VETERINARY MEDICINES REGULATIONS 2019

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Statutory Document No. 2019/0028

European Communities (Isle of Man) Act 1973

VETERINARY MEDICINES REGULATIONS 2019

Laid before Tynwald: *19 February 2019*
Coming into Operation: *25 March 2019*

The Council of Ministers makes the following Regulations under section 2B of the European Communities (Isle of Man) Act 1973.

PART 1 - INTRODUCTORY

1 Title

These Regulations are the Veterinary Medicines Regulations 2019.

2 Commencement

These Regulations come into operation on 25 March 2019[1].

3 Interpretation and scope

(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.

"**adverse reaction**" means a reaction to a veterinary medicinal product that is harmful and unintended and that occurs at doses normally used in

[1] Section 2B(9) of the European Communities (Isle of Man) Act 1973 specifies that regulations shall be laid before Tynwald and if Tynwald at the sitting before which such instrument is so laid or at the next following sitting resolves that the instrument shall be annulled, the regulations shall thereupon cease to have effect.

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[2];

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

"authorised manufacturer" means the holder of a manufacturing authorisation under the Veterinary Medicines Regulations 2013;

"**blood bank**" means a blood bank authorised under the Veterinary Medicines Regulations 2013 for the treatment of non-food producing animals;

"**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[3];

"**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[4];

"**the Department**" means the Department of Environment, Food and Agriculture;

"**equine stem cell centre**" means an equine stem cell centre authorised under the Veterinary Medicines Regulations 2013;

"**horse identification document**" means an identification document issued in accordance with the provisions of Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae[5];

"**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;

"**improvement notice**" has the meaning given in regulation 38;

[2] OJ No L136, 30.4.2004, p. 1.
[3] OJ No L334, 12.12.2008, p. 7.
[4] OJ No L 15, 20.1.2010, p. 1.
[5] OJ No L59, 3.3.2015, p. 1.

"**manufacturing authorisation**" means a manufacturing authorisation issued in accordance with the Veterinary Medicines Regulations 2013;

"**marketing authorisation**" means a marketing authorisation issued in accordance with the Veterinary Medicines Regulations 2013;

"**project licence**" has the same meaning as it has in the Cruelty to Animals Act 1997;

"**registered homeopathic remedy**" means a homeopathic remedy registered in accordance with the Veterinary Medicines Regulations 2013;

"**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 of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC[6];

"**seizure notice**" has the meaning given in regulation 41;

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

"**summary of product characteristics**" means the information pertaining to a veterinary medicinal product required by paragraph 3 of Schedule 1 to the Veterinary Medicines Regulations 2013;

"**third country**" means a country or territory outside the EU;

"**Veterinary Medicines Regulations 2013**" means the Veterinary Medicines Regulations 2013[7];

"**veterinary surgeon**" means a veterinary surgeon as defined by the Veterinary Surgeons Act 2005; and

"**withdrawal period**" has the meaning given in Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products[8];

(2) In these Regulations references to types of variation are to those specified in Commission Regulation (EC) No 1234/2008.

(3) In these Regulations any reference to a "**member State**" is a reference to Norway, Iceland and Liechtenstein and a member State of the European Union other than the United Kingdom.

[6] OJ No L229, 1.9.2009, p. 1. Regulation (EC) No 767 2009 was last amended by Commission Regulation (EU) 2017/2279 (OJ No L328, 12.12.2017, p. 3).
[7] SI 2013 No. 2033.
[8] OJ No L311, 28.11.2001, p. 1.

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

4 Products to which these Regulations do not apply

(1) These Regulations do not apply to a veterinary medicinal product based on radioactive isotopes.

(2) They do not apply in relation to a product intended for administration in the course of a procedure licenced under the Cruelty to Animals Act 1997 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 a project licence granted under the Cruelty to Animals Act 1997.

PART 2 - AUTHORISED VETERINARY MEDICINAL PRODUCTS

5 Placing a veterinary medicinal product on the market

(1) No person may place a veterinary medicinal product on the market unless that veterinary medicinal product has been granted a current valid marketing authorisation in accordance with the Veterinary Medicines Regulations 2013.

(2) No person may certify data in relation to a marketing authorisation if they know that those data are false, or do not believe that they are accurate.

(3) Schedule 1 (adverse reactions and homeopathic remedies) has effect.

6 Blood banks and equine stem cell centres

Schedule 2 (blood banks and equine stem cell centres) has effect.

7 Marketing of products not in accordance with a marketing authorisation

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.

8 Classification, supply and possession of the product

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

(2) No person may supply a veterinary medicinal product that has passed its expiry date.

(3) No person may open 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.

(4) No person may supply 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).

(5) No person may be in possession of a veterinary medicinal product that was supplied to that person other than in accordance with Schedule 3.

9 Administration of the product

No person may administer a veterinary medicinal product to an animal unless —

(a) the product has a marketing authorisation authorising its administration 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).

10 Importation of authorised veterinary medicinal products

(1) No person may import a veterinary medicinal product authorised under the Veterinary Medicines Regulations 2013 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.

11 Advertising the product

(1) No person may 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) No person may 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.

12 Advertising of prescription products and products containing psychotropic drugs or narcotics

(1) No person may 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, paragraph (1) does not apply to advertisements aimed at veterinary surgeons or pharmacists.

(3) Subject to paragraph (4) in the case of POM-V medicines, paragraph (1) does not apply to price lists, or to advertisements aimed at —

(a) veterinary surgeons;

(b) veterinary nurses;

(c) pharmacists; or

(d) professional keepers of animals.

(4) No person may advertise anti-microbials to professional keepers of animals.

(5) In the case of POM-VPS medicines, paragraph (1) 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; or

(e) professional keepers of animals.

13 Defence of publication in the course of business

In proceedings for an offence under regulation 43(g), 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.

14 Wholesale dealing

No person may 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 Department under this regulation and Schedule 3.

15 Manufacture and placing on the market of feedingstuffs containing a veterinary medicinal products

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

(2) The manufacture of veterinary medicinal products, except in accordance with Schedule 5, is prohibited.

(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.

16 Exemptions

(1) These Regulations do not apply to an inactivated autogenous vaccine that is manufactured or supplied in accordance with the Veterinary Medicines Regulations 2013, 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 6 (exemptions for small pet animals) has effect.

17 Fees

Schedule 7 (fees) has effect.

PART 3 - RECORDS

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

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).

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

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.

20 Food-producing animals: records of acquisition and administration

(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 19) 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.

21 Food-producing animals: retention of records

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 5 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.

22 Records by a holder of a wholesale dealer's authorisation

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 3 years.

23 Records of the receipt or supply of prescription products

(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 5 years.

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

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 5 years.

PART 4 - UNAUTHORISED VETERINARY MEDICINAL PRODUCTS

25 Importation of an unauthorised veterinary medicinal product

(1) No person may import or be concerned in the importation of an unauthorised veterinary medicinal product except in accordance with this regulation.

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

(3) A veterinary surgeon may import an unauthorised veterinary medicinal product that is authorised in a 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 Department, and the product may be imported by the veterinary surgeon personally or by using a wholesale dealer or pharmacist as an agent.

(4) 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 a member State or a third country;

(b) the Department 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 Island; and

(c) in the case of a wholesale dealer, the product is within the terms of the authorisation.

(5) The Department may authorise in writing the importation of any product or substance for use under a licence granted under the Cruelty to Animals Act 1997.

26 Possession of an unauthorised veterinary medicinal product

(1) No person may be in possession of an unauthorised veterinary medicinal product.

(2) No person may be in possession of an unauthorised veterinary medicinal product with the intention of supplying that product to another person.

(3) This regulation does not apply to —

(a) a veterinary medicinal product imported in accordance with a certificate granted by the Department 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.

(4) A veterinary surgeon who practises in both the Island and a member State may hold veterinary medicinal products authorised in that member State provided that the amount held does not exceed the amount expected to be used in that member State.

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

(6) A veterinary surgeon may have possession of an authorised human medicinal product intended for administration to animals under the cascade, provided that the amount held does not exceed the amount expected to be used under the cascade.

27 Supply of an unauthorised veterinary medicinal product

(1) No person may 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 Department under these Regulations.

(3) It is a defence for a person charged with failing to comply with 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

28 The Veterinary Products Committee

(1) There shall be a Veterinary Products Committee.

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

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

(4) The Department may consult the Committee at any time.

