STATUTORY INSTRUMENTS

2019 No. 744

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

Amendment of regulation 35 (annual list of suspected serious adverse reactions and safety report)

16.—(1) Regulation 35 is amended as follows.

(2) In paragraph (2)(b), for "EEA State" substitute "any country".

(3) In paragraph (3)—

(a) for "an EEA State" substitute "a country"; and

(b) for sub-paragraphs (a) and (b), substitute—

"(a) the date on which the trial was authorised by a regulatory body responsible for authorising clinical trials in that country; or

(b) where the clinical trial was conducted in a country without a formal authorisation process, a date designated by the sponsor that is linked to the commencement of the first clinical trial.".