

SCHEDULE 2

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

PART 3

Capital Fees for Assistance in Obtaining Marketing Authorizations in Other EEA States

Outgoing mutual recognition applications

34.—(1) The fee payable under regulation 16 (application to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorization in another EEA State or in other EEA States) is the fee specified in sub-paragraphs (2) to (5).

(2) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom (the application relating to that authorization is referred to in this paragraph as the “original application”) and the original application had been a major application or would fall within the meaning of a major application, in respect of—

- (a) the first application for regulatory assistance (“the first application”), the fee is £44,934;
- (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £29,516; and
- (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.

(3) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom and the original application had been a complex application or would fall within the meaning of a complex application, in respect of—

- (a) the first application for regulatory assistance (“the first application”), the fee is £11,623;
- (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £7,709; and
- (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.

(4) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom and the original application had been a standard application or would fall within the meaning of a standard application, in respect of—

- (a) the first application for regulatory assistance (“the first application”), the fee is £4,628;
- (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;

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- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £3,855; and
 - (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.
- (5) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom and the original application had been a simple application or would fall within the meaning of a simple application, in respect of—
- (a) the first application for regulatory assistance (“the first application”), the fee is £2,769;
 - (b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;
 - (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £2,769; and
 - (d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.
- (6) The condition referred to in sub-paragraphs (2) to (5) is that all applications fall within the meaning given to a set of applications in regulation 15.