STATUTORY INSTRUMENTS

2011 No. 2159

The Veterinary Medicines Regulations 2011

PART 1

Introduction

Title and commencement

1. These Regulations may be cited as the Veterinary Medicines Regulations 2011 and come into force on 1st October 2011.

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 given in paragraph 1 of Schedule 4;

"Commission Regulation (EC) No 1234/2008" means Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (**2**);

"Commission Regulation (EU) No 37/2010" means Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin(**3**);

(**1**) OJ No L136, 30.4.2004, p. 1.
(**2**) OJ No L334, 12.12.2008, p.7.
(**3**) OJ No L 15, 20.1.2010, p. 1.

"extension variation" has the same meaning as "Extension of a marketing authorisation" in Article 2 of Commission Regulation EC No 1234/2008;

"horse passport" means a passport issued in accordance with the provisions of Commission Regulation (EC) No 504/2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae(**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;

"Regulation (EC) No 470/2009 of the European Parliament and of the Council" means Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin(**5**);

"Regulation (EC) No 767/2009 of the European Parliament and of the Council" means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed in relation to feedingstuffs containing specified feed additives(**6**);

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

(a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product; or

(b) any risk of undesirable effects on the environment;

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

(3) In these Regulations references to Types of variation are to those specified in Commission Regulation (EC) No 1234/2008;

(4) 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.

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

Products to which these Regulations do not apply

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

(2) They do not apply in relation to a product intended for administration in the course of a procedure licensed under the Animals (Scientific Procedure) Act 1986(**7**), except that, if the animals are to be put into the human food chain, the only products that may be administered to the animals are—

(a) authorised veterinary medicinal products administered in accordance with their marketing authorisation, or

(b) products administered in accordance with an animal test certificate granted under paragraph 9 of Schedule 4.

(**4**) OJ No L 149, 7.6.2008, p. 3.
(**5**) OJ No L152, 16.6.2009, p. 11.
(**6**) OJ No L229, 1.9.2009, p. 1. Regulation (EC) No 767 2009 was last amended by Regulation (EC) 939/2010 (OJ No L277, 20.10. 2010, p. 4).
(**7**) 1986 c. 14.

PART 2

Authorised veterinary medicinal products

Placing a veterinary medicinal product on the market

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

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

(3) Schedule 1 (marketing authorisations) has effect.

Manufacture of veterinary medicinal products

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

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

(3) "Manufacture" includes any part of the manufacture of a veterinary medicinal product until the finished product is ready for sale in its final form as specified in the marketing authorisation but does not include the manufacture of an ingredient or breaking open the package of a veterinary medicinal product(**8**).

The finished product

6. The holder of a marketing authorisation for a veterinary medicinal product is guilty of an offence if either the holder or the manufacturer supplies a product that is not completely in accordance with the marketing authorisation.

Classification, supply and possession of the product

7.—(1) Schedule 3 (classification and supply, wholesale dealers and sheep dip) has effect.

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

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

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

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

(**8**) For provisions on breaking open packages see regulation 7(3).

Administration of the product

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

(a) the product has a marketing authorisation authorising its administration in the United Kingdom, and the administration is in accordance with that marketing authorisation; or

(b) it is administered in accordance with Schedule 4 (administration of a veterinary medicinal product outside the terms of a marketing authorisation) or Schedule 6 (exemptions for small pet animals).

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 for a veterinary medicinal product may import that veterinary medicinal product.

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

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

(a) the authorisation covers the product; and

(b) the dealer has notified the holder of the marketing authorisation in writing before importation.

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

(6) A suitably qualified person (registered in accordance with paragraph 14 of Schedule 3) may import any authorised veterinary medicinal product that that person is permitted to supply.

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

Advertising the product

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

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

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

(a) the list is sent following a request from the veterinary surgeon to whom it is sent; and

(b) the list states clearly that the product does not have a marketing authorisation as a veterinary medicinal product, and may only be prescribed and administered under the cascade.

Advertising of prescription products and products containing psychotropic drugs or narcotics

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

(a) is available on veterinary prescription only; or

(b) contains psychotropic drugs or narcotics.

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

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

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

(a) veterinary surgeons;

(b) pharmacists;

(c) suitably qualified persons registered in accordance with paragraph 14 of Schedule 3;

(d) other veterinary health care professionals;

(e) professional keepers of animals; or

(f) owners or keepers of horses.

