



**Veterinary Medicines  
Guidance Note**

**Manufacturing and  
Wholesale Dealer's  
Authorisations for  
Veterinary Medicines**

**No 10**



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



# VETERINARY MEDICINES GUIDANCE NOTE 10

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**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**

**WOODHAM LANE, NEW HAW, ADDLESTONE, SURREY KT15 3LS**  
**Telephone: (+44) (01932) 336911 Fax: (+44) (01932) 336618**  
**[www.vmd.gov.uk](http://www.vmd.gov.uk)**



**INVESTOR IN PEOPLE**

**TABLE OF CONTENTS**

<b>CONTENTS</b>	<b>PARAGRAPH</b>	<b>PAGE</b>
<b>INTRODUCTION</b>	<b>1</b>	<b>3</b>
Legal Provisions	<b>2</b>	<b>3</b>
<b>MANUFACTURING AUTHORISATIONS (MANAs)</b>		
Meaning of Manufacture	<b>3</b>	<b>3</b>
Requirements for a Manufacturing Authorisation	<b>4</b>	<b>3</b>
Application for a Manufacturing Authorisation	<b>6</b>	<b>4</b>
Requirements for Obtaining a Manufacturing Authorisation	<b>8</b>	<b>4</b>
Inspections	<b>9</b>	<b>5</b>
<b>WHOLESALE DEALER'S AUTHORISATIONS (WDAs)</b>		
Meaning of Wholesale Dealing	<b>10</b>	<b>5</b>
Requirement for a Wholesale Dealer's Authorisation	<b>11</b>	<b>5</b>
Application for a Wholesale Dealer's Authorisation	<b>12</b>	<b>5</b>
Requirements for Obtaining a Wholesale Dealer's Authorisation	<b>13</b>	<b>5</b>
Inspections	<b>16</b>	<b>6</b>
<b>VALIDITY OF AUTHORISATIONS</b>	<b>17</b>	<b>6</b>
<b>VARIATION OF AUTHORISATIONS</b>	<b>19</b>	<b>6</b>
<b>FEES</b>	<b>21</b>	<b>7</b>
<b>FURTHER GUIDANCE</b>	<b>22</b>	<b>7</b>

## 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 medicines in the UK. Basic information about the scope of the Regulations and the requirement for marketing authorisations is given in VMG Note 1: *An Introduction to Marketing Controls on Veterinary Medicines*. This note describes the arrangements for manufacturing authorisations (ManAs) and wholesale dealer's authorisations (WDAs).

## LEGAL PROVISIONS

2. The provisions specifically relating to manufacturing and wholesale dealer's authorisations are set out in the Regulations. Failure to comply with some provisions of the Regulations, eg the duties of the qualified person, is a criminal offence and may result in prosecution.

## MANUFACTURING AUTHORISATIONS (MANAS)

### MEANING OF MANUFACTURE

3. Under the Regulations "manufacture" includes any part of the manufacture of a veterinary medicinal product other than starting materials. It includes the packaging and labelling of the product up to the point where it is ready for sale in its final form.

### REQUIREMENT FOR A MANUFACTURING AUTHORISATION

4. An appropriate manufacturing authorisation is required for any manufacturing activity relating to a veterinary medicine that is intended to be placed on the market (but see paragraph 5) and such manufacture must be in accordance with that authorisation. A manufacturing authorisation is also required to manufacture veterinary medicines for export and to import veterinary medicines from countries outside the EU. In the latter case, this is because manufacturing facilities are necessary to carry out the required control tests and full qualitative and quantitative analysis of the product.
5. A manufacturing authorisation is **not** required:
  - for the manufacture of a veterinary medicine prescribed extemporaneously by a veterinary surgeon in accordance with the prescribing cascade if it is manufactured by a veterinary surgeon or a registered pharmacist in a registered pharmacy;
  - for the manufacture of a veterinary medicine for administration for research purposes in accordance with an Animal Test Certificate or a licence issued under the Animals (Scientific Procedures) Act 1986.

### APPLICATION FOR A MANUFACTURING AUTHORISATION

6. The Medicines and Healthcare products Regulatory Agency (MHRA) deals with the application and issue of manufacturing authorisations for veterinary medicines on behalf of the VMD. The MHRA is an agency of the Department of Health and has responsibility for the regulation of human medicines.
7. Guidance on applications and an application form are available on the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)) via the "medicines information" option and selecting from the sitemap/index, or from the Licensing Section, 17-1, MHRA, Market Towers, 1, Nine Elms Lane, London SW8 5NQ, telephone 020 7084 2605, fax 020 7084 2676 or e-mail ([info@mhra.gsi.gov.uk](mailto:info@mhra.gsi.gov.uk)).

### REQUIREMENTS FOR OBTAINING A MANUFACTURING AUTHORISATION

8. In order to obtain a manufacturing authorisation manufacturers must have at their disposal:
  - suitable and sufficient premises;
  - suitable and sufficient staff;
  - suitable and sufficient technical equipment and control facilities;
  - the services of at least one manufacturing qualified person (MQP) who meets the requirements and carries out the duties prescribed by the Regulations.

