

## SCHEDULES

### SCHEDULE 3

Regulations 30(1); 34;35(2) and (3); and  
36(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 total amount of time spent by each inspector in making the inspection.

##### Fees: general

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

- (a) £2,655, if the time taken to make the inspection is not more than 1 day; and
- (b) thereafter, £1,328 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) £994 if the time taken to make the inspection is not more than 3 hours;
- (b) £1,615 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 £1,615.

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### **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 under Article 111(1g)(a) of the 2001 Directive, is—

- (a) £994 if the time taken to make the inspection is not more than 3 hours;
- (b) £1,615 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 £1,615.

### **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 or variation 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, £1,936; and
- (b) if the time taken is 1 day or more, £1,936 for the first day and £968 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) £744 if the time taken to make the inspection is not more than 3 hours;
- (b) £1,367 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 £1,367.

### **Wholesale dealer's licences: inspection of short duration**

7.—(1) Sub-paragraph (3) 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 classified as subject to general sale under regulation 5(1) of the Human Medicines Regulations;
- (b) the site relates to a registered pharmacy as referred to in paragraph 31(3) of Part 2 of Schedule 2; 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) 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—

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- (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.
- (3) 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 £968.

### Broker's registrations

8.—(1) Except in the case of an inspection where sub-paragraph (2) applies, the inspection fee payable in connection with the grant, variation or review of a broker's registration is—

- (a) £1,936 if the time taken to make the inspection is not more than 1 day; and
- (b) if the time taken is 1 day or more, £1,936 for the first day and £968 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection.

(2) This paragraph applies where an application or variation of a broker's registration is considered under paragraph 10 but it is necessary to carry out a site inspection before the registration is granted or varied.

(3) If sub-paragraph (2) applies, a fee of £582 is payable in addition to any fee under paragraph 10.

### Active substance registrations

9.—(1) Except in the case of an inspection where sub-paragraph (2) applies, the fee payable in connection with the grant, variation or review of an active substance registration where the inspection relates to—

- (a) a manufacturer of an active substance, is—
  - (i) £2,655 if the time taken to make the inspection is not more than 1 day; and
  - (ii) if the time taken is 1 day or more, £2,655 for the first day and £1,328 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection;
- (b) an importer or distributor of an active substance, is—
  - (i) £1,936 if the time taken to make the inspection is not more than 1 day; and
  - (ii) if the time taken is 1 day or more, £1,936 for the first day and £968 for every subsequent period of 3 hours and 30 minutes or less taken to make the inspection.

(2) This paragraph applies where an application or variation of an active substance registration is considered under paragraph 10 but it is necessary to carry out a site inspection before the registration is granted or varied.

(3) If sub-paragraph (2) applies—

- (a) a fee of £792 is payable in addition to any fee under paragraph 10 where the inspection relates to a manufacturer of an active substance;
- (b) a fee of £582 is payable in addition to any fee under paragraph 10 where the inspection relates to an importer or distributor of an active substance.

### Office-based inspections

10. 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 £1,863 per day;

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(b) good distribution practice, is £1,354 per day.

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**Changes and effects yet to be applied to :**

- Sch. 3 para. 2(1)(a) sum substituted by [S.I. 2023/314 reg. 25\(2\)\(a\)](#)
- Sch. 3 para. 2(1)(b) sum substituted by [S.I. 2023/314 reg. 25\(2\)\(b\)](#)
- Sch. 3 para. 5(a) sum substituted by [S.I. 2023/314 reg. 25\(3\)\(a\)](#)
- Sch. 3 para. 5(b) sum substituted by [S.I. 2023/314 reg. 25\(3\)\(a\)](#)
- Sch. 3 para. 5(b) sum substituted by [S.I. 2023/314 reg. 25\(3\)\(b\)](#)
- Sch. 3 para. 6(2)(a) sum substituted by [S.I. 2023/314 reg. 25\(4\)\(a\)](#)
- Sch. 3 para. 6(2)(b) sum substituted by [S.I. 2023/314 reg. 25\(4\)\(b\)](#)
- Sch. 3 para. 6(2)(c) sum substituted by [S.I. 2023/314 reg. 25\(4\)\(b\)](#)
- Sch. 3 para. 7(3) sum substituted by [S.I. 2023/314 reg. 25\(5\)](#)
- Sch. 3 para. 8(1)(a) sum substituted by [S.I. 2023/314 reg. 25\(6\)\(a\)\(i\)](#)
- Sch. 3 para. 8(1)(b) sum substituted by [S.I. 2023/314 reg. 25\(6\)\(a\)\(i\)](#)
- Sch. 3 para. 8(1)(b) sum substituted by [S.I. 2023/314 reg. 25\(6\)\(a\)\(ii\)](#)
- Sch. 3 para. 8(3) sum substituted by [S.I. 2023/314 reg. 25\(6\)\(b\)](#)
- Sch. 3 para. 9(1)(a)(i) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(a\)\(i\)](#)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(a\)\(i\)](#)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(a\)\(ii\)](#)
- Sch. 3 para. 9(1)(b)(i) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(b\)\(i\)](#)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(b\)\(i\)](#)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(b\)\(ii\)](#)
- Sch. 3 para. 9(3)(a) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(c\)\(i\)](#)
- Sch. 3 para. 9(3)(b) sum substituted by [S.I. 2023/314 reg. 25\(7\)\(c\)\(ii\)](#)
- Sch. 3 para. 10(a) sum substituted by [S.I. 2023/314 reg. 25\(8\)\(a\)](#)
- Sch. 3 para. 10(b) sum substituted by [S.I. 2023/314 reg. 25\(8\)\(b\)](#)

