Note: this is a draft document meant purely as a tool to support consultation and the tracked changes do not constitute formal or final government policy. It is intended to reflect what the amended VMR may look like under proposals which are the subject of consultation, but it does not constitute the law. The text may not be completely accurate and remains subject to change. It is shared in the expectation that it will encourage feedback and further improvement. If Ministers proceed to make a statutory instrument following this consultation, it will be that formal instrument which actually contains and/or changes the law.

2013 No 2033

MEDICINES

Veterinary Medicines Regulations 2013

Made 6th August 2013

Laid before Parliament 20th August 2013

Coming into force 1st October 2013

The Secretary of State is a Minister designated**1** for the purposes of making Regulations under section 2(2) of the European Communities Act 1972**2** in relation to measures in the veterinary and phytosanitary fields for the protection of public health.

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**3**.

In accordance with section 56(1) of the Finance Act 1973**4**, the Treasury consent to the making of these Regulations.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by section 56(1) of the Finance Act 1973.

1 S.I. 1999/2027.
2 1972 c. 68.
3 OJ No L31, 1.2.2002, p. 1.
4 1973 c. 51.

Part 1 Introduction

1 Title and commencement

These Regulations may be cited as the Veterinary Medicines Regulations 2013 and come into force on 1st October 2013.

2 Definition of "veterinary medicinal product", 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.

or

(c) any substance or combination of substances that may be used for the purpose of euthanising an animal.

(2) In these Regulations—

"active substance" means any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product, that, when used in its production, becomes an active ingredient of that product;

"~~adverse reaction~~adverse event" means a reaction to a veterinary medicinal product that is harmful and unintended and that occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function;

"advertising" (in relation to veterinary medicinal products) means the making of a representation in any form in connection with those products in order to promote their supply, distribution, sale, prescription or use and includes any action taken for this purpose by way of the supply of samples or by means of sponsorship;

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

"antibiotic" means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases;

"antimicrobial" means any substance with a direct action on micro-organisms that is used for treatment or prevention of infections or infectious diseases and includes antibiotics, antivirals, antifungals and anti-protozoals;

"antimicrobial resistance" means the ability of micro-organisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill micro-organisms of the same species;

"benefit risk balance" means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product—

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

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

(c) any risk relating to the development of resistance;

"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, as last amended by Regulation (EU) No 712/20125;~~

"environmental event" means an event where an ecosystem is adversely affected as a result of exposure to a veterinary medicinal product, its active substances or its metabolites present in soil, water or animal remains;

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

"excipient" means any constituent of a veterinary medicinal product other than an active substance;

"horse passport" means an identification document which complies with Commission Implementing Regulation (EU) No 2015/262 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of Equidae**6**;

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

"immunological veterinary medicinal product" means a veterinary medicinal product intended to be administered to ~~animals~~an animal in order to produce active or passive immunity or to diagnose ~~the state~~its state of immunity;

"limited market" means a market for one of the following types of veterinary medicinal product—

(a) a veterinary medicinal product for the treatment or prevention of diseases that occur infrequently or in limited geographical areas;

(b) a veterinary medicinal product for an animal species other than cattle, sheep for meat production, pigs, chickens, dogs or cats;

"novel therapy" means a veterinary medicinal product which is considered to be in a nascent field in veterinary medicine, including a product of a type not previously authorised or which has other novel aspects requiring data for authorisation not currently required by these Regulations;

"pharmacologically equivalent" means containing an active substance in the same proportions, in the same dosage form and concentration (in the case of a liquid dose) and meeting the same or comparable standards in relation to the clinical needs of a patient at the time of use;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events or any other problem related to a medicinal product;

"pharmacovigilance system master file" means a detailed description of the pharmacovigilance system used by the holder of the marketing authorisation in relation to one or more authorised veterinary medicinal products;

"prophylaxis" means the administration of a medicinal product to an animal or group of animals before clinical signs of disease in order to prevent the occurrence of disease or infection;

"reference veterinary medicinal product" means a veterinary medicinal product authorised in accordance with Schedule 1;

"Regulation (EC) No 178/2002" means 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**7**;

"Regulation (EC) No 1831/2003" means Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition**8**;

"Regulation (EU) 2017/625" means Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application

~~5 OJ No L 209, 4.8.2012, p.4.~~
6 OJ No L 149, 7.6.2008, p. 3.
7 OJ No L334, 12.12.2008, p.7.
8 OJ No L 15, 20.1.2010, p. 1.

of food and feed law, rules on animal health and welfare, plant health and plant protection products;

"Regulation (EC) No 183/2005" means Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene**9**;

"Regulation (EC) No 470/2009 of the European Parliament and of the Council" means Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin**10**;

"Regulation (EC) No 767/2009 of the European Parliament and of the Council" means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed in relation to feedingstuffs containing specified feed additives**11**, as last amended by Regulation (EU) No 2017/2279;

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

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

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

"residue event" means any finding of a pharmacologically active substance or marker residue in a product of animal origin exceeding the maximum levels of residues established in accordance with Regulation (EC) No. 470/2009 after the set withdrawal period has been respected;

~~"strength means the amount of active substances in a dosage unit or unit of volume or weight.~~"strength" means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;

"wholesale dealing" means all activities consisting of procuring, holding, supplying, distributing or exporting veterinary medicinal products whether for profit or not, but does not include retail supply of veterinary medicinal products to the public;

"withdrawal period" means the minimum period under normal conditions of use between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health;

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

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

3 Products to which these Regulations do not apply

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

(2) They do not apply in relation to a product intended for administration in the course of a procedure licensed under the Animals (Scientific Procedures) Act 1986**12**, 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

9 OJ No L152, 16.6.2009, p. 11.
10 OJ No L152, 16.6.2009, p. 11.
11 OJ No L229, 1.9.2009, p. 1. Regulation (EC) No 767 2009 was last amended by Regulation (EC) 939/2010 (OJ No L277, 20.10. 2010, p. 4.
12 1986 c. 14.

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

Part 2 Authorised Veterinary Medicinal Products

4 Placing a veterinary medicinal product on the market

(1) No person may place a veterinary medicinal product on the market unless the Secretary of State has—

(a) as regards a product to which Schedule 1B applies, issued a QNIG certificate in respect of that product;

(b) otherwise, granted a marketing authorisation in respect of that product.

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

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

(4) Schedule 1A (converted EU marketing authorisations) has effect.

(5) Schedule 1B (Northern Ireland qualifying good marketing authorisations) has effect.

~~5 Manufacture of veterinary medicinal products~~

5 Manufacture of veterinary medicinal products

(1) The holder of a marketing authorisation must ensure that every stage in the manufacture of the veterinary medicinal product is carried out by the manufacturer specified in the marketing authorisation (whether the product is for sale in the United Kingdom or for export).

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

(3) Subject to paragraph (4), "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 and includes any processing, assembly, packaging, repackaging, labelling, relabelling, sterilising, storage or releasing for supply of the product as part of that process.

(4) For the purposes of these Regulations "manufacture" does not include preparation, dividing up of a product or changing in packaging or presentation of the product for retail purposes.

~~(1) The holder of a marketing authorisation must ensure that every stage in the manufacture of the veterinary medicinal product is carried out by the manufacturer specified in the marketing authorisation**13**.~~

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

~~(3) "Manufacture" includes any part of the manufacture of a veterinary medicinal product until the finished product is ready for sale in its final form as specified in the marketing authorisation but does not include the manufacture of an ingredient or breaking open the package of a veterinary medicinal product**14**.~~

6 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.

~~**13** If the manufacture is carried out in the United Kingdom~~Great Britain ~~the manufacturer must hold a manufacturing authorisation for that type of product granted by the Secretary of State.~~

~~**14** For provisions on breaking open packages see regulation 7(3).~~

7 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 (including a veterinary medicinal product which has been incorporated into a medicated feedingstuff or intermediate 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.

8 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 in the United Kingdom, and the administration is in accordance with that marketing authorisation; or

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

9 Importation of authorised veterinary medicinal products

(1) No person may import, or move into Great Britain from Northern Ireland, a veterinary medicinal product authorised for use in Great Britain 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.

10 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.~~

(1) No person may issue an advertisement relating to a relevant substance unless that advertisement—

(a) is set out in such a way that it is clear that the message is an advertisement for the purpose of promoting the supply, sale, prescription, distribution or use of the substance;

(b) encourages responsible use of the substance while presenting its characteristics in an objective manner;

(c) contains no information which—

(i) is misleading;

(ii) is incompatible with the summary of product characteristics in relation to the substance;

(iii) might encourage improper use of the substance; or

(iv) (where the relevant substance is a veterinary medicinal product) might suggest that the substance is a feedingstuff or a biocide.

(1A) No person may advertise a veterinary medicinal product (other than a product which is placed on the market in accordance with Schedule 6) that does not hold a marketing authorisation that has not been suspended in accordance with paragraph 38 of Schedule 1.

(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.

(4) In this regulation “relevant substance” means—

(a) a veterinary medicinal product;

(b) a premix;

(c) an intermediate feedingstuff;

(d) a compound feedingstuff.

10A Inducements and hospitality

(1) Subject to paragraphs (2) and (4), where veterinary medicinal products are being promoted to persons qualified to prescribe or supply veterinary medicinal products, no person may offer or promise to any person any gift, pecuniary advantage or benefit in kind unless it is inexpensive and relevant to the practice of veterinary medicine or pharmacy.

(2) The provisions of paragraph (1) do not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply veterinary medicinal products, provided that —

(a) such hospitality is reasonable in level;

(b) it is subordinate to the main scientific objective of the meeting; and

(c) is offered only to animal health professionals.

(3) Subject to paragraph (4), no person may offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of veterinary medicinal products unless—

(a) such hospitality is reasonable in level;

(b) is subordinate to the main purpose of the meeting or event, and

(c) the person to whom it is offered is an animal health professional.

(4) Nothing in this regulation affects measures or trade practices relating to prices, margins or discounts which were in existence on the date on which these Regulations come into force.

(5) No person qualified to prescribe or supply veterinary medicinal products may solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.

11 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.~~

(4) No person may advertise immunological veterinary medicinal products to professional keepers of animals unless the advertisement contains a statement that the professional keeper of animals must consult a veterinary surgeon before use of the product.

(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.~~

12 Defence of publication in the course of business

In proceedings for an offence under these 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.

13 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 Secretary of State under this regulation and Schedule 3.

14 Feedingstuffs

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

15 Exemptions

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

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

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

(b) used for the treatment of--

(i) other animals on the same site;

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

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

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

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

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

(c) ~~equine~~ stem cell products for use as an autologous treatment for ~~horses~~non-food animals from an ~~equine~~ collection centre authorised in accordance with ~~Part 5~~Part 2 of Schedule 2.

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

16 Fees

Schedule 7 (fees) has effect.

Part 3 Records

17 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).

18 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 as soon as is reasonably practicable 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.

19 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 18) the keeper must record--

(a) the name of the product;

(b) the date of administration;

(c) the quantity administered;

(d) the withdrawal period; and

(e) the identification of the animals treated.

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

(a) the date of disposal;

(b) the quantity of product involved; and

(c) how and where it was disposed of.

20 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 five years following the administration or other disposal of the product, irrespective of whether or not the animal concerned is no longer in that keeper's possession or has been slaughtered or has died during that period.

21 Records by a holder of a manufacturing authorisation

(1) The holder of a manufacturing authorisation must record the following information in respect of any veterinary medicinal product supplied by it—

(a) the name of the veterinary medicinal product and marketing authorisation number if applicable;

(b) the pharmaceutical form and strength of the product;

(c) the quantity of product supplied;

(d) the batch number and expiry date;

(e) the date of the transaction in which the product was supplied;

(f) the company name and the address of the principal place of business of the recipient of the supply.

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

~~(a) the name of the product;~~

~~(b) the quantity manufactured, assembled or supplied;~~

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

~~(d) the batch number and expiry date; and~~

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

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

(3) The holder must keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market or for one year after the date of expiry of the batch, whichever is the longer.

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 company name and the address of the principal place of business of the supplier in the case of purchase or the recipient in the case of sale of the product.

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

and must keep the records for at least ~~three years~~5 years.

23 Records of the receipt or supply of prescription products

(1) Where a retail transaction involving veterinary medicinal products which have been prescribed takes place the retailer of those products must keep a record of the following information—

(a) the date of the transaction on which the product was received or supplied;

(b) the name of the veterinary medicinal product;

(c) the pharmaceutical form and strength of the product;

(d) the batch number;

(e) the quantity of product received or supplied;

(f) the company name and the address of the principal place of business of the supplier in the case of purchase or the recipient in the case of sale of the product;

(g) if there is a written prescription the name and contact details of the prescriber (and where appropriate, a copy of the prescription).

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

~~(a) the date;~~

~~(b) the name of the veterinary medicinal product;~~

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

~~(d) the quantity;~~

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

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

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

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

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

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 five years.

24A Reporting of usage data in relation to antibiotics

(1) Where the Secretary of State serves a notice in writing on any person mentioned in sub-paragraph (2) requiring that person to provide any information held by that person in relation to sales and usage of antibiotics from any records made for the purposes of these Regulations the person must provide that information.

(2) The persons are—

(a) the holder of a manufacturing authorisation;

(b) the holder of a marketing authorisation;

(c) the holder of a wholesale dealer's authorisation;

(d) a keeper of food-producing animals;

(e) a feedingstuffs manufacturer;

(f) a veterinary surgeon.

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 marketing authorisation may import an unauthorised veterinary medicinal product if it is for the purpose of the manufacture of a veterinary medicinal product for which the importer holds the marketing authorisation.

(3) A holder of a manufacturing authorisation may import an unauthorised veterinary medicinal product if it is for the manufacture of a veterinary medicinal product that the importer is permitted to manufacture.

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

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

(6) A wholesale dealer or a pharmacist may import an unauthorised veterinary medicinal product for the purpose of storing it pending administration by a veterinary surgeon under the cascade or administration in exceptional circumstances in accordance with Schedule 4 if--

(a) the veterinary medicinal product is authorised in another country;

(b) the Secretary of State has issued a certificate certifying that--

(i) the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal;

(ii) delay in administering the product will seriously affect the health or welfare of the animal; and

(iii) there is no suitable veterinary medicinal product authorised in Great Britain ; and

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

(6A) A pharmacist may supply a product mentioned in paragraph (6) for the purposes of the cascade without the requirement to hold a wholesale dealer's authorisation.

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

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

(9) For the purposes of this regulation, references to the import or importation of an unauthorised veterinary medicinal product include the movement of such a product into Great Britain from Northern Ireland.

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 Secretary of State under these Regulations;

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

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

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

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

(4) A veterinary surgeon who practises in both Great Britain and another country may hold veterinary medicinal products authorised in the other country provided that the amount held does not exceed the amount expected to be used in that country.

(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 Secretary of State 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 continue to be a Veterinary Products Committee.

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

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

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

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

29 Veterinary Products Committee appeals procedure

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

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

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

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

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

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

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

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

30 Appeals to an appointed person

(1) A person aggrieved by a provisional decision of the Secretary of State under regulation 29 or a body aggrieved by a decision to suspend or revoke its recognition under paragraph 14 of Schedule 3 may appeal against the decision to a person appointed for the purpose by the Secretary of State in accordance with this regulation.

(2) So may an applicant for--

(a) a manufacturing authorisation;

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

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

(d) an authorisation of a blood bank;

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

(f) authorisation of ~~an equine stem cell centre~~ a stem cell centre;

(g) a wholesale dealer's authorisation;

(ga) registration in relation to active substances;

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

if such an application is refused.

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

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

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

31 Exports

(1) No person may export a veterinary medicinal product for use in another country unless the veterinary medicinal product may be lawfully supplied or administered in that country.

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

(a) the manufacturer holds a manufacturing authorisation;

(b) the manufacturer holds a certificate of good manufacturing practice; or

(c) the product has been marketed under a marketing authorisation.

(3) When issuing the certificate the Secretary of State must take account of ~~the model certificates issued by the World Health Organization~~[15] any relevant administrative arrangements in relation to the form and content of such certificates which are in existence between the United Kingdom and the country to which the product is to be exported.

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

~~15 Published by the World Health Organization at: www.who.int/medicines/en.~~

32 Time limits

(1) In any provision in these Regulations requiring the Secretary of State to issue an authorisation within a set time, the clock does not start to run until the Secretary of State 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 Secretary of State must issue any authorisation requires the clock is stopped when the Secretary of State requires an applicant to provide further data until all the further data required have been provided.

(3) The clock is also stopped during any period that the applicant is given to provide oral or written explanations or to provide any sample.

(4) The Secretary of State may stop the clock pending payment of outstanding fees.

33 Appointment of inspectors

The Secretary of State must appoint inspectors for the purposes of the enforcement of these Regulations and in these Regulations "inspector" means an inspector appointed under this regulation or a veterinary inspector appointed under the Animal Health Act 1981[16].

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 enactment 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 such other persons as the inspector considers necessary.

(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,

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16 1981 c. 22.

the justice may by signed warrant 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 enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and the premises of the marketing authorisation holder.

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

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

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

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;

(ca) purchase prescription only veterinary medicines for the purpose of carrying out tests;

(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 in the United Kingdom;

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

(g) seize any veterinary medicinal product, any additive to which Schedule 5 applies, any ~~premixture~~intermediate feedingstuff 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.~~

(2) The inspector may seize and retain an item appearing to the inspector to be an item mentioned in paragraph (1)(d) to (g) if the inspector reasonably believes that an offence under these Regulations is being or has been committed in relation to, or by means of, that item.

(3) An officer of any local authority who has entered premises exercising any statutory power of entry for the purposes of enforcing any legislation relating to food hygiene, feed hygiene or animal

health, may inspect any records made under these Regulations (in whatever form they are held) relating to food-producing animals, and may remove them to enable them to be copied.

(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 of the General Pharmaceutical Council appointed for the purpose.

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 magistrates' court or to the sheriff; and

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

38A Prohibition notices

1) An inspector who has reasonable grounds for believing that any person is failing to comply with a condition of an authorisation or with any requirement in these Regulations and that the risks to animal or human health or of damage to the environment of that failure are so serious that, until steps have been taken to reduce or remove that failure, one or more activity carried on by that person ought to be prohibited or restricted, may serve a notice on that person (a “prohibition notice”).

(2) A prohibition notice must—

(a) state that the inspector holds the said belief;

(b) specify the matters which the inspector believes give rise to the said risk;

(c) where the inspector believes that any of those matters involves a contravention of a condition of an authorisation or of a requirement of these Regulations, state that the inspector

holds that belief, specify the condition of the authorisation or the provision or provisions in relation to which the inspector holds that belief and give particulars of the reasons why the inspector holds that belief;

(d) specify any remedial action which the inspector believes would result in the revocation of the prohibition notice;

(e) direct that the person on whom the notice was served must not carry out any activity to which the notice relates until that person has provided evidence to the inspector that the remedial action specified under sub-paragraph (d) has been carried out and the inspector has confirmed to the person on whom the notice was served that the inspector is satisfied that the remedial action has been satisfactorily performed.

(3) A direction contained in a prohibition notice under paragraph (2)(e) above takes effect—

(a) at the end of the period specified in the notice; or

(b) if the notice so declares, immediately.

(4) A prohibition notice must state—

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

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

39 Appeals against improvement notices or prohibition notices

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

(2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980**17** applies to the proceedings.

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

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

(5) A court may suspend an improvement notice or a prohibition 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.

17 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c.39), section 47.

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

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

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

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

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

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

42 Publication

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

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

43 Offence

It is an offence[18] to fail to comply with--

(a) regulation 4(1) or (2);

(b) regulation 5(1);

(c) regulation 7(2), (3), (4) or (5);

(d) regulation 8;

(e) regulation 9(1);

(f) regulation 10(1) or (2);

(g) regulation 11(1);

(h) regulation 13;

(i) regulation 17;

(j) regulation 18

(k) regulation 19

(l) regulation 20

(m) regulation 21

(n) regulation 22

(o) regulation 23

(p) regulation 24;

(pa) regulation 24A;

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

(q) regulation 25(1);

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

(s) regulation 27(1);

(t) regulation 31(1);

(u) regulation 37;

(v) an improvement notice issued under regulation 38; ~~or~~

(va) a prohibition notice issued under regulation 38A; or

(w) regulation 41(3).

44 Penalties

(1) A person guilty of an offence under these Regulations is liable--

(a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or both, or

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

(2) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of--

(a) a qualified person appointed as such for the purposes of these Regulations;

(b) any director, manager, secretary or other similar person of the body corporate; or

(c) any person who was purporting to act in any such capacity,

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

(3) 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.

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

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

~~46 Review~~

~~(1) Before the end of each review period, the Secretary of State must--~~

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

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

~~(c) publish the report.~~

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

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

~~(a) Council Directive 90/167/EEC laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation (EC) No 183/2005~~**~~19~~**~~;~~

~~(b) Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products~~**~~20~~**~~;~~

~~(c) Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products~~**~~21~~**~~;~~

~~**19** OJ No L 92, 7.4.1990, p. 42.~~
~~**20** OJ No L 228, 17.8.1991, p. 70.~~
~~**21** OJ No L311, 28.11.2001, p. 1; last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ No L188, 18.7.2009, p. 14).~~

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

(f) Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;;

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

(h) Commission Regulation (EC) No 1234/2008**22**;

(i) Regulation (EC) No 470/2009 of the European Parliament and of the Council**23**;

(j) Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council, and Articles 15 and 17 of that Regulation as they refer to the labelling requirements for feedingstuffs containing specified feed additives**24**; and

(k) Commission Regulation (EU) No 37/2010**25**.

(4) The report must in particular--

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

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

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

(5) In this regulation--

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

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

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

47 Revocations

The following Regulations are revoked—

(a) the Veterinary Medicines Regulations 2011**26**, and

(b) the Veterinary Medicines (Amendment) Regulations 2012**27**.

David Heath

Minister of State for Agriculture and Food

Department for Environment, Food and Rural Affairs

17th July 2013

22 OJ No L334, 12.12.2008, p. 7.
23 OJ No L152, 16.6.2009, p. 11.
24 OJ No L229, 1.9.2009, p. 1, last amended by Commission Regulation (EU) No 939/2010 (OJ L277, 21.10.2010, p. 14).
25 OJ No L293, 11.11.2010, p.72; corrected at OJ L293, 11.11.2010, p. 72.
26 S.I. 2011/2159
27 S.I. 2012/2711

We consent

Anne Milton

Mark Lancaster

Two of the Lords Commissioners of Her Majesty's Treasury

6th August 2013

SCHEDULE 1 Marketing Authorisations in Great Britain

Regulation 4(3)

Part 1 Application for a Marketing Authorisation

1 Application for a marketing authorisation

An application under these Regulations for a marketing authorisation for a veterinary medicinal product must be made to the Secretary of State.

~~2 Information with the application~~

~~(1) An application must include all necessary administrative information, and all scientific documentation necessary for demonstrating the safety, quality and efficacy of the product.~~

~~(2) In particular, the applicant must provide all the data required in Annex I to Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products**28**, generated in accordance with that Annex.~~

~~(2A) The reference in paragraph 2(2) to Annex 1 to Directive 2001/82/EC is to be read subject to the following modifications—~~

~~(a) a reference to a member State is to be read as a reference to Great Britain;~~

~~(b) a reference to the national pharmacopoeia of a member State is to be read as a reference to the British Pharmacopoeia;~~

~~(c) a reference to an application for a marketing authorisation pursuant to Article 12 or 13 is to be read as a reference to an application for a marketing authorisation pursuant to this Schedule;~~

~~(d) a reference to the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via veterinary medicinal products is to be read as a reference to that document as it had effect immediately before IP completion day;~~

~~(e) a reference to Council Directive 87/18/EEC is to be read as a reference to Directive 2004/10/EC of the European Parliament and of the Council on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances**29**;~~

~~(f) a reference to Annex 5 of Council Directive 67/548/EEC is to be read as a reference to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures**30**;~~

~~(e) the following provisions are to be ignored—~~

~~(i) in Title 1—~~

~~(aa) in Part 1, in Chapter A, the fourth paragraph;~~

~~(bb) in Part 2, in Chapter A, paragraph 3.3;~~

~~**28** OJ No L 211, 28.11.2001, p. 1 as last amended by Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ No L152, 16.6.2009, p. 11). Annex I was inserted by Commission Directive 2009/9/EC (OJ No L 44, 14.2.2009, p. 10).~~

~~**29** OJ L No 50, 20.2.2004, p.44, as last amended by Regulation (EC) No 219/2009 (OJ L No 87, 31.3.2009, p.109).~~

~~**30** OJ L No 353, 31.12.2008, p.1, as corrected by Corrigendum to Regulation (EC) No 1272/2008 (OJ L No 349, 21.12.2016, p.1).~~

(ii) in Title 2, in Part 5, in Chapter A, the fifth paragraph.

