SCHEDULE 3 Regulation 7

Classification and supply, wholesale dealers and sheep dip

PART 1

Classification and supply of authorised veterinary medicinal products

Classification of veterinary medicinal products **E+W+S**

1.—(1) There shall be the following categories of authorised veterinary medicinal products—

(a) Prescription Only Medicine–Veterinarian (abbreviated to POM-V);

(b) Prescription Only Medicine–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);

(c) Non-Food Animal–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);

(d) Authorised Veterinary Medicine–General Sales List (abbreviated to AVM-GSL).

(2) The Secretary of State must specify the classification of the veterinary medicinal product when granting the initial marketing authorisation.

(3) The Secretary of State may change the classification after the marketing authorisation has been granted, either at the request of the marketing authorisation holder or in accordance with paragraph 37 of Schedule 1 (compulsory variation).

(4) When granting the marketing authorisation the Secretary of State must classify the following as POM-V—

(a) products containing narcotic or psychotropic substances;

(b) products intended for administration following a diagnosis or clinical assessment by a veterinary surgeon;

[F1(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**]**.

(5) When granting the marketing authorisation the Secretary of State must classify the following as POM-V or POM-VPS—

(a) products for food-producing animals;

(b) products in respect of which special precautions must be taken in order to avoid any unnecessary risk to—

(i) the target species;

(ii) the person administering the products to the animal; and

(iii) the environment;

(c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; F2...

(d) **[**F3immunological veterinary medicinal products.**]**

(6) The requirement in sub-paragraph (5)(a) relating to veterinary medicinal products for food-producing animals does not apply if all the following criteria are met—

(a) the administration of the veterinary medicinal product is restricted to formulations requiring no particular knowledge or skill in using the product;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious **[**[F4]adverse event**]** reporting;

(e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; and

(h) there is no risk to human or animal health as regards the development of resistance to **[**[F5]antibiotics**]** or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F1 Sch. 3 para. 1(4)(c)-(f) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **95(a)**

F2 Word in Sch. 3 para. 1(5)(c) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **95(b)(i)**

F3 Sch. 3 para. 1(5)(e) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **95(b)(ii)**

F4 Words in Sch. 3 para. 1(6)(d) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **95(c)(i)**

F5 Word in Sch. 3 para. 1(6)(h) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **95(c)(ii)**

Classification of veterinary medicinal products N.I.

1.—(1) There shall be the following categories of authorised veterinary medicinal products—

(a) Prescription Only Medicine–Veterinarian (abbreviated to POM-V);

(b) Prescription Only Medicine–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to POM-VPS);

(c) Non-Food Animal–Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS);

(d) Authorised Veterinary Medicine–General Sales List (abbreviated to AVM-GSL).

(2) The Secretary of State must specify the classification of the veterinary medicinal product when granting the initial marketing authorisation.

(3) The Secretary of State may change the classification after the marketing authorisation has been granted, either at the request of the marketing authorisation holder or in accordance with paragraph 37 of Schedule 1 (compulsory variation).

(4) When granting the marketing authorisation the Secretary of State must classify the following as POM-V—

(a) products containing narcotic or psychotropic substances;

(b) products intended for administration following a diagnosis or clinical assessment by a veterinary surgeon.

(5) When granting the marketing authorisation the Secretary of State must classify the following as POM-V or POM-VPS—

(a) products for food-producing animals;

(b) products in respect of which special precautions must be taken in order to avoid any unnecessary risk to—

(i) the target species;

(ii) the person administering the products to the animal; and

(iii) the environment;

(c) products that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures; and

(d) new veterinary medicinal products containing an active substance that has not been included in an authorised veterinary medicinal product for five years.

(6) The requirement in sub-paragraph (5)(a) relating to veterinary medicinal products for food-producing animals does not apply if all the following criteria are met—

(a) the administration of the veterinary medicinal product is restricted to formulations requiring no particular knowledge or skill in using the product;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;

(e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; and

(h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.

Extent Information

E19 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Wholesale supply of veterinary medicinal products E+W+S

2.—(1) Only a holder [F6]... of a manufacturing authorisation or the holder of a wholesale dealer's authorisation granted by the Secretary of State may supply a veterinary medicinal product wholesale, or be in possession of it for that purpose.

(2) A person mentioned in sub-paragraph (1) may only supply a veterinary medicinal product if—

(a) the authorisation in question relates to that product, and

(b) the supply **[**[F7]is to the holder of a manufacturing authorisation or**]** is to another person who is entitled to supply that product under these Regulations, either wholesale or retail.

