SCHEDULE 3

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES, TOXINS OR SERA

PART 5

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SERA

1. The licence holder shall ensure that blood used in the production of any serum shall only be collected from living animals in separate premises which—

(a) are used for no other purpose,

(b) have impervious walls and floors, and

(c) are capable of being washed and chemically disinfected.

2. The licence holder shall ensure that an adequate system of manure removal is in operation in the separate premises referred to in paragraph 1.

3. Before an animal is used in the production of any serum, the licence holder shall take all reasonable steps to ensure that it is free from disease and to this end shall keep the animal in quarantine and under observation for such period as the licensing authority may direct.

4. The licence holder shall notify the licensing authority if any animal which has been used in the production of any serum is found to be suffering from an infection other than an infection produced by living organisms against which it is being immunised or shows serious or persistent signs of ill-health not attributable to the process of immunisation and shall withhold any serum obtained from that animal from sale, supply or exportation until he has obtained the consent of the licensing authority in writing to its release.

5. The licence holder shall notify the licensing authority if any post-mortem examination on any animal indicates that any other animals used in the production of any serum are or are likely to be unhealthy, and the licence holder shall not use those animals for the production of any serum until either he has obtained the consent of the licensing authority in writing or has complied with any requirements the licensing authority may consider necessary in the interest of safety.

6. The licence holder shall ensure that laboratories in which any serum is processed are separate from premises in which animals are housed.

7. The licence holder shall provide such number of sterilizers as are necessary for the sterilization of all glassware and other apparatus used in the production of sera.

8. Without prejudice to any other requirements to keep records, the licence holder shall keep the following durable records relating to the production of sera readily available for inspection by a person authorised by the licensing authority, and shall ensure that those records are not destroyed for a period of five years from the date when the relevant production occurred—

(a) as to the cultures used—

(i) the source from which the culture was obtained,

(ii) the nature of the material from which the culture was isolated,

(iii) the date of the isolation, and

(iv) evidence of the identity and specificity of the culture;

(b) as to the procedure used in the immunizing of animals—

(i) the method of preparing the culture or antigen used for immunization,

(ii) the dosage and methods employed in administering the culture or antigen, and

(iii) the time in the course of immunization at which blood is withdrawn for preparation of the serum; and

(c) the results of any tests which may have been applied to the serum to determine its content of specific antibodies or its specific therapeutic potency.

9. Nothing in this Part shall operate so as to restrict the right of access to any premises of any person who is duly authorised by the enforcement authority to enter those premises in accordance with section 111 of the Act.