



**Veterinary Medicines
Guidance Note**

**Export
Certificates
Scheme**

No 25

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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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INVESTOR IN PEOPLE

EXPORT CERTIFICATES SCHEME

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INTRODUCTION

1. This is one of a series of Veterinary Medicines Guidance (VMG) Notes explaining the 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 will be updated as necessary and the date of the most recent update is shown on the front cover.
2. 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* gives basic information about the scope of the Regulations and the requirements for Marketing Authorisations (MAs). 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 was manufactured in accordance with the UK MA, if there is one, or if not, that the manufacturer holds a manufacturing authorisation in the UK for that type of product.
4. When issuing such Certificates, the following will apply:
 - the VMD will take into account the model certificates issued by the World Health Authority (WHO);
 - for VMPs intended for export which are authorised in the UK, the Summary of Product Characteristics (SPC) or an equivalent document must be provided;
5. The Certificate is valid for the specified consignment only, as detailed in the application.

TYPES OF CERTIFICATES

6. Different types of Certificates are available depending on the requirement of the exporter. Types of Certificates are as follows:

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Type of Certificate	Use
DEFRA-1	Applied for by the exporter or the manufacturer. Confirms the product has been manufactured in the UK by an authorised manufacturer for the specific type of product
DEFRA-2	Applied for by the exporter. Confirms the product is authorised for sale in the UK
DEFRA-3	Applied for by the manufacturer as the exporter. Confirms that the product has been manufactured in the UK by an authorised manufacturer for the specific type of product
DEFRA-4	Applied for by the exporter or manufacturer. Confirms the active substances are available in the UK for an authorised veterinary medicinal product and the exported product is manufactured in the UK by an authorised manufacturer
DEFRA-SFA	Applied for by the exporter or manufacturer. Confirms that the specified feed additive products listed in the Schedule are lawfully sold in the UK
DEFRA-GMP	Applied for by the exporter or manufacturer. Confirms that manufacturer is authorised in the UK to produce sterile/non-sterile, liquid/semi-solid products for internal/external use in accordance with Good Manufacturing Practice and are regularly inspected by the appropriate inspectorate.

7. DEFRA 1, 2 & 3 Certificates are also available in Spanish and French. DEFRA 4 Certificates are also available in French. DEFRA-SFA & DEFRA-GMP Certificates are also available in Spanish.
8. The Certificate is attached to the Schedule that is provided by the applicant. The Schedule should contain information regarding the manufacturer's authorisation, active substances and MA, if applicable. For UK authorised VMPs, the SPC, or equivalent document shall also be attached.

HOW TO APPLY

9. You may apply for an Export Certificate by post to: Licensing Services Section, Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS. The application must be in English with the appropriate number of copies of schedules for the number of original Certificates required.
10. You must provide a covering letter on headed paper (template example at Annex A) with a schedule of products to be exported (template example at Annex B). Where applicable, you must also provide the relevant approved SPC or equivalent document (legible and in English) for each product. If a product is not

authorised for sale within the UK, an explanation should be provided. The request 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).

11. A summary of the minimum details to be provided for each Certificate are listed in the table below:

Certificate Type	Information Required
DEFRA-1	Manufacturers' Authorisation number
DEFRA-2	Vm numbers of the products to be exported
DEFRA-3	Details of the manufacturing site and Authorisation number
DEFRA-4	Manufacturer's authorisation number and the formulation
DEFRA-SFA	The European Identification number of the Specified Feed Additive (Zootechnical Product) authorised in accordance with EU Regulations 1831/2003
DEFRA-GMP	Details of administrative and manufacturing sites within the UK

12. Examples of documents that the VMD will accept and may be attached to the Certificate:

Document:	Information provided:
Certificate of Pharmaceutical Product (CPP)	Details of the product and manufacturer as per model WHO certificate
Certificates of manufacture	Manufacturing site details
Order forms	Order details
Copies of Certificates issued by VMD/MHRA	Various
SPC & Product literature	Product details

13. The VMD will not stamp/approve documentation that:
- in the VMD's view are obviously false, misleading or unsubstantiated;
 - contains details of products which are not authorised in the UK or manufactured by a registered UK manufacturer.
14. The VMD will not provide a Certificate for a medical device.

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LETTER OF INDEMNITY

15. 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.
16. An example of a Letter of Indemnity is at Annex C. The template for this letter can be e-mailed to companies upon request.

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) DECLARATION

17. If the authorities in the importing country so require, the company may include a statement that the product(s) is/are free from ingredients of a ruminant origin on either their schedule or attached documents. This statement must be phrased so that it is clear that it is a statement from the company and not the VMD or Defra.

HOW THE VMD WILL DEAL WITH AN APPLICATION

18. 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.
19. If acceptable, the Certificate will be drawn up and sent to you, normally within four working days of being received. Copies of original Certificates can be issued on request.
20. After the Certificate has been issued the appropriate invoice will be sent to the applicant. Details on the relevant fees can be found in the Regulations, which are available on the VMD website (www.vmd.gov.uk).

FURTHER GUIDANCE FOR EXPORTS

21. The person authorised to supply veterinary medicinal products 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.
22. To be able to export veterinary medicines of any legal category other than AVM-GSL (please refer to VMGN 3 for more information on legal categories) 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. A manufacturer who holds an authorisation relevant to the product to be exported.
 - b. A holder of a wholesale dealer's authorisation (WDA).
 - c. A veterinary surgeon, pharmacist or Suitably Qualified Person (SQP) providing that the SQP's qualification is relevant to the product to be

exported and **Providing that the wholesale transactions represent less than 5% of annual turnover for veterinary medicines.**

FURTHER INFORMATION

23. 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.gov.uk).

ANNEX A

APPLICATION FOR EXPORT CERTIFICATES

[To be provided on company headed paper]

Licensing Services Section
Export Certificates
Veterinary Medicines Directorate
New Haw
Addlestone
Surrey
KT15 3LS

[Date]

Dear

Application for Export Certificates

Please supply the relevant certificates for export as specified below: -

1. Name & Address of applicant:
2. Name of Country for which Certificate is required:
3. The product(s) name:
4. Manufacturing Authorisation Number:
5. Marketing Authorisation Number: (if applicable)
6. Language required for: (English, French or Spanish Certificate available)
7. Certificate required: DEFRA-1/2/3/4, GMP or SFA
8. Number of copies required:
(Please enclose schedule for each)

Yours sincerely
[Signature of Authority]

ANNEX B

**SCHEDULE FOR
EXPORT**

SCHEDULE FOR EXPORT TO [*country*]

All Schedules to include the following information:

PRODUCT: [product name]

MANUFACTURER: [manufacturer name and ManA No.]

ADDRESS: [manufacturer address]

DEFRA-2 MARKETING AUTHORISATION No: [Vm number]

PHARMACEUTICAL FORM:

FORMULATION:

Active Substances:

Inactive Substances:

This product is manufactured, authorised and sold in the United Kingdom in accordance with the statutory requirements.

DEFRA-3 Schedule Not Required

DEFRA-4 FORMULATION:

Active Substances:

Inactive Substances:

DEFRA-SFA List of Zootechnical substances

DEFRA-GMP Address of the Administrative Offices as well as the Manufacturing site.

ANNEX C

LETTER OF INDEMNITY

[To be provided on company headed paper]

Licensing Services Section
Export Certificates
Veterinary Medicines Directorate
New Haw
Addlestone
Surrey
KT15 3LS

[Date]

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.

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]

VETERINARY MEDICINES GUIDANCE NOTE

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