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## STATUTORY INSTRUMENTS

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# 2002 No. 618

## The Medical Devices Regulations 2002

### PART VI

#### *Fees charged by the Secretary of State*

#### **Interpretation of Part VI**

**52.**—(1) In this Part<sup>F1</sup>...—

“Group A device” means a Class I medical device, a Class IIa medical device, or a Class IIb medical device which is neither an implantable device nor a long term invasive medical device;

“Group B device” means a Class IIb medical device which is either an implantable medical device or a long term invasive medical device, or a Class III medical device, or an active implantable medical device; and “half day” means a period of three and a half hours.

(2) For the purposes of this Part, medical devices are classified as being implantable or long term invasive medical devices in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42, and in the event of a dispute over the classification of a device, the Secretary of State shall determine the classification of the device in accordance with the definitions set out in Section 1 of Annex IX of Directive 93/42.

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#### **Textual Amendments**

**F1** Words in reg. 52(1) omitted (1.9.2003) by virtue of [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), 15

#### **Fees in connection with the registration of devices and changes to registration details**

**53.** Any person required to supply the Secretary of State with any information under regulation 19 or 44 shall, in respect of the processing of that information with regard to the possible registration of that person by the Secretary of State or possible changes to his registration details, pay to the Secretary of State a fee of £70, and that fee—

- (a) shall be payable when the information is supplied by that person to the Secretary of State; and
- (b) shall accompany that information when it is supplied.

#### **Fees payable in connection with the designation etc. of UK notified bodies**

**54.**—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 45 as a notified body shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of [<sup>F2</sup>£850]; or

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(b) in all other cases, a fee of [<sup>F3</sup>£3,400].

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 45(4) of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of [<sup>F4</sup>£1,700].

(3) Where, pursuant to regulation 45(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is one in respect of which the criteria set out in Annex 8 of Directive 90/385, Annex XI of Directive 93/42 [<sup>F5</sup>, read with article 4 of Directive 2003/32] or Annex IX of Directive 98/79 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, the body shall pay to the Secretary of State—

[<sup>F6</sup>(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).]

[<sup>F7</sup>(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;

(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 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).]

(4) A fee under this regulation—

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- (a) in connection with an application for designation under regulation 45(1) or a variation under regulation 45(4)—
  - (i) shall be payable when the application to the Secretary of State is made, and
  - (ii) shall accompany the application when it is made;
- (b) in connection with an inspection pursuant to regulation 45(7), shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

#### Textual Amendments

- F2** Word in reg. 54(1)(a) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(2)(a)(i)**
- F3** Word in reg. 54(1)(b) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(2)(a)(ii)**
- F4** Word in reg. 54(2) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(2)(b)**
- F5** Words in reg. 54(3) inserted (1.9.2003) by [The Medical Devices \(Amendment\) Regulations 2003 \(S.I. 2003/1697\)](#), regs. 1(1)(a), **16**
- F6** Reg. 54(3)(a)-(c) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(2)(c)**
- F7** Reg. 54(3A)(3B) inserted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(2)(d)**

#### Fees payable in connection with the designation etc. of EC conformity assessment bodies

**55.**—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 48 as an EC CAB shall, in connection with that application for designation, pay to the Secretary of State—

- (a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of [<sup>F8</sup>£850]; or
- (b) in all other cases, a fee of [<sup>F9</sup>£3,400].

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 48(4) of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of [<sup>F10</sup>£1,700].

(3) [<sup>F11</sup>Subject to paragraphs (3A) to (3C)] where, pursuant to regulation 48(7) the Secretary of State inspects premises for the purposes of deciding whether or not a body is capable of fulfilling the functions of an EC CAB arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, the body shall pay to the Secretary of State—

- [<sup>F12</sup>(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).]

