STATUTORY INSTRUMENTS

2023 No. 377

The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023

PART 2

Amendment of the Medical Devices Regulations 2002

Amendment of regulation 56 in relation to England, Scotland and Wales (fees payable in relation to clinical investigation notices)

- **13.**—(1) In regulation 56(1)(1)—
 - (a) in sub-paragraph (a)(i), for "£2,920" substitute "£5,711",
 - (b) in sub-paragraph (a)(ii), for "£3,570" substitute "£11,069",
 - (c) in sub-paragraph (b)(i), for "£3,820" substitute "£7,472", and
 - (d) in sub-paragraph (b)(ii), for "£5,040" substitute "£15,627".
- (2) After regulation 56(3A), insert—
 - "(3B) A person who requests a meeting with the Secretary of State in respect of an intended clinical investigation under regulation 16(1A) or 29(1A) must pay the following fees in advance of the meeting—
 - (a) £906 for a regulatory advice meeting under regulation 16(1A)(a) or 29(1A)(a); and
 - (b) £782 for a statistical review meeting under regulation 16(1A)(b) or 29(1A)(b).".