
STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VI

Fees charged by the Secretary of State

[^{F1}Fees payable in connection with pre-consultation meetings

56D.—(1) The fee payable by a person other than an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that person making an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(2) The fee payable by an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that body consulting the Secretary of State in relation to an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(3) The fee payable is—

- (a) £824, if the advice provided at that meeting consists of advice in connection with—
 - (i) quality development only, or
 - (ii) safety development only;
- (b) £1,044, if the advice provided at that meeting consists of advice in connection with—
 - (i) quality and safety development only, or
 - (ii) clinical development only;
- (c) £1,429, if the advice provided at that meeting consists of advice in connection with—
 - (i) quality and clinical development only, or
 - (ii) safety and clinical development only;
- (d) £1,813, if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development.

(4) Any fee payable under this regulation must be paid within 14 days following written notice from the Secretary of State requiring payment of that fee]

Textual Amendments

- F1** [Reg. 56D](#) inserted (E.W.S.) (1.4.2023) by [The Medical Devices and Blood Safety and Quality \(Fees Amendment\) Regulations 2023 \(S.I. 2023/377\)](#), regs. 1(2), **16**

Changes to legislation:

The Medical Devices Regulations 2002, Section 56D is up to date with all changes known to be in force on or before 20 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

[View outstanding changes](#)

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):

- Pt. 8 inserted by [S.I. 2019/791 reg. 10](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 10 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 54)
- Pt. 9 inserted by [S.I. 2019/791 reg. 11](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 11 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 55)
- Sch. 3 inserted by [2021 c. 3 Sch. 3 para. 2](#)
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(2\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 19 para. 5 words substituted by S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(2\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) heading words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(3\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- Sch. 24 para. 1(7) words omitted by virtue of S.I. 2019/791, reg. 12 (as amended) by [S.I. 2019/1385 Sch. 2 para. 11\(3\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 4D(10)(b) substituted by S.I. 2019/791, reg. 3(7) (as amended) by [S.I. 2019/1385 Sch. 2 para. 2\(3\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii))
- reg. 4E(7) words substituted by S.I. 2019/791, reg. 3(7) (as amended) by [S.I. 2019/1385 Sch. 2 para. 2\(3\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(a)(ii))
- reg. 6(d) inserted by [S.I. 2019/791 reg. 4\(2\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 4(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 10)
- reg. 33(1)(c) inserted by [S.I. 2019/791 reg. 6\(2\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
- reg. 33(2)(c) inserted by [S.I. 2019/791 reg. 6\(2\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 6(2) omitted immediately before IP completion day by S.I. 2020/1478, regs. 1(3), Sch. 2 para. 35)
- reg. 60A excluded by [2021 c. 3 Sch. 2 para. 4](#)
- reg. 60A excluded by [2021 c. 3 Sch. 2 para. 5\(2\)](#)
- reg. 60A-60C inserted by [2021 c. 3 Sch. 3 para. 1](#)
- reg. 75(3) words inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(2\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))

- reg. 75(7) inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 93(4) inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(3\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 119(6) words inserted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(4\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 124(5) words substituted by S.I. 2019/791, reg. 10 (as amended) by [S.I. 2019/1385 Sch. 2 para. 9\(5\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 149(5)(e) words substituted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(2\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(1) substituted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))
- reg. 158(3) inserted by S.I. 2019/791, reg. 11 (as amended) by [S.I. 2019/1385 Sch. 2 para. 10\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of S.I. 2020/1478, regs. 1(2), 4(2)(c))