICINES**

This document has been withdrawn as the content is out of date. Refer to [Veterinary medicines guidance - GOV.UK](https://www.gov.uk/guidance/veterinary-medicines-guidance)

# **CONTROLS OF VETERINARY MEDICINES**

Last updated July 2013

## QUICK START GUIDE

---

This Veterinary Medicines Guidance Note (VMGN) is aimed primarily at companies and individuals involved in the development and marketing of veterinary products who wish to market their products in the UK in accordance with the Veterinary Medicines Regulations (VMR).

The quick start guide is a summary of the provisions of the VMR; detailed information is found in the body of the guidance note.

The Veterinary Medicines Directorate's (VMD) aim is to protect public health, animal health and the environment and to promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines. The VMD will meet this aim through proportionate regulation, providing high quality services to stakeholders and clear agreements with service providers.

The VMD's aim is the responsible, safe and effective use of veterinary medicinal products, through regulatory services that meet the needs of consumers, industry, and government and that operate in an efficient and sustainable manner, whilst providing value for money.

The VMD's main statutory functions include assessing veterinary medicines for safety, quality and efficacy and granting Marketing Authorisations (MAs) to those veterinary medicines which meet the specified criteria; regulating the manufacture and distribution of veterinary medicinal products and animal feedingstuffs containing veterinary medicines and specified feed additives; surveillance of Adverse Events (AE) and the provision and implementation of policy advice on these matters to Ministers.

This guidance note explains when a product comes within the definition of a veterinary medicinal product and under what circumstances a product needs an MA. It details the various ways in which a product can be considered medicinal and the subsequent requirements for an MA and obligations placed on holders of MAs in the UK.

## FURTHER INFORMATION

---

Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: +44 (0)1932 336911; Fax: +44 (0)1932 336618, or e-mail: [VMGNNotes@vmd.defra.gsi.gov.uk](mailto:VMGNNotes@vmd.defra.gsi.gov.uk). Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website ([www.vmd.defra.gov.uk](http://www.vmd.defra.gov.uk)).

## TABLE OF CONTENTS

Contents	Paragraph	Page
<b>Introduction</b>	<b>1</b>	<b>5</b>
<b>Legislation and Guidance</b>		
European Community Law	3	5
Definition of Veterinary Medicinal Product	10	6
<b>Medicinal by Presentation</b>	<b>13</b>	<b>7</b>
Medicinal Word and Phrases	17	7
Diseases and Adverse Conditions	18	8
Marketing and other Promotional Material	20	8
Disclaimers	21	8
Reference to Studies	22	8
Customer Testimonials	23	9
Websites	24	9
False and Misleading Claims	26	9
Product Form	27	9
Packaging Presentation	28	9
<b>Medicinal by Function</b>	<b>29</b>	<b>9</b>
<b>Specific Topics</b>		
Feeding Stuffs intended for Particular Nutritional Purposes	31	10
Nutraceuticals	33	10
Insecticides and Repellents	34	10
Shampoos	37	10
Cosmetic Products	38	10
Teat and Udder Products	39	11
Disinfectants	40	11
Herbal Products	41	11
Homeopathic Remedies	42	11
Diagnostic Tools (Testing Kits)	43	11
Colostrum	44	11
<b>Products Excluded from the Scope of the Regulations</b>	<b>46</b>	<b>12</b>
<b>Obtaining Advice</b>	<b>47</b>	<b>12</b>
How to Apply	49	12
Fees	56	13
<b>Requirements for a Marketing Authorisation</b>	<b>57</b>	<b>13</b>
Administration of Products	58	13
Marketing and Administration in Exceptional Circumstances	60	14
The Centralised Procedure	62	14
The National Procedures	63	14
Mutual Recognition and Decentralised Procedures	64	14
Provisional Marketing Authorisations	66	14
Application, Grant and Renewal	69	15
Exemption from Prescription requirement for certain food animal Products	71	15
Obligations in Respect of Enforcement Activities	72	16
<b>Other Legislation</b>	<b>73</b>	<b>16</b>
<b>Further Information</b>	<b>74</b>	<b>16</b>

