SCHEDULE 7

WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

Reclassification

2.—(1) Where—

(a) an application for a marketing authorization includes a reclassification element within the meaning of paragraph 25 of Part 2 of Schedule 2; and

(b) the licensing authority is satisfied that the reclassification element does not require consideration by a committee established under section 4 (establishment of committees) of the Act(**1**) or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act(**2**),

50% of the additional amount payable under paragraph 25(1)(a) or (b) or 28(4)(a) of Part 2 of that Schedule shall be refunded, or if it has not yet been paid, shall be waived.

(2) Where—

(a) an application for variation of a marketing authorization is a reclassification variation application (not being an application falling within paragraph 37 of Part 4 of Schedule 2); and

(b) the licensing authority is satisfied that the application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act,

50% of the fee payable under paragraph 35 of Schedule 2 and entry 1(c)(i) of Table 1 referred to in that paragraph or of the fee payable under paragraph 48(a)(i) of Part 4 of Schedule 2 shall be refunded, or if it has not yet been paid, shall be waived.

(3) Where—

(a) an application for variation of a parallel import licence falls within paragraph 39(1)(a) of Part 4 of Schedule 2; and

(b) the licensing authority is satisfied that the application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act,

50% of the fee payable under that paragraph shall be refunded, or if it has not yet been paid, shall be waived.

(4) For the purposes of sub-paragraphs (1) to (3), a reclassification element or, as the case may be, a variation application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Commission established under section 2A (establishment of the Commission on Human Medicines) of the Act where—

(a) the licensing authority is satisfied that the application does not require consideration by such a committee or the Commission; and

(b) the committee or the Commission are consulted only by virtue of, or in accordance with, paragraph 5 of Schedule 2 to the Marketing Authorisation Regulations (procedural provisions relating to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorizations).

(**1**) Amendments and substitutions to section 4 have been made by S.I. 2004/1031, 2005/1094 and 2754 and 2006/2407.
(**2**) Section 2A was inserted by S.I. 2005/1094.