SCHEDULE 2

THE MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS

PART 2

Authorisation of manufacturers of autogenous vaccines

Authorisation to manufacture autogenous vaccines

15.—(1) The Secretary of State may authorise a person and premises to manufacture autogenous vaccines.

(2) In order to be authorised the premises must be under the supervision of—

(a) a veterinary surgeon, or

(b) 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 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) It is an offence to manufacture an autogenous vaccine other than in accordance with such an authorisation.

Commencement Information
I1 Sch. 2 para. 15 in force at 1.10.2006, see **reg. 1**

Types of authorisation

16.—(1) The authorisation shall specify the products that may be manufactured.

(2) It shall either be for the production of a single batch of product or for on-going production of the products specified in the authorisation.

(3) If it is for a single batch the authorisation shall be time-limited.

(4) Only the products specified in the authorisation may be manufactured, and in the case of an authorisation for a single batch the product may only be manufactured before the expiry of the authorisation.

Commencement Information
I2 Sch. 2 para. 16 in force at 1.10.2006, see **reg. 1**

Labelling

17.—(1) The operator of the premises must ensure that every container containing autogenous vaccine is labelled with—

(a) the name of the veterinary surgeon who ordered the vaccine;

(b) a precise description of the vaccine;

(c) the date the vaccine was produced;

(d) the name of the authorisation holder and 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.

Commencement Information

I3 Sch. 2 para. 17 in force at 1.10.2006, see **reg. 1**

Records

18.—(1) The operator of the premises must, as soon as is reasonably practicable, record—

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

(b) the identity of the source animal;

(c) the expiry date;

(d) 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.

Commencement Information

I4 Sch. 2 para. 18 in force at 1.10.2006, see **reg. 1**

Adverse reactions

19.—(1) The authorised person must notify the Secretary of State of any adverse reactions to an autogenous vaccine of which he becomes aware within 15 days of learning of the reaction.

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

Commencement Information

I5 Sch. 2 para. 19 in force at 1.10.2006, see **reg. 1**

Inspection of premises

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

Commencement Information

I6 Sch. 2 para. 20 in force at 1.10.2006, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2006, PART 2.