STATUTORY INSTRUMENTS

2019 No. 744

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

Insertion of regulation 27B (publication of information)

11. After regulation 27A (information sharing) [M1], insert—

"**Publication of information**

27B.—(1) Subject to paragraph (3), the licensing authority may make accessible to the public information contained in the items listed in paragraph (2) insofar as it relates to a clinical trial carried out, or being carried out, under these Regulations.

(2) The items listed in this paragraph are—

(a) the request for authorisation made under regulation 17;

(b) any amended request for authorisation made under regulation 18, 19 or 20;

(c) any amendment to the protocol made under regulation 23, 24 or 25;

(d) the favourable opinion of the ethics committee given in accordance with regulation 15 or the favourable opinion given by an appeal panel in accordance with paragraph 4 of Schedule 4;

(e) the notification of the end of the clinical trial made under regulation 27.

(3) Prior to making information available to the public under paragraph (1), the licensing authority must, after consulting such persons as the licensing authority considers appropriate, publish a list of the information which may be made accessible to the public under paragraph (1).".

Commencement Information

I1 Reg. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 Regulation 27A was inserted by S.I. 2006/1928.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019, Section 11.