<b>ANNEX A</b>	<b>18</b>
APPLICATION FORM FOR OBTAINING ADVICE	
 List of Abbreviations	 <b>22</b>

WITHDRAWN AS OUT OF DATE

## Introduction

1. This is one of a series of Veterinary Medicine Guidance Notes (VMGNs) explaining the requirements under the Veterinary Medicines Regulations (VMR). The VMR are revoked and replaced on a regular basis, so the references to the VMR should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument is not shown in the VMGN. This VMGN will be updated as necessary and the date of the most recent update is shown on the front cover. The VMR set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration.
2. The purpose of this guidance note is to describe the controls on veterinary medicines.

## Legislation and Guidance

### European Community Law

3. In November 2001, the main Community provisions relating to veterinary medicines were consolidated into a new directive – Directive 2001/82/EC on the Community code relating to veterinary medicinal products (VMPs). Following an extensive review of the operation of the Community procedures this was amended by Directive 2004/28/EC of 31 March 2004. Any reference to 'the Directive' should be taken as Directive 2001/82/EC as amended by Directive 2004/28/EC.
4. Regulation (EEC) No 2309/93 established a Community "centralised" authorisation procedure and a European Agency for the Evaluation of Medicinal Products (EC) No 726/2004. This sets out current provisions for the European centralised authorisation procedure under which the European Commission may issue a marketing authorisation (MA) that is valid in all Member States (MS). It also sets out modified provisions for the structure and operation of the European Agency and relevant committees.
5. Additionally, Commission Regulations (EC) No 1084/2003 and 1085/2003 control the variation of Marketing Authorisations (MA) issued under the centralised and decentralised/mutual recognition procedures respectively. Separate European Union (EU) legislation applies to controls on residues of veterinary medicines in animals and foodstuffs, which are outside the scope of this VMGN.
6. EU legislation for veterinary medicines is published by the European Commission in *The Rules Governing Medicinal Products in the European Union, Volume 5 - Pharmaceutical Legislation, Veterinary Medicinal Products*, which is updated periodically to take account of new legislation. This and other volumes in the same series are available on the Commission website:  
[http://www.ec.europa.eu/health/index\\_en.htm](http://www.ec.europa.eu/health/index_en.htm) or in print from The Stationery Office Ltd (telephone: 0870 600 5533) or from the Office for Official Publications of the European Communities in Luxembourg:  
[http://www.publications.europa.eu/index\\_en.htm](http://www.publications.europa.eu/index_en.htm) EU legislative documents are also available individually on the internet:  
[http://www.europa.eu/documentation/legislation/index\\_en.htm](http://www.europa.eu/documentation/legislation/index_en.htm)

7. The European Commission has also published guidance on the requirements of the relevant Community law in the *Rules Governing Medicinal Products in the European Union - Notice to Applicants, Veterinary Medicinal Products*, which is available in three volumes. Volume 6A covers procedures for marketing authorisations, Volume 6B gives guidance on the presentation and content of the data dossier required in support of an application and Volume 6C provides guidelines on various regulatory aspects. These volumes are available as above.
8. This VMGN relates to the provisions as implemented in the UK and it supplements, but does not replace, the Commission guidance in the *Notice to Applicants*, and should be read with it.
9. The VMR control VMP, including pre-mixes for medicated feeding stuffs, which are intended to be placed on the market within the UK. This VMGN examines what this means.

