

SCHEDULE 2

Regulations 27(1), 30,31(2), 32(1)

FEES FOR INSPECTIONS

General provisions relating to fees for inspections

1.—(1) In this Schedule, a reference to 1 day means a period of 7 hours.

(2) For the purposes of paragraphs 3(2)(c), 4(2)(c), 6(2)(c) and 8, in calculating the number of days taken to make an inspection, any part day shall be calculated as a whole day.

(3) Where an inspection is made at a site which is outside the United Kingdom, the fee for the inspection 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 the inspector in respect of that inspection as a result of its being at a site outside the United Kingdom.

(4) If an inspection is made by more than one inspector, the time taken by the licensing authority to make an inspection is the aggregate of times spent by each inspector in making the inspection.

Fees: general

2.—(1) The fee for an inspection made at a site is—

- (a) £2,583, if the time taken to make the inspection is not more than 7 hours; and
- (b) thereafter, £1,292 for every additional period of 3 hours and 30 minutes or less taken to make the inspection.

(2) Sub-paragraph (1) does not apply if the inspection is one for which a fee is payable under paragraphs 3 to 7.

Traditional herbal medicinal products

3.—(1) Sub-paragraph (2) applies if the site inspected is wholly concerned with the manufacture, assembly or import from a third country of traditional herbal medicinal products.

(2) If this sub-paragraph applies, the fee payable in respect of an inspection of a site in connection with the grant, variation or renewal of a manufacturer's licence or during the currency of such a licence, is—

- (a) £967, if the time taken to make the inspection is not more than 3 hours;
- (b) £1,571, if the time taken to make the inspection is more than 3 hours but not more than 1 day; and
- (c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days taken to make the inspection by £1,571.

Sites concerned with starting materials for traditional herbal medicinal products

4.—(1) Sub-paragraph (2) applies if the site inspected is wholly concerned with the manufacture or assembly of starting material for use in the manufacture of traditional herbal medicinal products.

(2) If this sub-paragraph applies, the fee payable in respect of an inspection of an API manufacturer pursuant to Article 111(1)(a) of the 2001 Directive, is—

- (a) £967, if the time taken to make the inspection is not more than 3 hours;
- (b) £1,571, if the time taken to make the inspection is more than 3 hours but not more than 1 day; and

- (c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days to make the inspection by £1,571.

Wholesale dealer’s licence: general

5. Except in the case of an inspection falling within paragraphs 6 or 7, the fee for an inspection of a site made in connection with the grant, variation or renewal of a wholesale dealer’s licence or during the currency of such a licence, is—

- (a) if the time taken to make the inspection is not more than 1 day, £1,882; and
- (b) if the time taken is 1 day or more, £1,882 for the first day and £941 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection.

Wholesale dealer’s licence: traditional herbal medicinal products

6.—(1) Sub-paragraph (2) applies if the site inspected is wholly concerned with the wholesale dealing of traditional herbal medicinal products.

(2) If this sub-paragraph applies, the fee payable in respect 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 is—

- (a) £724, if the time taken to make the inspection is not more than 3 hours;
- (b) £1,330, if the time taken to make the inspection is more than 3 hours but not more than 1 day; and
- (c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days taken to make the inspection by £1,330.

Wholesale dealer’s licences: inspection of short duration

7.—(1) Sub-paragraph (4) applies if the time taken to make the inspection is not more than 3 hours and 30 minutes, and

- (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 31(3) of Part 2 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 £35,000.

(2) In paragraph (c) of sub-paragraph (1), “turnover” means the gross amount of the total sales made during the period of 12 months preceding the date of the application.

(3) If paragraph (c) of sub-paragraph (1) applies because the applicant has not held a wholesale dealer’s licence during the 12 month period preceding the date of the application, sub-paragraph (1) does not apply unless at the time of making the application—

- (a) it is reasonable for the applicant to believe that the gross amount of total sales of authorised medicinal products likely to be made in the period of 12 months following the grant of the licence will not exceed £35,000; and
- (b) the applicant so informs the licensing authority.

(4) If this sub-paragraph applies, the fee payable in respect of an inspection of a site made in connection with the grant, variation or renewal of a wholesale dealer’s licence is £941.

Office-based inspections

8. The fee for an inspection comprising an office-based evaluation and risk assessment of documentation but not involving inspection of a site, in connection with the monitoring of—

- (a) good manufacturing practice, good clinical practice or good pharmacovigilance practice, is £1,812 per day;
- (b) good distribution practice, is £1,317 per day.