#### 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 for administration in accordance with regulation 15.
  - (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 she authorises the premises, the Secretary of State must be satisfied that the production process will produce a consistent, safe product.
- (4) 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.

### 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.

### Labelling

- **17.**—(1) The operator 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;
  - (g) instructions for use, if any.
  - (2) It is an offence to fail to comply with this paragraph.

#### Records

- **18.**—(1) The operator of premises manufacturing autogenous vaccines 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.

#### **Adverse reactions**

**19.** 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.

# **Inspection of premises**

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