Veterinary Medicines Directorate

VETERINARY MEDICINES GUIDANCE NOTE

No 9

GUIDANCE ON APPEALS AGAINST REGULATORY DECISIONS

Last updated July 2013

www.gov.uk

QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed primarily at those who wish to appeal against the intention of or the decision by, the Veterinary Medicines Directorate (VMD) acting on behalf of the Secretary of State, in relation to any matter covered by the Veterinary Medicines Regulations (VMR).

The quick start guide is a summary of the provisions of the VMR for appeals against a provisional decision of the Secretary of State.

The VMR provide an appeals' procedure for:

- any person who receives a notification from the Secretary of State informing that person (the appellant) of a right to an appeal to the Veterinary Products Committee (VPC), and

- an applicant for :
  - a manufacturing authorisation;
  - appointment as a Qualified Person for the purpose of a manufacturing authorisation;
  - an authorisation for a person or premises to manufacture autogenous vaccines;
  - an authorisation for a blood bank;
  - an authorisation for a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade;
  - an authorisation of an equine stem cell centre;
  - a wholesale dealer's licence;
  - the approval of premises for the supply of Prescription Only Medicine-Veterinarian, Pharmacist, Suitably Qualified Person (SQP) (POM-VPS) or Non-Food Animals-Veterinarian, Pharmacist, SQP (NFA-VPS) veterinary medicinal products by an SQP;

  aggrieved by a provisional decision of the Secretary of State, or

- a person served an Improvement Notice or Seizure Notice under the VMR.

Detailed information is found in the body of the guidance note.

FURTHER INFORMATION

For more information on the appeals' procedure please contact the VMD Committee and Office Support team on 01932 338490 or alternatively contact VMD reception on 01932 336911 and quote "the appeals' procedure".

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Introduction

1. This is one of a series of Veterinary Medicine Guidance Notes (VMGNs) explaining requirements under the Veterinary Medicines Regulations (VMR). The VMR are revoked and replaced on a regular basis, so any references to them should be read as referring to those currently in force. Therefore, the date and number of the Statutory Instrument are not shown in this VMGN. The VMGN will be updated as necessary and the date of the most recent update is shown on the front cover. The VMR and VMGN are available on the VMD website www.vmd.defra.gov.uk.

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 (VMD) website: http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx provides basic information about the scope of the VMR and the requirement for Marketing Authorisations (MAs).

3. The purpose of this VMGN is to describe the arrangements for appeals against the intention of, or decision by, the Veterinary Medicines Directorate (VMD) acting on behalf of the Secretary of State, in relation to any matter covered by the VMR.

Routes of Appeal

Applications for an MA made under the centralised procedures

4. The European Commission (EC) makes the final decision on an application made under the centralised procedures, taking account of advice from the Committee on Veterinary Medicinal Products (CVMP) where appropriate. Any appeal against the decision 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 which can be found on http://ec.europa.eu/health/files/eudralex/vol-5/dir_2001_82_cons2009/dir_2001_82_cons2009_en.pdf

Applications for an MA made under the mutual recognition or decentralised procedures

5. The Veterinary Co-ordination Group on Mutual Recognition and Decentralised Procedures (CMDv) makes the final decision on an application made under the mutual recognition or decentralised procedures. Any divergent opinion between Member States (MS) will result in a referral to CMDv under Article 33(1) of Directive 2001/82/EC (as amended). If the CMDv is unable to reach a consensus within a period of 60 days then a further referral is made to CVMP, via the EMA, under Article 33(4) of the above Directive. *In such cases the referral will follow* Articles 36, 37, 38 and 43.

Applications for MAs and variations or renewals of MAs, Animal Test Certificates (ATCs), approvals for active substances and suspensions of MAs made under the national procedures

6. The VMD makes the final decision on an application made under the national procedures for an MA, a variation or a renewal of an MA, an ATC or an approval of an active substance under Schedule 6. The VMD may also suspend a national MA, either immediately or after due notice, for the protection of animals, the environment or human health. Any appeal against the VMD's decision should be made to the Veterinary Products Committee (VPC). Following an unsuccessful appeal to the VPC a further appeal may be made under the 'appointed person' procedure.

