SCHEDULE 2 Regulations 4(b), 7(2)(b), 11(2) and 13(1)

FEES FOR INSPECTIONS

Interpretation

1.—(1) In this Schedule—

"major inspection" means an inspection at a site at which 60 or more, but fewer than 250, relevant persons are employed;

"minor inspection" means an inspection at a site at which fewer than 10 relevant persons are employed;

"relevant person" means any person directly or indirectly engaged in, or assisting in, the manufacture or assembly of medicinal products and includes any person connected with such production who is involved in management, quality control, site maintenance, packing, storage or distribution;

"standard inspection" means an inspection at a site at which 10 or more, but fewer than 60, relevant persons are employed;

"supersite inspection" means an inspection at a site at which 250 or more relevant persons are employed.

(2) In calculating the number of relevant persons for the purposes of this Schedule, any person partly engaged in or assisting in the manufacture or assembly of medicinal products (whether as a part-time employee or by virtue of being only partly employed in such work) shall be included in the calculation but only as a fraction calculated by reference to the amount of time spent by that person engaged or assisting in the manufacture or assembly of medicinal products or, where such a calculation is inappropriate, by reference to the percentage of his job which relates to the manufacture or assembly of such products and, in either case, by comparison with the average working week of a relevant person engaged in full-time employment at the same site.

(3) Any reference in sub-paragraphs (1) and (2) to the manufacture or assembly of medicinal products includes a reference to the preparation of substances which are used in the manufacture of an immunological product or a blood product.

Fees

2. Subject to paragraphs 3 to 6, the fee payable in respect of an inspection under these Regulations shall be—

(a) except in the case of an inspection falling within sub-paragraphs (b) to (d)—

(i) in respect of a minor inspection, £1,560;

(ii) in respect of a standard inspection, £2,945;

(iii) in respect of a major inspection, £4,750:

(iv) in respect of a supersite inspection, £9,025;

(b) where the site inspected is wholly or partly concerned with the manufacture of sterile products or the filling of the containers directly in contact with such products—

(i) in respect of a minor inspection, £1,740;

(ii) in respect of a standard inspection, £4,890;

(iii) in respect of a major inspection, £7,885;

(iv) in respect of a supersite inspection, £15,010;

(c) except in the case of an inspection falling within sub-paragraph (b) or (d), where the site inspected is concerned only with the assembly of medicinal products

(i) in respect of a minor inspection, £600;

(ii) in respect of a standard inspection, £1,680;

(iii) in respect of a major inspection, £2,790;

(iv) in respect of a supersite inspection, £5,225;

(d) where the site inspected is limited solely to the manufacture or assembly of medicinal products, the sale or supply of which does not require a marketing authorization and to which article 2(2)(i)(e) (exemption for certain special manufactured products) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 applies, £115.

3.—(1) Where any inspection at a site would be a supersite inspection and that site consists of two or more separate manufacturing operations on different parts of the site, an inspection may, pursuant to a request in writing from the applicant or, as the case may be, the marketing authorization or licence holder, relate to one or more manufacturing operations at that site.

(2) An inspection referred to in sub-paragraph (1) shall be categorised in accordance with the number of relevant persons employed in each manufacturing operation which is inspected as if that operation constituted the entire site, and the fee payable for that inspection shall be the appropriate fee specified for that category in paragraph 2, or if more than one manufacturing operation is inspected, the aggregate of the appropriate fees shall be payable.

4.—(1) Subject to sub-paragraph (2), unless the applicant or, as the case may be, the holder of the marketing authorization or licence establishes that an inspection is a minor inspection, standard inspection or major inspection, the fee payable shall be the appropriate fee specified in paragraph 2 for a supersite inspection.

(2) If, following an inspection, it becomes apparent that the inspection fell into a different category from that established by the applicant or the holder of the marketing authorization or licence, the fee payable in respect of that inspection shall be the fee payable in respect of an inspection falling within the category into which the inspection should have fallen.

5.—(1) In the case of an inspection of a site in connection with the grant, variation or renewal of a wholesale dealer's licence or during the currency of such a licence, the fee payable shall be £315 in a case falling within sub-paragraph (2) and, in any other case, £690.

(2) The cases referred to in paragraph (1) are cases where—

(a) the site is that of a wholesale dealer whose licence is limited to dealing only in medicinal products falling within a description or class specified in an Order made under section 51(1) (general sale lists) of the Act;

(b) the site relates to a registered pharmacy as referred to in paragraph 6(2) of Part II of Schedule 1; or

(c) the total turnover in respect of sales by way of wholesale dealing in authorised medicinal products of the wholesale dealer does not exceed £30.000.

6. The fee payable in respect of an inspection at a site outside the United Kingdom shall be increased by an amount equal to the travelling and subsistence costs of the inspector relating to the inspection and any additional costs (such as interpreters' fees) reasonably incurred by him in respect of that inspection as a result of its being at a site outside the United Kingdom.