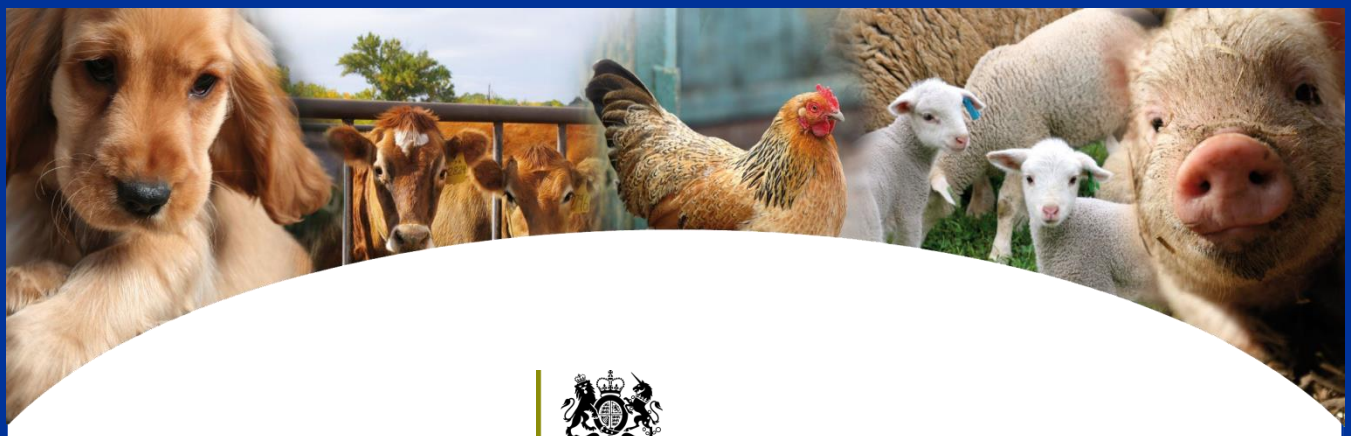

Veterinary Medicines Directorate

Document withdrawn as out of date. Please refer to guidance at [Veterinary medicines guidance - GOV.UK]

EXPORT CERTIFICATES SCHEME

Last updated July 2013

QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed primarily at those persons who wish to export veterinary medicinal products (VMPs).

The quick start guide is a summary of the provisions of the Veterinary Medicines Regulations (VMR) in relation to exportation of VMPs and the provision of export certificates; detailed information is found in the body of the guidance note.

The VMR implements requirements relating to the exportation of VMPs and the provision of export certificates, which are set out in European Union (EU) Directive 2001/82/EC (as amended).

Export certificates serve to certify that the product which is to be exported was manufactured in accordance with the UK marketing authorisation (MA), if there is one, or if not, that the manufacturer holds a manufacturing authorisation (ManA) in the UK for that type of product. Different types of certificates are available depending on the requirement of the exporter. All certificates are available in English, French and Spanish.

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

FURTHER INFORMATION

For more information on export of veterinary medicinal products and the provision of Export Certificates; please contact the VMD's Information Services' team on 01932 338392 or alternatively contact VMD reception on 01932 336911 and quote "export certificates".

TABLE OF CONTENTS

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 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 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 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 gives basic information about the scope of the VMR and the requirements for Marketing Authorisations (MA). The purpose of this Note is to provide guidance on the procedures for applying for an export certificate.

Scope for Export Certificates

3. Export certificates are issued at the request of the manufacturer or exporter of veterinary medicinal products (VMPs) to a third country. They serve to certify that the product which is to be exported was manufactured in accordance with the UK MA, if there is one, or if not, that the manufacturer holds a manufacturing authorisation (ManA) in the UK for that type of product.

4. When issuing such certificates, for VMPs intended for export which are authorised or manufactured in the UK, the Summary of Product Characteristics (SPC) and/or Manufacturing Authorisation (ManA) may be provided.

Types of Certificates

5. Different types of certificates are available depending on the requirement of the exporter. These are attached to a schedule and completed by the applicant. The schedule templates can be found at Annex B. Types of certificates are as follows:

