

**2005 No. 2745**

**MEDICINES**

# The Veterinary Medicines Regulations 2005

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| <i>Made - - - - -</i>               | <i>6th October 2005</i>  |
| <i>Laid before Parliament</i>       | <i>7th October 2005</i>  |
| <i>Coming into force</i>            |                          |
| <i>Except for regulation 14 and</i> |                          |
| <i>Schedule 5</i>                   | <i>30th October 2005</i> |
| <i>Regulation 14 and Schedule 5</i> | <i>1st January 2006</i>  |



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**ARRANGEMENT OF REGULATIONS**

**PART 1**

Introduction

1. Title and commencement
2. Definition of “veterinary medicinal product”, interpretation and scope
3. Products to which these Regulations do not apply

**PART 2**

Authorised veterinary medicinal products

4. Placing a veterinary medicinal product on the market
5. Manufacture of veterinary medicinal products
6. The finished product
7. Classification, supply and possession of the product
8. Administration of the product
9. Importation of authorised veterinary medicinal products
10. Advertising the product
11. Advertising of prescription products and products with psychotropic drugs or narcotics
12. Defence of publication in the course of business
13. Wholesale dealing
14. Feedingstuffs
15. Exemptions
16. Fees

## PART 3

### Records

17. Food-producing animals: proof of purchase of veterinary medicinal products
18. Food-producing animals: records of administration by a veterinary surgeon
19. Food-producing animals: records of purchase and administration
20. Food-producing animals: retention of records
21. Records by holders of a manufacturing authorisation
22. Records by wholesale dealers
23. Records of products supplied on prescription
24. Records of products administered to a food-producing animal under the cascade

## PART 4

### Unauthorised veterinary medicinal products

25. Importation of an unauthorised veterinary medicinal product
26. Possession of an unauthorised veterinary medicinal product
27. Supply of an unauthorised veterinary medicinal product

## PART 5

### Miscellaneous provisions, enforcement and offences

28. The Veterinary Products Committee
29. Representations to the Veterinary Products Committee
30. Duties on the Secretary of State relating to exports
31. Time limits
32. Appointment of inspectors
33. Powers of entry
34. Powers of inspectors
35. Inspection of pharmacies
36. Obstruction
37. Improvement notices
38. Appeals against improvement notices
39. Powers of a court on appeal
40. Seizure notices
41. Publication of notices
42. Penalties
43. Northern Ireland
44. Revocations and amendments

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SCHEDULE 1 — Marketing authorisations

SCHEDULE 2 — The manufacture of veterinary medicinal products

SCHEDULE 3 — Classification and supply and wholesale dealers

SCHEDULE 4 — Administration of a veterinary medicinal product outside the terms of a marketing authorisation

SCHEDULE 5 — Medicated feedingstuffs and specified feed additives

SCHEDULE 6 — Exemptions for small pet animals

SCHEDULE 7 — Fees

SCHEDULE 8 — Revocations and amendments.

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

She 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(c);

In accordance with section 56(1) of the Finance Act 1973(d), the Treasury consents to the making of these Regulations;

The Secretary of State makes these Regulations in exercise of the powers conferred on her 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 2005 and come into force—

- (a) except for regulation 14 and Schedule 5, on 30th October 2005;
- (b) in the case of regulation 14 and Schedule 5, on 1st January 2006.

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

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

- (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

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(a) S.I. 1999/2027.

(b) 1972 c. 68.

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

(d) 1973 c.51.

for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>(a)</sup>;

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

“the cascade” has the meaning assigned in paragraph 2 of Schedule 4;

“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 relating to the quality, safety and efficacy of the veterinary medicinal product as regards animal or human health; 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 all 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.

(2) They do not apply to a veterinary medicinal product that is the subject of a licence granted under the Animals (Scientific Procedure) Act 1986<sup>(b)</sup>, except that, if the animals used under that licence are to be put into the human food chain, the veterinary medicinal product must be administered in accordance with an animal test certificate granted under regulation 8(3).

## **PART 2**

### **Authorised veterinary medicinal products**

#### **Placing a veterinary medicinal product on the market**

4.—(1) It is an offence to place a veterinary medicinal product on the market unless that product has been granted a marketing authorisation by the Secretary of State or the Agency.

(2) Any person who certifies data in relation to an application for a marketing authorisation or in relation to an existing marketing authorisation and who knows that those data are false, or does not believe that they are accurate, is guilty of an offence.

(3) Schedule 1 (provisions relating to marketing authorisations) has effect.

#### **Manufacture of veterinary medicinal products**

5.—(1) The holder of a marketing authorisation must ensure that every stage in the manufacture of the veterinary medicinal product is carried out by the manufacturer specified in the marketing authorisation (who must, if the manufacture is carried out in the United Kingdom, hold a manufacturing authorisation for that type of product granted by the Secretary of State) and failure to do so is an offence.

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(a) OJ No. L136, 30.4.2004, p. 1.

(b) 1986 c. 14.

(2) Schedule 2 (provisions relating to the manufacture of veterinary medicinal products) has effect.

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

(4) Notwithstanding the above—

- (a) the holder of a wholesale dealer’s authorisation (in accordance with regulation 13) or a suitably qualified person (in accordance with paragraph 9 of Schedule 3) may break open packages (other than the immediate packaging of the veterinary medicinal product);
- (b) a pharmacist may break open any package other than the immediate packaging of injectable products; and
- (c) a veterinary surgeon may break open any package.

### **The finished product**

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

### **Classification, supply and possession of the product**

7.—(1) Part I of Schedule 3 (Classification and supply of authorised veterinary medicinal products) has effect.

(2) Any person who supplies a veterinary medicinal product that has passed its expiry date is guilty of an offence.

(3) Any person who supplies a medicinal product authorised for human use for administration to an animal (other than in accordance with a prescription from a veterinary surgeon for administration under the cascade) is guilty of an offence.

(4) Any person in possession of a veterinary medicinal product that was supplied to him other than in accordance with Schedule 3 is guilty of an offence.

### **Administration of the product**

8.—(1) It is an offence to administer a veterinary medicinal product to an animal unless—

- (a) the product has a marketing authorisation authorising its administration in the United Kingdom, and the administration is in accordance with that marketing authorisation; or
- (b) it is administered in accordance with Schedule 4 (Administration of a veterinary medicinal product outside the terms a marketing authorisation).

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

(3) This regulation does not apply in the case of a product administered for research purposes in accordance with a certificate (“an animal test certificate”) granted for the purpose by the Secretary of State.

### **Importation of authorised veterinary medicinal products**

9.—(1) It is an offence to import a veterinary medicinal product authorised for use in the United Kingdom except in accordance with this regulation.

(2) A holder of a marketing authorisation may import a veterinary medicinal product for which he holds the marketing authorisation.

(3) A holder of a manufacturing authorisation may import a veterinary medicinal product to which his authorisation relates.

(4) An authorised wholesale dealer may import a veterinary medicinal product if—

- (a) his authorisation covers the product;
- (b) the importation is in accordance with a certificate issued for the purpose by the Secretary of State; and
- (c) he has notified the holder of the marketing authorisation in writing before he imports it.

(5) A veterinary surgeon or a pharmacist may import any authorised veterinary medicinal product.

(6) A suitably qualified person (in accordance with paragraph 9 of Schedule 3) may import any authorised veterinary medicinal product that he is permitted to supply.

(7) There are no restrictions on the importation of an authorised veterinary medicinal product in category AVM-GSL.

### **Advertising the product**

**10.—**(1) It is an offence to advertise a veterinary medicinal product if the advertisement is misleading or contains any medicinal claim that is not in the summary of product characteristics.

(2) It is an offence to advertise a human medicine for administration to animals (including sending a price list of or including human medicines to a veterinary surgeon or veterinary practice).

(3) Paragraph (2) does not apply to the holder of a wholesale dealer's authorisation who supplies a list of human medicines, together with prices, to a veterinary surgeon for use under the cascade provided that—

- (a) the list is sent following a request from the veterinary surgeon to whom it is sent;
- (b) the veterinary surgeon has specified the type of human medicinal product he wishes to use, and the list is confined to human medicines of that type;
- (c) the list states clearly that the product does not have a marketing authorisation as a veterinary medicinal product, and may only be administered under the cascade; and
- (d) it only includes human medicines that may be administered legally under the cascade.

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

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

- (a) are available on veterinary prescription only; or
- (b) contain psychotropic drugs or narcotics.

(2) In the case of a product containing psychotropic drugs or narcotics, this does not apply to advertisements aimed at veterinary surgeons.

(3) In the case of POM-V medicines, this does not apply to price lists, or to advertisements aimed at veterinary surgeons, pharmacists or professional keepers of animals.

(4) In the case of POM-VPS medicines, this does not apply to price lists, or to advertisements aimed at—

- (a) veterinary surgeons;
- (b) pharmacists;
- (c) suitably qualified persons registered in accordance with paragraph 9 of Schedule 3;
- (d) other veterinary health care professionals;
- (e) professional keepers of animals;
- (f) owners or keepers of horses.

### **Defence of publication in the course of business**

12. In proceedings for an offence under these Regulations relating to advertising, it is a defence for the person charged to prove—

- (a) that he is a person whose business it is to publish or arrange for the publication of advertisements, and
- (b) that he received the advertisement in the ordinary course of business and did not know and had no reason to suspect that its publication would amount to an offence under these Regulations.

### **Wholesale dealing**

13. It is an offence to buy a veterinary medicinal product, other than by retail or for the purposes of retail supply in accordance with Schedule 3, unless the buyer has a wholesale dealer's authorisation granted by the Secretary of State under this regulation and Schedule 3.

### **Feedingstuffs**

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

### **Exemptions**

15.—(1) These Regulations do not apply to an inactivated autogenous vaccine that is manufactured, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal and used for the treatment of that animal.

(2) The requirements relating to marketing authorisations and manufacturing authorisations under Part 1 of Schedule 2 do not apply to an inactivated autogenous vaccine that is manufactured, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal and used for the treatment of other animals on the same site if the product has been manufactured in accordance with Part 2 of Schedule 2.

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

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

### **Fees**

16. Schedule 7 (fees) has effect.

## **PART 3**

### **Records**

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

17.—(1) The owner or keeper of food-producing animals must keep proof of purchase of all veterinary medicinal products acquired for those animals.

(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;
  - (c) the date of administration of the product;
  - (d) the amount of product administered;
  - (e) the identification of the animals treated;
  - (f) the withdrawal period.
- (2) It is an offence to fail to comply with this regulation.

**Food-producing animals: records of purchase and administration**

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

- (a) the name of the product;
- (b) the date of purchase;
- (c) the quantity purchased;
- (d) the withdrawal period;
- (e) 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 identity of the animals treated.

(3) If he disposes of it other than by treating an animal, he must record the date and route of disposal.

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

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

20.—(1) The keeper must retain the proof of purchase and the record for at least five years following the administration or other disposal of the product, irrespective of whether or not the animals concerned are no longer in his possession or have been slaughtered or have died during that period.

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

**Records by holders 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;
- (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 (manufacturing) 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 wholesale dealers**

22.—(1) A wholesale dealer must record, as soon as is reasonably practicable after each incoming or outgoing transaction (including disposals), the following—

- (a) the date and nature of the transaction;
- (b) the identity 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 products supplied on prescription**

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

- (a) the date;
- (b) the identity of the veterinary medicinal product;
- (c) the quantity;
- (d) the name and address of the supplier or recipient;
- (e) 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.

(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.

(4) When he starts to use the veterinary medicinal product he must also record the batch number and the date.

(5) He must keep the documentation and records for at least five years.

(6) 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 a food-producing animal 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 diagnosis;
- (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;
- (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 marketing authorisation holder 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 wholesale dealer 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 supervision 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.

#### **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 veterinary medicinal product prescribed by a veterinary surgeon under the cascade;
- (c) wholesale dealers if the possession is for re-export;
- (d) a holder of a manufacturer's authorisation or marketing authorisation if the intention is to manufacture a veterinary medicinal product.

(3) 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.

### **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.

## **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 shall appoint members of the Committee from professional people who are eminent in their field; and any lay members as she shall see 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 she may decide.

