STATUTORY INSTRUMENTS

2023 No.

MEDICINES

The Veterinary Medicines (Amendment) Regulations 2023

Made - - - -	***
Laid before Parliament	***
Coming into force - -	***

The Secretary of State, in exercise of the powers conferred by sections 10(1), 11, 12(1)(a) and (b) and 43(2) of the Medicines and Medical Devices Act 2021(**a**), makes the following Regulations.

In accordance with section 10(2) of the Act, the Secretary of State considers that these Regulations promote the objectives mentioned in that paragraphs (a), (b) and (c) of that provision, has had regard to the matters mentioned in paragraphs (a), (b) and (c) of section 10(3) and considers that the benefits of making the Regulations outweigh the risks in accordance with section 10(4) of the Act.

The Secretary of State has consulted in accordance with section 45(1) of the Act and has set out for the purpose of that consultation, in compliance with section 45(3) of the Act, a summary of the Secretary of State's assessment of the matters mentioned in section 10 of the Act.

In accordance with section 47(6)(a) of that Act, a draft of this instrument was laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

Introduction

Title and commencement

1. These regulations may be cited as the Veterinary Medicines (Amendment) Regulations 2023 and come into force on [***].

Interpretation

2. In these regulations—

["the Act" means the Medicines and Medical Devices Act 2021;]

"the principal regulations" means the Veterinary Medicines Regulations 2013(**b**).

(**a**) 2021 c. 3.
(**b**) S.I. 2013/2033 (as amended by S.I. 2014/599, 2018/761, 2019/676, 2019/865, 2019/1488, 2020/1631, 2020/1461 and 2020/1481).

Amendments to the principal regulations

3. The principal regulations are amended in accordance with Parts 2 to 10.

PART 2

Amendments to Parts 1 to 5 of the principal regulations

4. Parts 1 to 5 of the principal regulations are amended in accordance with regulations 5 to 29.

5. In regulation 2—

(a) in paragraph (1) in the definition of "veterinary medicinal product" at the end add—

"or

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

(b) in paragraph (2)—

(i) at the appropriate places in alphabetical order insert—

""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;";

""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;";

""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;";

""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;

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

""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;".

""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) 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;

““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;

““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;”;

(ii) in the definition of “adverse reaction” for “adverse reaction” substitute “adverse event”;

(iii) in the definition of “immunological veterinary medicinal product”—

(aa) after “a veterinary medicinal product” insert “intended to be”;

(bb) for “animals” substitute “an animal”;

(cc) for “the state” substitute “its state”;

(iv) for the definition of “strength” substitute—

““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;”;

(v) omit the definition of “Commission Regulation (EC) No. 1234/2008”;

(vi) omit the definition of “extension variation”;

(vii) omit the definition of “risk-benefit balance”;

(c) omit paragraph (3).

6. For regulation 5 substitute—

“Manufacture of veterinary medicinal products

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

specified in the marketing authorisation (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.".

7. In regulation 7(2) after "veterinary medicinal product" insert "(including a veterinary medicinal product which has been incorporated into a medicated feedingstuff or intermediate product)".

8. In regulation 10—

(a) for paragraph (1) substitute—

"(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.";

(b) at the end add—

"(4) In this regulation "relevant substance" means—

(a) a veterinary medicinal product;

(b) a premix;

(c) an intermediate feedingstuff;

(d) a compound feedingstuff.".

9. After regulation 10 insert—

"Inducements and hospitality

10A.—(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.".

10. In regulation 11—

(a) in paragraph (3)—

(i) at the end of sub-paragraph (c) omit "or";

(ii) omit sub-paragraph (d);

(b) for paragraph (4) substitute—

"(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. ";

(c) in paragraph (5)—

(i) at the end of sub-paragraph (d) omit "or";

(ii) omit sub-paragraph (e).

11. In regulation 11(4) for "anti-microbials" substitute "antibiotics".

12. In regulation 15(3)(c)—

(a) omit "equine" in both places where it occurs;

(b) for "horses" substitute "non-food animals";

(c) for "Part 5" substitute "Part 2".

13. In regulation 18 after "food-producing animal must" insert "as soon as is reasonably practicable".

14. In regulation 21—

(a) for paragraph (1) substitute—

"(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.";

(b) in paragraph (3) at the end add "or for one year after the date of expiry of the batch, whichever is the longer.".

15. In regulation 22—

(a) in paragraph (a) omit "and nature";

(b) in paragraph (c) omit "manufacturer's";

(c) for paragraph (f) substitute—

"(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.";

(d) for "three years" substitute "5 years".

16. For regulation 23(1) substitute—

"(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).".

17. After regulation 24 insert—

"Reporting of sales and usage data in relation to antibiotics

24A.—(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.".

18. In regulation 25 after paragraph (6) insert—

"(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.".

19. In regulation 30(1) after "regulation 29" insert "or a body aggrieved by a decision to suspend or revoke its recognition under paragraph 14 of Schedule 3".

20. In regulation 30(2)(f) for "an equine stem cell centre" substitute "a stem cell centre".

21. In regulation 30(2)—

(a) after sub-paragraph (g) insert—

"(ga) registration in relation to active substances;";

(b) in sub-paragraph (h) for "approval" substitute "authorisation".

22. In regulation 30(3)—

(a) for ", appointment or approvals" substitute "or appointments";

(b) after "suspension" insert ", revocation".

23. In regulation 31—

(a) in paragraph (2) for "to that effect" substitute—

"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.".

(b) in paragraph (3) for "the model certificates" to the end substitute "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".

24. In regulation 32(3) at the end add "or to provide any sample".

25. In regulation 34(3) omit "approved,".

26. In regulation 35—

(a) in paragraph (1)—

(i) in sub-paragraph (f) for "premixture" substitute "intermediate feedingstuff";

(ii) in sub-paragraph (g) for "premixture" substitute "intermediate feedingstuff";

(iii) after sub-paragraph (c) insert—

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

(b) for paragraph (2) substitute—

"(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.".

