



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

VETERINARY MEDICINES GUIDANCE NOTE

No 18

RELEASE OF VETERINARY MEDICINAL PRODUCTS TO THE UK MARKET

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www.vmd.defra.gov.uk

QUICK START GUIDE

- This Veterinary Medicines Guidance Note (VMGN) provides guidance on the batch release and specific batch control schemes, and is aimed at holders of Marketing Authorisations (MAs) and/or Autogenous Vaccine Authorisations (AVAs).
- The quick start guide is a summary of the provisions of the Veterinary Medicines Regulations (VMR) in relation to the batch release and specific batch control schemes; detailed information is found in the body of the guidance note.
- The batch release scheme relates to authorised Immunological Veterinary Medicinal Products (IVMPs), which cannot be placed onto the UK market without a batch release request being submitted to the Veterinary Medicines Directorate (VMD). This is a requirement of European Union (EU) Directive 2001/82/EC, as amended. The IVMP must have an MA that is applicable to the UK in order for them to be released onto the UK market, or for the VMD to permit release onto the EU/European Economic Area (EEA) and Swiss markets.
- The specific batch control scheme relates to authorised Veterinary Pharmaceuticals, which can be released onto the market without the requirement to inform the VMD if there is an MA for the medicine that is applicable to the UK. The batch of product must have been manufactured in accordance with the MA including meeting all of the appropriate in process and final batch testing requirements.
- In cases where a product does not meet these requirement and is authorised by means of an Animal Test Certificate (ATC) or by means of a National UK MA (not subject to Mutual Recognition Procedure (MRP)), the ATC or MA holder (MAH) may request the VMD to carry out Specific Batch Control. Specific Batch Control does not apply to any other type of authorisation.

Further Information

- For more information please contact the VMD's Licensing Admin team on +44 (0)1932 338421 or alternatively contact VMD reception on +44 (0)1932 336911 and quote "batch release" or "batch control".

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Introduction

1. This is one of a series of Veterinary Medicines Guidance Notes (VMGNs) explaining the requirements for Marketing Authorisations (MAs) under the Veterinary Medicines Regulations (VMR), which are revoked and replaced on a regular basis, so any references to them should be read as referring to those that are 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.
2. The VMR set out the UK controls on veterinary medicines including their manufacture, advertising, marketing, supply and administration. VMGN No 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 an MA, i.e. what constitutes a veterinary medicinal product (VMP).
3. This VMGN provides guidance on the batch release and specific batch control schemes.
4. Unless otherwise specified, all documents available on the VMD website will be found in the thematic area, 'Pharmaceutical Industry'.

CHAPTER 1

Batch Release Scheme: Immunological Products

5. Immunological Veterinary Medicinal Products (IVMP) cannot be placed onto the UK market without a batch release request being submitted to the VMD. This is a requirement of European Union (EU) Directive 2001/82/EC, as amended. The IVMP must have an MA that is applicable to the UK in order for them to be released onto the UK market, or for the VMD to permit release onto the EU/European Economic Area (EEA) and Swiss markets.

Types of Batch Release

6. The VMD has differentiated between the different types of batch release by categorising them as follows:

Article 81 – Not subject to re-testing

- **Type 81a** – Marketing Authorisation Holder (MAH) requests release of batch(es) in the EU (i.e. UK and/or other member states (MSs));
- **Type 81b** MAH sends VMD a batch release certificate issued by another MS authorising release onto the UK market;
- **Special** – MAH requests release of batch(es) under this Article, which are out-of-specification. The VMD will consider these requests for release in the UK only, and

Article 82 – Subject to re-testing

- **Type 82a** – MAH requests release of batch(es) in the EU (i.e. UK and/or other MSs), and
- **Type 82b** – MAH sends VMD a batch release certificate issued by another MS authorising release onto the UK market.

Autogenous Vaccine Authorisations (AVAs)

- **AVA** - The batch release arrangements are also applicable to autogenous vaccines, which are UK specific.