Defence of publication in the course of business

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

(a) that that person's business is to publish or arrange for the publication of advertisements, and

(b) that the advertisement was received in the ordinary course of business and the person charged did not know and had no reason to suspect that its publication would amount to an offence under these Regulations.

Wholesale dealing

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

Feedingstuffs

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

Exemptions

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

(2) Schedule 1 and Part 1 of Schedule 2 do not apply in relation to an inactivated autogenous vaccine that is—

(a) manufactured by a person and in premises authorised in accordance with Part 2 of Schedule 2, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal; and

(b) used for the treatment of—

(i) other animals on the same site;

(ii) animals intended to be sent to those premises; or

(iii) animals on a site that receives animals from those premises.

(3) Schedule 1 and Part 1 of Schedule 2 do not apply in relation to—

(a) blood or blood constituents from a blood bank authorised in accordance with Part 3 of Schedule 2;

(b) a product manufactured for administration under the cascade by a person and in premises authorised in accordance with Part 4 of Schedule 2; or

(c) equine stem cells products for use as an autologous treatment for horses from an equine collection centre authorised in accordance with Part 5 of Schedule 2.

(4) Schedule 6 (exemptions for small pet animals) has effect.

Fees

16. Schedule 7 (fees) has effect.

PART 3

Records

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

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

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

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

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

(a) the name of the veterinary surgeon;

(b) the name of the product and the batch number;

(c) the date of administration of the product;

(d) the amount of product administered;

(e) the identification of the animals treated; and

(f) the withdrawal period.

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

Food-producing animals: records of acquisition and administration

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

(a) the name of the product and the batch number;

(b) the date of acquisition;

(c) the quantity acquired; and

(d) the name and address of the supplier.

(2) At the time of administration (unless the administration is by a veterinary surgeon in which case the record must be in accordance with regulation 18) the keeper must record—

(a) the name of the product;

(b) the date of administration;

(c) the quantity administered;

(d) the withdrawal period; and

(e) the identification of the animals treated.

(3) A keeper who disposes of any or all of the veterinary medicinal product other than by treating an animal must record—

(a) the date of disposal;

(b) the quantity of product involved; and

(c) how and where it was disposed of.

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

Food-producing animals: retention of records

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

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

Records by a holder of a manufacturing authorisation

21.—(1) A holder of a manufacturing authorisation must, as soon as is reasonably practicable, make a record of each batch of veterinary medicinal product manufactured, assembled or supplied, which must include—

(a) the name of the product;

(b) the quantity manufactured, assembled or supplied;

(c) the date of manufacture, assembly or supply;

(d) the batch number and expiry date; and

(e) in the case of supply, the name and address of the recipient.

(2) The holder must keep with the record all certification provided by the qualified person (manufacture) in relation to that batch.

(3) The holder must keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market.

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

Records by a holder of a wholesale dealer's authorisation

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

(a) the date and nature of the transaction;

(b) the name of the veterinary medicinal product;

(c) the manufacturer's batch number;

(d) the expiry date;

(e) the quantity; and

(f) the name and address of the supplier or recipient,

and must keep the records for at least three years.

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

Records of the receipt or supply of prescription products

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

(a) the date;

(b) the name of the veterinary medicinal product;

(c) the batch number (except that, in the case of a product for a non-food-producing animal, this need only be recorded either on the date of receipt of the batch or the date a veterinary medicinal product from the batch is first supplied);

(d) the quantity;

(e) the name and address of the supplier or recipient; and

(f) if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription.

(2) If the documents do not include this information that person must make a record of the missing information as soon as is reasonably practicable following the transaction.

(3) As an alternative to paragraphs (1) and (2) that person may make a record of all the information required there provided that this is done as soon as is reasonably practicable following the transaction.

(4) The documentation and records must be kept for at least five years.

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

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

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

(a) the date of examination of the animals;

(b) the name and address of the owner;

(c) the identification and number of animals treated;

(d) the result of the veterinary surgeon's clinical assessment;

(e) the trade name of the product if there is one;

(f) the manufacturer's batch number shown on the product if there is one;

(g) the name and quantity of the active substances;

(h) the doses administered or supplied;

(i) the duration of treatment; and

(j) the withdrawal period,

and must keep the record for at least five years.