Type of Certificate	Use
Defra-1	Applied for by the manufacturer or exporter. Confirms the manufacturing site is in the UK and is Good Manufacturing Practice (GMP) compliant (and is inspected by the Medicines and Healthcare products Regulatory Agency (MHRA) or VMD). Confirms the UK administrative address and UK manufacturing site address(es) and the authorised operations at this site.
Defra-2	Applied for by the exporter or manufacturer. Confirms the product is authorised for sale in the UK.
Defra-3	Applied for by the manufacturer or exporter. Confirms the manufacturing site is in the UK and is GMP compliant (and is inspected by the MHRA or VMD). Confirms the UK administrative address and UK manufacturing site address(es) and the authorised operations at this site. No schedule attached.
Defra-4	Applied for by the exporter or manufacturer. Confirms the active substances are available in the UK in an authorised veterinary medicinal product and the exported product is manufactured in the UK by an authorised manufacturer. Confirms the UK administrative address and UK manufacturing site address(es) and the authorised operations at the UK manufacturing site.
Defra-SFA	Applied for by the manufacturer or exporter. Confirms the SFA manufacturing site OR product to be exported is an authorised Specified Feed Additive (SFA). Confirms the SFA site is in the UK and is GMP compliant (and is inspected by the MHRA or VMD). Confirms the UK administrative address and UK site address(es) if applicable and the authorised operations at this site.

6. All certificates are available in Spanish and French. If the schedule is required in Spanish or French a translation in English must also be provided as part of the application.

7. The certificate is attached to a standard Schedule that is provided by the applicant. The template for a schedule for each type of certificate can found at Annex B. The SPC or ManA may also be attached to the certificate and schedule.

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How to Apply

8. You may apply for an export certificate online at the following URL: https://www.vmd.defra.gov.uk/EC/Login.aspx?ReturnUrl=%2fec. Alternatively you can visit the VMD homepage www.vmd.defra.gov.uk and click on the 'Online export certificates' link, found under the 'Quick Links' section. To register to use the online export certificate system please contact 01932 338392.

9. Once logged into the online system you can select the required type of certificate and continue with your application. The system will allow you to upload word document schedules. Templates are available to download to create your schedule documentation which must be uploaded as part of the application process.

   For online FAQs please see the following URL: http://www.vmd.defra.gov.uk/pdf/ExportCertificatesFAQ.pdf

10. Please note that online applications are not available for Defra-SFA certificates. Please submit applications for a Defra-SFA electronically by email to exportcert@vmd.defra.gsi.gov.uk or by post addressed to: Information Services Section, Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS.

11. The application must be in English and if applying by post please include the appropriate number of copies of schedules for the number of certificates required.

12. If applying by email/post you must provide a covering letter on headed paper (template example at Annex A) with a schedule for each of the products to be exported (template examples at Annex B).

13. The covering letter and schedule must state the manufacturing activity that is being carried out on the exported product by the named manufacturer. If the product cited is not manufactured or assembled at this site, an export certificate cannot be supplied and the application will not be validated.

14. The covering letter must also state the full contact details of the authorities of the third country to which the certificate relates.

15. The application must be signed by a person authorised on behalf of the exporting company and must be supported by a valid Letter of Indemnity (template example at Annex C). Where applicable, you may provide the relevant approved SPC (legible and in English) for each product or request that the VMD attach this to the certificate. If the manufacturing site is regulated and inspected by the MHRA, for the first application a current version of the ManA must be submitted with the application.

16. Examples of documents that the VMD will accept and may be attached to the certificate are as follows:

Document	Information provided
Manufacturing Authorisations	Proof of manufacturing activities which are regulated by the MHRA or the VMD

SPC & Product Literature	For UK authorised products, the current SPC or Product literature which has been approved and signed by the VMD.
Marketing Authorisations	For UK authorised products, the Marketing Authorisation issued by the VMD

17. If you wish to attach Spanish or French versions of any of the above documents to the export certificate, English translations of the document must be provided and these will also be attached to the certificate.

18. The VMD will not stamp/approve documentation that:

- cannot be folded and stapled together at the left hand corner successfully due to volume of papers. This may be due to the number of documents required per product i.e. an SPC and ManA for each schedule may make up to 20 pages per product. Therefore the VMD advises no more than five products per certificate if the SPC and/or ManA are required.
- in the VMD's view is false, misleading or unsubstantiated;
- does not name the country of import;
- does not contain the complete formulation of the exported product as part of the application (Defra-1 and Defra-4 only)
- names the UK as the country of import;
- contains details of products which are not manufactured by a registered GMP UK manufacturer;
- company literature which does not form part of the ManA or MA in the UK and is not approved by the VMD, for example, Batch analysis tests, Health certificates or other test certificates;
- includes details of an unauthorised product which the VMD cannot verify from the ManA, for example, Batch numbers, container sizes and weight, Production and expiry dates. The VMD will not provide a certificate for a medical device.

19. A Defra-2 schedule must include the UK authorised product name i.e. the name of the product on the Marketing Authorisation. If required, the applicant may supply the Veterinary Medicinal Product name in country of import. Defra-2 schedules that do not include the product name as stated on the Marketing Authorisation will not be validated.

