



**Veterinary Medicines  
Guidance Note**

**Marketing Authorisations  
for Veterinary Medicinal  
Products –  
Appeals Procedures**

**No 11**



**ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES**



# VETERINARY MEDICINES GUIDANCE NOTE 11

*December 2005*

**THESE NOTES ARE ONLY A GENERAL GUIDE AND MUST NOT BE TREATED AS A COMPLETE OR AUTHORITATIVE STATEMENT OF THE LAW ON ANY PARTICULAR CASE**

## **VETERINARY MEDICINES DIRECTORATE**

**WOODHAM LANE, NEW HAW, ADDLESTONE, SURREY KT15 3LS**  
**Telephone: (+44) (01932) 336911 Fax: (+44) (01932) 336618**  
**[www.vmd.gov.uk](http://www.vmd.gov.uk)**



**INVESTOR IN PEOPLE**

**TABLE OF CONTENTS**

<b>CONTENTS</b>	<b>PARAGRAPH</b>	<b>PAGE</b>
<b>INTRODUCTION</b>	<b>1</b>	<b>3</b>
Urgent Action	<b>3</b>	<b>3</b>
Decentralised and Centralised Applications	<b>4</b>	<b>3</b>
<b>APPEALS TO THE VPC</b>	<b>5</b>	<b>4</b>
Written Appeals to the VPC	<b>11</b>	<b>4</b>
Oral Appeals to the VPC	<b>12</b>	<b>4</b>
<b>APPEALS TO AN APPOINTED PERSON</b>	<b>19</b>	<b>5</b>
Manufacturing and Wholesale Dealer’s Authorisations	<b>20</b>	<b>6</b>
Qualified Person (QP)	<b>21</b>	<b>6</b>
Autogenous Vaccines and Small Animal Blood Bank Certificates	<b>23</b>	<b>6</b>
Procedures for Appeals to an Appointed Person	<b>24</b>	<b>6</b>
<b>FEES</b>	<b>28</b>	<b>7</b>
<b>FURTHER INFORMATION</b>	<b>29</b>	<b>7</b>

## INTRODUCTION

1. This is one of a series of guidance notes explaining requirements under the Veterinary Medicines Regulations 2005. These Regulations came into effect on 30 October 2005 and set out controls on veterinary medicinal products in the UK. Basic information about the scope of the Regulations and the requirement for Marketing Authorisations (MA) is given in VMG Note 1: Introduction to Marketing Controls on Veterinary Medicines.
2. The purpose of this note is to describe the arrangements for appeals to either the Veterinary Products Committee (VPC) or Appointed Persons against decisions in connection with applications detailed in this Guidance Note. The following Veterinary Medicinal Guidance (VMG) Notes provide further information on the application procedures:
  - VMG Note 2: Marketing Authorisations for Veterinary Medicinal Products – Applications and Renewals.
  - VMG Note 4: Marketing Authorisations for Veterinary Medicinal Products – National (Type IA/IB/II) Variation Procedures.
  - VMG Note 8: Animal Test Certificates
  - VMG Note 10: Veterinary Medicines Manufacturers and Wholesale Dealers Authorisations.
  - VMG Note 17: Autogenous Vaccine Certificates.

## URGENT ACTION

- 3 If Ministers consider that it is necessary to suspend a Marketing Authorisation (MA) for a veterinary medicinal product urgently, for the protection of animals or human health, they may do so without consulting the VPC. However, the VPC must be consulted within three months of such action, and then the appeal procedures described below apply.

## DECENTRALISED AND CENTRALISED APPLICATIONS.

4. For applications made under the centralised or decentralised Community procedures, where final decisions will be made by the European Commission, taking account of advice from the Committee on Veterinary Medicinal Products (CVMP) where appropriate, there will be no right of appeal to the VPC. In such cases any appeal should be made to the CVMP via the European Medicines Evaluation Agency (EMA) as set out in Articles 36,37,38 and 43 of Directive 2001/82/EC as amended by Directive 2004/28/EC.

### APPEALS TO THE VPC

5. If, following the assessment of your application for a MA, a variation or a renewal of an MA or an Animal Test Certificate (ATC), it is decided that:
  - an authorisation should not be granted, or
  - if the Secretary of State considers it necessary on safety reasons to suspend, withdraw or revoke the authorisation, or
  - the application should be granted subject to changes,you will be notified and given the opportunity to appeal to the VPC. You will be given a maximum of 30 days to decide whether you wish to appeal. The appeal itself can be made in writing or in person.
6. Within 3 months of receipt of notification of your intention to appeal you will be informed of the date set for the hearing or consideration of the written representation. **New data may NOT be submitted for the appeal.**
7. On receipt of notification of your intention to make oral or written representations the VMD will make the necessary arrangements and inform you of the date, time and venue for the oral hearing or, in the case of a written representation, the date on which it will be considered.
8. The way in which you choose to present your case is, of course, for you to determine. It will normally involve a reasoned case of why data that has already been presented and considered should be regarded as sufficient to indicate compliance with the legislative requirements. Documentation setting out the grounds for the appeal or argumentation must be presented in a clear and concise form.
9. All documentation must be submitted to the VMD at least four weeks before the date set for consideration of your appeal so that it can be distributed to, and considered by, the Committee. If the documentation is not received by the appropriate date your appeal will be postponed.
10. The VMD will send you a copy of its assessment of your appeal documentation, at least two weeks before the hearing at which your appeal is due to be considered.

### WRITTEN APPEALS TO THE VPC

11. The VPC will discuss your appeal at its meeting, and will determine the advice it will give to the Secretary of State. The Committee will normally finalise that advice at its next meeting on confirmation of the Minutes. The VMD, acting on behalf of the Secretary of State, will advise you of the outcome.

