

- Urgent 'New' SIC/STC's: 5 working days from receipt of a valid application.

Please note these timescales do not include the time taken to request further information from the vet or product manufacturer.

The Special Import Site provides for both SIC and STC applications whether for previously imported products or new products so there is no need to submit any applications on paper. To import a new product some data will be required. For more information see the Special Import Site FAQ on the VMD website.

All online applications are free.

The VMD Exemption Scheme for Small Pet Animals

Veterinary medicines marketed under the VMD's Exemption Scheme for small pet animals do not have a Marketing Authorisation as they are **exempt** from this requirement. The scheme covers only products intended for use in cage birds, homing pigeons, aquarium animals, terrarium animals, small rodents, ferrets and pet rabbits. The products under this scheme do not include any to treat a condition that needs veterinary diagnosis. Also excluded are injections, ophthalmics, aural products, antibiotics, psycotropic drugs and products for food producing animals.

Products marketed under this scheme can be identified as the label includes a statement to show the veterinary medicine is exempt, such as marketed in accordance with the Exemption Scheme for Small Pet Animals. There is not a complete list of products marketed under this scheme. Instead on the VMD website there is a **list of those active substances** which may be included in products under the scheme; the list is categorised by species www.vmd.defra.gov.uk.

Measures to Improve Availability

The VMD is continuing to work with the pharmaceutical industry to encourage the authorisation of further veterinary medicines in the UK. You can help influence companies to commit to the development and registration of particular products by telling the pharmaceutical companies about the products you find the need to use regularly through the prescribing cascade.

Information on Supply Issues

When the VMD is made aware of a supply issue with a UK authorised product or a product used under an import certificate scheme and where this supply issue may be a cause for concern in terms of animal welfare, the VMD will publish information about this on the website www.vmd.defra.gov.uk. The VMD works with pharmaceutical industries, wholesale dealers, veterinary surgeons and other EU Member States to provide as much information on the supply issue as possible including details on how long the issue is likely to last and options for alternatives.

Further Information

The VMD issues a series of Veterinary Medicines Guidance Notes. These guidance notes provide further detail in connection with each of the above topics. They are available on the VMD website www.vmd.defra.gov.uk. Those relevant to the topics covered above are:

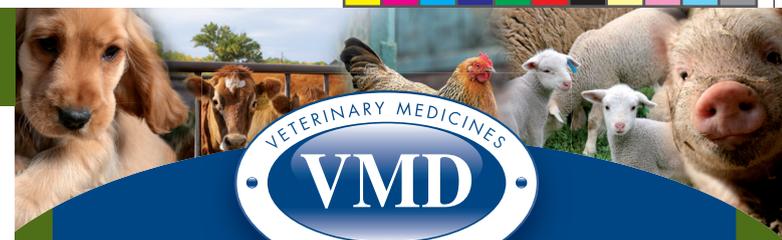
VMGN No 5	Import Certificates Scheme
VMGN No 12	Exemption Scheme for Small Pet Animals
VMGN No 13	Guidance on the Use of the Cascade

A publication from the VMD from January 2008 explaining the Cascade and the philosophy behind it can be found on our website www.vmd.defra.gov.uk.

You can also phone the VMD on 01932 336911 for any additional assistance about veterinary medicines.

You can also e-mail us at: postmaster@vmd.defra.gsi.gov.uk

Information correct at time of writing February 2013



ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES



Availability of Veterinary Medicines



Department
for Environment
Food & Rural Affairs

The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food & Rural Affairs

www.vmd.defra.gov.uk

www.vmd.defra.gov.uk

Veterinary Medicines Availability in the UK

Veterinary Medicines with a Marketing Authorisation in the UK

Veterinary medicines which have a **Marketing Authorisation** have been assessed to ensure that they are of the appropriate quality, can be used safely (for the animal, the user, the environment and if appropriate the consumer) and are effective when used in accordance with the instructions on the label.

