Veterinary Medicines Directorate

VETERINARY MEDICINES GUIDANCE NOTE

No 5

IMPORT CERTIFICATE SCHEMES

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QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is primarily aimed at veterinary surgeons and is intended to provide guidance on the various import certificate schemes. It is also aimed at wholesale dealers who wish to import and store medicines not authorised in the UK and at project licence holders who wish to import a product or substance for use in research under an Animal (Scientific Procedure) Act (A(SP)A) Licence.

The quick start guide is a summary of the provisions of the Veterinary Medicines Regulations (VMR); detailed information is found in the body of the guidance note.

The European Union (EU) controls on the regulation of veterinary medicinal products (VMPs) recognise that the range of species and diseases mean that it will be uneconomic for an authorised medicine to be available in all circumstances. The EU legislation, therefore, allows other products to be used when no authorised medicine is available (the cascade) either due to lack of availability or due to supply issues with authorised products. Veterinary surgeons are able to import authorised VMPs from other Member States (MS) and the UK legislation extends this provision to authorised VMPs in third countries and human authorised medicines from outside the UK.

The various different import certificate schemes are as follows:

- Special Import Certificate (SIC) Scheme: this is for use by veterinary surgeons where there is no suitable product authorised for use in the UK. This scheme allows a veterinary surgeon to import an alternative VMP from another EU MS.

- Special Treatment Certificate (STC) Scheme: this is for use by veterinary surgeons where there is no suitable product authorised for use in the UK or there is no suitable VMP authorised for use in an EU MS. This scheme allows a veterinary surgeon to import an alternative human product authorised in another EU MS or an alternative product authorised in a third country (veterinary or human).

- Wholesale Dealer's Import Certificate (WDIC) Scheme: this is for use by a holder of a Wholesale Dealer's Authorisation (WDA) or a registered pharmacist. A WDIC will allow the importer to hold and supply a product to the holder of a valid SIC or STC as appropriate.

- Research Import Certificate (RIC) Scheme: this is for use by the holder of an A(SP)A Licence. An RIC allows a product or substance to be imported by the project licence holder for administration under a licence granted under A(SP)A.

The various different import certificates can be applied for online.

There are specific obligations on certificate holders to keep records of each product imported, to appropriately inform the owner of the treated animal of the risks associated with using an unauthorised medicine and to report any adverse events (AE) following use of the product to the Veterinary Medicines Directorate (VMD).

FURTHER INFORMATION

- For more information on the requirements of Import Certificate Schemes please contact the VMD's Licensing Services Team on 01932 338442 or alternatively contact VMD reception on 01932 336911 and quote "Import Certificates".

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Introduction

1. This is one of a series of Veterinary Medicine 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 included in this VMGN. The VMGN is 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 provides basic information about the scope of the VMR and the requirement for Marketing Authorisations (MAs).

3. The purpose of the Guidance Note is to describe the procedures for applying for a:

   (a) Special Import Certificate (SIC);
   (b) Special Treatment Certificate (STC);
   (c) Wholesale Dealer's Import Certificate (WDIC);
   (d) Research Import Certificate (RIC).

Scope for Import Certificates

4. The European Union (EU) controls on the regulation of veterinary medicinal products (VMPs) recognise that the range of species and diseases mean that it will be uneconomic for an authorised medicine to be available in all circumstances. The EU legislation, therefore, allows other products to be used when no authorised medicine is available (the cascade). Veterinary surgeons are able to import authorised VMPs from other Member States (MS) and the UK legislation extends this provision to authorised VMPs in third countries and human authorised medicines from outside the UK.

5. Where there is no authorised VMP available in the UK which would be suitable 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 VMP authorised in another EU MS or failing this from outside the EU. This also applies where there is a supply issue with a VMP.

6. To facilitate and control these imports, the VMD introduced the SIC and STC schemes. If a product is to be imported from outside the EU, or is a human product, the STC scheme applies. If the product is fully authorised as a veterinary medicine and is being imported from within the EU, the SIC scheme applies. These schemes have been designed to enable vets to obtain products which they need to treat animals under their care and to enable the VMD to maintain a full audit trail of VMPs entering the UK to point of end use.