[[F8](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).**]**

(4) It is immaterial whether or not the supply is for profit.

(5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer with such products for the purpose of alleviating a temporary supply shortage that could be detrimental to animal welfare.

(6) A wholesale dealer may break open any package (other than the immediate packaging) of a veterinary medicinal product.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F6 Words in Sch. 3 para. 2(1) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **96(a)** (with reg. 202)

F7 Words in Sch. 3 para. 2(2)(b) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **96(b)**

F8 Sch. 3 para. 2(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **96(c)**

Wholesale supply of veterinary medicinal products N.I.

2.—(1) Only a holder of a marketing authorisation, the holder of a manufacturing authorisation or the holder of a wholesale dealer's authorisation granted by the Secretary of State may supply a veterinary medicinal product wholesale, or be in possession of it for that purpose.

(2) A person mentioned in sub-paragraph (1) may only supply a veterinary medicinal product if—

(a) the authorisation in question relates to that product, and

(b) the supply is to another person who is entitled to supply that product under these Regulations, either wholesale or retail.

(3) If the supply is to a suitably qualified person, it must be to the premises approved in accordance with paragraph 14.

(4) It is immaterial whether or not the supply is for profit.

(5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer with such products for the purpose of alleviating a temporary supply shortage that could be detrimental to animal welfare.

(6) A wholesale dealer may break open any package (other than the immediate packaging) of a veterinary medicinal product.

Extent Information

E20 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Retail supply of veterinary medicinal products E+W+S

3.—(1) This paragraph applies in relation to retail supply of veterinary medicinal products.

(2) A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.

(3) A veterinary medicinal product classified as POM-VPS may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 14,

and must be in accordance with a prescription from one of those persons.

(4) A veterinary medicinal product classified as NFA-VPS may be supplied without prescription, but may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 14.

(5) There are no restrictions on the supply of AVM-GSL products.

(6) In this paragraph—

[F9(a) "retail supply" means a supply whether or not for payment to the owner or keeper of an animal for administration to that animal; and**]**

(b) a person may supply a product irrespective of who owns it.

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F9 Sch. 3 para. 3(6)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **97**

Retail supply of veterinary medicinal products N.I.

3.—(1) This paragraph applies in relation to retail supply of veterinary medicinal products.

(2) A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.

(3) A veterinary medicinal product classified as POM-VPS may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 14,

and must be in accordance with a prescription from one of those persons.

(4) A veterinary medicinal product classified as NFA-VPS may be supplied without prescription, but may only be supplied by—

(a) a veterinary surgeon;

(b) a pharmacist; or

(c) a suitably qualified person in accordance with paragraph 14.

(5) There are no restrictions on the supply of AVM-GSL products.

(6) In this paragraph—

(a) "retail supply" means any supply other than to or from the holder of a wholesale dealer's authorisation, and whether or not for payment; and

(b) a person may supply a product irrespective of who owns it.

Extent Information

E21 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F10Supply 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.**]**

Textual Amendments

F10 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **98**

[F10Register 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.**]**

Textual Amendments

F10 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **98**

[F10Application 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.**]**

Textual Amendments

F10 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **98**

[F10Duties 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.**]**

Textual Amendments

F10 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **98**

[F10Retail 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.**]**

Textual Amendments

F10 Sch. 3 paras. 3A-3E inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **98**

Prescriptions by a veterinary surgeon

4.—(1) A veterinary surgeon who prescribes a veterinary medicinal product classified as POM-V **[**F11or a veterinary medicinal product under the cascade**]** must first carry out a clinical assessment of the animal, and the animal must be under that veterinary surgeon's care.

(2) This does not apply in relation to the administration of such a product to a wild animal where the administration is authorised by the Secretary of State.

Textual Amendments

F11 Words in Sch. 3 para. 4(1) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **99**

Prescriptions E+W+S

5.—(1) A prescription may be **[**F12verbal**]** or written, but a veterinary medicinal product classified as POM-V or POM-VPS **[**F13or a veterinary medicinal product prescribed under the cascade**]** may only be supplied—

(a) by the person who prescribed it;

(b) under a written prescription that complies with paragraph 6; or

(c) (in the case of POM-VPS) by a suitably qualified person in accordance with paragraph 14(5).

[F14(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**]**

(2) A person supplying such a product under a written prescription—

(a) may only supply the product specified in that prescription;

(b) must take all reasonable steps to be satisfied that the prescription has been written and signed by a person entitled to prescribe the product; and

(c) must take all reasonable steps to ensure that it is supplied to the person named in the prescription.

