DRAFT STATUTORY INSTRUMENTS

2021 No.

The Medical Devices (Northern Ireland Protocol) Regulations 2021

PART 3

Clinical investigations under Regulation (EU) 2017/745

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.