STATUTORY INSTRUMENTS

2024 No. 567

MEDICINES

The Veterinary Medicines (Amendment etc.) Regulations 2024

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

In accordance with section 10(2) of the Act, the Secretary of State's overarching objective in making these Regulations is to promote one or more of the matters specified in that subsection.

The Secretary of State—

(a) has had regard to the matters mentioned in paragraphs (a), (b) and (c) of section 10(3) of the Act; and

(b) considers that, in accordance with section 10(4) of the Act, the benefits of making these Regulations outweigh the risks.

The Secretary of State has consulted in accordance with section 45(1) of the Act and has set out in the consultation document, in accordance 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.

A draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament in accordance with section 47(3) and (6)(a) of the Act.

(**a**) 2021 c. 3.

PART 1

Introduction

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Veterinary Medicines (Amendment etc.) Regulations 2024 and come into force 21 days after the day on which they are made.

(2) These Regulations extend to England and Wales and Scotland.

Interpretation

2. In these Regulations, "the 2013 Regulations" means the Veterinary Medicines Regulations 2013(**a**).

PART 2

Amendments to Parts 1 to 5 of the 2013 Regulations

Introduction

3. Parts 1 to 5 of the 2013 Regulations are amended in accordance with this Part.

Amendment to regulation 2

4. In regulation 2 (interpretation)—

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

"; 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, is responsible for the activity of that veterinary medicinal product;

"adverse environmental event" means an event where a non-target organism, population or 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;

"adverse event" means any observation in animals that occurs after any use of a veterinary medicinal product, whether or not considered to be product-related, that is unfavourable and unintended;

"advertising" means, in relation to veterinary medicinal products, 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, and "advertise" and "advertisement" are to be construed accordingly;

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

(**a**) S.I. 2013/2033 (as amended by S.I. 2014/599, 2018/761, 2019/676 (itself amended by S.I. 2020/461), 865, 1488, 2020/1461 and 1631).

"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 antiprotozoals;

"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;

"ATCvet code" means, in relation to a veterinary medicinal product, the code issued in respect of that product by the World Health Organization Collaborating Centre for Drug Statistics Methodology, and published by that body in the ATCvet index(**a**);

"benefit-risk balance" means, in relation to a veterinary medicinal product, 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;

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

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

"biological substance" means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physical, chemical and biological testing, together with knowledge of the production process and its control;

"biological veterinary medicinal product" means a veterinary medicinal product where an active substance is a biological substance;

"complementary feedingstuffs" means compound feed which has a high content of certain substances and 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 two feed additives for oral animal-feeding in the form of complete or complementary feed;

"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;

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

"feed additives" means substances, micro-organisms or preparations, other than feed material and intermediate feedingstuff, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Schedule 5;

"feed materials" means products of vegetable or animal origin whose principal purpose is to meet animals' nutritional needs, and which are intended for use in oral animal feed either directly, or after processing, or in the preparation of compound feed, or as a carrier of intermediate feedingstuffs;

"feedingstuff" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

"generic veterinary medicinal product" means a veterinary medicinal product which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as a reference veterinary medicinal product;

"genetically modified organism" or "GMO" means a genetically modified organism for the purposes of the GMO Deliberate Release Regulations;

(**a**) The ATC index can be searched at www.whocc.no/atcvet/atcvet_index/.

"GMO Deliberate Release Regulations" means—

(a) as regards England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002(**a**);

(b) as regards Scotland, the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(**b**);

(c) as regards Wales, the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(**c**);

"good distribution practice" means that part of quality assurance which ensures that products are consistently stored, supplied and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications;

"good manufacturing practice" means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications;

"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;

"improvement notice" has the meaning given in regulation 38(1);

"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 of the following—

(a) a medicinal premix;

(b) a specified feed additive,

with feed materials or compound feed, exclusively intended to be used for the manufacture of a complete feed;

"lack of efficacy" means the apparent inability of an authorised veterinary medicinal product to have the expected efficacy in an animal, whether or not the product was used in accordance with the summary of product characteristics;

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

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

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

"manufacturing authorisation", except as regards Schedule 7, has the meaning given in paragraph 1 of Schedule 2;

"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 medicinal premixes or intermediate feedingstuff with feed materials or compound feed;

"medicinal premix" means a veterinary medicinal product authorised for incorporation into feedingstuffs;

"metaphylactic purposes", in relation to the administration of a veterinary medicinal product, means the administration of the veterinary medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the

(**a**) S.I. 2002/2443, amended by S.I. 2019/88, 1252; there are other amending instruments but none is relevant.
(**b**) S.S.I. 2002/541, amended by S.S.I. 2019/57, 86; there are other amending instruments but none is relevant.
(**c**) S.I. 2002/3188 (W. 304), amended by S.I. 2019/1316, 1492; there are other amending instruments but none is relevant.

disease to animals in close contact and at risk and which may already be subclinically infected;

"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, and "novel therapies" is to be construed accordingly;

"person responsible for release" and "PRR" have the meaning given in paragraph 16 of Schedule 2;

"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;

"principles of good laboratory practice" has the meaning given in regulation 2(1) of the Good Laboratory Practice Regulations 1999(**a**);

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

"qualified person (manufacture)", in relation to a veterinary medicinal product, means a person appointed under paragraph 9 of Schedule 2 with responsibility for that product;

"qualified person (pharmacovigilance)" has the meaning given in paragraph 56(9) of Schedule 1;

"reference veterinary medicinal product" has the meaning given in paragraph 10(1) of Schedule 1;

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

"signal management process" has the meaning given in paragraph 56C of Schedule 1;

"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;

"wholesale qualified person" has the meaning given in paragraph 17(2)(d) of Schedule 3;

"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 "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";

(iii) for the definition of "strength" substitute—

(**a**) S.I. 1999/3106, amended by S.I. 2004/994; there are other amending instruments but none is relevant.

""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;";

(iv) omit the definitions of "adverse reaction", "Commission Regulation (EC) No 1234/2008", "extension variation" and "risk-benefit balance";

(c) after paragraph (2) insert—

"(2A) In these Regulations, a biological veterinary medicinal product is treated as a single product even when more than one solvent is used in the preparation of different preparations of the final product (which may be for administration by different routes or methods).";

(d) omit paragraph (3).

Amendment to regulation 5

5. In regulation 5 (manufacture of veterinary medicinal products) omit paragraph (3).

Amendment to regulation 7

6. In regulation 7(2) (prohibition of supply past expiry date) after "veterinary medicinal product" insert "(including a veterinary medicinal product which has been incorporated into a medicated feedingstuff or intermediate feedingstuff)".

Amendment to regulation 10

7. In regulation 10 (advertising)—

(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, unless—

(a) a marketing authorisation has been granted in respect of that product, and

(b) that authorisation is not currently suspended in accordance with paragraph 38 of Schedule 1.";

(b) at the end insert—

"(4) In this regulation, subject to paragraph (5), "relevant substance" means—

(a) a veterinary medicinal product;

(b) a medicinal premix;

(c) an intermediate feedingstuff; or

(d) a compound feed.

(5) In this regulation, coccidiostats and histomonostats are not relevant substances.".

New regulation 10A

8. 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 supply, 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) it is subordinate to the main scientific objective of the event; and

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

(b) 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 the Veterinary Medicines (Amendment, etc.) Regulations 2024 came 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.".

Amendment to regulation 11

9. In regulation 11 (advertising of prescription products, etc.)—

(a) in paragraph (4) for "anti-microbials" substitute "antimicrobials";

(b) at the end insert—

"(6) A person advertising a veterinary medicinal product must—

(a) include in that advertisement the statement "prescription decisions are for the person issuing the prescription alone";

(b) ensure that all factual statements concerning the characteristics of the product in the advertisement are consistent with the summary of product characteristics submitted in respect of the product under Schedule 1, as amended.".

Amendment to regulation 15

10. In regulation 15(3) (exemptions)—

(a) in sub-paragraph (a), for "Part 3" substitute "Part 2";

(b) in sub-paragraph (b), for "Part 4" substitute "Part 2";

(c) in sub-paragraph (c)—

(i) omit "equine" in both places it occurs;

(ii) for "horses" substitute "non-food producing animals";

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

Amendment to regulation 18

11. In regulation 18 (records of administration) after "food-producing animal must" insert "as soon as is reasonably practicable".

Amendment to regulation 21

12. In regulation 21 (records by a holder of a manufacturing authorisation)—

(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 the holder—

(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 under which the product was supplied;

(f) the company name and the permanent address or registered place of business of the recipient of the supply.";

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

Amendment to regulation 22

13. In regulation 22 (records by a holder of a wholesale dealer's authorisation)—

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

(b) after paragraph (b) insert—

"(ba) the pharmaceutical form and strength of the product;";

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

(d) for paragraph (f) substitute—

"(f) the company name and permanent address or registered place of business of—

(i) in respect of a purchase, the supplier, and

(ii) in respect of a sale, the recipient,";

(e) for "three years" substitute "five years".

Amendment to regulation 23

14. For regulation 23(1) (records of the receipt or supply of prescription products) substitute—

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

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

(b) the name of the veterinary medicinal product;

(**a**) See paragraph 1 of Schedule 3 to S.I. 2013/2033 as regards classification of veterinary medicinal products.

(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 permanent address or registered place of business of—

(i) in respect of a purchase, the supplier;

(ii) in respect of a sale, the recipient;

(g) if there is a written prescription the name and contact details of the prescriber;

(h) the expiry date.

(1A) Where the duty in paragraph (1) applies in respect of a veterinary medicinal product for a non-food producing animal, the duty in respect of sub-paragraph (d) is satisfied by recording the batch number—

(a) on the date on which the batch is received, or

(b) on the date on which a veterinary medicinal product from the batch is first supplied.".

New regulation 24A

15. After regulation 24 (records of products administered to a food-producing animal under the cascade) 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 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.".

Amendment to regulation 25

16. In regulation 25 (importation of an unauthorised veterinary medicinal product) after paragraph (6) insert—

"(6A) A pharmacist may supply a product to which paragraph (6) applies to a veterinary surgeon for the purposes mentioned in that paragraph notwithstanding paragraph 2(1) of Schedule 3.".

Amendment to regulation 30

17. In regulation 30 (appeals to an appointed person)—

(a) in paragraph (1), after "regulation 29" insert "or a body aggrieved by a decision to suspend or revoke its recognition under paragraph 14(1) of Schedule 3";

(b) in paragraph (2)—

(i) after sub-paragraph (a) insert—

"(aa) a variation to a manufacturing authorisation;";

(ii) in sub-paragraph (f), for "an equine stem cell centre" substitute "a stem cell centre";

(iii) after sub-paragraph (g) insert—

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

(iv) in sub-paragraph (h), for "approval" substitute "authorisation";

(c) in paragraph (3)—

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

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

Amendment to regulation 31

18. In regulation 31 (exports)—

(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 words from "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".

Amendment to regulation 32

19. In regulation 32(3) (time limits) at the end insert "or to provide any sample".

Amendment to regulation 34

20. In regulation 34(3) (powers of entry) omit "approved,".

Amendment to regulation 35

21. In regulation 35 (powers of an inspector)—

(a) in paragraph (1)—

(i) after sub-paragraph (c) insert—

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

(cb) verify the destruction of a controlled drug listed in Schedule 2, 3 or 4 of the Misuse of Drugs Regulations 2001(**a**);";

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

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

(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".

(**a**) S.I. 2001/3998, amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136, 2011/448, 2012/1311, 2013/625, 2014/1275, 3277, 2015/891, 2018/1055, 1383; there are other amending instruments but none is relevant.

Amendment to regulation 38

22. In regulation 38 (improvement notices), after paragraph (1) insert—

"(1A) If the inspector considers that the matters constituting a person's perceived failure to comply involve risks to animal or human health or of damage to the environment which are so serious that, until steps have been taken to reduce or remove that failure, one or more activity carried on by the person ought to be prohibited or restricted, the improvement notice must state—

(a) the activity which is to be prohibited or restricted;

(b) the reasons why such prohibition or restriction is considered appropriate;

(c) the time and date at which the prohibition or restriction is to take effect (which may be immediately after the notice is served);

(d) that the person must not carry out the activity in breach of the prohibition or restriction until—

(i) that person has provided evidence to the inspector that measures have been undertaken to secure compliance, and

(ii) the inspector has confirmed to that person that the notice is revoked.

(1B) Where the person on whom an improvement notice to which paragraph (1A) applies has been served provides evidence to the inspector that the measures specified in the notice (or measures at least equivalent to them) have been undertaken to secure compliance, and the inspector is satisfied that the measures have been satisfactorily performed, the inspector must revoke the notice and inform the person of this.".

Amendment to regulation 41

23. In regulation 41(seizure notices)—

(a) in paragraph (2) for "product", in both places it occurs, substitute "item";

(b) in paragraph (3) for "products", in each place it occurs, substitute "items";

(c) in paragraph (4) for "product", in both places it occurs, substitute "item";

(d) in paragraph (5) for "product" substitute "item";

(e) in paragraph (6)—

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

(ii) for "product", in both places it occurs, substitute "item";

(f) in paragraph (9) for "product" substitute "item".

