DRAFT STATUTORY INSTRUMENTS

# 2024 No.

# The Veterinary Medicines (Amendment etc.) Regulations 2024

## 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;".