29 Veterinary Products Committee appeals procedure

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

(2) The appellant must inform the Department 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 Department at the time of the original decision.

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

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

(7) The Department must consider the report and then form a provisional decision.

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

30 Appeals to an appointed person

(1) A person aggrieved by a provisional decision of the Department under regulation 29 or an applicant for a matter to which paragraph (2) applies may appeal against the decision to a person appointed for the purpose by the Department in accordance with this regulation.

(2) This paragraph applies to an application for —

(a) an authorisation to manufacture medicated feedingstuffs in accordance with Schedule 5;

(b) a wholesale dealer's authorisation; and

(c) 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 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 Department at the time of the original decision) and any representations made by the Department and report in writing, with a recommended course of action, to the Department.

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

31 Exports

(1) No person may export a veterinary medicinal product for use in —

(a) a member State unless the veterinary medicinal product may be lawfully supplied or administered in that member State; or

(b) the United Kingdom unless the veterinary medical product may be lawfully supplied or administered in the United Kingdom.

(2) If the veterinary medicinal product is authorised in the Island the Department must ensure that the exporter or the competent authorities of the third country has access to the summary of product characteristics.

32 Time limits

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

(2) In calculating the period during which the Department must issue any authorisation requires the clock is stopped when the Department 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 Department may stop the clock pending payment of outstanding fees.

33 Appointment of inspectors

(1) The Department must appoint inspectors for the purpose of enforcing these Regulations.

(2) In these Regulations "inspector" means —

(a) an inspector appointed under this regulation; or

(b) a veterinary inspector appointed under the Animal Health Act 1996.

34 Powers of entry

(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, or any part of them, are approved, registered or authorised for the sale of veterinary medicines under paragraph 8, 10, 14(4) or 18 of Schedule 3 or for use as a feed business under paragraph 5(2)(e) or 7(2) of Schedule 5.

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

(5) An inspector may be accompanied by —

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

(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 of the peace may sign a warrant to authorise an 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 carry out an inspection at the request of a member State, the European Commission or the Agency.

35 Powers of an inspector

(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 or any additive to which Schedule 5 applies, if it is not authorised under the Veterinary Medicines Regulations 2013;

(f) seize any premixture or feedingstuff that contains a veterinary medicinal product or additive to which Schedule 5 applies that is not authorised under the Veterinary Medicines Regulations 2013 ;

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

(i) it has not been lawfully manufactured, incorporated or supplied in accordance with these Regulations;

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

(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) The powers of seizure under sub-paragraph (1)(e), (f) and (g) include a power to seize anything which purports to be, or which an inspector reasonably believes to be, something the inspector is entitled to seize under these powers.

(3) An officer of the Department 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.

(4) 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.

36 Inspection of pharmacies

In relation to a pharmacy, all the powers of an inspector to enforce these Regulations may also be exercised by an officer appointed for this purpose by the Department of Health and Social Care.

37 Obstruction

No person may —

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

(b) without reasonable cause, fail 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) furnish to any person acting in the execution of these Regulations any information knowing it to be false or misleading; or

(d) fail to produce a record when required to do so to any person acting in the execution of these Regulations.

38 Improvement notices

(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) An improvement notice must state —

(a) the right of appeal to a court of summary jurisdiction; and

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

39 Appeals against improvement notices

(1) Any person who is aggrieved by an improvement notice may appeal to a court of summary jurisdiction.

(2) The procedure on an appeal to a court of summary jurisdiction under paragraph (1) is by way of complaint, and the Summary Jurisdiction Act 1989 applies to the proceedings.

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

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

40 Powers of a court on appeal

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

41 Seizure notices

(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 no person other than an inspector may remove products identified under this paragraph from the premises.

(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 Department 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 Department 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 Department 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 court of summary jurisdiction, and if the court confirms the notice it must order its destruction.

(7) The procedure in a court of summary jurisdiction under this regulation is by way of complaint, and the Summary Jurisdiction Act 1989 applies to the proceedings.

(8) 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.

42 Publication

(1) The Department 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 Department 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.

43 Offence

It is an offence[9] to fail to comply with —

(a) regulation 5(1) or (2);

(b) regulation 8(2), (3), (4) or (5);

[9] Other offences are set out at the end of Schedules 1, 2, 3, 4 and 5.

(c) regulation 9;

(d) regulation 10(1);

(e) regulation 11(1) or (2);

(f) regulation 12(1);

(g) regulation 14;

(h) regulation 15(2);

(i) regulation 18;

(j) regulation 19;

(k) regulation 20;

(l) regulation 21;

(m) regulation 22;

(n) regulation 23;

(o) regulation 24;

(p) regulation 25(1);

(q) regulation 26(1), (2) or (6);

(r) regulation 27(1);

(s) regulation 31(1);

(t) regulation 37;

(u) an improvement notice issued under regulation 38;

(v) regulation 41(3); or

(w) any paragraph specified in a Schedule to these Regulations.

44 Penalties

(1) A person guilty of an offence under these Regulations is liable to the following maximum penalties —

(a) on summary conviction, to 3 months' custody, or a fine of level 5 on the standard scale or both; or

(b) on conviction on information, to 2 years' custody, a fine 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 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) If an offence under these Regulations committed by a partnership is shown —

(a) to have been committed with the consent or connivance of a partner; or

(b) to be attributable to any neglect on their part,

the partner as well as the partnership is guilty of the offence and liable to be proceeded against and punished accordingly.

MADE 31 JANUARY 2019

W GREENHOW
Chief Secretary

SCHEDULE 1

ADVERSE REACTIONS AND HOMEOPATHIC REMEDIES

[Regulation 5(3)]

PART 1 - ADVERSE REACTIONS

1 Adverse reactions to a veterinary medicinal product administered in the Island

(1) A marketing authorisation holder must act in accordance with this paragraph on learning of any suspected —

(a) serious adverse reaction;

(b) human adverse reaction; or

(c) unintended transmission of an infectious agent through a veterinary medicinal product, following the administration of the product in the Island.

(2) The holder must make a record of what happened.

(3) The holder must without delay and in any event within 15 days report it (electronically if this is practicable) to the Department.

(4) In addition, the holder must supply to the Department all relevant veterinary information that the holder possesses relating to the reaction, giving a full description of the incident and a list of all the symptoms using internationally recognised veterinary and medical terminology, either with the report or, if the information becomes available after the report has been sent, as soon after it becomes available as is reasonably practicable.

(5) In this paragraph —

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

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

2 Offences

It is an offence to fail to comply with paragraph 1.

PART 2 - HOMEOPATHIC REMEDIES

3 Meaning of "homeopathic remedy"

For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia[10] or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission or by the competent authority of any member State.

4 Placing a homeopathic remedy on the market in accordance with a registration

By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market if it is eligible to be placed on the market in the United Kingdom under the Veterinary Medicines Regulations 2013.

[10] ISBN 9287145873.

SCHEDULE 2

BLOOD BANKS AND EQUINE STEM CELL CENTRES

[Regulation 6]

PART 1 - BLOOD BANKS

1 Supply and administration of blood from a blood bank

(1) Only a veterinary surgeon may procure blood from a blood bank.

(2) No person other than a veterinary surgeon or someone acting under a veterinary surgeon's responsibility may administer blood.

(3) No person may administer blood to a food-producing animal.

PART 2 - EQUINE STEM CELL CENTRES

2 Stem cell centres

(1) No person may operate an equine stem cell centre.

(2) No person other than a veterinary surgeon or someone acting under a veterinary surgeon's responsibility may administer any product grown from collected equine stem cells.

(3) No person may administer any product grown from collected equine stem cells to a food-producing horse.

3 Offences

It is an offence to fail to comply with paragraphs 1 or 2 of this Schedule.

SCHEDULE 3

CLASSIFICATION AND SUPPLY, WHOLESALE DEALERS AND SHEEP DIP

[Regulation 8]

PART 1 - CLASSIFICATION AND SUPPLY OF AUTHORISED VETERINARY MEDICINAL PRODUCTS

1 Classification of veterinary medicinal products

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

(a) Prescription Only Medicine–Veterinarian (abbreviated to POM-V);

(b) Prescription Only Medicine–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);

(c) Non-Food Animal–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);

(d) Authorised Veterinary Medicine–General Sales List (abbreviated to AVM-GSL).

(2) The classification of the veterinary medicinal product is that stated in the initial marketing authorisation.

