SCHEDULE 2

THE MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS

PART 4

Authorisation of manufacturers of products for administration under the cascade

Authorisation to manufacture products for administration under the cascade

26.—(1) The Secretary of State may authorise a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade.

(2) In order to be authorised the premises must be under the supervision of a person who the Secretary of State is satisfied has sufficient qualifications and experience to manufacture the product safely.

(3) Before he authorises the premises, the Secretary of State must be satisfied that the production process will produce a 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) The authorisation shall specify what types of product it covers.

(6) It is an offence for the holder of an authorisation to manufacture a product other than in accordance with the authorisation.

Labelling

27.—(1) The authorised person must ensure that, before a veterinary medicinal product is supplied, every container is labelled with—

(a) the name of the veterinary surgeon who ordered the veterinary medicinal product;

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the name of the authorisation holder and the address of the authorised premises;

(e) the expiry date;

(f) any necessary warnings; and

(g) instructions for use.

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

Records

28.—(1) The authorised person must, as soon as is reasonably practicable, record—

(a) the name and address of the veterinary surgeon who ordered the veterinary medicinal product;

(b) a precise description of the veterinary medicinal product;

(c) the date of production;

(d) the expiry date; and

(e) the date of supply to the veterinary surgeon.

(2) He must keep the records for at least five years.

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

Adverse reaction

29.—(1) The authorised person must notify the Secretary of State of any adverse reaction to a product manufactured by him within 15 days of learning of the reaction.

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

Inspection of premises

30. The Secretary of State shall inspect the authorised premises every two years.