STATUTORY INSTRUMENTS

# 2008 No. 530

# FEES AND CHARGES

## The Medical Devices (Fees Amendments) Regulations 2008

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| *Made - - - -* | *27th February 2008* |
| *Laid before Parliament* | *6th March 2008* |
| *Coming into force - -* | *1st April 2008* |

The Secretary of State for Health, in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(**a**) and section 56(1) and (2) of the Finance Act 1973(**b**), hereby makes the following regulations.

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972(**c**) in relation to medicinal products and medical devices.

The Treasury has consented to the making of these Regulations as required by section 56(1) of the Finance Act 1973.

**Citation and commencement**

**1.** These Regulations may be cited as The Medical Devices (Fees Amendments) Regulations 2008 and shall come into force on 1st April 2008.

**Amendment of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995**

**2.**—(1) The Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**d**) are amended as follows.

(2) In regulation 3 (fees)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£4,141" substitute ""£4,374", and

(ii) in sub-paragraph (b), for "£9,653" substitute "£10,197";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£819" substitute "£865", and

(ii) in sub-paragraph (b), for "£2,291" substitute "£2,420";

(c) in paragraph (3)—

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(**a**) 1972 c.68.
(**b**) 1973.c.51.
(**c**) The Secretary of State was designated in relation to measures relating to active implantable medical devices in S.I. 1991/2289, and in relation to measures relating to medical devices other than active implantable medical devices in S.I. 1993/2651.
(**d**) S.I. 1995/449; relevant amending instrument is S.I. 2007/803.

(i) in sub-paragraph (a), for "£4,141" substitute "£4,374", and

(ii) in sub-paragraph (b), for ""£9,653" substitute "£10,197";

(d) in paragraph (4)—

(i) in sub-paragraph (a), for "£819" substitute "£865", and

(ii) in sub-paragraph (b), for "£2,291" substitute " £2,420";

(e) in paragraph (5)—

(i) in sub-paragraph (a), for "£42,352" substitute "£44,741", and

(ii) in sub-paragraph (b), for "£10,515" substitute "£11,108".

(3) In paragraph (2) of regulation 3A (fees for pre-consultation meetings)—

(a) in sub-paragraph (a), for "£750" substitute "£792";

(b) in sub-paragraph (b), for "£950" substitute "£1,004";

(c) in sub-paragraph (c) for "£1,300" substitute £1,373"; and

(d) for "(a) if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development, £1,650" substitute—

"(d) if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development, £1,173".

**Amendment of the Medical Devices Regulations 2002**

**3.**—(1) The Medical Devices Regulations 2002(**a**) are 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 "£850" substitute "£900", and

(ii) in sub-paragraph (b), for "£3,400" substitute "£3,600";

(b) in paragraph (2), for "£1,700" substitute "£1,800";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£4,200" substitute "£4,400",

(ii) in sub-paragraph (b)(i), for "£6,800" substitute "£7,200",

(iii) in sub-paragraph (b)(ii), for "£5,100" substitute "£5,400",

(iv) in sub-paragraph (b)(iii), for "£3,400" substitute "£3,600"; and

(v) in sub-paragraph (c), for "£3,400" substitute "£3,600"; and

(d) in paragraph (3A)—

(i) in sub-paragraph (a)(i), for "£240" substitute "£254", and

(ii) in sub-paragraph (a) (ii), for "£67.10" substitute "£70.45".

(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 "£850" substitute £900", and

(ii) in sub-paragraph (b), for "£3,400" substitute "£3,600";

(b) in paragraph (2), for "£1,700" substitute "£1,800";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£4,200" substitute "£4,400",

(ii) in sub-paragraph (b), for "£3,400" substitute "£3,600",

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(**a**) S.I. 2002/618; relevant amendments have been made by S.I. 2003/1697 and S.I. 2007/803.

(iii) in sub-paragraph (c), for "£1,700" substitute "£1,800", and

(iv) in sub-paragraph (d), for "£3,400" substitute "£3,600";

(d) in paragraph (3A), for "£4,200" substitute "£4,400" and for "£1,700" substitute "£1,800";

(e) in paragraph (3B), for "£3,400" substitute "£3,600" and for "£1,700" substitute "£1,800";

(f) in paragraph (3C), for "£1,700" substitute "£1,800"; and

(g) in paragraph (3D)—

(i) in sub-paragraph (a)(i), for "£240" substitute "£254", and

(ii) in sub-paragraph (a) (ii), for "£67.10" substitute "£70.45".

(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 "£1,800" substitute "£2,100", and

(ii) in sub-paragraph (ii), for "£2,400" substitute "£2,700"; and

(b) in sub-paragraph (b)—

(i) in sub-paragraph (i), for "£2,700"substitute "£3,000", and

(ii) in sub-paragraph (ii), for "£3,800" substitute "£4,100".

Signed by authority of the Secretary of State.

*Dawn Primarolo*
Minister of State,
27th February 2008 Department of Health

We consent

*Alan Campbell*
*Steve McCabe*
26th February 2008 Two of the Lords Commissioners of her Majesty's Treasury

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make amendments to the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 and the Medical Devices Regulations 2002.

The Medical Devices (Consultation Requirements) (Fees) Regulations 1995 prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC concerning medical devices(**a**). Regulation 2 of these Regulations amends the 1995 Regulations by increasing the amounts of the fees specified in regulations 3 and 3A of those Regulations (overall average increase of 6%).

The Medical Devices Regulations 2002 contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and putting into service of medical devices, set out in Council Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices (**b**), Council Directive 93/42/EEC concerning medical devices and Council Directive 98/79/EC on *in vitro* diagnostic devices(**c**).Regulation 3 of these Regulations amends regulations 54 to 56 of the Medical Devices Regulations 2002, which provide for the fees payable in connection with the designation etc of UK notified bodies and EC conformity assessment bodies and the fees payable in relation to clinical investigation notices. The overall increase in fees is 6%.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

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(**a**) OJ No. L169, 12.7.93, p.1 to which amendments have been made by Directive 2000/70/EC of the European Parliament and of the Council, OJ No. L 313, 13.12.2000, p.22, Directive 2001/104/EC of the European Parliament and of the Council, OJ No. L 6, 10.1.2002, p. 50 and Directive 2007/47/EC of the European Parliament and of the Council , OJ No L 247, 21.9.2007, p.21.

(**b**) OJ No. L189, 20.7.90, p.17 to which amendments have been made by Council Directive 93/68/EEC, OJ No. L 220, 30.8.1993, p.1 and Directive 2007/47/EC.

(**c**) OJ No. L331, 7.12.98, p.1.

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