7. It is the responsibility of the veterinary surgeon to clinically justify the use of the product according to the cascade and keep records to that effect. For further

information please refer to VMGN 13 Guidance on the Use of the Cascade, which is published on the VMD's website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

8. Veterinary surgeons practising in another MS of the European Economic Area (EEA) but providing services in the UK may bring with them and administer small quantities of non-immunological VMPs that are not authorised in the UK without applying for an import certificate. However, this is subject to the following conditions:

   (a) the overall range and quantities brought in must not exceed those generally required for daily needs of good veterinary practice;
   (b) the VMPs must be authorised in the MS in which the veterinary surgeon is established;
   (c) the VMPs must be transported into the UK by the veterinary surgeon in the original manufacturer's packaging;
   (d) VMPs for food-producing animals must have the same composition of active substances as a UK authorised product;
   (e) the veterinary surgeon must be familiar with good veterinary practices applied in the UK;
   (f) the veterinary surgeon must ensure that withdrawal periods specified on labels are complied with unless longer periods are appropriate;
   (g) only sufficient VMPs to complete the course of treatment may be supplied to animal owners/keepers;
   (h) the veterinary surgeon must keep records of animals treated, diagnosis, products administered, dosage, duration of treatment and withdrawal periods;
   (i) the veterinary surgeon must make such records available to a duly authorised person in the UK for at least three years.

   Additionally a veterinary surgeon that practices in both the UK and another MS may hold VMPs authorised in the other MS provided that the amount that he holds does not exceed the amount expected to be used.

9. In order for a certificate to be granted a veterinary surgeon will need to demonstrate that there is no suitable veterinary medicine authorised and available in the UK (applicable to SIC and STC) or there is no suitable VMP authorised and available in the EU (applicable to STC only). It is the responsibility of the veterinary surgeon to ascertain this fact. To help with this, complete information on UK authorised VMPs is available on the VMD's website
http://www.vmd.defra.gov.uk/ProductInformationDatabase/

10. The VMD must be satisfied that there is a positive benefit:risk assessment that has been performed by the responsible veterinary surgeon in relation to use of the product in the animal. It is the responsibility of the veterinary surgeon to obtain data about the product. The VMD may add specific warnings related to animal or user safety, and environmental safety, but it remains the responsibility of the veterinary surgeon to perform a full benefit:risk assessment and to ensure safe use and disposal of the product through the provision of appropriate advice to the animal owner where appropriate.

11. For these reasons, import certificates are less suited to obtaining products to treat food-producing species or for the importation and use of vaccines from countries outside of the EU. Particularly in the case of vaccines, the VMD must have available sufficient information on the quality, manufacture and safety of the product to be certain that no major safety risk will arise.

12. 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 an RIC to import that product or substance. The cascade does not apply.

13. Where a wholesaler imports and holds medicinal products and subsequently supplies these products to the holder of an SIC/STC, a WDIC is required.

14. 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.

15. 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

16. You may only apply for an SIC or STC if you are a veterinary surgeon registered with the Royal College 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. However, the certificate holder does not necessarily have to be the person administering the product; the product may be administered by a person acting in accordance with the directions of the certificate holder.

17. You must be a holder of a Wholesale Dealer's Authorisation (WDA) 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. Where a medicinal product is being imported and stored in anticipation of a veterinary surgeon applying for an SIC/STC, a WDIC is required. However, a WDIC is not required where an importer has been specified on an SIC/STC held by a veterinary surgeon in advance of a product being imported and the amount of product imported is to only cover the amount required by the SIC/STC. Examples of where a WDIC is or is not required can be found in Annex A. Please note that products subject to an SIC/STC do not need to pass through a wholesale dealer; veterinary surgeons may act as their own importers. A WDIC will not be issued for new products without evidence of the demand for the product; this should take the form of a supporting SIC/STC application.