### Definition of Veterinary Medicinal Product

10. Because they transpose the requirements of EU legislation, the VMR use the Community law definition of veterinary medicinal product. Article 1.2 of the Directive defines a "VMP" 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.*

11. A product may be a VMP because it falls within the first limb of the definition and is medicinal by presentation by giving the averagely well-informed consumer the impression that the product treats or prevents disease and/or because it falls within the second limb of the definition and is medicinal by function.
12. Although modified by the Directive, the definition continues to apply to products that are said to be medicinal "by presentation" or medicinal "by function". The VMR apply the provision in Article 2.2 of the Directive that, where a product falls within both the definition of a VMP and that of another type of product that is subject to other Community legislation, it is subject to the controls of the veterinary medicines legislation. This principle has, to a large extent, been followed for some time. For example, a number of veterinary medicines for the treatment of ectoparasites such as fleas, ticks and lice, which could be regarded as pesticides, have historically been regulated as veterinary medicines.

## Medicinal by Presentation

13. A product is medicinal by presentation if it gives the averagely well informed consumer the impression that the product treats or prevents disease, or if the averagely well-informed consumer gains that impression.

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 oral recommendations, or by other forms of literature relating to the product issued before, during or after the sale.

14. The case law of the European and domestic courts has established a number of principles relating to the presentation of products. In particular:
- The concept of presentation of a product must be broadly construed;
  - The presentation will be that of the manufacturer but that is not limited to the terms by which or the manner in which the manufacturer elects to package, describe or classify the product. When considering whether a product is medicinal by presentation, regard should be had to the warnings and express indications and recommendations on the packaging but they are not conclusive of the position;
  - The external form of the product may be relevant to ascertaining the manufacturer's intention but may also be material to the impression gained by the averagely well informed consumer;
  - The means of administration is an aspect of the presentation;
  - The fact that a product is not only used externally but is used internally may be relevant to its presentation and function.
15. Unless it benefits from the provisions of Schedule 6 to the VMR (Exemptions for small pet animals), a product which is medicinal by presentation must have an MA granted by the Secretary of State (SoS) or the European Medicines Agency (EMA) before it can be placed on the market.
16. Products marketed under the provisions of Schedule 6 of the VMR may be presented with medicinal claims provided that they comply with all the requirements of the scheme. For further information please refer to VMGN 12 Exemptions for Small Pet Animals, which is published on the Veterinary Medicines Directorate's (VMD's) website: [http://www.vmd.defra.gov.uk/public/vmr\\_vmgn.aspx](http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx)

### Medicinal Words and Phrases

17. Claims a product will treat, prevent or control a disease make a product medicinal by presentation. Certain words are considered medicinal as they are normally associated with authorised medicinal products. It is important to note that it will be necessary to look at the whole presentation of the product, including the packaging to determine whether the words used make the product appear medicinal.



## Diseases and Adverse Conditions

18. In Ballières's comprehensive veterinary dictionary (Blood & Studdert, Baillière Tindall, 1988), the term disease is defined as follows:

*“disease traditionally defined as a finite abnormality of structure or function with an identifiable pathological or clinicopathological basis, and with a recognizable syndrome of clinical signs. Its cause is more often than not unknown.*

*This definition has long since been widened to embrace subclinical diseases in which there is no tangible clinical syndrome but which are identifiable by chemical, haematological, biophysical, microbiological or immunological means. Nowadays it is becoming so that the definition is used even more widely still to include failure to produce at expected levels in the presence of normal levels of nutritional supply and environmental quality. It is to be expected that the detection of residues of disqualifying chemicals in foods of animal origin will also come to be included within the scope of disease.”*

19. References, expressed or implied, to the treatment or prevention of a disease or adverse condition or to improving the condition of the animal treated are medicinal claims. Such a reference, for example, to the treatment or prevention of *scours, mastitis, colic, footrot, laminitis, eczema*, and to *stress* related to nervous conditions such as hyperactivity, or any other condition which is not the normal state of a healthy animal, would be medicinal. 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.**

## Marketing and other Promotional Material

20. Claims made by a 3<sup>rd</sup> party, such as magazine reviews or articles published by independent analysts, will be taken to be those of the company marketing the product where evidence confirms that the 3<sup>rd</sup> party has a connection to the marketing company by way of solicitation, endorsement, sponsorship or funding.