Further information about Article 82

- Article 82 of the Directive allows an MS (if they wish) to request samples of each batch of a given specific type of IVMP to be submitted to a Competent Authority for official testing by an Official Medicines Control Laboratory before that batch is released onto the market. *The list of product types for which Article 82 is applied is available on the European Directorate for the Quality of Medicines (EDQM) website:* <http://www.edqm.eu/en/Product-Specific-Guidelines-Model-Protocol-Templates-OCABROBPR-85.html>.
- The VMD is not applying Article 82a at the current time. The MAH can apply to the VMD for batch release of IVMP for which Article 82a applies. The batch will be treated as an Article 81a release and, if the batch meets the requirements for release, an Article 81 EU/EEA release certificate will be issued.

Further information about Special Release

- Special Batch Release may be requested for a batch of IVMP where not all of the final product release tests meet specification, or where manufacture does not fully comply with the MA. A full justification as to why the batch does not meet specification along with assurances that the safety, efficacy and quality of the IVMP have not been compromised must be submitted with the batch release protocol. VMD will review the batch release protocol and accompanying documentation. Further clarifying information may be requested by the VMD. Depending on the outcome of the review the VMD will either approve or reject the request. If approval is granted, the batch of IVMP can be placed on the UK market only. In some instances approval may be given with conditions attached (e.g. additional stability testing of the batch).

Further information about Autogenous Vaccines

- Autogenous vaccines by their nature are emergency vaccines and do not require prior approval from the VMD before being placed on the market. However, a batch release protocol must be submitted to the VMD at the time of release. The batch of vaccine must not be released by the AVA holder until the purity, inactivation, sterility and on-farm safety tests have been completed and meet specification.

Timescales

11. The VMD has 10 days from receipt to process a batch release request (ex. Article 82a, which is subject to a different timescale). It is the responsibility of the MAH to plan their batch release schedules with the 10 day deadline in mind. If further information/clarification is required from the applicant, the clock will stop pending receipt of the outstanding information and will restart once this has been received; therefore, we encourage MAHs to respond to requests for additional information as quickly as possible in order to expedite the batch release process.
12. A high volume of requests are received on a daily basis, so, to ensure fairness to all MAHs, requests are dealt with in date order unless the urgent request rule applies – see below.

Urgent requests

13. In very exceptional circumstances, and for animal welfare reasons, there may be a need to have a batch release request dealt with in a shorter timeframe. In these cases, please send an email to the batch release section at batchr@vmd.defra.gsi.gov.uk, copied to Tom Nash at t.nash@vmd.defra.gsi.gov.uk and to Rick Parker at r.parker@vmd.defra.gsi.gov.uk providing justification for why the batch release request is urgent and the date you would like it dealt with by. The VMD will consider the request and, if the VMD agrees that the request is urgent, it will be dealt with accordingly.
14. Please note an urgent request should be the exception rather than the rule and will only be considered 'urgent' if non-release of the batch poses an animal welfare issue.
15. Where you are aware that an urgent request is likely to be necessary, for the purpose of planning work it would be helpful if you contacted the VMD a week prior to the intended submission date.

Submission of documentation

16. From 1st April 2012 we introduced new ways of e-working in the batch release area with a view to improving efficiency and reducing paper wastage; therefore, we would be very grateful if MAHs would submit their batch release requests in electronic format wherever possible. You should submit your batch release request via email (Eudralink or, if you wish, normal email; please note, other secure email systems will not be accepted) to: batchr@vmd.defra.gsi.gov.uk.
17. We will continue to accept hard-copies although we strongly encourage MAHs to move to e-submissions as soon as possible. If submitting in hard-copy, please send your requests to: *C/O Batch Release, Lic Admin team, VMD, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS.*
18. The MAH should submit the relevant documentation, in accordance with the guidance available on the EDQM website (www.pheur.org). Model protocols for different product types are available on the EDQM website (<http://www.edqm.eu/en/Product-Specific-Guidelines-Model-Protocol-Templates-OCABROBPR-85.html>). They are meant to encourage a harmonised presentation of

documentation by the MAH and should be used when preparing the documentation for review by the relevant MS.

