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## STATUTORY INSTRUMENTS

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# 2006 No. 2407

## The Veterinary Medicines Regulations 2006

### PART 2

#### *Authorised veterinary medicinal products*

##### **Placing a veterinary medicinal product on the market**

4.—(1) It is an offence to place a veterinary medicinal product on the market unless that product has been granted a marketing authorisation by the Secretary of State or the Agency.

(2) Any person who certifies data in relation to an application for a marketing authorisation or in relation to an existing marketing authorisation and who knows that those data are false, or does not believe that they are accurate, is guilty of an offence.

(3) Schedule 1 (marketing authorisations) has effect.

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##### **Commencement Information**

**II** Reg. 4 in force at 1.10.2006, see [reg. 1](#)

##### **Manufacture of veterinary medicinal products**

5.—(1) The holder of a marketing authorisation must ensure that every stage in the manufacture of the veterinary medicinal product is carried out by the manufacturer specified in the marketing authorisation (who must, if the manufacture is carried out in the United Kingdom, hold a manufacturing authorisation for that type of product granted by the Secretary of State) and failure to do so is an offence.

(2) Schedule 2 (the manufacture of veterinary medicinal products) has effect.

(3) “Manufacture” includes any part of the manufacture of a veterinary medicinal product until the finished product is ready for sale in its final form as specified in the marketing authorisation but does not include the manufacture of an ingredient.

(4) However—

- (a) a holder of a wholesale dealer’s authorisation (in accordance with regulation 13) or a suitably qualified person (in accordance with paragraph 13 of Schedule 3) may break open packages (other than the immediate packaging of the veterinary medicinal product);
- (b) a pharmacist may break open any package other than the immediate packaging of injectable products; and
- (c) a veterinary surgeon may break open any package.

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#### Commencement Information

**I2** Reg. 5 in force at 1.10.2006, see [reg. 1](#)

### The finished product

6. The holder of a marketing authorisation for a veterinary medicinal product is guilty of an offence if he or the manufacturer supplies a product that is not completely in accordance with the marketing authorisation.

#### Commencement Information

**I3** Reg. 6 in force at 1.10.2006, see [reg. 1](#)

### Classification, supply and possession of the product

7.—(1) Schedule 3 (classification and supply, wholesale dealers and sheep dip) has effect.

(2) Any person who supplies a veterinary medicinal product that has passed its expiry date is guilty of an offence.

(3) Any person who supplies a medicinal product authorised for human use for administration to an animal (other than in accordance with a prescription from a veterinary surgeon that specifically states that the medicinal product is for administration under the cascade, either by that veterinary surgeon or under his direction and responsibility) is guilty of an offence.

(4) Any person in possession of a veterinary medicinal product that was supplied to him other than in accordance with Schedule 3 is guilty of an offence.

#### Commencement Information

**I4** Reg. 7 in force at 1.10.2006, see [reg. 1](#)

### Administration of the product

8.—(1) It is an offence to administer a veterinary medicinal product to an animal unless—

- (a) the product has a marketing authorisation authorising its administration in the United Kingdom, and the administration is in accordance with that marketing authorisation; or
- (b) it is administered in accordance with Schedule 4 (administration of a veterinary medicinal product outside the terms of a marketing authorisation).

(2) This regulation does not apply in the case of a product administered for research purposes in accordance with a certificate (“an animal test certificate”) granted for the purpose by the Secretary of State.

(3) The Secretary of State may suspend or revoke an animal test certificate if this is necessary for reasons of animal or human health.

#### Commencement Information

**I5** Reg. 8 in force at 1.10.2006, see [reg. 1](#)

## Importation of authorised veterinary medicinal products

9.—(1) It is an offence to import a veterinary medicinal product authorised for use in the United Kingdom except in accordance with this regulation.

(2) A holder of a marketing authorisation may import a veterinary medicinal product for which he holds the marketing authorisation.

(3) A holder of a manufacturing authorisation may import a veterinary medicinal product to which his authorisation relates.

(4) An authorised wholesale dealer may import a veterinary medicinal product if—

- (a) his authorisation covers the product;
- (b) the importation is in accordance with a certificate issued for the purpose by the Secretary of State; and
- (c) he has notified the holder of the marketing authorisation in writing before he imports it.

(5) A veterinary surgeon or a pharmacist may import any authorised veterinary medicinal product.

(6) A suitably qualified person (in accordance with paragraph 13 of Schedule 3) may import any authorised veterinary medicinal product that he is permitted to supply.