(3) The application must contain the following information--

(a) the name of the person who will hold the marketing authorisation, that person's address and, if different, the name and address of all the manufacturers involved in each stage of the manufacture, and the sites where the manufacture will take place;

(b) the name of the veterinary medicinal product, which may be either--

(i) an invented name provided that this is not liable to be confused with the common name of the product or the international non-proprietary name (INN) recommended by the World Health Organization; or

(ii) a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder;

(c) the qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its INN recommended by the World Health Organization, where an INN exists, or its chemical name;

(d) a description of the method of manufacture;

(e) all therapeutic indications, contra-indications and adverse reactions;

(f) the dosage for each species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;

(g) any proposed precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals or disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human or animal health or to plants, together with the reasons;

(h) in the case of medicinal products intended for food producing species, the proposed withdrawal period necessary to ensure that the maximum residue limits established by an appropriate authority under Regulation (EC) No 470/2009 of the European Parliament and of the Council are not exceeded;

(i) a description of the testing methods to be used during manufacture;

(j) the results of--

(i) pharmaceutical (physico-chemical, biological or microbiological) tests;

(ii) safety tests and residue tests;

(iii) pre-clinical and clinical trials;

(iv) tests assessing the potential risks to the environment from the product;

(k) a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;

(l) a summary of the product characteristics, mock-ups of all proposed packaging and the proposed package leaflet, if any;

(m) a document showing that the manufacturer is authorised to produce veterinary medicinal products;

(n) copies (which must be updated if there are any changes while the application is being considered) of--

(i) any marketing authorisation obtained in another country for the relevant veterinary medicinal product, and a list of any other countries in which an application for authorisation of the product has been submitted;

(ii) if the product is already authorised outside the United Kingdom, the summary of product characteristics for each authorisation;

(iii) any decision to refuse authorisation in any other country and the reasons for that decision;

~~(o) proof that the applicant has the services of a qualified person responsible for pharmacovigilance (referred to in these Regulations as a qualified person (pharmacovigilance)) and has the necessary means for the notification of any adverse reaction suspected of occurring in another country;~~

~~(p) if the veterinary medicinal product is intended for food-producing species and contains one or more pharmacologically active substances for the species in question for which a maximum residue limit has not yet been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council, a document certifying that a valid application for the establishment of maximum residue limits has been submitted.~~

~~(4) All documents relating to the results of tests or trials must be accompanied by a detailed and critical expert report that has been drafted and signed by a person with the requisite technical or professional qualifications and that has a brief curriculum vitae of the person signing the report attached to it.~~

~~(5) In the case of immunological products, the applicant must submit a description of the methods used to establish that the manufacturing process will consistently produce a veterinary medicinal product that is in accordance with the marketing authorisation.~~

2 Information with the application

(1) An application (which must be submitted to the Secretary of State electronically) must include the matters mentioned in sub-paragraph (2) and—

(a) where the product is an antimicrobial veterinary medicinal product, the matters mentioned in sub-paragraph (3);

(b) subject to sub-paragraph (4), where the product is to be administered to a food-producing animal and is a product containing pharmacologically active substances that are not permitted under Regulation (EC) 470/2009, the matters mentioned in sub-paragraph (4);

(c) where the product contains or consists of genetically modified organisms, the matters mentioned in sub-paragraph (6).

(2) For the purposes of sub-paragraph (1) the matters are—

(a) the name of the person who will hold the marketing authorisation and that person's address or registered place of business;

(b) the name and address or registered place of business of—

(i) the manufacturer of the finished product;

(ii) any importer of the finished product;

(iii) the manufacturer of any active substances involved at each stage of the manufacture;

(c) the name and address of the sites where—

(i) each stage of the manufacture is carried out;

(ii) any imported products are held; or

(iii) any control or batch release is carried out;

(c) the legal basis for the application for the marketing authorisation;

(d) in relation to the veterinary medicinal product—

(i) the name and the Anatomical Therapeutic Chemical Veterinary Code;

(ii) a description of the active substances within the product and, if applicable, a description of any diluent;

(iii) the strength of the product, or, in the case of an immunological veterinary medicinal product, the biological activity, potency or titre;

(iv) the pharmaceutical form of the product;

(v) the route of administration;

(vi) a description of the target species;

(e) a document showing that a manufacturer is authorised to produce veterinary medicinal products or a certificate of good manufacturing practice issued by the Secretary of State or equivalent certification issued by an authority recognised by the Secretary of State for that purpose;

(f) the reference number and a summary of the pharmacovigilance system master file in relation to the product and, where appropriate, the risk management system that the applicant will put in place;

(g) the proposed summary of the product characteristics;

(h) a description of the final presentation, the packaging and labelling of the product;

(i) the proposed text of the information to be included on the immediate packaging, the outer packaging and the information leaflet accompanying the product;

(j) details of any country where—

(i) a marketing authorisation has been granted or revoked in relation to the product; or

(ii) a marketing authorisation has been submitted or refused;

(k) a summary of the product characteristics included in the terms of any marketing authorisation granted by another country;

(l) technical documentation demonstrating the quality, safety and efficacy of the product in accordance with Schedule 1C;

(m) critical expert reports on the quality, safety and efficacy of the product.

(3) For the purposes of sub-paragraph (1)(a) the matters are—

(a) information on the direct or indirect risks to public or animal health or to the environment arising from use of the antimicrobial product in animals;

(b) information about the methods of mitigating the development of antimicrobial resistance as a result of the use of the product.

(4) For the purposes of sub-paragraph (1)(b) the matter is a document certifying that a valid application for the establishment of maximum residue levels has been submitted to the Secretary of State.

(5) Sub-paragraph (1)(b) does not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption; but in this case the product must not include an active substance that has been classified under Article 14 of Regulation (EC) No. 470/2009 of the European Parliament and of the Council as prohibited for use in food producing animals.

(6) For the purposes of sub-paragraph (1)(c) the matters are—

(a) a copy of the written consent to the deliberate release into the environment of the genetically modified organisms for research and development purposes;

(b) the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;

(c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and

(d) the results of any investigations performed for the purposes of research or development.

(7) The applicant is responsible for the accuracy of the information submitted in relation to its application and must submit all study results whether favourable or otherwise that have a bearing on the suitability of the product for authorisation.

~~3 Summary of product characteristics~~

~~The summary of product characteristics required under the preceding paragraph must include the following information, set out in the same format--~~

~~**Summary of product characteristics**~~

~~1~~ ~~Name of the veterinary medicinal product, followed by its strength and pharmaceutical form.~~

~~2~~ ~~The name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons.~~

~~3~~ ~~Pharmaceutical form.~~

~~4~~ ~~Clinical particulars--~~

~~4.1~~ ~~target species;~~

~~4.2~~ ~~indications for use, specifying the target species;~~

~~4.3~~ ~~contra-indications;~~

~~4.4~~ ~~special warnings for each target species;~~

~~4.5~~ ~~special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals;~~

~~4.6~~ ~~adverse reactions (frequency and seriousness);~~

~~4.7~~ ~~use during pregnancy, lactation or lay;~~

~~4.8~~ ~~interaction with other medicinal products and other forms of interaction;~~

~~4.9~~ ~~amounts to be administered and administration route;~~

~~4.10~~ ~~overdose (symptoms, emergency procedures, antidotes) if necessary;~~

~~4.11~~ ~~withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero.~~

~~5~~ ~~Pharmacological properties--~~

~~5.1~~ ~~pharmacodynamic properties;~~

~~5.2~~ ~~pharmacokinetic particulars;~~

~~6~~ ~~Pharmaceutical particulars--~~

~~6.1~~ ~~list of excipients;~~

~~6.2~~ ~~major incompatibilities;~~

~~6.3~~ ~~shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time;~~

~~6.4~~ ~~special precautions for storage;~~

~~6.5~~ ~~nature and contents of immediate packaging;~~

~~6.6~~ ~~special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate;~~

~~7~~ ~~Marketing authorisation holder;~~

~~8~~ ~~Marketing authorisation number;~~

~~9~~ ~~Date of the first authorisation or date of renewal of the authorisation;~~

~~10~~ ~~Date of any revision of the text;~~

~~11~~ ~~Any other information required by the Secretary of State.~~

3 Summary of product characteristics

The summary of product characteristics required under the preceding paragraph must include the following information in the order indicated below—

---

1. Name of the veterinary medicinal product, followed by its strength and pharmaceutical form.

2. Qualitative and quantitative composition of the active substances and qualitative composition of excipients and other constituents stating their common name or their chemical description and their quantitative composition, if that information is essential for proper administration of the veterinary medicinal product.

3. Clinical information—

3.1 target species;

3.2 indications for use for each target species;

3.3 contra-indications;

3.4 special warnings;

3.5 special precautions for use, including in particular special precautions for safe use in the target species, special precautions to be taken by the person administering the veterinary medicinal product to the animals and special precautions for the protection of the environment;

3.6 frequency and seriousness of adverse events;

3.7 use during pregnancy, lactation or lay;

3.8 interaction with other medicinal products and other forms of interaction;

3.9 administration route and dosage;

3.10 symptoms of overdose and, where applicable, emergency procedures and antidotes in the event of overdose;

3.11 special restrictions for use;

3.12 special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance;

3.13 if applicable, withdrawal periods, even if such periods are zero.

4. Pharmacological information—

4.1 Anatomical Therapeutic Chemical Veterinary Code ("ATCvet Code");

4.2 pharmacodynamics;

4.3 pharmacokinetics.

5. Pharmaceutical particulars—

5.1 major incompatibilities;

5.2 shelf-life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time;

5.3 special precautions for storage;

5.4 nature and composition of immediate packaging;

5.5 special precautions for the disposal of unused veterinary medicinal products, if appropriate.

6. Name of the holder of the marketing authorisation.

7. Marketing authorisation number or numbers.

8. Date of the first marketing authorisation.

9. Date of the last revision of the summary of the product characteristics.

10. If applicable, the statement—

(i) "marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation"; or

(ii) "marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation".

11. Classification of the veterinary medicinal product.

4 Supply of a copy of the summary of product characteristics

A holder of a marketing authorisation must supply a copy of the summary of product characteristics to any person on demand.

~~5 Time limits for applications for products for use in food-producing animals~~

~~In the case of a veterinary medicinal product for food-producing animals, a marketing authorisation may not be applied for until at least six months after a valid application has been made for the establishment of a maximum residue limit.~~

Part 2 Derogations from Some of the Requirements in Part 1

6 Scope

This Part provides for applications for marketing authorisations in which not all the information required in Part 1 is required, but for the avoidance of doubt any applicant may apply for a marketing authorisation using Part 1 if the applicant wishes to do so.

7 Bibliographic application

(1) An applicant for a marketing authorisation need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials ~~if the active substance of the veterinary medicinal product has been in an authorised veterinary medicinal product for that species for at least ten years, and the applicant provides appropriate scientific literature to demonstrate this~~ if the applicant demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety.

(2) The applicant may use any publicly available document.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies, together with further clinical trials, a third party may not use those studies or trials in an application for a pharmacologically equivalent product for a period of three years from the grant of the authorisation for the additional species.

8 Application for a product using a new combination of active substances

If an application is for a veterinary medicinal product containing active substances already used in an authorised veterinary medicinal product but not previously used in that combination in a veterinary medicinal product, the applicant need not provide the safety and efficacy data for the individual active substances.

9 Application using existing data

If the Secretary of State has granted a marketing authorisation, the Secretary of State may, with the permission of the holder, use the data submitted in support of that marketing authorisation when assessing an application for another marketing authorisation.

10 Application for a ~~pharmacologically equivalent~~ generic veterinary medicinal product

(1) An applicant need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the applicant can demonstrate that the veterinary medicinal product is ~~pharmacologically~~a generic ~~equivalent~~ to a veterinary medicinal product already authorised in the United Kingdom ("the reference product").

(2) For the purposes of this paragraph a product is ~~pharmacologically equivalent to~~ a generic of an existing product if--

(a) it has the same qualitative and quantitative composition in active substances;

(b) it has the same pharmaceutical form as the reference product; and

~~(c) bioequivalence has been demonstrated by means of appropriate bioavailability studies.~~

(c) bioequivalence with the reference product has been demonstrated;

(3) For the purposes of this paragraph--

(a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

(b) if they do differ significantly in properties with regard to efficacy or safety, additional information intended to provide proof of the safety or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

(4) Different immediate-release oral pharmaceutical forms are regarded as the same pharmaceutical form.

(5) Bioavailability studies are not required if the bioequivalence guidelines produced by the European Medicines Agency or the Secretary of State exempt the product.

(6) In the case of a reference product authorised in another member State but not in the United Kingdom, the Secretary of State must be satisfied that the ~~risk-benefit balance~~benefit-risk balance of the original product is appropriate for the product to be placed on the market in the United Kingdom, and if the data provided under Article 13, third paragraph of Directive 2001/82/EC by the member State in which the product is authorised are insufficient for the Secretary of State to be satisfied of this, the Secretary of State may notify the applicant and require the applicant to provide further data.

(7) For the purposes of these Regulations, subject to sub-paragraph (8) the summary of the product characteristics of a generic veterinary medicinal product must be essentially similar to the summary of the product characteristics for the reference product.

(8) The requirement in sub-paragraph (7) does not apply in relation to those parts of the summary of the product characteristics of the reference product that refer to indications or pharmaceutical forms which are covered by patents at the time when the generic veterinary medicinal product is authorised.

(9) The holder of a marketing authorisation must not place a generic or hybrid veterinary medicine on the market before the end of the data protection period for the reference product.

10A Hybrid veterinary medicinal products

An applicant for a marketing authorisation must provide the results of relevant pre-clinical studies or clinical trials where the veterinary medicinal product for which the authorisation is sought is not pharmacologically equivalent to a generic reference product as a result of a difference in relation to—

(a) the active substance or substances contained in the product;

(b) the strength of the product;

(c) the indications for use of the product;

(d) the pharmaceutical form of the product;

(e) the route of administration of the product;

(f) the withdrawal period for the product; or

(g) bioavailability studies are not capable of demonstrating bioequivalence with a reference product.

11 Time limits for marketing authorisations granted under the procedure for a ~~pharmacologically equivalent~~generic veterinary medicinal product

(1) This paragraph establishes the time limits relating to granting a marketing authorisation under the procedure for a ~~pharmacologically equivalent~~ generic veterinary medicinal product.

(2) An application for a marketing authorisation cannot be made until two years before the product may be placed on the market in accordance with this paragraph.

~~(3) The product may not be placed on the market until ten years (or, in the case of medicinal products for fish or bees where the application for a marketing authorisation was submitted after 30th October 2005, thirteen years) have elapsed from the initial authorisation of the reference product.~~

(3) The product may not be placed on the market until the elapse of—

(a) subject to sub-paragraph (3A), 10 years in the case of a major species;

(b) 18 years in the case of bees; and

(c) 14 years for all other species.

(3A) Where the product—

(a) is intended for administration to a major species; and

(b) contains an antimicrobial active substance which has not been an active substance in a veterinary medicinal product previously subject to a marketing authorisation in Great Britain,

the period mentioned in sub-paragraph (3)(a) is 14 years.

(3B) Where a patent in relation to a reference product has lapsed, the summary of the product characteristic of the relevant generic product must be updated in order to include the protected information.

(3C) Where, as a result of a variation to an existing marketing authorisation a product is accorded a new marketing authorisation number any relevant protection period applies in relation to that product.

(4) Time limits in this paragraph are calculated from the first grant of the marketing authorisation for the reference product.

12 Extension of time limits

~~(1) This paragraph applies in relation to veterinary medicinal products that--~~

~~(a) are intended for administration to food-producing species; and~~

~~(b) contain a new active substance that was not authorised in the Community by 30th April 2004.~~

~~(2) If a person submitted an application for a marketing authorisation for a product on or after 30th October 2005, and within 5 years of the original marketing authorisation being granted, the marketing authorisation is extended to include additional food-producing species, the ten-year protection period is extended by one year for each additional food-producing species added to the marketing authorisation.~~(2) If a person submitted an application for a marketing authorisation or for a variation to a marketing authorisation for a product on or after 30th October 2005, and within 5 years of the original marketing authorisation being granted, the marketing authorisation is extended to include an additional major species or a new antimicrobial product, the 10 year protection period is extended by one year for each additional major species added to the marketing authorisation.

(2A) If a person submits an application for a marketing authorisation mentioned in sub-paragraph (2) and the marketing authorisation is extended to include an additional minor species, the 14 year protection period is extended by 4 years.

(2B) Where an application under this paragraph relates to a variation of a marketing authorisation, it must be submitted 3 years or more before the expiration of the protection period.

(2C) Subject to sub-paragraph (2D), a study, residue test or preclinical study in relation to the establishment of residue limits submitted by an applicant in relation to an application for a

marketing authorisation or a variation of a marketing authorisation may not be used for any other such application or variation until the period of 5 years from that submission has elapsed.

(2D) Sub-paragraph (2C) does not apply where an applicant has obtained a written authorisation to access a study, residue test or pre-clinical study mentioned in that sub-paragraph.

(2E) Subject to sub-paragraph (2F), a study, residue test or preclinical study submitted by an applicant for a marketing authorisation or a variation in a marketing authorisation which demonstrates a reduction in anti-microbial resistance in relation to a reference product may not be used for any other such application until a period of 4 years in addition to the period mentioned in paragraph 11(3)(a) has elapsed.

(2F) Sub-paragraph (2E) does not apply where an applicant has obtained a written authorisation to access a study, residue test or pre-clinical study mentioned in that sub-paragraph.

(3) The total period may not exceed ~~13~~18 years.

~~(4) The extension applies only if the marketing authorisation holder originally applied for determination of the maximum residue limits for the active substance.~~

~~13 Parallel imports~~

~~(1) The Secretary of State may grant a marketing authorisation in relation to a veterinary medicinal product authorised in another country and imported into the United Kingdom from that country in accordance with this paragraph without the data required in Part 1 if the applicant can demonstrate compliance with this paragraph.~~

~~(2) If the product is for a food-producing species it must be identical to a product authorised in the United Kingdom.~~

~~(3) Other products must be therapeutically the same as a product authorised in the United Kingdom unless the importer can justify any differences.~~

~~(5) The applicant must be established within the United Kingdom.~~

~~(6) The applicant must hold (or have a contract with the holder of) a wholesale dealer's authorisation in the United Kingdom appropriate to the type of product to be imported.~~

~~(7) If re-labelling is to take place in the United Kingdom the applicant must also be (or have a contract with) the holder of a suitable manufacturing authorisation in the United Kingdom.~~

14 Specific batch control scheme

(1) Where a veterinary medicinal product (other than a biological veterinary medicinal product) has been granted a marketing authorisation or an animal test certificate, and any starting material (active substance, excipient or packaging) or any batch of the product does not fully meet the requirements of the authorisation or animal test certificate, the holder may apply to the Secretary of State to place one or more batches on the market notwithstanding this.

(2) The Secretary of State may authorise the placing on the market on being satisfied that the safety, quality and efficacy of the product are not compromised, and that in all the circumstances of the case the product should be placed on the market.

(4) In this paragraph a biological veterinary medicinal product is a veterinary medicinal product, the active substance of which is a biological substance; and a biological substance is a substance that is produced by or extracted from a biological source and for which a combination of physico-chemical-biological testing and the production process and its control is needed for its characterisation and the determination of its quality.

~~15 Similar immunological products~~

~~Where an immunological veterinary medicinal product is pharmacologically equivalent to a reference product other than differences in raw materials or in the manufacturing process, the results of the appropriate pre-clinical tests or clinical trials must be provided, but the applicant need not provide the results of safety tests or residue tests.~~

16 Marketing a product authorised in another country

Where the health situation so requires, the Secretary of State may authorise the placing on the market of a veterinary medicinal product that has been authorised in another country.

Part 3 Grant of a Marketing Authorisation

17 Time limits

(1) The Secretary of State must ensure that the procedure for granting an authorisation for a veterinary medicinal product is completed within a maximum of 210 days after the submission of the application.

(2) The period mentioned in sub-paragraph (1) may be extended where a simultaneous assessment exercise is being conducted by the Secretary of State in conjunction with the relevant authority in another country.

~~18 Place of establishment of applicant~~

~~Only an applicant established in the United Kingdom may be granted a marketing authorisation.~~

18 Place of establishment of applicant

(1) Only an applicant established in the United Kingdom or an applicant who is not so established but who has appointed a Local Representative may be granted a marketing authorisation or a veterinary homeopathic registration.

(2) For the purposes of sub-paragraph (1) the Local Representative must—

(a) be a person established in the United Kingdom;

(b) be permanently available for the purposes of the applicant's business;

(c) have a good knowledge of the English language; and

(d) have sufficient knowledge and experience to address the requests mentioned in sub-paragraph (3)(c).

(3) The Local Representative must, on behalf of the applicant—

(a) oversee the pharmacovigilance arrangements in place for the purpose of collecting information and making reports to the Secretary of State;

(b) act for the holder of the marketing authorisation in relation to any inspections made by the Secretary of State;

(c) address requests made in connection with the product by the Secretary of State or other interested parties.

19 Procedure

The Secretary of State may require the applicant to provide additional information or to generate additional data, including laboratory testing, or may require the applicant to provide samples of any medicinal product, its starting materials and intermediate products or other constituent materials for testing in a laboratory.

21 Assessment reports

The Secretary of State must produce an assessment of the dossier, consisting of an evaluation of the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned, and any additional related information.

22 Grant of a marketing authorisation

(1) When granting a marketing authorisation, the Secretary of State must inform the applicant of the summary of product characteristics that has been approved, and the distribution category of the product.

(2) The Secretary of State must—

(a) verify that the data submitted complies with the requirements set out in these Regulations;

(b) assess the veterinary medicinal product; and

(c) reach a conclusion in relation to the benefit-risk balance of granting a marketing authorisation in respect of the veterinary medicinal product.

(3) The Secretary of State must set out any conditions in connection with placing the product on the market when granting a marketing authorisation.

(4) Where the marketing authorisation relates to an antimicrobial veterinary medicinal product the Secretary of State may require the holder of the marketing authorisation to conduct post authorisation studies in order to ensure that the benefit-risk balance remains positive in relation to the development of antimicrobial resistance.

22A Withdrawal of application for marketing authorisation

(1) Where an applicant for a marketing authorisation withdraws the application before the Secretary of State has produced an assessment of the dossier under paragraph 21 the applicant must give written reasons for so doing.

(2) Where an applicant withdraws an application for a marketing authorisation in the circumstances mentioned in sub-paragraph (1) the Secretary of State must publish—

(a) the fact that the application has been withdrawn; and

(b) any report prepared following the assessment mentioned in paragraph 21 but with any commercially confidential information omitted.

23 Marketing authorisations for food-producing species

(1) The Secretary of State must not grant a marketing authorisation for a veterinary medicinal product for food-producing species unless maximum residue limits have been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council in respect of all its pharmacologically active substances.

(2) This does not apply in the case of a marketing authorisation for a veterinary medicinal product for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption; but in this case the product must not include an active substance that has been classified under Article 14 of Regulation (EC) No 470/2009 of the European Parliament and of the Council as prohibited for use in food producing animals.

24 Refusal of a marketing authorisation

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

(2) In addition, the Secretary of State must refuse to grant it if--

(a) the data submitted with the application are inadequate;

(b) the ~~risk-benefit balance~~benefit-risk balance of the veterinary medicinal product is unfavourable;

~~(c) the product has insufficient therapeutic effect;~~(c) the applicant has not provided sufficient proof of the efficacy of the product in relation to the target species;

(d) the withdrawal period proposed by the applicant is not long enough to ensure food safety, or is insufficiently substantiated;

(e) the veterinary medicinal product is for a prohibited use;

(f) the way that the product will be used will have an unnecessarily undesirable effect on the environment.

(g) the product contains an antimicrobial that is reserved for human use;

(h) the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use in order to promote the growth of treated animals or to increase yields from treated animals;

(i) the risk for public health in case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health ;

(j) the risks to public or animal health or to the environment are not sufficiently addressed;

(k) the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the application;

(l) the active substance within the veterinary medicinal product meets the criteria for being considered persistent, bio-accumulative and toxic and the veterinary medicinal product is intended to be used in food-producing animals, unless it is demonstrated that the active substance is essential to prevent or control a serious risk to animal health.

(3) The Secretary of State may refuse to grant a marketing authorisation--

(a) if there is legislation pending that is incompatible with the requested authorisation; or

(b) if additional data have been requested and those data are not provided within such time limit as may be stipulated.

(4) If the Secretary of State, on the grounds of safety, quality or efficacy, intends to refuse an application, or proposes to grant a marketing authorisation that is different from the one applied for, the Secretary of State must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee.

25 Publication following the grant refusal, suspension, variation or revocation of a marketing authorisation

(1) On granting a marketing authorisation the Secretary of State must publish--

(a) the notice granting the marketing authorisation;

(b) the summary of the product characteristics;

(c) the assessment report that has already been prepared but with any commercially confidential or personal information deleted.

(2) The Secretary of State must update the assessment report whenever new information that is of importance and relates to the quality, safety or efficacy of the veterinary medicinal product becomes available.

