

SCHEDULES

SCHEDULE 2

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

PART 21

Amendment of Schedule 6 (insertion of new Schedule 12A (further provision as to the performance of pharmacovigilance activities))

192. In Schedule 6 (insertion of new Schedule 12A (further provision as to the performance of pharmacovigilance activities)), in the inserted Schedule 12A—

- (a) in paragraphs 1(3), 12(5), 16(3), 22(1)(d) and 30(g), for “UK marketing authorisation” substitute “UKMA(GB)”;
- (b) in paragraph 2(a)—
 - (i) at the end of paragraph (iii) omit “and”;
 - (ii) in paragraph (iv), for “pharmacovigilance;” substitute “pharmacovigilance, and”;
 - (iii) after paragraph (iv) insert—
 - “(v) responsibilities and contact details of the nominated person (where a person is nominated under regulation 182(2A));”;
- (c) in paragraph 2(d), for “handing” substitute “handling”;
- (d) omit paragraph 4(4);
- (e) in paragraph 7—
 - (i) omit sub-paragraph (1);
 - (ii) in sub-paragraph (2)—
 - (aa) after “qualified person” insert “and nominated person (where a person is nominated under regulation 182(2A))”;
 - (bb) for “has” substitute “have”.