Amendment to regulation 43

24. In regulation 43 (offences)—

(a) in paragraph (f) for "(1)" substitute "(1), (1A)";

(b) after paragraph (f) insert—

"(fa)regulation 10A(1), (3) or (5);";

(c) in paragraph (g) at the end insert "or (4) or (6)";

(d) after paragraph (p) insert—

"(pa) regulation 24A(1)".

Amendment to regulation 44

25. In regulation 44 (penalties)—

(a) in paragraph (1), at the beginning insert "As regards England and Wales,";

(b) after paragraph (1) insert—

"(1A) As regards Scotland, a person guilty of an offence under these Regulations is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding 12 months or both, or

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

Amendment to regulation 46

26. In regulation 46 (review)—

(a) omit paragraphs (2) and (3);

(b) in paragraph (5), for "beginning with the day on which these Regulations come into force" substitute "ending on 31st December 2028".

PART 3

Amendments to Schedule 1 to the 2013 Regulations

Introduction

27. Schedule 1 to the 2013 Regulations (marketing authorisations in Great Britain) is amended in accordance with this Part.

Amendment to paragraph 2

28. For paragraph 2 (information with the application) substitute—

"Information with the application: general

2.—(1) An application must include the matters mentioned in sub-paragraph (2) and—

(a) where the veterinary medicinal product is an antimicrobial, the matters mentioned in sub-paragraph (4);

(b) subject to sub-paragraph (6), 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) No 470/2009 of the European Parliament and of the Council(**a**), the matter mentioned in sub-paragraph (5);

(c) where the product contains or consists of genetically modified organisms, the matters mentioned in sub-paragraph (7).

(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 the 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;

(**a**) EUR 2009/470, amended by S.I. 2019/865 (itself amended by S.I. 2020/1461).

(ii) any imported products are held; or

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

(d) the nature of the marketing authorisation being applied for, and the provisions in Part 2 of Schedule 1 which are relevant to the application;

(e) in relation to the veterinary medicinal product—

(i) the name and the ATCvet 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 or a biological veterinary medicinal product that is not immunological, 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;

(f) a document showing that the 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, together with a description of the manufacturing process for the active substances and finished product which falls within scope of that authorisation or certificate;

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

(h) the proposed summary of product characteristics;

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

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

(k) details of any country where—

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

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

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

(m) technical documentation demonstrating the quality, safety and efficacy of the product;

(n) a report (a "critical expert report") on the quality, safety and efficacy of the product.

(3) For the purposes of sub-paragraph (2)(n), each critical expert report must—

(a) be prepared with regard to the state of scientific knowledge at the time of the application;

(b) include an evaluation of each test and trial referred to in the application, addressing all aspects relevant to quality, safety and efficacy, with detailed results and precise bibliographic references (including copies of the referenced material);

(c) where technical documentation within sub-paragraph (2)(m) is referenced, include precise cross-references;

(d) be signed and dated by the author, and include details of the author's educational background, training and occupational experience, and the author's professional relationship with the applicant.

(4) 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.

(5) 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.

(6) Sub-paragraph (1)(b) does not apply in respect of a veterinary medicinal product which—

(a) is for administration to a horse that has been declared on its horse passport as not intended for slaughter for human consumption, and

(b) includes 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.

(7) 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 issued under the GMO Deliberate Release Regulations;

(b) the complete technical file containing the information provided in respect of the application for that consent under the GMO Deliberate Release Regulations;

(c) the environmental risk assessment provided in respect of the application for that consent under the GMO Deliberate Release Regulations;

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

(8) In assembling the application for an authorisation under this Schedule, the applicant must—

(a) take into account the most up-to-date veterinary medicinal knowledge and scientific guidelines relating to the quality, safety and efficacy of veterinary medicinal products (including relevant monographs of the European Pharmacopoeia and British Pharmacopoeia);

(b) include in the application all information which is relevant to the evaluation of the veterinary medicinal product to which it relates, whether favourable or unfavourable to the product (including information relating to any incomplete or abandoned study or trial);

(c) ensure that the application supports, by reference to specific studies and trials, each claim made by the applicant with regard to the properties, effects and uses of the veterinary medicinal product to which it relates;

(d) otherwise ensure the accuracy of the information in the application.

(9) For the purposes of sub-paragraph (8)(c), pharmacological, toxicological, residue and pre-clinical studies and clinical trials must be carried out in conformity with the principles of good laboratory practice, where applicable.

Information with the application: format

2A.—(1) An application must be submitted electronically.

(2) Subject to sub-paragraph (3), the application must be structured as a single dossier in four parts—

(a) Part 1 (administrative information);

(b) Part 2 (pharmaceutical quality (physicochemical, biological or microbiological) data);

(c) Part 3 (safety documentation, including safety and residue tests);

(d) Part 4 (efficacy documentation, including pre-clinical studies and clinical trials).

(3) An application concerning the release of GMOs must set out the environmental risk assessment in respect of that release as a separate document, and that assessment must be presented in accordance with the following provision of the GMO Deliberate Release Regulations—

(a) as regards England or Scotland, regulation 6;

(b) as regards Wales, regulation 7.

Information with the application: animal testing

2B.—(1) Where information to be included in an application under paragraph 2(8) includes information concerning experiments on animals, this paragraph applies in respect of that information.

(2) The application must state whether the information was obtained from an experiment conducted in accordance with the requirements in sub-paragraph (4).

(3) The Secretary of State must, in assessing the application, disregard any information to which this paragraph applies which was not obtained from an experiment conducted in accordance with the requirements in sub-paragraph (4).

(4) The requirements are—

(a) the experiment was conducted in accordance with a detailed written protocol prepared in advance;

(b) the experiment was designed to use the minimum number of animals and cause the least pain, suffering or lasting harm, and there was no satisfactory alternative in vitro test available to be used which would have reduced these impacts;

(c) informed consent to the experiment and its consequences (including as regards disposal of treated animals and the taking of produce from treated animals) was obtained in writing from the owner of the animal before the animal was first treated under the experiment;

(d) the welfare of the animals was subject to veterinary supervision throughout the experiment.

Information with the application: POM-VPS, NFA-VPS and AVM-GSL

2C.—(1) Where an applicant proposes, under paragraph 2(2)(d), that a marketing authorisation be granted on the basis that the veterinary medicinal product is classified as POM-VPS, NFA-VPS or AVM-GSL, the requirements in this paragraph apply.

(2) The application must include a document which sets out a detailed justification for the suitability of such classification, having regard to—

(a) animal safety (both as regards treated animals and other animals);

(b) public health; and

(c) environmental safety.".

Amendment to paragraph 3

29. For paragraph 3 (summary of product characteristics) substitute—

"Summary of product characteristics

3.—(1) Subject to sub-paragraph (2), the summary of product characteristics required under paragraph 2(2)(h) 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 as regards—
	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 as regards—
	4.1	the ATCvet Code;
	4.2	pharmacodynamics;
	4.3	pharmacokinetics.
5.		Pharmaceutical particulars as regards—
	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	requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products.
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 product characteristics.
10.		If applicable, the statement—
	10.1	“marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation”; or
	10.2	“marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation”.
11.		Information on the take-back schemes referred to in point 5.5 applicable to the veterinary medicinal product concerned.
12.		Classification of the veterinary medicinal product.

(2) In the case of an immunological veterinary medicinal product or a biological veterinary medicinal product that is not immunological, in place of the information at points 4, 4.1, 4.2 and 4.3, the summary of product characteristics must include immunological information.".

Amendment to paragraph 5

30. Omit paragraph 5 (time limits for applications).

Amendment to paragraph 7

31. In paragraph 7 (bibliographic application)—

(a) in sub-paragraph (1), for the words from "if the active" to the end 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";

(b) after sub-paragraph (1) insert—

"(1A) Sub-paragraph (1) does not apply to applications for—

(a) biological (including immunological) veterinary medicinal products;

(b) novel therapies.".

Amendment to paragraph 8

32. In paragraph 8 (application for a product using a new combination of active substances)—

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

(b) after that text insert—

"(2) Notwithstanding sub-paragraph (1) the applicant must provide a sound scientific justification based on valid therapeutic principles for the combination of active substances, including clinical data, which demonstrates the need for and contribution of all active substances at the moment of treatment.".

Amendment to paragraph 10

33. In paragraph 10 (application for a pharmacologically equivalent medicinal product)—

(a) in sub-paragraph (1)—

(i) at the beginning insert "Subject to sub-paragraphs (2A), (9) and (10) and paragraph 10A,";

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

(iii) at the end add "("the reference veterinary medicinal product"), provided that the applicant provides data demonstrating the matters referred to in sub-paragraph (2)";

(b) in sub-paragraph (2)—

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

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

(iii) for paragraph (c) substitute—

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

(c) after sub-paragraph (2) insert—

"(2A) Sub-paragraph (1) does not apply to applications for biological (including immunological) veterinary medicinal products.";

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

(e) omit sub-paragraph (6);

(f) after sub-paragraph (6) insert—

"(7) For the purposes of these Regulations, subject to sub-paragraph (8), the summary of product characteristics of a generic veterinary medicinal product must be essentially similar to the summary of 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 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) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products intended to be administered by intramuscular, subcutaneous or transdermal routes, the applicant must provide—

(a) administration site target animal tolerance data;

(b) in respect of products intended for administration to food-producing species only, residues depletion data from the site of administration.

(10) Notwithstanding sub-paragraph (1), in respect of generic veterinary medicinal products containing antimicrobial or antiparasitic substances, the applicant must provide all available data (including published data) on the current level of resistance, together with a review of that data as it relates to target pathogens to the active substances concerned.

(11) An applicant must provide an environmental risk assessment for a generic veterinary medicinal product where—

(a) the marketing authorisation for the reference veterinary medicinal product was granted before 1st October 2005, and

(b) no marketing authorisation has been granted since 1st October 2005 in respect of a veterinary medicinal product which has the same active substance and pharmaceutical form as the reference veterinary medicinal product, and which is indicated for use in the same target species when administered at the same or a higher total dose,

unless the Secretary of State holds an environmental risk assessment for the reference veterinary medicinal product and has confirmed this to the applicant.";

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

New paragraph 10A

34. 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—

(a) bioavailability studies are not capable of demonstrating bioequivalence between the veterinary medicinal product for which the authorisation is sought and a reference veterinary medicinal product for the purposes of paragraph 10; or

(b) the veterinary medicinal product for which the authorisation is sought is not pharmacologically equivalent to a reference veterinary medicinal product for the purposes of paragraph 10 as a result of a difference in relation to—

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

(ii) the strength of the product;

(iii) the indications for use of the product;

(iv) the pharmaceutical form of the product;

(v) the route of administration of the product;

(vi) the withdrawal period for the product.".

Amendment to paragraph 11

35. In paragraph 11 (time limits for marketing authorisations – pharmacologically equivalent products)—

(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 end of the longest of the following periods which is relevant—

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

(b) 18 years in the case of a veterinary medicinal product authorised for bees; and

(c) 14 years for a veterinary medicinal product authorised for all other species.

(3A) Where the product—

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

(b) contains an active substance which is an antimicrobial 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 product characteristics 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.

(3D) In this regulation "major species" means cattle, sheep (for meat production), pigs, chickens, dogs and cats.";

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

Amendment to paragraph 12

36. In paragraph 12 (extension of time limits)—

(a) omit sub-paragraph (1);

(b) for sub-paragraph (2) substitute—

"(2) Subject to sub-paragraph (2B), if a person submits an application for a marketing authorisation or for a variation to a marketing authorisation for a product, and within five 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 relevant protection period is extended by one year for each additional major species added to the marketing authorisation.

(2A) Subject to sub-paragraph (2B), 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 relevant protection period is extended by four years.

(2B) Sub-paragraphs (2) and (2A) do not apply where the application to extend the marketing authorisation is made fewer than three years before the expiration of the protection period.";

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

(d) omit sub-paragraph (4).

New paragraph 12A

37. After paragraph 12 insert—

"Time limits – supplementary

12A.—(1) Subject to sub-paragraph (3), a study, residue test or pre-clinical 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 five years from that submission has elapsed.

(2) Subject to sub-paragraph (3), 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 antimicrobial resistance in relation to a reference product may not be used for any other such application until a period of four years in addition to the relevant protection period has elapsed.

(3) Sub-paragraphs (1) and (2) do not apply where an applicant has obtained a written authorisation to access a study, residue test or pre-clinical study mentioned in the relevant sub-paragraph.".

Amendment to paragraph 13

38. Omit paragraph 13 (parallel imports).

Amendment to paragraph 14

39. Omit paragraph 14(4) (specific batch control scheme).

Amendment to paragraph 15

40. Omit paragraph 15 (similar immunological products).

Amendment to paragraph 17

41. In paragraph 17 (time limits)—

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

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

"(2) Sub-paragraph (1) does not apply where a simultaneous assessment of the application is being conducted by the Secretary of State and the relevant authority in another country.".