(3) No person may alter a written prescription unless authorised to do so by the person who signed it.

[F15(4) No person may submit a written prescription to a retailer on more than one occasion where the prescription is not repeatable.**]**

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F12 Word in Sch. 3 para. 5(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **100(a)(i)** (with reg. 203)

F13 Words in Sch. 3 para. 5(1) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **100(a)(ii)** (with reg. 203)

F14 Sch. 3 para. 5(1A)(1B) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **100(b)** (with reg. 203)

F15 Sch. 3 para. 5(4) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **100(c)** (with reg. 203)

Prescriptions N.I.

5.—(1) A prescription may be oral or written, but a veterinary medicinal product classified as POM-V or POM-VPS may only be supplied—

(a) by the person who prescribed it;

(b) under a written prescription that complies with paragraph 6; or

(c) (in the case of POM-VPS) by a suitably qualified person in accordance with paragraph 14(5).

(2) A person supplying such a product under a written prescription—

(a) may only supply the product specified in that prescription;

(b) must take all reasonable steps to be satisfied that the prescription has been written and signed by a person entitled to prescribe the product; and

(c) must take all reasonable steps to ensure that it is supplied to the person named in the prescription.

(3) No person may alter a written prescription unless authorised to do so by the person who signed it.

Extent Information

E22 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Written prescriptions E+W+S

6.—[F16(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.**]**

(2) A written prescription for a controlled drug as specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001(**1**) is valid for 28 days.

(3) A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.

(4) If the prescription is repeatable it must specify the number of times the veterinary medicinal product may be supplied.

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F16 Sch. 3 para. 6(1)-(1B) substituted for Sch. 3para. 6(1) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **101** (with reg. 204)

Written prescriptions N.I.

6.—(1) A written prescription must include—

(a) the name, address and telephone number of the person prescribing the product;

(**1**) S. I. 2001/3998; relevant amending instruments are S. I. 2003/1432 and 2005/1653.

(b) the qualifications enabling the person to prescribe the product;

(c) the name and address of the owner or keeper;

(d) the identification (including the species) of the animal or group of animals to be treated;

(e) the premises at which the animals are kept if this is different from the address of the owner or keeper;

(f) the date of the prescription;

(g) the signature or other authentication of the person prescribing the product;

(h) the name and amount of the product prescribed;

(i) the dosage and administration instructions;

(j) any necessary warnings;

(k) the withdrawal period if relevant; and

(l) if it is prescribed under the cascade, a statement to that effect.

(2) A written prescription for a controlled drug as specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001(**1**) is valid for 28 days.

(3) A written prescription for any other drug is valid for six months or such shorter period as may be specified in the prescription.

(4) If the prescription is repeatable it must specify the number of times the veterinary medicinal product may be supplied.

Extent Information

E23 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Duties when a product is prescribed or supplied

7.—**[**F17(1)**]** A person who prescribes **[**F18a veterinary medicinal product under the cascade or**]** a product classified as POM-V or POM-VPS, or supplies a product classified as NFA-VPS—

(a) before doing so, must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised;

(b) when doing so, must advise on its safe administration and on any warnings or contra-indications on the label or package leaflet; and

(c) must not prescribe (or, in the case of a NFA-VPS product, supply) more than the minimum amount required for the treatment; but it is a defence to a charge of failing to comply with this paragraph to show that—

(i) the product prescribed or supplied was in a container specified in the marketing authorisation;

(ii) the manufacturer does not supply that veterinary medicinal product in a smaller container; and

(iii) the person prescribing or supplying is not a person authorised to break open the package before supply.

[F19(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.**]**

(**1**) S. I. 2001/3998; relevant amending instruments are S. I. 2003/1432 and 2005/1653.

Textual Amendments

F17 Sch. 3 para. 7 renumbered as Sch. 3 para. 7(1) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **102(a)**

F18 Words in Sch. 3 para. 7(1) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **102(b)**

F19 Sch. 3 para. 7(2) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **102(c)**

[F20Duties 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.**]**

Textual Amendments

F20 Sch. 3 para. 7A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **103**

Supply by a veterinary surgeon from registered premises

8.—(1) A veterinary surgeon may only supply a veterinary medicinal product from practice premises registered with the Royal College of Veterinary Surgeons as veterinary practice premises at which veterinary medicinal products are stored or supplied.

