Guidance

Apply for veterinary medicine wholesale dealer's authorisation (WDA)

How to obtain an authorisation to wholesale veterinary medicines.

The VMD is responsible for inspecting and authorising veterinary medicines wholesale dealers.

You can only wholesale veterinary medicines if you hold one of the following:

- a manufacturer’s authorisation
- a wholesale dealer’s authorisation (WDA)

And the authorisation in question relates to the products you’re wholesaling.

When you need a WDA

You must obtain a WDA to sell or supply medicines to anyone other than the end user. This includes:

- wholesalers that carry out all the activities involved in the wholesale of veterinary medicines; procurement/administration, storage/holding and distribution/supply
- ‘virtual wholesalers’, also known as procurement only wholesalers, that buy and sell veterinary medicine but contract out the physical handling of the medicine to another authorised wholesale dealer
- storage and/or distribution wholesalers, that are not involved in taking orders from retailers, but only store and distribute medicines on behalf of another WDA holder to those retailers

Apply for a WDA

Complete the application form for WDA (ODT, 69.5 KB) and send to inspections@vmd.gov.uk

If you need to vary your WDA, complete the variation application form for WDA (ODT, 70.1 KB) and send to inspections@vmd.gov.uk

Your site will be inspected before we grant your authorisation. This inspection should take place within 90 days of your application being validated.

You can't start wholesale dealing before you get confirmation in writing that your authorisation has been granted. In exceptional circumstances we may grant you a conditional authorisation to start operating before the inspection has taken place. But again, you may not start to operate until you receive this written confirmation.

Fees

You must pay a fee for the application and for your initial site inspection.

You'll also have ongoing annual and inspection fees.

The application and annual fees are not refundable or transferable.

You will qualify for a reduced inspection fee if you only deal in any of the following:

- medicines classified as Authorised Veterinary Medicines-General Sales List (AVM-GSL)
- products marketed under Schedule 6 of the Veterinary Medicines Regulations (VMR) (Exemptions for small pet animals)
- homeopathic products

The fees for a site in GB can be found here.

The fees for a site in NI can be found here.

Timescales

We aim to process applications within 10 days of receipt.

Your inspection should take place within 90 days of a valid application.

Post authorisation

Once you get your authorisation, you'll have regular inspections.

Inspections are risk based depending on your history of compliance with the Good Distribution Practice (GDP) requirements set out in the VMR and the type of veterinary medicines you wholesale.

You must make your site available for inspection and provide any information or samples requested. Failure to do so will be seen as obstruction, which is an offence.

Validity of authorisation

Your authorisation is valid indefinitely subject to satisfactory inspections. However, your authorisation will be revoked if you don't deal in veterinary medicines for 5 years.

Variation to an authorisation

You must notify the VMD before making any significant change to your premises, facilities, personnel or operations.

You must complete a variation application form for WDA (ODT, 70.1 KB) and send it to inspections@vmd.go.uk to change an existing authorisation.

Your authorisation could be compulsory varied, suspended or revoked, which you will be charged the appropriate variation fee for, if you make alterations before your change has been authorised.

Authorisation conditions

You must have an appropriate Home Office licence if you wish to wholesale controlled drugs.

You must have a signed requisition form, signed in ink, to sell any controlled drugs listed in schedule 2 or 3 of the Misuse of Drugs Regulations 2001.

For further information see the Controlled drugs: Veterinary medicines page.

You must have a valid and suitable contract in place if you want another wholesale dealer to be responsible for the storage and distribution of your medicines. The contract must state where the division of responsibilities lies. You must also use a wholesale dealer who is authorised to wholesale the types of products you wish them to. For example, if you wish them to be involved in any way with the wholesale of special import medicines then they must be authorised to deal in unauthorised products.

