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STATUTORY INSTRUMENTS

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**2007 No. 2539**

**MEDICINES**

**The Veterinary Medicines Regulations 2007**

*Made* - - - - *30th August 2007*

*Laid before Parliament* *4th September 2007*

*Coming into force* - - *1st October 2007*

The Secretary of State is a Minister designated<sup>(1)</sup> for the purposes of making Regulations under section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to measures in the veterinary and phytosanitary fields for the protection of public health.

He has carried out the consultation required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(3)</sup>.

In accordance with section 56(1) of the Finance Act 1973<sup>(4)</sup>, the Treasury consent to the making of these Regulations.

The Secretary of State makes these Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972 and by section 56(1) of the Finance Act 1973.

**PART 1**

**Introduction**

**Title and commencement**

1. These Regulations may be cited as the Veterinary Medicines Regulations 2007 and come into force on 1st October 2007.

**Definition of “veterinary medicinal product”, interpretation and scope**

2.—(1) In these Regulations “veterinary medicinal product” means—

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(1) S.I.1999/2027.

(2) 1972 c. 68.

(3) OJ No. L31, 1.2.2002, p. 1.

(4) 1973 c. 51.

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- (b) any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

(2) In addition—

“adverse reaction” means a reaction to a veterinary medicinal product that is harmful and unintended and that occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function;

“the Agency” means the European Medicines Agency established by Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>(5)</sup>;

“animal” means all animals other than man and includes birds, reptiles, fish, molluscs, crustacea and bees;

“the cascade” has the meaning given in paragraph 1 of Schedule 4;

“horse passport” means a passport issued in accordance with the provisions of—

- (a) the Horse Passports (England) Regulations 2004<sup>(6)</sup>;
- (b) the Horse Passports Regulations (Northern Ireland) 2004<sup>(7)</sup>;
- (c) the Horse Passports (Scotland) Regulations 2005<sup>(8)</sup>; or
- (d) the Horse Passports (Wales) Regulations 2005<sup>(9)</sup>,

and “horse” includes all species of equidae;

“immunological veterinary medicinal product” means a veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity;

“risk-benefit balance” means an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to—

- (a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product; or
- (b) any risk of undesirable effects on the environment;

“strength” means the amount of active substances in a dosage unit or unit of volume or weight.

(3) In these Regulations any reference to a member State is a reference to a member State of the European Union and Norway, Iceland and Liechtenstein.

(4) For the avoidance of doubt, these Regulations apply to veterinary medicinal products irrespective of whether or not there is other legislation controlling a product.

### **Products to which these Regulations do not apply**

3.—(1) These Regulations do not apply to a veterinary medicinal product based on radio-active isotopes.

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<sup>(5)</sup> OJ No. L136, 30.4.2004, p. 1.

<sup>(6)</sup> S.I. 2004/1397.

<sup>(7)</sup> S.R. (NI) 2004 No. 497.

<sup>(8)</sup> S.S.I. 2005/223 as amended by S. S. I. 2007/217.

<sup>(9)</sup> S.I. 2005/231 (W. 21).

(2) They do not apply in relation to the administration of a product in the course of a procedure licensed under the Animals (Scientific Procedure) Act 1986<sup>(10)</sup>, except that, if the animals are to be put into the human food chain, the only products that may be administered to the animals are—

- (a) authorised veterinary medicinal products administered in accordance with their marketing authorisation, or
- (b) products administered in accordance with an animal test certificate granted under paragraph 9 of Schedule 4.

## 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.

#### 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 or breaking open the package of a veterinary medicinal product<sup>(11)</sup>.

#### 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.

#### 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.

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<sup>(10)</sup> 1986 c. 14.

<sup>(11)</sup> For provisions on breaking open packages see regulation 7(3).

(3) Any person who opens the package (including the outer package) of a veterinary medicinal product before it has been supplied to the final user, other than as permitted under Schedule 3, is guilty of an offence.

(4) Any person who supplies an authorised human medicinal product for administration to an animal (other than a product supplied by a veterinary surgeon or in accordance with a written prescription from a veterinary surgeon that includes all the information specified in paragraph 6 of Schedule 3) is guilty of an offence.

(5) 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.** 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).

### **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; and
- (b) 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 14 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 an authorised human medicinal product for administration to animals (including sending a price list of or including authorised human medicinal products 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 authorised human medicinal products, 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 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

- (c) it only includes authorised human medicinal products that may be administered legally under the cascade.

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

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

- (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, veterinary nurses, 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 14 of Schedule 3;
- (d) other veterinary health care professionals;
- (e) professional keepers of animals; or
- (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) 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) Schedule 1 and Part 1 of Schedule 2 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.

### **Fees**

16. Schedule 7 (fees) has effect.

## **PART 3**

### **Records**

#### **Food-producing animals: proof of purchase of veterinary medicinal products**

17.—(1) The keeper of a food-producing animal must keep proof of purchase of all veterinary medicinal products (or, if he did not buy them, documentary evidence of how he acquired them) acquired for the animal.

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

#### **Food-producing animals: records of administration by a veterinary surgeon**

18.—(1) If a veterinary surgeon administers a veterinary medicinal product to a food-producing animal he must either enter the following information himself in the keeper's records or give it to the keeper in writing (in which case the keeper must enter the following into his records)—

- (a) the name of the veterinary surgeon;
- (b) the name of the product and the batch number;
- (c) the date of administration of the product;
- (d) the amount of product administered;
- (e) the identification of the animals treated; and
- (f) the withdrawal period.

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

#### **Food-producing animals: records of acquisition and administration**

19.—(1) When a veterinary medicinal product is bought or otherwise acquired for a food-producing animal the keeper must, at the time, record—

- (a) the name of the product and the batch number;
- (b) the date of acquisition;
- (c) the quantity acquired; and

- (d) the name and address of the supplier.
- (2) At the time of administration (unless the administration is by a veterinary surgeon in which case the record must be in accordance with regulation 18) he must record—
  - (a) the name of the product;
  - (b) the date of administration;
  - (c) the quantity administered;
  - (d) the withdrawal period; and
  - (e) the identification of the animals treated.
- (3) If he disposes of any or all of the veterinary medicinal product other than by treating an animal, he must record—
  - (a) the date of disposal;
  - (b) the quantity of product involved; and
  - (c) how and where he disposed of it.
- (4) It is an offence to fail to comply with this regulation.

#### **Food-producing animals: retention of records**

- 20.**—(1) The keeper of a food-producing animal must keep the documentation on the acquisition of a veterinary medicinal product and the records relating to the product for at least five years following the administration or other disposal of the product, irrespective of whether or not the animal concerned is no longer in his possession or has been slaughtered or has died during that period.
- (2) It is an offence to fail to comply with this regulation.

#### **Records by a holder of a manufacturing authorisation**

- 21.**—(1) A holder of a manufacturing authorisation must, as soon as is reasonably practicable, make a record of each batch of veterinary medicinal product manufactured, assembled or supplied by him, which must include—
  - (a) the name of the product;
  - (b) the quantity manufactured, assembled or supplied;
  - (c) the date of manufacture, assembly or supply;
  - (d) the batch number and expiry date; and
  - (e) in the case of supply, the name and address of the recipient.
- (2) He must keep with the record all certification provided by the qualified person (manufacturer) in relation to that batch.
  - (3) He must keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market.
  - (4) It is an offence to fail to comply with this regulation.

#### **Records by a holder of a wholesale dealer's authorisation**

- 22.**—(1) A holder of a wholesale dealer's authorisation must record the following as soon as is reasonably practicable after each incoming or outgoing transaction (including disposal) relating to a veterinary medicinal product—
  - (a) the date and nature of the transaction;

- (b) the name of the veterinary medicinal product;
  - (c) the manufacturer's batch number;
  - (d) the expiry date;
  - (e) the quantity; and
  - (f) the name and address of the supplier or recipient.
- (2) He must keep the records for at least three years.
- (3) It is an offence to fail to comply with this regulation.

### **Records of the receipt or supply of prescription products**

**23.**—(1) When any person permitted under these Regulations to supply a veterinary medicinal product classified as POM-V or POM-VPS receives or supplies any such veterinary medicinal product he must keep all documents relating to the transaction that show—

- (a) the date;
  - (b) the name of the veterinary medicinal product;
  - (c) the batch number (except that, in the case of a product for a non-food-producing animal, this need only be recorded either on the date he receives the batch or the date he starts to use it);
  - (d) the quantity;
  - (e) the name and address of the supplier or recipient; and
  - (f) if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription.
- (2) If the documents do not include this information he must make a record of the missing information as soon as is reasonably practicable following the transaction.
- (3) As an alternative to paragraphs (1) and (2) he may make a record of all the information required there provided that he does so as soon as is reasonably practicable following the transaction.
- (4) He must keep the documentation and records for at least five years.
- (5) It is an offence to fail to comply with this regulation.

### **Records of products administered to a food-producing animal under the cascade**

**24.**—(1) A veterinary surgeon administering a veterinary medicinal product to food-producing animals under the cascade, or permitting another person to administer it under his responsibility, must, as soon as is reasonably practicable, record—

- (a) the date he examined the animals;
- (b) the name and address of the owner;
- (c) the identification and number of animals treated;
- (d) the result of the veterinary surgeon's clinical assessment;
- (e) the trade name of the product if there is one;
- (f) the manufacturer's batch number shown on the product if there is one;
- (g) the name and quantity of the active substances;
- (h) the doses administered or supplied;
- (i) the duration of treatment; and
- (j) the withdrawal period.



- (2) He must keep the record for at least five years.
- (3) It is an offence to fail to comply with this regulation.

## PART 4

### Unauthorised veterinary medicinal products

#### **Importation of an unauthorised veterinary medicinal product**

**25.**—(1) It is an offence to import an unauthorised veterinary medicinal product except in accordance with this regulation.

(2) A holder of a marketing authorisation may import an unauthorised veterinary medicinal product if it is for the purpose of the manufacture of a veterinary medicinal product for which he holds the marketing authorisation.

(3) A holder of a manufacturing authorisation may import an unauthorised veterinary medicinal product if it is for the manufacture of a veterinary medicinal product that he is permitted to manufacture.

(4) A holder of a wholesale dealer's authorisation may import an unauthorised veterinary medicinal product for the purposes of re-export.

(5) A veterinary surgeon may import an unauthorised veterinary medicinal product that is authorised in another member State if it is for the purpose of administration by him or under his responsibility under the cascade or administration in exceptional circumstances in accordance with Schedule 4; the import must be in accordance with the appropriate certificate granted by the Secretary of State, and the product may be imported by the veterinary surgeon himself or by using a wholesale dealer or pharmacist as his agent.

(6) A wholesale dealer or a pharmacist may import an unauthorised veterinary medicinal product for the purpose of storing it pending administration by a veterinary surgeon under the cascade or administration in exceptional circumstances in accordance with Schedule 4 if—

- (a) the veterinary medicinal product is authorised in another member State or a third country;
- (b) the Secretary of State has issued a certificate certifying that—
  - (i) the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal;
  - (ii) delay in administering the product will seriously affect the health or welfare of the animal; and
  - (iii) there is no suitable veterinary medicinal product authorised in the United Kingdom; and
- (c) in the case of a wholesale dealer, the product is within the terms of his authorisation.

(7) The holder of an animal test certificate granted under paragraph 9 of Schedule 4 may import anything specified in the animal test certificate in accordance with the conditions in that certificate.

(8) The Secretary of State may authorise in writing the importation of any product or substance for use under a licence granted under the Animals (Scientific Procedures) Act 1986.

#### **Possession of an unauthorised veterinary medicinal product**

- 26.**—(1) It is an offence to be in possession of an unauthorised veterinary medicinal product.
- (2) This regulation does not apply to—

- (a) a veterinary medicinal product imported in accordance with a certificate granted by the Secretary of State under these Regulations;
- (b) a product prescribed by a veterinary surgeon under the cascade;
- (c) a holder of a wholesale dealer's authorisation if the possession is for re-export; or
- (d) a holder of a manufacturer's authorisation or marketing authorisation if the intention is to manufacture a veterinary medicinal product.

(3) A veterinary surgeon who practises in both the United Kingdom and another member State may hold veterinary medicinal products authorised in the other member State provided that the amount that he holds does not exceed the amount expected to be used in that member State.

(4) It is a defence for a person charged under paragraph (1) to prove that he was in possession of the veterinary medicinal product for the purposes of research or development of a veterinary medicinal product.

(5) A veterinary surgeon may have in his possession an authorised human medicinal product intended for administration to animals under the cascade, but he commits an offence if the amount in his possession exceeds the amount expected to be used under the cascade.

#### **Supply of an unauthorised veterinary medicinal product**

27.—(1) It is an offence to supply an unauthorised veterinary medicinal product.

(2) This regulation does not apply to—

- (a) a veterinary medicinal product prescribed by a veterinary surgeon under the cascade; or
- (b) a product supplied in accordance with a certificate granted by the Secretary of State under these Regulations.

(3) It is a defence for a person charged under paragraph (1) to prove that he supplied the veterinary medicinal product for the purposes of research or development of a veterinary medicinal product.

## **PART 5**

### **Miscellaneous provisions, enforcement and offences**

#### **The Veterinary Products Committee**

28.—(1) There shall continue to be a Veterinary Products Committee.

(2) The Secretary of State may appoint members of the Committee from professional people who are eminent in their field, and any lay members as he sees fit.

(3) The function of the Committee is to provide scientific advice on any aspect of veterinary medicinal products asked for by the Secretary of State and to carry out any functions specified in these Regulations.

(4) The Secretary of State may pay members of the Committee such amounts as he may decide.

(5) The Secretary of State may consult the Committee at any time.

#### **Veterinary Products Committee appeals procedure**

29.—(1) The following procedure applies when there is an appeal to the Veterinary Products Committee.

(2) The appeal may be written or oral, or both, at the choice of the appellant.

(3) The appellant may not present to the Committee any new data that were not available to the Secretary of State at the time of the original decision.

(4) The Committee must consider the appeal and any representations made by the Secretary of State, and report its findings in writing to the Secretary of State together with its recommendations.

(5) The Secretary of State must send a copy of the report to the appellant on request.

(6) The Secretary of State must consider the report and then form a provisional decision.

(7) He must then notify the provisional decision to the appellant, together with the reasons for it.

(8) The appellant may then appeal against the Secretary of State's provisional decision to a person appointed for the purpose by the Secretary of State.

(9) The appointed person must consider the appeal (but may not consider any new data that were not available to the Secretary of State at the time of the original decision) and any representations made by the Secretary of State and report in writing, with a recommended course of action, to the Secretary of State.

(10) The Secretary of State must then reach a final decision and notify the appellant, together with the reasons for it.

## **Exports**

**30.**—(1) It is an offence to export a veterinary medicinal product for use in another member State unless the veterinary medicinal product may be lawfully supplied or administered in that member State.

(2) If a veterinary medicinal product has been manufactured in accordance with a marketing authorisation, or if a product without a marketing authorisation has been manufactured under a manufacturing authorisation, and the product is intended for export outside the European Union, the Secretary of State must, at the request of the exporter or the competent authorities of the country of export, provide a certificate to that effect.

(3) When he issues the certificate the Secretary of State must take account of the model certificates issued by the World Health Organization<sup>(12)</sup>.

(4) If the veterinary medicinal product is authorised in the United Kingdom the Secretary of State must ensure that the exporter or the competent authorities of the third country has access to the summary of product characteristics.

## **Time limits**

**31.**—(1) In any provision in these Regulations requiring the Secretary of State to issue an authorisation within a set time, the clock does not start until the Secretary of State has checked that the application dossier is in accordance with these Regulations and has validated the application.

(2) The clock is stopped during any period that the Secretary of State requires an applicant to provide further data until all the further data required have been provided.

(3) The clock is also stopped during any period that the applicant is given to provide oral or written explanations.

(4) The Secretary of State may stop the clock pending payment of outstanding fees.

## **Appointment of inspectors**

**32.** The Secretary of State shall appoint inspectors for the purposes of the enforcement of these Regulations.

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(12) Published by the World Health Organization at: [www.who.int/medicines/en](http://www.who.int/medicines/en).

### **Powers of entry**

**33.**—(1) An inspector may, on producing a duly authenticated document showing his authority if required, enter any premises at any reasonable hour for the purpose of ensuring that the provisions of these Regulations are being complied with; and in this regulation “premises” includes any place, vehicle, trailer, container, stall, moveable structure, ship or aircraft.

(2) He may take with him—

- (a) such other persons as he considers necessary; and
- (b) any representative of the European Commission acting for the purpose of the enforcement of a Community obligation.

(3) Admission to any premises used only as a private dwellinghouse may not be demanded as of right unless 24 hours notice of the intended entry has been given to the occupier, or the entry is in accordance with a warrant granted under this regulation.

(4) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entry into any premises for the purposes of the enforcement of these Regulations, and either—

- (a) admission has been refused, or a refusal is expected, and (in either case) that notice to apply for a warrant has been given to the occupier;
- (b) asking for admission, or the giving of such a notice, would defeat the object of the entry;
- (c) the case is one of urgency; or
- (d) the premises are unoccupied or the occupier is temporarily absent,

the justice may by warrant signed by him authorise the inspector to enter the premises, if need be by reasonable force.

(5) A warrant under this section is valid for one month.

(6) If an inspector enters any unoccupied premises he must leave them as effectively secured against unauthorised entry as he found them.

(7) He may enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and the premises of the marketing authorisation holder.

(8) He may carry out an inspection at the request of another member State, the European Commission or the Agency.

(9) In this regulation, a reference to a justice of the peace—

- (a) in Scotland includes a reference to the sheriff and to a magistrate; and
- (b) in Northern Ireland, is a reference to a lay magistrate.

### **Powers of an inspector**

**34.**—(1) An inspector entering premises under the previous regulation may—

- (a) inspect the premises, and any plant, machinery or equipment;
- (b) search the premises;
- (c) take samples;
- (d) seize any computers and associated equipment for the purpose of copying documents provided they are returned as soon as practicable;
- (e) seize any veterinary medicinal product, anything purporting to be a veterinary medicinal product, or any additive to which Schedule 5 applies, if it is not authorised in the United Kingdom;

- (f) seize any premixture or feedingstuff that contains a veterinary medicinal product or additive to which Schedule 5 applies that is not authorised in the United Kingdom;
- (g) seize any veterinary medicinal product, anything purporting to be a veterinary medicinal product, any additive to which Schedule 5 applies, any premixture or any feedingstuff if—
  - (i) it has not been lawfully supplied in accordance with these Regulations;
  - (ii) it has been stored in a way that affects its safety, quality or efficacy;
  - (iii) it is sold or offered for sale by a person not permitted to supply it under these Regulations;
- (h) carry out any inquiries, examinations and tests;
- (i) have access to, and inspect and copy any documents or records (in whatever form they are held) relating to these Regulations, and remove them to enable them to be copied; and
- (j) have access to, inspect and check the operation of any computer and any associated apparatus or material that is or has been in use in connection with the records; and for this purpose may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford him such assistance as he may reasonably require and, where a record is kept by means of a computer, may require the records to be produced in a form in which they may be taken away.

