



Veterinary
Medicines
Directorate

**VETERINARY MEDICINES
GUIDANCE NOTE**

No 8

**WHOLESALE DEALER'S
AUTHORISATIONS
FOR
VETERINARY**

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www.gov.uk

QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed primarily at those persons who wish to wholesale supply veterinary medicinal products.

The quick start guide is a summary of the provisions of the Veterinary Medicines Regulations (VMR) in relation to wholesale dealing in veterinary medicinal products; detailed information is found in the body of the guidance note.

The VMR implement requirements relating to wholesale dealing of veterinary medicinal products (VMPs), which are set out in EU Directive 2001/82/EC (*as amended*)

http://ec.europa.eu/health/files/eudralex/vol-5/dir_2001_82_cons2009/dir_2001_82_cons2009_en.pdf

For the purposes of the VMR wholesale dealing means the procurement, holding, storage or distribution (whether or not for profit) of a VMP to retailers or other wholesale dealers.

It is an offence under the VMR for any person to buy a VMP other than by retail, or for the purposes of retail supply, unless that person has a wholesale dealers' authorisation (WDA) granted by the Secretary of State. This also applies to the import of unauthorised veterinary medicines for export. In order to obtain a WDA, a person must have:

- a suitable site from where the wholesaling takes place
- the services of a Wholesale Dealer Qualified Person (WQP) with responsibility for ensuring compliance with *EU Guidelines on Good Distribution Practice (GDP)* http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm and maintenance of a Quality System
- the services of technically competent staff
- an effective emergency recall plan
- documented procedures to ensure that VMPs are only obtained from, and supplied to, appropriately authorised persons
- appropriate facilities and equipment, and documented procedures, to ensure that (VMP) are stored in accordance with conditions specified in their authorisations

A WDA holder must keep records of all VMPs received and supplied.

WDA holders are subject to regular inspections by the VMD or, in the case of a WDA holder who also holds a Wholesale Dealers Licence (WL) for human medicines at the same site, by the Medicines and Healthcare products Regulatory Authority (MHRA).

FURTHER INFORMATION

For more information on wholesaling dealing veterinary medicinal products please contact the VMD's Inspections Administration Team by contacting VMD reception on 01932 336911 and quoting "wholesale dealing".

TABLE OF CONTENTS

Contents	Paragraph	Page
Introduction	1	4
Requirements for Obtaining a Wholesale Dealer's Authorisation	3	4
How to apply for a Wholesale Dealer's Authorisation	11	6
Validity of Authorisations	16	7
Variation of Authorisations	20	7
Fees	24	8
Wholesale Dealer Qualified Person - WQP		
WQP Requirements	26	8
Duties of WQP	35	9
Record Keeping Requirements	40	10
Contracting Supply to another WDA Holder	43	11
Virtual Wholesaling and Brokers		
Virtual wholesaling	50	12
Brokers (and/or buying groups)	51	12
Wholesale Supply of Controlled Drugs	52	12
Inspections	57	13
Further Information	66	15
ANNEX 1		
Guidance on Control and Monitoring of Storage and Transportation		16
ANNEX 2		
Guidance on the Requirements for a WDA Quality System		20
ANNEX 3		
Requirements for a Wholesale Dealer Qualified Person (WQP)		22
ANNEX 4		
Good Distribution Practice (GDP)		
Inspection Criteria – Specimen Report		24
List of Abbreviations		32

Introduction

1. This is one of a series of Veterinary Medicine Guidance Notes (VMGNs) explaining the requirements of 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.
2. The VMR set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. VMGN 1 Controls of Veterinary Medicines, which is published on the Veterinary Medicines Directorate's (VMD) website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx provides basic information about the scope of the VMR and the requirement for Marketing Authorisations (MAs).

This note describes the arrangements for wholesale dealer's authorisations (WDA).

Requirements for Obtaining a Wholesale Dealer's Authorisation

3. The provisions specifically relating to WDA are set out in Schedule 3 part 2 of the VMR. Failure by the holder of a WDA to comply with the provisions of the VMR is a criminal offence and may result in suspension, or compulsory variation, or revocation of their WDA or prosecution of the WDA holder.
4. For the purposes of the VMR, wholesale dealing means the procurement, holding, storage or distribution (whether or not for profit) of a veterinary medicinal product (VMP) to retailers or other wholesale dealers. Only the holder of a marketing authorisation (MAH), a holder of a manufacturer's authorisation (ManA) or the holder of a WDA may wholesale a VMP, or be in possession of a VMP for that purpose; and they may only wholesale a VMP if their authorisation relates to that product, and only supply it to another person permitted under the VMR to wholesale or retail that product.
5. Wholesale dealing does not include the retail supply of a VMP to the end user of that product. A WDA is granted by the Secretary of State on being satisfied that an applicant meets the relevant requirements of the VMR. A WDA may be granted to an individual or a company.
6. The requirements for obtaining a WDA are set out in Schedule 3, paragraphs 18-19 of the VMR. These are:
 - (i) The site from which wholesale dealing activities take place must be:
 - weatherproof;
 - secure and lockable;
 - clean;
 - free from contamination;

- capable of storing VMPs under the required storage conditions.

(ii) The WDA Holder must:

- have the services of technically competent staff;
- have an effective emergency recall plan;
- nominate and register a suitable Wholesale Dealer Qualified Person (WQP) responsible for compliance with the principles of GDP as set out in *EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use* (EC Directive 94/C63/03)
http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm;
- ensure that the WDA specifies all intended VMP distribution activities;
- notify the VMD (via a variation application) before making any significant change to the premises or facilities detailed in the WDA, or in the operations for which they're used;
- store VMPs in accordance with the terms of their MA (refer to Annex 1);
- carry out a stock audit at least annually;
- provide information or samples to a duly appointed inspector on demand.