27. After regulation 38 insert—

"Prohibition notices

38A.—(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.".

28. In regulation 39—

(a) In paragraph (1) after "an improvement notice" insert "or a prohibition notice".

(b) In paragraph (4) after "improvement notice" insert "or the prohibition notice".

(c) In paragraph (5) after "an improvement notice" insert "or a prohibition notice".

(d) In the heading at the end add "or prohibition notices".

29. In regulation 43—

(a) after paragraph (p) insert—

"(pa) regulation 24A;";

(b) in paragraph (v) omit "or";

(c) after paragraph (v) insert—

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

30. Omit regulation 46.

PART 3

Amendments to Schedule 1

31. Schedule 1 to the principal Regulations is amended in accordance with regulation 32 to 78.

32. For paragraph 2 substitute—

"Information with the application

2.—(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 [***];

(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.".

33. For paragraph 3 substitute—

"Summary of product characteristics

3. 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.

".

34. Paragraph 5 is omitted.

35. In paragraph 7(1) for the words from "if the active" to "demonstrate this" substitute "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".

36. In paragraph 10—

(a) in sub-paragraph (1)—

(i) for "pharmacologically equivalent" substitute "a generic";

(ii) at the end add "("the reference product")";

(b) in sub-paragraph (2)—

(i) for "pharmacologically equivalent to" substitute "a generic of";

(ii) in head (b) after "pharmaceutical form" insert "as the reference product";

(iii) for head (c) substitute—

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

(c) in sub-paragraph (5) after "Agency" insert "or the Secretary of State";

(d) in sub-paragraph (6) for "risk-benefit balance" substitute "benefit-risk balance";

(e) after sub-paragraph (6) add—

"(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.".

(f) in the heading for "pharmacologically equivalent" substitute "generic veterinary".

37. After paragraph 10 insert—

"Hybrid veterinary medicinal products

10A. 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 veterinary medicinal product.".

38. In paragraph 11—

(a) in sub-paragraph (1) for "pharmacologically equivalent" substitute "generic veterinary medicinal";

(b) for sub-paragraph (3) substitute—

"(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. ";

(c) in the heading for "pharmacologically equivalent" substitute "generic veterinary medicinal".

39. In paragraph 12—

(a) omit sub-paragraph (1);

(b) for sub-paragraph (2) substitute—

"(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.";

(c) in sub-paragraph (3) for "13" substitute "18";

(d) omit sub-paragraph (4).

40. Paragraph 13 is omitted.

41. Paragraph 15 is omitted.

42. In paragraph 17—

(a) the existing text is renumbered as sub-paragraph (1);

(b) after the renumbered sub-paragraph (1) insert—

"(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.".

43. For paragraph 18 substitute—

"Place of establishment of applicant

18.—(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.".

44. In paragraph 22—

(a) the existing text is renumbered as sub-paragraph (1);

(b) below that text insert—

"(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.".

45. After paragraph 22 insert—

"Withdrawal of application for marketing authorisation

22A.—(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.".

46. In paragraph 24(2)—

(a) in head (b) for "risk-benefit balance" substitute "benefit-risk balance";

(b) for head (c) substitute—

"(c) the applicant has not provided sufficient proof of the efficacy of the product in relation to the target species;";

(c) after head (f) add—

"(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.".

47. In paragraph 25—

(a) after sub-paragraph (3) add—

"(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.";

(b) in the heading after "grant" insert "refusal, suspension, variation or revocation".

48. At the end of paragraph 26(1)(b) add "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.".

49. In paragraph 27—

(a) in sub-paragraph (1) at the end add "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.";

(b) after sub-paragraph (2) add—

"(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.".

50. In paragraph 28 for "risk-benefit balance" substitute "benefit-risk balance" (in both places).

51. Paragraph 30 is omitted.

52. In paragraph 31—

(a) in sub-paragraph (2) after "United Kingdom" insert "or identifies a shortage for the veterinary medicinal product";

(b) after sub-paragraph (3) add—

"(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.".

53. for paragraph 32 substitute—

"Duration and validity of marketing authorisation

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

54. In paragraph 33—

(a) omit sub-paragraph (1);

(b) for sub-paragraph (3) substitute—

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

(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.".

55. After paragraph 33 insert—

"Variations requiring assessment

33A.—(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.

(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.

Unforeseen variations

33B.—(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.

Variations not requiring assessment

33C.—(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.".

56. In paragraph 34—

(a) omit sub-paragraph (1);

(b) in sub-paragraph (3)(b) for "Type II" to "application)" substitute "a variation requiring assessment".

57. Paragraph 35 is omitted.

58. In paragraph 38—

(a) for sub-paragraph (1) substitute—

"(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.";

(b) for sub-paragraph (3) substitute—

"(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.".

59. In paragraph 39 sub-paragraph (4) is omitted.

60. In paragraph 41 for sub-paragraph (1) substitute—

"(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.".

61. After paragraph 41 (and immediately before the heading for Part 6) insert—

"Temporary restrictions

41A. 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.".

62. After paragraph 41A (as inserted by paragraph 61 and before the heading to Part 6) insert—

"Restrictions in relation to immunological veterinary medicines

41B. 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.".

63. For paragraph 48 substitute—

"Labelling of immediate packaging of veterinary medicinal products

48.—(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.".

64. For paragraph 49 substitute—

"Labelling of the outer packaging of veterinary medicinal products

49.—(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.".

65. For paragraph 50 substitute—

"Labelling of small immediate packaging units of veterinary medicinal products

50.—(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.".

