SCHEDULE 3 Regulations 7(1) and 13

Classification and supply and wholesale dealers

# ARRANGEMENT OF PROVISIONS

PART 1

Classification and supply of authorised veterinary medicinal products



PART 2

Requirements for a wholesale dealer's authorisation



# 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 she grants the initial marketing authorisation.

(3) She 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 she 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 she grants the marketing authorisation she 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;

(iii) the environment;

(c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures;

(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.

(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 9.

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

(5) This paragraph shall 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 9,

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 9.

(5) Any person supplying a veterinary medicinal product in accordance with a prescription may only supply the product specified in that prescription.

(6) Any person who supplies a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS—

(a) must always advise on the safe administration of the veterinary medicinal product;

(b) must advise as necessary on any warnings or contra-indications on the label or package leaflet;

(c) must be satisfied that the person who will use the product is competent to use it safely, and intends to use it for a use for which it is authorised.

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

(8) 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.

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

**Supply of products for incorporation into feedingstuffs**

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

(a) an approved premixture manufacturer; or

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

**Prescriptions**

**5.**—(1) 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.

(2) It is an offence to prescribe more than the minimum amount of a veterinary medicinal product required for the treatment.

**Form of prescription**

**6.**—(1) A prescription may be oral or written, but must be written if the veterinary medicinal product is not supplied by the person who has prescribed it.

(2) A written prescription must be in ink or other indelible format, and must include—

(a) the name and address 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.

(3) A written prescription for a controlled drug as specified in the Misuse of Drugs Regulations 2001(**1**) is valid for three weeks.

(4) A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.

(5) 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.

**Labelling at the time of retail supply**

**7.** Notwithstanding the prohibition on placing a veterinary medicinal product on the market except in accordance with its marketing authorisation, a veterinary surgeon or a pharmacist may amend the label of a veterinary medicinal product at the time the product is supplied if this is done in accordance with a prescription issued by a veterinary surgeon.

**Supply of veterinary medicinal products for use under the cascade**

**8.**—(1) A veterinary medicinal product for use under the cascade must be prescribed by a veterinary surgeon and may only be supplied by a veterinary surgeon or a pharmacist.

(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 with at least the following information—

(a) the name and address of the dispensing pharmacy or veterinary surgery;

(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 dispensing;

(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.

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

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

**Supply by a suitably qualified person**

**9.**—(1) The Secretary of State shall recognise bodies that are suitable to provide training 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 an adequate training programme;

(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 set 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 and the suitably qualified person must be present at each supply of such product.

(5) 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.

(6) The Secretary of State shall publish a list of persons registered and premises approved under this paragraph.

**Annual audit**

**10.**—(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.

**Supply of sheep dip**

**11.**—(1) If the veterinary medicinal product is a sheep dip of any type the provisions of this paragraph apply, and it is an offence to supply the product by retail other than in accordance with this paragraph.

(2) The supply must be to a person who holds a Certificate of Competence in the Safe Use of Sheep Dips issued by the National Proficiency Tests Council, or by that Council and the Department of Agriculture for Northern Ireland, showing that Parts 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed; or to a person acting on behalf of such a person.

(3) The supplier must make a record of the Certificate number as soon as is reasonably practicable, and keep it for at least three years.

(4) If the active ingredient of the veterinary medicinal product is an organophosphorus compound, the supplier must give to the buyer—

(a) a double sided laminated notice meeting the specification set out in the following sub-paragraph (unless the notice has been provided to the buyer within the previous twelve

months and the supplier knows or has reasonable cause to believe that the buyer still has it available for use), and

(b) two pairs of gloves either as described in the notice or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves as so described.

(5) The notice shall be at least A4 size with a laminated transparent cover, coloured and printed to scale on front and back substantially in accordance with the following two diagrams, except that in Wales it may be in Welsh as well as in English—

# SHEEP DIPPING

## PLEASE READ THIS NOTICE FOR YOUR OWN SAFETY

1. The product label carries important advice. Please read it and do what it says.

2. Always wear the recommended protective clothing, including gloves. Sheep dip is absorbed through the skin.

3. Always wash protective clothing before taking it off.

4. If you get sheep dip on your skin wash it off immediately.

5. If you have questions, ask your sheep dip supplier. At your merchants you should speak to the Suitably Qualified Person.

