

SCHEDULES

SCHEDULE 2

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

PART 3

Amendment of Part 4 (amendment of Part 4 (requirement for authorisation))

33. In regulation 45 (amendment of regulation 46 (requirement for authorisation))—
- (a) for paragraph (2)(b) and (c) substitute—
 - “(b) after sub-paragraph (a) insert—
 - “(aa) an EU marketing authorisation;”.”;
 - (b) for paragraphs (4)(a) to (c) substitute—
 - “(a) after “in force for the product” insert “in the country in which the product is intended to be sold or supplied, or offered for sale or supply”;
 - (b) in sub-paragraph (a), before “marketing authorisation”, insert “UK”; and
 - (c) after sub-paragraph (a) insert—
 - “(aa) an EU marketing authorisation;”.”;
 - (c) omit paragraph (5).