SCHEDULE 5

Regulation 19

WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

1. Where the manufacture, assembly, sale or supply of medicinal products of a particular class or description will be, or is likely to be, interrupted for a period and in consequence thereof the health of the community will be, or is likely to be, put at risk, any capital fees payable under these Regulations in connection with an application for the grant of a product licence or a manufacturer's licence relating to a medicinal product falling within that class or description and made during that period or, if the period will, or is likely to, exceed 3 months, during the first 3 months of that period, shall be waived.

2.—(1) Subject to sub-paragraph (2), where an application for the grant of, or for a variation to, a product licence or a clinical trial certificate, or for the renewal of a clinical trial certificate is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulations 4(a), 7(a) or 10 in connection with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 medical, scientific or pharmaceutical assessment thereof has begun, 90%;

(b) except in a case to which sub-paragraph (c) below applies, if medical, 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, 25%.

(2) If an application for the grant of, or for a variation to, a product licence or clinical trial certificate, or for the renewal of a clinical trial certificate, is withdrawn either after medical, scientific or pharmaceutical assessment has been completed or following consideration of that application by a committee established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 regulations 4(a), 7(a) or 10 in connection with that application shall be made under this paragraph.

3. Where an application for the grant of, or a variation to, a manufacturer's or a wholesale dealer's licence is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulation 4(a) or 7(a) in connection with that application shall be refunded or, if it has not yet been paid, shall be waived—

(a) if the application is withdrawn before any inspection in connection with that application has been made, 90%;

(b) if such an inspection has been made, 50%.

4. Where the same site is inspected at the same time in connection with applications for the grant or variation 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.

5. In relation to a product licence (parallel import), the fee payable in respect of each such application shall be waived—

(a) where the licence relates to a medicinal product in respect of which a separate marketing authorisation has been granted pursuant to the provisions of Council Directive 65/65/EEC(**1**) in more than one Member State of the European Economic Community, those marketing authorisations are indicated on the product licence (parallel import) as having been validly granted in those Member States and the holder of that licence applies for

(**1**) O.J. No. 22, 9.2. 1965, p.369/65, as amended by Council Directives 75/319/EEC O.J. No.L147, 9.6. 1975, p.13, 83/570/EEC O.J. No.L332, 28.11. 1983, p.1, 87/21/EEC O.J. No. L15, 17.1. 1987, p.36 and 89/341/EEC O.J. No. L142, 25.5.1989, p.11.

the grant of a separate product licence (parallel import) in respect of each marketing authorisation which has been granted and so indicated; or

(b) the holder of the licence applies for a variation to the licence solely relating to a change in the number of a marketing authorisation referred to in sub- paragraph (a) above.