
STATUTORY INSTRUMENTS

2019 No. 775

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

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 199 (submission of draft study protocols for required studies)

- 159.**—(1) Regulation 199 is amended as follows.
- (2) In paragraph (2), for “body specified in paragraph (3)” substitute “licensing authority”.
 - (3) Omit paragraphs (3) and (4).
 - (4) In paragraph (5), omit “Where this paragraph applies”.
 - (5) In paragraph (6), omit sub-paragraph (b) (and “or” immediately preceding it).
 - (6) Omit paragraphs (7) and (8).