19. The manufacture of the batch of IVMP must be in full compliance with both the MA and Good Manufacturing Practice (GMP) and include a declaration by the Qualified Person (QP). If it is not in full compliance then the procedure for special batch release should be followed.
20. The batch release documentation should be accompanied by a covering letter/page, which should include the following information. If this information is not provided the request may be rejected and you will be asked to resubmit the request. Please note, providing the following information in this format will expedite the release of your request:
 - Type of batch release being applied for, e.g. Type 81a
 - Product Name/Trade Name
 - Name and address of MAH
 - Name and address of manufacturer, if different.
 - MA Number, i.e. Vm No.
 - Batch number (appearing on packaging)
 - Batch number of diluent (if applicable)
 - Type of container
 - Total number of containers in this batch
 - Number of doses per container
 - Volume per container (in millilitres)
 - Start date of period of validity
 - Expiry Date of the product
 - Any deviations from the MA
 - Contact name and email address
21. The batch control documentation provided should be signed by the responsible QP of the MAH before submission to the VMD. Please note that electronic signatures are acceptable.
22. Please ensure all information provided is legible. If any information is illegible the request will be rejected and you will be asked to resubmit.
23. It should be noted that batch release requests are charged for regardless of whether the request is approved, refused or rejected.

Requests for further information

24. The VMD will contact the MAH via email requesting further information, if required. At this point the clock will stop pending receipt of a full company response; once received, and the response is deemed satisfactory, the clock will restart. MAHs are encouraged to respond to these requests for further information as quickly as possible to ensure that the decision to approve/refuse is not unduly delayed. Therefore, it is extremely important that the MAH include a contact name and email address with their submission documentation.

Provision of labels

25. Submission of labels is not a requirement under the EU harmonised batch release arrangements; therefore, the MAH is not required to submit a copy of the label with the batch release request. It is the responsibility of the QP to ensure the label displays the correct expiry date and batch number, and is in accordance with the MA.

Notification of Approval or Refusal of a Batch Release Request

Article 81 (including special batch release)

26. The VMD will inform the MAH of the decision to approve or refuse a batch release request within 10 clock days of receipt of the initial request. The VMD suggests that it is in the interest of the MAH not to release batches until they have received confirmation from the VMD that the batch is acceptable.
- **Type 81a** – the MAH will be issued with a certificate approving the batch release request OR a formal notice notifying them of the decision to refuse (for non-compliance).
 - **Type 81b** – the MAH will receive an acknowledgement of receipt of the EU certificate informing them that the information provided is accurate OR requesting further information.
 - **Special** – the MAH will be notified by email of the decision to approve or refuse their request.

Article 82

27. **Type 82a** - The VMD, having performed the examination of the manufacturer's control reports and the repetition of tests for the given IVMP, will inform the MAH of the decision to approve or refuse a batch release request within 60 days of receipt of the samples together with the signed and complete MAH control protocol. In exceptional circumstances the period necessary to complete the tests may be extended, if necessary, and the marketing authorisation holder will be informed if this is done. Please note that VMD does not currently apply Type 82a release and does not carry out any repeat testing.
- The MAH will be issued with a certificate approving the batch release request OR a formal notice notifying them of the decision to refuse (for non-compliance).
28. **Type 82b** – The VMD will inform the MAH of the decision to recognise, or not, an EU release certificate issued by another MS within 10 days of receipt of that certificate.
- The MAH will receive an acknowledgement of receipt of the EU certificate informing them that the information provided is accurate OR requesting further information. If further information is requested the 10 day clock will stop until the requested information is received and is deemed satisfactory.

Autogenous Vaccines

29. The authorisation holder should submit a batch release protocol to the VMD once all tests are complete and at the time of release on to the market; however, confirmation of release from the VMD is not required, i.e. the batch can be dispatched to the market as soon as the batch release protocol has been submitted.

