STATUTORY INSTRUMENTS

2021 No. 905

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 3

Clinical investigations under Regulation (EU) 2017/745

[F1Legal representatives and contact persons for clinical investigations

A11.—(1) The first subparagraph of Article 62(2) (requirement to have a legal representative established in the Union) does not apply to a clinical investigation conducted in Northern Ireland if all of the following conditions are met—

(a) the clinical investigation is also being conducted in Great Britain;

(b) the clinical investigation is not also being conducted in a Member State;

(c) the sponsor—

(i) is established in Great Britain, or

(ii) has a written agreement with a legal representative established in Great Britain who is responsible for ensuring compliance with the sponsor's obligations pursuant to Regulation (EU) 2017/745;

(d) the sponsor has a contact person established in Northern Ireland in respect of the clinical investigation.

(2) A contact person referred to in this regulation must be the addressee for all communications with the sponsor provided for in Regulation (EU) 2017/745 and any communication with that contact person is deemed to be a communication with the sponsor.

(3) The agreement referred to in paragraph (1)(c)(ii) must provide for—

(a) the legal representative to be responsible for ensuring compliance with the sponsor's obligations pursuant to Regulation (EU) 2017/745,

(b) the legal representative to immediately inform the sponsor of all communications received in its capacity as the sponsor's legal representative, and

(c) the sponsor to share with its legal representative all communications and documentation necessary to enable the legal representative to fulfil its obligations under this regulation.

(4) A legal representative referred to in paragraph (1)(c)(ii) must have a written agreement with the contact person to provide for—

(a) the contact person to immediately inform the legal representative of all communications received in its capacity as the sponsor's contact person, and

(b) the legal representative to share with the contact person all communications and documentation necessary to enable the contact person to fulfil its obligations under this regulation.

(5) Where the sponsor is established in Great Britain, the sponsor must have a written agreement with the contact person to provide for—

(a) the contact person to immediately inform the sponsor of all communications received in its capacity as the sponsor's contact person, and

(b) the sponsor to share with the contact person all communications and documentation necessary to enable the contact person to fulfil its obligations under this regulation.

(6) Where the sponsor has a legal representative established in Great Britain, the application form and the clinical investigation plan drawn up in accordance with chapter II of Annex XV must include the name, address and contact details of the legal representative established in Great Britain.**]**

Textual Amendments

F1 Reg. A11 inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **34**

Ethical review of clinical investigations

11.—(1) A sponsor proposing to conduct a clinical investigation of a device in Northern Ireland must apply to an ethics committee for an ethical review of the proposed clinical investigation.

(2) The sponsor must submit to the Secretary of State a copy of the opinion of the ethics committee as soon as it becomes available and before the clinical investigation is started.

Commencement Information

I1 Reg. 11 in force at 27.7.2021, see **reg. 1(2)**

Prior authorisation of clinical investigations by the Secretary of State

12.—(1) A clinical investigation to which Article 70(7)(a) applies must not start unless—

(a) it has been authorised by the Secretary of State, and

(b) a favourable opinion in respect of the clinical investigation has been issued by an ethics committee.

(2) For the purposes of paragraph (1)(a) and subject to paragraph (3), the Secretary of State must notify the sponsor of whether the clinical investigation is authorised within—

(a) 65 days of the validation date provided for in Article 70(5), if the Secretary of State decides to consult experts for advice on whether the clinical investigation should be authorised, or

(b) 45 days of the validation date in any other case.

(3) If the Secretary of State requests additional information from the sponsor under Article 70(6), the expiry of the periods in paragraph (2) is suspended from the date of the first request until such time as the additional information has been received.

Commencement Information

I2 Reg. 12 in force at 27.7.2021, see **reg. 1(2)**

Arbitration following the refusal of a clinical investigation application

13.—(1) A sponsor notified of a refusal under Article 70(3), 71(4), or 78(10) may, within 28 days of being notified, apply to the Institute to appoint an adjudicator to review the refusal.

(2) The adjudicator must provide a report to the Secretary of State and the sponsor setting out any recommendations in respect of the disputed refusal.

(3) The Secretary of State must take the report of the adjudicator into account and decide whether to—

(a) confirm or alter the grounds for the refusal of the application,

(b) authorise the clinical investigation, or

(c) in the case of a refusal under Article 70(3), proceed to consider the application under Article 70.

(4) The Secretary of State must notify the sponsor of the decision in paragraph (3).

(5) The sponsor must pay any fees, costs or expenses of the Institute and its appointed adjudicator that are payable in connection with the application made under paragraph (1).

F2(6) . . . . . .

Textual Amendments

F2 Reg. 13(6) omitted (21.3.2024) by virtue of The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **35**

Commencement Information

I3 Reg. 13 in force at 27.7.2021, see **reg. 1(2)**

Damage compensation in relation to clinical investigations

14. A sponsor of a clinical investigation must hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability in the event of injury or death attributable to participation in the clinical investigation.

