

STATUTORY INSTRUMENTS

2019 No. 775

**The Human Medicines (Amendment
etc.) (EU Exit) Regulations 2019**

PART 4

Amendment of Part 4 (requirement for authorisation)

Amendment of regulation 46 (requirement for authorisation)

45.—(1) Regulation 46 is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (a), before “marketing authorisation”, insert “ UK ”;

[^{F1}(b) after sub-paragraph (a) insert—

“(aa) an EU marketing authorisation;”.]

(3) In paragraph (3), before “European Economic Area” insert “ United Kingdom or the ”.

(4) In paragraph (6)—

[^{F2}(a) after “in force for the product” insert “in the country in which the product is intended to be sold or supplied, or offered for sale or supply”;

(b) in sub-paragraph (a), before “marketing authorisation”, insert “UK”; and

(c) after sub-paragraph (a) insert—

“(aa) an EU marketing authorisation;”.]

^{F3}(5)

(6) In paragraph (9), before “European Economic Area” insert “ United Kingdom or the ”.

(7) In paragraph (11)(a), before “European Economic Area” insert “ United Kingdom or the ”.

Textual Amendments

F1 Reg. 45(2)(b) substituted for reg. 45(2)(b)(c) (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 33(a)**

F2 Reg. 45(4)(a)-(c) substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 33(b)**

F3 Reg. 45(5) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 33(c)**

Commencement Information

I1 Reg. 45 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 Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 45.