

VETERINARY MEDICINES DIRECTORATE ENFORCEMENT POLICY

This Enforcement Policy sets out the general principles and approach that the [Veterinary Medicines Directorate](#) (VMD) will take to enforce the [Veterinary Medicines Regulations](#) (Statutory instrument 2013 No. 2033, as amended).

The Secretary of State owns the powers provided by the Veterinary Medicines Regulations (VMR), which include [powers of entry](#) and [powers of an inspector](#). It is however the responsibility of the VMD to ensure these regulations are enforced in accordance with our [Privacy Notice](#) and the [Regulators' Code](#).

Introduction

We aim to protect public health, animal health and the environment, and to promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines. In accordance with the VMR the definition of a veterinary medicine is;

- Any substance or combination of substances presented as having properties for treating or preventing diseases in animals; or
- Any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to making a medical diagnosis; or
- Any substance or combination of substances that may be used for the purpose of euthanising an animal.

We meet our aims through proportionate risk-based regulation, providing high quality services to stakeholders and enforcement partners.

We receive information (raw, unverified and unevaluated data) and intelligence (processed, evaluated and perspective data) from a range of sources, such as the pharmaceutical industry, veterinarians, general public and other stakeholders. This data is analysed, and we may share it with our enforcement partners, in accordance with our Privacy Notice.

The purpose and method of enforcement

“Enforcement” refers to any action taken by us in relation to suspected breaches of the VMR.

The purpose of enforcement is to secure compliance with the requirements of the VMR.

In keeping with Defra’s approach to better regulation and enforcement, we recognise that the best way to achieve compliance is to ensure that those carrying out regulated or unregulated activities understand their responsibilities. We therefore seek to work with businesses and individuals to assist them in complying with the legislation through the [provisions of advice and guidance](#).

However, where necessary we will use more formal means of enforcement against a business or an individual to secure compliance, which includes:

- issuing advisory and warning letters;
- serving enforcement notices;
- removing non-compliant social media posts, posts from online marketplaces and websites;
- variation, suspension or revocation of authorisations ;
- destruction of products; and ultimately
- prosecution.

The principles of enforcement

This Enforcement Policy embraces the key principles of proportionality, consistency, and transparency.

Proportionality

All our enforcement action is risk-based. The enforcement action we take will be graduated and proportionate to the assessed risks associated with an illegal activity. Where the risks are considered to be low or there is no history of non-compliance, enforcement action will generally be delivered through advice. However, where the risks are considered greater, for example when dealing with an incident involving food-producing animals or antibiotics, or similar non-compliance has previously been identified, more formal action will be considered.

Consistency

We aim to be consistent in our approach when dealing with non-compliance. Therefore, similar non-compliances will be dealt with in the same measure and fashion.

Transparency

Offences are clearly specified in the VMR ([regulation 43](#) and, where appropriate, the final paragraph of the Schedules to the VMR). It is important that stakeholders, businesses and individuals understand what is expected of them, and the consequences of any non-compliance. Therefore, through routine engagement and publication of guidance and advice, we aim to make stakeholders, businesses, and individuals aware of the relevant requirements of the VMR. We will clearly explain the relevance of the statutory requirements and what is considered to be good practice.

Enforcement action

Advisory and Warning letters

Advisory and warning letters are the initial steps within our enforcement process. Letters are prepared on a case-by-case basis and aim to ensure the intended recipient is aware of the necessary requirements to achieve compliance with the VMR.

Advisory letters can be considered as 'educational' letters.

Removal of non-compliant posts online

We monitor content placed on online marketplaces and websites to ensure that they comply with the VMR and that there is no unauthorised marketing, sale and supply. In cases where non-compliance is identified we seek to remove offending posts, websites, and social media content.

Improvement Notices

The VMR gives inspectors the [powers to serve](#) an improvement notice on any person or business they believe is not complying with the legislation.

Depending on the seriousness of the risk, the notice may prohibit or restrict the person on whom it is served from carrying out an activity from a specific date (which may be immediately) or require them to take measures to comply from a specific date (which must be at least 14 days).

Immediate action or restriction with less than 14 days to comply

For non-compliance where an inspector believes the matter so serious (a risk to animal or human health or of damage to the environment) until reduced or rectified, then activities may be prohibited or restricted.

The notice will clearly set out

- the activity which is to be prohibited or restricted;
- the reasons why such prohibition or restriction is considered appropriate;
- the time and date at which the prohibition or restriction is to take effect

Where a person who has been served an improvement notice under this paragraph provides evidence to the inspector that the measures specified in the notice (or measures at least equivalent to them) have been undertaken to secure compliance, and the inspector is satisfied that the measures have been satisfactorily performed, the inspector must revoke the notice and inform the person of this.

Minimum of 14 days to comply

For other non-compliances (not deemed as serious as above) the notice will clearly set out:

- the inspector's grounds for believing this
- how that person or business is failing to comply with the VMR
- the exact nature of the failure
- the measures that need to be taken to comply.

This notice will give at least fourteen days within which required corrective action must be taken to ensure compliance.

Failure to comply with an improvement notice is an offence. In the case of a business authorised by the VMD to carry out an activity, this may result in a compulsory

variation, suspension, or in the most serious of cases, revocation of that business's authorisation. In this instance we will write to the business explaining the decision, the options for appeal, and outline the processes to be followed to [appeal](#) to an appointed person.

A person may [appeal](#) against being served an improvement notice to a magistrates' court or, in Scotland to the sheriff, within 28 days or the period specified in the improvement notice, whichever ends the earlier. The improvement notice sets out the appeals procedure.

Seizure Notices

The VMR gives inspectors the [power to seize](#) veterinary medicines, anything purporting to be a veterinary medicine, any additives to which Schedule 5 applies and any intermediate feedingstuff or feedingstuffs

which are not authorised in the UK, or which are not stored, manufactured or supplied correctly.

They have powers to seize computers and associated equipment, as well as documentation. The inspector must serve a [seizure notice](#) on the person appearing to be responsible for the seized item(s), which sets out details of:

- products / items that have been seized, and
- grounds for the seizure.

If inspectors are not able to remove seized items immediately, they may serve a notice on the person appearing to be responsible for the products prohibiting the products' movement from the premises until the product is collected.

A person may, within 28 days of seizure, notify any claim that the product was not liable to seizure to the Secretary of State at the address specified on the seizure notice, setting out the grounds in full.

Prosecution

Where there is a significant risk to human or animal health or the environment, or where a business or individual continues an illegal activity that has already been brought to their attention, the case will normally be considered for prosecution.

Investigations into such illegal activities are carried out by enforcement officers from the VMD, or by officers from Defra Investigation Services (DIS) on behalf of the VMD. All investigations will be carried out in accordance with relevant investigative procedures.

Following an investigation, and where there is sufficient evidence of an offence, the case may be referred to the Crown Prosecution Service or the Procurator Fiscal in Scotland.

A person prosecuted and found guilty of an offence under the VMR ([regulation 44](#)) is liable:

- on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or both; or

- on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

We may also look to prosecute under other regulations if further offences are identified.

Publication of Enforcement Action

We may publicise on [GOV.UK](#) enforcement notices, suspension and revocation of authorisations and approvals, and outcomes of prosecutions.

Further information

See our guidance pages [Veterinary medicines guidance - GOV.UK \(www.gov.uk\)](#)

Contact

To report to us please follow - [Report illegal animal medicines - GOV.UK \(www.gov.uk\)](#)

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