

## SCHEDULE 3

### CLASSIFICATION AND SUPPLY, WHOLESALE DEALERS AND SHEEP DIP

## PART 2

### Requirements for a wholesale dealer's authorisation

#### **Application**

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

#### **Time limits**

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

#### **Granting the authorisation**

17.—(1) The Secretary of State shall grant a wholesale dealer's authorisation if he is 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 at his disposal the services of technically competent staff; and
- (b) have an effective emergency recall plan.

#### **The authorisation**

18.—(1) The wholesale dealer's authorisation shall 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; and
- (e) the name of the qualified person nominated to act under the Guidelines on Good Distribution Practice under paragraph 21.

(2) It may cover more than one site.

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

*Status: This is the original version (as it was originally made).*

### **Suspension or revocation of the authorisation**

**19.** The Secretary of State may suspend 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.

### **Representations**

**20.**—(1) A person may make representations against a refusal, suspension or revocation of a wholesale dealer's authorisation to a person appointed for the purpose by the Secretary of State.

(2) The appointed person shall consider the representations and report in writing to the Secretary of State.

(3) The Secretary of State shall give written notification of his final determination and the reasons for it.

### **Duties on the holder of a wholesale dealer's authorisation**

**21.**—(1) The holder of a wholesale dealer's authorisation must store veterinary medicinal products in accordance with the terms of the marketing authorisation for each product.

(2) He must comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use<sup>(1)</sup> as if the veterinary medicinal products were products for human use.

(3) He must carry out a detailed stock audit at least once a year.

(4) He must supply information and samples to the Secretary of State on demand.

(5) He must notify the Secretary of State if there are any changes to the information held by him.

(6) It is an offence to fail to comply with this paragraph.

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(1) OJNo. C 63, 1.3.94, p. 4.