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

PART 4

Unauthorised veterinary medicinal products

Importation of an unauthorised veterinary medicinal product

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

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

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

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

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

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

Possession of an unauthorised veterinary medicinal product

26.—(1) It is an offence to be in possession of an unauthorised veterinary medicinal product.

(2) This regulation does not apply to—

(a) a veterinary medicinal product imported in accordance with a certificate granted by the Secretary of State under these Regulations;

(b) a product prescribed by a veterinary surgeon under the cascade;

(c) a holder of a manufacturing authorisation if the possession is for export;

(d) a holder of a wholesale dealer's authorisation if the possession is for export or re-export; or

(e) a holder of a manufacturer's authorisation or marketing authorisation if the intention is to manufacture a veterinary medicinal product.

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

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

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

Supply of an unauthorised veterinary medicinal product

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

(2) This regulation does not apply to—

(a) a veterinary medicinal product prescribed by a veterinary surgeon under the cascade; or

(b) a product supplied in accordance with a certificate granted by the Secretary of State under these Regulations.

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

PART 5

Miscellaneous provisions, enforcement and offences

The Veterinary Products Committee

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

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

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

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

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

Veterinary Products Committee appeals procedure

29.—(1) The following procedure applies when any person receives a notification from the Secretary of State informing that person (the appellant) of a right to an appeal to the Veterinary Products Committee.

(2) The appellant must inform the Secretary of State of an intention to appeal within 28 days of the notification which is the subject of the appeal.

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

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

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

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

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

(8) The Secretary of State must then notify the provisional decision to the appellant, together with the reasons for it.

(9) The appellant may then appeal against the Secretary of State's provisional decision to a person appointed for the purpose by the Secretary of State and the procedure in the next regulation applies.

Appeals to an appointed person

30.—(1) A person aggrieved by a provisional decision of the Secretary of State under the preceding regulation may appeal against the decision to a person appointed for the purpose by the Secretary of State in accordance with this regulation.

(2) So may an applicant for—

(a) a manufacturing authorisation;

(b) appointment as a Qualified Person for the purposes of a manufacturing authorisation;

(c) authorisation for a person or premises to manufacture autogenous vaccines;

(d) an authorisation of a blood bank;

(e) authorisation of a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade;

(f) authorisation of an equine stem cell centre;

(g) a wholesale dealer's authorisation;

(h) the approval of premises for the supply of POM-VPS or NFA-VPS veterinary medicinal products by a suitably qualified person,

if such an application is refused.

(3) A holder of any of the above authorisations, appointment or approvals may appeal against a suspension or compulsory variation in the same way.

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

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

Exports

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

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

(3) When issuing the certificate the Secretary of State must take account of the model certificates issued by the World Health Organization(**9**).

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

Time limits

32.—(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

33. The Secretary of State must appoint inspectors for the purposes of the enforcement of these Regulations and in these Regulations "inspector" means an inspector appointed under this regulation or a veterinary inspector appointed under the Animal Health Act 1981(**10**).

Powers of entry

34.—(1) An inspector may, on giving reasonable notice, and on producing a duly authenticated authorisation if required, enter any premises at any reasonable hour for the purpose of ensuring that the provisions of these Regulations are being complied with; and in this regulation "premises" includes any place, vehicle, trailer, container, stall, moveable structure, ship or aircraft.

(2) The requirement to give notice does not apply—

(a) where the entry is pursuant to any provision of an EU instrument which requires inspection without notice;

(b) where the requirement has been waived;

(c) where reasonable efforts to agree an appointment have failed;

(d) where an inspector has reasonable suspicion of a failure to comply with these Regulations; or

(e) in an emergency.

(3) Paragraph (1) does not apply in relation to any premises which are used wholly or mainly as a private dwelling, unless those premises are approved, registered or authorised for the sale of veterinary medicines under paragraph 8, 10, 14(4) or 18 of Schedule 3, or any part of those premises is so approved, registered or authorised for that purpose.

(4) Paragraphs (1) and (3) do not affect any right of entry conferred by a warrant issued by a justice of the peace.

(5) The inspector may be accompanied by—

(a) such other persons as the inspector considers necessary; and

(**9**) Published by the World Health Organization at: www.who.int/medicines/en.
(**10**) 1981 c. 22.

(b) any representative of the European Commission acting for the purpose of the enforcement of a Community obligation.

