

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

Clinical trial authorisations

44.—(1) The fee payable under regulation 19(1) in connection with a notice of amendment relating to amendment to the dossier accompanying a request for authorisation to conduct a clinical trial is—

- (a) £265, if the amendments relate to one of the parts of the dossier specified in sub-paragraph (2) only;
- (b) £530, if the amendments relate to two parts of the dossier specified in sub-paragraph (2) only; or
- (c) £795, if the amendments relate to all three parts of the dossier specified in sub-paragraph (2) only.

(2) The parts of the dossier specified in sub-paragraph (1) are—

- (a) the part containing the summaries of the chemical, pharmaceutical and biological data relating to the medicinal product tested or used in the trial;
- (b) the part containing the summaries of the non-clinical, pharmacological and toxicology data on that product; and
- (c) the part containing the summaries of the available data from previous clinical trials of, and human experience with, that product.