Veterinary Medicines Directorate

VETERINARY MEDICINES GUIDANCE NOTE

No 10

GUIDANCE ON ENFORCEMENT

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QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed at those to whom the Veterinary Medicines Regulations (VMR) apply and is intended to provide guidance on the general principles and approach that the Veterinary Medicines Directorate (VMD) will take to enforce the VMR.

This quick start guide is a summary of the provision of the VMR, detailed information is found in the body of the guidance note.

The VMD's aim is to:

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

- the responsible, safe and effective use of veterinary medicinal products (VMPs), 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.

The VMR provide a range of enforcement tools that can be used to secure compliance. These include:

- advisory/warning letters
- improvement notices
- seizure notices
- destruction of products
- variation, suspension or revocation of authorisations or approvals
- police cautions
- prosecution

FURTHER INFORMATION

For more information on the requirements of enforcement of the Veterinary Medicines Regulations please email the VMD's Enforcement Team on enforcement@vmd.defra.gsi.gov.uk or alternatively contact VMD reception on 01932 336911 and quote the "Enforcement Team".

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Introduction

1. This is one of a series of Veterinary Medicines Guidance Notes (VMGNs) explaining the requirements under the Veterinary Medicines Regulations (VMR). The VMR are revoked and replaced on a regular basis so reference to them should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument are 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 (VMDs) website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx provides basic information about the scope of the Regulations and the requirement for Marketing Authorisations (MAs).

The Purpose and Method of Enforcement

3. "Enforcement" refers to actions taken by the VMD in relation to breaches of the VMR.

4. The purpose of enforcement is to secure compliance with the requirements of the VMR and therefore to ensure that the aims of the VMD are met. To this end the VMD will 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 the VMD will use more formal means of enforcement to secure compliance.

5. The VMR provide a range of enforcement tools that can be used to secure compliance with the legislation. These include sending warning letters, serving improvement and seizure notices, seizure and destruction of products, variation, suspension or revocation of authorisations or approvals, police cautions and ultimately prosecution. Enforcement action, which may be taken against a business or an individual, is carried out in accordance with the VMD's Enforcement Strategy. The Strategy sets out the general principles and approaches taken to enforce the VMR. The Strategy can be found on:
http://www.vmd.defra.gov.uk/pdf/EnforcementStrategy.pdf

The Principles of Enforcement

6. The VMD recognises that the best way to achieve compliance with the law is to ensure, by guidance and advice, that those carrying out regulated activities understand the nature and extent of their responsibilities and comply voluntarily. However, there are times when conformity with the law needs to be sought by formal enforcement action. Formal enforcement is about securing compliance with regulatory requirements. To this end, there is a range of civil and criminal options available such as warning letters, enforcement notices with statutory effect (where an offence is committed if not obeyed), conditional cautions under the Criminal Justice Act 2003, seizure of illegal products, and criminal prosecutions before the courts. The effective use of enforcement powers in regulatory schemes is important to

secure compliance with the law and, where necessary, to ensure that those who have not complied may be held to account.

Proportionality

7. Enforcement action taken by VMD will be proportionate to the perceived risks [see paragraph 11] associated with an activity and in compliance with the VMR. Where the risks are considered to be low and there is no history of non-compliance, the VMD is unlikely to consider formal enforcement action. However, where the risks are greater or similar non-compliance has previously been noted, more formal action will generally be taken.

Consistency

8. The VMD aims to ensure that for non-compliances, in similar circumstances, similar enforcement action will be taken. The publication and implementation of the VMD Enforcement Strategy is one means by which this aim will be achieved.

Transparency

9. 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 engagement with business, stakeholders and publication of guidance and advice, the VMD aims to make all those dealing with veterinary medicinal products aware of the relevant requirements of the VMR and the measures which need to be taken to comply. The VMD will also clearly explain the statutory requirements and what is considered to be good practice. As part of the VMDs commitment to transparency details of improvement notices, seizure notices and prosecutions are published on the VMD's website and remain there for a period of one year.

Targeting

10. Targeting means ensuring that priorities for enforcement actions are directed at those businesses and individuals who are most likely to fail to comply with the VMR due to the nature or complexity of their activities, or because inadequate control measures or management of control measures are in place. Targeting involves risk assessment of businesses and the concentration of enforcement effort on those with the highest risk and/or lowest compliance.

Enforcement Action

Non-compliances

11. The VMD will deal with non-compliances depending on any perceived risk 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 the VMD believes 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. The VMD will generally send a formal warning letter setting 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 individual's 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.

Powers of an Appointed Inspector

12. An inspector may, on giving reasonable notice, and on producing a duly authenticated authorisation if required, enter any premise at any reasonable hour for the purpose of ensuring that the provisions of the VMR are being complied with.