66. For paragraph 51 substitute—

"Package leaflet of veterinary medicinal products

51.—(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.".

67. In paragraph 53(3)—

(a) for head (c) substitute—

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

(b) at the end add—

"(m) the withdrawal period, where applicable.".

68. Paragraph 55 is omitted.

69. For paragraph 56 substitute—

" Duties of marketing authorisation holder in relation to pharmacovigilance

56.—(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.

Duties of marketing authorisation holder in relation to signal management process

56A.—(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.".

Duties of qualified person (pharmacovigilance)

56B.—(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.

Signal management process

56C.—(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).".

70. In paragraph 57—

(a) in sub-paragraph (1)—

(i) in head (a) for "serious adverse reaction" substitute "animal adverse event";

(ii) in head (b)—

(aa) for "adverse reaction" substitute "adverse event";

(bb) omit "or";

(iii) after head (c) (and immediately before the words "following the administration") insert—

"or,

(d) occurrence of an environmental incident,"

(iv) in the words following head (d) (inserted by head (iii) above) after "the product" insert "to an animal";

(b) after sub-paragraph (1) insert—

"(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.";

(c) in sub-paragraph (3) for "15" substitute "30";

(d) after sub-paragraph (4) insert—

"(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 State; 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.";

(e) omit sub-paragraph (5);

(f) in the heading for "adverse reactions to" substitute "adverse events following administration of".

71. Paragraph 58 is omitted.

72. In paragraph 59—

(a) in sub-paragraph (1)—

(i) for "records of all adverse reactions (including nil reports)" substitute "a summary of pharmacovigilance activity";

(ii) for "a periodic update safety report" substitute "an annual benefit risk report";

(iii) omit the words from ", including" to the end;

(b) omit sub-paragraph (2);

(c) in sub-paragraph (3)—

(i) omit "periodic safety update";

(ii) for "and—" to the end of the sub-paragraph, substitute "and in any event, once in the course of every year during the period of validity of the authorisation.";

(d) in sub-paragraph (4) for "periods of notification" substitute "submission dates for the annual benefit-risk reports";

(e) in sub-paragraph (5)—

(i) omit "periodic safety update";

(ii) for "risk-benefit balance" substitute "benefit-risk balance";

(f) in sub-paragraph (6)—

(i) for "The periodic safety update report must include" substitute "The Secretary of State may request the following information to be included in the report";

(ii) in head (a) after "product sold" insert "in the UK and in other countries";

(iii) in head (b) for "adverse reactions" substitute "adverse events";

(iv) in head (c) for "adverse reactions" substitute "adverse events";

(v) after head (c) insert—

"(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);";

(vi) in head (d)(ii) for "serious, non-serious" substitute "animal";

(vii) at the end insert—

"(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.";

(g) omit sub-paragraph (7);

(h) omit sub-paragraph (8);

(i) in the heading for "Periodic safety update" substitute "Annual benefit risk".

73. In paragraph 60—

(a) in sub-paragraph (1) after "concerns to" insert "veterinary surgeons or";

(b) at the end add—

"(3) For the purposes of this paragraph "information" includes any information contained in advertising material.".

74. After paragraph 60 insert—

"Pharmacovigilance inspections by Secretary of State

60A.—(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.

Powers of Secretary of State in relation to signal management process

60B. 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. ".

75. In paragraph 61(1)—

(a) after "a marketing authorisation" insert "(or a group of marketing authorisations containing the same active substance)";

(b) in head (c)—

(aa) after paragraph (iv) omit "or";

(bb) after paragraph (v) add—

"or,

(vi) implement a risk management plan,".

76. In paragraph 63—

(a) in sub-paragraph (2) after "immunological" insert "or, subject to sub-paragraph (2A), a biological";

(b) after sub-paragraph (2) insert—

"(2A) Sub-paragraph (2) does not apply in relation to a homeopathic remedy which is derived from plants.";

(c) in sub-paragraph (3) after "must be" insert "either topical or oral and must be".

77. In paragraph 64(1)—

(a) in head (a) after "stock" insert "or stocks";

(b) in head (b)—

(i) after "stock is" insert "or stocks are";

(ii) for "its" substitute "their";

(iii) for "nature" substitute "use";

(c) in head (f) omit "or authorisations";

(d) for head (g) substitute—

"(g) the text which is to appear on the package leaflet, outer packaging and immediate packaging of the homeopathic remedy;";

(e) for head (h) substitute—

"(h) any relevant data concerning the stability of the homeopathic remedy;".

78. In paragraph 65 at the end add—

"(3) The Secretary of State must ensure that the procedure for granting a registration in relation to a homeopathic remedy is completed within a maximum of 210 days after the submission of the application.".

PART 4

Insertion of Schedule 1C

79. The Schedule to these Regulations is inserted into the principal Regulations as Schedule 1C immediately after Schedule 1B.

PART 5

Amendments to Schedule 2

80. Schedule 2 to the principal Regulations is amended in accordance with regulations 81 to 93.

81. For paragraph 1 substitute—

"Manufacturing authorisation

1.—(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 Great Britain or for export);

(b) the carrying out of 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.".

82. For paragraph 2 substitute—

"Application for authorisation

2.—(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.".

83. For paragraph 3 substitute—

"Procedure and time limits for authorisations

3.—(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.".

84. In paragraph 4—

(a) for sub-paragraph (1)(b) substitute—

"(b) the name and address of the site where the products are to be manufactured, controlled or imported;";

(b) in sub-paragraph (3) omit "if necessary";

(c) after sub-paragraph (3) insert—

"(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.".

85. In paragraph 5—

(a) in sub-paragraph (1)—

(i) after head (c) omit "or";

(ii) at the end add—

"(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.".

