SCHEDULE 1

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

PART 5

Capital Fees for Assessment of Labels and Leaflets

A set of changes

49.—(1) Unless paragraph 50 applies, the fee payable under regulation 22(1) in connection with a set of proposed changes to the labelling or the package leaflet of a medicinal product is—

(a) £559, in respect of a product which is the subject of a United Kingdom marketing authorization (other than a parallel import licence); and

(b) £354, in respect of a product which is the subject of a parallel import licence.

(2) If the proposed changes in respect of a product to which the fee in sub-paragraph (1)(a) applies are submitted in accordance with the National Guidance on labels and leaflets self-certification, the fee payable under regulation 22(1) is £201.

(3) For the purpose of this paragraph—

(a) changes are submitted in accordance with the National Guidance on labels and leaflets self-certification if they are of a type described in the National Guidance on labelling and patient information leaflets for self-certification and comply with the conditions set out in relation to those changes in that Guidance; and

(b) the "National Guidance on labelling and patient information leaflets for self-certification" means the documents entitled "Guidance on changes to labelling and patient information for self-certification" and "Guidance on changes to labelling for self certification – compliance with article 56(a) – inclusion of Braille on the labelling" published by the licensing authority and available on its website on 9th November 2009(**1**).

More than one set of charges proposed

50.—(1) In this paragraph, "clinical particulars" means the clinical particulars contained in the Summary of Product Characteristics for that product as specified in paragraph 4 of Article 11 of the 2001 Directive.

(2) This paragraph applies where more than one set of proposed changes falling within regulation 22(1) is submitted by the same marketing authorization holder at the same time and where—

(a) the sets of proposed changes consist of identical changes to the labelling or package leaflets of products with the same active ingredient or combination of ingredients, dosage form and clinical particulars; or

(b) the sets of proposed changes consist of identical changes to different versions of the labelling or package leaflet of the same product.

(3) Where this paragraph applies, the fee payable under regulation 22(1) is—

(**1**) Copies of the documents can be downloaded from the licensing authority's website at www.mhra.gov.uk or obtained by writing to the licensing authority at Market Towers, 1, Nine Elms Lane, London, SW8 5NQ or by sending an email to info@mhra.gsi.gov.uk.

(a) in connection with the first set of proposed changes considered by the licensing authority, the appropriate amount specified in paragraph 49; and

(b) in connection with each of the other sets of proposed changes, 50% of that amount.