Guidance

Appeal against a regulatory decision made by the VMD

You can appeal against certain decisions made by the Veterinary Medicines Directorate (VMD) that affect you.

The VMD will tell you about the procedures for dealing with your appeal once you have made a request to appeal.

A fee may apply for your appeal.

Can I appeal

You can appeal against a decision, or the intention to make a decision, by the VMD acting on behalf of the Secretary of State, on any matter covered by the Veterinary Medicines Regulations (VMR) if you:

- receive a notification from the Secretary of State informing you of a right to an appeal to the Veterinary Products Committee (VPC)
- feel aggrieved by a provisional decision of the Secretary of State
 under the Veterinary Products Committee appeals procedure
- are a body aggrieved by a decision to suspend or revoke its recognition under paragraph 14(1) of Schedule 3 to the VMR
- are served an Improvement Notice or Seizure Notice under the VMR
- are an applicant for:
 - a variation of a marketing authorisation
 - an animal test certificate
 - a manufacturing authorisation
 - a variation to a manufacturing authorisation
 - an appointment as a Qualified Person for the purpose of a manufacturing authorisation
 - an authorisation for a person or premises to manufacture autogenous vaccines
 - an authorisation for a non-food animal blood bank

- an authorisation for a person and premises to manufacture an unauthorised veterinary medicine for administration under the cascade
- an authorisation of a stem cell centre
- an authorisation to manufacture autogenous vaccines
- a registration in relation to active substances
- a wholesale dealer's authorisation
- the authorisation of premises for the supply of POM-VPS (Prescription Only Medicine – Veterinarian, Pharmacist, SQP) or NFA-VPS (Non-Food Animal – Veterinarian, Pharmacist, SQP) veterinary medicines by a suitably qualified person

Types of appeal

Appeals to the VPC

You can appeal to the VPC against the VMD's decision on the following applications:

- marketing authorisation (MA)
- registered veterinary homeopathic remedy (VHR)
- variations requiring an assessment or compulsory variations of an MA
- animal test certificate (ATC)
- approvals for active substances
- suspensions of an MA

You have up to 28 days to decide whether to appeal. You can either present your appeal in writing or in person.

If, following the VPC's advice, the VMD upholds its original decision, you will be given a further opportunity to appeal to a person appointed by the VMD.

Appeal to an appointed person

You can appeal against the VMD's decision to an appointed person for the following applications:

- manufacturing authorisation
- · variation to a manufacturing authorisation
- wholesale dealer's authorisation
- appointment as a Qualified Person for the purposes of a manufacturing authorisation
- authorisation for a person or premises to manufacture autogenous vaccines
- authorisation of a non-food animal blood bank
- authorisation for a person and premises to manufacture an unauthorised veterinary medicine (also known as a Special) for administration under the cascade
- authorisation of a stem cell centre
- registration in relation to active substances
- the authorisation of premises for the supply of POM-VPS or NFA-VPS veterinary medicines by a suitably qualified person

You will be notified how to do this when you receive the VMD's decision letter.

Improvement Notices

An inspector appointed under the VMR or the Animal Health Act 1981 may serve an Improvement Notice on you for failure to comply with the VMR.

The notice will set out the inspector's view on how you are failing to comply, the measures you need to take to comply and how quickly you should take them.

If you feel you have been unjustly served with an Improvement Notice you can appeal to a magistrates' court (England, Northern Ireland and Wales) or the sheriff (Scotland).

Your appeal must be lodged within 28 days of the issue of the Improvement Notice or by the end of the time set in the improvement notice, whichever is sooner. The court will decide whether to uphold, adjust or overturn the Improvement Notice.

Seizure Notices

An inspector appointed under the VMR or the Animal Health Act 1981 may seize items, including equipment and documentation. If you feel the item should not have been seized, you may make a claim to the VMD's Chief Executive against the notice you have been served with for the return of the property or compensation for its loss.

You must submit the claim within 28 days of the seizure and set out the grounds in full.

Fees

In most cases you will have to pay a fee for your appeal to cover the cost of any assessment work related to the appeal. The fee is refundable if, as a result of the appeal, the VMD changes the decision you appealed against.

The relevant fees are set out in the <u>Veterinary Medicines Regulations</u>.