(2) An officer of any local authority who has entered premises exercising any statutory power of entry for the purposes of enforcing any legislation relating to food hygiene, feed hygiene or animal health, may inspect any records made under these Regulations (in whatever form they are held) relating to food-producing animals, and may remove them to enable them to be copied.

### **Inspection of pharmacies**

**35.** In relation to a pharmacy, all the powers of an inspector to enforce these Regulations may also be exercised by an officer of the Royal Pharmaceutical Society of Great Britain appointed for the purpose.

### **Obstruction**

**36.** Any person who—

- (a) intentionally obstructs any person acting in the execution of these Regulations;
- (b) without reasonable cause, fails to give to any person acting in the execution of these Regulations any assistance or information that that person may reasonably require of him for the performance of his functions under these Regulations;
- (c) furnishes to any person acting in the execution of these Regulations any information that he knows to be false or misleading; or
- (d) fails to produce a record when required to do so to any person acting in the execution of these Regulations,

is guilty of an offence.

### **Improvement notices**

**37.—**(1) If an inspector has reasonable grounds for believing that any person is failing to comply with these Regulations he may serve a notice on that person (in these Regulations referred to as an “improvement notice”) that—

- (a) states the inspector’s grounds for believing this;
- (b) specifies the matters that constitute the failure to comply;

- (c) specifies the measures that, in the inspector's opinion, the person must take in order to secure compliance; and
  - (d) requires the person to take those measures, or measures at least equivalent to them, within the period (being not less than 14 days) specified in the notice.
- (2) It is an offence to fail to comply with an improvement notice.

### **Appeals against improvement notices**

**38.**—(1) Any person who is aggrieved by an improvement notice may appeal to a magistrates' court or, in Scotland, to the sheriff.

(2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980(13) applies to the proceedings.

(3) An appeal to the sheriff under paragraph (1) is by summary application.

(4) The period within which an appeal may be brought is 28 days or the period specified in the improvement notice, whichever ends the earlier.

(5) An improvement notice must state—

- (a) the right of appeal to a magistrates' court or to the sheriff; and
- (b) the period within which such an appeal may be brought.

(6) A court may suspend an improvement notice pending an appeal.

### **Powers of a court on appeal**

**39.** On an appeal against an improvement notice, the court may either cancel the notice or confirm it, with or without modification.

### **Seizure notices**

**40.**—(1) An inspector must follow the procedures set out in this regulation if he seizes anything under regulation 34.

(2) He must serve on the person appearing to him to be in charge of the seized product a notice (referred to in these Regulations as a "seizure notice")—

- (a) giving the grounds for seizing the product; and
- (b) informing him of his rights under this regulation to make a claim, and the address for the service of the claim.

(3) If an inspector is not able to remove products seized under this regulation immediately, he may mark the products in any way that he sees fit, and serve a notice on the person in charge of the products identifying them, and prohibiting the removal of the products from the premises until they are collected by an inspector, and any person other than an inspector who removes products identified under this paragraph from the premises is guilty of an offence.

(4) The person on whom the seizure notice was served or the owner of the seized product may, within 28 days of seizure, notify any claim that the product was not liable to seizure to the Secretary of State at the address specified in the seizure notice, setting out the grounds in full.

(5) If a notification of a claim is not received within 28 days, the Secretary of State may destroy the product.

(6) If a notification of a claim is received within 28 days, then, unless the product seized is being held for the purposes of pending or contemplated criminal proceedings, or for a criminal

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(13) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c. 39), section 47.

investigation, the Secretary of State must either return the product or take proceedings for an order for the confirmation of the seizure notice and the destruction of the veterinary medicinal product in a magistrates' court (or, in Scotland, the sheriff court), and if the court confirms the notice it must order its destruction.

(7) The procedure in a magistrates' court under this regulation is by way of complaint, and the Magistrates' Courts Act 1980 applies to the proceedings.

(8) The procedure before the sheriff is by summary application.

(9) The person on whom the seizure notice was served is liable for the costs of transport, storage for up to 28 days and destruction of the product seized unless a claim is made to a court and the court directs otherwise.

### **Publication**

**41.** The Secretary of State must publicise all improvement notices and seizure notices issued under these Regulations and the suspension or revocation of anything issued under these Regulations, and may do so in such manner as he sees fit.

### **Penalties**

**42.—**(1) A person guilty of an offence under these Regulations is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or both, or
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

(2) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of—

- (a) a qualified person appointed as such for the purposes of these Regulations;
- (b) any director, manager, secretary or other similar person of the body corporate; or
- (c) any person who was purporting to act in any such capacity,

he is guilty of the offence as well as the body corporate.

(3) For the purposes of paragraph (2) above, “director”, in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(4) Where an offence that has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner, he as well as the partnership is guilty of the offence.

### **Northern Ireland**

**43.—**(1) This regulation has effect in relation to the enforcement of these Regulations in Northern Ireland.

(2) The Department of Agriculture and Rural Development or the Department of Health, Social Services and Public Safety (or both Departments acting jointly) instead of the Secretary of State exercise the powers of the Secretary of State in—

- (a) regulation 32 (appointment of inspectors);
- (b) regulation 40 (seizure notices);
- (c) regulation 41 (publication); and

- (d) sub-paragraph (4) of paragraph 14 of Schedule 3 (approval of premises for suitably qualified persons).
- (3) The Department of Agriculture and Rural Development is the competent authority for—
- (a) Regulation (EC) No. 178/2002 (of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(14));
  - (b) Regulation (EC) No. 1831/2003 (of the European Parliament and the Council on additives for use in animal nutrition(15));
  - (c) Regulation (EC) No. 882/2004 (of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules(16)); and
  - (d) Regulation (EC) No. 183/2005 (of the European Parliament and of the Council laying down requirements for feed hygiene(17)).
- (4) In relation to pharmacies, an officer of the Pharmaceutical Society of Northern Ireland appointed by the Society for the purpose has all the powers of an inspector to enforce these Regulations.
- (5) In proceedings in a magistrates' court relating to an improvement notice under regulation 38 or a seizure notice under regulation 40 the Magistrates' Courts (Northern Ireland) Order 1981(18) applies.

#### **Revocation**

44. The Veterinary Medicines Regulations 2006(19) (other than paragraphs (2) to (4) of regulation 44 and Schedules 8 and 9) are revoked.

24th July 2007

*Jeff Rooker*  
Minister of State  
Department for Environment, Food and Rural  
Affairs

30th August 2007

*Dave Watts*  
*Steve McCabe*  
Two of the Lords Commissioners of Her  
Majesty's Treasury

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(14) OJ No. L 31, 1.2.2002, p. 1.  
(15) OJ No. L268, 18.10.2003, p. 29.  
(16) Corrected version at OJ No. L191, 28.5.2004, p. 1.  
(17) OJ No. L35, 8.2.2005, p. 1.  
(18) S. I. 1981/1675 (N.I. 26).  
(19) S. I. 2006/2407.



## SCHEDULE 1

Regulation 4(3)

### Marketing authorisations

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## PART 1

### Application for a marketing authorisation

#### Application for a marketing authorisation

1. An application under these Regulations for a marketing authorisation for a veterinary medicinal product must be made to the Secretary of State.

#### Information with the application

2.—(1) An application must include all necessary administrative information, and all scientific documentation necessary for demonstrating the safety, quality and efficacy of the product.

(2) In particular, the applicant must provide all the data required in Annex I to Directive [2001/82/EC](#) of the European Parliament and of the Council on the Community code relating to veterinary medicinal products<sup>(20)</sup>, generated in accordance with that Annex.

(3) The application must contain the following information—

- (a) the name of the person who will hold the marketing authorisation, that person’s address and, if different, the name and address of all the manufacturers involved in each stage of the manufacture, and the sites where the manufacture will take place;
- (b) the name of the veterinary medicinal product, which may be either—
  - (i) an invented name provided that this is not liable to be confused with the common name of the product or the international non-proprietary name (INN) recommended by the World Health Organization; or
  - (ii) a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder;

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<sup>(20)</sup> OJ No. L 311, 28.11.2001, p. 1 as amended by Directive [2004/28/EC](#) of the European Parliament and of the Council (OJ No. L 136, 30.4.2004, p. 58).

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- (c) the qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its INN recommended by the World Health Organization, where an INN exists, or its chemical name;
- (d) a description of the method of manufacture;
- (e) all therapeutic indications, contra-indications and adverse reactions;
- (f) the dosage for each species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;
- (g) any proposed precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals or disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human or animal health or to plants, together with the reasons;
- (h) in the case of medicinal products intended for food-producing species, the proposed withdrawal period necessary to ensure that the maximum residue limits specified in Council Regulation (EEC) No. 2377/90 (laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin<sup>(21)</sup>) are not exceeded;
- (i) a description of the testing methods to be used during manufacture;
- (j) the results of—
  - (i) pharmaceutical (physico-chemical, biological or microbiological) tests;
  - (ii) safety tests and residue tests;
  - (iii) pre-clinical and clinical trials;
  - (iv) tests assessing the potential risks to the environment from the product;
- (k) a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;
- (l) a summary of the product characteristics, mock-ups of all proposed packaging and the proposed package leaflet, if any;
- (m) a document showing that the manufacturer is authorised in his own country to produce veterinary medicinal products;
- (n) copies (which must be updated if there are any changes while the application is being considered) of—
  - (i) any marketing authorisation obtained in another member State or in a third country for the relevant veterinary medicinal product, and a list of any other member States in which an application for authorisation of the product has been submitted;
  - (ii) if the product is already authorised outside the United Kingdom, the summary of product characteristics for each authorisation;
  - (iii) any decision to refuse authorisation, whether in the Community or a third country and the reasons for that decision;
- (o) proof that the applicant has the services of a qualified person responsible for pharmacovigilance (referred to in these Regulations as a qualified person (pharmacovigilance)) and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country;
- (p) if the veterinary medicinal product is intended for food-producing species and contains one or more pharmacologically active substances not yet included for the species in question

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(21) OJ No. L224, 18.8.1990, p. 1 as last amended by Commission Regulation (EC) No. 869/2005 (OJ No. L 145, 9.6.2005, p. 19).

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in Annex I, II or III to Council Regulation (EEC) No. 2377/90, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with paragraph 5.

(4) All documents relating to the results of tests or trials must be accompanied by a detailed and critical expert report that has been drafted and signed by a person with the requisite technical or professional qualifications and that has a brief curriculum vitae of the person signing the report attached to it.

(5) In the case of immunological products, the applicant must submit a description of the methods used to establish that the manufacturing process will consistently produce a veterinary medicinal product that is in accordance with the marketing authorisation.

### Summary of product characteristics

3. The summary of product characteristics required under the preceding paragraph must include the following information, set out in the same format—

#### Summary of product characteristics

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1	Name of the veterinary medicinal product, followed by its strength and pharmaceutical form.
2	The name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons.
3	Pharmaceutical form.
4	Clinical particulars—
4.1	target species;
4.2	indications for use, specifying the target species;
4.3	contra-indications;
4.4	special warnings for each target species;
4.5	special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals;
4.6	adverse reactions (frequency and seriousness);
4.7	use during pregnancy, lactation or lay;
4.8	interaction with other medicinal products and other forms of interaction;
4.9	amounts to be administered and administration route;
4.10	overdose (symptoms, emergency procedures, antidotes) if necessary;

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4.11	withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero.
5	Pharmacological properties—
5.1	pharmacodynamic properties;
5.2	pharmacokinetic particulars.
6	Pharmaceutical particulars—
6.1	list of excipients;
6.2	major incompatibilities;
6.3	shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time;
6.4	special precautions for storage;
6.5	nature and contents of immediate packaging;
6.6	special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate.
7	Marketing authorisation holder.
8	Marketing authorisation number.
9	Date of the first authorisation or date of renewal of the authorisation.
10	Date of any revision of the text.
11	Any other information required by the Secretary of State.

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#### **Supply of a copy of the summary of product characteristics**

**4.** A holder of a marketing authorisation must supply a copy of the summary of product characteristics to any person on demand.

#### **Time limits for applications for products for use in food-producing animals**

**5.** In the case of a veterinary medicinal product for food-producing animals, a marketing authorisation may not be applied for until at least six months after a valid application has been made for the establishment of a maximum residue limit in accordance with Council Regulation (EEC) No. 2377/90.

## PART 2

### Derogations from some of the requirements in Part 1

#### Scope

6. This Part provides for applications for marketing authorisations in which not all the information required in Part 1 is required, but for the avoidance of doubt any applicant may apply for a marketing authorisation using Part 1 if he wishes to do so.

#### Bibliographic application

7.—(1) An applicant for a marketing authorisation need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the active substance of the veterinary medicinal product has been in an authorised veterinary medicinal product for that species in the Community for at least ten years, and the applicant provides appropriate scientific literature to demonstrate this.

(2) He may use any publicly available document.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies, together with further clinical trials, a third party may not use those studies or trials in an application for a pharmacologically equivalent product for a period of three years from the grant of the authorisation for the additional species.

#### Application for a product using a new combination of active substances

8. If an application is for a veterinary medicinal product containing active substances already used in an authorised veterinary medicinal product but not previously used in that combination in a veterinary medicinal product, he need not provide the safety and efficacy data for the individual active substances.

#### Application using existing data

9. If the Secretary of State has granted a marketing authorisation, he may, with the permission of the holder, use the data submitted in support of that marketing authorisation when assessing an application for another marketing authorisation.

#### Application for a pharmacologically equivalent medicinal product

10.—(1) An applicant need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if he can demonstrate that the veterinary medicinal product is pharmacologically equivalent to a veterinary medicinal product already authorised in the Community.

(2) For the purposes of this paragraph a product is pharmacologically equivalent to an existing product if—

- (a) it has the same qualitative and quantitative composition in active substances;
- (b) it has the same pharmaceutical form; and
- (c) bioequivalence has been demonstrated by means of appropriate bioavailability studies.

(3) For the purposes of this paragraph—

- (a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

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- (b) if they do differ significantly in properties with regard to efficacy or safety, additional information intended to provide proof of the safety or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.
- (4) Different immediate-release oral pharmaceutical forms are regarded as the same pharmaceutical form.
- (5) Bioavailability studies are not required if the bioequivalence guidelines produced by the Agency exempt the product.
- (6) In the case of a reference product authorised in another member State but not in the United Kingdom, the Secretary of State must be satisfied that the risk-benefit balance of the original product is appropriate for the product to be placed on the market in the United Kingdom, and if the data provided under Article 13, third paragraph of Directive 2001/82/EC by the member State in which the product is authorised are insufficient for him to be satisfied of this, he may notify the applicant and require the applicant to provide further data.

#### **Time limits for marketing authorisations granted under the procedure for a pharmacologically equivalent product**

- 11.—(1) This paragraph establishes the time limits relating to granting a marketing authorisation under the procedure for a pharmacologically equivalent product.
- (2) An application for a marketing authorisation cannot be made until two years before the product may be placed on the market in accordance with this paragraph.
  - (3) The product may not be placed on the market until ten years (or, in the case of medicinal products for fish or bees where the application for a marketing authorisation was submitted after 30th October 2005, thirteen years) have elapsed from the initial authorisation of the reference product.
  - (4) Time limits in this paragraph are calculated from the first grant of the marketing authorisation for the reference product.

#### **Extension of time limits**

- 12.—(1) This paragraph applies in relation to veterinary medicinal products that—
- (a) are intended for administration to food-producing species, and
  - (b) contain a new active substance that was not authorised in the Community by 30th April 2004.
- (2) If a person submitted an application for a marketing authorisation for a product on or after 30th October 2005, and within 5 years of the original marketing authorisation being granted, the marketing authorisation is extended to include additional food-producing species, the ten-year protection period is extended by one year for each additional food-producing species added to the marketing authorisation.
- (3) The total period may not exceed 13 years.
  - (4) The extension applies only if the marketing authorisation holder originally applied for determination of the maximum residue limits for the active substance.

#### **Parallel imports**

- 13.—(1) The Secretary of State may grant a marketing authorisation in relation to a veterinary medicinal product authorised in another member State and imported into the United Kingdom from that member State in accordance with this paragraph without the data required in Part 1 if the applicant can demonstrate compliance with this paragraph.



(2) If the product is for a food-producing species it must be identical to a product authorised in the United Kingdom.

(3) Other products must be therapeutically the same as a product authorised in the United Kingdom unless the importer can justify any differences.

(4) The member State from which it is imported must have authorised the product in accordance with Directive 2001/82/EC.

(5) The applicant must be established within the Community.

(6) The applicant must hold (or have a contract with the holder of) a wholesale dealer's authorisation in the United Kingdom appropriate to the type of product to be imported.

(7) If re-labelling is to take place in the United Kingdom the applicant must also be (or have a contract with) the holder of a suitable manufacturing authorisation in the United Kingdom.

### **Specific batch control scheme**

**14.**—(1) Where a veterinary medicinal product (other than a biological veterinary medicinal product) has been granted a marketing authorisation or an animal test certificate, and any starting material (active substance, excipient or packaging) or any batch of the product does not fully meet the requirements of the authorisation or animal test certificate, the holder may apply to the Secretary of State to place one or more batches on the market notwithstanding this.

(2) The Secretary of State may authorise the placing on the market if he is satisfied that the safety, quality and efficacy of the product are not compromised, and that in all the circumstances of the case the product should be placed on the market.

(3) This paragraph does not apply in relation to a product recognised in more than one member State.

(4) In this paragraph a biological veterinary medicinal product is a veterinary medicinal product, the active substance of which is a biological substance; and a biological substance is a substance that is produced by or extracted from a biological source and for which a combination of physico-chemical-biological testing and the production process and its control is needed for its characterisation and the determination of its quality.

### **Similar immunological products**

**15.** Where an immunological veterinary medicinal product is pharmacologically equivalent to a reference product other than differences in raw materials or in the manufacturing process, the results of the appropriate pre-clinical tests or clinical trials must be provided, but the applicant need not provide the results of safety tests or residue tests.

### **Marketing in exceptional circumstances**

**16.** Where the health situation so requires, the Secretary of State may authorise the placing on the market of a veterinary medicinal product that has been authorised by another member State or, if there is no such authorised product, authorised in a third country.