(2) This paragraph does not apply in relation to a veterinary medicinal product classified as AVM-GSL.

(3) The Royal College of Veterinary Surgeons must, on request, supply the Secretary of State with a copy of the register of veterinary practice premises.

(4) The Secretary of State must, from time to time, inspect premises registered under sub-paragraph (1), basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

(5) Where an inspection under sub-paragraph (4) reveals significant breaches of these Regulations the Secretary of State may require the Royal College of Veterinary Surgeons to remove the premises from the register maintained under sub-paragraph (1).

(6) Where the Secretary of State requires the removal of premises from the register the veterinary surgeon concerned may appeal using the procedure in regulation 30.

(7) Where premises have been removed from the register under sub-paragraph (5) they may not be re-registered without the approval of the Secretary of State.

(8) The Secretary of State may only grant approval under sub-paragraph (7) after a further inspection of the premises.

Supply by a veterinary surgeon

9.—(1) A veterinary surgeon supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the veterinary surgeon—

(a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.

(2) A veterinary surgeon or a person acting under a veterinary surgeon's responsibility may open any package containing a veterinary medicinal product.

Supply by a pharmacist **E+W+S**

10.—(1) A pharmacist may only supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS **[**F21, or prescribed under the cascade,**]** from—

(a) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland;

(b) premises registered with the Royal College of Veterinary Surgeons as being premises from which a veterinary surgeon supplies veterinary medicinal products; or

(c) (in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises **[**F22authorised**]** under paragraph 14.

(2) A pharmacist supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the pharmacist—

(a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.

(3) A pharmacist may supply any veterinary medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user.

(4) A pharmacist may supply a homeopathic remedy prepared extemporaneously by a pharmacist in a registered pharmacy (as well as any other homeopathic remedy permitted to be supplied by a pharmacist under these Regulations) provided that it is prepared in accordance with paragraph 63 of Schedule 1 and intended to be supplied directly to the end user.

(5) A pharmacist may break open any package containing a veterinary medicinal product for the purposes of supply other than the immediate packaging of an injectable product.

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F21 Words in Sch. 3 para. 10(1) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **104(a)**

F22 Word in Sch. 3 para. 10(1)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **104(b)**

Supply by a pharmacist N.I.

10.—(1) A pharmacist may only supply a veterinary medicinal product classified as POM-V, POM-VPS or NFA-VPS from—

(a) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland;

(b) premises registered with the Royal College of Veterinary Surgeons as being premises from which a veterinary surgeon supplies veterinary medicinal products; or

(c) (in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS) from premises approved under paragraph 14.

(2) A pharmacist supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the pharmacist—

(a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.

(3) A pharmacist may supply any veterinary medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and intended to be supplied directly to the end-user.

(4) A pharmacist may supply a homeopathic remedy prepared extemporaneously by a pharmacist in a registered pharmacy (as well as any other homeopathic remedy permitted to be supplied by a pharmacist under these Regulations) provided that it is prepared in accordance with paragraph 63 of Schedule 1 and intended to be supplied directly to the end user.

(5) A pharmacist may break open any package containing a veterinary medicinal product for the purposes of supply other than the immediate packaging of an injectable product.

Extent Information

E24 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply of a [F23medicinal premix] E+W+S

11.—(1) This paragraph applies in relation to the supply of a **[**F24medicinal premix**]**.

(2) F25... An authorised manufacturer of the product or an authorised wholesale dealer may only supply such a **[**F26medicinal premix**]** to—

(a) a veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person;

(b) an **[**F27authorised**][**F28intermediate feedingstuffs**]** manufacturer; or

(c) an **[**F27authorised**]** feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that **[**F26medicinal premix**]** (if the manufacturer

is the end-user the supply must be in accordance with a **[**[F29]medicated feedingstuffs prescription**]**).

(3) A veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person may only supply such a **[**[F30]medicinal premix**]** to—

(a) an **[**[F27]authorised**]****[**[F31]intermediate feedingstuffs**]** manufacturer; or

(b) an **[**[F27]authorised**]** feedingstuffs manufacturer if the **[**[F32]authorisation**]** permits the rate of incorporation specified on the label of that **[**[F30]medicinal premix**]** (if the manufacturer is the end user the supply must be in accordance with a prescription **[**[F33]for medicated feedingstuffs**]**).