18. You may only apply for an RIC if you are the appropriate project licence holder.

Special Import Certificates (SIC)

19. If a veterinary surgeon considers that there is not a suitable veterinary or human medicinal product authorised in the UK to treat a particular condition then it is possible under the cascade to import a VMP authorised in another EU MS. To do so he or she must apply for an SIC. An SIC will not be issued if a suitable product is authorised and available in the UK.

20. When applying for an SIC, the veterinary surgeon must reference any alternative product(s) authorised in the UK with a justification as to why these products are not suitable to treat the particular condition.

21. Withdrawal period will only be considered a justification if the UK authorised product is not indicated for the species in question but the proposed imported product is.

Special Treatment Certificates (STC)

22. If a veterinary surgeon considers that there is not a suitable veterinary or human medicinal product authorised in the UK or a suitable VMP authorised in another EU MS to treat a condition, a 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 MS.

23. 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.

24. If the veterinary surgeon identifies a product within Europe or from a third country that does not have a full MA, then this will also 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.

25. The justification for applying for the STC should be stated on the application form and should include the following:

    (a) the clinical details/history of the animal;
    (b) reference to any alternative products authorised in the UK (or EU) and a justification as to why these products cannot be used;
    (c) previous relevant treatments;
    (d) the results of any diagnostic tests which have been performed.

26. A separate justification should be included on **each** application. It is not sufficient to refer to previous applications and doing so will only delay the determination of an application.

Wholesale Dealer's Import Certificate (WDIC)

27. A WDIC will allow the importer to hold and supply a product to the holder of a valid SIC or STC as appropriate. The WDIC holder should be in possession of a copy of the SIC/STC before supplying the named veterinary surgeon with any product.

Research Import Certificate (RIC)

28. An RIC allows a product or substance to be imported by the project licence holder for administration under a licence granted under A(SP)A. For more information on RICs please contact the VMD (01932 338496).

How to Apply for an Import Certificate

29. You may apply for an SIC or STC on-line via our website: (https://www.vmd.defra.gov.uk/sis/default.aspx), however, currently you can only apply for a WDIC by emailing a completed form to Importcert@vmd.defra.gsi.gov.uk. The application forms are available to download from the special imports webpage.

30. Where the VMD considers that it does not need to evaluate the clinical justification for every application, we permit applications online via our website which is free and provides an immediate certification. For an STC, where the risks are generally considered to be higher as the products are not authorised in the EU, all initial applications for a particular animal must be assessed. However, in some circumstances we may permit online "repeats", allowing a veterinary surgeon to obtain further certificates for the same product, quantity and animal as applied for previously. A veterinary surgeon can apply for a repeat STC up to one week in advance of the date of the repeat specified on the original certificate, e.g. if you are permitted repeats at 6 monthly intervals the date you can download your next certificate will be 6 months from the date on the original certificate and one week prior to this. If there is a supply problem or known delays in receiving stock, the VMD should be contacted and it may be permitted to obtain a repeat certificate in advance.

On-Line Applications

31. 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. For an RIC 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.

32. When making an application please ensure that all sections are filled out correctly as incomplete applications will not be validated and this will delay the assessment of your application. The certificate will be valid for no more than one year and for SIC/STC the total amount required and proposed dosage schedule should reflect this.

33. The declaration must be accepted by the proposed certificate holder. In accepting you are confirming that:

(a) 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;

(b) for an SIC/STC you undertake to use the product in accordance with the cascade and to keep the relevant records for inspection by a suitably authorised person for at least five years.

This is a legally binding declaration.

34. 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. **Please pay special attention to the quantity and the units of the product you have requested before submitting you application and generating your certificate.** 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. When applying online, once the certificate has been generated, it is important to print the certificate straight away otherwise it will automatically be erased.

How the VMD validates applications

35. 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 and that the application has been filled out in its entirety. 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**.