Manufacturers must also:

- comply with the principles of good manufacturing practice as set out in EU legislation and hold a current certificate of good manufacturing practice;
- keep the records prescribed in the Regulations;
- when requested by a duly authorised officer, provide proof of all control tests carried out;
- provide samples when requested by a duly authorised officer;
- ensure that veterinary medicines are manufactured in accordance with the relevant marketing authorisation;
- label products in accordance with the Regulations, including the requirements for bulk packages.

### INSPECTIONS

9. Before a manufacturing authorisation may be issued, the premises concerned will be subject to inspection. After an authorisation has been issued regular inspections will be carried out to ensure the requirements are being maintained. Inspections will include any contract manufacture or test sites used. Inspections of manufacturers of non-immunological veterinary medicines are carried out by MHRA inspectors on behalf of the VMD. Inspections of immunological veterinary medicines are conducted by VMD inspectors.

## WHOLESALE DEALER'S AUTHORISATIONS (WDAs)

### MEANING OF WHOLESALE DEALING

10. For the purposes of the Regulations, wholesale dealing means the supply (whether or not for profit) of a veterinary medicine to retailers or other wholesale dealers. It does not include:
  - the supply by an authorised manufacturer or marketing authorisation holder respectively, of veterinary medicines they have manufactured or to which the marketing authorisation relates;
  - small quantities of medicines supplied by one retailer to another, provided the value of the total amount supplied in any one year does not exceed five percent of the supplier's turnover for that year.

### REQUIREMENT FOR A WHOLESALE DEALER'S AUTHORISATION

11. Wholesale dealing in veterinary medicines may only be carried out by the holder of an appropriate wholesale dealer's authorisation.

### APPLICATION FOR A WHOLESALE DEALER'S AUTHORISATION

12. As with manufacturing authorisations, the Medicines and Healthcare products Regulatory Agency (MHRA) deals with the application and issue of wholesale dealer's authorisations for veterinary medicines on behalf of the VMD. Guidance and an application form is available on the MHRA website (see paragraph 7 above).

### REQUIREMENTS FOR OBTAINING A WHOLESALE DEALER'S AUTHORISATION

13. In order to obtain a wholesale dealer's authorisation, wholesale dealer's must have at their disposal;
  - technically competent staff;
  - suitable and sufficient premises for the storage, handling and distribution of the medicines;
  - the services of at least one distribution qualified person (DQP) who meets the requirements and carries out the duties prescribed by the Regulations.

## MANUFACTURING & WHOLESALE DEALER'S AUTHORISATIONS FOR VETERINARY MEDICINES

Wholesale dealers are also required to:

- have an emergency recall plan;
- maintain the prescribed records for at least 3 years and make them available for inspection by a duly authorised officer;
- supply veterinary medicines only in accordance with the wholesale dealer's authorisation to persons lawfully permitted to receive them;
- carry out a stock audit at least annually;
- ensure proper stock turnover;
- comply with the principles of good distribution practice set out in EU legislation;
- provide information or samples to a duly authorised officer on demand.

A satisfactory inspection is required before a wholesale dealer's authorisation may be granted.

14. Wholesale dealers who import veterinary medicines, which are not authorised in the UK, must first obtain an import certificate from the VMD unless the imported medicines are to be exported immediately. Guidance on import certificates is contained in VMG Note 7.
15. A wholesale dealer who imports a veterinary medicine from another Member State must notify the holder of the marketing authorisation for that product of the import, unless the importing wholesaler is also the holder of the relevant marketing authorisation.

### INSPECTIONS

16. Holders of wholesale dealer's authorisations for veterinary medicines are subject to regular inspections. These are carried out by the MHRA on behalf of the VMD.

### VALIDITY OF AUTHORISATIONS

17. Once issued, a manufacturing or wholesale dealer's authorisation is valid indefinitely, subject to regular satisfactory inspection and compliance with all the legal requirements. However, a wholesale dealer's authorisation will lapse if the holder does not deal in veterinary medicines for five years. Either type of authorisation may be suspended or revoked if the requirements are not complied with.
18. Where an authorisation is refused, suspended or revoked, the applicant will be offered the opportunity to appeal (see VMG Note 11).

### VARIATION OF AUTHORISATIONS

19. If the holder of a manufacturing or wholesale dealer's authorisation wishes to make any changes to the details contained in the authorisation they must apply to vary the authorisation accordingly. Any such changes must not be put into effect

until the relevant variation application has been formally approved. Failure to comply with this requirement could result in the authorisation being suspended or revoked.

20. Applications for variations are dealt with by the MHRA on behalf of the VMD as above.

### FEES

21. A fee is normally charged for dealing with applications (including applications for variations) and for inspections. 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/](http://www.vmd.gov.uk/))

### FURTHER GUIDANCE

22. Further detailed guidance on requirements for manufacturers and wholesale dealers is produced by the MHRA in the publication *Rules and Guidance for Pharmaceutical Manufacturers and Distributors* (commonly known as “the orange guide”), which is updated periodically and is available from the Stationery Office (Tel 0171 873 9090). There is a charge for this publication. You are advised to contact the MHRA (see paragraph 7) to check currency and availability before obtaining a copy.

# MANUFACTURING & WHOLESALE DEALER'S AUTHORISATIONS FOR VETERINARY MEDICINES

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