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

New regulation 56B

14. After regulation 56A (fees in connection with approval of coronavirus test devices), insert—

"**Circumstances in which a fee is payable in relation to a consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device**

56B.—(1) Subject to paragraph (2), the fee payable by an approved body in respect of a consultation or further consultation with the Secretary of State in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device is the fee specified in regulation 56C.

(2) No fee is payable if it is the first time the Secretary of State has been consulted by any approved body in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device if the medicinal substance is an authorised medicinal product.".