SCHEDULE 3

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 animals will be, or is likely to be, put at risk, the licensing authority may decide that any fees otherwise payable under these Regulations—

(a) in connection with an application for the grant (variation or renewal) of a product licence relating to a medicinal product falling within that class or description; or

(b) in respect of any inspection made during the currency of such a licence

shall be waived during that particular period or, if the period will, or is likely to, exceed 3 months, during the first 3 months of that period.

2. The licensing authority may waive or reduce the payment of any capital fee payable under these Regulations in circumstances where—

(a) in its opinion the interests of human or animal health require a licence or certificate to be granted or an inspection to be made; and

(b) the medicinal product in respect of which an application for a licence or certificate has been made—

(i) is not intended for sale; or

(ii) is intended only for use in the treatment of rare conditions or in the treatment of a minor species of animal or as an emergency vaccine.

3.—(1) Subject to sub-paragraphs (2) to (5), where the licensing authority—

(a) is satisfied that the annual turnover (as calculated in accordance with Part I of Schedule 4) of a medicinal product during any calendar year of the first five years of the currency of the product licence, has not exceeded, or is unlikely to exceed, £30,000; and

(b) is of the opinion that the interests of human or animal health require a product licence to be granted

any capital fee otherwise payable under these Regulations in connection with an application for a product licence or an inspection during the currency of that licence, may be reduced or, if such a fee has already been paid, be refunded in part in proportion to the difference between the maximum turnover of the product in any calendar year (during any of the first five years of the currency of the licence) and the sum of £30,000.

(2) Before a licence holder pays any reduced fee or receives any refund pursuant to sub-paragraph (1), he shall furnish evidence to the satisfaction of the licensing authority of the amount of annual turnover, in respect of the particular medicinal product, in each calendar year of the first five years of the currency of the licence.

(3) Where a reduced fee is determined in accordance with sub-paragraph (1) at the time of application on the basis of the estimated likely maximum turnover of the medicinal product during the first five years of the currency of the licence, any fee so determined shall be regarded as a provisional payment on account.

(4) Where a provisional payment on account is made in accordance with sub-paragraph (3) and subsequently the turnover in any calendar year in the first five years of the currency of the licence exceeds £30,000, the licence holder shall be liable to pay the balance of the full fee otherwise payable under these Regulations within 28 days of notification by the licensing authority.

(5) Where any provisional payment on account is made in accordance with sub-paragraph (3), the reduced fee shall be recalculated in accordance with the provisions of sub-paragraph (1) at the end of

five years from the date of the grant of the licence and any difference between the fee so calculated and the provisional payment on account shall be payable by the applicant or, as the case may be, refunded to the applicant by the licensing authority within 28 days of a request for such a refund.

4. Where an application for the grant or renewal of a product licence is made at the specific written request of the licensing authority any fee otherwise payable under these Regulations in connection with that application shall be waived.

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, 25percnt;.

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.