Letter of Indemnity

20. Applications must be supported by a valid Letter of Indemnity which lasts for a period of one year. This serves to guarantee that all the details supplied by the applicant are correct. Should a fraudulent claim be made, the applicant will be responsible for any cost incurred by the VMD. An example of a Letter of Indemnity is at Annex C.

Letter of Access (Defra-1, Defra-3 & Defra-4)

21. If the applicant is not the Manufacturer of the exported product, the applicant must submit in support of their application a Letter of access. The Letter of access provides the VMD with permission to use the Manufacturers details and Manufacturer Authorisation number. See Annex D for a template Letter of Access.

Transmissible Spongiform Encephalopathy (TSE) Declaration

22. If the authorities in the importing country so require, the company may include a statement that the authorised product named is free from ingredients of a ruminant origin on the attached schedule. This statement must be phrased so that it is clear that it is a statement from the company and not the VMD or Defra. This statement can only be used on the schedule attached to a Defra-2 certificate.

How the VMD will deal with an Application

23. The application will be validated on receipt to ensure that all the required information has been provided. If any information required is missing you will be asked to provide it, or the application will be returned to you within four days of receipt.

24. If acceptable, the certificate will be drawn up and sent to you, within four working days of being received. Copies of original certificates can be issued on request at a fee.

25. After the certificate has been issued the appropriate invoice will be sent to the applicant. Details of the relevant fees can be found in the Veterinary Medicines Regulations (VMR), which are available on the VMD website (www.vmd.defra.gov.uk).

Further Guidance for Exports

26. A person authorised to supply VMPs in the UK must ensure that if they export an authorised VMP from the UK to another EU Member State, it can lawfully be supplied and administered in that Member State.

27. To be able to export veterinary medicines of any legal category other than AVM-GSL the exporter must be authorised to be in possession of the medicines in the UK. The following list indicates who is able to export on a wholesale basis:

    a) The holder of an MA which relates to the product to be exported.

    b) A manufacturer who holds an authorisation relevant to the product to be exported.

    c) A holder of a wholesale dealer's authorisation (WDA). For information on how to apply for a WDA, please contact the VMD on 01932 338469.

Further Information

28. The VMD strongly advises UK exporters to obtain an export certificate before shipment. If you have a specific export issue and require any guidance or assistance,

please contact Information Services before shipment. For more information about export certificates please contact the Information Services team on 01932 33 8392/8496 or exportcert@vmd.defra.gsi.gov.uk or alternatively contact the VMD reception on 01932 336911 and quote “export certificates”.

29. There are new controls in place on the export of drugs that can be used for lethal injection (death penalty). The link to the guidance on Controls on Torture Goods is: https://www.gov.uk/controls-on-torture-goods

30. This explains the details of what exporters need to do to apply for a licence if they are exporting any of the drugs / barbiturate agents controlled on an EU wide basis by Council Regulation 1352/2011 which amends the EU Torture Regulation.

31. Further guidance on other aspects of strategic export controls are published at https://www.gov.uk/beginners-guide-to-export-controls.

ANNEX A

COVERING LETTER FOR Defra-SFA EXPORT CERTIFICATE APPLICATIONS

[*To be provided on company headed paper*]

Information Services Section
Export Certificates
Veterinary Medicines Directorate
New Haw
Addlestone
Surrey
KT15 3LS [*Date*]

Dear

Application for Export Certificates

Please supply the relevant certificate as specified below:

1. Name and address of applicant:

2. Name and address of exporting company (if not applicant):

3. Name of Importing Country for which certificate is required:

4. Name, address and contact telephone number of regulatory authority (equivalent to the VMD) responsible for the import of veterinary medicinal product(s) into the country named in 3. above:

5. Exported product(s) name:

6. Marketing Authorisation Number: (if applicable)

7. Manufacturing Authorisation holder: (Defra-1, Defra-3 and Defra-4 only)

8. Formulation of Exported product including excipients: (Defra-1 and Defra-4 only)

9. The manufacturing activity that is being carried out on the exported product by the named manufacturer as stated on the Manufacturing Authorisation and on the schedule: (Defra-1, and Defra-4 only)

10. Manufacturing Authorisation Number:

11. Certificate language: (English, French or Spanish Certificate available)

12. Certificate required: DEFRA-1/2/3/4/SFA

13. VMD Reference number received for notification of export through the EU to third country: (If applicable)

14. Number of copies required: (Please enclose a schedule for each)

VMD will issue <u>one</u> original certificate per application with a unique certificate number. Please state the number of copies of this original required. The same certificate number will appear on all copies.

