

STATUTORY INSTRUMENTS

2019 No. 775

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

PART 7

Amendment of Part 7 (Traditional Herbal Registrations)

Amendment of regulation 135 (revocation, variation and suspension of traditional herbal registration)

119.—(1) Regulation 135^{M1} is amended as follows.

[^{F1}(1A) For paragraph (6) substitute—

“(6) Condition E is that the holder of the registration has ceased to be established in—

(a) the United Kingdom; or

(b) in relation to a THR(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.”.]

(2) In paragraph (7)(b), [^{F2}after “states other than EEA states” insert “/ countries other than approved countries for import”.]

[^{F3}(3) In paragraph (8)(a) omit “other than the United Kingdom”.]

(4) In paragraph (9), [^{F4}in sub-paragraph (b), at the beginning insert “in the case of a THR(NI) or THR(UK),”.]

[^{F5}(4A) After paragraph (10A) insert—

“(10B) Condition K is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.”.]

(5) Omit paragraph (11).

Textual Amendments

- F1** Reg. 119(1A) inserted (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. 91\(a\)](#)
- F2** Words in reg. 119(2) 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. 91\(b\)](#)
- F3** Reg. 119(3) 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. 91\(c\)](#)
- F4** Words in reg. 119(4) 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. 91\(d\)](#)
- F5** Reg. 119(4A) inserted (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. 91\(e\)](#)

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 119. (See end of Document for details)

Commencement Information

I1 Reg. 119 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 135 was amended by **S.I. 2013/1855**.

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 119.