30. Products that have failed a batch release test should not be marketed; if authorisation holders are found to be placing 'failed' products onto the market their authorisation will be revoked.

Further information

31. 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: VMGNNotes@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).
- on scientific aspects of the batch release scheme, please contact Rick Parker on +44 (0)1932 338445, or via email at: r.parker@vmd.defra.gsi.gov.uk.
 - on administrative aspects, please contact the VMD's Lic Admin team on +44 (0)1932 338498 or (0)1932 338421, or via email at: batchr@vmd.defra.gsi.gov.uk.

CHAPTER 2

Specific Batch Control Scheme: Pharmaceutical Products

32. Veterinary Pharmaceuticals can be released onto the market without the requirement to inform the VMD if there is an MA for the medicine that is applicable to the UK. The batch of product must have been manufactured in accordance with the MA including meeting all of the appropriate in process and final batch testing requirements.
33. In cases where a product does not meet these requirement and is authorised by means of an Animal Test Certificate (ATC) or by means of a National UK MA (not subject to Mutual Recognition procedure (MRP)), the ATC or MA holder may request the VMD to carry out Specific Batch Control. Specific Batch Control does not apply to any other type of authorisation.

Specific Batch Control

34. Specific Batch Control may be requested in relation to pharmaceutical products authorised by means of an ATC or by means of National UK MA that have not been the subject of a Mutual Recognition procedure. The Scheme does not apply to immunological products.
35. An ATC or MA holder may request the VMD to carry out Specific Batch Control where some element of the product differs in some way from those detailed in the ATC dossier or the MA. Such situations may relate to the quality characteristics of the batch of final product or to a starting material used during manufacture. In this context, starting material includes the active substance, excipient and packaging, which includes the primary packaging, and where they are described in the authorisation, the outer packaging and package leaflet. When making a request, the

ATC or MA holder must provide details of the deviation and submit relevant papers including supporting data relating to the batch deviation.

36. The VMD will consider the request and other papers in light of the MA or ATC and form a view based on the documents submitted. The VMD will then inform the MA or ATC holder whether or not it expects to take regulatory action. Such action may be to instigate recall or otherwise prohibit the supply of the product should the batch be released onto, or remain on, the UK market. The VMD will make its decision in light of the quality characteristics reported with the request for Specific Batch Control and accompanying papers.

Examples

37. The following are examples of situations where, subject to the provisos set out in paragraphs 2.1 and 2.6 of this VMGN, it may be appropriate to consider submitting an application for specific batch control:
- A batch of the finished product marginally fails to meet the agreed release Finished Product Specification (FPS) for one parameter which will not have a negative impact on the stability of the product nor its safety and efficacy.
 - A batch of the active substance has been subjected to an additional purification step and the rework procedure is not described in the MA dossier. The solvents used and their residual levels do not have an adverse impact on the safety of the product or its physico-chemical characteristics or stability. The batch of active substance may be destined for use in the manufacture of several batches of the finished product.
 - The labelling of the finished product is not in strict accordance with the agreed labelling but the differences are minor and will not have any adverse impact on the safe use of the product.
 - On-going stability studies for a particular production batch of finished product have identified that a parameter may just fall outside the agreed shelf-life. FPS limits the time the batch reaches the end of its shelf-life but this will not have an adverse impact on safety or efficacy of the product. A justified widening of the shelf-life limits for the relevant parameter is proposed for that specific batch.
 - A conservative extension to the shelf-life of one batch of the finished VMP beyond the approved shelf-life is required in order to avoid a supply problem in the market place. The batch has been retested against the complete FPS within three months of its expiry date and there is no evidence of any significant degradation.
38. It is understood that an initiative is being progressed within the EU to permit QPs some discretion in certain specific circumstances. Under this initiative and in the following circumstances, a batch of product may be placed on the market without the need for specific batch control.