(b) for sub-paragraph (2) substitute—

"(2) The Secretary of State may also suspend, vary or revoke the authorisation on being satisfied that the qualified person (manufacture), 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.";

(c) in the heading after "Suspension," insert "compulsory".

86. In paragraph 6—

(a) in sub-paragraph (1)—

(i) for "premises" (in the first and the third place it appears) substitute "sites";

(ii) for "premises'" substitute "site's";

(b) for sub-paragraph (2) substitute—

"(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.";

(c) at the end add—

"(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.

(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.";

(d) For the heading substitute "Good manufacturing practice certificates and inspection of sites".

87. In paragraph 8—

(a) for sub-paragraph (2) substitute—

"(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.";

(b) for sub-paragraph (3) substitute—

"(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.";

(c) at the end add—

"(6) A holder must keep detailed records of all veterinary medicinal products which the holder supplies.".

88. In paragraph 9—

(a) in sub-paragraph (1)—

(i) after "any person" insert "(including the manufacturer)"

(ii) after "practical experience" insert "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";

(b) after sub-paragraph (1) insert—

"(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.".

89. In paragraph 10—

(a) for "or revoke" substitute ", revoke, suspend or vary";

(b) for the heading substitute "Refusal, suspension, revocation or variation of appointment".

90. In paragraph 11—

(a) after sub-paragraph (1) insert—

"(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.";

(b) in sub-paragraph (2)—

(i) after "another country" insert "or if the manufacturer re-imports a product exported after original manufacture in the United Kingdom";

(ii) after "marketing authorisation" add "and that the batch has been manufactured in compliance with good manufacturing practice";

(c) after sub-paragraph (4) add—

"(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.".

91. In paragraph 13—

(a) in sub-paragraph (1) for "premises" substitute "a site";

(b) in sub-paragraph (2) for "premises" substitute "site";

(c) after sub-paragraph (2) insert—

"(2A) The site must be specified in an existing manufacturing authorisation and must be subject to a certificate of good manufacturing practice.";

(d) in sub-paragraph (3) for "Authorisation and inspection of the premises are" substitute "Inspection of the site is".

92. For Parts 2 to 5 substitute—

"PART 2

Authorisation of autogenous vaccines, blood-banks, stem-cell centres and products manufactured under the cascade

Authorisation to manufacture specific veterinary medicinal products

14.—(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.

Prohibition

15. No person may carry out any activity mentioned in paragraph 14 other than in accordance with the authorisation mentioned in that paragraph.

Personnel

16. 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.

Process of authorisation

17.—(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.

Authorisation in relation to blood banks

18.—(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.

Authorisation in relation to stem cells

19.—(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.

Authorisation in relation to products for administration under the cascade

20.—(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 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.

Suspension, compulsory variation or revocation of authorisation

21. 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.

Labelling

22.—(1) The holder of an authorisation must ensure that, in addition to the expiry date and any necessary warnings, every container 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.

Records

23. 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;

(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.

Adverse events

24. 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.

Inspection of sites

25.—(1) 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.".

93. After Part 2 (as substituted by regulation 92 above) insert—

"PART 3

Active Substances

Active substances

26. 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.

Prohibition on manufacture, importation or distribution of active substances

27.—(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.

Application for registration

28. 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).

Good manufacturing or distribution practice

29. 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.

Supply of information

30.—(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.

Inspection of sites

31. 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.

Report following inspection

32.—(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.

Offences

33. 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).".

PART 6

Amendments to Schedule 3

94. Schedule 3 to the principal Regulations is amended in accordance with regulations 95 to 119.

95. In paragraph 1—

(a) in sub-paragraph (4) at the end add—

"(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.";

(b) after sub-paragraph (5) insert—

"(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."; [

(c) in sub-paragraph (6)—

(i) in head (d) for "adverse reaction" substitute "adverse event";

(ii) in head (h) for "antimicrobials" substitute "antibiotics".

96. In paragraph 2—

(a) in sub-paragraph (1) omit "of a marketing authorisation, the holder";

(b) in sub-paragraph (2)—

(i) in head (a) at the beginning insert "subject to sub-paragraph (2A)";

(ii) in head (b) at the end add "or as a manufacturer";

(c) after sub-paragraph (2) insert—

"(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.";

(d) for sub-paragraph (3) substitute—

"(3) If the supply is to a veterinary surgeon, a pharmacist or a suitably qualified person, it must be to premises registered (or authorised as the case may be) in accordance with paragraph 8(1), paragraph 10(1) or paragraph 14(4).".

97. In paragraph 3(6) for head (a) substitute—

"(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".

98. After paragraph 3 insert—

"Supply of samples

3A.—(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.".

99. After paragraph 3A (inserted by regulation 98 above) insert—

"Register of online suppliers of veterinary medicinal products

3B.—(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.

Application for registration

3C. 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.

Duties in relation to online supply

3D. 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.".

100. After paragraph 3D (inserted by regulation 99 above) insert—

"Retail storage of veterinary medicinal products

3E. 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.".

101. In paragraph 4(1)—

(a) after "the animal" (in the first place where it appears) insert "or where there is more than one animal, of that group of animals";

(b) after "the animal" (in the second place where it appears) insert "or that group of animals";

(c) for "clinical assessment" substitute "clinical examination or other proper assessment".

102. In paragraph 5—

(a) after sub-paragraph (1) insert—

"(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.";

(b) after paragraph (3) add—

"(4) No person may submit a written prescription to a retailer on more than one occasion where the prescription is not repeatable.".

103. In paragraph 6 for sub-paragraph (1) substitute—

"(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.

(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.".

104. In paragraph 7—

(a) the existing text is renumbered as sub-paragraph (1).

(b) After that sub-paragraph add—

"(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.".

105. After paragraph 7 insert—

"Duties in relation to prescribing of antibiotic veterinary medicinal products

7A.—(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.".

