SCHEDULE 3 Regulation 7

Classification and supply, wholesale dealers and sheep dip

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Explanatory Note

# 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 must 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 for administration following a diagnosis or clinical assessment by a veterinary surgeon.

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

(a) 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.

(6) The requirement in sub-paragraph (5)(a) relating to veterinary medicinal products for food-producing animals does not apply if all the following criteria are met—

(a) the administration of the veterinary medicinal product is restricted to formulations requiring no particular knowledge or skill in using the product;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;

(e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; and

(h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

**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 14.

(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 the retailer who supplies the product.

(6) A wholesale dealer may break open any package (other than the immediate packaging) of a veterinary medicinal product.

(7) 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 14,

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 14.

(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;

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

(c) (in the case of POM-VPS) by a suitably qualified person in accordance with paragraph 14(5).

(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 take all reasonable steps to 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 identification (including the species) of the animal or group of animals to be treated;

(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; and

(l) if it is prescribed under the cascade, a statement to that effect.

(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

(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 veterinary surgeon from registered premises**

**8.**—(1) A veterinary surgeon commits an offence if he supplies a veterinary medicinal product from any premises not registered with the Secretary of State under this paragraph as premises at which veterinary medicinal products are stored or supplied.

(2) The Secretary of State must publish a list of registered premises.

(3) This paragraph does not take effect until 1st April 2009.

**Supply by a veterinary surgeon**

**9.**—(1) A veterinary surgeon supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless—

(a) he authorises each transaction individually before the product is supplied; and

(b) he has satisfied himself that the person handing it over is competent to do so,

and it is an offence to supply other than in accordance with this paragraph.

(2) A veterinary surgeon or a person acting under his responsibility may open any package containing a veterinary medicinal product.

**Supply by a pharmacist**

**10.**—(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

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

veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises approved under paragraph 14.

(2) A pharmacist may supply any veterinary medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user.

(3) 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 62 of Schedule 1 and intended to be supplied directly to the end user.

(4) A pharmacist may break open any package containing a veterinary medicinal product for the purposes of supply other than the immediate packaging of an injectable product.

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

**Supply of a veterinary medicinal product for incorporation into feedingstuffs**

**11.**—(1) This paragraph applies in relation to the supply of a veterinary medicinal product intended for incorporation into feedingstuffs.

(2) The marketing authorisation holder, an authorised manufacturer of the product or an authorised wholesale dealer may supply such a veterinary medicinal product to—

(a) a veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person;

(b) an approved premixture manufacturer; or

(c) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end-user the supply must be in accordance with a prescription).

(3) A veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person may supply such a veterinary medicinal product to—

(a) an approved premixture manufacturer; or

(b) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end user the supply must be in accordance with a prescription).

(4) In addition, an approved premixture manufacturer or an approved feedingstuffs manufacturer may supply such a veterinary medicinal product to another approved premixture manufacturer or approved feedingstuff manufacturer provided that the amount supplied does not exceed five per cent in terms of value of veterinary medicinal product incorporated annually by the person supplying the veterinary medicinal product.

(5) It is an offence to supply such a veterinary medicinal product other than in accordance with this paragraph.

**Labelling at the time of retail supply**

**12.**—(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 ensure that the container is suitably labelled and 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**

**13.**—(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, veterinary surgery or approved premises 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 (including the species) 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;

(k) the withdrawal period, if relevant; and

(l) the words “Keep out of reach of children” and “For animal treatment only”.

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

**Supply by a suitably qualified person**

**14.**—(1) The Secretary of State may 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 professional 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, and it is an offence to supply other than from those premises.

(5) A suitably qualified person who supplies a product classified as POM-VPS or NFA-VPS must either—

(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 must ensure that a suitably qualified person registered with it complies with the Code of Practice.

(8) The Secretary of State must publish a list of—

(a) suitably qualified persons; and

(b) the trading names and the addresses of premises approved under this paragraph.

(9) A suitably qualified person may break open any package (other than the immediate packaging) of a veterinary medicinal product.

(10) 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**

**15.**—(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 must be reconciled with products currently held in stock, any discrepancies being recorded.

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

# PART 2

## Requirements for a wholesale dealer's authorisation

**Application**

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

**Time limits**

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

**Granting the authorisation**

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

(2) The authorised site must be—

(a) weatherproof;

(b) secure and lockable;

(c) clean; and

(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**

**19.**—(1) The wholesale dealer's authorisation must 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 22.

(2) It may cover more than one site.

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

**Suspension or revocation of the authorisation**

**20.** 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.

**Appeals**

**21.**—(1) A person may appeal 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 must consider the appeal and report in writing to the Secretary of State.

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

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

**22.**—(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 authorised human medicinal products.

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

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

(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 him.

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

# PART 3

## Sheep dip

**Supply of sheep dip**

**23.**—(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 (or a person acting on his behalf) who holds a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed and issued by—

(a) in England, Wales, and Northern Ireland by the National Proficiency Tests Council, or by NPTC Part of the City & Guilds Group; or

(b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

(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 specifications 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 must 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).*

### Use of sheep dip

**24.**—(1) It is an offence to use sheep dip unless this is done by, or under the supervision and in the presence of, a person who holds a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed and issued by—

(a) in England, Wales and Northern Ireland by the National Proficiency Tests Council, or by NPTC Part of the City & Guilds Group; or

(b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

(2) In the case of a person who has had practical experience of sheep dipping before 1st October 2006, this paragraph does not apply until 31st December 2008.