

SCHEDULE 3

CLASSIFICATION AND SUPPLY, WHOLESALE DEALERS AND SHEEP DIP

PART 1

Classification and supply of authorised veterinary medicinal products

Classification of veterinary medicinal products

1.—(1) There shall be the following categories of authorised veterinary medicinal products—

- (a) Prescription Only Medicine—Veterinarian (abbreviated to POM-V);
- (b) Prescription Only Medicine—Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);
- (c) Non-Food Animal—Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);
- (d) Authorised Veterinary Medicine—General Sales List (abbreviated to AVM-GSL).

(2) The Secretary of State shall specify the classification of the veterinary medicinal product when he grants the initial marketing authorisation.

(3) He may change the classification after the marketing authorisation has been granted, either at the request of the marketing authorisation holder or in accordance with paragraph 37 of Schedule 1 (compulsory variation).

(4) When he grants the marketing authorisation the Secretary of State must classify the following as POM-V—

- (a) products containing narcotic or psychotropic substances;
- (b) products intended as treatments following a precise prior diagnosis.

(5) When he grants the marketing authorisation he must classify the following as POM-V or POM-VPS—

- (a) (after 1st January 2007) products for food-producing animals;
- (b) products in respect of which special precautions must be taken in order to avoid any unnecessary risk to—
 - (i) the target species;
 - (ii) the person administering the products to the animal; and
 - (iii) the environment;
- (c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; and
- (d) new veterinary medicinal products containing an active substance that has not been included in an authorised veterinary medicinal product for five years.

Wholesale supply of veterinary medicinal products

2.—(1) Only a holder of a marketing authorisation, the holder of a manufacturing authorisation or the holder of a wholesale dealer's authorisation granted by the Secretary of State may supply a veterinary medicinal product wholesale, or be in possession of it for that purpose.

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(2) They may only supply a veterinary medicinal product if their authorisation relates to that product, and they may only supply it to another person who may supply that product under these Regulations, either wholesale or retail.

(3) If the supply is to a suitably qualified person, it must be to the premises approved in accordance with paragraph 13.

(4) It is irrelevant whether or not the supply is for profit.

(5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer provided that in any one year the amount supplied by a retailer does not exceed five per cent in terms of value of turnover of veterinary medicinal products of that retailer.

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

Retail supply of veterinary medicinal products

3.—(1) This paragraph applies in relation to retail supply of veterinary medicinal products.

(2) A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.

(3) A veterinary medicinal product classified as POM-VPS may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 13,

and must be in accordance with a prescription from one of those persons.

(4) A veterinary medicinal product classified as NFA-VPS may be supplied without prescription, but may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 13.

(5) There are no restrictions on the supply of AVM-GSL products.

(6) In this paragraph—

(a) “retail supply” means any supply other than to or from the holder of a wholesale dealer’s authorisation, and whether or not for payment; and

(b) a person may supply a product irrespective of who owns it.

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

Prescriptions by a veterinary surgeon

4. A veterinary surgeon who prescribes a veterinary medicinal product classified as POM-V must first carry out a clinical assessment of the animal, and the animal must be under his care, and failure to do so is an offence.

Prescriptions

5.—(1) A prescription may be oral or written, but a veterinary medicinal product classified as POM-V or POM-VPS may only be supplied—

(a) by the person who prescribed it, or

(b) under a written prescription that complies with paragraph 6.

- (2) A person supplying such a product under a written prescription—
 - (a) may only supply the product specified in that prescription,
 - (b) must take all reasonable steps to satisfy himself that the prescription has been written and signed by a person entitled to prescribe the product; and
 - (c) must ensure that it is supplied to the person named in the prescription.
- (3) It is an offence to fail to comply with this paragraph.

Written prescriptions

- 6.—(1) A written prescription must include—
 - (a) the name, address and telephone number of the person prescribing the product;
 - (b) the qualifications enabling the person to prescribe the product;
 - (c) the name and address of the owner or keeper;
 - (d) the species of animal, identification and number of the animals;
 - (e) the premises at which the animals are kept if this is different from the address of the owner or keeper;
 - (f) the date of the prescription;
 - (g) the signature or other authentication of the person prescribing the product;
 - (h) the name and amount of the product prescribed;
 - (i) the dosage and administration instructions;
 - (j) any necessary warnings;
 - (k) the withdrawal period if relevant.
- (2) A written prescription for a controlled drug as specified in the Misuse of Drugs Regulations 2001⁽¹⁾ is valid for 28 days.
- (3) A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.
- (4) If the prescription is a repeatable prescription that does not specify the number of times the product may be supplied, the prescription may only be repeated once.