Applications for:

- **manufacturing authorisation**
- **wholesale dealer's authorisation**
- **appointment as a Qualified Person (QP) for the purposes of a manufacturing authorisation**
- **authorisation for a person or premises to manufacture autogenous vaccines**
- **authorisation of a blood bank**
- **authorisation for a person and premises to manufacture an unauthorised veterinary medicinal product (also known as a 'Special') for administration under the cascade**
- **authorisation of an equine stem cell centre, or**
- **the approval of premises for the supply of Prescription Only Medicines-Veterinarian, Pharmacist, Suitably Qualified Person (SQP) (POM-VPS) or Non Food Animals-Veterinarian, Pharmacist, SQP (NFA-VPS) veterinary medicinal products by an SQP.**

7. The VMD makes the final decision on an application for these authorisations and approvals. Any appeal against the VMD's decision to refuse an application, or suspend or revoke an authorisation or approval should be made under the 'appointed person' procedures.

Improvement Notices

8. Where a person fails to comply with a specified requirement of the VMR, an inspector appointed under the VMR may, in accordance with the VMD's Enforcement Strategy which can be found on www.vmd.defra.gov.uk, serve an improvement notice on that person. However, a person who believes that the improvement notice was unjustly served may appeal, in England, Northern Ireland and Wales, to a magistrates' court or, in Scotland, to the sheriff.

Seizure Notices

9. An inspector appointed under the VMR has the power to seize products, equipment and documentation. A person on whom a seizure notice is served by an inspector appointed under the VMR, who believes that the product should not have been seized, may make a claim to the Director of Operations, VMD who will act on behalf of the Secretary of State.

Appeals to the VPC

Introduction

10. If, having considered your application made under the national procedures for an MA, a variation or a renewal of an MA, an ATC or an approval of an active substance under Schedule 6, the VMD decides that an authorisation or approval should not be granted or should be granted subject to changes, or if the VMD intends to suspend your MA, you will be notified and given 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.

11. On receipt of notification of your intention to appeal the VMD will make the necessary arrangements and, within 28 days of that receipt, the VPC Secretary will inform you of the date of the meeting at which it will be considered. Other than in exceptional circumstances it will not be possible to postpone the date of the appeal. New data, i.e. data not available to the VMD when it made its decision, may not be submitted for the appeal, although previously presented data may be presented or analysed in a different manner.

12. Your appeal will involve the presentation of data relating to the points of refusal or suspension, 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. The way in which you choose to present your case is, of course, for you to determine but documentation setting out the grounds for the appeal must be presented in a clear and concise form.

13. You will be asked to provide an electronic version of your appeal data for distribution to the VPC and necessary officials at least 28 days before the date of the meeting at which it is to be considered so that it can be assessed by the VMD and distributed to the VPC for consideration. If the VPC does not receive your documentation by the appropriate date it will consider your appeal on the basis of the information before it and will advise the VMD accordingly.

Written Appeals to the VPC

14. Having received your appeal data in accordance with (13) above, the VMD will send you a copy of its assessment of it at least two weeks before the meeting at which your appeal is due to be considered.

15. The VPC will consider your appeal data and agree its advice to the Secretary of State. On confirmation of the minutes of the VPC meeting the VMD will advise you of the outcome of your appeal.

16. If, following the VPC's advice, the Secretary of State upholds its original decision, you will be notified and given the opportunity to make a further appeal under the 'appointed person' procedure (see paragraphs 41 – 46, below).

Oral Appeals to the VPC

17. If you choose to make an oral appeal, you will be given the opportunity to submit an electronic version of your appeal data for consideration by the VPC at the meeting before that set for your appearance (the pre-appeal meeting). This is to allow the VPC to examine it and advise of any issues that may be regarded as resolved so

that, when you appear before the VPC at the following meeting, you need only address the outstanding issues.

18. If you choose to take advantage of a pre-appeal consideration, you must submit an electronic version of your appeal data for distribution to the VPC and necessary officials at least 28 days before the pre-appeal meeting. The VMD will then send you a copy of its assessment of it at least two weeks before the pre-appeal meeting.

