STATUTORY INSTRUMENTS

2017 No. 207

CONSUMER PROTECTION

The Medical Devices (Fees Amendment) Regulations 2017

Made - - - -	*24th February 2017*
Laid before Parliament	*2nd March 2017*
Coming into force - -	*1st April 2017*

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

The Secretary of State has been designated for the purpose of section 2(2) of the European Communities Act 1972 in relation to medical devices(**3**).

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

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Devices (Fees Amendment) Regulations 2017 and shall come into force on 1st April 2017.

(2) In these Regulations, "the 2002 Regulations" means the Medical Devices Regulations 2002(**4**).

Amendment of regulation 53 of the 2002 Regulations

2. In regulation 53 of the 2002 Regulations (fees in connection with the registration of devices and changes to registration details), for "£70" substitute "£100".

(**1**) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7). 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.

(**2**) 1973 c.51. Section 56(1) was amended by article 6(1)(e) of the Treaty of Lisbon (Changes of Terminology) Order 2011 (S.I. 2011/1043).

(**3**) 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.

(**4**) S.I. 2002/618; relevant amending instruments are S.I. 2003/1697, 2007/803, 2008/530, 2010/557, 2013/525 and 2013/2327.

Amendment of regulation 54 of the 2002 Regulations

3.—(1) Regulation 54 of the 2002 Regulations (fees payable in connection with the designation etc. of UK notified bodies) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "£960" substitute "£2,063"; and

(b) in sub-paragraph (b), for "£3,840"substitute "£8,252".

(3) In paragraph (2), for "£1,880" substitute "£6,504".

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "£4,670" substitute "£15,904";

(b) in sub-paragraph (b), for each of "£7,670", "£5,760" and "£3,840" substitute "£10,160"; and

(c) in sub-paragraph (c), for "£3,840" substitute "£4,404".

(5) In paragraph (3A)—

(a) in sub-paragraph (a)(i), for "£271" substitute "£361.20"; and

(b) in sub-paragraph (a)(ii), for "£75.24" substitute "£90.30".

(6) After paragraph (3B) insert—

"(3C) A UK notified body that applies to the Secretary of State for a renewal of its designation pursuant to article 4 of Regulation (EU) No 920/2013 shall pay to the Secretary of State—

(a) a fee of £8,252 in respect of the application; and

(b) where an audit is carried out in connection with the application, a fee of £15,904 in respect of the audit.

(3D) Where the Secretary of State conducts an assessment of a UK notified body pursuant to article 5 of Regulation (EU) No 920/2013, the UK notified body shall pay to the Secretary of State—

(a) if the assessment relates to the UK notified body's assessment of clinical data only, a fee of £2,586; or

(b) in any other case, a fee of £3,876.

(3E) A UK notified body that submits a summary evaluation report to the Secretary of State pursuant to article 5(4) of Regulation (EU) No 722/2012 shall pay to the Secretary of State a fee of £532.".

(7) In paragraph (4)—

(a) in sub-paragraph (a)—

(i) for "regulation 45(1) or" substitute "regulation 45(1),",

(ii) after "regulation 45(4)" insert ", a renewal under Regulation (EU) No 920/2013 (but not any associated audit) or a submission of a summary evaluation report under Regulation (EU) No 722/2012", and

(iii) in paragraphs (i) and (ii), after "application" insert "or submission"; and

(b) in sub-paragraph (b), after "regulation 45(7)" insert "or an audit or assessment pursuant to Regulation (EU) No 920/2013".

(8) After paragraph (4), insert—

"(5) In this regulation, "Regulation (EU) No 920/2013" means Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation

and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices(**5**).".

Amendment of regulation 55 of the 2002 Regulations

4.—(1) Regulation 55 of the 2002 Regulations (fees payable in connection with the designation etc. of EC conformity assessment bodies) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "£960" substitute "£2,063"; and

(b) in sub-paragraph (b), for "£3,840"substitute "£8,252".

(3) In paragraph (2), for "£1,880" substitute "£6,504".

(4) In paragraph (3)—

(a) in sub-paragraph (a), for "£4,670" substitute "£15,904";

(b) in sub-paragraph (b), for "£3,840" substitute "£4,404"; and

(c) in sub-paragraph (d), for "£3,840" substitute "£4,404".

(5) In paragraph (3A), for "£4,670" substitute "£15,904".

(6) In paragraph (3B), for "£3,840" substitute "£4,404".

(7) In paragraph (3D)—

(a) in sub-paragraph (a)(i), for "£271" substitute "£361.20"; and

(b) in sub-paragraph (a)(ii), for "£75.24" substitute "£90.30".

Amendment of regulation 56 of the 2002 Regulations

5.—(1) Regulation 56 of the 2002 Regulations (fees payable in relation to clinical investigation notices) is amended as follows.

(2) In paragraph (2), after "paragraph (3)" insert "or (3A)".

(3) After paragraph (3) insert—

"(3A) Any person who submits an amendment to a notice of the supply of a device for the purposes of a clinical investigation under regulation 16(1) or 29(1) shall pay to the Secretary of State—

(a) a fee, if the device is a Group A device, of £207; or

(b) a fee, if the device is a Group B device, of £331.".

Signed by authority of the Secretary of State for Health.

O'Shaughnessy
Parliamentary Under-Secretary of State
Department of Health

23rd February 2017

(**5**) OJ No L 253 25.9.2013 p.8.

We consent

Guto Bebb
Robert Syms
Two of the Lords Commissioners of Her Majesty's Treasury

24th February 2017

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medical Devices Regulations 2002 (the 2002 Regulations).

The 2002 Regulations implement Directive 90/385/EEC on the approximation of laws of Member States relating to active implantable devices, Directive 93/42/EEC concerning medical devices and Directive 98/79/EC on in vitro diagnostic devices by setting out a scheme for regulating the placing on the market and putting into service of medical devices in the United Kingdom.

Part VI of the 2002 Regulations sets out the fees that are payable under the scheme.

Regulations 2, 3(1) to (5) and 4 increase existing fees payable to the Secretary of State in connection with the registration of devices and the designation of notified bodies.

Regulation 3(6) introduces new fees for work undertaken by the Secretary of State under Commission Implementing Regulation (EU) No 920/2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices. The new fees relate to applications for re-designation by notified bodies and inspections carried out by the Secretary of State in respect of those notified bodies.

Regulation 3(6) also introduces a new fee for work undertaken by the Secretary of State under Commission Implementing Regulation (EU) No 722/2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin. The new fee relates to the submission of summary evaluation reports by notified bodies to the Secretary of State where a notified body is assessing a device manufactured using animal tissue.

Regulation 5 introduces a new fee in connection with amendments made to clinical investigation notices submitted to the Secretary of State.

An impact assessment of the effects that this instrument will have on the costs of business and the voluntary sector is available from the Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road, London, SW1W 9SZ and is published with the explanatory memorandum alongside the instrument on www.legislation.gov.uk.