Amendment to paragraph 18

42. For paragraph 18 (place of establishment of applicant) substitute—

"Place of establishment of applicant

18. Only an applicant established in the United Kingdom or in a country which the Secretary of State considers to have demonstrated equivalent standards to those in the United Kingdom may be granted (or hold) a marketing authorisation or a veterinary homeopathic registration.".

Amendment to paragraph 22

43. In paragraph 22 (grant of marketing authorisation)—

(a) the existing text is renumbered as sub-paragraph (2);

(b) above that text insert—

"**22.**—(1) The Secretary of State must, before granting a marketing authorisation—

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

(b) assess the application and data submitted in respect of 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.".

(c) below the existing text (renumbered as sub-paragraph (2)) insert—

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

(4) Where the marketing authorisation relates to a veterinary medicinal product that contains an antimicrobial 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.".

New paragraph 22A

44. 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) a summary of the reasons for withdrawal.".

Amendment to paragraph 24

45. In paragraph 24(2) (refusal of a marketing authorisation)—

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

(b) for paragraph (c) substitute—

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

(c) after paragraph (f) insert—

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

(h) 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;

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

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

(k) 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 (except where

it is demonstrated that the active substance is essential to prevent or control a serious risk to animal health).".

Amendment to paragraph 25

46. In paragraph 25 (publication following the grant of a marketing authorisation)—

(a) after sub-paragraph (3) insert—

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

(5) Where the Secretary of State varies 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".

Amendment to paragraph 26

47. In paragraph 26 (marketing authorisations in exceptional circumstances)—

(a) in sub-paragraph (1)(a), after "further data" insert ", taking into account the benefit of the immediate availability on the market of the veterinary medicinal product in comparison to the risks";

(b) in sub-paragraph (1)(b), after "limited market" insert ", taking into account the benefit in relation to public or animal health of the availability of the product on the market in comparison to the risks.";

(c) after sub-paragraph (1) insert—

"(1A) An exceptional marketing authorisation may be granted subject to such further conditions, including any restrictions, as the Secretary of State considers appropriate.".

Amendment to paragraph 27

48. In paragraph 27 (provisions of samples and expertise)—

(a) in sub-paragraph (1) at the end insert "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) insert—

"(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 sub-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.".

Amendment to paragraph 28

49. In paragraph 28 (supply of information)—

(a) for "risk-benefit balance", in both places it occurs, substitute "benefit-risk balance";

(b) after sub-paragraph (3) insert—

"(4) A marketing authorisation holder must retain all of the original documents from every clinical trial from which data was derived in support of the application for authorisation under this Schedule, and in support of any variation of the authorisation

(whether granted or otherwise), for at least five years from the date on which the authorisation ceases.";

(c) in the heading, at the beginning insert "Records and".

Amendment to paragraph 30

50. Omit paragraph 30 (control tests).

Amendment to paragraph 31

51. In paragraph 31 (placing on the market), after sub-paragraph (2) insert—

"(2A) A holder of a marketing authorisation who identifies a shortage of the veterinary medicinal product must notify the Secretary of State as soon as is reasonably practicable.

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

Amendment to paragraph 32

52. For paragraph 32 (duration and validity of marketing authorisation) substitute—

"Duration and validity of marketing authorisation

32. Subject to any power of revocation provided under these Regulations a marketing authorisation is valid indefinitely.".

Amendment to paragraph 33

53. In paragraph 33 (variation of marketing authorisation)—

(a) omit sub-paragraph (1);

(b) for sub-paragraph (3) substitute—

"(3) An application for a variation under paragraph (2) may only relate to—

(a) a single variation, which may relate to one or more marketing authorisations, or

(b) one or more variations to a single marketing authorisation.".

New paragraph 33A

54. After paragraph 33 insert—

"**Variation procedure**

33A.—(1) Subject to sub-paragraphs (2) and (6), an application for a variation must be submitted to the Secretary of State electronically.

(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; and

(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 application.

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

(6) Where the Secretary of State is satisfied that it is not necessary for the application to contain certain information for the purposes of conducting an assessment, having regard to the risks involved with the proposed variation, the Secretary of State may waive the requirement to provide that information under sub-paragraph (3) (and the requirement in sub-paragraph (4) does not apply in respect of that information).

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

(8) Having assessed the application, the Secretary of State must—

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

(b) reject the proposed variation.

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

(10) The Secretary of State must ensure that the determination of an application for a variation of a marketing authorisation is completed within a maximum of 180 days after the submission of the application.".

Amendment to paragraph 34

55. In paragraph 34 (refusal of variation to marketing authorisation)—

(a) omit sub-paragraph (1);

(b) for sub-paragraph (3)(b) substitute—

"(b) the Secretary of State produced an assessment in respect of the variation under paragraph 33A(4),".

Amendment to paragraph 35

56. Omit paragraph 35 (administrative variations).

Amendment to paragraph 38

57. In paragraph 38 (suspension of marketing authorisation: grounds)—

(a) for sub-paragraph (1) substitute—

"(1) If the Secretary of State is satisfied at any time that the benefit-risk balance of a veterinary medicinal product is not positive or is insufficient to ensure food safety, the Secretary of State may—

(a) suspend the marketing authorisation;

(b) require the holder of the marketing authorisation to submit an application for its variation;

(c) revoke the marketing authorisation.";

(b) for sub-paragraph (3) substitute—

"(3) The Secretary of State may take the steps set out in sub-paragraph (1)(a), (b) and (c) on being satisfied at any time 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;

(h) the qualified person (pharmacovigilance) has failed to comply with the requirements of these Regulations";

(c) in the heading, after "suspension" insert ", revocation, etc".

Amendment to paragraph 39

58. In paragraph 39 (suspension of marketing authorisation: procedure) omit sub-paragraph (4).

Amendment to paragraph 41

59. In paragraph 41 (prohibiting supply of veterinary medicinal products) 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 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".

New paragraphs 41A and 41B

60. After paragraph 41 (and in Part 5) 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 a 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.

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 are largely absent from the territory concerned.".

Amendment to paragraph 48

61. For paragraph 48 (labelling with all information on immediate packaging) 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 of the marketing authorisation holder;

(e) the target species;

(f) the expiry date, in the format 'mm/yyyy', preceded by the abbreviation "Exp.";

(g) special storage precautions, if any;

(h) the route of administration;

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

(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.".

Amendment to paragraph 49

62. For paragraph 49 (products with immediate and outer packaging) substitute—

"Labelling of the outer packaging of veterinary medicinal products

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

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

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

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

(d) a warning that the veterinary medicinal product is "for animal treatment only";

(e) a recommendation to read the package leaflet, if there is one;

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

(g) the marketing authorisation number.

(2) The information referred to in sub-paragraph (1) must appear in easily legible and clearly comprehensible characters, or in abbreviations or pictograms.".

Amendment to paragraph 50

63. For paragraph 50 (package leaflets) substitute—

"Labelling of small immediate packaging units of veterinary medicinal products

50.—(1) Where the immediate packaging units of a veterinary medicinal product are too small to include in a legible form all of the information set out in paragraph 48, the immediate packaging must instead provide the following information—

(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 immediate packaging units mentioned in sub-paragraph (1) must be packed within outer packaging which provides the information required by paragraph 49.".

Amendment to paragraph 51

64. For paragraph 51 (ampoules) substitute—

"Package leaflet of veterinary medicinal products

51.—(1) Subject to sub-paragraphs (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;

(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;

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

(e) the indications for use;

(f) the contra-indications and adverse events;

(g) if applicable, the withdrawal period for each species, even if such a period is zero;

(h) special storage precautions, if any;

(i) information essential for safety or health protection, including any special precautions relating to use and any other 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 the summary of product characteristics.

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

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

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

(6) 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.

(7) Where the Secretary of State requires the leaflet to be made available electronically—

(a) an electronic package information leaflet which includes the information required by this paragraph must be provided in place of a leaflet in written form;

(b) the packaging of the veterinary medicinal product must include—

(i) a statement that the information which must be included on a package leaflet is provided electronically;

(ii) any necessary electronic link in order to access the relevant part of the website where the electronic package information leaflet is to be found;

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

(iv) instructions on how to obtain such a copy.

(8) Any information required by this paragraph to be provided on a package leaflet in written form may be otherwise provided on the packaging of the veterinary medicinal product.".

Amendment to paragraph 52

65. Omit paragraph 52 (small containers other than ampoules).

Amendment to paragraph 53

66. In paragraph 53(3) (homeopathic remedies)—

(a) for paragraph (c) substitute—

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

(b) after paragraph (k) omit "and";

(c) after paragraph (l) insert "and";

(d) at the end insert—

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

Amendment to paragraph 55

67. Omit paragraph 55 (qualified person responsible for pharmacovigilance).

Amendment to paragraph 56 and new paragraphs 56A, 56B and 56C

68. For paragraph 56 (duties related to qualified person) substitute—

"Duties of marketing authorisation holder in relation to pharmacovigilance

56.—(1) The marketing authorisation holder is responsible for 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 best practice in good veterinary 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 an adequate and effective 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 whose services are available permanently and continuously.

(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 and within appropriate pharmacovigilance agreements.

(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.

(14) The Secretary of State may at any time by notice require a marketing authorisation holder to provide a copy of the pharmacovigilance system master file.

(15) A marketing authorisation holder who is given notice under sub-paragraph (14) must comply with the requirement within seven days of receipt of the notice.

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 on reports received (whether those reports derive from the United Kingdom or any other country) 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 or a change in the benefit-risk balance of the product is identified, the marketing authorisation holder must notify the Secretary of State promptly and in any event within 30 days of such identification.

(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. 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 any relevant requirements in accordance with the process are carried out;

(c) maintain the pharmacovigilance system master file for each 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, if no equivalent to that regulatory measure has already been taken in the United Kingdom;

(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 through the use of audits and routine monitoring;

(h) following any action taken in accordance with paragraph (g), 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.

Signal management process

56C.—(1) For the purposes of these Regulations, "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 must consist of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action.

(3) A signal management process must be capable of identifying, at a minimum, 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 paragraphs (a) to (c).".

Amendment to paragraph 57

69. In paragraph 57 (adverse reactions to product administered in UK)—

(a) in sub-paragraph (1)—

(i) in paragraph (a) for "serious adverse reaction" substitute "adverse event in respect of an animal";

(ii) in paragraph (b)—

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

(bb) omit "or";

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

"(d) occurrence of an adverse environmental event, or

(e) lack of efficacy,";

(iv) omit "in the United Kingdom";

(b) after sub-paragraph (1) insert—

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

(a) after the end of the withdrawal period a product of animal origin is found to include a pharmacologically active substance or marker residue exceeding the maximum residue limit established in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council; or

(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) in sub-paragraph (4) for "reaction" substitute "event";

(e) 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 by which, or the period during which, the requirement must be complied with.";

(f) omit sub-paragraph (5);

(g) for the heading substitute—

"Adverse events following administration of a veterinary medicinal product".

Amendment to paragraph 58

70. Omit paragraph 58 (adverse reactions to product administered outside UK).

Amendment to paragraph 59

71. In paragraph 59 (periodic safety update reports)—

(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 safety update 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) for "the United Kingdom" substitute "Great Britain";

(ii) for "periodic safety update report" substitute "benefit-risk report";

(iii) for the words from "request and—" to the end of the sub-paragraph substitute "request 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) for sub-paragraph (5) substitute—

"(5) The report must include a statement regarding the benefit-risk balance of the veterinary medicinal product.";

(f) for sub-paragraph (6) substitute—

"(6) The annual benefit-risk report must include—

(a) the volume of the product sold in the United Kingdom and in other countries in the period covered by the report, with the volume of the product sold in the United Kingdom in each calendar year identified;

(b) 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); and

(c) 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-paragraphs (7) and (8);

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

Amendment to paragraph 60

72. In paragraph 60 (release of information by marketing authorisation holder)—

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

(b) at the end insert—

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

New paragraphs 60A and 60B

73. After paragraph 60 insert—

"Pharmacovigilance inspections by Secretary of State

60A.—(1) The Secretary of State must, from time to time, inspect the pharmacovigilance systems 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 marketing authorisation holder's history and the nature of the products included in their pharmacovigilance system.

(3) Within 90 days after an inspection, the Secretary of State must issue an inspection report to the holder of the marketing authorisation if the inspection established compliance with best practice in good veterinary pharmacovigilance practice.

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.".

Amendment to paragraph 61

74. In paragraph 61(1) (action taken on account of pharmacovigilance)—

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

(b) in paragraph (c)—

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

(bb) after sub-paragraph (v) insert—

"or

(vi) implement a risk management plan,".

Amendment to paragraph 63

75. In paragraph 63 (placing homeopathic remedy on market in accordance with registration)—

(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".

Amendment to paragraph 64

76. In paragraph 64(1) (application for registration)—

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

(b) in paragraph (b)—

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

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

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

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

(d) for paragraph (g) substitute—

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

(e) for paragraph (h) substitute—

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

Amendment to paragraph 65

77. In paragraph 65 (procedure for registration) at the end insert—

"(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.".