(3) The Secretary of State must send a copy of the assessment report, and any update, to the holder of the marketing authorisation before publication to enable the holder to make representations concerning any confidential or personal information that may be in it, and may specify a date by which representations must be made.

(4) Where the Secretary of State refuses to grant a marketing authorisation or suspends or revokes an authorisation the Secretary of State must publish the fact.

(5) Where the Secretary of State varies the text of a marketing authorisation in relation to the summary of product characteristics the Secretary of State must publish the terms of the variation.

26 Marketing authorisations in exceptional circumstances

(1) In exceptional circumstances, and if there is no other product with a full marketing authorisation for the indicated condition in the target species, the Secretary of State may grant an exceptional marketing authorisation consisting of--

(a) a provisional marketing authorisation subject to a requirement for the applicant to provide further data; or

(b) a limited marketing authorisation for a product with a limited market~~.~~ taking into account the benefits in relation to public or animal health or the availability of the product on the market in comparison to the risks.

(2) The Secretary of State must reassess each provisional or limited marketing authorisation annually.

27 Provisions of samples and expertise

(1) The Secretary of State may require a marketing authorisation holder to provide, at any time and at any stage of the manufacturing process, samples of starting materials or the veterinary medicinal product for testing and to provide the results of any control tests carried out in relation to such materials or the finished product in accordance with the methods to be used under the terms of the marketing authorisation.

(2) At the request of the Secretary of State, the marketing authorisation holder must provide technical expertise to facilitate any analysis of the product.

(3) The Secretary of State may require an applicant for a marketing authorisation to provide samples of a veterinary medicinal product for testing.

(4) The samples mentioned in paragraph (3) may be used—

(a) to test the veterinary medicinal product and its constituents at any stage of development of the product in order to ensure that the control methods used by the manufacturer are satisfactory; and

(b) to verify that, where a veterinary medicinal product is intended for administration to a food-producing animal, the means used for residue detection in relation to pharmacologically active substances are satisfactory.

28 Supply of information

(1) A marketing authorisation holder must immediately inform the Secretary of State on receipt of any new information that might adversely affect the ~~risk-benefit balance~~benefit-risk balance of the veterinary medicinal product.

(2) The holder must immediately inform the Secretary of State of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is authorised.

(3) The Secretary of State may at any time require the marketing authorisation holder to provide data relating to the ~~risk-benefit balance~~benefit-risk balance.

29 Duties on the holder of a marketing authorisation relating to an immunological product

(1) Before placing an immunological product on the market the holder of the marketing authorisation must notify the Secretary of State asking for written approval to do so.

(2) If notified under sub-paragraph (1) the Secretary of State must give or refuse a written approval as soon as is reasonably practicable.

(3) No person may place an immunological product on the market without a written approval issued by the Secretary of State.

~~30 Control tests~~

~~The holder of a marketing authorisation must give to the Secretary of State on demand evidence that the holder has carried out all control tests required under the marketing authorisation, and the results of those tests.~~

31 Placing on the market

(1) A holder of a marketing authorisation must notify the Secretary of State when the veterinary medicinal product is first placed on the market in the United Kingdom, and the date on which it was placed on the market.

(2) A holder of a marketing authorisation who removes the veterinary medicinal product from the market in the United Kingdom or identifies a shortage for the veterinary medicinal product must notify the Secretary of State at least two months (or a shorter period in exceptional circumstances) before doing so.

(3) Upon request by the Secretary of State, the marketing authorisation holder must provide--

(a) all data relating to the volume of sales of the veterinary medicinal product by the holder; and

(b) any data in the holder's possession relating to the number of prescriptions written for the product and the total volume supplied under those prescriptions.

(4) For the purposes of sub-paragraph (2) a shortage of a veterinary medicinal product occurs when supply does not meet demand at a national level within the United Kingdom.

32 Duration and validity of marketing authorisation

Subject to any power of revocation provided under these Regulations a marketing authorisation has indefinite validity.

~~32 Duration and validity of a marketing authorisation~~

~~(1) A marketing authorisation is initially valid for five years.~~

~~(2) The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.~~

~~(3) An application for renewal must be made at least six months, and not more than nine months, before the marketing authorisation ceases to be valid.~~

~~(4) An applicant who applies for the renewal of the marketing authorisation must enclose a list of all documents concerning the product that the applicant has submitted to the Secretary of State since the marketing authorisation was granted.~~

~~(5) The Secretary of State may require the applicant to provide a copy of any of the listed documents at any time.~~

~~(6) Once renewed, the marketing authorisation is valid indefinitely unless, within five years of the renewal, the Secretary of State notifies the holder, on justified grounds relating to pharmacovigilance, that the authorisation will cease to be valid five years from the first renewal unless the holder applies for a further renewal.~~

~~(7) The further renewal is not time-limited.~~

~~(8) Any marketing authorisation granted under these Regulations that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in the United Kingdom ceases to be valid.~~

~~(9) When a veterinary medicinal product authorised under these Regulations and previously placed on the market in the United Kingdom is not present on the market in the United Kingdom for a period of three consecutive years, its marketing authorisation ceases to be valid.~~

~~(10) The Secretary of State may, on human or animal health grounds, grant exemptions from sub-paragraphs (8) and (9).~~

Part 4 Variations of Marketing Authorisations on the Application of the Holder

33 Variation of a marketing authorisation

~~(1) The Secretary of State is the competent authority for the purposes of Commission Regulation (EC) No 1234/2008~~**~~31~~**~~.~~

(2) The holder of a marketing authorisation may apply to the Secretary of State for a variation of that marketing authorisation.

(3) Subject to sub-paragraph (3A) an application for a variation under paragraph (2) may only relate to a single variation.

~~An application for a variation under paragraph (2) may only relate to a "single variation" unless the application is submitted in accordance with--~~

~~(a) Article 7 of Commission Regulation (EC) No 1234/2008 ("grouped variations"), or~~

~~(b) Article 20 of Commission Regulation (EC) No 1234/2008 ("workshare variations").~~

(3A) Sub-paragraph (3) does not apply where the application is for an assessment of—

(a) a single variation which relates to 2 or more marketing authorisations; or

(b) 2 or more variations in respect of a single marketing authorisation.

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

33A Variations requiring assessment

(1) Subject to sub-paragraph (2), an application for a variation requiring assessment must be submitted to the Secretary of State by electronic means.

(2) Sub-paragraph (1) does not apply where the application is an emergency application.

(3) The application must contain—

(a) a description of the proposed variation;

(b) information in relation to any of the matters referred to in paragraph 2 which are relevant to the proposed variation;

(c) details of any marketing authorisation which may be affected by the proposed variation;

(d) where the proposed variation requires consequential variations to the terms of the marketing authorisation, a description of those variations.

(4) The Secretary of State must produce an assessment of the dossier within a maximum of 60 days after the submission of the information mentioned in sub-paragraph (3) unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

(5) The Secretary of State may require the applicant to provide additional information during the assessment process.

(6) The Secretary of State must send a copy of the report of the assessment mentioned in sub-paragraph (4) to the applicant.

(7) Within a maximum of 30 days of sending the report to the applicant, the Secretary of State must—

(a) amend the authorisation to correspond with the proposed variation; or

(b) reject the proposed variation and provide the applicant with a statement of the reasons for the rejection.

~~**31** OJ No L334, 12.12.2008, p. 7.~~

(8) Where the Secretary of State amends the authorisation in accordance with sub-paragraph (7)(a) the Secretary of State must notify the applicant in writing.

(9) Where the applicant is dissatisfied with the decision of the Secretary of State under sub-paragraph (7), the applicant may appeal to the Veterinary Products Committee.

33B Unforeseen variations

(1) Where the holder of a marketing authorisation requests a variation whose classification under these Regulations is unclear the holder may request the Secretary of State to provide a recommendation in relation to the classification of the variation.

(2) The Secretary of State must issue the recommendation under sub-paragraph (1) within 45 days following receipt of the request.

33C Variations not requiring assessment

(1) Where the holder of a marketing authorisation is of the view that a proposed variation is not a variation requiring assessment in accordance with paragraph 33A the holder must notify the Secretary of State of that view.

(2) Where the holder of the authorisation notifies the Secretary of State in accordance with sub-paragraph (1) the holder must submit to the Secretary of State within 30 days of the implementation of the variation —

(a) a summary of the characteristics of the product to which the authorisation relates; and

(b) the labelling or the package leaflet in relation to that product.

(3) The Secretary of State may request scientific data for assessment from the applicant where the applicant has submitted a notification under sub-paragraph (1).

(4) The Secretary of State must notify the holder of the marketing authorisation whether the Secretary of State agrees or disagrees with the holder's view.

(5) Where, following the submission of the data mentioned in sub-paragraph (3), the Secretary of State determines that the variation is a variation requiring assessment the application will be dealt with in accordance with paragraph 33A.

34 Refusal of a variation of a marketing authorisation

~~(1) This paragraph applies in relation to the refusal by the Secretary of State of an application for a variation unless the procedure following the refusal of a variation is one of those set out in Article 13 of Regulation 1234/2008.~~

(2) The grounds on which the Secretary of State may refuse an application for a variation of a marketing authorisation are those set out in paragraph 24 of this Schedule (refusal of a marketing authorisation).

(3) The Secretary of State must give written reasons for refusing to grant a variation; and if--

(a) those reasons are on the grounds of safety, quality or efficacy; and

(b) the variation is ~~Type II or an extension application (whether or not in each case as part of an application for a worksharing or grouped application)~~a variation requiring assessment,

the applicant may appeal to the Veterinary Products Committee.

~~35 Administrative variations~~

~~(1) The holder of a marketing authorisation may apply for a minor change in a marketing authorisation to be made without the Secretary of State considering any scientific data (an "administrative variation").~~

~~(2) If the Secretary of State grants an administrative variation, and subsequently establishes that this should have been a variation requiring consideration of scientific data, the Secretary of State~~

~~may notify the marketing authorisation holder, require the holder to submit an application for a variation enabling data to be assessed and revoke the administrative variation.~~

36 Changes after a marketing authorisation has been issued

After a marketing authorisation has been issued, the holder must take account of scientific and technical progress in manufacturing and control methods, and apply to the Secretary of State for any variation in the marketing authorisation that may be required to enable that veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

37 Compulsory variation

(1) If the Secretary of State decides, for any of the reasons for suspending a marketing authorisation specified in paragraph 38, or because the classification of a veterinary medicinal product should be changed, that a variation to a marketing authorisation is necessary, the Secretary of State must by a notification in writing to the holder of the marketing authorisation require that person to apply for a variation of the marketing authorisation, giving reasons for requiring the application to be made.

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

(3) If the variation is on the grounds of safety, quality or efficacy, the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

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

Part 5 Suspension, etc of a Marketing Authorisation

38 Suspension of a marketing authorisation: grounds

~~(1) The Secretary of State may suspend a marketing authorisation at any time on being satisfied that--~~

~~(a) this is necessary for the protection of animal or public health or the environment;~~

~~(b) the terms of the marketing authorisation have not been complied with; or~~

~~(c) the veterinary medicinal product has insufficient therapeutic effect.~~

(1) The Secretary of State may suspend, or revoke a marketing authorisation or require the holder of the authorisation to submit an application for variation at any time on being satisfied that the benefit-risk balance of the veterinary medicinal product is not positive or is insufficient to ensure food safety.

(2) The Secretary of State may also suspend a marketing authorisation on being satisfied that a marketing authorisation holder has failed to make an application for a variation to take account of scientific and technical progress in manufacturing and control methods to enable the veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(3) The Secretary of State may suspend or revoke a marketing authorisation or require the holder of the authorisation to submit an application for a variation on being satisfied that—

(a) information given in the application documents is incorrect;

(b) any control tests required have not been carried out;

(c) changes have been made to the manufacturing process without the authority of the Secretary of State;

(d) any information required to be supplied to the Secretary of State has not been so supplied;

(e) the holder of the marketing authorisation has failed to comply with the requirements of these Regulations;

(f) the pharmacovigilance system in relation to a veterinary medicinal product is inadequate;

(g) in the case of a generic authorisation, the reference product is updated to show a reduction in antimicrobial resistance;

(g) the Qualified Person for pharmacovigilance has failed to comply with the requirements of these Regulations.

~~(3) The Secretary of State must suspend a marketing authorisation on being satisfied that--~~

~~(a) the risk-benefit balance is unfavourable;~~

~~(b) the withdrawal period does not ensure that residues in foodstuffs obtained from the treated animal comply with Regulation (EC) No 470/2009 of the European Parliament and of the Council;~~

~~(c) information given in the application documents is incorrect;~~

~~(d) any control tests required have not been carried out;~~

~~(e) changes have been made to the manufacturing process without the authority of the Secretary of State; or~~

~~(f) any information required to be supplied to the Secretary of State has not been so supplied.~~

39 Suspension of a marketing authorisation: procedure

(1) If a marketing authorisation is suspended the Secretary of State must notify the holder immediately, and, unless the Secretary of State directs otherwise, the suspension has immediate effect, and continues in effect unless the marketing authorisation is reinstated.

(2) If the suspension is on the grounds of safety, quality or efficacy, the holder may, within 28 days of the notification, appeal to the Veterinary Products Committee.

~~(4) When a marketing authorisation is suspended, the Secretary of State may in addition prohibit the supply of the veterinary medicinal product, and if necessary require the marketing authorisation holder to recall the product.~~

40 Revocation

The Secretary of State may revoke any marketing authorisation that has been suspended for more than 28 days unless there is a current appeal to the Veterinary Products Committee, and may publicise a revocation in such manner as the Secretary of State sees fit.

41 Prohibiting the supply of veterinary medicinal products

~~(1) In addition to the powers to suspend a marketing authorisation, the Secretary of State, on being satisfied that a product has not been manufactured in accordance with the marketing authorisation, may prohibit the supply of a veterinary medicinal product, and if necessary require the marketing authorisation holder to recall it.~~

(1) The Secretary of State may prohibit the supply of a veterinary medicinal product or require the recall of the product at any time on being satisfied that—

(a) the benefit-risk balance of the veterinary medicinal product is not positive;

(b) the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the summary of the product characteristics;

(c) the recommended withdrawal period is insufficient to ensure food safety;

(d) the required control tests have not been carried out; or

(e) the incorrect labelling of the product might lead to a serious risk to human or animal health.

(2) The prohibition on supply and the requirement for recall may be confined to specific production batches.

41A Temporary restrictions

Where urgent action is necessary for protecting human or animal health or the environment, the Secretary of State may, on a temporary basis—

(a) restrict the supply of a veterinary medicinal product;

(b) restrict the use of a veterinary medicinal product;

(c) suspend the authorisation of the veterinary medicinal product;

(d) require the holder of a marketing authorisation for a veterinary medicinal product to submit an application for variation of the authorisation.

41B Restrictions in relation to immunological veterinary medicines

The Secretary of State may prohibit the manufacture, importation, distribution, supply or use of immunological veterinary medicines in any part of Great Britain where—

(a) the administration of the product to an animal interferes with the implementation of a programme for the diagnosis, control or eradication of animal disease;

(b) the administration of the product to an animal causes difficulty in relation to the certifying of absence of disease in live animals or contamination of foodstuffs or other products from treated animals; or

(c) the strains of disease agents in relation to which the product is intended to confer immunity is largely absent from the territory concerned.

Part 7 Labelling and Package Leaflets

45 Approval by the Secretary of State

The Secretary of State, when issuing a marketing authorisation, must approve all containers, packaging, labels and package leaflets.

46 Reference to being authorised

A label and package leaflet of an authorised veterinary medicinal product may contain in legible characters the words "UK authorised veterinary medicinal product" or, if the marketing authorisation provides, other wording specified in the authorisation indicating that the product is authorised in the United Kingdom.

47 Language

(1) All labels and package leaflets must be in English, but may contain other languages provided that the information given is identical in all the languages.

(2) This requirement does not apply in the case of a product imported by a veterinary surgeon and administered by or under the responsibility of that same veterinary surgeon.

48 Labelling of immediate packaging of veterinary medicinal products

(1) Subject to paragraph 50, the following information must be provided on the immediate packaging of a veterinary medicinal product—

(a) the name of the product, followed by its strength and pharmaceutical form;

(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common

names;

(c) the batch number, preceded by the word “Lot”;

(d) the name or company name or logo name of the marketing authorisation holder;

(e) the target species;

(f) the expiry date, in the format ‘mm/yyyy’, preceded by the abbreviation “Exp” and the in-use shelf life (if appropriate);

(g) any necessary special storage precautions;

(h) the route of administration;

(i) the withdrawal period (if applicable), even if such period is zero;

(j) the distribution category and where appropriate the words “To be supplied only on veterinary prescription”;

(k) the words “Keep the container in the outer carton”;

(l) the words “Read the package leaflet before use”.

2) Where there is no outer packaging for the product, the information set out in paragraph 49 must be included on the immediate packaging of the veterinary medicinal product.

(3) The information referred to in paragraph (1) must appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms approved by the Secretary of State.

~~48 Labelling with all the information on the immediate packaging~~

~~(1) If it is reasonably practicable to do so, the following must be provided on the immediate packaging, in legible characters--~~

~~(a) the name, strength and pharmaceutical form of the veterinary medicinal product;~~

~~(b) the name and strength of each active substance, and of any excipient if this is required under paragraph 2 of the summary of product characteristics;~~

~~(c) the route of administration (if not immediately apparent);~~

~~(d) the batch number;~~

~~(e) the expiry date;~~

~~(f) the words "For animal treatment only" and, if appropriate, "To be supplied only on veterinary prescription";~~

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

~~(h) the marketing authorisation number;~~

~~(i) the name and address of the marketing authorisation holder, the local representative designated under paragraph 18 of this Schedule or, if there is a distributor authorised in the marketing authorisation, that distributor;~~

~~(j) a suitably labelled space to record discard date (if relevant);~~

~~(k) the target species;~~

~~(l) the distribution category;~~

~~(m) the words "Keep out of reach of children";~~

~~(n) storage instructions;~~

~~(o) the in-use shelf-life (if appropriate);~~

~~(p) for food-producing species, the withdrawal period for each species or animal product concerned;~~

~~(q) any warning specified in the marketing authorisation;~~

~~(r) disposal advice;~~

~~(s) full indications;~~

~~(t) dosage instructions;~~

~~(u) contra-indications;~~

~~(v) further information required in the marketing authorisation;~~

~~(w) if the product is one that requires a dose to be specified for the animal being treated, a space for this.~~

~~(2) If all this is on the immediate packaging, there is no need for any outer packaging or a package leaflet.~~

49 Labelling of the outer packaging of veterinary medicinal products

(1) The following information must be provided on the outer packaging of a veterinary medicinal product—

(a) the information referred to in paragraph 48(1);

(b) the name of any excipient where knowledge of the excipient is required in order to ensure safe use;

(c) the contents by weight, volume or number of the immediate packaging units of the veterinary medicinal product;

(d) a warning that the veterinary medicinal product must be kept out of the sight and reach of children;

(e) the words “this veterinary medicinal product is for animal treatment only’;

(f) in the case of veterinary medicinal products not subject to a veterinary prescription, any indication for use of the product;

(g) the marketing authorisation number of the product.

(2) The information referred to in sub-paragraph (1) must appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms approved by the Secretary of State.

~~49 Products with immediate and outer packaging~~

~~(1) If it is not reasonably practicable to have all the required information on the immediate packaging then this paragraph applies.~~

~~(2) The immediate packaging must have at least the following information--~~

~~(a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;~~

~~(b) the name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons;~~

~~(c) the route of administration (if not immediately apparent);~~

~~(d) the batch number;~~

~~(e) the expiry date;~~

~~(f) the words "For animal treatment only" and if appropriate, "To be supplied only on veterinary prescription";~~

~~(g) the words "Keep the container in the outer carton".~~

~~(3) In addition, the immediate packaging must have as much of the required information as is reasonably practicable.~~

~~(4) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product in accordance with the following paragraph.~~

~~50 Package leaflets~~

~~(1) If it is not reasonably practicable to have all the required information on the immediate packaging or all of this information on the outer packaging, there must be a package leaflet supplied with the product, containing all the required information except for the batch number and the expiry date, and including the name of both the marketing authorisation holder and, if different, the name of the distributor named in the marketing authorisation.~~

~~(2) If there is a package leaflet, the immediate packaging and the outer packaging must both refer the user to it.~~

~~(3) A package leaflet must relate solely to the veterinary medicinal product with which it is included.~~

~~(4) It must be written in plain English.~~

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

50 Labelling of small immediate packaging units of veterinary medicinal products

(1) No information other than the following must be provided on immediate packaging units which are too small to include in a legible form the information set out in paragraph 48—

(a) the name of the veterinary medicinal product;

(b) the quantitative particulars of the active substances contained in the product;

(c) the batch number, preceded by the word “Lot”;

(d) the expiry date, in the form ‘mm/yyyy’, preceded by the abbreviation “Exp.”.

(2) The outer packaging of the immediate packaging units mentioned in sub-paragraph (1) must be accompanied by outer packaging which provides the information required by paragraph 49.

51 Package leaflet of veterinary medicinal products

(1) Subject to sub-paragraph (5) and (7) a package leaflet must be supplied with each veterinary medicinal product.

(2) The package leaflet must provide the following information—

(a) the name and address of the marketing authorisation holder and of the manufacturer and, where applicable, the distributor or the Local Representative of the marketing authorisation holder;

(b) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

(c) the qualitative and quantitative composition of any active substance contained in the product, and any excipients if required by these Regulations;

(d) the target species, the dosage for each species, the method and route of administration and if necessary, advice on the correct administration of the product;

(e) a statement of the indications for use;

(f) a statement of the contra-indications for use and known adverse events;

(g) in relation to a food-producing species, the withdrawal period for each species, even if such a period is zero;

(h) any special storage precautions that may be required;

(i) information essential for safety or health protection, including any special precautions

relating to use and any other appropriate warnings;

(j) the words “use take-back schemes for the disposal of any unused veterinary medicinal product or associated waste materials in accordance with local requirements and with any applicable national collection schemes”;

(k) the marketing authorisation number;

(l) contact details for the marketing authorisation holder or its representative, as appropriate, for the reporting of suspected adverse events;

(m) classification of the veterinary medicinal product as referred to in paragraph 11 of the summary of product characteristics, including its distribution category;

(n) a description of the pack sizes available, or if all required information is provided on the immediate label, the contents by weight, by volume or by number of immediate packaging units

(o) the words “this veterinary medicinal product must be kept out of the sight and reach of children”;

(p) the words “this veterinary medicinal product is for animal treatment only;

(q) the shelf life of the product and a suitably labelled space to record the date by which the product must be discarded (if appropriate).

(2) Providing that it complies with the marketing authorisation, the package leaflet may bear additional information concerning distribution, possession or any necessary precaution required, provided that this information is not promotional in character.

(3) The package leaflet must be in legible form and designed to be clear and understandable, in terms that are comprehensible to the general public.

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

(5) The Secretary of State may require the information set out in sub-paragraph (2) to be made available in written form or electronically, or both.

(6) Where the Secretary of State requires the leaflet to be made available electronically an electronic package information leaflet which includes the information required by this paragraph may be provided in place of a leaflet in written form; but in such a case the packaging of the veterinary medicinal product must include—

(a) a statement that the information is provided by electronic means;

(b) any necessary electronic link in order to access the relevant part of the website where the information required in relation to the product by sub-paragraph (2) is set out;

(c) a statement that a copy of the information in written form may be obtained on request; and

(d) instructions on how to obtain such information.

(7) The information required by this paragraph and by paragraph 48 may be otherwise provided on the packaging of the veterinary medicinal product.

~~51 Ampoules~~

~~(1) In the case of ampoules or other unit dose forms, where the container cannot bear legibly the required information, only the following information must be shown on the immediate packaging--~~

~~(a) the name of the veterinary medicinal product;~~

~~(b) the name and strength of the active ingredient;~~

~~(c) the route of administration (if not immediately apparent);~~

~~(d) the batch number;~~

~~(e) the expiry date;~~

~~(f) the words "For animal treatment only" and if appropriate, "To be supplied only on veterinary prescription".~~

~~(2) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product, except that the ampoule need not refer to the package leaflet.~~

52 Small containers other than ampoules

As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the required information, all the required information must appear on the outer packaging or outer packaging and package leaflet, but the immediate packaging must be labelled with the batch number and the expiry date and, if there is room, the other information in the preceding paragraph.

53 Homeopathic remedies

(1) A homeopathic remedy registered under these Regulations must be labelled in accordance with this paragraph.

(2) There must be no specific therapeutic indication on the labelling or in any information relating to it.

(3) The labelling (or labelling and package leaflet) must contain the following and no other information--

(a) the words "homeopathic remedy without approved therapeutic indications for veterinary use";

(b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used (if the homeopathic remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks);

~~(c) the name and address of the registration holder and (on the package leaflet) of the manufacturer;~~(c) the name or company name and permanent address or registered place of business of the registration holder and, where appropriate, of the manufacturer;

(d) the method and, if necessary, route of administration;

(e) the expiry date;

(f) the pharmaceutical form;

(g) the contents of the pack;

(h) any special storage precautions;

(i) the target species;

(j) any necessary special warnings;

(k) the batch number; and

(l) the registration number.