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## PART 3

### Grant of a marketing authorisation

#### Time limits

17. The Secretary of State must ensure that the procedure for granting an authorisation for a veterinary medicinal product is completed within a maximum of 210 days after the submission of the application.

#### Place of establishment of applicant

18. Only an applicant established in a member State may be granted a marketing authorisation.

#### Procedure

19. The Secretary of State may require the applicant to provide additional information or to generate additional data, including laboratory testing, or may require the applicant to provide samples of any medicinal product, its starting materials and intermediate products or other constituent materials so that he can test them in a laboratory.

#### Products authorised in another member State

20. Where the Secretary of State is informed or discovers that another member State has authorised a veterinary medicinal product that is the subject of an application for authorisation by the Secretary of State, he must reject the application unless it was submitted in accordance with the mutual recognition procedure or the decentralised procedure in Part 6.

#### Assessment reports

21. The Secretary of State must produce an assessment of the dossier, consisting of an evaluation of the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned, and any additional related information.

#### Grant of a marketing authorisation

22. When granting a marketing authorisation, the Secretary of State must inform the applicant of the summary of product characteristics that he has approved, and the distribution category of the product.

#### Marketing authorisations for food-producing species

23.—(1) The Secretary of State must not grant a marketing authorisation for a veterinary medicinal product for food-producing species unless all its pharmacologically active substances appear in Annex I, II or III to Council Regulation (EEC) No. 2377/90.

(2) This does not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption; but in this case the product must not include an active substance that appears on Annex IV to Council Regulation (EC) No. 2377/90 and must not be intended for the treatment of a condition for which a veterinary medicinal product is already authorised for horses.

### **Refusal of a marketing authorisation**

**24.**—(1) The Secretary of State must refuse to grant a marketing authorisation if the application does not comply with these Regulations.

- (2) In addition, he must refuse to grant it if—
- (a) the data submitted with the application are inadequate;
  - (b) the risk-benefit balance of the veterinary medicinal product is unfavourable;
  - (c) the product has insufficient therapeutic effect;
  - (d) the withdrawal period proposed by the applicant is not long enough to ensure that Council Regulation (EEC) No. 2377/90 is complied with, or is insufficiently substantiated;
  - (e) the veterinary medicinal product is for a prohibited use;
  - (f) the way that the product will be used will have an unnecessarily undesirable effect on the environment.
- (3) The Secretary of State may refuse to grant a marketing authorisation—
- (a) if there is Community legislation pending that is incompatible with the requested authorisation; or
  - (b) if he requests additional data and those data are not provided within such time limit as he may stipulate.

(4) If the Secretary of State, on the grounds of safety, quality or efficacy intends to refuse an application, or proposes to grant a marketing authorisation that is different from the one applied for, he must notify the applicant accordingly, and the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

### **Publication following the grant of a marketing authorisation**

**25.**—(1) When he grants a marketing authorisation the Secretary of State must publish—

- (a) the notice granting the marketing authorisation;
- (b) the summary of the product characteristics;
- (c) the assessment report that he has already prepared but with any commercially confidential or personal information deleted.

(2) He must update the assessment report whenever new information that is of importance and relates to the quality, safety or efficacy of the veterinary medicinal product becomes available.

(3) He must send a copy of the assessment report, and any update, to the holder of the marketing authorisation before he publishes it to enable the holder to make representations to him concerning any confidential or personal information that may be in it, and may specify a date by which representations must be made.

### **Provisional marketing authorisation**

**26.**—(1) In exceptional circumstances, the Secretary of State may grant a provisional marketing authorisation subject to a requirement for the applicant to provide further data.

- (2) The Secretary of State must reassess the authorisation annually.

### **Provisions of samples and expertise**

**27.**—(1) The Secretary of State may require a marketing authorisation holder to provide, at any time and at any stage of the manufacturing process, samples of starting materials or the veterinary medicinal product for testing.

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(2) At the request of the Secretary of State, the marketing authorisation holder must provide his technical expertise to facilitate any analysis of the product.

(3) It is an offence to fail to comply with this paragraph or a requirement under it.

### **Supply of information**

**28.**—(1) A marketing authorisation holder must immediately inform the Secretary of State if he receives any new information that might adversely affect the risk-benefit balance of the veterinary medicinal product.

(2) He must immediately inform the Secretary of State of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is authorised.

(3) The Secretary of State may at any time require the marketing authorisation holder to provide data relating to the risk-benefit balance.

(4) It is an offence to fail to comply with this paragraph or a requirement under it.

### **Duties on the holder of a marketing authorisation relating to an immunological product**

**29.**—(1) Before the holder of a marketing authorisation for an immunological product places that product on the market he must either—

(a) notify the Secretary of State and ask for his written approval to do so, or

(b) if he has already received written approval from another member State permitting the release of the product, send a copy of that approval to the Secretary of State.

(2) If the Secretary of State is notified under sub-paragraph (1)(a) he must give or refuse a written approval as soon as is reasonably practicable.

(3) It is an offence to place an immunological product on the market without a written approval issued by the Secretary of State or (if the approval was issued by another member State) without sending a copy of that approval to the Secretary of State.

### **Control tests**

**30.** The holder of a marketing authorisation must give to the Secretary of State on demand evidence that he has carried out all control tests required under the marketing authorisation, and the results of those tests, and failure to do so is an offence.

### **Placing on the market**

**31.**—(1) When a holder of a marketing authorisation first places the veterinary medicinal product on the market in the United Kingdom he must notify the Secretary of State that he has done so, and the date on which it was placed on the market.

(2) If he removes the veterinary medicinal product from the market in the United Kingdom, he must notify the Secretary of State at least two months (or a shorter period in exceptional circumstances) before he does so.

(3) Upon request by the Secretary of State, the marketing authorisation holder must provide him with—

(a) all data relating to the volume of sales of the veterinary medicinal product by him, and

(b) any data in his possession relating to the number of prescriptions written for the product and the total volume supplied under those prescriptions.

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

### **Duration and validity of a marketing authorisation**

- 32.**—(1) A marketing authorisation is initially valid for five years.
- (2) The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.
- (3) An application for renewal must be made at least six months, and not more than nine months, before the marketing authorisation ceases to be valid.
- (4) When he applies for the renewal of the marketing authorisation the applicant must enclose a list of all documents concerning the product that he has submitted to the Secretary of State since the marketing authorisation was granted.
- (5) The Secretary of State may require the applicant to provide a copy of any of the listed documents at any time.
- (6) Once renewed, the marketing authorisation is valid indefinitely unless, within five years of the renewal, the Secretary of State notifies the holder, on justified grounds relating to pharmacovigilance, that the authorisation will cease to be valid five years from the first renewal unless the holder applies for a further renewal.
- (7) The further renewal is not time-limited.
- (8) Any marketing authorisation granted under these Regulations that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in the United Kingdom ceases to be valid.
- (9) When a veterinary medicinal product authorised under these Regulations and previously placed on the market in the United Kingdom is not present on the market in the United Kingdom for a period of three consecutive years, its marketing authorisation ceases to be valid.
- (10) The Secretary of State may, on human or animal health grounds, grant exemptions from sub-paragraphs (8) and (9).

## **PART 4**

### **Variations of marketing authorisations on the application of the holder**

#### **Variation of a marketing authorisation for a mutually recognised veterinary medicinal product**

**33.** Where a veterinary medicinal product is authorised in more than one member State, the Secretary of State is the competent authority for the purposes of Commission Regulation (EC) No. 1084/2003 (concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a member State)(**22**).

#### **Variation of a marketing authorisation not authorised in another member State**

- 34.**—(1) Where a veterinary medicinal product is not authorised in another member State, an application to vary it must be made by the holder to the Secretary of State.
- (2) Paragraph 24 of this Schedule (refusal of a marketing authorisation) applies to an application for a variation in the same way as it applies to an application for a marketing authorisation.
- (3) If he grants a variation of a veterinary medicinal product the Secretary of State must (unless there are exceptional circumstances necessary to protect human or animal health or the

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(22) OJ No. L 159, 27.6.2003, p. 1.

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environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

(4) If he refuses to grant a variation he must give written reasons; and if those reasons are on the grounds of safety, quality or efficacy, the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

#### **Administrative variations**

**35.**—(1) The holder of a marketing authorisation may apply for a minor change in a marketing authorisation to be made without the Secretary of State considering any scientific data (an “administrative variation”).

(2) If the Secretary of State grants an administrative variation, and subsequently establishes that this should have been a variation requiring consideration of scientific data, he may notify the marketing authorisation holder, require him to submit an application for a variation enabling data to be assessed and revoke the administrative variation.

#### **Changes after a marketing authorisation has been issued**

**36.** After a marketing authorisation has been issued, the holder must take account of scientific and technical progress in manufacturing and control methods, and apply to the Secretary of State for any variation in the marketing authorisation that may be required to enable that veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

#### **Compulsory variation**

**37.**—(1) If the Secretary of State decides, for any of the reasons for which he may or must suspend a marketing authorisation specified in paragraph 38, or because the classification of a veterinary medicinal product should be changed, that a variation to a marketing authorisation is necessary, he must notify the marketing authorisation holder in writing of the required variation, together with his reasons.

(2) In the notification he may specify a time limit within which the marketing authorisation holder must apply for the variation.

(3) If the variation is on the grounds of safety, quality or efficacy, the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

(4) If the marketing authorisation holder fails to apply for the variation within that time limit the Secretary of State may suspend or revoke the marketing authorisation.

## **PART 5**

### **Suspension, etc. of a marketing authorisation**

#### **Suspension of a marketing authorisation: grounds**

**38.**—(1) The Secretary of State may suspend a marketing authorisation at any time if he is satisfied that—

- (a) this is necessary for the protection of animal or public health or the environment;
- (b) the terms of the marketing authorisation have not been complied with; or
- (c) the veterinary medicinal product has insufficient therapeutic effect.

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(2) He may also suspend a marketing authorisation if he is satisfied that a marketing authorisation holder has failed to make an application for a variation to take account of scientific and technical progress in manufacturing and control methods to enable the veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(3) He must suspend a marketing authorisation if he is satisfied that—

- (a) the risk-benefit balance is unfavourable;
- (b) the withdrawal period does not ensure that residues in foodstuffs obtained from the treated animal comply with Council Regulation (EEC) No. 2377/90;
- (c) information given in the application documents is incorrect;
- (d) any control tests required have not been carried out;
- (e) changes have been made to the manufacturing process without the authority of the Secretary of State; or
- (f) any information required to be supplied to the Secretary of State has not been communicated to him.

#### **Suspension of a marketing authorisation: procedure**

**39.**—(1) If the Secretary of State suspends a marketing authorisation he must notify the holder immediately, and, unless he directs otherwise, the suspension has immediate effect, and continues in effect unless he reinstates the marketing authorisation.

(2) If the suspension is on the grounds of safety, quality or efficacy, the holder may, within 28 days of the notification, appeal to the Veterinary Products Committee.

(3) If the veterinary medicinal product is authorised in more than one member State—

- (a) the Secretary of State must immediately refer the matter to the Agency, and must comply with a decision of the Commission within 30 days of the decision; and
- (b) he may suspend the marketing and the use of the veterinary medicinal product in the United Kingdom pending a decision of the Agency, but must inform the Commission and the other member States no later than the following working day of the reasons for his action.

(4) When he suspends a marketing authorisation, the Secretary of State may in addition prohibit the supply of the veterinary medicinal product, and if necessary require the marketing authorisation holder to recall the product; and failure to comply with a requirement or prohibition under this sub-paragraph is an offence.

#### **Revocation**

**40.**—(1) The Secretary of State may revoke any marketing authorisation that has been suspended for more than 28 days unless there is a current appeal to the Veterinary Products Committee.

(2) He may publicise a revocation in such manner as he sees fit.

#### **Prohibiting the supply of veterinary medicinal products**

**41.**—(1) In addition to his powers to suspend a marketing authorisation, if he is satisfied that a product has not been manufactured in accordance with the marketing authorisation the Secretary of State may prohibit the supply of a veterinary medicinal product, and if necessary require the marketing authorisation holder to recall it, and failure to comply with a requirement or prohibition under this sub-paragraph is an offence.

(2) He may confine the prohibition on supply and the requirement for recall to specific production batches.

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(3) In the case of an immunological veterinary medicinal product manufactured outside the United Kingdom, if a batch has had all the tests that were originally carried out by the manufacturer repeated by the competent authority of another member State, the Secretary of State may not prohibit the release of that batch if all the results have been submitted to him and the results demonstrate that the product is within the terms of the authorisation.

## PART 6

### Mutual recognition and multiple applications

#### **Application for a marketing authorisation where one already exists in another member State**

**42.**—(1) If a veterinary medicinal product has already received a marketing authorisation in another member State at the time of application, and the holder of the marketing authorisation applies for a marketing authorisation in the United Kingdom, the following procedure (“the mutual recognition procedure”) applies.

(2) The applicant must submit to the Secretary of State a dossier identical to the one submitted to the competent authority of the member State in which the veterinary medicinal product has been authorised (“the reference member State”).

(3) If there is a marketing authorisation current in more than one member State the applicant must identify which member State is acting as the reference member State.

(4) If the applicant is applying in more than one member State he must supply the Secretary of State with a list of all the States in which he is applying.

(5) The Secretary of State must obtain an assessment report from the reference member State and, where appropriate, an explanation of any extension of the period of data protection.

(6) Within 90 days after receipt of the assessment report, the Secretary of State must, subject to the following provisions, either—

- (a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or
- (b) notify the reference member State that he will not approve them, and provide the reference member State with a detailed statement of the reasons.

(7) He may only refuse an application on the grounds of serious risk to human or animal health or the environment.

(8) If he approves the assessment report, the summary of product characteristics, the labelling and the package leaflet he must ensure that he is in a position to decide whether or not to grant a marketing authorisation within 30 days of approving them.

(9) If the Secretary of State is notified by the reference member State that—

- (a) not all member States concerned have within 90 days approved the assessment report, summary of product characteristics, labelling or package leaflet; and
- (b) the reference member State has sent a detailed statement of the reasons to the other member States involved in the application, the applicant and the coordination group for action in accordance with Article 33(3) of Directive [2001/82/EC](#),

the Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

(10) The Secretary of State may grant the marketing authorisation even though not all member States have agreed to grant it, but must revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.



### **Application in another member State**

43.—(1) When the Secretary of State has granted a marketing authorisation for a veterinary medicinal product and he is notified by the marketing authorisation holder that he has applied to have that veterinary medicinal product authorised in another member State, he must prepare an assessment report for the product within 90 days of the notification and send it to the member State or States concerned.

(2) If the other member State (or, if there is more than one, all of them) agrees with the assessment report, the summary of product characteristics, the labelling and the package leaflet he need take no further action.

(3) If not all the other member States concerned so agree within a further 90 days he must send a detailed statement setting out why they have disagreed to the other member States, the applicant and the coordination group for action in accordance with Article 33(3) of Directive 2001/82/EC.

(4) The Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

### **Application for a marketing authorisation in multiple member States where a marketing authorisation does not exist in any member State**

44.—(1) If an applicant wishes to apply for a marketing authorisation in more than one member State, and a marketing authorisation does not exist in any member State for the product (“the decentralised procedure”), he must—

- (a) apply simultaneously in all the relevant member States;
- (b) submit a dossier to the Secretary of State that is identical to the dossier being submitted to all the other member States;
- (c) include a list of all member States in which he has applied; and
- (d) nominate one of them to act as the reference member State to prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet for consideration by the other member States (“the concerned member States”).

(2) If the United Kingdom is the reference member State, the Secretary of State must prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet within 120 days of the receipt of a valid application and must send them to the other concerned member States and to the applicant.

(3) If the United Kingdom is not the reference member State, within 90 days after receipt of the assessment report and drafts of the summary of product characteristics, labelling and package leaflet from the reference member State, the Secretary of State must, subject to the following provisions, either—

- (a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or
- (b) notify the reference member State that he will not approve it, and provide the reference member State with a detailed statement of the reasons.

(4) He may only refuse an application on the grounds of serious risk to human or animal health or the environment.

(5) If all the member States involved agree the assessment report, the summary of product characteristics, the labelling and the package leaflet within 90 days, the Secretary of State must ensure that he is in a position to decide whether or not to grant a marketing authorisation within 30 days.

(6) If, within 90 days, not all the member States have agreed the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human

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or animal health or to the environment, the Secretary of State (if the United Kingdom is the reference member State) must send a detailed statement of the reasons to the other member States involved in the application, the applicant, and the coordination group to act in accordance with Article 33(3) of Directive [2001/82/EC](#).

(7) If reference has been made to the coordination group by any member State, the Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

(8) If the Secretary of State wishes to do so, he may grant the marketing authorisation even though not all member States have agreed to grant it, but must revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.

## PART 7

### Labelling and package leaflets

#### **Approval by the Secretary of State**

45. When the Secretary of State issues the marketing authorisation he must approve all containers, packaging, labels and package leaflets.

#### **Reference to being authorised**

46. A label and package leaflet of an authorised veterinary medicinal product may contain in legible characters the words “UK authorised veterinary medicinal product” or, if the marketing authorisation provides, other wording specified in the authorisation indicating that the product is authorised in the United Kingdom.

#### **Language**

47.—(1) All labels and package leaflets must be in English, but may contain other languages provided that the information given is identical in all the languages.

(2) This requirement does not apply in the case of a product imported by a veterinary surgeon and administered by or under the responsibility of that same veterinary surgeon.

#### **Labelling with all the information on the immediate packaging**

48.—(1) If it is reasonably practicable to do so, the following must be provided on the immediate packaging, in legible characters—

- (a) the name, strength and pharmaceutical form of the veterinary medicinal product;
- (b) the name and strength of each active substance, and of any excipient if this is required under paragraph 2 of the summary of product characteristics;
- (c) the route of administration (if not immediately apparent);
- (d) the batch number;
- (e) the expiry date;
- (f) the words “For animal treatment only” and if appropriate, “To be supplied only on veterinary prescription”;
- (g) the contents by weight, volume or number of dose units;
- (h) the marketing authorisation number;

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- (i) the name and address of the marketing authorisation holder or, if there is a distributor authorised in the marketing authorisation, that distributor;
  - (j) a suitably labelled space to record discard date (if relevant);
  - (k) the target species;
  - (l) the distribution category;
  - (m) the words “Keep out of reach of children”;
  - (n) storage instructions;
  - (o) the in-use shelf-life (if appropriate);
  - (p) for food-producing species, the withdrawal period for each species or animal product concerned;
  - (q) any warning specified in the marketing authorisation;
  - (r) disposal advice;
  - (s) full indications;
  - (t) dosage instructions;
  - (u) contra-indications;
  - (v) further information required in the marketing authorisation;
  - (w) if the product is one that requires a dose to be specified for the animal being treated, a space for this.
- (2) If all this is on the immediate packaging, there is no need for any outer packaging or a package leaflet.

