



# Veterinary Medicines Guidance Note

## Marketing Authorisations for Veterinary Medicinal Products – Appeals Procedures

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ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES



**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**

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## INTRODUCTION

1. This is one of a series of Veterinary Medicine Guidance (VMG) Notes explaining requirements under the Veterinary Medicines Regulations ('the Regulations'). The Regulations are revoked and replaced every year, so the references 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 this VMG Note. The VMG Notes are updated as necessary and the date of the most recent update is shown on the front cover. The Regulations set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. VMG Note 1: *Introduction to Marketing Controls on Veterinary Medicines* 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 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: Wholesale Dealers Authorisations;
  - VMG Note 17 Authorisations for Specific Manufacturers
  - VMG Note 14: Marketing Authorisation Exemption Scheme for Pet Animal Medicines.

## URGENT ACTION

3. The Secretary of State may immediately suspend a Marketing Authorisation (MA) for a veterinary medicinal product, for the protection of animals, the environment or human health. The appeal procedures described below apply.

## CENTRALISED APPLICATIONS

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

### DECENTRALISED AND MUTUAL RECOGNITION APPLICATIONS

5. For applications made under the Mutual Recognition or Decentralised Procedure routes, the Veterinary Coordination Group on Mutual Recognition and Decentralised Procedures (CMDv) makes the final decisions. Again, there is no right of appeal to the VPC. The VPC will be consulted as appropriate during the assessment of such products but any divergent opinion between Member States will result in a referral to CMD(v) under Article 33 (1) of Directive 2001/82/EC (as amended).
6. If the CMD(v) is unable to reach a consensus within a period of 60 days then a further referral is made to CVMP, via the European Medicines Agency (EMA), under Article 33 (4) of the above Directive. In such cases the referral will follow Articles 36, 37, 38 and 43.

### APPEALS TO THE VPC

7. Following the assessment of your application for an MA, a variation or a renewal of an MA, an Animal Test Certificate (ATC) or an approval of an active substance under Schedule 6, it may be decided that:
  - an authorisation or approval should not be granted or
  - the application or approval should be granted subject to changes.

Alternatively the Secretary of State may consider it necessary on safety reasons to suspend, withdraw or revoke the authorisation or approval.

8. In these circumstances we will notify you and give you the opportunity to appeal to the VPC. You will be given a maximum of 28 days to decide whether you wish to appeal. You can make your appeal either in writing or in person.
9. On receipt of notification of your intention to make an oral or written representation the VMD will make the necessary arrangements and, within 28 days of that receipt, you will be informed of the date set for the hearing or consideration of the written representation. It will not be possible to postpone the date of the appeal. New data may NOT be submitted for the appeal, although previously presented data may be presented or analysed in a different manner.
10. 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 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, or both. Documentation setting out the grounds for the appeal must be presented in a clear and concise form.

### WRITTEN APPEALS TO THE VPC

11. All documentation must be submitted to the VMD at least 28 days before the date of the meeting at which it is to be considered so that it can be distributed to, and considered by, the VPC. If the VPC does not receive documentation by the appropriate date it will consider your appeal on the basis of the information it has before it and will advise the Secretary of State accordingly.
12. At least two weeks before the hearing at which your appeal is due to be considered, the VMD will send you a copy of its assessment of your appeal documentation.
13. The VPC will discuss your appeal 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

14. If you choose to make an oral appeal, you will be given the opportunity to submit your appeal documentation for consideration by the VPC at the meeting before that set for your appearance. This is to allow the Committee to examine the documentation and advise of any issues that may be regarded as resolved so that, when you appear before the Committee, you need only address the outstanding issues.
15. At least two weeks before the meeting at which your appeal is due to be considered the VMD will send you a copy of its assessment of your appeal documentation.
16. At that meeting the VPC will examine your appeal documentation, together with the VMD assessment report. The VMD will then advise you of any issues that may be regarded as resolved.
17. You have the right to support your case by appearing before the VPC with any experts whose assistance you may require. If you require audio/visual equipment you should contact the VMD at least one week before the date of the meeting at which you are to appear.
18. At the start of your presentation the Chairman will ask you to introduce your team. You will also 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.
19. 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;

