DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of regulation 54 (applications relating to products in well-established medicinal use)

59.—(1) Regulation 54 is amended as follows.

(2) In paragraph (1) before "European Union", insert "United Kingdom or the".

(3) For paragraph (2), substitute—

"(2) The applicant may, by way of derogation from paragraph 10 of Schedule 8, replace the results of pre-clinical tests or clinical trials with appropriate scientific literature.".