- The deviation is minor, one-off and unplanned in nature and relates only to the manufacturing process and/or the analytical control methods of either the starting materials or the medicinal product as described in the MA.
- The active substance and FPS as described in the MA are complied with.
- An assessment is performed by the manufacturer using the approaches described in ICH Q9, Quality Risk Management, to support a conclusion that the occurrence is a minor quality deviation that does not affect the safety and efficacy of the product.
- The risk assessment should assess the need for inclusion of the affected batches in the on-going stability programme.
- The Quality Risk Management Programme is integrated into the manufacturer's quality assurance system, notably the documentation system established to comply with GMP, and records are available for inspection by the Competent Authorities.
- All such deviations must be reviewed as part of the annual product quality review.

Inspectors will examine the files logging use of this system to ensure that it is not abused and will take a serious view of any abuse.

The Application Process

Prior to Submission

39. An MA or ATC holder must first consider whether it is appropriate to apply for specific batch control of a particular batch. This decision must be reached taking into account the views of the relevant QP as to the suitability of the batch for its intended use. In addition, consideration should be given as to whether or not sufficient supporting data already exist which would permit a variation application to be progressed instead. Wherever feasible, the submission of a variation application is preferable, as this will apply to all batches of the starting material or finished product. For further information on how to apply for a variation please refer to VMGN 2 Marketing Authorisations for Veterinary Medicinal Products - National (IA/IB/II) Variation Procedures, which is published on the VMD's website:
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.
40. In the case of a batch of product which is already on the UK market and the QP considers that a request for specific batch control is not appropriate and that recall of the batch is necessary. In such a case, the VMD's Suspected Adverse Reactions Surveillance Scheme (SARSS) should be contacted immediately and details of the nature and extent of the recall should be supplied.
41. For MAs only, if it is considered appropriate to proceed with the release of the relevant batch(es), then in the first place the MAH should contact the Supervisory Authority. This is the relevant body in the member state where the site of final product release into the EU is located. For veterinary medicines manufactured in the UK, the VMD is the Supervisory Authority. Thus, for a veterinary medicine manufactured and authorised in the UK, a single approach to the VMD in the form of

a specific batch control request should be made. Where a veterinary medicine is authorised in the UK but the VMD is not the Supervisory Authority, you should first approach the Supervisory Authority and then submit a request for specific batch control to the VMD.

Submission and Validation

42. Applications (application form and accompanying papers) may be submitted to the VMD either electronically (an eSubmission), or in hard-copy, although we strongly encourage applicants to submit their applications electronically. An eSubmission may be sent via email (using Eudralink or not; it is the applicant's choice) to s.response@vmd.defra.gsi.gov.uk. Note there is a 40mb limit on the Eudralink system. If submitting in hard-copy the applicant should send the application package to the following address:

Information Services
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

43. A copy of the application form can be found on the VMD's website: (www.vmd.defra.gov.uk). It is important to use the correct form and to complete all sections of it. Where the same issue affects a number of batches, a single form may be used. However, it should be noted that one fee is charged for each batch indicated on an application form.
44. The accompanying papers should include all supporting data and relevant material relating to the finding of a batch deviation; complete batch records are not required. The papers should include copies of the relevant Certificates of Analysis together with the data and/or arguments which justify the suitability of the batch for its intended use. In addition, where appropriate, the papers should address the need for any corrective measures to avoid a future recurrence of the problem. If relevant, they should also indicate any planned variation applications together with a timescale for the submission of these.
45. Specific Batch Control applications are subject to validation; therefore, upon receipt of an application package, a check will be made to ensure that all documents have been received and that the application form has been filled in correctly. Once the application is deemed valid it will progress into the assessment phase.

