STATUTORY INSTRUMENTS

2005 No. 2745

The Veterinary Medicines Regulations 2005

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(**1**).

(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

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

(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(**2**) 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

(**2**) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c. 39), section 47.

(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.

(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(**3**) shall apply.

Revocations and amendments

44.—(1) The Medicines Act 1968(**4**) does not apply in relation to veterinary medicinal products.

(2) The Medicines (Prohibition of Importation and Possession of Veterinary Drugs Order (Northern Ireland) 1977(**5**) 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(**6**) 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.

(**3**) S. I. 1981/1675 (N.I. 26).
(**4**) 1968 c. 67.
(**5**) S.R. (NI) 1977 No. 359.
(**6**) 1987 c. 43.

(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.