Applications for products not previously imported

36. For every application for a product that has not been previously imported into the UK we require a certain amount of information, depending on the nature of the product, in order to complete our evaluation. In order for an application for a new product to be considered valid and to proceed to evaluation, we require the following in addition to a fully completed application:

(a) copy of the Summary of Product Characteristics (SPC) or datasheet in English. This helps the VMD to evaluate the risks and benefits associated with allowing the product to enter the UK;

(b) copies of the labels for the product. This allows the VMD to see what information will be presented to the end user and whether additional warnings need to be entered on the certificate.

Applications for new products can be made via the online site where there is a facility to upload data in word, excel or pdf format.

If you would like to find out if a product has been imported into the UK previously then please phone the VMD on 01932 338442.

37. Once an application has “passed validation”, the application proceeds to the evaluation stage to consider whether the importation of the product is appropriate. This involves considering a number of factors depending on the type of product including whether the justification for importation is appropriate, legislative

requirements have been met, and that the product is not going to pose a risk to the existing UK animal population or to the user, consumers or the environment. Therefore, the VMD may request further information from the veterinary surgeon at this stage to facilitate this evaluation. In some cases the VMD may request data directly from the manufacturer of the product; this is usually where the data is of a confidential nature.

38. Once an evaluation has been completed and it is considered that the importation of a product not previously imported into the UK is appropriate, future applications for the same product would usually only require a fully completed application form to be considered valid. However during assessment the VMD may contact you if any detail on the application form is not clear or if we require further clarification on to the justification to import the product. Requests for further information on the product should also be limited compared to the initial application.

Where to Apply

39. On-line applications can be made via our website: https://www.vmd.defra.gov.uk/sis/default.aspx. Enquires should be directed via email to Importcert@vmd.defra.gsi.gov.uk or via telephone to 01932 338442. Any 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.

Animals and Species Cited on the Application

40. An STC application must be supplied for each individual animal so that the suitability of the imported product to treat the condition concerned can be evaluated. An application for a group of animals such as a herd or flock on the same treatment will be considered as one application. However a group of horses is not regarded as a herd. Poultry cannot be used as a species type, but one application can cover a flock of chickens or a flock of turkeys.

41. SIC applications can be made for a number of animals regardless of the species. It is acknowledged that some products are authorised for use in many species, and it may be desired by veterinary surgeons for these products to be held in stock for use in multiple species on a case by case basis. This is permitted and to accommodate this, the VMD have changed the online Import Scheme to allow 'mixed' to be selected as the chosen species for certain products. The decision to add 'mixed' as a species type on the online system for products will be made on a case by case basis following evaluation and the option of ‘other’ should not be used instead of ‘mixed’ when ‘mixed’ is not available. The ‘other’ option should only be selected when one specific species is not listed.

Holding product in stock

42. Generally, it is not permitted to hold stocks in veterinary practices of any imported human medicines or of veterinary medicines imported from countries outside of the EU. However, in exceptional circumstances a Special Treatment Certificate (STC) will be issued that will enable a product to be held in stock, this will be on the basis

that monthly records of use will be supplied. However, the quantity approved for import will be the amount required to treat the immediate need based on the product involved. It is expected that no more than one month's worth of stock will be held based on the average level of use of this medicine in practice. For longer term use in a particular animal, an individual STC application naming that animal should be submitted and the quantity applied for should correspond to the dosage required by that animal.

43. Where a product is held in stock and the certificate states 'monthly records to be supplied', records should be sent to the VMD indicating the quantity of product used in which species against each certificate number. There is a proforma for reporting retrospective records on the home page of the Special Import Scheme online site titled 'records of use'. Please complete this and email it to importcert@vmd.defra.gsi.gov.uk quoting the certificate number to which the records relate. If you do not send records, future applications to hold a product in stock will not be approved.

Supply Issues

44. Manufacturers have been encouraged to inform the VMD in advance of supply problems with UK authorised products. If other UK products are available these must be considered in advance of importing another product.

45. Where no other UK product exists, SIC or STC applications may be submitted. In some situations the VMD and/or the manufacturer of the UK products may have already identified an alternative product. Details of these products can be found on the supply issues page of the VMD website: (http://www.vmd.defra.gov.uk/vet/supply.aspx).

