
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 56C

15. After regulation 56B (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), insert—

“Fees payable in connection with a consultation or further consultation on the safety, quality and usefulness of a medicinal substance incorporated in a device

56C.—(1) Subject to regulation 56B(2) and paragraph (3), the fee in respect of a consultation in relation to a device which incorporates one or more medicinal substances is—

- (a) £4,550 if each medicinal substance is manufactured by an approved manufacturer of that substance;
- (b) £10,604 if any of the medicinal substances are not manufactured by an approved manufacturer of that substance.

(2) Subject to paragraph (3), the fee in respect of a further consultation in relation to a device which incorporates one or more medicinal substances is—

- (a) £900 if each medicinal substance is manufactured by an approved manufacturer of that substance;
- (b) £2,451 if any of the medicinal substances are not manufactured by an approved manufacturer of that substance.

(3) In relation to a device which incorporates a new medicinal substance, the fee is—

- (a) £46,526 for a consultation; and
- (b) £11,551 for a further consultation.

(4) Where an approved body consults the Secretary of State in relation to more than one device at the same time and those devices—

- (a) are of similar construction and are designed to perform similar functions;
- (b) incorporate medicinal substances of the same specification which are manufactured by the same manufacturer or manufacturers; and
- (c) do not incorporate any other medicinal substance;

the fee payable for that consultation is the fee which would be payable under this regulation for a consultation in relation to one of those devices.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(5) Any fee payable under this regulation must be paid to the Secretary of State not later than the day on which an approved body consults the Secretary of State.”