STATUTORY INSTRUMENTS

2021 No. 905

The Medical Devices (Northern Ireland Protocol) Regulations 2021

[F1Part 4A

Fees for consultation in relation to the safety, quality and usefulness of a medicinal substance incorporated in a device

Textual Amendments

F1 Pt. 4A inserted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **23**

Interpretation of Part 4A

19A. In this Part—

"approved manufacturer" in relation to a medicinal substance means a manufacturer who—

(a) holds a manufacturing authorisation which permits the manufacturer to manufacture that substance for inclusion in an authorised medicinal product; or

(b) holds a relevant conformity assessment certificate for a device incorporating that medicinal substance and that certificate was issued by a notified body under Regulation (EU) 2017/745 after consultation with the Secretary of State in respect of that substance;

"authorised medicinal product" means a medicinal product in respect of which a marketing authorisation has been granted;

"clinical development" means the conduct of studies of a medicinal substance in human subjects in order to—

(a) discover or verify the effects of such a substance,

(b) identify any adverse reaction to such a substance, or

(c) study absorption, distribution, metabolism and excretion of such a substance,

with the object of ascertaining the safety or efficacy of that substance, as required to verify the safety and usefulness of the substance in accordance with section 12.1 of Annex I;

"consultation" means a consultation required by section 5.2 or 5.4 of Annex IX or section 6 of Annex X;

"further consultation" means a consultation by a notified body in relation to any device which—

(a) may be placed on the market or put into service in accordance with Regulation (EU) 2017/745 and which is the subject of a relevant conformity assessment certificate issued by that notified body after consultation with the Secretary of State;

(b) is the subject of proposed changes within section 5(f) of Annex IX, and if that device is to be placed on the market or put into service, those changes may require the issue of a supplement to a relevant conformity assessment certificate previously issued by that notified body after consultation with the Secretary of State; or

(c) is of a similar design or type to a device which has been the subject of an unsuccessful application for a relevant conformity assessment certificate where—

(i) the person who made that unsuccessful application makes a further application for a relevant conformity assessment certificate to the notified body which determined that unsuccessful application; and

(ii) within the relevant period that further application becomes the subject of consultation between that notified body and the Secretary of State;

"incorporates" means incorporates as an integral part;

"marketing authorisation" has the meaning given by regulation 8 of the Human Medicines Regulations 2012;

"medicinal substance" means a substance which, if used separately from a device, may be considered to be a medicinal product, as defined in Schedule 1 (General interpretation provisions) to the Medicines (Products for Human Use) Fees Regulations 2016;

"new medicinal substance" means a medicinal substance which is not—

(a) an authorised medicinal product;

(b) an ingredient or, as the case may be, the sole active ingredient of such a product; or

(c) a substance which has been incorporated in a device in respect of which a relevant conformity assessment certificate has been issued by a notified body which has consulted the Secretary of State;

"quality development" means the chemical, pharmaceutical and biological testing required in order to verify the quality of a medicinal substance in accordance with section 12.1 of Annex I;

"relevant conformity assessment certificate" means either an EU technical documentation assessment certificate issued in accordance with Annex IX or an EU type-examination certificate issued in accordance with Annex X;

"relevant period" means the period of 5 years which starts on the first day on which the Secretary of State was consulted in respect of the unsuccessful application or, if there has been more than one such application in any particular case, in respect of the first of them;

"safety development" means the toxicological and pharmacological testing required in order to verify the safety of a medicinal substance in accordance with section 12.1 of Annex I; and

"scientific advice" means advice in connection with the quality, safety or clinical development for a medicinal substance incorporated, or to be incorporated, in a device.

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

19B.—(1) Subject to paragraph (2), the fee payable by a notified 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 regulations 19C.

(2) No fee is payable if it is the first time the Secretary of State has been consulted by any notified 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.

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

19C.—(1) Subject to regulation 19B(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 a notified 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.

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

Fees for pre-consultation meetings

19D.—(1) The fee payable by a person other than a notified 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 a relevant conformity assessment certificate in relation to a device incorporating a medicinal substance is specified in paragraph (3).

(2) The fee payable by a notified body with whom the Secretary of State holds a meeting in order to provide scientific advice to that body with a view to that body consulting the Secretary of State in relation to an application for a relevant conformity assessment 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.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Northern Ireland Protocol) Regulations 2021, Part 4A.