(m) the withdrawal period, where applicable.

54 Variations

The Secretary of State may permit variations in the above in any individual marketing authorisation if this is necessary for public or animal health purposes or the protection of the environment.

Part 8 Pharmacovigilance

~~55 Qualified persons responsible for pharmacovigilance~~

~~A marketing authorisation holder must have permanently and continuously the services of an appropriately qualified person responsible for pharmacovigilance ("a qualified person (pharmacovigilance)").~~

56 Duties of marketing authorisation holder in relation to pharmacovigilance ~~Duties relating to the qualified person~~

(1) The marketing authorisation holder is responsible for the duty of pharmacovigilance in relation to a veterinary medicinal product for which it holds a marketing authorisation and must continuously evaluate, by appropriate means, the benefit-risk balance of this veterinary medicinal product and, if necessary, take appropriate measures to address any risk presented by the product.

(2) A marketing authorisation holder must carry out the signal management process mentioned in paragraph 56C in relation to any veterinary medicinal product for which it holds an authorisation.

(3) A marketing authorisation holder must comply with good pharmacovigilance practice.

(4) A marketing authorisation holder must establish and maintain a system for collecting, collating and evaluating information in relation to suspected adverse events in respect of any veterinary medicinal product for which it holds an authorisation.

(5) Subject to sub-paragraph (6), a marketing authorisation holder must establish and maintain one or more pharmacovigilance system master files describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products.

(6) For each veterinary medicinal product, the marketing authorisation holder must not establish and maintain more than one pharmacovigilance system master file.

(7) A marketing authorisation holder must establish and maintain a local system for the purpose of receiving reports of suspected adverse events.

(8) The system mentioned in sub-paragraph (7) must be staffed by personnel trained for this purpose who are able to communicate in English.

(9) A marketing authorisation holder must designate not more than one qualified person responsible for pharmacovigilance (a “qualified person (pharmacovigilance)”) in relation to each pharmacovigilance system master file.

(10) Where the pharmacovigilance functions or the functions of the qualified person for pharmacovigilance are performed by a third party, any such arrangement must be specified in detail in the pharmacovigilance system master file.

(11) A marketing authorisation holder may introduce urgent safety restrictions where evidence comes to the attention of the holder of a risk posed to human or animal health or to the environment from the use of the product.

(12) Where a marketing authorisation holder takes any action under sub-paragraph (11) the holder must inform the Secretary of State no later than the following working day of the reasons for the action.

(13) A marketing authorisation holder must establish and maintain an adequate and effective quality management system for the performance of its pharmacovigilance activities.

56A Duties of marketing authorisation holder in relation to signal management process

(1) A marketing authorisation holder must carry out the signal management process mentioned in paragraph 56C in relation to any veterinary medicinal product for which it holds an authorisation.

(2) The marketing authorisation holder must record on an annual basis the results of the signal

management process mentioned in paragraph 56C in relation to the product.

(3) Where, as a result of the carrying out of the signal management process, a new risk is identified or a change in the benefit-risk balance of the product, the marketing authorisation holder must notify the Secretary of State promptly and in any event within 30 days of this risk or change in the benefit-risk balance being identified.

(4) Where the signal management process identifies the necessity for a variation in an authorisation the marketing authorisation holder must submit an application for such a variation to the Secretary of State promptly.

56B Duties of qualified person (pharmacovigilance)

(1) A qualified person (pharmacovigilance) must—

(a) establish and maintain a system which ensures that all suspected adverse events which are brought to the attention of the marketing authorisation holder in relation to a veterinary medicinal product are collected and recorded;

(b) monitor the performance of each product which is the subject of a marketing authorisation, apply the signal management process mentioned in paragraph 56C and ensure that the any relevant requirements in accordance with the process are carried out;

(c) maintain the pharmacovigilance system master file for such product;

(d) provide to the Secretary of State any information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product including the results of any study or clinical trial carried out in relation to the product;

(e) communicate the fact that a regulatory measure has been taken in a country other than the United Kingdom as a consequence of pharmacovigilance data and the nature of such measure to the Secretary of State within 30 days of the receipt of such information;

(f) answer fully and promptly any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefit-risk balance of that product;

(g) monitor the pharmacovigilance system and ensure that, if required, an appropriate preventative or corrective action plan is prepared and implemented on behalf of the marketing authorisation holder;

(h) following any action taken in accordance with head (e) ensure that any relevant amendments are made to the pharmacovigilance system master file;

(i) liaise with the Secretary of State in relation to any pharmacovigilance inspection carried out under paragraph 60A;

(j) ensure that any person employed by the marketing authorisation holder who is engaged in pharmacovigilance receives ongoing training which is relevant to that person's duties.

(2) The Secretary of State may at any time require the qualified person (pharmacovigilance) to submit to the Secretary of State a copy of the pharmacovigilance system master file.

(3) Where the Secretary of State makes a requirement in accordance with sub-paragraph (2) the qualified person (pharmacovigilance) must submit that copy promptly and at the latest within 7 days of the date of the requirement.

56C Signal management process

(1) For the purposes of paragraphs 56, 56A, 56B and 60B—

"Signal management process" means a process for performing active surveillance of pharmacovigilance data for veterinary medicinal products in order to assess the pharmacovigilance data and determine whether there is any change to the benefit-risk balance of those veterinary medicinal products, with a view to detecting risks to animal or public health or protection of the environment.

(2) A signal management process consists of tasks of signal detection, validation, confirmation,

analysis and prioritisation, assessment and recommendation for action.

(3) A signal management process must be able to identify in relation to a product—

(a) a sudden and unexpected increase in the number of adverse events;

(b) an unexpected increase in the frequency of a known clinical sign;

(c) a new clinical sign;

(d) reports in scientific literature of any of the matters mentioned in heads (a) to (c).

~~56 The marketing authorisation holder must ensure that the qualified person (pharmacovigilance)--~~

~~(a) establishes and maintains a system that ensures that information about all suspected adverse reactions reported to the marketing authorisation holder is collected and collated in order to be accessible;~~

~~(b) answers any request from the Secretary of State for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product fully and within any time limit imposed by the Secretary of State when the information was requested, including the volume of sales of the veterinary medicinal product concerned and, if available, details of prescriptions;~~

~~(c) provides to the Secretary of State any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, including appropriate information on post-marketing surveillance studies; and in this paragraph "post-marketing surveillance studies" means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying and investigating a safety hazard relating to an authorised veterinary medicinal product.~~

57 ~~Adverse~~Adverse events~~reactions to~~ following administration of a veterinary medicinal product administered in the United Kingdom

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

(a) ~~serious adverse reaction~~animal adverse event;

(b) human ~~adverse~~adverse event~~reaction~~; ~~or~~

(c) unintended transmission of an infectious agent through a veterinary medicinal product, or,

(d) occurrence of an environmental incident,

following the administration of the product to an animal in the United Kingdom.

(1A) A marketing authorisation holder must also act in accordance with this paragraph where—

(a) after the elapse of the withdrawal period the presence is suspected to have occurred in a product of a pharmacologically active substance or marker residue exceeding the maximum levels of residue established in accordance with Regulation (EC) No. 470/2009;

(b) there is evidence in published scientific literature of an adverse event in connection with the product.

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

(3) The holder must without delay and in any event within ~~15~~ 30 days report it (electronically if this is practicable) to the Secretary of State.

(4) In addition, the holder must supply to the Secretary of State all relevant veterinary pharmacovigilance 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.

(4A) The Secretary of State may require the marketing authorisation holder—

(a) to collect specific pharmacovigilance data (in addition to the data mentioned in sub-paragraph (4)) and submit those data to the Secretary of Stata; and

(b) to carry out specific post-marketing surveillance studies.

(4B) Where the Secretary of State exercises the power mentioned in sub-paragraph (4A), the Secretary of State must—

(a) state the reason for the requirement; and

(b) state the time for compliance with the requirement.

~~(5) In this and the following paragraph--~~

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

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

~~58 Adverse reactions to a veterinary medicinal product administered in another country~~

~~(1) A marketing authorisation holder for a veterinary medicinal product authorised in Great Britain must act in accordance with this paragraph on learning of any suspected--~~

~~(a) serious, unexpected adverse reaction (for these purposes a reaction is unexpected if its nature, severity or outcome is not consistent with the summary of the product characteristics);~~

~~(b) human adverse reaction; or~~

~~(c) unintended transmission of an infectious agent through a veterinary medicinal product,~~

~~following the administration of the product in another country.~~

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

~~(3) The holder must without delay and in any event within 15 days report the suspected reaction or transmission (electronically if this is practicable) to the Secretary of State,.~~

~~(4) In addition to the report, the holder must supply to the Secretary of State all relevant veterinary pharmacovigilance information in the holder's possession relating to the reaction as in the preceding paragraph.~~

59 ~~Periodic safety update~~Annual benefit risk reports

(1) The marketing authorisation holder must submit to the Secretary of State ~~records of all adverse reactions (including nil reports)~~ a summary of pharmacovigilance activity in the form of ~~a periodic safety update report~~an annual benefit risk report for each marketing authorisation in accordance with this paragraph~~, including a summary of each incident and a list of all the symptoms using internationally recognised veterinary and medical terminology~~.

~~(2) A marketing authorisation holder who has not yet placed a product on the market in the United Kingdom must submit a periodic safety update report immediately upon request of the Secretary of State and at least every six months after authorisation.~~

(3) Following the placing on the market in the United Kingdom, the marketing authorisation holder must submit a ~~periodic safety update~~ report to the Secretary of State immediately upon request ~~and--~~

~~(a) at least every six months during the first two years following the initial placing on the market;~~

~~(b) once a year for the following two years; and~~

~~(c) thereafter, at three-yearly intervals.~~and in any event, once in the course of every year during the period of validity of the authorisation.

(4) Following the granting of a marketing authorisation, the marketing authorisation holder may apply to the Secretary of State to change the ~~periods of notification~~ submission dates for the annual benefit-risk reports.

(5) The ~~periodic safety update~~ report must include a scientific evaluation of the ~~risk-benefit balance~~benefit-risk balance of the veterinary medicinal product.

(6) ~~The periodic safety update report must include~~The Secretary of State may request the following information to be included in the report--

(a) the volume of the product sold in the UK and in other countries in each year covered by the report, calculated on an annual basis beginning 1st January;

(b) the number of ~~adverse reactions~~ adverse events for each year of the report;

(c) the ratio of ~~adverse reactions~~adverse events to volume of product sold for each year of the report, together with an explanation of the basis of the calculation;

(ca) the notification of signals detected during the reporting period following pharmacovigilance activity in the United Kingdom or a country other than the United Kingdom for which further regulatory actions are required (including a summary of the regular review of adverse events carried out during the year);

(d) differentiation of data based on--

(i) target species (if the product is authorised for use in more than one species);

(ii) reaction type (such as ~~serious, non-serious~~animal, human, suspected lack of efficacy, unauthorised use or other);

(iii) the country of origin of the report.

(e) a record (expressed in internationally recognised veterinary and medical terminology) of all adverse events occurring in third countries, including a summary of each incident and a list of all the symptoms displayed;

(f) a discussion of the clinical relevance of the signals mentioned in head (ca) and providing relevant statistical analysis in relation to them; and

(g) where it appears from the observed data that there is cause for concern in relation to the safety of the product, recommendations on the need for further intervention by the Secretary of State.

~~(7) If the product is indicated for more than one species, the information in sub-paragraph (6)(c) must be based so far as is practicable on the estimated use of the product.~~

~~(8) Data relating to different formulations (either different dosage forms or different strengths) must be provided in separate reports.~~

60 Release of information by the marketing authorisation holder

(1) A marketing authorisation holder must not communicate information relating to pharmacovigilance concerns to veterinary surgeons or the general public in relation to its authorised veterinary medicinal product without giving prior or simultaneous notification to the Secretary of State.

(2) The marketing authorisation holder must ensure that such information is presented objectively and is not misleading.

(3) For the purposes of this paragraph “information” includes any information contained in advertising material.

60A Pharmacovigilance inspections by Secretary of State

(1) The Secretary of State must, from time to time, inspect the premises of marketing authorisation holders for the purpose of verifying compliance with the provisions of this Schedule in relation to pharmacovigilance.

(2) The frequency of inspections under sub-paragraph (1) must be based on the risks associated with each premises' history and the nature of the products handled at the premises.

(3) Within 90 days after an inspection, the Secretary of State must issue a certificate of good practice to the holder of the marketing authorisation if the inspection established compliance with the principles of good practice in relation to pharmacovigilance.

60B Powers of Secretary of State in relation to signal management process

The Secretary of State may decide to perform a targeted signal management process for a given veterinary medicinal product or a group of veterinary medicinal products.

61 Action taken on account of pharmacovigilance

(1) Where, as a result of the evaluation of veterinary pharmacovigilance data, the Secretary of State considers that a marketing authorisation (or a group of marketing authorisations containing the same active substance) should be--

(a) suspended;

(b) revoked; or

(c) varied so as to--

(i) restrict the indications;

(ii) change the distribution category;

(iii) amend the dose;

(iv) add a contraindication; ~~or~~

(v) add a new precautionary measure, or,

(vi) implement a risk management plan,

the Secretary of State must forthwith inform the marketing authorisation holder.

(2) If urgent action is necessary for protecting human or animal health, the Secretary of State may suspend the marketing authorisation of a veterinary medicinal product.

Part 9 Homeopathic Remedies

62 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**32** or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission.

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

(1) 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 in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation if it complies with this paragraph.

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32 ISBN 9287145873.

(2) It must not be an immunological or, subject to sub-paragraph (2A), a biological product.

(2A) Sub-paragraph (2) does not apply in relation to a homeopathic remedy which is derived from plants.

(3) The route of administration must be either topical or oral and must be as described in the European Pharmacopoeia.

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

64 Application for registration

(1) An applicant for registration must submit the following to the Secretary of State--

(a) the scientific name or other name of the homeopathic stock or stocks given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;

(b) a dossier describing how the homeopathic stock is or stocks are obtained and controlled, and justifying ~~its~~their homeopathic ~~nature~~use, on the basis of an adequate bibliography;

(c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;

(d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;

(e) a copy of the manufacturing authorisation for the product;

(f) copies of any registrations ~~or authorisations~~ obtained for the same homeopathic remedy;

~~(g) a mock-up of the outer packaging and immediate packaging;~~

(g) the text which is to appear on the package leaflet, outer packaging and immediate packaging of the homeopathic remedy;

~~(h) stability data;~~

(h) any relevant data concerning the stability of the homeopathic remedy;

(i) the proposed withdrawal period necessary to ensure that the provisions of Regulation (EC) No 470/2009 of the European Parliament and of the Council are complied with together with all necessary justification.

(2) These documents must demonstrate the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council.

65 Procedure for registration

(1) The procedure for registration is the same as the procedure for granting a marketing authorisation in accordance with Part 3, except--

(a) the applicant is not required to provide proof of efficacy;

(b) the product is not required to have a summary of product characteristics;

(c) the Secretary of State is not required to publish an assessment report.

(2) The procedure for variation, suspension and revocation is the same as for a marketing authorisation.

(3) The Secretary of State must ensure that the procedure for granting a registration relation to a homeopathic remedy is completed within a maximum of 210 days after the submission of the application.

66 Products on the market before 1994

A homeopathic remedy that was on the market before 1st January 1994 may be placed on the market without being registered.

67 Classification

The registration must specify the classification of the homeopathic remedy, which must be one of the classifications specified for a veterinary medicinal product in Schedule 3.

68 Offences

It is an offence to fail to comply with--

(a) a requirement made under paragraph 27(1);

(b) a request made under paragraph 27(2);

(c) paragraph 28(1) or (2);

(d) a requirement made under paragraph 28(3);

(e) paragraph 29(3);

(f) paragraph 30;

(g) paragraph 31(1) or (2);

(h) a request made under paragraph 31(3);

(i) a prohibition or requirement made under paragraph 39(4);

(j) a prohibition or requirement made under paragraph 41(1);

(k) paragraph 55;

(l) paragraph 56;

(m) paragraph 57;

(n) paragraph 58;

(o) paragraph 59; or

(p) paragraph 60.

SCHEDULE 1A Converted EU marketing authorisations

Regulation 4(4)

(1) In this Schedule—

"converted EU marketing authorisation" means an EU marketing authorisation to which paragraph 2 applies;

"EU marketing authorisation" means a marketing authorisation for a veterinary medicinal product granted by the European Commission in accordance with Title 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**33**.

(2) This paragraph applies to an EU marketing authorisation which—

(a) was granted before exit day, and

(b) remains in force immediately before exit day.

(3) A converted EU marketing authorisation has effect on and after exit day for the purposes of these regulations as if it were a marketing authorisation granted by the Secretary of State under these Regulations on the date it was originally granted—

(a) on the terms which were in force immediately before exit day,

(b) with the benefit of any periods of data marketing exclusivity from which the holder benefited immediately before exit day, and

(c) subject to any suspension or post-authorisation obligations which were in force immediately before exit day.

(4) Without prejudice to the generality of paragraph 3—

(a) the holder of a converted EU marketing authorisation is subject to the annual fee as set out in paragraph 26 of Schedule 7;

(b) a converted EU Marketing authorisation is to be treated as having been granted in accordance with regulation 4(3) and Schedule 1 for the purposes of Regulation (EC) No 469/2009.

SCHEDULE 1B Qualifying Northern Ireland good (QNIG) certificates

Regulation 4(5)

(1) In this Schedule—

"QNIG certificate" means a certificate issued under paragraph 3;

"QNIG certificate holder", in relation to a QNIG certificate, means the person to whom that certificate was issued under paragraph 3;

"qualifying Northern Ireland goods" has the meaning given to it from time to time in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

"Northern Ireland VMRs" means the Veterinary Medicines Regulations 2013 as they have effect in Northern Ireland.

(2) This Schedule applies to a veterinary medicinal product which is—

(a) a qualifying Northern Ireland good in respect of which there is a marketing authorisation valid in Northern Ireland under the Northern Ireland VMRs,

33 OJ No L 136, 30.4.2004, p 1, as last amended by Regulation (EU) No 1027/2012 (OJ No L 316, 14.11.2012, p 38).

(b) not a product in respect of which there is a marketing authorisation which is valid in Great Britain (including any marketing authorisation which has effect under paragraph 3 of Schedule 1A),

(c) not a product in respect of which a QNIG certificate issued under this Schedule already applies, and

(d) not a product to which Article 41(1) of the EU withdrawal agreement applies.

(3) If the condition in paragraph 4 is met in respect of the veterinary medicinal product, the Secretary of State must issue a QNIG certificate in respect of that product to the person who holds a marketing authorisation in respect of the product which is valid in Northern Ireland under the Northern Ireland VMRs.

(4) The condition is that the person who holds a marketing authorisation in respect of the product which is valid in Northern Ireland under the Northern Ireland VMRs, who must be a person established in Northern Ireland, has provided the Secretary of State with the following information—

(a) the Northern Ireland address of that person;

(b) all necessary administrative information, and all scientific documentation necessary for demonstrating the safety, quality and efficacy of the veterinary medicinal product, equivalent to that which would need to be provided under Schedule 1 if an application for a marketing authorisation was to be made in respect of that product under paragraph 1 of that Schedule (allowing for any relevant derogations provided for in Part 2 of that Schedule);

(c) the name and address of a person who resides in the United Kingdom or in a member State who is to provide in respect of the veterinary medicinal product, permanently and continuously, the services of a qualified person (pharmacovigilance) for the purposes of Part 8 of Schedule 1.

(5) A QNIG certificate has effect as if it were a marketing authorisation granted by the Secretary of State under these Regulations subject to the modification that the qualified person (pharmacovigilance) for the purposes of Part 8 of Schedule 1 is the person identified under paragraph 4(c).

(6) The QNIG certificate holder must provide to the Secretary of State from time to time such further information as is appropriate to ensure that the information provided under paragraph 4 remains accurate and complete.

(7) Without prejudice to any other power to suspend a marketing authorisation under Schedule 1, if the Secretary of State considers that a QNIG certificate holder is in breach of these Regulations as modified by paragraph 5, or that the information provided in respect of the matters specified in paragraph 4 is no longer accurate or complete, the Secretary of State may by notice suspend the QNIG certificate.

(8) The Secretary of State must publish any notice given under paragraph 7 in such manner as the Secretary of State considers appropriate from time to time.

(9) Paragraphs 39 and 40 of Schedule 1 apply to the suspension of a QNIG certificate under paragraph 7 as they would to the suspension of such a certificate under paragraph 38 of that Schedule as read with paragraph 5.

SCHEDULE 1C

SCHEDULE 2 The Manufacture of Veterinary Medicinal Products

Regulation 5(2)

Part 1 Manufacturing Authorisations

1 Manufacturing authorisation

(1) No person may carry out any activity mentioned in sub-paragraph (2) otherwise than in accordance with an authorisation granted under this paragraph.

(2) For the purposes of sub-paragraph (1) the activities are—

(a) the manufacture of veterinary medicinal products (whether for use in the Great Britain or for export);

(b) the carrying out any part of the process of bringing a veterinary medicinal product to its final state, including the processing, assembling, packaging or repackaging, labelling or relabelling, storing, sterilising or releasing for supply of a veterinary medicinal product;

(c) the importation of any veterinary medicinal product for use in Great Britain.

~~1 Application~~

~~An application for a manufacturing authorisation must be made to the Secretary of State.~~

~~2 Time limits~~

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

~~(2) The Secretary of State must process an application for a variation of a manufacturing authorisation within 30 days unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.~~

2 Application for authorisation

(1) An application for an authorisation under paragraph 1 (which must be submitted to the Secretary of State electronically) must include the matters mentioned in sub-paragraphs (2), (3) and (4).

(2) For the purposes of sub-paragraph (1) the matters are—

(a) the name of the person who will hold the manufacturing authorisation and that person's address or registered place of business;

(b) the names and addresses of the sites (including any site where work is undertaken on behalf of the proposed holder under contract) where—

(i) each stage of the manufacture is carried out;

(ii) any imported products are held; or

(iii) any control or batch release is carried out;

(c) a description of the veterinary medicinal products or pharmaceutical forms proposed to be manufactured under the authorisation;

(d) the name of the proposed qualified person (manufacture) for the purposes of paragraph 9;

(e) the name of the person proposed to have responsibility for quality control; and

(f) the name of the person proposed to have responsibility for production.

(3) For the purpose of sub-paragraph (1) the matters are the qualifications and a description of the relevant experience of the person proposed to have responsibility for quality control and the person proposed to have responsibility for production.

(4) For the purpose of sub-paragraph (1) the matters are

(a) a declaration that the applicant complies with good manufacturing practice and any

relevant legislation; and

(b) a declaration that any site mentioned in sub-paragraph (2)(b) is ready for inspection.

3 Procedure and time limits for authorisations

(1) The Secretary of State must process an application mentioned in paragraph 2 within 90 days of validating the application.

(2) The Secretary of State must inspect the sites mentioned in paragraph 2(2)(b) within 90 days of validating the application.

(3) Where the Secretary of State is satisfied, following the inspection mentioned in sub-paragraph (2) that—

(a) the sites are suitable for the intended purposes;

(b) the applicant has—

(i) suitable and sufficient staff, technical equipment and facilities for the manufacture, control, importation and storage of the products proposed to be manufactured; and

(ii) a documented quality management system in place,

the Secretary of State must grant the manufacturing authorisation.

(4) Where the Secretary of State is not satisfied in relation to one or more of the matters mentioned in sub-paragraph (3), the Secretary of State may grant a conditional authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

~~3 Granting the authorisation~~

~~The Secretary of State must grant a manufacturing authorisation on being satisfied that the applicant has suitable and sufficient premises, staff, technical equipment and facilities for the manufacture, control and storage of the products, and will comply with these Regulations~~.

4 The authorisation

(1) The manufacturing authorisation must specify--

(a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured or imported;

~~(b) the place where they are to be manufactured or controlled;~~

(b) the name and address of the site where the products are to be manufactured, controlled or imported;

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

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

(e) the names of all qualified persons nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

(3) The holder of a manufacturing authorisation must notify the Secretary of State, 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 to the operations for which they are used.

(4) The Secretary of State must process an application under sub-paragraph (3) within 30 days of receiving it unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

5 Suspension, compulsory variation or revocation of the authorisation

(1) The Secretary of State may suspend, vary or revoke a manufacturing authorisation if the holder--

(a) has not complied with these Regulations;

(b) has manufactured a veterinary medicinal product not authorised by the manufacturing authorisation;

(c) has produced a veterinary medicinal product outside the terms of a marketing authorisation; ~~or~~

(d) no longer has suitable premises or equipment.

