SCHEDULE 6 Regulation 15(4)

Exemptions for small pet animals

ARRANGEMENT OF PROVISIONS

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

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

Manufacture

3.—(1) The product must be manufactured in the United Kingdom, another member State or in Australia, Canada, New Zealand, or Switzerland (**1**).

(2) 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;

(**1**) Australia, Canada, New Zealand and Switzerland are the only countries outside the European Union that have mutual recognition agreements on the manufacture of veterinary medicinal products with the European Union.

(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.

(3) This paragraph shall not apply until 1st November 2007.

The active substance

4. The veterinary medicinal product must only contain an active substance specified in the following table for the species specified in that table.

Permitted substances and target species

Substance	Fish	Cagebirds	Pigeons
Amprolium hydrochloride			Y
Carnidazole			Y
Clazuril			Y
Cypermethrin cis50:trans50			Y
Dimetridazole			Y
Febantel			Y
Fenbendazole			Y
Levamisole Hydrochloride			Y
Piperazine dihydrochloride			Y
Piperonyl butoxide & Pyrethrum powder 1.3%		Y	Y
Pyrethrum extract 25% & piperonyl butoxide		Y	Y
Tricaine methane sulphonate	Y		

The product

5.—(1) The veterinary medicinal product must not be an antibiotic.

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

(3) 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.

(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.

(5) The requirement that a veterinary medicinal product may only contain an active substance specified in the table in paragraph 4 does not apply in relation to a veterinary medicinal product on the market at the time this Schedule comes into force until 1st November 2007.

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 manufacturing authorisation number (or, in the case of a product manufactured outside the European Union, the wholesale dealing licence number of the importer), and must contain 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 or importer;

(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;

(o) dosage instructions.

(3) This paragraph does not apply in relation to a veterinary medicinal product on the market at the time this Schedule comes into force until 1st November 2007.

Administration

7. The method of administration must not be parenteral or insertion into the inner ear.

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.

Adverse reactions

9.—(1) The manufacturer or importer must notify the Secretary of State of any adverse reactions to a product 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.