### **Products with immediate and outer packaging**

**49.**—(1) If it is not reasonably practicable to have all the required information on the immediate packaging then this paragraph applies.

(2) The immediate packaging must have at least the following information—

- (a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;
- (b) the name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons;
- (c) the route of administration (if not immediately apparent);
- (d) the batch number;
- (e) the expiry date;
- (f) the words “For animal treatment only” and if appropriate, “To be supplied only on veterinary prescription”;
- (g) the words “Keep the container in the outer carton”.

(3) In addition, the immediate packaging must have as much of the required information as is reasonably practicable.

(4) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product in accordance with the following paragraph.

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### **Package leaflets**

**50.**—(1) If it is not reasonably practicable to have all the required information on the immediate packaging or all of this information on the outer packaging, there must be a package leaflet supplied with the product, containing all the required information except for the batch number and the expiry date, and including the name of both the marketing authorisation holder and, if different, the name of the distributor named in the marketing authorisation.

(2) If there is a package leaflet, the immediate packaging and the outer packaging must both refer the user to it.

(3) A package leaflet must relate solely to the veterinary medicinal product with which it is included.

(4) It must be written in plain English.

(5) Only a package leaflet approved in the marketing authorisation may be included with the veterinary medicinal product.

### **Ampoules**

**51.**—(1) In the case of ampoules or other unit dose forms, where the container cannot bear legibly the required information, only the following information must be shown on the immediate packaging—

- (a) the name of the veterinary medicinal product;
- (b) the name and strength of the active ingredient;
- (c) the route of administration (if not immediately apparent);
- (d) the batch number;
- (e) the expiry date;
- (f) the words “For animal treatment only” and if appropriate, “To be supplied only on veterinary prescription”.

(2) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product, except that the ampoule need not refer to the package leaflet.

### **Small containers other than ampoules**

**52.** As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the required information, all the required information must appear on the outer packaging or outer packaging and package leaflet, but the immediate packaging must be labelled with the batch number and the expiry date and, if there is room, the other information in the preceding paragraph.

### **Homeopathic remedies**

**53.**—(1) A homeopathic remedy registered under these Regulations must be labelled in accordance with this paragraph.

(2) There must be no specific therapeutic indication on the labelling or in any information relating to it.

(3) The labelling (or labelling and package leaflet) must contain the following and no other information—

- (a) the words “homeopathic remedy without approved therapeutic indications for veterinary use”;

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- (b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used (if the homeopathic remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks);
- (c) the name and address of the registration holder and (on the package leaflet) of the manufacturer;
- (d) the method and, if necessary, route of administration;
- (e) the expiry date;
- (f) the pharmaceutical form;
- (g) the contents of the pack;
- (h) any special storage precautions;
- (i) the target species;
- (j) any necessary special warnings;
- (k) the batch number; and
- (l) the registration number.

#### **Variations**

**54.** The Secretary of State may permit variations in the above in any individual marketing authorisation if this is necessary for public or animal health purposes or the protection of the environment.

## **PART 8**

### **Pharmacovigilance**

#### **Qualified persons responsible for pharmacovigilance**

**55.—**(1) A marketing authorisation holder must have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance (“a qualified person (pharmacovigilance)”) who resides in a member State.

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

#### **Duties relating to the qualified person**

**56.—**(1) The marketing authorisation holder must ensure that the qualified person (pharmacovigilance)—

- (a) establishes and maintains a system that ensures that information about all suspected adverse reactions reported to the marketing authorisation holder is collected and collated in order to be accessible at least at one point in a member State;
- (b) answers any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product fully and within any time limit imposed by the Secretary of State when he requested the information, including the volume of sales of the veterinary medicinal product concerned and, if available, details of prescriptions;
- (c) provides to the Secretary of State any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, including appropriate information on post-marketing surveillance studies; and in this paragraph “post-marketing

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surveillance studies” means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying and investigating a safety hazard relating to an authorised veterinary medicinal product.

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

### **Adverse reactions to a veterinary medicinal product administered in the United Kingdom**

**57.**—(1) A marketing authorisation holder must act in accordance with this paragraph if he learns of any suspected—

- (a) serious adverse reaction;
- (b) human adverse reaction; or
- (c) unintended transmission of an infectious agent through a veterinary medicinal product,

following the administration of the product in the United Kingdom.

(2) He must make a record of what happened.

(3) He must without delay and in any event within 15 days report it (electronically if this is practicable) to the Secretary of State.

(4) In addition, he must supply to the Secretary of State all relevant veterinary pharmacovigilance information in his possession relating to the reaction, giving a full description of the incident and a list of all the symptoms using internationally recognised veterinary and medical terminology<sup>(23)</sup>, either with the report or, if the information becomes available after the report has been sent, as soon after it becomes available as is reasonably practicable.

(5) In this and the following paragraph—

“human adverse reaction” means a reaction that is noxious and unintended and that occurs in a human being following exposure to a veterinary medicine;

“serious adverse reaction” means an adverse reaction that results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly or birth defect, or that results in permanent or prolonged signs in the animals treated.

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

### **Adverse reactions to a veterinary medicinal product administered in a third country**

**58**

(1) A marketing authorisation holder for a veterinary medicinal product authorised in the United Kingdom must act in accordance with this paragraph if he learns of any suspected—

- (a) serious, unexpected adverse reaction (for these purposes a reaction is unexpected if its nature, severity or outcome is not consistent with the summary of the product characteristics);
- (b) human adverse reaction; or
- (c) unintended transmission of an infectious agent through a veterinary medicinal product,

following the administration of the product in a third country.

(2) He must make a record of what happened.

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(23) A list of clinical terms for reporting suspected adverse reactions to veterinary medicinal products (the Veterinary Dictionary for Drug Regulatory Activities) is published by the Committee for Medicinal Products for Veterinary Use. It is available at [www.veddra.org](http://www.veddra.org).

(3) He must without delay and in any event within 15 days report the suspected reaction or transmission (electronically if this is practicable) to the Secretary of State, the competent authorities of all member States in which the product is authorised, and the Agency.

(4) In addition to the report, he must supply to the Secretary of State, the competent authorities of all other member States where the product is authorised and the Agency, all relevant veterinary pharmacovigilance information in his possession relating to the reaction as in the preceding paragraph.

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

### **Periodic safety update reports**

**59.**—(1) The marketing authorisation holder must submit to the Secretary of State records of all adverse reactions (including nil reports) in the form of a periodic safety update report for each marketing authorisation in accordance with this paragraph, including a summary of each incident and a list of all the symptoms using internationally recognised veterinary and medical terminology.

(2) If the marketing authorisation holder has not yet placed a product on the market in the United Kingdom, he must submit a periodic safety update report immediately upon request of the Secretary of State and at least every six months after authorisation.

(3) Following the placing on the market in the United Kingdom, the marketing authorisation holder must submit a periodic safety update report to the Secretary of State immediately upon request and—

- (a) at least every six months during the first two years following the initial placing on the market;
- (b) once a year for the following two years; and
- (c) thereafter, at three-yearly intervals.

(4) Following the granting of a marketing authorisation, the marketing authorisation holder may apply to the Secretary of State to change the periods of notification.

(5) The periodic safety update report must include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product.

(6) The periodic safety update report must include—

- (a) the volume of the product sold in each year covered by the report, calculated on an annual basis beginning 1st January;
- (b) the number of adverse reactions for each year of the report;
- (c) the ratio of adverse reactions to volume of product sold together with an explanation of the basis of the calculation;
- (d) differentiation of data based on—
  - (i) target species (if the product is authorised for use in more than one species);
  - (ii) reaction type (such as serious, non-serious, human, suspected lack of efficacy, unauthorised use or other);
  - (iii) the country of origin of the report.

(7) If the product is indicated for more than one species, the information in sub-paragraph (6)(c) must be based so far as is practicable on the estimated use of the product.

(8) Data relating to different formulations (either different dosage forms or different strengths) must be provided in separate reports.

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

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### **Release of information by the marketing authorisation holder**

**60.**—(1) A marketing authorisation holder must not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised veterinary medicinal product without giving prior or simultaneous notification to the Secretary of State.

(2) The marketing authorisation holder must ensure that such information is presented objectively and is not misleading.

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

### **Action taken on account of pharmacovigilance**

**61.**—(1) Where, as a result of the evaluation of veterinary pharmacovigilance data, the Secretary of State considers that a marketing authorisation should be—

- (a) suspended;
- (b) revoked; or
- (c) varied so as to—
  - (i) restrict the indications;
  - (ii) change the distribution category;
  - (iii) amend the dose;
  - (iv) add a contraindication; or
  - (v) add a new precautionary measure,

he must forthwith inform the Agency, all other member States (irrespective of whether the product is authorised in another member State) and the marketing authorisation holder.

(2) If urgent action is necessary for protecting human or animal health, the Secretary of State may suspend the marketing authorisation of a veterinary medicinal product, but he must inform the Agency, the Commission and the other member States within one working day.

(3) If, following the opinion of the Agency, the Commission requests the Secretary of State to suspend, withdraw or vary the marketing authorisation, the Secretary of State must comply with that request immediately on a temporary basis.

(4) The Secretary of State must take final measures in accordance with the Decision of the Commission.

## **PART 9**

### **Homeopathic remedies**

#### **Meaning of “homeopathic remedy”**

**62.** For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia<sup>(24)</sup> or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission or by the competent authority of any member State.

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(24) ISBN 9287145873.



### **Placing a homeopathic remedy on the market in accordance with a registration**

**63.**—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation if it complies with this paragraph.

(2) It must not be an immunological product.

(3) The route of administration must be as described in the European Pharmacopoeia or, if it is not described there, by a pharmacopoeia currently used officially in any member State.

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

### **Application for registration**

**64.**—(1) An applicant for registration must submit the following to the Secretary of State—

- (a) the scientific name or other name of the homeopathic stock given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;
- (b) a dossier describing how the homeopathic stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate bibliography;
- (c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;
- (d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation;
- (e) a copy of the manufacturing authorisation for the product;
- (f) copies of any registrations or authorisations obtained for the same homeopathic remedy in other member States;
- (g) a mock-up of the outer packaging and immediate packaging;
- (h) stability data;
- (i) the proposed withdrawal period necessary to ensure that the provisions of Council Regulation (EEC) No. 2377/90 are complied with together with all necessary justification.

(2) These documents must demonstrate the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one that appears in Annex II to Regulation (EEC) No. 2377/90 and complies with any requirements in that Annex relating to that substance.

(4) If a product is registered in another member State, the Secretary of State may waive some or all of the requirements of this paragraph if he is satisfied that it is reasonable to do so.

### **Procedure for registration**

**65.**—(1) The procedure for registration is the same as the procedure for granting a marketing authorisation in accordance with Part 3, except—

- (a) the applicant is not required to provide proof of efficacy;
- (b) the product is not required to have a summary of product characteristics;

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(c) the Secretary of State is not required to publish an assessment report.

(2) The procedure for variation, suspension and revocation is the same as for a marketing authorisation.

#### **Products on the market before 1994**

**66.** A homeopathic remedy that was on the market before 1st January 1994 may be placed on the market without being registered.

#### **Classification**

**67.** The registration must specify the classification of the homeopathic remedy, which must be one of the classifications specified for a veterinary medicinal product in Schedule 3.

## SCHEDULE 2

Regulation 5(2)

### The manufacture of veterinary medicinal products

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## PART 1

### Manufacturing authorisations

#### **Application**

1. An application for a manufacturing authorisation must be made to the Secretary of State.

#### **Time limits**

2.—(1) The Secretary of State must process an application for a manufacturing authorisation within 90 days of receiving it.

(2) He must process an application for a variation of a manufacturing authorisation within 30 days unless he notifies the applicant in writing that he is extending the time to 90 days.

#### **Granting the authorisation**

3. The Secretary of State must grant a manufacturing authorisation if he is satisfied that the applicant has at his disposal suitable and sufficient premises, staff, technical equipment and facilities for the manufacture, control and storage of the products, and will comply with his duties under these Regulations.

#### **The authorisation**

- 4.—(1) The manufacturing authorisation must specify—
  - (a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured or imported;
  - (b) the place where they are to be manufactured or controlled;
  - (c) the name and address of the person holding the authorisation;
  - (d) the address of the premises to which it relates;

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(e) the name of the qualified person nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

### **Suspension or revocation of the authorisation**

5.—(1) The Secretary of State may suspend or revoke a manufacturing authorisation if the holder—

- (a) has not complied with these Regulations;
- (b) has manufactured a veterinary medicinal product not authorised by his manufacturing or authorisation;
- (c) has produced a veterinary medicinal product outside the terms of a marketing authorisation;
- (d) no longer has suitable premises or equipment.

(2) He may also suspend or revoke it if he is satisfied that the qualified person (manufacturer) is not fulfilling his duties.

### **Appeal to an appointed person**

6.—(1) A person may appeal against a refusal, suspension or revocation of a manufacturing 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 decision and the reasons for it.

### **Inspection of premises**

7.—(1) The Secretary of State must inspect the premises relating to a manufacturing authorisation on a regular basis to ensure compliance with good manufacturing practice.

(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection established that he is complying with the principles and guidelines on good manufacturing practice in accordance with Commission Directive [91/412/EEC](#) laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products<sup>(25)</sup>.

(3) If an inspection is carried out at the request of the European Pharmacopoeia to establish compliance with a monograph, the Secretary of State must issue a certificate of compliance with the monograph, if appropriate.

(4) The Secretary of State must provide details of each certificate of good manufacturing practice that he issues to the Agency for entry into a database.

(5) If the outcome of the inspection is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice, he must provide details to the Agency for entry into the database.

### **Report following inspection**

8.—(1) After each inspection of manufacturing premises, the inspector must make a written report to the Secretary of State on whether the principles and guidelines on good manufacturing practice and the conditions of these Regulations are being complied with.

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(25) OJ No. L 228, 17.8.91, p. 70.

- (2) The Secretary of State must inform the inspected manufacturer of the content of such reports.

#### **Duties on the holder of a manufacturing authorisation**

**9.—(1)** A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

(2) He must have permanently at his disposal the services of at least one qualified person (manufacture) who is on the register of qualified persons (manufacture) maintained by the Secretary of State.

(3) He must hold a current Certificate of Good Manufacturing Practice.

(4) He must have in place a system of Quality Assurance and Quality Control.

(5) He must give to the Secretary of State on request proof of all control tests carried out on the veterinary medicinal product or the constituents and intermediate products of the manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(6) If he makes up a bulk package of veterinary medicinal products he must ensure that the package is labelled, in a way that the label is clearly visible and legible, with—

- (a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;
- (b) the batch number;
- (c) the expiry date;
- (d) any storage requirements; and
- (e) any other warning necessary for the safe handling of the package.

(7) He must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if he requires it in writing.

#### **Qualified persons for manufacture**

**10.—(1)** The Secretary of State may appoint as a qualified person (manufacture) any person who is—

- (a) registered as a pharmaceutical chemist with the Royal Pharmaceutical Society of Great Britain or with the Pharmaceutical Society of Northern Ireland;
- (b) a Chartered Chemist or a Fellow, Member or Associate Member of the Royal Society of Chemistry; or
- (c) a Chartered Biologist or a Fellow, Member or Associate Member of the Institute of Biology,

who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent and who has sufficient practical experience to carry out the duties under this Schedule.

(2) The Secretary of State may exceptionally appoint a person who is not a member of one of those institutions to act as a qualified person (manufacture) if he is satisfied that he has the educational qualifications or practical experience to carry out the duties under this Schedule.

#### **Refusal or revocation of appointment**

**11.—(1)** The Secretary of State may refuse or revoke an appointment if he is not satisfied that a person has fulfilled or will fulfil his duties.

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(2) A person may appeal against a refusal or revocation to a person appointed for the purpose by the Secretary of State, and the procedure in paragraph 6 applies.

### **Duties on a qualified person**

**12.**—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under his responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from a third country, including a product manufactured in a member State, the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested in a member State, including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) The preceding paragraph does not apply where appropriate arrangements have been made by the European Community with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive [91/412/EEC](#) and to ensure that the controls in subparagraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

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

### **Register**

**13.** The Secretary of State must maintain and publish a register of holders of manufacturing authorisations and qualified persons (manufacture).

### **Test sites**

**14.**—(1) The Secretary of State may authorise premises to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The premises must have a current certificate of good manufacturing practice.

(3) Authorisation and inspection of the premises are the same as for a manufacturing authorisation.

## **PART 2**

### **Authorisation of manufacturers of autogenous vaccines**

#### **Authorisation to manufacture autogenous vaccines**

**15.**—(1) The Secretary of State may authorise a person and premises to manufacture autogenous vaccines.

(2) In order to be authorised the premises must be under the supervision of—

(a) a veterinary surgeon, or

- (b) a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.
- (3) Before he authorises the premises, the Secretary of State must be satisfied that the production process will produce a consistent, safe product.
- (4) Procedure for the suspension or revocation of the authorisation is the same as for the holder of a manufacturing authorisation.
- (5) It is an offence to manufacture an autogenous vaccine other than in accordance with such an authorisation.

### **Types of authorisation**

- 16.**—(1) The authorisation must specify the products that may be manufactured.
- (2) It may either be for the production of a single batch of product or for on-going production of the products specified in the authorisation.
- (3) If it is for a single batch it must be time-limited.
- (4) Only the products specified in the authorisation may be manufactured, and in the case of an authorisation for a single batch the product may only be manufactured before the expiry of the authorisation.

### **Labelling**

- 17.**—(1) The operator of the premises must ensure that every container containing autogenous vaccine is labelled with—
  - (a) the name of the veterinary surgeon who ordered the vaccine;
  - (b) a precise description of the vaccine;
  - (c) the date the vaccine was produced;
  - (d) the name of the authorisation holder and address of the authorised premises;
  - (e) the expiry date;
  - (f) any necessary warnings; and
  - (g) instructions for use.
- (2) It is an offence to fail to comply with this paragraph.

### **Records**

- 18.**—(1) The operator of the premises must, as soon as is reasonably practicable, record—
  - (a) the name and address of the veterinary surgeon who ordered the vaccine;
  - (b) the identification of the source animal;
  - (c) the expiry date;
  - (d) the date of supply to the veterinary surgeon.
- (2) He must keep the records for at least five years.
- (3) It is an offence to fail to comply with this paragraph.

