
STATUTORY INSTRUMENTS

2023 No. 377

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

Part 4

Amendment of the Medical Devices (Northern Ireland Protocol) Regulations 2021

New regulation 17A (advice in relation to intended clinical investigations)

21. After regulation 17 (clinical investigations not carried out for a purpose specified in Article 62(1)) insert—

“Advice in relation to intended clinical investigations

17A.—(1) A manufacturer or sponsor may request a meeting with the Secretary of State in advance of an application being submitted under Article 70(1) in order to—

- (a) obtain advice on regulatory requirements relating to an intended clinical investigation; or
- (b) obtain a statistical review in relation to an intended clinical investigation.

(2) A person who requests a meeting with the Secretary of State under paragraph (1), must pay the following fees in advance of that meeting—

- (a) £906 for a regulatory advice meeting under paragraph (1)(a); and
- (b) £782 for a statistical review meeting under paragraph (1)(b).

(3) In this regulation, “statistical review” means a review of the statistical sections of the application which a sponsor intends to submit to the Secretary of State under Article 70(1) in respect of an intended clinical investigation.”