2 Wholesale supply of veterinary medicinal products

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

(2) A person mentioned in sub-paragraph (1) may only supply a veterinary medicinal product if —

(a) the authorisation in question relates to that product; and

(b) the supply is to another person who is entitled to supply that product under these Regulations, either wholesale or retail.

(3) If the supply is to a suitably qualified person, it must be to the premises approved in accordance with paragraph 14.

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

(5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer with such products for the purpose of alleviating a temporary supply shortage that could be detrimental to animal welfare.

(6) A wholesale dealer may break open any package (other than the immediate packaging) of a veterinary medicinal product.

3 Retail supply of veterinary medicinal products

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

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

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

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 14,

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

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

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 14.

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

(6) In this paragraph —

(a) "retail supply" means any supply other than to or from the holder of a wholesale dealer's authorisation, and whether or not for payment; and

(b) a person may supply a product irrespective of who owns it.

4 Prescriptions by a veterinary surgeon

(1) A veterinary surgeon who prescribes a veterinary medicinal product classified as POM-V must first carry out a clinical assessment of the animal, and the animal must be under that veterinary surgeon's care.

(2) This does not apply in relation to the administration of such a product to a wild animal where the administration is authorised by the Department.

5 Prescriptions

(1) A prescription may be oral or written, but a veterinary medicinal product classified as POM-V or POM-VPS may only be supplied —

(a) by the person who prescribed it;

(b) under a written prescription that complies with paragraph 6; or

(c) (in the case of POM-VPS) by a suitably qualified person in accordance with paragraph 14(5).

(2) A person supplying such a product under a written prescription —

(a) may only supply the product specified in that prescription;

(b) must take all reasonable steps to be satisfied that the prescription has been written and signed by a person entitled to prescribe the product; and

(c) must take all reasonable steps to ensure that it is supplied to the person named in the prescription.

(3) No person may alter a written prescription unless authorised to do so by the person who signed it.

6 Written prescriptions

(1) A written prescription must include —

(a) the name, address and telephone number of the person prescribing the product;

(b) the qualifications enabling the person to prescribe the product;

(c) the name and address of the owner or keeper;

(d) the identification (including the species) of the animal or group of animals to be treated;

(e) the premises at which the animals are kept if this is different from the address of the owner or keeper;

(f) the date of the prescription;

(g) the signature or other authentication of the person prescribing the product;

(h) the name and amount of the product prescribed;

(i) the dosage and administration instructions;

(j) any necessary warnings;

(k) the withdrawal period if relevant; and

(l) if it is prescribed under the cascade, a statement to that effect.

(2) A written prescription for a controlled drug (as defined in section 2 the Misuse of Drugs Act 1976) is valid for 28 days.

(3) A written prescription for any other drug is valid for 6 months or such shorter period as may be specified in the prescription.

(4) If the prescription is repeatable it must specify the number of times the veterinary medicinal product may be supplied.

7 Duties when a product is prescribed or supplied

A person who prescribes a product classified as POM-V or POM-VPS, or supplies a product classified as NFA-VPS —

(a) before doing so, must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised;

(b) when doing so, must advise on its safe administration and on any warnings or contra-indications on the label or package leaflet; and

(c) must not prescribe (or, in the case of a NFA-VPS product, supply) more than the minimum amount required for the treatment; but it is a defence to a charge of failing to comply with this paragraph to show that —

(i) the product prescribed or supplied was in a container specified in the marketing authorisation;

(ii) the manufacturer does not supply that veterinary medicinal product in a smaller container; and

(iii) the person prescribing or supplying is not a person authorised to break open the package before supply.

8 Supply by a veterinary surgeon from registered premises

(1) A veterinary surgeon may only supply a veterinary medicinal product from practice premises registered with the Royal College of Veterinary Surgeons as veterinary practice premises at which veterinary medicinal products are stored or supplied.

(2) This paragraph does not apply in relation to a veterinary medicinal product classified as AVM-GSL.

(3) The Royal College of Veterinary Surgeons must, on request, supply the Department with a copy of the register of veterinary practice premises.

(4) The Department must, from time to time, inspect premises registered under sub-paragraph (1), basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(5) Where an inspection under sub-paragraph (4) reveals significant breaches of these Regulations the Department may require the Royal College of Veterinary Surgeons to remove the premises from the register maintained under sub-paragraph (1).

(6) Where the Department requires the removal of premises from the register the veterinary surgeon concerned may appeal using the procedure in regulation 30.

(7) Where premises have been removed from the register under sub-paragraph (5) they may not be re-registered without the approval of the Department.

(8) The Department may only grant approval under sub-paragraph (7) after a further inspection of the premises.

9 Supply by a veterinary surgeon

(1) A veterinary surgeon supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the veterinary surgeon —

(a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.

(2) A veterinary surgeon or a person acting under a veterinary surgeon's responsibility may open any package containing a veterinary medicinal product.

10 Supply by a pharmacist

(1) A pharmacist may only supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS from —

(a) premises registered as a pharmacy with the Department of Health and Social Care;

(b) premises registered with the Royal College of Veterinary Surgeons as being premises from which a veterinary surgeon supplies veterinary medicinal products; or

(c) (in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises approved under paragraph 14.

(2) A pharmacist supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the pharmacist —

(a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.

(3) A pharmacist may supply any veterinary medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user.

(4) A pharmacist may supply a homeopathic remedy provided that it is in accordance with Part 2 of Schedule 1 of these Regulations and intended to be supplied directly to the end user.

(5) A pharmacist may break open any package containing a veterinary medicinal product for the purposes of supply other than the immediate packaging of an injectable product.

11 Supply of a veterinary medicinal product for incorporation into feedingstuffs

(1) This paragraph applies in relation to the supply of a veterinary medicinal product intended for incorporation into feedingstuffs.

(2) The marketing authorisation holder, an authorised manufacturer of the product or an authorised wholesale dealer may only supply such a veterinary medicinal product to —

(a) a veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person;

(b) an approved premixture manufacturer; or

(c) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end-user the supply must be in accordance with a prescription).

(3) A veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person may only supply such a veterinary medicinal product to —

(a) an approved premixture manufacturer; or

(b) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end user the supply must be in accordance with a prescription).

(4) An approved premixture manufacturer or an approved feedingstuffs manufacturer may only supply such a veterinary medicinal product to another approved premixture manufacturer or approved feedingstuff manufacturer if the amount supplied does not exceed 5% in terms of value of veterinary medicinal product incorporated annually by the person supplying the veterinary medicinal product.

12 Labelling at the time of retail supply

(1) If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it must not be supplied if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.

(2) Sub-paragraph (1) does not apply to a veterinary surgeon who amends a label, or a pharmacist who amends it in accordance with a prescription

from a veterinary surgeon, provided that the unamended information remains clearly visible.

(3) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must ensure that the container is suitably labelled and must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely.

13 Supply of veterinary medicinal products for use under the cascade

(1) A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.

(2) Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information —

(a) the name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;

(b) the name of the veterinary surgeon who has prescribed the product;

(c) the name and address of the animal owner;

(d) the identification (including the species) of the animal or group of animals;

(e) the date of supply;

(f) the expiry date of the product, if applicable;

(g) the name or description of the product, which should include at least the name and quantity of active ingredients;

(h) dosage and administration instructions;

(i) any special storage precautions;

(j) any necessary warnings for the user, target species, administration or disposal of the product;

(k) the withdrawal period, if relevant; and

(l) the words "Keep out of reach of children" and "For animal treatment only".

14 Supply by a suitably qualified person

(1) The Department may recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

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

(a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;

(b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;

(c) maintains a programme of continuing professional development for persons registered with it;

(d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register.

(3) For the purposes of these Regulations, a suitably qualified person is a person who has passed examinations specified by such a body, and is registered with such a body as a suitably qualified person.

(4) A suitably qualified person may only supply a veterinary medicinal product classified as POM-VPS, NFA-VPS or AVM-GSL, and may only supply it from —

(a) premises approved by the Department as being suitable for the storage and supply of veterinary medicinal products by a suitably qualified person;

(b) premises registered as a pharmacy with the Department of Health and Social Care; or

(c) practice premises registered under these Regulations as being premises from which a veterinary surgeon supplies veterinary medicinal products.

