

# Veterinary Medicines Guidance Note

## Import Certificate Schemes

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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

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### INTRODUCTION

1. This is one of a series of Veterinary Medicine 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 included 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.
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*) provides basic information about the scope of the Regulations and the requirement for Marketing Authorisations (MAs).
3. The purpose of the Guidance Note is to describe the procedures for applying for a:
  - Special Import Certificate (SIC);
  - Special Treatment Certificate (STC);
  - Wholesale Dealers Import Certificate (WDIC);
  - Research Import Certificate (RIC).

### SCOPE FOR IMPORT CERTIFICATES

4. Where there is no suitable authorised product in the UK to treat a particular condition and when the health situation so requires, a veterinary surgeon may wish to seek an import certificate to obtain a veterinary medicinal product authorised in another EU Member State or outside the EU. For SICs it is the responsibility of the veterinary surgeon to justify the use of the product according to the 'prescribing cascade' and keep records to that effect. For STCs, no certificate will be granted if there is a suitable UK product or EU veterinary product available. It is the responsibility of the veterinary surgeon to ascertain this fact.
5. For STC's the VMD must be satisfied that there is a positive Risk:Benefit assessment that has been performed by the responsible veterinarian, in relation to use of the product in the animal, (the justification). This assessment should include the safety and quality of the product as well as its efficacy. The VMD may add specific warnings related to animal or user safety, and environmental safety, but it remains the responsibility of the veterinarian, to perform a full risk/benefit analysis and to ensure safe use and disposal of the product.
6. For these reasons, this may not be a suitable way of obtaining products to treat food-producing species or for the importation and use of vaccines. Particularly in the case of vaccines, the VMD must have available sufficient information on the

## IMPORT CERTIFICATES SCHEMES

quality, manufacture and safety of the product to be certain that no major safety risk will arise.

7. Where a product or substance is required for use in research performed under an Animal (Scientific Procedure) Act (A(SP)A) Licence, the appropriate project licence holder may apply, on-line, for a Research Import Certificate (RIC) to import that product or substance. The prescribing cascade does not apply.
8. Unless previously suspended or revoked, the import certificate will remain valid until the quantity specified has been imported and used, or the expiry date stated on the certificate, whichever occurs first. The period of validity for the import certificate does not have to extend to the whole course of treatment.
9. If any matters stated in the application are false or incomplete, in a way which influences the decision reached, we may refuse your application or revoke the certificate, if granted.

### WHO CAN APPLY

10. You may only apply for an SIC or STC if you are a veterinary surgeon registered with the Royal Collage of Veterinary Surgeons (RCVS). You will be required to quote your RCVS membership number on applying for either certificate. The holder of the SIC or STC certificate, which would normally be the individual veterinary surgeon who is caring for the animal concerned, is responsible for ensuring that the certificate conditions are met.
11. You must be a holder of a Wholesale Dealer's Authorisation or be a registered pharmacist to apply for a WDIC. On applying, you will be required to confirm that you are a registered wholesale dealer or pharmacist by entering your authorisation/registration number.
12. You may only apply for a RIC if you are the appropriate project licence holder.

### SPECIAL IMPORT CERTIFICATES (SIC)

13. If a veterinary surgeon considers that there is not a suitable veterinary medicinal product authorised in the UK to treat a particular condition then it is possible under the cascade scheme detailed in VMG Note 15 (*Controls on the Administration of Veterinary Medicines*) to import a veterinary medicinal product authorised in another EU Member State. To do so he or she must apply for a SIC.

### SPECIAL TREATMENT CERTIFICATES (STC)

14. If a veterinary surgeon considers that there is not a suitable veterinary medicinal product authorised in the UK or in another EU Member State to treat a condition. In this situation, the veterinary surgeon may apply for an STC to import a suitable authorised product from outside the EU. An STC will not be issued if a suitable product is authorised and available in the UK or in another EU Member State.

15. If the veterinary surgeon identifies a human medicinal product as being the only suitable alternative, this will require an STC, regardless of whether it is from Europe or a third country.
16. If the veterinary surgeon identifies a product within Europe or from a third country that does not have a full Marketing Authorisation, then this will require an STC. Additional data may be required by the VMD for such products so it may be advisable to contact the VMD for more information.