(7) There are no restrictions on the importation of an authorised veterinary medicinal product in category AVM-GSL.

### Commencement Information

**I6** Reg. 9 in force at 1.10.2006, see [reg. 1](#)

## Advertising the product

10.—(1) It is an offence to advertise a veterinary medicinal product if the advertisement is misleading or contains any medicinal claim that is not in the summary of product characteristics.

(2) It is an offence to advertise a human medicine for administration to animals (including sending a price list of or including human medicines to a veterinary surgeon or veterinary practice).

(3) Paragraph (2) does not apply to the holder of a wholesale dealer's authorisation who supplies a list of human medicines, together with prices, to a veterinary surgeon for use under the cascade provided that—

- (a) the list is sent following a request from the veterinary surgeon to whom it is sent;
- (b) the veterinary surgeon has specified the type of human medicinal product he wishes to use, and the list is confined to human medicines of that type;
- (c) the list states clearly that the product does not have a marketing authorisation as a veterinary medicinal product, and may only be administered under the cascade; and
- (d) it only includes human medicines that may be administered legally under the cascade.

### Commencement Information

**I7** Reg. 10 in force at 1.10.2006, see [reg. 1](#)

## Advertising of prescription products and products containing psychotropic drugs or narcotics

11.—(1) It is an offence to advertise a veterinary medicinal product that—

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- (a) is available on veterinary prescription only; or
  - (b) contains psychotropic drugs or narcotics.
- (2) In the case of a product containing psychotropic drugs or narcotics, this does not apply to advertisements aimed at veterinary surgeons or pharmacists.
- (3) In the case of POM-V medicines, this does not apply to price lists, or to advertisements aimed at veterinary surgeons, pharmacists or professional keepers of animals.
- (4) In the case of POM-VPS medicines, this does not apply to price lists, or to advertisements aimed at—
- (a) veterinary surgeons;
  - (b) pharmacists;
  - (c) suitably qualified persons registered in accordance with paragraph 13 of Schedule 3;
  - (d) other veterinary health care professionals;
  - (e) professional keepers of animals; or
  - (f) owners or keepers of horses.

#### Commencement Information

**18** Reg. 11 in force at 1.10.2006, see [reg. 1](#)

#### Defence of publication in the course of business

**12.** In proceedings for an offence under these Regulations relating to advertising, it is a defence for the person charged to prove—

- (a) that he is a person whose business it is to publish or arrange for the publication of advertisements, and
- (b) that he received the advertisement in the ordinary course of business and did not know and had no reason to suspect that its publication would amount to an offence under these Regulations.

#### Commencement Information

**19** Reg. 12 in force at 1.10.2006, see [reg. 1](#)

#### Wholesale dealing

**13.** It is an offence to buy a veterinary medicinal product, other than by retail or for the purposes of retail supply in accordance with Schedule 3, unless the buyer has a wholesale dealer's authorisation granted by the Secretary of State under this regulation and Schedule 3.

#### Commencement Information

**110** Reg. 13 in force at 1.10.2006, see [reg. 1](#)

#### Feedingstuffs

**14.** Schedule 5 (medicated feedingstuffs and specified feed additives) has effect.

**Commencement Information**

**I11** Reg. 14 in force at 1.10.2006, see [reg. 1](#)

**Exemptions**

**15.—(1)** These Regulations do not apply to an inactivated autogenous vaccine that is manufactured, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal and used for the treatment of that animal.

(2) Schedule 1 and Part 1 of Schedule 2 do not apply in relation to an inactivated autogenous vaccine that is—

- (a) manufactured by a person and in premises authorised in accordance with Part 2 of Schedule 2, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal; and
- (b) used for the treatment of—
  - (i) other animals on the same site;
  - (ii) animals intended to be sent to those premises; or
  - (iii) animals on a site that receives animals from those premises.

(3) They do not apply to blood from a blood bank authorised in accordance with Part 3 of Schedule 2, nor to a product manufactured for administration under the cascade by a person and in premises authorised under Part 4 of Schedule 2.

(4) Schedule 6 (exemptions for small pet animals) has effect.

**Commencement Information**

**I12** Reg. 15 in force at 1.10.2006, see [reg. 1](#)

**Fees**

**16.** Schedule 7 (fees) has effect.

**Commencement Information**

**I13** Reg. 16 in force at 1.10.2006, see [reg. 1](#)

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