(5) A suitably qualified person who supplies a product classified as POM-VPS or NFA-VPS must either —

(a) hand over or despatch the product personally;

(b) ensure that, when the product is handed over or despatched, the suitably qualified person is in a position to intervene if necessary; or

(c) check the product after it has been allocated for supply to a customer, and be satisfied that the person handing over or dispatching it is competent to do so.

(6) A suitably qualified person supplying products from premises approved under this regulation by the Department who considers that the premises no longer comply with the approval must notify the Department without unreasonable delay.

(7) The Department may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph must take appropriate action in accordance with any disciplinary code that applies to that body if a suitably qualified person registered with it does not comply with the Code of Practice.

(8) The Department must publish in a manner it considers will bring it to the attention of those likely to be affected by it, a list of —

(a) suitably qualified persons; and

(b) the trading names and the addresses of premises approved under this paragraph.

(9) A suitably qualified person may break open any package (other than the immediate packaging) of a veterinary medicinal product.

(10) The Department may suspend or revoke the approval of approved premises on being satisfied that they are no longer suitable for the storage and supply of veterinary medicinal products.

15 Annual audit

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

(2) The records referred to in sub-paragraph (1) must be disclosed to the Department upon request.

PART 2 - REQUIREMENTS FOR A WHOLESALE DEALER'S AUTHORISATION

16 Application

(1) An application for a wholesale dealer's authorisation must be made to the Department in such form as the Department may require.

(2) The Department may publish guidance for applicants for a wholesale dealer’s authorisation.

17 Time limits

The Department must endeavour as far as is practicable to process an application for a wholesale dealer's authorisation within 90 days of receiving it.

18 Granting the authorisation

(1) The Department must grant a wholesale dealer's authorisation on being satisfied that this paragraph is complied with.

(2) The authorised site must be —

(a) weatherproof;

(b) secure and lockable;

(c) clean; and

(d) free from contaminants.

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

(4) The authorisation holder must —

(a) have the services of technically competent staff;

(b) have an effective emergency recall plan; and

(c) name the qualified person nominated to act under the Guidelines on Good Distribution Practice of Medical Products for Human Use[11].

19 The authorisation

(1) The wholesale dealer's authorisation must specify —

(a) the types of veterinary medicinal products and pharmaceutical forms that may be dealt in;

(b) the place where they are to be stored;

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates;

(e) the name of the qualified person nominated to act under the Guidelines on Good Distribution Practice of Medical Products for Human Use.

(2) It may cover more than one site.

(3) It lapses if the holder does not deal in veterinary medicinal products for 5 years.

[11] OJ No C343, 23.11.2013, p. 3.

(4) The holder of a wholesale dealer's authorisation must notify the Department, and if necessary apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation, or in the operations for which they are used.

20 Suspension, variation or revocation of the authorisation

The Department may suspend, vary or revoke a wholesale dealer's authorisation if the holder —

(a) has not complied with these Regulations; or

(b) no longer has suitable premises or equipment.

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

The holder of a wholesale dealer's authorisation must —

(a) store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product;

(b) comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use as if the veterinary medicinal products were authorised human medicinal products;

(c) carry out a detailed stock audit at least once a year; and

(d) supply information and samples to the Department on demand.

PART 3 - SHEEP DIP

22 Supply of sheep dip

(1) A person who supplies by retail sheep dip which contains a veterinary medicinal product must supply it in accordance with this paragraph.

(2) The supply must be to a person (or a person acting on that person's behalf) who is qualified to use it in accordance with paragraph 23.

(3) The supplier must make a record of that person's certificate or award number as soon as is reasonably practicable, and keep it for at least 3 years.

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

(a) a double-sided laminated notice meeting the specifications in the following sub-paragraph (unless the notice has been provided to the buyer within the previous 12 months and the supplier knows or has reasonable cause to believe that the buyer still has it available for use); and

(b) two pairs of gloves either as described in the notice or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves as so described.

(5) The notice must be at least A4 size with a laminated transparent cover and must tell the user of the sheep dip —

(a) to read and act in accordance with the label, including instructions on measuring and diluting concentrate;

(b) that sheep dip is absorbed through the skin;

(c) always to wear the recommended protective clothing, including gloves, and have spare protective clothing available;

(d) always to wash protective clothing before taking it off; and

(e) to direct any questions to the supplier or manufacturer.

(6) The notice must contain a diagram showing recommended protective clothing.

23 Use of sheep dip

(1) No person may use sheep dip which contains a veterinary medicinal product unless the person is acting under the supervision and in the presence of, a person who holds either —

(a) a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed; or

(b) NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF).

(2) The certificate or award must be issued —

(a) in the Island, England, Wales and Northern Ireland by —

(i) the National Proficiency Tests Council;

(ii) NPTC Part of the City & Guilds Group; or

(iii) City and Guilds NPTC;

(b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

24 Offences

It is an offence to fail to comply with the following provisions of this Schedule —

(a) paragraph 2;

(b) paragraph 3;

(c) paragraph 4(1);

(d) paragraph 5;

(e) paragraph 7;

(f) paragraph 8(1);

(g) paragraph 9(1);

(h) paragraph 10;

(i) paragraph 11;

(j) paragraph 12(1) or (3);

(k) paragraph 13;

(l) paragraph 14(4), (5) or (6);

(m) paragraph 15;

(n) paragraph 19(4);

(o) paragraph 21;

(p) paragraph 22; or

(q) paragraph 23(1).

SCHEDULE 4

ADMINISTRATION OF A VETERINARY MEDICINAL PRODUCT OUTSIDE THE TERMS OF A MARKETING AUTHORISATION

[Regulation 9]

1 Administration under the cascade

(1) A veterinary surgeon acting under this paragraph who prescribes a veterinary medicinal product may either administer it personally or may direct another person to do so under the responsibility of the veterinary surgeon.

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

(a) a veterinary medicinal product authorised in the Island for use with another animal species, or for another condition in the same species; or

(b) if there is no such product that is suitable, either —

(i) a human medicinal product authorised in the Island; or

(ii) a veterinary medicinal product not authorised in the Island but authorised in a member State for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or

(c) if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist or a veterinary surgeon.

(3) In the case of a veterinary medicinal product imported from a member State, if the veterinary surgeon has not obtained a certificate from the Department under regulation 25(3) permitting importation, the veterinary surgeon must obtain a certificate from the Department before administration.

(4) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the cascade must be listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010.

2 Withdrawal periods

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

(2) The withdrawal period must ensure that, if there is a maximum residue limit specified for the active substance in Table 1 in the Annex to Commission Regulation (EU) No 37/2010, the level of residue of the active substance does not exceed that limit.

(3) In any event, unless the Department has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period (irrespective of whether or not a maximum residue limit is specified in Table 1 in the Annex to Commission Regulation (EU) No 37/2010) must not be less than —

(a) 7 days for eggs;

(b) 7 days for milk;

(c) 28 days for meat from poultry and mammals including fat and offal;

(d) 500 degree days[12] for fish meat.

3 Administration to food-producing horses

(1) If there is no authorised veterinary medicinal product for a food-producing horse (as shown on its horse identification document) and treatment under the cascade is unsuitable, substances may be administered in accordance with Commission Regulation (EU) No 122/2013 (establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae[13]).

(2) The person administering the substance must comply with Article 3(2) of Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae and of substances bringing added clinical benefit[14] (recording the details of the treatment in the animal's identification document).

4 Immunological products for serious epizootic disease

In the event of serious epizootic diseases, the Department may permit in writing the administration of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and

[12] The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.
[13] OJ No L42, 13.2.2013, p. 1.
[14] OJ No L367, 22.12.2006, p.33.

after informing the European Commission of the detailed conditions of use and may publicise any permit as the Department sees fit.

5 Immunological products for an imported or exported animal

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

6 Administration by veterinary surgeons from other member States

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

(a) the quantity does not exceed the requirements for the treatment of specific animals;

(b) the product is authorised in the member State in which the veterinary surgeon is established;

(c) the product is transported by the veterinary surgeon in the original manufacturer's packaging;

(d) in the case of administration to food-producing animals, there is a veterinary medicinal product authorised in the Island that has the same qualitative and quantitative composition in terms of active substances;

(e) the veterinary surgeon is acquainted with the Code of Professional Conduct for veterinary surgeons issued by the Royal College of Veterinary Surgeons[15].