7. Holders of a WDA are also required to:

- implement and maintain a quality system (refer to Annex 2);
- maintain records for at least 5 years and make them available for inspection by a duly appointed inspector;
- procure VMPs only from appropriately authorised manufacturers or wholesale dealers;
- supply VMPs in accordance with their WDA only to persons lawfully permitted to receive them, i.e. holders of WDA relating to those medicines and retailers who are authorised to supply those veterinary medicines to end users in accordance with the VMR. For further information please refer to VMGN 3 Guidance for Retailers, which is published on the VMD website;
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
- only supply an authorised VMP in accordance with the provisions of that authorisation;
- ensure proper stock rotation.

8. A satisfactory inspection for compliance with GDP is required before a WDA is first granted, and thereafter at regular intervals (please see paragraph 57).

9. WDA holders who import veterinary medicines that are not authorised in the UK must first ensure that an appropriate import certificate has been obtained from the VMD unless the imported medicines are to be exported immediately. For further guidance on import certificates please refer to VMGN 5 Import Certificates Schemes which is published on the VMD website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

10. WDA holders who import a UK authorised veterinary medicine from another Member State (MS) must notify the holder of the marketing authorisation (MA) for that product of the import, unless the importing wholesaler is also the holder of the relevant MA (for further information on this type of import please refer to VMGN 2 Marketing

Authorisations For Veterinary Medicinal Products which is published on the VMD website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

How to apply for a Wholesale Dealer's Authorisation

11. Application forms to wholesale only veterinary medicinal products are available from the VMD at:

Inspections Administration Team
VMD
Woodham Lane
ADDLESTONE
Surrey
KT15 3LS

Tel: 01932 336911

E-mail: inspections@vmd.defra.gsi.gov.uk

or they can be downloaded from the VMD website:
http://www.vmd.defra.gov.uk/mswd/forms_fees.aspx

12. Applications to wholesale both veterinary and human medicines, or an application to wholesale veterinary medicines by the holder of a Wholesale Dealer's Licence (WDL) for human medicines, should be made to the Medicines and Healthcare Products Regulatory Agency (MHRA) at:

151 Buckingham Palace Road
Victoria
London
SW1W 9SZ
020 3080 6000
E-mail: info@mhra.gsi.gov.uk

or downloaded from the MHRA website at:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicencerequestors/Licenceapplicationforms/index.htm>

13. If all required information is correctly provided, application forms will be validated by the VMD within 10 days of receipt and an inspection completed within 90 days of that validation. However, incomplete or incorrect applications will result in validation being deferred whilst the VMD contacts the applicant, which will delay the processing of the application. The most common reasons for deferring validation are:
- no curriculum vitae for the WQP submitted with the application;
 - no referees for the WQP submitted; and
 - the declaration in Section 5 unsigned and undated.

14. The VMD will only issue a WDA when it is satisfied, following an inspection of the site(s), that the information contained in the application is accurate and in compliance with the requirements of the legislation.
15. For further advice on how to complete the application form please contact the Inspections Administration Team on 01932 336911.

Validity of Authorisations

16. Once issued, a WDA is valid indefinitely, subject to regular satisfactory inspections and continued compliance with the VMR. However, a WDA will lapse if the holder does not deal in veterinary medicines for five years.
17. A WDA may be suspended or revoked if the requirements of the VMR are not complied with.
18. The VMD may suspend, vary or revoke a WDA if the holder fails to comply with the VMR or no longer has suitable premises or equipment.
19. Where an authorisation is refused, suspended, compulsorily varied or revoked, the applicant will be offered the opportunity to appeal; for further information please refer to VMGN 9 Appeals against Regulatory Decisions which is published on the VMD website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Variation of Authorisations

20. An appropriate variation application must be submitted to and approved by the VMD before changes to the information contained in the authorisation documents, such as material alterations to the premises, distribution methods or change of WQP, can be made. Failure to comply with this requirement could result in the authorisation being suspended, revoked or compulsorily varied.
21. Application forms to vary a WDA are available from the VMD at:

Inspections Administration Team
VMD
Woodham Lane
ADDLESTONE
Surrey
KT15 3LS
Tel: 01932 336911
E-mail: inspections@vmd.defra.gsi.gov.uk

or they can be downloaded from the VMD website:
www.vmd.defra.gov.uk/mswd/forms_fees.aspx

22. There are three categories of variations to a WDA:

Category	Person responsible for assessment	Example of variation
Scientific	Application requires assessment by an inspector	Addition of a WQP
Change of ownership	Application requires assessment by an inspector	Only applies to change of authorisation holder
Other	Application assessed by administrative staff	Removal of a category of products handled at the site

23. A fee is charged for these variations, dependant on the type of variation submitted. (See paragraph 24 – Fees).

Fees

24. A fee is normally charged for processing WDA applications, including variation applications, and for site inspections. Wholesale Dealer's are also subject to an annual fee. Details of the relevant fees can be found in the VMR, which can be found on www.vmd.defra.gov.uk under Manufacturers, Suppliers, Wholesalers and Distributors.

25. Fee reductions apply in respect of WDA applications, annual fees and inspection fees for businesses whose annual turnover (meaning gross value of all veterinary medicinal products sold) is less than £35,000. A fee reduction also applies to those wholesale dealers who only deal in Authorised Veterinary Medicines-General Sales List (AVM-GSL), Exemptions for Small Pet Animals and Homeopathic products.

