

SCHEDULES

SCHEDULE 1

Amendment of the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019

8. In regulation 24 (amendment of Schedule 3 (particulars and documents that must accompany an application for an ethics committee opinion, a request for authorisation, a notice of amendment and a notification of the conclusion of a trial))—

(a) for paragraph (3)(c) substitute—

“(c) in paragraph 7, after “details of any” insert “ manufacturing authorisation or any ”;”;

(b) for paragraph (3)(d)(i) substitute—

“(i) in sub-paragraph (1), after “in accordance with” insert “ regulation 43(2) or ”;”;

(c) for paragraph (3)(d)(ii) substitute—

“(ii) for sub-paragraph (2) substitute—

“(2) If an investigational medicinal product to be used in the clinical trial has been, or is to be—

(a) imported into Great Britain from a country other than Northern Ireland or imported into Northern Ireland from a country other than an EEA State, a statement from the qualified person at the disposal of the person holding the manufacturing authorisation in relation to that importation specifying—

(i) the address of any premises outside the United Kingdom at which the product was manufactured or assembled; and

(ii) the manufacturing or assembling operations performed at those premises;

(b) imported into Northern Ireland from an EEA State, a statement from the qualified person at the disposal of the person holding the authorisation referred to in Article 13 of the Directive in relation to that importation specifying—

(i) the address of any premises outside the European Economic Area at which the product was manufactured or assembled; and

(ii) the manufacturing or assembling operations performed at those premises.”.”.

Commencement Information

II Sch. 1 para. 8 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 8.