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

(3) The veterinary surgeon must —

(a) ensure that the withdrawal period specified on the label of the product is complied with, or the Island withdrawal period for the equivalent product authorised in the Island if this is longer than the one on the label; and

(b) keep detailed records of the animals treated, the diagnosis or clinical assessment, the products administered, the dosage administered, the duration of treatment and the withdrawal

[15] Published at http://www.rcvs.org.uk/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/.

period applied, and must keep them in the Island for at least 3 years.

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

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

7 Treatment in exceptional circumstances

(1) Where the health situation so requires, and where there is no suitable veterinary medicinal product available either as an authorised product or under the cascade, a veterinary surgeon may treat an animal with a medicinal product authorised in a third country; but a veterinary surgeon who has not obtained a certificate from the Department under regulation 25(3) permitting importation must obtain a certificate from the Department before treating the animal.

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

8 Administration of a homeopathic remedy

(1) A registered homeopathic remedy may be administered to an animal by anyone, subject to any restrictions specified in its registration.

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

(3) A veterinary surgeon may administer a homeopathic remedy authorised for human use in accordance with Part 6 of the Human Medicines Regulations 2012[16], either personally or under the veterinary surgeon's responsibility.

9 Offences

It is an offence to fail to comply with paragraph 3(2) or paragraph 6 of this Schedule.

[16] S.I. 2012/1916.

SCHEDULE 5

MEDICATED FEEDINGSTUFFS AND SPECIFIED FEED ADDITIVES

[Regulation 15]

1 Scope and interpretation

(1) This Schedule applies in relation to the following (referred to in this Schedule and Schedule 7 as "specified feed additives") when used as feed additives —

(a) coccidiostats;

(b) histomonostats; and

(c) all other zootechnical additives except —

(i) digestibility enhancers;

(ii) gut flora stabilisers; and

(iii) substances incorporated with the intention of favourably affecting the environment.

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

(3) In this Schedule —

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

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

2 Enforcement of Regulation (EC) No 178/2002

(1) For the purposes of Regulation (EC) No 178/2002 (of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[17]) the competent authority is the Department.

(2) No person may fail to comply with any of the following provisions of that Regulation —

(a) Article 11 (requirements relating to imports);

(b) Article 12 (requirements relating to exports);

(c) Article 15(1) (prohibition on the placing on the market or feeding unsafe feedingstuffs);

[17] OJ No L31, 1.2.2002, p. 1.

(d) Article 16 so far as it prohibits misleading labelling, advertising or presentation of feedingstuffs;

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

(f) Article 20 (responsibilities of feed business operators).

3 Enforcement of Regulation (EC) No 1831/2003

(1) For the purposes of Regulation (EC) No 1831/2003 (of the European Parliament and of the Council on additives for use in animal nutrition[18]) the competent authority is the Department.

(2) An authorisation under Article 3(2) of that Regulation must be in writing.

(3) No person may possess a specified feed additive, or a premixture or feedingstuffs containing a specified feed additive, unless the specified feed additive has been authorised under Regulation (EC) No 1831/2003 or is for export to a third country.

(4) No person may fail to comply with any of the following provisions of that Regulation —

(a) Article 3(1) or Article 3(3) (the authorisation, conditions of use and labelling of specified feed additives);

(b) Article 12(1) or (2) (conditions relating to specified feed additives);

(c) Article 16(1) (labelling);

(d) Article 16(3) (additional labelling requirement);

(e) Article 16(4) (premixtures containing specified feed additives);

(f) Article 16(5) (packaging).

4 Enforcement of Regulation (EC) No 882/2004

For the purposes of Regulation (EC) No. 882/2004 (of the European Parliament and the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[19]) the competent authority is the Department.

5 Enforcement of Regulation (EC) No 183/2005

(1) For the purposes of Regulation (EC) No 183/2005 (of the European Parliament and of the Council laying down requirements for feed hygiene[20]) the competent authority is the Department.

[18] OJ No L268, 18.10.2003, p. 29.
[19] OJ No L165, 30.4.2004, p. 1.
[20] OJ No L035, 8.2.2005, p. 1.

(2) No person may fail to comply with any of the following provisions of that Regulation —

(a) Article 5(2), (5) or (6) (specific obligations);

(b) Article 6(1) as read with (2) and (3) (HACCP system);

(c) Article 7(1) (documents concerning the HACCP system);

(d) Article 9(2) (official controls, notification and registration);

(e) Article 10(1) (approval of feed business establishments);

(f) Article 11 (prohibition on operating without approval or registration);

(g) Article 17(2) (exemption from on-site visits);

(h) Article 18(3) (declaration of compliance);

(i) Article 23(1) (conditions relating to imports from third countries);

(j) Article 25 (feedingstuffs produced for export to third countries).

(3) A manufacturer must ensure that, so far as is reasonably practicable, the active ingredient is evenly incorporated throughout the feedingstuffs.

(4) In the case of the refusal, suspension or revocation of an approval under the Regulation the appeals procedure relating to an authorisation to manufacture medicated feedingstuffs in regulation 30 applies.

6 Enforcement of Regulation (EC) No 767/2009

No person may contravene Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council in relation to feedingstuffs containing specified feed additives[21].

7 Approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products

(1) For the purposes of Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[22] the competent authority is the Department.

(2) No person may incorporate a veterinary medicinal product into a premixture or feedingstuff, or act as a distributor of premixtures or feedingstuffs containing a veterinary medicinal product, without being approved to do so by the Department.

(3) The conditions which govern approval of feed business establishments under Regulation (EC) No 183/2005 laying down requirements for feed

[21] OJ No L229, 1.9.2009, p. 1.

[22] OJ L 92, 7.4.1990, p. 42.

hygiene[23] also govern approval of manufacturers and distributors under sub-paragraph (2).

(4) The Department shall conduct inspections of manufacturers and distributors approved under sub-paragraph (2) basing the frequency of inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(5) A manufacturer must ensure that, so far as is reasonably practical, the veterinary medicinal product is evenly incorporated throughout the feedingstuffs.

(6) The provisions of this paragraph do not apply in relation to any person breeding or selling ornamental fish not intended for human consumption provided that the person does not use more than a total of 1kg of veterinary medicinal product annually for that purpose.

(7) In the case of the refusal, suspension or revocation of an approval under this paragraph the appeals procedure relating to an authorisation to manufacture medicated feedingstuffs in regulation 30 applies.

8 Incorporation of a veterinary medicinal product into a premixture

Any person who incorporates a veterinary medicinal product into a premixture —

(a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there; and

(b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive.

9 Top dressing

No person may promote or label any veterinary medicinal product, or anything containing a veterinary medicinal product, as being suitable for top dressing (that is, sprinkling it on to feedingstuffs without thoroughly incorporating it) unless the summary of product characteristics specifically permits this use.

10 Incorporation of a veterinary medicinal product into feedingstuffs

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

(a) must do so in accordance with the summary of product characteristics, and must take account of any interactions listed there;

[23] OJ No L 35, 8.2.2005, p. 1.

(b) must ensure that the veterinary medicinal product does not contain the same active substance as any other additive;

(c) must ensure that the veterinary medicinal product is incorporated in accordance with its marketing authorisation (unless it has been prescribed under the cascade) and the prescription; and

(d) must ensure that the daily dose of the veterinary medicinal product is contained in a quantity of medicated feedingstuffs corresponding to at least half the daily feedingstuffs ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral complementary feedingstuffs.

11 Additional record keeping requirements relating to veterinary medicinal products

(1) Any person who —

(a) incorporates a veterinary medicinal product into a premixture;

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

(c) incorporates a veterinary medicinal product into feedingstuffs,

must make a daily record of —

(i) the types and quantities of all veterinary medicinal products (and specified feed additives, if any) and premixture used in the manufacturing process; and

(ii) the quantity of feedingstuffs and premixture containing veterinary medicinal product manufactured that day.

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

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

(b) the quantity held.

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

(a) the date of delivery;

(b) the name and address of each consignee (or, in the case of a manufacturer supplying to a distributor, the name and address of the distributor);

(c) the type of feedingstuffs or premixture supplied;

(d) the quantity;

(e) the type of veterinary medicinal product incorporated into the feedingstuffs; and

(f) the expiry date.

(4) Records must be kept for 5 years.

