

## **Small Animal Exemption Scheme – Information Note**

The Veterinary Medicines Regulations 2006 include details of a scheme that permits certain veterinary medicines to be marketed without the requirement for a marketing authorisation.

This document is intended to be read in conjunction with VMG note 14 and to give guidance to companies currently marketing products that fall within the scheme.

The following is a step-by-step guide to the actions you need to take in order to market a product under the small animal exemption scheme. If you have any questions, or do not understand where your particular products fit, then please contact us.

The small animal exemption scheme was introduced in the Veterinary Medicines Regulations 2005 on 30 October 2005. Certain parts of the small animal exemption scheme have been deferred until 1 November 2007 to allow companies sufficient time to prepare. The Regulations will continue to be updated on an annual basis usually in October each year.

### **Products currently on the market without a Marketing Authorisation –**

From 30 October 2005 the product may only be labelled for administration to the groups of animals included in the scheme – other species must be deleted from the indications.

Products which are antibiotics, narcotics or psychotropic drugs must be withdrawn from sale on this date, as these do not fall under the scheme. If you are currently marketing an anaesthetic product please contact us for advice.

Products must not be for parenteral or ophthalmic administration or for administration into the ear canal. Fish treatments administered via the water but not intended for ophthalmic administration are permitted.

Pack sizes must only be sufficient for a single course of treatment. VMG note 14 has details of a practical interpretation of this.

### **Products that you wish to market after 1 November 2007 (including current products) –**

1. Request that the active substance(s) in your product are approved for use under the Scheme. Send the details set out in Annex 1 of this documents to the VMD. You will then be informed whether the substance is considered suitable for inclusion in the Scheme and if it has been approved. A list of approved substances will be made available on the VMD's website.
2. If you do not currently hold a manufacturer's authorisation, you will need to apply for one. For sites manufacturing products marketed only under the scheme, the VMD have introduced an authorisation specifically for this. An application form can be obtained on the VMD's website, or from our Licensing Administration team.

3. If your products are manufactured overseas, then you need to ensure that the site holds an appropriate manufacturing licence. To import the products into the UK you will need to hold a Wholesale Dealer's Licence.
4. Amend the product labelling as set out in VMG note 14. Products marketed under the Scheme must be labelled with the words "This veterinary medicine is marketed in accordance with the small animal exemption scheme."
5. Products manufactured after 1 November 2007 must comply fully with the scheme. Products already in the supply chain do not need to be withdrawn from sale.
6. If wished, notify us of the details of your product, and we will publish these on the VMD website ([www.vmd.gov.uk](http://www.vmd.gov.uk)).
7. Report any products that you believe do not comply with the details of the scheme to the VMD or your trade association.

If you need any further guidance on the scheme please contact us – telephone 01932 338306 or 01932 338308, email [s.hack@vmd.defra.gsi.gov.uk](mailto:s.hack@vmd.defra.gsi.gov.uk) or [b.Haycraft@vmd.defra.gsi.gov.uk](mailto:b.Haycraft@vmd.defra.gsi.gov.uk).

Enforcement Team  
Veterinary Medicines Directorate

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## ANNEX 1

### **Standard format for active substance details to be sent to VMD**

#### **Name of active substance**

Standard English name, for herbs use the Latin species name, CAS number if confusion is likely.

#### **Species to which the substance will be administered**

Ornamental fish, pigeons, cage birds, terrarium animals (reptiles, amphibians, insects), small rodents (please specify hamsters, guinea pigs, mice, rats, chinchillas, or others), rabbits, ferrets.

#### **Indications**

The name of the disease to be treated.

#### **Route of administration**

Specify topical, oral, or any other route.

#### **The pack size**

The maximum pack size that will be marketed.

#### **The concentration of the active substance**

Use standard terms of mg / ml, mg / tablet etc.

#### **The directions for use**

The dosage rate, frequency of treatment and any other information to be provided to the user.

#### **Your justification for requiring this substance in the scheme.**

Provide information on alternative authorised products (or lack of), welfare issues if product were to be lost from the market, experience of safe use (including date of first use / length of time product has been on the market) and any other information you consider helpful. Please do not submit any studies or reports unless specifically requested. A short paragraph will usually be sufficient.

## Actions companies need to take before 1 November 2007