Yours sincerely
[*Signature of Authority as named on letter of indemnity*]

ANNEX B

SCHEDULE TEMPLATES

Defra-1

Export Certificate Schedule. Details of Veterinary Medicinal Product for export from the UK to [Country]

Veterinary Medicinal Product name in country of import:

Pharmaceutical form:

Marketing Authorisation Vm number: (if not applicable remove this sentence)

UK Manufacturer address:

ManA number:

This Veterinary Medicinal Product does not hold a Marketing Authorisation in the UK. However, the above GMP compliant facility is authorised for the following:

(Add here product type manufactured and activity as stated in ManA)

or

This Veterinary Medicinal Product is authorised in the United Kingdom and the above GMP compliant facility is authorised for the following:

(Add here product type manufactured and activity as stated in ManA)

Defra-2

Export Certificate Schedule. Details of Veterinary Medicinal Product for export from the UK to [Country]

Veterinary Medicinal Product name as authorised in the UK:

Veterinary Medicinal Product name in country of import (if different from above):

Marketing Authorisation Vm number:

Pharmaceutical form:

Formulation (stated on the SPC):

TSE Declaration:

If you wish to enter a statement confirming that the above product is lawfully manufactured with raw materials of non-ruminant origin and is free of BSE/TSE and Foot and Mouth Disease, please add here.

This Veterinary Medicinal Product is authorised in the United Kingdom.

Defra-4

Export Certificate Schedule. Details of Veterinary Medicinal Product for export from the UK to [Country]

Veterinary Medicinal Product name in country of import:

Pharmaceutical form:

UK Manufacturer address:

ManA number:

Formulation [active substances]:

This exported Veterinary Medicinal Product does not hold a Marketing Authorisation in the UK. However, the above active ingredient(s) are available in the UK in an authorised Veterinary Medicinal Product and the above GMP compliant facility is authorised for the following:

(Add here product type manufactured and activity as stated in ManA)

Defra-SFA

Export Certificate Schedule. Details of Specified Feed Additive for export from the UK to [Country]

Specified Feed Additive (SFA) product name:

UK SFA Manufacturer name and address:

SFA Authorisation number:

Pharmaceutical form:

**Delete as appropriate*

*This SFA is authorised in the United Kingdom
*This SFA is authorised in the United Kingdom and the above GMP compliant facility is authorised for the following:

(Add here product type manufactured and activity as stated in UK SFA Manufacturer Authorisation)

* This SFA is not authorised in the UK. However, the above GMP compliant facility is authorised for the following:

(Add here product type manufactured and activity as stated in UK SFA Manufacturer Authorisation)

ANNEX C

TEMPLATE LETTER OF INDEMNITY

[*To be provided on company headed paper*]

Information Services Section
Export Certificates
Veterinary Medicines Directorate
New Haw
Addlestone
Surrey [*Date*]
KT15 3LS

Dear

Letter of Indemnity

I understand that all information given in the attached documents and schedules is entirely the responsibility of my Company. I certify that the contents of any documents supplied by my Company will be true and correct including, where applicable, that the named manufacturer is authorised to produce the types of products listed in the application and schedules which will be attached to export certificates issued by the VMD.

My Company will fully indemnify the VMD in respect of any loss, expense or other disbursement incurred as a direct result of any action arising from misleading or inaccurate information supplied by me for the purpose of the issue of the Export Certificate.

In addition, the following representatives listed below are the only ones who are authorised on behalf of the Company to apply for Export Certificates. The VMD will be notified immediately of any changes to this list.

Authorised to apply:

[*List*]

I understand that a further letter will be required after twelve months from the date of this letter before any more Export Certificates can be issued. Furthermore, it is the responsibility of our company to ensure that the VMD holds a valid Letter of Indemnity.

Yours sincerely

[*Signature of Authority from the Company stated on above Letter Head*]

ANNEX D

Template Letter of Access

[*To be provided on company headed paper*]

Information Services Section
Veterinary Medicines Directorate (VMD)
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS [Date]

Dear Information Services Section

Please accept this letter as confirmation that we permit [Company] to use our following Manufacturing site details* in applications for Export Certificates to the VMD. I accept that the authorised manufacturing activities at the site detailed below will be stated on the Export Certificate issued by the VMD.

Manufacturing site Name and address*
Manufacturing Authorisation number*

Yours sincerely

(Name and position)
[*Signature of Authority from the Company stated on above Letter Head*]

List of Abbreviations

AVM-GSL	Authorised Veterinary Medicine – General Sales List
CPP	Certificate of Pharmaceutical Product
Defra	Department for Environment, Food & Rural Affairs
EC	European Commission
EU	European Union
GMP	Good Manufacturing Practice
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
ManA	Manufacturing Authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
MS	Member State
SFA	Specified Feed Additive
SPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
WDA	Wholesale Dealers Authorisation
WHO	World Health Organisation

VETERINARY MEDICINES GUIDANCE NOTE

Veterinary Medicines Directorate
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Search for VMD on www.gov.uk