Wholesale Dealer Qualified Person – WQP

WQP Requirements

26. A WDA holder must have at its disposal, at all times, the services of a WQP who has:

- adequate knowledge of the activities to be carried out and of the procedures to be performed under the authorisation; and
- appropriate experience in those procedures and activities.

27. The requirements for appointment as a WQP are similar to those detailed for the Responsible Person (RP) for human medicinal products in the *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007* (also known as the *Orange Guide* published by the MHRA).

28. There is no statutory requirement for the WQP to be a pharmacist, although this is desirable. However, the WQP should have access to pharmaceutical knowledge and advice when it is required and have personal knowledge of:

- the relevant provisions of the VMR;
- articles 65-68 of EC Directive 2001/82 on the Community Code relating to

veterinary medicinal products, as amended;

- European Commission Guidelines on *Good Distribution Practice of Medicinal Products for Human Use* (94/C 63/03);
- the conditions attached to the WDA for which the WQP is nominated;
- the products distributed under the authorisation and the conditions necessary for their safe storage and distribution;
- the categories of persons to whom products may be distributed;
- the Quality System and Standard Operating Procedures employed by the WDA holder.

29. A WQP who is not a pharmacist or a person eligible to act as a Qualified Person (QP) (as defined in EC Directive 2001/82/EC), should have at least one year's practical experience in both or either of the following areas:

- handling, storage and distribution of medicinal products;
- transactions in or selling or procuring medicinal products;

30. In addition, the WQP should have at least one year's managerial experience in controlling and directing the activity of the wholesale distribution of medicinal products on a scale, and of a kind, appropriate to the authorisation for which that WQP is nominated.

31. It is for the VMD to determine if a particular WQP has the appropriate knowledge and experience for the scale and nature of the wholesale distribution operation for which the WQP is nominated (refer to Annex 3). If unsatisfactory the applicant will be formally informed of the reasons for rejection and the process for appeal.

32. The WQP does not have to be an employee of the WDA holder but must be at the WDA holders' continuous disposal. Where the WQP is not an employee there should be a written contract that specifies the WQP's responsibilities, duties, authority and so on.

33. A WQP may be nominated for more than one site but VMD will take into consideration the number of sites a WQP is responsible for when deciding whether or not to grant a WDA.

34. The WDA Holder is required to:

- notify the VMD of the name, address, qualifications and experience of the person who will carry out the functions of the WQP;
- notify the VMD of any changes to the WQP;
- not permit any person to act as the WQP other than the person named on the authorisation.

Duties of the WQP

35. To fulfil their duties, the appointed WQP should:

- have a clear reporting line to either the WDA holder or, where the WDA holder is a company, to the Managing Director;

- have access to all areas, sites, stores and records which relate to the authorised activities being carried out;
- regularly review and monitor all such areas, sites, etc;
- focus on the management of those activities that are the subject of the WDA, the accuracy and quality of records, compliance with established standard operating procedures (SOPs), the quality of handling and storage equipment and facilities, and the standards achieved; and
- keep appropriate records relating to the discharge of the WQP's responsibilities.

36. The WQP should also ensure that:

- a quality system is implemented and maintained;
- the WDA holder complies with GDP guidelines to ensure that the conditions under which the authorisation has been granted have been, and are being complied with.

37. The WQP may nominate deputies, e.g. where the WQP is contracted to the WDA holder or covers more than one site, provided appropriate reporting and delegating arrangements are in place. These arrangements should include the WQP receiving written reports that such actions have been carried out and that the necessary controls and checks are in place. There should be documented evidence that the deputy has received appropriate training to carry out their delegated duties. However, the WQP retains overall responsibility and should personally carry out the delegated functions at least once a year.

38. The WDA holder should ensure that there is a written SOP for receiving advice and comment from the WQP and recording the consequent action taken.

39. Should it prove impossible to resolve a disagreement between the authorisation holder and the WQP with regard to compliance within the terms of the WDA the VMD should be approached for advice. Whilst a joint referral is preferred, either party may approach the VMD for advice independently. A WQP who finds difficulty in meeting their statutory responsibilities and the activities being carried out under the authorisation may, in strict confidence, consult the VMD.

Record Keeping Requirements

40. WDA holders must keep detailed records for all incoming and outgoing transactions, including disposals, for at least 5 years. The records may be in the form of purchase and sales invoices, or on a computer, or in any other form, which provides, as a minimum, the following information:

- the date and nature of the transaction;
- the identity of the veterinary medicinal product;
- the manufacturer's batch number;
- the expiry date;
- the quantity;

- the name and address of the supplier or recipient.
41. The WDA Holder is required to carry out a detailed audit at least once a year. The audit must reconcile all incoming and outgoing veterinary medicinal products with products currently held in stock with any discrepancies being recorded.
 42. If discrepancies have occurred, for example, from spillage or breakage it is for the individual concerned to consider whether any discrepancies are acceptable or whether further action may be required.