(6) 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 signed warrant authorise the inspector to enter the premises, if need be by reasonable force.

(7) A warrant under this regulation is valid for one month.

(8) An inspector who enters any unoccupied premises must leave them as effectively secured against unauthorised entry as they were before entry.

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

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

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

(a) in Scotland includes a reference to the sheriff and to a magistrate; and

(b) in Northern Ireland, is a reference to a lay magistrate.

Powers of an inspector

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

(a) inspect the premises, and any plant, machinery or equipment;

(b) search the premises;

(c) take samples;

(d) seize any computers and associated equipment;

(e) seize any veterinary medicinal product, anything purporting to be a veterinary medicinal product, or any additive to which Schedule 5 applies, if it is not authorised in the United Kingdom;

(f) seize any premixture or feedingstuff that contains a veterinary medicinal product or additive to which Schedule 5 applies that is not authorised in the United Kingdom;

(g) seize any veterinary medicinal product, anything purporting to be a veterinary medicinal product, any additive to which Schedule 5 applies, any premixture or any feedingstuff if—

(i) it has not been lawfully supplied in accordance with these Regulations;

(ii) it has been stored in a way that affects its safety, quality or efficacy;

(iii) it is sold or offered for sale by a person not permitted to supply it under these Regulations;

(h) carry out any inquiries, examinations and tests;

(i) have access to, and inspect and copy or seize any documents or records (in whatever form they are held) relating to these Regulations; and

(j) have access to, inspect and check the operation of any computer and any associated apparatus or material that is or has been in use in connection with the records; and for this purpose may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford such assistance as may reasonably be required and, where a record is kept by means of a computer, may require the records to be produced in a form in which they may be taken away.

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

(3) Where an inspector has entered any premises and it is not reasonably practicable to determine at the time whether documents on those premises are relevant to these Regulations, the inspector may seize them to ascertain whether or not they are relevant.

Inspection of pharmacies

36. In relation to a pharmacy, all the powers of an inspector to enforce these Regulations may also be exercised by an officer of the General Pharmaceutical Council appointed for the purpose.

Obstruction

37. Any person who—

(a) intentionally obstructs any person acting in the execution of these Regulations;

(b) without reasonable cause, fails to give to any person acting in the execution of these Regulations any assistance or information that that person may reasonably require under these Regulations;

(c) furnishes to any person acting in the execution of these Regulations any information knowing it 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

38.—(1) An inspector who has reasonable grounds for believing that any person is failing to comply with these Regulations may serve a notice on that person (in these Regulations referred to as an "improvement notice") that—

(a) states the inspector's grounds for believing this;

(b) specifies the matters that constitute the failure to comply;

(c) specifies the measures that, in the inspector's opinion, the person must take in order to secure compliance; and

(d) requires the person to take those measures, or measures at least equivalent to them, within the period (being not less than 14 days) specified in the notice.

(2) It is an offence to fail to comply with an improvement notice.

Appeals against improvement notices

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

(2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980(**11**) applies to the proceedings.

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

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

(5) An improvement notice must state—

(a) the right of appeal to a magistrates' court or to the sheriff; and

(b) the period within which such an appeal may be brought.

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

Powers of a court on appeal

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

Seizure notices

41.—(1) An inspector must follow the procedures set out in this regulation when seizing anything under these Regulations.

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

(a) giving the grounds for seizing the product; and

(b) informing that person of the rights under this regulation to make a claim, and the address for the service of the claim.

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

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

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

(6) If a notification of a claim is received within 28 days, then, unless the product seized is being held for the purposes of pending or contemplated criminal proceedings, or for a criminal investigation, the Secretary of State must either return the product or take proceedings for an order for the confirmation of the seizure notice and the destruction of the veterinary medicinal product in a magistrates' court (or, in Scotland, the sheriff court), and if the court confirms the notice it must order its destruction.

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

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

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

(**11**) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c.39), section 47.

Publication

42.—(1) The Secretary of State must publicise all improvement notices and seizure notices issued under these Regulations and the suspension or revocation of anything issued under these Regulations, and may do so in such manner as the Secretary of State sees fit.

(2) This does not apply in relation to a seizure notice issued to a common carrier who does not own the seized goods.

Penalties

43.—(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,

that person is guilty of the offence as well as the body corporate.

