STATUTORY INSTRUMENTS

2013 No. 525

FEES AND CHARGES

The Medical Devices (Fees Amendment) Regulations 2013

Made - - - -	*7th March 2013*
Laid before Parliament	*11th March 2013*
Coming into force - -	*1st April 2013*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**a**) and section 56(1) and (2) of the Finance Act 1973(**b**).

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

Citation and commencement

1. These Regulations may be cited as the Medical Devices (Fees Amendment) Regulations 2013 and shall come into force on 1st April 2013.

Amendment of the Medical Devices Regulations 2002

2.—(1) Regulation 56 (fees payable in relation to clinical investigation notices) of the Medical Devices Regulations 2002(**d**) is amended as follows.

(2) in paragraph (1)—

(a) in sub-paragraph (a), for "£2,120" substitute "£2,920" and for "£2,770" substitute "£3,570";

(b) in sub-paragraph (b), for "£3,020" substitute "£3,820" and for "£4,240" substitute "£5,040".

(**a**) 1972 c.68. Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to Scottish Ministers of functions in relation to implementing obligations under European Union law in relation to devolved matters, the functions of the Secretary of State in relation to implementing these obligations continues to be exercisable by the Secretary of State as regards Scotland.

(**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. 1993/2661.

(**d**) S.I. 2002/618; relevant amendments have been made by S.I. 2003/1697, 2007/803, 2008/530 and 2009/383.

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
1st March 2013 Department of Health

We consent

Desmond Swayne
Stephen Crabb
7th March 2013 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 Regulations 2002 ("the 2002 Regulations").

Regulation 2 of these Regulations amends the 2002 Regulations by increasing the amounts of the fees specified in regulation 56 of those Regulations to cover the expertise required from external consultants in considering clinical investigations, further to the expansion of the definition of a medical device and consequent scope.

The 2002 Regulations contain the legislative measures necessary for the implementation of the European Union 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 devices(**a**), Council Directive 93/42/EEC concerning medical devices(**b**) and Council Directive 98/79/EC concerning in vitro diagnostic devices(**c**).

The increase in fees is by approximately £800 in each instance when clinical investigation notices are under consideration, all other fees for medical devices remaining unchanged.

An impact assessment has not been prepared for this instrument as no impact on the private or voluntary sector is foreseen.

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(**a**) OJ No. L189, 20.7.90, p.17 to which amendments have been made by Council Directive 93/42/EEC, (OJ No. L169, 12.7.93, p.1) Council Directive 93/68/EEC (OJ No. L220, 30.8.1993, p.1), Regulation http://www.legislation.gov.uk/legislation/european/regulation/2003/1882(EC) No. 1882/2003 of the European Parliament and Council (OJ No. L284, 31.10.03, p.1) and Directive 2007/47/EC of the European Parliament and of the Council (OJ No. L 331, 7.12.1998, p.1).

(**b**) OJ No. L169, 12.7.93, p.1 to which amendments have been made by Directive 98/79/EC of the European Parliament and of the Council (OJ No. L 331, 7.12.1998, p.1), Directive 2000/70/EC of the European Parliament and of the Council (OJ No. L313, 13.12.2000, p.22), Directive 2001/104/EC of the European Parliament and of the Council (OJ No. L6, 10.1.2002, p.50), Regulation http://www.legislation.gov.uk/legislation/european/regulation/2003/1882(EC) No. 1882/2003 of the European Parliament and of the Council (OJ No. L284, 31.10.2003, p.1) and Directive 2007/47/EC of the European Parliament and of the Council (OJ No. L94, 4.4.2007, p.23).

(**c**) OJ No. L331, 7.12.98, p.1 to which amendments have been made by Regulation http://www.legislation.gov.uk/legislation/european/regulation/2003/1882(EC) No. 1882/2003 of the European Parliament and Council (OJ No.L284, 31.10.03, p.1), Regulation (EC) No. 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.09, p.14) and Commission Directive 2011/100/EU (OJ No. L341, 22.12.11, p.50).

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