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

#### **Representations to the Veterinary Products Committee**

29.—(1) If the Secretary of State, on the grounds of the safety, quality or efficacy of the product intends to—

- (a) refuse to grant a marketing authorisation or animal test certificate;
- (b) grant one that is different from that which was applied for;
- (c) suspend it;
- (d) vary it other than on the application of the holder;
- (e) refuse to grant a variation applied for by the holder; or
- (f) revoke it,

she shall notify the applicant or holder of her intention.

(2) The applicant or holder may within 28 days of the notification give notice that he wishes to make representations to the Veterinary Products Committee concerning the notice.

(3) The Committee shall consider those representations.

(4) The representations may be written or oral, but may not include any data not available to the Secretary of State at the time of her decision.

(5) The Committee shall report in writing to the Secretary of State.

(6) If the appellant so requests, the Secretary of State shall give him a copy of the report.

(7) The Secretary of State shall give to the appellant written notification of her proposed determination and the reasons for it.

(8) A person may make representations concerning the Secretary of State's proposed determination to a person appointed for the purpose by the Secretary of State.

(9) The appointed person shall consider the representations (but shall not consider any data that was not available to the Secretary of State at the time of her decision) and report in writing, with a recommended course of action, to the Secretary of State.

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

(11) If the notification concerns suspension of a marketing authorisation, unless the Secretary of State directs otherwise, the suspension shall take effect when the notification is made and shall continue in force until she makes her final determination.

### **Duties on the Secretary of State relating to exports**

**30.**—(1) At the request of any person exporting a veterinary medicinal product to a third country, or the competent authorities of a third country to which a veterinary medicinal product is to be exported, the Secretary of State shall provide a certificate that the veterinary medicinal product was manufactured in accordance with the marketing authorisation, if there is one, and, if there is no marketing authorisation, that the manufacturer holds a manufacturing authorisation for that type of product.

(2) When she issues the certificate the Secretary of State shall take account of the model certificates issued by the World Health Organization<sup>(a)</sup>.

(3) If the veterinary medicinal product is authorised in the United Kingdom the Secretary of State shall 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.

### **Powers of entry**

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

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

(3) Admission to any premises used only as a private dwellinghouse shall 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 shall continue in force for one month.

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

(7) An inspector shall have the right to enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and of the premises of the marketing authorisation holder.

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

(9) In the application of this regulation to Scotland a reference to a justice of the peace includes a reference to the sheriff and to a magistrate.

### **Powers of inspectors**

**34.** 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) examine or seize any documents or records (including financial records);
- (e) seize any computers and associated equipment for the purpose of copying documents provided they are returned as soon as practicable;
- (f) seize any veterinary medicinal product or anything purporting to be a veterinary medicinal product, and if he does so in circumstances where regulation 40 applies he shall act in accordance with that regulation;
- (g) carry out any inquiries, examinations and tests;
- (h) have access to, and inspect and copy any documents or records (in whatever form they are held) kept under these Regulations, or remove such records to enable them to be copied;
- (i) have access to, inspect and check the operation of any computer and any associated apparatus or material which 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.

### **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.—(1) 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 which 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 which 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 which constitute the failure so to comply;
- (c) specifies the measures which, in the officer’s opinion, the person must take in order to secure compliance; and
- (d) requires the person to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be 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) shall be by way of complaint, and the Magistrates’ Courts Act 1980(a) shall apply to the proceedings.

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

(4) The period within which an appeal may be brought shall be one month or the period specified in the improvement notice, whichever ends the earlier.

(5) An improvement notice shall 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.

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

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

39. On an appeal against an improvement notice, the court may either cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the court may in the circumstances think fit.

### **Seizure notices**

40.—(1) If an inspector finds any veterinary medicinal product that does not appear to him to be authorised in the United Kingdom, or any authorised veterinary medicinal product not lawfully supplied in accordance with these Regulations, he may seize it.

(2) He shall give to the person appearing to him to be in charge of the veterinary medicinal 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 movement of the products until they are collected, and any person who moves products identified under this paragraph is guilty of an offence.

(4) Any person claiming that the product was not liable to seizure shall, within one month of the seizure notify his claim to the Secretary of State at the address specified in the original notice, setting out the grounds in full.

(5) If a notification of a claim is not received within one month the Secretary of State shall destroy the product.

(6) If a notification of a claim is received within one month, the Secretary of State shall either return the goods or take proceedings for an order for the destruction of the veterinary medicinal product in a magistrates’ court (or, in Scotland, the sheriff court), and if the court finds that the veterinary medicinal product did not have a marketing authorisation in the United Kingdom, or had not been supplied in accordance with these Regulations, it shall order its destruction.

(7) The person on whom the original notice was served is liable for the costs of destruction.

(8) This regulation applies to additives, premixtures and feedingstuffs specified in Schedule 5 in the same way as it applies to veterinary medicinal products.

### **Publication of notices**

41. The Secretary of State shall publicise improvement notices and seizure notices in such manner as she shall see 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, as well as the body corporate, is guilty of the offence and is liable to be proceeded against and punished accordingly.

(3) For the purposes of paragraph (2)(b) 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 which 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 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 shall exercise the powers of the Secretary of State in—

- (a) regulation 32 (appointment of inspectors);
- (b) regulation 40 (seizure notices);
- (c) regulation 41 (publication of notices); and
- (d) sub-paragraph (4) of paragraph 9 of Schedule 3 (approval of premises for suitably qualified persons).

(3) In proceedings in a magistrate’s court relating to an improvement notice under regulation 38, the Magistrates’ Courts (Northern Ireland) Order 1981(a) shall apply.

### **Revocations and amendments**

**44.**—(1) The Medicines Act 1968(b) does not apply in relation to veterinary medicinal products.

(2) The Medicines (Prohibition of Importation and Possession of Veterinary Drugs Order (Northern Ireland) 1977(c) continues in force notwithstanding paragraph (1), and the Medicines Act 1968 shall continue to apply in so far as is necessary for the operation of that Order.

(3) The Consumer Protection Act 1987(d) does not apply in relation to veterinary medicinal products.

(4) The instruments in Part 1 of Schedule 8 are revoked.

(5) The instruments in Part 2 of that Schedule are revoked on 1st January 2006.

(6) The instruments in Part 3 of that Schedule have effect subject to the amendments specified.

(7) Part 4 of that Schedule (transitional provisions) has effect, and the provisions relating to feedingstuffs have effect on 1st January 2006.

(8) For the avoidance of doubt, the fact that the Medicines Act 1968 does not apply in relation to veterinary medicinal products does not prevent the preparation of information on veterinary medicinal products in the British Pharmacopoeia.

17th September 2005

*Ben Bradshaw*  
Parliamentary Under-Secretary of State  
Department for Environment, Food and Rural Affairs

6th October 2005

*Joan Ryan*  
*Vernon Coaker*  
Two of the Lords Commissioners of Her Majesty’s Treasury

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(a) S. I. 1981/1675 (N.I. 26).  
(b) 1968 c. 67.  
(c) S.R. (NI) 1977 No. 359.  
(d) 1987 c.43.

Marketing authorisations

ARRANGEMENT OF PROVISIONS

PART 1

Application for a marketing authorisation

1. Application for a marketing authorisation
2. Information with the application
3. Summary of product characteristics
4. Supply of a copy of the summary of product characteristics
5. Time limits for applications for products for use in food-producing animals

PART 2

Derogations from some of the requirements in Part 1

6. Scope
7. Bibliographic applications
8. Applications for products using a new combination of active substances
9. Applications using existing data
10. Application for a pharmacologically equivalent medicinal product
11. Time limits for marketing authorisations granted under the procedure for a pharmacologically equivalent product
12. Extension of time limits
13. Parallel imports
14. Specific batch control scheme
15. Similar immunological products
16. Marketing in exceptional circumstances

PART 3

Grant of a marketing authorisation

17. Time limits
18. Place of establishment of applicant
19. Procedure
20. Products authorised in another member State
21. Assessment reports
22. Grant of a marketing authorisation
23. Marketing authorisations for food-producing animals
24. Refusal of a marketing authorisation
25. Publication following the grant of a marketing authorisation
26. Provisional marketing authorisation
27. Provisions of samples and expertise
28. Supply of information
29. Duties on the holder of a marketing authorisation relating to an immunological product
30. Control tests
31. Placing on the market

32. Duration and validity of a marketing authorisation

#### PART 4

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

33. Variation of a marketing authorisation for a mutually recognised veterinary medicinal product
34. Variation of a marketing authorisation not authorised in another member State
35. Administrative variations
36. Changes after a marketing authorisation has been issued
37. Compulsory variation

#### PART 5

##### Suspension and revocation of a marketing authorisation

38. Suspension, etc., of a marketing authorisation
39. Suspension, etc., of a marketing authorisation of a product authorised in more than one member State
40. Prohibiting the supply of veterinary medicinal products

#### PART 6

##### Mutual recognition and multiple applications

41. Application for a marketing authorisation where one already exists in another member State
42. Application in another member State
43. Application for a marketing authorisation in multiple member States where a marketing authorisation does not exist in any member State

#### PART 7

##### Labelling and package leaflets

44. Approval by the Secretary of State
45. Reference to being authorised
46. Language
47. Labelling with all the information on the immediate packaging
48. Products with immediate and outer packaging
49. Package leaflets
50. Ampoules
51. Small containers other than ampoules
52. Homoeopathic veterinary medicinal products
53. Variations

#### PART 8

##### Pharmacovigilance

54. Qualified persons responsible for pharmacovigilance
55. Duties relating to the qualified person
56. Adverse reactions to a veterinary medicinal product administered in the United Kingdom
57. Adverse reactions to a veterinary medicinal product administered in a third country
58. Periodic safety update reports

- 59. Release of information by the marketing authorisation holder
- 60. Action taken on account of pharmacovigilance

## PART 9

### Homoeopathic veterinary medicinal products

- 61. Meaning of “homoeopathic veterinary medicinal product”
- 62. Registration of a homoeopathic veterinary medicinal product
- 63. Application for registration
- 64. Procedure for registration
- 65. Products on the market before 1994
- 66. Administration

## 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 shall 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(a), generated in accordance with that Annex.

(3) The application shall 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 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;
- (c) the qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its international non-proprietary name (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;

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(a) 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).

- (g) any proposed precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals and 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>(a)</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, a copy of 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 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.

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<sup>(a)</sup> 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).

### Summary of product characteristics

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

| <b>Summary of product characteristics</b> |  |
|---|--|
| 1   | Name of the veterinary medicinal product, including 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;   |
| 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.  |

### 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 (including food-producing horses), 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 applications

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.

#### Applications for products 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.

#### Applications using existing data

9. If the Secretary of State has granted a marketing authorisation, the holder may permit her to use 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 shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

- (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(1), third paragraph of Directive 2001/82/EC by the member State in which the product is authorised are insufficient for her to be satisfied of this, she 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 shall 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 shall be 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 submits 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 period provided for in the paragraph 11(3) shall be extended by one year for each additional food-producing species added to the marketing authorisation.

(3) The total period shall not exceed 13 years.

(4) The extension shall be granted 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 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 European 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 she 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.

## **PART 3**

### **Grant of a marketing authorisation**

#### **Time limits**

**17.** The Secretary of State shall 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 she 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, she shall 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 shall 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 shall inform the applicant of the summary of product characteristics that she has approved, and the distribution category of the product.

## **Marketing authorisations for food-producing animals**

23.—(1) The Secretary of State shall 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 shall not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared as not intended for slaughter for human consumption in accordance with—

- (a) the Horse Passports (England) Regulations 2004(a);
- (b) the Horse Passports Regulations (Northern Ireland) 2004(b);
- (c) the Horse Passports (Scotland) Regulations 2005(c);
- (d) the Horse Passports (Wales) Regulations 2005(d),

but the product shall neither include active substances that appear in Annex IV to Council Regulation (EEC) No. 2377/90 nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorised for horses.

(3) In this paragraph “horse” includes any member of the equidae family.

## **Refusal of a marketing authorisation**

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

(2) In addition, she shall refuse to grant it if—

- 
- (a) S.I. 2004/1397.
  - (b) S.R. (NI) 2004 No. 497.
  - (c) S.S.I. 2005/223.
  - (d) S.I. 2005/231 (W. 21).

