STATUTORY INSTRUMENTS

2005 No. 2745

The Veterinary Medicines Regulations 2005

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 (provisions relating to marketing authorisations) has effect.

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 (provisions relating to the manufacture of veterinary medicinal products) has effect.

(3) "Manufacture" includes any part of the manufacture of a veterinary medicinal product and any ingredient of the product until the finished product is packaged, labelled and ready for sale in its final form but does not include the manufacture of starting materials intended for use as an active substance in a veterinary medicinal product.

(4) Notwithstanding the above—

(a) the holder of a wholesale dealer's authorisation (in accordance with regulation 13) or a suitably qualified person (in accordance with paragraph 9 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.

The finished product

6. The holder of a marketing authorisation for a veterinary medicinal product is guilty of an offence if the finished product supplied by him or the manufacturer is not completely in accordance with the marketing authorisation.

Classification, supply and possession of the product

7.—(1) Part I of Schedule 3 (Classification and supply of authorised veterinary medicinal products) 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 for administration under the cascade) 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.

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 a marketing authorisation).

(2) It is an offence to administer a veterinary medicinal product to a food-producing animal unless it was prescribed in accordance with Schedule 3 or is administered in accordance with Schedule 4.

(3) 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.

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 9 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.

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.

Advertising of prescription products and products with psychotropic drugs or narcotics

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

(a) are available on veterinary prescription only; or

(b) contain 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.

(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 9 of Schedule 3;

(d) other veterinary health care professionals;

(e) professional keepers of animals;

(f) owners or keepers of horses.

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.

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.

Feedingstuffs

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

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) The requirements relating to marketing authorisations and manufacturing authorisations under Part 1 of Schedule 2 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 other animals on the same site if the product has been manufactured in accordance with Part 2 of Schedule 2.

(3) They do not apply in relation to blood from blood banks operated in accordance with Part 3 of Schedule 2.

(4) Schedule 6 (small animals exemption) has effect.

Fees

16. Schedule 7 (fees) has effect.