

SCHEDULE 1

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

Amendment of Schedule 7 (waiver, reduction or refund of capital fees)

9. In Schedule 7, after paragraph 7, insert—

“Orphan marketing authorisation

7A. Where the licensing authority grants an orphan marketing authorisation, the following percentage of the fee otherwise payable under regulation 12(1)(a) in connection with the application for that authorisation shall be refunded or, if it has not yet been paid, shall be waived—

- (a) in the case of an application made by or on behalf of a small or medium company, 100%;
- (b) in the case of a major application that is not made by or on behalf of a small or medium company but to which paragraph 6 of Part II of Annex 1 to the 2001 Directive applies, 50%; or
- (c) in any other case, 10%.”.