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))

129. In regulation 161 (amendment of regulation 201 (submission and evaluation of final study reports for required studies))—

(a) for paragraph (2) substitute—

"(2) In paragraph (2) for "to the body specified in paragraph (3)" to the end substitute—

"to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation for the product is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation for the product is a UKMA(GB),

a final study report and an abstract of the study results.".";

(b) omit paragraph (3);

(c) in paragraph (4) for "omit from" to the end substitute "omit "for reports falling under paragraph (3)(a)" and "for reports falling under paragraph (3)(b)".