[[F34](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.**]**

Extent Information

E7 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F23 Words in Sch. 3 para. 11 heading substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(f)**

F24 Words in Sch. 3 para. 11(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(b)**

F25 Words in Sch. 3 para. 11(2) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(c)(ii)**

F26 Words in Sch. 3 para. 11(2) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(c)(i)**

F27 Word in Sch. 3 para. 11 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(a)**

F28 Words in Sch. 3 para. 11(2)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(c)(iii)**

F29 Words in Sch. 3 para. 11(2)(c) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(c)(iv)**

F30 Words in Sch. 3 para. 11(3) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(d)(i)**

F31 Words in Sch. 3 para. 11(3)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(d)(ii)**

F32 Word in Sch. 3 Sch. 3 para. 11(3)(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(d)(iii)(aa)**

F33 Words in Sch. 3 para. 11(3)(b) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(d)(iii)(bb)**

F34 Sch. 3 para. 11(4) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **105(e)**

Supply of a veterinary medicinal product for incorporation into feedingstuffs N.I.

11.—(1) This paragraph applies in relation to the supply of a veterinary medicinal product intended for incorporation into feedingstuffs.

(2) The marketing authorisation holder, an authorised manufacturer of the product or an authorised wholesale dealer may only supply such a veterinary medicinal product to—

(a) a veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person;

(b) an approved premixture manufacturer; or

(c) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end-user the supply must be in accordance with a prescription).

(3) A veterinary surgeon, pharmacist or, in the case of a product classified as POM-VPS, a suitably qualified person may only supply such a veterinary medicinal product to—

(a) an approved premixture manufacturer; or

(b) an approved feedingstuffs manufacturer if the approval permits the rate of incorporation specified on the label of that veterinary medicinal product (if the manufacturer is the end user the supply must be in accordance with a prescription).

(4) An approved premixture manufacturer or an approved feedingstuffs manufacturer may only supply such a veterinary medicinal product to another approved premixture manufacturer or approved feedingstuff manufacturer if the amount supplied does not exceed five per cent in terms of value of veterinary medicinal product incorporated annually by the person supplying the veterinary medicinal product.

Extent Information

E25 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Labelling at the time of retail supply

12.—(1) If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it must not be supplied if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.

(2) Sub-paragraph (1) does not apply to a veterinary surgeon who amends a label, or a pharmacist who amends it in accordance with a prescription from a veterinary surgeon, provided that the unamended information remains clearly visible.

(3) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must ensure that the container is suitably labelled and must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely.

Supply of veterinary medicinal products for use under the cascade E+W+S

13.—(1) A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.

(2) Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

(a) the name and address of the pharmacy, **[**[F35]veterinary practice premises**]** or **[**[F36]authorised**]** premises supplying the veterinary medicinal product;

(b) the name of the veterinary surgeon who has prescribed the product;

(c) the name and address of the animal owner;

(d) the identification (including the species) of the animal or group of animals;

(e) the date of supply;

(f) the expiry date of the product, if applicable;

(g) the name or description of the product, which should include at least the name and quantity of active ingredients;

(h) dosage and administration instructions;

(i) any special storage precautions;

(j) any necessary warnings for the user, target species, administration or disposal of the product;

(k) the withdrawal period, if relevant; and

(l) the words "Keep out of reach of children" and "For animal treatment only".

Extent Information

E8 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F35 Words in Sch. 3 para. 13(2)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **106(a)**

F36 Word in Sch. 3 para. 13(2)(a) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **106(b)**

Supply of veterinary medicinal products for use under the cascade N.I.

13.—(1) A veterinary medicinal product supplied for administration under the cascade may only be supplied in accordance with a prescription from a veterinary surgeon.

(2) Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

(a) the name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;

(b) the name of the veterinary surgeon who has prescribed the product;

(c) the name and address of the animal owner;

(d) the identification (including the species) of the animal or group of animals;

(e) the date of supply;

(f) the expiry date of the product, if applicable;

(g) the name or description of the product, which should include at least the name and quantity of active ingredients;

(h) dosage and administration instructions;

(i) any special storage precautions;

(j) any necessary warnings for the user, target species, administration or disposal of the product;

(k) the withdrawal period, if relevant; and

(l) the words "Keep out of reach of children" and "For animal treatment only".

Extent Information

E26 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Supply by a suitably qualified person E+W+S

14.—(1) The Secretary of State may recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

(2) In order to recognise such a body, the Secretary of State must be satisfied that the body—

(a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;

(b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;

(c) maintains a programme of continuing professional development for persons registered with it;

(d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register.

(3) For the purposes of these Regulations, a suitably qualified person is a person who has passed examinations specified by such a body, and is registered with such a body as a suitably qualified person.