## Disclaimers

21. Disclaimers e.g. on packaging or other marketing material, that declare the product to not be a VMP, or that any claims made are not intended to present the product as medicinal, are not sufficient to prevent a product from being considered medicinal by presentation.

## Reference to Studies

22. References in marketing material to studies may cause a product to be considered medicinal if the study indicates that the product, or one of its constituents, may have a medicinal effect or purpose.



### **Customer Testimonials**

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

### **Websites**

24. Product websites (including any chat room or forum) are considered in the same way as any other form of advertising and should not make medicinal claims for products that do not hold an MA.
25. UK based websites advertising non-UK authorised VMP, intended for sale and administration outside the UK, must clearly indicate that the products will not be sold to UK customers.

### **False and Misleading Claims**

26. 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 the remit of the VMR. False or misleading advertising claims about products that are not VMP are dealt with by local Trading Standards Officers under the Trade Descriptions Act 1968.

### **Product Form**

27. The dosage form in which a product is presented and the instructions for administration will be considered in determining if a product is medicinal by presentation. A product may be considered to be medicinal if it is presented in a form that suggests a medicinal purpose. For example a product such as a vitamin supplement administered by injection, may be considered to be medicinal by virtue of its presentation.

### **Packaging Presentation**

28. The appearance and design of packaging, and its similarity to that of authorised medicines will be taken into account when considering if a product is medicinal by presentation.

### **Medicinal by Function**

---

29. A product is medicinal by function if it is used or administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or making a medical diagnosis. Risk to health is a factor that must be taken into account when classifying a product as medicinal by function.
30. A product which is medicinal by function must have an MA granted by the Secretary of State or the EMA before it can be placed on the market. This requirement does not apply to those products marketed under Schedule 6 of the VMR.

## Specific Topics

### Feeding Stuff Intended for Particular Nutritional Purposes

31. The Animal Feed (England) Regulations 2010 (SI 2010/2503) provides for additives for nutritional purposes. For further information you should *contact the Food Standards Agency animal feeding stuffs helpline on 0207 276 8829*.
32. The Animal Feed (England) Regulations 2010 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 Animal Feed (England) Regulations 2010 apply in England only, separate but parallel legislation is in force in Scotland, Wales and Northern Ireland.

### Nutraceuticals

33. Nutraceutical products (a food or naturally occurring food supplement marketed as having a beneficial effect on health) are treated like any other products. They require a Marketing Authorisation if medicinal claims are made or if they contain certain ingredients that exert a pharmacological effect on the target animal.

### Insecticides and Repellents

34. Veterinary products which contain substances that kill insects or external parasites, such as pyrethrins, pyrethroids or organophosphate compounds, are medicinal by function and therefore, must have an MA. Products containing a repellent, such as diethyltoluamide (DEET) or ethylhexanediol, which is an insect repellent and not an insecticide may be marketed without an MA provided they claim only to repel external insects. The marketing of such products must be in accordance with Health and Safety Executive (HSE) Regulation as part of the Biocidal Products Regulations (SI 2001/880). For further information you should contact the Chemicals Regulation Directorate, [biocides@hse.gsi.gov.uk](mailto:biocides@hse.gsi.gov.uk), [www.hse.gov.uk/biocides/index.htm](http://www.hse.gov.uk/biocides/index.htm)
35. A veterinary product claiming, or which has the function of, control of internal parasites is considered to be a VMP and therefore must have an MA.
36. Products applied only to housing and/or bedding fall within the scope of the Biocides legislation and would not be considered a VMP.

### Shampoos

37. A shampoo for animals will be considered medicinal if it contains an insecticide or an ingredient which has a pharmacological effect or is presented as an insecticidal shampoo. Reference to skin conditions such as seborrhoea and dermatitis are medicinal and should not be made in connection with an unauthorised shampoo.

### Cosmetic Products

38. 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 considered to be veterinary medicines as long as they do not contain any pharmacologically active ingredients.

