



Veterinary Medicines Guidance Note

Veterinary Homeopathic Remedies

No 9

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**ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES**



THESE NOTES ARE ONLY A GENERAL GUIDE AND MUST NOT BE TREATED AS A COMPLETE OR AUTHORITATIVE STATEMENT OF THE LAW ON ANY PARTICULAR CASE

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INVESTOR IN PEOPLE

REGISTRATION OF VETERINARY HOMEOPATHIC REMEDIES

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INTRODUCTION

1. This is one of a series of Veterinary Medicine Guidance (VMG) Notes explaining the requirements under the Veterinary Medicines Regulations ('the Regulations'). The Regulations are revoked and replaced every year, so the references to them should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument is not included in this VMG Note. The VMG Notes will be updated as necessary and the date of the most recent update is shown on the front cover. The Regulations set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration.
2. This VMG note explains the procedures for the registration of homeopathic remedies, together with other ways in which homeopathic remedies may be placed on the market in the UK. The registration scheme provides a procedure for homeopathic remedies which are placed on the market without therapeutic indications and where there is sufficient dilution to guarantee the safety of the remedy.

PLACING VETERINARY HOMEOPATHIC REMEDIES ON THE MARKET

3. There are several ways in which homeopathic remedies may be placed on the market in the UK:
 - a. the remedy as manufactured by a specified manufacturer may be registered with VMD through the registration scheme;
 - b. the remedy may have 'grandfather rights' and have been included in the list of such remedies as manufactured by a specified manufacturer (see paragraph 7);
 - c. the remedy may be prepared extemporaneously and supplied directly to the end user by a pharmacist in a registered pharmacy in accordance with a homeopathic manufacturing procedure described in an official European Pharmacopoeia;
 - d. the remedy may be prescribed by a veterinary surgeon and either already registered or authorised for human use or have been prepared extemporaneously in accordance with the provisions of the prescribing cascade.
4. At present remedies classified as sarcodes or nosodes are not considered to fall within any of the above categories. The European Commission has been requested to advise on the status of these remedies with particular reference to whether they should be considered to be immunological products and / or whether there is any risk of transmission of spongiform encephalopathies through them such that their use should not be permitted. As soon as the advice is received interested parties will be informed and this VMG Note updated.

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REQUIREMENTS FOR ALL VETERINARY HOMEOPATHIC REMEDIES

5. In all cases the remedy must be manufactured by a person holding a manufacturing authorisation (MA) that covers the manufacture of this type of product. The provisions in the Regulations that relate to possession, manufacture, supply, administration and pharmacovigilance apply in exactly the same way as they do to any other veterinary medicinal product.

GRANDFATHER RIGHTS

6. Any remedy that was placed on the UK market before 1 January 1994 may continue to be manufactured and marketed without being registered through the scheme detailed below. This is because they were on the market when the registration scheme was introduced.
7. These remedies have so called “Grandfather Rights” provided they have been entered onto the list held by the VMD. **It is the responsibility of the manufacturer to have advised the VMD that the remedy is eligible for these rights and have made a declaration to that effect so that the remedy has been placed on the list.** The list of remedies eligible for “Grandfather Rights” is available on our website (www.vmd.gov.uk) under Product Information.

THE HOMEOPATHIC REGISTRATION SCHEME

8. It is not necessary to register all homeopathic remedies under the Scheme. Remedies made in other ways as described in paragraph 3 are outside the scope of the scheme and are covered separately.
9. However, there are additional categories of remedy which are also treated differently:
 - *remedies making specific therapeutic claims, including immunological claims*
 - *remedies not considered sufficiently dilute to guarantee safety*
 - *the route of administration is not as described in the European Pharmacopoeia or an official pharmacopoeia of a Member State*
10. These are considered to fall within the normal definition of a veterinary medicinal product and therefore require an MA before they can be placed on the UK market.

