SCHEDULES

SCHEDULE 2

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

PART 4

Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

36. In regulation 48 (amendment of regulation 49 (application for grant of UK marketing authorisation or parallel import licence))—

(a) in paragraph (3)—

(i) renumber the inserted paragraph (1A) as paragraph (1B);

(ii) before newly renumbered paragraph (1B) insert—

"(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part ("under the unfettered access route") and grant a UKMA(GB) only where—

(a) there is already in place, or will be at the time the UKMA(GB) is granted, a marketing authorisation in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in regulation 50(1A), and

(c) the medicinal product satisfies the definition of qualifying Northern Ireland goods.";

(iii) after newly renumbered paragraph (1B) insert—

"(1C) A marketing authorisation or parallel import licence must state whether it is in force in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that authorisation or licence being "in force" is limited to that territory.";

(b) for paragraph (4) substitute—

"(4) For paragraph (3) substitute—

"(3) The applicant, where it is applying for—

(a) a UKMA(NI)—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a UKMA(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) a UKMA(UK), must be established in the United Kingdom.”.”;

(c) in paragraph (6), in the text to be inserted—

(i) renumber paragraph (9) as paragraph (10);

(ii) before newly renumbered paragraph (10) insert—

“(9) The application must include a statement indicating whether the authorisation or licence sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.”.