SCHEDULES

SCHEDULE 2

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

PART 10

Amendment of Part 11 (amendment of Part 11 (Pharmacovigilance))

118. In regulation 151 (amendment of regulation 191 (obligation on holder to submit periodic safety update reports: general requirements))—

(a) in paragraph (2) for "for "EMA" substitute "licensing authority"" substitute "after "EMA" insert "and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,";

(b) omit paragraph (4);

(c) in paragraph (5), in the inserted paragraph (4A), after "A PSUR" insert "in relation to a product authorised under a UKMA(GB)";

(d) in paragraph (6), in the inserted paragraph (8A), after "conditional marketing authorisation" insert "in relation to a product authorised under a UKMA(GB)";

(e) for paragraph (7) substitute—

"(7) In paragraph (10)—

(a) for sub-paragraph (b) substitute—

"(b) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has not yet been placed on the market within the EEA or Northern Ireland, at least every six months following authorisation until the placing on the market within the EEA or Northern Ireland, or

(ii) in relation to a product authorised under a UKMA(GB), the product has not yet been placed on the market in Great Britain, at least every six months following authorisation until the placing on the market within Great Britain; and";

(b) for sub-paragraph (c) substitute—

"(c) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has been placed on the market within the EEA or Northern Ireland—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that;

(ii) in relation to a product authorised under a UKMA(GB), the product has been placed on the market in Great Britain—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that.”.”.