12 Labelling a premixture containing a veterinary medicinal product

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

(a) the words "MEDICATED PREMIXTURE" in upper case letters;

(b) the proprietary name of the veterinary medicinal product and the authorisation number;

(c) the name and amount of the active substance (mg/kg) in the premixture;

(d) the range of acceptable inclusion rates of the premixture into the final feedingstuffs, the range of acceptable levels of the active ingredients in the final feedingstuffs and the words "refer to the prescription for the exact inclusion rate" or equivalent wording;

(e) warnings and contra-indications;

(f) the withdrawal period, and a statement that, if the prescription requires a longer withdrawal period, that is the one that applies;

(g) the expiry date;

(h) any special storage instructions;

(i) where a prescription is required, a statement to this effect.

(2) If there is more than one veterinary medicinal product used, the longest withdrawal period must be shown on the label.

(3) If the premixture also contains a specified feed additive to which this Schedule applies it must also contain the information required under Article 16 of Regulation (EC) No 1831/2003[24].

(4) No person may supply such a premixture unless it is labelled in accordance with this paragraph.

13 Labelling of feedingstuffs containing a specified feed additive

No person may contravene the labelling requirements of Article 15 and Article 17 of Regulation (EC) No 767/2009 of the European Parliament and of the Council.

[24] OJ No L268, 18.10.2003, p. 29. Regulation (EC) no 1831/2003 was last amended by Article 1 of Regulation (EC) No 2015/2294 (OJ No L324, 10.12.2015, p. 3.)

14 Labelling of feedingstuffs containing a veterinary medicinal product

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

(a) the words "MEDICATED COMPLETE FEED" in upper case letters;

(b) the proprietary name, authorisation number and inclusion rate (kg/tonne or mg/kg) of the veterinary medicinal product incorporated into the feedingstuffs;

(c) the name and amount of the active substance (mg/kg) in the feedingstuffs;

(d) the species of animal for which the feedingstuffs are intended;

(e) warnings and contra-indications;

(f) the withdrawal period, and a statement that, if the prescription requires a longer withdrawal period, that is the one that applies;

(g) the expiry date;

(h) any special storage instructions required by the marketing authorisation;

(i) a statement to the effect that the feedingstuffs must only be fed in accordance with its prescription;

(j) the name and approval number of the manufacturer or the distributor.

(2) If there is more than one veterinary medicinal product used, the longest withdrawal period must be shown on the label.

(3) If the feedingstuff also contains a specified feed additive to which this Schedule applies it must also contain the information required by Articles 15 and 17 of Regulation (EC) No 767/2009 of the European Parliament and of the Council.

(4) No person may supply feedingstuffs unless they are labelled in accordance with this paragraph.

15 Supply of specified feed additives

(1) No person other than the person who manufactured a specified feed additive or an approved distributor may supply a specified feed additive.

(2) The person who manufactured the specified feed additive may only supply it to —

(a) an approved distributor;

(b) an approved premixture manufacturer or an approved complementary feedingstuffs manufacturer; or

(c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.

(3) An approved distributor may only supply it to —

(a) another approved distributor;

(b) an approved premixture manufacturer or an approved complementary feedingstuffs manufacturer; or

(c) a feedingstuff manufacturer approved to mix a specified feed additive directly into feedingstuff.

16 Supply of premixture

(1) No person other than the person who manufactured a premixture or an approved distributor may supply a premixture.

(2) The person who manufactured the premixture may only supply it to —

(a) an approved distributor; or

(b) a feedingstuff manufacturer approved to incorporate that premixture.

(3) An approved distributor may only supply it to —

(a) another approved distributor; or

(b) a feedingstuff manufacturer approved to incorporate that premixture.

17 Supply of a complementary feedingstuff

(1) No person other than —

(a) the person who manufactured a complementary feedingstuff containing a specified feed additive; or

(b) an approved distributor,

may supply a complementary feedingstuff containing a specified feed additive.

(2) The person who manufactured such complementary feedingstuff may only supply it to —

(a) an approved distributor; or

(b) a feedingstuff manufacturer approved to incorporate that complementary feedingstuff or approved to incorporate a premixture.

(3) An approved distributor may only supply it to —

(a) another approved distributor, or

(b) a feedingstuff manufacturer approved to incorporate that complementary feedingstuff or approved to incorporate a premixture.

(4) In this paragraph "complementary feedingstuff" has the meaning given to "complementary feed" in Article 3 of Regulation (EC) No 767/2009.

18 Supply of feedingstuffs containing a veterinary medicinal product

(1) No person other than the person who manufactured the feedingstuffs or an approved distributor may supply feedingstuffs containing a veterinary medicinal product.

(2) The person who manufactured the feedingstuff may only supply it to —

(a) an approved distributor; or

(b) a person who keeps animals for feeding to those animals.

(3) A distributor may only supply it to —

(a) another approved distributor; or

(b) a person who keeps animals for feeding to those animals.

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

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

(6) No manufacturer or distributor may supply a feedingstuff to anyone not specified in this paragraph, or otherwise than in accordance with this paragraph.

(7) The person supplying the feedingstuff must keep the prescription for 5 years.

19 Prescriptions for feedingstuffs containing a veterinary medicinal product

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

(a) the name and address of the person prescribing the product;

(b) the qualifications enabling the person to prescribe the product;

(c) the name and address of the keeper of the animals to be treated;

(d) the species of animal, identification and number of the animals;

(e) the premises at which the animals are kept if this is different from the address of the keeper;

(f) the date of the prescription;

(g) the signature or other authentication of the person prescribing the product;

(h) the name and amount of the product prescribed;

(i) the dosage and administration instructions;

(j) any necessary warnings;

(k) the withdrawal period;

(l) the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose);

(m) if the validity exceeds one month, a statement that not more than 31 days' supply may be provided at any time;

(n) the name, type and quantity of feedingstuffs to be used;

(o) the inclusion rate of the veterinary medicinal product and the resulting inclusion rate of the active substance;

(p) any special instructions;

(q) the percentage of the prescribed feedingstuffs to be added to the daily ration; and

(r) if it is prescribed under the cascade, a statement to that effect.

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

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

20 Writing the prescription

(1) The person who writes the prescription must —

(a) give a copy to the person incorporating the veterinary medicinal product into the feedingstuffs or to the distributor of the feedingstuffs;

(b) give one copy to the keeper of the animals to be treated;

(c) keep a copy.

(2) The person must be satisfied that —

(a) there is no undesirable interaction between the veterinary medicinal product and any feed additive used in the feedingstuffs; and

(b) the active substance of the veterinary medicinal product is not the same as an active substance in any feed additive used in the feedingstuffs.

(3) The person must prescribe a veterinary medicinal product authorised for incorporation in feedingstuffs but may, if there is no veterinary medicinal product authorised for a condition in a particular species —

(a) prescribe a veterinary medicinal product authorised for another species or for another condition in the same species; and

(b) prescribe more than one veterinary medicinal product,

provided all veterinary medicinal products prescribed are authorised for incorporation in feedingstuffs.

21 Possession

(1) No person other than a person holding the appropriate approval under this Schedule may be in possession of any —

(a) specified feed additive or veterinary medicinal product to which this Schedule applies;

(b) premixtures containing such an additive or a veterinary medicinal product; or

(c) feedingstuffs or complementary feedingstuffs containing such an additive or a veterinary medicinal product unless supplied under these Regulations.

(2) No person other than a manufacturer or distributor may be in possession of feedingstuffs incorporating a veterinary medicinal product unless it has been supplied under a prescription.

22 Sampling and analysis

(1) If any enforcement action is taken under this Schedule based on a sample, that sample must have been taken and analysed in accordance with Regulation (EC) No 152/2009 laying down methods of sampling and analysis for the official control of feedingstuffs[25].

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

Tolerance table for medicated feedingstuffs

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

(3) Unless otherwise specified in the Commission Regulation authorising the specified feed additive in question, it is a defence if the active ingredient of a specified feed additive in a feedingstuff sample is within the tolerances set out in Articles 11(5) and paragraph 1 of Part B of Annex IV

[25] OJ No L 54, 26.2.2009, p. 1.

to Regulation (EC) No 767/2009 of the European Parliament and of the Council.

23 Storage

No person may store a veterinary medicinal product intended for incorporation into feedingstuffs, or a premixture or feedingstuffs containing a veterinary medicinal product, except in —

(a) a suitable storage area that is locked when not in use; or

(b) a hermetic container designed to store those products.

24 Packages and other containers

No person may place on the market feedingstuffs containing a veterinary medicinal product except in packages or containers that are sealed in such a way that, when the package or container is opened, the seal is damaged.