### Teat and Udder Products

39. Products applied internally to teats and udders for the prevention of mastitis will be considered to be medicinal and will require an MA before they are placed on the UK market. Products applied topically to disinfect teats and udders and for which no medicinal claims are made will be regarded as biocidal products and dealt with by the HSE under the Biocidal Products Regulations (SI 2001/880). Companies making such products are advised to contact the HSE for guidance.

### Disinfectants

40. A product labelled as a disinfectant and which does not claim to treat or prevent disease does not require an MA. However, disinfectants may be regarded as biocidal products and be dealt with by the HSE under the Biocidal Products Regulations (SI 2001/880). Companies making such products are advised to contact the HSE for guidance.

### Herbal Products

41. Herbal products are treated like any other products. They require an MA if they are medicinal by presentation or function. For example, a product containing pyrethrum, pyrethrins or alkaloids, such as digoxin from *Digitalis* sp., would be considered medicinal by function.

### Homeopathic Remedies

42. A simplified registration scheme has been implemented for homeopathic remedies which are placed on the market without medicinal claims and where there is sufficient dilution to guarantee safety of the product. For further information please refer to VMGN 7 Veterinary Homeopathic Remedies, which is published on the VMD's website [www.vmd.defra.gov.uk/public/vmr\\_vmgn.aspx](http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx).

All new homeopathic veterinary remedies to be placed on the market must either be registered under the scheme or have a full MA. An MA for a homeopathic product that was on the market prior to 1 January 1994 is optional, provided no medicinal claims are made.

### Diagnostic Tools (Testing Kits)

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

### Colostrum

44. Colostrum or colostrum based products that contain pure colostrum are not required to hold an MA provided that no reference is made to disease, immunoglobulin, antibodies or immunity. Manufactured colostrum, including that from cows that have been treated to ensure the colostrum will contain particular antibodies, must have an MA.

45. Further information on the importation of bovine colostrum and colostrum based products can be found at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:237:0001:0009:EN:PDF>

or by contacting the Specialist Service Centre for Imports on telephone number 01245 398298 or e-mail [AHITChelmsford@animalhealth.gsi.gov.uk](mailto:AHITChelmsford@animalhealth.gsi.gov.uk)

## Products Excluded from the Scope of the Regulations

---

46. The VMR do not apply to:

- inactivated immunological VMP's that are manufactured from pathogens or antigens obtained from an animal and used for the treatment of that animal or other animals on the same site;
- veterinary medicines based on radioactive isotopes.

## Obtaining Advice

---

47. If you are in any doubt as to whether a specific product requires an MA you will be able to obtain confirmation from the VMD through a formal process. A fee is applicable for this procedure, the details of which can be found in the Veterinary Medicines Regulations, Schedule 7, which are published on the VMD website: [http://www.vmd.defra.gov.uk/public/vmr\\_legislation.aspx](http://www.vmd.defra.gov.uk/public/vmr_legislation.aspx)

48. It is not mandatory to seek formal confirmation of a product's status before it is placed on the UK market. However, should a product be placed on the market without an MA and it is deemed to be a veterinary medicine, enforcement action will be taken which could result in the product being seized without compensation.

### How to Apply

49. Application forms are available at Annex A or on the VMD's website: [http://www.vmd.defra.gov.uk/pharm/forms\\_new.aspx](http://www.vmd.defra.gov.uk/pharm/forms_new.aspx). Each application should be signed by the applicant or in the case of a corporate body by a proper officer and be accompanied by the supporting information referred to in the application form.

50. Applications may be submitted electronically by e-mail to: [borderline@vmd.defra.gsi.gov.uk](mailto:borderline@vmd.defra.gsi.gov.uk) or in duplicate hard copy to the Enforcement team.

51. The following information must accompany each application:

- Product name;
- Product dosage form (e.g. tablet, capsule, cream) and the way in which it is to be administered or applied;
- Whether the product contains an active substance that has been authorised as either a human or veterinary medicinal product in the UK/EU.
- Purpose of the product;
- Complete formula, listing active substances and other substances and the level and the purpose of each of these;
- Administration rate, frequency and duration;

- Product's mode of action;
- Any risks that use of the product may entail;
- Description of the container in which the product will be supplied (a sample may be requested as your application is considered);
- Mock-ups of the labels, leaflets and any associated literature which will be supplied with the product;
- Claims or wording that will be used to promote the product;
- Whether or not the product is authorised as a medicine in any EU country or you have been advised by another EU country that an MA is required.