106. In paragraph 10(1)(c) for "approved" substitute "authorised".

107. In paragraph 11—

(a) for "approved" substitute "authorised" (wherever occurring);

(b) in sub-paragraph (1) for "veterinary medicinal product for incorporation into feedingstuffs" substitute "premix";

(c) in sub-paragraph (2)—

(i) for "veterinary medicinal product" substitute "premix" (wherever occurring);

(ii) in head (b) for "premixture" substitute "intermediate feedingstuffs";

(iii) in head (c) for "prescription" substitute "medicated feedstuffs prescription";

(d) in sub-paragraph (3)—

(i) in head (a) for "premixture" substitute "intermediate feedingstuffs";

(ii) for "veterinary medicinal product" substitute "premix" (wherever occurring);

(iii) in head (b)—

(aa) for "approval" substitute "authorisation";

(bb) for "prescription" substitute "medicated feedstuffs prescription"

(e) for sub-paragraph (4) substitute—

"(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.";

(f) in the title for "veterinary medicinal product for incorporation into feedingstuffs" substitute "premix".

108. In paragraph 13(2)(a)—

(a) for "veterinary surgery" substitute "veterinary practice premises";

(b) for "approved" substitute "authorised".

109. In paragraph 14—

(a) for "approved" substitute "authorised" (wherever occurring);

(b) for "approval" substitute "authorisation" (wherever occurring);

(c) for sub-paragraph (5) substitute—

"(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.";

(d) after sub-paragraph (10) add—

"(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.".

110. For paragraph 15 substitute—

"Audit

15.—(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 records 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.".

111. For paragraph 16 substitute—

"Wholesale dealer's authorisation

16. No person may deal as a wholesale dealer in veterinary medicinal products otherwise than in accordance with an authorisation granted under this paragraph.".

112. For paragraph 17 substitute—

"Application for authorisation

17.—(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 matters 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.".

113. For sub-paragraph 18 substitute—

"Procedure and time limits for authorisations

18.—(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.".

114. For paragraph 19 substitute—

"The authorisation

19.—(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.".

115. For paragraph 20(b) substitute—

"(b) no longer has suitable premises, equipment or technically competent staff.".

116. In paragraph 21—

(a) the existing text is renumbered as sub-paragraph (1);

(b) in sub-paragraph (1)—

(i) for head (b) substitute—

"(b) comply with good distribution practice;";

(ii) omit head (c);

(iii) at the end add—

"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.".

117. After paragraph 21 (and immediately before the heading for Part 3) insert—

"Register of holders of authorised wholesale dealers

21A. The Secretary of State must establish, maintain and publish on a website a register of authorised wholesale dealers and their sites.

Documentation accompanying veterinary medicinal products supplied wholesale

21B.—(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.

Recalled products

21C.—(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.

Audit

21D.—(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 records 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.

Contractual arrangements between holders of wholesale dealer's authorisations

21E. 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.

Self-inspection plan

21F. 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.".

118. In paragraph 23—

(a) in sub-paragraph (1) after "unless the person" insert "either is a person or";

(b) for sub-paragraph (2) substitute—

"(2) The certificate must be issued by a body recognised by the Secretary of State.".

119. In paragraph 24—

(a) after sub-paragraph (b) insert—

"(ba) paragraph 3A;

(bb) paragraph 3B;

(bc) paragraph 3D;

(bd) paragraph 3E;

(b) after sub-paragraph (e) insert—

"(ea) paragraph 7A;";

(c) after sub-paragraph (o) insert—

"(oa) paragraph 21B;

(ob) paragraph 21C;

(oc) paragraph 21D;

(od) paragraph 21E;

(oe) paragraph 21F".

PART 7

Amendments to Schedule 4

120. Schedule 4 to the principal Regulations is amended in accordance with regulations 121 to 154.

121. In paragraph 1—

(a) in sub-paragraph (4)—

(i) for the words "Any pharmacologically active substances" substitute "All substances";

(ii) at the end add "or are substances considered as not falling within the scope of Regulation (EC) No. 470/2009";

(b) after sub-paragraph (4) insert—

"(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.".

122. In paragraph 2—

(a) in sub-paragraph (2)—

(i) after "active substance" (where it first appears) insert "for the treated species";

(ii) at the end add "or, where there is no maximum residue limit for a particular species 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";

(b) in sub-paragraph (3)—

(i) for head (a) substitute—

"(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;";

(ii) for head (b) substitute—

"(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;";

(iii) for head (c) substitute—

"(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;";

(iv) for head (d) substitute—

"(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. ";

(c) after sub-paragraph (3) add—

"(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.".

123. In paragraph 4—

(a) after "epizootic diseases" insert "or emerging diseases";

(b) in the heading at the end add "or emerging disease".

124. After paragraph 6 insert—

"Administration of autogenous vaccines

6A.—(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.".

125. In paragraph 9—

(a) in sub-paragraph (1) for "research purposes" substitute "clinical trials";

(b) in sub-paragraph (4) for "adverse reaction" substitute "adverse event".

126. After paragraph 9 insert—

"Misuse of the cascade

9A. A person must not encourage or facilitate use of the cascade which is not in accordance with this Schedule.".

127. In paragraph 10 at the end add—

"(d) paragraph 9A.".

PART 8

Amendments to Schedule 5

128. Schedule 5 to the principal Regulations is amended in accordance with regulations 131 to 154.

129. In paragraph 1(3) at the appropriate places in alphabetical order insert—

““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;”.

130. In paragraph 3(3) for “premixture” substitute “intermediate feedingstuff”.

131. In paragraph 5(2)—

(a) in head (e) for “establishments” substitute “premises”;

(b) in head (f) for “approval or registration” substitute “registration”.