(e) has failed to carry out the activity specified in the authorisation for a period of 5 years or more; or

(f) has not paid any fee required under these Regulations.

(2) The Secretary of State may also suspend, vary or revoke the authorisation on being satisfied that the qualified person (manufacture), or the person responsible for quality control or the person with responsibility for production is not fulfilling that person's duties under these Regulations.

(3) The Secretary of State may—

(a) suspend the manufacture of veterinary medicinal products;

(b) suspend the importation of veterinary medicinal products from countries other than the United Kingdom;

(c) suspend, revoke or vary the manufacturing authorisation for one or more pharmaceutical forms;

(d) suspend, revoke or vary the manufacturing authorisation for one or more activities in one or more manufacturing sites.

~~(2) The Secretary of State may also suspend, vary or revoke it on being satisfied that the qualified person (manufacture) is not fulfilling their duties under these Regulations.~~

6 Good manufacturing practice certificates and inspection of sites~~Inspection of premises~~

(1) The Secretary of State must, from time to time, inspect ~~premises~~ sites registered under paragraph 3, basing the frequency of the inspection on the risks associated with each ~~premises'~~ site's history and the nature of the products handled at the sites~~premises~~.

~~(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection established compliance with the principles and guidelines on good manufacturing practice in accordance with Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products[34].~~

(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection establishes that the manufacturer has complied with the requirements of these Regulations in respect of the site to which the inspection relates.

(3) Where the Secretary of State does not consider that compliance is established after inspection in accordance with sub-paragraph (2), the Secretary of State must enter that fact in the register mentioned in paragraph 12(a).

(4) The Secretary of State may carry out an inspection on a site occupied by a manufacturer established in a country other than the United Kingdom notwithstanding any arrangements that may have been entered into between the United Kingdom and that country.

~~[34] OJ No L 228, 17.8.91, p. 70.~~

(5) The importer of a veterinary medicinal product must ensure before importation that the manufacturer of that product has a current certificate of good manufacturing practice issued by the Secretary of State or by a regulatory authority with which the Secretary of State has an agreement or which the Secretary of State considers to have demonstrated equivalent standards to those in the United Kingdom.

7 Report following inspection

(1) After each inspection of manufacturing premises, the inspector must make a written report to the Secretary of State on whether the principles and guidelines on good manufacturing practice and the conditions of these Regulations are being complied with.

(2) The Secretary of State must inform the inspected manufacturer of the content of such reports.

8 Duties on the holder of a manufacturing authorisation

(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

(2) The holder must have permanently at the holder's disposal the services of—

(a) staff complying with any legal requirements in relation to manufacture of veterinary medicinal products; and

(b) at least one qualified person (manufacture) who is on the register of qualified persons (manufacture) maintained by the Secretary of State,

and the holder must place all necessary documents, premises and technical and other facilities in order to discharge that person's duties at the qualified person's disposal.

(2A) Where the qualified person ceases to be employed by the holder, the holder must give notice of the fact to the Secretary of State—

(a) at least 30 days in advance of the person's ceasing to be so employed; or

(b) where such notice is not possible, at the earliest opportunity.

~~(2) The holder must have permanently at their disposal the services of at least one qualified person (manufacture) who is on the register of qualified persons (manufacture) maintained by the Secretary of State and must place all necessary facilities at the qualified person's disposal.~~

(3) The holder must—

(a) comply with good manufacturing practice and have a current certificate of good manufacturing practice;

(b) use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice and good distribution practice for active substances;

(c) verify that each manufacturer, distributor or importer from whom the holder obtains active substances is registered with the Secretary of State;

(d) carry out audits based on a risk assessment in relation to the manufacturers, distributors and importers from which the holder obtains active substances;

(e) have in place a system of Quality Assurance and Quality Control; and

(f) give to the Secretary of State, on request, proof of any control test specified by the Secretary of State which has been carried out on the veterinary medicinal product or the constituents and intermediate products of the manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(3A) The holder of a manufacturing authorisation must inform the Secretary of State and the holder of any relevant marketing authorisation where the holder obtains information that veterinary medicinal products which fall within the scope of its manufacturing authorisation are falsified, or are

suspected of being falsified, irrespective of whether those products were distributed within the legal supply chain or by illegal means.

~~(3) The holder must--~~

~~(a) have a current Certificate of Good Manufacturing Practice;~~

~~(b) have in place a system of Quality Assurance and Quality Control; and~~

~~(c) give to the Secretary of State on request proof of all control tests carried out on the veterinary medicinal product or the constituents and intermediate products of the manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.~~

(4) A holder who makes up a bulk package of veterinary medicinal products must ensure that the package is labelled, in a way that the label is clearly visible and legible, with--

(a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;

(b) the batch number;

(c) the expiry date;

(d) any storage requirements; and

(e) any other warning necessary for the safe handling of the package.

(5) A holder must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if required in writing to do so.

(6) A holder must keep detailed records of all veterinary medicinal products which the holder supplies.

9 Qualified persons for manufacture

(1) The Secretary of State may appoint as a qualified person (manufacture) any person (including the manufacturer) who is--

(a) a member of the Royal Pharmaceutical Society or registered with the Pharmaceutical Society of Northern Ireland;

(b) a Chartered Chemist or a Fellow, Member or Associate Member of the Royal Society of Chemistry; or

(c) a Chartered Biologist or a Fellow, Member or Associate Member of the Society of Biology;

who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent and who has sufficient practical experience engaged in one or more of the activities mentioned in sub-paragraph (1A) over at least 2 years in employment with the holder of a manufacturing authorisation to carry out the duties under this Schedule.

(1A) For the purposes of sub-paragraph (1) the activities are—

(a) quality assurance of medicinal products;

(b) qualitative analysis of medicinal products; and

(c) quantitative analysis of active substances.

(1B) The duration of practical experience mentioned in sub-paragraph (1) may be reduced by one year where the formal course of study lasts for at least 5 years and by one and a half years where the formal course of study lasts for at least 6 years.

(2) The Secretary of State may exceptionally appoint a person who is not a member of one of those institutions to act as a qualified person (manufacture) on being satisfied that that person has the educational qualifications or practical experience to carry out the duties under this Schedule.

10 Refusal, suspension, revocation or variation of appointment~~Refusal or revocation~~

~~of appointment~~

The Secretary of State may refuse ~~or revoke~~, revoke, suspend or vary an appointment if the Secretary of State is not satisfied that a person has fulfilled or will fulfil duties under these Regulations.

11 Duties on a qualified person

(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under that person's responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(1A) The qualified person (manufacture) must produce a report in advance of the release of a batch of veterinary medicinal product to the market to verify that the requirements of sub-paragraph (1) have been satisfied.

(2) If a manufacturer imports a veterinary medicinal product from another country or if the manufacturer re-imports a product exported after original manufacture in the United Kingdom, the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested, including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation and that the batch has been manufactured in compliance with good manufacturing practice.

(3) Sub-paragraph (2) does not apply where the exporting country has demonstrated equivalent standards to those of the United Kingdom or where appropriate arrangements have been made with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

(5) The qualified person (manufacture) must make a record in respect of each released production batch and must keep such records for one year after the date of the expiry of the batch or for at least 5 years from the date on which the record is made, whichever period is the longer.

12 Register

The Secretary of State must maintain and publish a register of--

(a) holders of manufacturing authorisations; and

(b) qualified persons (manufacture) appointed under paragraph 9(2).

13 Test sites

(1) The Secretary of State may authorise a site~~premises~~ to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The ~~premises~~site must have a current certificate of good manufacturing practice.

(2A) The site must be specified in an existing manufacturing authorisation and must be subject to a certificate of good manufacturing practice.

(3) ~~Authorisation and inspection of the premises are~~ Inspection of the site is the same as for a manufacturing authorisation.

Part 2 Authorisation of Manufacturers of Autogenous Vaccines

14 Authorisation to manufacture autogenous vaccines

(1) The Secretary of State may authorise a person to manufacture autogenous vaccines and may authorise premises for the purpose of such manufacture by that person.

(2) In order to be authorised the premises must be under the supervision of--

(a) a veterinary surgeon; or

(b) a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before authorising the premises, the Secretary of State must be satisfied that the production process will produce a consistent, safe product.

(4) No person may manufacture an autogenous vaccine other than in accordance with an authorisation under sub-paragraph (1).

15 Types of authorisation

(1) The authorisation must specify the products that may be manufactured.

(2) It may either be for the production of a single batch of product or for ongoing production of the products specified in the authorisation.

(3) If it is for a single batch it must be time limited.

(4) Only the products specified in the authorisation may be manufactured, and in the case of an authorisation for a single batch the product may only be manufactured before the expiry of the authorisation.

16 Labelling

The operator of the premises must ensure that every container containing autogenous vaccine is labelled with--

(a) the name of the veterinary surgeon who ordered the vaccine;

(b) a precise description of the vaccine;

(c) the date the vaccine was produced;

(d) the name of the authorisation holder and address of the authorised premises;

(e) the expiry date;

(f) any necessary warnings; and

(g) instructions for use.

17 Records

The operator of the premises must, as soon as is reasonably practicable, record--

(a) the name and address of the veterinary surgeon who ordered the vaccine;

(b) the identification of the source animal;

(c) the expiry date;

(d) the date of supply to the veterinary surgeon,

and must keep the records for at least five years.

18 Adverse reactions

The authorised person must notify the Secretary of State of any adverse reactions to an autogenous vaccine within 15 days of learning of the reaction.

19 Inspection of premises

The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Part 3 Authorisation of Blood Banks

20 Authorisation of blood banks

(1) The Secretary of State may authorise blood banks for--

(a) the collection, storage and supply of blood, or

(b) the storage and supply of blood constituents obtained by the physical separation of donor blood into different fractions within a closed-bag system,

for the treatment of non-food-producing animals.

(2) The authorisation may be for either or both of these activities.

(3) In order to be authorised a blood bank must be under the supervision of--

(a) a veterinary surgeon named in the authorisation; or

(b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the blood bank.

(4) Before authorising a blood bank, the Secretary of State must be satisfied--

(a) that the welfare of animals used in the collection of blood will be respected; and

(b) that the production process will produce a consistent, safe product.

(5) The Secretary of State may suspend, vary or revoke an authorisation of a blood bank if--

(a) the holder no longer uses fit and proper processes;

(b) the premises in which the blood bank is being or is to be operated are not suitable;

(c) the equipment is not suitable; or

(d) the holder has not complied with these Regulations.

(6) Blood may only be collected under the responsibility of a veterinary surgeon.

(7) No person may operate a blood bank for treatment of animals other than in accordance with such an authorisation.

21 Supply and administration of blood from a blood bank

(1) The operator of a blood bank may only supply blood to a veterinary surgeon.

(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.

22 Labelling

(1) The operator of a blood bank must ensure that every container used for the blood is labelled with--

(a) the identification of the donor animal;

(b) the date of collection;

(c) the authorisation number of the blood bank;

(d) any necessary warnings;

(e) the expiry date.

(2) There must be no specific therapeutic indication on the label or on any information relating to the product.

23 Records

The operator of a blood bank must, as soon as is reasonably practicable, record--

(a) the date of collection;

(b) the identification of the donor animal;

(c) the veterinary surgeon who collected it;

(d) the expiry date;

(e) the date the blood was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied;

and must keep the records for at least five years.

24 Inspection of premises

The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Part 4 Authorisation of Manufacturers of Products for Administration Under the Cascade

25 Authorisation to manufacture products for administration under the cascade

(1) The Secretary of State may authorise a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade.

(2) In order to be authorised the premises must be under the supervision of a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before authorising the premises, the Secretary of State must be satisfied that the production process will produce a safe product.

(4) The authorisation must specify what types of product it covers.

(5) No person may manufacture an unauthorised veterinary medicinal product other than in accordance with an authorisation under sub-paragraph (1).

26 Labelling

The authorised person must ensure that, before a veterinary medicinal product is supplied, every container is labelled with--

(a) the name of the veterinary surgeon who ordered the veterinary medicinal product;

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the name of the authorisation holder and the address of the authorised premises;

(e) the expiry date;

(f) any necessary warnings; and

(g) instructions for use.

27 Records

The authorised person must, as soon as is reasonably practicable, record--

(a) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the expiry date; and

(e) the date of supply to the veterinary surgeon,

and must keep the record for at least five years.

28 Adverse reactions

The authorised person must notify the Secretary of State of any adverse reactions to a product manufactured by that person within 15 days of learning of the reaction.

29 Inspection of premises

The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Part 5 Authorisation of Equine Stem Cell Centres

30 Authorisation of stem cell centres

(1) The Secretary of State may authorise equine stem cell centres for the collection, storage, processing, production and administration of equine stem cells for use as an autologous treatment for horses.

(2) In order to be authorised a centre must be under the supervision of--

(a) a veterinary surgeon named in the authorisation; or

(b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the centre.

(3) Before authorising a centre, the Secretary of State must be satisfied--

(a) that the welfare of animals used in the collection of equine stem cells will be respected; and

(b) that the production process will produce a consistent, safe product.

(4) Equine stem cells may only be collected under the responsibility of a veterinary surgeon.

(5) The Secretary of State may suspend, vary or revoke an authorisation of an equine stem cell centre if--

(a) the holder no longer uses fit and proper processes;

(b) the premises in which the centre is being or is to be operated are not suitable;

(c) the equipment of the centre is not suitable; or

(d) the holder has not complied with these Regulations.

(6) No person may operate an equine stem cell centre other than in accordance with such an authorisation.

31 Supply and administration of stem cells

(1) The operator of an equine stem cell centre may only collect equine stem cells.

(2) The operator of an equine stem cell centre may not collect stem cells from embryonic tissues.

(3) 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.

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

32 Labelling

(1) The operator of an equine stem cell centre must ensure that every container used for the stem cell product is labelled with--

(a) the identification of the donor animal;

(b) the date of collection;

(c) the authorisation number of the equine stem cell centre;

(d) any necessary warnings;

(e) the expiry date.

(2) The operator of an equine stem cell centre must ensure that no specific therapeutic indication is included on the label or on any information relating to the product.

33 Records

The operator of an equine stem cell centre must, as soon as is reasonably practicable, record for each stem cell product--

(a) the identification of the donor animal;

(b) the date of collection;

(c) the veterinary surgeon under whose responsibility the stem cells were collected;

(d) the expiry date;

(e) the date the product was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied,

and must keep the records for at least five years.

34 Inspection of premises

The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

35 Offences

It is an offence to fail to comply with--

(a) paragraph 4(3);

(b) paragraph 11;

(c) paragraph 14(4);

~~(d) paragraph 16;~~

~~(e) paragraph 17;~~

~~(f) paragraph 18;~~

~~(g) paragraph 20(6) or (7);~~

~~(h) paragraph 21;~~

~~(i) paragraph 22;~~

~~(j) paragraph 23;~~

~~(k) paragraph 25(5);~~

~~(l) paragraph 26;~~

~~(m) paragraph 27;~~

~~(n) paragraph 28;~~

~~(o) paragraph 30(4) or (6);~~

~~(p) paragraph 31;~~

~~(q) paragraph 32; or~~

~~(r) paragraph 33.~~

Part 2 Authorisation of autogenous vaccines, blood-banks, stem-cell centres and products manufactured under the cascade

14 Authorisation to manufacture specific veterinary medicinal products

(1) The Secretary of State may authorise a person to—

(a) manufacture—

(i) autogenous vaccines; or

(ii) an unauthorised veterinary medicinal product for administration under the cascade;

(b) collect, store and supply blood;

(c) store and supply blood constituents obtained from the physical separation of donor blood into different fractions within a closed bag system, for the treatment of non-food animals; or

(d) produce, store and process stem cells for use as an autologous treatment for non-food animals,

and may authorise sites for the purpose of carrying out those activities by that person.

(2) A single authorisation under sub-paragraph (1) may confer permission to carry out the activities mentioned in both head (b) and (c) of that sub-paragraph.

15 Prohibition

No person may carry out any activity mentioned in paragraph 14 other than in accordance with the authorisation mentioned in that paragraph.

16 Personnel

In order to be authorised the site mentioned in paragraph 14(1) must be under the supervision of a named person responsible for release (a “PRR”) who in the opinion of the Secretary of State has sufficient qualifications and experience to manufacture the product safely.

17 Process of authorisation

(1) An applicant for authorisation under paragraph 14 must, at least 2 months before commencing an activity mentioned in that paragraph, submit the following to the Secretary of State—

(a) the name and address of the proposed holder of the authorisation;

(b) a description of the activity in which the applicant for authorisation proposes to be engaged;

(c) particulars (including the name and address) in relation to the site (whether in the occupation of the proposed holder or otherwise) at which the relevant activity is to be carried out and a description of the technical equipment on the site;

(d) particulars in relation to the qualifications and experience of the PRR who will supervise the activities at the site.

(2) The application must include a declaration that the applicant will comply with the requirements of these Regulations and confirmation that the site is ready for inspection.

(3) Before granting an authorisation in relation to a site, the Secretary of State must be satisfied that the production process carried on there will produce a consistent, safe product and, in the case of a blood bank or a stem cell centre, that the welfare of the animals involved in the processes will be respected.

18 Authorisation in relation to blood banks

(1) No person may collect blood other than under the responsibility of a veterinary surgeon.

(2) The holder of an authorisation to carry out an activity under paragraph 14(1)(b) or (c) may only supply blood or blood constituents to a veterinary surgeon.

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

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

19 Authorisation in relation to stem cells

(1) No person may collect stem cells other than under the responsibility of a veterinary surgeon.

(2) A person holding an authorisation to carry out an activity mentioned in paragraph 14(1)(d) may not collect stem cells from embryonic tissues.

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

20 Authorisation in relation to products for administration under the cascade

(1) Subject to sub-paragraph (2), no person may manufacture a product for administration under the cascade that is the pharmaceutical equivalent of an authorised veterinary medicinal product.

(2) The Secretary of State may authorise the manufacture of a product mentioned in sub-paragraph (1) where there is difficulty in relation to the supply of the product by other means.

(3) The holder of an authorisation under paragraph 14(1)(a)(ii) may not supply a product manufactured in accordance with that sub-paragraph other than to a veterinary surgeon who has prescribed the product under the cascade.

(4) The holder of an authorisation under sub-paragraph 14(1)(a)(ii) must—

(a) provide a list of products manufactured in accordance with that sub-paragraph to the Secretary of State annually or at the request of the Secretary of State;

(b) provide sales data for products supplied under sub-paragraph (3) at the request of the Secretary of State.

21 Suspension compulsory variation or revocation of authorisation

The Secretary of State may suspend, compulsorily vary or revoke an authorisation under paragraph 14 if the Secretary of State is satisfied that—

(a) the holder of the authorisation no longer uses fit and proper processes;

(b) the site at which the activity takes place is not suitable;

(c) the equipment is not suitable;

(d) the PRR has not carried out adequately the PRR's responsibilities under these Regulations;

(e) in the case of a person mentioned in paragraph 14(1)(a)(ii), the holder has manufactured a veterinary medicinal product that is not within the scope of its manufacturing authorisation;

(f) the holder has not conducted an activity relating to the authorisation for 5 years or more;

(g) the holder has not paid a required fee; or

(h) the holder has not complied with these Regulations.

22 Labelling

(1) The holder of an authorisation must ensure that, in addition to the expiry date and any necessary warnings, every contained used is labelled with a precise description of the product, the date the product was produced, the name and address of the authorisation holder, the address of the site named under the authorisation and its authorisation number and the instructions for use—

(a) in the case of an autogenous vaccine or an unauthorised veterinary medicinal product for administration under the cascade, the name of the veterinary surgeon who ordered the product;

(b) in the case of blood or a stem cell product—

(i) the identification of the donor animal; and

(ii) the date of collection;

(iii) the authorisation number of the blood bank or stem cell centre as the case may be.

(2) In the case of blood or blood constituents there must be no specific therapeutic indication on the label or any information related to the product.

(3) In the case of an unauthorised veterinary medicinal product for administration under the cascade the words "this veterinary medicinal product does not hold a marketing authorisation" must appear on the label.

23 Records

The holder of an authorisation must, as soon as is reasonably practicable, in addition to the expiry date of the product, record the following—

(a) in the case of an unauthorised veterinary medicinal product for administration under the cascade—

(i) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;

(ii) a precise description of the product;

(iii) the date of production;

(iv) the date of supply to the veterinary surgeon;

(b) in the case of stem cells or blood—

(i) the identification of the source animal;

(ii) the name of the veterinary surgeon who collected the product (or under whose responsibility it was collected);

(iii) the date of collection of the product;

(iv) the date that the product was used or if the product was supplied to another veterinary surgeon, the name and address of that veterinary surgeon and the date the product was supplied;t

(c) in the case of an autogenous vaccine—

(i) the name and address of the veterinary surgeon who ordered the vaccine;

(ii) the identification of the source animal;

(iii) the date of supply to the veterinary surgeon,

and must keep the records for at least 5 years.

24 Adverse events

The holder of an authorisation under paragraph 14 must notify the Secretary of State of any adverse event in relation to a product produced by that person under that authorisation within 30 days of learning of the event.

25 Inspection of sites

The Secretary of State must inspect the authorised site, basing the frequency of the inspection on the risks associated with each site's history and the nature of the products handled at the site.

Part 3 Active Substances

26 Active substances

For the purposes of this Part "active substance" means a substance used as a starting material in relation to the production of a veterinary medicinal product.

27 Prohibition on manufacture, importation or distribution of active substances

(1) No person may manufacture, import or distribute an active substance unless the person is registered in a register under sub-paragraph (2).

(2) The Secretary of State must establish and maintain a register of manufacturers, importers and distributors of active substances and the sites occupied by them for the purposes of manufacturing or holding active substances.

28 Application for registration

An applicant for registration under paragraph 27 must, at least 2 months before commencing an activity mentioned in paragraph 27(1) (or in the case of an existing manufacturer, within 2 months of the date on which this provision comes into force), submit the following to the Secretary of State—

(a) the name and address of the proposed registration holder;

(b) the name of the relevant active substance;

(c) a description of the activity proposed to be engaged in in relation to the relevant active substance; and

(d) particulars in relation to the site at which the relevant active substance is to be manufactured or held (as the case may be).

29 Good manufacturing or distribution practice

A manufacturer, or an importer or distributor of active substances used as starting materials in

veterinary medicinal products must comply with the principles and guidelines of, good manufacturing practice or good distribution practice as the case may be.

30 Supply of information

(1) A person registered under paragraph 27 must immediately inform the Secretary of State on receipt of any new information that might adversely affect the benefit-risk balance of the active substance.

(2) The person must immediately inform the Secretary of State of any prohibition or restriction in relation to the substance imposed by the competent authorities of any country other than the United Kingdom in which the active substance is authorised.

(3) The Secretary of State may at any time require the person to provide data relating to the risk-benefit balance in relation to the substance.

31 Inspection of sites

The Secretary of State may, from time to time, inspect sites registered under paragraph 27, basing the frequency of the inspection on the risks associated with each site's history and the nature of the substances handled at the site.

32 Report following inspection

(1) After each inspection of a site for the purposes of this Part, the inspector must make a written report to the Secretary of State on whether the principles and guidelines on good active substance handling practice and the conditions of these Regulations are being complied with.

(2) The Secretary of State must inform the inspected registered person of the content of such reports.

33 Offences

It is an offence to fail to comply with—

(a) paragraph 4(3);

(b) paragraph 11;

(c) paragraph 15;

(d) paragraph 18;

(e) paragraph 19;

(f) paragraph 20(1) or (2);

(g) paragraph 22;

(h) paragraph 23;

(i) paragraph 24;

(j) paragraph 27;

(k) paragraph 30(1) or (2).

SCHEDULE 3 Classification and Supply, Wholesale Dealers and Sheep Dip

Regulation 7

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 Secretary of State must specify the classification of the veterinary medicinal product when granting the initial marketing authorisation.

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

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

(a) products containing narcotic or psychotropic substances;

(b) products intended for administration following a diagnosis or clinical assessment by a veterinary surgeon.

(c) products containing antimicrobial substances;

(d) products for the purpose of euthanasia;

(e) immunological products;

(f) products with a hormonal or thyrostatic function;

(g) products containing beta-agonists.

(5) When granting the marketing authorisation the Secretary of State must classify the following as POM-V or POM-VPS--

(a) products for food-producing animals;

(b) products in respect of which special precautions must be taken in order to avoid any unnecessary risk to--

(i) the target species;

(ii) the person administering the products to the animal; and

(iii) the environment;

(c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; and

(d) new veterinary medicinal products containing an active substance that has not been included in an authorised veterinary medicinal product for five years.

(5A) Any product supplied in accordance with the cascade is to be subject to the same requirements as those classified by the Secretary of State as POM-V.

(6) The requirement in sub-paragraph (5)(a) relating to veterinary medicinal products for food-producing animals does not apply if all the following criteria are met--

(a) the administration of the veterinary medicinal product is restricted to formulations requiring no particular knowledge or skill in using the product;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious ~~adverse reaction~~ adverse event reporting;

(e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; and

(h) there is no risk to human or animal health as regards the development of resistance to ~~antimicrobials~~ antibiotics or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

2 Wholesale supply of veterinary medicinal products

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

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

(a) subject to sub-paragraph (2A) 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 or as a manufacturer.