Amendment to paragraph 68

78. In paragraph 68 (offences)—

(a) before sub-paragraph (a) insert—

"(za) paragraph 22A(1);";

(b) after sub-paragraph (d) insert—

"(da) paragraph 28(4);";

(c) omit sub-paragraph (f);

(d) omit sub-paragraph (i);

(e) after sub-paragraph (j) insert—

"(ja) a restriction or requirement made under paragraph 41A;

(jb) a prohibition made under paragraph 41B;";

(f) omit sub-paragraph (k);

(g) after sub-paragraph (l) insert—

"(la) paragraph 56A;

(lb) paragraph 56B;

(lc) paragraph 56C;";

(h) omit sub-paragraph (n).

PART 4

Amendments to Schedule 2 to the 2013 Regulations

Introduction

79. Schedule 2 to the 2013 Regulations (manufacture of veterinary medicinal products) is amended in accordance with this Part.

Amendment to paragraph 1

80. For paragraph 1 (application) 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 Schedule (a "manufacturing authorisation").

(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 another country);

(b) the carrying out of any part of the manufacturing process or 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.".

Amendment to paragraph 2

81. For paragraph 2 (time limits) substitute—

"**Application for authorisation**

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

(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 manufacturing process or of bringing a veterinary medicinal product to its final state, including processing, assembling, packaging or repackaging, labelling or relabelling, storing or sterilising, 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 or imported 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;

(f) the qualifications and a description of the relevant experience of the person proposed to have responsibility for quality control;

(g) the name of the person proposed to have responsibility for production;

(h) the qualifications and a description of the relevant experience of the person proposed to have responsibility for production;

(i) a declaration that the applicant complies with good manufacturing practice and any relevant legislation; and

(j) a declaration that any site mentioned in paragraph (b) is ready for inspection.".

Amendment to paragraph 3

82. For paragraph 3 (granting the authorisation) substitute—

"**Procedure for grant of authorisations and time limits**

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) The Secretary of State must grant the manufacturing authorisation if 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 proposed activities; and

(ii) a documented quality management system in place.

(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—

(a) reject the application; or

(b) grant a conditional manufacturing authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(5) The Secretary of State may extend the period for which a conditional manufacturing authorisation is granted under sub-paragraph (4)(b).

(6) Where a conditional manufacturing authorisation is granted under sub-paragraph (4)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect without those conditions.".

Amendment to paragraph 4

83. In paragraph 4(1) (authorisation)—

(a) in paragraph (a) after "be manufactured" insert ", controlled";

(b) for paragraph (b) substitute—

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

New paragraph 4A

84. After paragraph 4 insert—

"Application for variation to the authorisation

4A.—(1) The holder of a manufacturing authorisation must notify the Secretary of State, and apply for a variation of the authorisation, before—

(a) making a material alteration to the premises or facilities used under the authorisation, or to the operations for which they are used;

(b) changing the qualified person (manufacture), the person with responsibility for quality control or the person with responsibility for production.

(2) The Secretary of State must process an application under sub-paragraph (1) 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.

(3) The Secretary of State must grant the application under sub-paragraph (1) if satisfied in respect of the matters in paragraph 3(3) as regards the proposed variation.

(4) The Secretary of State may inspect any site to which the manufacturing authorisation or proposed variation relates in connection with the application.

(5) Where the Secretary of State is not satisfied for the purposes of sub-paragraph (3), the Secretary of State may—

(a) reject the application; or

(b) grant a conditional variation to the manufacturing authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(6) The Secretary of State may extend the period for which a conditional variation to the marketing authorisation is granted under sub-paragraph (5)(b).

(7) Where a conditional variation to the manufacturing authorisation is granted under sub-paragraph (5)(b) and the deficiency is addressed within the specified period to the

satisfaction of the Secretary of State, the authorisation continues to have effect as so varied without those conditions.".

Amendment to paragraph 5

85. In paragraph 5 (suspension, variation or revocation of authorisation)—

(a) in sub-paragraph (1)—

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

(ii) at the end insert—

"(e) has failed to carry out the activity specified in the authorisation for a period of five 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) In particular, the Secretary of State may—

(a) suspend the manufacture or import of veterinary medicinal products;

(b) suspend, revoke or vary the manufacturing authorisation for one or more pharmaceutical forms;

(c) suspend, revoke or vary the manufacturing authorisation for one or more activities in one or more manufacturing sites.";

(c) in the heading for "Suspension, variation or revocation" substitute "Suspension, revocation etc".

Amendment to paragraph 6

86. In paragraph 6 (inspection of premises)—

(a) in sub-paragraph (1)—

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

(ii) for "registered" substitute "authorised";

(iii) for "premises' history" substitute "site's history";

(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.

(2A) 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).

(2B) 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.

(2C) The importer of a veterinary medicinal product must ensure before importation that the manufacturer of that product has—

(a) a valid certificate of good manufacturing practice issued by the Secretary of State; or

(b) an equivalent certificate issued by a regulatory authority—

(i) with which the Secretary of State has an agreement or arrangement for such purposes; or

(ii) which the Secretary of State considers to have demonstrated equivalent standards to those in the United Kingdom.";

(c) for the heading substitute "Good manufacturing practice certificates and inspection of sites".

Amendment to paragraph 8

87. In paragraph 8 (duties on holder of manufacturing authorisation)—

(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).

(2A) The holder must place at the disposal of any qualified person (manufacture) all necessary documents, premises and technical and other facilities in order to enable that person to discharge their duties as the qualified person.

(2B) Where any qualified person (manufacture) ceases to be available to provide services to 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 available; 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 valid certificate of good manufacturing practice;

(b) use as starting materials only active substances which have been manufactured in accordance with good manufacturing practice and distributed in accordance with good distribution practice for active substances;

(c) verify that each manufacturer, distributor or importer from whom the holder obtains active substances and to which paragraph 26 applies is registered with the Secretary of State under that paragraph;

(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) after sub-paragraph (5) insert—

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

New paragraphs 8A and 8B

88. After paragraph 8 insert—

"Good manufacturing practice

8A.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with this paragraph, whether the manufacturing is performed by the holder or another person.

(2) The manufacturing operations must be conducted in accordance with a written methodology, to be known as the "pharmaceutical quality system" or "PQS".

(3) The PQS must be—

(a) clear;

(b) systematically reviewed from time to time in the light of experience; and

(c) capable of consistently manufacturing veterinary medicinal products which are of the required quality and which meet the requirements of the relevant marketing authorisation.

(4) The critical steps of the manufacturing process set out in the PQS must be validated.

(5) Any significant amendments to the PQS must be validated.

(6) The PQS must provide for—

(a) appropriately qualified and trained personnel;

(b) adequate premises and space;

(c) suitable equipment and access to services;

(d) suitable materials, containers and labelling;

(e) relevant procedures and instructions;

(f) suitable storage and transport;

(g) investigation into complaints and defects.

(7) The PQS must provide for any significant deviations from its provisions to be—

(a) fully recorded, and

(b) investigated, with appropriate corrective and preventative action implemented.

(8) The holder of a manufacturing authorisation must ensure that records of the manufacturing process, including distribution, are kept in a comprehensible and accessible form until the later of—

(a) the date which is five years after the date on which the veterinary medicinal product is placed on the market;

(b) the date which is one year after the expiry date of the batch of veterinary medicinal product.

(9) In this paragraph, a process (or part of a process) is "validated" if scientific evidence is assembled which demonstrates that it is capable of consistently delivering expected results.

Recalled and counterfeit products

8B.—(1) The holder of a manufacturing 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 manufacturing authorisation must record any veterinary medicinal product which is—

(a) recalled (whether or not the holder physically receives the recalled product); or

(b) discovered to be counterfeit.

(3) Where any veterinary medicinal product is recalled and physically received, the qualified person (manufacture) must assess the recalled product in order to determine whether—

(a) the product has been stored (including during transport) in accordance with the summary of product characteristics;

(b) the product is a genuine product and not counterfeit.

(4) Where the qualified person (manufacture) determines that a recalled veterinary medicinal product does not satisfy sub-paragraph (3)(a) or (b), or where it is not possible for the qualified person (manufacture) to determine whether the product does so, the product may not be re-sold.

(5) The qualified person (manufacture) must record any assessment and determination made under sub-paragraphs (3) and (4).

(6) Any veterinary medicinal products which may not be re-sold must be identified, held separately and destroyed and the holder of a manufacturing authorisation must develop a suitable procedure to set out the steps to be taken in accordance with this sub-paragraph.

(7) The holder of a manufacturing authorisation must keep any information recorded under this paragraph for five years.".

Amendment to paragraph 9

89. In paragraph 9 (qualified person for manufacture)—

(a) in sub-paragraph (1), after "any person" insert "(including the manufacturer of a veterinary medicinal product)";

(b) after sub-paragraph (1) insert—

"(1A) For the purposes of sub-paragraph (1), a person has sufficient practical experience if they have been engaged in one or more of the activities mentioned in sub-paragraph (1B) for at least two years in the provision of services to the holder of a manufacturing authorisation.

(1B) For the purposes of sub-paragraph (1A) the activities are—

(a) quality assurance of medicinal products;

(b) qualitative analysis of medicinal products;

(c) quantitative analysis of active substances.

(1C) The Secretary of State may treat the reference in sub-paragraph (1A) to two years of practical experience as a reference to—

(a) one year, where the person's formal course of study lasted for at least five years;

(b) six months, where the person's formal course of study lasted for at least six years."
.

Amendment to paragraph 10

90. In paragraph 10 (refusal or revocation of appointment)—

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

(b) for the heading substitute—

"Refusal, revocation, suspension or variation of appointment".

Amendment to paragraph 13

91. In paragraph 13 (test sites)—

(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.";

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

Amendment to Parts 2 to 5

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 in connection with the treatment of non-food animals;

(c) collect, store and supply blood constituents obtained by the physical separation of donor blood into different fractions within a closed bag system, for the treatment of non-food animals; or

(d) collect, process and store stem cells for use as an autologous treatment in 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 paragraph (b) and (c) of that sub-paragraph.

(3) In this paragraph, a "closed bag system" means a system in which the blood pack assembly is manufactured under clean conditions, sealed to the external environment and sterilised.

Prohibition

15. No person may carry out any activity mentioned in paragraph 14 otherwise than—

(a) in accordance with an authorisation mentioned in that paragraph; or

(b) pursuant to paragraph 1(2) of Schedule 4 (administration under the cascade).

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 two 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 at which the relevant activity is to be carried out (whether in the occupation of the proposed holder or otherwise) and a description of the technical equipment on the site;

(d) particulars in relation to the qualifications and experience of the proposed 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 out 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 for the purposes of a non-food animal blood bank other than a veterinary surgeon or a person acting 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 to a non-food producing animal.

(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 for the purposes of treating animals other than a veterinary surgeon or a person acting under the responsibility of a veterinary surgeon.

(2) No person may 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 notwithstanding sub-paragraph (1) where there is difficulty in relation to the supply of the authorised veterinary medicinal product.

(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.

(5) For the purposes of this paragraph, a product is the pharmaceutical equivalent of an authorised veterinary medicinal product if—

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

(b) it has the same pharmaceutical form.

Suspension, compulsory variation or revocation of authorisation

21. The Secretary of State may by notice suspend, 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 authorised under paragraph 14(1), that person has manufactured a veterinary medicinal product pursuant to that authorisation that is not within its scope;

(f) the holder has not conducted an activity relating to the authorisation for five years or more;

(g) the holder has not paid any fee required under these Regulations; or

(h) the holder has not complied with any other provision in these Regulations.

Labelling

22.—(1) The holder of an authorisation under paragraph 14 must ensure that every container used is labelled with—

(a) a precise description of the product;

(b) the date on which the product was produced;

(c) the name and address of the authorisation holder;

(d) the address of the site named under the authorisation and its authorisation number;

(e) the instructions for use;

(f) the expiry date;

(g) any necessary warnings;

(h) 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;

(i) in the case of blood or a stem cell product—

(i) the identification of the donor animal; and

(ii) the date of collection.

(2) In the case of blood or blood constituents there must be no specific therapeutic indication on the label or on 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 under paragraph 14 must, as soon as is reasonably practicable after the product is supplied, 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 five 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. The Secretary of State must inspect any site authorised under paragraph 14, 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.".

New Part 2A and Part 2B

93. After Part 2 (as substituted by the previous regulation) insert—

"PART 2A

Active Substances

Prohibition on manufacture, importation or distribution of active substances unless registered

26.—(1) No person may manufacture, import or distribute an active substance unless the person is registered in the register maintained 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

27.—(1) An applicant for registration under paragraph 26 must, at least two months before commencing an activity mentioned in paragraph 26(1) or, in the case of an existing manufacturer, within two 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).

(2) Information may be submitted to the Secretary of State pursuant to sub-paragraph (1) prior to the date on which this provision comes into force, and in such a case—

(a) as regards an applicant for registration who is not an existing manufacturer, the relevant period of two months is to be treated as having started on the date of submission;

(b) as regards an applicant for registration who is an existing manufacturer, the information is to be treated as having been submitted within the relevant period of two months.