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[<sup>F13</sup>(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) A fee under this regulation—
  - (a) in connection with an application for designation under regulation 48(1) or a variation under regulation 48(4)—
    - (i) shall be payable when the application to the Secretary of State is made, and
    - (ii) shall accompany the application when it is made;
  - (b) in connection with an inspection pursuant to regulation 48(7), shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

#### Textual Amendments

- F8** Word in reg. 55(1)(a) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(3)(a)(i)**
- F9** Word in reg. 55(1)(b) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(3)(a)(ii)**
- F10** Word in reg. 55(2) substituted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(3)(b)**
- F11** Words in reg. 55(3) inserted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(3)(c)(i)**
- F12** Reg. 55(3)(a)-(d) substituted for reg. 55(3)(a)-(c) (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(3)(c)(ii)**
- F13** Reg. 55(3A)-(3D) inserted (1.4.2007) by [The Medicines for Human Use and Medical Devices \(Fees Amendments\) \(No.2\) Regulations 2007 \(S.I. 2007/803\)](#), regs. 1(1)(b), **13(3)(d)**

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## Fees payable in relation to clinical investigation notices

56.—(1) Subject to paragraph (2), any person required to give the Secretary of State notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall, in respect of the consideration by the Secretary of State of the information that the person is required to submit, pay to the Secretary of State—

- (a) if, as regards that device, it is the second or subsequent occasion on which the person has given the Secretary of State notice of an intended clinical investigation, and the changes from the immediately preceding notice are limited to addressing the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation—
  - (i) a fee, if the device is a Group A device, of [<sup>F14</sup>£1,800], or
  - (ii) a fee, if the device is a Group B device, of [<sup>F15</sup>£2,400]; or
- (b) in all other cases—
  - (i) a fee, if the device is a Group A device, of [<sup>F16</sup>£2,700], or
  - (ii) a fee, if the device is a Group B device, of [<sup>F17</sup>£3,800].

(2) Except where paragraph (3) applies, no fee shall be payable in respect of a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) where the manufacturer or his authorised representative has previously given such notice in relation to that device.

(3) A fee shall be payable where the investigational plan which forms part of the statement accompanying the notice differs from the plan submitted with the immediately preceding notice in that it includes—

- (a) a change to address the grounds on which the Secretary of State has refused or withdrawn permission to hold a clinical investigation;
  - (b) a change to the number of patients or devices forming the basis of the proposed trial;
  - (c) a change or extension in the indications for use of the device or to the purpose or objectives of the trial;
  - (d) a change in any of the materials used in the device that come into direct contact with the human body if the new materials are not known to be biocompatible; or
  - (e) a change in the design of the device involving a novel feature not previously tested, being a change that has a direct effect on a vital physiological function.
- (4) A fee under this regulation—
- (a) shall be payable when the notice to which it relates is given to the Secretary of State; and
  - (b) shall accompany that notice when it is given.

### Textual Amendments

**F14** Word in reg. 56(1)(a)(i) substituted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(4)(a)(i)**

**F15** Word in reg. 56(1)(a)(ii) substituted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(4)(a)(ii)**

**F16** Word in reg. 56(1)(b)(i) substituted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(4)(b)(i)**

**F17** Word in reg. 56(1)(b)(ii) substituted (1.4.2007) by The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007 (S.I. 2007/803), regs. 1(1)(b), **13(4)(b)(ii)**

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## Unpaid fees

57. All unpaid sums due by way of, or on account of, any fees payable under this Part are recoverable as debts due to the Crown.

## Waivers, reductions and refunds

58.—(1) The Secretary of State may—

- (a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under this Part;
- (b) refund the whole or part of any fee paid pursuant to this Part.

(2) Without prejudice to the generality of paragraph (1), where—

- (a) a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) is withdrawn within the period of 7 days beginning with the date of its receipt by the Secretary of State; or
- (b) an application for designation as—
  - (i) a notified body under regulation 45(1), or
  - (ii) an EC CAB under regulation 48(1),

(other than one submitted only to address the grounds of rejection of a previous application) is withdrawn within the period of 21 days beginning with the date of its receipt by the Secretary of State,

the fee payable shall be reduced to fifty per cent of the fee otherwise payable in respect of such notice or application, and any excess already paid shall be refunded.

**Status:**

Point in time view as at 01/04/2007.

**Changes to legislation:**

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