(2A) A person mentioned in sub-paragraph (1) may import an unauthorised veterinary medicinal product for which a certificate has been issued by the Secretary of State for administration under the cascade.

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

(3) If the supply is to a veterinary surgeon, a pharmacist or a suitably qualified person, it must be to premises registered (or approved as the case may be) in accordance with paragraph 8(1), paragraph 10(1) or paragraph 14(4).

(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~~

(a) “retail supply” means a supply whether or not for payment to the owner or keeper of an animal for administration to that animal; and

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

3A Supply of samples

(1) Subject to sub-paragraph (2) A person mentioned in paragraph 2(1) or 3(2) may not supply a veterinary medicinal product for promotional purposes.

(2) Subject to sub-paragraph (3), the person may supply samples of product labelled in a way that clearly identifies them as such to—

(a) sales representatives who are responsible for promoting the product; or

(b) those entitled to supply the product during sponsored events.

(3) Sub-paragraph (2) does not apply in relation to a product containing an antimicrobial substance.

3B Register of online suppliers of veterinary medicinal products

(1) No person may supply or offer to supply a veterinary medicinal product by means of the internet to persons in Great Britain unless the person—

(a) is established within Great Britain;

(b) has an address within Great Britain; and

(c) is registered in a register under sub-paragraph (2).

(2) The Secretary of State must establish, maintain and publish on a website a register of persons who supply veterinary medicinal products by means of the internet.

3C Application for registration

An applicant for registration under paragraph 3B must, at least 2 months before commencing the activity mentioned in paragraph 3B(1) (or in the case of an existing supplier of veterinary medicinal products by means of the internet within 2 months of the date on which this provision comes into force), submit to the Secretary of State the name and the address within Great Britain of the proposed registration holder.

3D Duties in relation to online supply

Where a person offers to supply a veterinary medicinal product by means of the internet, that person must make available on each part of the website where the product is offered—

(a) a retailer logo approved by the Secretary of State;

(b) the contact details of the Secretary of State with responsibility for the oversight of veterinary medicinal products; and

(c) a link to the published register.

3E Retail storage of veterinary medicinal products

A retailer of veterinary medicinal products must store a veterinary medicinal product in accordance with the terms of any specific instructions on the label of the product and in accordance with the relevant summary of product characteristics.

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~~ clinical examination or other proper assessment of the animal or where there is more than one animal, of that group of animals, and the animal or that group of animals 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 Secretary of State.

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).

(1A) Where a veterinary medicinal product is supplied in accordance with an oral prescription the person who prescribes the product must make a record of the reason for prescribing the product.

(1B) A record made in accordance with sub-paragraph (1A) must be kept by the person mentioned in that sub-paragraph for a period of 5 years from the date on which the product is prescribed.

(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.

(4) No person may submit a written prescription to a retailer on more than one occasion where the prescription is not repeatable.

6 Written prescriptions

(1) A written prescription must include—

(a) the full name and contact details of the person prescribing the product, including that person's professional registration number (if available);

(b) the full name and contact details of the animal owner or keeper;

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

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

(e) the issue date;

(f) the signature or electronic signature of the prescriber;

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

(h) the pharmaceutical form and strength of the product;

(i) a statement of whether the product is prescribed for prophylactic purposes or metaphylactic purposes;

(j) the dosage regimen;

(k) any warnings necessary to ensure the proper use, including, where relevant, to ensure prudent use of antimicrobials;

(l) the words "It is an offence under the Veterinary Medicines Regulations 2013 for a person to alter a written prescription unless authorised to do so by the person who signed it";

(m) for food producing animal species, the withdrawal period or a statement that the withdrawal period is equal to zero days; and

(n) if the prescription relates to a product prescribed under the cascade, a statement to that effect.

~~(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.~~

(1A) Subject to any general duty in relation to animal welfare, a person may only prescribe an antibiotic veterinary medicinal product where the person is satisfied that the circumstances set out in sub-paragraph (1B) apply.

(1B) For the purposes of sub-paragraph (1A) the circumstances are that the product is not—

(a) used routinely;

(b) used to compensate for poor hygiene, inadequate animal husbandry, or poor farm management practices; or

(c) used to promote growth or increase yield.

(2) A written prescription for a controlled drug as specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001**35** is valid for 28 days.

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

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

(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

(1) 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.

(2) A person who prescribes antimicrobials must ensure that the product is prescribed for the most limited period that is consistent with the risk to be addressed.

7A Duties in relation to prescribing of antibiotic veterinary medicinal products

(1) Subject to sub-paragraphs (2) and (3) a person may not prescribe an antibiotic veterinary medicinal product for prophylactic purposes.

(2) A person may only prescribe an antibiotic veterinary medicinal product for administration to an animal for prophylactic purposes in exceptional circumstances where the risk of an infection or of an infectious disease is very high and where the consequences of not prescribing the product are likely to be severe.

(3) Subject to sub-paragraph (2), a person may only prescribe an antibiotic veterinary medicinal product for administration to a group of animals for prophylactic purposes where the circumstances set out in sub-paragraph (4) apply.

(4) For the purposes of sub-paragraph (3) the circumstances are that—

(a) the use of the product is not routine or predictable;

(b) the rationale for prescribing the product to the group of animals is clearly recorded by the person prescribing it; and

(c) a management review is carried out at, or as soon as reasonably practicable after administration of the product in order to identify factors and implement measures for the purpose of eliminating the need for any future such administration.

(6) A person who prescribes an antibiotic veterinary medicinal product must make a record in writing of the satisfaction of the relevant conditions for the purposes of its use in accordance with this paragraph and keep that documentation for at least 5 years.

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 Secretary of State with a copy of the register of veterinary practice premises.

(4) The Secretary of State 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 Secretary of State may require the Royal College of Veterinary Surgeons to remove the premises from the register maintained under sub-paragraph (1).

(6) Where the Secretary of State 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 Secretary of State.

(8) The Secretary of State 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 General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland;

(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~~authorised 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 prepared extemporaneously by a pharmacist in a registered pharmacy (as well as any other homeopathic remedy permitted to be supplied by a pharmacist under these Regulations) provided that it is prepared in accordance with paragraph 63 of Schedule 1 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~~premix ~~for incorporation into feedingstuffs~~

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

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

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

(b) an ~~approved~~authorised ~~premixture~~ intermediate feedingstuffs manufacturer; or

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

(a) an ~~approved~~authorised ~~premixture~~ intermediate feedingstuffs manufacturer; or

(b) an ~~approved~~authorised feedingstuffs manufacturer if the ~~approval~~authorisation permits the rate of incorporation specified on the label of that ~~veterinary medicinal product~~premix (if the manufacturer is the end user the supply must be in accordance with a ~~prescription~~ medicated feedingstuffs 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 five per cent in terms of value of veterinary medicinal product incorporated annually by the person supplying the veterinary medicinal product.~~

(4) This paragraph does not apply in relation to a feedingstuffs manufacturer approved to incorporate a premix who supplies another such feedingstuffs manufacturer with premix where the purpose of that supply is to alleviate a temporary supply shortage that could be detrimental to animal welfare.

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~~ practice premises or ~~approved~~authorised 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 Secretary of State 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 Secretary of State 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~~authorised by the Secretary of State 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 General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland; 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.~~

(5) A suitably qualified person who supplies a product classified as POM-VPS or NFA-VPS must be present when it is handed over unless the suitably qualified person—

(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.

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

(7) The Secretary of State 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 Secretary of State must publish a list of--

(a) suitably qualified persons; and

(b) the trading names and the addresses of premises ~~approved~~authorised under this paragraph**36**.

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

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

(11) The Secretary of State may suspend or revoke recognition of a body mentioned in sub-paragraph (1) where the body fails to comply with a provision of the Code of Practice issued under paragraph 14.

~~15 Annual audit~~

~~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.~~

15 Audit

(1) At least once a year, a retailer of prescription only veterinary medicinal products must carry out a detailed audit of stock and compare the incoming and outgoing veterinary medicinal products recorded with products currently held and make a record of this audit.

(2) Where, as a result of the audit mentioned in sub-paragraph (1) the retailer identifies a discrepancy the retailer must make a record of the fact.

(3) The retailer must keep the record mentioned in sub-paragraphs (1) and (2) for a period of 5 years from the date of the audit and the Secretary of State may require the retailer to provide a copy of it at any time within that period.

Part 2 Requirements for a Wholesale Dealer's Authorisation

16 Wholesale dealer’s authorisation

No person may deal as a wholesale dealer in veterinary medicinal products otherwise than in accordance with an authorisation granted under this paragraph.

36 Published at: http://www.vmd.defra.gov.uk/registers/sqpregister.aspx.

~~16 Application~~

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

17 Application for authorisation

(1) An application for an authorisation under paragraph 16 must include the matters mentioned in sub-paragraphs (2), (3) and (4).

(2) For the purposes of sub-paragraph (1) the matters are—

(a) the name of the person who will hold the wholesale dealer's authorisation and that person's address or registered place of business;

(b) the names and addresses of the sites where the veterinary medicinal products are to be stored;

(c) evidence that the sites mentioned in head (b) are—

(i) weatherproof;

(ii) secure and lockable;

(iii) clean;

(iv) free from contaminants;

(v) designed with designated areas for the receipt of veterinary medicinal products; and

(vi) where the veterinary medicinal products for which the authorisation is sought are subject to specific storage requirements, capable of fulfilling those requirements;

(d) the name of the wholesale qualified person nominated to act under the guidelines on good distribution practice;

(e) a description of the veterinary medicinal products proposed to be dealt in under the authorisation;

(f) evidence that the proposed holder of the authorisation has available to it the services of technically competent staff;

(g) evidence that the proposed holder of the authorisation has in place—

(i) an effective emergency recall plan; and

(iii) a quality system.

(3) For the purpose of sub-paragraph (1) the matters are the qualifications and a description of the relevant experience of the wholesale qualified person.

(4) For the purpose of sub-paragraph (1) the matter are—

(a) a declaration that the applicant complies with good distribution practice and any relevant legislation;

(b) a declaration that any site mentioned in sub-paragraph (2)(b) is ready for inspection.

~~17 Time limits~~

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

18 Procedure and time limits for authorisations

(1) The Secretary of State must inspect the sites mentioned in paragraph 17(2)(b) within 90 days of validating the application.

(2) Where the Secretary of State is satisfied, following the inspection mentioned in sub-paragraph (1) that—

(a) the sites are suitable for the intended purposes;

(b) the applicant has—

(i) suitable and sufficient staff and facilities for the storage of veterinary medicinal products; and

(ii) a documented quality system in place,

the Secretary of State must grant the wholesale dealer's authorisation.

(3) Where the Secretary of State is not satisfied in relation to one or more of the matters mentioned in sub-paragraph (2), the Secretary of State may grant a conditional authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

~~18 Granting the authorisation~~

~~(1) The Secretary of State 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; and~~

~~(b) have an effective emergency recall plan.~~

19 The authorisation

(1) A wholesale dealer's authorisation lapses where the holder does not deal in veterinary medicinal products for 5 years.

(2) The holder of a wholesale dealer's authorisation must notify the Secretary of State, and apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation or the operations for which the premises or facilities are used or where there is a change in the personnel carrying out the role of wholesale qualified person.

~~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 for Human Use37.~~

~~(2) It may cover more than one site.~~

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

~~37 OJ No C 63, 1.3.94, p. 4.~~

~~(4) The holder of a wholesale dealer's authorisation must notify the Secretary of State, 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 Secretary of State 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, equipment or technically competent staff.

~~(b) no longer has suitable premises or equipment~~.

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

(1) 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 good distribution practice;

~~(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 Secretary of State on demand; and

(e) notify the Secretary of State (and in relation to head (ii), the holder of the relevant marketing authorisation) where it has reason to suspect—

(i) a threat to the continued supply of a veterinary medicinal product;

(ii) that it has been offered veterinary medicinal products which are counterfeit.

21A Register of holders of authorised wholesale dealers

The Secretary of State must establish, maintain and publish on a website a register of authorised wholesale dealers and their sites.

21B Documentation accompanying veterinary medicinal products supplied wholesale

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

(2) The holder of a wholesale dealer's authorisation must ensure that a document accompanies each consignment of veterinary medicinal products specifying—

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

(b) the date on which the veterinary medicinal product was supplied;

(c) the quantity of product supplied;

(d) the batch number;

(e) the name and address of the wholesale dealer supplying the product;

(f) the means by which the product was transported and the required conditions of storage;

(g) the name of the person to whom the product was supplied and the address to which it is delivered.

(3) The holder of a wholesale dealer's authorisation must make a record of the information mentioned in sub-paragraph (2) and must keep it for at least 5 years.

21C Recalled products

(1) The holder of a wholesale dealer's authorisation must comply with any requirement by the Secretary of State to recall a veterinary medicinal product and must record the details of the recall operation.

(2) The holder of a wholesale dealer's authorisation must record any veterinary medicinal product which is—

(a) recalled; or

(b) discovered to be counterfeit.

(3) Where any veterinary medicinal product is recalled, the wholesale qualified person must assess the recalled product in order to determine whether the product has been stored in accordance with the requirements specified in paragraph 21B(2)(f).

(4) Where a recalled veterinary medicinal product has not been stored in accordance with the requirements specified in paragraph 21B(2)(f) or where it is not possible for the wholesale qualified person to determine whether the product has been stored in the manner specified, the product may not be re-sold.

(5) Any veterinary medicinal products which may not be re-sold must be identified, held separately and destroyed and the holder of a wholesale dealer's authorisation must develop a suitable procedure to set out the steps to be taken in accordance with this sub-paragraph.

(6) The holder of a wholesale dealer's authorisation must keep any information recorded under this paragraph for 5 years.

21D Audit

(1) At least once a year, the holder of a wholesale dealer's authorisation must carry out a detailed audit of stock and compare the incoming and outgoing veterinary medicinal products recorded with products currently held and record the results of the audit in written form.

(2) Where, as a result of the audit mentioned in sub-paragraph (1) the holder identifies a discrepancy the holder must make a record of that fact.

(3) The holder must keep the record mentioned in sub-paragraphs (1) and (2) for a period of 5 years from the date of the audit and the Secretary of State may require the holder to provide a copy of it at any time within that period.

21E Contractual arrangements between holders of wholesale dealer's authorisations

Where the holder of a wholesale dealer's authorisation contracts out any wholesale dealing activities to another such holder, the arrangement must record in writing the responsibilities of each party in relation to their respective roles in the supply process and in particular in connection with the recall of a veterinary medicinal product under paragraph 21C.

21F Self inspection plan

The holder of a wholesale dealer's authorisation must have in place a self-inspection programme which ensures that every aspect of its business is inspected annually in order to ensure that it is complying with good distribution practice.

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 three years.

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

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

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

(5) The notice 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 either is a person or 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 must be issued--~~

~~(a) in 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.~~

(2) The certificate must be issued by a body recognised by the Secretary of State.

24 Offences

It is an offence to fail to comply with--

(a) paragraph 2;

(b) paragraph 3;

(ba) paragraph 3A;

(bb) paragraph 3B;

(bc) paragraph 3D;

(bd) paragraph 3E;

(c) paragraph 4(1);

(d) paragraph 5;

(e) paragraph 7;

(ea) paragraph 7A;

(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;

(oa) paragraph 21B;

(ob) paragraph 21C;

(oc) paragraph 21D;

(od) paragraph 21E

(oe) paragraph 21F

(p) paragraph 22; or

(q) paragraph 23(1).

SCHEDULE 4 Administration of a Veterinary Medicinal Product Outside the Terms of a Marketing Authorisation

Regulation 8

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 United Kingdom 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 United Kingdom 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 United Kingdom; or

(ii) a veterinary medicinal product not authorised in the United Kingdom but authorised in another country 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, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(3) In the case of a veterinary medicinal product imported from another country, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation, the veterinary surgeon must obtain a certificate from the Secretary of State before administration.

(4) ~~Any pharmacologically active substances~~All substances included in a medicinal product administered to a food-producing animal under the cascade must be substances for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council or are substances considered as not falling within the scope of Regulation (EC) No. 470/2009.

(5) Where a substance mentioned in sub-paragraph (4) is administered, the maximum residue limits established in accordance with Regulation (EC) No. 470/2009 must be complied with.

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 established for the active substance for the treated species under Regulation (EC) No 470/2009 of the European Parliament and of the Council, the level of residue of the active substance does not exceed that limit or, where there is no maximum residue limit for a particular species in established in accordance with Regulation (EC) No. 470/2009 of the European Parliament and of the Council (but the substance itself is included), that the level of residue does not exceed the level determined by reference to implementing Regulation 2018/470.

(3) In any event, unless the Secretary of State has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period (irrespective of whether or not a maximum residue limit has been established must not be less than--

(a) for eggs—

(i) the longest withdrawal period in the summary of the product characteristics for any species multiplied by a factor of 1.5; or

(ii) 14 days, if the product is not authorised for animals producing eggs for human consumption;

~~(a) 7 days for eggs;~~

(b) for milk—

(i) the longest withdrawal period in the summary of the product characteristics for any species multiplied by a factor of 1.5;

(ii) 7 days, if the medicinal product is not authorised for animals producing milk for human consumption; or

(iii) one day, if the medicinal product has a zero hour withdrawal period;

~~(b) 7 days for milk;~~

(c) for meat and offal from food-producing mammals, poultry and farmed game-birds—

(i) the longest withdrawal period provided in its summary of the product characteristics for meat and offal, multiplied by a factor of 1.5;

(ii) 28 days if the medicinal product is not authorised for food-producing animals; or

(iii) one day, if the medicinal product has a zero-day withdrawal period;

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

(d) for aquatic species producing meat for human consumption—

(i) the longest withdrawal period for any of the aquatic species in the summary of the product characteristics multiplied by a factor of 1.5 and expressed as degree-days;

(ii) if the medicinal product is authorised for food-producing terrestrial animal species, the longest withdrawal period for any of the food-producing animal species in the summary of product characteristics multiplied by a factor of 50 and expressed as degree-days; or

(iii) 25 degree-days if the highest withdrawal period for any animal species is zero.

~~(d) 500 degree days**38** for fish meat.~~

(4) For the purposes of sub-paragraph (3)—

(a) if the calculation of a withdrawal period results in a fraction of days, the withdrawal period must be rounded to the nearest number of days, with any half of a day being rounded upwards;

(b) in relation to the calculation of the withdrawal period for milk, if the calculation of the period results in a milk withdrawal period not divisible by 12, the withdrawal period must be rounded up to the nearest multiple of 12 hours.

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 passport) and treatment under the cascade is unsuitable, substances may be administered in accordance with Commission Regulation (EC) 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**39**).

(2) The person administering the substance must comply with Article 3(2) of Commission Regulation (EC) No 122/2013 (recording the details of the treatment in the animal's passport).

4 Immunological products for serious epizootic disease or emerging disease

In the event of serious epizootic diseases or emerging diseases, the Secretary of State may permit in writing the administration of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and may publicise any permit as the Secretary of State sees fit.

5 Immunological products for an imported or exported animal

If an animal is imported from, or exported to, another country, the Secretary of State may permit the administration to that animal of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the United Kingdom but is authorised under the legislation of that other country.

6 Administration by veterinary surgeons from other countries

(1) Veterinary surgeons practising in another country with equivalent medicines regulation standards to those of the United Kingdom may bring into the United Kingdom and administer to animals small quantities of veterinary medicinal products that are not authorised for use in the United Kingdom if--

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

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

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

~~**38** The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.~~

39 OJ No L42, 13.2.2013, p. 1.

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

(e) the veterinary surgeon is acquainted with the Code of Professional Conduct for veterinary surgeons issued by the Royal College of Veterinary Surgeons**40**.

(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 United Kingdom withdrawal period for the equivalent product authorised in the United Kingdom if this is longer than the one on the label; and

(b) keep detailed records of the animals treated, the diagnosis or clinical assessment, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied, and must keep them in the United Kingdom for at least three 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.

6A Administration of autogenous vaccines

(1) An autogenous vaccine may only be administered to animals in exceptional circumstances where no immunological veterinary medicinal product has been authorised in relation to the target species and indication.

(2) Where a vaccine is used in accordance with sub-paragraph (1) it must be administered in accordance with a written prescription under the cascade.

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 another country; but a veterinary surgeon who has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation must obtain a certificate from the Secretary of State before treating the animal.

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

8 Administration of a homeopathic remedy

(1) A registered homeopathic remedy or a homeopathic remedy prepared and supplied by a pharmacist under paragraph 10 of Schedule 3 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, either personally or under the veterinary surgeon's responsibility--

(a) a homeopathic remedy authorised for human use, or

(b) a homeopathic remedy prepared extemporaneously by a veterinary surgeon, a pharmacist or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

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

9 Administration under an animal test certificate

(1) A medicinal product may be administered in accordance with an animal test certificate granted for clinical trials~~research purposes~~ by the Secretary of State.

(2) An application for an animal test certificate may be refused if this is necessary for the protection of animal or public health or the environment, and the animal test certificate may be varied, suspended or revoked in the same way as a marketing authorisation.

(3) The holder of an animal test certificate may not supply a product for administration that is not within the terms of the animal test certificate.

(4) The holder of an animal test certificate test who becomes aware of any serious ~~adverse reaction~~ adverse event following the administration of a product under an animal test certificate must report the reaction to the Secretary of State within 15 days of learning of it.

9A Misuse of the cascade

A person must not encourage or facilitate use of the cascade which is not in accordance with this Schedule.

10 Offences

It is an offence to fail to comply with--

(a) paragraph 3(2);

(b) paragraph 6; or

(c) paragraph 9(3) or (4).

(d) paragraph 9A.

SCHEDULE 5 Medicated Feedingstuffs and Specified Feed Additives

Regulation 14

1 Scope and interpretation

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

(a) coccidiostats;

(b) histomonostats; and

(c) all other zootechnical additives except--

(i) digestibility enhancers;

(ii) gut flora stabilisers; and

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

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

(3) In this Schedule--

"animal keeper" means any natural or legal person responsible for animals, whether on a permanent or a temporary basis;

"batch" means an identifiable quantity of feed determined to have common characteristics whether in relation to origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units when produced in continuous order and stored together;

"complementary feed" means compound feed which has a high content of certain substances but which by reason of its composition, is sufficient for a daily ration only if used in combination with other feed;

"complete feed" means compound feed which, by reason of its composition, is sufficient for a daily ration;

"compound feed" means a mixture of at least 2 feed additives for oral animal-feeding in the form of complete or complementary feed;

"cross-contamination" means contamination of a non-target feed with an active substance originating from the previous use of the relevant facilities or equipment;

"daily ration" means the average total quantity of feedingstuffs, calculated on a moisture content of 12%, required daily by an animal of a given species, age category and yield, to satisfy all its nutritional needs;

"distributor" means an establishment distributing specified feed additives, intermediate or final feedingstuffs containing specified feed additives or intermediate or final feedingstuffs containing premixes;

"establishment" means any unit of a feed business;

"feedingstuff" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

"feed additives" means substances, micro-organisms or preparations, other than feed material and intermediate feedingstuffs, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in this Schedule;

"feed business" means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

"feed business operator" means any person responsible for ensuring that the requirements of this Schedule are met within the feed business under that person's control;";

"feed materials" means products of vegetable or animal origin whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such or after processing or in the preparation of compound feed, or as a carrier of intermediate feedingstuffs;

"intermediate feedingstuffs" means a feed which is not ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more premixes with feed materials or compound feed, exclusively intended to be used for the manufacture of medicated feed;

"label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to the packaging or the container of feed;

"labelling" means the attribution of any words, particulars, trademarks, brand name, pictorial matter or symbol to a feed by placing this information on any medium referring to or accompanying such feed such as packaging, a container, a notice, a label, a document, a ring, a collar or the internet, including for advertising purposes;

"medicated feedingstuffs" means a feed which is ready to be directly fed to animals without any further processing, consisting of a homogenous mixture of one or more premixes or intermediate feedingstuffs with feed materials or compound feed;

"minimum storage life" means the period during which, under proper storage conditions, the person responsible for the labelling guarantees that the feed retains its declared properties;

"mobile mixer" means a feed business operator with a feed establishment consisting of a specially equipped vehicle for the manufacture of medicated feed;

"non-target feed" means feed, whether medicated or not which is not intended to contain a specific active substance;

"on-farm mixer" means a feed business operator manufacturing medicated feed for the exclusive use on its farm;

"premix" means a veterinary medicinal product authorised for incorporation into feedingstuffs;

"premixture" means a mixture of a ~~veterinary medicinal product~~premix 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 the competent authority is the Secretary of State.

(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);

(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 the competent authority is the Secretary of State.

(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~~intermediate feedingstuff 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 another 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 (EU) 2017/625

For the purposes of Regulation (EU) 2017/625 the competent authority is the Secretary of State.

