STATUTORY INSTRUMENTS

2024 No. 567

The Veterinary Medicines (Amendment etc.) Regulations 2024

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;

"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(**1**);

"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

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

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;

"GMO Deliberate Release Regulations" means—

(a) as regards England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002(**2**);

(b) as regards Scotland, the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(**3**);

(c) as regards Wales, the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(**4**);

"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;

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

"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 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(**5**);

"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;

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

"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—

""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(**6**) 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;

(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.".

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

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(**7**);";

(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".

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;

(**7**) 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.

(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".