SCHEDULE 2

The manufacture of veterinary medicinal products

PART 1

Manufacturing authorisations

Application

1. An application for a manufacturing authorisation must be made to the Secretary of State.

Time limits

2.—(1) The Secretary of State must process an application for a manufacturing authorisation within 90 days of receiving it.

(2) He must process an application for a variation of a manufacturing authorisation within 30 days unless he notifies the applicant in writing that he is extending the time to 90 days.

Granting the authorisation

3. The Secretary of State must grant a manufacturing authorisation if he is satisfied that the applicant has at his disposal suitable and sufficient premises, staff, technical equipment and facilities for the manufacture, control and storage of the products, and will comply with his duties under these Regulations.

The authorisation

4.—(1) The manufacturing authorisation must specify—

(a) the types of veterinary medicinal products and pharmaceutical forms that may be manufactured or imported;

(b) the place where they are to be manufactured or controlled;

(c) the name and address of the person holding the authorisation;

(d) the address of the premises to which it relates;

(e) the name of the qualified person nominated to act under this Schedule.

(2) It may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of the manufacturing authorisation to restrict access to premises or parts of premises to persons carrying out activities there.

Suspension or revocation of the authorisation

5.—(1) The Secretary of State may suspend or revoke a manufacturing authorisation if the holder—

(a) has not complied with these Regulations;

(b) has manufactured a veterinary medicinal product not authorised by his manufacturing or authorisation;

(c) has produced a veterinary medicinal product outside the terms of a marketing authorisation;

(d) no longer has suitable premises or equipment.

(2) He may also suspend or revoke it if he is satisfied that the qualified person (manufacture) is not fulfilling his duties.

Appeal to an appointed person

6.—(1) A person may appeal against a refusal, suspension or revocation of a manufacturing authorisation to a person appointed for the purpose by the Secretary of State.

(2) The appointed person must consider the appeal and report in writing to the Secretary of State.

(3) The Secretary of State must give written notification of his final decision and the reasons for it.

Inspection of premises

7.—(1) The Secretary of State must inspect the premises relating to a manufacturing authorisation on a regular basis to ensure compliance with good manufacturing practice.

(2) Within 90 days after an inspection, the Secretary of State must issue a certificate of good manufacturing practice to the manufacturer if the inspection established that he is complying with the principles and guidelines on good manufacturing practice in accordance with Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**1**).

(3) If an inspection is carried out at the request of the European Pharmacopoeia to establish compliance with a monograph, the Secretary of State must issue a certificate of compliance with the monograph, if appropriate.

(4) The Secretary of State must provide details of each certificate of good manufacturing practice that he issues to the Agency for entry into a database.

(5) If the outcome of the inspection is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice, he must provide details to the Agency for entry into the database.

Report following inspection

8.—(1) After each inspection of manufacturing premises, the inspector must make a written report to the Secretary of State on whether the principles and guidelines on good manufacturing practice and the conditions of these Regulations are being complied with.

(2) The Secretary of State must inform the inspected manufacturer of the content of such reports.

Duties on the holder of a manufacturing authorisation

9.—(1) A holder of a manufacturing authorisation must ensure that the veterinary medicinal product is manufactured in accordance with the marketing authorisation.

(2) He must have permanently at his disposal the services of at least one qualified person (manufacture) who is on the register of qualified persons (manufacture) maintained by the Secretary of State.

(3) He must hold a current Certificate of Good Manufacturing Practice.

(4) He must have in place a system of Quality Assurance and Quality Control.

(5) He must give to the Secretary of State on request proof of all control tests carried out on the veterinary medicinal product or the constituents and intermediate products of the manufacturing process in accordance with the data submitted in support of the application for the marketing authorisation.

(**1**) OJNo. L 228, 17.8.91, p. 70.

(6) If he makes up a bulk package of veterinary medicinal products he must ensure that the package is labelled, in a way that the label is clearly visible and legible, with—

(a) the name of the veterinary medicinal product, its strength as shown in the summary of product characteristics and its pharmaceutical form;

(b) the batch number;

(c) the expiry date;

(d) any storage requirements; and

(e) any other warning necessary for the safe handling of the package.

(7) He must keep an adequate number of representative samples of each batch of a veterinary medicinal product in stock at least until the expiry date of the batch, and must submit any such sample to the Secretary of State if he requires it in writing.

Qualified persons for manufacture

10.—(1) The Secretary of State may appoint as a qualified person (manufacture) any person who is—

(a) registered as a pharmaceutical chemist with the Royal Pharmaceutical Society of Great Britain or with the Pharmaceutical Society of Northern Ireland;

(b) a Chartered Chemist or a Fellow, Member or Associate Member of the Royal Society of Chemistry; or

(c) a Chartered Biologist or a Fellow, Member or Associate Member of the Institute of Biology,

who qualified on the basis of a formal course of study lasting not less than three years full-time or equivalent and who has sufficient practical experience to carry out the duties under this Schedule.

(2) The Secretary of State may exceptionally appoint a person who is not a member of one of those institutions to act as a qualified person (manufacture) if he is satisfied that he has the educational qualifications or practical experience to carry out the duties under this Schedule.

Refusal or revocation of appointment

11.—(1) The Secretary of State may refuse or revoke an appointment if he is not satisfied that a person has fulfilled or will fulfil his duties.

(2) A person may appeal against a refusal or revocation to a person appointed for the purpose by the Secretary of State, and the procedure in paragraph 6 applies.

Duties on a qualified person

12.—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under his responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from a third country, including a product manufactured in a member State, the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested in a member State, including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) The preceding paragraph does not apply where appropriate arrangements have been made by the European Community with the exporting country to ensure that the manufacturer of the

veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

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

Register

13. The Secretary of State must maintain and publish a register of holders of manufacturing authorisations and qualified persons (manufacture).

Test sites

14.—(1) The Secretary of State may authorise premises to act as a test site to carry out contract testing for a holder of a manufacturing authorisation.

(2) The premises must have a current certificate of good manufacturing practice.

(3) Authorisation and inspection of the premises are the same as for a manufacturing authorisation.