- (a) the data submitted with the application are inadequate;
  - (b) the risk-benefit balance of the veterinary medicinal product is unfavourable so that the risks outweigh the benefits;
  - (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 a marketing authorisation—
- (a) if there is Community legislation pending that is incompatible with the requested authorisation; or
  - (b) if she requests additional data and those data are not provided within such time limit as she may stipulate.

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

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

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

(2) She shall 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) She shall send a copy of the assessment report, and any update, to the holder of the marketing authorisation before she publishes it to enable the holder to make representations to her 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 shall 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.

(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) 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 at least ten days before he places the product on the market.

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

#### **Control tests**

**30.**—(1) 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.

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

#### **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 of the fact 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 her 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 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 valid indefinitely.

(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)(a).

#### **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 shall 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) In granting a variation of a veterinary medicinal product the Secretary of State shall (unless there are exceptional circumstances necessary to protect human or animal health or the environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

#### **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, she shall 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.

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

### **Compulsory variation**

37.—(1) If the Secretary of State decides, in order to protect human or animal health or the environment that a variation to a marketing authorisation is necessary, she shall notify the marketing authorisation holder in writing of the required variation, together with her reasons.

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

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

## **PART 5**

### **Suspension and revocation of a marketing authorisation**

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

38.—(1) The Secretary of State may suspend, vary or revoke a marketing authorisation at any time if she 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;
- (c) the veterinary medicinal product has insufficient therapeutic effect.

(2) She must suspend, vary or revoke a marketing authorisation if she 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;
- (f) any information required to be supplied to the Secretary of State has not been communicated to her.

(3) She may also suspend, vary or revoke a marketing authorisation if she 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 a veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(4) When she suspends, varies or revokes a marketing authorisation, the Secretary of State may additionally prohibit the supply of a 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.

(5) She shall publicise a revocation in such manner as she sees fit.

#### **Suspension, etc., of a marketing authorisation of a product authorised in more than one member State**

39.—(1) In the case of a veterinary medicinal product that is authorised in more than one member State, where the Secretary of State considers that a variation or its suspension or withdrawal is necessary for the protection of human or animal health or the environment, she shall immediately refer the matter to the Agency, and shall comply with a decision of the Agency within 30 days of the decision.

(2) Where the Secretary of State considers that immediate suspension is necessary to protect human or animal health or the environment, she may suspend the marketing and the use of the veterinary medicinal product concerned in the United Kingdom pending a decision of the Agency, and in this case she shall inform the Commission and the other member States no later than the following working day of the reasons for her action.

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

**40.**—(1) In addition to her powers to suspend a marketing authorisation, if she 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) She may confine the prohibition on supply and the requirement for recall to specific production batches.

(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 her 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**

**41.**—(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 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 shall obtain an assessment report from the reference member State and, if the application is made under paragraph 7 (bibliographic applications) or paragraph 10 (applications for pharmacologically equivalent products) of Part 2, ask for the report to include an explanation of any extension of the protection period generated under paragraph 11 or 12.

(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 shall inform the reference member State accordingly; or
- (b) notify the reference member State that she will not approve them, and provide the reference member State with a detailed statement of the reasons.

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

(8) If she approves the assessment report, the summary of product characteristics, the labelling and the package leaflet she shall ensure that she 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 shall comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission within 30 days.

(10) If the Secretary of State wishes to do so, she may grant the marketing authorisation even though not all member States have agreed to grant it, but shall 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**

42.—(1) When the Secretary of State has granted a marketing authorisation for a veterinary medicinal product and she is notified by the marketing authorisation holder that he has applied to have that veterinary medicinal product authorised in another member State, she shall 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 she need take no further action.

(3) If not all the other member States concerned agree with the assessment report, the summary of product characteristics, the labelling and the package leaflet within a further 90 days she shall 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 shall comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission within 30 days.

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

43.—(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 shall 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 shall 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 shall, subject to the following provisions, either—



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

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

(5) If all the member States concerned agree the assessment report, the summary of product characteristics, the labelling and the package leaflet within 90 days, the Secretary of State shall ensure that she 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 or animal health or to the environment, the Secretary of State (if the United Kingdom is the reference member State) shall 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 shall comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission within 30 days.

(8) If the Secretary of State wishes to do so, she may grant the marketing authorisation even though not all member States have agreed to grant it, but shall 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**

44. When the Secretary of State issues the marketing authorisation she shall approve all containers, packaging, labels and package leaflets.

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

45.—(1) All labels and package leaflets of an authorised veterinary medicinal product must contain in legible characters the words “UK authorised veterinary medicinal product”.

(2) The Secretary of State may stipulate in the marketing authorisation that this is not necessary on the label if she is satisfied that there is insufficient space.

#### **Language**

46.—(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 supervision of that same veterinary surgeon.

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

47.—(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;
- (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 necessity for any outer packaging or a package leaflet.

**Products with immediate and outer packaging**

48.—(1) If it is not reasonably practicable to have all the 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 information in paragraph 47 as is reasonably practicable, in the order set out in that paragraph.

(4) The outer packaging must contain all the information in paragraph 47 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.

### **Package leaflets**

**49.**—(1) If it is not reasonably practicable to have all the information in paragraph 47 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 information in paragraph 47 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 shall relate solely to the veterinary medicinal product with which it is included.

(4) It must be written in terms that are comprehensible to the general public.

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

### **Ampoules**

**50.**—(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 information in paragraph 47 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**

**51.** As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the particulars mentioned in paragraph 47, all the information in paragraph 47 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 veterinary medicinal products**

**52.**—(1) A homeopathic veterinary medicinal product 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 veterinary medicinal product without approved therapeutic indications for veterinary use”;

- (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 veterinary medicinal product 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**

**53.** 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**

**54.**—(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**

**55.**—(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 she 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 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**

**56.**—(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>(a)</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/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**

**57.**—(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.

(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, the information required under paragraph 56(4) in the manner set out in that paragraph.

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

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(a) 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)

### **Periodic safety update reports**

**58.**—(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 or 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) 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.

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

**59.**—(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**

**60.**—(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,

she shall forthwith inform the Agency, all other member States (irrespective of whether the product is authorised in another member State) and the marketing authorisation holder and shall ask for the opinion of the Agency.

(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 she 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 shall comply with that request immediately on a temporary basis.

(4) The Secretary of State shall take final measures in accordance with the Decision of the Commission in accordance with Article 78(3) of Directive 2001/82/EC.

## PART 9

### Homoeopathic veterinary medicinal products

#### **Meaning of “homoeopathic veterinary medicinal product”**

**61.** For the purposes of this Part, a homoeopathic veterinary medicinal product is a veterinary medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia<sup>(a)</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.

#### **Registration of a homoeopathic veterinary medicinal product**

**62.—**(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation, a homoeopathic medicinal product may be placed on the market in accordance with a registration by the Secretary of State instead of 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.

#### **Application for registration**

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

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(a) ISBN 9287145873

- (a) the scientific name or other name of the homoeopathic 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 homoeopathic stock is obtained and controlled, and justifying its homoeopathic 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 medicinal product 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, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) 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 she is satisfied that it is reasonable to do so.

#### **Procedure for registration**

**64.**—(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 therapeutic effect;
- (b) the product shall not have a summary of product characteristics;
- (c) the Secretary of State shall not 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**

**65.** The requirement to register does not apply in relation to a product that was on the market as a veterinary medicinal product before 1st January 1994.

#### **Administration**

**66.** The registration must specify that a homoeopathic veterinary medicinal product may only be administered under the responsibility of a veterinary surgeon.

## SCHEDULE 2

Regulation 5(2)

### The manufacture of veterinary medicinal products

## ARRANGEMENT OF PROVISIONS

### PART 1



## Manufacturing authorisation

1. Application
2. Time limits
3. Granting the authorisation
4. The authorisation
5. Suspension or revocation of the authorisation
6. Representation to the Secretary of State
7. Inspection of premises
8. Report following inspection
9. Duties on the holder of a manufacturing authorisation
10. Qualified persons for manufacture
11. Refusal or revocation of appointment
12. Duties on a qualified person
13. Register
14. Test sites

## PART 2

### Authorisation of manufacturers of autogenous vaccines

15. Authorisation to manufacture autogenous vaccines
16. Types of authorisation
17. Labelling
18. Records
19. Adverse reactions
20. Inspection of premises

## PART 3

### Authorisation of blood banks

21. Authorisation of blood banks
22. Supply and administration of blood from a blood bank
23. Labelling
24. Records
25. Inspection of blood banks

## PART 1

### Manufacturing authorisation

#### **Application**

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

#### **Time limits**

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

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

### **Granting the authorisation**

3. The Secretary of State shall grant a manufacturing authorisation if she 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 shall 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;
- (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 authorisation;
- (c) has produced a veterinary medicinal product outside the terms of a marketing authorisation;
- (d) no longer has suitable premises or equipment.

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

### **Representation to the Secretary of State**

6.—(1) A person may make representations 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 shall consider the representations and report in writing to the Secretary of State.

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

### **Inspection of premises**

7.—(1) The Secretary of State shall 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 shall 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>(a)</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 shall issue a certificate of compliance with the monograph, if appropriate.

(4) The Secretary of State shall provide details of each certificate of good manufacturing practice that she 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, she shall provide details to the Agency for entry into the database.

### **Report following inspection**

8.—(1) After each inspection of manufacturing premises, the inspector shall 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.

(2) The Secretary of State shall 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 she 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; or

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

- (b) a Chartered Chemist or a Fellow or a Member or Associate Member of the Royal Society of Chemistry; or
- (c) a Chartered Biologist or a Fellow (or a Member or an 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 she 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 she is not satisfied that a person has fulfilled or will fulfil his duties.

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

### **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 shall 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 sub-paragraph (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 shall 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 for administration in accordance with regulation 15.

(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 she 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 shall specify the products that may be manufactured.

(2) It shall 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 the authorisation shall 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 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;
- (g) instructions for use, if any.

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

#### Records

18.—(1) The operator of premises manufacturing autogenous vaccines must, as soon as is reasonably practicable, record—

- (a) the name and address of the veterinary surgeon who ordered the vaccine;
- (b) the identity 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. The authorised person must notify the Secretary of State of any adverse reactions to an autogenous vaccine of which he becomes aware within 15 days of learning of the reaction.

#### **Inspection of premises**

20. The Secretary of State shall 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 she authorises a blood bank, the Secretary of State must be satisfied —

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

(4) Procedure for the suspension or revocation of the authorisation shall be the same as for the holder of a manufacturing authorisation.

(5) Blood may only be collected under the supervision 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 supervision.

(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 must ensure that every container used for the blood is labelled with—

- (a) the identity of the donor animal;
- (b) the date of collection;
- (c) the name of the veterinary surgeon who collected it;
- (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 identity 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 shall inspect a blood bank every two years.

# **SCHEDULE 3**

Regulations 7(1) and 13

## **Classification and supply and wholesale dealers**

### **ARRANGEMENT OF PROVISIONS**

#### **PART 1**

##### **Classification and supply of authorised veterinary medicinal products**

1. Classification of veterinary medicinal products
2. Wholesale supply of veterinary medicinal products
3. Retail supply of veterinary medicinal products
4. Supply of products for incorporation into feedingstuffs
5. Prescriptions
6. Form of prescription
7. Labelling at the time of retail supply
8. Supply of veterinary medicinal products for use under the cascade
9. Supply by a suitably qualified person
10. Annual audit
11. Supply of sheep dip

#### **PART 2**

##### **Requirements for a wholesale dealer's authorisation**

12. Application
13. Time limits
14. Granting the authorisation
15. The authorisation
16. Suspension or revocation of the authorisation
17. Representations
18. Duties on the holder of a wholesale dealer's authorisation

## PART 1

### Classification and supply of authorised veterinary medicinal products

#### Classification of veterinary medicinal products

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

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

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

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

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

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

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

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

#### Wholesale supply of veterinary medicinal products

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

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

(3) If the supply is to a suitably qualified person, it must be to the premises approved in accordance with paragraph 9.

