
STATUTORY INSTRUMENTS

2019 No. 775

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

PART 3

**Amendment of Part 3 (manufacture and distribution
of medicinal products and active substances)**

**Amendment of regulation 33 (offence concerning data for advanced therapy medicinal
products)**

25.—(1) Regulation 33 is amended as follows.

(2) In paragraph (1)(a)—

- (a) for “Article 15(1) of Regulation 1394/2007” substitute “ paragraph 8 of Schedule 6 ”; and
- (b) for “Article 15(4) of that Regulation” substitute “ paragraph 9 of that Schedule ”.

(3) In paragraph (1)(b), for “Article 15(1)” substitute “ paragraph 8 ”.

(4) In paragraph (2) for “Article 15(4)” substitute “ paragraph 9 ”.

Commencement Information

- II** Reg. 25 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 25.