Good manufacturing or distribution practice

28. A manufacturer, importer or distributor of active substances must comply with good manufacturing practice or good distribution practice, as applicable.

Supply of information

29.—(1) A person registered under paragraph 26 must immediately inform the Secretary of State on receipt of any new information that might adversely affect the quality and safety of the active substance.

(2) A person registered under paragraph 26 must immediately inform the Secretary of State of any prohibition or restriction in relation to the active substance imposed by the competent authorities of any country other than the United Kingdom in which the active substance is authorised.

Inspection of sites

30. The Secretary of State may, from time to time, inspect sites registered under paragraph 26, basing the frequency of the inspections on the risks associated with each site's history and the nature of the substances handled at the site.

Report following inspection

31.—(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 requirements in this Part are being complied with.

(2) The Secretary of State must inform the inspected registered person of the content of such reports.

PART 2B

Schedule 2 Offences

Offences

32. It is an offence to fail to comply with—

(a) paragraph 1;

(b) paragraph 4(3);

(c) paragraph 8;

(d) paragraph 11;

(e) paragraph 15;

(f) paragraph 18;

(g) paragraph 19;

(h) paragraph 20(1), (3) or (4);

(i) paragraph 22;

(j) paragraph 23;

(k) paragraph 24;

(l) paragraph 26;

(m) paragraph 28;

(n) paragraph 29.".

PART 5

Amendments to Schedule 3 to the 2013 Regulations

Introduction

94. Schedule 3 to the 2013 Regulations (classification and supply, wholesale dealers and sheep dip) is amended in accordance with this Part.

Amendment to paragraph 1

95. In paragraph 1 (classification of veterinary medicinal products)—

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

"(c) products containing an antimicrobial;

(d) products for the purpose of euthanasia;

(e) products with a hormonal or thyrostatic function;

(f) products containing beta-agonists";

(b) in sub-paragraph (5)—

(i) at the end of paragraph (c) omit "and";

(ii) at the end insert—

"(e) immunological veterinary medicinal products.";

(c) in sub-paragraph (6)—

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

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

Amendment to paragraph 2

96. In paragraph 2 (wholesale supply of veterinary medicinal products)—

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

(b) in sub-paragraph (2)(b) after "the supply" insert "is to the holder of a manufacturing authorisation or";

(c) 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).".

Amendment to paragraph 3

97. In paragraph 3(6) (retail supply of veterinary medicinal products) for paragraph (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".

New paragraphs 3A, 3B, 3C, 3D and 3E

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.

Register of online suppliers of veterinary medicinal products

3B.—(1) No person may supply or offer to supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS 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) appears on the register maintained 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.—(1) An applicant for registration under paragraph 3B must, at least two 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 two 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.

(2) Information may be submitted to the Secretary of State pursuant to sub-paragraph (1) prior to the date on which this provision comes into force, and in such a case—

(a) as regards an applicant for registration who is not an existing supplier of veterinary medicinal products by means of the internet, the relevant period of two months is to be treated as having started on the date of submission;

(b) as regards an applicant for registration who is an existing supplier of veterinary medicinal products by means of the internet, the information is to be treated as having been submitted within the relevant period of two months.

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) the statement "registered internet retailer of veterinary medicines";

(b) the contact details of the Secretary of State; and

(c) a link to the published register.

Retail storage of veterinary medicinal products

3E. A retailer of veterinary medicinal products must store (including during transport) 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.".

Amendment to paragraph 4

99. In paragraph 4(1) (prescriptions by veterinary surgeon) after "POM-V" insert "or a veterinary medicinal product under the cascade".

Amendment to paragraph 5

100. In paragraph 5 (prescriptions)—

(a) in sub-paragraph (1)—

(i) for "oral" substitute "verbal";

(ii) after "POM-VPS" insert "or a veterinary medicinal product prescribed under the cascade";

(b) after sub-paragraph (1) insert—

"(1A) Where a veterinary medicinal product is supplied in accordance with a prescription which is not a written 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 five years from the date on which the product is prescribed";

(c) after paragraph (3) insert—

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

Amendment to paragraph 6

101. In paragraph 6 (written prescriptions) for sub-paragraph (1) substitute—

"(1) A written prescription must include—

(a) the full name, address and contact details of the person prescribing the product, including that person's professional registration number (if available);

(b) the full name, address 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) as regards veterinary medicinal products that are antibiotics which are prescribed for prophylactic purposes or metaphylactic purposes (as the case may be), a statement to that effect;

(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 the professional obligations of a veterinary surgeon to ensure the health and welfare of animals under their care, a veterinary surgeon may only prescribe a veterinary medicinal product that is an antibiotic where 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.".

Amendment to paragraph 7

102. In paragraph 7 (duties when a product is prescribed or supplied)—

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

(b) in that sub-paragraph after "who prescribes" insert "a veterinary medicinal product under the cascade or";

(c) after that sub-paragraph insert—

"(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.".

New paragraph 7A

103. After paragraph 7 insert—

"Duties in relation to prescribing of antibiotic veterinary medicinal products

7A.—(1) Subject to sub-paragraphs (2) and (3) a veterinary surgeon may not prescribe a veterinary medicinal product which is an antibiotic for prophylactic purposes.

(2) Without prejudice to paragraph 6(1A), a veterinary surgeon may only prescribe a veterinary medicinal product which is an antibiotic 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 veterinary surgeon may only prescribe a veterinary medicinal product which is an antibiotic 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 rationale for prescribing the product to the group of animals is clearly recorded by the veterinary surgeon prescribing it; and

(b) a management review is carried out by a veterinary surgeon 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.

(5) A veterinary surgeon who prescribes a veterinary medicinal product which is an antibiotic must make a record 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 five years.".

Amendment to paragraph 10

104. In paragraph 10(1) (supply by a pharmacist)—

(a) in the words before paragraph (a), after "NFA-VPS" insert ", or prescribed under the cascade,";

(b) in paragraph (c) for "approved" substitute "authorised".

Amendment to paragraph 11

105. In paragraph 11 (supply for incorporation into feedingstuffs)—

(a) for "approved", in each place it occurs, substitute "authorised";

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

(c) in sub-paragraph (2)—

(i) for "veterinary medicinal product", in both places it occurs, substitute "medicinal premix";

(ii) in the words before paragraph (a) omit "The marketing authorisation holder,";

(iii) in paragraph (b) for "premixture" substitute "intermediate feedingstuffs";

(iv) in paragraph (c) for "prescription" substitute "medicated feedingstuffs prescription";

(d) in sub-paragraph (3)—

(i) for "veterinary medicinal product", in both places it occurs, substitute "medicinal premix";

(ii) in paragraph (a) for "premixture" substitute "intermediate feedingstuffs";

(iii) in paragraph (b)—

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

(bb) after "a prescription" insert "for medicated feedingstuffs";

(e) for sub-paragraph (4) substitute—

"(4) This paragraph does not apply in relation to a feedingstuffs manufacturer approved to incorporate a medicinal premix who supplies another such feedingstuffs manufacturer with medicinal premix where the purpose of that supply is to alleviate a temporary supply shortage that could be detrimental to animal welfare.";

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

Amendment to paragraph 13

106. In paragraph 13(2)(a) (supply for use under the cascade)—

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

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

Amendment to paragraph 14

107. In paragraph 14 (supply by suitably qualified person)—

(a) for "approved", in each place it occurs, substitute "authorised";

(b) for "approval", in each place it occurs, substitute "authorisation";

(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) in sub-paragraph (7), after "suitably qualified persons" insert "and bodies recognised under this paragraph";

(e) after sub-paragraph (10) insert—

"(11) The Secretary of State must, from time to time, inspect premises authorised under sub-paragraph (4)(a) basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(12) 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 any Code of Practice issued under this paragraph.".

Amendment to paragraph 15

108. For paragraph 15 (annual audit) 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 five years from the date of the audit and the Secretary of State may require the retailer to provide a copy of them at any time within that period.".

Amendment to paragraph 16

109. For paragraph 16 (application) substitute—

"Wholesale dealer's authorisation

16. No person may carry out any wholesale dealing in veterinary medicinal products otherwise than in accordance with an authorisation granted under paragraph 18(2) (a "wholesale dealer's authorisation").".

Amendment to paragraph 17

110. For paragraph 17 (time limits) substitute—

"**Application for authorisation**

17.—(1) An application for a wholesale dealer's authorisation (which must be submitted to the Secretary of State electronically) must include the matters mentioned in sub-paragraph (2).

(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 from which wholesale dealing of veterinary medicinal products is to take place;

(c) evidence that the sites mentioned in paragraph (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 person nominated to act in accordance with good distribution practice (the "wholesale qualified person");

(e) the qualifications and a description of the relevant experience of the wholesale qualified person;

(f) a description of the veterinary medicinal products proposed to be dealt in under the authorisation;

(g) evidence that the proposed holder of the authorisation has available to it the services of technically competent staff;

(h) evidence that the proposed holder of the authorisation has in place—

(i) an effective emergency recall plan; and

(ii) a quality system;

(i) a declaration that the applicant complies with good distribution practice and any relevant legislation;

(j) a declaration that any site mentioned in paragraph (b) is ready for inspection.".

Amendment to paragraph 18

111. For paragraph 18 (granting authorisation) 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; and

(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—

(a) reject the application; or

(b) grant a conditional wholesale dealer's authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(4) The Secretary of State may extend the period for which a conditional wholesale dealer's authorisation is granted under sub-paragraph (3)(b).

(5) Where a conditional wholesale dealer's authorisation is granted under sub-paragraph (3)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect without those conditions.".

Amendment to paragraph 19

112. For paragraph 19 (authorisation) substitute—

"**Periodic inspections and suspension etc. for lack of use**

19.—(1) The Secretary of State must, from time to time, inspect the sites from which wholesale dealing of veterinary medicinal products takes place pursuant to a wholesale dealer's authorisation 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.

(2) The Secretary of State may suspend, vary or revoke a wholesale dealer's authorisation if, in respect of any one of the sites covered by that authorisation, the holder does not deal in veterinary medicinal products from that site for five years.".

New paragraph 19A

113. After paragraph 19 insert—

"Application for variation to the authorisation

19A.—(1) 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.

(2) The Secretary of State must process an application under sub-paragraph (1) 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.

(3) The Secretary of State must grant the application under sub-paragraph (1) if satisfied in respect of the matters in paragraph 18(2) as regards the proposed variation.

(4) The Secretary of State may inspect any site to which the wholesale dealer's authorisation or proposed variation relates in connection with the application.

(5) Where the Secretary of State is not satisfied for the purposes of sub-paragraph (3), the Secretary of State may—

(a) reject the application; or

(b) grant a conditional variation to the wholesale dealer's authorisation for a period specified by the Secretary of State until the deficiency has been addressed.

(6) The Secretary of State may extend the period for which a conditional variation to the wholesale dealer's authorisation is granted under sub-paragraph (5)(b).

(7) Where a conditional variation to the wholesale dealer's authorisation is granted under sub-paragraph (5)(b) and the deficiency is addressed within the specified period to the satisfaction of the Secretary of State, the authorisation continues to have effect as so varied without those conditions.".

Amendment to paragraph 20

114. For paragraph 20(b) (suspension, variation or revocation of authorisation) substitute—

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

Amendment to paragraph 21

115. In paragraph 21 (duties on holder of wholesale dealer's authorisation)—

(a) for sub-paragraph (b) substitute—

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

(b) omit sub-paragraph (c) (and the "and" following it);

(c) in sub-paragraph (d), at the end insert—

"; and

(e) notify the Secretary of State (and in relation to paragraph (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".

New paragraphs 21A, 21B, 21C, 21D, 21E and 21F

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

"Register 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;

(b) the strength and pharmaceutical form;

(c) the date on which the veterinary medicinal product was supplied;

(d) the quantity of product supplied;

(e) the batch number;

(f) the expiry date;

(g) the name and address of the wholesale dealer supplying the product;

(h) the means by which the product was transported and the required conditions of storage;

(i) the name of the person to whom the product was supplied and the address to which it is to be 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 five years.

Recalled, counterfeit or returned 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 (whether or not the holder physically receives the recalled product);

(b) discovered to be counterfeit; or

(c) returned.

(3) Where any veterinary medicinal product is recalled or returned and physically received, the wholesale qualified person must assess the product received in order to determine whether the product has been stored (including during transport) in accordance with the summary of product characteristics.

(4) Where a recalled or returned veterinary medicinal product has not been stored (including during transport) in accordance with the summary of product characteristics or where it is not possible for the wholesale qualified person to determine whether the product has been stored in accordance with the summary of product characteristics, 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 five 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—

(a) make a record of that fact,

(b) conduct an investigation for the purpose of discovering the cause of the discrepancy, and

(c) maintain records of that investigation.

(3) The holder must keep the records mentioned in sub-paragraphs (1) and (2) for a period of five years from the date of the audit and the Secretary of State may require the holder to provide a copy of them 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 programme

21F.—(1) 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 at least once a year in order to ensure that it is complying with good distribution practice.