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- Secretary to the Committee;
  - Officials who provided the assessments for the hearing.
20. Any objection to the presence of any official will be considered and recorded. The Chairman's decision will be final.
  21. The Chairman will identify the outstanding points to be addressed. Although you may present your appeal as you see fit, as the Committee will already have carefully reviewed your documentation it would 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.
  22. 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 consider the Committee's advice and inform you of the outcome of your appeal.
  23. If you fail to appear as arranged, the VPC will advise the Secretary of State on the basis of the information before it.

## APPEALS TO AN APPOINTED PERSON

### PROCEDURES FOR APPEALS TO AN APPOINTED PERSON

24. If following the VPC's advice the VMD, acting on behalf of the Secretary of State, upholds its original decision, we will notify you and give you the opportunity to appeal to an Appointed Person.
25. Your appeal to an Appointed Person can only be made in writing. In each case we will inform you of the date set for the consideration of the appeal as soon as possible, but in any case within 3 months of receipt of your notification of intention to appeal.
26. 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. New data that was not available at the time of the original decision may NOT be submitted for the appeal, although previously presented data may be presented or analysed in a different manner. You must present documentation setting out the grounds for the appeal in a clear and concise manner.
27. You must submit all documentation to the VMD at least 28 days before the date set for consideration of your appeal.

28. The Appointed Person will consider the VMD assessment report and 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.
29. If the documentation is not received by the appropriate date, the Appointed Person will advise the Secretary of State on the basis of the information available.
30. There are other circumstances where you can make an appeal to an Appointed Person and these are set out below.

### **MANUFACTURING AND WHOLESALE DEALER'S AUTHORISATIONS**

31. 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, we will notify you and give you the opportunity to appeal to a person appointed by the Secretary of State. You will be given a maximum of 28 days to decide whether to appeal. You may not submit new data for your appeal, although previously presented data may be presented or analysed in a different manner.

### **QUALIFIED PERSON (QP)**

32. These Qualified Persons (QPs) are eligible for right of appeal:
  - 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)
33. 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 28 days to decide whether to appeal.

### **RETAIL PREMISES APPROVED BY THE SECRETARY OF STATE**

34. If, following an application for an approval of premises for the sale and supply of veterinary medicinal products by an SQP, it is decided that an approval should not be granted, or if the Secretary of State considers it necessary on safety reasons to suspend, withdraw or revoke the approval, we will notify the owner of the premises. The applicant or approval holder will have the opportunity to appeal to a person appointed by the Secretary of State. You will be given a maximum of 28 days to decide whether to appeal. You may not submit new data for your appeal, although previously presented data may be presented or analysed in a different manner.

### **AUTOGENOUS VACCINES, NON-FOOD ANIMAL BLOOD BANK AUTHORISATIONS AND EQUINE STEM CELL CENTRES**

35. If, following the assessment of an application for an Autogenous Vaccine Manufacturer, a Non-Food Animal Blood Bank Authorisation or an Equine Stem Cell Centre, 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 28 days to decide whether to appeal. You may not submit new data for your appeal, although previously presented data may be presented or analysed in a different manner.

### **FEES**

36. In most cases a fee is payable appeals to the VPC or an Appointed Person to cover the cost of any assessment work related to the appeal. The fee is refundable if, as a result of the appeal, the Secretary of State changes the decision that was the subject of the appeal. Details on the relevant fees can be found in Schedule 7 of the Veterinary Medicines Regulations, which are available on the VMD website.

### **FURTHER INFORMATION**

37. 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 or E-mail: [VMGNotes@vmd.defra.gsi.gov.uk](mailto: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.gov.uk](http://www.vmd.gov.uk)).

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