Commencement Information

I4 Reg. 14 in force at 27.7.2021, see **reg. 1(2)**

Retention of documentation relating to clinical investigations

15.—(1) The liquidator or trustee in bankruptcy of a sponsor of a clinical investigation or of a sponsor's legal representative or contact person under Article 62(2), must—

(a) retain for the required period any documentation that consists of, or reasonably could consist of, any of the documentation referred to in Annex XV, and

(b) comply with any request made by the Secretary of State during the required period to provide the Secretary of State with the retained documentation.

(2) In this regulation, the required period is—

(a) in the case of documentation relating to the clinical investigation of a device that was subsequently placed on the market—

(i) if the device was an implantable device, 15 years after the last device was placed on the market, and

(ii) if the device was not an implantable device, 10 years after the last device was placed on the market;

(b) in any other case, 10 years after the clinical investigation ended.

Commencement Information

I5 Reg. 15 in force at 27.7.2021, see **reg. 1(2)**

Clinical investigation fees

16.—(1) The sponsor of a clinical investigation must pay the relevant fee for—

(a) an application submitted to the Secretary of State under Article 70(1);

(b) a notification to the Secretary of State of a substantial modification under Article 75(1).

(2) The relevant fee is payable when the application or notification to which it relates is made to the Secretary of State.

(3) If a sponsor fails to pay the relevant fee, the Secretary of State may reject the application, reject the notification or suspend the clinical investigation until the fee is paid.

(4) Fees for clinical investigations are set out in Schedule 1.

(5) In this regulation, "the relevant fee" means—

(a) for a clinical investigation of a class I device, class IIa device or **[**F3class IIb device, which is neither an implantable device nor a long-term invasive device**]**, the fee in table 1 in Schedule 1, and

(b) for a clinical investigation of **[**F4a class IIb device, which is either an implantable device or a long-term invasive device or a class III device**]**, the fee in table 2 in Schedule 1.

Textual Amendments

F3 Words in reg. 16(5)(a) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **20(a)**

F4 Words in reg. 16(5)(b) substituted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **20(b)**

Commencement Information

I6 Reg. 16 in force at 27.7.2021, see **reg. 1(2)**

Clinical investigations not carried out for a purpose specified in Article 62(1)

17.—(1) The provisions in paragraph (2) apply to clinical investigations of custom-made devices carried out for a purpose other than one of the purposes specified in Article 62(1), in addition to the provisions specified in Article 82(1).

(2) The provisions are—

(a) those of Article 62(4) not already specified in Article 82(1);

(b) Article 62(5) and (7);

(c) Article 63 except—

(i) in paragraph (2)(e), not the words "include the Union-wide unique single identification number of the clinical investigation referred to in Article 70(1) and"; and

(ii) in paragraph (6), not the words "in the electronic system on clinical investigations referred to in Article 73";

(d) Articles 64 to 69;

(e) Article 70 except—

(i) in paragraph (1), not the first sentence of the second subparagraph;

(ii) in paragraph (2), not the final sentence of the paragraph, and in the first sentence the words "data in the electronic system referred to in Article 73" to the end are to be read "documentation and submit the updated documentation to the Secretary of State";

(iii) in paragraph (3), in the first subparagraph, not the words "by means of the electronic system referred to in Article 73"; and

(iv) paragraphs (8) and (9);

(f) Article 71;

(g) Article 72;

(h) Article 75 except in paragraph (1), not the words "by means of the electronic system referred to in Article 73";

(i) Article 76 except—

(i) in paragraph (3), not the words "by means of the electronic system referred to in Article 73"; and

(ii) in paragraph (4), not the words "through the electronic system referred to in Article 73";

(j) Article 77 except—

(i) in paragraphs (1) and (7), not the words "through the electronic system referred to in Article 73";

(ii) paragraph (4);

(iii) in paragraph (5), not the second sentence of the second subparagraph;

(iv) paragraph (6); and

(v) in paragraph (7), in the second subparagraph, the words "entered into the electronic system pursuant to paragraph (5) of this Article" are to be read "submitted pursuant to paragraph (5) of this Article";

(k) Article 80 except—

(i) in paragraphs (2) and (3), not the words "by means of the electronic system referred to in Article 73"; and

(ii) paragraphs (4) and (5);

(l) Annex XV except section 3.1.1 in Chapter II.

Commencement Information

I7 Reg. 17 in force at 27.7.2021, see **reg. 1(2)**

[F5Advice 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.**]**

Textual Amendments

F5 Reg. 17A inserted (1.4.2023) by The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 (S.I. 2023/377), regs. 1(2), **21**

Changes to legislation:
There are currently no known outstanding effects for the The Medical Devices (Northern Ireland Protocol) Regulations 2021, PART 3.