SCHEDULE 5

Regulation 19(2)

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 marketing authorization 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. Where, at the specific written request of the licensing authority, an application is made for the variation of a marketing authorization so as to—

(a) restrict any one or more of the indications, dosage or target population, or

(b) add a contraindication or a warning or both of these,

as a consequence of new information having a bearing on the safe use of the product, the fee payable under regulation 7(1) shall be refunded or, if it has not yet been paid, shall be waived.

3.—(1) Subject to sub-paragraphs (2) and (3), where an application for the grant of, or for a variation to, a marketing authorization or a clinical trial certificate, or for the renewal of a clinical trial certificate is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulations 4(a), 7(1) or 10 in connection with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) 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) (provision of information to licensing authority) of the Act, 25%.

(2) In a case to which sub-paragraph (1)(a) applies, that provision shall not have effect so as to render an applicant liable to pay more than £1,500 in respect of the fee in connection with that application.

(3) If an application for the grant of, or for a variation to, a marketing authorization or clinical trial certificate, or for the renewal of a clinical trial certificate, is withdrawn either after medical, scientific and pharmaceutical assessment has been completed or following consideration of that application by a committee established under section 4 (establishment of committees) of the Act or by the Medicines Commission, no refund or waiver of the fee payable under regulation 4(a), 7(1) or 10 in connection with that application shall be made under this paragraph.

4. Where an application for the grant of, or for 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(1) 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%.

5. 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.

6. In relation to a marketing authorization (parallel import), the fee payable in respect of each such application shall be waived—

(a) where the authorization relates to a medicinal product in respect of which a separate marketing authorization has been granted pursuant to the provisions of Council Directive 65/65/EEC in more than one member State, those marketing authorizations are indicated on the marketing authorization (parallel import) as having been validly granted in those member States and the holder of that authorization applies for the grant of a separate marketing authorization (parallel import) in respect of each marketing authorization which has been granted and so indicated; or

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

(3) Where a marketing authorization is varied so as to include the provisions of another marketing authorization in the circumstances set out in paragraph 4(4) of Part III of Schedule 3, the fee payable in respect of that variation under regulation 7(1) shall be refunded or, if it has not yet been paid, shall be waived.