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

25.—(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 authorising the premises, the Secretary of State must be satisfied that the production process will produce a safe product.

(4) The authorisation must specify what types of product it covers.

(5) No person may manufacture an unauthorised veterinary medicinal product other than in accordance with an authorisation under sub-paragraph (1).

Labelling

26. 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.

Records

27. 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,

and must keep the record for at least five years.

Adverse reactions

28. The authorised person must notify the Secretary of State of any adverse reactions to a product manufactured by that person within 15 days of learning of the reaction.

Inspection of premises

29. The Secretary of State must inspect the authorised premises, basing the frequency of the inspection on the risks associated with each premises' history and the nature of the products handled at the premises.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 4.