Contracting Supply to another WDA Holder

43. If one WDA holder acts as a third party storage and distribution site for another WDA holder, an appropriate technical agreement must be put in place between the two businesses (and made available to Inspectors). The technical agreement needs to fully describe where the responsibility for various aspects of GDP rests, whether with the contract giver or the contract acceptor.
44. There are no specific guidelines published on technical agreements between wholesale dealers or manufacturers/wholesale dealers, but *Chapter 7 (pages 80-82 of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007)* outlines the requirements on Contract Manufacture and Analysis, and sets out the principle, details for the contract giver, details for contract acceptor and the contract. These requirements can also form the basis of technical agreements between wholesale dealers and their suppliers.
45. The contract, or technical agreement, between the two parties should clearly set out the various activities to be undertaken and detail exactly which company is responsible for what activity (including any joint responsibilities). The agreement should also address responsibilities such as:
 - the handling and processing of orders;
 - ensuring that VMP are handled and delivered in accordance with any specific requirements specified in their SPCs;
 - handling of complaints- in respect of both service and product quality;
 - the recall of VMP;
 - the handling of VMP returns.
46. The following scenario serves as an example of when a technical agreement is required. WDA holder 'A' places an order with WDA holder 'B' for direct delivery to a retail business 'C'. WDA holder 'A' receives payment from business 'C' for goods which have never actually been handled by WDA holder 'A' as WDA holder 'B' is providing the storage and distribution facility on behalf of WDA holder 'A'. Therefore WDA holder 'A' cannot confirm that their own GDP responsibilities have been met in relation to the products being distributed.
47. WDA holder 'B' should therefore be named on WDA holder 'A's' authorisation as a contracted-out warehousing function and WDA holder 'A' should perform annual

inspections at WDA holder 'B' (the contracted WDA) under the terms of the technical agreement between the two parties. Where no such technical agreement exists, then delivery should only be made by WDA holder 'B' to WDA holder 'A's authorised site and not directly to the retail business 'C'.

48. If no technical agreement is in place, the requirements of the VMR will not be met in relation to compliance with GDP and it is likely that enforcement action will be taken against both WDA holders involved. Such action could result in a temporary suspension of all related WDAs until the matter is resolved.
49. Where VMPs are delivered to a distribution centre (hub) that is under the management of a WDA holder for reloading onto vehicles for onward supply, then that hub must be a named site on the WDA. However, if the WDA holder employs the services of 3rd party courier to transport VMPs and the VMPs are delivered to that courier's distribution centre (hub) for reloading onto vehicles for onward supply, there is no requirement for that hub to be named on the supplying wholesaler's WDA or hold a WDA itself, unless the products are cold chain products or, in the case of non cold chain products, they are 'held' at the hub for more than 36 hours.

Virtual Wholesaling and Brokers

Virtual wholesaling

50. The VMR provide that it is an offence to buy a VMP other than by retail, or for the purposes of retail supply, unless the buyer has a WDA. If VMPs are purchased and sold by a business but all of the physical handling is contracted out to another WDA holder the practice is known as 'virtual wholesaling'. A business operating as a virtual wholesaler is required to hold a WDA even though they never physically handle VMP.

Brokers (and/or buying groups)

51. If a business negotiates terms for a retailer, or group of retailers, to enable them to purchase VMPs directly from an MA holder or WDA holder at reduced rates, without any VMPs being ever bought or sold by the business arranging the terms, then this practice is referred to as brokering. In these circumstances a broker may receive a payment/commission for their services from the VMP retailers. At the present time a broker is not required to hold a WDA.

Wholesale Supply of Controlled Drugs

52. A signed requisition is required for a CD specified in Schedule 2 or 3 of the *Misuse of Drugs Regulations 2001(MDR)*. The signature on CD requisitions must be handwritten in ink.
53. Requisitions forms may be received via email or fax on the condition that the original version is handed over to the delivery driver prior to the CDs being delivered to the requisitioner. This is necessary so that the supplier can satisfy themselves, as required under the MDR, of the authenticity of the signature and the profession/occupation of the person requisitioning the CD. Faxed and emailed requisition forms are only an instruction to prepare the CD for delivery.

54. The requisition form must contain the following information:
- Name, address and profession/occupation of the recipient;
 - Purpose for which the drug is supplied;
 - Name, form, strength of the drug and the total quantity supplied;
 - Signature of the prescriber (handwritten);
 - Date of order;
 - Name and address of the supplier. This **must** be recorded indelibly on the requisition form at the time the supply is made.
55. There is no requirement for a signed requisition for a CD specified in Schedule 4 or 5 but this is considered good practice.
56. For advice on the licensing requirements for wholesale supply of CDs you should contact the Home Office on drugs_licensing.aadu@homeoffice.gsi.gov.uk. The VMD also publishes a Veterinary Medicines Guidance note on Controlled Drugs which can be found here: <http://www.vmd.defra.gov.uk/pdf/vmgn/VMGNNote20.pdf>

Inspections

57. Wholesale dealers only distributing veterinary medicinal products under a WDA are subject to regular inspections by the VMD. Inspection enables the VMD to confirm that WDA holders are complying with the conditions of their authorisation, with the provisions of the VMR and with the requirements of GDP. Annex 4 sets out the GDP inspection criteria.
58. Amongst other things, VMD Inspectors are empowered to:
- inspect the premises, organised arrangements and procedures used in the storage and distribution of medicinal products;
 - interview key personnel named on authorisation;
 - take samples; and
 - examine any documentation or records relating to the manufacture, assembly, storage and distribution of veterinary medicinal products.

It is a requirement of both EC and UK national legislation that WDA holders shall make their premises available for inspections by the Licensing Authority at any reasonable time.

59. A fee is charged for these inspections (see paragraph 24).
60. Following an inspection, the VMD Inspector will send a letter, within 30 days of the last day of inspection, to the applicant or WDA holder detailing any deficiencies found and asking for details of the measures that have been, or will be, taken to correct them. The applicant's or WDA holder's responses will then be included in the inspector's final report which is sent to the company. The report sets out the inspector's observations of the applicant's/WDA holder's compliance with GDP and, based on those observations, the interval to the next inspection (see paragraph 64).