(4) A suitably qualified person may only supply a veterinary medicinal product classified as POM-VPS, NFA-VPS or AVM-GSL, and may only supply it from—

(a) premises **[**F37authorised**]** by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products by a suitably qualified person;

(b) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland; or

(c) practice premises registered under these Regulations as being premises from which a veterinary surgeon supplies veterinary medicinal products.

[F38(5) A suitably qualified person who supplies a product classified as POM-VPS or NFA-VPS must be present when it is handed over unless the suitably qualified person—

(a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.**]**

(6) A suitably qualified person supplying products from premises **[**F37authorised**]** under this regulation by the Secretary of State who considers that the premises no longer comply with the **[**F39authorisation**]** must notify the Secretary of State without unreasonable delay.

(7) The Secretary of State may issue a Code of Practice for suitably qualified persons **[**F40and bodies recognised under this paragraph**]**, and a body recognised under this paragraph must take appropriate action in accordance with any disciplinary code that applies to that body if a suitably qualified person registered with it does not comply with the Code of Practice.

(8) The Secretary of State must publish a list of—

(a) suitably qualified persons; and

(b) the trading names and the addresses of premises **[**F37authorised**]** under this paragraph(**2**).

(9) A suitably qualified person may break open any package (other than the immediate packaging) of a veterinary medicinal product.

(10) The Secretary of State may suspend or revoke the **[**F39authorisation**]** of **[**F37authorised**]** premises on being satisfied that they are no longer suitable for the storage and supply of veterinary medicinal products.

[F41(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.**]**

Extent Information

E9 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F37 Word in Sch. 3 para. 14 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **107(a)**

F38 Sch. 3 para. 14(5) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **107(c)**

F39 Word in Sch. 3 para. 14 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **107(b)**

F40 Words in Sch. 3 para. 14(7) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **107(d)**

F41 Sch. 3 para. 14(11)(12) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **107(e)**

Supply by a suitably qualified person N.I.

14.—(1) The Secretary of State may recognise bodies that are suitable to maintain a register for suitably qualified persons to prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS.

(2) In order to recognise such a body, the Secretary of State must be satisfied that the body—

(a) has in place a system for ensuring that persons applying for registration have adequate training to act as a suitably qualified person under these Regulations;

(b) has adequate standards in deciding whether or not to register someone as a suitably qualified person;

(c) maintains a programme of continuing professional development for persons registered with it;

(d) operates an adequate appeal system if it intends to refuse to register anyone with appropriate qualifications or to remove anyone from the register.

(**2**) Published at: http://www.vmd.defra.gov.uk/registers/sqpregister.aspx.

(3) For the purposes of these Regulations, a suitably qualified person is a person who has passed examinations specified by such a body, and is registered with such a body as a suitably qualified person.

(4) A suitably qualified person may only supply a veterinary medicinal product classified as POM-VPS, NFA-VPS or AVM-GSL, and may only supply it from—

(a) premises approved by the Secretary of State as being suitable for the storage and supply of veterinary medicinal products by a suitably qualified person;

(b) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland; or

(c) practice premises registered under these Regulations as being premises from which a veterinary surgeon supplies veterinary medicinal products.

(5) A suitably qualified person who supplies a product classified as POM-VPS or NFA-VPS must either—

(a) hand over or despatch the product personally;

(b) ensure that, when the product is handed over or despatched, the suitably qualified person is in a position to intervene if necessary; or

(c) check the product after it has been allocated for supply to a customer, and be satisfied that the person handing over or dispatching it is competent to do so.

(6) A suitably qualified person supplying products from premises approved under this regulation by the Secretary of State who considers that the premises no longer comply with the approval must notify the Secretary of State without unreasonable delay.

(7) The Secretary of State may issue a Code of Practice for suitably qualified persons, and a body recognised under this paragraph must take appropriate action in accordance with any disciplinary code that applies to that body if a suitably qualified person registered with it does not comply with the Code of Practice.

(8) The Secretary of State must publish a list of—

(a) suitably qualified persons; and

(b) the trading names and the addresses of premises approved under this paragraph(**2**).

(9) A suitably qualified person may break open any package (other than the immediate packaging) of a veterinary medicinal product.

(10) The Secretary of State may suspend or revoke the approval of approved premises on being satisfied that they are no longer suitable for the storage and supply of veterinary medicinal products.

Extent Information

E27 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F42Audit E+W+S

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.

