#### SCHEDULE 3

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 [F4adverse 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 [F5antibiotics] 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)
- 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**

E11 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 <sup>F6</sup>... 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 [<sup>F7</sup> 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.
- [<sup>F8</sup>(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.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

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

#### **Extent Information**

E12 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—

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

- (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**

**E13** 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

## [F10]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).

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

(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

## [F10 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.]

### **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** 

## [F10 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.

### **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

### [F10] 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.]

#### **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 [FII] or 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 [F13 or 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.]

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

#### **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**

E14 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;

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

- (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;

 $<sup>\</sup>textbf{(1)} \quad \text{S. I. } 2001/3998; \text{ relevant amending instruments are S. I. } 2003/1432 \text{ and } 2005/1653.$ 

- (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;
- (i) 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**

**E15** 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 contraindications 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.]

 $<sup>(1) \</sup>quad S.\ I.\ 2001/3998; relevant amending instruments are \ S.\ I.\ 2003/1432 \ and \ 2005/1653.$ 

#### **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)**

## [F20] 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.]

### **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**

E16 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 [F23 medicinal premix] E+W+S

- 11.—(1) This paragraph applies in relation to the supply of a [F<sup>24</sup>medicinal 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 [F27 authorised][F28 intermediate 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

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- 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 [F27authorised][F31intermediate feedingstuffs] manufacturer; or
  - (b) an [F27authorised] feedingstuffs manufacturer if the [F32authorisation] permits the rate of incorporation specified on the label of that [F30medicinal premix] (if the manufacturer is the end user the supply must be in accordance with a prescription [F33for medicated feedingstuffs]).
- [<sup>F34</sup>(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 enduser 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**

**E17** 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—

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- (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**

**E18** 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 [F40] and 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.

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

- (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.
- [<sup>F41</sup>(11) The Secretary of State must, from time to time, inspect premises authorised under subparagraph (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.

 $<sup>\</sup>begin{tabular}{ll} \textbf{(2)} & Published at: $http://www.vmd.defra.gov.uk/registers/sqpregister.aspx. \end{tabular}$ 

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

- (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**

**E19** 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.

 $<sup>\</sup>begin{tabular}{ll} \textbf{(2)} & Published at: $http://www.vmd.defra.gov.uk/registers/sqpregister.aspx. \end{tabular}$ 

Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1. (See end of Document for details)

(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**

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

## **Status:**

Point in time view as at 17/05/2024.

# **Changes to legislation:**

There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 1.