132. In paragraph 7—

(a) in sub-paragraph (2)—

(i) for “veterinary medicinal product” substitute “premix”;

(ii) for “a premixture” substitute “an intermediate feedingstuff”;

(iii) for “premixtures” substitute “intermediate feedingstuffs”;

(b) for sub-paragraph (5) substitute—

“(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.”;

(c) in sub-paragraph (6) for “veterinary medicinal product” substitute “premix”;

(d) for “approved” substitute “authorised” (wherever occurring);

(e) for “approval” substitute “authorisation” (wherever occurring);

(f) in the heading—

(i) for “Approval” substitute “Authorisation”;

(ii) For “veterinary medicinal products” substitute “premixes”.

133. In paragraph 8—

(a) for “veterinary medicinal product” (wherever occurring) substitute “premix”;

(b) for “a premixture” substitute “an intermediate feedingstuff”;

(c) in the heading for "veterinary medicinal product into a premixture" substitute "premix";

134. In paragraph 10—

(a) in sub-paragraph (a) for "the summary of product characteristics" substitute "its marketing authorisation and in accordance with its medicated feedingstuff prescription (unless it has been prescribed under the cascade)";

(b) in sub-paragraph (c) for "prescription" substitute "medicated feedingstuff prescription";

(c) for "a premixture containing a veterinary medicinal product" substitute "an intermediate feedingstuff";

(d) for "veterinary medicinal product" (wherever occurring) substitute "premix";

(e) in the heading for "veterinary medicinal product" substitute "premix".

135. In paragraph 11—

(a) in sub-paragraph (1)—

(i) for "veterinary medicinal product" (wherever occurring) substitute "premix";

(ii) for "a premixture" (wherever occurring) substitute "an intermediate feedingstuff";

(iii) in head (d)—

(aa) for "veterinary medicinal products" substitute "premixes";

(bb) for "premixture" substitute "intermediate feedingstuffs";

(iv) in head (e) for "premixture" substitute "intermediate feedingstuffs";

(b) in sub-paragraph (2)—

(i) for "veterinary medicinal products" substitute "premixes";

(ii) for "premixtures" substitute "intermediate feedingstuffs";

(iii) for "approved" substitute "authorised";

(c) in sub-paragraph (3)—

(i) in head (c) for "premixture" substitute "intermediate feedingstuffs";

(ii) in head (e) for "veterinary medicinal product" substitute "premix";

(d) in the heading for "veterinary medicinal products" substitute "premixes".

136. In paragraph 12—

(a) in sub-paragraph (1)—

(i) for "A premixture" substitute "An intermediate feedingstuff";

(ii) in head (a) for "MEDICATED PREMIXTURE" substitute "INTERMEDIATE FEEDINGSTUFF";

(iii) for "veterinary medicinal product" (in both places where it occurs) substitute "premix";

(iv) in head (c) for "premixture" substitute "intermediate feedingstuff";

(v) in head (d)—

(aa) for "premixture" substitute "intermediate feedingstuff";

(bb) for "prescription" substitute "medicated feedingstuffs prescription";

(vi) after head (e) insert—

"(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";";

(vii) in head (f) for "prescription" substitute "medicated feedingstuffs prescription";

(viii) in head (i) for "prescription" substitute "medicated feedingstuffs prescription";

(b) in sub-paragraph (2) for "veterinary medicinal product" substitute "premix";

(c) in sub-paragraph (3) for "premixture" substitute "intermediate feedingstuff";

(d) in sub-paragraph (4) for "premixture" substitute "intermediate feedingstuff";

(e) in the heading—

(i) for "a premixture" substitute "an intermediate feedingstuff";

(ii) for "veterinary medicinal product" substitute "premix".

137. In paragraph 14—

(a) in sub-paragraph (1)—

(i) for "veterinary medicinal product" (wherever occurring) substitute "premix";

(ii) after head (e) insert—

"(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;";"

(iii) in head (f) for "prescription" substitute "medicated feedingstuffs prescription";

(iv) in head (i) for "prescription" substitute "medicated feedingstuffs prescription";

(v) in head (j) for "approval" substitute "authorisation";

(b) in sub-paragraph (2) for "veterinary medicinal product" substitute "premix";

(c) in the heading for "veterinary medicinal product" substitute "premix".

138. In paragraph 16—

(a) in sub-paragraph (1) for "a premixture" (wherever occurring) substitute "an intermediate feedingstuff";

(b) in sub-paragraph (2) for "premixture" (in both places where it occurs) substitute "intermediate feedingstuff";

(c) in sub-paragraph (3) for "premixture" substitute "intermediate feedingstuff";

(d) for "approved" substitute "authorised" (wherever occurring);

(e) in the heading for "premixture" substitute "intermediate feedingstuff".

139. In paragraph 17—

(a) in sub-paragraph (2)(b) for "a premixture" substitute "an intermediate feedingstuff";

(b) in sub-paragraph (3)(b) for "a premixture" substitute "an intermediate feedingstuff";

(c) for "approved" substitute "authorised" (wherever occurring).

140. In paragraph 18—

(a) in sub-paragraph (1) for "veterinary medicinal product" substitute "premix";

(b) for "approved" substitute "authorised" (wherever occurring);

(c) in sub-paragraph (2)(b) for "a person who keeps animals" substitute "an animal keeper";

(d) in sub-paragraph (3)(b) for "a person who keeps animals" substitute "an animal keeper";

(e) in sub-paragraph (4) for "prescription" substitute "medicated feedingstuff prescription";

(f) in sub-paragraph (5) for "prescription" substitute "medicated feedingstuff prescription";

(g) in sub-paragraph (7) for "prescription" substitute "medicated feedingstuff prescription";

(h) at the end add—

"(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.";

(i) in the heading for "veterinary medicinal product" substitute "premix".