Duties when a product is prescribed or supplied

- 7.—(1) When a person prescribes a product classified as POM-V or POM-VPS, or supplies a product classified as NFA-VPS—
 - (a) before he does so, he must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised;
 - (b) when he does so, he must advise on its safe administration and on any warnings or contra-indications on the label or package leaflet; and
 - (c) he must not prescribe (or, in the case of a NFA-VPS product, supply) more than the minimum amount required for the treatment; but it is a defence for him to show that—
 - (i) the product prescribed or supplied by him was in a container specified in the marketing authorisation;
 - (ii) the manufacturer does not supply that veterinary medicinal product in a smaller container; and

(1) [S. I. 2001/3998](#); relevant amending instruments are [S.I.2003/1432](#) and [2005/1653](#).

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(iii) he is not a person authorised to break open the package before supply.

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

Supply by a pharmacist

8.—(1) A pharmacist may only supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS from premises registered as a pharmacy with the Royal Pharmaceutical Society of Great Britain or with the Pharmaceutical Society of Northern Ireland, or (in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises registered under paragraph 13.

(2) A pharmacist may supply a homeopathic remedy prepared extemporaneously by a pharmacist in a registered pharmacy (as well as any other homeopathic remedy that he is permitted to supply under these Regulations) provided that it is prepared in accordance with paragraph 61 of Schedule 1 for an individual customer.

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

Supply by a veterinary surgeon when he is not present

9.—(1) A veterinary surgeon supplying a veterinary medicinal product need not be present when it is handed over, but if he is not present—

(a) he must authorise each transaction individually before the product is supplied;

(b) he must have satisfied himself that the person handing it over is competent to do so.

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

Supply of products for incorporation into feedingstuffs

10.—(1) In the case of a veterinary medicinal product where the marketing authorisation specifies that it must be incorporated into feedingstuffs, the marketing authorisation holder, an authorised manufacturer of that product or an authorised wholesale dealer may supply it to—

(a) an approved premixture manufacturer; or

(b) a feedingstuffs manufacturer where the approval so permits.

(2) A veterinary surgeon, pharmacist or suitably qualified person who supplies a veterinary medicinal product for the purposes of incorporating it into a premixture or feedingstuff may only supply it to a person specified in paragraph 10(1)(a) or (b).

(3) In addition, an approved premixtures manufacturer or feedingstuffs manufacturer may supply a veterinary medicinal product to another approved premixtures manufacturer or feedingstuffs manufacturer provided that the amount supplied does not exceed five per cent in terms of value of veterinary medicinal product used annually.

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

Labelling at the time of retail supply

11.—(1) If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it is an offence to supply it if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.

(2) Sub-paragraph (1) does not apply to a veterinary surgeon who amends a label, or a pharmacist who amends it in accordance with a prescription from a veterinary surgeon, provided that the unamended information remains clearly visible.

(3) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely, and failure to do so is an offence.

Supply of veterinary medicinal products for use under the cascade

12.—(1) A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.

(2) Unless the veterinary surgeon who prescribed the veterinary medicinal product supplies the product himself and administers it to the animal himself, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

- (a) the name and address of the pharmacy or veterinary surgery supplying the veterinary medicinal product;
 - (b) the name of the veterinary surgeon who has prescribed the product;
 - (c) the name and address of the animal owner;
 - (d) the identification of the animal or group of animals;
 - (e) the date of supply;
 - (f) the expiry date of the product, if applicable;
 - (g) the name or description of the product which should include at least the name and quantity of active ingredients;
 - (h) dosage and administration instructions;
 - (i) any special storage precautions;
 - (j) any necessary warnings for the user, target species, administration or disposal of the product.
- (3) It is an offence to fail to comply with this paragraph.

Supply by a suitably qualified person

13.—(1) The Secretary of State shall recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

(2) In order to recognise such a body, the Secretary of State must be satisfied that the body—

- (a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;
- (b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;
- (c) maintains a programme of continuing development for persons registered with it;
- (d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register.

(3) To become a suitably qualified person it is necessary to pass examinations specified by such a body, and to be registered with such a body.

(4) The supply of products permitted to be supplied by a suitably qualified person must take place from premises approved by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products.

(5) A suitably qualified person must either—

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- (a) hand over or despatch the product himself;
 - (b) ensure that, when the product is handed over or despatched, he is in a position so that he can intervene if necessary; or
 - (c) check the product after it has been allocated for supply to a customer, and satisfy himself that the person handing over or dispatching it is competent to do so.
- (6) If a suitably qualified person considers that the premises in which he is operating no longer comply with the approval granted by the Secretary of State, he must notify the Secretary of State without unreasonable delay, and failure to do so is an offence.
- (7) The Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph shall ensure that a suitably qualified person registered with it complies with the Code of Practice.
- (8) The Secretary of State shall publish a list of—
- (a) suitably qualified persons; and
 - (b) the trading names and the addresses of premises approved under this paragraph.
- (9) The procedure for the suspension or revocation of the authorisation of the premises is the same as for the holder of a manufacturing authorisation.

Annual audit

- 14.—(1)** At least once a year every person entitled to supply a veterinary medicinal product on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicinal products shall be reconciled with products currently held in stock, any discrepancies being recorded.
- (2) It is an offence to fail to comply with this paragraph.