SCHEDULE 1

CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS TO, MARKETING AUTHORIZATIONS, LICENCES AND CERTIFICATES

PART III

CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF AUTHORIZATIONS, LICENCES AND CERTIFICATES

Marketing authorizations

1. In this Part of this Schedule—

"Type I Application" means an application by a marketing authorisation holder to vary a marketing authorization (not being a marketing authorization (parallel import)) which is a "minor variation" within the meaning of Article 3.1(a) of Regulation (EC) No. 541/95(**1**);

"Type II Application" means any application to vary a marketing authorization (not being a marketing authorization (parallel import) or a product licence of right) which is neither a Type I Application nor an application for a Type II complex variation nor a change to which Annex II to Commission Regulation (EC) 541/95 applies;

"Type II complex variation" means a variation of a marketing authorization which relates to a change—

(a) in the formulation of a medicinal product comprising one or more of the following

(i) a change which necessitates in-vivo bioavailability studies to be performed on that product:

(ii) a change in that product's preservative system; or

(iii) a change in that product's excipients which significantly affects the pharmaceutical or the therapeutic properties of that product; or

(b) in the therapeutic indications of a medicinal product, such as a change in respect of use in a new category of patients or as a treatment for a new category of disease, other than a change to which paragraph 2 (changes to therapeutic indications) of Annex II to Commission Regulation (EC) No. 541/95 applies;

(c) in the composition, manufacture or use of a medicinal product to which any one or more of paragraphs (c), (e), (g) to (j) or (n) of the definition of complex application would apply where an application for a marketing authorisation is made in respect of a medicinal product.

2. Subject to paragraphs 3 to 6 and 13 and 14, the fee payable under regulation 7(1) in connection with an application for variation of a marketing authorization shall be—

(a) where the application is a Type I Application, £190;

(b) where the application is a Type II Application, £342;

(c) where the application is for a Type II complex variation, £8,766.

3. Where, for the purposes of Commission Regulation (EC) No. 541/95, the United Kingdom is the reference member State as defined in Article 2.2 of that Regulation, the fee payable under regulation 7(1) in connection with an application for variation of a marketing authorization shall be—

(**1**) OJ No. L55, 11.3.95,p. 7.

(a) where the application is a Type I Application, £230;

(b) where the application is a Type II Application, £410;

(c) where the application is for a Type II complex variation, £10,520.

4. Subject to paragraph 5, where a marketing authorization has been granted in accordance with an application to which Section G of Part 4 of the Annex to Council Directive 75/318/EEC(**2**) applies, the fee in connection with the first application for variation of that marketing authorization made within 5 years of the date of the grant of that marketing authorization, so as to authorise use of the medicinal product in a new therapeutic area, shall, in addition to the fee payable under regulation 7(1), be the difference between the fee paid in connection with that application and the fee which would have been payable had the application been a major application.

5. Paragraph 4 shall not apply where the first application for variation of the marketing authorization relates to a therapeutic area, in respect of which the applicant would be entitled (had he not already held a marketing authorization) to apply for a marketing authorization to which Section G of Part 4 of the Annex to Council Directive 75/318/EEC applies.

6. The fee payable under regulation 7(1) in connection with an application for variation of a marketing authorization (parallel import)—

(a) where the variation applied for falls within one of the following sub-paragraphs

(i) a change of either or both of the name and the address of the holder of the authorization;

(ii) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the authorization where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, and any change of address does not involve a change of the site of manufacture, assembly or storage or of the site from which distribution takes place;

(iii) the removal from the authorization of details of one or more of the sites of manufacture, assembly or storage or of the sites from which distribution takes place;

(iv) the removal from the authorization of details of any of the activities to which the authorization relates;

(v) the removal from the authorization of details of any of the medicinal products which the holder of the authorization is authorized to import;

shall be £95; and

(b) in any other case, shall be £310.

Manufacturer's licences

7. Subject to paragraphs 8 and 13, the fee payable under regulation 7(1)(b) in connection with an application for variation of a manufacturer's licence shall be—

(a) in the case of a manufacturer's licence referred to in paragraph 5(2) of Part II of this Schedule, £90; and

(b) in any other case, £180.

8. The fee payable under regulation 7(1)(b) in connection with an application for variation of a manufacturer's licence shall be £90 in respect of each variation applied for which constitutes a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

(**2**) OJ No. L147, 9.6.75, p. 1. The Directive was amended by Directives 89/341/EEC (OJ No. L142, 25.5.89, p. 11), 91/507/EEC (OJ No. L270, 26.9.91, p. 32) and 93/39/EEC (OJ No. L214, 24.8.93, p. 22).

Wholesale dealer's licences

9. Subject to paragraphs 10 and 13, the fee payable under regulation 7(1)(b) in connection with an application for a variation of a wholesale dealer's licence shall be £210.

10. The fee payable under regulation 7(1)(b) in connection with an application for variation of a wholesale dealer's licence shall be £90 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Clinical trial certificates

11. Subject to paragraphs 12 and 13, the fee payable under regulation 7(1)(c) in connection with an application for variation of a clinical trial certificate shall be £240.

12. Where an application is made for a variation to a provision of a clinical trial certificate and the variation applied for consists of no more than a change of either or both the name and address of the holder of the certificate, the fee payable under regulation 7(1)(c) shall be £90.

Identical variations

13. Subject to paragraph 14, where more than one application by the same applicant is made at the same time for the variation of a marketing authorization, a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate and where the applications are for identical variations, the fee payable under regulation 7(1)—

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of this Schedule:

(b) in connection with each of the other applications shall be 50% of that amount.

14. Where more than one application for a Type II complex variation is made at the same time by the same applicant for the variation of a marketing authorization, the fee payable under regulation 7(1)

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of the Schedule;

(b) in connection with each of the other applications where the applications are for identical variations and in respect of which no further medical, scientific or pharmaceutical assessment is required shall be the amount which would be payable if the application was a Type II Application.