REMEDIES WHICH ARE ELIGIBLE FOR REGISTRATION

11. A single registration may cover multiple dosage forms and routes of administration and different degrees of dilution providing they are all derived from the same homeopathic stock or stocks. To be eligible for registration a veterinary homeopathic remedy must be:

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1. prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described in an official EU pharmacopoeia;
2. administered by a route described in such a pharmacopoeia, such as an oral or topical form;
3. sufficiently diluted to guarantee safety, that is, may not contain more than 1 part in 10,000 of the mother tincture.

WHERE TO APPLY

12. Applications for veterinary homeopathic remedies should be sent to:

Information Management Section
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

13. It would help the VMD to process your application more efficiently and speedily if, in addition to paper copies, you could provide an electronic copy of the application or of any parts of it that are available electronically. All word processing formats are acceptable but Microsoft Word held on a CD-ROM is preferred.

HOW TO APPLY

14. Multiple dosage forms, multiple routes of administration and different degrees of dilutions may be covered by a single registration provided they are all derived from the same homeopathic stock or stocks.
15. If you wish to apply for a registration under the homeopathic scheme then you must complete the application form which is available on the VMD web site under Industry Information / Applications Page and submit the data required below.
16. Applications should be made in accordance with the Regulations on the required form. They should be in English and be signed by the applicant. Three separately bound copies of the complete application should be submitted.

SUPPORTING DOCUMENTATION

17. Please submit all data detailed in Annex A, in two separate volumes as below:

Volume 1 should include:

- Manufacturing authorisation number;
- A copy of any registrations or authorisations by other EC Member States;

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- A copy of any authorisations granted for the remedy under the equivalent human registration scheme;
- Proposed labelling.

Volume 2 should include:

- Production and control of homeopathic stocks;
- Production and control of dosage form;
- Stability of the dosage form.

18. Companies wishing to submit more than ten applications for registration simultaneously should contact the VMD so that the timing can be arranged in order to ensure sufficient resources are available.

LABELS

19. At the time of application, where possible, mock-ups accompanied by text should be submitted with a new application. Where this is not possible, text should be submitted before the application can be validated. However, mock-ups must be submitted before the assessors can sign off an application. The assessors will deal with the submission of mock-ups during the assessment period and will inform the applicant of any required changes.

HOW THE VMD HANDLES APPLICATIONS

20. Your application will be validated within 10 days of receipt by the VMD. This process ensures that the application is complete, legible and in the required form. In all cases you will be notified of whether your application is considered valid or not. If one or more of the requirements have not been met you will be asked to either rectify the problem, or the application will be returned to you. Otherwise the application will be passed to the appropriate assessors.
21. VMD assessors will evaluate the application within 50 days from the date the application passed validation. If further information is required then the VMD assessors will explain to you what is required, and why. In this event the “clock” will be suspended until a reply is received.
22. Following a decision by assessors to approve the application, the registration documents will be issued to you within 10 days of final sign-off. If the decision is that a registration should not be granted you will be notified in writing.

THE Vh SYMBOL

23. If, following assessment, it is concluded that a registration should be issued, the registration holder will be required to include the **Vh** symbol as part of their registration number on product labelling, and packaging.

LEGAL CLASSIFICATION FOR SALE AND SUPPLY

24. The classification of a veterinary homeopathic remedy will follow the requirements of the distribution categories for Marketing Authorisations for veterinary medicinal products as detailed in VMG Note 3: *Marketing Authorisation for Veterinary Medicinal Products – Distribution Categories*. However, it is normally expected that most remedies will be distributed through the AVM – GSL (Authorised Veterinary Medicine – General Sales List) category.

OBLIGATIONS ON HOLDERS OF REGISTRATIONS

25. You must manufacture the remedy in accordance with the data submitted and approved, together with any conditions advised within the approval. Should you wish to make any changes to the manufacture or other data submitted prior to registration, approval must first be obtained through a variation.
26. A registration may be suspended or revoked should the remedy prove to be harmful under normal conditions of use, where its composition is not as declared or where any material information provided in connection with the application is found to be incorrect. Companies will be given the right of appeal. For further information please refer to VMG Note 11- *Appeals Procedures*.