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

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

Northern Ireland

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

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

(a) regulation 33 (appointment of inspectors);

(b) regulation 41 (seizure notices);

(c) regulation 42 (publication); and

(d) sub-paragraph (4) of paragraph 14 of Schedule 3 (approval of premises for suitably qualified persons).

(3) The Department of Agriculture and Rural Development is the competent authority for—

(a) Regulation (EC) No 178/2002 (of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**12**));

(**12**) OJ No L31, 1.2.2002, p. 1; last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ L188, 18.7.2009, p. 14).

(b) Regulation (EC) No 1831/2003 (of the European Parliament and the Council on additives for use in animal nutrition(**13**));

(c) Regulation (EC) No 882/2004 (of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules(**14**)); and

(d) Regulation (EC) No 183/2005 (of the European Parliament and of the Council laying down requirements for feed hygiene(**15**)).

(4) In relation to pharmacies, an officer of the Pharmaceutical Society of Northern Ireland appointed by the Society for the purpose has all the powers of an inspector to enforce these Regulations.

(5) In proceedings in a magistrates' court relating to an improvement notice under regulation 38 or a seizure notice under regulation 41, the Magistrates' Courts (Northern Ireland) Order 1981(**16**) applies.

Review

45.—(1) Before the end of each review period, the Secretary of State must—

(a) carry out a review of these Regulations other than the fees provisions;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the EU instruments, or provisions of EU instruments, to which this regulation applies are implemented in other Member States.

(3) The EU instruments, and provisions of EU instruments, to which this regulation applies are—

Council Directive 90/167 laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation (EC) No 183/2005(**17**)

Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**18**);

Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**19**);

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, in so far as it applies to veterinary medicinal products used in feedingstuffs;

Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, in so far as it applies to veterinary medicinal products used in feedingstuffs;

(**13**) OJ No L268, 18.10.2003, p. 29; last amended by Regulation (EC) No 767/2009 of the European Parliament and of the Council (OJ L229, 1.9.2009, p.1).
(**14**) Corrected version at OJ No L191, 28.5.2004, p. 1.
(**15**) OJ No L35, 8.2.2005, p. 1; last amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council (OJ L87, 31, 3.2009, p.109).
(**16**) S.I. 1981/1675 (N.I. 26).
(**17**) OJ L92, 7.4.1990, p. 42.
(**18**) OJ 228, 17.8.1991, p. 70.
(**19**) OJ L311, 28.11.2001, p. 1; last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ L188, 18.7.2009, p. 14).

Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, in so far as it applies to veterinary medicinal products used in feedingstuffs;

Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene, in so far as it applies to veterinary medicinal products used in feedingstuffs;

Commission Regulation (EC) No 1234/2008(**20**);

Regulation (EC) No 470/2009 of the European Parliament and of the Council(**21**);

Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council, and Articles 15 and 17 of that Regulation as they refer to the labelling requirements for feedingstuffs containing specified feed additives(**22**); and

Commission Regulation (EU) No 37/2010(**23**).

(4) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations, other than the fees provisions;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(5) In this regulation—

(a) "review period" means the period of five years beginning with the day on which these Regulations come into force, and, subject to paragraph (6), each successive period of five years thereafter; and

(b) "the fees provisions" means regulation 16 and Schedule 7.

(6) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

Revocations

46.—(1) The Veterinary Medicines Regulations 2009(**24**) are revoked.

(2) The Veterinary Medicines (Amendment) Regulations 2011(**25**) are revoked.

(3) In the Pharmacy Order 2010(**26**), in Schedule 4, paragraph 71 is revoked.

Henley
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

20th August 2011

(**20**) OJ L334, 12.12.2008, p. 7.
(**21**) OJ L152, 16.6.2009, p. 11.
(**22**) OJ L229, 1.9.2009, p. 1, last amended by Commission Regulation (EU) No 939/2010 (OJ L277, 21.10.2010, p. 14).
(**23**) OJ L293, 11.11.2010, p.72; corrected at OJ L293, 11.11.2010, p. 72.
(**24**) S.I. 2009/2297, amended by S.I. 2010/231 and 2011/1116.
(**25**) S.I. 2011/1116.
(**26**) S.I. 2010/231.

We consent

James Duddridge
Angela Watkinson
Two of the Lords Commissioners of Her Majesty's Treasury

25th August 2011