

Veterinary Medicines Guidance Note

The Registration of Homoeopathic Veterinary Medicinal Products Scheme

No 9



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES



December 2005

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

VETERINARY MEDICINES DIRECTORATE

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INVESTOR IN PEOPLE

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INTRODUCTION

1. This is one of a series of guidance notes explaining requirements under the Veterinary Medicines Regulations 2005. These regulations came into effect on 30 October 2005 and set out controls on Veterinary Medicinal Products in the UK. This Guidance note explains the procedures for the registration of Homoeopathic products under the Homoeopathic Medicinal Product Scheme. The scheme provides a simplified registration procedure for homoeopathic products, which are placed on the market, without therapeutic indications, and where there is sufficient dilution to guarantee the safety of the medicinal product.
2. The following products are outside the scope of this simplified scheme and are therefore not covered by this guidance note:
 - *Products making specific therapeutic claims, including immunological claims;*
 - *Products not considered sufficiently dilute to guarantee safety;*
 - *Products made up extemporaneously in response to a prescription.*
3. Any product that was placed on the UK market before 1 January 1994, may continue to be manufactured and marketed without being registered under this scheme. **It is the responsibility of the manufacturer to provide proof of the date the product was first placed on the market. This is a provision in the Regulations.**

PRODUCTS WHICH ARE ELIGIBLE FOR REGISTRATION

4. To be eligible for registration, a veterinary homoeopathic product must satisfy *all* of the following criteria:
 - It must be prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission;
 - It must be for administration by a route described in the appropriate pharmacopoeia;
 - It must be sufficiently dilute to guarantee safety and, in particular, it must contain no more than one part per 10,000 of the mother tincture, *and*, where the active principle is a veterinary prescription only medicine (POM), it must be at least 100 times more dilute than the smallest dose used in an allopathic veterinary medicine.

HOW TO APPLY FOR REGISTRATION UNDER THE HOMOEOPATHIC SCHEME

5. If you wish to apply for a registration under the homoeopathic scheme then you must complete the application form at Annex A and submit all data detailed at Annex C. Application forms and data must be submitted in English. If available, it would help the processing of your application if, in addition to paper copies, you provide an electronic copy of the dossier, or of any parts of it that are available electronically.
6. Four unbound copies of the application form, together with four (bound and paginated) copies of the supporting data should be sent to: Information Management Section, Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS.
7. Data should be submitted in two separate volumes:

Volume 1 should include:

- Manufacturing authorisation number;
- A copy of any registrations or authorisations by other EC Member States;
- A copy of any authorisations granted for the product under the equivalent human registration scheme;
- Proposed labelling.

Volume 2 should include:

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

ASSESSMENT OF APPLICATIONS

8. Your application will be validated by the VMD within 10 calendar days of receipt. This is a quality control procedure to ensure that all required information and number of copies have been provided. You will then be informed whether the application has passed validation or not. If one or more of the requirements have not been met the application will fail validation and you will be asked to either rectify the problem or the application will be returned to you.

Your applications will be processed within 20 calendar days from the validation date. However, if further information is required then the clock will be stopped. In this event, the VMD will explain to you what is required and why. The clock will not re-start until we are in receipt of the requested information.

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9. The VMD will notify you in writing when the application has been approved informing you of the registration number for your product.
10. If the decision following the assessment of the application is that an authorisation should not be granted, your rights of appeal will be explained to you. For further information please refer to VMG Note 11: *Marketing Authorisation for Veterinary Medicinal Products – Appeal Procedures*.

OBLIGATIONS ON HOLDERS OF REGISTRATIONS

11. You must manufacture the product 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 prior authorisation of a variation must be obtained.
12. A registration may be suspended or revoked where the product proves to be harmful in the 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 the VMG Note 11.

VARIATIONS AND RENEWALS OF REGISTRATIONS

DURATION OF REGISTRATIONS

13. Once issued, the registration will initially be valid for five years. Upon completion of this five year period, the registration holder must apply for a renewal which will authorise the product indefinitely unless it is revoked or expired.
14. Registration holders should apply for renewal at least 6 months before the expiry date. If a registration lapses a fresh application will be required, and the product must not be marketed until a new registration has been issued. Whilst 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 before the registration expires.