**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 2 para. 35A inserted by [S.I. 2023/314 reg. 24\(14\)](#)
- Sch. 2 para. 27(2)(a)(i) sum substituted by [S.I. 2023/314 reg. 24\(5\)\(a\)\(i\)](#)
- Sch. 2 para. 27(2)(b)(i) sum substituted by [S.I. 2023/314 reg. 24\(5\)\(a\)\(ii\)](#)
- Sch. 2 para. 27(2)(c)(i) sum substituted by [S.I. 2023/314 reg. 24\(5\)\(a\)\(iii\)](#)
- Sch. 2 para. 27(2)(d)(i) sum substituted by [S.I. 2023/314 reg. 24\(5\)\(a\)\(iv\)](#)
- Sch. 2 para. 27(3)(a)(i) sum substituted by [S.I. 2023/314 reg. 24\(5\)\(b\)](#)
- Sch. 2 para. 28(2)(a)(i) sum substituted by [S.I. 2023/314 reg. 24\(6\)\(a\)\(i\)](#)
- Sch. 2 para. 28(2)(b)(i) sum substituted by [S.I. 2023/314 reg. 24\(6\)\(a\)\(ii\)](#)
- Sch. 2 para. 28(2)(c)(i) sum substituted by [S.I. 2023/314 reg. 24\(6\)\(a\)\(ii\)](#)
- Sch. 2 para. 28(3)(b)(i) sum substituted by [S.I. 2023/314 reg. 24\(6\)\(b\)](#)
- Sch. 2 para. 28(3)(c)(i) sum substituted by [S.I. 2023/314 reg. 24\(6\)\(b\)](#)
- Sch. 2 para. 28A(1)(a)-(c) sum substituted by [S.I. 2023/314 reg. 24\(7\)\(a\)](#)
- Sch. 2 para. 28A(2)(a)-(c) sum substituted by [S.I. 2023/314 reg. 24\(7\)\(b\)](#)
- Sch. 2 para. 56(c) sum substituted by [S.I. 2023/314 reg. 24\(27\)\(b\)](#)
- Sch. 2 para. 57A(a) sum substituted by [S.I. 2023/314 reg. 24\(29\)\(a\)](#)
- Sch. 2 para. 57A(b) sum substituted by [S.I. 2023/314 reg. 24\(29\)\(b\)](#)
- Sch. 2 para. 57A(c) sum substituted by [S.I. 2023/314 reg. 24\(29\)\(c\)](#)
- Sch. 2 para. 57A(d) sum substituted by [S.I. 2023/314 reg. 24\(29\)\(d\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(i\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(ii\)](#)

- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(iii\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(iv\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(v\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(vii\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(viii\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(a\)\(ix\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(b\)\(i\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(b\)\(ii\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(b\)\(iii\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(b\)\(iv\)](#)
- Sch. 2 para. 57B(4) sum substituted by [S.I. 2023/314 reg. 24\(30\)\(b\)\(v\)](#)
- Sch. 4 para. 15(3) inserted by [S.I. 2023/314 reg. 26\(8\)](#)
- reg. 19A(1) sum substituted by [S.I. 2023/314 reg. 13\(a\)](#)
- reg. 19A(2)(a) sum substituted by [S.I. 2023/314 reg. 13\(b\)](#)
- reg. 19A(2)(b) sum substituted by [S.I. 2023/314 reg. 13\(c\)](#)
- reg. 19B sum substituted by [S.I. 2023/314 reg. 14](#)
- reg. 19C(2)(a) sum substituted by [S.I. 2023/314 reg. 15\(a\)\(i\)](#)
- reg. 19C(2)(b) sum substituted by [S.I. 2023/314 reg. 15\(a\)\(ii\)](#)
- reg. 19C(2)(c) sum substituted by [S.I. 2023/314 reg. 15\(a\)\(iii\)](#)
- reg. 19C(3)(a) sum substituted by [S.I. 2023/314 reg. 15\(b\)\(i\)](#)
- reg. 19C(3)(b) sum substituted by [S.I. 2023/314 reg. 15\(b\)\(ii\)](#)
- reg. 19C(3)(c) sum substituted by [S.I. 2023/314 reg. 15\(b\)\(iii\)](#)
- reg. 19E(2)(a) sum substituted by [S.I. 2023/314 reg. 16\(a\)](#)
- reg. 19E(2)(b) sum substituted by [S.I. 2023/314 reg. 16\(b\)](#)
- reg. 19EA inserted by [S.I. 2023/314 reg. 17](#)