52. All relevant information submitted in support of such applications is treated as commercially confidential.
53. Each application will be acknowledged and validated to check that all necessary information has been supplied within 10 calendar days of receipt.
54. Once an application has passed validation it will be considered by VMD staff. Within 30 calendar days of the application passing validation you will be informed of the VMD's view on whether a marketing authorisation is required, or will be asked to provide further information.
55. At the end of the procedure, the VMD will send a formal letter confirming whether an MA is required or not. This decision is only valid based on the documentation submitted as part of the application. Small changes to any of the information provided could invalidate the decision.

#### **Fees**

56. On receipt of a valid application, the VMD will send an invoice to the applicant for the correct amount per product as per application.

### **Requirements for a Marketing Authorisation**

---

57. The VMD require that any person who places a VMP on the market does so in accordance with an MA granted by the Secretary of State or by the EMA. In order to be legally placed on the market in the UK a VMP must be the subject of an MA valid in the UK.

#### **Administration of Products**

58. The VMD prohibit the administration of a VMP unless:
  - it is the subject of an MA;
  - it has been registered under the simplified scheme for homeopathic remedies
  - or has been notified to the VMD for inclusion on the "grandfather rights" list;
  - it is exempt from the requirements of an MA under the small pet animal exemption scheme;
  - it has been imported by a veterinary surgeon or his agent for the purpose of administration under the cascade;

- further restrictions apply in the case of food-producing animals.

59. Exceptions are provided for products administered for research purposes in accordance with a certificate granted by the Secretary of State or administered in accordance with the provisions of the VMR (including the “cascade”).

### **Marketing and Administration in Exceptional Circumstances**

60. The VMR provide that, where the health situation so requires, the Secretary of State may authorise the marketing or administration to animals of a VMP authorised in a country other than the UK.

61. There are four routes by which an MA may be obtained. These are summarised below. Except for Provisional Marketing Authorisations (PMA) the data requirements and criteria for authorisation are the same under each route.

### **The Centralised Procedure**

62. This is obligatory for high technology products and growth promoters defined in the Annex to EU Regulation 726/2004. It is optional for other innovative veterinary medicines. Under this procedure, applications are made to the EMA. MAs are issued by the European Commission and are valid in all EU MS.

### **The National Procedure**

63. This applies to products not already authorised in the EU and for which authorisation is required in only one MS. In the UK applications are made to the VMD who issue MAs. MAs issued under this procedure are valid in the UK only.

### **Mutual Recognition and Decentralised Procedures**

64. These apply where an applicant wishes to obtain authorisations for a product in two or more MS. If an authorisation has already been issued in the EU, the holder may apply to one or more MS to issue identical authorisations on the basis of mutual recognition of the “reference” authorisation.

65. Where an authorisation has not been issued, the applicant may submit identical applications to each MS in which authorisation is required and request one to act as “reference” MS (RMS). This is known as the decentralised procedure. MAs are issued by each MS to which an application is made on the basis of approval of the assessment report and related documents produced by the RMS. A binding arbitration procedure applies where MS are unable to agree a decision on an application.

### **Provisional Marketing Authorisations (PMA)**

66. In accordance with Article 26(3) of the Directive, a PMA may be granted in exceptional circumstances without the provision of a full data dossier. For further information please refer to VMGN 2 Marketing Authorisations for Veterinary Medicinal Products, which is published on the VMD’s website:

[http://www.vmd.defra.gov.uk/public/vmr\\_vmgn.aspx](http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx).

