STATUTORY INSTRUMENTS

2017 No. 207

The Medical Devices (Fees Amendment) Regulations 2017

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(**1**).".

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