RENEWALS AND VARIATIONS OF REGISTRATIONS

RENEWALS

27. Once a registration has been granted, it will initially be valid for five years. After five years, for the product to continue to be registered, it must be renewed, i.e. the registration will be re-assessed on the basis of the risk/benefit balance.
28. The renewal application must be submitted at least six months before the end of the five year period, and no earlier than nine months before. If a renewal application is not received, the registration will expire and the remedy must not be marketed. Whilst the VMD will normally inform you that your registration is due to expire this is a courtesy and it remains the responsibility of the registration holder to ensure that renewal applications are submitted in a timely manner.
29. A registration will only be renewed in its existing form. For any changes to be made, a variation application must be submitted and paid for separately.
30. Once renewed the registration will remain valid indefinitely unless the VMD considers a single, additional renewal is justified on grounds of pharmacovigilance (surveillance of suspected adverse reactions to the product) five years after the first renewal, or unless the registration is revoked or expired.

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VARIATIONS

31. If you wish to make a change to the formal documentation, or underlying data, submitted in support of the registration you should submit a variation application to the VMD. For example, if you wish to extend the shelf life of the product this would constitute a variation. However, an addition of a further stock (regardless of whether or not it has been previously registered or assessed) is not considered to be a variation, and an application for a new registration should be submitted.
32. For reasons of consistency the VMD will process variations to registrations in the same way as for variations to Marketing Authorisations. Guidance is available in VMG Note 4: *Marketing Authorisations for Veterinary Medicinal Products – National (IA/IB/II) Variation procedures*.

LABELLING OF REGISTERED HOMEOPATHIC REMEDIES

33. The labelling of containers and packages, and leaflets enclosed or supplied with the remedy, must contain the following but no other information:
 - (a) the words “homeopathic remedy without approved therapeutic indications for veterinary use”;
 - (b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used. If the homeopathic remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks;
 - (c) the name and address of the registration holder and (on the package leaflet) of the manufacturer;
 - (d) the method and, if necessary, route of administration;
 - (e) the expiry date;
 - (f) the pharmaceutical form;
 - (g) the contents of the pack;
 - (h) any special storage precautions;
 - (i) the target species;
 - (j) any necessary special warnings, i.e. “Keep out of reach of children”;
 - (k) the batch number; and
 - (l) the registration number.
34. The terms of the registration may permit difference to this if it is necessary for public or animal health purposes or for the protection of the environment.

CHANGES TO APPROVED LABELLING

35. All changes to labelling must be submitted for prior approval as a variation application. However, cosmetic modifications of labels are permissible without prior approval so long as **all** the requirements of the Regulations are met, all the information remains clear and all parts of the text are given the same prominence as they had on the original label.

REGISTRATION OF HOMEOPATHIC REMEDIES REGISTERED IN ANOTHER MEMBER STATE

36. Where a veterinary homeopathic remedy is registered in another Member State in accordance with their simplified registration procedure, an identical registration may be granted in the UK on the basis of mutual recognition. Where a registration is issued, the remedy will be allocated a distribution category in accordance with UK legislation.
37. To register a remedy in accordance with these provisions, the following information must be submitted to the VMD:
 - The Member State where the remedy is registered;
 - Three copies of the application that has been registered in that Member State;
 - A copy of the registration or a document attesting to it;
 - A signed declaration that the formulations are identical;
 - The withdrawal period, together with all requisite justification;
 - A mock-up of the labelling/packaging which should conform to the requirements of paragraph 33.
38. All documents should be in English or should be provided with an English translation attached.

MANUFACTURING AUTHORISATION

39. Manufacturers of homeopathic veterinary remedies require authorisation in order to manufacture the remedies. These are issued on behalf of the VMD by the Medicines and Healthcare products Regulation Agency (MHRA). Further information on different types of manufacturing authorisation is available in VMG Note 10.
40. Manufacturing Authorisations are not required for remedies which are marketed as eligible for “Grandfather Rights”.

PHARMACOVIGILANCE

41. Pharmacovigilance requirements for homeopathic remedies, including products eligible for “grandfather rights”, are the same as for products with MAs. Guidance on Pharmacovigilance is available in VMG Note 13.