25 Transport

(1) No person may transport feedingstuffs by road tankers or in bulk unless the labelling requirements are set out in a document accompanying the feedingstuffs, and the transporter must hand over details when delivering the feedingstuffs unless these have already been provided to the purchaser.

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

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

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

26 Possession, placing on the market and use of feedingstuffs

(1) No person may possess, place on the market or feed to animals any feedingstuffs incorporating veterinary medicinal products or specified feed additives unless they have been incorporated in accordance with this Schedule.

(2) No person may feed to any animal, or buy, possess or supply for the purpose of feeding to any animal, any feedingstuff containing a veterinary medicinal product or specified feed additive unless —

(a) that veterinary medicinal product or specified feed additive is authorised under the Veterinary Medicines Regulations 2013 for that species of animal and for the purpose for which it is used; or

(b) in the case of a veterinary medicinal product, it was prescribed for that animal.

(3) This paragraph does not apply in relation to feedingstuffs if the veterinary medicinal product has been incorporated in accordance with —

(a) a project licence issued under the Cruelty to Animals Act 1997;

(b) a UK animal test certificate granted under the Veterinary Medicines Regulations 2013t; or

(c) the feedingstuff has been imported in accordance with this Schedule.

27 Imports from third countries

No person may import a feedingstuff containing a veterinary medicinal product from a third country.

28 Trade between member States

No person may bring in from the UK or a member State a feedingstuff containing a veterinary medicinal product unless —

(a) the feedingstuff has been manufactured in accordance with the provisions of Council Directive 90/167/EEC (laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[26]) and Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for food hygiene; and

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

29 Import for incorporation into premixture or feedingstuffs for export

(1) A manufacturer of premixture or feedingstuffs who imports a veterinary medicinal product authorised in a Member State or third country for the purposes of incorporating it into premixture or feedingstuffs for export does not commit an offence under regulation 43(p) (importation of an

[26] OJ No L 92, 7.4.90, p. 42.

unauthorised veterinary medicinal product) or regulation 43(q) (possession of an unauthorised veterinary medicinal product).

(2) No person may place that premixture or feedingstuff on the market in the Island once the veterinary medicinal product has been incorporated into it.

30 Animals on domestic premises

(1) The requirements of paragraph 7 (approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal product) do not apply in relation to a person who incorporates a veterinary medicinal product into feedingstuffs in domestic premises for feeding, on those premises —

(a) non-food-producing animals; or

(b) food-producing animals provided that the animals or products from those animals are not sold or supplied commercially.

(2) Notwithstanding paragraphs 16 and 18 of this Schedule, a veterinary surgeon, a pharmacist or a suitably qualified person who is registered in accordance with paragraph 14 of Schedule 3 may be supplied with and may supply a premixture containing a veterinary medicinal product, or feedingstuffs containing a veterinary medicinal product, to such a producer.

(3) The requirement for a written prescription does not apply in relation to such supply, but the provisions of Schedule 3 relating to supply of a veterinary medicinal product apply in relation to the supply of premixture and feedingstuffs in the same way as they apply to a veterinary medicinal product.

31 Offences

It is an offence to fail to comply with the following provisions of this Schedule —

(a) paragraph 2(2);

(b) paragraph 3(3) or (4);

(c) paragraph 5(2) or (3);

(d) paragraph 6;

(e) paragraph 7(2) or (5);

(f) paragraph 8;

(g) paragraph 9;

(h) paragraph 10;

(i) paragraph 11;

(j) paragraph 12(4);

(k) paragraph 13;

(l) paragraph 14(4);

(m) paragraph 15;

(n) paragraph 16;

(o) paragraph 17;

(p) paragraph 18;

(q) paragraph 20;

(r) paragraph 21;

(s) paragraph 23;

(t) paragraph 24;

(u) paragraph 25;

(v) paragraph 26(1) or (2);

(w) paragraph 27;

(x) paragraph 28; or

(y) paragraph 29(2).

SCHEDULE 6

EXEMPTIONS FOR SMALL PET ANIMALS

[Regulation 16(4)]

32 Animals to which this Schedule applies

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

(a) aquarium animals;

(b) cage birds;

(c) ferrets;

(d) homing pigeons;

(e) rabbits;

(f) small rodents; and

(g) terrarium animals.

33 Placing on the market, importing and administering the product

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

34 Manufacture

The product must have been manufactured by —

(a) the holder of a manufacturing authorisation issued in accordance with the Veterinary Medicines Regulations 2013 if manufactured in the United Kingdom;

(b) the holder of a manufacturing authorisation issued under Directive 2001/82/EC if manufactured in a member State;

(c) in the case of Australia, Canada, New Zealand, or Switzerland, the holder of an authorisation from the competent authority permitting the manufacture of medicinal products; or

(2) in the case of any other country, a manufacturer whose premises have been inspected and approved by an officer of the Secretary of State.

35 The product

(1) The active substance in the veterinary medicinal product must be approved under the Veterinary Medicines Regulations 2013.

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

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

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

36 Labelling

(1) The product must be clearly labelled as being exempt from the requirements of the Veterinary Medicines Regulations 2013, in relation to a marketing authorisation.

(2) The labelling must show the following —

(a) the name of the veterinary product, including, if it is part of the name, its strength and pharmaceutical form;

(b) the authorisation number of the manufacturer;

(c) the name and strength of each active substance;

(d) the route of administration;

(e) the batch number;

(f) the expiry date;

(g) the words "For animal treatment only";

(h) the contents by weight, volume or number of dose units;

(i) the name and address of the manufacturer or distributor;

(j) the target species;

(k) the words "Keep out of reach of children";

(l) storage instructions;

(m) the shelf-life after the immediate packaging has been opened for the first time;

(n) disposal advice;

(o) full indications, including —

(i) therapeutic indications;

(ii) contra-indications;

(iii) interaction with other medicines and other forms of interaction; and

(p) dosage instructions.

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

(a) the name of the veterinary medicinal product;

(b) its active substance and its strength;

(c) the route of administration;

(d) the batch number;

(e) the expiry date; and

(f) the words "For animal treatment only".

37 Administration

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

38 Pack size

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

39 Adverse reactions

(1) The manufacturer, importer or retailer of a veterinary medicinal product must —

(a) notify the Department within 15 days of learning of any serious adverse reactions (as defined in paragraph 1 of Schedule 1); and

(b) make a record of each adverse reaction and serious adverse reaction on becoming aware of it and keep it for 3 years.

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

SCHEDULE 7

[Regulation 17]

FEES

PART 1 - INTRODUCTION

1 Interpretation

In this Schedule —

"turnover" means the sales value net of value added tax of all veterinary medicinal products (whether or not authorised for use in the Island) sold by way of wholesale dealing by the holder in the Island.

2 Payment of fees

All fees under this Schedule are payable to the Department.

3 Time of payment

All fees are payable on invoice unless otherwise specified.

4 Multiple inspections

If a site, premises or establishment is inspected for more than one type of authorisation, approval or registration at the same time, the fee is the sum of —

(a) the highest fee payable; and

(b) 50% of each of the other fees.

5 Expenses for inspections outside the Island

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

6 Translation

All translation costs are charged additionally.

PART 2 - FEES RELATING TO A WHOLESALE DEALER'S AUTHORISATION

7 Application for a wholesale dealer's authorisation

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

(a) £1,745;

(b) £785 if the application is accompanied by an estimate that the first year's turnover will be less than £35,000; or

(c) £785 if the authorisation only relates to products classified as AVM-GSL, homeopathic remedies, or products authorised under Schedule 6 (exemptions for small pet animals).

(2) An applicant who has paid a fee of £785 on the grounds of turnover must send a declaration of turnover for the first year of trading on the anniversary of the grant of the authorisation, and if the figure is more than £35,000 must pay the balance of £960 within 30 days.

(3) If the applicant paid £1,745 but the turnover for the first year of trading was lower than £35,000, if the applicant sends a declaration certifying the turnover, the Department must refund the excess.

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

8 Variation of a wholesale dealer's authorisation

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

(a) £515 if the variation requires scientific or pharmaceutical assessment;

(b) £430 if the variation only involves a change of ownership; and

(c) otherwise £300.

9 Annual fee for a wholesale dealer's authorisation

The annual fee for a wholesale dealer's authorisation is —

(a) £483; or

(b) £315, if —

(i) the holder certifies when making the payment that the turnover during the previous year was less than £35,000; or

(ii) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies;

(c) £215 if the authorisation only relates to products authorised under Schedule 6 (exemptions for small pet animals).