### **Adverse reactions**

- 19.**—(1) The authorised person must notify the Secretary of State of any adverse reactions to an autogenous vaccine within 15 days of learning of the reaction.

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

### **Inspection of premises**

20. The Secretary of State must inspect the authorised premises every two years.

## **PART 3**

### **Authorisation of blood banks**

#### **Authorisation of blood banks**

21.—(1) The Secretary of State may authorise blood banks for the collection, storage and supply of blood for the treatment of non-food-producing animals.

- (2) In order to be authorised a blood bank must be under the supervision of—

- (a) a veterinary surgeon named in the authorisation; or
- (b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the blood bank.

- (3) Before he authorises a blood bank, the Secretary of State must be satisfied—

- (a) that the welfare of animals used in the collection of blood will be respected; and
- (b) that the production process will produce a consistent, safe product.

(4) The procedure for the suspension or revocation of the authorisation is the same as for the holder of a manufacturing authorisation.

- (5) Blood may only be collected under the responsibility of a veterinary surgeon.

(6) It is an offence to operate a blood bank for treatment of animals other than in accordance with such an authorisation.

#### **Supply and administration of blood from a blood bank**

22.—(1) The blood may only be supplied to a veterinary surgeon.

- (2) It may only be administered by a veterinary surgeon or under his responsibility.

(3) It may only be administered to non-food-producing animals.

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

#### **Labelling**

23.—(1) The operator of a blood bank must ensure that every container used for the blood is labelled with—

- (a) the identification of the donor animal;
- (b) the date of collection;
- (c) the authorisation number of the blood bank;
- (d) any necessary warnings;
- (e) the expiry date.

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



## **Records**

- 24.**—(1) The operator of a blood bank must, as soon as is reasonably practicable, record—
- (a) the date of collection;
  - (b) the identification of the donor animal;
  - (c) the veterinary surgeon who collected it;
  - (d) the expiry date;
  - (e) the date the blood was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied.
- (2) He must keep the records for at least five years.
- (3) It is an offence to fail to comply with this paragraph.

## **Inspection of blood banks**

- 25.** The Secretary of State must inspect a blood bank every two years.

# **PART 4**

## **Authorisation of manufacturers of products for administration under the cascade**

### **Authorisation to manufacture products for administration under the cascade**

**26.**—(1) The Secretary of State may authorise a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade.

(2) In order to be authorised the premises must be under the supervision of a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before he authorises the premises, the Secretary of State must be satisfied that the production process will produce a safe product.

(4) The procedure for the suspension or revocation of the authorisation is the same as for the holder of a manufacturing authorisation.

(5) The authorisation must specify what types of product it covers.

(6) It is an offence for the holder of an authorisation to manufacture a product other than in accordance with the authorisation.

## **Labelling**

**27.**—(1) The authorised person must ensure that, before a veterinary medicinal product is supplied, every container is labelled with—

- (a) the name of the veterinary surgeon who ordered the veterinary medicinal product;
- (b) a precise description of the veterinary medicinal product;
- (c) the date of production;
- (d) the name of the authorisation holder and the address of the authorised premises;
- (e) the expiry date;
- (f) any necessary warnings; and
- (g) instructions for use.

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

### **Records**

- 28.**—(1) The authorised person must, as soon as is reasonably practicable, record—
- (a) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;
  - (b) a precise description of the veterinary medicinal product;
  - (c) the date of production;
  - (d) the expiry date; and
  - (e) the date of supply to the veterinary surgeon.
- (2) He must keep the records for at least five years.
- (3) It is an offence to fail to comply with this paragraph.

### **Adverse reactions**

- 29.**—(1) The authorised person must notify the Secretary of State of any adverse reactions to a product manufactured by him within 15 days of learning of the reaction.
- (2) It is an offence to fail to comply with this paragraph.

### **Inspection of premises**

- 30.** The Secretary of State must inspect the authorised premises every two years.

## SCHEDULE 3

Regulation 7

Classification and supply, wholesale dealers and sheep dip

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## 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—

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- (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

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- (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<sup>(26)</sup> 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 contraindications 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.

<sup>(26)</sup> S. I. 2001/3998; relevant amending instruments are S. I. 2003/1432 and 2005/1653.

### **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 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).

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(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.

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### **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<sup>(27)</sup> 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.

(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—

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(27) OJ No. C 63, 1.3.94, p. 4.

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- (a) a double sided laminated notice meeting the specifications in the following subparagraph (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.

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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.

## SCHEDULE 4

Regulation 8

Administration of a veterinary medicinal product outside the terms of a marketing authorisation

## CONTENTS

- 1. Administration under the cascade
  - 2. Withdrawal periods
  - 3. Administration to food-producing horses
  - 4. Immunological products for serious epizootic disease
  - 5. Immunological products for an imported or exported animal
  - 6. Administration by veterinary surgeons from other member States
  - 7. Treatment in exceptional circumstances
  - 8. Administration of a homeopathic remedy
  - 9. Administration under an animal test certificate
- Signature  
Explanatory Note

### Administration under the cascade

1.—(1) A veterinary surgeon acting under this paragraph may either administer a veterinary medicinal product prescribed by him personally or may direct another person to do so under his responsibility.

(2) If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following (“the cascade”), cascaded in the following order—

- (a) a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or
- (b) if and only if there is no such product that is suitable, either—
  - (i) a human medicinal product authorised in the United Kingdom; or
  - (ii) a veterinary medicinal product not authorised in the United Kingdom but authorised in another member State for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or

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(c) if and only if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(3) In the case of a veterinary medicinal product imported from another member State, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting him to import it, he must obtain a certificate from the Secretary of State before he administers it.

(4) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the cascade must be listed in Annex I, II or III to Council Regulation (EEC) No. 2377/90.

### **Withdrawal periods**

2.—(1) A veterinary surgeon prescribing or administering a veterinary medicinal product to a food-producing animal under the cascade must specify an appropriate withdrawal period.

(2) The withdrawal period must ensure that, if there is a maximum residue limit specified for the active substance in Council Regulation (EEC) No. 2377/90, the level of residue of the active substance does not exceed that limit.

(3) In any event, unless the Secretary of State has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period (irrespective of whether or not a maximum residue limit is specified in Council Regulation (EEC) No. 2377/90) must not be less than—

- (a) 7 days for eggs;
- (b) 7 days for milk;
- (c) 28 days for meat from poultry and mammals including fat and offal;
- (d) 500 degree days<sup>(28)</sup> for fish meat.

(4) In the case of a homeopathic remedy in which active principles figure in Annex II to Council Regulation (EEC) No. 2377/90, the withdrawal period is zero.

### **Administration to food-producing horses**

3.—(1) If there is no authorised veterinary medicinal product for a food-producing horse (as shown on its horse passport) and treatment under the cascade is unsuitable, substances may be administered in accordance with Commission Regulation (EC) No 1950/2006 (establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae<sup>(29)</sup>).

(2) The person administering the substance must comply with Article 3(2) of Commission Regulation (EC) No 1950/2006 (recording the details of the treatment in the animal's passport) and failure to do so is an offence.

### **Immunological products for serious epizootic disease**

4.—(1) In the event of serious epizootic diseases, the Secretary of State may permit in writing the administration of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

<sup>(28)</sup> The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.

<sup>(29)</sup> OJ No. L367, 22.12.2006, p. 33.



- (2) He may publicise any permit as he sees fit.

### **Immunological products for an imported or exported animal**

5. If an animal is imported from, or exported to, a third country, the Secretary of State may permit the administration to that animal of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the United Kingdom but is authorised under the legislation of the third country.

### **Administration by veterinary surgeons from other member States**

6.—(1) Veterinary surgeons practising in another member State may bring into the United Kingdom and administer to animals small quantities of veterinary medicinal products that are not authorised for use in the United Kingdom if—

- (a) the quantity does not exceed the requirements for the treatment of specific animals;
- (b) the product is authorised in the member State in which the veterinary surgeon is established;
- (c) the product is transported by the veterinary surgeon in the original manufacturer's packaging;
- (d) in the case of administration to food-producing animals, there is a veterinary medicinal product authorised in the United Kingdom that has the same qualitative and quantitative composition in terms of active substances;
- (e) the veterinary surgeon has acquainted himself with the Guide to Professional Conduct issued by the Royal College of Veterinary Surgeons<sup>(30)</sup>.

(2) The veterinary surgeon must only supply to the owner or keeper enough veterinary medicinal product to complete the treatment of animals concerned.

(3) He must—

- (a) ensure that the withdrawal period specified on the label of the product is complied with, or the United Kingdom withdrawal period for the equivalent product authorised in the United Kingdom if this is longer than the one on the label; and
- (b) keep detailed records of the animals treated, the diagnosis or clinical assessment, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied, and must keep them in the United Kingdom for at least three years,

and failure to comply with this sub-paragraph is an offence.

(4) The overall range and quantity of veterinary medicinal products carried by the veterinary surgeon must not exceed that generally required for the daily needs of good veterinary practice.

(5) This paragraph does not apply in relation to immunological veterinary medicinal products.

### **Treatment in exceptional circumstances**

7.—(1) Where the health situation so requires, and where there is no suitable veterinary medicinal product available either as an authorised product or under the cascade, a veterinary surgeon may treat an animal with a medicinal product authorised in a third country; but if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting him to import it, he must obtain a certificate from the Secretary of State before he treats the animal.

(2) The certificate may be granted subject to any condition the Secretary of State thinks fit.

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(30) Published at [www.rcvs.org.uk/PrintFullArticle.asp?NodeID=89642](http://www.rcvs.org.uk/PrintFullArticle.asp?NodeID=89642).

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### **Administration of a homeopathic remedy**

8.—(1) A registered homeopathic remedy or a homeopathic remedy prepared and supplied by a pharmacist under paragraph 10 of Schedule 3 may be administered to an animal by anyone, subject to any restrictions specified in its registration.

(2) A homeopathic remedy that was on the market before 1st January 1994 may be administered by anyone.

(3) A veterinary surgeon may administer, either himself or under his responsibility—

- (a) a homeopathic remedy authorised for human use, or
- (b) a homeopathic remedy prepared extemporaneously by a veterinary surgeon, a pharmacist or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

### **Administration under an animal test certificate**

9.—(1) A medicinal product may be administered in accordance with an animal test certificate granted for research purposes by the Secretary of State.

(2) An application for an animal test certificate may be refused if this is necessary for the protection of animal or public health or the environment, and the animal test certificate may be varied, suspended or revoked in the same way as a marketing authorisation.

(3) The holder of an animal test certificate is guilty of an offence if he supplies a product for administration that is not within the terms of the animal test certificate.

## SCHEDULE 5

Regulation 14

### Medicated feedingstuffs and specified feed additives

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3. Enforcement of Regulation [\(EC\) No. 1831/2003](#)
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- Signature  
Explanatory Note

### **Scope and interpretation**

1.—(1) This Schedule applies in relation to the following (referred to in this Schedule as “specified feed additives”) when used as feed additives—

- (a) coccidiostats;
- (b) histomonostats; and
- (c) all other zootechnical additives except—
  - (i) digestibility enhancers;
  - (ii) gut flora stabilisers; and
  - (iii) substances incorporated with the intention of favourably affecting the environment.

(2) It also applies in relation to the manufacture and placing on the market of feedingstuffs containing a veterinary medicinal product.

(3) In this Schedule—

“premixture” means a mixture of a veterinary medicinal product or a specified feed additive with feedingstuffs materials, intended for further mixing with feedingstuffs before being fed to animals;

“zootechnical additive” means any additive used to maintain animals in good health or favourably affect their performance.

### **Enforcement of Regulation (EC) No. 178/2002**

2.—(1) For the purposes of Regulation (EC) No. 178/2002 (of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(31)</sup>) the competent authority is the Secretary of State.

(2) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

- (a) Article 11 (requirements relating to imports);
- (b) Article 12 (requirements relating to exports);
- (c) Article 15 (1) (prohibition on the placing on the market or feeding unsafe feedingstuffs);
- (d) Article 16 so far as it prohibits misleading labelling, advertising or presentation of feedingstuffs;

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(31) OJ No. L 31, 1.2.2002, p. 1.

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- (e) Article 18 (2) and (3) (requirements of traceability) in so far as it relates to feed business operators; and
- (f) Article 20 (responsibilities of feed business operators).

#### **Enforcement of Regulation (EC) No. 1831/2003**

**3.**—(1) For the purposes of Regulation (EC) No. 1831/2003 (of the European Parliament and the Council on additives for use in animal nutrition<sup>(32)</sup>) the competent authority is the Secretary of State.

(2) When he grants an authorisation under Article 3(2) of that Regulation, the authorisation must be in writing.

(3) It is an offence to be in possession of a specified feed additive, or a premixture or feedingstuffs containing a specified feed additive, unless the specified feed additive has been authorised under Regulation (EC) No. 1831/2003 or is for export to a third country.

(4) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

- (a) Article 3(1) or Article 3(3) (the authorisation, conditions of use and labelling of specified feed additives);
- (b) Article 12(1) or (2) (conditions relating to specified feed additives);
- (c) Article 16(1) (labelling);
- (d) Article 16(3) (additional labelling requirement);
- (e) Article 16(4) (premixtures containing specified feed additives);
- (f) Article 16(5) (packaging).

#### **Enforcement of Regulation (EC) No. 882/2004**

**4.** For the purposes of Regulation (EC) No. 882/2004 (of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules<sup>(33)</sup>) the competent authority is the Secretary of State.

#### **Enforcement of Regulation (EC) No. 1831/2005**

**5.**—(1) For the purposes of Regulation (EC) No. 1831/2005 (of the European Parliament and of the Council laying down requirements for feed hygiene<sup>(34)</sup>) the competent authority is the Secretary of State.

(2) Any person who contravenes any of the following provisions of that Regulation is guilty of an offence—

- (a) Article 5(2), (5) or (6) (specific obligations);
- (b) Article 6(1) as read with (2) and (3) (HACCP system);
- (c) Article 7(1) (documents concerning the HACCP system);
- (d) Article 9(2) (official controls, notification and registration);
- (e) Article 11 (prohibition on operating without approval or registration);
- (f) Article 17(2) (exemption from on-site visits);
- (g) Article 18(3) (declaration of compliance);
- (h) Article 23(1) (conditions relating to imports from third countries);

<sup>(32)</sup> OJ No. L268, 18.10.2003, p. 29.

<sup>(33)</sup> Corrected version at OJ No. L191, 28.5.2004, p. 1.

<sup>(34)</sup> OJ No. L35, 8.2.2005, p. 1.

- (i) Article 25 (feedingstuffs produced for export to third countries).
- (3) A manufacturer must ensure that, so far as is reasonably practicable, the active ingredient is evenly incorporated throughout the feedingstuffs and failure to do so is an offence.
- (4) In the case of the refusal, suspension or revocation of an approval under the Regulation the appeals procedure relating to a manufacturing authorisation in paragraph 6 of Schedule 2 applies.

#### **Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products**

6.—(1) It is an offence to incorporate a veterinary medicinal product into a premixture or feedingstuffs, or to act as a distributor of premixtures or feedingstuffs containing a veterinary medicinal product, without being approved to do so by the Secretary of State.

(2) The requirements of this paragraph do not apply in relation to a person who incorporates a veterinary medicinal product into feedingstuffs in domestic premises for feeding, on those premises—

- (a) non-food-producing animals, or
- (b) food-producing animals kept purely for domestic consumption.

(3) The provisions of Regulation (EC) No. 183/2005 apply to those producers and distributors in the same way as to persons approved under Article 9 of that Regulation.

(4) A manufacturer must ensure that, so far as is reasonably practicable, the veterinary medicinal product is evenly incorporated throughout the feedingstuffs and failure to do so is an offence.

(5) In the case of the refusal, suspension or revocation of an approval under this paragraph the appeals procedure relating to a manufacturing authorisation in paragraph 6 of Schedule 2 applies.

#### **Incorporation of a veterinary medicinal product into a premixture**

7.—(1) Any person who incorporates a veterinary medicinal product into a premixture—

- (a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there; and
- (b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive.

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

#### **Incorporation of a veterinary medicinal product into feedingstuffs**

8.—(1) Any person who incorporates a veterinary medicinal product (or a premixture containing a veterinary medicinal product) into feedingstuffs—

- (a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there;
- (b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive;
- (c) must ensure that the veterinary medicinal product is incorporated in accordance with its marketing authorisation (unless it has been prescribed under the cascade) and the prescription;
- (d) must ensure that the daily dose of the veterinary medicinal product is contained in a quantity of medicated feedingstuffs corresponding to at least half the daily feedingstuffs ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral supplementary feedingstuffs.

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

### **Additional record keeping requirements relating to veterinary medicinal products**

9.—(1) Any person who—

- (a) incorporates a veterinary medicinal product into a premixture;
- (b) incorporates a premixture containing a veterinary medicinal product into feedingstuffs; or
- (c) incorporates a veterinary medicinal product into feedingstuffs,

must make a daily record of—

- (i) the types and quantities of all veterinary medicinal products (and specified feed additives, if any) and premixture used in the manufacturing process; and
- (ii) the quantity of feedingstuffs and premixture containing veterinary medicinal product manufactured that day.

(2) An approved distributor must make a daily record of—

- (a) the types and quantities of all premixtures and feedingstuffs containing veterinary medicinal products bought and sold that day;
- (b) the quantity held.

(3) A manufacturer and distributor must also record, as soon as reasonably practicable, for each consignment supplied—

- (a) the date of delivery;
- (b) the name and address of each consignee (or, in the case of a manufacturer supplying to a distributor, the name and address of the distributor);
- (c) the type of feedingstuffs or premixture supplied;
- (d) the quantity;
- (e) the type of veterinary medicinal product incorporated into the feedingstuffs; and
- (f) the expiry date.

(4) Records must be kept for five years.

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

### **Labelling a premixture containing a veterinary medicinal product**

10.—(1) A premixture containing a veterinary medicinal product must be clearly and legibly labelled with the following—

- (a) the words “MEDICATED PREMIXTURE” in upper case letters;
- (b) the proprietary name of the veterinary medicinal product and the authorisation number;
- (c) the name and amount of the active substance (mg/kg) in the premixture;
- (d) the range of acceptable inclusion rates of the premixture into the final feedingstuffs, the range of acceptable levels of the active ingredients in the final feedingstuffs and the words “refer to the prescription for the exact inclusion rate” or equivalent wording;
- (e) warnings and contra-indications;
- (f) the withdrawal period;
- (g) the expiry date;
- (h) any special storage instructions;
- (i) where a prescription is required, a statement to this effect.

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(2) The withdrawal period must be that specified in the marketing authorisation for the veterinary medicinal product, and if there is more than one veterinary medicinal product used it must be the longest.