FEES

42. Details on the relevant fees can be found in the Veterinary Medicines Regulations, which are available on the VMD website. An invoice will be sent once the application has been validated.

FURTHER INFORMATION

43. 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: VMGNotes@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.gov.uk).

ANNEX A

Accompanying Data

DATA REQUIRED TO ACCOMPANY THE APPLICATION FORM

REMEDY DETAILS:

- Scientific name (or other name used in a pharmacopoeia) of the homeopathic stock(s).
- Pharmaceutical form.
- Route of administration.
- Degree of dilution to be registered.

PRODUCTION AND CONTROL OF HOMEOPATHIC STOCKS

- A dossier describing how the homeopathic stock(s) is/are obtained and controlled.
- Bibliographic justification of the homeopathic nature of the stock(s).

The homeopathic stock should be named, with reference to an appropriate pharmacopoeial monograph. It must be prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission.

Please provide information on the source material (e.g. name of supplier, batch data), details concerning the preparation of the homeopathic stock, and batch data. In some cases additional information may be requested before the application is approved.

The homeopathic nature of the stocks used to prepare remedies should be justified by reference to a recognised homeopathic bibliography.

Where remedies contain substances which are of animal origin, it is necessary to include a description of all the methods taken to ensure the absence of pathogens from within that substance. Reference should also be made to the CPMP/CVMP guidelines 'Minimising the Risk of Transmitting Agents Causing Spongiform Encephalopathy via Medicinal Products' (Vol. III, addendum 2), and details should be provided of the relevant controls applied.

If any of the stocks you are using are, themselves, registered homeopathic remedies, you must provide the full registration numbers of these remedies.

Raw materials and vehicles used should be of an appropriate pharmacopoeial quality unless adequately justified.

The quantity of raw materials and vehicles used for each batch should be specified. If batch sizes vary, then a representative batch size should be stated.

The nature of containers used for the maceration process should be described, together with the times and conditions used.

CONTROL OF STARTING MATERIALS:

Raw Materials

Raw materials used should comply with the section on raw materials set out in individual monographs of a homeopathic pharmacopoeia.

In some instances it may be necessary to include additional controls for monographed raw materials, for example:

Plant Material

- Microscopic examination.
- Limit tests for pesticides - details of all pesticides used should be given
- Description of the part of the plant used
- Details of the geographical source of the plants and details of the cultivation methods and collection of plants/plant parts.
- Documentation should be provided to demonstrate that full testing for compliance with all specifications of source materials has been carried out.

Minerals of Natural Origin

- Bioburden controls and proof of the absence of pathogens.

Zoological Material

- Details of animal husbandry should be given.
- Details of the collection method of materials should be given.
- Documentary proof to demonstrate the absence of pathogens, fungal, bacterial and, wherever possible, viral contamination should be provided.

It is recognised that where companies purchase materials from elsewhere, some of the necessary documentation may not be forthcoming. In such cases companies can arrange for information to be sent, on a commercially restricted basis, directly to the VMD by the suppliers. Alternatively, if this is not possible, then applicants must demonstrate the quality of the starting materials that they use by providing details of the inspection and tests that they have carried out to verify that the materials meet the given specifications.

BOTANICAL NOMENCLATURE

The botanical identity of materials must be clearly defined. In order to avoid confusion and to facilitate easy passage of applications for remedies containing botanical materials, this reference should, wherever possible, be to the currently accepted names, synonyms and botanical authorities quoted in the 'Index Kewensis'.

ADDITIONAL INFORMATION

Applicants should provide data to demonstrate compliance with the agreed monograph (batch data or certificates of analysis for three batches). Where additional controls are necessary, evidence should be provided to show that these controls have been met.

Supporting data for plant material should include details of the source of the material, cultivation and time of harvesting. Details of any drying procedure used, and any treatment to reduce levels of microbial contamination should be stated. It is preferable for plant material to be grown organically.

Supporting data for zoological material should include information on the collection, treatment and storage of the source material.

VEHICLES

Vehicles used for the preparation of homeopathic stocks should be of an appropriate pharmacopoeial specification unless justified.