19. At the pre-appeal meeting the VPC will examine your appeal data, together with the VMD assessment report and advise the VMD of any issues it considers to have been resolved. The VMD will then advise you of the outstanding issues to be addressed in your oral appeal.

20. If you choose to forego the opportunity to have your appeal data considered by the VPC in advance of your oral hearing you must submit an electronic version of it for distribution to the VPC and necessary officials at least 28 days before the date of your hearing. The VMD will send you a copy of its assessment of it at least two weeks before the meeting at which you are to appear.

21. 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. It is also helpful to provide an electronic version of any presentation a few days before the meeting and to bring with you enough copies of the presentation sufficient for the VPC and necessary officials.

22. You have the right to support your case by appearing before the VPC with any experts whose assistance you may require. A few days before the meeting you should notify the VMD the names of those attending.

23. On the day of your hearing you should arrive at the VMD approximately 15 minutes before the time set for your hearing. You will be met by a member of the VMD who will be able to explain how the meeting will proceed. You will be asked for the copies of your presentation so that they can be tabled prior to your entering the meeting.

24. On entering the meeting you will be introduced to the Chairman who 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 VPC that decides upon the advice to be given.

25. However, the VPC has decided that the presence of the following officials is necessary to provide factual advice for the VPC and to keep an accurate record:

    Senior professional adviser
    Secretary to the VPC
    Officials who provided the assessment(s) for the hearing

26. Any objection to the presence of an official will be considered and recorded. The Chairman's decision will be final.

27. The Chairman will identify the outstanding points to be addressed. Although you may present your appeal as you see fit, as the VPC will already have carefully

reviewed your data, it would be preferable to make concise points. If any additional explanation of part of the data dossier is required, the VPC will ask for it. Following your presentation you may be asked questions on any points of detail requiring further clarification.

28. At the end of your presentation you will be asked whether you have any further comments. The Chairman will inform you that the VPC will report its findings and advice, and the reasons for that advice, to the VMD. On confirmation of the minutes of the VPC meeting the Secretary of State will consider that advice and inform you of the outcome of your appeal.

29. If, following the VPC's advice, the Secretary of State upholds its original decision, you will be notified and given the opportunity to make a further appeal under the 'appointed person' procedure (see paragraphs 41 – 46, below).

30. If you fail to appear as arranged, the VPC will advise the VMD on the basis of the information before it.

Appeals to an Appointed Person

Following an unsuccessful appeal to the VPC

31. If, following the VPC's advice, the VMD upholds its original decision, you will be notified and given the opportunity to appeal to a person appointed by the VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for a Manufacturing Authorisation

32. If, following the assessment of your application for a manufacturing authorisation, the VMD decides that it should not be granted, or if the VMD 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 VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for appointment as a Qualified Person (QP)

33. The following Qualified Persons are eligible for right of appeal:

    Manufacture Qualified Person
    Wholesale Dealer's Qualified Person
    Qualified Person for Feedingstuffs Production
    Qualified Person for Feedingstuffs Control
    Pharmacovigilance Qualified Person

34. The VMD may refuse your application for, or revoke your appointment as a QP if it is not satisfied that you have fulfilled or will fulfil your duties. In such cases, you will be notified and given the opportunity to appeal to a person appointed by the VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for an authorisation for a person or premises to manufacture Autogenous Vaccines

35. If, following the assessment of your application for a person or premises to manufacture autogenous vaccines, the VMD decides that an authorisation should not be granted, or if the VMD 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 VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for an authorisation for a Non-Food Animal Blood Bank

36. If, following the assessment of your application for a Non-Food Animal Blood Bank authorisation, the VMD decides that an authorisation should not be granted, or if the VMD 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 VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for the authorisation of a person and premises to manufacture an unauthorised veterinary medicinal product (also known as a 'Special') for administration under the cascade

37. If, following the assessment of your application for the authorisation of a person and premises to manufacture an unauthorised veterinary medicinal product (VMP) for administration under the cascade, the VMD decides that an authorisation should not be granted, or if the VMD 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 VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for an authorisation for an Equine Stem Cell Centre

38. If, following the assessment of your application for a Non-Food Animal Blood Bank authorisation, the VMD decides that an authorisation should not be granted, or if the VMD 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 VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for a Wholesale Dealer's Authorisation

39. If, following the assessment of your application for a wholesale dealer's authorisation, it is decided that an authorisation should not be granted, or if the VMD 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 VMD. The procedure is outlined at paragraphs 41 – 46, below.