61. In the case of the most serious deficiencies or failure to comply with the VMR, the VMD may consider formal action which can include the refusal to grant a WDA, making a compulsory variation to an existing WDA, suspension or revocation of all or part of a WDA, or prosecution. The VMD may also take action against the WQP for any failings or omissions by that person.
62. Where the VMD takes a decision to suspend, compulsory vary, or revoke a WDA, WDA holders have the right to appeal against such decisions and further guidance is provided in VMGN 9 Appeals against Regulatory Decisions which can be found on http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
63. For the purposes of wholesale dealing VMPs, the VMD categorises deficiencies as critical, major and other (minor). These are based on definitions included in the Compilation of Community Procedures on Inspections and Exchange of Information, which is published on the EMA website:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

A **Critical deficiency** is one that has:

- produced, or has the potential to produce, a significant risk to human or animal health, or the environment; or
- a deficiency which indicates a significant deviation from the requirements of the VMR through serious negligence or intent.

A **Major deficiency** is a non-critical deficiency that has:

- produced, or has the potential to produce, a possible risk to human or animal health, or the environment; or
- a deficiency which indicates a major deviation from the requirements of the VMR; or
- a deficiency which indicates a failure to carry out satisfactory procedures to ensure that products are stored or distributed in accordance with their specific requirements; or
- a combination of several other (minor) deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such; or
- other (minor) deficiencies that have been brought to the attention of the business on previous occasions.

An **Other (minor) deficiency** is one that is:

- minor and poses no potential risk to human or animal health, or the environment; or
- a deficiency which does not indicate a significant deviation from the requirements of the VMR, Codes' of Practice or Guidance; or
- a deficiency which cannot be classified as either critical or major, because there is insufficient information to classify it as such.

64. Inspection of veterinary only wholesale dealers sites are scheduled at intervals based on the number and type of deficiencies noted during an inspection, as follows:

GDP compliance rating			
Lower Risk sites (AVM-GSL, Exemptions for Small Pet Animals, homeopathics)		Higher Risk sites (POM-V, POM-VPS, NFA-VPS, Cascade, WDIC)	
No. Deficiencies	Max Re-inspection Frequency (M)	No. Deficiencies	Max Re-inspection Frequency (M)
≤3 'others'	60	n/a	n/a
≥4 'others'	48	≤3 'others'	48
1-2 'majors'	36	≥4 'others'	36
3-4 'majors'	24	1-3 'majors'	24
≥5 majors/ 1 critical	12	≥4 majors/ 1 critical	12

Targeted inspections may also take place, for example, when a variation authorisation is submitted or deficiencies are brought to the attention of the VMD.

65. Those WDA holders that also hold a Wholesale Dealer's Licence (WDL) to distribute human medicines are subject to inspection by the MHRA in accordance with the MHRA's inspection schedule. Details are provided on the MHRA's website: www.mhra.gov.uk

Further Information

66. 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. VMGN and other information, including details of VMD contacts, are available on the VMD website (www.vmd.defra.gov.uk).

ANNEX 1

GUIDANCE ON CONTROL AND MONITORING OF STORAGE AND TRANSPORTATION TEMPERATURES

Legislation and good practices oblige pharmaceutical manufacturers and distributors to exercise control over the distribution chain to ensure that the quality of medicines is maintained. Critical in this regard is control of the environmental conditions under which medicines are stored and transported. The MHRA's recommendations concerning the control and monitoring of storage and transportation temperatures were published in The Pharmaceutical Journal in July 2001⁽¹⁾. A summary of these is given below but the full guidance can be found on the MHRA's website:

<http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007569.pdf>

Introduction

1. EU requirements and guidelines on Good Distribution Practice (GDP) require distributors to *ensure that storage conditions are observed at all times, including during transportation*. The requirements are applicable not only to medicines that need to be stored at low temperatures (known as cold chain products) but also to medicines that should be stored below 25° or 30° C (known as temperate chain products). In addition an increasing number of products require storage and transportation at sub-zero temperatures and the application of appropriate controls to these is equally important. What follows gives guidance on how compliance with relevant standards of good practice may be achieved.

Cold Storage

2. Many medicinal products require storage at controlled low temperature. Some of these, such as, vaccines, insulins, blood products and some products of biotechnology can be denatured by freezing and thus must be maintained within a narrow temperature range above freezing point.
3. The temperature in small refrigerators used to store medicines should be measured continuously and the maximum and minimum temperatures recorded daily. Sufficient space should be maintained to permit adequate air circulation. If the refrigerator is filled to capacity the effect on temperature distribution should be investigated. Refrigerators used for vaccines and other sensitive products should be capable of maintaining the temperature between 2°C and 8°C with the minimum of intervention. Temperature monitoring of these should be by electronic max/min thermometer, with an accuracy of +/- 0.5°C, which should be readable from outside the unit. Refrigerators should not be sited in an environment where extremes of temperature (i.e. <10°C or >32°C) will affect their performance.
4. Large commercial refrigerators and walk-in cold rooms should be monitored with an electronic temperature-recording device that measures load temperature in one or more locations, depending on the size of the unit. Portable data-loggers that can be downloaded onto a computer may be used instead of a fixed device. Records should be checked daily. Internal air temperature distribution should be mapped on installation in the empty and full state and annually thereafter under conditions of normal use. Products should not be stored in areas shown by temperature mapping to present a risk (e.g. in the airflow from the refrigeration unit). Condensate from chillers should not be collected inside the unit.

¹ Taylor J, Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products. *The Pharmaceutical Journal*, 28 July 2001, Volume 267, pages 128-131.

5. Temperature alarms should be fitted to large and walk-in units and those smaller units used to store products at risk from freezing.