46. Imports permitted to cover short term out of stock situations will only be available from the online site for the duration of the supply problem as informed by the manufacturer of the UK product.

47. Once the supply of a UK authorised product is restored or if an alternative MA is granted in the UK containing the same active ingredient(s) for the same species, the imported product is blocked from import and further certificates will not be issued. Therefore any stock held under a WDIC could not be sold where an SIC/STC did not already exist. Existing certificates will remain valid but are limited by time or quantity. Imported stock held by veterinary surgeons can be used but no further product could be imported.

Controlled Drugs

48. If the product to be imported falls within the scope of *The Misuse of Drugs Regulations 2001*, in addition to complying with VMD requirements, it is also necessary to fulfil Home Office requirements. If you have in place a Home Office licence to supply Schedule 4 Part I drugs, in addition to a Wholesale Dealer's Import Certificate from the VMD, you will need to apply to the Home Office for an import licence to bring the controlled drug into the UK for onward supply (https://www.gov.uk/importing-or-exporting-drug-precursors).

49. In these circumstances, veterinary surgeons may find it easier and quicker to obtain the product from a company/wholesaler who has applied for and received a WDIC for the product concerned and has in place the necessary licences from the Home Office.

Consideration of Urgent Applications

50. The volume of applications that the VMD receives each year requires us to have an effective system to prioritise applications so that the most urgent applications are dealt with in the shortest timescale. An urgent application is considered to be for a product where the VMD has deemed there is an immediate clinically threatening need for the product, e.g. European Viper Venom Anti-serum. **All applications that a veterinary surgeon considers to be urgent should be clearly marked as such by the applying veterinary surgeon**

51. For performance monitoring purposes, an application that is marked as urgent but is for a product where the VMD has not considered there usually to be an immediate clinically threatening need, will be judged against the normal processing timescale. However, the VMD will attempt to expedite your application based on the situation and it is recommended to contact the VMD on 01932 338442 to inform us of the urgency of your application. If required, we can also email a copy of the certificate to the importer to help you receive the product faster.

Timescales for Evaluation

52. From receipt of a valid application, the timescales for issuing import certificates are as follows:

Situation	Timescale
SIC/STC/WDICs for previously imported products	10 Working Days
Urgent SIC/STC/WDICs for previously imported products	2 Working Days
SIC/STC/WDICs for “new” products	15 Working Days
Urgent SIC/STC/WDICs for “new” products	5 Working Days

Please note that these timescales do not include the time taken to request further information from the veterinary surgeon and/or manufacturer of the product.

Costs of Certificates

53. The costs of obtaining import certificates are as follows:

Situation	Cost
SICs processed as hard copy	£15
STCs processed as hard copy	£30
Repeat STCs processed as hard copy	£30
Online SICs	Free
Online repeat STCs	Free
WDIC where **less than** 100 SICs/STCs naming the wholesale dealer as the importer were supplied in the 12 month period before the application was made	Free
WDIC where **more than** 100 SICs/STCs naming the wholesale dealer as the importer were supplied in the 12 month period before the application was made	£760
RIC (Online applications only)	Free

54. The fees should not accompany the application; the VMD will send an invoice following the issue of the certificate(s).

Obligations Placed on the Holder of an Import Certificate

55. No one may import or be concerned in the importation of an unauthorised VMP except in the following circumstances:

(a) A holder of a marketing authorisation may import an unauthorised VMP if it is for the purpose of the manufacture of a VMP which the importer holds the marketing authorisation.
(b) A holder of a manufacturing authorisation may import an unauthorised veterinary medicinal product if it is for the manufacture of a VMP that the importer is permitted to manufacture.
(c) A holder of a WDA may import an unauthorised VMP for the purposes of re-export.
(d) A veterinary surgeon may import an unauthorised VMP in accordance with a valid SIC/STC. The product may be imported by the veterinary surgeon personally or by using a wholesale dealer or pharmacist as an agent.
(e) A wholesale dealer or a pharmacist may import an unauthorised VMP for the purpose of storing it in accordance with a valid WDIC pending administration by a veterinary surgeon who is in possession of a valid SIC/STC.
(f) The holder of an animal test certificate (ATC) may import anything specified in the ATC in accordance with the conditions in that certificate.
(g) The holder of a valid RIC may import a product or substance for use under a licence granted under the Animals (Scientific Procedures) Act 1986.