You must also do all of the following to meet the conditions of your authorisation:

- only obtain veterinary medicines from authorised manufacturers or wholesale dealers
- only supply veterinary medicines to people who are legally allowed to possess them, for example retailers who are authorised to supply veterinary medicines to end users
- If the supply is to a veterinary surgeon, a pharmacist or a suitably qualified person, it must be to a registered/authorised premises
- only supply veterinary medicines covered by your wholesale dealer's authorisation
- only complete the distribution activities listed in your authorisation
- store and transport animal medicines in line with each product's storage and transport conditions
- have proper stock rotation and carry out a detailed stock audit at least once a year

- have an emergency recall plan (a system in place that if a recall of the product is required then the company is readily able to identify and contact all their customers)
- have technically competent staff (who are trained in all of the company procedures and understand the principles of GDP)
- set up and maintain a quality system (a system detailing your quality and distribution procedures)
- have appropriate certificates in place and the correct authorisation on your WDA if you are dealing in imported veterinary medicines
- notify the VMD where you have reason to suspect there's a threat to the continued supply of a veterinary medicine
- notify the VMD and the holder of the relevant marketing authorisation if you have been offered a counterfeit veterinary medicine
- keep a record of any returned, recalled or counterfeit veterinary medicine

Site conditions

Your wholesale dealing premises must be all of the following:

- weatherproof
- secure and lockable
- clean
- free from contamination
- designed with designated areas for the receipt of medicines
- capable of storing veterinary medicines under the required storage conditions

You are breaking the law if you don't meet these conditions, and could lose your authorisation or face prosecution.

WDA Qualified Person

You must choose an appropriate person to be your wholesale dealer qualified person (WQP). You will need to provide us with their details when you apply for your authorisation, or when you need to vary your WQP. This is so we can assess their suitability to fulfil this role.

This person will be responsible for making sure you're meeting the conditions of your authorisation.

They are responsible for conducting self-inspections of your wholesale operations. At least once a year every aspect of the operation must be checked and the results of these self-inspections should be documented. Any non-compliances must be investigated and records kept of these investigations.

They will need to know about the conditions of your authorisation and the medicines you distribute.

They may be a pharmacist, vet or SQP, but if they're not one of these, they should have at least a year's experience in either of the following:

- handling, storing and distributing medicines
- supplying or obtaining medicines

They should also have at least a year's experience in managing the wholesale distribution of medicines on a similar scale.

You don't have to employ this person, but they must be available at all times.

They will be responsible for assessing any returned medicines to check if they've been stored (including during transport) in accordance with the relevant summary of product characteristics and product label. If it hasn't or it isn't possible for the WQP to determine whether it has, the product may not be re-sold. These medicines must be segregated from saleable stock before being destroyed.

Record keeping

You must keep records of all incoming and outgoing veterinary medicines for at least 5 years and have them available for inspection. Your records must include all of the following:

- date of the sale/receipt
- name of the medicine
- the pharmaceutical form and strength
- batch number
- expiry date

- quantity
- company name and address of the supplier or recipient

Storage and transport

You must make sure that proper storage conditions are always maintained, including during transportation, for all veterinary medicines including those that:

- need to be stored at low temperatures (known as cold chain products)
- should be stored below 25º or 30º C (known as temperate or ambient chain products)

You must record temperatures at low and high levels – this includes in contained storage areas within warehouses, for example flammable stores.

You need to continuously record the temperature if you're storing medicines either in small refrigerators or in warehouses.

If you're storing medicines in large warehouses you will need to use temperature mapping (noting the changes in temperature in a single space caused by things like doors opening).

You must repeat temperature mapping exercises regularly and after any major change to the premises, stock layout, or heating system to ensure you are still storing your medicines correctly.

You should fit temperature alarms to large and walk-in units and those smaller units used to store products at risk from freezing. Alarms must be checked for correct functioning at the designated set temperatures at least annually.

Transport temperature: cold-chain goods

Your storage responsibilities relating to cold-chain medicines also includes the transportation of these medicines.

You should label the storage requirements of any medicines that need to be stored at low temperatures.

You can use insulated containers to transport small volumes of cold-chain medicines. You must make sure that medicines which may be damaged by freezing don't come into direct contact with ice packs at sub-zero temperatures.