5 Enforcement of Regulation (EC) No 183/2005

(1) For the purposes of Regulation (EC) No 183/2005 the competent authority is the Secretary of State.

(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~~ premises);

(f) Article 11 (prohibition on operating without ~~approval or registration~~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 a manufacturing authorisation 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.

7 ~~Approval~~Authorisation of manufacturers and distributors of feedingstuffs containing ~~veterinary medicinal products~~premixes

(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 the competent authority is the Secretary of State.

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

(3) The conditions which govern ~~approval~~authorisation of feed business establishments under Regulation (EC) No 183/2005 laying down requirements for feed hygiene also govern ~~approval~~authorisation of manufacturers and distributors under sub-paragraph (2).

(4) The Secretary of State shall conduct inspections of manufacturers and distributors ~~approved~~authorised 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.~~

(5) A manufacturer must ensure that, so far as is reasonably practical the premix is evenly incorporated and homogeneously dispersed throughout the feedingstuffs, taking into account the specific properties of the premix and the mixing technology employed.

(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~~premix annually for that purpose.

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

8 Incorporation of a ~~veterinary medicinal product~~premix ~~into a premixture~~

Any person who incorporates a ~~veterinary medicinal product~~premix into an intermediate feedingstuff ~~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~~premix 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~~premix into feedingstuffs

Any person who incorporates a ~~veterinary medicinal product~~premix (or an intermediate feedingstuff~~a premixture~~ containing a ~~veterinary medicinal product~~premix) into feedingstuffs--

(a) must do so in accordance with the ~~summary of product characteristics~~ its marketing authorisation and in accordance with its medicated feedingstuff prescription (unless it has been prescribed under the cascade), and must take account of any interactions listed there;

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

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

(d) must ensure that the daily dose of the ~~veterinary medicinal product~~premix 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~~premixes

(1) Any person who--

(a) incorporates a ~~veterinary medicinal product~~premix into an intermediate feedingstuff~~a premixture~~;

(b) incorporates an intermediate feedingstuff ~~a premixture~~ containing a ~~veterinary medicinal product~~premix into feedingstuffs; or

(c) incorporates a ~~veterinary medicinal product~~premix into feedingstuffs,

must make a daily record of--

(d) the types and quantities of all ~~veterinary medicinal product~~premixes (and specified feed additives, if any) and intermediate feedingstuffs~~premixture~~ used in the manufacturing process; and

(e) the quantity of feedingstuffs and intermediate feedingstuff~~premixture~~ containing ~~veterinary medicinal product~~premix manufactured that day.

(2) An ~~approved~~authorised distributor must make a daily record of--

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

(b) the quantity held.

(3) A manufacturer and 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 intermediate feedingstuffs~~premixture~~ supplied;

(d) the quantity;

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

(f) the expiry date.

(4) Records must be kept for five years.

12 Labelling an intermediate feedingstuff~~a premixture~~ containing a ~~veterinary medicinal product~~premix

(1) ~~A premixture~~ An intermediate feedingstuff containing a ~~veterinary medicinal product~~premix must be clearly and legibly labelled with the following--

(a) the words "~~MEDICATED PREMIXTURE~~INTERMEDIATE FEEDINGSTUFF" (or, if it is to be labelled as "complementary feedingstuffs" under legislation implementing Council Directive 79/373/EEC on the marketing of compound feedingstuffs, "MEDICATED COMPLEMENTARY FEEDINGSTUFFS") in upper case letters;

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

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

(d) the range of acceptable inclusion rates of the intermediate feedingstuff~~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~~medicated feedingstuffs prescription for the exact inclusion rate" or equivalent wording;

(e) warnings and contra-indications;

(ea) a statement that the product must be used in accordance with its summary of product characteristics;

(eb) the contact details (including a free helpline number) for the supplier of the product;

(ec) the words “inappropriate disposal of this product poses a serious threat to the environment”;

(ed) in the case of a product containing an antibiotic, the words “inappropriate disposal of this product poses a serious threat to the development of anti-microbial resistance”;

(f) the withdrawal period, and a statement that, if the ~~prescription~~medicated feedingstuffs 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~~medicated feedingstuffs prescription is required, a statement to this effect.

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

(3) If the ~~premixture~~ intermediate feedingstuff 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.

(4) No person may supply such a intermediate feedingstuff~~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.

14 Labelling of feedingstuffs containing a ~~veterinary medicinal product~~premix

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

(a) the words "MEDICATED COMPLETE FEED" in upper case letters, or where feedingstuffs are to be labelled as a complementary feedingstuff and intended to be fed to animals without further mixing with feed materials, the words "MEDICATED COMPLEMENTARY FEEDINGSTUFF";

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

(ea) the contact details (including a free helpline number) for the supplier of the product;

(eb) the words “inappropriate disposal of this product poses a serious threat to the environment”;

(ec) in the case of a product containing an antibiotic, the words “inappropriate disposal of this product poses a serious threat to the development of anti-microbial resistance;”

(f) the withdrawal period, and a statement that, if the ~~prescription~~medicated feedingstuffs 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~~medicated feedingstuffs prescription;

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

(2) If there is more than one ~~veterinary medicinal product~~premix 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~~intermediate feedingstuff

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

(2) The person who manufactured the intermediate feedingstuff~~premixture~~ may only supply it to--

(a) an ~~approved~~authorised distributor; or

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

(3) An ~~approved~~authorised distributor may only supply it to--

(a) another ~~approved~~authorised distributor; or

(b) a feedingstuff manufacturer ~~approved~~authorised to incorporate that intermediate feedingstuff~~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~~authorised 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~~authorised distributor; or

(b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or ~~approved~~authorised to incorporate an intermediate feedingstuff~~a premixture~~.

(3) An ~~approved~~authorised distributor may only supply it to--

(a) another ~~approved~~authorised distributor, or

(b) a feedingstuff manufacturer registered to incorporate that complementary feedingstuff or ~~approved~~authorised to incorporate an intermediate feedingstuff~~a premixture~~.

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

18 Supply of feedingstuffs containing a ~~veterinary medicinal product~~premix

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

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

(a) an ~~approved~~authorised distributor; or

(b) ~~a person who keeps animals~~an animal keeper for feeding to those animals.

(3) A distributor may only supply it to--

(a) another ~~approved~~authorised distributor; or

(b) ~~a person who keeps animals~~an animal keeper for feeding to those animals.

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

(5) If a ~~prescription~~medicated feedingstuffs 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~~medicated feedingstuffs prescription for five years.

(8) For the avoidance of doubt, nothing in this paragraph prevents a commercial feed manufacturer from incorporating a premix with a feedingstuff in advance of receiving a written prescription for that feedingstuff.

19 Prescriptions for feedingstuffs containing a ~~veterinary medicinal product~~premix

(1) A prescription for feedingstuffs containing a ~~veterinary medicinal product~~premix 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;

(ea) the diagnosed disease to be treated or prevented (in the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects);

(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;~~

(h) the name, the active substance, the amount of the product prescribed and the inclusion rate of the veterinary medicinal product and resulting inclusion rate of the active substance;

(i) the dosage and administration instructions;

(j) any necessary warnings;

(ja) a statement that the prescription may not be re-used;

(k) the withdrawal period;

(l) the manufacturer or the distributor of the feedingstuffs (who must be ~~approved~~authorised 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;

(na) the overall amount of feedingstuff to be supplied under the prescription;

~~(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.

(2A) In the case of a prescription under this paragraph which relates to an antibiotic, the prescription is valid for no more than 5 days.

(2B) The prescription must contain a statement that the premix must not be re-used.

(2C) Subject to paragraph 7A in Schedule 3, a prescription for a medicated feedingstuff containing an antibiotic veterinary medicinal product may not—

(a) confer authority to administer more than one such product at a time; or

(b) be written for prophylactic purposes.

(3) In relation to food-producing animals a medicated feedingstuffs prescription may not confer authority for more than one course of treatment and the duration of the treatment must comply with the duration specified in the summary of product characteristics.

(4) Where the summary of product characteristics in relation to medicated feed contains no specification of duration of treatment, the duration of such treatment must be less than—

(a) 2 weeks where the prescription provides authority to administer an antibiotic;

(b) 4 weeks in any other case.

~~(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~~premix into the feedingstuffs and (where applicable) to the distributor ~~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~~premix and any feed additive used in the feedingstuffs; and

(b) the active substance of the ~~veterinary medicinal product~~premix 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~~premix authorised for incorporation in feedingstuffs but may, if there is no ~~veterinary medicinal product~~premix authorised for a condition in a particular species--

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

(b) prescribe more than one ~~veterinary medicinal product~~premix,

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~~authorisation under this Schedule may be in possession of any--

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

(b) intermediate feedingstuffs~~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~~premix unless it has been supplied under a ~~prescription~~medicated feedingstuffs 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.

(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 feedingstuff

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

~~**Tolerance table for medicated feedingstuff**~~

~~*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 2(e) of Annex IV to Regulation (EC) No 767/2009 of the European Parliament and of the Council~~.~~

22A Sampling for cross-contamination

(1) A feed business operator must ensure that cross-contamination of non-target feeds is as low as is reasonably achievable.

(2) A feed business operator must analyse samples of medicated feedingstuffs in order to determine whether cross-contamination into non-target feed has occurred.

(3) Where as a result of the process mentioned in sub-paragraph (2) it is determined that a cross-contamination rate of 1% compared to the authorised maximum content has occurred the feed business operator must make a record of this cross-contamination.

(4) Where as a result of the process mentioned in sub-paragraph (2) it is determined that a cross-contamination rate of 3% or more compared to the authorised maximum content has

occurred the feed business operator must conduct an investigation in order to discover the cause of the occurrence and make a record of the fact.

(5) The feed business operator must keep the records under sub-paragraph (3) and (4) for at least 5 years.

(6) Upon request of the Secretary of State, the feed business operator must provide any data in the feed business operator's possession relating to the matters mentioned in this paragraph.

23 Storage

No person may store a ~~veterinary medicinal product~~premix intended for incorporation into feedingstuffs, or ~~a premixture~~an intermediate feedingstuff or feedingstuffs containing a ~~veterinary medicinal product~~premix, 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~~premix 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~~premix 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~~premix 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~~premixes 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 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.

(2A) An animal keeper must ensure that any product to which this Schedule applies is appropriately stored in accordance with its authorisation.

(2B) An animal keeper must ensure that—

(a) no cross-contamination occurs between products held by the keeper;

(b) no product contaminates any feedingstuff or feed material;

(c) no product escapes into the environment; and

(d) a product is administered only to correctly identified animals mentioned on the medicated feedingstuffs prescription.

(2C) An animal keeper must comply with the withdrawal period in relation to any product.

(3) This paragraph does not apply in relation to feedingstuffs if the veterinary medicinal product has been incorporated in accordance with an animal test certificate or the feedingstuff has been imported in accordance with this Schedule.

26A Unused and expired medicated feedingstuffs

(1) A person who is the operator of a feed business or who is a professional keeper of animals must establish and maintain a system for safe disposal of unused medicated feedingstuffs or medicated feedingstuffs which have passed their expiry date.

(2) No person may feed medicated feedingstuffs which have passed their expiry date to an animal.

28 Trade between countries

No person may bring in from another country a feedingstuff containing a veterinary medicinal product unless--

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

29 Import for incorporation into intermediate feedingstuffs~~premixture~~ or feedingstuffs for export

(1) A manufacturer of intermediate feedingstuffs~~premixture~~ or feedingstuffs who imports a veterinary medicinal product authorised in another country for the purposes of incorporating it into intermediate feedingstuffs~~premixture~~ or feedingstuffs for export does not commit an offence under regulation 43(q) (importation of an unauthorised veterinary medicinal product) or regulation 43(r) (possession of an unauthorised veterinary medicinal product).

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

30 Animals on domestic premises

(1) The requirements of paragraph 7 (~~approval~~authorisation of manufacturers and distributors of feedingstuffs containing ~~veterinary medicinal product~~premix) do not apply in relation to a person who incorporates a ~~veterinary medicinal product~~premix 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 an intermediate feedingstuff ~~a premixture~~ containing a ~~veterinary medicinal product~~premix, or feedingstuffs containing a ~~veterinary medicinal product~~premix, 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~~ intermediate feedingstuffs 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--

(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;

(ra) paragraph 22;

(s) paragraph 23;

(t) paragraph 24;

(u) paragraph 25;

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

(va) paragraph 26A;

(x) paragraph 28; or

(y) paragraph 29(2).

SCHEDULE 6 Exemptions for Small Pet Animals

Regulation 15(4)

1 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.

2 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 and the manufacturer is registered under the register mentioned in paragraph 3A.

3 Manufacture

(1) The product must have been manufactured by--

(a) the holder of a manufacturing authorisation if manufactured in Great Britain;

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

(2) Sub-paragraph (1) does not apply where the exporting country has demonstrated equivalent standards to the United Kingdom or where appropriate arrangements have been made with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC**41**.

3A Register of persons placing veterinary medicinal products on the market (small pet animals)

(1) The person placing the product on the market must be registered in accordance with this paragraph.

(2) For the purposes of sub-paragraph (1) the Secretary of State must establish and maintain a register of persons placing on the market products to which this Schedule applies.

(3) The particulars entered on the register must include the name and the address of the person mentioned in sub-paragraph (1).

3B Persons registered in accordance with paragraph 3A: annual return

At least once a year a person registered under paragraph 3A must notify the Secretary of State in writing of the following—

(a) the name and registered address of the person (if different from that listed on the register);

(b) the person designated for the purpose of making the annual return under this paragraph;

(c) the telephone number and e mail address of the person mentioned in sub-paragraph (b);

(d) the name and address of the manufacturer of the product;

(e) the brand name of the product;

(f) the names and quantities of the active substances;

(g) the method and (if necessary) route of administration;

(h) the dosage instructions;

(i) the category of animal mentioned in paragraph 1 for which the product is intended.

4 Approval of the active substance

(1) The Secretary of State may approve an active substance for use in a veterinary medicinal product manufactured under this Schedule.

41 OJ No L 228, 17.8.1991, p.70.

(2) The Secretary of State may not grant an approval if the active substance requires veterinary control.

(3) The approval must specify the species of animals for which it is approved, and may specify how the active substance or a product containing it is to be administered.

(4) The Secretary of State may suspend or revoke the approval (or limit it to a smaller number of species) if--

(a) it is demonstrated that the substance requires veterinary control;

(b) serious ~~adverse reactions~~ adverse events are reported making suspension or revocation necessary; or

(c) it is demonstrated that the substance--

(i) is carcinogenic;

(ii) is genotoxic; or

(iii) shows developmental toxicity (including teratogenicity).

(5) The procedure for the refusal, suspension or revocation of an approval under this paragraph is the same as the procedure for a marketing authorisation.

5 The product

(1) The active substance in the veterinary medicinal product must be approved under paragraph 4.

(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.

6 Labelling

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

(2) The labelling must show the 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".

7 Administration

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

8 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.

9 ~~Adverse reactions~~Adverse events

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

(a) notify the Secretary of State within 15 days of learning of any serious ~~adverse reactions~~ adverse events (as defined in paragraph 57 of Schedule 1); and

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

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

SCHEDULE 7 Fees

Part 1 Introduction

1 Interpretation

(1) In this Schedule--

"pharmaceutical product" means any veterinary medicinal product other than an immunological product;

"simultaneous application" is an application in which, at the time an authorisation for a product is applied for, one or more additional applications are submitted for products that are identical to the first product except that--

(a) in the case of an immunological product, they have a lesser number of antigens than the first product, but only contain antigens contained in the first product; and

(b) in the case of a pharmaceutical product, they have different strengths of the active substance

(2) For the purposes of this Schedule "manufacturing authorisation" applies to the following activities—

(a) manufacture of an authorised veterinary medicinal product;

(b) manufacture of a product to which paragraph 2 in Schedule 6 relates;

(c) manufacture of a product for administration under the cascade;

(d) manufacture of—

(i) an autogenous vaccine;

(ii) a stem cell product; or

(iii) a blood product for administration to non-food animals.

2 Payment of fees

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

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, and in relation to the same legal entity, 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 United Kingdom

Whenever premises outside the United Kingdom 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 Marketing Authorisations

7 Application for a marketing authorisation for a pharmaceutical or immunological veterinary medicinal product

The following table sets out the fees relating to a pharmaceutical or immunological veterinary medicinal product for--

(a) an application for a marketing authorisation that is--

(i) a full application under Part 1 of Schedule 1; or

(ii) a bibliographic application for a pharmaceutical veterinary medicinal product; ~~or~~

~~(iii) an application based on pharmacological equivalence.~~

	Fee (£) per authorisation
Base fee	27,995
Fee for 1st additional strength	4,590
Fee for each subsequent additional strength	1,465

~~*Application*~~	~~*Full application under Part 1 of Schedule 1 (£)*~~	~~*Bibliographic application (£)*~~	~~*Pharmacologically equivalent application*~~ ~~*Reference product authorised in UK (£)*~~
~~Base Fee:~~	~~13,530~~	~~12,115~~	~~7,195~~
~~Additional fee if any of the target species is a food-producing animal:~~	~~3,905~~	~~3,585~~	~~2,155~~
~~Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom--~~			
~~food-producing animal:~~	~~7,465~~	~~6,595~~	~~5,885~~
~~non-food-producing animal:~~	~~6,525~~	~~5,855~~	~~5,590~~
~~Additional fee for each additional pack type:~~	~~740~~	~~740~~	~~605~~
~~Additional fee for each additional active ingredient (food-producing animal):~~	~~6,465~~	~~6,125~~	~~4,040~~
~~Additional fee for each additional active ingredient (non-food-producing animal):~~	~~4,310~~	~~4,105~~	~~3,235~~
~~Additional fee if there is more than one target species, for each additional species (food-producing animal):~~	~~3,970~~	~~3,565~~	~~2,425~~
~~Additional fee if there is more than one target species, for each additional~~	~~2,495~~	~~2,090~~	~~1,550~~

species (non- food-producing animal):			
Additional fee for each additional recommended route of administration (food-producing animal):	2,695	2,490	1,620
Additional fee for each additional recommended route of administration (non- food-producing animal):	1,215	1,010	740
Simultaneous applications: fee for each additional product in the application:	2,895	2,895	2,895

7A Application for a marketing authorisation for specific applications

The fee for an application for a marketing authorisation in relation to the following is £45,000—

(a) any biotechnical process involving recombinant DNA or the controlled expression of genes;

(b) a veterinary medicinal product containing a new active substance;

(c) a biopharmaceutical product.

9 Application for a marketing authorisation for an immunological or biosimilar product

(1) The fee for an application for a marketing authorisation relating to an immunological or biosimilar product is in accordance with the following table.

(2) In this paragraph a biosimilar application means an application made in accordance with Article 13(4) of Directive 2001/82/EC and a biosimilar product means a product which is the subject of such an application.

Fees for specified immunological and biosimilar applications

Application	*application for a marketing authorisation(£)*
1 Immunological or biosimilar product other than in paragraph 2 below: Base fee:	11,775
The following fees are in addition to the base fee--	
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:	7,405
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,345
More than one antigenic component--fee for each additional component:	1,350
More than one species--fee for each additional species:	5,380
More than one route of administration--fee for each additional route of administration:	5,380
Simultaneous application - fee for each	2,895

~~additional product in the application:~~	
~~2 Immunological or product that is identical to a product already authorised in the United Kingdom but with a lesser number of antigens and that only contains antigens contained in that product:~~	~~10,430~~

11 Application for a marketing authorisation based on informed consent

The fee for applications for marketing authorisations using identical data submitted simultaneously or on the basis of information provided under paragraph 9 of Schedule 1 is as follows—

Application	*Fee (£) per authorisation*
National application:	1,465

~~11 Application for a marketing authorisation based on informed consent~~

~~The fee for applications for marketing authorisations using identical data submitted simultaneously or on the basis of information provided under Article 13(c) of Directive 2001/82/EC is £945 per application.~~

12 Application for an exceptional marketing authorisation (pharmaceutical)

The fee for an application for an exceptional marketing authorisation for a pharmaceutical product is in accordance with the following table.

Fees for an exceptional marketing authorisation for a pharmaceutical product

Application	*Provisional (£)*	*Limited (£)*
Base Fee:	12,015	6,765
The following fees are in addition to the base fee--		
Additional fee if any of the target species is a food-producing animal:	3,905	1,952
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom--		
food-producing animal:	5,850	3,732
non-food-producing animal:	4,910	3,262
Additional fee for each additional pack type:	710	370
Additional fee for each additional active ingredient (food-producing animal):	5,955	3,232
Additional fee for each additional active ingredient (non-food-producing animal):	3,800	2,155
Additional fee if there is more than one target species, for each additional species (food-producing animal):	2,965	1,985
Additional fee if there is more than one target species, for each additional species (non-food-producing animal):	1,485	1,247
Additional fee for each additional recommended route of administration (food-producing animal):	2,185	1,347
Additional fee for each additional recommended route of administration (non-food-producing animal):	710	608
Simultaneous applications--fee for each additional product in the application:	2,895	1,447

13 Fees for an application for an exceptional marketing authorisation (immunological)

The fee for an application for an exceptional marketing authorisation for an immunological product is in accordance with the following table.

Fees for an exceptional marketing authorisation for an immunological product

Application	*Provisional (£)*	*Limited (£)*
Base fee:	10,810	5,887
The following fees are in addition to the base fee--		
Additional fee for each active ingredient not previously included in a veterinary medicinal product authorised in the United Kingdom, and for each new combination of active ingredients:	5,650	3,702
Additional fee for each adjuvant or preservative not previously included in a veterinary medicinal product authorised in the United Kingdom and for each new combination of adjuvants or preservatives:	1,350	672
More than one antigenic component--fee for each additional component:	1,190	675
More than one species--fee for each additional species:	4,060	2,690
More than one route of administration--fee for each additional route of administration:	4,060	2,690
Simultaneous application - fee for each additional product in the application:	2,895	1,447

14 Fee for the conversion from an exceptional to a full marketing authorisation

The fee for the conversion of an exceptional marketing authorisation to a full marketing authorisation is £3,000.

~~15 Application for a marketing authorisation relating to a parallel import~~

~~The fee for a marketing authorisation for a parallel import is in accordance with the following table.~~

~~**Parallel imports**~~

~~*Application*~~	~~*Fee (£)*~~
~~**Application where the imported product is identical to a product which is authorised for sale in the United Kingdom**~~	~~**2,130**~~
~~**Application where the imported product is therapeutically similar to a product which is authorised for sale in the United Kingdom (can only be applied to imported products for non-food producing species)**~~	~~**4,710**~~

15A Fee for a generic marketing authorisation

The fee for a generic marketing authorisation is in accordance with the following table.

	Generic national application

	Generic-hybrid	*Generic-normal*
Base Fee:	13,950	12,390
Fee for 1st additional strength	4,590	
Fee for each subsequent additional strength	1,465	

17 Application for a variation to a marketing authorisation

(1) This paragraph applies in relation to an application for a variation to one or more marketing authorisations except where paragraph 18, 19 or 21 applies.

(2) The fees for the variations to which this paragraph applies are set out in the following table.

(3) Where applications are made at the same time seeking an identical change to the terms of more than one marketing authorisation, and those applications are based on identical data, fees are payable as for a grouped variation.

(4) References in this paragraph to a grouped variation being "led" by a particular type of variation indicate that the principal variation in that group is a variation of that type.

"Type of variation:	Fee (£):
Single variations; one change for each product	
Variation requiring assessment – standard:	2,895
Variation requiring assessment – reduced:	885
Unless the variation requiring assessment is a:	
Change of route of administration, or the addition of a new one, of- -	
(i) an immunological product, or a pharmaceutical product for a non-food-producing animal:	5,390
(ii) a pharmaceutical product for a food-producing animal:	7,135
Change of bioavailability:	8,415
Change of active substance, where the change is to	
(i) use a different biologically active substance with a slightly different molecular structure	8,415
(ii) modify the vector used to produce the antigen or the source material, including a new master cell bank from a different source:	8,415
Change of pharmacokinetics:	8,415
Simultaneous application: fee for each additional product in the application:	1,465
Variation not requiring assessment:	455
Grouped variations:	
Variation requiring assessment – standard led:	
For the first nine changes:	6,280
For each subsequent group of up to 5 changes:	2,250
Variation requiring assessment – reduced led:	
For the first nine changes:	1,770
For each subsequent group of up to 5 changes:	2,250".