Controlled room temperature storage

6. The simplest monitoring would be with a max/min thermometer placed at a strategic location and read, recorded and reset at least weekly, more frequently during periods of exceptionally hot or cold weather. With the exception of very small stores, temperatures should be recorded at low and high levels. Continuous temperature recording is recommended for large warehouses. Self-contained storage areas within warehouses, (e.g. CD store, flammables store) should be included in temperature monitoring programmes.
7. All warehouses should be temperature mapped to determine the temperature distribution under extremes of external temperature. Mapping should be repeated every two to three years and after any significant modification to the premises, stock layout, or heating system. Medicines should not be stored in areas shown by temperature mapping or other consideration to be unsuitable, e.g. at high level in poorly insulated stores, or next to heaters.

Transportation

Cold-chain goods

8. The route and time of transportation, the local seasonal temperatures and the nature of the load should all be considered when arranging cold-chain distribution. For small volumes of cold-chain goods insulated containers may be used, in which case it is vital that products damaged by freezing are prevented from coming into direct contact with ice packs at subzero temperatures.
9. Larger volumes of cold-chain goods should be shipped in refrigerated transport, particularly if transit times may be prolonged. Temperatures within loads of products at risk from freezing should be strictly controlled and monitored with recording probes or individual temperature monitoring devices, giving consideration to the temperature gradient within the load. The temperature records for each consignment should be reviewed and there should be a procedure for implementing corrective action in the case of adverse events.
10. Distributors should ensure that consignments of cold-chain goods are clearly labelled with the required storage/transport conditions. Receivers should satisfy themselves that the goods have been transported under appropriate conditions and should place them in appropriate storage facilities as soon as possible after receipt.

Other goods

11. Consideration should be given to the possible extremes of temperature inside uninsulated, unventilated delivery vehicles and precautions should be taken to protect all products from heat challenge. This includes representatives' samples kept in car boots and goods distributed using postal services.

Systems Checks and Calibration

12. Any systems whose performance is critical to preserving the product should be tested and demonstrated to achieve what is intended. Measuring and recording devices that are used in critical areas (e.g. temperature monitoring of storage and transport facilities for cold chain goods at risk from freezing) should be calibrated at

least annually against a traceable reference device. Records should include pre and post-calibration readings and details of any adjustments made or corrections to be applied. Alarms should be checked for correct functioning at the designated set temperatures.

ANNEX 2

GUIDANCE ON THE REQUIREMENTS FOR A WDA QUALITY SYSTEM

WDA holders are required to implement a quality system that includes written procedures that describe the different operations which may affect the quality of the products or of the distribution activity:

Documented Procedures

- The WQP's defined responsibilities and authority and the requirement for delegated functions to be personally performed by WQP at least once per annum
 - Requirements ensuring VMP are only obtained from authorised 'bona fide' suppliers
 - Procedure for receipt and checking of deliveries
 - Procedure for storage of VMP and keeping storage condition records
 - Procedure for cleaning and maintenance (including pest control)
 - Procedure for ensuring appropriate security measures are in place on site and during transport
 - Procedure for stock rotation and withdrawal of non-conforming products (including counterfeits) from saleable stock
 - Procedure for ensuring VMP are only supplied to appropriately authorised customers
 - Procedure for urgent/non-urgent classes of recall and testing of recall plan
 - Procedure for assessing returned and recalled VMP and formal release by WQP
- The VMD have adopted MHRA policy regarding the maximum duration after which returned products from outside the registered supply chain can be considered acceptable for potential resale. A maximum duration of 5 days for ambient products and 24 hours for refrigerated products is considered acceptable if the appropriate technical justification is in place.
- Procedure for dealing with receiving and processing customer complaints
 - Procedure for record-keeping, including client orders, returned and recalled VMP
 - All procedures approved, signed and dated by person responsible for the quality system

Record Keeping

- All records (including electronic computer records) must be maintained so that significant events are traceable
- Records of staff training
- Records to demonstrate that VMP are examined at receipt against order and for damage
- Records of calibration of temperature monitoring devices
- Records of temperature mapping and monitoring of storage area temperatures
- Records maintained for client orders, returned products and recall plans
- Records to demonstrate that VMP are only supplied to customers with appropriate bona fides established
- Delivery note containing the date, product name and pharmaceutical form, quantity supplied and addresses of supplier and customer enclosed with product consignments
- Records of returned and recalled VMP and assessment and formal release by WQP
- Records of customer complaints and actions taken
- Self inspections (internal audits) conducted and recorded to monitor compliance with EU GDP and the Quality System

All documentation must be retained for 5 years and be readily available for inspection.

ANNEX 3

REQUIREMENTS FOR A WHOLESALE DEALER QUALIFIED PERSON (WQP)

The VMR do not specify any formal qualifications or experience necessary to be a Wholesale Dealer Qualified Person (WQP), but the VMD considers the following to be desirable:

A) Qualifications/Professional membership

- Veterinary Surgeon (MRCVS)
- Pharmacist (registered with the GPhC)
- Chartered Biologist and Member/Fellow of the Society of Biology (CBiol MSB/FSB)
- Chartered Chemist and Member/Fellow of Royal Society of Chemistry (CChem MRSC/FRSC)
- Suitably Qualified Person (SQP)

B) Experience

- At least one years experience in:
- Handling, storage and distribution of medicinal products
- Transactions in selling or procuring medicinal products
- Managing, controlling and directing the wholesale distribution of medicinal products on a scale and kind appropriate to the authorisation for which they are nominated

Other relevant qualification/experience will be considered on a case-by-case basis.

C) Supporting Documentation

The applicant must supply in support of their application:

- a copy of their relevant Qualifications
- a copy of their current Membership of the professional organisation, i.e. MRCVS, GPhC, MSB, MRSC, AMTRA0
- a CV setting out their experience of storing/handling/distributing VMP contact details of 2 previous or current employers. The VMD will contact these referees to request references supporting your experience.