(3) If the premixture also contains a specified feed additive to which this Schedule applies it must also contain the information required under Article 16 of Regulation (EC) No. 1831/2003.

(4) It is an offence to supply such a premixture not labelled in accordance with this paragraph.

### **Labelling of feedingstuffs containing a specified feed additive**

**11.**—(1) Feedingstuffs containing a specified feed additive must be clearly and legibly labelled with the following—

- (a) the name of the specified feed additive;
- (b) the name and amount of the active substance (mg/kg) in the feedingstuffs;
- (c) the withdrawal period if one is specified in the authorisation;
- (d) the expiry date;
- (e) the name and approval number of the manufacturer or the distributor;
- (f) any particulars concerning the proper use of the feedingstuffs specified in the authorisation of the specified feed additive.

(2) It is an offence to supply such feedingstuffs not labelled in accordance with this paragraph.

### **Labelling of feedingstuffs containing a veterinary medicinal product**

**12.**—(1) Feedingstuffs containing a veterinary medicinal product must be clearly and legibly labelled with the following—

- (a) the words “MEDICATED FEEDINGSTUFFS” in upper case letters;
- (b) the proprietary name, authorisation number and inclusion rate (kg/tonne or mg/kg) of the veterinary medicinal product incorporated into the feedingstuffs;
- (c) the name and amount of the active substance (mg/kg) in the feedingstuffs;
- (d) the species of animal for which the feedingstuffs are intended;
- (e) warnings and contra-indications;
- (f) the withdrawal period;
- (g) the expiry date;
- (h) any special storage instructions required by the marketing authorisation;
- (i) a statement to the effect that the feedingstuffs must only be fed in accordance with the prescription;
- (j) the name and approval number of the manufacturer or the distributor.

(2) The withdrawal period must be that specified in the marketing authorisation for the veterinary medicinal product.

(3) If there is more than one veterinary medicinal product used—

- (a) if there is a prescription at the time of labelling, it must be the period specified in the prescription or, if none is specified, the longest withdrawal period;
- (b) if there is no prescription at the time of labelling it must be the longest withdrawal period but the label must also state “If the prescription specifies a longer withdrawal period this must be applied”.

(4) It is an offence to supply feedingstuffs not labelled in accordance with this paragraph.

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### **Supply of specified feed additives**

**13.**—(1) It is an offence for any person other than the person who manufactured a specified feed additive or an approved distributor to supply a specified feed additive.

- (2) The person who manufactured the specified feed additive may only supply it to—
- (a) an approved distributor;
  - (b) an approved premixture manufacturer; or
  - (c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.
- (3) An approved distributor may only supply it to—
- (a) another approved distributor;
  - (b) an approved premixture manufacturer; or
  - (c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.

(4) It is an offence for a manufacturer or distributor to supply a specified feed additive to anyone not specified in this paragraph.

### **Supply of premixture**

**14.**—(1) It is an offence for any person other than the person who manufactured a premixture or an approved distributor to supply a premixture.

- (2) The person who manufactured the premixture may only supply it to—
- (a) an approved distributor; or
  - (b) a feedingstuff manufacturer approved to incorporate that premixture.
- (3) An approved distributor may only supply it to—
- (a) another approved distributor, or
  - (b) a feedingstuff manufacturer approved to incorporate that premixture.

(4) It is an offence for a manufacturer or distributor to supply a premixture to anyone not specified in this paragraph.

### **Supply of feedingstuffs containing a veterinary medicinal product**

**15.**—(1) It is an offence for any person other than the person who manufactured the feedingstuffs or an approved distributor to supply feedingstuffs containing a veterinary medicinal product.

- (2) The person who manufactured the feedingstuff may only supply it to—
- (a) an approved distributor, or
  - (b) a person who keeps animals for feeding to those animals.
- (3) A distributor may only supply it to—
- (a) another approved distributor, or
  - (b) a person who keeps animals for feeding to those animals.

(4) Supply to a person who keeps animals must be in accordance with a written prescription as specified in the following paragraph.

(5) If a prescription is for a period of longer than one month, the supplier may not provide more than one month's supply at any one time.



(6) It is an offence for a manufacturer or distributor to supply a feedingstuff to anyone not specified in this paragraph, or otherwise than in accordance with this paragraph.

(7) The person supplying the feedingstuff must keep the prescription for five years, and failure to do so is an offence.

### **Prescriptions for feedingstuffs containing a veterinary medicinal product**

**16.**—(1) A prescription for feedingstuffs containing a veterinary medicinal product must contain the following—

- (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 keeper of the animals to be treated;
  - (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 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;
  - (l) the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose);
  - (m) if the validity exceeds one month, a statement that not more than 31 days supply may be provided at any time;
  - (n) the name, type and quantity of feedingstuffs to be used;
  - (o) the inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance;
  - (p) any special instructions; and
  - (q) the percentage of the prescribed feedingstuffs to be added to the daily ration.
- (2) It is valid for three months or such shorter period as may be specified in the prescription.
- (3) It must be sufficient for only one course of treatment.

### **Writing the prescription**

**17.**—(1) The person who writes the prescription must—

- (a) give a copy to the person incorporating the veterinary medicinal product into the feedingstuffs or to the distributor of the feedingstuffs;
  - (b) give one copy to the keeper of the animals to be treated;
  - (c) keep a copy himself.
- (2) He must be satisfied that—
- (a) there is no undesirable interaction between the veterinary medicinal product and any feed additive used in the feedingstuffs; and
  - (b) the active substance of the veterinary medicinal product is not the same as an active substance in any feed additive used in the feedingstuffs.

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(3) For the avoidance of doubt, a veterinary surgeon may prescribe either a veterinary medicinal product authorised for that species and condition, or under the cascade.

(4) The requirement for a written prescription does not apply in relation to a veterinary medicinal product supplied to a person specified in paragraph 6(2) for incorporation into feedingstuffs in their premises, but in this case paragraph 5 of Schedule 3 applies in relation to the supply of the veterinary medicinal product.

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

### Possession

**18.**—(1) It is an offence for any person other than a person holding the appropriate approval under this Schedule to be in possession of any—

- (a) specified feed additive or veterinary medicinal product to which this Schedule applies;
- (b) premixtures containing such an additive or a veterinary medicinal product; or
- (c) feedingstuffs containing such an additive or a veterinary medicinal product unless supplied under these Regulations.

(2) It is an offence for any person other than a manufacturer or distributor to be in possession of feedingstuffs incorporating a veterinary medicinal product unless it has been supplied under a prescription.

### Sampling and analysis

**19.**—(1) If any enforcement action is taken under this Schedule based on a sample, that sample must have been taken and analysed in accordance with Council Directive [76/371/EEC](#) (establishing Community methods of sampling for the official control of feedingstuffs(**35**)).

(2) Unless otherwise specified in the marketing authorisation, it is a defence if the active ingredient in the sample is within the following tolerances—

#### Tolerance table

<i>Level of active ingredient specified on the label</i>	<i>Tolerance</i> £
≤50 mg/kg	±50%
>50 mg/kg £ ≤500 mg/kg	±40%
>500 mg/kg ≤5g/kg	±30%
>5g/kg ≤50g/kg	±20%
>50g/kg	±10%

### Storage

**20.** It is an offence to store a veterinary medicinal product intended for incorporation into feedingstuffs, or a premixture or feedingstuffs containing a veterinary medicinal product, except in—

- (a) a suitable storage area that is locked when not in use, or
- (b) a hermetic container designed to store those products.

(35) OJ No. L102, 15.4.76, p. 1.

### **Packages and other containers**

**21.** It is an offence to place on the market feedingstuffs containing a veterinary medicinal product except in packages or containers that are sealed in such a way that, when the package or container is opened, the seal is damaged.

### **Transport**

**22.—(1)** In the case of feedingstuffs distributed by road tankers or in bulk the labelling requirements must be given in a document accompanying the feedingstuffs, and the transporter must hand over details when he delivers the feedingstuffs unless these have already been provided to the purchaser.

(2) Any person transporting feedingstuffs containing veterinary medicinal products or specified feed additives in road tankers or similar containers must ensure that the vehicle or container is cleaned before any re-use if this is necessary to prevent undesirable interaction or contamination.

(3) In the case of feedingstuffs containing a veterinary medicinal product he must ensure that the vehicle is accompanied by documentation stating this.

(4) Any person operating an undertaking transporting feedingstuffs containing veterinary medicinal products or specified feed additives must give written instructions to drivers on how to load and unload vehicles so as to avoid cross-contamination, and take reasonable steps to ensure that the driver complies with those instructions.

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

### **Possession, placing on the market and use of feedingstuffs**

**23.—(1)** It is an offence for any person to possess, place on the market or feed to animals any feedingstuffs incorporating veterinary medicinal products or specified feed additives unless they have been incorporated in accordance with this Schedule.

(2) It is an offence to feed to any animal, or buy or possess for the purpose of feeding to any animal, any feedingstuff containing a veterinary medicinal product or specified feed additive unless that veterinary medicinal product or specified feed additive is authorised for that species of animal and for the purpose for which it is used (unless prescribed under the cascade).

(3) This paragraph does not apply in relation to feedingstuffs if the veterinary medicinal product has been incorporated in accordance with an animal test certificate or the feedingstuff has been imported in accordance with this Schedule.

### **Imports from third countries**

**24.** Any person who imports a feedingstuff containing a veterinary medicinal product from a third country is guilty of an offence.

### **Trade between member States**

**25.** Any person who brings in from another member State a feedingstuff containing a veterinary medicinal product is guilty of an offence unless—

- (a) the feedingstuff has been manufactured in accordance with the provisions of Council Directive [90/167/EEC](#) (laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community([36](#)) and Regulation (EC) [No. 183/2005](#); and

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(36) OJ No. L 92, 7.4.90, p. 42.

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- (b) it only contains a veterinary medicinal product that has the same quantitative and qualitative composition as a veterinary medicinal product authorised in the United Kingdom.

## SCHEDULE 6

Regulation 15(4)

### Exemptions for small pet animals

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- 1. Animals to which this Schedule applies
- 2. Placing on the market, importing and administering the product
- 3. Manufacture
- 4. Approval of the active substance
- 5. The product
- 6. Labelling
- 7. Administration
- 8. Pack size
- 9. Adverse reactions
- Signature
- Explanatory Note

### **Animals to which this Schedule applies**

1. This Schedule applies in relation to veterinary medicinal products intended solely for the following animals kept exclusively as a pet—

- (a) aquarium fish;
- (b) cage birds;
- (c) ferrets;
- (d) homing pigeons;
- (e) rabbits;
- (f) small rodents; and
- (g) terrarium animals.

### **Placing on the market, importing and administering the product**

2. A veterinary medicinal product intended solely for an animal to which this Schedule applies may be placed on the market, imported or administered without a marketing authorisation if it complies with this Schedule.

### **Manufacture**

3.—(1) The product must have been manufactured by—

- (a) the holder of a manufacturing authorisation if manufactured in the United Kingdom;

- (b) the holder of a manufacturing authorisation issued under Directive [2001/82/EC](#) if manufactured in another member State;
  - (c) in the case of Australia, Canada, New Zealand, or Switzerland, the holder of an authorisation from the competent authority permitting him to manufacture medicinal products;
  - (d) in the case of any other country, a manufacturer whose premises have been inspected and approved by an officer of the Secretary of State.
- (2) This paragraph does not apply until 1st November 2007.

### **Approval of the active substance**

4.—(1) The Secretary of State may approve an active substance for use in a veterinary medicinal product manufactured under this Schedule.

(2) The Secretary of State may not grant an approval if the active substance requires veterinary control.

(3) The approval must specify the animals for which it is approved, and may specify how the active substance or a product containing it is to be administered.

(4) The Secretary of State may suspend or revoke the approval (or limit it to a smaller number of species) if—

- (a) it is demonstrated that the substance requires veterinary control;
- (b) serious adverse reactions are reported making suspension or revocation necessary; or
- (c) it is demonstrated that the substance—
  - (i) is carcinogenic;
  - (ii) is genotoxic; or
  - (iii) shows developmental toxicity (including teratogenicity).

(5) The procedure for the refusal, suspension or revocation of an approval under this paragraph is the same as the procedure for a marketing authorisation.

### **The product**

5.—(1) The active substance in the veterinary medicinal product must be approved under paragraph 4.

(2) The veterinary medicinal product must not be an antibiotic.

(3) It must not contain any narcotic or psychotropic substance.

(4) It must not be intended for treatments or pathological processes that require a precise prior diagnosis or the use of which may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures.

(5) The requirement that a veterinary medicinal product may only contain an active substance under paragraph 4 does not apply until 1st November 2007 in relation to a veterinary medicinal product on the market on 30th October 2005.

### **Labelling**

6.—(1) The product must be clearly labelled as being exempt from the requirements of these Regulations in relation to a marketing authorisation.

(2) The labelling must show the following—

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- (a) the name of the veterinary product, including, if it is part of the name, its strength and pharmaceutical form;
- (b) the authorisation number of the manufacturer;
- (c) the name and strength of each active substance;
- (d) the route of administration;
- (e) the batch number;
- (f) the expiry date;
- (g) the words “For animal treatment only”;
- (h) the contents by weight, volume or number of dose units;
- (i) the name and address of the manufacturer;
- (j) the target species;
- (k) the words “Keep out of reach of children”;
- (l) storage instructions;
- (m) the shelf-life after the immediate packaging has been opened for the first time;
- (n) disposal advice;
- (o) full indications, including—
  - (i) therapeutic indications;
  - (ii) contra-indications;
  - (iii) interaction with other medicines and other forms of interaction; and
- (p) dosage instructions.

(3) If there is insufficient room on the label, the information may instead be in a package leaflet, but the leaflet must contain all the information in the preceding sub-paragraph other than the batch number and the expiry date, but the label on the product must contain at least the following—

- (a) the name of the veterinary medicinal product;
- (b) its active substance and its strength;
- (c) the route of administration;
- (d) the batch number;
- (e) the expiry date; and
- (f) the words “For animal treatment only”.

(4) This paragraph does not apply until 1st November 2007 in relation to a veterinary medicinal product on the market on 30th October 2005.

### **Administration**

7. The method of administration must be oral or topical or (in the case of a product for fish) by addition to the water.

### **Pack size**

8. The pack size must only be sufficient for a single course of treatment or, in the case of a veterinary medicinal product for aquarium fish, sufficient for a single course of treatment of no more than 7 administrations to an aquarium of 25,000 litres.

## Adverse reactions

9.—(1) The manufacturer, importer or retailer of a veterinary medicinal product must notify the Secretary of State of any serious adverse reactions (as defined in paragraph 57 of Schedule 1) of which he becomes aware within 15 days of learning of the reaction.

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

## SCHEDULE 7

Regulation 16

### Fees

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## PART 1

### Introduction

#### **Interpretation of Schedule 7**

**1.** In this Schedule—

“national application” means an application for a marketing authorisation that does not involve another member State;

“pharmaceutical product” means any veterinary medicinal product other than an immunological product;

“simultaneous application” is an application in which, at the time an authorisation for a product is applied for, one or more additional applications are submitted for products that are identical to the first product except that—

- (a) in the case of an immunological product, they have a lesser number of antigens than the first product, but only contain antigens contained in the first product; and
- (b) in the case of a pharmaceutical product, they have different strengths of the active substance,

and, in the case of an application involving more than one member State, the additional applications do not include a member State that was not included in the first application.

#### **Payment of fees**

- 2.** All fees under this Schedule are payable to the Secretary of State.

#### **Time of payment**

- 3.** All fees are payable on invoice unless otherwise specified.

#### **Multiple inspections**

- 4.** If a site is inspected for more than one type of authorisation at the same time, only one fee (the highest) is payable.

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**Expenses for inspections**

5. Whenever premises are inspected, the travel and subsistence costs of the inspectors and, in the case of an inspection outside the United Kingdom, interpreters' fees are payable in addition to the inspection fee specified.

**Translation**

6. All translation costs are charged additionally.

**PART 2**

**Fees relating to marketing authorisations**

**Fees for specified pharmaceutical applications**

7. The following table sets out the fees relating to a pharmaceutical veterinary medicinal product for—

- (a) a national application for a marketing authorisation that is—
  - (i) a full application under Part 1 of Schedule 1;
  - (ii) a bibliographic application; or
  - (iii) an application based on pharmacological equivalence;
- (b) an application for a marketing authorisation using the decentralised procedure where the United Kingdom is a concerned member State;
- (c) an application for the mutual recognition of a product authorised in another member State.

*Fees for specified pharmaceutical applications*

<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application</i>		
			<i>Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
<b>Base Fee:</b>	930	1,860	1,860	2,380	460

The following fees are in addition to the base fee:

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<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
<b>Quality assessment</b> (if quality data are assessed):	3,900	3,320	2,790	3,560	1,860
<b>Safety assessment</b> (if safety data are assessed):	3,900	3,120	1,060	1,360	1,860
<b>Efficacy assessment</b> (if efficacy data are assessed):	3,900	3,120	1,060	1,360	1,860
<b>Ecotoxicology assessment:</b> (if ecotoxicology data are assessed):	660	530	330	420	400
<b>Additional fee if any of the target species is a food-producing animal</b> (not payable if neither safety data nor ecotoxicology data are assessed):	3,850	3,520	2,120	2,710	1,390
Reduced by— if no safety data are assessed:	2,160	2,160	1,320	1,690	660

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<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
if no ecotoxicology data are assessed:	1,020	780	300	380	300
<b>Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—</b>					
food-producing animal:	7,350	6,500	5,770	7,370	2,590
non-food-producing animal:	6,430	5,770	5,510	7,030	2,260
<b>Additional fee for each additional pack type:</b>					
Reduced by— if no quality data are assessed:	360	360	360	460	120

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<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	60	60	60	80	60
if no ecotoxicity data are assessed:	60	60	—	—	60
<b>Additional fee for each additional active ingredient(food-producing animal):</b>	<b>6,360</b>	<b>6,030</b>	<b>3,980</b>	<b>5,090</b>	<b>2,060</b>
Reduced by— if no quality data are assessed:	1,440	1,440	1,440	1,840	480
if no safety data are assessed:	2,690	2,690	1,620	2,070	840
if no efficacy data are assessed:	900	720	540	690	300
if no ecotoxicity data are assessed:	720	600	—	—	240

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<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
<b>Additional fee for each additional active ingredient(non-food-producing animal):</b>	4,250	4,050	3,180	4,070	1,460
Reduced by— if no quality data are assessed:	1,440	1,440	1,440	1,840	480
if no safety data are assessed:	1,440	1,440	900	1,150	480
if no efficacy data are assessed:	900	720	540	690	300
if no ecotoxicity data are assessed:	60	60	—	—	60
<b>Additional fee if there is more than one target species, for each additional species (food-producing animal):</b>	3,910	3,520	2,390	3,050	1,260

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<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
Reduced by— if no quality data are assessed:	180	180	180	230	60
if no safety data are assessed:	1,440	1,440	900	1,150	480
if no efficacy data are assessed:	1,800	1,440	1,080	1,380	540
if no ecotoxicity data are assessed:	120	120	—	—	60
<b>Additional fee if there is more than one target species, for each additional species (non- food-producing animal):</b>	2,460	2,060	1,530	1,950	800
Reduced by— if no quality data are assessed:	180	180	180	230	60
if no safety data are assessed:	180	180	120	150	60

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<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
if no efficacy data are assessed:	1,800	1,440	1,080	1,380	540
if no ecotoxicity data are assessed:	60	60	—	—	60
<b>Additional fee for each additional recommended route of administration(food-producing animal):</b>	2,650	2,460	1,590	2,040	930
Reduced by— if no safety data are assessed:	1,440	1,440	900	1,150	480
if no efficacy data are assessed:	900	720	540	690	300
if no ecotoxicity data are assessed:	60	60	—	—	60
<b>Additional fee for each additional recommended route of administration(non-food-</b>	1,190	1,000	730	930	400



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<i>Menu</i>	<i>Full national application under Part 1 of Schedule 1 (£)</i>	<i>Bibliographic national application (£)</i>	<i>Pharmacologically Equivalent national application Reference product authorised in UK (£)</i>	<i>Reference product not authorised in UK (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
<b>producing animal):</b>					
Reduced by— if no safety data are assessed:	180	180	120	150	60
if no efficacy data are assessed:	900	720	540	690	300
<b>Simultaneous applications:</b> fee for each additional product in the application:	2,850	2,850	2,850	3,640	1,660

#### **Decentralised pharmaceutical application where the United Kingdom is the reference member State**

8.—(1) The fee for a decentralised application for a pharmaceutical product where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 7, with the addition of the fees in the following table.