Type of variation	
Single variations; one change for each product	
Extension:	
Change of strength or potency or the addition of a new strength or potency:	6,670
Change of pharmaceutical form or the addition of a new pharmaceutical form:	8,415
Change of route of administration, or the addition of a new one, of--	
(i) an immunological product, or a pharmaceutical product for a [non-food-producing] animal:	5,390
(ii) a pharmaceutical product for a food-producing animal:	7,135
Change or addition of a food producing target species:	9,620
Change of active substance, including:	8,415
use of a different salt, ester, complex or derivative of the same therapeutic moiety:	
use of a different biologically active substance with a slightly different molecular structure:	
modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source:	
use of a new ligand or coupling mechanism for a radiopharmaceutical:	
change of the extraction solvent or change of the ratio of herbal drug to herbal drug preparation:	
Change of bioavailability:	8,415
Change of pharmacokinetics:	8,415
Simultaneous application: fee for each additional product in the application:	2,895
Type II:	2,895
Type IB:	885
Type IA:	455
Grouped variations	
Extension-led:	
The fee for an application for an extension-led grouped variation is the fee for that extension as specified above plus –	
(a) if there is one variation in addition to the extension, the fee for that variation as specified above; or	
(b) if there is more than one variation in addition to the extension, the fee that would be payable for a grouped variation of that type as specified below.	
Type II led:	
For the first nine changes:	6,280
For each subsequent group of up to ten changes:	4,500
Type IB led:	
For the first nine changes:	1,770
For each subsequent group of up to ten changes:	4,500
Type IA led:	

For the first nine changes:	885
For each subsequent group of up to ten changes:	4,500

18 Application for a variation to a marketing authorisation dealt with under worksharing procedures

(1) This paragraph applies in relation to an application for a variation to a marketing authorisation dealt with in accordance with worksharing procedures as set out in Article 20 of Commission Regulation (EC) No 1234/2008.

(2) The fees for a worksharing application are specified in the following table.

Type of application			
Worksharing applications **The following fees apply for each change to each product:**			
Type II			
For the first nine changes:	6,240		
For each subsequent group of up to ten changes:	4,500		
Type IB			
For the first nine changes:	1,770		
For each subsequent group of up to ten changes:	4,500		

21 Exception for a variation relating to animal testing

If the only purpose of a variation is to remove animal testing or to reduce the numbers of animals used in testing, no fee is payable for the variation.

22 Application for the renewal of a marketing authorisationApplication for a reassessment of an exceptional marketing authorisation

(1) The fee for an application for the renewal of a marketing authorisation is £1,360.

(2) The fee for the first reassessment of an exceptional marketing authorisation is £305, and the fee for each subsequent reassessment is £1,360.

24 Registration of a homeopathic remedy

The fee for an application for the registration of a homeopathic remedy is in accordance with the following table.

Fee for the registration of a homeopathic remedy

Type of application	*Fees (£)*
If all stocks and the formulation have already been assessed by the Secretary of State--	
not more than five stocks:	160
more than five stocks:	375
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or if the formulation has already been assessed by the Secretary of State but one or more of the stocks have not been already assessed--	
not more than five stocks:	455
more than five stocks:	665
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State--	
not more than five stocks:	760
more than five stocks:	985
If the product is already authorised for human use in the United Kingdom, or for human or veterinary use in the United Kingdom --	
not more than five stocks:	160
more than five stocks:	375

~~25 Renewal of a homeopathic remedy~~

~~The fee for the renewal of a homeopathic remedy is £320.~~

26 Annual fees for marketing authorisations

(1) Within 30 days of receiving a written demand from the Secretary of State, a holder of a marketing authorisation must provide the Secretary of State with a statement of turnover for the previous calendar year.

(2) The annual fee, rounded to the next £1, is--

£ (0.67T / 100) + £230n

where--

(a) T is the annual turnover in the previous calendar year;

(b) and n is the number of active marketing authorisations held at any time during the previous calendar year.

(3) In the case of an authorisation holder with a turnover relating to all marketing authorisations held of less than £230,000, the annual fee, rounded to the next £1 is--

£ (0.67T / 100) + £200n

where--

(a) T is the annual turnover in the previous calendar year;

(b) and n is the number of active marketing authorisations held at any time during the previous calendar year.

(4) In this paragraph--

"turnover" means the sales value at manufacturers' prices of all authorised veterinary medicinal products sold or supplied in the United Kingdom;

"manufacturers' prices" means the prices charged (excluding value added tax) for authorised products by manufacturers to wholesalers, except to the extent that--

(a) the products are supplied by manufacturers direct to retailers, in which case it means the prices charged for the products by the manufacturers to the retailers reduced by such sum as, in the opinion of the Secretary of State, represents the difference between the prices paid by the retailers and those which could be expected to be charged by the manufacturers to wholesalers according to the practice prevailing during the period in question with regard to such products;

(b) a marketing authorisation holder sells or supplies products that the marketing authorisation holder has neither manufactured nor obtained from the manufacturer, in which case it means the prices paid by the marketing authorisation holder for those products.

27 Auditor's certificate

(1) The Secretary of State may at any time require an audit certificate in support of a statement of turnover.

(2) If the holder of the marketing authorisation does not provide an audit certificate before the date stipulated in the demand, an additional fee is payable for that year of £11,300 plus an additional £2,245 in respect of each marketing authorisation held.

(3) If the Secretary of State is not satisfied that the audit certificate provides sufficient assurance that the figures fairly present the financial records of the company, the Secretary of State may require the marketing authorisation holder to produce a further certificate and specify what further assurances are needed; and if these are not provided by the required date, the additional fee specified in sub-paragraph (2) is payable.

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

Part 3 Fees Payable by Manufacturers

28 Application for a manufacturing authorisation

(1) The fee for an application for a manufacturing authorisation for a veterinary medicinal product is £762.~~is--~~

(2) Fees relating to an application for a manufacturing authorisation are payable with the application.

~~(a) £3,040; or~~

~~(b) £530 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals).~~

29 Application for a variation of a manufacturing authorisation

The fee for an application for the variation of a manufacturing authorisation is--

(a) ~~£636~~£684 if the variation requires scientific or pharmaceutical assessment;

(b) ~~£443~~£105 if the variation only involves an administrative variation which includes a change of ownership~~a change of ownership~~;

~~(c) £210 if the authorisation only covers veterinary medicinal products manufactured under Schedule 6 (exemptions for small pet animals); and~~

~~(d) otherwise £350.~~

30 Application for an authorisation to manufacture ~~an autogenous vaccine or~~ a

product for administration under the cascade

(1) The fee for an application for a standard authorisation to manufacture ~~an autogenous vaccine or~~ a veterinary medicinal product for administration under the cascade is--

(a) £3,435 for a site in the United Kingdom;

(b) £3,270 for a site outside the United Kingdom.

~~(2) The fee for each inspection after a standard authorisation has been granted is (in each case) the same as the fee specified in paragraph (1).~~

(2) The fees for the inspection of sites authorised for the manufacture of unauthorised veterinary medicinal products for administration under the cascade are set out in the following table—

Inspection fees

Type of site	*Fee (£)*	
	United Kingdom site	*Site outside the United Kingdom*
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	6,425	7,719
Minor site	4,283	5,577

~~(3) In the case of an application for an individual authorisation to manufacture a single batch of autogenous vaccine, or a single batch of veterinary medicinal product for administration under the cascade the fee is £1,635.~~

~~(4) The fee to vary an authorisation is £305 if no further inspection is required, and otherwise is the full application fee.~~

30A **Autogenous vaccines**

(1) The fee for the scientific assessment of an authorisation to manufacture an autogenous vaccine is £6,962.

(2) The fees for the inspection of sites authorised for the manufacture of autogenous vaccines are set out in the following table—

Inspection fees

Type of site	*Fee (£)*	
	United Kingdom site	*Site outside the United Kingdom*
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	6,425	7,719
Minor site	4,283	5,577

30B Assessment of a variation of an authorisation to manufacture an autogenous vaccine

The fee for the scientific assessment of an application for the variation of an authorisation to manufacture an autogenous vaccine is—

(a) £2,895 if the variation requires complex scientific or pharmaceutical assessment;

(b) £885 if the variation requires simple scientific or pharmaceutical assessment;

(c) £455 in relation to an administrative variation.

31 Annual fee (manufacturing authorisations)

An annual fee of £575 is payable in respect of each manufacturing authorisation held.

~~31 Annual fees~~

~~(1) An annual fee of £550 is payable in respect of each manufacturing authorisation held (other than as specified in this paragraph).~~

~~(2) The annual fee for a manufacturing authorisation for an autogenous vaccine or a veterinary medicinal product for administration under the cascade is 0.67% of the turnover in the previous calendar year rounded to the next £1, with a minimum fee of £10.~~

~~(3) There is no annual fee for a manufacturing authorisation for a veterinary medicinal product manufactured in accordance with Schedule 6 for small pet animals.~~

~~(4) In this paragraph "turnover" means the sales value at manufacturers' prices net of value added tax of all authorised veterinary medicinal products sold or supplied in the United Kingdom.~~

32 Site inspections--type of site

For the purposes of deciding the fee for a site inspection--

"super site" is a site at which 250 or more relevant persons are employed;

"major site" is a site at which 60 or more, but fewer than 250, relevant persons are employed;

"standard site" is a site at which 10 or more, but fewer than 60 relevant persons are employed;

"minor site" is a site at which fewer than 10 relevant persons are employed;

"relevant person" means a person employed on the premises and systems inspected.

33 Inspection of a site where immunological veterinary medicinal products are manufactured

The fees for the inspection of a site where immunological veterinary medicinal products are manufactured are in accordance with the following table.

~~Sites where immunological veterinary medicinal products are manufactured~~

~~Type of site~~	*~~Fee (£)~~*	
	~~United Kingdom site~~	*~~Site outside United Kingdom~~*
~~Super site~~	~~24,071~~	~~22,867~~
~~Major site~~	~~16,785~~	~~15,946~~
~~Standard site~~	~~6,661~~	~~6,327~~
~~Minor site~~	~~4,757~~	~~4,519~~

Sites where immunological veterinary medicinal products are manufactured

Type of site	*Fee (£)*	
	United Kingdom site	*Site outside United Kingdom*
Super site	32,124	33,418
Major site	21,416	22,710
Standard site	10,708	12,002
Minor site	6,425	7,719”.

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

The following fees are payable for the inspection of a site where no immunological veterinary medicinal products are manufactured, but where sterile products are manufactured.

~~**Sites where sterile veterinary medicinal products are manufactured**~~

~~*Type of site*~~	~~*Fee (£)*~~ ~~*United Kingdom site*~~	~~*Site outside the United Kingdom*~~
~~Super site~~	~~23,324~~	~~22,157~~
~~Major site~~	~~13,010~~	~~12,359~~
~~Standard site~~	~~8,244~~	~~7,832~~
~~Minor site~~	~~5,022~~	~~4,770~~

Sites where sterile veterinary medicinal products are manufactured

Type of site	*Fee (£)* *United Kingdom site*	*Site outside the United Kingdom*
Super site	27,841	29,135
Major site	19,274	20,569
Standard site	10,708	12,002
Minor site	6,425	7,719

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

The following fees are payable for the inspection of a site where only non-immunological and non-sterile veterinary medicinal products are manufactured--

~~**Site where no immunological or sterile veterinary medicinal products are manufactured**~~

~~*Type of site*~~	~~*Fee (£)*~~ ~~*United Kingdom site*~~	~~*Site outside the United Kingdom*~~
~~Super site~~	~~14,180~~	~~13,471~~
~~Major site~~	~~8,325~~	~~7,909~~
~~Standard site~~	~~6,854~~	~~6,511~~
~~Minor site~~	~~3,789~~	~~3,600~~
~~If the site is only involved in the manufacture of veterinary medicinal products authorised under Schedule 6 (exemptions for small pet animals--~~		
~~Standard site~~	~~5,055~~	~~4,802~~
~~Minor site~~	~~2,728~~	~~2,592~~

Site where no immunological or sterile veterinary medicinal products are manufactured

Type of site	*Fee (£)* *United Kingdom site*	*Site outside the United Kingdom*
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	8,566	9,861
Minor site	4,283	5,577
If the site is only involved in the manufacture of veterinary medicinal products authorised under Schedule 6 (exemptions for small pet animals--		
Standard site	3,212	4,507
Minor site	2,142	3,436

36 Inspection of a site where veterinary medicinal products are assembled

The following fees are payable for the inspection of a site where the only manufacturing process in relation to veterinary medicinal products is their assembly after the product has been put into its immediate container.

~~**Site where medicinal products are assembled**~~

~~*Type of site*~~	~~*Fee (£)*~~ ~~*United Kingdom site*~~	~~*Site outside the United Kingdom*~~
~~Super site~~	~~11,025~~	~~10,474~~
~~Major site~~	~~5,949~~	~~5,652~~
~~Standard site~~	~~4,917~~	~~4,671~~
~~Minor site~~	~~2,035~~	~~1,933~~

Site where medicinal products are assembled

Type of site	*Fee (£)* *United Kingdom site*	*Site outside the United Kingdom*
Super site	17,133	18,427
Major site	10,708	12,002
Standard site	6,425	7,719
Minor site	4,283	5,577

37 Test sites

The fee for the inspection of a test site is £~~3,344~~3,212, or £~~3,177~~4,507 for a site outside the United Kingdom.

38 Animal blood bank or ~~equine~~ non-food animal stem cell centre authorisations

(1) The fee for the inspection of a blood bank is—

(a) £3,212 for a site in the United Kingdom; and

(b) £4,507 for a site outside the United Kingdom.

~~(1) The fee for an authorisation to operate a blood bank is--~~

~~(a) on a first inspection £3,113; and~~

~~(b) on each subsequent inspection--~~

~~(i) £3,113 for a site in the United Kingdom; and~~

~~(ii) £2,966 for a site outside the United Kingdom.~~

(2) The fee for the inspection of a non-food animal stem-cell centre is—

(a) £2,142 for a site in the United Kingdom; and

(b) £3,436 for a site outside the United Kingdom.

~~(2) The fee for an authorisation to operate an equine stem cell centre is £3,427, and £3,092 for each subsequent inspection~~.

~~(3) The fee for a variation to an authorisation to operate a blood-bank or equine stem cell centre is £320.~~

Part 4 Fees Relating to a Wholesale Dealer's Authorisation

~~39 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 Secretary of State must refund the excess.~~

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

~~(5) In this paragraph "turnover" means the sales value net of value added tax of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom.~~

39 Application for a wholesale dealer's authorisation

(1) The fee for an application for a wholesale dealer's authorisation is £344.

(2) Fees relating to an application for a wholesale dealer's authorisation are payable with the application.

40 Variation of a wholesale dealer's authorisation

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

(a) £~~515~~265 if the variation requires scientific or pharmaceutical assessment;

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

~~(c) otherwise £300~~(b) £105 for an administrative variation which includes a change of ownership.~~.~~

~~41 Annual fee for a wholesale dealer's authorisation~~

~~(1) 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).~~

~~(2) In this paragraph "turnover" means the sales value net of value added tax of all veterinary medicinal products (whether or not authorised for use in the United Kingdom) sold by way of wholesale dealing by the holder in the United Kingdom.~~

41 Annual fee for a wholesale dealer's authorisation

The annual fee for a wholesale dealer's authorisation is £427.

~~42 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).~~

42 Inspection of a wholesale dealer's premises

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

(a) £1,177; or

(b) £877 if—

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

(ii) the authorisation only relates to products marketed under Schedule 6 (exemptions for small pet animals).

Part 5 Fees Relating to Feedingstuffs

43 Fees for ~~approvals~~applications for authorisation and annual fees relating to feedingstuffs in Great Britain

(1) Subject to sub-paragraph (3) the fee for the application for ~~approval~~ authorisation of ~~establishments~~ sites manufacturing feedingstuffs and ~~approval~~ authorisation of distributors of feedingstuffs in Great Britain is ~~£70~~£105.

(2) An annual fee of ~~£70~~£122 is payable in respect of any such authorisation~~approval~~.

(3) No fee is payable under sub-paragraph (1) in respect of ~~an establishment~~a site where specified feed additives are manufactured if a veterinary medicinal product intended to be incorporated into feedingstuffs is manufactured at ~~that establishment~~that site in accordance with a manufacturing authorisation.

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

(5) Where more than one manufacturing activity is carried out at one ~~establishment~~site by the same legal entity only one fee (the highest) is payable.

44 Inspection fees relating to feedingstuffs in Great Britain

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

~~**Inspection fees**~~

~~*Type of establishment inspected*~~		~~*Fee payable (£)*~~
~~1~~	~~Establishment manufacturing a specified feed additive: (1)~~	~~1,810~~
~~2~~	~~Establishment manufacturing a premixture:~~	~~1,090~~
~~3~~	~~Establishment manufacturing feedingstuffs using~~	~~1,090~~

	~~specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures or specified feed additive complementary feedingstuffs:~~	
~~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 manufacturers 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~~

~~(1) No fee is payable for premises that already have a manufacturing authority relating to veterinary medicinal products for incorporating into feedingstuffs.~~

Inspection fees

Type of site inspected	*Fee payable (£)*
Manufacturer of a specified feed additive (SFA):	1,610
Manufacturer of intermediate feedingstuffs (including balancers) containing a premix or an SFA:	976
Manufacturer of a feedingstuff for sale containing: a premix and/or an SFA an intermediate feedingstuff containing a premix or an SFA	841
Manufacturer of a feedingstuff for feeding to their own animals only, containing: a premix and/or an SFA incorporated at a rate of at least 2kg/t an intermediate feedingstuff containing a premix and/or an SFA incorporated at a rate of at least 2kg/t	476
Manufacturer of a feedingstuff using a complementary feed containing an SFA, for feeding to own animals only	
Distributor or trader of Schedule 5 products (Sites distributing specified feed additives, or intermediate feedingstuffs containing specified feed additives or premixes; or feedingstuffs containing a premix)".	350

46 Fees relating to premises for supply by suitably qualified persons

(1) The fee for an application for the authorisation ~~to approve~~ of premises for the retail supply of veterinary medicinal products by suitably qualified persons is--

(a) £~~265~~105; ~~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.

(1A) The fees for the inspection of sites authorised for the retail supply of veterinary medicinal products by suitably qualified persons are set out in the following table—

Inspection Fees

Type of sites inspected	*Fee payable (£)*
Companion animal sites:	285
Equine sites:	285
Livestock sites:	338
Avian sites:	285

(2) The subsequent annual fee is--

(a) £~~185~~57; ~~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.

(3) The application fee for authorisation of sites for supply is payable with the application.

Part 6 General

47 Testing samples

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

48 Animal test certificates

(1) The fee for an animal test certificate is ~~£815~~£1,170.

(2) The fee for an animal test certificate to administer medicinal products in a small scale trial to test them for clinical safety or efficacy is ~~£30~~£40.

~~(4) The fee for an application for a variation of the certificate is £265 for each change.~~

(4) The fee for an application for the variation of the certificate is—

(a) in the case of a small scale trial, £40; and

(b) in the case of any other trial, £390.

~~(5) The fee for an application to renew a certificate is £130.~~

~~(5) The fee for an application to renew a certificate is £130.~~

(5) The fee for an application to renew a certificate is—

(a) in the case of a small scale trial, £40; and

(b) in the case of any other trial, £190

(6) The Secretary of State may waive the fee if satisfied that the application is in relation to developing a veterinary medicinal product for a limited market (for example, for a minor species, a minor use, or for a disease with restricted regional distribution).

49 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--

(b) ~~£30~~£13 if the veterinary medicinal product is authorised in another 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 Secretary of State 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 using the website of the Veterinary Medicines Directorate.~~

50 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 United Kingdom to enable it to be supplied for administration under Schedule 4 is £760.

(2) The fee is only payable if, in the twelve 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.

51 Specific batch control

The fee for an authorisation to release a veterinary medicinal product under specific batch control is--

(a) £560; and

(b) £100 for each additional batch affected by the same issue where the specific batch control application is made at the same time.

52 Submission of control tests of an immunological product

The fee for the submission of the results of tests carried out on a batch of immunological products other than autogenous vaccines prior to release is £80.

53 Export certificates

The fee for an application for an export certificate is ~~£30~~£54~~, and £15 for each certified copy~~.

54 Provision of advice

The fee for an application for written advice from the Secretary of State as to whether or not a product requires a marketing authorisation is £885.

54A Provision of scientific advice

The fee for an application for written advice from the Secretary of State in relation to scientific matters is £4,487.

55 Appeals to the Veterinary Products Committee

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

56 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.

57 Fees relating to a veterinary surgeon's practice premises

(1) ~~—~~The fees for the inspection of a veterinary practice premises are set out in the following table—

Type of premises inspected	*Fee payable (£)*
Companion animal premises:	536
Equine premises:	536
Livestock premises:	536
Mixed practice premises:	698
Any other type of practice	451.”;

~~(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~~38.

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

(4) For the purposes of sub-paragraph (1) “mixed practice” means premises supplying veterinary medicinal products to livestock in addition to any category mentioned in that provision.

57A Fee in relation to verifying destruction of controlled drug

The fee for verifying the destruction of a controlled drug as specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001 is—

(a) £142; or

(b) £31 (where the verification takes place during the course of an inspection for other purposes).

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

The Secretary of State 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 Secretary of State changes the decision that was the subject of the appeal.

59 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.

60 Non-payment of fees

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

61 Waiver or reduction of fees

(1) If the Secretary of State is satisfied that for reasons of human or animal health or the protection of the environment it is desirable that a product should be authorised for veterinary use or that an authorised product should remain on the market the Secretary of State may waive or reduce any fees payable under these Regulations.

(1A) If the Secretary of State is satisfied that exceptional circumstances exist the Secretary of State may waive or reduce an inspection fee payable under these Regulations.

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

62 Reduction of fees when an application is withdrawn

(1) Where an application for a marketing authorisation, or any variation referred to in paragraph 17 or 18 as a Type II variation, an extension, an extension-led grouped variation or a Type II led grouped variation is withdrawn before determination, the fee is reduced in accordance with this paragraph.

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

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

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

(5) If the further information requested has been supplied but has not yet been fully assessed or the application has not been referred to the Veterinary Products Committee, the reduction is 10%

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

63 Pharmacovigilance inspections

(1) In relation to a pharmacovigilance inspection the fee is—

(a) £3,600 in the case of a large marketing authorisation holder; and

(b) £1,650 in the case of a small marketing authorisation holder.

(2) In sub-paragraph (1)—

"large marketing authorisation holder" means a marketing authorisation holder who holds 30 or more marketing authorisations;

"small marketing authorisation holder" means a marketing authorisation holder who holds fewer than 30 marketing authorisations.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and remake with amendments the Veterinary Medicines Regulations 2011 (SI 2011/2159).

Principal changes to the 2011 Regulations

The major change to the Regulations is the adjustment of the fees with a view to achieving full cost recovery while avoiding cross-subsidy of one activity by another.

In Great Britain food businesses will pay a much lower fee on application for approval but will pay a larger fee for any inspection. Premises will be selected for inspection on the basis of risk analysis.

The fees for appeals to the Veterinary Products Committee are simplified.

Criminal offences have also been amended. Instead of creating an individual offence in relation to every obligation there is now a single offence governing all relevant obligations in the body of the Regulations and a single offence in each of Schedules 1 to 5.

Other changes

Regulation 35 extends inspectors' power of seizure to cover anything they reasonably believe to be, or which purports to be, a veterinary medicine.

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

The Regulations

The Regulations make provision for the authorisation, manufacture, 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;

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

(c) 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 191, 28.5.2004, p1), 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 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 marketing authorisation granted by the Secretary of State before being placed on the market, and they make provision for the grant of a marketing authorisation (regulation 4 and Schedule 1).

They specify that a veterinary medicinal product must be manufactured by a person holding a manufacturing authorisation, and make provision for granting an authorisation (regulation 5 and Schedule 2).

They regulate the supply and possession of veterinary medicinal products, and introduce new classifications of those products (regulation 7 and Schedule 3).

They provide that a veterinary medicinal product may only be administered as specified in its marketing authorisation or, in the case of administration by a veterinary surgeon, administration under the rules of the "cascade" (regulation 8 and Schedule 4).

They control bringing a veterinary medicinal product into the United Kingdom (regulation 9) and advertising (regulation 10 to 12).

They control wholesale dealing (regulation 13 and Schedule 3).

They control medicated feedingstuffs and feedingstuffs containing additives specified in the Regulations (regulation 14 and Schedule 5).

They provide for exemptions (regulation 15 and Schedule 6).

They provide for fees (regulation 16 and Schedule 7).

They require records to be kept (regulations 17 to 24).

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

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 a marketing authorisation (regulation 30).

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(u)) and of failing to comply with an improvement notice (regulation 43(v)).

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

(i) on summary conviction, by a fine not exceeding the statutory maximum or by imprisonment for a term not exceeding three months or both, or

(j) on conviction on indictment, by a fine or to imprisonment for a term not exceeding two years or both.

Regulation 46 requires the Secretary of State to review the operation and effect of these Regulations, other than regulation 16 and Schedule 7 (which relate to fees), and lay a report before Parliament within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

Regulation 47 revokes the Veterinary Medicines Regulations 2011.

A full impact assessment has been prepared and placed in the libraries of both Houses of Parliament. It is available, together with a transposition note and a table showing fee changes, on www.vmd.defra.gov.uk at "Publications, Veterinary Medicines Regulations and Guidance". It is also published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.