(**2**) Published at: http://www.vmd.defra.gov.uk/registers/sqpregister.aspx.

(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.**]**

Extent Information

E10 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F42 Sch. 3 para. 15 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **108**

Annual audit N.I.

15. At least once a year every person entitled to supply a veterinary medicinal product on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicinal products must be reconciled with products currently held in stock, any discrepancies being recorded.

Extent Information

E28 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

PART 2

Requirements for a wholesale dealer's authorisation

[F43Wholesale dealer's authorisation E+W+S

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").**]**

Extent Information

E11 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F43 Sch. 3 para. 16 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **109**

Application N.I.

16. An application for a wholesale dealer's authorisation must be made to the Secretary of State.

Extent Information

E29 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F44Application for authorisation E+W+S

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.**]**

Extent Information

E12 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F44 Sch. 3 para. 17 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **110**

Time limits N.I.

17. The Secretary of State must process an application for a wholesale dealer's authorisation within 90 days of receiving it.

Extent Information

E30 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F45Procedure and time limits for authorisations E+W+S

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.**]**

Extent Information

E13 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F45 Sch. 3 para. 18 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **111**

Granting the authorisation N.I.

18.—(1) The Secretary of State must grant a wholesale dealer's authorisation on being satisfied that this paragraph is complied with.

(2) The authorised site must be—

(a) weatherproof;

(b) secure and lockable;

(c) clean; and

(d) free from contaminants.

(3) If the veterinary medicinal products covered by the authorisation are subject to specific storage conditions, the site must be capable of fulfilling those requirements.

(4) The authorisation holder must—

(a) have the services of technically competent staff; and

(b) have an effective emergency recall plan.

Extent Information

E31 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F46Periodic inspections and suspension etc. for lack of use E+W+S

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.**]**

Extent Information

E14 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F46 Sch. 3 para. 19 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **112**

The authorisation N.I.

19.—(1) The wholesale dealer's authorisation must specify—

(a) the types of veterinary medicinal products and pharmaceutical forms that may be dealt in;

(b) the place where they are to be stored;

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates;

(e) the name of the qualified person nominated to act under the Guidelines on Good Distribution Practice for Human Use(**3**).

(2) It may cover more than one site.

(3) It lapses if the holder does not deal in veterinary medicinal products for five years.

(4) The holder of a wholesale dealer's authorisation must notify the Secretary of State, and if necessary apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation, or in the operations for which they are used.

Extent Information

E32 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F47Application 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.**]**

Textual Amendments

F47 Sch. 3 para. 19A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **113**

Suspension, variation or revocation of the authorisation E+W+S

20. The Secretary of State may suspend, vary or revoke a wholesale dealer's authorisation if the holder—

(**3**) OJ No C 63, 1.3.94, p. 4.

(a) has not complied with these Regulations; or

[F48(b) no longer has suitable premises, equipment or technically competent staff]

Extent Information

E15 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F48 Sch. 3 para. 20(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **114**

Suspension, variation or revocation of the authorisation N.I.

20. The Secretary of State may suspend, vary or revoke a wholesale dealer's authorisation if the holder—

(a) has not complied with these Regulations; or

(b) no longer has suitable premises or equipment.

Extent Information

E33 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Duties on the holder of a wholesale dealer's authorisation E+W+S

21. The holder of a wholesale dealer's authorisation must—

(a) store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product;

[F49(b) comply with good distribution practice;]

F50(c) . . . . . .

(d) supply information and samples to the Secretary of State on demand [F51; 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].

Extent Information

E16 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F49 Sch. 3 para. 21(b) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **115(a)**

F50 Sch. 3 para. 21(c) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **115(b)**

F51 Sch. 3 para. 21(e) and word inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **115(c)**

Duties on the holder of a wholesale dealer's authorisation N.I.

21. The holder of a wholesale dealer's authorisation must—

(a) store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product;

(b) comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use as if the veterinary medicinal products were authorised human medicinal products;

(c) carry out a detailed stock audit at least once a year; and

(d) supply information and samples to the Secretary of State on demand.

Extent Information

E34 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F52Register 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.**]**

Textual Amendments

F52 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **116**

[F52Documentation 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.**]**

Textual Amendments

F52 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **116**

[F52Recalled, 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.**]**

Textual Amendments

F52 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **116**

[F52Audit

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.**]**

Textual Amendments

F52 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **116**

[F52Contractual 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.**]**

Textual Amendments

F52 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **116**

[F52Self-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.**]**

Textual Amendments

F52 Sch. 3 paras. 21A-21F inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **116**

PART 3

Sheep dip

Supply of sheep dip

22.—(1) A person who supplies by retail sheep dip which contains a veterinary medicinal product must supply it in accordance with this paragraph.