141. In paragraph 19—

(a) in sub-paragraph (1)—

(i) for "veterinary medicinal product" (wherever occurring) substitute "premix";

(ii) after head (e) insert—

"(ea) the diagnosed disease to be treated or prevented (in the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects);";

(iii) for head (h) substitute—

"(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;";

(iv) after head (j) insert—

(ja) a statement that the prescription may not be re-used;";

(iv) in head (l) for "approved" substitute "authorised";

(v) after head (n) insert—

"(na) the overall amount of feedingstuff to be supplied under the prescription;";

(vi) omit head (o);

(b) after sub-paragraph (2) insert—

"(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.";

(c) for sub-paragraph (3) substitute—

"(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.";

(d) in the heading for "veterinary medicinal product" substitute "premix".

142. In paragraph 20—

(a) in sub-paragraph (1)—

(i) in head (a) for "or to the distributor" substitute "and (where applicable) to the distributor";

(ii) for "veterinary medicinal product" substitute "premix";

(b) in sub-paragraph (2) for "veterinary medicinal product" (wherever occurring) substitute "premix";

(c) in paragraph (3) for "veterinary medicinal product" (wherever occurring) substitute "premix".

143. In paragraph 21—

(a) in sub-paragraph (1)—

(i) for "premixtures" substitute "intermediate feedingstuffs";

(ii) for "approval" substitute "authorisation";

(b) in sub-paragraph (2)—

(i) for "veterinary medicinal product" substitute "premix";

(ii) for "prescription" substitute "medicated feedingstuffs prescription".

144. In paragraph 22—

(a) in sub-paragraph (2) for the table substitute—

"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%".

145. After paragraph 22 insert—

"Sampling for cross-contamination

22A.—(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.".

146. In paragraph 23—

(a) for "a premixture" substitute "an intermediate feedingstuff;

(b) for "veterinary medicinal product" (wherever occurring) substitute "premix".

147. In paragraph 24 for "veterinary medicinal product" substitute "premix".

148. In paragraph 25—

(a) in sub-paragraph (2) for "veterinary medicinal product" substitute "premix";

(b) in sub-paragraph (3) for "veterinary medicinal product" substitute "premix";

(c) in sub-paragraph (4) for "veterinary medicinal products" substitute "premixes".

149. In paragraph 26 after sub-paragraph (2) insert—

"(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.".

150. After paragraph 26 insert—

"Unused and expired medicated feedingstuffs

26A.—(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.".

151. In paragraph 28(b) for "veterinary medicinal product" (in the second place where it occurs) substitute "premix".

152. In paragraph 29—

(a) in sub-paragraph (1) for "premixture" (wherever occurring) substitute "intermediate feedingstuffs";

(b) in sub-paragraph (2) for "premixture" substitute "intermediate feedingstuff";

(c) in the heading for "premixture" substitute "intermediate feedingstuffs".

153. In paragraph 30—

(a) in sub-paragraph (1)—

(i) for "veterinary medicinal product" (wherever occurring) substitute "premix";

(ii) for "approval" substitute "authorisation";

(b) in sub-paragraph (2)—

(i) for "a premixture" substitute "an intermediate feedingstuff";

(ii) for "veterinary medicinal product" (wherever occurring) substitute "premix";

(c) in sub-paragraph (3) for "premixture" substitute "intermediate feedingstuffs".

154. In paragraph 31—

(a) after sub-paragraph (r) insert—

"(ra) paragraph 22;";

(b) after sub-paragraph (v) insert—

"(va) paragraph 26A;".

PART 9

Amendments to Schedule 6

155. Schedule 6 to the principal Regulations is amended in accordance with regulations 156 to 159.

156. In paragraph 2 at the end add "and the manufacturer is registered under the register mentioned in paragraph 3A".

157. After paragraph 3 insert—

"Register of persons placing veterinary medicinal products on the market (small pet animals)

3A.—(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).

Persons registered in accordance with paragraph 3A: annual return

3B. 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 ".

158. In paragraph 4(4)(b) for "adverse reactions" substitute "adverse events".

159. In paragraph 9(1)—

(a) for "manufacturer, importer or retailer" substitute "manufacturer or importer";

(b) in head (b) for "adverse reaction" substitute "adverse event" (in both places);

(c) for "adverse reactions" substitute "adverse events" (including the heading).

PART 10

Amendments to Schedule 7

160. Schedule 7 to the principal Regulations is amended in accordance with regulations 161 to 199.

161. In paragraph 1—

(a) the existing text is renumbered as sub-paragraph (1);

(b) after that sub-paragraph insert—

"(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.".

162. In paragraph 4—

(a) omit ", approval";

(b) after "time," insert "and in relation to the same legal entity,".

163. In paragraph 7—

(a) after "a pharmaceutical" insert "or immunological";

(b) in sub-paragraph (a)—

(i) at the end of head (i) insert "or";

(ii) in head (ii) omit "or";

(iii) in head (ii) after "application" insert "for a pharmaceutical veterinary medicinal product";

(iv) omit head (iii);

(c) in the heading, after "pharmaceutical" insert "or immunological";

(d) in sub-paragraph (c) for the table substitute—

	Fee (£) per authorisation
Base fee	27,995
Fee for 1st additional strength	4,590
Fee for each subsequent additional strength	1,465".

164. After paragraph 7 insert—

"Application for a marketing authorisation for specific applications

7A. 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.".

165. Paragraph 9 is omitted.

166. For paragraph 11 substitute—

"Application for a marketing authorisation based on informed consent

11. 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

167. Paragraph 15 is omitted.

168. After paragraph 15 insert—

"Fee for a generic marketing authorisation

15A. 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	

169. For the table in paragraph 17 substitute—

"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".