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

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

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



### **Retail supply of veterinary medicinal products**

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

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

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

- (a) a veterinary surgeon;
- (b) a pharmacist; or
- (c) a suitably qualified person in accordance with paragraph 9,

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

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

- (a) a veterinary surgeon;
- (b) a pharmacist; or
- (c) a suitably qualified person in accordance with paragraph 9.

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

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

- (a) must always advise on the safe administration of the veterinary medicinal product;
- (b) must advise as necessary on any warnings or contra-indications on the label or package leaflet;
- (c) must be satisfied that the person who will use the product is competent to use it safely, and intends to use it for a use for which it is authorised.

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

(8) In this paragraph—

- (a) “retail supply” means any supply other than to or from the holder of a wholesale dealer’s authorisation, and whether or not for payment; and
- (b) a person may supply a product irrespective of who owns it.

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

### **Supply of products for incorporation into feedingstuffs**

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

- (a) an approved premixture manufacturer; or
- (b) a feedingstuffs manufacturer where the approval so permits.

### **Prescriptions**

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

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

### **Form of prescription**

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

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

- (a) the name and address of the person prescribing the product;
- (b) the qualifications enabling the person to prescribe the product;
- (c) the name and address of the owner or keeper;
- (d) the species of animal, identification and number of the animals;
- (e) the premises at which the animals are kept if this is different from the address of the owner or keeper;
- (f) the date of the prescription;
- (g) the signature or other authentication of the person prescribing the product;
- (h) the name and amount of the product prescribed;
- (i) the dosage and administration instructions;
- (j) any necessary warnings;
- (k) the withdrawal period if relevant.

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

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

(5) If the prescription is a repeatable prescription that does not specify the number of times the product may be supplied, the prescription may only be repeated once.

### **Labelling at the time of retail supply**

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

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

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

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

- (a) the name and address of the dispensing pharmacy or veterinary surgery;
- (b) the name of the veterinary surgeon who has prescribed the product;
- (c) the name and address of the animal owner;
- (d) the identification of the animal or group of animals;
- (e) the date of dispensing;
- (f) the expiry date of the product, if applicable;
- (g) the name or description of the product which should include at least the name and quantity of active ingredients;
- (h) dosage and administration instructions;

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

- (i) any special storage precautions;
  - (j) any necessary warnings for the user, target species, administration or disposal of the product.
- (3) It is an offence to fail to comply with this paragraph.

### **Supply by a suitably qualified person**

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

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

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

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

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

(5) The Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph shall ensure that a suitably qualified person registered with it complies with the Code of Practice.

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

### **Annual audit**

**10.**—(1) At least once a year every person entitled to supply a veterinary medicinal product on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicinal products shall be reconciled with products currently held in stock, any discrepancies being recorded.

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

### **Supply of sheep dip**

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

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

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

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

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

# **SHEEP DIPPING**

## **PLEASE READ THIS NOTICE FOR YOUR OWN SAFETY**

1. The product label carries important advice. Please read it and do what it says.
2. Always wear the recommended protective clothing, including gloves. Sheep dip is absorbed through the skin.
3. Always wash protective clothing before taking it off.
4. If you get sheep dip on your skin wash it off immediately.
5. If you have questions, ask your sheep dip supplier. At your merchants you should speak to the Suitably Qualified Person.
6. Read the label for instructions on measuring and diluting concentrate.
7. Check that you have spare protective clothing, especially gloves, in case of damage.

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

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

The recommended protective clothing is:

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

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

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

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

**Wellington boots**



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

## PART 2

### Requirements for a wholesale dealer's authorisation

#### Application

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

#### Time limits

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

#### Granting the authorisation

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

(2) The authorised site must be—

- (a) weatherproof;
- (b) secure and lockable;
- (c) clean;
- (d) free from contaminants.

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

(4) The authorisation holder must—

- (a) have at his disposal the services of technically competent staff, and
- (b) have an effective emergency recall plan.

#### The authorisation

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

- (a) the types of veterinary medicinal products and pharmaceutical forms that may be dealt in;
- (b) the place where they are to be stored;
- (c) the name and address of the person holding the authorisation;
- (d) the address of the premises to which it relates;
- (e) the name of the qualified person nominated to act under the Guidelines on good distribution practice under paragraph 18.

(2) It may cover more than one site.

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

#### Suspension or revocation of the authorisation

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

- (a) has not complied with these Regulations; or
- (b) no longer has suitable premises or equipment.

## Representations

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

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

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

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

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

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

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

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

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

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

# SCHEDULE 4

Regulation 8

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

### ARRANGEMENT OF PROVISIONS

1. Administration
2. Administration under the cascade
3. Withdrawal periods
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

## Administration

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

## Administration under the cascade

2.—(1) If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, 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

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



- (b) if and only if there is no such product that is suitable, either—
  - (i) a medicinal product authorised in the United Kingdom for human use; 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
- (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.

(2) 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.

(3) For the purposes of this paragraph a food-producing animal includes an animal belonging to the equidae family unless it has been declared, in accordance with Commission Decisions 93/623/EEC (establishing the identification document (passport) accompanying registered equidae(a)) and 2000/68/EC (amending Decision 93/623/EEC and establishing the identification of equidae for breeding and production(b)), as not being intended for slaughter for human consumption.

(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**

3.—(1) A veterinary surgeon 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 (e) for fish meat.

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

### **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.

(2) She shall publicise any permit in such manner as she shall see fit.

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(a) OJ No. L298, 3.12.1993, p. 45.

(b) OJ No. L 23, 28.1.2000, p. 72.

(c) The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.

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

5. If an animal is being imported from, or exported to, a third country, the Secretary of State may permit the administration, for the animal in question, 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 Code of Professional Conduct issued by the Royal College of Veterinary Surgeons<sup>(a)</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, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied, and shall 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 veterinary 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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(a) Published at [www.rcvs.org.uk/P F A .asp?NodeID=89642](http://www.rcvs.org.uk/P F A .asp?NodeID=89642).

## Medicated feedingstuffs and specified feed additives

## ARRANGEMENT OF PROVISIONS

1. Scope and interpretation
2. Enforcement of Regulation (EC) No. 178/2002
3. Enforcement of Regulation (EC) No. 1831/2003
4. Enforcement of Regulation (EC) No. 882/2004
5. Enforcement of Regulation (EC) No. 183/2005
6. Incorporation of a veterinary medicinal product into premixtures
7. Incorporation of a veterinary medicinal product into feedingstuffs
8. Additional record keeping requirements relating to veterinary medicinal products
9. Additional labelling requirement for premixtures containing a veterinary medicinal product
10. Labelling of feedingstuffs containing specified feed additives
11. Labelling of feedingstuffs containing a veterinary medicinal product
12. Supply of specified feed additives
13. Supply of premixture
14. Supply of feedingstuffs containing a veterinary medicinal product
15. Possession
16. Sampling and analysis
17. Storage
18. Packages and other containers
19. Transport
20. Possession, placing on the market and use of feedingstuffs
21. Prescriptions for feedingstuffs containing a veterinary medicinal product
22. Imports from third countries
23. Trade between member States

**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 feed 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 Council 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>(a)</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 feed);
- (d) Article 16 so far as it prohibits misleading labelling, advertising or presentation of feed;
- (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>(b)</sup>) the competent authority is the Secretary of State.

(2) When she grants an authorisation under Article 3(2) of that Regulation the authorisation shall be in writing.

(3) 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>(c)</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>(d)</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) and (6) (specific obligations);

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

(b) OJ No. L 268, 18.10.2003, p. 29.

(c) Corrected version at OJ No. L 191, 28.5.2004, p. 1.

(d) OJ No. L35, 8.2.2005, p. 1.

- (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);
- (i) Article 25 (feed produced for export to third countries).

(3) In accordance with Article 10(2) of that Regulation—

- (a) a manufacturer incorporating a veterinary medicinal product into feedingstuffs, and
- (b) any person acting as a distributor of feedingstuffs containing a veterinary medicinal product,

must be approved in the same way as a manufacturer incorporating specified feed additives or distributor of feedingstuffs containing specified feed additives.

(4) 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.

(5) In the case of the refusal, suspension or revocation of an approval under the Regulation the representations procedure relating to a manufacturing authorisation in paragraph 6 of Schedule 2 shall apply.

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

6.—(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**

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

- (a) must ensure that the feedingstuff has been prescribed in writing by a person authorised to prescribe the veterinary medicinal product;
- (b) must incorporate in accordance with the summary of product characteristics, and must take account of any interactions listed there;
- (c) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive;
- (d) 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, if any;
- (e) 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 feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral supplementary feedingstuffs.

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

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

8.—(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,

shall maintain a daily record of—

- (i) the types and quantities of all veterinary medicinal products (and specified feed additives, if any) and premixtures used in the manufacturing process;
- (ii) the quantity of feedingstuffs and premixtures containing veterinary medicinal product manufactured that day;
- (iii) the quantity held;
- (iv) the quantity despatched;
- (v) the name and address of the distributor, if there is one.

(2) Manufacturers who supply feedingstuffs incorporating a veterinary medicinal product shall record the names and addresses of persons supplied and keep a copy of the prescription.

(3) An approved distributor shall record daily—

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

(4) He shall also record, in relation to each consignment supplied—

- (a) the date of delivery;
- (b) the name and address of each consignee;
- (c) the type of feedingstuff or premixture supplied;
- (d) the quantity;
- (e) the type of veterinary medicinal product incorporated into the feedingstuff; and
- (f) the expiry date.

(5) Records and prescriptions must be kept for five years.

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

### **Additional labelling requirement for premixtures containing a veterinary medicinal product**

9. A label on a premixture containing a veterinary medicinal product must contain the information required under Article 16 of Regulation (EC) No. 1831/2003 and, in addition, the following—

- (a) the words “medicated premixture”;
- (b) the proprietary name of the veterinary medicinal product and the authorisation number;
- (c) the strength;
- (d) the inclusion rate of the premixture into the feedingstuff;
- (e) the level of the active ingredient in the final feed;
- (f) warnings and contra-indications;
- (g) withdrawal period;
- (h) the expiry date;
- (i) any special storage instructions;
- (j) where a prescription is required, a statement to this effect;

and any person who supplies such a premixture not labelled in this way is guilty of an offence.

### **Labelling of feedingstuffs containing specified feed additives**

**10.**—(1) Feedingstuffs containing a specified feed additive or a premixture 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 of the active substance and the level incorporated in the feedingstuff;
- (c) the withdrawal period if one is specified in the authorisation;
- (d) the expiry date (if there are several additives with different expiry dates, the expiry date given must be the earliest 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 feedingstuffs not labelled in accordance with this paragraph.

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

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

- (a) the words “Medicated Feedingstuff”;
- (b) the proprietary name, authorisation number and inclusion rate (kg/t or mg/kg) of the veterinary medicinal product incorporated into the feed;
- (c) the name and amount of the active substance (mg/kg) in the feed;
- (d) the species of animal for which the feed is intended;
- (e) warnings and contra-indications required by the marketing authorisation for the veterinary medicinal product;
- (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 feed must only be fed in accordance with a prescription written by a veterinary surgeon, where a prescription is required;
- (j) the name and approval number of the manufacturer or the distributor.

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

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

**12.**—(1) A manufacturer of specified feed additives may only supply them to a person approved to hold them in accordance with this Schedule.

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

### **Supply of premixture**

**13.**—(1) A manufacturer of a premixture may only supply it to a person approved to hold it in accordance with this Schedule.

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

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

**14.**—(1) A manufacturer or distributor of feedingstuffs containing a veterinary medicinal product may only supply to—

- (a) a person approved to hold them in accordance with this Schedule, or

(b) a person who keeps animals.

(2) If the veterinary medicinal product requires a prescription, the manufacturer or distributor may supply to another manufacturer or a distributor without a prescription, but may only supply to a person who keeps animals in accordance with a prescription.

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

### **Possession**

**15.**—(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) feedingstuff containing 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 a feedingstuff incorporating a veterinary medicinal product unless it has been supplied under a prescription.