(2) The supply must be to a person (or a person acting on that person's behalf) who is qualified to use it in accordance with paragraph 23.

(3) The supplier must make a record of that person's certificate or award number as soon as is reasonably practicable, and keep it for at least three years.

(4) If the active ingredient of the veterinary medicinal product is an organophosphorus compound, the supplier must give to the buyer—

(a) a double-sided laminated notice meeting the specifications in the following sub-paragraph (unless the notice has been provided to the buyer within the previous twelve months and the supplier knows or has reasonable cause to believe that the buyer still has it available for use); and

(b) two pairs of gloves either as described in the notice or providing demonstrably superior protection to the proposed user against exposure to the dip than would be provided by gloves as so described.

(5) The notice must be at least A4 size with a laminated transparent cover and must tell the user of the sheep dip—

(a) to read and act in accordance with the label, including instructions on measuring and diluting concentrate;

(b) that sheep dip is absorbed through the skin;

(c) always to wear the recommended protective clothing, including gloves, and have spare protective clothing available;

(d) always to wash protective clothing before taking it off; and

(e) to direct any questions to the supplier or manufacturer.

(6) The notice must contain a diagram showing recommended protective clothing.

Use of sheep dip E+W+S

23.—(1) **[**[F53]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**]**—

(a) a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed; or

(b) NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF).

(2) The certificate must be issued—

(a) in England, Wales and Northern Ireland; by—

(i) the National Proficiency Tests Council;

(ii) NPTC Part of the City & Guilds Group; or

(iii) City and Guilds NPTC;

(b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

Extent Information

E17 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F53 Words in Sch. 3 para. 23(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **117**

Use of sheep dip N.I.

23.—(1) No person may use sheep dip which contains a veterinary medicinal product unless the person is acting under the supervision and in the presence of, a person who holds either—

(a) a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed; or

(b) NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF).

(2) The certificate must be issued—

(a) in England, Wales and Northern Ireland; by—

(i) the National Proficiency Tests Council;

(ii) NPTC Part of the City & Guilds Group; or

(iii) City and Guilds NPTC;

(b) in Scotland, by one of those organisations or the Scottish Skills Testing Service.

Extent Information

E35 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Offences E+W+S

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

(a) paragraph 2;

(b) paragraph 3;

[F54(ba) paragraph 3A;

(bb) paragraph 3B;

(bc) paragraph 3C;

(bd) paragraph 3D;

(be) paragraph 3E;**]**

(c) paragraph 4(1);

(d) paragraph 5;

[F55(da) paragraph 6;**]**

(e) paragraph 7;

[F56(ea) paragraph 7A;]

(f) paragraph 8(1);

(g) paragraph 9(1);

(h) paragraph 10;

(i) paragraph 11;

(j) paragraph 12(1) or (3);

(k) paragraph 13;

(l) paragraph 14(4), (5) or (6);

(m) paragraph 15;

[F57(ma) paragraph 16;]

F58(n) . . . . . .

(o) paragraph 21;

[F59(oa) paragraph 21B;

(ob) paragraph 21C;

(oc) paragraph 21D;

(od) paragraph 21E;

(oe) paragraph 21F;]

(p) paragraph 22; or

(q) paragraph 23(1).

Extent Information

E18 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F54 Sch. 3 paras. 24(ba)-(be) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **118(a)**

F55 Sch. 3 para. 24(da) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **118(b)**

F56 Sch. 3 para. 24(ea) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **118(c)**

F57 Sch. 3 para. 24(ma) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **118(d)**

F58 Sch. 3 para. 24(n) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **118(e)**

F59 Sch. 3 paras. 24(oa)-(oe) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **118(f)**

Offences N.I.

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

(a) paragraph 2;

(b) paragraph 3;

(c) paragraph 4(1);

(d) paragraph 5;
(e) paragraph 7;
(f) paragraph 8(1);
(g) paragraph 9(1);
(h) paragraph 10;
(i) paragraph 11;
(j) paragraph 12(1) or (3);
(k) paragraph 13;
(l) paragraph 14(4), (5) or (6);
(m) paragraph 15;
(n) paragraph 19(4);
(o) paragraph 21;
(p) paragraph 22; or
(q) paragraph 23(1).

Extent Information

E36 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, SCHEDULE 3.