VARIATIONS TO REGISTRATIONS

15. Applications to vary registration details should be submitted to the VMD's Information Management Section. Applications to extend the shelf life of products constitute variations however, 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.

LEGAL CLASSIFICATION FOR SALE AND SUPPLY

16. The classification of a veterinary homoeopathic product 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*.

REGISTRATION OF HOMOEOPATHIC PRODUCTS AUTHORISED IN ANOTHER MEMBER STATE

17. Where a veterinary homoeopathic medicinal product is registered in another member state in accordance with the simplified registration procedure, an identical registration may be granted in the UK on the basis of mutual recognition. Where a registration is issued, the product will be allocated a distribution category in accordance with UK legislation.

To register a product in accordance with these provisions, the following information must be submitted to the VMD:

- The Member State where the product is registered
- 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 20.

All documents should be in English or should be provided with an English translation attached.

MANUFACTURING AND IMPORT

MANUFACTURING AUTHORISATIONS

18. Manufacturers of homoeopathic veterinary medicinal products require authorisation in order to manufacture the products. These are issued on behalf of the VMD by the Medicines and Healthcare products Regulation Agency (MHRA). Please refer to VMG Note 10 'Manufacturing and Wholesale Dealer's Authorisations for Veterinary Medicines' for more information.

IMPORT AUTHORISATION:

19. A company that imports registered veterinary homoeopathic products from non-EEA countries will need an import authorisation. Please refer to VMG Note 7 'Import Certificate Schemes' for further information.

LABELLING OF REGISTERED HOMOEOPATHIC PRODUCTS

20. The labelling of containers and packages, and leaflets enclosed or supplied with the product, must conform to the provisions of the Veterinary Medicines Regulations 2005.

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CHANGES TO APPROVED LABELLING

21. All changes to labelling should 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.

FEES

22. Details on the relevant fees can be found in the Veterinary Medicines Regulations 2005, which are available on the VMD website (www.vmd.gov.uk/). The fee should not accompany the Homoeopathic application.

FURTHER INFORMATION

23. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: (+44) (01932) 336911, or Fax: (+44) (01932) 336618. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website (www.vmd.gov.uk/).

ANNEX A

Application Form



ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

VETERINARY MEDICINES DIRECTORATE
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Enquiries: 01932 336911 Fax: 01932 336618

For Licensing Authority Use	
Application No.	
VMP No.	
Date Acknowledged	
Cost Centre Code	
Invoice No.	
Amount £	
Signature	
Date	

Section A

APPLICATION FOR THE REGISTRATION OF A HOMOEOPATHIC VETERINARY MEDICINAL PRODUCT

Please complete this form in BLOCK LETTERS but before you do so please read VMG Note 9 – The Registration of Homoeopathic Veterinary Medicinal Products Scheme

- On receipt of this application the VMD will check if it is complete and, if so, will acknowledge its receipt and issue an invoice.
- Four copies of the complete application should be submitted to the VMD.
- The application must be accompanied by specimens or mock-ups of the packaging, labels and package inserts.

Section 1 – Applicant Details

1. Full name and address of the person submitting the application

2. Name and address of the proposed holder of the registration (if different to 1. above)

3. Company number, if known

Section 2 – Product Details

4. Name and Product

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5. Homoeopathic stock(s)

Stock Name	Specification	Dilution	Scale	Relevant Registration	Applications Other

6. Other Constituents:

	Name/ Specification	Modifier	Quantity/Dose Unit of % Quantity	Unit
Diluent				
Pharmaceutical Base Ingredient				

7. Pharmaceutical Form:

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8. Nature of Container and Closure:

Nature of Container	
Nature of Closure	
Pack Size	
Unit	
Shelf-Life A	
Shelf-Life B	

9. Route of Administration

10. Intended Target Species

11. Proposed Legal Status (POM-V, POM-VPS, NFAM or AVM-GSL)

Section 3 – Application Status

12. If this product has been registered for human use under the MHRA's scheme please provide the name by which the product is known under the scheme, the registration number and the date of registration.