An appointed inspector entering premises under the VMR may:

a) inspect the premises, and any plant, machinery or equipment;

b) search the premises;

c) take samples;

d) seize any computers and associated equipment;

e) seize any veterinary medicinal products (VMPs), anything purporting to be a VMP, anything which an inspector reasonably believes to be aVMP, any additive to which Schedule 5 applies, or any premixture or feedingstuff specified in Schedule 5 if:

- it is not authorised in the United Kingdom;
- it has not been lawfully supplied in accordance with the VMR;
- it has been stored in a way that affects its safety, quality or efficacy;
- it is sold or offered for sale by a person not permitted to supply it under the VMR;
- seize any premixture or feedingstuff if it contains a VMP or additive to which Schedule 5 applies and which is not authorised in the United Kingdom;

f) carry out any inquiries, examinations and tests;

g) have access to, and inspect and copy or seize any documents or records (in whatever form they are held) relating to the VMR;

h) have access to, inspect and check the operation of any computer and any associated apparatus or material that is or has been in use in connection with the records;

i) require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford him such assistance as he may reasonably require;

j) where a record is kept by means of a computer, require the records to be produced in a form in which they may be taken away.

13. Whenever an inspector has grounds for thinking a veterinary medicine is outwith the VMR, he/she may seize that product. For example, if the product is not labelled in English, or does not have a Vm number, then the product may be seized. The

person from whom the product was seized has 28 days in which to claim against the seizure. If any such claim is upheld then the product will be returned.

14. If an inspector enters a premise and it is not reasonably practicable to determine at the time whether documents on those premises are relevant to the VMR, the inspector may seize them to ascertain their relevance.

Seizure Notices

15. The VMR give appointed inspectors the powers to seize unauthorised and authorised VMPs that may have been illegally imported, supplied, marketed or administered. Inspectors also have the powers to seize all relevant equipment and documents.

    The Notice will clearly set out details of:

    - products that have been seized and
    - grounds for the seizure

16. If an inspector is not able to remove the products seized immediately they may mark the products in any way that they see fit. They may then serve on the person appearing to be in charge of the products a notice prohibiting the products' movement until they are collected. If the products are moved then the person identified in the notice is guilty of an offence.

Claims

17. The person on whom a Seizure Notice is served may notify the Secretary of State, at the address specified on the Notice, of any claim that the product was not liable to seizure, setting out the grounds in full. Any such claim must be made within 28 days of the seizure.

Destruction of Seized Product

18. Unless a valid claim is made within 28 days of the product being seized, it can be destroyed. Where such a claim is made, the court will decide whether the product should be destroyed or returned, or compensation paid for its loss.

Publication of Notices

19. The VMD will publish all Seizure Notices on the VMD website.

Improvement Notices

20. The VMR give appointed inspectors the powers to serve Improvement Notices on any person they believe is not complying with the legislation. Failure to comply with an Improvement Notice is an offence.

21. The Notice will clearly set out:
    - how that person is failing to comply with the VMR;
    - the exact nature of the failure;

- the measures that need to be taken to comply and
- how quickly they should be taken.

22. All Improvement Notices will give the person at least 14 days to take the necessary measures.

Appeals

23. If the recipient of an Improvement Notice believes it to have been unjustly served, he can appeal against it to a magistrates' court or in Scotland, to the sheriff. All Improvement Notices will include details of how to do this. Appeals must be lodged within 28 days of the issue of the Notice, or by the end of the time set in the Notice, whichever is sooner.

Publication of Notices

24. The VMD will publish all Improvement Notices on the VMD website.

Compulsory Variation, Suspension or Revocation of an authorisation or approval

25. The VMD may revoke, suspend or compulsorily vary an authorisation or approval. The circumstances in which such action can be justified are specified in the VMR.

Prosecution

26. In the most serious breaches of the VMR, where there is a significant risk to human or animal health or the environment, or where a business or individual continues an activity following the variation, suspension or revocation of an authorisation or approval for that activity, the case will normally be considered for prosecution.

27. Investigation into such illegal activities may be carried out by the VMD's own inspectors or by officers of Defra Investigation Services (DIS), on behalf of the VMD. All investigations will be carried out in accordance with relevant investigative procedures in particular, the Police and Criminal Evidence Act 1984 (PACE), the Regulation of Investigatory Powers Act 2000 (RIPA) and the Criminal Procedures and Investigation Act 1996 (CPIA).

28. Following an investigation and where there is sufficient evidence of an offence having been committed, the case will be referred to the Crown Prosecution Service..

29. 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 three 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 Prosecutions

30. The VMD will publicise prosecutions on the VMD website.

Further Information

31. A copy of the VMD's Enforcement Strategy is available on the VMD website http://www.vmd.defra.gov.uk/pdf/EnforcementStrategy.pdf

32. 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: VMGNotes@vmd.defra.gsi.gov.uk. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website (www.vmd.defra.gov.uk).

List of Abbreviations

CPIA	Criminal Procedures and Investigation Act 1996
CPS	Crown Prosecution Services
Defra	Department for Environment, Food & Rural Affairs
DIS	Defra Investigation Services
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
PACE	Police and Criminal Evidence Act 1984
RIPA	Regulation of Investigatory Powers Act 2000
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations

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