Assessment and Outcome

46. Valid applications are usually only assessed by a quality assessor who may, however, draw upon advice of colleagues from other disciplines in reaching a view on the material submitted. Where the VMD is also the Supervisory Authority, the quality assessor may liaise with the relevant Medicines and Healthcare products Regulatory Agency (MHRA) inspector.
47. If the VMD is satisfied that it can reach a view without the need for questions, we will indicate in writing whether it would expect to take regulatory action. Such action may

be to recall or otherwise prohibit the supply of the product should the batch be placed on the market. Any such decision would be based on its consideration of the material provided. In some situations, we may say that we would not expect to take such regulatory action provided that specified steps are taken by the MA or ATC holder when placing the batch on the market.

48. For example, where a product just fails to comply with the FPS limits for a single parameter, which is likely to have some bearing on stability, a reduction in the shelf life of the particular batch may be defined. Another example would be where a product fails to comply with the FPS for a single parameter, which could, but however is thought unlikely to, have an adverse effect on the stability of the product. Here the specified step may be to establish controlled stability studies on that batch and to inform the VMD immediately of any adverse results or trends.
49. The assessor may decide that further information is required before reaching a view. In this event, they will write to the MA or ATC holder with any questions they may have, seeking a complete response within 10 days of the date of the letter. We will assess the response and indicate in writing whether we would expect to take regulatory action referred to in paragraph 17. Alternatively, if the assessor thinks it appropriate, he/she may send one final further set of questions to the MA or ATC holder for response within 10 days, after which we will make the final assessment and give an indication regarding our anticipated regulatory response should the batch be placed on the market.
50. The VMD's documentation, containing our conclusion on the specific batch control request, be it positive or negative, should be forwarded to the QP who should ensure that it is included as part of the batch record.
51. Where a positive opinion from the VMD will result in a change to the labelling of a product which has a UK MA, for example where an extended shelf-life is approved, the over-labelling must be conducted at a suitably authorised premise. The premise will usually be the assembly site named on the MA Memorandum for the product. As a minimum the premise must possess a Manufacturing Authorisation that covers the relevant activities.
52. It is important to note that the relevant batch(es) should remain in quarantine until such time as the VMD has responded substantively to the request for Specific Batch Control to be undertaken.

Timetable for Specific Batch Control

53. Applications for specific batch control will be subject to a three day validation period and three day issue period.
54. The VMD will aim to complete the initial assessment of requests and accompanying papers within 10 calendar days of receipt of a valid application and to assess any responses to questions and reach a final view within 10 calendar days of receipt of a complete and satisfactory response.

55. MA or ATC holders requesting specific batch control may request an accelerated determination, but a justification for this should be provided. Where possible the VMD will accommodate such requests, particularly when an animal welfare issue could arise as a result of non-availability of a particular product.

Fees

56. A single fee applies to a batch even when that batch deviates from the authorisation in more than one respect. Details on the relevant fees can be found in the VMR, which are available on the VMD website (www.vmd.defra.gov.uk/).
57. The fee should not accompany the request form. The VMD will invoice the applicant on receipt of a properly completed request form and accompanying papers.
58. Whilst this scheme may not be used for those pharmaceutical products which have been the subject of an MRP, it may be possible to progress specific batch (Type II) mutual recognition variations. The Reference Member State (RMS) and relevant Concerned Member States (CMSs) will need to be contacted to establish if this is feasible for a specific product and a specific set of circumstances.

Further Information

59. 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: VMGNNotes@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).
- on scientific aspects of specific batch control, please contact one of the VMD's quality assessors on +44 (0)1932 33 + extension 8401, 8403, 8404 or 8405;
 - on administrative aspects, please contact the VMD's Lic Admin team on +44 (0)1932 338498 or (0) 1932 338421.

List of Abbreviations

ATC	Animal Test Certificate
AVA	Autogenous Vaccine Authorisation
CMS	Concerned Member State
Defra	Department for Environment, Food & Rural Affairs
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EU	European Union
FPS	Finished Product Specification
GMP	Good Manufacturing Practice
IVMP	Immunological Veterinary Medicinal Product
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
MS	Member State
RMS	Reference Member State
QP	Qualified Person
STC	Special Treatment Certificate
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations



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VETERINARY MEDICINES GUIDANCE NOTE

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