STATUTORY INSTRUMENTS

2005 No. 2745

The Veterinary Medicines Regulations 2005

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 for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**1**);

"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 —

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

(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(**2**), 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.

(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—

(**2**) 1986 c. 14.

(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(**3**).

(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.

(**3**) Published by the World Health Organization at: www.who.int/medicines

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.

(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(**4**) 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.

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.

(**4**) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c. 39), section 47.

(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(**5**) shall apply.

Revocations and amendments

44.—(1) The Medicines Act 1968(**6**) does not apply in relation to veterinary medicinal products.

(2) The Medicines (Prohibition of Importation and Possession of Veterinary Drugs Order (Northern Ireland) 1977(**7**) 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(**8**) 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.

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

17th September 2005

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

6th October 2005

(**5**) S. I. 1981/1675 (N.I. 26).
(**6**) 1968 c. 67.
(**7**) S.R. (NI) 1977 No. 359.
(**8**) 1987 c. 43.