You can ship larger volumes of cold-chain medicines in refrigerated transport. You need to use recording probes or individual temperature monitoring devices to monitor temperatures to protect medicines at risk from freezing.

You should review the temperature records for each shipment and have in place a procedure for corrective action if anything goes wrong.

Temperature system checks

You must use measuring and recording devices in critical areas, for example temperature monitoring of storage and transport facilities for cold chain medicines at risk from freezing.

Your measurements should be checked against a traceable reference device, that is the temperature must be calibrated, at least once a year. Your records should show the temperature before and after.

Documents required with deliveries

You must ensure that a document accompanies each consignment of medicines which states:

- the name of the medicine
- the strength and pharmaceutical form;
- the date on which the veterinary medicinal product was supplied;
- the quantity of product supplied;
- the batch number;
- the expiry date;
- the name and address of the wholesale dealer supplying the product;

- the means by which the product was transported and the required conditions of storage;
- the name of the person to whom the product was supplied and the address to which it is to be delivered.

Human medicines

If you wish to supply human medicines for veterinary use under the cascade, you must hold a WDA(H) issued by the Medicines and Healthcare products Regulatory Agency (MHRA).

The MHRA have an agreement with the VMD to issue and administer veterinary authorisations where the company undertakes both human and veterinary activities.

If your company intends to wholesale both veterinary and human products, you should apply to the MHRA. For more information, see their guidance.

Register

You can find a full list on the Register of veterinary-only Wholesale Dealer Sites

Inspections of Wholesale premises

We inspect authorised wholesaler premises to ensure they comply with the VMR.

Wholesale dealer premises will generally be inspected at least every 4 years. However, this period may be extended for compliant businesses that have received few deficiencies at previous inspections and conduct activities considered to be low risk. We will generally give wholesalers reasonable notice that we intend carrying out a routine inspection.

Inspectors are authorised under the VMR to:

- inspect the premises, organisational arrangements and procedures used in the storage and distribution of medicinal products
- interview key personnel named on the authorisation
- take samples
- examine any documentation or records relating to the manufacture, assembly, storage and distribution of veterinary medicines

Following an inspection, the inspector will give the wholesaler a report detailing any deficiencies, also referred to as non-compliances. For any deficiencies found, the inspector will request details of the measures that have been, or will be, taken to correct them and how the wholesaler will prevent them occurring again.

We categorise deficiencies as minor (other), major and critical. The report may also include recommendations; observations made by the inspector which, whilst not a legal requirement, are considered good practice.

Minor (Other) Deficiencies:

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

Major Deficiencies:

- non-critical but has produced, or has the potential to produce, a possible risk to human or animal health or the environment
- a major deviation from the requirements of the VMR
- a failure to carry out satisfactory procedures to ensure that products are manufactured, stored or distributed in accordance with their specific requirements
- a combination of more than six 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

- other (minor) deficiencies that have been brought to the attention of the business on previous occasions but have not been resolved

Critical Deficiencies:

- deficiencies that have produced, or have the potential to produce, a significant risk to human or animal health, or the environment
- a significant deviation from the requirements of the VMR through serious negligence or intent

Inspections are scheduled at intervals based on the number and type of deficiencies noted during an inspection, as follows:

Inspection findings	Compliance category	Inspection points*	Max inspection interval all GDP sites (months)
0 deficiencies; recommendations only	5	0	56 (low risk sites only) 48 (higher risk sites)
1-4 minor (other)	4	1-4	48 (all sites other than low risk)
More than 4 minors and/or 1-2 Majors	3	5-14	36

Inspection findings	Compliance category	Inspection points*	Max inspection interval all GDP sites (months)
2 Majors plus 1 or more minors up to and including 4 Majors	2	15-28	24
More than 4 Majors and / or any Critical	1	29 and over	Follow up inspection as specified on improvement notice, then next inspection in 9-12 months

*A minor deficiency = 1 point, a Major deficiency = 7 points and a Critical deficiency =36 points