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STATUTORY INSTRUMENTS

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**2007 No. 803**

**The Medicines for Human Use and Medical Devices  
(Fees Amendments) (No.2) Regulations 2007**

**Amendment of the Medical Devices Regulations 2002**

- 13.**—(1) The Medical Devices Regulations 2002 shall be amended as follows.
- (2) In regulation 54 (fees payable in connection with the designation etc of UK notified bodies)—
- (a) in paragraph (1)—
    - (i) in sub-paragraph (a), for “£650” substitute “ £850 ”, and
    - (ii) in sub-paragraph (b), for “£2,600” substitute “£3,400”;
  - (b) in paragraph (2), for “£1,300” substitute “£1,700”;
  - (c) in paragraph (3), for sub-paragraphs (a) to (c) substitute the following sub-paragraphs—
    - “(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of £4,200 plus the amounts specified in paragraph (3A);
    - (b) in respect of an inspection pursuant to regulation 45(7)(a), other than an initial inspection—
      - (i) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in all three of the Annexes referred to in this paragraph are met, a fee of £6,800,
      - (ii) if the inspection is for the purpose of deciding whether or not the body is one in respect of which the criteria set out in only two of the three Annexes referred to in this paragraph are met, a fee of £5,100, or
      - (iii) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in only one of the Annexes referred to in this paragraph are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, a fee of £3,400,
- plus the amounts specified in paragraph (3A); and
- (c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of £3,400 plus the amounts specified in paragraph (3A).”; and
- (d) after paragraph (3), insert the following paragraphs—
- “(3A) Subject to paragraph (3B), the additional amounts payable in respect of an inspection referred to in paragraph (3) shall be—
    - (a) an amount for time spent by a member of staff undertaking a site visit at a rate—
      - (i) for the time spent on site, of £240 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and
      - (ii) for the time spent travelling to and from the site, of £67.10 per hour;

*Status: This version of this provision no longer has effect.*

**Changes to legislation:** There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007, Section 13. (See end of Document for details)

- (b) the actual costs of travel, accommodation and subsistence; and
- (c) out of pocket expenses.

(3B) Where the Secretary of State conducts an inspection referred to in paragraph (3) (a) on the same date and at the same premises as an inspection pursuant to regulation 48(7) (a)—

- (a) the amount referred to in paragraph (3A)(3) shall include an amount for any time spent on site by a member of staff which is attributable to the conduct of the inspection pursuant to regulation 48(7)(a), at the rate referred to in paragraph (3A) (a)(i); and
- (b) the costs and expenses referred to in paragraph (3A)(b) and (c) shall include any additional costs and expenses attributable to the conduct of the inspection pursuant to regulation 48(7)(a).”.

(3) In regulation 55 (fees payable in connection with the designation etc of EC conformity assessment bodies)—

- (a) in paragraph (1)—
  - (i) in sub-paragraph (a), for “£650” substitute “ £850 ”, and
  - (ii) in sub-paragraph (b), for “£2,600” substitute “£3,400”;
- (b) in paragraph (2), for “£1,300” substitute “£1,700”;
- (c) in paragraph (3)—
  - (i) at the beginning insert “ Subject to paragraphs (3A) to (3C) ”, and
  - (ii) for paragraphs (a) to (c) substitute the following sub-paragraphs—
    - “(a) in respect of an initial inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), fee of £4,200 plus the amounts specified in paragraph (3D);
    - (b) in respect of any other inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), a fee of £3,400 plus the amounts specified in paragraph (3D);
    - (c) in respect of an inspection pursuant to regulation 48(7)(a) conducted on the same date and at the same premises as an inspection pursuant to regulation 45(7), a fee of £1,700;
    - (d) in respect of an inspection pursuant to regulation 48(7)(b), a fee of £3,400 plus the amounts specified in paragraph (3D).”;
- (d) after paragraph (3), insert the following paragraphs—
  - “(3A) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and one of the inspections is an initial inspection, the fee payable shall be £4,200 plus—
    - (a) £1,700 for each additional inspection; and
    - (b) the amounts specified in paragraph (3D).
  - (3B) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and none of the inspections is an initial inspection, the fee payable shall be £3,400 plus—
    - (a) £1,700 for each additional inspection; and
    - (b) the amounts specified in paragraph (3D)

(3C) Where the Secretary of State conducts two or more inspections referred to in paragraph (3)(c) on the same date and at the same premises, the fee payable for the inspections pursuant to regulation 48(7)(a) shall be £1,700 for each inspection.

(3D) The additional amounts payable in respect of an inspection referred to in paragraphs (3) to (3B) shall be—

- (a) an amount for time spent by a member of staff undertaking a site visit at a rate—
  - (i) for the time spent on site, of £240 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and
  - (ii) for the time spent travelling to and from the site, of £67.10 per hour;
- (b) the actual costs of travel, accommodation and subsistence, and
- (c) out of pocket expenses.”.

(4) In regulation 56 (fees payable in relation to clinical investigations), in paragraph (1)—

- (a) in sub-paragraph (a)—
  - (i) in sub-paragraph (i), for “£1,600” substitute “£1,800”, and
  - (ii) in sub-paragraph (ii), for “£2,100” substitute “£2,400”; and
- (b) in sub-paragraph (b)—
  - (i) in sub-paragraph (i), for “£2,200” substitute “£2,700”, and
  - (ii) in sub-paragraph (ii), for “£3,000” substitute “£3,800”.

**Status:**

This version of this provision no longer has effect.

**Changes to legislation:**

There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007, Section 13.