67. Neither Community nor UK law define “exceptional circumstances” although the Directive provides that such authorisations may only be granted for “objective and verifiable reasons”. The facility may be useful when there is no suitable authorised medicine available to treat a particular disease or to treat a new disease in the UK. A



new disease could either be one that has not previously been recorded in the UK, or an existing disease whose pattern has changed to such an extent that existing remedies have ceased to be effective.

68. A PMA will normally be valid for 1 year and may be subject to special conditions, dependent upon the circumstances prevailing in any individual case. Anyone interested in the possibility of applying for a PMA should contact the VMD at as early a stage as possible.

### **Application, Grant and Renewal**

69. The VMR transpose the provisions of Community law concerning MA, applications for which must be made in accordance with the provisions of the VMR and be accompanied by the data specified therein. For further information please refer to VMGN 2 Marketing Authorisations for Veterinary Medicinal Products, which is published on the VMD's website [http://www.vmd.defra.gov.uk/public/vmr\\_vmgn.aspx](http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx)
70. The VMD, acting on behalf of the Secretary of State, is the UK national competent authority for authorising VMP. It considers each application according to either the national or the decentralised/mutual recognition procedures. If the product meets the criteria of safety, quality and efficacy, has a favourable risk/benefit balance and does not contravene any other provision of Community law, an authorisation will be issued. Unless it is a PMA, it will be valid for 5 years initially.

### **Exemption from prescription requirement for certain food animal products**

71. In accordance with European law, veterinary medicines for food-producing animals would normally be required to be available only on prescription (either POM-V or POM-VPS). However, all MS may exempt a product for a food-producing species from this requirement if it meets all of the following criteria:
- a) the administration of a VMP is restricted to formulations requiring no particular knowledge or skill in using the products;
  - b) the VMP does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;
  - c) the summary of product characteristics (SPC) of the VMP does not contain any warnings of potential serious side effects deriving from its correct use;
  - d) neither the VMP nor any other product containing the same active substance has previously been the subject of frequent serious adverse event reporting;
  - e) the SPC does not refer to contra-indications related to other VMP commonly used without prescription;
  - f) the VMP is not subject to special storage conditions;
  - g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;



- h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

### Obligations in Respect of Enforcement Activities

72. The VMR provide for enforcement. They include provision for the appointment of enforcement officers and powers to carry out enforcement activities including powers of entry, inspection of premises, examination of records and documents, taking of samples and seizure of products. The VMR require MA holders to allow authorised enforcement officers to carry out their duties and exercise their powers as appropriate.

### Other Legislation

73. If a product does not fall within the definition of a VMP 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 1997/188) as amended.
  - The Biocidal Products Regulations (SI 2001/880) as amended.
  - The Animal Feed (England) Regulations 2010 (SI 2010/2503) as amended.

### Further Information

74. Whilst the VMD will be happy to assist with 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 VMR.
75. Copies of any national Regulations or Directives mentioned in this guidance are available from the 'Stationery Office Limited' or at [www.tso.co.uk](http://www.tso.co.uk). *Alternatively the Office of Public Sector Information (OPSI) website has access to Directives and Statutory Instruments at [www.opsi.gov.uk/legislation/index.htm](http://www.opsi.gov.uk/legislation/index.htm).* A charge may be made for these publications.
76. For further information regarding **unauthorised** products please contact:
- The Unauthorised Products Team  
 Veterinary Medicines Directorate  
 Woodham Lane, New Haw  
 Addlestone, Surrey  
 KT15 3LS
- Tel: 01932 338308 / 338310  
 Fax: 01932 336618  
 E-mail: [borderline@vmd.defra.gsi.gov.uk](mailto:borderline@vmd.defra.gsi.gov.uk)

77. For further information regarding **authorised** products please contact:

Licensing Administration Branch  
Veterinary Medicines Directorate  
Woodham Lane, New Haw  
Addlestone, Surrey  
KT15 3LS

Tel: 01932 336911

Fax: 01932 336618

Email: [postmaster@vmd.defra.gsi.gov.uk](mailto:postmaster@vmd.defra.gsi.gov.uk)

