SCHEDULE 1

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

PART 1

General: interpretation and categories of applications and variations

General: categories of Applications and Variations

2.—(1) In this Schedule, references to a particular type of application, variation or variation application shall be construed in accordance with this paragraph and paragraphs 3 to 23.

(2) A reference to—

"eCTD format" means the electronic format of the Common Technical Document referred to in the guidance published by the European Commission in Volume 2B of "The Rules Governing Medicinal Products in the European Union", referred to in paragraph (1) of the Introduction to Annex I to the 2001 Directive;

"eCTD format application" means an application made using the MHRA portal and in relation to which the accompanying particulars and documents are presented in eCTD format; and

"European reference product application" means an application for a marketing authorization to which the third sub-paragraph of Article 10(1) of the 2001 Directive applies.