STATUTORY INSTRUMENTS

1991 No. 1474

The Medicines (Products for Human Use — Fees) Regulations 1991

PART III

CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES AND FOR ASSOCIATED INSPECTIONS

Variations of licences and certificates

7. Subject to regulations 8, 9, 19 and 23, in connection with an application under section 30 of the Act for the variation of a provision of a product licence, a manufacturer's licence or a wholesale dealer's licence, and under section 39(4) for the variation of a clinical trial certificate, there shall be payable by the applicant—

(a) the fee prescribed in Part III of Schedule 1 in connection with that application; and

(b) in respect of any inspection of a description referred to in paragraph 1 of Schedule 2 made in connection with that application, the fee payable in accordance with paragraphs 2 to 5 of that Schedule.

Inspections in connection with multiple applications for variations of licences

8. Where an inspection mentioned in regulation 7(b) is made at a site which has been named as a possible site for manufacture or assembly of a medicinal product by more than one applicant for a variation to—

(a) a product licence and that site is located outside the United Kingdom; or

(b) a manufacturer's licence and that site is located in the United Kingdom,

the fee in respect of that inspection shall be payable in equal proportions by each of those applicants.

Applications for multiple variations

9.—(1) Subject to paragraph (2), a separate fee shall be payable in respect of each variation of each provision of a licence or certificate applied for in any one application.

(2) In respect of a variation which is wholly consequential upon another variation of a provision of a licence or certificate which is applied for in the same application, no separate fee shall be payable.