### **WHOLESALE DEALERS IMPORT CERTIFICATE (WDIC)**

17. A WDIC will allow the importer to hold and supply a product to the holder of a valid SIC or STC as appropriate. Further information on importing a product to be placed on the UK market is detailed in VMG Note 6 (*Marketing Authorisations for Veterinary Medicinal Products – Parallel Imports*).

### **RESEARCH IMPORT CERTIFICATE (RIC)**

18. A Research Import Certificate (RIC) allows a product or substance to be imported by the project licence holder for administration under a licence granted under the Animals (Scientific Procedure) Act. For more information on RICs please contact the VMD (01932 338496).

## **HOW TO APPLY FOR AN IMPORT CERTIFICATE**

19. You may apply for an SIC, STC or WDIC on-line via our website ([www.vmd.gov.uk](http://www.vmd.gov.uk)) or by post; however, you can only apply for RICs on-line. We would encourage you to use the on-line application route, if at all possible, although there will be circumstances where this will not be possible, for example:
  - ◆ if this is your first application for an STC for this medicinal product for use in the named animal since 31 October 2005;
  - ◆ for an STC, SIC or WDIC, the application is for an immunological product containing pathogens listed under the Specific Animal Pathogens Order 1994 (SAPO), for pathogens that are notifiable or that are under surveillance in the UK. If this is the case, it is advisable to discuss the particulars with the VMD.
  - ◆ The product has not been included in the VMD's database;
  - ◆ The product has not been approved for on-line applications.
20. An application for a group of animals such as a herd or flock on the same treatment will be considered as one application. A group of horses is not regarded as a herd. For STCs all information relating to the individual animals or groups of animals must be provided.
21. For products imported and used under the cascade (SIC), there is a fee charged for each certificate issued. For human EU products or for products imported from

a third country (STC), there is a fee charged for each animal applied for. For RICs a fee is charged for each certificate. There is no fee for a WDIC.

### ON-LINE APPLICATIONS

22. Once you have accessed the on-line form you will be asked to confirm that you are a:
- UK registered veterinary surgeon, by entering your RCVS membership number;
  - wholesale dealer, by entering your wholesale dealers authorisation number;
  - project licence holder, or pharmacist, by entering your RPSGB membership number.

For RICs you will be required to enter an A(SP)A project licence and Place of Certificate Designation (PCD) number. You will not be able to progress your application without this information.

23. Once you have successfully completed your application on-line you will be able to display and print out a copy of your certificate for your records. If there is a third party importer, the certificate holder will be required to provide them with a copy. Excluding the obligations placed upon the holder of the certificate, there will be no further notification or action required by the applicant.
24. For STCs there will only be one repeat application per certificate allowed on-line, so further applications will need to be submitted by post. Some products, such as Founderguard, may not be applied for on-line.

### APPLICATIONS BY POST

25. For written STC applications it would be helpful to supply a covering letter with the completed application form setting out the need for using the imported product. Legible copies of the product label and data sheet/package leaflet/material and safety data sheet should also be provided. The SIC and STC Application forms are available on the VMD website ([www.vmd.gov.uk](http://www.vmd.gov.uk)) under Industry Information > Applications Page.
26. The application should be in English and only one copy should be provided. The certificate will be valid for no more than one year and for SIC/STCs the total amount required and proposed dosage schedule should reflect this.
27. The declaration must be signed by the proposed certificate holder. In signing you are confirming that:
- ♦ the application includes all information known and available to you which is relevant to the evaluation of the application, and includes all details listed as part of the application;

- ♦ for SIC/STCs, you undertake to use the product in accordance with the prescribing cascade and to keep the relevant records for inspection by a suitably authorised person for at least five years;
- ♦ for SIC/STCs, you undertake to pay the appropriate fee.

This is a legally binding document.

28. RICs cannot be applied for by post; they are only available via the on-line system.

### HOW THE VMD DEALS WITH APPLICATIONS RECEIVED BY POST

29. Your application will be validated on receipt at the VMD. This is a checking process to ensure that all the required information has been provided. If any information required is missing you will be asked to provide it and if it is not **received by us within fourteen days, the application will be considered withdrawn.**
30. The application may then be passed to one of the VMD's scientific assessors, who may contact you if further information is required. If the decision is to approve the issue of the certificate it will be sent to you, normally within 10 working days of the application being received. If you need an urgent response please explain this in a covering letter.

