SCHEDULE 1

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

PART 4

Capital Fees for Applications for Variations of Authorizations, Licences and Registrations

Variation of marketing authorizations

36.—(1) Subject to sub-paragraph (3), if an application to vary a marketing authorization of a kind described in sub-paragraph (2) is—

(a) the first application to vary a marketing authorization;

(b) made within 5 years of the date of grant of the marketing authorization; and

(c) an application to authorise use of the medicinal product in a new therapeutic area,

the fee payable for that application is the fee payable under regulation 18(1) together with the difference between that fee and the fee which would have been payable if the application had been a major application.

(2) In this paragraph a marketing authorization is one which has been granted in accordance with an application to which point 6 of Part II of Annex I to the 2001 Directive applies or which is in respect of an orphan medicinal product.

(3) Sub-paragraph (1) and (2) 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 the applicant not already held a marketing authorization) to apply for a marketing authorization to which point 6 of Part II of Annex I to the 2001 Directive applies or which is in respect of an orphan medicinal product.