(2) Where, as a result of the self-inspection mentioned in sub-paragraph (1), the holder identifies any non-compliance the holder must—

(a) make a record of that fact,

(b) conduct an investigation for the purpose of discovering the cause of the non-compliance, and

(c) maintain records of that investigation.

(3) The holder must keep the records mentioned in sub-paragraph (2) for a period of five years from the date of the audit and the Secretary of State may require the holder to provide a copy of them at any time within that period.".

Amendment to paragraph 23

117. In paragraph 23(1) (use of sheep dip) for the words from the beginning to "holds either" substitute "No person may use sheep dip which contains a veterinary medicinal product unless they hold, or they are acting under the supervision and in the presence of a person who holds, either".

Amendment to paragraph 24

118. In paragraph 24 (offences)—

(a) after sub-paragraph (b) insert—

"(ba) paragraph 3A;

(bb) paragraph 3B;

(bc) paragraph 3C;

(bd) paragraph 3D;

(be) paragraph 3E;";

(b) after sub-paragraph (d) insert—

"(da) paragraph 6;";

(c) after sub-paragraph (e) insert—

"(ea) paragraph 7A;";

(d) after sub-paragraph (m) insert—

"(ma) paragraph 16;";

(e) omit sub-paragraph (n);

(f) after sub-paragraph (o) insert—

"(oa) paragraph 21B;

(ob) paragraph 21C;

(oc) paragraph 21D;

(od) paragraph 21E;

(oe) paragraph 21F;".

PART 6

Amendments to Schedule 4 to the 2013 Regulations

Introduction

119. Schedule 4 to the 2013 Regulations (administration outside terms of marketing authorisation) is amended in accordance with this Part.

Amendment to paragraph 1

120. In paragraph 1 (administration under the cascade)—

(a) in sub-paragraph (4)—

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

(ii) at the end insert "or substances which do not fall within the scope of Regulation (EC) No 470/2009 of the European Parliament and of the Council";

(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 of the European Parliament and of the Council must be complied with.".

Amendment to paragraph 2

121. In paragraph 2 (withdrawal periods)—

(a) for sub-paragraph (2) substitute—

"(2) The withdrawal period must ensure that—

(a) where there is a maximum residue limit established for the active substance for the treated species under Regulation (EC) No 470/2009 of the European Parliament and of the Council, the level of residue of the active substance does not exceed that limit; and

(b) where there is no maximum residue limit for the treated species established under Regulation (EC) No 470/2009 of the European Parliament and of the Council but one is established for the substance itself, the level of residue of the active substance does not exceed the level determined by reference to Commission Implementing Regulation (EU) 2018/470 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC(**a**).";

(b) in sub-paragraph (3)—

(i) for paragraph (a) substitute—

"(a) for eggs—

(i) the longest withdrawal period in the summary of product characteristics for any species multiplied by a factor of 1.5; or

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(**a**) EUR 2018/470.

(ii) 14 days, if the product is not authorised for animals producing eggs for human consumption;";

(ii) for paragraph (b) substitute—

"(b) for milk—

(i) the longest withdrawal period in the summary of product characteristics for any species multiplied by a factor of 1.5;

(ii) 7 days, if the veterinary medicinal product is not authorised for animals producing milk for human consumption; or

(iii) 1 day, if the medicinal product has a zero-hour withdrawal period;";

(iii) for paragraph (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 product characteristics for meat and offal, multiplied by a factor of 1.5;

(ii) 28 days if the veterinary medicinal product is not authorised for food-producing animals; or

(iii) 1 day, if the veterinary medicinal product has a zero-day withdrawal period;";

(iv) for paragraph (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 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) insert—

"(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.".

Amendment to paragraph 4

122. In paragraph 4 (immunological products for serious epizootic disease)—

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

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

New paragraph 6A

123. After paragraph 6 (administration by veterinary surgeons from other countries) insert—

"Administration of autogenous vaccines

6A.—(1) An autogenous vaccine may only be administered to animals in exceptional circumstances where no suitable 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 prescription under the cascade.".

Amendment to paragraph 9

124. In paragraph 9 (administration under animal test certificate)—

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

(b) in sub-paragraph (4)—

(i) for "serious adverse reaction" substitute "adverse event";

(ii) for "15 days" substitute "30 days".

New paragraph 9A

125. After paragraph 9 insert—

"Misuse of the cascade

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

Amendment to paragraph 10

126. In paragraph 10 (offences)—

(a) before sub-paragraph (a) insert—

"(za) paragraph 2;";

(b) in sub-paragraph (b) omit "or";

(c) after sub-paragraph (b) insert—

"(ba) paragraph 6A;";

(d) in sub-paragraph (c) for "(4)." substitute "(4); or";

(e) after sub-paragraph (c) insert—

"(d) paragraph 9A.".

PART 7

Amendments to Schedule 5 to the 2013 Regulations

Introduction

127. Schedule 5 to the 2013 Regulations (medicated feedingstuffs and specified feed additives) is amended in accordance with this Part.

Amendment to paragraph 1

128. In paragraph 1(3) (interpretation)—

(a) omit the definition of "premixture";

(b) at the appropriate place 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;

"cross-contamination" means contamination of a non-target feed with an active substance originating from the previous use of the relevant facilities or equipment;

"distributor" means a feed business operator distributing specified feed additives, intermediate feedingstuff or complete feed containing specified feed additives, or intermediate feedingstuff or complete feed containing medicinal premixes;

"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 their 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;

"non-target feed" means feed, whether medicated or not which is not intended to contain a specific active substance;

"premises" means any unit of a feed business;".

Amendment to paragraph 3

129. In paragraph 3(3) (enforcement of Regulation (EC) No 1831/2003) for "a premixture" substitute "an intermediate feedingstuff".

Amendment to paragraph 7

130. In paragraph 7 (approval of manufacturers and distributors of feedingstuffs containing veterinary medicinal products)—

(a) in sub-paragraph (2)—

(i) for "veterinary medicinal product", in each place it occurs, substitute "medicinal premix";

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

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

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

(b) in sub-paragraph (3)—

(i) for "approval", in both places it occurs, substitute "authorisation";

(ii) for "establishments" substitute "premises";

(c) in sub-paragraph (4) for "approved" substitute "authorised";

(d) for sub-paragraph (5) substitute—

"(5) A manufacturer must ensure that, so far as is reasonably practical the medicinal premix is evenly incorporated and homogeneously dispersed throughout the feedingstuffs, taking into account the specific properties of the medicinal premix and the mixing technology employed.";

(e) in sub-paragraph (6) for "veterinary medicinal product" substitute "medicinal premix";

(f) in sub-paragraph (7) for "approval" substitute "authorisation";

(g) in the heading—

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

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

Amendment to paragraph 8

131. In paragraph 8 (incorporation of veterinary medicinal product into premixture)—

(a) for “veterinary medicinal product”, in both places it occurs, substitute “medicinal premix”;

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

(c) in the heading for “veterinary medicinal product into a premixture” substitute “medicinal premix into an intermediate feedingstuff”.

Amendment to paragraph 10

132. In paragraph 10 (incorporation of veterinary medicinal product into feedingstuffs)—

(a) for “veterinary medicinal product”, in each place it occurs other than the occurrence dealt with in sub-paragraph (b), substitute “medicinal premix”;

(b) for “a premixture containing a veterinary medicinal product” substitute “an intermediate feedingstuff”;

(c) in sub-paragraph (c) for “prescription” substitute “medicated feedingstuff prescription”;

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

Amendment to paragraph 11

133. In paragraph 11 (additional record keeping requirements)—

(a) in sub-paragraph (1)—

(i) in paragraph (a)—

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

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

(ii) in paragraph (b)—

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

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

(iii) in paragraph (c) for “veterinary medicinal product” substitute “medicinal premix”;

(iv) in paragraph (d)—

(aa) for “veterinary medicinal products” substitute “medicinal premixes”;

(bb) for “premixture” substitute “intermediate feedingstuffs”;

(v) in paragraph (e)—

(aa) for “premixture” substitute “intermediate feedingstuffs”;

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

(b) in sub-paragraph (2)—

(i) for “approved” substitute “authorised”;

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

(iii) for “veterinary medicinal products” substitute “medicinal premixes”;

(c) in sub-paragraph (3)—

(i) in paragraph (c) for “premixture” substitute “intermediate feedingstuffs”;

(ii) in paragraph (e) for “veterinary medicinal product” substitute “medicinal premix”;

(iii) after paragraph (e) omit “and”;

(iv) after paragraph (f) insert—

"; and

(g) the batch number.";

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

Amendment to paragraph 12

134. In paragraph 12 (labelling a premixture containing veterinary medicinal product)—

(a) in sub-paragraph (1)—

(i) in the words before paragraph (a)—

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

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

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

(iii) in paragraph (b) for "veterinary medicinal product" substitute "medicinal premix";

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

(v) in paragraph (d)—

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

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

(vi) after paragraph (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 may contribute to antimicrobial resistance";";

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

(viii) in paragraph (h) at the end insert "required by the marketing authorisation";

(ix) in paragraph (i) for "prescription" substitute "medicated feedingstuffs prescription";

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

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

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

(e) in the heading—

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

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

Amendment to paragraph 14

135. In paragraph 14 (labelling of feedingstuffs containing veterinary medicinal product)—

(a) in sub-paragraph (1)—

(i) for "veterinary medicinal product", in each place it occurs, substitute "medicinal premix";

(ii) after paragraph (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 may contribute to antimicrobial resistance";";

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

(iv) after paragraph (f) insert—

"(fa)the batch number;";

(v) in paragraph (i) for "prescription" substitute "medicated feedingstuffs prescription";

(vi) in paragraph (j) for "approval" substitute "authorisation";

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

(c) in sub-paragraph (4) after "feedingstuffs" insert "containing a medicinal premix";

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

Amendment to paragraph 15

136. In paragraph 15 (supply of specified feed additives)—

(a) for "approved", in each place it occurs, substitute "authorised";

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

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

Amendment to paragraph 16

137. In paragraph 16 (supply of premixture)—

(a) for "approved", in each place it occurs, substitute "authorised";

(b) in sub-paragraph (1) for "a premixture", in both places it occurs, substitute "an intermediate feedingstuff or specified feed additive";

(c) in sub-paragraph (2) for "premixture", in both places it occurs, substitute "intermediate feedingstuff or specified feed additive";

(d) in sub-paragraph (3) for "premixture" substitute "intermediate feedingstuff or specified feed additive";

(e) in the heading for "premixture" substitute "intermediate feedingstuff or specified feed additive".

Amendment to paragraph 17

138. In paragraph 17 (supply of complementary feedingstuff)—

(a) for "approved", in each place it occurs, substitute "authorised";

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

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

(d) omit sub-paragraph (4).

Amendment to paragraph 18

139. In paragraph 18 (supply of feedingstuffs containing veterinary medicinal product)—

(a) for "approved", in each place it occurs, substitute "authorised";

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

(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)—

(i) for “a person who keeps animals” substitute “an animal keeper”;

(ii) 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) after sub-paragraph (7) insert—

“(8) Nothing in this paragraph prevents a commercial feed manufacturer from incorporating a medicinal premix with a feedingstuff in advance of receiving a written prescription for that feedingstuff.”;

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

Amendment to paragraph 19

140. In paragraph 19 (prescriptions for feedingstuffs containing veterinary medicinal product)—

(a) in sub-paragraph (1)—

(i) for “prescription” substitute “medicated feedingstuff prescription”;

(ii) for “veterinary medicinal product”, in both places it occurs, substitute “medicinal premix”;

(iii) after paragraph (e) insert—

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

(iv) for paragraph (h) substitute—

“(h) the name, active substance, amount of the product prescribed and inclusion rate of the medicinal premix and resulting inclusion rate of the active substance;”;

(v) after paragraph (j) insert—

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

(vi) in paragraph (l)—

(aa) for “approved” substitute “authorised”;

(bb) at the end insert “, whichever is the supplier to the end user”;

(vii) after paragraph (n) insert—

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

(viii) omit paragraph (o);

(b) in sub-paragraph (2) for “prescription” substitute “medicated feedingstuff prescription”;

(c) after sub-paragraph (2) insert—

“(2A) In the case of a prescription to which sub-paragraph (1) applies which relates to an antibiotic, the time between a prescription being issued and the course of treatment starting must be no more than five working days.

(2B) Subject to paragraph 7A in Schedule 3, a prescription for a medicated feedingstuff containing a medicinal premix which includes an antibiotic may not be issued for prophylactic purposes.”.

(d) 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.”;

(e) in the heading—

(i) for “Prescriptions” substitute “Medicated feedingstuff prescriptions”;

(ii) for “veterinary medicinal product” substitute “medicinal premix”.

Amendment to paragraph 20

141. In paragraph 20 (writing the prescription)—

(a) in sub-paragraph (1)—

(i) in the words before paragraph (a) for "prescription" substitute "medicated feedingstuff prescription";

(ii) in paragraph (a)—

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

(bb) at the end insert ", whichever is the supplier to the end user";

(b) in sub-paragraph (2) for "veterinary medicinal product", in both places it occurs, substitute "medicinal premix";

(c) in paragraph (3)—

(i) for "veterinary medicinal product", in each place it occurs, substitute "medicinal premix";

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

(d) in the heading for "prescription" substitute "medicated feedingstuff prescription".