### ORAL APPEALS TO THE VPC

12. You have the right to support your case by appearing before the Committee, together with any experts whose assistance you may require. If you require

audio/visual equipment please contact the VMD at least one week before the appeal date.

13. Immediately before the time set for your appeal the Committee will examine the documentation submitted and the assessment report.
14. At the start of your presentation you will be asked to introduce your team. You will then be asked if you object to the presence of any official. Officials take no part in the appeal other than to answer questions of fact at the invitation of the Chairman, as it is the Committee that decides upon the advice to be given. Any objections to the presence of any official will be considered and recorded. The Chairman's decisions will be final.
15. However, the VPC has decided that the presence of the following officials is necessary to provide factual advice for the Committee and to keep an accurate record:
  - Senior professional adviser
  - Secretary to the Committee
  - Officials who provided the assessments for the hearing.
16. The Chairman will identify the points to be addressed. Although you may present your appeal as you see fit, the Committee will already have carefully reviewed your documentation. It would therefore be preferable to make concise points. If any additional explanation of part of the data dossier is required, the Committee will ask for it. Following your presentation the Committee may ask questions on any points of detail requiring further clarification.
17. At the end of your presentation you will be asked whether you have any further comments. The Chairman will then inform you that the Committee will report its findings and advice, and the reasons for that advice, to the Secretary of State. Normally the Committee will finalise its advice at its next meeting on confirmation of the Minutes. The VMD, acting on behalf of the Secretary of State, will inform you of the outcome.
18. Failure to appear as arranged may lead to the VPC advising the Secretary of State on the basis of the information before it.

### APPEALS TO AN APPOINTED PERSON

19. There are several circumstances where an appeal may be made to an Appointed Person and these are set out below. Appeals to an Appointed Person can only be made in writing. In each case you will be informed of the date set for the consideration of the written representation as soon as possible, but in any case within 3 months of receipt of notification of intention to appeal.

### MANUFACTURING AND WHOLESALE DEALER'S AUTHORISATIONS

20. If, following the assessment of an application for a manufacturing or wholesale dealer's authorisation, it is decided that an authorisation should not be granted, or if the Secretary of State considers it necessary on safety reasons to suspend, withdraw or revoke the authorisation, you will be notified and given the opportunity to appeal to a person appointed by the Secretary of State. You will be given a maximum of 30 days to decide whether to appeal. **No new data may be submitted for the appeal.**

### QUALIFIED PERSON (QP)

21. There are six types of Qualified Person:
- Registered Qualified Person (RQP);
  - Manufacture Qualified Person (MQP);
  - Wholesale Dealer's Qualified Person (WQP);
  - Qualified Person for Feedingstuffs Production (QPFP);
  - Qualified Person for Feedingstuffs Control (QPFC);
  - Pharmacovigilance Qualified Person (PQP).
22. The appointment of any QP may be refused or revoked if the Secretary of State is not satisfied that a person has fulfilled or will fulfil his/her duties. The QP will be notified and given the opportunity to appeal to a person appointed by the Secretary of State. The QP will be given a maximum of 30 days to decide whether to appeal, which can only be by written representation.

### AUTOGENOUS VACCINES AND SMALL ANIMAL BLOOD BANK CERTIFICATES

23. If, following the assessment of an application for an Autogenous Vaccine Manufacturer, Autogenous Vaccine or a Small Animal Blood Bank Certificate, it is decided that a certificate should not be granted, or if the Secretary of State considers it necessary on safety reasons to suspend, withdraw or revoke the certificate you will be notified and given the opportunity to appeal in writing to a person appointed by the Secretary of State. You will be given a maximum of 30 days to decide whether to appeal. **No new data may be submitted for the appeal.**

### PROCEDURES FOR APPEALS TO AN APPOINTED PERSON

24. On receipt of notification of your intention to appeal, the VMD will make the necessary arrangements and inform you of the Appointed Person, date, time and venue.
25. The way in which you choose to present your case is, of course, for you to determine. Your appeal will involve the presentation of data relating to the points raised or of a reasoned case why data already presented and considered should be regarded as sufficient to indicate compliance with the legislative requirements, or both. Documentation setting out the grounds for the appeal must be presented in a clear and concise manner.

## VETERINARY MEDICINES GUIDANCE NOTE 11

26. All documentation must be submitted to the VMD at least four weeks before the date set for consideration of your appeal. If the documentation is not received by the appropriate date your appeal will be postponed.
27. The Appointed Person will consider your representations and determine the advice to be given to the Secretary of State. The VMD, acting on behalf of the Secretary of State, will advise you of the outcome.

### FEES

28. In most cases a fee is payable for written and oral appeals to cover the cost of any assessment work related to the appeal. Details on the relevant fees can be found in the Veterinary Medicines Regulations 2005, which are available on the VMD website ([www.vmd.gov.uk/](http://www.vmd.gov.uk/)).

### FURTHER INFORMATION

29. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: (+44) (01932) 336911, or Fax: (+44) (01932) 336618. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website ([www.vmd.gov.uk/](http://www.vmd.gov.uk/)).



# VETERINARY MEDICINES GUIDANCE NOTE

**VETERINARY MEDICINES DIRECTORATE**

**WOODHAM LANE, NEW HAW, ADDLESTONE, SURREY KT15 3LS**

**Telephone: (+44) (01932) 336911 Fax: (+44) (01932) 336618**

**[www.vmd.gov.uk](http://www.vmd.gov.uk)**



**ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES**