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))

111. In regulation 142 (amendment of regulation 182 (obligation on holder to operate a pharmacovigilance system))—

(a) in paragraph (2) for "for "resides and operates" to the end substitute "after "in the EU" insert "or United Kingdom"";

(b) after paragraph (2) insert—

"(2A) In paragraph (2)(b), after "pharmacovigilance system master file" insert "and ensure it is permanently and immediately available for inspection electronically in the United Kingdom at the single point from which the reports referred to in regulation 187(4) are accessible".

(2B) After paragraph (2) insert—

"(2A) Where the person the holder has permanently and continuously at its disposal under paragraph (2)(a) ("the qualified person") does not reside and operate in the United Kingdom, the holder must nominate a contact person for pharmacovigilance at a national level who reports to the qualified person, resides and operates in the United Kingdom and has permanent access to the pharmacovigilance system master file.

(2B) Paragraph (2A) has effect from the day twelve months after IP completion day."."; and

(c) for paragraph (3) substitute—

"(3) For paragraph (3) substitute—

"(3) Without prejudice to the requirements set out in regulation 65C and Schedule 10A (variations to a UK marketing authorisation) the holder must keep the licensing authority informed at all times of the name and contact details of—

(a) the appropriately qualified person mentioned in paragraph (2)(a); and

(b) the nominated person mentioned in paragraph (2A).

(3A) The holder must—

(a) ensure that the pharmacovigilance system master file is accessible electronically from the single point within the United Kingdom from which the reports referred to in regulation 187(4) are accessible; and

(b) immediately notify the licensing authority of any change to the single point where the pharmacovigilance system master file may be accessed electronically.".".