Amendment to paragraph 21

142. In paragraph 21 (possession)—

(a) in sub-paragraph (1)—

(i) in the words before paragraph (a) for "approval" substitute "authorisation";

(ii) in paragraph (a) for "veterinary medicinal product" substitute "medicinal premix";

(iii) in paragraph (b)—

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

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

(iv) in paragraph (c) for "such an additive or a veterinary medicinal product" substitute "a medicinal premix";

(b) in sub-paragraph (2)—

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

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

Amendment to paragraph 22

143. In paragraph 22 (sampling and analysis), 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%".

New paragraph 22A

144. 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 non-target feeds 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 has occurred which is 1% or more but less than 3% compared to the authorised maximum content, 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 has occurred of 3% or more compared to the authorised maximum content, the feed business operator must conduct an investigation in order to discover the cause of the occurrence and make a record of the fact and any conclusions.

(5) The feed business operator must keep the records under sub-paragraphs (3) and (4) for at least five years.

(6) Upon request of the Secretary of State, the feed business operator must provide any information in the feed business operator's possession relating to the matters mentioned in this paragraph.".

Amendment to paragraph 23

145. In paragraph 23 (storage)—

(a) for "veterinary medicinal product", in both places it occurs, substitute "medicinal premix";

(b) for "a premixture" substitute "an intermediate feedingstuff".

Amendment to paragraph 24

146. In paragraph 24 (packages and other containers) for "veterinary medicinal product" substitute "medicinal premix".

Amendment to paragraph 25

147. In paragraph 25 (transport)—

(a) in sub-paragraph (2) for "veterinary medicinal products" substitute "medicinal premixes";

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

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

Amendment to paragraph 26

148. In paragraph 26 (possession, placing on market and use of feedingstuffs)—

(a) in sub-paragraph (1) for "veterinary medicinal products" substitute "medicinal premixes";

(b) in sub-paragraph (2), for "veterinary medicinal product", in each place it occurs, substitute "medicinal premix";

(c) 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 in respect of any such product 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 such product.";

(d) in sub-paragraph (3) for "veterinary medicinal product" substitute "medicinal premix".

New paragraph 26A

149. After paragraph 26 insert—

"Unused and expired medicated feedingstuffs

26A. No person may feed medicated feedingstuffs which have passed their expiry date to an animal.".

Amendment to paragraph 28

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

Amendment to paragraph 29

151. In paragraph 29 (import for incorporation into premixture or feedingstuffs for export)—

(a) in sub-paragraph (1) for "premixture", in both places it occurs, substitute "intermediate feedingstuffs";

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

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

Amendment to paragraph 30

152. In paragraph 30 (animals on domestic premises)—

(a) in sub-paragraph (1)—

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

(ii) for "veterinary medicinal product", in both places it occurs, substitute "medicinal premix";

(b) in sub-paragraph (2)—

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

(ii) for "veterinary medicinal product", in both places it occurs, substitute "medicinal premix";

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

Amendment to paragraph 31

153. In paragraph 31 (offences)—

(a) after sub-paragraph (p) insert—

"(pa) paragraph 19;";

(b) after sub-paragraph (r) insert—

"(ra)paragraph 22A;";

(c) in sub-paragraph (v) for "or (2)" substitute ", (2), (2A), (2B) or (2C)";

(d) after sub-paragraph (v) insert—

"(va) paragraph 26A;".

PART 8

Amendments to Schedule 6 to the 2013 Regulations

Introduction

154. Schedule 6 to the 2013 Regulations (exemptions for small pet animals) is amended in accordance with this Part.

Amendment to paragraph 2

155. In paragraph 2 (placing on market, import and administration) at the end insert "and the manufacturer appears on the register maintained under paragraph 3A".

Amendment to paragraph 3

156. In paragraph 3 (manufacture) for sub-paragraph (2) substitute—

"(2) Sub-paragraph (1)(d) does not apply where the United Kingdom has a formal agreement with the exporting country that includes mutual recognition of good manufacturing practice or where the Secretary of State is satisfied that the exporting country requires manufacturers of veterinary medicinal products to apply standards of good manufacturing practice which are at least equivalent to those in Great Britain.".

New paragraphs 3A and 3B

157. After paragraph 3 insert—

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

3A.—(1) A person placing the product on the market must be registered in accordance with this paragraph.

(2) An application for registration in respect of that person must be submitted under sub-paragraph (4)—

(a) at least two months before that person places the product on the market, or

(b) where that person has already placed the product on the market, within six months of the date on which this provision comes into force.

(3) Information may be submitted to the Secretary of State pursuant to sub-paragraph (2) prior to the date on which this provision comes into force, and in such a case—

(a) as regards an applicant for registration who has not already placed the product on the market, the period of two months is to be treated as having started on the date of submission;

(b) as regards an applicant for registration who has already placed the product on the market, the information is to be treated as having been submitted within the period of six months.

(4) An application for registration must be made to the Secretary of State electronically and must include—

(a) the name and address of the person placing the product on the market;

(b) the individual making the application in respect of that person;

(c) the telephone number and email address of the individual 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 (where applicable) route of administration;

(h) the dosage instructions;

(i) the category of animal mentioned in paragraph 1 for which the product is intended.

(5) 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.

(6) 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 each calendar year a person registered under paragraph 3A must notify the Secretary of State in writing of the following in respect of each product placed on the market—

(a) the name and registered address of the person (if different from that listed on the register);

(b) the individual designated for the purpose of making the annual return under this paragraph;

(c) the telephone number and email address of the individual 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 (where applicable) route of administration;

(h) the dosage instructions;

(i) the category of animal mentioned in paragraph 1 for which the product is intended.

".

Amendment to paragraph 4

158. In paragraph 4(4)(b) (approval of active substance) for "serious adverse reactions" substitute "adverse events".

Amendment to paragraph 9

159. In paragraph 9 (adverse reactions)—

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

(b) in paragraph (a) for "adverse reactions (as defined in paragraph 57 of Schedule 1)" substitute "adverse events";

(c) in paragraph (b) for "adverse reaction", in both places it occurs, substitute "adverse event";

(d) omit sub-paragraph (2);

(e) in the heading for "Adverse reactions" substitute "Adverse events".

New paragraph 10

160. After paragraph 9 insert—

"Offences

10. It is an offence to fail to comply with—

(a) paragraph 3A(1);

(b) paragraph 3B; or

(c) paragraph 9(1).".

PART 9

Amendments to Schedule 7 to the 2013 Regulations

Introduction

161. Schedule 7 to the 2013 Regulations (fees) is amended in accordance with this Part.

Amendment to paragraph 1

162. In paragraph 1 (interpretation)—

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

(b) in sub-paragraph (1), in the definition of "pharmaceutical product", at the end insert "or a biological veterinary medicinal product that is not immunological";

(c) after that sub-paragraph insert—

"(2) For the purposes of this Schedule "manufacturing authorisation" means the following activities—

(a) manufacture or import of an authorised veterinary medicinal product;

(b) manufacture of a product to which paragraph 2 of 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.".

Amendment to paragraph 4

163. In paragraph 4 (multiple inspections)—

(a) omit ", approval";

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

Amendment to paragraph 7

164. In paragraph 7 (specified pharmaceutical applications)—

(a) after "a pharmaceutical" insert ", immunological or biological that is not immunological";

(b) in sub-paragraph (a)—

(i) at the end of paragraph (i) insert ", or";

(ii) in paragraph (ii)—

(aa) after "application" insert "for a pharmaceutical veterinary medicinal product";

(bb) omit "or";

(iii) omit paragraph (iii);

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

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

(d) in the heading, after "pharmaceutical" insert ", immunological or biological that is not immunological".

New paragraph 7A

165. After paragraph 7 insert—

"Application for a marketing authorisation for specific applications

7A. The fee for an application for a marketing authorisation which involves one or more of 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.".

Amendment to paragraph 9

166. Omit paragraph 9 (application for marketing authorisation for immunological or biosimilar product).

Amendment to paragraph 11

167. For paragraph 11 (application for marketing authorisation based on informed consent) 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*
Application	1,465".

Amendment to paragraph 13

168. In paragraph 13 (application for exceptional marketing authorisation – immunological)—

(a) after "immunological product", in both places it occurs, insert "or a biological veterinary medicinal product that is not immunological";

(b) in the heading, for "(immunological)" substitute "(immunological or biological non-immunological)".

Amendment to paragraph 15

169. Omit paragraph 15 (application for marketing authorisation for parallel import).

New paragraph 15A

170. After paragraph 15 insert—

"Fee for a generic marketing authorisation

15A.—(1) The fee for a marketing authorisation in respect of a generic veterinary medicinal product is to be calculated in accordance with the following table.

Application	*Fee (£) per authorisation*	
	Hybrid	*Standard*
Base Fee	13,950	12,390
Fee for 1st additional strength	4,590	
Fee for each subsequent additional strength	1,465.	

(2) In this paragraph "hybrid" means an application to which paragraph 10A of Schedule 1 applies.".

Amendment to paragraph 17

171. In paragraph 17 (application for variation to marketing authorisation under national or mutual recognition procedure)—

(a) in sub-paragraph (1) omit "18, 19 or";

(b) for the table substitute—

"*Type of variations*	*Fee (£)*
Single variations; one change for each product	
Variation – standard	2,895
Unless the variation is—	
(a) 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
(b) a change of bioavailability	8,415
(c) a 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
(d) a change of pharmacokinetics	8,415
Simultaneous application falling within (a) to (d): fee for each additional product in the application	1,465
Variation – reduced	885
Variation - no assessment	455
Grouped variations	
Variation – standard led	
For the first nine changes	6,280
For each subsequent group of five or fewer changes	2,250
Variation – reduced led:	
For the first nine changes	1,770
For each subsequent group of five or fewer changes	2,250".

Amendment to paragraph 18

172. Omit paragraph 18 (application for variation to marketing authorisation under worksharing procedure).

Amendment to paragraph 22

173. In paragraph 22 (application for renewal of marketing authorisation)—

(a) omit sub-paragraph (1);

(b) for the heading substitute—

"Application for a reassessment of an exceptional marketing authorisation".

Amendment to paragraph 25

174. Omit paragraph 25 (renewal of homeopathic remedy).

Amendment to paragraph 28

175. In paragraph 28 (application for manufacturing authorisation)—

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

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

(c) after sub-paragraph (1) insert—

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

Amendment to paragraph 29

176. In paragraph 29 (application for variation to manufacturing authorisation)—

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

(b) for sub-paragraph (b) substitute—

"(b) £105 if the variation only involves an administrative variation such as a change of ownership.";

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

Amendment to paragraph 30

177. In paragraph 30 (application for manufacturing authorisation for autogenous vaccine or product for administration under the cascade)—

(a) omit sub-paragraph (1);

(b) for sub-paragraph (2) substitute—

"(2) The fees for the inspection of sites in connection with an authorisation (or an application for authorisation) 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-paragraphs (3) and (4);

(d) for the heading substitute—

"Inspection of sites authorised to manufacture a product for administration under the cascade".

New paragraphs 30A and 30B

178. After paragraph 30 insert—

"**Autogenous vaccines**

30A.—(1) The fee for the scientific assessment of an authorisation (or an application for authorisation) to manufacture an autogenous vaccine is £6,962.

(2) The fees for the inspection of sites in connection with an authorisation (or an application for authorisation) to manufacture 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.".

Amendment to paragraph 31

179. For paragraph 31 (annual fees) substitute—

"Annual fee (manufacturing authorisations)

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

Amendment to paragraph 33

180. In paragraph 33 (inspection of manufacturing site for immunological veterinary medicinal products) for the table substitute—

"**Sites where immunological veterinary medicinal products are manufactured**

Type of site	*Fee (£)*	
	United Kingdom site	Site outside the 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".

Amendment to paragraph 34

181. In paragraph 34 (inspection of manufacturing site for sterile veterinary medicinal products) 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".

Amendment to paragraph 35

182. In paragraph 35 (inspection of manufacturing site for other veterinary medicinal products) 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".

Amendment to paragraph 36

183. In paragraph 36 (inspection of site where veterinary medicinal products are assembled) 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".

Amendment to paragraph 37

184. In paragraph 37 (test sites)—

(a) for "£3,344" substitute "£3,212";

(b) for "£3,177" substitute "£4,507".

Amendment to paragraph 38

185. For paragraph 38 (animal blood bank or equine stem cell centre authorisations) substitute—

"Animal blood bank or non-food animal stem cell centre authorisations

38.—(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.

(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".

Amendment to paragraph 39

186. For paragraph 39 (application for wholesale dealer's authorisation) 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.".

Amendment to paragraph 40

187. For paragraph 40 (variation of wholesale dealer's authorisation) substitute—

"Variation of a wholesale dealer's authorisation

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

(a) £265 if the variation requires scientific or pharmaceutical assessment;

(b) £105 for a change of ownership or other administrative variation.".