56. No one may be in possession of an unauthorised VMP with the intention of supplying that product to another person. This does not apply in the following circumstances:

(a) A VMP imported in accordance with an import certificate.

(b) A product prescribed by a veterinary surgeon under the cascade.
(c) A holder of a manufacturing authorisation if the possession is for export.
(d) A holder of a WDA if the possession is for export or re-export.
(e) A holder of a manufacturer's authorisation or marketing authorisation if the intention is to manufacture a VMP.
(f) A veterinary surgeon who practises in both the United Kingdom and another Member State may hold VMPs authorised in the other Member State provided that the amount held does not exceed the amount expected to be used in that member State.
(g) The product is for the purposes of research or development of a VMP and the appropriate authorisations have been obtained.
(h) A veterinary surgeon may have possession of an authorised human medicinal product intended for administration to animals under the cascade, provided that the amount held does not exceed the amount expected to be used under the cascade.

57. The holder of this certificate shall keep a record in respect of each product imported by him/her of:

(a) the date of sale or supply;
(b) the name of the product;
(c) the quantity supplied;
(d) the name and address of the recipient and identification records for the animals treated for STC and SIC holders;
(e) 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.

58. There are additional requirements in relation to food producing animals. For further information please refer to VMGN 14 Record Keeping Requirements for Veterinary Medicinal Products, which is published on the VMD's website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
The withdrawal period for an imported product should be set by a veterinary surgeon. For an RIC 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).

59. For products imported under an SIC, provided that the product is used strictly according to the terms of its EU authorisation, i.e. used in accordance with the SPC, the withdrawal period applied in UK should be the withdrawal period stated on the EU product literature. For products imported under an SIC and not used in accordance with the SPC the UK minimum statutory withdrawal periods will apply.

60. 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.

61. The holder of this certificate shall notify the VMD of any change to any of the particulars given in the application.

62. 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 benefit; risk 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. *This is a requirement of the RCVS Code of Professional Conduct for Veterinary Surgeons*.

Specific Obligations on SIC and STC Holders

63. The product, which is the subject of the STC may only be supplied to the animal named on the certificate by the holder of the certificate.

64. The product may only be administered by the veterinary surgeon named in the application or a person acting in accordance with their directions.

65. The holder of the certificate is responsible for pharmacovigilance. All AEs 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. For further information please refer to VMGN 11 Pharmacovigilance Guidance on Adverse Events which is published on the VMD's website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

66. The holder of the certificate should observe any contra indications, safety warnings and/or precautions specifically applied to the individual product. Standard warnings include:

(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 sight and reach of children;
(d) For use only as indicated.

67. The importer quoted must either be a member of the RCVS or an authorised wholesale dealer.

Specific Obligations on WDIC Holders

68. The product which is the subject of the certificate may only be imported and held for the purposes of:

(a) sale or supply by the holder of the WDIC to the holder of an STC or SIC;
(b) sale or supply by the holder of the WDIC to the holder of another WDIC.

Although a WDIC has been issued an STC or SIC may not necessarily be approved as this is dependent on the individual justification.

69. The product may only be released to:

(a) the veterinary surgeon named in the above-mentioned STC/SIC (not applicable for dual labelled products);
(b) the person/company named in the above-mentioned WDIC.

Specific Obligations on RIC Holders

70. 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).*

Further Information

71. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: +44 (0)1932 338442; 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).