CONTROL OF STOCKS

A specification should be provided for each stock.

Applicants should provide satisfactory evidence in the form of batch data or certificates of analysis to demonstrate that the stock meets the agreed specification.

Where additional controls are used for monographed stocks, evidence should be provided to show that these are met.

STABILITY OF STOCKS

Evidence of stability should be provided unless stocks are freshly prepared for immediate use.

The stability of homeopathic stocks should be established with due reference to the specification used to control the stock at the time of preparation.

Stability should be monitored over an appropriate time period in controlled conditions and a suitable shelf-life established, for example two years. This work may be carried out on an on-going basis, and applicants may apply to extend the shelf-life in the light of available information.

Manufacturers of stocks should provide clear advice concerning storage conditions, for example, "Store below 25°C", "Protect from light".

Diluted stocks should be assigned the same shelf-life (expiry date) as the original stock.

JUSTIFICATION OF THE HOMEOPATHIC NATURE OF THE STOCK

Reference should be made to a suitable Materia Medica such as Clarke or Bøericke. Where a stock has not been included in a Materia Medica, appropriate literature references should be provided.

PRODUCTION AND CONTROL OF THE DOSAGE FORM

- A manufacturing and control file for each pharmaceutical form.
- A description of the method of dilution and potentiation.

Where the diluted homeopathic stock is to be added to a base, for example a cream, ointment or pillule, details of the manufacture of that formulation must be provided. If the information you are giving relates to a number of remedies that are produced by one company, please provide the information in the form of a formulation masterfile.

The quality standards applied to homeopathic medicines are similar to those applied to allopathic medicinal remedies. The special nature of homeopathic remedies is such that where manufacturing processes for dosage forms are standardised, the supporting data on the formulation can be held in a masterfile to which the applicants may cross refer. Due to the extremely low levels of stocks present in the dosage form, it is particularly important to ensure that adequate planning and in-process control is applied to the manufacturing process in order to ensure batch to batch homogeneity.

FORMULATION MASTERFILES

Applicants may choose to present data on 'inert' or 'un-medicated' dosage forms (for example lactose tablets or dilution fluids) in the form of a formulation master file to which they may cross-refer following its approval.

The Formulation Master File should contain the following information:

- Formulation details
- Development pharmaceuticals
- Container to be used for marketing
- Method of manufacture, in-process controls, including application of the diluted stocks
- Specification for the inert or un-medicated dosage form
- Batch data for the inert or un-medicated dosage form
- Stability data for the inert or un-medicated dosage form

Complete composition

Full details of the formulation should be provided including the theoretical composition of excipients in the final formulation.

Development pharmaceuticals

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Details should be provided of any development work which is relevant to the formulation such as preservative efficacy data for topical creams, oral liquids, eye drops and multi-dose injections.

Container

A brief description of the container and closure should be provided.

Manufacture

Applicants should refer to the method set out in a named homeopathic pharmacopoeia, and should provide supplementary information as set out below. Applicants will be expected to comply with good manufacturing practice requirements (Directive 91/412/EEC) and take account of any special requirements for the production of homeopathic remedies (as set out in the Annex to the 'Orange Guide' to Good Manufacturing Practice). The following information should be included:

Batch size and manufacturing formula

Details of a typical batch size should be provided.

The quantity of stock to be added to the dosage form and the degree of dilution of the stock prior to it being added should be declared.

The manufacturing process

The key elements of the manufacturing process and any standard operating procedures used should be summarised.

Details should be provided of all measures taken to avoid cross-contamination. Any sterilisation procedures should be described.

In-process controls

Where in-process controls are used, for example during the dilution process, these should be stated.

Process validation

Information on process validation should be made available, particularly with regard to more sophisticated dosage forms. For sterile remedies (eye drops, intramammary remedies and injections) an accepted pharmacopoeial method of sterilisation should be used.

Specifications

Specifications should be provided for raw materials and stocks.

Specifications of excipients to be used in the un-medicated dosage form should be declared.

Container and closure specifications (size and shape) should be listed, and details should be provided of the materials used in their construction.