Amendment to paragraph 41

188. For paragraph 41 (annual fee for wholesale dealer's authorisation) substitute—

"Annual fee for a wholesale dealer's authorisation

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

Amendment to paragraph 42

189. For paragraph 42 (inspection of wholesale dealer's premises) substitute—

"Inspection of a wholesale dealer's sites

42. The fee for inspection of a wholesale dealer's site 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).".

Amendment to paragraph 43

190. In paragraph 43 (approval fees and annual fees for feedingstuffs in Great Britain)—

(a) in sub-paragraph (1)—

(i) for "approval", in both places it occurs, substitute "authorisation";

(ii) for "establishments" substitute "premises";

(iii) for "£70" substitute "£105";

(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 "premises";

(ii) for "veterinary medicinal product intended to be incorporated into feedingstuffs" substitute "medicinal premix";

(iii) for "that establishment" substitute "those premises";

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

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

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

Amendment to paragraph 44

191. In paragraph 44 (inspection fees for feedingstuffs in Great Britain)—

(a) in the words before the table for "establishments" substitute "premises";

(b) for the table substitute—

"**Inspection Fees**

Type of premises inspected	*Fee payable (£)*
Manufacturer of a specified feed additive (SFA)	1,610
Manufacturer of an intermediate feedingstuff (including balancers) containing a medicinal premix or an SFA	976
Manufacturer of a feedingstuff for sale containing— a medicinal premix and/or an SFA, and/or an intermediate feedingstuff containing a medicinal premix or an SFA	841
Manufacturer of a feedingstuff for feeding to their own animals only, containing— a medicinal premix and/or an SFA incorporated at a rate of at least 2kg/t, and/or an intermediate feedingstuff containing a medicinal premix and/or an SFA incorporated at a rate of at least 2kg/t	476
Distributor or trader of Schedule 5 products (A distributor of specified feed additives, or intermediate feedingstuffs containing specified feed additives or medicinal premixes; or feedingstuffs containing a medicinal premix)	350".

Amendment to paragraph 46

192. In paragraph 46 (premises for supply by suitably qualified persons)—

(a) in sub-paragraph (1)—

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

(ii) for "£265" substitute "£105";

(iii) omit paragraph (b) and the preceding "or";

(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 (£)*
Sites authorised to supply companion animal medicines	285
Sites authorised to supply equine medicines	285
Sites authorised to supply livestock medicines	338
Sites authorised to supply avian medicines	285.

(1B) Where a site is inspected in relation to a single authorisation, and falls within more than one of the categories in the table, only one fee (the highest) is payable.";

(c) in sub-paragraph (2)—

(i) for "£185" substitute "£57";

(ii) omit paragraph (b) and the preceding "or";

(d) after sub-paragraph (2) insert—

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

Amendment to paragraph 48

193. In paragraph 48 (animal test certificates)—

(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.".

Amendment to paragraph 53

194. In paragraph 53 (export certificates)—

(a) for "£30" substitute "£54";

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

New paragraph 54A

195. After paragraph 54 (provision of advice) 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.".

Amendment to paragraph 57

196. In paragraph 57 (veterinary surgeon's practice premises)—

(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 (£)*
Sites registered to supply companion animal medicines	536
Sites registered to supply equine medicines	536
Sites registered to supply livestock medicines	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) insert—

"(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.";

(d) in the heading omit "surgeon's".

New paragraphs 57A and 57B

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 listed in Schedule 2, 3 or 4 to the Misuse of Drugs Regulations 2001(**a**) is—

(a) £142; or

(b) £31 (where the verification takes place during the course of an inspection for other purposes).

Pharmacovigilance inspections

57B.—(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;

(**a**) S.I. 2001/3998, amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136, 2011/448, 2012/973, 1311, 2013/625, 2014/1275, 3277, 2015/891, 2016/1125, 2018/1055, 1383; there are other amending instruments but none is relevant.

"small marketing authorisation holder" means a marketing authorisation holder who holds fewer than 30 marketing authorisations.".

Amendment to paragraph 60

198. In paragraph 60 (non-payment of fees)—

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

(b) after "from the person" insert "or any authorisation held by the person".

Amendment to paragraph 61

199. After paragraph 61(1) (waiver or reduction of fees) 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."
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PART 10

Transitional provisions

Labelling

200.—(1) Notwithstanding the amendments made to the following paragraphs of Schedule 1 to the 2013 Regulations by this instrument—

(a) paragraph 48 (labelling of immediate packaging of veterinary medicinal products);

(b) paragraph 49 (labelling of the outer packaging of veterinary medicinal products);

(c) paragraph 50 (labelling of small immediate packaging units of veterinary medicinal products);

(d) paragraph 51 (package leaflet of veterinary medicinal products);

(e) paragraph 52 (small containers other than ampoules);

(f) paragraph 53 (homeopathic remedies),

it is not an offence under regulation 6 of the 2013 Regulations (marketing of products not in accordance with a marketing authorisation) for the holder of a marketing authorisation in respect of a veterinary medicinal product immediately before the coming into force of this instrument or the manufacturer to supply that veterinary medicinal product before 1st April 2029 in circumstances which would have been in accordance with those paragraphs as they had effect immediately before the coming into force of this instrument if, and for so long as, the conditions in paragraph (2) are met.

(2) The conditions are—

(a) there have been no amendments to the marketing authorisation which involve changes to the labelling approved by the Secretary of State under paragraph 45 of Schedule 1 to the 2013 Regulations since the coming into force of these Regulations;

(b) the information on the labelling remains accurate.

(3) As regards a veterinary medicinal product to which paragraph (1) applies immediately before 1st April 2029—

(a) the provisions referred to in paragraph (1)(a) to (f), as amended by this instrument, apply in respect of that product on and after that date,

(b) any further supply of that veterinary medicinal product which does not comply with those provisions is deemed not to be in accordance with the marketing authorisation for the

purposes of regulation 6 of the 2013 Regulations, notwithstanding any previous approvals given under paragraph 45 of Schedule 1 to the 2013 Regulations.

Advertising

201. Notwithstanding the amendments made to regulations 10 (advertising the product) and 11 (advertising of prescription products, etc.) of the 2013 Regulations by this instrument, it is not an offence under regulation 43(f) or (g) of the 2013 Regulations for a person to advertise a veterinary medicinal product before the end of the period which expires three months after the date on which this instrument comes into force if that advertisement would not have caused that person to fail to comply with regulations 10 or 11 of the 2013 Regulations as they had effect immediately before the coming into force of this instrument.

Wholesale supply of veterinary medicinal products by marketing authorisation holders

202. Notwithstanding the amendments made to paragraph 2(1) of Schedule 3 to the 2013 Regulations (wholesale supply of veterinary medicinal products) by this instrument, until the end of the period which expires six months after the date on which this instrument comes into force—

(a) that paragraph is to be read as if it continued to include reference to a holder of a marketing authorisation being able to supply a veterinary medicinal product wholesale, or to be in possession of it for that purpose, and

(b) it is not an offence under paragraph 24(a) of that Schedule for the holder of a marketing authorisation to make such a supply (or to be in such possession) in accordance with that paragraph.

Recording of reasons for prescriptions

203. Notwithstanding the amendments made to paragraph 5 of Schedule 3 to the 2013 Regulations (prescriptions) by this instrument, it is not an offence under paragraph 24(d) of that Schedule to fail to comply with paragraph 5(1A), (1B) or (4) of that Schedule before the end of the period which expires six months after the date on which this instrument comes into force.

Prescription requirements

204.—(1) Notwithstanding the amendments made to paragraph 6 of Schedule 3 to the 2013 Regulations (written prescriptions) by this instrument—

(a) it is not an offence under paragraph 24(da) of that Schedule to fail to comply with paragraph 6(1) before the end of the period which expires six months after the date on which this instrument comes into force;

(b) a written prescription issued before the end of the period which expires six months after the date on which this instrument comes into force in accordance with paragraph 6 of Schedule 3 to the 2013 Regulations as it had effect immediately before the coming into force of this instrument is to be treated as validly issued for the purposes of the 2013 Regulations.

(2) A written prescription issued before the end of the period which expires six months after the date on which this instrument comes into force in accordance with paragraph 6 of Schedule 3 to the 2013 Regulations as it had effect immediately before the coming into force of this instrument (including a written prescription to which paragraph (1)(b) applies) continues to be valid until it expires in accordance with paragraph 6(2) or (3) of that Schedule.

Feedingstuffs labelling requirements

205. Notwithstanding the amendments made to paragraphs 12 and 14 of Schedule 5 to the 2013 Regulations (labelling of premixtures and feedingstuffs containing veterinary medicinal product) by this instrument, it is not an offence under paragraph 31(j) or (l) of that Schedule to make a supply before the end of the period which expires six months after the date on which this

instrument comes into force which is labelled in accordance with paragraph 12 or 14 (as the case may be) as it had effect immediately before the coming into force of this instrument.

Medicated feedingstuffs prescription requirements

206. Notwithstanding the amendments made to paragraph 19 of Schedule 5 to the 2013 Regulations (prescriptions for feedingstuffs containing a veterinary medicinal product) by this instrument, a prescription issued before the end of the period which expires six months after the date on which this instrument comes into force in accordance with that paragraph as it had effect immediately before the coming into force of this instrument continues to be valid until it expires in accordance with paragraph 19(2).

Sampling for tolerances

207. Notwithstanding the amendments made to paragraph 22 of Schedule 5 to the 2013 Regulations (sampling and analysis) by this instrument, the defence referred to in paragraph 22(2) of that Schedule continues to be available in respect of a sample taken before the end of the period which expires six months after the date on which this instrument comes into force if the active ingredient in the medicated feedingstuff sample is within the tolerances set out in the table in that paragraph as it had effect immediately before the coming into force of this instrument.

Sampling for cross-contamination

208. Notwithstanding the insertion of paragraph 22A of Schedule 5 to the 2013 Regulations (sampling for cross-contamination) by this instrument, it is not an offence under paragraph 31(ra) of that Schedule to fail to comply with paragraph 22A before the end of the period which expires six months after the date on which this instrument comes into force.

PART 11

Consequential amendment to assimilated direct legislation

Commission Regulation (EC) No 1234/2008

209. Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products(**a**) is revoked.

Douglas-Miller
Parliamentary Under Secretary of State
25th April 2024 Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Veterinary Medicines Regulations 2013 (S.I. 2013/2033, "the 2013 Regulations") in respect of Great Britain only.

Part 2 amends Parts 1 to 5 of the 2013 Regulations. New and amended provision is made in respect of—

- the manufacture of veterinary medicinal products (regulation 5);

(**a**) EUR 2008/1234, revoked for certain purposes (subject to transitional provisions) by S.I. 2019/775.

- the prohibition of supply of veterinary medicinal products after their expiry date (regulation 6);
- advertising and promotion of veterinary medicinal products (regulations 7 to 9);
- exemptions from the scope of the 2013 Regulations (regulation 10);
- record-keeping requirements (regulations 11 to 15);
- imports of unauthorised veterinary medicinal products (regulation 16);
- appeals (regulation 17);
- exports (regulation 18);
- time limits (regulation 19);
- enforcement (regulations 20 to 25).

Regulation 4 amends the interpretation provision in the 2013 Regulations, and regulation 26 amends the statutory review clause so as to provide that the report in respect of the next review must be published by 31st December 2028.

Part 3 amends Schedule 1 to the 2013 Regulations, which governs applications for marketing authorisations in respect of veterinary medicinal products.

Part 4 amends Schedule 2 to the 2013 Regulations, which governs the manufacture of veterinary medicinal products. Regulation 92 inserts new Part 2 to that Schedule, concerning the authorisation of autogenous vaccines, blood-banks, stem cell centres and products manufactured under the cascade. Regulation 93 inserts new Part 2A (regulating active substances) and Part 2B (offences) to that Schedule.

Part 5 amends Schedule 3 to the 2013 Regulations, which governs classification and supply of veterinary medicines, wholesale dealers and sheep dip.

Part 6 amends Schedule 4 to the 2013 Regulations, which governs administration of veterinary medicines outside the terms of a marketing authorisation.

Part 7 amends Schedule 5 to the 2013 Regulations, which governs medicated feedingstuffs and specified feed additives.

Part 8 amends Schedule 6 to the 2013 Regulations, which governs exemptions from the 2013 Regulations in respect of small pet animals.

Part 9 amends Schedule 7 to the 2013 Regulations, which sets out fees in respect of the 2013 Regulations.

Part 10 sets out transitional provisions in respect of certain amendments in earlier Parts of the instrument concerning—

- labelling of veterinary medicinal products (regulation 200);
- advertising (regulation 201);
- wholesale supply of veterinary medicinal products by marketing authorisation holders (regulation 202);
- prescriptions (regulations 203 and 204);
- feedingstuffs labelling requirements (regulation 205);
- medicated feedingstuffs prescription requirements (regulation 206);
- sampling (regulations 207 and 208).

Part 11 contains a consequential amendment to assimilated direct legislation, revoking Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (EUR 2008/1234).

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

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