### **Sampling and analysis**

**16.**—(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<sup>(a)</sup>).

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

- (a) not exceeding 50 mg/kg of active ingredient: +/- 50%;
- (b) exceeding 50 mg/kg but not exceeding 500 mg/kg: +/- 40%;
- (c) exceeding 500 mg/kg but not exceeding 5g/kg: +/- 30%;
- (d) exceeding 5g/kg but not exceeding 50g/kg: +/- 20%;
- (e) exceeding 50g/kg: +/- 10%.

### **Storage**

**17.**—(1) Any person who stores veterinary medicinal products intended for incorporation into feedingstuffs, or premixtures or feedingstuffs containing such veterinary medicinal products shall do so in a suitable storage area that is locked when not in use or in hermetic containers designed to store those products.

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

### **Packages and other containers**

**18.**—(1) Any person placing feedingstuffs containing a veterinary medicinal product on the market in packages or containers must ensure that they are sealed in such a way that, when the package or container is opened, the seal is damaged.

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

### **Transport**

**19.**—(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

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



must hand over details when he delivers the feedingstuff 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 a feedingstuff 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**

**20.**—(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 shall 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.

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

**21.**—(1) It is an offence to supply feedingstuffs containing a veterinary medicinal product except in accordance with a written prescription that contains the following in addition to the information required by paragraph 6 of Schedule 3—

- (a) the manufacturer or the distributor;
- (b) a statement that, if the validity exceeds one month, only 31 days supply may be provided at any time;
- (c) the name, type and quantity of feedingstuffs to be used;
- (d) the inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance;
- (e) any special instructions for the stockfarmer;
- (f) the percentage of the prescribed feedingstuffs to be added to the daily ration.

(2) A prescription for feedingstuffs is valid for three months or such shorter period as may be specified in the prescription.

(3) The prescription must be sufficient for only one course of treatment.

(4) If the 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.

(5) The person who writes the prescription must—

- (a) give a copy to the person incorporating the veterinary medicinal product or to the distributor;
- (b) give one copy to the keeper of the animals to be treated;
- (c) keep a copy himself.

(6) The person who writes the prescription 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.

(7) 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.

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

### **Imports from third countries**

22. No person shall import feedingstuffs containing a veterinary medicinal product from a third country, and it is an offence to fail to comply with this paragraph.

### **Trade between member States**

23.—(1) No person shall bring in feedingstuffs containing a veterinary medicinal product from another member State unless—

- (a) it 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<sup>(a)</sup>) and Regulation (EC) No. 183/2005; and
- (b) it uses a veterinary medicinal product that has the same quantitative and qualitative composition as a veterinary medicinal product authorised in the United Kingdom.

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

## **SCHEDULE 6**

Regulation 15(4)

### **Exemptions for small pet animals**

#### **ARRANGEMENT OF PROVISIONS**

1. Animals to which this Schedule applies
2. Placing on the market
3. Manufacture
4. The active substance
5. The product
6. Labelling
7. Administration
8. Pack size
9. Adverse reactions

#### **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;

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(a) OJ No. L92, 7.4.90, p.42.

- (c) ferrets;
- (d) homing pigeons;
- (e) rabbits;
- (f) small rodents; and
- (g) terrarium animals.

### Placing on the market

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

### Manufacture

3.—(1) The product must be manufactured in the United Kingdom, another member State or in Australia, Canada, New Zealand, or Switzerland (a).

(2) 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 (EC) No. 2001/82 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.

(3) This paragraph shall not apply until 1st November 2007.

### The active substance

4. The veterinary medicinal product must only contain an active substance specified in the following table for the species specified in that table.

Permitted substances and target species

| <i>Substance</i>                           | <i>Fish</i> | <i>Cagebirds</i> | <i>Pigeons</i> |
|--|-------------|------------------|----------------|
| Amprolium hydrochloride                    |             |                  | Y              |
| Carnidazole                                |             |                  | Y              |
| Clazuril                                   |             |                  | Y              |
| Cypermethrin cis50:trans50                 |             |                  | Y              |
| Dimetridazole                              |             |                  | Y              |
| Febantel                                   |             |                  | Y              |
| Fenbendazole                               |             |                  | Y              |
| Levamisole Hydrochloride                   |             |                  | Y              |
| Piperazine dihydrochloride                 |             |                  | Y              |
| Piperonyl butoxide & Pyrethrum powder 1.3% |             | Y                | Y              |
| Pyrethrum extract 25% & piperonyl butoxide |             | Y                | Y              |
| Tricaine methane sulphonate                | Y           |                  |                |

(a) Australia, Canada, New Zealand and Switzerland are the only countries outside the European Union that have mutual recognition agreements on the manufacture of veterinary medicinal products with the European Union.

## **The product**

5.—(1) The veterinary medicinal product must not be an antibiotic.

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

(3) If it contains an active substance contained in a veterinary medicinal product authorised in the United Kingdom as a product that can only be prescribed by a veterinary surgeon, a product containing that active substance must have been so authorised for at least five years.

(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 specified in the table in paragraph 4 does not apply in relation to a veterinary medicinal product on the market at the time this Schedule comes into force until 1st November 2007.

## **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 manufacturing authorisation number (or, in the case of a product manufactured outside the European Union, the wholesale dealing licence number of the importer), and must contain the following —

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

(3) This paragraph does not apply in relation to a veterinary medicinal product on the market at the time this Schedule comes into force until 1st November 2007.

## **Administration**

7. The method of administration must not be parenteral or insertion into the inner ear.

### **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 treatment of an aquarium of 25,000 litres.

### **Adverse reactions**

9.—(1) The manufacturer or importer must notify the Secretary of State of any adverse reactions to a product 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**

#### **ARRANGEMENT OF PROVISIONS**

##### **PART 1**

###### **Introduction**

1. Payment of fees
2. Time of payment
3. Multiple inspections

##### **PART 2**

###### **Fees relating to national marketing authorisations**

4. Scope of Part 2
5. Standard application for a marketing authorisation
6. Application for a marketing authorisation for a product with an active substance not contained in a veterinary medicinal product previously authorised in the United Kingdom
7. Application for a marketing authorisation involving other aspects not previously authorised in a veterinary medicinal product in the UK
8. Pharmacologically equivalent products
9. Application for a marketing authorisation using identical data
10. Application for a provisional marketing authorisation
11. Application for a marketing authorisation relating to a parallel import
12. Application for a variation
13. Application for the renewal of a marketing authorisation
14. Registration of a homoeopathic veterinary medicinal product

##### **PART 3**

###### **Fees relating to decentralised and mutual recognition procedures**

15. Scope of Part 3
16. Provision of information relating to the recognition of United Kingdom marketing authorisation
17. Mutual recognition of a marketing authorisation already granted in another member State
18. Decentralised procedure where the United Kingdom is the reference member State

19. Decentralised procedure where the United Kingdom is not the reference member State
20. Application for a variation
21. Application for the renewal of a marketing authorisation

#### PART 4

##### Fees payable by manufacturers

22. Application for a manufacturing authorisation
23. Application for a variation of a manufacturing authorisation
24. Application for an authorisation to manufacture an autogenous vaccine
25. Annual fees
26. Site inspections – type of site
27. Inspection of a site where immunological veterinary medicinal products are manufactured
28. Inspection of a site where sterile veterinary medicinal products are manufactured
29. Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured
30. Inspection of a site where veterinary medicinal products are assembled
31. Test sites
32. Animal blood bank authorisations
33. Expenses

#### PART 5

##### Fees relating to a wholesale dealer's authorisation

34. Application for a wholesale dealer's authorisation
35. Variation of a wholesale dealer's authorisation
36. Annual fee for a wholesale dealer's authorisation

#### PART 6

##### Fees relating to feedingstuffs

37. Fees relating to feedingstuffs
38. Fees relating to distributors

#### PART 7

##### General

39. Annual fees for marketing authorisations
40. Auditor's certificate
41. Late payment of annual fees
42. Submission of samples in connection with applications for marketing authorisations and animal test certificates
43. Animal Test Certificates
44. Treatment under the cascade
45. Treatment in exceptional circumstances
46. Specific batch control
47. Submission of control tests of an immunological product
48. Export Certificates
49. Fees relating to premises for supply by suitably qualified persons
50. Application to the Veterinary Products Committee

51. Non-payment of fees
52. Waiver or reduction of fees
53. Reduction of fees when an application is withdrawn

## PART 1

### Introduction

#### **Payment of fees**

1. All fees under this Schedule are payable to the Secretary of State.

#### **Time of payment**

2. All fees are payable on invoice unless otherwise specified.

#### **Multiple inspections**

3. If a site is inspected for more than one type of authorisation, only one fee (the highest) is payable.

## PART 2

### Fees relating to national marketing authorisations

#### **Scope of Part 2**

4. This Part has effect in relation to marketing authorisations which are confined to the United Kingdom and where there is not, or has not been, an application using the decentralised or mutual recognition procedures.

#### **Standard application for a marketing authorisation**

5. The fee for an application (referred to in this Schedule as a “standard application”) for a marketing authorisation that does not fall into any of the following categories in this Part is £6,390.

#### **Application for a marketing authorisation for a product with an active substance not contained in a veterinary medicinal product previously authorised in the United Kingdom**

- 6.—(1) The fee for an application for a marketing authorisation for a veterinary medicinal product that contains an active substance which has not previously been included in an authorised veterinary medicinal product in the United Kingdom is £25,500.

(2) This is referred to in this Schedule as an “application for a new active substance”.

(3) If additional applications are submitted at the same time for different strengths of the same active substance in the same dosage form, the fee for each additional strength is £6,390.

(4) If an additional application is submitted at the same time for another dosage form the fee for that additional dosage form is £14,795 and the fee for additional applications for the same dosage form is £ 6,390.

(5) The fee for immunological products submitted at the same time with lesser combination of antigens is £6,390 for each application.

### **Application for a marketing authorisation involving other aspects not previously authorised in a veterinary medicinal product in the UK**

7.—(1) The fee for an application for a marketing authorisation where all the active substances of the veterinary medicinal product have previously been included in a veterinary medicinal product authorised in the United Kingdom but which has an element within the application and supporting data that has not previously been successfully assessed in relation to any of the active substances is £14,795.

(2) This is referred to in this Schedule as a “complex application”.

(3) Examples of applications covered by sub-paragraph (1) are the following relating to any of the active substances—

- (a) a different target species;
- (b) a different indication for the target species;
- (c) a different route of administration;
- (d) a different adjuvant or excipient;
- (e) a different method of sterilisation, synthesis or manufacture;
- (f) the product has a controlled release preparation which is new for that active substance;
- (g) in the case of an immunological product, the product uses a different growth medium;
- (h) the active substance in the product is manufactured by a different manufacturer;
- (i) the active substance is in a different dosage form.

(4) If additional applications are submitted at the same time for different strengths of the same active ingredient in the same dosage form, the fee for each additional strength is £6,390.

### **Pharmacologically equivalent products**

8.—(1) The fee for an application for a marketing authorisation for a product that is pharmacologically equivalent to a product authorised in the United Kingdom is £4,995.

(2) This is referred to in this Schedule as an “application for a pharmacologically equivalent product”.

(3) The fee for such an application where the reference product is authorised within the European Union but not within the United Kingdom is £6,390 plus any translation costs.

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

9. The fee for an application for a marketing authorisation that uses existing data relating to an authorised product and where the new product is identical in all respects (other than the name) to an existing product (referred to in this Schedule as an “application using identical data”) is £1,785.

### **Application for a provisional marketing authorisation**

10.—(1) The fee for an application for a provisional marketing authorisation for a new active substance is £14,795, and the fee for its conversion into a full marketing authorisation is—

- (a) £10,705 if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation, or
- (b) in any other case £25,500.

(2) The fee for a complex application for a provisional marketing authorisation is £6,390, and the fee for its conversion into a full marketing authorisation is—

- (a) £8,405 if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation, or
- (b) in any other case £14,795.



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

11.—(1) The fee for a marketing authorisation for a product imported in accordance with paragraph 13 of Schedule 1 (parallel imports) is £2000 for each member State from which a product is to be imported plus any translation costs.

(2) If the imported product has been authorised in accordance with the Mutual Recognition Procedure or Decentralised Procedure, and the United Kingdom is included within these procedures, the fee is £1650 for one member State on the application plus £330 for each additional member State on the application.