ANNEX 4

GOOD DISTRIBUTION PRACTICE (GDP) INSPECTION CRITERIA – SPECIMEN REPORT

Good Distribution Practice (GDP) Inspection Report

WDA Holder Name:

**WDA Holder
Address:**

WDA No.:

Tel. No.:

Fax No.:

Email:

Web:

Site Address:

Site No:

WQP:

Inspected by:

Date:

1. INSPECTION DETAILS

Inspection Type: Scheduled ☐ New site ☐ Targeted ☐

Site Type: Storage & Handling (Picking of Goods) ☐ Distribution Only ☐ Procurement/ administration only (no storage) 'virtual' ☐

LICENSING REQUIREMENTS – in accordance with VMR

Yes	No	N/A
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Has WDA holder actively traded veterinary medicinal product (VMP) in previous 5 years? (**Schedule 3, 19**)

Wholesale dealing activities reflect activities defined in the WDA authorisation? (**Schedule 3, 19**)

Are unauthorised VMP imported using Special Import Certificate (SIC) or Special Treatment Certificate (STC)? (**Regulation 25(6)b**)

Does the WDA holder hold a Wholesale Dealer Import Certificate (WDIC) to permit the import and holding of unauthorised VMP? (**Regulation 25(6)c**)

Are imported unauthorised VMP exported? (**Regulation 25(4)**)

Is this site named on another WDA or are any WDA activities subcontracted? (**Regulation 13**)

If so, is there a satisfactory technical agreement in place?

Comments

Categories of product handled at this site:

POM -V	POM -VPS	NFA - VPS	AVM- GSL	Unlicensed VMP	List any others below: (e.g. products for administration under the cascade, Exemptions for Small Pet Animals, homeopathics)

Inspection Fee :

Full

☐

Reduced (AVM-GSL / annual turnover <£35k)

☐

Storage requirements: (EMEA/CVMP/422/99/Rev3 'Guideline on Declaration of Storage Conditions'
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004345.pdf

No Specified Storage Conditions (>5°C)	Store below 30°C (5 to 30°C)	Store below 25°C (5 to 25°C)	Store in a Refrigerator (2 to 8°C)	Store in a Freezer (<0°C)	Controlled Drugs

Brief description of company business:

(Give brief description)

Warehouse/storage facilities	
Refrigerated storage	
Controlled Drugs store	
Hazardous chemical store	
Other (e.g. intermediate hubs/ delivery vehicles)	

Any changes to the operation since last inspection/planned changes:

Key personnel met/contacted during the inspection		
Name:	Position:	Qualification no:

2. GDP (GOOD DISTRIBUTION PRACTICE) INSPECTION FINDINGS

(In accordance with 92/25/EEC and 94/C 63/03)

This report details findings of compliance with the GDP requirements required by the current Veterinary Medicines Regulations at this site. Any failures to comply with Regulations are set out in the relevant section's comments and the Non Compliance Letter attached to this report.

The section reference numbers in this report relate to Chapter 2 (EU Guidance on Wholesale Distribution Practice) of "Rules and Guidance for Pharmaceutical Distributors 2007" unless otherwise stated.

<u>Key:</u>	Complies	Deficiency	Not Applicable
	C	D	N/A
Wholesale Qualified Person (WQP) appointed for site and has defined responsibility for the quality system? (EU GDP 1)?			
Where functions are delegated does the WQP personally carry out the activities at least once per year? (UK Guidance on Wholesale Distribution Practice)			
Is there an agreement in place for contracted WQPs? (UK Guidance on Wholesale Distribution Practice)			
Key warehouse personnel possess appropriate ability and experience? (EU GDP 2, VMR Schedule 3, 18(4)a)			
Staff trained and training recorded? (EU GDP 3)			

PERSONNEL

Wholesale Qualified Person (WQP) appointed for site and has defined responsibility for the quality system? (EU GDP 1)?

Where functions are delegated does the WQP personally carry out the activities at least once per year? (UK Guidance on Wholesale Distribution Practice)

Is there an agreement in place for contracted WQPs? (UK Guidance on Wholesale Distribution Practice)

Key warehouse personnel possess appropriate ability and experience? (EU GDP 2, VMR Schedule 3, 18(4)a)

Staff trained and training recorded? (EU GDP 3)

Comments

DOCUMENTATION – Orders, Procedures & Records

- All documentation made available upon request? **(EU GDP 4)**
- Products are only obtained from authorised suppliers with appropriate *bona fides* established? **(EU GDP 5)**
- Procedure(s) for receipt and checking of deliveries? **(EU GDP 6)**
- Procedure(s) for storage and storage condition records? **(EU GDP 6)**
- Procedure(s) for cleaning and maintenance of the premises (including pest control)? **(EU GDP 6)**
- Procedure(s) for appropriate security measures in place on site and during transit? **(EU GDP 6)**
- Procedure(s) for withdrawal from saleable stock (including counterfeits), client orders, returns and recalls? **(EU GDP 6)**
- All procedure(s) approved, signed and dated by person responsible for the quality system? **(EU GDP 6)**
- Records maintained for client orders, returned products and recall plans? **(EU GDP 6)**
- All records (including electronic computer records) are maintained so that significant events are traceable? **(EU GDP 7)**
- All records are maintained for minimum 5 years **(EU GDP 7)**

C	D	N/A

Records are kept of each purchase and sale, showing the date of purchase or supply, name of the medicinal product, quantity received or supplied and the name and address of the supplier or consignee. **(EU GDP 8)**

Records for transactions between manufacturers and wholesalers ensure traceability of origin and destination of medicinal product (using batch numbers) so that all suppliers and recipients of medicinal product can be identified? **(EU GDP 8, VMR Regulation 13)**

