

SCHEDULES

SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 2

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

- 29.** In regulation 40 (amendment of regulation 45E (criteria of broker's registration))—
- (a) for paragraph (a) substitute—
 - “(a) for sub-paragraph (b)(i) substitute—
 - “(i) ordered by—
 - (aa) in the case of a broker in Great Britain, the licensing authority or by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, or
 - (bb) in the case of a broker in Northern Ireland, the licensing authority or by the competent authority of any EEA State, or”;
 - (b) for paragraph (b) substitute—
 - “(b) in sub-paragraph (d)(iii), before “the batch number” insert “where the sale or supply of the medicinal product is in Northern Ireland.”.