WITHDRAWN AS OUT OF DATE

# ANNEX A

APPLICATION FORM FOR OBTAINING ADVICE

WITHDRAWN AS OUT OF DATE



ASSURING THE SAFETY, QUALITY & EFFICACY  
OF VETERINARY MEDICINES

## BORDERLINE PRODUCT ADVICE FORM

**Please use this form to request advice from the VMD on an unauthorised product only.**

Your request for advice will be acknowledged and a full reply will be sent in due course. Please be aware that submitting requests for advice on several products may cause a delay in our ability to respond. For this reason, we will normally limit our initial response to a maximum of 6 products. Any additional products are likely to be considered separately and at a later date depending on available resources.

Please provide as much detail as possible. Fields indicated with a \* are mandatory.

### Contact details:

Contact name\*  Title\*

Correspondence  
address\*

Postcode\*

Telephone number

E-mail address

Confirm e-mail address

### Company Details

Reference number (if any)

Company name\*

Company address\*

Invoicing address if  
different from above \*

### About the Product

**Note:** Opinion will only be based on the information provided

Product name\*

Product form\*   
e.g. tablet, capsule,  
cream etc.

**Please include details of the amount of each ingredient. If the ingredient is herbal, please give the botanical name and the part of the plant being used.**

**Ingredients\***

Ingredient	Amount/Purpose	Ingredient	Amount/Purpose
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Does this product contain an active ingredient authorised in either a human or veterinary medicine in the UK/EU?\*

*If YES, give details.*

Administration rate, route, frequency and duration.\*

Purpose of product?\*

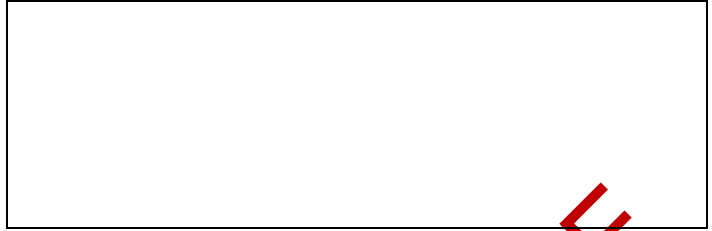
Any risks the use of the product may entail?

Product's mode of action.

Description of the container in which the product will be supplied.

**Claims/wording used to promote the product**

*Please give the actual text or wording used to promote the product\**



**Note:** All promotional material, including planned website pages, relating to the product must be attached.

**Note:** Opinion will only be based on the information provided.

Signed:

WITHDRAWN AS OUT OF DATE

## List of Abbreviations

<b>AE</b>	Adverse Event
<b>Defra</b>	Department for Environment, Food & Rural Affairs
<b>EC</b>	European Commission
<b>EEA</b>	European Economic Area
<b>EMA</b>	European Medicines Agency
<b>EU</b>	European Union
<b>HSE</b>	Health and Safety Executive
<b>MA</b>	Marketing Authorisation
<b>MS</b>	Member State
<b>NFA-VPS</b>	Non-Food Animal – Veterinarian, Pharmacist, Suitably Qualified Person
<b>OPSI</b>	Office of Public Sector Information
<b>PMA</b>	Provisional Marketing Authorisation
<b>POM-V</b>	Prescription Only Medicine - Veterinarian
<b>POM-VPS</b>	Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person
<b>RMS</b>	Reference Member State
<b>SoS</b>	Secretary of State
<b>VMD</b>	Veterinary Medicines Directorate
<b>VMGN</b>	Veterinary Medicines Guidance Note
<b>VMP</b>	Veterinary Medicinal Product
<b>VMR</b>	Veterinary Medicines Regulations



WITHDRAWN AS OUT OF DATE

#### **VETERINARY MEDICINES GUIDANCE NOTE**

Veterinary Medicines Directorate  
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS  
Telephone (+44) (01932) 336911 Fax: (+44) (01932) 336618  
Search for VMD on [www.gov.uk](http://www.gov.uk)