Veterinary Medicines Directorate

# VETERINARY MEDICINES DIRECTORATE
# ENFORCEMENT STRATEGY

1. This Enforcement Strategy sets out the general principles and approach that the Veterinary Medicines Directorate (VMD) will take to enforce the Veterinary Medicines Regulations (VMR).

2. The Secretary of State owns the powers provided by the VMR but it is for the VMD to ensure the regulations are enforced.

## Introduction

3. The VMD is an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra).

4. Our aims are:-

   i) to protect public health, animal health and the environment and to promote animal welfare by assuring the safety, quality and efficacy of veterinary medicines. We will meet this aim through proportionate regulation, providing high quality services to stakeholders and drafting clear agreements with service providers; and

   ii) the responsible, safe and effective use of veterinary medicines, through regulatory services that meet the needs of consumers, industry, and government and that operate in an efficient and sustainable manner, whilst providing value for money.

5. The VMD is responsible for:

   - The assessment, issue and maintenance of all national Marketing Authorisations (MA) for veterinary medicines in accordance with European Community and UK legislation;
   - acting as Reference Member State (RMS), Rapporteur, Co-Rapporteur or Concerned Member State (CMS) for designated European applications for centralised or decentralised or mutual recognition authorisations;
   - controls on the manufacture and distribution of veterinary medicinal products including inspections;
   - pharmacovigilance through the surveillance of Suspected Adverse Events (SAEs);

- surveillance for residues of veterinary medicines and illegal substances in animals and animal products;
- the inspection of manufacturers and distributors of medicated feedingstuffs and specified feed additives.
- enforcing the provisions of the VMR
- the provision and implementation of policy advice on these matters to Ministers;
- the management of the Research & Development (R&D) programme linked to veterinary medicine issues; and
- the co-ordination of Defra's work on antimicrobial resistance via the Defra Antimicrobial Resistance Coordination (DARC) Group.

**The Purpose and Method of Enforcement**

6. "Enforcement" refers to action taken by us in relation to breaches of the VMR.

7. 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, by guidance and advice, that those carrying out regulated activities understand their responsibilities. We therefore seek to work with businesses and individuals to assist them in complying with the legislation through the provision of advice and guidance. However, where necessary we will use more formal means of enforcement to secure compliance.

8. We use a range of enforcement tools to secure compliance with the legislation. This includes advisory and warning letters, the issue of improvement and seizure notices, destruction of products, variation, suspension or revocation of authorisations or approvals, and ultimately prosecution. Enforcement action may be taken against a business or an individual.

**The Principles of Enforcement**

9. This enforcement strategy embraces the key principles of proportionality, consistency, transparency and targeting.

Proportionality

10. The enforcement action we take will be graduated and proportionate to the assessed risks associated with an activity. Where the risks are considered to be low and there is no history of non-compliance enforcement will generally be through advice. However, where the risks are greater or similar non-compliance has previously been noted, more formal action may be taken.

Consistency

11. We aim to be consistence in our approach when dealing with non-compliance. Therefore similar non-compliances will be dealt with in similar fashion..

Transparency

12. In order to comply with the VMR, businesses and individuals need to understand what is expected of them and the consequences of non-compliance. Through regular contact, publication of guidance and advice we aim to make those regulated 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.

Targeting

13. Enforcement actions are directed at those businesses and individuals who are most likely to fail to comply with the VMR. Targeting involves risk assessment and the concentration of enforcement effort on those with the highest risk and/or lowest compliance.

**Enforcement Action**

**Non-compliances**

*N.B Non-compliances are also referred to as deficiencies within the work of the VMD.*

14. We will generally deal with non-compliances depending on the perceived risk, i.e. the potential to do harm, which includes risk to human and animal health or to the environment:

a. **Minor non-compliances** are those which are not considered to pose a significant risk and which we believe will be corrected through advice.

b. **Major non-compliances** are those which do not immediately give rise to significant risk but could do so if not addressed. We will generally set out the remedial measures that the business or individual must take, and the date by which those measures must be taken.

c. **Critical non-compliances** are those which pose a significant risk and include major non-compliances which have previously been brought to a businesses' or individuals' attention and have not been rectified; and offences committed through serious negligence or intent. Such non-compliances will generally be dealt with by formal enforcement action, as set out below.

15. Advisory/Warning letters

Advisory and warning letters are the steps on our enforcement process. Warning letters are invariably sent to those who have not acted upon advice given.

Improvement Notices

16.

The VMR give appointed inspectors the powers to serve improvement notices on any person they believe is not complying with the legislation.

The notices will clearly set out:

- 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

All improvement notices will give at least fourteen days in which to take the required measures to ensure compliance.

17. A person who is aggrieved by an improvement notice may appeal 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.

18. Failure to comply with an improvement notice is an offence. In the case of a business authorised or approved by the VMD to carry out an activity, this will generally result in a compulsory variation, suspension, or in the most serious of cases, revocation of that business's authorisation or approval. 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.

Seizure Notices

19. The VMR give appointed inspectors the powers to seize unauthorised or authorised veterinary medicines, anything purporting to be a veterinary medicine, additives, premixtures or feedingstuffs to which Schedule 5 applies, that may have been illegally imported, supplied, marketed or administered. Computers and associated equipment may also be seized.

The inspector must serve on the person appearing to be in charge of the seized product a seizure notice which sets out details of:

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

20. If an inspector is not able to remove the seized products immediately, they may mark the products accordingly, and serve a notice on the person appearing to be in charge of the products prohibiting the products movement until they are collected. Any person who removes products identified under such a notice is guilty of an offence.

A person who is aggrieved by a seizure notice 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 in the seizure notice, setting out the grounds in full. Inspectors will draw this information to the attention of the person at the time the notice is served.

Prosecution

21. 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.

22. Investigation into such illegal activities may be carried out by own inspectors 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.

23 Following an investigation and where there is sufficient evidence of an offence the case will be referred to Crown Prosecution Service.

24. A person prosecuted and found guilty of an offence under the VMR is liable:

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

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

Publication of Enforcement Action

25. We will publicise all improvement notices, seizure notices, suspension and revocation of authorisations and approvals, and outcome of prosecutions, on the Notices and Prosecutions page on our website and in MAVIS on-line. The information will remain on our website for one year.

**Working with Others**

26. We will take steps to ensure that other enforcement bodies undertaking enforcement work on behalf have due regard for this Strategy.

**Veterinary Medicines Directorate**
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