Name of Product	Registration Number	Date of Registration

13. If this product has been registered for veterinary use in any other Member State(s) please provide the name of the Member State(s), the registration number(s) and the date(s) of registration.

Member State	Registration Number	Date of Registration

Section 4 – Manufacturing Details

14. Name, Address and Manufacturer's Authorisation number for all the proposed sites for manufacture of the homeopathic stocks:

15. Name, Address and Manufacturer's Authorisation number for all the proposed sites for manufacture of the pharmaceutical base:

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16. Name, Address and Manufacturer's Authorisation number for all the proposed sites for manufacture of the finished product:

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Section 5 – Additional Information

17. Please complete the following to indicate where the necessary additional information for your product may be found

- (a) A brief description of the method of manufacture
Please indicate the page number at which it can be found
- (b) A specimen or mock-up of the proposed packaging
Please indicate the page number at which it can be found.
- (c) Have you provided an index to your dossier? Yes/No*
If yes, please indicate the page number at which it can be found.
- (d) Have you provided details of the finished product specification? Yes/No*
If yes, please indicate the page and paragraph number at which it can be found.
- (e) Are there any special warnings necessary for your product? Yes/No*
If yes, please provide the page and paragraph number at which they can be found.
- (f) Are there any special storage requirements for your product? Yes/No*
If yes, please provide the page and paragraph number at which they can be found.

18. Please provide the following addresses, where applicable.

i. The Storage Premises:

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ii. The Assembler:

iii. The Importer:

iv. The Distributor:

v. The site at which quality control will be carried out:

Section 6 - Declaration

I/We apply for the grant of a registration in respect of the product(s) to which this application form relates, the said registration to be for a period of five years.

Signature

Date

Name in
BLOCK LETTERS

Status

WARNING: If any matters stated in this application are false or incomplete in a material particular the Ministers may refuse this application or revoke your registration if granted.

Please send your completed application form and all accompanying data to the Information Management Section, Homoeopathic Registration Scheme, VMD at the address shown on page 1.

* Please delete as applicable

ANNEX B

Notes on the Completion of the Application Form

NOTES ON THE COMPLETION OF THE APPLICATION

PRODUCTS MANUFACTURED WITHIN THE EEA

Please submit a separate application for each series of dilutions or triturations and for each pharmaceutical form for which you seek registration. (For example, a series of dilutions prepared as Arnica tablets 6x, 6c, 30c and 200c may be covered in a single application form. A second application would be required for Arnica drops 6c and 30c). For combination products, please complete a separate application form for each formulation.

APPLICANT DETAILS

1. The full name and address of the person submitting the application.
2. The full name and address of the proposed holder of the registration if it is different to point 1.
3. Company number if known.

PRODUCT DETAILS

4. The name of the product, using the correct scientific or pharmaceutical name of the homoeopathic stock, the type of dosage form and the dilution.
5. Details of the homoeopathic stock as follows:-

Stock Name and Specification	Describe the stock using the correct scientific name. The specification should be that of a relevant pharmacopoeia.
Dilution	The degree of dilution, e.g. 6, 30 etc.
Scale	The scale of potency, i.e. x for decimal, c for centesimal
Relevant Registration	Details of any other the relevant registration number.
Other Applications	Details of any relevant related application in progress in the UK.

6. Details of the other constituents as follows:

Diluent	The name and specification of diluents e.g. Ethanol BP or Lactose EP. The quantity should be listed as 'qs' in the modifier column.
Pharmaceutical Base Ingredient	List all excipients present in the final pharmaceutical form; include the specification and quantity per unit dose for tablets or % quantity for liquids, creams etc..

