
STATUTORY INSTRUMENTS

2019 No. 775

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

PART 11

Amendment of Part 11 (Pharmacovigilance)

[^{F1}Amendment] of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive)

[^{F2}154. In regulation 194(1) after “medicinal product” insert “authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation”.]

Textual Amendments

- F1** Word in reg. 154 heading 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. 121(a)**
- F2** Words in reg. 154 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. 121(b)**
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Commencement Information

- I1** Reg. 154 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 154.