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."