SCHEDULE 6 Regulation 15(4)

Exemptions for small pet animals

CONTENTS

Animals to which this Schedule applies

1. This Schedule applies in relation to veterinary medicinal products intended solely for the following animals kept exclusively as a pet—

(a) aquarium fish;

(b) cage birds;

(c) ferrets;

(d) homing pigeons;

(e) rabbits;

(f) small rodents; and

(g) terrarium animals.

Placing on the market, importing and administering the product

2. A veterinary medicinal product intended solely for an animal to which this Schedule applies may be placed on the market, imported or administered without a marketing authorisation if it complies with this Schedule.

Manufacture

3. The product must have been manufactured by—

(a) the holder of a manufacturing authorisation if manufactured in the United Kingdom;

(b) the holder of a manufacturing authorisation issued under Directive 2001/82/EC if manufactured in another member State;

(c) in the case of Australia, Canada, New Zealand, or Switzerland, the holder of an authorisation from the competent authority permitting the manufacture of medicinal products;

(d) in the case of any other country, a manufacturer whose premises have been inspected and approved by an officer of the Secretary of State.

Approval of the active substance

4.—(1) The Secretary of State may approve an active substance for use in a veterinary medicinal product manufactured under this Schedule.

(2) The Secretary of State may not grant an approval if the active substance requires veterinary control.

(3) The approval must specify the species of animals for which it is approved, and may specify how the active substance or a product containing it is to be administered.

(4) The Secretary of State may suspend or revoke the approval (or limit it to a smaller number of species) if—

(a) it is demonstrated that the substance requires veterinary control;

(b) serious adverse reactions are reported making suspension or revocation necessary; or

(c) it is demonstrated that the substance—

(i) is carcinogenic;

(ii) is genotoxic; or

(iii) shows developmental toxicity (including teratogenicity).

(5) The procedure for the refusal, suspension or revocation of an approval under this paragraph is the same as the procedure for a marketing authorisation.

The product

5.—(1) The active substance in the veterinary medicinal product must be approved under paragraph 4.

(2) The veterinary medicinal product must not be an antibiotic.

(3) It must not contain any narcotic or psychotropic substance.

(4) It must not be intended for treatments or pathological processes that require a precise prior diagnosis or the use of which may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures.

Labelling

6.—(1) The product must be clearly labelled as being exempt from the requirements of these Regulations in relation to a marketing authorisation.

(2) The labelling must show the following—

(a) the name of the veterinary product, including, if it is part of the name, its strength and pharmaceutical form;

(b) the authorisation number of the manufacturer;

(c) the name and strength of each active substance;

(d) the route of administration;

(e) the batch number;

(f) the expiry date;

(g) the words “For animal treatment only”;

(h) the contents by weight, volume or number of dose units;

(i) the name and address of the manufacturer or distributor;

(j) the target species;

(k) the words "Keep out of reach of children";

(l) storage instructions;

(m) the shelf-life after the immediate packaging has been opened for the first time;

(n) disposal advice;

(o) full indications, including—

(i) therapeutic indications;

(ii) contra-indications;

(iii) interaction with other medicines and other forms of interaction; and

(p) dosage instructions.

(3) If there is insufficient room on the label, the information may instead be in a package leaflet, but the leaflet must contain all the information in the preceding sub-paragraph other than the batch number and the expiry date, but the label on the product must contain at least the following—

(a) the name of the veterinary medicinal product;

(b) its active substance and its strength;

(c) the route of administration;

(d) the batch number;

(e) the expiry date; and

(f) the words "For animal treatment only".

Administration

7. The method of administration must be oral or topical or (in the case of a product for fish) by addition to the water.

Pack size

8. The pack size must only be sufficient for a single course of treatment or, in the case of a veterinary medicinal product for aquarium fish, sufficient for a single course of treatment of no more than 7 administrations to an aquarium of 25,000 litres.

Adverse reactions

9.—(1) The manufacturer, importer or retailer of a veterinary medicinal product must—

(a) notify the Secretary of State within 15 days of learning of any serious adverse reactions (as defined in paragraph 57 of Schedule 1); and

(b) make a record of each adverse reaction and serious adverse reaction of which he becomes aware and keep it for three years.

(2) It is an offence to fail to comply with this paragraph.

Status:
Point in time view as at 01/10/2008.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2008, SCHEDULE 6.