### Application for a variation

12.—(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) The fee for an extension of a marketing authorisation as specified in Annex II to Commission Regulation (EC) No. 1084/2003 is the same as the fee for an application for a marketing authorisation for that product.

(3) If the variation is one specified in Annex I to Commission Regulation (EC) No. 1084/2003, the fee is £330 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 £770 except in the following case—

#### 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<br><br>Supporting data are identical<br><br>All applications are submitted at the same time | The fee for the first product is £770 and the fee for each subsequent product is £330 |

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No. 1084/2003 is £2,540 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.<br>– Supporting data are identical.<br>– All applications are submitted at the same time | The fee for the first product is £2540, and the fee for each subsequent product is £330 |
| b) Change of Distributor.                     | – No other aspect of the dossier is changed and the marketing authorisation holder remains the same.  | £770  |

| <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.  | £770       |
| d) Simple dosage instruction changes intended to remove ambiguity.   | – The change is not as a result of safety concerns.<br>– No new studies are required to support the change.<br>– The dosage regime remains the same.  | £770       |
| e) Addition or change to safety warnings.  | – No other aspects of the dossier are changed.<br>– No safety warnings are removed.<br>– 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.   | £770       |
| f) Corrections or simple text lay out 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.<br>– No new studies are required to support the change and no other aspect of the dossier is changed.<br>– The legibility of the current English labelling is not compromised.<br>– The indications and warnings are the same in all languages   | £770       |
| 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.<br>– The application has been resubmitted within 3 months of the date the refusal advice was issued  | £770       |
| 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.<br>– The change is not required as a result of the holder failing to keep the Part II (quality) data in accord with current practice or in line with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(a). | £770       |

(a) The Committee was established by Article 30 of 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, OJ No. L136, 30.4.2004, p. 1.

| <i>Change</i>   | <i>Conditions</i>  | <i>Fee</i> |
|---|--|------------|
| i) Approval of a mock-up for an authorised pack size.   | <ul style="list-style-type: none"> <li>– The pack size is already authorised.</li> <li>– No new studies are required to support the change and no other aspect of the dossier is changed.</li> </ul>                         | £770       |
| 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 UK 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 UK authorised product. | £770       |

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

13.—(1) The fee for the renewal of a marketing authorisation issued after these Regulations come into force is £1,275.

(2) In the case of a marketing authorisation issued before these Regulations come into force—

(a) if it is the first time the marketing authorisation has been renewed the fee is £1,275; and otherwise £290;

(b) if further assessment of post authorisation commitments is required the fee is £1,275.

(3) The fee for the first reassessment of a provisional marketing authorisation is £290, and the fee for each subsequent reassessment is £1,275.

### **Registration of a homoeopathic veterinary medicinal product**

14. The fee for an application for the registration of a homoeopathic veterinary medicinal product is in accordance with the following table:

Fee for the registration of a homoeopathic veterinary medicinal product

| <i>Type of application</i>  | <i>Fee (£)</i> |
|---|----------------|
| If all stocks and the formulation have already been assessed by the Secretary of State—   |                |
| – not more than 5 stocks  | 150            |
| – more than 5 stocks  | 350            |
| 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— |                |
| – not more than 5 stocks  | 430            |
| – more than 5 stocks  | 625            |
| If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—  |                |
| – not more than 5 stocks  | 710            |
| – more than 5 stocks  | 920            |
| 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—  |                |
| – not more than five stocks   | 150            |
| – more than five stocks   | 350            |

## PART 3

### Fees relating to decentralised and mutual recognition procedures

#### Scope of Part 3

15. This Part has effect in relation to marketing authorisations applied for or obtained using the decentralised procedure or the mutual recognition procedure.

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

16.—(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 the 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 application is made for her to provide the information to an additional member State within six months of the date she last provided the information—

- (a) if the product is not an immunological veterinary medicinal product and one of the target species is a food-producing animal the fee is £2,290;
- (b) if the product is an immunological veterinary medicinal product the fee is £2,000;
- (c) in any other case the fee is £1,775.

(3) In any other case —

- (a) if the product is not an immunological veterinary medicinal product and one of the target species is a food-producing animal the fee is £9,860;

- (b) if the product is an immunological veterinary medicinal product the fee is £8,385;
- (c) in any other case the fee is £6,905.

(4) The fees include the provision of information to one member State in the application; there is a further fee of £500 for each additional member State included in the application.

#### **Mutual recognition of a marketing authorisation already granted in another member State**

17.—(1) A fee for the recognition by the Secretary of State of a marketing authorisation already granted in another member State is as follows—

Fee for mutual recognition

| <i>Type of application</i>   | <i>Fee(£)</i>                    |
|--|----------------------------------|
| Standard application   | 4,225                            |
| Application for a new active substance   | 14,070                           |
| Complex application  | 8,445                            |
| Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom     | 3,305                            |
| Application for a pharmacologically equivalent product where the reference product is not authorised in the United Kingdom | 4,225 plus any translation costs |
| Application using identical data   | 1,120                            |

#### **Decentralised procedure where the United Kingdom is the reference member State**

18.—(1) Where an application is submitted using the decentralised procedure the following fees are payable if the United Kingdom is the reference member State—

Fee for the decentralised procedure where the United Kingdom is the reference member State

| <i>Type of application</i>   | <i>Fee(£)</i>                     |
|--|-----------------------------------|
| Standard application   | 10,400                            |
| Application for a new active substance   | 29,510                            |
| Complex application  | 18,800                            |
| Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom | 9,000                             |
| Application for a pharmacologically equivalent product where reference product is not authorised in the United Kingdom | 10,400 plus any translation costs |
| Application using identical data   | 4,075                             |

(2) In each case the fee includes the provision of information to one member State in the application; there is a further fee of £500 for each additional member State included in the application.

#### **Decentralised procedure where the United Kingdom is not the reference member State**

19.—(1) Where an application is submitted using the decentralised procedure the following fees are payable if the United Kingdom is not the reference member State—

Fee for the decentralised procedure where the United Kingdom is not the reference member State

| <i>Type of application</i>   | <i>Fee(£)</i>                    |
|--|----------------------------------|
| Standard application   | 4,225                            |
| Application for a new active substance   | 14,070                           |
| Complex application  | 8,445                            |
| Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom     | 3,305                            |
| Application for a pharmacologically equivalent product where the reference product is not authorised in the United Kingdom | 4,225 plus any translation costs |
| Application using identical data   | 1,680                            |

### Application for a variation

20.—(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) and the appropriate fee is payable for each application.

(3) If an applicant applies for an extension of a marketing authorisation as specified in Annex II to Commission Regulation (EC) No. 1084/2003—

- (a) if the applicant applies for a United Kingdom marketing authorisation the fee is the same as the fee for the application for a national marketing authorisation, plus any fees payable for any mutual recognition procedure; or
- (b) if the applicant uses the decentralised procedure, the fee is the same as the fee for a marketing authorisation using the decentralised procedure.

(4) Other fees are in accordance with the following table—

#### Variations

| <i>Type of variation</i>   | <i>RMS<br/>Fee(£)</i> | <i>CMS<br/>Fee(£)</i> |
|--|-----------------------|-----------------------|
| Type II variation  | 10,125                | 2,540                 |
| 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  |                       |                       |
| – all the applications are submitted at the same time  |                       |                       |
| the fee payable is   |                       |                       |
| – for the first variation  | 10,125                | 2,540                 |
| – for each subsequent variation  | 1,675                 | 330                   |
| 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 lay out 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   | 2,705                 | 355                   |
| Type 1A variation  | 1,675                 | 330                   |
| <i>Type of variation</i>   | <i>RMS<br/>Fee(£)</i> | <i>CMS<br/>Fee(£)</i> |

|  |       |     |
|--|-------|-----|
| Type 1B variation  | 2,705 | 355 |
| 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  | 2,705 | 355 |
| – for each subsequent variation  | 1,675 | 330 |

Note: the RMS fee is payable when the United Kingdom acts as the reference member State and the CMS fee is payable when the United Kingdom acts as the concerned member State.

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

**21.**—(1) The fee for the renewal of a marketing authorisation granted in more than one member State is —

- (a) £1,720 if the United Kingdom is the reference member State, and
- (b) £1,145 where the United Kingdom is a concerned member State.

## **PART 4**

### **Fees payable by manufacturers**

#### **Application for a manufacturing authorisation**

**22.** The fee for an application for a manufacturing authorisation for a veterinary medicinal product is £2,595.

#### **Application for a variation of a manufacturing authorisation**

**23.** The fee for an application to vary a manufacturing authorisation is £465 where the variation requires scientific or pharmaceutical assessment, and £160 where it does not.

#### **Application for an authorisation to manufacture an autogenous vaccine**

**24.**—(1) An application for a standard authorisation to manufacture an autogenous vaccine is £2,960 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, the fee is £1,480.

(3) The fee to vary an authorisation is £280 if no further inspection is required, and otherwise is the full application fee.

#### **Annual fees**

**25.**—(1) An annual fee of £240 is payable in respect of each manufacturing authorisation (other than a manufacturing authorisation in relation to an autogenous vaccine) held.

(2) The annual fee for a manufacturing authorisation for an autogenous vaccine is 0.67% of the turnover in the previous calendar year rounded up to the next £1, with a minimum fee of £10, and in this paragraph “turnover” has the meaning assigned in paragraph 39.

#### **Site inspections – type of site**

**26.** 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**

27. The following fees are payable for the inspection of a site where immunological veterinary medicinal products are manufactured—

Sites where immunological veterinary medicinal products are manufactured

| <i>Type of site</i> | <i>Fee (£)</i> |
|---------------------|----------------|
| Super site          | 24,015         |
| Major site          | 16,900         |
| Standard site       | 5,435          |
| Minor site          | 4,745          |

**Inspection of a site where sterile veterinary medicinal products are manufactured**

28. 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          | 17,685         |
| Major site          | 9,775          |
| Standard site       | 4,805          |
| Minor site          | 3,215          |

**Inspection of a site where no immunological or sterile veterinary medicinal products are manufactured**

29. 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          | 10,660         |
| Major site          | 5,610          |
| Standard site       | 4,025          |
| Minor site          | 2,170          |

**Inspection of a site where veterinary medicinal products are assembled**

30. 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          | 7,750          |
| Major site          | 5,235          |
| Standard site       | 2,570          |
| Minor site          | 1,325          |

### **Test sites**

31. The fee for the inspection of a test site is £2,665.

### **Animal blood bank authorisations**

32.—(1) The fee for an authorisation to operate a blood bank is £2,960, with the same fee for each subsequent inspection.

(2) The fee for a variation is £280.

### **Expenses**

33. In addition the travel and subsistence costs of the inspectors, and any additional costs reasonably incurred by them (including, in the case of an inspection outside the United Kingdom, interpreters' fees) are payable.

## **PART 5**

### **Fees relating to a wholesale dealer's authorisation**

#### **Application for a wholesale dealer's authorisation**

34.—(1) The fee for an application for a wholesale dealer's authorisation is —

- (a) £1,510, or;
- (b) £620 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 £620, he shall 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 shall pay the balance of £890 within 30 days.

(3) If the applicant paid £1,510 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 shall refund the excess.

(4) Nothing in this paragraph limits the powers of an inspector to examine financial records.

(5) For the purposes of this paragraph, "turnover" has the same meaning as paragraph 36.

#### **Variation of a wholesale dealer's authorisation**

35. The fee for an application to vary a wholesale dealer's authorisation is—

- (a) £465 if the variation requires scientific or pharmaceutical assessment;
- (b) otherwise £160.

#### **Annual fee for a wholesale dealer's authorisation**

36.—(1) The annual fee for a wholesale dealer's authorisation is—

- (a) £485, or,

- (b) £240 if the holder certifies when making the payment that his turnover for that year was less than £40,000.

payable on the anniversary of the grant of the authorisation.

(2) For the purposes of this regulation, “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 during the previous year.

