

SCHEDULE 2

The manufacture of veterinary medicinal products

PART 3

Authorisation of blood banks

Authorisation of blood banks

21.—(1) The Secretary of State may authorise blood banks for the collection, storage and supply of blood for the treatment of non-food-producing animals.

(2) In order to be authorised a blood bank must be under the supervision of—

- (a) a veterinary surgeon named in the authorisation; or
- (b) a person named in the authorisation who the Secretary of State is satisfied is suitably qualified to operate the blood bank.

(3) Before he authorises a blood bank, the Secretary of State must be satisfied—

- (a) that the welfare of animals used in the collection of blood will be respected; and
- (b) that the production process will produce a consistent, safe product.

(4) The procedure for the suspension or revocation of the authorisation is the same as for the holder of a manufacturing authorisation.

(5) Blood may only be collected under the responsibility of a veterinary surgeon.

(6) It is an offence to operate a blood bank for treatment of animals other than in accordance with such an authorisation.

Supply and administration of blood from a blood bank

22.—(1) The blood may only be supplied to a veterinary surgeon.

(2) It may only be administered by a veterinary surgeon or under his responsibility.

(3) It may only be administered to non-food-producing animals.

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

Labelling

23.—(1) The operator of a blood bank must ensure that every container used for the blood is labelled with—

- (a) the identification of the donor animal;
- (b) the date of collection;
- (c) the authorisation number of the blood bank;
- (d) any necessary warnings;
- (e) the expiry date.

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

Records

24.—(1) The operator of a blood bank must, as soon as is reasonably practicable, record—

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- (a) the date of collection;
 - (b) the identification of the donor animal;
 - (c) the veterinary surgeon who collected it;
 - (d) the expiry date;
 - (e) the date the blood was used or, if it was supplied to another veterinary surgeon, the name of that veterinary surgeon and the date it was supplied.
- (2) He must keep the records for at least five years.
- (3) It is an offence to fail to comply with this paragraph.

Inspection of blood banks

- 25.** The Secretary of State must inspect a blood bank every two years.