#### *Decentralised pharmaceutical application where the United Kingdom is the reference member State*

<i>Application</i>	<i>Additional fee (£)</i>
Food-producing animal: one member State:	3,650
Non-food-producing animal: one member State:	3,170
Each additional member State:	520

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,570 for one member State and £120 for each additional member State.

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### **Application for a marketing authorisation for an immunological product**

9.—(1) The fee for a national application for a marketing authorisation relating to an immunological product, a decentralised application where the United Kingdom is the concerned member State or the mutual recognition of a product authorised in another member State is in accordance with the following table.

#### *Fees for specified immunological applications*

<i>Menu</i>	<i>National application for a marketing authorisation (£)</i>	<i>Decentralised application where the UK is a concerned member State or recognition of a product authorised in another member State (£)</i>
Base fee:	11,600	5,700
The following fees are in addition to the base fee.		
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:	7,290	2,450
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,330	660
More than one antigenic component—fee for each additional component:	1,330	400
More than one species—fee for each additional species:	5,300	1,590
More than one route of administration—fee for each additional route of administration:	5,300	1,590
Simultaneous application—fee for each additional product in the application:	2,850	1,660

(2) The fee for an application for a marketing authorisation for an immunological product that is identical to a product already authorised in the United Kingdom but with a lesser number of antigens and which only contains antigens contained in the product already authorised is £10,270 (United Kingdom only) or £5,300 (decentralised application where the United Kingdom is the concerned member State).

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### **Decentralised immunological application where the United Kingdom is the reference member State**

**10.**—(1) The fee for a decentralised application for a marketing authorisation for an immunological product where the United Kingdom is the reference member State is the same as for a national application, with the additions of £3,420 for the first member State involved in the application and £520 for each additional member State.

(2) In the case of a simultaneous application the fee for each additional product in the application is £6,570 for one member State and £120 for each additional member State.

### **Application for a marketing authorisation using identical data**

**11.** The fee for an application for a marketing authorisation using identical data is in accordance with the following table.

#### *Identical data*

<i>Application</i>	<i>Fee (£)</i>
Any application other than decentralised where the United Kingdom is the reference member State:	930
Decentralised application where the United Kingdom is the reference member State—	
one member State:	4,105
each additional member State:	520

### **Application for a provisional marketing authorisation (pharmaceutical)**

**12.** The fee for an application for a provisional marketing authorisation for a pharmaceutical product is in accordance with the following table.

#### *Fees for a provisional marketing authorisation for a pharmaceutical product*

<i>Menu</i>	<i>Fee (£)</i>
Base Fee:	930
The following fees are in addition to the base fee:	
Quality assessment (if quality data are assessed):	3,900
Safety assessment (if safety data are assessed):	3,900
Efficacy assessment (if efficacy data are assessed):	2,420
Ecotoxicology assessment (if ecotoxicology data are assessed):	660
Additional fee if any of the target species is a food-producing animal (not payable if	3,850

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<i>Menu</i>	<i>Fee (£)</i>
neither safety data nor ecotoxicology data are assessed):	
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom—	
food-producing animal:	5,770
non-food-producing animal:	4,840
Additional fee for each additional pack type:	700
Additional fee for each additional active ingredient (food-producing animal):	5,860
Additional fee for each additional active ingredient (non-food-producing animal):	3,750
Additional fee if there is more than one target species, for each additional species (food-producing animal):	2,920
Additional fee if there is more than one target species, for each additional species (non- food-producing animal):	1,460
Additional fee for each additional recommended route of administration (food-producing animal):	2,160
Additional fee for each additional recommended route of administration (non-food-producing animal):	700
Simultaneous applications—fee for each additional product in the application:	2,850

**Fees for an application for a provisional marketing authorisation (immunological)**

**13.** The fee for an application for a provisional marketing authorisation for an immunological product is in accordance with the following table.

*Fees for a provisional marketing authorisation for an immunological product*

<i>Menu</i>	<i>Fee (£)</i>
Base fee:	10,650
The following fees are in addition to the base fee.	
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:	5,560
Additional fee for each adjuvant or preservative not previously included in a veterinary	1,330

<i>Menu</i>	<i>Fee (£)</i>
medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	
More than one antigenic component—fee for each additional component:	1,170
More than one species—fee for each additional species:	3,990
More than one route of administration—fee for each additional route of administration:	3,990
Simultaneous application—fee for each additional product in the application:	2,850

#### **Fee for the conversion from a provisional to a full marketing authorisation**

14. The fee for the conversion of a provisional marketing authorisation to a full marketing authorisation is the same as the fee for an application for a full marketing authorisation except that, if the application for conversion is made within two years of the grant of the provisional marketing authorisation—

- (a) if the application for the provisional marketing authorisation was made before 1st October 2006 the fee is £10,995; and
- (b) if the application for the provisional marketing authorisation was made on or after 1st October 2006 the fee is £5,780.

#### **Application for a marketing authorisation relating to a parallel import**

15. The fee for a marketing authorisation for a parallel import is in accordance with the following table.

##### *Parallel imports*

<i>Application</i>	<i>Fee (£)</i>
Application where the imported product has been authorised in accordance with the mutual recognition procedure or decentralised procedure, and the United Kingdom is included in these procedures—	
import from one member State:	1,730
each additional member State:	350
Application to add an additional member State after the marketing authorisation has been granted—fee for each member State:	450
Any other application—fee for each member State from which the product is imported:	2,100

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### Application for a variation

16.—(1) An applicant must make a separate application for a variation for each change in the marketing authorisation (unless a change is a direct consequence of the first change) and the appropriate fee is payable for each application.

(2) As an exception from sub-paragraph (1), if an applicant applies for more than one variation to the quality data in a marketing authorisation on the same application form, he may elect to pay a total fee £4,550; but this sub-paragraph does not apply—

- (a) if one or more of the variations relates to a new source of an active substance and the applicant does not submit a Certificate of Suitability issued by the European Pharmacopeia relating to the new source, or
- (b) if a significant formulation change is applied for that requires a new assessment of the safety or efficacy of the veterinary medicinal product.

(3) If the variation is one specified in Annex I to Commission Regulation (EC) No. 1084/2003, the fee is £450 for a variation specified as Type 1A in that Annex.

(4) If the variation is specified as Type 1B in that Annex, the fee is £870 except in accordance with the following table.

#### *Reductions to Type 1B fees*

<i>Variation</i>	<i>Conditions</i>	<i>Fee (£)</i>	
Identical changes to a number of products	All the products are from the same marketing authorisation holder	First product	870
		Each subsequent product	450
	Supporting data are identical		
	All applications are submitted at the same time		

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No. 1084/2003 is £2,275 except in the following cases, where the fee is as specified.

#### *Reductions to Type II fees*

<i>Change</i>	<i>Conditions</i>	<i>Fee (£)</i>	
a) Identical changes to a number of products	All the products are from the same marketing authorisation holder	First product	2,275
		Each subsequent product	450
	Supporting data are identical		
	All applications are submitted at the same time		
b) Change of distributor	No other aspect of the dossier is changed and the marketing authorisation holder remains the same	870	

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<i>Change</i>	<i>Conditions</i>	<i>Fee (£)</i>
c) Change of legal entity of marketing authorisation holder	No other aspect of the dossier is changed	870
d) Simple dosage instruction changes intended to remove ambiguity	The change is not as a result of safety concerns  No new studies are required to support the change  The dosage regime remains the same	870
e) Addition or change to safety warnings	No other aspects of the dossier are changed  No safety warnings are removed  No new studies are required to support the change and the proposed warnings serve to increase the protection of the user/environment/target species as appropriate	870
f) Corrections or simple text layout changes to summary of product characteristics and/or product literature. Included in this is the introduction of multilingual labelling	The changes are not a result of safety concerns  No new studies are required to support the change and no other aspect of the dossier is changed  The legibility of the current English labelling is not compromised  The indications and warnings are the same in all languages	870
g) Abbreviated resubmission of a previously refused Type II variation	At the time of refusal of a Type II variation, the Secretary of State has given written permission for resubmission under this category  The application has been resubmitted within 3 months of the date the refusal advice was issued	870
h) Submission made following the formal advice of the Secretary of State	The Secretary of State has already assessed the relevant data and formed an opinion on these  The change is not required as a result of the holder failing to keep the Part II (quality) data in accord	870

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<i>Change</i>	<i>Conditions</i>	<i>Fee (£)</i>
	with current practice or inline with current guidelines issued by the Committee for Medicinal Products for Veterinary Use <sup>(37)</sup>	
i) Approval of a mock-up for an authorised pack size	The pack size is already authorised	870
	No new studies are required to support the change and no other aspect of the dossier is changed	
j) Changes to the Summary of Product Characteristics and product literature of a Marketing Authorisation for Parallel Import as a direct consequence of the approval of a variation to the Summary of Product Characteristics and product literature for the United Kingdom authorised product	The only changes to the Summary of Product Characteristics and product literature are those required to bring the marketing authorisation for parallel import back in direct line with those of the United Kingdom authorised product	870
k) Changes to details of the marketing authorisation holder's pharmacovigilance system	No other changes to the dossier	870

### **Application for a variation to a marketing authorisation that has been issued in other member States**

17.—(1) In this paragraph the types of variation are those specified in Commission Regulation (EC) 1084/2003.

(2) An applicant must make a separate application for a variation for each change in the marketing authorisation (unless a change is a direct consequence of the first change).

(3) The fee is in accordance with the following table.

#### *Variations*

<i>Type of variation</i>	<i>UK is the reference member State (£)</i>	<i>UK is a concerned member State (£)</i>
<b>Type II variation:</b>	5,125	3,075
If a marketing authorisation holder applies for a Type II variation for a number of marketing authorisations, and—		
all the applications have identical supporting data		
all the changes are identical		

(37) The Committee was established by Article 30 of Regulation (EC) No. 762/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ No. L136, 30.4.2004, p. 1.



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<i>Type of variation</i>	<i>UK is the reference member State (£)</i>	<i>UK is a concerned member State (£)</i>
all the applications are submitted at the same time		
the fee payable is—		
– for the first variation:	5,125	3,075
– for each subsequent variation:	675	450
If a marketing authorisation holder—		
applies for a Type II variation to correct the Summary of Product Characteristics or product literature or where variations are required for simple text layout changes		
the change is not a result of safety concerns		
no new studies are required to support the change		
no other aspects of the dossier are changed		
the fee payable is:	1,305	870
Changes to details of the marketing authorisation holder's pharmacovigilance system (no other changes to the dossier):	1,305	870
<b>Type 1A variation:</b>	675	450
<b>Type 1B variation:</b>	1,305	870
If a marketing authorisation holder applies for a Type 1B variation for a number of marketing authorisations, and—		
all the applications have identical supporting data		
all the changes are identical		
all the applications are submitted at the same time		
the fee payable is—		
– for the first variation	1,305	675
– for each subsequent variation	870	450

#### **Application for an extension to a marketing authorisation**

**18.** The fee for an application for an extension to a marketing authorisation is in accordance with the following table.

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*Extension to a marketing authorisation*

<i>Extension</i>	<i>Fee if the marketing authorisation is UK only (£)</i>	<i>Fee for a decentralised application where the United Kingdom is a concerned member State or the mutual recognition of an extension authorised in another member State (£)</i>
Change of strength or potency or the addition of a new strength or potency	6,570	3,250
Change of pharmaceutical form or the addition of a new pharmaceutical form	8,290	3,780
Change of route of administration, or the addition of a new one, of — an immunological product, or a pharmaceutical product for a non food-producing animal:	5,310	7,030
— a pharmaceutical product for a food-producing animal:	2,850	3,380
Change or addition of target species	9,480	4,180
Change of active substance	8,290	3,780
Other	8,290	3,780
Simultaneous application: fee for each additional product in the application	2,850	1,660

**Decentralised application for an extension where the United Kingdom is the reference member State**

**19.**—(1) The fee for a decentralised application for an extension where the United Kingdom is the reference member State is the same as for a national application as set out in the table in paragraph 18, with the additions of the fees in the following table.

*Decentralised application for an extension where the United Kingdom is the reference member State*

<i>Application</i>	<i>Additional fee (£)</i>
Pharmaceutical product for a food-producing animal— one member State:	3,650
Pharmaceutical product for a non-food-producing animal— one member State:	3,170

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<i>Application</i>	<i>Additional fee (£)</i>
Immunological product—one member State:	3,410
Each additional member State:	520

(2) In the case of a simultaneous application, the fee for each additional product in the application is £6,570 for one member State and £115 for each additional member State.

### **Provision of information relating to the recognition of a United Kingdom marketing authorisation**

**20.**—(1) Where an application is made for the Secretary of State to provide information to other member States to enable them to recognise a marketing authorisation already granted by the United Kingdom the following fees are payable.

(2) Where a valid application to provide information to another member State is received within six months of the original grant of the marketing authorisation, or where the Secretary of State has already provided the information to a member State, and a further valid application is made for him to provide the information to an additional member State within six months of the date he last provided the information the fees are—

<i>Type of application</i>	<i>Fee (£)</i>
Pharmaceutical product for a food-producing animal—one member State:	2,405
Pharmaceutical product for a non-food-producing animal—one member State:	1,865
Immunological product—one member State:	2,100
Each additional member State:	525

(3) In any other case the fees are—

<i>Type of application</i>	<i>Fee (£)</i>
Pharmaceutical product for a food-producing animal—one member State:	10,360
Pharmaceutical product for a non-food-producing animal—one member State:	7,255
Immunological product—one member State:	8,810
Each additional member State:	525

(4) In the case of simultaneous applications, the above fees are payable for each additional product in the application for one member State, with a fee of £115 for each additional product for each additional member State.

### **Application for the renewal of a national marketing authorisation**

**21.**—(1) The fee for an application for the renewal of a marketing authorisation originally granted on or after 30th October 2005 is £1,340.

(2) In the case of a marketing authorisation originally granted before 30th October 2005—

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- (a) if it is the first time the marketing authorisation has been renewed the fee is £1,340, and otherwise £300;
  - (b) if further assessment of post authorisation commitments is required the fee is £650.
- (3) The fee for the first reassessment of a provisional marketing authorisation is £300, and the fee for each subsequent reassessment is £1,340.

### **Application for the renewal of a marketing authorisation granted in more than one member State**

**22.** The fee for an application for the renewal of a marketing authorisation granted in more than one member State is—

- (a) £1,810 if the United Kingdom is the reference member State, and
- (b) £1,205 where the United Kingdom is a concerned member State.

### **Registration of a homeopathic remedy**

**23.** The fee for an application for the registration of a homeopathic remedy is in accordance with the following table.

*Fee for the registration of a homeopathic remedy*

<i>Type of application</i>	<i>Fee(£)</i>
If all stocks and the formulation have already been assessed by the Secretary of State—	160
not more than five stocks:	370
more than five stocks:	
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or if the formulation has already been assessed by the Secretary of State but one or more of the stocks have not been already assessed—	450
not more than five stocks:	655
more than five stocks:	
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	750
not more than five stocks:	970
more than five stocks:	
If the product is already authorised for human use in the United Kingdom, or for human or veterinary use in the United Kingdom or in another member State—	160
not more than five stocks:	370
more than five stocks:	

### **Annual fees for marketing authorisations**

**24.**—(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation must provide him with a statement of his turnover for the previous calendar year; and, if specified in the demand, an audit certificate relating to the turnover.

(2) When he provides the statement of his turnover he must pay an annual fee, rounded up to the next £10, of—

$\pounds 0.67T100 + \pounds 225n$

where  $T$  is the annual turnover in the previous calendar year and  $n$  is the number of active marketing authorisations held at any time during the previous calendar year.

(3) In the case of an authorisation holder with a turnover relating to all marketing authorisations held of less than £220,000, the amount, rounded up to the next £10, is—

$\pounds 0.67T100 + \pounds 170n$

where  $T$  is the annual turnover in the previous calendar year and  $n$  is the number of active marketing authorisations held at any time during the previous calendar year.

(4) In this paragraph—

“turnover” means the gross value at manufacturers' prices of all authorised veterinary medicinal products sold or supplied in the United Kingdom;

“manufacturers' prices” means the prices charged for authorised products by manufacturers to wholesalers, except to the extent that—

- (a) the products are supplied by manufacturers direct to retailers, in which case it means the prices charged for the products by the manufacturers to the retailers reduced by such sum as, in the opinion of the Secretary of State, represents the difference between the prices paid by the retailers and those which could be expected to be charged by the manufacturers to wholesalers according to the practice prevailing during the period in question with regard to such products;
- (b) a marketing authorisation holder sells or supplies products that he has neither manufactured nor obtained from the manufacturer, in which case it means the prices paid by him for those products.

