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STATUTORY INSTRUMENTS

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**2019 No. 744**

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

**Amendment of regulation 34 (clinical trials conducted in third countries)**

**15.**—(1) In the heading of regulation 34, for “third countries” substitute “ countries other than the United Kingdom ”.

(2) In regulation 34—

(a) for “a third country” substitute “ another country ”; and

(b) for the words “entered into” to the end, substitute—

“reported as soon as possible to the licensing authority, and in any event—

(a) in the case of a reaction that is fatal or life-threatening, within 7 days beginning with the day after the sponsor was first aware of the reaction; or

(b) in any other case, within 15 days beginning with the day after the sponsor is first aware of the reaction.”.

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**Commencement Information**

**11** Reg. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)

**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 15.