## PART 6

### Fees relating to feedingstuffs

#### Fees relating to feedingstuffs

37.—(1) The following fees are payable in relation to feedingstuffs—

Fees relating to feedingstuffs

| <i>Application and inspection</i>   | <i>Fee payable in Great Britain</i> | <i>Fee payable in Northern Ireland</i> |
|---|-------------------------------------|--|
|   | £                                   | £                                      |
| Application for the approval of an establishment to manufacture a specified feed additive or a premixture using a specified feed additive, and the subsequent annual fee (in the case of premises that only manufacture specified feed additives and already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs, no fee is payable). | 866                                 | 466                                    |
| Application for the approval of an establishment to manufacture feedingstuffs using specified feed additives directly, premixtures using veterinary medicinal product or feedingstuffs using veterinary medicinal product at any concentration, and the subsequent annual fee.  | 546                                 | 368                                    |
| Application for the approval of an establishment to manufacture feedingstuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feedingstuffs are to be placed on the market, and the subsequent annual fee.  | 365                                 | 271                                    |

| <i>Application and inspection</i>  | <i>Fee payable in Great Britain</i> | <i>Fee payable in Northern Ireland</i> |
|--|-------------------------------------|--|
|  | £                                   | £                                      |
| 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.  | 188                                 | 145                                    |
| Application for the approval of an establishment to manufacture feedingstuffs using veterinary medicinal product only at a rate of 2kg per tonne or more when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee. | 135                                 | 111                                    |
| 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.                      | 115                                 | 93                                     |

(2) Where more than one of the above activities is carried out at one premises, only one fee (the highest) is payable.

(3) This paragraph has effect on 1st January 2006.

### **Fees relating to distributors**

**38.**—(1) The fee for an application or annual renewal to be a distributor of specified feed additives, veterinary medicinal products for incorporating into feedingstuffs, premixtures or feedingstuffs containing them is £128 in Great Britain and £59 in Northern Ireland.

(2) This paragraph has effect on 1st January 2006.

## **PART 7**

### **General**

#### **Annual fees for marketing authorisations**

**39.**—(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation shall provide her 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 shall pay an annual fee, rounded up to the next £10, of—

$$\frac{£0.67T}{100} + £215n$$

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 £215,000, the amount, rounded up to the next £10, is—

$$\frac{£0.67T}{100} + £55n$$

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 manufacturer’s 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 which 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**

**40.**—(1) If the Secretary of State required an audit certificate when she 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 £10,500 plus an additional £2,100 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, she shall require the marketing authorisation holder to produce within 30 days a further certificate and specify what further assurances she needs; and if this is 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**

**41.**—(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 of—

- (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,

rounded up to the nearest £10.

(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.

### **Submission of samples in connection with applications for marketing authorisations and animal test certificates**

**42.** 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**

**43.—**(1) The fee for an animal test certificate is £320 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 non-immunological veterinary medicinal product which has been authorised in a 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 non-immunological 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 £765.

(3) The fee for an application for a variation of the certificate is £250 for each change.

(4) The fee for an application to renew a certificate is £120.

### **Treatment under the cascade**

**44.** 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 in exceptional circumstances**

**45.—**(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 decide in writing that a fee for only one animal is payable.

### **Specific batch control**

**46.** The fee for an authorisation to release a veterinary medicinal product under specific batch control is £520.

### **Submission of control tests of an immunological product**

**47.—**(1) The fee for the submission of the results of tests carried out on a batch of immunological products prior to release is £75.

(2) As a transitional measure, no fee is payable in relation to results submitted before 1st April 2006.

## Export Certificates

48. The fee for an application for an export certificate is £30, and £15 for each certified copy.

## Fees relating to premises for supply by suitably qualified persons

49.—(1) The fee to approve premises for the retail supply of veterinary medicinal products by suitably qualified persons is —

- (a) £232, or
- (b) if the premises are only authorised to supply veterinary medicinal products for the treatment of horses and companion animals, £127.

(2) The subsequent annual fee is—

- (a) £165, or £197 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 horses and companion animals, £88, or £107 if the fee is not paid within 60 days of the invoice.

## Application to the Veterinary Products Committee

50.—If the Secretary of State refuses to grant a marketing authorisation or an animal test certificate, or grants one that is different from the authorisation applied for in accordance with regulation 29(1)(a) or (b), and the applicant gives notice that he wishes to make representations to the Veterinary Products Committee, the fee is in accordance with the following table—

Application to the Veterinary Products Committee

| <i>Type of application</i>                             | <i>Fee (£)</i> |
|--|----------------|
| Application for a new active substance                 | 1,820          |
| Complex application                                    | 1,050          |
| Standard application                                   | 485            |
| Application for a pharmacologically equivalent product | 485            |
| Application using identical data                       | 190            |
| Application for an animal test certificate             | 635            |

## Non-payment of fees

51. 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.

## Waiver or reduction of fees

52.—(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 she 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

53.—(1) Where an application for a marketing authorisation is withdrawn before determination, the Secretary of State shall refund a proportion of the fee in accordance with this paragraph.

(2) Where no payment has been made, the applicant may apply reductions of the fee otherwise payable in connection with that application in accordance with this paragraph.

(3) The request for a reduced fee must be made in writing within two months of the withdrawal of the application, or a refusal of the application on the grounds that data that she has requested have not been supplied within the specified time limit.

(4) If no assessment (veterinary, scientific or pharmaceutical) has begun, the refund or reduction is 90%.

(5) If assessment has begun but the Secretary of State has not yet requested further data, the refund or reduction is 50%.

(6) If the Secretary of State has requested further information but it has not yet been provided, the refund or reduction is 25%.

(7) 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 refund or reduction is 10%.

(8) Once the further information has been fully assessed, or the application has been referred to the Veterinary Products Committee, no reduction is made.

## SCHEDULE 8

Regulation 44

### Revocations and amendments.

#### PART 1

The following instruments are revoked—

The Medicines (Veterinary Products Committee) Order 1970 (S. I. 1970/1304)

The Medicines (Exportation of Specified Veterinary Products) Order 1971 (S. I. 1971/1309)

The Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977 (S. I. 1977/161)

The Medicines (Veterinary Drugs) (Exemption from Licences) (Importation) Order 1986 (S. I. 1986/228)

The Medicines (Chemical Sterilants) Order 1986 (S. I. 1986/2177)

The Medicines (Exemptions from Licences) (Carbadox and Olaquinox) Order 1987 (S. I. 1987/2217)

The Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988 (S. I. 1988/1009)

The Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993 (S. I. 1993/2399)

The Medicines (Standard Provisions for Manufacturer's Licences for Veterinary Medicinal Products) Regulations 1994 (S. I. 1994/2852)

The Medicines (Veterinary Medicinal Products) (Veterinary Surgeons From Other EEA States) Regulations 1994 (S. I. 1994/2986)

The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994 (S. I. 1994/2987)

The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (S. I. 1994/3142)

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 (S. I. 1997/322)

The Medicines (Registered Homoeopathic Veterinary Medicinal Products) (General Sale List) Order 1997 (S. I. 1997/1349)

The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Amendment Regulations 1997 (S. I. 1997/2884)

The Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998 (S. I. 1998/1044)

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 1998 (S. I. 1998/1045)

The Retailers' Records for Veterinary Medicinal Products Regulations 2000 (S. I. 2000/7)

The Marketing Authorisations for Veterinary Medicinal Products Amendment Regulations 2000 (S. I. 2000/776)

The Medicines (Data Sheets for Veterinary Drugs) Regulations 2000 (S. I. 2000/2386)

The Medicines (Exemptions for Merchants in Veterinary Drugs) (Amendment) Order 2000 (S. I. 2000/2686)

The Medicines (Veterinary Drugs) (General Sale List) Order 2001 (S. I. 2001/1645)

The Medicines (Veterinary Drugs) (Prescription Only) Order 2001 (S. I. 2001/1646)

The Marketing Authorisations for Veterinary Medicinal Products Regulations (Amendment) Regulations 2002 (S. I. 2002/269)

The Animal Test Certificates (Revocation) Regulations 2003 (S. I. 2003/3309)

The Medicines (Products for Animal Use – Fees) Regulations 2004 (2004/2750)

The Medicines (Vaccination against Foot-and-Mouth Disease) Order 2004 (2004/2779)

The Medicines (Products for Animal Use – Fees) (Amendment) Regulations 2004 (S. I. 2004/3081)

The Marketing Authorisations for Veterinary Medicinal Products (Revocation of Confidentiality Provision) Regulations 2004 (S. I. 2004/3193)

## PART 2

### Instruments revoked on 1st January 2006

The Medicated Feedingstuffs Regulations 1998 (S. I. 1998/1046)

The Medicated Feedingstuffs and Feedingstuffs (Zootechnical Products) (Consequential Provisions) Regulations 1998 (S. I. 1998/1048)

The Feedingstuffs (Zootechnical Products) Regulations 1999 (S. I. 1999 /1871)

The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) Regulations 2000 (S. I. 2000/1686)

The Feedingstuffs (Zootechnical Products) (Amendment) (England, Scotland and Wales) Regulations 2002 (S. I. 2002/696)

The Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2002 (S. I. 2002/697)

The Feedingstuffs (Zootechnical Products) (Amendment) Regulations 2003 (S. I. 2003/545)

The Medicated Feedingstuffs (Amendment) (Scotland, England and Wales) Regulations 2003 (S. I. 2003/752)

The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2004 (S. I. 2004/1036)

The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2005 (S. I. 2005/1033)



The Medicated Feedingstuffs (Amendment) Regulations (Northern Ireland) S.R. (NI) 2002 No.161

The Feedingstuffs (Zootechnical Products)(Amendment) Regulations (Northern Ireland) S.R. (NI) 2002 No. 162

The Medicated Feedingstuffs (Amendment) Regulations (Northern Ireland) S.R. (NI) 2004 No. 154

The Feedingstuffs (Zootechnical Products)(Amendment ) Regulations (Northern Ireland) S.R. (NI) 2004 No. 155

The Feedingstuffs (Zootechnical Products)(Amendment) Regulations (Northern Ireland) S.R. (NI) 2005 No. 183

The Medicated Feedingstuffs (Amendment) Regulations (Northern Ireland) S.R. (NI) 2005 No. 184

## PART 3

### Consequential amendments

The following instruments shall be amended as follows—

*The Medicines (Standard Provisions for Licences and Certificates) Regulations 1971*

1. After regulation 1 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (S.I. 1971/972) there shall be inserted the following—

**“Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products.”

*The Medicines (Applications for Manufacturer’s and Wholesale Dealer’s Licences) Regulations 1971*

2. After regulation 1 of the Medicines (Applications for Manufacturer’s and Wholesale Dealer’s Licences) Regulations 1971 (S.I. 1971/974) there shall be inserted the following—

**“Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products.”

*The Medicines (Control of Substances for Manufacture) Order 1971*

3. After article 1 of the Medicines (Control of Substances for Manufacture) Order 1971 (S.I. 1971/1200) there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines (Importation of Medicinal Products for Re-exportation) Order 1971*

4. After article 1 of the Medicines (Importation of Medicinal Products for Re-exportation) Order 1971 (S.I. 1971/1326) there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971*

5.—(1) In article 1(2) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 (S.I. 1971/1450) —

- (a) the definition of “intermediate feed” shall be deleted;
- (b) sub-paragraph (c) of the definition of “medicinal product” shall be deleted.

(2) After article 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

(3) Article 2(2)(i)(b) shall be deleted.

*The Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972*

6.—(1) In article 1(2) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 (S.I. 1972/1200)—

- (a) the definition of “intermediate feed” shall be deleted;
- (b) paragraph (b) in the definition of “medicinal product” shall be deleted.

(2) After article 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

(3) Article 2(1)(b) shall be deleted.

(4) Article 2(1)(c)(ii) shall be deleted.

(5) Article 2(4) shall be deleted.

(6) Article 2(7) shall be deleted.

(7) Article 4 shall be deleted.

*The Medicines (Extension to Antimicrobial Substances) Order 1973*

7. After article 1 of the Medicines (Extension to Antimicrobial Substances) Order 1973 (S.I. 1973/367) there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines (Exemptions from Licences) (Emergency Importation) Order 1974*

8. After article 1 of the Medicines (Exemptions from Licences) (Emergency Importation) Order 1974 (S.I. 1974/316) there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines (Exemption from Licences) (Ingredients) Order 1974*

9. In the Medicines (Exemption from Licences) (Ingredients) Order 1974 (S.I. 1974/1150) after article 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines (Labelling) Regulations 1976*

10.—(1) The Medicines (Labelling) Regulations 1976 (S.I. 1976/1726) shall be amended as follows.