Finished Product Specification

The finished product specification should control the organoleptic and physical characteristics of the remedy. Where possible an identity test should be included for the stock at low dilutions.

The finished product specification should take account of any special characteristics of the dosage form. For example, assay limits are required for preservatives, and sterility tests are required for remedies such as eye drops, intramammary remedies and injections.

Analytical Controls

All methods used should be pharmacopoeial (e.g. BP, PhEur). Where a method is not appropriate, a suitable, validated alternative should be used.

Batch Data

Batch data should be made available for at least three consecutive batches which should preferably be production batches.

Dilution and Potentiation

Details of the homeopathic method used for dilution and potentiation should be provided, together with the method used to incorporate the diluted stock into the inert dosage form. Validation data should be provided to demonstrate that this process is uniform.

The quality and quantity of diluent should be described, and details of any in-process controls provided.

Stability Studies

Stability studies should be carried out on at least two batches of the remedy stored for at least six months in the container for marketing and should be conducted at a defined temperature or range of temperatures. The results should justify the proposed shelf-life of the remedy. The extent to which stability studies are carried out will require careful consideration, and will depend upon the nature of the remedy. Examples of what might be required include preservative efficacy data for creams, or maintenance of alcohol content for oral liquids.

For parenteral preparations supplied in multi-dose containers in-use stability data should be provided. The purpose of such testing is to establish a period of time during which the remedy may be used following the removal of the first dose of remedy from the container without adversely affecting the integrity of the remedy. Further information on the data required can be found in the CVMP's Note For Guidance, 'In-use Stability Testing of Veterinary Medicinal Products' (EMA/CVMP 127/95).

The stability of tablets or granules medicated using high dilutions of stock can be established and the results extrapolated to other tablets, provided an identical container and manufacturing process are used.

For more complex dosage forms such as creams, intramammary remedies, injections or multidose eyedrops, stability should be evaluated for individual formulations.

STABILITY OF THE DOSAGE FORM

- Data concerning the stability of the remedy.

Stability testing of the dosage form is necessary to ensure that the finished product specifications are met throughout the claimed shelf life. This includes evidence to show that the dosage form remains stable over the claimed shelf life at a specified temperature.

REGISTRATION BY OTHER EUROPEAN ECONOMIC AREA (EEA) STATES

A copy of any registrations or authorisations obtained for the same remedy in other EEA states, including the number of the relevant manufacturing authorisation and all other supporting data submitted to that Member State. (The EEA comprises the EU Member States plus Iceland, Liechtenstein and Norway).

REGISTRATION BY THE MEDICINES & HEALTHCARE PRODUCTS REGULATORY AUTHORITY (MHRA)

A copy of any certificates of registration granted by the MHRA for the human version of the remedy under the equivalent human scheme, including all the supporting data submitted to the MHRA.

If you are applying to register a homeopathic remedy for veterinary use that is already registered under the equivalent human scheme, you will need to provide the VMD with all the details that you submitted to the MHRA, together with your completed application form and a copy of the MHRA's registration. There are a number of small differences between the two schemes which you may need to take into consideration when applying to the VMD. In conjunction with the dosage regime, you will need to identify the target species on either the label and/or sales presentation that you submit for each remedy.

LABELLING

A specimen or mock-up of the outer packaging and immediate packaging of the remedy to be registered. You should use the dummy code **Vh 9999/9999** on your mock-up or specimen label.

BIOLOGICAL SUBSTANCE

In the case a remedy containing biological substances, a description of the measures taken to ensure the absence of pathogens.

WITHDRAWAL PERIOD

It is necessary to detail the proposed withdrawal period necessary to ensure that the provisions of Regulation (EEC) No. 2377/90 are complied with together with all necessary justification.

APPLICATIONS FOR REMEDIES ALREADY REGISTERED ELSEWHERE IN THE EEA

If you are applying to register a homeopathic remedy for veterinary use that is already registered elsewhere in the EEA, you will need to provide the VMD with all the details that you submitted in your application to the original Member State, together with a copy of the certificate of registration. You will additionally need to submit all the requisite details to the VMD in English.

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