STATUTORY INSTRUMENTS

2019 No. 744

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

Amendment of regulation 3 (sponsor of a clinical trial) **U.K.**

5.—(1) Regulation 3 [M1] is amended as follows.

(2) In paragraph (11)(a), for "an EEA State", substitute " the United Kingdom or a country that is included in the list referred to in paragraph (11A) ".

(3) After paragraph (11), insert—

"(11A) The licensing authority must publish a list of countries where a sponsor of a clinical trial, or their legal representative, may be established for the purpose of paragraph (11).

(11B) In order to determine whether a country should be included in the list referred to in paragraph (11A), the licensing authority may, in particular, take into account—

(a) the mechanisms that the country has in place to assist the licensing authority in contacting, or obtaining information in respect of, a sponsor or legal representative that is established there; and

(b) the country's ability to assist the licensing authority in any action it may need to take in respect of a sponsor or legal representative that is established there.

(11C) The licensing authority must—

(a) review the countries it has included in the list referred to in paragraph (11A) to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(b) undertake such a review at least every three years beginning on the date on which that country is included in that list.".

Commencement Information

I1 Reg. 5 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 3 was amended 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 5.