10 Inspection of a wholesale dealer's premises

The fee for the inspection of a wholesale dealer's premises is —

(a) £3,058; or

(b) £1,442 if —

(i) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies; or

(ii) the turnover relating to all veterinary medicinal products in the calendar year preceding the inspection was less than £35,000;

(c) £830 if the authorisation only relates to products authorised under Schedule 6 (exemptions for small pet animals).

PART 3 - FEES RELATING TO FEEDINGSTUFFS

11 Fees for approvals and annual fees relating to feedingstuffs in the Island

(1) Subject to sub-paragraph (3) the fee for the application for approval of establishments manufacturing feedingstuffs and approval of distributors of feedingstuffs in the Island is £70.

(2) An annual fee of £70 is payable in respect of any such approval.

(3) Fees relating to feedingstuffs are payable with the application or on invoice for the subsequent annual fee.

(4) Where more than one manufacturing activity is carried out at one establishment only one fee (the highest) is payable.

12 Inspection fees relating to feedingstuffs in the Island

Fees for the inspection of establishments manufacturing or distributing feedingstuffs in the Island are in accordance with the following table.

Inspection fees

Type of establishment inspected		*Fee payable (£)*
1	Establishment manufacturing a specified feed additive	1,810
2	Establishment manufacturing a premixture:	1,090
3	Establishment manufacturing feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures or specified feed additive complementary feedingstuffs:	1,090
4	Establishment manufacturing feedingstuffs for placing on the market using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more:	961
5	Establishment manufacturing feedingstuffs using premixtures or specified feed additive complementary feedingstuffs containing specified feed additives when the feedingstuffs are to be placed on the market:	405
6	Establishment manufacturing feedingstuffs for the manufacturer's own use using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more:	320
7	Establishment manufacturing feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs:	240
8	Establishment distributing specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or complementary feedingstuffs containing veterinary medicinal products:	227

13 Fees relating to premises for supply by suitably qualified persons

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

(a) £265; or

(b) if the premises are only authorised to supply veterinary medicinal products for the treatment of —

(i) horses (or horses and companion animals) £145; or

(ii) companion animals £110.

(2) The subsequent annual fee is —

(a) £185; or

(b) if the premises are only authorised to supply veterinary medicinal products for the treatment of —

(i) horses (or horses and companion animals) £95; or

(ii) companion animals £70.

PART 4 - GENERAL

14 Testing samples

The fee for testing a sample required to be submitted by the Department is the full economic cost of the test.

15 Importation of a veterinary medicinal product for treatment under the cascade

(1) The fee for a certificate to import (if necessary) and be in possession of and administer a veterinary medicinal product under the cascade is —

(a) £15 if the veterinary medicinal product is authorised in a member State;

(b) £30 if the veterinary medicinal product is authorised in a third country.

(2) The fee is payable in respect of each animal treated, but in the case of administration to and treatment of a discrete group of animals, the Department may notify the applicant in writing that a fee for only one animal is payable.

(3) There is no fee if the application is made electronically as directed by the Department.

16 Wholesale dealer's import certificate

(1) The fee payable by the holder of a wholesale dealer's authorisation for a certificate to import and store a veterinary medicinal product not authorised in the Island to enable it to be supplied for administration under Schedule 4 is £760.

(2) The fee is only payable if, in the 12 month period immediately before the application, the applicant has supplied the veterinary medicinal product to which the certificate relates in accordance with at least 100 certificates.

17 Appeals to the Veterinary Products Committee

The fee for an appeal to the Veterinary Products Committee is £1,500.

18 Fee relating to an appointed person

The appellant is liable for the full economic cost of a referral to an appointed person subject to a maximum of £5,000.

19 Fees relating to a veterinary surgeon's practice premises

(1) The fee for the inspection of a veterinary surgeon's practice premises is £350.

(2) The initial registration and annual fee for the registration of veterinary practice premises with the Royal College of Veterinary Surgeons to supply veterinary medicinal products is £34.

(3) Notwithstanding paragraph 2 of this Schedule, this is payable to the Royal College of Veterinary Surgeons.

20 Refund of fees relating to the Veterinary Products Committee or appointed persons

The Department must refund the fee payable in relation to an appeal to the Veterinary Products Committee or to an appointed person if, as a result of the appeal, the Department changes the decision that was the subject of the appeal.

21 Fees relating to an improvement notice

If an improvement notice is served under these Regulations, the fee for any subsequent inspection necessary as a result of the notice is the full economic cost of the inspection, payable by the person on whom the notice was served.

22 Non-payment of fees

Where any fee (other than any fee relating to a wholesale dealer's authorisation) is not paid, the Department may, after giving one month's written warning, suspend the processing of any application from the person who has not paid the fee.

23 Waiver or reduction of fees

(1) If the Department is satisfied that for reasons of human or animal health or the protection of the environment it is desirable the Department may waive or reduce any fees payable under these Regulations.

(2) An applicant or the holder of a marketing authorisation must provide full written justification for any waiver or reduction.

EXPLANATORY NOTE

(This note is not part of the Regulations)

THE REGULATIONS

The Regulations make provision for the authorisation, classification, distribution and administration of veterinary medicinal products.

They implement the following EU instruments that are Directives:

(a) Council Directive 90/167/EEC laying down the 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; and

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

They provide for the enforcement of the following EU instruments that are Regulations besides that mentioned above:

(d) 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 (OJ No L 31, 1.2.2002 p. 1), in so far as it applies to veterinary medicinal products used in feedingstuffs;

(e) Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (OJ No L 268, 18.10.2003 p. 29), in so far as it applies to veterinary medicinal products used in feedingstuffs;

(f) 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 (OJ No L 165, 30.4.2004, p. 1), in so far as it applies to veterinary medicinal products used in feedingstuffs;

(g) Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene (OJ No L 35, 8.2.2005, p. 1), in so far as it applies to veterinary medicinal products used in feedingstuffs; and

(h) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.

In addition, by making it an offence to market a veterinary medicine on the Island without a UK marketing authorisation these Regulations also enforce 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 (OJ No L152, 16.6.2009, p. 11).

They provide that a veterinary medicinal product must have a UK marketing authorisation before being placed on the market (regulation 5).

They prohibit the manufacture of veterinary medical products on the Island (regulation 15).

They regulate the supply and possession of veterinary medicinal products, and introduce new classifications of those products (regulation 8 and Schedule 3).

They provide that a veterinary medicinal product may only be administered as specified in its marketing authorisation or, in the case of administration by a veterinary surgeon, administration under the rules of the "cascade" (regulation 9 and Schedule 4).

They control bringing a veterinary medicinal product into the Island (regulation 10) and advertising (regulation 11 to 13).

Veterinary practice premises must be registered with the Royal College of Veterinary Surgeons and paragraph 8 of Schedule 3 gives the Department a power to require the removal of premises from this register where they fail to meet the necessary standard.

They control wholesale dealing (regulation 14 and Schedule 3).

They control medicated feedingstuffs and feedingstuffs containing additives specified in the Regulations (regulation 15 and Schedule 5).

They provide for exemptions (regulation 16 and Schedule 6).

They provide for fees (regulation 17 and Schedule 7).

They require records to be kept (regulations 18 to 24).

They create an offence of importation, possession or supply of unauthorised veterinary medicinal products (regulation 43(p) to (r)).

They make provision for the existence of the Veterinary Products Committee (regulation 28). They make provision for an appeals procedure in the case of a refusal, etc., of authorisations, including those for wholesale dealing, supplying of veterinary medicines etc. (regulation 30).

They make inspectors' power to carry out inquiries, examinations, tests, inspect and search premises, take samples, seize anything they reasonably believe to be, or which purports to be, a veterinary medicine (regulation 35).

They create administrative arrangements for the enforcement of the Regulations (regulations 32 to 36 and 38 to 42) and create offences of obstructing a person acting in the execution of these Regulations (regulation 43(t)) and of failing to comply with an improvement notice (regulation 43(u)).

Under regulation 44 breach of the Regulations is an offence punishable —

(i) on summary conviction, by a fine not exceeding level 5 on the standard scale or by a term of custody not exceeding 3 months or both, or

(ii) on conviction on information, for a term of custody not exceeding 2 years, a fine or both.