STATUTORY INSTRUMENTS

2024 No. 221

The Medical Devices (In Vitro Diagnostic Devices etc.) (Amendment) Regulations 2024

PART 4

Amendments to the Medical Devices (Northern Ireland Protocol) Regulations 2021

New regulation A11 (legal representatives and contact persons for clinical investigations)

34. In Part 3 (clinical investigations under Regulation (EU) 2017/745), before regulation 11 insert—

"**Legal 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.".