STATUTORY INSTRUMENTS

2021 No. 905

The Medical Devices (Northern Ireland Protocol) Regulations 2021

[F1Part 3A

Performance studies under Regulation (EU) 2017/746

Textual Amendments

F1 Pt. 3A inserted (21.3.2024) by The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024 (S.I. 2024/221), regs. 1(2), **36**

Legal representatives and contact persons for performance studies

17B.—(1) The first subparagraph of Article 58(4) (requirement to have a legal representative established in the Union) does not apply to a performance study conducted in Northern Ireland if all of the following conditions are met—

(a) the performance study is also being conducted in Great Britain;

(b) the performance study 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 under Regulation (EU) 2017/746;

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

(2) A contact person referred to in this regulation must be the addressee for all communications with the sponsor provided for in Regulation (EU) 2017/746 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 under Regulation (EU) 2017/746,

(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 drawn up in accordance with Chapter I of Annex XIV and any clinical performance study plan drawn up in accordance with Part A of Annex XIII must include the name, address and contact details of the legal representative established in Great Britain.

Ethical review of performance studies

17C.—(1) In Regulation (EU) 2017/746 a reference to an ethics committee is a reference to an ethics committee within the meaning of regulation 3(1).

(2) In relation to a performance study to which Article 58(5)(b) applies, 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 performance study starts.

Arbitration following the refusal of a performance study application

17D.—(1) A sponsor notified of a refusal under Articles 66(3), 67(4) or 74(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 performance study, or

(c) in the case of a refusal under Article 66(3), proceed to consider the application under Article 66.

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

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

Damage compensation in relation to performance studies

17E. A sponsor of a performance study 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 performance study.

Retention of documentation relating to performance studies

17F.—(1) The liquidator or trustee in bankruptcy of a sponsor of a performance study, or of a sponsor's legal representative or contact person under Article 58(4), 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 XIV, 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 performance study of a device that was subsequently placed on the market, 10 years after the last device was placed on the market;

(b) in any other case, 10 years after the performance study ended.**]**

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