A detailed stock audit is carried out at least once a year? **(VMR Schedule 3, 21(1)c)**

Comments

DELIVERIES TO CUSTOMERS

- Products are only supplied to customers with appropriate *bona fides* established? **(EU GDP 17)**
- A delivery note is enclosed with product consignments containing the date, product name and pharmaceutical form, quantity supplied and addresses of supplier and customer? **(EU GDP 18)**
- Arrangements in place for emergency supply? **(EU GDP 19)**

C	D	N/A

Comments

RETURNS - Non Defective Products, Recall Plans & Counterfeits

- Returns are subject to a systematic examination products by WQP or trained and authorised staff before return to stock? **(EU GDP 23)**
- Formal release of returned products to stock by WQP? **(EU GDP 24)**
- Records of returns and formal release kept? **(EU GDP 24)**

C	D	N/A

Emergency plan for urgent/non-urgent classes of recall is documented in procedure? (EU GDP 25)			
Designated person identified as responsible for recall activities? (EU GDP 25)			
Records kept of recall activity? (EU GDP 26)			
Emergency plan permits rapid communication to competent authorities in other member states where product is distributed? (EU GDP 26)			
Distribution records permit all customers to be identified and contacted in the event of a recall? (EU GDP 27 28 29)			
Any recall message is approved by the MAH or competent authority? (EU GDP 30)			
Any recall message requests the removal and segregation of recalled stock prior to further instruction by the MAH? (EU GDP 30)			
An effective recall system is in place? (EU GDP 27, VMR Schedule 3, 18(4)b)			
There is a system to segregate any counterfeits found from good stock then alert VMD and MAH? (EU GDP 31)			
The WQP and the MAH are involved with any counterfeit investigation? (EU GDP 32)			
Records of counterfeit product receipt, final decision and disposal are kept? (EU GDP 32)			
Comments			

<u>SELF INSPECTIONS</u>	C	D	N/A
Self inspections conducted and recorded to monitor compliance with EU GDP and the Quality System? (EU GDP 33)			
Comments			

<u>PREMISES AND EQUIPMENT – Receipt & Storage</u>	C	D	N/A
Premises and equipment are suitable and adequate to ensure proper conservation and preservation of medicinal products (weatherproof, secure, lockable, clean and free from contaminants)? (EU GDP 9, VMR Schedule 3,18)			
Deliveries protected from bad weather during unloading? (EU GDP 10)			
Goods-in reception area separate from storage area? (EU GDP 10)			
Products examined at receipt against order and for damage? (EU GDP 10)			
Products with specific storage requirements are immediately identified and stored in accordance with written instructions and legal requirements? (EU GDP 11, VMR Schedule 3, 21(1)a)			
Products are segregated from other goods and stored under manufacturers' specified conditions? (EU GDP 12)			
Temperatures are monitored and recorded periodically? (EU GDP 12)			
Temperature records are subject to regular review? (EU GDP 12)			
Temperature recorders or other devices indicate excursions? (EU GDP 13)			
Monitoring devices are calibrated? (EU GDP 9)			
Temperature control throughout the storage area is demonstrated? (<i>Mapping</i>) (EU GDP 13)			

Storage areas are clean and free from litter, dust and pests? **(EU GDP 14)**

Precautions are taken against spillages, breakages, pests and cross-contamination? **(EU GDP 14)**

System in place to ensure stock rotation (FIFO/FEFO)? **(EU GDP 15)**

Regular checks for unsaleable products? **(EU GDP 15)**

Segregated area is available for unsaleable (counterfeit, damaged or expired) stock? **(EU GDP 15, 16)**

Returns are segregated from saleable stock? **(EU GDP 22)**

Products are transported safely and securely? **(EU GDP 20)**

Appropriate storage conditions maintained during transport? **(EU GDP 21)**

Comments

Non-compliances noted at previous inspection:

YES

NO

N/A

Have non-compliances raised at the last inspection been resolved?

Comments:

Documents or samples taken by the Inspector

Concluding Comments

Conclusion of Inspection

Closing meeting with company attended by:

Inspector's recommendations

Inspection Findings (EMA/INS/ GMP/3135 39/2006 Rev 1)	GDP Compliance Rating				Maximum Inspection Interval (Months)	Comments
	Lower Risk sites (AVM-GSL, ESPA, homeopathics)		Higher Risk sites (POM-V, POM-VPS, NFA-VPS, Cascade, WDIC)			
	No. Deficiencies	Max Re-inspection Frequency (M)	No. Deficiencies	Max Re-inspection Frequency (M)		
	≤3 ‘others’	60	n/a	n/a		
	≥4 ‘others’	48	≤3 ‘others’	48		
	1-2 ‘majors’	36	≥4 ‘others’	36		
	3-4 ‘majors’	24	1-3 ‘majors’	24		
	? Critical ? Major ? Other	≥5 majors/ 1 critical	12	≥4 majors/ 1 critical		

INSPECTOR'S NAME, SIGNATURE AND DATE

Inspector:

Signed:

Date:

List of Abbreviations

AVM-GSL	Authorised Veterinary Medicine – General Sales List
Defra	Department for Environment, Food & Rural Affairs
EC	European Commission
EU	European Union
GMP	Good Manufacturing Practice
GDP	Good Distribution Practice
MA	Marketing Authorisation
ManA	Manufacturing Authorisation
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Authority
RP	Responsible Person
SOP	Standard Operating Procedure
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
WDA	Wholesale Dealers Authorisation
WL	Wholesale Dealers Licence
WQP	Wholesale Dealer Qualified Person

VETERINARY MEDICINES GUIDANCE NOTE

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