By an applicant for the approval of premises for the supply of POM-VPS or NFA-VPS veterinary medicinal products by a suitably qualified person

40. If, following the assessment of your application for an approval of premises for the supply of POM-VPS or NFA-VPS veterinary medicinal products by a suitably qualified person, the VMD decides that an approval should not be granted, or if the VMD decides to suspend or revoke the approval of the approved premises because it is satisfied that they are no longer suitable for the storage and supply of veterinary medicinal products, you will be notified and given the opportunity to appeal to a person appointed by the VMD. The procedure is outlined at paragraphs 41 – 46, below.

Procedure

41. Following notification by the VMD you will have a maximum of 28 days to decide whether to appeal.

42. Your appeal to an appointed person can only be made in writing. The VMD will inform you of the name of the appointed person and the date set for the consideration of the appeal as soon as possible, but in any case within three months of receipt of your notification of intention to appeal.

43. 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.

44. All documentation setting out the grounds for the appeal must be presented in a clear and concise manner and must be submitted electronically to the VMD at least 28 days before the date set for consideration of your appeal.

45. The appointed person will consider the VMD assessment report and your representations and determine the advice to be given to the VMD. The VMD will advise you of the outcome.

46. 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.

Appeals to a Magistrates Court or, in Scotland, the Sheriff

Against the serving of an Improvement Notice

47. The VMR give appointed inspectors the powers to serve Improvement Notices on any person they believe is not complying with any aspect of them. If you are served with an Improvement Notice, it will clearly set out the inspector's view on how you are failing to comply with the VMR, the exact nature of the failure, the measures that you need to take to comply, and how quickly you should take them.

48. If you believe it to have been unjustly served, you can appeal to a Magistrates' Court in England and Wales or to the Sheriff in Scotland. Your appeals must be lodged within 28 days of the issue of the Improvement Notice, or by the end of the time set in the Improvement Notice, whichever is sooner.

49. The court will decide whether to uphold, adjust or overturn the Improvement Notice.

Appeals to the Director of Operations, VMD

Against the seizure of goods

50. The VMR give appointed inspectors the powers to seize both unauthorised and authorised VMPs, specified feed additives (SFAs), premixtures and feedingstuffs containing VMPs or SFAs if they have been illegally supplied or are being marketed or used illegally; and any computers and associated equipment, documents or records (in whatever form they are held) relating to the VMR.

51. In such cases the inspector will provide you with a Seizure Notice detailing why the products were seized; and in what circumstances.

52. If you believe that the products were not liable to seizure you can make a legal claim to the Director of Operations, VMD, for the return of the property or compensation for its loss. You must set out the grounds in full and submit the claim within 28 days of the seizure.

Fees

53. In most cases a fee is payable for 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 VMD changes the decision that was the subject of the appeal. Details on the relevant fees can be found in Schedule 7 of the VMR, which are available on the VMD website www.vmd.defra.gov.uk.

Further Information

54. 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

ATC	Animal Test Certificate
CMDv	The Veterinary Co-ordination Group on Mutual Recognition and Decentralised Procedures
CVMP	Committee on Veterinary Medicinal Products
Defra	Department for Environment, Food & Rural Affairs
EC	European Commission
EMA	The European Medicines Agency
MA	Marketing Authorisation
MS	Member State
NFA-VPS	Non-Food Animal – Veterinarian, Pharmacist, Suitably Qualified Person
POM-VPS	Prescription Only Medicine – Veterinarian, , Pharmacist, Suitably Qualified Person
QP	Qualified Person
SQP	Suitably Qualified Person
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
VPC	Veterinary Products Committee

VETERINARY MEDICINES GUIDANCE NOTE

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