

SCHEDULES

SCHEDULE 2

Capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates

PART 3

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

Outgoing mutual recognition applications

37.—(1) The fee payable for regulatory assistance under regulation 17 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 authorisation was granted in the United Kingdom (the application relating to that authorisation 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 £41,573;
- (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 £2,564;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £27,308; 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 £2,564.

(3) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorisation 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 £10,753;
- (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 £2,564;
- (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £7,133; 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 £2,564.

(4) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorisation 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 £4,282;

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- (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 £2,564;
 - (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £3,567; 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 £2,564.
- (5) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorisation 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 £2,564;
 - (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 £2,564;
 - (c) each subsequent application for regulatory assistance (“subsequent application”), the fee is £2,564; 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 £2,564.
- (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 16.