SCHEDULE 6 Regulation 15(3)

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.

Commencement Information

I1 Sch. 6 para. 1 in force at 1.10.2006, see **reg. 1**

Placing on the market, importing and administering the product

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

(2) There are no restrictions on its administration to the target species.

Commencement Information

I2 Sch. 6 para. 2 in force at 1.10.2006, see **reg. 1**

Manufacture

3.—(1) 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 (EC) No. 2001/82 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 him to manufacture 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.

(2) This paragraph does not apply until 1st November 2007.

Commencement Information

I3 Sch. 6 para. 3 in force at 1.10.2006, see **reg. 1**

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 must grant an approval if he is satisfied that the substance does not require veterinary control.

(3) The approval must specify the animals for which it is approved, and may specify how it 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).

Commencement Information

I4 Sch. 6 para. 4 in force at 1.10.2006, see **reg. 1**

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) If it contains an active substance contained in a veterinary medicinal product authorised in the United Kingdom as a product that can only be prescribed by a veterinary surgeon, a product containing that active substance must have been so authorised for at least five years.

(5) 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.

(6) The requirement that a veterinary medicinal product may only contain an active substance approved under paragraph 4 does not apply until 1st November 2007 in relation to a veterinary medicinal product on the market on 30th October 2005.

Commencement Information

I5 Sch. 6 para. 5 in force at 1.10.2006, see **reg. 1**

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 name and strength of each active substance;

(c) the route of administration;

(d) the batch number;

(e) the expiry date;

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

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

(h) the name and address of the manufacturer;

(i) the target species;

(j) the words “Keep out of reach of children”;

(k) storage instructions;

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

(m) disposal advice;

(n) full indications, including—

(i) therapeutic indications;

(ii) contra-indications;

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

(o) 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".

(4) This paragraph does not apply until 1st November 2007 in relation to a veterinary medicinal product on the market on 30th October 2005.

Commencement Information

I6 Sch. 6 para. 6 in force at 1.10.2006, see **reg. 1**

Administration

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

Commencement Information

I7 Sch. 6 para. 7 in force at 1.10.2006, see **reg. 1**

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 treatment of an aquarium of 25,000 litres.

Commencement Information

I8 Sch. 6 para. 8 in force at 1.10.2006, see **reg. 1**

Adverse reactions

9.—(1) The manufacturer or importer of a product must notify the Secretary of State of any serious adverse reactions (as defined in paragraph 56 of Schedule 1) of which he becomes aware within 15 days of learning of the reaction.

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

Commencement Information

I9 Sch. 6 para. 9 in force at 1.10.2006, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2006, SCHEDULE 6.