A small number of products have **Exceptional Marketing Authorisations**. These are usually for products needed in disease emergencies or if there is a limited market for the product where the benefits of having a product outweigh the risks of an incomplete set of supporting data. For example, at the time of initial authorisation, the missing data could be because efficacy field trials have not yet been completed. The label will highlight the nature of the missing data.

Each veterinary medicine with a Marketing Authorisation or Exceptional Marketing Authorisation, in addition to the label and any leaflet, has a **Summary of Product Characteristics (SPC)**. SPCs include all of the information on the labels/leaflets as well as some additional information, such as summary information on the pharmacokinetics (process of absorption and distribution) and pharmacodynamics (biochemical and physiological effects) of the product. SPCs for every veterinary medicine authorised in the UK can be found on the VMD website www.vmd.defra.gov.uk/ProductInformationDatabase/.

While products may have an authorisation, not all products are marketed. To check to see if a product is **marketed** either contact your usual wholesaler or contact the company who holds the Marketing Authorisation.

The Prescribing Cascade

Where a suitable veterinary medicine is not authorised and available in the UK to treat a particular species/indication, a Veterinary Surgeon may follow the prescribing **cascade**. The prescribing cascade increases the range of medicines available to Veterinary Surgeons. It has three levels, and it is necessary to work down this level by level:

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| Level 1 | Use of an UK authorised veterinary medicine indicated for the same species but for another condition or indicated for use in another species. |
| Level 2 | Use of an UK authorised human medicine, or use of a veterinary medicine authorised somewhere in the EU but not the UK (Special Import Certificate required). |
| Level 3 | Specially prepared (extemporaneous preparation) medicine made by a Veterinary Surgeon, Pharmacist or suitably authorised manufacturer (specials manufacturer). This level also includes products used in accordance with a Special Treatment Certificates. |

When treating food producing species with a product which is not indicated for use in the relevant species, or when using a product not authorised in the EU, it is also necessary to ensure that any pharmacologically active substances included in the medicine appear in Table 1 of the Annex of the Maximum Residue Limit Legislation (Commission Regulation (EU) No 37/2010) and it is necessary to apply a standard withdrawal period. In the case of meat this should be at least 28 days, for milk it should be at least 7 days and for eggs it should be at least 7 days. For veterinary medicines imported under a Special Import Certificate the withdrawal period is that stated on the EU product literature, if the medicine is used strictly in accordance to the terms of its SPC.

The VMD Special Import Schemes

To import into the UK an EU authorised veterinary medicine it is necessary to obtain a **Special Import Certificate (SIC)** from the VMD's online Special Import Site www.defra.gov.uk/sis.

Where there is no suitable UK product available the online system will in most cases provide instantaneous certificates for veterinary medicines authorised in Europe where the VMD has previously permitted the import of the particular products.

It is currently difficult to establish a complete list of **EU authorised veterinary medicines**. However, information on centrally authorised medicinal products can be found on the European Medicines Agency website. Other information sources to find out which products are authorised in the EU include:

- Drop down lists of products on the VMD Special Import Site. This is the list of products previously permitted to be imported into the UK. It is not a complete list of products.
- Marketing Authorisation holders who can inform you of authorised products they market in other parts of the EU but not the UK.
- Specialist wholesalers who can advise regarding the availability of medicines from outside the UK.
- The European Heads of Medicines Agencies website contains a page of links to European Heads of Medicines Agencies who authorise veterinary medicines. This is currently under the VMRI Heading/Product Information.

To import into the UK an authorised veterinary medicine from a country outside the EU or a human authorised product it is necessary to obtain a **Special Treatment Certificate (STC)** from the VMD's online Special Import Site.

This STC application for a named animal (or in some cases a herd) will be considered by VMD assessors and certificates issued within the following timeframes set: VMD published standards.

- Routine SIC/STC's: 10 working days from receipt of a valid application.
- Urgent SIC/STC's: 2 working days (the VMD have a record of those products which we believe to require a certificate urgently and a fax/email of the certificate will be provided).
- 'New' SIC/STC's (for products not imported before): 15 working days from receipt of a valid application.