

SCHEDULE 3

WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

5.—(1) Subject to sub-paragraph (2), where an application for a product licence is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable (under regulation 3(a)) in connection with that application shall be refunded or, if it has not yet been paid, shall be waived—

- (a) if the application has been received but no veterinary, scientific or pharmaceutical assessment thereof has begun, 90%;
- (b) except in a case to which paragraph (c) below applies, veterinary, scientific or pharmaceutical assessment has begun but not been completed, 50%;
- (c) if a request for further information in connection with the application has been made by the licensing authority under section 44(1) of the Act, 25percent;.

In the case of sub-paragraph (b) above, where an application has been withdrawn because it is deficient and a 50% refund of the fee has been made by the licensing authority, any subsequent reapplication in respect of the same product licence by the same applicant shall be charged at 50% of the fee otherwise payable under regulation 3(a).

(2) If an application for a product licence is withdrawn either after scientific or veterinary pharmaceutical assessment has been completed or following consideration of that application by a committee established under section 4 of the Act or by the Medicines Commission, no refund or waiver of the fee payable (under regulation 3(a) of these Regulations) in connection with that application shall be made under this paragraph.

(3) Where the same site is inspected at the same time in connection with applications for the grant, variation, or renewal of both a manufacturer's licence and a wholesale dealer's licence or during the currency of both such licences, the fee otherwise payable under these Regulations in respect of the inspection relating to the wholesale dealer's licence shall be waived.