STATUTORY INSTRUMENTS

1995 No. 1116

The Medicines (Products for Human Use — Fees) Regulations 1995

PART III

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

Variations of authorizations, licences and certificates

7.—(1) Subject to regulations 8, 9, 19 and 23, a person who makes an application—

(a) under regulation 4 of the 1994 Regulations for the variation of a United Kingdom marketing authorization;

(b) 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

(c) under section 39(4) of the Act for the variation of a provision of a clinical trial certificate,

shall pay the fees mentioned in paragraph (2).

(2) The fees referred to in paragraph (1) are—

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

(b) in respect of any inspection of a description referred to in paragraph 1 of Schedule 2 made in connection with the application, the fee payable in accordance with paragraphs 2 to 6 of that Schedule.

Inspections in connection with multiple applications for variations of authorizations and licences

8. Where an inspection is made at a site which has been named as a possible site for manufacture or assembly of a medicinal product, or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product, by more than one applicant for a variation to—

(a) a marketing authorization 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 marketing authorization, 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 marketing authorization, licence or certificate which is applied for in the same application, no separate fee shall be payable.