SCHEDULES

SCHEDULE 2

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

PART 16

Amendment of Part 17 (amendment of Part 16 (enforcement))

179. Omit regulation 219 (amendment of regulation 322 (validity of proceedings)).

180. In regulation 221 (amendment of regulation 327 (powers of inspection, sampling and seizure))—

(a) in paragraph (2), for sub-paragraphs (b) and (c) substitute—

"(b) after paragraph (v), insert—

"(va) an EU marketing authorisation;".";

(b) for paragraph (3) substitute—

"(3) In paragraph (2)(g), after paragraph (iv) insert—

"(iva) the requirements of Schedule 12A (further provision as to the performance of pharmacovigilance activities);".";

(c) omit paragraphs (4) and (5).

181. In regulation 222 (amendment of regulation 331 (findings and reports of inspections))—

(a) for paragraph (2) substitute—

"(2) In paragraph (1)—

(a) for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation";

(b) in sub-paragraph (c), at the beginning, insert "in the case of a product authorised under a UKMA(NI) or UKMA(UK),".";

(b) for paragraph (3) substitute—

"(3) In paragraph (4)—

(a) for sub-paragraph (b) substitute—

"(b) the guidelines on good distribution practice—

(i) in the case of Great Britain, published under, or that apply by virtue of, regulation C17;

(ii) in the case of Northern Ireland, published by the European Commission in accordance with Article 84 of the 2001 Directive;";

(b) after sub-paragraph (c) insert—

"(d) Schedule 12A; and

(e) the Implementing Regulation (as defined in regulation 177(5)).".".

182. In regulation 223 (insertion of regulation 331A (guidelines on inspections)), in the inserted regulation 331A(3), for "exit day" substitute "IP completion day".