DRAFT STATUTORY INSTRUMENTS

2023 No.

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

PART 2

Amendment of the Medical Devices Regulations 2002

New regulation 56D

16. After regulation 56C (fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device), insert—

"**Fees payable in connection with pre-consultation meetings**

56D.—(1) The fee payable by a person other than an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that person making an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(2) The fee payable by an approved body with whom the Secretary of State holds a meeting in order to provide scientific advice with a view to that body consulting the Secretary of State in relation to an application for an examination certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(3) The fee payable is—

(a) £824, if the advice provided at that meeting consists of advice in connection with—

(i) quality development only, or

(ii) safety development only;

(b) £1,044, if the advice provided at that meeting consists of advice in connection with—

(i) quality and safety development only, or

(ii) clinical development only;

(c) £1,429, if the advice provided at that meeting consists of advice in connection with—

(i) quality and clinical development only, or

(ii) safety and clinical development only;

(d) £1,813, if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development.

(4) Any fee payable under this regulation must be paid within 14 days following written notice from the Secretary of State requiring payment of that fee ".