6. Read the label for instructions on measuring and diluting concentrate.

7. Check that you have spare protective clothing, especially gloves, in case of damage.

A well designed sheep dip, with splash screens to limit contamination, reduces the risks, makes the job easier and makes wearing protective clothing more practical.

Everyone doing the job must be adequately trained. If they are not absolutely sure how to dip safely consider a training course.

The recommended protective clothing is:

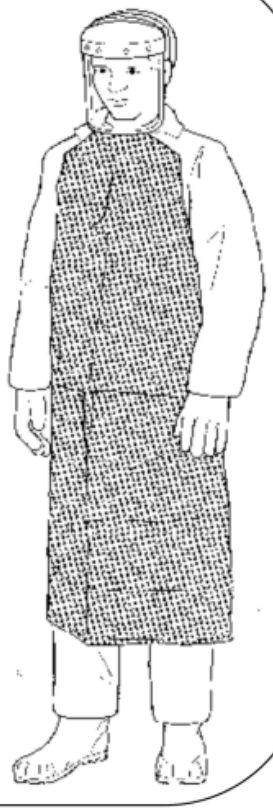
**Face Shield** (when handling dip concentrate)

**Bib apron** (over boiler suit) **or waterproof coat** (PVC or nitrile)

**Gloves** (non-lined, PVC or nitrile, heavy duty gauntlet style – 0.5 mm thick and at least 300 mm long)

**Waterproof leggings/trousers** (PVC or nitrile)

**Wellington boots**



*For more information you are recommended to read the Government's leaflet 'Sheep dipping' (AS29rev2).*

# PART 2

## Requirements for a wholesale dealer's authorisation

### Application

**12.** An application for a wholesale dealer's authorisation shall be made to the Secretary of State.

### Time limits

**13.** The Secretary of State shall process an application for a wholesale dealer's authorisation within 90 days of receiving it.

### Granting the authorisation

**14.**—(1) The Secretary of State shall grant a wholesale dealer's authorisation if she is satisfied that this paragraph is complied with.

(2) The authorised site must be—

(a) weatherproof;

(b) secure and lockable;

(c) clean;

(d) free from contaminants.

(3) If the veterinary medicinal products covered by the authorisation are subject to specific storage conditions, the site must be capable of fulfilling those requirements.

(4) The authorisation holder must—

(a) have at his disposal the services of technically competent staff, and

(b) have an effective emergency recall plan.

### The authorisation

**15.**—(1) The wholesale dealer's authorisation shall specify —

(a) the types of veterinary medicinal products and pharmaceutical forms that may be dealt in;

(b) the place where they are to be stored;

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates;

(e) the name of the qualified person nominated to act under the Guidelines on good distribution practice under paragraph 18.

(2) It may cover more than one site.

(3) It shall lapse if the holder does not deal in veterinary medicinal products for five years.

### Suspension or revocation of the authorisation

**16.** The Secretary of State may suspend or revoke a wholesale dealer's authorisation if the holder—

(a) has not complied with these Regulations; or

(b) no longer has suitable premises or equipment.

### Representations

**17.**—(1) A person may make representations against a refusal, suspension or revocation of a wholesale dealer's authorisation to a person appointed for the purpose by the Secretary of State.

(2) The appointed person shall consider the representations and report in writing to the Secretary of State.

(3) The Secretary of State shall give written notification of her final determination and the reasons for it.

### Duties on the holder of a wholesale dealer's authorisation

**18.**—(1) The holder of a wholesale dealer's authorisation must store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product.

(2) He must comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use(**2**) as if the veterinary medicinal products were products for human use.

(3) He must carry out a detailed stock audit at least once a year.

(4) He must supply information and samples to the Secretary of State on demand.

(5) He must notify the Secretary of State if there are any changes to the information held by her.

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

(**2**) OJNo. C 63, 1.3.94, p. 4.