170. Paragraph 18 is omitted.

171. In paragraph 22—

(a) omit sub-paragraph (1);

(b) for the title substitute "Application for a reassessment of an exceptional marketing authorisation".

172. Paragraph 25 is omitted.

173. In paragraph 28—

(a) the text is renumbered as sub-paragraph (1);

(b) for the words from "is—" to the end substitute "is £762".

(c) at the end add—

"(2) Fees relating to an application for a manufacturing authorisation are payable with the application.".

174. In paragraph 29 (variation of manufacturing authorisations)—

(a) in sub-paragraph (a) for "£636" substitute "£684";

(b) in sub-paragraph (b)—

(i) for "a change of ownership" substitute "an administrative variation which includes a change of ownership";

(ii) for "£443" substitute "£105";

(iii) (c) omit sub-paragraphs (c) and (d).

175. In paragraph 30—

(a) in sub-paragraph (1) omit "an autogenous vaccine or";

(b) for sub-paragraph (2) substitute—

"(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".

(c) omit sub-paragraph (3) and (4);

(d) in the heading omit "an autogenous vaccine or".

176. After paragraph 30 insert—

"Autogenous vaccines

30A.—(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".

Assessment of a variation of an authorisation to manufacture an autogenous vaccine

30B. 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.".

177. For paragraph 31 substitute—

"Annual fee (manufacturing authorisations)

31. An annual fee of £575 is payable in respect of each manufacturing authorisation held.
".

178. In paragraph 32 (site inspections)—

(a) after "major site" insert—

""standard pharmacovigilance site" means a site on which 30 or more relevant persons are employed;";

(b) after "standard site" insert—

""minor pharmacovigilance site" means a site on which fewer than 30 relevant persons are employed;".

179. In paragraph 33, for the table substitute—

"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".

180. In paragraph 34, for the table substitute—

"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".

181. In paragraph 35, for the table substitute—

"Sites 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".

182. In paragraph 36, for the table substitute—

"Sites 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".

183. In paragraph 37—

(a) for "£3,344" substitute "£3,212";

(b) for "£3,177" substitute "£4,507".

184. In paragraph 38—

(a) for sub-paragraph (1) substitute—

"(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.".

(b) for sub-paragraph (2) substitute—

"(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.".

(c) omit sub-paragraph (3);

(d) in the heading for "equine" substitute "non-food animal".

185. For paragraph 39 substitute—

"Application for a wholesale dealer's authorisation

39.—(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.".

186. In paragraph 40—

(a) in sub-paragraph (a) for "£515" substitute "£265";

(b) for sub-paragraph (b) to the end substitute—

"(b) £105 for an administrative variation which includes a change of ownership.".

187. For paragraph 41 substitute—

"Annual fee for a wholesale dealer's authorisation

41. The annual fee for a wholesale dealer's authorisation is £427.".

188. For paragraph 42 substitute—

"Inspection of a wholesale dealer's premises

42. 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).".

189. In paragraph 43—

(a) in sub-paragraph (1)—

(i) for "£70" substitute "£105";

(ii) for "approval" (in both places where it occurs) substitute "authorisation";

(iii) for "establishments" substitute "sites";

(b) in sub-paragraph (2)—

(i) for "£70" substitute "£122";

(ii) for "approval" substitute "authorisation";

(c) in sub-paragraph (3)—

(i) for "an establishment" substitute "a site";

(ii) for "that establishment" substitute "that site";

(d) in sub-paragraph (4) omit "or on invoice for the subsequent annual fee";

(e) in sub-paragraph (5) for "establishment" insert "site by the same legal entity";

(f) in the title for "approvals" substitute "applications for authorisation".

190. In paragraph 44, for the table substitute—

"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".

191. In paragraph 46—

(a) in sub-paragraph (1)—

(i) omit "or" after heads (a) and (b)(i);

(ii) for "£265" substitute "£105";

(iii) for "to approve" substitute "for an application for the authorisation";

(b) after sub-paragraph (1) insert—

"(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.".

(c) in sub-paragraph (2)—

(i) omit "or" after heads (a) and (b)(i);

(ii) for "£185" substitute "£57";

(d) at the end add—

"(3) The application fee for authorisation of sites for supply is payable with the application.".

192. In paragraph 48—

(a) in sub-paragraph (1) for "£815" substitute "£1,170";

(b) in sub-paragraph (2) for "£30" substitute "£40";

(c) for sub-paragraph (4) substitute—

"(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.";

(d) for sub-paragraph (5) substitute—

"(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.".

193. In paragraph 49—

(a) in sub-paragraph (1)(b) for "£30" substitute "£13";

(b) sub-paragraph (3) is omitted.

194. In paragraph 53—

(a) for "£30" substitute "£54";

(b) omit the words from ", and £15" to the end.

195. After paragraph 54 insert—

"Provision of scientific advice

54A. The fee for an application for written advice from the Secretary of State in relation to scientific matters is £4,487.".

196. In paragraph 57—

(a) for sub-paragraph (1) substitute—

"(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.";

(b) in sub-paragraph (2), for "£34" substitute "£38";

(c) after sub-paragraph (3) add—

"(4) For the purposes of sub-paragraph (1) "mixed practice" means premises supplying veterinary medicinal products to livestock in addition to any other category mentioned in that provision.".

197. After paragraph 57 insert—

"Fee in relation to verifying destruction of controlled drug

57A. 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).".

198. In paragraph 60—

(a) after "from the person" insert "or any authorisation held by the person";

(b) omit "(other than any fee relating to a manufacturing authorisation or wholesale dealer's authorisation)".

199. After paragraph 61(1) insert—

"(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.".

200. After paragraph 62 insert—

"Pharmacovigilance inspections

63.—(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.".

Signatory text

Name
Parliamentary Under Secretary of State
Department

Address
Date