### **Auditor's certificate**

**25.**—(1) If the Secretary of State required an audit certificate when he sent out the demand for the statement of turnover, and the holder of the marketing authorisation has not provided it within 30 days, an additional fee is payable for that year of £11,035 plus an additional £2,210 in respect of each marketing authorisation held.

(2) If the Secretary of State is not satisfied that the audit certificate provides sufficient assurance that the figures fairly present the financial records of the company, he may require the marketing authorisation holder to produce within 30 days a further certificate and specify what further assurances he needs; and if these are not provided within those 30 days the additional fee specified in sub-paragraph (1) is payable.

(3) Nothing in this paragraph limits the powers of an inspector to examine financial records.

### **Late payment of annual fees**

**26.**—(1) Where a person fails to pay the annual fee for a marketing authorisation within 30 days from and including the date of the demand, he must pay an additional fee, rounded up to the nearest £10, of—

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- (a) where payment is received after 30 but before 60 days have expired from and including the due date, 1% of the annual fee;
- (b) where payment is received after 60 but before 90 days have expired from and including the due date, 2% of the annual fee; and
- (c) where payment has not been received after the expiry of 90 days, 5% of the annual fee.

(2) Where a marketing authorisation holder has not provided the Secretary of State with a statement of his annual turnover so that the annual fee cannot be determined before the due date, he may make a payment of an amount on account of the annual fee, in which case the additional fee is calculated on the difference between the amount paid on account and the actual amount due.

## PART 3

### Fees payable by manufacturers

#### **Application for a manufacturing authorisation**

27. The fee for an application for a manufacturing authorisation for a veterinary medicinal product is—

- (a) £2,740; or
- (b) £500 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals).

#### **Application for a variation of a manufacturing authorisation**

28. The fee for an application to vary a manufacturing authorisation is—

- (a) £490 if the variation requires scientific or pharmaceutical assessment,
- (b) £345 if the variation only involves a change of ownership;
- (c) £170 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals); and
- (d) otherwise £270.

#### **Application for an authorisation to manufacture an autogenous vaccine or a product for administration under the cascade**

29.—(1) The fee for an application for a standard authorisation to manufacture an autogenous vaccine or a veterinary medicinal product for administration under the cascade is £3,110 for each manufacturing site, with the same fee for each subsequent inspection.

(2) In the case of an application for an individual authorisation to manufacture a single batch of autogenous vaccine, or a single batch of veterinary medicinal product for administration under the cascade the fee is £1,555.

(3) The fee to vary an authorisation is £290 if no further inspection is required, and otherwise is the full application fee.

#### **Annual fees**

30.—(1) An annual fee of £435 is payable in respect of each manufacturing authorisation held (other than as specified in this paragraph).

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(2) The annual fee for a manufacturing authorisation for an autogenous vaccine or a veterinary medicinal product for administration under the cascade is 0.67% of the turnover in the previous calendar year rounded up to the next £1, with a minimum fee of £10.

(3) There is no annual fee for a manufacturing authorisation for a veterinary medicinal product manufactured in accordance with Schedule 6 for small pet animals.

(4) In this paragraph “turnover” means the gross value at manufacturers' prices of all authorised veterinary medicinal products sold or supplied in the United Kingdom.

### Site inspections—type of site

**31.** For the purposes of deciding the fee for a site inspection—

“super site” is a site at which 250 or more relevant persons are employed;

“major site” is a site at which 60 or more, but fewer than 250, relevant persons are employed;

“standard site” is a site at which 10 or more, but fewer than 60 relevant persons are employed;

“minor site” is a site at which fewer than 10 relevant persons are employed;

“relevant person” means a person employed on the premises and systems inspected.

### Inspection of a site where immunological veterinary medicinal products are manufactured

**32.** The fees for the inspection of a site where immunological veterinary medicinal products are manufactured are in accordance with the following table.

*Sites where immunological veterinary medicinal products are manufactured*

<i>Type of site</i>	<i>Fee (£)</i>
Super site	25,230
Major site	17,760
Standard site	5,710
Minor site	4,985

### Inspection of a site where sterile veterinary medicinal products are manufactured

**33.** The following fees are payable for the inspection of a site where no immunological veterinary medicinal products are manufactured, but where sterile products are manufactured.

*Sites where sterile veterinary medicinal products are manufactured*

<i>Type of site</i>	<i>Fee (£)</i>
Super site	23,905
Major site	13,205
Standard site	8,450
Minor site	4,170

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### **Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured**

**34.** The following fees are payable for the inspection of a site where only non-immunological and non-sterile veterinary medicinal products are manufactured—

*Site where no immunological or sterile veterinary medicinal products are manufactured*

<i>Type of site</i>	<i>Fee (£)</i>
Super site	14,395
Major site	8,450
Standard site	7,020
Minor site	3,845

### **Inspection of a site where veterinary medicinal products are assembled**

**35.** The following fees are payable for the inspection of a site where the only manufacturing process in relation to veterinary medicinal products is their assembly after the product has been put into its immediate container.

*Site where medicinal products are assembled*

<i>Type of site</i>	<i>Fee (£)</i>
Super site	11,300
Major site	6,095
Standard site	4,120
Minor site	1,690

### **Test sites**

**36.** The fee for the inspection of a test site is £2,800.

### **Animal blood bank authorisations**

**37.—**(1) The fee for an authorisation to operate a blood bank is £3,110, with the same fee for each subsequent inspection.

(2) The fee for a variation is £290.

## **PART 4**

### **Fees relating to a wholesale dealer's authorisation**

#### **Application for a wholesale dealer's authorisation**

**38.—**(1) The fee for an application for a wholesale dealer's authorisation is—

- (a) £1,590, or;
- (b) £710 if the application is accompanied by an estimate that the first year's turnover will be less than £40,000.



(2) If the applicant paid a fee of £710, he must send a declaration of his turnover for the first year of trading on the anniversary of the grant of the authorisation, and if the figure is more than £40,000 he must pay the balance of £880 within 30 days.

(3) If the applicant paid £1,590 but his turnover for the first year of trading was lower than £40,000, if he sends a declaration certifying the turnover, the Secretary of State must refund the excess.

(4) Nothing in this paragraph limits the powers of an inspector to examine financial records.

(5) In this paragraph “turnover” means the gross value of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom.

### **Variation of a wholesale dealer’s authorisation**

**39.** The fee for an application to vary a wholesale dealer’s authorisation is—

- (a) £465 if the variation requires scientific or pharmaceutical assessment;
- (b) £390 if the variation only involves a change of ownership; and
- (c) otherwise £270.

### **Annual fee for a wholesale dealer’s authorisation**

**40.**—(1) The annual fee for a wholesale dealer’s authorisation, payable on the anniversary of the grant of the authorisation, is—

- (a) £285, or
- (b) £190 if the holder certifies when making the payment that his turnover during the previous year was less than £40,000.

(2) In this paragraph “turnover” means the gross value of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom.

### **Inspection of a wholesale dealer’s premises**

**41.** The fee for the inspection of a wholesale dealer’s premises is £1,690, or £795 if—

- (a) the authorisation only relates to products classified as AVM-GSL; or
- (b) his turnover relating to all veterinary medicinal products in the calendar year preceding the inspection was less than £40,000.

## **PART 5**

### **Fees relating to feedingstuffs**

#### **Fees relating to feedingstuffs**

**42.**—(1) Fees relating to feedingstuffs are payable with the application, or on invoice for the subsequent annual fee.

(2) Where more than one manufacturing activity is carried out at one premises, only one fee (the highest) is payable.

(3) Fees are in accordance with the following table.

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*Fees relating to feedingstuffs*

	Application and annual fee	Fee payable in Great Britain (£)		Fee payable in Northern Ireland (£)	
		Standard	Late <sup>(a)</sup>	Standard	Late <sup>(b)</sup>
1	Application for the approval of an establishment to manufacture a specified feed additive, and the subsequent annual fee (b):	935	1,115	500	600
2	Application for the approval of an establishment to manufacture a premixture, and the subsequent annual fee:	590	710	395	475
3	Application for the approval of an establishment to manufacture feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures, and the subsequent annual fee:	590	710	395	475
4	Application for the approval of an establishment to manufacture feedingstuffs using a veterinary medicinal product only at a rate of 2	395	470	290	350

**(a)** This column is the annual fee if it is not paid within 60 days of the invoice.

**(b)** No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

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	Application and annual fee	Fee payable in Great Britain (£)		Fee payable in Northern Ireland (£)	
		Standard	Late <sup>(a)</sup>	Standard	Late <sup>(b)</sup>
5	kg per tonne or more when the feedingstuffs are to be placed on the market, and the subsequent annual fee: Application for the approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be placed on the market, and the subsequent annual fee:	200	240	155	190
6	Application for the approval of an establishment to manufacture feedingstuffs using a veterinary medicinal product only at a rate of 2 kg per tonne or more when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee:	145	175	120	145

**(a)** This column is the annual fee if it is not paid within 60 days of the invoice.

**(b)** No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

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	Application and annual fee	Fee payable in Great Britain (£)		Fee payable in Northern Ireland (£)	
		Standard	Late <sup>(a)</sup>	Standard	Late <sup>(b)</sup>
7	Application for the approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee:	125	150	100	120
8	Application for approval as a distributor of specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products, and the subsequent annual fee:	140	165	65	75

(a) This column is the annual fee if it is not paid within 60 days of the invoice.

(b) No fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs.

### Fees relating to premises for supply by suitably qualified persons

43.—(1) The fee to approve premises for the retail supply of veterinary medicinal products by suitably qualified persons is—

(a) £250, or

- (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of—
  - (i) horses (or horses and companion animals) £140; or
  - (ii) companion animals, £105.
- (2) The subsequent annual fee is—
  - (a) £180, or £210 if the fee is not paid within 60 days of the invoice; or
  - (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of—
    - (i) horses (or horses and companion animals) £90, or £115 if the fee is not paid within 60 days of the invoice.
    - (ii) companion animals, £70, or £85 if the fee is not paid within 60 days of the invoice.

#### **Reduced fees**

- 44.** In the case of premises approved as both—
- (a) premises for the manufacture of feedingstuffs and for a distributor, or
  - (b) premises for the supply by a suitably qualified person and for a distributor,
- the subsequent annual fee payable is the higher fee plus 75% of the lower fee.

## **PART 6**

### **General**

#### **Testing samples**

**45.** The fee for testing a sample required to be submitted by the Secretary of State is the full economic cost of the test.

#### **Animal test certificates**

- 46.—**(1) The fee for an animal test certificate is £340 in the case of—
- (a) an immunological veterinary medicinal product that has been authorised in another member State for the species on which the proposed test will be conducted;
  - (b) a pharmaceutical veterinary medicinal product that has been authorised in another member State for use with a food-producing species on which the proposed test will be conducted where the same or similar dosage regime and method of administration is to be used in the medicinal test as is authorised; or
  - (c) a pharmaceutical veterinary medicinal product authorised in another member State for human or animal use where the test is to be conducted on companion animals only.
- (2) In any other case the fee is £805.
- (3) The fee for an application for a variation of the certificate is £260 for each change.
- (4) The fee for an application to renew a certificate is £130.

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### **Treatment under the cascade**

47. The fee for a certificate to import (if necessary) and be in possession of and administer a veterinary medicinal product authorised in another member State for treatment under the cascade is £15.

### **Treatment under the Animals (Scientific Procedures) Act 1986**

48. The fee for a certificate to import a product or substance for administration under a licence granted under the Animals (Scientific Procedure) Act 1986 is £15.

### **Treatment in exceptional circumstances**

49.—(1) The fee for a certificate to import (if necessary), be in possession of and administer a veterinary medicinal product authorised in a third country is £30 for the initial certificate and £30 for its renewal (£15 for a renewal if the certificate is renewed on-line using the website of the Veterinary Medicines Directorate) payable in respect of each animal treated.

(2) In the case of administration to and treatment of a discrete group of animals, the Secretary of State may notify the applicant in writing that a fee for only one animal is payable.

### **Specific batch control**

50. The fee for an authorisation to release a veterinary medicinal product under specific batch control is—

- (a) £550; or
- (b) £450 for each batch if a number of specific batch control applications are made at the same time and all the batches are affected by the same issue.

### **Submission of control tests of an immunological product**

51. The fee for the submission of the results of tests carried out on a batch of immunological products prior to release is £80.

### **Export certificates**

52. The fee for an application for an export certificate is £30, and £15 for each certified copy.

### **Appeals to the Veterinary Products Committee: marketing authorisations and ATCs**

53. If the Secretary of State refuses to grant a marketing authorisation or an animal test certificate, or grants one that is different from what was applied for, the fee for an appeal to the Veterinary Products Committee is in accordance with the following table.

*Application to the Veterinary Products Committee: authorisations and animal test certificates*

<i>Type of application</i>	<i>Fee(£)</i>
Application involving a new active substance	1,910
Standard application	505
Application for a pharmacologically equivalent product	505
Application using identical data	200

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<i>Type of application</i>	<i>Fee(£)</i>
Application for an animal test certificate	665

#### **Appeals to the Veterinary Products Committee: variations**

54. If the holder of a marketing authorisation applies for a variation and the Secretary of State refuses it, the fee for an appeal to the Veterinary Products Committee is in accordance with the following table.

##### *Appeal to the Veterinary Products Committee: variations*

<i>Type of application</i>	<i>Fee(£)</i>
Type 1A variation	200
Type 1B variation	200
Type II variation	265

#### **Appeal to the Veterinary Products Committee: suspensions**

55. The fee for an appeal to the Veterinary Products Committee following the suspension of a marketing authorisation or animal test certificate is £665.

#### **Appeal to the Veterinary Products Committee: active substance under Schedule 6**

56. The fee for an appeal to the Veterinary Products Committee against the refusal or suspension of an approval of an active substance under Schedule 6 is £665.

#### **Fees relating to an appointed person**

57. The appellant is liable for the full economic cost of a referral to an appointed person subject to a maximum of £5,000.

#### **Refund of fees relating to the Veterinary Products Committee or appointed persons**

58. The Secretary of State must refund the fee payable in relation to an appeal to the Veterinary Products Committee or to an appointed person if, as a result of the appeal, he changes the decision that was the subject of the appeal.

#### **Fees relating to an improvement notice**

59. If an improvement notice is served under these Regulations, the fee for any subsequent inspection necessary as a result of the notice is the full economic cost of the inspection, payable by the person on whom the notice was served.

#### **Non-payment of fees**

60. Where fees (other than fees relating to a manufacturing authorisation or wholesale dealer's authorisation) are not paid, the Secretary of State may, after giving one month's written warning, suspend the authorisation to which the fee relates.

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### **Waiver or reduction of fees**

**61.**—(1) If the Secretary of State is satisfied that for reasons of human or animal health or the protection of the environment it is desirable that a product should be authorised for veterinary use or that an authorised product should remain on the market he may waive or reduce any fees payable under these Regulations.

(2) An applicant or the holder of a marketing authorisation must provide full written justification for any waiver or reduction.

### **Reduction of fees when an application is withdrawn**

**62.**—(1) Where an application for a marketing authorisation, a Type II variation or a variation referred to in paragraph 16(2) is withdrawn before determination, the fee is reduced in accordance with this paragraph.

(2) If no assessment (veterinary, scientific or pharmaceutical) has begun, the reduction is 90%.

(3) If assessment has begun but the Secretary of State has not yet requested further data, the reduction is 50%.

(4) If the Secretary of State has requested further information but it has not yet been provided, the reduction is 25%.

(5) If the further information requested has been supplied but has not yet been fully assessed or the application has not been referred to the Veterinary Products Committee, the reduction is 10%.

(6) Once the further information has been fully assessed, or the application has been referred to the Veterinary Products Committee, there is no reduction.

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## **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations revoke and remake with amendments the Veterinary Medicines Regulations 2006.

### **Principal changes to the 2006 Regulations**

The new Regulations introduce a requirement for the registration of veterinary premises for the supply of veterinary medicinal products.

They implement Commission Directive [2006/130/EC](#) and enforce Commission Regulation [\(EC\) No 1950/2006](#).

They permit the advertising of POM-V medicines to veterinary nurses.

They extend the provision that the holder of a Marketing Authorisation for an immunological product must submit to the Secretary of State the results of all tests carried out on each batch of the product before he places the product on the market, to require that the holder must wait for confirmation from the Secretary of State before the product is placed on the market.

They control exports to other member States.

They update fees.



## The Regulations

The Regulations make provision for the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.

They implement Directive [2001/82/EC](#).

They enforce Regulations [\(EC\) No. 178/2002](#), No. 1831/2003, No. 882/2004, No. 183/2005, in so far as they apply to veterinary medicinal products used in feedingstuffs, and to some specified feed additives used in feedingstuffs.

They implement Council Directive 90/167 so far it is not superseded by Regulation [\(EC\) No. 183/2005](#).

They provide that a veterinary medicinal product must have a marketing authorisation granted by the Secretary of State before being placed on the market, and make provision for the grant of a marketing authorisation (regulation 4 and Schedule 1).

They specify that a veterinary medicinal product must be manufactured by a person holding a manufacturing authorisation, and make provision for granting an authorisation (regulation 5 and Schedule 2).

They regulate supply and possession of veterinary medicinal products, and introduce new classifications of those products (regulation 7 and Schedule 3).

They provide that a veterinary medicinal product may only be administered as specified in its marketing authorisation or, in the case of administration by a veterinary surgeon, administration under the “cascade” (regulation 8 and Schedule 4).

They control bringing a veterinary medicinal product into the United Kingdom (regulation 9) and advertising (regulation 10 to 12).

They control wholesale dealing (regulation 13).

They control medicated feedingstuffs and feedingstuffs containing additives specified in the Regulations (regulation 14 and Schedule 5).

They provide for exemptions (regulation 15 and Schedule 6).

They provide for fees (regulation 16 and Schedule 7).

They require records to be kept (regulations 17 to 24).

They create offences of importation, possession and supply of unauthorised veterinary medicinal products (regulations 25 to 27).

They make provision for the existence of the Veterinary Products Committee (regulation 28).

They make provision for an appeals procedure in the case of a refusal, etc., of a marketing authorisation (regulation 29).

They create administrative arrangements for the enforcement of the Regulations (regulations 32 to 41).

Under regulation 42 breach of the Regulations is an offence punishable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or both, or
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

A Regulatory Impact Assessment has been prepared and placed in the libraries of both Houses of Parliament. It is available, together with a transposition note and a table showing fee changes, on [www.vmd.gov.uk](http://www.vmd.gov.uk) at “Publications, Veterinary Medicines Regulations and Guidance”.

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