

## SCHEDULE 3

Classification and supply, wholesale dealers and sheep dip

### PART 2

Requirements for a wholesale dealer's authorisation

#### [<sup>F1</sup>Wholesale 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

**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. 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

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

#### [<sup>F2</sup>Application 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

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- (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

**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

**F2** [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

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

#### [<sup>F3</sup>Procedure 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 subparagraph (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

**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

**F3** [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

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

### [<sup>F4</sup>Periodic 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

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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

**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

**F4** [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<sup>(1)</sup>.

(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

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

### <sup>F5</sup> Application for variation to the authorisation

**19A.**—(1) The holder of a wholesale dealer's authorisation must notify the Secretary of State, and apply for a variation of the authorisation, before making a material alteration to the premises or facilities used under the authorisation or the operations for which the premises or facilities are used or where there is a change in the personnel carrying out the role of wholesale qualified person.

(2) The Secretary of State must process an application under sub-paragraph (1) within 30 days of receiving it unless the Secretary of State notifies the applicant in writing that the time has been extended to 90 days.

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

(1) OJ No C 63, 1.3.94, p. 4.

(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.]

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#### Textual Amendments

**F5** 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—

- (a) has not complied with these Regulations; or
- [<sup>F6</sup>(b) no longer has suitable premises, equipment or technically competent staff]

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#### 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

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#### Textual Amendments

**F6** 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.

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#### 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

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**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;
  - [<sup>F7</sup>(b) comply with good distribution practice;]
  - <sup>F8</sup>(c) .....
  - (d) supply information and samples to the Secretary of State on demand [<sup>F9</sup>; 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**

**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**

- F7** 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)**
- F8** 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)**
- F9** 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**

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

**[<sup>F10</sup>Register of authorised wholesale dealers**

**21A.** The Secretary of State must establish, maintain and publish on a website a register of authorised wholesale dealers and their sites.]

**Textual Amendments**

**F10** 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**

**[<sup>F10</sup>Documentation accompanying veterinary medicinal products supplied wholesale**

**21B.**—(1) This paragraph applies in relation to wholesale supply of veterinary medicinal products.

(2) The holder of a wholesale dealer’s authorisation must ensure that a document accompanies each consignment of veterinary medicinal products specifying—

- (a) the name of the veterinary medicinal product;
- (b) the strength and pharmaceutical form;
- (c) the date on which the veterinary medicinal product was supplied;
- (d) the quantity of product supplied;
- (e) the batch number;
- (f) the expiry date;
- (g) the name and address of the wholesale dealer supplying the product;
- (h) the means by which the product was transported and the required conditions of storage;
- (i) the name of the person to whom the product was supplied and the address to which it is to be delivered.

(3) The holder of a wholesale dealer’s authorisation must make a record of the information mentioned in sub-paragraph (2) and must keep it for at least five years.]

**Textual Amendments**

**F10** 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**

**[<sup>F10</sup>Recalled, counterfeit or returned products**

**21C.**—(1) The holder of a wholesale dealer’s authorisation must comply with any requirement by the Secretary of State to recall a veterinary medicinal product and must record the details of the recall operation.

(2) The holder of a wholesale dealer’s authorisation must record any veterinary medicinal product which is—

- (a) recalled (whether or not the holder physically receives the recalled product);
- (b) discovered to be counterfeit; or
- (c) returned.

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

(4) Where a recalled or returned veterinary medicinal product has not been stored (including during transport) in accordance with the summary of product characteristics or where it is not

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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

**F10** 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**

#### [<sup>F10</sup>Audit

**21D.**—(1) At least once a year, the holder of a wholesale dealer's authorisation must carry out a detailed audit of stock and compare the incoming and outgoing veterinary medicinal products recorded with products currently held and record the results of the audit in written form.

(2) Where, as a result of the audit mentioned in sub-paragraph (1), the holder identifies a discrepancy the holder must—

- (a) make a record of that fact,
- (b) conduct an investigation for the purpose of discovering the cause of the discrepancy, and
- (c) maintain records of that investigation.

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

#### Textual Amendments

**F10** 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**

#### [<sup>F10</sup>Contractual arrangements between holders of wholesale dealer's authorisations

**21E.** Where the holder of a wholesale dealer's authorisation contracts out any wholesale dealing activities to another such holder, the arrangement must record in writing the responsibilities of each party in relation to their respective roles in the supply process and, in particular, in connection with the recall of a veterinary medicinal product under paragraph 21C.]

#### Textual Amendments

**F10** 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**



[<sup>F10</sup>**Self-inspection programme**

**21F.**—(1) The holder of a wholesale dealer’s authorisation must have in place a self-inspection programme which ensures that every aspect of its business is inspected at least once a year in order to ensure that it is complying with good distribution practice.

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

- (a) make a record of that fact,
- (b) conduct an investigation for the purpose of discovering the cause of the non-compliance, and
- (c) maintain records of that investigation.

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

**Textual Amendments**

**F10** 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**

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