

SCHEDULE 1

CAPITAL FEES FOR APPLICATIONS, VARIATIONS AND RENEWALS OF LICENCES

PART V

fees for applications for renewals of licences

Product Licences

1. The fee payable under regulation 10(a) in connection with an application for renewal of a product licence shall be £250.

Manufacturers' Licences

2. The fee payable under regulation 10(a) in connection with an application for renewal of a manufacturer's licence shall be—

- (a) in the case of a manufacturer's licence referred to in paragraph 4(2) of Part II of this Schedule, £50;
- (b) in any other case, £500.

Wholesale Dealers' Licences

3. The fee payable under regulation 10(a) in connection with an application for renewal of a wholesale dealer's licence shall be £325. 2Regulations 3(b), 6(b), 10(b) and 13FEES FOR INSPECTIONS

Interpretation

1.—(1) In this Schedule—

“major inspection” means an inspection at a site at which 60 or more 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 also 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.

(2) In calculating the number of relevant persons for the purposes of this Schedule, any person partly engaged 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.

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Fees

2. Subject to paragraphs 3 to 5, 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) below—
 - (i) in respect of a minor inspection, £750;
 - (ii) in respect of a standard inspection, £1,500;
 - (iii) in respect of a major inspection, £3,000;
- (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, £1,250;
 - (ii) in respect of a standard inspection, £2,500;
 - (iii) in respect of a major inspection, £5,000;
- (c) except in the case of an inspection falling within sub-paragraph (b) above or sub-paragraph (d) below, where the site inspected is concerned only with the assembly of medicinal products—
 - (i) in respect of a minor inspection, £500;
 - (ii) in respect of a standard inspection, £1,000;
 - (iii) in respect of a major inspection, £2,000;
- (d) where the site inspected is limited solely to the manufacture or assembly of—
 - (i) medicinal products, the sale or supply of which do not require a product licence and to which Article 2(2)(i)(e) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 applies; or
 - (ii) emergency vaccines for use in poultry or other animals; £50.
- (e) For the purposes of sub-paragraph (d)(ii) “emergency vaccines” means (i) no other suitable licensed vaccines are readily available for such use and (ii) the vaccines are manufactured or assembled only from material obtained from the particular animal, flock or herd intended to be vaccinated.

3.—(1) Subject to paragraph (2), unless the applicant or, as the case may be, the holder of the licence establishes that an inspection is a minor inspection or a standard inspection, the fee payable shall be the appropriate fee specified in paragraph 2 above for a major 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 licence, the fee payable under these Regulations 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.

4. In the case of an inspection 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 under these Regulations shall be—

- (a) except in a case falling within sub-paragraph (b), £650;
- (b) where the site is that of a wholesale dealer whose licence is limited to dealing only in medicinal products falling within a description or class of such products specified in an Order made under section 51(1) of the Act, £250.

5. 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

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inspection and any additional costs reasonably incurred by him in respect of that inspection as a result of its being at a site outside the United Kingdom (such as interpreter's fees).