

SCHEDULE 1

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

Amendment of regulation 19 (capital fees for applications for variations of authorisations)

1. In regulation 19—

(a) in paragraph (1)(a), for paragraph (ii) substitute—

“(ii) 65C (variation of a UK marketing authorisation)”; and

(b) after paragraph (3) insert—

“(4) The reference in paragraph (1)(a)(ii) to an application under regulation 65C of the Human Medicines Regulations includes a reference to an application or notification submitted under paragraph 11(7) or 12(3) of Schedule 33A to the Human Medicines Regulations, or an application or notification which would have been submitted under those paragraphs but for its earlier submission in accordance with paragraph 13(1)(a) of that Schedule.”.