REGISTRATION OF HOMOEOPATHIC VMPS

7. **Pharmaceutical form** e.g. tablet, cream etc.
8. **Container and closure**

Nature of container and closure	Brief description of the container and closure e.g. 'amber glass tablet bottle, with polypropylene screw-on cap'.
Pack Size	Containing numbers of units only. Unit Where applicable enter the unit of measure as g, mL in the Unit box.
Shelf Life (A) = unopened container Shelf Life (B) = after opening for the first time	The shelf life should be expressed in months (M), weeks (W), or days (D).
9. **Route of administration** e.g. oral, topical, ophthalmic.
10. **Target species** The terms 'for Pet Animals Only' and 'for Non Food-Producing Animals Only' are acceptable.
11. Please request Legal Status (distribution category) of your product e.g. POM-V, POM- VPS, NFA-VPS, AVM-GSL etc. The approved classification will be determined during assessment and may differ from your request.

APPLICATION STATUS

12. Details of any registrations you hold for a related human product.
13. Please provide details of any registrations you hold elsewhere in the EEA for this product.

MANUFACTURING DETAILS

14. Name, address and Manufacturer's Licence number for: -

- the manufacture of the homoeopathic stocks.
- the manufacture of the pharmaceutical base.
- the finished product.

If the manufacturer of the stock and base (e.g. lactose tablets) differs from that of the final dosage form, please give details.

ADDITIONAL INFORMATION

17. The description of the method of manufacture refers to the final dosage form, and should include the method of dilution used. Reference to a Pharmacopoeia is not acceptable. Points (c) to (f) include YES/NO boxes, please indicate whether or not these points are relevant to your product and provide the additional information if necessary. For example some dosage forms may require a special warning regarding their use, and if special storage conditions are necessary you should

include precise details e.g. 'Store below 25°C'. Terms such as 'Room Temperature' or 'In a cool place' are not acceptable.

18. Where applicable please provide the addresses for the storage premises, the assembler, the importer and the distributor. You must provide details of the site at which quality control testing will be carried out and you should include the name of the person or organisation responsible for the quality control of the finished product.
- 19 If any part of the product will be manufacturer outside of the EEA, please provide the address of the manufacturer.

ANNEX C

Accompanying Data

DATA REQUIRED TO ACCOMPANY THE APPLICATION FORM

PRODUCT DETAILS:

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

PRODUCTION AND CONTROL OF HOMOEOPATHIC STOCKS

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

The homoeopathic stock should be named, with reference to an appropriate pharmacopoeial monograph. It must be prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic 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 homoeopathic stock, and batch data. In some cases additional information may be requested before the application is approved.

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

Where products 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 homoeopathic products, you must provide the full registration numbers of these products.

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 homoeopathic 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 products 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 homoeopathic 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 homoeopathic 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 HOMOEOPATHIC 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 potentisation.

Where the diluted homoeopathic 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 products that are produced by one company, please provide the information in the form of a formulation masterfile.

The quality standards applied to homoeopathic medicines are similar to those applied to allopathic medicinal products. The special nature of homoeopathic products 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

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 homoeopathic 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 homoeopathic products (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 products (eye drops, intramammary products 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 product. 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 products such as eye drops, intramammary products 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 Potentisation

Details of the homoeopathic method used for dilution and potentisation 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 product 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 product. The extent to which stability studies are carried out will require careful consideration, and will depend upon the nature of the product. 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 product may be used following the removal of the first dose of product from the container without adversely affecting the integrity of the product. Further information on the data required can be found in the CVMP's Note For Guidance, 'In-use Stability Testing of Veterinary Medicinal Products' (EMEA/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 products, injections or multidose eyedrops, stability should be evaluated for individual formulations.

STABILITY OF THE DOSAGE FORM

- Data concerning the stability of the product.

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 EEA STATES

- A copy of any registrations or authorisations obtained for the same product in other EEA states, including the number of the relevant manufacturing authorisation and all other supporting data submitted to that Member State.

REGISTRATION BY THE MHRA

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

If you are applying to register a homeopathic product 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 product.

LABELLING

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

BIOLOGICAL SUBSTANCES

In the case a product 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 PRODUCTS ALREADY REGISTERED ELSEWHERE IN THE EEA

If you are applying to register a homeopathic product 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.

VETERINARY MEDICINES GUIDANCE NOTE

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