(2) For regulation 3A there shall be substituted—

**“Veterinary medicinal products**

3A. These Regulations shall not apply in relation to veterinary medicinal products.”

(3) Regulation 7 (medicinal tests on animals) shall be deleted.

(4) Regulation 9(1)(b) (dispensed medicinal products for animal use) shall be deleted.

(5) Regulation 12(1)(a) (importation and exportation of medicinal products for animal use) shall be deleted.

(6) Regulation 14D (veterinary drugs) shall be deleted.

(7) In regulation 16—

(a) in paragraph (1) the following shall be omitted—

(i) the words “or in an animal test certificate”;

(ii) the words “or certificate”;

(iii) the words “or, as the case may be, certificate”.

(b) in paragraph (2) the words “or animal test certificate” shall be omitted.

(8) Regulation 17(7) and (8) shall be deleted.

(9) In Schedule 1 —

(a) in paragraph 3 the words “and, where the medicinal product is for use by being administered to animals, the purposes for which the medicinal product is to be used,” shall be omitted;

(b) paragraph 5 shall be deleted;

(c) paragraph 5A shall be deleted;

(d) paragraph 11A shall be deleted;

(e) paragraph 13 shall be deleted.

(10) Schedule 3 (particulars required in the labelling of containers and packages of medicinal products for medicinal tests on animals) shall be deleted.

(11) In Schedule 5 paragraphs 6, 7 and 8 shall be deleted.

(12) In Schedule 6 paragraphs 6 and 7 shall be deleted.

*The Medicines (Manufacturer’s Undertakings for Imported Products) Regulations 1977*

11. In the Medicines (Manufacturer’s Undertakings for Imported Products) Regulations 1977 (S.I. 1977/1038) after regulation 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products.”

*The Medicines (Certificates of Analysis) Regulations 1977*

12. In the Medicines (Certificates of Analysis) Regulations 1977 (S.I. 1977/1399) after regulation 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products.”

*The Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977*

13.—(1) In article 1(2) of the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 (S.I. 1977/2130) paragraph (b) of the definition of “external use” shall be deleted.

(2) After article 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977*

14. After article 1 of the Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977 (S.I. 1977/2131) there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines (Fluted Bottles) Regulations 1978*

15.—(1) In regulation 1(2) of the Medicines (Fluted Bottles) Regulations 1978 (S.I. 1978/40)—

(a) paragraph (b) in the definition of “external use” shall be deleted; and

(b) the definition of “marketing authorisation” shall be deleted.

(2) After regulation 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products.”

(3) For regulation 3(g) there shall be substituted—

“(g) where a product licence, a marketing authorisation within the meaning of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, or any variation of any such licence or authorisation, enables medicinal products to be contained in a bottle otherwise than in accordance with the requirements set out in regulation 2 above.”

*The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980*

16.—(1) In regulation 1(2)(a) of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (S.I. 1980/1923) the definition of “the Veterinary Drugs Exemption Order” shall be deleted.

(2) After regulation 1 of there shall be inserted the following—

**“Veterinary medicinal products**

**1A.** These Regulations shall not apply in relation to veterinary medicinal products.”

(3) In regulation 2(1) and regulation 2(2) for the words “neither registered pharmacies nor premises on which there are sold or supplied medicinal products to which the Veterinary Drugs Exemption Order applies” there shall be substituted “not registered pharmacies”.

(4) In regulation 2(3), sub-paragraph (b) shall be deleted.

(5) In regulation 5(1)(a) the words “or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply” shall be deleted.

(6) Regulation 8(3) shall be deleted.

(7) Schedule 3 shall be deleted.

*The Medicines (Pharmacy and General Sale – Exemption) Order 1980*

**17.**—(1) In article 1(2) of the Medicines (Pharmacy and General Sale – Exemption) Order 1980 (S.I. 1980/1924) —

(a) paragraph (ii) in the definition of “external use” shall be deleted;

(b) the definition of “person responsible for marketing” shall be deleted; and

(c) the definition of “registered homoeopathic veterinary medicinal product” shall be deleted.

(2) After article 1 there shall be inserted the following—

**“Veterinary medicinal products**

**1A.** This Order shall not apply in relation to veterinary medicinal products.”

(3) Article 4A(3)(c) shall be deleted.

(4) Article 4B(3)(c) shall be deleted.

(5) Article 4C(3) shall be deleted.

(6) Article 4D(3) shall be deleted.

(7) In article 5(3)(a) the words from “or a marketing authorisation” to “veterinary drug in question” shall be deleted.

(8) Article 5(3)(b) shall be deleted.

*The Medicines (Control of Substances for Manufacture) Order 1985*

**18.** After article 1 of the Medicines (Control of Substances for Manufacture) Order 1985 (S.I. 1985/1403) there shall be inserted the following—

**“Veterinary medicinal products**

**1A.** This Order shall not apply in relation to veterinary medicinal products.”

*The Medicines Act 1968 (Hearings by Persons Appointed)(Scotland) Rules 1986*

**19.** After rule 1 of The Medicines Act 1968 (Hearings by Persons Appointed) (Scotland) Rules 1986 (S.I. 1986/1700) there shall be inserted the following—

**“Veterinary medicinal products**

**1A.** These Rules shall not apply in relation to veterinary medicinal products.”

*The Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986*

20. After rule 1 of the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986 (S.I. 1986/1761) there shall be inserted the following—

**“Veterinary medicinal products**

1A. These Rules shall not apply in relation to veterinary medicinal products.”

*The Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990*

21.—(1) In article 1(2) of the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990 (S.I. 1990/566)—

- (a) the definition of “intermediate feed” is deleted;
- (b) the definition ““marketing authorisation” means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply” shall be deleted.
- (c) in the definition of “medicinal product” paragraph (c) shall be deleted.

(2) After article 1 there shall be inserted the following—

**“Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products.”

(3) In article 2(3) the words “or a ready-made veterinary drug” shall be deleted.

*The Medicines (Advisory Board On The Registration Of Homoeopathic Products) Order 1995*

22. Article 2(1)(b) of the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995 (S. I. 1995/309) shall be deleted.

## PART 4

### Transitional provisions

#### **Conversions of authorisations, etc.**

1.—(1) A marketing authorisation granted under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(a) and extant when these Regulations come into force becomes a marketing authorisation under these Regulations with the retail classification notified to the marketing authorisation holder by the Secretary of State.

(2) A registration of a homoeopathic veterinary medicine under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997(b) becomes a registration under these Regulations.

(3) A manufacturer’s licence as described in section 8(2) of the Medicines Act 1968(c) becomes a manufacturing authorisation under these Regulations and the expiry provisions in section 24 of the Medicines Act 1968 do not apply and the Certificate of Good Manufacturing Practice remains valid as issued.

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(a) S.I. 1994/3142, amended by S.I. 1997/1729, 2884, 1998/1048, 1999/1540, 2000/776, 2002/269, 2004/3193.

(b) S.I. 1997/322, amended by S.I. 1997/2884, 1999/342.

(c) 1968 c.67; section 8(8) was added by the Medicines Act 1968 (Amendment) Regulations 1993 (S.I. 1993/834), regulation 2; section 24 was amended by the Medicines Act 1968 (Amendment) Regulations 1977 (S.I. 1997/1050), regulation 4(4), and by the Medicines Act 1968 (Amendment) (No.2) Regulations 1994 (S.I. 1994/276), regulation 5.

(4) A wholesale dealer's licence as described in section 8(8) of the Medicines Act 1968 becomes a wholesale dealer's authorisation under these Regulations and expiry provisions in section 24 of the Medicines Act 1968 do not apply.

(5) An approval of premises under Part II of the Medicated Feedingstuffs Regulations 1998 becomes an establishment approval under Article 10(2) of Regulation (EC) No. 183/2005.

(6) An approval of a distributor under Part III of the Medicated Feedingstuffs Regulations 1998 becomes an approval referred to in Article 10(2) of Regulation (EC) No. 183/2005.

(7) An approval of an establishment under Part III of the Feedingstuffs (Zootechnical Products) Regulations 1999 becomes an approval referred to in Article 10(1) of Regulation (EC) No. 183/2005.

(8) An approval of an intermediary under Part IV of the Feedingstuffs (Zootechnical Products) Regulations 1999 becomes an approval referred to in Article 10(1) of Regulation (EC) No. 183/2005.

(9) An approval of a third country establishment under Part V of the Feedingstuffs (Zootechnical Products) Regulations 1999 becomes an authorisation under Article 24 of Regulation (EC) No. 183/2005.

(10) An animal test certificate granted under the Medicines Act 1968 becomes an animal test certificate under these Regulations.

(11) A special treatment authorisation granted by the Secretary of State becomes an import certificate granted under regulation 25 of these Regulations and a treatment certificate granted under paragraph 7 of Schedule 4, as appropriate.

(12) An exemption under section 9(2) of the Medicines Act 1968 and issued as an emergency product licence becomes an authorisation to manufacture an autogenous vaccine under these Regulations.

(13) A specific batch control certificate granted by the Secretary of State becomes an authorisation under specific batch control granted under these Regulations.

### **Suitably qualified persons**

2. Each person who is a suitably qualified person in relation to the supply of a veterinary medicinal product for the purposes of the Medicines (Exemption for Merchants in Veterinary Drugs) Order 1998 becomes a suitably qualified person for the purposes of Schedule 3, paragraph 9.

### **Existing applications**

3. An application pending when these Regulations come into force shall follow the procedure in these Regulations but the data requirements remain as they were before the Regulations come into force.

### **Existing procedures**

4. A revocation or suspension procedure pending when these Regulations come into force shall follow the procedure in these Regulations.

### **Records**

5. Any record being kept under any revoked provision when these Regulations come into force must be kept for the time specified in these Regulations, and failure to do so is an offence.

### **Labels**

6. Existing labels may be used for three years from the coming into force of these Regulations unless there is a variation to the marketing authorisation requiring a change to the label.

## Fees

7.—(1) Schedule 7 shall not apply to any application made before the coming into force of these Regulations in relation to which the fee payable under legislation revoked by this Schedule has been paid before the coming into force of these Regulations.

(2) Paragraph (1) does not apply where —

- (a) an inspection is made after the coming into force of these Regulations in connection with such an application, in which case the inspection fee payable is that due under these Regulations; or
- (b) such an application is a renewal application in relation to a permission due to expire after the coming into force of these Regulations, in which case the fee payable is that due under these Regulations.

## References to “coming into force”

8. In the Part, references to “coming into force” are to 1st January 2006 in the case of feedingstuffs, and 30th October 2005 in any other case.

### EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision for the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products. They revoke and amend the provisions set out in Parts 1 to 3 of Schedule 8, provide transitional provisions in Part 4 of that Schedule, and provide that the Medicines Act 1968 no longer regulates veterinary medicinal products.

They implement Directive 2001/82/EC of the European Parliament and of the Council on the Community Code relating to veterinary medicinal products (OJ No. L311, 28.11.2001, p.1), as amended by Directive 2004/28/EC (OJ No. L136, 30.4. 2004, p.58).

They also identify the competent authority for, and provide for enforcement of, Regulations (EC) No. 178/2002 (OJ No. L31, 1.2.2002, p.1), (EC) No. 1831/2003 (OJ No. L268, 18.10.2003, p.29), (EC) No. 882/2004 (corrected version at OJ No. L191, 28.5.2004, p.1) and (EC) No. 183/2005 (OJ No. L35, 8.2.2005, p.1), in so far as they apply to veterinary medicinal products used in feedingstuffs, and to the following additives used in feedingstuffs:

- (a) coccidiostats;
- (b) histomonostats;
- (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.

In addition they implement Council Directive 90/167 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ No. L92, 7.4.90, p.42) so far as they are not rendered spent 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 a representations 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 on [www.vmd.gov.uk](http://www.vmd.gov.uk) at “Publications, Veterinary Medicines Regulations 2005”.

A transposition note has been prepared and is available at [www.vmd.gov.uk](http://www.vmd.gov.uk) at “Publications, Veterinary Medicines Regulations 2005”.