ANNEX A

EXAMPLE SITUATIONS AND DETAILS OF WHEN AN SIC/STC/WDIC IS OR IS NOT REQUIRED

Situation	Requirements / Comments
Product being used is authorised in the UK as a VMP but in a different species or for a different indication than the intended use.	No SIC or STC required. The situation is permitted under the prescribing cascade.
Product being used is authorised in the UK as a human medicinal product.	No SIC or STC required. The situation is permitted under the prescribing cascade.
A veterinary surgeon is applying to import a VMP from another EU MS.	An SIC is required
A veterinary surgeon is applying to import a human product authorised in another EU MS.	An STC is required
A veterinary surgeon is applying to import a VMP authorised in third country.	An STC is required
A veterinary surgeon is applying to import a human product authorised in third country.	An STC is required
The product is authorised in the UK but UK labelled stock is not available therefore stock of the same product labelled for used in another country is being used instead.	An SIC or STC is required depending on the country the product is labelled for and whether the product concerned is a veterinary or human medicinal product.
A third party co-ordinates the “paperwork” of submitting an SIC/STC application to the VMD but the product is shipped directly to the veterinary surgeon and does not go via the third party.	Neither a WDA nor a WDIC is required.
A third party imports a product and then sends this onto veterinary surgeon when an SIC/STC is already in place naming the third party as an importer.	A WDA is required to permit wholesaling activities but a WDIC is not required.
A third party imports a product in anticipation of an SIC/STC being granted.	Both a WDA and a WDIC are required as the third party is holding the imported product (however, an initial SIC/STC is needed to show that there is a need for the product if the product has not been imported previously).

ANNEX B

SPECIAL DISPENSATION FOR ALLERGEN PRODUCTS

Due to the nature of allergen products, the way in which they are authorised in other countries and the animal welfare implications; special dispensation is allowed regarding importation and providing allergen products. Please note that these provisions are allowed for allergen products only

Situation	Requirements / Comments
Importation of finished product, BUT re-packaging / re-labelling required.	WDA required to permit dealing activities. WDIC required to permit importation prior to receipt of valid SIC/STC if this is not already in place. Laboratory must employ vet or pharmacist to permit re-labelling/ re-packaging under the extemporaneous preparations rules. Valid SIC/ STC from vet concerned, naming lab as importer. It is agreed that re-labelling and re-packing should, strictly speaking, be done under Good Manufacturing Practice (GMP) and should be covered by a ManA or a ManSA covering assembly and packaging. However, the VMD considers that this would be disproportionate in these circumstances. The alternative is to allow the vet or pharmacist to do the relabeling and repackaging as they are allowed to prepare extemporaneous preparation and in doing so they would be carrying out these activities.
Importation of concentrated allergen products, NOT in a finished state for administration to animals, in order to extemporaneously prepare an individual mixture of those concentrates for sale to veterinarian	WDA required to permit dealing activities. WDIC required to permit importation prior to receipt of valid SIC/STC if this is not already in place. Laboratory must employ vet or pharmacist to permit mixing of allergen concentrates and any subsequent re-labelling/re-packaging under the extemporaneous preparations rules. Valid SIC/STC from vet concerned, naming lab as importer. Allergens can be authorised as individual concentrates or, depending on the manufacturer, as blocks of allergens Sometimes it is possible to obtain the suitable product already mixed from the manufacturer but sometimes it necessary to prepare a tailored mix in house, using concentrated allergens stocks. Again, it is agreed that these operations should usually be done under GMP and should be covered by a ManSA.

List of Abbreviations

AE	Adverse Event
A(SP)A	Animal (Scientific Procedure) Act
ATC	Animal Test Certificate
Defra	Department for Environment, Food & Rural Affairs
EEA	European Economic Area
EU	European Union
GMP	Good Manufacturing Practice
MA	Marketing Authorisation
MS	Member State
PCD	Place of Certificate Designation
RCVS	Royal College of Veterinary Surgeons
RIC	Research Import Certificate
SAPO	Specific Animal Pathogen Order
SIC	Special Import Certificate
SPC	Summary of Product Characteristics
STC	Special Treatment Certificate
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
WDA	Wholesale Dealer’s Authorisation
WDIC	Wholesale Dealer’s Import Certificate

VETERINARY MEDICINES GUIDANCE NOTE

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