### WHERE TO APPLY

31. On-line applications can be made via our website; [www.vmd.gov.uk](http://www.vmd.gov.uk). or written applications and enquires should be directed to: Special Treatment/Imports Certificates, Licensing Services Section, Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS or tel: 01932 338496.

### OBLIGATIONS PLACED ON THE HOLDER OF AN IMPORT CERTIFICATE

32. The holder of this certificate shall keep a record in respect of each product imported by him/her of:
- ♦ the date of sale or supply;
  - ♦ the name of the product;
  - ♦ the quantity supplied;
  - ♦ the name and address of the recipient and identification records for the animals treated for STC and SIC holders,
  - ♦ the justification for using the product under the cascade.

The record must be kept available for inspection by a suitably authorised person for at least five years.

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33. There are additional requirements in relation to food producing animals. For further information see VMG Note 16 (*Record Keeping requirements for Veterinary Medicinal Products*). The withdrawal period for an imported product should be set by a veterinary surgeon. For RICs for food-producing species, conditions regarding entry to the food chain are detailed in the A(SP)A project licence and Animal Test Certificate (ATC).
34. For products imported under SIC, provided that the product is used strictly according to the terms of its EU authorisation, i.e. no "off label" use, the withdrawal period applied in UK should be the period stated on the EU product literature. For products imported under SIC and used "off label" the UK minimum statutory withdrawal periods will apply.
35. Should there be a change to the terms of the authorisation or the product is not being used within the terms of its authorisation, the minimum standard withdrawal periods for cascade products above continue to apply
36. The holder of this certificate shall notify the VMD of any change to any of the particulars given in the application.
37. The prescribing veterinary surgeon is fully responsible for the import and use of the product under the cascade. The responsible veterinary surgeon is accountable for the use of this preparation and should only proceed with treatment when satisfied that a positive risk/benefit assessment has been reached. The owner must be made aware of the potential risks and precautions related to its administration and must provide written consent to the use of an unauthorised medicine.

### **SPECIFIC OBLIGATIONS ON STC AND SIC HOLDERS**

38. The product, which is the subject of the certificate, may only be placed on the market for the purposes of sale or supply by the holder of the certificate for administration to animals under their care
39. The product may only be administered by the veterinary surgeon named in the application or a person acting in accordance with their directions.
40. The holder of this certificate is responsible for pharmacovigilance. All adverse reactions must be recorded, including lack of efficacy, and reported to the VMD immediately, and in any case within 15 days of their occurrence. The certificate holder shall provide such further information to the VMD as may be requested.
41. The holder of the certificate should observe any contra indications, safety warnings and/or precautions specifically applied to the individual product such as:
  - a) Not for prescription or administration other than to animals under the care of the certificate holder;
  - b) For animal treatment only;

- c) Keep out of the reach of children;
  - d) For use only as indicated.
42. The importer quoted must either be a member of the Royal College of Veterinary Surgeons (RCVS) or an authorised wholesale dealer.

### **SPECIFIC OBLIGATIONS ON WDIC HOLDERS**

43. The product which is the subject of the certificate may only be imported and held for the purposes of:
- sale or supply by the holder of the certificate to the holder of a STC or SIC;
  - sale or supply by the holder of the certificate to the holder of another WDIC.
44. The product may only be released to:
- the veterinary surgeon named in the above-mentioned STC/SIC (not applicable for dual labelled products);
  - the person/company named in the above-mentioned WDIC.

### **SPECIFIC OBLIGATIONS ON RIC HOLDERS**

45. The Project Licence Holder must comply with all other legislation relevant to the imported product or substance. This may include legislation relating to controlled substances, disposal requirements and others. The import of animal pathogens and/or carriers of animal pathogens may be subject to specific legislation and Defra's animal health and welfare directorate should be contacted for further information. The Defra helpline number is 08459 33 55 77)

## **FEES**

46. Details on the relevant fees can be found in the Veterinary Medicines Regulations, which is available on the VMD website.
47. The fees should not accompany the application; the VMD will send an invoice following the issue of the certificate(s).

## **FURTHER INFORMATION**

48. 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](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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